



dreaMS<sup>MD</sup>

# 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<sup>MD</sup> SaMD and in these instructions for use follow the European standard EN ISO 15223-1:2016.

	CE Marking
	Medical Device Manufacturer
	Caution - Please consult the accompanying documents

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# 1. Introduction

These instructions for use (IfU) are intended for Healthcare Providers (HCP) caring for persons diagnosed with Multiple Sclerosis (PwMS) and who are considering prescribing dreaMS<sup>MD</sup>.

dreaMS<sup>MD</sup> 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<sup>MD</sup> 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<sup>MD</sup> 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
Licensors & distributor	Healios AG, Postfach, 4001 Basel, Switzerland, <a href="http://www.healios.io">www.healios.io</a>
Product	dreaMS <sup>MD</sup> is a software device to assess neurological functions in Persons with Multiple Sclerosis in the following domains: Movements, Balance, Dexterity and Vision. dreaMS <sup>MD</sup> 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 <a href="http://www.dreams.care">www.dreams.care</a>
Digital instructions for use	This document is provided digitally. Please consult <a href="http://www.dreams.care">www.dreams.care</a> to ensure you are using the most current IfU for the version of dreaMS <sup>MD</sup>

Software Lifecycle	2021-05-06 Version 2.0
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## 1.2 Intended Use

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

dreaMS<sup>MD</sup> 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<sup>MD</sup> reports measurements to the treating HCP who accesses the data through the Healios Platform on their web browser.

dreaMS<sup>MD</sup> 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

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)
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<sup>MD</sup>

Step 1. Log into the Healios Platform (you will need to have signed up to the web-based Healios Platform): [www.healios.io](http://www.healios.io)

Step 2. Select PwMS to whom you would like to prescribe dreaMS<sup>MD</sup> (OR add new PwMS to the Healios Platform)

Step 3. Select dreaMS<sup>MD</sup> from among the available Software Medical Devices for which PwMS is eligible

Step 4. Set-up the schedule for the dreaMS<sup>MD</sup> tests

Step 5. Save and send information to the PwMS (PwMS will receive a link via email or text message to access dreaMS<sup>MD</sup>).

The PwMS will receive an invitation on their device to download the dreaMS<sup>MD</sup> mobile application. As soon as the PwMS begins to complete the tests according to the prescribed schedule, you will be able to visualise the PwMS data on the Healios Platform.

In case you experience any problems when getting started, please contact us at [support@healios.io](mailto:support@healios.io).

### 3. How to read the measurements

Measurements from the tests are shown in a table accessible via the Healios Platform:

MOVEMENT						
PROMENADE						
User-ID						
Measurements	Short descriptions	Long descriptions	Units	Date1	Date2	Date3
Mean step time	Average time of one step.	Average time of one step.	Seconds	0.4426	0.4624	0.4783
Cadence	Gait cadence; the number of steps per time unit.	Gait cadence; the number of steps per time unit.	Steps/seconds	22.5920	21.6260	20.9080
Mean step regularity	Step regularity is defined as the (Pearson) correlation between the original acceleration signals of each pair of consecutive steps.	Average step regularity. An unbiased autocorrelation procedure was used to measure the correlation of the acceleration signal for each step (first dominant period). Step regularity is defined as the correlation between the original acceleration signals of each pair of consecutive steps.	Unitless (%)	0.9211	0.925	0.9276

1. Domain: Relates to 1 of the 4 neurological functions measured by the tests
2. Name: Name of the test performed by the PwMS, e.g., "Promenade"
3. User-ID: The unique identifier of the PwMS
4. Measurement: label or name of the test measurement
5. Short description: Short explanatory description of the test measurement
6. Long description: Long explanatory description of the test measurement
7. Unit: the unit by which the test performance is measured
8. Date: the date when the test was performed by the PwMS



## 4. 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 dreaMS<sup>MD</sup>.

## 5. Technical requirements

### 5.1 Web browser for HCP

An active internet connection is required to access Healios Platform for Healthcare Providers. You can use the following web browsers to access dreaMS<sup>MD</sup> on the Healios Platform for HCPs:

- Google Chrome
- Mozilla Firefox
- Microsoft Edge
- Apple Safari
- Opera
- Brave

### 5.2 Smartphone for PwMS

dreaMS<sup>MD</sup> 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<sup>MD</sup> 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. dreaMS<sup>MD</sup> is compatible with the following devices (iOS and Android):

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

Devices not compatible	
Please note that the below list may not be complete, and is subject to regular updates on <a href="http://www.dreams.care">www.dreams.care</a>	
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

## 6. Safety and warranty

### 6.1 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 healthcare professionals and their PwMS under their care. Overall, the potential benefit of the device far exceeds the probable known and foreseeable risks.

### 6.2 Warranty

Please refer to the No Warranties section in the dreaMS<sup>MD</sup> Terms of Use.

### 6.3 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<sup>MD</sup>.



We advise that you consult with your PwMS on a case-by-case basis if you believe there are elements of the dreaMS<sup>MD</sup> tests that are not suitable for their condition. We encourage that you recommend to your PwMS to perform the tests on a regular basis.



dreaMS<sup>MD</sup> is designed to assist you and your team in improving PwMS care and treatment. It should not be interpreted as a replacement for the care and expertise that you provide in your regular clinical consultations with PwMS.

dreaMS<sup>MD</sup> 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 7 of this IfU.

HCPs should become familiar with the general risks associated with each individual test and advise PwMS accordingly.

	HCPs must ensure that PwMS needs, capacities and conditions are taken into consideration before the selection and prescription of tests.
	Some dreaMS <sup>MD</sup> tests may not be suitable for PwMS with severe balance (equilibrium) issues, typically found in PwMS with EDSS 6 or more.

	HCPs must ensure that tests are prescribed to the correct PwMS.
	HCPs must follow existing clinical processes for disease management and treatment and not base clinical decisions solely on the information provided by the device.

## 7.dreaMS<sup>MD</sup> tests

### 7.1 dreaMS<sup>MD</sup> Promenade test

Name	Short description	Basis
Promenade	Walk briskly for 2-minutes, without a break.	Inspired by EDSS motor function and endurance

#### Intended use

dreaMS<sup>MD</sup> Promenade test assesses locomotion functions but does not provide an interpretation or a clinical implication.

#### Contraindications







dreaMS<sup>MD</sup> 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).

#### Measurements

Promenade		
User-ID		
Measurements	Short descriptions	Units
Mean step time	Average time of one step.	Seconds
Cadence	Gait cadence; the number of steps per time unit.	Steps/seconds
Mean step regularity	Step regularity is defined as the (Pearson) correlation between the original acceleration signals of each pair of consecutive steps.	Unitless (%)
Mean step similarity	Average similarity, or regularity, between pairs of consecutive steps. Calculated by using Dynamic Time Warping (DTW) measure.	Unitless (%)
Mean even step similarity	Average similarity, or regularity, between consecutive even (i.e. each second) steps. Calculated by using Dynamic Time Warping (DTW) measure.	Unitless (%)
Mean odd step similarity	Average similarity, or regularity, between consecutive odd (i.e. each first of a stride) steps. Calculated by using Dynamic Time Warping (DTW) measure.	Unitless (%)
Mean stride time	Mean time per stride (two (2) steps).	Seconds
Mean stride similarity	Average similarity score between strides as calculated using Dynamic Time Warping (DTW) measure.	Unitless (%)

Gait symmetry	Gait symmetry; represents the percent difference between the regularity of steps and the regularity of strides	Unitless (%)
Step count	Number of steps counted by pedometer during the performance of the challenge.	Unitless
Distance (pedometer)	Distance covered during the performance of the challenge as calculated by the pedometer.	Meters
Mean step length	Mean step length.	Meters
Mean stride length	Mean stride (two steps) length.	Meters
Distance walked (pedometer)	Distance covered during the performance of the challenge as calculated by the pedometer.	Meters

## 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

## 7.2 dreaMS<sup>MD</sup> 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 motor function and endurance

### Intended use

dreaMS<sup>MD</sup> 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<sup>MD</sup> 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).







### Measurements

SPANISH STAIRS		
User-ID		
Measurements	Short descriptions	Units
Number of stairs climbed	Number of stairs climbed. This value is extracted from the survey conducted at the end of the challenge.	Unitless
Step count	Number of steps counted from the accelerometer signal.	Unitless
Mean step time	Average time for one step, calculated across both odd and even steps.	Seconds
Cadence	Gait cadence; the number of steps per time unit (steps/seconds).	Steps/seconds
Step time variability (standard deviation)	Standard deviation of step times (across both odd and even steps).	Seconds
Step time variability (coefficient of variation)	Coefficient of variation of time steps.	Unitless (%)
Mean step regularity	Step regularity is defined as the (Pearson) correlation between the original acceleration signals of each pair of consecutive steps.	Unitless (%)
Mean even step regularity	Average step regularity; for even steps.	Unitless (%)
Mean odd step regularity	Average step regularity; for odd steps.	Unitless (%)
Mean step similarity	Average similarity, or regularity, between pairs of consecutive steps. Calculated by using Dynamic Time Warping (DTW) measure.	Unitless (%)



Mean even step similarity	Average similarity, or regularity, between consecutive even (i.e. each second) steps. Calculated by using Dynamic Time Warping (DTW) measure.	Unitless (%)
Mean odd step similarity	Average similarity, or regularity, between consecutive odd (i.e. each first of a stride) steps. Calculated by using Dynamic Time Warping (DTW) measure.	Unitless (%)
Stride count	Number of strides (two steps) counted during the challenge.	Unitless (%)
Mean stride time	Average time of performing one stride (two steps).	Unitless (%)
Mean stride regularity	Average stride regularity, correlation of acceleration signals across consecutive pairs of strides (1st and 2nd, 2nd and 3rd, ...).	Unitless (%)
Mean stride similarity	Average similarity score between strides as calculated by using Dynamic Time Warping (DTW) measure.	Unitless (%)
Gait symmetry	Gait symmetry; the percent difference between the regularity of steps and the regularity of strides.	Unitless (%)

## 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 to perform the activity
	Persons suffering from, or with a recent history of fainting or losing consciousness should not perform this activity

### 7.3 dreaMS<sup>MD</sup> 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<sup>MD</sup> Swiss Guard test assesses the U-turn function but does not provide an interpretation or a clinical implication of the measurements.






#### Contraindications

dreaMS<sup>MD</sup> 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).

#### Measurements

SWISS GUARD		
User-ID		
Measurements	Short descriptions	Units
U-turn count	The number of U-turns performed.	Unitless
Mean U-turn time	Average time to perform a U-turn.	Seconds
Mean angular velocity to perform a U-turn	Average angular velocity to perform a U-turn.	Grad/s

#### 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 to perform the activity



Persons suffering from, or with a recent history of fainting or losing consciousness should not perform this activity

## 7.4 dreaMS<sup>MD</sup> Musical Chairs

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<sup>MD</sup> 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<sup>MD</sup> 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).

### Measurement

MUSICAL CHAIRS		
User-ID		
Measurements	Short descriptions	Units
Squat count	Number of squats performed by PwMS during the challenge.	Unitless
Mean time sitting	Average time PwMS took to sit down.	Seconds
Sit and stand mean time	Average time the PwMS took to perform a complete movement (sit down and stand up).	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
	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 in a clear and safe area

## 7.5 dreaMS<sup>MD</sup> Butler test

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

### Intended use

dreaMS<sup>MD</sup> Butler test assesses the balance and kinetic tremor functions but does not provide an interpretation or a clinical implication of the measurements.





### Contraindications

dreaMS<sup>MD</sup> 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).

### Measurements

BUTLER		
User-ID		
Measurements	Short descriptions	Units
Postural Stability - Medio Lateral (ML)	Postural Stability - ML; indicates deviation from center medio lateral (side-to-side)	Unitless
Postural Stability - Antero-Posterior (AP)	Postural Stability - AP; indicates deviation from center medio lateral (front-to-back)	Unitless
Mean velocity in Antero-Posterior (AP)	Mean velocity of the movement in antero posterior axis.	m/s
Kinetic tremor	Representation of kinetic tremor from the accelerometer signal.	m/s <sup>2</sup>

### 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

## 7.6 dreaMS<sup>MD</sup> 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<sup>MD</sup> Penguin test assesses the balance functions but does not provide an interpretation or a clinical implication of the measurements.





### Contraindications

dreaMS<sup>MD</sup> 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).

### Measurements

PENGUIN		
User-ID		
Measurements	Short descriptions	Units
Postural Stability - Medio Lateral (ML)	Postural Stability - ML; indicates deviation from center medio lateral (side-to-side)	Unitless
Postural Stability - Antero-Posterior (AP)	Postural Stability - AP; indicates deviation from center medio lateral (front-to-back)	Unitless

### 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

## 7.7 dreaMS<sup>MD</sup> 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 9HPT

### Intended use

dreaMS<sup>MD</sup> Catch-A-Cloud test assesses the dexterity function but does not provide an interpretation or a clinical implication of the measurements.



### Contraindications

dreaMS<sup>MD</sup> Catch-A-Cloud test may not be suitable for PwMS suffering from severe visual impairment (corrected near vision <0.5).

### Measurements

CATCH-A-CLOUD		
User-ID		
Measurements	Short Descriptions	Units
Accuracy (# clouds hit)	Number of times the PwMS touched the cloud successfully.	Unitless
Number of touches	Number of times the PwMS touched the screen (successful + failed touches).	Unitless
Precision of touches (distance to center)	Average distance (in millimetres) between the place where PwMS touches the screen and the cloud's position.	Mm

### 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



## 7.8 dreaMS<sup>MD</sup> 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<sup>MD</sup> Confetti test assesses dexterity functions but does not provide an interpretation or a clinical implication of the measurements.

### Contraindications



dreaMS<sup>MD</sup> Confetti test may not be suitable for PwMS suffering from severe visual impairment (corrected near vision <0.5).

### Measurements

CONFETTI		
User-ID		
Measurements	Short descriptions	Units
Times the user bent the arms	Times the PwMS bent the arm. It is detected automatically from the signals, so this may not equal to the times the PwMS touched the screen with his nose.	Unitless
Bullseye touch count	Total number of touches on the screen within the center of the bullseye (both hands).	Unitless
Total touch count	Times that the PwMS touched the screen (anywhere on the screen) of the smartphone with his/her nose.	Unitless
Mean time to bend and stretch arm	Average time to perform a complete move (bend and stretch the arm).	Seconds
Jerk swayness - bending	Average value of Jerk swayness while bending the arms (across both arms). Jerk swayness indicates the change in the movement smoothness.	$m^2/s^5$
Jerk swayness - stretching	Average value of Jerk swayness while stretching the arms (average across both arms). Jerk swayness indicates the change in the movement smoothness.	$m^2/s^5$
Kinetic tremor - stretching in - accelerometer	Average value of kinetic tremor while stretching the arms (average across both arms), as measured by the accelerometer.	$m/s^2$

Kinetic tremor - bending in - accelerometer	Average value of kinetic tremor while bending the arms (average across both arms), as measured by the accelerometer.	m/s <sup>2</sup>
Kinetic tremor - bending in - gyroscope	Average value of kinetic tremor while bending the arms (average across both arms), as measured by the gyroscope.	rad/s
Kinetic tremor - stretching in - gyroscope	Average value of kinetic tremor while stretching the arms (average across both arms), as measured by the gyroscope.	rad/s
Mean velocity - bending	Average value of velocity while bending the arms (across both arms).	m/s
Mean velocity - stretching	Average value of velocity while stretching the arms (across both arms).	m/s

### 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

## 7.9 dreaMS<sup>MD</sup> 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<sup>MD</sup> Fog test assesses the (corrected) near vision contrast functions but does not provide an interpretation or a clinical implication of the measurements.



### Contraindications

dreaMS<sup>MD</sup> Fog test may not be suitable for PwMS suffering from severe visual impairment (corrected near vision <0.5).

### Measurements

FOG		
User-ID		
Measurements	Short descriptions	Units
Contrast vision (Left eye)	(Corrected) visual contrast score achieved by PwMS with the left eye.	Unitless (score)
Contrast vision (Right eye)	(Corrected) visual contrast score achieved by PwMS with the right eye.	Unitless (score)

### 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

## 7.10 dreaMS<sup>MD</sup> 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<sup>MD</sup> Eagle eye test assesses the (corrected) near vision acuity functions but does not provide an interpretation or a clinical implication of the measurements.



### Contraindications

dreaMS<sup>MD</sup> Eagle Eye test may not be suitable for PwMS suffering from severe visual impairment (corrected near vision <0.5).



### Measurements

EAGLE EYE		
User-ID		
Measurements	Short descriptions	Units
Acuity vision (Left eye)	(Corrected) visual acuity score achieved by PwMS with the left eye.	Unitless (score)
Acuity vision (Right eye)	(Corrected) visual acuity score achieved by PwMS with the right eye.	Unitless (score)

### 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

## 8. dreaMS<sup>MD</sup> Product Label

	
dreaMS <sup>MD</sup>	Version 2.0 2021-05-06
eIFU: <a href="http://www.dreams.care">www.dreams.care</a>	
	©Healios AG Postfach 4001 Basel Switzerland support@healios.io
Intended purpose: dreaMS <sup>MD</sup> assesses neurological functions in the 4 following domains, Movement, Balance, Dexterity and Vision, and reports results to the Healthcare Provider.	

## 9. Contact and Support

Troubleshooting issues and general feedback can be sent to Healios via e-mail at: [support@healios.io](mailto: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

When contacting Healios AG about a troubleshooting issue, HCPs should never mention PwMS names. Please ensure that no PwMS name is sent to Healios AG in any way and anonymise any reports and/or screenshots if necessary.

## Appendix 1: Open-source software licenses

This document represents the status of the dependencies for each dreaMS<sup>MD</sup>. 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	<a href="https://github.com/hackiftekhar/IQKeyboardManager">https://github.com/hackiftekhar/IQKeyboardManager</a>
Moya	13.0.1	MIT	<a href="https://github.com/Moya/Moya">https://github.com/Moya/Moya</a>
KeychainSwift	19.0.0	MIT	<a href="https://github.com/evgenyneu/keychain-swift">https://github.com/evgenyneu/keychain-swift</a>
InputMask	6.1.0	MIT	<a href="https://github.com/RedMadRobot/input-mask-ios">https://github.com/RedMadRobot/input-mask-ios</a>
FSCalendar	2.8.2	MIT	<a href="https://github.com/WenchaoD/FSCalendar">https://github.com/WenchaoD/FSCalendar</a>
FlagPhoneNumber	0.8.0	Apache 2.0	<a href="https://github.com/iziz/libPhoneNumber-iOS">https://github.com/iziz/libPhoneNumber-iOS</a>
EVFaceTracker	1.1.0	MIT	<a href="https://github.com/evermeer/EVFaceTracker">https://github.com/evermeer/EVFaceTracker</a>
JGProgressHUD	2.2	MIT	<a href="https://github.com/JonasGessner/JGProgressHUD">https://github.com/JonasGessner/JGProgressHUD</a>
SwipeCellKit	2.7.1	MIT	<a href="https://github.com/JonasGessner/JGProgressHUD">https://github.com/JonasGessner/JGProgressHUD</a>
DataCompression	3.6.0	Apache 2.0	<a href="https://github.com/mw99/DataCompression">https://github.com/mw99/DataCompression</a>

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

MobileRTC.framework	5.2.42037.1112	<a href="https://github.com/zoom/zoom-sdk-ios/blob/master/LICENSE.pdf">https://github.com/zoom/zoom-sdk-ios/blob/master/LICENSE.pdf</a>	<a href="https://github.com/zoom/zoom-sdk-ios">https://github.com/zoom/zoom-sdk-ios</a>
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Frontend - Android (Kotlin)			
Library	Version	License	Link
CircleImageView	3.1.0	Apache 2.0	<a href="https://github.com/dodenhof/CircleImageView">https://github.com/dodenhof/CircleImageView</a>
Retrofit	2.9.0	Apache 2.0	<a href="https://github.com/square/retrofit">https://github.com/square/retrofit</a>
Firebase Messaging	20.3.0	Apache 2.0	<a href="https://github.com/firebase/firebase-android-sdk/tree/master/firebase-messaging">https://github.com/firebase/firebase-android-sdk/tree/master/firebase-messaging</a>
Firebase Crashlytics	17.4.1	Apache 2.0	<a href="https://github.com/firebase/firebase-android-sdk">https://github.com/firebase/firebase-android-sdk</a> , <a href="https://github.com/firebase/firebase-android-sdk/tree/master/firebase-crashlytics">https://github.com/firebase/firebase-android-sdk/tree/master/firebase-crashlytics</a>
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	<a href="https://github.com/google/flexbox-layout">https://github.com/google/flexbox-layout</a>
navigation-fragment	2.3.0	Google's service for navigation	



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

Backend - PHP			
Microservice - API Gateway			
Library	Version	License	Link
aws/aws-sdk-php-symfony	2.0	Apache 2.0	<a href="https://github.com/aws/aws-sdk-php-symfony">https://github.com/aws/aws-sdk-php-symfony</a>
enqueue/messenger-adapter	0.2.2	MIT	<a href="https://packagist.org/packages/sroze/messenger-enqueue-transport">https://packagist.org/packages/sroze/messenger-enqueue-transport</a>
enqueue/sqs	0.9.12	MIT	<a href="https://github.com/php-enqueue/sqs">https://github.com/php-enqueue/sqs</a>
nelmio/api-doc-bundle	3.4	MIT	<a href="https://github.com/nelmio/NelmioApiDocBundle">https://github.com/nelmio/NelmioApiDocBundle</a>

php-translation/symfony-bundle	0.9.1	MIT	<a href="https://github.com/php-translation/symfony-bundle">https://github.com/php-translation/symfony-bundle</a>
phpoffice/phpspreadsheet	1.10	MIT	<a href="https://github.com/PHPOffice/PhpSpreadsheet">https://github.com/PHPOffice/PhpSpreadsheet</a>
ramsey/uuid	3.8	MIT	<a href="https://github.com/ramsey/uuid">https://github.com/ramsey/uuid</a>
sensio/framework-extra-bundle	5.1	MIT	<a href="https://github.com/sensiolabs/SensioFrameworkExtraBundle">https://github.com/sensiolabs/SensioFrameworkExtraBundle</a>
sentry/sentry-symfony	3.0	Apache 2.0	<a href="https://github.com/getsentry/sentry-symfony">https://github.com/getsentry/sentry-symfony</a>
Microservice - Auth			
abraham/twitteroauth	1.1	MIT	<a href="https://github.com/abraham/twitteroauth">https://github.com/abraham/twitteroauth</a>
aws/aws-php-sns-message-validator	1.5	Apache 2.0	<a href="https://github.com/aws/aws-php-sns-message-validator">https://github.com/aws/aws-php-sns-message-validator</a>
aws/aws-sdk-php-symfony	2.0	Apache 2.0	<a href="https://github.com/aws/aws-sdk-php-symfony">https://github.com/aws/aws-sdk-php-symfony</a>
doctrine/doctrine-bundle	1.11	MIT	<a href="https://github.com/doctrine/DoctrineBundle">https://github.com/doctrine/DoctrineBundle</a>
doctrine/orm	2.6	MIT	<a href="https://github.com/doctrine/orm">https://github.com/doctrine/orm</a>
lexik/jwt-authentication-bundle	2.6	MIT	<a href="https://github.com/lexik/LexikJWTAuthenticationBundle">https://github.com/lexik/LexikJWTAuthenticationBundle</a>
phpunit/phpunit	7.0	Copyright (c) 2001-2021, Sebastian Bergmann <a href="https://github.com/sebastianbergmann/phpunit">https://github.com/sebastianbergmann/phpunit</a>	<a href="https://github.com/sebastianbergmann/phpunit">https://github.com/sebastianbergmann/phpunit</a>

		<a href="#">hpunit/blob/master/LICENSE</a>	
ramsey/uuid	3.8	MIT	<a href="https://github.com/ramsey/uuid">https://github.com/ramsey/uuid</a>
sentry/sentry-symfony	3.0	Apache 2.0	<a href="https://github.com/getsentry/sentry-symfony">https://github.com/getsentry/sentry-symfony</a>
Microservice - Engine			
abraham/twitteroauth	1.1	MIT	<a href="https://github.com/abraham/twitteroauth">https://github.com/abraham/twitteroauth</a>
aws/aws-sdk-php-symfony	2.0	Apache 2.0	<a href="https://github.com/aws/aws-sdk-php-symfony">https://github.com/aws/aws-sdk-php-symfony</a>
djchen/oauth2-fitbit	1.1	MIT	<a href="https://github.com/djchen/oauth2-fitbit">https://github.com/djchen/oauth2-fitbit</a>
enqueue/messenger-adapter	0.2.2	MIT	<a href="https://packagist.org/packages/sroze/messenger-enqueue-transport">https://packagist.org/packages/sroze/messenger-enqueue-transport</a>
enqueue/sqs	0.9.12	MIT	<a href="https://github.com/php-enqueue/sqs">https://github.com/php-enqueue/sqs</a>
facebook/graph-sdk	5.7	<a href="#">Copyright © 2017</a>	<a href="https://github.com/facebookarchive/php-graph-sdk">https://github.com/facebookarchive/php-graph-sdk</a>
google/apiclient	2.7	Apache 2.0	<a href="https://github.com/googleapis/google-api-php-client">https://github.com/googleapis/google-api-php-client</a>
joshcam/mysqli-database-class	2.9	<a href="#">Copyright © 2013</a>	<a href="https://github.com/ThingEngineer/PHP-MySQLi-Database-Class">https://github.com/ThingEngineer/PHP-MySQLi-Database-Class</a>
knpuniversity/oauth2-client-bundle	1.31	MIT	<a href="https://github.com/knpuniversity/oauth2-client-bundle">https://github.com/knpuniversity/oauth2-client-bundle</a>
monolog/monolog	1.22	MIT	<a href="https://github.com/Seldaek/monolog">https://github.com/Seldaek/monolog</a>

phpoffice/phpspreadsheet	1.9	MIT	<a href="https://github.com/PHPOffice/PhpSpreadsheet">https://github.com/PHPOffice/PhpSpreadsheet</a>
ramsey/uuid	3.8	MIT	<a href="https://github.com/ramsey/uuid">https://github.com/ramsey/uuid</a>
sensio/framework-extra-bundle	5.1	MIT	<a href="https://github.com/sensiolabs/SensioFrameworkExtraBundle">https://github.com/sensiolabs/SensioFrameworkExtraBundle</a>
sentry/sentry-symfony	3.0	Apache 2.0	<a href="https://github.com/getsentry/sentry-symfony">https://github.com/getsentry/sentry-symfony</a>
Microservice - Precard Manager			
Doctrine/orm	2.7	MIT	<a href="https://github.com/doctrine/orm">https://github.com/doctrine/orm</a>
ramsey/uuid	3.8	MIT	<a href="https://github.com/ramsey/uuid">https://github.com/ramsey/uuid</a>
sentry/sentry-symfony	3.0	Apache 2.0	<a href="https://github.com/getsentry/sentry-symfony">https://github.com/getsentry/sentry-symfony</a>
Microservice - Test Manager			
beberlei/doctrineextensions	1.2	<a href="https://github.com/beberlei/DoctrineExtensions">Copyright (c) 2010-2020, Benjamin Eberlei</a>	<a href="https://github.com/beberlei/DoctrineExtensions">https://github.com/beberlei/DoctrineExtensions</a>
doctrine/orm	2.7	MIT	<a href="https://github.com/doctrine/orm">https://github.com/doctrine/orm</a>
firebase/php-jwt	5.1	<a href="https://github.com/firebase/php-jwt">Copyright © 2011, Neuman Vong</a>	<a href="https://github.com/firebase/php-jwt">https://github.com/firebase/php-jwt</a>
ramsey/uuid	3.8	MIT	<a href="https://github.com/ramsey/uuid">https://github.com/ramsey/uuid</a>
sentry/sentry-symfony	3.0	Apache 2.0	<a href="https://github.com/getsentry/sentry-symfony">https://github.com/getsentry/sentry-symfony</a>
Microservice - User			

aws/aws-php-sns-message-validator	1.5	Apache 2.0	<a href="https://github.com/aws/aws-php-sns-message-validator">https://github.com/aws/aws-php-sns-message-validator</a>
aws/aws-sdk-php-symfony	2.0	Apache 2.0	<a href="https://github.com/aws/aws-sdk-php-symfony">https://github.com/aws/aws-sdk-php-symfony</a>
doctrine/orm	2.7	MIT	<a href="https://github.com/doctrine/orm">https://github.com/doctrine/orm</a>
ramsey/uuid	3.8	MIT	<a href="https://github.com/ramsey/uuid">https://github.com/ramsey/uuid</a>
sentry/sentry-symfony	3.0	Apache 2.0	<a href="https://github.com/getsentry/sentry-symfony">https://github.com/getsentry/sentry-symfony</a>

Backend - Python			
Microservice - Processor			
Library	Version	License	Link
Numpy	1.18.1	3-clause BSD	<a href="https://github.com/numpy/numpy">https://github.com/numpy/numpy</a>
Scipy	1.4.1	3-clause BSD	<a href="https://github.com/scipy/scipy">https://github.com/scipy/scipy</a>
Pandas	0.25.1	3-clause BSD	<a href="https://github.com/pandas-dev/pandas">https://github.com/pandas-dev/pandas</a>
Transform3d	0.3.1	2-clause BSD	<a href="https://github.com/matthew-brett/transforms3d">https://github.com/matthew-brett/transforms3d</a>
Ruptures	1.0.3	2-clause BSD	<a href="https://github.com/deepcharles/ruptures/">https://github.com/deepcharles/ruptures/</a>
Boto3	1.13.8	Apache 2.0	<a href="https://github.com/boto/boto3">https://github.com/boto/boto3</a>
Botocore	1.16.8	Apache 2.0	<a href="https://github.com/boto/botocore">https://github.com/boto/botocore</a>

Python-dotenv	0.13.0	<a href="#">Copyright © 2014, Saurabh Kumar</a>	<a href="https://github.com/t/heskumar/python-dotenv">https://github.com/t/heskumar/python-dotenv</a>
Requests	2.23.0	Apache 2.0	<a href="https://github.com/psf/requests">https://github.com/psf/requests</a>
Pylint	2.5.2	GPL-2.0	<a href="https://github.com/PyCQA/pylint">https://github.com/PyCQA/pylint</a>
Pylint-runner	0.5.4	MIT	<a href="https://github.com/MasterOdin/pylint_runner">https://github.com/MasterOdin/pylint_runner</a>
Pyts	0.11.0	3-clause BSD	<a href="https://github.com/johannfaouzi/pyts">https://github.com/johannfaouzi/pyts</a>
Scikit-learn	0.23.1	3-clause BSD	<a href="https://github.com/scikit-learn/scikit-learn">https://github.com/scikit-learn/scikit-learn</a>
Dask	2.19.0	3-clause BSD	<a href="https://github.com/dask/dask/">https://github.com/dask/dask/</a>
Sentry-sdk	0.16.2	2.clause BSD	<a href="https://github.com/getsentry/sentry-python">https://github.com/getsentry/sentry-python</a>
Coverage	5.3	Apache 2.0	<a href="https://github.com/edbat/coveragepy">https://github.com/edbat/coveragepy</a>