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NEMA STANDARDS PUBLICATION NO. XR 13

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Mechanical Safety Standard for Power Driven Motions of Electromedical Equipment

NEMA

NATIONAL ELECTRICAL MANUFACTURERS ASSOCIATION ■ 2101 L STREET, N.W., WASHINGTON, D.C. 20037

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NEMA XR 13-1990

XR 13

MECHANICAL SAFETY STANDARD FOR POWER DRIVEN MOTIONS OF ELECTROMEDICAL EQUIPMENT

Published by:

National Electrical Manufacturers Association
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Foreword

This Standards Publication outlines those areas that may require protection against single point failures, and operator or service errors which could cause an injury as a result of power driven motion.

User needs have been considered throughout the development of this publication. Proposed or recommended revisions should be submitted to:

Vice President, Engineering Department
National Electrical Manufacturing Association
2101 L Street, N.W., Suite 300
Washington, D.C. 20037

Scope

This Standards Publication covers all power driven equipment motions that are accessible to the patient or operator during intended use. This standard does not include the transport drives for mobile equipment.

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SECTION 1
DEFINITIONS

1.1 POWER DRIVEN MOTION

For the purpose of this standard "power driven motion" is defined as any accessible moving equipment part which is motor driven or force multiplied by a power assist.

NEMA Standard 9-5-1990.

1.2 ACCESSIBLE

Any part that can be touched without the use of a tool.

NEMA Standard 9-5-1990

1.3 SINGLE FAULT CONDITION

Conditions in which a single means of protection against a safety hazard in the equipment fails to provide the protection intended, or a single external abnormal condition is present.

Examples: Failure of a mechanical part, an electrical part, or a software program which is intended to protect against a hazardous motion.

NEMA Standard 9-5-1990.

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SECTION 2
GENERAL REQUIREMENTS

2.1 GENERAL

This Standards Publication shall be used for establishing design requirements for power driven motions of new products. When applying this standard, the entire system shall be considered, taking into account:

a. The patient/equipment, patient/operator and operator/equipment interface;
b. Patient conditions such as being unconscious or anesthetized; or connected to an IV, catheter or other such devices;
c. The operator's ability to see and control the interaction of equipment and patient or other people and equipment;
d. The energy available from the moving element;
e. Special safety provisions that would prevent injury; and
f. Operator training or skill.

NEMA Standard 9-5-1990.

2.2 CONTROLS

2.2.1 All power driven motions which could cause physical injury shall be provided with an emergency stop control. The emergency switch shall be colored red, shall be distinctive from the other controls, and shall maintain the off condition. A deliberate and different action shall be required to resume motion (example: a red 1 inch (2.54 cm) mushroom switch; push to stop, pull to reset). The emergency stop circuit shall be independent so that no failure of the normal motion control will prevent the emergency stop from halting the motion. In the event of an emergency stop, means shall be provided for patient access and removal while the equipment is disabled.

NEMA Standard 9-5-1990.

2.2.2 The movement of equipment parts which could otherwise cause physical injury shall be operated only under continuous control of the operator (dead man switch) or have provisions for preventing contact with the patient, or limit the pressure on the patient to an acceptable level (See paragraph 2.3).

NEMA Standard 9-5-1990.

2.2.3 When the operator cannot see the equipment/patient contact point and such contact could cause an injury, a sensing means shall be provided to detect patient contact and stop the motion.

NEMA Standard 9-5-1990.

2.2.4 Collisions of power driven equipment parts with other stationary or moving parts that could result in an injury shall be prevented. NEMA Standard 9-5-1990.

2.2.5 Power assist such as a spot film device shall require the operator to continuously apply a pressure or force to cause motion.

NEMA Standard 9-5-1990.

2.3 FORCE/AREA

2.3.1 The pressure allowed to be applied to the patient shall be analyzed as to the body part which may come in contact with the equipment, application requirements, and the potential for injury. As a general guideline, the pressure on the patient should be limited to 10 lbs./square inch (69 kilopascals) maximum and 40 lbs. (178 Newtons) maximum force.

NEMA Standard 9-5-1990.

2.3.2 Power assist devices such as a spot film device used near or against the patient shall limit the assist force only to that necessary to overcome the frictional inertia or gravitational forces resisting movement of the part. The power assist device shall limit the maximum static force to that specified in paragraph 2.3.1, or not be greater than two pounds (8.9 Newtons) more than that applied by the operator.

NEMA Standard 9-5-1990.

2.4 SPEED

Motions which position the equipment or patient such that the equipment could contact the patient with a risk of injury (example; an image intensifier "C" arm) shall limit the speed and control of the stopping response so the operator will have adequate control of the positioning without endangering the patient.

NEMA Standard 9-5-1990.

As a general guideline, when movement of power driven equipment toward the patient is within 12 inches (305 mm) of the patient tabletop, or within four inches (102 mm) of the table side, the speed should be limited to one-half the normal speed and an alarm should be activated. The motion when in this zone should not continue to travel more than 0.5 inch (13 mm) after the operator has activated the stop or motion reverse control.

Authorized Engineering Information 9-5-1990.

2.5 CLEARANCES

Clearances between moving parts, or between fixed and moving parts, which are accessible to the patient or operator shall be as listed below unless special safeguards are provided such as limiting the force:

a. Protection from finger entrapment: 0.75 inch (19 mm);

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b. Protection from foot entrapment: 1.50 inch (38 mm); *and,*
c. Protection from arm/leg entrapment: 4.00 inch (102 mm).

NEMA Standard 9-5-1990.

2.6 LIMITING MOTIONS

When travel is limited by the motion control system, a mechanical stop or other means must be provided as a back-up to restrict the motion in case of failure of the normal limiting means. Means shall be provided to alert the operator of a failure of the normal limiting means if the motion is allowed to function after such a failure.

NEMA Standard 9-5-1990.

2.7 UNINTENTIONAL MOTION

Means shall be provided to minimize the possibility of unexpected motion under normal operation and single fault conditions. The following shall apply in complying with this requirement:

a. Position, recess, or provide other means to prevent operator controls from being accidentally activated;
b. When appropriate for the application, provide a momentary switch which must be activated for the functional controls to be operable;
c. Motion controls in areas subject to liquid spills shall not cause unintended motion as a result of such spills;
d. Provide redundancy or other such protection for control circuits where failure (such as welded relay contacts) would result in uncontrolled motion. A failure of one of the redundant controls shall be indicated to the user (either directly or by user test);
e. Avoid using ground potentials which are connected to the chassis or equipment frame to activate control circuits (prevent short to ground from activating motion).

NEMA Standard 9-5-1990.

2.8 WARNINGS

When a guard is used to protect against a hazard which is not obvious when the guard is removed, a warning shall be located on the assembly inside the guard.

NEMA Standard 9-5-1990.

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NEMA STANDARDIZATION

The purpose of NEMA Standards, their classification and status are set forth in certain clauses of the NEMA *Standardization Policies and Procedures* manual and are referenced below:

Purpose of Standards

National Electrical Manufacturers Association Standards are adopted in the public interest and are designed to eliminate misunderstandings between the manufacturer and the purchaser and to assist the purchaser in selecting and obtaining the proper product for their particular needs. Existence of a National Electrical Manufacturers Association Standard does not in any respect preclude any member or nonmember from manufacturing or selling products not conforming to the standard.

(Standardization Policies and Procedures, p. 1)

Definition of a Standard

A standard of the National Electrical Manufacturers Association defines a product, process or procedure with reference to one or more of the following: nomenclature, composition, construction, dimensions, tolerances, safety, operating characteristics, performance, rating, testing, and the service for which they are designed.

(Standardization Policies and Procedures, p. 2)

Dimensions

Where dimensions are given for interchangeability purposes, alternate dimensions satisfying the other provisions of the Standards Publication may be capable of otherwise equivalent performance.

(Standardization Policies and Procedures, p. 8)

Categories of Standards

National Electrical Manufacturers Association Standards are of three classes:

1. NEMA Standard, which relates to a product, process or procedure commercially standardized and subject to repetitive manufacture, which standard has been approved by at least 90 percent of the members of the Subdivision eligible to vote thereon;
2. Suggested Standard for Future Design, which may not have been regularly applied to a commercial product, but which suggests a sound engineering approach to future development, which standard has been approved by at least two-thirds of the members of the Subdivision eligible to vote thereon.
3. Adoptive Standard, which is adopted in whole or in part from the standards of another organization, either domestic, regional, or international.

(Standardization Policies and Procedures, pp 7 & 16)

Authorized Engineering Information

Authorized Engineering Information consists of explanatory data and other engineering information of an informative character not falling within the classification of NEMA Standard or Suggested Standard for Future Design, which standard has been approved by at least two-thirds of the members of the Subdivision eligible to vote on the standard.

(Standardization Policies and Procedures, pp. 7 & 16)

Official Standards Proposal

An Official Standards Proposal is an official draft of a proposed standard which is formally recommended to an outside organization(s) for consideration, comment and/or approval, and which has been approved by at least 90 percent of the members of the Subdivision eligible to vote thereon. *(Standardization Policies and Procedures, pp 7 & 16)*

Identification of Status

Standards in NEMA Standards Publications are identified in the foreword or following each standard as "NEMA Standard" or "Suggested Standard for Future Design." These indicate the status of the standard. These words are followed by a date which indicates when the standard was adopted in its present form by the Association.

The material identified as "Authorized Engineering Information" and "Official Standards Proposal" is designated similarly.

July 17, 1990

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