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YY/T 1095-2015

Replacing YY/T 1095-2007

Myoelectric Biofeedback Equipment

肌电生物反馈仪

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Table of Contents

Foreword

This Standard was drafted as per the rules specified in GB/T 1.1-2009.

This Standard's safety requirements fully implement the contents of GB 9706.1-2007 *Medical Electrical Equipment - Part 1: General Requirements for Safety*, and GB 9706.15-2008 *Medical Electrical Equipment - Part 1-1: General Requirements for Safety - Collateral Standard: Safety Requirements for Medical Electrical Systems*.

This Standard replaces YY/T 1095-2007 *Myoelectric Biofeedback Equipment*.

Compared with YY/T 1095-2007, this Standard mainly has the following technical differences:

--- Modify this Standard's applicable scope (see Chapter 1);

--- Add the classification (see Chapter 4);

--- Modify the requirements for feedback instructions and test methods (see 5.2, 6.2 of this edition; 4.2.7, 5.2 of 2007 edition);

--- Add the requirements for feedback thresholds and test methods (see 5.3, 6.3);

--- Add the requirements for suppression of power-frequency noise and test methods (see 5.4, 6.3);

--- Delete the requirements for original measuring range and test methods (see 4.2.1, 5.3.1 of 2007 edition);

--- Add the requirements for the accuracy of indicating value and test methods (see 5.5.2, 6.5.1);

--- Delete the requirements for original sensitivity (see 4.2.8 of 2007 edition);

--- Add the requirements for resolution and test methods (see 5.5.3, 6.5.2);

--- Modify the requirements for passband and test methods (see 5.5.5, 6.5.4 of this edition; and 4.2.4, 5.3.4 of 2007 edition);

--- Add the requirements for power-frequency notch filter and test methods (see 5.5.8, 6.5.7);

--- Delete the requirements for original isolation (see 4.2.9 of 2007 edition);

--- Add the safety requirements (see 5.8);

--- Add the contents and requirements for instruction manual (see 5.7);

Myoelectric Biofeedback Equipment

1 Scope

This Standard specifies the terms and definitions, classification, requirements, test methods of myoelectric biofeedback equipment (hereinafter referred to as the myoelectric biofeedback equipment).

This Standard is applicable to the myoelectric biofeedback equipment stipulated in 3.1.

This Standard is not applicable to the equipment using needle electrode to record the myoelectric signal, and myoelectric evoked potential equipment.

2 Normative References

The following documents are essential to the application of this document. For the dated documents, only the versions with the dates indicated are applicable to this document; for the undated documents, only the latest version (including all the amendments) are applicable to this document.

GB 9706.1-2007 Medical Electrical Equipment - Part 1: General Requirements for Safety

GB 9706.15-2008 Medical Electrical Equipment - Part 1-1: General Requirements for Safety - Collateral Standard: Safety Requirements for Medical Electrical Systems

GB/T 14710-2009 Environmental Requirement and Test Methods for Medical Electrical Equipment

GB/T 16886.1-2011 Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process

YY 0505-2012 Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standards: Electromagnetic Compatibility - Requirements and Tests

3 Terms and Definitions

The following terms and definitions defined in GB 9706.1-2007 are applicable to this

5.6.1 The myoelectric biofeedback equipment surface shall be smooth, its mark shall be clear and accurate without obvious scratches or damages.

5.6.2 Fastener shall be connected tightly, function switch shall be installed accurately, adjustment shall be reliable.

5.7 Instruction manual

The instruction manual shall meet the requirements of GB 9706.1-2007 and GB 9706.15-2008 (if applicable); meanwhile it shall also include at least the following contents:

a) Technical parameters of myoelectric biofeedback equipment include measuring range of amplitude, feedback response frequency band, center frequency and the test points stipulated in Table 1.

b) Cleaning and disinfecting methods, and replacing cycle for the reusable electrode.

c) Provide a method for placing the electrode in firm contact with the skin; advise how to treat the skin before treatment.

d) The relationship between electrode size, shape and applicable muscle; the advice on the position and distance of placing electrode.

e) Recommended use environment: the radio frequency interference source shall be switched off, or keep away from the radio frequency emission source.

f) In the instruction manual, the feedback indication of myoelectric biofeedback equipment shall be described as per the different feedback response degree stipulated in Table 2.

   For the myoelectric biofeedback equipment with only two feedback responses, the instruction manual shall provide corresponding feedback indication description against the two feedback responses, namely, no response and initial response.

   Unless otherwise is specified by the manufacturer, the input signal shall be tested in accordance with the test points specified in Table 1; if necessary, these test points can be expanded, so that contain other characteristic parameter values designed by the manufacturer.

If applicable, the electric safety of the system shall meet the requirements of GB 9706.15-2008.

5.9 Environmental test requirements

The environmental test of the myoelectric biofeedback equipment shall be performed as per the provisions of GB/T 14710-2009.

5.10 Biocompatibility

Materials intended to use in contact with the human skin shall conduct the biocompatibility test or evaluation, and form document according to the guideline and principle stipulated in GB/T 16886.1-2011.

5.11 Electromagnetic compatibility requirements

Myoelectric biofeedback equipment shall meet the requirements of YY 0505-2012.

6 Test Methods

6.1 Working conditions

6.1.1 Pre-treatment

Before test, the myoelectric biofeedback equipment shall be parked on the test site for at least 24h without being energized; before the official test, the myoelectric biofeedback equipment shall be run as per the requirements of the instruction manual.

6.1.2 Test environment

See the requirement of 4.5 in GB 9706.1-2007.

Switch off or keep away from the surrounding radio frequency interference source.

6.1.3 Test circuit

The connection method of test circuit shall be shown as follows:

a) Unless otherwise specified, S_1 in Figure 1 shall be normally closed.

b) The reference electrode (if any) shall be grounded.

c) The dashed line in Figure 1 represents shielding case, and reference point connecting to the earth.

corresponding to the feedback threshold described in Table 1, record the signal amplitude at this time, and compare which with the feedback threshold stipulated by the manufacturer; the error shall conform to the provision of 5.3.

6.4 Inspection of power-frequency noise suppression

Connect the electrodes of the myoelectric biofeedback equipment as per the Figure 1; adjust the signal source to generate the sinusoidal signal output; adjust the signal frequency to reach the center frequency value stipulated by the manufacturer.

Make the amplitude on the input end of the myoelectric biofeedback equipment reach above the feedback threshold U_0 stipulated by the manufacturer; then observe the feedback indication of the myoelectric biofeedback equipment.

Then superimpose the power-frequency sinusoidal signal with amplitude 100μV (Peak-Valley Value) on the input end of myoelectric biofeedback equipment; observe the feedback indication of myoelectric biofeedback equipment, there shall be no observable change.

Then adjust the amplitude of the signal source to be below feedback threshold U_0, and repeat the above procedure to inspect.

6.5 Display system

6.5.1 Test for the accuracy of indicating value

Firstly, use the signal source to check the display system of the myoelectric biofeedback equipment, its accuracy shall conform to the requirements. The use the display of myoelectric biofeedback equipment to measure other technical indicators.

Connect the electrodes of myoelectric biofeedback equipment as per the Figure 1.

Adjust the signal source, add the sinusoidal AC signal to the input end of the myoelectric biofeedback equipment; the signal frequency is the median frequency designed by the manufacturer.

Adjust the amplitude of signal source, the test point shall be the maximum value or 10% maximum value (generally no less than 10μV) of each measuring range called in the instruction manual; read the display value of the myoelectric biofeedback equipment, its accuracy shall conform to the provision of 5.5.2.

6.5.2 Resolution (measuring sensitivity) test

Connect the electrodes of myoelectric biofeedback equipment as per the Figure 1.

Adjust the output frequency of signal source to be the center frequency designed by the manufacturer, the amplitude is 10mV; continue to adjust the voltage amplitude, when adjusting the amplitude 2mV each time, observe the display value of myoelectric

Appendix A

(Informative)

Guideline and Principle of Important Clauses

A.1 Guideline

This Standard established the performance key points and test methods of myoelectric biofeedback equipment, which is used for checking the effectiveness of feedback function of the equipment, as well as providing the users with sufficient data to judge the equipment performance.

This Standard believes that whether the myoelectric biofeedback equipment is equipped with the display capability of myoelectric signal amplitude or waveform or not, it shall be applicable to this Standard; this Standard doesn't require the myoelectric biofeedback equipment to have such display function, but once such function is equipped with, it shall conform to the relevant provisions of this Standard.

For the previous myoelectric biofeedback equipment, the standard clauses in YY 91095-1999 and YY/T 1095-2007 only provide the requirements for the amplifier performance and indicator; don't give the checking method for the feedback indication; the drafting team of this modified standard, through investigation and discussion, believe that for the myoelectric biofeedback equipment, it is the key to treatment to finally give feedback indication to the patients; therefore, this Standard emphasizes the inspection for the feedback capability of the myoelectric biofeedback equipment.

This Appendix explains the origination for some important clauses in this Standard.

A.2 The main contents checked by this Standard

The following two points are mainly considered in the proposed regulations:

a) How to check the correctness of response generated by myoelectric biofeedback equipment against the myoelectric signal. The Effective myoelectric signal:

The myoelectric signal is a weak electrical signal; for the healthy people, the myoelectric amplitude can reach 1000μV~3000μV (Peak-Valley Value); for the disabled people, the amplitude generally is less than 350μV (Peak-Valley Value); the effective frequency range of human skin surface myoelectric signal is 20Hz~500Hz; which mainly centralizes in the frequency range of 50Hz~150Hz. Therefore, when preparing the regulations, the drafting team of this Standard deem that, unless otherwise specified by the manufacturer, the signal above frequency 500Hz is invalid; which generates no expected

feedback response; while the signal below frequency 20Hz shall be deemed as noise to suppress.

b) The myoelectric biofeedback equipment shall generate no response towards the invalid signal and noise. The major noise signals are as follows:

1) Inherent noise of the electronic equipment;

2) Environmental noise (mainly electromagnetic radiation), when testing, this Standard requires to switch off or keep away from the surrounding radio frequency interference source; thus, the main environmental noise considered here is 50Hz power-frequency noise signal.

3) The noise introduced by skin, electrode and improperly placing of the cable; mainly centralizes below 20Hz.

A.3 Performance requirements

A.3.1 Overview

Unless otherwise stated, the amplitudes mentioned in this Standard are valid values (r.m.s.). That is because the ECG, EEG, and myoelectric signals collected by the surface electrode are the bioelectric signals of the human body; when analyzing these signals, the root-mean-square (RMS) or peak value can be used; for the equipment mainly using the ECG, EEG signals or myoelectrical diagram to analyze the biological characteristic waveform, it mostly adopts peak value analysis method; while for the myoelectric biofeedback device, it mainly focuses on the average level of myoelectric signal (i.e. quantitative value of muscle strength), so using the root-mean-square value (RMS) to analyze is more suitable.

A.3.2 Feedback indication

Due to the large randomicity of the myoelectric signal, it is very difficult to quantify and detect it; to make the myoelectric bioelectric equipment work properly, the valid myoelectric signal shall be correctly detected; and when the setting threshold is reached, the correct response can be made.

Generally, the parameters used for analyzing and evaluating the myoelectric signal at the time domain include integrated electromyogram (IEMG), root-mean-square (RMS), mean amplitude (MA); the following two indicators are usually used for analyzing in the frequency domain, namely, mean power frequency (MPF) and median frequency (MF); the characteristics of these evaluation parameters are voltage amplitude and frequency. Therefore, the method stipulated in this Standard is to test the validity of myoelectric biofeedback equipment through simulating the input of myoelectric signals with certain characteristic values (see Table 1).

Unless otherwise specified by the manufacturer, for instance, if there is special demand,

A.3.4 Power-frequency noise suppression

The detecting circuit of myoelectric biofeedback equipment can suppress the vast majority of the noise that may be encountered during the clinical use; the power-frequency sinusoidal signal amplitude of 100μV (Peak-Valley Value) is provided in YY 1079.

In addition to power-frequency noise, other random noise amplitude is generally lower than the power-frequency noise; which can be eliminated through correctly using electrodes. The power-frequency notch filter is in the working state during the above test.

A.3.5 Display system

Since the myoelectric biofeedback equipment proposed in this Standard is not intended to be used for the diagnosis of disease, the display accuracy requirements of myoelectric biofeedback equipment in this Standard are not as strict as those diagnostic devices; it neither proposes the requirements for the baseline stability of signal, output display and reconstruction accuracy. If the myoelectric biofeedback equipment provides the diagnostic function, then such function shall conform to other national standards.

A.3.6 Resolution (measuring sensitivity)

This Standard specifies that when the myoelectric signal measured in the feedback response band changes by 2μV, the display value of the myoelectric biofeedback equipment may have the observable changes. YY/T 1095-2007 specifies the measuring sensitivity is 0.2μV; but in practice, accurately load 0.2μV is difficult to achieve, furthermore, both this Standard and previous standard versions specify that the noise amplitude is allowed to reach 1μV; so requiring the measuring sensitivity 0.2μV is contradicted to that; in this case the, the drafting team of this Standard, through discussion, believe that measuring resolution amplitude 2μV is appropriate.

A.3.7 Passband

Considering the amplifier of myoelectric biofeedback equipment is able to detect valid myoelectric signal, while the recent literature and clinical studies have shown that the valid frequency range of myoelectric signal is 20Hz~500Hz; thus, this Standard specifies that the passband of myoelectric biofeedback equipment shall not be narrower than the above range.

In order to reduce the influence of unrelated clutter, some myoelectric biofeedback equipment (for instance, for specific demands or against specific muscle tissues) may install the filter circuit behind the amplifier; which may cause the display end of the myoelectric biofeedback equipment not to display all the detecting frequency; in this case, the manufacturer shall specify the passband of the myoelectric biofeedback

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