Report of Equivalence Comparison Medical Tests of the Production Sample of the Digital Portable Tonometer for IOP Measurement through the Eyelid diaton

1. Production Samples for Carrying out the Medical Tests

To carry out the comparison medical tests of the production samples the manufacturer gave:

- a production sample of tonometer Diaton
- operating manual;
- program and methodology of comparison medical tests approved by member of The Russian Academy of Medical Sciences, professor A. P. Nesterov.

2. Purpose of the Tests

The main purpose is to evaluate the reliability of tonometer Diaton results.

3. Place of carrying out the Tests

Ophthalmologic division of Municipal Clinical Hospital №15, Moscow

Ophthalmologic division of Central Clinical Hospital of the Russian Federation President's Administrative Department, Moscow

4. Use and Range Specification of Tonometer diaton.

4.1. Intended Use of Tonometer diaton

The tonometer is designed to measure IOP through the patient's eyelid without using anesthetics.

4.2. IOP Measurement Error

IOP measurement range is from 5 to 60 mm Hg with digital display.

IOP measurement error:

- in the range from 2 to 20 mm Hg - ±2 mm Hg,
- in the range from 20 to 60 mm Hg - ±10 %

5. Measurement Time

The time of a single IOP measurement is not more than 3 sec.

6. The Device Used while Carrying out the Tests.

6.1. Test Device Used for Comparison

During the tests the following device was used:

Goldmann tonometer

7. The Results of Comparison Medical Tests.

7.1. While carrying out the comparison medical tests the following order of IOP measurement was used:

- IOP measurement using Goldman tonometer
- IOP measurement using diaton tonometer with mean result registration

66 patients (126 eyes) at the age from 28 to 89 were examined during the period from 10.10.2004 to 26.12 2004. 41of them suffer from glaucoma of various degrees. 25 healthy volunteers (50 eyes) form a screening group. The results are shown in tables.

7.2. The reliability of diaton tonometer measurements was evaluated using the IOP measurement results in in 76 eyes of patients suffering from glaucoma and 50 eyes of healthy people.

The coincidence of Goldmann tonometer and diaton tonometer IOP measurement results equal to 2 mm Hg or less was observed in 32 eyes (64,0%) among the volunteers from the screening group and 48 eyes (63,2%) in the patients suffering from glaucoma.

The difference in Goldmann tonometer and diaton tonometer IOP measurement results equal to 3 mm Hg was observed in 6 eyes (12%) in healthy persons and in 9 eyes (11,8%) in the patients suffering from glaucoma. The difference in results equal to 4 mm Hg and more was observed in 12 eyes (24%) among the volunteers from the screening group and in 19 eyes (25%) in the patients suffering from glaucoma. Such disagreement in results equal to 3 mm Hg and more can be attributed to Goldmann tonometer error which was assigned equal to zero in calculations and also to mistakes in carrying out the procedure of IOP measurement using both tonometers.

Statistic analysis of the clinical study of IOP evaluation using diaton tonometer in comparison with Goldman tonometer is shown in tables 1, 2 and in pictures 1, 2.

Tables of results

Table 1. Screening group

№	Name	Age	Sex	Tested eye	IOP (Goldman)	IOP (Diaton)	Difference
1	BVY	68	m	OS	10	15	5
				OD	6	11	5
2	PIE	81	m	OS	14	16	2
				OD	15	16	1
3	ACK	38	f	OS	17	17	0
				OD	18	18	0
4	VAS	63	m	OS	11	10	1
				OD	14	12	2
5	VNS	75	m	OS	12	15	3
				OD	15	19	4
6	BAI	58	m	OS	15	16	1
				OD	17	18	1
7	KAD	75	f	OS	20	22	2
				OD	19	19	0
8	BCP	71	m	OS	16	18	2
				OD	15	18	3
9	BLA	51	f	OS	13	19	6
				OD	13	18	5
10	NPE	65	f	OS	14	12	2
				OD	15	17	2
11	BAI	59	f	OS	10	11	1
				OD	10	9	1
12	IYC	62	m	OS	16	18	2
				OD	14	14	0
13	NIZ	67	m	OS	12	14	2
				OD	14	13	1
14	AAV	70	m	OS	7	11	4
				OD	6	10	4
15	IRF	66	f	OS	18	19	1
				OD	21	20	1
16	KAB	65	m	OS	11	14	3
				OD	10	12	2
17	AAS	83	f	OS	14	14	1
				OD	12	15	3
18	BMR	74	f	OS	13	19	6
				OD	14	17	3
19	LPK	80	m	OS	13	18	5
				OD	14	18	4
20	MLO	40	f	OS	7	12	5
				OD	9	13	4
21	CHF	61	f	OS	19	16	3
				OD	20	18	2
22	LTM	42	f	OS	16	18	2
				OD	17	17	0
23	PAP	58	m	OS	15	16	1

				OD	18	17	1
24	OAP	28	f	OS OD	17 16	17 18	0 2
25	YOR	58	m	OS OD	20 18	19 17	1 1

Table 2. Glaucoma Patients

№	Name	Age	Sex	Tested eye	IOP (Goldman)	IOP (Diaton)	Difference
1.	SRS	58	F	OS OD	20 16	21 17	1 1
2.	VGB	74	F	OS OD	11 17	13 19	2 2
3.	ASK	56	M	OS OD	35 10	35 14	0 4
4.	SAV	55	F	OS OD	23 17	26 17	3 0
5.	LAS	71	F	OS OD	10 15	14 17	4 2
6.	PAI	61	M	OD	18	19	1
7.	RYA	70	M	OS OD	22 11	23 16	1 5
8.	FAN	45	M	OS	22	21	1
9.	BVA	78	M	OS OD	10 11	18 16	8 5
10.	HVA	60	M	OS OD	21 9	21 14	0 5
11.	SIA	55	F	OS OD	15 13	15 16	0 3
12.	KAS	56	M	OD	34	34	0
13.	MLM	77	M	OS OD	21 17	22 21	1 4
14.	YMP	75	F	OS OD	18 25	21 22	3 3
15.	PVA	55	M	OS OD	26 12	28 20	2 8
16.	AKA	68	M	OS OD	24 19	22 19	2 0
17.	MNO	58	M	OS OD	20 20	22 18	2 2
18.	HAP	71	M	OS OD	12 12	17 19	5 7
19.	PAP	69	M	OS OD	24 10	22 19	2 9
20.	VAF	81	M	OS	32	30	2
21.	KVA	66	M	OS OD	14 11	13 16	1 5

22.	IAI	51	F	OS	20	20	0
23.	BGA	89	M	OS OD	16 42	19 34	3 8
24.	SMN	78	f	OS OD	18 27	16 22	2 5
25.	DSN	67	M	OS OD	19 20	16 18	3 2
26.	SEK	75	M	OS OD	10 22	15 26	5 4
27.	GAT	72	M	OS OD	24 12	24 16	0 4
28.	HEA	70	M	OS OD	17 30	20 25	3 5
29.	KNG	71	M	OS OD	13 23	12 22	1 1
30.	BAB	72	M	OS OD	32 14	34 13	2 1
31.	SAI	65	F	OS OD	10 22	13 20	3 2
32.	RAI	78	F	OS OD	21 14	20 15	1 1
33.	SVM	75	M	OS OD	23 17	22 15	1 2
34.	SAD	65	M	OS OD	11 22	12 23	1 1
35.	KOO	72	M	OS OD	27 18	26 18	1 0
36.	KGL	71	M	OS OD	12 22	11 23	1 1
37.	PAI	68	M	OS OD	30 14	29 15	1 1
38.	GGN	73	F	OD	16	17	1
39.	BMS	62	M	OS OD	5 12	6 13	1 1
40.	AYT	71	M	OS OD	17 9	14 13	3 4
41.	PIM	76	F	OS OD	14 10	13 9	1 1

$$M = \frac{\sum_{i=1}^{n} x_i}{n};$$

In tables 3, 4 the results of the following calculations are shown:

δ standard deviation

$$\delta = \sqrt{\frac{\sum_{i=1}^{n} (x_i - M)^2}{n}}$$

$$\text{mean error} - m = \pm \frac{\delta}{\sqrt{n}}, \qquad m_\delta = \pm \frac{\delta}{\sqrt{2n}};$$

r - correlation coefficient (by Pirson)

$$r = \frac{\sum_{i=1}^{n} (x_{iT} - M_T)^2 \cdot (x_{iG} - M_G)}{\sqrt{\sum_{i=1}^{n} (x_{iT} - M_T)^2 \cdot \sum_{i=1}^{n} (x_{iG} - M_G)}}$$

where:

xiT - the ith IOP measurement result using diaton tonometer,
xiG - the ith IOP measurement result using Goldmann tonometer,
MT - IOP mesurement arithmetic mean value (diaton tonometer)
MG - IOP mesurement arithmetic mean value (Goldmann tonometer).

Table 3. Screening group of healthy volunteers

Тонометр	M ± SD	Min	Max	St. error of mean	R
Goldmann	*14,2* ±3,7	*6,0*	*21,0*	*0,52*	
Diaton	15,8 ±3,0	*9,0*	*22,0*	*0,43*	*0,78*

Picture 1

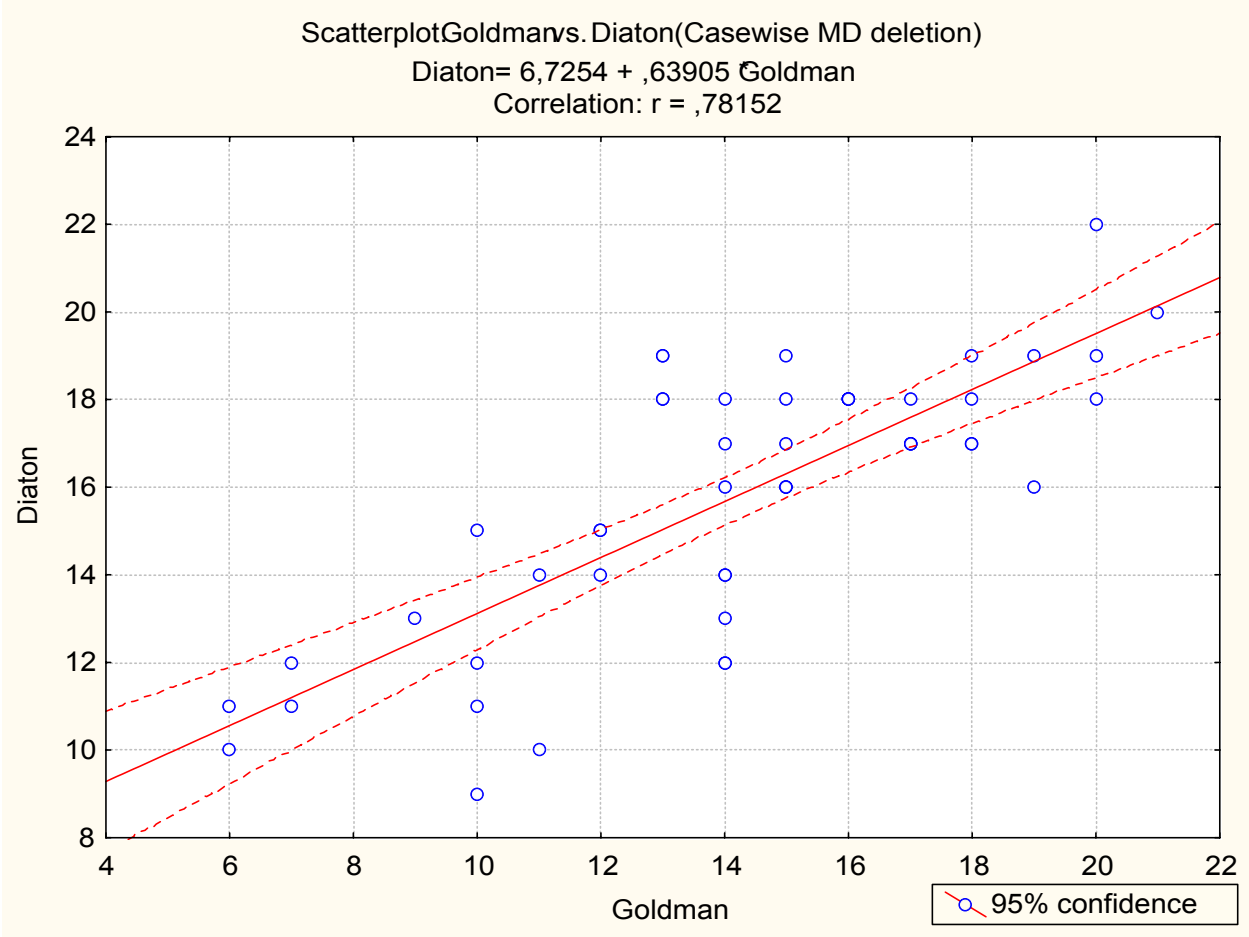
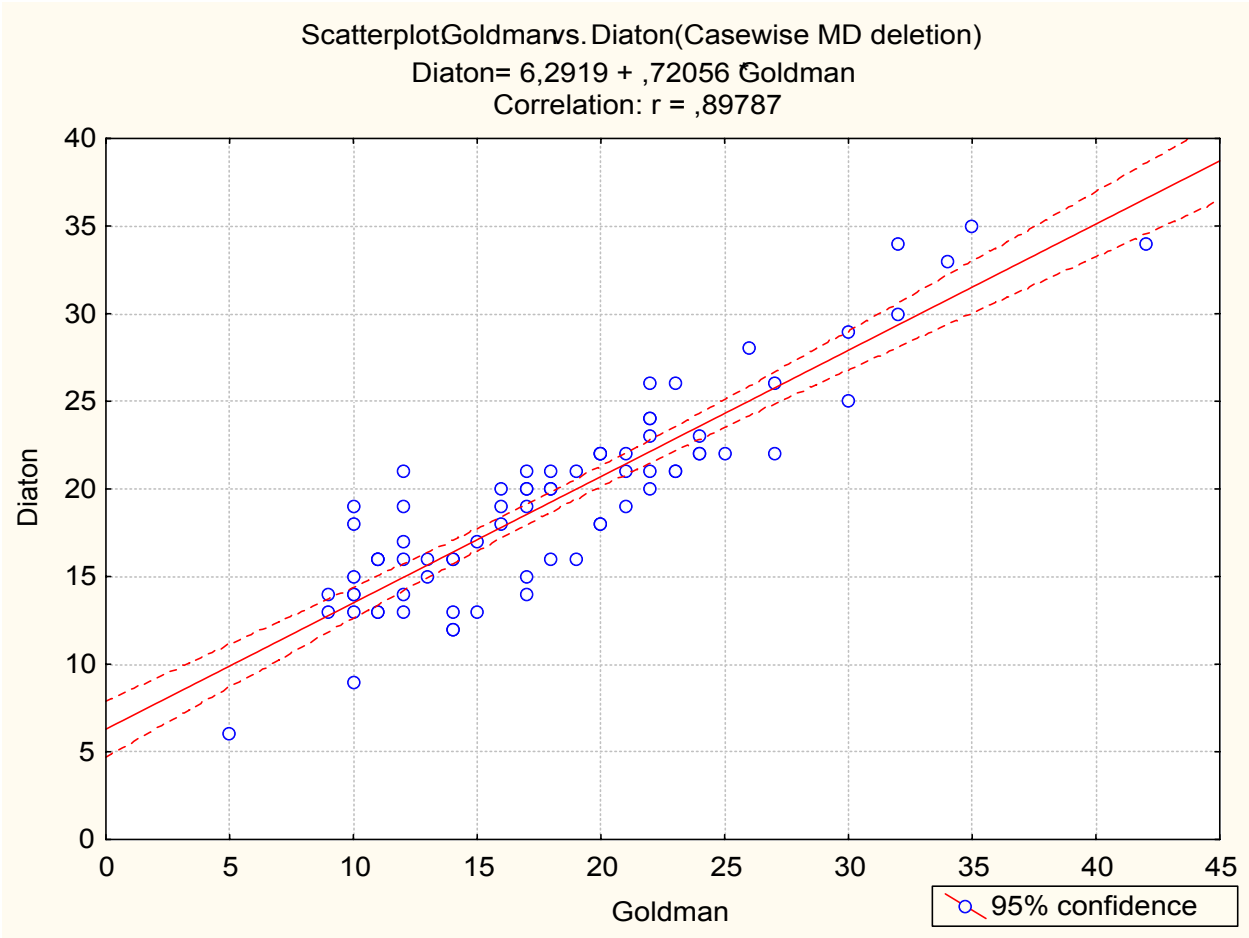


Table 4. Glaucoma patients

Тонометр	M ± SD	Min	Max	St. error of mean	R
Goldmann	*18,18* ±7,12	*5,0*	*42*	*0,81*	
Diaton	19,17 ±5,8	*6,0*	*35,0*	*0,66*	*0,89*

Picture 2



8. Conclusion

8.1. The results of the comparison medical tests of tonometer diaton and Goldmann tonometer demonstrated their high coincidence degree in the whole range. We achieved the same results from both devices.

8.2. Taking into account the comparison medical tests findings as well as tonometer diaton advantages (anesthetics and antiseptics are not necessary; elimination of infection risk; short-time measurement; results independent of cornea's crookedness) its wide application in ophthalmology is recommended alongside with Goldmann tonometer, especially while carrying out mass examination of population. Also, it is recommended for use at home to control ophthalmotone condition under drugs and medical treatment.

Opthalmologist MD, PhD A.R.Illarionova

Opthalmologist MD, PhD B.V.Obruch