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Endoscopy
Smith & Nephew, Inc
150 Minuteman Road
Andover, MA 01810

978 749 1000
978 749 1599 Fax
www.smith-nephew.com

FEB 2 5 2004

We are

K033981 (pg 1 of 3)

SECTION V
510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

as required by the Safe Medical Devices Act of 1990 and codified in 21 CFR 807.92 upon which the substantial equivalence is based.

Smith & Nephew ElectroThermal® 20S Spine Generator

Date Prepared: December 22, 2003

A. Submitter's Name:

Smith & Nephew, Inc., Endoscopy Division
150 Minuteman Road
Andover, MA 01810

B. Company Contact

Janice Haselton
Regulatory Affairs Specialist II
Phone: (978) 749-1494
Fax: (978) 749-1443

C. Device Name

Trade Name:	Smith & Nephew ElectroThermal® 20S Spine Generator
Common Name:	Electrosurgical Spine Generator
Classification Name:	Electrosurgical Cutting and Coagulation & Accessories

D. Predicate Devices

The Smith & Nephew Smith & Nephew ElectroThermal® 20S Spine Generator is substantially equivalent in Intended Use and Fundamental Scientific Technology to the following legally marketed device in commercial distribution: Smith & Nephew ORA-50 S, cleared in K993854 and Radionic's RFG-3C Plus Lesion Generator, cleared in K982489.

E. Description of Device

The proposed Smith & Nephew ElectroThermal® 20S Spine generator is a 20-watt electrothermal generator. It is intended to be used to create lesions in nervous tissue and to coagulate and decompress material when used in combination with Smith & Nephew thermal/coagulating probes. The generator provides temperature and impedance monitoring of energy to maintain effective tissue heating during temperature controlled applications. Smith & Nephew ElectroThermal® 20S Spine generator is designed to be used in conjunction with Smith and Nephew Spine products. These products include the Smith & Nephew SpineCATH® Intradiscal Catheter, the Smith & Nephew Decompression Catheter and the Smith & Nephew RF Denervation Probe and Smith & Nephew RF Probe.

F. Intended Use

The Smith & Nephew ElectroThermal® 20S Spine System is intended to create lesions in nervous tissue, and to coagulate and decompress disc material when used in combination with Smith & Nephew thermal/coagulating probes. The generator and accessories are intended for use by qualified medical personnel trained in the use of electrosurgical equipment.

Contraindications for Use:

There are no known absolute contraindications to the use of electrosurgery.

The Smith & Nephew ElectroThermal® 20S Spine System is contraindicated, when in the judgement of the physician, an electrosurgical procedure would be contrary to the best interest of the patient.

G. Comparison of Technological Characteristics

The Smith & Nephew ElectroThermal® 20S Spine generator is substantially equivalent to the Smith & Nephew ORA-50 S, cleared in K993854, based on the following:

- Both control and monitor temperature
- Both monitor impedance
- Both use RF energy to thermally heat the SpineCATH® and Decompression catheters
- Both provide preset settings for time and temperature to deliver RF.

The Smith & Nephew ElectroThermal® 20S Spine generator is substantially equivalent to the Radionic's RFG-3C Plus Lesion Generator cleared in K982489 based on the following:

- Both control and monitor temperature
- Both monitor impedance
- Both use a biphasic square wave to deliver stimulation voltage

- Both use temperature controlled RF energy to create lesions in nervous tissue

H. Summary Performance Data

The performance testing conducted on the Smith & Nephew ElectroThermal® 20S Spine generator demonstrates substantial equivalents to the Radionic's RFG-3C Plus Lesion Generator cleared in K982489 and the Smith & Nephew ORA-50 S cleared in K993854 based on deliverance of temperature and time of RF controlled energy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 5 2004

Ms. Janice Haselton
Regulatory Affairs Specialist II
Smith & Nephew, Inc.
Endoscopy Division
150 Minuteman Road
Andover, Massachusetts 01810

Re: K033981
Trade/Device Name: The Smith & Nephew ElectroThermal® 20S Spine Generator
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: December 22, 2003
Received: December 23, 2003

Dear Ms. Haselton:

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

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

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

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K033981

Device Name: The Smith & Nephew ElectroThermal® 20S Spine System

Indications For Use:

The Smith & Nephew ElectroThermal® 20S Spine System is intended to create lesions in nervous tissue, and to coagulate and decompress disc material when used in combination with Smith & Nephew thermal/coagulating probes. The generator and accessories are intended for use by qualified medical personnel trained in the use of electrosurgical equipment.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K033981

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 25 2004

Ms. Janice Haselton
Regulatory Affairs Specialist II
Smith & Nephew, Inc.
Endoscopy Division
150 Minuteman Road
Andover, Massachusetts 01810

Re: K033981
Trade/Device Name: The Smith & Nephew ElectroThermal® 20S Spine Generator
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: December 22, 2003
Received: December 23, 2003

Dear Ms. Haselton:

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

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

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K033981

Device Name: The Smith & Nephew ElectroThermal® 20S Spine System

Indications For Use:

The Smith & Nephew ElectroThermal® 20S Spine System is intended to create lesions in nervous tissue, and to coagulate and decompress disc material when used in combination with Smith & Nephew thermal/coagulating probes. The generator and accessories are intended for use by qualified medical personnel trained in the use of electrosurgical equipment.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K033981

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

December 23, 2003

SMITH & NEPHEW, INC.
ENDOSCOPY DIVISION
150 MINUTEMAN RD.
ANDOVER, MA 01810
ATTN: JANICE HASELTON

510(k) Number: K033981
Received: 23-DEC-2003
Product: SMITH & NEPHEW
ELECTROTHERMAL 20S
SPINE GENERATOR,
MODEL 7209975

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

The Act, as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA)(Public Law 107-250), authorizes FDA to collect user fees for premarket notification submissions. (For more information on MDUFMA, you may refer to our website at http://www.fda.gov/oc/mdufma).

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review". Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMICA. If you have other procedural or policy questions, or want information on how to check on the status of your submission, please contact DSMICA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsmamain.html or me at (301)594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Office of Device Evaluation
Center for Devices and Radiological Health

[redacted]

2003 DEC 23 A 11:46

SK14

15

K033981

Endoscopy
Smith & Nephew, Inc.
150 Minuteman Road
Andover, MA 01810

978 749 1000
978 749 1599 Fax
www.smith-nephew.com

We are smith & nephew

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

2003 DEC 23 A 11:45

December 22, 2003

RE: Traditional 510(k) Notification for the Smith & Nephew ElectroThermal® 20S Spine System

Dear Madam/Sir:

Pursuant to the requirements in 21 CFR 807.87, Smith & Nephew, Inc., Endoscopy Division hereby submits two (2) copies of the 510(k) notification for the Smith & Nephew ElectroThermal® 20S Spine System and two copies of this cover letter.

We consider technical information stamped **"CONFIDENTIAL"** to be trade secret and confidential commercial information, not available for disclosure under 21 CFR part 20. Smith & Nephew, Inc. also requests that the FDA keep and maintain confidential both the existence as well as the contents of this Premarket Notification in accordance with 21 CFR 807.95(b).

Smith & Nephew acknowledges that the introduction of this device into domestic commercial distribution will be contingent upon written clearance of the 510(k) by the Food and Drug Administration. The substantial equivalence information included in this document is for FDA marketing clearance only, and in no way reflects upon the patentability of the device.

If you have any questions regarding this submission, please contact me at;
Phone: (978) 749-1494
Fax: (978) 749-1443
E-mail: janice.haselton@smith-nephew.com
Sincerely,

Janice Haselton

Janice Haselton, R.A.C.
Regulatory Affairs Specialist II

SK14

SU II

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Traditional 510(k)

Smith & Nephew ElectroThermal® 20S Spine Generator

Medical Device User Fee Cover Sheet

Form Approved:OMB No. 0910-0511 Expiration Date: August 31, 2006. See instructions for OMB Statement.

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

PAYMENT IDENTIFICATION NUMBER: (b) (4)
Write the Payment Identification Number on your check.

A completed Cover Sheet must accompany each original application or supplement subject to fees. The following actions must be taken to properly submit your application and fee payment:

1. Electronically submit the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent.
2. Include a printed copy of this completed Cover Sheet with a check made payable to the Food and Drug Administration. Remember that the Payment Identification Number must be written on the check.
3. Mail Check and Cover Sheet to the US Bank Lock Box, FDA Account, P.O. Box 956733, St. Louis, MO 63195-6733. (*Note: In no case should payment be submitted with the application.*)
4. If you prefer to send a check by a courier, the courier may deliver the check and Cover Sheet to: US Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.)
5. For Wire Transfer Payment Procedures, please refer to the MDUFMA Fee Payment Instructions at the following URL: http://www.fda.gov/cdrh/mdufma/faqs.html#3a. You are responsible for paying all fees associated with wire transfers.
6. Include a copy of the completed Cover Sheet in volume one of the application when submitting to the FDA at either the CBER or CDRH Document Mail Center.

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

SMITH NEPHEW ENDOSCOPY DIVISION
150 MINUTEMAN ROAD
ANDOVER, MA 01810

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
510123924

2. CONTACT NAME
JANICE HASELTON

2.1 E-MAIL ADDRESS
janice.haselton@smith-nephew.com

2.2 TELEPHONE NUMBER (Include Area Code)
978-749-1494

2.3 FACSIMILE (FAX) NUMBER (Include Area Code)
978-749-1443

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

Select an application type:
- ☑ Premarket notification (510(k)); except for third party reviews
- ☐ Biologics License Application (BLA)
- ☐ Premarket Approval Application (PMA)
- ☐ Modular PMA
- ☐ Product Development Protocol (PDP)
- ☐ Premarket Report (PMR)

3.1 Select one of the types below:
- ☑ Original Application

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

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

- ☐ YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
- ☑ NO, I am not a small business

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

5. 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, parents, and partner firms
- ☐ This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
- ☐ The sole purpose of the application is to support conditions of use for a pediatric population
- ☐ The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

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

☐ YES ☑ NO

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (FOR FISCAL YEAR 2004)

(b) (4)

Form FDA 3601 (08/2003)

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CDRH SUBMISSION COVER SHEET

Date of Submission December 22, 2003	FDA Document Number

Section A Type of Submission

PMA	PMA Supplement	PDP	510(k)	Meeting
☐ Original submission ☐ Modular submission ☐ Amendment ☐ Report ☐ Report Amendment	☐ Regular ☐ Special ☐ Panel Track ☐ 30-day Supplement ☐ 30-day Notice ☐ 135-day Supplement ☐ Real-time Review ☐ Amendment to PMA Supplement	☐ Pre-submission summary ☐ Original PDP ☐ Notice of intent to start clinical trials ☐ Intention to submit Notice of Completion ☐ Notice of Completion ☐ Amendment to PDP ☐ Report	☒ Original submission ☒ Traditional ☐ Special ☐ Abbreviated ☐ Additional Information ☐ Traditional ☐ Special ☐ Abbreviated ☐ Report Amendment	☐ Pre-IDE mtg. ☐ Pre-PMA mtg. ☐ Pre-PDP mtg. ☐ 180-day mtg. ☐ Other (specify):

IDE	Humanitarian Device Exemption	Class II Exemption	Evaluation of Automatic Class III Designation	Other Submission
☐ Original submission ☐ Amendment ☐ Supplement	☐ Original submission ☐ Amendment ☐ Supplement ☐ Report	☐ Original submission ☐ Additional information	☐ Original submission ☐ Additional information	Describe submission:

Section B Applicant or Sponsor

Company/Institution Name: Smith & Nephew, Inc.			Establishment registration number: 1216828
Division name (if applicable): Endoscopy Division			Phone number (include area code): (978) 749-1494
Street Address: 150 Minuteman Road			FAX number (include area code): (978) 749-1443
City: Andover	State/Province: MA	Zip code: 01810	Country: U.S.A.
Contact name: Janice Haselton			
Contact title: Regulatory Affairs Specialist		Contact e-mail address: janice.haselton@smith-nephew.com	

Section C Submission correspondent (if different from above)

Company/Institution name:			Establishment registration number:
Division name (if applicable):			Phone number (include area code): ( )
Street Address:			FAX number (include area code): ( )
City:	State/Province:	Zip:	Country:
Contact name:			
ıtact title:		Contact e-mail address:	

Section D1 **Reason for Submission - PMA, PDP, or HDE**

- ☐ New device
- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Licensing agreement
- ☐ Change in design, component, or specifications:
  - ☐ Software
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other (specify below)
- ☐ Location change
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager
  - ☐ Distributor
- ☐ Process Change:
  - ☐ Manufacturing
  - ☐ Sterilization
  - ☐ Packaging
  - ☐ Other (specify below)
- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other (specify below)
- ☐ Report submissions:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment
- ☐ Response to FDA correspondence:
  - ☐ Request for applicant hold
  - ☐ Request for removal of applicant hold
  - ☐ Request for extension
  - ☐ Request to remove or add manufacturing site
- ☐ Change in Ownership
- ☐ Change in correspondent
- ☐ Other Reason (specify):

Section D2 **Reason for Submission - IDE**

- ☐ New device
- ☐ Addition of institution
- ☐ Expansion/extension of study
- ☐ IRB certification
- ☐ Request hearing
- ☐ Request waiver
- ☐ Termination of Study
- ☐ Withdrawal of application
- ☐ Unanticipated adverse effect
- ☐ Notification of emergency use
- ☐ Compassionate use request
- ☐ Treatment IDE
- ☐ Continuing availability request
- ☐ Change in:
  - ☐ Correspondent
  - ☐ Design
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing process
  - ☐ Protocol - feasibility
  - ☐ Protocol - other
  - ☐ Sponsor
- ☐ Report Submission:
  - ☐ Current investigator
  - ☐ Annual progress
  - ☐ Site waiver limit reached
  - ☐ 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
- ☐ Other reason (specify):

Section D3 **Reason for Submission - 510(k)**

- ☐ New Device
- ☒ Addition or expanded indications
- ☐ Other reason (specify):
- ☐ Change in technology
- ☒ Change in design
- ☐ Change in materials
- ☐ Change in manufacturing process

Section E **Additional Information on 510(k) Submissions**

Product codes of devices to which substantial equivalence is claimed:

1 GEI	2 HRX	3	4
5	6	7	8

Summary of, or statement concerning, safety and effectiveness data:
☒ 510(k) summary attached
☐ 510(k) statement

510(k) Number	**Trade or proprietary or model name**	*Manufacturer*
1 K982489	1 Radionics RFG-3C Plus Lesion Generator	1 Radionics
2 K993854	2 ORA-50 S Autotemp Electrothermal Spine Generator	2 Oratec Interventions
3	3	3
4	4	4
5	5	5
6	6	6

Section F **Product Information - Applicable to All Applications**

Common or usual or classification name: Electrosurgical Cutting and Coagulation Devices and Accessories

Trade or proprietary or model name	Model number
1 Smith &Nephew ElectroThermal® 20S Spine Generator	1 7209975
2	2
3	3
4	4
5	5

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

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

Data included in submission: ☒ Laboratory testing ☐ Animal trials ☐ Human trials

Section G **Product Classification - Applicable to All Applications**

Product code: GEI, HRX	C.F.R. section: 878.4400, 888.1100	Device class: ☐ Class I ☒ Class II ☐ Class III ☐ Unclassified

Classification panel: General and Plastic Surgery

Indications (From labeling):
The Smith & Nephew ElectroThermal® 20S Spine System is intended to create lesions in nervous tissue, and to coagulate and decompress disc material when used in combination with Smith & Nephew thermal/coagulating probes. The generator and accessories are intended for use by qualified medical personnel trained in the use of electrosurgical equipment.

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

Section H Manufacturing/Packaging/Sterilization Sites Relating to a Submission

☒ Original ☐ Add ☐ Delete	FDA establishment registration number: #1643264	☒ Manufacturer ☐ Contract sterilizer ☐ Contract manufacturer ☒ Repackager/relabler

Company/institution name: Smith & Nephew, Inc.		Establishment registration number: #1643264	
Division name (if applicable): Endoscopy Division		Phone number (include area code): 978-749-1494	
Street address: 600 NW 138th Street		FAX number (include area code): 978-749-1443	
City: Oklahoma	State/Province: OK	ZIP/Postal Code: 73134	Country: U.S.A.
Contact Name: Janice Haselton			
Contact Title Regulatory Affairs Specialist		Contact e-mail address: janice.haselton@smith-nephew.com	

☐ Original ☐ Add ☐ Delete	FDA establishment registration number:	☐ Manufacturer ☐ Contract sterilizer ☐ Contract manufacturer ☐ Repackager/relabler

Company/institution name:		Establishment registration number:	
Division name (if applicable):		Phone number (include area code): ( )	
Street address:		FAX number (include area code): ( )	
City:	State/Province:	ZIP/Postal Code:	Country: U.S.A.
Contact Name:			
Contact Title		Contact e-mail address:	

☐ Original ☐ Add ☐ Delete	FDA establishment registration number:	☐ Manufacturer ☐ Contract sterilizer ☐ Contract manufacturer ☐ Repackager/relabler

Company/institution name:		Establishment registration number:	
Division name (if applicable):		Phone number (include area code): ( )	
Street address:		FAX number (include area code): ( )	
City:	State/Province:	ZIP/Postal Code:	Country: U.S.A.
Contact Name:			
Contact Title:		Contact e-mail address:	

SCREENING CHECKLIST

☐ Special 510(k)	Do Sections 1 and 2
☐ Abbreviated 510(k)	Do Sections 1, 3 and 4
☒ Traditional 510(k)	Do Sections 1 and 4

Section 1: Required Elements for All Types of 510(k) submissions:

	Present	Inadequate or Missing
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510)] Manual.	√	
Table of Contents.	√	
Truthful and Accurate Statement.	√	
Device's Trade Name, Device's Classification Name and Establishment Registration Number.	√	
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).	√	
Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510)] Manual.	√	
Statement of Indications for Use that is on a separate page in the premarket submission.	√	
Substantial Equivalence Comparison, including comparisons of the new device with the predicate in areas that are listed on page 3-4 of the Premarket Notification [510)] Manual.	√	
510(k) Summary or 510(k) Statement.	√	
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.	√	
Identification of legally marketed predicate device. *	√	
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]		N/A
Class III Certification and Summary. **		N/A
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]		N/A
510(k) Kit Certification ***		N/A

* - May not be applicable for Special 510(k)s.

** - Required for Class III devices, only.

*** - See pages 3-12 and 3-13 in the Premarket Notification [510)] Manual and the Convenience Kits Interim Regulatory Guidance.

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

	Present	Inadequate or Missing
Name and 510(k) number of the sponsor's own, unmodified predicate device.		N/A
A description of the modified device and a comparison to the sponsor's predicate device.		N/A
A statement that the intended use(s) and indications of the modified device, as described in its labeling, are the same as the intended uses and indications for the sponsor's unmodified predicate device.		N/A
A statement that the modification has not altered the fundamental technology of the sponsor's predicate device.		N/A
A Design Control Activities Summary that includes the following elements (a-e):		
a. Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.		N/A
b. Based on the Risk Analysis, an identification of the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied.		N/A
c. A Declaration of Conformity with design controls that includes the following statements:		N/A
A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities.		N/A
A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities.		N/A

Section 3: Required Elements for an ABBREVIATED 510(k)* submission:

	Present	Inadequate or Missing
For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.)		N/A
For a submission, which relies on a recognized standard, a declaration of conformity , For a listing of the required elements of a declaration of conformity, SEE Required Elements for a Declaration of Conformity to a Recognized Standard.		N/A
For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		N/A
For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		N/A
For a submission, which relies on a non-recognized standard that has not been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device and any additional information requested by the reviewer in order to determine substantial equivalence.		N/A
Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence.		N/A

- - When completing the review of an abbreviated 510(k), please fill out an Abbreviated Standards Data Form and list all the guidance documents, special controls, recognized standards and/or non-recognized standards, which were noted by the sponsor.

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

	Present	Inadequate or Missing
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:		N/A
b) Sterilization and expiration dating information:		
i) sterilization process		N/A
ii) validation method of sterilization process		N/A
iii) SAL		N/A
iv) packaging		N/A
v) specify pyrogen free		N/A
vi) ETO residues		N/A
vii) radiation dose		N/A
c) Software Documentation:	√	

Premarket Notification*

Truthful and Accurate Statement Certification

[As required by 21 CFR 807.87(k)]

I certify that, in my capacity as Regulatory Specialist II of Smith & Nephew Inc., Endoscopy Division, I believe to the best of my knowledge, that all the data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

Janice Haselton

Signature

Janice Haselton

Typed Name

December 29, 2003

Dated

Premarket Notification [510(k)] Number: K033981

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

** Must be signed by a responsible person of the firm required to submit the premarket notification [e.g., not a consultant for the 510(k) submitter]*

Indications for Use

510(k) Number (if known): K033981

Device Name: The Smith & Nephew ElectroThermal® 20S Spine System

Indications For Use:

The Smith & Nephew ElectroThermal® 20S Spine System is intended to create lesions in nervous tissue, and to coagulate and decompress disc material when used in combination with Smith & Nephew thermal/coagulating probes. The generator and accessories are intended for use by qualified medical personnel trained in the use of electrosurgical equipment.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

SECTION II Required Elements for all 510(k) submissions: General Information

A. Device Name (Unmodified):

Device Trade Name:	Common/Classification Name:
The Smith & Nephew ElectroThermal® 20S Spine System	Electrosurgical Generator

B. Submitter Information:

Company Name	Smith & Nephew, Inc., Endoscopy Division
Address	150 Minuteman Road Andover, MA 01810
Contact	Janice Haselton Regulatory Specialist

C. Establishment Registration Number(s):

Owner/Operator Name	Smith & Nephew, Inc. Endoscopy Division
Address	150 Minuteman Road, Andover, MA 01810
Establishment Registration #	ER# 3003604053
Owner Operator #	#1216828
Manufacturing Site Address	Smith & Nephew, Inc. Endoscopy Division 600 NW 138th Street, Oklahoma City, OK 73134
Establishment Registration #	ER# 1643264
Owner Operator #	# 1216828

D. Device Classification: Regulation Number and Regulatory Status

Class	The Smith & Nephew ElectroThermal® 20S Spine System is Class II
Regulation Number	21 CFR § 878.4400
Procode	GEI
Panel	General and Plastic Surgery

E. Performance Standards

There are no known performance standards or special controls promulgated under section 514 of the Act for this device.

SECTION III
Premarket Notification: Proposed Device Specifics

A. Introduction

This submission covers the Smith & Nephew ElectroThermal® 20S Spine generator and it's associated indications for use. The Denervation catheter and probe used with the Smith & Nephew ElectroThermal® 20S Spine generator have been sent concurrently to the agency in a separate premarket notification submission. Tissue effect, biocompatability and sterility are addressed in that submission for those devices.

Neurophatic pain and annular disruptions of contained herniated discs have become a primary source of chronic back pain. Over the years advances in scientific and technological research have led to improved methods of diagnosis and treatment of pain caused by spinal problems. Pain management has become an integral part of treating lower back pain and radio frequency lesioning offers the surgeon, controlled temperatures, electrical stimulation, and precise target location.

Radio-frequency technology is one form of treatment for pain in the lumbar, thoracic or cervical facet joints. Radio frequency technology delivers radio frequency energy for localized tissue coagulation and to create lesions in nervous tissue.

The proposed Smith & Nephew ElectroThermal® 20S Spine generator is a 20-watt electrothermal generator that is intended to be used to create lesions in nervous tissue and to coagulate and decompress material when used in combination with Smith & Nephew thermal/coagulating probes. The generator provides temperature and impedance monitoring of energy to maintain effective tissue heating during temperature controlled applications. Smith & Nephew ElectroThermal® 20S Spine generator is designed to be used in conjunction with Smith and Nephew Spine products. These products include the Smith & Nephew SpineCATH® Intradiscal Catheter, the Smith & Nephew Decompression Catheter and the Smith & Nephew RF Denervation Probe and Smith & Nephew RF cannula. The Smith & Nephew RF Denervation Probe and Smith & Nephew RF Probe are the subject of a separate 510(k) premarket notification submission currently under FDA review.

Smith & Nephew's ElectroThermal® 20S Spine generator is substantially equivalent in intended use and design to the Smith & Nephew ORA-50 S Auto-Temp ElectroThermal Spine Generator cleared in K993854 and Radionic's RFG-3C Plus Lesion Generator cleared in K982489. The Smith & Nephew's ElectroThermal® 20S Spine generator is a software and hardware modification of the Smith & Nephew ORA-50 S Auto-Temp ElectroThermal Spine Generator. The expanded indications are based on substantial equivalence to Radionic's RFG-3C Plus Lesion Generator cleared in K982489.

B. Device Description

Device Design Summary

The Smith & Nephew's ElectroThermal® 20S Spine generator design modifications as compared to the predicate Smith & Nephew ORA-50 S Programmable ElectroThermal Spine Generator include:

- An LCD Display has been added to the front panel interface.
- An automatic probe recognition feature has been added. This feature incorporates a modification to the software to recognize the type of Smith & Nephew device that is connected to the generator. The software is programmed to read a resistor that is designed into the device handle. This allows the generator to automatically switch to the appropriate mode and default settings for that device thereby eliminating surgeon's need to manually adjust the generator settings.
- An AutoTemp Mode has been provided to maintain the temperature of the Decompression Catheter tip according to the time/temperature profile selected in the Set Profile display. The ORA- 50SP currently provides an AutoTemp mode for the ORATECH SpineCATH® Intradiscal Catheter only.
- For the Denervation probe the following modes were added:
    1. A Stimulate mode delivers biphasic square wave as selected in the settings of frequency, pulse width, and voltage amplitude.
    2. A RF Pulsed Mode delivers a selected frequency to maintain the temperature of the Denervation probe tip according to the time and temperature selected.
    3. A RF Lesion mode provides RF energy to lesion tissue according to the time and temperature selected.
- The extension cable provided with the Smith & Nephew's ElectroThermal® 20S Spine generator and the probe connector receptacle located on the front panel have been modified from a four pin connector to an eight pin connector. The additional pins in the connector allow for more functions to be performed such as the probe recognition feature and the different modes for the Denervation probe.
- A Stim Output Knob has been added to the front panel to allow for stimulation output voltage control.
- The operating software for the generator can be updated in the field by means of a manufacturer-supplied proprietary PC memory card.

The Smith & Nephew ElectroThermal® 20S Spine generator has control settings for (see front and rear panel diagrams located in Section IV.

- Front Panel:

-Mode/Function Changes	- Set Profile	- Set Time
- RF On/Off/Pause	- Reset	
-Start	- Width	
-Stim Output Knob	- Fault	

- Frequency
- Set Temperature

• Rear Panel:
-On/Off Switch
- Serial Communications Port

The Smith & Nephew ElectroThermal® 20S Spine generator has displays for:

- Stand-by mode
- Impedance
- Actual Temp
- Elapsed Time
- PAUSED
- Volts
- Frequency (Hz)

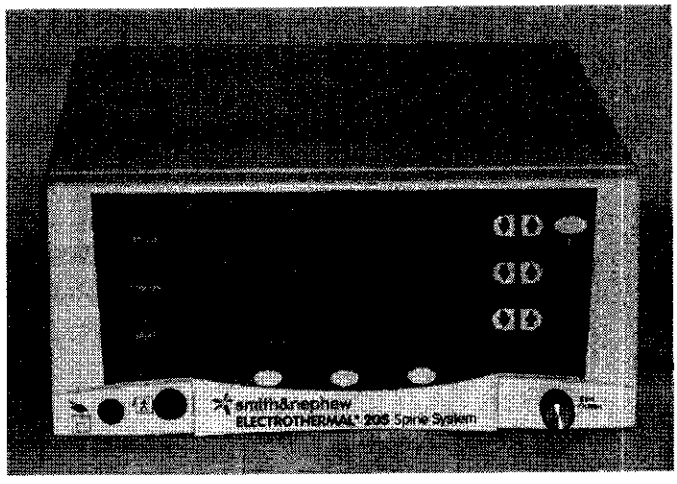
The Smith & Nephew ElectroThermal® 20S Spine generator has connections for:

• Front Panel: Universal Extension Cable Connector
Neutral Electrode Connector
• Rear Panel: Footswitch
Power Cord
PC Card
Serial Communications Port

Accessories provided with the Smith & Nephew ElectroThermal® 20S Spine generator include:

• A hospital grade power cord
• A pneumatic foot pedal.
• A universal extension cable

Reference Engineering drawings located in Exhibit A



The Smith & Nephew ElectroThermal® 20S Spine generator is a software controlled device and the modifications that were made to the software were reviewed per the FDA Guidance Document "Guidance for FDA and Industry for the Content of Premarket Submissions for Software Contained in Medical Devices". The Software Level of Concern was determined to be moderate and the flow chart depicting this determination is located in Exhibit D, Tab 1.

All other software requirements per the FDA Guidance Document "Guidance for FDA and Industry for the Content of Premarket Submissions for Software Contained in Medical Devices" can be located in Exhibit D, Tabs 2-5.
The risk analysis method used to assess the impact of the modifications to the generator was a Risk Analysis per EN 1441 and a Failure Mode and Effects Analysis (FMEA) located in Exhibit D, Tab 2.

The SRS and SSP (Software Requirement Specification, Software Specifications) are located in Exhibit D, Tab 3.

The Summary of the software lifecycle development is located in Exhibit D, Tab 4

The software revision history log, software verification, validation and testing are located in Exhibit D, Tab 5.

The software released version number is 0.13 as referenced in the software validation report in Exhibit D, Tab 5.

The Smith & Nephew ElectroThermal® 20S Spine generator is in compliance with the following electrical standards: EN 60601-1, 60601-1-2, 60601-2-2, 60601-2-10, FCC Part 18, and UL 2601- 1+A1.

Principle of Operation

The Smith & Nephew ElectroThermal® 20S Spine generator is a line powered radio-frequency generator capable of delivering up to twenty watts of power in an array of user modes for localized tissue coagulation and to create lesions in nervous tissue. The generator is a software driven device and provides five treatments or diagnostic modes. Other modes include MCU Initializing, POST, Standby, and Warning/Fault. An additional mode bypasses the RF self checks and displays calibration information for use during manufacturing and there is a mode that displays RF power and voltage output for use by Biomedical Engineering at the hospital.

Immediately following power-up, the generator initializes the MCU (micro control unit) and after successful completion, the system will go to POST (Power On Self Test) mode, where the operation and calibration of the RF and temperature measurement systems are verified. If the system fails any self-test, it goes to a Warning/Fault mode.

The user can then select the appropriate probe required for the procedure and connect it to the generator using the extension cable connector for the SpineCATH and Decompression Probes or directly to the connection port on the generator if using the Denervation Probe. Once the device is connected, the generator automatically determines the type of device and switches to the proper operating mode and default settings. After the operating mode is selected, the generator automatically begins continuous checking of the impedance, temperature and device identification. Impedance is continuously checked for all modes except stimulation.

When the SpineCATH™ or Decompression Probe is selected, the generator will enter the AutoTemp Mode, which is an automated procedure where the device temperature is gradually increased over a period of several minutes to a desired treatment temperature. This treatment temperature is then maintained for a specified dwell period to complete the procedure. The user can adjust the treatment temperature by changing the value of SET PROFILE, which has a default value of P90. During the procedure, the user can manually adjust the SET PROFILE and SET TEMPERATURE settings to achieve the desired clinical affect. The temperature will increase automatically as described in the AutoTemp Profile Table. The AutoTemp Profile Table is presented in the Operations manual, Exhibit B.

The Smith & Nephew ElectroThermal® 20S Spine generator contains functions for two Stimulate modes, sensory and motor. When the Denervation Probe is connected the generator defaults to the Sensory Stimulate (Stim: Sensory) Mode. In this mode the voltage always starts in the OFF position. The voltage can be manually increased up to 1.00 volts. The width of the stimulation pulses can be manually adjusted to 0.1, 0.5, 1, 2, or 3 mSec. The frequency of the pulses is fixed at 50 Hz.

Depressing any of the three keys, Motor Stimulate (Stim: Motor), Pulsed RF, and RF Lesion, it will allow you to exit from the Stim: Sensory Mode.

In the Stim: Motor Mode, the voltage starts in the OFF position. The voltage can be manually adjusted up to 10.0 volts. The width of the stimulation pulses can be manually adjusted to 0.1, 0.5, 1, 2, or 3 mSec. The frequency of the pulses is fixed at 2Hz.

Depressing any of the three keys, Motor Stimulate (Stim: Motor), Pulsed RF, and RF Lesion, will allow you to exit from the Stim: Motor Mode.

Operational Modes:

Standby
Only the "Start" key is active in this mode. Once a device is connected, the "Start" key is identified. Once the "Start" key is pressed, the generator automatically enters the appropriate operating mode for the device that is connected. If the device is unplugged the generator alerts the user to insert the device and remains in its current mode.

Warning/Fault Mode
The Warning/Fault mode displays the identification number of Warnings or Faults on the LCD screen. If the system enters the Warning/Fault mode as a result of a Fault, all user controls are inactive except for "Help"/"Exit Help" key. The "Help" key provides a description of possible causes and fixes. It is necessary to turn off the AC power and restart the system to resume operations. If it enters into a Warning/Fault mode because of a warning the "OK" key and "Help"/ "Exit Help" key is activated. When the user corrects the error condition and the "OK" key is depressed the system will return to the previous operating mode.

SpineCATH™ AutoTemp Mode

The SpineCATH™ AutoTemp Mode delivers the required RF power to maintain the profile temperature of the SpineCATH™ Intradiscal Catheter tip for the specified time. To prevent the SpineCATH™ device from being used more than a single time, the system only allows a single procedure to be performed without changing the device.

Decompression AutoTemp Mode

The Decompression AutoTemp mode delivers RF power to maintain profiled temperature of the Decompression Catheter tip for the profiled time. To prevent the Decompression device from being used more than a single time, the system only allows a single procedure to be performed without changing the device.

Stimulate Mode
The stimulate mode delivers a biphasic square wave at the specified settings of frequency, pulse width, and voltage amplitude to stimulate sensory or motor nerves. Since multiple sites are often treated, the output may be delivered repeatedly in this mode. The Denervation device is designed to be reusable.

RF Lesion Mode
RF power is delivered continuously to maintain the pre-selected temperature of the Denervation probe tip for the selected time. Since the Denervation device is designed to be reusable, the output may be delivered repeatedly in this mode.

Pulsed RF Mode

The Pulsed RF mode delivers 20 millisecond RF pulses at the selected frequency. RF power is controlled to maintain the pre-selected temperature of the Denervation probe tip for the selected time. Since the Denervation device is designed to be reusable, the output may be delivered repeatedly in this mode.

Major Components and Materials

The generator enclosure is constructed of 0.047 inch thick corrosion resistant stainless steel.
The front bezel is constructed of polyurethane.
The generator has no patient contacting parts and remains outside the sterile field.

Packaging and Sterilization

The Smith & Nephew ElectroThermal® 20S Spine generator is packaged in a doubled walled corrugated cardboard box with foam inserts.

The Smith & Nephew ElectroThermal® 20S Spine generator and footswitch are non-patient contacting and do not enter into the sterile field. Sterilization is not required, although it is recommend that the generator and footswitch be wiped down with any liquid disinfecting solution; non-flammable solution should be used whenever possible. Reference cleaning information, page 28, in the Smith & Nephew ElectroThermal® 20S Spine generator manual, Exhibit B.

C. Statement of Substantial Equivalence

The Smith & Nephew ElectroThermal® 20S Spine generator is substantially equivalent to the Smith & Nephew ORA-50 S, cleared in K993854, based on the following:

- Both control and monitor temperature
- Both monitor impedance
- Both use RF energy to thermally heat the SpineCATH® and Decompression catheters
- Both provide preset settings for time and temperature to deliver RF.

The Smith & Nephew ElectroThermal® 20S Spine generator is substantially equivalent to the Radionic's RFG-3C Plus Lesion Generator cleared in K982489 based on the following:

- Both control and monitor temperature
- Both monitor impedance

- Both use a biphasic square wave to deliver stimulation voltage
- Both use temperature controlled RF energy to create lesions in nervous tissue

The Smith & Nephew ElectroThermal® 20S Spine generator differs from the Smith & Nephew ORA-50 S cleared in K993854, and Radionic's RFG-3C Plus Lesion Generator cleared in K982489 in that:

- The indications have been expanded from the ORA-50 S to include lesioning in nervous tissue.
- The Smith & Nephew ElectroThermal® 20S Spine generator can deliver up to 20 watts of RF power compared to the ORA-50SP, and Radionics RFG-3C Plus which can deliver up to 50 watts of RF power. The ORA-50SP power output capability was never fully utilized with it's current indications. A max of 5 watts of power is required for the SpineCATH® or Decompression catheter applications. The Denervation applcation uses up to 20 watts. The difference in power supplied by the Smith & Nephew ElectroThermal® 20S Spine generator as compared to the predicate devices does not compromise the effectiveness of energy application. The tissue effect testing that was performed for the Denervation probe demonstrates that the power supplied by the Smith & Nephew ElectroThermal® 20S Spine generator was ample for the application. This testing is located in the Denervation catheter and Probe submission, which is concurrently in review with FDA.
- The Smith & Nephew ElectroThermal® 20S Spine generator has a preprogrammed time and temperature profile (AutoTemp routine) for the Decompression catheter while the ORA-50S requires manual user adjustments of Set Temperature. The parameters for the Decompression catheter AutoTemp routine were based on those that have been shown to provide efficacious results with this device.
- The Smith & Nephew ElectroThermal® 20S Spine generator controls Pulsed RF delivery as a function of temperature while the Radionics RFG-3C Plus requires manual user adjustments of the output voltage to maintain treatment temperatures.

A comparative evaluation table for the proposed and predicate devices is located in Exhibit E. The table shows the differences and similarities between the Smith & Nephew ElectroThermal® 20S Spine generator, the Smith & Nephew ORA-50 S generator, and the Radionic's RFG-3C Plus Lesion Generator. This comparison table will demonstrate that the Smith & Nephew ElectroThermal® 20S Spine generator is substantially equivalent to the predicate devices in intended use, technology, basic features, and design.

Side by side performance tests were conducted with the Smith & Nephew ElectroThermal® 20S Spine generator, the Smith & Nephew ORA-50 S generator cleared in K993854, and the Radionic's RFG-3C Plus Lesion Generator cleared in K982489.

(b) (4)

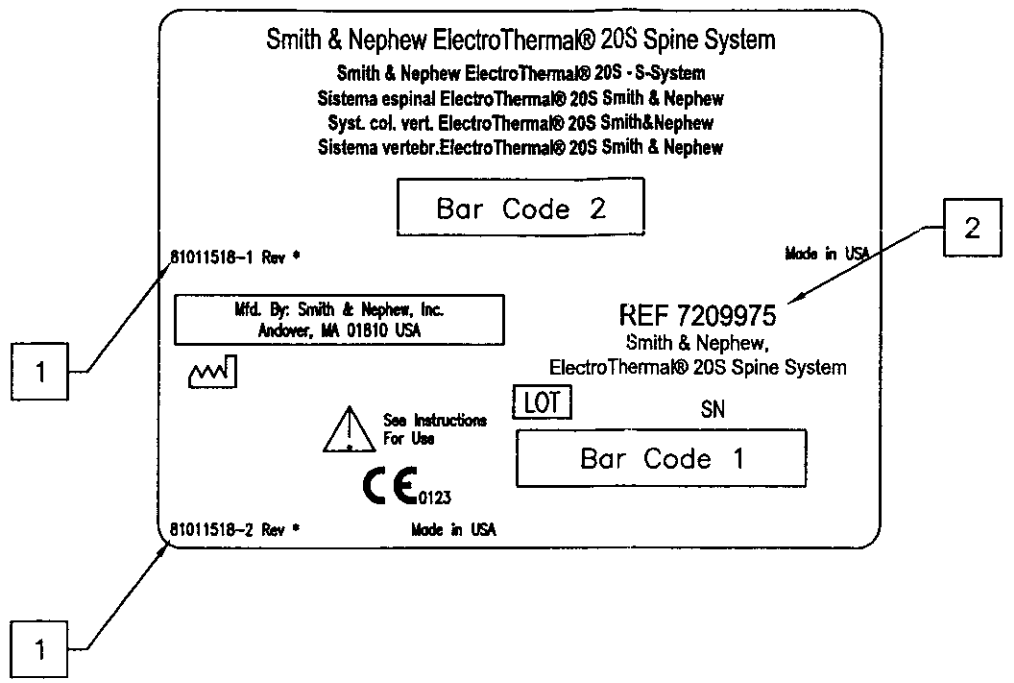
probes were connected to each generator. The probes were (b) (4)

(b) (4)

SECTION IV
Overlays and Labels

(b)(4) Schematics (Whole Page Redactions 41-42)

REVISION HISTORY			
REV	ECO NO.	CHNG BY	APVD BY/DATE
A	26929	RNC	RNC 11-26-03
PRODUCTION RELEASE			



NOTES:

1. THE ASTERISK INDICATES CURRENT REVISION LEVEL.

2. THE REF NUMBER ON THIS LABEL MAY APPEAR WITH THE FOLLOWING SUFFIX:
   F = REFURBISHED EQUIPMENT
   M = DISTRIBUTED FROM MIAMI WAREHOUSE
   S = SERVICE REPLACEMENT

ITEM NO	PART NO	REQ'D	DESCRIPTION
1	850-0435	1	LABEL, 3.875" x 2.875"

UNLESS OTHERWISE SPECIFIED:
DIMENSIONS ARE IN INCHES
TOLERANCES:
DECIMAL DIMENSIONS:
.XX ± .01
.XXX ± .005
.XXXX ± .0005
ANGULAR ± 1°
SURFACE ROUGHNESS 63 OR BETTER
INTERPRET DIM AND TOL PER ASME Y14.5M-1994

THIRD ANGLE PROJECTION

DRAWN: RNC	DATE: 11-26-03
CHK/QC:	DATE:
APVD:	DATE:
MFG:	DATE:

MATERIAL:	HEAT TREAT:
RAW MATERIAL NO.:	FINISH

Smith & Nephew, Inc.
ENDOSCOPY DIVISION

TITLE:
LABEL, PRODUCT IDENTIFICATION,
ELECTROTHERMAL 20S SPINE SYSTEM

SIZE:	CAGE CODE:	DWG NO.:	REV.:
B		81011	

SCALE: NONE | FILE NO.: 81011518

45

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We are smith&nephew

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SECTION V
510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

as required by the Safe Medical Devices Act of 1990 and codified in 21 CFR 807.92 upon which the substantial equivalence is based.

Smith & Nephew ElectroThermal® 20S Spine Generator

Date Prepared: December 22, 2003

A. Submitter's Name:

Smith & Nephew, Inc., Endoscopy Division
150 Minuteman Road
Andover, MA 01810

B. Company Contact

Janice Haselton
Regulatory Affairs Specialist II
Phone: (978) 749-1494
Fax: (978) 749-1443

C. Device Name

Trade Name:	Smith & Nephew ElectroThermal® 20S Spine Generator
Common Name:	Electrosurgical Spine Generator
Classification Name:	Electrosurgical Cutting and Coagulation & Accessories

D. Predicate Devices

The Smith & Nephew Smith & Nephew ElectroThermal® 20S Spine Generator is substantially equivalent in Intended Use and Fundamental Scientific Technology to the following legally marketed device in commercial distribution: Smith & Nephew ORA-50 S, cleared in K993854 and Radionic's RFG-3C Plus Lesion Generator, cleared in K982489.

E. Description of Device

The proposed Smith & Nephew ElectroThermal® 20S Spine generator is a 20-watt electrothermal generator. It is intended to be used to create lesions in nervous tissue and to coagulate and decompress material when used in combination with Smith & Nephew thermal/coagulating probes. The generator provides temperature and impedance monitoring of energy to maintain effective tissue heating during temperature controlled applications. Smith & Nephew ElectroThermal® 20S Spine generator is designed to be used in conjunction with Smith and Nephew Spine products. These products include the Smith & Nephew SpineCATH® Intradiscal Catheter, the Smith & Nephew Decompression Catheter and the Smith & Nephew RF Denervation Probe and Smith & Nephew RF Probe.

F. Intended Use

The Smith & Nephew ElectroThermal® 20S Spine System is intended to create lesions in nervous tissue, and to coagulate and decompress disc material when used in combination with Smith & Nephew thermal/coagulating probes. The generator and accessories are intended for use by qualified medical personnel trained in the use of electrosurgical equipment.

Contraindications for Use:

There are no known absolute contraindications to the use of electrosurgery.

The Smith & Nephew ElectroThermal® 20S Spine System is contraindicated, when in the judgement of the physician, an electrosurgical procedure would be contrary to the best interest of the patient.

G. Comparison of Technological Characteristics

The Smith & Nephew ElectroThermal® 20S Spine generator is substantially equivalent to the Smith & Nephew ORA-50 S, cleared in K993854, based on the following:

- Both control and monitor temperature
- Both monitor impedance
- Both use RF energy to thermally heat the SpineCATH® and Decompression catheters
- Both provide preset settings for time and temperature to deliver RF.

The Smith & Nephew ElectroThermal® 20S Spine generator is substantially equivalent to the Radionic's RFG-3C Plus Lesion Generator cleared in K982489 based on the following:

- Both control and monitor temperature
- Both monitor impedance
- Both use a biphasic square wave to deliver stimulation voltage

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- Both use temperature controlled RF energy to create lesions in nervous tissue

H. Summary Performance Data

The performance testing conducted on the Smith & Nephew ElectroThermal® 20S Spine generator demonstrates substantial equivalents to the Radionic's RFG-3C Plus Lesion Generator cleared in K982489 and the Smith & Nephew ORA-50 S cleared in K993854 based on deliverance of temperature and time of RF controlled energy.

Exhibit A

Engineering Drawings

(b)(4) Drawings (Whole Page Redactions 48-51)

Exhibit B

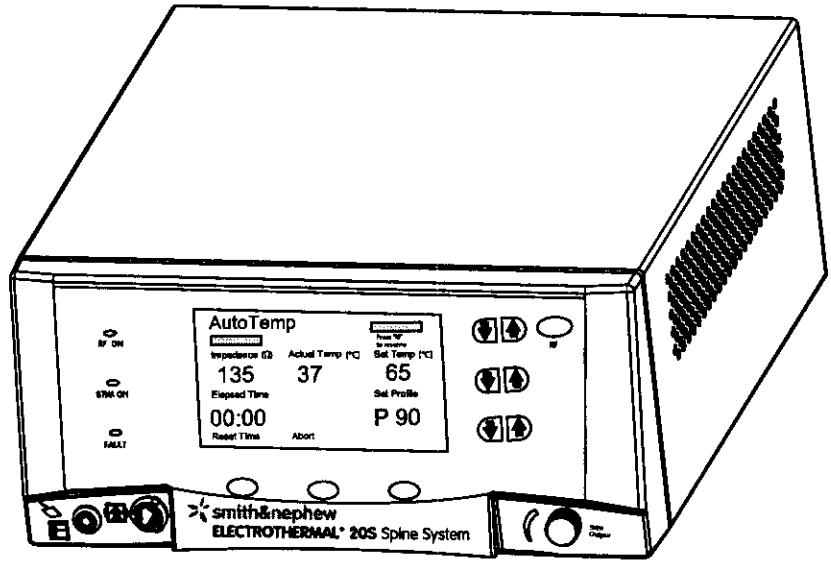
Proposed Device Labeling

54

Operations/Service Manual

smith&nephew

Smith & Nephew ELECTROTHERMAL® 20S Spine System



SS

Glossary of Symbols

CAUTION: U.S. Federal law restricts this device to sale by or on the order of a physician.	Catalog Number
CAUTION: See Instructions for Use	Date of Manufacture
Increase and Decrease buttons	Serial Number
Grounding Pad - isolated from earth at high frequency	UL Classification
EQUIPEMENT CLASSIFICATION -- Patient Isolation/Defibrillator Proof Type BF Applied Part	Protective earth (ground)
Stimulate Output Amplitude Control	Keep Dry
Power ON (Connection to the mains)	This Way Up
Power OFF (Disonnection from the mains)	Fragile; handle with care
Footswitch	CE mark
Dangerous Voltage: Danger of electric shock	European Representative
Indicates explosion risk in the presence of flammable anesthetics.	
Alternating Current	
Non-Ionizing Electromagnetic Radiation	
Fuse	
Equipotentiality	

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Preface

This manual contains information you need to operate and maintain the Smith & Nephew ElectroThermal 20S Spine System. It is essential that you read and understand all the information in this manual before using or maintaining the system.

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Introduction

The Smith & Nephew ELECTROTHERMAL® 20S Spine System is designed to provide finely-controlled radiofrequency (RF) energy for the coagulation of soft tissues in combination with Smith & Nephew thermal/coagulating devices. The generator is specifically designed for use with Smith & Nephew spine products.

During temperature-controlled procedures, the ELECTROTHERMAL 20S generator monitors temperature and impedance, automatically adjusting energy delivery to maintain effective tissue heating. The generator can be quickly configured for a procedure using default temperature and power settings. For procedures using the Smith & Nephew SPINECATH® Intradiscal Catheter and the Smith & Nephew Decompression Catheter, the Spine System offers a range of preprogrammed temperature profiles.

Smith & Nephew is dedicated to providing service and support to its customers. If you have any questions concerning the use of the ELECTROTHERMAL 20S Spine System, please contact your Smith & Nephew representative.

Caution: The Smith & Nephew ELECTROTHERMAL 20S Spine System and the devices used with it should only be used by physicians who have received training in their use.

Indications for Use

The Smith & Nephew ELECTROTHERMAL 20S Spine System is intended to create lesions in nervous tissue, and to coagulate and decompress disc material. The generator and accessories are intended for use by qualified medical personnel trained in the use of electrosurgical equipment.

Contraindications

There are no known absolute contraindications to the use of electrosurgery.

The use of the generator and accessories is contraindicated when, in the judgment of the physician, an electrosurgical procedure would be contrary to the best interest of the patient.

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⚠ Warnings

- DANGER: Risk of explosion if used in the presence of flammable anesthetics, skin preparation agents, or bio-intestinal gases.
- Hazardous electrical output. This equipment is for use only by qualified medical personnel trained in the use of electrosurgery.
- RISK OF BURNS OR FIRE. Do not use near conductive materials such as metal bed parts, inner-spring mattresses, etc.
- To prevent electric shock, do not remove the generator cover. There are no user-serviceable components inside. Dismantling the equipment will void the warranty. Refer servicing to qualified Smith & Nephew personnel.
- Burns to the surgeon's hands are possible if the probe comes into contact with a metal instrument or surface.
- If the hose that connects the footswitch to the unit becomes pinched or kinked, the footswitch may not operate correctly and the generator may remain activated.
- A disposable grounding pad with a banana plug such as a Radionics DGP-PM or equivalent is required. Improper pad selection, improper pad placement, or improper probe usage may result in patient burns at the return pad. To avoid this, follow the Instructions for Use included with the pad.
- Check that the electrical equipment is properly grounded (i.e., plugs contain a ground prong). The ELECTROTHERMAL 20S Spine System must be plugged into a hospital-grade AC outlet.
- Excessive risk (leakage) current may result if this equipment is connected to other than the manufacturer's recommended power distribution system.
- Any device connected to the serial communications port (RS 232) must comply with leakage current requirements of IEC 60601-1 for type BF equipment.
- Failure of the radiofrequency surgical equipment could result in unintended increase of output power.
- This device has been tested and verified to comply with IEC 60601-1-2 (EN 55011). This exceeds the requirements specified by FCC Part 18 for ISM equipment. This device is intended for operation in a medical facility only. Usage in a residential environment will likely cause unacceptable RF interference for which the user is held responsible.
- To prevent electric shock, unplug the unit from the electrical outlet before attempting to replace fuses.
- To avoid fire hazard, use only fuses of the correct type, voltage rating, and current rating.

Precautions

- CAUTION: FEDERAL LAW (USA) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.
- The Smith & Nephew ELECTROTHERMAL 20S Spine System is designed specifically for use only with Smith & Nephew SPINECATH Intradiscal catheters, Decompression catheters, RF Denervation probes, and RF cannulae. Do not use other catheters, probes, or cannulae with the ELECTROTHERMAL 20S Spine System.
- Use of electrosurgery for patients with internal or external pacemakers, implantable defibrillators or monitoring equipment may require special considerations. The attending cardiologist and/or the pacemaker manufacturer should be consulted prior to surgery.
- Safe use of monopolar electrosurgery demands proper grounding of the patient. Follow all instructions in the Instructions for Use accompanying the neutral electrode (grounding pad) for the placement of the neutral (return) electrode and for proper insulation between the patient and any metal surfaces.
- During monopolar electrosurgery, the patient should not come into contact with metal parts which are grounded or which have appreciable capacitance to earth (operating table, supports, etc.). The use of anti-static sheeting is recommended for this purpose.

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Warnings and Precautions *(continued)*

- During monopolar electrosurgery, skin-to-skin contact (i.e., between the arms and the body of the patient) should be avoided. Insertion of dry gauze or its equivalent is recommended.
- The cables to the surgical electrodes should be positioned in such a way that contact with the patient or other leads is avoided. Probes not in use should be stored isolated from the patient.
- When the ELECTROTHERMAL 20S Spine System is used simultaneously with physiological monitoring equipment on the same patient, any monitoring electrodes should be placed as far from the surgical electrodes as possible. Needle monitoring electrodes are not recommended. Monitoring systems using high frequency current-limiting devices are recommended.
- Use the lowest generator settings necessary to achieve the desired tissue effect.
- Check the LCD display screen to ensure that the proper probe identification and settings are displayed prior to beginning any procedure.
- Inspect the extension cables and power cord periodically for wear. Replace extension cables if evidence of deterioration is noted.
- Inspect the probe and extension cable connections for the presence of liquid before use or whenever a probe is connected or disconnected during a procedure. Liquid may enter the connection during a procedure. ANY liquid can cause the connections to short, resulting in erroneous probe recognition, or damage to the probe, cable, or generator.
- Use only the power cord and connector specified for this unit.
- This equipment is designed and tested to minimize interference with other electrical equipment. However, if interference occurs with other equipment it may be corrected by one or more of the following measures:

  Reorient or relocate this equipment, the other equipment, or both.

  Increase the separation between the pieces of equipment.

  Connect the pieces of equipment into different outlets or circuits.

  Consult a biomedical engineer.
- Grounding reliability can be achieved only when the ELECTROTHERMAL 20S Spine System is connected to an equivalent AC power receptacle marked "hospital only" or "hospital-grade."
- Electrical safety testing should be performed by a biomedical engineer or other qualified person.
- This equipment contains electronic printed circuit assemblies. At the end of the useful life of the equipment it should be disposed of in accordance with any applicable national or institutional policy relating to obsolete electronic equipment.

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System Components

The Smith & Nephew ELECTROTHERMAL 20S Spine System is a line-powered, radio-frequency generator capable of delivering up to 20 watts of power. The generator is designed for use with Smith & Nephew spine products. The instrument has been designed to meet UL and IEC 60601 safety and performance standards for medical equipment. The CE mark on the generator signifies compliance to the Medical Device Directive 93/42/EEC.

The ELECTROTHERMAL 20S Spine System provides controls for line power, mode and function changes, starting and stopping RF power delivery, setting temperature, setting treatment time, pausing RF power delivery, resetting elapsed times and treatment profiles, setting Stimulate Output Voltage, setting the frequency of RF power delivery, setting the pulse width of the Stimulate Pulse, and for selecting programmed treatment profiles.

An LCD screen displays the desired probe/tissue temperature or Set Temp, impedance, width, frequency, stimulate voltage, actual probe/tissue temperature, elapsed time, set time, mode setting, pause setting, preset selections, and messages.

The system has illuminated indicators for RF Power On, Stim On, and Fault conditions. When a Fault or warning occurs the system will also sound a brief alarm tone.

The ELECTROTHERMAL 20S Spine System software can be upgraded at the customer's site with a special card. An authorized Smith & Nephew representative will perform the software upgrade.

Unpacking and General Inspection

Carefully unpack and inspect all components shipped with your Smith & Nephew ELECTROTHERMAL 20S Spine System. If any parts are missing or damaged, contact your authorized Smith & Nephew representative. Save the carton and packing materials in the event a component must be returned for repair. You should have received the following:

Description	
1 ea.	REF 72109975 Smith & Nephew ELECTROTHERMAL 20S Spine System
1 ea.	hospital-grade power cord
1 ea.	REF 7209791 pneumatic footswitch with attached hose
1 ea.	REF 7210443 8-pin universal extension cable

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Front Panel Layout

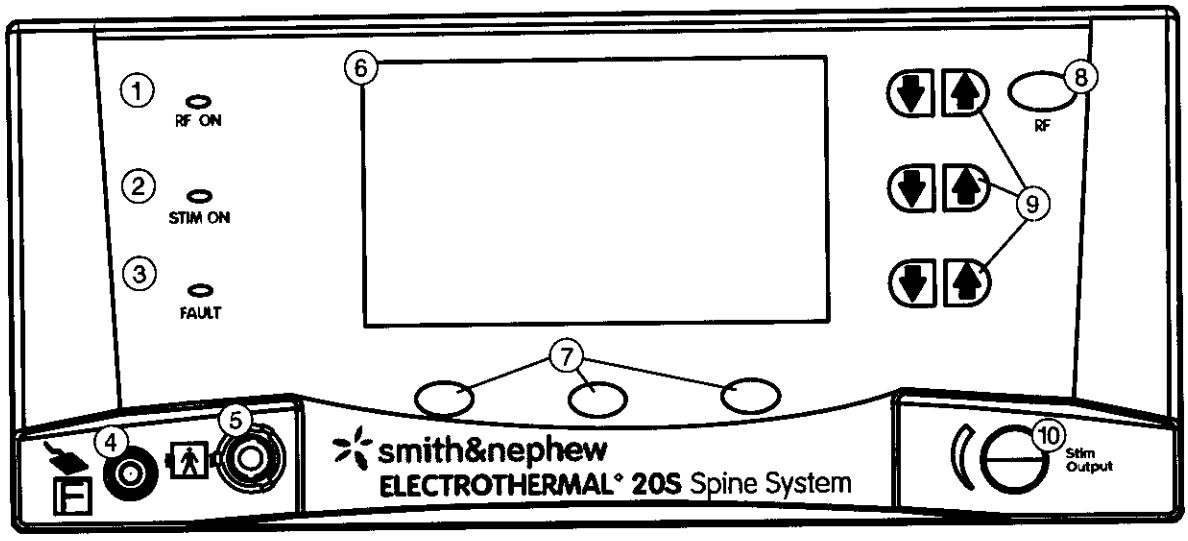

Figure 1. Smith & Nephew ELECTROTHERMAL® 20S Spine System front panel.

Control/Connections	Function
1. RF on (blue light)	Illuminated when generator is delivering RF power.
2. Stim on (yellow light)	Illuminated when generator is delivering Stimulate power.
3. Fault (red light)	Illuminated when a fault condition is detected.
4. Neutral electrode connection port	Used to connect a neutral electrode (grounding pad) to the generator.
5. Device connection port	Used to connect Smith & Nephew devices to the generator.
6. Display window	Displays the following generator information and operatating parameters. Act Temp, Elapsed Time, Frequency, Impedance, Mode, Paused, RF Volts, RF Power, Set Profile, Set Temp, Set Time, Stim Volts, Mode/Function Changes, Help/Exit Help, OK, Warnings, and Faults.
7. Soft keys	Soft key options vary based on generator mode. Soft keys include: Stim: Motor, Stim: Sensory, RF Lesion, Pulsed RF, Help/Exit Help, Start, Reset, and OK.
8. RF on button	Starts or stops RF power delivery.
9. Up/Down buttons	Used to increase or decrease function settings.
10. Stim output knob	Adjusts the Stimulate output voltage. Push and release the knob to turn Stimulate power on/off.

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Rear Panel Layout

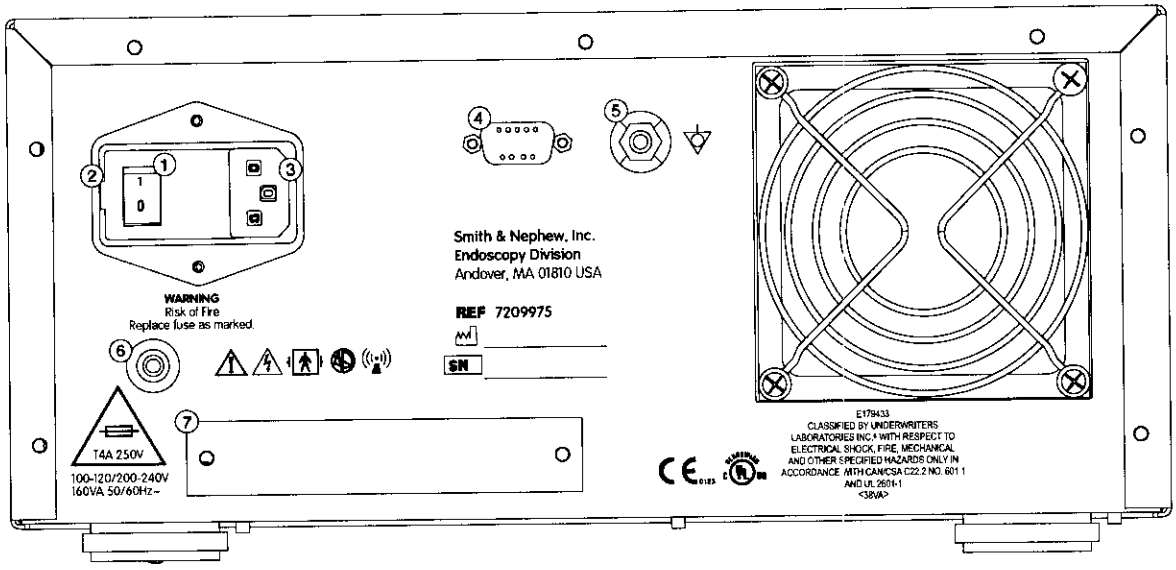

Figure 2. Smith & Nephew ELECTROTHERMAL 20S Spine System rear panel.

Controls/Connections	Function
1. On/Off rocker switch	Turns the generator main power on and off.
2. Fuse access door	Provides user access for fuse replacement. Use appropriate fuses to avoid hazards.
3. Power cord connector	This receptacle is an integral part of the power input module and accommodates the hospital grade power cord accessory.
4. RS 232 connector	For service use only.
5. Equipotential compensator terminal (case ground)	Used to bring other equipment into the same case potential as the generator.
6. Footswitch connector	Used to connect the pneumatic footswitch to the generator.
7. Security door	Allows access for software upgrades. Only an authorized Smith & Nephew representative may upgrade the generator software.

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Preoperative Setup

⚠ **Warning:** DANGER—Risk of explosion if used in the presence of flammable anesthetics, skin preparation agents, or bio-intestinal gases.

⚠ **Warning:** Hazardous electrical output. This equipment is for use only by qualified medical personnel trained in the use of electrosurgery.

⚠ **Warning:** This device has been tested and verified to comply with the IEC 60601-1-2 (EN 55011). This exceeds the requirements specified by FCC Part 18 for ISM equipment. This device is intended for operation in a medical facility only. Usage in a residential environment will likely cause unacceptable RF interference for which the user is held responsible.

⚠ **Warning:** Excessive risk (leakage) current may result if this equipment is connected to other than the manufacturer's recommended power distribution system.

⚠ **Warning:** RISK OF BURNS OR FIRE. Do not use near conductive materials such as metal bed parts, inner-spring mattresses, etc.

⚠ **Warning:** If used for laparoscopic procedures, gas embolism due to insufflation of gas in the abdomen may result, as with any electrosurgical device.

1. Plug the generator power cord into the rear panel power cord connector and a grounded AC power source.

CAUTION—Denervation Procedures Only: Prepare the patient using standard technique for monopolar electrosurgical procedures. The patient's entire body, including extremities, must be insulated against contact with grounded metal parts. The operating table itself should be grounded, and sufficient layers of electrically insulating sheets should be placed underneath the patient. A waterproof cover should be placed over the insulating sheets, with absorbent sheets placed between the patient and the waterproof cover to absorb any moisture. Make sure that fluids cannot or do not pool under the patient or in body depressions (such as the umbilicus) or in body cavities (such as the vagina) before or during the procedure. Any fluid pooled in these areas should be mopped up before the generator is used.

⚠ **Warning:** Check that the electrical equipment is properly grounded (i.e., plugs contain a ground prong). The generator must be plugged into a hospital-grade AC outlet.

2. Insert the footswitch hose firmly into back panel footswitch connector.

NOTE: Footswitch use is optional. The RF Button on the front panel performs the same functions as the footswitch.

CAUTION: Inspect the footswitch for any obvious defects. Do not apply pressure to the footswitch during connection. Ensure that the footswitch hose is not pinched or kinked.

⚠ **Warning:** If the hose that connects the footswitch to the unit becomes pinched or kinked, the footswitch may not operate correctly and the generator may remain activated.

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Operation

Power On

Turn the ELECTROTHERMAL 20S Spine System on using the rocker switch on the rear panel. The generator performs a system self-test to determine if it is performing properly.

During the self-test the generator will emit a long beep and all three front panel LEDs will illuminate. The software version number is displayed after power-up tests are complete. The version number is displayed transiently.

NOTE: If any of the tests fail, the Fault indicator on the front panel is illuminated and a three-second continuous tone sounds. The generator will also display a flashing "FAULT" message with an associated error number (Figure 3). If this happens, please note the error number and contact your Smith & Nephew representative.

Stand-by Mode

Immediately after power-up, the system enters Stand-by Mode and cannot deliver RF power. A cable with an attached device must be connected to the device connection port to exit this mode. While in Stand-by Mode, the Smith & Nephew splash screen appears in the display (Figure 4).

Device Connection Port

CAUTION: The Smith & Nephew ELECTROTHERMAL 20S Spine System is designed specifically for use only with Smith & Nephew SPINECATH Intradiscal catheters, Decompression catheters, RF Denervation probes, and RF cannulae. Do not use other catheters, probes, or cannulae with the ELECTROTHERMAL 20S Spine System.

The Smith & Nephew SpineCATH and Decompression catheters require the 8-pin universal extension cable to connect to the generator front panel.

Connect the 8-pin universal extension cable to the device connection port by aligning the cable so that the white dot and "PULL HERE" arrow are facing up and inserting the cable connector end firmly into the port. An audible "click" will be heard when a proper connection is made.

Insert the cable end connector into the device, algining the white markers (Figure 5A). Do not twist. An audible "click" will be heard when a proper connection is made. To disconnect the device, gently pull back on the cable collar (Figure 5B).

The Smith & Nephew RF Denervation probes include a reusable integrated cable. They connect directly to the front panel of the generator and do not require the 8-pin universal extension cable.

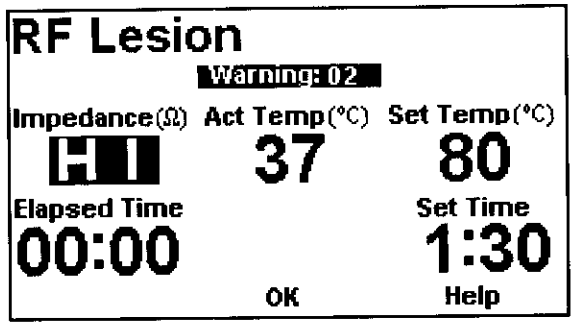

Figure 3: Display screen with Warning message

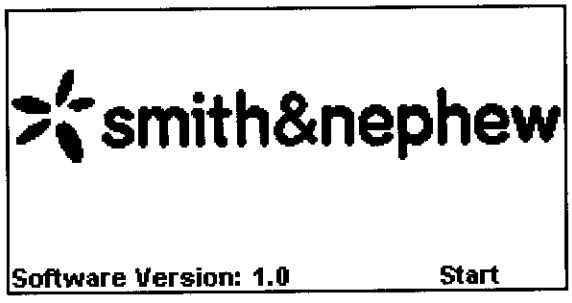

Figure 4: Display screen in Stand By Mode

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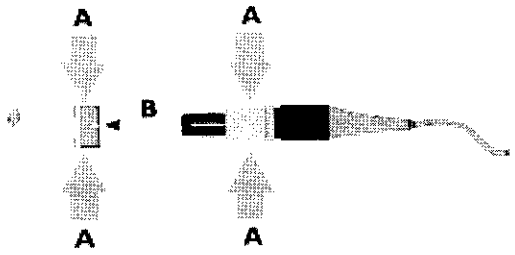

Figure 5: Device connection

Neutral Electrode Connection Port

SPINECATH and Decompression catheters do not require a neutral electrode (grounding pad).

For monopolar devices such as the RF Denervation probes, a disposable grounding pad with a banana plug such as a Radionics DGP-PM or equivalent is required. To attach a grounding pad, insert the plug into the neutral electrode connector port on the front panel. Assure the plug is fully seated with no metal exposed.

⚠ **Warning:** A disposable grounding pad with a banana plug such as a Radionics DGP-PM or equivalent is required. Improper pad selection, improper pad placement, or improper probe usage may result in patient burns at the return pad. To avoid this, follow the Instructions for Use included with the pad.

Device Recognition

The software recognizes which type of Smith & Nephew device is connected to the generator by reading a sensor in the handle of the device.

After a device is connected, the Start option will be displayed in the lower right corner. Pressing the Start soft key will automatically change the ELECTROTHERMAL 20S Spine System to the correct mode and default settings for the attached device. The default settings may be changed from their preset values using the appropriate Up/Down buttons.

NOTE: Once a mode is selected, the generator begins a continuous impedance check by emitting short bursts of low-level RF power. The blue RF indicator light blinks during the impedance check. This check occurs only when the generator is idle.

CAUTION: The Smith & Nephew ELECTROTHERMAL 20S Spine System is designed specifically for use only with Smith & Nephew SPINECATH Intradiscal catheters, Decompression catheters, RF Denervation probes, and RF cannulae. Do not use other catheters, probes, or cannulae with the ELECTROTHERMAL 20S Spine System.

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Operational Modes

SpineCATH AutoTemp Mode

Set Profile will default to P90 (Figure 6) . In this mode, the ELECTROTHERMAL 20S Spine System will automatically increase temperature and dwell at the maximum temperature according to a predetermined profile (see Table 1: SpineCATH AutoTemp Profiles). The profile can be adjusted by the user as needed. Energy delivery automatically stops at the completion of the Profile.

NOTE: Once a procedure is complete, another procedure cannot be started without removing the first device and inserting a new one.

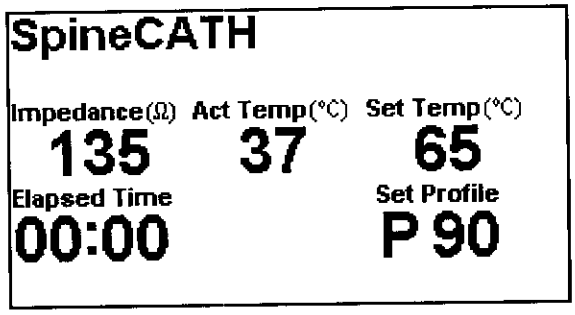

Figure 6: SpineCATH AutoTemp Mode Display

Decompression AutoTemp Mode

Set Profile will default to P90 (Figure 7). In this mode, the ELECTROTHERMAL 20S Spine System will automatically increase temperature and dwell at a maximum temperature according to a predetermined profile (see Table 2: Decompression AutoTemp Profiles). The profile can be adjusted by the user as needed. Energy delivery automatically stops at the completion of the Profile.

NOTE: Once a procedure is complete, another procedure cannot be started without removing the first device and inserting a new one.

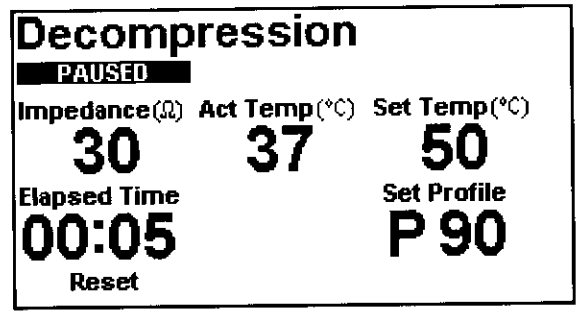

Figure 7: Decompression AutoTemp Mode Display

Stimulate Modes

Upon attachment of any RF Denervation probe the ELECTROTHERMAL 20S Spine System will start in the Stimulate Sensory mode (Figure 8). Frequency will default to 50 Hz; Width will default to 1 msec; Stim Volts (V) will default to display OFF. Once the Stim: Sensory Mode is activated, the output voltage always starts at 0.0.

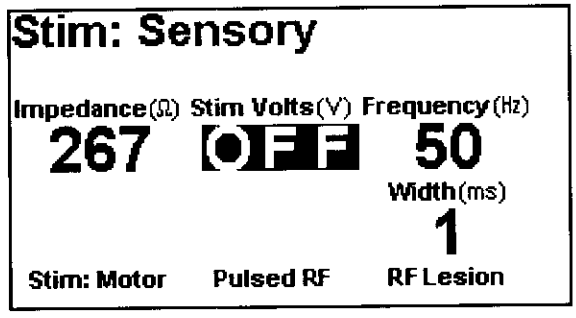

Figure 8: Stimulate Sensory Mode Display

The Stimulate Motor Mode (Figure 9) is selected using the soft key under the Stim:Motor option at the bottom left of the display (Figure 8). These options are only available while the voltage is OFF. Frequency will default to 2 Hz; Width will default to 1 msec; Stim Volts (V) will default to display OFF. Once the Stim: Motor Mode is activated, the output voltage always starts at 0.0.

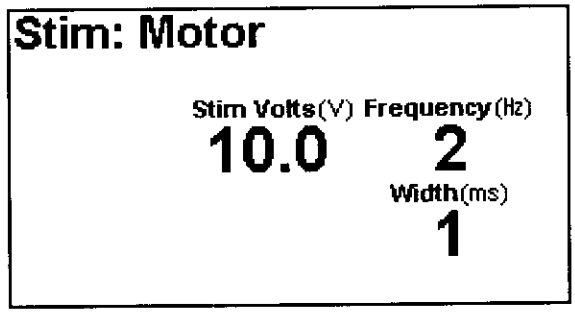

Figure 9: Stimulate Motor Mode Display

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RF Lesion Mode

Set Temp will default to 80° C; Set Time will default to 1 minute and 30 seconds (display will show 1:30). In this mode (Figure 10), the ELECTROTHERMAL 20S Spine System will automatically control power to reach and maintain the target temperature according to the selected Set Temp.

NOTE: Once a procedure is complete, the generator must be reset before a new procedure can be started.

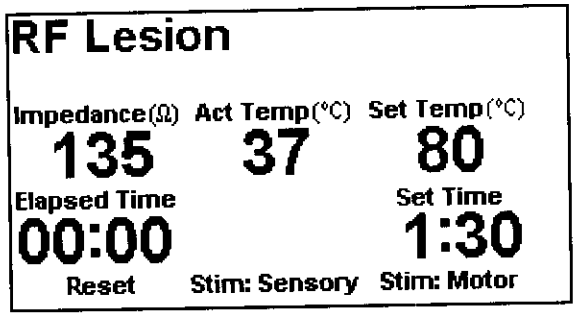

Figure 10: RF Lesion Mode Display

Pulsed RF Mode

Set Temp will default to 44° C; Set Time will default to 4 minutes (display will show 4:00); Frequency will display 2 Hz, RF Volts (V) will display 0.0. In this mode (Figure 11), the generator delivers pulsed RF energy to automatically reach and maintain the device temperature according to the selected Set Temp.

NOTE: Once a procedure is complete, the generator must be reset before a new procedure can be started.

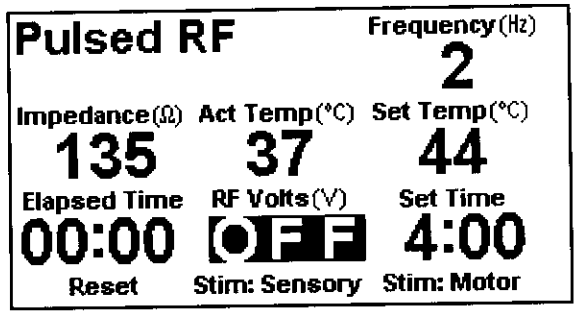

Figure 11: Pulsed RF Mode Display

Front Panel Displays

Act Temp (°C)

Displays the temperature, in Celsius, measured by the device. Not active in Stimulate Mode.

Elapsed Time

Displays current elapsed time during a procedure. Not active in Stimulate Mode.

Frequency (Hz)

Displays the power delivery frequency, in hertz (Hz). This display is only active in Stimulate and Pulsed RF modes. In Stim: Motor mode the frequency is fixed at 2 Hz; it is fixed at 50 Hz for Stim: Sensory Mode. For the Pulsed RF mode, the frequency defaults to 2 Hz and can be set to 1 Hz, 2 Hz, 4 Hz, or 8 Hz.

Impedance (Ω)

Displays impedance, in ohms, of the connected device. This is the internal device impedance for the Decompression and SpineCATH catheters and the device to grounding pad impedance for the monopolar devices.

Mode

Displays the current mode of the generator as determined by the attached device.

PAUSED

Displayed when RF power delivery is paused. SpineCATH AutoTemp, Decompression AutoTemp, RF Lesion and Pulsed RF may be paused by pressing the footswitch or RF On button during power delivery. Power delivery will cease and the timer will pause, but all other functions will continue to monitor and display the device parameters. Pressing the footswitch or RF On button again resumes power delivery and the elapsed time counter.

RF Volts (V)

Displays the RF output voltage, in volts. This display is only active in Pulsed RF and BioMed Mode. Ajustable with the Stim Output Knob.

RF Power (W)

Displays the RF output power, in watts. This display is only active in BioMed Mode.

Set Profile

Displays the Temperature Profile. This display is only active in SpineCATH and Decompression AutoTemp Modes.

Set Temp (°C)

Displays the target temperature, in Celsius. Not active in Stimulate Mode.

Set Time

Displays the RF power delivery time, in minutes. This control is only active in Stimulate Mode.

Stim Volts (V)

Displays the Stimulate Voltage, in volts. This display is only active in Stimulate Mode.

Width (ms)

Displays the pulse width of the Stimulate Pulse, in milliseconds. This control is only active in Stimulate Mode.

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Front Panel Controls

Stim Output Knob

Adjusts the Stimulate Output Voltage. Push and release knob to turn stim power on/off. Rotate knob clockwise to increase voltage output, shown under the Stim Volts (V) display. Rotate the knob counter-clockwise to decrease the voltage output.

Start

Appears when the generator is on and a device is attached. This control is only used to move generator out of Stand-By Mode.

RF On Button/Footswitch

Starts or stops RF Power delivery. Press and release the footswitch or RF On Button to start RF power delivery. Press and release the footswitch or RF On Button a second time to cease RF power delivery. Stopping RF power delivery during a procedure will "Pause" the procedure. The generator will display the "PAUSED" message and the elapsed time counter will pause, but all other functions will continue to monitor and display the device parameters.

Set Temp (°C) Up/Down buttons

Used to set the target tissue temperature, in Celsius. Press the Up/Down buttons to the right of the Set Temp display to increase or decrease the Set Temp value. Not active in the Stimulate Modes.

Set Profile Up/Down buttons

Used to set the Temperature Profile. Press the Up/Down buttons to the right of the Set Profile display to increase or decrease the profile setting. This control is only active in SpineCATH and Decompression AutoTemp Modes.

Set Time Up/Down buttons

Displays the Temperature Profile, set using the Up/Down buttons to the right of the display. This control is only active in SpineCATH and Decompression AutoTemp Modes.

Reset

The Reset soft key control will appear when the generator has been Paused or at the completion of an RF Lesion or Pulsed RF procedure. Pressing the Reset soft key while a procedure is Paused resets the Elapsed Time to 0:00 and resets the Set Temp in the SpineCATH and Decompression AutoTemp modes. This control is not active in the Stimulate Modes.

Width (ms)

Displays the pulse width of the Stimulate Pulse, in milliseconds, set using the Up/Down buttons to the right of the display. Width may be adjusted to 0.1, 0.5, 1, 2, or 3 mSec. This control is only active in Stimulate Mode.

Frequency (Hz)

Displays the frequency of energy delivery for the Pulsed RF, in hertz (Hz), set using the Up/Down buttons to the right of the display. This control is only active in Pulsed RF Mode.

Front Panel Controls Cont.

Mode/Function Changes

When the generator is paused in Stimulate, RF Lesion, or Pulsed RF mode, several options become available on the bottom of the display. These mode options vary depending on the active mode of the generator. Use the soft key under the displayed option to select the mode.

Mode options when paused in Stim: Sensory are Stim: Motor, Pulsed RF, and RF Lesion.

Mode options when paused in Stim: Motor are Stim: Sensory, Pulsed RF, and RF Lesion.

Mode options when paused in RF Lesion are Stim: Sensory and Stim: Motor

Note: The Reset soft key will appear when RF Lesion mode is paused and at the completion of the RF Lesion procedure.

Mode options when paused in Pulsed RF are Stim: Sensory and Stim: Motor

Note: The Reset soft key will appear when Pulsed RF mode is paused and at the completion of the Pulsed RF procedure.

Front Panel Indicators

RF On (blue light)

Illuminated when ElectroThermal 20S Spine System is delivering RF power.

Stim On (yellow light)

Illuminated when ElectroThermal 20S Spine System is delivering Stim power.

Fault (red light)

Illuminated when a fault condition is detected.

Other Indicators

Alarm Tone and Fault/Warning Display

The alarm tone is sounded briefly during generator start-up, and in the event of a fault or warning condition. In the rare event of a fault or warning, a numerical error code is displayed (Figure 12).

Help/Exit Help

The Help option appears when a fault or warning is detected (Figure 12). Pressing the Help soft key displays a message regarding the fault or warning. Pressing the Exit Help soft key returns you to the previous display.

OK

The OK option appears when a warning is detected (Figure 12). After resolving the warning, pressing the OK soft key will clear the warning display and move the generator into the paused state.

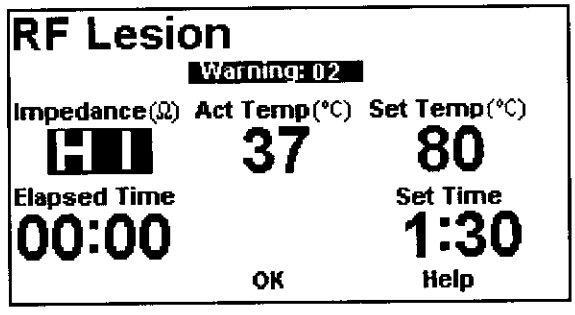

Figure 12: Display screen with Warning message

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Table 1: SpineCATH° AutoTemp° Profiles

Selected Profile	Peak Temperature (°C)	Time to Peak (min.)	Dwell Time (min.)	Total Treatment Time (min.)
P80	80	7.5	6.0	13.5
P81	81	8.0	5.7	13.7
P82	82	8.5	5.5	14.0
P83	83	9.0	5.5	14.5
P84	84	9.5	5.2	14.7
P85	85	10.0	5.0	15.0
P86	86	10.5	4.7	15.2
P87	87	11.0	4.5	15.5
P88	88	11.5	4.5	16.0
P89	89	12.0	4.2	16.2
***P90**	**90**	**12.5**	**4.0**	**16.5**
P91	91	13.0	4.0	17.0
P92	92	13.5	4.0	17.5
P93	93	14.0	4.0	18.0
P94	94	14.5	4.0	18.5
P95	95	15.0	4.0	19.0

* Default setting

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Table 2: Decompresssion AutoTemp® Profiles

Selected Profile	Peak Temperature (°C)	Time to Peak (min.)	Dwell Time (min.)	Total Treatment Time (min.)
P85	85	4.5	6.0	10.5
P86	86	4.8	6.0	10.8
P87	87	5.1	6.0	11.1
P88	88	5.4	6.0	11.4
P89	89	5.7	6.0	11.7
***P90**	**90**	**6.0**	6.0	**12.0**
P91	91	6.3	6.0	12.3
P92	92	6.6	6.0	12.6
P93	93	6.9	6.0	12.9
P94	94	7.2	6.0	13.2
P95	95	7.5	6.0	13.5

* Default setting

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Operation

SpineCATH AutoTemp Mode

1. Plug a SPINECATH catheter into the ELECTROTHERMAL 20S Spine System and press the Start soft key. The SpineCATH AutoTemp screen will appear on the display.

⚠ **Warning:** Burns to the surgeon's hands are possible if the device comes into contact with a metal instrument or surface.

The device impedance should display a value between 70-250 ohms (Ω). If the device impedance does not fall in this range see the Troubleshooting section.

Actual temperature should display the approximate room temperature if the catheter is in free air, or body temperature if the catheter is placed in the patient.

The Set Temp default is 65° C for the start of the automatic temperature ramp.

The default Set Profile value for SpineCATH AutoTemp Mode is P90, which corresponds to a dwell temperature (maximum) of 90° C.

2. Adjust the Set Temp and/or Set Profile if desired. The Set Profile and/or Set Temp value may be changed before or during power delivery by pressing the Up/Down buttons to the right of the display.

   Caution: Keep the power setting as low as possible to achieve the desired tissue effect.

3. To begin delivery of RF power to the catheter, press the RF button or the footswitch.

   Once delivery of RF power has begun, the Elapsed Time clock begins counting up.

   The temperature will increase at a rate of 1° C every 30 seconds until reaching the dwell temperature of the selected profile.

   Upon reaching the dwell temperature, the generator will hold that temperature for the predetermined duration outlined in the SpineCATH AutoTemp Profiles table.

NOTE: If the SpineCATH catheter does not reach the targeted temperature, RF power delivery will be stopped, an alarm will sound and "Warning: 03" will appear on the display. Check the integrity of the SpineCATH catheter and replace the device if damaged.

Option 1: Manually changing the Set Temperature using Set Profile during the AutoTemp procedure.

Use the Up/Down buttons to the right of the Set Profile display to change the selected profile. The value can be set from P80–P95.

When the Set Profile is increased, the generator will increase the SetTemperature 1° C every 30 seconds until reaching the new peak temperature. The dwell timer begins counting when the new peak temperature is reached.

When the Set Profile is decreased and the new peak temperature is below the current Set Temperature, the Set Temperature value will decrease simultaneously. The dwell timer begins counting when the new peak temperature is reached.

When the Set Profile is decreased while the current Set Temperature is below the peak temperature, the generator will continue to increase the Set Temperature 1° C every 30 seconds until reaching the new peak temperature. The dwell timer begins counting when the new peak temperature is reached.

When the Set Profile is changed once the peak temperature has been reached, the dwell duration timer is reset to the dwell duration related to the new Set Profile.

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Option 2: Manually changing the Set Temperature using Set Temp during the AutoTemp procedure.

Use the Up/Down buttons to the right of the Set Temp display to change the Set Temperature. The temperature is adjustable by 1° C for each key press. Set Temp can only be changed during RF delivery.

The allowable temperature range for adjustment is from 65° C to the peak temperature of the selected profile. This function may be used, for example, to manually expedite the temperature ramp.

NOTE: Patient comfort must always be considered when automatically or manually increasing the temperature.

When the Set Temp is manually changed the generator tracks the new temperature. Once the manual setting is complete, the generator will again automatically increase the Set Temperature 1° C every 30 seconds until reaching the peak temperature for the selected profile.

Pausing the AutoTemp procedure.

1. To Pause the delivery of RF power during an AutoTemp procedure, press the RF button or footswitch. RF power delivery will pause, the generator will display the "PAUSED" message and the timer will stop, but the generator will continue to monitor and display the device parameters.
2. To continue the AutoTemp Profile, press the RF button or footswitch. RF power delivery will commence and the timer will begin counting from where it left off.

Note: While paused, the procedure can be reset by pressing the Reset soft key. This action will reset the timer and the Set Temperature and leave the profile selection unchanged. RF power delivery can then be continued by press the RF button or the footswitch.

Note: The SPINECATH catheter is a single-use-only device.

Decompression AutoTemp Mode

1. Plug a Decompression catheter into the ELECTROTHERMAL 20S Spine System and press the Start soft key. The Decompression AutoTemp page will appear on the display.

⚠ **Warning:** Burns to the surgeon's hands are possible if the device comes into contact with a metal instrument or surface.

The device impedance should display a value between 15-50 ohms (Ω). If the device impedance does not fall in this range see the Troubleshooting section.

Actual temperature should display the approximate room temperature if the catheter is in free air, or body temperature if the catheter is placed in the patient.

The Set Temp default is 50° C for the start of the automatic temperature ramp.

The default Set Profile value for Decompression AutoTemp Mode is P90, which corresponds to a dwell temperature (maximum) of 90° C.

2. Adjust the Set Profile and/or Set Temp if desired. The Set Profile and/or Set Temp value may be changed before or during power delivery by pressing the Up/Down buttons to the right of the display.

   Caution: Keep the power setting as low as possible to achieve the desired tissue effect.

3. To begin delivery of RF power to the catheter, press the RF button or the footswitch.

   Once delivery of RF power has begun, the Elapsed Time clock begins counting up.

   The temperature will increase at a rate of 1° C every 6 seconds from 50° C to 80° C. Above 80° C and until reaching the dwell temperature of the selected profile, the temperature will increase at a rate of 1° C every 18 seconds.

   Upon reaching the dwell temperature, the generator will hold that temperature for the

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predetermined duration outlined in the Decompression AutoTemp Profiles table.

NOTE: If the Decompression catheter does not reach the targeted temperature, RF power delivery will be stopped, an alarm will sound and "Warning: 03" will appear on the display. Check the integrity of the Decompression catheter and replace the device if damaged.

Option 1: Manually changing the Set Temperature using Set Profile during the AutoTemp procedure.

Use the Up/Down buttons to the right of the Set Profile display to change the selected profile. The value can be set from P85–P95. Set Temp can only be changed during RF delivery.

When the Set Profile is increased, the generator will increase the Set Temperature 1° C every 18 seconds until reaching the new peak temperature. The dwell timer begins counting when the new peak temperature is reached.

When the Set Profile is decreased and the new peak temperature is below the current Set Temperature, the Set Temperature value will decrease simultaneously. The dwell timer begins counting when the new peak temperature is reached.

When the Set Profile is decreased while the current Set Temperature is below the peak temperature, the generator will continue to increase the Set Temperature 1° C every 18 seconds until reaching the new peak temperature. The dwell timer begins counting when the new peak temperature is reached.

When the Set Profile is changed once the peak temperature has been reached, the dwell duration timer is reset to the dwell duration related to the new Set Profile.

Option 2: Manually changing the Set Temperature using Set Temp during the AutoTemp procedure.

Use the Up/Down buttons to the right of the Set Temp display to change the set temperature. The temperature is adjustable by 1° C for each key press.

The allowable temperature range for adjustment is from 50° C to the peak temperature of the selected profile. This function may be used, for example, to manually expedite the temperature ramp.

NOTE: Patient comfort must always be considered when automatically or manually increasing the temperature.

When the Set Temp is manually changed the generator will track the new temperature. Once the manual setting is complete, the generator will again automatically increment every 6 seconds if the Set Temp is from 50° C to 80° C, and every 18 seconds from 80° C until reaching the peak temperature for the selected profile.

Pausing the AutoTemp procedure

1. To Pause the delivery of RF power during an AutoTemp procedure, press the RF button or footswitch. RF power will pause, the generator will display the "PAUSED" message and the timer will stop, but the generator will continue to monitor and display the device parameters.
2. To continue the procedure, press the RF button. RF power delivery will commence and the timer will begin counting from where it left off.

NOTE: Whiled paused, the procedure can be reset by pressing the Reset soft key. This action will reset the timer and the Set Temperature and leave the profile selection unchanged. RF power delivery can be continued by press the RF button or the footswitch.

Note: The Decompression catheter is a single-use-only device.

Stimulate Mode

The Stimulate Mode on the ELECTROTHERMAL 20S Spine System contains a function for Motor stimulation and a function for Sensory stimulation. Upon connection of an RF Denervation Probe, the generator defaults to Sensory Stimulate (Stim: Sensory) Mode.

CAUTION: The patient grounding pad must be properly placed on the patient before and during RF Denervation treatment. See the Instructions for Use provided with the patient gounding pad.

Sensory Stimulate (Stim: Sensory) Mode

1. Ensure the patient grounding pad is properly positioned on the patient.

⚠ Warning: A disposable grounding pad with a banana plug such as a Radionics DGP-PM or equivalent is required. Improper pad selection, improper pad placement, or improper probe usage may result in patient burns at the return pad. To avoid this, follow the Instructions for Use included with the pad.

2. Plug an RF Denervation Probe into the ELECTROTHERMAL 20S Spine System and press the Start soft key. The Stim: Sensory screen will appear on the display.

   NOTE: The width of the stimulate pulses can be changed with the Up/Down buttons next to the Width display. The Width may be adjusted to 0.1, 0.5, 1, 2, or 3 mSec. The Width may only be adjusted prior to turning the voltage ON.

   NOTE: The frequency of the pulses is fixed at 50 Hz for Stim: Sensory.

⚠ **Warning:** Burns to the surgeon's hands are possible if the device comes into contact with a metal instrument or surface.

3. After placing the probe in the patient, push the Stim knob once to turn the voltage ON. The OFF display will change to 0.0 volts.

   NOTE: The voltage in this mode always starts in the OFF position.

4. Turn the Stim knob clockwise to increase the stimulate voltage up to a maximum value of 1.0 volt.

5. The voltage may be turned off at any time by pressing the Stim knob.

NOTE: Subsequently pressing the Stim knob will toggle the voltage from ON to OFF. The voltage will always restart at 0.0.

To exit Sensory Stimulate mode, press one of the three soft keys across the bottom of the display. The three soft keys correspond to Motor Stimulate (Stim: Motor), Pulsed RF, and RF Lesion.

Motor Stimulate (Stim: Motor) Mode

1. Ensure the patient grounding pad is properly positioned on the patient.

⚠ **Warning:** A disposable grounding pad with a banana plug such as a Radionics DGP-PM or equivalent is required. Improper pad selection, improper pad placement, or improper probe usage may result in patient burns at the return pad. To avoid this, follow the Instructions for Use included with the pad.

2. Plug an RF Denervation Probe into the ELECTROTHERMAL 20S Spine System and press the Start soft key. The Stim: Motor screen will appear on the display.

   NOTE: The width of the stimulate pulses can be changed with the Up/Down buttons next to the Width display. The Width may be adjusted to 0.1, 0.5, 1, 2, or 3 mSec. The Width may only be adjusted prior to turning the voltage ON.

   NOTE: The frequency of the pulses is fixed at 2 Hz for Stim: Motor.

⚠ **Warning:** Burns to the surgeon's hands are possible if the device comes into contact with a metal instrument or surface.

3. After placing the probe in the patient, push the Stim knob once to turn the voltage ON. The OFF display will change to 0.0 volts.

   NOTE: The voltage in this mode always starts in the OFF position.

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4. Turn the Stim knob clockwise to increase the stimulate voltage up to a maximum value of 10.0 volts.
5. The voltage may be turned off at any time by pressing the Stim knob.

NOTE: Subsequently pressing the Stim knob will toggle the voltage from ON to OFF. The voltage will always restart at 0.0.

To exit Motor Stimulate mode,press one of the three soft keys across the bottom of the display. The three soft keys correspond to Sensory Stimulate (Stim: Sensory), Pulsed RF, and RF Lesion.

RF Lesion Mode

The RF Lesion Mode on the ELECTROTHERMAL 20S Spine System can only be selected through soft key access from the Stimulate Modes.

1. Ensure the patient grounding pad is properly positioned on the patient.

⚠ **Warning:** A disposable grounding pad with a banana plug such as a Radionics DGP-PM or equivalent is required. Improper pad selection, improper pad placement, or improper probe usage may result in patient burns at the return pad. To avoid this, follow the Instructions for Use included with the pad.

2. Plug an RF Denervation Probe into the generator. The Stimulate Mode will appear on the display.

⚠ **Warning:** Burns to the surgeon's hands are possible if the probe comes into contact with a metal instrument or surface.

3. Press the RF Lesion soft key to select the RF Lesion Mode.

   Actual temperature should display the approximate room temperature if the probe is in free air, or body temperature if the probe is placed in the patient. If the actual temperature reading is incorrect see the Troubleshooting section.

   The device impedance should display a value between 80-999 ohms (Ω) when the denervation probe and cannula are placed in the patient and the return electrode is properly placed on the patient. If the device impedance does not fall in this range see the Troubleshooting section.

   The Set Temp default is 80° C for the RF Lesion Mode. The temperature can be set from 50–90° C.

   The default Set Time value for the RF Lesion Mode is 1 minute and 30 seconds (display will show 1:30). The timer can be set to 0:30, 1:00, 1:30, or 2:00 minutes.

4. To begin delivery of RF power to the probe, press the RF button or the footswitch.

   The Elapsed Time display starts counting up when RF power delivery begins.

   RF power delivery ceases when the Elapsed Time reaches the Set Time.

NOTE: Before starting a new RF Lesion procedure the generator must be reset. Reset the generator using one of the following options:

- Press the Reset soft key.
- Use the Mode option soft keys to exit and return to RF Lesion Mode.
- Disconnect and reconnect the device to the generator.

NOTE: If the RF Denervation probe does not reach the targeted temperature, RF power delivery will be stopped, an alarm will sound and "Warning: 03" will appear on the display. Check the integrity of the RF Denervation probe and replace the device if damaged.

To exit RF Lesion mode press one of the two soft keys across the bottom of the display. The two soft keys correspond to Sensory Stimulate (Stim: Sens) and Sensory Motor (Stim: Motor).

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Manually changing the Set Temperature using Set Temp during RF delivery.

Use the Up/Down buttons to the right of the Set Temp display to change the Set Temperature. The value can be set from 50° C to 90° C.

When the Set Temp is increased, the generator will rapidly adjust the temperature output until the actual temperature reaches the new Set Temperature. When the Set Temp is decreased, the actual temperature value will decrease simultaneously.

Pausing the Power during RF Lesion.

1. To Pause the delivery of RF power during an RF Lesion procedure, press and release the RF button or footswitch. RF power will pause, the generator will display the "PAUSED" message, and the timer will stop. The generator will continue to monitor and display the device parameters.
2. To continue the RF power delivery, press and release the RF button or footswitch. The RF power delivery and timer resume.

NOTE: If the probe or cannula are repositioned during a Pause, a return to the Stimulate mode to confirm needle position may be required prior to recommencing denervation. Upon leaving the Stimulate Mode and returning to the RF Lesion or Pulsed RF Mode, the timer will reset to 0:00.

NOTE: While paused, the generator's timer can be reset by pressing the Reset soft key. This action will reset the elapsed time and leave the Set Temperature selection unchanged. Continue RF power delivery by pressing the RF button or the footswitch.

Manually changing the Set Time when RF delivery is PAUSED.

1. Pause RF power delivery by pressing the RF button or footswitch.
2. Use the Up/Down buttons to the right of the Set Time display to change the RF delivery time. Set time can be set to 0:30, 1:00, 1:30, or 2:00 minutes.
3. Resume RF power delivery by pressing the RF button or footswitch.

Pulsed RF Mode

The Pulsed RF Mode on the ELECTROTHERMAL 20S Spine System can only be selected through soft key access from the Stimulate Modes.

1. Ensure the Patient Grounding Pad is properly positioned on the patient.

⚠ **Warning:** A disposable grounding pad with a banana plug such as a Radionics DGP-PM or equivalent is required. Improper pad selection, improper pad placement, or improper probe usage may result in patient burns at the return pad. To avoid this, follow the Instructions for Use included with the pad.

2. Plug an RF Denervation Probe into the generator. The Stimulate Mode will appear on the display.

⚠ **Warning:** Burns to the surgeon's hands are possible if the probe comes into contact with a metal instrument or surface.

3. Press the Pulsed RF soft key to select the Pulsed RF Mode.

   Actual temperature should display the approximate room temperature if the probe is in free air, or body temperature if the probe is placed in the patient. If the actual temperature is incorrect see the Troubleshooting section.

   The device impedance should display a value between 80–999 ohms (Ω) when the denervation probe and cannula are placed in the patient and the neutral electrode (grounding pad) is properly placed. If the device impedance is not within this range see the Troubleshooting section.

   The Set Temp default is 44° C for the Pulsed RF Mode. The temperature can be set from 40–50° C.

   The Frequency default for Pulsed RF is 2 Hz. The Frequency can be set to 1 Hz, 2 Hz, 4 Hz, or 8 Hz.

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The default Set Time value for the Pulsed RF Mode is 4 minutes. Set Time can be set to 0:30, 1:00, 1:30, 2:00, 2:30, 3:00, 3:30, or 4:00 minutes.

4. To begin delivery of RF power to the probe, press and release the RF button or the footswitch.

   The Elapsed Time display starts counting up when RF power delivery begins.

   RF power delivery ceases when the Elapsed Time reaches the Set Time.

NOTE: Before starting a new RF Lesion procedure the generator must be reset. Reset the generator using one of the following options:

- Press the Reset soft key.
- Use the Mode option soft keys to exit and return to RF Lesion Mode.
- Disconnect and reconnect the device to the generator.

NOTE: If the RF Denervation probe does not reach the targeted temperature, RF power delivery will be stopped, an alarm will sound and "Warning: 03" will appear on the display. Check the integrity of the probe and replace the device if damaged.

The Pulsed RF mode can be exited by pressing one of the two soft keys across the bottom of the display. The two soft keys correspond to Sensory Stimulate (Stim: Sensory) and Sensory Motor (Stim: Motor).

Manually changing the Set Temperature using Set Temp during RF delivery.

Use the Up/Down buttons to the right of the Set Temp display to change the Set Temperature. The value can be set from 40° C to 50° C.

NOTE: When the Set Temp is increased in Pulsed RF mode, the actual increase in temperature will vary depending on the current Frequency setting. The temperature will increase more slowly with a low Frequency setting and more rapidly with a higher Frequency setting. When the Set Temp is decreased, the set temperature value will decrease simultaneously.

PAUSING the power during a Pulsed RF procedure.

1. To Pause the delivery of RF power during a Pulsed RF procedure, press and release the RF button or footswitch. RF power will pause, the generator will display the "PAUSED" message and the timer will stop. The generator will continue to monitor and display the device parameters.
2. To continue the RF power delivery, press and release the RF button or footswitch. The RF power delivery and timer will resume.

NOTE: If the probe/cannula are repositioned during a Pause, a return to the Stimulate mode to confirm needle position may be required prior to recommencing denervation. Upon leaving the Stimulate Mode and returning to the RF Lesion or Pulsed RF Mode, the timer will reset to 0:00.

NOTE: While paused, the generator's timer can be reset by pressing the Reset soft key. This action will reset the elapsed time and leave the Set Temperature selection unchanged. Continue RF power delivery by pressing the RF button or the footswitch.

Manually changing the Set Time when RF delivery is PAUSED.

1. Pause RF power delivery by pressing the RF button or footswitch.
2. Use the Up/Down buttons to the right of the Set Time display to change the RF delivery time. Set Time can be set to 0:30, 1:00, 1:30, 2:00, 2:30, 3:00, 3:30, or 4:00 minutes.
3 Resume RF power delivery by pressing the RF button or footswitch.

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Cleaning and Sterilization

ELECTROTHERMAL 20S Spine System

The exterior surface of the ELECTROTHERMAL 20S Spine System generator may be wiped down with any liquid disinfecting solution; non-flammable solution should be used whenever possible. The unit should be disconnected from the grounded AC outlet when being cleaned. Care must be taken not to allow any liquid to pass into any electrical connections or the interior of the unit. Let the surfaces dry thoroughly before plugging in the instrument. DO NOT steam sterilize the generator. DO NOT submerge generator for any reason.

Devices

Smith & Nephew SPINECATH and Decompression catheters are disposable and intended FOR SINGLE USE ONLY. Do not attempt to clean or resterilize any Smith & Nephew catheter. Discard used catheters as biohazardous waste.

Smith & Nephew Denervation probes are reusable. Refer to the Instructions for Use accompanying each device for cleaning and sterilization instructions.

Footswitch

The footswitch may be wiped down with any liquid disinfecting solution; non-flammable solution should be used whenever possible. DO NOT immerse footswitch hose.

8-Pin Universal Extension Cable

The 8-pin universal extension cable is reusable and may be cleaned and sterilized for reuse as follows:

1. Rinse the cable with warm running tap water for a minimum of two minutes or until all debris is removed.
2. Place the cable into an ultrasonic cleaning bath containing ENZOL enzymatic cleaning solution, diluted according to the manufacturers instructions, for a minimum of ten minutes.
3. Gently scrub with a soft, non-metallic brush.
4. Rinse the cable for a minimum of two minutes under running tap water.
5. Autoclave sterilization by one of the following parameters:

Pre-vac

Six (6) minutes pre-vacuum steam exposure at 270–275° F (132–135° C).

NOTE: Cables may be individually wrapped in surgical Kraft paper and then placed in individual sterilization pouches prior to pre-vac sterilization.

Flash Gravity

Unwrapped: Three minutes at 132° C (range 131.5–133.5° C)

Wrapped: Ten minutes at 132° C (range 131.5–133.5° C)

NOTE: Cables may be individually placed in sterilization pouch prior to flash gravity sterilization.

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Troubleshooting

If a problem is encountered while using the generator, review this section for possible solutions. If you cannot solve the problem using the information here, contact your Smith & Nephew representative.

Alarm on Power-Up

If the alarm sounds but no error code is displayed or if a non-numeric error code is displayed during generator power-up, a significant hardware failure that requires factory repair has occurred. Contact Smith & Nephew for instructions on returning the generator.

If a numeric error code is displayed (Figure 13), see the Error Codes section for more information.

Error Codes

The generator may display a numeric error code in the LCD screen when a Fault or Warning is detected. See Table 3: Warning Codes or Table 4: Fault Codes for a list of codes, an explanation of the problem, and corrective actions. If the suggested action does not correct the problem or if the error code signifies a factory-serviceable problem, make note of the error code and contact your Smith & Nephew representative.

A fault is generated when the generator detects a hardware error, such as an internal component failure. Once a fault is detected, the generator displays a "Fault" message and the Help soft key appears at the bottom of the display. Pressing the Help soft key displays a message regarding the fault.

NOTE: When the generator is displaying a Fault, RF power delivery is halted and all generator functions are locked. Reset the generator by turning it off and then on again. If the fault condition continues on restart please contact your Smith & Nephew representative.

A warning is generated when the generator detects an operational error. Once a warning is detected, the generator displays the "Warning" message and the OK and Help soft keys appear at the bottom of the display. Pressing the Help soft key displays a message regarding the warning (Figure 14). Generator operation may resume after resolving the warning and pressing the OK soft key. The generator will move into the PAUSED state. The same warning may be triggered again if the error condition persists.

For example, if a high impedance warning occurs due to an incorrectly connected catheter, the generator screen will display the Warning number, the impedance value will flash "HI", and the OK and Help options will appear. RF power delivery is halted and the generator controls are locked until the error is corrected and the OK soft key is pressed.

NOTE: Disconnecting and reconnecting a device will reset the generator to the default settings for that device.

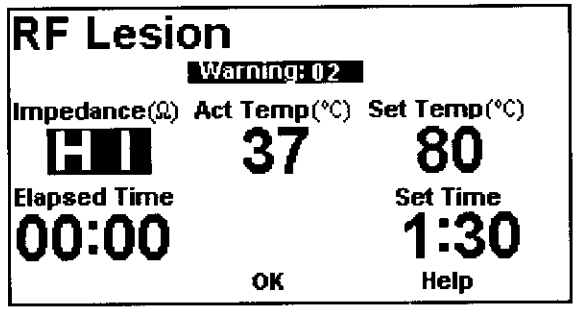

Figure 13: RF Lesion Screen with Error Code

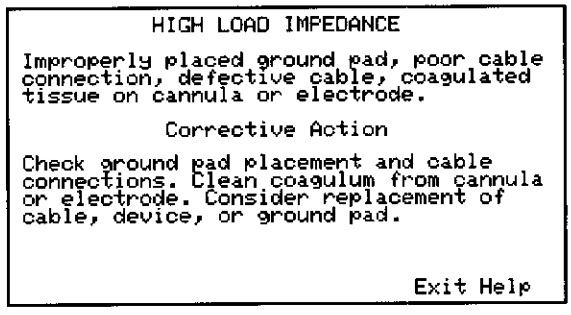

Figure 14: Help Screen

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Table 3: Warning Codes

Warning	Warnings	Description	Corrective actions
01	Low load impedance	Defective cable, device, or generator circuit.	Check all connections. Consider replacement of cable, device or ground pad (if applicable).
02	High load impedance	Catheters: Damaged catheter, poor cable connection, or defective cable. Denervation/Stim: Improperly placed ground pad, poor cable connection, defective cable, coagulated tissue on cannula or electrode.	Catheters: Check cable connections. Consider replacement of catheter or cable. Denervation/Stim: Check ground pad placement and cable connections. Clean coagulum from cannula or electrode. Consider replacement of cable, device, or ground pad.
03	Rise time is out of range	Device temperature rise is too slow due to a defective device or poor connection.	Check all connections. Consider replacement of cable, device, or ground pad (if applicable).
04	Device Not Connected	System is unable to detect a device.	Check all connections. Consider replacement of device or cable.
05	Replace Device	Catheters Only: A new device has not been detected since completion of the previous AutoTemp procedure.	Replace with a new catheter.
06	TC Not Detected	TC failure in the device or poor connection.	Check all connections. Consider replacement of device.
07	Restart New Procedure	System cannot start a new Denervation procedure without resetting timer or entering Stimulation Mode.	Press OK to clear the warning message. Then do one of the following to reset the generator: Press the Reset soft key. Use the Mode option soft keys to exit and return to RF Lesion Mode. Disconnect and reconnect the device to the generator.
08	Invalid Device ID	System detected a device ID change without first sensing "no device."	Check all connections. Consider replacement of device.

Table 4: Fault Codes

Fault	Faults	Corrective actions
01	Voltage Calibration Error	Restart generator. If fault recurs, note fault description and contact customer service.
02	RF Power Calibration Error	Restart generator. If fault recurs, note fault description and contact customer service.
03	RF Impedance Calibration Error	Restart generator. If fault recurs, note fault description and contact customer service.
04	Footswitch/Button Stuck On	Check the footswitch for damage and the footswitch hose for kinks. Re-start generator. If fault recurs, note fault description and contact customer service.
05	RAM Test Failure	Restart generator. If fault recurs, note fault description and contact customer service.
06	ROM Test Failure	Restart generator. If fault recurs, note fault description and contact customer service.
07	Cold-Junction Circuit Out of Range	Allow the generator to stabilize at room temperature for one hour prior to use. Re-start generator. If fault recurs, note fault description and contact customer service.
08	Auxiliary Power Error	Restart generator. If fault recurs, note fault description and contact customer service.
09	COP Timer Failure	Restart generator. If fault recurs, note fault description and contact customer service.
10	Watchdog Timeout	Restart generator. If fault recurs, note fault description and contact customer service.
11	High power (RF on)	Restart generator. If fault recurs, note fault description and contact customer service.
12	High power (RF off)	Restart generator. If fault recurs, note fault description and contact customer service.

Table 4: Fault Codes (continued)

Fault	Faults	Corrective actions
13	Temperature Control Failure	Restart generator. If fault recurs, note fault description and contact customer service.
14	Five-Volt Supply Out of Range	Restart generator. If fault recurs, note fault description and contact customer service.
15	Twelve-Volt Supply Out of Range	Restart generator. If fault recurs, note fault description and contact customer service.
16	Negative Twelve-Volt Supply Out of Range	Restart generator. If fault recurs, note fault description and contact customer service.
17	Twenty-Four-Volt Supply Out of Range	Restart generator. If fault recurs, note fault description and contact customer service.
18	Internal Temperature Out of Range	Restart generator. If fault recurs, note fault description and contact customer service.
19	CPU Interrupt Failure	Restart generator. If fault recurs, note fault description and contact customer service.
20	SPI Interface Timeout	Restart generator. If fault recurs, note fault description and contact customer service.
21	RF Power High During Impedance Check	Restart generator. If fault recurs, note fault description and contact customer service.
22	Internal State Error	Restart generator. If fault recurs, note fault description and contact customer service.
23	Stim Output Voltage Out of Range	Restart generator. If fault recurs, note fault description and contact customer service.
24	Power Factor Low	Restart generator. If fault recurs, note fault description and contact customer service.

Observed Problems

If no Error Codes are displayed and the system is not performing as expected, check the following list of conditions for possible remedies. Contact your Smith & Nephew representative if the suggested remedies do not correct the problem.

Cannot get tissue up to desired temperature.

1. Check the cable for proper connection:
   a. Disconnect and reconnect the 8-pin universal extension cable at the generator. Disconnect and reconnect the extension cable at the device, if applicable. See Operations: Device Connection Port for detailed instructions.
   b. Flex the cable near the generator and device end connections. If Impedance value dramatically changes (±500 Ω), replace cable.
2. If Actual Temp never reaches Set Temp:
   a. Ensure energy is delivered when footswitch or RF power button is pressed and released (a continous beeping should be heard).
   b. Check that Set Profile/Set Temp is set to the desired setting.
3. Was the catheter/probe aggressively handled or repeatedly bent?
   a. Yes. Thermocouple may be damaged. Replace catheter/probe. Contact a Smith & Nephew representative concerning warranty replacement.
   b. No. Device OK.
4. For Stimulate, RF Lesion and Pulsed RF procedures only:
   a. Check for proper return pad placement and location.
   b. Check for proper connection of return pad plug to generator.
   c. Check the cannula insulation for damage.

No indicators or displays are visable when the generator is turned on.

1. Be sure the generator is plugged into a working electrical outlet and the power switch at the rear of the unit is turned on.
2. Unplug the unit and inspect the integrity of the fuse on the rear panel. Fuses should only be replaced with those of the same type and rating according to the label on the rear of the unit or as listed in Technical Specifications.

⚠ **Warning:** To prevent electric shock, unplug the unit from the electrical outlet before attempting to replace the fuses.

⚠ **Warning:** To avoid fire hazard, use only fuses of the correct type, voltage rating, and current rating.

RF power does not turn on when footswitch or RF button is pressed.

1. Disconnect and reconnect the device and/or cable. Press the Start soft key. Be sure that the generator is in the correct Mode for the device.
2. Disconnect and reconnect the footswitch, if applicable. Check footswitch hose for kinks or bends.

Fault indicator light stays on and generator emits a continuous tone.

Turn unit off and back on again. Note any Fault number displayed in the Message window. If the light stays on, contact your Smith & Nephew representative.

RF Interferes with other equipment.

1. Ensure the device cables do not cross the cables from the affected equipment. Changing the settings on the affected equipment may alleviate interference.
2. Plug the affected equipment into a separate power outlet.

⚠ **Warning:** Do not attempt to open the back panel of the generator. This may cause serious injury and damage to the unit. It will void your warranty. If any problems are not resolved by the directions in the Troubleshooting section, please contact your Smith & Nephew Representative for further assistance.

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Service

Service Philosophy

There are no user-serviceable components inside the ELECTROTHERMAL 20S Spine System. Repairs and adjustments are to be performed only by Smith & Nephew authorized service centers.

If service becomes necessary, call your authorized Smith & Nephew Customer Service Representative prior to returning the device and request a Return Authorization (RA) number. Your representative can also explain the available Service Replacement and Repair Programs.

Service items should be carefully repackaged and returned post-paid to Smith & Nephew. Your Smith & Nephew Customer Service Representative can provide additional instructions.

NOTE: Product returned that is found to have been serviced by an unauthorized third party repair facility and/or sterilized with a sterilization method other than one approved by Smith & Nephew will incur additional costs, regardless of warranty status.

It is not necessary to include accessory items (i.e., power cords, footswitches, etc.) when returning a device for service.

Electrical Interference

CAUTION: This equipment is designed and tested to minimize interference with other electrical equipment. However, if interference occurs with other equipment it may be corrected by one or more of the following measures:

Reorient or relocate this equipment, the other equipment, or both.

Increase the separation between the pieces of equipment.

Connect the pieces of equipment into different outlets or circuits.

Consult a biomedical engineer.

Environmental Protection

CAUTION: This equipment contains electronic printed circuit assemblies. At the end of the useful life of the equipment it should be disposed of in accordance with any applicable national or institutional related policy relating to obsolete electronic equipment.

Replacing Fuses

⚠ **Warning:** To prevent electric shock, unplug the unit from the electrical outlet before attempting to replace the fuses.

⚠ **Warning:** To avoid fire hazard, use only fuses of the correct type, voltage rating, and current rating.

To inspect and/or replace fuses:

1. Unplug the power cord from the power outlet and from the generator.
2. Use a screwdriver to open the fuse compartment door on the AC receptacle and slide out the two fuse carriers (Figure 15).
3. Replace fuses. See Technical Specifications for replacement fuse types.
4. Re-insert fuse carriers using the arrows on the inside of the fuse compartment door as a guide.
5. Snap the fuse compartment door closed.

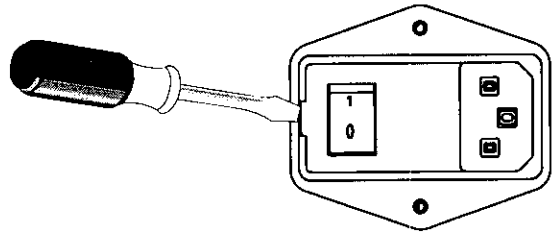

Figure 15: Rear panel fuse location

Maintenance

Generator Calibration

Smith & Nephew recommends yearly calibration of the temperature and power measurement function of the generator.

Temperature Calibration

Equipment Needed

Digital Thermometer (Omega Model HH21 or equivalent).

Smith & Nephew RF Generator Test Cable (REF 7210520)

Two glass or plastic beakers

Procedure

Temperature Measurement Verification

1. Turn on the generator and connect the RF Generator Test Cable.
2. Press the "Start" soft key on the front panel of the generator.
3. Confirm that the Biomed page is displayed (Figure 16). If not, check for proper cable connection or replace the cable.
4. Prepare two beakers of water, one with cool water (10–30° C) and one with hot water (50–90° C).
5. Measure and record the temperature of the cool water using the digital thermometer.
6. Immerse the tip of the RF Generator Test Cable into the cool water and record the Actual Temperature.

⚠ **Warning:** Do not turn the RF power ON while holding the RF Generator Test Cable. RF energy may be delivered causing a burn.

7. Repeat steps 5 and 6 using the hot water beaker.
8. The Actual Temperature reading with the test cable should be +/- 2° C of the thermometer reading in both cases. If a greater difference is observed, contact Smith & Nephew for assistance.

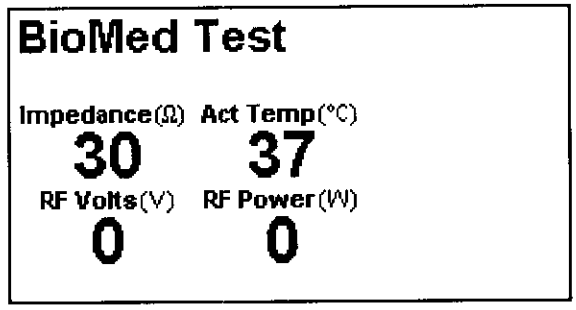

Figure 16: BioMed Test Screen

RF output calibration using an electrosurgical test unit.

Equipment Needed

Electrosurgical Test Unit or equivalent capable of measuring power across a non-inductive 100 ohm (Ω) load

Smith & Nephew RF Generator Test Cable (REF 7210520)

Banana plug to banana plug jumper cable (24" long or longer)

Procedure

RF Power Measurement Verification

1 Turn on the generator.

2. Connect proper connector of the Smith & Nephew RF Generator Test Cable to the generator.
3. Press the "Start" soft key on the front panel of the generator.
4. Confirm that the BioMed page is displayed (Figure 16). If not, check for proper cable connection or replace the cable.
5. Insert the banana plug of the Smith & Nephew RF Generator Test Cable into the Active Port of the Electrosurgical Test Unit RF Input.
6. Insert one end of the banana plug jumper cable into the Dispersive Port of the

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Electrosurgical Test Unit RF Input. Insert the other end into the Neutral Electrode Connection Port of the generator.

7. Turn the Electrosurgical Test Unit ON and set it for a 100 ohm (Ω) load.
8. Start RF power delivery by pressing and releasing the RF button or footswitch.
9. Confirm that the power measured at the Electrosurgical Test Unit is within +/- 20% of the value displayed (watts) on the generator. If a greater difference is observed, please contact your Smith & Nephew representative for assistance.

RF output calibration using a true RMS voltmeter

Equipment Needed

True RMS Voltmeter: operating range >460 kHz

A non-inductive 100 ohm (Ω) resistive load (1% accuracy) capable of 25 watt dissipation. (Caddock MP series or equivalent)

Smith & Nephew RF Generator Test Cable (REF 7210520)

Banana plug to banana plug jumper cable (24" long or longer)

Procedure

RF Power Measurement Verification

1. Turn on the generator.
2. Connect the Smith & Nephew RF Generator Test Cable to the generator.
3. Press the "Start" soft key on the front panel of the generator.
4. Confirm that the BioMed page is displayed (Figure 16). If not, check for proper cable connection or replace the cable.
5. Insert one end of the banana plug jumper cable into the Return Pad port of the generator.
6. Connect the non-inductive 100 ohm (25 watt) resistor between the banana plugs of the test cable and banana plug jumper cable. Assure the two banana plugs are not in direct contact.
7. Connect the True RMS Voltmeter across the resistor (Figure 17).
8. Start RF power delivery by pressing and releasing the RF button or footswitch.
9. Measure the voltage across the 100 ohm resistor.
10. Confirm the voltage measured across the resistor is within +/- 10% of the voltage displayed on the generator. If a greater difference is observed, please contact your Smith & Nephew representative for assistance.

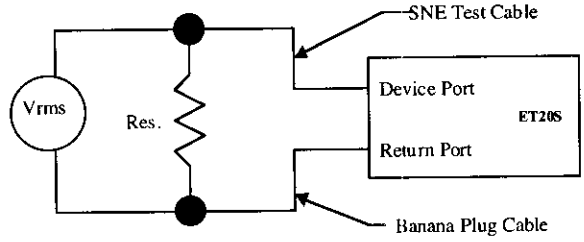

Figure 17: True RMS Voltmeter connection diagram

Replacing / returning worn or defective equipment or parts

Contact Smith & Nephew to order a replacement footswitch, 8-pin universal extension cable, or any accessories, and for instructions on disinfection and return of worn-out or defective equipment or parts.

Other than fuses, the ELECTROTHERMAL 20S Spine System has no customer-serviceable parts. For service, please contact your Smith & Nephew representative.

Specifications

Input Power	100–120/200–240V ± 10%, 50/60 Hz
Rated Power Input	160 VA
Output Power	20 watts (± 10%) into 90 - 250 ohms 0–5 watts, in SpineCATH Mode 0–3 watts, in Decompression Mode 0–10 volts, in Stimulate Mode 0–20 watts, in Denervation Mode
Max. Output Voltage	80V, rms
Operating Frequency	460 kHz (± 5kHz)
Power Delivery Modes	SpineCATH, Decompression, Stimulate, RF Lesion, Pulsed RF, BioMed
Set Temperature Range	40–99° C; this range varies for each Power Delivery Mode
Fuses	Dual fuses: 3.0 A/250 V
Waveform	Sine wave for SpineCATH, Decompression, RF Lesion, and Pulsed RF Modes Square wave for Stimulate Modes
Dimensions	5.75" H X 12.5" W X 13.0" D (146 mm X 318 mm X 330 mm)
Weight	12.6 lbs (5.7 kg)
Protection	Class I, Type BF Applied Part – defibrillator proof, IXP0, continuous operation. This equipment is not suitable for use in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide.
Controls	Line Power ON/OFF, RF On/Off, Stimulate Output, Front Panel soft keys (Start, Set Temp, Set Profile, Reset, Width, Frequency),
Displays	Impedance, Actual Temp, Elapsed Time, Paused, Volts, Frequency
Connections	Footswitch connector, power cord connector, 8-pin device connection port, neutral electrode connection port, RS-232 connector.

Environmental Conditions	Transport And/or Storage	Use
Temperature	-40° to +70° C	10° to 40° C
Humidity	30 – 100%	30 – 70%
Atmos. Pressure	500 – 1060 hPa	700–1060 hPa

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Accessories*

REF	Description
7210440	SpineCATH Intradiscal Catheter, 8 pin
7210441	SpineCATH XL Intradiscal Catheter, 8 pin
7210442	Decompression Catheter, 8 pin
7210273	5 cm RF Cannula, 4 mm Sharp Straight Tip
7210274	10 cm RF Cannula, 10 mm Blunt Curved Tip
7210275	10 cm RF Cannula, 10 mm Sharp Curved Tip
7210276	10 cm RF Cannula, 5mm Sharp Straight Tip
7210277	15 cm RF Cannula, 10 mm Blunt Curved Tip
7210278	15 cm RF Cannula, 10 mm Sharp Curved Tip
7210279	15 cm RF Cannula, 5 mm Sharp Straight Tip
7210270	RF Denervation Probe , 5 cm
7210271	RF Denervation Probe , 10 cm
7210272	RF Denervation Probe , 15 cm
7210443	8-pin Universal Extension Cable
7210520	RF Generator Test Cable
7209791	Pneumatic footswitch with attached hose

Caution: Inspect all components regularly for wear. Pay particular attention to potential damage to insulation, especially with universal extension cables.

Caution: Use only Smith & Nephew Spine devices and cables with the Smith & Nephew ELECTROTHERMAL *20S generator.*

Note: Smith & Nephew Spine devices must be used in a manner consistent with the Instructions for Use packaged with these Smith & Nephew devices.

Note: Smith & Nephew 8-pin universal extension cables may only be reused in accordance with the instructions in the "Cleaning and Sterilization" section.

** Contact Smith & Nephew or visit our web site for the most current list of available spine products.*

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Warranty

Smith & Nephew products are guaranteed to be free from defects in material and workmanship for the warranty period for a particular product, beginning from date of invoice. Refer to the current Smith & Nephew Product Catalog or contact Smith & Nephew Customer Service for specific warranty information.

This limited warranty is restricted to repair or replacement by Smith & Nephew, at its option, of any product found to be defective during the warranty period. Damage inflicted to a product by the user that causes it to be unsuitable for refurbishment may result in additional charges, regardless of warranty status. All warranties apply to the original buyer only. In no event shall Smith & Nephew be liable for any anticipated profits, consequential damages, or loss of time incurred by the buyer with the purchase or use of any product.

NO OTHER WARRANTY, EXPRESSED OR IMPLIED, IS GIVEN.

EC REP

Smith & Nephew
York Science Park
Heslington, York
YO10 5DF
United Kingdom

Service Replacement Units Warranty

The Smith & Nephew ELECTROTHERMAL® 20S Spine System replacement unit is warranted to be free from defects in material and workmanship for 90 days from the date of original invoice unless otherwise provided by local law.

Service Replacement Program

Smith & Nephew offers a 24-hour Service Replacement Program for its products to minimize downtime in your operating room. Our goal is to ship you a service replacement unit within 24 hours** of your call (during normal business hours). For a Return Authorization (RA) number or for additional information on this program, call Customer Service at 1-800-343-5717 in the U.S., or contact your authorized representative.

***24-hour shipment is not offered in all countries.*

Repair Service Program

For devices no longer under warranty, repairs can be made by Smith & Nephew or by an authorized agent. Non-warranty repairs will be made at the list price of replacement parts, plus labor. If requested, we will provide an estimate of repair cost and time required for the repair before any work is done. Repair items should be carefully repackaged, marked with the Return Authorization (RA) number, and returned postpaid to the appropriate Smith & Nephew Service Center. Smith & Nephew Customer Service or your local authorized representative can provide shipping information.

Endoscopy
Smith & Nephew, Inc.
Andover, MA 01810
USA

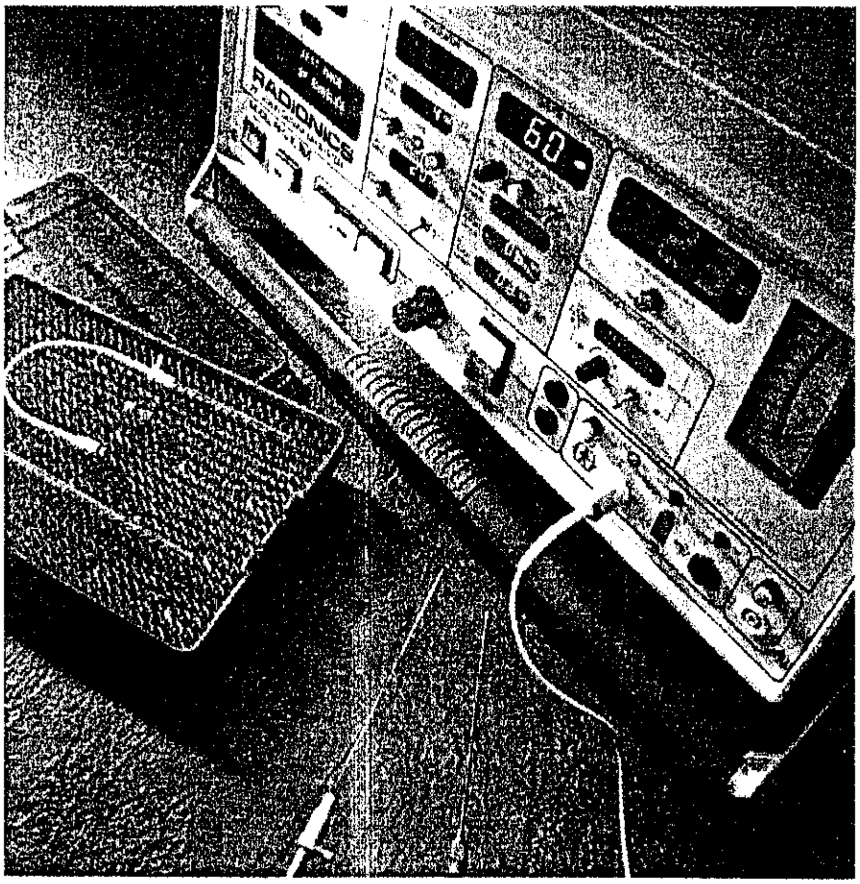
www.smith-nephew.com
978 749 1000
978 749 1108 Fax
800 343 5717 U.S. Customer Service

Exhibit C

Predicate Device Labeling

RFG-3C Plus

Lesion Generator



User's Manual

for Disc Enhanced Generators

Note: This manual is intended for use only with the RFG-3C Plus System Upgrade.
For generators that have been upgraded, this manual replaces the
RFG-3C Plus Operator's/User's Manual, Doc. No. 915-60-002.

CE
0120

915-60-003
Revision B

tyco
Healthcare

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TITLE AND PUBLICATION NUMBER

RFG-3C PLUS Lesion Generator User's Manual for System Upgrade Package
915-60-003 Rev. B (December 2000)

COPYRIGHT INFORMATION

CAUTION

U.S. Federal law restricts this device to sale by, or on the order of, a physician.

LIMITED WARRANTY

The Seller warrants to the original purchaser of this product that the product substantially conforms to its written specifications current at the date of delivery of such product and shall perform for a period of one year from such date of delivery substantially in accordance with those specifications. The obligations of the Seller and any affiliate of the Seller under this warranty shall be limited to repair or replacement of a non-conforming product, at the option of the Seller. The above warranty is contingent upon use of the product in accordance with its intended use and pursuant to operating instructions contained in the specifications. This warranty does not cover products that have been modified without the Seller's prior approval or which have been subject to unusual physical or electrical stress. EXCEPT AS STATED ABOVE, THERE ARE NO OTHER WARRANTIES. THE SELLER EXPRESSLY DISCLAIMS ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, WRITTEN OR ORAL, WITH RESPECT TO PRODUCTS, INCLUDING WITHOUT LIMITATION, IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, TITLE AND NON-INFRINGEMENT.

Temperature Monitoring Electrodes

Since electrodes are more subject to abuse the warranty differs. Barring mistreatment and misuse, if the electrode fails in the first three (3) months after date of shipment it is replaced free of charge; if it fails within three (3) to six (6) months it is replaced at 50% of its cost; and if it fails between six (6) to nine (9) months, it is replaced at 75% of its cost. Thereafter RADIONICS discontinues its warranty.

NOTICES

TRADEMARKS

RFG-3C Plus is a trademark of Radionics. All trade names referenced are the trademarks, registered trademarks, or products of their respective manufacturers.

CE 0120

Device is compliant with the European Communities Council Directive 93/42/EEC, Medical Device Directive.

MANUFACTURED BY

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http://www.radionics.com

Radionics is an ISO 9001 certified company.

SYMBOLS

Attention: Refer to Operator's Manual

REF — Reorder Number / Catalog Number

SN — Serial Number

FCC STATEMENT CONCERNING RFI

The RFG-3C Plus Lesion Generator generates and uses radio-frequencies. The equipment may cause interference with other medical equipment in the vicinity.

If interference occurs, one or more of the following measures could remedy the problem:

- Move the generator away from the affected equipment.
- Plug the generator into a separate outlet so that it is on a different branch circuit.

If necessary, consult the manufacturer of the affected equipment or an experienced technician. In addition, the booklet "How to Identify and Resolve Radio-TV Interference Problems" may be helpful. This booklet is published by the FCC and available from the U.S. Government Printing Office, Washington, D.C. 20402, Stock No. 004-00-00345-4.

CONTENTS

FOREWORD:

General Information, Device Classification, and Electrical Safety

General Information

Safe and effective lesioning is dependent not only on equipment design, but also on factors under the control of the operator. Do not attempt to operate the RFG-3C PLUS prior to completely reading and understanding the directions for use.

WARNING: Electric Shock Hazard

"CAUTION"

There are no user serviceable parts inside the RFG-3C PLUS. To avoid electric shock, return the device to Radionics for servicing. Refer to the service manual for maintenance and calibration instructions.

WARNING: Hazardous Electrical Output

This equipment is intended for use by qualified personnel only.

Do not use within 15 feet (4 meters) of a cardiac pacemaker.

This equipment has an output that is capable of causing a physiological effect.

Risk of Burns and Fire: Do not use near conductive materials such as metal bed parts or inner spring mattresses.

WARNING: Protective Earth Grounding

Grounding reliability can only be achieved when the equipment is plugged into a receptacle marked "Hospital Grade". Any interruption of the Protective Earth conductor will result in a potential shock hazard which could cause injury to patient or operator.

Device Classification

Classifications as per IEC 601-1/1988, the manufacturer describes the RFG-3C PLUS as:

Type of protection against Electric Shock:	Class I
Degree of protection against Electric Shock:	Type BF Defibrillator Protected
Degree of harmful ingress of water:	Ordinary
Mode of Operation:	Continuous Use
Degree of Safety in the Presence of Flammable Anesthetic Mixture with Air, Oxygen or Nitrous Oxide:	Not suitable for use

Electrical Safety and EMC

The Radionics RFG-3C PLUS has been tested to and meets the requirements of the following Electrical Safety Standards:

IEC 601-1	Medical Electrical Equipment (1988)
IEC 601-2-2	Particular Requirements for the Safety of High Frequency Surgical Equipment (1992)

The Radionics RFG-3C PLUS has been tested to and meets the requirements of the following EMC Standards:

IEC 601-1-2	Collateral Standards: Electromagnetic Compatibility (1993)

The following standards apply:

CISPR 11 Group 1, Class A, ISM
IEC 1000-4-2, 1000-4-3, 1000-4-4, 1000-4-5

Electrical Safety Information

The RFG-3C PLUS is a radio frequency lesion generator designed to produce local tissue heating at the tip of an electrode by the presence of radio frequency current. Special isolation transformers are imposed between power lines and internal RFG-3C PLUS circuitry, resulting in very low leakage current.

WARNING: A needle electrode should not be used as the dispersive electrode, as it is possible to burn the patient at this site due to high current densities. In all applications, care should be taken to maximize the surface area of the dispersive electrode. The dispersive electrode should be reliably attached with its entire area against the patient's body and as close to the operating field as possible.

The risk of igniting flammable gases or other materials is inherent in lesioning and cannot be eliminated by device design. Precautions must be taken to restrict flammable materials and substances from the electrosurgical site. The use of flammable anesthetics and nitrous oxide and oxygen should be avoided if a surgical procedure is carried out in the region of the thorax or the head, unless these agents are suctioned away. Flammable agents used for cleaning or disinfecting or as solvents of adhesives should be allowed to evaporate before the application of RF surgery. There is a risk of flammable solutions pooling under the patient and in body cavities. Any fluid pooled in these areas should be removed before the equipment is used. Avoid use of flammable materials, such as gauze or cotton wool when saturated with oxygen. These materials may be ignited by sparks produced in the normal operation of the RFG-3C PLUS.

WARNING: Apparent low power output or failure of the equipment to function correctly at normal settings may indicate faulty application of the dispersive electrode or failure of an electrical lead. Do not increase power before checking for obvious defects or misapplication. Effective contact between the patient and the dispersive electrode must be verified whenever the patient is repositioned after the initial application of the dispersive electrode.

WARNING: Set the output power setting as low as possible for the intended purpose.

WARNING: Electromagnetic interference (EMI) produced by the RFG-3C PLUS during normal operation may adversely affect the performance of other equipment. The performance of this device may be adversely affected by other high frequency surgical devices in close proximity. If problems occur, separate the devices.

WARNING: The use and proper placement of dispersive electrodes is a key element in the safe and effective use of this lesion generator, particularly in the prevention of burns. Read and follow the dispersive electrode manufacturer's instructions for preparation, placement, surveillance, removal and use of any dispersive electrode. The use of dispersive electrodes which meet or exceed ANSI/AAMI requirements (HF18) is recommended.

WARNING: Use a large area for the dispersive electrode, preferably a large area gel-pad or similar "ground" plate to disperse and return RF current over as large an area as possible, and thus minimize heating effects at that electrode. Use broad ground plates or gel pads as dispersive electrodes to avoid high current densities and resultant burns in adjacent tissue.

The ground pad should be placed in close proximity to the lesion site (e.g. for head and neck procedures at the scapula and for lumbar and thoracic procedures at the legs. Never place at the gluteus maximus).

WARNING: Observe the dispersive electrodes during lesioning for signs of excess heating.

WARNING: The long-term risks of protracted fluoroscopy and creation of RF lesions have not been established. Careful consideration must therefore be given for the use of the device in prepubescent children. Furthermore, the risk/benefit in asymptomatic patients has not been studied.

WARNING: The RFG-3C PLUS is capable of delivering a significant amount of output. Patient or operator injury can result from improper handling of the active electrode and dispersive electrode, particularly when operating the generator. During energy delivery, the patient should not be allowed to come in contact with metal parts which are earthed or which have an appreciable capacitance to earth. The use of antistatic sheeting is recommended for this purpose. Unshielded leads (active or return) should be positioned so that they cannot come into contact with the patient or other leads connected to the patient and so that they do not run parallel to nearby leads.

WARNING: Skin-to-skin contact should be avoided to prevent the possibility of accidental burns. It is recommended that gauze pads be placed in probable skin-to-skin contact sites (e.g. armpits, etc.).

WARNING: Electrodes and probes of monitoring, stimulating and imaging devices can provide paths for high frequency currents even if they are battery powered, insulated, or isolated at 60Hz. The risk of burns can be reduced, but not eliminated, by placing the electrodes or probes as far away as possible from the lesion site and from the dispersive electrode. Protective impedances incorporated into the monitoring leads may further reduce the risk of these burns and permit continuous monitoring during energy delivery. Needles should not be used as monitoring electrodes during such procedures.

WARNING: Potentially hazardous conditions may exist when accessories of similar connector types are combined. Use only appropriate accessories certified by an accredited test body.

WARNING: Never proceed in a temperature monitored procedure if the generator does not read body temperature before you begin delivering RF energy.

WARNING: Raise the temperature slowly, particularly with large electrodes. Displayed temperature lags behind the actual temperature due to the thermal mass of the electrode.

WARNING: The stimulator should not be used in any situation where the stimulating electrode could potentially come in contact with heart muscle, since these low frequency pulses could cause a serious physiological effect.

WARNING: Verify functional safety of the device before each use.

WARNING: For patients with a cardiac pacemaker or other medical devices, contact the device manufacturer to determine special use requirements during the radiofrequency procedure.

WARNING: In procedures with RF current flow through parts of the body with a relatively small cross-sectional area, use bipolar techniques to avoid unwanted coagulation.

CAUTION: Increase temperature at a slow and steady rate to prevent temperature overshoots.

Concentrate on maintaining the desired temperature response. If you cannot get a temperature rise, the voltage and current meters will indicate if the problem is an open circuit (abnormally low current and high voltage) or short circuit (abnormally high current and low voltage).

NOTICE: Always have spare electrodes and cables on hand in case a problem arises with the first one during a procedure.

Reusable cables and accessories should be periodically function and safety tested. Position cables to avoid contact with the patient or other leads.

Key to Device Markings

Type BF protection against electric shock. Floating or isolated applied part/defibrillator protected.

Neutral electrode isolated at low and high leakage currents.

Warning: Dangerous Voltage
No user-serviceable parts inside

OFF (for a mains switch).

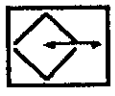
ON (for a mains switch).

Volume control (knob).

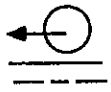
Footswitch input jack.

Output connection.

External (input) connection.



Data input/output (port).



Analog output connection.

Print function (button).

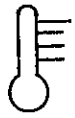
Fuse Warning: Replace as marked. Fire Hazard.

Warning: Consult Operator's Manual.

Equal potential jack terminal.

Percent relative humidity.

Non-condensing humidity.



Temperature in degrees C.

Alternating current (AC).

OFF (for mode).

ON (for mode).

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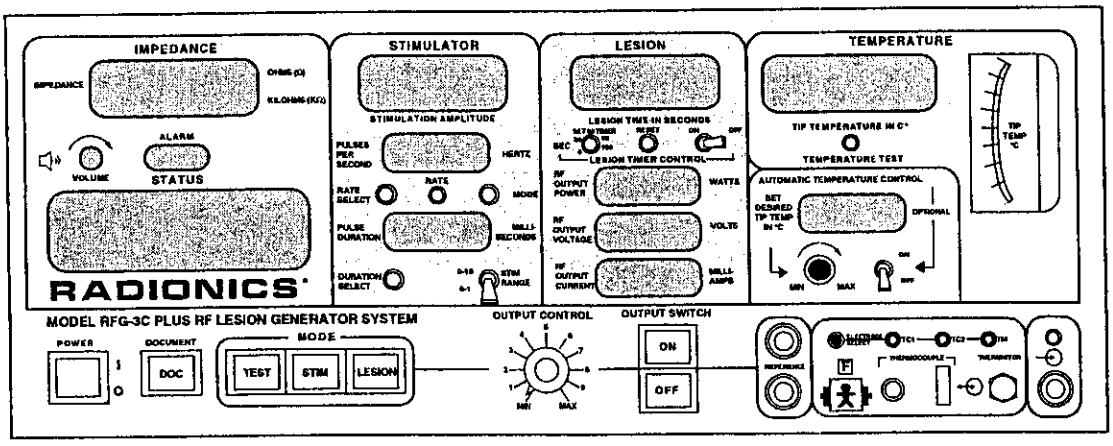
CHAPTER 1: GETTING STARTED



Description

The RFG-3C PLUS is a microprocessor-based lesion generator capable of supplying up to 50 watts of radio frequency power while continuously monitoring both the tissue impedance and the temperature at the tip of the selected electrode. It contains a stimulator section to facilitate the proper placement of the electrode before lesioning. Additionally, there are several built-in features, such as an automatic temperature control and audio tones that indicate impedance and temperature values. Finally, the status display indicates the mode and gives other important information, such as open circuit, temperature over boiling, etc. All of these functions are described in more detail in subsequent chapters.

Intended Use

The RFG-3C PLUS is intended to create lesions in nervous tissue, and for the coagulation and decompression of disc material to treat symptomatic patients with annular disruption of contained herniated discs.

Unpacking the RFG-3C PLUS

BOX 1 CONTAINS:

- RFG-3C PLUS
- Operator's Manual and test records.

The RFG-3C PLUS is packed surrounded by foam in a double-walled box. Remove the top foam and lift out the unit by the handle. Place the Operator's Manual and test records in a safe place for later reference.

Notice:	Save packaging materials for use in the event that the RFG-3C PLUS is shipped back to Radionics.

Cables and additional accessories are packed in Box 2.

BOX 2 CONTAINS:

- RFG-3C-TB Tool Box
- C119, C118-F, or C120 Power Cord, depending on destination
- C104-TM Connecting Cable for TM Electrodes
- C121 5' Black Reference Cord
- (2) SK-1R Red-Anodized Sterilizable Knobs
- (2) Spare Fuses CON-FU-0042 (1.6A or -0045 (3A))
- RFG-GPS Grounding Pad w/Shrouded Plug (International Sales only)
- RFG-FS Footswitch (Waterproof)
- CA-TC TC Active Jack Adapter

Turning on and Testing the RFG-3C PLUS

1. After unpacking the RFG-3C PLUS from the shipping box, plug the power cord into the rear of the unit.

Caution:	Make sure that the wall outlet voltage and frequency match those on the serial number label on the rear of the unit.

2. Plug the power cord into the proper AC receptacle. Rotate the RFG-3C PLUS's carrying handle downward by pressing the buttons on both sides of the handle. The handle will lock into a number of different positions to allow it to be used as an adjustable tilt stand as well as a carrying handle. Adjust this handle for easy viewing of the front panel.

Notice:	No electrodes or cables should be connected to the RFG-3C PLUS.

3. Connect the footswitch to the rear panel for this test. Press the green POWER switch. The RFG-3C PLUS performs the following self-tests: RAM test, ROM test, and a display test. During the display test, verify that all LEDs are lit. If any LED is not functioning, do not use the device and call Radionics. The Status window should read "SELECT MODE, CHECK CONNECTIONS." The Temperature and Impedance LED displays should read "---". The green light above TC1 should light.

4. Press the TEST button. The button should illuminate and the status window should display "TEST MODE." The impedance meter should read 100Ω ±20%. Both the analog and digital temperature meters display the temperature of the test resistor inside the RFG-3C PLUS, approximately room temperature.

Notice:	If the temperature is less than 20°C the display reads "---".

5. Press the STIM button. It should illuminate. Set the OUTPUT CONTROL knob to zero. The Stimulator section windows should display 50 Hz rate and 1.00 ms duration, and the Volt LED will be illuminated, indicating voltage stimulation mode is selected. The status window should display "TEST MODE, STIM MODE READY." If the knob is not set at zero, the display reads "TEST MODE , SET CONTROL TO MIN."

6. Turn the OUTPUT CONTROL knob to MIN. Press and hold down the footswitch. The ON button should light and the status window should display "TEST MODE , STIM ENABLED." Release the footswitch to change settings. Depending on the position of the OUTPUT CONTROL knob and the Stimulator range toggle switch, the stimulator voltage reads approximately 0-1 volt in the low range and approximately 0-10 volts in the high range.

7. Press the RATE button to shift between 2 and 50Hz. Hold in the RATE button to select a rate between 2 and 200Hz or one shot mode. Press the DURATION button repeatedly to change the Duration setting. Select One Shot mode by holding in the RATE SELECT button until dashes are displayed in the Frequency window. Press the footswitch; A single pulse is delivered every time the footswitch is pressed.

8. Press the MODE button. The milliamps (mA) LED will illuminate in the Stimulation window, indicating Current Stimulation mode is selected. Use the RATE button to select 5 Hz. Turn the OUTPUT CONTROL to MIN. Press and hold down the footswitch. The ON button should be illuminated, and the Status window should display "TEST MODE, STIM ENABLED." Release the footswitch to change settings.

9. Press the LESION button. The button should illuminate and the Lesion Time window should display the set time. Voltage, Current and Watts should read zero. The Status window should display "TEST MODE, LESION MODE READY." If the OUTPUT CONTROL knob is not already set at MIN, the window will display "TEST MODE, SET CONTROL TO MIN." The OFF button should be lit. If the ATC toggle switch is in the ON position, the Automatic Temperature Control window indicates the temperature set point. If the toggle is OFF, the window is blank.

10. Place the LESION TIMER CONTROL switch in the OFF position to perform this test. Turn the SET TIMER knob to zero. The timer window displays 00 or 01 sec. With the knob at its maximum setting, the timer display should read between 115 and 120 sec.

11. Move the ATC toggle switch to the ON position and turn the TEMPERATURE knob to 20°C. The ATC window should display between 15 and 25 °C. Turn the knob to its maximum setting. The display window should read between 93° and 95°C. Move the ATC toggle switch to the OFF position.

12. Turn the OUTPUT CONTROL knob to MIN. Press and hold the footswitch. Turn the OUTPUT CONTROL knob until the RF Volts display reads 50 volts. The RF Current display should read approximately 500 milliamps and the RF Watts display should read 25 watts. If the RF power is left on long enough, the test resistor will begin to heat up. This can be seen by an increase in the Temperature meter reading. Release the footswitch.

13. Press the MODE button in the Stimulator section. This will engage the Pulsed configuration of the Lesion mode. The Rate and Duration displays will illuminate with the factory default values. Pressing the RATE and DURATION buttons will cycle through the available RF pulse settings.

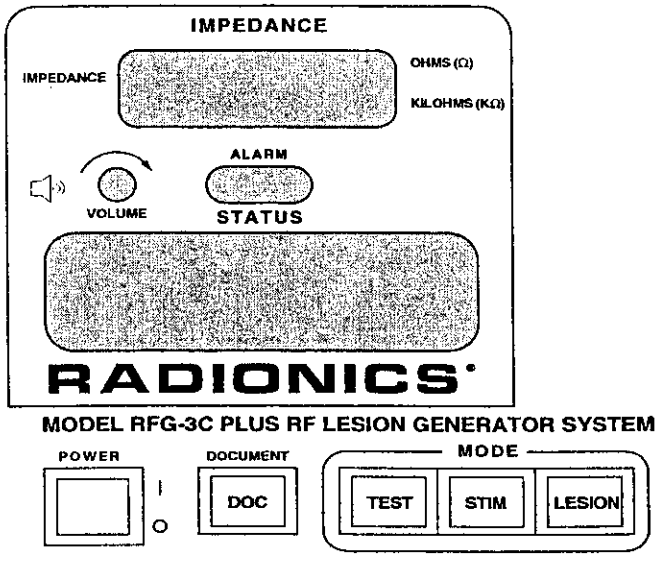
14. Push the ELECTRODE SELECT button. The TC2 electrode is selected, and the green light moves over the TC2 jack. Press the button again. The TM electrode is selected, and the green light above the TM jack illuminates. If pressed a third time, the TC1 electrode is selected and the green light above the TC1 jack again illuminates.

15. Push the TEMPERATURE TEST button. The Temperature display and the analog meter should read approximately 40 degrees and then change to 90 degrees after a few seconds. Repeat for the TC2 and TM electrodes.

The preliminary test of the RFG-3C PLUS is complete.

Contact your local Radionics distributor if you have any questions.

CHAPTER 2: IMPEDANCE SECTION



Test Mode Off

The RFG-3C PLUS continuously measures the impedance between the selected electrode and the dispersive electrode. The appropriate ohms (Ω) or kilo-ohms (kΩ) LED will light. If the measured impedance exceeds 5,000 ohms, the Impedance window will display dashes (---), and the Status window will display "CHECK CONNECTIONS." There is also an audible tone that is proportional to impedance when *not* in Lesion mode (the tone is proportional to the temperature when in Lesion mode). The volume can be adjusted by turning the VOLUME knob.

Notice:	Confirm that the TEST button is not illuminated when attempting to deliver energy to an electrode. Otherwise, the energy is delivered to the internal test load, and no energy is delivered to the tissue.

Test Mode On

The test resistance is 100 ohms ±20%. Whenever the TEST button is pushed, the status window displays "TEST MODE," and the Impedance window should display approximately 100 ohms.

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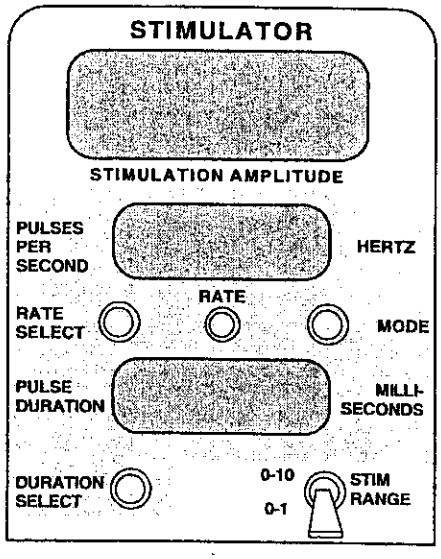
CHAPTER 3: STIMULATOR MODE



Test Mode Off

The stimulator is selected by pressing the yellow STIM mode button.

Voltage or Current stimulation mode is selected by pressing the MODE button. The Volts or Milliamps LED will illuminate, indicating which mode is selected.

The pulse amplitude is displayed in the Stimulation Amplitude window. It is increased by turning the OUTPUT CONTROL knob clockwise.

The pulse frequency is indicated in the Pulses Per Second window and is changed by pressing once or holding in the RATE SELECT button. When the Stimulator is activated, the Rate light flashes at the selected rate as an indicator that the Stimulator is working.

The pulse duration is indicated in the Pulse Duration window and is changed by pushing the DURATION SELECT button. Selecting the One Shot mode sends a single pulse to the output each time the stimulator is activated. One Shot mode is selected by holding in the RATE SELECT button until dashes are displayed in the Pulses Per Second window.

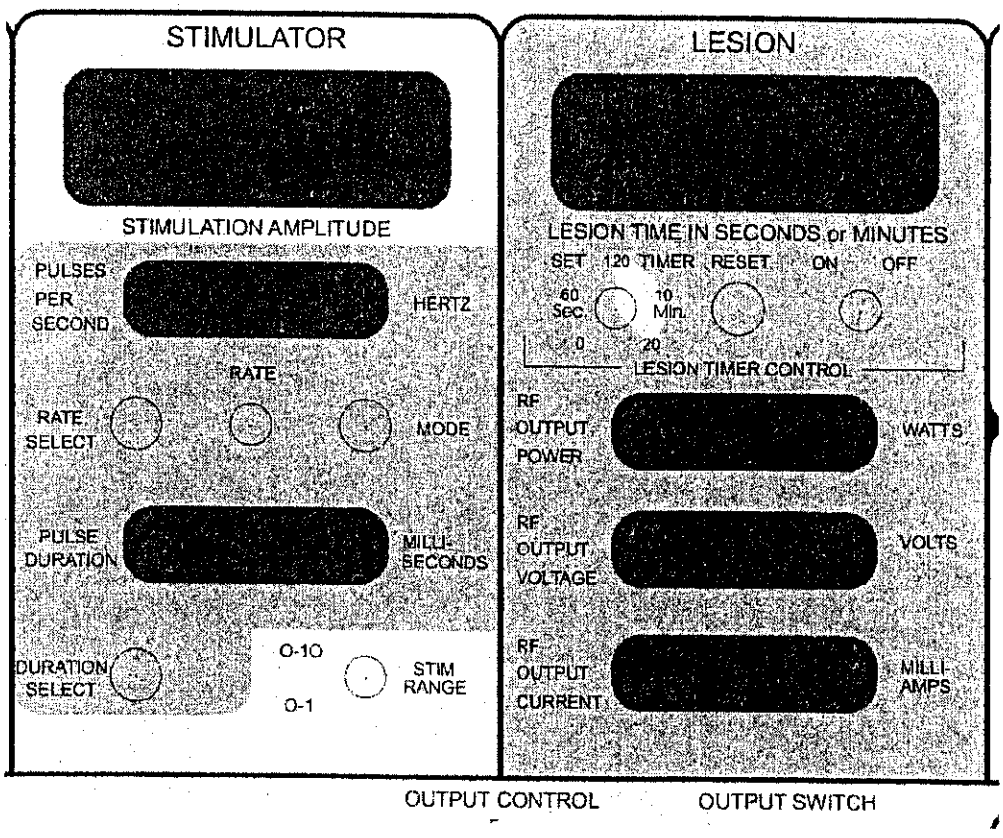
The Stimulator is activated by pressing and holding down the footswitch while in STIM mode. The microprocessor prevents the Stimulator from being turned on without first setting the OUTPUT CONTROL knob to MIN.

Notice:	Note that the readings of the Stimulator pulse frequency and pulse duration indicate their respective settings only. The status window displays "STIM OUTPUT ON," the rate light flashes and the Amplitude display illuminates when a stimulus is sent to the output.
Notice:	In Current Stimulation mode dashes are displayed, indicating the impedance is too high to maintain a constant current. This is corrected by lowering the stimulation current.

Test Mode On

The functions are identical as described above, except the output is directed to a 100 ohm internal test resistor instead of the selected electrode jack and the Rate LED does not illuminate.

CHAPTER 4: LESION MODE



Test Mode Off

Select Lesion mode by pressing the LESION mode button until it illuminates.

The Lesion Timer indicates lesion time in seconds or minutes and, if activated, counts up from zero to the set time, then disables the RF output. The timer can be set between 0 and 20 minutes (0 to 120 seconds, then 2.5 to 20 minutes) by turning the SET TIMER knob in the Lesion Timer Control section. Time is displayed in seconds when the "Sec" LED is illuminated, and in minutes when it is not illuminated. Pushing the timer RESET button resets the timer to zero.

If the lesioning is aborted prior to the timer disabling the RF output, the elapsed time freezes on the timer window until the RESET button is pressed or the output is reactivated.

The lesion timer is enabled by moving the ON-OFF toggle switch to the ON position, and is disabled by moving it to the OFF position.

The timer actually starts timing (if enabled) when the footswitch is pressed. It may also be enabled or reset at any time after the lesion power is turned on.

A lesion can not be started if Automatic Temperature Control (see page 13) is on and the displayed temperature is below 20°C. Also, a lesion cannot be started if the impedance display exceeds 5,000Ω. If the impedance exceeds 5,000Ω, lesioning will cease.

Turn on RF power by pressing the footswitch. The Rate LED will illuminate. The power is increased or decreased by turning the OUTPUT CONTROL knob. The micro-processor prevents turning on the RF when the OUTPUT CONTROL knob is set above MIN. The RMS RF output current, volts and power are displayed in their respective windows.

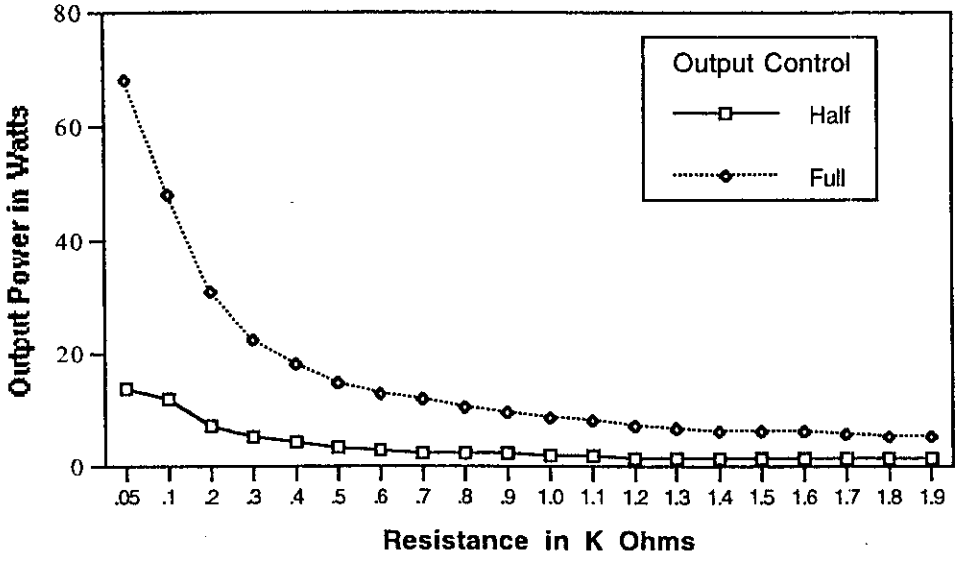
Select Pulsed mode by pressing the MODE button in the Stimulator section. NOTE: Voltage and currents displayed in this mode are peak values.

The Rate of RF pulses is selected by pressing the RATE button. The Duration of each pulse is selected by pressing the DURATION button.

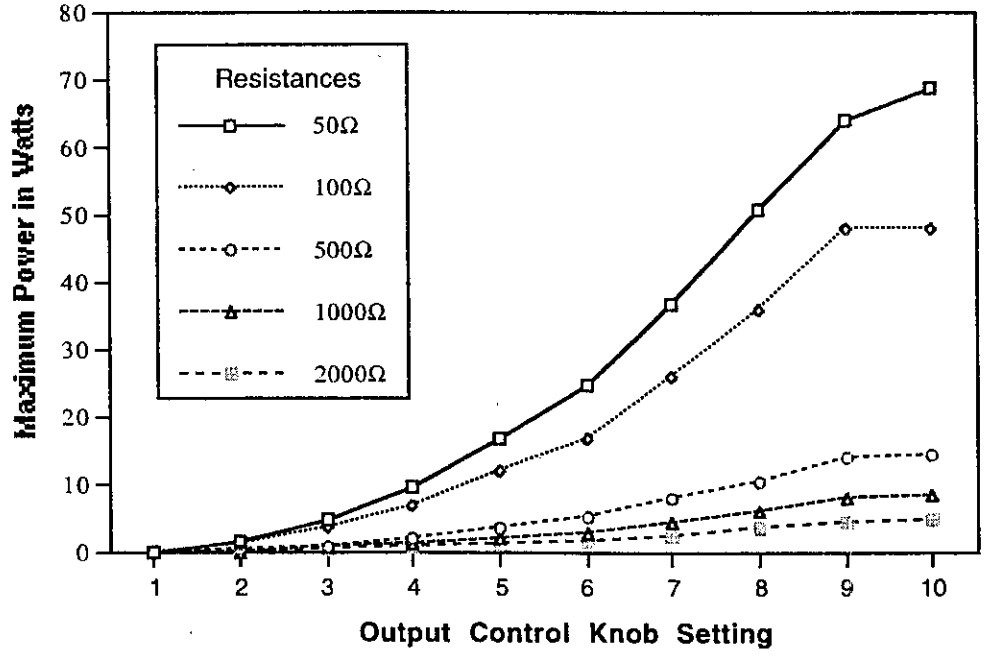
Test Mode On

The functions are identical to those described above, except the output is directed to a 100Ω internal test resistor instead of the output jacks and the Rate LED does not illuminate.

Resistance vs. Power



Power vs. Load Resistance



IMPORTANT NOTE: Output power varies with mains voltage ±20%. These readings were taken on a 240V/50Hz unit at 240Vac~. The output power displayed in the above graphs is the displayed, not the measured, value. The displayed value must be within ±15% of actual output power. Values displayed in the above graphs are RMS values.

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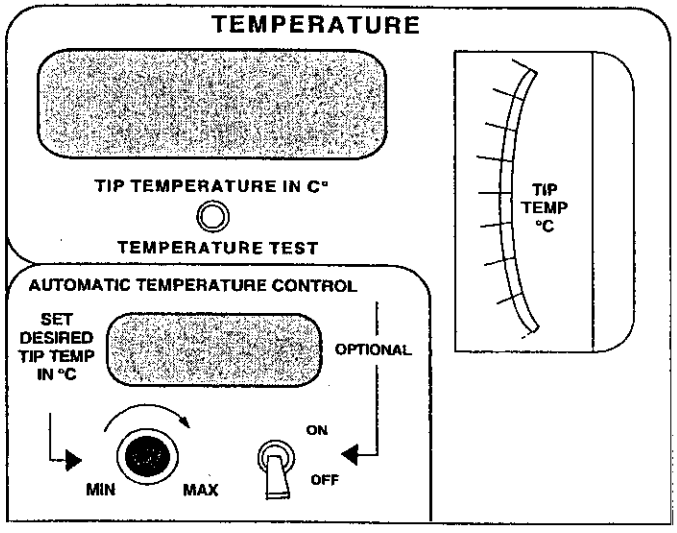
CHAPTER 5: TEMPERATURE MONITORING



Test Mode Off

Temperature

Temperature is displayed in the tip temperature window and indicates the tip temperature (°C) of the selected electrode. Pressing the TEMPERATURE TEST button performs a 40° and 90° test of the circuitry chosen by the ELECTRODE SELECT button. The measured output is displayed in the temperature window and on the analog meter so that a functional test and a calibration check can be performed at any time. It is considered acceptable if the temperature displayed is within ±2 °C of actual value, i.e. 38-42° for 40° test and 88-92° for 90° test.

ATC -- Automatic Temperature Control

The ATC prevents the tip temperature of the selected electrode from exceeding the preset temperature displayed in the automatic-temperature control window. If this temperature is exceeded, the amplitude of the RF power is modified. This is done by a feedback mechanism that regulates the temperature at the preset value. The Automatic Temperature Control can be set between 20°-95° with the Set Temperature knob. Note that the ATC circuit is activated only if the ATC toggle switch is in the ON position. If it is in the OFF position, the set temperature window is blank, and the operator must manually adjust the OUTPUT CONTROL knob in order to maintain a desired temperature.

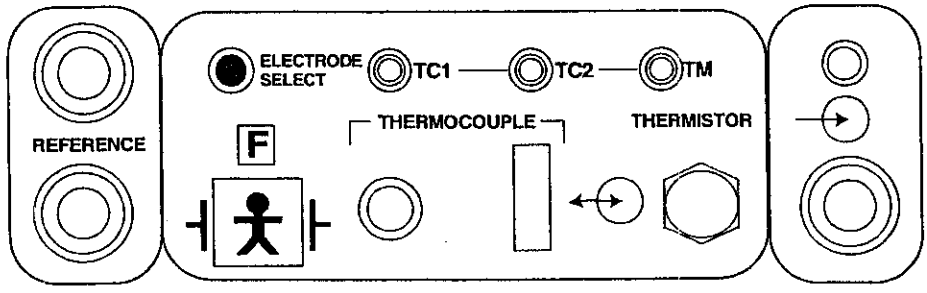
To use the ATC, set the Automatic Temperature Control at the desired lesion temperature, turn the RF POWER CONTROL knob to MAX and press the foot switch. The microprocessor now ramps up and regulates the RF power to maintain this temperature.

Notice:	When using this mode, the temperature can vary ±2°C from the set temperature. The microprocessor is setting the correct amplitude and is reacting to the thermal time constants of the tissue.

Test Mode On

When the TEST button is illuminated, the temperature displayed is the temperature of the internal thermocouples (TC1 or TC2) or thermistor (TM) depending on which electrode type is selected. This allows testing of the RF generator, temperature circuitry, and ATC if desired. All other functions are as described in Test Mode Off.

CHAPTER 6: OUTPUT CONNECTIONS



Patient Connections

Type BF defibrillator protected.

Neutral Electrode isolated at low and high frequencies.

Patient connections are made via the two output jacks marked "Reference." Either one may be used to accept the dispersive

electrode plug. Electrode jacks are selected by repeatedly pushing the ELECTRODE SELECT button until the desired LED lights.

External Connection

Three things happen when the EXTERNAL CONNECTION button is pushed:

1. The button illuminates.
2. The Status window displays "External Connection."
3. The External Connection jack is connected to the selected electrode.

Use the EXTERNAL CONNECTION button to connect an external device to the tip of the electrode without removing the electrode or the cable from the patient or the device.

WARNING: Any device connected to the External Connection jack must be of at least type BF Protection Against Electric Shock and meet the requirements set forth in IEC 601-1-1.

Footswitch

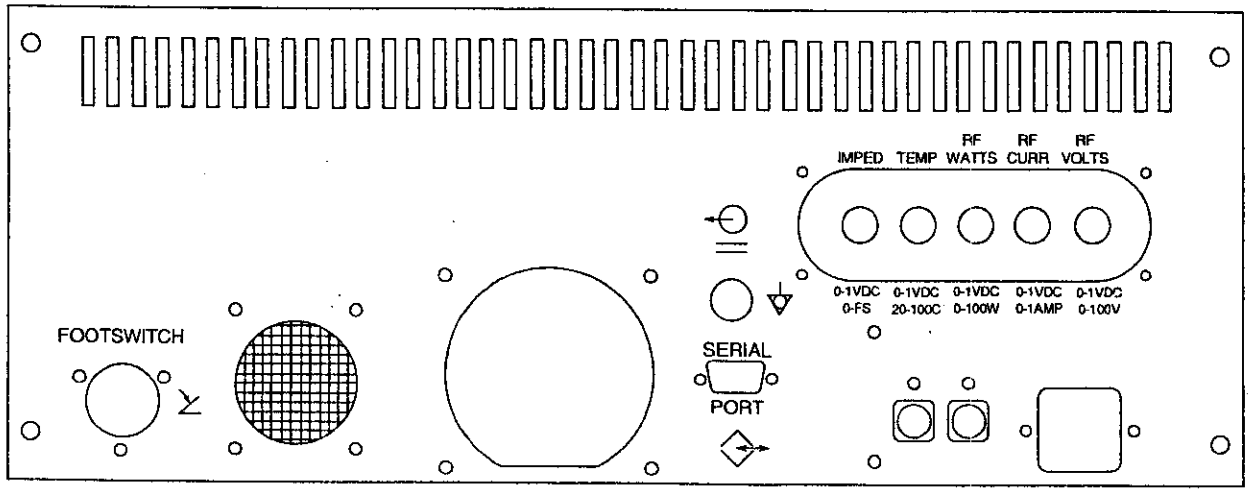
The RFG-3C PLUS is supplied with a footswitch of the momentary type. The footswitch must be plugged into the jack marked FOOTSWITCH on the rear of the unit. The RF output may be activated only by pressing and holding the footswitch. RF output is deactivated when the footswitch is released.

Analog Outputs (DC Volts)

Analog output BNC connectors for Impedance, Temperature, RF Watts, RF Current, and RF Volts are located on the rear of the RFG-3C PLUS. The outputs are adjusted to 1 volt DC for full scale reading, which is a standard input for most chart recorders.

Notice: Always record the wattage readings that correspond to a given temperature for a given technique. This gives extra guidance and helps Radionics diagnose problems.

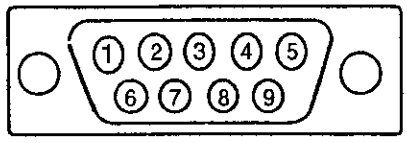
It is recommended that analog recordings be made for as many parameters as possible to provide data when questions arise. At minimum, Impedance, Temperature (if being used), and Watts should be recorded.



Serial Port

A serial output is provided on the back of the unit. This output conforms to the RS232C serial output configurations.

The connector is configured as shown below.



2TXD
3 RXD
4 DTR
5 SG
All other pins N/C

The Serial Port outputs watts, temperature, and power information that can be used by an intelligent peripheral device.

Used As	RS-232 Port 9-Pin Female		Cable 9-Pin Male/ 9-Pin Female	Laptop Computer Port 9-Pin Male	
			1 ---------- 1	1	CD
Out	TX1	2	2 ---------- 2	2	RXD
In	RX1	3	3 ---------- 3	3	TXD
In	DTR	4	4 ---------- 4	4	DTR
	ADGND	5	5 ---------- 5	5	SG
			6 ---------- 6	6	DSR
			7 ---------- 7	7	RQS
			8 ---------- 8	8	CTS
			9 ---------- 9	9	RI
			Shell ----- Shell	Shell	GND

The RFG-3C PLUS Port is configured for 9600 baud, no parity, 8 data bits, one stop-bit.

WARNING: When connecting any non-medical peripheral equipment to this device, it must be ensured that the equipment combination meets the requirements of IEC 601-1-1.

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APPENDIX A: STERILIZATION, CARE, AND SERVICE

Sterilization

Caution:	It is recommended that all cables and electrodes be gas sterilized (ETO). The cables and electrodes may be standard (gravity) autoclaved (121°C). The sterilizable knob may be flash autoclaved (132°C) No other parts may be autoclaved.

Care

The RFG-3C PLUS may be cleaned by wiping with a soft cloth dampened with a mild detergent. Do not allow liquid to get into the generator.

The cables, electrodes and cases may be wiped with mild cleaning solutions, taking care to keep moisture out of the connectors. Store in a clean, dry and non-corrosive atmosphere. The Lesion Generator is designed to withstand all normally encountered environmental conditions. Do not drop or bang the Lesion Generator.

Service

Caution:	The RFG-3C PLUS is not user serviceable, and the generator should be returned to Radionics if any problems arise.

To ensure accuracy of unit output and displays, return the unit to Radionics for yearly calibration.

In case of failure or malfunction of the device, discontinue use and report the failure or malfunction to Radionics.

For any electrical malfunction, accident, misuse, alteration, or other damage, return unit immediately to Radionics with a problem description.

Contact Radionics Customer Service for further assistance if needed.

Fuse Replacement

WARNING: Risk of fire. Fuses must be replaced as marked.

The RFG-3C PLUS has two fuses, one for line and one for neutral conductors. Replace with:

- 3.0A 250V for 100V-120V line operation
- T1.6A L 250V for 220-240V line operation

("T" indicates slow blow or time lag fuse.)

APPENDIX B: TROUBLESHOOTING

Troubleshooting

PROBLEM	POSSIBLE CAUSE
Unit will not turn on	• Bad AC outlet • Defective power cord • Blown fuses
No output	• Unit in TEST MODE • No ground connection • Problem with electrode • Break in electrode cable • Wrong electrode selected
No impedance readings	• No ground connection • Open circuit in cabling
RF output will not turn on	• Time set to zero • Output control set to a value other than zero • Footswitch defective
Power shuts down prematurely	• Set time on the time is too low
No response when a button is pressed	• Button is stuck in the depressed position

No temperature reading	• Not using temperature monitoring electrode • Bad cabling or electrode (can be verified if RFG-3C PLUS passes Temperature Test, see pg. 16)
Stimulator voltage too low	• Range switch in low position
Stimulator will not turn on	• Output control set to a value other than zero

WARNING: A COMMON PROBLEM THAT OCCURS DURING TRIGEMINAL NEURALGIA (TIC) PROCEDURES IS THE PATIENT MAY EXPERIENCE A STIMULUS EVEN WHEN THE GENERATOR IS UNPLUGGED FROM THE POWER SOURCE.

This occurs because the patient acts as an electrolyte, and when two plates of dissimilar metals (electrode and ground pad) are attached, a battery is formed. If a discharge path is connected across this voltage, the charge carriers present will flow through it, discharging the potential. This is the case when a lesion generator is connected across a patient via an electrode and ground plate. This discharge action may stimulate the patient if near the trigeminal nerve.

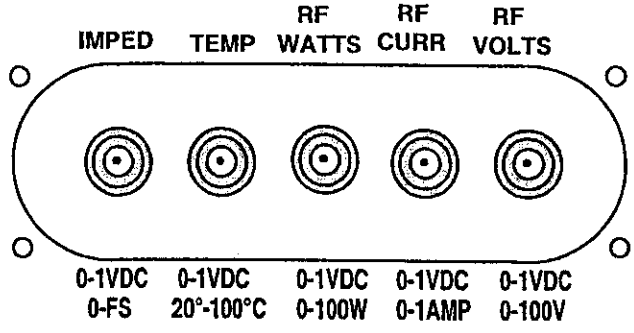
Use an electrode and ground plate composed of the same metals to remedy this. No significant charge develops across them when connected to the patient, and no current flows when connected to the generator.

Radionics will supply (international only), by request, a stainless steel ground pad [RFG-GP] for use with Radionics electrodes.

If unable to resolve the problem, contact Radionics Technical Support.

APPENDIX C: BNC CHART RECORDER CALIBRATION

BNC Chart Recorder Calibration



The following equipment is needed for this calibration:

- one 5kΩ ¼ watt 5% resistor
- one C102-B black reference cord
- one lesioning electrode and cable

Procedure

IMPEDANCE

1. Connect the chart recorder to the IMPED BNC connector on the back of the RFG-3C PLUS.
2. Connect the electrode and reference cords to their respective front panel jacks.
3. Connect the ends of the cords together.

Caution:	DO NOT TURN THE RF ON WHILE THE CORDS ARE SHORTED.

4. Turn the RFG-3C PLUS and the chart recorder on.

5. Adjust the chart recorder zero control until the pen reads zero.
6. Connect the electrode and reference leads from the unit to the 5kΩ resistor.
7. Adjust the chart recorder gain control for full scale reading.
8. Remove both of the cords.

TEMPERATURE

1. Connect the chart recorder to the TEMP BNC connector on the back of the RFG-3C PLUS.
2. Press the TEMPERATURE TEST button on the front panel.
3. When the temperature display reads 40°C, adjust the chart recorder zero to the position that you want to be the 40° line.
4. When the temperature display reads 90°C, adjust the chart recorder gain to the position that you want to be the 90° line.

WATTS

1. Connect the chart recorder to the WATTS BNC connector on the back of the RFG-3C PLUS.
2. Adjust the chart recorder zero control until the pen reads zero.
3. Press the TEST button on the front panel of the unit to put the unit into test mode.
4. Press the LESION button to put the unit into Lesion mode.
5. Switch the Timer ON/OFF switch to the OFF position.
6. Turn the OUTPUT CONTROL knob to zero and press the ON button.
7. Turn the OUTPUT CONTROL knob up slowly until the WATTS display reads 40.
8. Adjust the chart recorder gain control until the pen is where you want 40 watts to be (near full scale).
9. Turn the OUTPUT CONTROL knob to zero.

CURRENT

1. Connect the chart recorder to the CURRENT BNC connector on the back of the RFG-3C PLUS.
2. Turn the chart recorder zero adjust until the pen reads zero.
3. Turn the OUTPUT CONTROL knob up until the Current display reads 500 milliamps.
4. Adjust the chart recorder gain control until the pen reads half scale.

VOLTS

1. Connect the chart recorder to the VOLTS BNC connector on the back of the RFG-3C PLUS.
2. Adjust the chart recorder zero control until the pen reads zero.
3. Adjust the OUTPUT CONTROL knob until the Volts display reads 50V.
4. Adjust the chart recorder gain control until the pen reads half scale.

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APPENDIX D: SPECIFICATIONS, RFG-3C PLUS BLOCK DIAGRAM

Specifications for the RFG-3C PLUS Lesion Generator

ELECTRICAL SUPPLY

Voltage Specifications:	Volts (customer specified)	Volts input range
	100Vac	90-110
	117Vac	105-125
	220Vac	200-240
	240Vac	220-260

Maximum input voltage:	260Vac
Maximum voltage on any output connector:	260Vac
Maximum input power:	416VA
Supply current:	3.0 Amp ~ alternating current sinusoidal wave (117V units)
	1.6 Amp ~ alternating current sinusoidal wave (220V units)
Fusing:	3.0 Amp (T) time-lag (117V units) Domestic
	1.6 Amp (T) time-lag (220/240V units) Foreign
Frequency:	50/60 Hz

ENVIRONMENT OPERATING RANGE

Temperature:	15°C-40°C
Humidity:	20%-80% non-condensing relative humidity
Atmospheric Pressure:	500 hPa - 1060 hPa

TRANSPORT AND STORAGE ENVIRONMENT

Temperature:	5°C-50°C
Humidity:	20%-80% non-condensing relative humidity
Atmospheric Pressure:	500 hPa - 1060 hPa

IMPEDANCE MONITOR

Range:	0-5000 ohms digital
Resolution:	1 ohm
Accuracy:	10% of full scale

STIMULATOR OUTPUT

Rate: ONE SHOT, 2, 5, 10, 20, 50, 75, 100, 150, 180, 200 Hz

Duration: .1, .2, .5, 1.0 ms

Amplitude selectable:

Voltage stim mode:	0-1 volt 0-10 volts
Constant Current stim mode:	0-1 mA 0-10 mA

RF LESION GENERATOR OUTPUT

Timing:	*Selectable*:	0-20 minutes
	Accuracy:	0-120 seconds: ±.25 seconds
		2.0 minutes – 20 minutes: ± .1 minutes
	Resolution:	0-120 seconds: 1 second increments
		2.0 minutes – 20 minutes: .5 minute increments
Volts:	0-100 V	
	Accuracy:	10% of full scale
	Resolution:	±1 volt
Current:		0-999 mA
	Accuracy:	10% of full scale
	Resolution:	1 mA
Watts:	0-50 watts Max. (40 watts min. into 100Ω load)	
	Accuracy:	10% of full scale
	Resolution:	.1 watt
	Frequency:	500k Hz ± 10%

LESION GENERATOR PULSED MODE

Rate:	1, 2, 3, 4, 5, 6, 7, 8 Hz	
	Accuracy:	±10%
Duration:	10, 20, 30 mS	
	Accuracy:	±10%

TEMPERATURE MONITOR

TC1, TC2 and TM drift less than ±2° from ambient temperature

AUTOMATIC TEMPERATURE CONTROL

Range: TC1, TC2, and TM 20-95°C

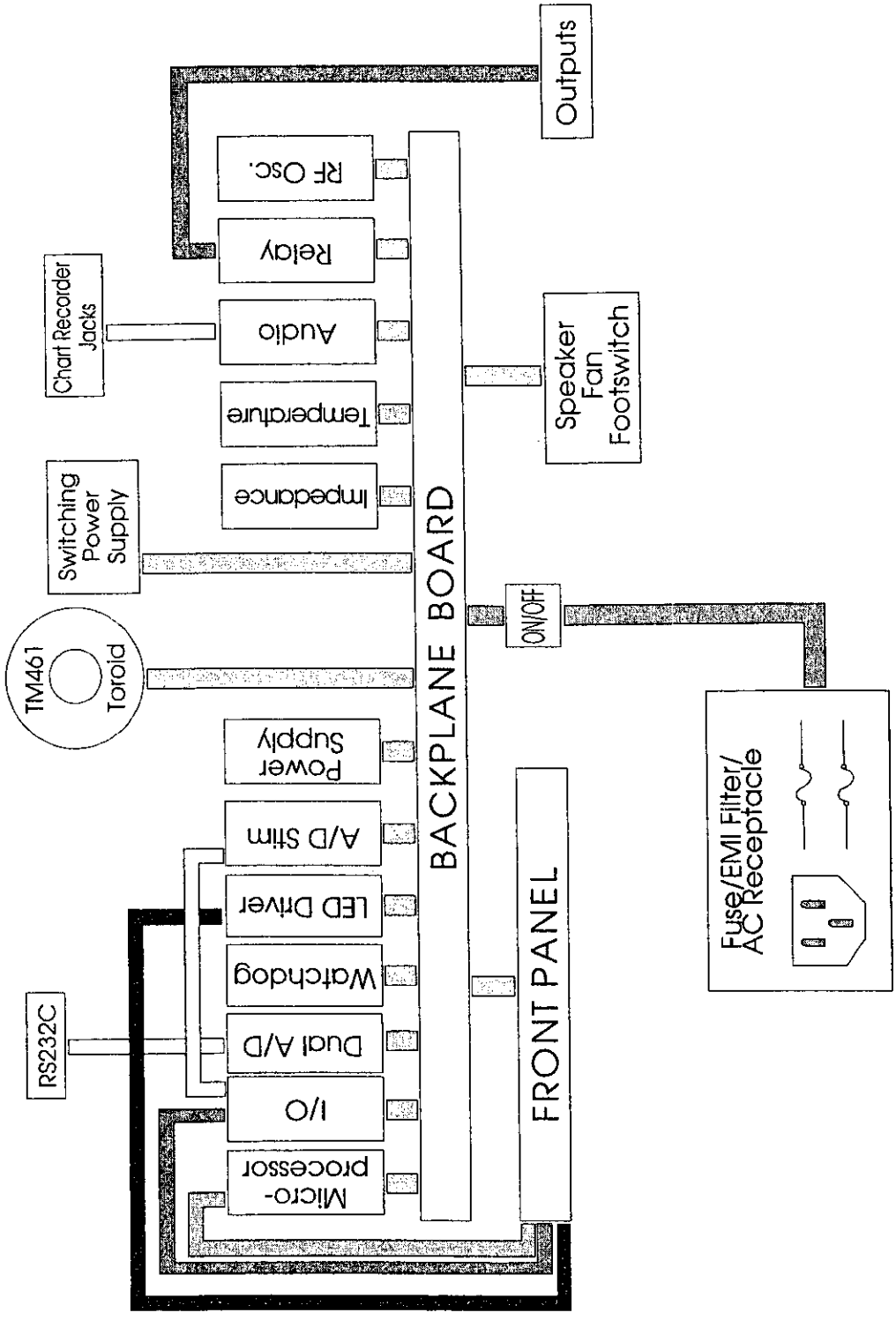
Resolution: ±1°C

OUTPUT JACKS (BNCS ON BACK PANEL)

RF Volts	0-100 RF volts	0-1 Vdc +/-20% FS
RF Current	0-1000 RF mA	0-1 Vdc +/-20% FS
RF Watts	0-50 RF watts	0-.5 Vdc +/-20% FS
Impedance	0-5000 ohms	0-1 Vdc +/-20% FS
Temperature	20-100°C	0-1 Vdc +/-20% FS

Notice: The above voltages are nominal since exact calibration is achieved by adjusting the offset and gain controls on the recording device to which this is connected.

Block Diagram of the RFG-3C PLUS



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APPENDIX E: ACCESSORIES

Radionics Part No.	Description
C104-TM	Thermistor Style Electrode Cable
C111-TC	Thermocouple Style Electrode Cable (low power)
C112-TC	Thermocouple Style Electrode Cable
RFG-FS	Footswitch (waterproof)
DGP-PM	Grounding Pad (disposable)
RFG-GPS	RFG Ground Plate
C118-F	Foreign Power Cord (foreign style, 230 volts)
SRK-14	Thermistor Style Electrode
TEW	Thermocouple Style Electrode
RFG-3C-FD	1.6 Amp Fuses (220/240V units)
RFG-3C-F	3.0 Amp Fuses (100/120V units)
DGP	Grounding Pad (disposable)

Exhibit D

Comparative Table

Comparative Table

The proposed Smith & Nephew ElectroThermal® 20S Spine generator versus Smith & Nephew ORA-50 S and Radionic's RFG-3C Plus Lesion Generator.

Characteristic	Proposed Smith & Nephew ElectroThermal® 20S Spine generator	Smith & Nephew ORA-50 S, K993854	Radionic's RFG-3C Plus Lesion Generator, K982489
Indications for Use	The Smith & Nephew ElectroThermal® 20s Spine System is intended to create lessions in nervous tissue, and to coagulate and decompress disc material when used in combination with Smith & Nephew thermal/coagulating probes. The generator and accessories are intended for use by qualified medical personnel trained in the use of electrosurgical equipment.	The Ora-50 S AutoTemp ElectroThermal Generator and Accessories are intended to be used for general surgical purposes in coagulation of soft tissues, in combination with ORATEC thermal/coagulating probes. The ORA-S AutoTemp ElectroThermal Generator and Accessories are intended for use by qualified medical personnel trained in the use of electrosurgical equipment.	The Radionics, Inc. RFG-3C PLUS Radiofrequency Lesion Generator is intended to create lesions in nervous tissue.
Power	1 channel, 0-20 watts	1 channel, 0-50 watts	1 channel, 0-50 watts
Power Delivery Accuracy	+/- 10%	+/- 10%	+/- 10%
Power Mode	Monopolar/Bipolar	Monopolar/Bipolar	Monopolar
Frequency	RF 460 kHz	RF 460 kHz	RF 480 kHz
Wave Form	Sine wave	Sine wave	Sine wave
Working Temperature Range	40-95° C	50-95° C	20-95° C
Temperature Accuracy	+/- 2° C	+/- 2 ° C	+/- 2 ° C
Impedence Monitoring	0-998 ohm	40-998 ohm	0-5000 ohms
Impedence Accuracy	+/- 10%	+/- 10%	+/- 20%
Lesion Time	0-120 sec	N/A	0 –120 sec
Power Supply	100-120/ 200-240V, 50-60 Hz	100-120/200-240V, 50-60 Hz,	100-120/220-240V, 50-60 Hz
Controls-Front			
RF Output Control	RF Power On /Off/Pause	RF On/Off	RF On
AC Power On	*On Rear Panel*	*On Rear Panel*	On/Off Switch
Pulsed RF Frequency	Frequency	Mode Select	N/A
Select Mode (on startup)	Start	Mode Select	N/A
Stimulation Pulse Width	Width	N/A	Width

Select Set Temperature	Set Temp Up/Down	Set Temperature Up/Down	Temperature min/max
Select Temperature Profile	Set Profile	Set Profile	N/A
Select Output Power	N/A	Set Power Up/Down	RF Power Knob
Select Procedure Time	Set Time	N/A	Set Timer
Clear Warning Message	Okay	N/A	N/A
Reset Procedure Timer	Reset	N/A	N/A
Select Stimulation Voltage	Stim Output Knob	N/A	Stim Output Knob
Indicate Fault	Fault LED	Fault LED	N/A
Indicate RF On	RF On LED	RF On LED	RF On LED
Indicate Stimulation Output On	Stimulate Output LED	N/A	Stimulate Output LED
Controls -Back	On/Off Switch	On/Off Switch	*On Front Panel*
Displays			
User Set Temperature	Set Temp	Set Temp	Automatic Temp Control
Measured Temperature	Actual Temp	Actual Temp	Tip Temperature
User Select Time	Set Timer	N/A	Lesion Timer
Measured Impedance	Impedance	Impedance	Impedance
Elapsed Time	Elapsed Time	Timer	Elapsed Time
Standby Mode Active	S&N Logo Screen	LED's Blanked	N/A
Procedure Paused	Paused	N/A	N/A
Pulsed RF Output Volts	RF Volts	N/A	RF Volts
User Set Profile	Set Profile	Set Profile	N/A
User Set Stimulation Volts	Volts	N/A	Volts
User Set Pulsed RF Frequency	Frequency	N/A	Frequency
Connections- Front	*On Rear Panel*	Footswitch	*On Rear Panel*
	8-Pin universal Probe connector	4-Pin universal Probe connector	Radionics Probe Connector
	Neutral electrode	Neutral electrode	Neutral electrode
Connections- Back	Footswitch	*On Front Panel*	Footswitch
	Power cord	Power cord	Power cord
	Serial Port	Serial Port	Serial Port
Protection	Class 1, Defibrillator Proof-Type BF applied part, IXPO, continuous operation	Class 1, Defibrillator Proof-Type BF applied part, IXPO, continuous operation	Class 1, Defibrillator Proof-Type BF applied part, IXPO, continuous operation

Exhibit E

Software Information

(b)(4) Specifications (Whole Page Redactions 145-373)

Exhibit F

Generator Performance Testing

(b)(4) Test Data (Whole Page Redactions 375-420)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

From: Reviewer(s) - Name(s) Elizabeth Frank

Subject: 510(k) Number K033981

To: The Record - It is my recommendation that the subject 510(k) Notification:

21 CFR 878.4400
79 GEI & Class II

- ☐ Refused to accept.
- ☐ Requires additional information (other than refuse to accept).
- ☒ Is substantially equivalent to marketed devices.
- ☐ NOT substantially equivalent to marketed devices.
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Section 522 Postmarket Surveillance?	☐ YES	☒ NO
Is this device subject to the Tracking Regulation?	☐ YES	☒ NO
Was clinical data necessary to support the review of this 510(k)?	☐ YES	☒ NO
Is this a prescription device?	☒ YES	☐ NO
Was this 510(k) reviewed by a Third Party?	☐ YES	☒ NO
Special 510(k)?	☐ YES	☒ NO
Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers	☐ YES	☒ NO

Truthful and Accurate Statement ☐ Requested ☒ Enclosed

- ☒ A 510(k) summary OR ☐ A 510(k) statement
- ☐ The required certification and summary for class III devices
- ☒ The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) N

Animal Tissue Source ☐ YES ☒ NO Material of Biological Origin ☐ YES ☒ NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

☐ No Confidentiality ☐ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 d

Predicate Product Code with class: 79 GEI & Class II

Additional Product Code(s) with panel (optional):

Review: _____ GSDB 2/24/04
(Branch Chief) (Branch Code) (Date)

Final Review: _____ 2/24/04
(Division Director) (Date)

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

Revised 12/2003

4

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K033981

Reviewer: Elizabeth L Frank

Division/Branch: DGRND/GSDB

Device Name: Smith & Nephew ElectroThermal® 20S Spine Generator

Product To Which Compared (510(K) Number If Known): K993854, K982489

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

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

1. **Intended Use:**
The Smith & Nephew ElectroThermal® 20S Spine System is intended to create lesions in nervous tissue, and to coagulate and decompress disc material when used in combination with Smith & Nephew thermal/coagulating probes. The generator and accessories are intended for use by qualified medical personnel trained in the use of electrosurgical equipment.

2. **Device Description:**
The Smith & Nephew ElectroThermal® 20S Spine (ET20S) generator is a 20 Watt electrothermal generator that provides temperature and impedance monitoring of energy to maintain effective tissue heating during temperature controlled applications. The generator is designed to work with the Smith & Nephew SpineCATH® Intradiscal Catheter and the Smith & Nephew Decompression Catheter. In addition, the Smith & Nephew RF Denervation Probe and Smith & Nephew RF cannula are currently under review in submission K034012 for use with this generator.

The Smith & Nephew ElectroThermal® 20S Spine generator is a software and hardware modification of the Smith & Nephew ORA-50 S Auto-Temp ElectroThermal Spine Generator (K993854). The software is a moderate level of concern. An LCD Display has been added to the front panel interface, an automatic probe recognition feature has been added that allows the generator to automatically switch to the appropriate mode and default settings for that device. An AutoTemp Mode has been provided to maintain the temperature of the Decompression Catheter tip according to the selected time/temperature profile. For the Denervation probe Stimulate mode, RF Pulsed mode and RF Lesion mode have been added. The extension cable provided with the Smith & Nephew's ElectroThermal® 20S Spine generator and the probe connector receptacle located on the front panel have been modified from a four pin connector to an eight pin connector. A Stim Output Knob has been added for stimulation output voltage control. The device is non-sterile and does not have direct patient contact.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. **Explain why not a device:**

2. **Explain why not subject to 510(k):**

3. **How does the new indication differ from the predicate device's indication:**

4. **Explain why there is or is not a new effect or safety or effectiveness issue:**

5. **Describe the new technological characteristics:**

6. **Explain how new characteristics could or could not affect safety or effectiveness:**

7. **Explain how descriptive characteristics are not precise enough:**
Descriptive characteristics are not precise enough because the software and hardware changes affect the delivery of energy. The addition of nervous tissue indications increases the risks associated with the use of the device. It is necessary to demonstrate that the software and hardware operate as indicated.

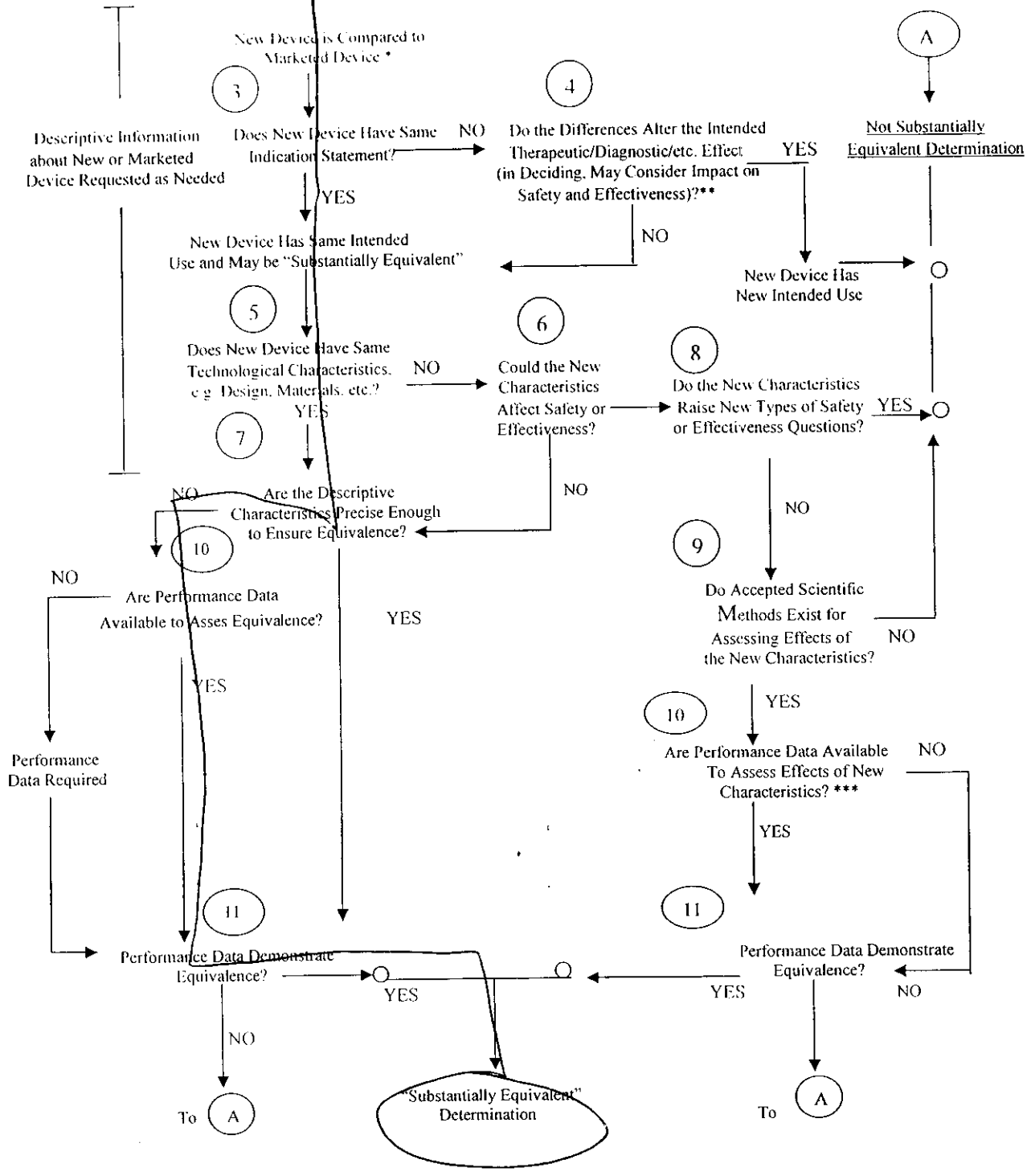
8. **Explain new types of safety or effectiveness questions raised or why the questions are not new:**

9. **Explain why existing scientific methods can not be used:**

10. **Explain what performance data is needed:**

11. **Explain how the performance data demonstrates that the device is or is not substantially equivalent:**
The performance data demonstrates the device is substantially equivalent to both the Smith & Nephew ORA-50S and Radionic's RFG-3C generators. The waveforms of the Radionic's device and the subject device are similar. Additionally, the temperature accuracy of the new device and the temperature delivery to tissue were compared to the ORA-50S device and then to the RFG-3C generator. There performance tests demonstrate that the subject device performs equivalently to the predicate devices.

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

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

S