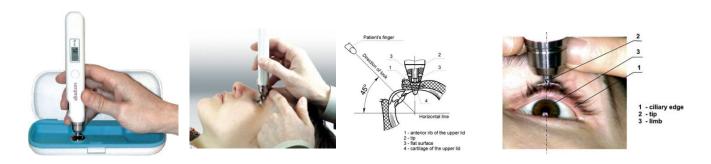


Presents:

Unique diaton Tonometer



Tonometry (Glaucoma IOP Test) Through the Eyelid!

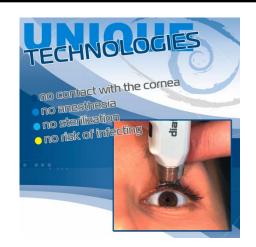


www.TonometerDiaton.com

diaton NO 14 marg

Presentation Summary

- Unique <u>Diaton Tonometer</u>
- Awards, New Technology Recognition
- > Typical uses of the Diaton Tonometer
- Benefits / Necessity of Diaton
- Advantages of the Diaton Tonometer
- Results of comparative analysis
- Clinical Study 1: accuracy correlating with GAT; safety and operating speed of NCT
- Clinical Study 2: Primary Care Physician and Patient Experience With Non-corneal Tonometer Glaucoma Screening
- Publications (articles from Ophthalmology and Optometry Times)
- Diaton Posters / Clinical Studies
- Brochures / Catalogue
- Diaton is delivered with: appearance of the tonometer / case
- Contact information
- SUMMARY



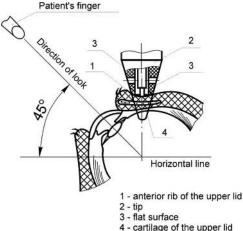




Unique Diaton Tonometer

"Diaton tonometry" is a unique approach to measuring intraocular pressure (IOP) through the Eyelid. Non-Contact (no contact with cornea), no anesthesia or sterilization required, pen like, hand-held, portable tonometer.





At the moment there are many methods to measure the intraocular pressure. Direct contact with the cornea is a disadvantage of all these methods. Our product, Diaton Tonometer, differentiates itself from all the other devices. The intraocular pressure is measured through the palpebra (the eyelid) near the derma, and because of this technique, any influence upon the mucosa is prevented.

This new Unique tonometer is a New Wave in Ophthalmology...!





Awards / New Technology Recognition

This new transpalpebral methodology has received many prestigious awards and Diplomas.

Gold Medal of the International Exhibition of Innovation Research and New Technology "Brussels Eureca" and

Gold Medal of the International Exhibition of Research and new Technology in "Geneva", plus many others.







Typical uses of the Diaton

Typical uses of the tonometer include the following:

- Mass screening of patients.
- IOP control during clinical observation and selection of adequate hypotensive therapy for glaucoma patients
- Serial tonometry for obtaining Diurnal curve
- IOP can be obtained without removing contact lenses
- IOP measuring in immobilized patients measurement can be done sitting or supine
- IOP measuring in children. Measurement is taken outside of the visual field
- Patients with the following conditions: chronic conjunctivitis, corneal pathology including keratitis, keratotone, corneal dimness, after penetrating keratoplastics, keratoprosthesis, laser refractive correction, high degree of ametropy, astigmatism
- On patients with medicinal allergies
- Lasik / LASEK / PRK (Diaton can be used for IOP measurement right after these surgeries)
- Diaton Tonometer is intended for use by Inpatient & Outpatient Clinics such as Hospitals, Emergency Rooms, Nursing & Elderly Homes, General & Specialty Practitioners as well as Ophthalmologists and Optometrists.





Necessity of Diaton

Need of quick, easy-to-use, sufficiently reliable tonometer in clinical practice for glaucoma screening

Major Benefits of Diaton Tonometer:

- No contact with the cornea (only upper eyelid)
- No anesthesia drops
- No risk of infecting or scratching cornea
- No consumables (no need to purchase replacement tips/covers..etc.,)
- No sterilization
- No pachymetry needed (no need to purchase pachymeter)
- No daily calibration needed
- Handheld / Portable + Easy to use



diaton O IO IN mois

Advantages of Diaton

Features	diaton	Goldmann Tonometer	Shiotz Tonometer	Air-jet	Tonopen
No contact with the cornea	+				
Portability	+		+		+
Displays independence from cornea's crookedness.	+				
Digital IOP indication	+			8 .+ 3	8 .+
Measurement in sitting position	+	+		+	+
Measurement in reclining position	+		+		+
Short-time measurement	+			8 + 8	
Sterilization is not required	+			+	
Anesthesia is not required	+			s I	
Lasik / PRK measurement	+				



tonometer 6

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Clinical Comparison 1

Clinical comparison of the Diaton and non-contact tonometers with the Goldmann (*Gold Standard*) applanation tonometer

Purpose: to compare the reliability of IOP measurements with digital non-invasive devices requiring no anesthesia:

- 1. Transpalpebral scleral Diaton tonometer
- 2. Non Contact pneumat Tonometer (NCT), and
- 3. The Goldmann Applanation Tonometer (GAT)

(continued)



diaton No 19 mg

Clinical Comparison 1 (cont)

Eighty-seven (87) patients (146 eyes) with chronic glaucoma

Ages - from 29 to 85

Male:female - 51:36

Inclusion criteria

- Duration of the disease not less then 1 year
- Lack of severe non-compensated general pathology

Exclusion criteria

 Occurrence of concomitant ophthalmopathology (eyelids pathology, high degree of ametropia, cornea pathology)



diaton No No

Diaton Tonometry





Clinical Comparison 1 Results:

Results of comparative analysis of DIATON, NON-CONTACT and GOLDMANN tonometry measurements

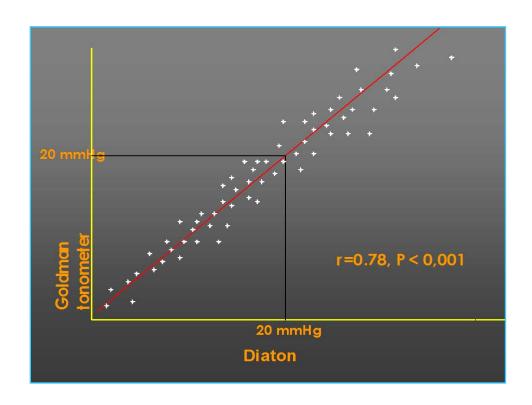
Tonometer	M±SD, mmHg	min, mmHg	max, mmH	Std err of mean	R , p<0,001
GAT	17,4±7,6	6	40	1,17	
NCT	21,4±9,13	5	47	1,91	0,87
Diaton	16,7±5,58	6	36	0,86	0,78

No significant difference of IOP mean values (t = -0.51, p < 0.001)





Results: Diaton Tonometry



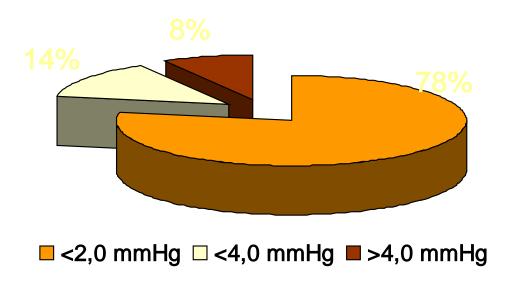
DIATON has both accuracy correlating with GAT and safety and operating speed of NCT





Results: Diaton Tonometry

Divergence in Diaton-tonometry, non-contact and Goldmann tonometry values



When divergence in values was greater than or equal to 4 mm Hg the registered IOP was more then 30 mm Hg





Comparison: Diaton Tonometry

The study shows high reliability of transpalpebral screral Diaton Tonometer

- sufficient for clinical purpose accuracy correlating with GAT
- safety and operating speed typical for non-contact tonometers

 possibility to get IOP digital result in cornea pathology and its thickness alteration



diaton No 19 mg

Clinical Study 2

Primary Care Physician and Patient Experience With Noncorneal Tonometer Glaucoma Screening

Purpose:

To evaluate the patients' and primary care physicians' experiences in using the Non-Corneal Tonometer Diaton for screening of glaucoma in the adult population

Methods:

Primary care physicians (PCPs) were trained to use the non-corneal tonometer using a round testing plate

PCP ensured that patient had no contraindications for tonometer use, then obtained informed consent from patient before using tonometer

Intraocular pressures (IOPs) were recorded and patient was referred to ophthalmology if >21 mmHg

PCP and patient each filled out a questionnaire afterwards to evaluate the experience





Clinical Study 2 (cont)

Usage:

Indications

Screening tool for elevated IOP by PCPs

Can measure IOP even in the presence of viral infections, allergic reactions, and/or dry eye syndrome, conditions contraindicated for corneal tonometry

Can serve as non-invasive day monitoring while selecting the adequate hypotensive medical treatment

Can measure IOP with contact lenses on

Can measure IOP on immobilized patients

Trained family members can monitor IOPs of glaucoma patients at home

Contraindications

Cannot use in the presence of upper lid pathology (inflammatory diseases, scars, eyelid deformation)

Cannot use if there is pathology of sclera and/or conjunctiva in the measuring area



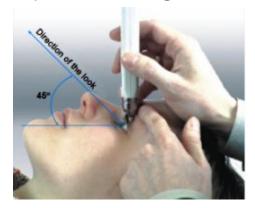


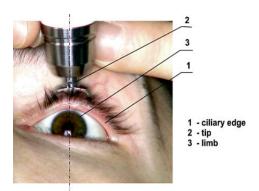
Clinical Trial 2 (cont)

Non-Corneal Measurement of IOP

Tonometery performed with patients in sitting or reclining position, with eye looking at a target at 45⁰







- •Tonometer tip placed vertically over the eyelid to measure IOP through the eyelid without direct contact to cornea
 - No anesthesia or sedation required





Clinical Trial 2 (cont)

Study Population: Characteristics

n = 159 patients

Gender : Male	100 (63%)	
Female	59 (37%)	
Age (mean +/- standard deviation; range)	55.35 +/- 12.04; 21-86	
Ethnicity: Asian	3 (1.8%)	
Black	60 (37.7%)	
Hispanic	61 (38.4%)	
White	22 (13.8%)	
Other	13 (8.1%)	
Diabetic	33 (20.8%)	
Hypertensive	71 (44.7%)	
Family history of glaucoma	20 (12.6%)	



diaton No 14 mg

BICOM,INC

Clinical Trial 2 (cont)

Results

n = 159 patients

Mean IOP +/- standard deviation (SD)	14.35 +/- 3.13 mmHg
IOP >21 mmHg	4/159 (2.5%)
Mean Discomfort Score (0 = none, 1 = mild, 2 = moderate, 3 = severe, 4 = extreme) +/- SD	0.17 +/- 0.43
Not mind PCP measuring IOP rather than an ophthalmologist	137/159 (86.2%)
Recommend Diaton Tonometry to family/friends	147/159 (92.5%)
Patients who had experienced Diaton and airpuff tonometry	
preferred Diaton tonometerpreferred airpuff tonometer	30/36 (83.3%) 6/36 (16.7%)



Clinical Trial 2 (cont)

Results

n = 8 Primary Care Physicians (PCP)

	,
Mean experience when training to use Diaton +/- SD	1.75 +/- 0.46 (very easy = 1, easy = 2,difficult = 3, very difficult = 4)
Mean experience using Diaton on patient +/- SD	1.75 +/- 0.46 (very easy = 1, easy = 2, difficult = 3, very difficult = 4)
Approx. time taken to measure IOP (from positioning to end) +/- SD	2.38 +/- 0.74 (30s = 1, 1 min = 2, 1.5 min = 3, 2 min = 4)
PCPs who like using Diaton	100%
PCPs who would use Diaton again	100%
PCPs who would recommend Diaton use by other PCPs	100%
PCPs would recommend Diaton use by allied/ancillary staff (non-MDs)	7/8 (87.5%)
Of PCPs who were familiar with Diaton and airpuff, preferred Diaton over airpuff	3/3 (100%)



Clinical Trial 2 (cont)

Conclusion

The Diaton non-corneal tonometer uses a transpalpebral approach to measure IOP through the eyelid without contact to the cornea

On average, Diaton causes virtually no discomfort to the patient

PCPs are easily trained to properly use the device

Most patients and physicians prefer Diaton over airpuff tonometer

Diaton was able to identify 4/159 patients with an IOP>21 mmHg

In summary, Diaton tonometer is a safe and easy-to-use screening tool for PCPs to identify patients at risk for glaucoma and refer them to ophthalmology





BICOM,INC

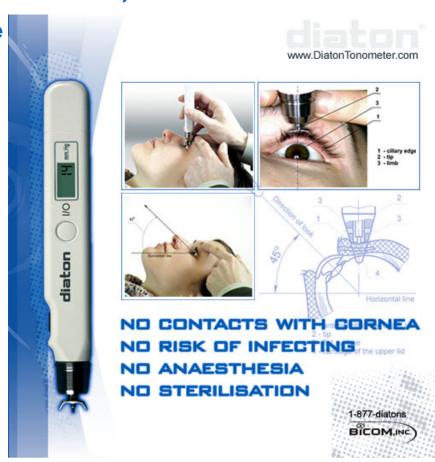
Approvals/ Clearance:

Diaton Tonometer is clinically proven and

FDA approved, Class 2, 510k cleared - USA

CE Mark 0535 - Europe

ISO 90001:2000



Publications:



42 glaucoma



Transpalpebral technique

Pen-like tonometer designed to be patient-friendly

Noncontact device measures IOP quickly, shows results similar to 'gold standard' in studies

Reviewed by John Hope, MD, and Mark I atine MD

Long Beach, NY-A handheld tonometer that measures IOP through the eyelid and over the sclera is proving to be helpful for ophthalmologists faced with patients who are apprehensive about seeing an instrument approaching their eyes or who have a corneal abnormalities, according to several ophthalmologists who have studied it.

The tonometer (Diaton, BiCOM) is a penlike instrument that measures IOP within seconds without the need for anesthesia or sterilization. Approved by the FDA in 2006, the instrument has been the subject of numerous clinical trials, where it has been found to be comparable with the gold standard: the Goldmann applanation tonometer.

According to Roman Iospa, the company's chief executive officer, the device is available in more than 50 countries, and more than 5.000 units are on the market. Additional accessories are not required.

Convenience for all

The device appeals to ophthalmologists who see pediatric patients and those with patients who have corneal edema or erosions or keratoprostheses, he said. Because the device is used on the upper eyelid and out of the patients' field of vision as they recline and look at a 45° angle, patients do not tend to blink or squeeze their eyes shut before the reading, which can skew the IOP measurement

"It is convenient for the doctor and painless for the patient," Iospa said. "There is really no discomfort, especially for the patient who might be slightly anxious."



members of the Department of Ophthalmology, Massachusetts Eve & Ear Infirmary. Boston, and Emil William Chynn, MD, an ophthalmologist in private practice at Park Avenue Laser in New York,



Figure 1 The pen-like tonometer (Diaton, BiCOM) measures IOP within seconds.

Take-Home Message

A proprietary tonometer (Diaton, BiCOM) has been found to be comparable with the Goldmann tonometer in several clinical trials.

performed a study of the tonometer to compare IOP measurements taken with the device with those from the Goldmann applanation tonometer in normal and glaucomatous eyes.

The study examined 66 eyes of 33 consec-

15.15% of the device measurements were exactly the same as those obtained with the Coldmann tonometer. The device underesti-

alaucoma

Tonometer

Continued from page 42

mated the IOP compared with the Goldmann in 37.87% of eyes, and it overestimated the IOP in 43.93% of eyes.

(diffupredicate ophricalmic onsulation 0.05%) inflat U.S. appressiz 2008 BRIEST SUMMARY: Based on rel prescribing information, Before prescribing, please consult hill prescribing information.

Jefore prescribing, prome consumers. NEXCONTRIBUTE AND USAGE: NEXT confirmation and pain to the breatment of inflammation and pain to

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The proprietary tonometer, however, correlated within 3 mm Hg of Goldmann in 83.3% of eyes and "may be a clinically useful screening device for measuring IOP," the authors concluded.

"At the end of the study, we

that the transpalpebral technique is a very promising method for tonome try, especially for screening and in patients with corneal pathology," Dr. Shazly said.

Dr. Chynn said that the device might be a good instrument for family practitioners who screen patients for glaucoma, because it does not require anesthesia and can be performed simply in

reached the conclusion

an office setting. "The [device] is easy to use, userfriendly, and it can be used on patients for mass screening," Dr. Shazly said, "It's portable, it's economical; it's really good for screening

Retrospective chart review

Richard S Davidson, MD, of the Rocky Mountain Lions Eye Institute, Aurora, CO, led a retrospective chart review of consecutive IOP measurements performed on 64 eyes of 32 patients aged 34 to 91 years with both tonometers. Dr. Davidson found that 83% of all measurements were within 2

mm Hg of each other. "The transpalpebral method of measuring IOP with the [proprietary] tonometer correlates well with Goldmann applanation," the study concluded. "[It] may be a clinically useful device for measuring IOP in routine eve exams."

A similar retrospective review, with Theodore H. Curtis, MD, affiliated with the Rocky Mountains Lions Eve Institute at the time of the study and now in private practice near Portland, OR, found that the tonometer's pressure measurements correlated well with measurements by another proprietary applanation tonometer (Tono-Pen, Reichert). The study found that the aforementioned device was useful when examining children who "were reassured by the fact that no drops were needed."

The proprietary tonometer regulres

> no anesthelsa and can be performed

in an office setting.

John Hope, MD, an ophthalmologist in private practice in Oklahoma City, said that he prefers the device because applanation tonometry is time-consuming and often requires support staff. Dr. Hope said that he has used the instrument routinely on every patient for at least

"This instrument is so userfriendly there are no rubber covers to deal with, and, after the

> initial purchase, it is virtually maintenance-free," he said. "I clean the instrument with an alcohol pad after each use, and it is easily portable in your pocket and can be transported from room to room or office to office.

"There is no corneal contact and pressures can be obtained in patients wearing contact lenses," Dr. Hope concluded. "The technique is easily and quickly learned. OT



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In poweral studios.

John Hope, MD E-mail: ihih7@cox.net Dr. Hope has no financial interest in the subject matter.

Mark Latina, MD E-mail: malatina@comcast.net Dr. Latina has no financial interest in the products described in the article.





utive subjects, 46 eyes having glaucoma and 20 eyes without. Goldmann tonometry was performed by one of the authors, whereas the proprietary device measurements were taken by another author in a masked fashion. In both the normal and glaucoma groups,

lovised: May 2000

SIRION

US PATENT 8,114,319

Monufactured for: Strion Therapeutics, Inc., Temps, P., 83619 By: Catalant Plannis Salutions, Inc., Woodstook, IL 800028



Clinical Posters:

Illinois Eye and Ear Infirmary

UIC Department of Ophthalmology & Visual Sciences

Excellence in eyecare | research | aducation for over 150 years

Agreement among Transpalpebral, Transcleral and Tactile Intraocular Pressure Measurements in Eyes with Type 1 Boston Keratoprosthesis

Jessica Liu, 1, 2 Thasarat S. Vajaranant, MD, 1 Maria S. Cortina, MD, 1 Jacob T. Wilensky, MD1

¹Department of Ophthalmology and Visual Sciences, University of Illinois at Chicago, Chicago, IL, ²School of Medicine, Saint Louis University

INTRODUCTION

 Currently, most forms of tonometry require an intact cornea to estimate intraocular pressure (IOP), which presents a problem in patients with corneal pathologies such as keratoprosthesis (KPro).
 Glaucoma is a major visual limiting factor in a majority of patients following keratoprosthesis, but an accurate method of monitoring intraocular pressure readings remains a challenge to Clinicians.

PURPOSI

To explore if transpalpebral IOP measurement with the Diaton tonometer can be an alternative method of measuring IOP and yield valuable data in eyes with KPro in comparison to commonly used tactile and pneumatonometry.

METHODS

- Retrospective case series
- 23 eyes in 20 patients with Type 1 Boston KPro who presented to the Illinois Eye and Ear Infirmary Cornea Service for follow up
- Inclusion Criteria: age ≥18 years, ability to understand procedures and willingness to comply with the study

IOP Measurements

- The first IOP was estimated tactilely by palpation of the globe performed by the patient's corneal surgeon
- The second IOP measurement was taken with a pneumatonometer placed on the sclera peripherally to the contact lens in the inferotemporal quadrant (Model 30 Classic;

Mentor, BioRad, Santa Ana, California, USA)

 The third and final IOP measurement was taken with the Diaton through the upper lid in accordance with the instructions by the manufacturer (BiCOM, Inc., Long Beach, NY, USA)

Analysis

- The average of two Diaton IOP measurements were recorded and used in the analysis
- Since the tactile IOP were recorded as a range rather than a
 definite number, the percent agreement and the percentage of
 eyes in which the pneumatonometer or Diaton IOPs were within 2
 mmHg of the tactile IOP range were computed
- Two-tailed T-test was used to compare the mean of the pneumatonometer and Diaton IOP measurements

RESULTS



FIGURE 1: Keratoprosthesis



FIGURE 2
Administration of the
Diaton test with the eyelid
coinciding with the limbus



FIGURE 4
Diaton is a no-contact hand-held trans-palpebral tonometer that minimizes risk for infection.



FIGURE 3
Preparation of the patient by fixing head horizontally and glance at 45 degree angle



FIGURE 5
The tonometer tip must be placed in parallel to the cartilaginous portion of the eyelid.

. The analysis included 23 eyes of 20 patients.

The overall IOP mean ± SD

- 17.2 ± 6 mmHg for pneumatonometer
- 13.8 ± 5 mmHg for Diaton tonometer
- 15.5 ± 5.2 mmHg for tactile by palpation
- The pneumatonometer consistently yielded higher IOP values, compared to Diaton (p = 0.04).

The percentage agreement :

85% between tactile range and pneumatonometer IOPs 95% between tactile range and Diaton IOPs

48% between the pneumatonometer and the Diaton.

Patient	Eye	Tactile IOP Range	Pneuma- Scleral IOP	Diaton IOP
1	OS	10>20	16	13.5
2	OS	13 > 19	10.5	9.5
3	OD	10> 15	11	10
4	OD	15>20	22	17.5
5	OD	15 > 20	15	13
6	OD	20 > 25	24.5	22
7	OD	13>19	20	13.5
	OS	15>20	17	17.5
8	OD	20 > 25	21	19.5
9	OD	5> 10	8.5	5
10	OS	12>18	20	16
11	OD	15 > 18	22	15
12	OD	10> 15	11.5	10
13	OD	20> 22	29	18.5
14	OD	~ 20	18	13
	OS	~ 20	21	14
15	OD	15> 20	26	21
16	OS	20> 25	16	20.5
17	OD	<5	10	3.5
18	OD	11>15	12	10
	OD	11> 15	13	11
19	OS	very soft	12	5
20	OD	20> 22	19	20

DISCUSSION

It is necessary to monitor IOP in KPro patients since glaucoma occurs in 75% of patients following keratoprosthesis.²

- In this study, the presence of KPro did not appear to interfere with Diaton IOP measurements.
- Previously, KPro also did not interfere with scleral pneumatonometry readings. ³ However, scleral pneumatonometry readings have been shown to estimate higher IOPs than corneal pneumatonometry. ³
- Our findings show that the Diaton tonometer yielded IOP readings that agreed more similarly to those obtained by palpation than by scleral pneumatonometry.

CONCLUSION

- There still remains a need to eliminate variability in IOP instruments to successfully monitor glaucoma in KPro patients.
- Transscleral pneumatonometry yielded higher IOP readings when compared to tactile and Diaton IOP estimates
- This study suggests that Diaton measurements may be an alternative method to tactile IOP and may be a device that can help alleviate physician dependent tactile IOP measurements.

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SUPPORT

Carson Gabriel Fund, Chicago, IL Research to Prevent Blindness







Clinical Poster (cont)



Comparative agreement among three methods of tonometry: Goldmann applanation, transpalpebral and dynamic contour.



5660

Zárate L. ¹, J. Jiménez-Román ¹, F. Gil-Carrasco ¹, ¹ Asociación para Evitar la Ceguera en México, I.A.P. Universidad Nacional Autónoma de México; México City.

Purpose:

To examine the intraocular pressure measurement obtained with the Goldmann applanation tonometer (GAT), the Pascal dynamic contour tonometer (DCT; Swiss Microtechnology AG, Port, Switzerland) and the Diaton tonometer (DT; Bicom Inc, Long Beach, NY, USA). A second objective was to correlate central corneal thickness (CCT) with the GAT, the DCT and the DT.

Methods:

The IOP measurements were obtained with the GAT, DCT and DT by the same observer. CCT measurements were made using the ultrasonic pachymeter. Six Diaton intraocular pressure measurements were obtained before the instillation of anesthesia, after which 2 GAT IOP and 3 DCT IOP measurements were obtained in a randomized order. The device agreement were calculated by Bland Altman analysis (mean difference [bias] and 95% limits of agreement [LoA]). Central corneal thickness were obtain by 3 measurements of each eye and its mean. The effect of central corneal thickness on the intraocular pressure measurement was calculated with the Pearson's correlation coefficient.







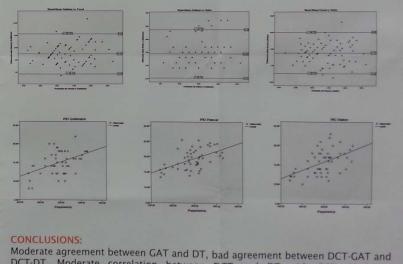






Results:

40 patients, 7 men, 33 women. Ages between 47-82 years. 38 right eyes, 39 left eyes. 26 with primary open angle glaucoma under treatment, 14 with glaucoma suspect. Mean IOP GAT: 14.4 mmHg, DCT: 18.8 mmHg, DT: 15.09 mmHg. Mean pachymetry: 546.2 µm. The agreement between GAT- DCT, GAT-DT and DCT- DT were 4.45, 0.69 and 3.71 mmHg, respectively. The correlation between GAT-CCT, DCT-CCT and DT-CCT were .449, .542 and .511, respectively (p<0.001).



Moderate agreement between GAT and DT, bad agreement between DCT-GAT and DCT-DT. Moderate correlation between DCT and DT with CCT. Mediocre correlation between GAT and CCT.





Diaton Brochures

diaton UNIQUE TONOMETRY THROUGH EYELID



Optometry Times

Optometry Times

Ophthalmology Web





















Diaton Brochures







Diaton Brochures / Catalogue





Front / Back

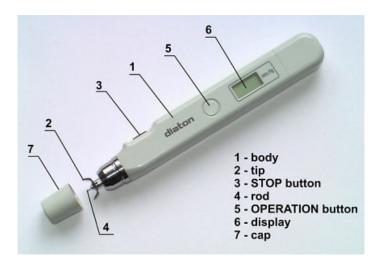


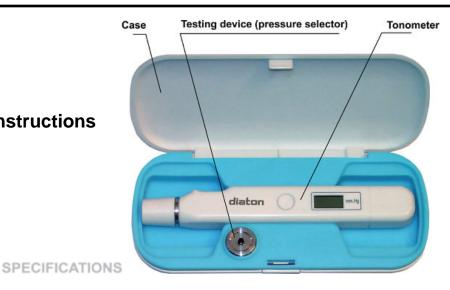


Diaton is delivered with:

Diaton Tonometer is delivered complete with:

- Carry-case with testing/calibration device
- Instruction DVD with self calibration and cleaning instructions (no need to send it away for service or cleaning)
- User Guide/Manuals
- Battery (3V battery, available everywhere)
- 24 months warranty
- Live support @ 1-877-diatons(342.8667)





Measurement range, mm Hg	5-60	
Measurement error	Limit of the admissable measurement error in the range, not more: from 5 to 20 mm Hg - ±2 mm Hg; from 20 to 60 mm Hg - ±10%	
The time of a single measurement, s, not more	3	
Supply voltage, V	3	
Number of measurements using one battery set, not less	1500	
Service life, not less	8	
Weight, g	89	
Dimensions, mm, not more	174 x 26 x 20	





International BiCOM Inc Contacts:

For inquiries please contact our

Customer Service @ 1-877-diatons(342.8667)

Or email Contact@TonometerDiaton.com

Web: http://www.TonometerDiaton.com





diaton No 19 mbs

SUMMARY:



Diaton Tonometer is Clinically Proven to be a Top Choice for Quick and Painless Intraocular Pressure (IOP) testing for Glaucoma in Children and Adults in *Any* Clinical Setting.

Diaton allows to be more efficient and armed with the latest technology available!

www.TonometerDiaton.com

