User Manual

Floodlight™ MS 2MWT

Software version: 1.1 | Document version: 3.0

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REF For iOS - 9342273001

For Android - 9342281001

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Floodlight™ MS 2MWT is a medical device.

Please contact Roche to request a printed version of this document.

Any serious incident that has occurred in relation to the device should be reported to Roche Customer Support and the competent authority where you reside. See the Support section for more information on how to contact Roche Customer Support.

Symbols used

The following table displays the symbols used in this User Manual.

	Product manufacturer: The name and address of the application's manufacturer.
	Reference Number: Indicates the Reference or Catalog number for this user manual.
	Warnings and Precautions: Highlights information that is critical for optimal performance of the system. May also indicate that loss of data or invalid data could occur if the precautions or instructions are not observed.

Contents

1 Overview

The Floodlight™ MS Two-Minute Walk Test (2MWT) activity measures any changes in your walking ability over time. This activity will help you collect data about the unique ways in which multiple sclerosis (MS) impacts you.

In this Section:

1.1 Intended Use

Intended Use

The Floodlight™ MS 2MWT is intended to provide an objective measurement of gait in patients 18 years of age and older with multiple sclerosis. The Floodlight™ MS 2MWT is used by patients in their home environment, and the results are reviewable by the patient and exported to a qualified healthcare professional (HCP) for review. The patient is not intended to take action on the device output without consultation of a qualified HCP.

The Floodlight™ MS 2MWT only provides objective measurements of gait and does not provide an interpretation or a clinical implication of the measurements. The Floodlight™ MS 2MWT should only be used as an adjunctive tool for measuring gait and is not intended to be used as a stand-alone diagnostic device nor to identify the presence or absence of clinical diagnoses.

1.2 Contraindications

None known.

1.3 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 patients. Overall, the potential benefit of the device far exceeds the probable known and foreseeable risks.

1.4 Warnings and Precautions

⚠️ Do the test as often as recommended by your provider. Please note that self-testing at home does not replace your regular visits with your provider.

Do not attempt to take the test if:

⚠️
- You cannot stand and keep your balance safely.
- You are not in a safe environment where you can walk for two minutes.
- You require use of a wheelchair for mobility.

⚠️ Do not try to interpret the data presented by the summary charts. Only your provider can interpret the data that you collect using the Floodlight™ MS 2MWT.

⚠️ Wear pants with front pockets or a running belt to put your phone in because failure to do so may result in inaccurate data. The measurement will also be inaccurate if you hold your phone in your hand.

⚠️ Increase the volume on your phone and turn off the Silent or Vibrate mode. This activity uses beeps and vibrations to tell you when to start and stop walking.

⚠️ Prior to beginning the activity, confirm that your surroundings are clear of obstructions that may cause you to trip or injure yourself during the activity.

2 2MWT Activity

The Two-Minute Walk activity measures any changes in your walking ability. This is achieved by monitoring your walking ability while you walk for 2 minutes.

In this Section:

2.1 Get Started

From the **2-Min Walk** screen, you can:

A. **Review Instructions** (on page 10) to see how to perform the activity.

B. **Start the Activity** (on page 12).

C. **Read the 2-Min Walk Product Label** (on page 12).

D. **Cancel the Activity** (on page 14).

Note: You cannot cancel the activity after you start.
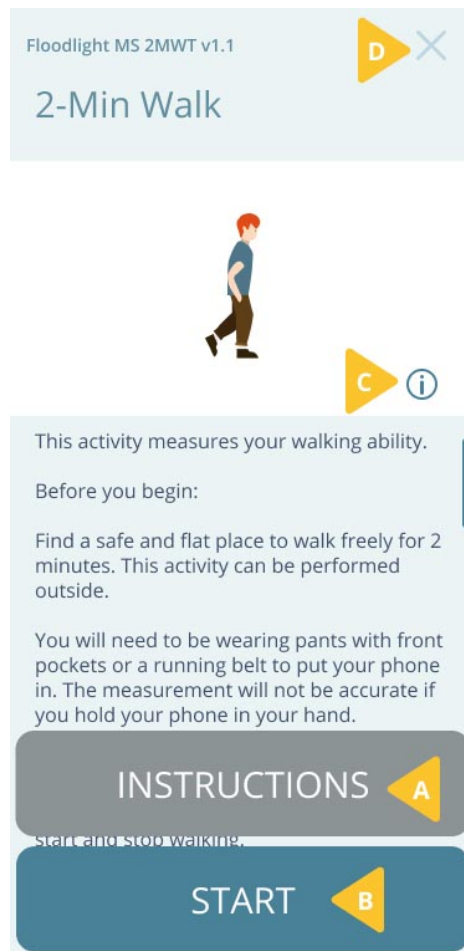
2.1.1 Review Instructions

You must follow the instructions when performing each activity. This ensures that the data collected for the activity is accurate. You can quickly review instructions from the starting screen for each activity. In addition, you can review this user manual to review more detailed

instructions for the activity.

The ***first five times*** you perform an activity, you will be prompted to review instructions when you tap **START**. After that, every time you press **START**, the activity will start without first displaying the instructions.

You can:

- Review the instructions on the screen
- Review this user manual

To review instructions for this activity:

1. From the activity start screen, tap **INSTRUCTIONS** to quickly review how to perform the activity.
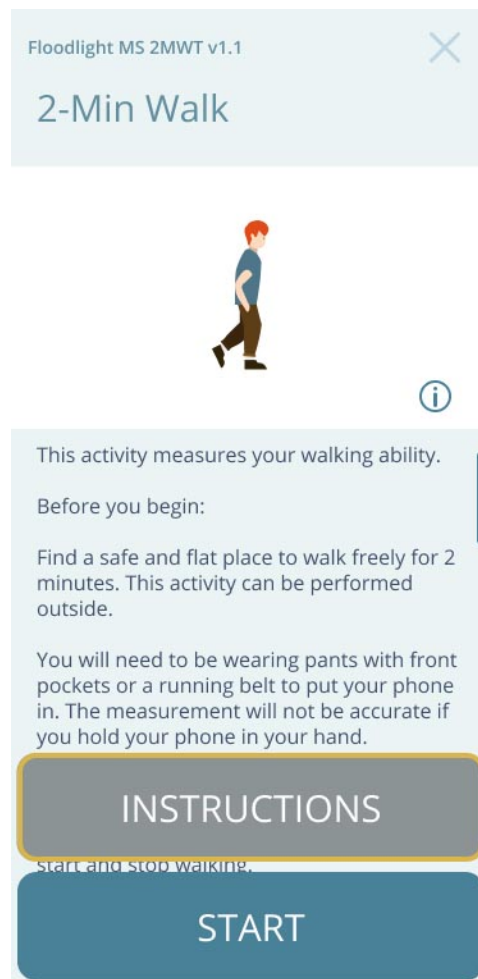
To review this user manual:

1. From the activity start screen, tap **INSTRUCTIONS**.
2. From the following screen, tap **User Manual** to see this user manual for the activity.
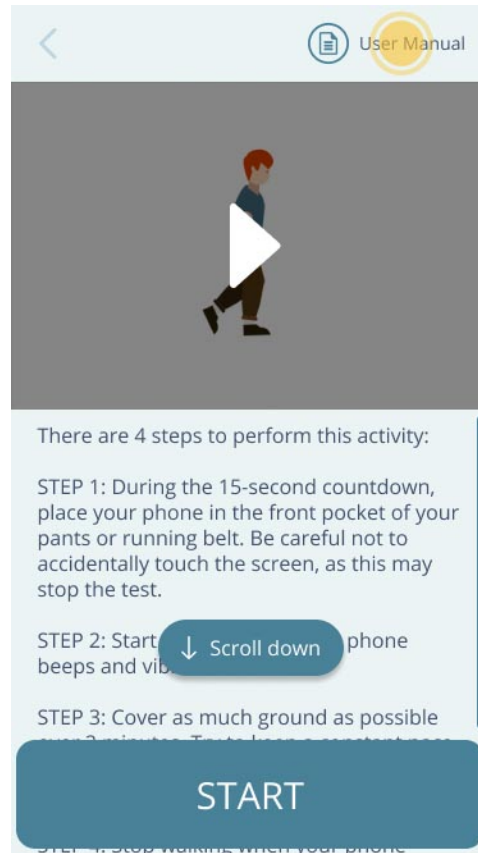
2.1.2 Start the Activity

Tip
It is best to complete your activities in an environment where you can focus, minimize interruptions, and walk safely.

When you are in a comfortable environment and ready to complete your activity, tap **START** to begin the activity.

Note: If you are not able to place the phone in the front pocket of your pants or a running belt, when prompted, tap **NO** to perform this activity at another time.

2.1.3 Read the 2-Min Walk Product Label

You can find out more information about the product in the product label.

To display the product label:

1. Tap the **Info** button ⓘ **(C)** on the **2-Min Walk** screen.
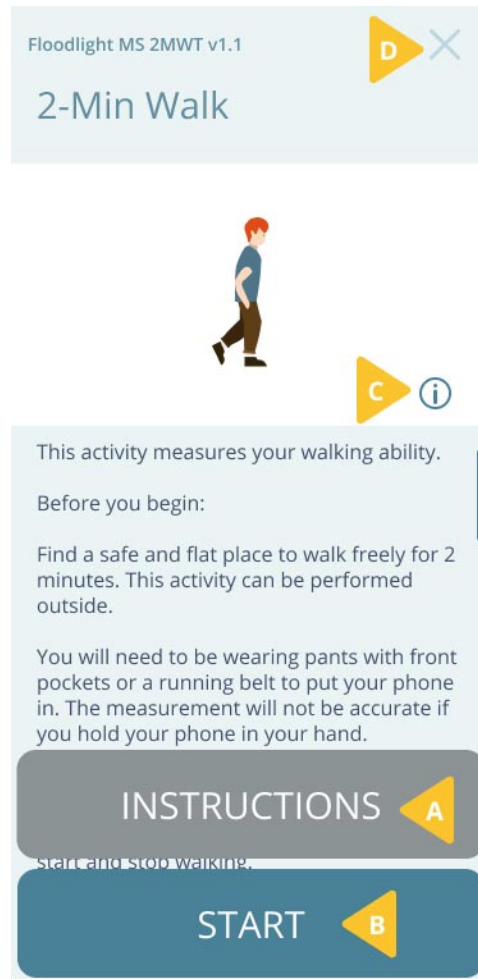
2. Tap the **Back** button ‹ to go back to the **2-Min Walk** screen.
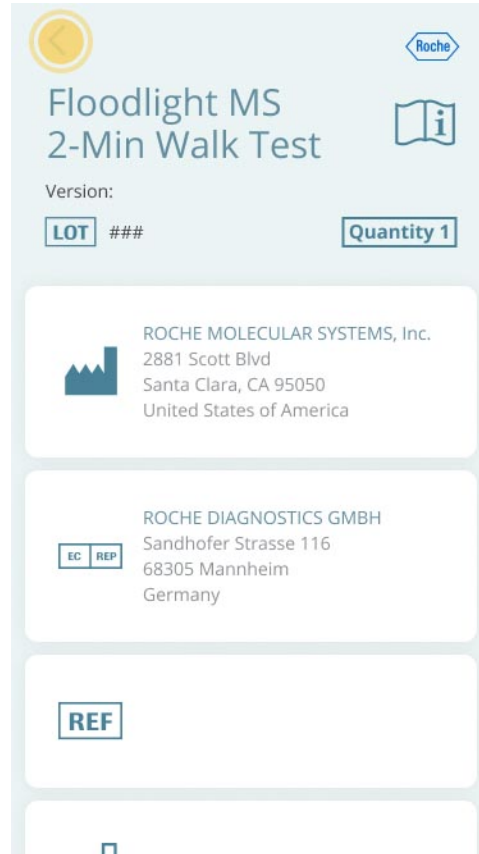
2.1.4 Cancel the Activity

You can cancel this activity before you tap **START**. If you cancel the activity, you will have an opportunity to come back later in the day and resume your routine from where you stopped.

The data for all activities that you have completed up until this point will be saved.

To cancel the activity:

1. Tap the **Close** button ✕ on the top-right corner.

2. Tap **YES** on the confirmation screen.
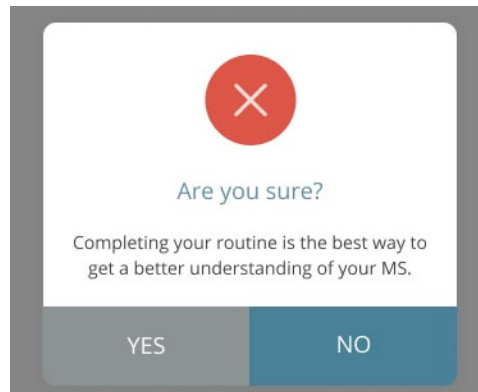
2.2 What will I see on my screen?

Reminder
Not placing the phone in the front pocket of your pants or a running belt will directly impact the accuracy of the data. For accurate measurements, please ensure the phone is placed in the front pocket of your pants or a running belt.

When the activity starts, you will be asked three safety questions:

A. Can you stand and keep your balance safely?
B. Are you in a safe environment to walk for 2 minutes?
C. Do you need a walking aid to stand safety for 2 minutes?

 If needed, use your walking aid to complete this activity.

If you answered YES for A & B, you will see:

(1) A reminder to place your phone in the front pocket of your pants
(2) A 15 second countdown

Note: If you are not able to place the phone in the front pocket of your pants or a running belt, when prompted, tap **NO** to perform this activity at another time.

2.3 How do I perform this activity?

Warning
Prior to beginning the activity, confirm that your surroundings are clear of obstructions that may cause you to trip or injure yourself during the activity.

To perform this activity:

1. Tap **START**.

2. Your phone screen will show a **15 second** countdown. During the 15-second countdown, place your phone in the front pocket of your pants or running belt. Be careful not to accidentally touch the screen, as this may stop the test.

3. When the countdown is almost done, your phone will vibrate and beep for the first time to indicate that you can start the activity. Your phone screen will now show a completion countdown for **120 seconds**.

4. Start walking. Cover as much ground as possible over 2 minutes. Try and keep a constant pace and avoid turning. Do not be concerned if you need to slow down or stop to rest.

5. Stop walking when your phone beeps and vibrates a second time, which indicates that

the activity is complete.

Things to remember:

While performing this activity, remember the following:

- Increase the volume on your phone and turn off the Silent or Vibrate mode. This activity uses beeps and vibrations to tell you when to start and stop walking.

- Ensure that you have enough distance to walk for **2 minutes**. For this activity, walk as straight as possible and avoid turning.

- Wear pants with front pockets or a running belt to put your phone in because failure to do so may result in inaccurate data. The measurement will also be inaccurate if you hold your phone in your hand.

- Do not be concerned if you need to slow down or stop to rest.

3 Troubleshoot

In this Section:

3.1 Why do I see the Instructions screens when I tap START?

The *first five times* you perform an activity, you will be prompted to review instructions when you tap **START**.

After this, you will be directed to the countdown screen when tapping the **START** button. You can always review instructions by tapping on the **INSTRUCTIONS** button when needed.

3.2 Can I cancel an activity after I start?

No, you **cannot** cancel an activity after you tap **START**.

3.3 How do I cancel an activity?

You can cancel an activity only before you start the activity. To cancel the activity, tap the **Cancel** button ✕ on the top-right corner of the activity start screen, as shown below:
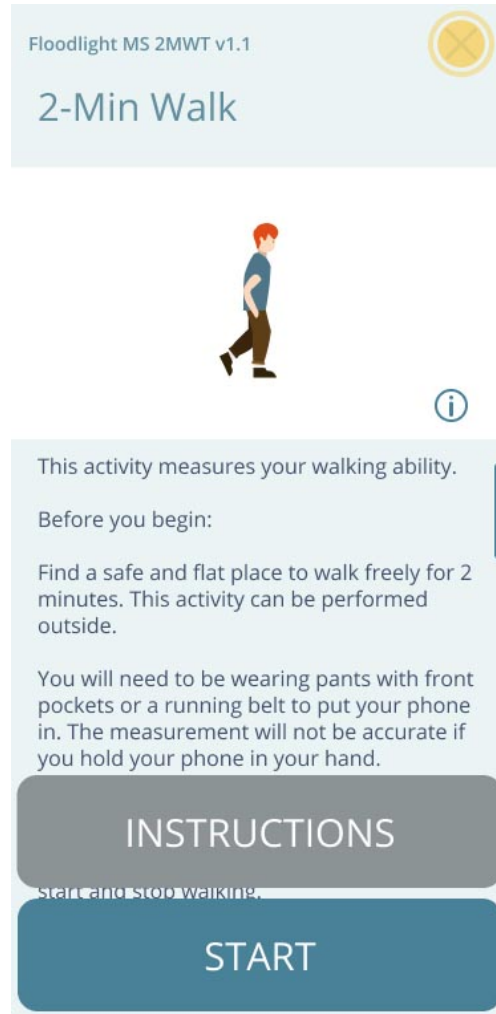
3.4 What if I get a call while performing the activity?

If you get a call while performing the activity, the activity is automatically stopped and no data is submitted. You can restart the activity at a later time.

3.5 What if I get interrupted or distracted by someone while performing this activity?

It is best to complete this activity in a location, or environment, where you can focus for better

accuracy. However, it is not a problem if you get interrupted, or distracted, as you perform this activity. You will have more opportunities to complete this test in the future. The data collected over an extended period of time is more relevant than a single data point.

3.6 Can I retake the activity?

You can retake the activity only if:

- You received a phone call during the activity.
- You canceled the activity earlier during the day.

4 Additional Information

In this Section:

4.1 Internet Connection

You can complete your activity in the Offline mode. However, you will need an internet connection (Wi-Fi or Cellular) to transfer your activity data to the server.

4.2 Adverse Events

An adverse event is defined as any untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal test results), related to the Floodlight MS test. While there are no known adverse events related to the test, potential adverse events include depression and/or suicidal behavior triggered by misinterpretation of test results, and physical injury if the test is performed in an unsafe environment. To mitigate these risks, note the following warnings: do not try to interpret the data presented by the summary charts (**Warnings and Precautions** section) and confirm that your surroundings are clear of obstructions that may cause you to trip or injure yourself during the activity (**How do I perform this activity?** section). If you experience or think you may have experienced an adverse event, please report this information (see the **Support** section for contact information).

4.3 Warranty

Please refer to the **No Warranties** section in the Floodlight™ MS Mobile Application Terms and Conditions.

5 Support

If you face any problem using the Floodlight™ MS Mobile Application, you can contact us at any time.

- **By Email:**
    - **Australia** – floodlightms_support.au@roche.com
    - **Austria** – floodlight_support.at@roche.com
    - **Finland** – floodlight_support.fi@roche.com
    - **Germany** – grenzach.support_floodlight@roche.com
    - **Italy** – italy.floodlightms@roche.com
    - **Portugal** – floodlightms_support.pt@roche.com
    - **Switzerland** – floodlightms_support.ch@roche.com
    - **United Kingdom** – uk.floodlightms_support@roche.com
    - **USA** – FloodlightMS_support.us@gene.com
- **By Phone:**
    - **Australia** – 1800 570 627
    - **Austria** – 0800 012 327
    - **Finland** – 800 02662
    - **Germany** – 0800 4268426
    - **Italy** – 800 098 389
    - **Portugal** – 800 910 428
    - **Switzerland** – 0800 35 66 35
    - **United Kingdom** – 0800 066 5557
    - **USA** – 888–455–8668 (888–ILLUMN8)

6 Appendix A

6.1 Open Source Software

6.1.1 Open source license notifications and licenses (For iOS)

The following table lists the Open Source software used as part of the Floodlight™ MS 2MWT for the iOS devices.

- Library=commons-csv-1.7.jar
  - Version=1.7
  - License=Apache 2.0
  - Link=https://www.apache.org/licenses/LICENSE-2.0
- Library=simpleclient_hotspot-0.9.0.jar
  - Version=0.9.0
  - License=Apache 2.0
  - Link=https://www.apache.org/licenses/LICENSE-2.0
- Library=simpleclient_dropwizard-0.9.0.jar
  - Version=0.9.0
  - License=Apache 2.0
  - Link=https://www.apache.org/licenses/LICENSE-2.0
- Library=commons-lang3-3.11.jar
  - Version=3.11
  - License=Apache 2.0
  - Link=https://www.apache.org/licenses/LICENSE-2.0
- Library=simpleclient_vertx-0.9.0.jar
  - Version=0.9.0
  - License=Apache 2.0
  - Link=https://www.apache.org/licenses/LICENSE-2.0
- Library=commons-math3-3.6.1.jar
  - Version=3.6.1
  - License=Apache 2.0, BSD 3

- Link=https://www.apache.org/licenses/LICENSE-2.0
- https://opensource.org/licenses/BSD-3-Clause
- Library=commons-math3-3.6.1.jar
  - Version=3.6.1
  - License=Apache 2.0, BSD 3
  - Link=https://www.apache.org/licenses/LICENSE-2.0
  - https://opensource.org/licenses/BSD-3-Clause
- Library=vertx-core-3.9.4.jar
  - Version=3.9.4
  - License=Apache 2.0, Eclipse 2.0
  - Link=https://www.apache.org/licenses/LICENSE-2.0
  - https://www.eclipse.org/legal/epl-2.0/
- Library=logback-classic-1.2.3.jar
  - Version=1.2.3
  - License=Eclipse 1.0, LGPL 2.1
  - Link=https://opensource.org/licenses/EPL-1.0
  - https://www.gnu.org/licenses/old-licenses/lgpl-2.1.en.html
- Library=json-20190722.jar
  - Version=20190722
  - License=MIT
  - Link=https://opensource.org/licenses/MIT
- Library=lombok-1.18.16.jar
  - Version=1.18.16
  - License=MIT
  - Link=https://opensource.org/licenses/MIT
- Library=jquery-3.5.1.min.js
  - Version=3.5.1
  - License=MIT
  - Link=https://opensource.org/licenses/MIT

6.1.2 Open source license notifications and licenses (For Android)

The following table lists the Open Source software used as part of the Floodlight™ MS 2MWT for the Android devices.

- Library=commons-csv-1.7.jar
  - Version=1.7
  - License=Apache 2.0
  - Link=https://www.apache.org/licenses/LICENSE-2.0
- Library=simpleclient_hotspot-0.9.0.jar
  - Version=0.9.0
  - License=Apache 2.0
  - Link=https://www.apache.org/licenses/LICENSE-2.0
- Library=simpleclient_dropwizard-0.9.0.jar
  - Version=0.9.0
  - License=Apache 2.0
  - Link=https://www.apache.org/licenses/LICENSE-2.0
- Library=commons-lang3-3.11.jar
  - Version=3.11
  - License=Apache 2.0
  - Link=https://www.apache.org/licenses/LICENSE-2.0
- Library=simpleclient_vertx-0.9.0.jar
  - Version=0.9.0
  - License=Apache 2.0
  - Link=https://www.apache.org/licenses/LICENSE-2.0
- Library=commons-math3-3.6.1.jar
  - Version=3.6.1
  - License=Apache 2.0, BSD 3
  - Link=https://www.apache.org/licenses/LICENSE-2.0
  - https://opensource.org/licenses/BSD-3-Clause
- Library=commons-math3-3.6.1.jar
  - Version=3.6.1
  - License=Apache 2.0, BSD 3
  - Link=https://www.apache.org/licenses/LICENSE-2.0
  - https://opensource.org/licenses/BSD-3-Clause
- Library=vertx-core-3.9.4.jar
  - Version=3.9.4

- License=Apache 2.0, Eclipse 2.0
  - Link=https://www.apache.org/licenses/LICENSE-2.0
  - https://www.eclipse.org/legal/epl-2.0/
- Library=logback-classic-1.2.3.jar
  - Version=1.2.3
  - License=Eclipse 1.0, LGPL 2.1
  - Link=https://opensource.org/licenses/EPL-1.0
  - https://www.gnu.org/licenses/old-licenses/lgpl-2.1.en.html
- Library=json-20190722.jar
  - Version=20190722
  - License=MIT
  - Link=https://opensource.org/licenses/MIT
- Library=lombok-1.18.16.jar
  - Version=1.18.16
  - License=MIT
  - Link=https://opensource.org/licenses/MIT
- Library=jquery-3.5.1.min.js
  - Version=3.5.1
  - License=MIT
  - Link=https://opensource.org/licenses/MIT