



dreaMS^{MD}

Instructions for Use

SOFTWARE MEDICAL DEVICE TO ASSESS NEUROLOGICAL FUNCTIONS IN PERSONS WITH MULTIPLE SCLEROSIS IN THE FOLLOWING DOMAINS: MOVEMENTS, BALANCE, DEXTERITY and VISION.

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Symbols in the dreaMS^{MD} SaMD and in these instructions for use follow the European standard EN ISO 15223-1:2016.




| | |
|---|---|
|  | CE Mark |
|  | Manufacturer |
|  | Caution - Please consult the accompanying documents |

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1. Introduction

These instructions for use (IfU) are intended for persons diagnosed with Multiple Sclerosis (PwMS) and who have been prescribed dreaMS^{MD} by their Healthcare Provider (HCP).

dreaMS^{MD} is a Software as Medical Device designed to assess neurological functions in PwMS with a focus in the following domains: Movements, Balance, Dexterity and Vision.

dreaMS^{MD} has been developed, manufactured, and tested according to the most demanding quality criteria with the goal of improving the lives of persons diagnosed with Multiple Sclerosis.

1.1. About this document and product

Before using this software for the first time, you must read these IfU. When obtaining a different version of dreaMS^{MD} than the one defined on the cover page of this document the user is bound to check that version's specific IfU.

Healios has made every effort to ensure that these IfU are as accurate as possible. However, Healios assumes no liability for any inaccuracies, out-datedness, incompleteness, or omissions that may have occurred. The software user must ensure to use the most recent version of this document corresponding to the software version in use. Healios provides the user with new versions of the IfU whenever published.

| | |
|-------------------------------|---|
| Manufacturer | Healios AG, Postfach, 4001 Basel, Switzerland |
| Licenser & distributor | Healios AG, Postfach, 4001 Basel, Switzerland, www.healios.io |
| Product | dreaMS ^{MD} is a software device to assess neurological functions in persons with Multiple Sclerosis in the following domains: Movements, Balance, Dexterity and Vision. dreaMS ^{MD} is a class I Medical Device. |
| Disclaimer | Please note that the information herein after is subject to change without notice. |
| Language | This document is also available in German, French, Italian |
| Safety & clinical performance | Our summary of safety and clinical performance can be found at www.dreams.care |
| Digital instructions for use | This document is provided digitally. Please consult www.dreams.care to ensure you are using the most current IfU for the version of dreaMS ^{MD} |

| | |
|--------------------|------------------------|
| Software Lifecycle | 2021-05-06 Version 2.0 |
|--------------------|------------------------|

1.2. Intended Use

dreaMS^{MD} is a Software as Medical Device designed to assess neurological functions in PwMS with a focus in the following domains: Movements, Balance, Dexterity and Vision.

dreaMS^{MD} is a Software-based Medical Device designed for persons diagnosed with Multiple Sclerosis (PwMS), made available by HCP via the Healios Platform.

dreaMS^{MD} uses smartphone sensor technology to collect data from PwMS and processes these data using regulated algorithms. This is done through performing the below 10 tests that are available through the users' smartphone. The technology uses signal processing and feature extraction algorithms to analyse Inertial Measurement Unit (IMU) sensors data.

dreaMS^{MD} reports measurements to the treating HCP who accesses the data through the Healios Platform on their web browser.

dreaMS^{MD} is used by PwMS at home, without support of professional medical staff or a Healthcare Provider. The PwMS may obtain support from a family member or other caregiver but should perform the test him-/herself. Not following test instructions may lead to incorrect results.

| Name | Short description | Basis |
|----------------|---|--|
| Promenade | Walk briskly for 2-minutes, without a break. | Inspired by Expanded Disability Status Scale (EDSS) ambulation score |
| Spanish Stairs | Walk up and down a set of stairs, answer a few questions regarding the exercise. | Inspired by Activities of Daily Living (ADL) and EDSS motor function and endurance |
| Swiss Guard | Make a U-turn after each 5 steps taken. | Inspired by clinical assessment of walking and balance |
| Musical Chairs | Stand-up and sit-down on a chair for 30 seconds. | Inspired by Timed Up & Go, reflects Activities of Daily Living (ADL). |
| Butler | Keep your arm up for 10 seconds each, first with eyes open and then with eyes closed. | Inspired by the Romberg test |

| | | |
|---------------|---|--|
| Penguin | Stand with arms along the body for 10 seconds, first with eyes open, then with eyes closed. | Inspired by the Romberg test |
| Catch-A-Cloud | Touch the moving cloud with your index finger as often as possible. | Dexterity, inspired by 9HPT |
| Confetti | Keep phone in hand and bend the arm so that the tip of the nose touches the bullseye on the screen, with each arm separately, eyes open and closed. | Inspired by clinical "Finger-To-Nose" test |
| Fog | Keep phone in hand and swipe in the direction of the open side of the letter C. | Inspired by standard contrast sensitivity test |
| Eagle Eye | Keep phone in hand and swipe in the direction of the open side of the letter E. | Inspired by standard visual acuity test |

2. Getting Started with dreaMS^{MD}

PwMS first needs to be prescribed dreaMS^{MD} by their HCP through the Healios platform in order to gain access. Opening dreaMS^{MD} on their smartphone, PwMS will be able to visualise the 10 tests and complete them according to the schedule prescribed by their HCP. Each test has the same introduction screen as shown below:



1. Watch the video instructions.
2. Check the time estimated and the level of effort required.
3. Review instructions to see how to perform the test.
4. Main warning for the test.
5. Start the test.
6. Read the dreaMS^{MD} Product Label.

Healios strongly recommends PwMS to read the available instructions before performing each test. We also recommend completing the tests in an environment where PwMS can focus and minimise interruptions.

3. Adverse Events

An adverse event is defined as any untoward medical occurrence, unintended disease or injury, or untoward clinical signs. There are no known adverse events related to the use of dreaMS^{MD}. Potential adverse events include personal injury if PwMS is unfit or test is performed in unsafe environment, risk related to misinterpretation of results or frustration because of PwMS inability to perform or complete the test. To minimize potential risk HCP and PwMS should read the warnings and precautions for every test.

4. Technical requirements

4.1. Smartphone for PwMS

dreaMS^{MD} is designed to run on iOS and Android mobile apps, which can be downloaded from the Apple Store and Google Play Store after you have registered the PwMS via the Healios platform.

For dreaMS^{MD} to be able to provide reliable and complete results, the PwMS smartphone will have to meet minimum requirements in terms of e.g. capacity and sensors available on the phone.

A number of dreaMS^{MD} tests require that you allow additional permissions to your smartphone device, e.g. the device camera.

| Minimum device requirements | |
|---|--|
| iOS | Android |
| <ul style="list-style-type: none"> ● iPhone 6 and later ● iOS 11 or later ● 1GB RAM (automatically covered by range above) ● 500MB storage capacity available | <ul style="list-style-type: none"> ● OS version 5.0 (API 21) or later ● Access to Google Play services ● 2GB RAM ● 500MB storage capacity available ● Sensors: GPS, Accelerometer, Gyroscope, Magnetometer, Step Detector ● Front camera |

| Devices not compatible | |
|--|---|
| Please note that the below list may not be complete, and is subject to regular updates on www.dreams.care | |
| Manufacturer | Model |
| Alcatel | 7 Tetra ZIP LTE |
| Apple | iPhone 1st generation through iPhone 5s |
| Caterpillar | All |
| DORO | All |

| | |
|----------------|--|
| Emporia | All |
| Gigaset | All |
| Huawei | Mate 10 Lite MateXs P10 P40 lite P Smart Y6 |
| LG Electronics | Aristo 2 K20 Plus K40 Rebel 4 Risio 3 Stylo 3 Plus Tribute Dynasty |
| Motorola | Moto E4 Moto E5 Play |
| OPPO | Models before 2020 |
| Ruggear | All |
| Samsung | Galaxy A3 Galaxy J6 |
| Wiko | View Lite 3 Y60 Y81 |

5. Safety and warranty

5.1. Risks and Benefits

All known and foreseeable risks have been reduced as much as possible and no unacceptable risk has been identified. Potential benefits include tracking measurements in key domains outside of the clinical setting and supporting informed consultations between HCP and PwMS. Overall, the potential benefit of the device far exceeds the probable known and foreseeable risks.

5.2. Warranty

Please refer to the No Warranties section in the dreaMS^{MD} Terms of Use.

5.3. Warnings and precautions

As a medical device manufacturer, Healios is legally required to inform the users of our products of any safety precautions which should be considered when operating these products. The following section contains a summary of the important technical safety features of dreaMS^{MD}.

We advise that you consult with your HCP if you believe there are elements of the dreaMS^{MD} tests that are not suitable for you. We encourage that you perform the dreaMS^{MD} tests on a regular basis, as prescribed by your HCP.

dreaMS^{MD} is designed to improving care and treatment for PwMS. It should not be interpreted as a replacement for the care and expertise that provided by your treating HCP.

dreaMS^{MD} tests should only be used as an additional tool for measuring neurological functions and are not intended to be used as a stand-alone diagnostic device nor to manage changes in the disease status.

Each test will come with warnings and precautions. These are outlined in more detail in sections 5 of the IfU.

6. dreaMS^{MD} tests

6.1. dreaMS^{MD} Promenade test

| Name | Short description | Basis |
|-----------|--|--|
| Promenade | Walk briskly for 2-minutes, without a break. | Inspired by EDSS Ambulation assessment |

Intended use

dreaMS^{MD} Promenade test assesses locomotion functions but does not provide an interpretation or a clinical implication.







Contraindications

dreaMS^{MD} Promenade may not be suitable for PwMS with severe balance (equilibrium) issues or PwMS that are no longer able to walk without walking aid or help (typically observed in PwMS with EDSS 6 or more).

Test instructions

| | |
|------------|--|
| Step1 | Find an open space where you can walk for 2 minutes without having to make sharp turns (large circles are okay). Do not start if you are not able to go outside or cannot find a big enough space indoors |
| Step 2 | Please only perform this test when you feel confident that you can finish it without taking a break or losing your balance. Use walking aids if needed |
| Step 3 | Press Start. Your phone will show a countdown of 5 seconds, place your phone in your front right pocket. Use a waist band if you do not have front pockets. Please do not press the home, standby or off button when you place the phone in your pocket, leaving the app open and the screen on. Walk briskly for 2 minutes without running, do not make sharp or U-turns |
| Attention! | Please do not take breaks if possible. Do not take you phone out of your pocket before the test is completed |

Warnings and Precautions

| | |
|---|--|
|  | Perform the test as often as recommended by your HCP. Please note that self-testing at home does not replace your regular visits with your HCP |
|  | Possible risk of falling, make sure there is enough space to perform the test and be careful of any obstacles |
|  | Persons suffering from severe visual impairment (corrected near vision <0.5) may not get reliable or meaningful results |
|  | This activity may not be suitable for PwMS with severe balance (equilibrium) issues (typically observed in PwMS with EDSS 6 or more) |
|  | Use walking aids if needed, as indicated in the instructions in the app |
|  | Persons suffering from, or with a recent history of, fainting or losing consciousness should not perform this activity |

6.2. dreaMS^{MD} Spanish Stairs test

| Name | Short description | Basis |
|----------------|--|--|
| Spanish Stairs | Walk up and down a set of stairs, answer a few questions regarding the exercise. | Inspired by ADL and EDSS Ambulation assessment |

Intended use

dreaMS^{MD} Spanish Stairs test assesses the walking functions when ascending and descending a flight of stairs but does not provide an interpretation or a clinical implication of the measurements.




Contraindications




dreaMS^{MD} Spanish Stairs test may not be suitable for PwMS with severe balance (equilibrium) issues or PwMS that are no longer able to walk (typically observed in PwMS with EDSS 6 or more).

Test instructions

| | |
|------------|--|
| Step 1 | Find a staircase with 8-14 steps and a handrail (spiral staircases are not suitable). Please only perform this test when you feel confident you can finish it without taking a break or losing your balance. Use walking aids if needed |
| Step 2 | Press 'Start'. Your phone will show a countdown of 5 seconds, place your phone in your front right pocket. Use a waist band if you do not have front pockets. Please do not press the 'home' or 'off' button when you place the phone in your pocket, leaving the app open and the screen on |
| Step 3 | Walk up the stairs down again at a normal pace (swiftly, without rushing). One step at a time, do not skip steps |
| Step 4 | At the bottom of the stairs, take your phone out of your pocket, press 'Finish' and fill out the short survey |
| Attention! | Do not take breaks if possible |

Warnings and Precautions

| | |
|---|--|
|  | Perform the test as often as recommended by your HCP. Please note that self-testing at home does not replace your regular visits with your HCP |
|  | Possible risk of falling, make sure there is enough space to perform the test and be careful of any obstacles |
|  | Persons suffering from severe visual impairment (corrected near vision <0.5) may not get reliable or meaningful results |

| | |
|---|--|
|  | This activity may not be suitable for PwMS with severe balance (equilibrium) issues (typically observed in PwMS with EDSS 6 or more) |
|  | Use walking aids if needed, as indicated in the instructions in the app |
|  | Persons suffering from, or with a recent history of fainting or losing consciousness should not perform this activity |

6.3. dreaMS^{MD} Swiss Guard test

| Name | Short description | Basis |
|-------------|---|--|
| Swiss Guard | Make a U-turn after each 5 steps taken. | Inspired by clinical assessment of walking and balance |

Intended use

dreaMS^{MD} Swiss Guard test assesses the U-turn function but does not provide an interpretation or a clinical implication of the measurements.




Contraindications




dreaMS^{MD} Swiss Guard test may not be suitable for PwMS with severe balance (equilibrium) issues or PwMS that are no longer able to walk (typically observed in PwMS with EDSS 6 or more).

Test instructions

| | |
|------------|--|
| Step 1 | Find an area with at least 4-5 meters walking space. Please only perform this test when you feel confident you can finish it without taking a break or losing your balance. Use walking aids if needed |
| Step 2 | Press 'Start'. Your phone will show a countdown of 5 seconds, place your phone in your front right pocket. Use a waist band if you do not have front pockets. Please do not press the 'home' or 'off' button when you place the phone in your pocket, leaving the app open and the screen on |
| Step 3 | When you hear the start signal, walk 5 steps in one direction, then turn around (U-turn, 180°) and repeat for half a minute. You can freely choose the direction of the turns |
| Attention! | Please do not take breaks if possible. Do not take your phone out of your pocket before it beeps and vibrates once the test is completed. |

Warnings and Precautions

| | |
|---|--|
|  | Perform the test as often as recommended by your HCP. Please note that self-testing at home does not replace your regular visits with your HCP |
|  | Possible risk of falling, make sure there is enough space to perform the test and be careful of any obstacles |
|  | Persons suffering from severe visual impairment (corrected near vision <0.5) may not get reliable or meaningful results |

| | |
|---|--|
|  | This activity may not be suitable for PwMS with severe balance (equilibrium) issues (typically observed in PwMS with EDSS 6 or more) |
|  | Use walking aids if needed, as indicated in the instructions in the app |
|  | Persons suffering from, or with a recent history of fainting or losing consciousness should not perform this activity |

6.4. dreaMS^{MD} Musical Chairs test

| Name | Short description | Basis |
|----------------|--|---|
| Musical Chairs | Stand-up and sit-down on a chair for 30 seconds. | Inspired by Timed Up & Go, reflects Activities of Daily Living (ADL). |

Intended use

dreaMS^{MD} Musical Chairs test assesses the PwMS standing up and sitting down function but does not provide an interpretation or a clinical implication of the measurements.





Contraindications



dreaMS^{MD} Musical Chairs test may not be suitable for PwMS with severe balance (equilibrium) issues or PwMS that are no longer able to walk (typically observed in PwMS with EDSS 6 or more).

Test instructions

| | |
|------------|--|
| Step 1 | Use a firm chair without wheels in a clear and safe area. Please only perform this test when you feel confident that you can finish it without taking a break or losing your balance |
| Attention! | Possible risk of falling, be careful |
| Step 2 | Press Start. Your phone will show a countdown of 5 seconds, place your phone in your front right pocket. Use a waist band if you do not have front pockets. Please do not press the home or off button when you place the phone in your pocket, leaving the app open and the screen on |
| Step 3 | When you hear the start signal, stand up and sit down as often as possible in 30 seconds |
| Attention! | Please do not take breaks if possible. Do not take your phone out of your pocket before it beeps and vibrates once the test is completed |

Warnings and Precautions

| | |
|---|--|
|  | Perform the test as often as recommended by your HCP. Please note that self-testing at home does not replace your regular visits with your HCP |
|  | Possible risk of falling, make sure there is enough space to perform the test and be careful of any obstacles |
|  | Persons suffering from severe visual impairment (corrected near vision <0.5) may not get reliable or meaningful results |
|  | This activity may not be suitable for PwMS with severe balance (equilibrium) issues (typically observed in PwMS with EDSS 6 or more) |

| | |
|---|---|
|  | Persons suffering from, or with a recent history of fainting or losing consciousness should not perform this activity |
|  | Use a firm chair without wheels in a clear and safe area |

6.5. dreaMS^{MD} Butler test

| Name | Short description | Basis |
|--------|---|------------------------------|
| Butler | Keep your arm up for 10 seconds each, first with eyes open and then with eyes closed. | Inspired by the Romberg test |

Intended use

dreaMS^{MD} Butler test assesses the balance and kinetic tremor functions but does not provide an interpretation or a clinical implication of the measurements.





Contraindications

dreaMS^{MD} Butler test may not be suitable for PwMS with severe balance (equilibrium) issues or PwMS that are no longer able to walk (typically observed in PwMS with EDSS 6 or more).

Test instructions

| | |
|------------|--|
| Step 1 | Find a space where you can stand freely with your arms stretched out. Keep your feet together. If that feels uneasy you may move them a bit further apart to be stable. Please only perform this test when you feel confident you can finish it without taking a break or losing your balance |
| Step 2 | Press 'Start'. Your phone will show a countdown of 5 seconds. Hold your phone flat in your right hand with your arm fully straight. Lift the right hand to shoulder height, turn your palm outward so it faces up. Hold with your eyes open for 10 seconds. When indicated, close your eyes and hold for another 10 seconds. When indicated, change to your left hand and repeat |
| Attention! | Your phone will signal or vibrate at each change and when the test is completed |

Warnings and Precautions

| | |
|---|--|
|  | Perform the test as often as recommended by your HCP. Please note that self-testing at home does not replace your regular visits with your HCP |
|  | Possible risk of falling, make sure there is enough space to perform the test and be careful of any obstacles |
|  | This activity may not be suitable for PwMS with severe balance (equilibrium) issues (typically observed in PwMS with EDSS 6 or more) |
|  | Persons suffering from, or with a recent history of fainting or losing consciousness should not perform this activity |

6.6. dreaMS^{MD} Penguin test

| Name | Short description | Basis |
|---------|---|------------------------------|
| Penguin | Stand with arms along the body for 10 seconds, with eyes open, then with eyes closed. | Inspired by the Romberg test |

Intended use

dreaMS^{MD} Penguin test assesses the balance functions but does not provide an interpretation or a clinical implication of the measurements.





Contraindications

dreaMS^{MD} Penguin test may not be suitable for PwMS with severe balance (equilibrium) issues or PwMS that are no longer able to walk (typically observed in PwMS with EDSS 6 or more).

Test instructions

| | |
|--------|---|
| Step 1 | Find a space you can stand freely. Keep your feet together. If that feels uneasy you may move them a bit further apart to be stable. Please only perform this test when you feel confident you can finish it without taking a break or losing your balance |
| Step 2 | Press 'Start'. Your phone will show a countdown of 5 seconds, place your phone in your front right pocket. Use a waist band if you do not have front pockets. Please do not press the 'home' or 'off' button when you place the phone in your pocket, leaving the app open and the screen on. Keep your arms next to your body. Stand still for 10 seconds with your eyes open. When indicated, close your eyes and stand still for another 10 seconds |

Warnings and Precautions

| | |
|---|--|
|  | Perform the test as often as recommended by your HCP. Please note that self-testing at home does not replace your regular visits with your HCP |
|  | Possible risk of falling, make sure there is enough space to perform the test and be careful of any obstacles |
|  | This activity may not be suitable for PwMS with severe balance (equilibrium) issues (typically observed in PwMS with EDSS 6 or more) |
|  | Persons suffering from, or with a history of fainting or losing consciousness should not perform this activity |

6.7. dreaMS^{MD} Catch-A-Cloud test

| Name | Short description | Basis |
|---------------|---|---|
| Catch-A-Cloud | Touch the moving cloud with your index finger as often as possible. | Dexterity, inspired by 9 Hole Peg Test (9HPT) |

Intended use

dreaMS^{MD} Catch-A-Cloud test assesses the dexterity function but does not provide an interpretation or a clinical implication of the measurements.




Contraindications

Not suitable for PwMS suffering from severe visual impairment (corrected near vision <0.5).

Test instructions

| | |
|------------|---|
| Step 1 | Perform this test seated. Do not rest your elbow on the arm of the chair or a table top |
| Attention! | Hold your phone in your non-dominant hand. Do not put your phone down. Touch the moving cloud with the index finger of your other hand as often as possible |

Warnings and Precautions

| | |
|---|--|
|  | Perform the test as often as recommended by your HCP. Please note that self-testing at home does not replace your regular visits with your HCP |
|  | Persons suffering from severe visual impairment (corrected near vision <0.5) may not get reliable or meaningful results |
|  | Persons suffering from, or with a history of fainting or losing consciousness should not perform this activity |

6.8. dreaMS^{MD} Confetti test

| Name | Short description | Basis |
|----------|---|--|
| Confetti | Keep phone in hand and bend the arm so that the tip of the nose touches the bullseye on the screen, with each arm separately, eyes open and closed. | Inspired by clinical "Finger-To-Nose" test |

Intended use

dreaMS^{MD} Confetti test assesses dexterity functions but does not provide an interpretation or a clinical implication of the measurements.



Contraindications

Not suitable for PwMS suffering from severe visual impairment (corrected near vision <0.5).

Test instructions

| | |
|------------|--|
| Step 1 | Perform this test seated. Do not rest your elbow on the arm of the chair or a tabletop. Keep your right arm stretched at your eyes' height with the screen facing you |
| Step 2 | Press Start. Your phone will show a countdown of 5 seconds. The aim is to touch the centre of the bullseye with the tip of your nose. Bend your right arm to touch the bullseye with your nose, stretch again fully and repeat for 15 seconds. When indicated, close your eyes and repeat for another 15 seconds. When indicated, change to your left hand and repeat |
| Attention! | Your phone will signal or vibrate at each change and when the test is completed |

Warnings and Precautions

| | |
|---|--|
|  | Perform the test as often as recommended by your HCP. Please note that self-testing at home does not replace your regular visits with your HCP |
|  | Persons suffering from severe visual impairment (corrected near vision <0.5) may not get reliable or meaningful results |

6.9. dreaMS^{MD} Fog test

| Name | Short description | Basis |
|------|--|--|
| Fog | Keep phone in hand and swipe in the direction of the open side of the letter C | Inspired by standard contrast sensitivity test |

Intended use

The dreaMS^{MD} Fog test assesses the (corrected) near vision contrast functions but does not provide an interpretation or a clinical implication of the measurements.



Contraindications

Not suitable for PwMS suffering from severe visual impairment (corrected near vision <0.5).

Test instructions

| | |
|--------|---|
| Step 1 | Perform this test seated. Always use glasses or contact lenses if needed. Please always use the same pair of glasses |
| Step 2 | Find a comfortable position with your arm to keep the phone 40 cm from your eyes (phone will guide you). For example, you could put your elbow on a table top or on your knee. Please always use the same position when performing the test |
| Step 3 | Swipe with the index finger of your dominant hand in the direction of the opening of the letter C: up, down, left or right. The letters will gradually become dimmer until you are no longer able to see clearly. Do this first with your right eye closed, then with your left eye closed |

Warnings and Precautions

| | |
|---|--|
|  | Perform the test as often as recommended by your HCP. Please note that self-testing at home does not replace your regular visits with your HCP |
|  | Persons suffering from severe visual impairment (corrected near vision <0.5) may not get reliable or meaningful results |

6.10. dreaMS^{MD} Eagle Eye test

| Name | Short description | Basis |
|-----------|--|---|
| Eagle Eye | Keep phone in hand and swipe in the direction of the open side of the letter E | Inspired by standard visual acuity test |

Intended use

dreaMS^{MD} Eagle eye test assesses the (corrected) near vision acuity functions but does not provide an interpretation or a clinical implication of the measurements.



Contraindications

Not suitable for PwMS suffering from severe visual impairment (corrected near vision <0.5).



Test instructions

| | |
|--------|--|
| Step 1 | Perform this test seated. Always use glasses or contact lenses if needed. Please always use the same pair of glasses |
| Step 2 | Find a comfortable position with your arm to keep the phone 40 cm from your eyes (phone will guide you). For example, you could put your elbow on a table top or on your knee. Please always use the same position when performing the test |
| Step 3 | Swipe with the index finger of your dominant hand in the direction of the opening of the letter E: up, down, left or right. The letters will gradually become smaller until you are no longer able to see clearly. Do this first with your right eye closed, then with your left eye closed |

Warnings and Precautions

| | |
|---|--|
|  | Perform the test as often as recommended by your HCP. Please note that self-testing at home does not replace your regular visits with your HCP |
|  | Persons suffering from severe visual impairment (corrected near vision <0.5) may not get reliable or meaningful results |

7. dreaMS^{MD} Product Label

| | |
|--|--|
|  | |
| dreaMS ^{MD} | Version 2.0 2021-05-06 |
| eIFU: www.dreams.care | |
|  | ©Healios AG Postfach 4001 Basel Switzerland support@healios.io |
| Intended purpose: dreaMS ^{MD} assesses neurological functions in the 4 following domains, Movement, Balance, Dexterity and Vision, and reports results to the Healthcare Provider. | |

8. Contact and Support

Troubleshooting issues and general feedback can be sent to Healios via e-mail at: support@healios.io. Please include anonymised screenshots of any issue encountered but not covered in this user manual.

You can also call Healios for support from Monday to Friday, during office hours, and not on Swiss national holidays: +41 61 539 19 54

Appendix 1: Open-source software licenses

This document represents the status of the dependencies for each dreaMS^{MD}. Note that each subsystem, especially for iOS and Android, may contain libraries affecting non-medical device components.

| Frontend - iOS (Swift) | | | |
|------------------------|---------|------------|---|
| Library | Version | License | Link |
| IQKeyboardManagerSwift | 6.5.6 | MIT | https://github.com/hackiftekhar/IQKeyboardManager |
| Moya | 13.0.1 | MIT | https://github.com/Moya/Moya |
| KeychainSwift | 19.0.0 | MIT | https://github.com/evgenyneu/keychain-swift |
| InputMask | 6.1.0 | MIT | https://github.com/RedMadRobot/input-mask-ios |
| FSCalendar | 2.8.2 | MIT | https://github.com/WenchaoD/FSCalendar |
| FlagPhoneNumber | 0.8.0 | Apache 2.0 | https://github.com/iziz/libPhoneNumber-iOS |
| EVFaceTracker | 1.1.0 | MIT | https://github.com/evermeer/EVFaceTracker |
| JGProgressHUD | 2.2 | MIT | https://github.com/JonasGessner/JGProgressHUD |
| SwipeCellKit | 2.7.1 | MIT | https://github.com/JonasGessner/JGProgressHUD |
| DataCompression | 3.6.0 | Apache 2.0 | https://github.com/mw99/DataCompression |

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|-----------------------|--------|------------|---|
| Firestore/Messaging | 7.10.0 | Apache 2.0 | https://github.com/firebase/firebase-ios-sdk |
| Firestore/InstanceID | 7.10.0 | Apache 2.0 | https://github.com/firebase/firebase-ios-sdk |
| Firestore/Crashlytics | 7.10.0 | Apache 2.0 | https://github.com/firebase/firebase-ios-sdk |
| Firestore/Analytics | 7.10.0 | Apache 2.0 | https://github.com/firebase/firebase-ios-sdk |
| RealmSwift | 10.7.2 | Apache 2.0 | https://github.com/realm/realm-cocoa |
| CSV.swift | 2.4.3 | MIT | https://github.com/yaslab/CSV.swift |
| OAuthSwift | 2.1.0 | MIT | https://github.com/OAuthSwift/OAuthSwift |
| Bugsnag | 6.8.3 | MIT | https://github.com/bugsnag/bugsnag-cocoa |
| RxSwift | 6.1.0 | MIT | https://github.com/ReactiveX/RxSwift |
| RxCocoa | 6.1.0 | MIT | https://github.com/ReactiveX/RxSwift |
| RxDataSources | 5.0.0 | MIT | https://github.com/RxSwiftCommunity/RxDataSources |
| ReachabilitySwift | 5.0.0 | MIT | https://github.com/shleymills/Reachability.swift |
| ZIPFoundation | 0.9.11 | MIT | https://github.com/weichsel/ZIPFoundation |

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|---------------------|----------------|---|---|
| MobileRTC.framework | 5.2.42037.1112 | https://github.com/zoom/zoom-sdk-ios/blob/master/LICENSE.pdf | https://github.com/zoom/zoom-sdk-ios |
|---------------------|----------------|---|---|

| Frontend - Android (Kotlin) | | | |
|-----------------------------|---------|-------------------------------------|--|
| Library | Version | License | Link |
| CircleImageView | 3.1.0 | Apache 2.0 | https://github.com/hdodenhof/CircleImageView |
| Retrofit | 2.9.0 | Apache 2.0 | https://github.com/square/retrofit |
| Firebase Messaging | 20.3.0 | Apache 2.0 | https://github.com/firebase/firebase-android-sdk/tree/master/firebase-messaging |
| Firebase Crashlytics | 17.4.1 | Apache 2.0 | https://github.com/firebase/firebase-android-sdk , https://github.com/firebase/firebase-android-sdk/tree/master/firebase-crashlytics |
| play-service-fitness | 19.0.0 | Google's service for fitness | |
| play-services-auth | 18.1.0 | Google's service for authentication | |
| play-services-location | 17.0.1 | Google's service for location | |
| Flexbox | 2.0.1 | Apache 2.0 | https://github.com/google/flexbox-layout |
| navigation-fragment | 2.3.0 | Google's service for navigation | |

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| Joda time | 2.9.9 | Apache 2.0 | https://github.com/JodaOrg/joda-time |
| google.mlkit:face-detection | 16.0.1 | Apache 2.0 | https://developers.google.com/ml-kit/vision/face-detection/android |
| NetworkResponseAdapter | 3.0.1 | Apache 2.0 | https://github.com/haroldadmin/NetworkResponseAdapter |
| Mobile RTC | 5.2.41727.0928 | https://github.com/zoom/zoom-sdk-ios/blob/master/LICENSE.pdf | https://github.com/zoom/zoom-sdk-android |
| Realm | 7.0.1 | Apache 2.0 | https://github.com/realm/realm-java |

| Backend - PHP | | | |
|--------------------------------|---------|------------|---|
| Microservice - API Gateway | | | |
| Library | Version | License | Link |
| aws/aws-sdk-php-symfony | 2.0 | Apache 2.0 | https://github.com/aws/aws-sdk-php-symfony |
| enqueue/messenger-adapter | 0.2.2 | MIT | https://packagist.org/packages/sroze/messenger-enqueue-transport |
| enqueue/sqs | 0.9.12 | MIT | https://github.com/php-enqueue/sqs |
| nelmio/api-doc-bundle | 3.4 | MIT | https://github.com/nelmio/NelmioApiDocBundle |
| php-translation/symfony-bundle | 0.9.1 | MIT | https://github.com/php-translation/symfony-bundle |
| phpoffice/phpspreadsheet | 1.10 | MIT | https://github.com/PHPOffice/PhpSpreadsheet |
| ramsey/uuid | 3.8 | MIT | https://github.com/ramsey/uuid |
| sensio/framework-extra-bundle | 5.1 | MIT | https://github.com/sensiolabs/SensioFrameworkExtraBundle |
| sentry/sentry-symfony | 3.0 | Apache 2.0 | https://github.com/getsentry/sentry-symfony |
| Microservice - Auth | | | |
| abraham/twitteroauth | 1.1 | MIT | https://github.com/abraham/twitteroauth |

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|-----------------------------------|-------|--|---|
| aws/aws-php-sns-message-validator | 1.5 | Apache 2.0 | https://github.com/aws/aws-php-sns-message-validator |
| aws/aws-sdk-php-symfony | 2.0 | Apache 2.0 | https://github.com/aws/aws-sdk-php-symfony |
| doctrine/doctrine-bundle | 1.11 | MIT | https://github.com/doctrine/DoctrineBundle |
| doctrine/orm | 2.6 | MIT | https://github.com/doctrine/orm |
| lexik/jwt-authentication-bundle | 2.6 | MIT | https://github.com/lexik/LexikJWTAuthenticationBundle |
| phpunit/phpunit | 7.0 | Copyright (c) 2001-2021, Sebastian Bergmann https://github.com/sebastianbergmann/phpunit/blob/master/LICENSE | https://github.com/sebastianbergmann/phpunit |
| ramsey/uuid | 3.8 | MIT | https://github.com/ramsey/uuid |
| sentry/sentry-symfony | 3.0 | Apache 2.0 | https://github.com/getsentry/sentry-symfony |
| Microservice - Engine | | | |
| abraham/twitteroauth | 1.1 | MIT | https://github.com/abraham/twitteroauth |
| aws/aws-sdk-php-symfony | 2.0 | Apache 2.0 | https://github.com/aws/aws-sdk-php-symfony |
| djchen/oauth2-fitbit | 1.1 | MIT | https://github.com/djchen/oauth2-fitbit |
| enqueue/messenger-adapter | 0.2.2 | MIT | https://packagist.org/packages/sroze/me |

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|------------------------------------|--------|----------------------------------|---|
| | | | ssenger-enqueue-transport |
| enqueue/sqs | 0.9.12 | MIT | https://github.com/php-enqueue/sqs |
| facebook/graph-sdk | 5.7 | Copyright © 2017 | https://github.com/facebookarchive/php-graph-sdk |
| google/apiclient | 2.7 | Apache 2.0 | https://github.com/googleapis/google-api-php-client |
| joshcam/mysqli-database-class | 2.9 | Copyright © 2013 | https://github.com/ThingEngineer/PHP-MySQLi-Database-Class |
| knpuniversity/oauth2-client-bundle | 1.31 | MIT | https://github.com/knpuniversity/oauth2-client-bundle |
| monolog/monolog | 1.22 | MIT | https://github.com/Seldaek/monolog |
| phpoffice/phpspreadsheet | 1.9 | MIT | https://github.com/PHPOffice/PhpSpreadsheet |
| ramsey/uuid | 3.8 | MIT | https://github.com/ramsey/uuid |
| sensio/framework-extra-bundle | 5.1 | MIT | https://github.com/sensiolabs/SensioFrameworkExtraBundle |
| sentry/sentry-symfony | 3.0 | Apache 2.0 | https://github.com/getsentry/sentry-symfony |
| Microservice - Precard Manager | | | |
| Doctrine/orm | 2.7 | MIT | https://github.com/doctrine/orm |
| ramsey/uuid | 3.8 | MIT | https://github.com/ramsey/uuid |

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|-----------------------------------|-----|---|---|
| sentry/sentry-symfony | 3.0 | Apache 2.0 | https://github.com/getsentry/sentry-symfony |
| Microservice - Test Manager | | | |
| beberlei/doctrineextensions | 1.2 | Copyright (c) 2010-2020, Benjamin Eberlei | https://github.com/beberlei/DoctrineExtensions |
| doctrine/orm | 2.7 | MIT | https://github.com/doctrine/orm |
| firebase/php-jwt | 5.1 | Copyright © 2011, Neuman Vong | https://github.com/firebase/php-jwt |
| ramsey/uuid | 3.8 | MIT | https://github.com/ramsey/uuid |
| sentry/sentry-symfony | 3.0 | Apache 2.0 | https://github.com/getsentry/sentry-symfony |
| Microservice - User | | | |
| aws/aws-php-sns-message-validator | 1.5 | Apache 2.0 | https://github.com/aws/aws-php-sns-message-validator |
| aws/aws-sdk-php-symfony | 2.0 | Apache 2.0 | https://github.com/aws/aws-sdk-php-symfony |
| doctrine/orm | 2.7 | MIT | https://github.com/doctrine/orm |
| ramsey/uuid | 3.8 | MIT | https://github.com/ramsey/uuid |
| sentry/sentry-symfony | 3.0 | Apache 2.0 | https://github.com/getsentry/sentry-symfony |

| Backend - Python | | | |
|--------------------------|---------|---|---|
| Microservice - Processor | | | |
| Library | Version | License | Link |
| Numpy | 1.18.1 | 3-clause BSD | https://github.com/numpy/numpy |
| Scipy | 1.4.1 | 3-clause BSD | https://github.com/scipy/scipy |
| Pandas | 0.25.1 | 3-clause BSD | https://github.com/pandas-dev/pandas |
| Transform3d | 0.3.1 | 2-clause BSD | https://github.com/matthew-brett/transforms3d |
| Ruptures | 1.0.3 | 2-clause BSD | https://github.com/deepcharles/ruptures/ |
| Boto3 | 1.13.8 | Apache 2.0 | https://github.com/boto/boto3 |
| Botocore | 1.16.8 | Apache 2.0 | https://github.com/boto/botocore |
| Python-dotenv | 0.13.0 | Copyright © 2014, Saurabh Kumar | https://github.com/theskumar/python-dotenv |
| Requests | 2.23.0 | Apache 2.0 | https://github.com/psf/requests |
| Pylint | 2.5.2 | GPL-2.0 | https://github.com/PyCQA/pylint |
| Pylint-runner | 0.5.4 | MIT | https://github.com/MasterOdin/pylint_runner |
| Pyts | 0.11.0 | 3-clause BSD | https://github.com/johannfaouzi/pyts |
| Scikit-learn | 0.23.1 | 3-clause BSD | https://github.com/scikit-learn/scikit-learn |

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|------------|--------|--------------|---|
| Dask | 2.19.0 | 3-clause BSD | https://github.com/dask/dask/ |
| Sentry-sdk | 0.16.2 | 2.clause BSD | https://github.com/getsentry/sentry-python |
| Coverage | 5.3 | Apache 2.0 | https://github.com/nedbat/coveragepy |