

INTERNATIONAL  
STANDARD

ISO  
20695

First edition  
2020-03

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## Enteral feeding systems — Design and testing

*Cathéters de nutrition entérale — Conception et essais*



Reference number  
ISO 20695:2020(E)

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Published in Switzerland

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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](http://www.iso.org/directives)).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see [www.iso.org/patents](http://www.iso.org/patents)).

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

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see [www.iso.org/iso/foreword.html](http://www.iso.org/iso/foreword.html).

This document was prepared by the European Committee for Standardization (CEN) Technical Committee CEN/TC 205, *Non-active medical devices*, in collaboration with ISO Technical Committee TC 84, *Devices for administration of medicinal products and catheters*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

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](http://www.iso.org/members.html).

## Introduction

Enteral feeding systems are intended to facilitate the delivery of enteral nutrition, medications and hydration to, or aspiration of gastric content from, humans. They are designed to pass enteral fluids or substances through the nose or mouth, or by gastrostomy, jejunostomy or oesophagostomy. Enteral feeding catheters are terminally placed in the stomach, duodenum, or jejunum.

The requirements and test methods of this document are specified so that, when used in current clinical practice, these medical devices do not compromise the clinical condition or the safety of patients.

Incidents have been reported of enteral fluids or substances being administered via incorrect routes, including intravenously and into the airway. An international effort has been made to reduce these incidents and two series of International Standards have been developed to provide application specific connectors:

- ISO 80369-3 specifies connectors intended for use between an enteral giving set, enteral extension sets, enteral syringes, enteral catheters, and enteral accessories;
- ISO 18250-3 specifies connectors intended for use between an enteral giving set, an enteral accessory and an enteral reservoir.

The use of these enteral-specific connectors has been specified in this document as well as small-bore connectors as specified in ISO 80369-1:2018, Clause 6.

ISO 80369-3 and ISO 18250-3 ensure that connectors for enteral giving sets, enteral extension sets, enteral syringes, enteral feeding catheters and enteral accessories are unique and are not able to be connected to other small-bore connectors specified in the ISO 80369 series for the following applications: intravascular and hypodermic, breathing systems and driving gases, urethral and urinary, limb cuff inflation and neuraxial systems.

The small-bore connectors and reservoir connectors, as defined in ISO 80369-3 and ISO 18250-3, respectively, for use in enteral applications should not, but may connect with the following connectors/ports in common use within the same environment:

- the cones and sockets of ISO 5356-1 and ISO 5356-2;
- the temperature sensor ports made in conformity with ISO 80601-2-74:2017, Annex EE;
- the nipples of EN 13544-2 and EN 13544-2+A1.

In this document, the conjunctive “or” is used as an “inclusive or” so a statement is true, if any combination of the conditions is true.

The verbal forms used in this document are as follows:

- “shall” means conformity with a requirement or a test is mandatory for conformity with this document,
- “should” means conformity with a requirement or a test is recommended but is not mandatory for conformity with this document, and
- “may” is used to describe a permissible way to achieve conformity with a requirement or test.

# Enteral feeding systems — Design and testing

## 1 Scope

This document specifies requirements for enteral feeding systems comprising enteral giving sets, enteral extension sets, enteral syringes, enteral feeding catheters, and enteral accessories.

This document is not applicable to oral syringes.

## 2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 7000, *Graphical symbols for use on equipment — Registered symbols*

ISO 7886-1:2017, *Sterile hypodermic syringes for single use — Part 1: Syringes for manual use*

ISO 7886-2:1996, *Sterile hypodermic syringes for single use — Part 2: Syringes for use with power-driven syringe pumps*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 11135, *Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices*

ISO 11137-1, *Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

ISO 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

ISO 11607-2, *Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly process*

ISO 14937, *Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices*

ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO 17665-1, *Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*

ISO 18250-3:2018, *Medical devices — Connectors for reservoir delivery systems for healthcare applications — Part 3: Enteral applications*

ISO 25424, *Sterilization of health care products — Low temperature steam and formaldehyde — Requirements for development, validation and routine control of a sterilization process for medical devices*

ISO 80369-1, *Small-bore connectors for liquids and gases in healthcare applications — Part 1: General requirements*

ISO 80369-3, *Small-bore connectors for liquids and gases in healthcare applications — Part 3: Connectors for enteral applications*

ASTM F640, *Standard Test Methods for Determining Radiopacity for Medical Use*

DIN 13273-7, *Catheter for medical use — Part 7: Determination of the x-ray attenuation of catheters; requirements and testing*

### 3 Terms and definitions

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

#### 3.1

##### **distal end**

end of the medical device furthest from the source of the nutrient or diet intended to be administered via an *enteral feeding catheter* (3.5)

Note 1 to entry: See [Figure 1](#).

#### 3.2

##### **proximal end**

end of the medical device closest to the source of nutrient or diet intended to be administered via an *enteral feeding catheter* (3.5)

Note 1 to entry: See [Figure 1](#).

#### 3.3

##### **enteral feeding system**

system comprising the following enteral feeding devices: *enteral giving sets* (3.6), *enteral syringes* (3.8), *enteral feeding catheters* (3.5), and *enteral accessories* (3.4)

#### 3.4

##### **enteral accessory**

medical device that is used within the enteral system for the purposes of device placement or access of an enteral device; or for the purposes of filling, directing, stopping, or controlling flow of nutrients, medication, or aspirates

EXAMPLE Sheaths, guidewires, introducers.

#### 3.5

##### **enteral feeding catheter**

indwelling tubular medical device to facilitate delivery or removal of fluids or substances into or from the gastrointestinal tract

#### 3.6

##### **enteral giving set**

medical device for transferring enteral fluids or substances from an enteral reservoir to an *enteral feeding catheter* (3.5)

Note 1 to entry: Also known as enteral feeding sets.

Note 2 to entry: See [Figure 1](#) for an example.

#### 3.7

##### **enteral extension set**

medical device for transferring enteral fluids or substances from an *enteral giving set* (3.6) to an *enteral feeding catheter* (3.5)

Note 1 to entry: Also known as extension tubing.

Note 2 to entry: See [Figure 1](#) for an example.

### 3.8

#### **enteral syringe**

medical device for introduction or removal of fluids or substances into or from the gastrointestinal tract by means of pressure

Note 1 to entry: This does not include syringes for introducing fluids or substances directly into the mouth, i.e. oral-only syringes.

### 3.9

#### **integral introducer**

component that is attached to a percutaneous *enteral feeding catheter* ([3.5](#)) which is designed to facilitate initial catheter placement starting from inside the gastro-intestinal tract and ending outside the abdominal wall

## 4 General requirements

### 4.1 General

The following requirements apply to all components of the enteral feeding system unless superseded in the specific requirements in [Clauses 5, 6, 7](#) and [8](#).

### 4.2 Risk management

An established risk management process shall be applied to the design and development of the enteral feeding system.

NOTE ISO 14971 provides requirements and guidance for risk management of medical devices.

Check conformity by inspection of the risk management file.

### 4.3 Usability

An established usability engineering process shall be applied to the design of the enteral feeding system to assess and mitigate risks caused by usability problems associated with correct use and use errors.

NOTE IEC 62366-1 provides requirements and guidance on the application of usability of medical devices.

Check conformity by inspection of the usability-engineering file.

### 4.4 Test methods

The medical device shall be tested in accordance with the test methods specified in [Annexes B](#) to [J](#). Alternative test methods may be used if an equivalent degree of safety is obtained and the results of those alternative test methods can be related to the results obtained using the test methods specified in this document.

Check conformity by inspection of the technical file.

### 4.5 Materials

For certain materials, specific labelling and risk assessment requirements might apply, depending on national or regional regulations.

EXAMPLE Natural rubber latex, certain plasticizers used in polyvinyl chloride (PVC).

Check conformity by inspection of the technical file.

## 4.6 Cleaning and disinfection

If not labelled for single use, the medical device shall be capable of being cleaned, disinfected, or sterilized, according to the manufacturer's instructions, without affecting the ability of the medical device to meet the requirements of this document throughout its claimed use life.

NOTE ISO 17664 provides requirements and guidance for information provided by the supplier for the processing of reusable medical devices.

Check conformity by inspection of the technical file.

## 4.7 Sterility

All devices supplied as "STERILE" shall be sterilized using a sterilization process that has been validated and is routinely controlled in accordance with an International Standard for the applicable method of sterilization to demonstrate achievement of a maximal sterility assurance level (SAL) of  $10^{-6}$ , i.e. applicable parts of ISO 17665-1, ISO 11135, ISO 11137-1, ISO 25424 or ISO 14937.

Check conformity by inspection of the technical file.

## 4.8 Packaging

All medical devices supplied and marked as "STERILE" shall be contained in a packaging system conforming to ISO 11607-1 and ISO 11607-2.

Check conformity by inspection of the technical file.

## 4.9 Biological safety

Enteral feeding systems shall be evaluated for biological safety in accordance with ISO 10993-1.

Check conformity by inspection of the technical file.

## 4.10 Corrosion resistance

Any metallic component exposed to the patient or in contact with enteral fluids or substances shall be manufactured from corrosion resistant materials.

Check conformity by the test given in [Annex B](#).

## 4.11 Surface finish

External surfaces of the parts of the enteral devices that are inserted into the body shall be free from extraneous matter and process and surface defects that can present an unacceptable risk of patient harm.

Check conformity by visual inspection by normal or corrected vision under a minimum  $2,5 \times$  magnification under an illuminance of  $215 \pm 5$  lx.

## 4.12 Information supplied by the manufacturer

### 4.12.1 Marking

If present, markings on the devices shall be clearly legible and durable.

Check conformity by rubbing the markings, without undue pressure, with a cloth soaked in either ethanol or isopropanol.

Verify that the markings can be viewed from a distance of  $50 \text{ cm} \pm 10 \text{ cm}$  by an operator having a normal or corrected-to-normal vision.

### 4.12.2 Symbols

Symbols should be used where appropriate and shall be in accordance with ISO 15223-1 or ISO 7000.

If symbols that are used are not defined in either of these International Standards, national or regional standards may be used or the symbols shall be described in the instructions for use (see [4.12.4 g](#)).

Check conformity by inspection.

### 4.12.3 Labelling

The information provided on enteral feeding system labelling shall conform to relevant international and national requirements for those medical devices. The packaging (sterile barrier system and/or packaging system) shall be labelled with the following information as a minimum:

- a) the name or trade name of the enteral feeding device;
- b) the name and address of the manufacturer and, where appropriate, the name and address of the manufacturers' authorized representative;
- c) the details necessary for the user to identify the enteral feeding device or contents of the packaging;
- d) where appropriate, the word "STERILE" and the method used to sterilize the enteral feeding device;
- e) the batch code, preceded by the word "LOT";
- f) an indication of the date by which the enteral feeding device should be used, expressed at least as the year and month;
- g) any special storage or handling conditions;
- h) if appropriate, an indication that the device is for single patient use (a manufacturer's indication of single use shall be consistent across its range).

NOTE Applicable regulatory requirements for Unique Device Identifier (UDI) can apply.

### 4.12.4 Instructions for use

If present, the instructions for use shall include at least the following information:

- a) where appropriate, an indication that the device is for single use or single patient use (a manufacturer's indication of single use shall be consistent across its range);
- b) any special operating instructions required for safe and effective use of the device;
- c) any specific warnings or precautions;
- d) where applicable, the method of cleaning, disinfecting or sterilization necessary prior to use;
- e) where applicable, Magnetic Resonance Imaging (MRI) compatibility information;
- f) the date of issue or the revision level of the instructions for use;
- g) where applicable, a description of any symbols used on the device or labelling (see [4.12.2](#) and [4.12.3](#)).

## 5 Additional requirements for enteral giving sets and enteral extension sets

### 5.1 General

Enteral giving sets and enteral extension sets shall consist of the following:

- a) inlet port(s) or reservoir(s);
- b) tubing;
- c) outlet port.

Enteral giving sets may also include other features such as the following:

- 1) an access port;
- 2) a drip chamber;
- 3) a pump insert;
- 4) a means for regulating and/or stopping the flow through the enteral giving set.

See [Figure 1](#).

### 5.2 Inlet ports

**5.2.1** The inlet port of an enteral giving set shall be:

- a) a reservoir connector conforming to ISO 18250-3:2018, Figure B.1 and Table B.1 or Figure B.6 and Table B.6;
- b) a wide neck screw cap; or
- c) a crown-cork cap.

NOTE 1 This does not apply if the reservoir is an integral part of the enteral giving set.

NOTE 2 Examples of screw caps and necks are defined in DIN 55525:1988, ASTM D2911-94 (reapproved 2001), DIN 6063-1:2011, DIN 6063-2:2011, DIN 168-1:1998. Examples of crown cork caps and necks are defined in DIN 6094-1:1982, ISO 12821, EN 14635.

**5.2.2** The inlet port of an enteral extension set shall be:

- a) a male enteral small-bore connector conforming to ISO 80369-3;  
or alternatively
- b) a connector conforming to ISO 80369-1.

### 5.3 Outlet ports

**5.3.1** The outlet port of an enteral giving set shall be:

- a) a female enteral small-bore connector conforming to ISO 80369-3; or alternatively;
- b) a connector conforming to ISO 80369-1.

**5.3.2** The outlet port of an enteral extension set shall be:

- a) a female small-bore connector conforming to ISO 80369-3; or alternatively;

- b) a connector conforming to ISO 80369-1.

#### 5.4 Access ports

If an access port of the enteral giving set is provided it shall be either:

- a) a male connector conforming to ISO 80369-3;  
or alternatively
- b) a connector conforming to the requirements of ISO 80369-1.

#### 5.5 Tensile strength

Enteral giving sets and enteral extension sets (including tubing, joints, and connections) shall withstand a tensile force of 15 N before breaking, becoming detached, or cracking.

Check conformity by the test method given in [Annex C](#).

#### 5.6 Leakage

**5.6.1** Enteral giving sets shall not show signs of leakage sufficient to form a falling drop of water while being subjected to the internally applied pressure given in [5.6.2](#) and [5.6.3](#).

**5.6.2** For enteral giving sets not designed for use with an enteral feeding pump, applied pressure shall be between 20 kPa and 22 kPa over a hold period of 30 s to 35 s.

**5.6.3** For enteral giving sets designed for use with an enteral feeding pump, applied pressure shall be:

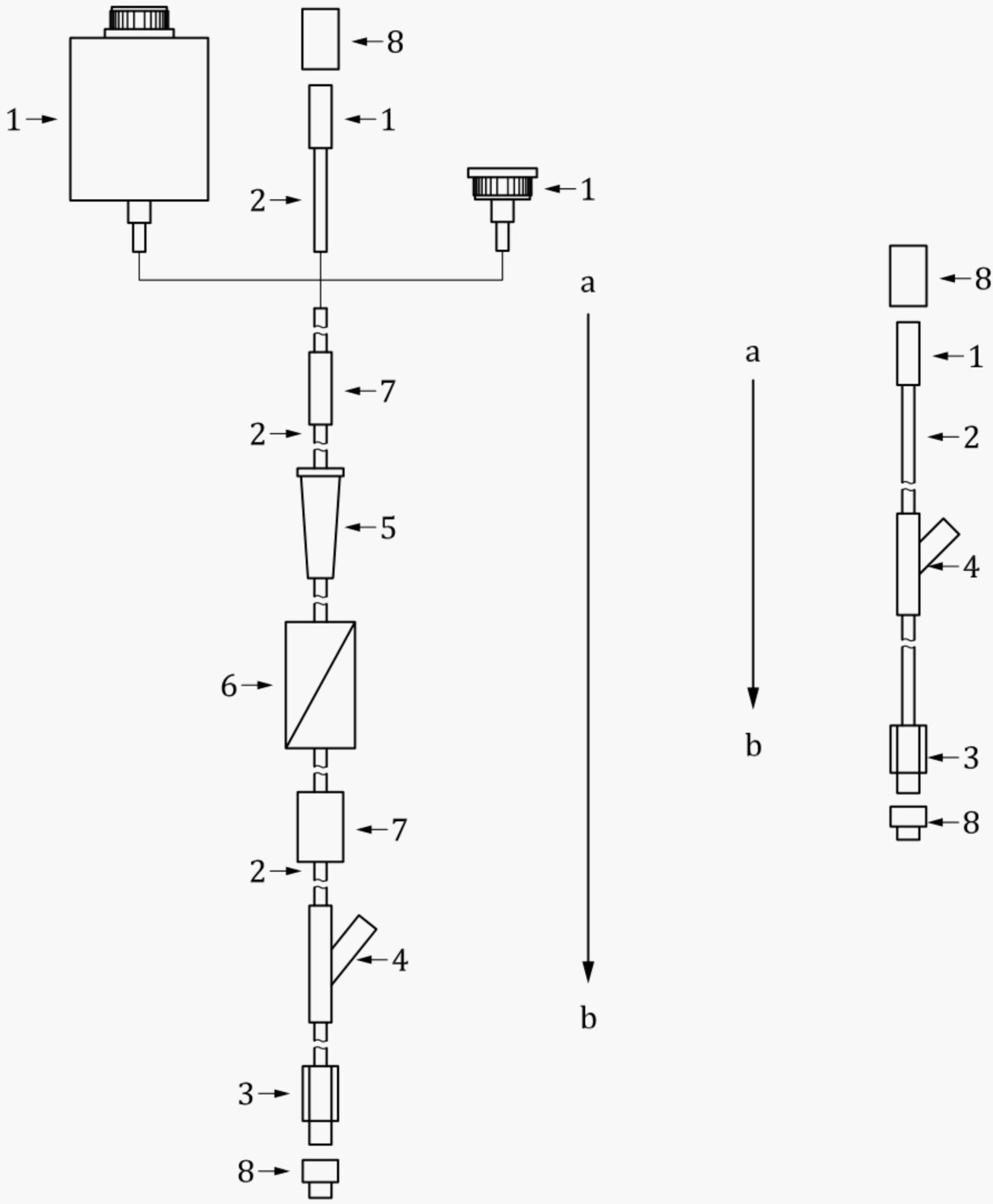
- a) distal to the driving mechanism of the pump — between 200 kPa and 220 kPa or greater than the maximum operating pressure of the pump with which they are designed to be used over a hold period of 120 s to 130 s; and
- b) proximal to the driving mechanism of the pump — between 20 kPa and 22 kPa over a hold period of 30 s to 35 s.

Check conformity by test method given in [Annex D](#).

#### 5.7 Additional information provided by the manufacturer

In addition to the general labelling requirements given in [4.12.3](#), enteral giving sets not designed to be used with an enteral feeding pump but designed for gravity use shall be labelled “for gravity use”.

Check conformity by visual inspection.



**Key**

- |   |                               |   |  |
|---|-------------------------------|---|--|
| 1 | inlet port(s) or reservoir(s) | 6 | optional driving mechanism of the pump                         |
| 2 | tubing                        | 7 | optional means for regulating and/or stopping the flow         |
| 3 | outlet port                   | 8 | optional dust cap or closure                                   |
| 4 | optional access port          | a | Proximal side of the enteral giving set/enteral extension set. |
| 5 | optional drip chamber         | b | Distal side of the enteral giving set/enteral extension set.   |

**Figure 1 — Example of enteral giving sets/extension sets with optional access port**

## 6 Additional requirements for enteral syringes

### 6.1 General

Enteral syringes shall consist of at least the following:

- a) a graduated container;
- b) unless the enteral syringe is designed for gravity use, there shall be a means to create pressure (e.g. a plunger or a bulb);
- c) an outlet port.

### 6.2 Outlet port

The outlet port of an enteral syringe shall be either:

- a) a female connector conforming to ISO 80369-3; or
- b) a connector conforming to the requirements of ISO 80369-1.

NOTE An example of an alternative enteral syringe tip is provided in [Annex K](#).

### 6.3 Enteral syringe requirements

Enteral syringes shall conform to ISO 7886-1:2017 and ISO 7886-2:1996 as listed in [Tables 1](#) and [2](#).

**Table 1 — Enteral syringe requirements in accordance with ISO 7886-1:2017**

Clause/subclause	Subject	Applicability
5	General requirements	All syringe types
6.2	Limits for acidity or alkalinity	All syringe types
6.3	Limits for extractable metals	All syringe types
7	Lubricant	Only for syringes with a plunger
8	Tolerance on graduated scale	All syringe types
9	Graduated scale	All syringe types
10	Barrel	Only for syringes with a plunger
11	Plunger stopper/plunger assembly	Only for syringes with a plunger
12.2	Position of nozzle on end of barrel	All syringe types
13.2	Freedom from air and liquid leakage past plunger stopper	Only for syringes with a plunger
13.3	Force to operate the piston	Only for syringes with a plunger

Table 2 — Enteral syringe requirements in accordance with ISO 7886-2:1996

Clause/subclause	Subject	Comment
11	Syringe design	Only for syringes with a plunger for fitment to a syringe pump
12	Piston/plunger assembly	Only for syringes with a plunger for fitment to a syringe pump
14.3	Flow characteristics	Only for syringes with a plunger for fitment to a syringe pump
14.4	Conformity of syringe	Only for syringes with a plunger for fitment to a syringe pump
14.5	Plunger movement forces	Only for syringes with a plunger for fitment to a syringe pump

Check conformity by inspection of technical file.

#### 6.4 Enteral Syringe dose accuracy requirement

Risk management shall be applied to the dose accuracy of the delivery from an enteral syringe to an access port (see [A.2.5](#)).

#### 6.5 Marking

The syringe shall be marked to identify that it is for enteral application.

Check conformity by inspection.

### 7 Additional requirements for enteral feeding catheters

#### 7.1 General

7.1.1 Enteral feeding catheters shall consist of at least the following:

- a) access port(s);
- b) tubing.

7.1.2 Enteral feeding catheters may also include other features, such as:

- a) a closure cap;
- b) a balloon inflation port;
- c) an integral introducer;
- d) a means for regulating and/or stopping the flow through the enteral feeding catheter;
- e) a weight;
- f) a stylet;
- g) an external retention bolster;
- h) an internal retention mechanism (e.g. balloon, bumper, pigtail).

## 7.2 Access ports

**7.2.1** Access port(s) at the proximal end of enteral feeding catheters shall be either:

- a) a male connector conforming to ISO 80369-3; or
- b) a connector conforming to the requirements of ISO 80369-1.

Access ports on skin level enteral feeding catheters are specifically excluded from this requirement, but manufacturers should check its non-interconnectability based on ISO 80369-1, and assess its risks.

**7.2.2** Enteral feeding catheters designed for large volume access, with internal lumens larger than 6,90 mm<sup>2</sup>, may include two proximal access ports. At least one of those ports shall conform to [7.2.1](#).

The manufacturer should identify in the labelling the intended use of any additional proximal access ports.

## 7.3 Tensile properties

### 7.3.1 Enteral feeding catheters designed for use without an integral introducer system

Enteral feeding catheters (including all joints and connections) shall not break, become detached or crack when subjected to the appropriate minimum linear tensile force specified in [Table 3](#).

Check conformity by the test method given in [Annex C](#).

**Table 3 — Minimum linear tensile force of enteral feeding catheter test specimens**

Outside diameter of tubing mm	Minimum linear tensile force N
≤2	5
>2	15

### 7.3.2 Enteral feeding catheters with an integral introducer system

Enteral feeding catheters with integral introducer (including all joints and connections) shall not break, become detached or crack when subjected to the appropriate minimum linear tensile force specified in [Table 4](#).

Check conformity by the test method given in [Annex C](#).

**Table 4 — Minimum linear tensile force of enteral feeding catheters with an integral introducer system**

Outside diameter of tubing mm	Minimum linear tensile force N
≤4	35
>4 and ≤6	55
>6	75

## 7.4 Leakage properties

Enteral feeding catheters, including all joints, connections, and access port caps and closures on multi access ports into the same lumen only, shall not show signs of leakage sufficient to form a falling drop of water while being subjected to the internally applied pressure of 50 kPa to 60 kPa.

All caps and closures on single access ports into the same lumen when assembled to access port(s) on enteral feeding catheters shall be able to withstand an internally applied pressure of a minimum of 3 kPa or clinically relevant pressure over a hold period of 120 s to 130 s without the formation of a falling drop of water.

Check conformity by the test method given in [Annex D](#).

### 7.5 Flow rate

If a flow rate is stated, it shall be tested in accordance with the method given in [Annex E](#).

Check conformity by inspection of technical file.

### 7.6 Enteral feeding catheter designated size

The designated size of enteral feeding catheters shall be within  $\pm 0,33$  mm (1 French) of the nominal outside diameter of the tubing expressed to the nearest 0,10 mm, excluding intentional protrusions (i.e. distal tip weights) and temporary attachments (i.e. integral introducers).

NOTE French size (Fr, CH) is a nominal dimensional identification of the outer size of enteral feeding catheters; calculated as three times the diameter (in millimetres): Fr size =  $3 \times$  Diameter (mm).

Collapsible retention mechanisms on enteral feeding catheters intended to be placed through the abdominal wall and into the gastro-intestinal tract (i.e. deflated balloons, obturated bumpers, encapsulated bumpers, etc.) when collapsed according to the manufacturer's instructions, shall pass through a test gauge no larger than the designated catheter size  $+1,33$  mm  $\pm 0,03$  mm without tearing or permanently distorting.

Check conformity by the test method given in [Annex F](#).

### 7.7 Requirements for enteral feeding catheters with retention balloons

#### 7.7.1 Balloon burst volume

The balloon shall withstand a volume of at least twice ( $2 \times$ ) its labelled maximum volume without leak, burst or rupture.

Check conformity by the test method given in [Annex G](#).

#### 7.7.2 Balloon recommended inflation volume

The manufacturer shall declare, in the instructions for use, the recommended inflation volume for the retention balloon when in situ.

Check conformity by inspection of the instructions for use.

The balloon shall withstand a volume of at least twice ( $2 \times$ ) the manufacturers' recommended inflation volume (see [7.7.1](#)) without leak.

Check conformity by the test method given in [Annex G](#).

#### 7.7.3 Balloon inflation system performance

The balloon inflation system [including the balloon, valve(s), and connecting lumen(s)] shall enable inflation, retain inflation volume and enable deflation of the retention balloon.

Check conformity by the test method given in [Annex H](#).

#### 7.7.4 Balloon concentricity

The balloon shall exhibit a concentricity ratio less than or equal to 2:1 when inflated to its recommended inflation volume (see [7.7.2](#)).

Check conformity by the test method given in [Annex I](#).

#### 7.7.5 Balloon integrity in simulated gastric fluid

The integrity of the balloon shall be maintained in simulated gastric solution for a period of 25 % of the labelled length of use.

Check conformity by the test method given in [Annex J](#).

### 7.8 Detectability

#### 7.8.1 General

The enteral feeding catheter shall be detectable by X-ray or by other means (ultra-sound, magnetic resonance imaging, etc.), if required by the risk assessment.

#### 7.8.2 Catheters designed to be radiopaque

Enteral feeding catheters shall exhibit radiopacity equivalent to an aluminium standard according to the appropriate method, i.e. ASTM F640 or DIN 13273-7.

Check conformity by inspection of technical file.

NOTE Enteral feeding catheters can be radiographically detectable in their entirety or partially (e.g. radiopaque tip, stripe, or intermittent marks).

#### 7.8.3 MRI compatibility

Enteral feeding catheters that are marked suitable for use in an MRI environment shall be evaluated by an appropriate method.

EXAMPLE The methods described in ASTM F2052, ASTM F2213, ASTM F2182, and ASTM F2119.

Check conformity by inspection of the risk management file.

### 7.9 Marking

If the catheter allows for legible markings, enteral feeding catheters shall be marked:

- a) with the designated size expressed in units of mm or French size (Fr or CH: 1/3 mm);
- b) if multiple access ports are present, they shall be marked to indicate their purpose.

Check conformity by visual inspection.

If the catheter does not allow for legible markings, the size of the catheter and the purpose of access ports (if applicable) shall be described on the packaging or in the instructions for use.

## 8 Additional requirements for enteral accessories

Enteral accessories include but are not limited to the following:

- a) draw up straws;
- b) access ports [e.g. Stopcock, Y-port, Percutaneous Endoscopic Gastrostomy (PEG) adaptors];



## Annex A (informative)

### Rationale and guidance

#### A.1 General guidance

This annex provides a rationale for some requirements of this document and is intended for those who are familiar with the subject of this document but who have not participated in its development. An understanding of the rationale underlying these requirements is considered to be essential for their proper application. Furthermore, as clinical practice and technology change, it is believed that a rationale for the present requirements will facilitate any revision of this document necessitated by those developments.

#### A.2 Rationale for particular clauses and subclauses

##### A.2.1 [4.7](#), Sterility

Enteral feeding through a natural orifice is a non-sterile procedure to non-sterile anatomy of the human body; therefore, sterility of the medical devices used for enteral feeding is not a requirement of this document.

##### A.2.2 [5.2](#), [5.3](#), [5.4](#), [6.2](#), [7.2](#), Inlet outlet and access port connectors

This document establishes design, safety and performance requirements for enteral feeding systems including enteral giving sets, enteral extension sets, enteral syringes, enteral feeding catheters and enteral accessories. This document requires that enteral devices and accessories employ the specified connectors in a manner that establishes fluid flow in the female to male direction.

In the past, the medical device and enteral nutrition industry supplied enteral giving sets and extension sets with a range of connectors. A male Luer tip to fit a female Luer port on enteral feeding catheter is a standard intravenous or parenteral connector combination. Since 2007, the UK National Patient Safety Agency (NPSA) has recommended that these should not be used for administering oral or enteral liquids, and it was further recommended that healthcare organizations not purchase those. Experience in the UK has demonstrated that a reversed (female to male) configuration can reduce inadvertent connection of enteral feeding lines to intravenous ports. This medical device orientation has found broad acceptance in the United Kingdom.

Enteral administration and extension sets should not contain any in-line female administration ports or connect to the patient using a male terminal connector.

##### A.2.3 [5.2.2](#), [5.3.1](#), [5.3.2](#) item b), Connectors

Concerns raised about the potential suitability of one single standard connector for specialized needs of very specific patient populations is the reason why CEN/TC 205/WG 16 decided to allow the use of connectors as defined by ISO 80369-1:2018, 6.2. Connectors in conformity with ISO 80369-1:2018, 6.2 are either proprietary or state-of-the-art de facto standard connectors, that, despite lacking a univocal definition into a published standard, satisfy the basic safety requirements.

##### A.2.4 [Clause 6](#), Additional requirements for enteral syringes

For the purposes of this document, an enteral syringe can comprise a barrel acting as a reservoir with an outlet connector or a barrel with a plunger that fits tightly within the barrel and is used to push the

content into the enteral feeding catheter or to exert negative pressure to extract fluids from the patient out of the enteral feeding catheter.

A manual syringe is a medical device consisting of a graduated barrel and a plunger in which liquids are stored and transferred to a patient by means of manual operation of the medical device. This medical device would conform to the requirements of ISO 7886-1, in accordance with [Table 1](#).

A pump syringe is a medical device consisting of a graduated barrel and a plunger in which liquids are stored and transferred to a patient by means of operation of the medical device by a power-driven syringe pump. This medical device would conform to the requirements of ISO 7886-2, in accordance with [Table 2](#).

A gravity syringe is a medical device consisting of a graduated barrel with or without some filtering media in which liquids are stored and transferred to a patient by means of gravity. A hanging bracket may be provided. The barrel of this medical device would conform to the requirements of ISO 7886-1, in accordance with [Table 1](#).

A bulb syringe is a medical device consisting of a graduated barrel and an elastomeric bulb in which liquids are stored and transferred to a patient by means of manual operation of the medical device. The barrel of this medical device would conform to the requirements of ISO 7886-1, in accordance with [Table 1](#).

For the purposes of this document, an enteral syringe is not intended to mean a reservoir barrel such as a feeding or hydration bag, bottle or commercial food barrel.

### **A.2.5 6.3, Enteral syringe requirements**

Dead space for a syringe with a female nozzle is different to that of a syringe with a male nozzle in that the volume of the female nozzle cannot be assessed until after it is connected to the corresponding male connector on the catheter. The main issue with a female nozzle is displacement of the fluid when it is connected to the connector on the catheter and whether the fluid leaks to atmosphere or flows down the catheter thereby increasing the dosage given to the patient.

This is why ISO 7886-1:2017, 13.1 was not included in this document.

### **A.2.6 6.4, Enteral syringe dose accuracy requirement**

Concerns had been raised regarding the use of enteral syringes with female E1 small-bore connectors specified in ISO 80369-3 and the possible risk of delivering inaccurate doses when dosing low volumes of medication that require high accuracy. This document does not provide a validated test method to confirm dose accuracy of the enteral system. Therefore, manufacturers should consider this point in their risk management file in order to market their products.

### **A.2.7 7.7.5, Balloon integrity in simulated gastric fluid**

During simulated use testing, in-dwelling enteral feeding devices and their retention mechanisms are exposed to a mixture of hydrochloric acid, pepsin, sodium chloride and water. This simulated gastric solution is mixed according to a United States Pharmacopeia (USP) formula and held at a pH of 1,2. The solution is representative of the acid levels secreted by the gastric mucosa during the various phases of digestion. However, constant exposure to this solution is extremely exaggerated from the conditions found within the gastric environment on a normal basis.

An enteral feeding retention mechanism (balloon or bumper) that rests against the gastric mucosa will experience the variable gastric pH of the gastric mucosa as secretions are started and stopped throughout the day. The proximal side of the balloon or bumper will experience the highest variability with pH ranging from 1,2 to 4,0 or higher. The distal side of the balloon or bumper will experience the environment within the "bulk" of the stomach which is typically maintained at pH of 2,0 or higher.

During a substantial meal and for a period afterward, a significant amount of gastric solution might be produced. However, as gastric pH falls below 2,0, the body will limit the secretion of gastric acid

in an effort to maintain a constant pH level in the intestines and to facilitate efficient and thorough processing of the food substances. Thus, the temporal exposure of an entity situated against the gastric mucosa to gastric solution of low pH (1,2) would look like a “roller coaster”, with peaks and valleys driven by the intra-gastric pH as sensed in the duodenum during the intestinal phase of digestion.

Because of this “roller coaster” effect, constant exposure to 1,2 pH is approximated to be (at most) 25 % of the total exposure time in the gastric anatomy. A 4:1 test acceleration factor makes logical sense when evaluated in the light of the human anatomical and functional aspects of the gastric environment and the gastric mucosa. This acceleration would effectively shorten a 3 month (90 days) in situ enteral feeding tube balloon test to approximately 23 days’ real time of full-time exposure to 1,2 pH gastric acid solution.

#### **A.2.8 [Annex K](#), Alternative enteral syringe tip**

CEN/TC 205 has decided to propose [Annex K](#) for information only as test results, coming from the different available test methods, lead to contradictory conclusions on dose accuracy with this alternative enteral syringe tip.

## Annex B (normative)

### Test method for corrosion resistance of metallic components

#### B.1 Principle

The test sample is immersed in the saline solution, then in boiling distilled water, and afterwards the metallic components are visually examined for evidence of corrosion.

#### B.2 Reagents

**B.2.1 Saline solution**, comprising 9 g/l of analytical reagent grade sodium chloride in distilled water.

**B.2.2 Distilled water**.

#### B.3 Apparatus

**B.3.1 Borosilicate glass beakers**.

#### B.4 Procedure

- a) Cut a test specimen containing the metallic component from the test sample. Do not strip away or cut open any coatings on metallic components.
- b) Immerse the test specimen in saline solution in a glass beaker at  $(23 \pm 5) ^\circ\text{C}$  for 5 h.
- c) Remove the test specimen and immerse it in boiling distilled water for 30 min. Allow the water and the test specimen to cool to, and remain at,  $(23 \pm 5) ^\circ\text{C}$  for 48 h.
- d) Remove the test specimen and allow it to dry at  $(23 \pm 5) ^\circ\text{C}$  and 30 % to 60 % Relative Humidity (RH).
- e) Disassemble test specimens that have two or more components which are intended to be separable in use. Do not strip away or cut open any coatings on metallic components.
- f) Inspect the metallic components of the test specimen visually for signs of corrosion (e.g. changes in colouration or other surface changes such as pits).

#### B.5 Test report

The test report shall include at least the following information:

- a) the sample;
- b) the International Standard used (including its year of publication);
- c) the method used if the standard includes several;
- d) the result (a statement as to whether corrosion occurred and when);
- e) any deviations from the procedure;

- f) any unusual features observed;
- g) the date of the test.

## Annex C (normative)

### Test method for tensile properties

#### C.1 Principle

Specimens are chosen so that each tubular portion, each junction between hub or connector and tubing, and each junction between tubular portions is tested. A tensile force is applied to each test specimen until the tubing breaks or the junction separates or until a specified force is applied.

#### C.2 Apparatus

**C.2.1 Tensile testing apparatus**, capable of exerting a force greater than the required minimum linear force.

#### C.3 Procedure

- a) Select test specimen(s) from the test sample. Include in the test specimen(s) the hub or connector, if present, and the junction between segments, e.g. between the tubing and the tip, if present. Exclude distal tips of lengths less than 3 mm from the test specimen junction.
- b) Condition the test specimen(s) from those parts of the test sample that are intended for insertion into the body in an atmosphere of 100 % relative humidity (RH), or water, and a temperature of  $(37 \pm 2)$  °C for 2 h minimum. Condition the remainder of the test specimen(s) at a minimum of 40 % RH and a temperature of  $(23 \pm 5)$  °C for 2 h minimum. Test the specimen within 1 min after removal from conditioning.
- c) Fix the test specimen in the tensile testing apparatus. If a hub or connector is present, use an appropriate fixture to avoid deforming the hub or connector.
- d) Measure the gauge length of the test specimen [i.e. the distance between fixed points of the tensile test. For test specimens containing elastic components (e.g. flexible tubing), the gauge length is the distance in which the elastic component is constrained, typically between the upper sample fixture and the bottom sample fixture].
- e) Apply a tensile strain at a unit strain rate of 20 mm/min per mm of gauge length (see [Table C.1](#)) until the test specimen separates into two or more pieces or until a specified force is applied.

**Table C.1 — Example strain rates**

Gauge length mm	Strain rate mm/min
10	200
20	400
25	500

Note the value in newtons of the applied peak tensile force or the value reached when the rupture is obtained. In case of rupture, note the location of the failure.

- f) If testing a catheter that consists of a single tubular portion having regions of different outside diameter, repeat [C.3 b\)](#) to [C.3 f\)](#) on test specimens of each different diameter.
- g) Do not perform more than one tensile test on each test specimen.

#### **C.4 Test report**

The test report shall include at least the following information:

- a) the test sample;
- b) the International Standard used (including its year of publication);
- c) the method used if the standard includes several;
- d) the result;
- e) any deviations from the procedure;
- f) any unusual features observed;
- g) the date of the test.

## Annex D (normative)

### Test method for resistance to liquid leakage under pressure

#### D.1 Principle

The test sample is connected as intended by the manufacturer and filled with water. A connection is made to a pressure system with a measuring gauge. A hydraulic pressure is applied and the assembly is then inspected for leakage.

#### D.2 Reagents

**D.2.1 Distilled or potable water.** Optionally, a very small amount of a colouring agent (e.g. methylene blue) may be added to the water to facilitate the detection of leaks.

#### D.3 Apparatus

**D.3.1 Hydraulic pressure system,** with a measuring gauge.

**D.3.2 Means for occluding the test specimen,** e.g. a clamp.

**D.3.3 Connector,** capable of making a leak proof coupling between the hydraulic system and the medical device.

#### D.4 Procedure

- a) Assemble the test sample under test to the hydraulic pressure system; both the test sample and hydraulic system being dry.
- b) Fill the system with water at  $(23 \pm 5)$  °C and expel the air.
- c) Ensure the outside of the test sample is dry.
- d) With the axis of the test sample horizontal, occlude the test sample and increase the internal water pressure as required.
- e) Maintain the pressure for the time required.
- f) Visually inspect for a falling drop of water from the test sample during the test period. One or more falling drops of water are considered to be a failure.

#### D.5 Test report

The test report shall include at least the following information:

- a) the test sample;
- b) the International Standard used (including its year of publication);
- c) the method used if the standard includes several;

- d) the result;
- e) any deviations from the procedure;
- f) any unusual features observed;
- g) the date of the test.

## Annex E (normative)

### Test method for determining the flow rate

#### E.1 Principle

Water is allowed to flow through the test sample and the amount of flow is measured either volumetrically or gravimetrically.

#### E.2 Reagents

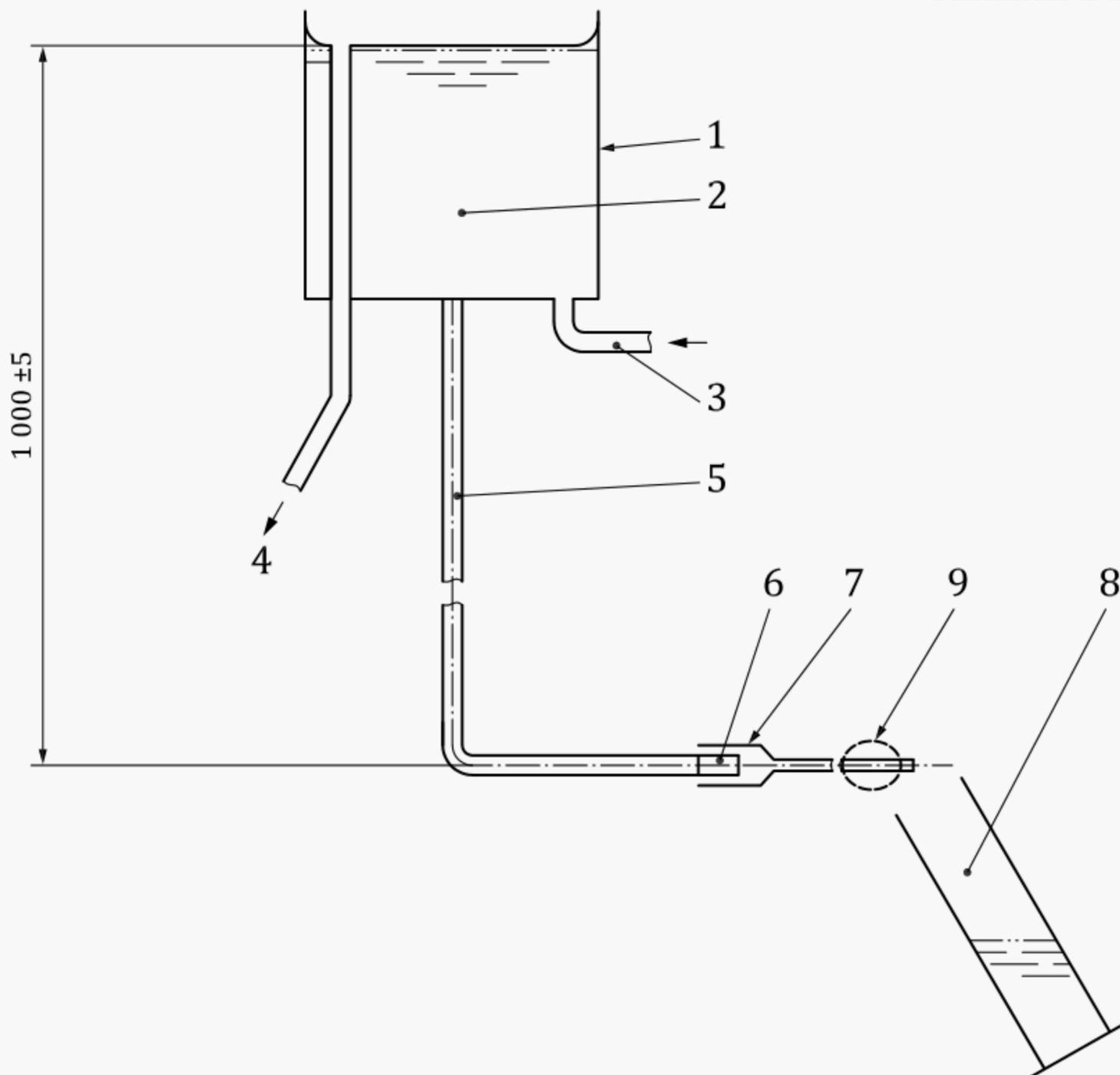
E.2.1 Distilled or potable water.

#### E.3 Apparatus

E.3.1 **Constant-level tank**, fitted with a delivery tube and a male (or female) taper fitting capable, when no test device is attached, of providing a flow rate of  $(500 \pm 25)$  ml/min.

The constant level tank should have a hydrostatic head of  $(1\ 000 \pm 5)$  mm, unless otherwise specified in the relevant product standard. An example of suitable materials is shown in [Figure E.1](#).

Dimensions in millimetres

**Key**

1	constant-level tank	6	connector fitting
2	distilled or deionized water	7	test sample
3	inlet	8	collecting/measuring vessel
4	overflow	9	inflated balloon
5	delivery tube		

**Figure E.1 — Example of apparatus for determination of flowrate****E.3.2 Measuring cylinders**, or collecting vessel with balance of accuracy  $\pm 1\%$ .

EXAMPLE ISO 4788 class A cylinders are suitable for all sizes. ISO 4788 class B cylinders are suitable for sizes 100 ml or more.

**E.4 Procedure**

- Supply the constant level tank with water at  $(23 \pm 5)^\circ\text{C}$ . Fit the test sample to the appropriate connector. If the test sample has a balloon, the balloon should be inflated to the rated nominal volume prior to testing. Ensure that the test sample outlet is maintained at a hydrostatic head height of  $(1\,000 \pm 5)$  mm.
- Flush air from the system by allowing water to flow briefly through the test sample.

- c) Start the water flowing through the test sample. Collect the efflux for a period of not less than 30 s in a suitable vessel and determine its volume by means of a measuring cylinder or by weighing using the assumption that the density of water equals 1 000 kg/m<sup>3</sup>. Perform three determinations on each test sample.

## **E.5 Expression of results**

- a) Calculate the average of the three determinations and express it as a water flow rate through the test sample in millilitres per minute.
- b) Round the calculated average water flow rate to the nearest whole number.

## **E.6 Test report**

The test report shall include at least the following information:

- a) the test sample;
- b) the International Standard used (including its year of publication);
- c) the method used if the standard includes several;
- d) the result;
- e) any deviations from the procedure;
- f) any unusual features observed;
- g) the date of the test.

## Annex F (normative)

### Test method for determining the designated outer diameter of enteral feeding catheters

#### F.1 Principle

The outer diameter of the enteral feeding catheter is measured to determine the size of the shaft and, when applicable, the retention balloon over the shaft.

#### F.2 Apparatus

**F.2.1 Calibrated steel ring gauge(s)**, which is  $(6,35 \pm 0,1)$  mm thick, sized according to [Table F.1](#). An example can be found in [Figure F.1](#).

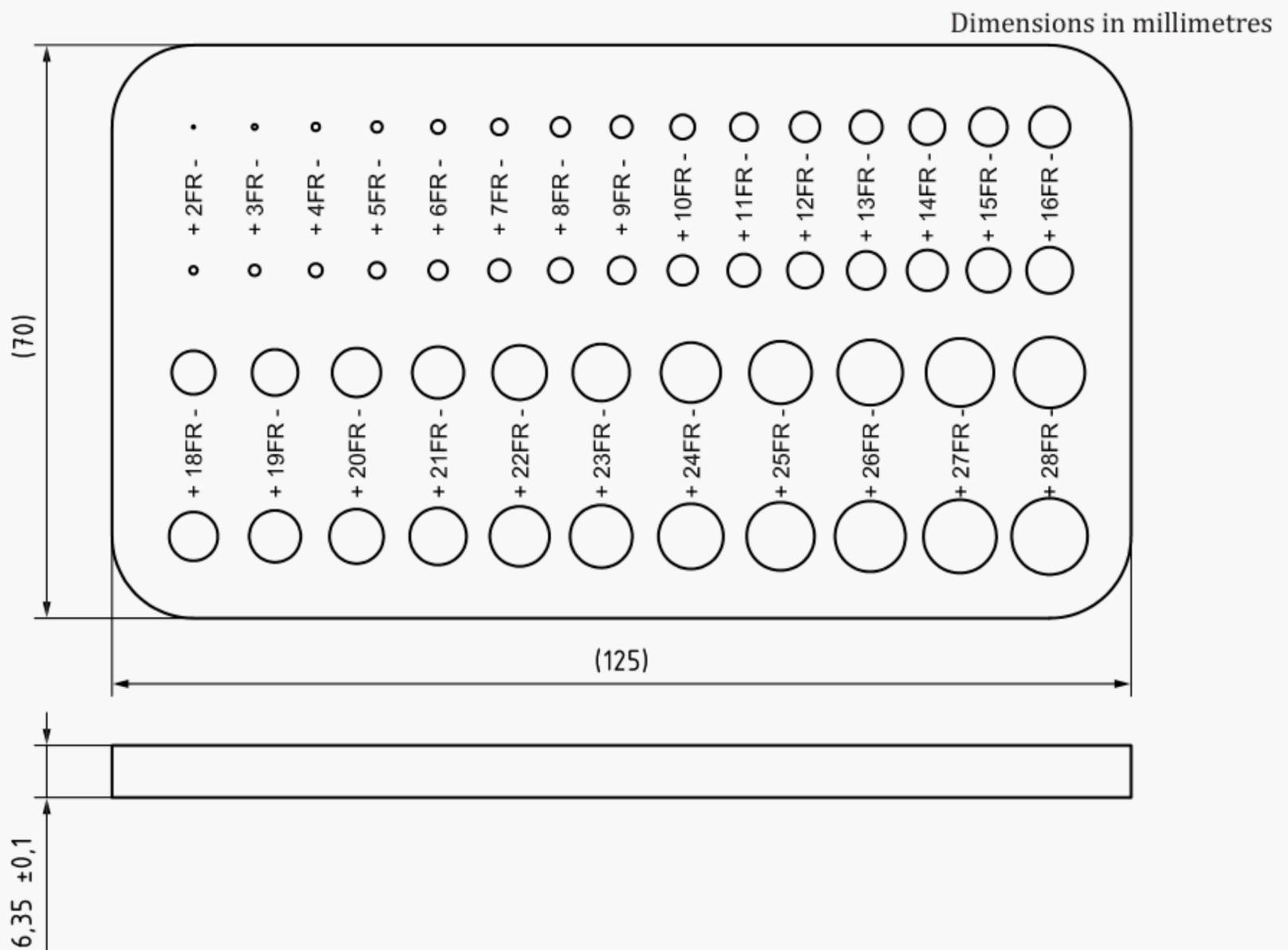


Figure F.1 — Example of apparatus (side view, not to scale)

Table F.1 — Apparatus dimensions

French size/ Nominal diameter in mm	No Go Ring Gauge diameter +0/-0,01 mm	Go Ring Gauge diameter +0,01/-0 mm
2 (0,67)	0,33	1,00
3 (1,00)	0,67	1,33
4 (1,33)	1,00	1,67
5 (1,67)	1,33	2,00
6 (2,00)	1,67	2,33
7 (2,33)	2,00	2,67
8 (2,67)	2,33	3,00
9 (3,00)	2,67	3,33
10 (3,33)	3,00	3,67
11 (3,67)	3,33	4,00
12 (4,00)	3,67	4,33
13 (4,33)	4,00	4,67
14 (4,67)	4,33	5,00
15 (5,00)	4,67	5,33
16 (5,33)	5,00	5,67
17 (5,67)	5,33	6,00
18 (6,00)	5,67	6,33
19 (6,33)	6,00	6,67
20 (6,67)	6,33	7,00
21 (7,00)	6,67	7,33
22 (7,33)	7,00	7,67
23 (7,67)	7,33	8,00
24 (8,00)	7,67	8,33
25 (8,33)	8,00	8,67
26 (8,67)	8,33	9,00
27 (9,00)	8,67	9,33
28 (9,33)	9,00	9,67

### F.3 Procedure — Shaft size

- Test at  $(23 \pm 5) ^\circ\text{C}$ .
- Prepare the test specimen by removing the proximal end connectors from the enteral feeding catheter shaft.
- Without lubrication, push the cut end of the enteral feeding catheter shaft through a calibrated ring gauge, advancing along the shaft.
- The shaft size is prescribed by the size of the smallest pair of holes into which it fits without undue insertion force.
- The enteral feeding catheter shaft shall not distort.
- Record the measured size.

#### **F.4 Procedure — Deflated balloon or collapsed retention mechanism size**

- a) Test at  $(23 \pm 5) ^\circ\text{C}$ .
- b) Push the deflated balloon or collapsed retention mechanism through the ring gauge, advancing it over the entire length of the deflated balloon or retention mechanism. Water soluble lubricant may be applied to the deflated balloon or retention mechanism. The deflated balloon or retention mechanism size is appropriately prescribed by the size of the smallest hole into which it would fit without undue insertion force.
- c) The balloon may wrinkle but shall not tear or permanently distort.
- d) Record the measured size.

#### **F.5 Test report**

The test report shall include at least the following information:

- a) the test sample;
- b) the International Standard used (including its year of publication);
- c) the method used if the standard includes several;
- d) the result;
- e) any deviations from the procedure;
- f) any unusual features observed;
- g) the date of the test.

## **Annex G** **(normative)**

### **Test method for determining balloon burst volume**

#### **G.1 Principle**

The balloon is inflated with water until rupture, which enables the balloon burst volume to be determined.

#### **G.2 Reagents**

**G.2.1 Distilled or potable water.**

#### **G.3 Apparatus**

**G.3.1 Water reservoir.**

**G.3.2 Leak proof connector.**

**G.3.3 Hydraulic pressure system.**

#### **G.4 Procedure**

- a) Test at  $(23 \pm 5) ^\circ\text{C}$ .
- b) The enteral feeding device is not to be immersed in water during the test.
- c) Fill the hydraulic pressure system with an amount of water sufficient for the test and attach the delivery mechanism to the balloon inflation lumen tube.
- d) Using hydraulic pressure system, inflate the retention balloon at a constant rate [e.g.  $(1,0 \pm 0,5) \text{ ml/s}$ ] until the volume is twice the manufacturer's recommended inflation volume.
- e) Verify that the balloon does not leak.

#### **G.5 Test report**

The test report shall include at least the following information:

- a) the test sample;
- b) the International Standard used (including its year of publication);
- c) the method used if the standard includes several;
- d) the result;
- e) any deviations from the procedure;
- f) any unusual features observed;

g) the date of the test.

## Annex H (normative)

### Test method for determining balloon inflation system performance

#### H.1 Principle

The retention balloon of the enteral feeding catheter is inflated with a test liquid. This test liquid contains a colorant which enables a leak of fluid to be observed. If no leak is observed, the integrity of the balloon inflation system is upheld, therefore maintaining the balloon volume.

#### H.2 Reagents

**H.2.1 Test liquid** — Methylene blue crystal solution or equivalent — Prepare 1 g of methylene crystals and dilute in 2 000 ml of distilled or potable water, to be detectable in the described retention test.

#### H.3 Apparatus

**H.3.1 Syringe.**

**H.3.2 Background material**, suitable for detection of any leakage (for example, paper towel).

#### H.4 Procedure

- a) Condition those parts of the enteral feeding catheter that are intended for insertion into the body in an atmosphere of 100 % relative humidity (RH), or water, and a temperature of  $(37 \pm 2)$  °C for 2 h minimum.
- b) Inflate the balloon with the test liquid to the labelled volume.
- c) Place the enteral feeding catheter on the background material for a minimum of 15 min. Cover or protect the enteral feeding catheter for the duration of the test.
- d) Verify that:
  - the balloon inflates to the specified volume;
  - the inflation volume of the balloon is maintained by checking for signs of leakage on the background material;
  - the balloon can be deflated.

#### H.5 Test report

The test report shall include at least the following information:

- a) the test sample;
- b) the International Standard used (including its year of publication);

- c) the method used if the standard includes several;
- d) the result;
- e) any deviations from the procedure;
- f) any unusual features observed;
- g) the date of the test.

## Annex I (normative)

### Test method for determining balloon concentricity

#### I.1 Principle

The retention balloon of the enteral feeding catheter is inflated with water and measured for concentricity.

#### I.2 Reagents

I.2.1 Distilled or potable water.

#### I.3 Apparatus

I.3.1 Syringe.

I.3.2 Non-contact measurement system.

#### I.4 Procedure

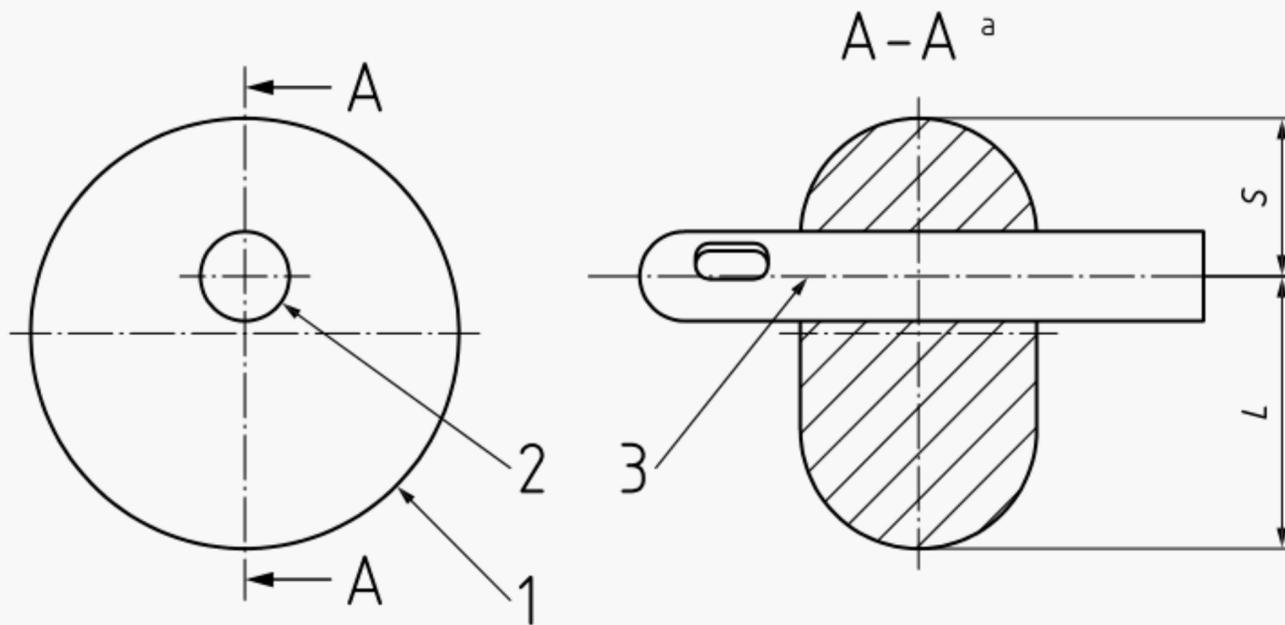
- a) Test at  $(23 \pm 5) ^\circ\text{C}$ .
- b) Attach a syringe to the enteral feeding catheter inflation valve and inflate balloon with the manufacturer specified nominal volume of water.
- c) Using the non-contact measurement system, measure the two sides of the balloon that visually appear to have the least symmetry. Measurements should be taken  $180^\circ$  from each other. See [Figure I.1](#) for measurement example.
- d) Divide larger measurement (L) by smaller measurement (S) and quotient equals concentricity ratio. Tabulate all results.
- e) Verify that the concentricity ratio is less than or equal to 2:1.

#### I.5 Test report

The test report shall include at least the following information:

- a) the test sample;
- b) the International Standard used (including its year of publication);
- c) the method used if the standard includes several;
- d) the result;
- e) any deviations from the procedure;
- f) any unusual features observed;

g) the date of the test.



**Key**

- 1 device balloon
- 2 device shaft
- 3 centreline of device shaft
- S smaller measurement
- L larger measurement
- a Section at diameter of greatest eccentricity.

**Figure I.1 — Measurement example**

## Annex J (normative)

### Test method for determining balloon integrity in simulated gastric fluid

#### J.1 Principle

Retention balloons are inflated with water and submerged in simulated gastric solution and evaluated for balloon rupture.

#### J.2 Reagents

J.2.1 Sodium chloride.

J.2.2 Purified pepsin, delivered from porcine stomach mucosa, with an activity of 800 to 2 500 units per mg of protein.

J.2.3 Hydrochloric acid.

J.2.4 Distilled or potable water.

#### J.3 Apparatus

J.3.1 Corrosion resistant containers, which should contain no exposed iron, copper, or brass elements.

J.3.2 Cover, permits enteral feeding devices with retention balloon to be placed vertically in the tank and inflated so that retention balloon is fully submerged in gastric fluid test solution. The cover should prevent as much evaporation from occurring as possible.

J.3.3 Graduated cylinder.

J.3.4 Balance.

J.3.5 Weigh boats or equivalent.

J.3.6 Mixing spatula.

J.3.7 Weighing utensils.

J.3.8 pH meter or equivalent.

J.3.9 Water bath.

#### J.4 Simulated gastric fluid preparation

- a) Prepare United States Pharmacopeia (USP) simulated gastric fluid test solution. Ensure that the solution is homogeneous.
- b) Per USP formula, dissolve 2,0 g of sodium chloride and 3,2 g of purified pepsin, in 7,0 ml of hydrochloric acid with sufficient water to make 1 000 ml.
- c) Confirm that the test solution delivers a pH of  $(1,2 \pm 0,1)$ .

#### J.5 Procedure

- a) The test specimen shall consist of new, finished and untested product.
- b) Place the enteral feeding catheter vertically into tank through cover so that retention balloon is fully submerged in simulated gastric fluid test solution.
- c) Inflate retention balloon with water to the manufacturer's specified nominal volume. Inspect test samples weekly for balloon volume. If needed, adjust the balloon volume to the manufacturer's specified nominal volume.
- d) Inspect test samples daily for balloon failures (bursts). Record number of balloon failures.
- e) Measure and record pH of simulated gastric fluid daily. The pH of the simulated gastric fluid should be maintained at a constant level of  $1,2 \pm 0,1$ . If necessary, adjust pH by the addition of water and/or hydrochloric acid. Maintain temperature of solution at  $(37 \pm 2) ^\circ\text{C}$ .

#### J.6 Test report

The test report shall include at least the following information:

- a) the test sample;
- b) the International Standard used (including its year of publication);
- c) the method used if the standard includes several;
- d) the result;
- e) any deviations from the procedure;
- f) any unusual features observed;
- g) the date of the test.

## Annex K (informative)

### Example of an alternative enteral syringe tip

This annex only provides information regarding an alternative tip design for enteral syringes.

#### K.1 Alternative enteral syringe tip dimensions

See dimensions in [Figure K.1](#) and [Table K.1](#).

#### K.2 Dose accuracy performance

CEN/TC 205 has not reached consensus regarding the ability of the alternative enteral syringe tip described in [Figure K.1](#) and [Table K.1](#) to reliably increase dose accuracy.

In addition, the design of this alternative enteral syringe tip might not ensure that the dose accuracy for enteral syringes is met; specific user information and education should accompany this alternative enteral syringe based upon the manufacturer's risk assessment.

CEN/TC 205 strives to completely characterize the dose accuracy performance of the alternative enteral syringe tip described in [Figure K.1](#) and [Table K.1](#) and/or develop additional enteral syringe tip designs to achieve the desired dose accuracy requirement. This requirement shall be defined.

#### K.3 Dose accuracy test method

A validated test method to verify the dose accuracy performance of an enteral syringe is not currently specified by this standard. Manufacturers should develop and validate a dose accuracy test method based upon the intended use of their enteral syringes in order to demonstrate dose accuracy, regardless of the syringe tip design.

CEN/TC 205 strives to develop a validated test method for dose accuracy of enteral syringes.

#### K.4 Potential incompatibility with ISO 80369-3:2016 Male E1 connector

The alternative enteral syringe tip described in [Figure K.1](#) and [Table K.1](#) might not be compatible with the male E1 connector defined in ISO 80369-3, when the male E1 connector does not conform to the alternative dimensions of the inside diameter at the tip of the male taper ( $\varnothing f$ ), the internal lumen draft angle (starting at  $\varnothing f$ ) (a3) and the internal lumen depth (r3) (see ISO 80369-3:2016/A 1:2019, Table B.1, Note g). The use of the alternative enteral syringe tip described in [Figure K.1](#) and [Table K.1](#) should be considered based upon the outcome of the risk management process for the applicable medical device. In addition, the use of male E1 connectors which do not conform dimensionally with the guidelines stated in ISO 80369-3:2016/A 1:2019, Table B.1, Note g, should be considered based upon the outcome of the risk management process for the applicable medical device.

#### K.5 Potential misconnection

##### K.5.1 Alternative syringe tip and ISO 80369-5 Male S1 connector

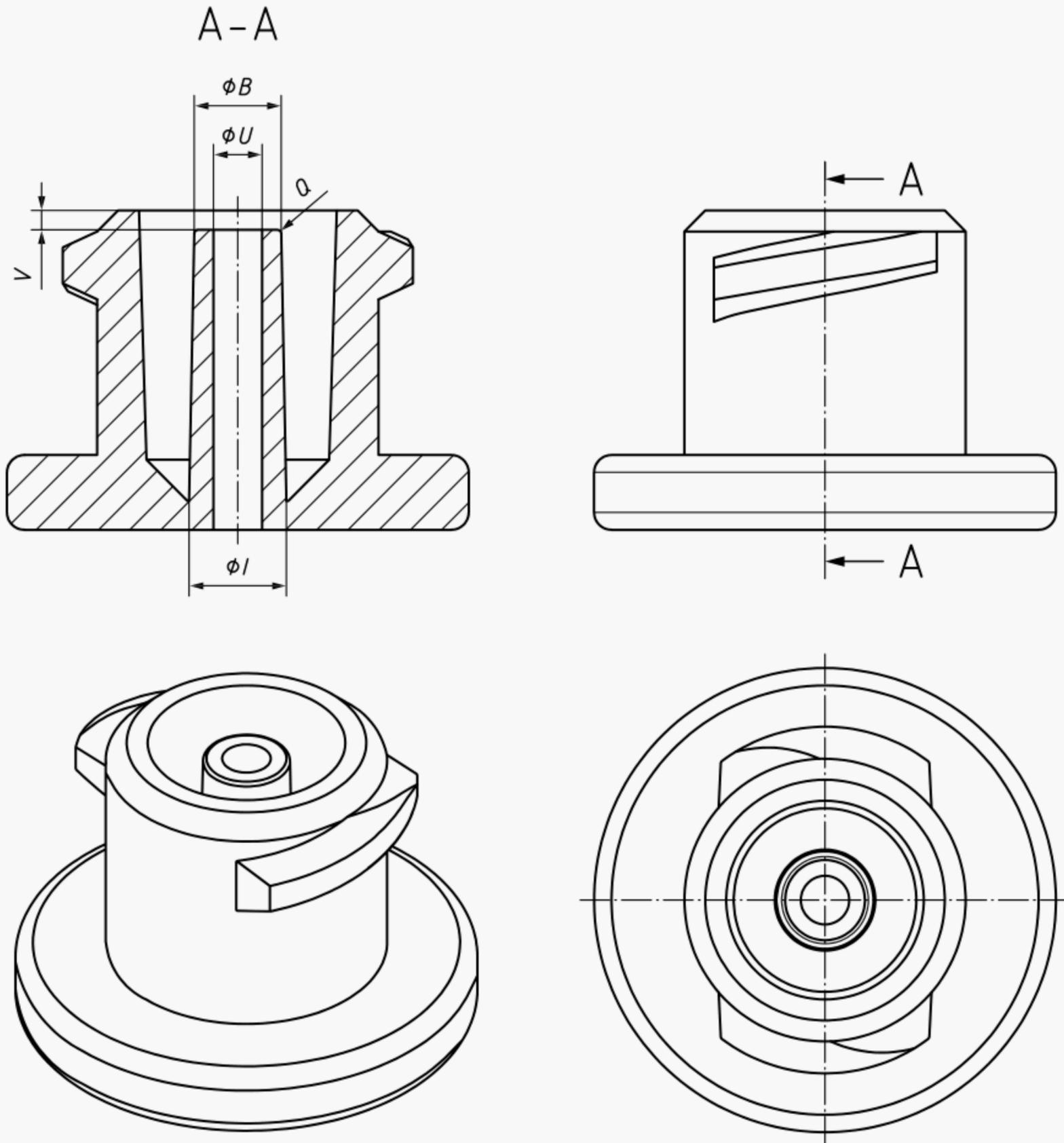
The alternative enteral syringe tip (described in [Figure K.1](#) and [Table K.1](#)) includes a male nozzle which allows it to be inserted into the through bore of the ISO 80369-5 male S1 limb cuff connector. The male S1 connector is used on the cuff. The cuff is not a pressure or fluid source. This misconnection could

connect an alternative enteral syringe tip to a cuff, which could allow a cuff to fill with fluid. Risks associated with this misconnection are considered low, however manufacturers should assess this particular misconnection as applied to their medical device.

### **K.5.2 Alternative syringe tip and ISO 80369-7 Male (Slip and Lock) L1 connector**

The alternative enteral syringe tip (described in [Figure K.1](#) and [Table K.1](#)) includes a male nozzle which could be inserted into the through bore of the male Luer (ISO 80369-7, L1) connector. The computer-aided design (CAD) analysis predicted that male L1 connectors with inner diameters of less than or equal to 2,24 mm will not misconnect. Male L1 connectors with inner diameters greater than 2,24 mm might misconnect with the alternative enteral syringe tip.

The male L1 connector is located on the administration device of intravenous (IV) systems, either on the IV syringe or on the distal end of the IV administration set. A misconnection with the alternative enteral syringe tip would result in an administration device-to-administration device connection (e.g. a syringe-to-syringe connection). Patient harm might occur when fluid is transferred from one administration device to another and the administration of this fluid into an unintended clinical administration route (e.g. fluid transfer from the alternative enteral syringe to the IV syringe and the administration of the enteral fluid into the IV system via the IV syringe). Risks associated with this misconnection are considered low, however manufacturers should assess this particular misconnection as applied to their medical device.



NOTE See [Table K.1](#).

Figure K.1 — Alternative ENTERAL SYRINGE tip

Table K.1 — Alternative ENTERAL SYRINGE tip

Reference	Designation	Dimension mm		
		Minimum	Nominal	Maximum
$\varnothing B$	Outside diameter at the tip of the male taper	2,45	2,50	2,55
$\varnothing I$	Outside diameter at the larger end of the male taper	—	—	2,85
$Q$	Radius at the outside tip of the male taper (REFERENCE ONLY)	—	—	0,15
$\varnothing U$	Inside diameter of the fluid lumen of the connector	1,20	—	1,45
$V$	Recess of the tip of the male taper from the open end of the female taper	0,45	0,55	0,65

NOTE All undefined dimensions in [Figure K.1](#) can be found in ISO 80369-3:2016, Figure B.2 and Table B.2.

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