



FOIA / PA Officer John Livornese
U.S. Securities & Exchange Commission
FOIA Office
100 F Street NE, Mail Stop 5100
Washington, DC 20549



March 27, 2018

Dear Mr. Livornese:

I request pursuant to the Freedom of Information Act (FOIA) 5 U.S.C. § 552. As Amended by Public Law No. 104-231, 110 Stat. 3048, copies of the following agreements.

Exhibit 10.1 to 10-Q/A filed on 01/07/1999 by Diametrics Medical Inc.

Exhibit Title: Distribution Agreement

CIK: 895380

Sectilis will pay up to \$61 for research, copies and review fees for all of the abovementioned agreements. Please forward all releasable material for copying. My daytime telephone number is 202-798-8809. Please call me or e-mail at research@sectilis.com to discuss the total cost or estimated cost of this research/copies should the amount exceed the price indicated in this request.

Sincerely,

Stella Vasconcellos
Research Assistant
Sectilis LLC
6931 Arlington Rd. # 580
Bethesda, MD 20814



UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
STATION PLACE
100 F STREET, NE
WASHINGTON, DC 20549-2465

Office of FOIA Services

May 10, 2018

Ms. Stella Vasconcellos
Sectilis LLC
6931 Arlington Rd. #580
Bethesda, MD 20814

RE: Freedom of Information Act (FOIA), 5 U.S.C. § 552
Request No. 18-03557-E

Dear Ms. Vasconcellos:

This letter is in response to your request, dated and received in this office on March 27, 2018, for Exhibit 10.1 to 10-Q/A, filed on January 07, 1999, by Diametrics Medical, Inc.

The search for responsive records has resulted in the retrieval of 50 pages of records that may be responsive to your request. They are being provided to you with this letter.

If you have any questions, please contact me at fultonc@sec.gov or 202-551-8186. You may also contact me at foiapa@sec.gov or (202) 551-7900. You also have the right to seek assistance from Lizzette Katilius as a FOIA Public Liaison or contact the Office of Government Information Services (OGIS) for dispute resolution services. OGIS can be reached at 1-877-684-6448 or Archives.gov or via e-mail at ogis@nara.gov.

Sincerely,

A handwritten signature in cursive script, reading "Charlotte Fulton".

Charlotte Fulton
FOIA Research Specialist

Enclosure

CONFIDENTIAL TREATMENTRECEIVED
OFFICE OF THE SECRETARY

NOV 17 1998

DISTRIBUTION AGREEMENT

DISTRIBUTION AGREEMENT, dated as of October 1, 1998, by and between DIAMETRICS MEDICAL INCORPORATED, a Minnesota corporation ("Diametrics"), and Johnson & Johnson Professional, Inc., a New Jersey corporation ("JJPI").

WHEREAS, JJPI markets instruments and accessories for the diagnosis and treatment of conditions affecting the central nervous system; and

WHEREAS, Diametrics manufactures and distributes diagnostic probes and related hardware and accessories used for monitoring certain components of tissue, blood and other bodily fluids; and

WHEREAS, the parties desire that JJPI distribute Diametrics's Products (as defined below) under the Diametrics Trademarks (as defined below) pursuant to the terms of this Agreement;

NOW, THEREFORE, in consideration of the mutual promises, covenants and agreements hereinafter set forth, the parties hereto agree as follows:

ARTICLE ONE**DEFINITIONS**

As used throughout this Agreement, each of the following terms shall have the respective meaning set forth below:

"Affiliate" of a party shall mean any entity or person that directly or indirectly controls, is controlled by or is under common control with such party. For purposes of this definition, "control" shall mean the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of an entity, whether through the ownership of voting securities, by contract or otherwise.

"Calendar Quarter" shall mean the calendar quarter customarily used by JJPI for internal accounting purposes consisting of approximately three months in which each of the first two months consists of four weeks and the third month consists of five weeks.

"Diametrics Patents" shall mean (i) all of the Patents, (ii) all other patents and applications for patents that cover the manufacture, use, importation or sale of any Product, in which Diametrics (or any Affiliate of Diametrics) has any rights, any foreign counterparts thereof, as well as

all continuations, continuations-in-part, divisions and renewals thereof, all patents which may be granted thereon, and all reissues, reexaminations and extensions.

“Diametrics Trademarks” shall mean (i) the Trademark and (ii) all other trademarks, applications for trademarks, copyrights, applications for copyrights, slogans, tradenames, artwork, names and other intellectual property that appear on or are otherwise used in connection with any Product, or any packaging therefor in which Diametrics (or any Affiliate of Diametrics) has any rights.

“Field” shall mean the measurement of physiological parameters anywhere within the central nervous system (i.e. the cranial cavity or the spinal column).

“Improvement” shall mean any adaptation, change, redesign, improvement, modification or development to any Product, the Specifications therefor, the Raw Materials or the method or process of manufacture or production of any Product.

“Know-How” shall mean all know-how relating to the development, manufacture, sale or use of any Product, including, without limitation, processes, techniques, methods, products, apparatuses, biological materials and other materials and compositions which are reasonably related thereto.

“Manufacturing Costs” shall mean the direct labor, direct overhead and Raw Materials costs incurred in the manufacture of Product.

“Net Sales” means the gross revenues received from the sale of Products to independent third parties during the applicable period less (i) discounts and rebates, (ii) credits or allowances granted upon claims or returns, (iii) freight charges paid for delivery and (iv) taxes and other governmental charges levied on or measured by the invoiced amount.

“Patents” shall mean the U.S. Patents set forth on Schedule D, along with any foreign counterparts thereof, as well as all continuations, continuations-in-part, divisions and renewals thereof, all patents which may be granted thereon, and all reissues, reexaminations, extensions, patents of addition, and any subsequent improvement patents or applications, such improvement patents and applications being those the practice of which falls within the claims any of said patents.

“Products” shall mean the fiber optic continuous probe for monitoring tissue, blood and other bodily fluid monitoring and components therefor, as described on Schedule A, along with any Improvements thereto (all for use in the Field).

“Raw Materials” shall mean the materials, components, and packaging required to manufacture and to package any Product in accordance with the Specifications.

“Specifications” shall mean the specifications for the design, composition, product safety assurance, manufacture, packaging, and/or quality control of any Product, as set forth on Schedule A attached hereto and made a part hereof, as the same may hereafter be modified by mutual agreement of the parties in writing.

“Trademark” shall mean the “Neurotrend” trademark (Federal Trademark Registration No. 75/323,109, applied for on July 11, 1997 (not yet issued)).

ARTICLE TWO

SUPPLY OF PRODUCT

2.01 Distribution Rights. (a) Subject to the terms and conditions of this Agreement, Diametrics hereby appoints JJPI, and JJPI hereby accepts appointment, as Diametrics’s exclusive worldwide distributor of the Products in the Field (including for the sale of Sensors and other accessories to customers using the Satellite System, Calibrator Patient Data Module or Senior Monitor System as of the date hereof); provided Diametrics may continue to service its existing (as of the date hereof) customers and sell Products until such time as JJPI notifies Diametrics to cease such activities on a country-by country basis. Diametrics understands and agrees that JJPI may utilize its Affiliates to act as distributor hereunder in certain geographic areas, provided that JJPI shall at all times remain responsible for performance of all of its obligations under this Agreement. Within six months following execution of this Agreement, and at least once every 12 months thereafter, representatives of JJPI and Diametrics will meet to discuss the progress being made on the development, manufacture and marketing of Products hereunder, including the development plans for Improvements and new products in the Field, if any, and the development plans, milestones and funding related thereto.

confidential (b) The parties acknowledge that Diametrics manufactures and markets blood monitoring probes and related components for use outside the Field, and that it is in their mutual interests to ensure that such other products are not used in the Field. Diametrics shall be responsible for maintaining differentiation and incompatibility between the Product and such other blood monitoring probes to inhibit the use of such other probes in the Field. Such differentiation and incompatibility may include variations in the connectors to monitor, the probe introducer system, packaging and labeling of the sensors and application specific software. The parties agree to meet within 30 days following the execution of this Agreement to agree on a plan to develop such differentiation and incompatibility. The parties acknowledge that to date, the Product and such other probes are differentiated with respect to probe shape and size and computer software only, and that there can be no guarantee that such additional differentiation or incompatibility will be developed. In the event Diametrics does not develop this additional differentiation or incompatibility by September 30, 1999, JJPI may, as its sole and exclusive remedy for such failure, terminate this Agreement upon written notice to Diametrics, which notice must be given, if at all, on or before December 31, 1999. In the event Diametrics becomes aware that any of its customers or users of blood monitor probes intended for use outside the Field are using such probes in the Field, Diametrics shall take all such reasonable actions as may be permitted by law to prevent or discourage such continued use in the Field.

(c) JJPI shall be responsible for developing devices for tunneling, anchoring and access that may be used in connection with the use of the Products, which development may include adaptation of existing products. Such devices shall be marketed by JJPI, and JJPI shall be responsible for obtaining and maintaining the required governmental approvals therefor. JJPI shall be the exclusive owner of any and all intellectual property, and shall be solely responsible for procuring and maintaining any proprietary rights therein. The parties acknowledge that there can be no assurance such devices will be developed or marketable. In the event JJPI does not develop and commence marketing of one of each such devices on or before December 31, 1999, Diametrics may, as its sole and exclusive remedy for JJPI's failure to develop such devices, terminate this Agreement upon written notice to JJPI, which notice must be given, if at all, on or before March 1, 2000. JJPI's obligation to develop a particular type of device pursuant to this Section 2.01(c) shall

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terminate in the event JJPI elects to market such a device using Diametrics' design (either by manufacturing such device under license from Diametrics or purchasing the device from Diametrics).

(d) The parties acknowledge that Diametrics is currently developing its own anchoring and access devices for the Products. Unless the parties agree in writing to develop such components jointly pursuant to Section 2.09, such devices shall not be included as Products hereunder, but shall be deemed to be new products in the Field for the purposes of Section 2.10.

2.02 Supply of Product. During the term of this Agreement, Diametrics shall supply JJPI (and its Affiliates) with all of those quantities of Product as ordered by JJPI (and its Affiliates) pursuant to this Agreement. Each such Product shall be packaged by Diametrics in accordance with the Specifications.

2.03 Prices. (a) The price (the "Price") for each Product component (other than sample units) shipped by Diametrics during the term of this Agreement shall be as set forth on Schedule B hereto. In addition, during the term of this Agreement, Diametrics shall supply JJPI with sample Products as reasonably requested by JJPI. Such sample Products shall be fully functional and shall be sold at the price set forth in Schedule B. The Prices set forth above include all costs of packaging in accordance with the Specifications and are F.O.B. Diametrics's factory in High Wycombe, England (Diametrics shall be responsible for loading Product onto the applicable carrier, and JJPI bears risk of loss and costs of delivery thereafter).

(b) The prices set forth on Schedule B shall remain in effect for at least 12 months following the first commercial sale of the Products by JJPI. Thereafter the prices may be adjusted on a component-by-component basis effective on each anniversary of such first commercial sale to reflect 100% of the actual increases, if any, in Diametrics' Manufacturing Costs since the most recent price increase; provided that in no event shall any price adjustment for a particular component be greater than the percentage change in the U.S. Medical Care component of the Consumer Price Index-All Urban Consumers (Current Series) as provided in Series Catalog CUUR0000SAM published by the U.S. Department Of Labor, Bureau of Labor Statistics (or if such index is not available, such similar index as the parties shall mutually agree) since the most recent price increase.

(c) Diametrics shall notify JJPI of any decreases in its Manufacturing Cost of the components of the Product excluding the Multiparameter sensor. If at any time there is at least a

confidential 10% reduction in Diametrics Manufacturing Costs of any of such components since the most recent price decrease (or since commercialization of the Product in the case of the first price decrease) Diametrics shall reduce the price of such component to JJPI prospectively by an amount equal to 40% of such cost decrease. Diametrics hereby agrees that it shall use its good faith efforts to minimize its Manufacturing Costs of producing the Products to the extent it may do so without compromising the quality of the Products or compliance with terms of this Agreement.

2.04 Forecasts. On or before December 31, 1998, JJPI shall provide to Diametrics a non-binding (except for the first quarter) forecast of its expected orders of Products (including samples) broken down on a component-by-component basis, for the following four calendar quarters (it being agreed such forecast shall not include the United States market until Diametrics has obtained 510K approval for the Product). JJPI shall provide an updated forecast at least 30 days before the beginning of the next Calendar Quarter which shall also cover the following four quarters. JJPI shall be obligated to order the quantity forecasted for the first quarter of each updated forecasted, and in no event shall JJPI be obligated to purchase or have any liability in respect of the quantities of Product set forth in second, third or fourth quarters of any such forecast.

2.05 Orders. JJPI shall place any binding orders for Product by written or electronic purchase order (or by any other means agreed to by the parties) to Diametrics. Such purchase orders shall set forth the desired date of delivery with respect to the Products ordered and shall be placed at least thirty (30) days prior to such desired date of delivery. To the extent of any conflict or inconsistency between this Agreement and any purchase order, purchase order release, confirmation, acceptance or any similar document, the terms of this Agreement shall govern. For any calendar quarter, Diametrics shall be deemed to have accepted, and shall be obligated to supply up to 110% of the quantity forecasted for first quarter of each updated forecasted provided pursuant to Section 2.04. Orders in excess of such 110% shall be subject to acceptance by Diametrics; provided that Diametrics will accept such excess orders to the extent it has the manufacturing capacity to supply them. *confidential*

2.06 Delivery. All charges for final packaging and transport packaging are included in the Price. All shipments must be accompanied by a packing slip which describes the articles, states the purchase order number and shows the shipment's destination. Diametrics agrees to promptly forward the original bill of lading or other shipping receipt for each shipment in accordance with

JJPI's instructions. Diametrics further agrees to promptly render correct and complete invoices to JJPI, and to accept payment by check or, at JJPI's discretion, cash or electronic transfer of funds. All invoices submitted by Diametrics shall be payable net within thirty (30) days after the date of such invoices. The date of invoice with respect to any Product shall not be earlier than the date of shipment of such Product.

2.07 Shipment. Diametrics shall ship Product, at JJPI's cost to the extent set forth in Section 2.03, to any location chosen by JJPI utilizing carriers approved by JJPI. The risk of loss with respect to all Product shall remain with Diametrics until the same is loaded on to the carrier specified by JJPI. Diametrics will package all Products in accordance with the packaging requirements included in the Specifications.

2.08 Initial Order; Minimum Purchase Requirements. (a) On or before October 15, 1998, JJPI shall issue a Purchase Order for at least \$150,000 of Product to be delivered on or before December 31, 1998. In addition if, by December 15, 1998 Diametrics has (A) obtained all regulatory approvals and clearances required to manufacture and market the Products in the United States and (B) completed to the satisfaction of JJPI the Supplier Qualification Activities set forth in Exhibit B, JJPI will issue a Purchase Order for an additional \$150,000 of Product for delivery within 30 days following the date of the Purchase Order. If Diametrics has not satisfied the conditions in (A) and (B) of the preceding sentence by December 15, 1998, JJPI shall pay to Diametrics prior to December 31, 1998, \$150,000 as a prepayment against future purchases of Product. Such prepayment shall be creditable at the rate of 100% against such future purchases.

(b) There will be no minimum purchase requirement during 1999. In the year 2000 JJPI shall purchase from Diametrics at least \$1,000,000 of Products (including Product used for Clinical Studies) as long as Diametrics has satisfied the Supplier Qualification Activities set forth in Exhibit B by June 30, 1999. JJPI shall notify Diametrics of those Supplier Qualification Activities which are not satisfactory by October 31, 1999. If Diametrics has not satisfied the Supplier Qualification Activities by January 1, 2000, JJPI shall have the right, as its sole and exclusive remedy for Diametrics' failure to timely satisfy such qualifications, to terminate this Agreement by written notice to Diametrics, which notice must be given, if at all, by March 1, 2000, provided that the January 1 and March 1 deadlines set forth in this sentence shall be delayed by one day

JJPI delays notifying Diametrics of unsatisfactory Supplier Qualification Activities after

1999 For each year commencing 2001, JJPI shall purchase from Diametrics at least the following percent of the previous year's actual purchases of Products (excluding Product used for clinical studies):

<u>Year</u>	<u>% of previous year's actual purchases</u>	
2001	115%	
2002	110%	
2003	110%	<i>confidential</i>
2004	100%	
2005	100%	

(c) The minimum purchase obligations shall be appropriately reduced to the extent (i) Diametrics is for any reason unable or unwilling to supply Product in accordance with the terms of this Agreement, (ii) any Product is recalled or withdrawn from the market for reasons of product safety, efficacy or quality, or (iii) a third party infringes any of the Patents and such infringement is deemed the cause for such minimums not to be met. Such minimum obligations shall be reduced to zero during the pendency of a claim that the manufacture, importation use or sale of the Product infringes the intellectual property rights of a third party, and will be appropriately adjusted prospectively upon final resolution of such claim.

(d) If JJPI does not actually purchase sufficient quantities of volume to fulfill its obligations under this Section 2.08, JJPI may, at its option, nevertheless be deemed to have fulfilled such obligations by paying Diametrics an amount equal the 50% of the difference between (A) the amount JJPI would have paid to Diametrics had it fulfilled its purchase obligations and (B) the amount JJPI has paid (or will pay) for Product actually purchased during the applicable period. Such payment, if made, shall be due within 30 days following the end of the applicable year in which JJPI did not fulfill its purchase obligation. *confidential*

(e) If JJPI does not fulfill any of its purchase obligations (or pay the applicable shortfall amount) under this Section 2.08, Diametrics shall have the right, as its sole and exclusive remedy, to (A) convert JJPI's distribution rights hereunder to become non-exclusive or (B) terminate this

Agreement, upon written notice to JJPI, which notice must be given, if at all, within 90 days following the end of the year in which JJPI did not fulfill its purchase obligation.

2.09 Research and Development. Diametrics shall, at its own expense conduct ongoing research and development for Product Improvements and new products in the Field. JJPI acknowledges that there can be no assurance any Product Improvements or new products will be developed, and the lack thereof shall not constitute a breach of this Agreement by Diametrics. Areas for Improvements include, without limitation, system accuracy, stability, mechanical integrity and strength, data display, calibrations processes and sensor extended shelf-life. If JJPI requests Diametrics to pursue a particular research and development project, such project shall be subject to the mutual agreement of the parties with respect to the scope, methodology and costs thereof.

2.10 New Products. If Diametrics develops or acquires rights to any new product for use in the Field, Diametrics shall offer JJPI the right to commercialize such new product (a "Proposed Transaction") (which Proposed Transaction may be in the form of a license, distributorship, supply arrangement, co-marketing arrangement or otherwise) in accordance with the right of refusal described herein. Diametrics shall not consummate or agree to consummate a Proposed Transaction with any party, or in any way dispose of or encumber any rights with respect to such new product, without first giving prompt notice thereof to JJPI in writing (the "Notice") (i) specifying the pricing, terms, conditions and other material provisions of such Proposed Transaction and (ii) providing a copy of a written agreement in principal or letter of intent, if any, setting forth the terms of such Proposed Transaction. In the event that JJPI elects to consummate a Proposed Transaction upon the same pricing, terms, conditions and other material provisions as specified in the Notice, JJPI shall have 30 days following receipt of the Notice to so notify Diametrics and the parties shall use their best efforts to facilitate the consummation of such a Proposed Transaction within 90 days following the receipt of such reply notification from JJPI. In the event that JJPI does not elect to enter into the Proposed Transaction within the above mentioned 30-day notice period, Diametrics may enter into an agreement with respect to the Proposed Transaction on terms that are, in the aggregate, not less favorable to Diametrics than the terms specified by Diametrics in the Notice or contained in the last subsequent proposal by Diametrics to JJPI, if any; provided, however, that if (x) Diametrics and the third party are unable to consummate the Proposed Transaction within the 180 days following the later of (i) the date of the Notice, or (ii) if JJPI elects to consummate the Proposed Transaction but

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the parties are unable to agree on definitive terms, the day on which such discussions terminate (either notice from JJPI or expiration of the 90 day period referred above), or (y) the pricing, terms, conditions and other material provisions of the Proposed Transaction are modified to be less favorable to Diametrics than were specified in the Notice or contained in the last subsequent proposal by Diametrics, if any, to JJPI, then Diametrics shall be required (each time such situation arises), pursuant to this Section 2.10, to give a new Notice to JJPI and comply with the right of first refusal set forth herein for an additional 30-day period following the receipt of such new Notice. The provisions of this Section 2.10 shall not apply if JJPI is in breach of any of its material obligations hereunder or if JJPI has satisfied the minimum purchase obligations set forth in Section 2.08 for the calendar year preceding the date of the applicable Notice only by paying the shortfall amount pursuant to Section 2.08(d). The provisions of this Section 2.10 shall survive the termination or expiration of this Agreement with respect to any Proposed Transaction for which the initial Notice was given during the term hereof (including any extensions or renewals hereof).

2.11 Marketing Plan. The Marketing Plan set forth in Schedule C represents JJPI's anticipated marketing and clinical program for the Products and JJPI undertakes to achieve all elements of such plan. The parties acknowledge however that there can be no assurance that each component of such plan will be achieved in a timely manner, if at all. If JJPI does not fulfill all elements of the Marketing Plan for a particular year, JJPI may nevertheless be deemed to have fully achieved the Marketing Plan for such year by (i) demonstrating that it has spent at least the applicable amount on marketing and clinical activities for the Products during such year as set forth below or (ii) by paying to Diametrics the amount by which JJPI has underspent the applicable commitment (in which event Diametrics shall apply such funds to internal manufacturing improvements for the Products, further development of the Products or its own marketing activities for the Products).

<u>Year</u>	<u>Expenditures</u>	
1998	\$ 160,000	<i>confidential</i>
1999	\$ 1,050,000	
2000	\$ 700,000	

For purposes of this Section 2.11, marketing and clinical expenditures shall include, without limitation, the following with respect to Products and related tunneling, anchoring and access devices: planning, patient monitoring, data analysis, reporting and Product purchases for clinical evaluations; training for customers, users (surgeons), and JJPI or Diametrics personnel or sales representatives; conventions, seminars, meetings, or presentations; advertising; promotions; mailings; user evaluations and direct in-service representative activities (and, in 1998, development of tunneling, anchoring and access devices). If JJPI has not fulfilled all elements of the Marketing Plan for a particular year and has not fulfilled either (i) or (ii) of the immediately preceding sentence, then Diametrics may, as its sole and exclusive remedy, terminate this Agreement on written notice to JJPI which notice must be given, if at all, within 90 days following the end of the applicable year. Upon request from Diametrics, JJPI will provide reasonable evidence of its marketing and clinical expenditures, not later than 30 days following the end of the applicable year.

ARTICLE THREE

ADDITIONAL OBLIGATIONS OF THE PARTIES

3.01 Sales of Product. All business decisions relating to the sale, price, marketing and promotion of any Product supplied under this Agreement, shall be within the sole discretion of JJPI. Diametrics further agrees that (i) payment by JJPI to Diametrics of the Prices set forth in Section 2.03 hereof for purchased Product, (ii) satisfying the minimum order requirements, or paying the shortfall amount, in accordance with Section 2.08, and (iii) compliance with the Marketing Plan, or expenditure of the minimum marketing and clinical expenditures, in accordance with Section 2.11, shall constitute complete satisfaction of any duty, whether express or implied, which could be imposed upon JJPI to commercially exploit its rights under this Agreement and are accepted by Diametrics in lieu of any best efforts obligations on the part of JJPI, and the remedies for the failure to fulfill any such obligations shall be limited, as applicable, to loss of exclusivity, termination or the payment of the Price for purchased Product as expressly set forth herein.

3.02 Package Labeling. Diametrics shall be responsible for the text and regulatory compliance of all package labels and Product inserts used in connection with the Products; provided

JJPI shall have the opportunity to review and comment on all such documents prior to their implementation (JJPI approval thereof is not required). JJPI shall develop all other labeling for the Products, including without limitation, all sales and promotional literature, subject to compliance with approved Product claims; provided that Diametrics shall have the opportunity to review and comment on such labeling prior to their implementation (Diametrics approval thereof is not required). Diametrics agrees that all labels and labeling shall prominently identify JJPI (or its Codman Affiliate) as the distributor of the Products to the extent permitted by law (except for Products subject to JJPI's initial order under Section 2.08(a)). All labels and labeling shall also prominently identify Diametrics as the manufacturer of the Products to the extent permitted by law. In addition, all Products shall be printed, embossed or engraved to prominently identify JJPI (or its Codman Affiliate) to the extent permitted by law (except for Products subject to JJPI's initial order under Section 2.08.(a)). For purposes of this Agreement the terms "label" and "labeling" shall have the meanings set forth in Sections 201(k) and 201(m) respectively of the U.S. Federal Food, Drug and Cosmetics Act.

3.03 Trademarks. JJPI shall distribute the Products purchased by it hereunder under the Diametrics Trademarks. JJPI acknowledges that Diametrics is the exclusive owner of and has all rights to the Diametrics Trademarks, subject to JJPI's rights under Section 9.01.

3.04 Provision of Information by Diametrics. Diametrics shall, at the request of JJPI, provide JJPI with the following information relating to the Products and to the extent reasonably available to Diametrics, at no cost to JJPI:

- (i) data, descriptions, processes, photographs and statements of claims for safety, efficacy or performance;
- (ii) the Device Master Record and Device History Record, as defined in 21 Code of Federal Regulations, Part 820, for the Products and components thereof;
- (iii) copies of all U.S. and foreign regulatory submissions, including the 510(k) submissions, for the Products;
- (iv) any labeling, inserts, sales literature or customer instruction prepared by Diametrics relating to the Products for JJPI review (it being understood and agreed that no such review shall relieve Diametrics of responsibility for the accuracy of such materials);

- (v) claim support for any claims, indications, or other representations included in any labeling, inserts, sales literature or customer instruction prepared by Diametrics relating to the Products (it being understood and agreed that in the event JJPI reasonably disagrees with any such claims, indications, or other representations, Diametrics shall modify the same in a manner agreeable to both parties subject to applicable regulatory requirements); and
- (vi) review of all training materials and sales and promotional literature developed by JJPI relating to the Products (it being understood and agreed that no such review shall relieve JJPI of responsibility for the accuracy of such materials).

3.05 Changes. In no event shall any significant change to any Product (or any change to the Specifications) be implemented or made without the prior written approval of JJPI. If the parties agree on any such change, they shall modify the Specifications to reflect the same. Diametrics further agrees that no significant changes to the method or process of manufacture or production of any Product or the Raw Materials shall be made without prior written notification to and approval of JJPI. As used in this Section 3.05, the term “significant change” shall mean any change that (i) results in a change to the Specifications (ii) affects Product performance, labeling, physical appearance or configuration, software (other than debugging or other error correction which does not otherwise affect on the performance of the software) , packaging, or sterilization processes, (iii) affects Product safety, reliability or integrity or (iv) requires a submission to or approval from a governmental body. In the event of any significant change, JJPI shall have the responsibility to establish an appropriate qualification protocol, if required by JJPI, and JJPI and Diametrics shall determine an appropriate inventory level for the pre-change Product in order to cover on-going requirements during the qualification process.

3.06 Insurance. Diametrics agrees to procure and maintain in full force and effect during the term of this Agreement valid and collectible insurance policies in connection with its activities as contemplated hereby which policies shall provide coverage in an amount not less than \$10 million per occurrence. Such policy shall name JJPI as an insured or an additional insured. Upon JJPI's request, Diametrics shall provide to JJPI certificate of coverage or other written evidence reasonably satisfactory to JJPI of such insurance coverage. Such insurance policy shall provide that in the event

such insurance coverage should be materially adversely changed or terminated for any reason, the insurer thereunder will give Diametrics and JJPI ten (10) days' prior notice. The existence of such coverage shall in no way limit Diametrics's liability or obligations hereunder.

3.07 Training. JJPI shall develop and implement training programs for its sales representatives and customers with respect to the operation and maintenance of the Products. Diametrics shall be responsible for the technical accuracy of all training materials and shall assist JJPI in preparing the technical aspects of such training programs. Diametrics shall actively participate in training JJPI trainers, who will in turn train JJPI sales representatives and customers.

3.08 Governmental Registrations. JJPI shall apply, in its name, for all governmental registrations required for JJPI to market Products as a distributor in those countries where JJPI desires to market Product, unless the applicable laws of a particular country require that such registrations be obtained by and in the name of the manufacturer of the applicable product, in which event Diametrics shall apply for such approvals. Diametrics shall reasonably cooperate with JJPI in its efforts to obtain such approvals. Upon termination or expiration of this Agreement for any reason, JJPI shall transfer to Diametrics, to the extent permitted by applicable law, those registrations obtained by JJPI. Diametrics agrees that JJPI shall have access to all of Diametrics regulatory submissions and technical files for the Products to the extent necessary to exercise its rights or fulfill its obligations hereunder.

ARTICLE FOUR

QUALITY/DEFECTIVE PRODUCT/INSPECTIONS/TESTING

4.01 Inspections. JJPI shall have the right, upon reasonable notice to Diametrics and during regular business hours, to inspect and audit the facilities being used by Diametrics (or any third party) for production and storage of Product to assure compliance by Diametrics (and its suppliers) with (i) all applicable statutes, laws and regulations, including, without limitation, Quality System Regulations ("QSRs") enforced by the United States Food and Drug Administration (the "FDA"), (ii) JJPI Quality Assurance Requirements attached as Exhibit A hereto, (iii) Johnson &

Johnson Corporate Quality Assurance Requirements attached as Exhibit B hereto, and (iv) the terms and provisions of this Agreement. Diametrics shall within fourteen days remedy or cause the remedy of any deficiencies which may be noted in any such audit or, if any such deficiencies can not reasonably be remedied within such fourteen day period, present to JJPI a written plan to remedy such deficiencies as soon as possible; and the failure by Diametrics to remedy or cause the remedy of any such deficiencies within such fourteen day period or to present such a plan within such fourteen day period and then use its best efforts to remedy or cause the remedy of such deficiencies in accordance with such written plan, as the case may be, shall be deemed a material breach of this Agreement. Diametrics acknowledges that the provisions of this Section 4.01 granting JJPI certain audit rights shall in no way relieve Diametrics of any of its obligations under this Agreement, nor shall such provisions require JJPI to conduct any such audits.

4.02 Acceptance; Disposition of Defective Product. JJPI shall have no obligation to pay for any Product that is subject to such a claim of non-compliance or defect; provided JJPI shall pay for Product within 30 days of receipt unless such Product has been rejected within such 30 day period. Diametrics shall replace at its own cost and expense, including reimbursement of freight and disposition costs incurred by JJPI, Product that fails to comply with the Specifications or other warranties made in Article Five, which replacement shall constitute JJPI's sole and exclusive remedy therefor (but in no way limiting Diametrics's indemnity obligations under Section 6.01). JJPI shall notify Diametrics of the existence and nature of any non-compliance or defect which comes to its attention and shall return such defective Product to Diametrics. Diametrics shall have a reasonable opportunity, not to exceed ten (10) days from receipt of such Product, to inspect such defective Product and provide JJPI an explanation of the defect and proposed course of action (ie. repair (including the nature of the repair) or replacement of the Product). The acceptance (or non-rejection) of any Products shall in no way limits JJPI's rights under Diametrics Product warranty or for indemnification hereunder; provided however that Diametrics shall replace defective Product (i) under this Section 4.02 if found to be defective within 60 days following receipt thereof by JJPI and (ii) under Section 5.01 if found to be defective after such 60 day period.

4.03 Independent Testing. If, after Diametrics's inspections of any Product, the parties disagree as to whether such Product conforms to the Specifications or whether the Product has such a defect, either party may deliver the item to an independent third-party laboratory, mutually and

reasonably acceptable to both parties, for analytical testing to confirm such item's conformance to the Specifications or the presence or absence of defects. All costs associated with such third-party testing shall be at JJPI's expense unless the tested item is deemed by such third-party to be defective or not in compliance with the Specifications, in which case all such costs, including reimbursement of freight and disposition costs, shall be promptly paid by Diametrics. No inspection or testing of or payment for Product by JJPI or any third-party agent of JJPI shall constitute acceptance by JJPI thereof, nor shall any such inspection or testing be in lieu or substitution of any obligation of Diametrics for testing, inspection and quality control as provided in the Specifications or under applicable local, state, or federal laws, rules, regulations, standards, codes or statutes.

4.04 Corrective Action. In the event any governmental agency having jurisdiction shall request or order, or if JJPI shall determine to undertake, any corrective action with respect to any Product, including any recall, corrective action or market action, and the cause or basis of such recall or action is attributable to a breach by Diametrics of any of its warranties, guarantees, representations, obligations or covenants contained herein, then Diametrics shall actively cooperate with JJPI in executing such corrective action relating to Product quality and performance, and Diametrics shall reimburse JJPI for the reasonable out of pocket costs of such action, including the cost of replacing any Product which is so recalled, whether or not any such specific unit of Product shall be established to be in breach of any warranty by Diametrics hereunder.

4.05 Notice of Audit or Inquiry. Each party agrees to promptly notify the other of any FDA audit, or any audit by any other regulatory body, of its facilities used for the manufacture, storage or distribution of Products, or any request for information from the FDA, or other regulatory body, related to the manufacture of Products, as soon as practicable after it received notice of such audit or request.

4.06 Complaint Handling. JJPI shall be responsible for interacting with customers regarding complaints and other product performance issues. Diametrics shall be responsible for all product performance complaint issues and will maintain MDR and other product performance tracking systems. JJPI shall reasonably cooperate with Diametrics in connection with its obligations under this Section 4.06 and provide to Diametrics, on a timely basis to permit Diametrics to fulfill its regulatory obligations, the necessary reports relating to complaints and product performance issues relating to the Products. Upon reasonable request by Diametrics, JJPI shall make such reports

(on behalf of Diametrics, if appropriate) directly to the appropriate regulatory authorities. In addition, JJPI shall maintain a tracking system for the Products, and shall provide such information to Diametrics upon reasonable request. Diametrics shall have the right to review and audit JJPI's complaint handling and product tracking systems for the Products, upon reasonable request during normal business hours. JJPI and Diametrics shall each be responsible for bearing their own costs associated with all complaint analyses and evaluations. Diametrics shall be responsible for bearing the cost of product replacement attributable to the failure of Product to comply with the requirements set forth in this Agreement. Diametrics shall, within 30 days following receipt of a returned Product, provide JJPI a written report of the results of the analysis and corrective actions taken with respect to such Product complaint.

4.07. Warranty Service. Diametrics agrees to perform repair, maintenance, modification and other services (including warranty repairs) on a timely basis on Products purchased by JJPI, its Affiliates, or its customers. All requests for service from customers shall be directed to JJPI, who will arrange for the customer to ship the applicable Product directly to Diametrics. Diametrics will repair and return product in accordance with JJPI instructions. In the case of out-of-warranty service, Diametrics will bill JJPI, who in turn will bill the customer. The rates for out-of-warranty service shall be agreed upon from time-to-time by JJPI and Diametrics. Diametrics agrees to maintain an inventory for spare and replacement parts for each Product sold under this Agreement if and when production ceases for a period of at least three (3) years following the delivery date of the particular Product.

ARTICLE FIVE

REPRESENTATIONS AND WARRANTIES

5.01 (a) Diametrics warrants to JJPI that the Products will meet the Specifications and will be free from material defects in material, workmanship and design for a period of eighteen (18) months from the date of shipment from Diametrics or twelve (12) months from the date of installation at the end user location, whichever is less, PROVIDED THAT:

1. The Product has been installed, stored, used and maintained in strict compliance with the safety procedures, Operating Instructions and storage and handling requirements provided with the Product.
2. Diametrics or an authorized Diametrics representative is notified, and the Product taken out of service, as soon as a defect appears.
3. The Product has not been subject to (i) neglect, misuse or operation contrary to the Operating Instructions provided with the Product or (ii) improper storage or handling contrary to the storage and handling requirements provided with the Product.
4. No repairs have been attempted or parts replaced by anyone not authorized by Diametrics to perform such repair, and that the Product serial number, date stamp or other identification marks have not been removed or defaced.

Diametrics's liability under this warranty is limited to the supply of replacement parts or Product, or labor and parts repair at an authorized Diametrics facility, to a value not exceeding the original Diametrics invoice price of the Product.

The warranty does not include:

- i) Packaging, freight and insurance to and from authorized Diametrics repair facility.
- ii) Products not provided by Diametrics or damage to the Diametrics Product that is caused by any such products.
- iii) Fuses
No rechargeable batteries
Cables
Lamps and Bulbs

Disposables or consumables

- (b) Diametrics represents and warrants that it complies and shall comply with applicable statutes, laws, ordinances, rules and regulations relating to the manufacture, assembly and supply of the Product, including, without limitation, those enforced by the FDA (including compliance with QSRs) and International Standards Organization (ISO) Rules 9,000 et seq. Diametrics represents and warrants that it has obtained ISO 9001 certification and has submitted to the FDA an application for 510K clearance for the Product and that the applications for such certification and clearance contain (or prior to certification or clearance will contain) complete and accurate information and that the information contained therein was obtained in good faith in compliance with all applicable statutes, laws, ordinances, rules and regulations.

(c) Diametrics warrants and represents that (a) the current Product is fully Year 2000 Compliant (as defined below), or it will be able to demonstrate Year 2000 compliance in a full production version of the Product, with accompanying documentation, no later than the specified delivery date if such date is on or before July 1, 1999; (b) Diametrics's information systems and other business systems for estimates, performance schedules, orders, confirmations, manufacture and delivery, invoicing and crediting of payments will accept and properly process input for dates before, on or after January 1, 2000 no later than July 1, 1999; and (c) Year 2000 Compliant products and/or services will be provided to JJPI under this Agreement in a timely and efficient manner without interruption and/or disruption at no additional fee or charge of any kind (including any installation, freight, or other costs or fees) to JJPI. On or before December 31, 1998 Diametrics shall provide to JJPI a written plan as to how it will achieve Year 2000 Compliance as required hereby. The term "Year 2000 Compliant" shall mean (a) the Product performs in a consistent manner and functions without interruptions regardless of the date in time on which the Product is delivered, used and/or further distributed, whether before, on or after January 1, 2000 and whether or not the dates are affected by leap years; (b) the Product, if computerized, accepts, calculates, compares, sorts, extracts, sequences and otherwise processes date inputs and date values, and returns and displays date values and performs, in a consistent manner regardless of the dates used, whether before, on or after January

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1, 2000; (c) the Product, if computerized, accepts and responds to two-digit year -date input in a manner that resolves any ambiguities as to the century in a defined, predetermined and appropriate manner; (d) the Product, if computerized, stores and displays date information in ways that are unambiguous as to the determination of the century; (e) the Product will be delivered and the services will be scheduled and performed in a timely manner without interruptions caused by the date in time on which the Product is ordered or is actually delivered or the services are scheduled or actually performed under normal procedures in the ordinary course, whether before, on or after January 1, 2000; (f) Diametrics is now planning and taking action to implement and will continue to implement, in a commercially reasonable manner, any and all measures to continue to perform this Agreement according to its terms and otherwise to meet the needs of its supplier-customer trading relationship with JJPI, including without limitation those required for due performance and continued performance without impairment due to interruption and/or disruption of estimates, performance schedules, orders, confirmations, manufacture and delivery of conforming products and/or services in a timely and efficient manner to fulfill JJPI's requirements and to enable JJPI to deal with its own business and its clients' needs and contract requirements, as well as to invoice JJPI and credit its payments in a timely and accurate manner; and (g) Diametrics will promptly provide to JJPI, in response to JJPI's periodic requests for updates, information concerning Diametrics's Year 2000 compliance program to the extent it affects performance of this Agreement itself according to the terms hereof or affects the performance of the products and/or services which are the subject matter of this Agreement and might impair its supplier-customer relationship with JJPI. JJPI may cancel, refuse to order and/or take delivery, reject and/or return non-complying goods and/or services and receive a full refund or credit against invoices, as applicable. In no event shall delays and failures caused by failures of Diametrics, its products or services to be fully Year 2000 Compliant constitute a force majeure event or excuse Diametrics from timely performance of its obligations.

5.02 Execution and Performance of Agreement. Diametrics and JJPI each represents and warrants to the other that it has full right, power and authority to enter into and perform its obligations under this Agreement. Diametrics and JJPI each further represents and warrants to the other that the performance of its obligations under this Agreement will not result in a violation or breach of, and will not conflict with or constitute a default under any agreement, contract, commitment or obligation to which such party or any of its Affiliates is a party or by which it is

bound and that it has not granted and will not grant during the term of this Agreement or any renewal thereof, any conflicting rights, license, consent or privilege with respect to the rights granted herein.

5.03 Intellectual Property. Diametrics represents and warrants to JJPI that Diametrics owns all of the rights, title and interest in and to the Diametrics Patents, Diametrics Trademarks, Know-How and all other intellectual property that appear on or are otherwise used in connection with the Products; no academic institution, member of an academic institution, corporation or other entity, or any local, state or federal government holds any property rights through it in any Product; Diametrics is able to consummate this Agreement in the capacity of a free agent; the manufacture, use and sale of the Products in accordance with the terms of this Agreement does not and will not infringe any third party's rights under any patent; the use of the Diametrics Trademarks by JJPI hereunder does not and will not infringe the rights of any third party; and Diametrics is presently aware of no infringement by any third party of any Diametrics Patent or any Diametrics Trademark.

5.04 (a) DIAMETRICS MAKES NO WARRANTY OTHER THAN THOSE EXPRESSLY MADE HEREIN, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION, ANY WARRANTY OF MERCHANTABILITY OR OF FITNESS FOR ANY PARTICULAR PURPOSE.

(b) THE ABOVE WARRANTY SHALL SUPERSEDE THE DISCLAIMER OF WARRANTIES STATEMENT WHICH IS INCLUDED IN THE OPERATING INSTRUCTIONS, OR ANY OTHER DOCUMENTATION PROVIDED WITH THE PRODUCT, TO THE EXTENT THE PROVISIONS OR SUCH DISCLAIMER OF WARRANTIES ARE INCONSISTENT WITH THIS WARRANTY.

(c) NOTHING CONTAINED IN THE ARTICLE 5 SHALL IN ANY WAY LIMIT DIAMETRICS INDEMNITY OBLIGATIONS UNDER SECTION 6.01.

ARTICLE SIX
INDEMNIFICATION

6.01 Indemnification by Diametrics. Diametrics shall indemnify and hold harmless JJPI and its Affiliates and their respective officers, directors and employees from and against any and all damages, liabilities, claims, costs, charges, judgments and expenses (including interest, penalties and reasonable attorneys' fees) (collectively "Damages") incurred by such party that arise out of or result from any third party claim (i) alleging any breach by Diametrics of any of its representations, warranties, guarantees, covenants or obligations contained herein, or (ii) otherwise arising out of the use of the Products except to the extent attributable to (A) claims made by JJPI that are beyond the scope of claims that have been approved by Diametrics or (B) defective or malfunctioning tunneling, anchoring, access or other devices manufactured by JJPI.

6.02 Indemnification by JJPI. JJPI shall indemnify and hold harmless Diametrics and its Affiliates and their respective officers, directors and employees from and against any and all Damages incurred by such party that arise out of or result from any third party claim (i) alleging any breach by JJPI of any of its representations, warranties, guarantees, covenants or obligations contained herein or (ii) arising out of the use of the Products to the extent attributable to (A) claims made by JJPI that are beyond the scope of claims that have been approved by Diametrics or (B) defective or malfunctioning tunneling, anchoring, access or other devices manufactured by JJPI.

6.03 Claims. Each indemnified party agrees to give the indemnifying party prompt written notice of any matter upon which such indemnified party intends to base a claim for indemnification (an "Indemnity Claim") under this Article Six. The indemnified party shall have the right to participate with the indemnifying party in the indemnifying party's defense, settlement or other disposition of any Indemnity Claim, subject to the ultimate control of the indemnifying party. With respect to any Indemnity Claim relating solely to the payment of money damages and which could not result in the indemnified party's becoming subject to injunctive or other equitable relief or otherwise adversely affect the business of the indemnified party in any manner, and as to which the indemnifying party shall have acknowledged in writing the obligation to indemnify the indemnified party hereunder, the indemnifying party shall have the sole right to defend, settle or otherwise dispose of such Indemnity Claim, on such terms as the indemnifying party, in its sole discretion,

shall deem appropriate, provided that the indemnifying party shall provide reasonable evidence of its ability to pay any damages claimed and with respect to any such settlement shall have obtained the written release of the indemnified party from the Indemnity Claim. The indemnifying party shall obtain the written consent of the indemnified party prior to ceasing to defend, settling or otherwise disposing of any Indemnity Claim if as a result thereof the indemnified party would become subject to injunctive or other equitable relief or the business of the indemnified party would be adversely affected in any manner.

ARTICLE SEVEN

FAILURE TO SUPPLY; FORCE MAJEURE

7.01 Failure to Supply. Notwithstanding the provisions of Section 7.02, in the event that Diametrics shall be unable or unwilling or has failed for any reason (including as a result of the commencement of a case by or against Diametrics under Title 11 (as defined in Section 9.02)) to supply to JJPI any Products in compliance with the desired delivery date specified in the purchase orders submitted by JJPI in accordance with Section 2.05 hereof (to the extent such quantities were included within the relevant forecasts submitted in accordance with Section 2.04 hereof) (a “Failure to Supply”), then, upon ninety (90) days written notice from JJPI (if Diametrics has failed to cure the breach during such ninety (90) day period, which cure may include the use of a third party manufacturer of Products that has satisfied the JJPI’s Supplier Qualification Activities), JJPI may use, sell, make and have made the Products and use the Diametrics Trademarks in connection therewith pursuant to the license granted in Section 9.01 until such time as Diametrics demonstrates to JJPI’s reasonable satisfaction its ability to fully resume its supply obligations hereunder (such time period, a “License Period”); provided that JJPI shall have no obligation to purchase Products from Diametrics, and the License Period shall continue, until the earlier of (i) any contractual obligations that JJPI has assumed in connection with producing the same or obtaining such substitute source of supply shall have terminated, and (ii) 180 days following the date on which Diametrics demonstrates to JJPI’s reasonable satisfaction its ability to fully resume its supply obligations hereunder. In the event of such Failure to Supply, Diametrics shall make available to JJPI or its designee access to all

Know-How and any other technical and proprietary materials, information and techniques necessary or helpful for JJPI to procure required raw materials or produce or arrange an alternative supplier of Product, and to provide advice and consultation in connection therewith. Diametrics shall not sell any Product to any third party during a License Period. JJPI shall pay to Diametrics a royalty equal to 6% of Net Sales of Product manufactured by or for JJPI under this Article 7 which, but for the license granted in Article 9 of this Agreement, would infringe a valid claim of a Diametrics Patent, and a royalty equal to 3% of Net Sales of Product manufactured by or for JJPI under this Article 7 which do not infringe a valid claim of a Diametrics Patent. The provisions of this Section 7.01 shall constitute JJPI's sole and exclusive remedy for a Failure to Supply except to the extent such Failure to Supply is attributable to an intentional or willful act, omission or decision by Diametrics.

7.02 Force Majeure Events. If either party is prevented from performing any of its obligations hereunder due to any cause which is beyond the non-performing party's reasonable control, including fire, explosion, flood, or other acts of God; acts, regulations, or laws of any government; war or civil commotion; strike, lock-out or labor disturbances; or failure of public utilities or common carriers (a "Force Majeure Event"), such non-performing party shall not be liable for breach of this Agreement with respect to such non-performance to the extent such non-performance is due to a Force Majeure Event. Such non-performance will be excused for three months or as long as such event shall be continuing (whichever period is shorter), provided that the non-performing party gives immediate written notice to the other party of the Force Majeure Event. Such non-performing party shall exercise all reasonable efforts to eliminate the Force Majeure Event and to resume performance of its affected obligations as soon as practicable.

ARTICLE EIGHT

CONFIDENTIALITY

8.01 Confidential Information. As used herein, "Confidential Information" shall mean all confidential or proprietary information that is reduced to writing, marked as confidential and given to one party by the other party relating to such other party or any of its Affiliates, including information regarding any of the products of such other party or any of its Affiliates, information regardin

advertising, distribution, marketing or strategic plans or information regarding its costs, productivity or technological advances. Neither party shall, during the term of this Agreement and for a period of five years (seven years with respect to Know-How and other technical and proprietary materials, information and techniques which may be provided to JJPI pursuant to Section 7.01 or 9.01) following the termination or expiration of this Agreement for any reason, use or disclose to third parties any Confidential Information of the other (except to the extent reasonably necessary to exercise its rights or comply with its obligations under this Agreement) and each party shall insure that its employees, officers and agents shall not use or disclose to third parties any Confidential Information of the other (except to the extent reasonably necessary to exercise its rights or comply with its obligations under this Agreement); provided, however, that JJPI may disclose Confidential Information of Diametrics to JJPI's Affiliates and consultants if such persons are informed of the confidential nature of such information and are under an obligation to keep such information confidential. Confidential Information shall not include information that (i) was already known to the receiving party at the time of its receipt thereof, as evidenced by its written records, (ii) is disclosed to the receiving party after its receipt thereof by a third party who has a right to make such disclosure without violating any obligation of confidentiality, (iii) is or becomes part of the public domain through no fault of the receiving party or (iv) is required to be disclosed to comply with applicable laws or regulations or an order of a court or regulatory body having competent jurisdiction. Nothing contained herein shall prevent JJPI from marketing and, if applicable pursuant to Sections 7.01 and 9.01, manufacturing or having manufactured the Products and JJPI shall be permitted to disclose such Confidential Information as is reasonably necessary in connection with such activities.

ARTICLE NINE

LICENSE RIGHTS

9.01 License. Diametrics hereby grants to JJPI an exclusive worldwide license, with the right to grant sub-licenses to its Affiliates, under the Diametrics Patents and Know how in the Field, to use, sell, make and have made the Products, and to use the Diametrics Trademarks in connection therewith; provided, however, that the license granted hereunder shall be effective only during

License Periods (as defined in Section 7.01) and JJPI shall not exercise its rights under this License other than during such License Periods. If JJPI does exercise its rights under this license, JJPI shall pay to Diametrics the royalties provided for in Section 7.01. The parties agree that under the license in the Diametrics Trademarks granted herein, in order to protect the goodwill in the Diametrics Trademarks, JJPI shall submit to Diametrics, for its written approval, specimens of labels, advertising, and other materials bearing the Diametrics Trademarks. Diametrics shall communicate its approval or disapproval of JJPI's use of the Diametrics Trademarks within five (5) days following receipt of such specimens. Failure of Diametrics to respond within such five (5) day period shall constitute approval of such use. Diametrics's approval of JJPI's use of the Diametrics Trademarks shall not be unreasonably withheld.

9.02 Rights Upon Insolvency. All rights and licenses to Diametrics Patents, Diametrics Trademarks and Know-How granted under this Agreement by Diametrics to JJPI are, for all purposes of Section 365(n) of Title 11 of the U.S. Code ("Title 11"), licenses of rights to intellectual property as defined in Title 11. Diametrics agrees during the term of this Agreement to create and maintain current copies or, if not amenable to copying, detailed descriptions or other appropriate embodiments, of all such Diametrics Patents, Diametrics Trademarks and Know-How. If a case is commenced by or against Diametrics under Title 11, then, unless and until this Agreement is rejected as provided in Title 11, Diametrics (in any capacity, including debtor-in-possession) and its successors and assigns (including, without limitation, a Title 11 trustee) shall either perform all of the obligations provided in this Agreement to be performed by Diametrics or provide to JJPI all such intellectual property reasonable required to make or have made, use and sell Products in the Field (including all embodiments thereof) held by Diametrics and such successors and assigns, as JJPI may elect in a written request, immediately upon such request. If a Title 11 case is commenced by or against Diametrics, this Agreement is rejected as provided in Title 11 and JJPI elects to retain its rights hereunder as provided in Title 11, then Diametrics (in any capacity, including debtor-in-possession) and its successors and assigns (including, without limitation, a Title 11 trustee) shall provide to JJPI all such intellectual property (including all embodiments thereof) held by Diametrics and such successors and assigns immediately upon JJPI's written request therefor. All rights, powers and remedies of JJPI, as a licensee hereunder, provided herein are in addition to and not in substitution for any and all other rights, powers and remedies now or hereafter existing at law or in

equity (including, without limitation, Title 11) in the event of the commencement of a Title 11 case by or against Diametrics. JJPI, in addition to the rights, powers and remedies expressly provided herein, shall be entitled to exercise all other such rights and powers and resort to all other such remedies as may now or hereafter exist at law or in equity (including Title 11) in such event.

9.03 Prosecution of Patents. Diametrics agrees to, at its expense, prosecute, or cause to be prosecuted to allowance or rejection, and reasonably maintain, in the United States and such other countries selected by mutual agreement of Diametrics and JJPI, the patents and patent applications included in the Diametrics Patents. Diametrics shall issue as a patent each such application prosecuted to allowance. Diametrics shall pay all government fees required to keep in force patents and applications therefor included in the Diametrics Patents and shall submit evidence to JJPI, upon request, that said government fees have been timely paid.

9.04 Registration of Trademarks. Diametrics shall be responsible for the registration and maintenance of all applications required to protect, in the United States and such other countries selected by mutual agreement of Diametrics and JJPI, all trademarks included in the Diametrics Trademarks. Diametrics shall pay all government fees required to keep in force trademarks and applications therefor included in the Diametrics Trademarks and shall submit evidence to JJPI, upon request, that said government fees have been timely paid. In the event that Diametrics decides not to register in a country elected by JJPI, not to pay a government fee due on, or otherwise to abandon a trademark or application therefor within the Diametrics Trademarks, Diametrics shall send JJPI written notice of said decision at least ninety (90) days in advance of the action or payment due date. JJPI shall thereupon have the option, but not the obligation, to register or pay the government fees, in which event the affected trademark or application shall be promptly assigned to JJPI.

9.05 Third-Party Infringement. In the event there is infringement by a third party of any Diametrics Patent or Diametrics Trademark and JJPI becomes aware of such infringement, JJPI shall give Diametrics written notice to that effect, including with such written notice evidence establishing a prima facie case of infringement by such third party. Diametrics shall bear all expenses of any suit brought by it based upon such infringement and shall retain all damages or other monies awarded or received in settlement of such suit. If, after the expiration of ninety (90) days from the date of such notice, Diametrics has not obtained a discontinuance of such infringement or brought suit against the third party infringer, then JJPI shall have the right, but not the obligation, to bring suit

against such infringer. Diametrics will cooperate with JJPI in any such suit for infringement brought by JJPI against a third party, and shall have the right to consult with JJPI and to participate in and be represented by independent counsel in such litigation at its own expense. JJPI shall bear all expenses of such suit, and shall retain any damages or other monies awarded or received in consequence of such litigation.

9.06 Escrow. Diametrics shall, within 60 days following execution of this Agreement, place with an escrow agent mutually acceptable to Diametrics and JJPI, a description of Diametrics's process for the manufacture of the Products in sufficiently clear and detailed terms that it can be readily followed and carried out by a trained scientist or engineer to make the Products in the manner Diametrics considers most efficient. Furthermore, should Diametrics alter, modify or change its process for manufacturing the Products, Diametrics shall amend the description in escrow to include such alteration, modification or change. The description held in escrow pursuant to this Section 9.06, shall be available to JJPI or its designee only during License Periods. JJPI shall negotiate and pay the fees of the escrow agent.

9.07 Ownership of Developments

(a) All inventions made, conceived or acquired by Diametrics, and the intellectual property related thereto, shall be the exclusive property of Diametrics. Diametrics will pay all expenses relating to the securing and maintaining of appropriate intellectual property protection with respect to such inventions.

(b) All inventions made, conceived or acquired by JJPI, and the intellectual property related thereto, will be the exclusive property of JJPI and that JJPI will pay all expenses relating to the securing and maintaining of appropriate intellectual property protection with respect to such inventions.

(c) In the event that personnel of Diametrics and JJPI jointly participate in an invention, such invention, and the intellectual property related thereto shall be owned jointly by the parties. The parties shall jointly own and share in the expenses of obtaining intellectual property protection of the invention. The parties shall agree on a single attorney to prepare and prosecute such intellectual property on behalf of both parties. For any intellectual property protection in any country that one of the parties refuses to share in such costs, that party shall assign all right, title and interest in such invention to the other party retaining only a paid up, non-exclusive license to make

(or have made), use and sell products using or incorporate
grant sublicenses (except to affiliates).

ARTICLE TEN
TERM AND TERMINATION

Diametrics
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10.01 Initial Term. The initial term of this Agreement (the "Initial Term") shall commence on the date hereof and continue until the sixth anniversary of the date hereof, unless sooner terminated as expressly provided under the terms of this Agreement.

10.02 Renewal. JJPI shall have the right to extend this Agreement for an additional two year term at the end of the Initial Term by giving Diametrics at least 60 days prior written notice of such election; provided such extension right is subject to the condition that JJPI has fulfilled its minimum purchase obligations pursuant the Section 2.8 (but not if JJPI has satisfied such obligations during the last year of the Initial Term only by paying the shortfall amount pursuant to Section 2.08(d)). JJPI's election to extend this Agreement shall be binding on Diametrics.

10.03 Termination for Breach. If either Diametrics, on the one hand, or JJPI, on the other hand, shall materially breach any covenant, agreement or obligation under this Agreement, then the other party may give notice to terminate this Agreement by giving such party notice of such breach. The party receiving such notice shall have ninety (90) days from the date of receipt thereof to cure such breach. If such breach is not cured within such ninety (90) day period, then the non-breaching party shall have the right to terminate this Agreement effective as of the end of such period. In the event such breach is cured during such period, such notice shall be of no force or effect and this Agreement shall not be terminated.

10.04 Termination for Insolvency. Either party may terminate this Agreement upon notice if the other party makes an assignment for the benefit of creditors, is the subject of proceedings in voluntary or involuntary bankruptcy instituted on behalf of or against such party, or has a receiver or trustee appointed for all or substantially all of its property; provided that in the case of an involuntary bankruptcy proceeding, such right to terminate shall only become effective if the other party consents to the involuntary bankruptcy or such proceeding is not dismissed within sixty (60)

days after the filing thereof.

10.05 Termination for Patent Infringement. JJPI may terminate this Agreement upon ninety (90) days written notice if a court of competent jurisdiction determines the manufacture, use, importation or sale of a Product infringes the patents rights of a third party.

10.06 Effect of Termination. Notwithstanding the termination of this Agreement for any reason, each party hereto shall be entitled to recover any and all damages (other than consequential damages) that such party shall have sustained by reason of the breach by the other party hereto of any of the terms of this Agreement. Termination of this Agreement for any reason shall be without prejudice to Diametrics's right to receive all payments accrued and unpaid on the effective date of termination and shall not release either party hereto from any liability which at such time has already accrued or which thereafter accrues from a breach or default prior to such expiration or termination, nor affect in any way the survival of any other right, duty or obligation of either party hereto which is expressly stated elsewhere in this Agreement to survive such termination.

10.07 Survival of Certain Provisions. The provisions of this Agreement set forth in Sections 10.06 and 8.01 and Articles Six and Eleven, and any remedies for the breach thereof, shall survive the termination of this Agreement under the terms hereof.

ARTICLE ELEVEN

MISCELLANEOUS

11.01 Arbitration a. Any dispute, claim or controversy arising from or related in any way to this agreement or the interpretation, application, breach, termination or validity thereof, including any claim of inducement of this agreement by fraud or otherwise, will be submitted for resolution to final and binding arbitration pursuant to the commercial arbitration rules then pertaining of the Center for Public Resources ("CPR"), except where those rules conflict with these provisions, in which case these provisions control. The arbitration will be held in New York City, New York.

b. The panel shall consist of three arbitrators chosen from the CPR Panels of Distinguished Neutrals each of whom is a lawyer specializing in business litigation with at least 15 years

experience with a law firm of over 25 lawyers or was a judge of a court of general jurisdiction. In the event the aggregate damages sought by the claimant are stated to be less than \$5 million, and the aggregate damages sought by the counterclaimant are stated to be less than \$5 million, and neither side seeks equitable relief, then a single arbitrator shall be chosen, having the same qualifications and experience specified above.

c. The parties agree to cooperate (1) to obtain selection of the arbitrator(s) within 30 days of initiation of the arbitration, (2) to meet with the arbitrator(s) within 30 days of selection and (3) to agree at that meeting or before upon procedures for discovery and as to the conduct of the hearing which will result in the hearing being concluded within no more than 9 months after selection of the arbitrator(s) and in the award being rendered within 60 days of the conclusion of the hearings, or of any post-hearing briefing, which briefing will be completed by both sides with 20 days after the conclusion of the hearings. In the event no such agreement is reached, the CPR will select arbitrator(s), allowing appropriate strikes for reasons of conflict or other cause and three peremptory challenges for each side. The arbitrator(s) shall set a date for the hearing, commit to the rendering of the award within 60 days of the conclusion of the evidence at the hearing, or of any post-hearing briefing (which briefing will be completed by both sides in no more than 20 days after the conclusion of the hearings), and provide for discovery according to these time limits, giving recognition to the understanding of the parties hereto that they contemplate reasonable discovery, including document demands and depositions, but that such discovery be limited so that the time limits specified herein may be met without undue difficulty. In no event will the arbitrator(s) allow either side to obtain more than a total of 40 hours of deposition testimony from all witnesses, including both fact and expert witnesses. In the event multiple hearing days are required, they will be scheduled consecutively to the greatest extent possible.

d. The arbitrator(s) shall render their award following the substantive law of New Jersey. The arbitrator(s) shall render an opinion setting forth findings of fact and conclusions of law with the reasons therefor stated. A transcript of the evidence adduced at the hearing shall be made and shall, upon request, be made available to either party.

e. To the extent possible, the arbitration hearings and award will be maintained in confidence.

f. The United States District Court for New Jersey may enter judgment upon any award. In the event the panel's award exceeds \$5 million in monetary damages or includes or consists of equitable relief, then the court shall vacate, modify or correct any award where the arbitrators' findings of fact are clearly erroneous, and/or where the arbitrators' conclusions of law are erroneous; in other words, it will undertake the same review as if it were a federal appellate court reviewing a district court's findings of fact and conclusions of law rendered after a bench trial. An award for less than \$5 million in damages and not including equitable relief may be vacated, modified or corrected only upon the grounds specified in the Federal Arbitration Act. The parties consent to the jurisdiction of the above-specified Court for the enforcement of these provisions, the entry of judgment on any award, and the vacatur, modification and correction of any award as above specified. In the event such Court lacks jurisdiction, then any court having jurisdiction of this matter may enter judgment upon any award and provide the same relief, and undertake the same review, as specified herein.

g. Each party has the right before or during the arbitration to seek and obtain from the appropriate court provisional remedies such as attachment, preliminary injunction, replevin, etc. to avoid irreparable harm, maintain the status quo, or preserve the subject matter of the arbitration.

h. EACH PARTY HERETO WAIVES ITS RIGHT TO TRIAL OF ANY ISSUE BY JURY.

i. EACH PARTY HERETO WAIVES ANY CLAIM TO PUNITIVE OR EXEMPLARY DAMAGES FROM THE OTHER.

j. EACH PARTY HERETO WAIVES ANY CLAIM OF CONSEQUENTIAL DAMAGES FROM THE OTHER EXCEPT WITH RESPECT TO ANY BREACH OF SECTION 8.01; IT BEING AGREED THAT A PARTY MUST PROVE THE EXISTANCE

**OF, AND ITS ENTITLEMENT TO, CONSEQUENTIAL DAMAGES WITH RESPECT TO
A BREACH OF SECTION 8.01 IN ACCORDANCE WITH APPLICABLE LAW.**

11.02 Publicity. Except as provided in Section 3.02, neither party hereto shall originate any publicity, news release, or other announcement, written or oral, whether to the public press, the trade, JJPI's or Diametrics's customers or otherwise, relating to this Agreement, or to performance hereunder or the existence of an arrangement between the parties without the prior written approval of the other party hereto. Diametrics shall not use the name of JJPI or any of its Affiliates for advertising or promotional purposes without the prior written consent of JJPI.

11.03 Headings. The Article and Section headings contained in this Agreement are for reference purposes only and shall not affect in any way the meaning and interpretation of this Agreement.

11.04 Notices. All notices and other communications hereunder shall be in writing. All notices hereunder of an Indemnity Claim, a Force Majeure Event, default or breach hereunder, or, if applicable, termination of the term hereof, or any other notice of any event or development material to this Agreement taken as a whole, shall be delivered personally, or sent by national overnight delivery service or postage pre-paid registered or certified U.S. mail, and shall be deemed given when delivered, if by personal delivery or overnight delivery service, or three business days after deposit in the mail, if sent by U.S. mail, and shall be addressed as follows:

If to Diametrics: Diametrics Medical Incorporated
 2658 Patton Road
 St. Paul, MN 55113
 Fax: (612) 638 1078
 Attention: Vice President, Commercial Business

with a copy to: Dorsey & Whitney LLP
 Pillsbury Center South
 220 South Sixth Street
 Minneapolis, MN 55402
 Attention: Ken Cutler, Esq.

If to JJPI: Johnson & Johnson Professional, Inc.
325 Paramount Drive
Raynham, MA 02767-0350
Attention: Vice President, New Business Development

with a copy to: Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933
Attention: Office of General Counsel

or to such other place as either party may designate by written notice to the other in accordance with the terms hereof.

11.05 Failure to Exercise. The failure of either party to enforce at any time for any period any provision hereof shall not be construed to be a waiver of such provision or of the right of such party thereafter to enforce each such provision.

11.06 Assignment. This Agreement, or any of the rights and obligations created herein, shall not be assigned or transferred, in whole or in part, by either party hereto without the prior written consent of the other party; provided, however, that either party shall have the right to assign any or all of its rights or obligations under this Agreement to any Affiliate, or a successor to that part of its business to which this Agreement relates, without such prior written consent; provided that any such assignee of Diametrics shall have all rights to the Diametrics Patents, Diametrics Trademarks and Know-How. Any attempted assignment or transfer of such rights or obligations without such consent, except as provided herein, shall be void. Subject to the foregoing sentence, this Agreement shall bind and inure to the benefit of the parties hereto and their respective successors and assigns.

11.07 Severability. In the event that any one or more of the provisions (or any part thereof) contained in this Agreement or in any other instrument referred to herein, shall, for any reason, be held to be invalid, illegal or unenforceable in any respect, then to the maximum extent permitted by law, such invalidity, illegality or unenforceability shall not affect any other provision of this Agreement or any other such instrument. Any term or provision of this Agreement which is invalid, illegal or unenforceable in any jurisdiction shall, to the extent the economic benefits conferred by this Agreement to both parties remain substantially unimpaired, not affect the validity, legality or enforceability of any of the terms or provisions of this Agreement in any other jurisdiction.

11.08 Relationship of the Parties. The relationship of JJPI and Diametrics established by

this Agreement is that of independent contractors, and nothing contained herein shall be construed to (i) give either party any right or authority to create or assume any obligation of any kind on behalf of the other or (ii) constitute the parties as partners, joint venturers, co-owners or otherwise as participants in a joint or common undertaking.

11.09 Competing Products. Diametrics recognizes and acknowledges that JJPI (and its Affiliates) has been, and will continue to be, actively involved in the design, development and marketing of instruments and accessories for the treatment of neurological, spinal and orthopedic disorders. Diametrics understands and agrees that JJPI (and its Affiliates) does or may design, develop, market, sell and distribute products which compete directly with the Product, and may continue to market, sell and distribute these and other competing products throughout the term of this Agreement. Notwithstanding the foregoing, JJPI shall not, during the term of this Agreement, design, develop or market, itself or through any Affiliates or third parties, an invasive probe for monitoring oxygen profusion (pO_2), carbon dioxide profusion (pCO_2), and/or acidity (pH) in tissue, blood or other bodily fluids in the central nervous system (i.e. the cranial cavity and spinal column) other than the Product; it being agreed by Diametrics that nothing contained in the Section 11.09 shall restrict an Affiliate of JJPI from engaging in any of such activities independently of JJPI.

11.10 Entire Agreement. It is the desire and intent of the parties to provide certainty as to their future rights and remedies against each other by defining the extent of their undertakings herein. This Agreement constitutes and sets forth the entire agreement and understanding between the parties with respect to the subject matter hereof and is intended to define the full extent of the legally enforceable undertakings of the parties hereto, and no promise, agreement or representation, written or oral, which is not set forth explicitly in this Agreement is intended by either party to be legally binding. Each party acknowledges that in deciding to enter into this Agreement and to consummate the transactions contemplated hereby it has not relied upon any statements, promises or representations, written or oral, express or implied, other than those explicitly set forth in this Agreement. This Agreement supersedes all previous understandings, agreements and representations between the parties, written or oral, with respect to the subject matter hereof.

11.11 Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

11.12 Expenses. Each party shall pay all of its own fees and expenses (including all legal, accounting and other advisory fees) incurred in connection with the negotiation and execution of this Agreement and the arrangements contemplated hereby.

11.13 Modifications and Amendments. This Agreement shall not be modified or otherwise amended except pursuant to an instrument in writing executed and delivered by each of the parties hereto.

11.14 Construction. The parties have participated jointly in the negotiation and drafting of this Agreement. In the event an ambiguity or question of intent or interpretation arises, this Agreement shall be construed as if drafted jointly by the parties and no presumption or burden of proof shall arise favoring or disfavoring any party by virtue of the authorship of any of the provisions of this Agreement.

11.15 Governing Law. This Agreement shall be governed by, and construed in accordance with, the laws of the State of New Jersey, without giving effect to the choice of laws provisions thereof.

11.16 Incorporation of Exhibits and Schedules. The Exhibits and Schedules identified in this Agreement are incorporated herein by reference and made a part hereof.

IN WITNESS WHEREOF, the parties hereto intending legally to be bound hereby, have each caused this Agreement to be duly executed as of the date first above written.

DIAMTERICS MEDICAL INCORPORATED

By: _____
Name: _____
Title: _____

JOHNSON & JOHNSON PROFESSIONAL, INC.

By: _____
Name: _____
Title: _____

SCHEDULE A

Product Specification: NEUROTREND®

1.0 OVERVIEW

The Neurotrend System is intended for continuous monitoring of intracranial pO₂, pCO₂, pH and temperature. The system consists of the following components:

- confidential*
- 1.1 Neurotrend Sensor: The sensor incorporates optical sensors for the measurement of pH, pO₂ and pCO₂, and a thermocouple for temperature measurement. It is a sterile, disposable, single-use device.
 - 1.2 Satellite Monitor: A microprocessor-based device incorporating a screen for continuous data display; keys for selecting data and printout; and a printer. The Satellite has no calibration facility. The sensor may be calibrated in the Calibrator or the Senior Monitor.
 - 1.3 Calibrator: A microprocessor based device incorporating all features and functions required to calibrate a Neurotrend Sensor.
 - 1.4 Patient Data Module (PDM): Provides the interface between the Neurotrend Sensor and the Satellite Monitor and/or Calibrator.
 - 1.5 Accessory Items: Calibration Gas Pack, Thermal Printer Paper, Dummy Load Unit, Calibrator Stand, Bed Clip for PDM Cable, AC Power Cable (US and Japan), AC Power Cable (UK), AC Power Cable (Europe)
 - 1.6 Senior Monitor: A microprocessor-based device incorporating a screen for continuous data display; keys for selecting data, calibration, or printout; a printer and a calibration chamber. The integrated system is mounted on a roll stand.

The purpose of this document is to provide a general performance description of the Neurotrend system components. A detailed Purchase Specification and Validation Protocol shall be developed separately. **All specifications are intended for internal JJPI and Diametrics use only and do not in all cases represent formal product claims.**

2.0 SPECIFICATIONS

2.1 Neurotrend Sensor

2.101 Measured Parameters:	pO ₂ , pCO ₂ , pH, temperature		
2.102 Range of Measurements:	pO ₂ :	10 to 430 mmHg	
	pCO ₂ :	10 to 160 mmHg	
	pH:	6.8 to 7.8	
	temperature:	10° to 42°C	
2.103 In vitro Accuracy:	pO ₂ :	± ±5% or ± ±3 mmHg <120 mmHg,	

confidential SCHEDULE A (continued)

	whichever is greater (95% confidence)	$\pm \pm 10\% > 120$ mmHg
	pCO ₂ :	$\pm \pm 3$ mmHg < 80 mmHg
	pH:	$\pm \pm 0.03$ pH units
	temperature:	$\pm \pm 0.3^{\circ}\text{C}$
2.104 In vitro Drift:	pO ₂ :	<0.3% / hour
(95% confidence)	pCO ₂ :	<0.3% / hour
	pH:	<.005 / hour
	temperature:	<0.005°C / hour, typical
2.105 Time to respond:	Less than 15 seconds	
2.106 90% Response Time:	Less 180 seconds at 37°C	
2.107 Outside tip diameter:	Less than 0.5 mm (average)	
2.108 Sensing Region Length:	Less than 2.5 cm	
2.109 Packaging:	Sterile product sealed within thermoform tray. Sensing elements enclosed in a sealed tonometer. Sensor equipped with protective "touch-free" sheath. Swab for cleaning PDM cable. The product must be packaged using materials that will maintain sterility and protect the device from damage due to mechanical and environmental extremes encountered during storage and transit. The product/packaging must comply with ISTA 1A/2A and any applicable European (IEC) standards.	
2.110 Labeling:	Labeling and instructions for use must be compliant with FDA and ISO/MDD Medical Device Regulations including IEC-878, EN 980 and EN1041.	
2.111 Sterilization:	Provided sterile, non-pyrogenic, via Gamma irradiation in accordance with FDA & ISO/MDD Regulations including ISO 11137, EN 552, EN 556.	
2.112 Shelf Life:	12 months from the date of sterilization	

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SCHEDULE A (continued)

- 2.113 Biocompatibility: All materials in contact with the patient must be biocompatible in accordance with FDA guidance document G95-1 and ISO-10993 (externally communicating device for <30 days).
- 2.114 Mechanical Integrity: The ability of the Sensor to withstand damage during transportation and clinical use must be satisfactory in the context of its intended application. Specific requirements for capacities such as break and leak resistance shall be defined in a separate validation protocol.
- 2.115 Storage/Shipping Temperature Range: 0°C to 40°C, do not freeze
- 2.116 Operating/Functional Temperature Range: 15°C to 40°C (patient)
- 2.117 Storage/Shipping Humidity Range: 10% to 95%R.H., non-condensing
- 2.118 Operating/Functional Humidity Range: n/a
- 2.119 Regulatory/Quality Systems: Designed and manufactured in compliance with the following Medical Device Regulations and Quality Systems: FDA GMP/QSR 21CFR part 820, ISO 9001/EN29001/EN46001, MDD 93/42/EEC
- 2.120 Duration of Intended Use 72 hours

2.2 Satellite/Senior/Calibrator/PDM

- 2.201 Power Supply: 100 VAC $\pm\pm$ 10%, 50/60 Hz
120 VAC $\pm\pm$ 10%, 50/60 Hz
230 VAC $\pm\pm$ 10 %, 50/60 Hz
- 2.202 Patient Isolation: Type CF, Class 1 (Senior & Satellite)
Class 1 (Calibrator)
- 2.203 Electrical Safety: Compliant with IEC-601-1 & UL2601

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2.204 EMC/EMI:	Compliant with EN55011, IEC 801-2/3/4/5
2.205 Protection against Moisture Ingress:	Ordinary (IPXO)
2.206 Display type:	Electroluminescent (Senior & Satellite) LCD (Calibrator)
2.207 Mode of operation:	Continuous
2.208 Data Output:	RS232C compatible
2.209 Calculated Parameters:	Bicarbonate
2.210 PDM Interchangeability:	The Patient Data Modules (PDM) must be capable of being transferred from one monitor to another (Senior or Satellite) or to the Calibrator with no adverse effect on Sensor function, accuracy and stability.
2.211 Weight:	Satellite: 6 Kg, approx Senior: 11.4 Kg, approx (55Kg complete system, approx) Calibrator: 14 Kg, approx PDM: 0.6 Kg, approx
2.212 Dimensions:	Satellite: 253 mm x 344 mm x 256 mm, approx Senior: 500mm x 300 mm x 251 mm, approx Calibrator: 340 mm x 440 mm x 180 mm, approx PDM: 140 mm x 180 mm, approx PDM Cable Length: 2.75 m, approx
2.213 Mechanical Integrity:	The ability of all hardware to withstand damage during clinical use must be satisfactory in the context of its intended application. Specific requirements for capacities such as drop and impact resistance shall be defined in a separate validation protocol.
2.214 Storage/Shipping Temperature Range:	-10°C to 40°C (Satellite & Senior) 0°C to 40°C (Calibrator)

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SCHEDULE A (continued)

2.215 Operating/Functional Temperature Range:	-10°C to 35°C
2.216 Storage/Shipping Humidity Range:	10% to 90% R.H., non-condensing
2.217 Operating/Functional Humidity Range:	10% to 90% R.H., non-condensing
2.218 Packaging:	The product must be packaged using materials that will protect the device from damage due to mechanical and environmental extremes encountered during storage and transit. The product/packaging must comply with ISTA 1A/2A and any applicable IEC standards.
2.219 Labeling:	Labeling and instructions for use must be compliant with FDA and ISO/MDD Medical Device Regulations including IEC-878, EN 980 and EN1041.
2.220 Sterilization:	The hardware components are not intended to be sterilized.
2.221 Software:	All software must be designed and maintained in accordance with ISO 9001, IEC-601-4, and any current or future FDA Guidance document.
2.222 Regulatory/ Quality Systems:	Designed and manufactured in compliance with the following Medical Device Regulations and Quality Systems: FDA GMP/QSR 21CFR part 820, ISO 9001/EN29001/EN46001, MDD 93/42/EEC
2.223 Agency Certifications	Certified to IEC-601, UL2601, CSA601, CE marked. Certification may include combined NTRL Agencies.

SCHEDULE B
Product Transfer Pricing*

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	<u>0-5,000</u>	Annual Unit Volumes:	
		<u>5,001-10,000</u>	<u>>10,000</u>
1. Neurotrend Multiparameter Sensor (MPS70048)	\$220	\$210	\$200
		Initial 12-months Per Unit Transfer Prices	
2. <u>Neurotrend Satellite System (MPS 7001), including monitor, patient data module, and thermal printer paper (2 rolls).</u>		\$7,900**	
3. <u>Calibration System with Gas Pack (XXXXXXX).</u>		\$ 6,000**	
4. <u>Patient Data Module (MDM 7002).</u>		\$ 2,200**	
5. <u>Calibration Gas Pack (3 Cylinders) (MCG 7010).</u>		\$ 300**	
6. <u>Thermal Printer Paper (2 rolls) (MPP 7005).</u>		\$ 25**	
7. <u>Dummy Load unit (25-1090).</u>		\$ 75**	
8. <u>Bed Clip for PDM Cable (25-1424)</u>		\$ 0.50	
9. <u>AC Power Cable (US and Japan) (25-1250)</u>		\$ 20.00	
10. <u>AC Power Cable (UK) (25-1251)</u>		\$ 6.00	
11. <u>AC Power Cable (Europe)(25-1252)</u>		\$ 4.75	
13. <u>Senior Monitor System</u>		\$15,200.00	

* All prices will be FOB, from point of manufacture.

** See Article 2.03b and 2.03c for price change formulas.

Sample Sensors (pursuant to Section 2.03(a)) shall be priced at the >10,000 unit price

If requested by JJPI, Diametrics shall give to JJPI, at no charge, any Product that has been rejected for quality reasons which would otherwise be scrapped, with JJPI paying the freight therefor.

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SCHEDULE C

Product Launch, Clinical, & Marketing Plan

A EUROPE

1. Projected Commercialization Dates: Assumes CE Mark received on all Products and all Products are available for sale in the intended markets:

- Cerebrovascular applications: 1Q1999
- Trauma applications: 3Q1999
- Assumes supplier qualification is completed by December 22 and audits raise no major issues.
- Assumes cranial access products (bolt, tunneler, introducer) are available as follows:
- 5/99: Introducer
Bolt with Y connector - compatible with MicroSensor
Tunneler is current Touhy Needle
- 8/99: Triple lumen bolt - compatible with MicroSensor and Camino subdural/basic sensor; optimal cranial access for trauma

2. Sales Training

- 4Q98: "Train the Trainer" Meeting - Phase 1 - Country representatives trained in order to support local training programs.
- 1/99: Training for Cerebrovascular launch at Winter Sales Conferences
- 4/99: "Train the Trainer" Meeting - Phase 2 - Country representatives trained to support Trauma launch and recap first quarter experience.
- 7/99: Training for Trauma launch at Mid-Year Sales Conferences

3. Clinical Plan

- 4Q98: Initiate Three-Five Clinical Sites - Cerebrovascular study in at least UK, France, Germany, Spain, Italy
- 3Q99: Initiate Three-Five Clinical Sites - Trauma study (potentially the same centers) in at least UK, France, Germany, Spain, Italy
- Clinical plan will drive as many as ten studies out of the European community. Overall objective same as U.S. plan.
- Product requirements would be included in the 1998 purchases outlined in Article 2.08(a) of the agreement.

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4. Marketing Support

- Promotional materials will be designed via a "franchise team" for worldwide use. Specifically, advertising and literature (promotional materials) described in the U.S. plan will be utilized as the European promotional support

5. Convention Support

- Product line will be highlighted in ~~at~~ major European meetings attended by Codman scheduled for 1999.

6. Surgeon Training

- At least one regional training courses will be held at an appropriate training facility in Europe. Course schedule and content to be determined.
- Additionally, at least one NEUROTREND Users Symposium will be scheduled in the second half of 1999.

7. Sales support

- Approximately 80 sales representatives in Europe are potentially available to sell the NEUROTREND line.

Projected Sample requirements: as required to support the product launch, clinical, and marketing plan and will be included as part of the 1998 Purchases as outlined in Article 2.08(a) of the agreement.

B. U.S.

1. Projected Commercialization Dates - U.S.: Assumes 510K approval received on all products.

- Cerebrovascular applications 1Q1999
- Trauma applications 3Q1999
- Assumes supplier qualification is completed by December 22 and audits raise no major issues.

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SCHEDULE C (continued)

- Assumes cranial access products (bolt, tunneler, introducer) are available as follows:
- 5/99 Introducer
- Bolt with Y connector - compatible with MicroSensor
- Tunneler is current Touhy needle.
- 8/99 Triple lumen bolt-compatible with Microsensor and Camino subdural/basic sensor ; optimal cranial access for trauma

2. Sales Training

- 4Q98 Initial pre-launch training for trainers.
- January 1999: Training for Cerebrovascular launch
- April 1999: Training for Trauma launch - customer evaluations to start in July

3. Clinical Plan

- 1998 - Initiate 3 sites-during 4Q
- 1999 - Initiate 14 sites
- 2000 - Initiate 8 sites
- Maximum product requirements would include the following:
 - 50 Monitors
 - 25 Calibrators
 - 1000 sensors
- Objective: Proactive clinical support will drive peer review publications and stimulate adoption of the technology by clinicians. These sites will become Centers of Reference and yield surgeon champions to support the NEUROTREND line. These centers will be managed by our Clinical Affairs Department and work will be undertaken according to an agreed upon protocol generated by the physician investigator.

4. Marketing Support - 1999

- Advertising- Production and three placements - 1999; JNS, NS, Trauma
- Literature - Point of Sale Brochure, Technical Abstract, Technique Guide, Set up Guide, Direct Mail piece

confidential SCHEDULE C (continued)

5. Convention Support

- AANS: Launch Trauma application
- Hold Trauma Panel for discussion of early clinical results at CNS, Critical Care, AACN, Applicable regional meetings

6. Sales Support

- 41 Neuro Specialists, 9 Divisions are available in the US to sell the Products.
- Evaluation Center - Hardware pool of Monitors/calibrators and Sensors to support product evaluations.
- Division Samples - non sterile sensors as appropriate
- In Serve Support - InServe specialists, as required, to assist neuro specialists in account training and maintenance.

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SCHEDULE D

Patent Portfolio for Neurotrend

<u>Title</u>	<i>Optical Transmitter and Reflector</i>	<i>Solid State Sensors</i>	<i>Optical Waveguide Sensors</i>	<i>Multi-parameter Sensor Apparatus</i>
<u>Description</u>	Mirrors embedded within optical fibre	Fluorescent chemistry	Laser-drilled optical fibres	Multi-parameter probe including biphasic (hydrophilic and hydrophobic) membrane
<u>Diametrics Reference</u>	DIAM-001	DIAM-006	DIAM-011	DIAM-020
<u>USA Expiry Date</u>	5257338 May 2012	5511547 Feb 2014	4889407 Dec 2008	5596988 Jun 2013
<u>Europe (EPC)</u>	Pending 93303579.2	Pending 95905214.3	0372802	Pending 98201837.6
Austria (EPC)	pending European	pending European	n/a	pending European
Belgium (EPC)	pending European	pending European	n/a	pending European
Switzerland (EPC)	pending European	pending European	0372802	pending European
Germany (EPC)	pending European	pending European	68920842	pending European
France (EPC)	pending European	pending European	0372802	pending European
UK (EPC)	pending European	pending European	0372802	pending European
Italy (EPC)	pending European	pending European	0372802	pending European
Netherlands (EPC)	pending European	pending European	n/a	pending European
Germany (PCT)	G9307561.8	G29580807	n/a	n/a
<u>Japan</u>	Pending 121450/93	Pending 521687/95	1970003	Pending 503377/95 and 98799/98

Other US Patents:

- 5,280,130: Assembly of a tube and a part and apparatus and method of manufacture
- 5,618,587: Vacuum rig apparatus
- 5,230,031: Barrier for a connector
- 5,246,109: Package for an active medical device
- 5,357,732: Method for assembling package for an active medical device

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EXHIBIT A
Johnson & Johnson Professional, Inc.
Quality Assurance Procedures for Product Evaluation

a. Product Development

a.01	SCP 1008	Overview of New Product Design and Introduction
a.02	SCP 1012	Device Design Verification
a.03	SCP 1013	Market Readiness Review
a.04	SCP 1014	Product Development File
a.05	SCP 1015	Authorization for Product Release
a.06	SCP 1032	Failure Modes and Effects Analysis
a.07	SOP 44015	Process Validation Procedure
a.08	SOP 44036	Qualification of Test Plans for Stability of Medical Devices
a.09	COP 055	Pilot Run Procedure

b. Assessment of Sub-Contractors

b.01	SCP 1037	Supplier Certification Programs
b.02	SCP 1042	Supplier Management Work Instruction
b.03	SCP 1046	Policy for Control of Suppliers
b.04	SCP 1053	On- Site Supplier Survey

c. Process Control

c.01	SCP 1017	Process Validation Policy
c.02	SCP 1036	Device History Record
c.03	SCP 1024	Quarterly Bioburden Audit Program
c.04	SOP 40003	Environmental Control Program
c.05	SOP 40218	Cobalt 60 Dose Mapping
c.06	PC 321	Preparation of Products for Cobalt 60 Sterilization
c.07	PC 354	Sterile Packaging Seal Integrity Validation
c.08	PC 400	Validation of Cobalt 60 Sterilization
c.09	PC 511	Cobalt 60 Dosimetry Audit
c.10	TM 022	Transportation Testing of Packaged Product
c.11	TM 064	Heat Seal Integrity Testing
c.12	TM 310	Accelerated Aging Studies

d. ISO Requirements

ISO / EN 11137 Sterilization of healthcare products
Requirements for validation and routine control

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Radiation Sterilization

ISO/ EN 11135 Medical Devices Validation and Routine Control
of Ethylene Oxide Sterilization
with Additional Johnson & Johnson Requirements

Reference ISO / EN 11607 Packaging for Terminally Sterilized Devices
ASTM D-4169 Standard Practice for Performance Testing
of Shipping Containers
National Safe Transit Association Projects 1,2,3
Pre Shipment Testing Packaged Products

Source: JJPI Reference Procedure Manual (SOP 44015)

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EXHIBIT B
Product and Supplier Qualification Activities

All activities to be initiated upon execution of the Agreement.

Part I: Duration: 13 Weeks

- Prepare JJPI specifications/drawings.
- Complete formal supplier audit of Diametrics. Audit shall include detailed reviews of the following (bold items are primary focus):
 - a. Quality Systems/Plan compliance per FDA GMP/QSR Part 820 and ISO 9001/EN46001
 - b. Product requirements document.
 - c. Design history files
 - d. Design verification & validation protocols & reports
 - e. Process verification & validation protocols & reports
 - f. Packaging verification & validations protocols & reports.
 - g. Sterilization verification & validation protocols & reports
 - h. Shelf life and expiration dating validation.
 - i. Design FMEA
 - j. Process FMEA
 - k. Material traceability systems
 - l. Material, in-process and final inspection plans
 - m. Customer complaints
 - n. Safety Agency Certifications and Reports
 - o. Engineering Change Control System
 - p. Calibration System
- Revise labeling
- Complete Product validation
- Initiate Product Development File (PDF)
- Complete Patent Infringement Search
- Complete Trademark Search

Part II: Duration: 7 weeks

- Complete initial inventory build
- Complete PDF File

Part III: To be completed by December 1998.

- Complete Sales and Marketing promotional materials
- Minimum for launch: Point of Sale Brochure, Training Manuals, Technical Abstract, Technique Guide, Set-Up Guide