ČESKÝ METROLOGICKÝ INSTITUT

Czech Metrology Institute

Okružní 31, 638 00 Brno

1. ------IND- 2018 0330 CZ- EN- ------ 20180803 --- --- PROJET

Executive summary for the EC *(not part of this legislation)*

Pure-tone audiometers are placed on the market and put into use in the Czech Republic pursuant to Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, as amended by Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998, Directive 2000/70/EC of the European Parliament and of the Council of 16 November 2000, Directive 2001/104/EC of the European Parliament and of the Council of 7 December 2001, Regulation (EC) No 1882/2003 of the European Parliament and of the Council of 29 September 2003, and Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007. Once they have been put into use, they become subject to national metrological regulation – verification at specified intervals.

This notified legislation only applies to the verification of measuring instruments that have already been put into use. It does not concern placing them on the market or putting them into use.

(End of executive summary.)

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PUBLIC DECREE

As the authority with substantive and territorial jurisdiction in the matter of laying down metrological and technical requirements for legally controlled measuring instruments and stipulating the testing methods for type approval and verification of legally controlled measuring instruments pursuant to § 14(1) of Act No 505/1990 on metrology, as amended (hereinafter the Metrology Act), and in accordance with the provisions of § 172 et seq. of Act No 500/2004, the Administrative Procedure Code (hereinafter the APC), on 29 February 2016, the Czech Metrology Institute (hereinafter the CMI) commenced ex officio proceedings pursuant to § 46 of the APC and, on the basis of supporting documents, issues the following:

I.

DRAFT GENERAL MEASURE

ref. No: 0111-OOP-C064-16

laying down the metrological and technical requirements for legally controlled measuring instruments, including testing methods for type approval and verification of the following legally controlled measuring instruments:

pure-tone audiometers

This legislation lays down the metrological and technical requirements for pure-tone audiometers to be applied in subsequent verification of these instruments after they have been placed on the market or put into use. These requirements comply with the requirements of special legislation[1] and apply the relevant requirements of harmonised standards.

The verification of pure-tone audiometers type approved under the Metrology Act, i.e. prior to the transposition of Council Directive 93/42/EEC, as amended, into Czech law, shall be subject to metrological requirements applicable at the time they were put into circulation.

1 Basic definitions

For the purposes of this general measure, terms and definitions pursuant to VIM and VIML[2] and the terms and definitions below shall apply.

1.1
pure-tone audiometer

an instrument for the measurement of hearing for pure tones and in particular of the threshold of hearing

1.2
artificial ear

a device for the calibration of earphones that presents an acoustic impedance load to the earphones equivalent to that of the average human ear of an adult. The artificial ear is equipped with a calibrated microphone for measuring sound pressure generated by earphones.

1.3
acoustic coupler

a cavity of predetermined shape and volume used for the calibration of earphones in conjunction with a calibrated microphone adapted to measure the sound pressure developed in the cavity.

1.4
ear simulator

a general term used to describe devices such as artificial ears (1.2) and acoustic couplers (1.3), which are used to measure sound pressure at the output of earphones.

1.5
mechanical coupler

a device equipped with an electromechanical transducer allowing the alternating force level at the surface contact between vibrator and mechanical coupler to be established; it is designed to present a specified mechanical impedance to the vibrator applied with a specified static force.

1.6
reference equivalent threshold sound pressure level (RETSPL)

the mean value of the equivalent threshold sound pressure level at a specified frequency of a sufficiently large number of ears of otologically normal persons of both sexes aged between 18 and 30

[1] Government Regulation No 54/2015 laying down technical requirements for medical devices

[2] TNI 01 0115 International Vocabulary of Metrology – Basic and General Concepts and Associated Terms (VIM) and International Vocabulary of Legal Metrology (VIML) are part of the technical harmonisation compendium ‘Terminology in the field of metrology’, which is publicly available at www.unmz.cz

years inclusive, expressing the threshold of hearing in a specified acoustic coupler or artificial ear for a specified type of earphones.

1.7
reference equivalent threshold force level (RETFL)

the mean value of the equivalent threshold force levels at a specified frequency of a sufficiently large number of ears of otologically normal persons of both sexes aged between 18 and 30 years inclusive, expressing the threshold of hearing on a specified mechanical coupler for a specified configuration of bone vibrator.

1.8
pure-tone hearing level (HL)

the sound pressure level or the vibratory force level at a specified frequency for a specific type of earphones or vibrator and for a specified manner of application produced by the earphones or vibrator in a specified ear simulator or mechanical coupler minus the appropriate reference equivalent threshold sound pressure level or reference equivalent threshold force level.

2 Metrological requirements

The metrological requirements are based on the requirements of special legislation[1] and the requirements and recommendations of the International Organisation of Legal Metrology.

The verification of measuring instruments type approved prior to the entry into force of the Metrology Act shall be subject to the metrological requirements applicable at the time they were put into circulation[3].

2.1 Pure-tone audiometers

2.1.1. Operating conditions

Specified combinations of temperature, relative humidity and static pressure:

Air temperature:	15–35 °C
Relative humidity:	30–90 %
Static pressure:	98–104 kPa

2.1.2 Measuring interval

The measuring intervals for each class of pure-tone audiometers are given in Table 1 and for extended high-frequency audiometers in Table 2.

[3] OIML R 104 ‘Pure-tone audiometers’ – *publicly available at* www.oiml.org

Table 1 Minimum number of fixed frequencies and minimum range of hearing levels.

Frequency (Hz)	**Hearing levels** *) (dB)						
	Class 1		**Class 2**		**Class 3**		**Class 4**
	Air conduction	**Bone conduction**	**Air conduction**	**Bone conduction**	**Air conduction**	**Bone conduction**	**Air conduction**
125	70	-	60	-	-	-	-
250	90	45	80	45	70	35	70
500	120	60	110	60	100	50	70
750	120	60	-	-	-	-	-
1 000	120	70	110	70	100	60	70
1 500	120	70	110	70	-	-	-
2 000	120	70	110	70	100	60	70
3 000	120	70	110	70	100	60	70
4 000	120	60	110	60	100	50	70
6 000	110	50	100	-	90	-	70
8 000	100	-	90	-	80	-	-

*) The maximum hearing level shall be at least equal to the values given in this table.
The lowest hearing level shall be -10 dB or lower.

Table 2: Extended high-frequency audiometers – minimum range of hearing levels.

Frequency (Hz)	8 000(*)	9 000	10 000(*)	11 200	12 500(*)	14 000(*)	16 000(*)
Hearing levels** (dB)	100	90	90	80	70	70	60

**) The minimum hearing levels shall be -10 dB or lower at all frequencies.
(*) These measuring signal frequencies are mandatory.

2.1.3 Maximum permissible error

2.1.3.1 Accuracy of sound pressure level and vibratory force level settings

The sound pressure level minus the reference equivalent threshold shall differ by not more than ±3.7 dB from the indicated value at indicated frequencies in the range 125 Hz to 4 kHz and by not more than ±6.2 dB at frequencies up to and including 8 kHz. At higher frequencies, this difference shall be within the tolerance of ±6.5 dB.

The force level produced by the bone vibrator minus the reference equivalent threshold force level shall differ by not more than ±5.5 dB in the frequency range 125 Hz to 4 kHz and by not more than ±7.0 dB at higher frequencies.

If more than one channel of the measurement signal or noise is connected simultaneously to a single transducer, the output level of either signal (or noise) from the transducer shall not differ by more than ±1.7 dB from the level obtained when only one channel is connected. This requirement shall be met at

frequencies from 125 Hz to 4 kHz. A tolerance of ±3.2 dB at frequencies from 5 kHz to 8 kHz and ±3.5 dB at frequencies from 8 kHz to 16 kHz shall be required. This shall apply to hearing levels up to 20 dB below the maximum output level.

2.1.3.2 Accuracy of masking level settings

The level of the masking sound produced by an earphone shall not differ from the indicated value by more than $^{+6}_{-4}$ dB.

2.1.3.3 Harmonic distortion

The maximum total harmonic distortion shall not exceed the values given in Table 3.

Table 3 Maximum permissible acoustic total harmonic distortion for supra-aural, circumaural and insert earphones and bone vibrators.

	Air conduction			**Bone conduction**		
Frequency range (Hz)	125 to 250	315 to 400	500 to 5 000	250 to 400	500 to 800	1 000 to 4 000
Hearing level *) (dB)	75	90	110	20	50	60
Total harmonic distortion (%)	3	3	3	6	6	6
*) Or the maximum output level of the audiometer, whichever is lower. For circumaural and insert earphones, the hearing level shall be 10 dB lower than the level specified in the table.						

2.1.3.4 Accuracy of frequency settings

For fixed frequency audiometers, the frequencies shall be equal to the stated values with the following tolerances:

Class 1 and 2: ±1.5 %

Class 3 and 4: ±2.5 %

For continuous sweep frequency audiometers, the frequency of the test tone shall agree with the value indicated in the audiogram with an accuracy of ±5.5 %.

2.1.3.5 Accuracy of control

The difference (in decibels) between the measured difference and indicated difference between two subsequent hearing level settings shall be less than or equal to the lower of the following values:

- three-tenths of the indicated difference in decibels, or
  - 1.5 dB for hearing level settings between -10 dB and 0 dB;
  - 1.4 dB for hearing level settings between 0 dB and 45 dB;
  - 1.2 dB for hearing level settings at 45 dB or higher.

2.1.3.6 Test tone on/off ratio for audiometers with manual control

With the test tone switch in the OFF position and the hearing level control set at 60 dB or below, the output shall be at least 10 dB below the reference equivalent threshold level. At higher hearing level settings and with the test tone switch still in the OFF position, the output shall not rise by more than 10 dB for each 10 dB increase in the hearing level setting above 60 dB.

2.1.3.7 Static force

The headband shall generate static force:

- earphones: 4.5 N ± 0.5 N
- bone vibrator: 5.4 N ± 0.5 N

3 Technical requirements

The technical requirements are based on the requirements of special legislation[1].

The verification of measuring instruments type approved prior to the entry into force of the Metrology Act shall be subject to the technical requirements applicable at the time they were put into circulation.

3.1 Requirements for specific classes of fixed frequency audiometers

Requirements for minimum facilities for the following four classes of audiometers are given in Table 4.

Class 1 Audiometers for advanced clinical/research work

Class 2 Audiometers for clinical work

Class 3 Audiometers for basic diagnostics

Class 4 Audiometers for screening/monitoring

Table 4 Minimum facilities of fixed frequency audiometers.

Facilities	**Class 1**	**Class 2**	**Class 3**	**Class 4**
Air conduction: - two earphones - additional insert earphone	 YES YES	YES	YES	YES
Bone conduction	YES	YES	YES	
Hearing levels and test frequencies (see Table 2 and Table 3)				
Narrow-band masking noise	YES	YES	YES	
External signal input	YES	YES		
Test tone switching - tone presentation - tone interruption - pulsed tone	 YES YES YES	 YES YES YES	YES	 YES [I.] YES [II.]
Masking method - contralateral earphone - ipsilateral earphone - bone vibrator	 YES YES YES	YES	YES	
Reference tone [III.] - alternate presentation - simultaneous presentation	 YES YES	YES		
Subject response system	YES	YES	YES	YES [b]
Electrical signal output	YES	YES		
Signal indicator	YES	YES		

Acoustic monitor for the tone signal - pure tones and noise - external input	 YES YES			
Speech communication - operator with subject - subject with operator	 YES YES	YES		
NOTE The extended high-frequency range (EHF range) is optional for all four classes of audiometers.				
I. Not mandatory for automatic recording audiometers, except for calibration purposes. II. Not mandatory for manual audiometers. III. The minimum requirement is for the presentation of reference tones of the same frequency as the test tones.				

3.2 General safety requirements

Audiometers shall conform to safety requirements.

3.3 Acoustic safety requirements

A non-auditory warning indication to the operator is required for all hearing level settings above 100 dB.

3.4 Environmental conditions

The technical requirements shall be met for the following specified combinations of temperature within the range of 15 °C to 35 °C, relative humidity within the range 30 % and 90 % and static pressure within the range 98 kPa and 104 kPa.

3.5 Warm-up time (5.4)

The performance requirements shall be met after the stated warm-up time has elapsed and after any setting-up adjustments have been carried out in accordance with the manufacturer's instructions.

The minimum warm-up time of the instrument shall be specified by the manufacturer. However, if the audiometer has been kept at the ambient temperature of the test environment, the warm-up time shall not exceed 10 minutes.

3.6 Power supply variation

3.6.1 Interruption of power supply

In the event of a complete power supply failure of up to five seconds, the audiometer shall be able to revert to a condition ensuring that the subject's hearing is not endangered and the results obtained are not incorrect.

3.6.2 Mains operation

Within the limits of ±10 % of the stated mains supply voltage and ±5 % of the stated mains frequency, the technical requirements shall be met for any long-term combined deviation of supply voltage or frequency of the mains which is the least favourable.

3.6.3 Battery operation

The manufacturer shall specify the limits of battery voltage within which the technical requirements will be complied with. The audiometer shall be fitted with a suitable battery voltage indicator so that it

is always clear that the battery voltage is within the specified limits. The technical requirements for the audiometer shall be complied with at all battery voltages within the specified limits.

3.6.4 Other power supply sources

If the audiometer is powered by means other than by mains or battery, the manufacturer shall specify the type of power supply, its characteristics and tolerances within which the specifications of the audiometer will be met.

3.7 Electromagnetic compatibility (EMC)

The unwanted sound from any air conduction transducer shall not exceed a hearing level corresponding to 80 dB during and as a result of any electromagnetic compatibility immunity tests and under any test conditions of electromagnetic compatibility.

3.8 Unwanted sound

3.8.1 Unwanted sound radiated by an audiometer

Where audiometers are intended to be used with the subject in the same room, no sound generated due to the operation of the audiometer's controls during the actual listening test or radiated from the audiometer or radiated from any part of a computer system used in conjunction with the audiometer may be audible at any hearing level control setting up to and including 50 dB.

3.9 Interface connections

No unintentional change of the audiometer's calibration shall be possible via any interface.

4 Measuring instrument markings

The following information shall be provided on audiometers:

- the manufacturer's name;
- model, class (see Chapter 3.1);
- serial number.

These identification details shall also be provided on the measuring signal transducers.

The left and right earphones shall also be readily identifiable. If colour-coded, the left earphone shall be blue and the right earphone shall be red.

Any inscriptions and markings provided on the audiometer or, if applicable, on the tone signal transducers shall be clearly visible and legible under normal operating conditions and shall not impede reading the measuring instrument.

5 Type approval of the measuring instrument

Pure-tone audiometers are not subject to type approval under the provisions of the Metrology Act.

The measuring instruments shall be placed on the market and put into use after conformity assessment in accordance with special legislation[1].

6 Initial verification

The measuring instruments shall be placed on the market and put into use after conformity assessment in accordance with special legislation[1].

7 Subsequent verification

7.1 In general

7.1.1 Overview of the tests conducted

Subsequent verification of pure-tone audiometers shall comprise the following tests conducted sequentially:

a) visual inspection,

b) accuracy test.

7.1.2 Test equipment

The following equipment shall be used for the tests:

a) ear simulator, mechanical coupler, sound level meter or sound analyser with one third octave filters, multimeter, apparatus for measuring static force;

b) thermometer with a measuring range of 15–35 °C, hygrometer, barometer.

7.2 Visual inspection

The purpose of visual inspection shall be to check that:

- the audiometer is not mechanically damaged and is free of defects visually detectable without the use of any aids;
- the transducer cables are not obviously damaged;
- the audiometer has the appropriate markings.

If the pure-tone audiometer fails to meet visual inspection requirements, no further tests are performed.

7.3 Accuracy test

All the tests referred to in Article 7.3 shall be conducted under the operating conditions referred to in Article 2.1.

7.3.1 Accuracy of sound pressure level and vibratory force level settings

The test shall be conducted by measuring the output of each earphone, at all available frequencies, using the specified ear simulator with the hearing level set at 70 dB or at the maximum level, whichever is lower. For bone vibrators, the hearing level shall be set at 30 dB or at the maximum value, whichever is lower and the measurement shall be performed on the mechanical coupler.

7.3.2 Accuracy of masking level settings

The test shall be conducted in the same manner as under 7.3.1.

7.3.3 Harmonic distortion

The test shall be conducted at the hearing levels given in Table 3 or with the audiometer set at the highest hearing level, whichever is lower. Measurement of harmonics above 16 kHz is not required. In the case of air conduction, the distortion shall be measured acoustically on an ear simulator of the type used when specifying the reference equivalent threshold levels. In the case of bone conduction, the distortion shall be measured on the mechanical coupler.

7.3.4 Accuracy of frequency settings

The test of accuracy of frequency settings shall be conducted for all used frequencies by direct measurement using a reader or a multimeter.

7.3.5 Accuracy of control

The test of accuracy of hearing level control shall be conducted at 1 kHz; if the audiometer is equipped for an extended high-frequency range, an additional test at 8 kHz shall be conducted. As far as possible, the tests shall be conducted acoustically. If electrical measurements are made, it is recommended to use the Y splitter where the common part is connected to the audiometer output and the multimeter and earphones are connected to the splitter.

7.3.6 On/off signal ratio

The test of the on/off signal ratio for manual audiometers shall be conducted by electrical measurement using a Y splitter.

7.3.7 Static force

7.3.7.1 Headband for supra-aural and circumaural earphones

The test shall be conducted by stretching the headband with the earphones horizontally to a length of 145 mm, while adjusting the height of the headband to a vertical distance of 129 mm measured between the centre (top) of the headband and the line passing through the centres of the earphones. The dimensional tolerance is ±5 mm.

7.3.7.2 Headband for bone vibrators

The test shall be conducted as described in 7.3.7.1 with the difference that when placing the bone vibrator on the forehead, the distance shall be 190 mm with a tolerance of ±5 mm.

8 Notified standards

For the purposes of specifying the metrological and technical requirements for measuring instruments and specifying the testing methods for their type approval and verification stemming from this general measure, the CMI shall notify the Czech technical standards, other technical standards or technical documents of international or foreign organisations, or other technical documents containing more detailed technical requirements (hereinafter notified standards). The CMI shall publish a list of these notified standards attached to the relevant measures, together with the general measure, in a manner accessible to the public (on www.cmi.cz).

Compliance with notified standards or parts thereof is considered, to the extent and under the conditions stipulated by a general measure, to be compliance with the requirements stipulated by this measure to which these standards or parts thereof apply.

Compliance with notified standards is one way of demonstrating compliance with the requirements. These requirements may also be met by using another technical solution guaranteeing an equivalent or higher level of protection of legitimate interests.

II.

GROUNDS

The CMI has issued this general measure laying down metrological and technical requirements for legally controlled measuring instruments and tests for verification of these legally controlled measuring instruments in accordance with § 14(1)(j) of the Metrology Act to implement § 9(1) and § 11a(3) of the Metrology Act.

Implementing Decree No 345/2002 specifying measuring instruments for mandatory verification and measuring instruments subject to type approval, as amended, classifies ‘pure-tone audiometers’ under item 6.1.3 of the annex entitled ‘List of the types of legally controlled measuring instruments’ as measuring instruments subject to verification.

The CMI has issued this draft general measure laying down metrological and technical requirements and testing methods for the verification of these legally controlled measuring instruments to implement § 9(1) and § 11a(3) of the Metrology Act for this type of measuring instruments.

This legislation (general measure) will be notified in accordance with Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services.

III.

INSTRUCTIONS

In accordance with § 172(l), in conjunction with § 39(l) APC, the CMI has stipulated a time limit for comments of 30 days as of the date of posting on the official notice board. Comments submitted after this time will not be considered.

The persons concerned are hereby invited to comment on this draft general measure. With a view to the provisions of § 172(4) APC, comments shall be submitted in writing and meet the requirements for submissions in accordance with § 37 APC.

The comments shall include the particulars referred to in § 37(2) APC and clearly state the following: who is making the comments; which general measure they concern; to what extent the comments challenge the measure; how the general measure runs contrary to legislation or how the general measure or the procedure that preceded it is inaccurate; which matters the comments concern and what is being proposed. Said comments must also identify the administrative authority to which they are addressed and be signed by the person making them.

The supporting documents for this draft general measure may be consulted at the Czech Metrology Institute, Legal Metrology Department, Okružní 31, 638 00 Brno, after making arrangements by telephone.

This general measure shall be posted for 15 days.

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RNDr. Pavel Klenovský

Director-General

Person responsible for accuracy: Mgr. Tomáš Hendrych

Posted on: 27 July 2017

Signature of the authorised person confirming posting: .....

Removed on:

Signature of the authorised person confirming removal: .....