iCare HOME2 Tonometer for Intra-Ocular Pressure Monitoring in Glaucoma

1) Product Overview and Details

- The iCare HOME2 is a rebound tonometer used for measuring intra-ocular pressure (IOP) in glaucoma patients.
- IOP measures have a diurnal rhythm and 75% of IOP elevations occur outside of normal clinic hours (Liu et al, 2020).
- Glaucoma often goes undiagnosed in 50% of patients due to the IOP variability, thus home IOP monitoring has become the new standard to (Ertel et al, 2021):
1. Diagnose and Prevent disease progression.
2. Monitor medication adherence and treatment regimes.
3. Monitor post surgical outcomes.

iCare, 2023

Module 3 - Portfolio Assignment: Digital/Virtual Health Product Infographic for
Specialized Graduate Certificate in Health Informatics
Concentration: Digital Health
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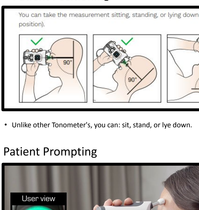
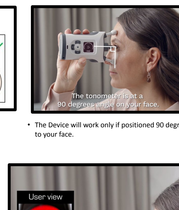
Technical Details

- The iCare HOME2 is the newest version of the iCare product line of home tonometer's.
- Each tonometer has a carrying case.
- Included are:
  - iCare HOME2 tonometer
  - Probe applicator
  - USB cables for mobile and PC connection
  - USB stick with instructions for use
  - 4 x AA 1.5 V alkaline batteries

Setup



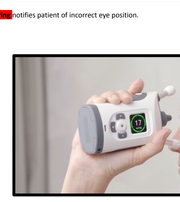
- User inserts sterile probe through the probe applicator.



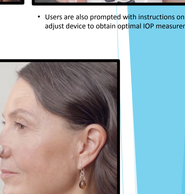
- Remove probe applicator and ready for use.

Patient Positioning

- Unlike other Tonometer's, you can: sit, stand, or lye down.

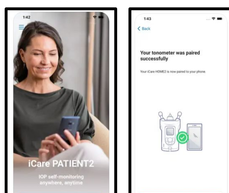


- The Device will work only if positioned 90 degrees to your face.

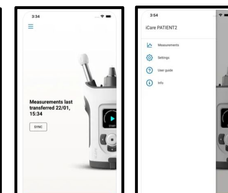


- Anatomical design automatically positions the IOP probe 5 mm perpendicular to the eye.

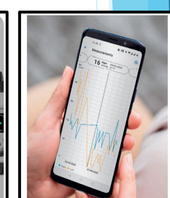
Patient Prompting



- **Green** ring notifies patient of optimal eye position.

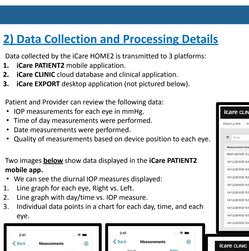


- **Red ring** notifies patient of incorrect eye position.

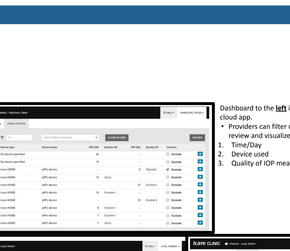


- Users are also prompted with instructions on how to adjust device to obtain optimal IOP measurements.

Measuring the IOP

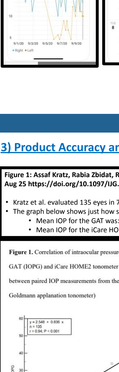


- iCare HOME2 positioned 90 degrees to face.
- User will press side buttons 6 times or hold.
- The green circle lights up with a "beep" for each of the 6 IOP measurements performed.

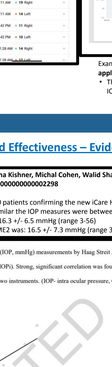


- Result of a successful IOP measurement displayed on LED screen.

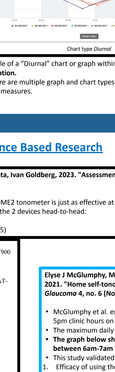
Mobile Application: iCare PATIENT2

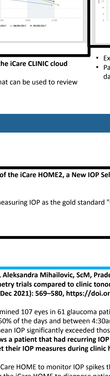


- App available for download via iPhone and Android app stores.

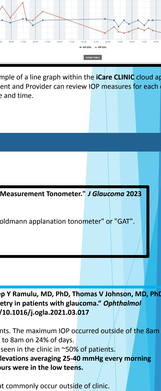


- App acts as a "copilot" sending user notifications such as:
1. Bluetooth pairing.
2. IOP results transmitted from device to mobile app or other destination such as computer or cloud.





- User interface is friendly.



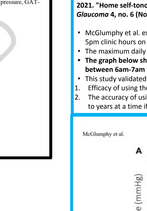
- Patient and Provider can review and analyze IOP measures on the mobile app in real-time with data visualizations.

2) Data Collection and Processing Details

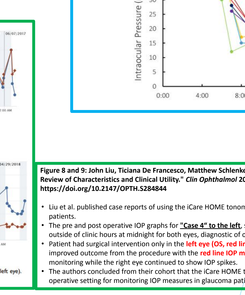
Data collected by the iCare HOME2 is transmitted to 3 platforms:
1. **iCare PATIENT2** mobile application.
2. **iCare CLINIC** cloud database and clinical application.
3. **iCare EXPORT** desktop application (not pictured below).

Patient and Provider can review the following data:
- IOP measurements for each eye in mmHg.
- Time of day measurements were performed.
- Date measurements were performed.
- Quality of measurements based on device position to each eye.

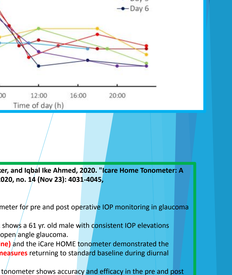
Two images **below** show data displayed in the **iCare PATIENT2 mobile app.**
- We can see the diurnal IOP measures displayed:
1. Line graph for each eye, Right vs. Left.
2. Line graph with day/time vs. IOP measure.
3. Individual data points in a chart for each day, time, and each eye.



Dashboard to the **left** is the provider's **iCare CLINIC** cloud app.
1. Time/Day
2. Device used
3. Quality of IOP measures



Example of a "Diurnal" chart or graph within **the iCare CLINIC cloud application.**
- There are multiple graph and chart types that can be used to review IOP measures.



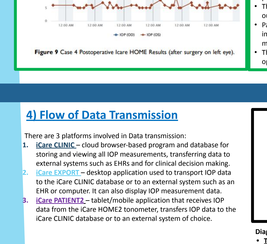
- Example of a line graph within the **iCare CLINIC** cloud app.
- Patient and Provider can review IOP measures for each eye, date and time.

3) Product Accuracy and Effectiveness – Evidence Based Research

Figure 1: Assaf Kratz, Rabia Zbidat, Rina Kishner, Michal Cohen, Walid Shalata, Ivan Goldberg, 2023. "Assessment of the iCare HOME2, a New IOP Self-Measurement Tonometer." *J Glaucoma* 2023 Aug 25 https://doi.org/10.1097/IJG.0000000000002298

- Kratz et al. evaluated 135 eyes in 70 patients confirming the new iCare HOME2 tonometer is just as effective at measuring IOP as the gold standard "Goldmann applanation tonometer" or "GAT".
- The graph below shows just how similar the IOP measures were between the 2 devices head-to-head:
  - Mean IOP for the GAT was: 16.3 +/- 6.5 mmHg (range 3-56)
  - Mean IOP for the iCare HOME2 was: 16.5 +/- 7.3 mmHg (range 3-55)

Figure 1. Correlation of intraocular pressure (IOP, mmHg) measurements by Haag Streit AT900 GAT (IOPG) and iCare HOME2 tonometer (IOPi). Strong, significant correlation was found between paired IOP measurements from the two instruments. (IOP- intra ocular pressure, GAT- Goldmann applanation tonometer)



Elyse J McGlumphy, MD, Aleksandra Mihailovic, ScM, Pradeep Y Ramulu, MD, PhD, Thomas V Johnson, MD, PhD, 2021. "Home self-tonometry trials compared to clinic tonometry in patients with glaucoma." *Ophthalmol Glaucoma* 4, no. 6 (Nov-Dec 2021): 569–580, https://doi.org/10.1016/j.ogla.2021.03.017

- McGlumphy et al. examined 107 eyes in 61 glaucoma patients. The maximum IOP occurred outside of the 8am to 5pm clinic hours on ~50% of the days and between 4:30am to 8am on 24% of days.
- The maximum daily mean IOP significantly exceeded those seen in the clinic in ~50% of patients.
- **The graph below shows a patient that had recurring IOP elevations averaging 25-40 mmHg every morning between 6am-7am yet their IOP measures during clinic hours were in the low teens.**
- This study validated:
1. Efficacy of using the iCare HOME to monitor IOP spikes that commonly occur outside of clinic.
2. The accuracy of using the iCare HOME to diagnose patients with glaucoma who will go undiagnosed for months to years at a time if they never have an IOP spike during clinic hours.

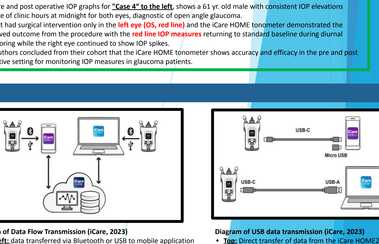


Figure 8 Case 4 Preoperative Icare HOME Results.

Figure 9 Case 4 Postoperative Icare HOME Results (after surgery on left eye).

Figure 8 and 9: John Liu, Ticiana De Francesco, Matthew Schlenker, and Iqbal Ike Ahmed, 2020. "Icare Home Tonometer: A Review of Characteristics and Clinical Utility." *Clin Ophthalmol* 2020, no. 14 (Nov 23): 4031-4045, https://doi.org/10.2147/OPTH.S284844

- Liu et al. published case reports of using the iCare HOME tonometer for pre and post operative IOP monitoring in glaucoma patients.
- The pre and post operative IOP graphs for **"Case 4" to the left**, shows a 61 yr. old male with consistent IOP elevations outside of clinic hours at midnight for both eyes, diagnostic of open angle glaucoma.
- Patient had surgical intervention only in the **left eye (OS, red line)** and the iCare HOME tonometer demonstrated the improved outcome from the procedure with the **red line IOP measures** returning to standard baseline during diurnal monitoring while the right eye continued to show IOP spikes.
- The authors concluded from their cohort that the iCare HOME tonometer shows accuracy and efficacy in the pre and post operative setting for monitoring IOP measures in glaucoma patients.

4) Flow of Data Transmission

There are 3 platforms involved in Data transmission:
1. **iCare CLINIC** – cloud browser-based program and database for storing and viewing all IOP measurements, transferring data to external systems such as EHRs and for clinical decision making.
2. iCare EXPORT – desktop application used to transport IOP data to the iCare CLINIC database or to an external system such as an EHR or computer. It can also display IOP measurement data.
3. iCare PATIENT2 – tablet/mobile application that receives IOP data from the iCare HOME2 tonometer, transfers IOP data to the iCare CLINIC database or to an external system of choice.

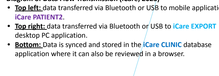


Diagram of Data Flow Transmission (iCare, 2023)
- **Top left:** data transferred via Bluetooth or USB to mobile application iCare PATIENT2.
- **Top right:** data transferred via Bluetooth or USB to iCare EXPORT desktop PC application.
- **Bottom:** Data is synced and stored in the **iCare CLINIC** database application where it can also be reviewed in a browser.

Diagram of USB data transmission (iCare, 2023)
- **Top:** Direct transfer of data from the iCare HOME2 to the iCare PATIENT2 mobile app.
- **Bottom:** Direct transfer of data from the iCare HOME2 to the iCare EXPORT.