Patient Information Note V1.112
Remote monitoring of cardiac rhythmic prosthesis

Dear Sir/Madam,

This information note is provided to you as part of the monitoring of your cardiac electronic rhythmic prosthesis, in order to inform you and, if necessary, to allow you to consent with complete transparency to the remote monitoring.

1.In what context is your data collected?

Your data is collected as part of your medical monitoring following the implantation of a cardiac prosthesis and/or the provision of any other electronic device allowing this follow-up.
Remote monitoring does not constitute any form of emergency management but is simply an aid for the monitoring your prosthesis. In case of emergency you should, as usual, contact your doctor and possibly call "112".

2.What personal data is collected and processed?

The use by your doctor of the Implicity platform implies the collection and processing of your personal data, including health data, and in particular :

- Personal details such as your identity and contact details ;
- Health data transmitted by the electronic devices that have been provided to you, such as your cardiac rhythmic prothesis ;
- Data relating to your medical follow-up, including your social security number.

3.For what purposes is your data used?

Use for your medical follow-up and the monitoring of the technical solutions :
In accordance with articles 6.1.b and 9.2.h of the GDPR, your health data will be used to :
Allow the collection and storage of your health data and the data related to your medical monitoring ;
Allow your cardiologist and the authorised care team to use the technical solution provided by the manufacturer of your cardiac device or the Implicity platform in order to access your data ;
Provide the care team with reports and notifications linked to events detected by your electronic device ;
Control and ensure the correct operation of the technical solutions.

Use for research purposes
In accordance with Articles 6.1.f and 9.2.j of the GDPR, your *pseudonymised* **or anonymized** data will be used for the following purposes :
Improvement of the performance and functions of the technical solution by its supplier ;
Research and development, including the design of algorithms to calculate the risk of cardiovascular events in patients with cardiac insufficiency or arrhythmia such as acute cardiac insufficiency and atrial fibrillation ;
Contribution to increase of medical knowledge and improve patient care ;
Medical research ;
Evaluation and research ;
Statistical studies on implantable cardiac devices.

Through your participation, you are likely to benefit directly or indirectly from the results of this work.

4.Who is responsible for the processing your data?

In accordance with EU Regulation 2016/679 dated 27 April 2016 on the protection of individuals with regard to the processing of personal data and the free movement of such data (the "Regulation"), the following legal persons are responsible for the processing of your data :

Processing for the purposes of medical follow-up and monitoring of the technical solutions :

Your cardiologist and the authorised care team are responsible for :

- the collection, processing and sharing of your personal data, as data controller ;
- the remote medical monitoring ;
- invoicing the corresponding procedures to health insurance organisations.

The manufacturer of the technical solution (whose contact details are provided at the end of this note) is responsible for :

- collecting and processing your personal data in order to ensure the operation, control and maintenance of the solution;
- invoicing the compulsory health insurance organisations if necessary;
- the pseudonymisation of your data.

Processing for research purposes :

The health facility in which you are treated and the companies responsible for the remote monitoring solution each act as controllers for the processing operations performed as part of their research activities. These controllers will give you access to specific information about their research project for each new processing activity. In any event, they complete all the necessary formalities required by the relevant supervisory authorities, in accordance with applicable legal and regulatory provisions.

Regarding research activities for which Implicity acts as data controller, further details about the processing of your personal data are available on the following website : https://www.implicity.com/recherche-innovation/our-innovation/

Each controller identified above may appoint subcontractors who apply sufficient guarantees, especially in terms of confidentiality and security.

5.Who is your data for?

You are advised that your data is intended for use by the authorised healthcare professionals who make up the healthcare team that provides your care and in particular your cardiologist, the company responsible for the remote monitoring solution identified below, and the subcontractors they use for all technical operations relating to your data.

Where applicable, your pseudonymised data is intended for use by the sponsors of health studies and evaluations (authorised personnel), subject to your specific opposition to each study brought to your attention beforehand.

6. Use of algorithmic data processing

In the context of diagnosis and care, healthcare professionals use a software medical device with algorithmic data processing developed using machine learning technology. The purpose of this software device is to help healthcare professionals analyze the signals emitted by your implanted cardiac prosthesis. This technology is an aid to diagnosis and is in no way used as the sole means of diagnosis.

7. Data transfer outside the EU

The companies responsible for the technical solutions of remote monitoring may transfer your data outside the European Union :

For the **manufacturer of your cardiac prosthesis** : for the purposes of hosting your data or ensuring the maintenance and continuity of the remote monitoring service ;
For **Implicity, responsible for the technical solution of remote monitoring** : only for the purpose of sending you an SMS. Implicity has set up an application to enable you to inform your doctor of the reasons why your cardiac prosthesis is no longer transmitting data on the remote monitoring solutions, or to communicate clinical data useful for your medical follow-up. In this context, the technical service providers used by Implicity to send these SMS cannot guarantee that your data will be kept within the European Union. Only your telephone number and the content of the SMS may be transferred outside the EU. None of your other personal data will be transferred outside the European Union when Implicity is acting as a technical monitoring solution.

If your data must be transferred to a third country where the legislation has not been recognized as providing an adequate level of protection for personal data, the necessary security measures and appropriate safeguards will be put in place to ensure the protection of your personal data in accordance with the various applicable laws.

8.How long is Personal Data kept for?

Your medical monitoring data, including your remote monitoring data, will normally be kept for twenty years.
Data that must be processed to improve the performance and functionalities of the technical remote monitoring solution is normally kept for two years.
With regard to processing operations carried out as part of a study, evaluation or research, your data is kept for the duration of the research.

9.What are your rights?

You have the right to access the information in your file at any time. Under certain conditions, you also have the right to withdraw your consent ; to rectify, delete and transfer your personal information ; and to object to or restrict its use. You also have the right to communicate your instructions concerning what happens to your personal data after your death.

If you have any questions about the protection of your personal data or if you wish to exercise your rights, you may directly contact your doctor or the companies responsible for the technical remote monitoring solution, whose details are given below.

If you consider that your rights have not been respected after contacting the person(s) responsible(s) for the processing of your personal data, you may file a complaint with the data protection authority of your country.

Doctor/establishment responsible for remote monitoring of prostheses	Company responsible for the technical remote monitoring solution (manufacturer of prosthesis)	Company responsible for the technical solution (remote monitoring software platform)
Name: Contact details:	ABBOTT Telephone: 0 800 000 565 BIOTRONIK Telephone: 0 800 801 034 BOSTON SCIENTIFIC Telephone: 0 805 540 422 MEDTRONIC Telephone: 0 800 381 700 MICROPORT Telephone: 0 805 980 041	IMPLICITY Data Protection Officer : dpo@implicity.com

Patient consent form
Remote monitoring of cardiac rhythmic prosthesis

I, the undersigned (Last and First Name) _____,
acknowledge :

- having received and read the information note V1.112 attached to this consent form ;
- having received an information note from the supplier of the technical solution concerning the operation and use of the electronic device allowing remote monitoring ;
- that the functioning and conditions of use of the remote monitoring, the therapeutic assistance associated with it, and of the electronic device allowing the remote monitoring have been clearly explained to me;
- and that all the questions I have asked have been answered satisfactorily.

I understand the need to attend appointments with my doctor and that the success of the treatment performed depends on following the instructions given to me.
I note that my doctor may decide at any time to terminate the remote monitoring of my pacemaker as part of my remote medical monitoring. In this case, I will return the transmitter and other electronic devices as soon as possible.
I understand that remote monitoring is not an emergency system.

By signing this document :

- **I agree to the remote monitoring of the electronic device that was provided to me and to the therapeutic assistance (if applicable) under the conditions described to me**. I am aware that I can withdraw my consent at any time and that in this case my medical treatment will not be otherwise affected.
- **I understand that the remote monitoring of my cardiac prosthesis involves the processing of my personal health data** in accordance with the Regulation and under the conditions described in the attached information note.
- **I understand that my pseudonymized or anonymized personal health data may be reused for evaluation and research purposes**, and that I have a "**right to object**" at any time to the use of my personal data for these purposes (to exercise this right, you may contact the persons whose contact details are provided in section 8 of the information note attached to this consent form).

I am aware that the doctor may have to contact me and I therefore undertake to inform him/her of any change in my contact information (as noted below).

Place : Patient's signature :
Date :

Patient's contact information :

Address: _____

PC: _____ City: _____
Landline: _____ Mobile: _____
E-mail: _____

Done in 2 copies, one given to the patient and the other archived in the patient's file

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