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Traditional Chinese medicine — Air extraction cupping device

Médecine traditionnelle chinoise — Dispositif de bombement à extraction d'air

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 249, *Traditional Chinese medicine*.

Introduction

Cupping therapy is one of the most widely used traditional medical methods, which creates a partial vacuum in cups placed on the skin either by means of heat or mechanical devices (hand or electrical pumps). In the Middle East, cupping therapy has been used since 1550 B.C. and widely spread by Muhammad as Hijama. In East Asia, cupping therapy has been used since the Han dynasty and developed to slide cupping, medicated cupping, retained cupping, etc. In Europe, cupping also has been used since the Greek era and developed as cupping therapy in England, Schröpfkopf in German, Ventouse in France, Vanka in Russia, etc. These days, cupping devices are commonly used in traditional therapies through various techniques. Even though cupping device is widely used and produced in a number of countries and companies, there is no international standard for cupping device yet. In the aspect of safety, the cupping device directly contacts the skin, and in the case of bloodletting cupping, it directly contacts open wounds which involves bleeding. To prevent wound infection, it should be distinguished and developed differently in the case of intact skin or wounded skin usage. In addition, as a medical device that directly contacts blood, it requires the use of disposable cups. The performance requirements specified in this document are needed.

Traditional Chinese medicine — Air extraction cupping device

1 Scope

This document specifies requirements for an air extraction cupping device which operates using negative pressure. This document includes requirements for the material, pressure, sterilization or disinfection, and packaging of the cupping device, as well as appropriate test methods.

The document is applicable to single-use type and multiple-use type devices.

This document does not apply to the suction pump used to create the negative pressure.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 10993 (all parts), *Biological evaluation of medical devices*

ISO 11135, *Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices*

ISO 11137-1, *Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO 17664, *Sterilization of medical devices — Information to be provided by the manufacturer for the processing of resterilizable medical devices*

ISO 17665-1, *Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— IEC Electropedia: available at http://www.electropedia.org/

— ISO Online browsing platform: available at http://www.iso.org/obp

3.1
cupping therapy
therapy in which cups are placed on the skin to create localized *negative pressure* (3.8) by means of either heat or a *suction pump* (3.7), for affecting the surface of the body or for increasing *bloodletting* (3.2)

3.2
bloodletting
therapeutic method of withdrawing blood by pricking the skin with a needle in order to treat or prevent illness and disease

3.3
air extraction cupping device
device for medical cupping, which consists of a body, an *air outlet* (3.5) and a valve unit for the air outlet

3.4
body of the cupping device
device which maintains *negative pressure* (3.8) generated by a *suction pump* (3.7) and has an internal cavity and an open end to contact the body surface

3.5
air outlet
means, in the upper part of the cupping device, for connecting to a *suction pump* (3.7) to deliver *negative pressure* (3.8) generated by the suction pump

3.6
valve unit for air outlet
one-way valve installed at the *air outlet* (3.5) to deliver the *negative pressure* (3.8) generated by a *suction pump* (3.7)

3.7
suction pump
device for generating *negative pressure* (3.8) in a cupping device

3.8
negative pressure
air pressure generated by a *suction pump* (3.7) in the inner cavity of the *body of the cupping devices* (3.4)

3.9
single-use type device
disposable cupping device for bloodletting cupping

Note 1 to entry: This type of cupping device is used when contact with blood and body fluids is likely.

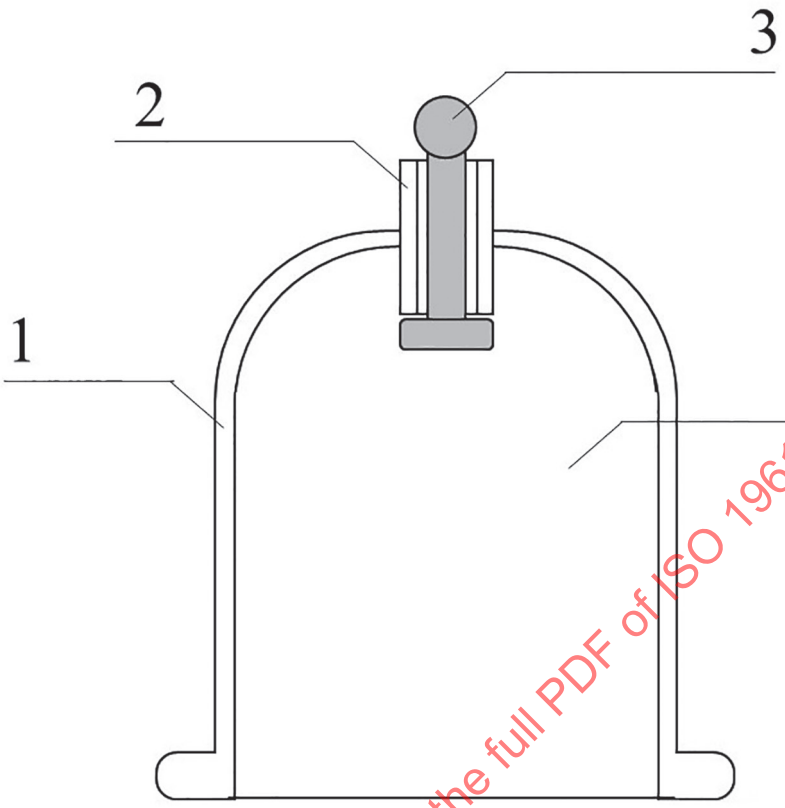
3.10
multiple-use type device
cupping device for multiple-use which is used on intact area of skin with non-bloodletting cupping

Note 1 to entry: This type of cupping device is used when contact with blood and body fluids is not likely.

4 Configuration

4.1 Configuration of cupping device

The configuration of the cupping device and the name of each of its parts are shown in Figure 1.



Key

1 body of cupping device
2 air outlet
3 valve unit for air outlet
4 inner volume

Figure 1 — Example of a typical structure of a cupping device

4.2 Dimensions

4.2.1 Inner volume

The inner volume of the cup shall be specified as shown in Table 1.

Table 1 — Inner volume of the cup

Dimensions in millilitres

Cup number	Inner volume
1	70 ± 7
2	55 ± 5,5
3	40 ± 4,0
4	25 ± 2,5
5	15 ± 1,5

4.2.2 Smoothness of the skin contacting edge

The skin contacting edge of the body of the cupping device shall be sufficiently rounded to prevent injury in the surface of the skin during the cupping treatment. The roundness of the skin contacting edge shall be assessed by visual inspection.

4.2.3 Diameters of air outlet

The air outlet shall at least have a portion of its outer diameter measuring 11 mm.

5 Requirements

5.1 Biological compatibility

The body of the cupping device intended to be exposed to blood during the bloodletting cupping technique shall be assessed and documented according to the guidance and principles given in the ISO 10993 series.

Compliance is demonstrated by

a) analogy with published data,

b) the selection of materials already shown to be biocompatible by proven clinical use in a similar application,

c) experience with similar devices already on the market together with evidence of traceability to the materials used in cupping device, or

d) by compliance with published procedures for biological evaluation of medical devices (see Table 2).

Table 2 — Biological evaluation for type

Biological evaluation	Type	
	Single-use type device	Multiple-use type device
1) Cytotoxicity	X	X
2) Sensitization	X	X
3) Intracutaneous reactivity	X	—
4) Acute systemic toxicity test	X	—
5) Hemocompability test	X	—
6) Ethylene oxide (EO) sterilization residuals (if using EO to sterilize)	X	X

NOTE Testing is done in accordance with the ISO 10993 series.

5.2 Performance requirements

5.2.1 Resisting negative pressure

Resisting negative pressure of the cupping device shall not be less than the maximum instantaneous pressure of −91,50 kPa. See A.2.

5.2.2 Pressure maintenance

Pressure loss between the body of cupping device and skin shall not be less than 10 % of its maximum pressure for 10 min. See A.3.

5.2.3 Mechanical stability

Regarding the performance of the cupping device when resisting pressure, pressure shall be maintained after the impact at a force of 0,5 J ± 0,05 J using a universal spring hammer. See A.4.

5.2.4 Transparency

The body of the cupping device shall be sufficiently transparent to observe and distinguish the changes of skin colour. See A.5.

5.2.5 Repeated disinfection resistance

Multiple-use cupping device shall not exhibit changes in performance after repeated disinfection. See A.6.

5.3 Sterilization and disinfection

5.3.1 Sterilization for single-use type devices

Single-use type devices shall be sterilized using a validated sterilization procedure that shall comply with ISO 11135, ISO 11137-1 or ISO 17665-1.

5.3.2 Disinfection for multiple-use type devices

Multiple-use type devices shall be disinfected using a validated disinfection procedure that shall comply with ISO 17664 [see 7.3 g)].

6 Package

6.1 Primary package

The cupping device shall be sealed in a primary package. There shall be no foreign matter within the primary package under visual inspection.

The material and design of this primary package shall not have detrimental effects on the contents. The material and design of this primary package should be such as to ensure

a) the maintenance of sterility and disinfection of the contents under dry, clean and adequately ventilated storage conditions,

b) the minimum risk of contamination of the contents during removal from the package,

c) adequate protection of the contents during normal handling, transit and storage, and

d) that once opened, the package cannot be easily resealed, and it shall be obvious that the package has been opened.

Requirements of materials, sterile barrier systems and packaging systems for terminally sterilized medical devices are provided in ISO 11607-1.

6.2 Secondary package

One or more primary packages shall be packaged in a secondary package. The secondary package shall be sufficiently robust to protect the contents during handling, transport and storage. One or more secondary packages may be packaged in storage and/or a transit package.

7 Labelling

7.1 General

The symbols used on the package shall comply with ISO 15223-1.

7.2 Primary package

The primary package shall be marked with at least the following information:

a) the name or trademark or logo of the manufacturer and/or supplier;

b) a description of the contents, including the designated metric size in accordance with 5.1;

c) the lot number, prefixed by the word “LOT” and/or date of manufacture;

d) for single-use type devices, expiry date;

e) for single-use type devices, method of sterilization, the word “STERILE” or symbol;

f) for single-use type devices, the words “For single use” or “Do not reuse” or symbol;

g) a warning to check the integrity of each primary package before use, such as “Do not use if package is damaged” or symbol.

7.3 Secondary package

The secondary package shall be marked with at least the following information:

a) the name, address and trademark of the manufacturer and/or supplier;

b) description of the contents, including the designated metric size in accordance with 5.1, the quantity and the type;

c) the lot number, prefixed by the word “LOT” and/or date of manufacture;

d) for single-use type devices, expiry date;

e) for single-use type devices, method of sterilization, the word “STERILE” or symbol;

f) for single-use type devices, the words “For single use” or “Do not reuse” or symbol;

g) for multiple-use type devices, the maximum number of times the devices can be cleaned and disinfected and the method(s) of cleaning and disinfection recommended by the manufacturer, (see 5.3.2).

h) information for handling, storage and transportation;

i) a warning to check the integrity of each secondary package before use, such as “Do not use if package is damaged” or symbol;

