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1993
ISO 10079-1 :
1991
*(Incorporating Technical
Corrigendum 1 : 1992)*

Medical electrical equipment

Part 2. Particular requirements for safety

Section 2.28 Specification for electrically powered suction equipment

UDC 616-089.816-7

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

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Medical electrical equipment
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equipment

NOTE. This amendment implements Technical Corrigendum 2 to ISO 10079 : Part 1 : 1991, the technical content of which was included in national annex NA of BS 5724 : Section 2.28 : 1993.

Corrections

National foreword

In paragraph 1, line 4, delete 'Technical Corrigendum 1 : 1992', and substitute 'Technical Corrigenda 1 : 1992 and 2 : 1993'.

Delete the second paragraph.

AMD 7947/November 1993

Clause 1.3.5

After the definition, insert the following.

'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.'

AMD 7947/November 1993

Clause 9.52.6

Delete the second paragraph and substitute the following.

'Except for equipment intended for use in transport or in the field, when the requirements of 52.8 shall apply, compliance shall be checked by the test given in 52.7.'

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Clause 10.56.8

After item 6), insert the following.

'NOTE. If equipment intended for field and transport use is fitted with a vacuum regulator with a variable control, a vacuum indicator is required in order to comply with 56.8 1)'.
'

AMD 7947/November 1993

National annex NA. Guidance on interpretation of 9.52.6, 9.52.8 and 10.56.8

Delete the annex entirely.

AMD 7947/November 1993

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National foreword

This Part of BS 5724 has been prepared under the direction of the Health Care Standards Policy Committee and is identical with ISO 10079-1 : 1991 *Medical suction equipment — Part 1 : Electrically powered suction equipment — Safety requirements*, and its Technical Corrigendum 1 : 1992, published by the International Organization for Standardization (ISO). ISO 10079-1 was prepared by ISO Technical Committee ISO/TC 121, Anaesthetic and respiratory equipment. It supersedes BS 5724 : Section 2.28 : 1990, which is withdrawn.

Attention is drawn to national annex NA which gives guidance on the interpretation of **9.52.6**, **9.52.8** and **10.56.8**. This clarification was given by ISO/TC 121 at its meeting in 1992 in response to a request for an interpretation of the standard so as to overcome ambiguities that hindered the verification of conformity of electrically powered suction equipment to ISO 10079-1. It is recommended that users of this British Standard follow the guidance given in national annex NA when testing equipment for compliance.

Attention is drawn also to BS 7259 : Part 1 and Part 2 which specify requirements respectively for manually powered medical suction equipment and non-electrical suction equipment powered from a vacuum or pressure source.

Cross-references

International standard	Corresponding British Standard
ISO 32 : 1977	BS 1319 : 1976 <i>Specification for medical gas cylinders, valves and yoke connections</i> (Technically equivalent)
ISO 3744 : 1981	BS 4196 <i>Sound power levels of noise sources</i> Part 4 : 1981 <i>Engineering methods for determination of sound power levels for sources in free-field conditions over a reflecting plane</i> (Identical)
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)
IEC 651 : 1979	BS 5969 : 1981 <i>Specification for sound level meters</i> (Identical)
IEC 695-2- : 1980	BS 6458 <i>Fire hazard testing for electrotechnical products</i> Section 2.2 : 1984 <i>Needle-flame test</i> (Identical)

The Technical Committee has reviewed the provisions of IEC 529 : 1976, to which normative reference is made in the text, and has decided that they are acceptable for use in conjunction with this standard. Attention is drawn to the fact that a revised edition of IEC 529 was published in 1989 and is identical to BS EN 60529 : 1991.

Textual errors. When adopting the text of the international standard the textual errors listed below were discovered. They have been marked in the text and have been reported to ISO in a proposal to amend the text of the international standard.

In **7.46d**), last line, the word 'lower' should be read as 'power'.

In **10.56**, first line, 'ISO 601-1' should be read as 'IEC 601-1'.

In **59.12**, second line, the words 'the filter' should be read as 'a filter'.

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

Medical suction equipment —

Part 1:

Electrically powered suction equipment — Safety requirements

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.

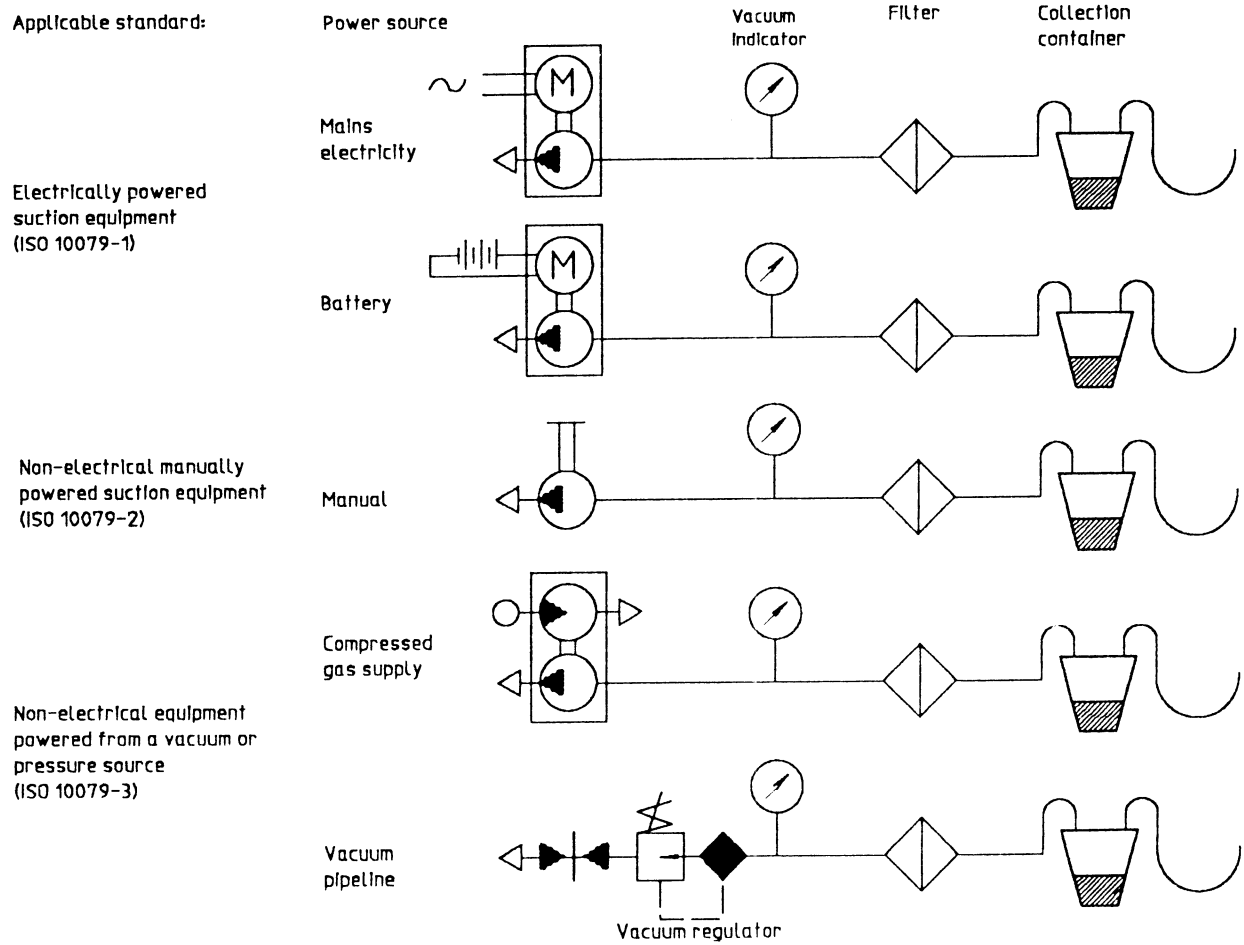
The Scope and Object given in clause 1 of IEC 601-1 : 1988 applies except that 1.1 shall be replaced by the following:

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.



NOTES

- 1 This part of ISO 10079 applies to mains electricity and battery-powered suction equipment.
Part 2 of ISO 10079 applies to non-electrical manually powered suction equipment.
Part 3 of ISO 10079 applies to non-electrical suction equipment powered from a vacuum or pressure source.
- 2 Components illustrated are not necessarily required by this International Standard.
- 3 Suction equipment shown are only examples, and actual systems may consist of other arrangements and components not illustrated in the figure.

Figure 1 — Schematic drawing illustrating suction equipment

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*.