aba stroke

INFORMATION LEAFLET

FOR PATIENTS AND THEIR FAMILIES

Wersja: ABA-DT IFU rev. 2_EN
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INFORMATION LEAFLET FOR PATIENTS AND THEIR FAMILIES

Contains detailed information on the operation, safety, precautions, indications, and contraindications necessary for the patient's use of the device.

VERSION OF THE INSTRUCTIONS FOR USE INTENDED FOR THE USA MARKET AND UE MARKET.

MD CE 0197 Medical Device: ABAStroke

SN Software Version: 1.0.2

UDI (01) 05905753795010
(8012) 1.0.2

INTENDED USE

The ABAStroke application is intended for adults over 18 years of age who experience cognitive deficits after a stroke. It is aimed at individuals who require regular cognitive function rehabilitation in a home setting. It enables work on:

- Attention
- Memory
- Executive functions
- Perception
- Reasoning / Thinking

RECOMMENDATIONS FOR USE

In adult patients over 18 years of age diagnosed with cognitive deficits with a MoCA scale score of less than 15 or more than 25 points, ABAStroke therapy may not be fully effective.

The clinical efficacy of the device has not been proven when the ABAStroke application is used outside the intended use specified by the manufacturer, including:

- use of the application for the rehabilitation of cognitive deficits resulting from conditions other than a stroke;
- use of the application in patients whose ischemic or hemorrhagic stroke occurred more than 6 months ago;
- use of the application in patients diagnosed with cognitive deficits with a MoCA scale score of less than 15 points, or using other diagnostic tests.

Unless otherwise recommended by a doctor, it is advised to use the application for 90 days to maximize the rehabilitation effect.

WARNINGS

If the application is used for cognitive function rehabilitation outside the indications specified by the manufacturer, i.e., in patients diagnosed with cognitive deficits with a MoCA scale score of less than 15 points or using other diagnostic tests, the patient may not be able to use the application. Additionally, for patients with a MoCA scale score of more than 25 points, the use of the product may be unwarranted.

To use the ABAStroke application, the patient must have the necessary motor skills to be able to independently operate a smartphone and the application on the phone.

Before starting a rehabilitation session, ensure a quiet and calm space around you, assume a comfortable position, and ensure good lighting to see the phone screen clearly. Remember to have a well-charged phone (above 60%).

The minimum exercise time on ABAStroke should be 3 sessions per week, with a recommendation of 7 sessions per week. One session, lasting approximately 45 minutes, can be completed per day.

During the first use of the application, we will ask you to perform a few tasks. The results will allow us to prepare personalized exercises tailored to your difficulties and abilities.

During rehabilitation, try to focus solely on performing the exercise. Do not interrupt the exercises while they are in progress.

CONTRAINDICATIONS

Epilepsy/seizure disorders - due to the standard contraindication for individuals with this condition regarding the use of electronic screens, which can potentially trigger a seizure.

INFORMATION

The product has undergone a clinical study. Due to the specifics of the study, some individuals could not participate due to certain medical conditions or medications. Below is a list of these exclusion criteria:

1. Visual impairments of various etiologies that prevent the efficient use of a device with electronic displays.
2. Occurrence of psychotic episodes and/or manic episodes and/or severe depression (26 or more points on the Beck scale) within the last year.
3. History of alcohol abuse or physical dependence on opioids within the last 2 years.
4. Severe aphasia.
5. Dementia greater than moderate.
6. Treatment with pro-cognitive drugs in the last 6 months before starting ABAStroke therapy:

- cholinesterase inhibitors: donepezil, rivastigmine, galantamine,
- NMDA receptor antagonist: memantine,
- nootropic (pro-cognitive) drugs: cerebrolysin, citicoline, vinpocetine, nicergoline, piracetam, Ginkgo Biloba preparations, lecithin.

CAUTION!

Stop using the application and immediately contact your doctor or another qualified healthcare professional if any of the following occur:

1. Seizure / epileptic fit.
2. Sudden or progressive loss of balance, severe dizziness.
3. Double vision or a sudden deterioration in visual acuity.
4. Sudden, very severe headache with no obvious cause.
5. Problems with speech, orientation, or memory (disorientation, slurred speech).
6. Unilateral weakness, numbness, or paralysis of the face/limbs.
7. Any other concerning symptoms related to your health.

TECHNICAL REQUIREMENTS

Supported operating systems

Minimum version for systems:

- Android (minimum version: 9)
- iOS (minimalna wersja: 15)

Recommended minimum hardware requirements

Recommended minimum screen resolution: 360x640 px
Mobile device with at least 150 MB of free memory

Make sure the application is always updated to the latest version through system updates of the device you are using!

PATIENT JOURNEY

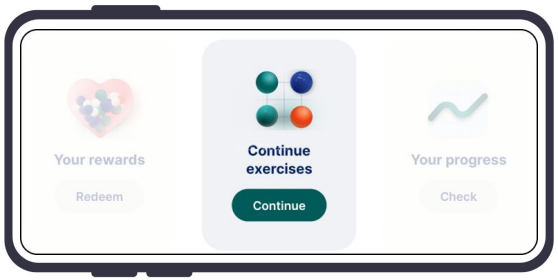
aba stroke

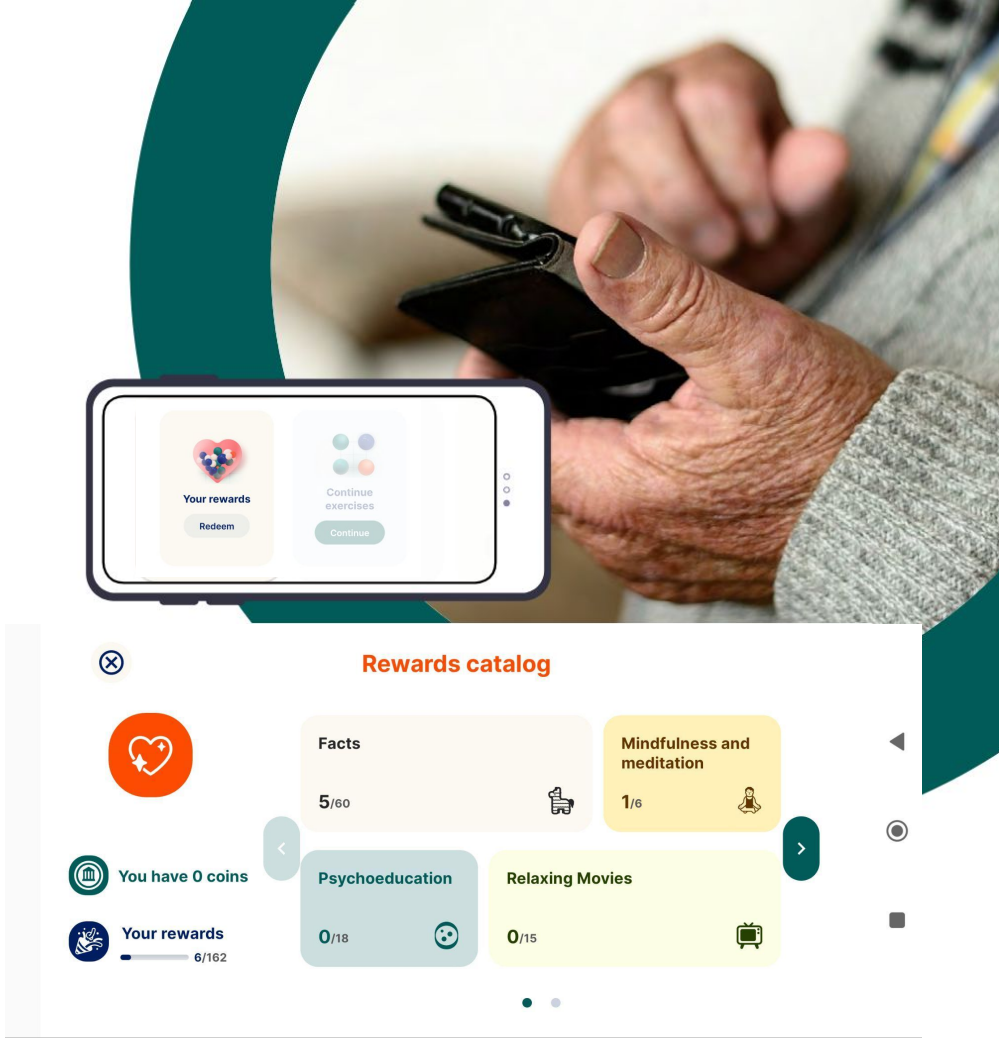
PRE-TEST

During your first use of the application, we will ask you to perform a few tasks. The results will allow us to prepare personalized exercises tailored to your difficulties and abilities.

EXERCISES

Every day, you will participate in a session lasting about 45 minutes, with the exercises themselves taking about 30 minutes. Each day, we will prepare an individual training plan for you, adjusted to your needs and progress.





REWARDS

For correct answers, you will collect coins that you can exchange for rewards. We have prepared a wide range of rewards in various forms and topics, such as psychoeducation, relaxation, fun facts, daily life tips, and speech therapy exercises.

STATISTICS

You can track your progress in the statistics module. There you will find information about your effectiveness and regularity, as well as the cognitive deficits you are working on.

INSTALLATION

If the installation was successful:

- The ABAStroke icon will appear on the main (home) screen of your smartphone.
- By tapping the icon, the application will launch without any error messages.
- You will be able to navigate the application freely - for example, moving from the home screen to exercises and back.
- In the application menu, you will find easy access to information about ABAStroke as a medical device.

REMEMBER

- Set up a screen lock / PIN or biometric authentication on your phone.
- Keep your phone's operating system up to date.
- Use trusted Wi-Fi networks only.
- Respond to suspicious messages or activity.
- Report security issues to: tech@abastroke.com

HOW TO LOG IN TO THE APPLICATION?

Launch the ABAStroke application by tapping its icon on the phone's display.

On the first use, the application may ask you for an **access code**. Enter the code in the appropriate field. Activating the code provides access to the application for 90 days. **Do not share the code** or access credentials with third parties.

Start your exercises!

AVAILABILITY OF THE INFORMATION LEAFLET

The Information Leaflet for Patients and Their Families is available to all users in digital format on the manufacturer's website : **www.pomoc.abastroke.com**

The ABAStroke application user can also receive a paper version of the instructions free of charge within 7 business days from the date of the request. To do so, please send an email to: **contact@abastroke.com** with the subject line "**Patient Information Leaflet**".

The label and IFU are available in electronic form within the application after tapping the button on the ABAStroke start screen.

REPORTING SERIOUS MEDICAL INCIDENTS

Any serious incident related to **the ABAStroke application** should be immediately reported to the manufacturer at contact@abastroke.com and to the competent authority of the State in which the user or patient is established.

Serious incident - means any incident that directly or indirectly led, might have led or might lead to any of the following:

a) the death of a patient, user or other person;
b) the temporary or permanent serious deterioration of a patient's, user's or other person's state of health;
c) a serious public health threat.

Incident - means any malfunction or deterioration in the characteristics or performance of a device made available on the market, including use-error due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer and any undesirable side-effect.

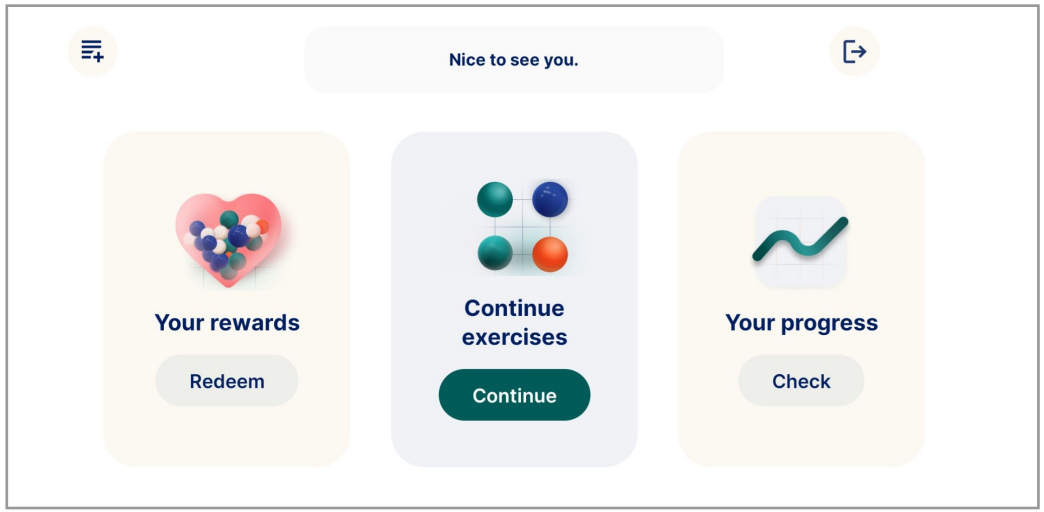
TROUBLESHOOTING

1. The application asks for the code again:
Re-enter the access code.

2. The application freezes or an error appears:
Close the application and try to restart it. If the problem persists, go to the application's info settings and clear its cache, then restart the application.

3. The session loading time is very long:
Make sure you have internet access. If the problem persists, close the application and try to restart it. If the problem continues, go to the application's info settings and clear its cache, then restart the application.

In case of other recurring difficulties or questions, contact us at **: contact@abastroke.com**



Symbols Used

	Manufacturer
CE	Conformity with European regulations
MD	Medical device
	Consult instructions for use
UDI	Unique device identifier (1) – UDI-DI code/ Global Trade Item Number (GTIN) (8012) – Software version number
SN	*Revision, Software version number*
	Label symbol in the application
	Log out of the application

CONTACT THE MANUFACTURER

ABAStroke Sp. z o.o.
ul. Warszawska 3/3
31-155 Kraków, Poland
contact@abastroke.com