User Manual

Floodlight MS U Turn Test

Software version: 1.1 | Document version 1.0

Material Numbers: For iOS - 9342290001; For Android - 9342311001

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CE

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Floodlight MS U Turn 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 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 gait and dynamic balance 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 U Turn Test is intended to provide an objective measurement of gait and dynamic balance in patients 18 years of age and older with multiple sclerosis. The Floodlight MS U Turn 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 U Turn Test only provides objective measurements of gait and dynamic balance and does not provide an interpretation or a clinical implication of the measurements. The Floodlight U Turn Test should only be used as an adjunctive tool for measuring gait and dynamic balance, 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 between two points at least five steps apart.
- 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 U Turn Test.

Place your phone in the front pocket of your pants because failure to do so may result in inaccurate data.

Ensure that your phone is not in the Silent or Vibrate mode while performing this activity.

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

2 U Turn Test

This activity measures your gait and dynamic balance over time. This is achieved by:

- Asking you to walk between two points at least five steps apart and make at least five U-turns
- Monitoring your gait and speed with which you make a U-turn
- Tracking how many U-turns you can make in 60 seconds

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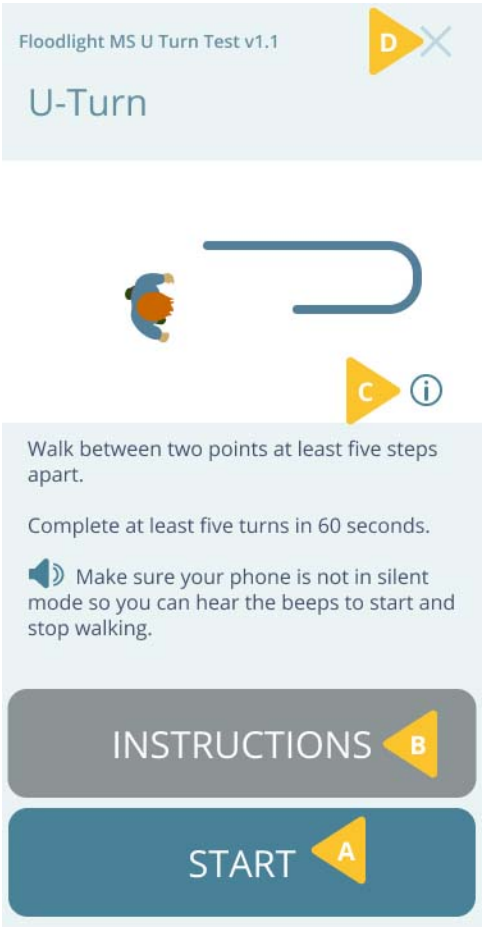
2.1 Get Started

From the **U-Turn** start screen, you can:

A. **Start the Activity** (on page 9).
B. **Review Instructions** (on page 10) to see how to perform the activity.
C. **Read the U Turn Product Label** (on page 1).
D. **Cancel the Activity** (on page 13).

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



2.1.1 Start the Activity

Tip

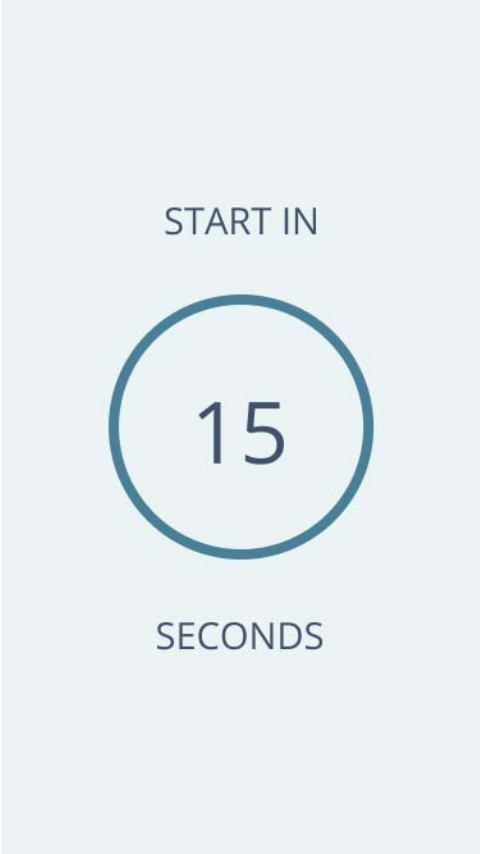
It is best to complete your activities in an environment where you can focus, minimize interruptions, and walk safely.

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

1. Place your phone in the front pocket of your pants. This is **important** for the **accuracy of data** collected for this activity.

Note: If you are not able to place the phone in your front pant pocket or do not have any pockets at the moment, tap **LATER** to perform this activity at another time.

2. Tap **START** to begin the activity.
3. A **15 second** countdown screen will appear.



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

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

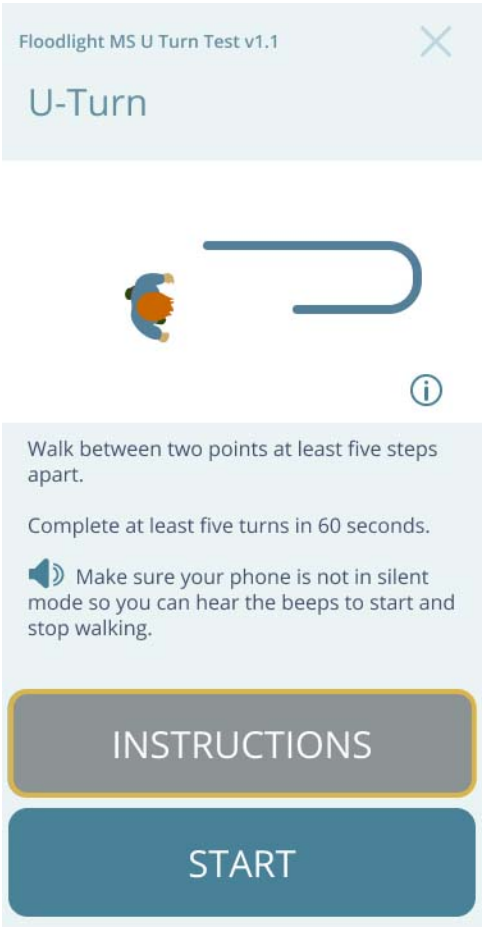
you tap **START**. After that, every time you press **START**, the activity will start without first displaying the instructions.

You can:

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

To review the instructions for this activity:

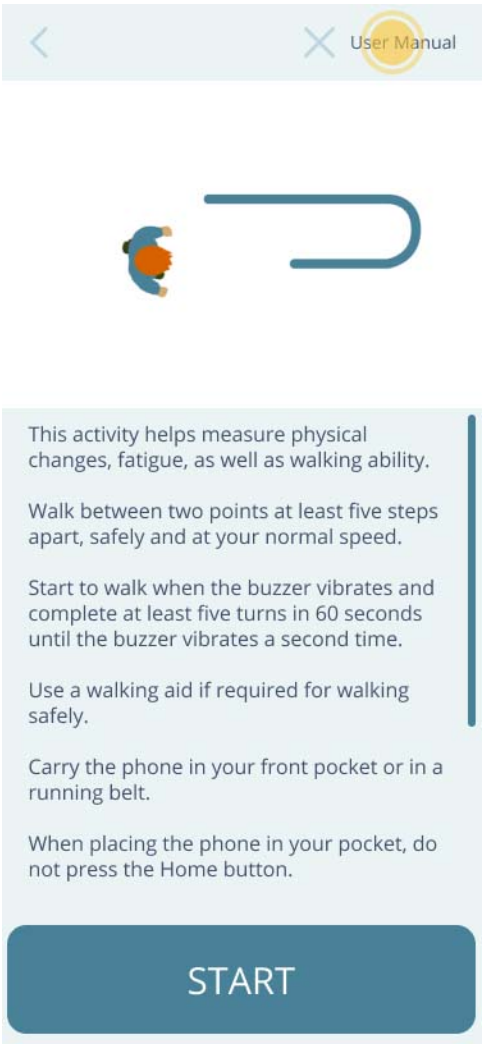
1. From the activity start screen, tap **INSTRUCTIONS** to quickly review how to perform the activity.



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.



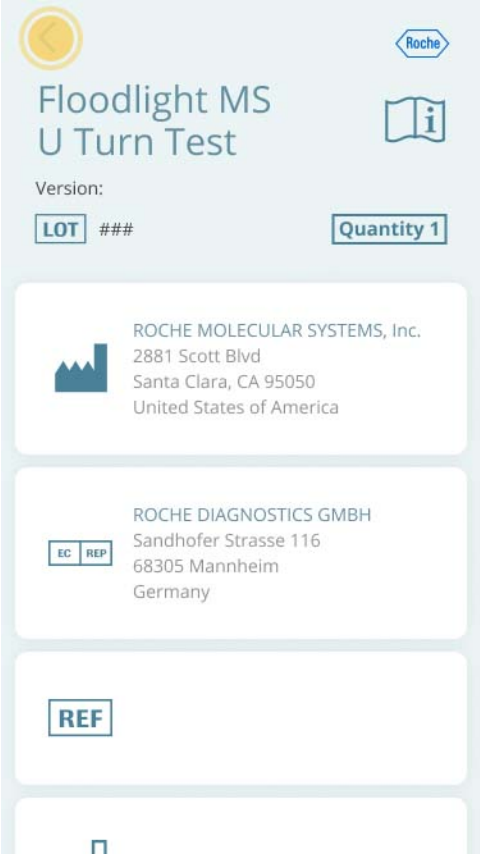
2.1.3 Read the U Turn Product Label

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 **U-Turn** start screen.

2. Tap the **Back** button to go back to the **U-Turn** start screen.



2.1.4 Cancel the Activity

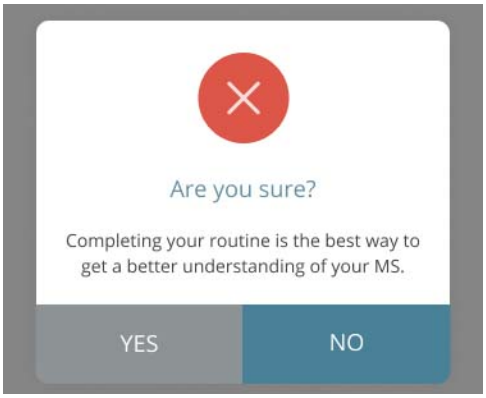
You can cancel this activity before you tap **START**. If you cancel the activity, you will have an opportunity to come back later in the day and resume your routine from where you stopped.

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

To cancel the activity:

1. Tap the **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 pant pocket will directly impact the accuracy of the data. For accurate measurements, please ensure the phone is placed in a front pant pocket.

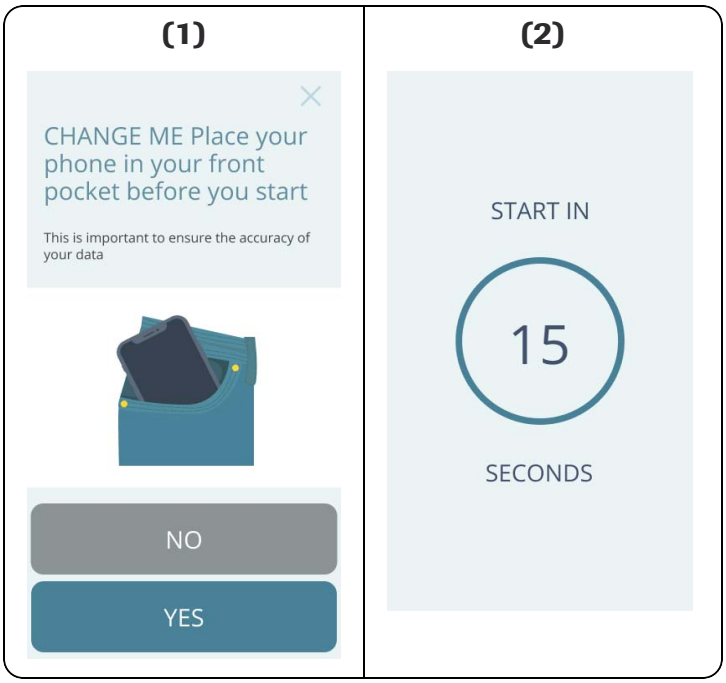
When the activity starts, you will be asked three safety questions:

A. Can you stand and keep your balance safely?
B. Are you in a safe environment to walk between two points at least five steps apart?
C. Do you need a walking aid to stand safety for 60 seconds?

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 your front pant pocket
(2) A 15 second countdown



Note: If you are not able to place the phone in your front pant pocket or do not have any pockets at the moment, tap **LATER** to perform this activity at another time.

2.3 How do I perform this activity?

Warning
Prior to beginning the activity, please 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. Wait for the 15 seconds countdown to go to **0**. Use this time to place the phone in your front pant pocket.

2. When the countdown is almost done, you will hear three short beeps and a long beep to indicate that you can start the activity. Your phone screen will now show a completion countdown for **60 seconds**.

3. Start walking in a straight line between two points at least five steps apart.
4. Make a U-turn and walk back to the starting point in a straight line.
5. Make another U-turn and continue this pattern until the countdown has ended. When the countdown is almost done, you will again hear three short beeps and a long beep to indicate that the activity is complete.

3 Troubleshoot

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3.2 Can I cancel an activity after I start? 18

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3.5 What if I get interrupted or distracted by someone while performing this activity? 19

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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**.

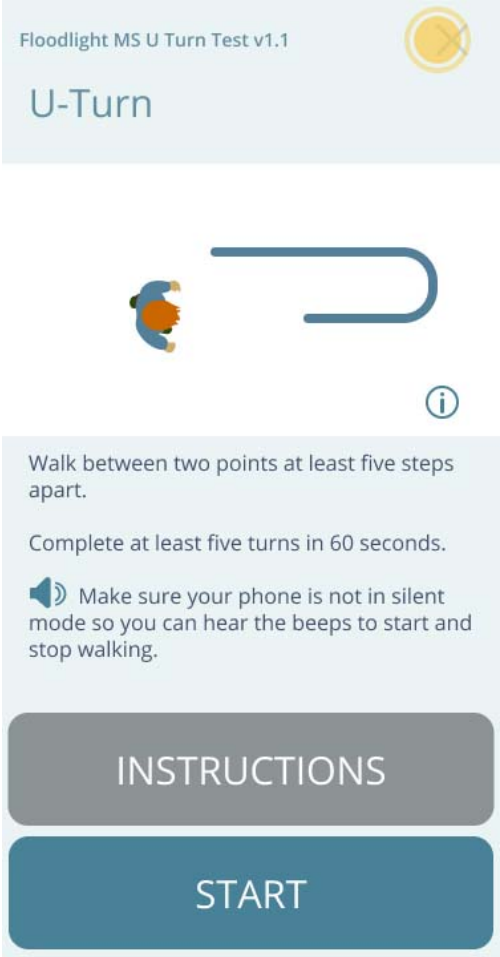
After this, you will be directed to the countdown screen when tapping the **START** button. You can always review instructions by tapping on the **INSTRUCTIONS** button when needed.

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.

4 Additional Information

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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 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:**
  - **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 U Turn Test for the iOS devices.

- 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=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=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=jquery-3.5.1.min.js
    - Version=3.5.1
    - License=MIT
    - Link=https://opensource.org/licenses/MIT
- 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
- Library=disruptor-3.4.2.jar
    - Version=3.4.2
    - License=Apache 2.0
    - Link=https://www.apache.org/licenses/LICENSE-2.0
- Library=logback-core-1.2.3.jar
    - Version=1.2.3
    - License=Apache 2.0
    - Link=https://www.apache.org/licenses/LICENSE-2.0

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 U Turn Test for the Android devices.

- 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=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=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=jquery-3.5.1.min.js

    - Version=3.5.1
    - License=MIT
    - Link=https://opensource.org/licenses/MIT
- 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
- Library=disruptor-3.4.2.jar
    - Version=3.4.2
    - License=Apache 2.0
    - Link=https://www.apache.org/licenses/LICENSE-2.0
- Library=logback-core-1.2.3.jar
    - Version=1.2.3
    - License=Apache 2.0
    - Link=https://www.apache.org/licenses/LICENSE-2.0