

SLOVENSKI STANDARD

SIST EN ISO 80601-2-72:2015

01-december-2015

Nadomešča:

SIST EN ISO 10651-2:2009

Medicinska električna oprema - 2-72. del: Posebne zahteve za osnovno varnost in bistvene lastnosti respiratorjev za oskrbo od aparata odvisnih pacientov na domu (ISO 80601-2-72:2015)

Medical electrical equipment - Part 2-72: Particular requirements for basic safety and essential performance of home healthcare environment ventilators for ventilator-dependent patients (ISO 80601-2-72:2015)

Medizinische elektrische Geräte - Teil 2-72: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Heimbeatmungsgeräten für vom Gerät abhängige Patienten (ISO 80601-2-72:2015)

Appareils électromédicaux - Partie 2-72: Exigences particulières pour la sécurité de base et les performances essentielles des ventilateurs utilisés dans l'environnement des soins à domicile pour les patients ventilo-dépendants (ISO 80601-2-72:2015)

Ta slovenski standard je istoveten z: EN ISO 80601-2-72:2015

ICS:

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

EN ISO 80601-2-72

NORME EUROPÉENNE

EUROPÄISCHE NORM

September 2015

ICS 11.040.10

Supersedes EN ISO 10651-2:2009

English Version

Medical electrical equipment - Part 2-72: Particular requirements for basic safety and essential performance of home healthcare environment ventilators for ventilator-dependent patients (ISO 80601-2-72:2015)

Appareils électromédicaux - Partie 2-72: Exigences particulières pour la sécurité de base et les performances essentielles des ventilateurs utilisés dans l'environnement des soins à domicile pour les patients ventilo-dépendants (ISO 80601-2-72:2015)

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This European Standard was approved by CEN on 7 May 2015.

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Contents	Page
European foreword	3
Annex ZA (informative) Relationship between this Document and the Essential Requirements of EU Directive 93/42/EEC	4

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[SIST EN ISO 80601-2-72:2015](https://standards.iteh.ai/catalog/standards/sist/a1769fe3-cf46-4ecb-a563-ce5050a9833e/sist-en-iso-80601-2-72-2015)
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European foreword

This document (EN ISO 80601-2-72:2015) has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" in collaboration with 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 2016, and conflicting national standards shall be withdrawn at the latest by September 2018.

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

This document supersedes EN ISO 10651-2:2009.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this document.

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, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 80601-2-72:2015 has been approved by CEN as EN ISO 80601-2-72:2015 without any modification.

Annex ZA (informative)

Relationship between this Document and the Essential Requirements of EU Directive 93/42/EEC

This Document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means to conforming to Essential Requirements of the New Approach Directive 93/42/EEC, Council Directive of 14 June 1993 on the approximation of the laws of the Member States concerning medical devices” (Medical Device Directive).

Once this document is cited in the Official Journal of the European Communities under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this document given in Table ZA.1, within the limits of the scope of this document, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA.1 — Correspondence between this Document and Directive 93/42/EEC

Clause/subclause of this Document	Corresponding essential requirement of Directive 93/42/EEC	Qualifying remarks/notes
201.11.6.4, 201.11.6.6	7.2	Only the parts of ER 7.2 relating to safety in use for the patient are addressed.
201.11.6.4, 201.11.6.6	7.3	Only the part of the first sentence relating to design is addressed.
201.11.6.4	7.5	
201.11	7.6	
201.11.6.6, 201.11.6.7	8.1	The part of ER 8.1 relating to easy handling is not addressed.
201.11.6.7	8.4	Validated processes for sterilization are required via the normative references to ISO 11135-1, ISO 11137-1 and ISO 17665-1.
201.4.6, 201.4.11, 201.7.2.4.101, 201.7.2.13.101, 201.7.2.17.101, 201.7.2.101, 201.7.9.2.2.101, 201.7.9.2.14.101, 201.12.1.102, 201.12.1.103, 201.16, 201.101, 201.102, 201.106	9.1	
201.4.11.101, 201.9, 202, 206, 211	9.2	The 4th indent of ER 9.2 is not addressed.
201.11	9.3	
201.12.1, 201.102	10.1	The part of ER 10.1 relating to stability is not addressed.
201.7, 201.12.1, 206, 208	10.2	

Clause/subclause of this Document	Corresponding essential requirement of Directive 93/42/EEC	Qualifying remarks/notes
201.7.4.3	10.3	
201.14	12.1	
201.14	12.1 a)	
202	12.5	
201.8	12.6	
201.9	12.7.1	
201.9	12.7.2	
201.9	12.7.3	
201.8, 201.15, 201.101.1, 201.101.2	12.7.4	
201.11	12.7.5	
201.12.1	12.8.1	Only the protection of the patient is covered.
201.12.4	12.8.2	Only the first sentence of ER 12.8.2 is covered.
201.7, 206	12.9	
201.7, 201.11.6.4	13.1	
201.7.2.3, 201.7.2.13.101, 201.7.2.17.101, 201.7.2.101, 201.8, 201.9, 201.11.6.4	13.2	
201.7.9.1	13.3 a)	
201.7.2.17.101	13.3 b)	
201.7, 201.7.2.17.101 a)	13.3 c)	
201.7.2.17.101	13.3 d)	Is only covered if the batch number is preceded by the word LOT.
201.7.2.17.101	13.3 f)	
201.7.2.101 a), 211	13.3 i)	
201.7.2.101 b), 201.7.2.101 d), 211	13.3 j)	
201.7.2.101 b)	13.3 k)	
201.7, 201.7.2.17.101 a)	13.3 m)	Presumption of conformity is only provided if one of the symbols 5.21 to 5.24 are utilized, as applicable.
201.7.9.1, 201.7.9.2, 201.16	13.6 a)	
201.7.9.2.5.101	13.6 b)	
201.7.9.2.14.101, 201.16, 201.102	13.6 c)	
201.7, 201.7.9.2.8.101, 201.7.9.2.13.101, 201.16	13.6 d)	
201.16	13.6 f)	

EN ISO 80601-2-72:2015 (E)

Clause/subclause of this Document	Corresponding essential requirement of Directive 93/42/EEC	Qualifying remarks/notes
201.7.9.2.1.101, 201.7.9.2.12, 201.16, 211	13.6 h)	
201.7	13.6 i)	
211	13.6 k)	
211	13.6 l)	
211	13.6 n)	
211	13.6 p)	

WARNING Other requirements and other EU Directives may be applicable to the products falling within the scope of this European Standard.

For devices which are also machinery within the meaning of Article 2(a) of Directive 2006/42/EC on Machinery, in accordance with Article 3 of Directive 93/42/EEC the following Table ZA.2 details the relevant essential requirements of Directive 2006/42/EC on Machinery to the extent to which they are more specific than those of Directive 93/42/EEC along with the corresponding clauses of this European Standard. Table ZA.2, however, does not imply any citation in the OJEU under the machinery directive and thus does not provide presumption of conformity for the machinery directive.

Table ZA.2 — Relevant Essential Requirements from Directive 2006/42/EC on machinery that are addressed by this Document (according to article 3 of amended Directive 93/42/EEC)

Clause(s)/sub-clause(s) of this EN	EHSR of 2006/42/EC	Qualifying remarks/Notes
—	1.1.4	This relevant EHSR is not covered by this standard.
201.12.1, 201.12.102, 201.12.103	1.2.2	
201.7.2.101 c), 201.7.2.101 d), 201.101	1.5.4	
—	1.6.2	This relevant EHSR is not covered by this standard
201.8	1.6.3	

INTERNATIONAL
STANDARD

ISO
80601-2-72

First edition
2015-09-01

Medical electrical equipment

Part 2-72:

**Particular requirements for basic
safety and essential performance of
home healthcare environment
ventilators for ventilator-dependent
patients**

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Appareils électromédicaux

*Partie 2-72: Exigences particulières pour la sécurité de base et
les performances essentielles des ventilateurs utilisés dans
l'environnement des soins à domicile pour les patients ventilo-
dépendants*

Reference number
ISO 80601-2-72:2015(E)



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Published in Switzerland

Contents	Page
Foreword	vii
Introduction.....	ix
201.1 Scope, object and related standards.....	1
201.1.1 *Scope	1
201.1.2 Object	2
201.1.3 Collateral standards	2
201.1.4 Particular standards	2
201.2 Normative references	3
201.3 Terms and definitions	5
201.4 General requirements	7
201.4.3 ESSENTIAL PERFORMANCE	7
201.4.3.101 *Additional requirements for ESSENTIAL PERFORMANCE	8
201.4.6 *ME EQUIPMENT or ME SYSTEM parts that contact the PATIENT.....	8
201.4.10.2 *SUPPLY MAINS for ME EQUIPMENT and ME SYSTEMS.....	8
201.4.11.101 *Additional requirements for pressurized gas input.....	9
201.4.11.101.1 Overpressure requirement	9
201.4.11.101.2 Compatibility requirement	9
201.5 General requirements for testing of ME EQUIPMENT.....	10
201.5.101 *Additional requirements for general requirements for testing of ME EQUIPMENT.....	10
201.5.101.1 VENTILATOR test conditions	10
201.5.101.2 *Gas flowrate and leakage specifications	10
201.5.101.3 *VENTILATOR testing errors	10
201.6 Classification of ME EQUIPMENT and ME SYSTEMS	10
201.7 ME EQUIPMENT identification, marking and documents.....	10
201.7.2.3 *Consult ACCOMPANYING DOCUMENTS.....	10
201.7.2.4.101 Additional requirements for ACCESSORIES.....	11
201.7.2.13.101 Additional requirements for physiological effects	11
201.7.2.17.101 Additional requirements for protective packaging.....	11
201.7.2.101 Additional requirements for marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts	11
201.7.4.2 Control devices.....	12
201.7.4.3 *Units of measurement	12
201.7.9.1 Additional general requirements.....	12
201.7.9.2 Instructions for use.....	12
201.7.9.2.1.101 Additional general requirements.....	12
201.7.9.2.1.102 Additional general requirements.....	13
201.7.9.2.2.101 *Additional requirements for warnings and safety notices	13
201.7.9.2.8.101 *Additional requirements for start-up PROCEDURE	14
201.7.9.2.9.101 *Additional requirements for operating instructions	15
201.7.9.2.9.101.1 *LAY OPERATOR operating instructions	15
201.7.9.2.9.101.2 *Supervising clinician operating instructions	15
201.7.9.2.12 Cleaning, disinfection, and sterilization.....	16

201.7.9.2.13.101 Additional requirements for maintenance.....	17
201.7.9.2.14.101 *Additional requirements for ACCESSORIES, supplementary equipment, used material.....	17
201.7.9.3.1.101 *Additional general requirements	17
201.7.9.3.101 Additional requirements for the technical description.....	18
201.8 Protection against electrical HAZARDS from ME EQUIPMENT.....	18
201.9 Protection against mechanical HAZARDS of ME EQUIPMENT and ME SYSTEMS.....	18
201.9.4.3.101 Additional requirements for instability from unwanted lateral movement.....	18
201.9.4.4 Grips and other handling devices	18
201.9.6.2.1.101 Additional requirements for audible acoustic energy	18
201.10 Protection against unwanted and excessive radiation HAZARDS	19
201.11 Protection against excessive temperatures and other HAZARDS.....	19
201.11.1.2.2 *APPLIED PARTS not intended to supply heat to a PATIENT.....	19
201.11.6.4 Leakage.....	20
201.11.6.6 *Cleaning and disinfection of ME EQUIPMENT or ME SYSTEM	20
201.11.6.7 Sterilization of ME EQUIPMENT or ME SYSTEM	21
201.11.8 Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT.....	21
201.11.8.101 Additional requirements for interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT	21
201.12 *Accuracy of controls and instruments and protection against hazardous outputs.....	21
201.12.1 Accuracy of controls and instruments	21
201.12.1.101 Breath types.....	22
201.12.1.102 Volume-controlled breath type	22
201.12.1.103 Pressure-controlled breath type.....	25
201.12.1.104 DELIVERED VOLUME MONITORING EQUIPMENT	28
201.12.4 Protection against hazardous output.....	29
201.12.4.4 Incorrect output	29
201.12.4.101 Oxygen monitor.....	29
201.12.4.102 *Measurement of AIRWAY PRESSURE.....	30
201.12.4.103 *Measurement of expired volume and low-volume ALARM CONDITIONS	30
201.12.4.104 *Expiratory end-tidal CO ₂ MONITORING EQUIPMENT	31
201.12.4.105 *MAXIMUM LIMITED PRESSURE PROTECTION DEVICE	31
201.12.4.106 High-pressure ALARM CONDITION and PROTECTION DEVICE	31
201.12.4.107 *Obstruction ALARM CONDITION	32
201.12.4.108 *Partial-occlusion ALARM CONDITION	32
201.12.4.109 Hypoventilation ALARM CONDITION.....	32
201.12.4.110 Continuing positive-pressure ALARM CONDITION.....	33
201.12.4.111 *Leakage ALARM CONDITION.....	33
201.12.101 *Protection against accidental adjustments	33
201.13 HAZARDOUS SITUATIONS and fault conditions.....	33
201.13.2.101 *Additional specific SINGLE FAULT CONDITIONS	33
201.13.101 Failure of one gas supply to a VENTILATOR.....	34
201.13.102 *Independence of ventilation control function and related RISK CONTROL measures.....	34
201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)	34
201.14.1 General	34
201.15 Construction of ME EQUIPMENT	34
201.15.101 Mode of operation.....	34
201.15.102 ACCESSORY pre-use check.....	34
201.15.103 Integrated dual-limb VBS	34

201.16	ME SYSTEMS.....	35
201.16.1.101	Additional general requirements for ME SYSTEMS.....	35
201.17	Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	35
201.101	Gas connections	35
201.101.1	Connection to the MEDICAL GAS PIPELINE SYSTEM	35
201.101.2	VBS connectors.....	35
201.101.2.1	*General	35
201.101.2.2	Other named ports	35
201.101.2.2.1	PATIENT-CONNECTION PORT	35
201.101.2.2.2	GAS OUTPUT PORT and GAS RETURN PORT.....	35
201.101.2.2.3	*MANUAL VENTILATION PORT	36
201.101.2.2.4	FLOW-DIRECTION-SENSITIVE COMPONENTS	36
201.101.2.2.5	ACCESSORY port.....	36
201.101.2.2.6	Monitoring probe port.....	36
201.101.2.2.7	Gas EXHAUST PORT	36
201.101.2.2.8	Oxygen inlet port	36
201.102	Requirements for the VBS and ACCESSORIES.....	37
201.102.1	*General	37
201.102.2	Labelling	37
201.102.3	Breathing tubes	37
201.102.4	*Humidification.....	37
201.102.4.1	HUMIDIFIER.....	37
201.102.4.2	HEAT AND MOISTURE EXCHANGER (HME)	37
201.102.5	BREATHING SYSTEM FILTERS (BSF)	37
201.102.6	VENTILATOR BREATHING SYSTEMS	38
201.102.6.1	Leakage from VBS	38
201.102.6.2	*Non-invasive ventilation.....	38
201.103	*Spontaneous breathing during loss of power supply.....	38
201.104	*Training.....	38
201.105	*Indication of duration of operation.....	39
201.106	FUNCTIONAL CONNECTION	39
201.106.1	General	39
201.106.2	*Connection to an electronic health record	39
201.106.3	*Connection to a DISTRIBUTED ALARM SYSTEM	39
201.106.4	Connection for remote control	39
201.107	Display loops.....	39
201.107.1	Pressure-volume loops.....	39
201.107.2	Flow-volume loops.....	39
201.108	POWER SUPPLY CORDS	40
201.109	VENTILATOR security	40
202	Electromagnetic disturbances – Requirements and tests	40
202.4.3.1	*Compliance criteria	40
202.5.2.2.1	Requirements applicable to all ME EQUIPMENT and ME SYSTEMS	40
202.8.1.101	Additional general requirements	41
206	Usability.....	41

ISO 80601-2-72:2015(E)

208	General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	42
208.6.8.3.101	Additional requirements for global indefinite ALARM SIGNAL inactivation states	42
208.6.8.4.101	*Additional requirements for termination of ALARM SIGNAL inactivation	42
208.6.12.101	*Additional requirements for ALARM SYSTEM logging	42
211	Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment	43
211.8.4.101	*Additional requirements for interruption of the power supply/SUPPLY MAINS to ME EQUIPMENT	43
211.10.1.1	General requirements for mechanical strength.....	44
Annex C (informative)	Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS	45
Annex D (informative)	Symbols on marking.....	52
Annex AA (informative)	Particular guidance and rationale	53
Annex BB (informative)	Data interface requirements	72
Annex CC (informative)	Reference to the Essential Principles.....	79
Annex DD (informative)	Alphabetized index of defined terms used in this particular standard	81
Bibliography	85

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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 (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).

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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](http://Foreword-Supplementary%20information).

The committee responsible for this document is ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment*, and Technical Committee IEC/TC 62, *Electrical equipment in medical practice*, Subcommittee SC D, *Electrical equipment*.

This first edition of ISO 80601-2-72 cancels and replaces the second edition of ISO 10651-2:2004. This edition of ISO 80601-2-72 constitutes a major technical revision of ISO 10651-2:2004 and includes an alignment with the third edition of IEC 60601-1 and the second edition of IEC 60601-1-11.

The most significant changes are the following modifications:

- extending the scope to include the VENTILATOR and its ACCESSORIES, where the characteristics of those ACCESSORIES can affect the BASIC SAFETY and ESSENTIAL PERFORMANCE of the VENTILATOR, and thus, not only the VENTILATOR itself;
- identification of ESSENTIAL PERFORMANCE for a VENTILATOR and its ACCESSORIES;
- modification of the obstruction of the expiratory limb (continuing AIRWAY PRESSURE) ALARM CONDITION requirement;

and the following additions:

- tests for ventilation performance;
- tests for mechanical strength (via IEC 60601-1-11);
- new symbols;