## Release Notes

# Floodlight™ MS Activities

**Software version: 1.7 | Document version: 2.0**

Material Number: For iOS: 09865063001; For Android: 09865071001

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# About

| | |
|---|---|
| UDI | For iOS - (01)07613336222317(8012)1.7<br>For Android - (01)07613336222324(8012)1.7 |

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|---|---|
| | Roche Molecular Systems, Inc.<br>2881 Scott Boulevard<br>Santa Clara, California 95050<br>United States of America |
| Made in the USA | |
| REF | For iOS - 09865063001<br>For Android - 09865071001 |
| GTIN | For iOS - 07613336222317<br>For Android - 07613336222324 |
| **Date of Publication** | 04-04-2023 |
| MD | |
| Rx Only | Federal law restricts this device to sale by or on the order of a healthcare practitioner |
| | floodlightms.com |

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 Release Notes.

| | |
|---|---|
| UDI | **UDI symbol:** The Unique Device Identifier represents a series of numeric or alphanumeric characters that is created through internationally accepted device identification and coding standards and that allows unambiguous identification of specific devices on the market. |
| | **Product manufacturer:** The name and address of the application's manufacturer. |
| REF | **Reference Number:** Indicates the Reference or Catalog number for this user manual. |
| GTIN | **Global Trade Item Number (GTIN):** This is a globally unique 14-digit number used to identify trade items, products, or services. |
| MD | **Medical Device:** Floodlight™ MS Activities includes the five medical device assessments (U Turn Test, 2MWT, Pinching Test, Draw a Shape Test, and Cognitive Test). |
| Rx Only | **Prescription Use Only:** Federal law restricts this device to sale by or on the order of a healthcare practitioner |
| | **Consult instructions for use:** The device includes electronic instructions for use (eIFU). |

| | |
|---|---|
| ⚠ | **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. |

# Preface

Floodlight™ MS Activities consists of five medical device assessments for patients 18 years of age and older with Multiple Sclerosis (MS). These assessments help you, as a person living with multiple sclerosis (MS), collect data over time and help inform the conversation around your care.

The U Turn Test measures your gait and dynamic balance. The 2MWT measures your walking ability. The Pinching Test and the Draw a Shape Test measure your hand function. The Cognitive Test measures your cognitive function or how quickly you process information.

# Intended Use

Floodlight™ MS Activities consists of five medical device assessments for patients 18 years of age and older with Multiple Sclerosis (MS). The U Turn Test is intended to provide an objective measurement of gait and dynamic balance. The 2MWT is intended to provide an objective measurement of gait. The Pinching Test is intended to provide an objective measurement of hand function. The Draw a Shape Test is intended to provide an objective measurement of hand function. The Cognitive Test is intended as a cognitive assessment aid to determine the level of cognitive functioning. Floodlight™ MS Activities 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 consulting a qualified HCP. Floodlight™ MS Activities allows configuring one, several or all five medical device assessments to be accessed by an application. The assessments in Floodlight™ MS Activities only provide objective measurements and do not provide an interpretation or a clinical implication of the measurements. Floodlight™ MS Activities should only be used as an adjunctive tool, and is not intended to be used as a stand-alone diagnostic device nor to identify the presence or absence of clinical diagnoses.

# Supported Platforms

The following table displays the supported platforms for Floodlight™ MS Activities.

| Platforms | Version |
|---|---|
| iOS version | 14.x to 16.x |
| Android version | 10 to 13 |
| Floodlight™ MS SDK: iOS | 1.7 |
| Floodlight™ MS SDK Android | 1.7 |
| Floodlight™ MS SDK Backend | 1.7 |
| DHP: dhp-api-gateway | dev_2168 |
| DHP: dhp-gql-query-svc | dev_1396 |
| DHP: dhp-patient-mgmt-svc | dev_5195 |

# Unsupported Phones

The Floodlight™ MS Activities is not supported on the following phones.

| Brand | Model Name |
|---|---|
| Alcatel | 7 |
| Alcatel | Tetra |
| Alcatel | ZIP LTE |
| Alcatel | REVVL 2 Plus |
| Alcatel | Raven LTE |
| Alcatel | REVVL 2 |
| Alcatel | 1X (2018) |
| Alcatel | PulseMix |
| Alcatel | Verso |
| Alcatel | IdealXcite |
| Alcatel | One Touch Idol 5 |
| Alcatel | REVVL |
| Alcatel | 3V |
| Alcatel | 1X Evolve |

| Brand | Model Name |
|---|---|
| Alcatel | A30 |
| Alcatel | Cameox 4G |
| Alcatel | LX 4G |
| Alcatel | A30 Fierce |
| Alcatel | A30 Plus |
| Alcatel | Avalon V |
| Alcatel | One Touch Idol 5S |
| Alcatel | Onyx |
| Alcatel | LX1 |
| Alcatel | LX2 |
| Alcatel | Jitterbug Smart2 |
| Alcatel | Kora |
| Alcatel | A50 |
| Alcatel | Ideal |
| Alcatel | Streak |
| Alcatel | A1 |

| Brand | Model Name |
|---|---|
| Alcatel | Axia |
| Alcatel | Fierce 4 |
| Alcatel | One Touch Idol 4 |
| Alcatel | One Touch Pixi Eclipse |
| Alcatel | Jitterbug Smart |
| Alcatel | One Touch Pixi Avion |
| Alcatel | One Touch Pixi Glitz |
| Alcatel | Allura |
| Alcatel | One Touch Idol 3 (5.5) |
| Alcatel | Dawn |
| Alcatel | One Touch Idol 4s |
| Alcatel | One Touch Flint 4G |
| Alcatel | One Touch Pixi 4 (5) |
| Alcatel | Tru |
| Alcatel | One Touch Pop 4S |
| Alcatel | One Touch Pixi Pulsar |

| Brand | Model Name |
|---|---|
| Alcatel | One Touch Pixi 4 (6) |
| Alcatel | One Touch Pop 4+ |
| Huawei | P20 Lite (2018) |
| Huawei | P Smart (2018) |
| Huawei | Mate 10 Lite |
| Huawei | Mate 20 Lite (2018 Sep) |
| Huawei | Y6 (2018) |
| Huawei | P10 (2017) |
| LG Electronics | Aristo 2 (2018) |
| LG Electronics | Stylo 4 (2018) |
| LG Electronics | K20 Plus (2016 Dec) |
| LG Electronics | Risio 3 |
| LG Electronics | Tribute Dynasty |
| LG Electronics | Rebel 4 |
| LG Electronics | Stylo 3 Plus |
| Motorola | Moto E5 Play (2018 Jul) |

| Brand | Model Name |
|---|---|
| Motorola | Moto E4 (2017 Jun) |
| Motorola | Moto E7 |
| Samsung | Galaxy A13 |
| Samsung | Galaxy J6 (2018 May) |
| Sony Mobile | Sony Xperia 10 III |
| Sony Mobile | Sony Xperia 10 III Lite |

# Known Limitations and Workarounds

The following issues are identified as known issues with workarounds in the current release of Floodlight™ MS Activities.

### Using the Android Back button in the middle of an activity takes you to the wrong screen

If you are using an Android phone and tap the Android Back button in the middle of an activity, occasionally, you may be taken back to the start screen for the activity. In this case, you will have to start the activity again.

### Historical Data is not displayed correctly if the Date and Time on the phone is set to a date in the past

If you manually change the date and time on your phone to a past date and time, you may not see your **Historical Data** and the past results on the **Dashboard**. To view your Historical Data and past results, reset the date and time to the Automatic setting on your phone.

### PDF print-out displays data in UTC + 0 time zone

If you are exporting data to PDF to share it with your provider, the data will be in UTC. The data is also available in the charts screen and your provider also has access to it through the Floodlight™ MS Healthcare Professional's Portal.

### Voice assistant does not work when used to start an activity

On an Android phone, sometimes the voice assistant does not work when you try to use it to start an activity. In this case, to properly start an activity with the voice assistant open, you will have to exit the activity and restart it again.

### For some Android phones with very small screen size, the instruction text and the scroll bar overflow under the START and INSTRUCTIONS buttons.

On some Android phones with very small screen size, the **START** and **INSTRUCTIONS** buttons overlap the instruction text. However, in this case, a user can still scroll the screen up and down to read all the instructions before starting an activity.

### Average Data calculations cause the Historical Data retrieval request to time out if the time range is too long

The request to retrieve Historical Data also includes the request to calculate the average data for the same time period. However, if the specified time range is too long, the average data calculation times out and also fails to return the Historical Data. To avoid this error, use shorter time ranges when retrieving Historical Data.

### Test results for the 2MWT and the U Turn Test may vary if the placement of the phone changes between tests

The test results for the 2MWT and the U Turn Test may vary if the placement of the phone changes between tests. For example, this can happen if you place the phone on your belt one time and then in a trouser pocket that may be loose or lower down your leg. It is recommended that you wear similar kind of clothing when taking the test because a significant change in the placement or the size of the pocket may affect the consistencies of your test results.

### The Floodlight™ MS SDK cannot correctly integrate into third-party applications using the automatic build management option.

When deploying the Floodlight™ MS SDK to integrate with a third-party application, the integration fails if the third-party application is using an automatic build management option. To avoid this error, it is recommended that the automatic build management option should be disabled and the build numbers should be set manually on the third-party application.

### The Floodlight™ MS SDK Gradle build configuration file is missing the AndroidX Lifecycle dependency for LiveData.

When starting the Floodlight™ MS tests using a third-party application implemented in Java, the application crashes due to the missing AndroidX Lifecycle dependency for LiveData from the application's Gradle build configuration file. To resolve this issue, a possible workaround is to manually add the missing dependency in the custom gradle build configuration file as: `implementation 'androidx.lifecycle:lifecycle-livedata-ktx:2.5.1'`.

### Unplugging or plugging in the phone charger during the 15 seconds countdown for the walking activities (2-Min Walk and U-Turn) interrupts the activity

On an iOS phone, unplugging or plugging in the phone charger during the 15 seconds countdown to start the walking activities (2-Min Walk and U-Turn), interrupts the activity but not the countdown timer. As a result, though you are returned to the **Dashboard** screen in

the app, you may hear the residual counter from the previous attempt in the background. To prevent this error, unplug the phone charger before starting either the U-Turn or the 2-Min Walk activities.

# Known Limitations without present workarounds

The following limitations are unresolved in this version of Floodlight™ MS Activities. Resolutions or workarounds will be communicated in future release notes.

- On an iOS phone, the beeping sound at the end of the countdown for the 2MWT and the U Turn Test is not 3-5 seconds long as is expected by a user.
- The Start Date and the End Date captured in the Draw a Shape Test feature data JSON file do not match the Start Date and the End Date captured in the Draw a Shape Test raw data JSON file.
- Due to the nature of your disease, you may feel dizzy while taking the U-Turn activity. If this occurs, please stop the activity and consult with your provider.
- In some cases, the Floodlight™ MS Mobile Application may display a result for the U-Turn activity even if your phone does not have a gyroscope. This happens because with some specific movements and readings from the accelerometer, the algorithm can interpret a few spikes that may meet the criteria for recording a U-turn.
- The Charts library version 3.6.0 used by the Floodlight™ MS Mobile Application is not supported in Xcode 14.0. As a result, a third-party application cannot be built using the Floodlight™ MS SDK. This issue will be resolved in the next hot fix for the Floodlight™ MS Mobile Application.
- For the walking activities (2-Min Walk and U-Turn), the Floodlight™ MS Mobile Application overrides the volume settings on your phone and increases it to the maximum during the countdown and the execution of the activities.