



Title:	Privacy Policy
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1. Objective

Cardiaccs has established a privacy policy for all personal data which are collected, through feedback and complaint processes for example as per [SOP-52 Feedback](#) .

Before collecting data, this policy is sent to the relevant person (e.g complainant) as per relevant procedure. **By continuing the process of collecting data, it means that this person consents to Cardiaccs privacy policy.**

2. Scope

This privacy policy is the foundation for Cardiaccs AS requirements for all data collection.

3. Responsibilities

Top Management is responsible for establishing and maintaining this Quality Policy.

4. Terms and Definitions

N/A

5. Policy

5.1 What we collect, why and for how long

Cardiaccs controls processes (such as feedback and complaint) that can collect personal data. This data may be sensitive (e.g. health data), as defined in the European Union General Data Protection Regulation 2016/679 (GDPR). We collect this data to improve the safety and performance of our products and services. We do not sell your data.

Please read carefully our Privacy Policy below. By continuing to use our processes and services, it means that you, as a data subject, consent to Cardiaccs' Privacy Policy.

5.1.1 Identity & contact information

In order to communicate and reply to your inquiries, we require your email address. We also give you the option to add a name, but we do not normally look at or access this information. We'll never sell your personal info to third parties, and we won't use your name in marketing statements without your permission either.

5.1.2 Information related to the use of the product

When necessary and for investigation purposes, we may request more information regarding which products have been used, how they have been used and by whom.

5.1.2 Voluntary correspondence

When you write to us with a question or to ask for help, we keep that correspondence, including the email address, so that we have a history of past correspondences to reference if you reach out in the future.

5.1.3 How long will we keep your data

Your data will be kept for at least 10 years after the last device has been placed on the market (and 15 years if your data are related to implantable devices). If you want us to delete your data, please see section 5.4 below.

5.2 When we share your information

The only times we will share your info is when required under applicable law. If the appropriate law enforcement authorities have the necessary warrant, criminal subpoena, or court order requiring we share data, we have to comply. And unless we're legally prevented from it, we'll always inform you when such requests are made.

5.3 How we secure your data

Data you share with us is uploaded via 128-bit SSL encryption into our quality management system (Qualio). The database backups are also encrypted.

Our quality management system is hosted on Amazon (<https://aws.amazon.com/>), a global industry leader in hosting scalable architectures in the cloud. Encryption offered by Amazon is performed on top of the one performed by Qualio.

For more information on our server security, you can contact info@cardiaccs.com.

5.4 Your Rights With Respect to Your Information

At Cardiaccs, we apply the same data rights to all customers, regardless of their location. These rights include:

- **Right to Know.** You have the right to know what personal information is collected, used, shared or sold. We outline both the categories and specific bits of data we collect, as well as how they are used, in this privacy policy.
- **Right of Access.** This includes your right to access the personal information we gather about you, and your right to obtain information about the sharing, storage, security and processing of that information.
- **Right to Correction.** You have the right to request correction of your personal information.
- **Right to Erasure / "To be Forgotten".** This is your right to request, subject to certain limitations under applicable law, that your personal information be erased from our possession and, by extension, all of our service providers.
- **Right to Complain.** You have the right to make a complaint regarding our handling of your personal information with the appropriate supervisory authority. To identify your specific authority or find out more about this right, EU individuals should go to https://edpb.europa.eu/about-edpb/board/members_en.
- **Right to Restrict Processing.** This is your right to request restriction of how and why your personal information is used or processed, including opting out of sale of personal information. (Again: we never have and never will sell your personal data).
- **Right to Object.** You have the right, in certain situations, to object to how or why your personal information is processed.
- **Right to Portability.** You have the right to receive the personal information we have about you and the right to transmit it to another party.
- **Right to not be subject to Automated Decision-Making.** You have the right to object and prevent any decision that could have a legal, or similarly significant, effect on you from being made solely based on automated processes. This right is limited, however, if the decision is necessary for performance of any contract between you and us, is allowed by applicable law, or is based on your explicit consent.

These rights can be exercised by contacting us at info@cardiaccs.com . You can also contact us if you have questions about exercising these rights or need assistance.

5.5 Changes & questions

We may update this policy as needed to comply with relevant regulations and reflect any new practices. Whenever we make a significant change to this policy, we will announce it at <https://www.cardiaccs.com/>.

Have any questions, comments, or concerns about this privacy policy, your data, or your rights with respect to your information? Please get in touch by emailing us at info@cardiaccs.com and we'll be happy to answer them!

6. References

<https://www.cardiaccs.com/>

https://edpb.europa.eu/about-edpb/board/members_en.

7. Related Documents

- [SOP-32 Complaint Handling](#)
- [SOP-46 Vigilance, reporting and field safety corrective Action](#)
- [SOP-52 Feedback](#)

8. Attachments

No attachments.