List of Titles

American National Standard

ANSI/AAMI NS28:1988/(R)2001

Intracranial pressure monitoring devices

AAMI Association for the Advancement of Medical Instrumentation

List of Titles

Association for the Advancement of Medical Instrumentation
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NS28 Intracranial Pressure Monitoring Devices (Corrected Copy)

Intracranial Pressure Monitoring Devices

Developed by
Association for the Advancement of Medical Instrumentation

Approved 17 November 1988 by
American National Standards Institute

Reaffirmed 23 July 2001

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:

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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

monitoring).

2. Applicable Documents.

To the extent specified by this standard, compliance with the following documents is required.

2.1 American Society for Testing and Materials. Standard classification for silicone elastomers used in medical applications (ASTM F604-78). Philadelphia, PA: ASTM: 1978.

2.2 American Society for Testing and Materials. Standard practice for assessment of compatibility of nonporous polymeric materials for surgical implants with regard to effect of materials on tissue (ASTM F469-78). Philadelphia, PA: ASTM: 1978.

2.3 American Society for Testing and Materials. Standard practice for evaluating and specifying implantable shunt assemblies for neurosurgical application (ASTM F647-79). Philadelphia, PA: ASTM; 1979.

2.4 American Society for Testing and Materials. Standard specification for cast cobalt-chromium-molybdenum alloy for surgical implant applications (ASTM F75-76). Philadelphia, PA: ASTM; 1976.

2.5 American Society for Testing and Materials. Standard specification for stainless steel bar and wire for surgical implants (ASTM F55-82). Philadelphia, PA: ASTM; 1982.

2.6 American Society for Testing and Materials. Standard specification for stainless steel bar and wire for surgical implants (special quality) (ASTM F138-82). Philadelphia, PA: ASTM; 1982.

2.7 American Society for Testing and Materials. Standard specification for unalloyed titanium for surgical implant applications (ASTM F67-77). Philadelphia, PA: ASTM; 1977.

2.8 American Society for Testing and Materials. Standard specification for wrought cobalt-chromium-tungsten nickel alloy for surgical implant applications (ASTM F90-82). Philadelphia, PA: ASTM; 1982.

2.9 American Society for Testing and Materials. Standard test methods for radiopacity of plastics for medical use (ASTM F640-79). Philadelphia, PA: ASTM; 1979.

2.10 Association for the Advancement of Medical Instrumentation. Safe current limits for electromedical apparatus (ANSI/AAMI ES1-1985). Arlington, VA: AAMI; 1985.

2.11 Rosenbluth, S.A.; Weddington, G.R.; Guess, W.L.; Autian, J. Tissue culture method for screening toxicity of plastic materials to be used in medical practice. J. Pharm. Sci. 54: 156-159: 1965.

2.12 United States Pharmacopeia (Vol. 21). Easton, PA: Mack Publishing Company; 1985.

3. Requirements

3.1 Labeling Requirements

The requirements of this section, in addition to the requirements of federal regulations applicable to all medical devices, shall apply to ICP devices.

3.1.1 Device and Package Labeling

3.1.1.1 Device Identification. Identifying information shall be clearly marked on each ICP device, or, if the device is too small or it is otherwise inappropriate to label directly on the device, on the immediate device package. This information shall consist of the following:

(1) The manufacturer's name, symbol, trademark, or other clear means of identification

(2) The manufacturer's address

(3) The device's name, catalog or model number, or other clear means of identification

(4) The device's lot number, serial number, or both

3.1.1.2 Storage Conditions. Labeling on the device or its package shall describe recommended storage conditions or refer the user to the package insert for information on storage conditions.

3.1.1.3 Sterility Designation. Whether or not the device is supplied sterile shall be indicated on the device, its package, or both.

3.1.1.4 Directionality Marking. Any ICP device or component that must be inserted or joined in a specific manner for proper placement or function shall be labeled or marked with arrows, insertion characters, or other indicators, or shall be accompanied by clear directions in the package insert.

3.1.1.5 Calibration. Calibration requirements to ensure the proper function of the ICP device shall appear on the device, in the package insert, or in other provided labeling.

3.1.1.6 Controls and Indicators. The functions of all controls and indicators shall be clearly labeled on the device and explained in the package insert or other provided labeling.

3.1.2 Physician Information. A package insert or an instruction or operator's manual containing technical and performance information, adequate instructions for proper use of the device, and appropriate warnings and precautions shall be provided with each ICP device. At a minimum, the following information shall be included.

3.1.2.1 Device Characteristics

(1) The maximum *frequency response* of the ICP system, including the ICP readout display, at peak pressures of 10, 20, and 50 tort (mmHg).

(2) The *slew rates* (the system's fastest output during a unit of time) from zero to peak and peak to zero for peak pressures of 10, 20, and 50 tort.

(3) The *time constants* for full-scale deflection of the system, with both increasing and decreasing pressure.

(4) The *pressure range* over which the ICP system will accurately perform, specified in torr, centimeters of water, or both, and the *accuracy* of the ICP system, specified in both absolute values and in percentage error, over the minimum range of 3.2.1 and (if applicable) over the extended pressure range claimed by the manufacturer. The expected time period during which the device will maintain the specified accuracy shall also be disclosed (see also 3.2.2).

(5) The *pressure range of the display module,* specified in torr, centimeters of water, or both, and the *accuracy of the display module* over the specified pressure range.

(6) The *size of the intracranial portion* of the ICP monitoring system, described in three dimensions.

(7) The *size of the skull hole* needed for safe implantation of the intracranial portion of the ICP monitor.

(8) The *stability of the pressure measurements* of the complete system, including any external transducers and strain gauges, over the temperature range of 20 to 39°C (68 to 102°F).

(9) The *expected drift of the zero-point reading* of the ICP sensing device and readout and the frequency with which the zero point should be corrected because of drift. For fully implantable ICP devices, the expected daily drift shall be given in torr, centimeters of water, or both. The length of time over which the recordings are likely to be meaningful shall be specified.

(10) The volume of *dead space,* in milliliters or cubic centimeters, for intraventricular, percutaneous, hydrostatic devices.

3.1.2.2 Cautions, Warnings, and Handling Instructions. The package insert, instruction manual, or operator's manual shall describe the risks or side effects known to be associated with device use. In addition, the following minimum warnings and handling instructions shall be provided.

(1) Instructions for the proper care of the ICP device or system to prevent contamination of devices supplied sterile

(2) A warning against reuse of portions of the ICP system that have been partially or totally implanted in a patient

Note: Devices that are designed for reuse (that can tolerate without degradation of their safety and performance characteristics steam autoclaving at 132°C for one hour or immersion in 1N sodium hydroxide for one hour at room temperature) and that are so labeled, are exempt from this requirement.

(3) Handling instructions, including recommended procedures for handling, storing, cleaning, and (if applicable) sterilizing and resterilizing the device

(4) A warning that additions or modifications of the basic system (except for those supplied or recommended by the manufacturer) may interfere with performance (see also 1.3)

(5) A warning, if applicable, that the materials of composition of implantable portions of the system may cause magnetic interference with magnetic resonance imaging

3.1.2.3 Instructions for Use. Adequate instructions for the proper application and use of the device shall be provided, including the following minimum information:

(1) If applicable, a recommended surgical procedure to implant the device

(2) For intracranial devices requiring skull fixation within a burr hole, the size of the commercially available device needed to create the hole, unless a special device for making the hole is provided as part of the ICP system

(3) For fully implantable devices, a description of the techniques or interrogation procedures needed to obtain ICP readings

(4) For intraventricular, percutaneous, fluid-coupled devices, a description of the procedures for controlling drainage of intraventricular cerebrospinal fluid to prevent contamination of the system

(5) If applicable, a diagram of the device position for the zero reference point

(6) The connection requirements, including the required length or other specifications of any percutaneous device, connecting cable, or tubing between the intracranial portion of the system and the transducer or display module

(7) Information on common problems associated with the device, instructions for detecting, preventing, or remedying device failures that cause loss or inaccuracy of pressure observations, and information on the availability (if any) of specialized back-up technical assistance from the manufacturer

(8) For systems without automatic compensation for temperature and barometric pressure changes, instructions on how the user can compensate for such changes, if compensation is needed

3.1.3 Patient Registration Card. A multi-part registration card shall be provided with each fully implantable ICP monitoring system intended to remain implanted beyond the hospitalization period. The card is to be used to register each patient receiving the implantable ICP monitor. Copies of the card shall be provided for the patient or the patient's legal representative, the physician, the hospital, and the manufacturer. The manufacturer shall maintain a file of the cards returned. The card shall contain at least the following information:

(1) The name and address of the patient

(2) The name and address of the responsible manufacturer or distributor

(3) The established name, trade name, and model of the device

(4) A brief description of the device

(5) Appropriate warnings and precautions

3.2 Safety and Performance Requirements

3.2.1 Pressure Range. The minimum pressure range of the ICP monitoring system and of the pressure display module shall be 0 to 100 torr or 0 to 140 cm of water.

3.2.2 Accuracy. The ICP monitoring system, including readout display, shall have a maximum error, measured in vitro, of ± 2 cm of water in the range of 0 to 20 cm of water, or ± 2 torr in the range of 0 to 20 torr. In the range of 20 to 100 torr (20 to 140 cm of water), the maximum error shall be ± 10 percent.

3.2.3 Pressure-Tight Connections. All connections in an ICP system that are coupled to an external transducer by either fluid or air shall be designed to prevent leakage, in a pressure range of - 10 to 185 torr (- 15 to 250 cm of water), into or out of the system. Connections shall remain pressure-tight for the maximum recommended implant time, or 10 days, whichever is longer.

3.2.4 Risk Currents. Percutaneous devices that are connected with or are a part of electrically powered systems, and fully implantable devices that are interrogated by powered external devices that can contact the patient, shall comply with the risk current limits specified in the American National Standard, *Safe Current Limits for Electromedical Apparatus* (Applicable Document 2.10).

3.2.5 Maximum Temperatures. Implantable portions of ICP systems shall not produce temperatures exceeding 40°C (104°F).

3.2.6 Maximum Pressures. Implantable intracranial portions of ICP monitoring devices shall remain intact and undamaged under the maximum pressures that can be generated by the device. The ICP monitoring device shall include external failsafe and warning mechanisms to indicate if the applied pressures become excessive. If applicable, the device shall include alarms to report the occurrence of pumping events that could produce excessive pressure.

3.2.7 Measurement Recordings. The ICP system shall provide either a "hard-copy" permanent record of pressure measurements or an interface for user-provided recording devices.

3.2.8 Temperature and Pressure Compensation. Systems with intracranial components sensitive to temperature and barometric pressure shall have an automatic means of compensating for the changes, or a means shall be provided for the user to compensate for the changes.

3.2.9 Materials of Composition. The following metals, when used to fabricate implantable components of ICP monitoring systems, shall comply with the standards indicated:

(1) *Stainless steel:* ASTM F55-82 (Applicable Document 2.5) or ASTM F138-82 (Applicable Document 2.6)

(2) *Titanium:* ASTM F67-92 (Applicable Document 2.7)

(3) *Cast cobalt-chromium-molybdenum alloy:* ASTM F75-76 (Applicable Document 2.4)

(4) *Wrought cobalt-chromium-tungsten-nickel alloy:* ASTM F90-82 (Applicable Document 2.8)

3.2.10 Radiopacity. All implantable components of ICP monitoring systems shall have radiopaque portions.

3.2.11 Biocompatibility

3.2.11.1 Extractable Metals. Polymeric materials used in implantable components of ICP monitoring systems shall have 10 ppm or less, each, of extractable antimony, arsenic, bismuth, copper, lead, cadmium, mercury, and tin.

3.2.11.2 Tissue Reaction. Each polymeric formulation used in implantable components of ICP monitoring systems shall be tested by cell culture, by extraction and intracutaneous injection in rabbits, and by the method described in ASTM F469-78 (Applicable Document 2.2), and shall produce tissue reactions acceptable for implantable devices.

3.2.12. Interfaces. Interfaces of mated ICP components (for example, connector-catheter interfaces) shall be fabricated from the same materials or nonreactive materials.

3.2.13 Cleanliness. Implantable components of an ICP system shall be clean and free of visible surface particulates and foreign matter.

3.2.14 Surface Irregularities. Components of an ICP monitoring system shall be free of surface irregularities, molding or extrusion defects, and any other physical imperfections that could harm the patient or cause measurement inaccuracy.

3.2.15 Sterile Packaging. An ICP device or component that is claimed to be sterile shall be packaged to allow for sterile-pass-through procedures in the operating room.

3.2.16 Pyrogenicity. If provided sterile, implantable components of an ICP system shall be nonpyrogenic.

4. Tests.

This section describes test methods and procedures by which compliance of the device with the requirements of Section 3 can be verified. These methods are intended as referee tests and are not necessarily suitable for routine quality assurance. However, quality control should be maintained to ensure continued compliance with the standard. For design qualification, alternative tests may be used if they yield results equivalent to those obtained with the referee tests. The paragraphs of this section are numbered to correspond to the requirements of Section 3; for example, compliance with the requirements of 3.2.1 can be ascertained by test method 4.2.1.

4.1 Labeling Requirements

4.1.1 Device and Packaging Labeling. Compliance with 3.1.1 can be verified by inspection.

4.1.2 Physician Information

4.1.2.1 Device Characteristics

(1) *Frequency Response.* Testing is carried out in a pressure chamber that provides a means of varying sinusoidally, with a known frequency, the pressure of the fluid in the chamber. A reference transducer, consisting of a strain gauge and recording system with a known high-frequency response, is directly coupled to the pressure chamber to detect the actual pressure variations within the chamber. The temperature of the chamber must be controllable and maintained at 37 ± 0.5°C (98.6 ± 1°F). (See 4.2.2[1].) The maximum frequency response specified by the manufacturer can be verified by the following method.

(a) Place the ICP system in the pressure chamber in a fashion that simulates actual use as closely as possible.

(b) Using the strain gauge and recording system to monitor chamber pressures. adjust the sinusoidal pressure generator to provide a peak chamber pressure of 10 torr at the lowest frequency that can

be selected. Record the pressure indicated by the ICP analog display or recording device (approximately 10 torr).

(c) Slowly increase the frequency of the chamber pressure variations, taking care to ensure that the peak pressure in the chamber remains at 10 torr, while monitoring the pressure indicated by the ICP display. Record the frequency at which the pressure indicated by the ICP display has decreased by 3 decibels.

(d) Repeat steps (a) through (d) for peak chamber pressures of 20 torr and 50 torr.

Note: Frequency response can be *estimated* by determining the slew rate at 10-, 20-, and 50-torr peak chamber pressures (4.1.2.1 [2]) and calculating the frequency response according to $F = SR/2V_p$, where F = maximum frequency response, SR = slew rate, and V_p = peak pressure.

(2) *Slew Rates.* The slew rates specified by the manufacturer can be verified by the following procedure.

(a) Use the same test apparatus used to verify frequency response (4.1.2.1 [1]), except substitute square-wave pressure waveforms for sinusoidal waveforms.

(b) Adjust the square-wave pressure variations so that the square wave pressure varies from 0 to 10 torr. Adjust the width of the square wave so that the analog output of the ICP system can be used to determine the time required for the ICP system to transition from a low pressure (P1) to a high pressure (P2) (see Figure 1).

(c) Determine the slew rate from the dynamic response of the ICP system to the square wave, by dividing the change in pressure by the change in time: slew rate = change in pressure/change in time.

(d) Repeat steps (a) through (c) for peak chamber pressures of 20 torr and 50 torr.

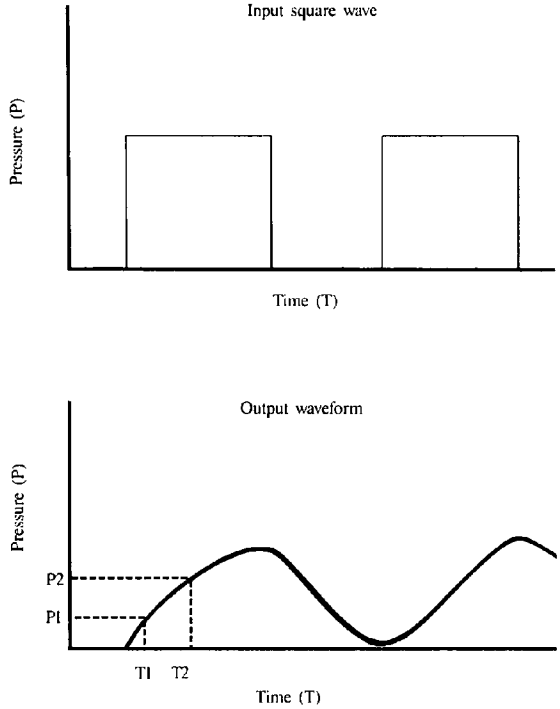

Figure 1. Determining slew rate (slew rate = $\Delta P/\Delta T$ = [P2-P1]/[T2-T1]).

(3) *Time Constants.* Use the test apparatus used to measure slew rate. Using a square-wave pressure waveform with a peak pressure of 10 torr, measure the time required for the ICP system to reach 63 percent of maximum output on the positive-going edge of the waveform. Repeat the measurement on the negative-going edge of the waveform, except record the time required for the system output to

fall 63 percent. Repeat this procedure for peak chamber pressures of 20 torr and 50 torr.

(4) *Pressure Range and Accuracy of the ICP System.* See 4.2.2.

(5) *Pressure Range and Accuracy of the Display Module.* See 4.2.2.

(6) *Size of the lntracranial Portion of the ICP System.* Compliance with 3.1.2.1(6) can be verified by measuring the dimensions of the intracranial portion of the ICP monitoring system and comparing them with the dimensions specified by the manufacturer.

(7) *Size of the Skull Hole.* Compliance with 3.1.2.1(7) can be verified by inspecting the manufacturer's labeling.

(8) *Stability of the Pressure Measurements.* The test setup of 4.2.2 can be used. Adjust the chamber temperature to 20 ± 1°C (68 ± 2°F). Set the chamber pressure to 10 torr, and record the pressure indicated by the ICP display system. Adjust the temperature of the chamber to 39 ± 1°C (102 ± 2°F). With the chamber pressure still set at 10 torr, again record the pressure indicated by the ICP system. Compare the indicated pressures at the two temperatures and record the difference. Repeat for pressures of 20 torr and 50 torr.

(9) *Expected Drift of the Zero-Point Reading.* Calibrate the device according to the manufacturer's instructions in isotonic saline medium at 37°C (98.6°F). During the test of 4.2.2, recheck the zero point periodically. Record and compare any drift in the zero point with the manufacturer's specifications. For specific zero-point testing, set and maintain the pressure in the test chamber (see 4.2.2) at 0 torr or 0 centimeters of water, and record the pressure on the ICP device continuously for a minimum of 10 days. Record any zero-point drift on a 24-hour basis and compare the drift with the manufacturer's specifications.

(10) *Dead Space.* Completely fill the ICP system pressure pathway with water. Drain the water into a calibrated container, and record the volume of water required to fill the pressure pathway.

4.1.2.2 Cautions, Warnings, and Handling Instructions. Compliance with 3.1.2.2 can be verified by inspection.

4.1.2.3 Instructions for Use. Compliance with 3.1.2.3 can be verified by inspection.

4.1.3 Patient Registration Card. Compliance with 3.1.3 can be verified by inspection.

4.2 Safety and Performance Requirements

4.2.1 Pressure Range. See 4.2.2.

4.2.2 Accuracy. The accuracy of the system can be verified by the following method.

(1) Place the ICP sensing device in a pressure chamber that simulates in vivo implantation in a fluid medium. The pressure chamber must be able to regulate the temperature around the sensor to 38 to 40°C (100 to 104°F) and must allow pressures to be held with a reference sensor at 0, 10, 20, 50, and 100 torr (or the appropriate pressures in centimeters of water) for at least 10 days.

(2) Connect the external parts of the ICP system to the ICP sensor in the pressure chamber. Using a calibrated thermometer, adjust the temperature of the medium around the sensor to 38 to 40°C (100 to 104°F).

(3) After the chamber and the ICP sensor have stabilized, continuously record the pressure indicated by the ICP system display, the chamber temperature, and the pressure indicated by the reference sensor. Continue the test for a period at least as long as the recommended implant time for the ICP system, but not less than 10 days.

(4) Repeat steps (1) through (3) for the chamber pressures of 50, 20, 10, and 0 torr.

4.2.3 Pressure Connections. Compliance with 3.2.3 can be ascertained by drawing a vacuum for negative pressure (-5 torr) and conducting the test of 4.2.2.

4.2.4 Risk Currents. Test methods to ascertain compliance of the ICP device with the risk current limits specified in Applicable Document 2.10 are provided in that standard.

4.2.5 Maximum Temperatures. Compliance with 3.2.5 can be determined by daily measurement of surface temperatures during the test of 4.2.2.

4.2.6 Maximum Pressures. The test of 4.2.2 is conducted at the maximum pressure specified for the device and under simulated alarm conditions. The requirements of 3.2.6 are satisfied if there are no disconnections between components and if the device alarms upon occurrence of the conditions specified by the manufacturer.

4.2.7 Measurement Recordings. Compliance with 3.2.7 can be verified by inspection.

4.2.8 Temperature/Pressure Compensation. Compliance with 3.2.8 can be verified by inspection.

4.2.9 Materials of Composition. Criteria to ascertain compliance with Applicable Documents 2.4 through 2.8 are provided in those standards.

4.2.10 Radiopacity. Compliance with 3.2.10 can be verified by means of the test methods of Applicable Document 2.9.

4.2.11 Biocompatibility

4.2.11.1 Extractable Metals. Compliance with 3.2.11.1 can be verified by conventional methods of extraction and microanalysis conforming to Applicable Document 2.12.

4.2.11.2 Tissue Reaction. Compliance with 3.2.11.2 can be verified by the test methods in Applicable Documents 2.2, 2.11, and 2.12.

4.2.12 Interfaces. Standard materials chemistry tests provide criteria for judging the reactivity of materials.

4.2.13 Cleanliness. The requirements of 3.2.13 are satisfied if implantable components of the ICP system are clean and free of visible surface particulates and foreign matter as judged by the unaided eye (having original or restored 20/20 vision) at a distance of 12 to 18 inches with 200 ± 20 footcandles (2,150 ± 215 lux) illuminance.

4.2.14 Surface Irregularities. The requirements of 3.2.14 are satisfied if implantable components of the ICP system are free of surface irregularities and molding or extrusion defects as judged by the unaided eye (having original or restored 20/20 vision) at a distance of 12 to 18 inches and with 200 ± 20 footcandles (2,150 ± 215 lux) illuminance.

4.2.15 Sterile Packaging. Compliance with 3.2.15 can be verified by inspection and by standard techniques for aerobic and anaerobic bacterial and fungal culturing.

4.2.16 Pyrogenicity. Compliance with 3.2.16 can be verified by methodology specified in Applicable Document 2.12.

5. Glossary

Coplanarity. The property of lying in the same plane.

Decibel. One tenth of a bel, the unit used to express power ratios equal to the logarithm to the base 10 of the ratio of any two powers.

Dynamic response. An output expressed as a function of time, resulting from application of specified input under specified operating conditions. Also termed *time response.*

Fontanel. The physiologic soft spot or transcutaneous or transdural "window" in the incompletely ossified skull of the infant, through which can be transduced waveform activity reflecting intracranial pressure, respirations, and pulse rate changes.

Frequency response. The measure of an amplifier's ability to respond to a sinusoidal signal.

Fully implantable device. A surgically inserted device completely internalized within a patient.

Hard copy. A permanent record of a display.

Interrogator. A radiotransmitter and radioreceiver combined to interrogate a transponder and display the resulting replies.

Lead, electrical. A conductor of electricity that connects the transducer portion of a device to the signal-conditioning, display portion.

Lead, optical. A conductor that transmits light and connects the transducer portion of a device to the signal-conditioning, display portion.

Lead, pneumatic. A conductor that transmits gas and connects the transducer portion of a device to the signal-conditioning, display portion.

Module, display. A mechanical, optical, electromechanical, or electronic device for presenting information to the operator about the state or condition of transducers associated with the system.

Monitor assembly, intracranial pressure. The complete system for monitoring intracranial pressure.

Monitoring device, intracranial pressure. A mechanical or electrical contrivance for measuring the cerebrospinal fluid pressure within the brain.

Noninvasive. Not piercing the skin.

Oscillator, variable. An apparatus for producing alternating current, the output frequency of which is determined by the characteristics of the device.

Passive absorption device. A device that monitors fluid absorption caused by pressure (in this case, intracranial pressure).

Passive resistance circuit. A device that measures the amount of physical tension placed on the dura or surface of the brain.

Pneumatic device, internal. An implanted device powered by or using compressed gases.

Power source. The source of energy activating a system.

Pressure-balancing device. The part of the instrument used to adjust the bellows in a pneumatic device or oscillating fluid-pressure device.

Pyrogenic. Fever-producing.

Receiver. An apparatus used to translate a signal from a communications channel.

Servomechanism-regulated device. Any feedback control system.

Slew rate. A measure of programming speed or current-regulator-response timing.

Strain gauge. A device that measures strain by detecting the change in resistance of a thin wire as it is

stretched.

Time constant. The value T in an exponential response term $A^{(-1/T)}$ or in one of the transform factors.

Time response. See Dynamic response.

Tonometric device. An instrument for measuring pressure through an open fontanel by means of surface apposition.

Torr. The unit of pressure equal to 1.3×10^{-3} normal atmospheric pressure, or the pressure necessary to support a column of mercury 1 mm high at 0°C and standard gravity.

Transducer, remote. A device located a distance away from the patient and by means of which energy from one or more transmission systems and media can flow.

Appendix A
Rationale for the Development and Provisions of This Standard

A1. Introduction.

This standard was developed by the ICP Device Subcommittee of the AAMI Neurosurgery Committee. It sets forth the labeling, safety, and performance requirements that the committee considered would provide reasonable assurance of the safety and effectiveness of devices used for ICP monitoring. This standard, like all other standards, is the product of current technology, and as advances in the field occur, it must be modified to reflect new data. In this standard, devices are classified as percutaneous hydrostatic (fluid-coupled) devices, patient-device interfaces, implantable electrical transducers, and fully implantable devices. Although these devices are all used to monitor ICP, they range in complexity from very simple fluid-filled columns to sophisticated, fully implantable, telemetric systems.

A1.1 Intracranial Pressure Monitoring Systems. The most mechanically simple ICP monitoring system consists of a ventricular catheter inserted in the ventricle and connected to a water manometer by means of a hydrostatic column. Ventriculostomy has been associated with minimal morbidity when used to measure ICP for periods of a few days. Several alternative methods of ICP monitoring have been developed (Flitter 1980: Wilkinson 1982), in which intracranial pressure is measured from the subarachnoid, subdural, or epidural space; these methods further reduce the risks of the procedure. With totally implantable systems, ICP monitoring may be performed for several years. A wide variety of commercially available devices are now in routine use. In addition, some clinicians assemble systems using devices, such as infant feeding tubes and red rubber catheters, which have been designed for other purposes. A number of types of solid-state or implantable transducers have been used, with varying degrees of success.

If information on intracranial pressure and waveforms is accurate, deleterious signs may be identified and the patient treated before an irreversible state of brain damage is reached. The ideal pressure monitoring system should minimize the risk of infection and should remain stable with minimal changes due to temperature fluctuations or alterations in atmospheric conditions. These characteristics facilitate routine nursing care.

Lundberg (1960) proposed the following six basic requirements for ICP monitoring.

(1) The procedure should minimize trauma or irritation of intracranial structures.

(2) The risks of intracranial infection should be negligible.

(3) The link between the ventricle and the monitoring apparatus should not leak.

(4) It should be possible to record pressure measurements long-term without discomfort to the patient or disturbance of routine patient care.

(5) It should be possible to continuously record pressure during various diagnostic and therapeutic procedures.

(6) The apparatus should be easily handled, stable, reliable, and reasonably foolproof.

A1.2 History. When disease or trauma disturbs the body's homeostatic mechanisms, progressive deterioration and death may occur. By monitoring various parameters such as ICP, it is often possible to obtain sufficient warning of impending deteriorative changes to take therapeutic actions to maintain the body's physiological systems until normal homeostatic balance returns. Significantly elevated ICP adversely affects cerebral blood flow, cerebral tissue perfusion, and autoregulation (Marmarou and Tabbador 1982). Therapeutic intervention includes cerebrospinal fluid drainage, head elevation, hyperventilation, sedation, maintenance of fluid balance, administration of medications, and surgical intervention (Marshall and Bowers 1982; Tabbador 1982). Physiological monitoring has become a routine procedure in the management of severely ill patients. Most patients are monitored if their state of consciousness deteriorates to the point that they do not open their eyes. Selected patients with subarachnoid hemorrhage, tumor, stroke, severe hypoxia, or encephalopathy are also commonly monitored.

The first serious efforts to measure pressure in the human central nervous system were made at the beginning of this century by Quincke (1905, 1911), Queckenstedt (1916), Ayala (1923), and Ayer (1929). Thus, cerebrospinal fluid pressure was measured and its clinical significance was known before arterial blood pressure monitoring was generally accepted. The normal range of cerebrospinal fluid pressure and the effects of specific respiratory maneuvers and postural changes were determined. Browder and Meyers (1936) measured lumbar cerebrospinal fluid pressures in patients with head injuries and questioned the reliability of clinical observations in predicting changes in ICP. In 1951, Guillaume and Janny demonstrated that neurological signs were unreliable indicators of the presence (or absence) of elevated ICP. They established a firm basis for the usefulness of ICP monitoring and demonstrated the value of continuous ICP monitoring. Several years later, Ryder and coworkers (1953) confirmed their results and amplified their findings.

Lundberg (1960) began the current era of routine and widespread use of ICP monitoring. He assessed the difficulty of making indirect ICP measurements and evaluated the feasibility, safety, reliability, and clinical significance of continuous ICP monitoring. He reported detailed observations of patients in whom pressure had been monitored using ventricular cannulation. The cannula was connected to a rigid, fluid-filled system and then to a pressure transducer/recorder system (or a water manometer). The transducer displayed waveform measurements. This method of ICP monitoring remains the standard against which other techniques are measured. Lundberg found continuous ICP monitoring to be feasible, even in cases of small or displaced ventricles, and he was able to characterize in detail the intracranial pressure waveforms associated with various pathological states. The rate of infection reported in Lundberg's studies was low and clinically acceptable.

A1.3 Clinical Risks. Patients undergoing acute monitoring of ICP are critically ill, and their homeostatic mechanisms are either unbalanced or delicately balanced. Portions of ICP devices come into direct contact with tissues of the central nervous system. Percutaneous devices communicate with the environment and introduce the risk of infection. There are general risks associated with ICP monitoring, as well as specific risks associated with the particular type of monitoring system used. With all systems, the risk of infection accompanies implantation and use. With totally implantable systems, the risk increases with implantation time and decreases after skin incisions heal. With percutaneous systems, the risk continues until the device is removed.

A number of factors are involved in measurement inaccuracies, which also pose a risk to patients. In hydrostatically coupled systems, blockages or air bubbles trapped in the fluid column can obliterate or dampen the monitored waveforms. Fluid leakage at connections in these systems can distort the recorded

waveform and significantly increase the risk of infection. Inaccurate measurements can also result from the drift associated with transducer portions of systems, or from the effects of temperature or barometric pressure changes on transducers. Since decisions on whether or not to intervene are made based on information provided by ICP monitoring, the physician must know how to assess the accuracy of the system employed and must understand which factors contribute to inaccuracies.

A2. Need for a Standard.

Since clinical decisions are made based solely on information derived from ICP monitoring devices, ICP measurements and waveforms must be accurate. Clinicians must be able to determine the accuracy limitations of the system being employed. Manufacturers must produce devices constructed of safe, biocompatible materials, since such materials come into direct contact with central nervous system tissues. Intracranial portions must be free of surface defects and contamination. Devices labeled sterile must be sterile. Device design should not expose patients to unacceptable risks of infection. Devices that are electrically powered must not expose patients to the risk of electrical shock. This standard was developed to address these issues and thus provide reasonable assurance of the safety and effectiveness of commercially available ICP monitoring devices.

Work on the development of a standard for ICP monitoring devices began in 1978, under the auspices of the AAMI Neurosurgery Committee. The goal was to establish criteria that would help provide reasonable assurance that ICP devices were safe and effective for the indications claimed in their labeling. In addition, a standard means of testing and reporting the performance of these devices was considered important, so that physicians evaluating ICP monitoring devices for purchase would be able to make informed comparisons of and selections from commercially available equipment. The committee's conclusion that a performance standard was needed for ICP monitoring devices was reinforced by the published medical literature (see A1.3) and by regulatory action taken on these devices under the Medical Device Amendments of 1976.

On 28 November 1978, the U.S. Food and Drug Administration (FDA) published a proposed rule to classify intracranial pressure monitoring devices as Class II devices. Classifying a device as Class II authorizes the FDA to develop performance standards to assure safety and effectiveness. The FDA's advisory panel on neurological devices had recommended this classification, based on the following risks to health associated with ICP monitoring devices:

(a) Brain damage by pressure. An excessively bulky device could exert damaging pressure on the brain. (b) Brain damage by surgical trauma. The surgery involved in inserting this device presents inherent risks. (c) Inaccurate pressure readings. A defect in the device can result in inaccurate pressure readings. (d) Leakage of cerebrospinal fluid. The device needs to have a tight seal to prevent leakage of cerebrospinal fluid. (e) Infection. Infection may result if the device is not sterile or if contaminants enter the surgical opening.

The advisory panel did not believe that general controls (Class I) would adequately address these potential risks. Premarket approval (Class III), on the other hand, was not deemed necessary, because the panel judged that a performance standard would provide reasonable assurance of safety and effectiveness, and because the panel believed there was sufficient information available to establish such a standard (FDA 1978). On 4 September 1979, the final classification rules for neurosurgical devices were published. Intracranial pressure monitoring devices remained in Class II as originally proposed (FDA 1979).

A3. Rationale for the Specific Provisions of This Standard

A3.1 Labeling Requirements

A3.1.1 Device and Package Labeling/A3.1.2 Physician Information. The requirements of 3.1.1 and 3.1.2 are intended to ensure that sufficient product information will be available to the physician to enable safe and effective use of the device.

The requirement of 3.1.2.2(2) (the warning against reuse of implantable portions of the ICP system) derives

from the committee's concern about the potential transmission of such diseases as Creutzfeldt-Jakob ~~disease by highly resistant "slow viruses"~~ or other transmissible spongiform encephalopathy variants that may be transmitted by highly resistant 'prions'[*] that cannot be reliably killed by conventional inhospital sterilization techniques (including ethylene oxide sterilization and steam autoclaving at 121°C or 132°C for 15 to 30 minutes). According to the American Neurological Association Committee on Health Care Issues, however, the transmitting agent of Creutzfeldt-Jakob disease can be effectively inactivated by subjecting contaminated materials to steam autoclaving for one hour at 132°C or to immersion in 1N sodium hydroxide for one hour at room temperature (American Neurological Association 1986). Consequently. the committee decided to allow an exemption to the requirement for properly labeled devices designed to withstand these sterilizing conditions.

A3.1.3 Patient Registration Card. The registration of chronically implanted intracranial pressure monitoring devices is considered essential for responsible follow-up of product performance by the manufacturer.

A3.2 Safety and Performance Requirements

A3.2.1 Pressure Range. The specified minimum range encompasses the spectrum of observed cerebrospinal fluid pressures in humans. The average cerebrospinal fluid pressure in normal humans, in the lateral recumbent position, has been variously reported as approximately 120 mm saline (12 cm water) (Spina-Franca 1963), approximately 150 mm saline (15 cm water) (Masserman 1934: Merritt and Fremont-Smith 1937: Shulman, Yarnell, and Ransohoff 1964), and approximately 170 mm saline (17 cm water), depending on where the pressure is measured. Pressures between 5 and 18 cm of water are generally considered to be in the normal range, those between 18 and 20 cm of water to be marginally abnormal. and those above 20 cm of water to be definitely indicative of hypertension. Cerebrospinal fluid pressure varies with physiological state, posture, level of wakefulness, body movements, and activities such as yawning and crying. When measured in subjects in the sitting position, the average lumbar cerebrospinal fluid pressure in normal humans has been reported to be approximately 40 cm of water or nearly three times that measured in subjects in the supine position (Masserman 1934). The committee judged that ICP monitoring devices should be capable of measuring and displaying pressures up to 140 cm of water (100 torr) in order to accommodate, with a generous margin, the pressures that would be seen in patients with abnormally elevated pressures measured at the sites and in the patient positions that are conventionally used in clinical practice.

A3.2.2 Accuracy. As described in A3.2.1, cerebrospinal fluid pressure fluctuates with the posture, level of wakefulness, yawning and crying activities, body movements, and physiological state of the subject. Also, cerebrospinal fluid pressure pulsates with the cardiac pulse and with respiration. The higher the mean pressure, the larger are the pulses. The pressure variation is greater measured intracranially than in the cisterna magna or lumbar subarachnoid space. These phenomena are well discussed in Davson (1970) and Milhorat (1972). Since the ICP monitoring device measures pressures in a dynamic system with inherent pressure variations, the goal is to minimize the measurement errors attributable to the device itself. The accuracy specifications of 3.2.2 are technologically feasible, yet the permissible maximum errors reflect pressure variations below those which would be considered clinically significant.

A3.2.3 Pressure Connections. Leaks in the intracranial pressure monitoring system can affect measurement accuracy and can result in patient infection.

A3.2.4 Risk Currents. The rationale for the risk current limits specified in the American National Standard, *Safe Current Limits for Electromedical Apparatus*, is provided in that standard.

A3.2.5 Maximum Temperatures. Temperatures exceeding 40°C may interfere with the performance of the ICP monitoring system or damage brain tissue.

A3.2.6 Maximum Pressures. If implantable portions of the device cannot withstand the maximum pressures that can be generated by the device, injury to brain tissue is a risk and, in addition, measurement

[*] Erratum issued June 2001

accuracy may be compromised.

A3.2.7 Measurement Recordings. A permanent record of intracranial pressure measurements enables the physician to evaluate fluctuations in pressure over time. It also is needed for patient records.

A3.2.8 Temperature and Pressure Compensation. Pressure measurements can be significantly affected by temperature and barometric pressure, which must be compensated for to ensure meaningful, accurate measurements.

A3.2.9 Materials of Composition. Long clinical experience with the metals listed in 3.2.9 has demonstrated their safety and effectiveness for surgical implant purposes.

A3.2.10 Radiopacity. Radiopacity of implantable components of ICP monitoring systems is necessary to facilitate placement of components at the time of implantation and to evaluate their integrity and position after implantation. Also, if components become disengaged, radiopacity facilitates retrieval.

A3.2.11 Biocompatibility

A3.2.11.1 Extractable Metals. Extractable metals within polymeric materials can cause serious brain tissue damage if present at levels sufficient to leach out of the polymer.

A3.2.11.2 Tissue Reaction. Implantable components of ICP monitoring systems may be in contact with brain tissue for as long as 41 days (Tindall et al. 1975)—or even permanently—and thus must be shown to be biocompatible. The tests referenced in 4.2.11.2 are those commonly used to evaluate biocompatibility.

A3.2.12 Interfaces. Electrochemical reactions between materials will cause them to deteriorate, and leaks in the intracranial monitoring system or inaccurate measurements may result.

A3.2.13 Cleanliness. Particulates can cause granulomas, blood clots and emboli, and antigenic reactions.

A3.2.14 Surface Irregularities. Surface irregularities may interfere with implantation or removal of the components or may injure brain tissue.

A3.2.15 Sterile Packaging. Packaging allowing for sterile-pass-through procedures in the operating room gives the best assurance that the device or component will not be inadvertently contaminated prior to or during implantation, thus minimizing the risk of patient infection.

A3.2.16 Pyrogenicity. Sterilization processes destroy living microorganisms and spores, but do not remove bacterial fragments that can cause febrile reactions in patients. Therefore, care must be taken, during the manufacture of devices to be used sterile, to minimize the number of microorganisms on devices (that is, their bioburden) so that the amount of bacterial debris will be small enough to avoid pyrogenicity. The test specified in 4.2.16 is the conventional test used by industry to evaluate pyrogenicity.

A3.3 Other Safety and Performance Considerations. Other safety and performance criteria should be considered in the design of an intracranial pressure monitoring device. However, many of these criteria are difficult to specify, because they are subject to clinical judgment and compliance cannot easily be verified by in vitro testing or animal investigations. Among these criteria are the following:

(1) Percutaneous systems should allow adequate scalp wound closure to minimize the risk of fluid leakage around the lead and should not inherently cause ischemic tissue damage.

(2) Intracranial portions of ICP devices intended to be placed subdurally or epidurally should not inherently produce undue cerebral tissue damage. Intraventricular catheters used in ICP devices should not produce undue tissue damage when introduced or removed by standard neurosurgical techniques.

(3) Percutaneous devices intended for use with ventricular catheters should allow drainage of cerebrospinal fluid under controlled sterile conditions and should be designed to allow the user to

ensure reasonable stability of the catheter position. It should be noted, though, that the validity of simultaneous ICP monitoring and drainage remains controversial.

(4) Insertion of intracranial sensors or transducers that rely on contact between the dura or brain and a pressure-sensitive membrane should allow the entire pressure-sensitive membrane to be placed in contact with the dura or brain. Such devices should be constructed so that adequate contact will be made if the recommended instructions for use are followed. They should also be constructed so that the indentation of the membranes or tissues will not in itself cause curvature effects that will alter the intrinsic accuracy of measurements. In addition, indentation of brain tissue should be minimal to avoid undue pressure on or structural damage to brain tissue. The volume of an implantable sensor should be small enough not to affect overall intracranial pressure.

(5) The ICP monitoring system should not preclude patient mobility, routine nursing care, safe positioning, or transport of the patient.

(6) Systems using intracranial transducers, either percutaneous or fully implantable, should not produce, during usual and customary insertion procedures, additional intracranial pressure elevation to a degree that is potentially harmful. Use of a lumen or system filter should not affect intracranial pressure/flow characteristics. Remote-sensor, servomechanism ICP monitoring devices should be designed so that excessive pumping of gas or fluid intracranially, which would produce excessive pressure and consequently damage the device or harm the patient, is prevented.

(7) Magnetic materials will interfere with magnetic resonance imaging. Therefore, implantable portions of ICP monitoring systems should, preferably, be composed of materials that are radiopaque but nonmagnetic.

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Note: This appendix is not part of ANSI/AAMI NS28-1988. but is included for information only.