

Medical suction equipment —

Part 3: Suction equipment powered from vacuum or pressure source

The European Standard EN ISO 10079-3:1996 has the status of a British Standard

ICS 11.140

Committees responsible for this British Standard

The preparation of this British Standard was entrusted by the Health Care Standards Policy Committee (HCC/-) to Technical Committee HCC/4, 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 Care Standards Policy Committee, was published under the authority of the standards Board and comes into effect on 15 February 1993

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National foreword

This Part of BS 7259 has been prepared under the direction of the Health Care Standards Policy Committee and is identical with ISO 10079-3:1992 *Medical suction equipment — Part 3: Suction equipment powered from vacuum or pressure source* prepared under the direction of Technical Committee 121, Anaesthetic and respiratory equipment, of the International Organization for Standardization (ISO).

In 1996 the European Committee for Standardization (CEN) accepted ISO 10079-3:1992 as a European Standard EN ISO 10079-3:1996. As a consequence of implementing the European Standard, this British Standard is renumbered as BS EN ISO 10079-3:1997.

Attention is drawn to BS EN ISO 10079-2 which specifies requirements for manually powered medical suction equipment and to BS EN ISO 10079-1 which specifies requirements for safety of electrically-powered medical suction equipment.

Cross-references

International standard	Corresponding British Standard
ISO 407:1991	BS 1319:1976 <i>Specification for medical gas cylinders, valves and yoke connections</i> ^a (Technically equivalent)
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> (Identical)
IEC 601-1:1988	BS 5724 <i>Medical electrical equipment</i> Part 1:1989 <i>General requirements for safety</i> (Identical)

^a BS 1319:1976 is technically equivalent to ISO 407:1983. It is expected that BS 1319 will be revised so that it becomes technically equivalent to ISO 407:1991.

The Technical Committee has reviewed the provisions of ISO 5359:1989, to which reference is made in the text, and has decided that they are acceptable for use in conjunction with this standard.

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 and ii, the EN title page, pages 2 to 20, 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: Medical equipment, pneumatically — operated devices, medical suction equipment, specifications, performance evaluation, safety requirements, tests, marking, instructions for use

English version

Medical suction equipment — Part 3: Suction equipment powered from vacuum or pressure source

(ISO 10079-3:1992)

Appareils d'aspiration médicaux —
Partie 3: Appareils d'aspiration alimentés par
une source d'aspiration (vide) ou de pression
(ISO 10079-3:1992)

Medizinische Absauggeräte —
Teil 3: Vakuumoder druckquellenbetriebene
Absauggeräte
(ISO 10079-3:1992)

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.

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CEN

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

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Foreword

The text of the International Standard ISO 10079-3:1992 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.

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.*

According to 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. Annex A forms an integral part of ISO 10079.

Introduction

This International Standard, which has been prepared under the responsibility of Sub-Committee 8 of ISO/TC 121, comprises part 3 of the standard for medical suction equipment, and deals only with suction equipment powered from a vacuum or pressure source. Part 1 deals with safety requirements for electrically powered suction equipment, whereas part 2 deals with manually powered suction equipment.

This International Standard has been prepared in response to a need for a safety and performance standard for suction systems. Suction is used to clear the airway and remove unwanted material from body cavities. Suction is also used to assist drainage and decompress body cavities. Suction and vacuum systems are used widely both in health care facilities such as hospitals, for domiciliary care of patients who are nursed at home, and in emergency situations both outside hospitals in field conditions and during transport in ambulances.

As far as possible, this International Standard has been written specifying performance requirements corresponding with those needed for effective and safe treatment of the patient.

Some devices specified in this standard are intended to be operated in conjunction with a pipeline complying with ISO 7396.

Annex A gives test methods to be used to verify compliance with the requirements given in this part of ISO 10079.

1 Scope

This part of ISO 10079 specifies safety and performance requirements for medical suction equipment powered from a vacuum or pressure source (see Figure 1). In particular it applies to connections for pipelines and venturi attachments.

Suction equipment, e.g. electronic timing, controlled by electrical means, may also need to comply with IEC 601-1:1988.

This part of ISO 10079 does not apply to electrically powered suction equipment, whether mains electricity or battery-powered, which is dealt with in ISO 10079-1, nor to manually powered suction equipment which is dealt with in ISO 10079-2, nor to the following:

- 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 systems 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) breast pumps;
- q) liposuction;
- r) uterine aspiration.

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 407:1991, *Small medical gas cylinders — Pin-index yoke-type valve connections*.

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

ISO 5359:1989, *Low-pressure flexible connecting assemblies (hose assemblies) for use with medical gas systems*.

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

3 Definitions

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

3.1 collection container

container in which liquids or solid particles are collected

3.2 drainage

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

3.3
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 at the first detachable connection

3.4
exhaust opening

port or ports through which exhaust is discharged

3.5
filter

device for separation of particulate matter

3.6
free air flow

unrestricted flow of air through a nominated inlet

3.7
high flow

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

