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General technical requirements for electrolarynx

电子人工喉通用技术要求

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1 Scope

This document specifies the technical requirements, test methods, inspection rules, marks, labels, packaging, transportation, and storage of the electrolarynx.

This document applies to the production, use, and distribution of the electrolarynx. It is suitable for patients who have received laryngectomy and lost vocal function due to diseases, accidents, and other reasons.

2 Normative references

The following documents contain the provisions which, through normative reference in this document, constitute the essential provisions of this document. For the dated referenced documents, only the versions with the indicated dates are applicable to this document; for the undated referenced documents, only the latest version (including all the amendments) is applicable to this document.

GB/T 191 Packaging - Pictorial marking for handling of goods

GB 9706.1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

GB/T 10111 Generation of random numbers and procedures applied to sampling inspection for product quality

GB/T 14710 The environmental requirement and test methods for medical electrical equipment

GB/T 16886.5-2017 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

GB/T 16886.10-2017 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

YY 0505 Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests

3 Terms and definitions

The following terms and definitions apply to this document.

3.1 electrolarynx

A voice recovery device powered by a battery.

Note: It can transmit the vibrating sound signal to the pharynx through the patient's neck tissue, and the signal is modulated by the upper part of the vocal tract to form an electronic artificial laryngeal voice at the lip end; it belongs to the speech compensation rehabilitation aids.

3.2 external electrolarynx

A voice recovery device whose vibration device is located outside the body, and the vibration signal is transmitted to the oral cavity through the neck tissue or the sound transmission tube.

3.3 Internal electrolarynx

A voice recovery device whose vibration device is located in the body, and the vibration signal directly forms in the mouth.

3.4 vibrating membrane

A component of an electrolarynx, which can be pressurized by electromechanical control and cause vibration and sound.

3.5 volume adjuster

A device that can adjust the sound intensity of an electrolarynx.

3.6 pitch adjuster

A device that can adjust the vibration frequency of a vibrating membrane.

3.7 laser measuring micro-displacement instrument

An instrument that can directly measure the vibration frequency of a vibrating membrane.

3.8 vibration measuring instrument

An instrument that uses mechanical means, optical means, vibration sensors, etc. to measure the vibration amplitude, acceleration, speed, and frequency of objects.

Note: The vibration measurement accuracy should be less than 100 μm, and the measurement range

4.3.2 After the test sample is subjected to the button life test according to the method specified in 5.3.2, the fundamental frequency of the sample shall not exceed ±10% of the fundamental frequency before the test.

4.4 Packaging requirements

The test sample (with packaging) shall be able to work normally after being tested according to the method in 5.4.

4.5 Environmental adaptability

The environmental test of the electrolarynx shall meet the requirements of GB/T 14710.

4.6 Biological evaluation

4.6.1 In vitro cytotoxicity

Cytotoxicity shall be less than grade 2.

4.6.2 Skin irritation

The primary irritation score shall be less than 1.

4.6.3 Delayed-type hypersensitivity reaction

There shall be no delayed-type hypersensitivity.

4.7 Electrical safety and electromagnetic compatibility

The test results shall meet the requirements of GB 9706.1 and YY 0505.

5 Inspection methods

5.1 Inspection methods for appearance and structure

The method can be visual inspection and touch detection, which shall meet the requirements of 4.1.

5.2 Performance test method

5.2.1 Sound pressure level

5.2.1.1 Install the test sample on the fixture and place the sound level meter at a distance of 1000 mm in front of it (see Figure 1).

5.2.1.2 Apply a certain contact pressure to the control switch of the test sample to generate sound.

5.3.1 Service life test method

Install the test sample on the fixture, so that it can simulate the button action in the normal working mode; press once every 5 s and hold for 3 s; operate intermittently, and control the button with a load value of greater than 30 N; the "press + release" counts as once, and repeat it for 3×10^4 times. After the test, the sample shall meet the requirements of 4.3.1.

5.3.2 Button life test method

Use different samples of the same batch for the test; after turning off the power supply or taking out the battery, install the test sample on the fixture, and load the button pressure of greater than 30 N cyclically; the frequency shall be less than or equal to 1 Hz, and the number of tests shall be greater than or equal to 1×10^5 times. After the test, the sample shall meet the requirements of 4.3.2.

5.4 Packaging test

Drop the packaged test sample freely onto the cement floor from a height of 1000 mm; carry out 2 times tests for each of the 6 surfaces. After the test, the sample shall meet the requirements of 4.4.

5.5 Environmental test

The test shall be carried out according to the relevant provisions in GB/T 14710, and the results shall meet the requirements of 4.5.

5.6 Biological evaluation test

5.6.1 In vitro cytotoxicity

Take the cell complete medium as the extraction medium, according to the ratio of 0.2 g/mL, and extract for 24 h under the condition of (37±1) ℃; the test shall be carried out according to the liquid extraction method specified in GB/T 16886.5-2016. The results shall meet the requirements of 4.6.1.

5.6.2 Skin irritation

The test shall be carried out in accordance with the primary skin irritation method specified in GB/T 16886.10-2017, and the results shall meet the requirements of 4.6.2.

5.6.3 Delayed-type hypersensitivity reaction

Take normal saline and vegetable oil as the extraction medium respectively, according to the ratio of 0.2g/mL, and extract for (72±2) h under the condition of (37±1) ℃; the test shall be carried out according to the maximum dose method specified in GB/T 16886.10-2017, and the results shall meet the requirements of 4.6.3.

If any performance required by electrical safety does not qualify, such as the protectiveness to continuity of the earthed circuit, insulation diagram, and withstand voltage performance, or if two or more of the other performances do not qualify, then the type inspection is judged as failed; if one of the other performances does not qualify, it is allowed to recheck multiple selected prototypes for the re-inspection of the unqualified item (if there is only one prototype, it is allowed to be repaired); if the result is still unqualified, then the type inspection is judged as failed.

7 Marks and labels

7.1 The following information shall be marked in the appropriate position of an electrolarynx:

a) Manufacturer's name, trademark;

b) Product name and model;

c) Product number or date of manufacture;

d) Supply voltage;

e) The fundamental frequency range over which the product operates;

f) The medical device registration certificate number or filing document number.

7.2 There shall be a certificate of quality in the packing box, and the certificate of quality shall contain the following contents:

a) Name of the manufacturer;

b) Product name and model;

c) Date of inspection;

d) Product number;

e) Inspector code;

f) The word "Qualified".

7.3 The large packing box of the electrolarynx shall have the following contents:

a) Manufacturer's name, factory address, postal code, and telephone;

b) Product name, model, and registered trademark;

c) The medical device registration certificate number or filing document number,

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