WFAS STANDARDS (DRAFT)
世界针灸学会联合会标准草案汇编

- **WFAS -001: Acupuncture Needles**
- **WFAS-002:Nomenclature and Location of Auricular Points**
- **WFAS-003: Manipulation of Moxibustion**
- **WFAS-004: Manipulation of Scalp Acupuncture**

World Federation of Acupuncture-Moxibustion Societies

世界针灸学会联合会

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WFAS STANDARD—001:××××

Acupuncture Needles Standard

(Draft Standard)

World Federation of Acupuncture-Moxibustion Societies

世界针灸学会联合会

CONTENTS

Acupuncture Needles

1. Scope

The standard specifies the requirements for the classification, criteria, test methods, inspection rules, packaging, labelling, instructions for use, transport, storage, and time limit of use for the acupuncture needles.

The standard applies to the use of un-sterilized acupuncture needles (reusable acupuncture needles) and sterile acupuncture needles for single use.

2. Normative references

The following referenced documents are indispensable for the application of the document. 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 testing

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 15223:2000 Medical Devices - Symbols for Use in Labelling, Sign and Information of Medical Devices

3. Classification

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

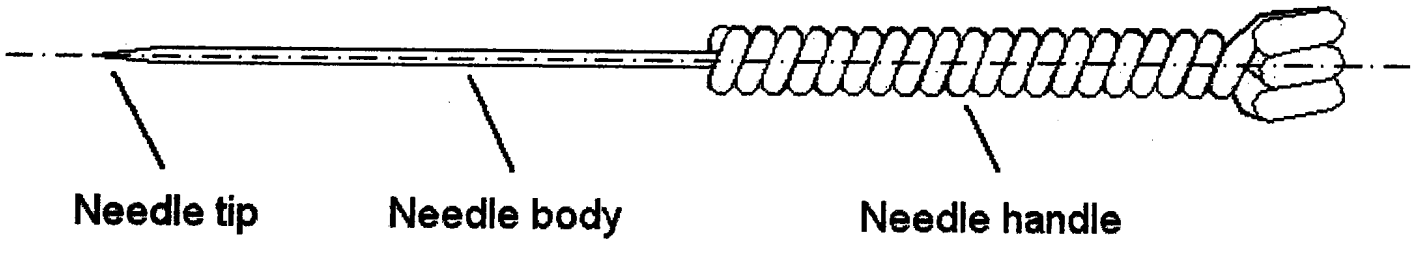


Figure 1 Typical Structure of Acupuncture Needle

3.2 The varieties of acupuncture needles include un-sterilized acupuncture needles (reusable acupuncture needles that a practitioner must sterilize before each use) and sterile acupuncture needles (acupuncture needles

for single use).

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

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

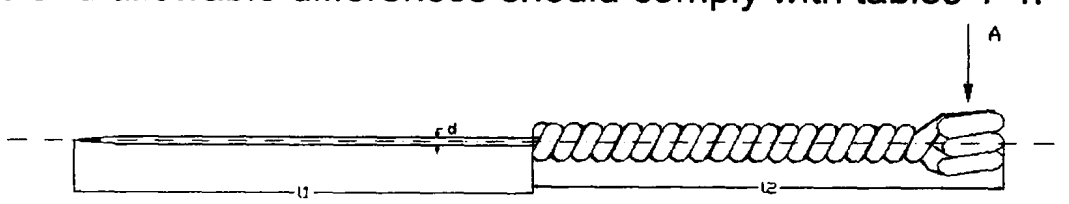
3.4 The types of needle handles are the ring handle, the plain handle, the flower handle, the metal tube handle, and the plastic handle.

3.5 The types of acupuncture needles are the ones that come with guide tubes and the ones that do not.

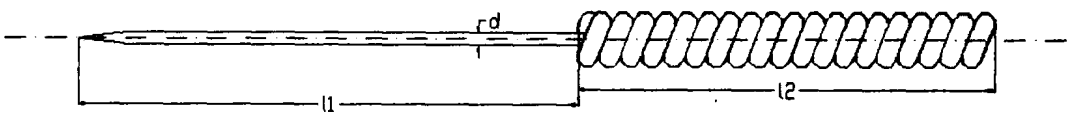
3.6 The specifications of the acupuncture needle are marked as:
needle diameter × needle length

e.g.: φ0.30mm×40mm

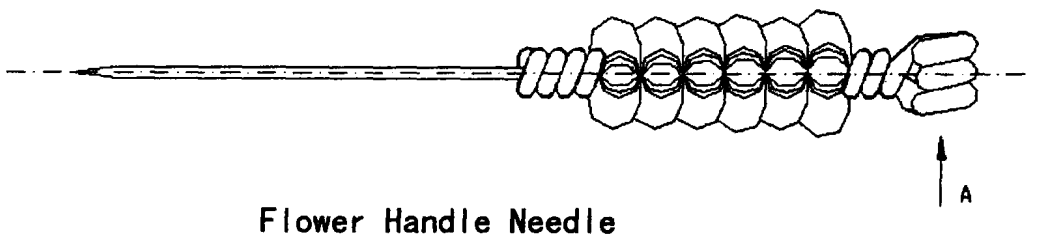
3.7 The types of acupuncture needles are shown in Figure 2 below. The basic dimensions and allowable differences should comply with tables 1-4.



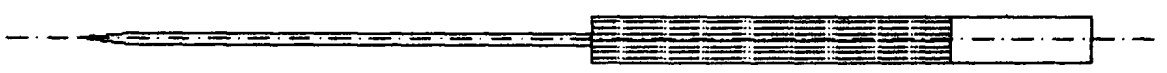
Ring Handle Needle



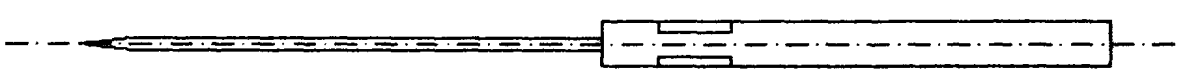
Plain Handle Needle



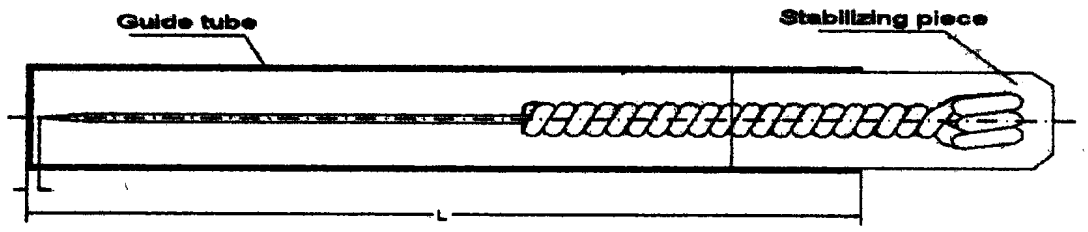
Flower Handle Needle



Plastic Handle Needle



Metal Tube Handle Needle



Sterile Acupuncture Needle (with guide tube)

Figure 2: 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.

3.6.1 The needle diameter should comply with Table 1.

TABLE 1: Basic Measurement of Needle Diameter (mm)

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

NOTE: The roundness of needle diameter should be no more than 0.005 mm.

3.6.2 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
$5 < l_1 \leq 25$	±0.50
$25 < l_1 \leq 75$	±1.00
$75 < l_1 \leq 150$	±1.50
$100 < l_1 \leq 200$	±2.00

3.6.3 The length of the needle handle should be no less than 20mm±1.50 mm.

TABLE 3: Length of Needle Handle (mm)

Needle Handle Type	Needle Length of Standard Range (l_1)	Needle Handle Length (l_2)	
		Needle Handle Length (l_2)	Allowable Difference
Ring Handle	$5 < l_1 \leq 15$	22	±1.50

Flower Handle	$15<l_1\leq30$	27	
	$30<l_1\leq75$	35	
	$75<l_1\leq200$	50	±2.00
Plain Handle	$5<l_1\leq15$	20	±1.50
	$15<l_1\leq30$	25	
	$30<l_1\leq75$	30	
	$75<l_1\leq200$	40	±2.00
Metal Tube Handle Plastic Handle	$5<l_1\leq150$	20	±1.50
		25	

3.6.4 The specifications of the coiling handle wire should comply with Table 4. The diameter of the plastic handle and the metal tube handle should comply with Table 5..

TABLE 4: 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 5: Diameter of the Plastic Handle and the Metal Tube Handle (mm)

Type of Needle Handle	Handle Diameter
Metal Tube Handle, Plastic Handle, etc.	0.80 - 2.50

4. Requirements

4.1 The basic dimensions of the acupuncture needle should comply with the specifications listed in Clause 3.6.

4.2 The acupuncture needle's body shall be made by X5CrNil8-9 Austenite Stainless Steel are given in ISO /TS 15510:2007 shall apply.

NOTE 1: Although there is no uniform regulation regarding the material of the needle handle, it should be of good biocompatibility.

NOTE 2: 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 ISO10993-1:2009 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).

4.3 The hardness of the needle body should comply with the specifications in Table 6.

TABLE 6: Hardness of the Needle Body

Needle Diameter of Standard Range (d; mm)	Hardness ($HV_{0.2kg}$)	
	Sterile Acupuncture Needles	Un-sterilized Acupuncture Needles
0.12≤d<0.25	≥480, ≤630	≥480, ≤630
0.25≤d ≤0.30	≥460, ≤630	≥460, ≤630
0.30<d ≤0.45	≥450, ≤630	
0.45<d ≤0.80	≥420, ≤530	≥420, ≤530

4.4 The Intensity and Puncture Performance of the Needle Tip.

4.4.1 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 7.

TABLE 7: 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≤0.35	0.5	0.8
0.35<d≤0.45	0.6	0.9
0.45<d≤0.80	0.7	1.0

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

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

4.6 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 8.

TABLE 8: Appearance Quality and Ra Value

Product Variety	Sterile Acupuncture Needles	Un-sterilized Acupuncture Needles
Appearance Quality	Should not have any obvious defects such as scars, bends, or fine scratches.	No scars, bends, or depressions allowed.
Ra	0.63	0.4

4.7 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 9.

TABLE 9: Pulling Force

Needle Diameter of Standard Range (d; mm)	Pulling Force (N)	
	Sterile Acupuncture Needles	Un-sterilized Acupuncture Needles
$0.12 \leq d \leq 0.18$	7	8
$0.18 < d \leq 0.25$	9	10
$0.25 < d \leq 0.35$	14	15
$0.35 < d \leq 0.45$	19	20
$0.45 < d \leq 0.80$	24	25

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

4.9 The needle handle should not have any protuberances.

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

4.11 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.

4.12 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.

4.13 The needle body should have good corrosion resistance.

4.14 Sterility assurance for sterile acupuncture needles.

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 E. 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.

5. Test Methods

5.1 Appearance

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

5.2 Surface coarseness: inspect with the naked eye or corrected visual acuity , compare with the surface coarseness sample.

5.3 Measurement

Measure using general and specialized measuring tools.

5.4 Function

5.4.1 Hardness Test

Assess the hardness test according to the requirements given in ISO 6507-1:2005, which should comply with Clause 4.3.

5.4.2 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 4.4.1 and 4.4.2, respectively.

5.4.3 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 4.5.

5.4.4 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 4.7. Afterwards, the needle length should be measured again according to Clause 4.7.

5.4.5 Test for Protuberances on the Needle Handle

When touching the needle handle with the hands, there should be no detectable protuberances according to Clause 4.9.

5.4.6 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 4.13.

5.4.7 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 4.14.

6. Packaging

6.1 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 ISO11607 and EN868. The content of the standard should be considered by the manufacturer during

the evaluation and design of the packaging of sterile acupuncture needles.

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

6.3 Secondary Package is the smallest package unit for inspection and sale.

6.4 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.

7. Labelling

7.1 Primary package and unit package

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

a) manufacturer's name, and or trademark;

b) name of product;

c) specifications;

d) quantity (applicable to unit packaging);

e) date of manufacture or batch number.

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

a) method of sterilization; the word "sterile" and or symbol;

b) the words "For single use" or "Do not reuse" and or symbol;

c) expiration date.

7.2 Secondary Package

7.2.1 The same type and specifications for primary package or unit 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 or batch number;

e) certificate number according to the requirements of the regulations;

f) if appropriate, that the name or composition of additive (such as Lubricant) are coated on the surface of needle body;

g) Those who are allergic to the material of needle body should make use with caution or following the instruction of an acupuncture physician;

h) Warning: Electrical stimulation is possible to produce corrosion to needles.

7.2.2 The following labels should be on the secondary package:

a) method of sterilization, the word "Sterile" and symbol;

b) the words "For single use" or "Do not reuse" and or symbol;

c) expiration date;

d) Before use, check to see that warnings such as "use is prohibited if package is broken" and "destroy (by melting / burning) after use" are on the secondary package, unless such warnings are already primary package or unit package.

7.3 The labels, marks, and information on the packaging should comply with ISO 15223-1:2007.

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

8. Storage, Transport, and Time Limit of Use

8.1 The transport requirements should comply with the order contract.

8.2 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.

8.3 Time limit of use

8.3.1 Once they are packaged, the acupuncture needles are subject to the regulations regarding the conditions of storage. The time limit of use should be between two to five years from the manufacture date.

8.3.2 After the acupuncture needles are sterilized, the time limit of use should not be less than two years or more than five years from the manufacture date in accordance with the storage regulations.

Annex A
(Normative)

Test Methods for the Strength and Sharpness of Acupuncture Needle Tip

A1 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.

A2 Apparatus for Measuring the Strength and Sharpness of the Acupuncture Needle Tip (Table A1)

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

A2.1 The unit of the sharpness of the needle tip's puncture force is shown as "N".

A2.2 The full load, minimum value, and speed of the apparatus should comply with Table A1.

TABLE A1

Items	Designation
Full Load	1.2 N
Minimum Value	0.0098 N
Speed	≤0.098 N/s

A2.3 The apparatus's erroneous differences in value should be no more than 0.0098 N.

A2.4 The apparatus should have an auto-correction capability and an antishock device. The needle clamp should be stable during use.

A2.5 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.

A2.6 The starting inductive quantity of the apparatus should be no more than 0.0186 N.

A3 The steel block surface of the strength of the sample acupuncture needle tip should be smooth and without rust.

A4 The Aluminum Foil of the Measuring Apparatus Used to Test the Sharpness of the Acupuncture Needle Tip

A4.1 The aluminum foil surface should be clean and smooth and without overlaps, severe wrinkles, mildew stains, or sand holes.

A4.2 The aluminum foil is a pliable material. The thickness should be 0.05 mm with deviations of $\pm$0.002 mm and purity of no less than 99.5%.

A4.3 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%.

A5 Test Methods

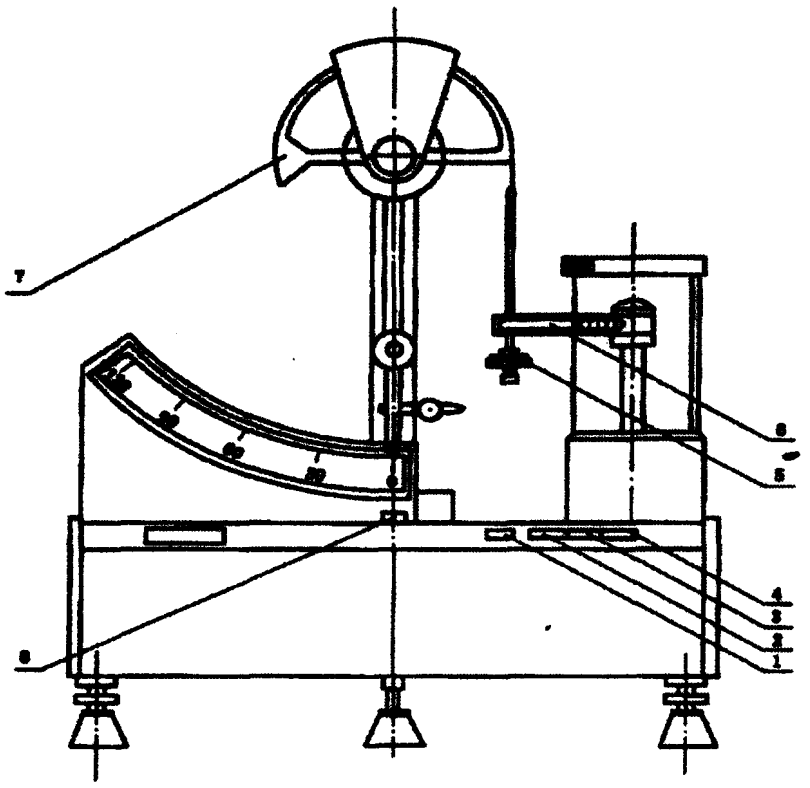
A5.1 Testing the strength of the needle tip: After the test sample is affixed to the apparatus (with 5 mm of the acupuncture needle tip exposed), the needle tip is thrust vertically onto the steel block. According to the rule in A2.2, increase force, speed and load until they reach the numerical values of the standard set by 4.4.1, 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.

A5.2 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.

A5.3 Press the on-off button of the function controls to allow the swaying rod and pointer to return to their original positions.

A5.4 Move the aluminum foil in the clamp to allow the diameter of each pierced hole to exceed three times that of the test sample.

A5.5 Repeat the above steps, A5.2, A5.3, and A5.4; measure 3 times to obtain the average values.

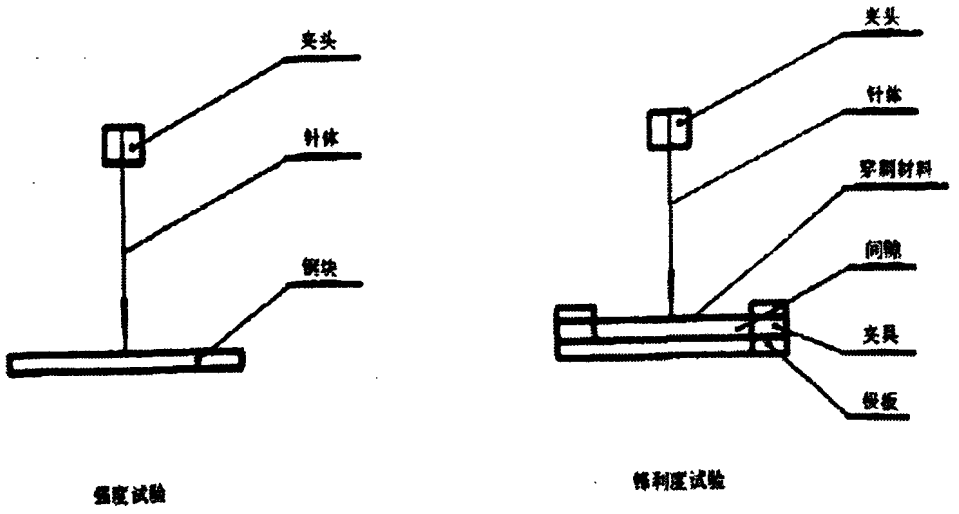


1——电源开关；
2～4——工作控制开关；
5——铝箔夹具；
6——缝针夹具；
7——调节摆杆；
8——水平仪。

电源开关 = power button (on and off)　工作控制开关 = function control button (on and off)

铝箔夹具 = aluminum foil clamping apparatus　缝针夹具 = sewing needle clamping apparatus

调节摆杆 = adjustment rod　水平仪 = (carpenter's) level



针尖锋利度和强度试验方法原理图

夹头 = clamped head　针体 = needle body

钢块 = steel block　强度试验 = strength test

穿刺材料 = punctured material　间隙 = gap

极板 = plate　锋利度试验 = sharpness test

针尖锋利度和强度试验方法原理图 = The Principles of the Method of Testing for the Sharpness and Strength of the Needle Tip

Annex B
(Normative)

Test Methods for the Puncture Performance of the Acupuncture Needle Tip

B1 Method 1: Test Method of the qualitative

Cover the mouth of a cup (diameter of 100 mm) with the membrane of surgical rubber gloves (in accordance with ISO 10282:2002) and tighten it properly with a rubber band. Puncture the membrane perpendicularly with the acupuncture needle. During the piercing, if the dent of the membrane is small and there is little resistance, this indicates that the needle tip is sharp. Otherwise, the needle tip is blunt.

NOTE: This method can be qualitatively evaluated depending on the needle's puncture performance. This method is suitable for the cross-comparison of the purchaser and the quality control of production.

B2 Method 2: Test Method of the quantitative

B2.1 The Testing Apparatus for Evaluating Puncture Force

Figure B1 is a sketch map produced by the typical apparatus for measuring and recording puncture force. Other apparatuses of similar performance and precision can also be used. The apparatus should provide the following:

a) speed V=(50-250) mm/min; the average drive precision ≤ established drive speed ±5%

b) average precision of the (0-50) sensor is ±5% of full range

c) puncture diameter of polymerized film after clamping is 10 mm