

Instructions for use CASC App

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Mobile Healthcare Solutions GmbH, % HIP, Röntgenstraße 24, 22335 Hamburg Email:
info@getcasc.com Website: www.getcasc.com



Basis-UDI-DI: 426240484CASCAPP93

The CASC app is a Class 1 medical device in accordance with Regulation EU 2017/745.
EMDN Code: V92

Symbols and their explanation:



In vitro diagnostic device
In-Vitro-Diagnostikum



List number
Katalognummer



Read the instructions before use
Beachten Sie die Gebrauchsanweisung



CE marking
CE-Kennzeichnung



Lot number
Chargenbezeichnung



Legal manufacturer
Hersteller

Product description

Intended use

The CASC App is a software as a medical device intended for human use and fulfills the following specific medical purpose in combination with a stand-alone in vitro diagnostic device (test strip):

Investigation of a physiological process or condition

For this purpose, the CASC app analyzes the color representation of the test areas of the test strip after it has been used for its intended purpose. The CASC app uses the test strip manufacturer's reference color values to display the values measured by the test strip in the app (hereinafter referred to as test results).

The CASC app provides information on possible dietary and/or lifestyle adjustments that are related to the analyte.

Information on the analyte itself is also provided.

This information is of a general nature and not a recommendation for action based on a measured value.

The results of the CASC app are intended solely as a guide for reading the test strip: a discrepancy between the value read by the user and the value determined by the app indicates an error in the reading. The user can either repeat the test or consult a doctor. The decisive measurement result is that of the underlying test, not that of the app.

The results are not intended as a basis for diagnostic or therapeutic decisions and do not themselves constitute a diagnostic or therapeutic recommendation. Furthermore, they are not intended for the monitoring of physiological processes or parameters.

Characterization of the user profile

The typical users of the software are laypersons. It can be assumed that they already have experience with a mobile app, with smartphones in general and with the use of rapid tests. The experience with rapid tests was recently confirmed by the lay user group as part of the

Corona pandemic. Depending on the test to be performed and the user's experience, the software takes around four to 15 minutes to use per application.

Characterization of the patient population

There are no restrictions regarding the patient population. The restrictions of the respective test, if any, must be observed.

Ambient condition

The software is compatible with Apple devices that support the iOS 11 operating system and higher, as well as with smartphones that support the Android 9 operating system and higher. A list of compatible devices can be found under "Hardware". The device is typically used in the home environment. Ideally, natural light and the avoidance of shadows on the test should also be taken into account.

The software can be used in the home environment.

Exclusions

The software is not suitable for monitoring physiological conditions. Nor is it suitable for diagnosing diseases or conditions resulting from them. The results are not intended as a basis for diagnostic or therapeutic decisions and do not themselves constitute a diagnostic or therapeutic recommendation.

The results of the app do not replace the result of the rapid test.

Security information

The software only serves as a readout aid when recording results. No diagnostic or therapeutic decision should be made based on the presentation of results in the software. Recommendations within the software refer exclusively to general tips for a healthy lifestyle (e.g. sufficient exercise, a balanced diet or sufficient sleep). If there are any discrepancies between the results obtained by eye and those displayed by the software, the results obtained by eye apply. A doctor should be consulted if anything is unclear. For a diagnostic interpretation, all results must be thoroughly checked by a qualified doctor.

Contraindications

There are no known contraindications for the CASC app.

The respective contraindications of the rapid test, if there are any, must be observed.

Warnings and residual risks

The instructions for use must be checked thoroughly before carrying out the test in order to reduce or avoid application errors during use. If you have any questions or uncertainties, please contact support. Particular care must be taken to place the test correctly on the test surface and to avoid excessive shadowing on the test surface.

of the test surface. The test should be photographed at a slight angle to avoid the light being reflected back into the camera.

Language

The software is provided in German.

System requirements

Hardware

The following smartphones are compatible with the CASC app:

Samsung Galaxy S10, Samsung Galaxy S9, Samsung Galaxy S8, Samsung Galaxy Note 9, Samsung Galaxy Note 8, Google Pixel 3, Google Pixel 3 XL, Google Pixel 2, Google Pixel 2 XL, OnePlus 6T, OnePlus 6, Huawei Mate 20 Pro, Huawei P30 Pro, LG G7 ThinQ, LG V40 ThinQ, Sony Xperia XZ3, Xiaomi Mi 9, Xiaomi Mi Mix 3, Nokia 9 PureView, Oppo R17 Pro, Vivo NEX S, Essential PH-1, Razer Phone 2, Asus Zenfone 5Z, LG V30, LG V30+, Moto Z3, Moto Z3 Play, OnePlus 5T, OnePlus 5, OnePlus 3T, OnePlus 3, Samsung Galaxy S7, Samsung Galaxy S7 edge, Samsung Galaxy S7 Active, Samsung Galaxy S6, Samsung Galaxy S6 edge, Samsung Galaxy S6 edge+, Samsung Galaxy S6 Active, Samsung Galaxy Note 5, Google Pixel, Google Pixel XL, Nexus 6P, Nexus 5X, Huawei Mate 9, Huawei Mate 9 Pro, Huawei P10, Huawei P10 Plus, LG V20, LG G6, LG G6+, LG G6 Pro, Sony Xperia XZ2, Sony Xperia XZ2 Compact, Sony Xperia XZ2 Premium, Xiaomi Mi 6, Xiaomi Mi Mix 2, Xiaomi Mi Mix 2S, Nokia 8, Oppo R11, Vivo X20, Vivo X20 Plus, Essential PH-1, Razer Phone, Asus Zenfone 4 Pro, Asus Zenfone 4, LG V30S ThinQ, LG V35 ThinQ, LG V40 ThinQ, Moto Z2 Force, Moto Z2 Play, OnePlus 3T, OnePlus 5T, OnePlus 6, Samsung Galaxy S8, Samsung Galaxy S8+, Samsung Galaxy Note 8, Google Pixel 2, Google Pixel 2 XL, Huawei Mate 10, Huawei Mate 10 Pro, Huawei Mate 10 Porsche Design, Huawei P20, Huawei P20 Pro, LG G7 ThinQ, LG V30, LG V30+, Sony Xperia XZ Premium, Sony Xperia XZ1, Sony Xperia XZ1 Compact, Xiaomi Mi 8, Xiaomi Mi Mix 2S, Nokia 8 Sirocco, Oppo Find X, Vivo NEX S, Vivo NEX A, Essential PH-1, Razer Phone 2, Asus Zenfone 5Z, LG V40 ThinQ, Moto Z3, Moto Z3 Play, OnePlus 6T, Samsung Galaxy S9, Samsung Galaxy S9+, Samsung Galaxy Note 9, iPhone X, iPhone 8, iPhone 8 Plus, iPhone 7, iPhone 7 Plus, iPhone 6s, iPhone 6s Plus, iPhone 6, iPhone 6 Plus, iPhone SE, iPhone 5s.

Software

The smartphone must support the operating version iOS 11 (or higher) or Android 9 (or higher) in order to download the CASC app.

IT security measures

Users protect their data in their profile. Access is linked to their e-mail address. The profile is protected by a one-time password. Customer data is pseudonymized unless the personal reference is absolutely necessary for the result. The separation of customer data is ensured by software-based system management, e.g. by storing the data in separate folders. Each user has their own folder to which only they have access. Results data can be deleted by the user at any time. The account will be deleted immediately at the user's request.

Installation

The CASC app can be installed from the relevant app stores using the smartphones mentioned above. To begin with, the user logs in using a one-time password, which is sent to their e-mail address. With this password, the user gains access to the app. If the user logs out, they must repeat the process with the same email address to gain access to their data. Users can only view their own data.

Safety and maintenance

New developments or features go through a detailed process before they are published. First there is a linting, a formal and automated review of the code that the developer has written. The developer then submits a pull request (dual control principle), which must be confirmed by another developer. There are manual QAs for the front end. Firstly, there is feature QA, which checks the functionality of new developments that have been built, and then there is release QA, which tests the entire app before a release. Here a QA list is processed. There are further automated tests for the backend (unit testing, integration testing). A release is staggered over 7 days. This ensures that any errors are detected at an early stage before all users are using the latest version. However, should any malfunctions occur, users can [contact](mailto:hallo@getcasc.com) our support team at hallo@getcasc.com at any time.

The test procedure can be found in the enclosed instructions for use as well as in the video tutorial in the app.

The app does not have to be used to obtain a test result. Users can also read out the test by eye as usual.