International Standard

ISO 80601-2-74

Medical electrical equipment —

Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment

Appareils électromédicaux —

Partie 2-74: Exigences particulières pour la sécurité de base et les performances essentielles des équipements d'humidification respiratoire

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Foreword

ISO (the International Organization for Standardization) and IEC (the International Electrotechnical Commission) form the specialized system for worldwide standardization. National bodies that are members of ISO or IEC participate in the development of International Standards through technical committees established by the respective organization to deal with particular fields of technical activity. ISO and IEC technical committees collaborate in fields of mutual interest. Other international organizations, governmental and non-governmental, in liaison with ISO and IEC, also take part in the work.

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 document 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 or www.iec.ch/members_experts/refdocs).

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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. In the IEC, see www.iec.ch/understanding-standards.

This document was prepared jointly by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Respiratory devices and related equipment used for patient care*, and Technical Committee IEC/TC 62, *Medical equipment, software, and systems*, Subcommittee SC 62D, *Particular medical equipment, software, and systems*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 215, *Respiratory and anaesthetic equipment*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This third edition cancels and replaces the second edition (ISO 80601-2-74:2021), which has been technically revised.

The main changes compared to the previous edition are as follows:

— updated normative references;

— added requirements for the fill *connector*; and

— clarified *system recovery* requirements.

A list of all parts in the ISO 80601 and IEC 80601 series can be found on the ISO and IEC websites.

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 and www.iec.ch/national-committees.

Introduction

This document specifies requirements for respiratory humidifying equipment intended for use on *patients* in *home healthcare environment* and in professional healthcare environment. *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 in the inspired gas 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[27] [37]. Heat is employed to increase the water output of the *humidifier*.

In addition, many *humidifiers* utilize heated *breathing tubes* in order to increase operating efficiency and reduce water loss (condensate) as well as heat loss in the *breathing tube*. Some *ventilator* and anaesthesia *breathing tubes* in common use cannot withstand the heat generated by *humidifiers* and *breathing tube* heating mechanisms.

Many *humidifier manufacturers* use off-the-shelf electrical *connectors* for their electrically heated *breathing tubes*. However, since different *manufacturers* have used the same electrical *connector* for different power outputs, electrically heated *breathing tubes* can be physically, but not electrically, interchangeable. Use of improper electrically heated *breathing tubes* has caused overheating, circuit melting, *patient* and *operator* burns and fires. It was not found practical to specify the interface requirements for electrical *connectors* to ensure compatibility between *humidifiers* and *breathing tubes* produced by different *manufacturers*.

Since the safe use of a *humidifier* depends on the interaction of the *humidifier* with its many *accessories*, this document sets total system performance requirements up to the *patient-connection port*. These requirements are applicable to *accessories* such as *breathing tubes* (both heated and non-heated), temperature sensors and equipment intended to control the environment within these *breathing tubes*.

Humidification can also be used by respiratory support *ME equipment* to increase *patient* comfort and compliance with the therapy. Examples are obstructive sleep apnoea and nasal high-flow therapy equipment. The *humidification output* requirements of such *ME equipment* is less demanding as the *patient's* upper airway is not bypassed.

Humidifiers are commonly used with air and air-oxygen mixtures and any *humidifier* should be able to operate with these gases. Care should be taken if using other gas mixes such as helium-oxygen mixtures, as the different physical and thermal properties of these gases may disturb the operation of the *humidifier*.

In this document, the following print types are used:

— requirements and definitions: roman type;

— t*est specifications and terms defined in Clause 3 of the general standard, in this document or as noted: 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;

In referring to the structure of this document, the term

— "clause" means one of the five numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 201 includes subclauses 201.7, 201.8, etc.);

— "subclause" means a numbered subdivision of a clause (e.g. 201.7, 201.8 and 201.9 are all subclauses of Clause 201).

References to clauses within this document are preceded by the term "Clause" followed by the clause number. References to subclauses within this document are by number only.

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.

For the purposes of this document, the auxiliary verb:

— “shall” indicates a requirement;

— “should” indicates a recommendation;

— “may” indicates a permission;

— "can" is used to describe a possibility or capability; and;

— "must" is used to express an external constraint.

Annex C contains a guide to the *marking* and labelling requirements in this document.

Annex D contains a summary of the *symbols* referenced in this document.

Medical electrical equipment —

Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment

201.1 Scope, object and related standards

Clause 1 of IEC 60601-1:2005+AMD1:2012+AMD2:2020 applies, except as follows.

NOTE The general standard is IEC 60601-1:2005+AMD1:2012+AMD2:2020.

201.1.1 Scope

Replacement:

NOTE 1 There is guidance or rationale for this subclause contained in AA.2.1.

This document applies to the *basic safety* and *essential performance* of a *humidifier*, also hereafter referred to as *ME equipment,* in combination with its *accessories*, the combination also hereafter referred to as *ME system.*

This document is also applicable to those *accessories* intended by their *manufacturer* to be connected to a *humidifier* where the characteristics of those *accessories* can affect the *basic safety* or *essential performance* of the *humidifier*.

EXAMPLE 1 Heated *breathing tube*s (heated-wire *breathing tubes*) or *ME equipment* intended to control these heated *breathing tubes* (*heated breathing tube controllers*).

NOTE 2 Heated *breathing tubes* and their controllers are *ME equipment* and are subject to the requirements of IEC 60601-1.

NOTE 3 ISO 5367 specifies other safety and performance requirements for *breathing tubes*.

This document includes requirements for the different medical uses of humidification, such as invasive ventilation, non-invasive ventilation, nasal high-flow therapy, and obstructive sleep apnoea therapy, as well as humidification therapy for tracheostomy *patients*.

NOTE 4 A *humidifier* can be integrated into other equipment. When this is the case, the requirements of the other equipment also apply to the *humidifier*.

EXAMPLE 2 Heated *humidifier* incorporated into a critical care *ventilator* where ISO 80601-2-12 also applies.

EXAMPLE 3 Heated *humidifier* incorporated into a homecare *ventilator* for dependent *patients* where ISO 80601-2-72 also applies.

EXAMPLE 4 Heated *humidifier* incorporated into sleep apnoea therapy equipment where ISO 80601-2-70 also applies.

EXAMPLE 5 Heated *humidifier* incorporated into ventilatory support equipment where either ISO 80601-2-79 or ISO 80601-2-80 also apply.

EXAMPLE 6 Heated *humidifier* incorporated into respiratory high-flow therapy equipment where ISO 80601-2-90 also applies.

This document also includes requirements for an *active HME* (*heat and moisture exchanger*), *ME equipment* which actively adds heat and moisture to increase the humidity level of the gas delivered from the *HME* to the *patient*. This document is not applicable to a passive *HME*, which returns a portion of the expired moisture and heat of the *patient* to the respiratory tract during inspiration without adding heat or moisture.

NOTE 5 ISO 9360-1 and ISO 9360-2 specify safety and performance requirements for a passive *HME*.

NOTE 6 If a clause or subclause is specifically intended to be applicable to *ME equipment* only, or to *ME systems* only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to *ME equipment* and to *ME systems*, as relevant.

Hazards inherent in the intended physiological function of *ME equipment* or *ME systems* within the scope of this document are not covered by specific requirements in this document except in IEC 60601-1:2005+AMD1:2012+AMD2:2020, 7.2.13 and 8.4.1.

NOTE 7 Additional information can be found in IEC 60601-1:2005+AMD1:2012+AMD2:2020, 4.2.

This document does not specify the requirements for cold pass-over or cold bubble-through humidification devices, the requirements for which are given in ISO 20789.

This document is not applicable to equipment commonly referred to as “room humidifiers” or humidifiers used in heating, ventilation and air conditioning systems, or *humidifiers* incorporated into infant incubators to humidify the chamber air (i.e., are not directly connected to the *patient*).

This document is not applicable to nebulizers used for the delivery of a drug to *patients*.

NOTE 8 ISO 27427 specifies the safety and performance requirements for nebulizers.

201.1.2 Object

Replacement:

The object of this document is to establish particular *basic safety* and *essential performance* requirements for a *humidifier,* as defined in 201.3.240, and its *accessories*.

Accessories are included because the combination of the *humidifier* and the *accessories* needs to be adequately safe. *Accessories* can have a significant impact on the *basic safety* or *essential performance* of a *humidifier*.

NOTE 1 This document has been prepared to address the relevant *essential principles* and labelling guidances of the International Medical Devices Regulators Forum (IMDRF) as indicated in Annex II.

NOTE 2 This document has been prepared to address the relevant general safety and performance requirements of European regulation (EU) 2017/745[19].

201.1.3 Collateral standards

Addition (add after existing text):

This document refers to those applicable collateral standards that are listed in Clause 2 of the general standard and in 201.2 of this document.

IEC 60601-1-2:2014+AMD1:2020, IEC 60601-1-6:2010+AMD1:2013+AMD2:2020, IEC 60601-1-8:2006+AMD1:2012+AMD2:2020 and IEC 60601-1-11:2015+AMD1:2020 apply as modified in Clauses 202, 206, 208 and 211, respectively. IEC 60601-1-3:2008+AMD1:2013+AMD2:2021 and IEC 60601-1-9:2007+AMD1:2013+AMD2:2020 do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards define *basic safety* and *essential performance* requirements, and may modify, replace or delete requirements contained in the general standard and collateral standards as appropriate for the particular *ME equipment* under consideration.

A requirement of a particular standard takes priority over the general standard.

For brevity, IEC 60601-1:2005+AMD1:2012+AMD2:2020 is referred to in this document as the general standard. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this document corresponds to that of the general standard with the prefix "201" (e.g. 201.1 in this document addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix "20x", where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this document addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 208.6 in this document addresses the content of Clause 6 of the IEC 60601-1-8 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words:

"Replacement" means that the clause or subclause of the general standard or applicable collateral standard is replaced completely by the text of this document.

"Addition" means that the text of this document is additional to the requirements of the general standard or applicable collateral standard.

"Amendment" means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this document.

Clauses, subclauses, figures or tables which are additional to those of the general standard are numbered starting from 201.101. However, due to the fact that definitions in the general standard are numbered 3.1 through 3.154, additional definitions in this document are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses, figures or tables which are additional to those of a collateral standard are numbered starting from 20x, where "x" is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 211 for IEC 60601-1-11, etc.

The term "this document" is used to make reference to the general standard, any applicable collateral standards and this particular document taken together.

Where there is no corresponding clause or subclause in this document, the clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this document.

201.2 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.

Clause 2 of IEC 60601-1:2005+AMD1:2012+AMD2:2020 applies, except as follows.

Addition:

ISO 3744:2010, *Acoustics — Determination of sound power levels and sound energy levels of noise sources using sound pressure — Engineering methods for an essentially free field over a reflecting plane*

ISO 5356-1:2015, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets*

ISO 5359:2014+AMD1:2017, *Anaesthetic and respiratory equipment — Low-pressure hose assemblies for use with medical gases*

ISO 5367:2023, *Anaesthetic and respiratory equipment — Breathing sets and connectors*

ISO 7000, *Graphical symbols for use on equipment — Index and synopsis*[1]

ISO 7010, *Graphical symbols — Safety colours and safety signs — Registered safety signs*[2]

ISO 7396-1:2016+AMD1:2017, *Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum*

ISO 14937:2009, *Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices*

ISO 17664-1:2021, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices*

ISO 17664-2:2021, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 2: Non-critical medical devices*

ISO 18562-1:2024, *Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 1: Evaluation and testing within a risk management process*

ISO 20417:2026, *Medical devices — Information to be supplied by the manufacturer*

ISO 80369-1:2025, *Small-bore connectors for liquids and gases in healthcare applications — Part 1: General requirements*

ISO 80369-2:2024, *Small-bore connectors for liquids and gases in healthcare applications — Part 2: Connectors for respiratory applications*

IEC 60601-1:2005+AMD1:2012+AMD2:2020, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

IEC 61672-1:2013, *Electroacoustics — Sound level meters — Part 1: Specifications*

IEC 62304:2006+AMD1:2015, *Medical device software — Software life cycle processes*

IEC 62570:2025, *Standard practice for marking medical devices and other items for safety in the magnetic resonance environment*

IEC 81001-5-1:2021, *Health software and health IT systems safety, effectiveness and security — Part 5-1: Security — Activities in the product life cycle*

IEC Guide 115:2023, *Application of uncertainty of measurement to conformity assessment activities in the electrotechnical sector*

[1] The graphical symbol collections of ISO 7000, ISO 7001, ISO 7010 and IEC 60417 can be previewed and purchased on the Online Browsing Platform (OBP), www.iso.org/obp

[2] The graphical symbol collections of ISO 7000, ISO 7001, ISO 7010 and IEC 60417 can be previewed and purchased on the Online Browsing Platform (OBP), www.iso.org/obp

Bibliography

[1] ISO 4135:2022, *Anaesthetic and respiratory equipment — Vocabulary*

[2] ISO 8185:2007[4], *Respiratory tract humidifiers for medical use — Particular requirements for respiratory humidification systems*

[3] ISO 9000:2015, *Quality management systems — Fundamentals and vocabulary*

[4] ISO 9360-1, *Anaesthetic and respiratory equipment — Heat and moisture exchangers (HMEs) for humidifying respired gases in humans — Part 1: HMEs for use with minimum tidal volumes of 250 ml*

[5] ISO 9360-2, *Anaesthetic and respiratory equipment — Heat and moisture exchangers (HMEs) for humidifying respired gases in humans — Part 2: HMEs for use with tracheostomized patients having minimum tidal volumes of 250 ml*

[6] ISO 13732-1:2006, *Ergonomics of the thermal environment — Methods for the assessment of human responses to contact with surfaces — Part 1: Hot surfaces*

[7] ISO 19223:2019, *Lung ventilators and related equipment — Vocabulary and semantics*

[8] ISO 20789, *Anaesthetic and respiratory equipment – Passive humidifiers*

[9] ISO 27427, *Anaesthetic and respiratory equipment — Nebulizing systems and components*

[10] ISO 80369-7:2021, *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications*

[11] ISO 80601-2-12, *Medical electrical equipment — Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators*

[12] ISO 80601-2-70, *Medical electrical equipment — Part 2-70: Particular requirements for basic safety and essential performance of sleep apnoea breathing therapy equipment*

[13] ISO 80601-2-72, *Medical electrical equipment — Part 2-72: Particular requirements for basic safety and essential performance of home healthcare environment ventilators for ventilator-dependent patients*

[14] ISO 80601-2-79, *Medical electrical equipment — Part 2-79: Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory impairment*

[15] ISO 80601-2-80, *Medical electrical equipment — Part 2-80: Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory insufficiency*

[4] Withdrawn.

[16] ISO 80601-2-90, *Medical electrical equipment — Part 2-90: Particular requirements for basic safety and essential performance of ventilatory high-flow therapy equipment*

[17] IEC/TR 60878:2022, *Graphical symbols for electrical equipment in medical practice*

[18] IEC 62366-1:2015+AMD1:2020, *Medical devices — Part 1: Application of usability engineering to medical devices*

[19] (EU) 2017/745, (2017) Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices. OJ L 117, Official Journal of the European Union, pp. 1-175

[20] IMDRF/GRRP WG/N47:2024[5], *Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices*

[21] IMDRF/GRRP WG/N52:2024[5], *Principles of Labeling for Medical Devices and IVD Medical Devices*

[22] BUCK A.L. New Equations for Computing Vapor Pressure and Enhancement Factor. *J. Appl. Meteorol.* 1981 **20**(12) pp. 1527–1531

[23] Buck Research Instruments LLC, *Model CR-1A operating manual*, 2012

[24] CENGEL Y., BOLES M. Thermodynamics – An Engineering Approach (2nd ed), McGraw-Hill Inc, 1994, equation 13-7, p.693

[25] CHASE M.W. JR. NIST-JANAF Thermochemical Tables, Fourth Edition, 1998 J. Phys. Chem. Ref. Data, Monograph 9, 1-1951

[26] CONSTANTINDIS J., KNOBBER D., STEINHART H., KUHN J., IRO H. Fine-structural investigations of the effect of nCPAP-mask application on the nsal mucosa. *Acta Otolaryngol.* 2000, **120**(3) pp. 432–437

[27] DOYLE A., JOSHI M., FRANK P., CRAVEN T., MOONDI P., YOUNG P. A change in humidification system can eliminate endotracheal tube occlusion. *J. Crit. Care*. 2011, **26**(6) p. 23

[28] GALLAGHER S., VERCRUYSSEN M., DENO N. Hot air breathing: effects of elevated wet bulb temperatures on tissue temperatures of the mouth. *Am. Ind. Hyg. Assoc. J.* 1985, **46**(6) pp. 332–335

[29] Handbook of Chemistry and Physics. 73rd Edition, 1992 Ed. David R. Lide. CRC Press: Boca Raton Chapter 6, p. 11

[30] KILLICK E. *Physiological response to breathing hot air*. Dept of Physiology, University of Leeds, 1931

[31] KILPATRICK, S.J., PAPILE, L., MACONES, G.A. and WATTERBERG, K.L., *Physical Facilities.* In: Guidelines for perinatal care. Elk Grove Village, Chicago, American Academy of Pediatrics, 2017, p.79

[32] KONRAD F., SCHREIBER T., BRECHT-KRAUS D. Mucociliary Transport in ICU patients. *Chest*. 1994, **105**(1) pp. 237–241

[5] Available at http://www.imdrf.org/documents/documents.asp.

[33] KOUTSOURELAKIS I., VAGIAKIS E., PERRAKI E., KARATZA M., MAGKOU C., KOPAKA M. et al. Nasal inflammation in sleep apnoea patients using CPAP and effect of heated humidification. *Eur. Respir. J.* 2011, **37**(3) pp. 587–594

[34] LELLOUCHE F, et al. Influence of ambient and ventilator output temperatures on performance of heated-wire humidifiers. *Am J Resp Crit Care.* 2004, **170**(10), pp. 1073-1079

[35] MADOR MJ, KRAUZA M, PERVEZ A, PIERCE D, BRAUN M, Effect of heated humidification on compliance and quality of life in patients with sleep apnea using nasal continuous positive airway pressure. *Chest*. 2005 **128**(4), pp.2151-2158

[36] MARTIN DE ARAUJO M., VIERA S., VASQUEZ E., FLEURY B. Heated humidification or face mask to prevent upper airway dryness during continuous positive airway pressure therapy. *Chest*. 2000, **117**(1) pp. 142–147

[37] MIYAO H., HIROKAWA T., MIYASAKA K., KAWAZOE T. Relative humidity, not absolute humidity, is of great importance when using a humidifier with a heating wire. *Crit. Care Med.* 1996, **20** (5) pp. 674–679

[38] MORITZ A.R., HENRIQUES F.C. JR. Studies of thermal injury I. The relative importance of time and surface temperature in the causation of cutaneous burns. *Am. J. Pathol.* 1947, **23**(5) pp. 695–720

[39] NIST Chemistry WebBook. (2011) http://webbook.nist.gov/chemistry/, Retrieved 1 May 2013, National Institute of Standards and Technology

[40] OTO J., NAKATAKI E., OKUDA N., ONODERA M., IMANAKA H., NISHIMURA M. Hygrometric properties of inspired gas and oral dryness in patients with acute respiratory failure during noninvasive ventilation. *Respir. Care*. 2014, **39**(45) pp. 39–45

[41] PALM A, MIDGREN B, THEORELL-HAGLOW J, EKSTROM M, LJUNGGREN M, JANSON C, LINDBERG E, Factors influencing adherence to continuous positive airway pressure treatment in obstructive sleep apnea and mortality associated with treatment failure – a national registry-based cohort study, *Sleep Medicine.* 2018 **51** pp. 85-91

[42] PRIMIANO F., SAIDEL G., MONTAGUE F., KRUSE K., GREEN C., HOROWITZ J. Water vapour and emperature dynamics in the upper airways of normal and CF subjects. *Eur. Respir. J.* 1968, **1**(5) pp. 401–414

[43] Report of the Naval Medical Research and Development Command, Physiological Design Goals for Thermal Protection for Divers, Conference report of 5 September 1980

[44] RICARD, J. Humidification in: Principles and Practice of Mechanical Ventilation, Second edition; (ed. TOBIN, M.J., MD), McGraw-Hill, New York. 2006, pp. 1109-1120

[45] SCHIFFMANN H., RATHGEBER J., SINGER D., HARMS K., BOLLI A., ZÜCHNER K., Airway humidification in mechanically ventilated neonates and infants: a comparative study of a heat and moisture exchanger vs. a heated humidifier using a new fast-response capacitive humidity sensor. *Crit Care Med*. 1997 **25**(10), pp. 1755-1760

[46] STROTHER G.K., *Physics, with applications in life sciences*, Houghton Mifflin Co., USA, 1977, pp. 71-73

[47] TUGGEY J., DELMASTRO M., ELLIOTT M. The effect of mouth leak and humidification during nasal non-invasive ventilation. *Respir. Med.* 2007, **101**(9) pp. 1874-1879

[48] *US Standard Atmosphere*. US government printing office, 1976

[49] WIEST G., LEHNERT G., BRUCK W., MEYER M., HAHN E., FICKER J. A heated humidifier reduces upper airway dryness during continuous positive airway pressure therapy. *Respir. Med.* 1999, **93**(1) pp. 21–26

[50] WIEST GH, FOERST J, FUCHS FS, SCHMELZER AH, HAHN EG, FICKER JH, In vivo efficacy of two heated humidifiers used during CPAP-therapy for obstructive sleep apnea under various environmental conditions. *Sleep*. 2001 **24**(4),pp. 435-440

[51] WILLIAMS R., RANKIN N., SMITH T., GALLER D., SEAKINS P. Relationship between the humidity and temperature of inspired gas and the function of the airway mucosa. *Crit. Care Med.* 1996, **24**(11) pp. 1920–1929