For Industry and FDA Staff

Guidance[1] on Electrosurgical Devices and the Application of the Performance Standard for Electrode Lead Wires and Patient Cables.

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Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to, William C. Maloney, Diagnostic Devices Branch, HFZ-322, Office of Compliance, 2094 Gaither Rd., Rockville, MD 20850. Comments may not be acted upon by the Agency until the document is next revised or updated. For questions regarding the use or interpretation of this guidance contact William C. Maloney at 301 594-4591 or by electronic mail at WCM@CDRH.FDA.GOV.

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Guidance[1] on Electrosurgical Devices and the Application of the Performance Standard for Electrode Lead Wires and Patient Cables.

This level 2 guidance concerns the applicability of the Performance Standard for Electrode Lead Wires and Patient Cables (Code of Federal Regulations, Chapter 21, Part 898) to active leads used with electrosurgical devices.

The performance standard was established to prevent unintended electrical connections between patients and electrical power sources. The performance standard applies to electrode lead wires and patient cables intended for use with a medical device.

There are two types of leads that are used with monopolar electrosurgical devices, one for the active electrode and one for the dispersive electrode. The active electrode lead is that part of the device that delivers the RF current to the patient for therapeutic effect. The active electrode is under direct control of the surgeon when it is in contact with the patient. This is not the case with the dispersive electrode, which is attached to the patient. Lead wires used with dispersive electrodes are subject to the Performance Standard for Electrode Lead Wires and Patient Cables. This is consistent with Section 4.2.6.2 of the AAMI/ANSI Standard HF18, Electrosurgical Devices.

The active electrode lead wire (both for monopolar and bipolar systems) is not subject to the Performance Standard. This is consistent with the IEC 60601-2-2 International Standard. Under Section Ten clause 56.3, active electrodes are specifically exempted from the requirement that any neutral connector be constructed such that no conductive connection which is remote from the patient can contact conductive parts of fixed mains socket outlets and mains connectors. (See IEC 60601-2-2 Section 10 Clause 56.3 for the full requirement.) The rationale given for this exemption is as follows, "The situation with electrosurgical APPLIED PARTS is quite different, because this kind of EQUIPMENT is intended to be used only under the control of a doctor or trained medical staff."

If you have any questions on this interpretation, please contact Mr. William C. Maloney at (301) 594-4591.

Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health

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