User Manual

Floodlight™ MS Draw a Shape Test

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Floodlight™ MS Draw a Shape Test is a medical device.

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To the maximum extent permitted by law, you shall not decompile and/or reverse engineer the software or any part thereof.

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.

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1 Overview

Welcome to the Floodlight™ MS Draw a Shape Test User Manual. This User Manual is applicable to both the iOS and Android platforms and uses the Floodlight™ MS Mobile Application as an example of a supported application that includes the Floodlight™ MS Draw a Shape Test.

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1.1 What is the Floodlight™ MS Draw a Shape Test?

The Floodlight™ MS Draw a Shape Test is a medical device that measures your hand function. This activity will help you, as a person living with multiple sclerosis (MS), collect and review hand function data over time.

1.2 Intended Use

The Floodlight™ MS Draw a Shape Test is intended to provide an objective measurement of hand function in patients 18 years of age and older with multiple sclerosis. The Floodlight™ MS Draw a Shape Test 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 Draw a Shape Test only provides objective measurements of hand function and does not provide an interpretation or a clinical implication of the measurements. The Floodlight™ MS Draw a Shape Test should only be used as an adjunctive tool for measuring hand function and is not intended to be used as a stand-alone diagnostic device nor to identify the presence or absence of clinical diagnoses.

1.3 Performance

The Floodlight™ MS Draw a Shape Test precision is expected to be 95% or higher.

Precision is how close values will be from each other if you repeat the test multiple times with the exact same input. Precision can be impacted by many factors including the accuracy and precision of the sensors available in your device.

For a list of unsupported phones, see **Unsupported Phones** (on page 11) and for the supported operating systems (OS), see **Minimum Requirements – Software** (on page 10)

1.4 Contraindications

None known.

1.5 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.

1.6 Warnings and Precautions

Do the activity 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 try to interpret the data presented by the summary charts. Only your provider can interpret the data that you collect using the Floodlight™ MS Draw a Shape Test.

Place your phone on a flat surface. Not placing the phone on a flat surface will change the accuracy of your data.

Use only your ***index finger*** to perform the activity and do not lift your finger from the screen before you complete tracing a shape.

Use the correct hand, as indicated on the **Instructions** screen or **Draw a Shape** screen, to perform the activity.

1.7 Security

To ensure protected information is as secure as possible, take the following precautions:

- Select a strong password that cannot be easily guessed by an intruder.
- Do not share your password.
- Do not use a jail-broken device.

1.8 Updates related to Safety

None.

1.9 Training Requirements

You do not need any specific training to use this medical device. You are simply required to know how to complete basic operations on your phone, such as download and start a mobile app.

2 Download and Install

The Floodlight™ MS Draw a Shape Test is a medical device and is available as part of several supported applications. One of the supported applications used as an example in this user manual is the Floodlight™ MS Mobile Application. In this user manual, the instructions for downloading, installing, setting up, and using the Floodlight™ MS Draw a Shape Test medical device are based on how the device works within the Floodlight™ MS Mobile Application.

Note

If you are not using the Floodlight™ MS Mobile Application to access the Floodlight™ MS Draw a Shape Test medical device, **sections 2.1 through 2.4 of this chapter** do not apply to you. To download, install, and set up the supported mobile app, please consult the instructions for the supported mobile app that you are using to access Floodlight™ MS Draw a Shape Test.

To use the Floodlight™ MS Draw a Shape Test medical device, you need an application, such as the Floodlight™ MS Mobile Application, which is compatible with both iOS and Android phones. If you install the Floodlight™ MS Mobile Application, it will also install the Floodlight Software Development Kit (SDK). In this case, no additional system requirements or configurations are required.

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2.1 For iOS or Apple Phones

Complete the following steps on your iOS phone:

1. Open the **App Store**.
2. Search for Floodlight™ MS.
3. Tap the icon to see the details and tap **Get**.
4. Tap **Install** to start the installation process.
5. You may be asked for your **App Store** password.

After you enter the password, the Floodlight™ MS Mobile Application will begin to download and install.

2.2 For Android Phones

Complete the following steps on your Android phone:

1. Open the **Google Play Store** on your phone.
2. Search for Floodlight™ MS.
3. Tap the icon to see the details.
4. Tap **Install** to start the installation process.
5. You will be asked to accept the download conditions by Google.

After you accept, the Floodlight™ MS Mobile Application will begin to download and install.

2.3 Minimum Requirements – Software

The Floodlight™ MS Mobile Application requires the following:

- iOS version 12.x to 14.x
- Android version 8 to 11

2.4 Minimum Requirements – Hardware

The minimum hardware requirements for Floodlight™ MS Mobile Application are:

For iOS Phones:

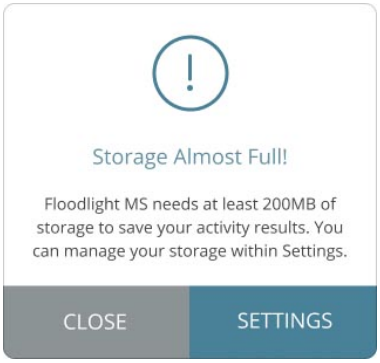
- iPhone SE 2nd generation or newer

For Android Phones:

- **Minimum Screen Dimensions:**110mm x 56mm (4.33 x 2.20 in)
- The following sensors are required:
  - Magnetometer
  - Accelerometer
  - Gyroscope

In addition, the Floodlight™ MS Mobile Application requires a minimum of **450MB** of available storage space on your phone. This ensures that if you complete an activity in the offline mode, your activity data is still saved on the phone.

If your phone does not have at least **200MB** of available storage space, the app displays the following message:



Once you have the required storage available on your phone, you can continue using the Floodlight™ MS Mobile Application.

2.5 Unsupported Phones

The Floodlight™ MS Draw a Shape Test is not supported on the following phones:

Brand	Model Name
Alcatel	7
Alcatel	Tetra
Alcatel	ZIP LTE

Brand	Model Name
Huawei	P20 Lite
Huawei	P Smart (2018)
Huawei	Mate 10 Lite
Huawei	Y6 (2018)
Huawei	P10
LG Electronics	Aristo 2
LG Electronics	K20 Plus
LG Electronics	Risio 3
LG Electronics	Tribute Dynasty
LG Electronics	Rebel 4
LG Electronics	Stylo 3 Plus
Motorola	Moto E5 Play
Motorola	Moto E4
Samsung	Galaxy J6

3 Logout and Uninstall

The Floodlight™ MS Draw a Shape Test is a medical device and is available as part of several supported applications. One of the supported applications used as an example in this user manual is the Floodlight™ MS Mobile Application. In this user manual, the instructions for uninstalling and logging out of Floodlight™ MS Draw a Shape Test medical device are based on how the device works within the Floodlight™ MS Mobile Application.

Note

If you are not using the Floodlight™ MS Mobile Application to access the Floodlight™ MS Draw a Shape Test medical device, **this chapter does not apply to you**. To uninstall and log out of the supported mobile app, please consult the instructions for the supported mobile app that you are using to access Floodlight™ MS Draw a Shape Test.

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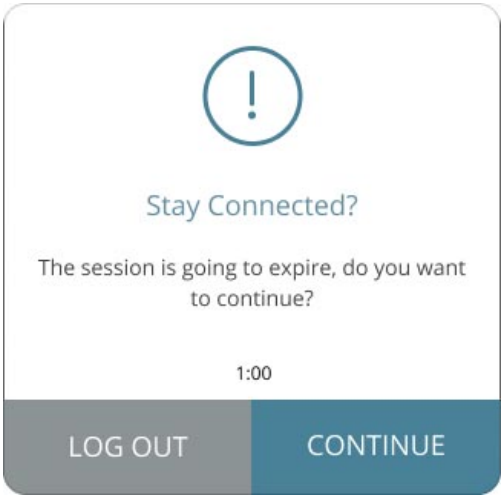
3.1 Logout of the Floodlight™ MS Mobile Application

For security reasons, you are automatically logged out of your Floodlight™ MS Mobile Application account after **30 minutes** of inactivity.

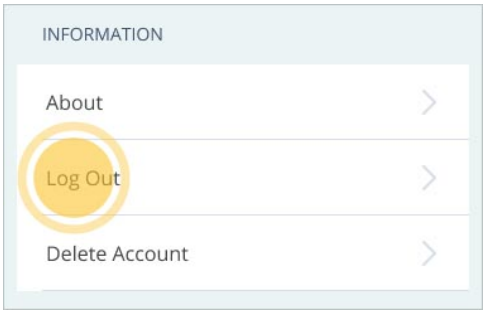
The Floodlight™ MS Mobile Application displays the following warning message **five minutes** before your session is about to expire. From this message screen, you can tap **CONTINUE** to continue your session or **LOGOUT** to log out of your session.



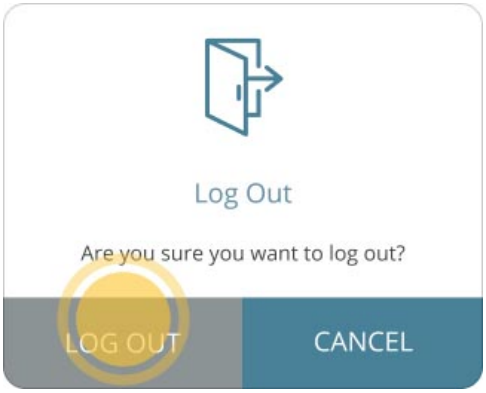
You can also log out from the **Settings** screen.

To log out:

1. Tap the **Settings** icon on the bottom right of your screen.
2. On the **Settings** screen, scroll to the bottom and tap **Logout**.



3. On the confirmation screen, tap **LOGOUT**.



Note: You can also tap **CANCEL** to continue using the Floodlight™ MS Mobile Application.

3.2 Delete your Account

Uninstalling the Floodlight™ MS Mobile Application does not delete your account or your data. If you do not want to use the Floodlight™ MS Mobile Application anymore and wish to delete your account and all the data associated with your account, you can use the **Delete Account** option from the **Settings** screen.

Note

Your Floodlight™ MS Mobile Application account can only be deleted from within the Floodlight™ MS Mobile Application. Therefore, perform the following steps before you uninstall the Floodlight™ MS Mobile Application. For more information on uninstalling the app, see **Uninstall** (on page 16)

To delete your account:

1. Tap the **Settings** icon on the bottom right of your screen.
2. On the **Settings** screen, tap **Delete Account**.
3. On the **Delete Account?** screen, type **DELETE** in the text field.

The text entry is case-sensitive.

4. Tap **DELETE ALL**.
5. Tap **OKAY**.

3.3 Uninstall

This section includes instructions on how to uninstall the Floodlight™ MS Mobile Application from an iOS phone or an Android phone. You can perform these steps if you do not want to use the Floodlight™ MS Mobile Application anymore.

Note

Uninstalling the Floodlight™ MS Mobile Application does not delete your account or your data. If you do not want to use the Floodlight™ MS Mobile Application anymore and wish to delete your account and all the data associated with your account, you can use the **Delete Account** option from the **Settings** screen before you uninstall the app. For more information, see **Delete your Account** (on page 15).

3.3.1 For iOS or Apple Phones

Complete the following steps on your iOS phone to uninstall the Floodlight™ MS Mobile Application:

1. Locate the Floodlight™ MS Mobile Application on your home screen.
2. Tap and hold the Floodlight™ MS Mobile Application icon to open a quick actions menu.
3. Tap **Remove App**.
4. Tap **Delete App** to delete it from your phone.

3.3.2 For Android Phones

Complete the following steps on your Android phone to uninstall the Floodlight™ MS Mobile Application:

1. Open the **Google Play Store**.
2. Tap the **My apps & games** menu.
3. Tap the Floodlight™ MS Mobile Application.
4. Tap **Uninstall**.

4 Draw a Shape Activity

This activity measures your hand function. This is achieved by:

- Using your index finger to join the dots along a shape on your screen
- Measuring how fast and accurately you join the dots along each shape

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4.1 Get Started

From the **Draw a Shape** start screen, you can:

A. Check the correct hand to use for the activity.
B. **Review Instructions** (on page 18) to see how to perform the activity.
C. **Start the Activity** (on page 20)
D. **Read the Draw a Shape Product Label** (on page 21).
E. **Cancel the Activity** (on page 23).

Note: You cannot cancel an activity after you start.

4.1.1 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.

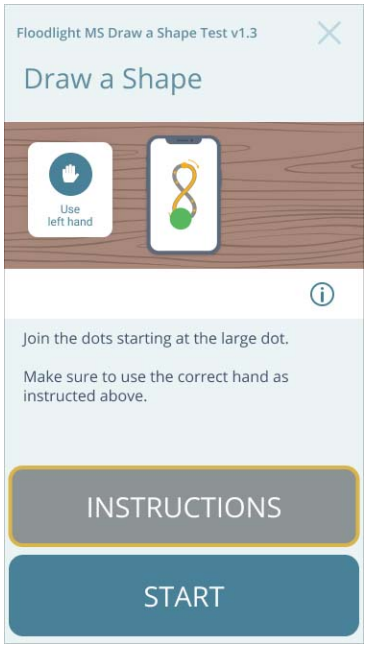
The ***first five times*** you perform an activity, you will be prompted to review instructions when you tap **START**. After that, every time you press **START**, the activity will start without first displaying the instructions.

You can:

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

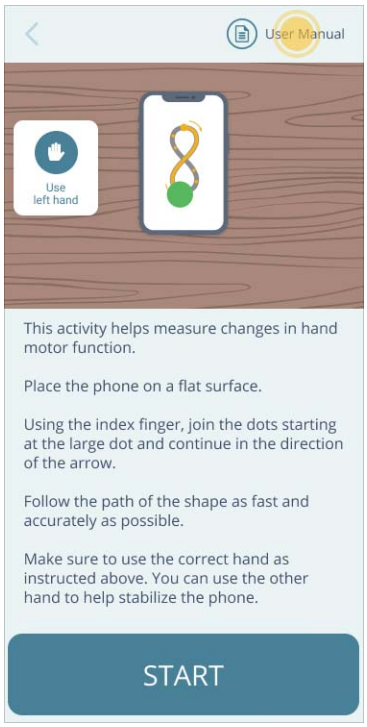
To review instructions for this activity:

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.



4.1.2 Start the Activity

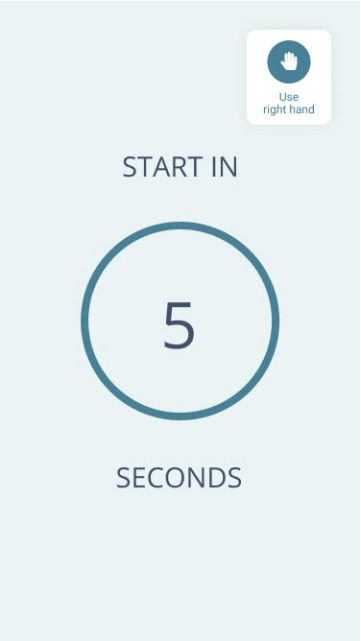
Tip

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

When you are in a comfortable environment and ready to complete your activity:

1. Place your phone on a flat surface such as a table or a desk.
2. Tap **START** to begin the activity.

3. A **5 second** countdown screen will appear. Make sure to use the correct hand to complete this activity.



Relax and get ready to complete the activity once the countdown runs out.

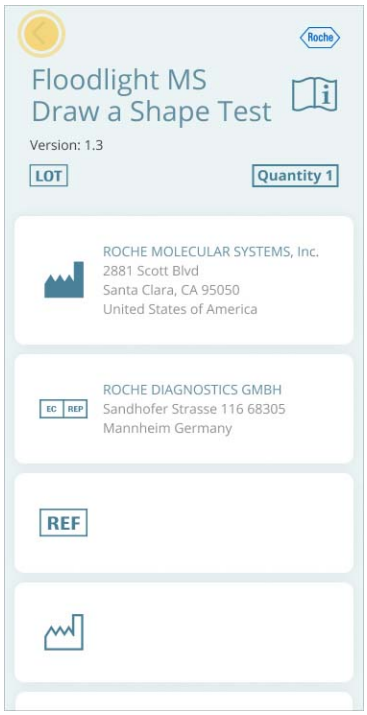
4.1.3 Read the Draw a Shape Product Label

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

To display the product label:

1. Tap the **Info** button ⓘ **(D)** on the **Draw a Shape** screen.

2. Tap the **Back** button < to go back to the **Draw a Shape** screen.



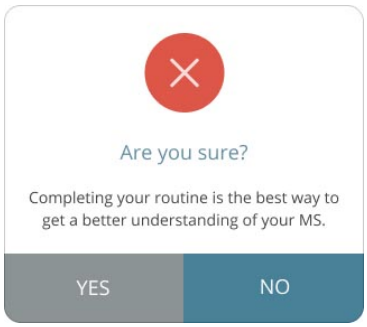
4.1.4 Cancel the Activity

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.

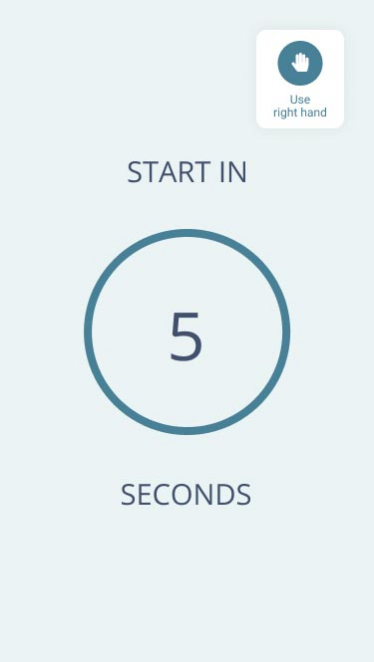
To cancel the activity:

1. Tap the **Cancel** button ✕ on the top-right corner.
2. Tap **YES** on the confirmation screen.



4.2 What will I see on my screen?

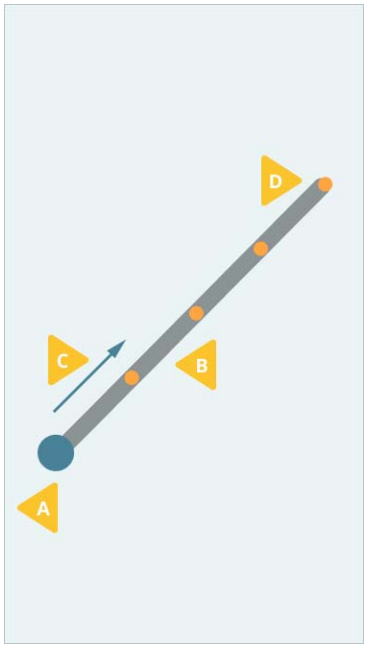
When the activity starts, you will first see a counter for 5 seconds to allow you to get ready. This screen will also remind you that you have to use a specific hand to perform this activity.



Next, you will see:

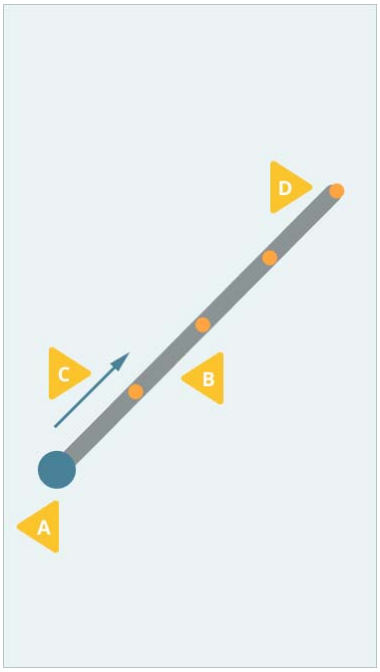
A. A *large dot* that is your starting point.
B. The *shape* that you will trace to connect the dots.
C. An *arrow* to show the direction in which you will connect the dots.

D. Several *smaller dots* that you will connect along the shape.



4.3 How do I perform this activity?

Start at the **large dot (A)**, trace along the **shape (B)** in the direction of the **arrow (C)** while connecting the **dots (D)** along the shape.



To complete this activity, connect the dots for all the shapes as quickly and as accurately as possible. This activity includes the following shapes:

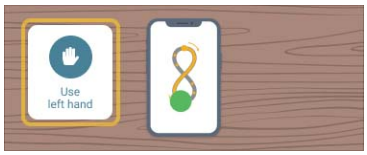
- a line
- a square
- a circle
- a figure 8
- a spiral

You will trace each shape two times before you see the next shape. The activity automatically stops after you trace the last shape.

Things to remember:

While performing the activity, remember to:

- Place your phone on a flat surface. Not placing the phone on a flat surface will change the accuracy of your data.
- Use the correct hand to perform the activity. This is displayed on the screen when you start the activity, as shown below:



- Use only your ***index finger*** of the ***correct hand*** to connect the dots and do not lift your finger from the screen before you complete tracing a shape.

5 Troubleshoot

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5.1 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**.

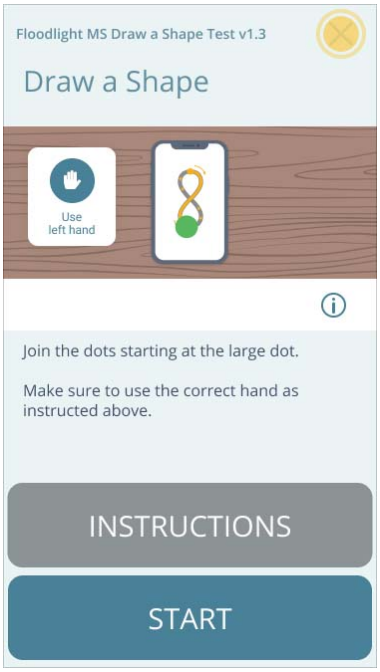
After this, you will be directed to the countdown screen when tapping the **START** button. You can always review instructions by tapping on the **INSTRUCTIONS** button when needed.

5.2 Can I cancel an activity after I start?

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

5.3 How do I cancel an activity?

You can cancel an activity only before you start it. To cancel the activity, tap the **Cancel** button ✕ on the top-right corner of the activity start screen, as shown below:



5.4 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.

5.5 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 activity in the future. The data collected over an extended period of time is more relevant than a single data point.

5.6 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.

6 Additional Information

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6.1 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.

6.2 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 this Floodlight™ MS activity. While there are no known adverse events related to the activities, potential adverse events include depression and/or suicidal behavior triggered by misinterpretation of test results. To mitigate this risk note the warning not to try to interpret the data presented by the summary charts (**Warnings and Precautions** section). If you experience or think you may have experienced an adverse event, please report this information (see section **Support** for contact information).

6.3 Warranty

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

7 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
  - **Brazil** - floodlightms_support.br@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
  - **Spain** - FloodlightMS_support.es@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
  - **Brazil** - 0800 555 2125
  - **Finland** - 800 02662
  - **Germany** - 0800 4268426
  - **Italy** - 800 098 389
  - **Portugal** - 800 910 428
  - **Spain** - 0900 922 301
  - **Switzerland** - 0800 35 66 35
  - **United Kingdom** - 0800 066 5557
  - **USA** - 888-455-8668 (888-ILLUMN8)

8 Appendix A

8.1 Open Source Software

8.1.1 Open source license notifications and licenses (For iOS)

The following table lists the Open Source software used as part of the Floodlight™ MS Draw a Shape Test 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

8.1.2 Open source license notifications and licenses (For Android)

The following table lists the Open Source software used as part of the Floodlight™ MS Draw a Shape Test 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