Irish Standard
I.S. EN ISO 20789:2019

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

I.S. EN ISO 20789:2019

Incorporating amendments/corrigenda/National Annexes issued since publication:

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I.S. xxx: Irish Standard — national specification based on the consensus of an expert panel and subject to public consultation.

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National Foreword

I.S. EN ISO 20789:2019 is the adopted Irish version of the European Document EN ISO 20789:2019, Anaesthetic and respiratory equipment - Passive humidifiers (ISO 20789:2018)

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 20789

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.

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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of an identical text or by endorsement, at the latest by March 2020, and conflicting national standards shall be withdrawn at the latest by March 2020.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.

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Endorsement notice

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

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INTERNATIONAL STANDARD

ISO 20789

First edition
2018-07

Anaesthetic and respiratory equipment — Passive humidifiers

Matériel d'anesthésie et de réanimation respiratoire — Humidificateurs passifs

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Foreword

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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

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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*.

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.

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.

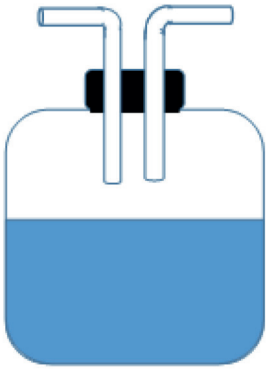

Figure 1 — Cold pass-over PASSIVE HUMIDIFIER

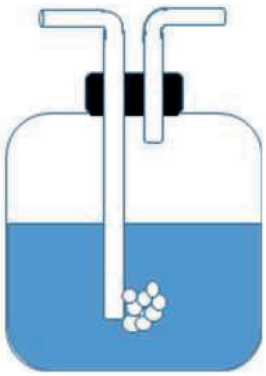

Figure 2 — Cold bubble-through PASSIVE HUMIDIFIER

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.