

This Agreement applies to the Services (defined below) provided in conjunction with the Merlin.net™ Patient Care Network.

**IMPORTANT– Please read the following Agreement together with the documents referred to on it carefully before proceeding. This is a legal document between you and us (as both terms are defined below). Before using the Services (defined below), you should read carefully this Agreement as it governs use of the Services.**

**Your use of the Services constitutes, and is conditioned upon, your agreement to be bound by this Agreement. By clicking “accept”, you explicitly consent and agree that this Agreement will apply to your use of Merlin.net. If you, or a person on whose behalf you are using Merlin.net, do not agree to this Agreement, do not click accept and do not use Merlin.net.**

**By accepting this Agreement and using Merlin.net, you affirm that you are agreeing either on your own behalf, or on behalf of another person for whom you have actual authority to legally bind that person to this Agreement. If you are a person accessing and using Merlin.net on behalf of, or for the benefit of, any corporation, partnership, hospital, national health service organization, or other entity with which you are associated with, employed, or engaged by (a “Clinic”), then you are agreeing to this Agreement on behalf of both yourself and such Clinic, and you represent and warrant that you are duly authorized to bind such Clinic to this Agreement.**

Any terms in any purchase order or other documentation issued by or on behalf of you that contains additional or conflicting terms or purports to replace, reject, modify, or be a counteroffer to this Agreement are expressly rejected and are void as such.

Any words following the terms "including," "include," "in particular," "for example" or any similar phrase shall be construed as illustrative and shall not limit the generality of the related general words. Headings in this Agreement are for your convenience only, and do not limit, define, or fully explain each section.

**1. Information about Us:** Merlin.net is a Site operated by Abbott.

**2. Key Terms:** The following terms have the following meaning in this Agreement:

**Administrator.** The Merlin.net system administrator to whom the Clinic provides an administrator ID for creating, administering and maintaining clinic IDs.

**Agreement.** These Terms and Conditions, together with the documents referred to herein, including any updates posted at [www.merlin.net](http://www.merlin.net) or other such URL as we may provide.

**Commands.** Commands or parameters you directly submit into the Services or that you direct us to submit on your behalf that are transmitted to a Monitor to assist you in monitoring and/or managing certain Patient's Devices. Commands are not Data.

**Data Protection Laws.** All applicable laws, rules, regulations, directives and governmental requirements relating in any way to the privacy, confidentiality, security, medical secrecy, integrity and protection of personal data, including without limitation the EU, Swiss and UK General Data Protection Regulations (“GDPR”), as amended or superseded from time to time, and any related national implementing legislation.

**Data.** Patient data or information collected from a Device through a Monitor and uploaded to the Services and data submitted by you through the Services.

**Device.** Any implanted cardiac device compatible with Merlin.net™ PCN that is obtained from us or any of our subsidiaries or affiliates.

**Heightened Cybersecurity Requirements.** All applicable laws, rules, regulations, directives and governmental requirements, and national standards, or industry or public authority schemes and sanctions, which are applicable to you or your Users relating to the security of network and information systems and security breach and incident reporting requirements, in particular the Cybersecurity Directive ((EU) 2016/1148), Commission Implementing Regulation ((EU) 2018/151), or applicable national implementing legislation, the Network and Information Systems Regulations 2018 (SI 506/2018), all as amended or updated from time to time.

**Locations.** Any place where you receive the Services or where the Services are performed. For example, “your Locations” include the clinical sites where Patients are treated. “Our Locations” include our facilities or other places where we perform the Services.

**Merlin.net Privacy Notice.** The Privacy Notice available at <https://www.cardiovascular.abbott/int/en/policies/merlin-net.html>.

**Monitor.** Electronic equipment or applications in whatever form used to transmit Data and/or transmit/receive Commands as part of the Services and to assist the Clinic or User in monitoring and/or managing a Patient's Device. Monitors may be portable and may include, smartphones, tablets, tabletop transmitters and other electronic equipment used by a Patient or by medical personnel. Monitors may also include any other hardware on which the Patient Mobile App is installed. Monitors may or may not be provided and/or supported by us.

**Patient.** Any individual patient whose Abbott Device a Clinic or User monitors and/or manages via the Services.

**Patient Mobile App.** A mobile application provided by us and used as a Monitor by a Patient in connection with a Patient's use of a Device.

**Services.** The online and other services and hardware we provide to you, each where offered, under this Agreement associated with the Merlin.net PCN located at [www.merlin.net](http://www.merlin.net), or other such URL ("**Merlin.net**" or "**Site**") as Abbott may provide to you, and which is used to support the Devices; technical support and maintenance; training; Patient education and assistance, including with the setting up and activation of remote monitoring on Merlin.net, including the remote, contactless pairing of the Device to a Monitor where such Services are available; collection and hosting of Device-related Data; reporting; and upon request, assistance with the interpretation or analysis of certain Device-related information. The Services may also include, upon your instructions and authorization, and following Patient enrolment, Abbott directly contacting Patients on your behalf to provide online and/or telephone support related to Monitor set-up, its operation and/or connectivity to Merlin.net and/or to ship a separate Monitor, where necessary and available. The Services may request provision by you of a specific login to Merlin.net for Abbott to support patient enrolment. Depending on the Device implanted in a Patient, the Services may permit you to tell your Patient about adjustments you make to their medications or permit you to make other treatment changes. The Services do not include the provision of any medical advice or assistance by Abbott to Patients. The Services are designed exclusively for the support of Abbott Devices obtained from us or our distributors.

**User.** Any medical or healthcare provider, physician (and their duly authorized representatives and agents) or other user associated with a Clinic and provided by that Clinic with user credentials to access and use Merlin.net.

**We, us, our and/or Abbott.** "We", "us" and "our" will refer to the relevant Abbott company as set out in Section 39 which is the counterparty to this Agreement. The relevant Abbott company may use other Abbott affiliated companies to provide and perform the Services. "Parties" means you and the relevant Abbott company for your Location.

**You, your, and yours.** The Clinic, Administrator or User.

**3. Description of the Merlin.net Services:** The Services are designed to assist you in monitoring and managing aspects of Patient Data and/or Devices and, where compatible, export Data to an electronic health record system. The Services are dependent upon access to the internet, telecommunication systems, third-party service providers, platforms, software and Monitors, that may not be provided by us. We are not responsible or liable for any third party's performance, delayed performance, errors, damage or loss of Data or non-performance. The Services allow the Clinic to remotely gather certain information about the Patient's Device from the Clinic's location and, where offered and approved, may allow Users to remotely adjust a Patient's Device.

Services are not health services directly used by Patients, and we are not a provider or supplier of any health care services. YOU SHOULD INSTRUCT YOUR PATIENTS TO CALL YOU OR LOCAL EMERGENCY SERVICES IF THEY SUSPECT THEY MAY HAVE A MEDICAL EMERGENCY. Our technical support personnel are not authorized to tell the Clinic's Patients about the substance, meaning, or possible consequences of any Data transmitted from the Patient or their Device.

The Services may be limited from time to time, and we cannot guarantee that the Services will be available at all times. To function properly, the Services require many kinds of mechanical, electrical, computational, transmission, communication and human factors, each of which are subject to limitations, errors, and untimely failures from time to time. Many of those factors are outside the control of either party.

**4. Service Access:** Access to the clinical parts of our Site is restricted to Users. Users of our Site are provided with unique User IDs by the Clinic with which they are associated and must choose a password of their choice to sign on to our Site. Users must provide personal contact information, and you must ensure that your information is kept up to date at all times. User IDs and passwords constitute an electronic signature and will be used by us to authenticate access to our Site. If a User opts to sign onto Merlin.net, the User will be able to take advantage of the non-public sections of our Site. If a User opts not to sign onto our Site, their access to our Site will be restricted to the public sections of our Site only. If you are provided with a User ID, password or any other piece of information as part of our security procedures, you must treat such information as confidential, and you must not disclose it to any third party. We have the right to disable any User ID at any time, if in our opinion, you have failed to comply with any of the provisions of this Agreement. You may only use our Site as set out in this Agreement. Any illegal or unauthorized use of our Site shall constitute a violation of this Agreement. You do not have permission to access our Site in any way that violates this Agreement or breaches any applicable law. You agree to keep your and your Patients' Data accurate, current and complete. You may print off or download extracts of page(s) from our Site for your use in Patient care or insertion into a Patient's electronic health records only.

**5. Content:** Our Site is intended for the exclusive use and support of certain Abbott Devices. You acknowledge and agree that the Site and the Services are provided to enhance your care of your Patients, and you understand that these are not a substitute for your professional judgment or for your responsibilities to your Patients. Unless otherwise stated, our Site is for information only. Health information content appearing on Merlin.net is based on information provided by health care practitioners and Device-related Data transmissions from Patients. Health information content appearing on Merlin.net, is not intended as, and shall not be received or construed as Patient-specific advice or a substitute for Patient-specific advice. Any of the health information content on Merlin.net may be out of date at any given time, and we are under no obligation to update such content since it is based on information provided by Users and Device-related data transmissions from your Patients.

YOU ACKNOWLEDGE THAT WE ARE NOT A HEALTHCARE PROVIDER AND DO NOT PROVIDE MEDICAL ADVICE TO PATIENTS. YOU ACKNOWLEDGE THAT THE HEALTH INFORMATION CONTENT ON OUR SITE IS NOT INTENDED NOR RECOMMENDED AS A SUBSTITUTE FOR PROFESSIONAL MEDICAL ADVICE, IS FOR GENERAL INFORMATION ONLY, AND IS DESIGNED TO SUPPORT, NOT REPLACE, THE RELATIONSHIP THAT EXISTS BETWEEN HEALTH CARE PRACTITIONERS AND THEIR PATIENTS. WE AND OUR OFFICERS, DIRECTORS, EMPLOYEES, AGENTS, AFFILIATES AND RELATED COMPANIES ASSUME NO RESPONSIBILITY FOR ERRORS OR OMISSIONS IN THE CONTENT, INCLUDING BUT NOT LIMITED TO HEALTH INFORMATION CONTENT, POSTED ON OUR SITE OR FOR THE ACCURACY, TRUTHFULNESS OR CONTENT, INCLUDING BUT NOT LIMITED TO HEALTH INFORMATION CONTENT, OF OUR SITE AND NEITHER YOU, NOR ANYONE WHO YOU MAY INFORM OF ITS CONTENTS, SHOULD RELY ON SUCH CONTENT FOUND ON OUR SITE.

YOU ARE SOLELY RESPONSIBLE AND LIABLE FOR THE COMMANDS AND YOUR RELIANCE ON, AND DECISIONS YOU MAKE WITH RESPECT TO, THE DATA AND OTHER INFORMATION DISPLAYED THROUGH THE SERVICES. WE ARE NEITHER RESPONSIBLE NOR LIABLE FOR THESE COMMANDS OR YOUR RELIANCE ON THE INFORMATION MADE AVAILABLE THROUGH THE SERVICES. Our personnel are not authorized to tell Patients about the substance, meaning, or possible consequences of any Data.

**6. Prohibited uses of our Site and Services:** We reserve the right to disable any User ID at any time if, in our opinion, you have failed to comply with any of the provisions of this Agreement applicable to you. When using our Site you may not engage in the prohibited uses set out below. Where required by law, Users must neither enrol a Patient nor create any Patient profile in Merlin.net without having first obtained their informed, voluntary and explicit consent. You agree that you will NOT use the Services or Site:

- (i) to harm or attempt to harm any person, including minors, or gather, store or upload data on any Patient or person without first having received their prior consent, where required by applicable law, or without otherwise being authorized to do so;

- (ii) to transmit advertising or other unsolicited promotional materials, or frame or link to our Site, unless we expressly authorize such frame or link in writing;
- (iii) to copy, reproduce, republish, upload, post, transmit, export or distribute in any way any material, documentation, or other information from or about the Services without our prior written approval, except as specifically provided in this Agreement or where you have obtained our prior written approval to integrate the Services into your electronic health records system; except to the extent such restriction is prohibited under applicable law;
- (iv) in an unlawful manner or otherwise violate any law, statute, ordinance or regulation;
- (v) to attempt to use, resell, redistribute, broadcast or transfer the health information content or use the health information content derived from our Site in a searchable, machine-readable database, except as otherwise authorized or used in a Patient's electronic medical record;
- (vi) to collect personal information about Users or Patients in violation of the Merlin.net Privacy Notice or otherwise;
- (vii) to upload, post, email, transmit, store or otherwise make available any material that contains viruses or any other computer code, files or programs designed to harm, interfere or limit the normal operation of the Site or the Services or designed to surreptitiously intercept or expropriate any system, Data or personal information;
- (viii) to interfere with or disrupt the Site (including accessing the Site through any automated means, such as scripts or web crawlers), or any servers or networks connected to the Services, or any policies, requirements or regulations of networks connected to our Site (including any authorized access to use or monitoring of data or traffic thereon) or otherwise use any device, software, or routine to interfere with the proper working of our Site or with any other person's use of our Site;
- (ix) to disclose information about the Services or Site features or performance to any third party without our prior consent, except as required for legal or regulatory purposes or to assist in the provision of your medical treatment of a Patient or otherwise use our Site in any manner that could damage, disparage, or otherwise negatively impact us;
- (x) to create derivative works from, integrate with any other computer systems or programs, reverse engineer, decompile, or disassemble the Services, Monitor or any software, hardware, components or other parts that make up the Services,
- (xi) to gather, store or upload personal information, including health information, on any other persons of the Site or Services or any Patient with a Device in connection with any of the foregoing prohibited activities, or
- (xii) to infringe any person's intellectual property rights (including uploading any content to which you do not have the right to upload).

If you print, copy, republish or download any part of our Site in breach of this Agreement, you must destroy any unauthorized copies of materials you may have made.

**7. Trademarks:** Merlin.net™ PCN and related brands are trademarks and service marks of Abbott and its related companies in various jurisdictions and any goodwill that may arise from the Merlin.net PCN™ and related brands trademarks and service marks via use of the Services shall inure to the benefit of and, where applicable, shall be assigned to Abbott. Other trademarks are the property of their respective owners. No licence or right, express or implied, is granted to you in any of the aforesaid trademarks. You further agree that you shall not remove, obscure, or alter any proprietary notices (including trademark and copyright notices) that may be affixed to or contained within the Merlin.net™ PCN or Services. No use of any Abbott logo, service mark, trademark, trade name, or trade dress may be made without the prior written authorization of Abbott, except to identify the product or services of the company.

**8. Proprietary Rights:** You acknowledge and agree that Abbott and/or its licensors own all legal rights, titles and interest, including all copyrights, patents, trade secret rights, trademarks, and other intellectual property rights in and to the Merlin.net, Services and Monitors we provide, including but not limited to design, graphics, user interface, page headers, images, illustrations, audio clips, text, the scripts, database structures and software used to implement the Site, and any software or documents provided to you as a part of and/or in connection with the Services,

including all intellectual property rights that exist therein, whether registered or not, and wherever in the world they may exist. You further agree that the Merlin.net, Services and Monitors contain proprietary and confidential information that is protected by applicable intellectual property rights and other laws, including but not limited to copyright. You agree that you will not use such proprietary information or materials in any way whatsoever except for use of the Merlin.net and related Services in compliance with this Agreement. No portion of the Site or Services may be reproduced in any form or by any means, except as expressly permitted in this Agreement or where permitted by applicable law. You shall not remove any product or Device identification, copyright notices or proprietary restrictions from Merlin.net. You expressly acknowledge and agree that the Services are licensed and not sold to you, and that Abbott, its licensors, affiliates and suppliers, grant you a non-exclusive, non-sublicensable and non-transferable license to use Merlin.net on the basis of this Agreement, and that your use of Merlin.net is also subject to any rules or policies applied by Abbott's third-party providers. You therefore agree that Abbott and/or its licensors do not transfer to any User any ownership or proprietary rights in Merlin.net, any intellectual property rights, or any other technology, information or materials, and as between the Parties, Abbott, its affiliates, its suppliers, and its licensors, retain exclusive ownership of all rights, titles and interest in and to all aspects of Merlin.net, any intellectual property rights, and all other technology, information and materials, as well as any and all copies or modifications thereof (by whomever and whenever made). RIGHTS NOT EXPRESSLY GRANTED HEREIN ARE RESERVED BY ABBOTT AND/OR ITS LICENSORS. The use of this material and the associated rights of Abbott, its affiliates and its suppliers, are hereby acknowledged except solely to the extent that the foregoing is ineffective in certain countries/states/provinces/jurisdictions.

**9. Feedback:** Any data, comments or materials that you supply or if you transmit any ideas, information, concepts, know-how or techniques or materials to us or provide to Abbott in order to receive support or for improving or modifying the Services, Monitor or any software, hardware, components or other parts that make up the Services, including feedback data, such as questions, comments, suggestions or the like ("Feedback"), shall be deemed to be non-confidential and non-proprietary. Abbott shall have no obligation of any kind with respect to such Feedback and shall be free to reproduce, use, disclose, exhibit, display, transfer, create derivative works and distribute the Feedback (other than Data and personal information which might be included in the Feedback but is subject to section entitled "License" below) through our Site or otherwise, and your Feedback shall become the exclusive property of Abbott and can be used by Abbott for any purpose without compensation to you. Furthermore, Abbott shall be free to use any ideas, concepts, know-how or techniques contained in such Feedback for any purpose whatsoever, including developing, manufacturing and marketing products incorporating such Feedback.

**For Users in the EEA, Lebanon, Serbia, Switzerland, Turkey, Ukraine and United Arab Emirates:** Section 9 makes no restrictions on your moral rights or, where applicable, any financial rights under applicable copyright laws, and to the extent permitted by applicable law, you hereby waive, renounce or procure the waiver of all moral and/or financial rights in relation to Feedback that you supply or transmit to Abbott.

**10. License:** Abbott does not claim ownership of personal information that you transmit or submit to the Site or via the Services. By disclosing your personal information to Abbott, you grant it a worldwide, royalty-free, transferable, non-exclusive, sublicensable and fully paid up license to use, distribute, reproduce, modify, adapt, publish and translate such data for the purpose of providing you with the Services for the period in which Abbott is obligated to provide you with such Services. Abbott may create, access, retain, use or disclose to third-party researchers, aggregated, anonymized, de-identified (or pseudonymized to the extent permitted by your law) data derived from the Services for the purposes of research, to evaluate how the Services are provided, to evaluate its use and its various components and equipment, to evaluate performance or impact on clinical staff or across clinics, to enhance the functioning of the Site and Devices, to validate Site or Monitor upgrades, or for product development and quality and safety of medical devices. You agree that the license herein permits Abbott to take any such actions. Where personal information is provided to third-party suppliers to assist us with the provision of the Services, they are required to keep personal information confidential and secure and may only use personal information to the minimum extent necessary.

**11. Provision of the Services by Abbott:** We will provide the Services in accordance with this Agreement. The Services may be unavailable: (a) for planned or unplanned downtime, maintenance, modification, or suspension, (b) power utility failures (including load-shedding) and telecommunications failures, or (c) when caused by circumstances beyond our reasonable control, including without limitation, and where legally permitted, acts of God, acts of government, floods, fires, earthquakes, civil unrest, acts of terror, strikes or other labour problems (other than those involving our employees), Internet service provider failures or delays, failures or delays of any third party platforms, services or software or application stores or Monitors provided by third parties, utilized by the Patient in connection with the Services, or denial of service attacks.

Services support and training will be provided to the Clinic by Abbott's local service representative or distributor. We may provide additional online or telephone-based training and support for the Services and technical support may be provided by an Abbott affiliated company.

The Services may change over time as features are added or changed. We reserve the right from time to time and in our sole discretion to add, change, and remove certain functionality, and otherwise improve the Services. For the most current description of the Services at any time visit [www.merlin.net](http://www.merlin.net) or contact the service representative or distributor that handles your Clinic's customer account. We will make commercially reasonable efforts to notify you in advance of material changes and ask for your agreement to those change if required by applicable law. From time to time, there will be Service upgrades, or emergency updates, and we may not be able to provide the Services to you at those times. When reasonably possible, we will give you prior notice if we are unable to provide the Services.

We will use commercially reasonable efforts to ensure that Data and Commands transmitted via the Services is maintained accurately and is available to you free from viruses and other defects.

You agree that we are not responsible or liable for the form, availability, accuracy, timeliness, or content of any Data or Commands beyond such commercially reasonable efforts.

We may provide Monitors that are new or refurbished, and all warranties, conditions and other terms implied by law or statute are, to the fullest extent permitted by law, excluded from this Agreement.

We are not responsible for any delays, delivery failures, or any other loss or damage resulting from the transfer of Data and Commands over communications networks and facilities, including the internet, and you acknowledge that the Services may be subject to limitations, delays and other problems inherent in the use of such communications facilities.

As well as providing Merlin.net to the Clinic to monitor a Device and Data, Abbott will also provide the Clinic with technical and clinical support pursuant to our contract with the Clinic. The Clinic or a User may authorize Abbott staff to access Data where necessary for it to receive the Services, including to receive technical and clinical support, such as assistance with debugging, upgrading or troubleshooting the Services or interpreting Data transmitted from a Device. When Abbott undertakes this processing on the Clinic's behalf or at the Clinic's request, Abbott does so as a processor/operator.

**12. Clinic obligations:** As a condition of receiving the Services, the Clinic agrees that:

- (i) it is responsible for supervising, monitoring, and training its employees, representatives, contractors, agents, and others at the Clinic, and each User that it authorizes to use the Services at the Clinic's locations, to ensure proper use and security. The Clinic will limit access to the Services at its locations to duly authorized Users. The Clinic will be responsible for their Users' (a) use of the Services, (b) compliance with this Agreement and (c) for the consequences of any breach of security that is caused by such Users or that occurs at Clinic location.
- (ii) it will comply with the Services procedures, guidelines, updates, and changes as they exist from time to time;
- (iii) it will ensure all Users of the Services comply with this Agreement, user manuals, updates and any laws and regulations that apply, and Clinics are solely responsible and liable for any non-compliance;
- (iv) it and its Users will promptly report to us any defects or problems Users observe with the Services, and will fully cooperate with us in resolving such issues;

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- (v) it will promptly report to us any security incident at [cybersecurity@abbott.com](mailto:cybersecurity@abbott.com) or personal data breach at [cnprivacy@abbott.com](mailto:cnprivacy@abbott.com) connected to the Services that you observe or reasonably suspect, and fully cooperate with us, law enforcement or other applicable regulatory body in addressing the breach;
- (vi) upon our reasonable notice, it will make its locations available to us during normal business hours for technical service and support, and at other times for critical service and support;
- (vii) it acknowledges and agrees that the Services are provided to enhance the Clinic's care of its Patients, but you understand that the Services are not a substitute for your professional judgment or your responsibilities to your Patients;
- (viii) it will be responsible for providing health care to its Patients when the Clinic uses the Services, including conducting a timely review of the Data and following up by arranging appropriate health care to its Patient or, where applicable, scheduling for Patient monitoring; and
- (ix) it will be responsible for obtaining and maintaining any internet connections, power supplies, computing equipment, supplies, third-party software and personnel necessary for Users to receive the Services. The Services may require the use of software provided by unaffiliated third parties (e.g., a web browser and Adobe PDF viewer) ("**Third-Party Software**") to enable the full functionality of the Services. The Clinic's use of Third-Party Software shall be subject to the applicable terms and conditions set forth by the providers of such Third-Party Software, and the Clinic shall comply with such terms and conditions and, if applicable, pay fees for the use of such Third-Party Software. We disclaim all responsibilities, warranties, and liabilities relating to the use of Third-Party Software.

The Data available to the Clinic through the Services are not or intended to be electronic medical records. The Clinic must download and/or print any Data that the Clinic, in its sole discretion, deems necessary to include in Patient's medical records at the Clinic locations.

The Clinic will be provided with an administrator ID. The Administrator ID, User IDs and passwords are equivalent to an electronic signature, which will be used to authenticate access to and use of the Services. The Clinic is responsible for ensuring that the Administrator ID, User IDs and passwords for the Clinic locations are treated as confidential and are unique for each User. The Clinic is responsible for ensuring that all IDs and passwords are not disclosed to unauthorized persons for any reason, and you will be responsible for all actions that take place with the use of IDs and passwords. The Clinic acknowledges and agrees that we are not responsible for the internal management or administration of the Clinic's Users. We may audit the Clinic's use of IDs and passwords for proper use and access to the Services and to identify any changes made to the Data. If there is any reason to believe that an ID or password has been compromised, the Clinic will immediately take all actions necessary to change the affected password, remove the User ID or take such other steps as necessary to protect the Clinic's use of the Services, including by notifying us that the password should be changed. We will change IDs and passwords upon the Clinic's request and reserve the right to change them at any time in the event of a suspected or threatened security breach.

The Clinic shall ensure that all persons provided with a User ID and authorized to process Data have committed themselves and are contractually bound to confidentiality or are under an appropriate statutory obligation of confidentiality ("**Data Secrecy**"). All Users agree to adhere to this duty of Data Secrecy.

Any violation of any of the security requirements under this Agreement by a Clinic or a User may be considered a breach of this Agreement and may result in the immediate loss of the Clinic's or User's access to the Services. Both you and we will promptly report security violations to the other so that proper actions may be taken.

You will not disclose information about Service features or performance to any third party without our prior consent, except as required for legal, regulatory, or accreditation purposes, or to assist in the provision of medical treatment by you of a Patient.

**13. Mutual obligations:** You and we will cooperate to resolve any problems or faults in connection with the Services. You and we both agree to comply with all applicable laws, rules, and regulations that apply to use of the Services.

**14. Confidentiality:** You and we will protect and will take commercially reasonable steps to protect, as if it was its own, the other Party's confidential or proprietary information that is indicated as such. Each Party will use the other party's confidential or proprietary information only as allowed by this Agreement and in connection with the Services. Information will no longer be considered confidential if it becomes public without breach of this Agreement, is already known, is independently developed by the receiving Party apart from this Agreement, or is properly obtained from a third party that had a right to disclose the information.

**15. Abbott use of content and data:** You acknowledge that as a medical device manufacturer, Abbott is subject to certain legal requirements in relation to quality, safety and post-market vigilance and that as a consequence of these legal obligations on Abbott, Abbott may be required to use Services-related data which may be contained in Merlin.net or which relate to Monitors and Devices for the following purposes:

- (i) to improve the quality, security and effectiveness of medical devices and systems and to allow for the development of innovative and effective treatment of heart-related conditions;
- (ii) to validate Merlin.net Services functionality and upgrades, including monitoring and improving the safety and security of such services;
- (iii) where necessary to establish, exercise or defend legal claims or as otherwise required by applicable law; and
- (iv) where the Services or Devices are eligible for medical reimbursement or are otherwise entitled to social security, insurance or public funding.

In addition, Abbott may seek to use Data from the Services to conduct research, develop and test medical devices, including new and existing features and functionality and to test and improve the Merlin.net Services, the Monitors and Abbott Devices for product development, data analysis, statistical and survey purposes, and where it seeks to do so, will obtain your or your Patient's consent where required by law.

**16. Abbott processing of Patient and User personal data**

- (i) When providing the Services, Abbott will process personal information of Patients and Users on behalf of the Clinic. A description of the processing of personal information by Abbott is set out in Annex II to the Data Processing Agreement ("DPA") which follows this Agreement. Unless otherwise expressly provided in this Clause 16, the remaining provisions of the DPA are excluded from this Agreement and do not apply.

**For Clinics in Canada, the EEA, Japan, Switzerland and the UK only:**

- (ii) The DPA is hereby incorporated into this Agreement and applies to the processing of Patient personal data by Abbott on behalf of the Clinic. No other provision set out in this Section 16 shall apply.

**17. Your data privacy obligations:** The Clinic is required and agrees to inform Users and Patients about our processing of personal information in relation to use of the Services. The Clinic and its Users will only enrol those Patients in the Services from whom the Clinic has provided the Merlin.net Privacy Notice, and where required, has obtained prior consent. See <https://www.cardiovascular.abbott/int/en/policies/merlin-net.html>. Where the Clinic is required by applicable law to obtain Patient consent for the use of information for additional purposes, the Clinic will provide a copy of the executed consents to Abbott. It is a misuse of the Services to enter Data relating to a Patient or any other person without first providing the Merlin.net Privacy Notice to the Patient or other person, and where applicable, obtaining the Patient's written acknowledgement or consent, or confirmation that the Patient has read and accepted the Merlin.net Privacy Notice. Abbott will not accept any liability in relation to the Clinic's use of the Services, including the entering of Data relating to a Patient or any other person, where these conditions have not been satisfied.

**18. Security:** We use commercially reasonable efforts to maintain the ongoing confidentiality, integrity, availability and resilience of the Services. We agree to maintain any information security standards, such as ISO 27001 for the term of this Agreement. Communication between our Site



and User accounts is encrypted using secured socket layer (SSL) technology. We do not warrant that the Services will be uninterrupted or error-free or that the Services will comply with any Heightened Cybersecurity Requirements.

**19. Marketing:** Informational content provided by Users of the Services may be used to personalize and target content of any e-mails or SMS you may receive from us that are used to improve our service to you as a User. Visitors and/or Users of our Site will not receive any marketing solicitation from us as a result of visiting our Site nor will we sell or use the information other than in conjunction with the services provided via Merlin.net.

**20. Termination:** This Agreement is effective for as long as Clinic has an Administrator or User and shall continue in effect until terminated. The Clinic may end this Agreement at any time by giving us 30 days written notice. We may end this Agreement for your material breach by giving you 30 days written notice, unless you cure your breach in that period. We may end this Agreement at any time by giving you 90 days written notice.

**21. Liability exclusions and limitations:**

- (i) WE MAKE NO REPRESENTATIONS ABOUT THE SUITABILITY OF OUR SITE FOR ANY PURPOSE. MERLIN.NET™ PCN IS PROVIDED "AS IS" WITHOUT ANY GUARANTEES, CONDITIONS, OR REPRESENTATIONS OR WARRANTIES AS TO ITS ACCURACY. TO THE EXTENT PERMITTED BY LAW, WE AND OTHER MEMBERS OF OUR GROUP OF COMPANIES EXPRESSLY EXCLUDE AND DISCLAIM ALL WARRANTIES, EXPRESS OR IMPLIED, INCLUDING THE IMPLIED WARRANTIES OF NON-INFRINGEMENT, MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. WE DO NOT WARRANT THAT THE SERVICES OR DATA WILL BE ACCURATE, RELIABLE, COMPLETE, TIMELY, AVAILABLE, USEABLE, UNINTERRUPTED OR ERROR-FREE. The Internet cannot be guaranteed to be 100% secure, and we cannot ensure or warrant the security of any information you provide to us. IN NO EVENT SHALL WE, OR ANY OTHER MEMBERS OF OUR GROUP OF COMPANIES, BE LIABLE FOR ANY SPECIAL, INDIRECT OR CONSEQUENTIAL DAMAGES OR ANY DAMAGES WHATSOEVER RESULTING FROM USE, LOSS OF USE OF DATA, LOSS CAUSED BY A COMPUTER OR ELECTRONIC VIRUS, LOSS OF INCOME OR PROFIT, LOSS OF REPUTATION, LOSS OF OR DAMAGE TO PROPERTY, CLAIMS OF THIRD PARTIES OR OTHER LOSSES OF ANY KIND OR CHARACTER, WHETHER IN AN ACTION IN CONTRACT, NEGLIGENCE OR OTHER TORT (OR DELICT) OR ANY OTHER LEGAL ACTION, ARISING OUT OF OR IN CONNECTION WITH THE USE OR PERFORMANCE OF OUR SITE, EVEN IF WE HAVE BEEN ADVISED OF THE POSSIBILITY OF SUCH LOSSES, EXCEPT AS OTHERWISE EXPRESSLY SET OUT IN ANY APPLICABLE AND DULY EXECUTED TERMS AND CONDITIONS BETWEEN US AND OUR CUSTOMERS GOVERNING THE USE OF MERLIN.NET™ PCN. THIS LIMITATION OF LIABILITY APPLIES TO, BUT IS NOT LIMITED TO, THE TRANSMISSION OF ANY DISABLING DEVICE OR VIRUS THAT MAY INFECT YOUR EQUIPMENT, FAILURE OF MECHANICAL OR ELECTRICAL EQUIPMENT OR COMMUNICATION LINES, TELEPHONE OR OTHER INTERCONNECT PROBLEMS (FOR EXAMPLE, YOU CANNOT ACCESS YOUR INTERNET SERVICE PROVIDER), UNAUTHORIZED ACCESS OR OPERATOR ERRORS. NOTHING IN THIS AGREEMENT SHALL EXCLUDE OR LIMIT OUR LIABILITY FOR ANY LIABILITY WHICH CANNOT BE EXCLUDED OR LIMITED UNDER APPLICABLE LAW.
- (ii) SOME JURISDICTIONS DO NOT ALLOW THE EXCLUSION OR LIMITATION OF LIABILITY FOR CONSEQUENTIAL OR INCIDENTAL DAMAGES. ACCORDINGLY, THE ABOVE LIMITATION MAY NOT APPLY TO YOU. FURTHERMORE, NOTHING IN THESE TERMS LIMITS OR EXCLUDES ANY LIABILITY THAT CANNOT BE LIMITED OR EXCLUDED BY LAW.
- (iii) To the extent permitted by applicable law in no event will we be liable to the Clinic or Users (or the Clinic's patients, employees, contractors, or agents) for any indirect, special, consequential or pure economic losses, costs, damages, charges or expenses of any kind arising out of or in connection with this Agreement (whether in warranty, contract or tort, including negligence, delict, or product liability even if informed about the possibility thereof), including without limitation medical expenses, legal fees, loss of revenue or profits (whether direct or indirect), loss or interruption of business, loss of goodwill, loss of anticipated

- savings, loss of use, or loss or corruption of Data or information. In no event will Abbott or any of its any Abbott affiliated companies involved in providing the Services as a 'subprocessor' accept any form of liability or be jointly liable with Abbott.
- (iv) Except for the indemnification obligations set forth herein, our total aggregate liability to the Clinic (including any liability for the acts or omissions of our employees, agents, consultants and subcontractors) arising out of or in connection with this Agreement or the Services provided hereunder, whether in contract, tort (including negligence or breach of statutory duty), delict, misrepresentation, restitution or otherwise shall be limited to fixing, repairing or otherwise rectifying any Service faults, even if any such loss was foreseeable or contemplated by the Parties, or where applicable, shall not exceed the greater of the amount actually paid by the Clinic for the Services, USD\$100.00 or the equivalent amount in the Clinic's jurisdiction calculated based on the time of the claim.
  - (v) In no event will we be liable to the Clinic (or the Clinics patients, employees, contractors, agents or users) for any losses, costs, damages, charges or expenses resulting from loss, misappropriation, unauthorized access to or modification of Data by any third party, or from mistakes, omissions or delays in transmission of information, or from interruptions in telecommunications connections to the Service, viruses or failures of performance or from the impact of the Services on your information or communications systems, for interception or compromise of the Services, including without limitation the network services or any record or other communication provided by you, any Patient or by us under this Agreement.
  - (vi) Nothing in this Agreement limits or excludes liability for death or personal injury resulting from negligence, an act or omission for any damage or liability incurred as a result of our fraud or fraudulent misrepresentation or intentional misconduct, or blatant gross negligence, meaning a blatant indifference to a severe degree of negligence equivalent to reckless disregard.

**22. Indemnities:** We will indemnify the Clinic against any third party claim or action alleging an infringement of their patent, copyright, trademark, trade secret, or other intellectual property or proprietary right arising out of your receipt of the Services in accordance with this Agreement. As a condition of this protection, the Clinic must give us prompt written notice of the action or claim, give us the right to choose legal representation and control the defence, and fully cooperate with us in the defence of any such claim or action.

If any administrative, regulatory, or other third party legal action is brought against us, our employees, agents, or representatives, resulting in any fine, award of damages, or other costs (including legal fees and court costs) for a breach of your obligations and requirements under this Agreement, you agree to indemnify us for any such costs.

The indemnified party will have the right to defend or settle and/or to select legal representation and the indemnifying party shall provide all reasonable assistance, at your expense.

**23. Remedies:** Violations of this Agreement may be investigated and appropriate legal action may be taken, including civil, criminal or equitable relief. You understand and agree that Abbott, in its sole discretion, and without prior notice, may terminate your access to our Site, remove any unauthorized user content or exercise any other remedy available if we believe, in our sole discretion, that your conduct or the conduct of any person with whom we believe you act in concert with, or the user content that you provide, violates or is inconsistent with this Agreement or applicable law or violates our rights or the rights of our affiliates, licensors or another User of our Site. You agree that monetary damages may not provide us with a sufficient remedy for violations of this Agreement and you consent to injunctive/interdict or other equitable relief for such violations. A printed version of this Agreement and of any related notice given in electronic form shall be admissible in judicial or administrative proceedings based upon or relating to this Agreement to the same extent and subject to the same conditions as other business documents and records originally generated and maintained in printed form.

**24. Entire agreement:** This Agreement constitutes the entire agreement between the Parties and supersedes and extinguishes all previous agreements, promises, assurances, warranties, representations and understandings between them, whether written or oral, relating to its subject matter. Each party agrees that it shall have no remedies in respect of any statement, representation, assurance or warranty (whether made innocently or negligently) that is not set out

in this Agreement. Each party agrees that it shall have no claim for innocent or negligent misrepresentation or negligent misstatement based on any statement in this Agreement.

**25. Independent contractors:** The relationship between the Clinic and us is solely that of independent contractors and nothing in this Agreement is intended to create a partnership or joint venture between the Clinic and us.

**26. Assignment:** You cannot assign any of your rights or responsibilities under this Agreement without our prior written consent, including in connection with the transfer of control or ownership of your locations or medical practice. We understand that persons and entities under contract to you may perform certain administrative services on your behalf under this Agreement.

**27. Benefit of the Parties:** You and we specifically intend that you and we are the only beneficiaries of this Agreement. No Patient or other person or entity who is a third party to this Agreement, other than other members of our group of companies as expressly set out herein, shall have any rights under or in connection with this Agreement, unless otherwise entitled by law.

**28. Surviving terms:** Any part or promise of this Agreement that would, by its practical nature, survive the termination of this Agreement, will survive.

**29. Intervening forces:** If a party is prevented from performing either its obligations or its purposes under this Agreement due to causes beyond its control, including but not limited to, an act of God, public enemy, war, riot, disaster, storm, earthquake, other natural forces, by government order, decree or advisory, by public emergency, strike, significant curtailment of transportation systems or communications utilities, or by the intentional acts of anyone not a party to this Agreement, then that party, upon written notice to the other, will be excused from that performance for the reasonable duration of that event.

**30. Waiver:** If either party waives any breach of this Agreement, it will not be considered a waiver of any other breach of this Agreement. Our failure to insist on strict performance of any of the terms and conditions of this Agreement will not operate as a waiver by us of that or any subsequent default or failure of performance.

**31. Severability:** If, for any reason, any term, provision or part of this Agreement is invalid, illegal or cannot be enforced in any jurisdiction, all other terms, provisions or parts will remain in effect nor affect any other term, provision or part or invalidate or render unenforceable such term, provision or part in any other jurisdiction. The invalid or unenforceable part will be reformed only to the extent necessary to make it valid and enforceable and upon such determination, such reform will seek to give effect to the original intent of the Parties as set out in this Agreement to the greatest extent possible.

**32. Reservation of rights in services:** Subject to the limited rights expressly granted hereunder, we reserve all rights, title and interest in and to the Services, including all related intellectual property rights. No rights are granted to you other than as expressly set forth herein.

**33. Language:** The Parties agree that the English language will be the official language of this Agreement and all documents contemplated by this Agreement. If there is any conflict, apparent conflict or ambiguity between any of the clauses of this Agreement in the English language and the translated language, the wording of the English language shall prevail.

**34. Applicable law and place of venue:**

**General:** The terms of this Agreement shall be governed and construed as set out below in this Section without regard to its choice of law provisions. In the event of any conflict between the laws, rules, and regulations of the location of the Clinic and those of the governing law set out below for a particular jurisdiction, the laws, rules and regulations of the designated country and not the laws of the location of the Clinic shall govern to the fullest extent possible. Notwithstanding the foregoing, in the event of such breach or threatened breach of your obligations with respect to confidentiality or intellectual property, we will be entitled to equitable relief, including a restraining order, an injunction, specific performance and any other relief that may be available from any court of competent jurisdiction. You agree that this Agreement shall be fully performable in the location of the Clinic receiving the Services under this Agreement, and you agree that the jurisdiction and the venue are properly designated with respect to any proceedings arising from this Agreement or the relationship between the Parties hereto. The Parties hereby agree that the United Nations Convention on Contracts does not govern this Agreement for the International Sale of Goods.

**For Clinics in Belarus, EEA, Japan, and Switzerland:** This Agreement and any dispute or claim arising out of or in connection with it or its subject matter or formation (including non-contractual

disputes or claims) shall be governed by and construed in accordance with the laws of Ireland, except where the Clinic is a public entity such as a national health service organization, in which case this Agreement shall be governed by and construed in accordance with the laws of the location of the Clinic. Each party irrevocably agrees to submit to the exclusive jurisdiction of the Irish courts over any dispute or claim arising out of or in connection with this Agreement or its subject matter or formation (including non-contractual disputes or claims), except where the Clinic is a public entity such as a national health service organization, in which case the Parties agree to the exclusive jurisdiction of the location of the Clinic.

**35. Dispute Resolution:** If a dispute arises between the Parties regarding this Agreement, the Parties will attempt to resolve such dispute in good faith by direct negotiation by representatives of each Party. If such negotiation does not resolve the matter within twenty-eight (28) days after notice of the dispute is given, the matter will be resolved by the following alternative dispute resolution (“ADR”) procedure, except to the extent that this Agreement is subject to the exclusive jurisdiction of a country’s courts as expressly set out in Section 34.

To begin an ADR proceeding, a Party shall provide written notice to the other Party of the issues to be resolved by ADR. Within fourteen (14) days after its receipt of notice of ADR, the other Party may, by written notice, add additional issues to be resolved. Within twenty-one (21) days following receipt of the original ADR notice, the Parties shall select a mutually acceptable independent, impartial and conflicts-free neutral to preside over the proceeding. If the Parties are unable to agree on a mutually acceptable neutral within such period, each Party will select one independent, impartial and conflicts-free neutral and those two neutrals will select a third independent, impartial and conflicts-free neutral within ten (10) days thereafter. None of the neutrals selected may be current or former employees, officers or directors of either Party or its subsidiaries or affiliates. The Parties shall convene in a location mutually agreed upon to conduct a hearing before the neutral no later than fifty-six (56) days after selection of the neutral (unless otherwise agreed upon by the Parties).

The ADR process shall include a pre-hearing exchange of exhibits and summary of witness testimony upon which each Party is relying, proposed rulings and remedies on each issue, and a brief in support of each Party’s proposed rulings and remedies not to exceed twenty (20) pages. The pre-hearing exchange must be completed no later than ten (10) days prior to the hearing date. Any disputes relating to the pre-hearing exchange shall be resolved by the neutral. No discovery shall be permitted by any means, including depositions, interrogatories, requests for admissions, or production of documents. The language to be used in the ADR proceeding shall be English, unless otherwise agreed by the Parties.

The hearing shall be conducted on two (2) consecutive days, with each Party entitled to five (5) hours of hearing time to present its case, including cross-examination. The neutral shall adopt in its entirety the proposed ruling and remedy of one of the Parties on each disputed issue but may adopt one Party’s proposed rulings and remedies on some issues and the other Party’s proposed rulings and remedies on other issues. The neutral shall rule within fourteen (14) days of the hearing, shall not issue any written opinion, and shall not refer any portion of the dispute to mediation without the Parties’ prior, written consent. The rulings of the neutral shall be binding, and non-appealable and may be entered as a final judgment in any court having jurisdiction. The neutral(s) shall be paid a reasonable fee plus expenses. These fees and expenses, along with the reasonable legal fees and expenses of the prevailing Party (including all expert witness fees and expenses), the fees and expenses of a court reporter, and any expenses for a hearing room, shall be paid as follows:

- (i) if the neutral(s) rule(s) in favor of one Party on all disputed issues in the ADR, the losing Party shall pay 100% of such fees and expenses.
- (ii) if the neutral(s) rule(s) in favor of one Party on some issues and the other Party on other issues, the neutral(s) shall issue with the rulings a written determination as to how such fees and expenses shall be allocated between the Parties. The neutral(s) shall allocate fees and expenses in a way that bears a reasonable relationship to the outcome of the ADR, with the Party prevailing on more issues, or on issues of greater value or gravity, recovering a relatively larger share of its legal fees and expenses.

**36. Notice Regarding Apple:** This section only applies to the extent you are using our mobile application(s) on an iOS device in connection with the Services. You acknowledge that this Agreement is between you and us only, not with Apple Inc. (“**Apple**”), and Apple is not responsible for the Services and the content thereof. Your right to use the Services in application form on an iOS device is limited to a non-transferable license to use the application on any Apple-branded products that the user owns or controls and as permitted by the Usage Rules set forth in the Apple Media Services Terms and Conditions. Apple has no obligation whatsoever to furnish any maintenance and support services with respect to the Services. In the event of any failure of the Services to conform to any applicable warranty, you may notify Apple and Apple will refund any applicable purchase price for the mobile application to you; and, to the maximum extent permitted by applicable law, Apple has no other warranty obligation whatsoever with respect to the Services. Apple is not responsible for addressing any claims by you or any third party relating to the Services or your possession and/or use of the Services, including: (a) product liability claims; (b) any claim that the Services fail to conform to any applicable legal or regulatory requirement; and (c) claims arising under consumer protection, privacy, or similar legislation. All such responsibility is allocated between us and you under this Agreement. Apple is not responsible for the investigation, defence, settlement and discharge of any third-party claim that the Services and/or your possession and use of the Services infringe third party’s intellectual property rights. You agree to comply with any applicable third-party terms when using the Services. Apple and Apple’s subsidiaries are third-party beneficiaries of this Agreement, and upon your acceptance of this Agreement, Apple will have the right (and will be deemed to have accepted the right) to enforce this Agreement against you as a third party beneficiary of this Agreement. You agree that Apple is not responsible for any maintenance and support services in connection with the Services.

**37. Notice Regarding Google:** This section only applies to the extent you are using our mobile application(s) on an Android device in connection with the Services. You acknowledge that this Agreement is between you and us only, not with Alphabet Inc. (“**Google**”), and Google is not responsible for the Services and the content thereof. You agree that Google is not responsible for any maintenance and support services in connection with the Services. The Clinic agrees to only use the Data to provide care to Patients.

**38. Changes to this Agreement:** Abbott reserves the right to change this Agreement at any time at our discretion and without prior notice. Users of our Site are expected to regularly check this Agreement for changes as they are binding on you. We encourage you to review this Agreement every time you use our Site. Updates will be indicated by a change in the Effective Date and your continued use of our Site and continued access to the Merlin.net PCN and Services following any such change constitutes your agreement to follow and be bound by the most recent version of this Agreement. You will be able to store or print out changes to these Terms of Use in legible form.

**39. Definition of Abbott.** For the purposes of this Agreement, Abbott means your local Abbott affiliated company for your principal Location, as listed at <https://www.cardiovascular.abbott/int/en/hcp/products/cardiac-rhythm-management/affiliates.html>

**40. Contact information:** If you have any questions regarding this Agreement, if you no longer wish to be a User of our Site or if a Patient no longer wishes to participate in Merlin.net, please contact us at [cnprivacy@abbott.com](mailto:cnprivacy@abbott.com). **Please print a copy of this Agreement for your records.**

FOR USERS IN THE EEA, PLEASE SEE DATA PROCESSING AGREEMENT BELOW

**MERLIN.NET™ PATIENT CARE NETWORK DATA PROCESSING AGREEMENT**

Effective Date: January 2024

**INCORPORATING THE EUROPEAN COMMISSION STANDARD CONTRACTUAL CLAUSES  
BETWEEN CONTROLLERS AND PROCESSORS UNDER ARTICLE 28(7) OF THE GDPR UNDER  
DECISION (EU) 2021/915 OF 4 JUNE 2021**

These Clauses form part of the Merlin.net™ PCN Agreement (“**Agreement**”) that governs the provision of Services (as defined in the Agreement) to the controller and only apply when the processor is processing personal data on behalf of the controller. The controller acknowledges that processor is subject to EU and EU Member State laws relating to medical devices, which requires it to process certain personal data as a controller to comply with such laws, in particular for post-market surveillance, medical device quality management including product development and improvement, safety, performance and vigilance. The processor reserves the right to verify that any request for portability has arisen from a data subject rather than the controller.

**SECTION I**

Clause 1

**Purpose and scope**

- (a) The purpose of these Standard Contractual Clauses (the Clauses) is to ensure compliance with Article 28(3) and (4) of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data.
- (b) The controllers and processors listed in Annex I have agreed to these Clauses in order to ensure compliance with Article 28(3) and (4) of Regulation (EU) 2016/679 and/or Article 29 (3) and (4) Regulation (EU) 2018/1725.
- (c) These Clauses apply to the processing of personal data as specified in Annex II.
- (d) Annexes I to IV are an integral part of the Clauses.
- (e) These Clauses are without prejudice to obligations to which the controller is subject by virtue of Regulation (EU) 2016/679 and/or Regulation (EU) 2018/1725.
- (f) These Clauses do not by themselves ensure compliance with obligations related to international transfers in accordance with Chapter V of Regulation (EU) 2016/679 and/or Regulation (EU) 2018/1725.

Clause 2

**Invariability of the Clauses**

- (a) The Parties undertake not to modify the Clauses, except for adding information to the Annexes or updating information in them.
- (b) This does not prevent the Parties from including the standard contractual clauses laid down in these Clauses in a broader contract, or from adding other clauses or additional safeguards provided that they do not directly or indirectly contradict the Clauses or detract from the fundamental rights or freedoms of data subjects.

Clause 3

**Interpretation**

- (a) Where these Clauses use the terms defined in Regulation (EU) 2016/679 or Regulation (EU) 2018/1725 respectively, those terms shall have the same meaning as in that Regulation.
- (b) These Clauses shall be read and interpreted in the light of the provisions of Regulation (EU) 2016/679 or Regulation (EU) 2018/1725 respectively.
- (c) These Clauses shall not be interpreted in a way that runs counter to the rights and obligations provided for in Regulation (EU) 2016/679 / Regulation (EU) 2018/1725 or in a way that prejudices the fundamental rights or freedoms of the data subjects.

Clause 4

**Hierarchy**

In the event of a contradiction between these Clauses and the provisions of related agreements between the Parties existing at the time when these Clauses are agreed or entered into thereafter, these Clauses shall prevail.

Clause 5

**Docking clause**

- (a) Any entity that is not a Party to these Clauses may, with the agreement of all the Parties, accede to these Clauses at any time as a controller or a processor by completing the Annexes and signing Annex I.
- (b) Once the Annexes in (a) are completed and signed, the acceding entity shall be treated as a Party to these Clauses and have the rights and obligations of a controller or a processor, in accordance with its designation in Annex I.
- (c) The acceding entity shall have no rights or obligations resulting from these Clauses from the period prior to becoming a Party.

**SECTION II – OBLIGATIONS OF THE PARTIES**

Clause 6

**Description of processing(s)**

The details of the processing operations, in particular the categories of personal data and the purposes of processing for which the personal data is processed on behalf of the controller, are specified in Annex II.

Clause 7

**Obligations of the Parties**

**7.1. Instructions**

- (a) The processor shall process personal data only on documented instructions from the controller, unless required to do so by Union or Member State law to which the processor is subject. In this case, the processor shall inform the controller of that legal requirement before processing, unless the law prohibits this on important grounds of public interest. Subsequent instructions may also be given by the controller throughout the duration of the processing of personal data. These instructions shall always be documented.
- (b) The processor shall immediately inform the controller if, in the processor's opinion, instructions given by the controller infringe Regulation (EU) 2016/679 / Regulation (EU) 2018/1725 or the applicable Union or Member State data protection provisions.

## **7.2. Purpose limitation**

The processor shall process the personal data only for the specific purpose(s) of the processing, as set out in Annex II, unless it receives further instructions from the controller.

## **7.3. Duration of the processing of personal data**

Processing by the processor shall only take place for the duration specified in Annex II.

## **7.4. Security of processing**

- (a) The processor shall at least implement the technical and organisational measures specified in Annex III to ensure the security of the personal data. This includes protecting the data against a breach of security leading to accidental or unlawful destruction, loss, alteration, unauthorised disclosure or access to the data (personal data breach). In assessing the appropriate level of security, the Parties shall take due account of the state of the art, the costs of implementation, the nature, scope, context and purposes of processing and the risks involved for the data subjects.
- (b) The processor shall grant access to the personal data undergoing processing to members of its personnel only to the extent strictly necessary for implementing, managing and monitoring of the contract. The processor shall ensure that persons authorised to process the personal data received have committed themselves to confidentiality or are under an appropriate statutory obligation of confidentiality.

## **7.5. Sensitive data**

If the processing involves personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, genetic data or biometric data for the purpose of uniquely identifying a natural person, data concerning health or a person's sex life or sexual orientation, or data relating to criminal convictions and offences ("sensitive data"), the processor shall apply specific restrictions and/or additional safeguards.

## **7.6 Documentation and compliance**

- (a) The Parties shall be able to demonstrate compliance with these Clauses.
- (b) The processor shall deal promptly and adequately with inquiries from the controller about the processing of data in accordance with these Clauses.
- (c) The processor shall make available to the controller all information necessary to demonstrate compliance with the obligations that are set out in these Clauses and stem directly from Regulation (EU) 2016/679 and/or Regulation (EU) 2018/1725. At the controller's request, the processor shall also permit and contribute to audits of the processing activities covered by these Clauses, at reasonable intervals or if there are indications of non-compliance. In deciding on a review or an audit, the controller may take into account relevant certifications held by the processor.
- (d) The controller may choose to conduct the audit by itself or mandate an independent auditor. Audits may also include inspections at the premises or physical facilities of the processor and shall, where appropriate, be carried out with reasonable notice.
- (e) The Parties shall make the information referred to in this Clause, including the results of any audits, available to the competent supervisory authority/ies on request.

## **7.7. Use of sub-processors**

- (a) The processor has the controller's general authorisation for the engagement of sub-processors from an agreed list. The processor shall specifically inform in writing the controller of any intended changes of that list through the addition or replacement of sub-processors at least 90 days in advance, thereby giving the controller sufficient time to be able to object to such changes prior to the engagement of the concerned sub-processor(s). The processor shall provide the controller with the information necessary to enable the controller to exercise the right to object.
- (b) Where the processor engages a sub-processor for carrying out specific processing activities (on behalf of the controller), it shall do so by way of a contract which imposes on the sub-processor,



in substance, the same data protection obligations as the ones imposed on the data processor in accordance with these Clauses. The processor shall ensure that the sub-processor complies with the obligations to which the processor is subject pursuant to these Clauses and to Regulation (EU) 2016/679 and/or Regulation (EU) 2018/1725.

- (c) At the controller's request, the processor shall provide a copy of such a sub-processor agreement and any subsequent amendments to the controller. To the extent necessary to protect business secret or other confidential information, including personal data, the processor may redact the text of the agreement prior to sharing the copy.
- (d) The processor shall remain fully responsible to the controller for the performance of the sub-processor's obligations in accordance with its contract with the processor. The processor shall notify the controller of any failure by the sub-processor to fulfil its contractual obligations.
- (e) The processor shall agree a third party beneficiary clause with the sub-processor whereby - in the event the processor has factually disappeared, ceased to exist in law or has become insolvent - the controller shall have the right to terminate the sub-processor contract and to instruct the sub-processor to erase or return the personal data.

#### **7.8. International transfers**

- (a) Any transfer of data to a third country or an international organisation by the processor shall be done only on the basis of documented instructions from the controller or in order to fulfil a specific requirement under Union or Member State law to which the processor is subject and shall take place in compliance with Chapter V of Regulation (EU) 2016/679 or Regulation (EU) 2018/1725.
- (b) The controller agrees that where the processor engages a sub-processor in accordance with Clause 7.7. for carrying out specific processing activities (on behalf of the controller) and those processing activities involve a transfer of personal data within the meaning of Chapter V of Regulation (EU) 2016/679, the processor and the sub-processor can ensure compliance with Chapter V of Regulation (EU) 2016/679 by using standard contractual clauses adopted by the Commission in accordance with of Article 46(2) of Regulation (EU) 2016/679, provided the conditions for the use of those standard contractual clauses are met.

#### Clause 8

##### **Assistance to the controller**

- (a) The processor shall promptly notify the controller of any request it has received from the data subject. It shall not respond to the request itself, unless authorised to do so by the controller.
- (b) The processor shall assist the controller in fulfilling its obligations to respond to data subjects' requests to exercise their rights, taking into account the nature of the processing. In fulfilling its obligations in accordance with (a) and (b), the processor shall comply with the controller's instructions
- (c) In addition to the processor's obligation to assist the controller pursuant to Clause 8(b), the processor shall furthermore assist the controller in ensuring compliance with the following obligations, taking into account the nature of the data processing and the information available to the processor:
  - (1) the obligation to carry out an assessment of the impact of the envisaged processing operations on the protection of personal data (a 'data protection impact assessment') where a type of processing is likely to result in a high risk to the rights and freedoms of natural persons;
  - (2) the obligation to consult the competent supervisory authority/ies prior to processing where a data protection impact assessment indicates that the processing would result in a high risk in the absence of measures taken by the controller to mitigate the risk;
  - (3) the obligation to ensure that personal data is accurate and up to date, by informing the controller without delay if the processor becomes aware that the personal data it is processing is inaccurate or has become outdated; and

- (4) the obligations in Article 32 Regulation (EU) 2016/679.
- (d) The Parties shall set out in Annex III the appropriate technical and organisational measures by which the processor is required to assist the controller in the application of this Clause as well as the scope and the extent of the assistance required.

Clause 9

**Notification of personal data breach**

In the event of a personal data breach, the processor shall cooperate with and assist the controller for the controller to comply with its obligations under Articles 33 and 34 Regulation (EU) 2016/679 or under Articles 34 and 35 Regulation (EU) 2018/1725, where applicable, taking into account the nature of processing and the information available to the processor.

**9.1 Data breach concerning data processed by the controller**

In the event of a personal data breach concerning data processed by the controller, the processor shall assist the controller:

- (a) in notifying the personal data breach to the competent supervisory authority/ies, without undue delay after the controller has become aware of it, where relevant/(unless the personal data breach is unlikely to result in a risk to the rights and freedoms of natural persons);
- (b) in obtaining the following information which, pursuant to Article 33(3) Regulation (EU) 2016/679, shall be stated in the controller's notification, and must at least include:
  - (1) the nature of the personal data including where possible, the categories and approximate number of data subjects concerned and the categories and approximate number of personal data records concerned;
  - (2) the likely consequences of the personal data breach; and
  - (3) the measures taken or proposed to be taken by the controller to address the personal data breach, including, where appropriate, measures to mitigate its possible adverse effects.

Where, and insofar as, it is not possible to provide all this information at the same time, the initial notification shall contain the information then available and further information shall, as it becomes available, subsequently be provided without undue delay; and

- (c) in complying, pursuant to Article 34 Regulation (EU) 2016/679, with the obligation to communicate without undue delay the personal data breach to the data subject, when the personal data breach is likely to result in a high risk to the rights and freedoms of natural persons.

**9.2 Data breach concerning data processed by the processor**

In the event of a personal data breach concerning data processed by the processor, the processor shall notify the controller without undue delay after the processor having become aware of the breach. Such notification shall contain, at least:

- (a) a description of the nature of the breach (including, where possible, the categories and approximate number of data subjects and data records concerned);
- (b) the details of a contact point where more information concerning the personal data breach can be obtained; and
- (c) its likely consequences and the measures taken or proposed to be taken to address the breach, including to mitigate its possible adverse effects.

Where, and insofar as, it is not possible to provide all this information at the same time, the initial notification shall contain the information then available and further information shall, as it becomes available, subsequently be provided without undue delay.

The Parties shall set out in Annex III all other elements to be provided by the processor when assisting the controller in the compliance with the controller's obligations under Articles 33 and 34 of Regulation (EU) 2016/679.

**SECTION III – FINAL PROVISIONS**

Clause 10

**Non-compliance with the Clauses and termination**

- (a) Without prejudice to any provisions of Regulation (EU) 2016/679 and/or Regulation (EU) 2018/1725, in the event that the processor is in breach of its obligations under these Clauses, the controller may instruct the processor to suspend the processing of personal data until the latter complies with these Clauses or the contract is terminated. The processor shall promptly inform the controller in case it is unable to comply with these Clauses, for whatever reason.
- (b) The controller shall be entitled to terminate the contract insofar as it concerns processing of personal data in accordance with these Clauses if:
  - (1) the processing of personal data by the processor has been suspended by the controller pursuant to point (a) and if compliance with these Clauses is not restored within a reasonable time and in any event within one month following suspension;
  - (2) the processor is in substantial or persistent breach of these Clauses or its obligations under Regulation (EU) 2016/679 and/or Regulation (EU) 2018/1725; or
  - (3) the processor fails to comply with a binding decision of a competent court or the competent supervisory authority/ies regarding its obligations pursuant to these Clauses or to Regulation (EU) 2016/679 and/or Regulation (EU) 2018/1725.
- (c) The processor shall be entitled to terminate the contract insofar as it concerns processing of personal data under these Clauses where, after having informed the controller that its instructions infringe applicable legal requirements in accordance with Clause 7.1 (b), the controller insists on compliance with the instructions.
- (d) Following termination of the contract, the processor shall, at the choice of the controller, delete all personal data processed on behalf of the controller and certify to the controller that it has done so, or, return all the personal data to the controller and delete existing copies unless Union or Member State law requires storage of the personal data. Until the data is deleted or returned, the processor shall continue to ensure compliance with these Clauses.

**ANNEX I LIST OF PARTIES**

**Controller:**

- 1. Name: Clinic  
Address: Clinic Location  
Contact person's name, position and contact details: Clinic DPO

**Processor:**

- 1. Name and Address: Abbott entity as set out in Clause 37 of the Agreement  
Contact person's name, position and contact details: Abbott EU DPO available at <https://www.abbott.com/eudpofoms.html>

**ANNEX II: DESCRIPTION OF THE PROCESSING**

*Categories of data subjects whose personal data is processed*

- (i) Those clinic's employees or other authorized users provided with an administrative user ID for the Merlin.net™ Patient Care Network and those authorized users of the clinic provided with a user ID to the Merlin.net™ Patient Care Network; and
- (ii) Patients enrolled in Merlin.net by a clinic.

*Categories of personal data processed*

**Clinic employees or other Authorized Users:** name, phone number, email address, clinic name, and clinic country. Additional information, if provided by the clinic, include job title or role and clinic ID.

**Patients enrolled in Merlin.net™ by you:** Required patient data fields include date of birth, serial number of the implanted device, and information relating to the functioning of the implanted device. The patient's first name and last name may be required depending on whether a Patient ID is provided by the clinic. Depending on the implanted device, a patient's primary phone, email, and/or implant date may be required. Additional patient data, if provided by the clinic, includes gender, preferred language, a clinic assigned patient number or other patient identifier, and an emergency contact for the patient, including their name, phone number, and address.

*Sensitive data processed (if applicable) and applied restrictions or safeguards that fully take into consideration the nature of the data and the risks involved, such as for instance strict purpose limitation, access restrictions (including access only for staff having followed specialised training), keeping a record of access to the data, restrictions for onward transfers or additional security measures.*

Additional patient data, if provided by the clinic, includes race, medications, hospitalisations, information about the patient's condition, diagnoses and treatment.

*Nature of the processing*

The personal data shall be subject to the following processing operations:

- Receiving data, including collection, accessing, retrieval, recording and data entry;
- Holding data, including storage, organisation and structuring;
- Protecting data, including restricting, encrypting, and security testing;
- Returning data to the data exporter;
- Erasing data, including destruction and deletion;
- Supporting the implanted cardiac devices;
- For devices that support remote programming capabilities, enabling the health care provider to make adjustments to the devices remotely through Merlin.net;
- Training and maintenance of Merlin.net™;
- Data collection and hosting;
- Transmission via electronic transmitters (monitors);
- Information and transmission reporting;
- Upon request by you, assistance with the interpretation or analysis of certain device-related information;
- Technical and clinical support services; and
- Patients implanted with an Abbott implanted cardiac device may send automated transmissions of information collected from their respective implanted medical device to Merlin.net for that Patient's clinic and medical team to receive regular updates on the performance and status of their implanted cardiac device for the remote monitoring of certain aspects of the Patient's condition.

*Purpose(s) for which the personal data is processed on behalf of the controller*

To provide, operate and maintain the Merlin.net™ Patient Care Network, including processing necessary to provide support services in connection with the operation of Devices monitored by the Merlin.net Services.

*Duration of the processing*

The data importer will continue to store data exporter's patients' personal data for the period that the Controller uses the services, unless Controller chooses to delete their patient personal data sooner. Further, processor may retain personal data in accordance with applicable legal requirements.

*For processing by (sub-) processors, also specify subject matter, nature and duration of the processing*

<b>Sub-processor name</b>	<b>Sub-processor address</b>	<b>Description of services</b>	<b>Location from which services are provided</b>
Abbott Laboratories	15900 Valley View Court, Sylmar, California 91342 USA,	To provide, operate and maintain the Merlin.net™ Patient Care Network	USA <a href="#">Processor-to-Processor Standard Contractual Clauses</a>
St. Jude Medical Sweden AB	Isafjordsgata 15 164 40 Kista Sweden	Providing Customer support, in particular troubleshooting and other application and software support.	Sweden
Microsoft Azure	700 Bellevue Way NE - 22nd Floor Bellevue, Washington, 98004 USA	Azure hosting service for encrypted data from 3Q23	Ireland <a href="#">Licensing Documents (microsoft.com)</a>
Twilio	101 Spear Street, First Floor, San Francisco, California 94105 USA	Used by Abbott Heart Failure for the automated phone message service described in the Merlin Privacy Notice	USA
Five9	3001 Bishop Drive, Suite 350, San Ramon, California 94583 USA	Used by CardioRhythm Management Division as a cloud-based phone communications system for Merlin support services	USA
Salesforce	415 Mission Street, 3rd Floor, San Francisco, California 94105, United States	Customer relationship management system used by the Abbott's CardioRhythm Management Division to provide device support services for SyncUp	USA

**ANNEX III TECHNICAL AND ORGANISATIONAL MEASURES INCLUDING TECHNICAL AND ORGANISATIONAL MEASURES TO ENSURE THE SECURITY OF THE DATA**

**ABBOTT MERLIN.NET™ PATIENT CARE NETWORK MEASURES**

**Accreditations/Certifications**

**1. ISO 27001:**

Abbott and Merlin.net is certified with the Information Security Management standard ISO/IEC 27001:2013. The ISO certification recognizes that Merlin.net has established processes and standards that maintain the required levels of confidentiality, integrity and availability for customers. A current copy of the ISO certification for Merlin.net is available upon request.

**Security Measures**

Abbott has implemented the following technical and organisational security measures to ensure the ongoing confidentiality, integrity, availability and resilience of its processing systems and services:

**1. Physical access control of processing areas (confidentiality):**

Steps taken by Abbott's industry-leading cloud service provider to prevent unauthorized access to data processing equipment (for example, telephones, database and application servers, and associated hardware) in which personal data is processed include the following appropriate measures:

- (i) Merlin.net assets are housed within two ISO/IEC 27001:2013 certified computer data centres;

- (ii) Data centres are monitored around the clock by security guards and/or security cameras and other sensors that can detect and track unauthorized persons;
- (iii) Physical access to facilities, including data centres, is granted based on job responsibility and requires management approval;
- (iv) Visitors sign a visitor log prior to entry and must be escorted by Abbott personnel at all times; and
- (v) Physical access rights and authentication controls (for example, card readers) at entry and exit points are implemented, documented and regularly checked.

**2. Access control to data processing systems (confidentiality):**

Abbott takes appropriate measures to prevent its data processing systems from being used by unauthorized persons. This is achieved by:

- (i) Multi-factor authentication;
- (ii) Restricting access to services through encryption, signature algorithms and secure certificates;
- (iii) Storing data on a secure database that uses disk-level encryption;
- (iv) Using industry standard encryption and password requirements (for example, minimum length, use of special characters, expiration and so on); and
- (v) Locking access following unsuccessful login attempts or inactivity and having a method to reset locked access identifiers.

**3. Access control for the use of certain areas of data processing systems by authorized Abbott personnel (confidentiality):**

Abbott personnel authorized to use data processing systems may only access personal data where they have sufficient access authorisation. To this end, Abbott has implemented the following controls:

- (i) Access is restricted on the basis of roles and responsibilities and is granted to users in accordance with need-to-know and least-privilege principles;
- (ii) Privileged access is granted to authorized administrators, in line with job responsibilities;
- (iii) Access rights are reviewed periodically to ensure that correct access rights are granted;
- (iv) When roles and responsibilities change, access rights are removed, even in the event of termination; and
- (v) Effective disciplinary action against individuals who access personal data without authorization.

**4. Clinic setup and security:**

Abbott's Remote Care Operations group is responsible for the initial setup of clinics upon enrolment. One clinic administrator account is provided for the purpose of creating, administering and maintaining user IDs. Clinic users, including administrators, are responsible for protecting their Merlin.net credentials. The following controls are implemented:

- (i) Clinicians are restricted from directly accessing the database and infrastructure supporting Merlin.net;
- (ii) For support and troubleshooting purposes, authorized Abbott personnel utilise a designated administrative account.
- (iii) Minimum default password parameter configurations are established; and
- (iv) Merlin.net offers two-factor authentication, which customers may elect to implement.

**5. Transfer control (integrity):**

Abbott takes steps to prevent personal data from being read, copied, altered or deleted by unauthorized persons during its transmission or transfer. This is achieved by:

- (i) The transfer of data from external sources to Merlin.net infrastructure is encrypted;
- (ii) Servers use secure network connectivity that is restricted to HTTPS only; and
- (iii) Policies and standards are in place to restrict the use of removable media for transportation purposes and on corporate laptops or other mobile devices.

**6. Input control (integrity):**

Abbott does not access personal data for any purposes other than those set out in the Merlin.net™ PCN Agreement and the Data Processing Agreement (DPA).

Abbott takes appropriate measures to protect personal data against unauthorized access or deletion. This is achieved by:

- (i) Protective measures for reading, changing and deleting stored data;
- (ii) Documentation to control which persons are authorized and responsible for making entries into data processing systems on the basis of their tasks; and

(iii) Protocols that require the logging of possible entries and / or deletions of personal data.

**7. Order control:**

Abbott takes steps to ensure that, where personal data is processed, it is processed strictly in accordance with your instructions. This is achieved by:

(i) Clear instructions to Abbott on the scope of required personal data processing as set out in the Agreement and this DPA.

**8. Availability control (availability):**

Abbott takes steps to ensure that personal data is protected from accidental destruction or loss. This is achieved by:

(i) Regular data backups and periodic restores;

(ii) Backup logs are monitored and escalation protocols exist in case of a critical failure;

(iii) Use of anti-virus/anti-malware software to protect against malicious threats such as viruses, worms and spyware;

(iv) Conducting internal and external vulnerability scans on a regular basis; and

(v) Implementation of a Business Continuity Plan, which includes an IT Disaster Recovery Plan, listing the roles, tasks and responsibilities.

**9. Separation of processing for different purposes:**

Abbott takes steps to ensure that personal data is protected from accidental destruction or loss. This is achieved by:

(i) Ensuring database-driven security by separating production and support and system monitoring databases; and

(ii) Designing interfaces, batch processes, and reports for specific purposes and functions only, so data collected for specific purposes is processed separately.

**10. Resilience:**

Abbott has implemented the following technical and organisational security measures, in particular to ensure the reliability of our processing systems and services:

(i) Data protection management policies and procedures;

(ii) Incident response policies and procedures;

(iii) Data protection-friendly pre-settings (under Article 25(1)) of Regulation (EU) 2016/679; and

(iv) Order control.

**ANNEX IV: LIST OF SUB-PROCESSORS**

Not applicable.