世界针灸学会联合会标准

WFAS STANDARD 001:2013

针 灸 针

Acupuncture Needles

2013—05—14发布 2014—01—01实施

中国中医药出版社

Preface

The standard of World Federation of Acupuncture – Moxibustion Societies, which is put forward by World Federation of Acupuncture – Moxibustion Societies in accordance with the general requirements of sterile acupuncture needles for single use (refers to Filiform Needles), of clinical practice, and of medical devices.

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7. Serial numbers of the chapters were re – adjusted.

Annex A, Annex B and Annex C of this standard are normative.

Annex D of this standard is informative.

The drafting Units: Suzhou Medical Appliance Factory, China.

Main drafters: Cao Yang, Xu Aimin, Jiang Xinsui.

Members of the International working group: James Flowers (Australia), Wu Binjiang (Canada), Cao Yang (China), Huang Longxiang (China), Liu Baoyan (China), Tan Yuansheng (China), Denis Colin (France), Francois Dumont (France), Andreas Rinnoessel (Germany), Sergio Bangrazi (Italy), Cho Geun Sik (Korea), Liao Chunhua (Malaysia), Liu Yun (USA).

International observers: Naoto Ishizaki (Japan).

图书在版编目(CIP)数据

针灸针/世界针灸学会联合会. —北京：中国中医药出版社，2016.11
ISBN 978-7-5132-3593-8

Ⅰ.①针… Ⅱ.①世… Ⅲ.①针灸针 Ⅳ.①TH789

中国版本图书馆 CIP 数据核字（2016）第 202640 号

世界针灸学会联合会
针灸针
WFAS STANDARD 001:2013

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中国中医药出版社出版
北京市朝阳区北三环东路 28 号易亨大厦 16 层
邮政编码 100013
网址 www.cptcm.com
传真 010 64405750
廊坊市晶艺印务有限公司印刷
各地新华书店经销

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开本 880×1230 1/16 印张 2.5 字数 92 千字
2016 年 11 月第 1 版 2016 年 11 月第 1 次印刷

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书号 ISBN 978-7-5132-3593-8 定价 50.00 元

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书店网址 csln.net/qksd/

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Introduction

The Standard applies to Sterile Acupuncture Needles for single use (refers to Filiform Needles) used by professional acupuncturists. The sterile acupuncture needles for single are sterilized before leaving the factory in order to guarantee that the product is germ – free, the healthcare professional can open the sealed package and use the needle immediately.

In order to encourage innovation, the standard will no longer enforce the combination of the needle diameter and length. However, considering the clinical usage requirements, the standard provides the specifications for the needle diameter and length.

The sharpness and puncture performance of the needle tip are of a very important clinical significance. Annex A states the guidelines and the evaluation methods for the strength and the sharpness of the needle tip, while Annex B provides two qualitative and quantitative evaluation methods to determine the tip's puncture performance.

The qualitative methods to evaluate the tip's puncture performance are described in Annex B. The methods are simple, direct and practical. It makes them especially suitable for the routine inspection and for the cross-comparison of the acupuncture needles clinical applications. They also play a very important role in the enhancement of the quality of the acupuncture needle tip. The methods to evaluate the puncture performance of the needle tip can be used to further evaluate the puncture and puncture performance of the acupuncture needle. Currently, the more appropriate method is to use the needle tip to pierce through polyurethane material; however, this method has not yet been implemented internationally. Considering the consistency of standards in the future, this standard provides the methods to evaluate the puncture performance of the needle tip and ranks Clause 5. 4. 2 as a recommendatory one. The standard does not provide the sharpness index of the piercing through polyurethane material by the needle tip. This index will be added to the standard when it becomes appropriate. To improve product quality, all inspection reports should include the inspection information as well as the results of the performance evaluation.

Since every manufacturer's design, production, and sterilization methods are different, no regulations exist for the materials of the acupuncture needle handle. Still, the needle body and the needle handle of acupuncture needle should have good biocompatibility. The guidance for the biological evaluation of the medical devices given in ISO 10993 – 1 should be applied. It is highly advised that the manufacturer adheres to the guidelines when evaluating their products in order to enhance their quality. The evaluation should include the effect of the sterilization process on the acupuncture needle.

At the same time, in order to ensure product safety and efficacy, the manufacturer should perform risk analysis and enforce risk management in addition to adhering to the requirements of local rules and regulations, the relevant background data of the medical devices and clinical practice throughout the entire duration of the product's life cycle. ISO 14971 has provided manufacturers a framework for the effective management of hazards associated with the use of medical devices.

In some countries, the requirements proposed here are subject to legal sanctions. Such rules and regulations should take precedence over the standards set forth in this document.

1 Scope

The standard specifies the requirements for the classification, criteria, test methods, inspection rules, packaging, labelling, instructions for use, transport, storage for the sterile acupuncture needles for single use.

The standard applies to the sterile acupuncture needles for single use (refers to Filiform Needles) .

2 Normative References

The following references are indispensable for the proper application of the corresponding standards. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO/TS 15510: 2007 Stainless steels – Chemical composition

ISO 10993 – 1: 2009 Biological evaluation of medical devices – Part 1: Evaluation and experiment in the process of risk management

ISO 6507 – 1: 2005 Metallic materials – Vickers hardness test – Part 1: Test method

ISO 11737 – 2: 2007 Sterilization of medical devices – Microbiological methods – Part 2: Tests of sterility performed in the validation of a sterilization process

ISO 15223 – 1 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements

3 Terms and Definitions

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

3. 1 Body of the Needle

The part of the acupuncture needle that is inserted into the body (Figure 1) .

3. 2 Handle of the Needle

The part of the acupuncture needle that is not inserted into the body (Figure 1) .

3. 3 Tip of the Needle

The sharp apex at the end of the acupuncture needle body is inserted into the body (Figure 1) .

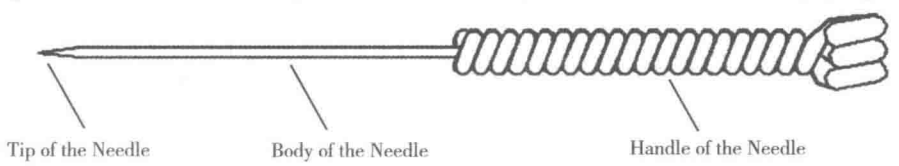


Figure 1 Typical Structure of Acupuncture Needle

3. 4 Root of the Needle

The part of the acupuncture needle that connects the needle body to the needle handle (Figure 1) .

3. 5 Tail of the Needle

The end part of the needle handles at the opposite side of the needle apex (Figure 1) .

3. 6 Sterile Acupuncture Needles

The acupuncture needles that have been sterilized.

3. 7 Un – sterilized Acupuncture Needles

The acupuncture needles that have not been sterilized.

3. 8 Guide Tube

An assistant tool inthe shape of slender, long tube into which the needle is put and used for easy inserting.

Note: In order to facilitate the use, guide tube should be made of transparent materials.

3.9 Hardness of Needle Body

The body of acupuncture needle has a characteristic of resisting permanent deformation.

3.10 Primary Package

The material that first envelops the product and holds it.

Note: This usually is the smallest unit package of use and is the package which is in direct contact with a piece or several pieces of acupuncture needles.

3.11 Secondary Package

The package of several primary packages for distribution and keeping.

4 Classification

4.1 The configuration of the acupuncture needle and the name of each of its parts are shown in Figure 1.

4.2 The acupuncture needle includes two types, one with guide tube and another without guide tube. The acupuncture needle with guide tube is shown in Figure 2.

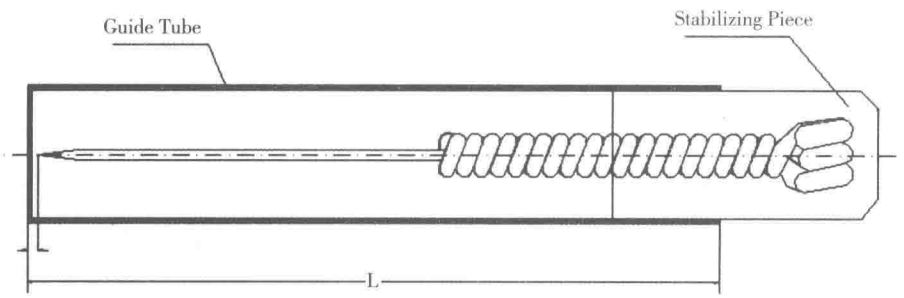
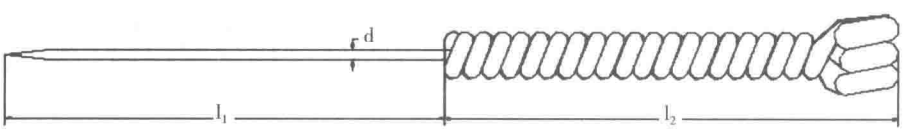


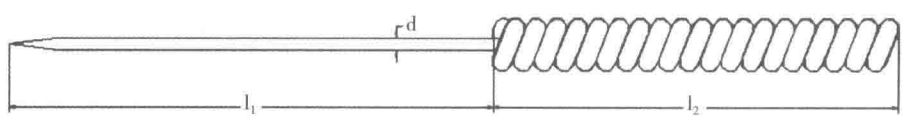
Figure 2 Sterile Acupuncture Needle (with Guide Tube)

Note: No uniform requirement is provided for the fixing method of needle tube as shown in Figure 2.

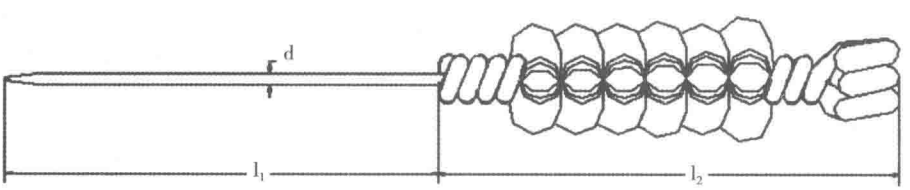
4.3 The types of needle handles are the ring handle, the plain handle, the flower handle, the metal tube handle, and the plastic handle. The types of acupuncture needles are shown in Figure 3 below.



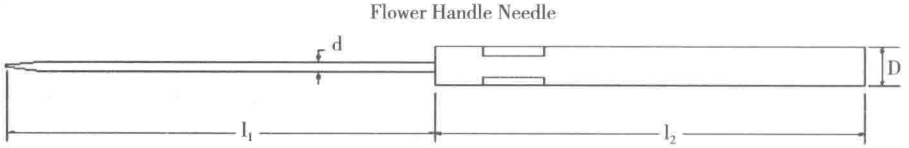
Ring Handle Needle



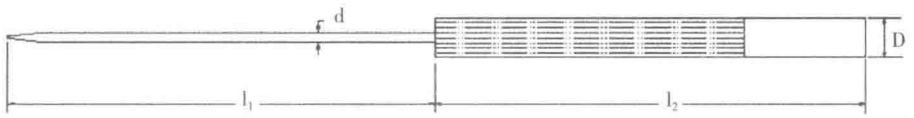
Plain Handle Needle



Flower Handle Needle



Metal Tube Handle Needle



Plastic Handle Needle

d: diameter of needle body

D: diameter of needle handle

l_1: length of needle body

l_2: length of needle handle

Figure3 The Types of Acupuncture Needles

Note: The types of needles in the above figure show certain kinds of typical structures. There are no uniform regulations regarding the method of using guide tubes to stabilize the needle.

4.4 The specifications of the acupuncture needle are marked as: needle diameter × needle length.

Example: φ0.30mm × 40mm

4.5 The basic dimensions and tolerance of acupuncture needles should comply with Tables 1 ~ 4.

4.5.1 The needle diameter should comply with Table 1.

Table 1 Basic Measurement of Needle Diameter (mm)

Needle Diameter of Standard Range (d)	Allowable Difference
$0.12 \leqslant d < 0.25$	±0.008
$0.25 \leqslant d \leqslant 0.45$	±0.015
$0.45 < d \leqslant 0.80$	±0.020

4.5.2 The needle length should comply with Table 2.

Table 2 Basic Measurement of Needle Length (mm)

Needle Length of Standard Range (l_1)	Allowable Difference
$5 < l_1 \leqslant 25$	±0.50
$25 < l_1 \leqslant 75$	±1.00
$75 < l_1 \leqslant 150$	±1.50
$100 < l_1 \leqslant 200$	±2.00

4.5.3 The length of the needle handle should be no less than 13mm.

4.5.4 The specifications of the coiling handle wire should comply with Table 3. The diameter of the plastic handle and the metal tube handle should comply with Table 4.

Table 3 Diameter of the Coiling Handle Wire (mm)

Needle Diameter of Standard Range (d)	Diameter of Coiling Handle Wire
$0.12 \leqslant d < 0.20$	0.30
$0.20 \leqslant d < 0.30$	0.35
$0.30 \leqslant d < 0.40$	0.40
$0.40 \leqslant d < 0.50$	0.45

Table 4 Diameter of the Plastic Handle and the Metal Tube Handle (mm)

Type of Needle Handle	Handle Diameter (d)
Metal Tube Handle, Plastic Handle, etc.	0.80 ~ 2.50

5 Requirements

5.1 The basic dimensions of the acupuncture needle should comply with the specifications listed in Clause 4.5.

5.2 There is no uniform regulation regarding the material of the needle handle and body. It should be of good biocompatibility. Currently, the popularly used needle body material is made of X5CrNil8 – 9, X7CrNil8 – 9 Austenite Stainless Steel etc are given in ISO/TS 15510: 2007.

Note: When the material of the acupuncture needle body has been altered, there will be an additional coating (such as Lubricant) on the surface of the needle body or there will be evidence indicating that it can cause harmful side effects to the human body. In such circumstances, in accordance with ISO 10993 – 1: 2009 for guidance on biocompatibility, it is necessary to perform biological evaluation of the material and the final product. The basic evaluation and testing are:

a. Cytotoxicity;

b. Sensitization;

c. Intracutaneous Reactivity;

d. Ethylene oxide sterilization residuals (if using EO. to sterilize).

5.3 The hardness of the needle body should comply with the specifications in Table 5.

Table 5 Hardness of the Needle Body

Needle Diameter of Standard Range (d, mm)	Hardness ($HV_{0.2kg}$)
0.12≤d<0.25	≥480, ≤650
0.25≤d≤0.30	≥460, ≤650
0.30<d≤0.45	≥450, ≤650
0.45<d≤0.80	≥420, ≤530

5.4 The intensity and puncture performance of the needle tip.

5.4.1 The tip of the acupuncture needle should be round and without defects, and it should have good strength. The needle tip should not have any hooks or bends after a set amount of pressure has been applied. The puncture force should not exceed the values set forth in Table 6.

Table 6 Pressure and Puncture Force

Needle Diameter of Standard Range (d, mm)	Pressure (N)	Puncture Force (N)
0.12≤d<0.25	0.4	0.7
0.25≤d≤0.30	0.5	0.8
0.30<d≤0.45	0.6	0.9
0.45<d≤0.80	0.7	1.0

5.4.2 The tip of the acupuncture needle should be round and without defects, and it should have good puncture performance.

5.5 The acupuncture needle should be of sufficient toughness, and it should not exhibit any cracks, breaks or separation of layers after the winding test.

5.6 The needle surface should be smooth, clean and free of any defect or foreign matter produced during the metal processing course and its appearance quality and coarseness parameter (Ra value) should comply with Table 7.

Table 7 Appearance Quality and Ra Value

Appearance Quality	Should not have any obvious defects such as scars, bends, or fine scratches
Ra value	≤0.63μm

5.7 The point at which the needle handle and body connects should be firm and sturdy, and both axial displacements should be no more than 3 mm during the pulling test by the force values shown in Table 8.

Table 8 Pulling Force

Needle Diameter of Standard Range (d, mm)	Pulling Force (N)
0.12≤d≤0.18	7
0.18 < d≤0.25	9
0.25 < d≤0.30	14
0.30 < d≤0.45	19
0.45 < d≤0.80	24

5.8 If the needle handle is made with winding coils, the spiral loop should be arranged symmetrically without obvious gaps.

5.9 The needle handle should not have any protuberances.

5.10 The acupuncture needle should be straight and without obvious bends or curves.

5.11 The color and luster of the surface of the needle handle should be even. If the handle is made with plating, it should not exhibit layering or shedding.

5.12 No visible microsphere is formed on the surface of needle when observed with normal or corrected visual acuity if lubricant is applied to the needle body.

5.13 The needle body should have good corrosion resistance.

5.14 Sterile Acupuncture Needles should be sterilized through a confirmed sterilization procedure in order to assure that the products are sterile.

Note: For appropriate sterilization methods, see Annex D. The Requirements for validation and routine control of a sterilization process for medical devices are provided in ISO 11135 – 1: 2007, ISO 11137 – 1: 2006 and ISO 17665 – 1: 2006 should apply.

6 Test Methods

6.1 Appearance

Inspect with the naked eye or corrected visual acuity or with a 10 times magnifier.

6.2 Surface Coarseness

Inspect with the naked eye or corrected visual acuity or with a 10 times magnifier, compare with the surface coarseness sample.

6.3 Measurement

Measure using general and specialized measuring tools.

6.4 Function

6.4.1 Hardness Test

Assess the hardness test according to the requirements given in ISO 6507 – 1: 2005, which should comply with Clause 5.3.

6.4.2 Test for Needle Tip Strength, Sharpness and Puncture Performance

Perform the tests according to the requirements noted in Annex A and B, which should comply with clauses 5.4.1 and 5.4.2, respectively.

6. 4. 3 Test for Resilience of the Needle Body.

The needle body should be encircled by a tight coil along the direction of a helical line in the central axis with the diameter of 3 times that of the needle body. The needle body should be wound by two circles if the needle body length is ≤15mm and by five circles if the needle body length is any of the other specifications, which should comply with Clause 5. 5.

6. 4. 4 Test for the Firmness of the Connecting between the Needle Body and the Handle

Firstly, measure the length of the needle body in advance, then affix the needle body in the clamp. Perform the non – impactive pulling test along the axis of the needle body on the surface of the needle handle according to Clause 5. 7. Afterwards, the needle length should be measured again according to Clause 5. 7.

6. 4. 5 Test for Protuberances on the Needle Handle

When touching the needle handle with the hands, there should be no detectable protuberances according to Clause 5. 9.

6. 4. 6 Test for the Corrosive Nature of the Needle Body

Test for the corrosive nature according to the requirements noted in Annex C, which should comply with Clause 5. 13.

6. 4. 7 Test of Sterility

Tests of sterility performed in the validation of a sterilization process according to the requirements given in ISO 11737 – 2: 2007, Sterile Acupuncture needles should comply with Clause 5. 14.

7 Packaging

7. 1 Primary package of sterile acupuncture needles should be well sealed; the package should not contain any foreign objects visible to the naked eye. The material and design of the package should be ensured and should not cause any damage to the product contained within:

a. When stored in dry, clean, and sufficiently ventilated conditions, the products should be guaranteed to be sterile when used before the expiration date.

b. The packaged product should be exposed to minimal contamination risk when being removed from the package.

c. During normal transference, transport, and storage, the packaged product should be fully protected.

d. Once the package has been opened, it can no longer be easily resealed, and thus it should have noticeable traces of tear when opened.

Note: The Requirements for materials, sterile barrier systems and packaging systems for terminally sterilized medical devices are provided by ISO 11607 *and EN* 868. *The content of the standard should be considered by the manufacturer during the evaluation and design of the packaging of sterile acupuncture needles.*

7. 2 Primary Package should guarantee that the acupuncture needles will not rust before the expiration date.

7. 3 Secondary Package is the smallest package unit for inspection and distribution.

7. 4 Out package should be secure enough to ensure that the products will remain undamaged during normal transport and storage and that the labels or marking should remain clear and legible for many years.

8 Labelling

8. 1 Primary Package

The following information should be on the label of both the primary package at least:

a. Manufacturer's name and (or) trademark;

b. Name of product;

c. Specifications;

d. Quantity (if applicable) ;

e. Date of manufacture and (or) batch number;

f. Method of sterilization, the word "sterile" and (or) symbol;

g. The words "For single use" or "Do not reuse" and (or) symbol;

h. Expiration date.

8. 2 Secondary Package

The same type and specifications for primary package of acupuncture needles should be shown on the secondary package, along with the following information at least:

a. Manufacturer's name, address and trademark;

b. Name of product;

c. Type, specifications and quantity;

d. Date of manufacture and (or) batch number;

e. Certificate number according to the requirements of the regulations;

f. Method of sterilization, the word "Sterile" and (or) symbol;

g. The words "For single use" or "Do not reuse" and (or) symbol;

h. Expiration date;

i. If appropriate, that the name or composition of additive (such as Lubricant) are coated on the surface of needle body.

j. Warning: Those who are allergic tothe material of needle body should make use with caution or following the instruction of an acupuncture physician; Electrical stimulation is possible to produce corrosion to needles; use is prohibited if package is broken; destroy (by melting / burning) after use.

Before use, check to see that warnings are onthe secondary package, unless such warnings are already primary package.

8. 3 The labels, symbols, and information on the packaging should comply with ISO 15223 - 1.

8. 4 Revisions of the instructions for use should comply with Medical Devices Regulatory.

9 Storage and Transport

9. 1 The transport requirements should comply with the order contract.

9. 2 After packaging, the acupuncture needles should be stored in a clean, well - ventilated, non - contaminated environment with a relative humidity level of no more than 80%. The needles should have sufficient protection from damage.

Annex A

(Normative)

Test Methods for the Strength and Sharpness of the Acupuncture Needle Tip

A. 1 Definitions

The strength of the acupuncture needle tip: refers to the needle's ability to resist breakage when thrust vertically on the steel block.

The sharpness of the acupuncture needle tip: refers to the force required by the needle tip to vertically pierce the aluminum foil.

A. 2 Apparatus for Measuring the Strength and Sharpness of the Acupuncture Needle Tip

The apparatus (Figure A1) should comply with the following requirements and should be manufactured according to the design and documents approved by the regulated procedure.

A. 2. 1 The unit of the sharpness of the needle tip's puncture force is shown as "N".

A. 2. 2 The full load, minimum value and speed of the apparatus should comply with Table A1.

Table A1 The Full Load, Minimum Value and Speed of the Apparatus

Items	Designation
Full Load	1. 2N
Minimum Value	0. 01N
Speed	≤0. 1mm/s

A. 2. 3 The apparatus's erroneous differences in value should be no more than 0. 01N.

A. 2. 4 The apparatus should have an auto – correction capability and an antishock device. The needle clamp should be stable during use.

A. 2. 5 The transmission of the apparatus should be sensitive and reliable. The pointer should stop automatically when it pierces through the aluminum foil and meets the electrode.

A. 2. 6 The starting inductive quantity of the apparatus should be no more than 0. 02N.

A. 3 The Steel Block of the Strength of the Sample Acupuncture Needle Tip

The steel block surface of the strength of the sample acupuncture needle tip should be smooth and without rust.

A. 4 The Aluminum Foil of the Measuring Apparatus Used to Test the Sharpness of the Acupuncture Needle Tip

A. 4. 1 The aluminum foil surface should be clean and smooth and without overlaps, severe wrinkles, mildew stains, or sand holes.

A. 4. 2 The aluminum foil is a pliable material. The thickness should be 0. 05mm with deviations of ±0. 002mm and purity of no less than 99. 5%.

A. 4. 3 The strength of the pull resistance of the aluminum foil should be no less than 3 kg/mm^2, and the tensility rate should be no less than 3%.

A. 5 Test Methods

A. 5. 1 Testing the strength of the needle tip: After the test sample is affixed to the apparatus (with 5mm of

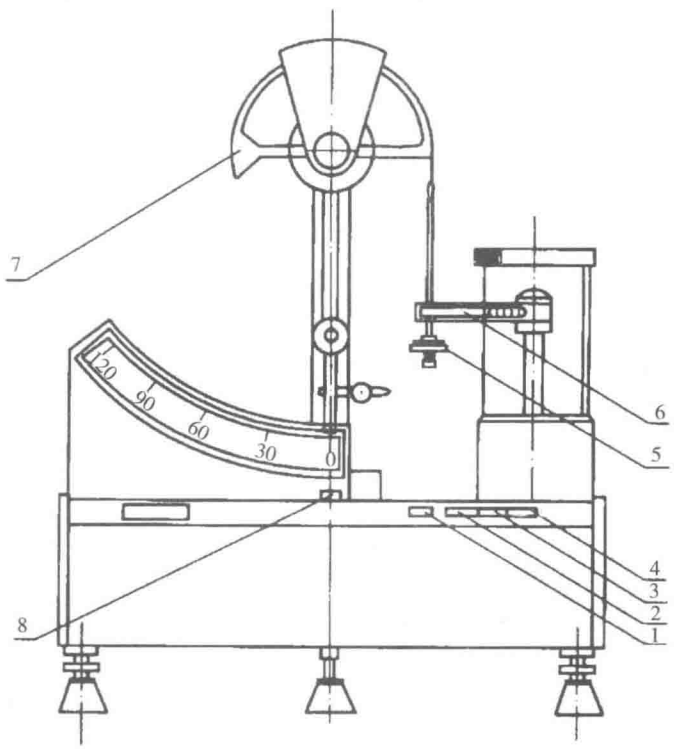
the acupuncture needle tip exposed), the needle tip is thrust vertically onto the steel block. According to the rule in A. 2. 2, increase force, speed and load until they reach the numerical values of the standard set by 5. 4. 1, removing the load after 5 seconds. Then, observe the sample under a 5 times magnifying glass. The needle tip should not have any bends or hooks. In addition, when the needle tip is dragged along the surface of sterilized cotton, it should not pull any fibers.

A. 5. 2 After the strength test, keep the sample acupuncture needle clamped in the test apparatus and allow the needle to gradually increase its force exerted on the aluminum foil (by way of the transmission); the swaying rod will react accordingly. When the force acting on the acupuncture needle exceeds the resistance of the aluminum foil, the needle tip will pierce through the aluminum foil and come into contact with the electrode. The apparatus will automatically stop increasing the force. At this time, the value indicated by the pointer on the swaying rod is the piercing force of the needle tip.

A. 5. 3 Press the on – off button of the function controls to allow the swaying rod and pointer to return to their original positions.

A. 5. 4 Move the aluminum foil in the clamp to allow the diameter of each pierced hole to exceed three times that of the test sample.

A. 5. 5 Repeat the above steps, A. 5. 2, A. 5. 3 and A. 5. 4; measure 3 times to obtain the average values.



1: power button (on and off)

2, 3, 4: function control button (on and off)

5: aluminum foil clamping apparatus

6: needle clamping apparatus

7: adjustment rod

8: (carpenter's) level