



図3 海外機種の出力波形例 (500 Ω固定抵抗負荷時)

記載されているもの (C1、C2) 電圧値のみが記載されているもの (C7) がみられ、C5、C6 については固定抵抗負荷 250 Ω が用いられていた。

出力波形は、C4を除くすべての機種で矩形波＋三角波の非対称性双極波形となっていた。ただし、三角波成分の波高値は機種により大きく異なっており、出力値の変化によっても大きく変動した。また、C4についてはほぼ対称な矩形波＋矩形波の双極性となっており、出力値の変化に対しても大きくバランスが変化することはなかった。

最大出力時発生時の出力波形データからピーク電圧値、ピーク電流値、および電流実効値と平均値を算出した結果を表4に示す。C5とC6ではマニュアルに記載されている数値とピーク出力値が大きくかけ離れていた。また、電流実効値および平均値はそれぞれ 1.4～15.7 mA、-0.06～-0.43 mA と機種により大きな差が認められた。

表4 海外機種のピーク出力・実効値・平均値 (500 Ω固定抵抗負荷時)

機種(パルス幅)	電圧(V)		電流(mA)			
	実測値	spec	実測値	spec	実効値	平均値
C1(260 μm)	19.8		38.4	40.0	6.1	-0.0962
C2(40 μm)	20.9		40.5	40.0	6.9	-0.1101
C2(350 μm)	20.9		40.5	40.0	7.2	-0.0910
C3(50 μm)	22.5	22.5	43.5	45.0	3.4	-0.0643
C3(500 μm)	22.4	22.5	43.4	45.0	10.0	-0.0898
C4(80 μm)	15.5	15.0	30.0	30.0	8.5	-0.0825
C4(100 μm)	15.4	15.0	29.8	30.0	7.9	-0.0730
C4(200 μm)	15.5	15.0	29.9	30.0	8.5	-0.0776
C4(HAN H)	14.8	15.0	28.7	30.0	3.2	-0.0660
C4(HAN L)	14.8	15.0	28.5	30.0	1.4	-0.0659
C5(200 μm)	28.5		55.4	10.0	6.7	-0.1596
C6(200 μm)	19.5		37.9	10.0	5.1	-0.0874
C7(600 μm)	51.8	50.0	101.0		15.7	-0.4349

D. 考察と結論

今回の調査によって、中国・香港製の鍼電極低周波治療器は欧米諸国に広く流通していることが明らかとなった。輸出に際し、これらの製品は CE マーク取得、IEC60601 シリーズに適合させるなど、日本国内に流通している日本製品より、海外マーケットを視野に入れた積極的な取り組みがなされていた。その一例として、IEC60601 シリーズにおける神経筋刺激装置に関する個別要求事項 (IEC60601-2-10) は、APPLIED PART である電極ケーブルについて、本体への接続コネクタ部も含めて導体が露出しない形状であることを要求しているが、今回調査した中国・香港製品は C1 を除く全機種が基準を満たすと思われるコネクタを採用していた。これに対し、日本製品のうち、基準を満たすと思われるコネクタを採用している機種は半数の 2 機種であった。

500 Ω 抵抗負荷条件における各機器の出力波形は、国内機器と同様な矩形波+極性反転三角波が多かったが、パルス幅やオーバーシュートの程度などに差異が認められた。また、国内機器と大きく異なる点は、パルス幅や波形を調整出来る製品が存在していたことと、最大刺激周波数が 100 Hz を大きく超える機種が存在している点であった。生理学的には、500 Hz に近い刺激周波数は神経・筋の不応期に刺激を入力することになることから、神経筋刺激用としては適さないと考えられるため、どのような目的を持って設定されているのか、臨床応用レベルも含めてさらに調査する必要があると考えられた。

最大出力値は一部の例外を除き、マニュアルに記載された性能諸元を逸脱していなかった。ただし、最大出力値のマニュアルへの記載方法は、電圧のみ、電流のみ、双方など様々であった。マニュアル、あるいは添付文書への性能記載事項は、今後策定される国際規格において統一される必要があると思われた。

他方、刺激パルスの実効値と電流平均値は、機器間で大きな相違がみられた。実効値は、電流のピーク値やパルス幅等、全ての波形構成要素が反映された通電量の指標といえ、電流平均値はいわゆるチャージバランスの目安となる。これらのパラメータは、電極としての鍼の電気分解に直接関係するものであることから鍼電極低周波治療器の性能を評価する上で重要であると考えられる。また、固定抵抗負荷条件ではなく、実際の生体や疑似生体に通電した場合、波形は大きく変化することが知られているため、そのような条件下におけるこれらパラメータの変動も今後検討する必要があると考えられた。

E. 健康危険情報

なし

F. 研究発表

1. 国際学会または国際会議

なし

2. 国内学会

なし

G. 知的財産権の出願・登録状況

なし

- 資料1 WD 18586 Requirements for Basic Safety for Electroacupuncture Stimulators
- 資料2 WD 19663 The quality of electroacupuncture (EA) stimulators
- 資料3 医道の日本記事 巻頭企画 道具としての鍼を語る
鍼に関する初めてのISO規格 滅菌済単回使用毫鍼の国際基準とは
(医道の日本 2014年7月号)



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Quality and safety of medical devices other than acupuncture needles

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Requirements for Basic Safety for Electroacupuncture Stimulator

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

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ISO 18586 was prepared by Technical Committee ISO/TC 249, *Traditional Chinese Medicine (Provisional)*.

ISO/WD 18586

Introduction

The minimum safety requirements specified in this standard are considered to provide for a practical degree of safety in the operation of electroacupuncture stimulator.

In any medical domain, stimulations to body surface, such as manual, mechanical and thermal stimulus, have existed as primitive remedies or therapies and used to alleviate various types of pain or symptoms. Among the stimulation used in acupuncture practice are traditional hand operating stimulation and electrical stimulation. In the history of acupuncture, application of electrical stimulation to acupuncture needle was first attempted in the first half of the 19th century by a French doctor, Salandiere. Though the boom of the use of the stimulator did not last long in Europe, acupuncture stimulator came to attract attention of medical practitioners in 1970's, after spread of the report of acupuncture anesthesia. Today, electroacupuncture stimulator is widely used in acupuncture treatment especially in the field of pain control.

As for the standards for the safety of medical electrical equipment, such as Transcutaneous electrical nerve stimulation (TENS), Silver spike point (SSP) stimulator, and massage chair, there have been already relevant standards developed in IEC.

From the view of safety, the only and the most important difference between those equipment and electroacupuncture stimulator is that needles inserted in acupuncture points are used as electrode. Thus, in this standard, in order to guarantee the safety of electroacupuncture stimulator, in addition to the requirements specified in IEC 60601-2-10:2012 *Particular requirements for the safety of nerve and muscle stimulator*, safe level of metal erosion of needle electrode and prevention of electrical burn is specified.

Requirements for Basic Safety for Electroacupuncture Stimulator

1 Scope

This International Standard specifies the requirements for the safety for electroacupuncture stimulators in use of the practice of acupuncture treatment.

2 Normative references

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

IEC 60601-1:2012, *Medical electrical equipment - Part 1: General requirements for basic safety and essential performance*

IEC 60601-1-2:2007, *Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests*

IEC 60601-2-10:2012, *Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators*

ISO 14971:2007, *Medical devices — Application of risk management to medical devices*

ISO 13485:2003, *Medical devices – Quality management systems – Requirements for regulatory purposes*

ISO/IEC Guide 51:1999, *Safety aspects – Guidelines for their inclusion in standards*

ISO DIS 17218:2013, *Sterilized Acupuncture needle for Single Use.*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-2-10:2012 apply, except as follows

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Bibliography

- [1] ISO/IEC Directives, Part 2, *Rules for the structure and drafting of International Standards*, 2001
- [2] ISO/IEC TR 10000-1, *Information technology — Framework and taxonomy of International Standardized Profiles — Part 1: General principles and documentation framework*
- [3] ISO 10241, *International terminology standards — Preparation and layout*
- [4] ISO 128-30, *Technical drawings — General principles of presentation — Part 30: Basic conventions for views*
- [5] ISO 128-34, *Technical drawings — General principles of presentation — Part 34: Views on mechanical engineering drawings*
- [6] ISO 128-40, *Technical drawings — General principles of presentation — Part 40: Basic conventions for cuts and sections*
- [7] ISO 128-44, *Technical drawings — General principles of presentation — Part 44: Sections on mechanical engineering drawings*
- [8] ISO 31 (all parts), *Quantities and units*
- [9] IEC 60027 (all parts), *Letter symbols to be used in electrical technology*
- [10] ISO 1000, *SI units and recommendations for the use of their multiples and of certain other units*
- [11] ISO 690, *Documentation — Bibliographic references — Content, form and structure*
- [12] ISO 690-2, *Information and documentation — Bibliographic references — Part 2: Electronic documents or parts thereof*

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ISO/TC 249/WG 4
Quality and safety of medical devices other than acupuncture needles

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The quality of electroacupuncture (EA) stimulators

Qualité de électoroacupuncture stimulators (EA)

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Foreword

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ISO 18663 was prepared by Technical Committee ISO/TC 249, *Traditional Chinese Medicine (Provisional)*

Introduction

This part of ISO/WD 18663 was developed in response to the worldwide demand for minimum specification of an electroacupuncture stimulator which can be used to intensify the effect of manual acupuncture for the treatment of disorders or diseases. Acupuncture is an ancient healing technique used in China for more than 2400 years, with《the Yellow Emperor's Classic》as the classical medical literature of traditional Chinese Medicine. The technique has been constantly improved along with the development of science and technology, for example, from sharp-edged tools made of silver and copper to filiform needles made of stainless steel, from mechanical manipulation of the needles (manual needling) to electrical stimulation by connecting needles with an electroacupuncture (EA) stimulator. Currently, EA is an alternative to manual needling for the treatment of many symptoms and diseases. There was no previous international standard prepared for the specification of the quality and safety of an electroacupuncture device. The most relevant international standard is the ISO/IEC 60601-2-10 edition 2.0: 2012^[1], which is the international standard of particular requirements for the basic safety and essential performance of nerve and muscle stimulator. The major difference between the two devices resides on how to deliver electricity to the body. A nerve and muscle stimulator delivers electrical stimulation via skin pad of several square centimeters in size, while an electroacupuncture stimulator delivers electricity through fine needles inserted into the skin with diameter of 0.2-0.5 mm. Hence the electrical current needed for electroacupuncture can be 10 times less than that for nerve and muscle stimulation. While ISO WD 18663 deals with the quality of electroacupuncture stimulator, there was a parallel standard (ISO/WD 18586) dealing with the safety of the device. These two standards shall be viewed together in order to have a full understanding of the international standard of quality and safety of an electroacupuncture stimulator.

The quality of electroacupuncture (EA) stimulators

1 Scope and objective

1.1 Scope

1.1.1 General consideration

This International Standard specifies the particular requirements for the minimum quality to secure the clinical functionality and clinical effectiveness of electroacupuncture (EA) STIMULATORS, defined in subclause 3.205, for use in the practice of electroacupuncture treatment, hereinafter referred to as EA STIMULATORS.

1.1.2 Specific considerations

In order to secure the clinical functionality and clinical effectiveness, the electrical parameters of the output should be strictly specified, including the current intensity, the pulse duration (pulse width) and the frequency of pulsatile electrical waves, that are strong enough to produce therapeutic effect, yet not too strong in order to prevent the patient from physical and psychic damage.

1.1.3 Applicability

It is applicable in the condition where an electrical stimulation is delivered to the body via acupuncture needles inserted through the skin to reach the nerve and muscle tissues. It is not applicable to the condition where the needle is inserted into the internal organs, such as the heart, lung, liver, spleen or kidney. It is also not applicable to the condition where the electrode is placed on the surface of the skin.

1.2 Objective

The objective of this particular standard is to establish minimum requirements for achieving clinical functionality and therapeutic effectiveness of EA STIMULATORS.

2 Normative references

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

ISO/IEC 60601-2-10 Edition 2.0: 2012 Medical electrical equipment – Particular requirements for the safety and essential performance of nerve and muscle stimulators