American National Standard

ANSI/AAMI BP22:1994/(R)2016

Blood pressure transducers

AAMI
Advancing Safety in Healthcare Technology

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ANSI/AAMI BP22:1994/(R)2001/(R)2006/(R)2011/(R)2016
Revision/combination of
ANSI/AAMI BP22:1986 &
ANSI/AAMI BP23:1986

Blood pressure transducers

Developed by
AAMI

Approved 30 August 1994 and reaffirmed 14 December 2011 and 6 January 2017 by
American National Standards Institute, Inc.

Abstract:

This standard provides performance and safety requirements for transducers, including cables, designed for blood pressure measurements through an indwelling catheter or direct puncture, and also provides disclosure requirements to permit the user to determine the compatibility between the transducer and blood pressure monitor. This standard is a combined revision of two American National Standards (ANSI/AAMI BP22—1986 and ANSI/AAMI BP23—1986).

Association for the Advancement of Medical Instrumentation

Blood Pressure Monitoring Committee

This standard was developed by the **AAMI Blood Pressure Monitoring Committee**. Committee approval of the standard does not necessarily imply that all committee members and reviewers voted for its approval. The committee currently has the following members:

Cochairpersons: Tommy Cooper, MSEE, PE
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Members: John M.K. Bruner, MD, American Society of Anesthesiologists
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Alternates: Roy Hays, SpaceLabs Medical
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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 is a combination and a revision of two American National Standards, *Blood pressure transducers, general* (BP22) and *Interchangeability and performance of resistive bridge type blood pressure transducers* (BP23), both of which were originally approved in 1986.

This standard was developed by the Blood Pressure Monitoring Committee of the Association for the Advancement of Medical Instrumentation. The objective of this standard is to provide labeling and performance requirements, test methodology, and terminology that will help ensure that health care professionals are supplied with safe, accurate blood pressure transducers.

Substantive changes from the original standards appear in this revision/combination. The requirement for a standard connector to achieve interchangeability was eliminated; however, many of the electrical requirements for ensuring interchangeability were retained. The sensitivity and nonlinearity/hysteresis requirements were replaced by an accuracy error band requirement. A test method using alternating current excitation was added along with a synchronous demodulator circuit for performing the test. Catheter tip transducers were included in this standard. A labeling provision was added to allow transducers that cannot withstand defibrillation discharges to be identified. The volume displacement requirement, which was to ensure adequate reproduction of pressure waveforms, was replaced by a frequency response requirement.

This standard reflects the conscientious efforts of concerned health care professionals, device manufacturers, and government representatives to develop a standard for those performance levels that could be reasonably achieved at this time.

The concepts incorporated in this document should not be considered inflexible or static. This standard, like any other, must be modified as advances are made in technology and as new data become available. AAMI standards development procedures require that all standards are reviewed and, if necessary, updated at least once every five years.

As used within the context of this document, "shall" indicates requirements strictly to be followed in order to conform to the standard; "should" indicates that among several possibilities one is recommended as particularly suitable, without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required, or that (in the negative form) a certain possibility or course of action should be avoided but is not prohibited; "may" is used to indicate a course of action is permissible within the limits of the recommended practice; and "can" is used as a statement of possibility and capability. "Must" is used only to describe "unavoidable" situations, including those mandated by government regulation.

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

NOTE—This foreword is not a part of the American National Standard, *Blood pressure transducers* (ANSI/AAMI BP22—1994).

Blood pressure transducers

1 Scope

1.1 General

This standard applies to pressure transducers, including cables, used to measure blood pressure through catheters or direct vascular puncture. Physiological measurements other than blood pressure may be taken with this transducer, although the requirements and tests of this standard were developed and designed with blood pressure measurement as the intended application of the device. Even though this standard addresses the safety and efficacy of the transducer for measurement of blood pressure, care should be exercised to ensure the compatibility of the particular transducer and blood pressure monitor.

1.2 Inclusions

Included within the scope of this standard are safety and performance requirements for transducers, including cables, designed for blood pressure measurements through an indwelling catheter or direct puncture and disclosure requirements to permit the user to determine compatibility between the transducer and blood pressure monitor.

1.3 Exclusions

Excluded from the scope of this standard are transducers designed specifically for the measurement of other physiological parameters. This standard does not address operating procedures for the transducer or monitor. Therefore, it is necessary to consult appropriate instruction manuals to set up, balance, and calibrate the system properly.

NOTE—For an explanation of the rationale for the provisions of this standard as well as a statement of the need for the standard, see annex A.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of the American National Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below.

2.1 ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Cardiac defibrillator devices*. ANSI/AAMI DF2—1989. Arlington (Vir.): AAMI, 1989.

2.2 ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Evaluation of clinical systems for invasive blood pressure monitoring.* AAMI TIR9. Arlington (Vir.): AAMI, 1992.

2.3 ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Safe current limits for electromedical apparatus.* ANSI/AAMI ES1—1993. Arlington (Vir.): AAMI, 1993.

2.4 AMERICAN NATIONAL STANDARDS INSTITUTE. *Medical materiel—Luer taper fittings—Performance.* ANSI/HIMA MD 70.1—1983. New York, NY: ANSI, 1983. (Withdrawn.)

NOTE—The following international standards are equivalent to the above-mentioned American National Standard:

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION. *Conical fittings with a 6% (Luer) taper for syringes, needles, and certain other medical equipment—Part 1: General requirements.* ISO 594/1—1986. Geneva, Switzerland: ISO, 1986; and