

MEDTRONIC CARELINK® NETWORK TERMS OF USE AND DEVICE MANAGER AND MEDTRONIC COMPUTER AGREEMENT

This **MEDTRONIC CARELINK® NETWORK TERMS OF USE AND DEVICE MANAGER AND MEDTRONIC COMPUTER AGREEMENT ("Agreement")** is made by and between Medtronic USA, Inc. ("Medtronic"), and the County of Monterey, a political subdivision of the State of California (hereinafter, "the County"), on behalf of Natividad Medical Center ("each herein an "Affiliate" or, in the Terms of Use, a "User" and collectively the "Affiliates" or "Users"), a general acute care teaching hospital wholly owned and operated by the County. Medtronic offers patients with CareLink-enabled implantable cardiac devices and their health care providers access to the Medtronic CareLink Network for the purpose of remotely monitoring device information.

Medtronic also provides hardware for the purpose of interrogating Medtronic implanted medical devices. Access to the CareLink Network and the hardware for those purposes is provided to health care providers pursuant to the attached terms of use ("Terms of Use"), Device Manger and Medtronic Computer Agreement ("Device Manager Agreement" and the business associate agreement described below ("Business Associate Agreement").

Network access and hardware Cost to User: No Charge.

In consideration for access to the CareLink Network and the Medtronic supplied hardware for the purpose of remotely monitoring device information and interrogating Medtronic implanted medical devices, and for other good and valuable consideration, the undersigned accepts the Terms of Use and the Device Manager Agreement on behalf of itself and its affiliates indicated on the attached Attachment A (each herein an "Affiliate" or, in the Terms of Use, a "User" and collectively the "Affiliates" or "Users") shall apply to these Terms of Use and the Device Manager Agreement. As of the Effective Date, any other CareLink Network Terms of Use or Device Manager Agreement between Medtronic and User or User's Affiliates are hereby rescinded and replaced with these Terms of Use.

By signing below, the undersigned represents and warrants that it is authorized to bind, and hereby binds to the CareLink Network Terms of Use or Device Manager Agreement each Affiliate as if each such Affiliate had executed this agreement, and will be jointly and severally responsible with each such Affiliate for such Affiliate's performance under this agreement. Each Affiliate is bound by the terms of this agreement.

Even though for efficiency the parties are using this single contract document, the undersigned and each Affiliate will be deemed to have entered into this agreement independent of the others. As a result, each Affiliate will have its own account in the CareLink Network such that data retained therein is not and will not be accessible to other Affiliates.

Agreed to and accepted by: The County of Monterey on behalf of Natividad Medical Center Attn: Contracts Division 1441 Constitution Blvd Salinas, CA 93906 Fax: 831-757-2592 By _____ Print Name _____ Title _____ Date _____	User acceptance acknowledged by: MEDTRONIC USA, INC. 8200 Coral Sea Street NE (MVC52) Mounds View, MN 55112 Contact person: Derek Erickson Phone: 763.526.2477 Email: derek.d.erickson@medtronic.com Fax: 763.355.1217 By <u>Derek Erickson</u> Print Name <u>Derek Erickson</u> Title <u>Contract Analyst</u> Date <u>9-8-2021</u>
---	---

Reviewed and approved as to form.



Chief Deputy County Counsel, 10/10/2021
Carelink Terms of Use (Multi-site) and Device Manager Agreement 2018-8-9

Reviewed for Fiscal Provisions
10-11-2021



Chief Deputy Auditor-Controller

INFORMATION ABOUT MEDTRONIC CARELINK® NETWORK

The CareLink Network is an Internet-based method of obtaining device-related data ("CareLink Network"). Medtronic allows patients and health care providers to access the CareLink Network for the purposes of exchanging information relating to devices and related technical support, interrogating the Medtronic implantable cardiac devices listed on the CareLink website and transmitting and accessing device data ("Device Data").

The CareLink Network includes access to the CareLink Clinician Site ("Clinician Site"), an Internet web site used to access CareLink Network capabilities including the capability for User to view Device Data for the management and treatment of Patients. The CareLink Monitor ("Monitor") is made available for patients for whom a Monitor has been prescribed and who have been enrolled for Use ("Patient(s)"). The CareLink Express® Monitor may be made available to clinicians to facilitate certain device technical support services.

To facilitate Patient and health care provider use of the CareLink Network, Medtronic provides implementation and training information on the use of the Monitor and Clinician Site and basic technical support services for CareLink Network users and Patients, during standard business hours. Additional technical assistance is available via Medtronic's toll free technical support service, 24 hours per day. Medtronic complies with applicable federal and state health information confidentiality laws and uses industry standard safeguards, procedures and systems to protect the privacy and security of Device Data it receives, creates, or discloses in the course of operating the CareLink Network, including using multiple levels of security and encryption technologies. Medtronic takes commercially reasonable steps to ensure that the Device Data provided on the Clinician Site is accurate and free from viruses or other defects and that the Clinician Site is available 24 hours per day, seven days per week, with the exception of scheduled maintenance or system upgrades. Medtronic provides advance notice of system modifications that materially impact use of the CareLink Network or the Clinician Site.

MEDTRONIC CARELINK NETWORK TERMS OF USE

1. USE AND USER RESPONSIBILITIES. Medtronic allows health care providers to access CareLink Network designated capabilities including remote monitoring of CareLink-enabled Medtronic implantable cardiac devices (the "Use"). User is responsible for obtaining equipment, software, supplies and Internet connections to access and utilize the CareLink Network. When enrolling a Patient, User shall train the Patient to use the Monitor in an appropriate, careful and proper manner and in compliance with all user manuals, laws and regulations. User is responsible for issuing appropriate access credentials to its personnel and for maintaining the confidentiality and security of all CareLink Network passwords and other user identifications of health care providers and other User employees, contractors and agents, and is responsible for any consequences that may result from their disclosure.

2. PROPRIETARY RIGHTS. User agrees and acknowledges that Medtronic owns all right, title and interest in and to all components of the CareLink Network, including Monitors (including any demonstration models), the Clinician Site, as well as any software, hardware, content, design, documentation and other features and parts thereof, and including all copyrights, patents, trade secret rights, trademarks and other intellectual property rights therein. User shall not copy, reproduce, republish, upload, post, transmit, export or distribute in any way any material, data or other information from the Clinician Site except as specifically provided in these Terms of Use without Medtronic's prior written approval. User shall not create derivative works from, integrate with any other computer systems or programs (other than to integrate into User's other computer systems or programs a copy of Patient-specific information that has been downloaded from the Clinician Site), reverse engineer, decompile or disassemble the Monitor or Clinician Site or any software, hardware or other parts thereof.

User will not provide any ideas to Medtronic using the Clinician Site or by other means of communication in the absence of a separate agreement specifically pertaining to such disclosure. If User or any of its clinicians or other employees, contractors or agents provide any ideas, information, concepts, know-how or techniques or materials to Medtronic using the Clinician Site or otherwise, User, on behalf of itself and its clinicians and other employees, contractors and agents, grants Medtronic an unrestricted, royalty-free, irrevocable license to use, reproduce, display, perform, modify, transmit and distribute such ideas in any medium and agrees that Medtronic is free to use them for any purpose.

All training materials or other written information or documentation provided by Medtronic that bear a legend "Confidential," "Proprietary" or words of similar import are confidential and proprietary to Medtronic. User shall take reasonable steps to protect the confidentiality of such materials, written information and documentation, shall not disclose them to third parties and shall use them only in connection with Use of the CareLink Network.

3. USER ACKNOWLEDGEMENTS. User acknowledges that the CareLink Network, including the Monitor, is not the exclusive method of interrogating Patients' implanted cardiac devices, nor is the CareLink Network intended

to be used as a life-sustaining or interventional tool during medical emergencies; Medtronic is not, and shall not be deemed to be, a provider of patient health care services by virtue of its provision of access to the CareLink Network; the Clinician Site is not an electronic medical record; and, use of the CareLink Network does not in any way relieve User or its doctors and/or other employees or agents from using their best medical judgment to determine a proper course of treatment for Patients.

4. LIMITED WARRANTY, WARRANTY EXCLUSIONS AND LIMITATION OF LIABILITY. Medtronic warrants to CareLink Network users that have agreed to these Terms of Use, including User, that it has obtained the necessary FDA approval to provide the Use and that the intended functions of the Monitor and Clinician Site have been, and future versions of each will be, verified through component and system testing. Each Monitor is provided by Medtronic with the limited warranty that is delivered with the Monitor (the "Monitor Limited Warranty").

NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY OR ANY THIRD PARTY UNDER ANY LEGAL THEORY, WHETHER IN AN ACTION BASED ON A CONTRACT, TORT (INCLUDING NEGLIGENCE AND STRICT LIABILITY) OR ANY OTHER LEGAL THEORY, HOWEVER ARISING, FOR ANY INCIDENTAL, SPECIAL, EXEMPLARY, CONSEQUENTIAL DAMAGES, OR ANY OTHER SIMILAR DAMAGES OF EVERY FORM AND TYPE, INCLUDING BUT NOT LIMITED TO MEDICAL EXPENSES, LOSS OF REVENUE OR PROFITS, OR DAMAGES RESULTING FROM LOSS, MISAPPROPRIATION OR UNAUTHORIZED ACCESS TO OR MODIFICATION OF DEVICE DATA, OR FROM MISTAKES, OMISSIONS, OR DELAYS IN TRANSMISSION OF INFORMATION, OR FROM INTERRUPTIONS IN TELECOMMUNICATIONS CONNECTIONS, VIRUSES OR FAILURES OF PERFORMANCE, OR FROM THE IMPACT OF THE USE ON ANY USER SYSTEM, EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY OR ANY THIRD PARTY UNDER ANY LEGAL THEORY FOR INTERCEPTION OR COMPROMISE OF THE CARELINK NETWORK, OR OF ANY RECORD OR OTHER COMMUNICATION PROVIDED BY THE OTHER PARTY OR ANY THIRD PARTY PURSUANT TO THE OTHER PARTY'S OR THIRD PARTY'S USE OF THE CARELINK NETWORK.

IN ANY EVENT, NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY OR ANY THIRD PARTY FOR DAMAGES FOR ANY CAUSE RELATED TO OR ARISING OUT OF THIS AGREEMENT, WHETHER IN CONTRACT, NEGLIGENCE OR TORT, IN AN AMOUNT THAT SHALL NOT EXCEED THE AGGREGATE LIMITS OF THE INSURANCE AS STATED IN SECTION 6 INSURANCE.

5. INDEMNIFICATION. Medtronic shall defend, indemnify, and hold harmless User and its officers, directors, employees, agents and Affiliates from and against any claim, proceeding, or demand ("Infringement Claim"), arising out of any claim by a third party that User's authorized use of the Software and/or Services infringes that third party's intellectual property rights. Medtronic's obligations to indemnify Customer are reduced to the extent liability under an Infringement Claim is due to Customer's alteration of CareLink Express, components not provided to Customer by Medtronic, or use contrary to instructions provided by Medtronic. User shall: (i) give Medtronic prompt written notice of such claim; and (ii) allow Medtronic to control, and fully cooperate with Medtronic (at Medtronic's sole expense) in, the defense and all related negotiations. Medtronic shall not enter into any stipulated judgment or settlement that purports to bind User without User's express written authorization, which shall not be unreasonably withheld or delayed. Customer shall not settle any Infringement Claim nor incur any cost or expense for which it will seek reimbursement hereunder without the prior written consent of Medtronic.

If the Software or Service becomes or is likely to become the subject of an infringement claim, then, in addition to defending the claim and paying any damages and attorneys' fees as required above, Medtronic shall, at its option and in its sole discretion, either (a) immediately replace or modify the Software or Service, without loss of material functionality or performance, to make it non-infringing or (b) immediately procure for User the right to continue using the Software or Services pursuant to the Terms of Use and Device Manager Agreement. Any costs associated with implementing either of the above alternatives will be borne by Medtronic. If Medtronic fails to provide one of the foregoing remedies within forty-five (45) days of notice of the claim, the Terms of Use and Device Manager Agreement shall terminate. Medtronic reserves the right to modify CareLink Express at any time to make it non-infringing, and Customer reserves the right to terminate this Agreement by written notice to Medtronic following such a modification to CareLink Express if the modification results in a material diminution in the features or functionality of the system. Customer's remedies under this section are Customer's sole and exclusive remedies for any Infringement Claims.

6. INSURANCE.

6.1 Evidence of Coverage:

Prior to commencement of this Agreement, Medtronic shall provide a "Certificate of Insurance" certifying that coverage as required herein has been obtained. Individual endorsements executed by the insurance carrier shall

accompany the certificate. In addition, the Medtronic upon request shall provide a certified copy of the policy or policies.

This verification of coverage shall be sent to User's Contracts/Purchasing Department, unless otherwise directed. Medtronic shall not receive a "Notice to Proceed" with the work under this Agreement until it has obtained all insurance required and User has approved such insurance. This approval of insurance shall neither relieve nor decrease the liability of Medtronic.

6.3 Insurance Coverage Requirements: Without limiting Medtronic's duty to indemnify, Medtronic shall maintain in effect throughout the term of this Agreement a policy or policies of insurance with the following minimum limits of liability:

Commercial general liability insurance, including but not limited to premises and operations, including coverage for Bodily Injury and Property Damage, Personal Injury, Contractual Liability, Broad form Property Damage, Independent Contractors, Products and Completed Operations, with a combined single limit for Bodily Injury and Property Damage of not less than \$1,000,000 per occurrence.

Exemption/Modification (Justification attached; subject to approval).

Business automobile liability insurance, covering all motor vehicles, including owned, leased, non-owned, and hired vehicles, used in providing services under this Agreement, with a combined single limit for Bodily Injury and Property Damage of not less than \$1,000,000 per occurrence.

Exemption/Modification (Justification attached; subject to approval).

Workers' Compensation Insurance. If Medtronic employs others in the performance of this Agreement, in accordance with California Labor Code section 3700 and with Employer's Liability limits not less than \$1,000,000 each person, \$1,000,000 each accident and \$1,000,000 each disease.

Exemption/Modification (Justification attached; subject to approval).

Health Care Professional liability insurance, if required for the professional services being provided, (e.g., those persons authorized by a license to engage in a business or profession regulated by the California Business and Professions Code), in the amount of not less than \$1,000,000 per claim and \$2,000,000 in the aggregate, to cover liability for malpractice or errors or omissions made in the course of rendering professional services. If professional liability insurance is written on a "claims-made" basis rather than an occurrence basis, the Medtronic shall, upon the expiration or earlier termination of this Agreement, obtain extended reporting coverage ("tail coverage") with the same liability limits. Any such tail coverage shall continue for at least three years following the expiration or earlier termination of this Agreement.

Exemption/Modification (Justification attached; subject to approval).

6.4 Other Requirements:

Unless otherwise specified by this Agreement, all such insurance shall be written on an occurrence basis, or, if the policy is not written on an occurrence basis, such policy with the coverage required herein shall continue in effect for a period of three years following the date Medtronic completes its performance of services under this Agreement.

Each policy shall provide coverage for Medtronic and additional insured with respect to claims arising from each subcontractor, if any, performing work under this Agreement.

Commercial general liability and automobile liability policies shall provide an endorsement naming the County of Monterey, its officers, agents, and employees as Additional insureds with respect to liability arising out of the Medtronic's work, including ongoing and completed operations, **and shall further provide that such insurance is primary insurance to any insurance or self-insurance maintained by the County and that the insurance of the Additional Insureds shall not be called upon to contribute to a loss covered by the Medtronic's insurance.** The required endorsement from for Commercial General Liability Additional Insured is ISO Form CG 20 10 11-85 or CG 20 10 10 01 in tandem with CG 20 37 10 01 (2000). The required endorsement from for Automobile Additional Insured Endorsement is ISO Form CA 20 48 02 99.

Prior to the execution of this Agreement by User, Medtronic shall file certificates of insurance with User's Contracts/Purchasing Department, showing that the Medtronic has in effect the insurance required by this Agreement.

Medtronic shall file a new or amended certificate of insurance within five (5) calendar days after any change is made in any insurance policy, which would alter the information on the certificate then on file. Acceptance or approval of insurance shall in no way modify or change the indemnification clause in this Agreement, which shall continue in full force and effect.

Medtronic shall at all times during the term of this Agreement maintain in force the insurance coverage required under this Agreement and shall send, upon request by User no more than once annually, certificates to User's Contracts/Purchasing Department. Failure by Medtronic to maintain such insurance is a default of this Agreement, which entitles User, at its sole discretion, to terminate the Agreement immediately.

7. **TERM.** The term of the Agreement is from 12/1/2021 through 11/30/2024 unless sooner terminated pursuant to the terms of the Agreement. This Agreement is of no force or effect until signed by both Medtronic and User and with User signing last and Medtronic may not commence work before User signs this Agreement.

6. **TERMINATION OF USE.** These Terms of Use shall begin on the date accepted by Medtronic, as indicated on the cover page (the "Effective Date") and shall continue until terminated pursuant to this Section 5. User may terminate use of the CareLink Network for any reason upon at least thirty (30) days prior written notice to Medtronic. Medtronic may terminate User's use of the CareLink Network (a) for material breach by User of these Terms of Use upon at least thirty (30) days prior written notice to User, provided such breach is not cured within the notice period, (b) without cause upon at least ninety (90) days prior written notice to User; or (c) immediately if User terminates the Business Associate Agreement. Medtronic may discontinue or change features and capabilities of the CareLink Network at any time without notice to User, provided however, Medtronic provides advance notice of system modifications that materially impact use of the CareLink Network or the Clinician Site. In the event User's utilization of the CareLink Network is terminated for any reason, User will use reasonable efforts to cause Monitors to be returned to Medtronic pursuant to Medtronic's standard Monitor return procedures.

7. **MISCELLANEOUS.**

7.1 Medtronic may amend these Terms of Use upon at least 60 days written notice to User by way of an amendment to the Terms of Use signed by both parties.

7.2 Any notice required or permitted to be given pursuant to these Terms of Use shall be in writing and, as applicable, addressed to the recipient at the recipient's address or facsimile number set forth on the cover page. Notices will be deemed duly given (a) if delivered personally, when received, (b) if sent by recognized overnight courier service, on the date of the receipt provided by such courier service, (c) three days after mailing by United States First Class mail, postage prepaid, (d) on the day received when sent by email; or (e) on the date given upon User's log-in to the Clinician Site.

7.3 These Terms of Use and the Business Associate Agreement constitute the entire agreement between the parties with respect to User's utilization of the CareLink Network and supersede any prior and contemporaneous written or oral agreements or understandings relating to such subject matter. The preprinted provisions of User's purchase order, if any, shall be deemed deleted and of no effect whatsoever.

7.4 User may not assign any of its rights or responsibilities under these Terms of Use without the prior written consent of Medtronic. User shall not assign its rights in, transfer and/or sublicense the Monitor or access to the Clinician Site or any part thereof.

7.5 No person or entity other than Medtronic or User, including without limitation any Patient, is or shall be a third party beneficiary of these Terms of Use or otherwise entitled to bring any action to enforce any provision of these Terms of Use against Medtronic or User. These Terms of Use shall be governed by and interpreted, construed, and enforced in accordance with the laws of the State of California (exclusive of the choice of law rules thereof). In the event that any provision of these Terms of Use violates any applicable statute, ordinance or rule of law, such provision shall be ineffective to the extent of such violation without invalidating any other provision of these Terms of Use. Neither Medtronic nor User shall be liable to the other for any loss or damage due to delays or failure to perform obligations under these Terms of Use resulting from events beyond the reasonable control of such party. No provision of these Terms of Use may be waived except by an agreement in writing signed by the waiving party. A waiver of any term or provision shall not be construed as a waiver of any other term or provision. Sections 1-4, 6 and 7.4 of these Terms of Use will survive termination

8. **ASSIGNMENT AND SUBCONTRACTING.** Medtronic shall not assign, sell, or otherwise transfer its interest or obligations in this Agreement without the prior written consent of User, except that Medtronic may assign this Agreement without such consent upon written notice to the other party in connection with a merger, acquisition,

corporate reorganization or sale of all or substantially all of its assets unless such transaction would result in assignment to an entity reasonably deemed to be a direct competitor of the other party and provided such assignee has not been excluded or barred from participation in any state or federal health care program or convicted of a criminal offense related to health care. Notwithstanding any subcontracting, Medtronic shall continue to be liable for the performance of all requirements of this Agreement.

9. USER COLLABORATION.

9.1 The CareLink Network offers features that permit User to choose to interact with other users of the CareLink Network, for example to co-manage a Patient within the network or to transfer a Patient from one Primary User to another Primary User. When used in these Terms of Use, "Primary User" means the user associated in the CareLink Network with a particular Patient as determined by such designation in the CareLink Network. (In most cases, the Primary User is the device clinician.) Medtronic may transfer a patient from one Primary User to another Primary User when the Primary Users are not cooperating and in Medtronic's judgment the interests of the patient warrant Medtronic making the transfer. When used in these Terms of Use, "Specialty User" means an authorized user of the CareLink Network that is not the Primary User.

9.2 User may authorize Specialty Users within User's organization to have access to CareLink Network capabilities designated for Specialty Users, such as the ability to request collaboration with Primary Users, both inside and outside of User's organization. A Primary User that chooses to collaborate with a Specialty User may utilize the CareLink Network to provide such Specialty User with access to Patient Device Data to co-manage a Patient. These Terms of Use do not authorize a Specialty User to provide Monitors to patients and enroll patients for Use. User acknowledges that a Specialty User's ability to collaborate with a Primary User and access data about a Patient is contingent upon the consent of the Primary User, which may be withdrawn at any time. Withdrawal of consent terminates Specialty User's access with respect to a Patient or with respect to collaboration in general with the Primary User, depending upon the nature of the consent withdrawn.

9.3A health care provider that provides cardiac care but does not routinely implant medical devices ("HF Clinician") that is an authorized user of the CareLink Network is a type of Specialty User that may use the CareLink Network to request collaboration with a Primary User, and to request access to certain Patient data on a Patient-by-Patient basis. The CareLink Network is designed to ensure there is collaboration and data access only if the Primary User uses the CareLink Network to consent to the HF Clinician user's request for collaboration.

9.4 Unless expressly provided otherwise in connection with a specific feature of the CareLink Network services: (a) Device Data about a particular Patient is controlled by the Primary User; and, (b) Information about a Patient that is added to the CareLink Network by a Specialty User is initially made available to the user adding the information but thereafter becomes Device Data controlled by the Primary User. User shall not issue log-in access to any person outside User's organization. User shall hold Medtronic harmless from all claims and losses arising from User's interaction with another user of the CareLink Network. Medtronic may discontinue or change features and capabilities of the CareLink Network at any time without notice to User, provided however, Medtronic provides advance notice of system modifications that materially impact use of the CareLink Network or the Clinician Site.

**DEVICE MANAGER AND MEDTRONIC COMPUTER AGREEMENT
(THIS AGREEMENT IS APPLICABLE TO HARDWARE SUPPLIED BY MEDTRONIC TO
INTERROGATE MEDTRONIC IMPLANTED MEDICAL DEVICES)**

This Device Manager and Medtronic Computer Agreement ("Agreement") governs the use by the customer signing the cover page and the customer's owned affiliate facilities indicated on the attached Attachment A or as later added to the Agreement as described below (each a "Facility" and collectively with the undersigned ("You", "Your" or "Customer") of systems supplied by Medtronic to program and interrogate Medtronic implanted medical devices ("Device Manager"). Device Managers may use Medtronic software and if so, may use a mobile computer, such as a tablet computer. To use the Device Manager, You install any applicable Medtronic software obtained via the internet and use the Medtronic patient connector hardware and, if applicable, base station hardware (collectively "Patient Connector"). If a mobile computer is used with the Device Manager, You may use a mobile computer supplied by Medtronic ("Medtronic Computer") or Your own mobile computer that meets the Device Manager's specifications ("Customer Computer"). Although the mobile computer is necessary to operate the Device Manager, the computer is not made by Medtronic and is not part of the Device Manager. By initiating a transmission, You are requesting Medtronic device check technical support pursuant to a physician's order. The Device Manager will not function with implanted devices from other manufacturers or Medtronic devices that are not CareLink® enabled.

Patient Data. This section applies to Device Managers You control as well as to other Device Managers Medtronic personnel use to provide You with technical support for Medtronic implantable devices. Unless configured otherwise, when the Device Manager has the required functionality and an active connection to the internet, the Device Manager will act on Your behalf and send the device data obtained from the use of the Device Manager ("Device Data") to the Medtronic CareLink Network ("CareLink"). When the Device Data arrives, CareLink will attempt to match the Device Data with a CareLink enrolled patient. If no match is found, the transmission data will remain in the CareLink holding area for the period identified in the Device Manager Instructions for Use ("Retention Period") for it to be either associated with a CareLink patient and clinic or deleted. The Device Manager will attempt to send the Device Data to CareLink after the implanted device has been interrogated even if the Device Manager does not have an active connection to the internet. If the Device Data is not successfully transmitted to CareLink within the Retention Period, the Device Manager will delete the Device Data from the Device Manager.

Business Associate Agreement. You agree that You either have an applicable Business Associate Agreement (as that term is defined by HIPAA) ("BAA") with Medtronic or that, before You use the Device Manager to transmit data through the system, You will enter into an applicable BAA with Medtronic.

Information Security. You shall promptly report lost or stolen Medtronic Computers to Medtronic. Medtronic reserves the right to render a Medtronic Computer inoperable after it is reported lost or stolen. Your agreement with Medtronic with respect to information security is found in Your BAA.

This Agreement applies to all Device Managers supplied by Medtronic, including new versions that may be released in the future. Medtronic retains ownership of the Patient Connector and the Medtronic Computers. Medtronic hereby grants to Customer, and Customer's employees and physicians with privileges at Customer's facilities, a non-transferable, non-exclusive term license to use the Medtronic Computer solely for the Device Manager application and any other Medtronic application Medtronic makes available for use on Medtronic Computers ("Medtronic Application"). The term of this license ends when Customer is no longer using a Medtronic Application with a Medtronic Computer. Medtronic hereby grants to Customer and Customer's employees and physicians with privileges at Customer's facilities a non-transferable, non-exclusive term license to use the Patient Connector only for the implant and management of compatible Medtronic devices. You shall not permit access to the Device Manager, the Medtronic Computer, or any of its components, or any application on any mobile computer used in conjunction with the foregoing to unauthorized persons, including representatives of companies that compete with Medtronic

You agree to promptly notify Medtronic if a Device Manager or Medtronic Computer is malfunctioning, discontinue its use, and make it available to Medtronic for maintenance, repair, or replacement. Promptly after You inform Medtronic of a malfunction, Medtronic will repair or replace the malfunctioning Device Manager or Medtronic

Computer at Medtronic's expense, which is Your exclusive remedy for malfunction of the Device Manager. Medtronic does not warrant that use of the Device Manager will be uninterrupted or error free. You agree that a failure of connectivity to transmit data to the CareLink Network is not a malfunction of the Device Manager or Medtronic Computer. Although Medtronic will make reasonable efforts to help Customer with connectivity challenges, Medtronic does not guarantee connectivity at Customer's site. Medtronic assumes no obligation to repair or replace damaged, lost, stolen, or obsolete Medtronic Computers.

Medtronic Computers are configured to support only Medtronic authorized applications. Device Managers and Medtronic Computers are provided without charge because they have no independent value, i.e. no value other than supporting the use of Medtronic implantable devices. You agree to return the Patient Connector and Medtronic Computers to Medtronic at the end of Your use or, if requested by Medtronic, responsibly dispose or recycle them as required by applicable law.

You shall: (a) only use the Device Manager in a manner consistent with its IFU and other documentation provided by Medtronic; (b) treat the Device Manager and Medtronic Computer with the same care and security You treat other medical equipment; (c) allow only trained and authorized personnel to operate the Device Manager and Medtronic Computer; (d) at Your own expense perform all breach notification and other activities resulting from the loss or theft of a Medtronic Computer licensed to You; (e) obtain equipment, software and connectivity suitable to utilize the Device Managers, and maintain appropriate safeguards, procedures and systems to protect the privacy and security of information on such equipment and software, including available software patches; (f) maintain appropriate safeguards, procedures and systems to protect the privacy and security of information stored or transmitted and on any third-party software Medtronic permits to be loaded on a Medtronic Computer (such as an e-mail application), including available software patches; (g) if Your user takes the Device Manager to another facility, configure the application to transmit the information collected to the appropriate recipient, and obtain the agreement or consent of the facility necessary to comply with applicable law and the Medtronic agreements that pertain to the Medtronic Computer and the Medtronic Application; and (h) pay Medtronic the then-current replacement fee for Device Managers and Medtronic Computers You lose or recklessly damage.

You shall not: (a) sell or otherwise transfer the Device Manager and/or Medtronic Computer except as authorized in writing by Medtronic; (b) permit any lien or encumbrance to attach to the Device Manager and/or Medtronic Computer; or (c) obscure any labeling on the Device Manager and/or Medtronic Computer identifying it as the property of Medtronic.

Medtronic warrants that it has obtained the necessary FDA approval to provide the Device Manager and that the intended functions of the Device Manager have been, and future versions of each will be, verified through component and system testing. MEDTRONIC EXPRESSLY DISCLAIMS ANY AND ALL OTHER WARRANTIES, INCLUDING WITHOUT LIMITATION, THE IMPLIED WARRANTIES OF MERCHANTABILITY, AND WITH RESPECT TO THE USE, FITNESS FOR A PARTICULAR PURPOSE.

This Agreement, the applicable software terms of use that accompany Medtronic Applications, CareLink Network Terms Of Use, and the BAA make up the entire agreement between You and Medtronic with respect to Your use of the Device Manager. You can (i) discontinue Your use of the Device Manager and terminate this Agreement for any reason and in whole or with respect to an individual Facility or (ii) add an additional Facility by contacting your local sales representative. Medtronic may terminate this Agreement by written notice to you. Medtronic may amend this Agreement upon at least 30 days written notice to You, except that Medtronic cannot unilaterally amend the notice periods for termination or amendment. All other amendments to the Agreement must be in writing signed by both parties. Notices to amend will be deemed duly given: (a) if sent by courier service, on the date of the receipt provided by such service; (b) three days after mailing by United States First Class mail postage prepaid; (c) on the day received when sent by email to the e-mail address on file or (d) on the date given upon Customer's log-in to the Express Website. These terms will be governed by the laws of the State of California, except for the choice of law provisions.

Attachment A
Affiliates/Users

ACCOUNT NAME	ACCOUNT NUMBER	CITY	STATE

EXHIBIT A

Justification for Exemption to Auto Insurance Requirements

Both NMC and Medtronic agree that because there is no driving associated with providing the services as per this Agreement and its Scope of Services, Medtronic is not required to comply with the auto insurance requirements as stated herein.

Should the scope of services change at any time during the term of this Agreement, this exemption may be revoked.

BUSINESS ASSOCIATE AGREEMENT

This Business Associate Agreement (“BAA”) effective _____, 20__ (“Effective Date”), is entered into by and among between the County of Monterey, a political subdivision of the State of California, on behalf of Natividad Medical Center (“Covered Entity”) and Medtronic USA, Inc. for its Patient Management business (“Business Associate”) (each a “Party” and collectively the “Parties”).

RECITALS

A. WHEREAS, Business Associate provides certain Services for Covered Entity that involve the Use and Disclosure of Protected Health Information (“PHI”) that is created, received, transmitted, or maintained by Business Associate for or on behalf of Covered Entity, pursuant to the Medtronic CareLink Network Terms of Use and Device Manager and Medtronic Computer Agreement, dated _____, 20__ and such other agreements in which the Parties expressly agree to rely on this BAA for the protection of PHI (each a “Services Agreement” and collectively the “Services Agreements”).

B. WHEREAS, The Parties are committed to complying with the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), as amended by the Health Information Technology for Economic and Clinical Health Act (the “HITECH Act”), and their implementing regulations, including the Standards for the Privacy of Individually Identifiable Health Information, 45 C.F.R. Part 160 and Part 164, Subparts A and E (the “Privacy Rule”), the Breach Notification Standards, 45 C.F.R. Part 160 and 164 subparts A and D (the “Breach Notification Rule”), and the Security Standards, 45 C.F.R. Part 160 and Part 164, Subpart C (the “Security Rule”), (collectively “HIPAA”), all as amended from time to time.

C. WHEREAS, The Parties are also committed to complying with the California Confidentiality Laws (defined below).

E. WHEREAS, The Privacy and Security Rules require Covered Entity and Business Associate to enter into a business associate agreement that meets certain requirements with respect to the Use and Disclosure of PHI. This BAA, sets forth the terms and conditions pursuant to which PHI, and, when applicable, Electronic Protected Health Information (“EPHI”) shall be handled, in accordance with such requirement.

NOW THEREFORE, in consideration of the mutual promises below and the exchange of information pursuant to this BAA, the Parties agree as follows:

AGREEMENT

1. DEFINITIONS

*Approved by the County of Monterey Board of Supervisors on 11/01/16
and revised on 12/09/16*

(c) Use PHI to provide Data Aggregation Services for the Health Care Operations of Covered Entity, if not prohibited by the Services Agreement and as permitted by 45 C.F.R. § 164.504(e)(2)(i)(B);

(d) Use PHI if necessary for the proper management and administration of Business Associate, including without limitation monitoring the quality, safety, and performance of its devices, or to carry out the legal responsibilities of Business Associate as permitted by 45 C.F.R. § 164.504(e)(4)(i);

(e) Disclose PHI for the proper management and administration of Business Associate, including without limitation monitoring the quality, safety, and performance of its devices, or to carry out the legal responsibilities of Business Associate as permitted under 45 C.F.R. § 164.504(e)(4)(ii), provided that Disclosures are Required by Law, or Business Associate obtains reasonable assurances from the person to whom the information is Disclosed that it will remain confidential and be Used or further Disclosed only as Required by Law or for the purpose for which it was Disclosed to the person, and that such person will notify the Business Associate of any instances of which such person is aware that the confidentiality of the information has been breached;

(f) Use PHI to report violations of law to appropriate Federal and state authorities, consistent with 45 C.F.R. § 164.502(j)(1); and

(g) De-identify any PHI obtained by Business Associate under this BAA in accordance with 45 C.F.R. § 164.514 and Use or Disclose such de-identified information only as not prohibited to provide Services pursuant to the Services Agreement between the Parties, or with the prior written approval of Covered Entity.

3. RESPONSIBILITIES OF THE PARTIES WITH RESPECT TO PHI

3.1. Responsibilities of Business Associate. With regard to its Use and/or Disclosure of PHI, Business Associate shall:

(a) Notify the Privacy Officer of Covered Entity, in writing, of: (i) any Use and/or Disclosure of the PHI that is not permitted or required by this BAA; (ii) any Security Incident of which Business Associate becomes aware; and (iii) any suspected Breach. Such notice shall be provided within five (5) business days of Business Associate's discovery of such unauthorized access, acquisition, Use and/or Disclosure. Notwithstanding the foregoing, the Parties acknowledge the ongoing existence and occurrence of attempted but ineffective Security Incidents that are trivial in nature, such as pings and other broadcast service attacks, and unsuccessful log-in attempts. The Parties acknowledge and agree that this Section 3.1(a) constitutes notice by Business Associate to Covered Entity of such ineffective Security Incidents and no additional notification to Covered Entity of such ineffective Security Incidents is required, provided that no such Security Incident results in a Breach. A ransomware attack shall not be considered an ineffective Security Incident and shall be reported to Covered Entity, irrespective of whether such Security Incident results in a Breach. Business Associate shall investigate each Security Incident or unauthorized access, acquisition, Use, or Disclosure of PHI, or

*Approved by the County of Monterey Board of Supervisors on 11/01/16
and revised on 12/09/16*

Entity to the Secretary of the Department of Health and Human Services (“Secretary”) in a time and manner designated by the Secretary for purposes of determining Covered Entity’s or Business Associate’s compliance with the Privacy Rule. In addition, Business Associate shall promptly make available to Covered Entity such books, records, or other information relating to the Use and Disclosure of PHI for purposes of determining whether Business Associate has complied with this BAA or maintains adequate security safeguards, upon reasonable request by Covered Entity;

(f) Document Disclosures of PHI and information related to such Disclosure and, within thirty (30) days of receiving a written request from Covered Entity, provide to Covered Entity such information as is requested by Covered Entity to permit Covered Entity to respond to a request by an individual for an accounting of the Disclosures of the individual’s PHI in accordance with 45 C.F.R. § 164.528. At a minimum, the Business Associate shall provide the Covered Entity with the following information: (i) the date of the Disclosure; (ii) the name of the entity or person who received the PHI, and if known, the address of such entity or person; (iii) a brief description of the PHI Disclosed; and (iv) a brief statement of the purpose of such Disclosure which includes an explanation of the basis for such Disclosure. In the event the request for an accounting is delivered directly to the Business Associate, the Business Associate shall, within ten (10) days, forward such request to the Covered Entity. The Business Associate shall implement an appropriate recordkeeping process to enable it to comply with the requirements of this Section;

(h) Disclose to its Subcontractors or other third parties, and request from Covered Entity, only the minimum PHI necessary to perform or fulfill a specific function required or permitted hereunder;

(i) If all or any portion of the PHI is maintained in a Designated Record Set:

(i) Upon ten (10) days’ prior written request from Covered Entity, provide access to the PHI to Covered Entity to meet a request by an individual under 45 C.F.R. § 164.524. Business Associate shall notify Covered Entity within ten (10) days of its receipt of a request for access to PHI from an Individual; and

(ii) Upon ten (10) days’ prior written request from Covered Entity, make any amendment(s) to the PHI that Covered Entity directs pursuant to 45 C.F.R. § 164.526. Business Associate shall notify Covered Entity within ten (10) days of its receipt of a request for amendment of PHI from an Individual;

(j) To the extent that Business Associate carries out one or more of Covered Entity’s obligations under the Privacy Rule, Business Associate shall comply with the requirements of the Privacy Rule that apply to Covered Entity in the performance of such obligations;

(k) Unless prohibited by law, notify the Covered Entity within five (5) days of the Business Associate’s receipt of any request or subpoena for PHI. To the extent

Associate's receipt of written notice of such breach, if the breach is not cured to the satisfaction of Covered Entity.

4.3 Automatic Termination. This BAA shall automatically terminate without any further action of the Parties upon the termination or expiration of Business Associate's provision of Services to Covered Entity.

4.4 Effect of Termination. Upon termination or expiration of this BAA for any reason, Business Associate shall: (i) retain only that PHI which is necessary for Business Associate to continue its proper management and administration or carry out its legal responsibilities; (ii) continue to extend the protections of this BAA to the PHI for as long as Business Associate retains PHI; and (iii) limit further Uses and Disclosures of such PHI to those purposes that make the return or destruction of the PHI not feasible and subject to the same conditions as set out in Section 2 above, which applied prior to termination; and (iv) return to Covered Entity the PHI retained by Business Associate when it is no longer needed by Business Associate for its proper management and administration or to carry out its legal responsibilities.

5. MISCELLANEOUS

5.1 Survival. The respective rights and obligations of Business Associate and Covered Entity under the provisions of Sections 2.1, 4.4, 5.7, 5.8, 5.11, and 5.12 shall survive termination of this BAA until such time as the PHI is returned to Covered Entity or destroyed. In addition, Section 3.1(i) shall survive termination of this BAA, provided that Covered Entity determines that the PHI being retained pursuant to Section 4.4 constitutes a Designated Record Set.

5.2 Amendments; Waiver. This BAA may not be modified or amended, except in a writing duly signed by authorized representatives of the Parties. To the extent that any relevant provision of HIPAA, the HITECH Act, or California Confidentiality Laws is materially amended in a manner that changes the obligations of the Parties, the Parties agree to negotiate in good faith appropriate amendment(s) to this BAA to give effect to the revised obligations. Further, no provision of this BAA shall be waived, except in a writing duly signed by authorized representatives of the Parties. A waiver with respect to one event shall not be construed as continuing, or as a bar to or waiver of any right or remedy as to subsequent events.

5.3 No Third Party Beneficiaries. Nothing express or implied in this BAA is intended to confer, nor shall anything herein confer, upon any person other than the Parties and the respective successors or assigns of the Parties, any rights, remedies, obligations, or liabilities whatsoever.

5.4 Notices. Any notices to be given hereunder to a Party shall be made via U.S. Mail or express courier to such Party's address given below, and/or via facsimile to the facsimile telephone numbers listed below.

If to Business Associate, to:

*Approved by the County of Monterey Board of Supervisors on 11/01/16
and revised on 12/09/16*

for the protection of Protected Health Information in connection with such other business associate relationship.

5.10 Insurance. In addition to any general and/or professional liability insurance required of Business Associate, Business Associate agrees to maintain, at its sole expense, liability insurance on an occurrence basis, covering any and all claims, liabilities, demands, damages, losses, costs and expenses arising from a breach of the obligations of Business Associate, its officers, employees, agents and Subcontractors under this BAA. Such insurance coverage will be maintained for the term of this BAA, and a copy of such policy or a certificate evidencing the policy shall be provided to Covered Entity at Covered Entity's request.

5.11 Legal Actions. Promptly, but no later than five (5) business days after notice thereof, Business Associate shall advise Covered Entity of any actual or potential action, proceeding, regulatory or governmental orders or actions, or any material threat thereof that becomes known to it that may affect the interests of Covered Entity or jeopardize this BAA, and of any facts and circumstances that may be pertinent to the prosecution or defense of any such actual or potential legal action or proceeding, except to the extent prohibited by law.

5.12 Audit or Investigations. Promptly, but no later than five (5) calendar days after notice thereof, Business Associate shall advise Covered Entity of any audit, compliant review, or complaint investigation by the Secretary or other state or federal agency related to compliance with HIPAA, the HITECH Act, or the California Confidentiality Laws.

5.13 Scope of Agreement. The Parties acknowledge that Covered Entity may disclose Individually Identifiable Health Information ("IIHI") to Business Associate that is not Protected Health Information under the terms of this BAA because it was not provided to Business Associate as Covered Entity's business associate. For example, this could include IIHI that Business Associate receives from Covered Entity for public health activities, when providing technical support as a part of treatment, or as a part of Research. Business Associate will use and disclose any such IIHI in accordance with applicable laws.

IN WITNESS WHEREOF, each of the undersigned has caused this BAA to be duly executed in its name and on its behalf as of the Effective Date.

BUSINESS ASSOCIATE

COVERED ENTITY

By: _____

By: Derek Erickson
Digitally signed by Derek Erickson
DN: cn=Derek Erickson, o=County of Monterey

Print Name _____

Print Name: Derek Erickson

*Approved by the County of Monterey Board of Supervisors on 11/01/16
and revised on 12/09/16*