

Metrological and technical requirements on machines on measurement pressure blood- tonometers

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1 Basic terms _

For purposes this measure in general nature applies terms and definition according to VI M (International metrological dictionary - Basic and general terms and associated terms) and following:

1.1

tonometer

Apparatus for measurement arterial blood pressure

1.2 mechanic tonometer (mercury or deformation tonometer

)

Tonometer using for measurement cuff pressure either mercurial, or deformation pressure gauge, possibly another mechanic measuring apparatus

1.3 electronic tonometer

Tonometer inclusive electromechanical measuring system on measurement blood pressure powered electrical energy

2 Metrological requirements

Metrological requirements they are founded on requirements ordinance government C. 54/2015 Coll., O technical requirements on medical mean y^2 , s utilization relevant requirements harmonized norms.

2.1 Stipulated working conditions

Gauge must be capable to measure arterial blood pressure in scope temperature from 10 °C to 40 °C. Requirements for biggest holiday error cuff pressure must be fulfilled at least ranging temperature Surroundings from 15 °C to 25 °C and scope relative humidity from 15 % to 85 %.

Exams for authentication with they perform at next reference conditions:

- temperature surrounding environment $(20 \pm 5) ^\circ\text{C}$;
- change temperature surrounding environment can not after time exams exceed 2 °C.

2.2 Measuring interval

Measuring interval pressure gauge cuff pressure must be from 0 mmHg to at least 260 mmHg (from 0 kPa to at least 35 kPa).

2.3 The largest holiday error

Biggest holiday error indication cuff pressure is $\pm 3 \text{ mmHg}$ ($\pm 0.4 \text{ kPa}$).

2.4

Hysteresis

Biggest holiday value hysteresis in individual points at rising and descending pressure Yippee

4 mmHg (0.5 kPa
).

3 Technical requirements

Technical requirements they are founded on requirements ordinance government C. 54/2015 Coll., O technical pose - taxpayers on medical means), with utilization relevant requirements harmonized norms.

3.1 Construction gauges

Tonometer with composes of pressure gauge and pneumatic system inclusive cuff, draining valve (often in combination with quick release valve) small or electromechanical pump and connection - vaca hose.

3.1.1 Mercury tonometer

Portable apparatus must be equipped adjustable and arresting mechanism, who him will ensure in spec - fictitious position to use .

Between stack and capillary must be placed blocking device, which prevent spillage mercury during transport.

3.2 Indicative device

Indicative device displays the value measured blood pressure in units mmHg , or kPa . Indian ducks device of mercury and deformational tonometers can not contain parallel or double scale v different units.

3.2.1 Mercury tonometer

Division scale must be:

- a) 2 mmHg for graduated divided in mmHg ;
- b) 0.2 kPa for graduated divided in kPa .

You can accept and another distinction fulfilling requirements relevant European norms.

Quicksilver must be clean (99.99 _ %), without visible admixture oxidants, which would they could stick to on capillaries.

3.2.2 Deformation tonometer

Pointer must overlap 1/3 until 2/3 length features the smallest piece scale.

3.2.3 Movement indicators cuff pressure

Movement mercury at of mercury tonometers and indicators at deformational tonometers must be fluent without the seer -

of them
jumps.

3.2.4 Electronic tonometer

Indicator must be designed and arranged so, that was possible information containing values measurement read a easily distinguish.

If they are on indicator used abbreviations, acts with O

following: "S" or "SYS" systolic blood pressure (value) ;

- "D" or "YES" diastolic blood pressure (value) ;
- "M" or "MAP" medium arterial blood pressure (value).

After power on tonometer to mode measurement with on display must display zero.

Resolution at least one indicator electronic tonometer must be at ordinary use
1 mmHg (0.1 kPa).

3.3 Pneumatic system

3.3.1

Tightness

Decrease pressure in as a result leakage air can not exceed holiday marginal value, which Yippee:

at mechanical tonometers 4 mmHg /min (0.5 kPa / min) ;

at electronic tonometers 6 mmHg /min (0.8 kPa /min); at those devices, at of which with blood pressure ur hears manually help stethoscope, can not decrease pressure exceed 4 mmHg /min {0.5 kPa /min }.

3.3.2 Speed reducing pressure

By hand controlled and self- linearizing draining valves must be capable Settings speed discharge from 2 mmHg /sec to 3 mmHg /sec (from 0.3 kPa to 0.4 kPa). These values must be at by hand controlled valves easily adjustable.

3.3.3 Fast discharging

Any measurement blood pressure must be always possible cancel the only one by act that will ensure quick discharge.

Time fast discharging can not in scope pressure of 260 mmHg on 15 mmHg (that 35 kPa on 2 kPa) trans
to step 10 s.

3.4 Protection against unauthorized intervention

AT tonometers equipped adjustments elements must be effective way done security at step to these elements.

4 Marking m. lightning rod

Tonometers must be marked at least the following data:

- mark or name producer;
- measuring unit;
- detail O electric power supply (at electronic tonometers) ;
- mark approval type, respectively designation "CE" with identification by number notified persons;
- next information provided by the manufacturer medical devices including relevant graph - sneeze brands.

Except that must be apparatus marked the following data:

- center air soul cuffs, that determines correctly location cuffs on arteries;
- designation cuffs, stating circuit extremities, for lower Yippee appropriate.

5 Approval type gauges

Gauges they are featured on market and to operation with assessment matches according to ordinance government C. 54/2015 Coll., Fr technical requirements on medical means ².

This gauges are not subject to approval type in meaning of the law C. 50511990 Coll., O metrology, in wording of later ones regulations.

6 Primitive check

Gauges they are featured on market and to operation with assessment matches according to ordinance government C. 54/2015 Coll., Fr technical requirements on medical means ².

These gauges are not subject to initial verification in meaning of the law C. 50511990 Coll., on metrology, in wording of later ones regulations.

7 Next _ check

7.1 In general

7.1.1 Overview of performed exams

At subsequent authentication tonometers with they perform gradually these exams:

at of mercury tonometers:

- a) visual visitation
- b) examination tightness pneumatic system
- C) exam influence device on closure mercury
- d) exam speed reducing pressure and movement mercury
- E) exam function fast discharging
- F) exam correctness indication cuff pressure u

deformational tonometers:

- a) visual visitation
- b) exam tightness pneumatic system
- C) exam dynamic responses at normal use
- d) exam speed reducing pressure and movement indicators
- E) exam function fast discharging
- F) exam correctness indication cuff pressure

G) evaluation hysteresis

u electronic tonometers:

- and) visual visitation
- b) exam tightness pneumatic system
- C) exam function automatic Settings zeros d)
- exam function fast discharging
- E) exam correctness indication cuff pressure

Trial device can not report vibration and blows which would at mechanical tonometers they could to cause change positions meniscus or indicators more than 0.1/1.0 the smallest piece scale.

Before exam must be gauge tempered in reference conditions according to Art. 2.1 after time the least 3 hours.

If gauge pressure blood listed to operation will not fulfill at authentication some of requirements specify - of them in chapters 2, 3 and 4 PPE with exception biggest holidays mistakes, and in the case deformational tone - three also hysteresis, Yippee it the reason to refusal check only in case that with by that deviates from specifications established by the manufacturer.

7.1.2 Trial equipment

To exams with will use following equipment:

- and) benchmark pressure gauge with upper between measuring interval at least 300 mmHg (40 kPa), with the greatest holiday by mistake smaller than 0.8 mmHg (0.1 kPa).
- b) thermometer with options measurement ranging temperature (15 until 25) °C, with distinctness least 0.1 °C.
- C) stopwatch with value the smallest piece 0h, 1 with and with biggest holiday by mistake 1 s/hour

7.2 Visual visitation

At visual tour with checks:

- whether with tonometer submitted to check matches with approved by type or with execution, at who -
- rého she was declared conformity in framework induction on market;
- whether does not show obvious marks damage, pollution or corrosion;
- readability scales/displays;
- completeness and readability prescribed I'll write and brands according to chap. 4.

AT of mercury tonometers can not be to fulfillment requirements Art. 3.1.1 _ detected occurrence droplet mercury in tonometer case and assesses with purity mercury and capillaries according to Art. 3.2.1

7.3 Exam tightness pneumatic system

Exam tightness pneumatic system with performs by measurement changes overpressure in dependencies on time when closed discharging valve or at elimination his function at electronic tonometers.

Cuff with wrap around cylindrical bodies corresponding sizes cuffs and in pneumatic system se infers pressure close upper between measuring interval. After 5 minutes with they subtract values pressure always after 60 with measured stopwatches.

At this one exam must be filled requirements Art. 3.3.1

7.4 Exam influence device on closure mercury

Source pressure will connect direct to tube head to stack mercury, respectively to deformation pressure gauge (without connection cuffs). After achievement higher pressure than 200 mmHg (25 kPa) with fast disconnects connection

pressure gauge and measures with time, for which it will pass top meniscus of mercury columns, respectively pointer, between feature kami 200 mmHg (25 kPa) and 50 mmHg (5

kPa). Measured value can not exceed 1.5

with.

7.5 Exam dynamic responses at normal use

Exam Yippee identical with exam according to Art. 7.4 .

7.6 Exam speed reducing pressure and movement mercury/indicators

AT by hand controlled discharges valves with in pneumatic tonometer system infers pressure near the top between measuring interval. Help stop sign with will review ability Settings speed decline discharge pressure valve in scope (2 until 3) mmHg /s, eventual (0.3 until 0.4) kPa /sec.

AT self-linearizing discharges valves with measures speed reducing pressure on human or artificial limbs. IN pneumatic system tonometer with infers pressure close upper border measuring interval. After opening self-linearizing valve with help stop sign will measure time passage peak mercury meniscus columns respectively indicators between 180 mmHg (25 kPa) and 60 mmHg (10 kPa).

During this one exams with is watching and movement of mercury columns in capillaries, eventual indicators. Movement must be fluent, without obvious bouncing around whose campaign with of mercury columns after capillaries.

Time passage must be for graduated in mmHg in scope (60 until 40) with, in the case scale in kPa in distr

sahu (50 until 37.5) with.

7.7 Exam function automatic Settings zeros

Visually with is watching fulfillment request Art. 3.2.4 on display zeros after power on tonometer.

7.8 Exam function fast discharging

At this one exam with cuff will replace fixed container O volume 500 Jr. AT measuring systems on blood measurement pressure capable to measure in newborn/infant mode, or for measurement on wrist, with the cuff will replace fixed container O volume 100 Jr. Benchmark pressure gauge with help connecting I have terial engages to pneumatic system. Pneumatic system with pressures on 260 mmHg (at measuring systems capable to measure in neonatal/infant mode on 150 mmHg) and after stabilization pressure will be listed in activity quick release valve. Help stop sign with will measure time necessary to achievement marginal throw a note 15 mmHg (u systems capable to measure in newborn/infant mode marginal values

5 mmHg
).

Time discharging can not exceed 10 with (at systems capable to measure in newborn/infant re
I'm pressing can not
exceed 5 s).

7.9 Exam accuracy indication cuff pressure

7.9.1 Exam accuracy indication cuff pressure of mercury tonometer

At this one exam with cuff tonometer will replace fixed closed container. Exam with performs next to mine by comparison data pressure gauge tonometer with data benchmark pressure gauge connected to pneuma - tic system after disconnection inflatable balloon with discharging valve or electromechanical pump (according to type gauges) help connectors T-pieces and tube together with additional source pressure.

He's trying with in individual points at decline pressure O maximum 50 mmHg from upper limits interval degrees

nice to 0
mmHg .

Found out error measurement in to everyone point measuring interval while descending pressure can not be larger than the biggest holiday error listed in Art. 2.3 .

7.9.2 _ Exam accuracy indication cuff pressure deformation tonometer

At this one exam with cuff tonometer will replace fixed closed container. Exam with performs next to mine by comparison data pressure gauge tonometer with data benchmark pressure gauge connected to pneuma - tic system after disconnection inflatable balloon with discharging valve or electromechanical pump (according to type gauges) help connectors T-pieces and tube together with additional source pressure.

He's trying with in individual points at increase pressure O maximum 50 mmHg from 0 mmHg , and it until to upper between interval scale; here with pressure maintains after time 5 minutes and then with in the same ones points tries at decline pressure.

Found out error measurement in to everyone point measuring interval at rising and descending pressure can not be bigger than biggest holiday error listed in Art. 2.3 .

7.9.3 Exam accuracy indication cuff pressure electronic tonometer

At this one exam with cuff tonometer will replace fixed closed container. Exam with performs next to mine by comparison data all of them indicative device pressure gauge tonometer with data benchmark pressure - measure connected to pneumatic system after disconnection inflatable balloon with discharging venti - hem or electromechanical pumps (according to type gauges) help connectors T-pieces and tube together with additional source pressure.

He's trying with in individual points at increase pressure O maximum 50 mmHg from 0 mmHg , and it until to upper between interval scale and then in the same ones points at decline pressure.

Found out error measurement in to everyone point measuring interval at rising and descending pressure can not be bigger than biggest holiday error listed in Art. 2.3

7.10 Evaluation hysteresis

Evaluation hysteresis will be performed only at deformational tonometers. For each point at exam according to Art. 7.9.2 with calculate absolute value hysteresis measured values at rising pressure P . A goes down - crying pressure *subject* :

$$h = |P_{ts} - P_{tk}|$$

AND

Calculated hysteresis can not exceed value stated in Art. 2.4

8 Testing on request concerned persons according to § IIa

User established gauges Yippee obligated on request persons, which can be affected his incorrect measurement, ask O testing established gauges. Tonometer must comply with metrological pose - taxes mentioned in Art. 2.3 and in the case deformational tonometers also in Art. 2.4 this PPE.

Method testing Yippee identical with by procedure at subsequent authentication according to chapters 7.

9 Announced norms

CMI will announce for purposes specifications metrological and technical requirements on gauges and for for specification purposes methods testing at authentication, resulting of this measure in general nature, Czech technical _ standards, next technical norms or technical documents international or foreign organizations, or other technical documents containing more detailed technical requirements (further just " he announces - less standards"). List these announced norms with by assignment to to the relevant one measure will announce CMI together with measure in general nature publicly available way (at web website www.cmi.cz).

Fulfillment announced norms or fulfillment their parts with consider, in scope and under conditions determined by the measure in general nature, for fulfillment those requirements established hereby measure, to whom with these standards or their parts they relate