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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.

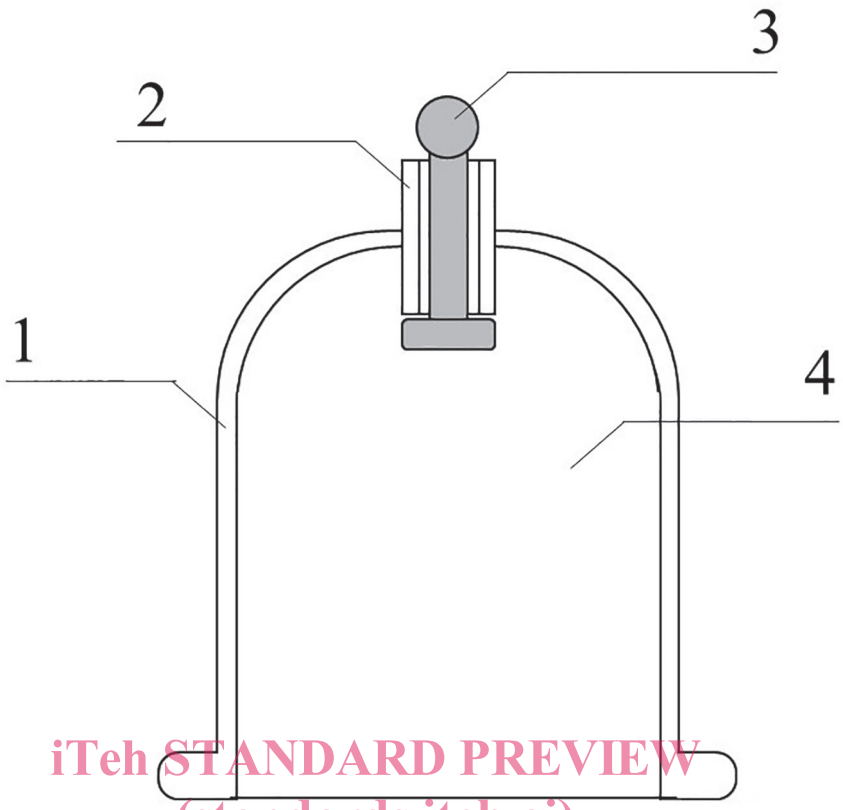
3.10
multiple-use type device
cupping device for multiple-use which is used on intact area of skin with non-bloodletting cupping

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