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# GUIDANCE FOR TENS 510(K) CONTENT

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**This guidance document may contain references to addresses and telephone numbers that are now obsolete. The following contact information is to be used instead:**

- **While this guidance document represents a final document, comments and suggestions may be submitted at any time for Agency consideration to the Restorative Devices Branch, 9200 Corporate Blvd., HFZ-410, Rockville, MD 20850.**
- **For questions regarding the use or interpretation of this guidance, contact the Restorative Devices Branch at 301-594-1296.**
- **To contact the Division of Small Manufacturers Assistance (DSMA), call 800-638-2041 or 301-443-6597; fax 301-443-8818; email dsmo@cdrh.fda.gov; or write to DSMA (HFZ-200), Food and Drug Administration, 1350 Piccard Drive, Rockville, Maryland 20850-4307. FACTS-ON-DEMAND (800-899-0381 or 301-827-0111) and the World Wide Web (CDRH home page: http://www.fda.gov/cdrh/index.html) also provide easy access to the latest information and operating policies and procedures.**

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
Center for Devices and Radiological Health
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## INTRODUCTION

This draft guidance is intended to facilitate the writing and review of premarket notifications, or "510(k)'s", for transcutaneous electrical nerve stimulators, or "TENS". The earlier guidance material was first compiled to expedite the work of FDA review staff and to help provide a consistent level of review scrutiny for these premarket notifications. Subsequently, the this material was revised to enhance its usefulness by providing manufacturers guidance in preparing complete notifications to facilitate the review process.

This draft version has been amended to include more specific information concerning the design of safe electrode connectors (II.B.4), additional data needed for devices that include programmable microcircuits (II.D), and specific test data needed to assure adequate performance in the environment of electromagnetic interference (II.C).

## I. BASIC DESIGN DESCRIPTION

The manufacturer should provide a comparison between the basic design features of his device and those of other devices that have been legally marketed. This must include sufficient pictures, drawings, schematics, etc., to completely describe the device, its controls, and its functional characteristics. The manufacturer should indicate his source of information concerning the devices to which he is making a comparison; e.g., the number of a prior 510(k) or published data for preamendment devices.

## II. DEVICE SPECIFICATIONS

A. Electrical Output.

1. A complete and precise description of all possible electrical outputs must be provided. Typically, this requires a graphic record of the output waveform showing two complete cycles (voltage or current) obtained by actual measurements under several load conditions in the range from 500 ohms to 10K ohms. This must include data showing the waveform at the maximum possible current amplitude and pulse width, and these maximum values must be clearly stated. The amplitude and time axes must be labeled clearly and unambiguously with the units of measurement.

2. All possible output adjustments must be identified (e.g., pulse width, amplitude, and frequency) and the operating range specified for each.

3. Modes such as "burst" or "surge" must be accurately defined. Graphic data should be provided when needed for clarity.

4. If the electrical output is complex, the most fundamental pulse components must be illustrated in detail, showing instantaneous current (or voltage) as a function of time.

5. The manufacturer should specify the maximum charge per phase for each phase of the fundamental component. The "maximum" is the greatest possible output current, with controls adjusted for maximum amplitude and maximum pulse width. All test data, assumptions, and calculations should be provided.

6. The manufacturer should specify the allowable variation in supply voltage that will assure proper function. If the electrical output does not remain stable during expected variations in supply voltage, the effects of supply variation must be stated.

B. Electrical Safety.

1. The most typical TENS devices employ a pulse width between 0.01 and 1 millisecond. For these typical devices, specification of the charge (microcoulombs) delivered per pulse (for pulses in this range) can be used to evaluate safety, based on data published for external cardiac pacers (Zoll and Linenthal, 1964).

2. If device is line powered, explain how design and testing has assured that a component failure will not put the user in jeopardy. Output isolation from ground is typically achieved by transformer coupling. The isolation transformer should be designed in conformance with UL544, i.e., failure of insulation on windings will not allow line voltage (or ground) to reach the user through the electrodes. These precautions are necessary because cutaneous electrodes provide a low impedance current path to the body and therefore they greatly increase the risk of electrocution. If the device is powered by a low voltage battery, provide assurance that it cannot be operated with a line-powered battery charger; otherwise, line isolation is necessary.

3. The leakage current to ground must be specified. How does it compare with industry standards (e.g., AAMI or UL544)?

4. The connection between the device and the patient leads must be described. Connectors and electrode pins must be designed to preclude any accidental contact with a dangerous power source, e.g. an AC power outlet. (See Refs. 7 and 10.)

C. Standards.

1. Design qualifications tests must be performed to show that the device will not malfunction when subjected to the electromagnetic interference environment described in Reference 12.

2. The manufacturer must indicate the extent to which the device conforms to the AAMI (ANSI) standard.

D. Software and Microprocessor-controlled Systems.

If the device employs a microprocessor or other software-controlled components, the firm must provide documentation of the software development process in accordance with the appropriate level of concern, as described in "Reviewer Guidance Document for Computer Controlled Medical Devices", Reference 11. Documentation should include the system requirements specification, identification of system failure modes and associated hazards, procedures for software verification and validation, results of verification and validation testing, quality assurance procedures; and certification of the software development process.

## III. OUTPUT CRITERIA

A. Monophasic pulses. (not exceeding 1 millisecond)*

| Charge/phase (μC) | | |
|---|---|---|
| Minimum for effectiveness | 3 | (ref.2) |
| Maximum for effectiveness | 7 | |

| | |
|---|---|
| Safe through chest (ANSI/AAMI NS-4--1985) | 20 |
| Hazardous through chest | 75 |
| Cardiac threshold for pacing | 100 ±25 |

*charge delivered after 1 ms has little effect on nerve depolarization

B. Biphasic pulses. In the absence of data, assume the worst case (safety) by adding charge transferred in both pulses to compare with monophasic data.

C. Any waveform other than pulse trains. Data must be provided that assures safety and effectiveness.

## IV. ELECTRODES AND CONDUCTIVE MEDIA (GEL)

A. Preamendment status.

1. The manufacturer should provide data by reference if the electrodes and gels were previously distributed as pre-Amendment products or found "equivalent"; otherwise, a complete 510(k) disclosure for a new electrode or gel.

2. If the device employs electrodes or gels that are being produced by another firm and repackaged, the other firm and product name must be specified.

3. If "new" electrodes (or gel) are being introduced for the first time, a complete description and data -- usually the subject of a separate 510(k) -- must be included. (There is another review guideline that covers toxicity testing for cutaneous electrodes.)

B. Multiple electrode pairs. If the generator drives more than a single pair of electrodes, the manufacturer must assure that there is differential isolation. (A common "return" will produce cross-electrode current that could be hazardous.)

C. Instructions. Any preparation that is needed for good conductivity (to prevent skin burns) must be specified in the labeling.

D. Thermal burn hazard. The electrode dimensions and contact area must be specified. The average power density must be calculated to estimate the risk of thermal injury. (Data derived from heated electrodes at 46$^{o}$C and from RF current burns indicates that 0.25 W/cm$^{2}$ can produce a burn.)

## V. LABELING

If labeling does not conform to 21 CFR 801.109, it may cause the product to be misbranded. Copies or drafts of all written material (advertisements, promotional material, brochures, operating instructions, etc.) must be provided.

A. Claims of effectiveness (indications). Pre-Amendment TENS devices were used only for symptomatic relief of chronic intractable pain. For some devices, this claim has been extended to include post-traumatic and post-surgical pain relief, based on clinical data. Any other intended use must be supported by valid scientific data. Documentation must describe clinical studies that utilized the subject device, the results of the study, and analysis that supports the claim of effectiveness. If a new use raises new questions of effectiveness, then the device is a new device, and not "substantially equivalent" to any TENS device.

B. Prescription labeling. TENS devices are prescription devices and must have prescription labeling in accordance with 21 CFR Section 801.109. Both the device and its labeling must bear the prescription legend.

C. Contraindications -- Labeling statements must exclude the following:

1. Any electrode placement that applies current to the carotid sinus (neck) region.

2. Any use of TENS on patients who have a demand-type cardiac pacemaker.

3. Any electrode placement that causes current to flow transcerebrally (through the head).

4. The use of TENS whenever pain syndromes are undiagnosed, until etiology is established.

D. Warnings. Must include:

1. The safety of TENS devices for use during pregnancy or birth has not been established.

2. TENS is not effective for pain of central origin. (This includes headache.)

3. TENS devices should be used only under the continued supervision of a physician.

4. TENS devices have no curative value.

5. TENS is a symptomatic treatment and as such suppresses the sensation of pain which would otherwise serve as a protective mechanism.

6. The user must keep the device out of the reach of children.

7. Electronic monitoring equipment (such as ECG monitors and ECG alarms) may not operate properly when TENS stimulation is in use.

8. If the device is capable of delivering a charge per pulse of 25 microcoulombs (μC) or greater, there should be a prominently placed statement warning that stimulus delivered by this device may be sufficient to cause electrocution. Electrical current of this magnitude must not flow through the thorax because it may cause a cardiac arrhythmia.

E. Precautions. Caution statements should include:

1. Isolated cases of skin irritation may occur at the site of electrode placement following long-term application.

2. Effectiveness is highly dependent upon patient selection by a person qualified in the management of pain patients.

F. Adverse reactions. Skin irritation and electrode burns are potential adverse reactions.

G. Operating Instructions for Physician: Requires an accurate and complete description of the device and its output parameters, including:

1. A picture or scaled drawing depicting the output waveform (either current or voltage) with a load (e.g., 500 ohm) as a function of time.

2. Pulse duration (microseconds). If adjustable, range of variability is also to be specified.

3. Pulse frequency (pulses/second). If adjustable, the range of variability is to be specified.

4. Output voltage range (typical load).

5. Peak pulse output current (milliamperes). If adjustable, range is to be specified.

6. Power source specifications (e.g., type of battery, recharging method).

7. A brief explanation of the intended mode of action of the device and the principles of its design.

8. Indications for use, contraindications, warnings, precautions, and adverse reactions (see V).

9. Instructions for care and use -- includes (but not be limited to): an explanation of the controls and how to use them; an explanation of how the electrodes are attached to the patient and the device; how to maintain the electrodes; identification of the conductive medium to be used with the electrodes and how it is used; identify the battery size; and an explanation of any other miscellaneous features of the device.

H. Patient Information -- should include indications for use, contraindications, warnings, precautions, possible adverse reactions, and instructions for the care and use of the device.

## REFERENCES


1. C.M. Becker, I.V. Malhotra, and J. Hedley-Whyte, "The Distribution of Radiofrequency Current and Burns," Anesthesiology, Vol. 38, No.2, pp. 106-122, Feb. 1973.

2. M. Linzer, and D.M. Long, "Transcutaneous Neural Stimulation for Relief of Pain," IEEE Transactions on Biomedical Engineering, Vol. BME-23, No. 4, pp. 341-345, July 1976.

3. J.A. Pearce, et al., "Skin Burns from Electrosurgical Current," Medical Instrumentation, Vol. 17, No. 3, pp. 225-231, May-June 1983.

4. P.M. Zoll and A.J. Linenthal, "External Electrical Stimulation of the Heart," Ann. NY Acad. Sci., Vol. III, pp. 932-937, 1964.

5. American National Standard for Transcutaneous Electrical Nerve Stimulators ANSI/AAMI NS4--1985. Association for the Advancement of Medical Instrumentation, 1901 North Fort Meyer Drive, Suite 602, Arlington, Virginia 22209.

6. Standard for Medical and Dental Equipment -- UL 544, Second Ed. 1976, Underwriters Laboratories, Inc., 333 Pfingsten Road, Northbrook Illinois 60062.

7. "Connection of Electrode Lead Wires to Line Power", Health Devices, Emergency Care Research Institute, pp. 44-46, Feb. 1987.

8. M. N. Leeming, C. Ray, and W. S. Howland, "Low-Voltage Direct-Current Burns", JAMA 214:1681-1684, 1970.

9. Health Devices Source Book, Emergency Care Research Institute, 5200 Butler Pike, Plymouth Meeting, PA 19462, June 1981, pp.179-195.

10. FDA Public Health Advisory: Unsafe Electrode Lead Wires and Patient Cables Used with Medical Devices, D. Bruce Burlington, M.D., FDA/CDRH Director, Dec. 28, 1993.

11. "Reviewer Guidance Document for Computer Controlled Medical Devices", can be obtained from the FDA, CDRH, Division of Small Manufacturers Assistance by calling (800) 638-2041.

12. "Electromagnetic Compatibility Standard for Medical Devices", MDS-201-0004, can be obtained from the FDA, CDRH, Division of Small Manufacturers Assistance by calling (800) 638-2041.