Records Processed under FOIA Request 2016-1547; Released by CDRH on 08/24/2016

ERBE
USA INCORPORATED

FDA CDRH DMC
NOV 18 2014
Received

K143306

November 14, 2014

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

RE: Traditional 510(k) for ERBE WaterJet Model ERBEJET® 2 System with HybridAPC Probe

Attn: Document Mail Clerk

Per CFR 807.90, enclosed is one (1) original paper copy of the submission. Per the instructions in the eCopy Program for Medical Device Submissions Guidance for Industry and Food and Drug Administration Staff, two (2) CDs with an eCopy are being provided with this submission and they are an exact duplicate of the original paper submission.

Please forward this submission to the appropriate office of device evaluation group for review.

Sincerely,

John Tartal
Director of Quality and Regulatory Affairs
ERBE USA, Inc.

2-CD

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

Form Approved: OMB No. 0910-0511 Expiration Date April 30, 2016. See Instructions for OMB Statement.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION **MEDICAL DEVICE USER FEE COVER SHEET**	PAYMENT IDENTIFICATION NUMBER (b) (4) Write the Payment Identification number on your check.

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

1. COMPANY NAME AND ADDRESS (Include name, street address, city state, country, and post office code)	2. CONTACT NAME
ERBE USA INC 2225 NORTHWEST PARKWAY MARIETTA GA 30067-9317 US	John Tartal 2.1 E-MAIL ADDRESS John.Tartal@erbe-usa.com 2.2 TELEPHONE NUMBER (Include Area code) 770-955-4400 2.3 FACSIMILE (FAX) NUMBER (Include Area code) 770-955-2577
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****8374	

11/7/14

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:	3.1 Select a center
[X] Premarket notification(510(k)); except for third party	[X] CDRH
[ ] 513(g) Request for Information	[ ] CBER
[ ] Biologics License Application (BLA)	3.2 Select one of the types below
[ ] Premarket Approval Application (PMA)	[X] Original Application
[ ] Modular PMA	Supplement Types:
[ ] Product Development Protocol (PDP)	[ ] Efficacy (BLA)
[ ] Premarket Report (PMR)	[ ] Panel Track (PMA, PMR, PDP)
[ ] 30-Day Notice	[ ] Real-Time (PMA, PMR, PDP)
	[ ] 180-day (PMA, PMR, PDP)

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

[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA

[X] NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number:

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?

[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)

[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

[ ] This application is the first PMA submitted by a qualified small business, including any affiliates	[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only	[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

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

[ ] YES [X] NO

PAPERWORK REDUCTION ACT STATEMENT

Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 8455 Colesville 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

(b) (4)

07-Nov-2014

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
11/14/2014	(b)(4)	

SECTION A — TYPE OF SUBMISSION

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

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

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

SECTION B — SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name: ERBE USA, Inc.	Establishment Registration Number *(if known)*: 1507212		
Division Name *(if applicable)*:	Phone Number *(including area code)*: 770-955-4400		
Street Address: 2225 Nothwest Parkway	FAX Number *(including area code)*: 770-955-2577		
City: Marietta	State / Province: GA	ZIP/Postal Code: 30067	Country: USA
Contact Name: John Tartal			
Contact Title: Director of Quality and Regulatory Affairs	Contact E-mail Address: John.Tartal@erbe-usa.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 Code:	Country:
Contact Name:			
Contact Title:	Contact E-mail Address:		

PSC Publishing Services (301) 443-6740 EF

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

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

- [ ] New Device
- [ ] Withdrawal
- [ ] Additional or Expanded Indications
- [ ] Request for Extension
- [ ] Post-approval Study Protocol
- [ ] Request for Applicant Hold
- [ ] Request for Removal of Applicant Hold
- [ ] Request to Remove or Add Manufacturing Site

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

- [ ] Location change:
  - [ ] Manufacturer
  - [ ] Sterilizer
  - [ ] Packager

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

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

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

- [ ] Change in Ownership
- [ ] Change in Correspondent
- [ ] Change of Applicant Address

- [ ] Response to FDA correspondence:

- [ ] Other Reason *(specify)*:

SECTION D2 — REASON FOR APPLICATION - IDE

- [ ] New Device
- [ ] New Indication
- [ ] Addition of Institution
- [ ] Expansion / Extension of Study
- [ ] IRB Certification
- [ ] Termination of Study
- [ ] Withdrawal of Application
- [ ] Unanticipated Adverse Effect
- [ ] Notification of Emergency Use
- [ ] Compassionate Use Request
- [ ] Treatment IDE
- [ ] Continued Access

- [ ] Change in:
  - [ ] Correspondent / Applicant
  - [ ] Design / Device
  - [ ] Informed Consent
  - [ ] Manufacturer
  - [ ] Manufacturing Process
  - [ ] Protocol - Feasibility
  - [ ] Protocol - Other
  - [ ] Sponsor

- [ ] Report submission:
  - [ ] Current Investigator
  - [ ] Annual Progress Report
  - [ ] Site Waiver Report
  - [ ] Final

- [ ] Response to FDA Letter Concerning:
  - [ ] Conditional Approval
  - [ ] Deemed Approved
  - [ ] Deficient Final Report
  - [ ] Deficient Progress Report
  - [ ] Deficient Investigator Report
  - [ ] Disapproval
  - [ ] Request Extension of Time to Respond to FDA
  - [ ] Request Meeting
  - [ ] Request Hearing

- [ ] Other Reason *(specify)*:

SECTION D3 — REASON FOR SUBMISSION - 510(k)

- [x] New Device
- [x] Additional or Expanded Indications
- [ ] Change in Technology

- [ ] Other Reason *(specify)*:

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

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SECTION E — ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	FQH	2	FBK	3	GEI	4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

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

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

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K072404	1	ERBEJET® 2 System	1	ERBE Elektromedizin GmbH
2	K092090	2	ERBELIFT™ Hand Pump and Flexible Probe	2	ERBE Elektromedizin GmbH
3	K083608	3	ERBE Hybrid Knife™	3	ERBE Elektromedizin GmbH
4	K060183	4	ERBE APC Integrated Filter Probes with Adaptor	4	ERBE Elektromedizin GmbH
5		5		5	
6		6		6	

SECTION F — PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

WaterJet Unit with Combination WaterJet and Argon Plasma Coagulation (APC) Probe

	Trade or Proprietary or Model Name for This Device		Model Number
1	ERBE WaterJet System	1	ERBEJET 2
2	ERBE HybridAPC Probe	2	Part Number 20150-215
3		3	
4		4	
5		5	

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

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

Data Included in Submission

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

SECTION G — PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
FQH and GEI	880.5475 and 878.4400	[ ] Class I [x] Class II [ ] Class III [ ] Unclassified

Classification Panel

General Hospital as well as General & Plastic Surgery

Indications *(from labeling)*

ERBEJET® 2 System - The ERBEJET 2 is intended for lifting mucosal lesions by injection into the submucosa as well as the cutting and dissection of soft tissue in neurosurgery and soft tissue such as the liver, kidney, etc. within the abdomen, including Total Mesorectal Excision (TME) in open as well as endoscopic surgery.

HybridAPC Probe - The HybridAPC probe is indicated for the induction of sterile normal saline into the submucosa to lift mucosal lesions using direct visualization through an endoscope and for HF ablation of the mucosal lesions by Argon Plasma Coagulation (APC).

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

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Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.	FDA Document Number *(if known)*

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

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number: 8010173	☒ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler
Company / Institution Name: ERBE Elektromedizin GmbH		Establishment Registration Number: 9610614
Division Name *(if applicable)*		Phone Number *(including area code)*: +49-7071-7550
Street Address: Waldhoernlestr. 17		FAX Number *(including area code)*: +49-7071-755-179
City: Tuebingen	State / Province: N/A	ZIP Code: 72072 / Country: Germany
Contact Name: Axel Retzlaff	Contact Title: Regulatory Affairs Manager	Contact E-mail Address: axel.retzlaff@erbe-med.com

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number: 9035331	☐ Manufacturer ☒ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler

(b)(4)

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

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

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SECTION I UTILIZATION OF STANDARDS

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

	Standards No.	Standards Organization	Standards Title	Version	Date
1	14971	EN ISO	Medical devices- Application of risk management to medical devices	N/A	07/01/2009
2	10993-1	DIN EN ISO	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management system	N/A	10/1/2009
3	60601-1	ANSI / AAMI / ES	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	Third Edition	01/01/2005
4	60601-1	EN	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	Third Edition	10/01/2006
5	60601-1-2	EN	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	Third Edition	01/01/2007
6	62366	EN	Medical devices. Application of usability engineering to medical devices	N/A	01/01/2008
7	660601-2-2	EN	Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories	Fifth Edition	01/01/2009

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.

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

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SECTION I	UTILIZATION OF STANDARDS (Continued)				
	Standard No.	Standard Organization	Standard Title	Version	Date
8	60601-2-18 with A1: 2000	EN	Medical electrical equipment - Part 2-18: Particular requirements for the safety of endoscopic equipment	N/A	1996
	Standard No.	Standard Organization	Standard Title	Version	Date
9	1041	DIN EN	Information supplied by the manufacturer of medical devices	N/A	2008
	Standard No.	Standard Organization	Standard Title	Version	Date
10	15223-1	DIN EN ISO	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements	N/A	2013
	Standard No.	Standard Organization	Standard Title	Version	Date
11	11607-1	EN ISO	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier system and packaging systems	N/A	2009
	Standard No.	Standard Organization	Standard Title	Version	Date
12	11607-2	EN ISO	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes	N/A	2006
	Standard No.	Standard Organization	Standard Title	Version	Date
13	2A	ISTA	Preshipment Testing Procedures - Combination Tests for packaged-products weighing 150 lbs. (68kg) or less	N/A	2011
	Standard No.	Standard Organization	Standard Title	Version	Date
14	556-1 with Ber. 1:2006-12	DIN EN	Sterilization of medical devices, Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices	N/A	2012
	Standard No.	Standard Organization	Standard Title	Version	Date
15	11135-1	DIN EN ISO	Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices	N/A	2007

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

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SECTION I	UTILIZATION OF STANDARDS (Continued)				
	Standard No.	Standard Organization	Standard Title	Version	Date
16	10993-7	EN ISO	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals	N/A	2008

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

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ERBE
USA INCORPORATED

November 14, 2014

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

RE: Traditional 510(k) for ERBE WaterJet Model ERBEJET® 2 System with HybridAPC Probe

Dear Reviewer:

In accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act and in conformance with 21 CFR Part 807, premarket notification is hereby made of the intention of ERBE USA, to introduce into interstate commerce for commercial distribution the ERBE WaterJet Model ERBEJET® 2 System with HybridAPC Probe. The cover letter format for Traditional and Abbreviated 510(k)s was followed for this submission. The Administrative Information, Basis for the Submission, as well as Design and Use of the Device is provided as follows:

Administrative Information	
Type of 510(k) Submission	Traditional
Device Type/Common Name	WaterJet Model ERBEJET® 2 System with HybridAPC Probe
510(k) Submitter	ERBE USA, Inc. 2225 Northwest Parkway Marietta, GA 30067
Contact Person	John Tartal Director of Quality and Regulatory Affairs Phone Number: 1-770-955-4400, Ext. 133

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

Administrative Information Continued	
Confidentiality Statement	This document and any print made therefrom are proprietary property of ERBE USA Incorporated and protected under title 5, section 552, US Code. Unauthorized disclosure is prohibited. The information and design disclosed herein was originated by and is the property of ERBE USA Incorporated. ERBE USA Incorporated reserves all patent, proprietary, design, manufacturing, reproduction, use and sale rights thereto, and to any article disclosed therein, except to the extent rights are expressly granted in writing to others.
Classification Regulations	Jet lavage (21 CFR 880.5475) as well as Electrosurgical cutting and coagulation device and accessories (21 CFR 878.4400)
Class	II
Panels	FQH and GEI

Basis for the Submission
The ERBE WaterJet Model ERBEJET® 2 System with HybridAPC Probe is being submitted to expand the indications for use of the WaterJet Unit (ERBEJET® 2) to include lifting mucosal lesions by injection into the submucosa as well as to introduce the HybridAPC Probe which is a combination device that will inject the sterile normal saline into the submucosa to lift mucosal lesions and ablate the lesions by HF Argon Plasma Coagulation (APC).

Design and Use of the Device		
Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 801 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?	X[1]	X[2]
Is the device intended for single use?	X[1]	X[2]
Is the device a reprocessed single use device? If yes, does this device type require reprocessed validation data?		X
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?	X[2]	
Does the submission include clinical information?	X[3]	
Is the device implanted?		X

[1]HybridAPC Probe
[2]WaterJet Model ERBEJET 2 System
[3]Yes, but only as references/support for a term (HF ablation) that is being included in the intended use of the HybridAPC Probe to better clarify its use.

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

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It was ERBE USA's objective to provide all necessary information to support FDA's review. However, if any more information is needed or questions arise, please feel free to contact me. I may be reached at 1-770-955-4400, Ext. 133.

Thank you in advance for your timely review.

Sincerely,

John Tartal
ERBE USA, Inc.
Director of Quality and Regulatory Affairs

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

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Indications for Use

510(k) Number (if known): _____

Device Name: ERBE WaterJet Model ERBEJET® 2 System with HybridAPC Probe

Indications For Use:

ERBEJET® 2 System

The ERBEJET 2 is intended for lifting mucosal lesions by injection into the submucosa as well as the cutting and dissection of soft tissue in neurosurgery and soft tissue such as the liver, kidney, etc. within the abdomen, including Total Mesorectal Excision (TME) in open as well as endoscopic surgery.

HybridAPC Probe

The HybridAPC probe is indicated for the induction of sterile normal saline into the submucosa to lift mucosal lesions using direct visualization through an endoscope and for HF ablation of the mucosal lesion by Argon Plasma Coagulation (APC).

Prescription Use ___**X**____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

Records Processed under FOIA Request 2016-1547; Released by CDRH on 08/24/2016

510(k) SUMMARY
[As Required by 21 CFR 807.92(c)]

Submitted By:	ERBE USA, Inc. 2225 Northwest Parkway Marietta, GA 30067 Tel: 770-955-4400 Fax: 770-955-2577
Contact Person:	John Tartal Director of Quality and Regulatory Affairs
Date Prepared:	November 14, 2014
Trade (Proprietary) Name:	ERBE WaterJet System ERBE HybridAPC Probe
Common Name:	WaterJet Unit with Combination WaterJet and Argon Plasma Coagulation (APC) Probe
Classification Name and Code:	Jet Lavage (21 CFR Part 880.5475) and Electrosurgical Cutting and Coagulation Device and Accessories (21 CFR 878.4400)
Product Code:	FQH and GEI
Legally Marketed Predicate Device:	ERBEJET® 2 System, 510(k) Number K072404 ERBELIFT™ Hand Pump and Flexible Probe, 510(k) Number K092090 ERBE Hybrid Knife™, 510(k) Number K083608 ERBE APC Integrated Filter Probes (FiAPC Probes) with Adaptor, 510(k) Number K060183

Note: The only change to the current ERBEJET 2 System is the addition of lifting mucosal lesions by injection into the submucosa in the Intended Use. There are no other changes to the current System being marketed in the U.S. Therefore, most of the information being provided is for the new device, HybridAPC Probe.

Device Description:

The HybridAPC Probe is used with the Water Jet Model ERBEJET 2 and an ERBE Argon Plasma Coagulator (APC) Model APC 2/ElectroSurgical Unit (ESU) VIO Model System. The Water Jet delivers pressurized sterile normal saline through the

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

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Probe to provide a saline cushion beneath mucosal lesions. The induction of the saline into the submucosa is a routine practice and acts as a cushion which can reduce/limit unwanted tissue damage (penetration depth) when applying argon plasma coagulation. The APC/ESU System with the Probe supplies ionized (electrically charged) argon gas to create the HF argon plasma for the ablation of the lifted lesions. The HybridAPC Probe consists of tubing to the Water Jet, a cable with a filter integrated connector for the APC, and dual lumen tubing. The inside lumen delivers the pressurized sterile normal saline and the outer lumen delivers the electrically charged argon gas for the HF argon plasma. Clinicians would attach the Probe to the Water Jet and APC/ESU System. Then the Probe is positioned at the operative site under direct visualization endoscopically. If an operative endoscope is utilized, the working channel must be greater than 2.5 mm. Upon the setup of the Water Jet and APC/ESU System, the Probe is ready for use. The pedal of the ERBEJET 2 footswitch activates its water-jet capabilities. The tip of the Probe is placed against a lesion and the saline accumulates within the submucosal layer which cushions the lesion. Then the tip of the Probe is placed in close proximity of the raised lesion (not touching/non-contact modality). Finally, the footswitch for the APC/ESU System is depressed which delivers the ionized argon gas to create the HF argon plasma for the ablation of the lesion. The HybridAPC Probe's dimensional working parameters (tubing/tip interfacing with scope as applicable/tissue) are 2.3 mm Outer Diameter, 1.9 m Length. The device is manufactured with typical materials or agents used in the medical device industry such as tungsten, stainless steel, plastics, silicone, etc. The HybridAPC Probe is provided sterile and is single use.

Intended Use:

ERBEJET® 2 System - The ERBEJET 2 is intended for lifting mucosal lesions by injection into the submucosa as well as the cutting and dissection of soft tissue in neurosurgery and soft tissue such as the liver, kidney, etc. within the abdomen, including Total Mesorectal Excision (TME) in open as well as endoscopic surgery.

HybridAPC Probe - The HybridAPC probe is indicated for the induction of sterile normal saline into the submucosa to lift mucosal lesions using direct visualization through an endoscope and for HF ablation of the mucosal lesions by Argon Plasma Coagulation (APC).

Similarities and Differences of the Proposed Device to the Current Device (Predicate Comparison/Substantial Equivalence):

Similarities

1. The HybridAPC Probe (proposed device) is manufactured with the same materials as well as processes as the predicates HybridKnife and/or FiAPC Probes.

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2. The proposed device is used in endoscopy like all of the predicate devices.
3. The HybridAPC Probe is a combination device that delivers pressurized sterile normal saline and electrical output to target tissue like the predicate HybridKnife.
4. The HybridAPC Probe with the ERBEJET 2 System has the capacity to lift mucosal lesions like the predicate ERBELIFT Hand Pump and Flexible Probe.
5. The addition of injecting into the submucosa to lift mucosal lesions in the intended use for the ERBEJET® 2 System and its inclusion in the intended use of the HybridAPC Probe is the same as the predicate ERBELIFT Hand Pump and Flexible Probe.
6. The proposed device has the same dimensions (2.3 mm Outer Diameter, 1.9 m Length) as the predicate, one of the FiAPC Probes.
7. The HybridAPC Probe has the same maximum electrical capacity (4,300 Vp) and maximum gas flow (2.4 Liters/Minute) as the predicate, one of the FiAPC Probes.
8. The proposed device's maximum wattage (80 watts) is within the range of the predicate FiAPC Probes
9. The HybridAPC Probe is compatible with the same equipment (ERBEJET 2 System and/or Argon Plasma Coagulator (APC 2)/ElectroSurgical Unit (ESU Model VIO) and has the same operating principles as the HybridKnife in regards with delivering pressurized sterile normal saline to target tissue as well as the FiAPC Probes in regards to delivering argon plasma to target tissue.
10. The HybridAPC Probe is packaged in the same manner as the predicate, HybridKnife.
11. The proposed device is sterilized via Ethylene Oxide, single use, and disposable the same way as the predicate devices.
12. The HybridAPC Probe is manufactured by ERBE Elektromedizin GmbH like the predicate, HybridKnife.

Differences

1. Intended Uses
   a. ERBEJET 2
      i. The intended use for the ERBEJET 2 has been modified to include "lifting mucosal lesions by injection into the submucosa". The ERBEJET 2 has been found to provide sufficient pressure to lift the submucosa.
   b. HybridAPC Probe
      i. The intended use is slightly different for the HybridAPC Probe in comparison to the FiAPC Probe in that upon the addition of lifting of mucosal lesions (via the injection of normal saline like the predicate ERBELIFT), "HF ablation of the mucosal lesions" by Argon Plasma Coagulation" for clarification purposes was added. This clarification

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is to inform the end user that raised/cushioned mucosal lesions are to be ablated. The association of the term ablation and coagulation has been established for many years. See added Section 21, Clinical References (Note: This search was not exhaustive, but a sufficient list of literature demonstrating that lesions are ablated by argon plasma coagulation.).

Performance testing demonstrated that the ERBE WaterJet Model ERBEJET® 2 System with HybridAPC Probe can lift mucosal lesions by injection of sterile normal saline into the submucosa and with a designated APC/ESU system ablate the lesion using argon plasma coagulation.

2. The ERBE WaterJet Model ERBEJET® 2 System with HybridAPC Probe is capable of delivering the sterile normal saline at a higher pressure (up to Effect 80 or 1,160 psi); than the predicate, ERBELIFT Hand Pump and Flexible Probe (up to 650 psi). Performance testing with the ERBE WaterJet Model ERBEJET® 2 System with HybridAPC Probe at Effect 70 (1,015 psi, near the maximum setting) to lift the submucosa of esophageal tissue showed no detrimental damage to the tissue (i.e., no perforation) [Note: Fluid would travel the least path of resistance, that is within the submucosa.]. See Section 18, Performance Testing - Bench. The availability of having the capacity to deliver greater pressure to inject into the submucosa will allow clinicians the possibility to lift more difficult mucosal lesions. Additionally, there is more control of the pressurization (effects can be changed incrementally by 1 or 14.5 psi) with the ERBEJET 2 System than when using the ERBELIFT Hand Pump. Finally, in the instructions of the ERBEJET 2 and HybridAPC Probe the user is informed to use the lowest possible setting to achieve the desired tissue outcome.

Conclusion:

The ERBE WaterJet Model ERBEJET® 2 System with HybridAPC Probe has the same principles of operation and technological characteristics as the predicate devices, ERBEJET 2 System, ERBELIFT Hand Pump and Flexible Probe, Hybrid Knife, and/or FiAPC Probes.

The ERBE WaterJet Model ERBEJET® 2 System with HybridAPC Probe has been verified or validated in design control. ERBE Elektromedizin GmbH, in accordance with established procedures, directs and controls design activities. These procedures involve design and development planning, design input, design review, design verification/design output, design validation, design transfer, as well as design change control. The activities provide the oversight and forum for project approval, formal management/design review, evaluation, and final project approval. This work is documented within design review and the approvals are documented as part of the current change control system.

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In addition to performance testing, the ERBE WaterJet Model ERBEJET® 2 System with HybridAPC Probe was tested to "Recognized Consensus Standards". Animal or clinical performance testing was not considered necessary.

All the changes with the proposed devices were verified or validated. As a result, the changes did not raise safety or efficacy concerns nor adversely affect safety or effectiveness. In conclusion, there are no issues with the ERBE WaterJet Model ERBEJET® 2 System with HybridAPC Probe that would raise additional safety or efficacy issues, when compared to the predicate devices.

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

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TRUTHFUL AND ACCURACY STATEMENT
[As Required by 21 CFR 807.87(k)]

I certify, as ERBE USA, Inc.'s Director of Quality and Regulatory Affairs, to the best of my knowledge that all data and information submitted in this premarket notification for the ERBE WaterJet Model ERBEJET® 2 System with HybridAPC Probe are truthful and accurate and that no material fact has been omitted.

John Tartal
Director of Quality and Regulatory Affairs
ERBE USA, Inc.

11/14/14
Date

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CLASS III SUMMARY AND CERTFICATION

Not Applicable

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

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Form Approved: OMB No. 0910-0616. Expiration Date: 2/28/2015. See PRA Statement on page 2.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Certification of Compliance

Under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. Name of Sponsor/Applicant/Submitter
ERBE USA, Inc.

2. Date of the Application/Submission Which This Certification Accompanies
11/14/2014

3. Address

Address 1 *(Street address, P.O. box, company name c/o)*
2225 Northwest Parkway

Address 2 *(Apartment, suite, unit, building, floor, etc.)*

City	State/Province/Region
Marietta	GA

Country	ZIP or Postal Code
USA	30067

4. Telephone and Fax Numbers *(Include country code if applicable and area code)*
(Tel): 770-955-4400
(Fax): 770-955-2577

PRODUCT INFORMATION

5. **For Drugs/Biologics:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s).
For Devices: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)

ERBE WaterJet Model ERBEJET® 2 System with HybridAPC Probe, Jet lavage (21 CFR 880.5475) and Electrosurgical cutting and coagulation device and accessories (21 CFR 878.4400), ERBEJET 2 and HybridAPC Probe (Part Number 20150-215)

Continuation Page for #5

APPLICATION / SUBMISSION INFORMATION

6. Type of Application/Submission Which This Certification Accompanies

☐ IND ☐ NDA ☐ ANDA ☐ BLA ☐ PMA ☐ HDE ☒ 510(k) ☐ PDP ☐ Other

7. Include IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/ Other Number *(If number previously assigned)*

If BLA was selected in item 6, provide Supplement Number

8. Serial Number Assigned to Application/Submission Which This Certification Accompanies

CERTIFICATION STATEMENT / INFORMATION

9. Check only one of the following boxes *(See instructions for additional information and explanation)*

☒ A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

☐ B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

☐ C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

Certification Statement / Information section continued on page 2

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

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CERTIFICATION STATEMENT / INFORMATION *(Continued)*

10. If you checked box C, in number 9, provide the National Clinical Trial (NCT) Number(s) for any "applicable clinical trial(s)," under 42 U.S.C. § 282(J)(1)(a)(i), section 402(j)(1)(a)(i) of the Public Health Service Act, referenced in the application/ submission which this Certification accompanies. *(Add continuation page as necessary.)*

NCT Number(s): _____ _____ _____ _____ _____

Continuation Page for #10

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.

Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. Name and Title of the Person who Signs Number 15

Name	Title
John Tartal	Director of Quality and Regulatory Affairs

12. Address

Address 1 *(Street address, P.O. box, company name c/o)*	2225 Nothwest Parkway
Address 2 *(Apartment, suite, unit, building, floor, etc.)*	
City	Marietta
State/Province/Region	GA
Country	USA
ZIP or Postal Code	30067

13. Telephone and Fax Numbers *(Include country code if applicable and area code)*

(Tel): 770-955-4400

(Fax): 770-955-2577

14. Date of Certification

11/10/14

15. Signature of Sponsor/Applicant/Submitter or an Authorized Representative *(Sign)*

Sign

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 15 minutes and 45 minutes (depending on the type of application/ submission) 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
PRAStaff@fda.hhs.gov

"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."

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DECLARATION OF CONFORMITY AND SUMMARY REPORTS

The Risk Analysis method(s) used to assess the impact of the ERBEJET 2 System with HybridAPC Probe was EN ISO 14971: 2009 Medical devices - Application of risk management to medical devices (Identical with ISO 14971: 2007) [Note: The level of concern involving software with the associated equipment (ERBEJET 2, etc.) remained the same, moderate level.].

A summary of the verification and validation activities with the respective standards used or applied/met is in the following Table.

Verification and Validation Activity Summary Table	
Verification/Validation Activity (Brief Description)	Standard Used or Applied/Met
Biological Evaluation of Materials and Tests	EN ISO 10993-1*
Electrical Characteristics in Regards with Safety and Efficacy (Including Usability)	ANSI / AAMI ES 60601-1, EN 60601-1, EN 60601-1-2, EN 62366**, EN 60601-2-2, EN 60601-2-18
Labels and Labeling	DIN EN 1041, DIN EN ISO 15223-1
Packaging	EN ISO 11607-1, EN ISO 11607-2, ISTA 2A
Sterilization	DIN EN 556-1, DIN EN ISO 11135-1, EN ISO 10993-7

*Also applied 'Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing"', Draft Guidance for Industry and Food and Drug Administration Staff, 04/23/13
**Also applied "Applying Human Factors and Usability Engineering to Optimize Medical Device Design", Draft Guidance for Industry and Food and Drug Administration Staff, 06/22/2011

EN ISO 10993-1: 2009, Biological evaluation of medical devices - Part 1: Evaluation and testing

ANSI / AAMI ES 60601-1: 2005 (Third Edition), Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

EN 60601-1: 2006 (Third Edition), Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (Identical with IEC 60601: 2005)

EN 60601-1-2: 2007 (Third Edition), Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (Identical with IEC 60601-1-2: 2007)

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EN 62366: 2008, Medical devices. Application of usability engineering to medical devices (Identical with IEC 62366: 2007)

EN 60601-2-2: 2009 (Fifth Edition), Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories (Identical with IEC 60601-2-2: 2009)

EN 60601-2-18: 1996 (+ A1 12/2000), Medical electrical equipment - Part 2-18: Particular requirements for the safety of endoscopic equipment (Identical with IEC 60601-2-18: 1996 + A1: 2000)

DIN EN 1041: 2008, Information supplied by the manufacturer of medical devices

DIN EN ISO 15223-1: 2013, Medical devices - Symbols to be used with medical devices labels, labelling and information to be supplied - Part 1: General requirements (Identical with ISO 15223-1: 2012)

EN ISO 11607-1: 2009, Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier system and packaging systems

EN ISO 11607-2: 2006, Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes (Identical with ISO 11607-2: 2006)

ISTA 2A: 2011, Preshipment Testing Procedures - Combination Tests for packaged-products weighing 150 lbs. (68kg) or less

DIN EN 556-1: 2002 (Ber. 1: 2006-12), Sterilization of medical devices, Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices

DIN EN ISO 11135-1: 2007, Sterilization of health care products - Ethylene oxide - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices (Identical with ISO 11135-1: 2007)

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

Note: Where applicable the associated WaterJet and ElectroSurgical Unit/Argon Plasma Coagulator Systems were used in the testing with the standards.

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Standard Data Report for 510(K)s; EN ISO 14971: 2009 Medical devices - Application of risk management to medical devices (Identical with ISO 14971: 2007)

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Standard Data Report for 510(K)s; DIN EN ISO 10993-1: 2009, Biological evaluation of medical devices - Part 1: Evaluation and testing

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

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Standard Data Report for 510(K)s; ANSI / AAMI ES 60601-1: 2005 (Third Edition), Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

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

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Standard Data Report for 510(K)s; EN 60601-1: 2006 (Third Edition), Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (Identical with IEC 60601: 2005)

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

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Standard Data Report for 510(K)s; EN 60601-1-2: 2007 (Third Edition), Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (Identical with IEC 60601-1-2: 2007)

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Standard Data Report for 510(K)s; EN 60601-2-2: 2009 (Fifth Edition), Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories

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

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Standard Data Report for 510(K)s; EN 60601-2-18: 1996 (+ A1 12/2000), Medical electrical equipment - Part 2-18: Particular requirements for the safety of endoscopic equipment (Identical with IEC 60601-2-18: 1996 + A1: 2000)

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Standard Data Report for 510(K)s; EN ISO 11607-1: 2009, Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier system and packaging systems

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Standard Data Report for 510(K)s; EN ISO 11607-2: 2006, Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes (Identical with ISO 11607-2: 2006)

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

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Standard Data Report for 510(K)s; ISTA 2A: 2011, Preshipment Testing Procedures - Combination Tests for packaged-products weighing 150 lbs. (68kg) or less

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

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Standard Data Report for 510(K)s; DIN EN 556-1: 2002 (Ber. 1: 2006-12), Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices

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

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Standard Data Report for 510(K)s; DIN EN ISO 11135-1: 2007, Sterilization of health care products - Ethylene oxide - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices (Identical with ISO 11135-1: 2007)

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

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Standard Data Report for 510(K)s; EN ISO 10993-7: 2008, Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals

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

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DECLARATION OF CONFORMANCE WITH CONSENSUS STANDARDS SUMMARY REPORTS

Note: Where designated the "Current Device" are the predicate device(s) evaluated/tested with associated equipment as applicable and the "Proposed Device" is the HybridAPC Probe evaluated/tested with associated equipment as applicable.

Standard: EN ISO 14971: 2009 Medical devices - Application of risk management to medical devices (Identical with ISO 14971: 2007)
The Risk Analysis was performed and is a part of the Design History File (DHF) of the products. In summary, all risks associated with the device were mitigated and were found to be at an acceptable level.

Standard: DIN EN ISO 10993-1: 2009, Biological evaluation of medical devices - Part 1: Evaluation and testing
All requirements were met to demonstrate biocompatibility. See Section 15, Biocompatibility.

Standard: ANSI / AAMI ES 60601-1: 2005 (Third Edition), Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
Standard: EN 60601-1: 2006 (Third Edition), Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (Identical with IEC 60601: 2005)

Requirement	**Current Device**	**Proposed Device**
Section 4 General requirements	Complies (Pass)	Complies (Pass)
Section 5* General requirements for testing ME equipment	Complies (Pass)	Complies (Pass)
Section 6* Classification of ME equipment and ME systems	Complies (Pass)	Complies (Pass)
Section 7 ME Equipment identification, marking and documents	Complies (Pass)	Complies (Pass)
Section 8* Protection against electrical hazards from ME equipment	Complies (Pass)	Complies (Pass)
Section 9* Protection against mechanical hazards of ME equipment and ME Systems	Complies (Pass)	Complies (Pass)
Section 10* Protection against unwanted and excessive radiation hazards	Complies (Pass)	Complies (Pass)
Section 11* Protection against excessive temperatures and other hazards	Complies (Pass)	Complies (Pass)
Section 12* Accuracy of controls and instruments and protection against hazardous outputs	Complies (Pass)	Complies (Pass)

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

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Requirement	Current Device	Proposed Device
Section 13* Hazardous situations and fault conditions	Complies (Pass)	Complies (Pass)
Section 14* Programmable electrical medical systems (PEMS)	Complies (Pass)	Complies (Pass)
Section 15 Construction of ME equipment	Complies (Pass)	Complies (Pass)
Section 16* ME Systems	Complies (Pass)	Complies (Pass)

*Each section contains multiple clauses and all clauses within a specific section, where applicable, passed.

Standard: EN 60601-1-2: 2007 (Third Edition), Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (Identical with IEC 60601-1-2: 2007)

Requirement	Current Device	Proposed Device
Section 4 General requirements	Complies (Pass)	Complies (Pass)
Section 5 Identification, marking and documents	Complies (Pass)	Complies (Pass)
Section 6 Electromagnetic compatibility*	Complies (Pass)	Complies (Pass)

Also; see Section 17, Electromagnetic Compatibility and Electrical Safety.

Standard: EN 62366: 2008, Medical devices. Application of usability engineering to medical devices (Identical with IEC 62366: 2007)

Requirement	Current Device	Proposed Device
Section 4 Principles	Not Applied	Complies (Pass)
Section 5 Usability engineering process	Not Applied	Complies (Pass)
Section 6 Accompanying document	Not Applied	Complies (Pass)

Standard: EN 60601-2-2: 2009 (Fifth Edition), Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories

Requirement	Current Device	Proposed Device
Section 201.4 General requirements	Complies (Pass)	Complies (Pass)
Section 201.5 General requirements for testing of ME equipment	Complies (Pass)	Complies (Pass)
Section 201.6 Classification of ME equipment and ME Systems	Complies (Pass)	Complies (Pass)
Section 201.7 ME equipment identification, marking and documents	Complies (Pass)	Complies (Pass)
Section 201.8 Protection against electrical hazards from ME equipment	Complies (Pass)	Complies (Pass)

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Requirement	Current Device	Proposed Device
Section 201.9 Protection against mechanical hazards of ME equipment and ME Systems	Complies (Pass)	Complies (Pass)
Section 201.10 Protection against unwanted and excessive radiation hazards	Complies (Pass)	Complies (Pass)
Section 201.11 Protection against excessive temperatures and other Hazards	Complies (Pass)	Complies (Pass)
Section 201.12 Accuracy of controls and instruments and protection against hazardous outputs	Complies (Pass)	Complies (Pass)
Section 201.13 Hazardous situations and fault conditions	Complies (Pass)	Complies (Pass)
Section 201.14 Programmable electrical Medical systems (PEMS)	Complies (Pass)	Complies (Pass)
Section 201.15 Construction of ME equipment	Complies (Pass)	Complies (Pass)
Section 201.16 ME Systems	Complies (Pass)	Complies (Pass)
Section 201.17 Electromagnetic compatibility of ME equipment and ME systems	Complies (Pass)	Complies (Pass)
Section 202* Electromagnetic compatibility – requirements and tests	Complies (Pass)	Complies (Pass)
Section 208 General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	Complies (Pass)	Complies (Pass)

*Also; see Section 17, Electromagnetic Compatibility and Electrical Safety.

Standard: EN 60601-2-18: 1996 (+ A1 12/2000), Medical electrical equipment - Part 2-18: Particular requirements for the safety of endoscopic equipment (Identical with IEC 60601-2-18: 1996 + A1: 2000)

Requirement	Current Device	Proposed Device
Section 1 General	Complies (Pass)	Complies (Pass)
Section 4 Protection against mechanical hazards	Complies (Pass)	Complies (Pass)
Section 7 Protection against excessive temperatures and other safety hazards	Complies (Pass)	Complies (Pass)

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Standard: DIN EN 1041: 2008, Information supplied by the manufacturer of medical devices
Standard: DIN EN ISO 15223-1: 2013, Medical devices - Symbols to be used with medical devices labels, labelling and information to be supplied - Part 1: General requirements (Identical with ISO 15223-1: 2012)
All requirements for information were met for symbols on labels and labeling (Note: FDA requirements apart of 21 CFR 801 were also met.). See Section 13, Proposed Labeling.

Standard: EN ISO 11607-1: 2009, Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier system and packaging systems
Standard: EN ISO 11607-2: 2006, Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes (Identical with ISO 11607-2: 2006)
Standard: ISTA 2A: 2011, Preshipment Testing Procedures - Combination Tests for packaged-products weighing 150 lbs. (68kg) or less
Standard: DIN EN 556-1: 2002 (Ber. 1: 2006-12), Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices
Standard: DIN EN ISO 11135-1: 2007, Sterilization of health care products - Ethylene oxide - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices (Identical with ISO 11135-1: 2007)
Standard: EN ISO 10993-7: 2008, Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
All requirements were met for packaging and sterilizing. See Section 14, Sterilization and Shelf Life.

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DECLARATION OF CONFORMITY WITH DESIGN CONTROL STATEMENTS

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EXECUTIVE SUMMARY

Note: The only change to the current ERBEJET 2 System is the addition of lifting mucosal lesions by injection into the submucosa in the Intended Use. There are no other changes to the current System being marketed in the U.S. Therefore, most of the information provided is for the ERBE HybridAPC Probe.

Device Description

The HybridAPC Probe is used with the Water Jet Model ERBEJET 2 and an ERBE Argon Plasma Coagulator (APC) Model APC 2/ElectroSurgical Unit (ESU) VIO Model System. The Water Jet delivers pressurized sterile normal saline through the Probe to provide a saline cushion beneath mucosal lesions. The induction of the saline into the submucosa is a routine practice and acts as a cushion which can reduce/limit unwanted tissue damage (penetration depth) when applying argon plasma coagulation. The APC/ESU System with the Probe supplies ionized (electrically charged) argon gas to create the HF argon plasma for the ablation of the lifted lesions. The HybridAPC Probe consists of tubing to the Water Jet, a cable with a filter integrated connector for the APC, and dual lumen tubing. The inside lumen delivers the pressurized sterile normal saline and the outer lumen delivers the electrically charged argon gas for the HF argon plasma. Clinicians would attach the Probe to the Water Jet and APC/ESU System. Then the Probe is positioned at the operative site under direct visualization endoscopically. If an operative endoscope is utilized, the working channel must be greater than 2.5 mm. Upon the setup of the Water Jet and APC/ESU System, the Probe is ready for use. The pedal of the ERBEJET 2 footswitch activates its water-jet capabilities. The tip of the Probe is placed against a lesion and the saline accumulates within the submucosal layer which cushions the lesion. Then the tip of the Probe is placed in close proximity of the raised lesion (not touching/non-contact modality). Finally, the footswitch for the APC/ESU System is depressed which delivers the ionized argon gas to create the HF argon plasma for the ablation of the lesion. The HybridAPC Probe's dimensional working parameters (tubing/tip interfacing with scope as applicable/tissue) are 2.3 mm Outer Diameter, 1.9 m Length. The device is manufactured with typical materials or agents used in the medical device industry such as tungsten, stainless steel, plastics, silicone, etc. The HybridAPC Probe is provided sterile and is single use.

Indications For Use/Intended Use

<u>ERBEJET® 2 System</u>

The ERBEJET 2 is intended for lifting mucosal lesions by injection into the submucosa as well as the cutting and dissection of soft tissue in neurosurgery and soft tissue such as the liver, kidney, etc. within the abdomen, including Total Mesorectal Excision (TME) in open as well as endoscopic surgery.

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HybridAPC Probe

The Hybrid APC probe is indicated for the induction of sterile normal saline into the submucosa to lift mucosal lesions using direct visualization through an endoscope and for HF ablation of the mucosal lesion by Argon Plasma Coagulation (APC).

Technology

The technology of the ERBE HybridAPC Probe is very basic. The combination Device is a conduit for delivering pressurized normal saline to lift mucosal lesions as well as HF argon plasma to ablate lesions. Both medical applications have been used together (via separate devices) for many years and this practice is well documented.

Device Comparison Table

Characteris-tics	Predicate Devices			Proposed Device
	ERBE Hybrid Knife	ERBELIFT Hand Pump and Flexible Probe*	ERBE APC Integrated Filter Probes and Adapter*	ERBE HybridAPC Probe
510(k) Applicant	ERBE USA, Inc.	Byrne Medical, Inc.**	ERBE USA, Inc.	ERBE USA, Inc.
Specification Developer or Manufacturer	ERBE Elektromedizin GmbH	Same	Same	Same
510(k) Number	K083608	K092090	K060183	

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Characteris-tics	Predicate Devices			Proposed Device
	ERBE Hybrid Knife	ERBELIFT Hand Pump and Flexible Probe*	ERBE APC Integrated Filter Probes and Adapter*	ERBE HybridAPC Probe
Indications For use/Intended Use	The ERBE Hybrid Knife™ is intended to be used in combination with the Water Jet System/ ERBEJET 2 and an ERBE ESU VIO Model to cut and dissect soft tissue in neurosurgery and soft tissue such as the liver, kidney, etc. within the abdomen, including Total Mesorectal Excision (TME) via the Water Jet System as well as to provide monopolar cutting and coagulation of the target tissue by the ESU in open and as well as endoscopic surgery.	The ERBELIFT Hand Pump in conjunction with an ERBELIFT Flexible Probe is indicated for the induction of sterile normal saline in the submucosa to lift polyps or other mucosal lesions using direct visualization through a flexible endoscope.	Argon Plasma Coagulation	The HybridAPC probe is indicated for the induction of sterile normal saline into the submucosa to lift mucosal lesions using direct visualization through an endoscope and for HF ablation of the mucosal lesion by Argon Plasma Coagulation (APC).
Materials	Plastics, Teflon, Stainless Steel	Plastics, Medical grade Inks with Reducer	Plastics, Brass, Stainless Steel, Tungsten, Ceramic, Adhesives/Glues	Stainless Steel, Tungsten, Plastics, Colorants
Physical Attributes				
General Description	Probe with WaterJet and ESU Connectors, Catheter (Tubing), and Extendable/ Retractable Electrode	Probe with Standard Luer Lock Connector and Catheter (Tubing)	Probe with APC Connector having a 0.45 µm Filter and Catheter (Tubing)	Probe with WaterJet Connector as well as APC Connector having a 0.45 µm Filter and Catheter (Tubing)

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Characteris-tics	Predicate Devices			Proposed Device
	ERBE Hybrid Knife	ERBELIFT Hand Pump and Flexible Probe*	ERBE APC Integrated Filter Probes and Adapter*	ERBE HybridAPC Probe
Electrical Instrument Recognition	No	No	Yes	Yes
Dimensional Working Parameters (Tubing/Tip Interfacing with Scope/ Tissue)	2.3 mm Outer Diameter (O.D.), 1.9 m Length	1.3 mm Outer Diameter (O.D.), 2.6 m Length	1.5 mm to 3.2 mm Outer Diameter (O.D.), 1.5 m to 3 m Length	2.3 mm Outer Diameter (O.D.), 1.9 m Length
Performance Attributes				
Sterile Normal Saline Pressurized Force if Applicable	Effect/Pressure: 1 (14.5 PSI) to 60 (870 PSI)* *With WaterJet	Pressure: 145 PSI to 650 PSI* *With Hand Pump	Not Applicable	Effect/Pressure: 1 (14.5 PSI) to 80 (1,160 PSI)* *With WaterJet
Electrical Parameters (From ESU) if Applicable	Voltage: 2,500 Vp Maximum Power: 80 Watts Maximum	Not Applicable	Voltage: 4,300 Vp Maximum Power: 50 Watts to 120 Watts Maximum	Voltage: 4,300 Vp Maximum Power: 80 Watts Maximum
Argon Gas Flow Rate (From APC) if Applicable	Not Applicable	Not Applicable	Flow Rate: 1.0 Liters/Minute (L/M) to 5.0 L/M	Flow Rate: 2.4 L/M Maximum
Labeling	Outer Packaging Pouch Label and Box Label as well as Notes On Use	Outer Packaging Pouch Label and Box Label as well as Instruc-tions For Use	Outer Packaging Pouch Label and Box Label as well as Notes On Use	Outer Packaging Pouch Label and Box Label as well as Notes On Use
Packaging Configuration	1 Tray/Pouch and Distribution Quantity 5/Box	1/Pouch and Distribution Quantity 5/Box	1/Pouch and Distribution Quantity 10/Box	1 Tray/Pouch and Distribution Quantity 5/Box
Provided Condition	Sterile/ Disposable/ Single Use	Sterile/ Disposable/ Single Use	Sterile/ Disposable/ Single Use	Sterile/ Disposable/ Single Use
Sterilization Method Used	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide

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Characteris-tics	Predicate Devices			Proposed Device
	ERBE Hybrid Knife	ERBELIFT Hand Pump and Flexible Probe*	ERBE APC Integrated Filter Probes and Adapter*	ERBE HybridAPC Probe
Associated Accessories and Equipment	WaterJet and Endoscopes	Syringe and Endoscopes	APC (with Compatible ESU) and Endoscopes	WaterJet, APC (with Compatible ESU), and Endoscopes
Target Population	Patients requiring open or endoscopic surgery in neurosurgery and in and around the abdomen.	Endoscopic Patient Candidates with Polyps or Mucosal Lesions	Endoscopy Patients	Endoscopic Patient Candidates with Mucosal Lesions
Anatomical Site	Soft tissue in neurosurgery and soft tissue such as the liver, kidney, etc. within the abdomen, including Total Mesorectal Excision (TME), in open as well as endoscopic surgery.	Esophagus, Stomach, Duodenum, Small Intestine, and Large Intestine	Various General Surgical Sites	Various General Surgical Sites

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Characteris-tics	Predicate Devices			Proposed Device
	ERBE Hybrid Knife	ERBELIFT Hand Pump and Flexible Probe*	ERBE APC Integrated Filter Probes and Adapter*	ERBE HybridAPC Probe
FDA Guidance Documents Used if Applicable	Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s: August 12, 2005	Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s, 8/12/05	Not Applicable	Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s, 08/12/05; Draft Guidance for Industry and Food and Drug Administration Staff: Applying Human Factors and Usability Engineering to Optimize Medical Device Design, 06/22/11; and Draft Guidance for Industry and Food and Drug Administration Staff: Use of International Standard ISO-10993, “Biological Evaluation of Medical Devices Part 1: Evaluation and Testing”, 04/23/13
Performance Standards Used or Applied/Met if Applicable	IEC 60601-1, UL 60601-1, IEC 60601-2-2, IEC 60601-2-18	Not Applicable	AAMI HF-18, IEC 60 601-1, IEC 60 601-2-2, and IEC 60 601-2-18	ANSI/AAMI ES 60601-1, EN 60601-1, EN 60601-1-2, EN 62366, EN 60601-2-2, EN 60601-2-18

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Characteris-tics	Predicate Devices			Proposed Device
	ERBE Hybrid Knife	ERBELIFT Hand Pump and Flexible Probe*	ERBE APC Integrated Filter Probes and Adapter*	ERBE HybridAPC Probe
Other Standards Used or Applied/Met	EN ISO 14971, EN ISO 10993-1, ANSI/AMMI/ISO 10993-4, ANSI/ AMMI/ISO 10993-5, ISO 10993-10, ISO 10993-11, EN 980, EN ISO 11607, EN 1041, EN 550	AAMI/ANSI/ISO 10993-1, AAMI /ANSI/ISO 11607-2, AAMI/ ANSI/ISO 11135-1, AAMI/ANSI/ISO 10993-7	EN ISO 10993, EN 556, EN 980, EN 1041, ISO 11607, EN 868-1, ISO 11134, ISO 11135, EN 550, EN 554, EN ISO 14971	EN ISO 10993-1, DIN EN 1041, DIN EN ISO 15223-1, EN ISO 11607-1, EN ISO 11607-2, ISTA 2A, DIN EN 556-1, DIN EN ISO 11135-1, EN ISO 10993-7

*Focus on Probe
**ERBE Acquired 510(k)

Performance Testing
A detailed summary of the performance testing involved with ERBE WaterJet Model ERBEJET 2 System with HybridAPC Probe can be found in Section 18, Performance Testing - Bench. The following is a summary of the performance tests that specifically demonstrate substantial equivalency of the proposed devices to the predicates.

1. *General Specification Testing of the HybridAPC Probe*
   Testing demonstrated that the HybridAPC Probe is compatible and functions with (even under stressful conditions) the ERBEJET 2 System as well as the designated Argon Plasma Coagulator (APC)/ElectroSurgical Unit (ESU) like the respective predicate devices as applicable.
2. *Comparison of injection capacity of HybridAPC/ERBEJet 2 with the ERBELIFT system*
   The comparison evaluation showed that the ERBE WaterJet Model ERBEJET 2 System with HybridAPC Probe can lift the submucosa as well as the predicate device, ERBELIFT Hand Pump and Flexible Probe. Additionally, the proposed devices have the capacity to deliver the normal sterile saline at higher pressures if needed than the predicate device to lift the more difficult mucosal lesions by injection into the submucosa.
3. *The tissue effect of argon-plasma coagulation with prior submucosal injection (Hybrid-APC) versus standard APC: a randomized ex-vivo study*
   The testing showed that ERBE WaterJet Model ERBEJET 2 System with HybridAPC Probe can lift, cushion, and ablate mucosal lesions with less undesired tissue damage (less penetration depth) than when just using standard argon plasma coagulation that would be applied like the predicate FiAPC Probe.

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DEVICE DESCRIPTION

Design Requirements with Performance Specifications

Note: The only change to the current ERBEJET 2 System is the addition to the Intended Use, "lifting mucosal lesions by injection into the submucosa". There are no other changes to the current System being marketed in the U.S. Therefore, most of the information being provided in this section is for the ERBE HybridAPC Probe.

Num-ber	Design Requirements	Performance Specifications	Specification, Evaluation, and/or Validation Activity	Summary/ Discussion as Applicable
1	The ERBE HybridAPC Probe must be provided in a configuration that is standard to the medical community in endoscopy.	The distributed quantity of five (5) ERBE HybridAPC Probes in which each Probe is individually packaged in a tray and pouched per shelf box. This configuration has been found to be acceptable in endoscopy.	Section 14, Sterilization and Shelf Life; as well as Technical Packaging Engineering Drawing (Page 011 - 7)	Product is Packaged to Specification
2	ERBE HybridAPC Probe (Product) shall be packaged in such a manner that they are not damaged in shipping, handling, and storage.	Packaging materials which maintain product integrity were used. The packaging materials for the Probe are similar to the predicate ERBE Hybrid Knife. The performance characteristics of the packaging materials are well documented without any packaging issues and package testing demonstrated its appropriateness.	Section 9, Declaration of Conformity and Summary Reports; Section 14, Sterilization and Shelf Life; as well as Technical Packaging Engineering Drawing (Page 011 - 7)	Packaging and Con-figuration Suitable for Product
3	The Product must be easily identified and as needed be accompanied with suitable instructions. Additionally, labels/labeling must meet U.S. regulatory requirements.	The ERBE HybridAPC Probes are labeled in such a manner that they are easily recognized and have adequate labeling [Notes On Use (NOU) to provide sufficient guidelines for use]. Labels/Labeling meets all U.S. regulatory requirements.	Section 9, Declaration of Conformity and Summary Reports as well as Section 13, Proposed Labeling	Labels/ Labeling Acceptable

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Num-ber	Design Requirements	Performance Specifications	Specification, Evaluation, and/or Validation Activity	Summary/ Discussion as Applicable
4	The ERBE HybridAPC Probe should be provided with a sufficient shelf life.	A three (3) year shelf life from the packaging date has been validated for the HybridAPC Probe per evaluating/testing accelerated aged samples.	Section 14, Sterilization and Shelf Life	Protocol Continuing to be Executed to Evaluate/ Test Real Time Aged Samples
5	Each HybridAPC Probe must be provided sterile.	The Product is rendered sterile via Ethylene Oxide (EO) sterilization. The Cycle has been qualified for the HybridAPC Probe.	Section 14, Sterilization and Shelf Life	Sterilization Cycle Valid for Product
6	The Product must not be harmful with regards to biocompatibility.	The ERBE HybridAPC Probe is manufactured/ processed with medical grade materials or materials commonly used in medical devices. Specific direct patient contacting materials are Stainless Steel, Tungsten, Plastic PTFE; with indirect contact materials being Stainless Steel, Plastic PA, and Silicone. Testing of these materials in predicate products that have the same manufacturing processes has demonstrated biocompatibility.	Section 15, Biocompatibility	Product is Biocompat-ible
		Ethylene oxide (EO) residual levels per established international standards will be met prior to distribution of the HybridAPC Probe.	Section 14, Sterilization and Shelf Life	The Product will Meet EO Residual Levels Prior to Distribution
7	Each Product with associated equipment shall meet all applicable international electrical standards.	The ERBE HybridAPC Probe with associated equipment conforms to all applicable international electrical standards.	Section 9, Declaration of Conformity and Summary Reports	Product with Associated Equipment Meets Applicable Electrical Standards

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Num-ber	Design Requirements	Performance Specifications	Specification, Evaluation, and/or Validation Activity	Summary/ Discussion as Applicable
8	The ERBE HybridAPC Probe should be compatible with (i.e., attaches to, works with, detaches from, etc.) designated equipment/ accessory (Water Jet Model ERBEJET 2 via ERBEJET Pump Cartridge and Argon Plasma Coagulator (APC) Model APC 2 (via APC receptacle w/wo adapter as applicable)/Electro-Surgical Unit (ESU) VIO Model System.	The Product has been found to properly connect and detach from designated equipment/accessory. Once connected, there are no water leaks, argon gas leakages, or leakage currents above international standards.	Section 9, Declaration of Conformity and Summary Reports; Section 17, Electromagnetic Compatibility and Electrical Safety Section 18; Performance Testing - Bench; as well as Technical Device Engineering Drawing (Page 011 - 6)	Product is respectively Compatible with Desig-nated Equipment/ Accessory
9	Each ERBE HybridAPC Probe should be compatible with endoscopes designed for High Frequency (HF) surgical devices and have a working channel greater than 2.5 mm and having a length less than 1.9 m.	The Product's working Outer Diameter (OD) is 2.3 mm with a 1.9 m length.	Technical Device Engineering Drawing (Page 011 - 6)	The Product is respectively Compatible with Designated Scopes

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Num-ber	Design Requirements	Performance Specifications	Specification, Evaluation, and/or Validation Activity	Summary/ Discussion as Applicable
10	The Product must deliver pressurized sterile normal saline via the ERBEJET 2 that is comparable or greater than the predicate ERBELIFT Hand Pump and Flexible Probe as well as ionized argon gas to create (HF argon plasma) from an APC Model APC 2/ESU VIO Model System that is comparable to the predicate APC Integrated Filter Probes (FiAPC Probes).	The ERBE HybridAPC Probe has been found to deliver a sufficient pressure output of normal saline to lift mucosal lesions by injection into the submucosa (1 - 80 effect) from the Water Jet that is greater than the ERBELIFT Hand Pump and Flexible Probe as well as sufficient electrically charged (ionized) argon gas (max. 4,300 Vp, 80 watts, 2.4 L/M argon gas flowrate) to create HF argon plasma to ablate lesions from the APC/ESU System that is comparable to FiAPC Probes.	Section 18, Performance Testing - Bench	Product Met Performance Requirements
11	The ERBE HybridAPC Probe should be durable.	The Product is durable and functional for single patient use (i.e., met stress testing requirements).	Section 18, Performance Testing - Bench	The Product is Durable and Functional for Single Patient Use

Involved Products/Devices

Part Number (REF)	**Description**
20150-215	ERBE HybridAPC Probe

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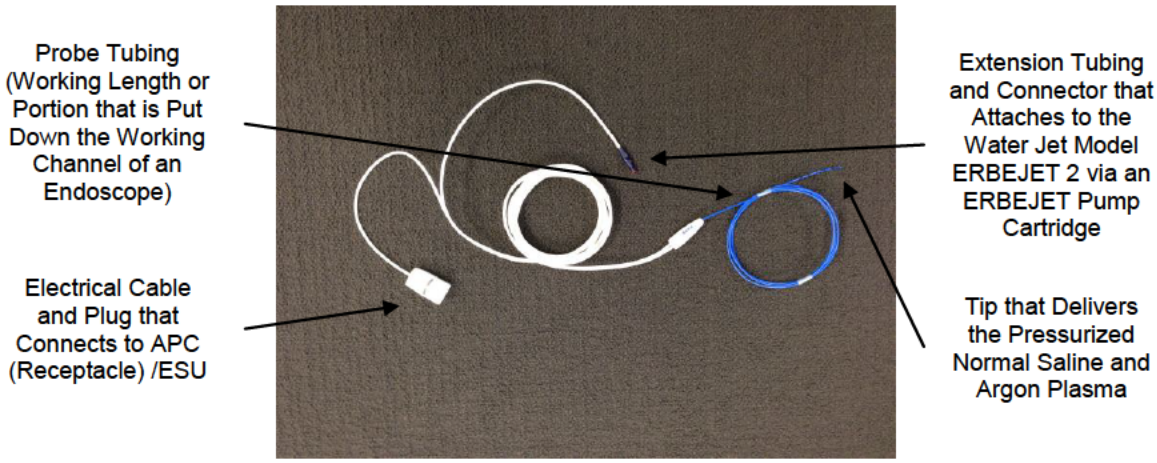
Device Design Specifications

Included is a photograph/pictorial (with descriptions of parts) as well as technical device and packaging drawings to best describe the design of the product/device.

Photograph/Pictorial



ERBE HybridAPC Probe

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Technical Device Engineering Drawing

(b)(4)

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Technical Packaging Engineering Drawing

(b)(4)

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SUBSTANTIAL EQUIVALENCE DISCUSSION

Characteristics	Predicate Devices	Proposed Devices
510(k) Submitter/ Holder	ERBE USA, Inc.	Same
Trade Name, Model (As Applicable), 510(k) Number (As Applicable)	ERBEJET® 2 System, 510(k) Number K072404 ERBELIFT™ Hand Pump and Flexible Probe, 510(k) Number K092090 ERBE Hybrid Knife™, 510(k) Number K083608 ERBE APC Integrated Filter Probes (FiAPC Probes) with Adaptor, 510(k) Number K060183	ERBE WaterJet Model ERBEJET® 2 System with HybridAPC Probe

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Characteristics	Predicate Devices	Proposed Devices
Indications For Use	ERBEJET® 2 System: The ERBEJET 2 is intended for the cutting and dissection of soft tissue in neurosurgery and soft tissue such as the liver, kidney, etc. within the abdomen, including Total Mesorectal Excision (TME) in open as well as endoscopic surgery. ERBELIFT™ Hand Pump and Flexible Probe: The ERBELIFT Hand Pump in conjunction with an ERBELIFT Flexible Probe is indicated for the induction of sterile normal saline in the submucosa to lift polyps or other mucosal lesions using direct visualization through a flexible endoscope.	ERBEJET® 2 System: The ERBEJET 2 is intended for lifting mucosal lesions by injection into the submucosa as well as the cutting and dissection of soft tissue in neurosurgery and soft tissue such as the liver, kidney, etc. within the abdomen, including Total Mesorectal Excision (TME) in open as well as endoscopic surgery. *Discussion* The addition of "lifting mucosal lesions by injection into the submucosa" in the intended use of ERBEJET 2 was demonstrated by showing that the WaterJet can generate pressures equal to or higher than the predicate device's force amplifier, EBELIFT Hand Pump (Proposed: 14.5 psi to 1,160 psi versus Predicate: 145 psi to 650 psi). Additionally, induction of sterile normal saline into the submucosa to lift mucosal lesions was proven in comparison testing (ERBEJET 2 with HybridAPC Probe versus ERBELIFT Hand Pump and Flexible Probe) on various tissue types and finally by lifting created esophageal mucosal lesions (using a setting closest to maximum). See Section 18, Performance Testing Bench.

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Characteristics	Predicate Devices	Proposed Devices
Indications For Use Continued	ERBE Hybrid Knife™: The ERBE Hybrid Knife™ is intended to be used in combination with the Water Jet System/ ERBEJET 2 and an ERBE ESU VIO Model to cut and dissect soft tissue in neurosurgery and soft tissue such as the liver, kidney, etc. within the abdomen, including Total Mesorectal Excision (TME) via the Water Jet System as well as to provide monopolar cutting and coagulation of the target tissue by the ESU in open and as well as endoscopic surgery. ERBE APC Integrated Filter Probes (FiAPC Probes) with Adaptor: Argon Plasma Coagulation	ERBE HybridAPC Probe: The HybridAPC probe is indicated for the induction of sterile normal saline into the submucosa to lift mucosal lesions using direct visualization through an endoscope and for HF ablation of the mucosal lesion by Argon Plasma Coagulation (APC). *Discussion* The ERBE HybirdAPC Probe's intended use is a combination of the ERBELIFT Hand Pump and Flexible Probe as well as FiAPC Probes with an additional clarification to the end user for the HF ablation of mucosal lesions by Argon Plasma Coagulation (APC). The use of the term ablation in association with argon plasma coagulation is well documented in clinical literature. See Section 21, Clinical References. Additionally, created and lifted esophageal mucosal lesions were ablated using argon plasma coagulation in bench testing. See Section 18, Performance Testing Bench.
Technology	The predicates generate or deliver pressurized normal sterile saline, electrical output, and/or ionized argon gas (argon plasma) to target tissue.	Same

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Characteristics	Predicate Devices	Proposed Devices
Performance Specifications	ERBE WaterJet Model ERBEJET® 2 System with ERBE Hybrid Knife Effect/Pressure: 1 (14.5 psi) to 60 (870 psi) ERBELIFT™ Hand Pump and Flexible Probe Pressure: 145 psi to 650 psi	ERBE WaterJet Model ERBEJET® 2 System with HybridAPC Probe Effect/ Pressure: 1 (14.5 psi) to 80 (1,160 psi) *Discussion* The ERBE WaterJet Model ERBEJET® 2 System with HybridAPC Probe is capable of delivering the sterile normal saline at a higher pressure (up to Effect 80 or 1,160 psi); than the predicate, ERBELIFT Hand Pump and Flexible Probe (up to 650 psi). Performance testing with the proposed devices at Effect 70 (1,015 psi, near the maximum setting) to lift the submucosa of esophageal tissue showed no detrimental damage to the tissue (i.e., no perforation) [Note: Fluid would travel the least path of resistance, that is within the submucosa.]. See Section 18, Performance Testing - Bench. The availability of having the capacity to deliver greater pressure to inject into the submucosa will allow clinicians the possibility to lift more difficult mucosal lesions. Additionally, there is more control of the pressurization (effects can be changed incrementally by 1 or 14.5 psi) with the ERBEJET 2 System than when using the ERBELIFT Hand Pump. Finally, in the instructions of the ERBEJET 2 and HybridAPC Probe the user is informed to use the lowest possible setting to achieve the desired tissue outcome.

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Characteristics	Predicate Devices	Proposed Devices
Performance Specifications Continued	ERBE WaterJet Model ERBEJET® 2 System with ERBE Hybrid Knife Electrical Output/Argon Gas Parameters with APC/ESU System as applicable: Voltage- 2,500 Vp Maximum; Power- 80 Watts Maximum FiAPC Probes Electrical Output/Argon Gas Parameters with APC/ESU System: Voltage- 4,300 Vp Maximum; Power- 50 Watts to 120 Watts Maximum; Flow Rate- 1.0 Liters/Minute (L/M) to 5.0 L/M	ERBE WaterJet Model ERBEJET® 2 System with HybridAPC Probe Electrical Output/Argon Gas Parameters with APC/ESU System: Voltage- 4,300 Vp Maximum; Power- 80 Watts Maximum; Flow Rate- 2.4 L/M Maximum *Discussion* The ERBE WaterJet Model ERBEJET® 2 System with HybridAPC Probe's electrical output/argon parameters are all within the parameters collectively of the predicate devices.
Conclusion The ERBE WaterJet Model ERBEJET® 2 System with HybridAPC Probe has basically the same intended use as well as the same principles of operation and technological characteristics as the predicate devices, ERBEJET 2 System, ERBELIFT Hand Pump and Flexible Probe, Hybrid Knife, and/or FiAPC Probes. There are no issues with the ERBE WaterJet Model ERBEJET® 2 System with HybridAPC Probe that would raise additional safety or efficacy issues when compared to the predicate devices.		

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PROPOSED LABELING (Including Claims/Marketing Statements)

List of Draft Labels, Labeling, and Claims/Marketing Statements

Description	Page Numbers
ERBEJET 2 System*	
Labeling	
User Manual	013 - 3 to 013 - 60
HybridAPC Probe	
Labels	
Outer Packaging Pouch Label	013 - 62
Patient Chart Label	013 - 62
Outer Packaging Box Label	013 - 63
Labeling	
Notes On Use	013 - 64 to 013 - 78
Claims/Marketing Statements	
ERBE WaterJet Model ERBEJET® 2 System with HybridAPC Probe Claims/Marketing Statements	013 - 79 to 013 - 88

* The only change to the current ERBEJET 2 System is the addition of lifting mucosal lesions by injection into the submucosa in the Intended Use; therefore, no other Labels/Labeling were submitted for the System.

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ERBEJET 2 Labeling, User Manual

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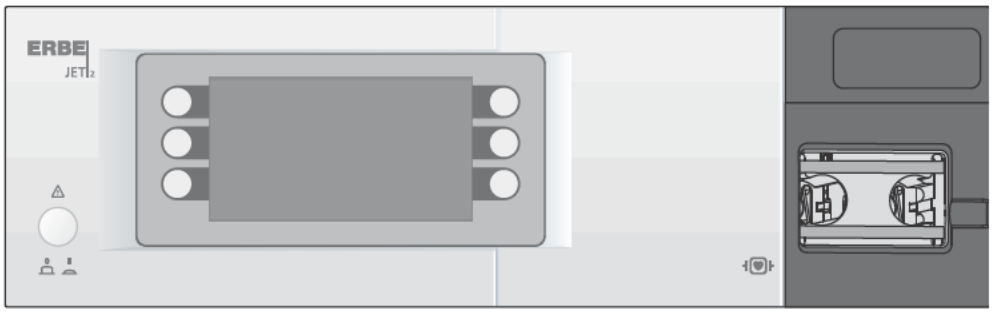
User Manual

ERBEJET® 2

V 1.1.x



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User Manual

ERBEJET® 2

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MEDICAL - GENERAL MEDICAL EQUIPMENT
AS TO ELECTRICAL SHOCK, FIRE
AND MECHANICAL HAZARDS ONLY
IN ACCORDANCE WITH
ANSI/AAMI ES60601-1 (2005),
CAN/CSA-C22.2 No. 60601-1 (2008)
19NA

CE 0124

EN ISO 9001 EN ISO 13485

User Manual Art. No. 80110-814

Product Art. No. 10150-000

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CHAPTER 1

Safety Instructions

Intended Use

The ERBEJET 2 is intended for lifting mucosal lesions by injection into the submucosa as well as the cutting and dissection of soft tissue in neurosurgery and soft tissue such as liver, kidney, etc. within the abdomen, including Total Mesorectal Excision (TME), in open and endoscopic surgery.

Safety notations

⚠ DANGER

indicates an imminently hazardous situation which, if not avoided, will result in death or serious injury.

⚠ WARNING

indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

⚠ CAUTION

indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury.

NOTICE

indicates a potentially hazardous situation which, if not avoided, may result in property damage.

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Meaning of the note

"Note:"

Refers a) to manufacturer's information that relates directly or indirectly to the safety of people or protection of property. The information does not relate directly to a risk or dangerous situation.

Refers b) to manufacturer's information that is important or useful for operating or servicing the unit.

Who must read this User Manual?

Knowledge of the User Manual is absolutely essential for correct operation of the unit.

Therefore everyone who is concerned with

- preparing,
- adjusting,
- operating,

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- disassembling, as well as
- cleaning and disinfecting

the unit must read the User Manual.

Please pay particular attention to the safety instructions in each chapter.

Compliance with safety information

Working with medical equipment is associated with certain risks to patients, medical personnel and the environment. Risks cannot be entirely eliminated by design measures alone.

Safety does not depend solely on the equipment. Safety depends to a large extent on the training of medical personnel and correct operation of the equipment.

The safety instructions in this chapter must be read, understood and applied by everyone who is working with the equipment.

Structure of safety instructions

The safety instructions are structured according to the following risks:

- Operating errors and incorrect installation by persons without training
- Risks due to the environment
- Electric shock
- Risk of infection
- Fire / explosion
- Defective unit, defective accessories
- Interference caused by the unit
- Safety information for use of ERBEJET 2
- Notes

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Operating errors and incorrect installation by persons without training

⚠ WARNING

Operating errors and incorrect installation by persons without training

Persons without training can operate or install the unit incorrectly.

Risk of injury or death for patients and medical staff! Risk of damage to property.

➡ The equipment may only be used and installed by persons who have been trained on how to use and install it properly according to this User Manual.

➡ Training may only be carried out by persons who are suitable on the basis of their knowledge and practical experience.

➡ In the event of uncertainties or if you have any questions, please contact ERBE USA. You will find the contact information at the end of this User Manual.

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Risks due to the environment

NOTICE

Interference with the unit by portable and mobile HF communication devices (e.g. mobile phones, WLAN equipment)

Electromagnetic waves emitted by portable and mobile HF communication devices can effect the unit.

The equipment may fail or not perform properly.

➡ Please see the table "Recommended separation distances between portable and mobile HF communications equipment and the equipment" at the end of this User Manual.

NOTICE

Unsuitable temperature or level of humidity during operation

If you operate the equipment at an unsuitable temperature or level of humidity, it may sustain damage, fail, or not perform properly.

➡ Operate the equipment at a suitable temperature and level of humidity. You will find the tolerances for temperature and humidity in the Technical Data.

➡ If other ambient conditions have to be observed for operation of the equipment, you will also find them in the Technical Data.

NOTICE

Unsuitable temperature or humidity in transit or storage

If you transport or store the equipment at an unsuitable temperature or level of humidity, it may sustain damage and fail.

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➡ Transport and store the equipment at a suitable temperature and level of humidity. You will find the tolerances for temperature and humidity in the Technical Data.

➡ If other ambient conditions have to be observed for transport and storage of the equipment, you will also find them in the Technical Data.

NOTICE

Insufficient acclimatization time, unsuitable temperature during acclimatization

If the device was stored or transported below or above a certain temperature, it will take a certain time and temperature to acclimatize.

If you do not observe the rules , the device can sustain damage and fail.

➡ Acclimatize the device according to the rules in the Technical Data.

NOTICE

Overheating of the device due to poor ventilation

If ventilation is poor, the device can overheat, sustain damage, and fail.

➡ Install the device in such a way that there is an unobstructed circulation of air around the housing. Installation in confined wall recesses is prohibited.

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NOTICE

Penetration of liquid into the device

The housing is not absolutely watertight. If liquid penetrates, the device can sustain damage and fail.

- Make sure no liquid can penetrate the device.
- Do not place vessels containing liquids on top of the device.
- Take care when connecting the cutting medium to the pump cartridge that the unit does not come into contact with the cutting medium. The same applies when removing the cutting medium.

Electric shock

⚠ WARNING

Defective grounded power outlet, power supply network without proper grounding, inferior-quality power cord, incorrect line voltage, multiple power outlets, extension cords

Risk of electric shock and other injuries to the patient and medical personnel! Risk of damage to property.

- Connect the unit / the equipment cart to a properly installed grounded power outlet.
- Only connect the unit to a power supply network with proper grounding.
- Only use the ERBE power cord or an equivalent power cord for this purpose. The power cord must bear the applicable national test symbol.
- Check the power cord for damage. You must not use a damaged power cord.
- The supply voltage must match the voltage specified on the unit's rating plate.
- Do not use multiple power outlets.
- Do not use extension cords.

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⚠ WARNING

Incorrect line fuse, defective device

Risk of electric shock to the patient and medical personnel! Risk of damage to property.

- Blown line fuses may only be replaced by a competent technician. Only replacement fuses that have the same rating as the one specified on the unit's rating plate may be used.
- When a fuse has been changed, the function of the unit must be verified. If the unit does not function properly or there are any concerns, please contact ERBE USA.

⚠ WARNING

Connection of unit / equipment cart and power supply during cleaning and disinfection

Risk of electric shock to the medical personnel!

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➡ Switch off the device. Unplug the power cord of the device/ equipment cart.

Risk of infection

⚠ WARNING

Non-sterile accessories or mishandling

The patient can be infected by the use of accessories that should be sterile (e.g. applicator or probe, pump cartridge, etc.) but are not or by contamination due to the mishandling of accessories.

➡ Use only sterile accessories as designated.

➡ Use aseptic techniques during the handling and connection of accessories. Specifically ensure that aseptic techniques are utilized when connecting the applicator or probe as well as the tubing set to the unit (e.g. pump cartridge, etc.).

⚠ WARNING

Non-sterile normal saline and/or tubing set

The patient can be infected by the use of non-sterile normal saline and/or tubing set.

➡ Only use sterile normal saline and tubing set.

⚠ WARNING

Contaminated normal saline by body fluids

Normal saline contaminated with the patient's body fluids spraying or splashing on the medical staff.

Risk of infection for the medical staff.

➡ Wear personal protective equipment (e.g. gown, faceshield or eye protection, mask, gloves, etc.) to minimize the risk of exposure to infectious agents due to undesirable/unexpected spraying or splashing.

➡ Avoid the accumulation of used normal saline with body fluids in the operating area. Ensure adequate suction.

⚠ WARNING

Contaminated accessories

Risk of infection for the medical staff.

➡ Wear personal protective equipment (e.g. gown, faceshield or eye protection, mask, gloves, etc.) to minimize the risk of exposure to infectious agents while handling, disconnecting, and disposing of used accessories.

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Fire / explosion

⚠ WARNING

Ignition of anesthetics, skin cleansers, and disinfectants in potentially explosive atmospheres

If you place the device in a potentially explosive atmosphere, anesthetics, skin cleansers, and disinfectants can ignite.

Risk of fire and explosion to the patient and medical personnel! Risk of damage to property.

➡ Do not place the device in potentially explosive atmospheres.

Defective/Damaged unit and/or accessories

⚠ WARNING

Failure of display elements

If display elements fail, you can no longer operate the device safely.

Risk of injury or death for patients and medical staff!

➡ You must not use the unit.

⚠ WARNING

Routine safety testing not being done

Risk of injury or death for patients and medical staff! Risk of damage to property.

➡ Have the device checked for safety at least once a year.

➡ You must not use a device that is not safe.

⚠ WARNING

Defective/Damaged device and/or accessories, modified device and/or accessories

Risk of injury to the patient and medical personnel! Risk of damage to property.

➡ Check the unit and accessories (e.g. footswitch, cables, applicators or probe, etc.) for damage every time before use.

➡ You must not use damaged equipment or damaged accessories. Exchange defective accessories.

➡ If the unit or accessories are damaged, please contact customer service.

➡ For your safety and that of the patient: Never attempt to perform repairs or make modifications yourself. Any modification will invalidate liability on the part of ERBE Elektromedizin GmbH.

NOTICE

Alcohol-based spray disinfectant for fast disinfection

With membrane keyboards and paint surfaces there is the risk of cracks. Propanol and ethanol will erode surfaces.

➡ Do not use these substances.

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NOTICE

Alternate use of disinfectant solutions based on different active ingredients

A color reaction may occur with plastics.

➡ Do not use these substances alternately.

Interference caused by the unit

NOTICE

Use of non-approved internal cables by Technical Service

This can result in the increased emission of electromagnetic waves or reduce the immunity of the device.

The equipment may fail or not perform properly.

➡ Technical Service may only use the internal cables that are listed in the service manual for the device.

NOTICE

Stacked devices

If you stack the device next to other equipment or with other equipment, the devices can affect each other.

The equipment may fail or not perform properly.

➡ The device may only be stacked next to or with VIO series units.

➡ If it is necessary to operate the device near other equipment or stacked together with other equipment, check whether the devices are affecting each other: Are the devices behaving unusually? Do errors occur?

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Safety information for use of ERBEJET 2

⚠ WARNING

Use of unsuitable solutions

The use of an unsuitable solution can change the effect of the water jet. Risk of injury to the patient.

➡ Only use sterile normal saline.

⚠ WARNING

Effect level set too high

The higher the effect level, the greater the risk of accidental tissue damage.

➡ Use the lowest possible effect setting to achieve the desired surgical outcome. Always begin at a low setting and increase as necessary.

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⚠ WARNING

Activating without confirming settings on the screen

If the user does not verify that the settings on the display are appropriate/desired, then the greater the risk of accidental tissue damage.

➡ Prior to activation, confirm that the desired settings are displayed on the unit's screen.

⚠ CAUTION

During the priming process, normal saline may come out the tip of the applicator or probe

Depending on the dimensions of the applicator or probe, normal saline may come out the tip and damage skin or the eyes.

➡ Never point the applicator or probe tip at medical personnel. Never point the the tip of the applicator or probe at the patient during the priming process.

➡ For safety purposes, medical personnel should wear personal protective equipment (e.g. gown, faceshield or eye protection, mask, gloves, etc.).

➡ During priming, if normal saline comes out the tip of the applicator or probe, stop the process by pressing the display/selection button R2 that corresponds with *STOP* on the screen.

⚠ CAUTION

Uncontrolled use of the equipment

Uncontrolled use of the water jet can cause unintentional damage to skin or eyes.

➡ Do not point the applicator or probe tip at medical personnel or accidentally point it at the patient.

➡ For safety purposes, medical personnel should wear personal protective equipment (e.g. gown, faceshield or eye protection, mask, gloves, etc.).

➡ Only direct the tip of the applicator or probe at the operative site and only activate to cut or dissect and/or suction as necessary.

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NOTICE

Tension on an applicator's delivery tubing/suction hose junction

If an applicator hose's delivery tubing/suction hose junction is subjected to tension, it may leak aspirated fluids that could be contaminated from the branch (1).

➡ For applicators with suction, do not subject the delivery tubing/suction hose junction to tension.

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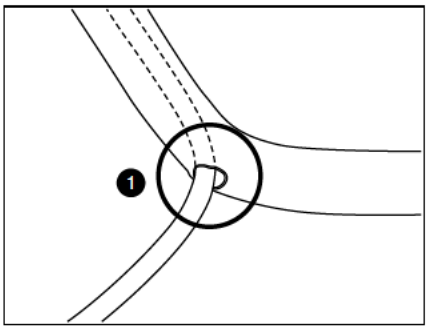

Fig. 1-1

NOTICE

Applicator's or probe's delivery tubing and/or suction hose kinked

If the delivery tubing and/or suction hose is kinked/crimped, the delivery of the normal saline and/or the suction will decrease or cease. If the crimp is severe (in the delivery tubing or the delivery tubing inside the suction hose), the ERBEJET 2 will display a message prompting a pump cartridge (including an applicator or probe) change.

➡ Do not kink the delivery tubing and/or suction hose.

Application Precautions

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In General and Endoscopic Procedures

1. Wearing of protective glasses and the use of a sheet (waterproof barrier drape) that surrounds the area of dissection are recommended.
2. Heating of the normal saline to 40 °C (104 °F) prior to the procedure may result in less foaming and positive effect on local blood coagulation. Therefore heating is recommended and can be achieved using a designated warmer unit designed for infusion/irrigation fluids.
3. In laparoscopy/endoscopy, maintain optimal visibility (i.e., minimize/ prevent splashing and foaming) and equilibration in the cavity by keeping the tip of the applicator close to the tissue, adequately suctioning, and keeping the scope farther back during activation.
4. With an ESM 2 attached, the suction pressure can be adjusted via the display screen of the ERBEJET 2 to maximize the aspiration of the minute amounts of dissecting medium (saline) and maintain adequate pneumoperitoneum.
5. Blood vessels may be disrupted by the water jet depending on the effect / pressure setting.
6. Keep a margin of safety. Dissection of the tissue should be made at an adequate distance from the edge of the carcinoma.
7. In case of longer surgical procedures, control of serum electrolyte levels is recommended.

In Renal Procedures

1. The ERBEJET 2 is not intended for dissection of the renal capsule.
2. Resection with the ERBEJET 2 may produce a zone of vacuolization of 100 - 300 µm (e.g., in renal surgery).

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In Neurosurgical Procedures

1. In neurosurgery, the ERBEJET 2 is not intended for dissecting tumor capsules. Furthermore, in addition to the device, conventional methods may be required to dissect/remove firmer masses or structures from the brain parenchyma.

Notes

Grounding

Note: If necessary, the equipment can be connected to the external grounding system of the room with the grounding pin on the back of the unit and/or Cart using a connecting cable designed for this purpose. Affects of low frequency leakage currents due to a defective grounding system within the room may be eliminated through external grounding.

Use of a defibrillator

Note: The equipment conforms to the requirements of Type CF and is protected against the effects of a defibrillator discharge.

Membrane keyboards

Note: If alcohol-based disinfectants are used on units with membrane keyboards, the anti-glare finish will be removed. However, the user surfaces remain fully functional.

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001_13 Proposed Labeling
013 - 18
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CHAPTER 2

Description of the Controls

Controls on the front panel

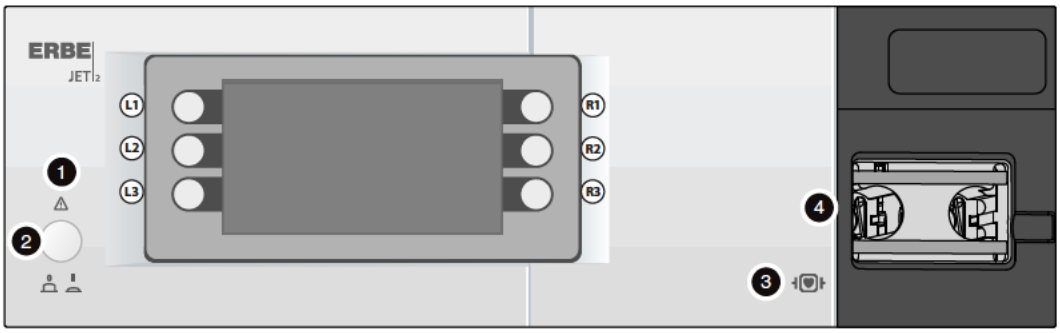

Fig. 2-1

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Symbol **(1)**

Instructs medical personnel to read the User Manual before switching on and using the unit.

Power switch **(2)**

Unit's "On" / "Off" switch.

Symbol **(3)**

Designates that the equipment conforms to the requirements of Type CF (Cardiac Float) and is protected against the effects of a defibrillator discharge.

Pump cartridge slot **(4)**

Slot to insert a pump cartridge.

Display/Selection buttons **(L1) (L2) (L3) (R1) (R2) (R3)**

Buttons that correlate to different functions depending on what is displayed on the screen. Take note of the function(s) that refers to the respective buttons.

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Controls on the back

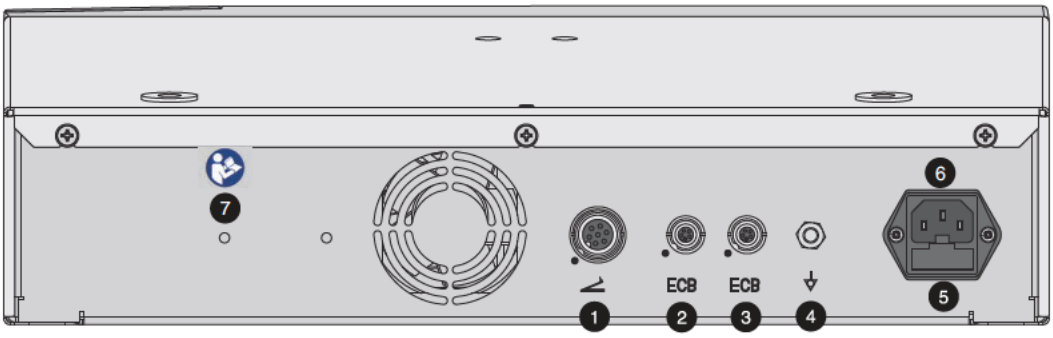

Fig. 2-2

Sockets **(1) Footswitch socket**

Socket to connect an ERBEJET 2 footswitch.

(2) (3) ERBE Communication Bus (ECB) socket

Sockets for connecting compatible ERBE equipment (e.g. ESM 2) via an ECB cable. The ECB ensures communication between the units. Connect an ECB cable to one of these sockets and then to the compatible equipment.

Grounding Terminal Pin **(4)**

Pin to ground the unit via a grounding connecting cable and a ground source. The unit may be grounded to an ERBE VIO Cart as applicable. Then the ERBE VIO Cart could be grounded to the room's external grounding system (Note: The unit could be directly grounded to the external grounding system of the room via a connecting cable designed for this purpose.). Affects of low frequency leakage currents due to a defective grounding system within the room may be eliminated through external grounding.

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Power Fuses **(5)**

Fuses for protecting the unit. If a fuse is blown, then a spare fuse with the same power rating must be used as its replacement. However, the unit must be checked out by a trained technician and found to be performing within specifications prior to being used in patient procedures.

Power connection **(6)**

Unit's socket for connecting it to a power supply via an ERBE power cord or an equivalent (hospital grade) power cord for this purpose. The unit may be connected to the power strip on an ERBE VIO Cart Art. No. 20180-000 as applicable. Then the cart is connected to a power supply. Nonetheless, the power supply outlet must be properly grounded and within the unit's voltage requirements.

Symbol **(7)**

Instructs medical personnel to read the User Manual before switching on and using the unit.

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CHAPTER 3

Working with ERBEJET 2

Turning "On" the unit, connecting an applicator or probe

Note: If a suction module, Model ESM 2 is to be used in conjuction with the ERBEJET 2 then refer to the ESM 2 User Manual for its installation and installation of its components as well as attaching accessories.

⚠ WARNING

Defective/Damaged device and/or accessories, modified device and/or accessories

Risk of injury to the patient and medical personnel! Risk of damage to property.

- Check the unit and accessories (e.g. footswitch, cables, applicators or probe, etc.) for damage every time before use.
- You must not use damaged equipment or damaged accessories. Exchange defective accessories.
- If the unit or accessories are damaged, please contact customer service.
- For your safety and that of the patient: Never attempt to perform repairs or make modifications yourself. Any modification will invalidate liability on the part of ERBE Elektromedizin GmbH.

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Turning "On" the unit

Fig. 3-1

1. Use the power switch to turn the ERBEJET 2 "On". The unit performs a self check. As a part of the unit's selfcheck it will recognize an attached footswitch as well as compatible equipment (e.g. ESM 2) that is connected and turned "On". Also, the software version of the unit and attachments respectively will be displayed during the selfcheck.

⚠ WARNING

Failure of display elements

If display elements fail, you can no longer operate the device safely.

Risk of injury or death for patients and medical staff!

- You must not use the unit.

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Connecting an applicator or probe

⚠ WARNING

Non-sterile accessories or mishandling

The patient can be infected by the use of accessories that should be sterile (e.g. applicator or probe, pump cartridge, etc.) but are not or by contamination due to the mishandling of accessories.

- Use only sterile accessories as designated.
- Use aseptic techniques during the handling and connection of accessories. Specifically ensure that aseptic techniques are utilized when connecting the applicator or probe as well as the tubing set to the unit (e.g. pump cartridge, etc.).

1. Open intact packages of an applicator or probe and a pump cartridge onto the sterile field while ensuring/verifying the integrity of the accessories.

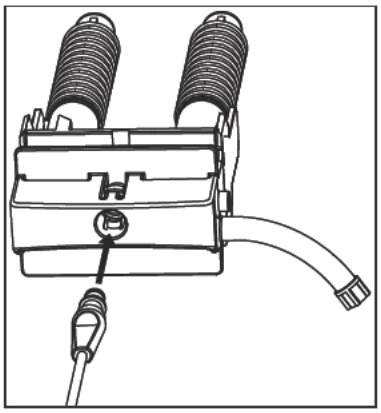

Fig. 3-2

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2. Remove the protective cap from the applicator's or probe's connector of the delivery tubing and insert the connector into the hole of the pump cartridge. It should lock into place and not be able to be removed from the cartridge.

Selecting a program, connecting a pump cartridge, connecting normal saline, priming the pump cartridge and the applicator or probe

Selecting a program

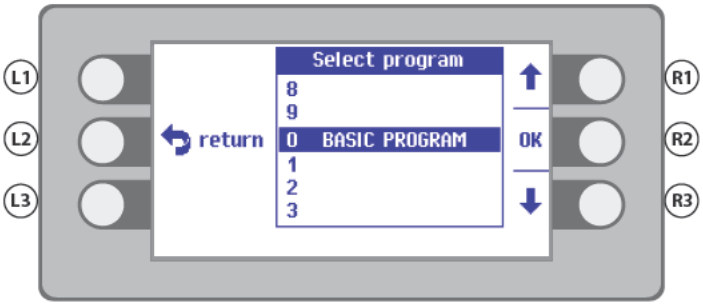

Fig. 3-3

1. When the ERBEJET 2 has been turned "On" and completed its power up sequence, a selection list of programs should be displayed on the unit's screen.

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2. Scan and view all programs in the list by using display/selection buttons R1 and R3.
3. When the desired program is in the middle of the screen and highlighted at "OK", press display/selection button R2. **Example: 0 BASIC PROGRAM**

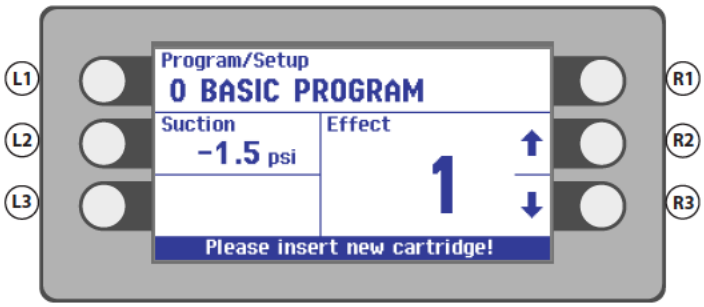

Fig. 3-4

4. Once the desired program is selected, the system will prompt you to insert a new pump cartridge.

Connecting a pump cartridge

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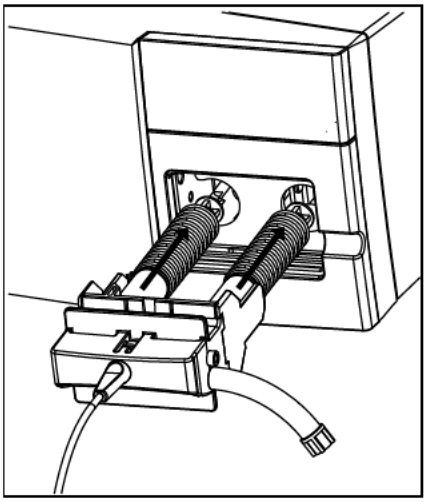

Fig. 3-5

1. Slide the pump cartridge (with the attached applicator or probe) into the pump cartridge slot of the unit until it is engaged. The screen should display "Connecting cartridge - Please wait" and then "Ready".

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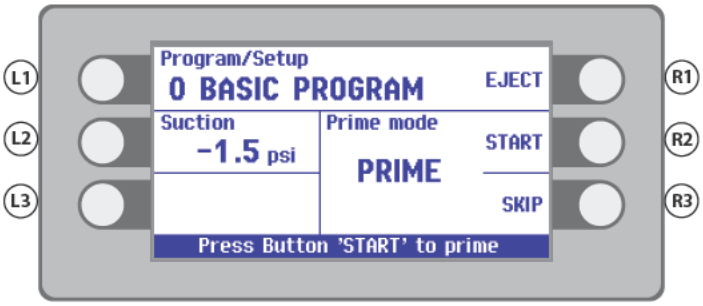

Fig. 3-6

2. As soon as the pump cartridge has been connected, the system will prompt you to prime the pump cartridge with applicator or probe. However, normal saline will need to be connected prior to the priming process of the pump cartridge.

Connecting normal saline

⚠ WARNING

Use of unsuitable solutions

The use of an unsuitable solution can change the effect of the water jet. Risk of injury to the patient.

➡ Only use sterile normal saline.

⚠ WARNING

Non-sterile normal saline and/or tubing set

The patient can be infected by the use of non-sterile normal saline and/or tubing set.

➡ Only use sterile normal saline and tubing set.

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⚠ WARNING

Non-sterile accessories or mishandling

The patient can be infected by the use of accessories that should be sterile (e.g. applicator or probe, pump cartridge, etc.) but are not or by contamination due to the mishandling of accessories.

➡ Use only sterile accessories as designated.

➡ Use aseptic techniques during the handling and connection of accessories. Specifically ensure that aseptic techniques are utilized when connecting the applicator or probe as well as the tubing set to the unit (e.g. pump cartridge, etc.).

1. With the tubing set, spike and hang the bag of normal saline. Open the line to allow the solution to migrate to the end of the tubing.

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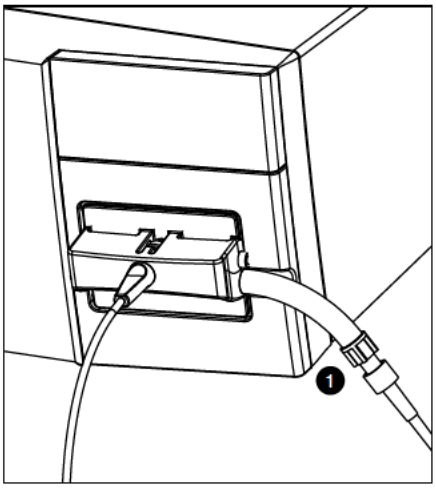

Fig. 3-7

2. Remove the protective cap from the luer lock of the pump cartridge. Connect the primed tubing to the luer lock (1).

Priming the pump cartridge and the applicator or probe

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⚠ CAUTION

During the priming process, normal saline may come out the tip of the applicator or probe

Depending on the dimensions of the applicator or probe, normal saline may come out the tip and damage skin or the eyes.

- ➡ Never point the applicator or probe tip at medical personnel. Never point the the tip of the applicator or probe at the patient during the priming process.
- ➡ For safety purposes, medical personnel should wear personal protective equipment (e.g. gown, faceshield or eye protection, mask, gloves, etc.).
- ➡ During priming, if normal saline comes out the tip of the applicator or probe, stop the process by pressing the display/selection button R2 that corresponds with *STOP* on the screen.

Fig. 3-8

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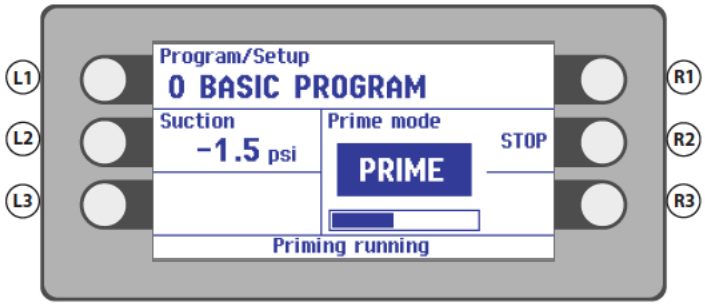

Fig. 3-9

1. On the screen in the Prime mode, select START by pressing display/selection button R2 to prime the pump cartridge. However in the Prime mode, *SKIP* can be selected by pressing display/selection button R3 to avert any priming if desired at this time.
2. If the Prime Mode is initiated, priming can be stopped at anytime during the process. During "Priming running", select *STOP* by pressing display/selection button R2. Stop priming if normal saline comes out the tip of the applicator or probe (See Safety Instuctions.).
3. Complete or perform the priming of the pump cartridge and applicator or probe (i.e. the delivery tubing) by depressing the attached footswitch. The time that it takes to have the cartridge and tubing primed will be depended upon the Effect setting of the program being used (Note: An Effect of 20 in the Basic program could be employed for priming.). Nonetheless, priming will be complete when the air is displaced and the water jet stream is consistent from the applicator or probe tip (See Safety Instuctions.)

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Attaching as applicable the applicator's suction hose

NOTICE

Tension on an applicator's delivery tubing/suction hose junction

If an applicator hose's delivery tubing/suction hose junction is subjected to tension, it may leak aspirated fluids that could be contaminated from the branch (1).

➡ For applicators with suction, do not subject the delivery tubing/suction hose junction to tension.

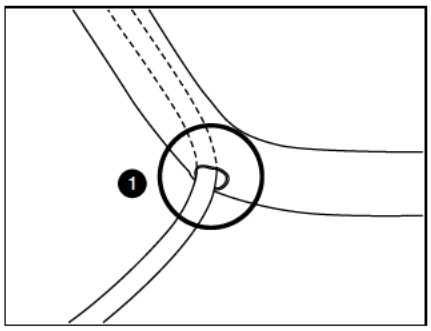

Fig. 3-10

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Note: The ESM 2 is only to be used with the ERBEJET 2 and an ERBEJET 2 applicator with suction.

1. If using the ESM 2, follow the connection instructions in its User Manual. In general, the suction hose of the applicator is to be attached to the suction (patient) port on the lid of an ESM suction container with a bag. The ESM 2 must also be appropriately linked up with the ERBEJET 2 via an ECB cable, connected to the suction container, and turned "On".

Note: The suction hose of an ERBEJET 2 applicator with suction may be connected to an alternative suction device, but the suction (vacuum) pressure must not exceed -11.6 psi (-800 mbar).

Viewing a program as well as selecting settings for effect and suction

Viewing a program

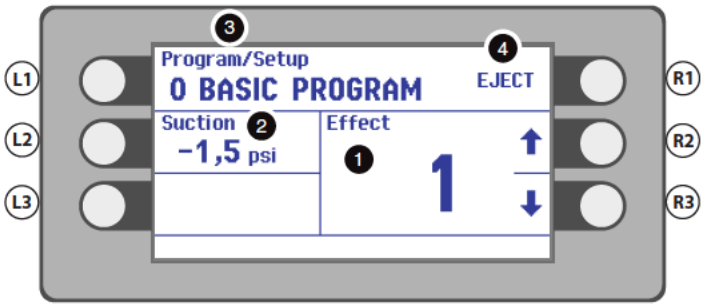

Fig. 3-11

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Note: If the suction module Model ESM 2 is not used/connected and turned "On", then the setting on the screen for Suction will be "off-line".

The following parameters are stored in each program:

- *Effect*
- *Suction*

In the program you can:

- Change the *Effect* (1).
- Access the features and parameters for *Suction* (2)
- Access the elements of the *Program/Setup* (3)

Note: Setup, Service, Save/Erase Program, Select Program, and Return are the categories/possibilities in "Program/Setup" which can be accessed by pressing display/selection button L1.

- If connected, remove the pump cartridge from the unit with *EJECT* (4) by pressing the display/selection button R1.

Note: "EJECT" will not appear on the screen or be an option if a pump cartridge is not already engaged in the unit.

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Selecting effect

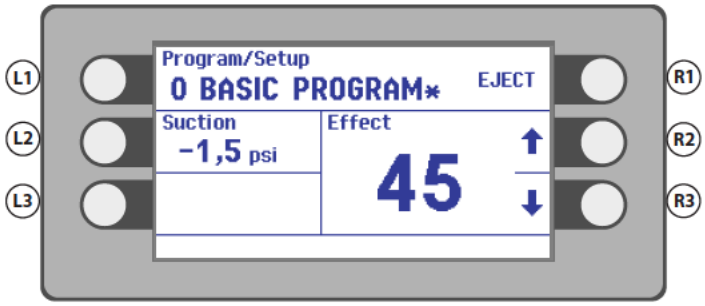

Fig. 3-12

Decrease or increase the *Effect* by pressing display/selection buttons R3 and R2 respectively within a range of Effect from 1 to 80. **Example setting: Effect 45**.

Note: The selected Effect psi equivalent will be displayed on the bottom of the screen. That is for the above example of Effect 45, "Corresponds to 652 psi" will be on the display for 3 seconds upon being selected.

Accessing and selecting features as well as parameters of suction

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Note: The possibility of suctioning with the system can only be achieved by using an ERBEJET 2 applicator with suction and the suction module Model ESM 2.

Access features and parameters for *Suction* by pressing display/selection button L2.

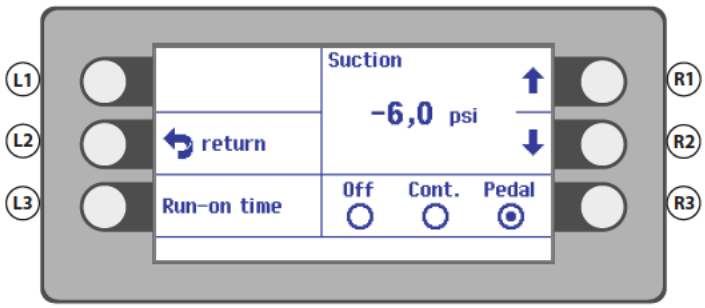

Fig. 3-13

For *Suction*, several features and parameters can be set as follows:

To set the type of suction, press display/selection button R3 to select;

- *Off*: If no suction is desired,
- *Cont*: If a continuous suction is preferred, or

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Note: With "Cont.", the selected suction psi will be constant and independent of activating the water jet via the pedal.

- *Pedal*: If suction upon pedal activation is needed.

Note: With the selection of "Pedal", another feature designated as "Run-on time" is a possibility.

Example Selection: Pedal.

To increase or decrease the *Suction* press display/selection buttons R1 and R2 respectively within a range of Suction from -1.5 to -12 psi. **Example setting: - 6.0 psi**.

To have suction for a period of time after activating the water jet (i.e. upon removing foot from pedal), a *Run-on time* may be selected by pressing display/selection button L3.

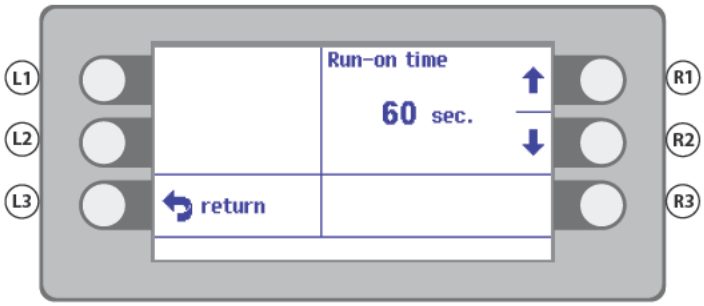

Fig. 3-14

The time of suctioning after the activation of the water jet (*Run-on time*) can be increased and decreased by pressing display/selection buttons R1 and R2 respectively within a range of Time from Off to 60 seconds (sec.). **Example setting: 60 sec.**

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Note: A return to the program from the *Run-on time* screen can be achieved through selecting the return designation by pressing the display/selection button L3. Where as from the screen of the features/parameters for Suction, select the return designation by pressing the display/selection button L2.

Activation

⚠ WARNING

Effect level set too high

The higher the effect level, the greater the risk of accidental tissue damage.

➡ Use the lowest possible effect setting to achieve the desired surgical outcome. Always begin at a low setting and increase as necessary.

⚠ WARNING

Activating without confirming settings on the screen

If the user does not verify that the settings on the display are appropriate/desired, then the greater the risk of accidental tissue damage.

➡ Prior to activation, confirm that the desired settings are displayed on the unit's screen.

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⚠ CAUTION

Uncontrolled use of the equipment

Uncontrolled use of the water jet can cause unintentional damage to skin or eyes.

- Do not point the applicator or probe tip at medical personnel or accidentally point it at the patient.
- For safety purposes, medical personnel should wear personal protective equipment (e.g. gown, faceshield or eye protection, mask, gloves, etc.).
- Only direct the tip of the applicator or probe at the operative site and only activate to cut or dissect and/or suction as necessary.

NOTICE

Applicator's or probe's delivery tubing and/or suction hose kinked

If the delivery tubing and/or suction hose is kinked/crimped, the delivery of the normal saline and/or the suction will decrease or cease. If the crimp is severe (in the delivery tubing or the delivery tubing inside the suction hose), the ERBEJET 2 will display a message prompting a pump cartridge (including an applicator or probe) change.

- Do not kink the delivery tubing and/or suction hose.

⚠ WARNING

Contaminated normal saline by body fluids

Normal saline contaminated with the patient's body fluids spraying or splashing on the medical staff.

Risk of infection for the medical staff.

- Wear personal protective equipment (e.g. gown, faceshield or eye protection, mask, gloves, etc.) to minimize the risk of exposure to infectious agents due to undesirable/unexpected spraying or splashing.
- Avoid the accumulation of used normal saline with body fluids in the operating area. Ensure adequate suction.

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Cutting/Dissection and suction possibilities	Suction features and as applicable setting	Pedal activation required
Cutting/Dissection Only	Off	Yes
Cutting/Dissection and Suction Only when Activated	Pedal, Run-on time Off	Yes
Cutting/Dissection when Activated and Suction Continuing upon Activation for a Period of Time	Pedal, Run-on time 1 to 60 sec. (seconds)	Yes
Cutting/Dissection when Activated and Suction Continuous	Cont. (Continuous)	Yes
Suction Only	Cont. (Continuous)	No

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Note: During activation (i.e. when the pedal of the footswitch is depressed), the Effect on the screen will be highlighted in blue. As set and/or selected, an activation tone may also be heard. Also, it is possible to make changes to the Effect during operation. If changes are made an (*) will appear at the end of the program name. Be aware that any changes of settings in a program will be lost unless saved as new or by overwriting.

Upon deactivation (i.e. when your foot is removed from the pedal of the footswitch), there is residual pressure and normal saline in the line which will dissipate. Therefore, keep the tip of the applicator pointed at the surgical site for a few seconds after activation until saline is no longer being delivered.

Note: During suction, the set maximum vacuum is shown inverted on the display of ERBEJET 2 (white numbers on blue background).

Using the basic program to create and save a new program as well as new programs for the ReMode function

Using the basic program to create and save a new program

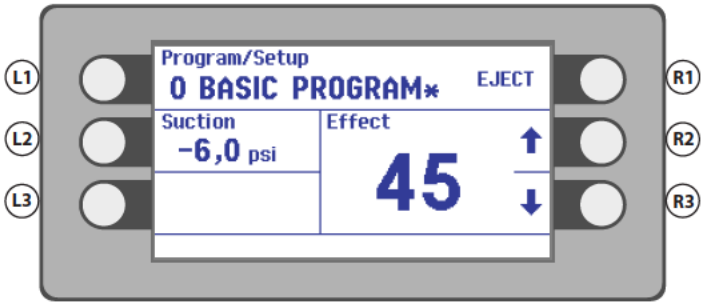

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Fig. 3-15

Upon selecting the basic program and making any changes, an (*) will appear at the end of the program name. The changes will be lost unless they are saved as a new program.

Note: Overwriting/Permanent changes to the basic program and saving those changes as the basic program is not possible.

Choose all the desired parameters and features for Effect and as applicable Suction (settings, etc.) for the new program being created, then perform the following steps.

1. On the screen displayed, select *Program/Setup* by pressing display/selection button L1.
2. On the screen displayed, select *SAVE/ERASE program* by pressing display/selection button L3.
3. On the screen displayed, select *SAVE* by pressing display/selection button L1.
4. On the screen displayed, select *SAVE settings as new Program by pressing display/selection button L2*.

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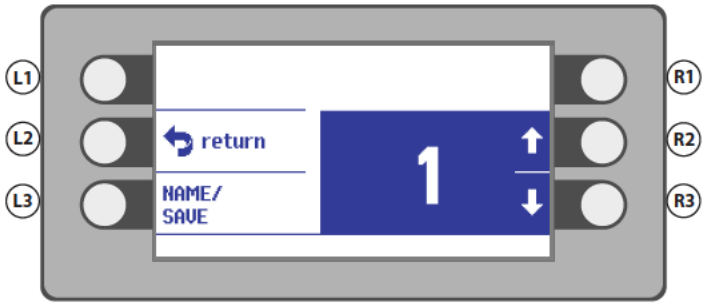

Fig. 3-16

5. On the screen displayed, the sequential remaining open numbers for the new program will be accessible by increasing or decreasing the number using display/selection buttons R2 and R3 respectively within a range of possible saved programs from 1 to 9. **Example: 1**

6. Upon selecting the program number, select *NAME/SAVE* by pressing display/selection button L3.

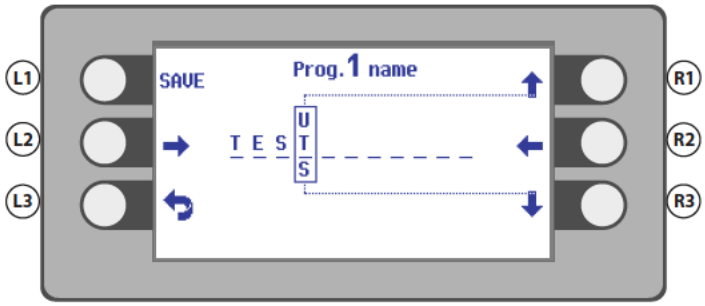

Fig. 3-17

7. Identify/Name the new program with a character range from 1 to 11 spaces. For each space, scroll through the characters up and down using display/selection buttons R1 and R3 respectively within a range of 0 to 9, blank space, all alphabet letters and a period.

8. Characters are selected by positioning it to correspond with display/selection button R2. Then to add the next character (to the right) as necessary, press display/selection button L2.

9. Repeat step 8 to add characters as needed to identify/name the new program. **Example: TEST**.

10. Upon identifying/naming the new program, select *SAVE* by pressing and holding display/selection button L1 until the message *PROGRAM SAVED* appears on the screen.

11. Select the return designation (which will display the new program) by pressing display/selection button L3.

Creating and saving programs for the ReMode function

Two programs can be set up so that the user can toggle (i.e. go back and forth) between the programs by pressing the ReMode button on the footswitch. For this purpose, a and b level programs are created and saved by performing the following sequences and steps.

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Creating and saving program a

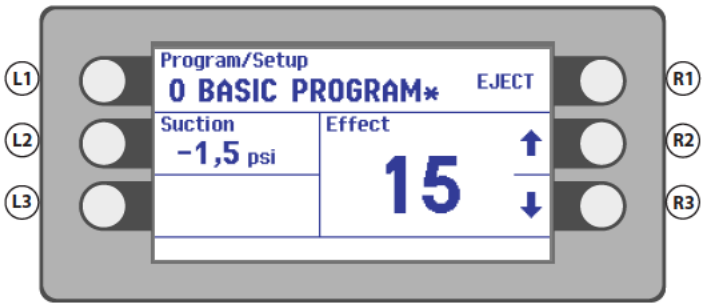

Fig. 3-18

1. Starting with the basic program, make changes to settings to create, name, and save first program as previously instructed. Also, return to the newly created program.

Note: The identifier (a) will be assigned for this program when the b program is created, etc. For this exercise, the program was assigned program number 2 and named EXAMPLE (See below).

Creating and saving program b

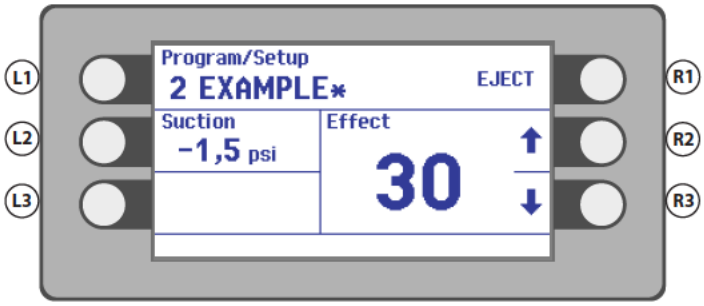

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Fig. 3-19

1. Change the settings as desired of the newly created program (i.e. 2 EXAMPLE).
2. On the screen displayed, select *Program/Setup* by pressing display/selection button L1.
3. On the screen displayed, select *SAVE/ERASE program* by pressing display/selection button L3.
4. On the screen displayed, select *SAVE* by pressing display/selection button L1.
5. On the screen displayed, select *SAVE settings as new Program by pressing display/selection button L2*.

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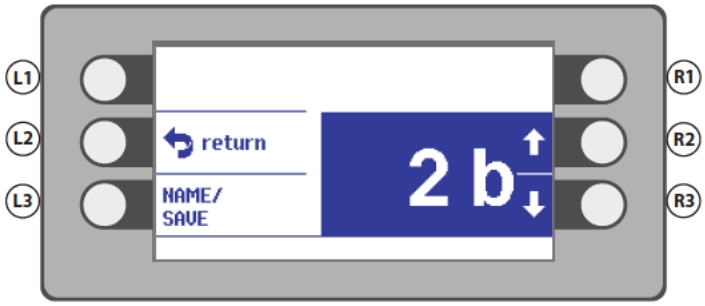

Fig. 3-20

6. On the screen displayed, the program number and level for the second program (b) will be assigned (For this exercise the program number was 2 and now b is assigned.). To continue, select *NAME/SAVE* by pressing display/selection button L3.
7. On the screen displayed, select *SAVE* by pressing and holding display/selection button L1 until the message *PROGRAM SAVED* appears on the screen.
8. Select the return designation (which will display the second newly created program) by pressing display/selection button L3.
9. To view the created programs in the list for the ReMode function, select *Program/Setup* by pressing display/selection button L1. On this next screen, choose *SELECT program* by pressing display/selection button L2.

   Note: The second program (b) may be identified/named differently than the first program (a) as previously instructed. However, the program number as well as a and b levels will remain.

With the ReMode button on the footswitch, it is now possible to toggle (i.e. go back and forth) between the two a and b level programs.

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Deleting and overwriting a program

Deleting a program

1. On the screen displayed for the program being deleted, select *Program/Setup* by pressing display/selection button L1.
2. On the screen displayed, select *SAVE/ERASE program* by pressing display/selection button L3.
3. On the screen displayed, select *ERASE program* by pressing display/selection button L2.
4. On the screen displayed, select *ERASE program* by pressing and holding display/selection button L3 until message PROGRAM ERASED appears on the screen.
5. Select the return designation by pressing display/selection button L2 (this will show the name and settings erased and display the basic program settings unless it is a ReMode program. In that case, it will display the other associated program).

Note: To see the remaining available programs and see that the program is no longer in the list, select *Program/Setup* by pressing display/selection button L1. On this next screen, choose *SELECT program* by pressing display/selection button L2.

Overwriting a program

1. On the screen displayed for the program being overwritten (i.e. for cases where changes were made to the settings and now want to be saved for the program), select *Program/Setup* by pressing display/selection button L1.

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2. On the screen displayed, select *SAVE/ERASE program* by pressing display/selection button L3.
3. On the screen displayed, select *SAVE program* by pressing display/selection button L1.
4. On the screen displayed, select *OVERWRITE current Program* by pressing display/selection button L3.
5. On the screen displayed, select *SAVE* by pressing and holding display/selection button L1 until message PROGRAM SAVED appears on the screen.
   Note: The revised/overwritten program may be identified/named differently by following previous instructions.
6. Select the return designation (which will display the revised/overwritten program) by pressing display/selection button L3.

Fluid Volume Pumped Signal (ml-signal)

A feature to alert the clinicain via an audio tone when each ml of normal saline is pumped can be turned "On" in the Setup program. To activate this option, *ml-signal*, see the following section "Accessing and changing parameters in Setup".

Displaying delivered fluid volume, Resetting fluid volume being displayed (Volume Measurement)

Displaying delivered fluid volume

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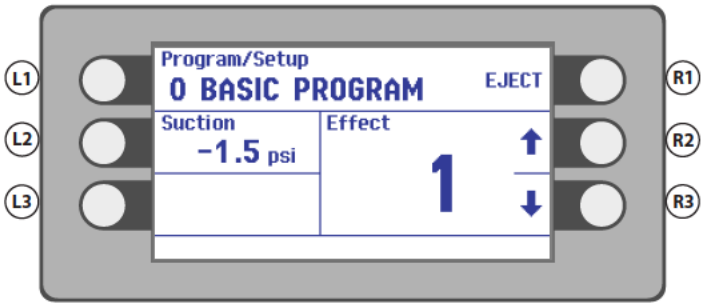

Fig. 3-21

A feature to be informed of the volume of fluid delivered per pump cartridge or as desired with a cartridge can be turned "On". However contact an ERBE representative to have this feature, *Volume Measurement*, activated (Note: It is turned "On" in the Service program of the system which requires an access code to enter the program.).

1. Once this feature is turned "On.", then on the screen displayed select *Program/Setup by pressing display/selection button L1*.

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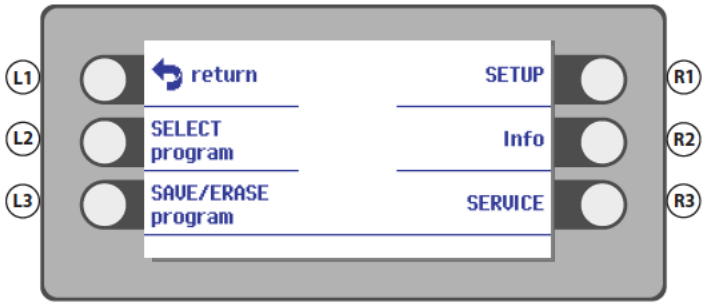

Fig. 3-22

2. On the screen displayed, select Info by pressing display/selection button R2.

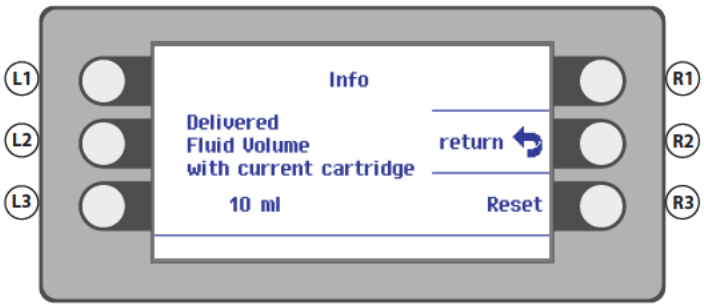

Fig. 3-23

Resetting fluid volume being displayed

When inserting a new pump cartridge, the display of the delivered fluid volume is automatically reset to 0. Also, when using a pump cartridge the fluid volume can be reset to 0 at anytime. This can be accomplished on the screen displayed in Info for *Reset* by pressing display/selection R3 (Note: Enter Info to see the delivered fluid volume).

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Equivalent unit of pressure

Besides psi, the corresponding equivalent Effect setting can be displayed in mbar or kPa. However the possibility of having one of these other unit of pressures shown at the bottom of the display screen, the change will need to be made in the Service program. Please contact an ERBE representative to assist if desired in changing the Effect's correponding value that is displayed for 3 seconds at the bottom of the screen from psi to mbar or kPa.

Accessing and changing parameters in Setup

In Setup, several visual and sound acuities as well as an automatic time can be adjusted/tailored to the needs of your facility. Adjustments can be made to these settings as follows.

1. From a display screen of a program, select *Program/Setup* by pressing display/selection button L1.
2. On the screen displayed, select *SETUP* by pressing display/selection button R1.

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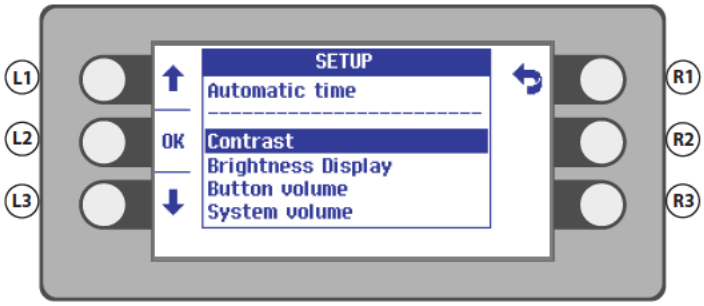

Fig. 3-24

3. Scan and view all setup parameters in the list by using display/selection buttons L1 and L3.
4. When the desired parameter is in the middle of the screen and highlighted at "OK", press display/selection button L2. **Example: Contrast**

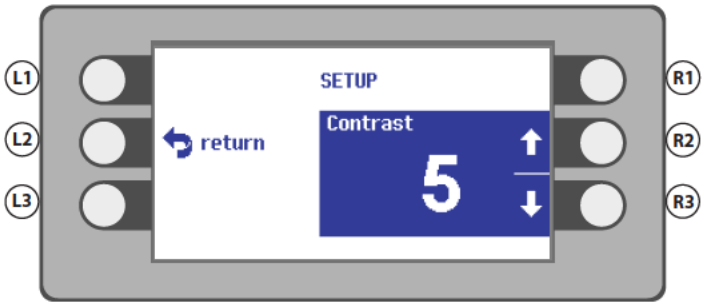

Fig. 3-25

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5. The settings of the parameter can be increased or decreased by pressing the display/selection buttons R2 and R3 respectively. **Example: Contrast 5**.
6. Upon setting the parameter at the desired level, select the return designation by pressing display/selection button L2 to return to the list of the other parameters in Setup.

The following are all the parameters that can be adjusted in Setup with the range of levels.

- **Contrast:** Screen contrast in 10 levels.
- **Brightness Display:** Screen brightness in 10 levels.
- **Button volume:** Sound volume upon depressing a button in 10 levels (1 to 10) or "Off".
- **ml-signal volume:** Sound volume after every ml of normal saline pumped from the system in 10 levels (1 to 10) or "Off".
- **System volume:** Sound volume of alarms/warning signals in 8 levels (3 to 10). The sound must be at a level that is clearly audible!
- **Activation volume:** Sound volume upon/during activation in 10 levels (1 to 10) or "Off"
- **Automatic time**: Time in which the screen displayed will default to the display screen of the selected or highlighted program (if not already displaying the program screen) in times of Off and 3 to 30 sec. (seconds). If "Off" is selected then screens will not default to the selected/highlighted program display screen.

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CHAPTER 4

Status Messages, Error Messages

Status messages in alphabetical order

Status messages are of an informative nature or will prompt you to take operational action.

Status message	Description
Connecting cartridge - Please wait	The unit is in the process of integrating/attaching the new pump cartridge.
ERBEJET has cooled down! / Activation is possible again!	The ERBEJET 2 has overheated and now is cool enough to resume activation.
Please insert new cartridge!	A new pump cartridge needs to be inserted into the unit's pump cartridge slot.
Press button 'START' to prime	Mode to prime the pump cartridge (Note: Complete priming of the applicator's or probe's delivery tubing is still necessary.).
Priming running	The time in which the pump cartridge is priming.
Priming completed.	Completion of priming the pump cartridge.
Priming aborted	Priming of the pump cartridge has been ceased by the operator upon pressing STOP that was on the displayed screen via display/selection button R2.
Ready	Note: Ensure that all of the tubing is connected, primed, etc. prior to activation for clinical use.
Referencing completed	If referencing was needed, then the unit's drives have reached their starting positions.
Referencing running-please wait	Upon powering up the unit (i.e. the ERBEJET 2) and during the selfcheck, the device may need to reset its drives to their starting positions which will cause this message to occur.
Remove used cartridge!	The used pump cartridge needs to be removed from unit's pump cartridge slot.
Suction Module recognized!	The suction module, Model ESM 2 has been connected (via an ECB cable) to the ERBEJET 2 as well as turned "On". It is ready to suction per the programming and/or setting of the ERBEJET 2.
The footswitch has been disconnected	The footswitch has been detached from the unit.
The footswitch is ready for operation	The footswitch has been attached to the unit.
Uncoupling cartridge - Please wait	The unit is in the process of disconnecting/ejecting the used pump cartridge.

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Error messages

An error message consists of an Error Code (EC) and/or a text. The ERBEJET 2 will display two different types of error messages as follows.

a) Error messages that are more related to problems or defects with the unit(s), components, and/or accessories (i.e. device related). They have an Error Code as well as text and can be found in the following table: Error messages in numerical order.

b) Error messages that are more related to the user (but they also include messages relating to the mishandling and/or damaging of the unit(s), components, and/or accessories). They have an error text and can be found in the following table: Error messages in alphabetical order.

Note: In cases where Technical Service is to be contacted, please document/record what happened (i.e. the situation) as well as the displayed Error Code(s) and/or text(s).

Error messages with error codes in numerical order

EC	Error text	Possible cause(s)	Action(s) to be taken
J-5D	ESM 2: Software incompatible!	The suction module, Model ESM 2's software is not compatible with the ERBEJET 2.	Use a suction module, ESM 2 in which its software is compatible with the ERBEJET 2. Contact Technical Service to have the ESM 2 updated with the compatible software, etc.
J-5E	FS: Software incompatible!	The footswitch's software is not compatible with the ERBEJET 2.	Use a footswitch in which its software is compatible with the ERBEJET 2. Contact Technical Service to have the footswitch updated with the compatible software, etc.
J-06	Activation has been interrupted.	A system error has occurred.	Reactivate the ERBEJET 2 (i.e. remove foot from pedal of the footswitch and depress the pedal again). If the error is re-occurring, contact Technical Service.
J-07	Please check the position of the cartridge in the slot.	The pump cartridge has not been properly installed (i.e. put into the cartridge slot of the unit) or can not be engaged into the ERBEJET 2.	Eject the pump cartridge (with the attached applicator or probe) if necessary and try once again to slide it in to the slot of the unit until it is engaged. If unsuccessful, use another pump cartridge with applicator or probe. If the problem is re-occurring contact Technical Service.
J-20	Module conn. to ECB not compatible.	A device has been connected (via an ECB cable) to the ERBEJET 2 that is not compatible.	Detach the non-compatible device from the ERBEJET 2.
J-21	Check date/clock time adjustment.	A discharge of the battery has occurred which may have caused the date and time settings to be lost.	Besides the loss of the date and time settings, no other problems are related. Nonetheless, contact Technical Service.

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EC	Error text	Possible cause(s)	Action(s) to be taken
J-23	Check date/clock time adjustment.	An internal issue has occurred resulting in the date and time settings to be inconsistent.	Besides the inconsistency with the date and time settings, no other problems are related. Nonetheless contact Technical Service.
J-24	Module conn. to ECB not compatible.	A footswitch has been connected to ERBEJET 2 that is not compatible.	Detach the noncompatible footswitch from the ERBEJET 2.

Error messages in alphabetical order

Error text	Possible cause(s)	Action(s) to be taken
Critical temperature reached! / Let ERBEJET cool down!	The units drives have reached a temperature that is too high due to over or continuous activation and/or environmental condition(s) causing heat retention.	If possible and as necessary, let the unit cool down and don't overactivate or activate continuously. Remedy any environmental situation that may be or is causing the unit to heat up.
ERBEJET overheated / Activation not possible!	The units drives have reached a temperature that is too high due to over or continuous activation and/or environmental condition(s) causing heat retention which resulted in the ERBEJET not being operational (i.e. the drives are "Off").	Let ERBEJET 2 cool down until the following message is displayed:"ERBEJET has cooled down! / Activation is possible again!". Don't overactivate or activate the unit continously. Remedy any environmental situation that may be or is causing the unit to overheat.
ERBEJET 2 not ready for operation!	An attempt was made to activate the ERBEJET 2 prior to the drives being set or having a pump cartridge installed.	Wait until the screen displays "Ready" or install (put in) a pump cartridge so that the screen displays "Connecting cartridge - Please wait" then "Ready" before attempting to activate again.
Error: Power failure	There is internal damage.	Contact Technical Service.
Keypad error (Info J-87)	During the power up sequence, a display/selection button(s) was pressed or a button was jammed/is damaged.	Turn "Off" and then turn "On" the unit without pressing a display/selection button. If the erroring is not resolved, contact Technical Service.
Please interrupt activation	The pedal of the footswitch was depressed when activation is not possible (e.g. during the powering up sequence, etc.) or there is internal damage.	Release/Remove foot from pedal until activation is possible. If the issue is not resolved, contact Technical Service.
Program not used	You are trying to delete a program that is not used.	Don't try to delete programs that are not used.
Pulsemode is not available!	On the program display screen, the display/selection button associated for the pulse mode was inadvertently pressed but the software option for the mode has not yet been released or is not a mode installed in the unit.	Press the desired display/selection button.

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Error text	Possible cause(s)	Action(s) to be taken
Pump damaged or reused! / Please press button EJECT.	The tip of the applicator may have become clogged or an attempt was made to engage/ install a used pump cartridge (with applicator). The issue may also be caused by an internal problem (i.e. blocked/damaged slot, etc.).	Select EJECT by pressing display/selection button R1. Remove the pump cartridge with applicator or probe. Insert a new pump cartridge with (new) applicator or probe. If the issue is not resolved, contact Technical Service.
ReMode: Level 'b' is not available!	The ReMode button on the footswitch was depressed, but the selected program doesn't have two levels.	Do not press the ReMode button, select a program with two levels, or create and save a program with two levels.
Suction: Activation interrupted.	The suction module, Model ESM 2 has been disconnected from the ERBEJET 2 (via the ECB cable) or turned "Off". The issue may also be caused by a damaged cable or an internal problem (i.e. communication issue, etc.).	Check and ensure that the ESM 2 is connected via the ECB cable and turned "On" with power (i.e. green LED). If the issue is not resolved, contact Technical Service.
Suction not ready for operation!	The suction module, Model ESM 2 has been disconnected from the ERBEJET 2 (via the ECB cable) or turned "Off". The issue may also be caused by a damaged cable or an internal problem (i.e. communication issue, etc.).	Check and ensure that the ESM 2 is connected via the ECB cable and turned "On" with power (i.e. green LED). If the issue is not resolved, contact Technical Service.
The footswitch is not ready.	Upon the powering up sequence, the footswitch is not connected or the software is not compatible with the ERBEJET 2.	Connect the footswitch or use a footswitch in which its software is compatible with the ERBEJET 2. Contact Technical Service to have the footswitch updated with the compatible software, etc.
You have exceeded the Max. ON time!	The time limit set in the service program for activation has been exceeded.	Reactivate the ERBEJET 2 (i.e. remove foot from pedal of the footswitch and depress the pedal again). As desired, see that the maximum "On" time is turned "Off' or increased.

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CHAPTER 5

Installation

Environmental conditions

⚠ WARNING

Ignition of anesthetics, skin cleansers, and disinfectants in potentially explosive atmospheres

If you place the device in a potentially explosive atmosphere, anesthetics, skin cleansers, and disinfectants can ignite.

Risk of fire and explosion to the patient and medical personnel! Risk of damage to property.

➡ Do not place the device in potentially explosive atmospheres.

NOTICE

Interference with the unit by portable and mobile HF communication devices (e.g. mobile phones, WLAN equipment)

Electromagnetic waves emitted by portable and mobile HF communication devices can effect the unit. The equipment may fail or not perform properly.

➡ Please see the table "Recommended separation distances between portable and mobile HF communications equipment and the equipment" at the end of this User Manual.

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NOTICE

Unsuitable temperature or level of humidity during operation

If you operate the equipment at an unsuitable temperature or level of humidity, it may sustain damage, fail, or not perform properly.

➡ Operate the equipment at a suitable temperature and level of humidity. You will find the tolerances for temperature and humidity in the Technical Data.

➡ If other ambient conditions have to be observed for operation of the equipment, you will also find them in the Technical Data.

NOTICE

Unsuitable temperature or humidity in transit or storage

If you transport or store the equipment at an unsuitable temperature or level of humidity, it may sustain damage and fail.

➡ Transport and store the equipment at a suitable temperature and level of humidity. You will find the tolerances for temperature and humidity in the Technical Data.

➡ If other ambient conditions have to be observed for transport and storage of the equipment, you will also find them in the Technical Data.

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NOTICE

Insufficient acclimatization time, unsuitable temperature during acclimatization

If the device was stored or transported below or above a certain temperature, it will take a certain time and temperature to acclimatize.

If you do not observe the rules, the device can sustain damage and fail.

- Acclimatize the device according to the rules in the Technical Data.

NOTICE

Overheating of the device due to poor ventilation

If ventilation is poor, the device can overheat, sustain damage, and fail.

- Install the device in such a way that there is an unobstructed circulation of air around the housing. Installation in confined wall recesses is prohibited.

NOTICE

Penetration of liquid into the device

The housing is not absolutely watertight. If liquid penetrates, the device can sustain damage and fail.

- Make sure no liquid can penetrate the device.
- Do not place vessels containing liquids on top of the device.
- Take care when connecting the cutting medium to the pump cartridge that the unit does not come into contact with the cutting medium. The same applies when removing the cutting medium.

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⚠ WARNING

Defective/Damaged device and/or accessories, modified device and/or accessories

Risk of injury to the patient and medical personnel! Risk of damage to property.

- Check the unit and accessories (e.g. footswitch, cables, applicators or probe, etc.) for damage every time before use.
- You must not use damaged equipment or damaged accessories. Exchange defective accessories.
- If the unit or accessories are damaged, please contact customer service.
- For your safety and that of the patient: Never attempt to perform repairs or make modifications yourself. Any modification will invalidate liability on the part of ERBE Elektromedizin GmbH.

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Electrical installation

⚠ WARNING

Defective grounded power outlet, power supply network without proper grounding, inferior-quality power cord, incorrect line voltage, multiple power outlets, extension cords

Risk of electric shock and other injuries to the patient and medical personnel! Risk of damage to property.

- Connect the unit / the equipment cart to a properly installed grounded power outlet.
- Only connect the unit to a power supply network with proper grounding.
- Only use the ERBE power cord or an equivalent power cord for this purpose. The power cord must bear the applicable national test symbol.
- Check the power cord for damage. You must not use a damaged power cord.
- The supply voltage must match the voltage specified on the unit's rating plate.
- Do not use multiple power outlets.
- Do not use extension cords.

⚠ WARNING

Incorrect line fuse, defective device

Risk of electric shock to the patient and medical personnel! Risk of damage to property.

- Blown line fuses may only be replaced by a competent technician. Only replacement fuses that have the same rating as the one specified on the unit's rating plate may be used.
- When a fuse has been changed, the function of the unit must be verified. If the unit does not function properly or there are any concerns, please contact ERBE USA.

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⚠ WARNING

Defective/Damaged device and/or accessories, modified device and/or accessories

Risk of injury to the patient and medical personnel! Risk of damage to property.

- Check the unit and accessories (e.g. footswitch, cables, applicators or probe, etc.) for damage every time before use.
- You must not use damaged equipment or damaged accessories. Exchange defective accessories.
- If the unit or accessories are damaged, please contact customer service.
- For your safety and that of the patient: Never attempt to perform repairs or make modifications yourself. Any modification will invalidate liability on the part of ERBE Elektromedizin GmbH.

Note: If necessary, the equipment can be connected to the external grounding system of the room with the grounding pin on the back of the unit and/or Cart using a connecting cable designed for this purpose. Affects of low frequency leakage cur-

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rents due to a defective grounding system within the room may be eliminated through external grounding

Installing the ERBEJET 2

The ERBEJET 2 and components (including the suction module, Model ESM 2) should be installed on an ERBE VIO Cart or boom mounted. See the respective user manual, installation sheet/instructions, and notes on uses for mounting, securing, as well as connecting the unit and components. In general ensure that:

- The surface is stable and free of vibration,
- the system is not in direct sunlight (so that heating is not a problem and the display screen is readable),
- and the unit(s) are connected to a properly installed grounded outlet(s). Only use an ERBE power cord or an equivalent power cord for this purpose. The power cord must bear the national test symbol.

In general, the power cord is plugged into the receptacle for power that is on the back of the ERBEJET 2 and an approriate power source. The cable of the footswitch is attached to the footswitch socket on the back of the unit. The ERBEJET 2 is grounded via a grounding cable connected to the grounding terminal on the back of the unit and approriately grounded. As applicable, the ERBEJET 2 is connected to the suction module, ESM 2 via an ECB cable.

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CHAPTER 6

Disassembly, Cleaning and Disinfection

Detaching the normal saline as well as pump cartridge with applicator or probe from the ERBEJET 2

⚠ WARNING

Contaminated accessories

Risk of infection for the medical staff.

➡ Wear personal protective equipment (e.g. gown, faceshield or eye protection, mask, gloves, etc.) to minimize the risk of exposure to infectious agents while handling, disconnecting, and disposing of used accessories.

Detaching the normal saline

Disconnect the tubing from the normal saline from the pump cartridge. Properly dispose of the used tubing set and bag of normal saline.

Disconnecting as applicable the applicator's suction hose from the suction device

As applicable disconnect the applicator's suction hose from the suction device. If the suction module, ESM 2 (with its associated components and accessories) was used follow the disassembly instructions in the ESM 2 User Manual.

Detaching the pump cartridge with applicator or probe

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On the display screen of a program, select *EJECT* by pressing display/selection button R1. Upon uncoupling and prompting the removal of the used cartridge, remove the pump cartridge with applicator or probe. Properly dispose of the used pump cartridge and applicator.

Wipe disinfection

For cleaning and disinfecting the surfaces of the unit or of the equipment cart, ERBE recommends a wipe disinfection. Use only disinfectant which complies with the relevant national standards.

⚠ WARNING

Connection of unit / equipment cart and power supply during cleaning and disinfection

Risk of electric shock to the medical personnel!

➡ Switch off the device. Unplug the power cord of the device/ equipment cart.

NOTICE

Penetration of liquid into the device

The housing is not absolutely watertight. If liquid penetrates, the device can sustain damage and fail.

➡ Make sure no liquid can penetrate the device.

➡ Do not place vessels containing liquids on top of the device.

➡ Take care when connecting the cutting medium to the pump cartridge that the unit does not come into contact with the cut-

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ting medium. The same applies when removing the cutting medium.

NOTICE

Alcohol-based spray disinfectant for fast disinfection

With membrane keyboards and paint surfaces there is the risk of cracks. Propanol and ethanol will erode surfaces.

➡ Do not use these substances.

NOTICE

Alternate use of disinfectant solutions based on different active ingredients

A color reaction may occur with plastics.

➡ Do not use these substances alternately.

Instructions for cleaning and disinfection

Mix the disinfectant in the concentration specified by the manufacturer.

Clean surfaces contaminated with blood before using the disinfectant, otherwise it may be less effective.

Wipe the surfaces. Make sure the surfaces are treated uniformly. Comply with the action time of the disinfectant specified by the manufacturer.

Note: As applicable, to clean/disinfect the suction module, ESM 2 and associated components follow the instructions in its User Manual.

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CHAPTER 7

Technical Data

Power connection	
Rated supply voltage	100 – 240 V
Line current	0.4 – 1.2 A
Rated supply frequency	50 Hz / 60 Hz
Power fuses	2 x T 3.15 A H / 250 V

Data specific to the unit	
Effect / Pressure range in bar / in psi	1 – 80 (± 20 %) / 14.5 – 1160.3 (± 20 %)
Volume flow in ml/min.	1 – 55 (± 10 %)
Program storage capability	Up to 9 programs
Activation	Footswitch
Pump cartridge	Sterile single-use double cylinder pressure generating cartridge
Applicators or probe	Sterile single-use applicators or probe, rigid and flexible varying in size
Nozzle/ Jet diameter	120 µm
Cutting medium	Sterile, normal saline
Suction module, ESM 2 (separate compatible unit)	Adjustable -100 to -800 mbar (± 50 mbar) Adjustable -1.45 to -11.60 psi (± 0.73 psi)

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Dimensions and weight	
Width x height x depth	410 x 130 x 370 mm / 16.1" x 5.1" x 14.6"
Weight	11 kg / 24 lbs. 4 oz.

Ambient conditions for transport and storage of unit	
Temperature	-25 °C to +50 °C / -13 °F to +122 °F
Relative humidity	15 % – 80 %

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Ambient conditions for operation of the unit	
Temperature	+10 °C to +40 °C / +50 °F to +104 °F
Relative humidity	15% – 80%, noncondensing

Acclimatizing
If the unit has been stored or transported at temperatures below +10 °C / +50 °F or above +40 °C / +104 °F, the unit will require approx. 3 hours to acclimatize at room temperature.

Standards	
Classification according to EC Directive 93/42/EEC	II b
Protection class as per EN 60 601-1	I
Type as per EN 60 601-1	CF

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CHAPTER 8

Information on ElectroMagnetic Compatibility (EMC)

Where EMC is concerned, medical electrical equipment is subject to special safety measures and must be installed and commissioned according to the EMC instructions stated herein.

NOTICE

Use of non-approved internal cables by Technical Service

This can result in the increased emission of electromagnetic waves or reduce the immunity of the device. The equipment may fail or not perform properly.

➡ Technical Service may only use the internal cables that are listed in the service manual for the device.

NOTICE

Stacked devices

If you stack the device next to other equipment or with other equipment, the devices can affect each other.

The unit may fail or not perform properly.

➡ The device may only be stacked next to or with VIO series units.

➡ If it is necessary to operate the device near other equipment or stacked together with other equipment, check whether the devices are affecting each other: Are the devices behaving unusually? Do errors occur?

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Guidance and manufacturer's declaration - electromagnetic emissions

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

Emissions test	Compliance	Electromagnetic environment - guidance
HF emissions CISPR 11	Group 1	The equipment or system uses HF energy only for its internal function. Therefore its HF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
HF emissions CISPR 11	Class A	The unit is suited for use in environments other than domestic areas and in ones directly connected to a public power supply system that also supplies buildings being used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

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Guidance and manufacturer's declaration - electromagnetic immunity

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

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Discharge of static electricity /ESD) to IEC 61000-4-2	±6 kV contact discharge ±8 kV air discharge	±6 kV contact discharge[a)] ±8 kV air discharge[a)] a) Repeated occurrence can trigger a restart of the unit in rare cases.	The floor should be of wood or concrete or be tiled with ceramic tiles. If the floor is provided with non-conductive synthetic material, the relative humidity must be at least 30%.
Electrical fast transient/ burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the equipment requires continued operation during power mains interruptions, it is recommended that the equipment be powered from an uninterruptible power supply or a battery.
Power frequency (50/ 60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note: U_T is the a.c. mains voltage prior to application of the test level.

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Guidance and manufacturer's declaration - electromagnetic immunity

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

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile HF communications equipment should be used no closer to any part of the equipment, including cables, than the recommended separation distance. The separation distance is calculated from various equations depending on the frequency of the portable and mobile HF communications equipment:
			Recommended separation distance
Conducted HF IEC 61000-4-6	3 V_{rms} 150 kHz to 80 MHz	3 V_{rms}	Equation 1) $d=1.2\ P^{1/2}$
Radiated HF IEC 61000-4-3	3 V/m 80 MHz to 800 MHz	3 V/m	Equation 2) $d=1.2\ P^{1/2}$
	3 V/m 800 MHz to 2.5 GHz	3 V/m	Equation 3) $d=2.3\ P^{1/2}$
			P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. *d* is the recommended separation distance in meters (m). Field strengths from fixed transmitters, as determined by an electromagnetic site survey[a)] should be less than the compliance level in each frequency range[b)]. Interference may occur in the vicinity of equipment marked with the following symbol:

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Guidance and manufacturer's declaration - electromagnetic immunity

Note 1: At 80 MHz equation 2) applies. At 800 MHz equation 3) 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 HF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the equipment is used exceeds the applicable compliance level above, the equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the equipment.

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

Recommended separation distances between portable and mobile HF communications equipment and the equipment

The equipment is intended for use in an electromagnetic environment in which radiated HF disturbances are controlled. The customer or the user of the equipment can help prevent electromagnetic interference. This can be achieved by maintaining the minimum distance recommended below between the communications equipment (transmitters) and the equipment. The minimum distance depends on the maximum output power and the frequency of the communications equipment.

)Rated maximum output power of transmitter (W)	)Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d=1.2\ P^{1/2}$	**80 kHz to 800 MHz** $d=1.2\ P^{1/2}$	**800 MHz to 2.5 GHz** $d=2.3\ P^{1/2}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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

Note 1: An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the frequency bands between 80 MHz and 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

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

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CHAPTER 9

Maintenance, Customer Service, Warranty, Disposal

Maintenance

Authorized persons

Modifications and repairs may only be undertaken by ERBE or by persons expressly authorized by ERBE. ERBE accepts no liability if modifications and repairs to the unit or accessories are made by unauthorized persons. This will also invalidate the warranty.

Safety checks

The unit should have a technical safety/operational inspection at least once a year.

Modifications and repairs

Modifications and repairs are to be completed by ERBE or by persons expressly authorized by ERBE.

What safety checks must be performed?

For this device the following safety checks have been stipulated:

- Checking of labels and User Manual
- Visual inspection of unit and accessories for damage
- Testing the grounded conductor in accordance with EN 60601-1 (UL-60601-1) Section 18
- Testing the leakage current in accordance with EN 60601-1 (UL-60601-1) Section 19
- Functional testing of all the unit's operating and control elements
- Testing the monitoring equipment
- Testing of mechanical pressure production

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The results of the safety checks have to be documented.

If during the safety checks any defects are found which might endanger patients, staff or third parties, the device may no longer be operated until the defects have been remedied by competent service technicians.

Customer Service

If you are interested in a service contract, please contact ERBE.

Servicing

Procure service work as follows:

1. Contact the Technical Service Department at ERBE USA, Inc. for a Service Call or to obtain a Return Authorization Number. This Number must appear on all correspondences.

   Telephone:
   770-955-4400 or 1-800-778-3723
   E-Mail: technicalservice@erbe-usa.com
   FAX: 770-955-2577

2. Address:
   ERBE USA, Inc.
   2225 Northwest Parkway
   Marietta, GA 30067

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3. If the product is being returned to ERBE USA, Inc.; the shipment must be insured as well as safely and securely packed. Preferably it should be packaged in its original shipping carton with a letter explaining the problem and making reference to the Return Authorization Number. All transportation and insurance charges and risk of loss are the responsibility of the customer and must be prepaid. A purchase order must be issued to ERBE USA, Inc. to cover all transportation and insurance charges for the return shipment after service.

Authorization from the ERBE USA, Inc. Customer or Technical Service Departments must be obtained prior to the return of equipment and/or accessory(ies) for servicing. To obtain an appropriate Return Authorization Number (R.A. #), please be prepared to give the following information when contacting ERBE:

1. The customer name.
2. The name and telephone number of the contact person.The catalog number, or model number, and serial number of the involved equipment and/or accessory(ies).The REASON or problem.

The R.A. #, and the name and telephone number of the contact person at your location MUST be clearly indicated on the packing list you send with the equipment and/or accessory(ies).

The user must decontaminate any item being returned that possesses a risk of transmitting disease.

ERBE USA, Inc. reserves the right to refuse and/or return, transportation charges collect, any return item(s) that does not have an appropriate R.A. # as issued by the Customer or Technical Service Department. All shipments must be insured, and safely and securely packed, preferably in the original shipping carton. All transportation and insurance charges and risk of loss are the responsibility of the customer and must be prepaid.

Additional Information needed?

Please contact ERBE with any concerns regarding the equipment or this Manual. Also, as requested and available, copies of scientific publications will be provided.

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Warranty

ERBE warrants the material and workmanship of the ERBEJET 2 for a period of 1 year from the delivery date with the accessories (e.g., cables/cords, footswitch(es), etc.) having a 90 day warranty from the delivery date.

At installation, the equipment should be inspected for transportation damage and any other deficiency. A report should be prepared with the information being brought to ERBE's attention.If this product should become inoperable due to a defect in material or workmanship during the warranty period, ERBE will at its option repair or replace the product. This action will be performed by ERBE authorized personnel. This limited warranty does not include replacement or service to repair damage from improper installation, external electrical fault, accident, disaster, use for a purpose other than that for which originally designed or indicated in this Manual, negligence, modification, unauthorized service by non ERBE personnel, or normal wear.The sole and exclusive remedy under this warranty shall be repair or replacement. In no event will ERBE be liable for any damages arising out of the loss of use, or any other incidental or consequential damages.No person, agent, distributor, dealer, or company is authorized to change or modify the terms of this warranty.

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Disposal

Your product bears a crossed-out garbage can icon (see image). Meaning: In all EU countries this product must be disposed of separately in accordance with the national laws implementing EU Directive 2002/96/EC of January 27, 2003, WEEE.

In non-EU countries the local regulations must be observed.

If you have any questions about disposal of the product, please contact your ERBE branch or your local distributor.

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CHAPTER 10

Combination with other Equipment, Third Party Accessories

The ERBEJET 2 has a compatible but separate suction module, ESM 2. The ESM 2 is connected to the ERBEJET 2 by an ECB cable. The ERBEJET 2 will incorporate the features and functions of the suction module (i.e. features and parameters of the ESM 2 can be accessed and set through the display screen of the ERBEJET 2).

The suction hose of an ERBEJET 2 applicator with suction can be connected to other suction devices. However, the suction (vacuum) pressure should not exceed -11.6 psi (-800 mbar). Also, the other suction device cannot be integrated (i.e., attached by an ECB cable) with the ERBEJET 2.

Do not use pump cartridges and applicators from other manufacturers with the ERBEJET 2.

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HybridAPC Probe Labels and Labeling

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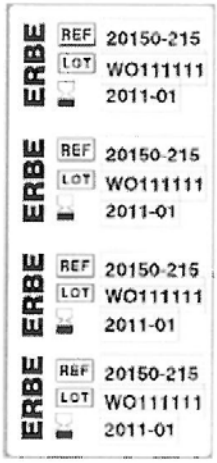
Outer Packaging Pouch Label



Patient Chart Label
[Note: Example of the Four (4) Peel-off Chart Labels that are on the Pouch Label]

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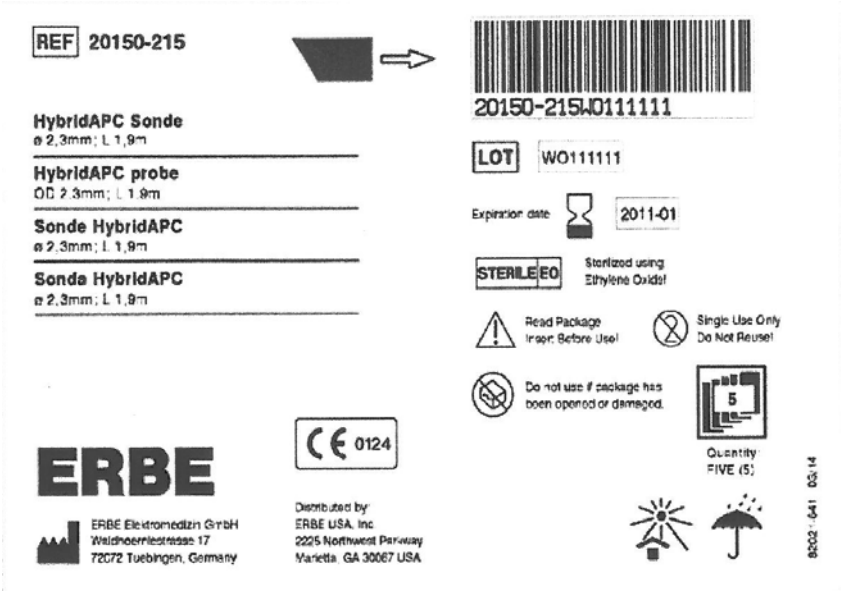

Outer Packaging Box Label

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Notes on use

usa

HybridAPC probe

20150-215

Single use only! Sterility not guaranteed if package has been opened or damaged. Discard if package is damaged.

STERILE EO

ERBE

Notes On Use, Cover

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IMPORTANT!

Please read all information carefully.

These notes on use do not replace the User Manuals of the Water Jet System, Argon Plasma Coagulator and ElectroSurgical Unit (ESU) used! Read the User Manuals of the units and ask ERBE or your distributor in case of doubt!

Caution! Federal law (USA) restricts this device to sale by or on the order of a physician!

1 Intended Use

The HybridAPC probe is indicated for the induction of sterile normal saline into the submucosa to lift mucosal lesions using direct visualization through an endoscope and for HF ablation of the mucosal lesion by Argon Plasma Coagulation (APC).

This device should not be used for uncooperative patients.

2 Normal Use

The HybridAPC probe is to be used with the following ERBE units and accessories:

- Water Jet System Model ERBEJET 2 with accessories.
- Argon Plasma Coagulator Model APC 2 in conjunction with a compatible ESU VIO Model.

Connection to a standard APC receptacle requires the use of adapter 20132-228.

The product is intended for single use.

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3 Maximum Electrical Capacity

The maximum electrical capacity of this product is:

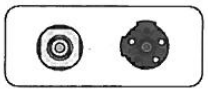
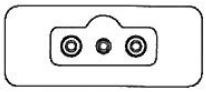
- 4300 V_p

4 Operating Materials and Accessories

To use the product you require the following items:

- Pump cartridge (Art. No. 20150-300)
- Cutting medium: to select the suitable cutting medium please read the Notes on use for the pump cartridge
- possibly commercial dye

Note! The ERBE Argon Plasma Coagulator may have a receptacle which requires an Adapter to connect the product to it. See the following descriptions of receptacles and if the associated Adapter is needed.

Receptacle type	Accessory for connecting up the probe
APC standard receptacle 	Adapter Art.-No. 20132-228
FiAPC receptacle 	No further accessories required.

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5 Safety Instructions

WARNING!

5.1 Sterile product for single use

ERBE recommends that the product not be reprocessed after use. Reprocessing can affect material properties and/or product function making its Normal Use no longer possible. Concerns involve:

- Components/connections that are damaged by high temperatures (e.g. in the autoclave).
- Components (e.g. filter, extremely small lumen, etc.) that may prevent internal cleaning/disinfection.

5.2 User requirements

This product may only be used by medical personnel who have been trained per these instructions.

Do not use the product if you are unfamiliar with its operation in conjunction with the ESU and the Argon Plasma Coagulator.

5.3 General information about protection of the user, patient, and product

Do not use in the presence of combustible or explosive materials!

Never lay this product on the patient or in his/her direct vicinity.

Protect this product from any form of mechanical damage! Do not throw! Do not use force! If there is a cable, and unless stated otherwise, do not kink it or wrap it around the accompanying product!

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Do not kink the tube or wrap it round the product to which it belongs!

If damaged, do not use this product!

5.4 Danger of mechanical perforation

Do not puncture the mucosa with the probe's tip.

5.5 Danger of fires in the gastrointestinal tract

Before using Argon Plasma Coagulation (APC), always ensure that no endogenous gases are present in the lumen of the relevant organ.

5.6 Danger of fire in the tracheobronchial system

The high temperatures of argon plasma can cause flammable materials to ignite. Please refer to therapeutic guidelines for O_2 saturation when actively ventilating patients during use of thermal energy sources (i.e. laser or electrosurgical units). For this reason, please always observe the following rules:

- Avoid APC activating during active oxygen (O_2) ventilation. Follow hospital policy and procedure when using thermal energy sources, such as APC, in the airway.
- O_2 use and APC activation should alternate, thus lowering the O_2 concentration.

Please also observe the ERBE brochure concerning use of the APC in the tracheobronchial system.

5.7 Gas embolisms, gas emphysema

To prevent gas embolisms, the argon flow rate must not be set high enough that argon is blown into open vessels. To prevent gas embolisms or emphysema, never point the distal end of

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APC probes directly towards open vessels or press against tissue.

5.8 Danger of unintentional damage to nerve structures

Bear in mind that during an APC application in the direct vicinity of nerve structures, stimulation may be induced by electric currents.

In the case of nerves which require protection it is advisable to keep the APC activation time short and adapt minimum power output to the required indication.

5.9 Protection against HF leakage current at the eyepiece

HF leakage current at the eyepiece of the endoscope can cause the user thermal damage. To avoid this please only use endoscopes that are designed for use with electrosurgical accessories.

5.10 Risk of burns to the patient

Flash-overs, activation in the working channel of the endoscope or without visual control of the distal end of the probe can cause unwanted thermal injuries to the patient. Therefore, check that the distal end of the probe (1) protrudes at least 10 mm out of the endoscope before each activation. This is ensured when the first black ring (2) on the distal end of the probe is visible through the endoscope.

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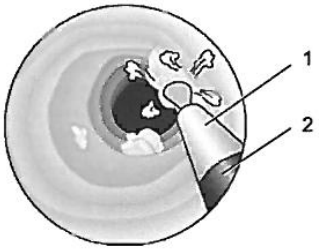

Fig. 1: View of the markings through the endoscope.

5.11 Danger of burns

Argon plasma can strongly heat electrically conductive materials, e.g. metal. To avoid burns, never direct argon plasma towards electrically conductive materials.

Risk of burns. The cutting medium can act as an electric conductor when activating the HF voltage. Make sure that cutting medium from leading parts (e.g. tubes, bags, etc.) does not touch patients or personnel during HF activation.

5.12 Modification of the product by the user

ERBE Elektromedizin expressly warns against modifying the instrument, e.g. cutting off the probe tip. Any modification will exempt ERBE Elektromedizin from all liability.

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6 Recommended Unit Settings

This chapter describes unit settings that may be used to operate the product without causing damage.

When operating this product, you must observe the setting limits specified in these instructions. Adapt the power to the planned procedure. Begin with the lowest possible power setting and increase gradually as required.

6.1 Permitted settings on the ERBEJET 2

Rinsing with to high of a pressure can lead to tissue damage. Therefore always select for rinsing the lowest possible effect on the ERBEJET 2.

Effect levels 1 – 80 may be used. However too high of a pressure can lead to tissue damage. Therefore use the lowest possible settings to achieve the desired surgical outcome.

6.2 Permitted settings on the ERBE VIO

Forced APC, Precise APC, and Pulsed APC modes:

- Effect: Effect with an HF peak voltage (U HF) $\leq 4{,}300\ V_p$ [1)]
- Power: maximum 80 watts
- Gas flow: maximum 2.4 l/minute

Settings that are too high can lead to unwanted tissue damage. Theredore use the lowes possible settings to achieve the desired surgical outcome.

1.) The HF peak voltage of an effect depends on the mode selected and the power setting (Watt) used. More information about selecting an appropriate effect is available in the User Manual for the VIO HF electrosurgical unit.

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7 Information on electromagnetic compatibility (EMC) of the units

Notwithstanding the specifications in the ERBEJET 2 and VIO User Manuals, HF emissions are classified as Class A[2)] according to CISPR 11 for common use of the product with the units. All other EMC specifications in the User Manuals for the recpective units apply for their common uses.

8 How to Use

8.1 Sterile product for single use

ERBE recommends that the product not be reprocessed after use. Reprocessing can affect material properties and/or product function making its Normal Use no longer possible. Concerns involve:

- Components/connections that are damaged by high temperatures (e.g. in the autoclave).
- Components (e.g. filter, extremely small lumen, etc.) that may prevent internal cleaning/disinfection.

8.2 Check the expiration date

An expiration date is printed on the packaging of the product. Do not use any product beyond its expiration date!

2.) The system is suited for use in environments other than domestic areas and in ones directly connected to a public power supply system that also supplies buildings being used for domestic purposes. The customer or the user of the system should ensure that it is used in such an environment.

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8.3 Control and open packaging

Use this product only if the packaging has not been opened or damaged. If the packaging is open or damaged, the product is no longer sterile and must not be used. In this case, throw the product away!

Use aseptic techniques when removing the product from the packaging!

8.4 Check the product

Before use, check that the product including all the insulation is intact. Verify that there are no signs of physical damage.

If damaged, do not use this product!

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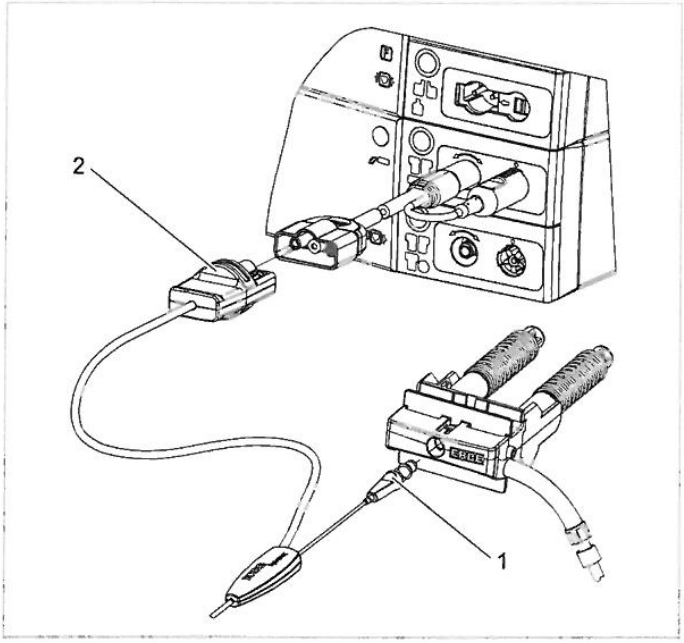
8.5 Connecting the product to the ERBEJET 2 + APC 2 with the APC standard receptacle

IMPORTANT! The adapter, Art. No. 20132-228, must be plugged to the APC standard receptacle!



1. Establish the water jet connection: On the sterile field, plug the extension tubing connector (1) into a pump cartidge by snapping it into place until it clicks. The attached pump cartridge is then inserted into the Water Jet System ERBEJET 2. Follow the instructions in the ERBEJET 2 User Manual to prime, etc.
2. Establish APC connection: Plug the FiAPC plug (2) into adapter 20132-228. The operating parameters of the adapter (not of the probe) are automatically set on the VIO electrosurgical unit.

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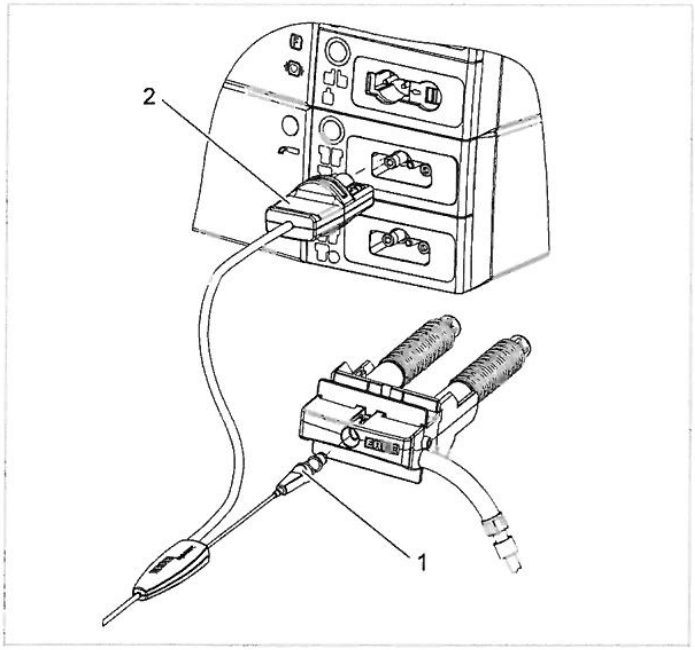
3. See chapter "Recommended Unit Settings" and adjusted settings of the Water Jet System and VIO to achieve the desired surgical outcome.

8.6 Connecting the product to the ERBEJET 2 + APC 2 with the FiAPC receptacle



1. Establish the water jet connection: On the sterile field, plug the extension tubing connector (1) into a pump cartidge by snapping it into place until it clicks. The attached pump cartridge is then inserted into the Water Jet System ERBEJET 2. Follow the instructions in the ERBEJET 2 User Manual to prime, etc.

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2. Establish APC connection: Plug the FiAPC plug (1) into a FiAPC receptacle. The probe will be detected by the VIO electrosurgical unit.
3. See chapter "Recommended Unit Settings" and adjusted settings of the Water Jet System and VIO to achieve the desired surgical outcome.

8.7 Endoscope selection

HF leakage current at the eyepiece of the endoscope can cause the user thermal damage. To avoid this please only use endoscopes that are designed for use with electrosurgical accessories.

The endoscope's working channel must have a diameter larger than 2.5 mm.

8.8 Using the product

The water jet and APC are **alternately** activated via different footswitches.

The water jet is activated via the ERBEJET 2 footswitch, the APC via the COAG pedal of the VIO footswitch.

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ERBE WaterJet Model ERBEJET® 2 System with HybridAPC Probe Claims/Marketing Statements

ERBEJET® 2 System (Note: No new statements added/same as in initial submission).

General Advantages

- Simple, intuitive and easy to use System.
- Compatible with existing ERBE equipment into a stacked workstation.
- No thermal trauma.
- Extremely uniform water jet; delicate, precise and reproducible effects.
- Integrated suction with individually adjustable run-on time.
- Ergonomically designed single-use instruments.
- Footswitch with "ReMode" function allows Physicians to independently switch between programs by using the toggle button control on the Footswitch.
- Programs can be individually stored.
- Simple operation via the display screen:
  - The ERBEJET 2 Unit has an easy-to-operate user interface. The parameters can be adjusted according to an individual indication and saved in 9 different program settings.
  - The impact of the water jet [Effect (that correlates to psi)] can be adjusted to create reproducible dissection results. The Effect can even be altered during activation.
  - The interface of the ERBEJET 2 Unit is also used to enter the settings of the Suction Module, Model ESM 2.
- Upon activation, the ERBEJET 2 System delivers a continuous stream of cutting medium to the operative site.
- The cutting medium is any "available" Sterile 0.9% Normal Saline for Irrigation. It is connected using a standard administration set.
- The Suction Module, Model ESM 2 is a separate and optional accessory but integrated with the ERBEJET 2 Unit and has the following features:

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- The type and degree of suction of the ESM 2 Unit is adjusted via the interface of the ERBEJET 2 Unit. Activation is switched "On" (continuous or pedal activated) as selected using the Footswitch.
- The suction may be programmed to continue running for a certain time after the water jet is no longer activated (i.e. a run-on time setting). This ensures good visibility at the operative site even after the water jet has been stopped.

Statements for/from Clinical Applications

- All previously approved statements from ERBE USA Helix Hydro Jet 510(k)'s.

Hepatic/Liver Surgery:

- During resection of the liver, the blood vessels and the bile ducts are prepared and washed free of surrounding tissue. Depending on their size, they can then be either coagulated or selectively treated using a ligature/clip/stapler.
- The time required for the intervention is shorter than that of comparable surgical interventions and is reduced even more by the simultaneous use of electrosurgery.
- The inter-operative blood loss is also reduced and thus the transfusion requirements are also lower. Depending upon the physician's technique, a cross – clamping of the blood supply to the organ (i.e. the Pringle Maneuver) may not be necessary when using the System.
- Additional Advantages in Hepatic Surgery-
  - Application possible in both laparoscopic and open surgery.
  - Precise dissection planes free of disruption, thermal artifact, and/or cavitations relative to other energy devices.
- The following statements are from the Referenced Clinical Publications.
  - "Water jet dissection enables us to separate organ structures[1]
    - This anatomically suitable tissue penetration allows for different physical characteristics, for example, structure, firmness and elasticity of the organs…

1 Lammers B, Lukas Hospital in Neuss, Germany European Hospital Journal (www.european-hospital.com/topics/article/454.html 8/9/07)

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* In the beginning we hoped to use this method for the clean, blood-conserving preparation of malignant tumors, particularly in resections of the liver, kidney and rectal tumors. Over the years, the method has fulfilled all our expectations - and more…

* The incredible precision in the removal of malignant cells and preservation of healthy tissue achieved with the water jet has astonished us…

* The fact that out of a total of 100 operations the blood supply to the liver had to be stopped during only one of those operations is further proof of how precise the method is. In all other cases, the liver's arterial supply was maintained throughout the whole surgical procedure…

* We also have been able to significantly lower the amount of blood loss occurring during surgery. On average, patients lost around 350 ml, and around 80% of our tumor patients did not need any blood transfusions or plasma. This presents an enormous relief for the patients' organs…

* We have also found that, in general, patients recover from this type of surgery much faster. In addition, there is definitely a lower rate of infectious complications. Problems with liver function or liver failure hardly ever occur. A further positive effect has been seen in surgery on rectal carcinoma. As the nerves are protected during this type of surgery, 97% of patients who underwent resection of the rectum with total excision did not require a catheter. Before the introduction of water jet dissection around 50% of patients left the hospital with a catheter! We can say with confidence that due to water jet dissection the healing process is faster and patients are mobilized quicker. Apart from the obvious health benefits to the patients, there is also a cost-saving element as patients' hospital stays are reduced…

* Water jet surgery has become established in many surgical disciplines and offers not only extremely selective dissection but many other advantages. In addition to low intra-operative blood loss, operating times are reduced, particularly in general, visceral and orthopedic surgery."

o "Optimal dissection is achieved at a pressure setting of 550 - 650 pounds per square inch (psi) for a liver with normal consistency, but varies with cirrhotic and fibrotic livers requiring greater pressure (> 700 psi) and steatotic livers needing less.[2]

* The tip of the hand-held applicator is kept 1-2 mm away from the tissue in a "no-touch" fashion…

2 Vollmer CM et al. Water-jet Dissection for Parenchymal Division During Hepatectomy. Presented at AHPBA, Miami, FL 2003

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* Fluid buildup, consisting of saline and blood as well as disintegrated parenchymal tissue, is scavenged throughout the dissection by the suction element that is integrated with the applicator tip…

o "Blood loss generally consists of minor slow oozing from the side-walls, not brisk vascular hemorrhage, and is easily controlled with the cautery. It is at this point that the fine, trabecular infrastructure of the parenchyma becomes apparent, and is either cauterized or ligated with clips depending upon caliber of the elements…

* Large, intrahepatic vascular structures such as the middle hepatic vein and its segmental branches are easily and safely identified with the Water-jet. These are further exposed by circumferentially 'cleaning' the surrounding parenchymal tissue for distances that allow safe, controlled application of occlusive ligatures or the Endo-GIA stapler. A 'drilling' motion, where the jet stream is applied in a constant position over and under the edges of these structures, avoiding the center of the vessel itself, has proven to be extremely effective in their identification. This technique is also useful in precisely defining the hilar plate that invests the bile duct elements prior to transection…

* There was a significant improvement in patients requiring blood transfusion in favor of the Water-jet (13% vs 27%; p=0.031), as well as those who required more than two units of blood when transfused. Complications were less frequent in the Water-jet group (39% vs 53%; p=0.07), and mortality rates were 1% for Water-jet vs 6.4% for CUSA. Length of stay was significantly lower for the Water-jet group (8.4 days vs 10.7 days; p=0.03). These overall positive findings in favor of the Water-jet were further accentuated when comparing the cohort of Major Resections between the two techniques (data not shown)…

* (Dissected) … Multiple consistencies of hepatic parenchyma, including cirrhotic and fatty tissue, were also tested, as were various indications for resection (benign, malignant and infectious). Nonselective inflow occlusion was rarely necessary. The exceptional quality of performance by the Water-jet was enough to convince our group to abandon use of the previously favored CUSA…

* The Water-jet technique is relatively simple and easy to learn, for both the surgeons and the operative nursing staff. It has a short learning curve (fewer than 10 cases) as the surgeon becomes familiar with the technique. This fact, combined with the perceived superior precision attained, quickly made this the preferred application of each of the five surgeons in the study...

* Dissection of large venous structures, or the biliary plate, is usually complete enough to allow for even endovascular stapler ligation. Occlusion or ligation with suture material is rarely required…

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* The Water-jet, as a no-touch technique, is less traumatic to the vascular structures than the directly applied ultrasonic aspirator tip. The application is atraumatic, so that dissection without direct visualization can be safely adopted. The jet power can be adjusted in accordance with the consistency of the parenchyma. For normal tissue, we employ settings between 500 - 650 psi. We have found that dissection of cirrhotic or fibrotic tissue is more efficient at levels of 700 - 800 psi, and that less pressure is required for steatotic livers that disintegrate with less force…

* Furthermore, since these cases (i.e. Living Donor) are performed with no inflow or outflow occlusion at all, they allow for analysis of the technique under the most demanding conditions for hemostatic control. Interestingly, despite these obstacles, in this scenario there was markedly better control with 225 cc's less median blood loss than observed in the other Major resections…

* Cirrhotic livers with gross fibrosis pose the most difficult conditions for hepatic transection to the surgeon. There has been skepticism about the ability of the Water-jet to transect these livers with equivalent proficiency. We feel that the Water-jet performs in a superior manner to other techniques - particularly since the amount of force applied can be varied in real time to the conditions encountered (i.e. elevating the psi). Our data supports this subjective impression and indicates that there is markedly less median blood loss in these challenging livers (600 vs. 900 mL)…

* Rau et al. found the Water-jet to be significantly faster than the CUSA with less required Pringle occlusion and fewer transfusions…

* We are under the subjective opinion that the Water-jet is more efficient in terms of speed of transection."

o "The jet-cutting technique proved to be faster than the CUSA in conventional liver surgery, and blood loss was reduced in patients operated on with the Jet-Cutter. These advantages are also valid for laparoscopic surgery with a more selective dissection of the liver parenchyma by the Jet-Cutter.[3]

* Blood loss did not differ significantly between the two groups with a mean of 457 + 343.7 ml in laparoscopic and 555.9 + 385.8 ml in conventionally operated patients."

<u>Urology:</u>

3 Rau HG et al. Laparoscopic Liver Resection Compared with Conventional Partial Hepatectomy - A Prospective Analysis. Hepato-Gastroenterology 1998;45:2333-2338

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- The selectivity of the water jet reduces the risk of sexual dysfunction and/or urinary incontinence in prostatectomy procedures. Blood vessels and NeuroVascular Bundles (NVB) remain largely intact during hydrodissection of the NVB away from the prostate.
- As with hepatic surgery, when the water jet is used to carry out partial nephrectomy, this does not lead to necrosis of the resection margins. This helps retain as much of the organ's functionality as possible during these nephron sparing procedures.
- The renal blood vessels, ductal structures and collecting systems are selectively dissected and can subsequently be treated individually.
    - Additional Advantages in Urology-
    - o Minimized blood loss, less transfusion requirements
    - o Distinctly shorter operating times
    - o Lower rate of complications
    - The following statements are from the Referenced Clinical Publications or News Articles Quotes.
    - o "It also allows him to use a nerve-sparing technique called hydro-dissection, using a tool that looks much like a water pick to separate surrounding tissue and muscle fiber from the prostate gland and the tumor growing on it. Parekattil said his results to date using hydro-dissection suggest that the technique means less chance of incontinence and impotence following surgery."[4]
    - o "The potential for better nerve preservation"[5]
    - o "Hemostatic Hydro dissection of the Neurovascular Bundles (HYNEB) during LRP and RALP may promote the early return of continence and erectile function."[6]
    - o "Our survival study supports the feasibility of Hydrojet-assisted LPN without hilar vessel control, thus completely avoiding warm ischemia. This approach has the potential to decrease the level of technical difficulty inherent in LPN.[7]
        - * The water jet produced a corridor in the desired dissection line without interfering with the intrarenal vessels and pelvicaliceal system. This way, precise hemostasis was possible and damage to the surrounding tissue was avoided. Resection took between 14 and 40 minutes with minimal intraoperative blood loss. No significant postoperative complication occurred. Histologic evaluation

4 Chun D. Surgeries involving robots result in quicker recoveries. Gainesville Sun 4/11/07
5 Pow-Sang JM et al.Pure Laparoscopic and Robotic-Assisted Laparoscopic Radical Prostatectomy in the Management of Prostate Cancer. Cancer Control 2007; 14:250-257
6 Parekattil SJ & Dahm P. Hemostatic Hydrodissection of the Neurovascular Bundles (HYNEB) during Laparoscopic and Robotic Radical Prostatectomy: Early Potency and Continence Outcomes (Abstract) WCE 2007
7 Moinzadeh A et al. Water Jet Assisted Laparoscopic Partial Nephrectomy without Hilar Clamping in the Calf Model. J Urology 2005;174:317-321

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demonstrated a sharp dissection line without thermal alterations or deep necrosis. Only a small disruption zone could be seen at the margin of the dissection…

* Water jet resection is a gentle method for dissection of kidney tissue. Histologic examination confirmed minimal traumatic parenchymal alteration."

o "Certain technical caveats are emphasized. Hydro-jet® dissection allowed identification of the intact collecting system, which was then sharply incised with scissors.[8]

* For tissue dissection, the water jet was directed at the desired line of transaction. The saline jet cuts the kidney unusually regularly and precisely. By correctly adjusting the pressure of the jet, an actual discrimination between different tissue types can be achieved, apparently according to their different tensile strengths. The intrarenal vessels and the pelvicaliceal system remained undamaged. In this way, selective hemostasis was possible and no urinary fistulae occurred…

* Renal parenchyma was transected successfully without any additional surgical tool. The renal capsule could not be dissected by water jet and had to be incised by electrocautery. Good visual control of the operating field by avoiding formation of air bubbles was provided by an integrated suction system…

* Water jet technology has proven to provide significant advantages concerning resection time and blood loss in comparison with other surgical techniques such as blunt dissection or the ultrasonic aspirator. Another disadvantage of the older methods is their thermal and mechanical damage to the surrounding tissue. In order to overcome this problem, a water jet device was developed and established in liver surgery. It has been applied successfully in brain surgery, as the water jet does not produce deep necrosis or damage to the surrounding tissue…

* In the present study, the water jet dissector was demonstrated to wash away the parenchyma, leaving other anatomic strictures intact. This way, precise and selective hemostasis was possible."

<u>Gastro/Intestinal (GI):</u>

- Selective submucosal water jet hydro-dissection is achieved by dissecting the submucosa and mucosa from inner circular muscle layer. Larger submucosal vessels are left largely intact and can be treated separately.

- Total Mesorectal Excision (TME) is another procedure, which benefits from the advantages of conserving tissue structures. The selective vessel-sparing

8 Basting RF, Djakovic N & Widmann P. Use of Water Jet Resection in Organ Sparing Kidney Surgery. J Endourology 200;14:500-504

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dissection of the mesorectum layer by layer reduces post operative urinary incontinence and sexual dysfunction.

- Blood vessels and nerve structures in the following statements are from the Referenced Clinical Publications.
- The following statements are from the Referenced Clinical Publications.
  - "Controlled submucosal injection and cutting which accelerates the procedure."[9]
  - "The transmucosal application of liquids using the water jet technique offers a new method for mucosal lift-off prior to mucosal resection."[9]
  - "Produced strictly selective liquid cushions in the submucosa."[10]
  - "The possibility of using a precisely focused water jet to penetrate the mucosa and to selectively create fluid cushions into the submucosa facilitates the endoscopic mucosal resection and is a promising alternative of the standard needle injection. The water jet application is potentially more efficient and could therefore help to develop a new minimal invasive therapy of mucosal tumors which could not be treated endoscopically so far, for reasons of size, extension and position."[10]
  - "The application of a focused water jet to the mucosa of the gastrointestinal tract results in the selective accumulation of fluid in the lamina submucosa after penetration of the lamina mucosa; there is a wide range of pressures which can be applied before this will result in any damage to the lamina muscularis propria."[11]
  - "Histological investigation confirmed the selective nature of the fluid accumulation in the submucosal tissue which spared the lamina mucosa and the lamina muscularis propria."[11]

<u>Neurosurgery:</u>

- Precise preparation and dissection along the margins between the tumor and brain tissue. Tumor resection is selective with minimal trauma to healthy brain parenchyma and nerve structures are largely preserved. There is no thermal necrosis along the margins of the dissection plane or cavitations/disruptions relative to other energy devices or scalpel dissection.

9 B. Schumacher; K. Deinert; M. Philipper; H. Neuhaus. Experimental testing of a new hybrid knife for endoscopic submucosal dissection (ESD) in the esophagus. DDW 2007.
10 Kaehler GF. Submucosal cushioning with waterjet before endoscopic mucosal resection: which substances are effective? DDW 2007
11 Kaehler GF. Selective Tissue Elevation by Pressure Injection (STEP) Facilitates Endoscopic Mucosal Resection (EMR) 2007

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- Specific treatment areas in neurosurgery:
  - Gliomas
  - Metastases
  - Epileptic surgery
- The following statements are from the Referenced Clinical Publications.
  - "Waterjet dissection versus Ultrasonic Aspiration in Epilepsy Surgery.[12]
    - * Water dissection is currently under close investigation in neurosurgery. Experimentally, precise brain parenchyma dissection with vessel preservation has been demonstrated. Clinically, the safety of the instrument has already been proved. However, precise data demonstrating that waterjet dissection indeed reduces surgical blood loss are still missing…
    - * The authors applied the waterjet device in a prospective randomized study in comparison with the ultrasonic aspirator. Because there is little variability in the procedure, 30 patients with temporal lobe epilepsy receiving a tailored temporal lobe resection between December 1999 and October 2002 were selected for this study. Intraoperative vessel preservation, intraoperative blood loss, surgical complications and epilepsy outcome were evaluated. All patients were followed at 3-month intervals…
    - * During surgery, both instruments were easy to handle. Only with the waterjet dissector, however, where even small intraparenchymal blood vessels were preserved. Intraoperative blood loss was significantly reduced with the waterjet (mean 70 + 46 ml) compared with the ultrasonic aspirator (mean 121 + 48 ml). However, no difference in the necessity for blood transfusion occurred. No difference was observed with respect to operation tie (238.6 + 37.0 min with the water jet, 247.5 + 41.5 min with the ultrasonic aspirator), surgical complications and outcome…
    - * The water jet dissector enables a significant reduction of intraoperative blood loss in the investigated setting…
    - * Less traumatic and less blood loss compared with CUSA in vivo-study"
- "Vessel preservation in all pathologies below 20 bar (290 psi)"[13,14]

12 J.Oertel, M.R. Gaab, T. Shiller, D. Pillich, R. Warzok, J. Piek, "Water jet dissection is less traumatic than ultrasonic aspiration: an experimental study in the rabbit", German Society of Neurosurgery, Presentation (05/2003) P 25-07
13 J. Piek. J. Oertel, M.R. Gaab, "Water jet dissection of gliomas in neurosurgical procedures: clinical results in 35 patients", Journal of Neurosurgery (2002) 96: 690-696
14 J. Oertel, M.R. Gaab, J. Piek,"Clinical application of the water jet instrument: a detailed account of this technique after more than 100 procedures", German Society of Neurosurgery, Presentation (05/2003) MI 05-03

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- "Good correlation between applied water jet and cutting depth"[15]

HybridAPC Probe

- A combination device that applies waterjet technology to lift and cushion mucosal lesions and argon plasma coagulation to ablate the lesions.
- Extremely uniform water jet; delicate, precise and reproducible effects.
- Ergonomically designed single-use instrument.
- Easy to use device.
- An easier and less demanding method of generating force to drive the fluid into the submucosa.
- Needle-less submucosal elevation.
- No mechanical trauma of using a needle, need to find the submucosal plane with a needle, or perforation with a needle.
- There is no needle to cause damage to the channel of the scope.

15 J.Oertel, M.R. Gaab, A. Knapp, H. Essig, R Warzok, J. Piek "Water jet dissection in Neurosurgery: experimental results in porcine cadveric brain", Neurosurgery (2003) 52: 153 - 159

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

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STERILIZATION AND SHELF LIFE

Note: The only change to the current ERBEJET 2 System is the addition of lifting mucosal lesions by injection into the submucosa in the Intended Use. Additionally, the WaterJet is not sterilized. Therefore, this section is not applicable for the ERBE WaterJet Model ERBEJET 2 System and only the information for the ERBE HybridAPC Probe is provided.

Sterilization

The ERBE HybridAPC Probe is labeled as a sterile device. Pursuant to the 510(k) sterility review guidance for sterilized medical devices (February 12, 1990), the following information is provided.

1. Sterilization Methods Used:
   100% Ethylene Oxide Gas

2. Description of Sterilization Validation Cycle:
   The validation was designed per DIN EN 556-1: 2002 (Ber. 1: 2006-12), Sterilization of medical devices, Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices as well as DIN EN ISO 11135-1: 2007, Sterilization of health care products - Ethylene oxide - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices. The HybridAPC Probe has been qualified for sterilization in the same validated cycle as predicates, ERBE Hybrid Knife and ERBE APC Integrated Filtered Probes (FiAPC Probes).

   Note: Annex B.

3. Sterility Assurance Level:
   10^{-6}

4. Description of Packaging:

(b)(4)

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(b)(4)

5. Ethylene Oxide Residuals:
The ethylene oxide residual levels were evaluated by following EN ISO 10993-7: 2008, Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals. Prior to distribution, the HybridAPC Probe will meet the ethylene oxide acceptable level of ≤ 4 mg/day and ethylene chlorohydrin acceptable level of ≤ 9 mg/day.

Shelf life
The ERBE HybridAPC Probe has a current shelf life/expiration date of three (3) years via evaluation/testing of accelerated aged samples (Note: To be confirmed via evaluating/testing real time aged samples.). A summary of the inspection, testing, and results are as follows:

Inspection/Test	Specification*	Result
Packaging/Pouch		
Visual Inspection	(b)(4)	Samples Met Specification
Dye Test		Samples Met Specification
Peel Test		Samples Met Specification
Bubble Emission Test		Samples Met Specification
Burst Test		Samples Met Specification
HF Leakage Test		Samples Met Specification
Dielectric Strength		Samples Met Specification
Functionality with WaterJet and Argon Plasma Coagulator (APC)		Samples Met Specification

*As applicable Per Respective International Standards

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BIOCOMPATIBILITY

Note: The only change to the current ERBEJET 2 System is the addition of lifting mucosal lesions by injection into the submucosa in the Intended Use. Additionally, the WaterJet does not come into direct contact with the patient. Therefore, this section is not applicable for the ERBE WaterJet Model ERBEJET 2 System and only the information for the ERBE HybridAPC Probe is provided.

Background

(b)(4)

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Therefore, the following biocompatibility testing of the predicate devices is applicable or would apply to the proposed device.

Biocompatibility Tests, Results, and Reference Report Numbers

Test	Result	Reference Report Number	
		FiAPC Probes[1]	Hybrid Knife[2]
Cytotoxicity: MEM Elution	(b)(4)		
Sensitization: Sensitization Guinea Pig Maximization Sensitization			
Irritation: Intracutaneous Reactivity			
Systemic Toxicity: Acute Systemic Injection			
Haemocompatibility: Hemolysis[3]			

(b)(4)

Conclusion
An evaluation of the HybridAPC Probe was performed per EN ISO 10993-1: 2009, Biological evaluation of medical devices - Part 1: Evaluation and testing. No biocompatibility issues were found with the materials/products of the predicate devices which encompass the proposed device. Therefore the HybridAPC Probe is biocompatible.

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SOFTWARE

ERBEJET 2 System
The only change to the current ERBEJET 2 System is the addition of lifting mucosal lesions by injection into the submucosa in the Intended Use. The software is the same as for the System being currently marketed.

HybridAPC Probe
The Probe has an instrument recognition chip [or Electrically Erasable Programmable Read Only Memory (EEPROM) Chip]. When connected directly to an APC (Model APC 2)/ESU (VIO Model) System (compatible System), the Probe is recognized and the System display's on its screen basic default settings for the HybridAPC Probe in regards to Mode, Effect, Wattage, and Gas Flow [Note: This recognition chip is the same as the predicate ERBE APC Integrated Filter Probes. The software with all of the involved equipment is the same with the level of concern being the same (moderate)].

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ELECTROMAGNETIC COMPATIBILITY AND ELECTRICAL SAFETY

The ERBE HybridAPC Probe as with the predicate ERBE Hybrid Knife is a combination device. Along with delivering pressurized saline to lift the submucosa like the predicate ERBELIFT Flexible Probe, it also like the predicate ERBE APC Integrated Filter Probes (FiAPC Probes) ionizes argon gas to deliver HF argon plasma to target tissue. Additionally, along with the ERBE Water Jet Model ERBEJET 2, the other associated equipment and some of the accessories to the HybridAPC Probe also have electronic components. As a result and where applicable, the Probe and all the associated equipment and accessories had to be evaluated/qualified per international electrical standards as a system. In general, the HybridAPC Probe and all of the involved equipment/accessories evaluated together consisted of:

ERBE HybridAPC Probe
ERBE APC Model APC 2 (including its accessories- ECB cable, etc.)
ERBE ESU VIO Model (including its accessories- power cord, cart, etc.)
ERBE Water Jet Model ERBEJET 2 (including its accessories - pump cartridge, etc.)
2 Footswitches (including their cables) [one linked to the ESU to activate the APC, the other to the ERBEJET 2]
Neutral Electrode (including cable)

Specifically, the international electrical standards and parts of standards involved with ElectroMagnetic Compatibility (EMC) to ensure both emissions (interference with electronic products) and immunity (interference with device performance created by emissions from other electronic products) were applied. Conformance to the involved standards can be found in Section 9, Declaration of Conformity and Summary Reports.

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

(b)(4)Performance Testing-Bench

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(b)(4)Performance Testing-Bench

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(b)(4) Performance Testing-Bench

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PERFORMANCE TESTING - ANIMAL

Not Applicable

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

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PERFORMANCE TESTING - CLINICAL

Not Applicable

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

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CLINICAL REFERENCES

Note: The list is not exhaustive, but of a sample of clinical references using the term "ablation" in association with argon plasma coagulation.

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The 510(k) documentation has been compiled according to FDA Guidelines: Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s: August 12, 2005. To include the referencing of clinical literature, the Table Of Contents (TOC) and Sections structure were extended by designating Section 21 as “Clinical References” and then having Section 22 as “Other”.

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ERBE
USA INCORPORATED

November 14, 2014

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

RE: Traditional 510(k) for ERBE WaterJet Model ERBEJET® 2 System with HybridAPC Probe

Attn: Document Mail Clerk

Per CFR 807.90, enclosed is one (1) original paper copy of the submission. Per the instructions in the eCopy Program for Medical Device Submissions Guidance for Industry and Food and Drug Administration Staff, two (2) CDs with an eCopy are being provided with this submission and they are an exact duplicate of the original paper submission.

Please forward this submission to the appropriate office of device evaluation group for review.

Sincerely,

John Tartal
Director of Quality and Regulatory Affairs
ERBE USA, Inc.

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

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Acceptance Checklist
for Traditional 510(k)s

Organizational Elements *Failure to include these items alone generally should not result in an RTA designation*		
	Yes	**No**
a. Submission contains Table of Contents	X	
b. Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	X	
c. All pages of the submission are numbered *All pages should be numbered in such a manner that information can be referenced by page number. This may be done either by consecutively numbering the entire submission, or numbering the pages within a section (e.g., 12-1, 12-2…).*	X	
d. Type of 510(k) is identified– traditional, abbreviated, or special *If type of 510(k) is not designated, review as a traditional*	X	
Comments:		

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

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Elements of a Complete Submission (RTA Items) **(21 CFR 807.87 unless otherwise indicated)** Submission should be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
A.	**Administrative**					
	1.	All content used to support the submission is written in English (including translations of test reports, literature articles, etc,)		X		
		Comments:				
	2.	510(k) cover letter that identifies:				
		a.	Device trade name or proprietary name	X		
		b.	Device common name	X		
		c.	Device class and panel	X		
		Comments:				
	3.	Submission contains Indications for Use Statement with Rx and/or OTC designated (see also 801.109) *Submitter should use format appropriate for the reviewing Center/Office (CDRH/ODE, CDRH/OIVD, CBER/OBRR, CBER/OCTGT). If not provided in correct format, request the correct format during substantive review.*		X		
		Comments:				
	4.	Submission contains 510(k) Summary or 510(k) Statement *Either a) or b) must be answered "Yes" to be considered complete. Identify any missing element(s) as Comments.*		X		
		a.	Summary contains all elements per 21 CFR 807.92 *See also 510(k) Summary Checklist*	X		
		b.	Statement contains all elements per 21 CFR 807.93	X		
		Comments:				

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.		**Yes**	**N/A**	**No**
	5.	Submission contains Truthful and Accuracy Statement per 21 CFR 807.87(k) *See recommended format*	X		
		Comments:			
	6.	Submission contains Class III Summary and Certification *See recommended content* *Form should be signed by a responsible person of the firm, not a consultant. CDRH is not currently able to accept a digital signature.* *"N/A" only if submission is not a Class III 510(k).*		X	
		Comments:			
	7.	If submission relies upon a national or international standard as part of demonstration of substantial equivalence, submission contains Standards Data Report for 510(k)s (FDA Form 3654) or includes detailed information about how and the extent to which the standard has been followed *There should be a completed form for each referenced national or international standard.* *"N/A" only if submission does not reference any standards.*	X		
		Comments:			
	8.	Does submission contain clinical data? *Select "N/A" for this item and 8.a. and 8.b. if the submission does not contain clinical data. If submission does contain clinical data, parts a. and b. must be answered "yes" for the 510(k) to be complete.*		X	
		a. Submission includes Financial Certification/Disclosure Statement		X	

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Elements of a Complete Submission (RTA Items) **(21 CFR 807.87 unless otherwise indicated)** Submission should be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
		b.	Submission includes Certification of Compliance with requirements of ClinicalTrials.gov Data Bank (FDA Form 3674) (42 U.S.C. 282(j)(5)(B))	X		
		Comments:				
	9.	If this is a bundled submission, the submission has been appropriately bundled [i.e., the correct user fee(s) have been paid for the devices/indications (section 738 of the FD&C Act)] *See* Guidance for Industry and FDA Staff: Bundling Multiple Devices or Multiple Indications in a Single Submission. *"N/A" if not a bundled submission*				X	
		Comments:				
	10.	The submission identifies prior submissions for the same device for which FDA provided feedback related to the data or information needed to support substantial equivalence (e.g., submission numbers for Pre-Submission, IDE, prior not substantially equivalent (NSE) determination, prior 510(k) that was deleted or withdrawn) or states that there were no prior submissions.			X	
		a.	If there were prior submissions: within current submission, the sponsor has identified where in the current submission any issues related to substantial equivalence outlined in prior communications are addressed.		X	
		Comments:				
B.	**Device Description**					

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

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.		**Yes**	**N/A**	**No**
	11.	If there is a device-specific guidance document or special controls applicable to this submission, documentation has been provided to establish that the submitter has followed the recommendations in the applicable device-specific guidance document or special controls regarding the device description or otherwise met the applicable statutory or regulatory criteria through an alternative approach. *Select "No" if the submission does not include a rationale for any omitted information or any alternative approaches.* *Select "N/A" if there is no device-specific guidance document*			X	
		Comments:				
	12.	All descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling), including:		X		
		a.	A description of the principle of operation and mechanism of action for achieving the intended therapeutic/diagnostic effect.	X		
		b.	A description of all conditions of use such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	X		
		c.	A list and description of each model for which clearance is requested. *Select "N/A" if there is only one model.*	X		
		Comments:				
	13.	Where applicable, submission contains engineering drawing(s), schematics, illustrations and/or figures of the device that are clear and legible, and include dimensions		X		

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
		a.	If engineering drawings, schematics, illustrations and/or figures are provided, one is provided for each model to be marketed	X		
		Comments:				
	14.	If device is intended to be marketed with multiple components, accessories, and/or as part of a system, *Select "N/A" if the device is not intended to be marketed with multiple components, accessories, and/or as part of a system.*		X		
		a.	A description (as detailed in item 12.a. and b. and 13 above) is provided for each component or accessory.	X		
		b.	A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance. *Select "N/A" if the submission states that the component(s)/ accessory(ies) do not have a prior 510(k) clearance.*	X	X	
		Comments: The ERBEJET 2 System has prior approval, but HybridAPC Probe does not.				
C.	**Substantial Equivalence Discussion**					
	15.	Submitter has identified a predicate(s) device		X		
		a.	Predicate's 510(k) number, trade name, and model number (if applicable) provided	X		
		b.	The identified predicate(s) is consistent throughout the submission (i.e., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing	X		
		Comments:				
	16.	Submission includes a comparison of the following for the predicate(s) and subject device		X		

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
		a.	Indications for use	X		
		b.	Technology, including features, materials, and principles of operation	X		
		Comments:				
	17.	Submission includes an analysis of why any differences between the subject device and predicate(s) do not render the device NSE (e.g., do not constitute a new intended use, affect safety or effectiveness, or raise different questions of safety and effectiveness) (see section 513(i)(1)(A) of the FD&C Act) *If there is no difference between the subject and predicate(s) with respect to indications for use or technology, this should be explicitly stated, in which case "N/A" should be selected. Select "No" only if the submission does not include an analysis of differences as described above or a statement that there are no differences. Note that due to potential differences in manufacturing that may not be known to the submitter, no identified differences does not necessarily mean that no performance testing is needed.*			X		
		Comments:				
D.	**Proposed Labeling (see also 21 CFR part 801)**					
	18.	Submission includes proposed labels, labeling (e.g., instructions for use, package insert, operator's manual), and advertisements that describe the device, its intended use, and the directions for use		X		
		a.	Indications for use stated in labeling (21 CFR 801.61) and identical to IFU form and 510(k) Summary (if applicable)	X		

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
		b.	Directions for use included (including relevant hazards, warnings, precautions, contraindications), including directions for layperson (see 21 CFR 801.5) unless submission states that device qualifies for exemption per 21 CFR 801 Subpart D.	X		
		Comments:				
	19.	If indicated for prescription use, labeling includes the prescription use statement (see 21 CFR 801.109(b)(1)) or "Rx only" symbol [See also Alternative to Certain Prescription Device Labeling Requirements] *Select "N/A" if not indicated for prescription use.*		X		
		Comments:				
	20.	General labeling provisions		X		
		a.	Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1)	X		
		b.	Labeling includes device common or usual name (21 CFR 801.61)	X		
		Comments:				
	21.	If there is a device-specific guidance, special controls, or regulation, the provided labeling establishes that the submitter has followed the recommendations in the applicable guidance document, special controls, or regulation, or otherwise has met the applicable statutory or regulatory criteria through an alternative approach. *Select "N/A" if there is no device-specific guidance or regulation.*			X	
		Comments:				
	22.	If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10. *Select "N/A" if not an in vitro diagnostic device.*			X	

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.		**Yes**	**N/A**	**No**
E.	**Performance Data – General**				
	Submission: (*one of the below must be checked*) ☒ does ☐ does not contain performance data. *If "does not" is selected, the performance data-related criteria below are omitted from the*				
	Comments:				
	23.	Full test report is provided for each completed test to explain how the data generated from the test supports a finding of substantial equivalence. (A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre-defined pass/fail criteria, results summary, and conclusions.)	X		
		Comments:			
	24.	Submission includes document to establish that the submitter has followed the recommendations for performance data outlined in the applicable device-specific guidance document or special controls, or otherwise met the applicable statutory or regulatory criteria through an alternative approach. *Select "N/A" if there is no device-specific guidance document.*		X	
		Comments:			
	25.	If literature was used as performance data, submission includes reprints or a summary of each article, and a discussion as to how each article is applicable to support the substantial equivalence of the subject device to the predicate.		X	
		Comments: Literature is not used as performance data but for rational of terminology.			
	26.	If an animal study was conducted, *Select "N/A" if no animal study was conducted.*		X	

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
		a.	Submission includes a study protocol and final study report to explain how the data generated from the study supports a finding of substantial equivalence. (A final study report includes a contributing scientist report for each preclinical endpoint of evaluation within the protocol, such as performance/handling, in life, imaging, pathology, etc.)		X	
		b.	Submission contains a statement that the study was conducted in compliance with applicable requirements in the GLP regulation (21 CFR Part 58), or, if the study was not conducted in compliance with the GLP regulation, the submission explains why the noncompliance would not impact the validity of the study data provided to support a substantial equivalence determination.		X	
		Comments:				
F.	**Sterilization**					
	Submission states that the device and/or accessories are: (*one of the below must be checked*) ☒ sterile ☐ non-sterile but sterilized by the end ☐ user non-sterile when used This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "non-sterile when used" is selected, the sterility-related criteria below are omitted from the checklist.* *If information regarding the sterility status of the device is not provided, select "No."*					
	Comments:					
	27.	Assessment of the need for sterilization information		X		

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
		a.	Identification of device, and/or accessories, and/or components that are provided sterile.	X		
		b.	Identification of device, and/or accessories, and/or components that are end user sterilized	X		
		c.	Identification of device, and/or accessories, and/or components that are reusable and cleaning/disinfection instructions are provided.	X		
		Comments:				
	28.	If the device, and/or accessory, and/or a component is provided sterile: *Select "N/A" if no part of the device, accessories, or components is provided sterile, otherwise complete a-f below.*		X		
		a.	Sterilization method is stated for each component (including parameters such as dry time for steam sterilization, radiation dose, etc.)	X		
		b.	A description of method to validate the sterilization cycle (e.g., half-cycle method and full citation of FDA-recognized standard, including date) is provided	X		
		c.	For devices sterilized using chemical sterilants such as ethylene oxide (EO) and hydrogen peroxide, submission states maximum levels of sterilant residuals remaining on the device and sterilant residual limits. *Select "N/A" if not sterilized using chemical sterilants.*	X		
		d.	Submission includes description of packaging and packaging contents (e.g., if multiple devices are included within the same package)	X		
		e.	Sterility Assurance Level (SAL) stated	X		

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
		f.	If device is blood-contacting, a permanent implant, or contacts cerebrospinal fluid, or device is labeled "non-pyrogenic," submission contains a description of the endotoxin method used to make a determination (e.g., LAL), endotoxin release specification (e.g., 20 EU/device), and a rationale for the specification. *Select "N/A" if device is not blood-contacting, not a permanent implant, does not contact cerebrospinal fluid, and is not labeled "non-pyrogenic." Select "N/A" if a rationale for omission is provided.*		X	
		Comments:				
	29.	All sterility information provided as recommended in the following guidance documents or special controls, or information provided indicating the submitter has otherwise met the applicable statutory or regulatory criteria through an alternative approach: *Either "a" or "b" must be answered "Yes" to be considered complete.*			X	
		a.	Device-specific guidance document or special controls *Select "N/A" if no device-specific guidance document.*		X	
		b.	Cross-cutting guidance document (for more information see "Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile") *Select "N/A" if device-specific guidance followed instead.*		X	
		Comments:				
G.	**Shelf Life**					

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

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
	30.	If the device is provided sterile or the device is provided non-sterile and storage conditions (i.e., aging) could impact device safety or effectiveness, address the following: *Select "N/A" if the device is not provided sterile and the submitter states that storage conditions could not affect device safety or effectiveness.*		X		
		a.	Proposed shelf life/expiry date stated	X		
		b.	Submission includes description of shelf life validation method(s) used to ensure device performance and sterility, as applicable, remain substantially equivalent to that of the predicate device throughout the stated shelf life.	X		
		Comments:				
H.	**Biocompatibility**					
	Submission states that there: (*one of the below must be checked*) ☒ are ☐ are not direct or indirect (e.g., through fluid infusion) patient-contacting components. This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "are not" is selected, the biocompatibility-related criteria below are omitted from the checklist. If information regarding whether the device is patient-contacting is not provided, select "No."*					
	Comments:					
	31.	Submission includes list of patient-contacting device components and associated materials of construction, including identification of color additives, if present		X		

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

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.		**Yes**	**N/A**	**No**
		Comments:			
	32.	Submission identifies contact classification (e.g., surface-contacting, less than 24 hour duration)	X		
		Comments:			
	33.	Biocompatibility assessment of patient-contacting components Submission includes: Test protocol (including identification and description of test article), methods, pass/fail criteria, and results provided for each completed test, OR a statement that biocompatibility testing is not needed with a rationale (e.g., materials and manufacturing/processing are identical to the predicate).	X		
I.	**Software**				
	Submission states that the device: (*one of the below must be checked*) ☒ does ☐ does not contain software. This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "does not" is selected, the software-related criterion is omitted from the checklist. If information regarding whether the device contains software is not provided, select "No."*				
	Comments:				

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.		**Yes**	**N/A**	**No**
	34.	All appropriate categories of software verification and validation documentation provided based on stated level of concern, as described in Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, or the submitter has provided documentation that it has otherwise met the applicable statutory or regulatory criteria through an alternative approach.	X		
		Comments:			
J.	**EMC and Electrical Safety**				
	Submission states that the device: (*one of the below must be checked*) ☒ does ☐ does not require EMC and Electrical Safety evaluation. This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "does not" is selected, the EMC-related and Electrical Safety-related criteria below are omitted from the checklist. If information regarding whether the device requires EMC and Electrical Safety evaluation is not provided, select "No."*				
	Comments:				
	35.	Submission includes evaluation of electrical safety per IEC 60601-1 or equivalent FDA-recognized standard and if applicable, the device-specific standard OR submission includes electrical safety evaluation using methods or standards that are not FDA-recognized and information indicating that these methods/standards otherwise meet applicable statutory and regulatory requirements.	X		
		Comments:			

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

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	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.		**Yes**	**N/A**	**No**
	36.	Submission includes evaluation of electromagnetic compatibility per IEC 60601-1-2 or equivalent FDA-recognized standard and if applicable, the device-specific standard OR submission includes electromagnetic compatibility evaluation using methods or standards that are not FDA-recognized and information indicating that these methods/standards otherwise meet applicable statutory and regulatory requirements.		X		
		Comments:				
K.	**Performance Characteristics – In Vitro Diagnostic Devices Only (see also 21 CFR 809.10(b)(12))**				
	Submission indicates that device: (*one of the below must be checked*) ☐ is ☒ is not an in vitro diagnostic device (IVD). *If "is not" is selected, the performance data-related criteria below are omitted from the checklist.*				
	Comments:				
	37.	Submission includes the following analytical studies, including associated protocols and line data:		X	
		a. Precision/reproducibility (at least 3 sites generally necessary)		X	
		b. Accuracy (includes linearity, assay cut-off, method comparison or comparison to clinical outcome, matrix comparison, reference range, and stability protocol and acceptance criteria)		X	
		c. Sensitivity (detection limits (LoB, LoD, and LoQ))		X	
		d. Analytical specificity		X	
		Comments:			

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

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K143306/S001

ERBE
USA INCORPORATED

FDA CDRH DMC
MAR 03 2015
Received

February 27, 2015

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

RE: Response to December 2nd, 2014 Refuse To Accept (RTA) involving K143306; ERBE Water Jet System, ERBE HybridAPC Probe

Attn: Document Mail Clerk

As instructed, one (1) CD [an eCopy] is being provided with the paper copy. The eCopy is an exact duplicate of the paper copy.

Please forward this response to the lead reviewer, Mr. Edwin Ramirez.

Sincerely,

John Tartal
Director of Quality and Regulatory Affairs
ERBE USA, Inc.

004_eCopy Cover Letter

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

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ERBE
USA INCORPORATED

February 27, 2015

FDA CDRH DMC
MAR 03 2015
Received

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

RE: Response to December 2nd, 2014 Refuse To Accept (RTA) involving K143306; ERBE Water Jet System, ERBE HybridAPC Probe

Included below respectively is our response with reference (Attachments) to revised or additional 510(k) documentation as requested per the 12/02/14 RTA Notification (Comments). The 12/02/14 RTA Notification is included as Attachment 1.

D. Proposed Labeling,

17) Comments: The submission provided a user manual for the ERBE jet2. However, no packaging and / or individual unit labels were provided for the ERBE jet 2.

18) Comments: The device is indicated for Rx use. However, no "Rx only" symbol or "Prescription use only" statement was provided for the labeling for both the ERBE Jet 2 and the HybridAPC

Response:

As requested, the 510(k) Section 13, Proposed Labeling has been revised to include the ERBEJET 2 Unit's Type Plate Label and its Outer Package Label. Additionally, the "Prescription use only" statement "Caution: Federal Law (USA) restricts the device to sale by or on the order of a physician." is included on the ERBEJET 2 Unit's Outer Package Label as well as the HybridAPC Probe Outer Package Labels. See Attachment 2, Revised Proposed Labeling.

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

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I. EMC and Electrical Safety,

34) Comments: The submission discloses that it utilized a standard not recognized by FDA (EN 60601-1: 2006) stating that the standard is "identical" to the one recognized by the FDA (IEC 60601-1: 2005 3rd Edition). However, the submission did not provide any reports and / or documentation describing the results of the testing or a valid scientific rationale disclosing the differences between the standards. Stating that the standards are "identical" is not an acceptable justification / rationale. Please provide a valid scientific justification as to how the testing results from the provided standard (EN 60601-1: 2006) are comparable to the FDA recognized standard or provide the results of the complete system testing conducted for your device.

35) Comments: Same issue as #34 applies for all additional standards named in the submission.

Response:

Being a European based manufacturer, ERBE Elektromedizin GmbH uses the equivalent European Norm (EN) to the FDA recognized standard when possible. The EN designation is the European Community published translation of an IEC, etc. standard. To address FDA's concern, an extensive comparison as applicable was performed between the standards used/applied and current/acceptable FDA recognized standards. See the following table of the findings.

Standard Applied	Current or Acceptable FDA Recognized Consensus Standard as Applicable	Findings
EN ISO 14971: 2009	ISO 14971: 2007 Second Edition	No differences were found.
EN ISO 10993-1: 2009	AAMI ANSI ISO 10933-1: 2009/(R)2013	No differences were found.
EN 60601-1: 2006 (Third Edition)	IEC 60601-1: 2005 3rd Edition	No differences were found.
EN 60601-1-2: 2007 (Third Edition)	IEC 60601-1-2: 2007 (Third Edition)	The following difference was found: Last phrase of Subclause 4.2 in Annex A (which is an informative Annex), should read: "(...)These HAZARDS shall be considered in the RISK MANAGEMENT PROCESS." The IEC version uses the word "should" instead.
EN 62366: 2008	AAMI ANSI IEC 62366: 2007/(R)2013	No differences were found.
EN 60601-2-2: 2009 (Fifth Edition)	AAMI ANSI IEC 60601-2-2: 2009	No differences were found.
EN 60601-2-18: 1996 (+ A1 12/2000)	IEC 60601-2-18: 2009 (Edition 3.0)	No differences were found on both EN 60601-2-18: 1996 and A1/2000.

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

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Standard Applied	Current or Acceptable FDA Recognized Consensus Standard as Applicable	Findings
DIN EN 1041: 2008	Not Applicable- No Equivalent Current FDA Recognized Standard	
DIN EN ISO 15223-1: 2012	AAMI ANSI ISO 15223-1: 2012	No differences were found.
EN ISO 11607-1: 2009	AAMI ANSI ISO 11607-1: 2006/(R)2010	No differences were found.
EN ISO 11607-2: 2006	AAMI ANSI ISO 11607-2: 2006/(R)2010	No differences were found.
ISTA 2A: 2011	Not Applicable- No Equivalent Current FDA Recognized Standard	
DIN EN 556-1: 2002 (Ber. 1: 2006-12),	Not Applicable- No Equivalent Current FDA Recognized Standard	
DIN EN -11135-1: 2007	ISO 11135: 2007 (Second Edition)	No differences were found.
EN ISO 10993-7: 2008	AAMI ANSI ISO 10993-7:2008(R)2012	No differences were found.

In conclusion, in comparing the applied standards and the current FDA recognized consensus standards, there was no impact on application of the standard, evaluation, and/or testing.

J. Performance Data - General,

38) Comments: The submission provides a list of articles for Clinical reference. However, no summary of relevance or discussion on how this relates to the submission was provided.

Response:

The use of the clinical literature referenced in the 510(k) was explained/discussed in Sections 3, 5, and 12. In summary, the clinical references were included in the 510(k) exclusively to demonstrate that the terms "ablation" and "coagulation" have been used in association for many years which justifies the addition of the text: "HF ablation of the mucosal lesions by Argon Plasma Coagulation" into the HybridAPC Probe's intended use. The additional text clarifies for the end user that raised/cushioned mucosal lesions are to be ablated. The list of clinical references only deems to show the correct usage of terminology when combining the terms "ablation" and "coagulation".

39) Comments: The submission indicated that it did not conduct animal studies. However, a randomized ex-vivo study was found in the Performance / bench test section. No statement of conformance with 21 CFR 58 was found in the documentation. Please clarify if this study was conducted in accordance with 21 CFR 58.

Response:

In 21 CFR 58 Subpart A, Section 58.3 (d) definition of a nonclinical study is as follows: "*Nonclinical laboratory study* means in vivo or in vitro experiments in which test articles are studied prospectively in test systems under laboratory conditions to determine their safety. The term does not include studies utilizing human subjects or

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clinical studies or field trials in animals. The term does not include basic exploratory studies carried out to determine whether a test article has any potential utility or to determine physical or chemical characteristics of a test article." The testing presented in Section 18 of the 510(k) was only conducted where applicable on ex-vivo/harvested tissue. No in vivo or in vitro experiments were conducted under laboratory conditions to demonstrate safety. Ex vivo work was done exclusively for performance comparison purposes between the proposed device ERBEJET 2 System with the HybridAPC Probe and the ERBELIFT Hand Pump and Flexible Probe (one of the predicate devices) for lifting. Additionally, an ex-vivo experiment was conducted with the ERBEJET 2 System with the HybridAPC Probe when lifting and ablating lesions via argon plasma versus just ablating via argon plasma coagulation. In conclusion, as previously presented, all of the testing in Section 18 is bench testing and not subjected to 21 CFR 58.

We believe that the response enclosed has adequately resolved the request as noted. However, if you have any further questions or need to contact me, please call me at (770) 955-4400 or email direct at "John.Tartal@erbe-usa.com".

Sincerely,

John Tartal
ERBE USA, Inc.
Director of Quality and Regulatory Affairs

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

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ERBE
USA INCORPORATED

February 27, 2015

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

RE: Response to December 2nd, 2014 Refuse To Accept (RTA) involving K143306; ERBE Water Jet System, ERBE HybridAPC Probe

Included below respectively is our response with reference (Attachments) to revised or additional 510(k) documentation as requested per the 12/02/14 RTA Notification (Comments). The 12/02/14 RTA Notification is included as Attachment 1.

D. Proposed Labeling,

17) Comments: The submission provided a user manual for the ERBE jet2. However, no packaging and / or individual unit labels were provided for the ERBE jet 2.

18) Comments: The device is indicated for Rx use. However, no "Rx only" symbol or "Prescription use only" statement was provided for the labeling for both the ERBE Jet 2 and the HybridAPC

Response:

As requested, the 510(k) Section 13, Proposed Labeling has been revised to include the ERBEJET 2 Unit's Type Plate Label and its Outer Package Label. Additionally, the "Prescription use only" statement "Caution: Federal Law (USA) restricts the device to sale by or on the order of a physician." is included on the ERBEJET 2 Unit's Outer Package Label as well as the HybridAPC Probe Outer Package Labels. See Attachment 2, Revised Proposed Labeling.

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

I. EMC and Electrical Safety,

34) Comments: The submission discloses that it utilized a standard not recognized by FDA (EN 60601-1: 2006) stating that the standard is "identical" to the one recognized by the FDA (IEC 60601-1: 2005 3rd Edition). However, the submission did not provide any reports and / or documentation describing the results of the testing or a valid scientific rationale disclosing the differences between the standards. Stating that the standards are "identical" is not an acceptable justification / rationale. Please provide a valid scientific justification as to how the testing results from the provided standard (EN 60601-1: 2006) are comparable to the FDA recognized standard or provide the results of the complete system testing conducted for your device.

35) Comments: Same issue as #34 applies for all additional standards named in the submission.

Response:

Being a European based manufacturer, ERBE Elektromedizin GmbH uses the equivalent European Norm (EN) to the FDA recognized standard when possible. The EN designation is the European Community published translation of an IEC, etc. standard. To address FDA's concern, an extensive comparison as applicable was performed between the standards used/applied and current/acceptable FDA recognized standards. See the following table of the findings.

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Response:

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

clinical studies or field trials in animals. The term does not include basic exploratory studies carried out to determine whether a test article has any potential utility or to determine physical or chemical characteristics of a test article." The testing presented in Section 18 of the 510(k) was only conducted where applicable on ex-vivo/harvested tissue. No in vivo or in vitro experiments were conducted under laboratory conditions to demonstrate safety. Ex vivo work was done exclusively for performance comparison purposes between the proposed device ERBEJET 2 System with the HybridAPC Probe and the ERBELIFT Hand Pump and Flexible Probe (one of the predicate devices) for lifting. Additionally, an ex-vivo experiment was conducted with the ERBEJET 2 System with the HybridAPC Probe when lifting and ablating lesions via argon plasma versus just ablating via argon plasma coagulation. In conclusion, as previously presented, all of the testing in Section 18 is bench testing and not subjected to 21 CFR 58.

We believe that the response enclosed has adequately resolved the request as noted. However, if you have any further questions or need to contact me, please call me at (770) 955-4400 or email direct at "John.Tartal@erbe-usa.com".

Sincerely,

John Tartal
ERBE USA, Inc.
Director of Quality and Regulatory Affairs

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

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John Tartal

From:	Edwin Ramirez <edwin.ramirez@fda.hhs.gov>
Sent:	Tuesday, December 02, 2014 7:28 AM
To:	John Tartal
Cc:	Edwin Ramirez
Subject:	K143306 is on Hold Pending Your Response
Attachments:	K143306_RTA_Checklist-signed.pdf

December 2, 2014

Acceptance Review Notification - Refuse To Accept (RTA)

We have completed the administrative acceptance review of your premarket notification (510(k)) submission K143306. Our review indicates that your 510(k) submission does not meet the criteria established for administrative completeness. Thus, we regret to inform you that we are unable to conduct a substantive review of your submission at this time and are placing it on RTA hold.

Please submit two copies of your response (1 eCopy and 1 paper copy), referencing the 510(k) number K143306, addressing the elements identified as missing or inconsistent in the attached checklist to:

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

FDA will permit your 510(k) submission to remain on hold for a maximum of 180 days from the date of this email. If you do not correct the missing or inconsistent elements identified in the checklist within 180 days, we will consider this 510(k) submission to be withdrawn, and we will delete it from our review system.

Upon receipt of the requested information, FDA will conduct another administrative review of your 510(k) submission.

Should you have questions about this email, you may contact Edwin Ramirez, the lead reviewer assigned to your 510(k) submission.

For additional information regarding the Refuse to Accept Policy for 510(k)s please refer to the guidance document available at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014.pdf.

*** This is a system-generated email notification ***

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

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Contains Nonbinding Recommendations

Print Form

Acceptance Checklist for Traditional 510(k)s

(Should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.

510(k) #: K143306 Date Received by DCC: Nov 18, 2014

Lead Reviewer: Edwin Ramirez

Branch: GSDB2 Division: DSD Center/Office: CDRH/ODE

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete. It means the reviewer did not assess the element during RTA and the element will be assessed during the substantive review.

Preliminary Questions

Answers in the shaded blocks indicate consultations with Center advisor is needed	Yes	No
1) Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)? If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Office Jurisdiction Liaison to determine the appropriate action, and inform division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If the product does not appear to be a device or such a combination product, mark "No."	X	
Comments?		
2. Is the application with the appropriate Center? If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the application is not with the appropriate Center or you are unsure, consult with the CDRH Jurisdictional Officer or CBER Office Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If application should not be reviewed by your Center mark "No."	X	
Comments?		
3) If a Request for Designation was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD # and confirm the following: a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission? b) Are the indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission ? If you believe the product or the indications presented in the 510(k) have changed from the RFD, or you are unsure, consult with the CDRH Jurisdictional Officer or appropriate CBER Jurisdiction Liaison to determine the appropriate action and inform your division management. Provide summary of Jurisdictional Officer's/Liaison's determination. If the answer to either question is no, mark "No." If there was no RFD, skip this question.		
Comments? N/A		
4) Is this device type eligible for a 510(k) submission? If a 510(k) does not appear to be appropriate (e.g., Class III type and PMA required, or Class I or II type and 510(k)-exempt), you should consult with the CDRH 510(k) Program Director or appropriate CBER staff during the acceptance review. If 510(k) is not the appropriate regulatory submission, mark "No."	X	
Comments?		

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5) Is there a pending PMA for the same device with the same indications for use? If yes, consult division management and the CDRH 510(k) Program Director or appropriate CBER staff to determine the appropriate action.		X
Comments?		
6) If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)? If yes, consult with the CDRH Office of Compliance/Division of Bioresearch Monitoring (OC/DBM - BIMO) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action. Check on web at http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/ucm134453.htm		X
Comments?		

If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and issue the "Original Jurisdictional Product" letter.
If the answer to 3a or 3b appears to be "No," then stop the review and contact the CDRH Jurisdictional Officer or CBER Office of Jurisdiction Liaison.
If the answer to 4 is "No," the lead reviewer should consult division management and other Center resources to determine the appropriate action.
If the answer to 5 is "Yes," then stop review of the 510(k), contact the CDRH 510(k) Staff and PMA Staff, or appropriate CBER staff.
If the answer to 6 is "Yes," then contact CDRH/OC/DBM-BIMO or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with the BIMO Staff, and indicate BIMO's recommendation/action.

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Organizational Elements

Failure to include these items alone generally should not result in an RTA designation.

	Yes	No
1) Submission contains a Table of Contents	X	
2) Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	X	
3) All pages of the submission are numbered.	X	
4) Type of 510(k) is identified (i.e., traditional, abbreviated, or special)	X	
Comments?		

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Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
A. Administrative				
1) All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	X			
2) Submission identifies the following (such as in CDRH Premarket Review Submission Cover Sheet (Form 3514) or 510(k) cover letter):	X			
a) Device trade name or proprietary name	X			
b) Device common name	X			
c) Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	X			
3) Submission contains Indications for Use Statement with Rx and/or OTC designation (see also 21 CFR 801.109).	X			
4) Submission contains 510(k) Summary or 510(k) Statement	X			
a) Summary contains all elements per 21 CFR 807.92 *(See also* 510(k) Summary Checklist*)*	X			
b) Statement contains all elements per 21 CFR 807.93			X	
5) Submission contains Truthful and Accuracy Statement per 21 CFR 807.87(k) *See recommended* format.	X			
6) Submission contains Class III Summary and Certification. *See recommended* content.	X			
7) Submission contains clinical data			X	
8) If submission references use of a national or international standard as part of demonstration of substantial equivalence, submission contains Standards Data Report for 510(k)s (Form 3654) or includes detailed information about how and the extent to which the standard has been followed.	X			
9) The submission identifies prior submissions for the same device for which FDA provided feedback related to the data or information needed to support substantial equivalence (e.g., submission numbers for Pre-Submission, IDE, prior not substantially equivalent (NSE) determination, prior 510(k) that was deleted or withdrawn) or states that there were no prior submissions for the subject device.	X			
a) If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence outlined in prior communications are addressed. For additional information regarding the Pre-Submission process, please refer to the Draft Guidance "Medical Devices: The Pre-Submission Program and Meetings with FDA Staff." Once finalized, this guidance will represent the Agency's current thinking on this topic.			X	
B. Device Description				
10)				

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Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
a) If there are requirements regarding the device description, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes device description information to establish that the submitter has followed the device-specific requirement.			X	
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes device description information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			X	
11) Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling), including:				
a) A description of the principle of operation and mechanism of action for achieving the intended effect.	X			
b) A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	X			
c) A list and description of each device for which clearance is requested.	X			
12) Submission contains representative engineering drawing(s), schematics, illustrations and/or figures of the device that are clear, legible, labeled, and include dimensions.	X			
13) If device is intended to be marketed with multiple components, accessories, and/or as part of a system				
a) Submission includes a list of all components and accessories to be marketed with the subject device.	X			
b) Submission includes a description (as detailed in item 11(a) and (b) and 12 above) of each component or accessory.	X			
c) A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance.			X	
C. Substantial Equivalence Discussion				
14) Submitter has identified a predicate device.	X			
a) Predicate's 510(k) number, trade name, and model number (if applicable) provided. For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding* documenting preamendment status *is available online.*	X			
b) The identified predicate(s) is consistent throughout the submission (i.e., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing.	X			
15) Submission includes a comparison of the following for the predicate(s) and subject device				
a) Indications for Use	X			
b) Technology, including features, materials, and principles of operation	X			

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Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

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16) Submission includes an analysis of why any differences between the subject device and predicate(s) do not render the device NSE (e.g., does not constitute a new intended use; and any differences in technological characteristics are accompanied by information that demonstrates the device is as safe and effective as the predicate and do not raise different questions of safety and effectiveness than the predicate), affect safety or effectiveness, or raise different questions of safety and effectiveness (see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f))	X			
D. Proposed Labeling (see also 21 CFR part 801)				
If *in vitro* diagnostic (IVD) device, criteria 17 & 19 may be omitted.				
17) Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual) that include a description of the device, its intended use, and the directions for use.		X		X
a) Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided).	X			
b) Submission includes directions for use that - include statements of all conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) AND - includes directions for layperson (see 21 CFR 801.5) OR submission states that device qualifies for exemption per 21 CFR 801 Subpart D	X			
Comments? The submission provided a user manual for the ERBE jet2. However, no packaging and / or individual unit labels were provided for the ERBE jet 2.				
18) If indicated for prescription use, labeling includes the prescription use statement (see 21 CFR 801.109(b)(1)) or "Rx only" symbol [See also Alternative to Certain Prescription Device Labeling Requirements]		X		X
Comments? The device is indicated for Rx use. However, no "Rx only" symbol or "Prescription use only" statement was provided for the labeling for both the ERBE Jet 2 and the HybridAPC				
19) General labeling provisions				
a) Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1).	X			
b) Labeling includes device common or usual name. (21 CFR 801.61)	X			
20)				
a) If there are requirements regarding labeling, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes labeling to establish that the submitter has followed the device-specific requirement.			X	
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes labeling to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			X	

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Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

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- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
c) If there is a special controls document applicable to the device, the submission includes labeling to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.			X	
21) If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10.			X	
E. Sterilization				
If IVD device and sterilization is not applicable, select "N/A" and criteria below will be omitted from checklist.				X
Submission states that the device and/or accessories are: (one of the below must be checked)				
X provided sterile				
provided non-sterile but sterilized by the end user				
non-sterile when used				
Information regarding the sterility status of the device is not provided.				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				
Comments? Only the HybridAPC is patient contacting and provided sterile				
22) Assessment of the need for sterilization information				
a) Identification of device, and/or accessories, and/or components that are provided sterile.	X			
b) Identification of device, and/or accessories, and/or components that are end user sterilized.			X	
c) Identification of device, and/or accessories, and/or components that are reusable and cleaning /disinfection instructions are provided.	X			
23) If the device, and/or accessory, and/or a component is provided sterile:				
a) Sterilization method is stated for each component (including parameters such as dry time for steam sterilization, radiation dose, etc.).	X			
b) A description of method to validate the sterilization parameters (e.g., half-cycle method and full citation of FDA-recognized standard, including date) is provided for each proposed sterilization method. *Note, the sterilization validation report is not required.*	X			
c) For devices sterilized using chemical sterilants such as ethylene oxide (EO) and hydrogen peroxide, submission states maximum levels of sterilant residuals remaining on the device and sterilant residual limits.	X			
d) Submission includes description of packaging and packaging contents (e.g., if multiple devices are included within the same package, Tyvek packaging, etc.)	X			
e) Sterility Assurance Level (SAL) is stated.	X			

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Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
24) If the device, and/or accessory, and/or a component is end user sterilized:			X	
25)				
a) If there are requirements regarding sterility, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes sterility information to establish that the submitter has followed the device-specific requirement.			X	
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes sterility information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			X	
c) If there is a special controls document applicable to the device, the submission includes sterility information to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.			X	
F. Shelf Life				
26) Proposed shelf life/expiration date stated	X			
27) For sterile device, submission includes summary of methods used to establish that device will remain sterile through the proposed shelf life or a rationale for why testing to establish shelf life is not applicable.	X			
28) Submission includes summary of methods used to establish that device performance is not adversely affected by aging or includes a rationale for why the storage conditions are not expected to affect device safety or effectiveness.	X			
G. Biocompatibility				
If IVD device, select "N/A" and the below criteria will be omitted from checklist.				
Submission states that there: (one of the below must be checked)				
X are direct or indirect (e.g., through fluid infusion) patient-contacting components.				
are no direct or indirect (e.g., through fluid infusion) patient-contacting components.				
Information regarding the patient contact status of the device is not provided.				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				
29) Submission includes list of patient-contacting device components and associated materials of construction, including identification of color additives, if present	X			
30) Submission identifies contact classification (e.g., surface-contacting, less then 24 hour duration, etc.)	X			

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Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
31) Biocompatibility assessment of patient-contacting components Submission includes: Test protocol (including identification and description of test article), methods, pass/fail criteria, and results provided for each completed test, OR a statement that biocompatibility testing is not needed with a rationale (e.g., materials and manufacturing/processing are identical to the predicate).	X			
H. Software				
Submission states that the device: (one of the below must be checked)				
X does contain software/firmware.				
does not contain software/firmware.				
Information regarding whether the device contains software is not provided.				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				
32) Submission includes a statement of software level of concern and rationale for the software level of concern.	X			
33) All applicable software documentation provided based on level of concern identified by the submitter, as described in Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, or the submitter has provided an alternative approach with a rationale.	X			X
Comments? The submission discloses that the software is unchanged from the predicate				
I. EMC and Electrical Safety				
Submission states that the device: (one of the below must be checked)				
X does require EMC and Electrical Safety evaluation.				
does not require EMC and Electrical Safety evaluation.				
Information regarding whether the device requires EMC and Electrical Safety evaluation is not provided.				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				
34) Submission includes evaluation of electrical safety (e.g., per IEC 60601-1, or equivalent FDA-recognized standard, and if applicable, the device-specific standard), OR submission includes electrical safety evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).		X		X
Comments? The submission discloses that it utilized a standard not recognized by FDA (EN 60601-1: 2006) stating that the standard is "identical" to the one recognized by the FDA (IEC 60601-1: 2005 3rd Edition). However, the submission did not provide any reports and / or documentation				

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Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
describing the results of the testing or a valid scientific rationale disclosing the differences between the standards. Stating that the standards are "identical" is not an acceptable justification / rationale. Please provide a valid scientific justification as to how the testing results from the provided standard (EN 60601-1: 2006) are comparable to the FDA recognized standard or provide the results of the complete system testing conducted for your device.				
35) Submission includes evaluation of electromagnetic compatibility (e.g., per IEC 60601-1-2 or equivalent FDA-recognized standard and if applicable, the device-specific standard) OR submission includes electromagnetic compatibility evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).		X		X
Comments? Same issue as #34 applies for all additional standards named in the submission.				
J. Performance Data - General If IVD device, select "N/A" and the below criteria will be omitted from checklist. Performance data criteria relating to IVD devices will be addressed in Section K.				
36) Full test report is provided for each completed test. A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre-defined pass/fail criteria, results summary, conclusions, and an explanation of how the data generated from the test supports a finding of substantial equivalence.	X			
37)				
a) If there are requirements regarding performance data, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes performance data to establish that the submitter has followed the device-specific requirement.			X	
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes performance data to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			X	
c) If there is a special controls document applicable to the device, the submission includes performance data to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.			X	
38) If literature is referenced in the submission, submission includes:				X
a) Legible reprints or a summary of each article.		X		
b) Discussion of how each article is applicable to support the substantial equivalence of the subject device to the predicate.		X		
Comments? The submission provides a list of articles for Clinical reference. However, no summary of relevance or discussion on how this relates to the submission was provided.				

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Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
39) For each completed nonclinical (i.e., animal) study conducted				X
a) Submission includes a study protocol which includes all elements as outlined in 21 CFR 58.120.		X		
b) Submission includes final study report which includes all elements outlined in 21 CFR 58.185.		X		
c) Submission contains a statement that the study was conducted in compliance with applicable requirements in the GLP regulation (21 CFR Part 58), or, if the study was not conducted in compliance with the GLP regulation, the submission explains why the noncompliance would not impact the validity of the study data provided to support a substantial equivalence determination.		X		
Comments? The submission indicated that it did not conduct animal studies. However, a randomized ex-vivo study was found in the Performance / bench test section. No statement of conformance with 21 CFR 58 was found in the documentation. Please clarify if this study was conducted in accordance with 21 CFR 58.				

K. Performance Characteristics - In Vitro Diagnostic Devices Only

(Also see 21 CFR 809.10(b)(12))

Submission states that the device: (one of the below must be checked)	
	is an in vitro diagnostic device.
X	is not an in vitro diagnostic device.

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Decision: ○ Accept ◉ Refuse to Accept

If Accept, notify applicant.

If Refuse to Accept, notify applicant in writing and include a copy of this checklist.

Digital Signature Concurrence Table

Reviewer Sign-Off	Digitally signed by Edwin J. Ramirez -S Date: 2014.12.01 13:35:16 -05'00'
Branch Chief Sign-Off (digital signature optional)*	Joshua C. Nipper -S 2014.12.01 15:44:57 -05'00'
Division Sign-Off (digital signature optional)*	David Krause -S 2014.12.02 07:27:08 -05'00'

* Branch and Division review of checklist and concurrence with decision required. Branch and Division digital signature optional.

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PROPOSED LABELING (Including Claims/Marketing Statements)

List of Draft Labels, Labeling, and Claims/Marketing Statements

Description	Page Numbers
ERBEJET 2 Unit	
Labels	
Type Plate Label	013 - 3
Outer Packaging Label	013 - 3
Labeling	
User Manual	013 - 4 to 013 - 61
HybridAPC Probe	
Labels	
Outer Packaging Pouch Label	013 - 63
Patient Chart Label	013 - 63
Outer Packaging Box Label	013 - 64
Labeling	
Notes On Use	013 - 65 to 013 - 79
Claims/Marketing Statements	
ERBE WaterJet Model ERBEJET® 2 System with HybridAPC Probe Claims/Marketing Statements	013 - 80 to 013 - 90

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ERBEJET 2 Unit Labels and Labeling (User Manual)

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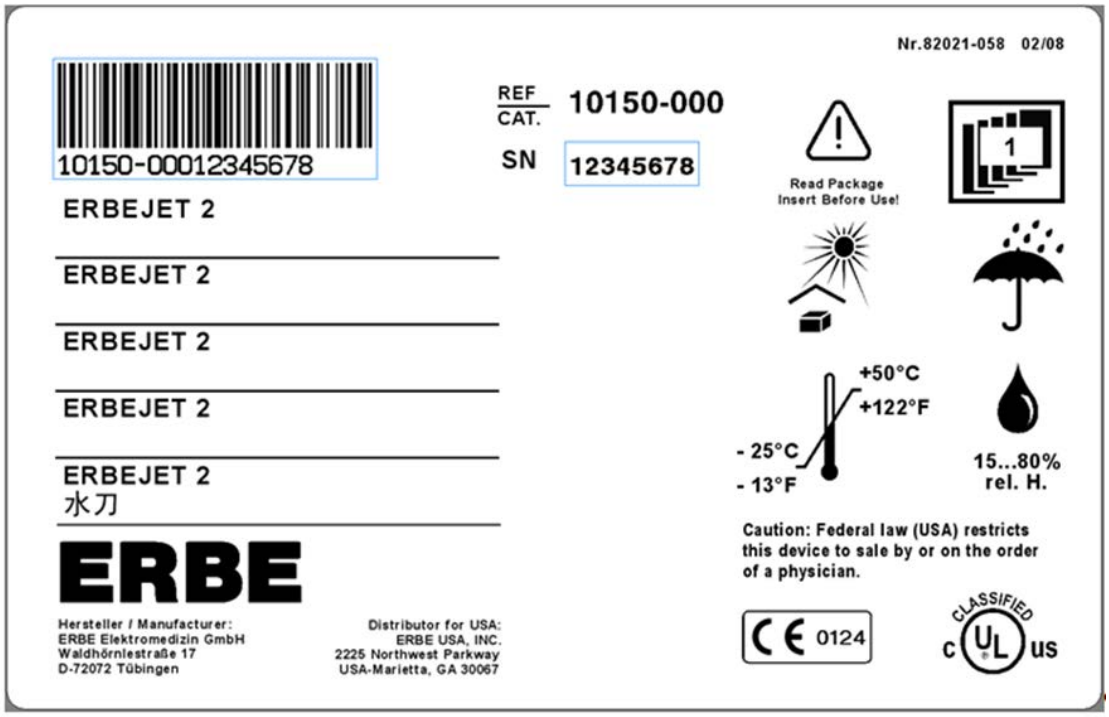
Type Plate Label



Outer Packaging Label

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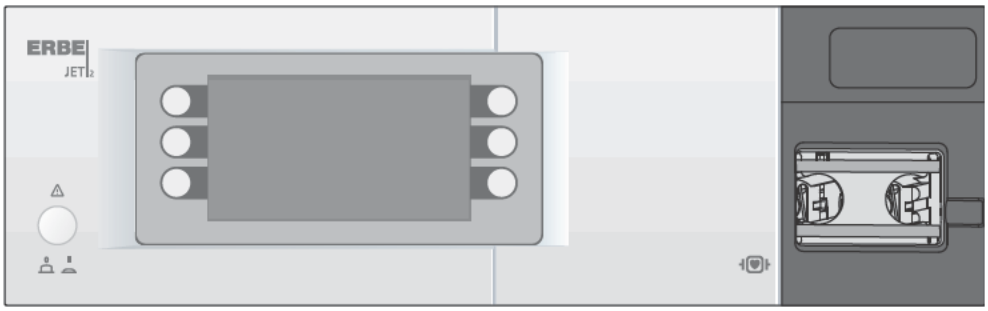
USA

User Manual

ERBEJET® 2

V 1.1.x



xx.xx

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User Manual

ERBEJET® 2

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MEDICAL - GENERAL MEDICAL EQUIPMENT
AS TO ELECTRICAL SHOCK, FIRE
AND MECHANICAL HAZARDS ONLY
IN ACCORDANCE WITH
ANSI/AAMI ES60601-1 (2005),
CAN/CSA-C22.2 No. 60601-1 (2008)
19NA

CE 0124

EN ISO 9001 EN ISO 13485

User Manual Art. No. 80110-814

Product Art. No. 10150-000

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CHAPTER 1

Safety Instructions

Intended Use

The ERBEJET 2 is intended for lifting mucosal lesions by injection into the submucosa as well as the cutting and dissection of soft tissue in neurosurgery and soft tissue such as liver, kidney, etc. within the abdomen, including Total Mesorectal Excision (TME), in open and endoscopic surgery.

Safety notations

⚠ DANGER

indicates an imminently hazardous situation which, if not avoided, will result in death or serious injury.

⚠ WARNING

indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

⚠ CAUTION

indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury.

NOTICE

indicates a potentially hazardous situation which, if not avoided, may result in property damage.

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Meaning of the note

"Note:"

Refers a) to manufacturer's information that relates directly or indirectly to the safety of people or protection of property. The information does not relate directly to a risk or dangerous situation.

Refers b) to manufacturer's information that is important or useful for operating or servicing the unit.

Who must read this User Manual?

Knowledge of the User Manual is absolutely essential for correct operation of the unit.

Therefore everyone who is concerned with

- preparing,
- adjusting,
- operating,

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- disassembling, as well as
- cleaning and disinfecting

the unit must read the User Manual.

Please pay particular attention to the safety instructions in each chapter.

Compliance with safety information

Working with medical equipment is associated with certain risks to patients, medical personnel and the environment. Risks cannot be entirely eliminated by design measures alone.

Safety does not depend solely on the equipment. Safety depends to a large extent on the training of medical personnel and correct operation of the equipment.

The safety instructions in this chapter must be read, understood and applied by everyone who is working with the equipment.

Structure of safety instructions

The safety instructions are structured according to the following risks:

- Operating errors and incorrect installation by persons without training
- Risks due to the environment
- Electric shock
- Risk of infection
- Fire / explosion
- Defective unit, defective accessories
- Interference caused by the unit
- Safety information for use of ERBEJET 2
- Notes

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Operating errors and incorrect installation by persons without training

⚠ WARNING

Operating errors and incorrect installation by persons without training

Persons without training can operate or install the unit incorrectly.

Risk of injury or death for patients and medical staff! Risk of damage to property.

➡ The equipment may only be used and installed by persons who have been trained on how to use and install it properly according to this User Manual.

➡ Training may only be carried out by persons who are suitable on the basis of their knowledge and practical experience.

➡ In the event of uncertainties or if you have any questions, please contact ERBE USA. You will find the contact information at the end of this User Manual.

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Risks due to the environment

NOTICE

Interference with the unit by portable and mobile HF communication devices (e.g. mobile phones, WLAN equipment)

Electromagnetic waves emitted by portable and mobile HF communication devices can effect the unit.

The equipment may fail or not perform properly.

➡ Please see the table "Recommended separation distances between portable and mobile HF communications equipment and the equipment" at the end of this User Manual.

NOTICE

Unsuitable temperature or level of humidity during operation

If you operate the equipment at an unsuitable temperature or level of humidity, it may sustain damage, fail, or not perform properly.

➡ Operate the equipment at a suitable temperature and level of humidity. You will find the tolerances for temperature and humidity in the Technical Data.

➡ If other ambient conditions have to be observed for operation of the equipment, you will also find them in the Technical Data.

NOTICE

Unsuitable temperature or humidity in transit or storage

If you transport or store the equipment at an unsuitable temperature or level of humidity, it may sustain damage and fail.

➡ Transport and store the equipment at a suitable temperature and level of humidity. You will find the tolerances for temperature and humidity in the Technical Data.

➡ If other ambient conditions have to be observed for transport and storage of the equipment, you will also find them in the Technical Data.

NOTICE

Insufficient acclimatization time, unsuitable temperature during acclimatization

If the device was stored or transported below or above a certain temperature, it will take a certain time and temperature to acclimatize.

If you do not observe the rules , the device can sustain damage and fail.

➡ Acclimatize the device according to the rules in the Technical Data.

NOTICE

Overheating of the device due to poor ventilation

If ventilation is poor, the device can overheat, sustain damage, and fail.

➡ Install the device in such a way that there is an unobstructed circulation of air around the housing. Installation in confined wall recesses is prohibited.

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NOTICE

Penetration of liquid into the device

The housing is not absolutely watertight. If liquid penetrates, the device can sustain damage and fail.

- Make sure no liquid can penetrate the device.
- Do not place vessels containing liquids on top of the device.
- Take care when connecting the cutting medium to the pump cartridge that the unit does not come into contact with the cutting medium. The same applies when removing the cutting medium.

Electric shock

⚠ WARNING

Defective grounded power outlet, power supply network without proper grounding, inferior-quality power cord, incorrect line voltage, multiple power outlets, extension cords

Risk of electric shock and other injuries to the patient and medical personnel! Risk of damage to property.

- Connect the unit / the equipment cart to a properly installed grounded power outlet.
- Only connect the unit to a power supply network with proper grounding.
- Only use the ERBE power cord or an equivalent power cord for this purpose. The power cord must bear the applicable national test symbol.
- Check the power cord for damage. You must not use a damaged power cord.
- The supply voltage must match the voltage specified on the unit's rating plate.
- Do not use multiple power outlets.
- Do not use extension cords.

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⚠ WARNING

Incorrect line fuse, defective device

Risk of electric shock to the patient and medical personnel! Risk of damage to property.

- Blown line fuses may only be replaced by a competent technician. Only replacement fuses that have the same rating as the one specified on the unit's rating plate may be used.
- When a fuse has been changed, the function of the unit must be verified. If the unit does not function properly or there are any concerns, please contact ERBE USA.

⚠ WARNING

Connection of unit / equipment cart and power supply during cleaning and disinfection

Risk of electric shock to the medical personnel!

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➡ Switch off the device. Unplug the power cord of the device/ equipment cart.

Risk of infection

⚠ WARNING

Non-sterile accessories or mishandling

The patient can be infected by the use of accessories that should be sterile (e.g. applicator or probe, pump cartridge, etc.) but are not or by contamination due to the mishandling of accessories.

➡ Use only sterile accessories as designated.

➡ Use aseptic techniques during the handling and connection of accessories. Specifically ensure that aseptic techniques are utilized when connecting the applicator or probe as well as the tubing set to the unit (e.g. pump cartridge, etc.).

⚠ WARNING

Non-sterile normal saline and/or tubing set

The patient can be infected by the use of non-sterile normal saline and/or tubing set.

➡ Only use sterile normal saline and tubing set.

⚠ WARNING

Contaminated normal saline by body fluids

Normal saline contaminated with the patient's body fluids spraying or splashing on the medical staff.

Risk of infection for the medical staff.

➡ Wear personal protective equipment (e.g. gown, faceshield or eye protection, mask, gloves, etc.) to minimize the risk of exposure to infectious agents due to undesirable/unexpected spraying or splashing.

➡ Avoid the accumulation of used normal saline with body fluids in the operating area. Ensure adequate suction.

⚠ WARNING

Contaminated accessories

Risk of infection for the medical staff.

➡ Wear personal protective equipment (e.g. gown, faceshield or eye protection, mask, gloves, etc.) to minimize the risk of exposure to infectious agents while handling, disconnecting, and disposing of used accessories.

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Fire / explosion

⚠ WARNING

Ignition of anesthetics, skin cleansers, and disinfectants in potentially explosive atmospheres

If you place the device in a potentially explosive atmosphere, anesthetics, skin cleansers, and disinfectants can ignite.

Risk of fire and explosion to the patient and medical personnel! Risk of damage to property.

➡ Do not place the device in potentially explosive atmospheres.

Defective/Damaged unit and/or accessories

⚠ WARNING

Failure of display elements

If display elements fail, you can no longer operate the device safely.

Risk of injury or death for patients and medical staff!

➡ You must not use the unit.

⚠ WARNING

Routine safety testing not being done

Risk of injury or death for patients and medical staff! Risk of damage to property.

➡ Have the device checked for safety at least once a year.

➡ You must not use a device that is not safe.

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⚠ WARNING

Defective/Damaged device and/or accessories, modified device and/or accessories

Risk of injury to the patient and medical personnel! Risk of damage to property.

➡ Check the unit and accessories (e.g. footswitch, cables, applicators or probe, etc.) for damage every time before use.

➡ You must not use damaged equipment or damaged accessories. Exchange defective accessories.

➡ If the unit or accessories are damaged, please contact customer service.

➡ For your safety and that of the patient: Never attempt to perform repairs or make modifications yourself. Any modification will invalidate liability on the part of ERBE Elektromedizin GmbH.

NOTICE

Alcohol-based spray disinfectant for fast disinfection

With membrane keyboards and paint surfaces there is the risk of cracks. Propanol and ethanol will erode surfaces.

➡ Do not use these substances.

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NOTICE

Alternate use of disinfectant solutions based on different active ingredients

A color reaction may occur with plastics.

➡ Do not use these substances alternately.

Interference caused by the unit

NOTICE

Use of non-approved internal cables by Technical Service

This can result in the increased emission of electromagnetic waves or reduce the immunity of the device.

The equipment may fail or not perform properly.

➡ Technical Service may only use the internal cables that are listed in the service manual for the device.

NOTICE

Stacked devices

If you stack the device next to other equipment or with other equipment, the devices can affect each other.

The equipment may fail or not perform properly.

➡ The device may only be stacked next to or with VIO series units.

➡ If it is necessary to operate the device near other equipment or stacked together with other equipment, check whether the devices are affecting each other: Are the devices behaving unusually? Do errors occur?

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Safety information for use of ERBEJET 2

⚠ WARNING

Use of unsuitable solutions

The use of an unsuitable solution can change the effect of the water jet. Risk of injury to the patient.

➡ Only use sterile normal saline.

⚠ WARNING

Effect level set too high

The higher the effect level, the greater the risk of accidental tissue damage.

➡ Use the lowest possible effect setting to achieve the desired surgical outcome. Always begin at a low setting and increase as necessary.

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⚠ WARNING

Activating without confirming settings on the screen

If the user does not verify that the settings on the display are appropriate/desired, then the greater the risk of accidental tissue damage.

➡ Prior to activation, confirm that the desired settings are displayed on the unit's screen.

⚠ CAUTION

During the priming process, normal saline may come out the tip of the applicator or probe

Depending on the dimensions of the applicator or probe, normal saline may come out the tip and damage skin or the eyes.

➡ Never point the applicator or probe tip at medical personnel. Never point the the tip of the applicator or probe at the patient during the priming process.

➡ For safety purposes, medical personnel should wear personal protective equipment (e.g. gown, faceshield or eye protection, mask, gloves, etc.).

➡ During priming, if normal saline comes out the tip of the applicator or probe, stop the process by pressing the display/selection button R2 that corresponds with *STOP* on the screen.

⚠ CAUTION

Uncontrolled use of the equipment

Uncontrolled use of the water jet can cause unintentional damage to skin or eyes.

➡ Do not point the applicator or probe tip at medical personnel or accidentally point it at the patient.

➡ For safety purposes, medical personnel should wear personal protective equipment (e.g. gown, faceshield or eye protection, mask, gloves, etc.).

➡ Only direct the tip of the applicator or probe at the operative site and only activate to cut or dissect and/or suction as necessary.

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NOTICE

Tension on an applicator's delivery tubing/suction hose junction

If an applicator hose's delivery tubing/suction hose junction is subjected to tension, it may leak aspirated fluids that could be contaminated from the branch (1).

➡ For applicators with suction, do not subject the delivery tubing/suction hose junction to tension.

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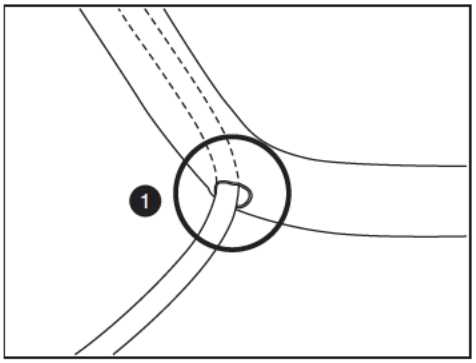

Fig. 1-1

NOTICE

Applicator's or probe's delivery tubing and/or suction hose kinked

If the delivery tubing and/or suction hose is kinked/crimped, the delivery of the normal saline and/or the suction will decrease or cease. If the crimp is severe (in the delivery tubing or the delivery tubing inside the suction hose), the ERBEJET 2 will display a message prompting a pump cartridge (including an applicator or probe) change.

➡ Do not kink the delivery tubing and/or suction hose.

Application Precautions

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In General and Endoscopic Procedures

1. Wearing of protective glasses and the use of a sheet (waterproof barrier drape) that surrounds the area of dissection are recommended.
2. Heating of the normal saline to 40 °C (104 °F) prior to the procedure may result in less foaming and positive effect on local blood coagulation. Therefore heating is recommended and can be achieved using a designated warmer unit designed for infusion/irrigation fluids.
3. In laparoscopy/endoscopy, maintain optimal visibility (i.e., minimize/ prevent splashing and foaming) and equilibration in the cavity by keeping the tip of the applicator close to the tissue, adequately suctioning, and keeping the scope farther back during activation.
4. With an ESM 2 attached, the suction pressure can be adjusted via the display screen of the ERBEJET 2 to maximize the aspiration of the minute amounts of dissecting medium (saline) and maintain adequate pneumoperitoneum.
5. Blood vessels may be disrupted by the water jet depending on the effect / pressure setting.
6. Keep a margin of safety. Dissection of the tissue should be made at an adequate distance from the edge of the carcinoma.
7. In case of longer surgical procedures, control of serum electrolyte levels is recommended.

In Renal Procedures

1. The ERBEJET 2 is not intended for dissection of the renal capsule.
2. Resection with the ERBEJET 2 may produce a zone of vacuolization of 100 - 300 µm (e.g., in renal surgery).

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In Neurosurgical Procedures

1. In neurosurgery, the ERBEJET 2 is not intended for dissecting tumor capsules. Furthermore, in addition to the device, conventional methods may be required to dissect/remove firmer masses or structures from the brain parenchyma.

Notes

Grounding

Note: If necessary, the equipment can be connected to the external grounding system of the room with the grounding pin on the back of the unit and/or Cart using a connecting cable designed for this purpose. Affects of low frequency leakage currents due to a defective grounding system within the room may be eliminated through external grounding.

Use of a defibrillator

Note: The equipment conforms to the requirements of Type CF and is protected against the effects of a defibrillator discharge.

Membrane keyboards

Note: If alcohol-based disinfectants are used on units with membrane keyboards, the anti-glare finish will be removed. However, the user surfaces remain fully functional.

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CHAPTER 2

Description of the Controls

Controls on the front panel

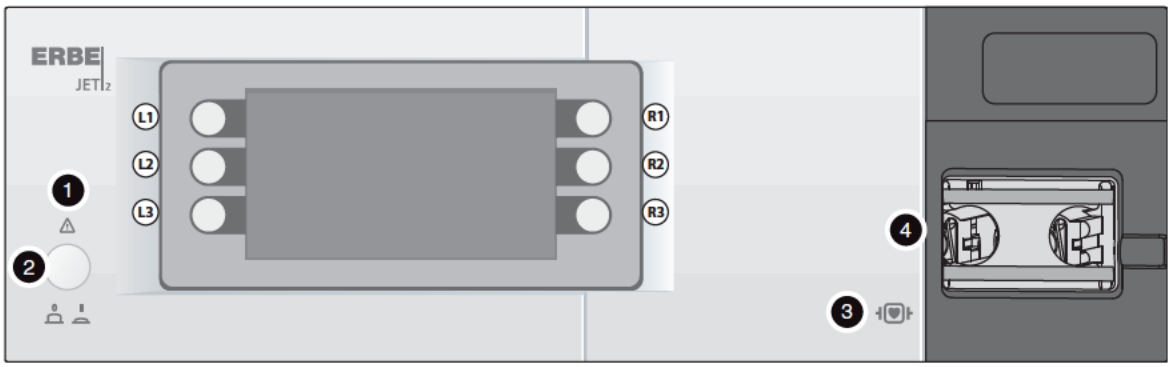

Fig. 2-1

Symbol **(1)**

Instructs medical personnel to read the User Manual before switching on and using the unit.

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Power switch **(2)**

Unit's "On" / "Off" switch.

Symbol **(3)**

Designates that the equipment conforms to the requirements of Type CF (Cardiac Float) and is protected against the effects of a defibrillator discharge.

Pump cartridge slot **(4)**

Slot to insert a pump cartridge.

Display/Selection buttons **(L1) (L2) (L3) (R1) (R2) (R3)**

Buttons that correlate to different functions depending on what is displayed on the screen. Take note of the function(s) that refers to the respective buttons.

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Controls on the back

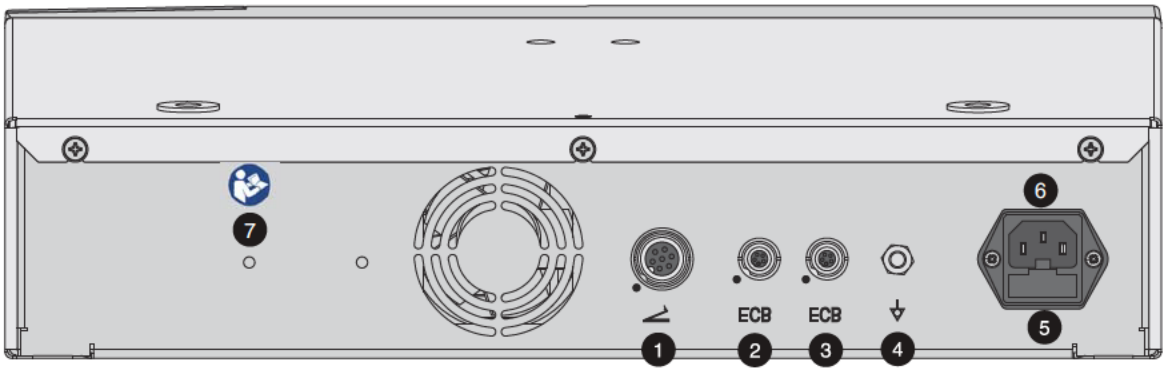

Fig. 2-2

Sockets **(1) Footswitch socket**

Socket to connect an ERBEJET 2 footswitch.

(2) (3) ERBE Communication Bus (ECB) socket

Sockets for connecting compatible ERBE equipment (e.g. ESM 2) via an ECB cable. The ECB ensures communication between the units. Connect an ECB cable to one of these sockets and then to the compatible equipment.

Grounding Terminal Pin **(4)**

Pin to ground the unit via a grounding connecting cable and a ground source. The unit may be grounded to an ERBE VIO Cart as applicable. Then the ERBE VIO Cart could be grounded to the room's external grounding system (Note: The unit could be directly grounded to the external grounding system of the room via a connecting cable designed for this purpose.). Affects of low frequency leakage currents due to a defective grounding system within the room may be eliminated through external grounding.

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Power Fuses **(5)**

Fuses for protecting the unit. If a fuse is blown, then a spare fuse with the same power rating must be used as its replacement. However, the unit must be checked out by a trained technician and found to be performing within specifications prior to being used in patient procedures.

Power connection **(6)**

Unit's socket for connecting it to a power supply via an ERBE power cord or an equivalent (hospital grade) power cord for this purpose. The unit may be connected to the power strip on an ERBE VIO Cart Art. No. 20180-000 as applicable. Then the cart is connected to a power supply. Nonetheless, the power supply outlet must be properly grounded and within the unit's voltage requirements.

Symbol **(7)**

Instructs medical personnel to read the User Manual before switching on and using the unit.

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CHAPTER 3

Working with ERBEJET 2

Turning "On" the unit, connecting an applicator or probe

Note: If a suction module, Model ESM 2 is to be used in conjuction with the ERBEJET 2 then refer to the ESM 2 User Manual for its installation and installation of its components as well as attaching accessories.

⚠ WARNING

Defective/Damaged device and/or accessories, modified device and/or accessories

Risk of injury to the patient and medical personnel! Risk of damage to property.

- Check the unit and accessories (e.g. footswitch, cables, applicators or probe, etc.) for damage every time before use.
- You must not use damaged equipment or damaged accessories. Exchange defective accessories.
- If the unit or accessories are damaged, please contact customer service.
- For your safety and that of the patient: Never attempt to perform repairs or make modifications yourself. Any modification will invalidate liability on the part of ERBE Elektromedizin GmbH.

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Turning "On" the unit

Fig. 3-1

1. Use the power switch to turn the ERBEJET 2 "On". The unit performs a self check. As a part of the unit's selfcheck it will recognize an attached footswitch as well as compatible equipment (e.g. ESM 2) that is connected and turned "On". Also, the software version of the unit and attachments respectively will be displayed during the selfcheck.

⚠ WARNING

Failure of display elements

If display elements fail, you can no longer operate the device safely.

Risk of injury or death for patients and medical staff!

- You must not use the unit.

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Connecting an applicator or probe

⚠ WARNING

Non-sterile accessories or mishandling

The patient can be infected by the use of accessories that should be sterile (e.g. applicator or probe, pump cartridge, etc.) but are not or by contamination due to the mishandling of accessories.

- ➡ Use only sterile accessories as designated.
- ➡ Use aseptic techniques during the handling and connection of accessories. Specifically ensure that aseptic techniques are utilized when connecting the applicator or probe as well as the tubing set to the unit (e.g. pump cartridge, etc.).

1. Open intact packages of an applicator or probe and a pump cartridge onto the sterile field while ensuring/verifying the integrity of the accessories.

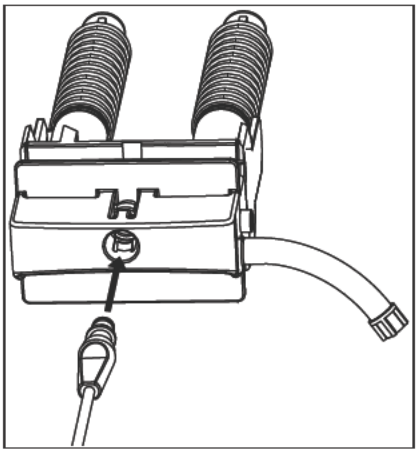

Fig. 3-2

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2. Remove the protective cap from the applicator's or probe's connector of the delivery tubing and insert the connector into the hole of the pump cartridge. It should lock into place and not be able to be removed from the cartridge.

Selecting a program, connecting a pump cartridge, connecting normal saline, priming the pump cartridge and the applicator or probe

Selecting a program

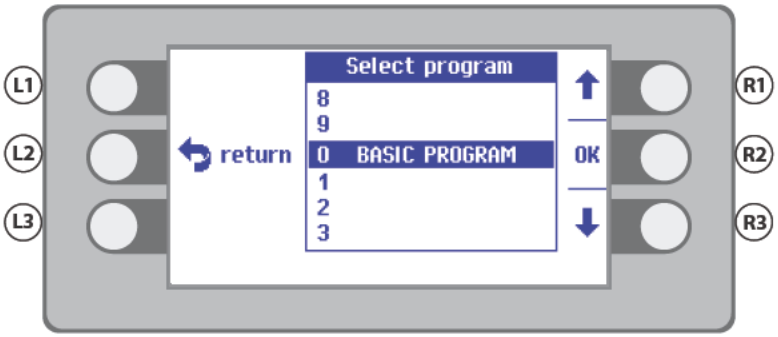

Fig. 3-3

1. When the ERBEJET 2 has been turned "On" and completed its power up sequence, a selection list of programs should be displayed on the unit's screen.

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2. Scan and view all programs in the list by using display/selection buttons R1 and R3.
3. When the desired program is in the middle of the screen and highlighted at "OK", press display/selection button R2. **Example: 0 BASIC PROGRAM**

Fig. 3-4

4. Once the desired program is selected, the system will prompt you to insert a new pump cartridge.

Connecting a pump cartridge

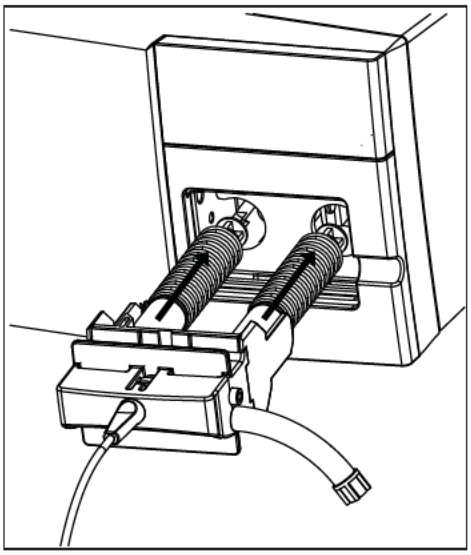

Fig. 3-5

1. Slide the pump cartridge (with the attached applicator or probe) into the pump cartridge slot of the unit until it is engaged. The screen should display "Connecting cartridge - Please wait" and then "Ready".

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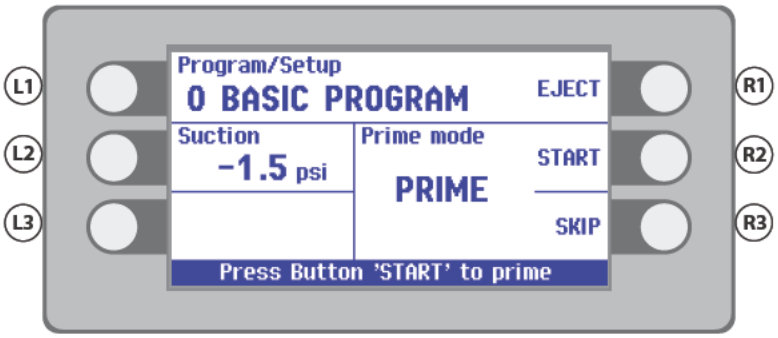

Fig. 3-6

2. As soon as the pump cartridge has been connected, the system will prompt you to prime the pump cartridge with applicator or probe. However, normal saline will need to be connected prior to the priming process of the pump cartridge.

Connecting normal saline

⚠ WARNING

Use of unsuitable solutions

The use of an unsuitable solution can change the effect of the water jet. Risk of injury to the patient.

➡ Only use sterile normal saline.

⚠ WARNING

Non-sterile normal saline and/or tubing set

The patient can be infected by the use of non-sterile normal saline and/or tubing set.

➡ Only use sterile normal saline and tubing set.

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⚠ WARNING

Non-sterile accessories or mishandling

The patient can be infected by the use of accessories that should be sterile (e.g. applicator or probe, pump cartridge, etc.) but are not or by contamination due to the mishandling of accessories.

➡ Use only sterile accessories as designated.

➡ Use aseptic techniques during the handling and connection of accessories. Specifically ensure that aseptic techniques are utilized when connecting the applicator or probe as well as the tubing set to the unit (e.g. pump cartridge, etc.).

1. With the tubing set, spike and hang the bag of normal saline. Open the line to allow the solution to migrate to the end of the tubing.

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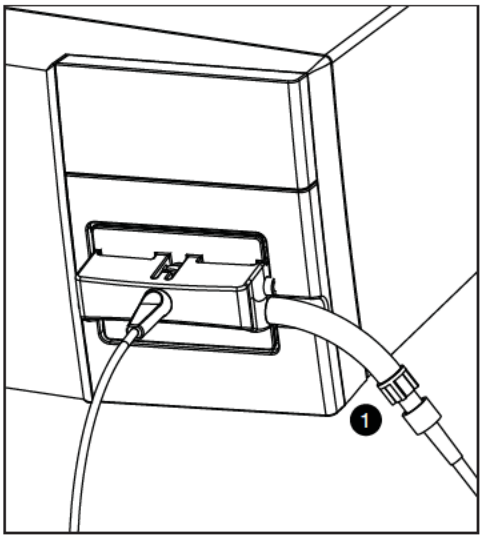

Fig. 3-7

2. Remove the protective cap from the luer lock of the pump cartridge. Connect the primed tubing to the luer lock (1).

Priming the pump cartridge and the applicator or probe

⚠ CAUTION

During the priming process, normal saline may come out the tip of the applicator or probe

Depending on the dimensions of the applicator or probe, normal saline may come out the tip and damage skin or the eyes.

- Never point the applicator or probe tip at medical personnel. Never point the the tip of the applicator or probe at the patient during the priming process.
- For safety purposes, medical personnel should wear personal protective equipment (e.g. gown, faceshield or eye protection, mask, gloves, etc.).
- During priming, if normal saline comes out the tip of the applicator or probe, stop the process by pressing the display/selection button R2 that corresponds with *STOP* on the screen.

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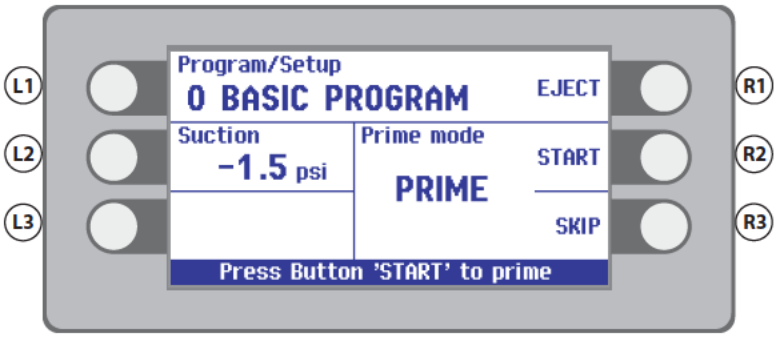

Fig. 3-8

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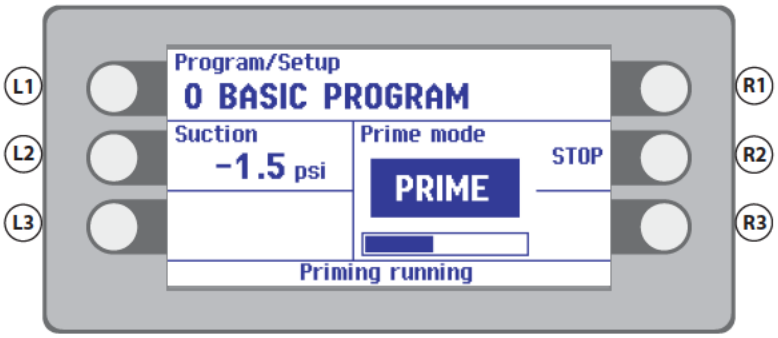

Fig. 3-9

1. On the screen in the Prime mode, select START by pressing display/selection button R2 to prime the pump cartridge. However in the Prime mode, *SKIP* can be selected by pressing display/selection button R3 to avert any priming if desired at this time.

2. If the Prime Mode is initiated, priming can be stopped at anytime during the process. During "Priming running", select *STOP* by pressing display/selection button R2. Stop priming if normal saline comes out the tip of the applicator or probe (See Safety Instuctions.).

3. Complete or perform the priming of the pump cartridge and applicator or probe (i.e. the delivery tubing) by depressing the attached footswitch. The time that it takes to have the cartridge and tubing primed will be depended upon the Effect setting of the program being used (Note: An Effect of 20 in the Basic program could be employed for priming.). Nonetheless, priming will be complete when the air is displaced and the water jet stream is consistent from the applicator or probe tip (See Safety Instuctions.)

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Attaching as applicable the applicator's suction hose

NOTICE

Tension on an applicator's delivery tubing/suction hose junction

If an applicator hose's delivery tubing/suction hose junction is subjected to tension, it may leak aspirated fluids that could be contaminated from the branch (1).

➡ For applicators with suction, do not subject the delivery tubing/suction hose junction to tension.

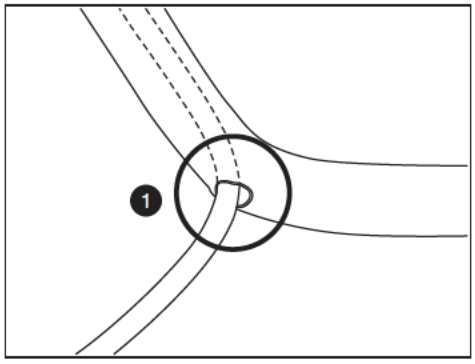

Fig. 3-10

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Note: The ESM 2 is only to be used with the ERBEJET 2 and an ERBEJET 2 applicator with suction.

1. If using the ESM 2, follow the connection instructions in its User Manual. In general, the suction hose of the applicator is to be attached to the suction (patient) port on the lid of an ESM suction container with a bag. The ESM 2 must also be appropriately linked up with the ERBEJET 2 via an ECB cable, connected to the suction container, and turned "On".

Note: The suction hose of an ERBEJET 2 applicator with suction may be connected to an alternative suction device, but the suction (vacuum) pressure must not exceed -11.6 psi (-800 mbar).

Viewing a program as well as selecting settings for effect and suction

Viewing a program

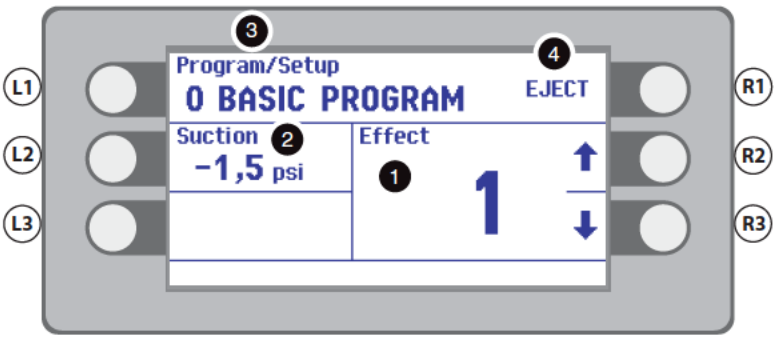

Fig. 3-11

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Note: If the suction module Model ESM 2 is not used/connected and turned "On", then the setting on the screen for Suction will be "off-line".

The following parameters are stored in each program:

- *Effect*
- *Suction*

In the program you can:

- Change the *Effect* (1).
- Access the features and parameters for *Suction* (2)
- Access the elements of the *Program/Setup* (3)

Note: Setup, Service, Save/Erase Program, Select Program, and Return are the categories/possibilities in "Program/Setup" which can be accessed by pressing display/selection button L1.

- If connected, remove the pump cartridge from the unit with *EJECT* (4) by pressing the display/selection button R1.

Note: "EJECT" will not appear on the screen or be an option if a pump cartridge is not already engaged in the unit.

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Selecting effect

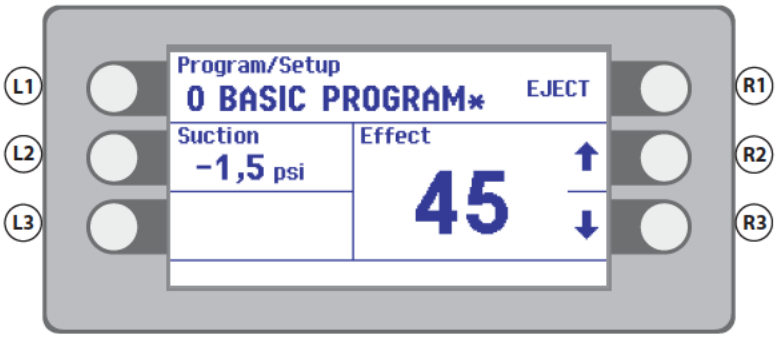
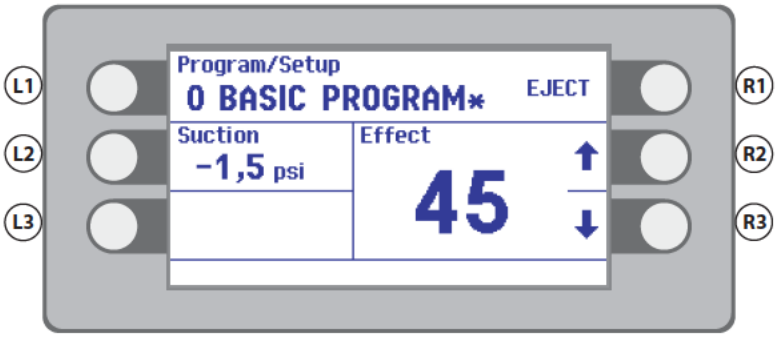


Fig. 3-12

Decrease or increase the *Effect* by pressing display/selection buttons R3 and R2 respectively within a range of Effect from 1 to 80. **Example setting: Effect 45**.

Note: The selected Effect psi equivalent will be displayed on the bottom of the screen. That is for the above example of Effect 45, "Corresponds to 652 psi" will be on the display for 3 seconds upon being selected.

Accessing and selecting features as well as parameters of suction



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Note: The possibility of suctioning with the system can only be achieved by using an ERBEJET 2 applicator with suction and the suction module Model ESM 2.

Access features and parameters for *Suction* by pressing display/selection button L2.

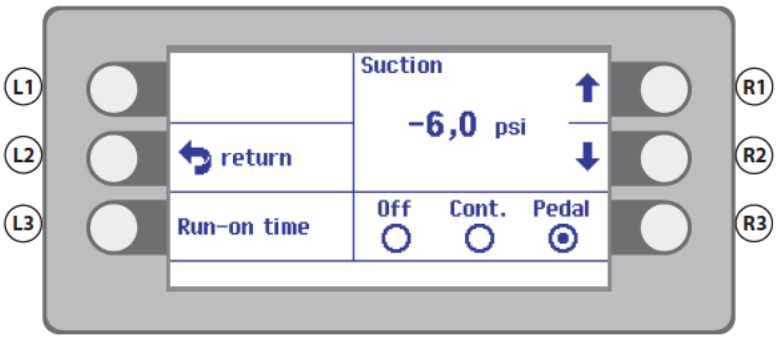

Fig. 3-13

For *Suction*, several features and parameters can be set as follows:

To set the type of suction, press display/selection button R3 to select;

- *Off*: If no suction is desired,
- *Cont*: If a continuous suction is preferred, or

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Note: With "Cont.", the selected suction psi will be constant and independent of activating the water jet via the pedal.

- *Pedal*: If suction upon pedal activation is needed.

Note: With the selection of "Pedal", another feature designated as "Run-on time" is a possibility.

Example Selection: Pedal.

To increase or decrease the *Suction* press display/selection buttons R1 and R2 respectively within a range of Suction from -1.5 to -12 psi. **Example setting: - 6.0 psi**.

To have suction for a period of time after activating the water jet (i.e. upon removing foot from pedal), a *Run-on time* may be selected by pressing display/selection button L3.

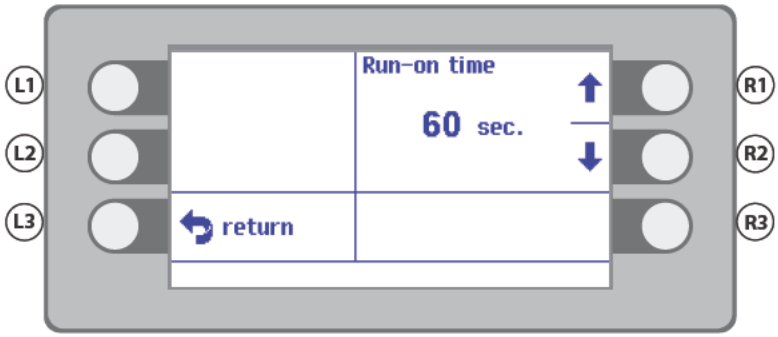

Fig. 3-14

The time of suctioning after the activation of the water jet (*Run-on time*) can be increased and decreased by pressing display/selection buttons R1 and R2 respectively within a range of Time from Off to 60 seconds (sec.). **Example setting: 60 sec.**

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Note: A return to the program from the *Run-on time* screen can be achieved through selecting the return designation by pressing the display/selection button L3. Where as from the screen of the features/parameters for Suction, select the return designation by pressing the display/selection button L2.

Activation

⚠ WARNING

Effect level set too high

The higher the effect level, the greater the risk of accidental tissue damage.

➡ Use the lowest possible effect setting to achieve the desired surgical outcome. Always begin at a low setting and increase as necessary.

⚠ WARNING

Activating without confirming settings on the screen

If the user does not verify that the settings on the display are appropriate/desired, then the greater the risk of accidental tissue damage.

➡ Prior to activation, confirm that the desired settings are displayed on the unit's screen.

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⚠ CAUTION

Uncontrolled use of the equipment

Uncontrolled use of the water jet can cause unintentional damage to skin or eyes.

- Do not point the applicator or probe tip at medical personnel or accidentally point it at the patient.
- For safety purposes, medical personnel should wear personal protective equipment (e.g. gown, faceshield or eye protection, mask, gloves, etc.).
- Only direct the tip of the applicator or probe at the operative site and only activate to cut or dissect and/or suction as necessary.

NOTICE

Applicator's or probe's delivery tubing and/or suction hose kinked

If the delivery tubing and/or suction hose is kinked/crimped, the delivery of the normal saline and/or the suction will decrease or cease. If the crimp is severe (in the delivery tubing or the delivery tubing inside the suction hose), the ERBEJET 2 will display a message prompting a pump cartridge (including an applicator or probe) change.

- Do not kink the delivery tubing and/or suction hose.

⚠ WARNING

Contaminated normal saline by body fluids

Normal saline contaminated with the patient's body fluids spraying or splashing on the medical staff.

Risk of infection for the medical staff.

- Wear personal protective equipment (e.g. gown, faceshield or eye protection, mask, gloves, etc.) to minimize the risk of exposure to infectious agents due to undesirable/unexpected spraying or splashing.
- Avoid the accumulation of used normal saline with body fluids in the operating area. Ensure adequate suction.

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Cutting/Dissection and suction possibilities	Suction features and as applicable setting	Pedal activation required
Cutting/Dissection Only	Off	Yes
Cutting/Dissection and Suction Only when Activated	Pedal, Run-on time Off	Yes
Cutting/Dissection when Activated and Suction Continuing upon Activation for a Period of Time	Pedal, Run-on time 1 to 60 sec. (seconds)	Yes
Cutting/Dissection when Activated and Suction Continuous	Cont. (Continuous)	Yes
Suction Only	Cont. (Continuous)	No

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Note: During activation (i.e. when the pedal of the footswitch is depressed), the Effect on the screen will be highlighted in blue. As set and/or selected, an activation tone may also be heard. Also, it is possible to make changes to the Effect during operation. If changes are made an (*) will appear at the end of the program name. Be aware that any changes of settings in a program will be lost unless saved as new or by overwriting.

Upon deactivation (i.e. when your foot is removed from the pedal of the footswitch), there is residual pressure and normal saline in the line which will dissipate. Therefore, keep the tip of the applicator pointed at the surgical site for a few seconds after activation until saline is no longer being delivered.

Note: During suction, the set maximum vacuum is shown inverted on the display of ERBEJET 2 (white numbers on blue background).

Using the basic program to create and save a new program as well as new programs for the ReMode function

Using the basic program to create and save a new program

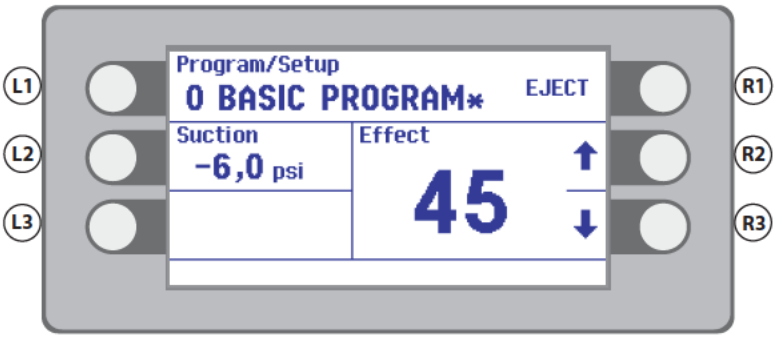

Fig. 3-15

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Upon selecting the basic program and making any changes, an (*) will appear at the end of the program name. The changes will be lost unless they are saved as a new program.

Note: Overwriting/Permanent changes to the basic program and saving those changes as the basic program is not possible.

Choose all the desired parameters and features for Effect and as applicable Suction (settings, etc.) for the new program being created, then perform the following steps.

1. On the screen displayed, select *Program/Setup* by pressing display/selection button L1.
2. On the screen displayed, select *SAVE/ERASE program* by pressing display/selection button L3.
3. On the screen displayed, select *SAVE* by pressing display/selection button L1.
4. On the screen displayed, select *SAVE settings as new Program by pressing display/selection button L2*.

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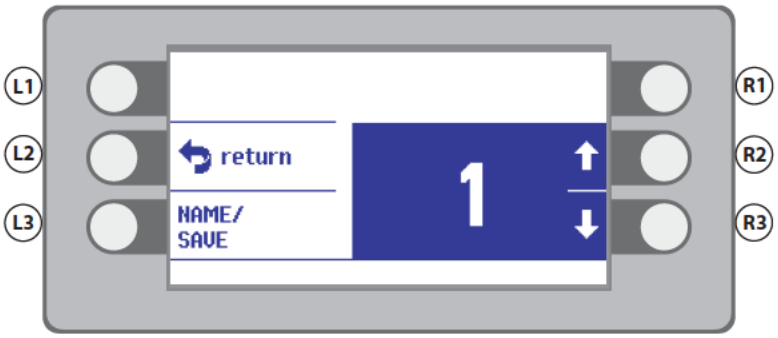

Fig. 3-16

5. On the screen displayed, the sequential remaining open numbers for the new program will be accessible by increasing or decreasing the number using display/selection buttons R2 and R3 respectively within a range of possible saved programs from 1 to 9. **Example: 1**

6. Upon selecting the program number, select *NAME/SAVE* by pressing display/selection button L3.

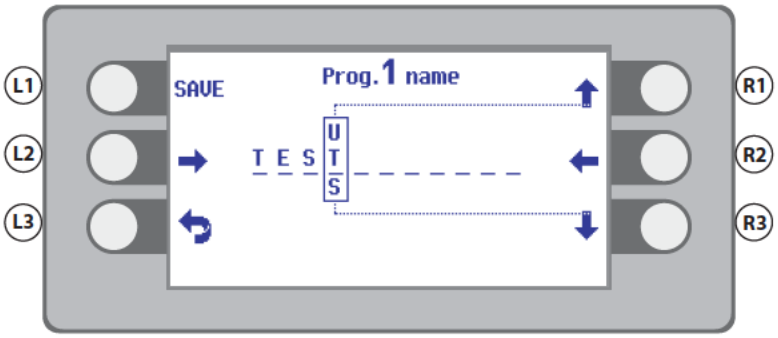

Fig. 3-17

7. Identify/Name the new program with a character range from 1 to 11 spaces. For each space, scroll through the characters up and down using display/selection buttons R1 and R3 respectively within a range of 0 to 9, blank space, all alphabet letters and a period.

8. Characters are selected by positioning it to correspond with display/selection button R2. Then to add the next character (to the right) as necessary, press display/selection button L2.

9. Repeat step 8 to add characters as needed to identify/name the new program. **Example: TEST**.

10. Upon identifying/naming the new program, select *SAVE* by pressing and holding display/selection button L1 until the message *PROGRAM SAVED* appears on the screen.

11. Select the return designation (which will display the new program) by pressing display/selection button L3.

Creating and saving programs for the ReMode function

Two programs can be set up so that the user can toggle (i.e. go back and forth) between the programs by pressing the ReMode button on the footswitch. For this purpose, a and b level programs are created and saved by performing the following sequences and steps.

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Creating and saving program a

Fig. 3-18

1. Starting with the basic program, make changes to settings to create, name, and save first program as previously instructed. Also, return to the newly created program.

Note: The identifier (a) will be assigned for this program when the b program is created, etc. For this exercise, the program was assigned program number 2 and named EXAMPLE (See below).

Creating and saving program b

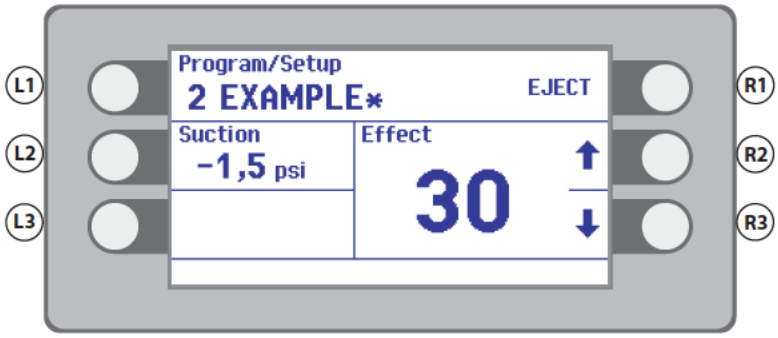

Fig. 3-19

1. Change the settings as desired of the newly created program (i.e. 2 EXAMPLE).
2. On the screen displayed, select *Program/Setup* by pressing display/selection button L1.
3. On the screen displayed, select *SAVE/ERASE program* by pressing display/selection button L3.
4. On the screen displayed, select *SAVE* by pressing display/selection button L1.
5. On the screen displayed, select *SAVE settings as new Program by pressing display/selection button L2*.

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Fig. 3-20

6. On the screen displayed, the program number and level for the second program (b) will be assigned (For this exercise the program number was 2 and now b is assigned.). To continue, select *NAME/SAVE* by pressing display/selection button L3.
7. On the screen displayed, select *SAVE* by pressing and holding display/selection button L1 until the message *PROGRAM SAVED* appears on the screen.
8. Select the return designation (which will display the second newly created program) by pressing display/selection button L3.
9. To view the created programs in the list for the ReMode function, select *Program/Setup* by pressing display/selection button L1. On this next screen, choose *SELECT program* by pressing display/selection button L2.

   Note: The second program (b) may be identified/named differently than the first program (a) as previously instructed. However, the program number as well as a and b levels will remain.

With the ReMode button on the footswitch, it is now possible to toggle (i.e. go back and forth) between the two a and b level programs.

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Deleting and overwriting a program

Deleting a program

1. On the screen displayed for the program being deleted, select *Program/Setup* by pressing display/selection button L1.
2. On the screen displayed, select *SAVE/ERASE program* by pressing display/selection button L3.
3. On the screen displayed, select *ERASE program* by pressing display/selection button L2.
4. On the screen displayed, select *ERASE program* by pressing and holding display/selection button L3 until message PROGRAM ERASED appears on the screen.
5. Select the return designation by pressing display/selection button L2 (this will show the name and settings erased and display the basic program settings unless it is a ReMode program. In that case, it will display the other associated program).

Note: To see the remaining available programs and see that the program is no longer in the list, select *Program/Setup* by pressing display/selection button L1. On this next screen, choose *SELECT program* by pressing display/selection button L2.

Overwriting a program

1. On the screen displayed for the program being overwritten (i.e. for cases where changes were made to the settings and now want to be saved for the program), select *Program/Setup* by pressing display/selection button L1.

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2. On the screen displayed, select *SAVE/ERASE program* by pressing display/selection button L3.
3. On the screen displayed, select *SAVE program* by pressing display/selection button L1.
4. On the screen displayed, select *OVERWRITE current Program* by pressing display/selection button L3.
5. On the screen displayed, select *SAVE* by pressing and holding display/selection button L1 until message PROGRAM SAVED appears on the screen.

   Note: The revised/overwritten program may be identified/named differently by following previous instructions.
6. Select the return designation (which will display the revised/overwritten program) by pressing display/selection button L3.

Fluid Volume Pumped Signal (ml-signal)

A feature to alert the clinicain via an audio tone when each ml of normal saline is pumped can be turned "On" in the Setup program. To activate this option, *ml-signal,* see the following section "Accessing and changing parameters in Setup".

Displaying delivered fluid volume, Resetting fluid volume being displayed (Volume Measurement)

Displaying delivered fluid volume

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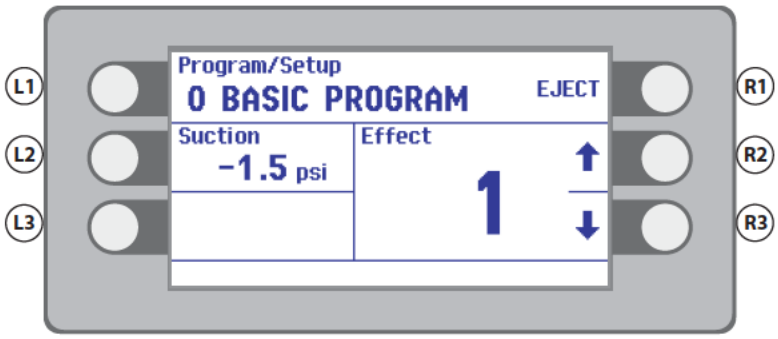

Fig. 3-21

A feature to be informed of the volume of fluid delivered per pump cartridge or as desired with a cartridge can be turned "On". However contact an ERBE representative to have this feature, *Volume Measurement*, activated (Note: It is turned "On" in the Service program of the system which requires an access code to enter the program.).

1. Once this feature is turned "On.", then on the screen displayed select *Program/Setup by pressing display/selection button L1*.

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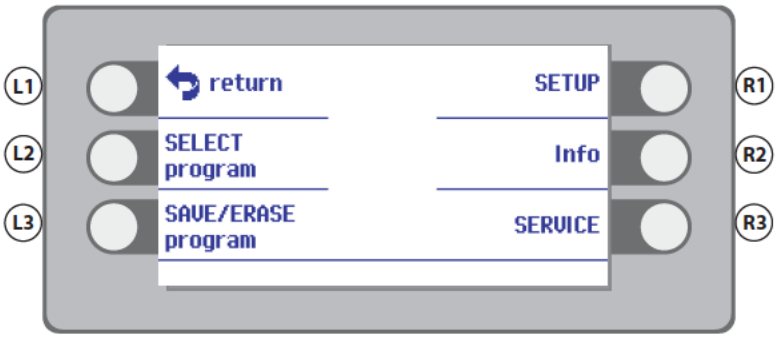

Fig. 3-22

2. On the screen displayed, select Info by pressing display/selection button R2.

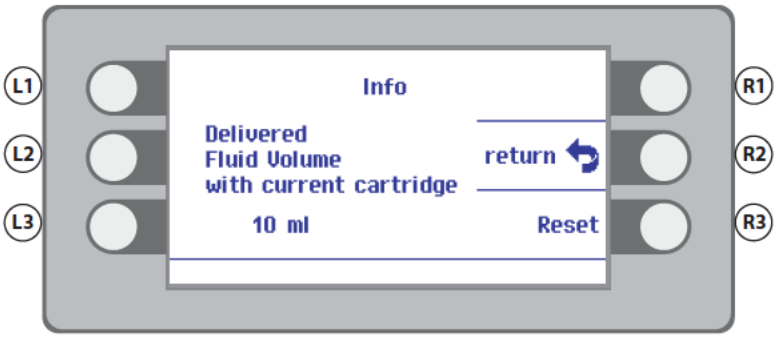

Fig. 3-23

Resetting fluid volume being displayed

When inserting a new pump cartridge, the display of the delivered fluid volume is automatically reset to 0. Also, when using a pump cartridge the fluid volume can be reset to 0 at anytime. This can be accomplished on the screen displayed in Info for *Reset* by pressing display/selection R3 (Note: Enter Info to see the delivered fluid volume).

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Equivalent unit of pressure

Besides psi, the corresponding equivalent Effect setting can be displayed in mbar or kPa. However the possibility of having one of these other unit of pressures shown at the bottom of the display screen, the change will need to be made in the Service program. Please contact an ERBE representative to assist if desired in changing the Effect's correponding value that is displayed for 3 seconds at the bottom of the screen from psi to mbar or kPa.

Accessing and changing parameters in Setup

In Setup, several visual and sound acuities as well as an automatic time can be adjusted/tailored to the needs of your facility. Adjustments can be made to these settings as follows.

1. From a display screen of a program, select *Program/Setup* by pressing display/selection button L1.
2. On the screen displayed, select *SETUP* by pressing display/selection button R1.

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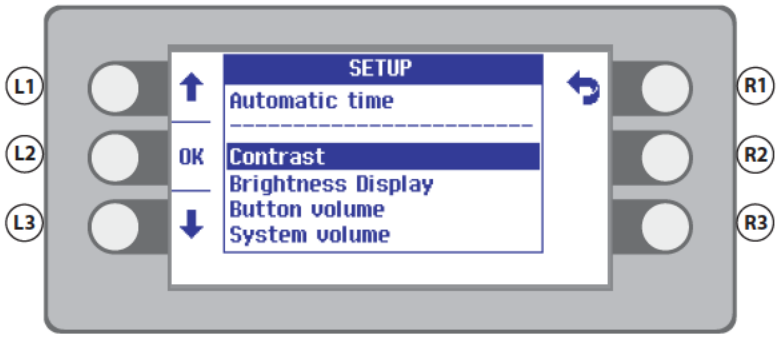

Fig. 3-24

3. Scan and view all setup parameters in the list by using display/selection buttons L1 and L3.
4. When the desired parameter is in the middle of the screen and highlighted at "OK", press display/selection button L2. **Example: Contrast**

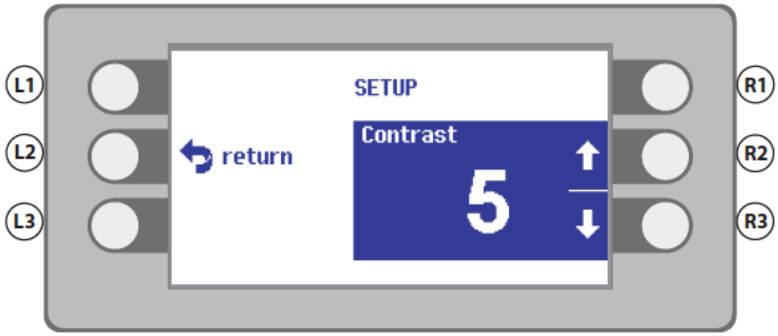

Fig. 3-25

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5. The settings of the parameter can be increased or decreased by pressing the display/selection buttons R2 and R3 respectively. **Example: Contrast 5**.
6. Upon setting the parameter at the desired level, select the return designation by pressing display/selection button L2 to return to the list of the other parameters in Setup.

The following are all the parameters that can be adjusted in Setup with the range of levels.

- **Contrast:** Screen contrast in 10 levels.
- **Brightness Display:** Screen brightness in 10 levels.
- **Button volume:** Sound volume upon depressing a button in 10 levels (1 to 10) or "Off".
- **ml-signal volume:** Sound volume after every ml of normal saline pumped from the system in 10 levels (1 to 10) or "Off".
- **System volume:** Sound volume of alarms/warning signals in 8 levels (3 to 10). The sound must be at a level that is clearly audible!
- **Activation volume:** Sound volume upon/during activation in 10 levels (1 to 10) or "Off"
- **Automatic time**: Time in which the screen displayed will default to the display screen of the selected or highlighted program (if not already displaying the program screen) in times of Off and 3 to 30 sec. (seconds). If "Off" is selected then screens will not default to the selected/highlighted program display screen.

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CHAPTER 4

Status Messages, Error Messages

Status messages in alphabetical order

Status messages are of an informative nature or will prompt you to take operational action.

Status message	Description
Connecting cartridge - Please wait	The unit is in the process of integrating/attaching the new pump cartridge.
ERBEJET has cooled down! / Activation is possible again!	The ERBEJET 2 has overheated and now is cool enough to resume activation.
Please insert new cartridge!	A new pump cartridge needs to be inserted into the unit's pump cartridge slot.
Press button 'START' to prime	Mode to prime the pump cartridge (Note: Complete priming of the applicator's or probe's delivery tubing is still necessary.).
Priming running	The time in which the pump cartridge is priming.
Priming completed.	Completion of priming the pump cartridge.
Priming aborted	Priming of the pump cartridge has been ceased by the operator upon pressing STOP that was on the displayed screen via display/selection button R2.
Ready	Note: Ensure that all of the tubing is connected, primed, etc. prior to activation for clinical use.
Referencing completed	If referencing was needed, then the unit's drives have reached their starting positions.
Referencing running-please wait	Upon powering up the unit (i.e. the ERBEJET 2) and during the selfcheck, the device may need to reset its drives to their starting positions which will cause this message to occur.
Remove used cartridge!	The used pump cartridge needs to be removed from unit's pump cartridge slot.
Suction Module recognized!	The suction module, Model ESM 2 has been connected (via an ECB cable) to the ERBEJET 2 as well as turned "On". It is ready to suction per the programming and/or setting of the ERBEJET 2.
The footswitch has been disconnected	The footswitch has been detached from the unit.
The footswitch is ready for operation	The footswitch has been attached to the unit.
Uncoupling cartridge - Please wait	The unit is in the process of disconnecting/ejecting the used pump cartridge.

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Error messages

An error message consists of an Error Code (EC) and/or a text. The ERBEJET 2 will display two different types of error messages as follows.

a) Error messages that are more related to problems or defects with the unit(s), components, and/or accessories (i.e. device related). They have an Error Code as well as text and can be found in the following table: Error messages in numerical order.

b) Error messages that are more related to the user (but they also include messages relating to the mishandling and/or damaging of the unit(s), components, and/or accessories). They have an error text and can be found in the following table: Error messages in alphabetical order.

Note: In cases where Technical Service is to be contacted, please document/record what happened (i.e. the situation) as well as the displayed Error Code(s) and/or text(s).

Error messages with error codes in numerical order

EC	Error text	Possible cause(s)	Action(s) to be taken
J-5D	ESM 2: Software incompatible!	The suction module, Model ESM 2's software is not compatible with the ERBEJET 2.	Use a suction module, ESM 2 in which its software is compatible with the ERBEJET 2. Contact Technical Service to have the ESM 2 updated with the compatible software, etc.
J-5E	FS: Software incompatible!	The footswitch's software is not compatible with the ERBEJET 2.	Use a footswitch in which its software is compatible with the ERBEJET 2. Contact Technical Service to have the footswitch updated with the compatible software, etc.
J-06	Activation has been interrupted.	A system error has occurred.	Reactivate the ERBEJET 2 (i.e. remove foot from pedal of the footswitch and depress the pedal again). If the error is re-occurring, contact Technical Service.
J-07	Please check the position of the cartridge in the slot.	The pump cartridge has not been properly installed (i.e. put into the cartridge slot of the unit) or can not be engaged into the ERBEJET 2.	Eject the pump cartridge (with the attached applicator or probe) if necessary and try once again to slide it in to the slot of the unit until it is engaged. If unsuccessful, use another pump cartridge with applicator or probe. If the problem is re-occurring contact Technical Service.
J-20	Module conn. to ECB not compatible.	A device has been connected (via an ECB cable) to the ERBEJET 2 that is not compatible.	Detach the non-compatible device from the ERBEJET 2.
J-21	Check date/clock time adjustment.	A discharge of the battery has occurred which may have caused the date and time settings to be lost.	Besides the loss of the date and time settings, no other problems are related. Nonetheless, contact Technical Service.

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EC	Error text	Possible cause(s)	Action(s) to be taken
J-23	Check date/clock time adjustment.	An internal issue has occurred resulting in the date and time settings to be inconsistent.	Besides the inconsistency with the date and time settings, no other problems are related. Nonetheless contact Technical Service.
J-24	Module conn. to ECB not compatible.	A footswitch has been connected to ERBEJET 2 that is not compatible.	Detach the noncompatible footswitch from the ERBEJET 2.

Error messages in alphabetical order

Error text	Possible cause(s)	Action(s) to be taken
Critical temperature reached! / Let ERBEJET cool down!	The units drives have reached a temperature that is too high due to over or continuous activation and/or environmental condition(s) causing heat retention.	If possible and as necessary, let the unit cool down and don't overactivate or activate continuously. Remedy any environmental situation that may be or is causing the unit to heat up.
ERBEJET overheated / Activation not possible!	The units drives have reached a temperature that is too high due to over or continuous activation and/or environmental condition(s) causing heat retention which resulted in the ERBEJET not being operational (i.e. the drives are "Off").	Let ERBEJET 2 cool down until the following message is displayed:"ERBEJET has cooled down! / Activation is possible again!". Don't overactivate or activate the unit continously. Remedy any environmental situation that may be or is causing the unit to overheat.
ERBEJET 2 not ready for operation!	An attempt was made to activate the ERBEJET 2 prior to the drives being set or having a pump cartridge installed.	Wait until the screen displays "Ready" or install (put in) a pump cartridge so that the screen displays "Connecting cartridge - Please wait" then "Ready" before attempting to activate again.
Error: Power failure	There is internal damage.	Contact Technical Service.
Keypad error (Info J-87)	During the power up sequence, a display/selection button(s) was pressed or a button was jammed/is damaged.	Turn "Off" and then turn "On" the unit without pressing a display/selection button. If the erroring is not resolved, contact Technical Service.
Please interrupt activation	The pedal of the footswitch was depressed when activation is not possible (e.g. during the powering up sequence, etc.) or there is internal damage.	Release/Remove foot from pedal until activation is possible. If the issue is not resolved, contact Technical Service.
Program not used	You are trying to delete a program that is not used.	Don't try to delete programs that are not used.
Pulsemode is not available!	On the program display screen, the display/selection button associated for the pulse mode was inadvertently pressed but the software option for the mode has not yet been released or is not a mode installed in the unit.	Press the desired display/selection button.

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Error text	Possible cause(s)	Action(s) to be taken
Pump damaged or reused! / Please press button EJECT.	The tip of the applicator may have become clogged or an attempt was made to engage/ install a used pump cartridge (with applicator). The issue may also be caused by an internal problem (i.e. blocked/damaged slot, etc.).	Select EJECT by pressing display/selection button R1. Remove the pump cartridge with applicator or probe. Insert a new pump cartridge with (new) applicator or probe. If the issue is not resolved, contact Technical Service.
ReMode: Level 'b' is not available!	The ReMode button on the footswitch was depressed, but the selected program doesn't have two levels.	Do not press the ReMode button, select a program with two levels, or create and save a program with two levels.
Suction: Activation interrupted.	The suction module, Model ESM 2 has been disconnected from the ERBEJET 2 (via the ECB cable) or turned "Off". The issue may also be caused by a damaged cable or an internal problem (i.e. communication issue, etc.).	Check and ensure that the ESM 2 is connected via the ECB cable and turned "On" with power (i.e. green LED). If the issue is not resolved, contact Technical Service.
Suction not ready for operation!	The suction module, Model ESM 2 has been disconnected from the ERBEJET 2 (via the ECB cable) or turned "Off". The issue may also be caused by a damaged cable or an internal problem (i.e. communication issue, etc.).	Check and ensure that the ESM 2 is connected via the ECB cable and turned "On" with power (i.e. green LED). If the issue is not resolved, contact Technical Service.
The footswitch is not ready.	Upon the powering up sequence, the footswitch is not connected or the software is not compatible with the ERBEJET 2.	Connect the footswitch or use a footswitch in which its software is compatible with the ERBEJET 2. Contact Technical Service to have the footswitch updated with the compatible software, etc.
You have exceeded the Max. ON time!	The time limit set in the service program for activation has been exceeded.	Reactivate the ERBEJET 2 (i.e. remove foot from pedal of the footswitch and depress the pedal again). As desired, see that the maximum "On" time is turned "Off' or increased.

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CHAPTER 5

Installation

Environmental conditions

⚠ WARNING

Ignition of anesthetics, skin cleansers, and disinfectants in potentially explosive atmospheres

If you place the device in a potentially explosive atmosphere, anesthetics, skin cleansers, and disinfectants can ignite.

Risk of fire and explosion to the patient and medical personnel! Risk of damage to property.

➡ Do not place the device in potentially explosive atmospheres.

NOTICE

Interference with the unit by portable and mobile HF communication devices (e.g. mobile phones, WLAN equipment)

Electromagnetic waves emitted by portable and mobile HF communication devices can effect the unit. The equipment may fail or not perform properly.

➡ Please see the table "Recommended separation distances between portable and mobile HF communications equipment and the equipment" at the end of this User Manual.

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NOTICE

Unsuitable temperature or level of humidity during operation

If you operate the equipment at an unsuitable temperature or level of humidity, it may sustain damage, fail, or not perform properly.

➡ Operate the equipment at a suitable temperature and level of humidity. You will find the tolerances for temperature and humidity in the Technical Data.

➡ If other ambient conditions have to be observed for operation of the equipment, you will also find them in the Technical Data.

NOTICE

Unsuitable temperature or humidity in transit or storage

If you transport or store the equipment at an unsuitable temperature or level of humidity, it may sustain damage and fail.

➡ Transport and store the equipment at a suitable temperature and level of humidity. You will find the tolerances for temperature and humidity in the Technical Data.

➡ If other ambient conditions have to be observed for transport and storage of the equipment, you will also find them in the Technical Data.

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

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NOTICE

Insufficient acclimatization time, unsuitable temperature during acclimatization

If the device was stored or transported below or above a certain temperature, it will take a certain time and temperature to acclimatize.

If you do not observe the rules, the device can sustain damage and fail.

➡ Acclimatize the device according to the rules in the Technical Data.

NOTICE

Overheating of the device due to poor ventilation

If ventilation is poor, the device can overheat, sustain damage, and fail.

➡ Install the device in such a way that there is an unobstructed circulation of air around the housing. Installation in confined wall recesses is prohibited.

NOTICE

Penetration of liquid into the device

The housing is not absolutely watertight. If liquid penetrates, the device can sustain damage and fail.

➡ Make sure no liquid can penetrate the device.

➡ Do not place vessels containing liquids on top of the device.

➡ Take care when connecting the cutting medium to the pump cartridge that the unit does not come into contact with the cutting medium. The same applies when removing the cutting medium.

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⚠ WARNING

Defective/Damaged device and/or accessories, modified device and/or accessories

Risk of injury to the patient and medical personnel! Risk of damage to property.

➡ Check the unit and accessories (e.g. footswitch, cables, applicators or probe, etc.) for damage every time before use.

➡ You must not use damaged equipment or damaged accessories. Exchange defective accessories.

➡ If the unit or accessories are damaged, please contact customer service.

➡ For your safety and that of the patient: Never attempt to perform repairs or make modifications yourself. Any modification will invalidate liability on the part of ERBE Elektromedizin GmbH.

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Electrical installation

⚠ WARNING

Defective grounded power outlet, power supply network without proper grounding, inferior-quality power cord, incorrect line voltage, multiple power outlets, extension cords

Risk of electric shock and other injuries to the patient and medical personnel! Risk of damage to property.

- Connect the unit / the equipment cart to a properly installed grounded power outlet.
- Only connect the unit to a power supply network with proper grounding.
- Only use the ERBE power cord or an equivalent power cord for this purpose. The power cord must bear the applicable national test symbol.
- Check the power cord for damage. You must not use a damaged power cord.
- The supply voltage must match the voltage specified on the unit's rating plate.
- Do not use multiple power outlets.
- Do not use extension cords.

⚠ WARNING

Incorrect line fuse, defective device

Risk of electric shock to the patient and medical personnel! Risk of damage to property.

- Blown line fuses may only be replaced by a competent technician. Only replacement fuses that have the same rating as the one specified on the unit's rating plate may be used.
- When a fuse has been changed, the function of the unit must be verified. If the unit does not function properly or there are any concerns, please contact ERBE USA.

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⚠ WARNING

Defective/Damaged device and/or accessories, modified device and/or accessories

Risk of injury to the patient and medical personnel! Risk of damage to property.

- Check the unit and accessories (e.g. footswitch, cables, applicators or probe, etc.) for damage every time before use.
- You must not use damaged equipment or damaged accessories. Exchange defective accessories.
- If the unit or accessories are damaged, please contact customer service.
- For your safety and that of the patient: Never attempt to perform repairs or make modifications yourself. Any modification will invalidate liability on the part of ERBE Elektromedizin GmbH.

Note: If necessary, the equipment can be connected to the external grounding system of the room with the grounding pin on the back of the unit and/or Cart using a connecting cable designed for this purpose. Affects of low frequency leakage cur-

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rents due to a defective grounding system within the room may be eliminated through external grounding

Installing the ERBEJET 2

The ERBEJET 2 and components (including the suction module, Model ESM 2) should be installed on an ERBE VIO Cart or boom mounted. See the respective user manual, installation sheet/instructions, and notes on uses for mounting, securing, as well as connecting the unit and components. In general ensure that:

- The surface is stable and free of vibration,
- the system is not in direct sunlight (so that heating is not a problem and the display screen is readable),
- and the unit(s) are connected to a properly installed grounded outlet(s). Only use an ERBE power cord or an equivalent power cord for this purpose. The power cord must bear the national test symbol.

In general, the power cord is plugged into the receptacle for power that is on the back of the ERBEJET 2 and an approriate power source. The cable of the footswitch is attached to the footswitch socket on the back of the unit. The ERBEJET 2 is grounded via a grounding cable connected to the grounding terminal on the back of the unit and approriately grounded. As applicable, the ERBEJET 2 is connected to the suction module, ESM 2 via an ECB cable.

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CHAPTER 6

Disassembly, Cleaning and Disinfection

Detaching the normal saline as well as pump cartridge with applicator or probe from the ERBEJET 2

⚠ WARNING

Contaminated accessories

Risk of infection for the medical staff.

➡ Wear personal protective equipment (e.g. gown, faceshield or eye protection, mask, gloves, etc.) to minimize the risk of exposure to infectious agents while handling, disconnecting, and disposing of used accessories.

Detaching the normal saline

Disconnect the tubing from the normal saline from the pump cartridge. Properly dispose of the used tubing set and bag of normal saline.

Disconnecting as applicable the applicator's suction hose from the suction device

As applicable disconnect the applicator's suction hose from the suction device. If the suction module, ESM 2 (with its associated components and accessories) was used follow the disassembly instructions in the ESM 2 User Manual.

Detaching the pump cartridge with applicator or probe

On the display screen of a program, select *EJECT* by pressing display/selection button R1. Upon uncoupling and prompting the removal of the used cartridge, remove the pump cartridge with applicator or probe. Properly dispose of the used pump cartridge and applicator.

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Wipe disinfection

For cleaning and disinfecting the surfaces of the unit or of the equipment cart, ERBE recommends a wipe disinfection. Use only disinfectant which complies with the relevant national standards.

⚠ WARNING

Connection of unit / equipment cart and power supply during cleaning and disinfection

Risk of electric shock to the medical personnel!

➡ Switch off the device. Unplug the power cord of the device/ equipment cart.

NOTICE

Penetration of liquid into the device

The housing is not absolutely watertight. If liquid penetrates, the device can sustain damage and fail.

➡ Make sure no liquid can penetrate the device.

➡ Do not place vessels containing liquids on top of the device.

➡ Take care when connecting the cutting medium to the pump cartridge that the unit does not come into contact with the cut-

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ting medium. The same applies when removing the cutting medium.

NOTICE

Alcohol-based spray disinfectant for fast disinfection

With membrane keyboards and paint surfaces there is the risk of cracks. Propanol and ethanol will erode surfaces.

➡ Do not use these substances.

NOTICE

Alternate use of disinfectant solutions based on different active ingredients

A color reaction may occur with plastics.

➡ Do not use these substances alternately.

Instructions for cleaning and disinfection

Mix the disinfectant in the concentration specified by the manufacturer.

Clean surfaces contaminated with blood before using the disinfectant, otherwise it may be less effective.

Wipe the surfaces. Make sure the surfaces are treated uniformly. Comply with the action time of the disinfectant specified by the manufacturer.

Note: As applicable, to clean/disinfect the suction module, ESM 2 and associated components follow the instructions in its User Manual.

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CHAPTER 7

Technical Data

Power connection	
Rated supply voltage	100 – 240 V
Line current	0.4 – 1.2 A
Rated supply frequency	50 Hz / 60 Hz
Power fuses	2 x T 3.15 A H / 250 V

Data specific to the unit	
Effect / Pressure range in bar / in psi	1 – 80 (± 20 %) / 14.5 – 1160.3 (± 20 %)
Volume flow in ml/min.	1 – 55 (± 10 %)
Program storage capability	Up to 9 programs
Activation	Footswitch
Pump cartridge	Sterile single-use double cylinder pressure generating cartridge
Applicators or probe	Sterile single-use applicators or probe, rigid and flexible varying in size
Nozzle/ Jet diameter	120 µm
Cutting medium	Sterile, normal saline
Suction module, ESM 2 (separate compatible unit)	Adjustable -100 to -800 mbar (± 50 mbar) Adjustable -1.45 to -11.60 psi (± 0.73 psi)

Dimensions and weight	
Width x height x depth	410 x 130 x 370 mm / 16.1" x 5.1" x 14.6"
Weight	11 kg / 24 lbs. 4 oz.

Ambient conditions for transport and storage of unit	
Temperature	-25 °C to +50 °C / -13 °F to +122 °F
Relative humidity	15 % – 80 %

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001_13 Proposed Labeling
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Ambient conditions for operation of the unit	
Temperature	+10 °C to +40 °C / +50 °F to +104 °F
Relative humidity	15% – 80%, noncondensing

Acclimatizing
If the unit has been stored or transported at temperatures below +10 °C / +50 °F or above +40 °C / +104 °F, the unit will require approx. 3 hours to acclimatize at room temperature.

Standards	
Classification according to EC Directive 93/42/EEC	II b
Protection class as per EN 60 601-1	I
Type as per EN 60 601-1	CF

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CHAPTER 8

Information on ElectroMagnetic Compatibility (EMC)

Where EMC is concerned, medical electrical equipment is subject to special safety measures and must be installed and commissioned according to the EMC instructions stated herein.

NOTICE

Use of non-approved internal cables by Technical Service

This can result in the increased emission of electromagnetic waves or reduce the immunity of the device. The equipment may fail or not perform properly.

➡ Technical Service may only use the internal cables that are listed in the service manual for the device.

NOTICE

Stacked devices

If you stack the device next to other equipment or with other equipment, the devices can affect each other.

The unit may fail or not perform properly.

➡ The device may only be stacked next to or with VIO series units.

➡ If it is necessary to operate the device near other equipment or stacked together with other equipment, check whether the devices are affecting each other: Are the devices behaving unusually? Do errors occur?

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Guidance and manufacturer's declaration - electromagnetic emissions		
The equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should ensure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
HF emissions CISPR 11	Group 1	The equipment or system uses HF energy only for its internal function. Therefore its HF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
HF emissions CISPR 11	Class A	The unit is suited for use in environments other than domestic areas and in ones directly connected to a public power supply system that also supplies buildings being used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

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Guidance and manufacturer's declaration - electromagnetic immunity

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

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Discharge of static electricity /ESD) to IEC 61000-4-2	±6 kV contact discharge ±8 kV air discharge	±6 kV contact discharge[a)] ±8 kV air discharge[a)] a) Repeated occurrence can trigger a restart of the unit in rare cases.	The floor should be of wood or concrete or be tiled with ceramic tiles. If the floor is provided with non-conductive synthetic material, the relative humidity must be at least 30%.
Electrical fast transient/ burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the equipment requires continued operation during power mains interruptions, it is recommended that the equipment be powered from an uninterruptible power supply or a battery.
Power frequency (50/ 60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note: U_T is the a.c. mains voltage prior to application of the test level.

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Guidance and manufacturer's declaration - electromagnetic immunity

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

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile HF communications equipment should be used no closer to any part of the equipment, including cables, than the recommended separation distance. The separation distance is calculated from various equations depending on the frequency of the portable and mobile HF communications equipment:
			Recommended separation distance
Conducted HF IEC 61000-4-6	3 V_{rms} 150 kHz to 80 MHz	3 V_{rms}	Equation 1) $d=1.2\ P^{1/2}$
Radiated HF IEC 61000-4-3	3 V/m 80 MHz to 800 MHz	3 V/m	Equation 2) $d=1.2\ P^{1/2}$
	3 V/m 800 MHz to 2.5 GHz	3 V/m	Equation 3) $d=2.3\ P^{1/2}$
			P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. *d* is the recommended separation distance in meters (m). Field strengths from fixed transmitters, as determined by an electromagnetic site survey[a)] should be less than the compliance level in each frequency range[b)]. Interference may occur in the vicinity of equipment marked with the following symbol:

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Guidance and manufacturer's declaration - electromagnetic immunity

Note 1: At 80 MHz equation 2) applies. At 800 MHz equation 3) 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 HF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the equipment is used exceeds the applicable compliance level above, the equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the equipment.

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

Recommended separation distances between portable and mobile HF communications equipment and the equipment

The equipment is intended for use in an electromagnetic environment in which radiated HF disturbances are controlled. The customer or the user of the equipment can help prevent electromagnetic interference. This can be achieved by maintaining the minimum distance recommended below between the communications equipment (transmitters) and the equipment. The minimum distance depends on the maximum output power and the frequency of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d=1.2\ P^{1/2}$	**80 kHz to 800 MHz** $d=1.2\ P^{1/2}$	**800 MHz to 2.5 GHz** $d=2.3\ P^{1/2}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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

Note 1: An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the frequency bands between 80 MHz and 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

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

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CHAPTER 9

Maintenance, Customer Service, Warranty, Disposal

Maintenance

Authorized persons

Modifications and repairs may only be undertaken by ERBE or by persons expressly authorized by ERBE. ERBE accepts no liability if modifications and repairs to the unit or accessories are made by unauthorized persons. This will also invalidate the warranty.

Safety checks

The unit should have a technical safety/operational inspection at least once a year.

Modifications and repairs

Modifications and repairs are to be completed by ERBE or by persons expressly authorized by ERBE.

What safety checks must be performed?

For this device the following safety checks have been stipulated:

- Checking of labels and User Manual
- Visual inspection of unit and accessories for damage
- Testing the grounded conductor in accordance with EN 60601-1 (UL-60601-1) Section 18
- Testing the leakage current in accordance with EN 60601-1 (UL-60601-1) Section 19
- Functional testing of all the unit's operating and control elements
- Testing the monitoring equipment
- Testing of mechanical pressure production

The results of the safety checks have to be documented.

If during the safety checks any defects are found which might endanger patients, staff or third parties, the device may no longer be operated until the defects have been remedied by competent service technicians.

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Customer Service

If you are interested in a service contract, please contact ERBE.

Servicing

Procure service work as follows:

1. Contact the Technical Service Department at ERBE USA, Inc. for a Service Call or to obtain a Return Authorization Number. This Number must appear on all correspondences.

   Telephone:
   770-955-4400 or 1-800-778-3723
   E-Mail: technicalservice@erbe-usa.com
   FAX: 770-955-2577

2. Address:
   ERBE USA, Inc.
   2225 Northwest Parkway
   Marietta, GA 30067

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

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3. If the product is being returned to ERBE USA, Inc.; the shipment must be insured as well as safely and securely packed. Preferably it should be packaged in its original shipping carton with a letter explaining the problem and making reference to the Return Authorization Number. All transportation and insurance charges and risk of loss are the responsibility of the customer and must be prepaid. A purchase order must be issued to ERBE USA, Inc. to cover all transportation and insurance charges for the return shipment after service.

Authorization from the ERBE USA, Inc. Customer or Technical Service Departments must be obtained prior to the return of equipment and/or accessory(ies) for servicing. To obtain an appropriate Return Authorization Number (R.A. #), please be prepared to give the following information when contacting ERBE:

1. The customer name.
2. The name and telephone number of the contact person.The catalog number, or model number, and serial number of the involved equipment and/or accessory(ies).The REASON or problem.

The R.A. #, and the name and telephone number of the contact person at your location MUST be clearly indicated on the packing list you send with the equipment and/or accessory(ies).

The user must decontaminate any item being returned that possesses a risk of transmitting disease.

ERBE USA, Inc. reserves the right to refuse and/or return, transportation charges collect, any return item(s) that does not have an appropriate R.A. # as issued by the Customer or Technical Service Department. All shipments must be insured, and safely and securely packed, preferably in the original shipping carton. All transportation and insurance charges and risk of loss are the responsibility of the customer and must be prepaid.

Additional Information needed?

Please contact ERBE with any concerns regarding the equipment or this Manual. Also, as requested and available, copies of scientific publications will be provided.

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Warranty

ERBE warrants the material and workmanship of the ERBEJET 2 for a period of 1 year from the delivery date with the accessories (e.g., cables/cords, footswitch(es), etc.) having a 90 day warranty from the delivery date.

At installation, the equipment should be inspected for transportation damage and any other deficiency. A report should be prepared with the information being brought to ERBE's attention.If this product should become inoperable due to a defect in material or workmanship during the warranty period, ERBE will at its option repair or replace the product. This action will be performed by ERBE authorized personnel. This limited warranty does not include replacement or service to repair damage from improper installation, external electrical fault, accident, disaster, use for a purpose other than that for which originally designed or indicated in this Manual, negligence, modification, unauthorized service by non ERBE personnel, or normal wear.The sole and exclusive remedy under this warranty shall be repair or replacement. In no event will ERBE be liable for any damages arising out of the loss of use, or any other incidental or consequential damages.No person, agent, distributor, dealer, or company is authorized to change or modify the terms of this warranty.

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

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Disposal

Your product bears a crossed-out garbage can icon (see image). Meaning: In all EU countries this product must be disposed of separately in accordance with the national laws implementing EU Directive 2002/96/EC of January 27, 2003, WEEE.

In non-EU countries the local regulations must be observed.

If you have any questions about disposal of the product, please contact your ERBE branch or your local distributor.

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CHAPTER 10

Combination with other Equipment, Third Party Accessories

The ERBEJET 2 has a compatible but separate suction module, ESM 2. The ESM 2 is connected to the ERBEJET 2 by an ECB cable. The ERBEJET 2 will incorporate the features and functions of the suction module (i.e. features and parameters of the ESM 2 can be accessed and set through the display screen of the ERBEJET 2).

The suction hose of an ERBEJET 2 applicator with suction can be connected to other suction devices. However, the suction (vacuum) pressure should not exceed -11.6 psi (-800 mbar). Also, the other suction device cannot be integrated (i.e., attached by an ECB cable) with the ERBEJET 2.

Do not use pump cartridges and applicators from other manufacturers with the ERBEJET 2.

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HybridAPC Probe Labels and Labeling

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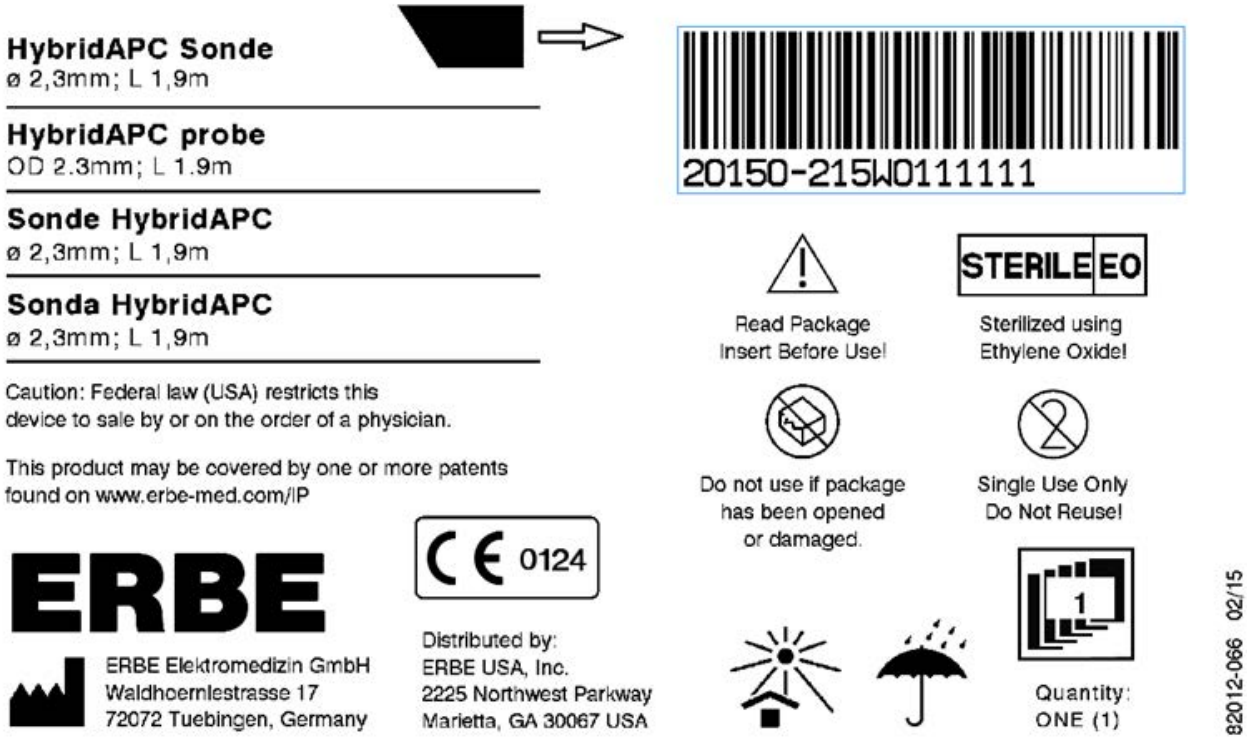
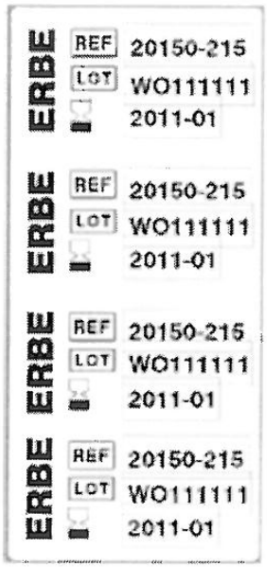


Outer Packaging Pouch Label



Patient Chart Label
[Note: Example of the Four (4) Peel-off Chart Labels that are on the Pouch Label]

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

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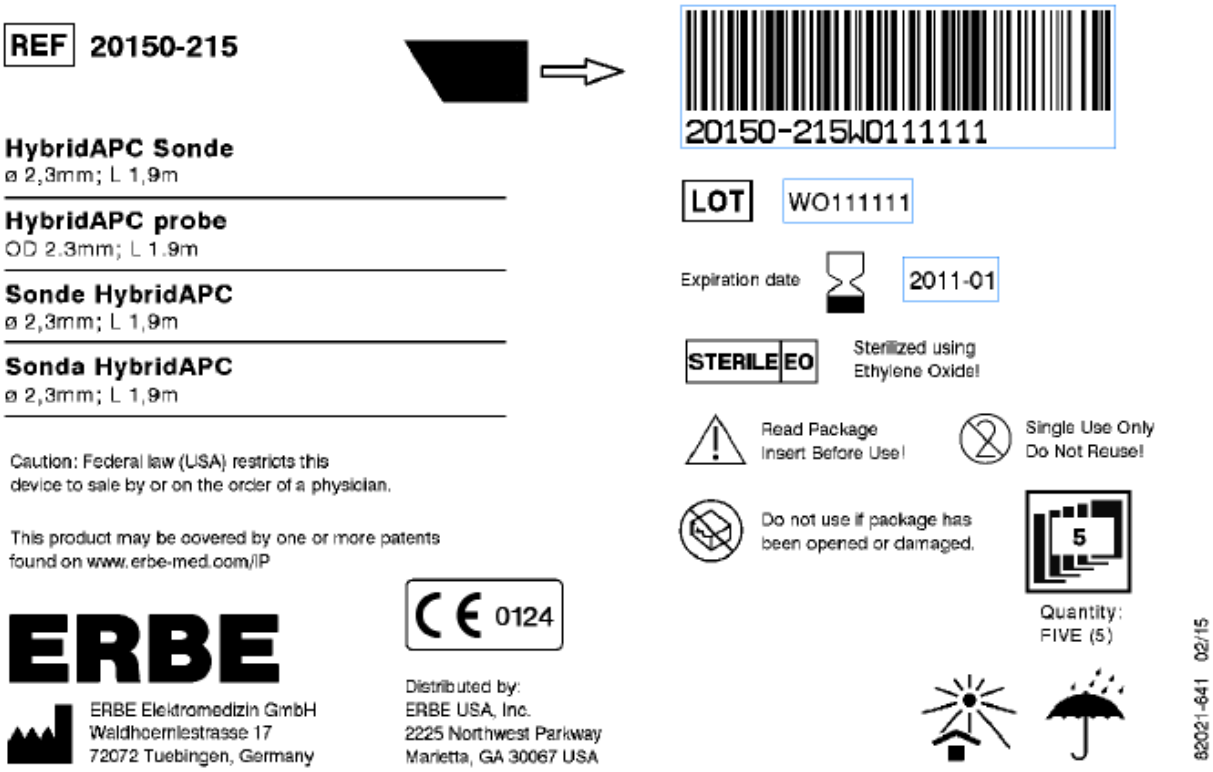

Outer Packaging Box Label

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

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Notes on use

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HybridAPC probe

20150-215

Single use only! Sterility not guaranteed if package has been opened or damaged. Discard if package is damaged.

STERILE EO

ERBE

Notes On Use, Cover

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IMPORTANT!

Please read all information carefully.

These notes on use do not replace the User Manuals of the Water Jet System, Argon Plasma Coagulator and ElectroSurgical Unit (ESU) used! Read the User Manuals of the units and ask ERBE or your distributor in case of doubt!

Caution! Federal law (USA) restricts this device to sale by or on the order of a physician!

1 Intended Use

The HybridAPC probe is indicated for the induction of sterile normal saline into the submucosa to lift mucosal lesions using direct visualization through an endoscope and for HF ablation of the mucosal lesion by Argon Plasma Coagulation (APC).

This device should not be used for uncooperative patients.

2 Normal Use

The HybridAPC probe is to be used with the following ERBE units and accessories:

- Water Jet System Model ERBEJET 2 with accessories.
- Argon Plasma Coagulator Model APC 2 in conjunction with a compatible ESU VIO Model.

Connection to a standard APC receptacle requires the use of adapter 20132-228.

The product is intended for single use.

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3 Maximum Electrical Capacity

The maximum electrical capacity of this product is:

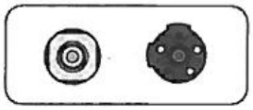
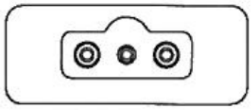
- 4300 V_p

4 Operating Materials and Accessories

To use the product you require the following items:

- Pump cartridge (Art. No. 20150-300)
- Cutting medium: to select the suitable cutting medium please read the Notes on use for the pump cartridge
- possibly commercial dye

Note! The ERBE Argon Plasma Coagulator may have a receptacle which requires an Adapter to connect the product to it. See the following descriptions of receptacles and if the associated Adapter is needed.

Receptacle type	Accessory for connecting up the probe
APC standard receptacle 	Adapter Art.-No. 20132-228
FiAPC receptacle 	No further accessories required.

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5 Safety Instructions

WARNING!

5.1 Sterile product for single use

ERBE recommends that the product not be reprocessed after use. Reprocessing can affect material properties and/or product function making its Normal Use no longer possible. Concerns involve:

- Components/connections that are damaged by high temperatures (e.g. in the autoclave).
- Components (e.g. filter, extremely small lumen, etc.) that may prevent internal cleaning/disinfection.

5.2 User requirements

This product may only be used by medical personnel who have been trained per these instructions.

Do not use the product if you are unfamiliar with its operation in conjunction with the ESU and the Argon Plasma Coagulator.

5.3 General information about protection of the user, patient, and product

Do not use in the presence of combustible or explosive materials!

Never lay this product on the patient or in his/her direct vicinity.

Protect this product from any form of mechanical damage! Do not throw! Do not use force! If there is a cable, and unless stated otherwise, do not kink it or wrap it around the accompanying product!

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Do not kink the tube or wrap it round the product to which it belongs!

If damaged, do not use this product!

5.4 Danger of mechanical perforation

Do not puncture the mucosa with the probe's tip.

5.5 Danger of fires in the gastrointestinal tract

Before using Argon Plasma Coagulation (APC), always ensure that no endogenous gases are present in the lumen of the relevant organ.

5.6 Danger of fire in the tracheobronchial system

The high temperatures of argon plasma can cause flammable materials to ignite. Please refer to therapeutic guidelines for O_2 saturation when actively ventilating patients during use of thermal energy sources (i.e. laser or electrosurgical units). For this reason, please always observe the following rules:

- Avoid APC activating during active oxygen (O_2) ventilation. Follow hospital policy and procedure when using thermal energy sources, such as APC, in the airway.
- O_2 use and APC activation should alternate, thus lowering the O_2 concentration.

Please also observe the ERBE brochure concerning use of the APC in the tracheobronchial system.

5.7 Gas embolisms, gas emphysema

To prevent gas embolisms, the argon flow rate must not be set high enough that argon is blown into open vessels. To prevent gas embolisms or emphysema, never point the distal end of

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APC probes directly towards open vessels or press against tissue.

5.8 Danger of unintentional damage to nerve structures

Bear in mind that during an APC application in the direct vicinity of nerve structures, stimulation may be induced by electric currents.

In the case of nerves which require protection it is advisable to keep the APC activation time short and adapt minimum power output to the required indication.

5.9 Protection against HF leakage current at the eyepiece

HF leakage current at the eyepiece of the endoscope can cause the user thermal damage. To avoid this please only use endoscopes that are designed for use with electrosurgical accessories.

5.10 Risk of burns to the patient

Flash-overs, activation in the working channel of the endoscope or without visual control of the distal end of the probe can cause unwanted thermal injuries to the patient. Therefore, check that the distal end of the probe (1) protrudes at least 10 mm out of the endoscope before each activation. This is ensured when the first black ring (2) on the distal end of the probe is visible through the endoscope.

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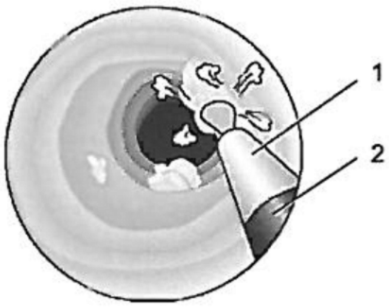

Fig. 1: View of the markings through the endoscope.

5.11 Danger of burns

Argon plasma can strongly heat electrically conductive materials, e.g. metal. To avoid burns, never direct argon plasma towards electrically conductive materials.

Risk of burns. The cutting medium can act as an electric conductor when activating the HF voltage. Make sure that cutting medium from leading parts (e.g. tubes, bags, etc.) does not touch patients or personnel during HF activation.

5.12 Modification of the product by the user

ERBE Elektromedizin expressly warns against modifying the instrument, e.g. cutting off the probe tip. Any modification will exempt ERBE Elektromedizin from all liability.

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6 Recommended Unit Settings

This chapter describes unit settings that may be used to operate the product without causing damage.

When operating this product, you must observe the setting limits specified in these instructions. Adapt the power to the planned procedure. Begin with the lowest possible power setting and increase gradually as required.

6.1 Permitted settings on the ERBEJET 2

Rinsing with to high of a pressure can lead to tissue damage. Therefore always select for rinsing the lowest possible effect on the ERBEJET 2.

Effect levels 1 – 80 may be used. However too high of a pressure can lead to tissue damage. Therefore use the lowest possible settings to achieve the desired surgical outcome.

6.2 Permitted settings on the ERBE VIO

Forced APC, Precise APC, and Pulsed APC modes:

- Effect: Effect with an HF peak voltage (U HF) $\leq 4{,}300\ V_p$ [1)]
- Power: maximum 80 watts
- Gas flow: maximum 2.4 l/minute

Settings that are too high can lead to unwanted tissue damage. Theredore use the lowes possible settings to achieve the desired surgical outcome.

1.) The HF peak voltage of an effect depends on the mode selected and the power setting (Watt) used. More information about selecting an appropriate effect is available in the User Manual for the VIO HF electrosurgical unit.

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7 Information on electromagnetic compatibility (EMC) of the units

Notwithstanding the specifications in the ERBEJET 2 and VIO User Manuals, HF emissions are classified as Class A[2)] according to CISPR 11 for common use of the product with the units. All other EMC specifications in the User Manuals for the recpective units apply for their common uses.

8 How to Use

8.1 Sterile product for single use

ERBE recommends that the product not be reprocessed after use. Reprocessing can affect material properties and/or product function making its Normal Use no longer possible. Concerns involve:

- Components/connections that are damaged by high temperatures (e.g. in the autoclave).
- Components (e.g. filter, extremely small lumen, etc.) that may prevent internal cleaning/disinfection.

8.2 Check the expiration date

An expiration date is printed on the packaging of the product. Do not use any product beyond its expiration date!

2.) The system is suited for use in environments other than domestic areas and in ones directly connected to a public power supply system that also supplies buildings being used for domestic purposes. The customer or the user of the system should ensure that it is used in such an environment.

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8.3 Control and open packaging

Use this product only if the packaging has not been opened or damaged. If the packaging is open or damaged, the product is no longer sterile and must not be used. In this case, throw the product away!

Use aseptic techniques when removing the product from the packaging!

8.4 Check the product

Before use, check that the product including all the insulation is intact. Verify that there are no signs of physical damage.

If damaged, do not use this product!

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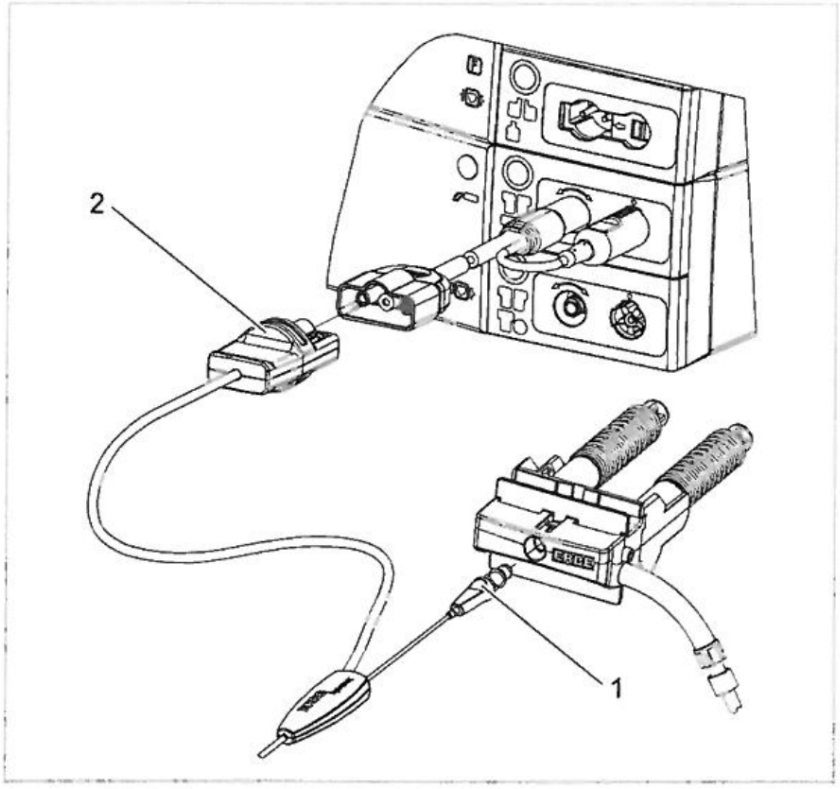
8.5 Connecting the product to the ERBEJET 2 + APC 2 with the APC standard receptacle

IMPORTANT! The adapter, Art. No. 20132-228, must be plugged to the APC standard receptacle!



1. Establish the water jet connection: On the sterile field, plug the extension tubing connector (1) into a pump cartidge by snapping it into place until it clicks. The attached pump cartridge is then inserted into the Water Jet System ERBEJET 2. Follow the instructions in the ERBEJET 2 User Manual to prime, etc.
2. Establish APC connection: Plug the FiAPC plug (2) into adapter 20132-228. The operating parameters of the adapter (not of the probe) are automatically set on the VIO electrosurgical unit.

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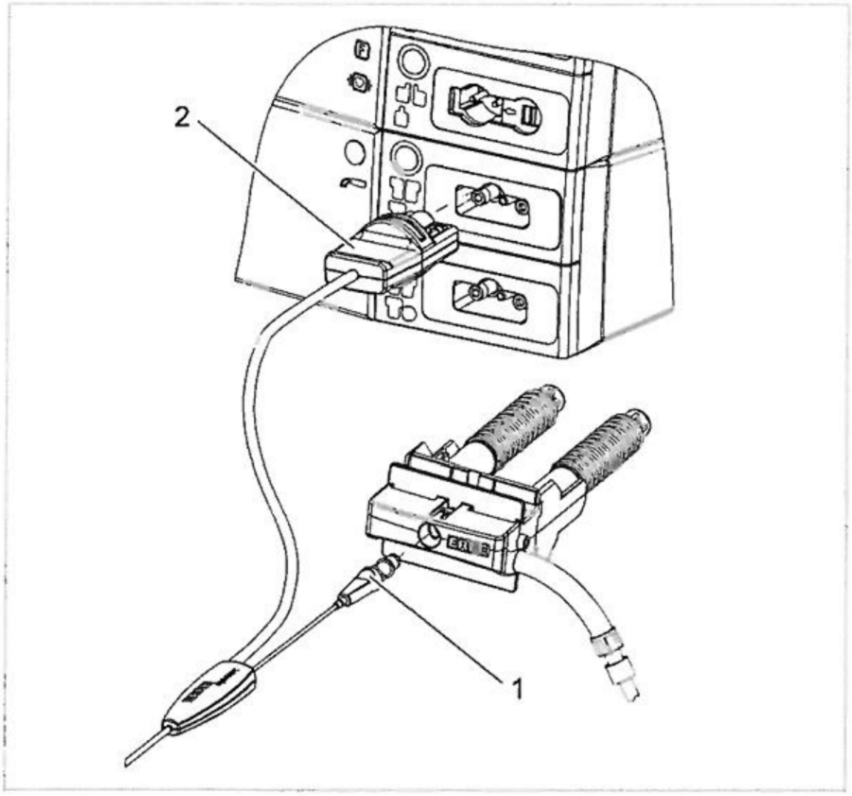
3. See chapter "Recommended Unit Settings" and adjusted settings of the Water Jet System and VIO to achieve the desired surgical outcome.

8.6 Connecting the product to the ERBEJET 2 + APC 2 with the FiAPC receptacle



1. Establish the water jet connection: On the sterile field, plug the extension tubing connector (1) into a pump cartidge by snapping it into place until it clicks. The attached pump cartridge is then inserted into the Water Jet System ERBEJET 2. Follow the instructions in the ERBEJET 2 User Manual to prime, etc.

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2. Establish APC connection: Plug the FiAPC plug (1) into a FiAPC receptacle. The probe will be detected by the VIO electrosurgical unit.
3. See chapter "Recommended Unit Settings" and adjusted settings of the Water Jet System and VIO to achieve the desired surgical outcome.

8.7 Endoscope selection

HF leakage current at the eyepiece of the endoscope can cause the user thermal damage. To avoid this please only use endoscopes that are designed for use with electrosurgical accessories.

The endoscope's working channel must have a diameter larger than 2.5 mm.

8.8 Using the product

The water jet and APC are **alternately** activated via different footswitches.

The water jet is activated via the ERBEJET 2 footswitch, the APC via the COAG pedal of the VIO footswitch.

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ERBE WaterJet Model ERBEJET® 2 System with HybridAPC Probe Claims/Marketing Statements

ERBEJET® 2 System (Note: No new statements added/same as in initial submission).

General Advantages

- Simple, intuitive and easy to use System.
- Compatible with existing ERBE equipment into a stacked workstation.
- No thermal trauma.
- Extremely uniform water jet; delicate, precise and reproducible effects.
- Integrated suction with individually adjustable run-on time.
- Ergonomically designed single-use instruments.
- Footswitch with “ReMode” function allows Physicians to independently switch between programs by using the toggle button control on the Footswitch.
- Programs can be individually stored.
- Simple operation via the display screen:
  - The ERBEJET 2 Unit has an easy-to-operate user interface. The parameters can be adjusted according to an individual indication and saved in 9 different program settings.
  - The impact of the water jet [Effect (that correlates to psi)] can be adjusted to create reproducible dissection results. The Effect can even be altered during activation.
  - The interface of the ERBEJET 2 Unit is also used to enter the settings of the Suction Module, Model ESM 2.
- Upon activation, the ERBEJET 2 System delivers a continuous stream of cutting medium to the operative site.
- The cutting medium is any “available” Sterile 0.9% Normal Saline for Irrigation. It is connected using a standard administration set.

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- The Suction Module, Model ESM 2 is a separate and optional accessory but integrated with the ERBEJET 2 Unit and has the following features:
  - The type and degree of suction of the ESM 2 Unit is adjusted via the interface of the ERBEJET 2 Unit. Activation is switched "On" (continuous or pedal activated) as selected using the Footswitch.
  - The suction may be programmed to continue running for a certain time after the water jet is no longer activated (i.e. a run-on time setting). This ensures good visibility at the operative site even after the water jet has been stopped.

Statements for/from Clinical Applications

- All previously approved statements from ERBE USA Helix Hydro Jet 510(k)'s.

Hepatic/Liver Surgery:

- During resection of the liver, the blood vessels and the bile ducts are prepared and washed free of surrounding tissue. Depending on their size, they can then be either coagulated or selectively treated using a ligature/clip/stapler.

- The time required for the intervention is shorter than that of comparable surgical interventions and is reduced even more by the simultaneous use of electrosurgery.

- The inter-operative blood loss is also reduced and thus the transfusion requirements are also lower. Depending upon the physician's technique, a cross – clamping of the blood supply to the organ (i.e. the Pringle Maneuver) may not be necessary when using the System.

- Additional Advantages in Hepatic Surgery-
  - Application possible in both laparoscopic and open surgery.
  - Precise dissection planes free of disruption, thermal artifact, and/or cavitations relative to other energy devices.

- The following statements are from the Referenced Clinical Publications.
  - "Water jet dissection enables us to separate organ structures[1]

1 Lammers B, Lukas Hospital in Neuss, Germany European Hospital Journal (www.european-hospital.com/topics/article/454.html 8/9/07)

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* This anatomically suitable tissue penetration allows for different physical characteristics, for example, structure, firmness and elasticity of the organs…

* In the beginning we hoped to use this method for the clean, blood-conserving preparation of malignant tumors, particularly in resections of the liver, kidney and rectal tumors. Over the years, the method has fulfilled all our expectations - and more…

* The incredible precision in the removal of malignant cells and preservation of healthy tissue achieved with the water jet has astonished us…

* The fact that out of a total of 100 operations the blood supply to the liver had to be stopped during only one of those operations is further proof of how precise the method is. In all other cases, the liver's arterial supply was maintained throughout the whole surgical procedure…

* We also have been able to significantly lower the amount of blood loss occurring during surgery. On average, patients lost around 350 ml, and around 80% of our tumor patients did not need any blood transfusions or plasma. This presents an enormous relief for the patients' organs…

* We have also found that, in general, patients recover from this type of surgery much faster. In addition, there is definitely a lower rate of infectious complications. Problems with liver function or liver failure hardly ever occur. A further positive effect has been seen in surgery on rectal carcinoma. As the nerves are protected during this type of surgery, 97% of patients who underwent resection of the rectum with total excision did not require a catheter. Before the introduction of water jet dissection around 50% of patients left the hospital with a catheter! We can say with confidence that due to water jet dissection the healing process is faster and patients are mobilized quicker. Apart from the obvious health benefits to the patients, there is also a cost-saving element as patients' hospital stays are reduced…

* Water jet surgery has become established in many surgical disciplines and offers not only extremely selective dissection but many other advantages. In addition to low intra-operative blood loss, operating times are reduced, particularly in general, visceral and orthopedic surgery."

o "Optimal dissection is achieved at a pressure setting of 550 - 650 pounds per square inch (psi) for a liver with normal consistency, but varies with cirrhotic

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and fibrotic livers requiring greater pressure (> 700 psi) and steatotic livers needing less.[2]

* The tip of the hand-held applicator is kept 1-2 mm away from the tissue in a “no-touch” fashion…

* Fluid buildup, consisting of saline and blood as well as disintegrated parenchymal tissue, is scavenged throughout the dissection by the suction element that is integrated with the applicator tip…

o “Blood loss generally consists of minor slow oozing from the side-walls, not brisk vascular hemorrhage, and is easily controlled with the cautery. It is at this point that the fine, trabecular infrastructure of the parenchyma becomes apparent, and is either cauterized or ligated with clips depending upon caliber of the elements…

* Large, intrahepatic vascular structures such as the middle hepatic vein and its segmental branches are easily and safely identified with the Water-jet. These are further exposed by circumferentially ‘cleaning’ the surrounding parenchymal tissue for distances that allow safe, controlled application of occlusive ligatures or the Endo-GIA stapler. A ‘drilling’ motion, where the jet stream is applied in a constant position over and under the edges of these structures, avoiding the center of the vessel itself, has proven to be extremely effective in their identification. This technique is also useful in precisely defining the hilar plate that invests the bile duct elements prior to transection…

* There was a significant improvement in patients requiring blood transfusion in favor of the Water-jet (13% vs 27%; p=0.031), as well as those who required more than two units of blood when transfused. Complications were less frequent in the Water-jet group (39% vs 53%; p=0.07), and mortality rates were 1% for Water-jet vs 6.4% for CUSA. Length of stay was significantly lower for the Water-jet group (8.4 days vs 10.7 days; p=0.03). These overall positive findings in favor of the Water-jet were further accentuated when comparing the cohort of Major Resections between the two techniques (data not shown)…

* (Dissected) … Multiple consistencies of hepatic parenchyma, including cirrhotic and fatty tissue, were also tested, as were various indications for resection (benign, malignant and infectious). Nonselective inflow occlusion was rarely necessary. The exceptional quality of performance by the Water-jet was enough to convince our group to abandon use of the previously favored CUSA…

2 Vollmer CM et al. Water-jet Dissection for Parenchymal Division During Hepatectomy. Presented at AHPBA, Miami, FL 2003

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* The Water-jet technique is relatively simple and easy to learn, for both the surgeons and the operative nursing staff. It has a short learning curve (fewer than 10 cases) as the surgeon becomes familiar with the technique. This fact, combined with the perceived superior precision attained, quickly made this the preferred application of each of the five surgeons in the study...

* Dissection of large venous structures, or the biliary plate, is usually complete enough to allow for even endovascular stapler ligation. Occlusion or ligation with suture material is rarely required…

* The Water-jet, as a no-touch technique, is less traumatic to the vascular structures than the directly applied ultrasonic aspirator tip. The application is atraumatic, so that dissection without direct visualization can be safely adopted. The jet power can be adjusted in accordance with the consistency of the parenchyma. For normal tissue, we employ settings between 500 - 650 psi. We have found that dissection of cirrhotic or fibrotic tissue is more efficient at levels of 700 - 800 psi, and that less pressure is required for steatotic livers that disintegrate with less force…

* Furthermore, since these cases (i.e. Living Donor) are performed with no inflow or outflow occlusion at all, they allow for analysis of the technique under the most demanding conditions for hemostatic control. Interestingly, despite these obstacles, in this scenario there was markedly better control with 225 cc's less median blood loss than observed in the other Major resections…

* Cirrhotic livers with gross fibrosis pose the most difficult conditions for hepatic transection to the surgeon. There has been skepticism about the ability of the Water-jet to transect these livers with equivalent proficiency. We feel that the Water-jet performs in a superior manner to other techniques - particularly since the amount of force applied can be varied in real time to the conditions encountered (i.e. elevating the psi). Our data supports this subjective impression and indicates that there is markedly less median blood loss in these challenging livers (600 vs. 900 mL)…

* Rau et al. found the Water-jet to be significantly faster than the CUSA with less required Pringle occlusion and fewer transfusions…

* We are under the subjective opinion that the Water-jet is more efficient in terms of speed of transection."

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- o "The jet-cutting technique proved to be faster than the CUSA in conventional liver surgery, and blood loss was reduced in patients operated on with the Jet-Cutter. These advantages are also valid for laparoscopic surgery with a more selective dissection of the liver parenchyma by the Jet-Cutter.[3]
  - * Blood loss did not differ significantly between the two groups with a mean of 457 + 343.7 ml in laparoscopic and 555.9 + 385.8 ml in conventionally operated patients."

Urology:

- The selectivity of the water jet reduces the risk of sexual dysfunction and/or urinary incontinence in prostatectomy procedures. Blood vessels and NeuroVascular Bundles (NVB) remain largely intact during hydrodissection of the NVB away from the prostate.
- As with hepatic surgery, when the water jet is used to carry out partial nephrectomy, this does not lead to necrosis of the resection margins. This helps retain as much of the organ's functionality as possible during these nephron sparing procedures.
- The renal blood vessels, ductal structures and collecting systems are selectively dissected and can subsequently be treated individually.
  - Additional Advantages in Urology-
  - o Minimized blood loss, less transfusion requirements
  - o Distinctly shorter operating times
  - o Lower rate of complications
  - The following statements are from the Referenced Clinical Publications or News Articles Quotes.
  - o "It also allows him to use a nerve-sparing technique called hydro-dissection, using a tool that looks much like a water pick to separate surrounding tissue and muscle fiber from the prostate gland and the tumor growing on it. Parekattil said his results to date using hydro-dissection suggest that the technique means less chance of incontinence and impotence following surgery."[4]
  - o "The potential for better nerve preservation"[5]

3 Rau HG et al. Laparoscopic Liver Resection Compared with Conventional Partial Hepatectomy - A Prospective Analysis. Hepato-Gastroenterology 1998;45:2333-2338
4 Chun D. Surgeries involving robots result in quicker recoveries. Gainesville Sun 4/11/07
5 Pow-Sang JM et al.Pure Laparoscopic and Robotic-Assisted Laparoscopic Radical Prostatectomy in the Management of Prostate Cancer. Cancer Control 2007; 14:250-257

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- "Hemostatic Hydro dissection of the Neurovascular Bundles (HYNEB) during LRP and RALP may promote the early return of continence and erectile function."[6]
- "Our survival study supports the feasibility of Hydrojet-assisted LPN without hilar vessel control, thus completely avoiding warm ischemia. This approach has the potential to decrease the level of technical difficulty inherent in LPN.[7]
  - The water jet produced a corridor in the desired dissection line without interfering with the intrarenal vessels and pelvicaliceal system. This way, precise hemostasis was possible and damage to the surrounding tissue was avoided. Resection took between 14 and 40 minutes with minimal intraoperative blood loss. No significant postoperative complication occurred. Histologic evaluation demonstrated a sharp dissection line without thermal alterations or deep necrosis. Only a small disruption zone could be seen at the margin of the dissection…
  - Water jet resection is a gentle method for dissection of kidney tissue. Histologic examination confirmed minimal traumatic parenchymal alteration."
- "Certain technical caveats are emphasized. Hydro-jet® dissection allowed identification of the intact collecting system, which was then sharply incised with scissors.[8]
  - For tissue dissection, the water jet was directed at the desired line of transaction. The saline jet cuts the kidney unusually regularly and precisely. By correctly adjusting the pressure of the jet, an actual discrimination between different tissue types can be achieved, apparently according to their different tensile strengths. The intrarenal vessels and the pelvicaliceal system remained undamaged. In this way, selective hemostasis was possible and no urinary fistulae occurred…
  - Renal parenchyma was transected successfully without any additional surgical tool. The renal capsule could not be dissected by water jet and had to be incised by electrocautery. Good visual control of the operating field by avoiding formation of air bubbles was provided by an integrated suction system…

6 Parekattil SJ & Dahm P. Hemostatic Hydrodissection of the Neurovascular Bundles (HYNEB) during Laparoscopic and Robotic Radical Prostatectomy: Early Potency and Continence Outcomes (Abstract) WCE 2007
7 Moinzadeh A et al. Water Jet Assisted Laparoscopic Partial Nephrectomy without Hilar Clamping in the Calf Model. J Urology 2005;174:317-321
8 Basting RF, Djakovic N & Widmann P. Use of Water Jet Resection in Organ Sparing Kidney Surgery. J Endourology 200;14:500-504

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* Water jet technology has proven to provide significant advantages concerning resection time and blood loss in comparison with other surgical techniques such as blunt dissection or the ultrasonic aspirator. Another disadvantage of the older methods is their thermal and mechanical damage to the surrounding tissue. In order to overcome this problem, a water jet device was developed and established in liver surgery. It has been applied successfully in brain surgery, as the water jet does not produce deep necrosis or damage to the surrounding tissue…
* In the present study, the water jet dissector was demonstrated to wash away the parenchyma, leaving other anatomic strictures intact. This way, precise and selective hemostasis was possible."

Gastro/Intestinal (GI):

- Selective submucosal water jet hydro-dissection is achieved by dissecting the submucosa and mucosa from inner circular muscle layer. Larger submucosal vessels are left largely intact and can be treated separately.

- Total Mesorectal Excision (TME) is another procedure, which benefits from the advantages of conserving tissue structures. The selective vessel-sparing dissection of the mesorectum layer by layer reduces post operative urinary incontinence and sexual dysfunction.

- Blood vessels and nerve structures in the following statements are from the Referenced Clinical Publications.

- The following statements are from the Referenced Clinical Publications.
  - "Controlled submucosal injection and cutting which accelerates the procedure."[9]
  - "The transmucosal application of liquids using the water jet technique offers a new method for mucosal lift-off prior to mucosal resection."[9]

9 B. Schumacher; K. Deinert; M. Philipper; H. Neuhaus: Experimental testing of a new hybrid knife for endoscopic submucosal dissection (ESD) in the esophagus. DDW 2007.

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- "Produced strictly selective liquid cushions in the submucosa."[10]
- "The possibility of using a precisely focused water jet to penetrate the mucosa and to selectively create fluid cushions into the submucosa facilitates the endoscopic mucosal resection and is a promising alternative of the standard needle injection. The water jet application is potentially more efficient and could therefore help to develop a new minimal invasive therapy of mucosal tumors which could not be treated endoscopically so far, for reasons of size, extension and position."[10]
- "The application of a focused water jet to the mucosa of the gastrointestinal tract results in the selective accumulation of fluid in the lamina submucosa after penetration of the lamina mucosa; there is a wide range of pressures which can be applied before this will result in any damage to the lamina muscularis propria."[11]
- "Histological investigation confirmed the selective nature of the fluid accumulation in the submucosal tissue which spared the lamina mucosa and the lamina muscularis propria."[11]

<u>Neurosurgery:</u>

- Precise preparation and dissection along the margins between the tumor and brain tissue. Tumor resection is selective with minimal trauma to healthy brain parenchyma and nerve structures are largely preserved. There is no thermal necrosis along the margins of the dissection plane or cavitations/disruptions relative to other energy devices or scalpel dissection.
- Specific treatment areas in neurosurgery:
  - Gliomas
  - Metastases
  - Epileptic surgery
- The following statements are from the Referenced Clinical Publications.

10 Kaehler GF. Submucosal cushioning with waterjet before endoscopic mucosal resection: which substances are effective? DDW 2007
11 Kaehler GF. Selective Tissue Elevation by Pressure Injection (STEP) Facilitates Endoscopic Mucosal Resection (EMR) 2007

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- "Waterjet dissection versus Ultrasonic Aspiration in Epilepsy Surgery.[12]
  - Water dissection is currently under close investigation in neurosurgery. Experimentally, precise brain parenchyma dissection with vessel preservation has been demonstrated. Clinically, the safety of the instrument has already been proved. However, precise data demonstrating that waterjet dissection indeed reduces surgical blood loss are still missing…
  - The authors applied the waterjet device in a prospective randomized study in comparison with the ultrasonic aspirator. Because there is little variability in the procedure, 30 patients with temporal lobe epilepsy receiving a tailored temporal lobe resection between December 1999 and October 2002 were selected for this study. Intraoperative vessel preservation, intraoperative blood loss, surgical complications and epilepsy outcome were evaluated. All patients were followed at 3-month intervals…
  - During surgery, both instruments were easy to handle. Only with the waterjet dissector, however, where even small intraparenchymal blood vessels were preserved. Intraoperative blood loss was significantly reduced with the waterjet (mean 70 + 46 ml) compared with the ultrasonic aspirator (mean 121 + 48 ml). However, no difference in the necessity for blood transfusion occurred. No difference was observed with respect to operation tie (238.6 + 37.0 min with the water jet, 247.5 + 41.5 min with the ultrasonic aspirator), surgical complications and outcome…
  - The water jet dissector enables a significant reduction of intraoperative blood loss in the investigated setting…
  - Less traumatic and less blood loss compared with CUSA in vivo-study"

- "Vessel preservation in all pathologies below 20 bar (290 psi)"[13,14]

- "Good correlation between applied water jet and cutting depth"[15]

12 J.Oertel, M.R. Gaab, T. Shiller, D. Pillich, R. Warzok, J. Piek, "Water jet dissection is less traumatic than ultrasonic aspiration: an experimental study in the rabbit", German Society of Neurosurgery, Presentation (05/2003) P 25-07
13 J. Piek. J. Oertel, M.R. Gaab, "Water jet dissection of gliomas in neurosurgical procedures: clinical results in 35 patients", Journal of Neurosurgery (2002) 96: 690-696
14 J. Oertel, M.R. Gaab, J. Piek,"Clinical application of the water jet instrument: a detailed account of this technique after more than 100 procedures", German Society of Neurosurgery, Presentation (05/2003) MI 05-03
15 J.Oertel, M.R. Gaab, A. Knapp, H. Essig, R Warzok, J. Piek "Water jet dissection in Neurosurgery: experimental results in porcine cadveric brain", Neurosurgery (2003) 52: 153 - 159

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HybridAPC Probe

- A combination device that applies waterjet technology to lift mucosal lesions and argon plasma coagulation to ablate the lesions.
- Extremely uniform water jet; delicate, precise and reproducible effects.
- Ergonomically designed single-use instrument.
- Easy to use device.
- An easier and less demanding method of generating force to drive the fluid into the submucosa.
- Needle-less submucosal elevation.
- No mechanical trauma of using a needle, need to find the submucosal plane with a needle, or perforation with a needle.
- There is no needle to cause damage to the channel of the scope.

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ERBE
USA INCORPORATED

February 27, 2015

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

RE: Response to December 2nd, 2014 Refuse To Accept (RTA) involving K143306; ERBE Water Jet System, ERBE HybridAPC Probe

Attn: Document Mail Clerk

As instructed, one (1) CD [an eCopy] is being provided with the paper copy. The eCopy is an exact duplicate of the paper copy.

Please forward this response to the lead reviewer, Mr. Edwin Ramirez.

Sincerely,

John Tartal
Director of Quality and Regulatory Affairs
ERBE USA, Inc.

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

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K143306/S002

FDA CDRH DMC
SEP 30 2015
Received

ERBE
USA INCORPORATED

September 28, 2015

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002
Attention: Edwin Ramirez, Electrical Engineer/FDA Reviewer

Re: ERBE WaterJet System with HybridAPC Probe, 510(k) Number K143306

Dear Mr. Ramirez,

The included additional information is being provided per FDA's 04/29/15 Hold Letter. The deficiency questions are followed by our responses.

We believe that the response has adequately resolved the request as noted. However, if you have any further questions or need to contact me, please call me at (770) 955-4400 or email direct at: John.Tartal@erbe-usa.com.

Sincerely,

John Tartal
Director of Quality and Regulatory Affairs
ERBE USA, Inc.

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

Records Processed under FOIA Request 2016-1547; Released by CDRH on 08/24/2016

FDA/CDRH/DCC
SEP 30 2015
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ERBE
USA INCORPORATED

September 28, 2015

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

RE: ERBE WaterJet System with HybridAPC Probe, 510(k) Number K143306
Response to 04/29/15 Request for Additional Information

Attn: Document Mail Clerk

Per CFR 807.90, enclosed is one (1) original paper copy of the submission. Per the instructions in the eCopy Program for Medical Device Submissions Guidance for Industry and Food and Drug Administration Staff, two (2) CDs with an eCopy are being provided with this response and they are an exact duplicate of the original paper submission.

Sincerely,

John Tartal
Director of Quality and Regulatory Affairs
ERBE USA, Inc.

93

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

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Sincerely,

John Tartal
Director of Quality and Regulatory Affairs
ERBE USA, Inc.

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

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Labeling

1. The submission provided a draft of the "Notes on Use" for the Hybrid APC probe. However, review of the provided labeling disclosed items that should be addressed:

   a. The Magnetic Resonance (MR) status of the HybridAPC probe is not explained properly. Please add the appropriate MR status symbol for the probe to the unit labeling.
   Response:
   To our knowledge, no ERBE product has been used in the MR environment. Also, there is no medical reason for the HybridAPC probe to be used on a patient or be in a patient in an MR environment as it is not an implantable or a passive implantable device. Therefore, no symbol is necessary.

   b. Please move subsection 5: Safety instructions (as seen Notes on Use, Page 5; page 013- 69 of submission) to the first page of the "Notes on use" to ensure the end user is made aware of the safety limitations and warnings for this type of device before proceeding to use said device.
   Response:
   As requested the Safety Instructions section was moved up to section 3 following the Intended and Normal Use sections. See Attachment 1, Revised Draft Notes on use, HybridAPC probe.

   c. Please add a warning instructing the end user of the need to use the device with a neutral electrode.
   Response:
   As requested, a warning in the Safety Instructions was added to address the need for a neutral electrode. See Attachment 1, Revised Draft Notes on use, HybridAPC probe (Specifically, see 3.12 specifying need for using a neutral electrode to have electrical output).

   A submission should provide a draft of the labeling for the proposed device. The labeling should provide adequate contraindications, warnings, precautions and adverse reactions to using the device and should be in compliance with 21 CFR 801 and any applicable guidance. Clear and concise labeling will help the end user make safe and effective decisions in regards to the use of the device while minimizing the risk of improper procedures / misuse.
   Response:
   See Attachment 1, Revised Draft Notes on use, HybridAPC probe.

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

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Performance Testing

(b)(4)

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(b)(4)

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Notes on use

usa

HybridAPC probe

20150-215

Single use only! Sterility not guaranteed if package has been opened or damaged. Discard if package is damaged.

STERILE EO

ERBE

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IMPORTANT!

Please read all information carefully.

These notes on use do not replace the User Manuals of the Water Jet System, Argon Plasma Coagulator and ElectroSurgical Unit (ESU) used! Read the User Manuals of the units and ask ERBE or your distributor in case of doubt!

Caution! Federal law (USA) restricts this device to sale by or on the order of a physician!

1 Intended Use

The HybridAPC probe is indicated for the induction of sterile normal saline into the submucosa to lift mucosal lesions using direct visualization through an endoscope and for HF ablation of the mucosal lesion by Argon Plasma Coagulation (APC).

This device should not be used for uncooperative patients.

2 Normal Use

The HybridAPC probe is to be used with the following ERBE units and accessories:

- Water Jet System Model ERBEJET 2 with accessories.
- Argon Plasma Coagulator Model APC 2 in conjunction with a compatible ESU VIO Model.

Connection to a standard APC receptacle requires the use of adapter 20132-228.

The product is intended for single use.

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

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3 Safety Instructions

WARNING!

3.1 Sterile product for single use

Erbe recommends that the product not be reprocessed after use. Reprocessing can affect material properties and/or product function making its Normal Use no longer possible. Concerns involve:

- Components/connections that are damaged by high temperatures (e.g. in the autoclave).
- Components (e.g. filter, extremely small lumen, etc.) that may prevent internal cleaning/disinfection.

3.2 User requirements

This product may only be used by medical personnel who have been trained per these instructions.

Do not use the product if you are unfamiliar with its operation in conjunction with the ESU and the Argon Plasma Coagulator.

3.3 General information about protection of the user, patient, and product

Do not use in the presence of combustible or explosive materials!

Never lay this product on the patient or in his/her direct vicinity.

Protect this product from any form of mechanical damage! Do not throw! Do not use force! If there is a cable, and unless stated otherwise, do not kink it or wrap it around the accompanying product!

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Do not kink the tube or wrap it round the product to which it belongs!

If damaged, do not use this product!

3.4 Danger of mechanical perforation

Do not puncture the mucosa with the probe's tip.

3.5 Danger of fires in the gastrointestinal tract

Before using Argon Plasma Coagulation (APC), always ensure that no endogenous gases are present in the lumen of the relevant organ.

3.6 Danger of fire in the tracheobronchial system

The high temperatures of argon plasma can cause flammable materials to ignite. Please refer to therapeutic guidelines for O_2 saturation when actively ventilating patients during use of thermal energy sources (i.e. laser or electrosurgical units). For this reason, please always observe the following rules:

- Avoid APC activating during active oxygen (O_2) ventilation. Follow hospital policy and procedure when using thermal energy sources, such as APC, in the airway.
- O_2 use and APC activation should alternate, thus lowering the O_2 concentration.

3.7 Gas embolisms, gas emphysema

To prevent gas embolisms, the argon flow rate must not be set high enough that argon is blown into open vessels. To prevent gas embolisms or emphysema, never point the distal end of APC probes directly towards open vessels or press against tissue.

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3.8 Danger of unintentional damage to nerve structures

Bear in mind that during an APC application in the direct vicinity of nerve structures, stimulation may be induced by electric currents.

In the case of nerves which require protection it is advisable to keep the APC activation time short and adapt minimum power output to the required indication.

3.9 Protection against HF leakage current at the eyepiece

HF leakage current at the eyepiece of the endoscope can cause the user thermal damage. To avoid this please only use endoscopes that are designed for use with electrosurgical accessories.

3.10 Risk of burns to the patient

Flash-overs, activation in the working channel of the endoscope or without visual control of the distal end of the probe can cause unwanted thermal injuries to the patient. Therefore, check that the distal end of the probe (1) protrudes at least 10 mm out of the endoscope before each activation. This is ensured when the first black ring (2) on the distal end of the probe is visible through the endoscope.

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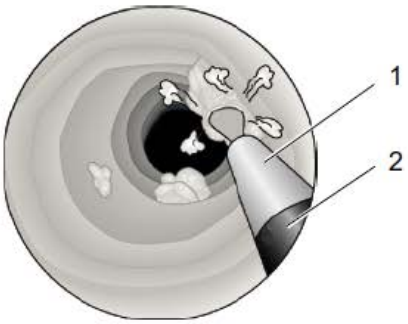

Fig. 1: View of the markings through the endoscope.

3.11 Danger of burns

Argon plasma can strongly heat electrically conductive materials, e.g. metal. To avoid burns, never direct argon plasma towards electrically conductive materials.

Risk of burns. The cutting medium can act as an electric conductor when activating the HF voltage. Make sure that cutting medium from leading parts (e.g. tubes, bags, etc.) does not touch patients or personnel during HF activation.

3.12 No electrical output delivered

The device has an electrical output. Therefore a suitable neutral electrode must be used with the generator.

3.13 Modification of the product by the user

Erbe Elektromedizin expressly warns against modifying the instrument, e.g. cutting off the probe tip. Any modification will exempt Erbe Elektromedizin from all liability.

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4 Maximum Electrical Capacity

The maximum electrical capacity of this product is:

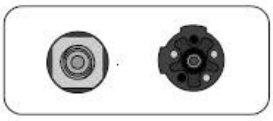
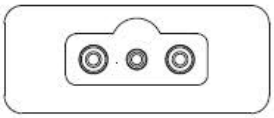
- 4300 V_p

5 Operating Materials and Accessories

To use the product you require the following items:

- Pump cartridge (Art. No. 20150-300)
- Cutting medium: to select the suitable cutting medium please read the Notes on use for the pump cartridge
- possibly commercial dye

Note! The ERBE Argon Plasma Coagulator may have a receptacle which requires an Adapter to connect the product to it. See the following descriptions of receptacles and if the associated Adapter is needed.

Receptacle type	**Accessory for connecting up the probe**
APC standard receptacle 	Adapter Art.-No. 20132-228
FiAPC receptacle 	No further accessories required.

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6 Recommended Unit Settings

This chapter describes unit settings that may be used to operate the product without causing damage.

When operating this product, you must observe the setting limits specified in these instructions. Adapt the power to the planned procedure. Begin with the lowest possible power setting and increase gradually as required.

6.1 Permitted settings on the ERBEJET 2

Rinsing with to high of a pressure can lead to tissue damage. Therefore always select for rinsing the lowest possible effect on the ERBEJET 2.

Effect levels 1 – 80 may be used. However too high of a pressure can lead to tissue damage. Therefore use the lowest possible settings to achieve the desired surgical outcome.

6.2 Permitted settings on the Erbe VIO

Forced APC, Precise APC, and Pulsed APC modes:

- Effect: Effect with an HF peak voltage (U HF) $\leq$ 4,300 V_p [1)]
- Power: maximum 80 watts
- Gas flow: maximum 2.4 l/minute

Settings that are too high can lead to unwanted tissue damage. Theredore use the lowes possible settings to achieve the desired surgical outcome.

1.) The HF peak voltage of an effect depends on the mode selected and the power setting (Watt) used. More information about selecting an appropriate effect is available in the User Manual for the VIO HF electrosurgical unit.

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

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7 Information on electromagnetic compatibility (EMC) of the units

Notwithstanding the specifications in the ERBEJET 2 and VIO User Manuals, HF emissions are classified as Class A[2)] according to CISPR 11 for common use of the product with the units. All other EMC specifications in the User Manuals for the recpective units apply for their common uses.

8 How to Use

8.1 Sterile product for single use

Erbe recommends that the product not be reprocessed after use. Reprocessing can affect material properties and/or product function making its Normal Use no longer possible. Concerns involve:

- Components/connections that are damaged by high temperatures (e.g. in the autoclave).
- Components (e.g. filter, extremely small lumen, etc.) that may prevent internal cleaning/disinfection.

8.2 Check the expiration date

An expiration date is printed on the packaging of the product. Do not use any product beyond its expiration date!

2.) The system is suited for use in environments other than domestic areas and in ones directly connected to a public power supply system that also supplies buildings being used for domestic purposes. The customer or the user of the system should ensure that it is used in such an environment.

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

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8.3 Control and open packaging

Use this product only if the packaging has not been opened or damaged. If the packaging is open or damaged, the product is no longer sterile and must not be used. In this case, throw the product away!

Use aseptic techniques when removing the product from the packaging!

8.4 Check the product

Before use, check that the product including all the insulation is intact. Verify that there are no signs of physical damage.

If damaged, do not use this product!

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

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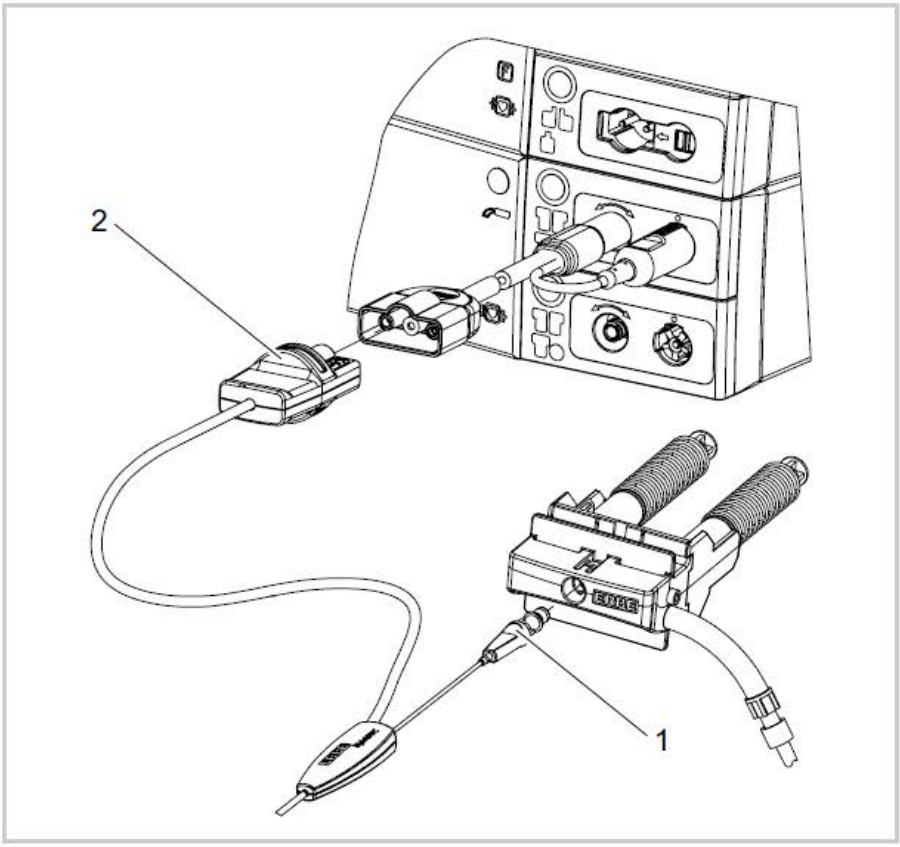
8.5 Connecting the product to the ERBEJET 2 + APC 2 with the APC standard receptacle

IMPORTANT! The adapter, Art. No. 20132-228, must be plugged to the APC standard receptacle!



1. Establish the water jet connection: On the sterile field, plug the extension tubing connector (1) into a pump cartidge by snapping it into place until it clicks. The attached pump cartridge is then inserted into the Water Jet System ERBEJET 2. Follow the instructions in the ERBEJET 2 User Manual to prime, etc.
2. Establish APC connection: Plug the FiAPC plug (2) into adapter 20132-228. The operating parameters of the adapter (not of the probe) are automatically set on the VIO electrosurgical unit.

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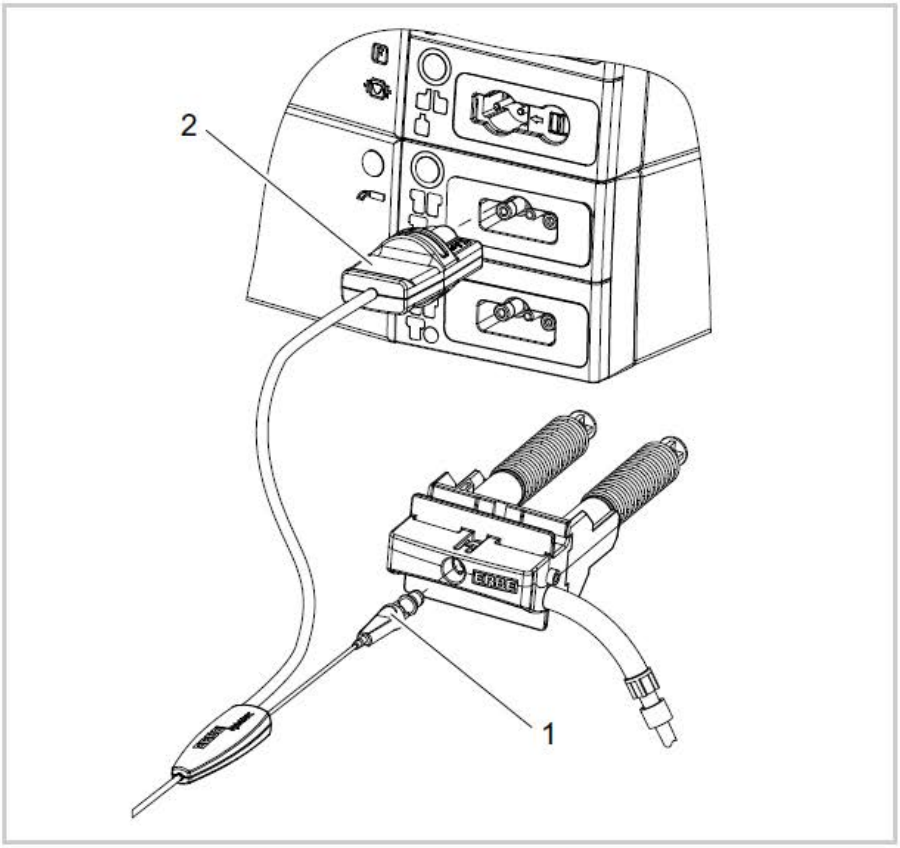
3. See chapter "Recommended Unit Settings" and adjusted settings of the Water Jet System and VIO to achieve the desired surgical outcome.

8.6 Connecting the product to the ERBEJET 2 + APC 2 with the FiAPC receptacle



1. Establish the water jet connection: On the sterile field, plug the extension tubing connector (1) into a pump cartidge by snapping it into place until it clicks. The attached pump cartridge is then inserted into the Water Jet System ERBEJET 2. Follow the instructions in the ERBEJET 2 User Manual to prime, etc.

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2. Establish APC connection: Plug the FiAPC plug (1) into a FiAPC receptacle. The probe will be detected by the VIO electrosurgical unit.
3. See chapter "Recommended Unit Settings" and adjusted settings of the Water Jet System and VIO to achieve the desired surgical outcome.

8.7 Endoscope selection

HF leakage current at the eyepiece of the endoscope can cause the user thermal damage. To avoid this please only use endoscopes that are designed for use with electrosurgical accessories.

The endoscope's working channel must have a diameter larger than 2.5 mm.

8.8 Using the product

The water jet and APC are **alternately** activated via different footswitches.

The water jet is activated via the ERBEJET 2 footswitch, the APC via the COAG pedal of the VIO footswitch.

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Record 1, Processed with FOIA Request 2016-1547; Released by CDRH on 08/24/2016

Exhibit 1

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