

# DRAFT AMENDMENT

## ISO 80369-3:2016/DAM 2

ISO/TC 210

Secretariat: ANSI

Voting begins on:  
2017-03-07

Voting terminates on:  
2017-05-29

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### Small-bore connectors for liquids and gases in healthcare applications —

#### Part 3: Connectors for enteral applications

#### AMENDMENT 2: .

*Raccords de petite taille pour liquides et gaz utilisés dans le domaine de la santé —*

*Partie 3: Raccords destinés à des applications entérales*

*AMENDEMENT 2: .*

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ICS: 11.040.25

[ISO 80369-3:2016/DAMd 2](#)

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Member bodies are requested to consult relevant national interests in IEC/SC 62D before casting their ballot to the e-Balloting application.

This document is circulated as received from the committee secretariat.

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Reference number  
ISO 80369-3:2016/DAM 2:2017(E)

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The committee responsible for this document is ISO/TC 210, *Quality management and corresponding general aspects for medical devices*, and IEC/SC 62D, *Electromedical equipment*. The draft was circulated for voting to the national bodies of both ISO and IEC.

ISO 80369 consists of the following parts, under the general title *Small-bore connectors for liquids and gases in healthcare applications*:

- *Part 1: General requirements*
- *Part 2: Connectors for breathing systems and driving gases applications*
- *Part 3: Connectors for enteral applications*
- *Part 5: Connectors for limb cuff inflation applications*
- *Part 6: Connectors for neuraxial applications*
- *Part 7: Connectors with 6 % (Luer) taper for intravascular or hypodermic applications*
- *Part 20: Common test methods*

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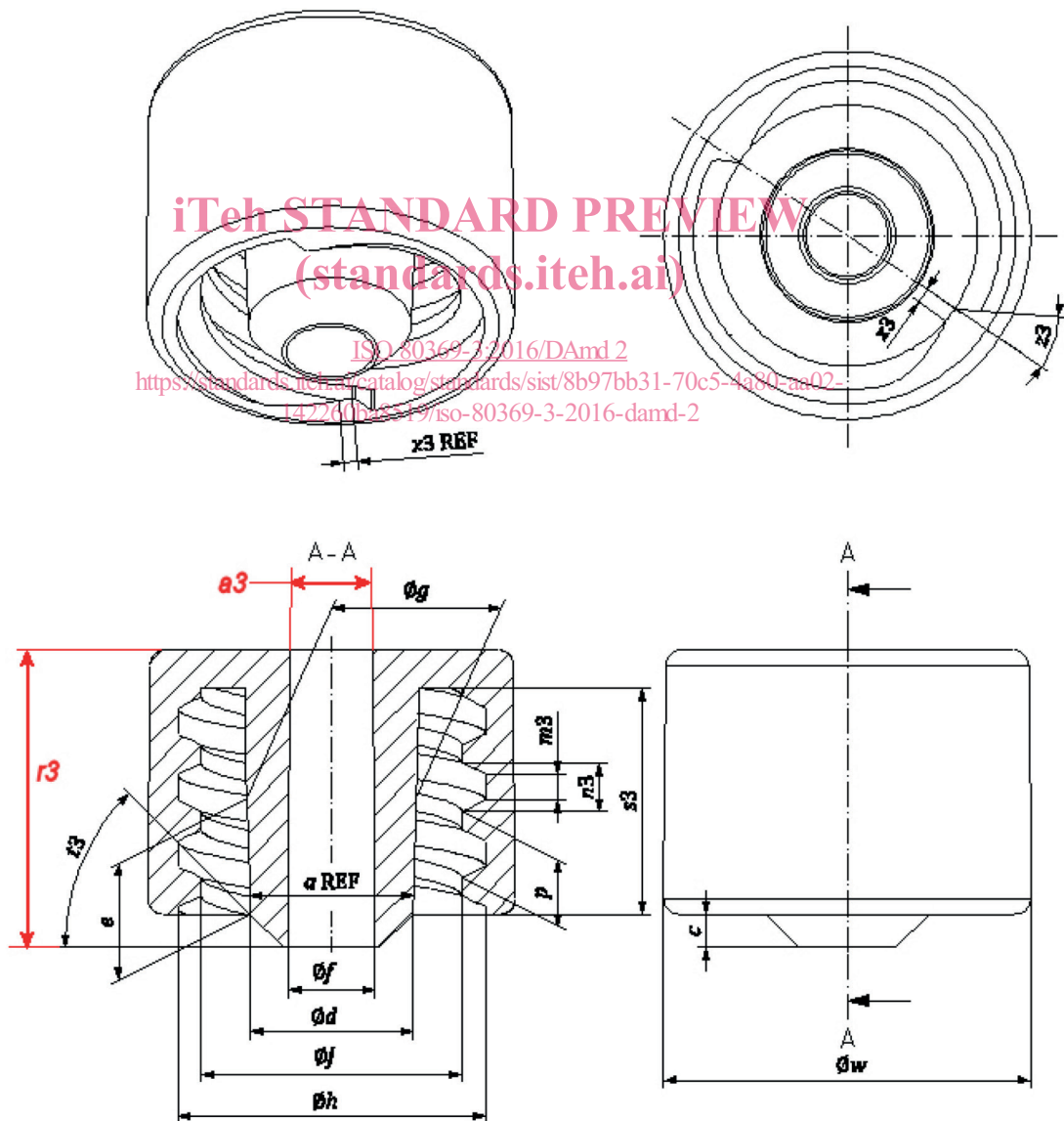
# Small-bore connectors for liquids and gases in healthcare applications —

## Part 3: Connectors for enteral applications

### AMENDMENT 2: .

#### 1 Modification to [Figure B.1](#)

Revise [Figure B.1](#) to add new dimension a3 and r3.



NOTE [Table B.1](#) contains the dimensions for [Figure B.1](#).

Figure B.1 — Male E1 SMALL-BORE CONNECTOR

In [Figure B.1](#), the male ENTERAL SMALL-BORE CONNECTOR may utilize a rotatable collar. The requirements for dimension *c* shall be maintained.

**2 Modification to [Table B.1](#)**

Revise [Table B.1](#) as follows:

Add second  $\emptyset f$  designation with minimum dimension of 2,85 mm

Add 2 new designations with dimensions

- 1) *a3* - Internal lumen draft angle (starting at  $\emptyset f$ ) maximum of 2°
- 2) *r3* - Internal lumen depth (starting at  $\emptyset f$ ) minimum of 8,00 mm

Add note g applicable to designations  $\emptyset f$ , *a3* & *r3* “The tightened specifications shown may be required in order to interface with finished devices. These dimensions are within the tolerances of the non-tightened dimensions specified.”

Add note h applicable to designations *a3* & *r3* “Should the tightened specification for dimension  $\emptyset f$  not be followed, requirements for dimension *a3* and *r3* may be ignored.”

**Table B.1 — Male E1 SMALL-BORE CONNECTOR dimensions**

Dimensions in mm unless otherwise indicated

Male E1 SMALL-BORE CONNECTOR				
Reference	Designation	Dimension		
		Minimum	Nominal	Maximum
( <i>a</i> )	Angle of taper (6% taper nominal) (degrees, reference)	—	(3,44°)	—
* <i>c</i>	Projection of the tip of the connector from thread collar	1,00	1,10	1,20
$\emptyset d$	Outside diameter at the tip of the male taper	5,36	5,41	5,46
* <i>e</i>	Length of male taper ( $\emptyset d$ to $\emptyset g$ )	3,72	3,82	3,92
$\emptyset f$	Inside diameter at the tip of the male taper	0,00	2,90	2,95
$\emptyset f$ g	Inside diameter at the tip of the male taper	2,85	2,90	2,95
* $\emptyset g$	Outside diameter of the larger end of the male taper at <i>e</i> from the tip (small end) of the male taper <sup>a</sup>	5,59	5,64	5,69

<sup>a</sup> Region of male taper between dimensions *e* and *s3* defined by  $\emptyset g$  may have draft in the direction of pull no greater than 1,0 degree inclusive (0,5 °/side).

<sup>b</sup> This dimension is required to provide clearance for the inside diameter at the open end of the female taper ( $\emptyset D$ ) and face of female CONNECTOR. Maximum thread profile length is not specified but shall provide clearance for the thread of the male CONNECTOR. The geometry defined by  $\emptyset d$  is flush to the face of the collar.

<sup>c</sup> This dimension is only required where the male CONNECTOR is a source of fluid flow.

<sup>d</sup> The minimum value of *w* shall be maintained for the length of 1,00 mm and the maximum value shall be maintained for the length of *e*. This dimension may be achieved by either the CONNECTOR or the MEDICAL DEVICE which incorporates this CONNECTOR. Alternatively, NON-INTERCONNECTABLE characteristics may be demonstrated using ISO 80369-1:2010, Annex B.

<sup>e</sup> This dimension is only required where the male CONNECTOR is not a source of fluid flow.

<sup>f</sup> Other geometries that begin and end at the limits of this specified angle line may be used.

<sup>g</sup> The tightened specifications shown may be required in order to interface with finished devices. These dimensions are within the tolerances of the non-tightened dimensions specified.

<sup>h</sup> Should the tightened specification for dimension  $\emptyset f$  not be followed, requirements for dimension *a3* and *r3* may be ignored.

Table B.1 (continued)

Male E1 SMALL-BORE CONNECTOR				
Reference	Designation	Dimension		
		Minimum	Nominal	Maximum
$\varnothing h$	Major inside thread diameter (diameter at thread root)	10,13	10,23	10,33
$\varnothing j$	Minor inside thread diameter (diameter at thread crest)	8,55	8,65	8,75
$(L)$	Length of engagement (reference) (see Figure B.3)	(3,00)	(4,67)	(6,33)
$m3$	Width of the thread groove at the root (symmetrical with $n3$ )	1,05	1,15	1,25
$n3$	Width of the thread groove at the crest (symmetrical with $m3$ )	1,80	1,90	2,00
$p$	Pitch of double-start, right-hand thread (reference 5 mm lead)	2,45	2,50	2,55
* $s3$	Length of nozzle from end of collar <sup>b</sup>	6,82	—	—
$t3$	Angle of projection of nozzle from end of collar (degrees)	40°	45°	50°
* $\varnothing w^c$	Diameter of the smallest cylinder that encompasses the outside surfaces of external features of the collar <sup>d</sup>	13,30	—	—
* $\varnothing w^e$	Diameter of the smallest cylinder that encompasses the outside surfaces of external features of the collar <sup>d</sup>	12,00	12,20	—
* $x3$	Chord length of thread minor diameter ( $\varnothing j$ ) at thread start	0,25	0,50	1,50
* $z3$	Face angle at thread start <sup>f</sup> (degrees)	—	—	40°
$a3^g$ <sup>h</sup>	Internal lumen draft angle (starting at $\varnothing f$ )	—	—	2°
$r3^g$ <sup>h</sup>	Internal lumen depth (starting at $\varnothing f$ )	8,00	—	—

<sup>a</sup> Region of male taper between dimensions  $e$  and  $s3$  defined by  $\varnothing g$  may have draft in the direction of pull no greater than 1,0 degree inclusive (0,5 °/side).

<sup>b</sup> This dimension is required to provide clearance for the inside diameter at the open end of the female taper ( $\varnothing D$ ) and face of female CONNECTOR. Maximum thread profile length is not specified but shall provide clearance for the thread of the male CONNECTOR. The geometry defined by  $\varnothing d$  is flush to the face of the collar.

<sup>c</sup> This dimension is only required where the male CONNECTOR is a source of fluid flow.

<sup>d</sup> The minimum value of  $w$  shall be maintained for the length of 1,00 mm and the maximum value shall be maintained for the length of  $e$ . This dimension may be achieved by either the CONNECTOR or the MEDICAL DEVICE which incorporates this CONNECTOR. Alternatively, NON-INTERCONNECTABLE characteristics may be demonstrated using ISO 80369-1:2010, Annex B.

<sup>e</sup> This dimension is only required where the male CONNECTOR is not a source of fluid flow.

<sup>f</sup> Other geometries that begin and end at the limits of this specified angle line may be used.

<sup>g</sup> The tightened specifications shown may be required in order to interface with finished devices. These dimensions are within the tolerances of the non-tightened dimensions specified.

<sup>h</sup> Should the tightened specification for dimension  $\varnothing f$  not be followed, requirements for dimension  $a3$  and  $r3$  may be ignored.

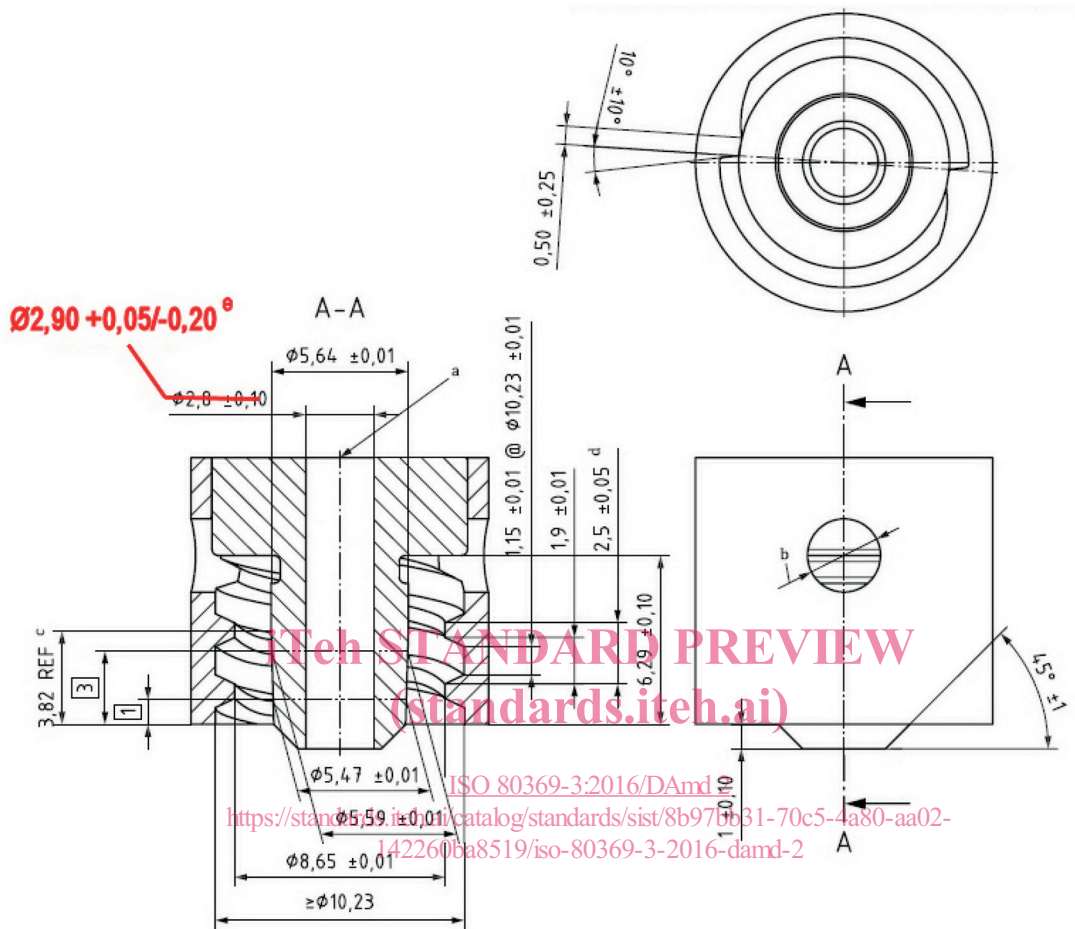
**3 Modification to Figure C.3**

Revise Figure C.3 as follows:

Change through bore dimension from  $\varnothing 2,8$  to  $\varnothing 2,90$  mm

Change through bore tolerance from  $\pm 0,10$  to  $+0,05$  mm/ $-0,20$ mm

Add note e associated with revised bore dimension “Some devices may require a minimum of 2,85 to allow a proper connection for testing”



**Key**

- a Fitting for leakage test required
- b Optional hole
- c Taper length
- d 5,0 thread lead
- e Some devices may require a minimum of 2,85 to allow a proper connection for testing

**Figure C.3 — Male reference CONNECTOR for testing female ENTERAL CONNECTOR for leakage, disconnection by unscrewing, separation from unscrewing, stress cracking, and NON - INTERCONNECTABLE characteristics**

**4 Modification to [Figure C.4](#)**

Revise [Figure C.4](#) as follows:

Change through bore dimension from  $\phi 2,8$  to  $\phi 2,90$  mm

Change through bore tolerance from  $\pm 0,10$  to  $+0,05$  mm/ $-0,20$ mm

Add note d associated with revised bore dimension “Some devices may require a minimum of 2,85 to allow a proper connection for testing”