INTERNATIONAL STANDARD

ISO 19611

First edition
2017-05

Traditional Chinese medicine — Air extraction cupping device

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

Reference number
ISO 19611:2017(E)

© ISO 2017



COPYRIGHT PROTECTED DOCUMENT

© ISO 2017, Published in Switzerland

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

Contents

Page

Foreword ... **iv**
Introduction ... **v**
1 Scope ... **1**
2 Normative references ... **1**
3 Terms and definitions ... **1**
4 Configuration ... **2**
4.1 Configuration of cupping device ... 2
4.2 Dimensions ... 3
4.2.1 Inner volume ... 3
4.2.2 Smoothness of the skin contacting edge ... 4
4.2.3 Diameters of air outlet ... 4
5 Requirements ... **4**
5.1 Biological compatibility ... 4
5.2 Performance requirements ... 4
5.2.1 Resisting negative pressure ... 4
5.2.2 Pressure maintenance ... 4
5.2.3 Mechanical stability ... 5
5.2.4 Transparency ... 5
5.2.5 Repeated disinfection resistance ... 5
5.3 Sterilization and disinfection ... 5
5.3.1 Sterilization for single-use type devices ... 5
5.3.2 Disinfection for multiple-use type devices ... 5
6 Package ... **5**
6.1 Primary package ... 5
6.2 Secondary package ... 5
7 Labelling ... **6**
7.1 General ... 6
7.2 Primary package ... 6
7.3 Secondary package ... 6
Annex A (normative) **Test methods for a cupping device** ... **7**
Bibliography ... **9**

© ISO 2017 – All rights reserved

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.

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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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*.

© ISO 2017 – All rights reserved

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.

© ISO 2017 – All rights reserved

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

© ISO 2017 – All rights reserved

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.

© ISO 2017 – All rights reserved