

Exeter Diabetes App R1 v1 - Instructions for Use

UNCONTROLLED IF PRINTED **PRODUCT DEVELOPMENT**

Introduction

Thank you for purchasing this RDE Medical Devices product. The Exeter Diabetes App R1 aims to provide information and algorithms to support clinical decisions when classifying subtypes of diabetes.

Intended Use

The Exeter Diabetes App R1 is intended to provide information and algorithms to support clinical decisions when classifying subtypes of diabetes. In this version, the app provides the MODY calculator which calculates the probability that a person has a genetic form of diabetes (particularly the subtype called MODY) based on their clinical features, using a validated clinical prediction model. The app also provides links to further information on this condition, as well as information on further screening tests that can be used to aid classification, and how to request a molecular genetic diagnostic test needed to make a diagnosis of MODY.



Please read this instruction manual thoroughly before using Exeter Diabetes App. Please keep these instructions for future reference.

Safety Information

Safety Instructions



Warning: Indicates a potentially hazardous situation which, if not avoided, could result in patient death or serious impact to the health of patients.

Please follow the mandatory safety information supplied with the Exeter Diabetes App.

The Exeter Diabetes App cannot take the place of clinical assessment. No medical decision should be based solely on results provided by this program.

Cautions



Caution: Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate impact to the health of patients.

This app is not intended to replace clinical decisions. A diagnosis of MODY must be made by diagnostic genetic testing.

The MODY calculator has not been validated in non-White populations so caution is required when interpreting results in non-White patients as the probability is likely to be lower (a warning message will appear in the app if non-White ethnicity is selected).

Time to insulin requirement within the first 6 months is an input on the MODY calculator so if adding in patient details at diagnosis, please note the probability may change if the patient's insulin requirements change within the first 6 months (a warning message will appear if age and age at diagnosis are the same).

Pre-Use Requirements and Dependencies

To use the Exeter Diabetes App, you will require a browser running on a Windows PC or an Android or Apple phone or tablet. You will also require access to the internet for updates.

The Exeter Diabetes App has been tested on the following device / OS / Browser combinations:

Device	OS	Browser	Notes
PC	Windows 10 Professional	Chrome (81.0.4044.138)	
PC	Windows 10 Professional	Edge (42.17134.1098.0)	
PC	Windows 10 Professional	Firefox (76.0.1)	
PC	Windows 10 Professional	Opera (68.0)	
PC	Windows 10 Professional	IE 11 (11.1304.17134.0)	Will not work offline
Apple Macbook Pro	Mojave (10.14 beta 18A347e)	Safari (12.0 14606.1.30)	
Apple Macbook Pro	Mojave (10.14 beta 18A347e)	Firefox (76.0.1)	
Apple Macbook Pro	Mojave (10.14 beta 18A347e)	Chrome (81.0.4044.138)	Will not work offline
Samsung Galaxy S7 Edge (SM-G935F)	Android 8.0	App	
Samsung Galaxy S7 Edge (SM-G935F)	Android 8.0	Chrome (81.0.4044.138)	
Samsung Galaxy S7 Edge (SM-G935F)	Android 8.0	Samsung Internet 11.2.1.3	
iPhone X (MQAD2B/A)	12.3.1	App	
iPhone X (MQAD2B/A)	12.3.1	Safari (12.3.1)	
iPhone 6/7/8 (Firefox emulator)	iOS 11	Firefox (76.0.1)	
Huawei P30 Pro (VOG-L09)	Android 10	Chrome (81.0.4044.138)	
Huawei P30 Pro (VOG-L09)	Android 10	App	
Lenovo Tablet (TB-X704F)	Android 7.1.1	Chrome (80.0.3987.119)	
iPad 5th Gen (A1822)	12.1.4 (16D57)	Safari 12.1.4	
Moto G4 (Chrome emulator)		Chrome (81.0.4044.138)	

Software Installation, Upgrade and Configuration

Step by Step Instructions - Initial Installation

1. Open your browser.
2. Navigate to the app website: <https://diabetesgenes.org/exeter-diabetes-app>

3. When you first access the site, you may be prompted by your browser to save or install the site to your home screen. Click “accept” or equivalent - this will allow you to use the app offline. If the prompt does not appear, please follow the instructions appropriate to your browser in the following section.

Install the App for Offline Use

Follow the instructions for installing a Progressive Web App (PWA) described in the help for your device or browser. Links for common browsers are shown below:

Chrome

PC: <https://support.google.com/chrome/answer/9658361?co=GENIE.Platform%3DDesktop&hl=en&oco=1>

Android: <https://support.google.com/chrome/answer/9658361?co=GENIE.Platform%3DAndroid&hl=en&oco=1>

iOS: Offline use is not supported on Chrome for iOS.

Safari

iPhone: See <https://support.apple.com/en-gb/guide/iphone/iph42ab2f3a7/ios> and follow the instructions in section “Add a website icon to your iPhone Home screen”.

iPad: See <https://support.apple.com/en-gb/guide/ipad/ipadc602b75b/ipados> and follow the instructions in section “Add a website icon to your iPad Home screen”.

Firefox

See https://developer.mozilla.org/en-US/docs/Web/Progressive_web_apps/Add_to_home_screen

Edge

See <https://docs.microsoft.com/en-us/microsoft-edge/progressive-web-apps-chromium/#pwas-on-microsoft-edge-chromium>

Internet Explorer

Offline use is not supported on Internet Explorer.

Other Browsers

See https://developer.mozilla.org/en-US/docs/Web/Progressive_web_apps/Developer_guide/Installing

Step by Step Instructions - Update

If you are online, the app will automatically check for updates on startup and once per day while it is running. If an update is available, the app will download it and then prompt you to restart. *Note:* This can take a few seconds.

Step by Step Instructions - Uninstalling

PC

In the app, click the settings icon (a horizontal or vertical line of dots in the top menu bar) and choose the “Uninstall” option.

iPhone / iPad / Android

Drag the app icon to the uninstall space like any other app.

Using the MODY Probability Calculator

1. Click or tap “MODY Calculator” on the home page.
2. Enter the requested information on the inputs screen:

- a. Invalid entries are highlighted in red with a message explaining why they are invalid. Valid entries are highlighted in green.
 - b. HbA1c can be entered either as a percentage *or* as a concentration in mmol/mol.
 - c. In the “Other” section, check the boxes for any conditions that apply to the patient.
3. When all entries are green, click or tap the “Calculate” button at the bottom of the screen.
 4. The calculated probability of MODY is shown in the box at the top of the screen. Please read the accompanying notes carefully. Click or tap the navigation buttons for further information.
 5. Click or tap the “Reset” button to clear all data from the calculator and return to the home page.
 6. More information about the app and the calculator can be found by tapping or clicking the Information button on the home page.

Troubleshooting

iPhone / iPad: The app was working, but now won't start

This can occur if the app has not been used in the last two weeks and you are offline. The iOS operating system assumes that you no longer want to use the app and silently deletes its cached files. The app should start working again if you start it while online.

Technical Specifications

N/A

Regulatory Information



This device fulfils the provisions of the European Commission (EC) Directive 93/42/EEC (Medical Devices Directive).

This software product has been designed according to:

ISO 13485:2016 - Medical devices - Quality management systems for medical devices

ISO 14971:2012 - Medical devices — Application of risk management to medical devices

IEC 62304:2006 Amd 1:2015 - Medical device software – Software lifecycle processes

DCB0129:2018 - Clinical risk management: its Application in the manufacture of health IT systems.

This device has been developed under the strict quality management system of Royal Devon and Exeter NHS Foundation Trust