Release notes

Floodlight™ MS Activities

Software version: 1.8.4 | Document version: 9.0

About

UDI	For iOS – (01)07613336222317(8012)1.8 For Android – (01)07613336222324 (8012)1.8

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Floodlight™ MS Activities, Floodlight™ MS 2MWT, Floodlight™ MS Cognitive Test, Floodlight™ MS Draw a Shape Test, Floodlight™ MS Pinching Test and Floodlight™ MS U Turn Test are included on the Australian Register of Therapeutic Goods (ARTG) as software-based medical devices.

Any serious incident that has occurred in relation to the device should be reported to Roche Customer Support and to the Therapeutic Goods Administration (TGA). 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 alpha-numeric characters, which is created through internationally accepted device identification and coding standards, and which allows the unambiguous identification of specific devices on the market.
(manufacturer symbol)	**Product manufacturer:** the name and address of the application's manufacturer.
REF	**Reference number:** indicates the reference or catalogue 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).
(book with i symbol)	**Consult instructions for use:** the device includes electronic instructions for use (eIFU).

⚠	**Warnings and precautions:** highlights information that is critical for the optimal performance of the system. May also indicate that the 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 will 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	15.x to 17.x
Android version	10 to 14
Floodlight™ MS SDK: iOS	1.8.4
Floodlight™ MS SDK Android	1.8.4
Floodlight™ MS SDK Backend	1.8.4
DHP: dhp-api-gateway	dev_2206
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)

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

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 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.

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

On some Android phones with a 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 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 a 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 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'.`

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 Android phone, if you accidentally click the **Back** button during an activity, it interrupts the activity and redirects you to the **Instructions** screen for the activity. In this case, the activity is not complete and you will need to retake the activity to record your results.
- When a user starts an activity and the user manuals are not available, no error message is displayed to the user.