

THE INFORMATION IN THIS BOX IS NOT A PART OF THE CONTRACT AND IS FOR COUNTY USE ONLY



Contract Number

21-740

SAP Number

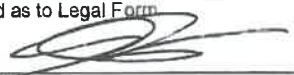
Arrowhead Regional Medical Center

Department Contract Representative	William L. Gilbert
Telephone Number	(909) 580-6150
Contractor	Medtronic USA, Inc.
Contractor Representative	Kathryn Blanchetie
Telephone Number	909-580-2492
Contract Term	
Original Contract Amount	\$912,697
Amendment Amount	
Total Contract Amount	\$912,697
Cost Center	7421

Briefly describe the general nature of the contract: Agreement with Medtronic USA, Inc., for the purchase of the O-arm Surgical Imaging System, for minimally invasive surgical procedures, in the amount of \$912,697.

FOR COUNTY USE ONLY

Approved as to Legal Form


Charles Phan, Deputy County Counsel

Date 9/23/2021

Reviewed for Contract Compliance


Date

Date

Reviewed/Approved by Department


William L. Gilbert, Director

Date

9/28/21



Medtronic USA, Inc
826 Coal Creek Circle
Louisville, CO 80027
www.medtronic.com

EXECUTIVE SUMMARY

PREPARED FOR:

San Bernardino County on behalf of Arrowhead Regional Medical Center, Colton, CA

Quotation Number: 160749-0001106317-6-6

September 13, 2021

All Prices in \$USD

Item Number	Item Description	QTY	Ext. List Price	Ext. Net Price
BI70002000	O-ARM O2 BASE UNIT	1	\$ 656,000.00	\$ 467,320.00
BI75000027	CONFIG BI75000027 O2 SYSTEM NAVIGATION INTERFACE	1	\$ 39,655.00	\$ 28,551.60
BI75000024	KIT BI75000024 MVS PRINTER OPTION	1	\$ 9,064.00	\$ 6,526.08
BI75000034	CONFIG BI75000034 O2 MULTIPLE FIELD OF VIEW	1	\$ 39,655.00	\$ 28,551.60
BI75000030	CONFIG BI75000030 O2 ADVANCED VIEWING	1	\$ 22,660.00	\$ 16,315.20
BI75000031	CONFIG BI75000031 O2 ISO-WAG™ ROTATION	1	\$ 14,729.00	\$ 10,604.88
BI75000032	CONFIG BI75000032 O2 COLLIMATED AXIAL 3D	1	\$ 16,995.00	\$ 12,236.40
BI75000033	CONFIG BI75000033 O2 ENHANCED CRANIAL 3D – EC3D	1	\$ 28,325.00	\$ 20,394.00
BI75000029	CONFIG BI75000029 O2 HIGH DEFINITION 3D – HD3D	1	\$ 28,325.00	\$ 20,394.00
BI75000045	CONFIG BI75000045 O2 2D LONG FILM	1	\$ 39,655.00	\$ 28,551.60
EK800N	KIT MIDAS MR8 ELEC MOTOR STEALTH- MIDAS	1	\$ 27,449.00	\$ 19,763.28
MR8-AVA10	ATT MR8 10CM VARIABLE ANGLE 2.4MM	1	\$ 4,990.00	\$ 3,584.16
MR8-AVS10	ATT MR8 10CM VARIABLE STRAIGHT 2.4MM	1	\$ 3,215.00	\$ 2,309.04
MR8-AVA14	ATT MR8 14CM VARIABLE ANGLE 3.2MM	1	\$ 4,990.00	\$ 3,584.16
MR8-AVS14	ATT MR8 14CM VARIABLE STRAIGHT 3.2MM	1	\$ 3,215.00	\$ 2,309.04
MR8-AVA15	ATT MR8 15CM VARIABLE ANGLE 2.4MM	1	\$ 4,990.00	\$ 3,584.16
MR8-AVS15	ATT MR8 15CM VARIABLE STRAIGHT 2.4MM	1	\$ 3,215.00	\$ 2,309.04
MR8-ASMC09	ATT MR8 9CM METAL CUTTER 3.2MM	1	\$ 2,480.00	\$ 1,781.28
9735500	Basic Spine Referencing	1	\$ 14,420.00	\$ 10,382.40
9735502	UPGRADE SET 9735502 PERC PIN	1	\$ 9,500.00	\$ 6,861.60
9734723K	Clamp, Double Standard	1	\$ 3,605.00	\$ 2,595.60
9734724K	Clamp, Double Short	1	\$ 3,605.00	\$ 2,595.60
9735501	Revision Referencing Tray	1	\$ 7,210.00	\$ 5,191.20
9735522	Revision Referencing Tray Upgrade	1	\$ 6,180.00	\$ 4,449.60
9735465	CD HORIZON® SOLERA® Awl-Tip Taps	1	\$ 12,360.00	\$ 8,899.20
9734492	SOLERA DEFORMITY TAPS UPGRADE	1	\$ 6,000.00	\$ 4,320.00
9735283	SOLERA 5.5/6.0 DRIVERS	1	\$ 10,815.00	\$ 7,786.80

Prices and Terms Valid until November 01, 2021

Requested By: Kathryn Blanchette, BSN, Area Sales Manager (951) 775-5651

Prepared By: Mikala Brees, Principal Sales Administrator (720) 890-3251

Fax No: 720-890-3699

Quote #: 160749-0001106317-6-6

CONFIDENTIAL

All Prices in \$USD

Item Number	Item Description	QTY	Ext. List Price	Ext. Net Price
9734494	INST SET 9734494 TACTILE PROBES	1	\$ 20,155.00	\$ 14,511.60
9735173	INST KIT 9735173 2.25MM PED PROBE	1	\$ 6,165.00	\$ 4,438.80
9734507	STEALTHSTATION® UNIVERSAL DRILL GUIDE	1	\$ 7,317.00	\$ 5,268.24
NAV2001K	TAP NAV2001 SOLERA AWLTIPTAP 4.0 MM	1	\$ 1,545.00	\$ 1,112.40
NAV2003K	TAP NAV2003 SOLERA AWLTIPTAP 5MM	1	\$ 1,545.00	\$ 1,112.40
9735607	Vertex Select Instrument Set	1	\$ 11,742.00	\$ 8,454.24
9735032	POWEREASE™ ADAPTER	1	\$ 3,090.00	\$ 2,224.80
KINEVOS8 UPGRADE	KINEVO KIT W/ S8 UPGRADE HARDWARE	1	\$ 52,000.00	\$ 37,440.00
961-574	INSTRUMENT SET - SURETRAK II PASSIVE	1	\$ 8,112.00	\$ 5,840.64
EK001	NT INTEGRATED POWER CONSOLE KIT	1	\$ 28,632.00	\$ 20,615.04
Line Item Sub Total			\$ 1,163,605.00	\$ 832,769.68
Grand Total				\$ 832,769.68

Prices and Terms Valid until November 01, 2021

Requested By: Kathryn Blanchette, BSN, Area Sales Manager (951) 775-5651
 Prepared By: Mikala Brees, Principal Sales Administrator (720) 890-3251

Fax No: 720-890-3699
 Quote #: 160749-0001106317-6-6
CONFIDENTIAL



Medtronic, Inc
826 Coal Creek Circle
Louisville, CO 80027 USA
www.medtronic.com
tel: 888.580.8860

PREPARED FOR:

San Bernardino County on behalf of Arrowhead Regional Medical Center, Colton, CA

Quotation Number: 160749-0001106317-6-6

September 13, 2021

All Prices in \$USD

Item Number	Item Description	QTY	Ext. List Price	Ext. Net Price
BI70002000	O-ARM O2 BASE UNIT	1	\$ 656,000.00	\$ 467,320.00
	• Complete Multidimensional Surgical Imaging System • 3D, multi-plane Fluoro imaging capability • Lateral patient access without compromising mobility • Faster imaging, reduced dose with automated real-time, and pre-set positioning • 2K x 1.5K digital flat detector enables higher dynamic range and resolution • Automated multi-plane imaging eliminates manual repositioning or need for a second system (bi-planar Fluoro) • System includes the O-arm Imaging Stand, Mobile View Station (MVS) • DICOM 3.0 Compliant. The system supports sending locally created images across the network to another system. It also supports saving images to CD • Includes VGA • Includes new 12: 1 X-Ray Grid - Achieves improvement in contrast with higher grid ratio and carbon cover • High Definition 3D - HD3D enabled			
BI75000027	CONFIG BI75000027 O2 SYSTEM NAVIGATION INTERFACE	1	\$ 39,655.00	\$ 28,551.60
	• Unique iso-centric rotation relative to the lateral image in fluoroscopy mode. • Rotation around the vertical axis while keeping the anatomy of interest in the imaging field.			
BI75000024	KIT BI75000024 MVS PRINTER OPTION	1	\$ 9,064.00	\$ 6,526.08
BI75000034	CONFIG BI75000034 O2 MULTIPLE FIELD OF VIEW	1	\$ 39,655.00	\$ 28,551.60
BI75000030	CONFIG BI75000030 O2 ADVANCED VIEWING	1	\$ 22,660.00	\$ 16,315.20
BI75000031	CONFIG BI75000031 O2 ISO-WAG™ ROTATION	1	\$ 14,729.00	\$ 10,604.88
BI75000032	CONFIG BI75000032 O2 COLLIMATED AXIAL 3D	1	\$ 16,995.00	\$ 12,236.40
BI75000033	CONFIG BI75000033 O2 ENHANCED CRANIAL 3D – EC3D	1	\$ 28,325.00	\$ 20,394.00
BI75000029	CONFIG BI75000029 O2 HIGH DEFINITION 3D – HD3D	1	\$ 28,325.00	\$ 20,394.00
BI75000045	CONFIG BI75000045 O2 2D LONG FILM	1	\$ 39,655.00	\$ 28,551.60
EK800N	KIT MIDAS MR8 ELEC MOTOR STEALTH-MIDAS	1	\$ 27,449.00	\$ 19,763.28

Requested By: Kathryn Blanchette, BSN, Area Sales Manager (951) 775-5651
Prepared By: Mikala Brees, Principal Sales Administrator (720) 890-3251

Fax No: 720-890-3699
Quote #: 160749-0001106317-6-6
CONFIDENTIAL

All Prices in \$USD

Item Number	Item Description	QTY	Ext. List Price	Ext. Net Price
MR8-AVA10	ATT MR8 10CM VARIABLE ANGLE 2.4MM	1	\$ 4,990.00	\$ 3,584.16
MR8-AVS10	ATT MR8 10CM VARIABLE STRAIGHT 2.4MM	1	\$ 3,215.00	\$ 2,309.04
MR8-AVA14	ATT MR8 14CM VARIABLE ANGLE 3.2MM	1	\$ 4,990.00	\$ 3,584.16
MR8-AVS14	ATT MR8 14CM VARIABLE STRAIGHT 3.2MM	1	\$ 3,215.00	\$ 2,309.04
MR8-AVA15	ATT MR8 15CM VARIABLE ANGLE 2.4MM	1	\$ 4,990.00	\$ 3,584.16
MR8-AVS15	ATT MR8 15CM VARIABLE STRAIGHT 2.4MM	1	\$ 3,215.00	\$ 2,309.04
MR8-ASMC09	ATT MR8 9CM METAL CUTTER 3.2MM	1	\$ 2,480.00	\$ 1,781.28
9735500	Basic Spine Referencing	1	\$ 14,420.00	\$ 10,382.40

Includes:

- FRAME, SPINE AIR
- CLAMP, SINGLE STANDARD
- CLAMP, SINGLE SHORT
- REFERENCE ELBOW, TITANIUM
- INST 960-559 PLANAR PASSIVE BALL 1.5MM
- DILATOR 9733817 NAVIGATED
- TRACKER 9733816 DILATOR
- DRIVER, T HANDLE
- Spine Referencing Tray
- TOOLS CD

9735502	UPGRADE SET 9735502 PERC PIN	1	\$ 9,500.00	\$ 6,861.60
9734723K	Clamp, Double Standard	1	\$ 3,605.00	\$ 2,595.60
9734724K	Clamp, Double Short	1	\$ 3,605.00	\$ 2,595.60
9735501	Revision Referencing Tray	1	\$ 7,210.00	\$ 5,191.20

Includes:

- REFERENCE, ROD 4.75
- REFERENCE, ROD 5.5/6.0
- REFERENCE, ROD 6.35
- ROD CLAMP, LONG
- Spine Referencing Revision Tray
- DRIVER, T HANDLE

9735522	Revision Referencing Tray Upgrade	1	\$ 6,180.00	\$ 4,449.60
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Includes:

- ROD, CLAMP, SHORT
- REFERENCE ELBOW, TITANIUM
- Spine Air Frame
- TOOLS CD

9735465	CD HORIZON® SOLERA® Awl-Tip Taps	1	\$ 12,360.00	\$ 8,899.20
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Setup Includes:

- Awl-Tip Tap 4.5 mm
- Awl-Tip Tap 5.5 mm
- Awl-Tip Tap 6.5 mm
- Awl-Tip Tap 7.5 mm
- Small Tissue Protector

All Prices in \$USD

Item Number	Item Description	QTY	Ext. List Price	Ext. Net Price
	• Large Tissue Protector • Percutaneous Tray • Taps Module			
9734492	SOLERA DEFORMITY TAPS UPGRADE	1	\$ 6,000.00	\$ 4,320.00
9735283	SOLERA 5.5/6.0 DRIVERS	1	\$ 10,815.00	\$ 7,786.80
	Kit Includes:			
	• Driver, 5.5/6.0 MAS Driver Cannulated • Driver, 5.5/6.0 FAS/SAS Driver Cannulated • Driver, 5.5/6.0 MAS Driver Non Cannulated • Driver, 5.5/6.0 RMAS Driver Non Cannulated			
9734494	INST SET 9734494 TACTILE PROBES	1	\$ 20,155.00	\$ 14,511.60
9735173	INST KIT 9735173 2.25MM PED PROBE	1	\$ 6,165.00	\$ 4,438.80
9734507	STEALTHSTATION® UNIVERSAL DRILL GUIDE	1	\$ 7,317.00	\$ 5,268.24
NAV2001K	TAP NAV2001 SOLERA AWLTIPTAP 4.0 MM	1	\$ 1,545.00	\$ 1,112.40
NAV2003K	TAP NAV2003 SOLERA AWLTIPTAP 5MM	1	\$ 1,545.00	\$ 1,112.40
9735607	Vertex Select Instrument Set	1	\$ 11,742.00	\$ 8,454.24
	Set Includes:			
	• 3.0 mm Tap • 3.5 mm Tap • 4.0 mm Tap • 4.5 mm Tap • VERTEX Driver(NAV2081) • Egg Handle • Vertex Tray • Tray Lid			
9735032	POWEREASE™ ADAPTER	1	\$ 3,090.00	\$ 2,224.80
	• Enable hands-free use of POWEREASE™ compatible navigated instruments • Used in conjunction with the Medtronic Spine and Biologics POWEREASE™ Surgical Instruments • The adapter prevents the NavLock™ Tracker component from freely rotating within the powered instrument • Includes (50) O-rings			
KINEVOS8 UPGRADE	KINEVO KIT W/ S8 UPGRADE HARDWARE	1	\$ 52,000.00	\$ 37,440.00
	Includes:			
	• Enables Stealth Integration with Zeiss Kinevo Microscope • Injects StealthStation™ images through microscope oculars while maintaining visualization of the patient's anatomy • Navigate the microscope's focal point like a virtual probe Includes navigation bracket, interface cables and calibration software • StealthStation panel components to enable integration with Zeiss Kinevo microscope			
961-574	INSTRUMENT SET - SURETRAK II PASSIVE	1	\$ 8,112.00	\$ 5,840.64

Requested By: Kathryn Blanchette, BSN, Area Sales Manager (951) 775-5651
Prepared By: Mikala Brees, Principal Sales Administrator (720) 890-3251

Fax No: 720-890-3699
Quote #: 160749-0001106317-6-6

All Prices in \$USD

Item Number	Item Description	QTY	Ext. List Price	Ext. Net Price
	• Powerful SureTrak II Software for Universal Instrument Calibration • Enables Image Guidance of a Wide Variety of Surgical Instruments • (3) Passive, Wireless Trackers • (3) Ergonomic Clamp Sizes (S,M,L) • Autoclavable Sterilization Tray for Safe and Efficient Storage			
EK001	NT INTEGRATED POWER CONSOLE KIT	1	\$ 28,632.00	\$ 20,615.04

Requested By: Kathryn Blanchette, BSN, Area Sales Manager (951) 775-5651
Prepared By: Mikala Brees, Principal Sales Administrator (720) 890-3251

Fax No: 720-890-3699
Quote #: 160749-0001106317-6-6



Medtronic USA, Inc
826 Coal Creek Circle
Louisville, CO 80027
www.medtronic.com
tel: 888.580.8860

SALES AND SUPPORT PROPOSAL

Purchase Orders and Signed Proposals can be faxed to: 720-890-3699

This is a Sales & Support Proposal ("Proposal") by and between Medtronic USA, Inc. for its ENT Products and Navigation Products (collectively, "MEDTRONIC") located at 826 Coal Creek Circle, Louisville, Colorado 80027 and San Bernardino County on behalf of Arrowhead Regional Medical Center ("CUSTOMER"), located in Colton CA. The date of the proposal is the date on the first page of this Proposal ("Proposal Date").

Thank you for requesting this Proposal for the O-arm® System ("Product"). MEDTRONIC looks forward to partnering with you and the staff at San Bernardino County on behalf of Arrowhead Regional Medical Center to provide for your image guidance needs.

The pricing contained in this proposal is valid until 11/01/2021

I. OFFER AND ACCEPTANCE

This Proposal is an offer by MEDTRONIC to sell the Product described above to the CUSTOMER on the terms of this Proposal and the Medtronic Master Terms and Conditions, attached hereto as Attachment A, which are incorporated into this Proposal by reference in their entirety. CUSTOMER accepts this Proposal and places an order for the Product described herein by signing the Proposal at the signature block by an individual authorized to bind the CUSTOMER and returning the Proposal with an appropriate Purchase Order to MEDTRONIC. Upon receipt by MEDTRONIC of the appropriately signed Proposal and Purchase Order, an authorized representative of MEDTRONIC will sign the Proposal on behalf of MEDTRONIC whereupon the Proposal will become a binding Agreement between the parties ("Agreement").

II. PAYMENT TERMS

- Payment to MEDTRONIC by Buyer on invoices from MEDTRONIC under this agreement shall be due within 60 days of the date of the invoice.
- FOB Destination.

III. INSTALLATION AND IN-SERVICE

The price of the Product includes: installation, complete on-site Product testing and run through.

All site modifications and preparations are the CUSTOMER's responsibility and are to be completed to the specifications given by MEDTRONIC, prior to the date of the installation.

MEDTRONIC is committed to providing CUSTOMER with ongoing technical service and software support on the Product for the Term of this agreement. Details of MEDTRONIC's Customer Support Program are set out in the accompanying Terms and Conditions. However, highlights of this Program are: Software support and maintenance, 24-hour telephone technical assistance, and Software enhancement upgrades to currently owned software packages. The cost of parts associated with the repair of equipment that is out of stated warranty period will be billed to the CUSTOMER.

IV. TRAINING

O-arm® System - MEDTRONIC is committed to providing the necessary training to ensure your staff is capable of operating the O-ARM® System autonomously. All OR Staff, Surgeons, Radiologic Technologists, etc. who will be utilizing the O-ARM® System must be trained by an authorized MEDTRONIC representative. Upon installation of the O-ARM® System, a MEDTRONIC representative will schedule training for up to five (5) business days at a mutually agreed upon date and time at the hospital site. MEDTRONIC may, at its discretion, provide additional on-site training it deems necessary during the warranty period at its expense.

V. SURGERY SUPPORT

Upon request by the CUSTOMER, MEDTRONIC will provide up to six (6) surgical support visits during the warranty period. MEDTRONIC may, at its discretion and depending on the CUSTOMER circumstance (new hospital staff, new surgical procedure introduced, new accessories or equipment), provide additional surgical support at no charge. The CUSTOMER has the option at any time to purchase through MEDTRONIC guaranteed surgical coverage.

VI. LIMITED WARRANTY

The Product shall be subject to the MEDTRONIC Standard Limited Warranty, applicable to this Product as contained in the Terms and Conditions, for the Term of the agreement. MEDTRONIC SPECIFICALLY DISCLAIMS ALL OTHER WARRANTIES, INCLUDING, WITHOUT LIMITATION, THOSE OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

VII. SOFTWARE LICENSE

MEDTRONIC hereby grants to CUSTOMER, and CUSTOMER hereby accepts, a non-transferable, non-exclusive license ("License") to use Licensed Materials in perpetuity if and for so long as CUSTOMER agrees to and abides by the terms and conditions of this Agreement. CUSTOMER may not copy, modify or transfer the Licensed Materials, in whole or in part, except as provided by MEDTRONIC. CUSTOMER may only use the Licensed Materials in connection with the proper usage and operation of the Products.

VIII. TERM OF AGREEMENT

This agreement shall become effective on the date of the last signature in the signature block below ("Execution Date") and shall have a term of one (1) calendar year from the Acceptance Date of the Product ("Term").

IX. CONFIDENTIALITY

Unless otherwise required by law,, all portions of this Proposal are to be considered confidential and are not to be shared with anyone other than an employee or authorized agent of MEDTRONIC, or personnel of CUSTOMER or their representative, unless approved by MEDTRONIC.

X. DELIVERY AND TRANSFER OF OWNERSHIP

Transfer of ownership from MEDTRONIC to CUSTOMER of the Product shall take place immediately upon delivery. The warranty period will commence seven (7) business days following the delivery date, unless otherwise specified in the additional terms section. Installation and training will be scheduled at a mutually agreed upon date.

XI. ADDITIONAL TERMS

- All prices are quoted in US Dollars.
- Please make the Purchase Order (PO) out to Medtronic USA, Inc. (TAX ID# 41-1493213) and reference quotation number on the purchase order. Please return this page signed with the purchase order.
- Shipping, handling and installation included in quoted price and will not be added to Customer's invoice. Valued at \$5,000.00.

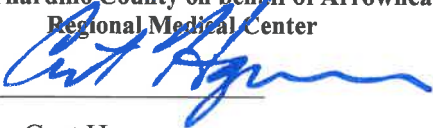
XII. COMPLETE AGREEMENT

When executed as prescribed herein, this Sales and Support Proposal constitutes a legally binding agreement between the parties. It is the entire agreement between the parties with respect to the subject matter hereof and supersedes all previous proposals, negotiations, representations or commitments between the parties, both written and oral. The terms of this Sales and Support Proposal may be amended only by a writing signed by both parties hereto and shall prevail in the event that there is a conflict or variance with the terms and conditions of any purchase order form or other document submitted by CUSTOMER or with any invoice or other document submitted by MEDTRONIC. This Agreement may be executed in any number of counterparts, each of which so executed shall be deemed to be an original, and such counterparts shall together constitute one and the same Agreement. The parties shall be entitled to sign and transmit an electronic signature of this Agreement (whether by facsimile, PDF or other email transmission), which signature shall be binding on the party whose name is contained therein. Each party providing an electronic signature agrees to promptly execute and deliver to the other party an original signed Agreement upon request.

ACCEPTANCE

This agreement sets forth the entire understanding between the parties and supersedes any prior or oral agreements with respect to the matters covered by this agreement. An authorized representative of San Bernardino County on behalf of Arrowhead Regional Medical Center and MEDTRONIC have signed and executed the agreement below.

**San Bernardino County on behalf of Arrowhead
Regional Medical Center**

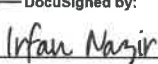
Signature: 

Print Name: Curt Hagman

Title: Chairman, Board of Supervisors

Date: OCT 05 2021

**Medtronic USA, Inc. for its ENT Products
and Navigation Products**

Signature: 

Print Name: Irfan Nazir

Title: Director Sales Ops

Date: 9/13/2021

SIGNED AND CERTIFIED THAT A COPY OF
THIS DOCUMENT HAS BEEN DELIVERED
TO THE CHAIRMAN OF THE BOARD
LYNNA MONELL
Clerk of the Board of Supervisors
of the County of San Bernardino

By 
Deputy

Attachment A

Medtronic

Master Terms and Conditions

1 DEFINITIONS:

- a. **"Medtronic"** means Medtronic USA, Inc. for its ENT Products and Navigation Products (collectively, "Medtronic") or its authorized representatives.
- b. **"Customer"** means the person or company named in the invoice, statement or credit application form and in the case of an individual, his executors, and/ or administrators and assignees and in the case of a company, its successors and/or assignees
- c. **"Component"** identifies accessory devices such as, but not limited to, AxiEM®, microscope interface hardware, wireless trackers (such as O-arm® or C-Arm trackers). Components are additional hardware pieces that are typically connected to the System. Components are typically purchased *in addition to* the overall System.
- d. **"Corrective Maintenance"** means repairs done to return Products to good working order.
- e. **"Documentation"** means the installation instructions and user manuals supplied to Customer pertaining to the operation of the System.
- f. **"Instrument"** means a tool, implement or device with a particular purpose that is used with, but is not part of, a System.
- g. **"Licensed Material"** means any Software placed on or provided with Products by Medtronic at the time of System acquisition or at any other time, including any accompanying documentation related thereto.
- h. **"Location"** means the site where the Products were originally installed or where they were relocated with the prior approval of Medtronic, and which is identified in this Agreement.
- i. **"Medtronic Technical Services"** means Medtronic's customer support department. Medtronic Technical Services can be reached by either phone or email at (800) 595-9709 or dl.navtechnicalservices@medtronic.com
- j. **"Normal Coverage Hours"** means Monday through Friday from 7:00 a.m. to 4:00 p.m. local time, excluding holidays observed by Medtronic. Services performed outside Normal Coverage Hours are considered Optional Services during which Services will be provided onsite.
- k. **"Notice"** means providing written notice that includes facts sufficient to describe the issue to the other party by certified mail or standard overnight delivery service at the address identified in the Sales and Support Proposal to which this Agreement applies.
- l. **"Optional Services"** means services performed or provided by Medtronic that are outside the scope of this Agreement, including but not limited to services performed outside the Normal Coverage Hours, relocation of Products, surgical support visits by Medtronic clinical specialists, additional Planned Maintenance, inspections or Corrective Maintenance (as hereinafter defined) required due to unauthorized relocation, modification or for other exclusions, which will be billed separately at the then-current Medtronic standard time and materials billing rates.
- m. **"Planned Maintenance"** means a pre-scheduled maintenance of the System performed by Medtronic which may include one or all of the following, as determined by Medtronic: a performance evaluation of all covered Products, System inspection, cleaning, lubrication, adjustments, and/or other Corrective Maintenance of a non-emergency nature.
- n. **"Product"** means goods and/ or services sold by Medtronic to Customer.
- o. **"Remote Support"** means a digital service that allows MEDTRONIC to provide features such as; remote diagnostics, predictive part failure reporting, remote troubleshooting support, and remote software install. Remote Support requires an active, secured Internet connection between the Covered Product and MEDTRONIC for connectivity. Upon execution of this Agreement Medtronic will enable Remote Support. Remote Support is not available on all systems and features may vary by product.
- p. **"Sales and Support Proposal"** means a proposal from Medtronic to sell the Product or Products to the Customer on the terms of this Proposal and the Master Terms and Conditions which are incorporated into the Sales and Support Proposal by reference in their entirety. Upon acceptance, the Sales and Support Proposal constitutes a legal binding Agreement between Medtronic and Customer.
- q. **"Service and Support Agreement"** or **"SSA"** means the provision of services related to the Product by Medtronic to Customer pursuant to the terms of a separate written agreement signed by both parties.
- r. **"Services"** means the services provided during the warranty or SSA term, and more specifically set forth in any supplemental terms and conditions in the exhibits, if applicable.
- s. **"Single Use Items," "Disposables" or "Consumables"** means any item this is depleted after use or that is designed to be disposed of after use rather than refilled or repaired. Fiducial markers, passive spheres, receiver coils are considered Single Use Items.
- t. **"Software"** means the operating system, software applications, features, and modules that reside on the System

Medtronic

Terms and Conditions

- u. **"Software Application"** means a separate software program that integrates with, but is not part of, the operating system. Software Applications are designed to perform specific functions that enable the Customer to perform specific procedures.
 - v. **"Software Feature"** means modifications to or development of software that may include new features, modules or products which enable the software to perform new or different functions or increases the capacity or capability of the software and are NOT designated by Medtronic as either a Software Application or a Software Upgrade.
 - w. **"Software Upgrade"** means modifications that may include internal changes designed to refine or otherwise provide minor improvements to the Software without changing its basic design, structure or functionality and are NOT designated by Medtronic as either a Software Feature or a Software Application
 - x. **"System"** means the capital equipment, hardware or platform on which Software resides.
- 2 **PRICES.** All prices will be those ruling at the date of delivery and unless otherwise expressly indicated such prices will include freight charges.
- 3 **VALIDITY OF QUOTATION** Unless otherwise stated, quotations are open for acceptance for thirty (30) days from date of quotation, and thereafter, are subject to confirmation before acceptance.
- 4 **USE OF COMPANY NAME** Neither party will use the name of the other party or the other party's logo in advertising, stationery, business cards or literature without the prior written approval of the other party.
- 5 **PAYMENT TERMS.** Fees for the Products identified in this Agreement are payable net sixty (60) days after the invoice date.
- a. Fees are billed and payable in US Dollars.
 - b. Notwithstanding the foregoing, fees for Optional Services will be billed at the current standard rate for time and materials for a minimum of four (4) hours to include travel time, which will be payable net sixty (60) days after the invoice date.
 - c. Prices in the Agreement and/or invoices do not include sales, use or other similar applicable taxes, which Customer will pay unless a tax exemption certificate is provided to Medtronic.
 - d. The initial payment for Services or Optional Services will be accompanied by a purchase order or equivalent Customer purchase record.
- 6 **INSTALLATION AND TRAINING.**
- a. Installation and initial on-site testing provided under this Agreement are defined in the Sales and Support Proposal.
 - b. Product Training provided under this Agreement is defined in the Sales and Support Proposal
 - c. All site modifications and preparations are Customer's responsibility and are to be completed in accordance with the specifications given by Medtronic prior to the date of the installation.
- 7 **LIMITED PRODUCT WARRANTY**
- a. **COVERAGE**
 - i. Medtronic warrants that the System will be free from defects in materials or workmanship for 1 year (365 days). The warranty period will commence seven (7) business days following the delivery date. Should the System fail to function within Medtronic's published specifications due to a defect in materials or workmanship within the LIMITED PRODUCT WARRANTY period, Medtronic will at its option:
 - 1. repair or replace any part or parts of the System; or
 - 2. issue a credit to the original purchaser equal to the purchase price, against the purchase of the replacement System; or
 - 3. provide a functionally comparable replacement System at no charge; or
 - 4. As used herein, purchase price shall mean the lesser of the net invoiced price of the original (adjusted to reflect the age of the System), or current functionally comparable, or replacement System.
 - ii. When the System or any part thereof is replaced, any replacement System or replacement part becomes property of the Customer and the replaced System or replacement part becomes the property of Medtronic. When a credit is issued to the Customer, the respective Product becomes the property of Medtronic
 - iii. The warranty on replacement parts expires with the expiration of the original LIMITED PRODUCT WARRANTY
 - iv. This LIMITED PRODUCT WARRANTY is extended only to the Customer that purchased the System directly from Medtronic.

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- v. The warranty period for any related Instruments, Components, or Single Use Items purchased, if applicable, is ninety (90) days from the date the Instrument, Component or Single Use Item is delivered to Customer.
- vi. StealthStation® Electromagnetic Technology (EM): Medtronic warrants that the EM box, emitter, and cables will be free from defects in materials or workmanship for 1 year (365 days). The warranty period will commence seven (7) business days following the delivery date. Negligent abuse of EM cables and emitter are not covered under this agreement. Applies to StealthStation® systems only.
- b. **SERVICES.** Unless otherwise specified in the exhibits, Medtronic will provide Customer the following Services on the System at the Location during the LIMITED PRODUCT WARRANTY period in accordance with the terms and conditions herein:
 - i. **Planned Maintenance:** At a mutually agreed upon time during Normal Coverage Hours, Medtronic will provide one (1) planned maintenance visit per year during the LIMITED PRODUCT WARRANTY period which will include a performance evaluation of the System, System inspection, cleaning and lubrication, adjustments, and other remedial maintenance of a non-emergency nature.
 - ii. **Remote Support:**
 - a. **Remote Connectivity:** In order to utilize remote connectivity, Customer is required to connect the Covered Product to its internet in order to activate the remote support features. The connection needs to remain actively available in order to support the Covered Product.
 - b. **Remote Support:** MEDTRONIC may troubleshoot reported problems using Remote Support. MEDTRONIC will provide Remote Support on Covered Product.
 - iii. Medtronic shall provide telephone support 24/7/365 through Medtronic Technical Services by calling (800)595-9709.
- c. **EXCLUSIONS.** Upon Customer's request, any service, support or maintenance for exclusions may be performed at the discretion of Medtronic as Optional Services. The following items shall be considered exclusions and are not included as or part of the Services under this Agreement:
 - i. Providing any service or replacement part specifically excluded under this Agreement, including its exhibits;
 - ii. Software is delivered "as is" and is excluded from the LIMITED PRODUCT WARRANTY;
 - iii. Maintenance or repair of third-party or non-Medtronic products or software, even if packaged or sold with Medtronic Products and recommended by Medtronic;
 - iv. Problems caused by unauthorized modifications, maintenance or repairs of the Products or any other modification, maintenance or repair of the Products not performed by Medtronic;
 - v. Problems caused by external power sources, including the incoming power supply;
 - vi. Repair of damage caused by accident, negligence or any cause other than ordinary use, including Customer's failure to follow operation instructions, failure to provide a reasonably suitable environment for Products, or use of the Products for purposes other than those for which they were designed;
 - vii. Damage to the Products caused by disaster, such as, fire, flood, wind, earthquake, terrorism, lightning or natural disaster;
 - viii. Movement of the System from the Location unless performed by Medtronic as an Optional Service;
 - ix. Expendable materials and accessories, such as straps, fabric, as well as Corrective Maintenance necessary to repair accessories;
 - x. Future Software Upgrades, Software Features and Software Applications or any other Software that was not originally part of this Agreement, unless otherwise entitled in the Sales and Support Proposal; and
 - xi. Optional Services.
- d. **QUALIFYING.** To qualify for this LIMITED PRODUCT WARRANTY, the following conditions must be met:
 - i. The Products must be used in accordance with any Product labeling or any Product documentation provided and as solely determined by Medtronic;
 - ii. Products must not have been altered or subjected to misuse, modification, abuse, accident or improper handling;
 - iii. Medtronic must be notified within thirty (30) days following discovery of a defect;
 - iv. The Product must be returned to Medtronic within thirty (30) days of Medtronic receiving notice as provided above; and

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- v. The Products must not have been repaired or altered outside of Medtronic's supervision or by non-Medtronic personnel in any way which, in the judgment of Medtronic, affects its stability or reliability.
- e. **LIMITATIONS.** This LIMITED PRODUCT WARRANTY is limited to its express terms. In particular:
 - i. EXCEPT AS EXPRESSLY PROVIDED BY THIS LIMITED PRODUCT WARRANTY AND TO THE MAXIMUM EXTENT PERMITTED BY LAW, THIS WARRANTY AND THE REMEDIES SET FORTH ABOVE ARE EXCLUSIVE AND IN LIEU OF ALL OTHER WARRANTIES, REMEDIES AND CONDITIONS, WHETHER ORAL OR WRITTEN, EXPRESS OR IMPLIED. MEDTRONIC SPECIFICALLY DISCLAIMS ANY AND ALL IMPLIED WARRANTIES, INCLUDING, WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. IF MEDTRONIC CANNOT LAWFULLY DISCLAIM OR EXCLUDE IMPLIED WARRANTIES UNDER APPLICABLE LAW, THEN TO THE EXTENT POSSIBLE ANY CLAIMS UNDER SUCH IMPLIED WARRANTIES SHALL EXPIRE ON EXPIRATION OF THE WARRANTY PERIOD.
 - ii. THIS LIMITED PRODUCT WARRANTY IS MADE ONLY TO THE ORIGINAL PURCHASER OF THE PRODUCT. AS TO ANY THIRD PARTY, MEDTRONIC MAKES NO WARRANTY, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY, OR FITNESS FOR A PARTICULAR PURPOSE WHETHER ARISING FROM STATUTE, COMMON LAW, CUSTOM OR OTHERWISE. NO EXPRESS OR IMPLIED WARRANTY TO THE PATIENT SHALL EXTEND BEYOND THE PERIOD SPECIFIED IN THE PARAGRAPH ABOVE. THIS LIMITED PRODUCT WARRANTY SHALL BE THE EXCLUSIVE REMEDY AVAILABLE TO ANY PARTY.
 - iii. FOR ORIGINAL PURCHASERS WHO HAVE THE BENEFIT OF CONSUMER PROTECTION LAWS OR REGULATIONS IN THEIR STATE OR COUNTRY OF PURCHASE OR, IF DIFFERENT, THEIR COUNTRY OF RESIDENCE, THE BENEFITS CONFERRED BY THIS WARRANTY ARE IN ADDITION TO ALL RIGHTS AND REMEDIES CONVEYED BY SUCH CUSTOMER PROTECTION LAWS AND REGULATIONS. TO THE EXTENT THAT LIABILITY UNDER SUCH CONSUMER PROTECTION LAWS AND REGULATIONS MAY BE LIMITED, MEDTRONIC'S LIABILITY IS LIMITED, AT ITS SOLE OPTION TO REPLACEMENT OR REPAIR OF THE PRODUCT OR SUPPLY OF THE REPAIR SERVICE AGAIN.
 - iv. The exclusions and limitations set out above are not intended to, and should not be construed so as to contravene mandatory provisions of applicable law. If any part or term of this LIMITED PRODUCT WARRANTY is held to be illegal, unenforceable or in conflict with applicable law by a court of competent jurisdiction, the validity of the remaining portions of the LIMITED PRODUCT WARRANTY shall not be affected, and all rights and obligations shall be construed and enforced as if this LIMITED PRODUCT WARRANTY did not contain the particular part or term held to be invalid.
 - v. EXCEPT AS IS EXPRESSLY SET FORTH ABOVE, MEDTRONIC EXPRESSLY DISCLAIMS ANY REPRESENTATION OR WARRANTY OF ANY KIND, EXPRESS OR IMPLIED, WHETHER AS TO MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR ANY OTHER MATTER. THE REMEDIES SET FORTH IN THIS WARRANTY ARE THE EXCLUSIVE REMEDIES AVAILABLE FOR BREACH OF WARRANTY.

- 8 **CUSTOMER RESPONSIBILITIES.** During the term of this agreement, Customer agrees to comply with the following obligations, failure of which will be considered a breach and, where noted, will void this Agreement.
- a. Ensure all Planned Maintenance requirements are fulfilled. Planned Maintenance requirements are detailed in the Product's technical manual.
 - b. Ensure the Location is maintained in a condition reasonably suitable for the Products, as detailed in the Product's technical manual, including but not limited to temperature and humidity control, incoming power supply, and fire protection system.
 - c. Ensure the Products are used in accordance with relevant specifications by personnel who are properly trained on the operation and usage of the Products.
 - d. Contact Medtronic prior to relocation of Products. Although Products that are mobile may be moved within the Location during use, relocation that would result in the Product being lifted, dropped, tilted or jarred and any relocation outside the Location will void this Agreement if undertaken by Customer or a third party without prior

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notification to Medtronic Technical Services. Alternatively, Medtronic will relocate Products for Customer as an Optional Service.

- e. Promptly notify Medtronic of any problem, failure or malfunction of Products which result in the inability of the Product to perform in accordance with its specifications and provide the identification number for all Products and/or Software name and version number when reporting problems to Medtronic or requesting Services, and Customer agrees to provide Medtronic Technical Services personnel with sufficient system issue description, technical information and/or modem/network/internet access as deemed necessary by Medtronic Technical Services personnel to diagnose and attempt to resolve technical issue.
- f. Designate Customer personnel who are trained by Medtronic to perform diagnostic activities recommended by Medtronic and attempt to resolve issues at the Location prior to requesting onsite Services by Medtronic. To expedite repairs, Customer agrees to physically swap replacement parts under the telephone direction of Medtronic Technical Services in an effort to quickly and cost-effectively return the Products to operational status.
- g. Provide reasonable and safe access to Products, at no cost to Medtronic, for any period when on-site Services are required or requested by Customer.
- h. Comply with the license terms provided at the time of Product purchase for any Medtronic Software.
- i. Customer acknowledges that the Products are or may be medical devices subject to federal regulations and agrees not to tamper with, alter, service, or modify any Product (including the loading of additional software) without prior written consent from Medtronic as unauthorized modifications could render the device unsafe or ineffective for its intended use. Any such unauthorized modification will void this Agreement. This provision shall survive termination, expiration or lapse of this Agreement.

9 TERMINATION.

- a. Termination without Cause. Either party may terminate this Agreement for any reason or no reason, with thirty (30) days prior written notice to the other party.
- b. Termination for Cause. Either party may terminate this Agreement immediately, without prior written notice to the other party, if the other party
 - i. makes an assignment for the benefit of creditors, or a receiver, trustee in bankruptcy or similar officer is appointed to take charge of all or any part of the other party's property or business;
 - ii. is adjudicated bankrupt;
 - iii. neglects or fails to perform or observe any of its obligations under this Agreement and does not cure such neglect or failure within thirty (30) days after receipt of written notice from the party alleging such non-compliance (hereinafter, collectively referred to as "Cause").
- c. Termination for License Misuse. Medtronic may terminate this Agreement immediately, without prior notice to Customer if Customer misuses the Licensed Material and/or uses the Licensed Material in violation of any license provided under this Agreement. If Medtronic terminates this Agreement under this Section, Customer shall not be entitled to a refund of any portion of any fees paid by Customer under this Agreement.
- d. Result of Termination.
 - i. If Medtronic terminates this Agreement for any reason other than for Cause, Medtronic will pay Customer a pro-rata refund of the fees that Customer paid for the year in which the Agreement is terminated based on the remaining period in such year.
 - ii. If Customer terminates this Agreement for any reason other than for Cause, Customer shall not be entitled to a refund of any portion of any fees paid by Customer under this Agreement but Customer shall be excused from any obligation to pay any future fees beyond the year in which the Agreement was terminated.
 - iii. If Customer terminates this Agreement for Cause, Medtronic will pay Customer a pro-rata refund of the fees that Customer paid for the year in which the Agreement is terminated based on the remaining period in such year.

10 SERVICE AND SUPPORT AGREEMENTS (SSA). For Services excluded from the Sales and Support Proposal or that extend beyond the LIMITED PRODUCT WARRANTY, Customer may purchase a SSA. For any Service that is requested by Customer after expiration of the LIMITED PRODUCT WARRANTY, and before a new SSA or reinstatement of such, Customer may be required to pay for such requested Service billed at the current rate for time and materials. At its discretion, Medtronic may issue or reinstate the SSA provided it determines the previously covered Products are within technical specifications after Customer pays Medtronic for Optional Services that may include:

- a. an inspection of the Products, related equipment, hardware and software to ensure it is in good operating order
- b. any necessary Corrective Maintenance, and

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- c. any necessary Software
 - d. any necessary hardware upgrades required as part of a software upgrade
- 11 **END OF GUARANTEED SERVICE (EoGS):** Medtronic will guarantee the delivery of support and service for all Medtronic built Products for a minimum of seven (7) years after the date of Customer installation. For linked or embedded third party products, the End of Life Policy of the original equipment manufacturer will be applied.
- a. **Discontinuation of Services:** If Medtronic discontinues offering Planned Maintenance, Corrective Maintenance or Optional Services for any Customer owned Products, Medtronic guarantees to notify Customer in writing 90 days in advance of such discontinuation. If Customer has pre-paid for SSA coverage beyond the EoGS date, Customer shall be entitled to a pro rata credit or appropriate adjustment of the maintenance fee attributable to such discontinued Product if such Product is not upgradeable.
 - b. **Software Support:** Medtronic shall offer support for the current release plus one release prior for Software Products listed on Medtronic's then current price list. All other previous versions of Software shall be considered end of life and shall not be supported except on an "as available basis" and at Medtronic's then current price list.
 - c. **Best Efforts.** Beyond the EoGS date, Medtronic may agree to support the Product on a commercial best efforts basis. During this period, the below services may be limited based on resource availability.
 - i. replacement parts
 - ii. response time guarantees
 - iii. Comprehensive Service and Support Agreements, covering all hardware and software, may not be available after the End of Guaranteed Service date
 - d. Medtronic will use its commercial best efforts to continue to support all products throughout complete obsolescence. Complete obsolescence occurs when all systems are removed from clinical use.
 - e. At times, some Software might be compatible with multiple System types, and therefore be supported beyond the seven (7) year commitment. While Medtronic may make the decision to support specific Software versions beyond the 7 year commitment, this does not extend the support commitments of any System replacement parts.
 - f. Throughout the Products life cycle, Medtronic maintains the right to replace parts with functionally comparable replacement parts
 - g. EoGS on Software and Components sold after the original System purchase date is limited to the System's respective End of Guaranteed Service date.
- 12 **SOFTWARE LICENSE**
- a. Medtronic hereby grants to Customer, and Customer hereby accepts, a non-transferable, non-exclusive license ("License") to use Licensed Materials in perpetuity if and for so long as Customer agrees to and abides by the terms and conditions of this Agreement. Customer may not copy, modify or transfer the Licensed Materials, in whole or in part, except as provided by Medtronic. Customer may only use the Licensed Materials in connection with the proper usage and operation of the Products.
 - b. Customer may terminate this License at any time by destroying the Licensed Materials together with all copies. This Agreement shall also terminate automatically and without notice if Customer fails to comply with any term or condition of this Agreement.
 - c. The Licensed Materials are, and shall remain, the sole property of Medtronic unless such Licensed Materials are destroyed.
 - d. Customer agrees to take all reasonable steps to safeguard the Licensed Materials to ensure that no unauthorized person shall have access thereto, and that no copy, publication, disclosure or distribution, in whole or in part, in any form shall be made. Customer acknowledges that the Licensed Materials contain valuable, confidential information and trade secrets of Medtronic and that copying of or allowing unauthorized access to the Licensed Material is harmful and damaging to Medtronic.
- 13 **WARRANTY OF TITLE, PATENTS, AND COPYRIGHTS.** In addition to the warranties set forth in the previous paragraphs, Medtronic warrants that it has good title to the Products free of any encumbrance and that the Products shall be delivered free from the rightful claim of any third person for infringement of patent or copyright or other intellectual property right. Medtronic will defend Customer against any claim of infringement and will pay resulting actual but reasonable costs, damages and attorney fees finally awarded, provided that
- a. Customer promptly notifies Medtronic in writing of any claim and
 - b. Medtronic has sole control of the defense and all related settlement negotiations; provided that Medtronic may not settle the claim or suit absent the written consent of Customer unless such settlement (a) includes a release of all claims pending against Customer, (b) contains no admission of liability or wrongdoing by Customer, and (c) imposes no obligations upon Customer other than an obligation to stop using the goods or services that are the subject of the claim.

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- c. If a claim arises, Customer will allow Medtronic, at Medtronic's option and expense, to procure the right for Customer to continue using the Products, to replace or modify the Products so that they become non-infringing, without incurring a material diminution in performance or function, or to grant Customer a refund of the purchase price in exchange for the return to Medtronic of the infringing Product.

This provision shall survive termination or expiration of this Agreement.

- 14 **LOSS, DAMAGE OR DELAY.** Transfer of ownership is FOB Destination. Freight is Prepaid by Medtronic and added to Customer invoice. All risk of loss or damage and legal title (subject to a retained purchase-money security interest in Medtronic until payment in full) shall pass to Customer at this time.
- 15 **LIMITATION OF LIABILITY.** Neither party will be liable to the other for special, incidental, consequential, punitive or indirect damages, including without limitation, lost revenues or profits, in connection with this Agreement or performance hereunder, whether arising out of warranty, contract, tort or otherwise.
- 16 **FORCE MAJEURE.** Neither Customer nor Medtronic shall be liable to the other for any delay or failure to perform that results from any event or cause that is beyond the reasonable control of the party obligated to perform.
- 17 **EXPORT RESTRICTIONS.** This Agreement covers products and/or technology that may be controlled under the US Export Administration Regulations and may be subject to the approval of the US Department of Commerce prior to export. Any export or re-export by Customer, directly or indirectly, in contravention of such regulations is prohibited.
- 18 **CONFIDENTIAL INFORMATION.** Customer and Medtronic agree that this Agreement, including the exhibits, represents and/or contains confidential information, including but not limited to pricing, that shall not be disclosed to any third party or otherwise made public, without prior written authorization of the other party, except where such disclosure is required by law and then only after Notice to the other party to allow for an objection to such disclosure.
- 19 **PRIVACY.** Medtronic agrees to comply with any applicable federal and state health information confidentiality laws and regulations. Medtronic is not a covered entity under the Health Insurance Portability and Accountability Act (HIPAA), but may receive Protected Health Information (PHI), as defined by the HIPAA Privacy Rule, for functions such as billing and invoicing of its services, providing technical support related to Products, or for other purposes related to the quality, safety and effectiveness of FDA regulated products. Customer acknowledges the use and disclosure of PHI by Medtronic for these purposes. The Parties agree that Office for Civil Rights (OCR) guidance in FAQ #490 on February 4, 2004 governs this relationship and that a business associate agreement is not required between a covered entity (Customer) and a medical device manufacturer (Medtronic) even if the device manufacturer provides support and guidance to the patient or surgeon during surgery, or receives PHI for billing and invoicing of its services, or for other purposes related to the quality, safety and effectiveness of FDA regulated products. At Customer's request Medtronic shall provide Customer with a Medtronic Pledge to Protect Patient Privacy for Customer's internal record keeping related to privacy. To the extent that Medtronic is asked to provide services to Customer that do require a business associate agreement under HIPAA, the parties will negotiate such an agreement before those services begin.
- 20 **COMPLIANCE WITH LAWS.** Customer and Medtronic agree to comply with obligations under federal, state or other applicable laws or regulations with respect to the performance of this Agreement. The parties acknowledge that it is their intent to establish a business relationship in which rebates, discounts, payments and credits provided to Customer comply with the exceptions to the Medicare and Medicaid Anti-Kickback statute set forth at 42 U.S.C. § 1320a-7b(b)(3) and the "Safe Harbor" regulations regarding discounts set forth in 42 C.F.R. § 1001.952(h); and the parties believe that the relationship contemplated by this Agreement is in compliance with those requirements.
- 21 **ACCESS TO RECORDS.** Notwithstanding the confidentiality provision herein, to the extent required by the Social Security Act, as amended, Medtronic will, upon request, allow the United States Department of Health and Human Services, the Comptroller General of the United States, the State Department of Health, the State Department of Finance, and their duly authorized representatives access to this Agreement and to all books, documents, and records necessary to verify the nature and extent of the costs of Services provided by it under this Agreement at any time during the term of this Agreement and for an additional period of four (4) years following the last date Services are provided under this Agreement.
- 22 **WAIVER.** The waiver or failure of Medtronic to exercise any right provided for in this Agreement shall not be deemed a waiver of such right in any other instance.
- 23 **ENTIRE AGREEMENT/ PRECEDENCE.** This Agreement, which is comprised of the Sales and Support Proposal, these terms and conditions, and all attached exhibits and/or addenda, contains the entire agreement between the parties and supersedes all prior or concurrent agreements between the parties, whether oral or written, relating to its subject matter. The provisions of this Agreement may not be modified except in a writing signed by authorized representatives of both parties; therefore any different or additional terms in any Customer purchase order or other document are objected to and will not be binding. If any terms conflict, the terms of this Agreement will apply in the following order of precedence:

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- a. The Sales and Support Proposal;
- b. any supplemental terms and conditions
- c. Medtronic's Master Terms and Conditions
- d. any other exhibit, addendum or schedule attached to this Agreement.

- 24 **GOVERNING LAW.** The validity, construction and performance of this Agreement shall be governed by and construed in accordance with the laws of the State of California.
- 25 **DEBARMENT AND SUSPENSION.** Medtronic hereby represents and warrants that it is not and at no time has been convicted of any criminal offense related to health care nor has been debarred, excluded, or otherwise ineligible for participation in any federal or state government health care program, including Medicare and Medicaid. Further, Medtronic represents and warrants that no proceedings or investigations are currently pending or to Medtronic's knowledge threatened by any federal or state agency seeking to exclude Medtronic from such programs or to sanction Medtronic for any violation of any rule or regulation of such programs.
- 26 **DAMAGE TO CUSTOMER PROPERTY.** Medtronic shall repair, or cause to be repaired, at its own cost, all damages to Customer vehicles, facilities, buildings or grounds to the extent they are caused by the willful or negligent acts of Medtronic or its employees or agents. Such repairs shall be made immediately after Medtronic becomes aware of such damage, but in no event later than thirty (30) days after the occurrence.
- 27 **GENERAL INDEMNIFICATION.** Medtronic agrees to indemnify, defend (with counsel reasonably approved by Customer) and hold harmless the Customer and its authorized officers, employees, agents and volunteers from any and all third party claims, actions, losses, damages and/or liability to the extent they are caused by the malfunction or defect of the Products provided pursuant to this Agreement except where such indemnification is prohibited by law. This provision shall survive termination or expiration of the Agreement.
- 28 **INSURANCE.** Medtronic shall maintain the following insurance coverage at the following minimum limits for the Term of this Agreement:

- Workers' Compensation/Employer's Liability – A program of Workers' Compensation insurance or a state-approved, self-insurance program in an amount and form to meet all applicable requirements of the Labor Code of the State of California, including Employer's Liability with \$250,000 limits covering all persons.
- Commercial/General Liability Insurance – General Liability Insurance covering all operations performed by or on behalf of Medtronic providing coverage for bodily injury and property damage with a combined single limit of not less than one million dollars (\$1,000,000), per occurrence. The policy coverage shall include: Products and completed operations, Broad form property damage (including completed operations), Personal injury, Contractual liability, and a \$2,000,000 general aggregate limit.
- Automobile Liability Insurance – Primary insurance coverage shall be written on ISO Business Auto coverage form for all owned, hired and non-owned automobiles or symbol 1 (any auto). The policy shall have a combined single limit of not less than one million dollars (\$1,000,000) for bodily injury and property damage, per occurrence.

All policies, except for Worker's Compensation, shall contain additional endorsements naming Customer as an additional named insured with respect to liabilities arising out of this Agreement. When applicable, and when requested by Customer, evidencing proof of the foregoing coverage shall be furnished to Customer.

Medtronic shall require the carriers of required coverages to waive all rights of subrogation against the Customer, its officers, employees, agents, volunteers, contractors and subcontractors. All general or auto liability insurance coverage provided shall not prohibit Medtronic and Medtronic's employees or agents from waiving the right of subrogation prior to a loss or claim. Medtronic hereby waives all rights of subrogation against Customer.

All policies required herein are to be primary and non-contributory with any insurance or self-insurance programs carried or administered by the Customer.

Medtronic agrees to ensure that coverage provided to meet these requirements is applicable separately to each insured and there will be no cross liability exclusions that preclude coverage for suits between Medtronic and Customer or between Customer and any other insured or additional insured under the policy.

Unless otherwise approved by Customer's Department of Risk Management, insurance shall be written by insurers authorized to do business in the State of California and with a minimum "Best" Insurance Guide rating of "A- VII".

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29 GENERAL PROVISIONS

- a. The parties hereto submit to the exclusive jurisdiction of the State and Federal courts in the State of California with respect to any dispute hereunder.
- b. The captions used herein are for convenience only and shall not be considered in construing or interpreting the provisions hereof.
- c. If any provision of this Agreement shall be held to be invalid, illegal or unenforceable, the validity, legality and enforceability of the remaining provisions shall in no way be affected or impaired thereby.
- d. If any legal action is instituted to enforce any party's rights hereunder, each party shall bear its own costs and attorney fees, regardless of who is the prevailing party. This paragraph shall not apply to those costs and attorney fees directly arising from a third-party legal action against a party hereto and payable as an indemnification obligation.
- e. Except to the extent required by applicable law, neither party shall make any public announcement or statement regarding the relationship of the parties hereunder inconsistent with the Release or any public filings of either party without the prior written consent of the other party, which shall not be unreasonably withheld.