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SCM

世界中医药学会联合会

World Federation of Chinese Medicine Societies

SCM **-20**

特定电磁波治疗器

Specified electromagnetic wave therapy equipment

世界中联国际组织标准

International Standard of WFCMS

20**–**–**发布实施

Issued & implemented on ** **, 20**

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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。

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特定电磁波治疗器

1 范围

本文件规定了特定电磁波治疗器的定义、结构与组成、要求和试验方法。

本文件适用于符合辐射器所含元素在一定温度下受热激发，产生出的能量主要分布在2μm～25μm 波长范围内电磁波的治疗器（以下简称治疗器）。

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

IEC 60695-11-10　Fire hazard testing - Part 11-10: Test flames - 50 W horizontal and vertical flame test methods

3 术语和定义

下列术语和定义适用于本文件。

3. 1

特定电磁波

特定电磁波是指辐射器所含元素在一定温度下受热激发，产生出的能量主要分布在2μm～25μm 波长范围内的电磁波。

3. 2

升温时间

辐射器表面温度从室温上升到标称温度 90％时所需的时间。

4　结构与组成

4. 1 治疗头

应包括加热元件、辐射器和防护罩等。

4. 2 加热元件

应将电能转换为热能的导电发热材料，为辐射器提供热量。

4.3 辐射器

本身具有特定元素成分或涂层，预期用于吸收热量并向患者辐射电磁波，且使用时不与人体直接接触的部件。

5 要求

5.1 波长范围

辐射器产生的能量应主要分布在 2μm～25μm 波长范围内。

5.2 温度控制

5.2.1 辐射器表面的温度误差应不大于标称值的±10%。

5.2.2 辐射器表面温度不均匀度，应不超过 10%。金属基体辐射器可不受此限制。

5.2.3 在正常使用的最坏情况，包括说明书中规定的工作环境最高温度运行时，治疗器部件温度不应超过表 1 给定值。

表1 容许的温度值

部 位	最高温度，℃			
试验角表面	90			
防护罩：	接触时间：t＜1s；1s≤t＜10s；10s≤t＜1min；1min≤t			
——金属和液体：……	74	56	51	48
——玻璃、瓷器和玻璃质材料：……	80	66	56	48
——模制材料，塑料，橡胶，木材：…	86	71	60	60

5.3 时间控制

5.3.1 升温时间应不超过 20min；

5.3.2 治疗器如配备可调定时器，当达到预定工作时间后，加热器立即停止工作，并发出声或光指示，定时器准确度误差应不超过±10%。

5.4 过热保护

应具有过热保护装置，保护装置应动作可靠。过热保护装置动作后应发出声或光提示，且不可自动恢复。

5.5 耐燃性

由非金属材料构成的治疗头防护罩、治疗头外壳应能耐燃。

5.6 外部标记

任何标记应标在明显位置；标志颜色应与背景颜色形成反差；并保证在设备安装后仍能清晰可见；在施加额定电压的 110%使设备达到热稳态时，标记不可脱落、变形。

“禁止覆盖”字样及标记见图 1：

图1 “禁止覆盖”字样及标记

符号高度应至少15mm，字体高度应至少3mm。

5.7 使用说明书

5.7.1 使用说明书中应提供关于治疗人体不同部位的照射时间和安全照射距离的说明；

5.7.2 使用说明书中应告诫对于其接受治疗部位热敏感性差的患者，须在医生指导下进行。

5.7.3 制造商应在说明书中明确告知使用者辐射器的使用寿命，并应详细描述辐射器使用寿命到达时如何处置以及更换的步骤、避免烫伤的警告和建议。

5.7.4 使用说明书中应具有“注意事项”相关内容：

——不得直接对眼部进行辐射的警告；

——治疗位置不当有过热灼伤的危险；

——使用不当有倾倒造成烫伤的危险；

——设备不宜使用在有易燃麻醉气体或其他易燃物质的场合。

5.8 外观和结构

5.8.1 治疗器外壳应光亮整洁，色泽均匀，无明显划痕、破损及变形。

5.8.2 调节机构定位应可靠。

5.8.3 紧固件应安装牢固，无松动。

5.8.4 若辐射器为金属基体，则表面涂层应薄厚均匀、不应有起泡、剥落及局部堆积现象；非金属基体辐射器表面应无开裂、破损及变形等明显缺陷。

5.8.5 若治疗头与支架的装配方式为悬挂方式，则治疗头装配方式的设计应避免任何可能导致不可接受风险的不正确装配。

5.9 工作温度下的电介质强度

治疗器在充分发热条件下应能承受电介质强度试验，无击穿或闪络现象。

5.10 有害射线

治疗器配置的辐射器应无有害射线产生。

6 试验方法

6.1 试验条件

6.1.1 预处理：开始试验前，治疗器应在试验场所不工作地停放至少 24 小时。

6.1.2 温度应在 20±2℃之间，相对湿度在 65±10％。

6.1.3 电源条件：a.c220V±22V，50Hz±1Hz。

6.2 波长范围

使用黑体炉和红外光谱仪进行检测，检测结果应符合 5.1 的要求。

6.3 温度控制

6.3.1 辐射器表面温度

将治疗器通电 20min 后，用测温仪测量加热器表面温度，测量应按均匀分布的原则适当确定测温点（至少 9 点），取算术平均值，应符合 5.2.1 条规定。测试时应避开螺钉和孔，测试点参考图 2，且可以不仅限于图 1 的规定。具有多块辐射器的被测设备可单独测量。

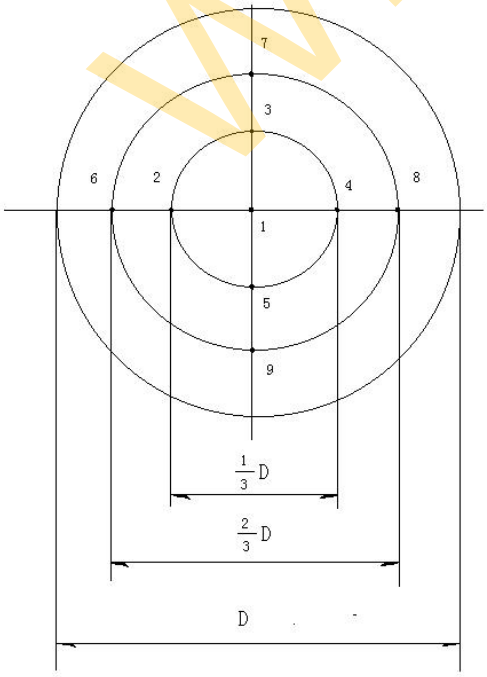
温度测试装置及治疗头摆放位置由制造商在技术文件中规定。

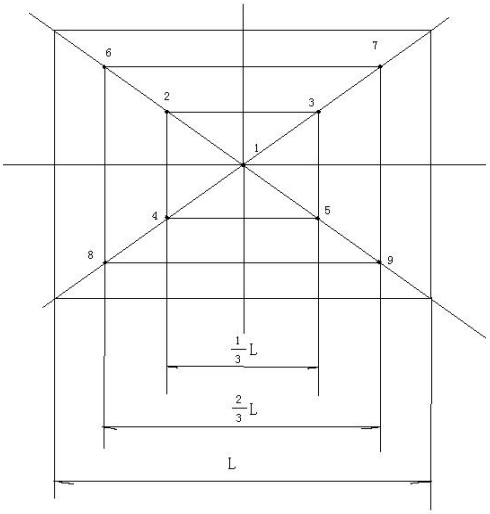
制造商可选用以下方法之一进行温度测量。

a) 如使用接触式测温仪测量时应尽量减少周围环境对测试结果的影响，必要时可使用耐高温隔热材料（如耐热胶）包裹温度传感器探头金属裸露部分，以减少高温源与周围环境的较 b) 大温差而形成的热对流对测试结果的影响。

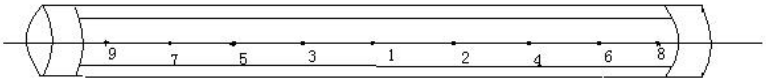
如使用点接触式热电偶测温仪可配合使用附录A中的测试柱进行测试，将热电偶金属部分全部放入测试柱中间的小孔内，待温度稳定后读取温度值。

c) 如使用辐射测温仪测量时应根据辐射面的法向全发射率值，对辐射测温仪进行修正。然后根据辐射测温仪的视场确定测温距离，使每个测温点的直径均相等，且充满测温仪视场。辐射面的法向全发射率值应在技术文件中说明。





圆形辐射器表面测试点　　方形辐射器表面测试点



管形辐射器测试点

图 2 测试点分布示意图

6.3.2 温度不均匀度

测量均匀分布点（至少 9 点）温度值，按下式计算应符合 5.2.2 的要求。

$$a = \frac{1}{T_z}\sqrt{\frac{1}{n}\sum_{i=1}^{n}(T_i - T_z)^2}$$

式中：a——温度分布系数；

T_z——辐射器表面上几何中心点温度值（单位：℃）。

T_i——辐射器表面上第i点的温度值（单位：℃）。

n——除辐射器表面上几何中心处测温点外的测温点数目。

6.3.3 最大允许温度

治疗器放置于正常使用位置的最不利情况，通电额定电压的 110%20min 以后，用接触式测温仪分别测量治疗头防护罩的前罩、后罩（如处于正常使用位置时不可能与患者接触或在明显位置标有禁止碰触的标记的部位可不受此项限制，但应在说明书中明示最高温度，且明示安全接触的条件：例如断电多久时间以后才可接触、接触者须配备的保护装置等），测得温度最高值应符合 5.2.3 的规定。

6.4 时间控制

6.4.1 升温时间

给被测设备施加额定工作电压，通电加热的同时，按 6.3.1 的方法测量辐射器表面几何中心部位，并记录从室温升至温度稳定状态的温升曲线，如图 3 所示。根据曲线记录，取从室温升至温度稳定状态的 90%所需要的时间作为升温时间，应符合 5.3.1 的要求。

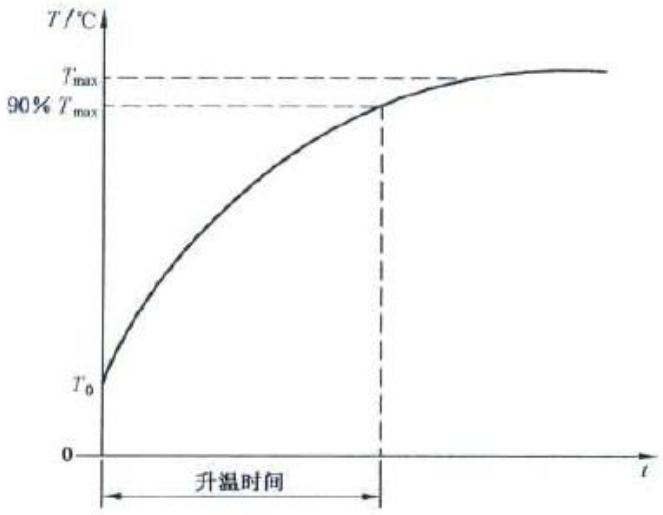


图 3 升温时间曲线图

6.4.2 定时器

用秒表测量定时器设定时间，其误差应符合 5.3.2 规定的要求。

6.5 过热保护

对于标称动作温度的热保护装置，通过检查元器件的相关数据和证书来验证是否符合要求。

对治疗器施加额定工作电压 110%，当到达稳态时，将一块干燥的单位面积质量为 130g/m2 到 165 g/m2 的棉布或棉织法兰绒布（二至四层）严密地包裹治疗头（不覆盖治疗面），在布冒烟或点燃之前保护装置应动作。如在治疗器可设置的最长工作时间内（不包括长通）没有冒烟或点燃则认为符合要求。不冒烟的变黑可忽略不计。

6.6 耐燃性

对于可移动的治疗器非金属治疗头防护罩、治疗头外壳的材料应具有（或优于）符合 IEC 60695-11-10 的 V-2 的可燃性等级，对于不可移动的治疗器非金属治疗头防护罩、治疗头外壳的材料应具有（或优于）V-1 的可燃性等级。检查材料相关的数据来验证，或按照 IEC 60601-1 中 11.3a)的要求进行检验，应符合 5.5 的要求。

6.7 外部标记

通过目力观察，应符合 5.6 的要求。

6.8 用说明书

检查和查阅文件，应符合 5.7 的要求。

6.9 外观和结构

目力观察以及操作仪器，应符合 5.8 的规定。

6.10 工作温度下的电介质强度

在治疗器施加额定电压的110％并达到工作温度后切断电源，按照IEC 60601-1中8.8.3进行，应符合5.9的要求。

在治疗器施加额定电压的110％并达到工作温度后切断电源进行，按图3试验电路连接，试验电压施加在：

a）加热元件两引出线与可触及部件之间（包括外壳、防护罩和使用试验指可触及到的所有部件在内，如金属反射罩、电热丝引出线护套等可以被试验指接触时，护套至少是双重绝缘）；

b）加热元件两引出线与可能和金属外壳接触的电线绝缘部件之间（包括治疗头附近的用于连接网电源的电线，应拧转治疗头使电线缠绕接触金属外壳最不利情况下通电加热后试验，至少是双重绝缘）。

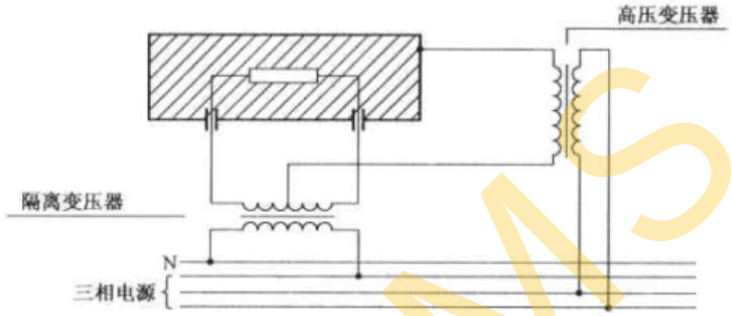


图4 工作温度下的电介质强度试验电路图

6.11 有害射线

使用射线检测仪进行检测，在设备正常运行操作条件下，在距设备的任何可达表面0.1m处所引起的周围剂量当量率或定向剂量当量率不超过1uSv/h，则符合5.10的要求。

7 标志、包装、运输、贮存

7.1 标志

7.1.1 治疗器在适当的明显位置，应固定铭牌一块，铭牌上应有下列标志：

a）生产、供应单位；

b) 产品名称和型号；

c) 与电源连接及输入功率；

d）产品出厂编号；

e）出厂日期；

f）产品注册号和产品标准号；

g)安全分类。

7.1.2 包装箱上应有下列标志：

a) 制造厂名称及地址；

b）产品名称及型号；

c）净重、毛重；

d）外型尺寸（长×宽×高）；

e）出厂日期；

F）“小心轻放”、“向上”、“怕湿”等字样或标志；

G）产品注册号。

7.2 包装

7.2.1 治疗器应装在具有防潮、防震措施的包装箱内。

7.2.2 包装箱内应有下列文件：

A）说明书；

b）装箱单；

7.3 运输

按订货合同规定。

7.4 贮存

包装后的治疗器应贮存在温度-40℃～55℃、相对温度不超过 90%、无腐蚀性气体和通风良好的室内。

附 录 A
（资料性）
测试柱相关信息

A.1 测试柱相关信息

测试柱相关信息见图 A.1。

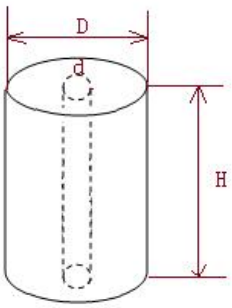


图 A.1 测试柱

尺寸：D=1cm,

d=2.5mm，

H=2cm。

材质 ：黄铜，外表涂无反射黑漆。

Foreword

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Specified Electromagnetic Wave Therapeutic Apparatus

1 Scope

This standard specifies the definition, structure and composition, requirements and test methods of specified electromagnetic wave therapeutic apparatus.

This standard is applicable to the therapeutic apparatus in which the elements contained in the radiator are excited by heat at a certain temperature with the generated energy mainly distributed in the wavelength range of 2 μm to 25 μm (hereinafter referred to as the therapeutic apparatus).

2 Normative references

The contents in the following documents constitute the indispensable clauses of this document through normative references in the text. Among them, for dated references, only the version corresponding to the date applies to this document; for undated references, the latest version (including all amendments) applies to this document.

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

IEC 60695-11-10 Fire hazard testing - Part 11-10: Test flames - 50 W horizontal and vertical flame test methods

3 Terms and definitions

The following terms and definitions apply to this document.

3.1

specified electromagnetic wave

The specified electromagnetic wave refers to the electromagnetic wave in which the elements contained in the radiator are excited by heat at a certain temperature with the generated energy mainly distributed in the wavelength range of 2 μm to 25 μm.

3.2

temperature rise time

The time required for the surface temperature of the radiator to rise from room temperature to 90% of the nominal temperature.

4 Structure and composition

4.1 Treatment head

Includes heating elements, radiators, protective covers, etc.

4.2 Heating element

A kind of conductive heating material that should convert electrical energy into thermal energy to provide heat to the radiator.

4.3 Radiator

A kind of part that itself has a specific elemental composition or coating, intended to absorb heat and radiate electromagnetic waves to the patient, and not in direct contact with the human body during use.

5 Requirement

5.1 Wavelength range

The energy generated by the radiator should be mainly distributed in the wavelength range of 2 μm to 25 μm.

5.2 Temperature control

5.2.1 The temperature error on the surface of the radiator should not be greater than ±10% of the nominal value.

5.2.2 The unevenness of the surface temperature of the radiator should not exceed 10%. Metal matrix radiators are not subject to this limitation.

5.2.3 In the worst case during normal use, including the maximum temperature in the working environment specified in the manual, the temperature of the components of the therapeutic apparatus should not exceed the value given in Table 1.

Table 1 Allowable temperature values

Part	Maximum temperature, °C			
Test corner surface				
Protective cover:	90			
— Metal and liquid:	Contact time: t<1s; 1s≤t＜10s; 10s≤t＜1min; 1min≤t			
— Glass, porcelain and vitreous material:	74	56	51	48
	80	66	56	48
— Molding material, plastic, rubber, wood:	86	71	60	60

5.3 Time control

5.3.1 The heating time should not exceed 20min;

5.3.2 If the therapeutic apparatus is equipped with an adjustable timer, when the preset working time is reached, the heater will stop working immediately and give out sound or light indication, and the accuracy error of the timer should not exceed ±10%.

5.4 Overheating protection

There should be an overheating protection device with reliable operation. After the overheating protection device is activated, it should give out sound or light alert, which cannot be restored automatically.

5.5 Flame resistance

The protective cover and the enclosure of the treatment head made of non-metallic materials should be flame-resistant.

5.6 External mark

Any mark should be marked in an obvious position. The color of the mark should be in contrast with the background color. It is ensured that it is still clearly visible after the equipment is installed. When 110% of the rated voltage is applied to make the equipment reach a thermal steady state, the mark should not fall off or deform.
There should have the words "No Coverage" and the following markings:

The symbol height should be at least 15mm and the font height should be at least 3mm.

5.7 Instruction manual

5.7.1 The instructions on the irradiation time and safe irradiation distance for treating different parts of the human body should be provided in the instruction manual;

5.7.2 The patients with poor thermal sensitivity on the treatment site should be warned that the treatment should be carried out under the guidance of a doctor in the instruction manual.

5.7.3 The manufacturer shall clearly inform the user of the service life of the radiator in the instructions, and shall describe in detail how to dispose of the radiator when its service life reaches, the replacement steps, and the warnings and suggestions to avoid scalding.

5.7.4 The instruction manual should contain relevant contents of "precautions":
——Do not directly give warning of radiation to the eyes;
——Improper treatment position may cause overheating and burns;
——Improper use may cause scalding due to dumping;
——The equipment should not be used in places with flammable anesthetic gas or other flammable substances.

5.8 Appearance and structure

5.8.1 The enclosure of the therapeutic apparatus should be bright and clean, with uniform color and without obvious scratches, breakage and deformation.

5.8.2 The positioning of the adjustment mechanism should be reliable.

5.8.3 The fasteners should be installed firmly without loosening.

5.8.4 If the radiator is a metal base, the surface coating should be uniform in thickness, with no blistering, peeling or local accumulation; the surface of the non-metallic base radiator should be free of obvious defects such as cracking, damage and deformation.

5.8.5 If the treatment head and the stand are assembled in a suspended manner, the assembly method of the treatment head shall be designed to avoid any incorrect assembly that may lead to unacceptable risks.

5.9 Dielectric strength at operating temperature

The therapeutic apparatus should be able to withstand the dielectric strength test under sufficient heating conditions without breakdown or flashover.

5.10 Harmful rays

The radiator equipped with the therapeutic device shall be free from harmful rays.

6 Test method

6.1 Test condition

6.1.1 Preconditioning: Before starting the test, the therapeutic apparatus should be parked at the test site without working for at least 24 hours.

6.1.2 The temperature should be between 20±2℃ and the relative humidity should be 65±10%.

6.1.3 Power supply condition: a.c 220V±22V, 50Hz±1Hz.

6.2 Wavelength range

Use a blackbody furnace and an infrared spectrometer for testing, and the test results should meet the requirements in 5.1.

6.3 Temperature control

5. 4

5. 5

6.3.1 Surface temperature of the radiator

After the therapeutic apparatus is energized for 20 minutes, use a thermometer to measure the surface temperature of the heater. The measurement should be based on the principle of uniform distribution to properly determine the temperature measurement points (at least 9 points), and take the arithmetic mean, which should comply with the provisions in Article 5.2.1. During the test, the screws and holes should be avoided. For the test points, refer to Figure 1, and may not be limited to the provisions in Figure 1. The equipment under test with multiple radiators can be measured individually.

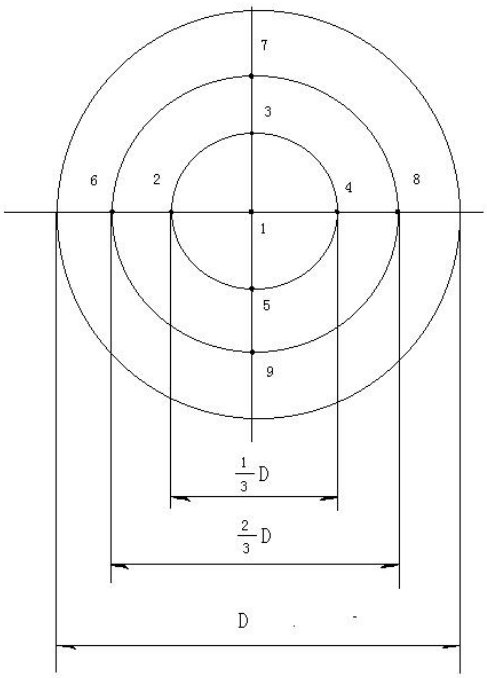
The placement of the temperature testing device and the treatment head is specified by the manufacturer in the technical documentation.

The manufacturer can use one of the following methods for temperature measurement.

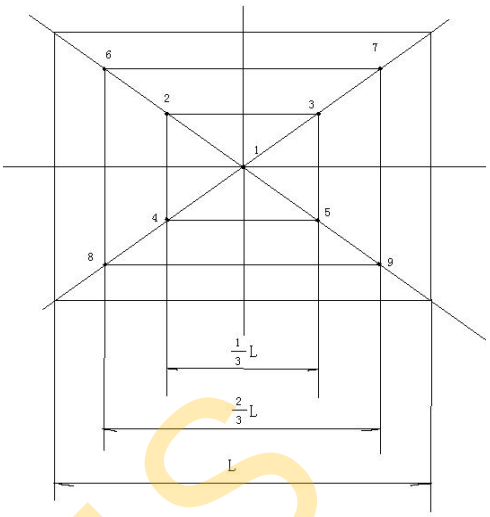
a. If a contact thermometer is used for measurement, the influence of the surrounding environment on the test results should be minimized. If necessary, the exposed metal part on the temperature sensor probe can be wrapped with high-temperature resistant insulation materials (such as heat-resistant glue) to reduce the influence of thermal convection formed by the large temperature difference between the high temperature source and the surrounding environment on the test results.

b. If a point-contact thermocouple thermometer is used, the test column specified in Appendix A can be used for test. Put all the metal parts of the thermocouple into the small hole in the middle of the test column, and read the temperature value after the temperature is stable.

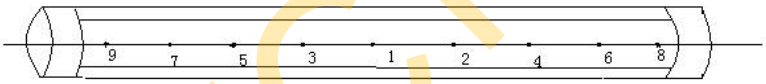
c. If a radiation thermometer is used for measurement, the radiation thermometer should be corrected according to the normal total emissivity value of the radiation surface. Then determine the temperature measurement distance according to the field of view of the radiation thermometer, so that the diameter of each temperature measurement point is equal and fills the field of view of the thermometer. The normal total emissivity value of the radiating surface shall be stated in the technical documentation.



Surface test points of circular radiator



Surface test points of square radiator



Test points of tubular radiator

Figure 1 Schematic diagram of test point distribution

6.3.2 Temperature unevenness

Measure the temperature value of evenly distributed points (at least 9 points), and calculate according to the following formula, which shall meet the requirements in 5.2.2.

$$a = \frac{1}{T_Z}\sqrt{\frac{1}{n}\sum_{i=1}^{n}(T_i - T_Z)^2}$$

In the formula: a - temperature distribution coefficient;

T_z - Temperature value of the geometric center point on the surface of the radiator (unit: °C).

T_i - Temperature value of the i-th point on the surface of the radiator (unit: °C).

n - Number of temperature measurement points except the temperature measurement points at the geometric center on the surface of the radiator.

6.3.3 Maximum allowable temperature

In the most unfavorable situation when the therapeutic apparatus is placed in the normal use position, after 110% of the rated voltage is energized for 20 minutes, use a contact thermometer to measure the front cover and rear cover of the protective cover of the treatment head respectively (If it is in the normal use position, it is impossible to contact

the patient or the part marked with a no-touch mark in an obvious position is exempt from this restriction, but the maximum temperature should be clearly stated in the instruction manual, as well as the conditions for safe contact: for example, how long after the power outage can be contacted, the protective devices that the contact must be equipped with, etc.), and the maximum temperature measured shall comply with the provisions in 5.2.3.

6.4 Time control

5. 6

6.4.1 Temperature rise time

Apply the rated working voltage to the device under test, measure the geometric center on the surface of the radiator according to the method in 6.3.1 while heating with electricity, and record the temperature rise curve from room temperature to stable temperature, as shown in Figure 2. According to the curve record, take the time required to rise from room temperature to 90% of the stable temperature as the temperature rise time, which should meet the requirements in 5.3.1.

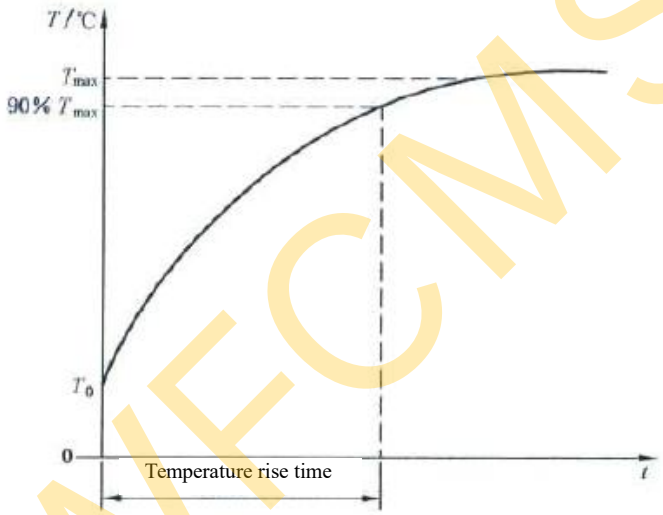


Figure 2 Temperature rise time curve

6.4.2 Timer

Use a stopwatch to measure the set time of the timer, and its error should meet the requirements specified in 5.3.2.

6.5 Overheating protection

For thermal protection devices with nominal operating temperature, the compliance with the requirements is verified by checking the relevant data and certificates of the components.

Apply 110% of the rated working voltage to the therapeutic apparatus. When the steady state is reached, a dry cotton cloth or flannelet cloth (two to four layers) with a mass per unit area of 130 g/m^2 to 165 g/m^2 is tightly wrapped around the treatment head (without covering the treatment surface). The protective device should operate before the cloth smokes or ignites. If there is no smoke or ignition within the maximum working time (excluding long power-on) that can be set by the therapeutic apparatus, it is considered to meet the requirements. The blackening without smoke is negligible.

6.6 Flame resistance

For movable therapeutic apparatus, the materials of the protective cover and the enclosure of the non-metallic treatment head shall have (or be better than) the flammability level of V-2 in accordance with IEC 60695-11-10. For non-movable therapeutic apparatus, the materials of the protective cover and the enclosure of the non-metallic treatment head shall have (or be better than) the flammability level of FV-1. Check the data related to the material for verification, or carry out the inspection according to the requirements in 11.3a) of IEC 60601-1, which shall meet the requirements in 5.5.

6.7 External mark

It should meet the requirements in 5.6 through visual observation.

6.8 Instruction manual

It should meet the requirements in 5.7 through inspection and review of documents.

6.9 Appearance and structure

It should meet the requirements in 5.8 through visual observation and instrument operation.

6.10 Dielectric strength at operating temperature

After the therapeutic apparatus is applied with 110% of the rated voltage and reaches the working temperature, cut off the power supply, and operate in accordance with 8.8.3 in GB 9706.1-2020, which should meet the requirements in 5.9.

After the therapeutic apparatus is applied with 110% of the rated voltage and reaches the working temperature, cut off the power supply, and test the circuit according to figure 3. The test voltage is applied:

— Between the two lead wires of the heating element and the accessible part (including the enclosure, protective cover and all parts that can be touched by the test finger, such as the metal reflector, the sheath of the lead wire of the heating wire, etc., and the sheath is at least double insulated when it can be touched by the test finger);

— Between the two lead wires of the heating element and the insulating part of the electric wire that may be in contact with the metal enclosure (including the wires near the treatment head used to connect to the power grid. The treatment head should be twisted so that the wire is wound around the metal enclosure, and in the most unfavorable case, the test is performed after heating, at least double insulation).

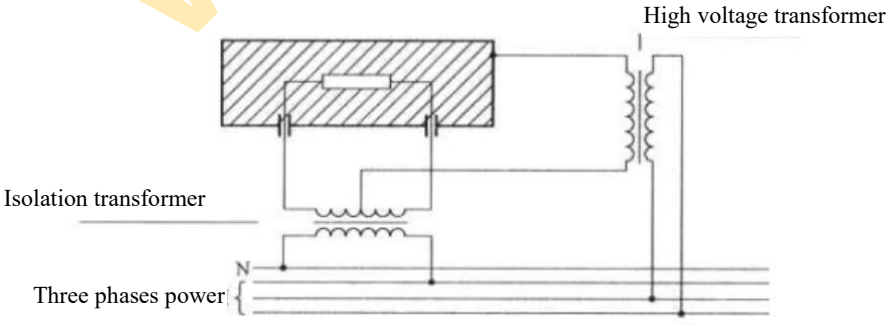


Figure 3 Circuit diagram of dielectric strength test at operating temperature

6.11 Harmful rays

Use a ray detector to detect. Under the normal operating conditions of the equipment, if the ambient dose equivalent rate or directional dose equivalent rate caused at any place

0.1M away from the accessible surface of the equipment does not exceed 1usv/h, it meets the requirements of 5.10.

Appendix A

(informative appendix)

A.1 Information about the test column

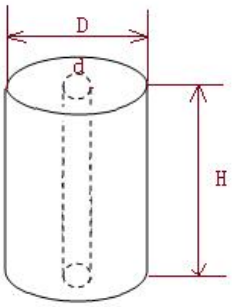


Figure A.1 Test column

Dimension: D=1cm,

d=2.5mm,

H=2cm.

Material: brass, coated with non-reflective black paint.