

**American
National
Standard**

ANSI/AAMI BP22:1994/(R)2006

Blood pressure transducers



**Association for the Advancement
of Medical Instrumentation**

1110 N. Glebe Rd., Suite 220

Arlington, VA 22201-4795

PREVIEW COPY

© 2000 by the Association for the Advancement of Medical Instrumentation.
This is a preview edition of an AAMI guidance document and is
intended to allow potential purchasers to evaluate the content of the
document before making a purchasing decision.
All Rights Reserved

For a complete copy of this AAMI document,
contact AAMI at (877) 249-8226
or visit www.aami.org.

Copyright and Permissions

Publication, reproduction, photocopying, storage, or transmission, electronically or otherwise, of all or any part of these documents without the prior written permission of the Association for the Advancement of Medical Instrumentation or the copyright holder (if not AAMI) is prohibited by law. It is illegal under federal law (17 U.S.C. § 101, *et seq.*) to make copies of all or any part of these documents (whether internally or externally) without the prior written permission of the copyright holder. Violators risk legal action, including civil and criminal penalties, and damages of \$100,000 per offense. For permission regarding the use of all or any part of these documents, contact AAMI, 1110 N. Glebe Road, Suite 220, Arlington, VA 22201-4795. Phone: (703) 525-4890; Fax: (703) 525-1067.

Violators of this copyright policy should be reported to AAMI's legal counsel:

McKenna & Cuneo, L.L.P.
1900 K Street, N.W.
Washington, DC 20006
Attn: Jacqueline A. Henson, Esq.
Phone: (202) 496-7500

Blood pressure transducers

American National Standard

ANSI/AAMI BP22:1994/(R)2001/(R)2006

Revision/combination of
ANSI/AAMI BP22:1986 &
ANSI/AAMI BP23:1986

Blood pressure transducers

Developed by

Association for the Advancement of Medical Instrumentation

Approved 30 August 1994 by

American National Standards Institute, Inc.

This standard is a preview edition of an AAMI guidance document and is intended to allow potential purchasers to evaluate the content of the document before making a purchasing decision.

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
A. William Paulsen, PhD, CCE

Members: John M.R. Bruner, MD, American Society of Anesthesiologists
LeRoy Buckhoy, CBET, Loyola University Medical Center,
Maywood, Illinois
Harlow B. Christianson, PhD, Abbott Laboratories
Tommy Cooper, MSEE, PE, Cooper Consulting Services
Steve Daleo, PPG Biomedical
Melvin Fink, CBET, ServiceMaster
Wesley T. Frazier, MD, Emory University Hospital, Atlanta, Georgia
Alvis Jordans, U.S. Food and Drug Administration
Martin J. Kutik, ppd Consulting
H.D. Millar, Millar Instruments
Carl A. Pantiskas, SpaceLabs Medical
A. William Paulsen, PhD, CCE, West Virginia University Health
Sciences Center, Morgantown, West Virginia

John W. Raynes, Becton Dickinson & Company
Kay Rutishauser, RN, American Association of Critical Care Nurses
Dwight E. Shields, University of Washington Hospital,
Seattle, Washington
Joshua E. Tsitlik, PhD, Johns Hopkins Medical Institutions,
Baltimore, Maryland
William Dean Wallace, MD, PhD, Utah Medical Products
Gregory Welyczko, Ohmeda Anesthesia

Alternates: Roy Hays, SpaceLabs Medical
Steven G. Slaughter, Abbott Critical Care Systems
Jeffrey P. Milsap, CCE, Ohmeda Anesthesia

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 included. 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](#).