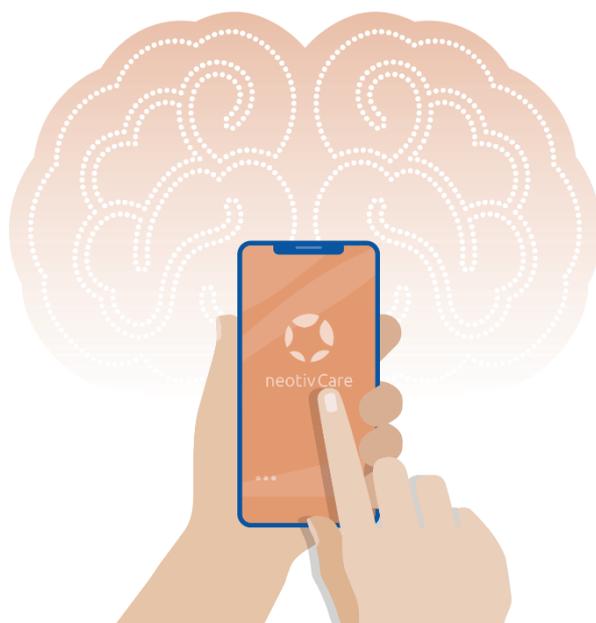




Instructions for use



Language: English

TABLE OF CONTENT

- I. GLOSSARY 3**
- II. SYMBOLS AND EXPLANATIONS 4**
- III. STATUS OF INFORMATION 5**
- IV. DESCRIPTIVE INFORMATION 6**
 - PURPOSE OF THE DEVICE (INDICATIONS FOR USE)..... 6*
 - INDICATIONS..... 6*
 - DESCRIPTION OF THE DEVICE..... 6*
 - WHEN THE DEVICE SHOULD NOT BE USED (CONTRAINDICATIONS)..... 7*
- V. RISKS AND BENEFIT 7**
 - GENERAL WARNINGS AND PRECAUTIONS..... 7*
 - POSSIBLE RISKS THAT COULD ARISE FROM USING NEOTIVCARE IN AN IMPROPER FASHION MIGHT INCLUDE 7*
 - THESE RISKS MIGHT RESULT IN THE FOLLOWING..... 8*
 - ENSURE THE FOLLOWING TO MINIMIZE THESE RISKS 8*
 - OTHER RISKS, THAT ARE NOT ASSOCIATED WITH IMPROPER USAGE OF THE APP MIGHT INCLUDE..... 8*
 - THIS RISK MIGHT RESULT IN THE FOLLOWING..... 9*
 - HOW ARE THESE RISKS ADDRESSED?..... 9*
 - BENEFITS OF USING NEOTIVCARE INCLUDE..... 9*
 - THESE BENEFITS MIGHT RESULT IN THE FOLLOWING 9*
- VI. OPERATING INFORMATION 9**
 - EXPECTATIONS OF THE DEVICE AND THE PROCEDURE ASSOCIATED WITH IT..... 9*
 - SETUP INSTRUCTIONS..... 10*
 - OPERATING INSTRUCTIONS 11*
- VII. TROUBLESHOOTING INFORMATION 13**
- VIII. TRAVEL OR INTERNATIONAL USE..... 18**
- IX. USER ASSISTANCE INFORMATION..... 18**

I. GLOSSARY

| Term | Explanation |
|----------------------|--|
| Android | Operating system of some mobile phones and tablets (e.g. Samsung smartphones and tablets). |
| Contraindication | Contraindications are conditions under which the device should not be used. |
| ICD | International Statistical Classification of Diseases and Related Health Problems |
| IFU | Instructions for Use: Instructions that describe how the product is supposed to be used providing as well as additional information about the software and customer support. |
| iOS | Operating system of Apple iPhones and iPad tablets. |
| MB | Megabyte: A unit that describes the size of digital storage units, such as hard drives. |
| MCI | Mild Cognitive Impairment: A medical condition that describes a mild decline in cognitive abilities commonly associated with aging. |
| Medical Professional | Healthcare professional (e.g. primary or specialized physicians, nurse practitioner) |
| Wi-Fi | Wireless network protocol that allows local devices to access the internet. |

II. SYMBOLS AND EXPLANATIONS

| SYMBOLS | Explanation |
|---|---|
|  eIFU Indicator | Electronic Instructions for use |
|  | Unique Device Identifier |
|  | Name of manufacturer, address, website and contact for support. |
|  | Date of manufacture |
|  | Medical device |

III. STATUS OF INFORMATION



eFU Indicator

2024 - 07 - 31



(01)4262390860015
(8012)V1.0.0



neotiv GmbH

Hegelstr. 19

39104 Magdeburg

Germany

<http://www.neotiv.com>

SUPPORT

Email: support@neotivcare.com



2024 - 07 - 31



neotivCare

IV. DESCRIPTIVE INFORMATION

These instructions for use are intended to provide additional information and support the use of the neotivCare software for smartphones and tablets (app). Patients can download and install the application themselves on their own device. The use of neotivCare is safe and self-explanatory even without instructions for use. The instructions in this document can also be taken into account during use. If you have any questions, please contact the neotiv support team at support@neotivcare.com.

PURPOSE OF THE DEVICE (INDICATIONS FOR USE)

The interactive software application "neotivCare" is intended to enable an assessment of cognitive performance to detect and monitor cognitive impairment in adults, especially in 60- to 80-year-olds.

Intended users perform the tests independently in their domestic environment. The findings letter obtained is intended to be discussed with a supervising medical professional and support diagnostic and therapeutic decision making.

INDICATIONS

neotivCare is intended for the assessment of self-reported or suspected memory impairment in adults.

The software is to be used in cases of suspected (ICD-10 classification):

F06.7 Mild cognitive impairment

DESCRIPTION OF THE DEVICE

neotivCare is a software as a medical device, that comes in the form of a mobile application that can be downloaded from the Android Play Store and the Apple (for iPhones and iPads) App Store installed on mobile phones/ smartphones and tablets, depending on the brand of your device.

WHEN THE DEVICE SHOULD NOT BE USED (CONTRAINDICATIONS)

neotivCare should not be used when:

- Patients are not able to use smartphones or tablets confidently.
- Patients don't have access to a stable wireless internet connection (e.g. Wi-Fi).
- Patients suffer from physical limitations that prevent the safe use of smartphones/ tablets.
- Patients don't have sufficient language proficiency in English.
- Patients are younger than 18 years old.

If you are unsure whether you fit one of these groups, please reach out to us (neotiv) or a medical professional for clarification.

V. RISKS AND BENEFIT

GENERAL WARNINGS AND PRECAUTIONS

neotivCare is not a stand-alone diagnostic assessment and does not identify the presence or absence of clinical diagnoses.

There are currently no known side-effects of using neotivCare. If you suspect you have encountered a previously unidentified one, please report them to:

support@neotivcare.com.

It is important that you adhere to the care regimen described in this IFU, to ensure that you maximize the benefits of neotivCare, while minimizing the risks of using it.

POSSIBLE RISKS THAT COULD ARISE FROM USING NEOTIVCARE IN AN IMPROPER FASHION MIGHT INCLUDE

- Distraction
- Inaccurate test results
- Mobile data usage
- Difficulties with handling the app

If you perceive a rapid deterioration in your cognitive abilities, we recommend that you consult a medical professional immediately and, if necessary, discontinue the test with neotivCare. Self-perceived memory problems and intense preoccupation with the subject of memory problems may in individual cases lead to increased anxiety, fear and depression. In this case, please contact a medical professional immediately.

THESE RISKS MIGHT RESULT IN THE FOLLOWING

- Accidents, if the device is used in a hazardous situation, for example while operating a motor vehicle.
- The need for further diagnostics due to missed tests or poor performance, requiring repetition.
- Delayed diagnostics if someone helps you, resulting in inaccurate test results.
- Mobile data charges.
- Loss of time.

ENSURE THE FOLLOWING TO MINIMIZE THESE RISKS

- Use the neotivCare app in an environment suitable for safe operation and mobile device use. Avoid using it in hazardous situations, such as while driving a motor vehicle.
- Choose a quiet and undisturbed environment to ensure attentive test performance and useful results. Schedule a test time in the app that fits easily into your daily routine, such as during free time in the afternoon.
- Perform the tests without external help.
- Use Wi-Fi to avoid charges from mobile data networks, as neotiv GmbH accepts no liability for such charges.
- Confirm that you do not fall within any of the "when the device should not be used" groups described in the previous section.

OTHER RISKS, THAT ARE NOT ASSOCIATED WITH IMPROPER USAGE OF THE APP MIGHT INCLUDE:

Loss of sensitive, health related data by sharing your email address or passwords with others.

THIS RISK MIGHT RESULT IN THE FOLLOWING

Other people, or a third-party gaining access to your personal and health related data.

HOW ARE THESE RISKS ADDRESSED?

- You need to confirm your account information (name and password) with your email.
- The password manager in the app helps you to set up a secure password.

BENEFITS OF USING NEOTIVCARE INCLUDE

- neotivCare detects cognitive impairments better than one-time standard diagnostics at a doctor's office or other clinical setting (sensitivity of 79% and a specificity of 75% for 60–80-year-olds).
- Performing tests in a domestic environment reduces influence of stress and improves reliability of test results.

THESE BENEFITS MIGHT RESULT IN THE FOLLOWING

- Saving time and obtaining more accurate results by performing tests at home.
- Earlier detection or confirmation of the absence of cognitive impairment.

VI. OPERATING INFORMATION

EXPECTATIONS OF THE DEVICE AND THE PROCEDURE ASSOCIATED WITH IT

When using neotivCare, don't be discouraged if you perceive the tests to be difficult at first. This is a common experience among users of the app and is expected, so there is no cause for concern.

SETUP INSTRUCTIONS

What you will need to start using neotivCare:

- A smartphone or tablet with at least 50 MB of free storage space and a display size of at least 4.7 inches
- A stable internet connection, ideally Wi-Fi.
- A minimum operating system version of iOS 12.0 for Apple devices or Android 9.0 for Android devices.

The software checks if these requirements are met; otherwise, you cannot install and use the app. This is for safety reasons, including internet security and test performance.

- Your own email address and access to your email account.
- A 16-letter activation code provided by your medical professional.
- Glasses or contact lenses if needed for clear vision.

Step-By-Step instructions

1. Download and installation of the neotivCare App:

1. Open the Apple App-Store, or the Google Play App-Store and search for "neotivCare" using the search function.
2. Select the neotivCare app with the orange-colored icon.
3. Tap "install"/ "load".

2. App-Start and entering the activation code:

1. When starting the neotivCare app for the first time, create your personal user account by pressing the "Create New Account" button.
2. Read and accept the user agreement and data protection agreement. Only after agreeing to them will you be able to press the button to continue.
3. If you haven't already, activate the screen-lock functionality on your phone or tablet (using a PIN, password, or biometrics like fingerprint or face recognition). To do this, leave the app and go to your device's system settings. After enabling screen-lock, return to the neotivCare app and press "Continue."
4. Enter your 16-digit activation code, taking care to differentiate between "O" and "0". If needed, ask your physician for help. Then press "Continue."

3. Creation of your user account:

1. Enter your email address, then press the button to continue.
2. Set up a strong password. Your password should meet the following requirements: it contains 8 digits. it has at least one capital and one minor case letter, it has at least two numbers.

4. Confirmation of your email address:

1. After you have created your account, neotiv will send you an email to confirm your email address. Please check your inbox and also your spam folder. Please note, that it can take a few minutes. Also make sure to check your spam-folder.
2. Open the confirmation email and click the button to confirm your email address.
3. Go back to the neotivCare app, you will now see the email confirmation screen. If you don't see it, please refresh the screen.
4. You have created your user account. Press the button to continue and follow the instructions of the app.

OPERATING INSTRUCTIONS

Directions for use

As soon as the activation code has been verified, the memory tests within the app are unlocked.

For the memory tests it is important that you can recognize the images on your screen well. It is also important to ensure that a possible impairment in vision does not impact your test performance. Therefore, we test your vision before you start the memory tests. Please note, this test is not a test that measures your vision the same way as ophthalmologists or opticians.

Number of tests: You will perform memory tests on your smartphone or tablet for a duration of 12 weeks. Each week you will perform 1 memory test. The app will always show you when the next test is available.

Structure of the tests: Each test consists of two parts. The tests are either divided into a memorization phase and a recall phase or into two levels of difficulty. There is a break between the two parts, which can vary in length.

The tests: There are 3 different memory tests (Spot the difference, Remember the objects, Inside & Outside). Each test addresses different aspects of your memory

function. The aim of the tests is to check the performance of your memory. After each test you will be asked to rate your performance and describe factors that may have influenced your performance, such as trouble sleeping or any ambient noise.

Findings Letter: After performing the memory tests you can create a report in the app that contains all your test results. This report is called the “Findings Letter”. You can create the findings letter at any time. You can open it directly in the app or you can send it to your registered email address. The findings letter is the summary of all your test results. These can only be evaluated by a medical professional (e.g. your physician). In order to have it evaluated by a medical professional, you can print the file, show the digital file on your mobile device or you can forward it via email from your private inbox. The medical professional will evaluate the findings letter and discuss the results with you. The medical professional will recommend further action or additional testing if necessary.

IMPORTANT NOTE: Do not try to interpret the findings letter on your own. Only a medical professional can do so.

Deletion of user account

If your test period ends and no further activation code is used, your user account will be deleted after 3 years, and all associated data anonymized.

You can delete your user account at any time. To delete your account tap the menu button and follow this path: User account > Personal settings. Then tap the button to delete the user account. This will immediately and irrevocably delete all data generated by you from your device and the server.

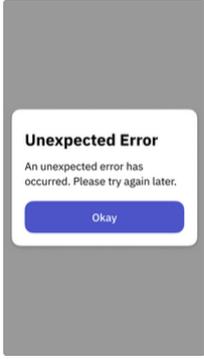
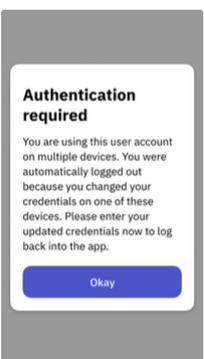
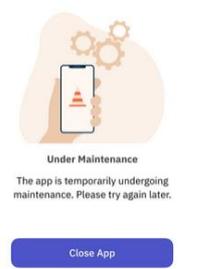
In both cases, once your account is deleted, you will no longer be able to log in or access your data.

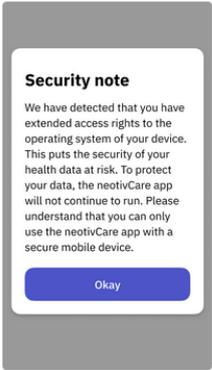
IMPORTANCE OF THE NEED TO MONITOR THE ACTIVITY OF THE DEVICE

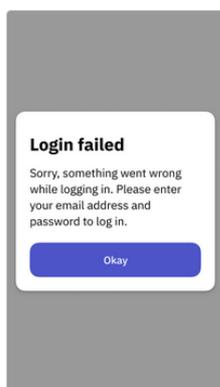
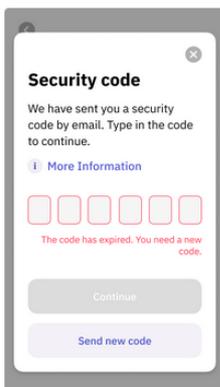
To perform your tests regularly as intended, allow notifications for neotivCare on your mobile device. Ensure your device is fully charged. Avoid using do-not-disturb mode, airplane mode, or sleep mode to ensure you receive notifications.

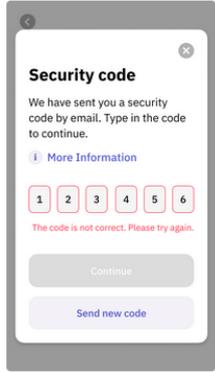
If you do not have the latest version of the app installed, you will need to update to the latest version before you can use the app. The newest version is always checked, if you start the app. If you feel like something doesn't work the way it should, please reach out to us via email to: support@neotivcare.com.

VII. TROUBLESHOOTING INFORMATION

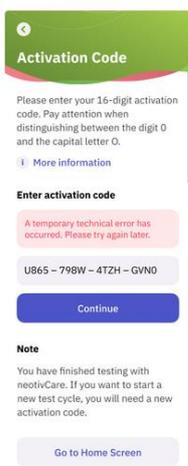
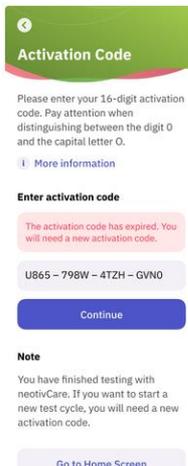
| General problems | | |
|---|---|---|
| Screen | Description | What you can do |
|  | <p>Unexpected Error</p> <p>An unexpected error has occurred. Please try again later.</p> | <p>Try to close and restart the app. If the message occurs again, please contact our customer support via email: support@neotivcare.com.</p> |
|  | <p>Error sending the message</p> <p>An unexpected error occurred while sending the message, please try again later.</p> | <p>Try to send the message again or contact our customer support via email: support@neotivcare.com.</p> |
|  | <p>Authentication required</p> <p>You are using this user account on multiple devices. You were automatically logged out because you changed your credentials on one of these devices.</p> | <p>Please enter your new credentials to login into the app.</p> |
|  | <p>Under Maintenance</p> <p>The app is temporarily undergoing maintenance. Please try again later. The maintenance mode is shown, when updates are uploaded. It can require a download of the new app version.</p> | <p>Please close the app and try to start the app again later. If the message occurs again, please contact our customer support via email: support@neotivcare.com.</p> |

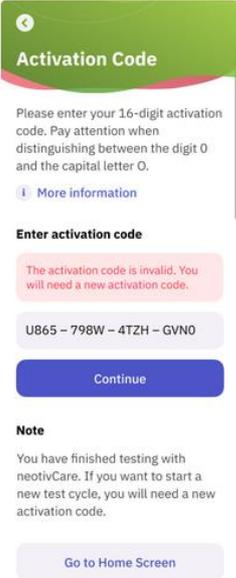
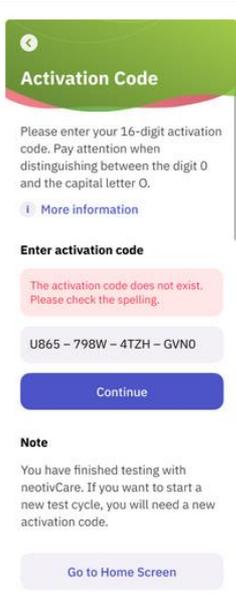
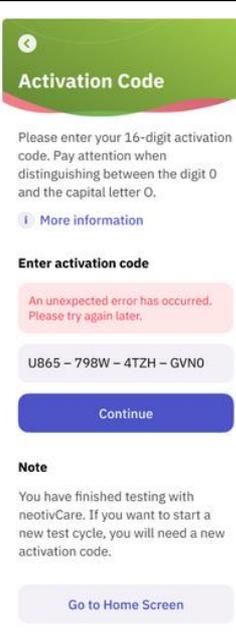
| Technical prerequisites | | |
|---|--|---|
| Screen | Description | What you can do |
| <p>neotivCare is not compatible with your screen size</p> | <p>neotivCare is not compatible with your screen size</p> <p>This popup appears if you use a device that has a screen size less than 4.7 inches. The app is designed for screen sizes of at least 4.7 inches, otherwise you might experience layout issues and problems recognizing the images in the memory tests.</p> | <p>Unfortunately, the screen size of your device is too small to use neotivCare. Please use neotivCare on a mobile device with a larger screen. Sorry for the inconvenience.</p> <p>For iPhone/iPad users: If you see this message even though you are using an iPhone with sufficient screen size, you may have enabled the "Display Zoom" feature on your iPhone. Please check in the system settings of your iPhone if Display Zoom is activated. If necessary, set the display zoom back to "Default". (Settings > Display & Brightness > Display Zoom).</p> |
|  | <p>neotivCare cannot be used if your device is rooted because it is not secure</p> <p>The app checks on start if the device is rooted (system settings might be manipulated). When you start the app, we'll show this popup with the information that the app cannot be used, because the device is rooted and this is overall too insecure for a medical device.</p> | <p>We have detected that you have extended access rights to the operating system of your device. This puts the security of your health data at risk. To protect your data, the neotivCare app will not continue to run. Please understand that you can only use the neotivCare app with a secure mobile device. You can proceed with neotivCare on an unrooted device.</p> |

| | | |
|---|--|---|
|  | <p>No connection to the internet (wifi/data) to use the app</p> <p>Your device is not connected to the internet.</p> | <p>Please check your internet connection in the settings and try again. Make sure you have enabled WiFi or mobile data usage. This screen might occur if your device is in flight mode or located in an area with poor internet availability.</p> |
| <p>Login</p> | | |
| <p>Screen</p> | <p>Description</p> | <p>What you can do</p> |
|  | <p>Login failed</p> <p>Sorry, something went wrong while logging in. Please enter your email address and password to log in.</p> | <p>Enter your email address and password again. Pay attention to the spelling. If you have forgotten your password, please reset your password.</p> |
| <p>Problems during entering the security code (2 Factor Authentication)</p> | | |
| <p>Screen</p> | <p>Description</p> | <p>What you can do</p> |
|  | <p>Security code has expired</p> <p>You haven't entered the security code within the given time frame/ within the time frame of 5 minutes. The code is no longer valid.</p> | <p>The security code has expired. You will need a new code. Please tap the button to send a code. Then check your email inbox as well as the spam folder. You need to enter the code within 5 minutes.</p> <p>If you are still experiencing problems, please contact our customer support via email: support@neotivcare.com</p> |

| | | |
|---|---|--|
|  | <p>Security code was entered wrong</p> <p>You haven't entered the correct security code.</p> | <p>Please check the correct numbers and try again.</p> |
|---|---|--|

Problems during usage of the activation code

| Screen | Description | What you can do |
|---|--|--|
|  | <p>Activation code is incomplete</p> <p>The activation code is incomplete until 16 digit have been entered.</p> | <p>Please enter the full 16 digits activation code.</p> |
|  | <p>Temporary technical error</p> <p>A temporary technical error has occurred. Therefore, the activation code cannot be activated. Please try again later.</p> | <p>Please try again later. If you are still experiencing problems, please contact our customer support via email: support@neotivcare.com</p> |
|  | <p>Invalid activation code</p> <p>You have entered an activation code that has expired already.</p> | <p>Please make sure that you have entered the activation code correctly. If the error occurs again contact our customer support via email: support@neotivcare.com.</p> |

| | | |
|--|--|--|
|  <p>Invalid activation code</p> <p>You have entered an activation code that is invalid.</p> | <p>Please make sure that you have entered the activation code correctly. If the error occurs again, contact our customer support via email: support@neotivcare.com.</p> | |
|  <p>Activation code not found</p> <p>The activation code you have entered does not exist.</p> | <p>Please make sure that you have entered the activation code correctly. Pay attention to the spelling. If the error occurs again, contact our customer support via email: support@neotivcare.com.</p> | |
|  <p>Unexpected error</p> <p>An unexpected error has occurred, please try again later.</p> | <p>Try to enter the activation code again. If the error occurs again, contact our customer support via email: support@neotivcare.com.</p> | |

VIII. TRAVEL OR INTERNATIONAL USE

If you are travelling to foreign countries, make sure that your charger for your device is compatible with foreign power systems.

neotivCare does not send out push notifications to remind you for upcoming tests, when your device is in flight mode.

If you want to adjust your upcoming tests to the new time zone you should:

- Finish the current test (both parts, if scheduled) and start the next test when you have travelled to your new time zone or
- Skip or postpone the start of the first part of your test until you have reached your new time zone

Please take into consideration that jetlag and reduced sleep can have an impact on your cognitive performance.

IX. USER ASSISTANCE INFORMATION

NEOTIVCARE UNIQUE DEVICE IDENTIFIER



(01)4262390860015
(8012)V1.0.0

MANUFACTURER



neotiv GmbH

Hegelstr. 19

39104 Magdeburg

Germany

SUPPORT

Email: support@neotivcare.com