



SLOVENSKI STANDARD
SIST EN ISO 11196:2000
01-januar-2000

ANESTEZIJSKA, RESPIRATORNA IN REANIMACIJSKA OPREMA
ANAESTHETIC GAS MONITORS

Anaesthetic gas monitors (ISO 11196:1995 including Technical Corrigendum 1:1997)

Überwachungsgeräte für Anästhesiegase (ISO 11196:1995 einschließlich Technisches
Korrigendum 1:1997)

STANDARD PREVIEW

Dispositifs de contrôle de gaz d'anesthésie (ISO 11196:1995 Rectificatif Technique
1:1997 inclus)

[SIST EN ISO 11196:2000](https://standards.iteh.ai/catalog/standards/sist/14d23324-5b2f-406c-8334-ab07b472ead/sist-en-iso-11196-2000)

Ta slovenski standard je istoveten z: EN ISO 11196:1997

ICS:

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

SIST EN ISO 11196:2000

en

iTeh STANDARD PREVIEW
(standards.iteh.ai)

SIST EN ISO 11196:2000

<https://standards.iteh.ai/catalog/standards/sist/14d23324-5b2f-406c-8334-abb7b472fead/sist-en-iso-11196-2000>

EUROPEAN STANDARD

EN ISO 11196

NORME EUROPÉENNE

EUROPÄISCHE NORM

August 1997

ICS 11.040.10

Descriptors: see ISO document

English version

**Anaesthetic gas monitors (ISO 11196:1995
including Technical Corrigendum 1:1997)**

Dispositifs de contrôle de gaz d'anesthésie
(ISO 11196:1995 Rectificatif Technique 1:1997
inclus)

Überwachungsgeräte für Anästhesiegase
(ISO 11196:1995 einschließlich Technisches
Korrigendum 1:1997)

(standards.iteh.ai)

SIST EN ISO 11196:2000

<https://standards.iteh.ai/catalog/standards/sist/14d23324-5b2f-406c-8334-abb7b472fead/sist-en-iso-11196-2000>

This European Standard was approved by CEN on 1996-11-08. 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 Central Secretariat or to any CEN member.

The European Standards exist 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 Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

Central Secretariat: rue de Stassart, 36 B-1050 Brussels

Foreword

The text of the International Standard from Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" of the International Organization for Standardization (ISO) has been taken over as a European Standard 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 February 1998, and conflicting national standards shall be withdrawn at the latest by June 1998.

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

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of the International Standard ISO 11196:1995 has been approved by CEN as a European Standard without any modification (standards.iteh.ai)

NOTE: Normative references to International Standards are listed in annex ZB (normative).

<https://standards.iteh.ai/catalog/standards/sist/14d23324-5b2f-406c-8334-abb764722a0c/sist-en-iso-11196-2000>



Annex ZA (informative) Clauses of this European Standard addressing essential requirements or other provisions of EU Directives

This European Standard 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 93/42/EEC.

WARNING : Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

The clauses of this standard, as detailed in Table ZA.1, are likely to support requirements of Directives.

Compliance with these clauses of this standard provides one means of conforming with the specific essential requirements of the Directive concerned and associated EFTA regulations.

iTeh STANDARD PREVIEW
(standards.iteh.ai)

SIST EN ISO 11196:2000

<https://standards.iteh.ai/catalog/standards/sist/14d23324-5b2f-406c-8334-abb7b472fead/sist-en-iso-11196-2000>

TABLE ZA.1 - Correspondence between this European Standard and EU Directives

Clause/subclause of this European Standard*	Corresponding Essential Requirement of Directive 93/42/EEC	Comments
All	1, 2	
Section 3	12.6	
Section 4	9.2, 12.7.1	
Section 6	7.3	
1.4 (3.6 j))	9.3	
1.4 (3.6 j) b))	12.1	
1.6 (6.1)	13.1, 13.6 a)	
1.6 (6.1 ac) 2))	13.3 e)	
1.6 (6.1 ac) 4))	13.3 b)	
1.6 (6.1 ac) 5))	13.3 a), 13.3 d), 13.3 m), 13.5	
1.6 (6.1 ac) 7))	13.3 f)	
1.6 (6.1 ac) 8))	8.7, 13.3 c)	
1.6 (6.1 ad) 1))	13.3 j)	
1.6 (6.1 ad) 2))	13.3 k)	
1.6 (6.1 ad) 5)	13.3 l)	
1.6 (6.1 dd) 4))	13.4	
1.6 (6.1 dd) 6))	13.4	
1.6 (6.1 f))	13.3 b)	
1.6 (6.2)	12.6, 13.1	
1.6 (6.3)	12.9, 13.1	
1.6 (6.3 h))	12.9	
1.6 (6.3 h) 1))	10.2, 10.3	
1.6 (6.3 h) 2))	10.2, 10.3	
1.6 (6.4)	13.1, 13.2	
1.6 (6.5)	12.6	
1.6 (6.6)	12.7.4	
1.6 (6.8)	13.1	

TABLE ZA.1 - Correspondence between this European Standard and EU Directives

Clause/subclause of this European Standard	Corresponding Essential Requirement of Directive 93/42/EEC	Comments
1.6 (6.8.1)	13.6 a)	
1.6 (6.8.2 a))	9.1, 13.4, 13.6 b), 13.6 d), 13.6 f)	
1.6 (6.8.2 c))	13.6 c)	
1.6 (6.8.2 d))	13.6 g), 13.6 h)	
1.6 (6.8.2 g))	13.6 g)	
1.6 (6.8.3 a))	10.1, 13.6 b), 13.6 d), 13.6 f), 13.6 i)	
1.6 (6.8.3 a) 3rd dash)	7.5	
1.6 (6.8.3 d))	13.3 i)	
2.3 (10)	4, 5	
3.5 (17)	7.3	
4.1 (21)	4, 5	
4.6 (26)	12.7.2, 12.7.3	
4.7 (27)	12.7.4	
5.1 (29)	11.1, 11.3.1	
5.2 (30)	11.1, 11.3.1	
5.3 (31)	11.1, 11.3.1	
5.4 (32)	11.1, 11.3.1	
5.6 (34)	11.1, 11.3.1	
5.7 (35)	11.1, 11.3.1	
5.8 (36)	9.2, 12.5	
6.2 (38)	13.2, 13.6 a)	
7.1 (42)	9.2, 12.7.5	
7.2 (43)	7.1, 7.3, 9.3	
7.3 (44.6)	7.6	
7.3 (44.7)	8.1	
7.3 (44.7.2)	8.4	
7.3 (44.7.3)	8.6	
7.4 (45)	9.2	

TABLE ZA.1 - Correspondence between this European Standard and EU Directives

Clause/subclause of this European Standard	Corresponding Essential Requirement of Directive 93/42/EEC	Comments
7.5 (46)	9.1	
7.6 (47)	9.2	
8.1 (50.1)	10.1	
8.2 (51.5)	3	
8.2 (51.5.1)	10.1	
8.2 (51.5.2)	3, 10.1	
8.2 (51.6)	3, 10.1	
8.2 (51.7.1)	3	
8.2 (51.7.2)	3	
8.2 (51.7.3)	3	
8.2 (51.8)	12.4	
8.2 (51.8.13)	12.4	
10.3 (56.12)	10.2, 10.3	
10.4 (57)	12.7.4	
11.1 (60)	7.3	
11.1 (60.1)	3	
11.3	9.1	
11.4	8.1	

* Clause numbers in **bold type** refer to clauses in EN ISO 11196. Clause numbers in ordinary type refer to the clauses, amended or original of IEC 601-1 to which reference is made in EN ISO 11196.

Annex ZB (normative)
**Normative references to international publications
with their relevant European publications**

This European Standard incorporates by dated or undated references, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN</u>	<u>Year</u>
ISO 4135	1995	Anaesthesiology - Vocabulary	EN ISO 4135	1996

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[SIST EN ISO 11196:2000
https://standards.iteh.ai/catalog/standards/sist/14d23324-5b2f-406c-8334-
abb7b472fead/sist-en-iso-11196-2000](https://standards.iteh.ai/catalog/standards/sist/14d23324-5b2f-406c-8334-abb7b472fead/sist-en-iso-11196-2000)

iTeh STANDARD PREVIEW
(standards.iteh.ai)

SIST EN ISO 11196:2000

<https://standards.iteh.ai/catalog/standards/sist/14d23324-5b2f-406c-8334-abb7b472fead/sist-en-iso-11196-2000>

INTERNATIONAL STANDARD

ISO
11196

First edition
1995-10-15

Anaesthetic gas monitors

Dispositifs de contrôle de gaz d'anesthésie
iTeh STANDARD PREVIEW
(standards.iteh.ai)

[SIST EN ISO 11196:2000](https://standards.iteh.ai/catalog/standards/sist/14d23324-5b2f-406c-8334-abb7b472fead/sist-en-iso-11196-2000)
<https://standards.iteh.ai/catalog/standards/sist/14d23324-5b2f-406c-8334-abb7b472fead/sist-en-iso-11196-2000>



Reference number
ISO 11196:1995(E)

Contents

	Page
Section 1 General	1
1.1 Scope	1
1.2 Normative references	1
1.3 Definitions	2
1.4 General requirements and general requirements for tests ...	4
1.5 Classification	5
1.6 Identification, marking and documents	5
1.7 Power input	9
Section 2 Environmental conditions	10
2.1 Basic safety categories	10
2.2 Removable protective means	10
2.3 Environmental conditions	10
Section 3 Protection against electric shock hazards	11
3.1 General	11
3.2 Requirements related to classification	11
3.3 Limitation of voltage and/or energy	11
3.4 Enclosures and protective covers	11
3.5 Separation	11
3.6 Protective earthing, functional earthing and potential equalization	11
3.7 Continuous leakage current and patient auxiliary currents ..	11
3.8 Dielectric strength	11
Section 4 Protection against mechanical hazards	12
4.1 Mechanical strength	12
4.2 Moving parts	12

© ISO 1995

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from the publisher.

International Organization for Standardization
Case Postale 56 • CH-1211 Genève 20 • Switzerland

Printed in Switzerland

4.3	Surface, corners and edges	12
4.4	Stability in normal use	12
4.5	Expelled parts	12
4.6	Vibration and noise	12
4.7	Pneumatic and hydraulic power	12
4.8	Suspended masses	12
Section 5 Protection against hazards from unwanted or excessive radiation		13
5.1	X-radiation	13
5.2	Alpha, beta, gamma, neutron radiation and other particle radiation	13
5.3	Microwave radiation	13
5.4	Light radiation (including lasers)	13
5.5	Infrared radiation	13
5.6	Ultraviolet radiation	13
5.7	Acoustical energy (including ultrasonics)	13
5.8	Electromagnetic compatibility	13
Section 6 Protection against hazards of ignition of flammable anaesthetic mixtures		14
6.1	Locations and basic requirements	14
6.2	Marking, accompanying documents	14
6.3	Common requirements for categories AP and APG equipment	14
6.4	Requirements and tests for category AP equipment, parts and components	14
6.5	Requirements and tests for category APG equipment, parts and components	14
Section 7 Protection against excessive temperatures and other safety hazards		15
7.1	Excessive temperatures	15
7.2	Fire prevention	15
7.3	Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization and disinfection	15
7.4	Pressure vessels and parts subject to pressure	15
7.5	Human errors	16
7.6	Electrostatic charges	16

iTeh STANDARD PREVIEW
(standards.iteh.ai)

<https://standards.iteh.ai/catalog/standards/sist/14d23324-5b2f-406c-8334-abb7b472fead/sist-en-iso-11196-2000>

7.7	Materials in applied parts in contact with body of patient ..	16
7.8	Interruption of power supply	16
Section 8	Accuracy of operating data and protection against hazardous output	17
8.1	Accuracy of operating data	17
8.2	Protection against hazardous output	17
Section 9	Abnormal operation and fault conditions; environmental tests	21
9.1	Abnormal operation and fault conditions	21
9.2	Environmental tests	21
Section 10	Constructional requirements	22
10.1	General	22
10.2	Enclosures and covers	22
10.3	Components and general assembly	22
10.4	Main parts, components and layout	22
10.5	Protective earthing — Terminals and connections	22
10.6	Construction and layout	22
Section 11	Additional requirements specific to anaesthetic gas monitors	23
11.1	Interfering gas and vapour effects (other than water vapour)	23
11.2	Obstruction of sampling tube	23
11.3	Breathing system connections	24
11.4	Contamination of breathing systems	24
Annexes		
A to L	25
M	Test of anaesthetic agents for non-flammability	26
N	Rationale	27
P	Bibliography	32

iTech STANDARD PREVIEW
(standards.iteh.ai)

SIST EN ISO 11196:2000
<https://standards.iteh.ai/catalog/standards/sist/14d23324-5b2f-406c-8334-62000>

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.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

International Standard ISO 11196 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 1, *Breathing attachments and anaesthetic machines*.

SIST EN ISO 11196:2000

<https://standards.iteh.ai/catalog/standards/sist/14d23324-5b2f-406c-8334-abb7b472fead/sist-en-iso-11196-2000>