Anaesthetic and respiratory equipment - Voice prostheses (ISO 21917:2021)

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 21917:2022 sisaldab Euroopa standardi EN ISO 21917:2022 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 21917:2022 consists of the English text of the European standard EN ISO 21917:2022.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 21.12.2022.	Date of Availability of the European standard is 21.12.2022.
Standard on kättesaadav Eesti Standardimis-ja Akrediteerimiskeskusest.	The standard is available from the Estonian Centre for Standardisation and Accreditation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 11.040.10, 11.040.40

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 21917

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English Version

Anaesthetic and respiratory equipment - Voice prostheses (ISO 21917:2021)

Matériel d'anesthésie et de réanimation respiratoire - Implants phonatoires (ISO 21917:2021)

Anästhesie- und Beatmungsgeräte - Stimmprothesen (ISO 21917:2021)

This European Standard was approved by CEN on 18 December 2022.

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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Ref. No. EN ISO 21917:2022 E

European foreword

The text of ISO 21917:2021 has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" of the International Organization for Standardization (ISO) and has been taken over as EN ISO 21917:2022 by Technical Committee CEN/TC 215 "Respiratory and anaesthetic equipment" the secretariat of which is held by BSI.

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of an identical text or by endorsement, at the latest by June 2023, and conflicting national standards shall be withdrawn at the latest by June 2023.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

Any feedback and questions on this document should be directed to the users' national standards body. A complete listing of these bodies can be found on the CEN website.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

Endorsement notice

The text of ISO 21917:2021 has been approved by CEN as EN ISO 21917:2022 without any modification.

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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).

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).

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.

This document was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 2, *Airways and related equipment* and is written following the format of ISO 18190 *General standard for airways and related equipment*. The requirements in this device-specific standard take precedence over any conflicting requirements in the general standard.

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.

Introduction

Voice prostheses are used to restore voice in patients after total laryngectomy. They are placed into a surgically created tracheoesophageal puncture (TEP). The placement can be performed during the laryngectomy (primary placement), later after healing as an endoscopic procedure (secondary placement) or in order to replace a *voice prosthesis* (replacement procedure). There exist different prosthesis specific placement tools to insert a *voice prosthesis* into the TEP. Placement of the *voice prosthesis* can be performed via the tracheostoma (anterograde), via the mouth (retrograde) and via the surgical wound (intraoperative).

Voice prostheses have three essential functions:

— they prevent spontaneous closure of the TEP;

— they allow airflow into the pharynx for the creation of speech;

— they seal the TEP during swallowing.

Safe retention of the *voice prosthesis* is achieved by the oesophageal and tracheal flanges. The oesophageal flange is placed into the oesophagus, the tracheal flange is placed in the trachea. In order to prevent leakage of food and saliva into the trachea *voice prostheses* have a one-way valve that opens in the direction of the oesophagus.

Voice prostheses have a limited service life and have to be replaced if they start leaking or if they are overgrown with a biofilm.

There are two groups of *voice prostheses*:

— indwelling *voice prostheses*, and

— non-indwelling *voice prostheses.*

Indwelling *voice prostheses* are placed by a professional (e.g., speech-language pathologist, physician) and left in the TEP until they fail. They are then replaced.

Non-indwelling *voice prostheses* are replaced by the patient himself after a certain training period.

The following three most common test methods have been included to determine:

a) *Leakage*, which provides information about the basic one-way function of the *voice prosthesis* valve.

b) The valve *opening pressure*, which evaluates the ability of the valve to withstand phenomena that can cause leaking/aspiration during swallowing and inspiration.

c) *Characteristic curve*, which allows an assessment of the air flow resistance of the *voice prosthesis* during speech.

Annex A contains rationale statements for some of the requirements of this document and recommendations that have been incorporated into this document. It is considered that knowledge of the reasons for the requirements and recommendations will not only facilitate the proper application of this document but will expedite any subsequent revisions.

Throughout this document the following print types are used:

— Requirements and definitions: roman type.

— Informative material appearing outside of tables, such as notes, examples and references: smaller type.

— *Terms defined in Clause 3: italic type.*

Anaesthetic and respiratory equipment — Voice prostheses

1 Scope

This document specifies performance requirements for *voice prostheses* including requirements for marking, packaging and information to be provided by the manufacturer as well as test methods for the evaluation of physical characteristics of *voice prostheses*.

NOTE There is guidance or rationale for this list item contained in A.2.

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

ISO 18190:2016, *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*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 18190 and the following apply.

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

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
characteristic curve
curve that defines the relationship between pressure and flow across the voice prosthesis

3.2
flange dimension
main dimensions of the tracheal and oesophageal flanges

EXAMPLE For a round flange, the outside diameter; for an oval flange, the major and minor dimensions.

3.3
in-situ service life
time between insertion and removal of a voice prosthesis

3.4
leakage
the rate at which the test media leaks from the oesophageal side to the tracheal side of the voice prosthesis