American National Standard

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PREVIEW COPY

Intracranial pressure monitoring devices

AAMI Association for the Advancement of Medical Instrumentation

Association for the Advancement of Medical Instrumentation
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Intracranial Pressure Monitoring Devices

Developed by
Association for the Advancement of Medical Instrumentation

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American National Standards Institute

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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
Eric R. Cosman, Ph.D., Radionics
Robert M. Crowell, M.D., University of Illinois, Chicago
J. S. Donovan, Pain Suppression Labs
Marc A. Flitter, M.D., Erie, PA
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Harry Friedman, M.D., Memphis Neurosurgical Clinic, Memphis, TN
Eric King-Smith, Ph.D., 3M
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Pierre L. LeRoy, M.D., Wilmington, DE
Alex Lifson, M.D., Sister Kenny Institute, Minneapolis, MN
Donlin Long, M.D., Johns Hopkins Hospital, Baltimore, MD
Carl P. Mason, M.S.B.E., VA Rehabilitation Engineering Center, New York, NY
Keith Mullett, Medtronic
Robert Munzner, Ph.D., Center for Devices and Radiological Health, FDA
Richard Penn, M.D., Rush Presbyterian/St. Luke's Medical Center, Chicago, IL
Michael Salcman, M.D., University of Maryland, Baltimore
Marvin Sussman, Ph.D., Cordis Corporation

Clark Watts, M.D., University of Missouri, Columbia
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 Court, NJ
Marc A. Flitter, M.D., Erie, PA
Harry Friedman, M.D., Memphis Neurosurgical Clinic, Memphis, TN
Floyd L. Haar, M.D., University of Texas Medical School, Houston
John Hall, American Edwards Laboratories
Pierre L. LeRoy, M.D., Wilmington, DE
Allan B. Levin, M.D., University of Wisconsin Hospital, Madison
C. Patrick McGraw, Ph.D., University of Louisville School of Medicine, Louisville, KY
Glenn A. Meyer, M.D., Medical College of Wisconsin, Milwaukee
Robert Munzner, Ph.D., Center for Devices and Radiological Health, FDA
David Piepgras, M.D., Ph.D., Mayo Clinic, Rochester, MN
Harold Portnoy, M.D., Oakland Neurological Clinic, Bloomfield Hills, MI
Richard Saunders, M.D., Hitchcock Medical Center, Hanover, NH
Gerald Silverberg, M.D., Stanford University Medical Center, Stanford, CA
Marvin Sussman, Ph.D., Cordis Corporation
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, Ladd 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

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monitoring).