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Dental Electrosurgical Equipment

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AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION SPECIFICATION NO. 44 FOR DENTAL ELECTROSURGICAL EQUIPMENT

FOREWORD

There are many specific reasons why separate standards are needed for medical and dental electrosurgical devices. These relate in large measure to the contrasting clinical conditions under which the respective devices are utilized, and to the special requirements created by the vast differences in tissue characteristics and therapeutic objectives of medical and dental electrosurgery.

Medical electrosurgery is essentially a hospital operating room procedure that usually involves life-threatening conditions which require concurrent use of monitoring and/or therapeutic electronic devices that create special demands on the medical electrosurgical devices, procedures and performance. Dental electrosurgery is essentially a dental office procedure on ambulatory, fully clothed patients, for non-life-threatening procedures that do not require concurrent use of electronic monitoring or therapeutic devices.

The enormous difference in medical and dental clinical electrosurgical procedures, and the unique demands these make on the electrical capabilities of the respective devices, dictate the need for separate standards. Separate standards assure clear-cut, concise, comprehensive pertinent specifications for the respective devices that will facilitate their easy understanding and compliance. By contrast, a standard that attempts to provide an umbrella approach to cover all types of electrosurgical devices in a single all-inclusive document is inherently much more complex and likely to inpede easy interpretation and compliance.

There are additional persuasive contributory considerations for separate standards. All electrosurgical device standards must provide adequate safeguards against the hazards of accidental patient burns and electric shock to patients and/or attending personnel. This standard also takes cognizance of an additional hazard that is unique to dental electrosurgery; the matter of depth of heat penetration into the adjacent and subjacent tissues. Hemostasis is the most important consideration in medical electrosurgery, thus depth of heat penetration rarely is a significant factor. In dental electrosurgery hemostasis is desirable but not critically essential. The critically important factor is the depth of heat penetration into the adjacent and subjacent tissues, due to the stringently restrictive oral anatomic limitations created by the 1 or 2 mm thickness of normal gingival mucosa that is attached to periosteum which is attached to viable bone that usually contains vital teeth. In this anatomic environment, heat penetration to a depth greater than a mere matter of layers of tissue cells becomes excessive and potentially destructive.

This standard provides comprehensive specifications for the basic requirements for electrosurgical systems designed specifically for use in a dental operatory or an operating room for procedures on the oral and perioral tissues. These systems consist of a radio frequency electronic generator, a dispersive electrode which is capacitively coupled to the patient, a hand controlled active electrode, a foot switch, and associated interconnecting cables. The standard pertains not only to the electronic generator and dispersive electrode but in addition addresses the aspects of safety, efficacy, and hazards that are unique to surgery and associated dental procedures in the oral cavity.

The operating frequency of the generators in the dental electrosurgery systems is usually in the range of 1.5 to 4 megahertz, with power output not exceeding 100 watts. The tissues incised or treated with this modality are confined to those present within and around the oral cavity such as the lips, cheeks, tongue, and gingival tissues attached to the alveolar and palatal bones and teeth. Incisions are made with very rapid movement of the electrode wielding hand that is unlike the deliberate hand movements used for steel scalpel incisions, to prevent excessive heat penetration and retention. A significant factor in dental electrosurgery systems is that the dispersive electrode is capacitively coupled to the ambulatory clothed patient.

The operating frequency of the generators in the electrosurgery systems used in the general medical operating theater is in the order of 400 kilohertz, with power output capabilities of up to 400 watts. The dispersive electrode normally is *conductively* coupled to the patient's bare skin. The types of tissues incised, excised, or coagulated, such as epithelium, muscle, vessels, neutral components, visceral and other vital organs, and other gross tissues are unlike those found in the oral cavity. In general, medical procedures electrosurgical incisions usually are made with slow deliberate electrode movements similar to those used for steel scalpel incisions.

This standard for dental electrosurgical devices takes into account the differences that exist in the electrosurgical systems, method of dispersive electrode coupling, tissue considerations, and surgical methodology that exist between the modality in dentistry and general medical (surgical) practice.

This standard reflects the conscientious efforts of concerned dentists, clinical engineers, and manufacturers, to develop a standard covering performance characteristics which are essential to avoid known and potential problems relating to safety and efficacy. The members of this ANSI Committee MD156, Subcommittee 44 and its consultants are:

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This Committee has conscientiously considered all suggestions offered by the interested parties who have reviewed and evaluated its previous drafts. All but a few that would have disproportionately entailed major format changes have been adopted and incorporated into this draft.

The Committee is greatly indebted to all who have actively participated in the reviews and evaluations of the drafts.

AMERICAN NATIONAL STANDARDS/AMERICAN DENTAL ASSOCIATION SPECIFICATION NO. 44 FOR DENTAL ELECTROSURGICAL EQUIPMENT

1. INTRODUCTION AND SCOPE

1.1 *Scope.* This standard covers the minimal requirements for dental electrosurgical devices that operate in the 1.5 to 4 MHz frequency range and have a maximum power output capability of 100 watts or less, but not less than a maximum capability of 50 watts, and are used principally in the oral cavity for performing clinical dental electrosurgery procedures by biterminal technique. The elements covered in this standard include: the electrosurgical high-frequency generator and directly related accessories such as the active cables and electrodes, dispersive electrode and cable, foot switches, and other operator-controlled mechanisms for activation of the generator output. Unless otherwise designated, the terms "electrosurgical device" or "electrosurgery unit" shall signify a DENTAL electrosurgical device throughout this standard.

NOTE: Radiation from dental electrosurgical devices can cause electromagnetic interference to electrical devices (e.g., physiologic monitoring devices, EKG, EEG, etc.) operating in the vicinity of the electrosurgical generator. However, since these auxiliary medical electrical devices are not used in the dental office, the normal environment for use of dental electrosurgical devices, electromagnetic compatibility factors shall not be considered in this standard.

1.2 *Purpose.* The purpose of this standard is to provide general requirements for electrosurgical devices to assure that, to the extent that safety and performance efficiency can be controlled by device design, dental electrosurgical devices are effective for their intended use and the risks of injury to patient and attending personnel are minimized.

1.3 *Definitions.* The technical terminology, for the purpose of this standard, is defined as follows:

Active Cable: The conductor between the electrosurgical generator and the active electrode handpiece.

Active Electrode: The electrode that comes into contact with the tissues at the site where the electrosurgical effect is intended. It is usually in the form of a fine wire needle, fine wire loop, or solid metal round ball, tapered conical or cylindrical electrode, that provides and introduces a high current density into the tissues to achieve the desired surgical cutting, coagulating, or fulgurating (desiccating) effect.

Bipolar Electrode: An active electrode with twin wire tips (projecting from a common shaft) which are applied simultaneously