

Brainlab Cognition - Privacy Statement

Last updated on October 21, 2021

1. General

Welcome to the Brainlab Cognition App provided by the Brainlab AG and Brainlab Ltd. (Israel) (“Brainlab”). We are highly committed to protecting your privacy and treat your personal data with utmost care. We collect and use your data only according to the applicable data protection provisions. Our employees and agents are obliged to comply with the data protection provisions in accordance with statutory requirements.

Hereinafter we inform you about the extent, type and purpose of the collection and use of your personal data when using the Brainlab Cognition App (the “App”).

2. Scope and purpose of data processing and legal basis

The App provides a verbal memory test. You will be asked to repeat words given previously as part of the testing in order to test your verbal memory skills. For this, the App has voice recognition. Voice recognition is made while pressing and holding the displayed microphone symbol during the test. You can revoke permission to access the iPad microphone in the application settings. Then you will not be able to use the App.

The use of the voice recordings by the SiriKit software requires your prior express consent. You will be asked for your consent for the collection and use of your voice recordings when starting the App and accepting the Terms of Use.

You may revoke your already given consent at any time during the use of the App without giving any reason to prevent future use of the data. To revoke your consent you can click the home button of the device on which you use the App. This will exit the App and will lead you to the start page.

SiriKit will collect no personally identifiable data. No data which will make it possible to identify you personally will be sent by Siri to Apple Inc. along with the voice data, as none is asked by the App or stored on the App or the device. When Siri is turned on, the device creates random identifiers for use with the voice recognition and Siri servers. These identifiers are used only within Siri and are utilized to improve the service. If Siri is subsequently turned off, the device will generate a new random identifier to be used if Siri is turned back on.

When clicking the reset button in the App all data stored in the App will be removed from the device. However, the created test report will be retained by Brainlab and will not be deleted.

The answer to the questions, particularly the words which you are asked to repeat by the App are not likely to allow any reference to you as a specific person. You will not be asked to provide any identifying information such as your name or address. If you do not want to be identifiable we recommend you not to use words or phrases providing a reference to your identity. You will not be asked to provide any such personally identifiable information. However, the disclosure of any such personally identifiable information by you will be given voluntarily and be based on your consent.

The results for each task, such as correct responses, incorrect responses, time to finish the task and reaction time to stimuli will be contained in an evaluation report. Additionally, the treating

physician will enter your date of birth, from which your age is determined, gender, education and very basic treatment and tumor clinical information such as tumor location, tumor and target volume, start date and type of treatment, clinical parameters (Karnofsky performance status) and medications which will be stored on the iPad. This information will allow your healthcare provider to have information about your cognitive performance throughout time. Your healthcare provider can export the evaluation report as PDF file, print it or send it to his/her e-mail account. Besides this, the data will only be used by Brainlab for research purposes and to improve the product.

In case you do not give this express consent no voice recording and IP address is collected or used, but you will not be able to use the App. You may revoke your already given consent at any time during the use of the App without giving any reason to prevent future use of the data. To revoke your consent you can click the home button of the device on which you use the App. This will exit the App and will lead you to the start page.

Otherwise, your personal data will not be collected and used unless you have given your express consent prior to such collection and use of data.

When clicking the reset button in the App all data stored in the App will be removed from the device. However, the created test report will be retained by Brainlab and will not be deleted.

3. Recipients or categories of recipients and Transfer of personal data to third countries

Your personal data may be accessible by associated companies and service providers e.g. IT providers and others who help Brainlab provide the services to you.

These service providers will only get access to those specific data that is required to fulfill their services. Otherwise, your personal or personally identifiable data will not be transferred to third parties unless you have given your express consent prior to such data transfer.

Some of these associated companies and service providers are located outside the scope of the law of the European Union (e.g. United States or Israel). Should third parties come into contact with your personal data, we make use of legal, technical and organizational measures and monitor the service providers on a regular basis to ensure that such parties comply with the relevant data protection regulations and with this Privacy Statement as well.

Particularly, where service providers are involved which are located in a country not considered as providing an adequate level of protection for personal data transferred from the European Union. These service providers are obliged on the basis of contractual agreements ensuring an adequate level of data protection.

3.1. Service and Support

Service and support for the App are provided besides the Controllers as well by the subsidiary Brainlab Inc. (USA). For this purpose, patient data may be transferred to Brainlab Inc. (such as subject ID, selected language, date of birth, age, gender, ethnicity, education, health data (date of primary cancer diagnosis, date of brain metastasis diagnosis (if applicable), diagnosis name, diagnosis location, number of brain lesions, Karnofsky Performance Status, tumor volume (cm³), start date and type of treatment, medication) and test results (test date, tests results (number of correct and incorrect responses, duration for each task of the test)).

We ensure an adequate level of data protection when transferring data to the USA by concluding standard data protection clauses provided by the Commission of the European Union between the Brainlab AG and the Brainlab Inc. Appropriate guarantees to ensure that your data is processed as securely as within the European Union are thereby given.

3.2. Voice Data

Your voice data will be transferred to Apple Inc., based in California, USA, without any data which will identify you as a person for speech recognition, processing and/or transcription purposes. Apple uses approved Model Contractual Clauses for the international transfer of personal information collected in the European Economic Area and Switzerland to ensure an adequate level of data protection.

When using the App the voice recognition software will be sending the recorded audio data to Apple for speech recognition, processing and/or transcription purposes.

4. Duration of data storage

We store your personal data for as long as necessary to provide the App or to fulfil legal and contractual obligations.

If the storage of your data is no longer necessary to provide the App or to fulfil legal or contractual obligations, we will delete your data unless the storage is necessary for the fulfilment of regulatory storage obligations according to Annex IX, section 2.1 of the Medical Device Regulation.

4.1. Voice Recordings

User voice recordings are saved for a six-month period so that the recognition system can utilize them to better understand the user's voice. After six months, another copy is saved, without its identifier, for use by Apple in improving and developing Siri for up to two years.

For further information please refer to Apple's privacy policy <https://www.apple.com/legal/privacy/en-ww/> and their security policy https://www.apple.com/business/site/docs/iOS_Security_Guide.pdf.

5. Obligation to provide personal data

There is no legal or contractual obligation to provide personal data. The provision of personal data is also not required for the conclusion of a contract. The basis for the processing of your data is just your consent. The consequence of not providing your personal data is that you cannot use the App.

6. Automated decision-making

You are not subject to a decision based solely on automated processing, including profiling, which produces legal effects concerning you or similarly significantly affects you (see Art. 22 GDPR).

7. Your Rights as a Data Subject

You have the right

- pursuant to Art. 15 GDPR to request information about your personal data processed by us;

- pursuant to Art. 16 GDPR to demand the rectification of inaccurate or the completion of incomplete personal data stored by us;
- pursuant to Art. 17 GDPR to demand the deletion of your personal data stored by us;
- pursuant to Art. 18 GDPR to obtain the restriction of the processing of your personal data;
- pursuant to Art. 20 GDPR to receive your personal data, you have provided to us, in a structured, commonly used and machine-readable format or to request transmission to another controller;
- pursuant to Art. 21 (i), under certain conditions, to object to the processing of your personal data based on Art. 6 Sec. 1 lit. e GDPR (in the public interest) or pursuant to Art. 6 Sec. 1 lit. f GDPR (for safeguarding a legitimate interest), or (ii) to object to the processing for direct marketing purposes;
- pursuant to Art. 7 Sec. 3 GDPR to withdraw a consent once given to us at any time. This also applies to the withdrawals of consents that were given to us prior to the entry into force of the General Data Protection Regulation, ie before 25 May 2018. As a result, we will not be allowed to continue the processing based on this consent for the future without affecting the legality of the processing carried out on the basis of the consent until the withdrawal;
- pursuant to Art. 77 GDPR lodge a complaint with a supervisory authority.

For asserting the statutory data subject rights and for all other questions about data processing, please write to the address of Brainlab AG listed below or send an e-mail to legal@brainlab.com. The exercise of your above rights is free of charge for you.

8. Contact details of the controller and the data protection officer

Controller	Legal representatives	Data protection officer
Brainlab AG Olof-Palme-Straße 9 81829 Munich Germany	<p>Chairman of the supervisory board: Dietrich von Buttler</p> <p>Board of Directors Stefan Vilsmeier (CEO) Rainer Birkenbach Jan Merker</p>	Katharina Ruhenstroth intersoft consulting services AG Beim Strohhouse 17 20097 Hamburg Germany
Brainlab Ltd. 35 Efal Street PetachTikva 4951132, Israel	<p>Board of directors Stefan Vilsmeier Yifat Mushkin</p>	

Please note that SiriKit itself and Siri servers are owned by Apple Inc. as an independent controller. Please refer to their privacy policy <https://www.apple.com/legal/privacy/en-ww/> for more information.

9. Changes to this Privacy Statement

We reserve the right to change or amend this Privacy Policy at any time in accordance with applicable data protection laws.

For inquiries, please contact legal@brainlab.com.