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世界中医药学会联合会

World Federation of Chinese Medicine Societies

SCM 000*-202*

电动拔罐设备

Electrical Cupping equipment

征求意见草案

（Committee Draft）

世界中联国际组织标准

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目　次

前　　言

请注意本文件的某些内容可能涉及专利。本文件的发布机构不承担识别专利的责任。

主要起草单位：天津市医疗器械质量监督检验中心。

参与起草的单位：苏州医疗用品厂、天津中医药大学、西安中医脑病医院。

主要起草人：刘博、李雅楠、张赟、李立宾、李佳、张龙飞、侯飞翔、宋虎杰、杜晓刚。

参与起草人及审阅专家（按姓氏拼音排序）：

中　　国：高山、徐爱民、于志峰；高也陶（中国澳门）

加 拿 大：James Yuan

日　　本: 竹原 浩成

匈 牙 利：David Yu。

本文件的起草程序遵守了世界中医药学会联合会发布的 SCM1.1-2021《标准化工作导则第 1 部分：标准制修订与发布》。

电动拔罐设备

1 范围

本文件规定了电动拔罐设备的术语和定义、要求、试验方法、检验规则、标志、包装、及贮存。

本文件适用于在传统中医拔罐疗法中使用的电动拔罐设备。设备中含有电动抽气装置，预期与符合 ISO 19611 的抽气罐配合使用，利用其产生的负压使抽气罐吸附在人体皮肤上进行治疗。

2 规范性引用文件

下列文件中的内容通过文中的规范性引用而构成本文件必不可少的条款。其中，注日期的引用文件，仅该日期对应的版本适用于本文件；不注日期的引用文件，其最新版本（包括所有的修改单）适用于本文件。

ISO 780 Packaging — Distribution packaging — Graphical symbols for handling and storage of packages

ISO 19611 Traditional Chinese medicine — Air extraction cupping device

IEC 60601-1 Medical electrical equipment –Part 1: General requirements for basic safety and essential performance

IEC 60601-1-11 Medical electrical equipment—Part1-11: General requirements for basic safety and essential performance—Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

IEC 61672-1 Electroacoustics - Sound level meters - Part 1: Specifications

3 术语和定义

下列术语和定义适用于本文件。

3. 1

电动拔罐设备

通过电动抽气装置使置于人体皮肤上的抽气罐中产生负压，利用负压进行中医拔罐治疗的医用电气仪器。

3. 2

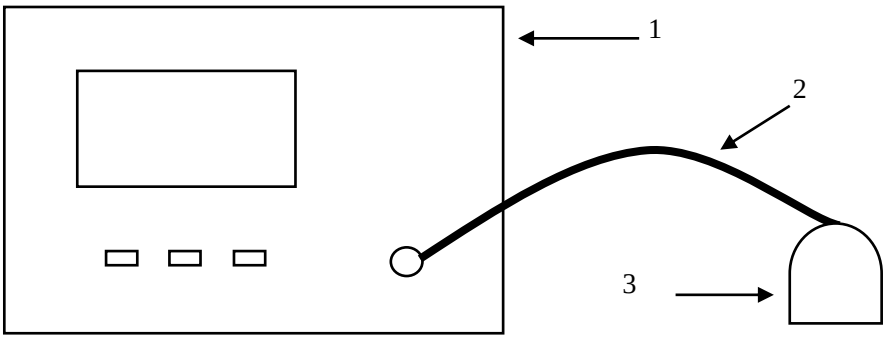
抽气罐

包括罐体、排气口和排气阀，用于拔罐治疗的器具。

[来源：ISO 19611，3.3]

4 结构与组成

电动拔罐设备通常由电动抽气装置、抽气罐、连接管路组成，见图 1。



1 电动抽气装置

2 连接管路

3 抽气罐

图 1 电动拔罐设备的典型结构

电动抽气装置为电动拔罐设备的核心组件，主要由供电电路、抽气泵、控制电路和外壳构成。

根据预期用途的不同，电动抽气装置可连接单个抽气罐使用，也可以通过分支连接管路连接多个抽气罐，对多个抽气罐同时抽气。

5 要求

5.1 外观

电动拔罐设备的表面应平整光洁、色泽均匀、无明显伤痕，文字标志清晰，控制部件灵活，紧固件无松动。

5.2 抽气罐

抽气罐的性能应符合 ISO 19611 的要求。

5.3 极限负压

极限负压值应不大于 91.5kPa。如在特殊临床用途中需使用更大负压值的话，制造商应通过风险管理过程对相关风险进行分析控制。

5.4 抽气停止

在抽气过程中，电动拔罐设备应提供可在任意时刻终止抽气的方法。

5.5 负压消除

应提供消除罐体内负压的方法，该方法应在任意时刻均能完成，且不依赖于空气从罐体

与皮肤接触面进入罐体。

5.6 机械冲击

手持的电动拔罐设备从 1m 高处坠落在混凝土地面后设备应能正常工作。

注：允许坠落试验后对脱落的部件进行重新装配。

5.7 噪声

在正常使用时，设备工作噪声的应不超过 70dB（A）。

5.8 方便操作

电动拔罐设备应设计成可由一个人在无帮助情况下即可独立操作，并便于正确连接。

5.9 负压调节

负压可调的电动拔罐设备应设计成负压值不应随输出设定的下降而升高。

5.10 随附文件

随附文件应包含下列信息：

a) 对于不同尺寸的抽气罐，应给出推荐使用部位的说明；

b) 若长时间使用可能产生风险，应给出安全使用建议，包括但不限于推荐治疗时间、推荐负压设定等。

5.11 通用要求

电动拔罐设备的电气安全应符合 IEC 60601-1 的要求。

在家庭护理环境中使用的电动拔罐设备应符合 IEC60601-1-11 的要求。

5.12 灭菌与消毒

一次性使用抽气罐和重复使用抽气罐的灭菌应符合 ISO 19611 中 5.3.1 的要求，消毒应符合 ISO 19611 中 5.3.2 的要求。

6 试验方法

6.1 外观

通过目测和手动操作予以验证。

6.2 抽气罐

按照 ISO19611 中规定的试验方法进行检验。

6.3 极限负压

按照附录 A 连接设备与测试装置，按照说明书在最大负压档位启动设备，随着抽气的进行，待抽气罐内负压达到极值时记录此时的数据，应满足 5.2 的要求。

6.4 抽气停止

通过检查和功能性试验予以验证，应符合 5.3 的要求。

6.5 负压消除

通过检查和功能性试验予以验证，应符合 5.4 的要求。

6.6 机械冲击

设备在 1m 高处以最不利状态自由坠落到混凝土地面上，然后对设备进行必要的再装配，检查并进行功能性试验。

6.7 噪声

使用符合 IEC 61672-1 中声级计的要求，测量电动拔罐设备几何中心 1m 半径处的 A 计权声压值。环境噪声应至少比被测噪声低 10dB。分别进行两种状态下的测试：（1）电动拔罐器在最大负压档位运行，所连接的抽气罐开口暴露于大气中，无任何阻塞物。（2）电动拔罐器在最大负压档位运行，抽气罐开口处用至少 3mm 厚硅胶板堵塞。

6.8 方便操作

通过检查和功能性试验予以验证。

6.9 负压调节

通过检查和负压测量验予以验证。

6.10 随附文件

查阅随附文件予以验证。

6.11 通用要求

按照 IEC60601 中规定的试验方法进行检验。

6.12 灭菌与消毒

按照 ISO 19611 的 5.3.1 和 5.3.2 规定的方法进行确认。

7 标志、包装及贮存

7.1 标志

7.1.1 设备标志

电动拔罐设备的外部标记应符合 IEC 60601-1 中 7.2 的要求及当地法规的要求。

7.1.2 包装标志

外包装上至少应有下列标志：

a) 制造厂名称和地址；

b) 产品名称；

c) 型式或规格

d) “怕雨”等字样或标志，标志应符合 ISO 780 的有关规定；

7.2 包装

包装应能充分保护内装物，在正常的流通运输条件下，确保内装物的安全与完整。

7.3 贮存

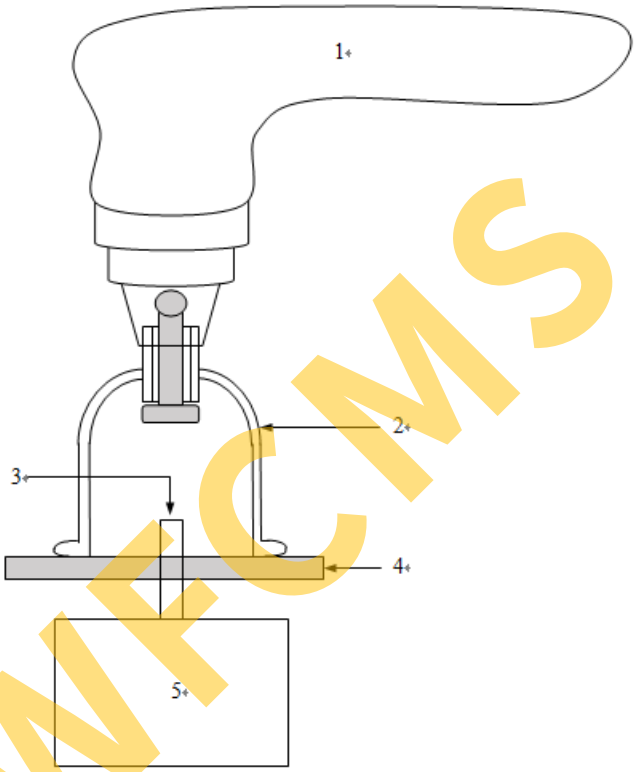
包装后的电动拔罐设备，贮存条件应由制造商规定。

附录 A

（资料性）

电动拔罐设备负压测试布置

电动拔罐设备负压测试布置如图 A.1 所示，将抽气罐放置在硅胶板（厚度不低于 3mm）上，压力表通过管路与抽气罐内部连通，在标准大气压下，测量罐内形成的负压。



1 电动拔罐设备

2 抽气罐

3 管路

4 硅胶板

5 压力表

图 A.1 电动拔罐设备负压测试布置图

参考文献

[1] WFCMS. SCM 0008-2011 International TCM Physicians Classification Standard of Professional and Technical Titles, People's Medical Publishing House, 2011

[2] ISO 19611 Traditional Chinese medicine — Air extraction cupping device

Content

Foreword

Please note that some contents of this document may involve patents. The issuing authority of this document shall not be responsible for identifying the patent.

Main drafting unit: Tianjin Medical Device Quality Supervision and inspection center.

Units involved in drafting: Suzhou medical supplies factory and other companies, Tianjin University of traditional Chinese medicine， Xi'an TCM Hospital of Encephalopathy.

Main drafters: Liu Bo, Li Yanan, Zhang Yun, Li Libin, Li Jia, Zhang Longfei, Hou Feifei, Song Hujie, Du Xiaogang.

Participating drafters and reviewers (sorted by surname Pinyin):

China: Gao Shan, Xu Aimin, Yu Zhifeng;
Macao, China: Gao Yatao;
Canada: James Yuan;
Japan: Hirosei Takehara;
Hungary: David Yu.

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Electric Cupping Device

1 Scope

This document specifies the terms, definitions, requirements, test methods, inspection rules, marks, packaging, and storage of electric cupping equipment.

This document applies to electric cupping devices used in traditional Chinese medicine cupping therapy. The device contains an electric air extractor, which is expected to be used in conjunction with a suction cup that complies with the ISO 19611:2017 standard. The negative pressure generated by the air extractor is used to make the suction cup adsorb on the human skin for treatment.

2 Normative references

The following referenced documents are indispensable for the application 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 780 Packaging — Distribution packaging — Graphical symbols for handling and storage of packages

ISO 19611 Traditional Chinese medicine - Air extraction cupping device

IEC 60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

IEC 60601-1-11 Medical electrical equipment—Part1-11: General requirements for basic safety and essential performance—Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

IEC 61672-1 Electroacoustics - Sound level meters - Part 1: Specifications

3 Terms and definitions

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

3.1

Electric cupping device

medical electrical equipment that generates negative pressure in the suction cup placed on the human skin through the electric air extractor, and uses the negative pressure to perform traditional Chinese medicine cupping therapy..

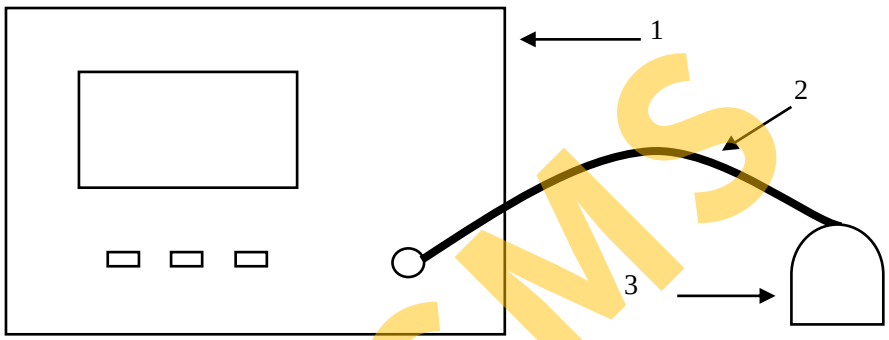
3.2

Suction cup

apparatus for cupping therapy, including a body, an air outlet and an exhaust valve.

4 Structure and composition

Electric cupping equipment is usually composed of electric air extraction device, air extraction tank and connecting pipeline, see Figure 1.



Key

1 Electric cupping equipment

2 connecting pipeline

3 air extraction tank

Figure 1 Typical structure of electric cupping equipment

Electric air extraction device is the core component of electric cupping equipment, which is mainly composed of power supply circuit, air extraction pump, control circuit and shell.

According to the different intended uses, the electric air extraction device can be connected to a single air extraction tank, or multiple air extraction tanks can be connected through branch connecting pipelines to extract air from multiple air extraction tanks at the same time.

5 Requirements

5.1 Appearance

The surface of electric cupping equipment should be flat and smooth, with uniform color and no obvious scars, clear text markings, flexible control components, and no loose fasteners.

5.2 Suction cup

The performance of the Suction cup shall comply with the requirements of ISO 19611.

5.3 Ultimate negative pressure

Unless the manufacturer confirms that the relevant risk is acceptable through the risk management process, the ultimate negative pressure value of the equipment should not be greater than 91.5kPa.

5.4 Suction stop

During the air extraction process, the electric cupping device should provide measures to terminate the air extraction at any time.

5.5 Negative pressure elimination

Measures should be provided to eliminate the negative pressure in the tank, which should be able to be completed at any time and not rely on the air entering the tank from the contact surface of the tank with the skin.

5.6 Mechanical shock

The hand-held electric cupping device should work normally after it falls from a height of 1m on the concrete floor.

Note: The reassembly of dropped parts is permitted after the drop test

5.7 Noise

In normal use, the working noise of the equipment should not exceed 70dB (A).

5.8 Easy to operate

The electric cupping device should be designed to be operated independently by one person without assistance.

5.9 Pressure regulation

The pressure-adjustable electric cupping device should be designed so that the negative pressure value should not increase with the decrease of the output setting.

5.10 Accompanying documents

The accompanying documents should contain the following information:

a) For different sizes of suction cups, a description of the recommended used parts should be given;

b) If long-term use may cause risks, suggestions for safe use should be given, including but not limited to recommended treatment time, recommended negative pressure settings, etc.

5.11 General requirements

The electric cupping device shall comply with the requirements of IEC 60601-1 and its collateral standards.

5.12 Sterilization and disinfection

The sterilization and disinfection of disposable and reusable Suction cup shall comply with the requirements of 5.3.1 and 5.3.2 of ISO 19611 respectively.

6 Test methods

6.1 Appearance

Verify through visual inspection and manual operation.

6.2 Suction cup

Conduct the test according to the test methods specified in ISO19611.

6.3 Ultimate negative pressure

Connect the equipment and the test device according to Appendix A, start the equipment at the maximum negative pressure gear according to the instructions, and record the data when the negative pressure in the suction cup reaches the extreme value as the air extraction proceeds, which should meet the requirements of 5.2.

6.4 Suction stop

Verify by inspection and functional tests, which should meet the requirements of 5.3.

6.5 Negative pressure elimination

Verify by inspection and functional tests, which should meet the requirements of 5.4.

6.6 Mechanical shock

The equipment falls freely to the concrete floor in the most unfavorable state at a height of 1m, and then the necessary reassembly, inspection and functional tests are carried out for the equipment.

6.7 Noise

Use a sound level meter that conforms to the IEC 61672-1 standard to measure the A-weighted sound pressure value at a radius of 1 m from the geometric center of the electric cupping device. The ambient noise should be at least 10dB lower than the measured noise. Tests are carried out in two states: (1) The electric cupping device is running at the maximum negative pressure gear, and the opening of the connected suction cup is exposed to the atmosphere without any obstructions. (2) The electric cupping device operates at the maximum negative pressure gear, and the opening of the suction cup is blocked with a silicone plate with a thickness of at least 3mm.

6.8 Easy to operate

Verify by inspection and functional tests

6.9 Pressure regulation

Verify by inspection and negative pressure measurement

6.10 Accompanying documents

Check the accompanying documents for verification

6.11 General requirements

Conduct the test in accordance with the test methods specified in the applicable IEC60601 series of standards

6.12 Sterilization and disinfection

Confirm according to the methods specified in 5.3.1 and 5.3.2 of ISO 1961.

7 Marking, packaging and storage

7.1 signs

7.1.1 equipment signs

The external marking of electric cupping equipment shall comply with Clause 7.2 of IEC 60601-1 and the requirements of local regulations:

7.1.2 package marks

The outer package shall at least have the following marks:

a) Name and address of the manufacturer;

b) Product name;

c) Type or specification

d) Words or signs such as "fear of rain" shall comply with the relevant provisions of ISO 780;

7.2 packaging

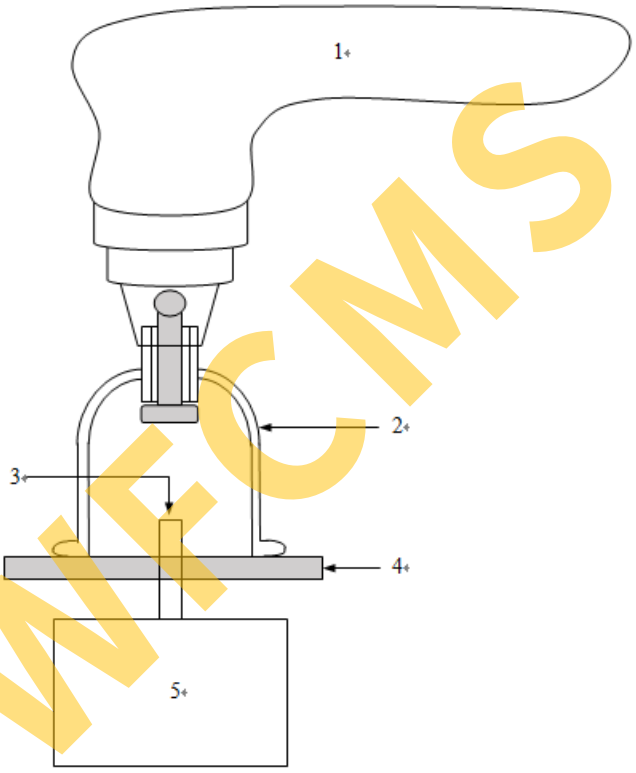
The package shall be able to fully protect the contents and ensure the safety and integrity of the contents under normal circulation and transportation conditions.

7.3 storage

The storage conditions of packaged electric cupping equipment shall be specified by the manufacturer.

ANNEX A
（Normative）
Negative pressure test layout of electric cupping device

The negative pressure test layout of the electric cupping device is shown in Figure A.1. The suction cup is placed on a silicone plate (thickness not less than 3mm), and the pressure gauge is connected to the inside of the suction cup through a pipeline. At normal atmospheric pressure, measure the negative pressure formed in the tank.



1 Electric cupping device
2 Suction cup
3 Silicone plate
4 Piping
5 Pressure gauge

Figure A.1 Negative pressure test layout of electric cupping device

Bibliography

[1] WFCMS. SCM 0008-2011 International TCM Physicians Classification Standard of Professional and Technical Titles, People's Medical Publishing House, 2011

[2] ISO 19611 Traditional Chinese medicine — Air extraction cupping device