

LIVANOVA HIPAA BUSINESS ASSOCIATE AGREEMENT

Healthcare professionals who use or request LivaNova products and services, acting as Covered Entities, agree to the terms of this Business Associate Agreement ("BAA") with LivaNova USA, Inc., acting as Business Associate ("Service Agreement"), which, as this BAA, may be amended by LivaNova USA, Inc. from time to time with written notice to Covered Entities.

1 DEFINITIONS

- 1.1 Capitalized terms used but not otherwise defined in this Agreement shall have the same meaning given to those terms by HIPAA, the HITECH Act, or any of the implementing regulations promulgated thereunder, including without limitation the Privacy Rule and the Security Rule, as in effect or as amended from time to time.
- 1.2 “*Protected Health Information*” or “*PHI*” has the same meaning as the term “protected health information” in 45 C.F.R. § 160.103 of the Privacy Rule, limited to the information created or received by Business Associate for or on behalf of Covered Entity for the purposes of the Services. For the avoidance of doubt, the term Protected Health Information shall include Electronic Protected Health Information (or “*Electronic PHI*”).
- 1.3 “*Services*” means the services provided by Business Associate to Covered Entity that involve the use and/or disclosure of Protected Health Information for and/or on behalf of Covered Entity. Services may include, but are not limited to: ongoing product maintenance; technical consultation and support regarding LivaNova products, including on-site support at Covered Entity’s facilities; physician referral assistance; patient coordination of care; insurance verification, preauthorization, predetermination, and appeals; product end of service or near end of service estimations; analysis of patient data and health information to generate information on product use, performance and status; combining PHI or other information provided under this Agreement with other patient data not provided under this Agreement to generate product status information; use of web-based applications for product and technical support and product status information; and/or providing education regarding LivaNova products.
- 1.4 “*Services Agreement*” means any present or future contractual arrangement(s) between Covered Entity and Business Associate under which Business Associate provides Services to Covered Entity.

2 OBLIGATIONS AND ACTIVITIES OF BUSINESS ASSOCIATE

- 2.1 Acknowledgement. Business Associate acknowledges and agrees that all PHI that is created by or received from Covered Entity and used by or disclosed to Business Associate or created or received by Business Associate on Covered Entity’s behalf for the purpose of the Services or pursuant to the Services Agreement shall be subject to this Agreement.
- 2.2 Use and Disclosure. Business Associate agrees not to use or disclose PHI other than as permitted or required by this Agreement or the Services Agreement or as Required by Law.
- 2.3 Appropriate Safeguards. Business Associate agrees to use appropriate physical, technical and administrative safeguards and comply, where applicable, with the Security Rule with respect to Electronic PHI to prevent the use or disclosure of PHI other than as provided for by this Agreement.
- 2.4 Reporting. Business Associate agrees to promptly report to Covered Entity following Business Associate’s discovery of: (a) any use or disclosure of PHI not provided for by this Agreement, or (b) any Breach or Security Incident of which it becomes aware, but in no case later than thirty (30) days after discovery of either (a) or (b); provided that notice is hereby deemed given for attempted but Unsuccessful Security Incidents and no further notice of such Unsuccessful Security Incidents will be given. “*Unsuccessful Security Incidents*” include but are not limited to firewall pings and other broadcast attacks, port scans, unsuccessful log-on attempts, denial-of service attacks, and any combination of the foregoing that do not result in unauthorized access, acquisition, Use or Disclosure of PHI. The notice

shall include, to the extent available, the identification of each individual whose Unsecured PHI has been, or is reasonably believed by Business Associate to have been, accessed, acquired or disclosed during the Breach, as well as any other available information set forth in 45 C.F.R. § 164.404(c).

- 2.5 Mitigation. Business Associate agrees to take reasonable steps to mitigate, to the extent practicable, any harmful effect that is known to Business Associate of a use or disclosure of PHI by Business Associate in violation of the requirements of this Agreement, the Privacy Rule, or the Security Rule.
- 2.6 Subcontractors. Business Associate shall ensure that all Subcontractors that create, receive, maintain or transmit PHI on behalf of Business Associate agree in writing to substantially the same restrictions and conditions that apply to Business Associate with respect to such PHI.
- 2.7 Access to Designated Record Sets. To the extent that Business Associate maintains PHI in a Designated Record Set, within thirty (30) days of a request by Covered Entity, Business Associate agrees to provide access to PHI maintained in a Designated Record Set to Covered Entity in order to meet the requirements of 45 C.F.R. § 164.524. If Business Associate receives a request for access to PHI directly from an Individual, Business Associate shall forward such request to Covered Entity within fifteen (15) business days. Covered Entity shall have the sole responsibility to make decisions regarding whether to approve a request for access to PHI.
- 2.8 Amendments to Designated Record Sets. To the extent that Business Associate maintains PHI in a Designated Record Set, within thirty (30) days of a request by Covered Entity, Business Associate agrees to make any amendment(s) to PHI maintained in a Designated Record Set pursuant to 45 C.F.R. § 164.526 as necessary to comply with 45 C.F.R. § 164.526. If Business Associate receives a request for an amendment to PHI directly from an Individual, Business Associate shall forward such request to Covered Entity within fifteen (15) business days. Covered Entity will have the sole responsibility to make decisions regarding whether to approve a request for amendment to PHI.
- 2.9 Access to Books and Records. Business Associate agrees to make its internal practices, books, and records relating to the use and disclosure of PHI created or received by Business Associate for and/or on behalf of Covered Entity available to the Secretary of the U.S. Department of Health and Human Services (“Secretary”) for purposes of the Secretary determining Covered Entity’s and Business Associate’s compliance with the Privacy Rule or the Security Rule.
- 2.10 Accountings. Business Associate agrees to document disclosures of PHI and information related to such disclosures as would be required to respond to a request by an Individual for an accounting of disclosures of PHI in accordance with 45 C.F.R. § 164.528 and the HITECH Act. Within thirty (30) days of Covered Entity’s request for an accounting of disclosures of PHI, Business Associate agrees to make available to Covered Entity such information in Business Associate’s possession as would be required for Covered Entity to respond to a request by an Individual for an accounting of disclosures of PHI in accordance with HIPAA. If Business Associate receives a request for an accounting directly from an Individual, Business Associate shall forward such request to Covered Entity within ten (10) business days. Covered Entity will have the sole responsibility to provide an accounting of disclosures.
- 2.11 To the extent Business Associate is required to carry out Covered Entity’s obligations under the Privacy Rule (and only to the extent specified in the Services Agreement), Business Associate agrees to comply with the requirements of the Privacy Rule that apply to Covered Entity in performing such obligations.

3 PERMITTED USES AND DISCLOSURES BY BUSINESS ASSOCIATE

- 3.1 Services. Except as otherwise limited in this Agreement, Business Associate may use or disclose PHI to provide Services or to perform functions, activities, or services as specified in the Services Agreement, as required, for or on behalf of Covered Entity, provided that such use or disclosure would not violate HIPAA if done by Covered Entity.
- 3.2 Minimum Necessary Standard. Business Associate shall only request, use and disclose the minimum amount of PHI reasonably necessary to accomplish the purpose of the request, use or disclosure.

- 3.3 Use for Administration of Business Associate. Business Associate may use PHI for the proper management and administration of Business Associate and/or to carry out the present and/or future legal or regulatory responsibilities of Business Associate.
- 3.4 Disclosure for Administration of Business Associate. Business Associate may disclose PHI for the proper management and administration of Business Associate, provided that: (a) disclosures are required by law; or (b) Business Associate obtains reasonable assurances from the third party to whom the PHI is disclosed that such third party will (i) protect the confidentiality of the PHI, (ii) use or further disclose the PHI only as required by law or for the purpose for which it was disclosed to the third party, and (iii) notify Business Associate of any instances of which it is aware in which the confidentiality of the PHI has been breached.
- 3.5 Data Aggregation. Business Associate may use PHI to provide Data Aggregation services relating to the Health Care Operations of Covered Entity if required or permitted under this Agreement or the Service Agreement.
- 3.6 De-Identified Information. Business Associate may de-identify PHI in accordance with 45 CFR § 164.514(a)-(c).

4 OBLIGATIONS OF COVERED ENTITY

- 4.1 Permissible Requests by Covered Entity. Except as set forth in Section 3, Covered Entity shall not request Business Associate to use or disclose PHI in any manner that would not be permissible under the Privacy Rule if done by Covered Entity.
- 4.2 Minimum Necessary PHI. When Covered Entity discloses PHI to Business Associate, Covered Entity shall provide only the minimum amount of PHI reasonably necessary for Business Associate to carry out the Services.
- 4.3 Permissions; Restrictions. Covered Entity warrants that it has obtained and will obtain any consents, authorizations and/or other legal permissions required under HIPAA and any other applicable law for the disclosure of PHI to Business Associate.
- 4.4 Notices by Covered Entity. Covered Entity shall promptly notify Business Associate of:
 - (a) any limitations in its notice of privacy practices in accordance with 45 C.F.R. § 164.520, and shall specifically identify such limitations, to the extent that such limitations may affect Business Associate's use or disclosure of PHI for the purposes described in this Agreement.
 - (b) any changes in, or revocation of, permission by an Individual to use or disclose PHI, to the extent that such changes may affect Business Associate's use or disclosure of PHI for the purposes described in this Agreement.
 - (c) any restriction to the use or disclosure of PHI that Covered Entity has agreed to in accordance with 45 C.F.R. § 164.522, to the extent that such restriction may affect Business Associate's use or disclosure of PHI for the purposes described in this Agreement.
 - (d) address for notices: LivaNova USA, Inc., 100 Cyberonics Blvd, Houston, TX 77058; Attention: Chief Privacy Officer

5 TERM AND TERMINATION

- 5.1 Term. This Agreement shall be effective as of the Effective Date and shall expire when all of the PHI provided by Covered Entity to Business Associate, or created or received by Business Associate for and/or on behalf of Covered Entity, is destroyed or returned to Covered Entity, or, if it is infeasible to return or destroy PHI, protections are extended to such PHI in accordance with this Section 5.
- 5.2 Termination Upon Breach. Either Party (the "*Non-Breaching Party*") may terminate this Agreement and any provisions of the Services Agreement that involve the use or disclosure of PHI if the other Party (the

“Breaching Party”) has breached a material term of this Agreement and failed to cure such breach within thirty (30) days following written notice of the breach from the Non-Breaching Party.

5.3 Effect of Termination.

- (a) Except as provided in Section 5.3(b), upon termination of this Agreement for any reason, Business Associate shall: (i) return to Covered Entity or destroy all PHI in its possession or control which was created or received by Business Associate for and/or on behalf of Covered Entity, including PHI in the possession of subcontractors of Business Associate; and (ii) not retain copies of the PHI.
- (b) In the event that Business Associate reasonably determines that returning or destroying the PHI is infeasible, Business Associate shall extend the protections of this Agreement to such PHI and limit further uses and disclosures of such PHI to those purposes that make the return or destruction infeasible, for so long as Business Associate maintains such PHI.

6 GENERAL

- 6.1 Regulatory References. A reference in this Agreement to a section in HIPAA, the HITECH Act, or any of the implementing regulations promulgated thereunder, including without limitation the Privacy Rule and the Security Rule, means the section as in effect or as amended or modified from time to time, including any corresponding provisions of subsequent superseding laws or regulations.
- 6.2 Interpretation. Any conflict, inconsistency or ambiguity in or between this Agreement and HIPAA or the HITECH Act shall be resolved in favor of a meaning that permits the Parties to comply with HIPAA and the HITECH Act and any implementing regulations promulgated thereunder, including but not limited to the Privacy Rule and the Security Rule.
- 6.3 Amendment. The Parties agree to take such action as is necessary to amend this Agreement from time to time as is necessary for the Parties to comply with the requirements of HIPAA. No amendments or modifications to the Agreement shall be effective unless executed by both Parties in writing.
- 6.4 Survival. The following sections shall survive the expiration or termination of this Agreement: Sections 0 (Definitions), 5.3 (Effect of Termination) and 6 (General).
- 6.5 Conflicts. In the event of any conflict or inconsistency between this Agreement and the Services Agreement or any other contract between Business Associate and Covered Entity related to the subject matter of this Agreement, the provisions of this Agreement shall control.
- 6.6 Entire Agreement & Counterparts. This Agreement constitutes the entire agreement between the Parties with respect to the subject matter herein and supersedes any prior business associate agreement or addendum entered into by the Parties relating to this subject matter. This Agreement may be executed in counterparts, each of which when taken together shall constitute one original. Any PDF or facsimile signatures to this Agreement shall be deemed original signatures to this Agreement.