SLOVENSKI STANDARD

oSIST prEN ISO 8836:2018

01-november-2018

Aspiracijski katetri za čiščenje dihalnih poti (ISO/DIS 8836:2018)

Suction catheters for use in the respiratory tract (ISO/DIS 8836:2018)

Absaugkatheter zur Verwendung im Atemtrakt (ISO/DIS 8836:2018)

Sondes d'aspiration pour les voies respiratoires (ISO/DIS 8836:2018)

Ta slovenski standard je istoveten z: prEN ISO 8836

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

oSIST prEN ISO 8836:2018 en

DRAFT INTERNATIONAL STANDARD

ISO/DIS 8836

ISO/TC **121**/SC **2** Secretariat: **ANSI**

Voting begins on: **2018-08-21**

Voting terminates on: **2018-11-13**

Suction catheters for use in the respiratory tract

Sondes d'aspiration pour les voies respiratoires

ICS: 11.040.25; 11.040.10

This document is circulated as received from the committee secretariat.

ISO/CEN PARALLEL PROCESSING

Reference number
ISO/DIS 8836:2018(E)

COPYRIGHT PROTECTED DOCUMENT

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

A.3.2 CLOSED SUCTION CATHETER MANIFOLD 23
A.3.18 SUCTION CATHETER CONNECTOR 23
A.4 General requirements for open and CLOSED SUCTION CATHETERS 24
A.6.3.5 SUCTION CATHETER CONNECTORS 24
A.6.4.2.3 CLOSED SUCTION CATHETER MANIFOLD rotation 24
A.6.4.2.7 Internal volume 25
A.6.4.4 SUCTION CONTROL DEVICE 25
A.6.5.4 Leakage 25
A.6.5.5 Resistance to flow 25
A.Annex D 26
A.Annex D.2.2 26
Annex B (normative) ***Test method for security of attachment** 27
B.1 Principle 27
B.2 Apparatus 27
B.3 Procedure 27
B.4 Expression of results 27
Annex C (normative) **Measurement of residual vacuum** 28
C.1 Principle 28
C.2 Apparatus 28
C.3 Procedure 28
C.4 28
Expression of results 28
Annex D (normative) ***Method of testing leakage** 30
D.1 Principle 30
D.2 Apparatus 30
D.3 Procedure 30
D.4 Expression of results 30
Annex E (informative) **Hazard identification for risk assessment** 31
General 31
E.1 Patient harm associated with the use of SUCTION CATHETERS 31
E.1.1 Patient harm associated with the placement, removal and use of SUCTION CATHETERS 31
E.1.2 Patient harm associated with routine use of normal saline instillation and SUCTION CATHETERS 31
E.1.3 Patient or user harm associated with toxicity 32
E.2 Hazardous situations and hazards associated with the use of SUCTION CATHETERS 32
Bibliography 34

86

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. 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. 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 on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 2, *Airways and related equipment.*

This fifth edition of ISO 8836 cancels and replaces the fourth edition (ISO 8836:2014), of which it constitutes a technical revision.

The main changes are: The Standard has been formatted to align with ISO 18190, Anaesthetic and respiratory equipment -- General requirements for airways and related equipment. It is no longer a requirement to have only male type SUCTION CATHETER CONNECTOR on the SUCTION CATHETER, female type SUCTION CATHETER CONNECTOR has been reinstated following removal in the 2014 version of this Standard. The Terms and definitions in the standard have been revised. The conditions for the measurement of residual vacuum in CLOSED SUCTION CATHETERS has been revised.

Introduction

This International Standard specifies dimensions and requirements for SUCTION CATHETERS for use in the respiratory tract. It is concerned with the basic requirements and method of size designation of both OPEN and CLOSED SUCTION CATHETERS made of flexible materials.

The method of describing tube dimensions and configuration has been devised in order to assist clinicians in the selection of the most suitable SUCTION CATHETER for a particular patient. Size is designated by outside diameter which is important when selecting a catheter because of its relationship to the ease with which the catheter can be passed through a TRACHEAL OR TRACHEOSTOMY TUBE.[2][3]

Throughout this International Standard the following print types are used:

— Requirements and definitions: roman type;

— *Compliance checks and test specifications: italic type;*

— Informative material appearing outside of tables, such as notes, examples and references: smaller type. The normative text of tables is also in smaller type;

— DEFINED TERMS APPEAR IN SMALL CAPS

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex A.

The attention of Member Bodies and National Committees is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised ISO or IEC publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for implementation nationally not earlier than 3 years from the date of publication for equipment newly designed and not earlier than 5 years from the date of publication for equipment already in production.

Suction catheters for use in the respiratory tract

1 Scope

This International Standard specifies requirements for SUCTION CATHETERS, made of flexible materials and intended for use in suctioning of the respiratory tract.

SUCTION CATHETERS intended for use with flammable anaesthetic gases or agents, lasers or electrosurgical equipment are not covered by this International Standard.

NOTE See ISO/TR 11991 for guidance on airway management during laser surgery of the upper airway.[5]

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 5356-1, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets*

ISO 5367:2016 *Anaesthetic and respiratory equipment — Breathing sets and connectors*

ISO 10079-1, *Medical suction equipment — Part 1: Electrically powered suction equipment*

ISO 10079-2, *Medical suction equipment — Part 2: Manually powered suction equipment*

ISO 10079-3, *Medical suction equipment — Part 3: Suction equipment powered from a vacuum or positive pressure gas source*

ISO 14971:2007, *Medical devices — Application of risk management to medical devices*

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

ISO 18190, *Anaesthetic and respiratory equipment -- General requirements for airways and related equipment*

ISO 18562-1, *Biocompatibility evaluation of breathing gas pathways in healthcare applications -- Part 1: Evaluation and testing within a risk management process*

ISO 80369-7, *Small-bore connectors for liquids and gases in healthcare applications -- Part 7: Connectors for intravascular or hypodermic applications*

EN 15986, *Symbol for use in the labelling of medical devices — Requirements for labelling of medical devices containing phthalates*

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

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 4135[1] and ISO 14971 and the following apply.

3.1
***CLOSED SUCTION CATHETER**
SUCTION CATHETER enclosed within a PROTECTIVE SLEEVE that allows its use within the airway without opening the BREATHING SYSTEM directly to atmosphere

3.2
***CLOSED SUCTION CATHETER MANIFOLD**
part of the CLOSED SUCTION CATHETER that provides a connection to an airway device

3.3
CONNECTOR
fitting to join together two or more components

[SOURCE: ISO 4135:2001, 4.2.2.1]

3.4
EYE
side hole near the patient end of the SUCTION CATHETER

[SOURCE: ISO 4135:2001, 8.3.6]

3.5
MACHINE END
that end of the catheter which is intended to be connected to suction tubing

[SOURCE: ISO 4135:2001, 8.3.2]

3.6
PATIENT END
The end of the SUCTION CATHETER which is intended to be inserted into a patient

[Source: ISO 4135:2001, 8.3.3]

3.7
PATIENT CONNECTION PORT
opening intended for connection to an airway device

[SOURCE: ISO 4135:2001, 4.2.1.2]

3.8
PROTECTIVE SLEEVE
flexible barrier that encloses the SUCTION CATHETER shaft to prevent contact with the user while connected to the VBS

3.9
RESIDUAL VACUUM
negative pressure at the TIP of the CLOSED SUCTION CATHETER when the SUCTION CONTROL DEVICE is in the relief position

3.10

RISK
combination of the probability of occurrence of harm and the severity of that harm

[SOURCE: ISO 14971:2007]

3.11
RISK ANALYSIS
systematic use of available information to identify hazards and to estimate the RISK

Note to entry RISK ANALYSIS includes examination of different sequences of events that can produce hazardous situations and harm (see ISO 14971:2007, Annex F).

[SOURCE: ISO 14971:2007]

3.12
RISK ASSESSMENT
overall process comprising a RISK ANALYSIS and a RISK EVALUATION

[SOURCE: ISO 14971:2007]

3.13
RISK EVALUATION
process of comparing the estimated RISK against given RISK criteria to determine the acceptability of the RISK

[SOURCE: ISO 14971:2007]

3.14
RISK MANAGEMENT
systematic application of management policies, procedures and practices to the tasks of analysing, evaluating, controlling and monitoring RISK

[SOURCE: ISO 14971:2007]

3.15
RISK MANAGEMENT FILE
set of records and other documents that are produced by RISK MANAGEMENT

[SOURCE: ISO 14971:2007, 2.23]

3.16
SHAFT
main part of the SUCTION CATHETER which is of uniform outside diameter

3.17
SINGLE-FAULT CONDITION
condition in which a single means for reducing a RISK is defective or a single abnormal condition is present

3.18
SUCTION CATHETER
flexible tube designed for introduction into the respiratory tract or an airway device to remove material by suction

[SOURCE: ISO 4135]