TECHNICAL SPECIFICATION

ISO/TS 16976-2

Second edition 2015-04-01

Respiratory protective devices — Human factors —

Part 2: **Anthropometrics**

Appareils de protection respiratoire — Facteurs humains — Partie 2: Anthropométrie



ISO/TS 16976-2:2015(E)



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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 94, *Personal safety — Protective clothing and equipment*, Subcommittee SC 15, *Respiratory protective devices*.

This second edition cancels and replaces the first edition (ISO/TS 16976-2:2010), which has been technically revised. It also incorporates the Technical Corrigendum ISO 16976-2 Corr.1:2011.

The major technical changes are:

- a) Inclusion of ISO/TS 16976-2 TECHNICAL CORRIGENDUM 1:2011
- b) Change of values for W_5 and W_6 in 8.3.

ISO/TS 16976 consists of the following parts, under the general title *Respiratory protective devices* — *Human factors*:

- *Part 1: Metabolic rates and respiratory flow rates* [Technical Specification]
- Part 2: Anthropometrics [Technical Specification]
- Part 3: Physiological responses and limitations of oxygen and limitations of carbon dioxide in the breathing environment [Technical Specification]
- Part 4: Work of breathing and breathing resistance: Physiologically based limits [Technical Specification]
- Part 5: Thermal effects [Technical Specification]
- Part 6: Psycho-physiological effects [Technical Specification]
- Part 7: Hearing and speech [Technical Specification]
- *Part 8: Ergonomic factors* [Technical Specification]

Introduction

For an appropriate design, selection, and use of respiratory protective devices, basic physiological demands of the user must be considered. Type and intensity of work affect the metabolic rate (energy expenditure) of the wearer. Weight and weight distribution of the device on the human body can also influence metabolic rate. Metabolic rate is directly correlated with oxygen consumption, which determines the respiratory demands and flow rates. The work of breathing is influenced by the air flow resistances of the device and the lung airways. The work (or energy cost) of a breath is related to the pressure gradient created by the breathing muscles and the volume that is moved in and out of the lung during the breath. Anthropometric and biomechanical data are required for appropriate design of various components of a respiratory protective device, as well as for the design of relevant test methods.

This Technical Specification forms one part of a series of documents providing basic anthropometric measurement methods and data on humans. It contains information about the description, definition, and diagram of landmarks and dimensions, up-to-date head and face data for various race/ethnic groups, and human test panels.

Respiratory protective devices — Human factors —

Part 2:

Anthropometrics

1 Scope

This part of ISO/TS 16976 is one part of a series of Technical Specifications that provide information on factors related to human anthropometry, physiology, ergonomics, and performance for the preparation of standards for design, testing, and use of respiratory protective devices. This part of ISO/TS 16976 contains information related to anthropometry. In particular, information is given for:

- anthropometric measurement methods;
- anthropometric data for head, face, and neck dimensions;
- anthropometric data for torso dimensions;
- human test panels;
- models of headforms.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN 14143, Respiratory equipment — Self-contained re-breathing diving apparatus

3 Terms and definitions

For the purposes of this document, the terms and definitions given in Annexes A and B apply.

4 Anthropometric measurements

4.1 Anthropometric instrument and software

The standard measurement tools which are recommended are the anthropometer, a spreading calliper, a sliding calliper, a pupillometer, and a steel measuring tape. A suitable data entry, editing, and analysis software is described in References [3] and [4].

- **4.1.1 Anthropometer**, a specialized tool for measuring linear distance between points on the body and standard reference surfaces, such as the floor or a seat platform.
- **4.1.2 Spreading and sliding callipers**, used for measuring the breadth and depth of body segments, as well as the distance between reference marks.
- **4.1.3 Measuring tape**, used for measuring the arc and circumference of body segments.
- **4.1.4 Pupillometer**, a standard ophthalmic device used for measuring the interpupillary distance.

4.2 Measurement procedures

4.2.1 Landmarking

Landmarks are generally, although not always, skeletal points that are usually marked on the skin overlying the point. Selected landmarks are listed in $\underline{\text{Table 1}}$ and described in $\underline{\text{Annex A}}$. Subjects are landmarked with a surgical marker or an eyeliner pencil prior to measurement.

Table 1 — List of landmarks

Landmarks	Landmark positioning
Alare	Right and left
Cheilion	Right and left
Chin	_
Ectocanthus	Right and left
Frontotemporale	Right and left
Glabella	_
Gonion	Right and left
Infraorbitale Right and left	
Menton	_
Nasal root point	Right and left
Pronasale	_
Pupil	Right and left
Sellion	_
Subnasale	_
Top of head	_
Tragion	Right and left
Zygion	Right and left
Zygofrontale	Right and left

4.2.2 Measuring

After landmarking, subjects are measured for each of the dimensions. Data are recorded on data sheets and simultaneously entered into computer software. The data entry and editing software evaluate each measurement as it is entered and indicate when a measurement value is out of the previously measured range or is otherwise unexpected. In such cases, the measurement shall be repeated or data input errors corrected.

4.3 Dimensions to be measured

The dimensions to be measured are listed in <u>Table 2</u>. The detailed dimension descriptions are provided in <u>Annex B</u>. All dimensions are measured in millimetres and body weight is measured in kilograms.

Table 2 — List of face dimensions

Dimensions	Common terms
Bigonial breadth	Jaw width
Bitragion chin arc	
Bitragion coronal arc	
Bitragion frontal arc	
Bitragion subnasale arc	
Bizygomatic breadth	Face width
Head breadth	
Head circumference	
Head length	
Interpupillary distance	
Lip length	
Maximum frontal breadth	
Menton-sellion length	Face length
Minimum frontal breadth	
Nasal root breadth	
Neck circumference	
Nose breadth	
Nose protrusion	
Subnasale-sellion length	Nose length
Stature	Height
Weight	

5 Anthropometric data for head, face, and neck dimensions

Test panels for the development of an International Standard must be representative of the world population. An anthropometric study of the US work population was conducted by the National Institute for Occupational Safety and Health (NIOSH) in 2003 (see Reference [3]). The survey consisted of three age strata (18 years to 29 years, 30 years to 44 years, 45 years to 66 years), two gender strata (male and female), and four racial/ethnic group strata (white, African American, Hispanic, and other). The selected test panel could be seen as almost representative for the worldwide population, since the US population is multi-ethnic. Height, weight, 19 face dimensions, and neck circumferences were measured using traditional methods. A total of 3 997 subjects (2 543 male and 1 454 female) were measured. The sampling strategy called for equal representation in each of the sampling cells. This was done to ensure that we had adequately captured the anthropometric variability in all segments of the population. NIOSH research has resulted in the development of Table 3.

The NIOSH data were supplemented with additional measurements in China and other data for various countries. See References [5] and [6]. The data were compared to the NIOSH US Data and were found to be within the 5th and 95th percentiles for US population in Table 3.

Table 3 — Anthropometric data for head, face, and neck dimensions by gender (weight in kilograms, all other values in millimetres)

			Standard	_		Percentiles		
Dimension	Number	Mean	deviation	Min.	Max.	5th	50th	95th
	,		Males			,		
Bigonial breadth	2 543	120,4	10,4	90	160	105	120	140
Bitragion chin arc	2 543	331,2	15,5	271	393	306	330	355
Bitragion coronal arc	2 543	350,7	13,9	310	405	330	350	375
Bitragion frontal arc	2 543	304,1	13,0	263	349	282	305	326
Bitragion subnasale arc	2 543	294,8	13,2	253	345	275	295	315
Bizygomatic breadth	2 543	143,5	6,9	120	170	132	143	155
Head breadth	2 543	153,0	6,0	135	179	144	153	163
Head circumference	2 543	575,7	17,1	520	639	547	575	604
Head length	2 543	197,3	7,4	174	225	185	197	210
Interpupillary distance	2 543	64,5	3,6	53	79	59	65	71
Lip length	2 543	51,1	4,2	40	70	44	51	58
Maximum frontal breadth	2 543	112,3	5,5	95	131	104	112	122
Menton-sellion length	2 543	122,7	7,0	100	156	111	123	135
Minimum frontal breadth	2 543	105,5	5,7	90	127	95	105	115
Nasal root breadth	2 543	16,6	2,3	10	29	13	16	20
Neck circumference	1 023	406,7	32,6	312	570	355	403	465
Nose breadth	2 543	36,6	4,1	26	58	31	36	45
Nose protrusion	2 543	21,1	2,7	13	32	17	21	26
Stature	2 543	1 753,9	67,7	1 488	2 012	1 642	1 754	1 866
Subnasale-sellion length	2 543	52,0	4,1	40	66	45	52	59
Weight	2 540	90,4	17,5	42,9	167,8	65,7	88,4	122,7
			Females					
Bigonial breadth	1 454	110,1	8,9	88	150	98	110	125
Bitragion chin arc	1 454	303,9	14,9	248	375	280	305	328
Bitragion coronal arc	1 454	339,3	15,0	290	425	315	340	365
Bitragion frontal arc	1 454	287,4	11,9	250	330	270	287	305
Bitragion subnasale arc	1 454	277,5	13,1	238	335	258	277	300
Bizygomatic breadth	1 454	135,1	6,5	115	157	124	135	146
Head breadth	1 454	146,8	5,6	129	165	137	146	156
Head circumference	1 454	554,9	17,8	475	654	527	555	585
Head length	1 454	187,5	7,2	152	215	175	187	199
Interpupillary distance	1 452	61,9	3,5	52	78	56	62	68
Lip length	1 454	48,0	4,0	35	63	42	48	55
Maximum frontal breadth	1 454	108,6	5,3	92	130	100	108	117
Menton-sellion length	1 454	113,4	6,1	91	135	104	113	124
Minimum frontal breadth	1 454	102,9	5,4	84	126	94	103	111
Nasal root breadth	1 454	16,3	2,0	10	25	13	16	20
Neck circumference	793	339,5	30,9	260	505	295	335	395

Table 3 (continued)

Dimension	Number	Mean	Standard	Min	Mov	P	ercentile	s
Dimension	Number	меап	deviation	Min.	Max.	5th	50th	95th
Nose breadth	1 454	33,2	3,9	22	54	28	33	41
Nose protrusion	1 454	19,8	2,7	11	29	16	20	25
Stature	1 454	1 625,4	67,5	1 310	1 862	1 513	1 627	1 731
Subnasale-sellion length	1 454	48,2	3,8	32	59	42	48	55
Weight	1 454	75,7	18,7	34,2	176,4	51,8	72,1	112,1

6 Anthropometric data for torso dimensions

The application for the torso to be developed is to hold an RPD (respiratory protective device) designed to be worn on the human body, in position, during testing. The data given for this torso are not appropriate for use in the design of the RPD. Since there will be no test where ergonomic features are checked by using the torso, it has been agreed to use the ADULTDATA handbook[Z] mean values of males and females. A subset of the ADULTDATA including anthropometric data for a number of surveys from UK, Sweden, Italy, France, China, Japan, and USA was used.

The mean values of the designated measurements identifying the main dimensions of a torso shown in <u>Figure 1</u> are given in <u>Table 4</u>. The measure reference identification numbers have been taken from the ADULTDATA handbook as they are numbered originally to allow comparison.

The last column in <u>Table 4</u> gives the mean for male and female mean data which leads to the neutral dimension to be taken for modelling of the torso.

The torso is positioned on an elliptical contoured platform with the axis a = 200 mm, b = 300 mm, and a minimum height of 150 mm. This generates some space for parts of an RPD extending beyond the torso, but which are not in contact with the plateau, whichever way the torso is placed. The RPD will be fixed to the torso by the harness without touching the plateau.

The torso will have a socket at the top for inserting the headforms described in this part of ISO/TS 16976.

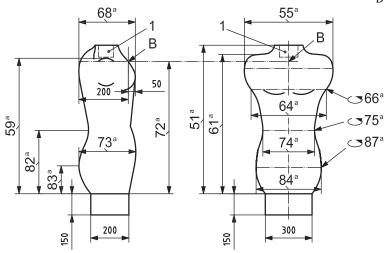
Table 4 — Mean anthropometric data for torso dimensions by gender and combined population

ADULTDATA measure reference identification number	Description	Dimension 50 % male	Dimension 50 % female	Dimension 50 % mean mm
51	Height of prominent neck vertebra, sitting	667	628	648
55	Shoulder breadth (deltoid)	458	416	437
59	Shoulder (acromion) height, sitting	605	569	587
61	Mid-shoulder height, sitting	632	579	606
64	Chest breadth, at level of nipples	329	282	306
66	Chest circumference, at level of nipples	916	921	919
68	Chest depth, at level of nipples	248	251	250
72	Trunk height to the top of breast bone, sitting	597	573	585
73	Lower abdominal depth	284	250	267
74	Waist breadth	259	264	262
75	Waist circumference – natural indentation	839	769	804

Table 4 (continued)

ADULTDATA measure reference identification number	Description	Dimension 50 % male mm	Dimension 50 % female mm	Dimension 50 % mean mm
82	Height of maximum lumbar curvature, sitting	241	232	237
83	Sacral height, sitting	162	159	161
84	Hip breadth	327	321	324
87	Mid-hip circumference	1 060	1 056	1 058
NOTE Measure ref	ference numbers are taken from ADULTDATA handbook	dimensions.		

Dimension in millimetres



Key

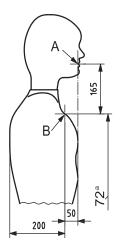
- 1 socket for headform
- **B** top of breast bone
- a All numbers are reference numbers in accordance with <u>Table 4</u>.

Figure 1 — Torso contour given by measure references

7 Interface between headform and torso

The torso described in this part of ISO/TS 16976 will be able to carry the five different headforms by a socket at the top. In order to test the RPD in its operational position, the headforms will be used to connect the RPD with the breathing machine/simulator whilst fixed to the torso. The headform will have a fixed position in relation to the torso by using reference points (A and B) which are illustrated in Figure 1 and Figure 2. The reference for all headforms is the point A, the centre of the mouth opening. This point will be positioned always 165 mm above the top of the breast bone (point B) as defined by measure reference number 72 of the torso contour. The length of the headform necks have to be designed accordingly. This relation is based on the information given in EN 14143.

Dimension in millimetres



Key

- A centre of the mouth opening
- **B** top of breast bone, according to measure 72 of <u>Table 4</u>
- a All numbers are reference numbers in accordance with <u>Table 4</u>.

Figure 2 — Interface between head and torso

8 Human test panels for facial features

8.1 General

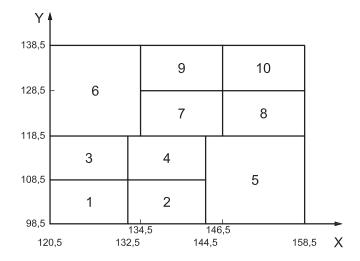
This clause shows how collected anthropometric data are used to develop human test panels (see Reference [4]). Two such panels are described.

8.2 Bivariate panel

The human test panel based on face length and face width is shown in Figure 3. This panel covers 96,7% of males and 98,7% of females of the selected population. This panel has limits of 98,5 mm to 138,5 mm for face length and 120,5 mm to 158,5 mm for face width. These limits were first based on the male mean plus two standard deviations (SDs) and the female mean minus two SDs. Cell boundaries were then adjusted so that the population can be distributed among cells as uniformly as possible. The boundaries were set so that at least 95% of the population was included in the panel. See also Annex C.

The standards writers can use this bivariate panel, the composition of which will be representative of target populations. A test panel shall use a minimum of ten subjects with at least one subject from each of the cells representing the target population.

In <u>Figure 3</u>, the cells are numbered from 1 to 10. When the subject's face length or face width falls on the boundaries, the subject is classified into the higher number cells with greater face dimensions.



Key

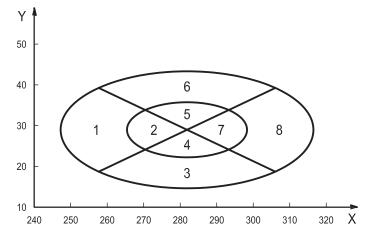
- X face width in millimetres
- Y face length in millimetres

Figure 3 — Bivariate panel based on face length and face width

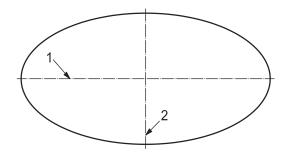
8.3 Principal component analysis (PCA) panel

The human test panel based on the PCA scores is shown in Figure 4. This panel covers 95,3% of the males and 97,6% of the females of the selected population. The layout of cells is different from the bivariate panel. The limit of this panel is based on an ellipse in which more than 95% of the population is included. The inner ellipse includes 50% of the population. The rationale for the rest of the PCA configuration is to have uniform distributions for each cell. Thus, two lines were used to divide the two ellipses into four quadrants resulting in eight cells. The population is then uniformly distributed among the cells.

The standards writers can use this PCA panel, the composition of which will be representative of target populations. A test panel shall use a minimum of ten subjects with at least one subject from each of the cells representing the target population.



a) PCA panel based on two principal components with cells numbered from 1 to 8



b) PCA panel based on two principal components with cells numbered from 1 to 4

Key

X first principal component

Y second principal component

1 major axis

2 minor axis

Figure 4

To construct the PCA panel, the ten face dimensions or the 18 face dimensions (see <u>Table 2</u>), as measured in millimetres in accordance with <u>Clause 4</u> and <u>Annex B</u>, are entered into the following algorithm. The first and second principal components (PC1 and PC2) are then calculated as follows.

$$PC1 = \sum_{n=1}^{10} W_n M_n \tag{1}$$

where

 $W_1 = 0.343264$

 $W_2 = 0,426498$

 $W_3 = 0.372717$

 $W_4 = 0.329648$

 $W_5 = 0.363474$

 $W_6 = 0.372241$

 $W_7 = 0,113578$

 $W_8 = 0.301 125$

 $W_9 = 0,202311$

 $W_{10} = 0,193650$

 M_1 = minimum frontal breadth (A)

 M_2 = face width (B)

 M_3 = bigonial breadth (C)

 M_4 = menton sellion length (D)

 M_5 = interpupillary distance (E)

 M_6 = head breadth (F)

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 M_7 = nose protrusion (G)

 M_8 = nose breadth (H)

 M_9 = nasal root breadth (J)

 M_{10} = subnasale-sellion length (K)

$$PC2 = \sum_{n=1}^{10} V_n M_n \tag{2}$$

where

 $V_1 = -0.152951$

 $V_2 = -0.039087$

 $V_3 = -0.093\ 279$

 $V_4 = 0.359799$

 $V_5 = -0.173099$

 $V_6 = 0.013306$

 $V_7 = 0,551842$

 $V_8 = -0.210833$

 $V_9 = -0.341235$

 $V_{10} = 0,584\ 261$

 M_1 = minimum frontal breadth (A)

 M_2 = face width (B)

 M_3 = bigonial breadth (C)

 M_4 = menton sellion length (D)

 M_5 = interpupillary distance (E)

 M_6 = head breadth (F)

 M_7 = nose protrusion (G)

 M_8 = nose breadth (H)

 M_9 = nasal root breadth (J)

 M_{10} = subnasale-sellion length (K)

Then make the following calculations:

$$x = PC1 - 281,6217618$$

$$y = PC2 - 28,9865054$$

slope = 5,584 793 0/13,699 110 8 = 0,407 675 6

 $a = 2,54 \times 13,699 \ 110 \ 8$

 $b = 2,54 \times 5,5847930$

$$c = 1,21 \times 13,699 \ 110 \ 8$$

$$d = 1,21 \times 5,5847930$$

$$r_1 = \sqrt{\frac{x^2}{a^2} + \frac{y^2}{b^2}}$$

$$r_2 = \sqrt{\frac{x^2}{c^2} + \frac{y^2}{d^2}}$$

where

x and y are new coordinates for translating the origin of PC1 and PC2 from their mean values (281,621 761 8 for PC1 and 28,986 505 4 for PC2) to zero;

slope is the slope value for the two lines dividing the ellipse into eight cells;

a is a constant for the length of the semi-major axis for the outer ellipse (see the illustration below);

b is the constant for the length of the semi-minor axis for the outer ellipse (see the illustration below);

c is a constant for the length of the semi-major axis for the inner ellipse;

d is the constant for the length of the semi-minor axis for the inner ellipse;

 r_1 and r_2 are values calculated to determine where a particular data point or a subject is, e.g. the data point is outside the outer ellipse when $r_1 > 1$ or on the outer ellipse when $r_1 = 1$ or inside the outer ellipse when $r_1 < 1$.

Use the x, y, and r_1 values and the algorithm below to determine if the subject is in cells 1, 3, 6, and 8:

if $x \ge 0$ and $y \ge 0$ and $r_1 \le 1$ and $abs(y)/abs(x) \le slope$, then cell = 8;

if $x \ge 0$ and y < 0 and $r_1 \le 1$ and abs(y)/abs(x) < slope, then cell = 8;

if $x \ge 0$ and y < 0 and $r_1 \le 1$ and $abs(y)/abs(x) \ge slope$, then cell = 3;

if x < 0 and y < 0 and $r_1 \le 1$ and abs(y)/abs(x) > slope, then cell = 3;

if x < 0 and y < 0 and $r_1 \le 1$ and $abs(y)/abs(x) \le slope$, then cell = 1;

if x < 0 and $y \ge 0$ and $r_1 \le 1$ and abs(y)/abs(x) < slope, then cell = 1;

if x < 0 and $y \ge 0$ and $r_1 \le 1$ and $abs(y)/abs(x) \ge slope$, then cell = 6;

if $x \ge 0$ and $y \ge 0$ and $r_1 \le 1$ and abs(y)/abs(x) > slope, then cell = 6.

If the r_2 value ≤ 1 , use the following algorithm to adjust the cell number:

if cell = 8 and $r2 \le 1$, then cell = 7;

if cell = 3 and $r2 \le 1$, then cell = 4;

if cell = 1 and $r2 \le 1$, then cell = 2;

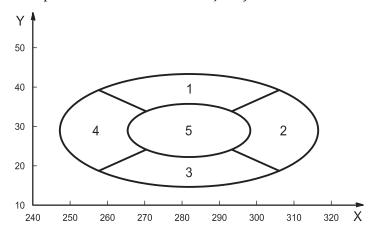
if cell = 6 and $r2 \le 1$, then cell = 5.

The measurement of these ten dimensions is described in <u>Annex B</u>. A test panel member should be remeasured when the member has a condition that can interfere with the respirator seal, e.g. a significant change in weight, a change to the face in the sealing area (e.g. scarring, facial surgery), or dental changes.

NOTE A video tape (see Reference [8]) is available which demonstrates the landmarking and measuring techniques with the traditional tools. A computer program (see Reference [9]) is available which provides a tool for recording measurements and determining the cell number for each subject.

9 Models of headforms

This clause shows how collected anthropometric data are used to develop models of headforms. Based on the PCA panel, five models of headforms are developed. [10] Four models (small, short/wide, long/narrow, and large) represent subjects in cells 1, 3, 6, and 8 respectively (see Figure 4). Subjects in cells 2, 4, 5, and 7 are represented by one model (medium). Figure 5 shows the distribution of the five headforms. The key dimensions (i.e. the ten facial dimensions used for defining the PCA panel) for each model are obtained by averaging the values for the subjects each model represents, including subjects who fall outside the PCA panel (all five models represent a total of 3 997 subjects) and are summarised in Table 5.



Key

- 1 long-narrow
- 2 large
- 3 short-wide
- 4 small
- 5 medium

Figure 5 — Distribution of the five headforms

Table 5 — Mean values for key facial dimensions of headforms

Dimensions in millimetres

Facial article ^a	Headform cell 1 (small)	Headform cell 3 (short/wide)	Headform cells 2, 4, 5, 7 (medium)	Headform cell 6 (long/narrow)	Headform cell 8 (large)
A Minimum frontal breadth	98	106	104	103	110
B Face width	128	141	140	140	151
C Bigonial breadth	101	118	115	113	131
D Face length ^b	110	112	119	127	127

For the definition and diagram of the facial article, see also Annex B.

Menton-sellion.

Subnasale-sellion.

Facial article ^a	Headform cell 1 (small)	Headform cell 3 (short/wide)	Headform cells 2, 4, 5, 7 (medium)	Headform cell 6 (long/narrow)	Headform cell 8 (large)
E Interpupillary distance	59	65	64	63	68
F Head breadth	142	149	150	151	158
G Nose protrusion	19	17	20	23	21
H Nose breadth	32	39	36	35	41
J Nasal root breadth	15	17	16	15	18
K Nose ^b length ^c	47	44	50	56	52

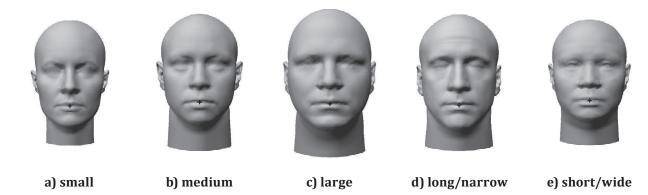
- For the definition and diagram of the facial article, see also Annex B.
- b Menton-sellion.
- c Subnasale-sellion.

Based on the mean values for the ten key facial dimensions, five subjects with facial features close to these mean values for each model were selected. Five scans in each category were chosen based on PCA scores calculated from 3-D scan data and averaged together to construct a representative headform for each size category.

After scanned heads of the appropriate size and shape were identified and selected, the scan data were averaged to develop models of headforms using Polyworks software. Designing a single headform is a multi-step process. After subjects with scanned heads of the appropriate size and shape were selected, their 3-D scans were aligned using Polyworks, a program that allows the user to edit 3-D scans. In order to obtain the optimum average of the five subjects, each head scan was aligned using the Frankfort plane and a vertical symmetry plane constructed from the midpoint between three facial features for each scan. Once in proper alignment, Polyworks was used to create a single averaged headform from all five digital scans.

The resultant averaged headform can contain regions of missing information around important facial features such as the mouth, nose, and eye regions. However, the forehead, cheeks, and chin regions provide a smooth average. The medium average had holes in the eyes that required a simple patching procedure, but the nose was missing enough information to require an additional step. If necessary, subsequent alignments were used for individual facial features: the nose, lips, and each eye. The average of the medium nose was stitched on to the initial average and the remaining holes were patched. Patching the headform included the removal of the noisy ear regions, as well as creating a smooth scalp. Once the entire headform was patched, it was duplicated and mirrored so that a symmetric average of the headform could be created. Ears, a neck, and a "+" sign at the centre of each mouth were added to complete each headform. The models of the five headforms are shown in Figure 6.

The digital models of headforms for producing physical models are available¹⁾.



NOTE All headforms are lined up on their reference points, the centre of mouth opening.

Figure 6 — Models of headforms

¹⁾ Models of headforms are available at the National Institute for Occupational Safety and Health, National Personal Protective Technology Laboratory, http://www.cdc.gov/niosh/npptl/default.html. This information is given for the convenience of users of this Technical Specification and does not constitute an endorsement by ISO of the product named. Equivalent products may be used if they can be shown to lead to the same results.

Annex A

(normative)

Description, definition, and diagrams of selected landmarks

Description	Definition	Diagram
Alare right and left	The lateral point on the flare or wing of the nose. Method: It is located by visual inspection.	
Cheilion right and left	The lateral point of the juncture of the fleshy tissue of the lips with the facial skin at the corner of the mouth. Method: It is located by visual inspection.	
Chin	The most protruding point on the bottom edge of the chin, along the jawline. Method: It is located by visual inspection.	
Ectocanthus right and left	The outside corner of the eye formed by the meeting of the upper and lower eyelids (unmarked). Method: It is located by visual inspection.	
Frontotemporale right and left	The point of deepest indentation of the temporal crest of the frontal bone above the brow ridges. Method: It is located by palpation.	
Glabella	The anterior point on the frontal bone midway between the bony brow ridges. Method: It is located by visual inspection and palpation.	
Gonion right and left	The most lateral, most inferior, and most posterior point on the angle of the mandible (jawbone). Method: The subject stands with head in the Frankfort plane and with teeth together (lightly occluded). Stand in front of the subject and locate the posterior angles of the mandible by palpation. The landmarks are the most lateral points of these angles.	

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Description	Definition	Diagram
Infraorbitale right and left	The lowest point on the anterior border of the bony eye socket. Method: It is located by palpation.	
Menton	The inferior point of the mandible in the midsagittal plane (bottom of the chin). Method: Subject stands with head in the Frankfort Plane and teeth together. Stand in front of the subject. Locate the landmark by palpation of the lower jawbone just under the chin, and place an adhesive dot on it.	
Nasal root point right and left	The point on the side of the nasal root at a depth equal to half the distance from the bridge of the nose to the eyes. Method: The subject stands looking straight ahead. Stand to the right side of the subject and locate the nasal root point by inspection.	
Pronasale	The point of the anterior projection of the tip of the nose. Method: It is located by visual inspection.	
Pupil	The centre of the pupil of a subject looking straight ahead. Method: It is not marked on the subject, but is located by visual inspection on the scan.	
Sellion	The point of the deepest depression of the nasal bones at the top of the nose. Method: The subject stands looking straight ahead. Stand to the right of the subject and palpate the point of the deepest depression of the bridge of the nose in the midsagittal plane. On some subjects, however, there is no distinctly deepest point and judgment will have to be used to establish its location. Place an adhesive dot on the bridge of the nose at the landmark.	To state of the st
Subnasale	The point of intersection of the philtrum (groove of the upper lip) with the inferior surface of the nose in the midsagittal plane. Method: It is located by visual inspection.	
Tragion right and left	The superior point on the juncture of the cartilaginous flap (tragus) of the ear with the head. Method: Palpate the tragus to find the superior point of attachment to the head. Place an adhesive dot on each landmark.	

Description	Definition	Diagram
Zygion right and left	The most lateral point on the zygomatic arch (unmarked). Method: The subject stands, looking straight ahead, with facial muscles relaxed. Stand in front of the subject and locate the most lateral point by palpation. (When unmarked, this is located by movement of the tips of the spreading calliper during measurement.)	
Zygofrontale right and left	The lateral point of the frontal bone on its zygomatic process. Method: It is located by palpation.	

Annex B

(normative)

Description, definition, and diagram of dimensions to be measured

Description ^a	Definition	Diagram			
A Minimum frontal breadth	The straight-line distance between the right and left frontotemporale landmarks on the temporal crest on each side of the forehead is measured with a spreading calliper. The subject sits looking straight ahead. Only enough pressure is exerted to ensure that the calliper tips are on the landmarks.				
B Face width	Maximum horizontal breadth of the face as measured with a spreading calliper between the zygomatic arches. The subject sits looking straight ahead and with teeth together (lightly occluded). Only enough pressure is exerted to ensure that the calliper tips are on the zygomatic arches.				
C Bigonial breadth	Straight-line distance measured with a spreading calliper between the right and left gonion landmarks on the corners of the jaw. The subject sits looking straight ahead and with teeth together (lightly occluded). Only enough pressure is exerted to ensure that the calliper tips are on the landmarks.				
D Menton-sellion length	The distance in the midsagittal plane between the menton landmark at the bottom of the chin and the sellion landmark at the deepest point of the nasal root depression is measured with a sliding calliper. The subject sits looking straight ahead and with teeth together (lightly occluded). The fixed blade of the calliper is placed on the sellion. Only enough pressure is exerted to obtain contact between the calliper and the skin is exerted.				
E Interpupillary distance	Distance as measured with a pupillometer at the centre of the right and the centre of the left pupil.				
F Head breadth	Maximum horizontal breadth of the head as measured with a spreading calliper above the level of the ears. The subject sits looking straight ahead. Enough pressure is exerted to obtain contact between the calliper and the skin.				
G Nose protrusion	The straight-line distance between the pronasale landmark at the tip of the nose and the subnasale landmark under the nose is measured with a sliding calliper. The subject sits looking straight ahead. The sliding blade of the calliper is reversed and the base of the calliper is placed on the subnasale landmark. The beam of the calliper is parallel to the line of the protrusion of the nose.				
^a For mean values for key facial dimensions of headforms according to description A to K, see also <u>Table 5</u> .					

Description ^a	Definition	Diagram
H Nose breadth	Straight-line distance as measured with a sliding calliper between the right and left alare landmarks. The subject sits looking straight ahead. Only enough pressure is exerted to obtain contact between the calliper and the skin.	
J Nasal root breadth	The horizontal breadth of the nose at the level of the deepest depression in the root (sellion landmark) and at a depth equal to half the distance from the bridge of the nose to the eyes is measured with a sliding calliper. The subject sits looking straight ahead. The blunt points of the sliding calliper are used. Only enough pressure is exerted to obtain contact between the calliper and the skin.	
K Subnasale-sellion length	Straight-line distance as measured with a sliding calliper between the subnasale landmark and the sellion landmark. The subject sits looking straight ahead. Only enough pressure is exerted to obtain contact between the calliper and the skin.	
Bitragion chin arc	The surface distance between the right and left tragion landmarks across the anterior point of the chin is measured with a tape. The subject sits looking straight ahead and with teeth together (lightly occluded). Enough tension is exerted to maintain light contact between the tape and the skin. The chin will be slightly compressed.	
Bitragion coronal arc	The surface distance between the right and left tragion landmarks across the top of the head in the coronal plane is measured with a tape. The subject sits with head in the Frankfort plane. Enough tension is exerted to compress the hair.	
Bitragion frontal arc	The surface distance between the right and left tragion landmarks across the forehead just above the ridges of the eyebrows (supraorbital ridges) is measured with a tape. The subject sits looking straight ahead. Enough tension is exerted to maintain light contact between the tape and the skin.	
Bitragion subnasale arc	The surface distance between the right and left tragion landmarks across the subnasale landmark at the bottom of the nose is measured with a tape. The subject sits looking straight ahead. Enough tension is exerted to maintain light contact between the tape and the skin, but not enough to compress the soft tissue under the nose.	
Head circumference	The maximum circumference of the head just above the ridges of the eyebrows (supraorbital ridges) and the attachment of the ears is measured with a tape. The subject sits looking straight ahead. The plane of the tape will be higher in the front than in the back and the sides should be parallel. Enough tension is exerted to compress the hair.	V. conde Table 5

ISO/TS 16976-2:2015(E)

Descriptiona	Definition	Diagram			
Head length	The maximum length of the head in the midsagittal plane is measured with a spreading calliper. The subject sits looking straight ahead. One tip of the calliper is placed on the glabella landmark between the brow ridges and the other tip is moved up and down the back of the head until a maximum measurement is obtained. Light pressure is exerted on the glabella and at the back of the head to compress the hair.	The site of the si			
Lip length	The straight-line distance between the right and left chelion landmarks at the corners of the closed mouth is measured with a sliding calliper. The subject sits looking straight ahead with teeth together (lightly occluded). The facial muscles are relaxed, and the mouth is closed.				
Maximum frontal breadth	The straight-line distance between the right and left zygofrontale landmarks at the upper margin of each bony eye socket is measured with a spreading calliper. The subject sits looking straight ahead. Only enough pressure is exerted to ensure that the calliper tips are on the landmarks is exerted.				
Neck circumference	The circumference of the neck at the level of the infrathyroid landmark (Adam's apple) is measured with a tape. The plane of the measurement is perpendicular to the long axis of the neck. The subject stands erect with head in the Frankfort plane. The shoulders and upper extremities are relaxed.				
Stature	The vertical distance between the standing surface and the top of the head is measured with an anthropometer. The subject stands erect with heels together and head in the Frankfort plane. The shoulders and arms are relaxed. Enough pressure is exerted to compress the hair. The measurement is taken at the maximum point of quiet respiration.				
Weight	The weight of the subject is taken to the nearest half kilogram. The subject stands on the centre of the platform looking straight ahead. The heels are together and the weight evenly distributed on both feet.				
For mean values for key facial dimensions of headforms according to description A to K, see also <u>Table 5</u> .					

Annex C (informative)

Examples of application of human test panels for facial features

C.1 General

This annex gives examples of how human test panels can be used, based on the US civilian population.

C.2 Bivariate panel

The human test panel based on face length and face width is shown in Figure C.1.

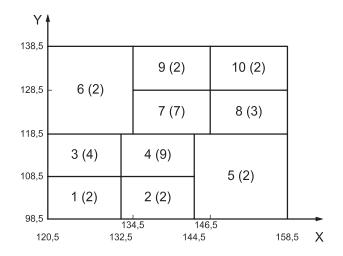
The number of subjects by cell is also summarised in Figure C.1. This panel covers 96,7 % of males and 98,7 % females of the selected population. This panel has limits of 98,5 mm to 138,5 mm for face length and 120,5 mm to 158,5 mm for face width. These limits were first based on the male mean plus two standard deviations (SDs) and the female mean minus two SDs. Cell boundaries were then adjusted so that the population can be distributed among cells as uniformly as possible. The boundaries were set so that at least 95 % of the population was included in the panel. See 8.2.

For example, if a panel size of 25 subjects is used for testing one-size-fits-all models, a minimum of two subjects from each cell is used and the remainder of the subjects selected proportional to the target population. This sample size is the same as the Los Alamos National Laboratory (LANL) panel. It is a compromise between the need for a sufficient number of tests to develop good statistics and the requirement to test all devices submitted for approval in a reasonable length of time. For two-size systems such as small/medium and medium/large, it is recommended that the small/medium be tested on subjects from cells 1-6 and medium/large be tested with subjects from cells 5-10. The total number of subjects becomes 29 for two-size systems. For three-size systems such as small, medium, and large, they are tested with subjects from cells 1-4 for small, cells 4-7 for medium, and cells 6-10 for large. The total number of subjects becomes 34 for three-size systems.

Another option is to test each size (e.g. small, medium, or large) with a sufficient number of subjects from whichever cells manufacturers deem have a good fit. For example, if manufacturers deem that a small-size respirator fits cells 1-7 better, a sufficient number of subjects from cells 1-7 is selected to test this small-size respirator. The number of subjects in each cell can be based on the percentages for cells 1-7 in Table C.1.

The standards writers can decrease or increase the panel size and adjust the number of test subjects per cell accordingly.

In <u>Figure C.1</u>, the cells are numbered from 1 to 10 and the numbers in parentheses indicate the number of subjects to be sampled from each cell. When the subject's face length or face width falls on the boundaries, the subject is classified into the higher number cells with greater face dimensions.



Key

- X face width in millimetres
- Y face length in millimetres

Figure C.1 — Bivariate panel based on face length and face width

Table C.1 — Percentage of population and number of subjects by cell and gender for the panel based on face length and face width

Cell	Male %	Female %	Total %	Male	Female	Total
1	0,3	10,6	5,5		2	2
2	1,0	9,5	5,3		2	2
3	1,9	19,0	10,5		2	2
4	15,5	34,3	25,0	2	3	5
5	9,7	4,5	7,1	1	1	2
6	4,9	6,5	5,7	1	1	2
7	30,7	12,0	21,3	3	1	4
8	15,9	1,7	8,7	2		2
9	9,9	0,6	5,2	2		2
10	6,9	0,1	3,5	2		2
Total	96,7	98,7	97,7	13	12	25

C.3 Principal component analysis (PCA) panel

The human test panel based on the PCA scores is shown in Figure C.2. The number of subjects by cell is also summarised in Figure C.2. This panel covers 95,3 % of the males and 97,6 % of the females of the selected population. The layout of cells is different from the bivariate panel. The limit of this panel is based on an ellipse in which more than 95 % of the population is included. The inner ellipse includes about one-third of the population. The rationale for the rest of the PCA configuration is to have uniform distributions for each cell. Thus, two lines were used to divide the two ellipses into four quadrants resulting in eight cells. The population is then uniformly distributed among cells. See 8.3.

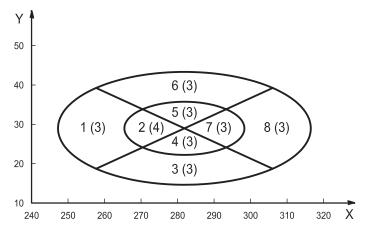
For example, if a panel size of 25 subjects is used for testing one-size-fits-all models (i.e. applicable to all cells), a minimum of two subjects from each cell is used and the remainder of the subjects selected proportional to the target population. For two-size systems such as small/medium and medium/large, it is recommended that the small/medium tested on subjects from cells 1-4 and medium/large tested with

subjects from cells 5-8. The total number of subjects is also 25 for two-size systems. For three-size systems such as small, medium, and large, they are tested with subjects from cells 1 and 3 for small, cells 2, 4, 5, and 7 for medium and cells 6 and 8 for large. The total number of subjects is still 25 for three-size systems.

Another option is to test each size (e.g. small, medium, or large) with a sufficient number of subjects from whichever cells manufacturers deem have a good fit. For example, if manufacturers deem that a small-size respirator fits cells 1-5 better, a sufficient number of subjects from cells 1-5 is selected to test this small-size respirator. The number of subjects in each cell can be based on the percentages for cells 1-5 in Table C.2.

The standards writers can decrease or increase the panel size and adjust the number of test subjects per cell accordingly.

In <u>Figure C.2</u>, the cells are numbered from 1 to 8. Three subjects are sampled from each cell except cell 2 in which four subjects are sampled.



Key

- X first principal component
- Y second principal component

Figure C.2 — PCA panel based on two principal components

Table C.2 — Percentage of population and number of subjects by cell and gender for the panel based on two principal components

Cell	Male %	Female %	Total %	Male	Female	Total
1	1,1	22,0	11,6	0	3	3
2	5,7	21,6	13,7	1	3	4
3	5,6	17,8	11,7	1	2	3
4	9,1	15,5	12,3	1	2	3
5	16,7	8,1	12,4	2	1	3
6	17,9	6,6	12,2	2	1	3
7	18,4	5,1	11,7	2	1	3
8	20,8	1,0	10,8	3	0	3
Total	95,2	97,6	96,4	13	12	25

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