

English

**iCare** PATIENT2



iCare PATIENT2  
Instruction Manual for iOS

**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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**Icare Finland Oy**

Äyritie 22

01510 Vantaa, Finland

Ph. +358 0 9775 1150

**[www.icare-world.com](http://www.icare-world.com), [info@icare-world.com](mailto:info@icare-world.com)**

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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.

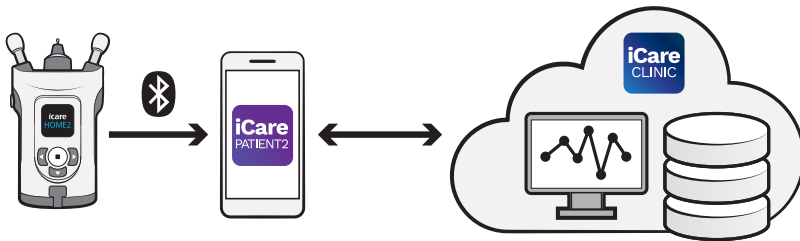
# 2. Safety notices

-  **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 HOME2 tonometer, for measuring eye pressure
- iCare PATIENT2 mobile application, where patients and healthcare professionals can view measurement data, or transfer and store it to the iCare CLINIC, or to the 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 HOME2, using iCare PATIENT2. Patients can store their measurement data to a private account in the iCare CLOUD service, if 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 HOME2 device, see iCare HOME2 Instruction Manual.

## 4. System requirements for iCare PATIENT2

- iPhone or iPad
- Operating system iOS 12 or newer
- Internet connection

To make sure that the iCare PATIENT2 app works properly, 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 App 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 HOME2 tonometer is registered to a clinic or hospital CLINIC account, contact the clinic or hospital to get 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 e-mail 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 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 HOME2(s) to the iCare CLINIC, in which case logging into PATIENT2 is not needed.

## 6. Install the app

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








## 7. Connect your mobile device to the tonometer using Bluetooth®

### 7.1. Switch on the tonometer

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

**NOTE!** iCare HOME is compatible with Android mobile devices only.

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

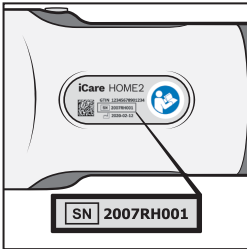
1. Press  until you hear a beep to switch on the tonometer.
2. Press  until you see **SETTINGS** on the tonometer screen, and press .
3. Press  until you see **BLUETOOTH**, and press .
4. If Bluetooth is off, press  until you see **TURN ON**, and press .

### 7.2. Pair the tonometer with your mobile device

1. Go to your mobile device’s settings and switch Bluetooth on.
2. Open the iCare PATIENT2 app and tap **START USING THE APP**.
3. Select your area of residence and the correct option for where your eye pressure data will be stored.
4. 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.

5. Tap **CONTINUE**.
6. Tap **SCAN DEVICES**. If the app asks for a permission to use Bluetooth, tap **OK**.
7. 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.



8. Tap **PAIR TONOMETER**.
9. At the Bluetooth pairing request, enter the PIN code shown on the tonometer's screen, and tap **Pair**.
10. When the tonometer has been successfully paired with your mobile device, 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

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.

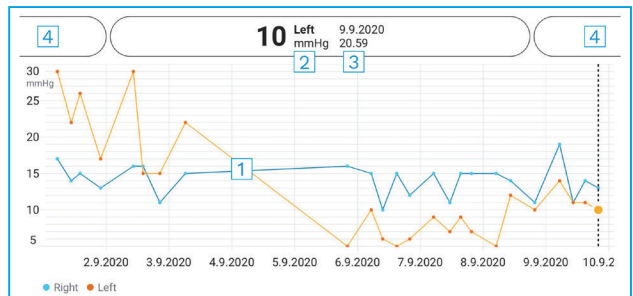
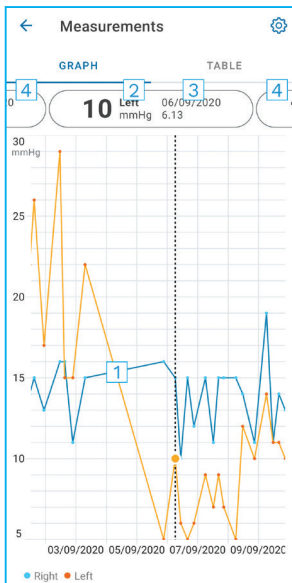
Measurement results are deleted from the tonometer’s memory after they have been stored to the cloud.

## 9. View your measurement results

### 9.1. 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

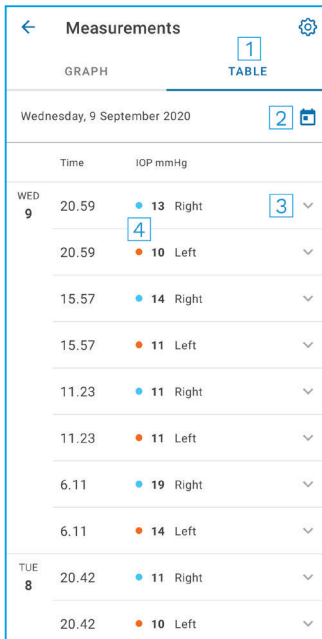
To scroll on the graph, slide your finger across the screen.

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. 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.

## 9.2. Table functionality



Time	IOP mmHg
WED 9	
20.59	● 13 Right
20.59	● 10 Left
15.57	● 14 Right
15.57	● 11 Left
11.23	● 11 Right
11.23	● 11 Left
6.11	● 19 Right
6.11	● 14 Left
TUE 8	
20.42	● 11 Right
20.42	● 10 Left

- 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.

## 10. Change the iCare PATIENT2 settings


In Home view, 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.

## 11. 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.

In Home view, 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.

## 12. Troubleshooting

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

<b>Issue</b>	<b>Possible explanation and solution</b>
You receive the error message <b>Cannot scan for devices</b> .	<ol style="list-style-type: none"><li data-bbox="568 948 1020 999">1. Switch on the Bluetooth connection on your mobile device.</li><li data-bbox="568 1015 1020 1118">2. Allow iCare PATIENT2 permission to use Bluetooth on your mobile device: go to <b>Settings</b> of your mobile device &gt; <b>iCare PATIENT2</b>, and switch Bluetooth on.</li></ol>

Issue	Possible explanation and solution
You receive the error message <b>Error during pairing.</b>	<ol style="list-style-type: none"> <li>1. Make sure that your mobile device is connected to a network.</li> <li>2. Pair the tonometer with your mobile device again and make sure that you entered the correct PIN code in Bluetooth pairing request.</li> <li>3. Make sure that the tonometer is switched on and that the Bluetooth connection is on, both on the tonometer and on your mobile device.</li> <li>4. Make sure that using Bluetooth is permitted on your mobile device.</li> </ol>
You have transferred your measurements from the tonometer, but you cannot see them in your measurement results.	<ol style="list-style-type: none"> <li>5. Make sure the tonometer is registered under your name. Contact your healthcare professional, tonometer distributor, or iCare.</li> <li>6. 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.</li> </ol>
You receive the error message <b>Error while reading measurements from tonometer.</b>	<ol style="list-style-type: none"> <li>1. Make sure that the tonometer is switched on and the Bluetooth connection is on, both on the tonometer and on your mobile device.</li> <li>2. Make sure that you have allowed iCare PATIENT2 permission to use Bluetooth on your mobile device: go to Settings of your mobile device &gt; iCare PATIENT2, and switch Bluetooth on.</li> </ol>
You receive the error message <b>Error while sending measurements to CLINIC.</b>	Make sure your mobile device is connected to a network.
You receive the error message <b>Connection error to server. Can't load measurements.</b>	<ol style="list-style-type: none"> <li>1. Make sure your mobile device is connected to a network.</li> <li>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.</li> </ol>
You receive the error message <b>User is not authorized. Can't load measurements.</b>	Your login session has expired. Log in again.

Issue	Possible explanation and solution
You receive the error message <b>Tonometer has not been registered.</b>	Your tonometer needs to be registered. See chapter “5. Obtain iCare credentials” for information on how to register your tonometer.
You receive the error message <b>Login failed due to an unexpected error.</b>	<ol style="list-style-type: none"> <li>1. Make sure your mobile device is connected to a network.</li> <li>2. Try logging in to the iCare PATIENT2 app again.</li> </ol> <p>If the problem persists, contact your healthcare professional, tonometer distributor, or iCare.</p>
You receive the error message <b>Invalid credentials. Please check the security code and try again.</b>	<ol style="list-style-type: none"> <li>1. Make sure your security code is correct. Ask for the security code from your healthcare provider.</li> <li>2. Try to send the measurement results again.</li> </ol> <p>If the problem persists, contact home-software-support@icare-world.com.</p>
You receive the error message <b>Device license has expired.</b>	Ask your healthcare or service provider to renew the license.
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**.

## 13. Technical description

When the iCare HOME2 tonometer is connected to a mobile device with a 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 HOME2 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 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.

## 14. Symbols

	Manufacturer
	Caution
<b>Rx Only (U.S.)</b>	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





### Icare Finland Oy

Äyritie 22  
01510 Vantaa, Finland  
Ph. +358 0 9775 1150  
info@icare-world.com

### Icare USA, Inc.

4700 Falls of Neuse Rd. Ste 245  
Raleigh, NC. 27609  
Ph. +1 888.422.7313  
Fax +1 877.477.5485  
infoUSA@icare-world.com

[www.icare-world.com](http://www.icare-world.com)

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