INTERNATIONAL STANDARD

ISO 10079-1

First edition
1991-05-15

Medical suction equipment —

Part 1:
Electrically powered suction equipment — Safety requirements

Matériel d'aspiration médical —

Partie 1: Matériel électrique d'aspiration — Prescriptions de sécurité

Reference number
ISO 10079-1 : 1991 (E)

Contents

International Organization for Standardization
Case postale 56 • CH-1211 Genève 20 • Switzerland
Printed in Switzerland

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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

International Standard ISO 10079-1 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Sub-Committee SC 8, *Suction devices for hospital and emergency care use.*

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

— *Part 1: Electrically powered suction equipment — Safety requirements*

— *Part 2: Non-electrical manually powered suction equipment*

— *Part 3: Non-electrical suction equipment powered from a vacuum or pressure source*

Annexes M, N and P of this part of ISO 10079 are for information only.

Introduction

This part of ISO 10079, which has been prepared under the responsibility of Sub-Committee 8 of ISO/TC 121, comprises Part 1 of the standard for Medical Suction Equipment, and deals only with safety requirements for electrically powered suction equipment.

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.

In this part of ISO 10079, vacuum readings are specified as gauge (relative) pressures to assist clinical personnel. However, this is not intended to prevent engineering groups from using absolute vacuum in their design process.

Test methods other than those specified in this part of ISO 10079, but of equal or greater accuracy, may be used to verify compliance with the given requirements. However, in the event of a dispute, the methods specified in this part of ISO 10079 are to be used as the reference methods.

A rationale for the most important requirements is given in annex M. It is considered that a knowledge of the reasons for the requirements will not only facilitate the proper application of the standard, but will expedite any subsequent revision. This annex does not form part of the standard.

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;

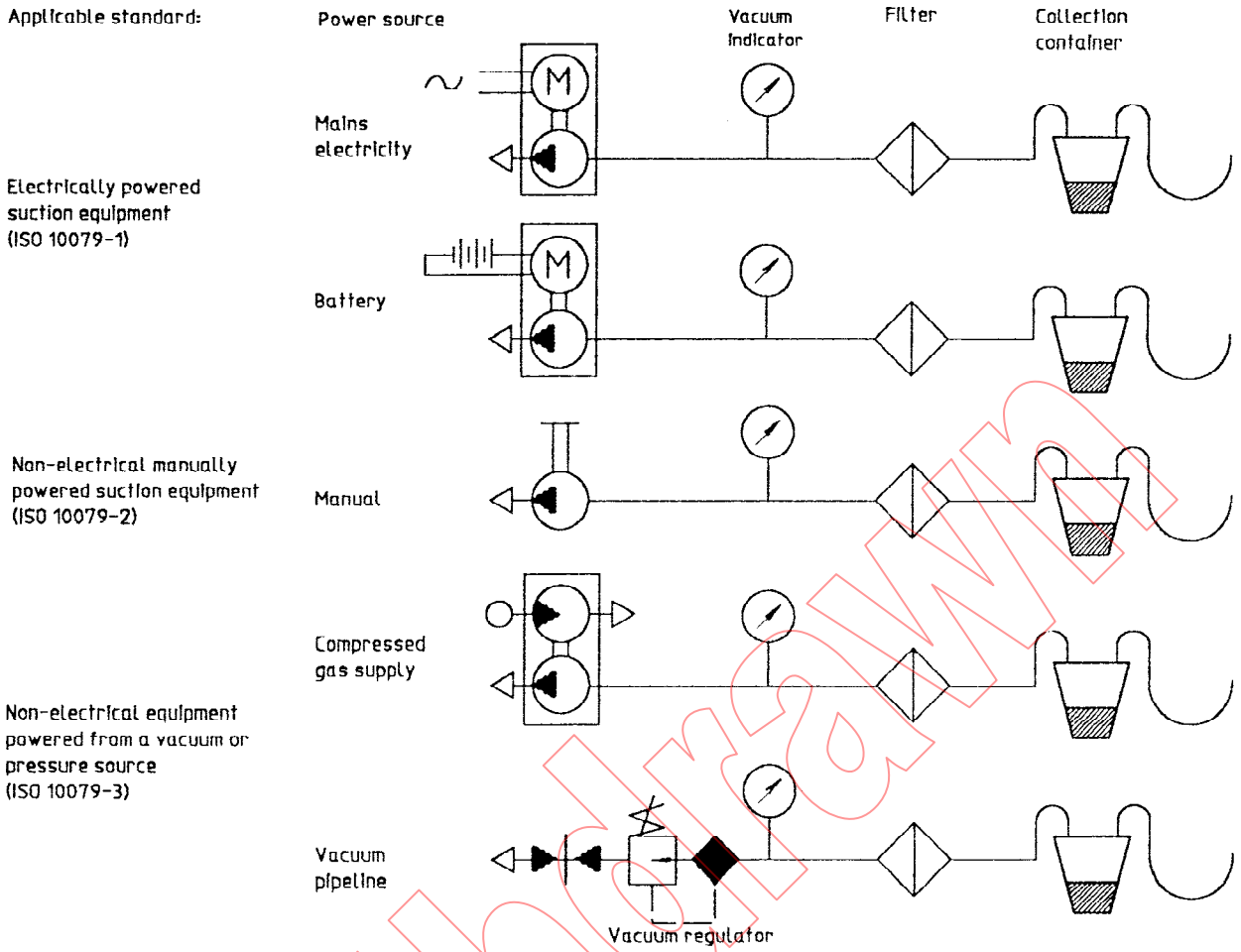
l) suction equipment where the collection container is downstream of the vacuum pump;

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 3743 : 1988, *Acoustics — Determination of sound power levels of noise sources — Engineering methods for special reverberation test rooms.*

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.*