

APPROVED
R&D Center Director
Eduard Klevtsov
2018



REPORT

**Bench testing of intraocular pressure tonometer TVGD-02 (“EASYTON”)
to confirm accuracy, repeatability and reproducibility**

Ryazan 2018

Name of device:

Intraocular pressure tonometer TVGD-02 ("EASYTON")

Manufacturer of device: Yelatma Instrument Making Enterprise, JSC

Address of manufacturer: 391351, Russia, Ryazan region, Kasimov district, Yelatma, Yanina str, 25.

Tests conducted by: Research and Development Center of Yelatma Instrument Making Enterprise, JSC;

Address: 390026, Ryazan, Visokovoltnaya str, 48

Director: Eduard Klevtsov

The purpose of testing a medical device:

Testing of intraocular pressure tonometers TVGD-02 " EASYTON " for the accuracy and repeatability of measurements on cadaver eyes.

Device intended use: Intraocular pressure measurement.

The class of potential risk of using a medical device in accordance with the nomenclatural classification of medical devices: 2a

Number of samples submitted: 2

Number of Users: 2

Number of test subjects: 3

Date of tests: 10-11 April 2018

Report on the testing of intraocular pressure tonometers TVGD-02 “EASYTON” for the accuracy and repeatability of measurements on cadaver eyes, where a hydraulic pressure system is used as the reference intraocular pressure.

Tests were conducted on 10 and 11 April 2018 on the basis of the Department of Forensic Medicine of the Ryazan State Medical University, at an ambient temperature of +10 ° C, a relative humidity of 70% and an atmospheric pressure of 744 mm. Hg.

The tests were carried out by two users with two different EasyTon tonometers using three subjects, the details of which are indicated in Appendix 1.

The block diagram of the hydraulic pressure system used in the tests is shown in Figure 1, and the actual appearance in Figure 2.

The pressure in the examined eye is established by feeding distilled water through the needle into the eye. The pressure is set by the height of the water column, measured on a millimeter scale from the geometric center of the eye. The pressure is additionally controlled by a pressure gauge, also located at the level of the geometric center of the eye. The manometer is intended for convenience only and calibrated for the height of the water column, which is in 13.59 times more than the pressure in mm. Hg. at 4 ° C, or in 13.55 times at 20 ° C.

After setting the required pressure and immediately before the measurement, the valve located on the connecting tube next to the needle is blocked, this prevents the outflow of water from the eye due to the measuring effect. After measuring the IOP, the valve opens and a pressure gauge is checked to confirm that there are no fluid leaks during the measurement.

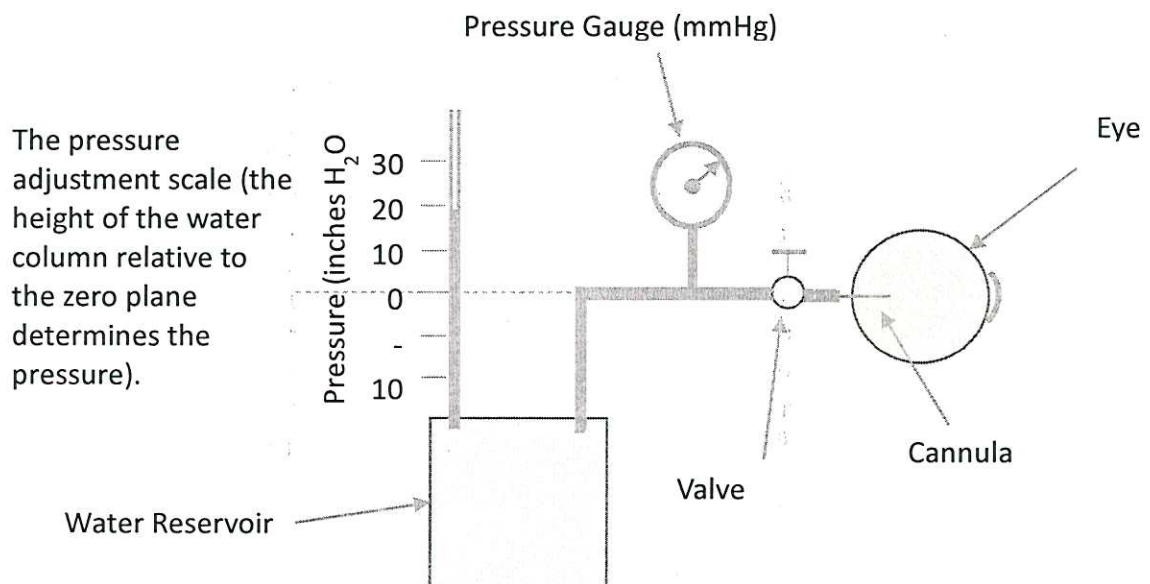


Fig. 1

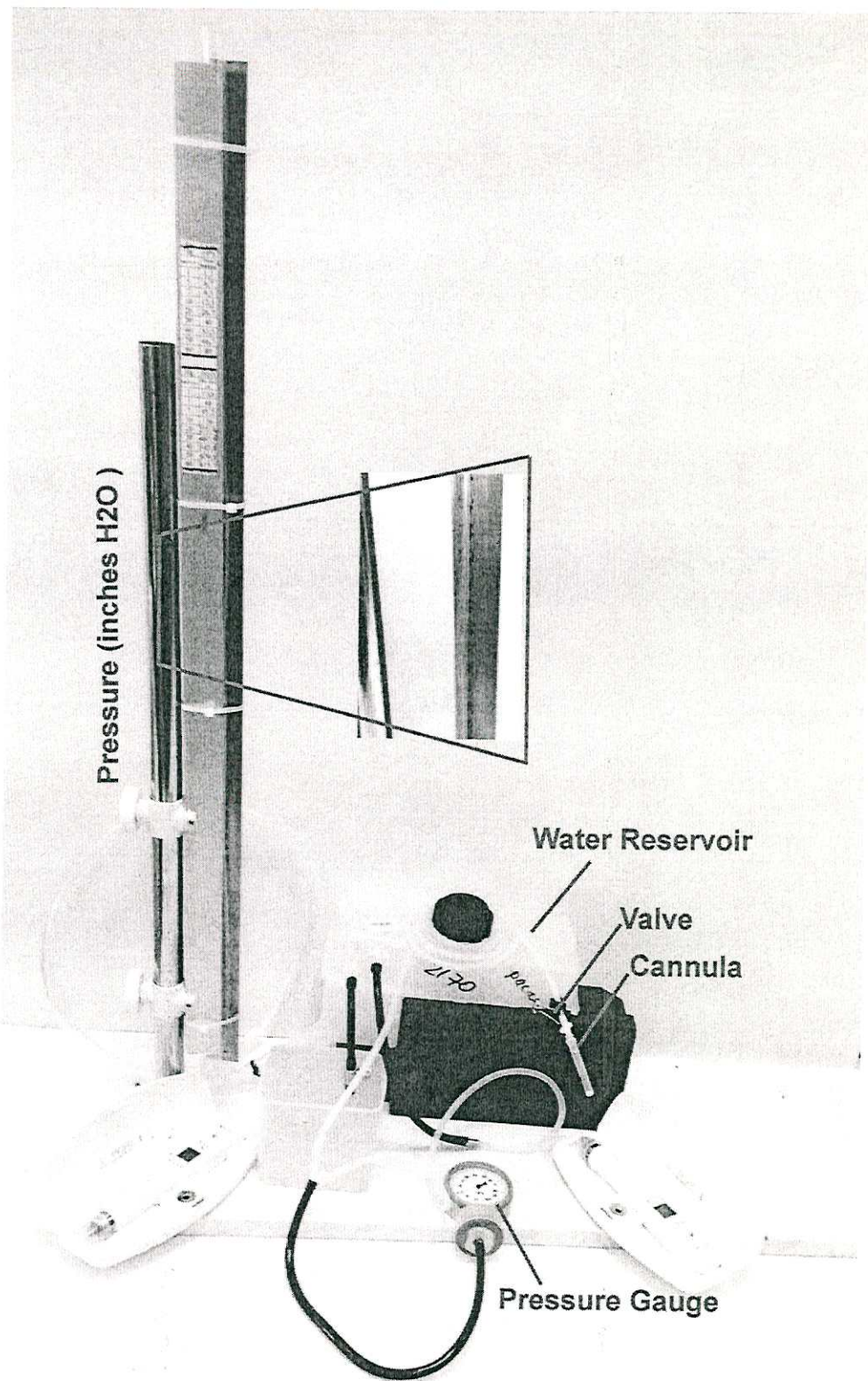


Fig. 2

The measurements were performed by two tonometers:

- Tonometer A - TVGD-02 "EASYTON" serial No. 00520 production date 05.2017
- Tonometer B - TVGD-02 "EASYTON" serial No. 01366 production date 12.2017

at a pressure of 7, 10, 20, 30, 40 and 50 mm Hg for 10 measurements at each value.

1. Studies to determine the accuracy of the measurement were carried out on subject 1 (see annex 2). For each reference pressure the average value (the column of the table "Average"), the standard deviation (column of the "SD" table), and the variation (column of the table "V") are determined.
2. Studies to determine repeatability were carried out on three subjects, see annexes 2.3 and 4. For each reference pressure, the average value (column of the table "Average"), standard deviation (column of the table "RMS"), as well as the variation (column of table "V") are determined.

The final values for determining the accuracy at IOP level = 20 mm. Hg are given in Table 1.

Table 1

Reference pressure, mm. Hg	Subject 1 (Annex 2)		Subject 2 (Annex 3)		Subject 3 (Annex 4)		Overall	
	Average, mm. Hg	V	Average, mm. Hg	V	Average, mm. Hg	V	Average, mm. Hg	V
10	10,00	0,0816	10,70	0,0631	10,30	0,0655	10,33	0,07
20	21,20	0,0536	20,40	0,0413	19,70	0,0482	20,4	0,0477
30	31,70	0,0471	31,00	0,0304	29,40	0,0287	30,7	0,0354

3. Studies for determining reproducibility were performed on one subject by two different users and by two different tonometer's (See annexes 5 and 6). For each pressure, the average value (column of the table "Average"), standard deviation (the column of the table "RMS"), as well as the variation (column of table "V") are determined.

The average measured values for determination of reproducibility are given in Table 2.

Table 2

Reference pressure, mm. Hg	Average pressure, mm. Hg	
	User 1, Tonometer B (see annex 5)	User 2, Tonometer A (see annex 6)
7	8,10	7,64
10	10,00	10,10
20	19,50	19,30
30	29,80	28,80
40	38,90	39,00
50	48,80	48,80

Conclusion:

For the seven measurement ranges, the maximum coefficient of variation is 0.0816, so measurements are generally considered to be accurate (Annex 1).

In three different eyes for the seven measurement ranges, the maximum coefficient of variation is 0.07, so measurements are generally considered repeatable (Table 1).

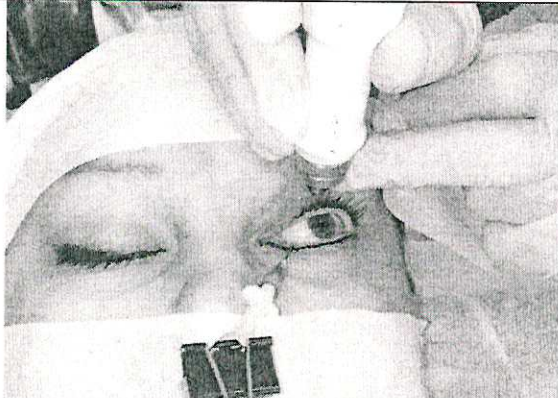


The average values when measured by two different users on seven measurement ranges by two-tonometer's have a sufficient correlation, therefore measurements are considered to be reproducible (Table 2).

Report performed by:

Lead engineer

Ivanishev K.V

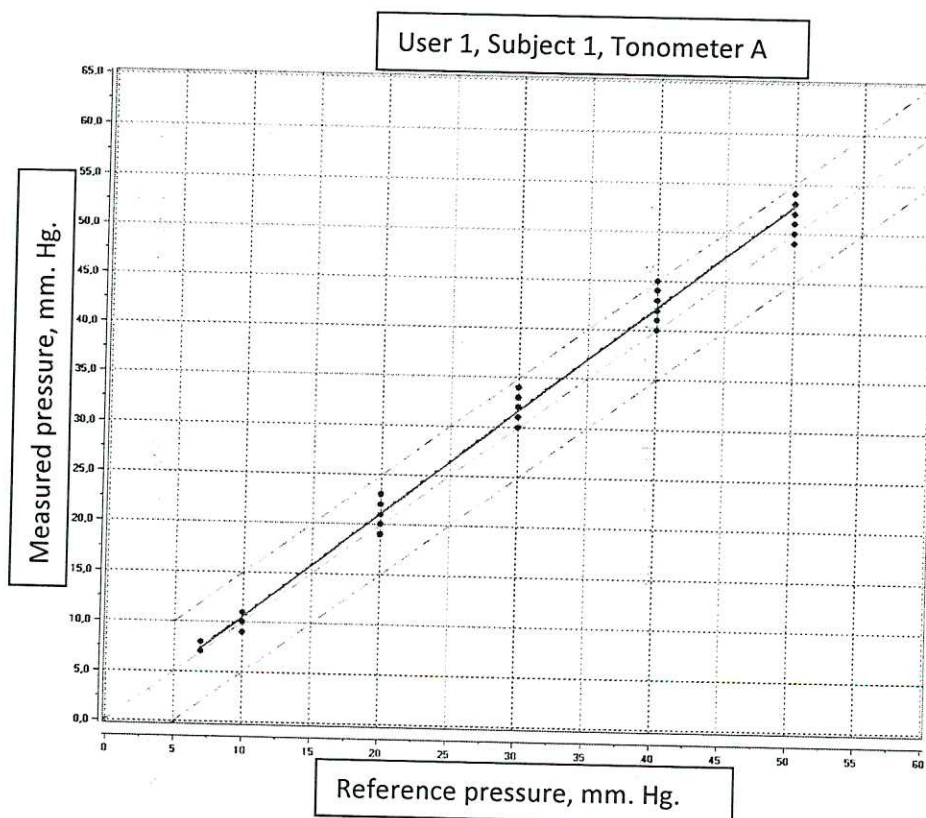
Tested subjects

	<p>Subject 1 a woman of 40 years old, death occurred on 10 April 2018 at 4:10 a.m. in result of thrombophlebitis of the profunda venis of the sinistro crure; facial skull, including nose, eyes, eyelids, lips - undamaged.</p> <p>Characteristics of the eyelid Europeoid eyelids, 2.1 mm thick</p>
	<p>Subject 2 a man of 24 years old, death occurred on 10 April 2018 at 2:50 a.m. in result of a stab wound of the left part of thorax; facial skull, including nose, eyes, eyelids, lips - undamaged.</p> <p>Characteristics of the eyelid Europeoid eyelids, 2.3 mm thick</p>
	<p>Subject 3 a man of 60 years old, death occurred on 11 April 2018 more precisely the period from 00.00 to 02.00 a.m., in result of subendocardial anterior myocardial infarction of the left ventricle; facial skull, including nose, eyes, eyelids, lips - undamaged.</p> <p>Characteristics of the eyelid Europeoid eyelids, 2.8 mm thick</p>

User 1, Subject 1



Reference pressure, mm. Hg.	Tonometer A, mm. Hg										Average, mm. Hg	SD	V
	7	8	8	8	7	8	8	7	7	8			
7	7	8	8	8	7	8	8	7	7	8	7,60	0,52	0,0679
10	10	11	11	11	10	9	9	9	10	10	10,00	0,82	0,0816
20	21	22	20	21	19	21	21	22	22	23	21,20	1,14	0,0536
30	30	31	32	29	33	32	31	33	32	34	31,70	1,49	0,0471
40	40	44	45	43	42	41	45	43	43	45	43,10	1,73	0,0401
50	54	55	52	53	50	54	54	51	50	49	52,20	2,10	0,0402

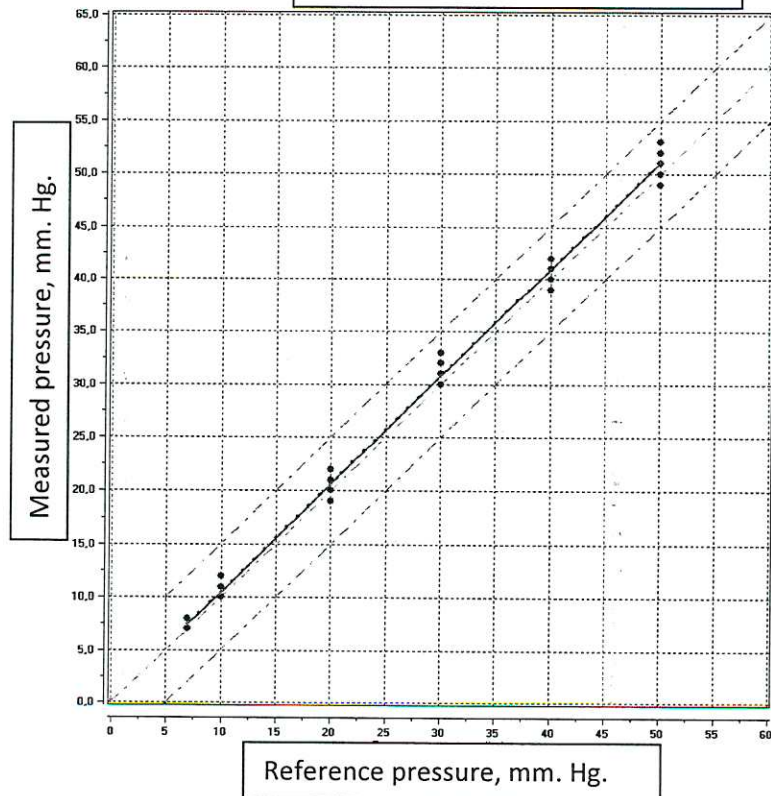


User 1, Subject 2

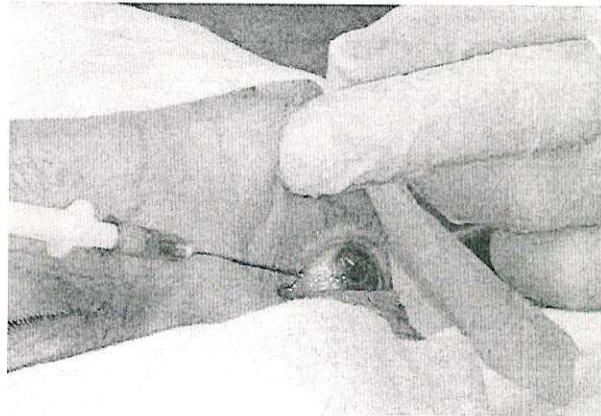


Reference pressure, mm. Hg.	Tonometer A, mm. Hg										Average, mm. Hg	SD	V
7	7	7	7	8	8	8	7	7	8	7	7,40	0,52	0,0698
10	10	10	11	10	11	11	11	11	10	12	10,70	0,67	0,0631
20	20	20	20	21	20	21	21	20	22	19	20,40	0,84	0,0413
30	31	31	31	30	32	31	33	30	31	30	31,00	0,94	0,0304
40	41	42	40	41	40	39	41	40	41	41	40,60	0,84	0,0208
50	52	52	51	53	52	51	51	49	52	50	51,30	1,16	0,0226

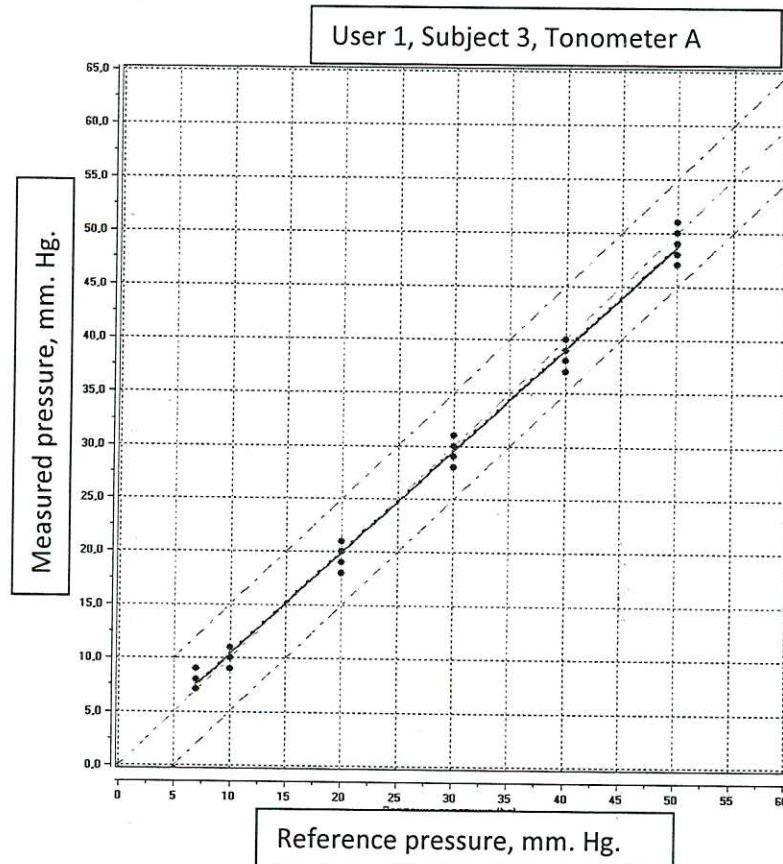
User 1, Subject 2, Tonometer A



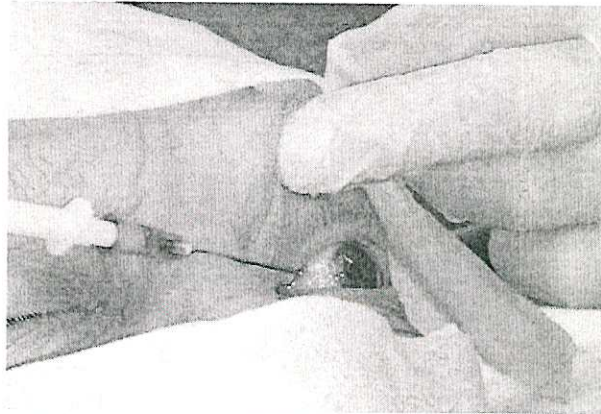
User 1, Subject 3



Reference pressure, mm. Hg.	Tonometer A, mm. Hg										Average, mm. Hg	SD	V
	7	8	8	9	8	8	8	8	7	8			
7	7	8	8	9	8	8	8	8	7	8	7,90	0,57	0,0719
10	9	11	10	10	10	10	10	11	11	11	10,30	0,67	0,0655
20	19	20	20	21	19	18	20	19	21	20	19,70	0,95	0,0482
30	30	29	28	31	30	29	29	30	29	29	29,40	0,84	0,0287
40	40	39	40	40	38	40	40	38	39	37	39,10	1,10	0,0281
50	50	51	49	48	49	48	48	49	49	47	48,80	1,14	0,0233

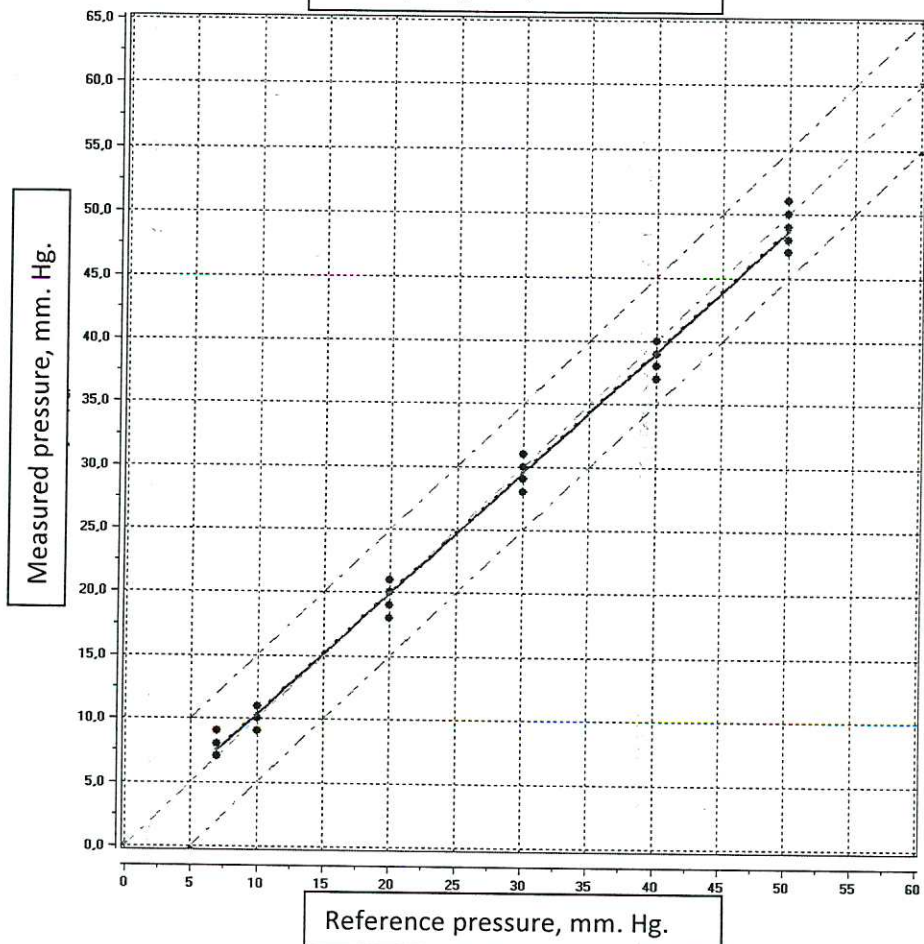


User 1, Subject 3



Reference pressure, mm. Hg.	Tonometer B, mm. Hg										Average, mm. Hg	SD	V
7	9	8	9	9	8	8	8	8	7	7	8,10	0,74	0,0911
10	11	11	11	10	10	9	10	10	9	9	10,00	0,82	0,0816
20	21	20	20	19	19	18	20	20	19	19	19,50	0,85	0,0436
30	31	30	31	31	30	29	29	30	29	28	29,80	1,03	0,0347
40	40	39	39	39	40	39	39	39	37	38	38,90	0,88	0,0225
50	50	51	50	48	49	48	48	49	48	47	48,80	1,23	0,0252

User 1, Subject 3, Tonometer B



User 2, Subject 3



Reference pressure, mm. Hg.	Tonometer A, mm. Hg										Average, mm. Hg	SD	V
7	7	8	8	7	8	8	8	8	7	8	7,64	0,48	0,0633
10	11	11	10	10	10	10	10	10	10	9	10,10	0,57	0,0562
20	19	20	21	19	19	18	20	19	18	20	19,30	0,95	0,0492
30	29	29	28	30	30	29	29	28	27	29	28,80	0,92	0,0319
40	40	40	39	40	38	39	40	39	38	37	39,00	1,05	0,0270
50	50	50	51	49	49	48	48	49	47	47	48,80	1,32	0,0270

User 2, Subject 3, Tonometer A

