

General Conditions of use & privacy policy

16-03-2021

Statement concerning the protection of personal data

The respect of the privacy of our users and the safety of their personal data has been given the greatest attention by HeartKinetics, the editor of the OKCARDIO mobile application. This privacy policy covers all the information about the data collected and stored by HeartKinetics using the OKCARDIO mobile application, as well as the use that is made of it.

The mobile application that you are about to use further to the recommendation of your hospital or medical care center (hereinafter the "HOSPITAL") creates a link between you and the Hospital you have authorized to access your clinical and personal data. The purpose of this declaration is to inform you about the conditions which the collection and processing of your personal information will be subject to if you make use of this IT solution and the associated services, which are referred to collectively hereinafter as the "application" or "OKCARDIO". This privacy policy applies only to this mobile application. You may view this document at all times by opening your profile and clicking on the link to the declaration.

The medical certification of the OKCARDIO application is currently ongoing. It may be used only in the context of a clinical study and/or for the evaluation of its performance. In no case may it be used for taking clinical and/or therapeutic decisions. If this application has been made available to you, your profile must conform to one of the following criteria:

- You have been recruited by a clinical research center (hereinafter the HOSPITAL) to take part in our clinical trial on a voluntary basis;
- You have received a code allowing you to download the application and use it free of charge for a period of 30 days; if this applies to you, you are invited to contact one of the approved centers where the clinical assessment can be planned;
- You are a health professional or equivalent to whom the application has been provided for evaluation purposes. In this case, the application may not be used for making a clinical diagnosis; it may only be used in the strict context of assessing the technical performance of the application.

HeartKinetics' mission is the provision of technological tools that allow remote diagnosis and therapeutic decisions. We also have the mission to complete this aid by delivering personalized information intended for the patient and where applicable his/her chronic illness. The patient may with the aid of OKCARDIO share his/her information with the carers that he/she has identified as being his/her case manager. By sharing the information collected with the OKCARDIO application with the hospital's research team, you contribute both to scientific research and the development and testing of various functionalities of the application.

When you signed up for the application, the HOSPITAL asked you or will ask you for your explicit consent so that we can anonymously process your personal data as identified below strictly in the context of this clinical study and your course of treatment. By using the application you confirm this consent.

If you have any additional questions or need more information, please do not hesitate to contact us by sending an email to info@okcardio.com.

You may also contact our data protection officer at privacy@okcardio.com.

By using our application you accept this privacy policy and consent to the use of your clinical data in the context of the clinical protocol that has been given to you.

The General Data Protection Regulation (hereinafter 'GDPR') requires that all information concerning your rights is communicated to you in a concise and transparent manner using easily understood language. This statement is aimed at that objective.

If you are a minor, you have the right to ask for a simple and easily understood explanation about the essential elements of this statement. Do not hesitate to ask any questions.

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What data is collected?

By accepting this contract, the user grants HeartKinetics and the clinical teams concerned access to the data referred to below.

The data is divided into the following categories:

- the personal information and details that the user gives us;
- the data and information that we collect with the help of the sensors of the smartphone used by the application;
- technical data about the use and performance of the application.

We have installed appropriate measures to ensure that your personal information will be processed in compliance with the safety obligations imposed by the GDPR.

A few definitions

The term “data of a personal nature” or “personal data” is used here to designate all information relating to an identified or identifiable physical person.

The term “physical data” or “physiological data” is used here to indicate all the digital data collected by means of the sensors of the patient’s smartphone and which relate to the cardiac and respiratory activity of the patient as well as all supplementary digital data (height, weight, blood pressure, etc.) that may be collected or entered by the patient him- or herself.

The term “technical data” refers to all other types of data that are not personal data nor physical data; such technical data serves for the evaluation of the satisfactory functioning of the application and any improvements to be made to it as well as for contextualizing the collection of the physical data.

The term “processing” refers to any operation or any set of operations carried out with the aid of automated procedures or otherwise and applied to data or sets of data of a personal nature, such as the collection, registration, organization, structuring, conservation, adaptation or modification, extraction, consultation, use, communication by transmission or distribution in any other form which makes them available, reconciliation or interconnection, limitation, deletion or destruction of data.

Personal Information

To create an account, the user must supply us with the following information:

- surname, first name, date and place of birth, gender;
- contact details: email address, telephone number;
- details about your course of treatment: your medical treatment, your feelings about and experience of the medical treatment, your medication and confirmation that you have taken them, the physiological parameters needed to monitor your condition, your physical activity;
- limited identifying data of the attending physicians who will have access to the physiological data of a diagnostic nature: surname, first name, email address, telephone number.

Physical and clinical data

In order to make an optimal diagnosis and to monitor cardiac function as reliably as possible, the following additional data is collected:

- Height, weight, date of birth and gender;
- The date and time of registration;
- The answers to a standardized clinical questionnaire about the patient’s health;
- Limited geolocation data supplied by the mobile phone at the time of measurement in order to determine whether the measurements have been made at home or somewhere else;
- Technical information making it possible to identify the make and model of the mobile phone as well as details about the version of its operating system.

To collect the physical data, the application uses the movement sensors: the accelerometers and gyroscopes of the mobile phone. These are physiological data and they are used for diagnostic recommendations about cardiac and pulmonary function.

Technical Information

To improve our services the application is also able to access the following additional data:

- error reports and information about system activity;
- data about your “behaviour” when you use our application: such as the links you click on in the application, the internal pages of the application that you visit, external pages you visit from the application, frequency of use, etc.
- Cookies (cookies are files containing small amounts of information and which may include a unique and anonymous identifier; cookies are sent to your browser by a website and are stored on the hard drive (or equivalent) of your device). We use those basic cookies that are necessary for the satisfactory operation of the application (management of connection time and language preferences).

If you elect to contact us directly, we may receive additional information such as your telephone number, the contents of the messages and/or the attachments you wish to send us, as well as all other information that you choose to share with us.

Data Processing

The personal data collected are used to identify the user and to link them to the physical data concerning the cardiac and pulmonary function that he/she has helped to collect.

The identification of the subject is achieved by creating an account, which requires a username and an email address.

Processing of physical data & physiological parameters

The accelerometers and gyroscopes of the smartphone are used to measure the vibration of the rib cage of the user which are generated by his/her vital physiological processes: cardiac contractions, movement of the blood following its expulsion from the heart and the breathing function.

The following data is calculated:

- Amplitude of the breathing motion and frequency
- Heart rhythm and variability
- Force, kinetic energy and power of the cardiac contraction
- Energy density distribution during the cardiac cycle
- Instants relating to the various phases of the cardiac cycle

Processing of technical data

The following additional data is collected and used in order to improve the processing of patient data and to personalize them:

- Brand, model and version number of the smartphone; such information makes it possible to recover information about information such as the physical characteristics (dimensions and weight) which allow us to calibrate our data;

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- Time and date information so that the patient can keep a record of the measurements. The other personal information makes it possible to analyse the calculated values.
 - The geolocation data makes it possible to have a generalized context for the measurement. This for example makes it possible to study the geographic distribution of cardiac pathologies.
 - The additional data collected allows us to offer our users a high-performance platform and a personalized experience. It also helps us develop new services.

Personal Data Storage

The personal data is stored both on the user's mobile and on our on-line servers, which are located in Europe. They will be deleted at the user's request. To do this it is enough to open your profile and request the deletion of your data.

Disclosure of personal data to your physician and/or to your hospital

Your personal and medical data are communicated and shared with your hospital and the physicians you will have indicated in your profile so that your medical team can have access to them. They will have access to the following information:

Surname, first name(s), gender, height, weight, date of birth, name of your general practitioner (house doctor) and your cardiologist, information about your pathology and about the treatment, the answers to the standard questions you have provided, including the time and date you completed the questionnaire, and the physical and physiological data from the observations of your cardiac and respiratory functions.

Only the authorized medical and nursing personnel of the hospital with whom you were registered when signing up will have access to your personal data.

The physical and physiological data relating to your cardiac and pulmonary function will be processed after anonymization, this means it will be stripped of all elements that could allow it to be linked to your profile. It will then be made available to the personnel of HeartKinetics and to scientific teams taking part in validation studies and who also contribute to the improvement of our solutions. Such data may also be used for statistical studies aimed at highlighting the benefits of the solution. In no case will either your personal or medical data be disclosed to third parties.

Transfer of personal data

Your personal data will not be transferred to enterprises or entities other than the aforementioned without your prior consent, except in the following cases:

- The processing is necessary in the context of compliance with a legal obligation to which HeartKinetics is subject;
- The processing is necessary for the performance of tasks in the public interest or falls within the scope of the exercise of official authority vested in HeartKinetics.

In the above cases HeartKinetics will draft a protocol and will publish it on its website.

Data protection

The protection of your personal data is paramount for Heartkinetics. For this reason we work with the middleware software of the Swiss company Pryv SA. As a result we are confident that your personal data will be properly protected in compliance with the GDPR.

Your rights as a user of the OKCARDIO application

We want to be sure that you are fully aware of your rights concerning the personal data that we are processing.

If you wish to exercise your rights, please contact us in one of the following ways:

1. by letter sent by post to HeartKinetics SRL, rue Auguste Piccard 48, 6041 Gosselies, Belgium
2. by email to privacy@okcardio.com

Please enclose a copy of your identity card with your letter. It will be destroyed once your request has been processed. Should your request involve the responsibility of the hospital or your referring physician, HeartKinetics will inform you thereof.

Your rights are set out in detail below.

You have the following rights:

The right to information - You have the right to ask for information about what personal data is being processed and the rationale for such processing.

The right to withdraw your consent – You have the right to withdraw your consent at any time whatsoever. Such a withdrawal will not affect the legitimacy of the processing of the data on the basis of your consent before its withdrawal.

The right to access your personal data – You can request a copy of your personal data. You may also request additional information about the purpose of the processing, the category of data, the existence of any third parties, how long the personal data is stored and your additional rights concerning such data.

The right to rectification of your personal data – You may request us to correct certain data that you consider to be incorrect. You may also request the completion of information that you deem to be incomplete.

The right to delete your personal data – You have the right to ask us to delete your personal data. This may limit the functionalities of the application.

Your request will be implemented as quickly as possible provided that the processing of your personal data is based on your consent alone and you have withdrawn your consent.

This right to deletion does not apply to the extent that the processing is necessary:

- for complying with a legal obligation;
- for the exercise or the possible defence of our rights in a legal dispute ongoing in court.

The right to request to restrict the processing of your data – You can ask us to restrict the processing of your data subject to certain conditions. This may nonetheless limit the functionality of the application.

Your request will be confirmed if one of the following conditions is met:

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- you dispute the accuracy of your data: the use of your data will then be limited during the time needed to verify their accuracy;
 - in the event of illegal processing, you object to the deletion of your data, but request instead that their use be limited;
 - we no longer need your data, but you need them for determining, exercising or defending your rights in law;

Right to object to the processing of your data – You have the right to object to our processing of the data.

Right to the portability of the data – You have the right to transfer the data that we have collected to another organization or directly to yourself. The data will be transferred in a compatible .csv format.

You may file a complaint with the controlling authority, the Autorité des protection des données / Gegevensbeschermingsautoriteit.

If you want to make a request, we have one (1) month to reply. You do not have to state your reasons. Do not hesitate to contact us.

How do we keep your data safe?

Your data is digitized and saved locally on the mobile phone you installed the application on and in the secure database of our server(s). All exchanges between the application and the server or servers are encrypted in accordance with the standard protocols. We ensure that your personal data is protected by appropriate technical and organizational security measures against all loss, unauthorized alteration, use, disclosure or access, whether accidental or illegal.

With respect to the technical aspects our teams manage the general maintenance of the solution, which is hosted in the cloud, with the help of cyber-security experts in redundant centres all over Europe. High level protection is provided:

- Access security: the centres are equipped with access control technology;
- Redundant power supplies;
- Cooling of IT equipment by suitable means;
- Fire protection by means of specialized extinguishing systems and other physical precautions (e.g., smoke detectors).

Additional Information

The present statement is a concise statement of the rights and duties associated with the processing of your personal data in the context of the use of the OKCARDIO application. We remain at your entire disposal should you require any further clarification of this statement.

The link shown below takes you to the full text of the GDPR:

[Regulation \(EU\) 2016/679 of the European Parliament and of the Council of 27 April 2016.](#)

Amendment of this statement

We may be obliged to amend this statement in the future. In that event we will inform you and explain the changes and reasons for such amendment. You will of course continue to be able to exercise your rights as provided by the GDPR and national legislation.

How to contact us

By ordinary mail: HeartKinetics SRL, rue Auguste Piccard 48, 6041 Gosselies, Belgium

By email: privacy@okcardio.be