

English

iCare PATIENT2



iCare PATIENT2
Instruction Manual for Android

icare

Rx Only (U.S.)

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This device complies with:

Medical Device Regulation (MDR) 2017/745

This instruction manual applies to the iCare PATIENT2 software version 1.1.x, where x is a maintenance revision without impact to this instruction manual.

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1. Intended use

iCare PATIENT2 (TS05) is a mobile app intended for transferring ophthalmic measurement data to iCare CLINIC or to an external system. It also has the capability of displaying ophthalmic measurement data and aiding in glaucoma management. It is indicated for use by healthcare professionals and lay persons.

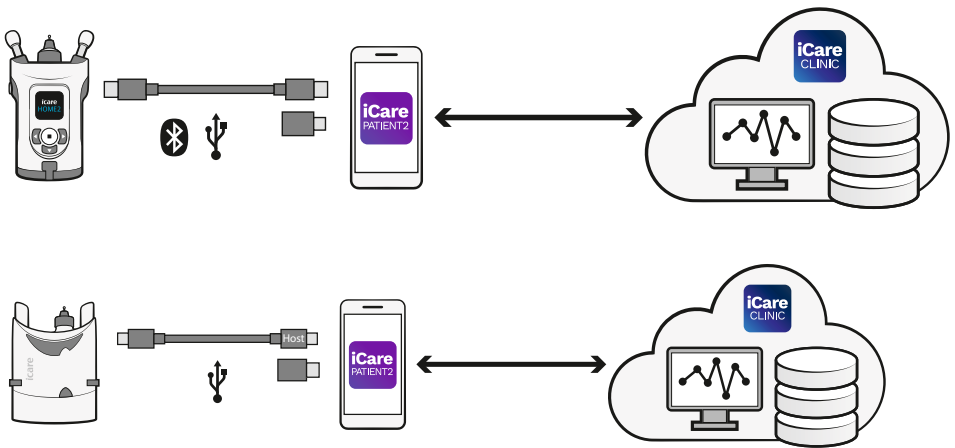
2. Safety notices

-  **WARNING!** Make sure that the mobile device with the iCare PATIENT2 app installed is set to the correct time and date.
-  **WARNING!** Before taking measurements, update the tonometer's clock to your local time manually from the tonometer's settings or automatically by connecting the tonometer to the iCare PATIENT2 app.
-  **PRECAUTION!** Report any serious incidents related to the tonometer to your competent health authority and the manufacturer or the manufacturer's representative.

3. Introduction

The iCare software system consists of the following:

- iCare tonometer (iCare HOME or iCare HOME2), for measuring eye pressure
- iCare PATIENT2 mobile application, where patients and healthcare professionals can view measurement data, as well as transfer and store it to iCare CLINIC, or to iCare CLOUD service
- iCare CLINIC, a browser-based software service, where healthcare professionals and patients can view the measurement data



iCare CLOUD can be used to store eye pressure measurement results transferred from iCare HOME, or iCare HOME2 using iCare PATIENT2. Patients can store their measurement data to a private account in the iCare CLOUD service, providing their tonometer is not registered to a healthcare professional's iCare CLINIC account.

In order to view measurement results with the PATIENT2 app, you need to log in with iCare credentials. For information on how to obtain iCare credentials, see chapter “5. Obtain iCare credentials”.

Your credentials protect your measurement results from others. If the app notifies you of invalid credentials, you have entered a wrong password, or email address, or your password may have been stolen. Do not give your password to anyone else.

If you are a healthcare professional, you can use iCare PATIENT2 just for transferring eye pressure measurement results to the iCare CLINIC. iCare PATIENT2 does not show measurement results with an iCare CLINIC professional account.

iCare PATIENT2 is expected to be used in various conditions changing from home to usage while outside of home. The applications do not introduce any unacceptable residual risk or undesirable side effects and they do not have any contraindications.

For more information on how to operate the HOME or HOME2 devices, see the device's instruction manual.

4. System requirements for iCare PATIENT2

- Android smartphone or tablet with Bluetooth connection or USB OTG support
- Operating system v 6.0 or newer
- USB OTG compliant cable and adaptors, supplied with the iCare HOME or iCare HOME2 tonometer
- Internet connection

To make sure that the iCare PATIENT2 app works correctly, always install the latest software updates available for your mobile device and the iCare PATIENT2 app.

The latest security patches of iCare PATIENT2 are installed with the software updates. Updates are distributed via Google Play store.

5. Obtain iCare credentials

In order to view measurement results with the iCare PATIENT2 app, you need to log in with iCare credentials. If your iCare HOME or iCare HOME2 tonometer is registered to a clinic or hospital CLINIC account, contact the clinic or hospital to obtain the credentials.

Note for healthcare professionals: The patient credentials can be created in iCare CLINIC under the Patient profile tab, in the User account

section, by providing the patient's e-mail address. The patient will receive an invitation email including a link for creating a password.

If your tonometer is not registered to any clinic or hospital CLINIC account, you need to register your tonometer to the iCare CLOUD, in order to use the iCare PATIENT2 app. Please check the "Getting started" guide, delivered together with the iCare HOME or iCare HOME2 tonometer, for instructions on how to register your tonometer. You will get your iCare credentials during the registration process.

If you need help, contact your healthcare professional, tonometer distributor or iCare.

NOTE! iCare CLINIC professional user (doctor, trainer or administrator) credentials cannot be used for logging into the PATIENT2 app. The PATIENT2 app is used only for reviewing an individual patient's results, using an individual patient's CLINIC credentials. The app is also used for uploading measurement data from iCare HOME (s) or iCare HOME2(s) to the iCare CLINIC, in which case logging into PATIENT2 is not needed.

6. Install and start using the app

1. Open Google Play on your mobile device.
2. Search for iCare PATIENT2.
3. Follow the installation instructions shown on the screen.








To start using the app, tap **START USING THE APP**. Select your area of residence and the correct option for where your eye pressure data will be stored. Read the terms of service and agree to the terms of use and to the processing of your personal data, by checking the respective boxes. Choose your tonometer (iCare HOME2 or iCare HOME).

7. Connect to the tonometer using Bluetooth®

7.1. Switch on the tonometer

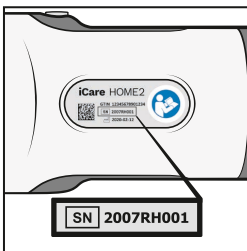
NOTE! The Bluetooth connection is compatible with the iCare HOME2 tonometer only.

Bluetooth may be already activated on your tonometer. You can check your tonometer's Bluetooth status and turn Bluetooth on, if needed, by following these instructions.

1. Press  until you hear a beep to switch on the tonometer.
2. Press  until you see **SETTINGS** on the tonometer screen, and press .
3. Press  until you see **BLUETOOTH**, and press .
4. If Bluetooth is off, press  until you see **TURN ON**, and press .

7.2. Pair the tonometer with your mobile device

1. Tap **Bluetooth**. Allow the prompted requests to continue pairing.
2. Select the correct tonometer from the list of detected iCare HOME2 tonometers. Make sure that the serial number of the tonometer on the mobile device's screen matches that of the one found at the back of the tonometer. The serial number found on your tonometer is marked with SN.



3. Tap **PAIR TONOMETER**.
4. At the Bluetooth pairing request, enter the PIN code shown on the tonometer's screen, and tap **OK**.
5. When the tonometer has been successfully paired, tap **CONTINUE** on the PATIENT2 screen.

You can now tap SYNC to transfer measurement results from the tonometer to iCare CLINIC or iCare CLOUD, or log into the iCare PATIENT2 app, to see your previous measurement results.

8. Transfer measurement data via Bluetooth®

Tip: If you have previously paired your tonometer via USB cable, you will need to pair it again. Go to the settings and tap **Change the tonometer** and re-pair to use Bluetooth pairing.

1. Switch on the tonometer.
2. On your mobile device, open the iCare PATIENT2 app.
3. Tap **SYNC** to transfer your measurements from the tonometer to your mobile device.
4. If a pop up requesting your iCare credentials opens up, type in your user name and password or security code provided by your healthcare provider.

Transferring the measurement results may take up to a couple of minutes, depending on the network connection. You will see the message “[number of] measurements transferred” or the message “no new measurements”, once the data transfer has been completed.

The measurement results remain in the iCare HOME2 tonometer’s memory after the measurement data transfer.

9. Connect and transfer measurement data via USB cable

Tip: If your mobile device asks for your permission to use the iCare PATIENT2 app or the tonometer, tap **OK**. Otherwise, you won’t be able to transfer data and use the app. To avoid having to give the permission every time you use the app, tap the check box in the dialog.

Note: Only use the USB cable supplied with the iCare tonometer.

1. Make sure your mobile device’s screen and keys are not locked.

2. Connect the tonometer to your mobile device with the USB cable provided in the tonometer’s carrying case. Use the USB adaptor delivered in the tonometer carrying case in the event that the cable does not fit into your mobile phone.
3. If a pop up requesting your iCare credentials opens up, type in your user name and password or security code provided by your healthcare provider.

Once the USB cable is successfully connected, the measurement data is transferred automatically from the tonometer to your mobile device and to iCare CLINIC or iCare CLOUD.

Transferring the measurement results may take up to a minute or more, depending on the network connection. You will see the message “[number of] measurements transferred” or the message “no new measurements”, once the data transfer has been completed. Unplug the USB cable after a successful data transfer.

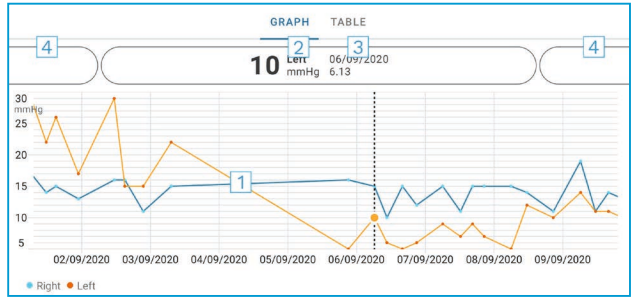
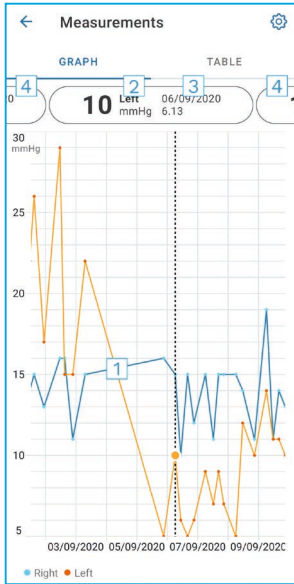
After measurement data transfer, the measurement results are deleted from the iCare HOME2 and HOME tonometers.

10. View your measurement results

10.1. Graph functionality

1. Open the iCare PATIENT2 app on your mobile device.
2. If you are not logged in yet, tap **LOGIN** and enter your iCare credentials. Check chapter “5. Obtain iCare credentials” for information on how to obtain your credentials.
3. Tap **MEASUREMENTS**.

The blue graph shows the measurements of the right eye and the orange graph shows the measurements of the left eye. The graph can be viewed in portrait mode or in landscape mode.



- 1: Selected measurement on the graph
- 2: The result of the selected measurement in mmHg
- 3: Date and time of the measurement
- 4: Tap to open previous or next measurement

To scroll on the graph, slide your finger across the screen.

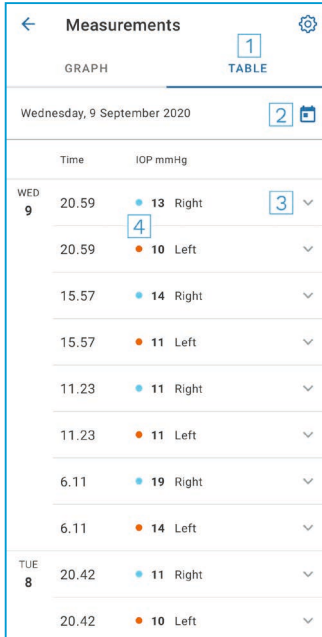
To zoom in and out on the graph, pinch on the touch screen with two fingers and slide them apart or together horizontally.

To see the result of each measurement, tap the dots on the graph or tap the measurement results at the top of the screen. You can also slide the measurement results with your finger to see the next or the previous result.

If a measurement is marked with **◆**, the measurement is outside the selected scale. Tap **◆** to see the measurement result.

To change the scale, tap **⚙️** and tap **Max value in graph** or **Min value in graph**, and select the new values.

10.2. Table functionality



- 1: Tap **Table** to view measurements in list format
- 2: Select date from
- 3: Tap to view measurement quality
- 4: The blue dot shows the measurement of the right eye and the orange dot shows the measurement of the left eye

To scroll on the list, slide your finger vertically across the screen.

11. Change the iCare PATIENT2 settings

Tap > **Settings**.

To define which values are shown on the graph, tap **Max value in graph** or **Min value in graph**, and select the new value.

If you want to use another tonometer with the app, tap **Change the tonometer**. You are automatically logged out from the app.

The app is then ready to transfer measurement data from another device.

12. Log out from iCare PATIENT2

In daily use, you don't need to log out from the app. However, if you have any privacy concerns, log out from the app to prevent others from seeing your measurement results.

Tap  > **Settings > Logout.**

When you are logged out, you can still transfer measurements from the tonometer **to the iCare CLINIC or iCare CLOUD**, but you cannot see them on your mobile device.

If you no longer need to use the iCare PATIENT2 app, you can uninstall it. Uninstalling the app will not delete your eye pressure measurement data from the iCare CLINIC or iCare CLOUD.

13. Troubleshooting

Tip: For contact info, such as iCare’s email addresses, tap  > **Info.**

Issue	Possible explanation and solution
You have connected the USB cable to the tonometer and your mobile device but nothing happens.	Make sure you have connected the cable correctly to your mobile device. Make sure that the app is not in the Measurements view.
You have transferred your measurements from the tonometer, but you cannot see them in your measurement results.	<ol style="list-style-type: none"><li data-bbox="568 762 1016 863">1. Make sure the tonometer is registered under your name. Contact your healthcare professional, tonometer distributor, or iCare.<li data-bbox="568 884 1016 1043">2. Check also that the tonometer’s clock shows the correct time. If it doesn’t, transfer measurement data once from the tonometer to your mobile device. The tonometer’s clock is updated during the transfer.

Issue	Possible explanation and solution
<p>You receive the error message Error occurred during pairing.</p>	<ol style="list-style-type: none"> 1. Make sure that Bluetooth is turned on on your mobile device. 2. Make sure that you have allowed location permission to the app. 3. Make sure that mobile device's location is turned on. <p style="text-align: center;">OR</p> <ol style="list-style-type: none"> 1. Make sure your mobile device is connected to a network. 2. Make sure that the tonometer is switched on and that the Bluetooth connection is on, both on the tonometer and on your mobile device. 3. Restart your mobile device and try again.
<p>You receive the error message Error while reading measurements from tonometer.</p>	<ol style="list-style-type: none"> 1. If connecting via USB cable, disconnect the USB cable from your mobile device and the tonometer, and then connect it again. 2. If connecting via Bluetooth, make sure that the tonometer is switched on and that the Bluetooth connection is on, both on the tonometer and your mobile device. Then tap RETRY or SYNC to try again. 3. Restart your mobile device, open iCare PATIENT2 app, and tap SYNC to try again.
<p>You receive the error message Error while sending measurements to CLINIC.</p>	<p>Make sure your mobile device is connected to a network.</p>

Issue	Possible explanation and solution
<p>You receive the error message USB permission denied.</p>	<ol style="list-style-type: none"> 1. Disconnect the USB cable from your mobile device and then connect it again, allow permission in the pop-up that appears on your mobile device screen. 2. If this does not help, disconnect the USB cable from your mobile device, go to your mobile device's settings and allow permission for the iCare PATIENT2 app to use the USB functionality of your mobile device. Then connect the USB cable again to your mobile device.
<p>You receive the error message Connection error to server. Can't load measurements.</p>	<ol style="list-style-type: none"> 1. Make sure your mobile device is connected to a network. 2. Close the measurements view and open it again. You will also get this error message if you have logged in to the iCare PATIENT2 app with CLINIC healthcare professional credentials instead of patient credentials.
<p>You receive the error message User is not authorized. Can't load measurements.</p>	<p>Your login session has expired. Log in again.</p>
<p>You receive the error message Tonometer has not been registered. Check help for support and more info.</p>	<p>Your tonometer needs to be registered. See chapter "5. Obtain iCare credentials" for information on how to register your tonometer.</p>
<p>You receive the error message Login failed due to an unexpected error.</p>	<ol style="list-style-type: none"> 1. Make sure your mobile device is connected to a network. 2. Try logging in to the iCare PATIENT2 app again. <p>If the problem persists, contact your healthcare professional, tonometer distributor, or iCare.</p>
<p>You receive the error message Invalid credentials. Please check the security code and try again.</p>	<ol style="list-style-type: none"> 1. Make sure your security code is correct. Ask for the security code from your healthcare provider. 2. Try to send the measurement results again <p>If the problem persists, contact home-software-support@icare-world.com.</p>
<p>You receive the error message Device license has expired.</p>	<p>Ask your healthcare or service provider to renew the license.</p>

Issue	Possible explanation and solution
You need help with the iCare PATIENT2 app.	Contact your healthcare professional, tonometer distributor, or iCare.

If the iCare PATIENT2 app is not working correctly, or you find mistakes in this instruction manual, contact **info@icare-world.com**, or if you are located in the U.S., contact **infoUSA@icare-world.com**.

14. Technical description

When the iCare tonometer is connected to a mobile device with the USB cable provided in the tonometer’s carrying case, or via Bluetooth connection, the iCare PATIENT2 app reads eye pressure measurement results from the tonometer. The app also transfers and stores the results in the iCare CLINIC or iCare CLOUD database, on the internet, using the mobile device’s data connection. The app also uses the data connection to read the measurement results from the database, as the results are stored in the database only, not on the mobile device.

Do not connect the mobile device with the iCare PATIENT2 app installed to a healthcare professional’s IT network, to which the healthcare professional’s medical devices or software are connected.

The mobile device with the iCare PATIENT2 app installed can use any internet connection that allows HTTPS communication.





If the data connection fails, the measurement results cannot be transferred from the iCare tonometer to the iCare CLINIC database, and the measurement results cannot be viewed.

The eye pressure measurement results are displayed in millimeters of mercury (mmHg) with the precision of one millimeter of mercury. The available scale of the y-axis is from 5 mmHg to 50 mmHg.

The specified measurement scale of iCare HOME tonometer is 5-50 mmHg, and the specified measurement scale of iCare HOME2 tonometer is 7-50 mmHg.

The main cybersecurity risk of iCare PATIENT2 is related to malware and virus protection of your mobile device. Make sure that the virus and malware protection are up to date in your mobile device.

15. Symbols

	Manufacturer
	Caution
Rx Only (U.S.)	Federal law (U.S.) restricts this device to sale by or on the order of a physician or properly licensed practitioner.
	CE mark
	Product is a medical device



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