Recommendations on Safety Standards for Electroacupuncture Stimulator

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The Japan Society of Acupuncture and Moxibustion
Electroacupuncture Stimulator Research Committee

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Preface

The recommendations herein were established as voluntary standards by the Japan Society of Acupuncture and Moxibustion for the use of electro-acupuncture stimulator with needles (hereafter, collectively referred to as “electro-acupuncture stimulator”) in an effort to ensure the performance and safety of such devices. The recommendations were created by modifying a section of the technical contents in the Japanese Industrial Standard’s medical electrical equipment-parts 2-10: particular requirements for the safety of nerve and muscle stimulators (JIS T 0601-2-10:2005), and are not intended to loosen the standards, but rather to ensure the safe use of electro-acupuncture stimulator. The standards described herein are based on the general requirements for safety (JIS T 0601-1).
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Recommendations on Safety Standards for Electro-acupuncture Stimulator

Scope
These recommendations are voluntary standards for electro-acupuncture stimulator for nerve and muscle stimulation in physical therapy (excluding devices for use in the home setting).

Definitions
Electro-acupuncture stimulator: An electrical stimulation device used in acupuncture which comprises an external stimulator and an applied part (such as electro-acupuncture needles) used to stimulate nerves and muscles for pain relief and the treatment of muscle atrophy by delivering electrical stimulation through the needles.

Applied part: Electro-acupuncture needles and other parts that are electrically connected to the stimulator.

Stimulator: A device used to deliver electrical current through electro-acupuncture needles by direct contact with the patient for the treatment of neuromuscular diseases.

Safety standards
The following items are safety specifications and standards for the use of electro-acupuncture stimulator.

Indicator
a) Visibility of electro-acupuncture needle output (current or voltage). (Ability to confirm from the display and volume)

Output unit
a) Use of output terminal and output cables (such as low output resistance cables used for electro-acupuncture needles) dedicated to electro-acupuncture.

Electro-acupuncture needles
a) Materials recommended for electro-acupuncture needles are specified in JIS T9301 (acupuncture needles for single use) and include: JIS G4308 (stainless steel wire rods), JIS G4309 (stainless steel wires), and JIS G4314 (stainless steel wires for springs). Furthermore, a needle diameter over φ0.20mm is recommended, with the following exceptions:
- Gold needles (acupuncture needle for single use (JIS T9301), Appendix 1)
- Silver needles (acupuncture needle for single use (JIS T9301), Appendix 2)

User manual and appendix
The following are addendums to user manuals and appendices:
a) Information on the effects of load impedance by parameters such as output waveform, use of the direct current component, pulse width, pulse repetition frequency, output voltage and/or current, and maximum amplitude. (Appendix)
b) Advice on the size of the electro-acupuncture needle for use in different types of treatment. (Appendix)
c) Advice on preventative measures that are required if the direct current component is used as output.
d) Advice on refraining from the use of electro-acupuncture therapy on patients with implanted electronic devices (such as pacemakers) without prior consent from a physician. (Appendix)
e) Potential hazard warnings:
   - Injury to patient (burns) and damage to the device caused by misplacement of electrodes on the stimulator when an electric scalpel (electrosurgical device) is simultaneously connected to the stimulator. (Appendix)
   - Unstable output of stimulator during simultaneous operation of shortwave therapy and microwave therapy devices in close proximity (1 m). (Appendix)
   - Insertion of electrodes in the vicinity of the chest may increase the risk of cardiac fibrillation. (Appendix)
f) Stimulator warnings:
   - Information on the maximum allowable electrode output of the stimulator as specified by the manufacturer. (Appendix)
   - Advice on situations that require special attention by the user. (e.g., record important points in the user manual or appendix, such as the gradual increase of output voltage and/or current while observing the patient during treatment)

**Restriction of output**
a) Stimulator
Output current for minimum load impedance should not exceed the limit value in Table 1. (minimum load impedance is less than 500Ω)

Table 1. Current limit

<table>
<thead>
<tr>
<th>Frequency (Hz)</th>
<th>Current limit (effective value) mA</th>
<th>Size of current (per treatment) C</th>
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<tr>
<td>≤100</td>
<td>1</td>
<td>1</td>
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**Requirements for retail**

*Destination*
Healthcare facilities and offices of physicians, dentists, and acupuncturists. Note: Refer to attachment 1 for the use of low-frequency therapy device by acupuncturists (59th medical notification from the Medical Affairs Bureau Director of the Ministry of Health, Labour and Welfare addressed to the Director of the Department of Health in each prefecture on August 14, 1954).

**Other requirements**
a) Follow the stimulator's compatibility checklist for basic requirements of low-frequency therapy devices.
b) Implement risk management for the use of electro-acupuncture needles.