

Icare rebound tonometer to measure intraocular pressure

Medtech innovation briefing

Published: 15 March 2016

www.nice.org.uk/guidance/mib57

Summary

Icare products are the only devices that currently use rebound tonometry to measure intraocular pressure. These help to assess the risk of developing glaucoma, and also to detect and monitor the condition. The 4 functionally similar Icare tonometers measure the deceleration and rebound time of a small, lightweight probe, which makes brief contact with the cornea. Evidence from 1 systematic review and meta-analysis of studies published before 2010 showed that 52% (pooled value) of Icare intraocular pressure measurements were estimated to be within 2 mmHg of Goldmann applanation tonometer measurements. Five cross-sectional studies (published after 2010) of mixed quality assessed the agreement between measurements obtained with Icare and those obtained with the Goldmann applanation tonometer, with variable results. The Icare tonometers cost between £1,595 and £3,695 excluding VAT. The disposable probes for each model cost between £50 and £100 for 100 probes.

Product summary and likely place in therapy	Effectiveness and safety
<ul style="list-style-type: none">• Icare tonometers measure intraocular pressure in adults and children of all ages. Intraocular pressure is measured to assess the risk of developing glaucoma, and also detect and monitor the condition.• They can be used in any setting and can either replace, or be used in addition to, existing tonometers.	<ul style="list-style-type: none">• The published evidence summarised in this briefing comes from 1 systematic review and meta-analysis of studies published before 2010 (n=11,582 people; n=15,525 eyes); and 5 cross-sectional studies of mixed quality published after 2010 (n=1025 people; n=1123 eyes). Only 1 of the studies was conducted in the UK. All 6 studies used the Goldmann applanation tonometer as a comparator.• The systematic review included 14 Icare studies. Evidence showed that 52% (pooled value) of Icare intraocular pressure measurements were estimated to be within 2 mmHg of the Goldmann applanation tonometer measurement.• In 1 cross-sectional study (n=102 children), Icare overestimated intraocular pressure, whereas in a second study (n=99 people), it underestimated intraocular pressure. Two studies (n=327 and n=347 people) found agreement (using Bland–Altman analysis) between the 2 methods; however, there was less agreement at higher intraocular pressure values.

	<ul style="list-style-type: none"> • One study (n=150 people) found that measurements obtained with the Icare PRO were more accurate than those obtained with the Icare ONE.
<p>Technical and patient factors</p> <ul style="list-style-type: none"> • Icare tonometers are handheld, battery operated devices that use small, lightweight, single-patient use probes. • Icare tonometers measure the deceleration and rebound time of the probe as it briefly touches the cornea, which it uses to calculate the intraocular pressure. • Icare tonometers can be used without local anaesthesia. • There are 4 models that use the same technology: Icare TA01i, Icare ic100, Icare PRO and Icare HOME (previously known as Icare ONE). Icare TA01i, Icare ic100 and Icare PRO are designed for use by optometrists or ophthalmologists and could be used in primary, secondary or tertiary care settings. Icare HOME is designed for use by patients or their carers in the home. Only healthcare professionals can view Icare HOME measurement results using Icare LINK software. 	<p>Cost and resource use</p> <ul style="list-style-type: none"> • The capital cost of the Icare tonometers is £2,195 (Icare TA01i), £2,395 (Icare ic100), £3,695 (Icare PRO) and £1,595 (Icare HOME), excluding VAT. • The disposable probes cost £70 for 100 (Icare TA01i and Icare ic100), £50 for 100 (Icare PRO), and £50 for 50 (Icare HOME). • No published evidence on cost consequences and resource use was available.

Introduction

Glaucoma is a disease in which the optic nerve becomes damaged, leading to progressive loss of visual field and eventually to visual impairment and blindness. There are several

types of glaucoma, which differ mainly by cause and speed of symptom development (acute or chronic; NHS Choices 2014).

The damage to the optic nerve can occur because of raised pressure inside the eye (intraocular pressure, IOP). This can happen if the drainage tubes within the eye (called the trabecular meshwork) become blocked, so the fluid (aqueous humour) cannot drain out of the eye properly (NHS Choices 2014). IOP is normally about 15 mmHg. If it is greater than 21 mmHg on 2 or more occasions in 1 or both eyes (College of Optometrists 2012), this is classed as ocular hypertension (OHT). Although glaucoma is most commonly related to prolonged OHT, it can also occur when IOP is not raised (referred to as normal tension glaucoma).

OHT affects 5% of people aged over 40 years in the UK. This equates to around 1 million people (Burr et al. 2012). Risk factors for OHT include increasing age, short-sightedness (myopia), diabetes, vascular disease, and a family history of OHT (International Glaucoma Association 2015; NHS Choices 2014) as well as a previous eye injury or existing eye condition.

The most common type of glaucoma, accounting for over 90% of all cases, is chronic open-angle glaucoma (COAG), which is a slow-developing glaucoma without an obvious cause (such as ocular injury or inflammation, or pharmacological treatment; European Glaucoma Society 2008; NICE guideline on [glaucoma](#)). COAG is usually asymptomatic until irreversible vision loss has occurred. The peripheral vision is typically lost first before the damage progresses towards the centre of the visual field. About 10% of UK blindness registrations are related to glaucoma and around 2% of white European people over the age of 40 years and 10% of those aged over 75 years have COAG. The prevalence may be higher in people of African or African-Caribbean family origin or in those who have a family history of glaucoma. Based on these estimates, about 480,000 people have COAG in England (see the NICE guideline on [glaucoma](#) for more information).

People with OHT, or who have or are suspected of having COAG, need regular monitoring of IOP. This, together with other assessment tests (see NICE guideline on [glaucoma](#)), is used to identify changes that may indicate treatment is needed.

Technology overview

This briefing describes the regulated use of the technology for the indication specified, in the setting described, and with any other specific equipment referred to. It is the

responsibility of healthcare professionals to check the regulatory status of any intended use of the technology in other indications and settings.

About the technology

CE marking

The Icare tonometers are CE marked as class IIa devices under the medical device directive 93/42/EEC. CE marks were awarded in 2003 for TA01i, 2010 for Icare PRO, and 2015 for Icare ic100. Icare ic100 is functionally similar to Icare TA01i, which is expected to be discontinued in 2017. Icare ONE received CE marking in 2010. In 2014, the Icare ONE was updated (removing the display and adding positioning assistant technology, automatic left or right eye recognition and automated measuring sequences) and received CE marking as the Icare HOME. The 4 devices are manufactured by Icare Finland Oy. In the UK, Icare tonometers are supplied by Mainline Instruments.

Description

Icare tonometers are portable, handheld devices used to measure IOP. They assess the deceleration and rebound time of a small, lightweight probe, which makes brief contact with the cornea and can be used without local anaesthesia.

There are 4 Icare models, all of which use the same rebound technology: Icare TA01i, Icare ic100, Icare PRO and Icare HOME (previously known as Icare ONE; see [table 1](#)). Each model has a built-in adjustable forehead support and is supplied with single-patient use probes, a spare probe base and a container for cleaning the probe base (recommended every 3–6 months). The probes are disposable and must be changed for each patient, but can be used for both eyes assuming there is no eye infection. Several additional accessories are supplied with each model, including a USB cable and a USB memory stick with Icare LINK software for the Icare PRO and Icare HOME, and a USB charger (for rechargeable battery) for the Icare PRO. Icare HOME is also supplied with a carrying case.

Icare PRO and Icare HOME can be connected to a computer. Icare LINK software can be installed on the computer and used by healthcare professionals to transfer, analyse and store measurement data from the handheld device.

Table 1 Features of Icare TA01i, Icare ic100, Icare PRO and Icare

HOME

	Icare TA01i	Icare ic100	Icare PRO	Icare HOME
<i>Approximate dimensions (mm)</i>	230×80×32	215×95×29	225×90×46	110×80×30
<i>Approximate weight, with batteries (g)</i>	250	230	275	150
<i>Display</i>	Monochromatic 7-digit liquid crystal display (LCD)	128×128 pixel organic light-emitting diode (OLED) display	128×128 pixel organic light-emitting diode (OLED) display	No display
<i>Data transfer</i>	No data transfer	No data transfer	USB port for data transfer to PC with Icare LINK software	USB port for data transfer to PC with Icare LINK software
<i>Data storage</i>	Stores previous 10 readings	Stores over 1000 readings	Stores over 1000 readings	Stores over 1000 readings
<i>Position of the person during the measurement</i>	Standing or sitting	Standing or sitting	Standing, sitting or lying down in the supine position	Standing or sitting
<i>Notification of incorrect device position</i>	Two short beeps and an error message on the display	Red light on probe base for incorrect positioning or green light for correct positioning	Two short beeps and an error message on the display	Red light on probe base for incorrect positioning or green light for correct positioning

<i>Eye recognition</i>	None	None	User can manually select 'left' or 'right' depending on which eye is being measured	Automatic eye recognition to identify left or right eye
<i>Probe material(s)</i>	Wire pin with a plastic tip	Wire pin with a plastic tip	Plastic	Wire pin with a plastic tip
<i>Power supply</i>	4 AA non-rechargeable lithium batteries	4 AA non-rechargeable batteries	Rechargeable internal lithium-ion battery	2 CR123 non-rechargeable batteries

Icare tonometers are used as follows:

- The tonometer is switched on by pressing the 'measurement' button (or 'main' button for Icare PRO). A new single-patient use probe is inserted into the probe base and the button is pressed again to activate the probe.
- The person is positioned appropriately according to the tonometer in use: standing or sitting for all devices, or supine for Icare PRO only. The person looks straight ahead and the tonometer is brought close to the eye with the probe perpendicular to the centre of the cornea. The forehead support should be positioned against the forehead. The distance between the tip of the probe and the cornea should be 4–8 mm for Icare TA01i, Icare ic100 and Icare HOME and 3–7 mm for Icare PRO. The person taking the measurements can move the forehead support by turning the adjustment wheel to ensure the probe is correctly positioned.

- The IOP reading is based on 6 individual readings (1 measurement sequence, which takes about 2 seconds). The user must press the 'measurement' button to perform 1 individual IOP measurement. Both Icare ic100 and Icare HOME also have a 'series' mode, in which the user only needs to press the 'measurement' button once and keep the button pressed down to activate 6 automatic measurements. Each device calculates the final IOP measurement by discarding the highest and lowest readings and displaying the average of the remaining 4 readings. The probe moves to the cornea and back during every measurement and a short beep sounds after each measurement has been taken. The Icare TA01i, ic100 and PRO tonometers show results and measurement reliability on the display. The Icare HOME tonometer does not display the final IOP, but measurements can be transferred to a computer directly from the device by a healthcare professional using the Icare LINK software during routine monitoring assessments.

Setting and intended use

The Icare TA01i, Icare ic100 and Icare PRO devices are intended to measure IOP. They would be used by optometrists or ophthalmologists in primary, secondary or tertiary care settings. Although professionals should read the user manual before using Icare, no additional training is needed. However, a training session is offered by the manufacturer, if needed.

Icare HOME is intended to be used by adult patients or adult carers in the home to monitor IOP. According to the instructions for use, an eye care professional should observe the patient using the tonometer and provide certification before the device can be used in the home. Certification should be provided if the readings taken by the patient and the healthcare provider fall within 5 mmHg of each other, the range of the (3) readings taken by the patient is 7 mmHg or less and the position of the tonometer during the measurement is judged to be correct.

The manufacturer does not list contraindications for these devices; however, they state that their safety and effectiveness have not been evaluated in people with a variety of eye pathologies, including (but not limited to) corneal scarring, dry eyes, or corneal or conjunctival infections.

Current NHS options

NICE's guideline on [glaucoma](#) recommends that Goldmann applanation tonometry (GAT)

should be used to measure IOP in people with ocular hypertension (OHT) or chronic open-angle glaucoma (COAG), and in those who are suspected of having COAG. GAT is a contact technique for measuring pressure in the eye, in which the patient is given anaesthetic eye drops before the pressure inside the eye is measured by applying force directly to the cornea. Optometrists use both contact and non-contact (such as air-puff) tonometry to detect glaucoma (College of Optometrists and Royal College of Ophthalmologists 2013).

The NICE guideline on [glaucoma](#) also recommends the following tests, in addition to GAT, for people with OHT, COAG, or suspected COAG:

- central corneal thickness (CCT) measurement
- peripheral anterior chamber configuration and depth assessments using gonioscopy
- visual field measurement using standard automated perimetry (central thresholding test)
- optic nerve assessment, with dilatation, using stereoscopic slit lamp biomicroscopy with fundus examination.

The results of these tests estimate the risk of progression to glaucoma (CCT measurement, visual field measurement and optic nerve assessment) and assess for angle closure (peripheral anterior chamber configuration and depth assessments), thus indicating the level of clinical supervision and treatment needed. The guideline recommends that people with OHT or suspected COAG are monitored at regular intervals (every 4–6 months for people at high risk and 12–24 months for people at low risk of COAG). Monitoring intervals for people with confirmed COAG are based on their risk of progression to sight loss, and range from every 2–6 months to every 6–12 months. NICE recommends that an optometrist or ophthalmologist should perform GAT at every monitoring assessment for all people with OHT, or COAG, or those suspected of having COAG.

Icare tonometers are the only devices that currently use rebound tonometry to measure IOP. NICE is aware of the following CE-marked devices that appear to provide alternatives to GAT:

- Pascal Dynamic Contour tonometer (Swiss Microtechnology)
- Perkins Mk3 (Haag-Streit UK)

- Tono-Pen (Reichert Technologies)
- Triggerfish (SENSIMED); NICE has produced a medtech innovation briefing on [Triggerfish](#)
- Diaton tonometer (TGDC-01 Ryazan State Instrument, Ryazan)
- Ocular response analyser (Reichert Technologies)
- Corvis ST tonometer (Oculus).

Costs and use of the technology

Information on the cost of using the technology has been sourced from the manufacturer. The capital components of each Icare tonometer system have the following prices, excluding VAT:

- Icare TA01i: £2,195
- Icare ic100: £2,395
- Icare PRO: £3,695
- Icare HOME: £1,595

The probe bases for each system have the following prices (excluding VAT):

- Icare TA01i and ic100: £40
- Icare PRO: £50
- Icare HOME: £40

The disposable probes for each system cost (excluding VAT):

- Icare TA01i and ic100: 100 for £70
- Icare PRO: 100 for £50
- Icare HOME: 50 for £50

A staff training session is included in the price of an Icare tonometer if needed.

No other practical difficulties have been identified in using or adopting the technology.

The manufacturer suggests that the lifespan of these 3 technologies is 'tens of years'; a lifespan of 15 years has been assumed in this briefing. Both the Icare TA01i and Icare ic100 use 4 AA batteries, which cost an average of £1.06. The Icare HOME needs 2 CR123 batteries, which cost about £3.23. No routine maintenance or calibration is needed for any of the Icare tonometers, but the probe base and batteries should be replaced every 12 months for Icare HOME, Icare TA01i and Icare ic100. The probe base (and connected probe holder) should be replaced every 6 months for Icare PRO.

If a monitoring session with a healthcare professional takes 15 minutes, up to 30 Icare TA01i, ic100 or PRO measurements could be taken per day (7.5 hours), and 7,200 taken in 1 year (240 annual working days). Icare HOME measurements (self-monitoring) are typically taken 5 times per day (Asrani et al. 2011). Assuming that the Icare HOME is loaned to a different patient each week, this leads to 1,825 monitoring sessions per year. Using the standard annuity method with a discount rate of 3.5% gives the following costs per IOP assessment (inclusive of capital cost and costs of regular replacement of probe base, batteries and disposable probe):

- Icare TA01i and ic100: £0.70
- Icare PRO: £0.60
- Icare HOME: £1.10

No unit cost for GAT is reported in nationally representative sources. The NICE guideline on [glaucoma](#) uses the national tariff figure for follow-up visit to an outpatient ophthalmology clinic as the cost for a monitoring session. It notes that these monitoring sessions can include measurement of IOP with GAT. This method gives a cost of £59 (NHS National Tariff 2014/15; WF01A, 130), which may indicate the unit cost of GAT and includes a variety of resource uses (for example, the ophthalmologist's time).

Likely place in therapy

Icare rebound tonometers would be used for measuring IOP as a replacement, or addition to, existing tonometry methods.

Specialist commentator comments

Two specialist commentators stated that Icare tonometers may be most useful in paediatric and community care settings; one of the commentators noted that Icare tonometers could also be useful in secondary care ophthalmology clinics. Two commentators stated that fast pressure measurement is particularly important in paediatric ophthalmology and one of these commentators also noted that Icare tonometers could be useful for paramedics. Two commentators noted that anaesthetic eye drops are not needed when using Icare tonometers, which one commentator felt would be preferred by most children, and it also allows them to be used by trained non-medical personnel. However, according to another specialist, the Icare tonometer is unreliable when used in children's glaucoma clinics because the results do not correspond to those obtained with GAT. One commentator added that there is evidence that Icare is useful in the neonatal setting, specifically in the special care department, citing the study by Rodrigues and Chan (2014). Two commentators stated that Icare tonometers can also be used in patients with disabilities, and are easy to use.

Two specialist commentators stated that Icare may not be useful in clinical settings already using GAT, which is likely to be the preferred measurement method. One of the commentators considered that GAT may be used to supplement IOP results if the Icare reading is unusual or a more accurate reading is needed. Another commentator reiterated this point, stating that in the hospital setting, Icare should only be used for patients in whom GAT measurements are unobtainable, whereas in primary care, the indication for using Icare should be similar to that of other non-contact tonometers.

Two specialist commentators stated that Icare is useful as a screening tool, whereas a third specialist noted that additional technologies would be needed alongside Icare for screening in a hospital clinic. A fourth specialist commentator stated that more research should be done to evaluate the effectiveness of Icare for screening. One specialist commentator noted that GAT is the preferred tool for monitoring IOP in people who have confirmed glaucoma.

One specialist commented on the poor repeatability reported in the published Icare studies discussed in the briefing, stating that it may be a result of users not positioning the device in the centre of (or perpendicular to) the cornea. This was supported by another specialist who stated that ensuring the centre of the cornea is 'hit' with the probe is more difficult to guarantee with Icare than with a conventional tonometer. The commentator explained that rebound tonometry is affected by corneal hysteresis (a biomechanical

property of the cornea relating to its elasticity), which is why peripheral measurements can give erroneous results (although these will not necessarily be clinically significant).

Two specialist commentators noted that other potential causes of incorrect Icare IOP readings include biomechanical changes to the cornea caused by medicated eye drops to treat glaucoma, and 'stiff' corneas associated with diabetes. These specialist commentators also noted that Icare readings may be affected by different corneal biomechanics and other visual pathologies (including myopia), and such inaccuracies can often result in false referrals for these people. One of the commentators stated that this problem can also happen with non-contact tonometers, but less often. Three commentators emphasised the importance of measuring CCT, because this influences IOP measurement and will vary across a population. One of the commentators specified that Icare will overestimate GAT where CCT is high and underestimate it where CCT is low.

One commentator discussed costs, stating that it is unlikely that monitoring sessions will take place every day of the week and there will be high variability in the frequency of tonometer use depending on the setting. They also noted that it is unlikely that Icare HOME would be used as often as 5 times per day every day of the year. A second commentator stated that Icare is affordable and a third commentator noted that Icare may be associated with a reduction in costs because, unlike GAT, it does not need clinically qualified staff time (clinical assistants can use the device). Additionally, the commentator stated that the cost per measurement of the Icare devices (about £1 based on the cost of the disposable probe) is similar to the cost of using GAT with a disposable prism and topical anaesthetic.

Equality considerations

NICE is committed to promoting equality, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. In producing guidance, NICE aims to comply fully with all legal obligations to:

- promote race and disability equality and equality of opportunity between men and women
- eliminate unlawful discrimination on grounds of race, disability, age, sex, gender reassignment, marriage and civil partnership, pregnancy and maternity (including women post-delivery), sexual orientation, and religion or belief (these are protected characteristics under the Equality Act 2010).

Vision loss may be classified as a disability depending on its effect on the ability to carry out normal day-to-day activities. Disability is a protected characteristic defined in the Equality Act (2010). People who are registered as blind or partially sighted are automatically considered to be disabled under the Act.

People with diabetes are more likely to develop OHT and glaucoma and, therefore, may particularly benefit from Icare devices. Diabetes is a chronic disease. Chronic disease is treated as a disability if it has a substantial and long-term adverse effect on a person's ability to carry out normal day-to-day activities. Older populations and people of African and African-Caribbean family origin are also at increased risk of developing OHT and glaucoma. Age and race are protected characteristics defined in the Equality Act 2010.

Evidence review

Clinical and technical evidence

Regulatory bodies

A search of the Medicines and Healthcare Products Regulatory Agency website revealed no manufacturer Field Safety Notices or Medical Device Alerts for this device. There were 2 reports representing 1 adverse event identified from a search of the US Food and Drug Administration (FDA) database: Manufacturer and User Device Facility Experience (MAUDE) from 2003 to the present. The event, which did not result in patient harm, seemed to be related to the replacement of the Icare probes with a non-FDA approved version; however, it was unclear who supplied or manufactured the replacement probes.

Clinical evidence

A literature search found 116 full-text journal articles that reported on Icare tonometers. Studies were included if they used the Goldmann applanation tonometer (GAT) as the comparator. Retrospective studies, studies from developing countries, studies done outside of the European Union, studies involving fewer than 150 eyes (except Dahmann-Noor et al. 2013, which was set in the UK and so may be more relevant to NHS practice) and primary studies published before 2010 (see Cook et al. 2012) were excluded. A total of 6 studies, including 1 systematic review and 5 cross-sectional studies, have been included in this briefing.

Cook et al. (2012) did a systematic review and meta-analysis to assess the agreement of intraocular pressure (IOP) measurements taken using tonometers available in clinical practice and GAT. A total of 102 studies involving 11,582 patients (15,525 eyes) were included in the review; 99 studies were included in the meta-analysis. The included studies each directly compared 1 of 8 different types of tonometer with GAT (14 studies used Icare [models not reported]; 32 used dynamic contour tonometers; 4 used handheld applanation tonometers; 26 used non-contact tonometers; 3 used Ocuton S; 12 used ocular response analysers; 14 used Tono-Pen; 20 used transpalpebral tonometers). About 50% of all measurements from other tonometer types and 52% of all Icare measurements were estimated to be within 2 mmHg of the GAT measurements, based on pooled values across all relevant studies. Icare, which ranked fourth out of the 8 tonometers in terms of its accuracy, had a mean difference of 0.9 mmHg (95% confidence interval [CI] 0.4 to 1.4) when compared with GAT. Non-contact and handheld applanation tonometer measurements were the most similar to GAT measurements, with 66% and 59% of IOP measurements estimated to be within 2 mmHg of the GAT measurement respectively. The authors concluded that non-contact tonometers and handheld applanation tonometers achieve the closest values to GAT (see [table 2](#)).

Avitabile et al. (2010) was a single-centre, cross-sectional study set in Italy. The aim of the study was to evaluate the effect of refractive errors and central corneal thickness (CCT) on the measurement of IOP by Icare (model not stated) and its agreement with GAT measurements. Reproducibility of IOP measurements was also analysed for each method. Healthy volunteers (n=327) were recruited among students, staff and relatives of patients referred to a university eye clinic, and allocated to 1 of 4 groups: emmetropic (perfect vision, n=78), hyperopic (far-sightedness, n=83), myopic (near-sightedness, n=87), and astigmatic (blurred vision due to an irregular curve of the cornea, n=79). The order in which IOP was measured using Icare or GAT was randomised, and IOP was measured twice for each device by 2 experienced ophthalmologists (who each did 1 measurement sequence for each device). The reproducibility of IOP measurements was high with both Icare and GAT and no significant difference was found between the IOP readings obtained by the 2 different operators for either method. The mean difference showed that Icare measurements were slightly higher than GAT in emmetropic (0.6 ± 1.5 mmHg, $p=0.000$), hyperopic (0.7 ± 1.5 mmHg, $p=0.000$) and astigmatic (0.6 ± 1.2 mmHg, $p=0.000$) eye groups, with the greatest mean difference reported in myopic eyes (1.6 ± 1.8 mmHg, $p=0.000$). The difference between Icare and GAT was greater in higher IOP readings ($p<0.001$). In all groups, increasing IOP values were correlated with increasing CCT ($p<0.001$) but the discrepancy between Icare and GAT values was correlated with refraction ($p<0.001$). The authors concluded that the Icare measurements were reproducible in healthy volunteers

and were slightly higher than GAT measurements of IOP in all groups (see [table 3](#)).

Dahlmann-Noor et al. (2013) did a single-centre, cross-sectional study in England. The aim of the study was to examine the agreement between IOP measurements using Icare (model unknown) and GAT, in children with glaucoma (n=102) recruited from a tertiary care centre. Two different observers measured IOP using Icare (the first observer taking 2 measurements and the second taking 1 measurement), and a third observer measured IOP using GAT. The children's preferred method of measurement was also recorded by the third observer. The amount of available data varied for the different comparisons (see [table 4](#)). The mean difference between the 2 Icare readings taken by observer 1 was not statistically significant ($p=0.427$), nor was the mean difference between Icare readings taken by observers 1 and 2 ($p=0.8$). Icare generally gave higher readings than GAT with a mean difference between GAT and Icare readings of 3.3 mmHg ($p<0.001$). There was an association between the extent of the difference between the 2 methods and the level of the measurement, with smaller differences being seen with lower IOP measurements. There was increased disagreement (larger discrepancies) between IOP measurements using Icare and GAT with higher CCT values. Eleven children preferred GAT, 70 preferred Icare and 21 gave no preference. The authors concluded that there was poor agreement between Icare and GAT in children with glaucoma and that Icare often overestimated IOP.

Marini et al. (2011) did a single-centre, cross-sectional study in Italy to test the agreement between IOP measurements taken with Icare (model unknown) and GAT in people with glaucoma and ocular hypertension (n=347). IOP was measured using Icare first (IC1), then GAT, and finally a second Icare measurement was taken (IC2). The mean IOP reading taken with IC2 was significantly lower than IC1 values ($p<0.001$); however, it was significantly higher than for GAT ($p=0.011$). A significant linear correlation was found between CCT and IC1 as well as CCT and IC2, in which a 4.6 and 4.1 mmHg increase in IOP was seen for each 100 micrometre increase in CCT respectively. Smaller differences between Icare and GAT measurements were seen with lower IOP measurements ($p<0.001$). The authors concluded that the agreement between the methods was acceptable for low IOP measurements but not for high IOP values (see [table 5](#)).

Moreno-Montanes et al. (2015) did a multicentre, cross-sectional study in Spain. The aim was to compare patient-obtained IOP measurements using Icare ONE and clinician-obtained values using Icare PRO with GAT measurements. The usability of Icare ONE was also assessed. People (n=150; 60 people without glaucoma and 90 people with glaucoma or OHT) were recruited from routine clinical visits at 2 departments of ophthalmology. All patients had best-corrected visual acuity of 10/20 or better. Three

measurements were taken using Icare ONE and 1 measurement each was taken using Icare PRO and GAT. The order in which Icare PRO and Icare ONE measurements were taken was randomised. GAT was the last measurement taken in all people, after the anaesthetic drops were given. For all participants, the mean IOP values were 16.6 ± 4.43 mmHg with GAT, 17.5 ± 5.42 mmHg with Icare ONE ($p=0.32$ compared with GAT), and 16.6 ± 4.77 mmHg with Icare PRO ($p=0.75$ compared with GAT). The IOP values were within 3 mmHg of the GAT values in 67.1% of eyes with Icare ONE and in 79.6% of eyes with Icare PRO. Icare ONE results were significantly lower than GAT results for lower IOP values ($p<0.001$). The differences in IOP values between Icare ONE and GAT ($p=0.08$) and between Icare PRO and GAT ($p=0.06$) were not related to CCT. Using Icare ONE was classified as very easy by 37 participants (24.7%), easy by 79 participants (52.7%), complicated by 21 participants (14%) and very complicated by 13 participants (12.5%). The perception of increased difficulty using Icare ONE correlated with increased age ($p=0.003$). The authors concluded that results from Icare PRO were more similar to GAT results than those from Icare ONE (see [table 6](#)).

Rosentreter et al. (2013) carried out a single-centre, cross-sectional study in Germany. The study aimed to evaluate the agreement between IOP measurements obtained using an Icare tonometer (model unknown) and GAT or Pascal dynamic contour tonometry (DCT) in patients with corneal abnormalities. The authors also examined the influence of CCT, corneal diameter, corneal radius and axial length on IOP measurements. One experienced ophthalmologist took 3 measurements using each method in 99 patients (171 eyes with different corneal abnormalities and 26 eyes with normal vision). About 42% of Icare measurements were estimated to be within 2 mmHg of the GAT measurements. Icare and GAT readings were not significantly influenced by CCT, axial length, corneal diameter or corneal radius. In the eyes with corneal abnormalities, IOP measurements were difficult to obtain with GAT and DCT because of sutures interfering with the tip of the tonometers, corneal surface irregularities and corneal scars, whereas IOP was measureable with Icare with all corneal abnormalities. The agreement between Icare, GAT and DCT was clinically acceptable in corneal dystrophy and keratoconus but poor in eyes after keratoplasty. The authors concluded that although there was an acceptable agreement between the 3 methods, Icare significantly underestimated IOP in all groups compared with GAT and DCT (see [table 7](#)).

Recent and ongoing studies

Four ongoing or in-development trials on Icare for measuring IOP were identified in the preparation of this briefing:

- Technology-based eye care services (TECS) Compare ([NCT02558712](#)): a prospective interventional study that aims to compare the TECS protocol to the standard face-to-face ophthalmological examination. Participants are adults without acute or chronic ocular issues, who are patients at an eye clinic in the USA. The study is not yet open for participant recruitment and has a planned closing date of September 2017.
- Comparison of different portable tonometers ([NCT01325324](#)): a prospective interventional study of Icare Pro, TONO-Pen AVIA, Perkins Tonometer and PASCAL Hand Held Dynamic Contour Tonometer. Participants are healthy adults without glaucoma or other optic neuropathies. The planned study completion date was December 2015; however, the entry states that the study is currently enrolling by invitation only in Switzerland.
- The intraocular pressure measured by different tonometers in corneal edema ([NCT01998568](#)): a cross-sectional study that aims to assess the effect of corneal oedema on IOP values measured by GAT in comparison with dynamic contour tonometer, Icare and Tono-Pen. Participants are adults with clinical central corneal oedema. The study, which began in November 2013, is currently recruiting participants in Thailand. It had a planned closing date of February 2016.
- The effect of corneal biomechanical properties on rebound tonometer in patients with normal tension glaucoma ([ISRCTN16912051](#)): a cross-sectional study to examine the effect of the structure and functioning of the cornea on IOP measurements taken with Icare, ocular response analyser and GAT. Participants are adults with or without glaucoma from a university hospital in South Korea. The study, which began in January 2013, is currently recruiting patients. The study has a planned closing date of January 2023.

Costs and resource consequences

The costing report from NICE's guideline on [glaucoma](#) estimates that 172,000 referrals are made each year to hospital eye services in England for people with ocular hypertension or suspected chronic open-angle glaucoma (COAG). This indicates the potential usage of Icare tonometers in the NHS. In addition, a third of these people are expected to need long-term and repeated monitoring of IOP.

According to the manufacturer, Icare tonometers are being used at 115 sites in the UK, 109 of which are NHS hospitals. They are also used in primary care settings and in people's homes, to measure and monitor IOP.

If any of the Icare tonometers were adopted, there would be no need to change the way current services are organised or delivered. No other additional facilities or technologies are needed alongside the technology.

No published evidence on the resource consequences of adopting Icare tonometers was identified in the systematic review of evidence.

Strengths and limitations of the evidence

Excluding the systematic review (which did not outline individual study designs), most of the evidence considered in this briefing was from single-centre, prospective cross-sectional studies. In the 5 individual studies summarised, participants were children (n=102) or adults (n=923 people; n=1021 eyes), who had either normal vision or had glaucoma, ocular hypertension or corneal abnormalities. No randomised controlled trials were identified. All included studies were carried out in Europe and all studies compared IOP measurement using Icare with GAT, the reference standard.

The evidence shows variations in the reported accuracy and repeatability of Icare tonometers. The systematic review by Cook et al. (2012) reported heterogeneity in the results of the included studies. This was because the studies used varying numbers of observations for the tonometers and reference standard, included more than 1 eye per participant (resulting in clustering of data), and there was a lack of standardisation in reporting. In addition, the analysis did not take into account the effect of CCT, which varies across a population and influences IOP measurement (giving higher IOP values when the cornea is thick and underestimating it when the cornea is thin). These all limited the extent to which the authors could accurately represent the evidence or reach meaningful conclusions about the accuracy of each available tonometer. Also, Cook et al. (2012) did not report the repeatability of GAT measurements (or whether these were included in each Icare study reviewed), which is a useful metric in evaluating comparators. Additionally, no sub-analysis of the 14 Icare studies included in the review was done and, therefore, no conclusions can be drawn regarding their heterogeneity.

The limits of agreement between Icare and the comparator in the studies by Moreno-Montanes et al. (2015), Marini et al. (2011) and Rosentreter et al. (2013) were very large. The repeatability for Icare in the Dahlmann-Noor et al. (2013) study was also larger than that recorded in the broader literature for GAT (about ± 3.5 mmHg), although Icare repeatability was more similar to GAT in the Marini et al. (2011) study. Both the mean difference between Icare and GAT and limits of agreement with GAT will be affected by the

population examined, such as the effect of CCT and refractive errors. The mean difference between GAT and Icare of ± 1.6 mmHg reported in Avitabile et al. (2010) is not necessarily clinically meaningful for all refractive errors and is similar to the variability inherent to GAT; however, it may be relevant to people with myopic eyes who have a higher risk of glaucoma. Corneal astigmatism could have contributed to varied results in this study.

Dahlmann-Noor et al. (2013) was the only study done in the UK and so these results may be more relevant to the NHS. This was also the only study that reported the use of a sample size calculation (determined by recommendations for Bland–Altman analysis). It is unclear whether the other studies that did not report the use of a sample size calculation were adequately powered to detect differences in the outcomes. However, the studies all included large sample sizes (minimum of 150 eyes), which should increase the probability of detecting a difference between groups where such a difference exists (type II error) and should also make it less likely that a significant finding was actually a false positive.

The operators performing GAT in the study by Moreno-Montanes et al. (2015) were masked to the Icare ONE and Icare PRO readings. The operators in the other 4 prospective studies were not blinded to the intervention. This may introduce performance bias. Another source of potential bias is the experience of the user and the resulting proficiency with the procedure. Avitabile et al. (2010) and Dahlmann-Noor et al. (2013) used 2 observers to measure IOP in their studies. Avitabile et al. (2010) specified that the measurements were taken by experienced ophthalmologists but Dahlmann-Noor et al. (2013) did not specify the experience of the 2 observers taking Icare measurements. In both studies, there was no significant difference in the inter-observer variability in Icare readings. None of the other studies indicated the users' level of experience.

Avitabile et al. (2010) randomised the order in which patients had Icare and GAT. Moreno-Montanes et al. (2015) randomised the order in which patients had Icare PRO and Icare ONE to eliminate order-effect bias. However, they did not randomise the order of Icare and GAT. The remaining 3 cross-sectional studies did not randomise the order in which patients received the intervention methods.

The results from Moreno-Montanes et al. (2015) cannot be generalised to patients with advanced glaucoma, who often have low visual acuity, because only patients with a best-corrected visual acuity of 10/20 or better were included. In this study, 3 Icare ONE measurements were taken, whereas only 1 Icare PRO and GAT measurement was taken. This may have introduced reporting bias.

Three studies (Dahlmann-Noor et al. 2013; Avitabile et al. 2010; Marini et al. 2011) found that the difference between GAT and Icare increased with increasing IOP values, which may limit the clinical utility of this device in the detection and diagnosis of ocular hypertension and glaucoma. The effect of CCT on Icare readings reported in the Marini et al. (2011) paper was higher than those generally seen in clinical practice for GAT.

Dahlmann-Noor et al. (2013) examined patient preference; however, they did so only after the last measurement. Asking for the patient preference after the final IOP test (as opposed to being asked to rate each individual test and comparing responses, for example) could result in recall bias. In addition, this study was limited because it had missing data, therefore the amount of available data varied for the reproducibility and repeatability of IOP measurements using Icare.

None of the authors of the publications reported any financial incentive or conflicts of interest.

Relevance to NICE guidance programmes

NICE has issued the following guidance:

- [Glaucoma in adults](#) (2011) NICE quality standard 7
- [Glaucoma: diagnosis and management](#) (2009) NICE guideline CG85

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Table 2 Overview of the Cook et al. (2012) systematic review

Study component	Description
Objectives/ hypotheses	To assess the agreement of IOP measurements using tonometers available for clinical practice with GAT as the reference standard.
Study design	Systematic review and meta-analysis.
Setting	n/a

Inclusion/ exclusion criteria	<p>Inclusion:</p> <ul style="list-style-type: none"> • directly comparative studies that assessed the agreement of 1 or more tonometers compared with GAT in the same group of people • patients 16 years or older. <p>Exclusion:</p> <ul style="list-style-type: none"> • tonometers that were not commercially available or judged unsuitable for monitoring ocular hypertension in routine clinical practice (including applanation resonance tonometer, ocular blood flow instrument, Schiötz, SmartLens, pneumatonometer and manometry) • studies published in a non-English language and conference abstracts.
Primary outcomes	Agreement between a tonometer and the reference standard, reliability (inter- and intra-observer variation) associated with measurements, and the proportion of participants with a recorded IOP measurement ('recordability').
Statistical methods	95% limit of agreement interval was calculated for each candidate tonometer from pooled estimates of the mean difference between a tonometer measurement and GAT.
Studies and total sample size included	<p>A total of 102 studies involving 11,582 patients (15,525 eyes) were included in the review; 99 of these studies were included in a meta-analysis.</p> <p>In the 102 studies, 8 different tonometers were compared with GAT: 14 studies used Icare (model unknown), 32 studies used dynamic contour tonometers, 4 used handheld applanation tonometers, 26 used non-contact tonometers, 3 used Ocuton S, 12 used ocular response analysers, 14 used Tono-Pen, and 20 used transpalpebral tonometers.</p>

Results	<p>Non-contact tonometers had the smallest mean difference compared with mean GAT value (0.2 mmHg) in contrast with Ocuton S, which had the largest difference (2.7 mmHg). Icare had a mean difference of 0.9 mmHg (95% CI 0.4 to 1.4) compared with GAT, ranking fourth out of 8 for accuracy.</p> <p>Approximately 50% of all tonometer measurements were estimated to be within 2 mmHg of the GAT measurement, including 52% of all Icare measurements.</p> <p>For all tonometers (except the non-contact tonometer), a mean difference of greater than 2 mmHg compared with GAT fell within the 95% prediction interval.</p> <p>The sensitivity analyses did not have a substantial effect on the results, nor did the subgroup analyses provide informative results. Non-contact tonometer measurements and handheld applanation tonometers were the most similar to GAT, with 66% and 59% of IOP measurements within 2 mmHg of the GAT value respectively.</p> <p>Recordability was reported in 4 Icare studies with a median of 100% (range 50–100%). The median study size for Icare was 145 people (range 36–150).</p>
Conclusions	The non-contact tonometer and handheld applanation tonometers achieve the closest values to those using GAT.
Abbreviations: CI, confidence interval; GAT, Goldmann applanation tonometry; IOP, intraocular pressure; n/a, not applicable.	

Table 3 Overview of the Avitabile et al. (2010) study

Study component	Description
Objectives/ hypotheses	To evaluate the effect of refractive errors and CCT on the measurement of IOP by Icare (model unknown), and its agreement with measurements using GAT.
Study design	Prospective cross-sectional.

Setting	Italy, recruited from May 2007 to January 2008 No follow-up period.
Inclusion/ exclusion criteria	Inclusion: <ul style="list-style-type: none"> healthy volunteers recruited among students, personnel, and relatives of patients referred to the Eye Clinic of the University of Catania. Exclusion: <ul style="list-style-type: none"> people unable to provide Icare or GAT measurements.
Primary outcomes	Repeatability and reproducibility of IOP measurements.
Statistical methods	Wilcoxon signed-rank test was used to compare the IOP values measured by the 2 operators for both Icare and GAT. The repeatability coefficient was calculated for inter-test differences. Bland–Altman analysis was used to assess the clinical agreement of IOP measurements between the 2 methods.
Patients included	327 total (89 male, 238 female): emmetropic (n=78); hyperopic (n=83); myopic (n=87); and astigmatic (n=79). Age range 18–85 years.
Results	No significant difference was found between the IOP values obtained by the 2 operators with Icare or GAT. Bland–Altman analysis showed agreement between the 2 methods. In each refraction group, IOP values detected by Icare were higher than those detected by GAT (paired t-test p=0.000). The greatest mean difference was in myopic eyes (1.6±1.8 mmHg) with 95% limits of agreement from –1.90 to 5.16. The mean difference was less than 1 mmHg in emmetropic, hyperopic, and astigmatic eye groups. No significant difference in CCT was seen among the 4 groups. In all groups the IOP values correlated with CCT (p<0.05) but the discrepancy between Icare and GAT values correlated with refraction (p<0.001). The difference between GAT and Icare was greater when Icare detected higher IOPs (p<0.001).
Conclusions	Icare gave higher IOP measurements than GAT, with myopic eyes showing the biggest difference. The measurements were reproducible in healthy volunteers.

Abbreviations: CCT, central corneal thickness; GAT, Goldmann applanation tonometry; IOP, intraocular pressure.

Table 4 Overview of the Dahlmann-Noor et al. (2013) study

Study component	Description
Objectives/ hypotheses	To evaluate the agreement of Icare (model unknown) and GAT in children with glaucoma.
Study design	Prospective cross-sectional study.
Setting	England, recruited from January 2009 to March 2010. No follow-up period.
Inclusion/ exclusion criteria	Inclusion: <ul style="list-style-type: none"> patients attending paediatric glaucoma service at Moorfields Eye Hospital, London. Exclusion: not stated.
Primary outcomes	Accuracy and reliability of Icare compared with GAT for measuring IOP, reproducibility when used by different observers, child preference for measurement method.
Statistical methods	Summary statistics and Bland–Altman limits of agreement method for intra- and inter-observer agreement.
Patients included	102 children with glaucoma (53 male, 49 female); mean age 11.9±3.2 years (age range 4.9–19 years).

Results	<p>Two different observers measured IOP using Icare (the first observer took 2 measurements while the second took 1 measurement) and a third observer measured IOP using GAT. The mean difference between the 2 Icare readings taken by observer 1 was 0.135 ± 1.45 mmHg ($p=0.427$). The limits of agreement for intra-observer readings were -2.71 to 2.98 mmHg. The mean difference between observer 1 and observer 2 Icare readings was 0.11 ± 2.99 mmHg ($p=0.8$) with limits of agreement from -5.75 to 5.97 mmHg.</p> <p>Icare frequently gave higher readings than GAT, with a mean difference of 3.3 ± 5.31 mmHg ($p < 0.001$). The degree of disagreement depended on the level of IOP being assessed, with smaller differences being seen with lower measurements (< 21 mmHg).</p> <p>GAT readings were missing for 12 children. For 45 children, only the first Icare reading by observer 1 and the Icare reading by observer 2 were available. Data were available for 74 children who had 2 readings by observer 1.</p> <p>Icare was the preferred method for 70% of the children.</p> <p>There was increased disagreement (larger discrepancies) in IOP measures between Icare and GAT with higher CCT values. The normal range is defined as 460–650 micrometres. The median pachymetry reading ($n=67$) was 581 micrometres and disagreements in children with readings of 581 micrometres could be greater than 10 mmHg.</p>
Conclusions	The authors concluded there was poor agreement between Icare and GAT in children with glaucoma due to Icare overestimating IOP.
Abbreviations: GAT, Goldmann applanation tonometry; IOP, intraocular pressure.	

Table 5 Overview of the Marini et al. (2011) study

Study component	Description
Objectives/ hypotheses	To compare Icare (model unknown) and GAT measurements of IOP in people with glaucoma and ocular hypertension and evaluate CCT influence on Icare readings.

Study design	Prospective cross-sectional study.
Setting	Spain, recruited from January to August 2009. No follow-up period.
Inclusion/exclusion criteria	Inclusion: <ul style="list-style-type: none"> • people with glaucoma or ocular hypertension. Exclusion: <ul style="list-style-type: none"> • contact lens wearers • patients with previous corneal refractive surgery or corneal diseases associated with oedema or scarring • people with astigmatism greater than 2 dioptres.
Primary outcomes	Comparison of GAT and Icare, effect of CCT on IOP readings obtained with Icare.
Statistical methods	Descriptive statistics, Bland–Altman method and limits of agreement.
Patients included	347 eyes in 347 people (194 female, 153 male); mean age 62.3 years (range 43–82 years). n=89 with ocular hypertension, n=258 with glaucoma.

Results	<p>Icare measurement of IOP was taken first (IC1), followed by a GAT measurement, and finally a second Icare measurement was taken (IC2). Mean IOP measured with IC1 (18.1 ± 4.3 mmHg) was significantly higher ($p < 0.001$) than with GAT (15.6 ± 3.3 mmHg). The mean IOP reading taken with IC2 (16.3 ± 3.9 mmHg) was significantly lower than IC1 values ($p < 0.001$), even though still significantly higher than for GAT ($p = 0.011$). Mean difference was 2.54 ± 2.47 mmHg with 95% limits of agreement between -2.3 and 7.38 for IC1 compared with GAT. Mean difference for IC2 compared with GAT was 0.71 ± 2.20 mmHg with 95% limits of agreement between -3.6 and 5.02. A significant linear correlation was identified between CCT and both IC1 and IC2, where a 4.6 and 4.1 mmHg increase in IOP was seen for each 100 micrometres increase in CCT respectively.</p>
Conclusions	<p>The authors concluded that when used first, Icare significantly overestimated IOP compared with GAT, however, differences decreased when Icare was used immediately after GAT. Agreement between the instruments was acceptable for low IOP values but worsened with increasing IOP. Icare was significantly influenced by CCT.</p>
<p>Abbreviations: CCT, central corneal thickness; GAT, Goldmann applanation tonometry; IOP, intraocular pressure.</p>	

Table 6 Overview of the Moreno-Montanes et al. (2015) study

Study component	Description
Objectives/hypotheses	To compare patient-obtained IOPs using Icare ONE (the predecessor to Icare HOME), clinician-obtained values using Icare PRO and GAT values and analyse the ease of use of Icare ONE.
Study design	Prospective cross-sectional study.
Setting	Spain, recruited from October 2011 to March 2012. No follow-up period.

Inclusion/ exclusion criteria	<p>Inclusion:</p> <ul style="list-style-type: none"> • patients with IOPs in normal range and those with ocular hypertension or glaucoma • best-corrected visual acuity of 10/20 or better • normal corneas. <p>Exclusion:</p> <ul style="list-style-type: none"> • history of ocular trauma.
Primary outcomes	Accuracy of Icare ONE and Icare PRO compared with GAT, and ease of use as measured by patients.
Statistical methods	The differences between the measurements obtained using the 3 instruments were evaluated using the Wilcoxon test. Linear regression and the Bland–Altman plots were drawn to assess the agreement between the 3 methods and the presence of systemic bias.
Patients included	150 eyes of 150 people (mean age 57.0±18.1 years; range 15 to 89 years). n=60 without glaucoma, n=22 with ocular hypertension, n=68 with glaucoma.

Results	<p>For all participants, the mean IOP values were 16.6 ± 4.43 mmHg with GAT, 17.5 ± 5.42 mmHg with Icare ONE ($p=0.32$ compared with GAT), and 16.6 ± 4.77 mmHg with Icare PRO ($p=0.75$ compared with GAT).</p> <p>The mean IOP values obtained for the first, second, and third measurement using the Icare ONE were 16.5 ± 5.04, 16.7 ± 4.95, and 16.6 ± 4.77 mmHg respectively. The mean of these 3 measurements was used in the following comparisons.</p> <p>The Bland–Altman analysis of IOP measurements showed that the mean difference between GAT and Icare ONE was -0.33 ± 3.28 mmHg (limits of agreement -6.77 to 6.10); the mean difference between Icare PRO and Icare ONE was -0.33 ± 3.51 mmHg (limits of agreement -7.14 to 6.62); and the mean difference between GAT and Icare PRO was -0.01 ± 2.16 mmHg (limits of agreement -4.25 to 4.22).</p> <p>Regression analysis indicated that GAT results were higher than Icare ONE for lower IOP values ($p < 0.001$); in contrast, GAT results were lower than Icare ONE with higher IOP values. The regression line comparing Icare PRO and GAT showed a normal distribution of all values ($p=0.43$).</p> <p>CCT was related to the IOP measurements using Icare ONE ($p < 0.05$) and Icare PRO ($p=0.01$). However, the CCT was unrelated to the differences between Icare ONE and GAT ($p=0.08$) or between Icare PRO and GAT ($p=0.06$).</p> <p>The ease of use of Icare ONE was classified as very easy by 37 patients (24.7%), easy by 79 patients (52.7%), complicated by 21 patients (14%), and very complicated by 13 patients (8.7%). Perceived difficulty in using Icare ONE was related to increasing age ($p=0.003$).</p>
Conclusions	The Icare PRO measurements were more similar to GAT than the Icare ONE measurements.
Abbreviations: CCT, central corneal thickness; GAT, Goldmann applanation tonometry; IOP, intraocular pressure.	

Table 7 Overview of the Rosentreter et al. (2013) study

Study component	Description
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Objectives/ hypotheses	To evaluate the agreement between IOP measurements obtained using an Icare tonometer (model unknown) and GAT or DCT in patients with corneal abnormalities.
Study design	Prospective cross-sectional study.
Setting	Germany (recruitment dates not reported; no follow-up period).
Inclusion/ exclusion criteria	Inclusion: <ul style="list-style-type: none"> patients with corneal abnormalities. Exclusion: not reported.
Primary outcomes	Comparison of GAT and DCT with Icare, effect of CCT, corneal diameter, corneal radius, and axial length on IOP measurements.
Statistical methods	Descriptive analysis, Mann–Whitney test, Spearman correlation, Bland–Altman analysis and linear regression.
Patients included	99 patients (171 eyes with different corneal abnormalities and 26 healthy control eyes with normal corneal status).
Results	<p>About 42% of Icare measurements were estimated to be within 2 mmHg of the GAT measurement and 23% were within 1 mmHg of the GAT measurement.</p> <p>Icare was successfully used for 171 eyes with corneal abnormalities and all healthy eyes (n=26) resulting in a mean IOP measurement of 12.7±4.1 mmHg. GAT was successfully used for 168 eyes with corneal abnormalities (98%) and all healthy eyes resulting in a mean IOP measurement of 15.5±4.4.</p> <p>The mean difference between Icare and GAT was –2.8 mmHg, with 95% limits of agreement of –10.5 to 4.9 mmHg. The mean difference between Icare and DCT was –3.8 mmHg, with 95% limits of agreement of –12.2 to 4.6 mmHg.</p> <p>Icare and GAT readings were not significantly influenced by CCT, axial length, corneal diameter or corneal radius.</p>

Conclusions	IOP was difficult to obtain using GAT and DCT in people with corneal abnormalities because of sutures interfering with the tip of the tonometers, corneal surface irregularities and corneal scars, whereas Icare was able to determine IOP in all eyes with corneal abnormalities. The authors concluded that while there is acceptable agreement between the 3 methods, Icare significantly underestimated IOP in all groups compared with GAT and DCT.
Abbreviations: CCT, central corneal thickness; DCT, dynamic contour tonometry; GAT, Goldmann applanation tonometry; IOP, intraocular pressure.	

Search strategy and evidence selection

Search strategy

For the clinical evidence

Embase 1974 to 2015 November 16

1. exp intraocular pressure/
2. intraocular pressure/ or chronic open angle glaucoma.mp. or glaucoma/ or intraocular hypertension/
3. (chronic open angle glaucoma or glaucoma or intraocular hypertension).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
4. (intra-ocular pressure or intra ocular pressure).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
5. intraocular pressure.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]

6. 1 or 2 or 3 or 4 or 5

7. icare.mp.

8. tonometer/ or tonometry/

9. (tonometer or tonometry).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]

10. rebound.mp. or rebound/

11. 8 or 9

12. 10 and 11

13. 7 or 12

14. 6 and 13

15. limit 14 to English language

16. limit 15 to yr="2005-current"

Ovid MEDLINE(R) In-Process and Other Non-Indexed Citations and Ovid MEDLINE(R) 1946 to Present

1. exp Intraocular Pressure/

2. intraocular pressure.mp.

3. (intraocular pressure or intra-ocular pressure).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]

4. Intraocular Pressure/ or Glaucoma, Open-Angle/ or chronic open angle glaucoma.mp. or Ocular Hypertension/

5. (ocular hypertension or glaucoma).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]

6. 1 or 2 or 3 or 4 or 5

7. icare.mp.

8. Tonometry, Ocular/ or tonometer.mp.

9. tonometry.mp.

10. rebound.mp.

11. 8 or 9

12. 10 and 11

13. 7 or 12

14. 6 and 13

15. limit 14 to (English language and yr="2005 -Current")

16. remove duplicates from 15

For the economic evidence

Embase 1974 to 2015 December 1, Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) 1946 to Present; Searched on 1 December 2015

1. exp intraocular pressure/

2. intraocular pressure/ or chronic open angle glaucoma.mp. or glaucoma/ or intraocular hypertension/

3. (chronic open angle glaucoma or glaucoma or intraocular hypertension).mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kw, nm, kf, px, rx, an, ui]

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5. intraocular pressure.mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kw, nm, kf, px, rx, an, ui]

6. 1 or 2 or 3 or 4 or 5

7. icare.mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kw, nm, kf, px, rx, an, ui]

8. tonometer/ or tonometry/

9. (tonometer or tonometry).mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kw, nm, kf, px, rx, an, ui]

10. rebound.mp. or rebound/

11. 8 or 9

12. 10 and 11

13. 7 or 12

14. 6 and 13

15. limit 14 to English language

16. limit 15 to yr="2005-Current"

17. (cost* or economic*).mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kw, nm, kf, px, rx, an, ui]

18. 16 and 17

Cochrane Database of Systematic Reviews: Issue 12 of 12, December 2015

Database of Abstracts of Reviews of Effect: Issue 2 of 4, April 2015

Cochrane Central Register of Controlled Trials: Issue 11 of 12, November 2015

Cochrane Methodology Register: Issue 3 of 4, July 2012

Health Technology Assessment Database: Issue 4 of 4, October 2015

NHS Economic Evaluation Database: Issue 2 of 4, April 2015

#1 intraocular pressure or glaucoma or ocular hypertension

#2 intra-ocular pressure or intra ocular pressure

#3 #1 or #2

#4 icare

#5 tonometer or tonometry

#6 rebound

#7 #5 and #6

#8 #4 or #7

#9 #8 and #3

#10 cost* or economic*

#11 #9 and #10

Evidence selection

For the clinical evidence

- Total number of publications reviewed: 493
- Total number of publications considered relevant: 117 (excluding duplicates, case studies, letters, editorials, non-English studies, and animal studies)
- Total number of publications selected for inclusion in this briefing: 6.

For the health economics evidence

- Total abstracts: 5
- Duplicates: 2
- Abstracts reviewed: 3
- Full papers reviewed: 1
- Studies for review: 0.

Exclusion criteria: retrospective studies, conference proceedings and abstracts, studies from developing countries, studies conducted outside of the European Union, studies without Goldmann applanation tonometer as the comparator, studies involving fewer than 150 eyes (except Dahlmann-Noor et al. 2013) and primary studies published before 2010 (see Cook et al. 2012).

About this briefing

Medtech innovation briefings summarise the published evidence and information available for individual medical technologies. The briefings provide information to aid local decision-making by clinicians, managers and procurement professionals.

Medtech innovation briefings aim to present information and critically review the strengths and weaknesses of the relevant evidence, but contain no recommendations and **are not formal NICE guidance**.

Development of this briefing

This briefing was developed for NICE by King's Technology Evaluation Centre. The [interim process and methods statement](#) sets out the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.

Project team

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Medical Technologies Evaluation Programme, NICE

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Specialist commentators

The following specialist commentators provided comments on a draft of this briefing:

- Edward Mallen, Head of Optometry and Vision Science and Professor of Physiological Optics, University of Bradford
- Wai-Hong Chan, Consultant Ophthalmologist, Betsi Cadwaladr University Health Board
- David (Ted) Garway-Heath, Consultant Ophthalmologist, Moorfields Eye Hospital NHSFT
- Peng Tee Khaw, Consultant Ophthalmic Surgeon and Professor of Glaucoma and Ocular Healing, Moorfields Eye Hospital NHSFT
- Julie Hatchell, Optician, Hatchell Opticians

Declarations of interest

- David (Ted) Garway-Heath has co-authored peer-reviewed scientific publications on the accuracy and precision of various tonometers (not including Icare). He is the International Glaucoma Association Professor of Ophthalmology, which has an interest in all aspects of glaucoma management. He is the Vice-President of the European Glaucoma Society, which publishes practice guidelines and he sits on the guideline development group. Tonometry accuracy and precision is of fundamental relevance to the practice guidelines. He authored the response from Moorfields Eye Hospital to the draft NICE Guideline for the diagnosis and management of glaucoma and ocular hypertension. He is a co-applicant on a successful NIHR i4i grant to develop a contact lens tonometer (due to be completed in 2016). If the development is successful, the contact lens tonometer could be a competitor to Icare in some (but not all) clinical scenarios (for example, home testing).
- Peng Tee Khaw had a previous (one-off) specialist consultancy on specific pharmaceutical issues relating to glaucoma and wound repair and regeneration from Celltech, Pfizer, Novartis, Alcon and Allergan and. He is co-author in a research audit paper comparing Icare with Goldmann Tonometry in children (non-sponsored).
- No other relevant interests declared.

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ISBN: 978-1-4731-1762-4