iCare CLINIC and EXPORT
Instruction Manual
for Patients

icare

iCare CLINIC (Type: TS02) and iCare EXPORT (Type: TS03) - Instruction Manual for Patient

The information in this document is subject to change without prior notice. In a conflict situation, the English version prevails.

Made in Finland

This device complies with:
Medical Device Regulation (MDR) 2017/745

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MD

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1   Safety and security instructions

⚠ **PRECAUTION!** It is important that the internal clock of the iCare HOME(2) tonometer is up to date when measuring. The time of the clock may need to be updated if the 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 connect the tonometer to computer using the provided cable and start iCare EXPORT. The internal clock gets automatically updated to the time of the connected computer.

⚠ **PRECAUTION!** Ensure that the computer running iCare EXPORT is set to the correct time and date.

⚠ **PRECAUTION!** Always consult your healthcare provider before changing your treatment.

⚠ **PRECAUTION!** Do not share iCare CLINIC username and password with other users of the software.

2   Introduction

2.1   System introduction

This is the patient's instruction manual for the iCare CLINIC and EXPORT applications.

In this document iCare HOME(2) refers to both the first generation iCare HOME and the second generation HOME2 tonometer unless specifically stated otherwise.

For instructions on how to use the PATIENT2 app, refer to the PATIENT2 Instruction Manuals.

iCare CLINIC is a browser-based software service managed by healthcare professionals designed for viewing 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 HOME(2) tonometers to the database of the iCare CLINIC service. iCare EXPORT can also be used for viewing the IOP results stored in an iCare HOME(2) tonometer and storing the IOP results in a local file. Refer to chapter 4.5 for the use of the iCare EXPORT.

iCare CLOUD is designed for patients to create a private account for storing and viewing iCare HOME(2) measurement results. For information on how to set up a private account to the iCare CLOUD, read the Getting Started Guide for iCare HOME or iCare HOME2, found in the product's sales package.

NOTE: The iCare HOME(2) tonometer can be connected to either iCare CLINIC or iCare CLOUD, but not both. Patients can store their measurement data to a private account in the iCare CLOUD, if their tonometer is not registered to a healthcare professional's iCare CLINIC account.

The iCare CLOUD user interface is similar to the iCare CLINIC patient user interface.. After creating a private account in iCare CLOUD, you can follow the instructions in the "4.4 Using iCare CLINIC"-chapter of this manual for instructions on how to use iCare CLOUD.

This instruction manual is applicable for iCare CLINIC service version 1.7.x and iCare EXPORT application version 2.2.x where x indicates a maintenance revision. New versions of this instruction manual are created on an as needed basis.

iCare CLINIC is expected to be used in typical healthcare facilities. iCare EXPORT is expected to be used in typical healthcare facilities or home environment.

The applications do not introduce any unacceptable residual risk or undesirable side effects and they do not have any contraindications

Safety incidents: Report any serious incidents related to the software or a tonometer used with it to your competent health authority and the manufacturer or the manufacturer's representative. For reporting faulty information in this document, contact info@icare-world.com.

2.2   Related documentation

Other documents related to the system are:
• iCare PATIENT2 Instruction Manual for Android

- iCare PATIENT2 Instruction Manual for iOS
- iCare PATIENT2 and EXPORT Quick Guide
- iCare HOME Instruction Manual
- iCare HOME Patient Guide
- iCare HOME2 Instruction Manual
- iCare HOME2 Quick Guide
- iCare HOME2 Getting Started Guide

3   Intended use

The intended use of the family of software consisting of iCare CLINIC and iCare EXPORT is, per software:

- iCare CLINIC is a software intended for storing and viewing of ophthalmic measurement data and for transferring it to external systems, supporting clinical decision making.
- iCare EXPORT is a software application intended for transferring ophthalmic measurement data to iCare CLINIC or to an external system. It also has the capability of displaying ophthalmic measurement data.

iCare CLINIC and iCare EXPORT are indicated for use by healthcare professionals and lay persons.

4   Getting started

iCare CLINIC and iCare CLOUD are used over an internet connection. For you to use iCare CLINIC, your healthcare provider needs to subscribe to iCare CLINIC. Once your healthcare provider has activated your access to iCare CLINIC, you will be sent an email (titled "Choose a password for your iCare account") with information on how to access the service.

In case your healthcare professional has not subscribed to iCare CLINIC, you can use iCare CLOUD for storing and viewing your IOP data. For starting to use iCare CLOUD, you need to create a private account according to the instructions in the Getting Started Guide available in the iCare HOME2 sales package.

NOTE: The results of the measurements you take with your tonometer before it has been registered to iCare CLINIC or iCare CLOUD will not be available in iCare CLINIC or iCare PATIENT2.

Users needs iCare EXPORT or iCare PATIENT2 to upload IOP data to the iCare CLINIC database. iCare EXPORT installer file can be downloaded from the Help menu of iCare CLINIC.

See chapter 4 for information about installing and starting iCare CLINIC and iCare EXPORT. See chapter 4.3 for a description about how the iCare applications are typically used.

4.1   Installation and system requirements

iCare CLINIC is a service provided from a server located in the internet. It does not require installation by the patient. To install iCare EXPORT, you need administrator's privileges on a computer used.

4.1.1   System requirements for using iCare CLINIC and iCare CLOUD

- Internet connection
- Minimum web browser versions: Edge (90.0.818.51 and later), Chrome (v 100 and later), Firefox (v 91 and later) and Safari (13.1 and later)

### 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 10 or Windows 11
- Internet connection (when used to upload results to iCare CLINIC)

**To install iCare EXPORT on the PC, follow the instructions in the steps below:**

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**.
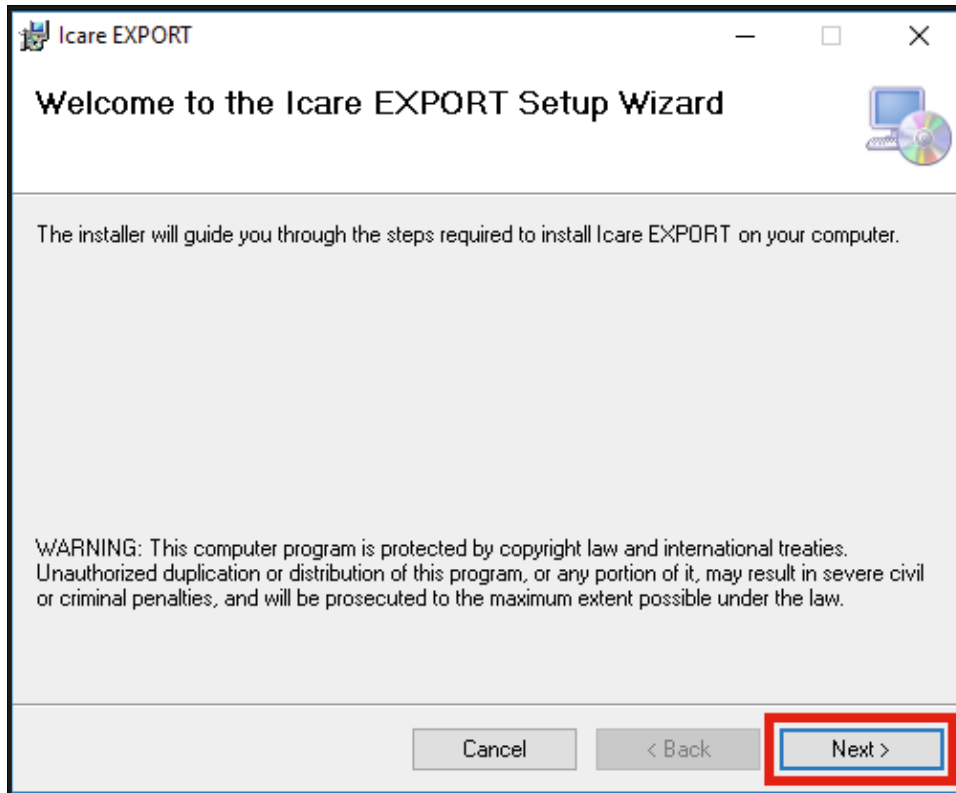
2. A window requesting agreement with the licensing terms appears. Confirm the terms by ticking **I agree** and click **Next**.
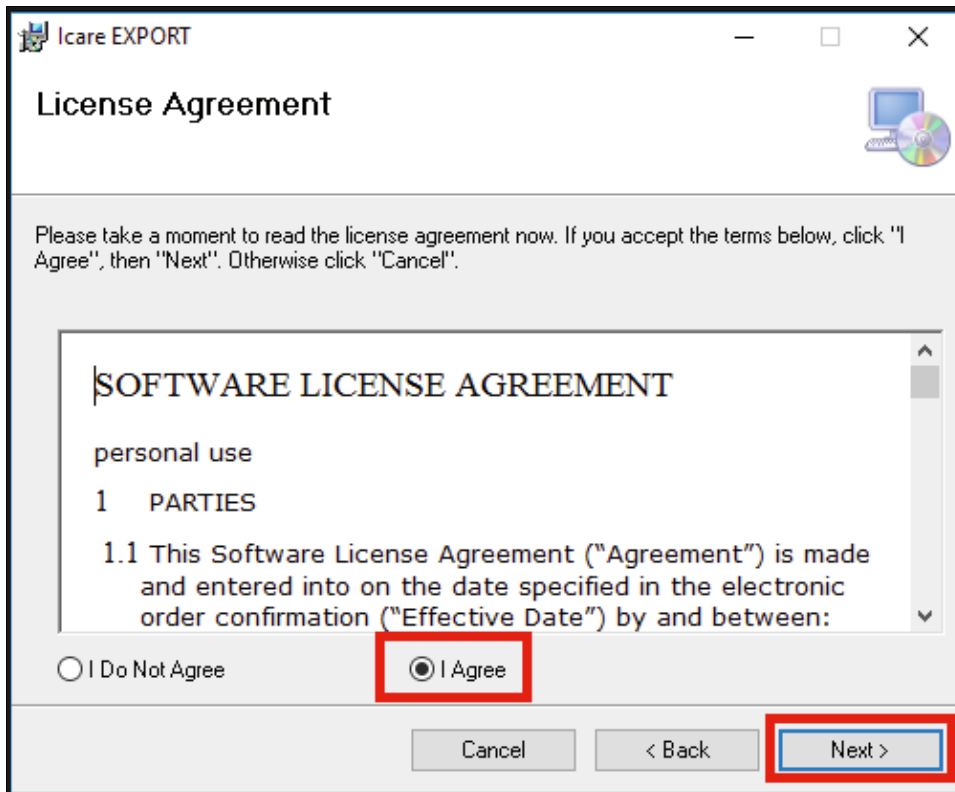
3. A window for selecting the installation folder appears. Select a folder to install the application. Select **Everyone** to allow iCare EXPORT to be visible to all users of the computer; select **Just me** to restrict use of the application to the user installing the application. Click **Next**.
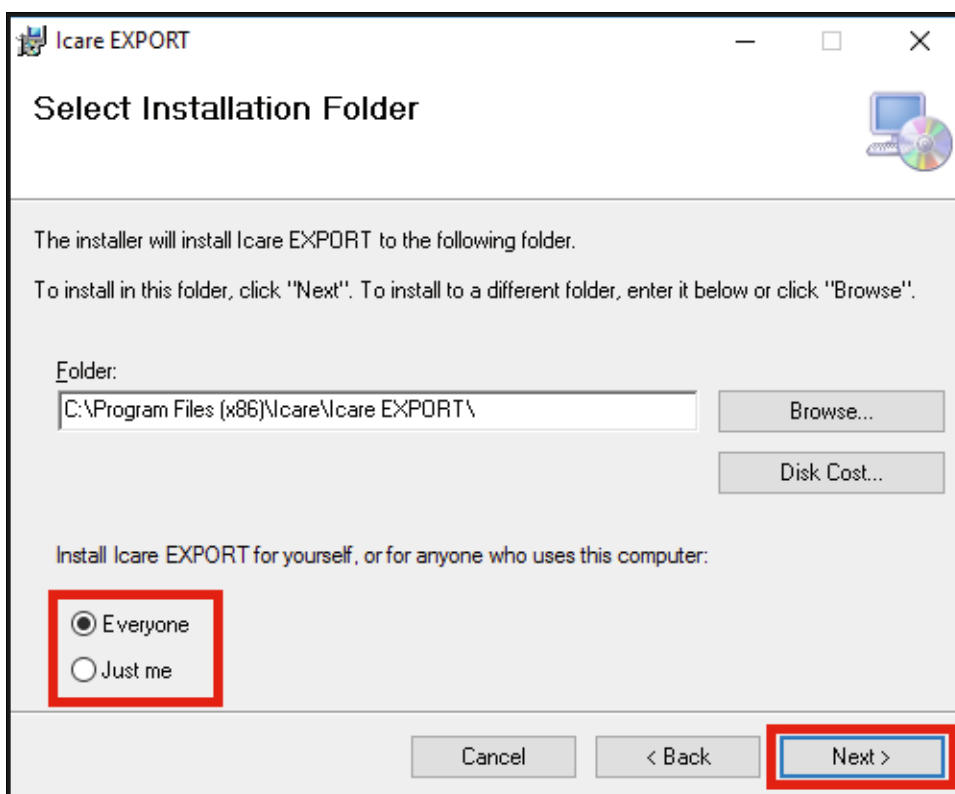

4. Choose to install iCare EXPORT in cloud mode or local mode. In cloud mode iCare EXPORT sends the measurement results to your healthcare provider using the iCare CLINIC service. Local mode

should be selected to manage the IOP measurement results locally in the computer used. The mode setting can be changed after installing iCare EXPORT.
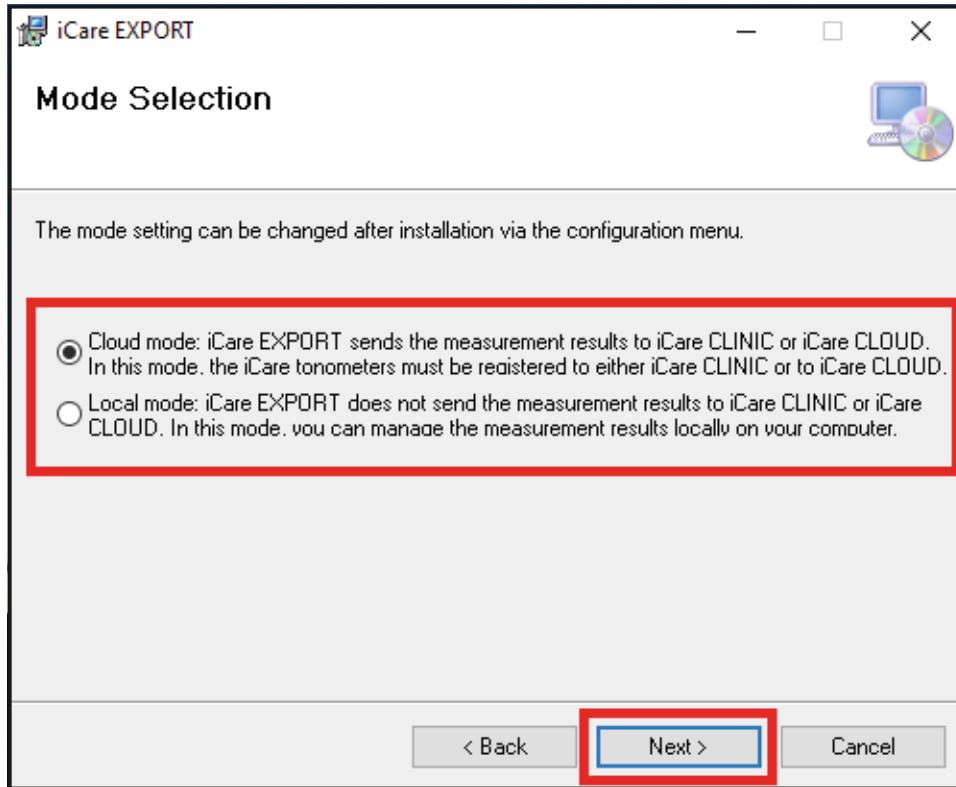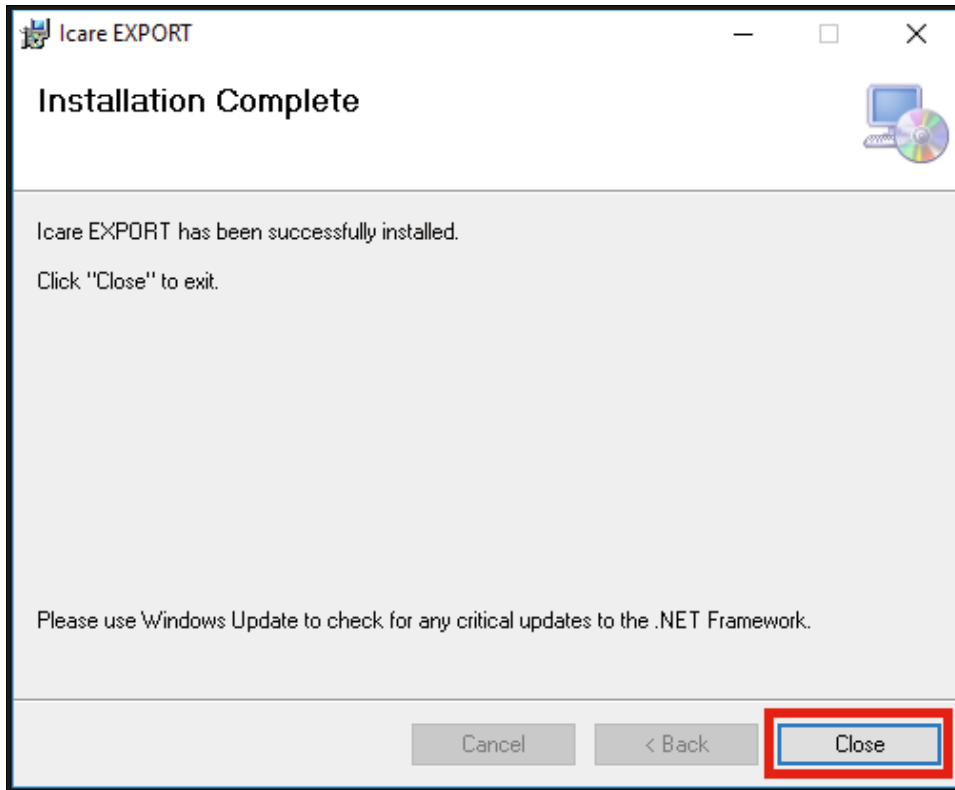

5. A window to confirm installation of iCare EXPORT appears. Click **Next** to start installation.
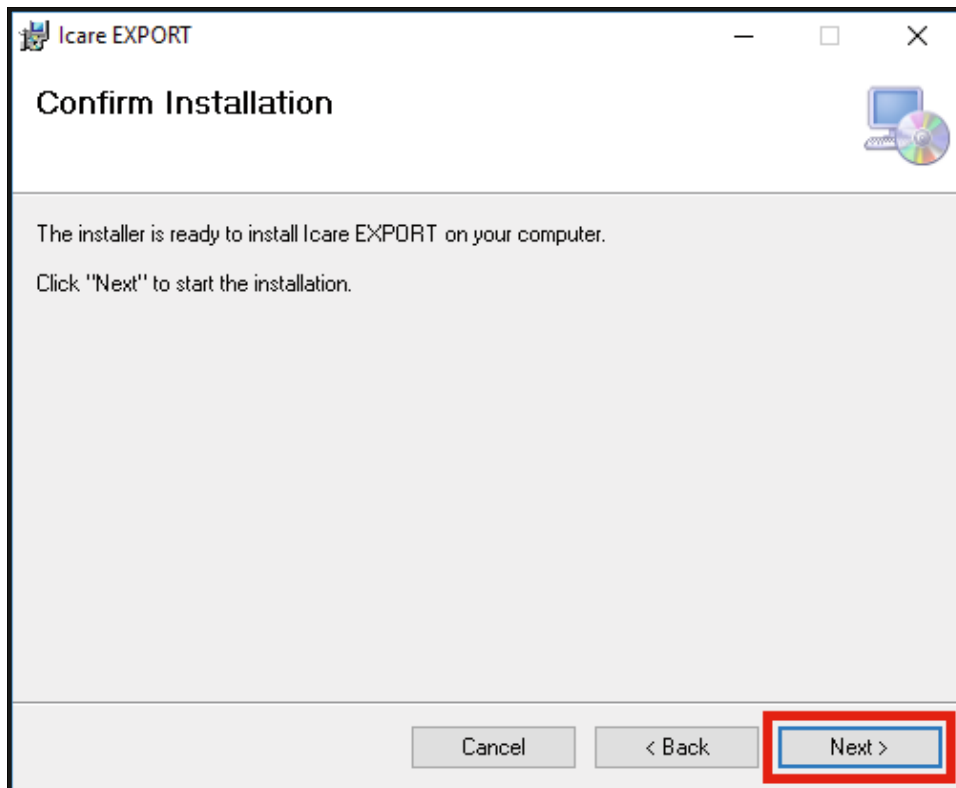
6. A window indicating completed installation appears. Click **Close** to finish installation process.

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.

4.2 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 asking you to set your password after your healthcare provider activated your access to iCare CLINIC). The "Other login options" tab is for professional users only.
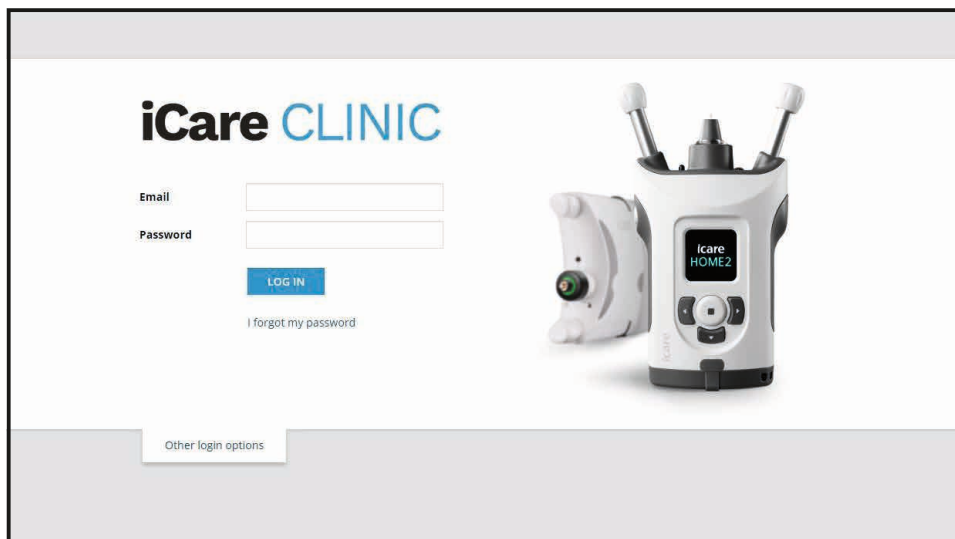
To stop using iCare CLINIC and exit, select the logout function from the drop-down menu, accessed from the top right-hand corner of the user interface.
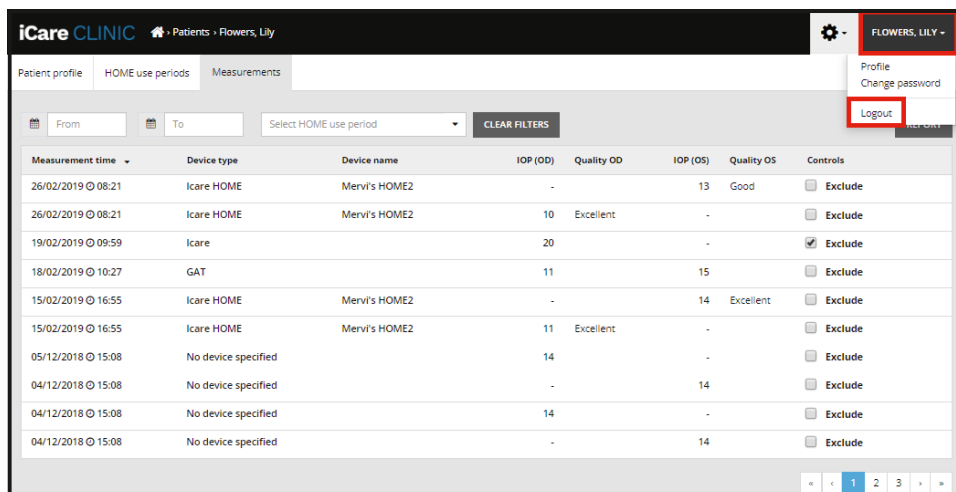
To start iCare EXPORT, click the icon on the PC desktop. The icon is created during the installation of iCare EXPORT.

To shut-down iCare EXPORT, click the close symbol (x) in the upper right-hand corner of the application window.
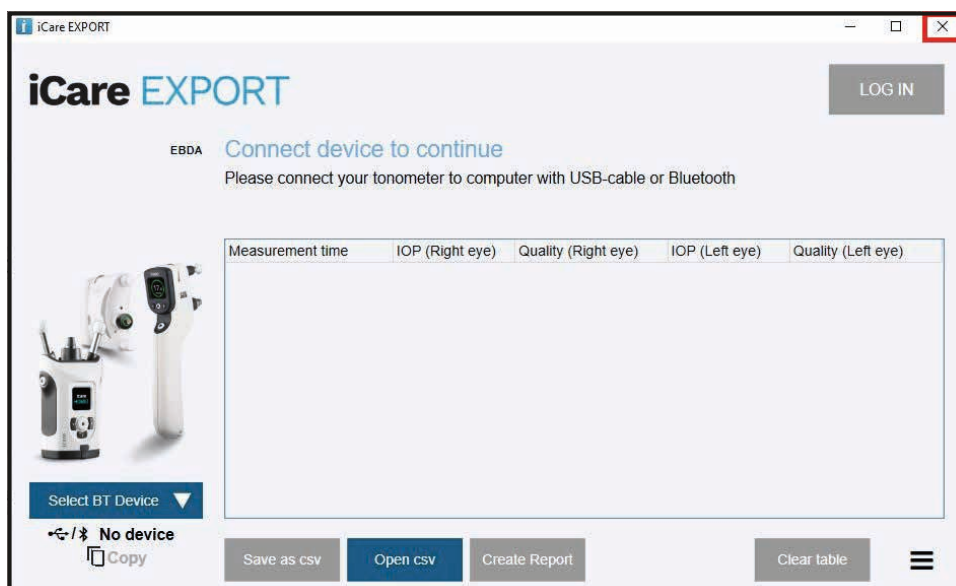
4.3 Using the iCare HOME(2) tonometer, iCare CLINIC and iCare EXPORT together

Typically, the iCare HOME(2) tonometer and the iCare CLINIC and iCare EXPORT applications are used as follows:

1. Self-measure according to your healthcare provider's instructions.

⚠️ **PRECAUTION!** It is important that the internal clock of the iCare HOME(2) tonometer is up to date when measuring. The time of the clock may need to be updated if the 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 connect the tonometer to computer using the provided cable and start iCare EXPORT. The internal clock gets automatically updated to the time of the connected computer.

⚠️ **PRECAUTION!** Ensure that the computer running iCare EXPORT is set to the correct time and date.

2. After self-measuring your IOP one or several times, you can use iCare EXPORT on your PC to upload the IOP results from your tonometer to the iCare CLINIC or iCare CLOUD database. You may perform upload at any time convenient to you.

3. You can then login to iCare CLINIC to view your measurement results by your health care provider's permission. **Or** you can log in to iCare CLOUD with the credentials that you obtained when you created a private account.

Note that to download measurement results from your iCare HOME(2) tonometer, you can always choose to use your PC with iCare EXPORT or your smartphone or tablet with the iCare PATIENT2 app – whichever is the most convenient.

4.4 Using iCare CLINIC

This chapter describes the use of iCare CLINIC. The use of iCare CLOUD is identical and the instructions are valid also for the use of the iCare CLOUD private account.

4.4.1 Introduction to the user interface of iCare CLINIC

Patient profile shows your personal information. This information includes your personal forehead and cheek support settings. You should check that these settings are the same as documented in the patient profile before self-measuring. You are not able to modify your patient profile information yourself.

HOME use periods list shows the periods during which you have previously been self-measuring IOP with the iCare HOME(2) tonometer.

Measurement list shows your measurements, either your self-measured readings (indicated by the device type iCare HOME(2)) or those measured by your healthcare provider. By default, the IOP measurements from the most recent HOME(2) use period are shown. OD means the right eye. OS means the left eye.

4.4.2 Deactivating tonometer in iCare CLOUD

You can deactivate your tonometer in iCare CLOUD. Click **Devices** and then click **Deactivate**. This will end your ongoing HOME use period and remove the device from your account. After deactivating you won't be able to transfer measurement results to your iCare CLOUD account.

NOTE! Deactivating your device will remove your tonometer permanently from your account.

You can still see the measurement results and log into your account in iCare CLOUD after deactivating your tonometer.

4.4.3 Managing IOP results and creating reports

IOP measurements are listed under the **Measurements** tab. OD means the right eye. OS means the left eye. The listed measurements can be filtered either by entering **From** and **To** dates or by selecting a HOME(2) use period from the **Select** period drop down list.

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.

An IOP report is created from the rows of IOP measurement data listed. The healthcare professional 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.

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.
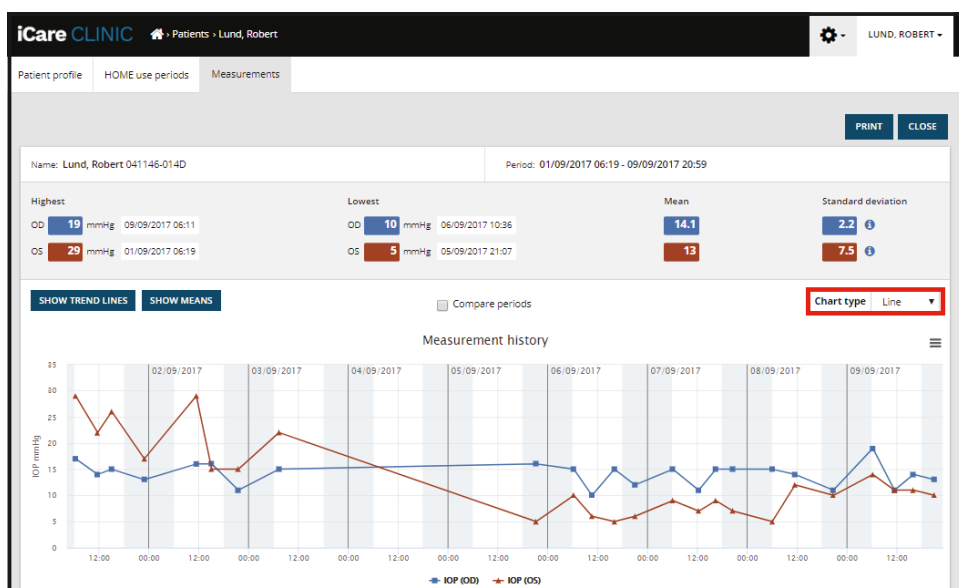
Chart type Line

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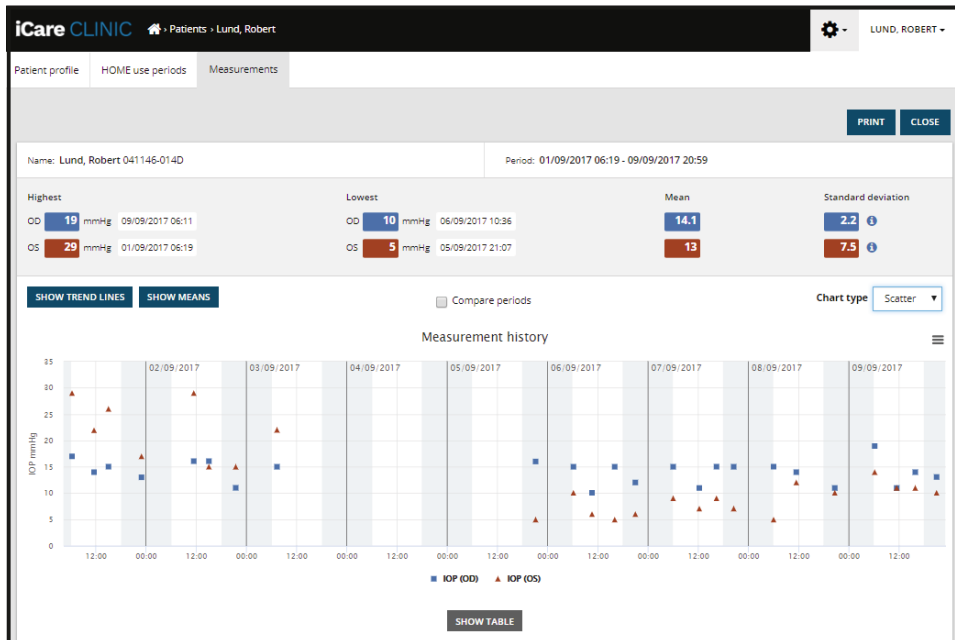
Chart type Scatter

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.
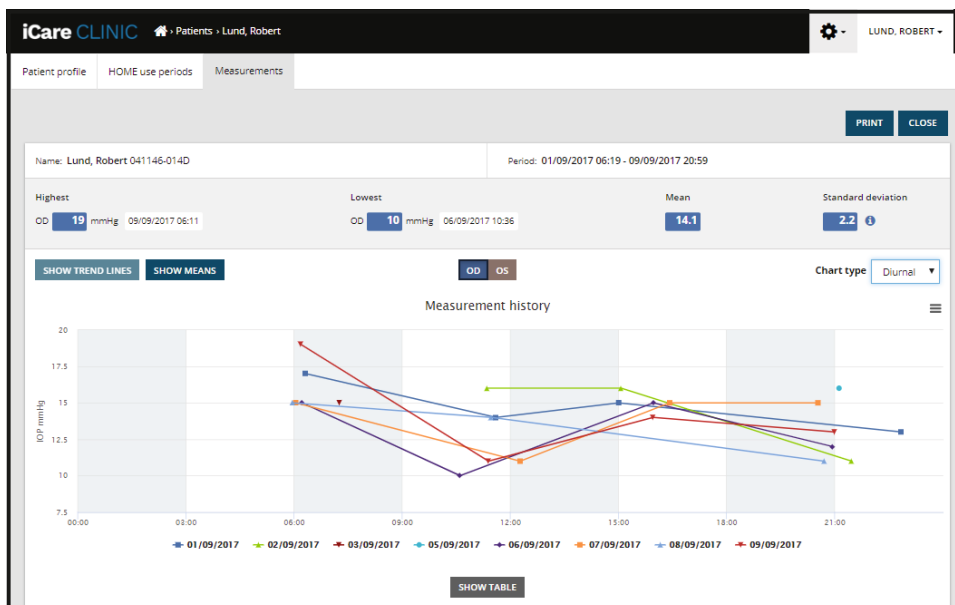
Chart type Diurnal

The chart type **Diurnal Periods** positions combined IOP data points into three hour time slots on a 24 hour x-axis. The combined data points measured display the mean value of the measurements of the three hour time slot. The IOP data points of each time slot are connected with direct lines. The graph shows the standard deviation bars of three hour time slots over the selected period of measurements.

Chart type Diurnal Periods

Ticking the **Compare periods** check box 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.
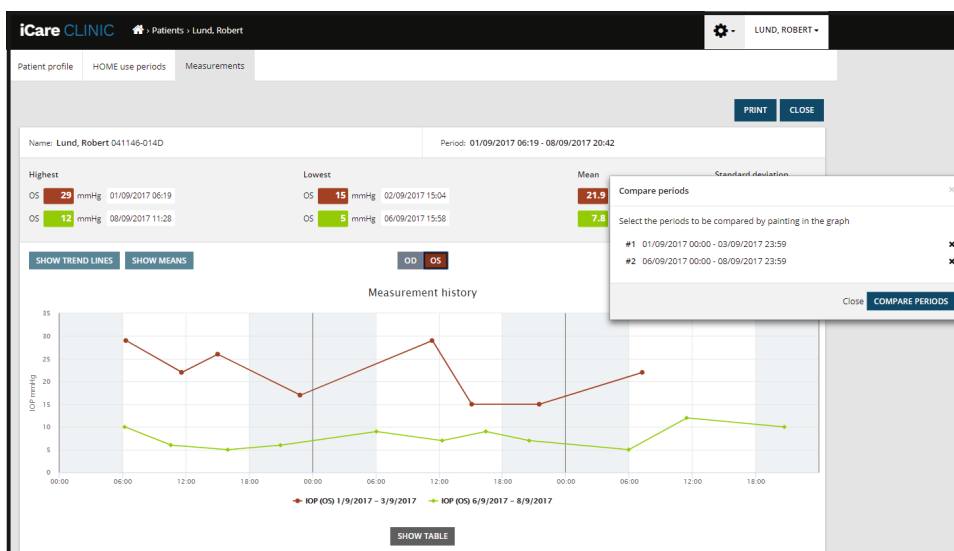
Compare periods

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 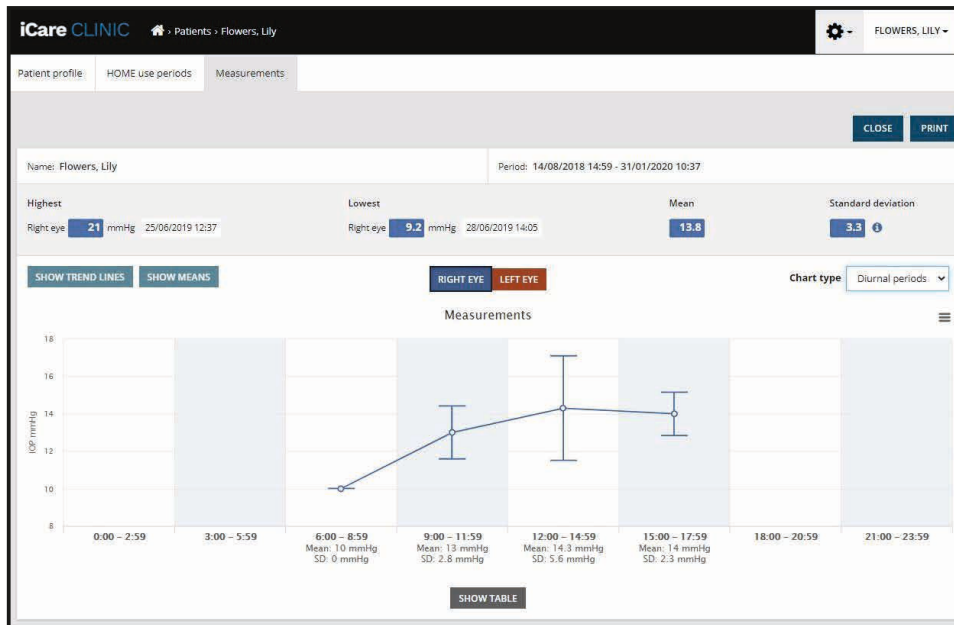on the report. Click the **SHOW TABLE** button to open and display the measurement list below the graph. The measurement list shows the measurement date and time, device type, measurement IOP and quality and patient position. Patient position is Sitting, Supine or Reclined.
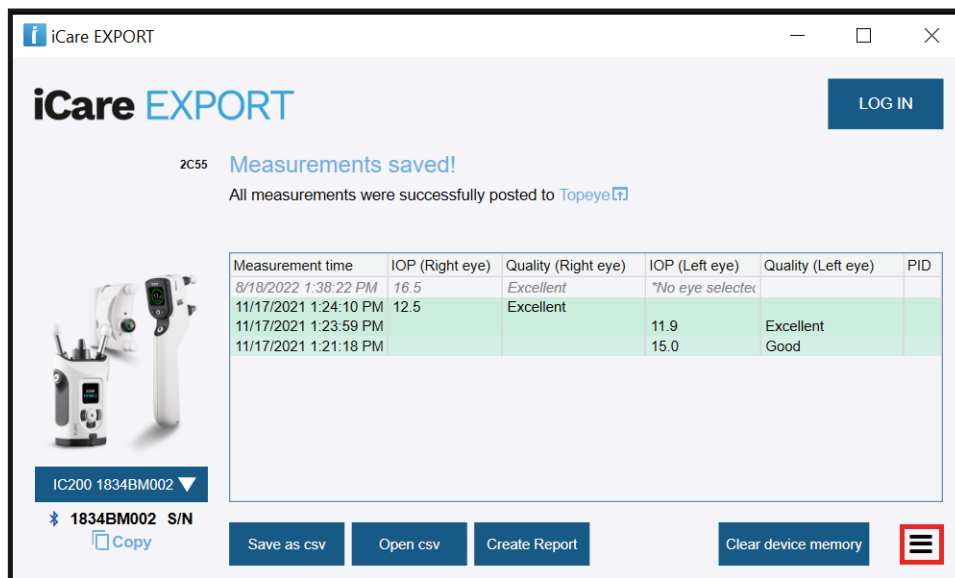
Date / Time ▾	Device type	Device name	IOP (OD)	Quality OD	IOP (OS)	Quality OS	Position
20/05/2021 ⓘ 10:48	iCare HOME2	Ann's device	17	Excellent	-		Sitting
20/05/2021 ⓘ 10:47	iCare HOME2	Ann's device	-		⚑ 16	Excellent	Sitting
20/05/2021 ⓘ 10:46	iCare HOME2	Ann's device	13	Excellent	-		Sitting
20/05/2021 ⓘ 10:45	iCare HOME2	Ann's device	-		⚑ 17	Excellent	Sitting
20/05/2021 ⓘ 10:44	iCare HOME2	Ann's device	14	Satisfactory	-		Sitting
20/05/2021 ⓘ 10:44	iCare HOME2	Ann's device	-		⚑ 17	Excellent	Sitting

4.5 Using iCare EXPORT to upload IOP results from the iCare HOME and iCare HOME2 tonometer

Once you have made some measurements, perform the following steps:

1. Connect the iCare HOME or HOME2 tonometer to the PC using a USB cable (HOME) or the wireless functionality (HOME2, see chapter 4.5.1). iCare EXPORT starts up when the tonometer is connected.

2. 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.

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 the uploaded results in chronological order. The results can be saved to a local csv file by clicking the **Save csv** button. The results are appended to the selected csv file if an existing csv file has been selected.

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

The results can also be saved to a PDF format by clicking the **Create report** button. Fill in the patient name and patient ID. The report includes measurement time, IOP results and quality of measurement for both right and left eye, measurement position and the tonometer model.

By default, all results that have been uploaded to the iCare CLINIC or iCare CLOUD database are removed from the memory of the iCare HOME or HOME2 tonometer. Click the **LOG IN** link on the upper right-hand side to login to iCare CLINIC (if enabled by your healthcare provider) for viewing your full measurement result history.

Results are not uploaded to the iCare CLINIC or iCare CLOUD database if the used iCare HOME or HOME2 tonometer does not belong to the device fleet of any healthcare provider or **Local mode** is set in iCare EXPORT. In these cases, the results in the memory of the connected iCare HOME or HOME2 tonometer can be removed by clicking the **Clear device memory** button and by confirming the removal.

iCare EXPORT can also be used in high contrast mode. Set your computer to high contrast mode through the computer settings.

4.5.1 Connecting iCare HOME2 tonometer with Bluetooth to iCare EXPORT

The iCare HOME2 tonometer has the capability to wirelessly transfer results to iCare EXPORT and further to iCare CLINIC or iCare CLOUD. Pairing of the iCare HOME2 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 HOME2 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 HOME2 tonometer.

5. The selected HOME2 tonometer activates the connection with iCare EXPORT.

NOTE! 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 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 a HOME2 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 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.

5 Maintenance and updates

iCare CLINIC and iCare CLOUD are automatically updated by Icare Finland Oy. This does not require any action from the user.

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

The customer is advised to verify the digital signature of iCare EXPORT always before installing it.

6 Decommisioning

iCare EXPORT can be uninstalled at any time without loss of data.

7 Troubleshooting

Open csv 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.

You have uploaded the IOP measurement result to iCare CLINIC, but they do not show up under your patient record. The possible reasons are the following:

a) Your health care provider has not registered the iCare HOME(2) device for your use. Contact your health care provider to verify that your iCare HOME(2) device is registered to you.

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 your IOP records. Contact your healthcare provider for assistance.

The results loaded from an iCare HOME(2) tonometer do not appear in iCare CLINIC. Make sure you have set cloud mode in iCare EXPORT. Reconnect the tonometer to iCare EXPORT.

8 Symbols

	Manufacturer
	CE mark
MD	Product is a medical device
	Refer to the instruction manual

9 Appendix 1 Technical description

The iCare CLINIC service is provided from internet servers using a web browser. TSL 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(2) tonometers are always displayed as integers of mmHg.

For the proper use of the iCare EXPORT on a PC, 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 date format used in the iCare CLINIC service is defined in the web browser's language settings. The date format used by iCare EXPORT is defined in the MS Windows operating systems settings.

iCare EXPORT reads 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 sends the measurement results read from a connected tonometer to iCare CLINIC. If the network fails to transfer results to iCare CLINIC, try again later.

9.1 Recommended security practices

You are strongly recommended to maintain virus protection up-to-date in the PCs used. You are also recommended to install security updates to the used web browsers and PCs when available.

The main risks of iCare CLINIC and CLOUD are related to controlling the access to information stored in it. Always use strong passwords. Do not share your password with others. Logout of iCare CLINIC or CLOUD after using it. Maintain malware and virus protection in the computers and smartphones iCare CLINIC or CLOUD is used with.

The main risk of iCare EXPORT is related to storing the IOP results to a local file. The user makes sure that access control to used computers is in good shape.

10   Appendix 2 System, error and fault messages

10.1   iCare CLINIC

Message	Situation	Explanation and possible action
Could not save file	When saving measurement results to a file.	It was not possible to save the results in the selected file. This may be due to a temporary failure in the system.
Token cannot be empty	When clicking password selection link in the received email.	The web link to activate user account is faulty. Contact your healthcare provider
Activation token does not exist	When clicking password selection link in the received email.	The web link to activate user account is faulty. Contact your healthcare provider.
The activation token has expired	When clicking password selection link in the received email.	The web link to activate user account has expired. Contact your healthcare provider.
Password change token does not exist	When clicking password reset link in the received email.	The web link to reset password is faulty. Contact your healthcare provider.
The password change token has expired	When clicking password reset link in the received email.	The web link to reset password has expired. Contact your healthcare provider.
Current password does not match	When entering new password.	The password provided by the user is incorrect.
Internal server error	Any time accomplishing some task.	There was a temporary failure in the system. Try again. If the error persists, contact your healthcare provider.

10.2 iCare EXPORT

Message	Situation	Explanation and possible action
Unknown device!	When connecting a tonometer to the computer with iCare EXPORT installed.	The connected device does not belong to any organization using iCare CLINIC or the iCare EXPORT version used is not the latest release. Ask your healthcare provider to register your tonometer to iCare CLINIC, or update iCare EXPORT from https://www.icare-world.com/export/ or from iCare CLINIC. If you don't have a healthcare provider, run iCare EXPORT in local mode.
Unable to post measurements into iCare CLINIC database!	When connecting a tonometer to the computer with iCare EXPORT installed.	The fault may be due to a temporary error in the service. Try later again.
Error connecting device	When connecting a tonometer to the computer with iCare EXPORT installed.	There was an error in connecting the device to iCare EXPORT. Reconnect the device.
Unable to write measurements to file	When saving measurement results shown in the iCare EXPORT user interface to a file.	The results could not be stored to file. This may be due to missing write permission for the selected file and folder or the file is open in another application.
Device info is not valid. Please, contact technical service.	When connecting a tonometer to the computer with iCare EXPORT installed.	iCare EXPORT could not read some information from the tonometer. Contact your healthcare provider.
BT adapter supporting Low Energy is not found.	When connecting an iCare HOME2 tonometer to the computer with iCare EXPORT installed.	The function you are trying to use requires Bluetooth Low Energy functionality which is missing from the used computer.
Cannot send measurement results to iCare CLINIC due to an expired device license. Ask your healthcare or service provider to renew the license.	When sending measurement results using iCare EXPORT or iCare PATIENT2.	License of the connected tonometer has expired. Ask your healthcare provider to renew the device license.

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