SLOVENSKI STANDARD
SIST EN 1733:2000

01-januar-2000

Aspiracijski katetri za ļ iģļ enje dihalnih poti

Suction catheters for use in the respiratory tract

Absaugkatheter zur Verwendung im Atemtrakt

Sondes d'aspiration pour les voies respiratoires

Ta slovenski standard je istoveten z: **EN 1733:1998**

ICS:

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment
11.040.25	Injekcijske brizge, igle in katetri	Syringes, needles an catheters

SIST EN 1733:2000 **en**

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN 1733

February 1998

ICS 11.040.10; 11.040.20

Descriptors: medical equipment, tracheal tubes, specifications, definitions, designation, dimensions, design, mechanical strength, tests, packing, marking, labelling

English version

Suction catheters for use in the respiratory tract

Sondes d'aspiration pour les voies respiratoires

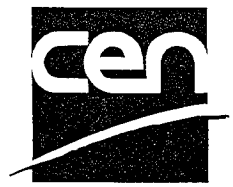
Absaugkatheter zur Verwendung im Atemtrakt

This European Standard was approved by CEN on 5 July 1997.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.



EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Central Secretariat: rue de Stassart, 36 B-1050 Brussels

Contents **Page**

Foreword

This European Standard has been prepared by Technical Committee CEN/TC 215 "Respiratory and anaesthetic equipment", the secretariat of which is held by BSI.

This European Standard is based on ISO 8836: 1988 Suction catheters for use in the respiratory tract, prepared by ISO/TC 121. However, it differs from ISO 8836 in that it introduces a table of colour identification for use with suction catheters. It no longer includes requirements for suction catheters made of rubber, and the size should be designated by outside diameter expressed in millimetres.

Annexes A, B and C are normative and form part of this European Standard. Annexes D and E are for information only.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by August 1998, and conflicting national standards shall be withdrawn at the latest by August 1998.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Introduction

This European Standard specifies dimensions and requirements for suction catheters for use in the respiratory tract.

Size is designated by outside diameter which is important when selecting catheters, because of its relationship to the ease with which the catheter can be passed through a tracheal or tracheostomy tube (see prEN 1782 for details of tracheal tube standards and EN 1282-1 and EN 1282-2 for details of tracheostomy tube standards). Requirements for suction catheters made of rubber have been deleted because such catheters are no longer in general use.

Flammability of suction catheters, for example if flammable anaesthetics or lasers are used, is a well-recognized hazard that is addressed by appropriate clinical management, and is outside the scope of this standard.

1 Scope

This European Standard specifies requirements for suction catheters made of plastics materials and intended for use in suction of the respiratory tract. Specialized suction catheters are excluded from the scope of this standard. Angled tip suction catheters (e.g. Coudé catheters) are not considered to be specialized and are therefore included in the scope.

2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

EN 556: 1994	Sterilization of medical devices - Requirements for medical devices to be labelled 'STERILE'
EN 868-1	Packaging materials and systems for medical devices which are to be sterilized - Part 1: General requirements and test methods
EN 30993-1	Biological evaluation of medical devices - Part 1: Guidance on selection of tests (ISO 10993-1 : 1992 + Technical Corrigendum 1 : 1992)
ISO 468	Surface roughness - Parameters, their values and general rules for specifying requirements

3 Definitions

For the purposes of this European Standard, the following definitions apply.

3.1 adaptor: Specialized connector to establish functional continuity between otherwise disparate or incompatible components.

3.2 connector: Fitting to join together two or more components. [EN ISO 4135: 1996]

3.3 effective shaft length: The main part of the catheter which is of uniform outside diameter.

3.4 eye: Lateral aperture near the patient end of the catheter. [EN ISO 4135: 1996]

3.5 machine end: That end of the catheter which is intended to be connected to a source of vacuum [EN ISO 4135 : 1996].

3.6 patient end: That end of the catheter which is intended to be inserted into the patient [EN ISO 4135 : 1996].

3.7 residual vacuum: The negative pressure at the patient end of the suction catheter when the vacuum control device is in the relief position.

3.8 suction catheter: Flexible tube designed for introduction into a respiratory tract to remove material by suction. [EN ISO 4135: 1996]

3.9 tip: Extremity of the patient end of a catheter. [EN ISO 4135: 1996]

3.10 vacuum control device: Means provided at the machine end of a catheter to control the flow of air and entrained material [EN ISO 4135 : 1996].

3.11 terminal orifice: Central opening of the patient end of the suction catheter.

4 Size designation and dimensions

4.1 Size designation

4.1.1 The size of suction catheters shall be designated by the following:

a) the outside diameter of the effective shaft length, expressed in millimetres;

NOTE: It can additionally be expressed in French (Charrière) gauge size.

b) the nominal effective shaft length, expressed in millimetres.

4.1.2 The size of the catheter can additionally be designated by the use of colour identification at the machine end. If a colour code is used it shall be in accordance with table 1.

Table 1: Colour identification for designated size of suction catheter

Designated size		Colour identification
Nominal outside diameter (mm)	French (Charrière) size equivalent	
1,67	5	grey
2,0	6	light green
2,5	7,5	pink
2,67	8	light blue
3,0	9	turquoise
3,33	10	black
4,0	12	white
4,67	14	green
5,0	15	brown
5,33	16	orange
6,0	18	red
6,67	20	yellow

4.2 Dimensions

4.2.1 The outside diameter and the minimum inside diameter of suction catheters excluding at the tip shall be in accordance with table 2 or table 3.

NOTE: For the purposes of this European Standard, the French (Charrière) gauge system of size is based on the outside diameter of the shaft gauged in steps of thirds of a millimetre (1 millimetre corresponds to 3F); the French gauge size is not an SI unit. Size designation in millimetres facilitates matching suction catheter outside diameter to the inside diameter of the tracheal or tracheostomy tube.

4.2.2 The minimum inside diameter at the tip shall be not less than 90 % of the minimum inside diameter specified in tables 2 and 3.

Table 2: Basic dimensions of suction catheters - Metric sizes

Designated size		Outside diameter tolerance mm	Minimum inside diameter mm
Nominal outside diameter mm	French (Charrière) size equivalent [1)]		
1,5	4,5 F	± 0,1	0,8
2	6 F	± 0,1	1,05
2,5	7,5 F	± 0,1	1,45
3	9 F	± 0,15	1,75
4	12 F	± 0,15	2,45
5	15 F	± 0,2	3,2
6	18 F	± 0,2	3,9

[1)] The letters "Ch" can replace the letter "F" in the size designation (see 4.1.1); 1 F or 1 Ch corresponds to one-third of a millimetre for the outside diameter (see also 9.3b) and 9.4b)).

Table 3: Basic dimensions of suction catheters - French (Charrière) sizes

Designated size		Outside diameter tolerance (mm)	Minimum inside diameter (mm)
French size[1)]	Outside diameter equivalent [1)] (mm)		
4 F	1,33	± 0,1	0,55
5 F	1,67	± 0,1	0,8
6 F	2	± 0,1	1,05
8 F	2,67	± 0,1	1,5
10 F	3,33	± 0,15	2
12 F	4	± 0,15	2,45
14 F	4,67	± 0,2	2,95
16 F	5,33	± 0,2	3,4
18 F	6	± 0,2	3,9
20 F	6,67	± 0,2	4,3

[1)] The letters "Ch" can replace the letter "F" in the size designation (see 4.1.1); 1 F or 1 Ch corresponds to one-third of a millimetre for the outside diameter (see also 9.3b) and 9.4b)).

4.2.3 The actual effective shaft length shall be the marked effective length subject to a tolerance of ± 5 %.

5 Materials

Suction catheters for use in the respiratory tract, in their ready-for-use state after any preparation for use recommended by the manufacturer, shall satisfy appropriate biological safety testing, as indicated in EN 30993-1.

NOTE: It is recommended that the shaft be colourless and either transparent or translucent