



Icare CLINIC



Icare EXPORT



Icare PATIENT app

**INSTRUCTION MANUAL**  
FOR HEALTHCARE PROFESSIONALS  
ENGLISH



Rx only

Icare CLINIC (Type: TS02), Icare EXPORT (Type: TS03) and Icare PATIENT (Type: TS04) - Instruction Manual for Healthcare Professionals TS02-013-US-2.4

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The information in this document is subject to change without prior notice.

In a conflict situation, the English version prevails.

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## 1 SAFETY INSTRUCTIONS



It is important that the internal clock of the Icare HOME tonometer is up to date when measuring. The time of the clock may need to be updated if tonometer has been stored without batteries, if the batteries have run out of charge, or if the user of the tonometer has travelled to a new time zone. Therefore, in these situations, it is recommended to either

- a) connect the tonometer to computer using the provided cable and start Icare EXPORT or
- b) using the provided cable, connect the tonometer to smartphone or tablet that has Icare PATIENT installed.

The internal clock gets automatically updated to the time of the connected computer, smartphone or tablet.



Ensure that the computer, smartphone or tablet running the Icare EXPORT or PATIENT application is set to the correct time and date.



The IOP notifications received via email do not replace healthcare professionals' established processes for IOP supervision.



Federal law (U.S.) restricts this device to sale by or on the order of a physician.

## 2 INTRODUCTION

This is the healthcare professional's instruction manual for the Icare CLINIC, PATIENT and EXPORT applications.

**Icare CLINIC** is a browser-based software service designed for managing patient information, managing patient training and certification for the use of the Icare HOME tonometer, managing a clinic's fleet of Icare tonometers and managing the IOP measurement data. Refer to chapter 4.4 for the use of the Icare CLINIC service.

**Icare EXPORT** is a desktop application for installation on a PC running an MS Windows operating system. It is designed for uploading IOP results from Icare tonometers (ic200, HOME) to the database of the Icare CLINIC service. Icare EXPORT can also be used for viewing the IOP results stored in an Icare tonometer and storing the IOP results in a local file. Refer to chapter 4.50 for the use of the Icare EXPORT application.

**Icare PATIENT** is a smartphone / tablet app designed for uploading IOP results from an Icare HOME tonometer to the database of the Icare CLINIC service. Refer to chapter 4.6 for the use of the Icare PATIENT application.

This instruction manual is applicable for Icare CLINIC service version 1.4.x, Icare EXPORT application version 2.0.x and Icare PATIENT app version 1.1.x where x indicates a minor revision. New versions of this instruction manual are created on an as needed basis.

**Safety incidents:** For reporting serious incidents with the software or a tonometer used with it, contact Icare technical service at [www.icaretonometer.com](http://www.icaretonometer.com).

### 3 INDICATIONS FOR USE

The family of software consisting of Icare CLINIC, Icare EXPORT and Icare PATIENT is indicated for:

- transferring IOP (intraocular pressure) measurement data from Icare tonometers to the Icare CLINIC service
- showing and printing charts based on the measurement data
- exporting, importing and maintaining patient data and measurement history

### 4 GETTING STARTED

Icare CLINIC is used over an internet connection. A user's organization needs to subscribe to Icare CLINIC in order to use it. See [www.icarehome.com](http://www.icarehome.com) for information about subscribing to Icare CLINIC. Once an organization has subscribed to Icare CLINIC, the organization's administrator, as defined when subscribing to Icare CLINIC, is sent access instructions. The administrator then adds more users, with each then receiving personal access instructions via their email.

Users need either Icare EXPORT or Icare PATIENT to upload IOP data to the Icare CLINIC database. Icare EXPORT installer file can be downloaded from the *Help* menu of Icare CLINIC.

Icare PATIENT is available free-of-charge from the Google Play application store. See 4.1 for information about installing and starting Icare CLINIC, Icare EXPORT and Icare PATIENT. See 4.3.2 for description about typical process of using the service and applications.

## 4.1 Installation and system requirements

Icare CLINIC is installed by Icare Finland Oy on a server located in the internet. Refer to Appendix 1 Technical description for further information. Icare EXPORT is to be installed by a person with administrator's privileges on the Windows based PC used. Icare PATIENT is installed by the user on a compatible smartphone or tablet.

### 4.1.1 System requirements for using Icare CLINIC

- Internet connection
- Minimum web browser versions: IE 11, Chrome (v 58), Firefox (v 53) and Safari (5.1.7)

### 4.1.2 System requirements and installation of Icare EXPORT

Minimum PC requirements for Icare EXPORT:

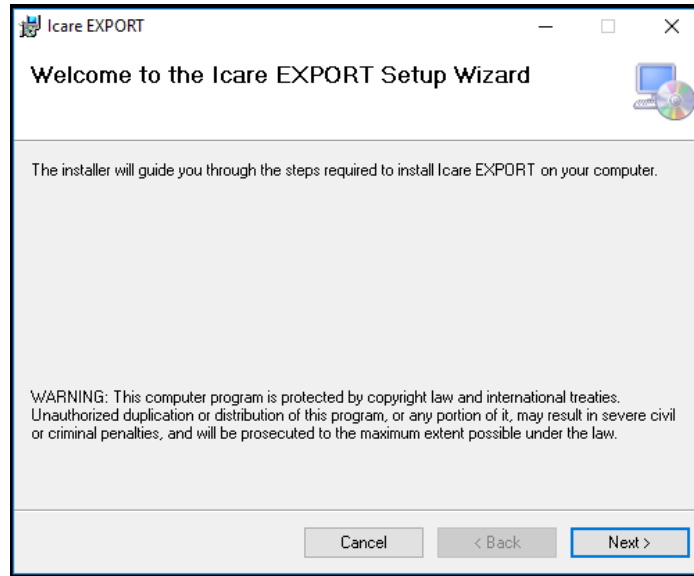
- x86 or x64 1 GHz Pentium processor or equivalent
- 512 MB RAM
- 512 MB of hard disk space (in addition, 4.5 GB if .NET not already installed, see step 1)
- USB 2.0 connection
- 800 x 600 resolution display with 256 colors
- DirectX 9 compatible Graphics Card
- .NET Framework 4.6.1 or greater
- Operating System: Windows 7, Windows 8 or Windows 10
- Internet connection

In addition to the requirements above, the PC requirements for using Icare EXPORT with the ic200 tonometer are

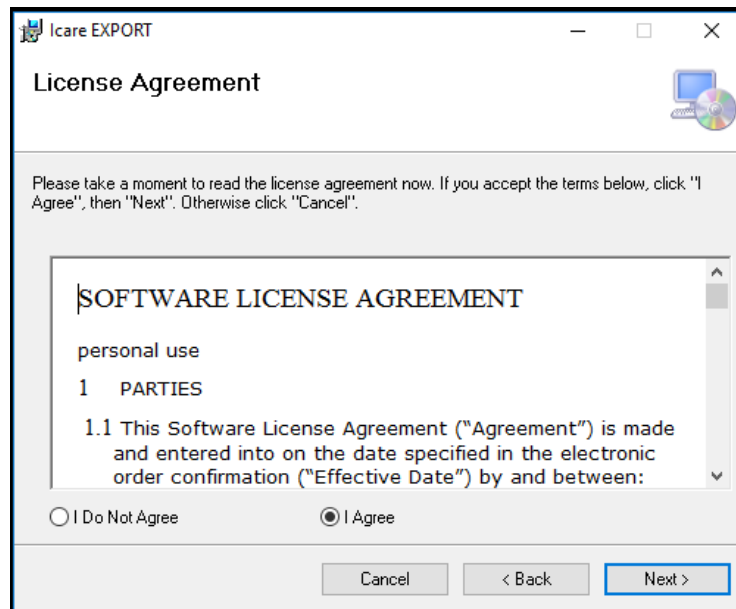
- Operating system: Windows 10 version 1703 or newer
- Bluetooth Low Energy (BLE)

To install Icare EXPORT, follow the instructions in the following steps:

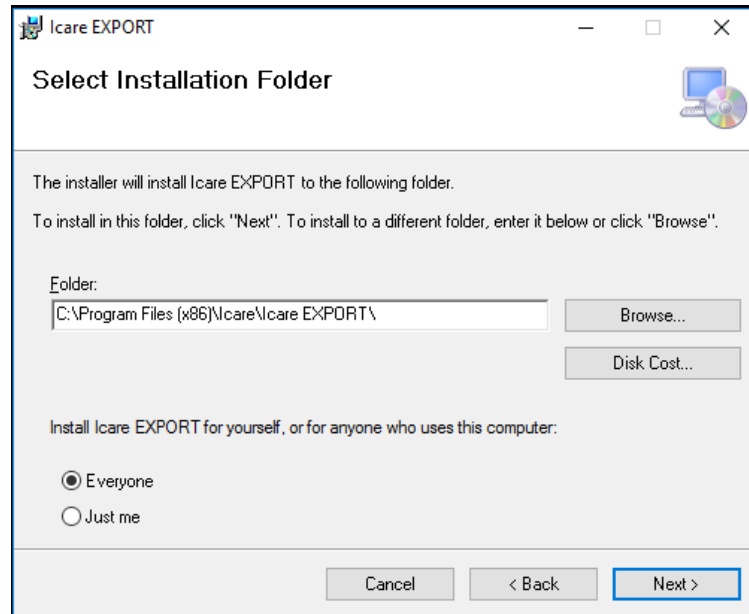
1. Double-click the *Icare EXPORT Setup.exe* file. A setup wizard window appears. The PC will notify if Microsoft's .NET framework has not been installed. (Follow the instructions displayed by the PC to install the .NET framework). Click *Next*.



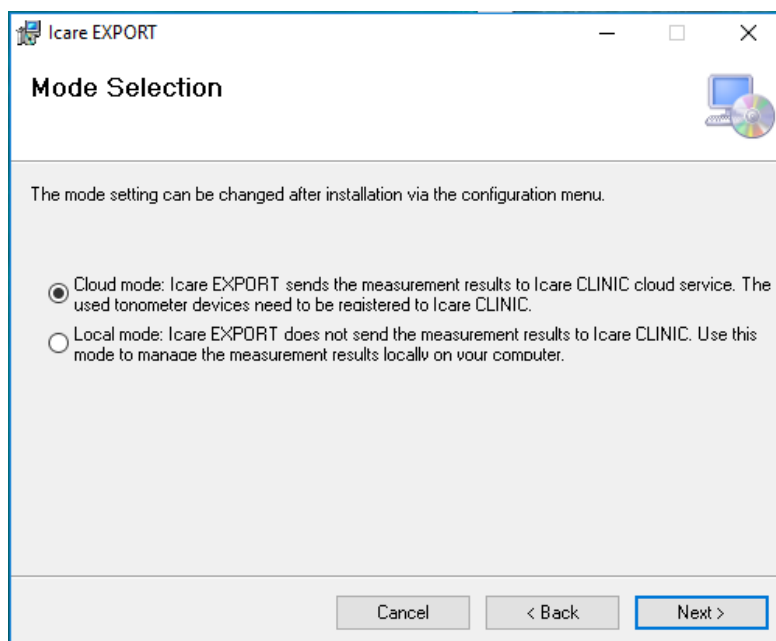
2. A window requesting agreement with the licensing terms appears. Confirm the terms by ticking *I agree* and click *Next*.



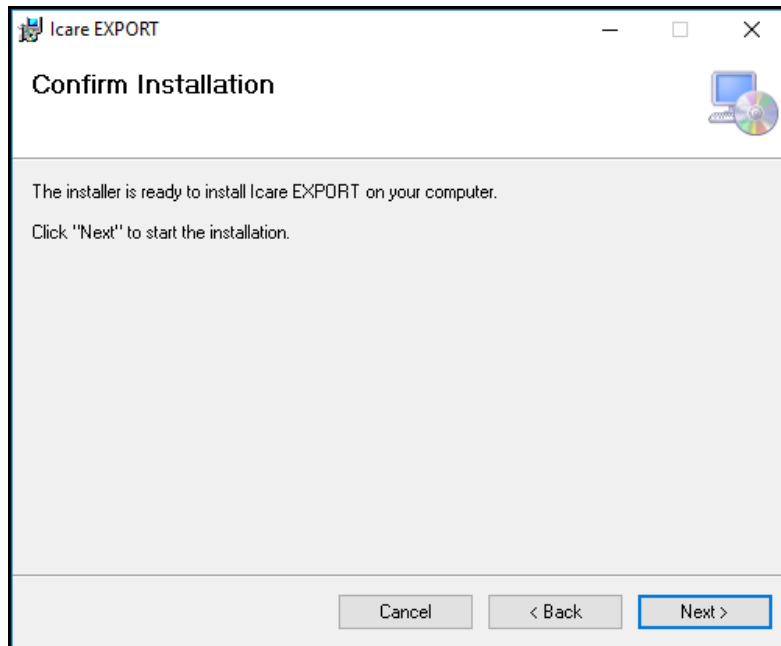
3. A window for selecting the installation folder appears. Select a folder to install the application. Select *Everyone* to allow Icare EXPORT to be visible to all users of the computer; select *Just me* to restrict use of the application to the installer of the application. Click *Next*.



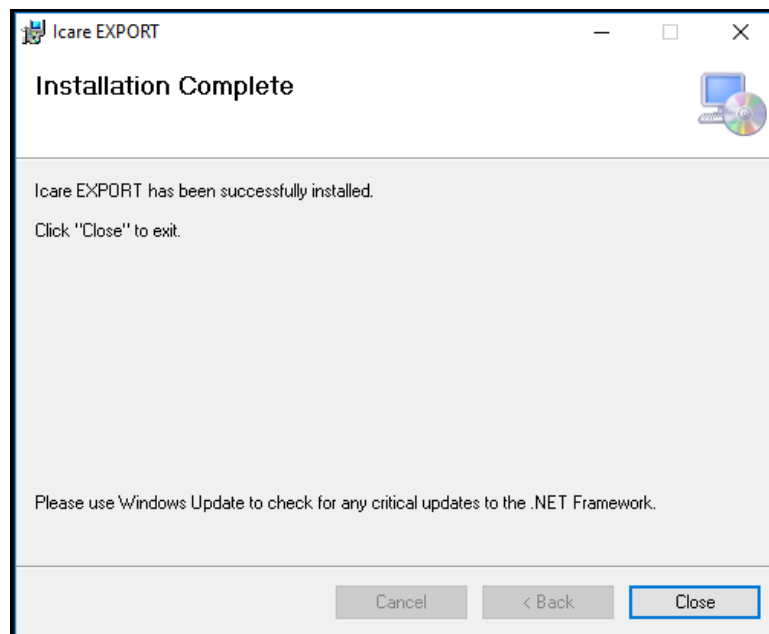
4. Choose to install Icare EXPORT in cloud mode or local mode. In cloud mode Icare EXPORT sends the measurement results from the device to Icare CLINIC service. Local mode should be selected if the user's purpose is to manage the IOP measurement results locally in the computer. The mode setting can be changed after installing Icare EXPORT.



5. A window to confirm installation of Icare EXPORT appears. Click *Next* to start installation.



6. A window indicating completed installation appears. Click *Close* to finish installation process.



You are now ready to start using the Icare EXPORT application. Start the application by clicking the Icare EXPORT icon on the desktop of the PC.

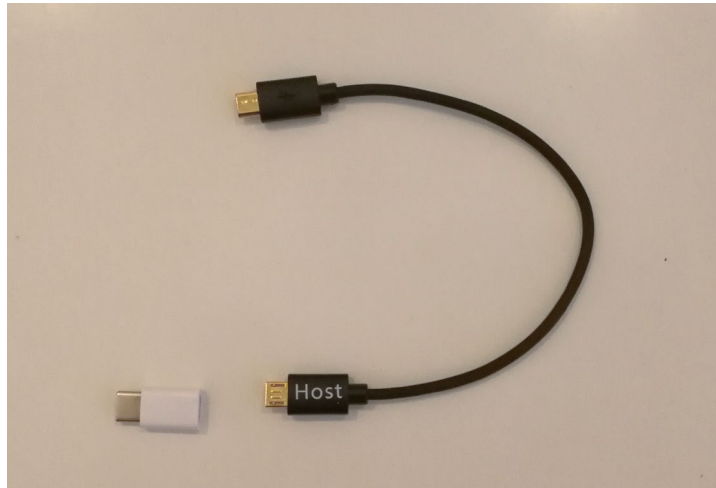
#### 4.1.3 System requirements and installation of Icare PATIENT

Minimum system requirements for the Icare PATIENT app:

Android smartphone (or tablet) with

- Operating system v 4.0.1 or later with USB OTG support
- USB OTG micro B male – micro B male cable (available from your Icare HOME distributor).

**NOTE:** Connect the plug marked **Host** to your smartphone or tablet. Depending on your smartphone or tablet, you may have to plug in an additional USB micro B to C (the small part in the picture), or other adapter to the **Host** plug of the cable.



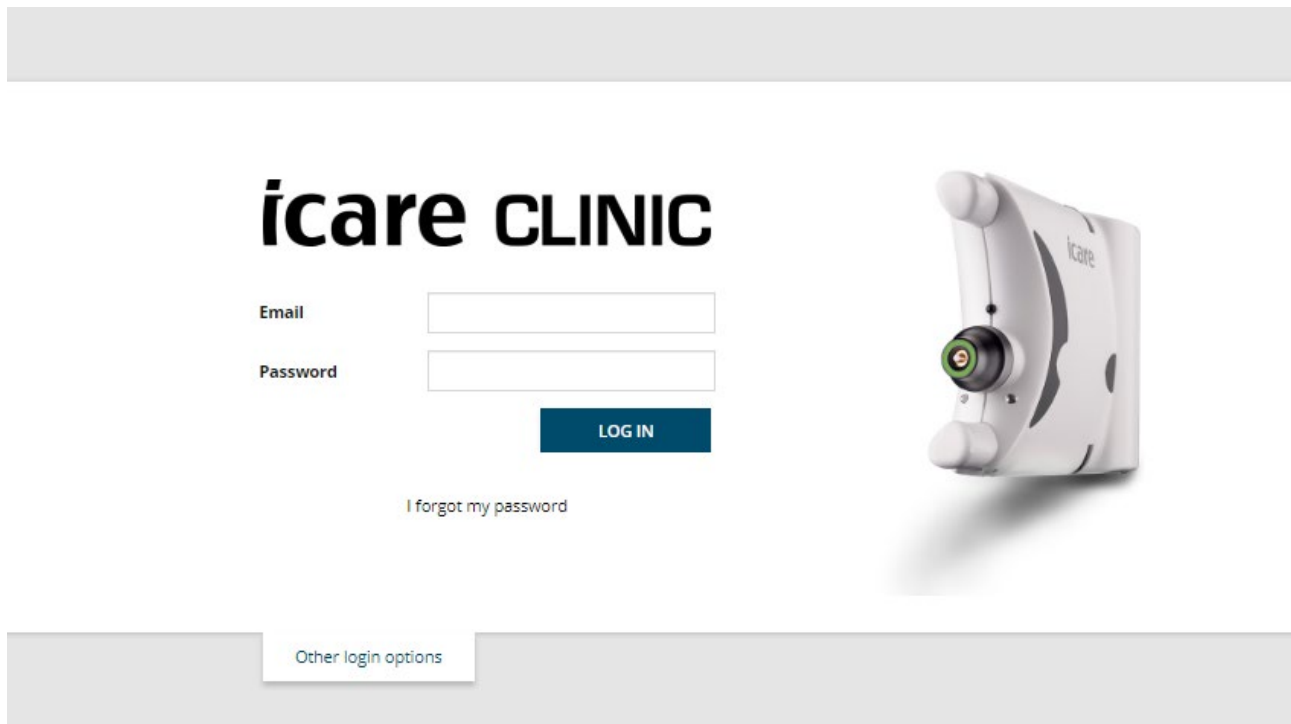
- Internet connection

To verify the required USB OTG support in the smartphone or tablet, you may use OTG? (available from Google Play) or another application providing equivalent functionality.

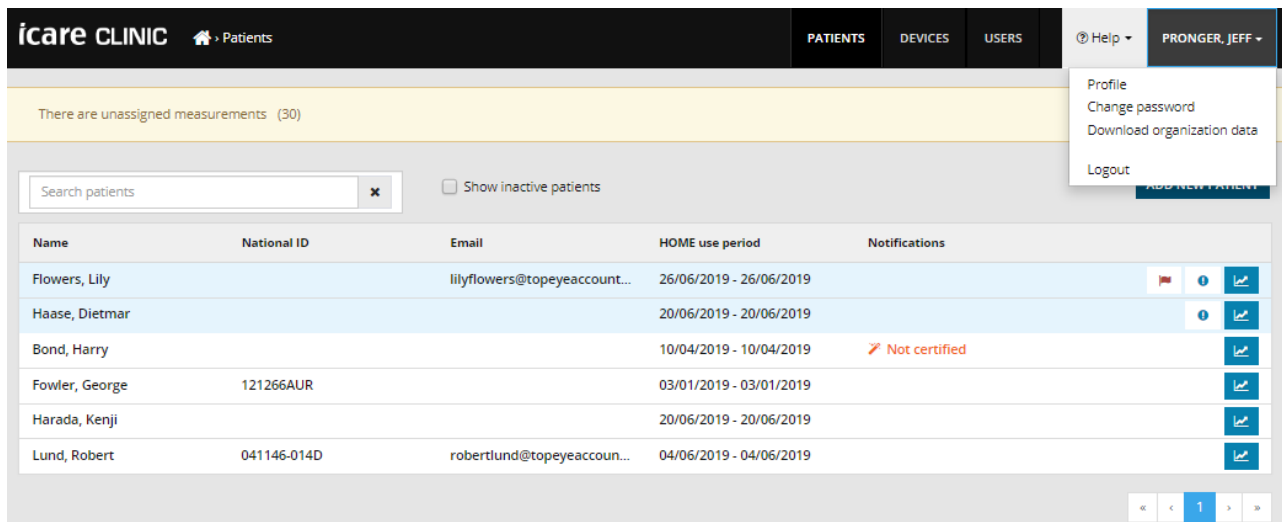
To install Icare PATIENT search for Icare PATIENT in the Google Play application store and then follow the installation instructions displayed on the smartphone or tablet screen.

## 4.2 Start-up and shutdown

To start Icare CLINIC, open a web browser on the login page and login with your email address and password. You will have earlier received an email providing the link to the login page and asking you to set a password after your organization's administrator added you as a user to Icare CLINIC. Alternatively, it is possible to configure Icare CLINIC to use a username and password provided by your organization to login to Icare CLINIC. In that case, click *Other login options* and choose your organization from the list opened. Contact [icare-mhome-support@icarefinland.com](mailto:icare-mhome-support@icarefinland.com) for information how to set this configuration for your organization.



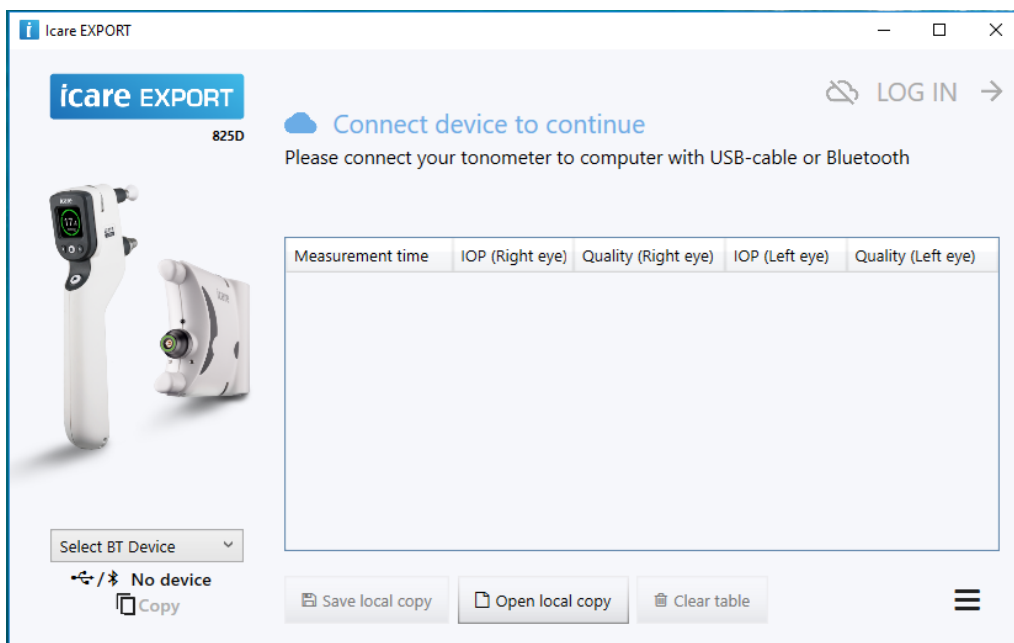
To stop using Icare CLINIC and exit, select the logout function from the drop-down menu, accessed from the top right-hand corner of the user interface.



To start Icare EXPORT, click the icon on the PC desktop or connect an Icare tonometer to the computer using the USB cable provided. The icon is created during the installation of Icare EXPORT.



To shut-down Icare EXPORT, click the close symbol (x) in the upper right-hand corner of the application window.



To start Icare PATIENT, connect an Icare HOME tonometer to the used smartphone or tablet using the USB OTG cable. To shut down Icare PATIENT app, use the application management functionality of the smartphone or tablet.

## 4.3 Overview of Icare CLINIC

### 4.3.1 User rights by user role

	Patient	Physician and trainer	Administrator
Create new users			X
View user list			X
View and edit user information			X
View and edit organization			X
Manage organization's devices		X	X
Add patients to Icare CLINIC		X	X
View patient list		X	X
View and edit patient information		X	X
Activate and deactivate patients		X	X
Certify patients		X	X
Define HOME use periods		X	X
View results and reports		X	X
Upload results from ic200 tonometer using Icare EXPORT		X	X
Upload results from HOME tonometer using Icare PATIENT	X	X	X
Upload results from HOME tonometer using Icare EXPORT	X	X	X
View own patient profile*	X		
View own HOME use periods*	X		
View own results and reports*	X		

*Table 1 Features enabled for the various user roles*

\* It is required that a physician or trainer enables a patient to view their own results.

### 4.3.2 Typical use of the Icare CLINIC service with the Icare HOME tonometer

In clinics, the Icare CLINIC service is typically used as described below.

1. A physician or trainer adds a new patient to the database when needed. See 4.4.3.
2. A physician or trainer trains and certifies the new patient. See 4.4.5.
3. A physician or trainer defines a new HOME use period for a patient. See 4.4.6.

The patient can loan a HOME tonometer from the clinic or use their own tonometer during the period.

4. The patient self-measures their own IOP using an Icare HOME tonometer during the defined HOME use period.



#### PRECAUTION

It is important that the internal clock of the Icare HOME tonometer is up to date when measuring. The time of the clock may need to be updated if tonometer has been stored without batteries, if the batteries have run out of charge, or if the user of the tonometer has travelled to a new time zone. Therefore, in these situations, it is recommended to either

- a) connect the tonometer to computer using the provided cable and start Icare EXPORT or
- b) using the provided cable, connect the tonometer to smartphone or tablet that has Icare PATIENT installed.

The internal clock gets automatically updated to the time of the connected computer, smartphone or tablet.



#### PRECAUTION

Ensure that the computer, smartphone or tablet running the Icare EXPORT or PATIENT application is set to the correct time and date.

5. The patient, or a professional user uses Icare EXPORT or Icare PATIENT to upload measurement results to the Icare CLINIC database. See 4.50 and 4.6 for uploading the results.
6. A physician or trainer creates a report from the patient's selected IOP results. The report may be printed or saved as a PDF and stored to another software system of the clinic for later review. See 4.4.7.
7. A physician or trainer marks the tonometer as returned by clicking the v symbol in the HOME use periods list. The tonometer cannot be used for another HOME use period before it has been marked as returned.

## 4.4 Using Icare CLINIC

### 4.4.1 Introduction to the user interface of Icare CLINIC

The **Landing page** lists the patients with information available. Logging into Icare CLINIC initially takes the user to the landing page.

The screenshot shows the 'Patients' page in Icare CLINIC. The header includes the logo, a breadcrumb 'Patients', and navigation tabs for 'PATIENTS', 'DEVICES', and 'USERS'. A user profile for 'PRONGER, JEFF' is shown in the top right. A yellow notification banner states 'There are unassigned measurements (9)' with an 'Assign measurements' button. Below this is a search bar for patients, a checkbox for 'Show inactive patients', and an 'ADD NEW PATIENT' button. The main content is a table of patients:

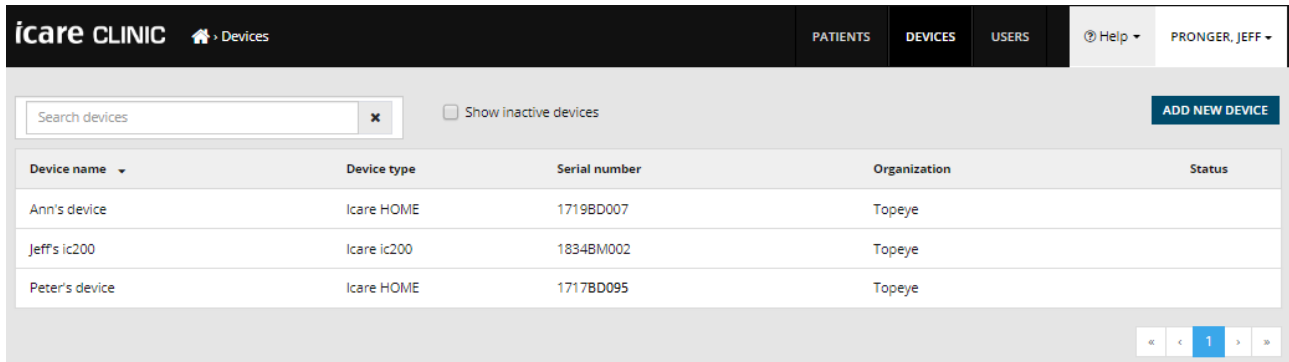
Name	National ID	Email	HOME use period	Notifications
Harrison, Peter			09/01/2019 - 09/01/2019	Not certified
Harrison, William	031066-011D		10/12/2018 - 12/12/2018	
Flowers, Lily		lily.flowers@telco.com	22/01/2019 - 24/01/2019	
Fowler, George	121266AUR		03/01/2019 - 03/01/2019	Return overdue
Lund, Robert	041146-014D		09/09/2017 - 09/09/2017	Not certified

**User list** displays the organization's professional users to the administrator. To access the user list, organization's administrator clicks the *USERS* button. Users only having the role Trainer or Physician cannot access the user list.

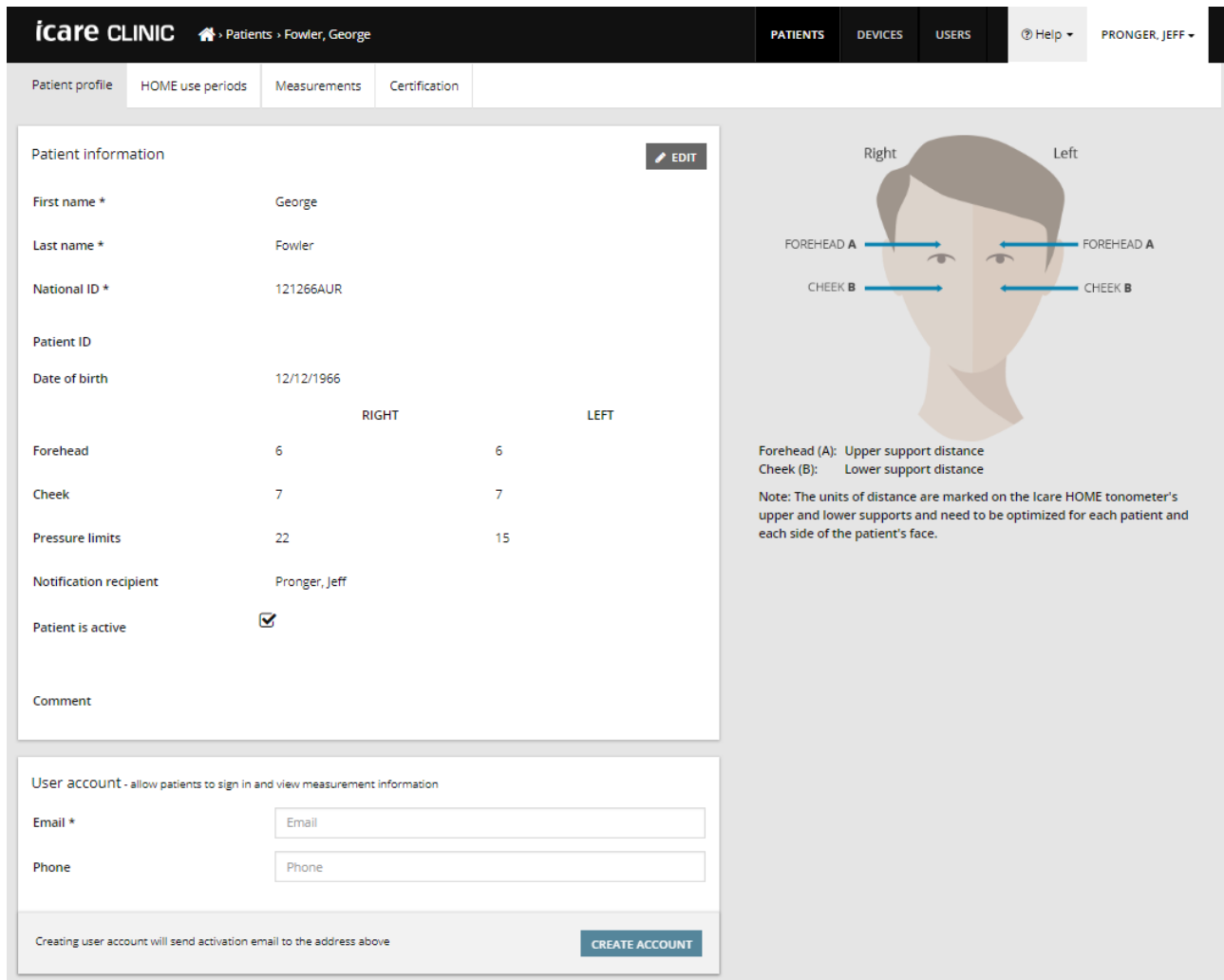
The screenshot shows the 'Users' page in Icare CLINIC. The header includes the logo, a breadcrumb 'Users', and navigation tabs for 'PATIENTS', 'DEVICES', and 'USERS'. A user profile for 'PRONGER, JEFF' is shown in the top right. A search bar and an 'ADD NEW USER' button are visible. The main content is a table of users:

Name	Email	Organization	Status	Last login
Elliot, Peter	peter.elliott@topeye.com	Topeye	Trainer	14/12/2018
Lewinsky, Ann	ann.lewinsky@topeye.com	Topeye	Physician	14/12/2018
Pronger, Jeff	Jeff.Pronger@topeye.com	Topeye	Administrator	14/12/2018

**Device list** displays the organization’s devices. To view the device list, click the *DEVICES* button.



**Patient profile** shows each patient’s individual information. To view a patient profile, click a patient name in the patient list shown on the landing page.



**HOME use periods** list shows the periods during which a patient has previously been self-measuring with the Icare HOME tonometer. New HOME use periods are also defined from this page. To access HOME use periods, click the HOME use periods information on the landing page or click the *HOME use periods* tab after selecting a patient from the landing page.

The screenshot shows the Icare CLINIC interface for patient 'Flowers, Lily'. The 'HOME use periods' tab is active. The table below lists the recorded use periods:

Period start	Period end	Device type	Device name	Measurement count
22/01/2019 @ 10:25	24/01/2019 @ 23:59	Icare HOME	Ann's device	0
03/12/2018 @ 15:06	07/12/2018 @ 23:59	Icare HOME	Ann's device	12
13/08/2018 @ 14:07	17/08/2018 @ 23:59	Icare HOME	Ann's device	12

**Measurement list** shows the measurements from a patient. To access the measurement list, click the measurement icon on the landing page or click the *Measurements* tab after selecting a patient from the landing page.

The screenshot shows the Icare CLINIC interface for patient 'Harrison, Peter'. The 'Measurements' tab is active. The table below lists the recorded measurements:

Measurement time	Device type	Device name	IOP (OD)	Quality OD	IOP (OS)	Quality OS	Controls
14/12/2018 @ 16:01	No device specified		19		-		<input type="checkbox"/> Exclude
14/12/2018 @ 16:00	Icare HOME	Jeff's device	-		8	Rejected	<input checked="" type="checkbox"/> Exclude
14/12/2018 @ 16:00	Icare HOME	Jeff's device	10	Good	-		<input type="checkbox"/> Exclude
14/12/2018 @ 15:59	Icare HOME	Jeff's device	-		10	Excellent	<input type="checkbox"/> Exclude
14/12/2018 @ 15:59	Icare HOME	Jeff's device	10	Excellent	-		<input type="checkbox"/> Exclude
14/12/2018 @ 15:58	Icare HOME	Jeff's device	-		10	Excellent	<input type="checkbox"/> Exclude
14/12/2018 @ 15:57	Icare HOME	Jeff's device	8	Excellent	-		<input type="checkbox"/> Exclude
14/12/2018 @ 15:55	Icare HOME	Jeff's device	7	Excellent	-		<input type="checkbox"/> Exclude
14/12/2018 @ 15:48	Icare HOME	Jeff's device	7	Good	-		<input type="checkbox"/> Exclude

#### 4.4.2 Managing user accounts

An organization's administrator is defined when the organization subscribes to Icare CLINIC. The administrator user adds additional users to Icare CLINIC. The administrator clicks the *USERS* button on the landing page to view the user list. The administrator clicks the *ADD NEW USER* button to add a new user.

The screenshot shows the 'New user' form in the Icare CLINIC interface. The form is a modal window with the following fields:

- Email \***: Text input field with placeholder 'Email'.
- First name \***: Text input field with placeholder 'First name'.
- Last name \***: Text input field with placeholder 'Last name'.
- Address**: Text input field with placeholder 'Address'.
- Zip code**: Text input field with placeholder 'Zip code'.
- City**: Text input field with placeholder 'City'.
- Phone**: Text input field with placeholder 'Phone'.
- Role \***: Dropdown menu with placeholder 'Role'.

At the bottom of the form are two buttons: 'CANCEL' and 'SUBMIT'. The background shows a user list table with columns for Name and Email, and a status legend on the right.

In the user profile, the obligatory information is: email address, first name, last name and the user's role. The email address is used as a user's user name to log into Icare CLINIC. The web link needed for defining the password is sent via email to the added user.

### 4.4.3 Managing patient information

After logging into Icare CLINIC, a user is displayed the landing page showing a patient list comprising the patients added to the Icare CLINIC's database. The patients can be sorted in alphabetical order (column *Name*) or based on ID (column *ID*) or email address (column *Email*). Patients with results that have exceeded the defined IOP notification limit (red flag) populate the beginning of the list. Patients with new results (exclamation mark) are listed next and then the rest of the patients.

The screenshot shows the Icare CLINIC interface for managing patients. At the top, there is a navigation bar with 'icare CLINIC' and 'Patients' on the left, and 'PATIENTS', 'DEVICES', 'USERS', 'Help', and 'PRONGER, JEFF' on the right. Below the navigation bar, there is a yellow banner indicating 'There are unassigned measurements (9)' with an 'Assign measurements' button. A search bar is present with the text 'Search patients' and a 'Show inactive patients' checkbox. A table lists patients with the following data:

Name	National ID	Email	HOME use period	Notifications
Harrison, Peter			09/01/2019 - 09/01/2019	Not certified
Harrison, William	031066-011D		10/12/2018 - 12/12/2018	
Flowers, Lily		lily.flowers@telco.com	22/01/2019 - 24/01/2019	
Fowler, George	121266AUR		03/01/2019 - 03/01/2019	Return overdue
Lund, Robert	041146-014D		09/09/2017 - 09/09/2017	Not certified

Each row in the table has a small icon (flag or exclamation mark) and a blue button with a magnifying glass icon. At the bottom right of the table, there is a pagination control showing '1' and navigation arrows.

The column *HOME use period* indicates the most recent period during which a patient has been measuring IOP using an Icare HOME tonometer. Clicking the shown period opens the list of all HOME use periods of the selected patient, see 4.4.6 for more.

The column *Notifications* provides information on the patient's status. *Return overdue* indicates that the patient has not returned the device loaned by the clinic (defined by the HOME use period). The *Return overdue* notification appears after a full calendar day has elapsed since the end of the HOME use period. *Not certified* indicates that the patient has not been certified to use the Icare HOME tonometer following the patient certification procedure of Icare CLINIC.

To view a user profile of a patient, click one of: name, ID or email address on the patient list.

Click *Add new patient* to add a new patient into the database. Fill in at least the obligatory fields marked with an \* sign. Either a National ID No. or a Patient ID is obligatory.

It is recommended to measure and store a patient's forehead and cheek support settings during the patient certification process (see 4.4.5). The user can set *IOP notification limits* for the patient. If an IOP measurement result is equal or greater than the defined limit, an IOP notification email is sent to the user defined in the *Notification recipient* field. The recipient must be a user of the Icare CLINIC software.



The IOP notifications received via email do not replace healthcare professionals' established processes for IOP supervision.

The *Patient is active* box is ticked by default but can be unticked. If unticked, the patient is not shown in the patient list on the landing page. A free text comment can be added to the *Comment* field.

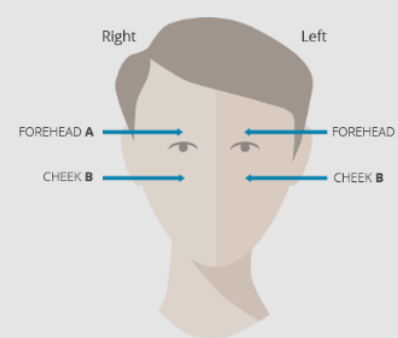
To allow a patient to login and view their information, provide the patient's email address in the *Email* field and click CREATE account. Icare CLINIC sends the patient an email with a web link for setting a password. The patient does not see the IOP notification limits or the *Comment* field. The *User account* part of the user interface is not shown immediately after clicking the ADD NEW PATIENT button but only after the new patient entry has been saved.

icare CLINIC
Home > Patients > Harrison, Peter
PATIENTS DEVICES USERS Help PRONGER, JEFF

Patient profile
HOME use periods
Measurements
Certification

**Patient information** EDIT

First name *	Peter	
Last name *	Harrison	
National ID		
Patient ID *	2d4567	
Date of birth	21/08/1959	
	RIGHT	LEFT
Forehead	6	7
Cheek	7	7
IOP notification limits ⓘ	15	15
Notification recipient ⓘ		
Patient is active	<input checked="" type="checkbox"/>	
Comment		



Forehead (A): Upper support distance  
 Cheek (B): Lower support distance

Note: The units of distance are marked on the Icare HOME tonometer's upper and lower supports and need to be optimized for each patient and each side of the patient's face.

**User account** - allow patients to sign in and view measurement information

Email \*

Phone

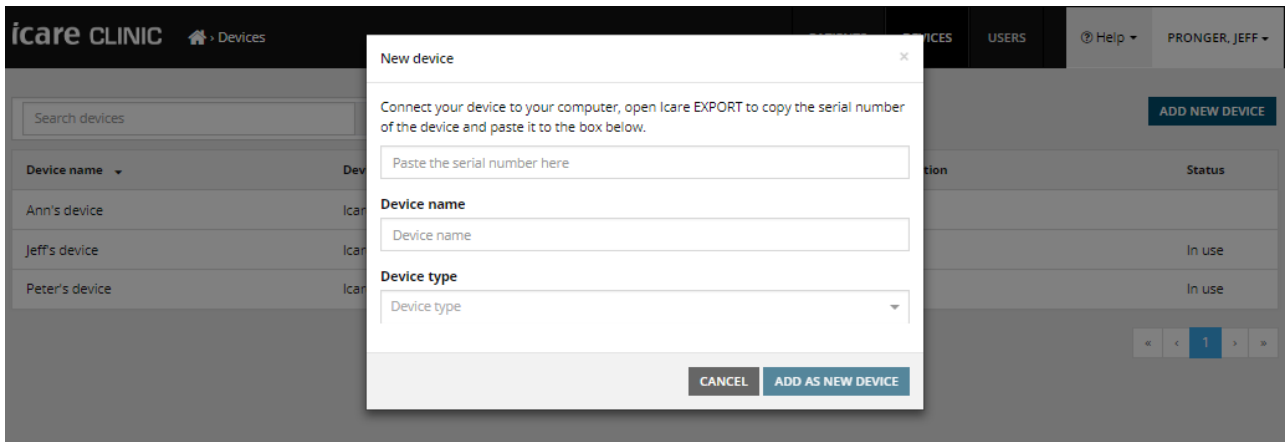
Creating user account will send activation email to the address above

CREATE ACCOUNT

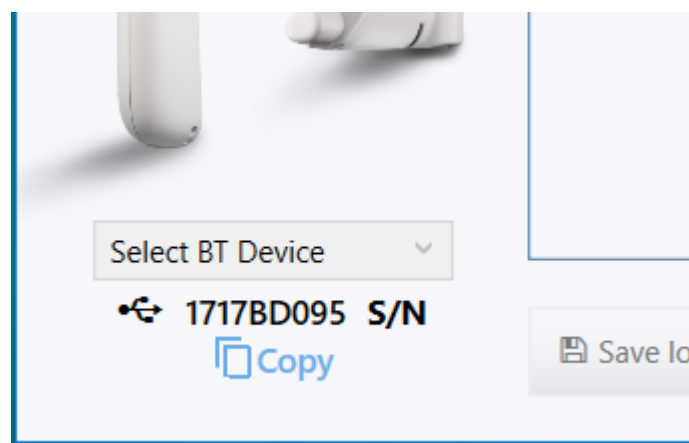
#### 4.4.4 Managing device fleet

To transfer results from a tonometer, the tonometer must first be added to the device fleet.

1. Click the *DEVICES* button to enter device management.
2. Click *ADD NEW DEVICE*.



3. Connect the tonometer to the computer using a USB cable or Bluetooth functionality.
4. Copy the serial number of the connected device using the *Copy* button below the tonometer image.



5. Paste the serial number of the connected device where it says *Paste serial number here*.
6. Give the tonometer a unique, easily recognized name. Type the name of the device into the *Device name* field. Consider putting a sticker (with the chosen name) on each tonometer to make them easily recognizable.
7. Select *Device type*, Icare HOME, Icare ic200 or Icare PRO. By default, a tonometer is automatically activated when it is added to the system. An inactive device can be activated later. Note that a non-active device cannot be assigned to a patient.

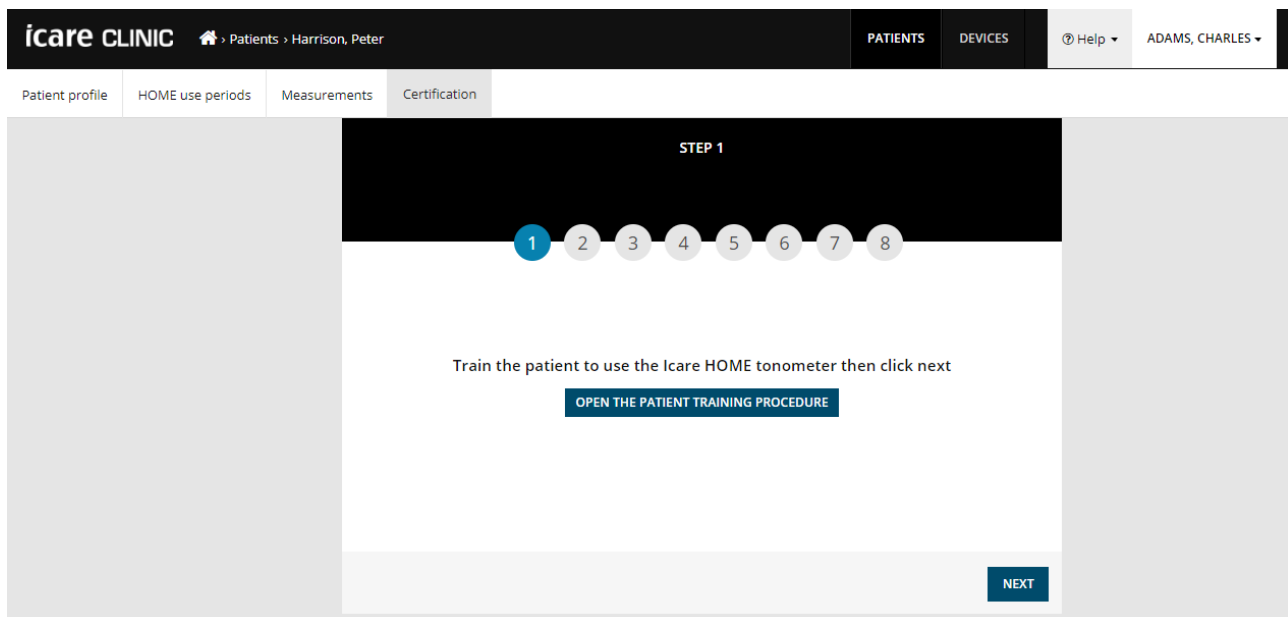
8. Click ADD AS NEW DEVICE.

The new tonometer is now visible in the device list. A tonometer can be removed from the device fleet by unticking the *Active* box which is shown when the device row is clicked. A device that is active cannot be added to or activated on the device fleet of another clinic.

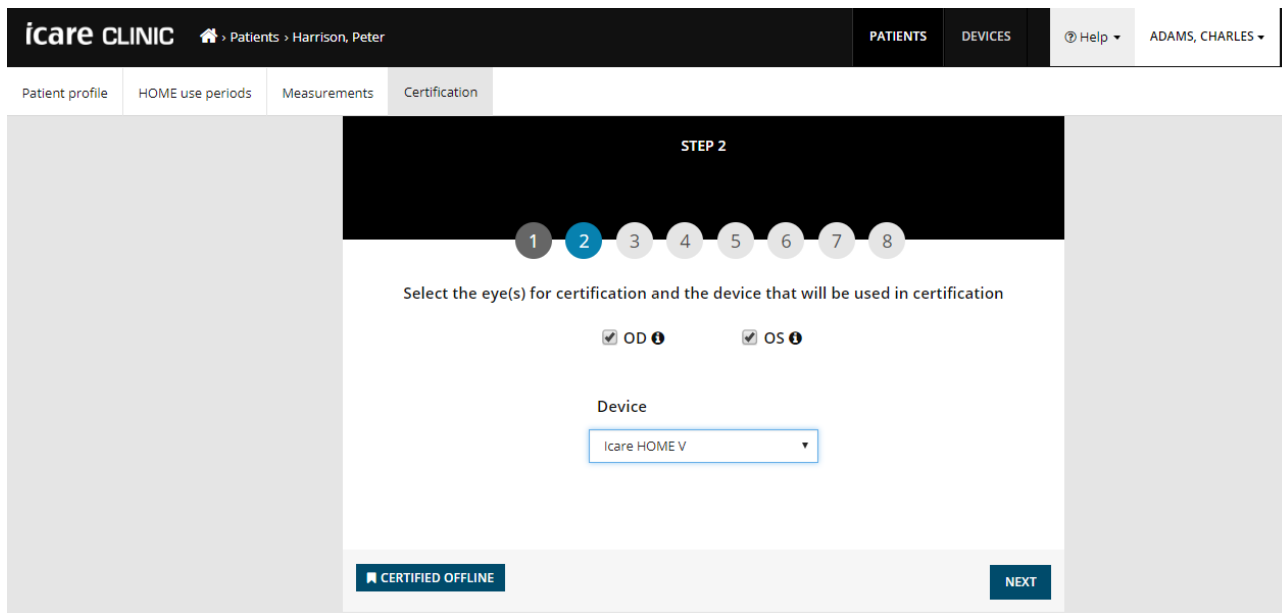
#### 4.4.5 Managing patient certification for Icare HOME tonometer

The Icare CLINIC guides a professional user to certify a patient to use an Icare HOME tonometer. The system guides a professional user through the following steps:

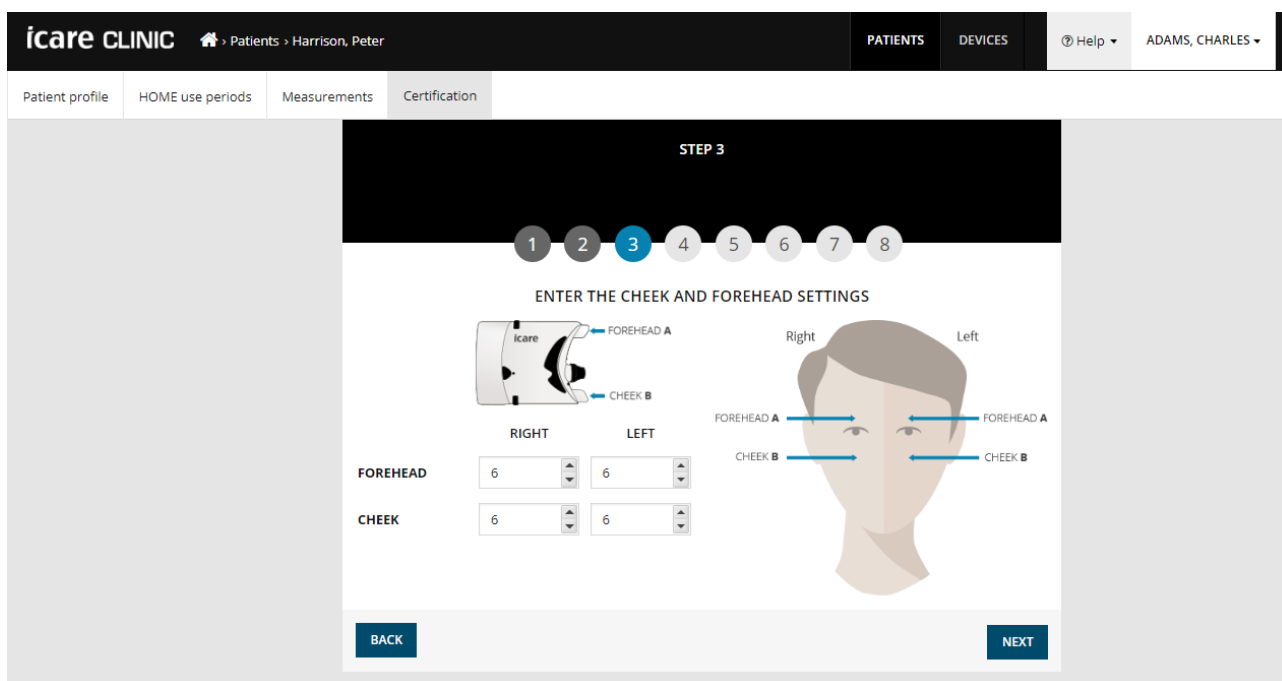
1. Step 1: Select the desired patient and go to the tab *Certification*. Clicking on the *OPEN THE PATIENT TRAINING PROCEDURE* opens instructions for training the patient to use Icare HOME tonometer. Train the patient according to the procedure. Click *NEXT* when training has been accomplished.



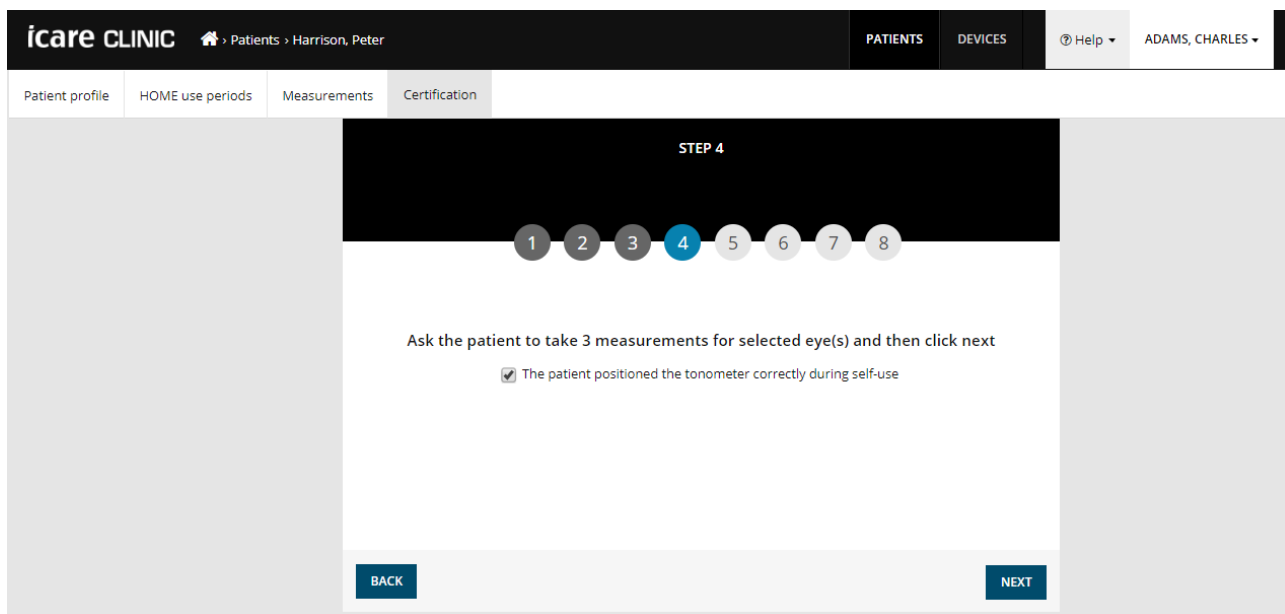
- Step 2: Select the eye(s) to be certified. By default, both eyes are selected for certification. Select the device that the patient uses in the certification. It is also possible to click CERTIFIED OFFLINE to proceed directly to storing of certificate. This can be practical if the patient has been previously certified for using the Icare HOME tonometer without the help of Icare CLINIC. Click NEXT.



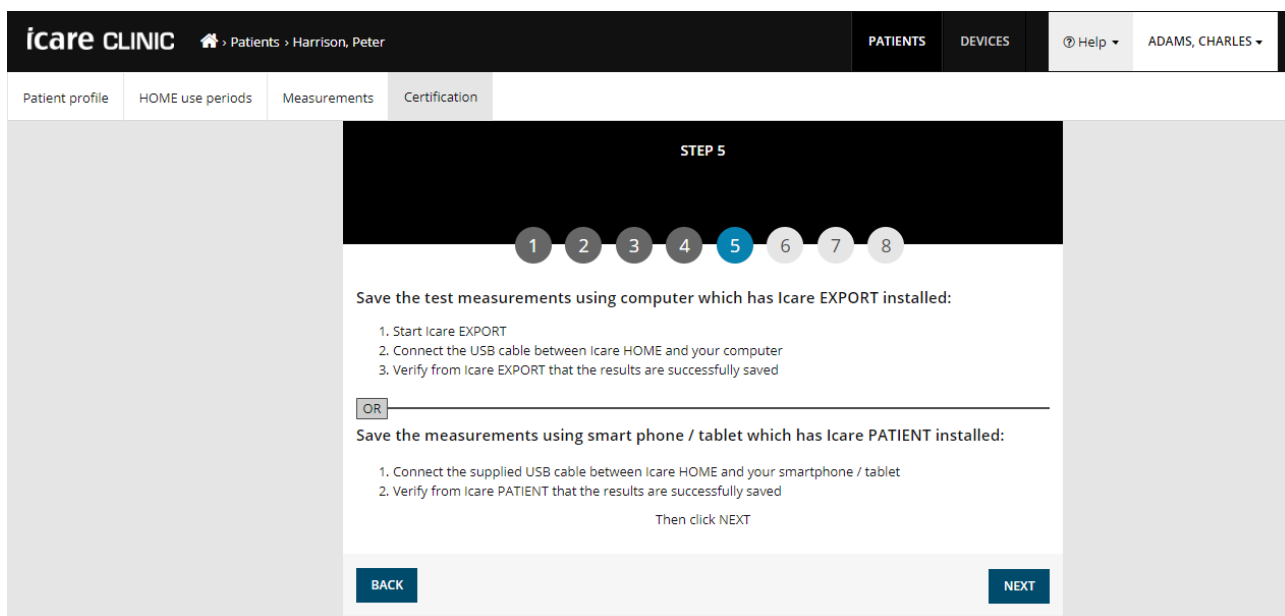
- Step 3: Provide the forehead and cheek support settings that were found when the patient was trained to use the Icare HOME tonometer. Click NEXT.



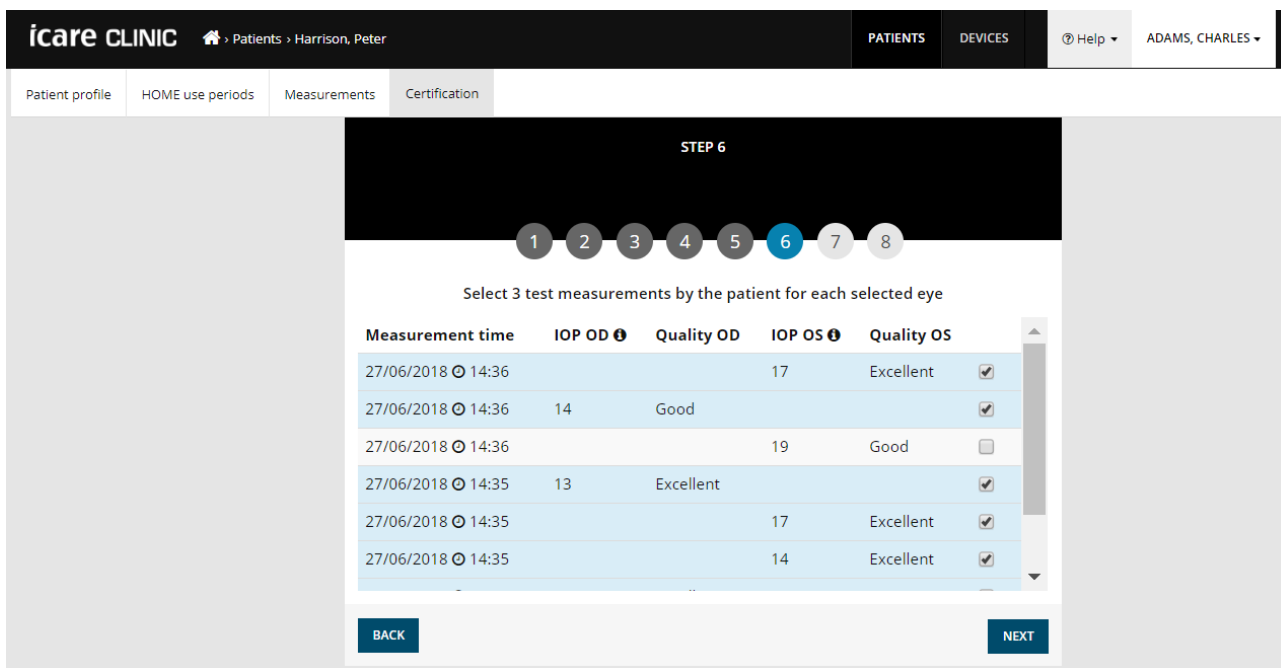
- Step 4: Ask the patient to independently take 3 test measurements for each of the eyes selected for the certification. Supervise that the patient can correctly position the tonometer during self-use and tick the check box if so. Click NEXT.



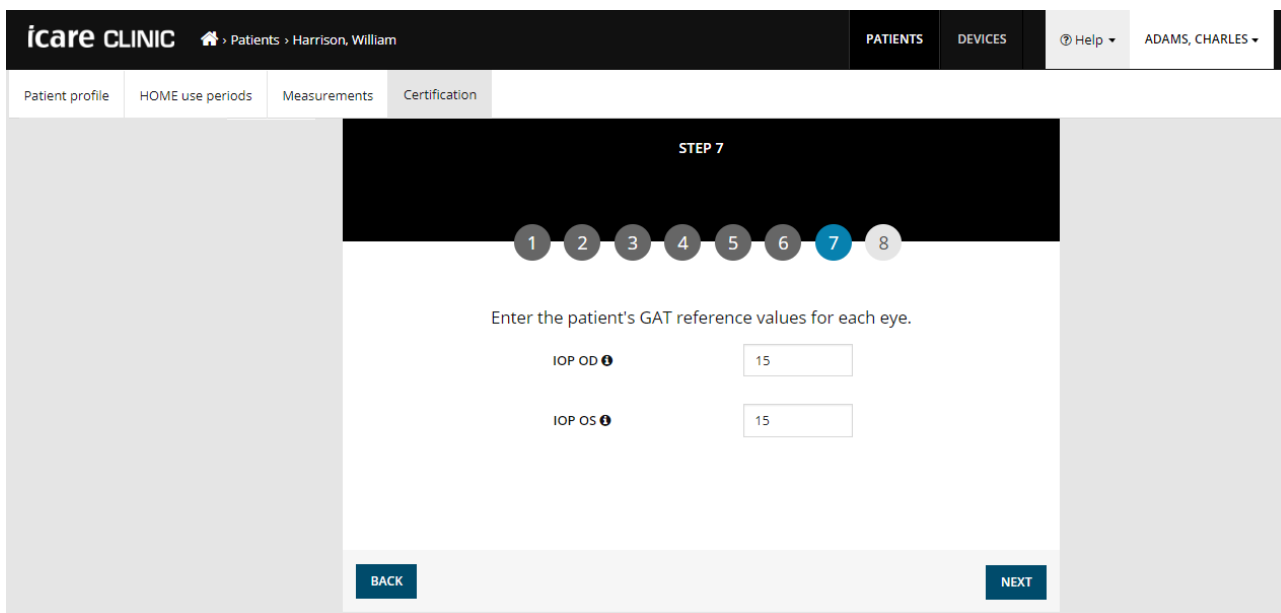
- Step5: Use either Icare EXPORT or Icare PATIENT to send the test measurements to Icare CLINIC. Make sure that the used application indicates successful sending of the measurements with the Measurements saved! notification. Click NEXT.



- Step 6: The list shows all the measurements taken with the connected tonometer during the previous hour. Use the time stamps to identify the three reference IOP values (measured by the patient) for each eye. Tick the values. Then click NEXT to continue.



- Step 7: Enter IOP reference values measured by a professional.



8. Final step, summary: Icare CLINIC accepts completion of the patient's training based on the reference IOP values, including collecting three patient's reference IOP measurements for selected eye(s).

The screenshot shows the 'CERTIFICATION SUMMARY' screen in the Icare CLINIC software. The interface includes a navigation bar at the top with 'Patients > Harrison, William' and 'PATIENTS DEVICES' tabs. Below the navigation bar, there are tabs for 'Patient profile', 'HOME use periods', 'Measurements', and 'Certification'. The main content area features a blue header with 'CERTIFICATION SUMMARY' and a progress bar with 8 steps, where step 8 is highlighted. A table displays IOP values for OD and OS eyes, comparing GAT reference values with the patient's test measurement values. A green banner at the bottom indicates 'CERTIFICATION SUCCESSFUL!' with an information icon. Buttons for 'CLOSE' and 'SHOW CERTIFICATION' are visible at the bottom.

Value type	IOP OD ⓘ	IOP OS ⓘ
GAT reference values	15	15
Patient's test measurement value(s)	16 15 14	19 18 18

For successful certification, the measurement criteria to be met are:

- The first of the three HOME readings self-measured by the patient differs by 5 mmHg, or less, from the professional's reference IOP values entered in step 7.
- The range (maximum-minimum) of the three IOP readings self-measured by the patient is 7 mmHg, or less.
- The patient positions the tonometer correctly during self-use.

After the criteria for self-measurement concordance and variation have been met, the patient is certified by the system and a certificate is saved into the patient's profile.



#### 4.4.6 Managing HOME use periods

A user can manage HOME use periods by clicking the tab *HOME use periods*. A HOME use period is defined as the duration of the time a user self-measures their IOP using an Icare HOME tonometer.

A user can access the *HOME use periods* tab by clicking the *HOME use period* column on the Landing page. The tab lists the history of HOME use periods. The *Period start* and *Period end* columns indicate the starting and ending dates of the period. The *Device name* column indicates the device that is used during the measurement period. The *Measurement count* column shows the total number of measurements performed during the self-measurement period. Clicking the right-most icon of the HOME use period row opens the measurement list for the selected period.

Period start	Period end	Device type	Device name	Measurement count
22/01/2019 10:25	24/01/2019 23:59	Icare HOME	Ann's device	0
03/12/2018 15:06	07/12/2018 23:59	Icare HOME	Ann's device	12
13/08/2018 14:07	17/08/2018 23:59	Icare HOME	Ann's device	12

To define a new HOME use period, the user clicks the *ADD PERIOD* button. The starting and ending dates and times are selected from a calendar / clock menu. Clicking on a date and time field opens the date picker tool. Select the device used during HOME use period from the drop down menu.

To confirm and activate the new HOME use period, click the *SAVE NEW PERIOD* button.

#### 4.4.7 Managing IOP results and creating reports

IOP measurements are listed under the *Measurements* tab. The listed measurements can be filtered either by entering *From* and *To* dates or by selecting a HOME use period from the *Select period* drop down list.

Measurement time	Device type	Device name	IOP (OD)	Quality OD	IOP (OS)	Quality OS	Controls
09/01/2019 13:20	No device specified		20		-		Exclude
14/12/2018 16:01	No device specified		19		-		Exclude
14/12/2018 16:00	Icare HOME	Jeff's device	-		8	Rejected	Exclude
14/12/2018 16:00	Icare HOME	Jeff's device	10	Good	-		Exclude
14/12/2018 15:59	Icare HOME	Jeff's device	-		10	Excellent	Exclude
14/12/2018 15:59	Icare HOME	Jeff's device	10	Excellent	-		Exclude
14/12/2018 15:58	Icare HOME	Jeff's device	-		10	Excellent	Exclude
14/12/2018 15:57	Icare HOME	Jeff's device	8	Excellent	-		Exclude
14/12/2018 15:55	Icare HOME	Jeff's device	7	Excellent	-		Exclude
14/12/2018 15:48	Icare HOME	Jeff's device	7	Good	-		Exclude

The quality of the measurement, as calculated by the tonometer, is shown to the right of the displayed IOP value. The term *Excellent* for quality indicates a low variation among the IOP data sampled by the tonometer during a measurement. The term *Good* indicates fairly low variation among the data sampled. *Satisfactory* indicates higher but still acceptable variation of the data sample for IOP values 19 mmHg or lower. *Rejected* indicates high variation in the sampled data and the IOP result should not be used for clinical determination.

The user may have defined an *IOP notification limit* for a patient (see 4.4.3). If the measurement result is equal or greater than the notification limit, there is a red flag symbol beside the result. Clicking the *ACKNOWLEDGE* button resets all the red flags and changes them to white flags.

A *Trainer* or *Physician* can add a comment to a measurement result by clicking the eye symbol at the far right of a measurement result row. There is a blue note symbol beside such results.

A new IOP measurement can be manually added by clicking the *ADD* button. See 4.4.8 for details of adding measurements to a patient.

An IOP report is created from the rows of IOP measurement data listed. The user can exclude a measurement by ticking the *Exclude* box on the measurement row. To create a report, click on the *REPORT* button. A report shows a graph with time on the x-axis and the IOP measurements from both eyes (if both were measured) on the y-axis. The measurement time and the calculated IOP for individual measurements are revealed by moving the cursor (with the PC mouse) over the IOP results on the graph. The user can zoom the graph by moving the cursor over the graph while pressing and holding down the left-side button on the PC mouse (painting the graph). The statistics describing the data vary according to the user’s zooming and are dynamically recalculated for display.

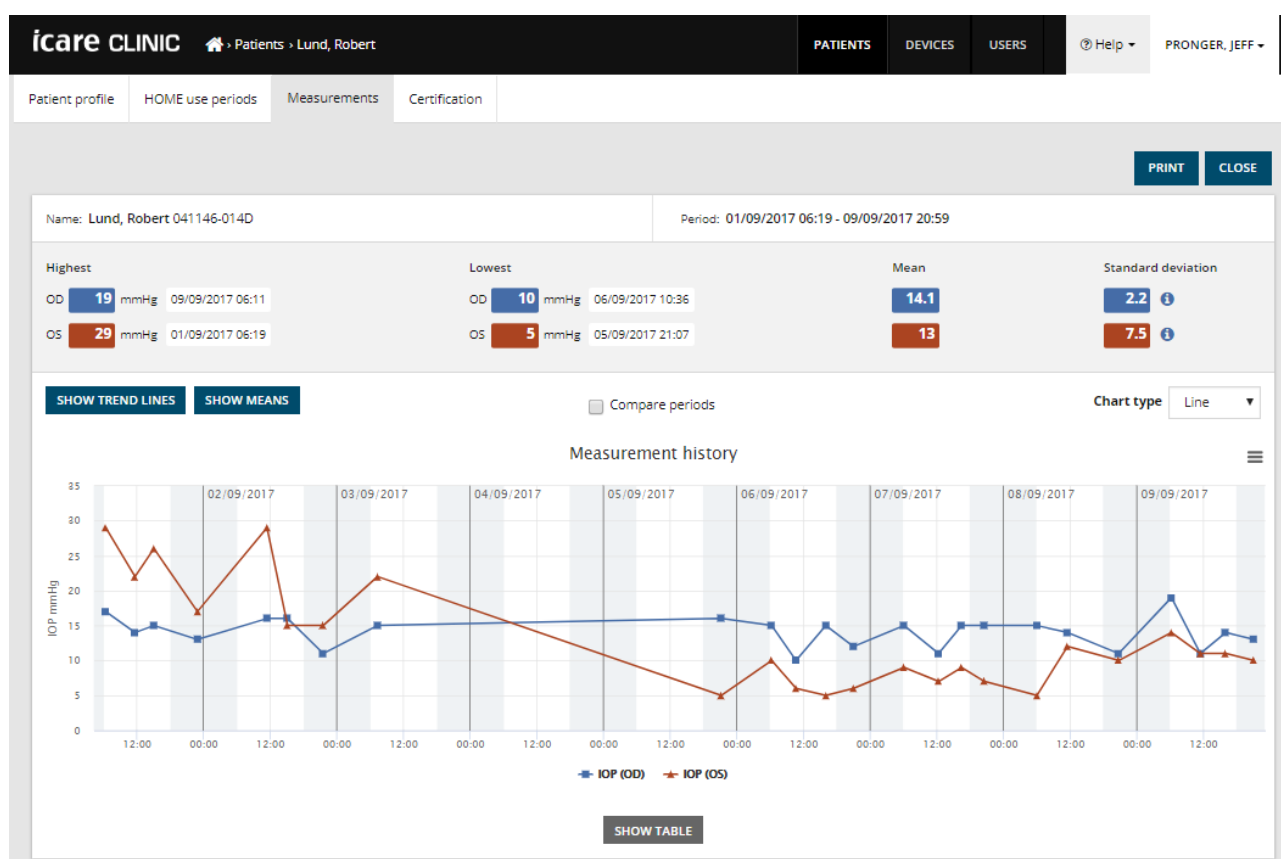


Chart type *Line*

The format of the graph can be changed using the *Chart type* menu. The chart type *Line* connects the presented data points with direct lines.

The chart type *Scatter* displays the data points without connecting them with lines.

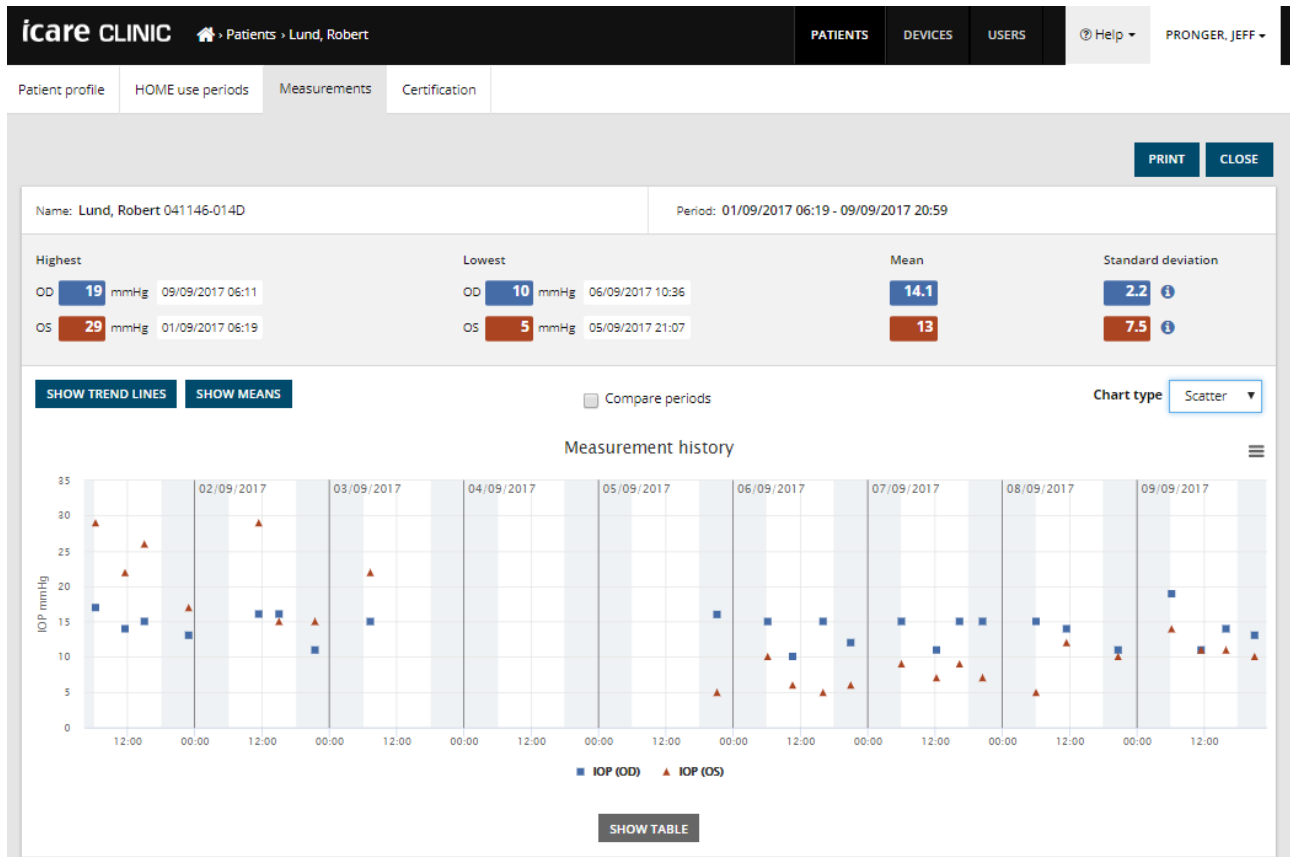


Chart type *Scatter*

The chart type *Diurnal* positions all the IOP data points to a 24-hour x-axis. Thus, all data points measured at the same time of the day will show at the same point on the x-axis. The IOP data points of each day are connected with direct lines.

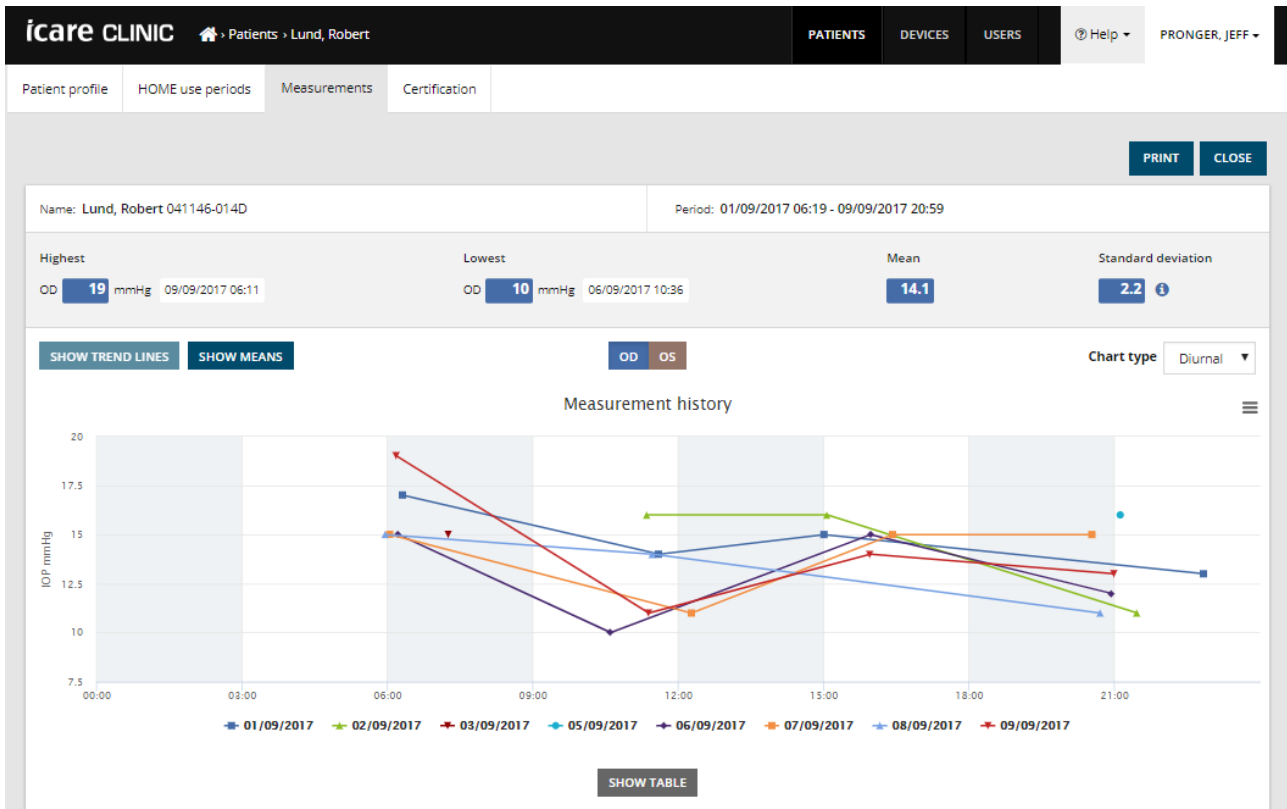
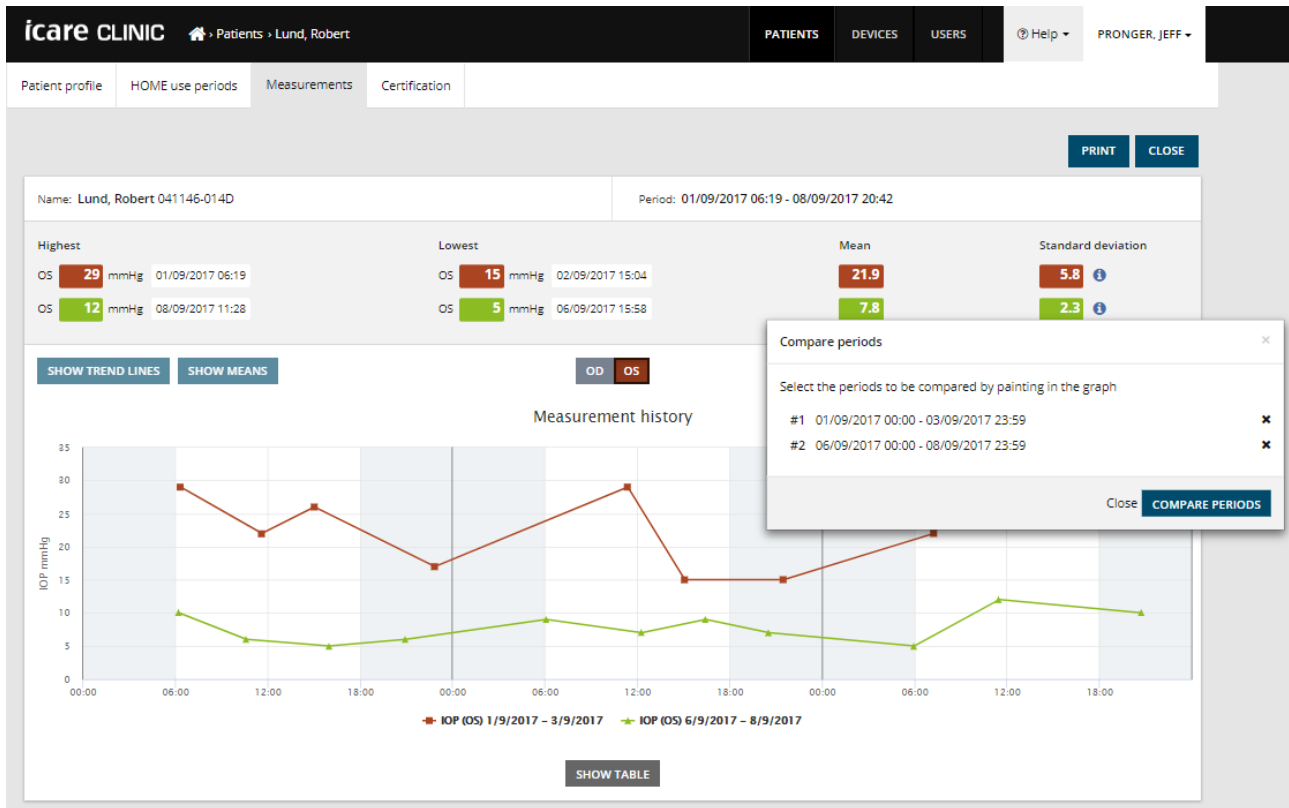


Chart type *Diurnal*

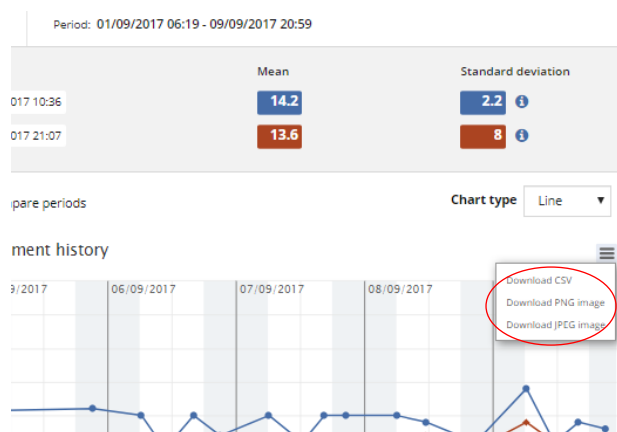
Ticking the *Compare* periods check box (shown when *Line* or *Scatter* chart type is selected) when the chart type *Line* is displayed, allows the user to select two sub-periods from the displayed chart and compare the periods to each other one eye at a time. The sub-periods are selected by painting the displayed chart.



### Compare periods

Clicking on the *SHOW TABLE* button below the graph opens a list of all the measurements on the graph. The entire report can be printed or saved as PDF file by clicking the *PRINT* button on the report. Click the *SHOW TABLE* button to open and display a measurement list below the graph.

The measurement results displayed in the graph can be exported to a csv file, and the graph can be saved as an image via the dropdown menu at the upper right-hand side of the graph. The language of the csv file is fixed to English despite the language selection of the user interface.



#### 4.4.8 Managing results that do not belong to a HOME use period

Normally, a HOME use period (see 4.4.6) is defined before measuring. Defining a HOME use period associates a specific tonometer to a specific patient. If no HOME use period has been defined, measurements are nevertheless uploaded to Icare CLINIC's database. In that case the results go to the list of unassigned results. From there, any of the results can be manually assigned to a patient (or deleted).

Any unassigned results from earlier measurements are indicated at the top of the landing page. To manage the unassigned results, click *Assign measurements*.

The screenshot shows the Icare CLINIC interface. At the top, there is a navigation bar with 'Patients' selected. Below the navigation bar, a yellow banner indicates 'There are unassigned measurements (38)' and includes an 'Assign measurements' button. Below the banner, there is a search bar for patients and a table of patient data. The table has columns for Name, National ID, Email, HOME use period, and Notifications. The data rows are as follows:

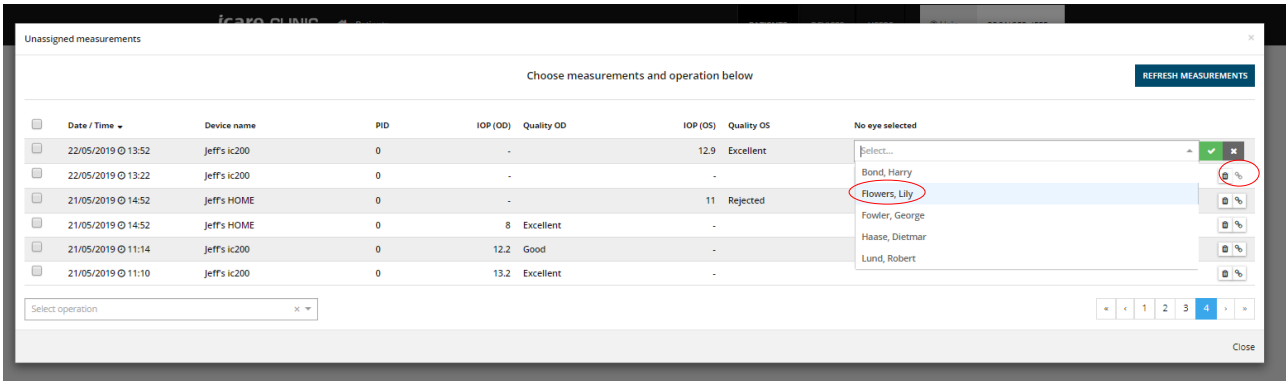
Name	National ID	Email	HOME use period	Notifications
Lund, Robert	041146-014D	robertlund@topeyeaccount...	04/06/2019 - 04/06/2019	
Bond, Harry			10/04/2019 - 10/04/2019	Not certified
Flowers, Lily		lilyflowers@topeyeaccount...	26/02/2019 - 26/02/2019	
Fowler, George	121266AUR		13/02/2019 - 13/02/2019	
Haase, Dietmar			24/05/2019 - 24/05/2019	

Select the results you want to assign by ticking the boxes to the left of the *Date / Time* column. Select *Assign measurements* from the drop-down menu at the bottom of the window, select the patient and then click **ASSIGN MEASUREMENTS**.

The screenshot shows the 'Unassigned measurements' dialog box. It contains a table of measurements with columns for Date / Time, Device name, PID, IOP (OD), Quality OD, IOP (OS), Quality OS, and No eye selected. The first two rows are checked. Below the table, there is a drop-down menu for 'Assign measurements' with 'Fowler, George' selected. At the bottom right, there is a button labeled 'ASSIGN MEASUREMENTS'.

Date / Time	Device name	PID	IOP (OD)	Quality OD	IOP (OS)	Quality OS	No eye selected
07/06/2019 @ 16:42	Jeff's HOME	0	-	-	11	Excellent	
07/06/2019 @ 16:42	Jeff's HOME	0	10	Satisfactory	-	-	
05/06/2019 @ 14:43	Jeff's ic200	0	-	-	16.1	Excellent	
05/06/2019 @ 12:33	Merv's ic200	99	-	-	12.9	Excellent	
05/06/2019 @ 10:52	Jeff's HOME	0	-	-	13	Good	
05/06/2019 @ 10:52	Jeff's HOME	0	10	Good	-	-	
05/06/2019 @ 10:52	Jeff's HOME	0	-	-	15	Satisfactory	
05/06/2019 @ 10:52	Jeff's HOME	0	10	Satisfactory	-	-	
04/06/2019 @ 13:54	Merv's ic200	99	14.6	Excellent	-	-	
04/06/2019 @ 13:53	Merv's ic200	99	-	-	16.1	Excellent	

Alternatively, click on the chain symbol at the far right of a row and select the associated patient from the drop-down menu that then appears.

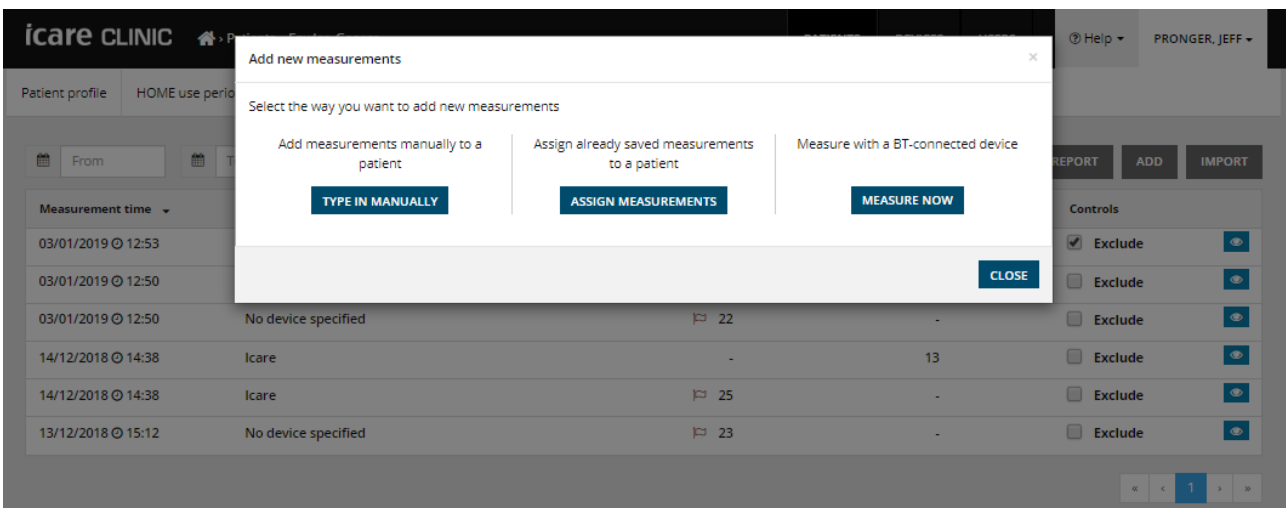


Any unassigned measurements can be deleted by first selecting one or more measurements, then choosing the *Delete measurements* selection in the drop-down menu and clicking the **DELETE MEASUREMENTS** button at the lower right-hand side of the window. Alternatively, select a measurement and click the “trashcan” symbol displayed at the right of the measurement row.

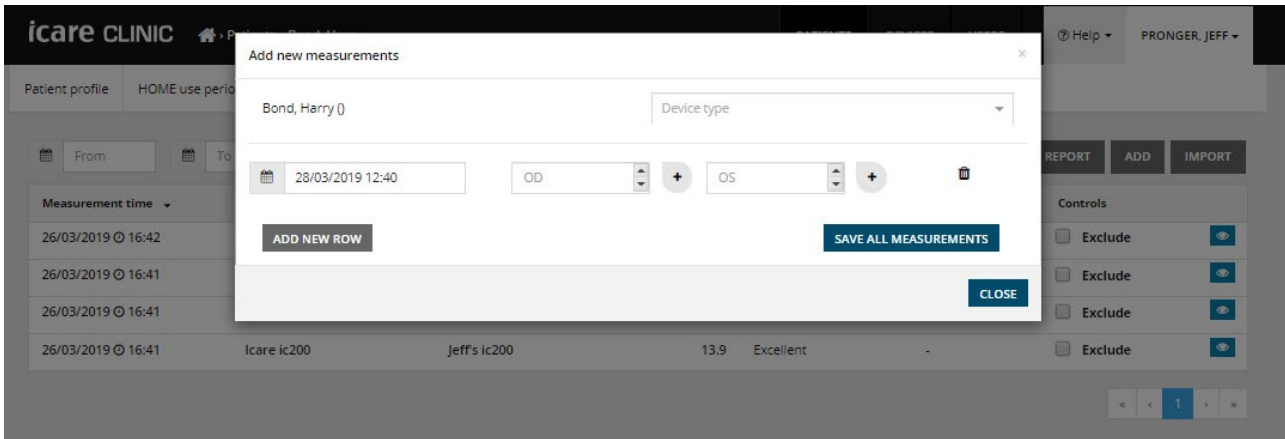
The PID column displays the Patient ID that may have been set in the ic200 tonometer when measuring the IOP (0 if no patient ID was set). The PID is not copied to patient’s records when the IOP measurement result is assigned.

#### 4.4.9 Adding measurement results for a patient

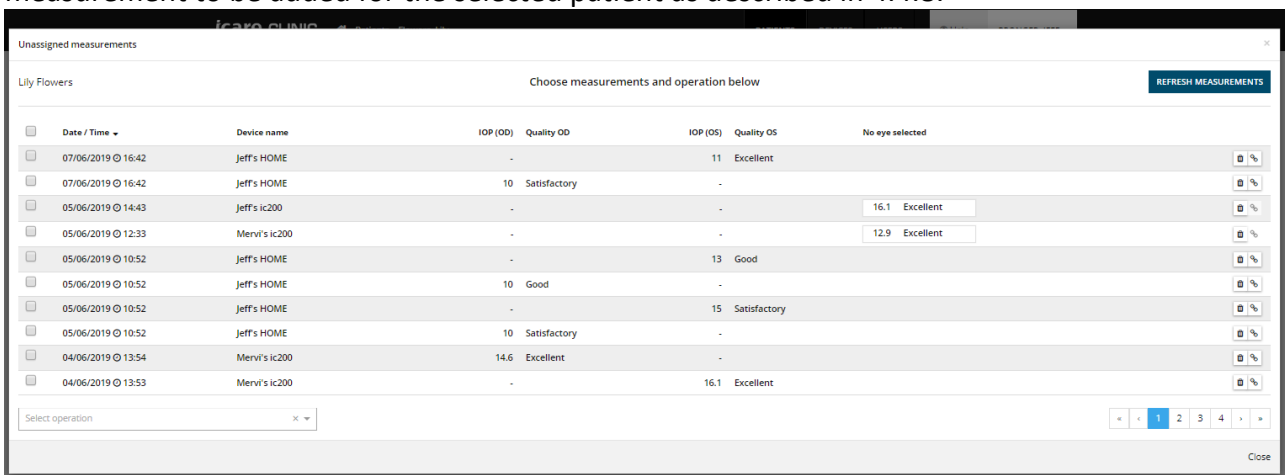
To add measurements, click **ADD** button at the upper right-hand corner of the *Measurements* tab.



To add a measurement manually, click the **TYPE IN MANUALLY** button. Select the date and time of the measurement using the date picker and fill in the IOP value of the right and/or left eye. The device type can be optionally selected from the *Device type* drop down menu. You may add new rows by clicking the **ADD NEW ROW** button. Remember to click the **SAVE ALL MEASUREMENTS** button to save the added measurements.

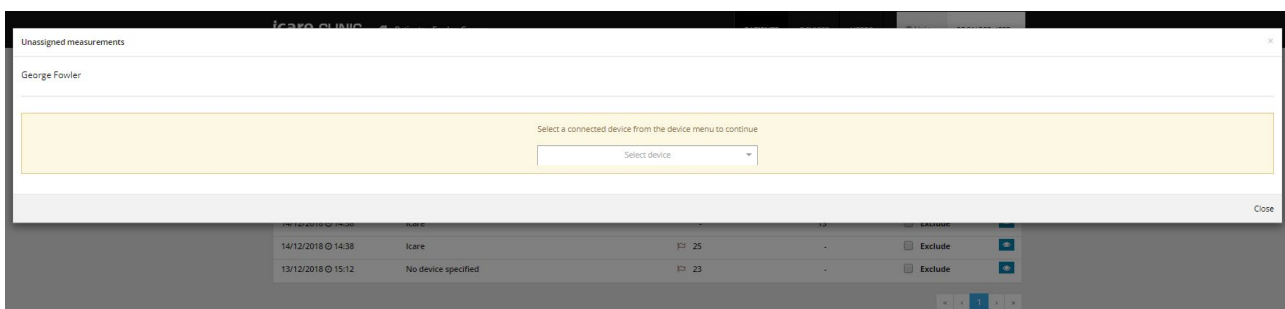


To add IOP measurements previously loaded from a tonometer, click **ASSIGN MEASUREMENTS** button in the *Add new measurements* window. List of measurements that have not been assigned to any patient opens. Clicking the **REFRESH MEASUREMENTS** button updates the list with the measurements that have been read from a tonometer after this window was opened. Select the measurement to be added for the selected patient as described in 4.4.8.

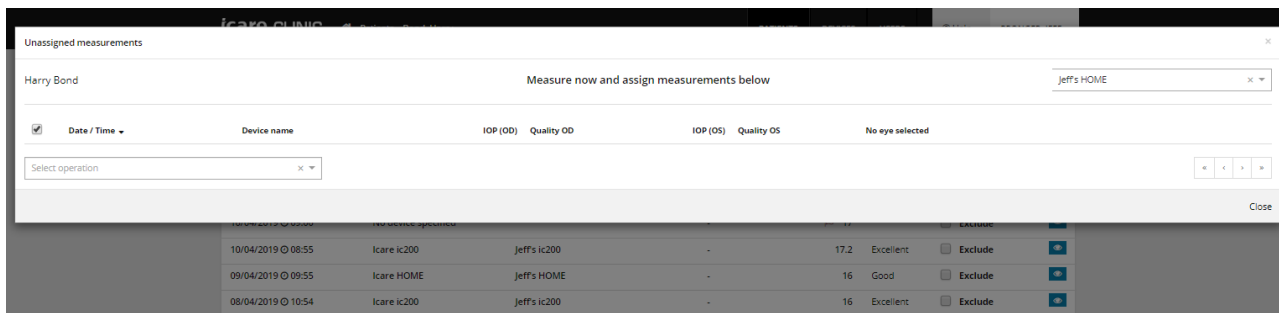


**NOTE:** *Ic200* measurements without eye selection are listed in the **No eye selected** column of the **Unassigned measurements** list of *Icare CLINIC*. The eye needs to be selected before it can be assigned to a patient.

To add measurements directly from an ic200 tonometer while measuring, click **MEASURE NOW** button in the *Add new measurements* window. Select the device that is used for measuring IOP from the dropdown menu. at the upper right-hand corner.



An empty window opens. The window gets filled with new measurements taken with the selected ic200 tonometer. Assign the measurements to the patient as described earlier. Measurements that are not needed and invalid measurements can be deleted by clicking the trashcan symbol to the far right of a row.



#### 4.4.10 Importing IOP measurement results

IOP measurement results can be exported from Icare CLINIC by choosing *Download CSV* in the menu displayed in an IOP report graph, see 4.4.7. Also, the IOP results stored in the earlier generation Icare LINK software can be exported to a csv file. The results in the csv files can be imported for a patient in Icare CLINIC.

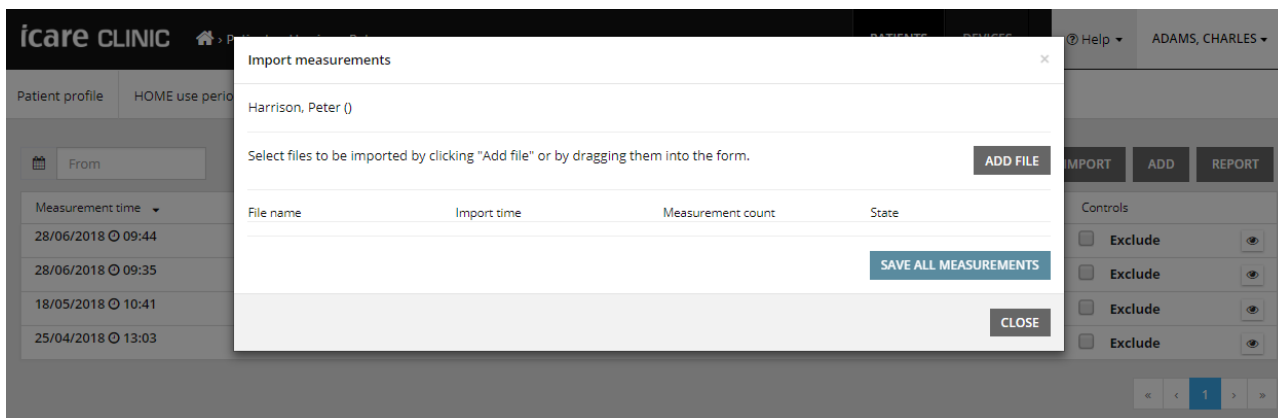
Measurement time	Device type	Device name	IOP (OD)	Quality OD	IOP (OS)	Quality OS	Controls
14/12/2018 16:01	No device specified		19		-		Exclude
14/12/2018 16:00	Icare HOME	Jeff's device	-		8	Rejected	Exclude
14/12/2018 16:00	Icare HOME	Jeff's device	10	Good	-		Exclude
14/12/2018 15:59	Icare HOME	Jeff's device	-		10	Excellent	Exclude
14/12/2018 15:59	Icare HOME	Jeff's device	10	Excellent	-		Exclude
14/12/2018 15:58	Icare HOME	Jeff's device	-		10	Excellent	Exclude
14/12/2018 15:57	Icare HOME	Jeff's device	8	Excellent	-		Exclude
14/12/2018 15:55	Icare HOME	Jeff's device	7	Excellent	-		Exclude
14/12/2018 15:48	Icare HOME	Jeff's device	7	Good	-		Exclude

**NOTE:** The language selection of Icare LINK while exporting results to a csv file must be English GB if the results are to be imported to Icare CLINIC.

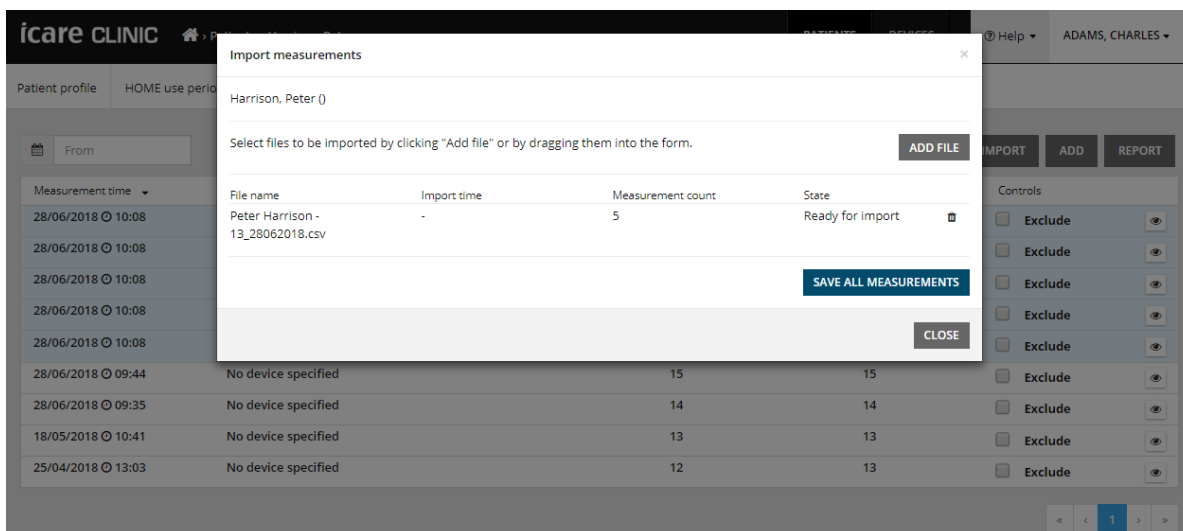
To import IOP results to Icare CLINIC

1. Go to the Measurements tab of the selected patient. Click IMPORT button.

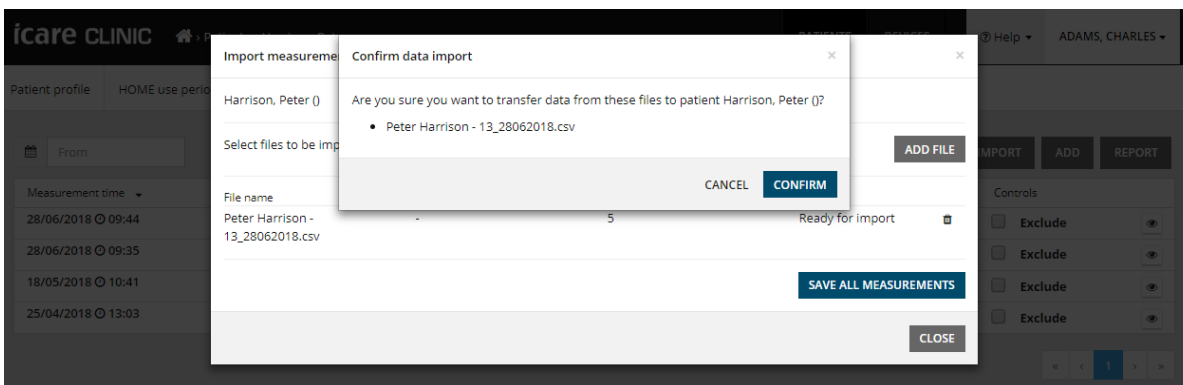
- Click ADD FILE button and select the data file to be imported. Alternatively, drag and drop the data file over the *Import measurements* window.



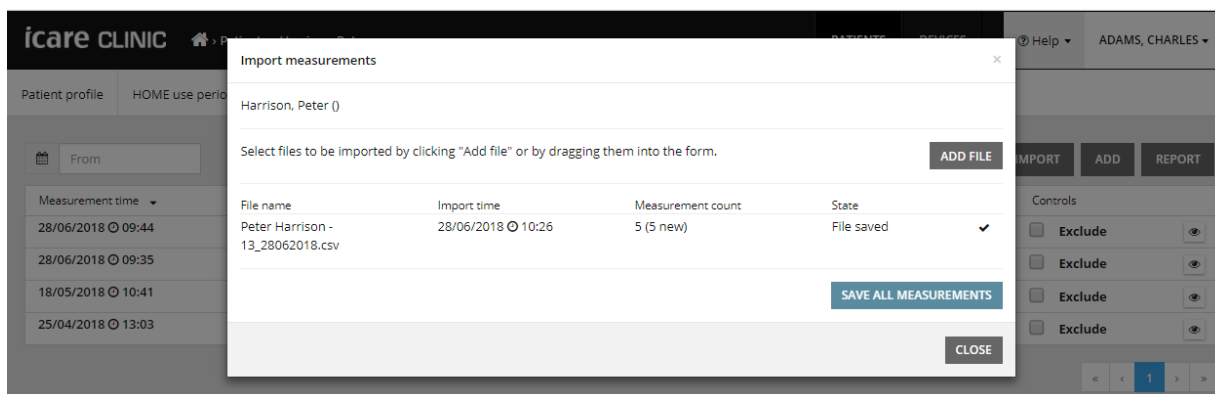
- The import function verifies the data file and counts the number of measurements in the file. Click SAVE ALL MEASUREMENTS.



- Click CONFIRM to confirm that you really want to import the measurement results in the selected data file to the selected patient.



5. The check mark indicates successful importing. Measurement count shows the number of imported measurements. Click CLOSE to close the window.



## 4.5 Using Icare EXPORT to upload IOP results from Icare tonometer to Icare CLINIC

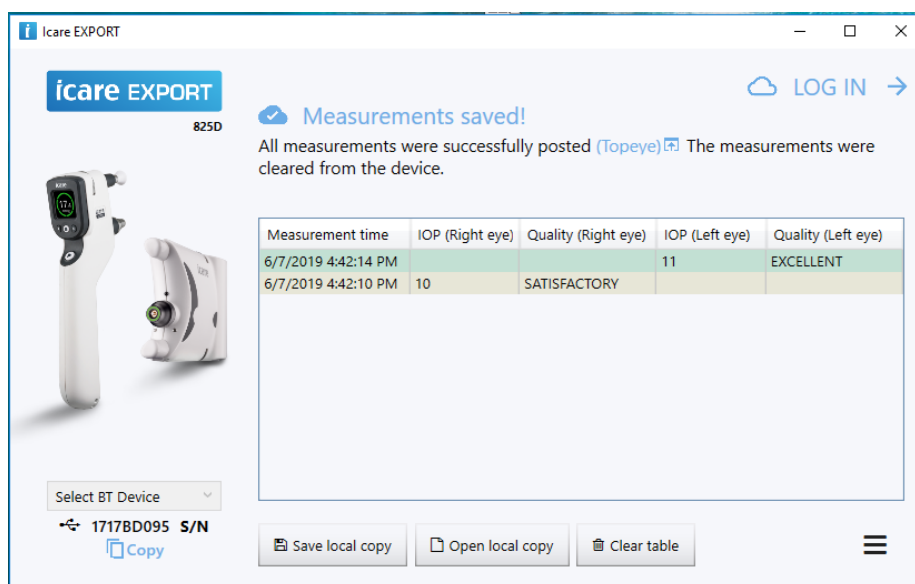
The language of the Icare EXPORT user interface can be selected from the settings menu at the lower right-hand corner of the application window.

To upload results from an Icare HOME tonometer directly to a patient's record in Icare CLINIC, the patient must have a HOME use period defined, see 4.4.6. To upload results from an ic200 tonometer to a patient's record, the user needs to use the *ADD – MEASURE NOW* functionality, see 4.4.9. Without defining a HOME use period or using the *MEASURE NOW* functionality to add real-time measurements, the measurements are loaded to the list of unassigned results of Icare CLINIC, see 4.4.8.

To upload results from an Icare tonometer

1. Launch Icare EXPORT
2. Connect the tonometer
  - Connect the Icare HOME tonometer to the PC using USB cable or
  - Connect the ic200 tonometer to the PC using the wireless functionality. See 4.5.1 for information about setting up the wireless connection.
3. Successful uploading is confirmed by Icare EXPORT with Measurements saved!

- NOTE! By default, Icare EXPORT uploads the measurement results to Icare CLINIC. Icare EXPORT does not send the results to Icare CLINIC in the *Local mode*. The mode can be set via the configuration menu in the lower right-hand side of the user interface.



Icare EXPORT displays uploaded results in chronological order. The results can be saved to a local file by clicking the *Save local copy* button. The results are appended to the selected file if an existing file is selected.

If a local copy of results has been saved earlier, it can be accessed by clicking on the *Open local copy* button and selecting the file name where the results were originally saved.

By default, all results that have been uploaded to the Icare CLINIC database are removed from the memory of the Icare HOME tonometer. Results are not uploaded to the Icare CLINIC database if the connected Icare HOME tonometer has not been added to device fleet or Icare EXPORT is used in *Local mode*. In *Local mode*, the results in the memory of the connected Icare HOME tonometer can be removed by clicking the *Clear device memory* button and by confirming the removal.

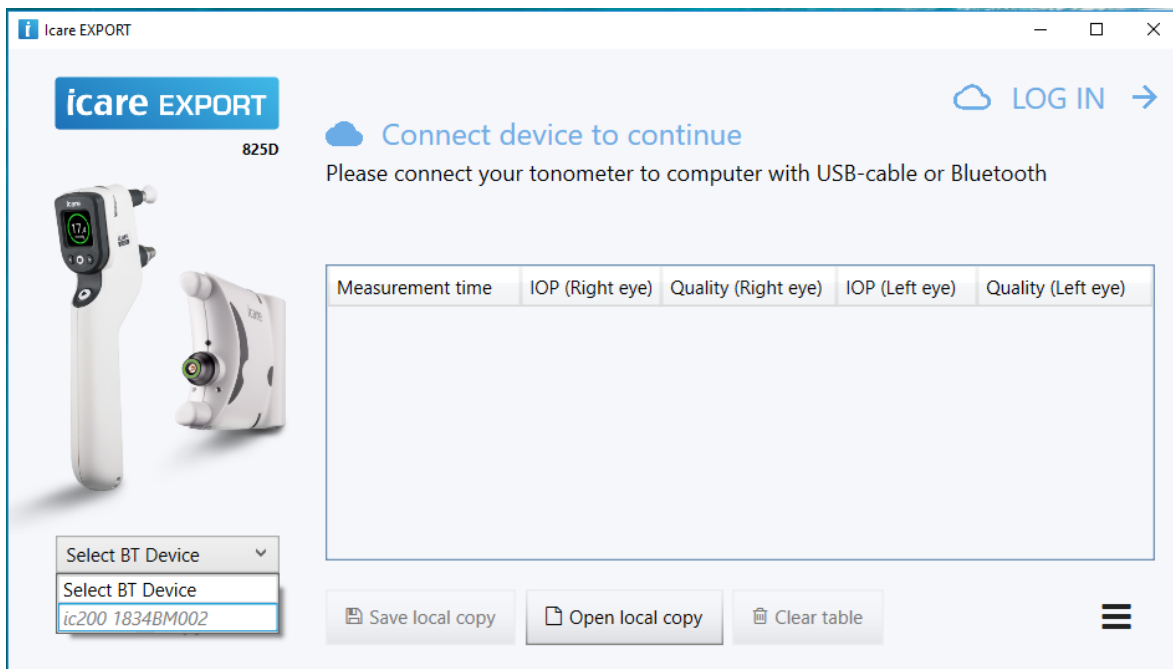
The results uploaded from an ic200 tonometer are not removed after they have been uploaded to Icare CLINIC. User can remove the results by clicking the *Clear device memory* button in Icare EXPORT when the tonometer is connected.

#### 4.5.1 Connecting ic200 tonometer to Icare EXPORT

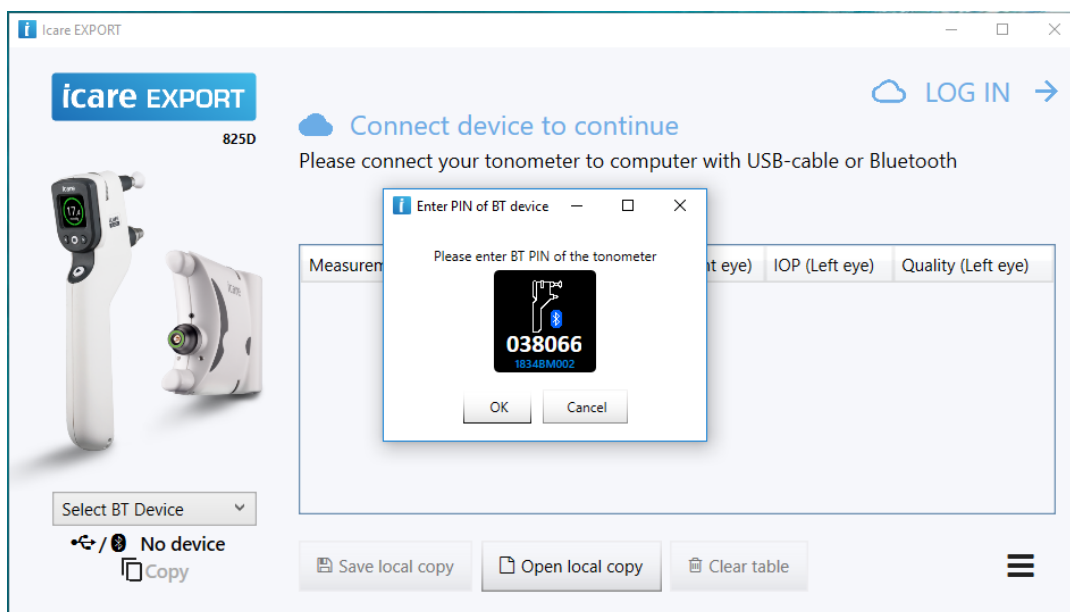
The ic200 tonometer has the capability to wirelessly transfer results to Icare EXPORT and further to Icare CLINIC. Pairing of the ic200 tonometer with the computer running Icare EXPORT must be established to enable transferring the results. To establish the pairing

1. Make sure you have Bluetooth enabled in the computer

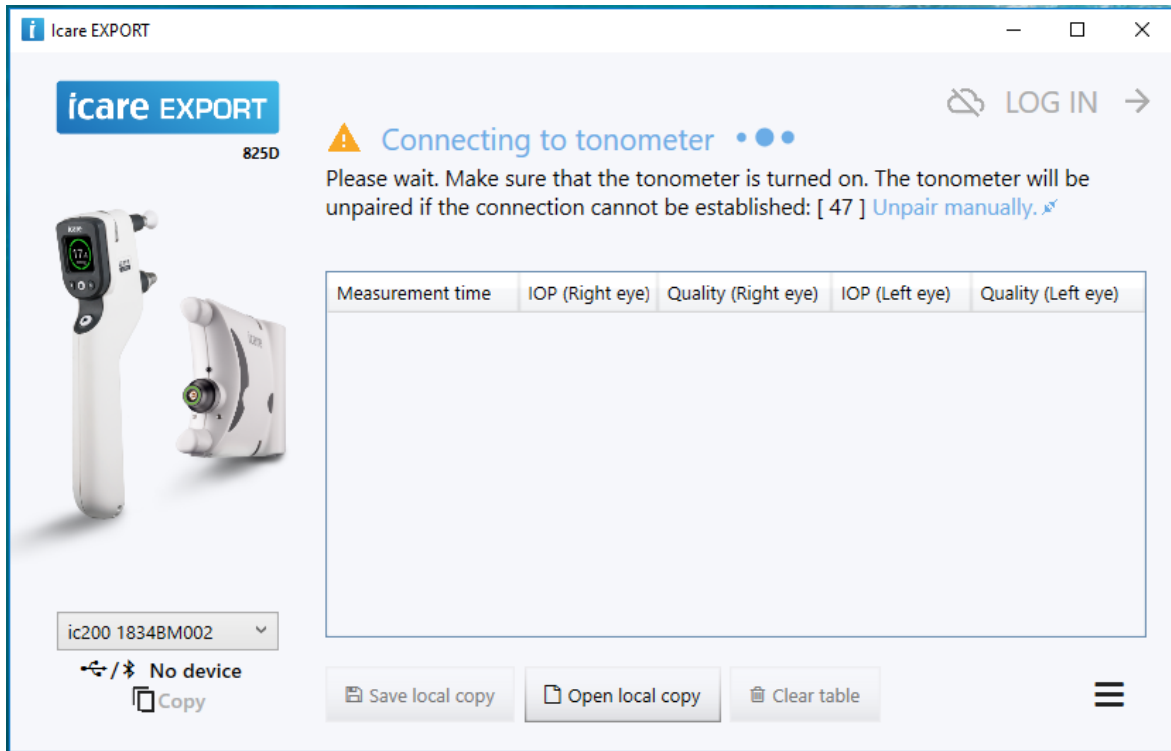
2. Initiate the pairing from the ic200 tonometer as described in the instruction manual of the tonometer.
3. Select the tonometer from the dropdown menu of Icare EXPORT based on the serial number displayed on the tonometer. The serial number of a device that is not paired is greyed and displayed in italic font.



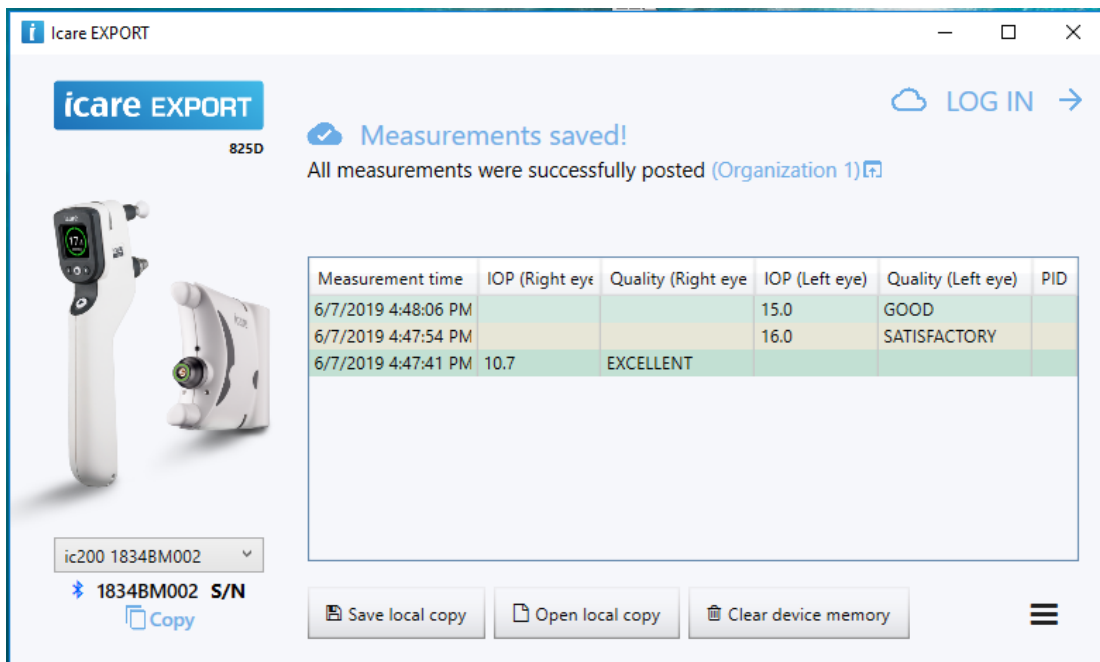
4. Provide the PIN code displayed by the ic200 tonometer



5. The selected ic200 tonometer activates the connection with Icare EXPORT.

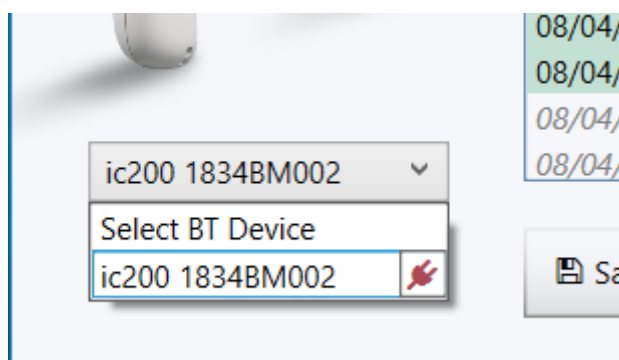


6. Icare EXPORT loads the measurements stored in the ic200 device. By default, the results are displayed in the user interface and transferred and stored to Icare CLINIC. Icare EXPORT indicates the successful transfer and storing of the measurements with the *Measurements saved!* message.



In local mode, Icare EXPORT only displays the measurements in the user interface. *Measurements loaded successfully!* message indicates that the measurements were successfully loaded from the device.

Once the pairing of the tonometer with Icare EXPORT has been established, the tonometer can be disconnected from Icare EXPORT by selecting another tonometer or by selecting *Select BT Device* from the menu. A tonometer that is paired with Icare EXPORT is connected to Icare EXPORT by selecting it from the BT Device menu. The paired tonometer device can be unpaired from Icare EXPORT and the used computer by clicking the symbol to the right of the serial number of the device.



The pairing between the tonometer and Icare EXPORT needs to be done only once. The next time an ic200 tonometer should be connected to Icare EXPORT, ensure that the tonometer is powered on, the Bluetooth is activated in the device and choose the device from the dropdown menu. When Bluetooth functionality is activated in the tonometer and a pairing exists with Icare EXPORT, the tonometer's Bluetooth menu shows a four-letter identifier, e.g. 825D. This identifier is also shown in Icare EXPORT the tonometer is paired with as shown in the picture below.

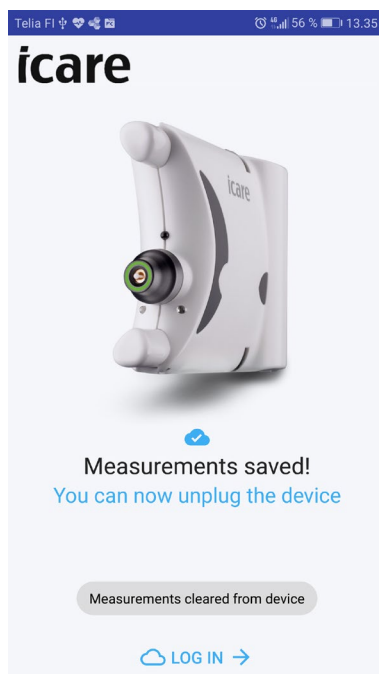


## 4.6 Using Icare PATIENT to upload IOP results from the Icare HOME tonometer

The language of the Icare PATIENT user interface depends on the language selected in the Android operating system of the used Android smartphone or tablet. In case the language selected in the smartphone or tablet is not supported by Icare PATIENT, English language is used.

To upload results from an Icare HOME tonometer to a patient's record, a patient must have a HOME use period defined, see 4.4.6. Without defining a HOME use period, the measurements are loaded to the list of unassigned results of Icare CLINIC, see 4.4.8. Once the HOME use period has been defined and some measurements have been made, perform the following steps:

1. Connect the Icare HOME tonometer to the smartphone or tablet using the USB OTG cable. **NOTE:** The **Host** plug of the cable must be connected to the smartphone or tablet.
2. The Icare PATIENT app automatically starts up in the smartphone or tablet and the results are uploaded to the Icare CLINIC database. The results are removed from the memory of the Icare HOME tonometer.



Click the “LOG IN →” text at the bottom of the display to log into Icare CLINIC to view uploaded results in the web browser of the smartphone or tablet.

## 5 MAINTENANCE AND UPDATES

Icare CLINIC is updated by Icare Finland Oy. This does not require any action from the users. The organization's administrator will receive information about the imminent updates for example via email.

The latest version of Icare EXPORT installer file can be downloaded from the *Help* menu of Icare CLINIC.

The latest version of Icare PATIENT is available in Google Play application store. The smartphone or tablet will indicate to the user if an update is available and guide the update process.

**NOTE:** *Updates never modify patient information or measurement results.*

## 6 DECOMMISSIONING

An organization can use Icare CLINIC for the duration of a valid subscription. Users defined as physician or trainer can continue to use Icare CLINIC during a three months' grace period after the payment due date. The organization administrator has a period of 6 months to export and store data collected from Icare CLINIC, after payment due date.

Icare EXPORT and Icare PATIENT can be uninstalled at any time without loss of data.

## 7 TROUBLESHOOTING

**Open local copy button in Icare EXPORT does not open the file in the application expected.**

The application used for opening a file is defined in the settings of the PC's operating system. In MS Windows 10, the default applications are defined in Settings / System / Default apps / Choose default apps by file type.

**The USB OTG cable has been connected between the Icare HOME tonometer and the smartphone or tablet, but nothing happens.** Make sure that the Host end of the USB OTG cable has been connected to the smartphone or tablet.

**Icare PATIENT pauses and displays "Connecting device, please wait – Do not unplug the device during progress." when Icare HOME is connected to the smartphone or tablet.** Disconnect and reconnect the cable to the smartphone or tablet and/or restart the Icare PATIENT app.

**Data import function in Icare CLINIC displays an error when the csv file exported from the Icare LINK software is selected.** Make sure that Icare LINK is set for *English (GB)* language when the csv data file is exported. Close the *Import measurements* window and try importing again.

**You have uploaded the IOP measurement results from an Icare HOME tonometer to Icare CLINIC, but they do not show up under the correct patient record.** The possible reasons are the following:

- a) A HOME use period for that specific patient was not defined for the device from which the results were uploaded. If the device was not defined for any patient, the IOP measurement results can be found in the list of unassigned measurements, see 4.4.8. If the device was erroneously assigned to another patient, the results show under that patient's record.
- b) The time in the tonometer's clock was not correct for example due to storing the tonometer for some time without batteries or due to change in time zone. The Icare CLINIC software could not show the results correctly in the patient's timeline. Contact [icare-mHOME-support@icarefinland.com](mailto:icare-mHOME-support@icarefinland.com) for assistance.

**An ic200 is selected from Icare EXPORT device menu but Icare EXPORT fails to connect to the tonometer.** Make sure the Bluetooth functionality of the tonometer is on. If it is on, remove pairing of the tonometer from Icare EXPORT (see 4.5.1) and remove pairing from the ic200 tonometer (see instruction manual of the ic200 tonometer). Pair the tonometer with Icare EXPORT again.

**Icare EXPORT shows "Connecting to device" and eventually fails to connect with the ic200 tonometer.** Remove pairing of the tonometer from Icare EXPORT and remove pairing from the ic200 tonometer. Pair the tonometer with Icare EXPORT again.

**Icare EXPORT does not show the ic200 tonometer in the device menu.** Remove pairing from the tonometer and pair the tonometer with Icare EXPORT again.

**The results loaded from an ic200 tonometer do not appear in Icare CLINIC.** Make sure you have set cloud mode in Icare EXPORT. Reconnect the tonometer to Icare EXPORT.

**Icare EXPORT or Icare PATIENT displays "Device not registered!" when a tonometer is connected to it.** Add the tonometer to clinic's device fleet in Icare CLINIC. You need to have subscribed to Icare CLINIC to have access to it.

## 8 SYMBOLS



Consult instructions for use



Manufacturer

Rx only      Federal law (U.S.) restricts this device to sale by or on the order of a physician.

## APPENDIX 1 TECHNICAL DESCRIPTION

Icare CLINIC service is provided from internet servers using a web browser. SSL in TCP port 443 is used for encrypting the data connections. For the proper use of Icare CLINIC, the user's network environment must allow the web browsers to access the internet. Failure to access the internet makes any functionality of the Icare CLINIC service unavailable.

Icare CLINIC displays the IOP values with a resolution of one decimal point mmHg. IOP results downloaded from Icare HOME tonometers are always displayed as integers of mmHg.

For the proper use of the Icare EXPORT application, the user's network environment must allow Icare EXPORT to access the internet using TCP port 443. Failure to access the internet through the defined port prevents the sending of data from a device connected to Icare EXPORT to the database in the Icare CLINIC service.

The user's network environment must allow Icare PATIENT to access the internet using TCP port 443. Failure to access the internet through the defined port prevents sending of data from a device connected to Icare PATIENT app to the database in the Icare CLINIC service.

The date format used in the Icare CLINIC service is defined in the web browser's language settings. The date format used by the Icare EXPORT application is defined in the MS Windows operating systems settings.

The responsible organization is strongly recommended to maintain virus protection up-to-date in the PCs and smart phones used. The responsible organization is also recommended to install security updates to the used web browsers, PCs and smartphones when available.

Execution of the Icare CLINIC, Icare PATIENT and Icare EXPORT application on customer's IT-network may result in previously unidentified risks to patients, users or third parties. The customer is advised to identify, analyze, evaluate and control these risks. Subsequent changes to the IT-network may introduce new risks and require additional analysis. Changes to the IT-network

include: 1) changes in IT-network configuration; 2) addition of items (hardware and/or software platforms or software applications) to the IT-network; 3) removal of items from the IT-network; 4) update of hardware and/or software platforms or software applications on the IT-network; and 5) upgrade of hardware and/or software platforms or software applications on the IT-network.

Icare EXPORT and Icare PATIENT read IOP measurement results from an Icare tonometer over a USB cable or via Bluetooth connection. If the connection fails, try reconnecting the tonometer.

Icare EXPORT and Icare PATIENT send the measurement results read from a connected tonometer to Icare CLINIC. If the network fails to transfer results to Icare CLINIC, try again later.