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REVIEW ON CLINICAL DATA

ON 24-HOUR IOP MONITORING AND ICARE HOME

INTRODUCTION

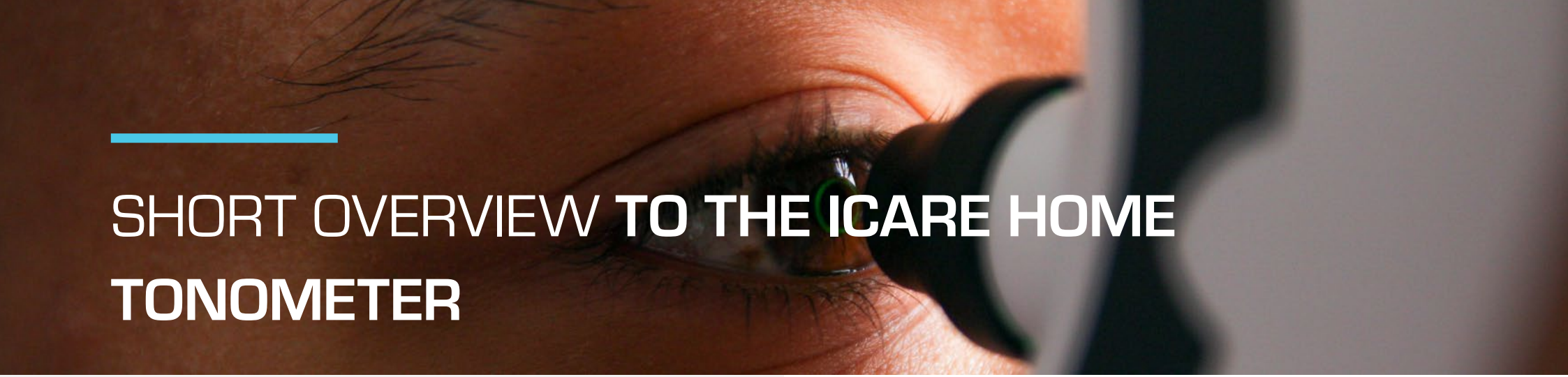
Glaucoma is the second leading cause of blindness in the world, according to the World Health Organization. There were an estimated 60.5 million people with glaucoma in 2010 and the figure is estimated to rise to 79.6 million by 2020 [1].

Aging is one of the major risk factors for glaucoma [2], and it is predicted that the prevalence of glaucoma will continue to increase in the aging societies, resulting in 111.8 million glaucoma patients by 2040 [3].

Elevated intraocular pressure (IOP) is another major risk factor for glaucoma. IOP is also the only disease parameter that can be influenced using eye drops, laser treatment or surgery.

Healthcare professionals typically measure IOP from glaucoma patients using a Goldmann applanation tonometer (GAT) or a comparable device in the clinical environment, often only in daytime and a few times yearly [4]. More frequent IOP monitoring over extended periods of time is rarely done in a hospital setting due to several limitations, including labor intensity, costliness and poor reflection of physiological IOP in a patient's usual environment. This may not be the ideal glaucoma diagnosis and management strategy as 24-hour IOP behavior in glaucoma patients can have implications for both disease pathogenesis and disease management.

This document reviews existing evidence on the importance of 24-hour IOP-monitoring in glaucoma management and presents the Icare HOME tonometer designated for monitoring of IOP in normal daily life by glaucoma patients or by their caregivers. The literature available on Icare HOME's accuracy and practicality is also reviewed.



SHORT OVERVIEW **TO THE ICARE HOME TONOMETER**

The Icare HOME is a handheld tonometer designed for self-measurement of IOP by glaucoma patients or their caregivers. The measurement is based on rebound technology which is the same patented technology as is used in the Icare tonometers designed for healthcare professional use.

The manufacturer Icare Finland is a market leader in handheld tonometers. More than 60 000 Icare tonometers have already been sold worldwide in over 90 countries since the introduction of the first Icare tonometer in 2003.

In a rebound tonometry measurement, a very light-weight, sterile probe is used to make a momentary contact with the cornea. The probe briefly pops out from its tube-like probe base, touches the cornea and rebounds back. An advanced algorithm analyzes deceleration of the probe and contact time of the probe with cornea, both of which are affected by IOP. In simple terms, the higher the IOP, the faster the probe decelerates and the shorter the contact time with cornea. An induction-based coil system is used for launching the magnetized light-weight probe towards the eye and for measuring the motion parameters. The device performs a measurement by gently and rapidly tapping the probe against the eye a total of six times. Anesthesia is not needed in rebound tonometry since the touch of the probe is so gentle that the measurement is barely noticed by the patient.

The Icare HOME supersedes the Icare ONE, the previous Icare self-tonometer model. Both rely on the same rebound technology and the measurement is performed in roughly the same way.

ACCURACY AND EASE OF USE **OF THE ICARE HOME TONOMETER**

The Icare HOME is used by patients or their caregivers under supervision of an eye care professional. Icare HOME is easy to use and well accepted by most of the patients. Learning to use the Icare HOME takes about 20 minutes [12]. The unit has two adjustable supports, one for the forehead and second for the cheek, to ensure accurate alignment and to prevent the housing of the instrument from contacting the patient's eye. The tonometer has an automatic eye recognition system using LEDs to identify which eye (OD/OS) is being tested, and an alignment guide to ensure that probe is correctly centered over to cornea.

Several studies have compared the IOP readings from the Icare HOME tonometer to Goldmann applanation tonometry. The reported mean differences between the Icare HOME and GAT measurements range from -1.31 mmHg to 0.7 mmHg in studies except for one study which gives a difference of -2.7 mmHg. Three of the studies report that the Icare HOME measurement results are within 3 mmHg from the GAT measurement value in 70%, 78.6% and 90.6% of cases respectively. One study reports that the Icare HOME measurement results are within 2 mmHg from the GAT measurement value in 68% of cases. One further study reports that the Icare HOME measurement value is within 5 mmHg from the GAT measurement value in 91.3% of cases. [4-12, 45]

In the light of the reported correlations between Icare HOME and GAT IOP readings, it can be stated that Icare HOME can be used for reliably monitoring short- and long-term IOP variations in a patient's day to day life. **The authors of the comparison studies state in their conclusions:**

+ "Most patients were able to perform self-tonometry and found it acceptable for home use. Measurements using rebound self-tonometry could improve the quality of intraocular pressure data and optimize treatment regimen."[45]
+ "Icare HOME appears to be accurate and could be used to monitor short- and long-term IOP variations." [4]
+ "The Icare HOME tonometer provides reliable and reproducible IOP values in glaucoma patients." [5]
+ "The Icare HOME tonometer is feasible for use in self-monitoring of IOP." [6]
+ "Self-tonometry has the potential to improve patient engagement, while also providing a more complete picture of IOP changes over time." [7]
+ "Icare HOME readings correlate well with the GAT results." [9]
+ "The Icare HOME device is safe and reliable for self-tonometry. The device has the potential to address an unmet need by providing more frequent IOP measurements in a patient's day to day life." [8]
+ "The Icare HOME can be used as a self/home-tonometer." [10]
+ "Measurements made using rebound self-tonometry are accurate and could be used to complement the investigation of patients with glaucoma. Intraocular pressure curves provide valuable data usable when adapting glaucoma treatment." [11]
+ "Icare HOME tonometry can be used for self-measurement by a majority of trained subjects." [12]

The studies also looked at how big percentage of glaucoma patients learn to use the Icare HOME correctly. Percentages range between 73% and 100% in different studies. In one study patients were asked about easiness and comfortability of measurement: 71% of patients thought that self-tonometry is easy and 92% thought that it is comfortable and that they would do it again. In another study 84% of patients thought that the device was easy to use and 95% thought that the measurement is comfortable. [4-12, 41]

Summaries of the main findings of the available comparison and usability studies on Icare HOME are presented in the table on the following pages.

Publication	Patient population and measurement schedule	How big % learned to use HOME correctly	Comparison of patient measurement with HOME to GAT or other method	Repeatability	Ease of use
Cvenkel, Jordanova et al. (2019 Eur J Ophthalmol) [45]	117 patients with glaucoma and ocular hypertension, 57±15 years old Measurements at the clinic	82%	Mean Icare HOME IOP 1.2 mmHg lower than GAT IOP (95% CI -3.4–5.9 mmHg) 68% of Icare HOME measurements within 2 mmHg of GAT		73% thought self-tonometry easy, 81% responded would use at home
Quérat, Chen et al. (2017 Acta Ophthalmol) [4]	60 healthy subjects, 48±15 years old Baseline clinic visit, measurements at home for 3 days, second clinic visit	97%	Mean Icare HOME IOP 0.27 mmHg lower than mean GAT IOP 70% of Icare HOME measurements within 3 mmHg of GAT		
Valero, Renard et al. (Journal francais d'ophtalmologie 2017) [5]	52 glaucoma patients, mean age 70.2±9.7 years Measurements at the clinic	85%	Mean IOP with HOME (patient measuring) 13.43±4.65 mmHg, with HOME (doctor measuring) 14.13±4.29 mmHg and with GAT 14.74±3.84 mmHg Mean difference between GAT and HOME 1.31 mmHg (95% CI -3.34 to 5.96 mmHg)	ICC 0.872 (0.824 - 0.910)	
Takagi, Yamamoto et al. (J Glaucoma 2017) [6]	130 glaucoma patients or suspects, mean age 57.5±13.1 mmHg; measurements at the clinic	98%	Mean IOP with Icare HOME (patient) 12.8±3.7 mmHg, with Icare HOME (specialist) 13.1±3.8 mmHg and with GAT 12.2±2.8 mmHg. The mean difference between Icare HOME (pat) and GAT was 0.7 mmHg (95% CI -3.07 to 4.46 mmHg). The IOP difference between Icare HOME (pat) and GAT was < 3 mmHg in 90.6% of the patients. The difference was > 5 mmHg in 3 patients (2.3%). Difference between HOME (pat) and GAT values was increased with increasing CCT. A 10% increase in CCT predicted a 1.2% increase in the difference.		
Pronin, Tatham et al. (JAMA Ophthalmol 2017) [7]	100 glaucoma patients, 67±10.9 years; measurements at clinic	73% met complete success criteria	Mean Icare HOME IOP 2.7 mmHg lower than GAT IOP (95% CI -3.5 to 8.8)	Excellent, ICC 0.903 (95% CI, 0.867-0.928)	71% thought self-tonometry easy, 92% thought comfortable and would do again
Mudie, Friedman et al. (Ophthalmology 2016) [8]	189 glaucoma patients or suspects, mean age 62.1±9.8 years; measurements at the clinic	80%	Mean difference between Icare HOME and GAT IOP 0.33 mmHg (SD 3.11 mmHg) HOME and GAT measurements agreed in 91.3% of cases within 5 mmHg	ICC 0.92 (95% confidence interval 0.89-0.95)	

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Publication	Patient population and measurement schedule	How big % learned to use HOME correctly	Comparison of patient measurement with HOME to GAT or other method	Repeatability	Ease of use
Termühlen, Rosentreter et al. (J Glaucoma 2016) [9]	101 glaucoma patients and 53 subjects without glaucoma, mean age 58.7 ± 17.3 years; measurements at the clinic	100%	Mean IOPs for right eyes were 14.9±6.3 mmHg with Icare HOME measured by the patient and 15.8±4.4 mmHg measured by the GAT. The bias between Icare HOME measurement by doctor and patient was 0.1 mmHg (95% CI -4.9 to 5.1 mmHg) and between Icare HOME measurement by doctor and GAT measurement -0.8 mmHg (95% CI -7.2 to 5.6 mmHg). There was a dependency on readings on CCT so that below 617.3 µm CCT HOME slightly underestimated IOP compared to GAT and over 617.3 µm CCT HOME slightly overestimated IOP.		Icare HOME was found to be well operable, safe and comfortable with readings of 1.9±0.9, 1.9± 0.8 and 1.7± 0.7 when the range from (1) excellent to (5) poor was used
Noguchi, Kiuchi et al. (J Glaucoma 2016) [10]	43 healthy young subjects, mean age 28.3 ± 4.7 years; a single HOME measurement at clinic six times a day from 8 am to 6 pm	100%	Icare HOME showed a similar diurnal IOP curve to that of GAT. At 12pm, 4 pm and 6 pm Icare HOME showed a statistically significant difference to GAT. The mean difference between GAT and Icare HOME was 1.03 mmHg (95% CI -3.91 to 5.98 mmHg).		39,5% answered that the device was easy to use, 46,5% answered normal and 14% answered difficult to use
Chen, Åkerstedt et al. (Acta Ophthalmol 2016) [11]	87 glaucoma patients, mean age 64 ± 13 years; baseline measurement clinic visit, measurements at home for 3 days 5 times a day, measurement at second clinic visit	98%	Mean difference between GAT and Icare ONE/HOME values varied from 0 to 1 mmHg Seventy-eight percent of Icare ONE/HOME measurements were within 3 mmHg of the GAT measurements.		
Dabasia, Murdoch et al (Br J of Ophthalmol 2015) [12]	76 eye clinic patients of which 62 glaucoma patients, median age 68 years; three measurements from both eyes in clinic	74%	Mean bias compared to GAT was -0.3 mmHg (95% CI -4.6 to 5.2) The bias was greatest for below 500 µm and above 600 µm CCT (central corneal thickness)		High agreement that device was easy to use (84%), reading was quick to obtain (88%) and measurement was comfortable (95%)
Mihailovic, Rosentreter et al (Ophthalmologe 2016) [41]	95 glaucoma patients and 52 healthy subjects, mean age 58.6 ± 17.4 years; at the clinic, use until got one successful measurement				On a scale from 1 (very good) to 5 (very poor) the Icare HOME was found to be easily handled (1.85±0.87), safe (1.87±0.81) and comfortable (1.66±0.72)

CLINICAL SIGNIFICANCE OF **24-HOUR IOP MONITORING**

Lowering IOP remains the only proven method of preventing or slowing down the rate of glaucoma injury. Studies suggest that the greater the lowering of IOP, the greater is the effect in preventing or slowing glaucomatous optic nerve damage [13-16].

Intraocular pressure varies throughout the diurnal and nocturnal periods [17-19]. Measurements made during office hours capture the IOP at specific moments and therefore do not reflect IOP fluctuations over a 24-hour period. Studies indicate, that when performing only sporadic intraocular pressure measurements during office hours there is a high probability of missing important IOP peaks. In studies by Awadalla, Nakakura and Barkana, there were IOP peaks outside of office hours in 7,8%, 66% and 69% of patients, respectively [25, 22, 21]. The IOP 24-hour patterns varied during different days in 63% and 47% of patients in studies by Quérat and by Chen, respectively [4, 11].

Infrequent measurements may make it difficult to assess effectiveness of a pharmaceutical or surgical treatment. Assumption of controlled IOP when IOP is in fact fluctuating may lead to undertreatment. Studies have shown that undertaking frequent IOP monitoring often results in changes to clinical management. 24-hour IOP monitoring resulted in a change in glaucoma treatment in 56%, 56%, 36% and 79% of patients in studies by Chen, Sood, Barkana and Hughes, respectively [11, 23, 21, 17]. In [43] Cho et al. describe how Icare ONE was used to monitor the effect of Tafluprost on diurnal variation of IOP.

Barkana et al. conclude in their article: "In glaucoma patients with advanced disease or progression that are disproportionate to known IOP measurements, 24-hour monitoring of IOP may reveal a greater role for pressure-related risk for glaucoma progression than previously suspected and may alter treatment strategies." [21] In their article Hughes et al. conclude: "Twenty-four-hour monitoring of IOP frequently led to a change of glaucoma management by identifying IOP fluctuations and spikes. High IOP and wide diurnal IOP variation are considered major risk factors for glaucoma progression, and standard clinic follow-up evaluations failed to identify these phenomena." [17]

Diurnal IOP fluctuations may be an independent glaucoma risk factor in addition to mean IOP over time or peak pressures over a safe level. Asrani et al. [26] looked at progression of visual field loss during a mean follow up period of 5 years and compared it to results from 5 days of diurnal IOP home monitoring at baseline. The diurnal IOP range and the IOP range over multiple days were significant risk factors for progression. Eighty-eight percent of patients in the upper twenty-fifth percentile of home IOP range and 57% of patients in the lower twenty-fifth percentile progressed. In Alpar's study those subjects with ocular hypertension whose home measured IOPs were 4-13 mmHg higher than office IOP developed progressive glaucomatous damage in two years, whereas those subjects whose home IOPs were lower than those measured at the clinic did not develop further damage in five years [27].

In addition to IOP fluctuations that occur over hours to a few days there are long-term fluctuations that happen over months or years. These have been evaluated in analysis of several well-known glaucoma clinical trials [35]. In Collaborative Initial Glaucoma Treatment Study, maximum, standard deviation and range of IOP were associated with worsening visual field scores [28]. In Advanced Glaucoma Intervention Study the investigators reported that IOP fluctuation remained significantly associated with glaucoma progression when the analysis accounted for cataracts and for changes in management due to advanced glaucoma [29]. Several smaller studies have reported similar results [30, 31, 32], but the role of long-term fluctuation in glaucomatous progression is not without controversy [33, 34]. The controversial results may suggest that long-term variation in IOP is less essential in early disease or that it may take more than a typical 5-year study period to demonstrate the effects of long-term IOP fluctuation in early disease [35].

Katz and Myers have suggested, "Not only is an ideal mean target IOP needed, but also a target for IOP fluctuation" [36]. Pronin and al. summarize, "Although the significance of diurnal and long-term IOP fluctuations remains uncertain, it is unsatisfactory to base treatment decisions on small number of measurements of what is a highly dynamic variable." [7]. In [35] professor Asrani states: "There is no widely accepted target IOP fluctuation. That said, in my opinion, the range should be less than 5 mmHg for patients with mild glaucoma, less than 4 mmHg for those with moderate glaucoma, and less than 3 mmHg for those with advanced glaucoma. There are, of course, many considerations in addition to these guidelines, including central corneal thickness measurements, the rate of disease progression, and myriad other factors that necessitate therapy tailored to the individual."

A further reason for performing home monitoring of IOP is that dangerously high increases in IOP between office visits may go undetected before optic nerve damage occurs [37, 38]. In patients with advanced glaucoma, IOP peaks post cataract surgery may lead to further progression of visual field defects [9, 39, 40]. In [44] Awadalla et al. describe the IOP monitoring with Icare HOME post selective laser trabeculoplasty to confirm reduced IOP levels and absence of pressure spikes after the operation.

More frequent IOP measurements also help to increase patient's engagement with their disease and compliance to medication and ease in the assessment of patient compliance.

Findings of studies looking at clinical significance of 24-hour IOP monitoring are summarized in the table on the following pages.

Publication	Patient population and measurement schedule	In how big % peak IOP recorded outside of office hours	Circadian pattern of IOP	Different IOP patterns on consecutive days	Change in clinical management/ effect of treatment/IOP vs. progression
Huang, Zangerl et al. (Optom Vis Sci 2018) [24]	40 glaucoma patients; measurements with Icare HOME at home four times a day over four to six weeks		Two dominant circadian IOP fluctuation patterns: peak upon awakening or peak at midday. Additionally, two patients exhibited a third pattern with IOP higher in the evening.		Within 24 hours of treatment commencement (Latanoprost 0.005%), IOP reduced from 23.9 to 16.1 mmHg
Awadalla, Craig et al. (ARVO poster 2018) [25]	153 glaucoma patients; measurements with the Icare HOME four times per day for two to four consecutive days	12 (7,8%) had elevated IOP outside office hours not previously recorded in a clinical setting (mean spike IOP of 35.6±8.2 mmHg)			The twelve participants who had elevated IOP outside office hours also showed significant progression on retinal nerve fiber layer (mean RNFL GPA - 3.9±2.9 µm/year)
Quérat, Chen et al. (Acta Ophthalm ol 2017) [4]	60 healthy subjects; measurements with Icare HOME were performed at baseline clinic visit, at home for 3 days and on the second clinic visit	Sixteen % of the study eyes had IOP peaks outside office hours during two of the three monitored days and 10% had peaks outside office hours during one of the days.		Sixty-three per cent of the study eyes had different IOP patterns on consecutive days.	
Chen, Åkerstedt et al. (Acta Ophthalm ol 2016) [11]	87 glaucoma patients; measurements with Icare HOME or ONE were performed at baseline clinic visit, at home for 3 days 5 times a day and at the second clinic visit		64% of the study eyes had higher IOP in the morning than in the afternoon/evening	Circadian patterns differed between consecutive days in 47% of the study eyes	56% of patients required change in clinical management due to 24-hour IOP monitoring
Sood, Ramanathan et al. (J Glaucoma 2016) [23]	18 glaucoma patients; Each patient had daytime (08:00 to 16:00) IOP phasing with GAT. Self-measured IOPs were recorded at home at night time using Icare ONE between 18:00 and 06:00 (at 2-hour intervals).		Mean peak IOP was significantly higher during night time phasing (15.8±4.8 mm Hg) compared with daytime phasing (12.8±2.7 mm Hg, p=0.0018).		A change in management occurred in 10 of 18 patients (56%)

Publication	Patient population and measurement schedule	In how big % peak IOP recorded outside of office hours	Circadian pattern of IOP	Different IOP patterns on consecutive days	Change in clinical management/ effect of treatment/IOP vs. progression
Durairaj (Clin Pharmacokinet 2015) [42]	A model was built for optimal sampling frequency of 24-hour IOP. The database included IOP values from 30 published clinical studies comprising 1404 patients.	Restricting the sampling time between 8 a.m. and 4 p.m. underestimates the fluctuation in diurnal IOP	At least four samples should be collected at 5:45 a.m., 2:15 p.m., 8:00 p.m., and 12:00 a.m. for reliable estimation of diurnal IOP variation		
Nakakura, Shiraki et al. (J Glaucoma 2007) [22]	42 POAG patients; Twenty-four-hour IOP values were obtained in the hospital with GAT at 3-hour intervals	Maximum IOP occurred outside of office hours in 66% of cases. Although there was no significant difference between mean office IOP and mean 24-hour IOP, there was no correlation between office IOP and 24-hour IOP fluctuation or office IOP fluctuation and 24-hour IOP fluctuation, stressing the importance of 24-hour monitoring.			
Barkana, Liebmann et al. (Arch. Ophthalmol.2006) [21]	32 glaucoma patients; measurements with GAT in a hospital setting during 24 hours	Peak IOP was recorded outside of office hours in 69% of the cases	36% of patients required change in clinical management due to 24-hour IOP monitoring		
Jonas, Junemann et al. (Am J Ophthalmol 2005) [20]	547 glaucoma patients and suspects; 24-hour monitoring with GAT in a hospital setting		A single intraocular pressure measurement has a higher than 75% chance to miss the highest point of a diurnal curve		
Hughes, Diamond et al. (J. Glaucoma 2003) [17]	29 patients; 24-hour GAT monitoring in a hospital setting				79% of patients required change in clinical management due to 24-hour IOP monitoring
Asrani, Giesel et al. (J. Glaucoma 2000) [26]	64 glaucoma patients; 5 measurements per day for 5 days at home with self-tonometer developed by the authors				Diurnal IOP range and the IOP range over multiple days were significant risk factors for progression. 88% of patients in the upper twenty-fifth percentile of home IOP range and 57% of patients in the lower twenty-fifth percentile progressed.

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ICARE FINLAND
- VISIONARY IN VISION

Icare Finland is the original developer of the rebound technique for tonometry. The clinical performance and ease-of-use of our devices has allowed Icare Finland to quickly become the global leader in handheld tonometry. Our proprietary technology is protected by over 20 patents and patent applications globally. Today, Icare Finland is the trusted partner for professional tonometry devices in ophthalmology.

The Icare® product line offers a range of tonometry devices for accurate, consistent and reproducible measurement of intraocular pressure in virtually any circumstances. All Icare® devices are manufactured in Finland under an ISO 13485-certified quality system.

Our range of tonometers includes:

Icare® **ic200**, Icare® **ic100**, Icare® **TA01i**, Icare® **PRO**, Icare® **HOME**,
Icare® **TONOVET PLUS**, Icare® **TONOVET** *and* Icare® **TONOLAB**

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