## User Manual

# Floodlight MS Pinching Test

**Software version: 1.1 | Document version 1.0**

Material Numbers: For iOS - 9341862001; For Android - 9341889001

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CE

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Floodlight MS Pinching Test is a medical device.

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

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# 1 Overview

You can complete this activity to measure your hand function over time. This activity will help you collect data about the unique ways in which multiple sclerosis (MS) impacts you.

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## 1.1 Intended Use

The Floodlight MS Pinching 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 Pinching 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 Pinching Test only provides objective measurements of hand function and does not provide an interpretation or a clinical implication of the measurements. The Floodlight MS Pinching 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.

## 1.2 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 try to interpret the data presented by the summary charts. Only your provider can interpret the data that you collect using the Floodlight MS Pinching 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 thumb and index finger to perform the activity. Start with your thumb and index finger wide apart to pinch the tomato.

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

# 2 Pinch a Tomato Activity

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

- Asking you to use your thumb and index finger to pinch the image of a tomato on your screen
- Measuring how many tomatoes you pinched in the given amount of time

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## 2.1 Get Started

From the **Pinch a Tomato** start screen, you can:

A. Check the correct hand to use for the activity.
B. **Start the Activity** (on page 8)
C. **Review Instructions** (on page 9) to see how to perform the activity.
D. **Read the Pinch a Tomato Product Label** (on page 1).
E. **Cancel the Activity** (on page 12).

**Note:** You cannot cancel the activity after you start.

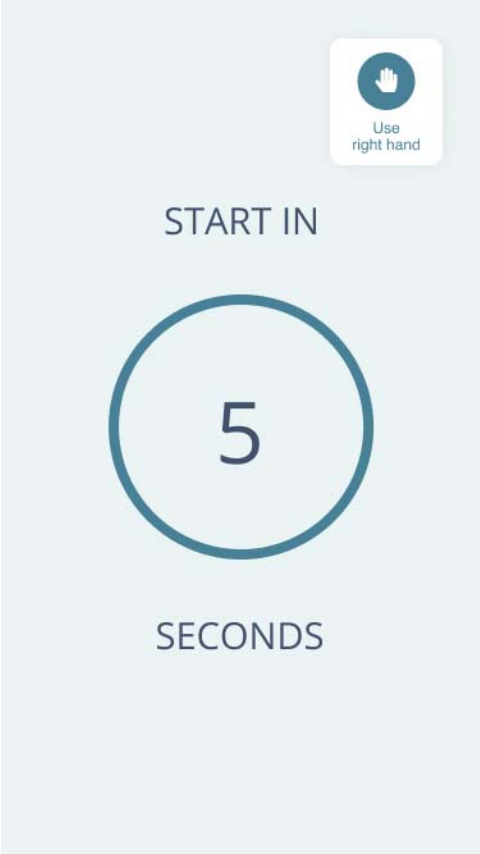
### 2.1.1 Start the Activity

**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.

### 2.1.2 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.

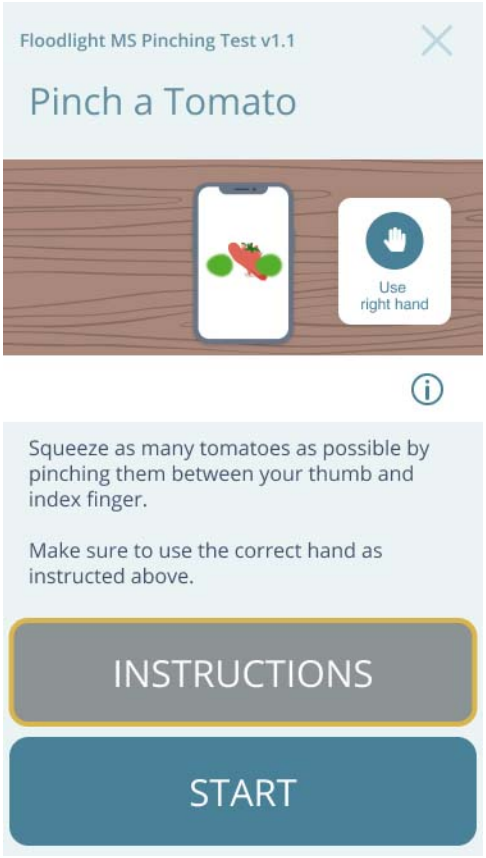
The ***first five times*** you perform an activity, you will be prompted to review instructions when you tap **START**. After that, every time you press **START**, the activity will start without first displaying the instructions.

You can:

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

**To review instructions for this activity:**

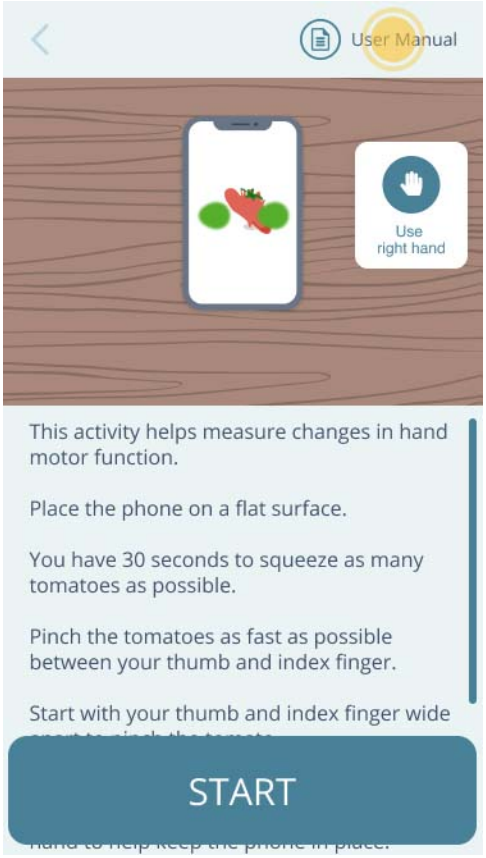
1. From the activity start screen, tap **INSTRUCTIONS** to quickly review how to perform the activity.




**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.



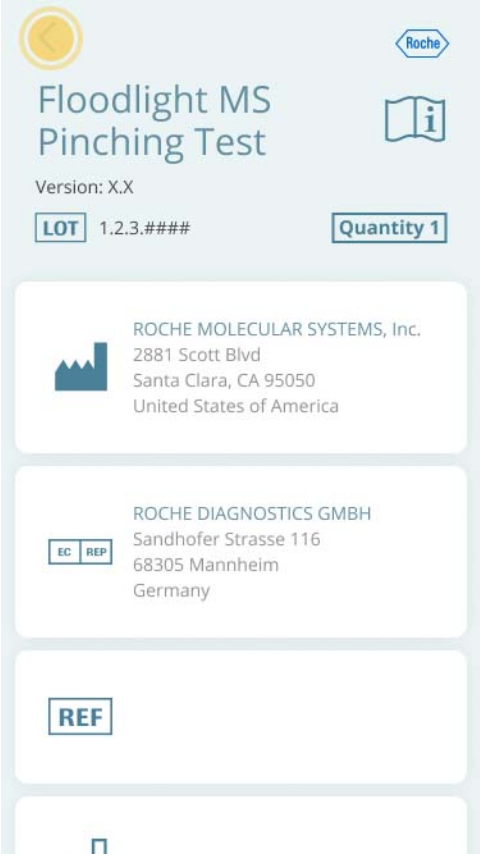

### 2.1.3 Read the Pinch a Tomato Product Label

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

**To display the product label:**

1. Tap the **Info** button ⓘ on the **Pinch a Tomato** start screen.

2. Tap the **Back** button to go back to the **Pinch a Tomato** start screen.




## 2.1.4 Cancel the Activity

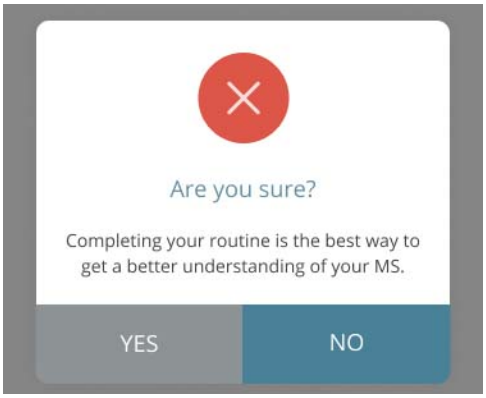
You can cancel this activity before you tap **START**. If you cancel the activity, you will have an opportunity to come back later in the day and resume your routine from where you stopped.

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

### To cancel the activity:

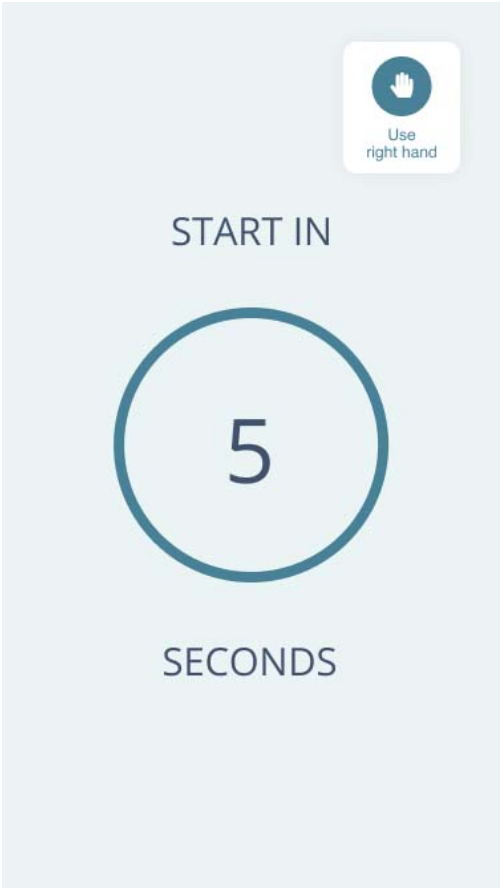
1. Tap the **Cancel** button on the top-right corner.

2. Tap **YES** on the confirmation screen.




## 2.2 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 the image of a tomato.

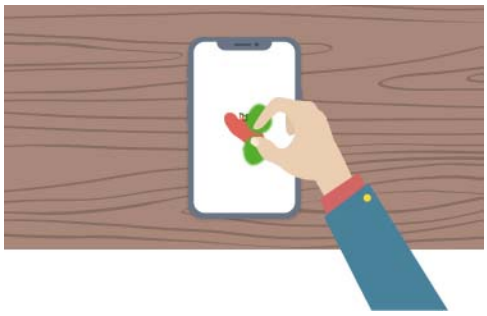
Once you have successfully pinched a tomato, it will disappear and a new tomato will appear at a different location. Keep pinching as many tomatoes as you can until the activity ends after **30 seconds**.

## 2.3 How do I perform this activity?

To complete this activity, squeeze as many tomatoes as possible by pinching them between your thumb and index finger.

**To complete this activity:**

1. Make sure to use the correct hand as instructed on the screen. You can use the other hand to help keep the phone in place.
2. Start with your thumb and index finger wide apart to pinch a tomato.



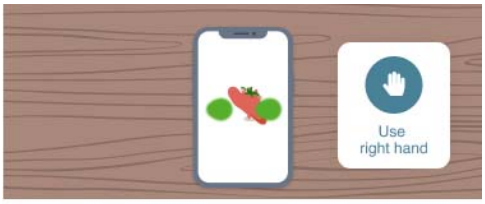
3. When the tomato pops a new image of a tomato appears at a different location on the screen.
4. To complete this activity, pinch as many tomatoes as possible in the next **30 seconds**.

The activity automatically stops, when the time is up.

**Things to remember:**

Keep in mind the following instructions in order to successfully pinch a tomato:

- Use only the thumb and index finger to pinch the tomato. Be careful not to touch the screen with another part of your hand.
- Start the pinch with your thumb and index finger wide apart (a little over 1 inch apart).
- Try to keep the tomato centered between your thumb and index finger while you pinch.
- Only move your thumb and index finger toward each other.
- Place your phone on a flat surface. Not placing the phone on a flat surface will effect 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:



# 3 Troubleshoot

**In this Section:**

3.1 Why do I see the Instructions screens when I tap START? ..... 17

3.2 Can I cancel an activity after I start? ..... 17

3.3 How do I cancel an activity? ..... 17

3.4 What if I get a call while performing the activity? ..... 18

3.5 What if I get interrupted or distracted by someone while performing this activity? ..... 18

3.6 Can I retake the activity? ..... 18

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## 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**.

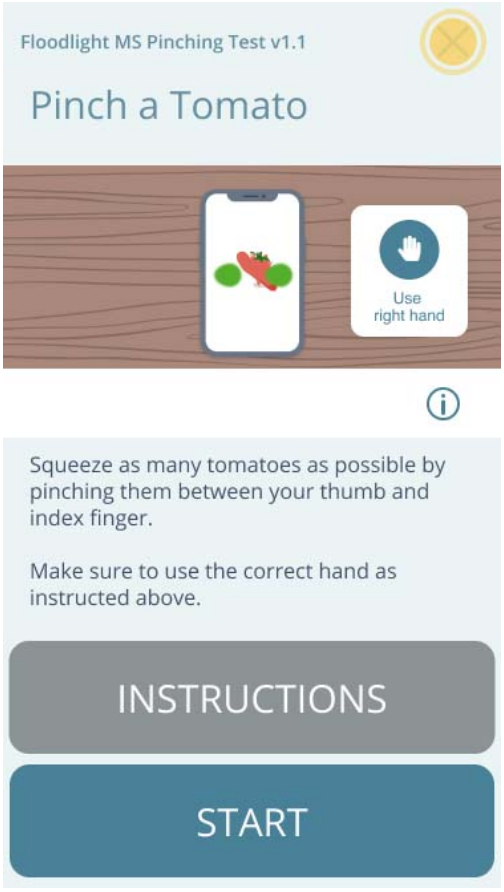
After this, you will be directed to the countdown screen when tapping the **START** button. You can always review instructions by tapping on the **INSTRUCTIONS** button when needed.

## 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 if:

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

## 3.7 Why am I not able to squish a tomato every time I pinch?

Please be patient. It may take some time for you to get comfortable with the activity. You may still not be able to pinch some tomatoes but this is to be expected.

Keep in mind the following instructions in order to successfully pinch a tomato:

- Use the correct hand to perform the activity.
- Use only the thumb and index finger to pinch the tomato. Be careful not to touch the screen with another part of your hand.
- Start the pinch with your thumb and index finger wide apart (a little over 1 inch apart).
- Try to keep the tomato centered between your thumb and index finger while you pinch.
- Only move your thumb and index finger toward each other.
- Place your phone on a flat surface. Not placing the phone on a flat surface will effect the accuracy of your data.

# 4 Additional Information

**In this Section:**

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## 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 activity. 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. 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).

## 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:**
  - **Finland** - floodlight_support.fi@roche.com
  - **Germany** - grenzach.support_floodlight@roche.com
  - **Italy** - italy.floodlightms@roche.com
  - **Portugal** - floodlightms_support.pt@roche.com
  - **USA** - FloodlightMS_support.us@gene.com
- **By Phone:**
  - **Finland** - 080002662
  - **Germany** - 0800 4268426
  - **Italy** - 800 098 389
  - **Portugal** - 351 800 910 428
  - **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 Pinching Test for the iOS devices.

- Library=vertx-pg-client-3.8.4.jar
  - Version=3.8.4
  - 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-math3-3.6.1.jar
  - Version=3.6.1
  - License=Apache 2.0, BSD 3
  - 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
  - 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=lombok-1.18.16.jar
    - Version=1.18.16
    - License=MIT
    - Link=https://opensource.org/licenses/MIT
- Library=TrueTime-5.0.3
    - Version=5.0.3
    - License=Apache 2.0
    - Link=https://www.apache.org/licenses/LICENSE-2.0
- Library=artifactory-3.0.15.gem
    - Version=3.0.15
    - License=Apache 2.0
    - Link=https://www.apache.org/licenses/LICENSE-2.0
- Library=chef-16.10.17.gem
    - Version=16.10.17
    - License=Apache 2.0
    - Link=https://www.apache.org/licenses/LICENSE-2.0
- Library=jquery-1.11.3.min.js
    - Version=1.11.3
    - License=MIT
    - Link=https://opensource.org/licenses/MIT
- Library=bootstrap-3.3.5.min.js
    - Version=3.3.5
    - License=MIT
    - Link=https://opensource.org/licenses/MIT

- Library=jquery-3.4.1.min.js
    - Version=3.4.1
    - 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
- Library=xcov-1.7.5.gem
    - Version=1.7.5
    - License=MIT
    - Link=https://opensource.org/licenses/MIT
- Library=jazzy-0.13.6.gem
    - Version=0.13.6
    - License=MIT
    - Link=https://opensource.org/licenses/MIT
- Library=Amplitude-7.2.2
    - Version=7.2.2
    - License=MIT
    - Link=https://opensource.org/licenses/MIT
- Library=xcode-install-2.6.8.gem
    - Version=2.6.8
    - License=MIT
    - Link=https://opensource.org/licenses/MIT
- Library=fastlane-plugin-create_xcframework-1.1.2.gem
    - Version=1.1.2
    - License=MIT
    - Link=https://opensource.org/licenses/MIT
- Library=slather-2.7.0.gem
    - Version=2.7.0
    - License=MIT
    - Link=https://opensource.org/licenses/MIT

- Library=changelog-0.8.gem
    - Version=0.8
    - License=MIT
    - Link=https://opensource.org/licenses/MIT
- Library=fastlane-plugin-appcenter-1.11.0.gem
    - Version=1.11.0
    - License=MIT
    - Link=https://opensource.org/licenses/MIT
- Library=SwiftLint-0.42.0
    - Version=0.42.0
    - License=MIT
    - Link=https://opensource.org/licenses/MIT
- Library=commons-lang3-3.11.jar
    - Version=3.11
    - 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-csv-1.7.jar
    - Version=1.7
    - License=Apache 2.0
    - Link=https://www.apache.org/licenses/LICENSE-2.0
- Library=json-20190722.jar
    - Version=20190722
    - 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 Pinching Test for the Android devices.

- Library=library-3.4
  - Version=1.0.0
  - License=Apache 2.0
  - Link=https://www.apache.org/licenses/LICENSE-2.0
- Library=vertx-pg-client-3.8.4.jar
  - Version=2.16.13
  - License=Apache 2.0
  - Link=https://www.apache.org/licenses/LICENSE-2.0
- Library=simpleclient_hotspot-0.9.0.jar
  - Version=13
  - License=Apache 2.0
  - Link=https://www.apache.org/licenses/LICENSE-2.0
- Library=simpleclient_dropwizard-0.9.0.jar
  - Version=0.0.19
  - License=Apache 2.0
  - Link=https://www.apache.org/licenses/LICENSE-2.0
- Library=simpleclient_vertx-0.9.0.jar
  - Version=3.4.2
  - License=Apache 2.0
  - Link=https://www.apache.org/licenses/LICENSE-2.0
- Library=commons-math3-3.6.1.jar
  - Version=1.7
  - 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=2.8.6
  - 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=3.8.4

    - 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=lombok-1.18.16.jar
    - Version=1.3.71
    - License=MIT
    - Link=https://opensource.org/licenses/MIT
- Library=commons-lang3-3.11.jar
    - Version=1.3.71
    - License=Apache 2.0
    - Link=https://www.apache.org/licenses/LICENSE-2.0
- Library=commons-math3-3.6.1.jar
    - Version=1.1.0
    - License=Apache 2.0, BSD 3
    - Link=https://www.apache.org/licenses/LICENSE-2.0
    - https://opensource.org/licenses/BSD-3-Clause
- Library=commons-csv-1.7.jar
    - Version=1.1.0
    - License=Apache 2.0
    - Link=https://www.apache.org/licenses/LICENSE-2.0
- Library=json-20190722.jar
    - Version=0.0.19
    - License=MIT
    - Link=https://opensource.org/licenses/MIT