

PRIVACY POLICY

1 GENERAL INFORMATION

1.1

With the browser-based software *ICPicture*, data can be collected, compiled, displayed and evaluated (e.g. mean, amplitudes, histogram) for research purposes in order to convert data for commonly used file formats in the field of science.

1.2

You must create an account in order to be able to use *ICPicture*. You can find out more about the application in the Terms of Use at:

<https://icpicture.miethke.com/nutzungsbedingungen.html?readonly=true>.

1.3

Data processing, in particular session storage and Indexed Database API, takes place locally on the user's device. All other aspects are regulated in this Privacy Policy.

1.4

The controller for the processing of personal data on this website is

Christoph Miethke GmbH & Co. KG (in short: MIETHKE)

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14469 Potsdam Germany

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Fax: +49 331 620 83-40

info@miethke.com

Legal notice: <https://www.miethke.com/impressum/>

2 PROCESSING OF PERSONAL DATA

2.1 Types of data

The following types of personal data may be processed when using our website <https://icpicture.miethke.com/>:

- Contact details (e.g. email address, telephone number, etc.)
- Content data (e.g. your data entered in the contact form)
- User data (e.g. user ID, name, institution)
- Interaction data (e.g. website interactions, error messages)
- Metadata & communication data (e.g. IP addresses, device information, browser version, random session ID, length of time spent on the website, website speed, duration of import process)
- Pressure measurement data (e.g. time & pressure readings, measuring duration & mode, number of patients, number of patient measurements, patient position, as well as the encrypted and thus anonymised sensor ID exclusively in the case of the import of data from an *M.scio*[®] / a *SENSOR RESERVOIR* / a *SENSOR PRECHAMBER*)
- Patient data (age, shunt component, general well-being)

2.2 Categories of data subject

The data subjects are the visitors and users of *ICPicture* and their patients.

2.3 Purposes of processing & legal basis

The purposes of processing are:

- a) the provision of the website for processing and converting measurement data (Article 6 (1) b GDPR)
- b) answering contact requests by email to icpicture@miethke.com or via the contact form at: <https://icpicture.miethke.com> (Article 6 (1) a GDPR)
- c) measures to guarantee IT security (Article 6 (1) f GDPR)
- d) improving the website (Article 6 (1) f GDPR)
- e) post-market surveillance (Article 9 (2) i GDPR in connection with Art. 83 (1) MDR (Medical Device Regulation))

2.4 Responsibilities of users

Users are responsible for the processing of patient measurement data in compliance with data protection law. In Europe, either consent must be obtained in accordance with Article 9 (2) a GDPR or other permission according to Article 9 GDPR must have been provided.

3 RETENTION PERIOD

The patient data processed by users in *ICPicture* is only briefly processed for the amplitude calculation anonymously on the MIETHKE server's working memory and is not stored. Therefore, all data must be stored locally and backed up by the user.

The anonymised data which is processed within the framework of post-market surveillance is stored on the MIETHKE server and will be erased 15 years after the last marketing of the *M.scio*[®] / *SENSOR RESERVOIR* / *SENSOR PRECHAMBER*. (Article 10 (8) GDPR)

After this, the further processing of the data then only takes place locally on the user's end device. The retention period of all the other data can depend on various factors. Your data will be erased if:

- the legal basis for the processing no longer exists
- you withdraw your consent to the processing
- the purpose of the processing no longer exists
- statutory erasure periods have been reached
- you object to the processing of your data and no other statutory storage periods prevent erasure

4 POST-MARKET SURVEILLANCE

For post-market surveillance of the *M.scio*[®], the meta information and the pressure measurement data specified in Section 2.1 of this Privacy Policy shall be anonymised and transmitted to MIETHKE in an encrypted manner. The user provides MIETHKE with a guarantee that it has informed its patients before using *ICPicture* pursuant to Article 13 (1) e GDPR.

The aim of post-market surveillance with *ICPicture* is:

- to systematically identify risks associated with the practical use of the product
- to review the performance of the products 'in the field'
- to find product faults and security issues that have not been discovered
- to continuously update the risk/benefit evaluation and
- to quickly introduce the necessary measures, e.g. recalls

Furthermore, as part of the post-market surveillance, individual surveys will appear in *ICPicture*, in which general questions will be asked about the use of the *M.scio*[®], as well as your name and your institution.

5 RIGHTS OF THE DATA SUBJECTS

As a data subject in connection with processing, you have the following rights at all times:

- Free access to information on whether and which personal data about you is being processed, particularly the purposes of the processing, the categories of processed personal data, the recipients of the data, where possible the storage period for the personal data or the criteria used to determine that period (Art. 15 GDPR)
- Rectification of your data (Art. 16 GDPR)
- Erasure of your data (Art. 17 GDPR)
- Restriction of processing of your data (Art. 18 GDPR)
- Objection to processing based on legitimate interests (Art. 21 GDPR)
- Withdrawal of consent to the processing of personal data (Art. 7 (3) GDPR)
- Lodging a complaint with a supervisory authority (<https://www.lida.brandenburg.de/de/beschwerdeformular>)
- Access to all available information about the origin of your data
- The provision of the data transmitted by you in a commonly used, structured, machine-readable format ('right to data portability', Art. 20 GDPR)

Automated decision-making, such as profiling, does not take place.

Since the server-side processing of the pressure measurement data is only temporarily stored in the MIETHKE server working memory and we cannot identify the data subjects with regard to the processing of data within the framework of post-market surveillance, we are unable to guarantee the abovementioned rights for data subjects.

6 INFORMATION ABOUT YOU TO THIRD PARTIES

No data will be passed on to third parties.

7 INFORMATION SECURITY

To ensure that information is secure, we implement technical and organisational as well as contractual measures in order to ensure compliance with the requirements in Art. 32 GDPR.

8 SESSION STORAGE

Session storage is a technique of temporarily storing data locally in a browser. However, only the page which is viewed can access this data using a script. Opening a web page using http and https generates two different session storage data packages. Unlike cookies, the content cannot be read or changed by third parties when using session storage. The data in the session storage is erased immediately after the browser window is closed.

When using <https://icpicture.miethke.com>, the communication data and meta data is anonymised in session storage in order to create usage statistics and to optimise *ICPicture*. This serves to optimise our website (see point 11 'Analysis' of this Privacy Policy).

The following information is stored in session storage:

- Randomly generated session ID as well as the time a session begins and ends
- Time and designation of a selected element of the website

- Browser, language and operating system of the user
- User information that is required on the user side for the session.
- Meta information of measurements, such as measuring mode, file size, measurement date, measurement duration, statistical values of the measurement data, duration of the data import
- Meta information of patients, such as the number of patients in the user's local database (see point 10 'Indexed Database API' of this Privacy Policy)
- Irreversibly encrypted SensorID

9 LOCAL STORAGE

Local storage works in the same way as session storage. However, unlike session storage, the data is permanently stored locally in the browser.

The following information is stored in local storage:

- Randomly generated client ID
- The configuration settings

10 INDEXED DATABASE API

This technology, abbreviated to Indexed Database API (Indexed DB), is an object-based database that is created in the user directory of the user who is logged in on the PC. This is where the application stores the analysis results and histories locally (incl. notes and patient data). Other websites and user accounts on the computer cannot access these databases. The Indexed DB is used in *ICPicture* for the persistent storage of the archive information in the user account of the local computer. Each user is responsible for preventing the loss of the information stored therein, e.g. by using the archive's export function.

11 ANALYSIS

In order to improve our website, we use our own self-hosted analysis system to create visitor statistics and user statistics. This system involves transmitting anonymised contents of the session storage, meta information of the Indexed Database API (e.g. number of patients) as well as error messages to MIETHKE servers via an encrypted connection and storing them there.

Collecting information about the way our users use the website allows us to identify areas of improvement that can help make the experience better. Furthermore, it is essential to monitor how the application is working to ensure that the product has no errors. Therefore, this application may only be used if users consent to the collection of usage statistics. These are not passed on to third parties and are not used for advertising purposes.

12 PROCESSING WITHIN THE FRAMEWORK OF THE USE OF *ICPICTURE*

Patient data on <https://icpicture.miethke.com> is mainly processed locally on the end device of the user of this website. The processing of the pressure measurement data of the data subjects takes place on the MIETHKE servers due to the complexity.

As such, this qualifies as processing in accordance with Art. 28 GDPR. The controller within the meaning of Art. 4 GDPR is the user of the website <https://icpicture.miethke.com> and the processor within the meaning of Art. 4 GDPR is MIETHKE. Measured data (only the selected and necessary time and pressure readings) from intracranial pressure measurements of patients are processed for the purposes of the processing of pressure measurement data. For the purpose of processing,

the measurement data is encrypted and transmitted to the MIETHKE servers before being processed. The processing takes place exclusively on the working memory of the MIETHKE server and the data is not stored. Furthermore, no additional personal data is processed on the MIETHKE servers. After completion of processing, the data is only available locally on the user's device. Since the measurement data is processed in encrypted form, no MIETHKE employees have access to the data which is to be processed. All MIETHKE employees are also bound by an obligation of confidentiality. The data is not transmitted to third countries.

MIETHKE shall support the controller in complying with the requirements of Art. 32 to 36 GDPR insofar as possible.

The controller shall bear sole responsibility for complying with Section 3 GDPR, as MIETHKE cannot directly access the measured data or identify the data subjects as the data is encrypted and immediately erased.

MIETHKE uses technical and organisational measures such as encryption, data minimisation and access restrictions to comply with the requirements of Art. 28 (1) GDPR and Art. 32 GDPR.

MIETHKE uses cionix GmbH (<http://cionix.de/impressum/>) as the processor for the provision of the servers, with whom a data processing agreement according to Art. 28 (4) GDPR exists. If there is a change to the processor, the controller shall be informed thereof in advance in accordance with Art. 28 (2) GDPR and given the opportunity to object to the change. If other processors are used, a contract according to Art. 28 (4) GDPR will be concluded with them.

13 DATA PROTECTION OFFICER

Our data protection officer, Mr Meyer, is responsible for ensuring compliance with this Privacy Policy during our daily work. If you have any questions about this Privacy Policy, please contact us:

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Data protection officer
Jonathan Meyer
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14 CHANGES

This Privacy Policy may be revised over time if legal requirements have to be implemented. The Privacy Policy valid at the time applies.

Potsdam, 01/02/2022