CareLink™ Personal Privacy Statement

Effective 24 September 2020

Your Privacy Matters

Medtronic's mission is to contribute to human welfare by the application of biomedical engineering in the research, design, manufacture, and sale of instruments or appliances that alleviate pain, restore health, and extend life. Central to this mission is our commitment to be transparent about Personal Data Medtronic collects, how it is used and with whom it is shared.

This Privacy Statement applies to the Personal Data (including Patient Health Data) of Users processed in CareLink™ Personal. CareLink™ Personal is a webbased software designed to help take information that is uploaded CareLink[™] Personal from compatible devices and diabetes management tools insulin pump, continuous monitor. blood alucose alucose meter(s), logbooks and associated mobile applications - and organize it into easy-to-read charts, graphs and tables. These reports can help Patients, Legal Guardians, Care Partners and Health Care Providers discover trends and other information that can lead to improved therapy management for greater this control. In Privacy Statement is described what Personal Data of Users is collected, how these Personal Data are processed, how long Personal Data are retained, with whom Personal Data is shared, which rights data subjects have as well as how they can exercise those rights and how Users can contact Medtronic.

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1.	- Definitions	
Introduction		
	"Associated mobile applications" means	all
	mobile applications that require registering	for

CareLink[™] Personal. Please check the End User License Agreement of a Medtronic mobile application to find out if it is an associated mobile application within the meaning of this Privacy Statement.

"Care Partner" means any individual that has been granted access by a Patient to view a secondary display with the Patient's diabetes information in CareLinkTM Personal.

"Health Care Provider" means a medical professional, such as a doctor or nurse, that provides medical advice and services to individuals under their care (e.g., their patients).

"Health Data" means different types of health related data generated and measured through the compatible devices and diabetes management tools that are uploaded to CareLinkTM Personal or CareLinkTM System.

"Legal Guardian" means any individual that registers to CareLinkTM Personal on behalf of a Patient, under 18 years of age, that is under their guardianship.

"patient" means a hospital, clinic, or other health care institution where health and/or medical advice and services are provided to individuals (e.g., Patients).

"Patient" means any individual that uses CareLink[™] Personal for their diabetes management.

"Personal Data" means all the information which relates to an identified/identifiable natural person. This means that any information that can lead to knowing who you are (either directly or indirectly) is qualified as 'Personal Data'.

"Users" means Patients, Legal Guardians, Care Partners and Health Care Providers who use CarelinkTM Personal.

- What is $CareLink^{TM}$ Personal and what purpose does the software serve?

CareLink[™] Personal is a web-based software designed to help take information that is uploaded to CareLink[™]

Personal from compatible devices and diabetes management tools – insulin pump, continuous glucose monitor, blood glucose meter(s), logbooks and associated mobile applications – and organize it into easy-to-read charts, graphs and tables. These reports can help Patients, Legal Guardians, Care Partners and Health Care Providers discover trends and other information that can lead to improved therapy management for greater control.

CareLink[™] Personal is a CE marked Class I medical device.

- Connection to the CareLink™ System Software

Establishing a link to CareLink[™] Personal will enable the Medical Center to view their Patients' Health Data from compatible devices and diabetes management tools as uploaded in CareLink[™] Personal (e.g. blood glucose levels, log book entries) in CareLink[™] System. CareLink[™] System is used by Medical Centers and Health Care Providers to inform therapy decisions and to improve engagement.

When a link is established between CarelinkTM Personal and CareLinkTM System, due to the bi-directional exchange of data between these systems, Patients will also have direct access in CarelinkTM Personal to their device data as originally uploaded in CareLinkTM System.

In order to establish the link, an explicit consent is built into CareLink[™] System to which a Patient needs to agree in addition to performing a one-time confidential entering of their unique username and password. A Patient can decide to delink his Carelink[™] Personal account from CareLink[™] System at any time in the settings of their CareLink[™] Personal account which will stop any further sharing of their future CareLink[™] Personal Data with that CareLink[™] System account.

Please note that when a Patient consents to establish a link between CarelinkTM Personal and CareLinkTM System, the following categories of Personal Data are exchanged and processed for all the purposes to which the Patient has consented in CareLinkTM Personal:

- **Health Data**: Different types of Health Data generated and measured through the compatible

devices and diabetes management tools that are uploaded to CareLink $^{\text{TM}}$ System by the Health Care Provider.

2. What Personal Data does Medtronic collect and use?

Medtronic collects, stores and uses Personal Data (including Patient Health Data) of Users that they provide directly into CareLink™ Personal or that is generated through the use of CareLink™ Personal and diabetes devices that are compatible with CareLink™ Personal or diabetes management tools supported by Medtronic: insulin pumps, blood glucose meter(s), continuous glucose monitoring systems, logbooks. The following types of Personal Data are processed through CareLink™ Personal:

Patients

- Contact and account details: Name, phone number, email address, home address, country of residence, username, password, security question and answer;
- **Demographic data**: Age category and gender;
- **Technical Device Data**: Type of connected device and its serial number; historical usage data;
- **Health Data**: Different types of Health Data generated and collected through compatible devices and diabetes management tools (e.g. glucose values, insulin values, physical exercise, information on meals consumed, carbohydrates intake).

Legal Guardians and Care Partners

- Contact and account details: name, email address, username, password and telephone number;
- **Technical Device data**: Type of connected device and its serial number; historical usage data.

Associated mobile applications

The following types of Personal Data of Patients are processed through the associated mobile applications:

- CareLink[™] Personal login information;
- Diabetes related Health Data;
- Physical exercise information;
- Meal consumption information;
- Other information that Users decide to enter and record in the application and that is related to their diabetes management such as information on medication intake.

Cookies on the associated mobile applications

The following types of Personal Data of patients are collected and processed through Adobe Analytics cookies on associated mobile applications:

- The pages you open and interact with after each launch

of the mobile application; Number of times you launch and use the mobile applications on a daily and monthly basis as well as the day and the hour the mobile applications are launched; The session length of your use each time you launch the mobile applications and the aggregated total session length; Number of times the mobile application crashes; Number of days since last use; The operating system version of your device and device name. 3. Who is Medtronic is responsible for processing of your Personal Data. responsible for data processing? Medtronic processes Personal Data of Users obtained through 4. For what CareLink[™] Personal for the purposes listed below. For each purposes purpose, the legal basis to process Personal Data is specified as does Medtronic well as the legal ground that allows for the processing of Health Data where this is the case. process **Personal Data** of Users? a) Processing for the provision of services CareLink[™] Personal is designed to process Health Data of Patients from compatible devices and provide Users with insights in the form of reports. Medtronic also processes Personal Data (including Patient Health Data) of Users to: Provide Users with customer and product support such as technical and operational support to help Users resolve problems, issues or questions regarding CareLink™ Personal or devices diabetes the compatible and management tools; Provide Users with communications of an operational nature such as planned outages, software updates and maintenance of the product: Monitor and diagnose technical issues which can limit the functionalities or working of CareLink™ Personal; Monitor the safety and reliability of the Carelink™ their Personal services and underlying systems and software.

Medtronic is required to obtain the explicit consent of Patients to process their Personal Data (including Health Data) for this purpose. Patients are under no obligation to provide their consent. However, as this is related to the primary function of CareLink Personal, Medtronic cannot provide Carelink Personal or the associated mobile applications to Users without the explicit consent of Patients. If Patients do not provide their consent, however, they are still able to use their device (e.g. insulin pump with continuous glucose monitoring, blood glucose meter, etc.) with exception of the Guardian Connect Continuous Glucose Monitor.

Medtronic currently sends urgent (non-marketing) communications of an operational nature (e.g. planned outages or updates) about CareLink™ Personal through email. From time to time, we may also send such communications by SMS text or push notifications if available with the Medical Device that you use (please refer to your app user guide). Medtronic asks the explicit consent of Patients to contact them through SMS text messaging for this purpose.

Depending on the features of a patient's medical device, Medtronic also uses the SMS text message and push notifications functionality as part of its Care Partner application to send alerts. These alerts enable the Care Partner to know when a Patient is about to or is currently experiencing a low or high blood glucose episode and status information about the Patient's devices. Care Partners will receive alerts that contain a Patient identifier that the Patient chooses and information about the specific alert that can contain Health Data (e.g. low sensor glucose or high sensor glucose). Please be aware that such SMS text messages, containing a Patient's Health Data, are transmitted to Care Partners without encryption and that they will be visible to third-party service providers that may be located outside your country who facilitate the sending of SMS text messages as well as applicable wireless carriers. These third-party services providers may not comply with all data protection and security standards under your country's protection laws. The SMS text service is optional and will only be provided when Patients and their selected Care Partners both consent to the SMS text message functionality.

Medtronic processes user engagement data of Patients through Adobe Analytics cookies on the associated mobile applications in order to improve user experience. Medtronic asks the explicit consent of Patients to process their Personal Data (including Health Data) for this purpose. Please note that a Patient's consent is voluntary and that they will not be stopped or prevented from using the associated mobile applications if they decide not to provide consent.

b) Processing necessary to comply with a legal obligation to which Medtronic is subject

Medtronic processes Personal Data (including Patient Health Data) of Users to comply with its vigilance and post-market surveillance duties to ensure high standards of quality and safety of its medical devices applicable medical devices regulation. CareLink[™] Personal software and associated products are medical devices whose operation may require monitoring under applicable regulations. If Medtronic detects potential abnormalities, the company is required by law to notify Users and/or regulatory authorities and to inform Users of any remedial action. Therefore, Medtronic processes Personal Data of Users to comply with a legal obligation. Health Data of Patients is processed for this purpose as it can be necessary to ensure high standards of medical devices. Where sufficient to meet the legal obligation, Medtronic pseudonymizes Personal Data, or creates and uses aggregated statistics calculated from Personal Data (including Health Data) of Patients. Aggregated data does not contain any information that can be used to directly identify Patients, but it does not completely exclude the possibility of identifying Patients. These statistics will be shared with regulatory bodies to obtain regulatory approval for products and services.

Medtronic may be requested to process Personal Data (including Patient Health Data) of Users to comply with any reasonable request from competent law enforcement agents or representatives, governmental agencies or bodies, including competent data protection authorities, in which case the processing will be limited to what is minimally required to comply with the order.

c) Processing for the establishment, exercise or defense of legal claims

Medtronic processes Patient Health Data as necessary for the establishment, exercise or defense of legal claims or in the case where courts are acting in their judicial capacity. Processing of Personal Data of Users for this purpose is based on the legitimate interests of Medtronic.

d) Processing for the improvement and development of products and services and overall improvement of therapy management

Medtronic intends to further research and to develop new products and services for Diabetes Management and improve existing products and services, investigate and document Patient outcome and device safety, as well as to improve therapy management and Patient treatment overall. For this purpose, Medtronic would like to create and use statistics calculated from Personal Data (including Health Data) of Patients in CareLink™ Personal and the associated mobile applications as well as the data coming from CareLink™ System (in case Patients have linked their CareLink™ Personal account to CareLink™ System in a hospital). Aggregated data does not contain any information that can be used to directly identify Patients, but it doesn't completely exclude the possibility of identifying Patients. These statistics will, among other things, be shared with regulatory bodies and help obtain funding for products and services.

Medtronic asks the explicit consent of Patients to process their Personal Data (including Health Data) for this purpose. Please note that a Patient's consent is voluntary and that they will not be stopped or prevented from accessing CareLink $^{\text{TM}}$ Personal if they decide not to provide consent.

e) Processing for the development of marketing materials

Medtronic uses Personal Data (including Health Data) of Patients to develop marketing materials. These materials are used to demonstrate product performance and are presented at conferences and to Health Care Providers or enable Medtronic to improve training, education and support programs. Medtronic

would like to create and use aggregated statistics calculated from your Personal Data (including Health Data) for this purpose. Aggregate data does not contain any information that can be used to directly identify you, but it doesn't completely exclude the possibility of identifying you.

For this purpose, Medtronic asks the explicit consent of Patients to process their Personal Data (including Health Data) for this purpose. Please note that a Patient's consent is voluntary and that they will not be stopped or prevented from accessing CareLink $^{\text{TM}}$ Personal if they decide not to provide consent.

f) Processing for direct marketing purposes

To the extent allowed by your country laws, Medtronic would like to process your Personal Data (including Health Data) such as your name, email and home address, diabetes type to send you marketing and promotional information about Medtronic and third-party products that can be used together with Medtronic's existing and future products. Additionally, Medtronic would like to contact you to conduct market research related to your use of our products. Medtronic intends to provide any such information or contact in writing (by regular mail, e-mail or fax).

Medtronic asks the explicit consent of Patients for these direct marketing related purposes. Please note that a Patient's consent is voluntary and that they will not be stopped or prevented from accessing CareLink $^{\text{TM}}$ Personal if they decide not to provide consent.

5. Provisions for Legal Guardians and Care Partners

a) Processing of Personal Data of Legal Guardians and Care Partners

The Personal Data of Legal Guardians and Care Partners is processed to allow them to access the CareLink[™] Personal web site and associated mobile applications. Medtronic will process the name, email address, username, password of Legal Guardians and Care Partners for this purpose as it is necessary to enable them to use CareLink[™] Personal.

Depending on the features of a patient's medical device, Legal Guardians and Care Partners can receive alerts and notices sent by SMS text message, or receive push notifications through the mobile

- application. Please see your app user guide to determine the communications option that is applicable for your country.
- o Activation of the SMS text message functionality for Care Partners is subject to the Patient's approval for the care partner to have a CareLink care partner account and also subject to Care Partner's consent to receive SMS text messages. In order to be able to send SMS text messages to Care Partners, Medtronic processes the Care Partner's name and telephone number. With certain products, if SMS texts are not enabled, you will not receive alerts.
- o Enabling push notifications requires appropriate set-up in the notifications settings in your mobile device. Account owners are encouraged to enable push notifications. Push notifications in the mobile application are limited to important alerts or updates relating to their software or supported device. With certain products, if push notifications are not enabled, you will not receive alerts.

b) Parental consent

Medtronic is under a legal obligation to obtain parental consent for underage Users of CareLinkTM Personal and in this context is allowed to process Personal Data to verify the identity and role of Legal Guardians.

c) Access to Care Partners

A Patient or Legal Guardian can invite a Care Partner who can be a caregiver (e.g. a parent, other family member or friend) or a Health Care Provider to view their diabetes information on the CareLink Personal web site. When using compatible devices, the Patient can enable a secondary display of diabetes information for Care Partners.

6. How does Medtronic protect Personal Data of Users?

To protect Personal Data (including Patient Health Data) of Users, Medtronic maintains appropriate administrative, technical and organizational safeguards. The appropriate safeguards include individual user accounts to which access is only granted with a valid username and password, and two-factor authentication (if enabled). Personal Data is encrypted when it is transferred from the insulin pump to the CareLink™ Personal on the Patient's computer or laptop and then the Personal Data is encrypted again when it goes from the

Patient's browser to the CareLink™ Personal server. The CareLink™ Personal server is continuously monitored for potential attacks or intrusions. Medtronic regularly reviews its policies and procedures, and the physical environment of its equipment to improve the technical and organizational measures taken in regard to security measures with the aim to protect Personal Data (including Patient Health Data) of Users against accidental, unlawful or unauthorized disclosure, alteration or destruction.

7. How does Medtronic share Personal Data of Users?

The Personal Data (including Patient Health Data) of Users collected and processed through CareLink™ Personal, the compatible devices and diabetes management tools – insulin pump, continuous glucose monitor, blood glucose meter(s), logbooks and associated mobile applications – are securely processed in an ISO 27001 certified physical data center located in the Netherlands.

Medtronic does not disclose Personal Data (including Patient Health Data) of Users to third parties except for the purposes described in this section of the Privacy Statement. Medtronic shares Personal Data (including Patient Health Data) of Users with our affiliates as described below. Medtronic will also share Personal Data (including Patient Health Data) of Users with third-party service providers who perform services for Medtronic; these third parties all act as data processors which means that they will process Personal Data (including Patient Health Data) of Users on behalf of Medtronic and only do so based on documented instructions from Medtronic.

a) Recipients associated with processing for the provision of services

Medtronic MiniMed Inc. based in 18000 Devonshire Street, Northridge, CA 91325, United States, is the legal manufacturer of CareLink™ Personal, the compatible devices and diabetes management tools – insulin pump, continuous glucose monitor, blood glucose meter(s), logbooks and associated mobile applications – and determines the processing of Personal Data (including Patient Health Data) of Users.

Medtronic MiniMed Inc. will provide second-level and third-level technical and customer support if an issue cannot be resolved at first-level which is performed by local Medtronic support staff through regional hubs.

Medtronic BV with registered address at Industry

Park, Earl Bakkenstraat 10, 6422 PJ, the Netherlands, is responsible for server installation and maintenance of the CareLink[™] Personal servers in the data center located in the Netherlands.

- **F.** Hoffmann-La Roche Ltd based in Grenzacherstrasse 124, CH-4070 Basel, Switzerland. F. Hoffmann-La Roche Ltd is the manufacturer of the blood glucose meters that collect blood glucose data. Medtronic shares business operational data that is aggregated (e.g. total number of blood glucose meter Users) with **F.** Hoffmann-La Roche Ltd.
- b) Recipients associated with processing in accordance with legal requirements

Medtronic MiniMed[™] Inc. is the legal manufacturer of CareLink[™] Personal, the compatible devices and diabetes management tools (such as supported insulin pumps, continuous glucose monitor, logbooks, and associated mobile applications) within the meaning of the European Medical Directive, and starting from its entry into force, the Medical Device Regulation, as well as any country-specific implementing regulation (hereafter referred to as 'Medical device regulations') and the addressee of the statutory provisions. Any processing of Personal Data to comply with a legal obligation will be done in compliance with the requirements as prescribed by the legal obligations.

Medtronic Bakken Research Center BV based in Endepolsdomein 5, 6229 GW Maastricht, Netherlands receives Personal Data (including Health Data) of Patients to provide regional support for regulatory filings/approvals.

Legal requirements also oblige Medtronic to share Personal Data (including Health Data) of Patients with regulatory bodies or governmental agencies.

c) Recipients associated with processing for the improvement and development of products and services

Medtronic Bakken Research Center BV receives Personal Data (including Health Data) of Patients in order to improve CareLink™ Personal, compatible devices and diabetes management tools – insulin pump, continuous glucose monitor, blood glucose meter(s), logbooks and associated mobile applications

- or to develop new products and services for diabetes management. d) Recipients associated with processing for the development of marketing materials **Medtronic MiniMed Inc.** and its affiliates develop marketing and promotional materials on the basis of aggregated statistics collected from Personal Data (including Health Data) of Patients. The local Medtronic entities will receive these presentations and publications and share them with academics, doctors, regulators, hospital administrators and other Health Care Professionals. e) Recipients associated with processing for direct marketing purposes To the extent allowed by country laws, the local Medtronic entities are involved with processing of Personal Data (including Health Data) of Patients in order to provide them with marketing and promotional information about Medtronic and third-party products that can be used together with Medtronic's existing and future products. f) Recipients associated with text message functionality for Care Partners **Twilio Inc.** based in 375 Beale Street, Suite 300, San Francisco, CA 94105, United States. Twilio Inc. and Clickatell (Pty) Ltd based in 100 Edward Street, 7th Floor, Manhattan Plaza, Bellville, 7530 Cape Town, South Africa receive and process Personal Data (including Patient identifiers and Health Data) of Patients as well as Personal Data of Care Partners and shares them with US based telecom providers, subprocessors, in order to provide the Care Partners with SMS text message notifications. 8. Cross In case Medtronic transfers Personal Data (including Health border data Data) of Users to a different country, the transfer will take place transfers based on standard contractual clauses. If you wish to receive a copy of the mechanisms used for cross border data transfers, please direct your request to the following email address: rs.askdpo@medtronic.com Medtronic keeps Personal Data (including Patient Health Data) 9. How long of Users for 10 years in the live CareLink™ Personal Database does starting from the last date of service as defined by Medtronic Medtronic

retain Corporate policies unless a legal obligation or a judicial or **Personal Data** administrative order requires Medtronic to keep the data for of Users? longer than 10 years. 10. What are With respect to the processing of Personal Data by Medtronic in accordance with local and international data protection laws, the rights of Users as data Patients, Legal Guardians and Care Partners have the following subjects? rights: Users have the right to receive access to their Personal Data that are processed by Medtronic. They can exercise their right to access their Personal Data directly through the CareLink™ Personal services. For those data which are not accessible through the CareLink[™] Personal services. Users can contact Medtronic as explained below. Please indicate for which Personal Data and which activities you want to exercise your right of access; In cases where processing is based on consent, Users have the right to withdraw their consent at any time and without giving reasons. However, this will not affect the lawfulness of data that have been processed before you withdrew consent; Note that if you withdraw the consent required to provide you with the CareLink[™] Personal services, Medtronic will no longer be able to provide you the services; Users have the right to correct incorrect information about themselves. Users can directly implement this right themselves by correcting their information in the settings of their CareLink™ Personal account; If Users are not able to correct their information themselves and would like Medtronic to do it for them, they can contact Medtronic as explained below. Please be informed that Medtronic can ask Users to demonstrate that the Personal Data they want to correct are indeed erroneous: Users have the right to request that Medtronic provides their Personal Data in a common file format that they can transfer to another organization; Users have the right to ask for the deletion of their Personal Data that is being processed or retained by Medtronic, but only when these Personal Data are no longer necessary in light of the purposes explained above and there is no legal or regulatory obligation

which obliges Medtronic to keep those Personal Data; Users have the right to restrict the processing of their Personal Data if and when (a) they contest the accuracy of that data, (b) the processing is illegitimate and the user opposes the erasure of the Personal Data, requesting the restriction of their use instead (c) the data are no longer needed for the purposes which

- are outlined above, but you need them to defend yourself in judicial proceedings;
- Users have a right to object to the processing of their Personal Data but considering that the processing of Personal Data is largely based on the consent of Users, they may simply withdraw their consent;
- Users have the right to lodge a complaint with a Data Protection Authority or turn to court if they believe their privacy rights are breached.

Please note that some of the rights listed above for Users might be limited as Medtronic has to comply with legal requirements.

Users can exercise some of the rights listed above themselves through the settings of their CareLink™ Personal account, such as the withdrawal of their consent or when they wish to access their Personal Data. If Users cannot directly exercise their rights themselves, they may direct their request to the following email address: rs.askdpo@medtronic.com

11. Updates to this Privacy Statement

Medtronic reviews and updates this Privacy Statement periodically to reflect changes in the way Personal Data (including Patient Health Data) of Users are processed with regards to the CareLink[™] services or changes in the applicable law. Medtronic will post a notice in the CareLink™ Personal Software to notify Users of changes to this Privacy Statement. In the case this Privacy Statement changes in a way that significantly affects how Medtronic uses Personal Data (including Patient Health Data) of Users, Personal Data (including Patient Health Data) of Users that was previously gathered will not be used as described in the updated Privacy Statement without providing notice and/or obtaining consent of Users, as appropriate. Minor changes to this Privacy Statement that will not significantly affect the way Personal Data (including Patient Health Data) of Users are processed may occur without notice or consent. Any changes will be effective when the revised Privacy Statement is posted. Users can check at the top of this Privacy Statement when it was most recently updated.

12. Contact

For questions regarding the processing of Personal Data (including Patient Health Data) of Users by Medtronic in accordance with this Privacy Statement, Users can contact the Data Protection Officer at the following e-mail address: rs.askdpo@medtronic.com