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AMENDMENT 1
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**Small-bore connectors for liquids and
gases in healthcare applications —**

**Part 3:
Connectors for enteral applications**

AMENDMENT 1

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

Partie 3: Raccords destinés à des applications entérales

AMENDEMENT 1



Reference number
ISO 80369-3:2016/Amd.1:2019(E)

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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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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.

A list of all the parts in the ISO 80369 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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

Part 3: Connectors for enteral applications

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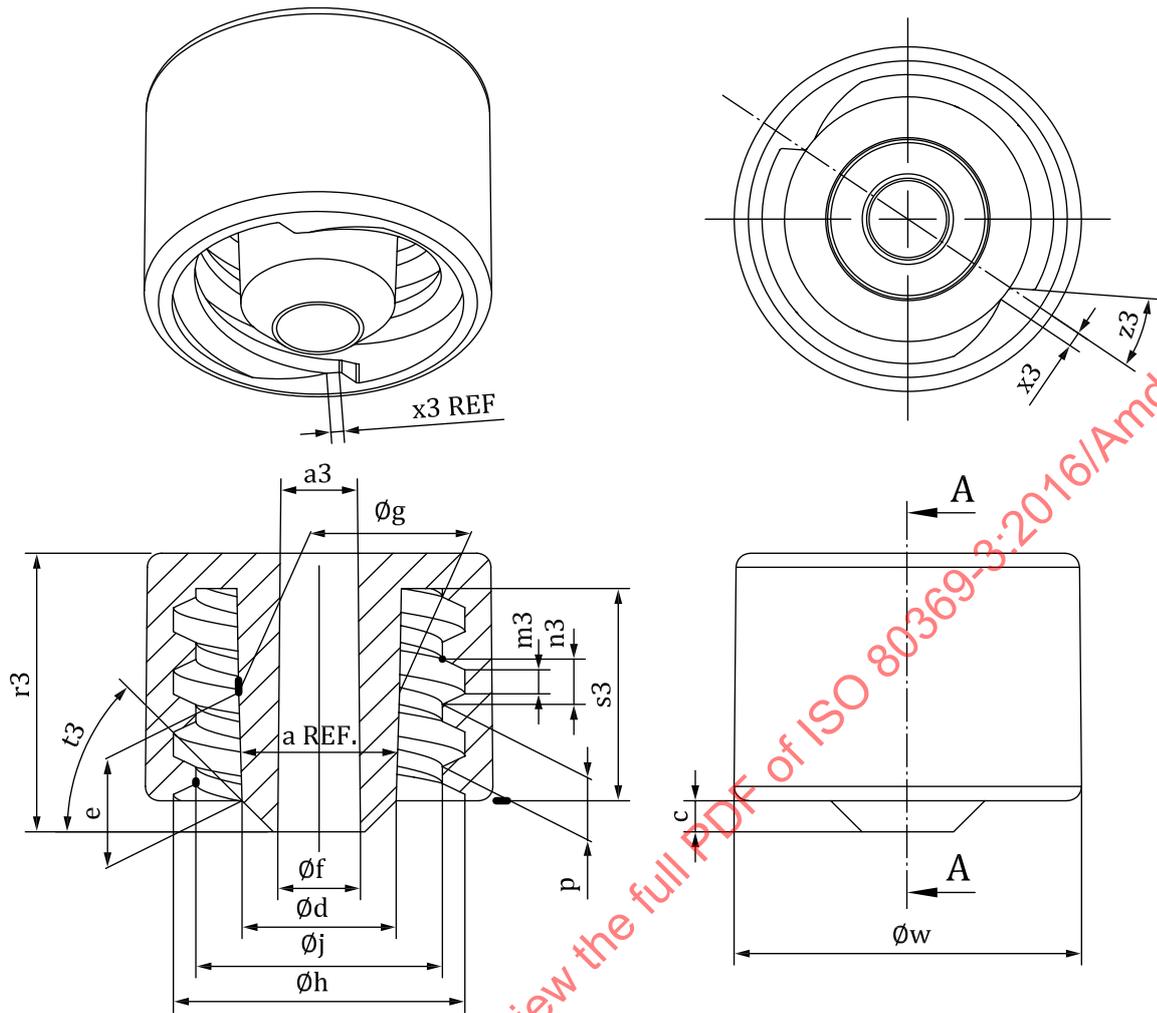
Scope

Remove the following text from the bulleted list under “This part of ISO 80369 does not specify requirements for SMALL-BORE CONNECTORS that are used for the following:”

“MEDICAL DEVICES for rectal drainage, rectal administration of medicines or fluid, and any other rectal access MEDICAL DEVICE”

Figure B.1

Revise Figure B.1 to add new dimension a_3 and r_3 and add a new NOTE 2.



NOTE 1 Table B.1 contains the dimensions for Figure B.1.

NOTE 2 Dimensions a_3 and r_3 start at \varnothing_f .

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.

Table B.1

Revise Table B.1 as follows:

Add superscript "g" to \varnothing_f .

Add a footnote "g" applicable to designations \varnothing_f , a_3 and r_3 , "A minimum diameter of 2,85 for \varnothing_f , a maximum angle of 2° for a_3 and a minimum depth of 8,00 for r_3 may be required in order to interface with certain finished devices".

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

Dimensions in millimetres unless otherwise indicated

Male E1 SMALL-BORE CONNECTOR				
Reference	Designation	Dimension		
		Minimum	Nominal	Maximum
(a)	Angle of taper (6 % taper nominal) (degrees, reference)	—	(3,44°)	—
*c	Projection of the tip of the connector from thread collar	1,00	1,10	1,20
$\varnothing d$	Outside diameter at the tip of the male taper	5,36	5,41	5,46
*e ^a	Length of male taper ($\varnothing d$ to $\varnothing g$)	3,72	3,82	3,92
$\varnothing f_g$	Inside diameter at the tip of the male taper.	0,00	2,90	2,95
* $\varnothing g$	Outside diameter of the larger end of the male taper at <i>e</i> from the tip (small end) of the male taper ^{ab}	5,59	5,64	5,69
$\varnothing h$	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)
<i>m</i> 3	Width of the thread groove at the root (symmetrical with <i>n</i> 3)	1,05	1,15	1,25
<i>n</i> 3	Width of the thread groove at the crest (symmetrical with <i>m</i> 3)	1,80	1,90	2,00
<i>p</i>	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 ^b	6,82	—	—
<i>t</i> 3	Angle of projection of nozzle from end of collar (degrees)	40°	45°	50°
* \varnothing_{wc}	Diameter of the smallest cylinder that encompasses the outside surfaces of external features of the collar ^d	13,30	—	—
* \varnothing_{we}	Diameter of the smallest cylinder that encompasses the outside surfaces of external features of the collar ^d	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 ^f (degrees)	—	—	40°

Table B.1 (continued)

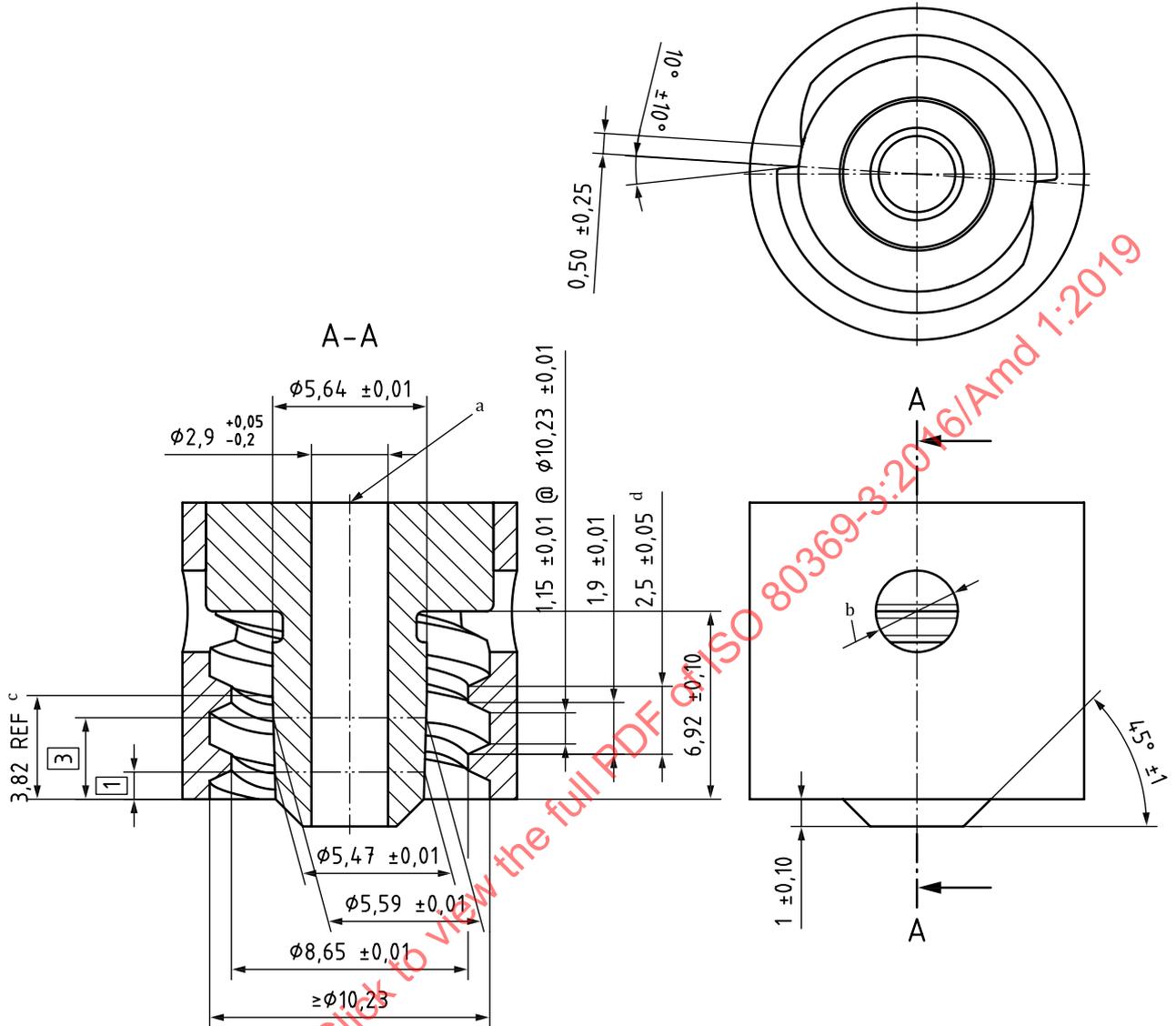
Male E1 SMALL-BORE CONNECTOR				
Reference	Designation	Dimension		
		Minimum	Nominal	Maximum
<i>a3g</i>	Internal lumen draft angle (starting at $\emptyset f$)	—	—	—
<i>r3g</i>	Internal lumen depth (starting at $\emptyset f$)	—	—	—
<p>a Region of male taper between dimensions <i>e</i> and <i>s3</i> defined by $\emptyset g$ may have draft in the direction of pull no greater than 1,0 degree inclusive (0,5°/side).</p> <p>b 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.</p> <p>c This dimension is only required where the male CONNECTOR is a source of fluid flow.</p> <p>d The minimum value of <i>w</i> shall be maintained for the length of 1,00 mm and the maximum value shall be maintained for the length of <i>e</i>. 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.</p> <p>e This dimension is only required where the male CONNECTOR is not a source of fluid flow.</p> <p>f Other geometries that begin and end at the limits of this specified angle line may be used.</p> <p>g A minimum diameter of 2,85 for $\emptyset f$, a maximum angle of 2° for <i>a3</i> and a minimum depth of 8,00 for <i>r3</i> may be required in order to interface with certain finished devices.</p>				

Figure C.3

Revise Figure C.3 as follows:

Change through bore dimension from $\emptyset 2,8$ to $\emptyset 2,9$ mm.

Change through bore tolerance from $\pm 0,10$ to $+0,05$ mm/ $-0,2$ mm.



- a Fitting for leakage test required.
- b Optional hole.
- c Taper length.
- d 5,0 thread lead.

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

Figure C.4

Revise Figure C.4 as follows:

Change through bore dimension from $\varnothing 2,8$ to $\varnothing 2,9$ mm.

Change through bore tolerance from $\pm 0,10$ to $+0,05$ mm/ $-0,2$ mm.