

APPROVED BY
Technical Director, Yelatma Instrument
Making Enterprise, JSC
Klevtsov E.A.
2019 г.



REPORT of the reference IOP measurements performed with tonometer TVGD-02” EASYTON”, with the use of a Goldmann tonometer as referents standard

The purpose of the study: analysis of the range of indications of intraocular pressure (IOP) in comparison with measurements made by a standard application tonometer, such as Goldmann's tonometer according to ANSI Z80.10-2014 standard (with the exception of: within Annex B: (5.3 last paragraph); 5.5; 7.2)

Research method: Simultaneous measurement of IOP tonometer TVGD-02” EASYTON” No. 00005 and Goldmann’s reference tonometer Z0009 No. 06112635.

The study was conducted in the IPO "Glaucoma Society" in the period from 11.11.2018 to 30.01.2019 in 156 patients (eyes). For each subject, IOP was measured with Goldmann’s tonometer and tonometer TVGD-02 ”EAYTON” only on each subject’s right eye.

Total 156 reference IOP measurements were performed in 3 OIP ranges:

1. In the range of 7 up to (and including) 16 mmHg : 46 measurements;;
2. In the range above 17 up to (and including) 23 mmHg : 40 measurements;
3. In the range above 23 mmHg : 40 measurements

Including 30 measurements: 10 highly astigmatic eyes (>3 D of corneal astigmatism) each in the low, medium and high IOP ranges.

The result of the measurements were grouped according to the 3 above mentioned ranges and enlisted in the Records below.

Records of the reference OIP measurement performed tonometer TVGD-02 "EASYTON" with a Goldmann tonometer as reference standard (main group)

Under 17 mm Hg					
№	Goldmann tonometer	TVGD-02	№	Goldmann tonometer	TVGD-02
1	14	13	31	13	15
2	16	15	32	15	16
3	16	17	33	12	14
4	14	15	34	13	15
5	16	18	35	15	13
6	13	15	36	14	16
7	16	15	37	14	16
8	16	17	38	14	16
9	16	16	39	14	14
10	16	16	40	8	10
11	16	18	41	13	12
12	16	18	42	13	12
13	16	19	43	14	14
14	14	14	44	15	16
15	15	16	45	10	11
16	14	15	46	16	18
17	16	16			
18	16	18			
19	12	13			
20	15	17			
21	16	17			
22	16	16			
23	16	16			
24	16	18			
25	16	15			
26	16	17			
27	15	14			
28	15	14			
29	14	17			
30	16	14			

Records of the reference OIP measurement performed tonometer TVGD-02 "EASYTON" with a Goldmann tonometer as reference standard (main group)

17-23 mm Hg					
№	Goldmann tonometer	TVGD-02	№	Goldmann tonometer	TVGD-02
1	22	22	31	18	20
2	18	20	32	21	19
3	22	20	33	19	19
4	18	15	34	19	22
5	18	15	35	17	14
6	22	22	36	23	24
7	20	21	37	21	22
8	18	17	38	21	23
9	20	21	39	20	20
10	18	17	40	21	20
11	18	15			
12	18	19			
13	22	24			
14	18	15			
15	22	23			
16	23	24			
17	19	21			
18	22	19			
19	17	17			
20	18	21			
21	23	23			
22	21	20			
23	20	19			
24	17	17			
25	19	19			
26	22	20			
27	21	20			
28	20	22			
29	21	22			
30	23	20			

Records of the reference OIP measurement performed tonometer TVGD-02 "EASYTON" with a Goldmann tonometer as reference standard (main group)

Above 23 mm Hg					
№	Goldmann tonometer	TVGD-02	№	Goldmann tonometer	TVGD-02
1	29	30	31	32	32
2	30	31	32	26	25
3	48	49	33	34	29
4	36	33	34	33	34
5	26	28	35	29	30
6	30	29	36	26	27
7	38	35	37	30	29
8	34	31	38	32	29
9	28	27	39	26	27
10	26	25	40	38	36
11	34	33			
12	28	27			
13	31	29			
14	31	32			
15	34	35			
16	32	33			
17	26	25			
18	28	27			
19	27	30			
20	40	42			
21	42	44			
22	28	33			
23	24	21			
24	30	29			
25	25	22			
26	38	39			
27	27	29			
28	28	33			
29	37	44			
30	40	42			

Records of the reference OIP measurement performed tonometer TVGD-02 "EASYTON" with a Goldmann tonometer as reference standard (astigmatic group)

Under 17 mm Hg		
№	Goldmann tonometer	TVGD-02
1	15	16
2	10	11
3	13	13
4	12	13
5	15	14
6	13	15
7	13	13
8	15	17
9	14	16
10	15	16

Records of the reference OIP measurement performed tonometer TVGD-02 "EASYTON" with a Goldmann tonometer as reference standard (astigmatic group)

17-23 mm Hg		
№	Goldmann tonometer	TVGD-02
1	20	19
2	16	16
3	19	22
4	20	18
5	19	18
6	21	22
7	24	26
8	20	20
9	23	23
10	17	18

Records of the reference OIP measurement performed tonometer TVGD-02 "EASYTON" with a Goldmann tonometer as reference standard (astigmatic group)

Above 23 mm Hg		
№	Goldmann tonometer	TVGD-02
1	39	43
2	38	37
3	24	23
4	25	24
5	28	29
6	30	32
7	27	29
8	35	39
9	34	33
10	24	27

Analysis of results in accordance with paragraph 5 of the FDA recommendations

The graphical presentation of comparative test results for main group is given in Fig. 1.

The linear regression formula based on the result of the test appears as follows:

$$P_{tvgd} = P_g * 0.978 + 0.739;$$

Where:

P_{tvgd} – IOP according to TVGD-02;

P_g – IOP according to Goldmann tonometer;

Pearson correlation coefficient - 0.97.

Root-mean-square deviation - 1.94.

Slope of the regression line - 0.978.

Displacement of the regression line - 0.25 average for Bland-Altman (Bias), and initially coordinates 0.739.

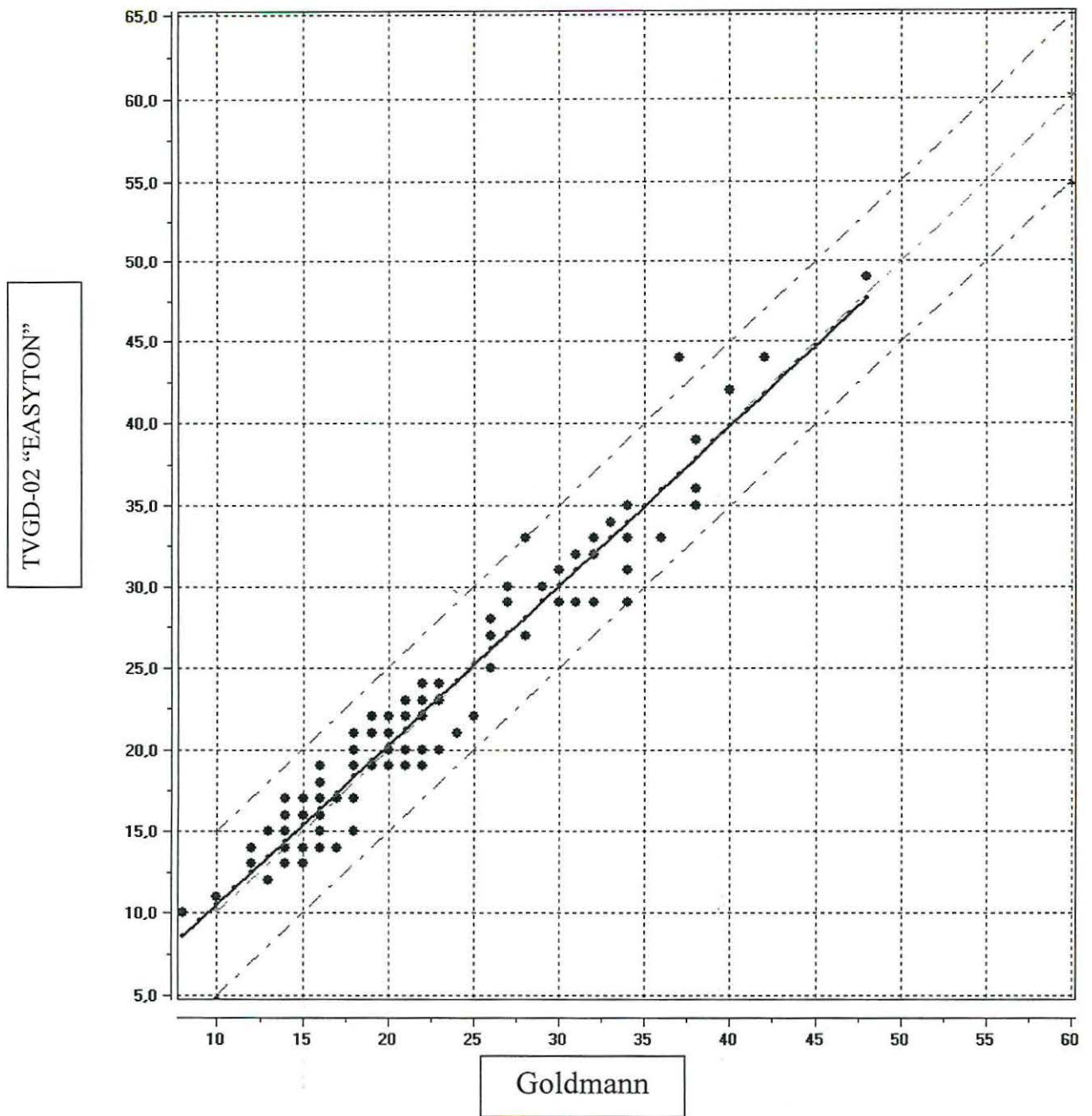


Fig 1. Scatter plot of measured IOP values (main group)

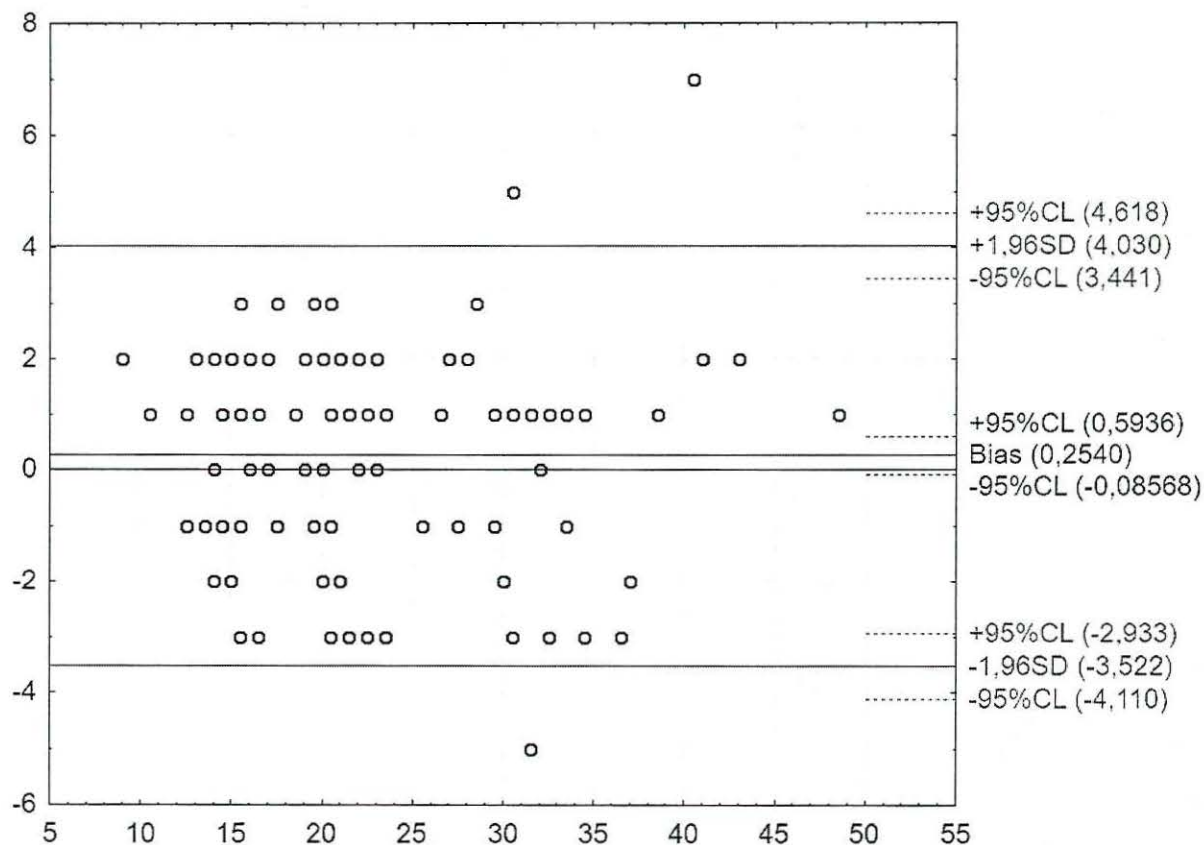


Fig. 2. Bland-Altman type plot (main group)

The graphical presentation of comparative test results astigmatic group is given in Fig. 3.

The linear regression formula based on the result of the test appears as follows:

$$P_{tvgd} = 1.035P_g + 0.06;$$

Where:

P_{tvgd} – IOP according to TVGD-02;

P_g – IOP according to Goldmann tonometer;

Pearson correlation coefficient - 0.982.

Root-mean-square deviation - 1.751.

Slope of the regression line - 1.035.

Displacement of the regression line - 0.83 average for Bland-Altman (Bias), and initially coordinates 0.06.

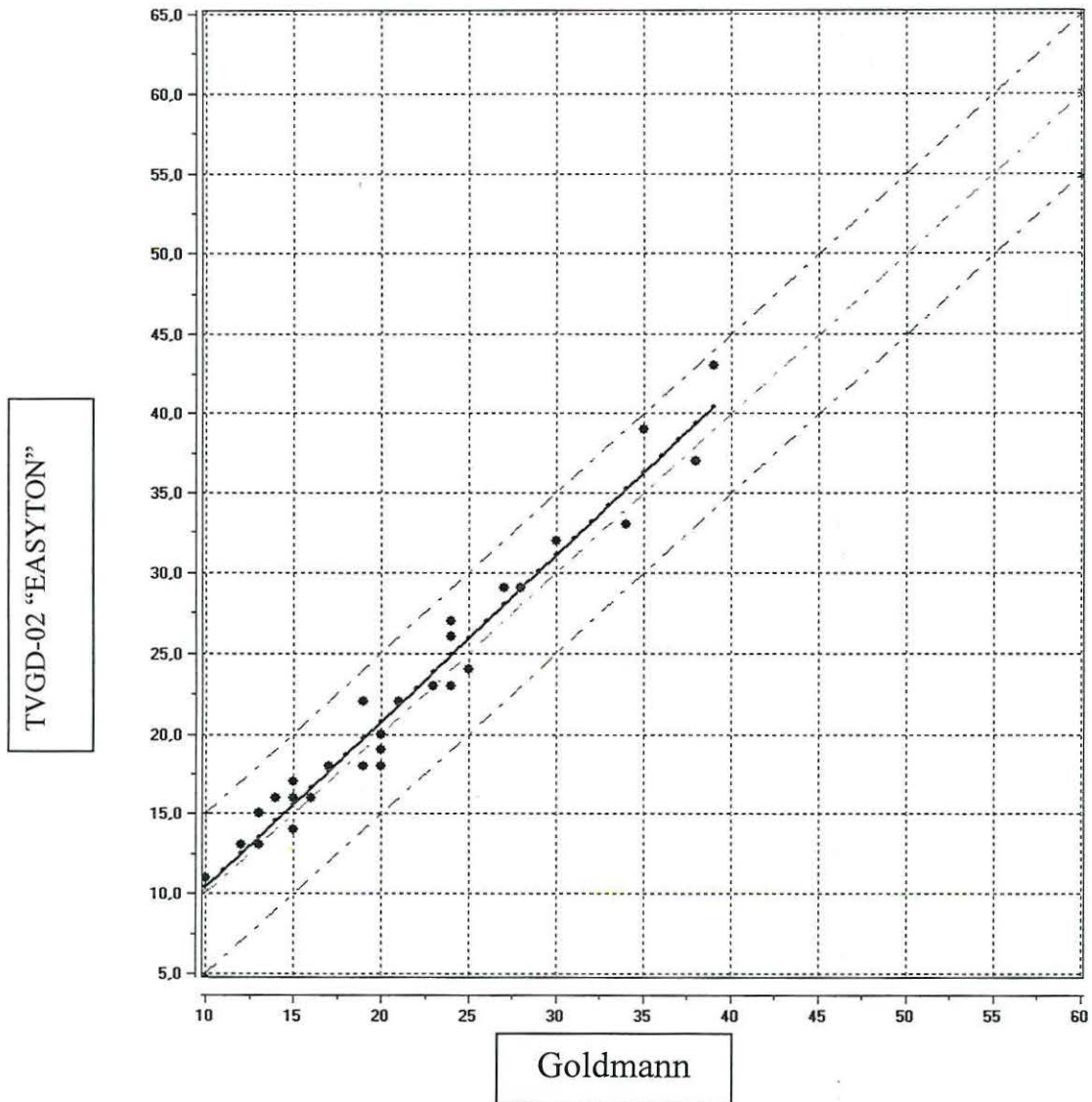


Fig 3. Scatter plot of measured IOP values (astigmatic group)

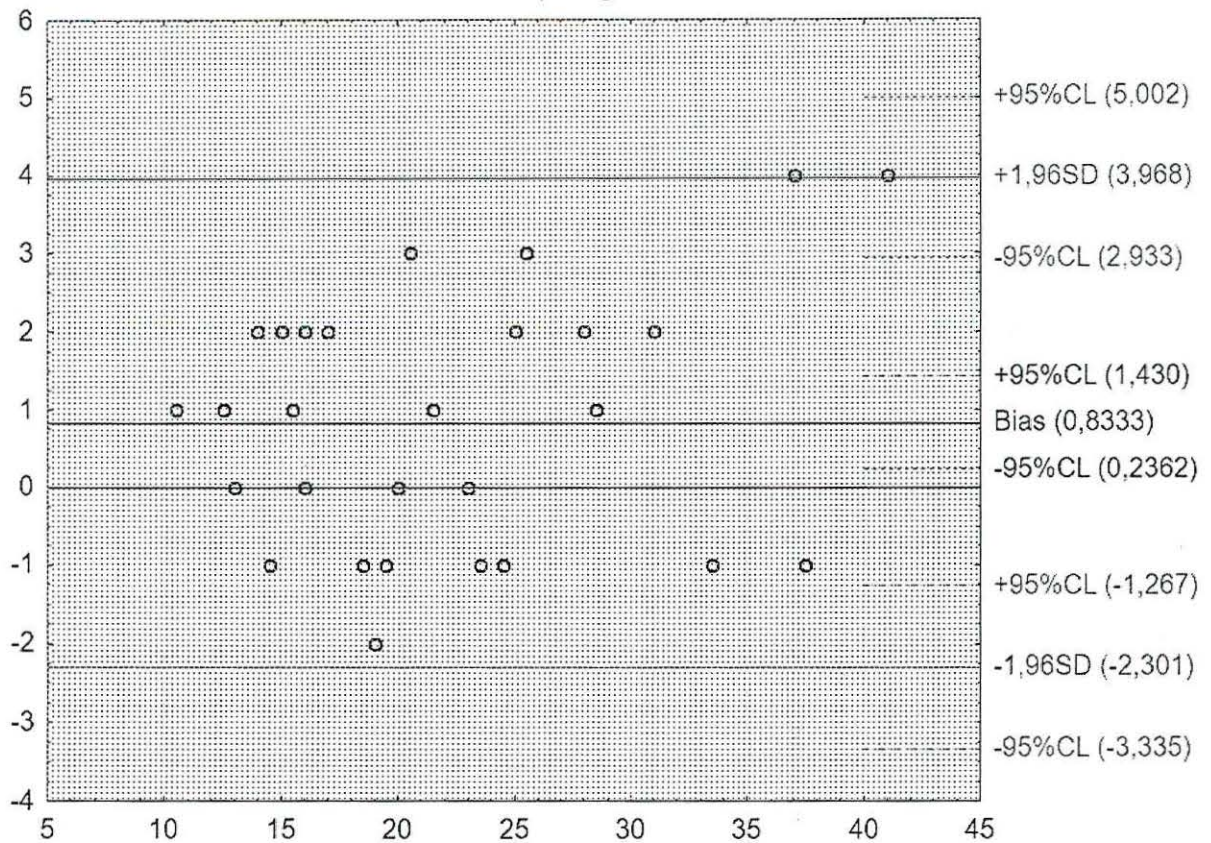


Fig. 4. Bland-Altman type plot (astigmatic group)

Comparability with a Goldmann-type tonometer

The measurement results tonometer TVGD-02 “EASYTON” have a high correlation with the results tonometer Goldmann. This indicates a high repeatability and reproducibility of tonometer TVGD-02 “EASYTON”.

Deviations [reference tonometer measurement] - [measurement of TVGD-02], exceeding the permissible deviations in accordance with ANSI Z80.10-2003, were not revealed.

Conclusion:

The obtained results meet the requirements of the document "Guidance for Industry and FDA Staff. Tonometers – Premarket Notification [510(k)] Submissions"

TVGD Chief Designer

Ivanishchev K. V.