



**SLOVENSKI STANDARD
SIST EN ISO 20789:2019**

01-november-2019

Anestezijska in dihalna oprema - Pasivni vlažilniki (ISO 20789:2018)

Anaesthetic and respiratory equipment - Passive humidifiers (ISO 20789:2018)

Anästhesie- und Beatmungsgeräte - Passive Anfeuchter (ISO 20789:2018)

Matériel d'anesthésie et de réanimation respiratoire - Humidificateurs passifs (ISO 20789:2018)

ITEH STANDARD PREVIEW
(standards.iteh.ai)

Ta slovenski standard je istoveten z: EN ISO 20789:2019

[SIST EN ISO 20789:2019](https://standards.iteh.ai/catalog/standards/sist/141e491b-da81-46bd-82c4-0df24f29fad/sist-en-iso-20789-2019)

<https://standards.iteh.ai/catalog/standards/sist/141e491b-da81-46bd-82c4-0df24f29fad/sist-en-iso-20789-2019>

ICS:

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment
-----------	--	--

SIST EN ISO 20789:2019

en

iTeh STANDARD PREVIEW
(standards.iteh.ai)

SIST EN ISO 20789:2019

<https://standards.iteh.ai/catalog/standards/sist/141e491b-da81-46bd-82c4-0df24f29fad/sist-en-iso-20789-2019>

EUROPEAN STANDARD

EN ISO 20789

NORME EUROPÉENNE

EUROPÄISCHE NORM

September 2019

ICS 11.040.10

English Version

Anaesthetic and respiratory equipment - Passive humidifiers (ISO 20789:2018)

Matériel d'anesthésie et de réanimation respiratoire -
Humidificateurs passifs (ISO 20789:2018)

Anästhesie- und Beatmungsgeräte - Passive Anfeuchter
(ISO 20789:2018)

This European Standard was approved by CEN on 28 July 2019.

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 CEN-CENELEC Management Centre 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 CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of 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, Turkey and United Kingdom.

<https://standards.iteh.ai/catalog/standards/sist/141e491b-da81-46bd-82c4-0df24f29fad/sist-en-iso-20789-2019>



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

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

Contents	Page
European foreword.....	3

iTeh STANDARD PREVIEW
(standards.iteh.ai)

SIST EN ISO 20789:2019
<https://standards.iteh.ai/catalog/standards/sist/141e491b-da81-46bd-82c4-0df24f29fad/sist-en-iso-20789-2019>

European foreword

The text of ISO 20789:2018 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 20789:2019 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 March 2020, and conflicting national standards shall be withdrawn at the latest by March 2020.

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.

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, Turkey and the United Kingdom.

iTeh STANDARD PREVIEW **Endorsement notice** **(standards.iteh.ai)**

The text of ISO 20789:2018 has been approved by CEN as EN ISO 20789:2019 without any modification.

[SIST EN ISO 20789:2019](https://standards.iteh.ai/catalog/standards/sist/141e491b-da81-46bd-82c4-0df24f29fad/sist-en-iso-20789-2019)

<https://standards.iteh.ai/catalog/standards/sist/141e491b-da81-46bd-82c4-0df24f29fad/sist-en-iso-20789-2019>

iTeh STANDARD PREVIEW
(standards.iteh.ai)

SIST EN ISO 20789:2019

<https://standards.iteh.ai/catalog/standards/sist/141e491b-da81-46bd-82c4-0df24f29fad/sist-en-iso-20789-2019>

INTERNATIONAL
STANDARD

ISO
20789

First edition
2018-07

**Anaesthetic and respiratory
equipment — Passive humidifiers**

*Matériel d'anesthésie et de réanimation respiratoire —
Humidificateurs passifs*

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[SIST EN ISO 20789:2019](https://standards.iteh.ai/catalog/standards/sist/141e491b-da81-46bd-82c4-0df24f29fad/sist-en-iso-20789-2019)

<https://standards.iteh.ai/catalog/standards/sist/141e491b-da81-46bd-82c4-0df24f29fad/sist-en-iso-20789-2019>



Reference number
ISO 20789:2018(E)

© ISO 2018

iTeh STANDARD PREVIEW (standards.iteh.ai)

SIST EN ISO 20789:2019

<https://standards.iteh.ai/catalog/standards/sist/141e491b-da81-46bd-82c4-0df24f29fad/sist-en-iso-20789-2019>



COPYRIGHT PROTECTED DOCUMENT

© ISO 2018

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

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

Contents

	Page
Foreword	v
Introduction	vi
1 * Scope	1
2 Normative references	2
3 Terms and definitions	3
4 General requirements for testing	5
4.1 Water level.....	5
4.2 PASSIVE HUMIDIFIER test conditions.....	6
4.3 * Gas flowrate and leakage specifications.....	6
4.4 * PASSIVE HUMIDIFIER testing errors.....	6
5 General requirements	6
5.1 Mechanical BASIC SAFETY for all PASSIVE HUMIDIFIERS.....	6
5.1.1 General.....	6
5.1.2 * Requirements for instability from unwanted lateral movement.....	6
5.1.3 * Requirements for audible acoustic energy.....	7
5.1.4 * Overflow.....	8
5.1.5 * Overpressure requirement.....	8
5.2 Compatibility requirement.....	9
5.3 General requirements for mechanical strength.....	9
6 Identification, marking and ACCOMPANYING DOCUMENTATION	10
6.1 Legibility and durability of markings.....	10
6.1.1 Legibility.....	10
6.1.2 Durability.....	10
6.2 Markings on the outside of the PASSIVE HUMIDIFIER or its parts.....	10
6.2.1 Identification.....	10
6.2.2 Additional requirements.....	11
6.2.3 Requirements for physiological effects.....	12
6.2.4 Requirements for packaging.....	12
6.2.5 Symbols.....	12
6.3 Units of measurement.....	12
6.4 Instructions for use.....	12
6.4.1 Identification.....	12
6.4.2 General requirements.....	13
6.4.3 * Requirements for warnings and safety notices.....	14
6.4.4 Requirements for installation.....	14
6.4.5 Requirements for start-up PROCEDURE.....	14
6.4.6 * Requirements for operating instructions.....	14
6.4.7 Requirements for CLEANING, DISINFECTION, and STERILIZATION.....	16
6.4.8 Requirements for maintenance.....	16
6.4.9 Requirements for ACCESSORIES, supplementary equipment and used material.....	16
6.4.10 Unique version identifier.....	16
6.5 Technical description.....	17
7 * HUMIDIFICATION OUTPUT	17
8 Systems requirements	17
9 Specific SINGLE FAULT CONDITIONS	18
10 * CLEANING and DISINFECTION	18
10.1 General.....	18
10.2 Home healthcare environment.....	18
11 * BREATHING SYSTEM connectors and ports	18
11.1 General.....	18

ISO 20789:2018(E)

11.2	Outlet connector.....	19
11.2.1	Directly connected to the supply source.....	19
11.2.2	Indirectly connected to the supply source.....	19
11.3	FLOW-DIRECTION-SENSITIVE COMPONENTS.....	19
11.4	* Accessory port.....	19
11.5	Monitoring probe port.....	20
11.6	Oxygen inlet port.....	20
11.6.1	Directly connected to the supply source.....	20
11.6.2	Indirectly connected to the supply source.....	20
11.7	Air inlet port.....	20
11.7.1	Directly connected to the supply source.....	20
11.7.2	Indirectly connected to the supply source.....	20
11.8	Filling port.....	20
12	* Requirements for the BREATHING SYSTEM and ACCESSORIES.....	21
12.1	General.....	21
12.2	Accompanying documentation.....	21
12.3	BREATHING TUBES.....	21
12.4	Liquid container level.....	21
12.5	Filling cap.....	21
13	Compatibility with substances.....	22
14	* BIOCOMPATIBILITY.....	22
15	* Requirements for fire prevention.....	22
16	USABILITY.....	23
Annex A	(informative) Rationale and guidance.....	25
Annex B	(informative) Symbols on marking.....	33
Annex C	(normative) Determination of HUMIDIFICATION OUTPUT.....	35
Annex D	(informative) Reference to the ESSENTIAL PRINCIPLES.....	39
Annex E	(informative) Terminology — Alphabetized index of defined terms.....	41
Bibliography	43

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 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 WTO principles in the Technical Barriers to Trade (TBT) see the following URL: [Foreword - Supplementary information](#)

This document was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment*.

<https://standards.iteh.ai/catalog/standards/sist/141e491b-da81-46bd-82c4-0df24f29fad/sist-en-iso-20789-2019>

ISO 20789:2018(E)

Introduction

This document specifies requirements for so called “cold bubble-through or cold pass-over” respiratory tract PASSIVE HUMIDIFIERS intended for use on PATIENTS in home care and in healthcare facilities. PASSIVE HUMIDIFIERS are used to raise the water content of gases delivered to PATIENTS. Gases available for medical use do not contain sufficient moisture and can damage or irritate the respiratory tract or desiccate secretions of PATIENTS whose upper airways have been bypassed. Inadequate humidity at the PATIENT-CONNECTION PORT can cause drying of the upper airway, or desiccation of tracheo-bronchial secretions in the tracheal or tracheostomy tube, which can cause narrowing or even obstruction of the airway^{[1][2]}¹⁾.

PASSIVE HUMIDIFIERS rely on moisture being transferred from a LIQUID RESERVOIR to the gas at room temperature, without heating of either the HUMIDIFICATION CHAMBER or BREATHING TUBES, to increase the water content of gases delivered to PATIENTS. Hence, such respiratory tract PASSIVE HUMIDIFIERS have a lower mg/l output than active humidifiers. Refer to ISO 80601-2-74 for BASIC SAFETY and ESSENTIAL PERFORMANCE of active humidifiers.

Since the safe use of a PASSIVE HUMIDIFIER depends on the interaction of the PASSIVE HUMIDIFIER with its ACCESSORIES, this document sets total system performance requirements up to the PATIENT-CONNECTION PORT. These requirements are applicable to ACCESSORIES such as BREATHING TUBES.

This document also constitutes a major technical revision of a portion of ISO 8185:2007^[3], which it replaces in combination with ISO 80601-2-74. The most significant changes relative to ISO 8185:2007 for PASSIVE HUMIDIFIERS are the following modifications:

- extending the scope to include the PASSIVE HUMIDIFIER and its ACCESSORIES, where the characteristics of those ACCESSORIES can affect the BASIC SAFETY or ESSENTIAL PERFORMANCE of the PASSIVE HUMIDIFIER, and thus not only the PASSIVE HUMIDIFIER itself;
 - modification of the humidification test PROCEDURE and the disclosure of humidification performance;
- and the following additions:

- requirements for mechanical strength (via IEC 60601-1-11);
- new symbols;
- requirements for a PASSIVE HUMIDIFIER as a component of a system;
- requirements for CLEANING and DISINFECTION PROCEDURES;
- requirements for BIOCOMPATIBILITY;
- requirements for fire prevention;
- requirements for USABILITY.

PASSIVE HUMIDIFIERS are commonly used with air and air-oxygen mixtures and a PASSIVE HUMIDIFIER should be able to operate with these gases. Care should be taken if using other gas mixtures such as helium/oxygen mixtures as their physical properties are different from those of air and oxygen.

In this document, the following print types are used:

- requirements and definitions: roman type;
- *test specifications: italic type;*
- informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type;

1) Figures in square brackets refer to the Bibliography.

— TERMS DEFINED IN [CLAUSE 3](#) OF THIS DOCUMENT OR AS NOTED: SMALL CAPITALS.

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 conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this document, the auxiliary verb:

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

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](#).

iTeh STANDARD PREVIEW (standards.iteh.ai)

[SIST EN ISO 20789:2019](#)

<https://standards.iteh.ai/catalog/standards/sist/141e491b-da81-46bd-82c4-0df24f29fad/sist-en-iso-20789-2019>

iTeh STANDARD PREVIEW
(standards.iteh.ai)

SIST EN ISO 20789:2019

<https://standards.iteh.ai/catalog/standards/sist/141e491b-da81-46bd-82c4-0df24f29fad/sist-en-iso-20789-2019>

Anaesthetic and respiratory equipment — Passive humidifiers

1 * Scope

This document specifies requirements for so-called “cold bubble-through” or “cold pass-over” humidifying equipment, hereafter referred to as a PASSIVE HUMIDIFIER. [Figure 1](#) and [Figure 2](#) illustrate these PASSIVE HUMIDIFIERS.

NOTE 1 PASSIVE HUMIDIFIER HUMIDIFICATION CHAMBERS are at room temperature so they have a lower HUMIDIFICATION OUTPUT than active humidifiers.



SIST EN ISO 20789:2019
<https://standards.iteh.ai/catalog/standards/sist/en-iso-20789-2019/0df24f29fad/sist-en-iso-20789-2019>
Figure 1 — Cold pass-over PASSIVE HUMIDIFIER

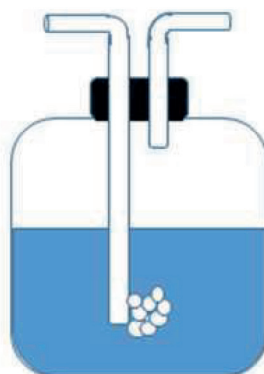


Figure 2 — Cold bubble-through PASSIVE HUMIDIFIER

This document is also applicable to those ACCESSORIES intended by their MANUFACTURER to be connected to a PASSIVE HUMIDIFIER.

A PASSIVE HUMIDIFIER integrated into another MEDICAL DEVICE is subject to the requirements of the standard of the other MEDICAL DEVICE.

EXAMPLE 1 The requirements in ISO 80601-2-69^[4] also apply to a PASSIVE HUMIDIFIER integrated into an oxygen concentrator.

EXAMPLE 2 The requirements in ISO 80601-2-70^[5] also apply a PASSIVE HUMIDIFIER integrated into sleep apnoea therapy equipment.