American National Standard

ANSI/AAMI NS28:1988/(R)2015

Intracranial pressure monitoring devices

AAMI
Advancing Safety in Healthcare Technology

Objectives and uses of AAMI standards and recommended practices

It is most important that the objectives and potential uses of an AAMI product standard or recommended practice are clearly understood. The objectives of AAMI's technical development program derive from AAMI's overall mission: the advancement of medical instrumentation. Essential to such advancement are (1) a continued increase in the safe and effective application of current technologies to patient care, and (2) the encouragement of new technologies. It is AAMI's view that standards and recommended practices can contribute significantly to the advancement of medical instrumentation, provided that they are drafted with attention to these objectives and provided that arbitrary and restrictive uses are avoided.

A voluntary *standard* for a *medical device* recommends to the manufacturer the information that should be provided with or on the product, basic safety and performance criteria that should be considered in qualifying the device for clinical use, and the measurement techniques that can be used to determine whether the device conforms with the safety and performance criteria and/or to compare the performance characteristics of different products. Some standards emphasize the information that should be provided with the device, including performance characteristics, instructions for use, warnings and precautions, and other data considered important in ensuring the safe and effective use of the device in the clinical environment. Recommending the disclosure of performance characteristics often necessitates the development of specialized test methods to facilitate uniformity in reporting; reaching consensus on these tests can represent a considerable part of committee work. When a drafting committee determines that clinical concerns warrant the establishment of *minimum* safety and performance criteria, referee tests must be provided and the reasons for establishing the criteria must be documented in the rationale.

A *recommended practice* provides guidelines for the use, care, and/or processing of a medical device or system. A recommended practice does not address device performance *per se*, but rather procedures and practices that will help ensure that a device is used safely and effectively and that its performance will be maintained.

Although a device standard is primarily directed to the manufacturer, it may also be of value to the potential purchaser or user of the device as a frame of reference for device evaluation. Similarly, even though a recommended practice is usually oriented towards healthcare professionals, it may be useful to the manufacturer in better understanding the environment in which a medical device will be used. Also, some recommended practices, while not addressing device performance criteria, provide guidelines to industrial personnel on such subjects as sterilization processing, methods of collecting data to establish safety and efficacy, human engineering, and other processing or evaluation techniques; such guidelines may be useful to health care professionals in understanding industrial practices.

In determining whether an AAMI standard or recommended practice is relevant to the specific needs of a potential user of the document, several important concepts must be recognized:

All AAMI standards and recommended practices are *voluntary* (unless, of course, they are adopted by government regulatory or procurement authorities). The application of a standard or recommended practice is solely within the discretion and professional judgment of the user of the document.

Each AAMI standard or recommended practice reflects the collective expertise of a committee of health care professionals and industrial representatives, whose work has been reviewed nationally (and sometimes internationally). As such, the consensus recommendations embodied in a standard or recommended practice are intended to respond to clinical needs and, ultimately, to help ensure patient safety. A standard or recommended practice is limited, however, in the sense that it responds generally to perceived risks and conditions that may not always be relevant to specific situations. A standard or recommended practice is an important *reference* in responsible decision-making, but it should never *replace* responsible decision-making.

Despite periodic review and revision (at least once every five years), a standard or recommended practice is necessarily a static document applied to a dynamic technology. Therefore, a standards user must carefully review the reasons why the document was initially developed and the specific rationale for each of its provisions. This review will reveal whether the document remains relevant to the specific need of the user.

Particular care should be taken in applying a product standard to existing devices and equipment, and in applying a recommended practice to current procedures and practices. While observed or potential risks with existing equipment typically form the basis for the safety and performance criteria defined in a standard, professional judgment must be used in applying these criteria to existing equipment. No single source of information will serve to identify a particular product as "unsafe". A voluntary standard can be used as one resource, but the ultimate decision as to product safety and efficacy must take into account the specifics of its utilization and, of course, cost-benefit considerations. Similarly, a recommended practice should be analyzed in the context of the specific needs and resources of the individual institution or firm. Again, the rationale accompanying each AAMI standard and recommended practice is an excellent guide to the reasoning and data underlying its provision.

In summary, a standard or recommended practice is truly useful only when it is used in conjunction with other sources of information and policy guidance and in the context of professional experience and judgment.

INTERPRETATIONS OF AAMI STANDARDS AND RECOMMENDED PRACTICES

Requests for interpretations of AAMI standards and recommended practices must be made in writing, to the AAMI Vice President, Standards Policy and Programs. An official interpretation must be approved by letter ballot of the originating committee and subsequently reviewed and approved by the AAMI Standards Board. The interpretation will become official and representation of the Association only upon exhaustion of any appeals and upon publication of notice of interpretation in the "Standards Monitor" section of the *AAMI News*. The Association for the Advancement of Medical Instrumentation disclaims responsibility for any characterization or explanation of a standard or recommended practice which has not been developed and communicated in accordance with this procedure and which is not published, by appropriate notice, as an *official interpretation* in the *AAMI News*.

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Intracranial Pressure Monitoring Devices

Developed by
Association for the Advancement of Medical Instrumentation

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Abstract:

This standard establishes minimum labeling, safety, and performance requirements for intracranial pressure monitoring devices, whether percutaneous, fully implantable, or noninvasive. Also covered are referee test methods and the rationale for the provisions of the standard.

Association for the Advancement of Medical Instrumentation Neurosurgery Committee

This standard was developed by the ICP Device Subcommittee of the AAMI Neurosurgery Committee. Committee approval of the standard does not necessarily imply that all committee and subcommittee members voted for its approval.

The AAMI Neurosurgery Committee has the following members:

Cochairpersons: Richard Penn, M.D.
Marvin Sussman, Ph.D.

Members:
Roger Avery, Avery Custom Med Lab, Inc.
Richard Black, M.D., University of Texas Health Science Center, Houston, TX
Gilbert Buchalter, R.P., M.Sc., Pharmaceutical Innovations
Alan Coombes, Codman and Shurtleff
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Keith Mullett, Medtronic
Robert Munzner, Ph.D., Center for Devices and Radiological Health, FDA
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Michael Salcman, M.D., University of Maryland, Baltimore
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Stephen L. Weitz, M.D., Albert Einstein School of Medicine, Bronx, NY

Alternates: Deryck Duncalf, M.D., American Society of Anesthesiology
R.L. Pratt, 3M

ICP Device Subcommittee

The ICP Device Subcommittee of the AAMI Neurosurgery Committee currently has the following members:

Cochairpersons: Marc A. Flitter, M.D.
Marvin Sussman, Ph.D.

Members: Hossein Baharestani, Marquette Electronics
Alan Coombes, Codman and Shurtleff
Maurice Davidson, M.D., Cape May Cour, NJ
Marc A. Flitter, M.D., Erie, PA
Harry Friedman, M.D., Memphis Neurosurgical Clinic, Memphis, TN
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John Hall, American Edwards Laboratories
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Harold A. Wilkinson, M.D., Ph.D., University of Massachusetts Medical Center, Worcester, MA

Alternates: Sue Monis, Marquette Electronics
David Wahl, American Edwards Laboratories

The Subcommittee had the following additional members at the time this standard was balloted:
John Arnott, Medtronic Research Industries
Eric R. Cosman, Ph.D., Radionics
Steven R. Loveland, Medex

Acknowledgments

The committee wishes to acknowledge the contributions of William Sones, Medical Measurements, who submitted commentary on the standard during its development.

Note: Participation by federal agency representatives in the development of this standard does not constitute endorsement by the federal government or any of its agencies.

Foreword

This standard was developed by the ICP Device Subcommittee of the AAMI Neurosurgery Committee.

The purpose of this standard is to provide labeling, safety, and performance requirements and test methods that will help assure a reasonable level of safety and effectiveness of devices intended for use in the

measurement of intracranial pressure.

The concepts incorporated in this standard should be considered flexible and dynamic. As advances are made in intracranial pressure measurement technology and as new data become available this standard will be reviewed and, if necessary, revised.

This standard reflects the conscientious efforts of clinicians, device manufacturers, and other professionals concerned with its scope and provisions to develop those safety and performance criteria that could reasonably be achieved at this time.

Recommendations for improving this standard are invited. Comments should be sent to AAMI, 3330 Washington Boulevard, Suite 400, Arlington VA, 22201-4598.

Note: This foreword is not part of the American National Standard, *Intracranial Pressure Monitoring Devices* (ANSI/AAMI NS28-1988), but does provide important information about its development and use.

Intracranial Pressure Monitoring Devices

1. Scope

1.1 General

This standard establishes minimum labeling, safety, and performance requirements for intracranial pressure (ICP) monitoring devices, whether percutaneous, fully implantable, or noninvasive. Also covered by this standard are test and calibration methods needed to establish compliance with the standard.

1.2 Inclusions

The following components, which individually or in combination comprise ICP monitor assemblies, are within the scope of this standard when supplied by the manufacturer of the ICP monitoring device:

(1) *Percutaneous fluid-coupled devices,* such as ventricular catheters, skull-fixated subarachnoid and subdural devices, subdural balloons and subdural catheters, and connecting tubing for percutaneous fluid-coupled devices

(2) *Patient/device interfaces for remote-sensor, servomechanism-regulated devices,* such as percutaneous optical, pneumatic, or electrical leads; remote transducers; internal pneumatic devices; and display modules

(3) *Implantable electrical transducers with percutaneous leads* (strain gauges), such as implantable, diaphragm-mounted, strain-gauge transducers and implantable, passive-resistance, circuit transducers (variable inductance and capacitance)

(4) *Fully implantable devices,* such as variable oscillators, passive-absorption devices, and interrogators, receivers, display modules, power sources, and pressure-balancing devices for the transducers in (3)

1.3 Exclusions

This standard does not cover components that may be used with the ICP monitoring device to expand its therapeutic or diagnostic applications (for example, drainage bags for cerebrospinal fluid collection or computer additions for trend analysis). Neither does this standard cover tonometric devices limited to external scalp-fontanel applications. If such additions to the ICP monitoring device are supplied by the manufacturer, the manufacturer must demonstrate that they do not compromise compliance with this standard. Specifically, the manufacturer must address the possibility of physiologic alterations in the patient that might compromise the accuracy or reliability of the ICP monitor (for example, ventricular collapse might occur with use of fluid-coupled ventricular monitors during simultaneous CSF drainage and ICP