

**Device:**  
 ME&MG Mobile Application

**Applicable for app versions:**  
 v1.1.X

Clinical trial entitled :	“The ME&MG digital solution for autonomous assessment of Myasthenia Gravis: a validation study”
Acronym :	DOMYA
	NCT : 05564936 / ADS-DOMYA-2023
Sponsor :	Ad Scientiam SAS 21-23 rue Albert Bayet 75013 Paris France







## INSTRUCTIONS FOR USE For Patients

**CAUTION - Investigational device.**  
 Limited by United States law to investigational use

*This document is strictly for the use of the users of ME&MG. It cannot be used or distributed for any other purpose, and/or otherwise disclosed, communicated or reproduced without the prior written consent of its manufacturer, Ad Scientiam.*

*Please contact your investigator to request a printed version of this document.*

<b>REF</b>	DA303-IOS DA303-ANDROID	   <small>Medical Device</small> eIFU
	Ad Scientiam SAS 21-23 rue Albert Bayet 75013 Paris - France www.adscientiam.com	

## Table of Contents

[About this document](#)

[Useful information](#)

[What is ME&MG?](#)

[General description](#)

[Intended use of the device](#)

[Intended users of the device](#)

[Indications for use and intended patient population](#)

[Recommendations for use](#)

[Performances](#)

[Risks and Benefits](#)

[General Warnings and Precautions for use](#)

[Contraindications](#)

[Benefits and residual risks](#)

[Adverse events](#)

[Setup](#)

[Minimum requirements for smartphone compatibility](#)

[Downloading the application](#)

[Login](#)

[Use of the ME&MG Application](#)

[ME&MG test sessions](#)

[My Eyelids test](#)

[My Voice test](#)

[My Breathing test](#)

[My Arms test](#)

[My Legs test](#)

[“My Daily Activities”](#)

[“My Mental Health”](#)

[“My Pain”](#)

[“My Sleep”](#)

[My Quality of Life](#)

[Log out](#)

[Saving, modifying and deleting personal data](#)

[Synchronization of data](#)

[Modifying and deleting data](#)

[Maintenance of the application](#)

[Deletion of the application](#)

[Contact](#)

## **About this document**

These instructions for use are intended for people living with Myasthenia Gravis (MG).

Before using ME&MG for the first time, you must read this document entirely.

This document is also available in electronic format via the "Help & Contact" section of the mobile application.

## **Useful information**

The product and its instruction manual use symbols and icons whose meaning is described below:



Your attention is required in the following



Refer to the electronic instructions for use



This product is a Software as a Medical Device (SaMD) exclusively for clinical investigations



Device catalog reference



Name of the manufacturer of the Software as a Medical Device (SaMD) and contact address



Date and country of manufacture of the Software as a Medical Device (SaMD).  
Note: FR = France



Unique Device Identifier

## **What is ME&MG?**

### **General description**

ME&MG is a smartphone application developed by Ad Scientiam with the collaboration of patient groups and healthcare professionals experts in Myasthenia Gravis (MG).

ME&MG contains different modules:

- Digital tests, based on conventional clinical assessments:
  - "My Eyelids" Test (MET) to assess drooping eyelids
  - "My Voice" Test (MVT) to assess changes in your voice
  - "My Breathing" Test (MBT) to assess your respiratory muscles' strength
  - "My Arms" Test (MAT) to assess your arms' muscle strength
  - "My Legs" Test (MLT) to assess your legs' muscle strength
  
- E-questionnaires, based on conventional questionnaires:
  - My Daily Activities, based on the Myasthenia Gravis Activities of Daily Living (MG-ADL), to assess the impact of MG on your daily activities.
  - My Mental Health Questionnaire, based on the Patient Health Questionnaire-8 (PHQ8) to assess depression
  - My Pain Questionnaire, based on a Pain Likert scale (0-100) to assess pain
  - My Sleep Questionnaire, based on the Insomnia Severity Index (ISI) to assess sleep disorders
  - My Quality of Life Questionnaire, based on the Myasthenia Gravis Quality of Life Scale (MG-QOL-15) to assess your quality of life

### **Intended use of the device**

ME&MG is a Software as a Medical Device consisting of a mobile application running on smartphones.

During the DOMYA study, the ME&MG smartphone application used is an investigational version of the Software as a Medical Device. This means that this version of the application was specifically developed by Ad Scientiam for this clinical investigation.

The mobile application is intended to be used by patients living with Myasthenia Gravis (MG) in their home environment, as an unsupervised self-assessment digital tool of various functional parameters. These parameters include ocular, bulbar, respiratory and muscular functions assessed with digital tests. ME&MG also includes e-questionnaires related to activities of daily living, depression, pain, insomnia, and quality of life.

The results of the tests and questionnaires will not be displayed to the users during the DOMYA study.

### **Intended users of the device**

ME&MG (mobile application) is intended to be used by the patients if they meet the criteria of the intended patient population.

### **Indications for use and intended patient population**

The ME&MG mobile application is intended to be used by the patients who have expressed their consent to participate in the DOMYA study.

ME&MG is intended for the follow-up of adult patients diagnosed with MG who meet the DOMYA study inclusion criteria :

- 18 to 60 years old
- Diagnosed with gMG at screening with generalized muscle weakness meeting the clinical criteria for diagnosis of MG, as defined by the MGFA Clinical Classification Class II, III, or IV, and likely not in need of a respirator for the duration of the study, in the investigator's opinion
- With positive serologic testing for Anti-Acetylcholinesterase receptor (AChR) autoantibody at screening
- Able to use a smartphone and to read and interpret texts and pictograms on this support

### **Recommendations for use**

It is not recommended to do the tests more than twice a day.

During your participation in the DOMYA study, you will have to use ME&MG as described in the Informed Consent Form:

- Perform the **ME&MG Digital Checkup - in clinic** under the supervision of your study doctor during the three scheduled in-clinic visits at D0, after 3 months and after 12 months;
- Perform the **ME&MG Digital Checkup - morning** and **Digital Checkup - evening on the same day** at home without supervision at D1, D2, D3, D30, D60 D87, D88, D89, D91, D120, D150, D180, D210, D240, D270, D300, D330, D360 and D364
- Perform the **ME&MG Questionnaires** at home without supervision, once a month
- Answer online questionnaires that you will receive via email or text message.

*You will receive push notifications, emails and/or text messages to remind you to do the ME&MG assessments when you will be at home.*


## Performances

The performances of the five digital tests of ME&MG are expressed as the expected analytical mean error in absolute or percentage (%) of the outcomes values (covering both iOS and Android operating systems). The numbers in brackets [...] indicate either the percentage (%) of outcomes values that have an expected error below X%, or the standard deviation of the value.

Digital Test	Outcome	Mean error [% of outcomes with error ≤ 10%]
MAT	Time holding the arm (sec)	≤ 10% [≤ 75%]
MBT	Maximum phonation time (sec)	≤ 10% [≤ 85%]
Digital Test	Outcome	Mean error [± Standard Deviation]
MLT	Number of sit-to-stand actions	≤ 1 sit-to-stand [± 2]
MVT	Dysarthria onset (sec)	≤ 1.5 secs [± 2.5 secs]
MET	Margin to Reflex Distance (mm)	≤ 1 mm [± 0.5 mm]

## Risks and Benefits

### General Warnings and Precautions for use

	<p>Please note that you should wait at least <b>8 hours</b> when you have to repeat the Digital Checkups on the same day. It is not recommended to do the tests more than twice a day.</p>
---	--

## Contraindications



The use of ME&MG is not recommended for people with a neurological disease other than MG and for patients with a physical or mental incapacity to use a smartphone.

## Benefits and residual risks

For the claimed intended-use and indications, using this device will not bring you any personal benefit. However, the information obtained through this application may benefit other people in the future and contribute to the creation of new tests, new treatments or other elements that may expand knowledge about MG and its management through the use of innovative digital tools.

All known and foreseeable risks of the device have been reduced as far as possible and no remaining unacceptable risk has been identified.

## Adverse events

An adverse event means any untoward medical occurrence, unintended disease or injury or any untoward clinical signs, including an abnormal laboratory finding, in subjects, users or other persons, in the context of a clinical investigation, whether or not related to the investigational device.

The following complications of phone applications including self-testing functions may appear : occasional temporary fatigue following the execution of some tests or an inability to perform the tests, and physical injuries when executing some tests in an unsafe environment or state of health.

To prevent these risks, you should follow the instructions of this manual, as well as the instructions given on the ME&MG mobile application, and contact your study doctor in case of any doubt.

If you think you are experiencing an adverse event while using ME&MG, contact your study doctor.

## Setup

### Minimum requirements for smartphone compatibility



Do not use ME&MG on a damaged smartphone (cracked or broken glass for instance) as this could compromise the measurement performance of the device.

To function properly, the application must be used on a smartphone whose language of use is supported by the application. This smartphone must run on Android or iOS operating systems, according to one of the following configurations:

Apple® smartphones	Android® smartphones
Operating Systems (OS): <b>iOS 14 or higher version</b> Models: any model (with the compatible OS) Internal storage: 150 MB minimum RAM: 1 GB minimum Screen size : width of at least 360 CSS-px	Operating Systems (OS): <b>Android 8 or higher version</b> Models: any model (with the compatible OS) Internal storage: 150 MB minimum RAM: 1 GB minimum Screen size : width of at least 360 CSS-px

You can find the OS version information on your phone settings the following way :

If you are an Android user:

1. Open your phone's Settings application.
2. Near the bottom, tap “About phone”.
3. Tap Software information, then “Android version”.

If you are an iPhone user:

1. Open your phone's Settings application.
2. Select General. Tap “About”.
3. The software version of your device should appear on this screen



## Downloading the application

An internet connection (WiFi/3G/4G/5G) is required to download and install ME&MG.

Open your application store:

- App Store for Apple® smartphones;
- Google Play for Android® smartphones.

Open the search function, enter manually the name of the application: "ME&MG" and validate the search. To start the download and installation of this application, click on the "get" or "install" button. The application will download and install automatically. The installation is successful when the ME&MG application is present in the application directory. It can be identified by its logo and name:



## Login

Your study doctor will give you a unique email address, associated with a password that will secure your access to the application during your participation in the study.

The email will be composed as follows: countrycode-sitecode-000X@domya.study

No identifying information will be collected in ME&MG.

The study doctor will maintain the login information in their medical record to assist with the access to the application. If you forget your email or password, please contact them using the contact provided at the end of this document.


You must not share the password with anyone.

## Use of the ME&MG Application

<b><i>IMPORTANT NOTE:</i></b>	<b><i>YOUR PHONE MUST BE SUFFICIENTLY CHARGED TO PERFORM THE TESTS (AT LEAST 30% BATTERY POWER AVAILABLE).</i></b>
-------------------------------	--

### **ME&MG test sessions**


You can access the ME&MG tests and e-questionnaires in the different sessions proposed by the mobile application: Three Digital Checkups and the 'Questionnaires' session.




**Digital checkup in clinic**

Complete the tests during your consultation, under the supervision of your healthcare professional.


🕒 Available ● 0/6


**My Eyelids** 

1 minute


**My Voice** 


2 minutes





**My Breathing** 

1 minute



**My Arms** 







**Digital Check-up: evening**


Complete the tests at home in the evening. The evening checkup must be completed at least 8 hours after the morning checkup. Once you do the first test, you will have 2 hours to complete the session.

🕒 1h52min left 📉 1/5


**My Eyelids** 

1 minute




**My Voice** 

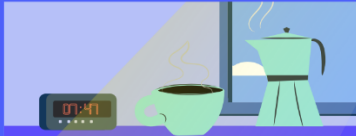
2 minutes

**My Breathing** 

1 minute



←




### Digital Check-up: morning


Complete the tests at home in the morning. The morning checkup must be completed at least 8 hours after the evening checkup. Once you do the first test, you will have 2 hours to complete the session.

🕒 52min left      🔄 3/5


**My Eyelids** ✓


1 minute 

**My Voice** ✓


2 minutes 

**My Breathing** ✓

1 minute 

**My Arms** 

←




### Questionnaires


Complete the questionnaires independently at home.

🕒 10h25      🔄 2/5

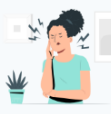
**My Daily Activities Questionnaire** ✓


1 minute 

**My Mental Health Questionnaire** ✓


2 minutes 


**My Pain Questionnaire** ✓

1 minute 

**My Sleep** 

Session	What's in it ?	When should I do it ?	How long do I have to complete it ?
Digital Checkup - in clinic	MET, MVT, MBT, MAT, MLT then MG-ADL	In-clinic with your study doctor at D0, after 3 months and after 12 months.	2 hours
Digital Checkup - morning	MET, MVT, MBT, MAT then MLT	at home in autonomy at D1, D2, D3, D30, D60 D87, D88, D89, D91, D120, D150, D180, D210, D240, D270, D300, D330,D360 and D364	2 hours
Digital Checkup - evening	MET, MVT, MBT, MAT, MLT then MG-ADL		
Questionnaires	My Mental health, My Pain, My Sleep, My Quality of life	At-home, once a month	12 hours

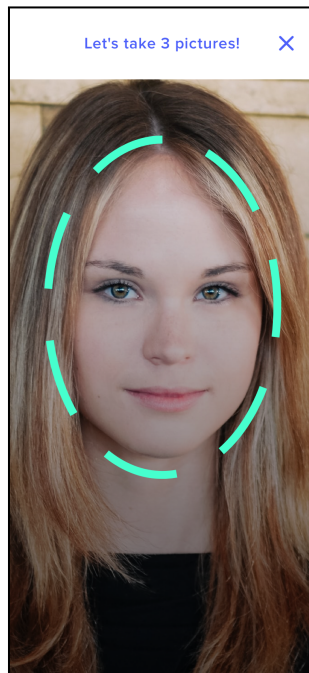
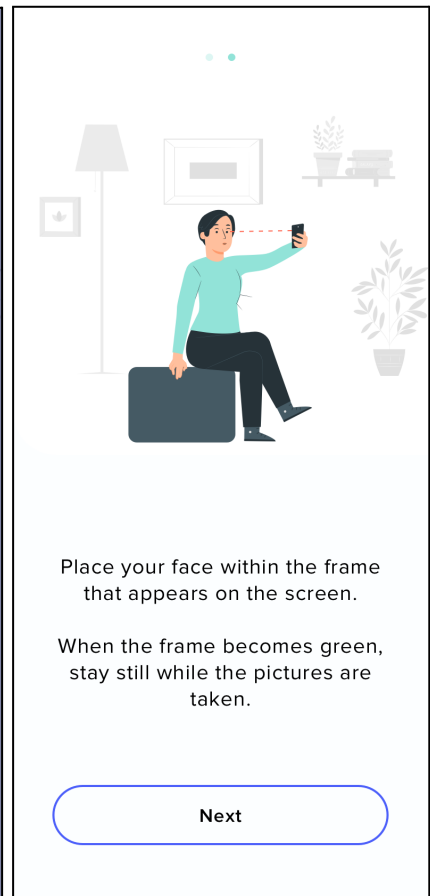
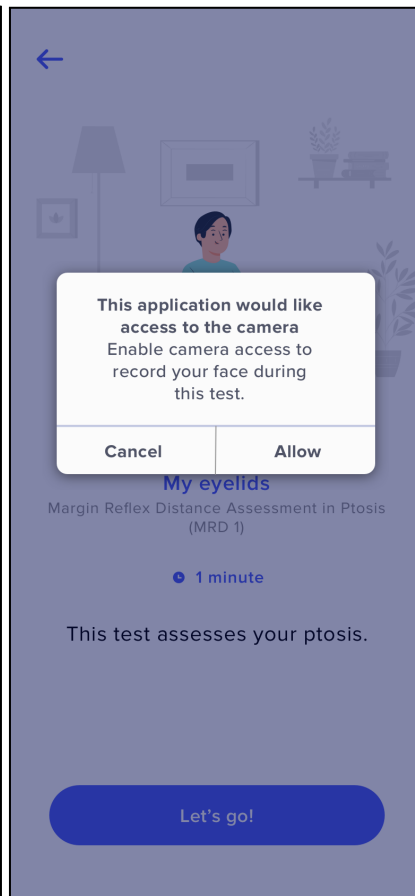
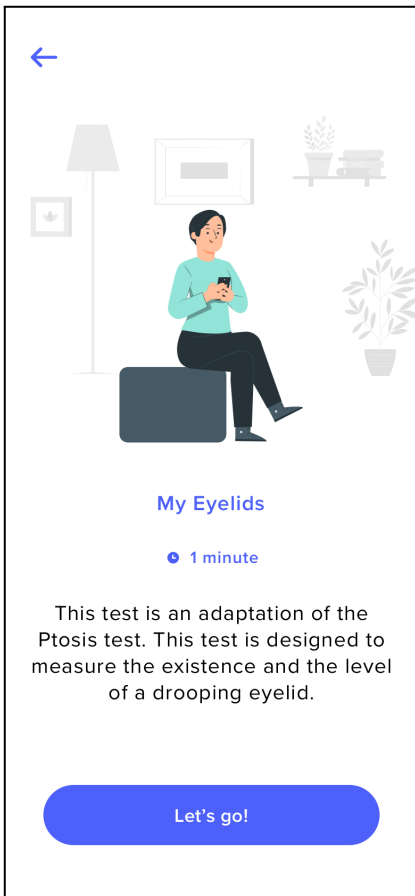
 If you do not complete all the tests and questionnaires in time, the ME&MG sessions will be locked and you will not be able to perform them again until 12 hours later.

 To help you remember, you will receive push notifications, emails and/or text messages to remind you to do your Digital Checkups at home, and to complete them if you have started them but not finished the totality of the tests and questionnaires.

Before starting the Digital Checkup, you will need to indicate in the application whether you are taking a symptomatic or maintenance treatment for your MG

If you feel too tired to complete all of the tests and questionnaires in one go, please wait until you feel capable of resuming your session.

## My Eyelids test



- You need to grant access to the camera before starting.
- The test starts with a mandatory tutorial to explain the test condition.

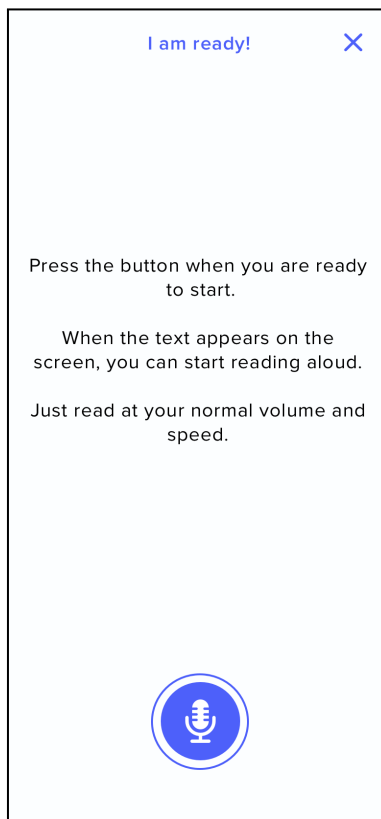
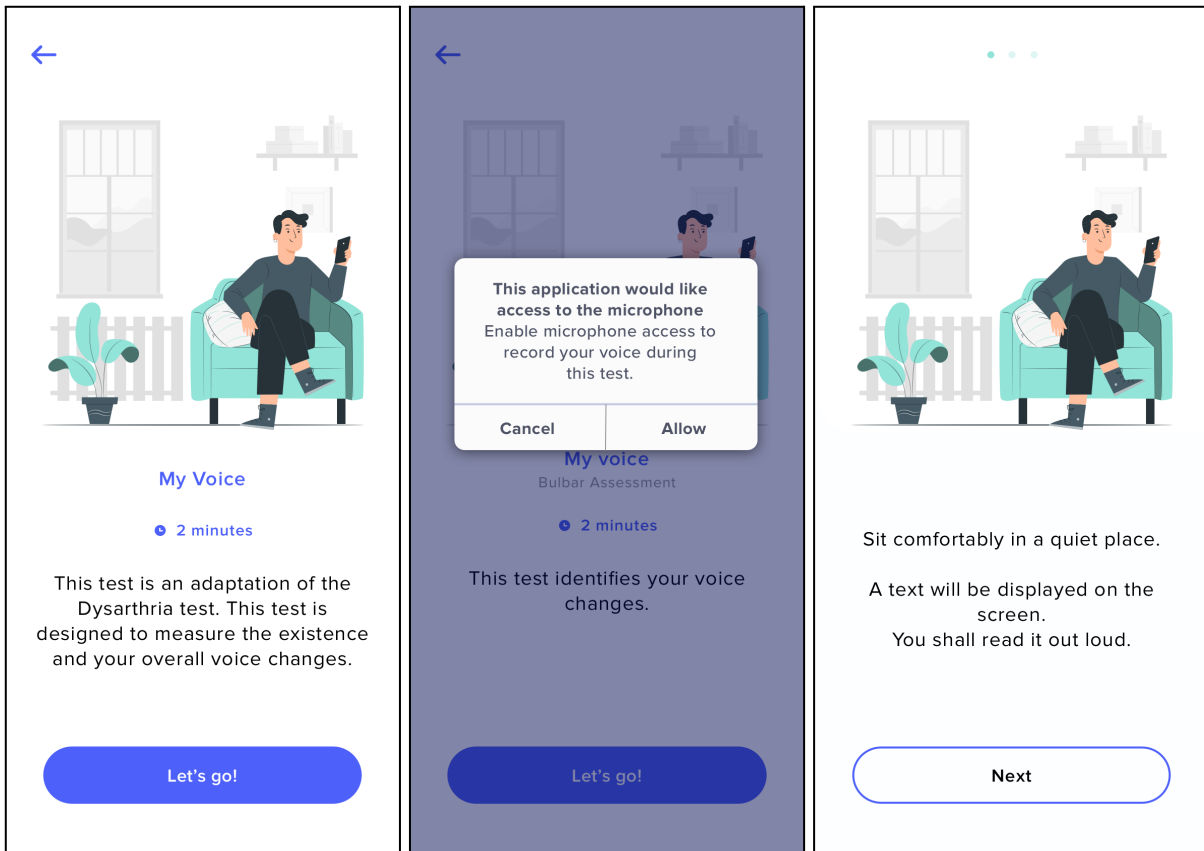
Sit comfortably. Before starting the test, a checklist will pop up to confirm that:

- You are facing the light
- You are keeping your smartphone at eye level
- You have a neutral expression
- You keep your eyes wide open as best as you can
- You are not wearing glasses.

Once this checklist is complete, place your face in the frame. As soon as the right position is achieved, the frame turns green and three pictures are taken automatically by the application.

The test stops once the three pictures are taken. If you do not place your face correctly in the frame, an error message pops-up after 30 seconds. You can then try again or quit the test. If you tap on the cross, the test is canceled.

## My Voice test





You need to grant access to the microphone to perform this test. The test starts with a mandatory tutorial explaining the test conditions.

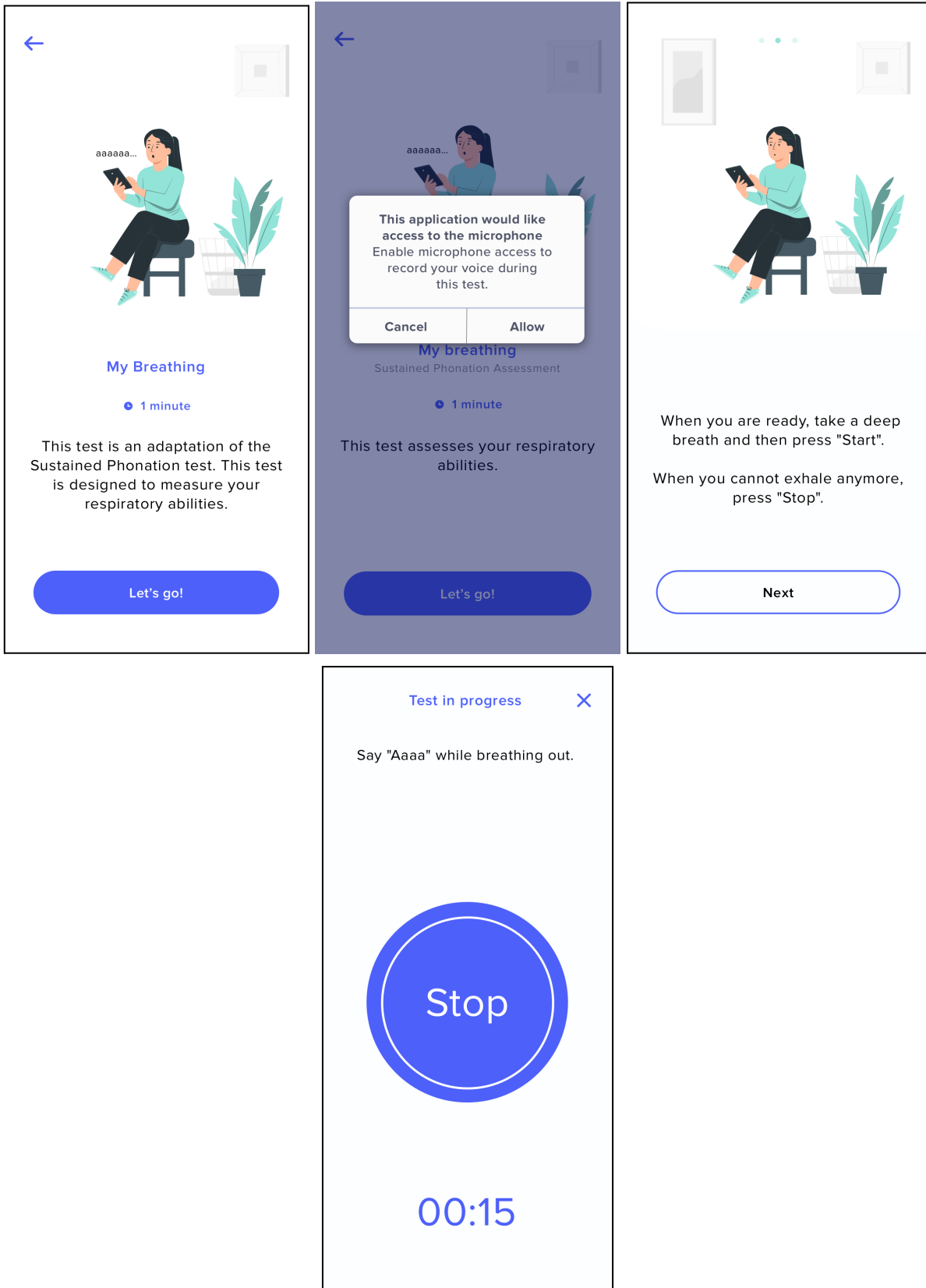
You need to sit comfortably in a quiet place. An analysis of the surroundings is done before starting the test to make sure that your environment is quiet enough.

If your environment is too noisy, the test cannot be completed and you will be asked to redo the analysis of the surroundings.

Once the analysis is validated, start the test by pressing on the microphone icon, read the text that is displayed out loud and stop the test when finished by tapping on “Done”.

The test is over when you end it. If you tap on the cross, the test is canceled.

## My Breathing test



- You need to grant access to the microphone to perform the test.
- The test starts with a mandatory tutorial explaining the test conditions.

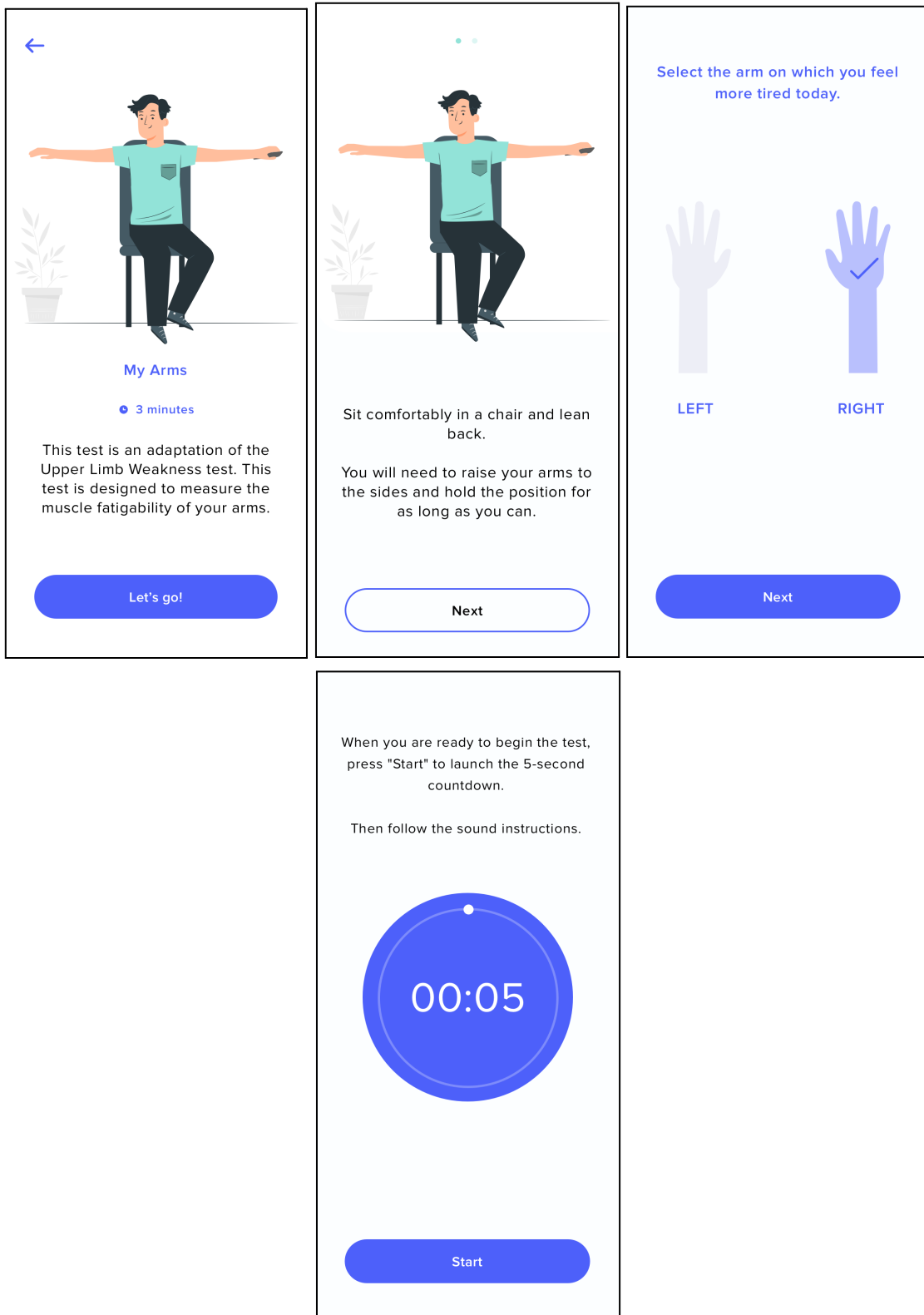
Sit comfortably in a quiet place.

An analysis of the surroundings is done before starting the test to make sure that your environment is quiet enough. If the environment is too noisy, the test cannot be completed, and you will be asked to redo the analysis of the surroundings.

Once the analysis is validated, you should take a deep breath, tap on "Start" and exhale while holding an "Aaaa" sound for as long as possible. When you can no longer exhale, press "Stop".

The test is over when you end it. If you tap on the cross, the test is canceled.

## My Arms test



←

**My Arms**

• 3 minutes

This test is an adaptation of the Upper Limb Weakness test. This test is designed to measure the muscle fatigability of your arms.

Let's go!

...

Sit comfortably in a chair and lean back.

You will need to raise your arms to the sides and hold the position for as long as you can.

Next

Select the arm on which you feel more tired today.

LEFT RIGHT

Next

When you are ready to begin the test, press "Start" to launch the 5-second countdown.

Then follow the sound instructions.

00:05

Start

The test begins with a mandatory tutorial explaining the test conditions.

You will be asked to sit comfortably in a chair and lean back.

Before starting the test, indicate the arm that feels more tired, you will use it to hold the phone during the test. Adjust the volume of your smartphone in order to hear the audible instructions.


The test starts after a 5-second countdown. Raise and extend your arms to the side, holding the smartphone in the previously selected hand, palm down.

The test stops automatically after 2 minutes 30 seconds. You can also stop the test manually by holding the “Hold to stop” button. You will then be asked why you finished the test before 2 min 30. If you tap on the cross, the test is canceled.

## My Legs test



Do not attempt to perform My legs test (MLT) if you are not in a safe indoor environment, or if you feel unsure you can keep your balance during the test. Make sure to be well rested before starting the test and, if needed, take a break before starting.

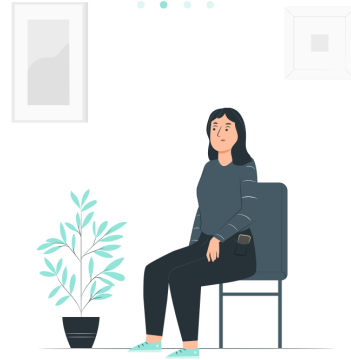


**My Legs**

• 1 minute

This test is an adaptation of the One-Minute Sit-to-Stand test. This test is designed to measure the muscle fatigability of your legs.

**Let's go!**

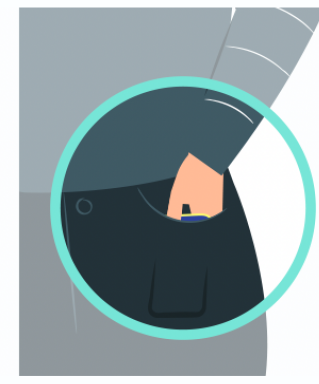


Place a stable chair without wheels against a wall and sit comfortably.

Please be mindful of your physical safety throughout the test.

If needed, you can use a chair with armrests to lean on.

**Next**




Store your smartphone completely inside your front pocket.

This test stops automatically after 1 minute.


If you need to, you can stop the test anytime.

**Next**

Test in progress



**00:30**

 **Hold to stop**

Before you start, you must answer the pop-up message to confirm that you feel safe to perform the test. If you do not feel safe, do not perform the test.

If you click on “not today”, the test is interrupted. If you click on “continue”, then a mandatory tutorial explaining the test conditions is presented.

You will be asked to place a stable chair without casters against a wall and to sit comfortably. Wear pants or other clothing with a front pocket.

Before starting the test, you must check all items in the checklist to confirm that :

- You have placed the chair against the wall,
- You feel well enough physically to perform the test,
- You understand the need to put your safety first,
- You understand that it is possible to quit the test at any time.

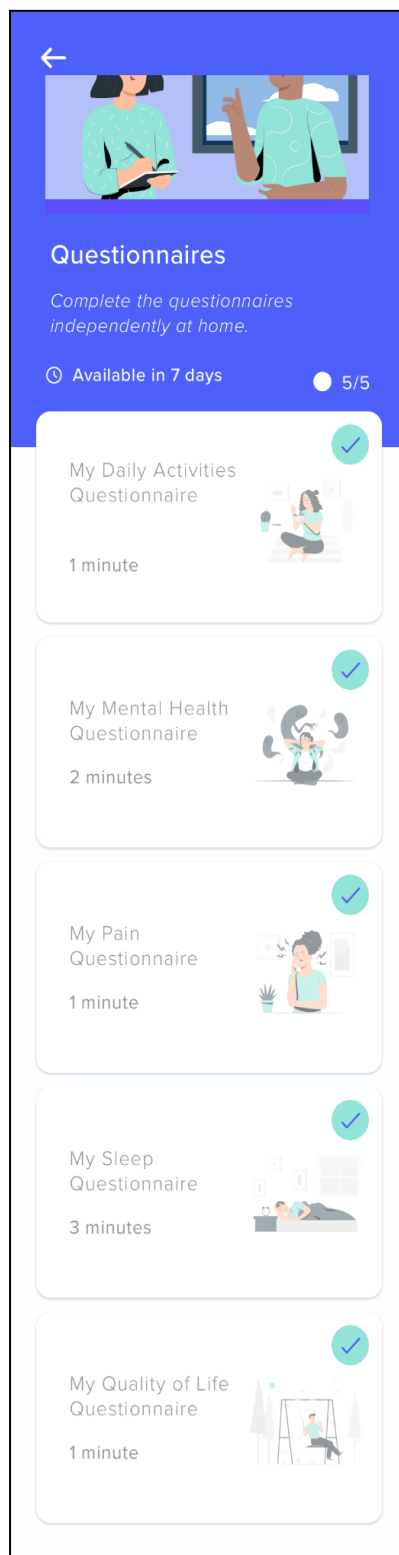
Adjust the volume of your smartphone in order to hear the audible instructions.

Choose the time needed to store your smartphone in your front pocket. The test begins after the beep.

You must stand up and sit down as many times as possible for one minute straight.

The test stops automatically after one minute. If you need to interrupt the test, you can stop it manually by holding the “Hold to stop” button. Then you will be asked why you finished the test before one min. If you tap on the cross, the test is canceled.

## Questionnaires



### “My Daily Activities”

Digitized version of the Myasthenia Gravis Activities of Daily Living (MG-ADL). It is a scale that measures MG symptoms and functional status.

To fill it in, you must answer each question and validate your answers at the end of the questionnaire by clicking on “validate”.

### “My Mental Health”

Digitized version of the Patient Health Questionnaire (PHQ-8). It is a multiple-choice questionnaire to assess depressive symptoms.

To fill it in, you must answer each question and validate your answers at the end of the questionnaire by clicking on “validate”.

### “My Pain”

Digitized version of the Pain Likert scale. The pain Likert scale is graduated vertically from 0 to 10, to assess pain intensity.

To fill it in, you must move the cursor to the answer you selected and then click on “validate”.

### “My Sleep”

Digitized version of the Insomnia Severity Index (ISI). It is a brief questionnaire to assess the severity of both nighttime and daytime components of insomnia.

To fill it in, you must answer each question and validate your answers at the end of the questionnaire by clicking on “validate”.

### My Quality of Life

Digitized version of the Myasthenia Gravis Quality of Life 15-item Scale revised (MG-QoL 15r). It is a questionnaire that aims to assess aspects of quality of life in MG.

To fill it in, you must answer each question and validate your answers at the end of the questionnaire by clicking on “validate” “My Daily Activities”.



## **Log out**

To log out of the application, go to the Help & Contact page from the navigation menu at the bottom of the screen (the "Help & Contact" button is at the far right of the menu).

Then, click on the "Logout" button at the bottom of the Help & Contact page and confirm the action by selecting "Confirm".

## **Saving, modifying and deleting personal data**



Always ensure that your smartphone is protected by a passcode or other secure means of identification

The Privacy Policy of ME&MG is available via the Information Notice accessible in the "Help & Contact" section of the mobile application.

## **Synchronization of data**

The data entered in the application and the acquisitions of the ME&MG tests are temporarily stored on the smartphone. Once synchronized, these data and acquisitions are stored in a certified health data server.

If the connection is adequate, the results are sent to the server at the end of each test. If there is data that could not be sent, disconnection triggers a message informing you that some data is still being sent and that you should only disconnect afterwards.

## **Modifying and deleting data**

All the information regarding ME&MG users' rights for the processing of their personal data is described in the Privacy Policy, which can be accessed via the Information Notice in the "Help & Contact" section of the mobile application.

Important Note:

Once submitted, the deletion of the account data is irreversible.

## **Maintenance of the application**

The application may require regular updates which are necessary to maintain the performances of ME&MG. When a new application version is available on the stores, you will be invited to perform the upgrade. The process to upgrade is the same as for any other mobile application.

## **Deletion of the application**

Important Note	Log out of the application first before any application deletion to trigger the upload of any remaining data of tests.
----------------	--

To uninstall the ME&MG application, perform the logout operation and then the standard operation to delete a mobile application on your smartphone :

- On an iPhone, make a long press on the application icon from the home view of the smartphone, then click on "Remove" (These instructions may differ depending on your smartphone's operating system).
- On an Android smartphone, go to the applications library and make a long press on the application icon, then click on "Uninstall". Alternatively, make a long press on the application icon from the home view of the smartphone, then click on "Information", then on "Uninstall" (These instructions may differ depending on your smartphone's operating system).

Directly uninstalling the application will not delete the account data.

## **Contact**

For more information, contact your study doctor:

Name: \_\_\_\_\_

Phone: \_\_\_\_\_

Email: \_\_\_\_\_