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Stainless steel needle tubing for the manufacture of medical devices — Requirements and test methods

Tubes d'aiguilles en acier inoxydable pour la fabrication de matériel médical — Exigences et méthodes d'essai

Reference number
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ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

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Foreword

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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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Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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 84, *Devices for administration of medicinal products and catheters*.

This second edition cancels and replaces the first edition (ISO 9626:1991), which has been technically revised. It also incorporates the Amendment ISO 9626:1991/Amd 1:2001.

The main changes to the previous edition of ISO 9626 introduced by this revision are the following:

a) addition of specifications for stainless steel needle tubing for metric sizes 0,18 mm, 0,2 mm 0,23 mm and 0,25 mm and to reflect the introduction of thinner tubing to allow greater comfort when injecting, particularly for infants and in paediatric use;

b) addition of wall thickness designations beyond regular-walled and thin-walled tubing;

c) addition of minimum inner diameters for additional items where possible;

d) revision of the means of specifying the steels to be used;

e) revision of the table of tubing dimensions and stiffness parameters.

Annex A, Annex B, Annex C, Annex D and Annex E form an integral part of this International Standard.

Introduction

Guidance on transition periods for implementing the requirements of this International Standard is given in ISO/TR 19244.

Stainless steel needle tubing for the manufacture of medical devices — Requirements and test methods

1 Scope

This International Standard applies to rigid stainless steel needle tubing suitable for use in the manufacture of hypodermic needles and other medical devices primarily for human use.

This International Standard provides requirements and test methods for the tubes manufactured for needles as component used in medical devices. Additional performance testing on the tube aspect may be required when the component is incorporated in the ready-to-use device.

This International Standard specifies the dimensions and mechanical properties of steel tubing of designated metric sizes 3,4 mm (10 Gauge) to 0,18 mm (34 Gauge).

It does not apply to flexible stainless steel tubing because the mechanical properties differ from those specified for rigid tubing in this International Standard. However, manufacturers and purchasers of flexible tubing are encouraged to adopt the dimensional specifications given in this International Standard.

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.

ISO 3696, *Water for analytical laboratory use — Specification and test methods*

ISO 15510, *Stainless steels — Chemical composition*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
designated metric size
outer diameter designation of the tubing as defined in Table 1

Note 1 to entry: It is expressed in millimetres.

3.2
gauge
legacy size designation

Note 1 to entry: A particular gauge size corresponds to a designated metric size defining limits for outer diameters.

3.3
wall thickness
material thickness between the inner and outer diameter of the tube

Note 1 to entry: It is expressed as RW=Regular Wall, TW=Thin Wall, ETW= Extra Thin Wall, and UTW=Ultra Thin Wall as designated in Table 1.

4 Materials

Tubing shall be made of stainless steels listed in ISO 15510. The chosen materials shall be in accordance with the requirements indicated in this International Standard. Selection of specific stainless steel material shall be made in consideration with the intended use, e.g. long-term contact with drugs and should consider biocompatibility requirements.

NOTE Suitable biocompatibility requirements can be found in ISO 10993-1.

5 Requirements

5.1 General

For the selection of tubing for a specific application and intended use, a risk based approach shall be applied.

5.2 Surface finish and visual appearance

When examined by normal or corrected vision, the outside surface of the tubing shall be smooth and free from defects.

Surface finish specifications may be different based on the final function of the medical device; in such cases, the medical device manufacturer should prepare specific specifications for surface finishing.

When examined by normal or corrected vision, the needle tube shall appear straight and of regular roundness.

5.3 Cleanliness

When examined by normal or corrected vision, the surfaces of the tubing shall be free from metal soil and processing agents.

Cleanliness specifications may be different based on the final function of the medical device; in such cases, the medical device manufacturer should prepare specific specifications for cleanliness.

5.4 Limits for acidity and alkalinity

When determined with a laboratory pH meter and using a general purpose electrode, the pH value of an extract prepared in accordance with Annex A shall be within one pH unit of that of the control fluid.

5.5 Size designation

Tubing size shall be designated by the nominal outer diameter, expressed in millimetres (i.e. the designated metric size), corresponding gauge size (e.g. G31 or 31G), and by wall thickness.

EXAMPLE 0,25 mm (31G) ETW.

5.6 Dimensions

The dimensions of tubing shall be as given in Table 1.

Table 1 — Dimensions of tubing

Designated metric size mm	Gauge	OD_{MIN} mm	OD_{MAX} mm	Wall	ID_{MIN} mm
0,18	34	0,178	0,191	RW	0,064
				TW	0,091
				ETW	0,105
0,20	33	0,203	0,216	RW	0,089
				TW	0,105
				ETW	0,125
0,23	32	0,229	0,241	RW	0,089
				TW	0,105
				ETW	0,125
				UTW	0,146
0,25	31	0,254	0,267	RW	0,114
				TW	0,125
				ETW	0,146
				UTW	0,176
0,30	30	0,298	0,320	RW	0,133
				TW	0,165
				ETW	0,190
				UTW	0,240
0,33	29	0,324	0,351	RW	0,133
				TW	0,190
				ETW	0,240
				UTW	0,265
0,36	28	0,349	0,370	RW	0,133
				TW	0,190
0,40	27	0,400	0,420	RW	0,184
				TW	0,241
0,45	26	0,440	0,470	RW	0,232
				TW	0,292
0,50	25	0,500	0,530	RW	0,232
				TW	0,292
0,55	24	0,550	0,580	RW	0,280
				TW	0,343
0,60	23	0,600	0,673	RW	0,317
				TW	0,370
				ETW	0,460

NOTE 1 RW = Regular Wall; TW = Thin Wall; ETW = Extra Thin Wall; UTW = Ultra Thin Wall.

NOTE 2 Needle sizes below 0,25 mm, consideration can be made to the measurement uncertainty of existing measurement equipment.

NOTE 3 This International Standard does not specify maximum inner diameter.

NOTE 4 OD = outer diameter; ID = inner diameter.

Table 1 *(continued)*

Designated metric size mm	**Gauge**	**OD$_{\text{MIN}}$** mm	**OD$_{\text{MAX}}$** mm	**Wall**	**ID$_{\text{MIN}}$** mm
0,70	22	0,698	0,730	RW	0,390
				TW	0,440
				ETW	0,522
0,80	21	0,800	0,830	RW	0,490
				TW	0,547
				ETW	0,610
				UTW	0,645
0,90	20	0,860	0,920	RW	0,560
				TW	0,635
				ETW	0,687
				UTW	0,713
1,10	19	1,030	1,100	RW	0,648
				TW	0,750
				ETW	0,850
				UTW	0,891
1,20	18	1,200	1,300	RW	0,790
				TW	0,910
				ETW	1,041
1,40	17	1,400	1,510	RW	0,950
				TW	1,156
				ETW	1,244
				UTW	1,276
1,60	16	1,600	1,690	RW	1,100
				TW	1,283
				ETW	1,390
1,80	15	1,750	1,900	RW	1,300
				TW	1,460
				ETW	1,560
2,10	14	1,950	2,150	RW	1,500
				TW	1,600
				ETW	1,727
2,40	13	2,300	2,500	RW	1,700
				TW	1,956
2,70	12	2,650	2,850	RW	1,950
				TW	2,235

NOTE 1 RW = Regular Wall; TW = Thin Wall; ETW = Extra Thin Wall; UTW = Ultra Thin Wall.

NOTE 2 Needle sizes below 0,25 mm, consideration can be made to the measurement uncertainty of existing measurement equipment.

NOTE 3 This International Standard does not specify maximum inner diameter.

NOTE 4 OD = outer diameter; ID = inner diameter.

Table 1 *(continued)*

Designated metric size mm	Gauge	OD_{MIN} mm	OD_{MAX} mm	Wall	ID_{MIN} mm
3,00	11	2,950	3,150	RW	2,200
				TW	2,464
3,40	10	3,300	3,500	RW	2,500
				TW	2,819

NOTE 1 RW = Regular Wall; TW = Thin Wall; ETW = Extra Thin Wall; UTW = Ultra Thin Wall.

NOTE 2 Needle sizes below 0,25 mm, consideration can be made to the measurement uncertainty of existing measurement equipment.

NOTE 3 This International Standard does not specify maximum inner diameter.

NOTE 4 OD = outer diameter; ID = inner diameter.

5.7 Sample size

Where sampling is applicable, the sample sizes shall be determined on the basis of risk assessment principles and be included in the tube specification and based on the intended use.

5.8 Stiffness

When tested in accordance with Annex B, the tubing shall show a deflection not greater than the relevant value given in Table 2.

For tubes where stiffness test parameters are not defined in this International Standard, the medical device manufacturer shall prepare specific stiffness requirements based on a risk assessment of the final intended use of the tube.

Consideration should be given to the final product intended use of the tube to determine if additional tests are required.

Table 2 — Conditions for stiffness test

	Regular-walled tubing			**Thin-walled tubing**			**Extra-thin walled tubing**			**Ultra-thin walled tubing**		
Designated metric size	Span mm ± 0,1	Bending force N ± 0,1	Maximum deflection mm	Span mm ± 0,1	Bending force N ± 0,1	Maximum deflection mm	Span mm ± 0,1	Bending force N ± 0,1	Maximum deflection mm	Span mm ± 0,1	Bending force N ± 0,1	Maximum deflection mm
0,18	[a]	[a]	[a]	[a]	[a]	[a]	[a]	[a]	[a]	[a]	[a]	[a]
0,2	5,0	0,6	0,25	5,0	0,6	0,27	[a]	[a]	[a]	[a]	[a]	[a]
0,23	5,0	0,9	0,20	5,0	0,9	0,20	5,0	0,9	0,22	5,0	0,9	0,25
0,25	5,0	1,1	0,17	5,0	1,1	0,18	5,0	1,1	0,21	5,0	1,1	0,24
0,3	5,0	1,3	0,11	5,0	1,3	0,11	5,0	1,3	0,16	5,0	1,3	0,20
0,33	5,0	1,6	0,09	5,0	1,6	0,12	5,0	1,6	0,17	5,0	1,6	0,19
0,36	5,0	3,6	0,14	5,0	3,6	0,14	[a]	[a]	[a]	[a]	[a]	[a]
0,4	9,5	2,7	0,52	7,5	3,4	0,34	[a]	[a]	[a]	[a]	[a]	[a]
0,45	10,0	3,1	0,45	10,0	3,1	0,51	[a]	[a]	[a]	[a]	[a]	[a]
0,5	10,0	5,1	0,37	10,0	5,1	0,40	[a]	[a]	[a]	[a]	[a]	[a]
0,55	10,0	6,4	0,34	10,0	6,4	0,36	[a]	[a]	[a]	[a]	[a]	[a]
0,6	12,5	4,8	0,33	12,5	4,8	0,43	12,5	4,8	0,51	[a]	[a]	[a]
0,7	15,0	6,7	0,42	15,0	6,7	0,52	15,0	6,7	0,60	[a]	[a]	[a]
0,8	15,0	9,6	0,38	15,0	9,6	0,45	15,0	9,6	0,51	[a]	[a]	[a]
0,9	17,5	9,0	0,48	17,5	9,0	0,56	17,5	9,0	0,60	[a]	[a]	[a]
1,1	25,0	9,7	0,71	25,0	9,7	0,97	25,0	9,7	1,08	[a]	[a]	[a]
1,2	25,0	12,2	0,51	25,0	12,2	0,81	[a]	[a]	[a]	[a]	[a]	[a]
1,4	25,0	16,6	0,46	25,0	16,6	0,68	25,0	16,6	0,82	[a]	[a]	[a]
1,6	25,0	22,0	0,25	25,0	22,0	0,30	25,0	22,0	0,34	[a]	[a]	[a]
1,8	25,0	25,0	0,35	25,0	25,0	0,45	[a]	[a]	[a]	[a]	[a]	[a]
2,1	30,0	40,0	0,40	30,0	40,0	0,50	[a]	[a]	[a]	[a]	[a]	[a]
2,4	40,0	40,0	0,38	40,0	40,0	0,65	[a]	[a]	[a]	[a]	[a]	[a]
2,7	40,0	50,0	0,31	40,0	50,0	0,45	[a]	[a]	[a]	[a]	[a]	[a]
3	50,0	50,0	0,41	50,0	50,0	0,55	[a]	[a]	[a]	[a]	[a]	[a]
3,4	50,0	60,0	0,32	50,0	60,0	0,46	[a]	[a]	[a]	[a]	[a]	[a]

[a] No data are available; therefore, this International Standard does not specify stiffness properties for these sizes of tubing.

5.9 Resistance to breakage

When tested in accordance with Annex C, the tubing shall not show visible breakage when examined by normal or corrected vision.

NOTE Consideration can be given to the final product's intended use to determine if additional tests are warranted.

5.10 Resistance to corrosion

When tested in accordance with Annex D, the immersed half of the tubing shall show no evidence of corrosion resulting from the test.

NOTE Consideration can be given to the final product's intended use to determine if additional tests are warranted, e.g. long term drug product contact.

Annex A
(normative)

Methods for preparation of extracts

A.1 Principle

The stainless steel tubing is immersed in water in order to extract soluble components.

A.2 Apparatus and reagents

A.2.1 Freshly distilled or deionized water, of grade 3 in accordance with ISO 3696.

A.2.2 Selection of laboratory borosilicate glassware.

A.3 Procedure

A.3.1 Immerse 3 g of tubing in 250 ml of water (A.2.1) in a suitable container made from borosilicate glass (A.2.2). Ensure that the surface of the stainless tubing, including the inside of the tubing, is in contact with the water.

Maintain the water at a temperature of $(37\ {}^{+3}_{0})$ °C for (60 ± 2) min. Remove the tubing and ensure that all water from the inside and outside surfaces of the tubing are returned to the container.

A.3.2 Prepare the control fluid by following the procedure given in A.3.1 but omitting the tubing.

Annex B
(normative)

Test method for stiffness of tubing

B.1 Principle

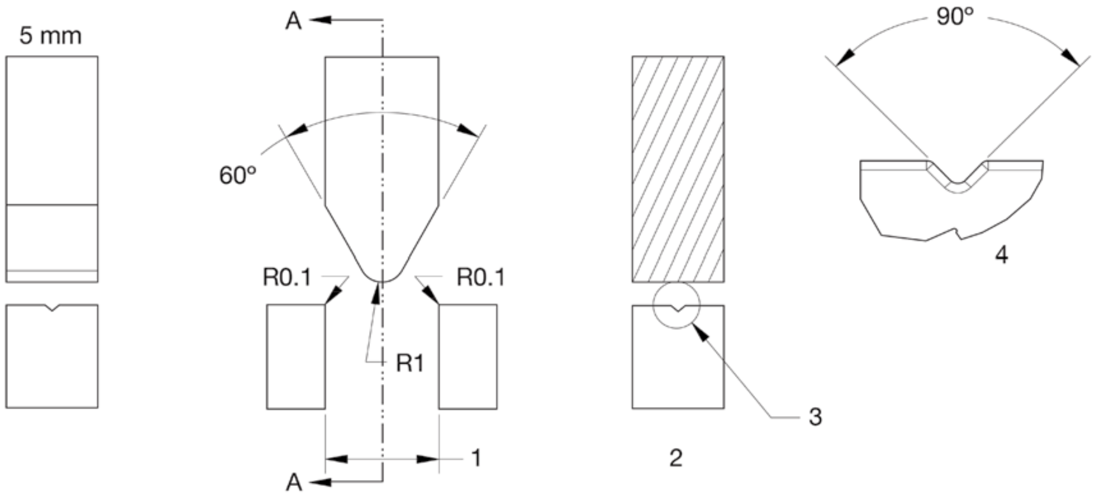
A specified force is applied to the centre of the specified length of tubing, which is supported at both ends, and the amount of deflection measured.

B.2 Apparatus

B.2.1 Stiffness testing apparatus, capable of applying a force of up to 60 N downwards normal to the tubing with an accuracy of ±0,1 N, by means of a plunger having a lower end in the form of a blunt wedge formed by two plane surfaces inclined at 60° to one another and a cylindrical surface of radius of 1 mm and length at least 5 mm.

An example of a suitable apparatus is illustrated in Figure B.1.

B.2.2 Equipment, capable of measuring the deflection of the tubing to the nearest 0,01 mm.



Key

1 span

2 section A-A

3 see detail 4

4 detail

Figure B.1 — Apparatus for stiffness test

B.3 Procedure

B.3.1 Place the tubing on the stiffness testing apparatus (B.2.1) and adjust the tubing and the stiffness testing apparatus so that

a) span is as given in Table 2 for the designated metric size of the tubing,

b) the bottom surface of the plunger is at the centre of the span, and

c) the tubing is normal to the supporting members and the loading plunger, and the centre of the tubing is at the centre of the span.

B.3.2 Apply a downward force given in Table 2 for the designated metric size of the tubing at a speed between 1 mm/min and 10 mm/min.

B.3.3 Measure and record (B.2.2) to the nearest 0,01 mm the deflection of the tubing at the point of application of the force.

B.4 Test report

The test report shall contain at least the following information:

a) the identity and designated metric size of the tubing;

b) whether the tubing was of RW, TW, ETW or UTW type;

c) the measured deflection, expressed in millimetres to the nearest 0,01 mm;

d) the date of testing;

e) the type of stainless steel alloy used, chosen according to Clause 4.

Annex C
(normative)

Test method for resistance of tubing to breakage

C.1 Principle

One end of the tubing is firmly fixed and a force applied to the tubing at a specified distance from the point of fixation, so as to bend the tubing through a specified angle, first in one direction and then in the opposite direction, for a specified number of cycles.

C.2 Apparatus

C.2.1 Support and device for fixing the tubing.

C.2.2 Equipment, capable of applying a force to the tubing sufficient to bend it through an angle of up to 25°.

C.3 Procedure

C.3.1 Rigidly fix one end of the tubing in the support (C.2.1).

C.3.2 Apply (C.2.2), at the distance given in Table C.1, a force of sufficient magnitude to cause the tubing to bend in one plane through an angle of (25 ± 1)° for regular-walled tubing, (20 ± 1)° for thin-walled tubing, or (15 ± 1)° for extra-thin-walled and ultra-thin walled tubing.

C.3.3 Apply the force in the reverse direction so as to cause the tubing to bend through the same angle in the reverse direction.

C.3.4 Perform 20 complete cycles of reversal of force at a rate of 0,5 Hz and examine the tubing visually for breakage.

C.4 Test report

The test report shall contain at least the following information:

a) the identity and designated metric size of the tubing;

b) whether the tubing was of regular-walled, thin-walled, extra-thin walled or ultra-thin walled type;

c) whether the tubing shows visible breakage during the test;

d) the date of testing;

e) the type of stainless steel alloy used, chosen according to Clause 4.

Table C.1 — Conditions for resistance to breakage test

Designated metric size	Distance between rigid support and point of application of bending force mm ±0,1
0,18	6
0,2	6
0,23	6
0,25	8
0,3	8
0,33	8
0,36	8
0,4	8
0,45	10
0,5	10
0,55	12,5
0,6	15
0,7	17,5
0,8	20
0,9	25
1,1	27,5
1,2	30
1,4	31,5
1,6	31,5
1,8	31,5
2,1	31,5
2,4	31,5
2,7	31,5
3	31,5
3,4	31,5

Annex D
(normative)

Test method for resistance to corrosion

D.1 Principle

The tubing is partially immersed in sodium chloride solution for a specified time and afterwards the immersed portion compared visually with the unimmersed portion for signs of corrosion.

D.2 Reagents and apparatus

D.2.1 Solution of sodium chloride, *c*(NaCl) = 0,5 mol/l (analytical grade reagent) in distilled or deionized water of grade 3 in accordance with ISO 3696.

D.2.2 Selection of laboratory borosilicate glassware.

D.3 Procedure

Place a piece of needle tubing in a glass vessel (D.2.2) containing sodium chloride solution (D.2.1) at (23 ± 2) °C, so that approximately half the length of the tubing is immersed. Maintain the liquid and tubing at (23 ± 2) °C, for 7 h ± 5 min. Remove the needle tubing, wipe it dry and compare the immersed and un-immersed portions under normal or corrected vision for signs of corrosion caused by the immersion.

D.4 Test report

The test report shall contain at least the following information:

a) the identity and designated metric size of the tubing;

b) whether the tubing was of regular-walled, thin-walled, extra-thin walled or ultra-thin-walled type;

c) whether corrosion occurred on the immersed half during the test;

d) the date of testing;

e) the type of stainless steel alloy used, chosen according to Clause 4.

Annex E
(informative)

Rationale with respect to test method for stiffness of tubing

E.1 General

This Annex provides rationale for the requirements of the stiffness test of Table 2. This summary is intended for those who are familiar with the stiffness test indicated in this International Standard but who have not participated in its revision. An understanding of the approach and reasoning supporting the prescribed load conditions and maximum deflection limits is considered to be essential for proper application of the standard. Furthermore, as clinical practice and technology change, a documented rationale for the stiffness test will facilitate any revision of this International Standard necessitated by those developments.

The stiffness test requirements have been selected to strike a balance between objectives; namely that the test should be strict enough to ensure tubing of poor quality does not comply yet provide a reasonable expectation of compliance for tubing of acceptable quality. It was also the Committee's aim to avoid unnecessary and unintended burden on manufacturers that might occur as a result of fundamental changes in test methodology or hardware.

Therefore, the three-point-bending test configuration and the span prescribed for each designated metric size remain unchanged. The changes to the content of Table 2 as compared with the prior revision of this International Standard have been limited to applied load at centre of the span and the respective acceptance criteria (maximum allowable deflection at the centre of the span).

Toward these stated objectives, the Committee took the following approach.

a) Analyse the current loading conditions to establish reasonable bending moments to be applied for each tube (gage and wall thickness designation). While it should be considered acceptable to cause some amount of permanent deformation (i.e. yielding) during the test, the applied bending moment should not be greater than the expected maximum attainable (i.e. plastic moment). The moment applied should be selected based on expected ranges of

   - yield strength (between 205 MPa and 760 MPa),
   - Young's Modulus (between 150 GPa and 200 GPa apparent value based on experiment), and
   - plastic section modulus, Z (for each tube but limited by maximum and assumed least material conditions or "MMC" and LMC").

b) Evaluate relationships between bending moment and deflection under limiting cases for assumed material behaviour

   - linear elastic (resulting in the lowest expected deflection), and
   - elastic-fully plastic (resulting in the greatest expected deflection).

c) Specify the maximum allowable deflection for each tube designation considering the following:

   - fully annealed, LMC combinations should likely not be considered acceptable (i.e. should fail the test);
   - expectations of stiffness based on the previous revision of this International Standard;
   - empirical data and deviations from ideal behaviour.

Table E.1 — Definition of terms[4][5][6]

Line	Term	Definition	Consistent units of measure for calculation
1	σ_y	Yield strength of the material	Pa
2	r_o, r_i	Outer radius and inner radius, respectively of the cross section	m
3	P	Applied load at the centre of the span	N
4	L	Width of span between supports	m
5	E	Young's modulus of the tube material	Pa
6	$I = \frac{\pi}{4}\left(r_o^4 - r_i^4\right)$	Area moment of inertia of the tube's cross section	m^4
7	$M = \frac{PL}{4}; M_y = \frac{P_y L}{4}; M_P = \frac{P_P L}{4}$	Bending moment at the centre of the span; Bending moment at the onset of yield; Fully plastic bending moment	Nm
8	$Z = \frac{M_P}{\sigma_y} = \frac{4}{3}\left(r_o^3 - r_i^3\right)$	Plastic section modulus for tubular cross section	m^3
9	$\delta = \frac{PL^3}{48EI} = \frac{PL^3}{12E\pi\left(r_o^4 - r_i^4\right)}$	Deflection at the beam centre (applicable within the linear elastic range of the material, i.e. prior to onset of yield)	m
10	$M_P = Z\sigma_y = \frac{4}{3}\left(r_o^3 - r_i^3\right)\sigma_y$	"Plastic moment" or value of the bending moment	Nm
11	$\sigma_{y,h}$	Yield strength of a strain hardened steel	Pa
12	$\sigma_{y,s}$	Yield strength of a fully annealed or soft steel	Pa

E.2 Determination of load

Implicit in the application of a three-point bend test with maximum allowable deflection is the expectation that the tubing sample should not collapse under the test conditions prescribed. Therefore, we begin with analysis of three-point bending of tubes of circular cross section to evaluate the material and geometric properties influencing bending strength and whether the load and span values specified in the previous edition of this International Standard are reasonable.

Subject to certain assumptions, the strength of a uniform cylindrical beam in three-point bending is determined by cross-sectional dimensions of the beam and the yield strength of its material. We may express the strength of a beam in terms of the maximum bending moment it may resist or "plastic moment", M_p. For a load applied at the centre of the span and assuming elastic-perfectly plastic material behaviour, the plastic moment may be calculated as given in Formula (E.1)[5]:

$$M_p = Z\sigma_y = \frac{4}{3}\left(r_o^3 - r_i^3\right)\sigma_y \tag{E.1}$$

The value of "Z" or plastic section modulus is therefore a property only of inner and outer radii expressed as Formula (E.2):

$$Z = \frac{4}{3}\left(r_o^3 - r_i^3\right) \tag{E.2}$$

The bending moment, M, applied to a beam in three-point bending may be expressed as a function of the span, L, and applied load, P, at the centre of the span as given in Formula (E.3):

$$M = \frac{PL}{4} \tag{E.3}$$

Using these relationships and an assumed range of yield strength, we may compare the bending moments prescribed for the stiffness test to the plastic moments expected to cause failure for each tube. To achieve this, plastic section modulus Z is first tabulated for each tube at least material condition, or LMC, and maximum material condition, or MMC.

While MMC is easily defined using the greatest allowable outer diameter and the smallest allowable inner diameter for a specified tube, definition of the LMC requires an additional assumption. We should assume that the maximum allowable inner diameter for a given tube corresponds with the minimum allowable inner diameter for a tube of the same gauge but next thinner wall thickness designation.

NOTE Note that this approach is not intended to enforce a maximum inner diameter, but rather to establish bounds for analysis.

Thus, for example, the LMC condition is not defined for a TW tube if ISO does not define an ETW tube of the same gauge. In such cases, an alternate method is offered to estimate inner diameter for calculation of LMC plastic section modulus.

For cases of undefined LMC, the maximum allowable inner diameter is calculated by assuming proportionate moments of inertia. In this manner, we may determine a maximum inner diameter in these special cases. The example shown in Formula (E.4) to Formula (E.7) below illustrates the procedure to calculate the maximum inner diameter of a thin wall (TW) tube on the basis of the moments of inertia for the NW tube of the same designated metric size (i.e. gauge). An analogous approach is employed as needed for tubes of adjacent wall thickness designations (e.g. TW and ETW; ETW and UTW; or UTW).

$$\left[\frac{I_{\text{LMC}}}{I_{\text{MMC}}}\right]_{\text{NW}} = \left[\frac{I_{\text{LMC}}}{I_{\text{MMC}}}\right]_{\text{TW}} \tag{E.4}$$

$$\left[I_{\text{LMC}}\right]_{\text{TW}} = \left[\frac{I_{\text{LMC}}}{I_{\text{MMC}}}\right]_{\text{NW}} \left[I_{\text{MMC}}\right]_{\text{TW}} \tag{E.5}$$

$$\frac{\pi}{64}\left(D_{o,\text{MIN,TW}}^4 - D_{i,\text{MAX,TW}}^4\right) = \left[I_{\text{LMC}}\right]_{\text{TW}} = \left[\frac{I_{\text{LMC}}}{I_{\text{MMC}}}\right]_{\text{NW}} \left[I_{\text{MMC}}\right]_{\text{TW}} \tag{E.6}$$

$$D_{i,\text{MAX,TW}} = \left\{D_{o,\text{MIN,TW}}^4 - \frac{64}{\pi}\left[\frac{I_{\text{LMC}}}{I_{\text{MMC}}}\right]_{\text{NW}} \left[I_{\text{MMC}}\right]_{\text{TW}}\right\}^{1/4} \tag{E.7}$$

The steel's yield strength influences both the point at which the relationship between load and deflection deviates from linear, as well as the maximum load the beam is expected to bear. Therefore, we should consider a range of yield strength over which to evaluate the relationship between load and deflection in three-point bending. We estimate the yield strength of a 304 stainless steel[4] between 205 MPa (fully annealed) and 760 MPa (half hard).

On the basis of the foregoing, we may estimate bending moment expected to induce failure, M_p, as a function of tubing dimensions and yield strength. Upper and lower bounds of M_p were obtained by evaluating M_p at the upper and lower bounds of material yield strength using Formula (E.8) and Formula (E.9):

$$M_{\text{p,Hard}} = Z\sigma_{y,\text{Hard}} = Z \times 760\,\text{MPa} \tag{E.8}$$

$$M_{\text{p,Soft}} = Z\sigma_{y,\text{Soft}} = Z \times 205\,\text{MPa} \tag{E.9}$$

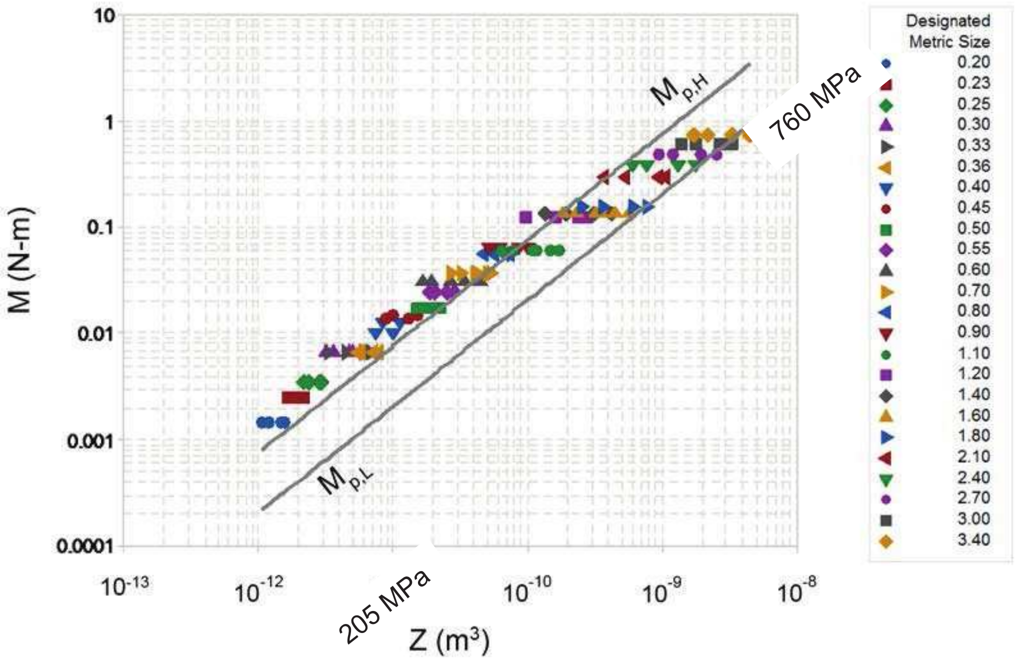
By plotting the tabulated values (as per the previous edition of this International Standard) of bending moment M and plastic section modulus Z for both LMC and MMC conditions along with the relationships of Formula (E.8) and Formula (E.9), we have

M is the bending moment, in N-m;

Z is the plastic section modulus, in m^3;

$M_{p,H}$ is the plastic bending moment for yield strength of 760 MPa;

$M_{p,L}$ is the plastic bending moment for yield strength of 205 MPa.



Key

M bending moment, in N-m

Z plastic section modulus, in m^3

$M_{p,H}$ plastic bending moment for yield strength of 760 MPa

$M_{p,L}$ plastic bending moment for yield strength of 205 MPa

Figure E.1 — ISO and fully plastic moment, M_p, versus plastic section modulus

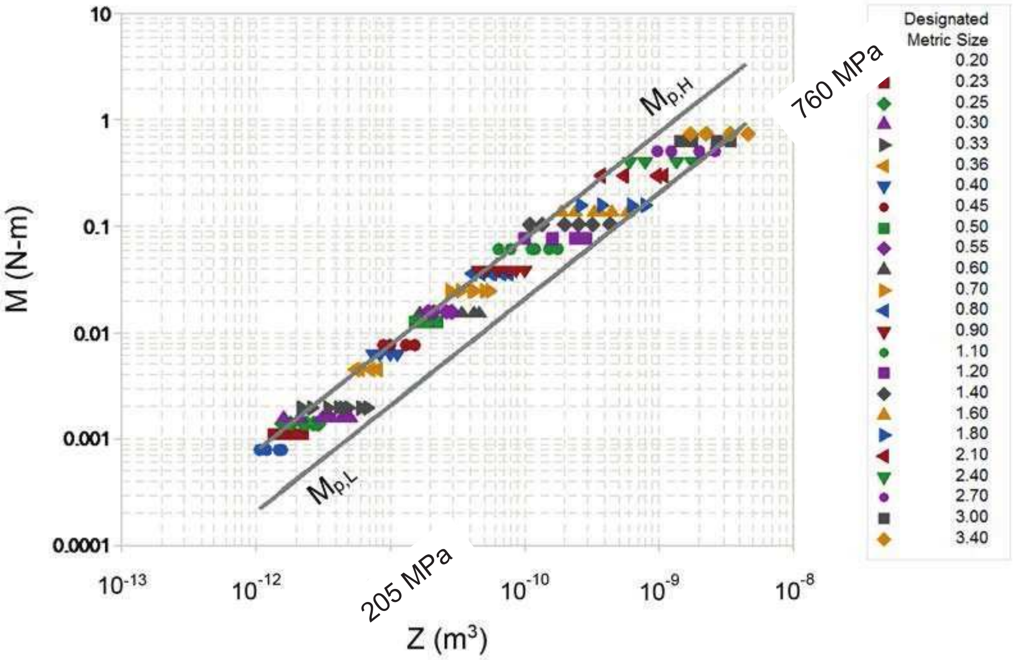
We see by inspection of Figure E.1 that many of the prescribed bending moments lie well above the predicted plastic moments even for material of 760 MPa yield strength in MMC; this International Standard is likely too stringent in many cases.

A reduction in prescribed bending moment for tubes between 1,4 mm and 0,20 mm designated metric size has been implemented. By "shifting" (i.e. prescribing a lower value) bending moment to become equal to the plastic moment corresponding to the lowest defined plastic section modulus of each gauge to the 760 MPa curve and specifying the same bending moment for each tube within the gauge, we have determined the proposed bending moments.

NOTE 1 Lowest defined section modulus is calculated using the smallest outer diameter for the designated metric size and the minimum inner diameter of the next thinner wall designation of the same designated metric size.

NOTE 2 Plastic section modulus is calculated on the basis of the newly defined dimensions for this revision of the International Standard; tubes that have changed since the 2001 version are ETW and UTW for 0,33 mm to 0,23 mm metric sizes; ETW for 0,2 mm metric size; and all 0,18 mm metric sizes.

This "shift" was only done for tubes where the plastic moment, M_p, for the lowest defined plastic section modulus is above the 760 MPa line. Then by substitution into Formula (E.3) and since span L has been maintained, the load P to be applied to each tube for stiffness testing was calculated.



Key

M	bending moment, in N-m
Z	plastic section modulus, in m^3
$M_{p,H}$	plastic bending moment for yield strength of 760 MPa
$M_{p,L}$	plastic bending moment for yield strength of 205 MPa

Figure E.2 — New bending moments for use in this International Standard and M_p versus plastic section modulus

E.3 Definition of acceptable design space and determination of allowable deflection

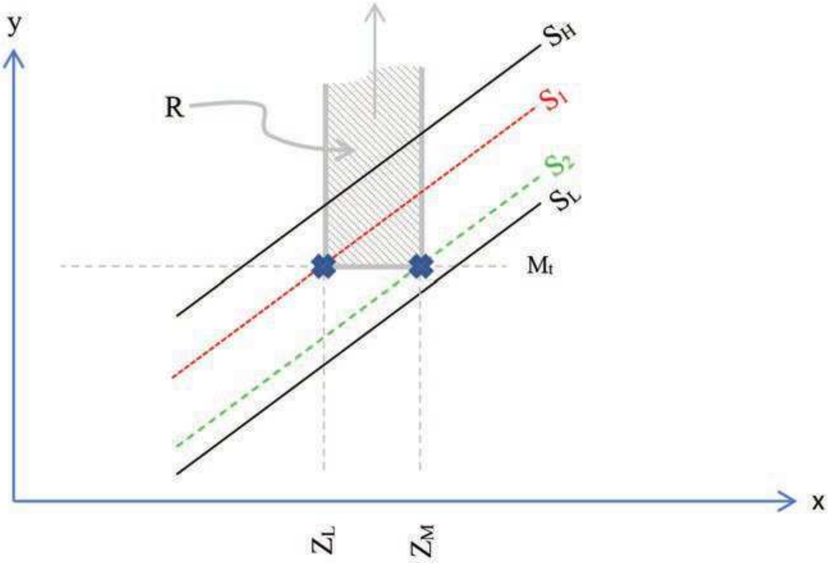
While beam theory provides a well proven relationship between load and deflection for a simply supported beam within the linear elastic region, this relationship does not hold beyond the onset of yield.

The relationship between applied load and resultant deflection for the three-point bending configuration while the beam material is **within the linear elastic range** is given as Formula (E.10)[5]:

$$\delta = \frac{PL^3}{48EI} \tag{E.10}$$

Due to a number of complexities, a closed form expression for the relationship between load and deflection after the onset of yield may not be determined. Numerical simulation has therefore been applied. Input values for each simulation were selected to evaluate the maximum deflection predicted for extreme cases of material properties and tube geometry.

E.1 determined the span and load to be applied for each tube size. The "worst case" combinations of yield strength and material condition (LMC or MMC) were evaluated for each tube. Yield strength was selected such that the prescribed bending moment was equal to the plastic moment for each load case simulated. Consider Figure E.3, which shows a schematic of bending moment versus plastic section modulus on a log-log scale.



Key

x	logarithm (base 10) of Z, the plastic section modulus
y	logarithm (base 10) of bending moment at failure based on yield strength and Z value
R	acceptable design space region
S_h	yield strength = 760 MPa
S_1	minimum yield strength required for a tube in least material condition or $\sigma_{y,\text{min,LMC}}$
S_2	minimum yield strength required for a tube in maximum material condition or $\sigma_{y,\text{min,MMC}}$
S_L	yield strength = 205 MPa
M_t	bending moment prescribed for this tube
Z_L	plastic section modulus of tube in least material condition
Z_M	plastic section modulus of tube in maximum material condition

Figure E.3 — Schematic of acceptable design space and selection of load cases to be simulated

To calculate the lowest allowable yield strength for a tube in LMC or MMC, Formula (E.1) is rearranged to obtain Formula (E.11) and Formula (E.12):

$$\sigma_{y,\mathrm{min,LMC}} = \frac{M_{\mathrm{test}}}{\frac{4}{3}\left(r_{o,\mathrm{min}}^3 - r_{i,\mathrm{max}}^3\right)} \tag{E.11}$$

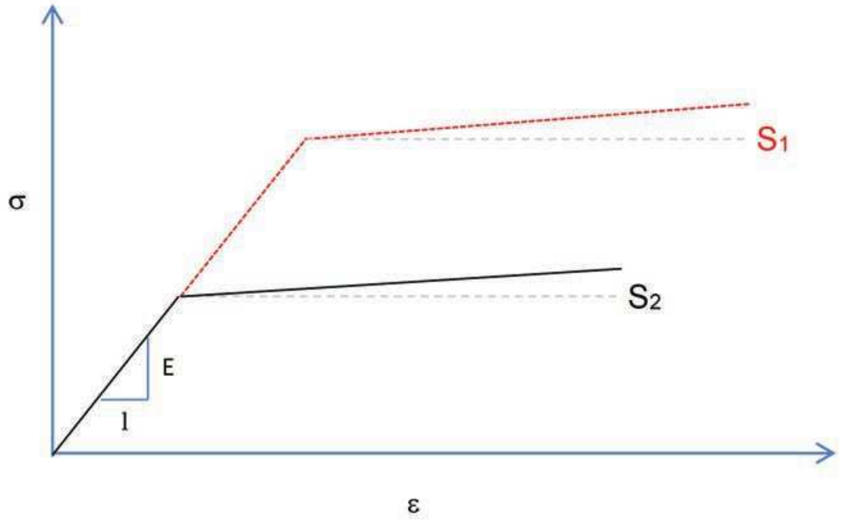
$$\sigma_{y,\mathrm{min,MMC}} = \frac{M_{\mathrm{test}}}{\frac{4}{3}\left(r_{o,\mathrm{max}}^3 - r_{i,\mathrm{min}}^3\right)} \tag{E.12}$$

Therefore, load, span, dimensions (inner and outer radius), yield strength, and elastic modulus were tabulated for each tube and two simulations per tube were conducted – one at LMC with $\sigma_{y,\mathrm{min,LMC}}$ and one at MMC with $\sigma_{y,\mathrm{min,MMC}}$ as calculated from Formula (E.11) and Formula (E.12), respectively.

The "worst case" or greatest deflections occurred for tubes of LMC with $\sigma_{y,\mathrm{min,LMC}}$; these values were selected as maximum allowable deflections for this International Standard.

E.4 Methods and results

The finite element (FE) method was used to simulate three-point bending and to estimate the deflection under the conditions for various tubes as described in E.3. A model of one quarter symmetry was used to reduce solution time. Material behaviour of the model is assumed to be nearly elastic-perfectly plastic as shown in Figure E.4.



Key

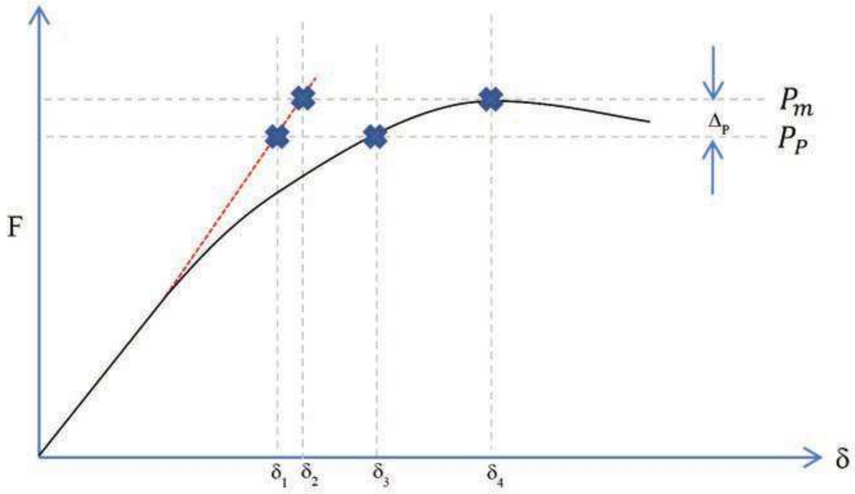
σ	engineering stress
S_1	minimum yield strength required for a tube in least material condition
S_2	minimum yield strength required for a tube in maximum material condition
ε	engineering strain
E	slope of linear portion = E (Young's Modulus) = 150 GPa

Figure E.4 — Assumed material behaviour for simulations

For this analysis, a moderate, positive slope of the stress versus true strain curve beyond the yield point has been implemented; this is required in some cases to avoid solution/numerical instability.

A low estimate for Young's Modulus of 150 GPa was used in FE models based on a range of apparent values from experiment using known span, force, and cross-section dimensions within the linear portion of force-deflection curves. This selection and the assumption of elastic-perfectly plastic material behaviour provide a factor of safety for allowable deflection.

As many of the finite element models predict a slightly higher peak force than predicted by closed form solution, the maximum allowable deflection is determined in a manner shown schematically in Figure E.5.The maximum force predicted by the FE model is defined as $P_{\mathrm{max,sim}}$ while proposed force to be applied is defined as P_P.



Key

F	force
δ	deflection
δ_1, δ_2	deflections of a linear elastic tube subjected to loads P_p and P_m, respectively
δ_3, δ_4	deflections predicted by simulation of an elastic-plastic tube subjected to loads P_p and P_m, respectively
P_p	load to be applied to a particular tube for the stiffness test
P_m	maximum load the simulation predicts the tube will bear = $P_{\mathrm{max,sim}}$
Δ_p	difference between applied load and simulation predicted maximum load

Figure E.5 — Schematic of possible outcomes of simulation

P_p has been calculated as the load required to cause the beam to become a plastic hinge. This may be shown using Formula (E.6) and the relationship between load at centre span and bending moment as given in Formula (E.13):

$$P_\mathrm{p} = \frac{4M_P}{L} = \frac{4Z\sigma_y}{L} = \frac{16}{3L}\left(r_o^3 - r_i^3\right)\sigma_y \qquad \text{(E.13)}$$

The proposed acceptance criteria of maximum allowable deflection is δ_c as shown schematically in Figure E.5 and determined by finite element model under the LMC and corresponding yield strength [as per Formula (E.11)] for each tube.

One hundred and eight (108) test cases were simulated using FE models. Key findings include:

FE models generally predict a higher maximum load than Pp, but agreement between theoretical and FE predicted maximum load is generally acceptable [model results show between 1,8 % to 8,9 % higher maximum force than predicted by Formula (E.13)]. This is likely due to the small amount of strain hardening implemented in the material model of the FE solution.

Models for very thin tubes and/or wall thickness exhibit failure modes not predicted/allowed by beam theory (i.e. local buckling of the critical cross section); as a result, some of the design space may not be allowable and specification limits for certain tubes are not included.

Two simulations were conducted for most tubes. Each case uses the previously proposed force and span. The two cases differ by tube dimensions and yield strength as defined in Figure E.3, Formula (E.11) and Formula (E.12). In all cases, the maximum deflection occurs for LMC and corresponding $\sigma_{y,\mathrm{min,LMC}}$.

Some special cases are noted.

Stiffness test parameters will not be defined at this time for any 0,18mm (34G) tubes.

Stiffness test parameters will not be defined at this time for 2,1 mm (14G) ETW, 1,8 mm (15G) ETW and 1,2 mm (18G) ETW tubes.

The table of stiffness testing parameters of this International Standard is based on the FE modelling results; the table is not recounted here but is included in this International Standard.

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