

Medical suction equipment —

Part 1: Electrically powered suction equipment — Safety requirements

The European Standard EN ISO 10079-1:1996 has the status of a British Standard

ICS 11.140

Committees responsible for this British Standard

The preparation of this British Standard was entrusted to Technical Committee CH/4, Suction equipment, upon which the following bodies were represented:

- Association of Anaesthetists of Great Britain and Ireland
- British Anaesthetic and Respiratory Equipment Manufacturers' Association
- British Association of Otolaryngologists
- British Dental Trade Association
- British Society for Restorative Dentistry
- British Surgical Trades Association
- Department of Health
- Electro Medical Trade Association Limited
- Intensive Care Society
- Medical Sterile Products Association
- Ministry of Defence

This British Standard, having been prepared under the direction of the Health and Environment Sector Board, was published under the authority of the Standards Board and comes into effect on 15 January 1997

© BSI 11-1998

First published September 1990
Second edition April 1993
Third edition January 1997

The following BSI references relate to the work on this standard:
Committee reference CH/4
Draft for comment 89/51670 DC

ISBN 0 580 26794 6

Amendments issued since publication

Amd. No.	Date	Comments

Contents

	Page
Committees responsible	Inside front cover
National foreword	iv
Foreword	2
Section 1. General	
1.1 Scope	3
1.2 Normative references	3
1.3 Definitions	4
1.4 General requirements and general requirements for tests	5
1.5 Classification	6
1.6 Identification, marking and documents	6
1.7 Power input	7
Section 2. Environmental conditions	
2.8 Basic safety categories	8
2.9 Removable protective means	8
2.10 Environmental conditions	8
2.11 Special measures with respect to safety	8
2.12 Single fault condition	8
Section 3. Protection against electric shock hazards	
3.13 General	9
3.14 Requirements related to classification	9
3.15 Limitation of voltage and/or energy	9
3.16 Enclosures and protective covers	9
3.17 Separation	9
3.18 Protective earthing, functional earthing and potential equalization	9
3.19 Continuous leakage current and patient auxiliary currents	9
3.20 Dielectric strength	9
Section 4. Protection against mechanical hazards	
4.21 Mechanical strength	10
4.22 Moving parts	10
4.23 Surfaces, corners and edges	10
4.24 Stability in normal use	10
4.25 Expelled parts	10
4.26 Vibration and noise	10
4.27 Pneumatic and hydraulic power	10
4.28 Suspended masses	10
Section 5. Protection against hazards from unwanted or excessive radiation	
5.29 X-radiation	11
5.30 Alpha, beta, gamma, neutron radiation and other particle radiation	11
5.31 Microwave radiation	11
5.32 Light radiation (including lasers)	11
5.33 Infra-red radiation	11
5.34 Ultraviolet radiation	11
5.35 Acoustical energy (including ultra-sonics)	11
5.36 Electromagnetic compatibility	11

	Page
Section 6. Protection against hazards of ignition of flammable anaesthetic mixtures	
6.37 Locations and basic requirements	12
6.38 Marking and accompanying documents	12
6.39 Common requirements for AP and APG equipment	12
6.40 Requirements and tests for AP equipment, parts or components	12
6.41 Requirements and tests for APG equipment, equipment parts or components	12
Section 7. Protection against excessive temperatures and other safety hazards	
7.42 Excessive temperatures	13
7.43 Fire prevention	13
7.44 Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization and disinfection	13
7.45 Pressure vessels and parts subject to pressure	15
7.46 Human errors	15
7.47 Electrostatic charges	15
7.48 Materials in applied parts in contact with body of patient	15
7.49 Interruption of power supply	15
Section 8. Accuracy of operating data and protection against hazardous output	
8.50 Accuracy of operating data	16
8.51 Protection against hazardous output	16
Section 9. Abnormal operation and fault conditions: environmental tests	
9.52 Abnormal operation and fault conditions	17
9.53 Environmental tests	17
Section 10. Constructional requirements	
10.54 General	19
10.55 Enclosures and covers	19
10.56 Components and general assembly	19
10.57 Mains parts, components and layout	21
10.58 Protective earth terminals	21
10.59 Construction and layout	21
Annex M (informative) Rationale statement	25
Annex N (informative) Table of typical range of volumes for collection containers for specific uses	25
Annex P (informative) Lumen (passageway) size and its effects on flow	26
Annex ZA (informative) Clauses of this European Standard addressing essential requirements or other provisions of EU Directives	27
Annex ZB (normative) Normative references to international publications with their relevant European publications	29
Figure 1 — Schematic drawing illustrating suction equipment	4
Figure 2 — Typical test apparatus for evaluating leakage of collection container for general use	14
Figure 3 — Typical test apparatus for evaluating leakage of collection container designated for use in thoracic drainage system	14
Figure 4 — Typical test apparatus for evaluating thoracic drainage system performance	19
Figure 5 — Test apparatus for suction tubing	21

	Page
Figure 6 — Test apparatus for thoracic drainage	23
Figure 7 — Test apparatus for battery-powered transportable suction equipment	23
Figure 8 — Apparatus for testing resistance to implosion of collection container	24
Table N.1 — <i>Untitled</i>	25
Table P.1 — Relative flow rates of straight tubing	26
Table ZA.1 — Correspondence between this European Standard and EU Directives	27
List of references	Inside back cover

National foreword

This British Standard has been prepared by Technical Committee CH/4 and is the English language version of EN ISO 10079-1:1996 *Medical suction equipment — Part 1: Electrically powered suction equipment — Safety requirements*, published by the European Committee for Standardization (CEN). It supersedes BS 5724-2.28:1993, which is withdrawn.

NOTE This standard is a new edition and does not differ technically from BS 5724-2.28:1993.

It was derived by CEN from ISO 10079-1:1991 including Technical Corrigenda 1:1992 and 2:1993 published by the International Organization for Standardization (ISO).

Attention is drawn also to BS EN ISO 10079-2 and BS EN ISO 10079-3 which specify requirements respectively for manually powered medical suction equipment and non-electrical suction equipment powered from a vacuum or pressure source.

Cross-references

Publication referred to	Corresponding British Standard
ISO 3744	BS EN ISO 3744:1995 <i>Acoustics. Determination of sound power levels of noise sources using sound pressure. Engineering method in an essentially free field over a reflecting plane</i>
ISO 5356-1:1987	BS 3849 <i>Conical connectors for anaesthetic and respiratory equipment</i> Part 1:1988 <i>Specification for cones and sockets (excluding 8.5 mm size)</i>
IEC 529	BS EN 60529:1992 <i>Specification for degrees of protection provided by enclosures (IP Code)</i>
IEC 601-1:1988	BS 5724 <i>Medical electrical equipment</i> Part 1:1989 <i>General requirements for safety</i>
IEC 651:1979	BS EN 60651:1994 <i>Specification for sound level meters</i>
IEC 695-2-2	BS EN 60695 <i>Fire hazard testing</i> Part 2. <i>Test methods</i> Section 2.2:1995 <i>Needle-flame test</i>

A British Standard does not purport to include all the necessary provisions of a contract. Users of British Standards are responsible for their correct application.

Compliance with a British Standard does not of itself confer immunity from legal obligations.

Summary of pages

This document comprises a front cover, an inside front cover, pages i to iv, the EN title page, pages 2 to 30, an inside back cover and a back cover.

This standard has been updated (see copyright date) and may have had amendments incorporated. This will be indicated in the amendment table on the inside front cover.

ICS 11.040.10

Descriptors: See ISO document

English version

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)

Matériel d'aspiration médical —
Partie 1: Matériel électrique d'aspiration —
Prescriptions de sécurité
(ISO 10079-1:1991, Rectificatif
Technique 1:1992 et Rectificatif
Technique 2:1993 inclus)

Medizinische Absauggeräte —
Teil 1: Elektrisch betriebene Absauggeräte —
Sicherheitsanforderungen
(ISO 10079-1:1991, enthält Technisches
Korrigendum 1:1992 und Technisches
Korrigendum 2:1993)

This European Standard was approved by CEN on 1996-04-05. 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.

This European Standard exists 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, 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

© 1996 Copyright reserved to CEN members

Ref. No. EN ISO 10079-1:1996 E
 **Documents**
Document Sharing Hub

Foreword

The text of the international standard ISO 10079-1:1991, including Technical Corrigendum 1:1992 and Technical Corrigendum 2:1993 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 the Technical Committee CEN/TC 215, Respiratory and anaesthetic equipment, the secretariat of which is held by BSI. 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).

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 November 1996, and conflicting national standards shall be withdrawn at the latest by June 1998.

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

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

ISO 10079 consists of the following parts, under the general title *Medical suction equipment*:

- *Part 1: Electrically powered suction equipment;*
- *Part 2: Manually powered suction equipment;*
- *Part 3: Suction equipment powered from vacuum or pressure source.*

The annexes M, N and P of this international standard are informative.

NOTE Normative references to international standards are listed in annex ZB (normative).

Section 1. General

1.1 Scope

NOTE See also annex M (in this part of ISO 10079).

ISO 10079-1 is one of a series of International Standards based on IEC 601-1; in IEC 601-1 (the "General Standard"), this type of International Standard is referred to as a "Particular Standard". As stated in 1.3 of IEC 601-1:1988, the requirements of this International Standard take precedence over those of IEC 601-1.

The Scope and Object given in clause 1 of IEC 601-1:1988 applies except that 1.1 shall be replaced by the following:

This part of ISO 10079 specifies minimum safety and performance requirements for medical and surgical suction equipment (see Figure 1) in health care facilities such as hospitals, for domiciliary care of patients and for field and transport use. Although equipment may be driven by centrally powered piped vacuum systems, compressed gases, electricity or be manually powered for a variety of applications, this part addresses only equipment powered electrically.

Excluded from the standard are:

- a) central power supply (by vacuum/compressed air generation), piping systems of vehicles and buildings, and wall connectors;
- b) catheter tubes, drains, curettes and suction tips;
- c) syringes;
- d) dental suction equipment;
- e) waste gas scavenging systems;
- f) laboratory suction;
- g) autotransfusion systems;
- h) passive urinary drainage;
- i) closed system for wound drainage;
- j) gravity gastric drainage;
- k) orally operated mucous extractors;
- l) suction equipment where the collection container is downstream of the vacuum pump;

- m) equipment marked as suction unit for permanent tracheostomy;
- n) ventouse (obstetric) equipment;
- o) neonatal mucous extractors;
- p) suction equipment marked for endoscopic use only.

1.4 Environmental conditions

The requirements given in 1.4 of IEC 601-1 apply except that the following modification shall be made to 1.4 b) 1).

Substitute "+ 5 °C" for "+ 10 °C" and "+ 35 °C" for "40 °C".

For field and transport use, environmental conditions shall be as specified in 53.

1.2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 10079. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 10079 are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 32:1977, *Gas cylinders for medical use — Marking for identification of content*.

ISO 3744:1981, *Acoustics — Determination of sound power levels of noise sources — Engineering methods for free-field conditions over a reflecting plane*.

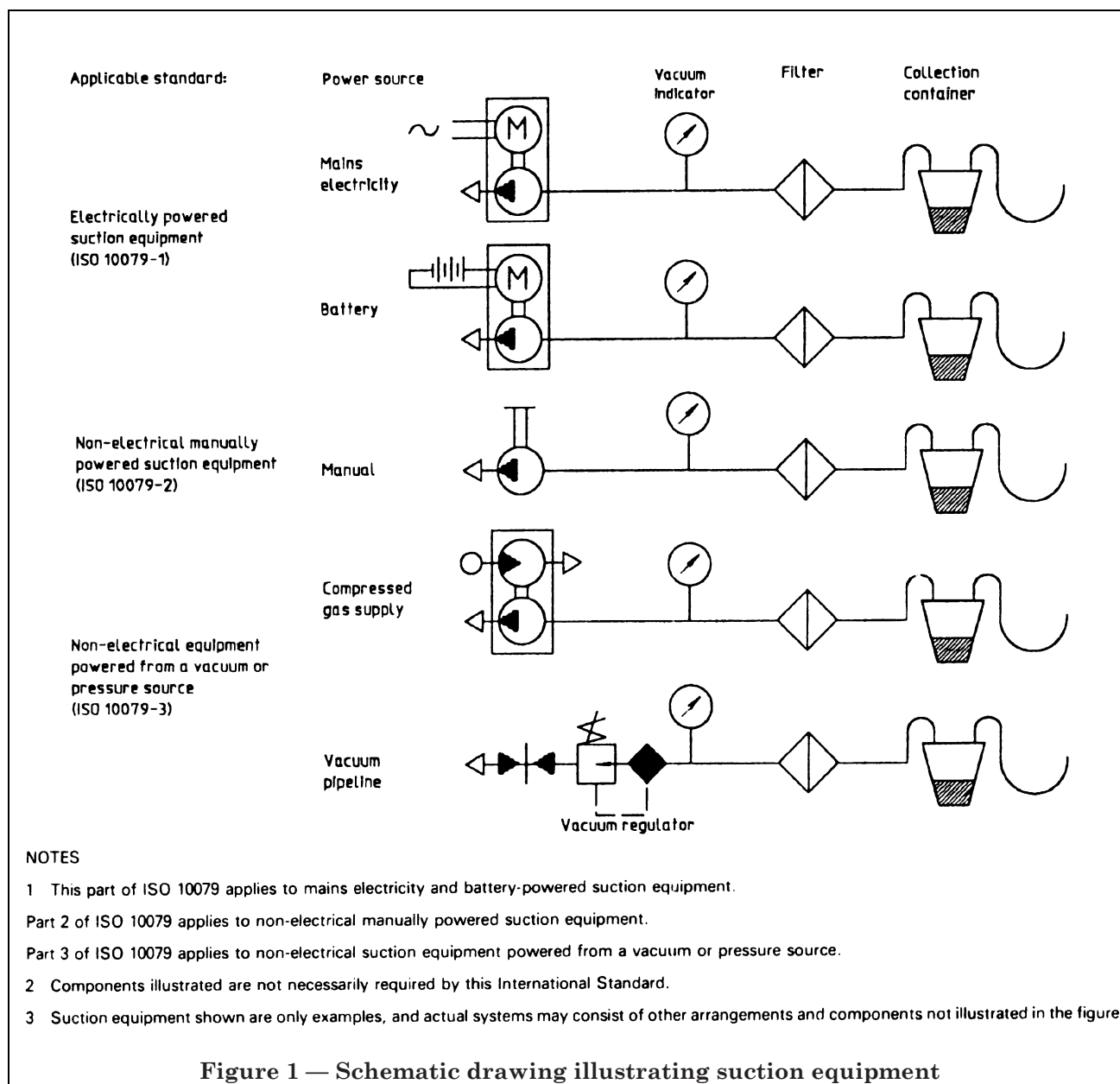
ISO 5356-1:1987, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets*.

IEC 529:1976, *Classification of degrees of protection provided by enclosures*.

IEC 601-1:1988, *Medical electrical equipment — Part 1: General requirements for safety*.

IEC 651:1979, *Sound level meters*.

IEC 695-2-2:1980, *Fire hazard testing — Part 2: Test methods — Needle-flame test*.



1.3 Definitions

For the purposes of this part of ISO 10079, the definitions given in clause 2 of IEC 601-1:1988 apply except that the definition given in 2.1.5 shall be replaced by the following:

applied part: All parts in the liquid pathway.

Add to definition 2.4.3 the following:

safety extra-low voltage (SELV): Includes the electrical sources which are isolated (e.g. car battery) and do not require a separate transformer or converter with separate windings.

For the purposes of this part of ISO 10079, the following definitions also apply.

1.3.1 vacuum

pressure less than atmospheric pressure, normally expressed as a difference from atmospheric pressure

1.3.2 high vacuum

vacuum of at least – 60 kPa

1.3.3 medium vacuum

vacuum less than – 60 kPa and greater than – 20 kPa

1.3.4**low vacuum**

vacuum not more than – 20 kPa

1.3.5**vacuum regulator**

device for controlling the maximum vacuum applied to the patient

NOTE A series of push buttons or a rotary switch or similar by which it is possible to set different vacuum levels constitute a vacuum regulator.

1.3.6**vacuum indicator**

device for displaying the level of vacuum

1.3.7**suction**

application of vacuum to remove fluids or solid particles

1.3.8**high flow**

suction with a free air flow of 20 l/min or greater

1.3.9**low flow**

suction with a free air flow less than 20 l/min

1.3.10**inlet**

part of a component through which fluids and/or solid particles enter

1.3.11**outlet**

part of a component through which fluids and/or solid particles exit

1.3.12**exhaust opening**

port or ports through which exhaust is discharged

1.3.13**collection container**

container in which fluids or solid particles are collected

1.3.14**collection container assembly**

collection container and its closure

1.3.15**overflow device**

device intended to prevent liquid or solid particles entering the intermediate tubing

1.3.16**filter**

device for separation of particulate matter

1.3.17**end-piece**

that part of the suction equipment applied to the patient. The end-piece starts at the site where material is drawn in and ends upstream of the first detachable connection

1.3.18**vacuum pump**

powered device for generating vacuum

1.3.19**thoracic drainage**

drainage by application of suction to the thoracic cavity of the patient

1.3.20**intermittent suction**

suction where the negative pressure applied to the end-piece is automatically and periodically returned to atmospheric pressure

NOTE Cycling may be determined by end-piece occlusion.

1.3.21**drainage**

removal of fluids from a body cavity or wound, assisted by vacuum

1.3.22**free air flow**

unrestricted flow of air through a nominated inlet

1.3.23**suction tubing**

tubing as supplied or recommended by the manufacturer for conduction of fluids from the end-piece to the collection container

1.3.24**breast pump**

vacuum pump for the collection of breast milk

1.3.25**pharyngeal suction**

suction applied to the human pharynx through the mouth

1.3.26**intermediate tubing**

tubing between the collection container and the vacuum pump

1.4 General requirements and general requirements for tests

The requirements given in clauses 3 and 4 of IEC 601-1:1988 apply together with the following addition:

- In 4.6, add the following additional item:
 - f) Where reference is made in test methods to tubing, that supplied or recommended by the manufacturer shall be used.

1.5 Classification

The classification given in clause 5 of IEC 601-1:1988 applies.

1.6 Identification, marking and documents

The requirements given in clause 6 of IEC 601-1:1988 apply except for the following additions and modifications:

- Replace 6.1 p) by the following:
 - 1) All equipment generating suction shall be marked with words indicating suction, and with an indication of the available level of vacuum as determined by the manufacturer. This marking shall be visible in the normal working position.

NOTE Equipment should be marked with the designation “high vacuum/high flow”, “high vacuum/low flow”, “medium vacuum/low flow”, “low vacuum/high flow” or “low vacuum/low flow”, as appropriate. Vacuum regulators should also comply with this requirement.

 - 2) Low vacuum equipment with a level of vacuum which is not adjustable by the user shall be marked either with the level of vacuum which can be attained or with words indicating low vacuum.
 - 3) Intermittent suction equipment shall be marked with words indicating intermittent suction. Equipment which can provide continuous and also intermittent suction shall have the mode control clearly marked.
 - 4) If there is a single exhaust opening, it shall be marked with words indicating exhaust opening.
 - 5) Suction equipment intended for thoracic drainage and complying with 59.7 shall be marked as such.
 - 6) The inlet connection to the collection container shall be identified unless misconnection is prevented by a design feature.
 - 7) If the suction equipment is intended for use in the field or in transport and does not comply with 53.1, it shall be marked on the case as not suitable for use at temperatures below “... °C” or above “... °C” with the appropriate limiting temperatures marked. If no case is provided, the statement shall be marked on the equipment.

- In 6.1, add the following additional items:
 - aa) Equipment containing a filter which is intended to be cleaned or changed by the user shall have clearly marked on the equipment or on the filter unit, wording to the effect that the filter should be changed in accordance with the manufacturer’s recommendations.
 - ab) The capacity of the collection container.
- In 6.3 c), add the following:

If a progressive variation of the degree of vacuum is available, the direction of adjustment to increase vacuum shall be clearly and permanently marked.
- In 6.8.1, add the following:

The collection container capacity shall be stated in the accompanying documents.
- In 6.8.2 a), add the following:

The instructions for use shall additionally include the following information:

 - 1) Instructions for operating the vacuum regulator, if supplied, and for setting the required vacuum.
 - 2) The size and type of suction tubing recommended for use with the suction equipment and its means of connection to the collection container.
 - 3) Recommended methods for cleaning and disinfection or sterilization of all applied parts.
 - 4) The method for removing the collection container for emptying.
 - 5) Details of the operation of any overfill device fitted to the collection container assembly and the usable capacity of the collection container in all the recommended inclined planes of operation.
 - 6) If applicable, the method of controlling frothing in the collection container.
 - 7) Instructions, if applicable, for the replacement or cleaning of air filters, and for cleaning or sterilization of the filter housing.
 - 8) Either the type of equipment, e.g. medical suction, high vacuum, high flow, or the level of vacuum and flow obtainable or the vacuum and air flow characteristics obtainable from the equipment as required by 6.1 p) 1), 2) or 3), as appropriate.
 - 9) Instructions to inspect suction tubing, collection containers and any other components that are subject to wear or damage.