

Anaesthetic workstations and their modules — Particular requirements

The European Standard EN 740:1998, with the incorporation of amendment A1:2004, has the status of a British Standard

ICS 11.040.10

National foreword

This British Standard is the official English language version of EN 740:1998 and incorporates its corrigendum published in December 1998, including amendment A1:2004. It supersedes BS 5724-2-13:1999 which has been withdrawn. Clause 111 of this standard, together with BS EN 737-2:1998 and BS EN 737-4:1998, supersedes BS 6834:1997 which has been withdrawn.

Attention is drawn to the Special National Conditions in Annex TT.

The UK participation in its preparation was entrusted by Technical Committee CH/44, Anaesthetic machines, breathing attachments, medical gas pipeline systems and hose assemblies, to Subcommittee CH/44/1, Anaesthetic machines, breathing systems and anaesthetic gas scavenging systems, which has the responsibility to:

- aid enquirers to understand the text;
- present to the responsible international/European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;
- monitor related international and European developments and promulgate them in the UK.

A list of organizations represented on this subcommittee can be obtained on request to its secretary.

Cross-references

The British Standards which implement international publications referred to in this document may be found in the *BSI Catalogue* under the section entitled “International Standards Correspondence Index”, or by using the “Search” facility of the *BSI Electronic Catalogue* or of British Standards Online.

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English version

Anaesthetic workstations and their modules — Particular requirements

(including amendment A1:2004)

Systèmes d'anesthésie et leurs modules —
Règles particulières
(inclut l'amendement A1:2004)

Anästhesie-Arbeitsplätze und ihre Module —
Besondere Festlegungen
(enthält Änderung A1:2004)

This European Standard was approved by CEN on 2nd March 1998; amendment A1 was approved by CEN on 4 December 2003.

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.

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CEN

European Committee for Standardization
Comité Européen de Normalisation
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Foreword

This European Standard has been prepared 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 1999, and conflicting national standards shall be withdrawn at the latest by February 1999.

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(s).

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

This European Standard specifies particular requirements for anaesthetic workstations and their modules. It applies in conjunction with EN 60601-1:1990. As stated in EN 60601-1:1990, **1.3** the requirements in this European Standard take priority over those of EN 60601-1:1990. Clauses and subclauses additional to those in EN 60601-1:1990 are numbered beginning "101". Additional annexes are lettered beginning "AA". Additional figures and tables are numbered beginning "101". Additional items in lettered lists are lettered beginning "aa".

Annex BB contains rationale statements for this European Standard. The clauses which have corresponding rationale statements are marked with "R" after their number.

Because this standard has been developed and structured in the way described in the scope, particular attention is drawn to the clarification printed in bold type in 51.101.

Annex AA, Annex CC, Annex DD, Annex EE, Annex FF, Annex GG, Annex HH, Annex JJ, Annex KK, Annex LL, Annex MM, Annex NN, Annex QQ, Annex RR and Annex TT are normative parts of this European Standard. Annex BB, Annex PP, Annex SS and Annex ZA are given for information.

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.

Foreword to amendment A1

This document (EN 740:1998/A1:2004) has been prepared by Technical Committee CEN/TC 215, Respiratory and anaesthetic equipment, the Secretariat of which is held by BSI.

This amendment to the European Standard EN 740:1998/A1:2003 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by July 2004, and conflicting national standards shall be withdrawn at the latest by July 2004.

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, Hungary, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Slovakia, Spain, Sweden, Switzerland and the United Kingdom.

Contents

	Page
Foreword	2
Section 1. General	
1 Scope	5
2 Normative references	5
3 Terminology and definitions	7
4 General requirements and general requirements for test	11
5 Classification	11
6 Identification, marking and documents	11
7 Power output	18
Section 2. Environmental conditions	
8 Basic safety categories	19
9 Removable protection means	19
10 Environmental conditions	19
11 Not used	19
12 Not used	19
Section 3. Protection against electrical shock hazards	
13 General	20
14 Requirements related to classification	20
15 Limitation of voltage and/or energy	20
16 Enclosures and protective covers	20
17 Separation	20
18 Protective earthing, functional earthing and potential equalization	20
19 Continuous leakage current and patient auxiliary currents	20
20 Dielectric strength	20

	Page		Page
Section 4. Protection against mechanical hazards		51 Protection against hazardous output	26
21 Mechanical strength	21	Section 9. Abnormal condition and fault conditions environmental tests	
22 Moving parts	21	52 Abnormal operation and fault conditions	34
23 Surfaces, corners, and edges	21	53 Environmental tests	34
24 Stability in normal use	21	Section 10. Constructional requirements	
25 Expelled parts	21	54 General	34
26 Vibration and noise	21	55 Enclosures and covers	34
27 Pneumatic and hydraulic power	21	56 Components and general assembly	34
28 Suspended masses	21	57 Mains parts, components and layout	35
Section 5. Protection against hazards from unwanted or excessive radiation		58 Protective earthing — terminals and connections	35
29 X-radiation	22	59 Construction and layout	35
30 Alpha, beta, gamma, neutron radiation and other particle radiation	23	Section 11. Additional requirements specific to anaesthetic workstations	
31 Microwave radiation	22	101 Gas supply pressure monitors	36
32 Light radiation (including lasers)	22	102 Pressure regulators	36
33 Infra-red radiation	22	103 Machine gas piping	36
34 Ultra-violet radiation	22	104 Anaesthetic gas delivery module	37
35 Acoustical energy (including ultrasonic)	22	105 Anaesthetic vapour delivery module	40
36 Electromagnetic compatibility	22	106 Respiratory gas conducting components	41
Section 6. Protection against hazards of ignition of flammable anaesthetic mixtures		107 Anaesthetic breathing systems	42
37 Locations and basic requirements	23	108 Heat and moisture exchangers	46
38 Marking, accompanying documents	23	109 Humidifiers	46
39 Common requirements for category AP and category APG equipment	23	110 Suction equipment	46
40 Requirements and tests for category AP equipment, parts and components thereof	23	111 Anaesthetic gas scavenging system (AGSS)	46
41 Requirements and tests for category APG equipment, parts and components thereof	23	112 Anaesthetic ventilator modules	50
Section 7. Protection against excessive temperatures, and other safety hazards		Annex AA (normative) R: Test of anaesthetic agents for non-flammability	53
42 Excessive temperatures	24	Annex BB (informative) Rationale	54
43 Fire prevention	24	Annex CC (normative) Applicable requirement clauses for separate modules of an anaesthetic workstation	61
44 Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization, disinfection and compatibility	24	Annex DD (normative) Test method for expired volume monitors	62
45 Pressure vessels and parts subject to pressure	24	Annex EE (normative) Test method for accuracy of anaesthetic vapour delivery modules without applied back pressure	64
46 Human errors	24	Annex FF (normative) Test method for anaesthetic vapour delivery module accuracy with applied back pressure	65
47 Electrostatic charges	25	Annex GG (normative) Test methods for anaesthetic breathing systems and breathing attachments	66
48 Materials in applied parts in contact with the body of the patient	25	Annex HH (normative) Colour coding of anaesthetic vapour delivery modules	73
49 Interruption of the power supply	25	Annex JJ (normative) Test methods for resistance to flow of the receiving system	73
Section 8. Accuracy of operating data and protection against hazardous output			
50 Accuracy of operating data	26		

	Page
Annex KK (normative) Test method for flow and resistance of AGSS	74
Annex LL (normative) Test method for transfer systems	76
Annex MM (normative) Test method for induced flow and sub-atmospheric pressure of AGSS	79
Annex NN (normative) Test method for spillage from the transfer and receiving systems	81
Annex PP (informative) Guidelines for situations in which AGSS are used with flammable anaesthetic gases and/or volatile agents	83
Annex QQ (normative) Ergonomics and symbols	83
Annex RR (normative) Method of test for draw-over vaporizers used with emergency anaesthetic equipment	84
Annex SS (informative) Bibliography	85
Annex TT (normative) Special national conditions	86
Annex ZA (informative) Clauses of this European Standard addressing essential requirements or other provisions of EU Directives	87

Section 1. General

1 R: Scope

EN 60601-1:1990, Clause 1 applies with the following amendment.

This European Standard provides particular requirements for modules which, although considered as individual devices in their own right, may be utilized, in conjunction with other relevant devices, to form an anaesthetic workstation to a given specification.

It is the intent of this European Standard that both anaesthetic workstations supplied complete and individual modules be commercially available to users to allow the configuration of an anaesthetic workstation to meet the needs of their clinical practice. To this end, this European Standard has been structured in such a way as to identify clearly particular requirements of specific modules currently available. Different configurations of anaesthetic workstations are illustrated in Table 101.

This European Standard also specifies the particular requirements for emergency anaesthetic equipment (see Table 102).

For the purpose of this European Standard a module is defined as a self-contained unit of an anaesthetic workstation that performs a specific task or class of tasks in support of the major function of the anaesthetic workstation.

Such modules are e.g. anaesthetic gas delivery, anaesthetic vapour delivery, anaesthetic ventilators, anaesthetic breathing systems, anaesthetic gas scavenging systems (AGSS), specific monitoring, alarm and protection modules.

This European Standard also specifies particular requirements for the transfer and receiving system of an active AGSS intended to reduce the exposure of hospital personnel to anaesthetic gases and vapour and specifies the inlet flow conditions for which systems should be designed.

Although this European Standard does not specify the provision of patient monitors, attention is drawn to recommendations for patient monitoring during anaesthesia made by many national clinical and regulatory bodies.

Manufacturers of anaesthetic workstations are encouraged to make provision for additional monitors as well as for devices for the intravenous administration of drugs (see Annex SS “Bibliography” for appropriate equipment standards) so that the user can assimilate more easily the data output and so that the alarm function of the various monitors can be integrated.

2 Normative references

This European Standard incorporates by dated or undated reference, 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.

Appendix L of EN 60601-1:1990 applies with the following additions.

EN 475, *Medical devices — Electrically-generated alarm signals.*

EN 737-1, *Medical gas pipeline systems — Part 1: Terminal units for compressed medical gases and vacuum.*

prEN 737-3, *Medical gas pipeline systems — Part 3: Pipelines for compressed medical gases and vacuum.*

EN 737-4, *Medical gas pipeline systems — Part 4: Terminal units for anaesthetic gas scavenging systems.*

prEN 737-6, *Medical gas pipeline systems — Part 6: Dimensions of probes for terminal units for compressed medical gases and vacuum.*

EN 738-1, *Pressure regulators for use with medical gases — Part 1: Pressure regulators and pressure regulators with flow metering devices.*

EN 739:1998, *Low pressure flexible hose assemblies for use with medical gases.*

EN 850, *Transportable gas cylinders — Pin-index, yoke-type valve outlet connections for medical use.*

EN 864, *Medical electrical equipment — Capnometers for use with humans — Particular requirements.*

EN 980, *Graphical symbols for use in the labelling of medical devices.*

EN 1041, *Information supplied by the manufacturer with medical devices.*

EN 1089-3, *Transportable gas cylinders — Cylinder identification — Part 3: Colour coding.*

EN 1280-1:1997, *Agent specific filling systems for anaesthetic vaporizers — Part 1: Rectangular keyed filling systems.*

EN 1281-1, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets.*

EN 1281-2, *Anaesthetic and respiratory equipment — Conical connectors — Part 2: Screw-threaded weight-bearing connectors.*

(ISO 5356-2:1987, modified)

EN 1820, *Anaesthetic reservoir bags.*

prEN 12342, *Breathing tubes intended for use with anaesthetic apparatus and ventilators.*

EN ISO 4135, *Anaesthesiology — Vocabulary.*

(ISO 4135:1995)

prEN 12598, *Oxygen monitors for patient breathing mixtures — Particular requirements.*

EN ISO 8185-1, *Humidifiers for medical use — Part 1: General requirements for humidification systems.*

(ISO/DIS 8185-1:1997)

EN ISO 10079-1, *Medical suction equipment — Part 1: Electrically powered suction equipment — Safety requirements.*

(ISO 10079-1:1991 including Technical Corrigendum 1:1992 and Technical Corrigendum 2:1993)

EN ISO 10079-2, *Medical suction equipment — Part 2: Manually powered suction equipment.*

(ISO 10079-2:1992)

EN ISO 10079-3, *Medical suction equipment — Part 3: Suction equipment powered from vacuum or pressure source.*

(ISO 10079-3:1992)

EN ISO 11196, *Anaesthetic gas monitors.*

(ISO 11196:1995 including Technical Corrigendum 1:1997)

EN 60601-1:1990, *Medical electrical equipment — Part 1: General requirements for safety.*

(IEC 60601-1:1988)

EN 60601-1-1, *Medical electrical equipment — Part 1: General requirements for safety —*

1. Collateral standard: Safety requirements for medical electrical systems.

(IEC 60601-1-1:1992)

EN 60601-1-2, *Medical electrical equipment — Part 1: General requirements for safety —*

2. Collateral standard: Electromagnetic compatibility — Requirements and tests.

(IEC 60601-1-2:1993)

EN 60801-2, *Electromagnetic compatibility for industrial-process measurement and control equipment — Part 2: Electrostatic discharge requirements.*

(IEC 801-2:1991)

IEC 60079-3, *Electrical apparatus for explosive gas atmospheres — Part 3: Spark-test apparatus for intrinsically-safe circuits.*

IEC 60079-4, *Electrical apparatus for explosive gas atmospheres — Part 4: Method of test for ignition temperature.*

ISO 2878, *Rubber, vulcanized — Antistatic and conductive products — Determination of electrical resistance.*

ISO 2882, *Rubber, vulcanized — Antistatic and conductive products for hospital use — Electrical resistance limits.*

EN ISO 3746, *Acoustics — Determination of sound power levels of noise sources using sound pressure — survey method using an enveloping measurement surface over a reflecting plane.*
(ISO 3746:1995)

ISO 9360, *Anaesthetic and respiratory equipment — Heat and moisture exchangers for use in humidifying respired gases in humans.*

3 Terminology and definitions

EN 60601-1:1990, Clause 2 applies together with EN ISO 4135 and the following amendments and additions.

In 2.1.5, replace the text with the following.

2.15 R

applied part

the fresh gas outlet, if provided, and all other parts of the anaesthetic workstation intended to be connected with the patient or with the anaesthetic breathing system

Add the following.

3.1

anaesthetic workstation

system for the administration of inhalation anaesthesia which includes one or more actuator modules, their particular monitoring and alarm modules and essential hazard protection modules

3.2 R

module

self-contained unit of an anaesthetic workstation that performs a specific task or class of tasks in support of the major function of the anaesthetic workstation

3.3 R

actuator module

module which performs the task of delivery of energy or substances in controlled quantities

3.4 R

monitoring module

module which performs the task of displaying or indicating a variable to the operator

3.5 R

alarm module

module which performs the task of providing a visual and/or audible alarm signal(s) when an alarm condition is present

3.6 R

protection module

module which, without intervention of the operator, performs the task of protecting the patient against hazardous output due to incorrect delivery of energy or substances

3.7

anaesthetic gas scavenging system; AGSS

system which is connected to the exhaust port(s) of an anaesthetic workstation or which is integrated into an anaesthetic workstation for the purpose of conveying expired and/or excess anaesthetic gases to an appropriate place of discharge

NOTE Functionally, an AGSS comprises three different parts, a transfer system, a receiving system and a disposal system. These three functionally discrete parts may be either separate or sequentially combined in part or in total. In addition, one or more parts of an AGSS may be sequentially combined with a breathing system to include the transfer system or transfer and receiving system.

3.8

gas mixing system

device or assembly which receives separate supplies of oxygen and other medical gas(es) and which delivers the mixed gases in operator-adjustable concentrations

3.9

machine gas piping

all pipework, including unions, from unidirectional valves in the pipeline inlets and from the pressure regulator outlets to the flow meter controls and auxiliary gas outlets. It includes piping leading to and from pneumatic alarm systems, gauges and oxygen flush valves

3.10

flow control system

device or assembly that controls the flow of gas(es)

3.11

anaesthetic vapour delivery module; vaporizer

device or assembly where anaesthetic agent is transformed from the liquid to the gaseous phase and is mixed in a controllable concentration with the fresh gas or breathing gas

3.12

pressure regulator

gas pressure reducing and controlling device designed to provide a constant delivery pressure over a range of variable inlet pressures and/or flows

3.13

emergency anaesthetic equipment

transportable system for the administration of inhalation anaesthesia which includes but is not limited to one or more actuator modules, their recommended particular monitoring and alarm modules and particular hazard protection modules for use e.g. in the open field for rescue operation, in disaster areas or in areas where anaesthesia is not normally administered

3.14

medical gas supply system

either

a) a medical gas pipeline system comprising a central supply system, control equipment, a pipeline distribution system and terminal units at the point where non-flammable medical gases or vacuum may be required; or

b) any other installation having no permanent pipeline system but employing a medical gas supply source complete with pressure regulators

3.15 R

flammable anaesthetic agent

anaesthetic agent which is ignited by the test specified in Annex AA of this European Standard

3.16 R

non-flammable anaesthetic agent

anaesthetic agent which is not ignited by the test specified in Annex AA of this European Standard

3.17

anaesthetic ventilator

automatic actuator module which is connected to the patient's airway and is designed to augment or provide ventilation of the patient during anaesthesia

3.18

fresh-gas outlet; common gas outlet

that port through which the dispensed mixture from the anaesthetic gas delivery module is delivered to the anaesthetic breathing system

3.19

anaesthetic gas

gas and/or the vapour of a volatile agent used in anaesthesia

3.20**anaesthetic gas delivery module**

actuator module which controls the flow and composition of the fresh gas delivered during anaesthesia. It may consist of a flow control system, flow meters and/or a gas mixing system and may be combined with an anaesthetic vapour delivery module

3.21**enabled condition**

one of the conditions necessary to make an action possible

3.22**draw-over vaporizer**

calibrated vaporizer intended to be installed in a breathing system from which the flow of a gas vapour mixture is produced by lowering the pressure at its outlet below that at its inlet by the patient's inspiratory effort or by mechanical means

3.23**permanent connection**

connection which can be detached only by the use of a tool

3.24**anaesthetic breathing system**

those inspiratory and expiratory gas pathways, excluding the anaesthetic ventilator, between the fresh gas outlet and the patient connection port which contain gas at respiratory pressure

NOTE Gas pathways exclusively concerned with AGSS are not regarded as part of an anaesthetic breathing system.

3.25**circle system**

anaesthetic breathing system in which the direction of gas flow through separate inspiratory and expiratory pathways is determined by e.g. unidirectional valves and in which the two pathways form a circle

3.26**circle absorption system**

circle system incorporating a carbon dioxide absorber

3.27**circle absorber assembly**

that part of a circle system which comprises a carbon dioxide absorber, ports for connection to breathing tubes and which may include a reservoir bag port, a fresh gas inlet and an APL valve

3.28**fresh-gas inlet**

that port on a breathing attachment through which the dispensed mixture from the anaesthetic gas delivery module is delivered to the anaesthetic breathing system

3.29**respiratory gas-conducting components**

all components of the anaesthetic ventilator and the anaesthetic breathing system which are in contact with the patient's inhaled gas during any form of ventilation

NOTE 1 Such components are e.g. anaesthetic breathing systems, anaesthetic breathing system attachments, ventilator bellows, microbial filters, adjustable pressure limiting (APL) valves and CO₂-absorber assemblies.

NOTE 2 When sampled gas is returned to the anaesthetic breathing system the gas sampling line is considered to be a respiratory gas conducting component.

3.30**transfer system**

that part of an AGSS, which may or may not incorporate tubing, which transfers expired and/or excess anaesthetic gases from the exhaust port of the anaesthetic breathing system and/or anaesthetic ventilator to the receiving system and which may contain a means of pressure relief

NOTE See also 3.7 and Figure 106 of this European Standard.

3.31

transfer tube

that part of an AGSS which transfers expired and/or excess gases from the anaesthetic breathing system and/or anaesthetic ventilator to the receiving system

3.32

receiving system

that part of an AGSS which provides an interface between the transfer system and the disposal system and may contain means of sub-atmospheric and/or positive pressure relief

3.33

receiving hose

that part of an AGSS which transfers expired and/or excess gases from the receiving system to the disposal system

3.34

disposal system

means by which the expired or excess anaesthetic gases are conveyed from the receiving system to an appropriate place of discharge

NOTE A place of discharge may be, for example, the exterior of a building or a non-recirculating extract ventilation system.

3.35

power device

that part of the disposal system of an AGSS which provides the gas flow for scavenging

3.36

AGSS terminal unit

connection point between the receiving system and the disposal system

3.37

maximum extract flow

highest flow of gas at the entry to the disposal system which can be accommodated without exceeding the limitations for induced flow or sub-atmospheric pressure

3.38

minimum extract flow

lowest flow of gas at the entry to the disposal system which ensures that the permissible spillage to atmosphere is not exceeded

3.39

induced flow

that flow at the inlet of the transfer system which is caused by the sub-atmospheric pressure generated in the AGSS

3.40

spillage

volume of expired or excess anaesthetic gas which cannot be accommodated by the AGSS over a given period

3.41

clearly legible

visual attribute of information displayed by the equipment that allows the operator to discern (or identify) qualitative or quantitative values or functions under a specific set of environmental conditions

3.42

operator's position

intended orientation of the operator with respect to the equipment for normal use according to the instructions for use

4 General requirements and general requirements for test

4.1 Modifications to EN 60601-1:1990, Clause 3

Anaesthetic workstations shall comply with EN 60601-1-1. EN 60601-1:1990, Clause 3 applies with the following additions.

3.1 Add the following to 3.1.

All parts of an anaesthetic workstation and its modules shall be designed and manufactured to minimize health risks by reducing the leaching of substances from the devices during normal use to levels below those assumed to be non-toxic.

3.6 Add the following items.

3.6aa) R: Applicable single fault conditions are short or open circuits of components or wiring which can:

- cause sparks to occur; or
- increase the energy of sparks; or
- increase temperatures (see Section 7 of this European Standard).

3.6bb) R: An oxidant leak which is not detected by e.g. an alarm or periodic inspection shall be considered a normal condition and not a single fault condition.

4.2 Modifications to EN 60601-1:1990, Clause 4

EN 60601-1:1990, Clause 4 applies with the following additions:

4.5aa), If not stated otherwise gas leakage values shall be measured at an ambient pressure of 101,3 kPa and 20 °C or shall be corrected to these conditions.

4.101 Type testing of modules of anaesthetic workstations

For type testing of modules of an anaesthetic workstation only the appropriate clause(s) as listed in Annex CC of this European Standard shall apply to demonstrate compliance with this European Standard.

For the purpose of this European Standard the phrase “shall be operated with” shall be interpreted to mean that:

- either the workstation is equipped with the module; or
- the module is intended to be added to the system before the workstation is used.

5 Classification

EN 60601-1:1990, Clause 5 applies with the following addition.

NOTE An anaesthetic workstation may have applied parts of different types.

6 Identification, marking and documents

EN 60601-1:1990, Clause 6 applies with the following additions and modifications.

In Clause 6, second dash add the following:

- see Annex QQ of this European Standard for compliance.

In 6.1j), replace the first sentence with the following.

R: The rated input marking required in EN 60601-1:1990, 6.1j) shall be given in amperes for the anaesthetic workstation and for the sum of the current ratings for the anaesthetic workstation and the auxiliary mains socket outlets.

Replace 6.1k) with the following.

R: Each auxiliary mains socket outlet shall be marked with the maximum allowed output in amperes.

If auxiliary mains socket outlets(s) can accept a mains plug, the auxiliary mains socket outlet(s) shall be marked with symbol 14 of Table D1, Annex D in EN 60601-1:1990.

In 6.1 add the following additional items:

6.1aa) All operator-detachable, flow-direction-sensitive components, breathing attachments or modules shall be clearly and durably marked with an arrow showing direction of gas flow.

6.1bb) Each gas-specific inlet and outlet shall be identified by clear and durable marking using gas name or chemical symbol in accordance with EN 739. If colour coding is used in addition it shall be in accordance with EN 1089-3. See Special National Conditions in Annex TT.

6.1cc) Respiratory gas conducting components

— **Marking of a ventilator port**

The ventilator port on an anaesthetic breathing system, if provided, shall be marked with the word “VENTILATOR” or an appropriate symbol.

— **Marking of a reservoir bag port**

The connection port(s) for reservoir bag(s) shall be marked with the word “BAG” or with a symbol to denote “bag” (see also 107.1.3).

— **Marking of antistatic and conductive parts**

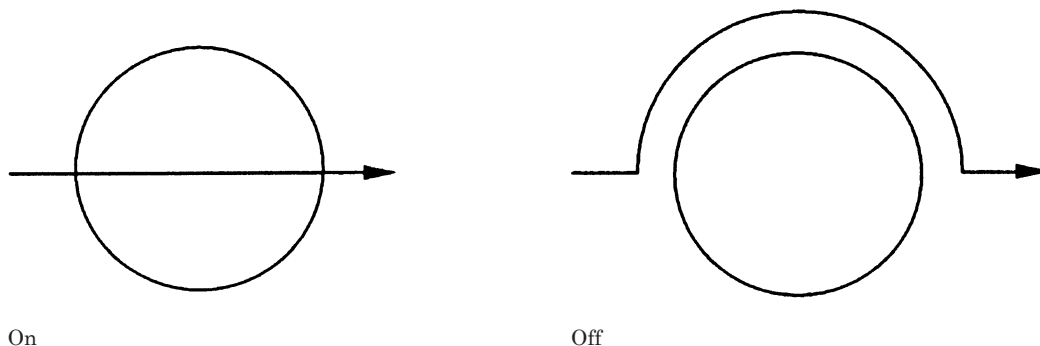
Anaesthetic breathing systems, breathing attachments and integrally-attached non-metallic components made of antistatic or conductive materials in accordance with EN 60601-1:1990, 39.3b) shall be clearly marked with the word “ANTISTATIC” or “CONDUCTIVE” (see 107.2).

NOTE They can also bear a continuous indelible yellow-coloured line throughout their length.

— **Bypass to carbon dioxide-absorber assemblies**

If a means of bypassing the absorbent is provided, its control shall be marked either “absorber on”, and “absorber off” and/or with the symbols given in Figure 101. (See also subclause 107.5.)

The “absorber-off” indicator shall be visible to the operator from a normal operating position.



NOTE 1 The symbols “on” and “off” may be preceded by the word “absorber”.

NOTE 2 The “off” position means that gas does not pass through the absorbent.

Figure 101 — Symbols on CO₂-absorber assembly control

6.1dd) Marking of devices, labels and packaging

Devices, labels and/or packaging shall include the following information as applicable:

- if the intended purpose of the device is not obvious to the operator, the device shall be provided with instructions for use;
- the name or trademark and address of the manufacturer. For devices imported into the European Union the following shall also be included: the name and address of the person responsible or of the authorized representative of the manufacturer or the importer established within the European Community shall be provided with the device or with the accompanying documents;
- a device identification and content information;
- where appropriate the symbol STERILE as specified in EN 980, together with the method of sterilization;
- where appropriate, the batch code, preceded by the symbol LOT, as specified in EN 980, or serial number;
- where appropriate, an indication of the date by which the device can be used in safety, expressed as the year and month;
- where appropriate, an indication that the device is for single use;
- any special storage and/or handling conditions;
- any warning or precautions to take;
- for active medical devices the year of manufacture except for those covered by sixth dash above;
- where appropriate, the recommended method(s) of cleaning, disinfection and sterilization;
- device packaging and/or labelling shall differentiate between the same or similar products placed on the market both sterile and non-sterile by the same manufacturer;
- packages containing breathing attachments or complete anaesthetic breathing systems made of antistatic or conductive material shall be clearly marked with the word “ANTISTATIC” or “CONDUCTIVE” (see 107.2);
- the necessary instructions in the event of the sterile pack being damaged and, where appropriate, details of appropriate methods of re-sterilization.

6.1ee) Marking of anaesthetic ventilators

The relief pressure of the maximum airway pressure protection module shall be marked on an anaesthetic ventilator not provided with an operator-adjustable pressure limiting system (see 51.113).

In 6.3 add the following additional items.

6.3aa) Pressure displays

Gas supply pressures shall be displayed in units of kPa times 100.

NOTE Additional units e.g. bar can be used.

Each gas specific pressure display shall be identified by the gas name or chemical symbol in accordance with EN 739.

If colour coding is used in addition it shall be in accordance with EN 1089-3. See Special National Conditions in Annex TT.

Pressures in the anaesthetic breathing system shall be displayed in Pa times 100.

NOTE Additional units e.g. cm H₂O can be used.

6.3bb) Anaesthetic gas delivery modules

- Each flow adjustment control of a single gas supply and each concentration adjustment control or their surroundings shall be identified by clear and durable marking using the gas name or chemical symbol in accordance with EN 739.

If colour coding is used in addition it shall be in accordance with EN 1089-3. See Special National Conditions in Annex TT.

- The scale including the minimum and maximum concentration mark of the gas mixture control of a gas mixing system shall be marked to indicate the concentration of oxygen % (V/V) in the delivered gas.

- The oxygen flush control shall be clearly marked with one of the following:
 - “oxygen flush”
 - “O₂ flush”
 - “O₂ +”
- The value to which the pressure at the fresh gas outlet is limited shall be marked near to the fresh gas outlet.
- The point of reference for reading the float shall be marked on the flow meter assembly.

6.3cc) Anaesthetic vapour delivery modules

- The maximum and minimum filling levels shall be marked on the liquid level indicator. As an alternative the actual usable volume shall be clearly displayed.
- Each operator-detachable anaesthetic vapour delivery module shall be marked with either the words “see instructions for use” or the symbol for “Attention, consult accompanying documents” (No.14 in Table D1 of EN 60601-1:1990).
- If operator-accessible the anaesthetic vapour delivery module or the anaesthetic agent reservoir and/or filling port shall be marked with the generic name of the anaesthetic agent. The control activating the delivery of a specific anaesthetic agent shall be marked with the generic name in full spelling or abbreviated form.

If colour coding is used it shall be in accordance with Annex HH.

- The unit in which the control of the anaesthetic vapour delivery module is graduated shall either be marked on the control or shall be clearly displayed.
- Graduated controls if provided shall be marked “0” or “off” or with both if the zero-position is not also the “off”-position.

In **6.6**, add the following additional item:

aa) See **6.1bb)** of this European Standard.

In **6.7** add the following additional item:

aa) Requirements for visual alarm indications are given in **51.114**.

In **6.8.2a)** add the following additional items.

- EN 1041 shall apply.
- Instructions for use shall include information about the purpose and intended use of the anaesthetic workstation and/or its modules.
- The manufacturer/supplier of the anaesthetic workstation or actuator module(s) shall provide a list of the necessary monitoring, alarm and protection module(s) which are not an integral part of the anaesthetic workstation or actuator module(s) as specified in this European Standard (see Table 101 or Table 102 respectively).
- The instructions for use shall state that the monitoring, alarm and protection module(s) listed in **6.8.2a)** third additional dash, i.e. which are not an integral part of the anaesthetic workstation or actuator module(s), are required to protect against hazardous output and that they have to be in compliance with this European Standard.
- The instructions for use shall contain a warning statement to the effect that when in use the anaesthetic workstation shall have not more than four operator-accessible auxiliary mains socket outlets.
- The instructions for use shall contain the conditions under which measured values are displayed [e.g. BTPS (Body Temperature Pressure Saturated), ATPS (Ambient Temperature Pressure Saturated), STPD (Standard Temperature Pressure Dry)].

In 6.8.2 add the following additional items.

aa) The instructions for use of category APG anaesthetic workstations shall include statements to the effect that:

- this anaesthetic workstation has been constructed to comply with the requirements for category APG equipment;
- any modification to the anaesthetic workstation may compromise its safety in the presence of flammable anaesthetic agents;
- provided that the following precautions are strictly observed this anaesthetic workstation is safe to use with flammable anaesthetic agents such as diethyl-ether and cyclopropane:
 - the discharge of flammable anaesthetic agents or mixtures whilst the anaesthetic breathing system is disconnected is to be avoided;
 - only equipment classified and marked as APG should be used within 5 cm of any point of possible emission of flammable anaesthetic agents or mixtures;
 - only equipment classified and marked as AP or APG should be used within 25 cm of any point of possible emission of flammable anaesthetic agents;
- where applicable, the manufacturer shall disclose the supply pressure(s) at which the anaesthetic workstation ceases to function and give a warning that a malfunctioning of the central gas supply system can cause more than one or even all anaesthetic workstations connected to it to stop their operation simultaneously.

bb) **R:** The instructions for use of anaesthetic workstations marked as APG but having parts which are not category APG shall include full information to identify such parts.

cc) **R:** The instructions for use of category APG anaesthetic workstations shall include a warning statement to the effect that:

- when using agents forming flammable mixtures only antistatic or electrically conductive components shall be used in the anaesthetic breathing system. This does not apply to tracheal tubes, tracheal tube connectors and oropharyngeal airways.

dd) **R:** The instructions for use of anaesthetic workstations not specified as category APG equipment shall include a statement to the effect that:

- to avoid explosion hazards, flammable anaesthetic agents such as ether and cyclopropane shall not be used in this anaesthetic workstation. Only anaesthetic agents which comply with the requirements for non-flammable anaesthetic agents in this European Standard are suitable for use in this anaesthetic workstation.

NOTE It is recommended that manufacturers of inhalation/volatile anaesthetic agents should state in their labelling whether the agent complies with the tests set out in Annex AA of this European Standard and is therefore safe for use in anaesthetic workstations not classified APG.

ee) **R:** The instructions for use of anaesthetic workstations not specified as category APG shall include a statement to the effect that:

- burns can occur if antistatic or electrically-conductive breathing tubes are used while high-frequency electric surgery equipment is in use. Therefore, such breathing tubes are not recommended.

ff) If auxiliary mains socket outlet(s) accept a standard mains plug the instructions for use shall contain a warning relating to symbol 14 of EN 60601-1:1990 required in 6.1k) of this European Standard to the effect that:

- the connection of equipment to the auxiliary mains socket outlet(s) can increase the patient leakage currents to values exceeding the allowable limits in the event of a defective protective earth conductor.

gg) The instructions for use shall contain information on methods of cleaning and/or sterilization prior to use.

hh) **Information about anaesthetic gas delivery modules**

Instructions for use shall contain:

- if the anaesthetic workstation is fitted with a gas mixing system an instruction to disconnect the anaesthetic workstation from the gas supply after use to prevent contamination or pollution of the pipeline system;
- a schematic flow diagram;
- the pressure at which the gas cut-off device specified in 51.110 is activated, if provided.

ii) Information about anaesthetic vapour delivery modules

If the anaesthetic workstation is fitted with an anaesthetic vapour delivery module by the manufacturer or it is intended that a recommended anaesthetic vapour delivery module is to be fitted according to the manufacturer's instructions, the following shall be contained in the instructions for use:

- details of the anaesthetic vapour delivery module performance, including the effects of variation in ambient temperature, ambient pressure, tilting, back pressure, input flow and gas mixture composition;
- instructions for use of any agent specific filling device(s) with which the anaesthetic vapour delivery module is fitted;
- the carrier gas and gas flow(s) which were used for calibration of the anaesthetic vapour delivery module and, if the anaesthetic workstation is recommended for use with an anaesthetic ventilator, the anaesthetic ventilator settings used when calibrating the anaesthetic vapour delivery module;
- a statement that the anaesthetic vapour delivery module should not be used between “off” and the first graduation above zero, if the anaesthetic vapour delivery module cannot be calibrated in this range;
- if applicable, the volume of agent required to fill the agent reservoir from the minimum to the maximum filling level, and the total capacity;
- instructions for testing for correct connection of any operator-detachable anaesthetic vapour delivery module;
- advice on handling and transportation and storage.

jj) Information about respiratory gas conducting components

The instructions for use shall contain the following information:

- a schematic diagram of the gas flow within the anaesthetic breathing system and the anaesthetic ventilator module identifying their components and their location(s);
- the volume, resistance and compliance of anaesthetic breathing systems supplied complete. Resistance shall be disclosed for flows of 60 l/min for adult use, 30 l/min for paediatric use and 5 l/min for neonatal use;
- if the fresh gas utilization is stated the test method shall be disclosed.
- for circle absorber assemblies:
 - a diagram of the absorber bypass mechanism, if present;
 - the material specification of the carbon dioxide absorbent recommended for use in the absorber;
 - instruction for draining water from the absorber assembly, if applicable;
 - instruction to check the colour change of the absorbent;
 - the proportion of gas which does not pass through the absorbent with the by-pass control, if fitted, in the “on” position. The operating conditions and the method(s) of testing shall be disclosed;
 - the internal compliance of the circle absorber assembly, measured with the carbon dioxide absorbent container filled with fresh absorbent of the type recommended by the manufacturer, and expressed as a volume in millilitres at 3 kPa (30 cm H₂O);
 - the volume of the carbon dioxide absorbent container(s) expressed in millilitres;
 - instructions for changing the carbon dioxide absorbent, cleaning the absorber and maintaining the leak-tightness of the absorber;
 - if the circle absorber assembly is provided with a bypass the leakage from the circle absorber assembly, measured as described in **GG.11** with and without the carbon dioxide absorbent container(s) fitted;
 - the pressure generated by a wet unidirectional valve when tested as described in **GG.12**;
 - the pressure to open a wet unidirectional valve when tested as described in **GG.13**.

kk) Information about monitoring, alarm and protection modules

The instructions for use shall contain:

- a description of the methods of verifying alarm functions;
- details of any pressure-relief valves fitted to the anaesthetic workstation;
- details of the oxygen-failure alarm system(s) and the associated cut-off devices.

ll) *Information about anaesthetic gas scavenging systems*

The manufacturer shall provide the following information with AGSS components:

- the maximum and minimum allowable extract flow and differential pressure measured at the interface point between the receiving system and the disposal system or between the receiving system and the power device (see Figure 106).

NOTE This allows a disposal system to be matched to an AGSS transfer and receiving system without using the AGSS to measure the performance of the disposal system.

- the functional characteristics of particle filters according to 111.4.3.

mm) *Information about electromagnetic compatibility*

The instructions for use shall include a warning statement to the effect that:

- the functioning of this anaesthetic workstation or module, as applicable, may be adversely affected by electromagnetic interference exceeding the levels specified in EN 60601-1-2.

NOTE If it can be demonstrated that the anaesthetic workstation or module, as applicable, is resistant to the levels exceeding those specified in EN 60601-1-2, the instructions for use can state the appropriate higher levels to which the equipment has been tested.

nn) *Information about disposal*

The instructions for use shall include information about any precautions to be taken if there is a specific unusual risk associated with the disposal of the device.

oo) *Information about functioning with reserve power*

If the anaesthetic workstation or its modules are provided with a reserve power supply the functioning after a switch-over to the reserve power supply shall be described.

6.8.3 *Technical description*

In 6.8.3a) add the following additional item.

- The technical description shall additionally include the following information:
 - **R:** Accuracies, display resolutions and ranges of displayed values and calibrated controls.

NOTE The accuracies should be expressed in the form of maximum zero error (bias) quoted directly in appropriate units plus a sensitivity error (linearity, precision), e.g. quoted as a percentage of the reading.

- Interdependence of controls, if applicable.

In 6.8.3 add the following additional items.

6.8.3aa) *Technical description of anaesthetic gas delivery modules*

The technical description shall include the following:

- the pressure and flow characteristics of any gas power outlet under worst-case conditions stated by the manufacturer;
- the specified range of flows from the anaesthetic gas delivery module, if applicable;
- a statement of the composition and dryness specification for all gases to be supplied to the anaesthetic gas delivery module;
- details of non-return valves and pressure-relief valves and their characteristics, if fitted.

6.8.3bb) Technical description of the anaesthetic ventilator module

The technical description shall include the following information as far as applicable:

- a listing of the following pressures:
 - maximum limited pressure ($P_{\text{lim, max}}$);
 - range of values to which the maximum working pressure can be set and the means by which the maximum is assured (e.g. pressure-cycling, pressure-limiting, pressure generation) and a statement whether sub-atmospheric pressure is available in the expiratory phase;
 - minimum sub-atmospheric limited pressure ($P_{\text{lim, min}}$);
 - range of values to which the minimum sub-atmospheric working pressure can be set and the means by which the minimum is assured;
- a listing of the ranges of the following parameters:
 - cycling pressure;
 - end-expiratory pressure;
 - if there is a facility for sub-atmospheric pressure in the expiratory phase, the limiting pressure and generated pressure, if applicable, shall be listed for the expiratory phase and the inspiratory phase;
- a technical description of the means of triggering;
- the purpose, type, range and sensing position of all measuring and display devices either incorporated into the anaesthetic ventilator module or recommended by the manufacturer for use with the anaesthetic ventilator module.

In **6.8** add the following additional item.

6.8.101 Check list

Each anaesthetic workstation and its modules shall be provided with a check list(s) which summarizes the test and operating procedures recommended by the manufacturer which have to be performed by the operator prior to use (see **51.116**).

The use of electronic displays, e.g. cathode ray tube (CRT), is permitted.

7 Power output

EN 60601-1:1990, Clause **7** applies.

Section 2. Environmental conditions

8 Basic safety categories

Not used.

9 Removable protection means

Not used.

10 Environmental conditions

EN 60601-1:1990, Clause 10 applies with the following addition.

10.101 Pneumatic power supply

If the anaesthetic workstation and its modules are intended to be connected to a medical gas supply system (either a medical gas pipeline system complying with prEN 737-3 or a pressure regulator complying with EN 738-1) they shall operate and meet the requirements of this European Standard for pneumatic power supplied throughout a range of 280 kPa to 600 kPa and shall cause no safety hazard under the single fault condition of the medical gas supply system of 1 MPa inlet pressure.

The time-weighted average over 10 s and the steady-state flow for each medical gas required by the anaesthetic workstation shall not exceed 60 l/min at a pressure of 280 kPa measured at the gas inlet port.

11 Not used

12 Not used

Section 3. Protection against electrical shock hazards

13 General

EN 60601-1:1990, Clause 13 applies.

14 Requirements related to classification

EN 60601-1:1990, Clause 14 applies.

15 Limitation of voltage and/or energy

EN 60601-1:1990, Clause 15 applies.

16 Enclosures and protective covers

EN 60601-1:1990, Clause 16 applies.

17 R: Separation

EN 60601-1:1990, Clause 17 applies.

18 Protective earthing, functional earthing and potential equalization

EN 60601-1:1990, Clause 18 applies.

19 Continuous leakage current and patient auxiliary currents

EN 60601-1:1990, Clause 19 applies with the following addition.

In 19.4h) add the following additional item.

12) R: Measurement of the patient leakage currents

The patient leakage current shall be measured from all applied parts classified as the same type (see EN 60601-1:1990, 14.6). These parts shall be connected together electrically. Parts connected to the protective earth terminal shall be tested separately.

20 Dielectric strength

EN 60601-1:1990, Clause 20 applies.

Section 4. Protection against mechanical hazards

21 Mechanical strength

EN 60601-1:1990, Clause 21 applies.

22 Moving parts

EN 60601-1:1990, Clause 22 applies.

23 Surfaces, corners, and edges

EN 60601-1:1990, Clause 23 applies.

24 Stability in normal use

EN 60601-1:1990, Clause 24 applies.

25 Expelled parts

EN 60601-1:1990, Clause 25 applies.

26 Vibration and noise

Not used.

27 Pneumatic and hydraulic power

EN 60601-1:1990, Clause 27 applies.

28 Suspended masses

EN 60601-1:1990, Clause 28 applies.

Section 5. Protection against hazards from unwanted or excessive radiation

29 X-radiation

EN 60601-1:1990, Clause 29 applies.

30 Alpha, beta, gamma, neutron radiation and other particle radiation

EN 60601-1:1990, Clause 30 applies.

31 Microwave radiation

EN 60601-1:1990, Clause 31 applies.

32 Light radiation (including lasers)

EN 60601-1:1990, Clause 32 applies.

33 Infra-red radiation

EN 60601-1:1990, Clause 33 applies.

34 Ultra-violet radiation

EN 60601-1:1990, Clause 34 applies.

35 Acoustical energy (including ultrasonic)

EN 60601-1:1990, Clause 35 applies.

36 Electromagnetic compatibility

EN 60601-1:1990, Clause 36 applies with the following additions.

36.101 Electromagnetic compatibility

The anaesthetic workstation and its modules shall continue to function and meet the requirements of this European Standard or shall fail without causing a safety hazard when tested in accordance with EN 60601-1-2.

If an anomaly occurs, such as display interruption or alarm activation, it shall be possible to restore normal operation within 30 s after the electromagnetic disturbances have been applied.

36.102 Electrostatic discharge

Discharge shall be applied only to accessible parts and coupling planes as defined in EN 60801-2.

Section 6. R: Protection against hazards of ignition of flammable anaesthetic mixtures

37 Locations and basic requirements

EN 60601-1:1990, Clause 37 applies with the following additions.

37.101 R: Anaesthetic agents which are ignited by the test in Annex AA of this European Standard shall be regarded as flammable anaesthetic agents.

Anaesthetic workstations specified for use with such agents shall be classified and marked as category APG equipment and shall comply with the requirements of APG equipment in EN 60601-1:1990.

NOTE Diethyl-ether and cyclopropane are such agents in use.

37.102 R: Anaesthetic agents which are not ignited by the test in Annex AA of this European Standard shall be regarded as non-flammable anaesthetic agents.

Anaesthetic workstations specified for use only with such agents shall comply with subclause 37.103 of this European Standard.

NOTE Such an agent in use is, e.g. halothane (2-bromo 2-chloro 1,1,1-trifluoro-ethane).

37.103 R: Requirements for anaesthetic workstations not specified and marked as category APG equipment.

In an anaesthetic workstation not classified as category APG equipment electrical circuits which may be a source of ignition under normal condition and single fault condition in enclosed compartments within which anaesthetic mixtures with oxygen and/or nitrous oxide are produced or used, shall comply with the requirements of Clause 43 of this European Standard.

38 Marking, accompanying documents

EN 60601-1:1990, Clause 38 applies.

39 Common requirements for category AP and category APG equipment

EN 60601-1:1990, Clause 39 applies with the following addition.

In 39.3, add the following additional item.

aa) **R:** An anaesthetic workstation specified and marked as APG shall provide a continuous current path for electrostatic charges from the fresh gas outlet to earth with a resistance less than 1 megaohm.

Compliance is checked by the following test.

The resistance shall be measured between the fresh gas outlet(s) and in turn:

- a conductive plate on which the anaesthetic workstation is placed;
- any protective earth terminal;
- any terminal for potential equalization conductor.

40 R: Requirements and tests for category AP equipment, parts and components thereof

EN 60601-1:1990, Clause 40 applies.

41 Requirements and tests for category APG equipment, parts and components thereof

EN 60601-1:1990, Clause 41 applies.

Section 7. Protection against excessive temperatures, and other safety hazards

42 Excessive temperatures

EN 60601-1:1990, Clause 42 applies.

43 R: Fire prevention

EN 60601-1:1990, Clause 43 applies with the following addition.

In order to reduce the risk to patients, other persons or the surroundings due to fire, ignitable materials, under normal and single fault conditions, shall not, at the same time, be subjected to conditions in which:

- the temperature of the material is raised to its minimum ignition temperature; and
- an oxidant is present.

The minimum ignition temperature shall be determined in accordance with IEC 60079-4 using the oxidizing conditions present under the normal and single fault condition.

Compliance is checked by determining the temperature the material is raised to under the normal and single fault condition.

If sparking can occur under normal or single fault conditions, the material subjected to the energy dissipation of the spark shall not ignite under the oxidizing conditions present.

Compliance is checked by observing if ignition occurs under the most unfavourable combination of normal conditions with a single fault.

44 Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization, disinfection and compatibility

EN 60601-1:1990, Clause 44 applies with the following additions.

44.3 Add

The anaesthetic workstation and its modules shall be so constructed that spillage does not wet components which, when wetted, can cause a safety hazard.

Compliance shall be checked by the test given in EN 60601-1:1990, 44.3

44.7 Add

47.101 In order to minimize the risk of infection to the patient from respiratory gas conducting components, all components specified as reusable by the manufacturer which come into contact with the inspiratory gas shall be sterile or disinfected, or sterilizable or disinfectable, or be provided with a microbial filter.

47.102 If a claim is made in the labelling that a device is sterile, the device shall have been sterilized using a validated method.

47.103 Non-sterile device packaging systems shall be designed to maintain products which are intended to be sterilized before use at their intended level of cleanliness and shall be designed to minimize the risk of microbial contamination.

45 Pressure vessels and parts subject to pressure

EN 60601-1:1990, Clause 45 applies.

46 Human errors

Not used.

47 Electrostatic charges

Not used.

48 R: Materials in applied parts in contact with the body of the patient

EN 60601-1:1990, Clause 48 applies.

49 Interruption of the power supply

EN 60601-1:1990, Clause 49 applies with the following additions.

49.101 Means shall be provided to prevent inadvertent operation of the “off” switch.

Compliance shall be checked by inspection.

49.102 R: Transient interruptions of the power supply shall not cause a safety hazard.

Compliance shall be checked by inspection and functional testing.

Section 8. Accuracy of operating data and protection against hazardous output

50 Accuracy of operating data

EN 60601-1:1990, Clause 50 applies.

51 Protection against hazardous output

EN 60601-1:1990, Clause 51 applies with the following additions.

51.101 The particular requirements of the monitoring and alarm modules apply when the anaesthetic workstation is operating under normal power supply condition.

When operating under reserve power supply, if provided, see **51.102.2** and **51.102.3**.

Each anaesthetic workstation or actuator module for use in an anaesthetic workstation shall be provided with means of protection against hazards from delivery of energy or substances to the patient. These means shall either be integrated into the anaesthetic workstation or the actuator module or, if not integrated, the manufacturer shall provide information about which monitoring, alarm and protection modules are necessary and how to use them (see **6.8.2** of this European Standard).

The particular requirements of these monitoring, alarm and protection modules are specified in this document (Clause 6 and Clause 51 and Section 10) and are summarized in Annex CC.

For the purpose of this European Standard the phrase “if the anaesthetic workstation is in use with a ‘xxxx’ module, it shall be operated with ‘yyyy’” shall be interpreted to mean:

- either,
the anaesthetic workstation is equipped with “yyyy”
- or,
that the “yyyy” module is intended to be added to the system before the anaesthetic workstation is used.

51.102 Power failure alarm module

51.102.1 The anaesthetic workstation shall be operated with a driving power failure alarm which activates an audible alarm signal for at least 7 s duration if the driving power falls below the minimum value specified by the manufacturer for normal operation.

51.102.2 In case of an automatic switch-over to a reserve power supply this mode of operation shall be indicated by a low priority signal as specified in EN 475 or by a visual indicator.

In this case the applicable requirements of **51.114** also apply.

51.102.3 Devices with an internal power source shall be equipped with a means of determining the state of this power source. [See **6.8.200**) of this European Standard.]

Table 101 — Anaesthetic workstation configuration for protection against hazardous output

Actuator modules	Monitoring and alarm modules																Protection modules				
	Power failure alarm	O ₂ -supply failure alarm	Inspiratory oxygen concentration		Anaesthetic agent concentration			Airway pressure			Expired volume		Breathin g system integrity	CO ₂ concentration			N ₂ 0 cut off	AGSS	Maximum pressure limitation	Adjustable pressure limitation	
			M	L	M	L	H	M	L	H	M	L		M	L	H					
Driving power — electrical — pneumatic	+ +																				
Anaesthetic gas delivery — O ₂ — Air — Premixed (1) — Others		+	+	+													+	+			
Anaesthetic vapour delivery module					+	+	+											+			
Anaesthetic ventilator module								+	o (3)	+	+	o (3)	+						+	+	(2)
Anaesthetic breathing system			+	+				+	o	o	o (2)	o (3)	o	+	+	+			+	o	
M Monitor (measurement and display) H High level alarm L Low level alarm + Requirement o Recommendation													(1) Premixed gas of 50 % N ₂ 0 and 50 % O ₂ . (2) Conditional requirement (see appropriate clause). (3) See 51.108.1 NOTE.								