Release Notes

Floodlight™ MS Cognitive Test

Software version: 1.2 | Document version: 3.0

Material Numbers: For iOS - 9341897001; For Android - 9341919001

© 2021 F. Hoffmann-La Roche Ltd

Roche Molecular Systems, Inc.

2881 Scott Boulevard

Santa Clara, California 95050

United States of America

REF

For iOS - 9341897001

For Android - 9341919001

Date of Publication 07-13-2021

Rx Only

Federal law restricts this device to sale by or on the order of a healthcare practitioner

Please contact Roche to request a printed version of this document.

© 2021 F. Hoffmann-La Roche Ltd
All rights are reserved. Reproduction or transmission in whole or in part, in any form or by any means, electronic, mechanical or otherwise, is prohibited without the prior written consent of the copyright owner.

Copyrights and all other proprietary rights in any software and related documentation ("Software") made available to you rest exclusively with Roche or its licensors. No title or ownership in the Software is conferred to you. Use of the software is subject to end user license agreement.

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.

Preface

Floodlight™ MS Cognitive Test can help you measure your cognitive function over time.

Intended Use

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

Unsupported Phones

The Floodlight™ MS Cognitive Test is not supported on the following phones:

Brand	Model Name
Alcatel	7
Alcatel	Tetra
Alcatel	ZIP LTE
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

Known Limitations and Workarounds

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

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.

Cognitive test icon stays active for two consecutive days

On an iOS phone, a user can see the cognitive test enabled everyday. However, the user is not able to actually take the Cognitive test if it has been done in the past 6 days and this is expected behavior.

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 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.

Extremely fast consecutive responses in the Floodlight™ MS Cognitive Test lead to data issues

For the Floodlight™ MS Cognitive Test, if you provide the response for each symbol extremely fast, consecutive responses may have the same time stamp that could lead to inaccurate data. To avoid this problem, perform the activity at a natural pace.