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世界中医药学会联合会
World Federation of Chinese Medicine Societies

SCM **-20**

红外热辐射治疗设备安全专用要求

Particular requirements for the safety of TCM heat therapy equipment

（征求意见草案）
（Committee Draft）

世界中联国际组织标准
International Standard of WFCMS

20**–**–**发布实施
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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。

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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》。

中医热辐射治疗设备安全专用要求

1 范围

本文件规定了热辐射类治疗设备的安全专用要求。

本文件适用于通过辐射器热辐射效应所辐射出的远红外线照射患者病患部位来进行治疗的中医电气设备。不适用于治疗过程中，辐射器与患者直接接触的设备。

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。

IEC 60417 Graphical symbols for use on equipment 电气设备用图形符号

GB 9706.1-2020 医用电气设备 第 1 部分:基本安全和基本性能的通用要求（IEC 60601-1:2012,MOD）

3 术语和定义

下列术语和定义适用于本文件。

3.1

热辐射

物体由于具有温度而辐射电磁波的现象。

3.2

辐射器

本身具有较强红外辐射能力且使用时不与人体直接接触的部件，可将吸收的热量有效地转换为红外辐射能量。

注：辐射器不能与患者直接接触，否则辐射器和患者之间热交换的主要方式为热传导而非热辐射。

3.3

热辐射类治疗设备

利用被加热到一定温度（不低于 56℃）的辐射器的热辐射效应所辐射出的，能量集中在 3um～25um 波长范围内的远红外线直接照射患者病患部位来进行治疗的电气设备。

注：辐射器以外的其他设备组成部分，如热防护件、设备外壳等同样具有热辐射效应，同样会辐射远红外线，但预期不用于对患者进行治疗。

3.4

热防护件

防止患者与辐射器表面直接接触的部件，通常采用不影响辐射传播的镂空结构或透明材料制成。

3.5

稳态工作温度

辐射器在正常使用条件下通电升温达到热平衡时的平均工作温度。

3.6

法向发射率

某一物体在一特定波长和温度下的发射辐射强度与理想黑体在相同波长和温度下所发射的辐射强度之比。

4 分类

4.1 按使用方式分类

a) 接触式：工作时，仅通过热防护件与患者直接接触的设备。
b) 非接触式：工作时，辐射器及热防护件均不与患者接触的设备。

5 识别、标记和文件

5.1 设备或设备部件的外部标记

a) 生理效应（符号和警告性声明）：设备应有防止过热灼伤的警示标记（采用 IEC 60417 的 5041 符号  ），应标在明显位置，并保证在设备安装后仍能清晰可见。

b) 机械稳定性：非接触式设备应有小心倾倒的警示标记（  ：小心倾倒）。

6 随机文件

6.1 使用说明书

安全警告：

a) 设备不得直接对眼部进行辐射的警告；
b) 设备治疗位置不当有过热灼伤的危险；
c) 长时间使用接触式设备有低温烫伤的危险；
d) 非接触式设备的倾倒有造成烫伤的危险；

e) 设备不宜在有易燃麻醉气体或其他易燃物质的场合使用。

6.2 技术说明书

技术说明书中应包括辐射器的使用寿命、辐射器表面最高温度，对于非接触式设备，还应包含有关辐射距离的信息。

7 稳定性

7.1 正常使用时的稳定性

设备的调整机构在活动范围内应能任意调节和固定。固定后不应由于自身的重力而发生下垂。

试验方法：将调整机构置于最不利的位置，通过检查来检验是否符合要求。

7.2 倾倒防护

非接触式设备正常工作时，由于疏忽造成设备的倾倒时，设备应自动切断输出，直至设备恢复到正常工作位置。

试验方法：通过实际操作，模拟设备倾倒状态，观察其辐射器是否停止输出来检验是否符合要求。

8 温度要求

8.1 辐射器表面的稳态工作温度

最大输出状态下辐射器表面的稳态工作温度应不低于 56℃，且不高于 300℃。

注：按照黑体辐射定律，此时辐射光谱的峰值波长介于 5um～9um 之间。

试验方法：调节红外热像仪和辐射器的测温距离，使得被测辐射器表面尽可能充满红外热像仪的视场范围。使设备工作在最大输出状态下，等待辐射器表面温度达到热平衡，在辐射器表面均匀选取 9 点并设定被选区域的法向发射率，取 9 点的温度平均值作为辐射器表面的稳态工作温度，验证其是否符合要求。

注：9 点的选取与辐射器的形状有关，图 1 是推荐的测温点分布。

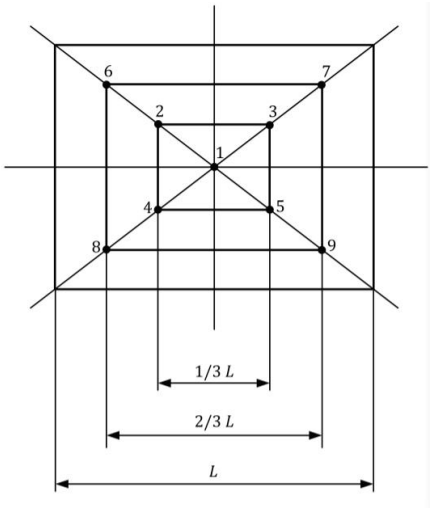

图 1-1 方形辐射器测温点分布

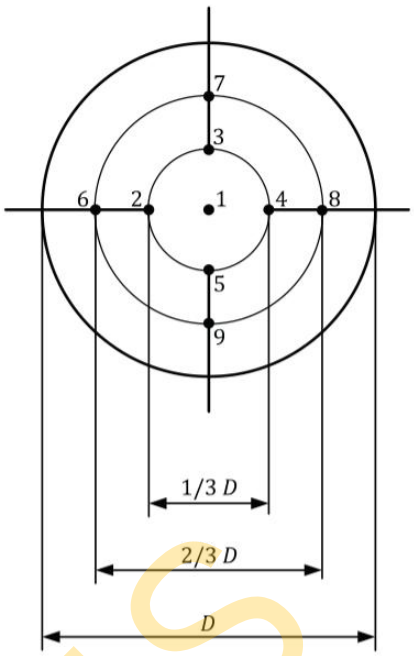

图 1-2 圆形辐射器测温点分布

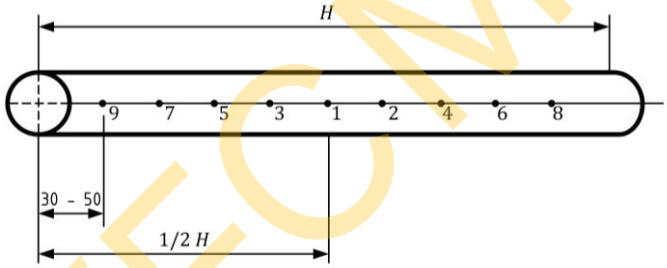

图 1-3 管形辐射器测温点分布（单位：mm）

其中：

L 代表方形辐射器的长度；

D 代表圆形辐射器的直径；

H 代表管形辐射器的高度。

8.2 热防护件

设备应装有防止与辐射器表面接触的热防护件，且仅用工具才能拆下。

接触式设备的热防护件，表面温度不得超过 60℃。对于非接触式设备，超过 GB 9706.1-2020 表 23*中 1 s≤t＜10 s（t 为可能接触的时间）对应可触及部分容许的最高温度时应有明显的高温警示标记。

试验方法：采用接触式温度计或红外热像仪按照 8.1 的测试方法进行测试。

GB 9706.1-2020 表 23 ME 设备可能被触及部件容许的最高温度

ME 设备及其部件	最高温度[a]/℃		
	金属和液体	玻璃，瓷器，玻璃	模制材料，塑料，

			质材料	橡胶，木材
ME 设备外表面可能接触的时间“t”	t＜1 s	74	80	86
	1 s≤t＜10 s	56	66	71
	10 s≤t＜1 min	51	56	60
	1 min≤t	48	48	48
a 这些温度限制适用于触及成人的健康皮肤。其不适用于当大面积皮肤（全身表面的 10%或更大）可能与热表面接触，也不适用于头部表面 10%以上皮肤接触的情况。如果是这种情况，应确定适当的限值并记录在风险管理文档中。				

9 法向发射率

辐射器在 3um～25um 范围内的法向发射率应不低于 0.85。

试验方法：采用红外傅里叶变换光谱仪或等效方法进行测试，必要时在样品附近增加水冷光阑。

10 辐射功率密度

制造商应给出距离辐射器一定距离处的以 mW/cm^2 为单位的辐射功率密度值，允差不超过±20%。

试验方法：采用在 3um～25um 波长范围内具有均匀响应的功率计在制造商规定的使用距离处进行辐射功率测试，结果除以功率计有效接收面的面积即为辐射功率密度，以此检验是否符合要求。

11 危险输出的防止

接触式设备应具有过热保护的措施，当热防护件表面温度升高到 60℃时，过热保护措施应起作用。

试验方法：通过对过热保护器件的试验来检验是否符合要求。

12 输出指示

除非有显而易见的指示，设备在输出时，应配备黄色指示灯指示处于输出状态。

试验方法：通过检查设备上显而易见的指示（如视觉、听觉指示）或指示灯颜色来检验是否符合要求。

13 定时器

设备应配有定时器，在预设运行时间结束后切断辐射器的加热电路。定时范围不超过 120min，误差不超过±1min。

试验方法：在最长工作时间下通过秒表来检验是否符合要求。

参 考 文 献

[1] ISO 20493:2018 Traditional Chinese medicine—Infrared moxibustion-like instrument 中医-红外仿灸仪

Foreword

Please note that certain contents of this document may involve patents. The publishing institution of this document does not assume the responsibility of identifying patents.

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The drafting process of this document follows the SCM1.1-2021 "Guidelines for Standardization Work Part 1: Standard Preparation, Revision and Release" issued by the World Federation of Chinese Medicine Societies.

1 Scope

This special standard specifies the particular safety requirements for heat radiation therapy equipment.

This document applies to traditional Chinese medical electrical equipment that uses far-infrared radiation emitted by the thermal radiation effect of radiators to irradiate the patient's area for treatment.This standard does not apply to the equipment in which the radiator is in direct contact with the patient during treatment.

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 editioncited applies.For undated references, the latest edition of the referenced document (including all amendments) applies.

IEC 60417 Graphical symbols for use on equipment

GB 9706.1-2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance(IEC 60601-1:2012,MOD)

3 Terms and definitions

3.1

Heat Radiation

The phenomenon that an object radiates electromagnetic waves due to its temperature is called heat radiation.

3.2

Radiator

The components that have strong infrared radiation and are not in direct contact with the human body during use, which can effectively convert the absorbed heat into infrared radiation energy.

Note: The radiator cannot be in direct contact with the patient, otherwise the main way of heat exchange between the radiator and the patient is heat conduction rather than heat radiation. However, for contact devices, the thermal protection part is allowed to be in direct contact with the patient.

3.3

Heat Radiation Therapy Equipment

An electrical device that directly irradiates the patient for treatment with infrared rays whose energy is concentrated in the wavelength range of 3um to 25um, which is radiated by the radiator heated to a certain temperature (not lower than 60 °C) through the thermal radiation effect.

Note: Other equipment components other than radiators, such as heat protection parts, equipment enclosure, etc., also have thermal radiation effects and radiate infrared rays, but are not expected to be used to treat patients.

3.4

Heat Protection Part

Parts that prevent the patient from coming into direct contact with the surface of the radiator, which are usually made of hollow structures or transparent materials that do not affect radiation transmission.

3.5

Steady state operating temperature

The average operating temperature of a radiator when it is heated to thermal equilibrium under normal operating conditions.

3.6

Normal emissivity

The ratio of the radiation intensity emitted by an object at a specific wavelength and temperature to the radiation intensity emitted by a blackbody at the same wavelength and temperature.

4 Classification

4.1 Classification by usage;

- Contact type: the equipment that only comes into direct contact with the patient through the heat protection part during operation.
- Non-contact type: the equipment in which neither the radiator nor the heat protection part is in contact with the patient during operation.

Note: The heat protection part is considered an applied part of the equipment, regardless of whether it is a contact or non-contact device.

5 Identification, labeling, and documentation

5.1 External marking of equipment or equipment parts

- Physiological effects (symbols and warning statements): The equipment should have warning signs to prevent overheating and burns(IEC 60417:5041symbols), which should be marked in obvious positions and

still clearly visible after the equipment is installed.

– Mechanical stability: The non-contact equipment should have warning signs of caution for dumping(⚠ Be careful dumping) .

6 Accompanying documents

6.1 Instruction manual

– A warning that the device must not directly radiate to the eyes;
– There is a danger of overheating and burns due to improper treatment position of the equipment;
– There is a danger of low temperature scalding when using contact equipment for a long time;
– There is a danger of scalding due to the dumping of non-contact equipment;
– The equipment should not be used in situations where there are flammable anesthetic gases or other flammable substances;

6.2 Technical specification

The service life of the radiator, the maximum temperature on the surface of the radiator, the normal total emissivity, the radiation wavelength range, the radiation power density shall be included in the technical specification, and for non-contact ME equipment, the information on the radiation distance shall also be included.

7 Stability

7.1 Stability during normal use

The adjustment mechanism of the equipment should be able to be adjusted and fixed arbitrarily within the scope of activity. It should not sag due to its own gravity after fixation.

Test method: Put the adjustment mechanism in the most unfavorable position, and check whether it meets the requirements by inspection.

7.2 Dumping protection

When the non-contact device is working normally, the device should automatically cut off the output in case of dumping due to negligence, until the device returns to the normal working position.

Test method: Through practical operation, simulate the tilting state of the device, observe whether the radiator stops outputting, and verify whether it meets the requirements.

8 Temperature requirement

8.1 The steady-state operating temperature of the radiator surface

The maximum surface temperature of the radiator under the maximum output state should not be lower than 56℃, and not higher than 300℃.

note: According to the blackbody radiation law, the peak wavelength of the radiation spectrum is between 5um and 9um.

Test method: Adjust the temperature measurement distance between the infrared thermal imager and the radiator to make the surface of the tested radiator as full as possible of the field of view of the infrared thermal imager. Operate the device in its maximum output state, wait for the surface temperature of the radiator to reach thermal equilibrium, select 9 points uniformly on the surface of the radiator and set the normal emissivity of the selected area. Take the average temperature of 9 points as the steady-state working temperature of the radiator surface, and verify whether it meets the requirements.

note: The selection of 9 points is related to the shape of the radiator, and Figure 1 shows the recommended distribution of temperature measurement points.

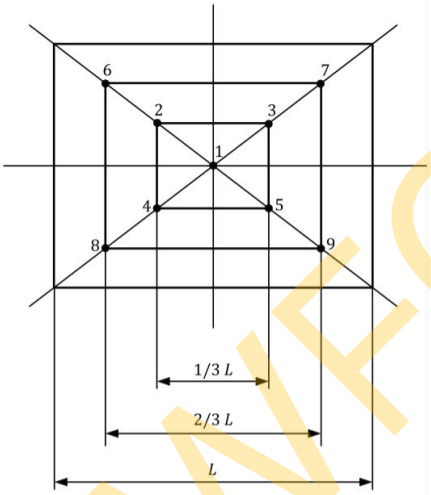

Figure1: Distribution of temperature measurement points for square radiators

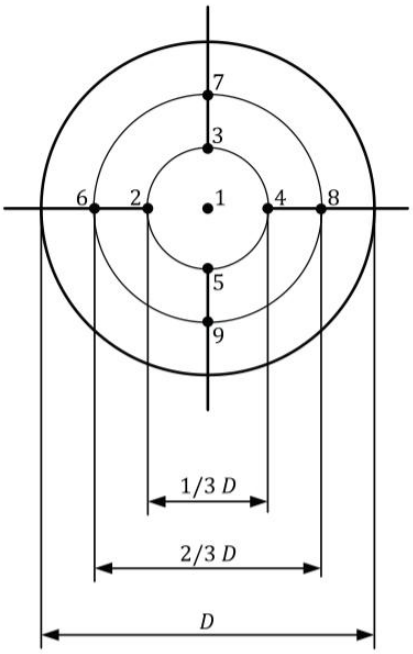

Figure 1-2 Distribution of temperature measurement points for circular radiators

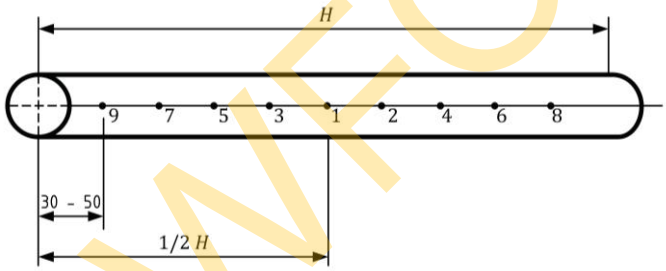

Figure 1-3 Distribution of temperature measurement points for tubular radiators (unit: mm)

Which: (unit: mm)
L--The length of a square radiator
D-- The diameter of a circular radiator
H-- The height of a tubular radiator

8.2 Heat protection part

The equipment shall be fitted with the heat protection parts to prevent contact with the radiator surface, which shall only be removed with a tool.

For contact equipment, the surface temperature of the heat protection part shall not exceed 60℃; for non-contact equipment, When the maximum allowable

temperature of the accessible part exceeds 1s ≤ t ＜ 10s (t is the possible contact time) in Table 1(Equal to table 23 of IEC 60601-1:2020), there should be obvious high temperature warning signs nearby.

Test method: Use a contact thermometer or infrared thermal imager to test according to the testing method in 8.1.

Table 1: Allowable maximum temperatures for Accessible partsthat are likely to be touched

ME EQUIPMENT and its parts		Maximum temperature [a] °C		
		Metal and liquids	Glass, porcelain, vitreous material	Moulded material, plastic, rubber, wood
External surfaces of ME EQUIPMENT that are likely to be touched for a time "*t*"	*t* < 1 s	74	80	86
	1 s ≤ *t* < 10 s	56	66	71
	10 s ≤ *t* < 1 min	51	56	60
	1 min ≤ *t*	48	48	48

[a] These temperature limit values are applicable for touching the healthy skin of adults. They are not applicable when large areas of the skin (10 % of total body surface or more) can be in contact with a hot surface. This also applies in the case of skin contact with over 10 % of the head surface. Where this is the case, appropriate limits shall be determined and documented in the RISK MANAGEMENT FILE.

9 Normal total emissivity

The normal total emissivity of the radiator in the range of 3um to 25um should not be lower than 0.85.

Test method: The infrared Fourier transform spectrometer or equivalent method is used for the test to check whether it meets the requirements.

10 Radiant power density

The manufacturer shall give the value of the radiant power density in mW/cm2at a certain distance from the radiator, with a tolerance not exceeding ±20%.

Test method: The power meter with uniform response in the wavelength range of 3um to 25um is used to test the radiated power. The radiant power density is just the result divided by the area of the effective receiving surface of the power meter, which is used to check whether it meets the requirements.

11 Prevention of hazardous outputs

The contact equipment should have measures for overheating protection. When the surface temperature of the heat protection part rises to 60°C, the overheating protection measures should take effect.

Test method: Check the compliance with the requirements by testing the overheating protection device.

12 Output indication

Unless there is an obvious indication, the device should be equipped with a yellow indicator light to indicate that it is in the output state when outputting.

Test method: The compliance is checked by inspection and functional tests.

13 Timer

The equipment shall be equipped with a timer to cut off the heating circuit of the radiator after a preset operating time has elapsed. The timing range does not exceed 120min, with the error not exceeding ±1min.

Test method: The compliance is checked by inspection and functional tests.

References

[1] ISO 20493:2018 Traditional Chinese medicine—Infrared moxibustion-like instrument