List of Titles

American National Standard

ANSI/AAMI BP22:1994/(R)2001

Blood pressure transducers

AAMI Association for the Advancement of Medical Instrumentation

List of Titles

Association for the Advancement of Medical Instrumentation
1110 N. Glebe Rd., Suite 220
Arlington, VA 22201-4795

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BP22 Blood Pressure Transducers

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American National Standard

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

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.

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

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION. *Conical fittings with a 6% (Luer) taper for syringes, needles, and certain other medical equipment—Part 2: Lock fittings.* ISO 594/2—1991. Geneva, Switzerland: ISO, 1991.

2.5 INSTRUMENT SOCIETY OF AMERICA. *Electrical transducer nomenclature and terminology*. ANSI/ISA-S37.1—1975 R1982. Research Triangle Park (NC): ISA, 1982.

3 Definitions

For the purposes of this American National Standard, the following definitions apply:

3.1 accuracy: Ratio of the error (measured minus true) to the true or theoretical value expressed as a percentage.

3.2 balance: Either a condition of symmetry in a Wheatstone bridge or the condition of zero output from the bridge when properly energized.

3.3 critical damping: Value of damping which yields the minimum settling time to a step input without overshoot.

3.4 damping: Energy-dissipating characteristics which together with natural frequency determine the upper limits of frequency response and the response time characteristics of the transducer.

3.5 damping coefficient: Ratio of the actual damping to the damping required for critical damping.

3.6 diaphragm: Sensing element consisting of a membrane placed between two volumes. The membrane is deformed by the pressure differential applied across it.

3.7 electrical calibration: Calibration of accessory equipment during which the transducer is deliberately unbalanced electrically by means of a calibration resistor placed across one leg of the bridge or a ratio divider across the excitation to simulate a known pressure.

3.8 excitation: External electrical voltage or current applied to a transducer for its proper operation.

3.9 excitation impedance: Impedance presented to the excitation source and measured across the excitation terminal of the transducer. Sometimes called "input impedance."

3.10 frequency response: Change in output amplitude ratio for a sinusoidal varying pressure, which for a second order system is defined by the undamped natural frequency and damping coefficient.

3.11 15% bandwidth: The bandwidth over which the frequency response amplitude is within 15% of the flat low-frequency amplitude.

3.12 hysteresis: Maximum difference in output of a pressure-measuring device at a given pressure value within a range when the value is approached first with increasing and then with decreasing pressure.

3.13 point-based linearity: Nonlinearity expressed as deviation from a straight line passing through a given point or points.

3.14 resistive bridge transducer: Transducer capable of excitation from alternating or direct currents and whose output is directly proportional to the product of the applied pressure and excitation.

3.15 resonant frequency: Frequency at which an electrical or mechanical system (second order) will oscillate when the damping coefficient is zero. Also called the "undamped natural frequency."

3.16 sensitivity: Ratio of the change in transducer output to a change of the value of the pressure at a given excitation voltage.

3.17 signal impedance: Effective impedance across the output terminals of the transducer presented by the

transducer to the associated external circuitry. Sometimes called "output impedance."

3.18 symmetry: Centering of the transducer common mode signal output between the excitation voltages.

4 Requirements

4.1 Labeling requirements

The term "labeling" refers to any printed matter or markings that appear on the device, its accessory items, or its container, and to all documentation that accompanies the device. In addition to federal regulations applicable to the labeling of all medical devices, the requirements contained in the section shall apply to devices within the scope of this standard.

4.1.1 Device markings

The device (or package, in the case of disposable devices) shall be permanently and visibly marked with the following information:

a) the model number;

b) the name of the manufacturer;

c) the serial number or other manufacturing control identification;

d) the reusable electrical components should be marked with the serial number or other controlling identification.

4.1.2 Instruction manual

Instructions shall be provided with each transducer or reusable cable or, in the case of multiple units, as stipulated in the purchase order. At a minimum, the following information shall be included in the instruction manual:

a) the excitation voltage (or voltage range);

b) the excitation frequency (or frequency range);

c) the excitation impedance or component characteristics for the excitation voltage and frequency specified in (a) and (b);

d) the transducer signal impedance, with a specified tolerance;

e) the maximum phase shift or phase characteristic over the excitation frequency range specified in (b), where applicable;

f) the nominal transducer sensitivity for the ideal transducer output;

g) the transducer cable to monitor connector and corresponding monitor manufacturer, including a wiring table to enable connection to the blood pressure monitor for proper operation and safety;

h) cautions and warnings about storage, use, handling, and sterilization of the transducer assembly;

i) a list of recommended accessories to be used with the transducer, including domes, mounting clips, and other devices;

j) the recommended procedure for connecting the transducer to the hydraulic system;

k) detailed instructions for cleaning and sterilizing the transducer, dome, and other related parts, if applicable;

l) instructions for use, care, storage, handling, and maintenance of the transducer to ensure functional integrity of the device;

m) the names and addresses of acceptable customer service facilities;

n) the magnitude of half-sine shock acceleration that the transducer can be subjected to on each axis and still meet the requirements of section 4.2, given that the unbalance limits of 4.2.3.7 may increase to 150 mmHg;

o) the maximum deviation from the initial transducer zero at 25 ± 1°C over 4 hours in mmHg after the recommended warm-up time;

p) the error band of zero shift in mmHg for a temperature change of 25°C to 15°C and 25°C to 40°C in mmHg after the recommended warm-up time;

q) the error band of sensitivity from 25°C to 15°C and from 25°C to 40°C expressed as a percentage change from 25°C;

r) the light sensitivity of the transducer at 3,000 foot-candles from a 3,400° Kelvin (K) tungsten light source at zero pressure in mmHg. The maximum error should be stated over the stated excitation voltage range.

4.2 Performance requirements for the transducer

4.2.1 Environmental performance

Unless stated otherwise, the transducer shall meet the requirements of 4.2 after storage at temperatures in the range of -25°C to + 70°C (-13°F to 158°F) and when operated under the following conditions:

a) operating temperatures: 15°C to 40°C (59°F–104°F);

b) humidity: 10% to 90%, noncondensing;

c) atmospheric pressure: 425 to 850 torr.

4.2.2 Mechanical requirements

The following requirements cover all configurations of pressure transducers when used with domes or fittings recommended by the transducer manufacturer and when the domes or fittings are applied according to the manufacturer's recommended procedures.

4.2.2.1 Pressure range

The transducer shall perform over an operating range of -30 to 300 mmHg, and it shall not be damaged by an overpressure of -400 to 4,000 mmHg.

4.2.2.2 Mounting requirement

The transducer shall meet the performance requirements of 4.2 when mounted on any axis.

4.2.2.3 Requirements for the fittings

Luer-lock or Linden fittings meeting the requirements of the American National Standard, *Performance standard for medical luer taper fittings* (normative reference 2.4), shall be used for transducers capable of connecting to needles or catheters.

4.2.2.4 Frequency response

The frequency response in Hertz (Hz) based on 15% bandwidth established in AAMI TIR9, *Evaluation of clinical systems for invasive blood pressure monitoring* (see normative reference 2.2), with all integral, reusable, or disposable domes recommended by the transducer manufacturer when the domes are applied according to the manufacturers's recommended procedures shall be a minimum of 200 Hz.

4.2.3 Electrical performance

This section describes electrical requirements that ensure a functional monitoring system when the

transducer or interface is coupled to a blood pressure monitor.

4.2.3.1 Transducer excitation

The transducer shall meet the requirements of 4.2 when excited from direct current (dc) to 5,000 Hz and in the voltage range of 4 to 8 volts (V) root-mean-square (rms) or when excited using the excitation voltage and frequency (range) disclosed in the instruction manual.

4.2.3.2 Phase shift

For sinusoidal excitation, the phase shift between excitation and signal, including the cable, shall be less than 5° over the excitation frequency range, or the phase shift or phase characteristic shall be disclosed in the instruction manual.

CAUTION—Capacitive imbalance should be compensated (balanced) to avoid affecting the phase shift measurements.

4.2.3.3 Transducer excitation impedance

Transducer excitation impedance shall be greater than 200 ohms for frequencies from dc to 5,000 Hz or shall be disclosed in the instruction manual for the frequency range used.

4.2.3.4 Transducer signal impedance

Transducer signal impedance shall be less than 3,000 ohms from dc to 5,000 Hz or shall be disclosed over the frequency (range) used.

4.2.3.5 Transducer symmetry

Any added impedance to calibrate or compensate the bridge shall be split to maintain common mode symmetry to within ± 5% between signal output and either excitation terminal. Symmetry may not be required for nonresistive type transducers.

4.2.3.6 Sensitivity

The nominal sensitivity of 5 μV/V/mmHg or the value disclosed in the instruction manual shall be used to determine the ideal output for the accuracy in 4.2.3.8.

4.2.3.7 Unbalance

The transducer shall be internally balanced to within ± 75 mmHg when it is mounted on any axis.

NOTE—Monitor manufacturers should provide a balance range from + 150 mmHg to -150 mmHg.)

4.2.3.8 Accuracy

The combined effect of sensitivity, repeatability, nonlinearity, and hysteresis errors shall be within ± 1 mmHg plus ± 1% of reading over the pressure range -30 to 50 mmHg and ± 3% of reading over the range from 50 to 300 mmHg (see figure 1). The errors shall be measured with respect to the ideal output computed using the nominal sensitivity in 4.2.3.6.

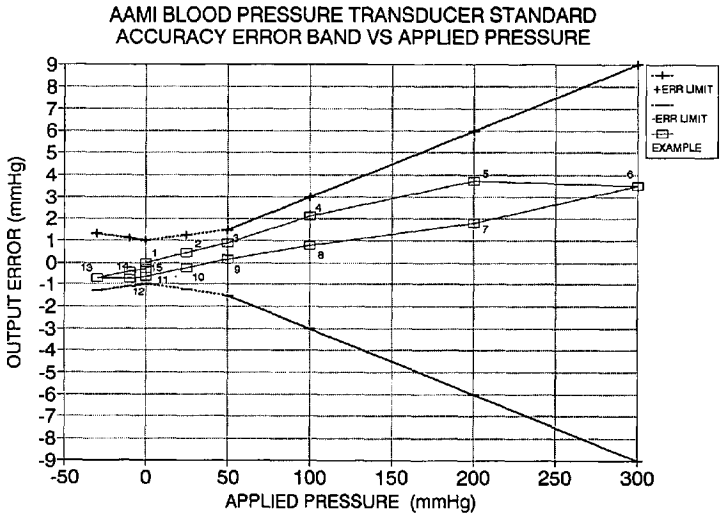

Figure 1—Accuracy error band

4.2.4 Safety requirements

4.2.4.1 Liquid isolation

The transducer (without isolating domes) shall maintain electrical isolation between the fluid column and the case and all electrical terminals connected together.

NOTE—Liquid isolation requirements as described in 4.2.4.1, 4.2.4.2, and 4.2.4.3 are considered met by means of an isolation amplifier if the amplifier and transducer are provided by the transducer manufacturer as a system. Measurements are made at the specified connector to the monitor.

4.2.4.2 Risk current

With 120 V, 60 Hz, applied between the liquid column and the case (exposed metal, if any) and the terminals connected together, the risk current limits shall conform to the requirements for "isolated patient connection" in the American National Standard, *Safe current limits for electromedical apparatus* (normative reference 2.3).

4.2.4.3 Defibrillator withstand

The transducer shall withstand five repeated discharges within 5 minutes of 360 Joules (J) of a damped sinusoidal waveform described in the American National Standard, *Cardiac defibrillator devices* (normative reference 2.1, 4.2.1.5.1) delivered into 50 ohms when the fluid side of the transducer is connected to one side while the case (exposed metal) and terminals are connected to the other side.

Transducers may be excluded from this requirement if an obvious caution label is attached to the transducer assembly with the following statement:

CAUTION—This pressure transducer is not protected against defibrillation discharges. It must be used only with monitors labeled as having an isolated defibrillator-protected patient connection.

4.3 Requirements for the cable

The connecting cable assembly between the transducer and the cable connector shall meet the following requirements:

a) the cable lengths available from the manufacturer shall be disclosed;

b) the assembly shall provide transducer venting so that the transducer measures pressures relative to atmospheric pressure;

c) the assembly shall withstand (i.e., no insulation breakdown) five repeated discharges within 5 minutes of 360 J of a damped sinusoidal waveform described in normative reference 2.1, 4.2.1.5.1, delivered into 50 ohms when connected between the wires connected together and a foil surrounding the cable for 6 inches.

5 Tests

This section provides test methods and procedures by which compliance of the transducer with the performance requirements of section 4 can be verified. These referee tests, or their equivalents, may be suitable for design qualification, but are not necessarily intended for quality assurance purposes or testing in the field. Most of these tests are suitable for resistive strain gauge type transducers and alternating current (ac) bridge type transducers. Equivalent tests may be developed by manufacturers for testing transducers utilizing alternate technologies. The numbering of this section corresponds to that of the requirements in section 4, with the exception of the first digit; for example, compliance with 4.2.3 of the standard can be determined by the test of 5.2.3. Compliance with some of the requirements can be established by visual inspection and this is stated wherever appropriate. General instrumentation and procedures for conducting the tests are described below.

Test conditions. Unless stated otherwise, all measurements and tests shall be performed at a specified temperature (Ts) in the range of 20 to 25°C, maintained to within ± 1°C of Ts (measured to an accuracy of 0.25°C) a relative humidity of 40 ± 20%, and atmospheric pressures of 425 to 850 torr.

Combining tests. Since temperature characteristics of the transducer are included in the requirements, several tests at different temperatures are required to validate these requirements. Combining these tests, where indicated, during each temperature run will permit determination of the temperature characteristics of the transducer and of operation over the temperature range.

Test apparatus. The following test equipment is required:

a) a dual channel oscilloscope with differential input amplifiers having 60 decibels (dB) common mode rejection minimum up to 5,000 Hz, an input impedance of at least 1 megohm, and a phase shift of less than 1° at 5 kiloHertz (kHz);

b) a digital voltmeter able to measure ac/dc voltages in a range of 1 millivolt (mV) to 10 V with an input impedance of greater than 10 megohms, a resolution of 1 microvolt (μV), and an accuracy of ± 0.1% of reading;

c) a signal generator able to generate sinusoidal waveforms with frequencies ranging up to 5,000 Hz. The signal generator shall have an adjustable voltage output up to at least 10 V rms into 200 ohms. The output voltage should be floating in reference to ground with a 2 megohm minimum isolation impedance at 5 kHz;

d) a defibrillator capable of delivering a damped sinusoidal waveform of 360 J into a 50-ohm load according to normative reference 2.1;

e) a pressure source with a precision gauge capable of supplying and reading pressures to 300 mmHg accurate to within ± 0.2% at 100 mmHg;

f) a vacuum source capable of supplying -400 mmHg, accurate to within ± 0.2% at -30 mmHg;

g) a pressure waveform generator capable of producing square-wave pressure signals of 25 mmHg peak-to-peak (p-p) amplitude at 2 Hz;

h) a synchronous demodulator capable of operating over the excitation voltage and frequency range per 4.2.3.1 with less than ± 0.5 mmHg added effect and ± 0.2% of reading error. The circuit in figure 2 is provided for use in this test.

5.1 Labeling requirements

Compliance with many of the labeling requirements of 4.1 can be determined by visual inspection. Test procedures are necessary to verify the technical information called for by some of the disclosure requirements of 4.1.2.

5.1.1 Device markings

Compliance with 4.1.1 can be verified by inspection.

5.1.2 Instruction manual

Compliance with subsections (h) through (m) of 4.1.2 can be verified by inspecting the manual. Performance values reported in subsections (b) through (g) are taken from the results of test procedures 5.2.3.1 through 5.2.3.4 and 5.2.3.6.

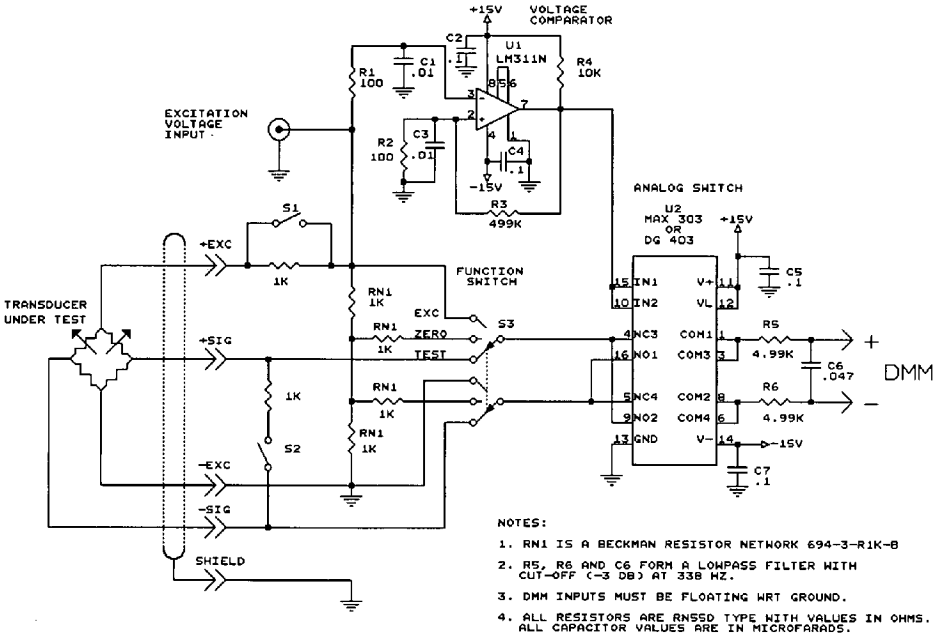

Figure 2—Synchronous demodulator

n) The transducer is to be subjected on each axis to a one-half sine shock. The magnitude of acceleration shall be equal to the disclosed value. After this series of shocks, test the transducer for unbalance (5.2.3.7), accuracy (5.2.3.8) and transducer safety (5.2.4). The performance of the device shall be consistent with the requirements of 4.2.3.7, 4.2.3.8, and 4.2.4.

o), p), & q) The following procedure combines the test for drift, temperature error band at zero pressure, and temperature error band of sensitivity (see figure 3):

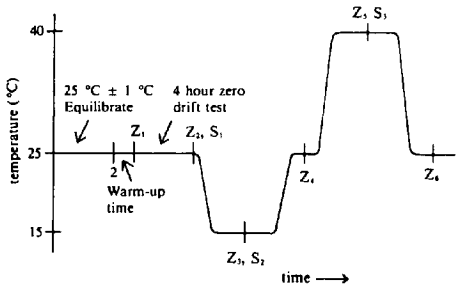

Figure 3—Time course of combined test of drift, temperature error band of zero pressure, and temperature error band of sensitivity

1) Equilibrate all components at 25°C ± 1°C for 2 hours.

2) Connect the dome and other necessary parts of the measuring system and fill them with distilled water.

3) Connect the transducer to the excitation source and digital multimeter (DMM) per figure 4. Set the DMM to the 20 V dc scale. Set switch S3 to excitation (EXC) and adjust the excitation source to 6 V dc or 6 V ac average sinewave at 2.5 kHz (6.664 V rms) or as specified by the manufacturer.

NOTE—The output at V3 of the synchronous demodulator circuit is equivalent to a full wave rectified signal. For sinewave excitation, the readings are equivalent to the one-half cycle average value. The one-half cycle average sinewave (hereinafter referred to as ac average) value for the excitation voltage should also be used for any conversion from signal output voltage to equivalent mmHg reading. The synchronous demodulator circuit also operates with dc excitation but may be removed for dc only testing. The formula for conversion from rms to ac average sinewave is:

$$\text{ac average} = \text{rms} \times 0.9003.$$

4) Set the DMM to 20 mV dc scale. Set switch S3 to TEST and measure the signal output.

5) Record the initial unbalance reading (Z_1) and initiate a test cycle for 4 hours at 25°C ± 1°C. Chart the output at zero pressure and record (in mmHg) the maximum deviation from the initial reading over this time period.

6) Record output readings for zero pressure and for a 100 mmHg pressure change (see 5.2.3.6) as Z_2 and S_1. Set the temperature chamber to 15°C. Wait for 1 hour after the chamber has settled to within ±1°C of 15°C, then record output readings for zero pressure and a 100 mmHg pressure change (Z_3 and S_2). Following this same protocol, change the temperature to 25°C, to 40°C, and back to 25°C, and measure output readings for zero pressure (Z_4, Z_5 and Z_6) at each point. Measure the output readings for a 100 mmHg pressure change at 40°C (S_3).

The zero drift error is the maximum deviation from the Z_1 data point obtained over the 4-hour test expressed in mmHg. The zero drift error band due to temperature is the greater of (Z_3-Z_2), (Z_4-Z_2), (Z_5-Z_2), or (Z_6-Z_2) expressed in ± mmHg. The sensitivity change due to temperature is:

$$\frac{(S_2 - S_1)}{S_1} \times 100 \textit{ or } \frac{(S_3 - S_1)}{S_1} \times 100 \text{ (+/- percent)}$$

whichever is greater.

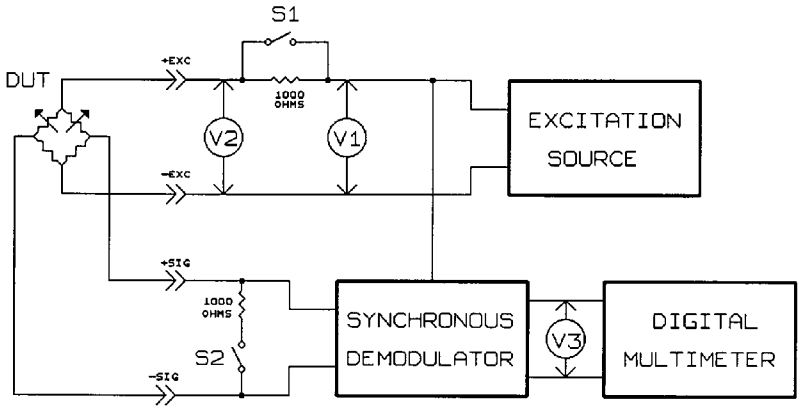

Figure 4—Electrical test setup

r) Set up the transducer and a 3,400° K tungsten light source having a 3,000 footcandle output. Excite the transducer with the recommended excitation level, cover it with a black drop cloth, and insert a metal plate between the light source and the transducer. Zero the output reading, remove the cover, and expose the transducer to the light source. Rotate the transducer for maximum change in output from the dark reading; observe the output change in mmHg. Repeat this test over the excitation range specified by the manufacturer in order to find the maximum response; report the largest reading in mmHg.

5.2 Performance requirements for the transducer

5.2.1 Environmental performance

When performance requirements may be affected by environmental changes, procedures are described to ensure successful testing over the required range. Where dictated by the particular test, the temperature shall be set within ± 1°C at 15°C, Ts (see *Test conditions*, section 5), and 40°C, to verify performance over the environmental range specified in 4.2.1. The transducer and cable assembly shall be stored for 24 hours at -25°C, brought back to room temperature for 24 hours, then stored at 70°C for another 24 hours, and finally returned to room temperature before testing against the requirements.

5.2.2 Mechanical requirements

5.2.2.1 Pressure range

Operating range characteristics will be tested during the accuracy test of 5.2.3.8. To test the overrange capability, the transducer shall be connected to a suitable test setup with adequate protection for both equipment and personnel. The pressure shall be increased to 4,000 mmHg and held for one second. After this application of pressure, the transducer shall be subjected to a negative pressure of 400 mmHg for 1 second. The transducer shall then be tested for unbalance (5.2.3.7), accuracy (5.2.3.8), and safety (5.2.4).

5.2.2.2 Mounting requirement

The transducer shall be mounted by means of a clamp in each of its three positions: diaphragm up, diaphragm down, and diaphragm vertical. In each position, the transducer shall be tested for sensitivity (5.2.3.6), unbalance (5.2.3.7), and accuracy (5.2.3.8).

5.2.2.3 Requirements for the fittings

Fittings shall be tested according to the procedures described in normative reference 2.4.

5.2.2.4 Frequency response

The following step response test procedure is used to measure the natural frequency F_n and damping

coefficient for the transducer. These values are used to compute the 15% bandwidth for the transducer.

a) Connect the transducer to the excitation source as indicated in figure 4. Replace the DMM with the oscilloscope. Set the excitation voltage to 8.0 V ± 0.5 V dc or ac rms sinewave at 2.5 kHz or as recommended by the manufacturer;

b) Turn on the oscilloscope and set the sensitivity to 1mV/div and the sweep to 10 msec/div;

c) Follow the manufacturer's instructions to set up the pressure generator. Fill the pressure chamber with air-free water (freshly boiled);

d) Connect the transducer to the pressure chamber and remove all air bubbles from the dome. Close the stopcock to seal the fluid pathway;

e) Set the pressure generator for a square wave output at a frequency of 2 Hz;

f) Measure and record the time (t_p) between peaks of the damped oscillations;

g) Measure the amplitude of the first peak (M_p) and the final amplitude (M_f);

h) Compute the overshoot (M_o) and damped resonant frequency (F_d) using the equations below (see normative reference 2.2);

$$M_O = (M_p - M_f)/M_f = (M_p/M_t) - 1$$

$$F_d = 1/t_p$$

i) Compute the damping coefficient (D) and natural frequency (F_n) using the equations below:

$$D = \frac{-\,In\ M_O}{(II^2 + (In\ M_O)^2)^{0.5}}$$

$$F_n = F_d\,/(1 - D^2)^{0.5}$$

j) The 15% bandwidth is computed using the following equation:

$$F_{15} = (.208514)\ (F_n)\ (2(529\ D^4 - 529D^2 + 100)^{0.5} - 46D^2 + 23)^{0.5}$$

5.2.3 Electrical performance

NOTE—The tests for phase shift (5.2.3.2), transducer excitation impedance (5.2.3.3), and transducer signal impedance (5.2.3.4) are for resistive bridge type transducers and are not suitable for ac transducers.

5.2.3.1 Transducer excitation

The test for excitation frequency range and voltage range capabilities is included with other tests: phase shift (5.2.3.2), excitation impedance (5.2.3.3), signal impedance (5.2.3.4), and accuracy (5.2.3.8).

5.2.3.2 Phase shift

In order to ensure the accuracy of measurements, a verification test for the measurement system's common mode rejection and phase shift is recommended. This test employs Lissajous figures for phase shift measurement.

Common-mode test. Set up the oscilloscope for sweep mode as shown in figure 5 (see next page). Set Y_2 sensitivity to 2mV/div. Increase the generator output until deflection of Y_1 equals 2 V p-p. Deflection of Y_2 should be less than 2 mV p-p.

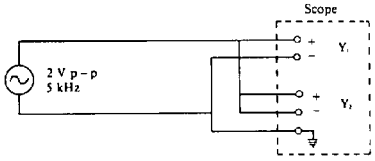

Figure 5—Scope common-mode test

Phase shift test. Set up the oscilloscope to an X-Y display as shown in figure 6. Set Y_1 sensitivity to 2 V/div. Set Y_2 sensitivity to 2mV/div. The measured phase shift shall be less than 1°. The phase shift is the arc sine of A/B, where A is the width of the loop crossing the vertical axis and B is the maximum vertical deflection.

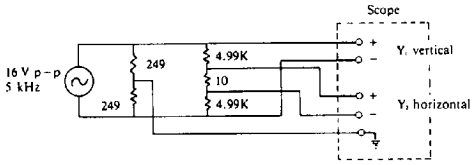

Figure 6—Scope phase-shift test (All resistors 1%)

To measure the phase shift of the transducer, set up the transducer as shown in figure 7 and place the oscilloscope in the X-Y mode. Then:

a) Set Y_1 sensitivity to 2 V/div;

b) Set Y_2 sensitivity to 2 mV/div;

c) With no pressure applied to the transducer, adjust C_{BAL} and R_{BAL} to balance the transducer bridge. This will be represented by a closed loop appearing as a straight vertical line on the oscilloscope;

d) Apply pressure (about 200 mmHg) to the transducer to obtain full scale oscilloscope deflection;

e) The measured phase shift shall be less than 5° or the phase characteristics shall be disclosed in the instruction manual for the frequency (range) used.

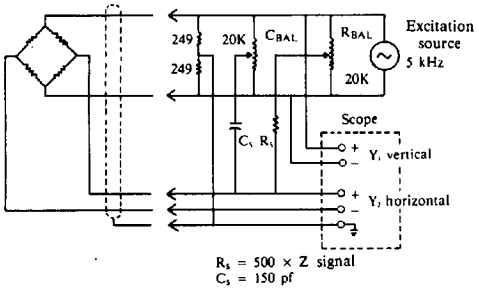

Figure 7—Phase-shift measurement

5.2.3.3 Transducer excitation impedance

Connect the transducer as shown in figure 4, using a dc power source. With S_1 and S_2 open, set V_2 to 6 V dc and measure V_1. Repeat this test at frequencies of 2 kHz and 5 kHz with V_2 set to 6 V ac average (or 6.664 V rms). Compute the excitation impedance as the lowest value from the equation:

$$Z_{in} = 1000 \frac{V_2}{V_1 - V_2} \ ohms$$

5.2.3.4 Transducer signal impedance

Connect the transducer in the circuit as shown in figure 4, with S_1 closed and S_2 open, using a 6-V dc power source. Apply about 100 mmHg pressure to the transducer and read V_3 with S_2 open (V_0) and with S_2 closed (V_c). Repeat this test at frequencies of 2 kHz and 5 kHz with V_1 set to 6 V ac average (or 6.664 V rms). Compute the signal impedance as the largest value from the equation:

$$Z_{out} = 1000 \left(\frac{V_o}{V_c} - 1\right) \ ohms$$

5.2.3.5 Transducer symmetry

Connect + signal and - signal wires of the transducer bridge together to form +/- signal. Energize the transducer with 6 V dc or ac average. Measure the voltage from - excitation to +/- signal as V_x, and from +/- signal to + excitation as V_y. Calculate the ratio V_x/V_y. This ratio should be 1.0 ± 0.05.

5.2.3.6 Sensitivity

The nominal sensitivity (S_n) is disclosed in the instruction manual.

5.2.3.7 Unbalance

Connect the transducer as shown in figure 4 with S_1 closed and S_2 open. Excite the transducer with 6 V dc or ac average. Measure V_3 and compute the equivalent offset pressure as:

$$Unbalance = \frac{V_3}{S_n V_{exc}} \ mmHg$$

S_n is the nominal sensitivity (5.2.3.6). Unbalance shall be within ± 75 mmHg.

5.2.3.8 Accuracy

Connect the transducer as shown in figure 4 with S_1 closed and S_2 open. Excite the transducer with 6 V dc or ac average sinewave at 2.5 kHz from a well-regulated source. Connect a pressure source and associated gauge known to have a combined nonlinearity and hysteresis of less than 0.2% of reading to the transducer. After the manufacturer's recommended warm-up period apply pressure to the transducer in the following sequence [mmHg (count), 0(1), 25(2), 50(3), 100(4), 200(5), 300(6), 200(7), 100(8), 50(9), 25(10), 0(11), -10(12), -30(13), -10(14), 0(15)]. (See figure 1.)

Points (2) through (6) are approached from lower pressure, points (7) through (13) are approached from higher pressure, and points (14) and (15) are approached from lower pressure. It follows, therefore, that the pressure source shall make the transition from one pressure to the next smoothly without overshoot or pressure spikes. To avoid reversing applied pressure, the actual pressure used may vary ± 10% from specified values. Record the actual input pressure measured and the corresponding output voltage in microvolts for the device under test over the given sequence for use in the indicated calculations. The electrical output at each required pressure will be referred to as V_x, where x is the sequential count number

of the data point. Likewise, P_x refers to the pressure reading from the reference gauge at each data point, in mmHg. Analyze the data in the following steps:

a) Subtract V_1 from points V_1 through V_{15} inclusive. It is assumed that the reference gauge has no zero offset;

b) Find the error in mmHg for each of the points (1 to 15) as follows:

$$E_x = \frac{V_x - V_1}{S_n V_{exc}} - P_x \ mmHg$$

Where S_n is the nominal sensitivity in µV/V/mmHg as specified with instruction manual. For most transducers the nominal sensitivity is 5 µV/V/mmHg or 40 µV/V/mmHg;

c) For points (1) through (3) and (9) through (15) inclusive, the maximum permitted error is ± 1 mmHg plus ±1 percent of the corresponding P_x;

d) For points (4) through (8) inclusive, the maximum error is ± 3% of the corresponding P_x;

e) This test shall be performed at 4 and 8 V dc or ac rms (3.6 and 7.2 ac average sinewave) at 2.5 kHz excitation.

The accuracy error band is illustrated in figure 1.

5.2.4 Safety requirements

5.2.4.1 Liquid isolation

Isolation of the liquid column is demonstrated in the risk current measurements of 5.2.4.2. Measurements are made at the connector to the monitor. The system shall include any intermediate amplifier provided as part of the transducer system supplied by the transducer manufacturer.

5.2.4.2 Risk current

Make an electrical connection to the transducer diaphragm through a 12" column of normal saline, having an internal diameter of 1 millimeter (mm), as shown in figure 8. Before the test, make sure that the hydraulic system is debubbled. Connect any exposed metal of the transducer or intermediate amplifier (if part of the transducer system) to the connector pins and to ground. Apply a 120 V 60 Hz, signal to the saline column, and measure the current which flows as described in normative reference 2.3.

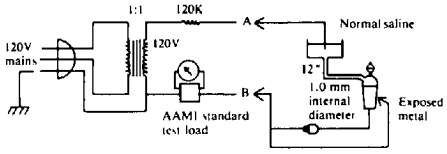

Figure 8—Defibrillator withstand

5.2.4.3 Defibrillator withstand

In the setup of the risk current test (5.2.4.2), replace the 120 V source with a defibrillator having the damped sinusoidal waveform described in normative reference 2.1, the output of which is loaded with 50 ohms as shown in figure 9. Connect the column of normal saline to one terminal of the defibrillator load, and connect the electrical terminations and any exposed metal to the other side of the defibrillator load. Charge the defibrillator so as to deliver 360 J into the 50 ohms; discharge across the load and transducer. Repeat this test every minute for 5 minutes. Verify that the transducer is functioning properly by testing its unbalance

(5.2.3.7), accuracy (5.2.3.8), and risk current (5.2.4.2).

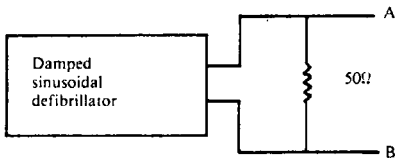

Figure 9—Defibrillator withstand test

5.3 Requirements for the cable

Compliance with the requirements (a) and (b) of 4.3 can be verified by inspection.

c) Wrap the sheath for 6" with conductive foil. Apply terminals A and B of the defibrillator (with load) as shown in figure 9 between the terminals of the transducer connected together and the foil surrounding the cable. Discharge the defibrillator. Repeat this test every minute for 5 minutes. Inspect the cable for evidence of breakdown and test for risk current. Replace the defibrillator with a 120 V, 60 Hz source and measure risk current. The current limit shall meet the requirements for isolated patient connection contained in normative reference 2.3.

Annex A

(Informative)

Rationale for the development and provisions of this standard

A.1 Introduction

The continuous monitoring of blood pressure by use of indwelling catheters or direct puncture is common practice. These measurements are made in conjunction with pressure transducers and electronic patient monitors. About 95% of the pressure transducers used primarily for the measurement of blood pressure are of the resistive bridge type; that is, they can be excited by alternating or direct current. Among these transducers are the bonded and unbonded strain wire bridges as well as silicon and piezoresistive elements. In addition, these transducers are in general interchangeable in that their characteristics of excitation and signal impedance range, their excitation requirement, sensitivity, unbalance range, etc., are compatible and designed into most pressure monitors. These specific requirements are identified by a given value with exceptions allowed if identified in the manual.

The remaining 5% of the transducers used for blood pressure measurement do not meet all the functional requirements of a resistive bridge type transducer because of limitations on their excitation characteristics or the use of techniques other than bridge unbalance. Thus, their application is limited to certain monitors unless an interface circuit is provided. Examples of these transducers are the variable reluctance, differential transformer, fiberoptic sensors, and capacitive bridge type units. These transducers are not precluded from this standard although some modification of the test procedures may be required to evaluate the requirements.

Standardization of performance and safety alone is not sufficient to address interchangeability of pressure transducers. Although the same transducer may be used with monitors provided by different manufacturers, there is no uniformity in the cable connector sets used. Even if the cable connector set fits a given monitor, there is no guarantee that the pin assignments will match or that the system will function properly.

Industry has adapted to the lack of interchangeability among various monitors by introducing reusable cables with disposable transducers. The cables are monitor specific but allow the transport of the disposable transducer and plumbing system.

Although the application of pressure transducers for the measurement of blood pressure is most common,

these same transducers can be used in many cases for the measurement of other fluid-coupled physiological pressures, such as intracranial, gastroenterological, uterine, and bladder pressure. Thus, while blood pressure measurement is the focus of this standard, those transducers used for other measurements as well are not excluded insofar as they have common elements.

This standard includes only those transducers that are isolated and meet the accepted safe current limits previously established. The use of catheters or a direct puncture introduces a conductive pathway directly to the heart, and even though the conductivity of this pathway is significantly lower than that of an intracardiac electrode, it was agreed that nonisolated transducers presented an unacceptable risk to the patient. Transducers that do not meet the defibrillator withstand requirements must have a warning label which requires that they be used with an isolated defibrillation protected amplifier.

This standard does not provide all answers to problems associated with pressure monitoring systems. Rather, it confines itself to the transducer/cable connector interface and recognizes that additional standards should be developed to address pressure monitors, catheters, manifolds, valves, and so forth. This standard is designed to serve the technology of today and of the immediate future. Innovations to a transducer or monitoring system that cannot be accommodated by this standard will necessitate the development of another standard to address the performance of the new configuration.

A.2 Need for the standard

In 1974, the Food and Drug Administration established classification panels to serve as advisory committees to the agency in determining how cardiovascular devices in commercial distribution could best be regulated; that is, by general controls (Class I), performance standards (Class II), or premarket clearance (Class III). This action was taken in anticipation of the passage of the Medical Device Amendments to the U.S. Food, Drug, and Cosmetic Act (enacted on May 18, 1976). In the February 5, 1980 *Federal Register*, the Food and Drug Administration finalized regulations that would classify blood pressure transducers as Class II devices. This proposed regulation was based on the final recommendations of the Cardiovascular Device and Anesthesiology Device Classification Panels:

> The Panels recommend that extravascular blood pressure transducers be classified into Class II, because this electrically operated device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. If the device is inadequate for accurate and precise measurement of blood pressure, the resulting misdiagnosis could have a significant negative effect on the patient's health. This device is attached to the body by in-line contact with the blood in a catheter system and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of the device, e.g., electrical leakage current, need to meet certain requirements. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's ability to sense blood pressure, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained....The Panels believe that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

The final regulation can be found in 21CFR 870.2850 and the generic name is *extravascular blood pressure transducer*. Additionally, in 21CFR 870.2870 catheter tip pressure transducers are also classified as Class II. Thus both types of transducers require a performance standard.

A.3 Definitions

A.4 Rationale for the specific provisions of the standard

A.4.1 Labeling requirements

There are two fundamental factors which control the label content of a medical device. There are the requirements defined in Part 820, Chapter I, Title 21, of the *Code of Federal Regulations*—Good Manufacturing Practice for Medical Devices—in particular, sections 820.120, 820.121, and 820.130. These regulations establish requirements for proper handling, legibility, and many other aspects of labeling as they pertain to good manufacturing practices. In addition, Part 801, Chapter 1, Title 21, of the Code of Federal Regulations, and Section 502 of the Federal Food, Drug, and Cosmetic Act (as amended October 1976) state what constitutes proper labeling and misbranding of a drug or device. These two groups of requirements are comprised in the federal regulations referred to in 4.1 of this standard. All labeling pertaining to blood pressure transducers is controlled by these regulations and must comply with them.

But there are other critical facts which shall be set forth in the labeling in order to ensure that the device is used correctly by the physician or user and that the user will be provided with sufficient information concerning the performance characteristics of the device. In view of the widespread use of these devices, it was deemed particularly important to develop labeling requirements that would provide the user with the necessary information about care and use, together with cautions to ensure the safety and efficacy of the device. Section 4.1.2 provides for the inclusion of this information in the instruction manual.

A.4.1.1 Device markings

The serial number or other controlling identification for the transducer and cable to monitor interface needs to be known so that its explicit characteristics can be traced.

A.4.1.2 Instruction manual

The user needs information about the care and use, as well as warnings to ensure the safety and efficacy, of the device. Sections (h) through (m) of 4.1.2 provide for the inclusion of this information in the instruction manual. In addition, there are certain characteristics of the device that should be known to the users so that they can select transducers that fit their particular needs. These are called out in (a) through (g), and (n) through (r) and are thought to be especially important for the following reasons:

a) & b) *Excitation voltage and frequency requirements*. Although not transducer-specific, this information should be included so that the user can readily ensure that the monitor properly excites the transducer to maximize performance and stability.

c) *Excitation impedance.* The excitation impedance of the transducer should be known so that the user can make sure that the blood pressure monitor can drive it.

d) *Signal impedance.* The signal impedance of a transducer can vary over a wide range and in many cases with a broad tolerance, whereas blood pressure monitors have widely varying input impedance. To ensure that these impedances are compatible or that the monitor can be properly calibrated, it is necessary that this information be disclosed.

e) *Phase shift.* The phase shift of the output signal over the excitation frequency range may be important with certain combinations of transducers and monitors (i.e., those monitors that use ac excitations and synchronous detection).

f) *Sensitivity.* Since the sensitivity of most blood pressure transducers used today is 5.0 μV/V/mmHg ± 1% and the vast majority of monitor manufacturers preset their input to this sensitivity level, the committee felt that the general nature of this standard requires that this characteristic of the transducer be specified.

g) *Connector and connections.* The transducer connector and connections shall be known to permit proper hook-up to the blood pressure monitor.

n) *Shock*. While the committee agreed that a transducer should be considered a fragile, delicately calibrated device to be handled with extreme care, it recognized that the transducer should be able to withstand a

reasonable amount of abuse without failure or loss of accuracy—even though it has not been possible to define the word "abuse". Acceleration forces recorded from a transducer's 1 meter fall onto a vinyl asbestos tile floor exceeded 4,500 G; a 1' fall, 2,000 G. The shock is a function of the mass, acceleration, drop height, and hardness of the materials. The large range of forces makes it impossible to cover present transducers for all conditions. Thus, it is appropriate to require that the manufacturer disclose the results of a given test method.

o) *Drift*. During the development of this standard it was brought to the attention of the committee that transducers appear to drift with time as well as temperature. Since the amount of drift that can be tolerated without introducing clinical errors depends on the pressure monitoring site, and since an established limit at this time would inhibit improvements, a definite value seemed restrictive. It was determined that a disclosure requirement would provide the information needed by the user to make a valid judgement.

p) *Temperature error band of zero*. The operating temperature of the transducer can be expected to change from normal room temperature toward body temperature, a change of +15°C; in cases of hypothermia, a change of -10°C. If the transducer is balanced (zeroed) at room temperature, the resulting temperature change estimated at 10°C should not result in excessive shift in baseline. This requirement can best be served by disclosure.

q) *Temperature effect on sensitivity*. The temperature variations expected in normal operation should also not produce an excessive change in sensitivity and introduce clinical errors. For the same reasons stated in (18) above, this goal can also best be served by a disclosure requirement.

r) *Sensitivity to light*. The development of silicon strain gauges and their use in very small disposable transducers have introduced another potential source of error because of silicon's sensitivity to light. The error is primarily in zero shift. Because absolute values that can be expected at this time are unknown, and the effect is the same as described above, it was agreed that this also should be a disclosure requirement.

A.4.2 Performance requirement for the transducer

A.4.2.1 Environmental performance

Although blood pressure transducers are normally used in the protective surroundings of a hospital, they may be exposed to extremes of temperature, humidity, and altitude during shipment, storage, and use. In addition, the device may be exposed to mechanical shock, and it may be repeatedly sterilized. No measurement device, particularly an electronic one, is totally invulnerable to all conceivable environmental extremes. Since exposure to such conditions is often unavoidable, it is important that the device be designed and manufactured to maintain its accuracy under adverse conditions.

Although normal environmental conditions within a hospital can be addressed by a performance range of 20°C to 40°C (68°F to 104°F), temperatures as low as 5°C to 10°C (41°F to 50°F) from patients experiencing hypothermia can, through the liquid column, reduce the operating temperature of the transducer. A range of 15°C to 40°C (59°F to 104°F) for the transducer would accommodate the potential differential and be consistent with today's transducer technology. The range of storage temperatures was broadened to embrace temperatures from -25°C to +70°C (-13°F to +158°F) to account for variations during shipment and storage where the environmental conditions are less well controlled. Humidity varies widely, too, not only in the "controlled" environment of the hospital, but also under special conditions such as in a wet room where the relative humidity approaches 100%.

A.4.2.2 Mechanical requirements

Secondary to disposable transducers, the continued acceptance of reusable transducers with disposable domes necessitate that the requirements of this standard be met when either these domes or the standard reusable domes are employed. In addition, since domes affect the overall assembly, only those accessories by model designation recommended by the transducer's manufacturer should be used during the evaluation

of the device. Because the technique for assembling these parts also affects the transducer's characteristics, the manufacturer's recommended procedure shall be followed.

A.4.2.2.1 Pressure range

It has been demonstrated that peak pressures in humans rarely exceed 300 mmHg, and thus the requirement that the device perform accurately at a maximum pressure of 300 mmHg would seem to embrace most conditions of use. Pressure applied to the transducer in excess of values found commonly in humans occurs only in instances where the device is mishandled (e.g., where the fluid-filled system has been closed off from atmosphere or where the pressure source has been manually applied to the system as with a syringe when flushing with a stopcock in an improper setting). It is impossible to protect the device completely from excessive pressure due to misuse; a value of 4,000 mmHg for the overrange requirement was nonetheless considered reasonable from the viewpoint of both user and manufacturer.

On the low end of the pressure range, negative pressures are occasionally found as a result of thoracic volume changes with respiration. A nominal negative pressure capability accommodates these situations. Excessive negative pressures can be generated by pulling on a syringe (10 to 12 ml) when a blood sample is drawn with an improperly set stopcock. This negative pressure is expected to be less than -400 mmHg.

A.4.2.2.2 Mounting requirement

Transducer mounting techniques vary according to hospital protocol and thus cannot be controlled. For this reason, the transducer should meet the requirements of this standard when operating in any position.

A.4.2.2.3 Requirements for the fittings

Standard connections for catheters, tubings, manifolds, and so forth, are made with Luer taper, Luer-lock, and Linden fittings. These connections have become an industry standard and are simple to use; therefore, the transducer fittings should match. For reasons of safety, however, the connections are limited to Luer-lock and Linden to prevent inadvertent disconnection.

A.4.2.2.4 Frequency response

Normally, the frequency response of a transducer is characterized by the natural frequency and damping coefficient which describe a second order system. It is not obvious when the frequency response is adequate with any combination of these two parameters. Using these values, the bandwidth over which the amplitude is within 15% of the low-frequency flat response amplitude can be computed. Thus, the 15% frequency can be used to compare the frequency response of transducers with significant differences in the natural frequency and damping coefficient values. The committee felt that an established limit of 200 Hz was required to ensure that the transducer did not degrade waveform reproduction. The 200 Hz limit was chosen because it is a factor of 10 times higher than the usually accepted upper limit for most physiological pressure signals. The committee recognized that, in general, the fluid filled tubing that connects the transducer to the measurement location in the body would degrade the frequency response of the system far more than the transducer.

A.4.2.3 Electrical performance

Establishing electrical performance requirements for the transducer helps ensure that connecting the transducer will permit functional operation of the monitoring system. It is still necessary, however, for users to follow the instructions of the pressure monitor's manufacturer to ensure proper balancing, calibration, and overall functioning of the system.

A.4.2.3.1 Transducer excitation

While higher excitation voltages will increase output and thus decrease the stability requirements of the amplifier, excessive excitation voltages increase self-heating, resulting in possible drift, nonlinearity, and

changes in null and sensitivity beyond the limits established. A 4- to 8-volt range provides a reasonable compromise between these levels.

Although dc operation is more common for the integrated circuits of today's devices, ac excitation permits direct electrical isolation by transformer coupling for excitation and output. A limit of 5,000 Hz covers all monitors presently being used and allows an extended frequency response of several hundred hertz for the pressure monitoring system.

A.4.2.3.2 Phase shift

The use of synchronous detection in demodulating ac-driven transducers requires that the phase shift between the signal output and the excitation be limited to ensure a properly functioning system. A limit of 5° should still permit direct operation.

A.4.2.3.3 Transducer excitation impedance

A minimum excitation impedance is necessary to ensure that the transducer does not load down the pressure monitor. A 200-ohm minimum covers all known transducers and is a reasonable level for the monitor to excite.

A.4.2.3.4 Transducer signal impedance

The trend toward solid-state transducers has resulted in a shift upward in impedance. This development shall be balanced against acceptable monitor input impedance to maintain sensitivity accuracy. A compromise 3,000-ohm output is established as the maximum for a transducer to operate with an amplifier having a 1-megohm (or greater) input impedance.

A.4.2.3.5 Transducer symmetry

It is common practice to add series resistance in the excitation line to standardize the sensitivity of the transducer or to compensate for temperature shifts. The addition of this resistance can exaggerate the common mode signal of the bridge output, which if excessive, can cause measurement errors or reduced balance range in some monitors. A 5% shift in symmetry was deemed reasonable to achieve and for the amplifiers to handle.

A.4.2.3.6 Sensitivity

The sensitivity of 5 μV/V/mmHg has been an industry standard for many years because it is obtainable directly from wire strain gauges. Although the new semiconductor transducers have inherently higher sensitivities, they have followed the industry standard by appropriate attenuation to the level of 5 μV/V/mmHg. Thus, this value should be maintained. It is also acceptable to the monitor manufacturer because it is compatible with the noise and drift specifications of present-day semiconductor technology. However, there are some transducers that operate with other sensitivities, either type or transducer dependent, that should be included. By providing this information in the manual or calibration sheet, its use can be determined.

Electrical calibration of the transducers—common practice in present-day monitoring systems—was the subject of much debate during development of this standard. Electrical calibration is accomplished in many cases by including a shunt resistor either in the monitor or in the transducer or partially in each. The wide variation in signal impedance necessitates that this resistor become part of the transducer, if it were to be included. For mass-produced disposable transducers, this would become expensive because the resistor would need to be selectively trimmed to a value based on each transducer. Though originally addressed in the standard, the addition of a calibration resistor was dropped.

A.4.2.3.7 Unbalance

A range of ± 75 mmHg for unbalance, in addition to providing for manufacturing tolerances, is broad

enough to accommodate the effects of temperature, excitation voltage, and gravity. Most reusable transducers in use today have a lower unbalance when new. It is recommended that monitors provide a balancing range of ± 150 mmHg to cover mishandling which might cause the transducer to shift from initial values. Transducer manufacturers indicate that such a shift in unbalance will not drive the transducer out of its linear mode of operation.

A.4.2.3.8 Nonlinearity and hysteresis

Pressure monitoring errors can result from "plumbing" problems, transducer errors, and monitor/display errors. In order to hold overall measurement errors to less than ± 2 mmHg or ± 5% of the reading, whichever is greater, a reasonable band for the transducer alone is ± 1 mmHg or ± 2% of reading, whichever is greater, since the transducer is the greatest cause of static error. This is well within the limits of today's technology. Point-based linearity at normally established values of 0 and 100 mmHg seems an appropriate way for specifying these requirements since these values are normally used in balancing and calibration procedures.

A.4.2.4 Safety requirements

A.4.2.4.1 Liquid isolation

This section is redundant if the transducer meets the risk current limit established below. Nevertheless, it serves to indicate the intent of this section; that is, to ensure that the blood column which forms a conductive pathway to the heart is isolated from ground or other electrical terminations.

The introduction of disposable transducers, with their advantages of miniaturization and reduced cost, has caused some devices to give up their basic liquid isolation. Transducer manufacturers have incorporated isolation amplifiers in the connecting cable to the monitor. These nondisposable amplifiers are considered more cost effective. Since the combination of transducer and isolation amplifier forms a single system that meets the intent of this requirement, it was felt that isolation amplifiers should be acceptable.

A.4.2.4.2 Risk current

The American National Standard, *Safe current limits for electromedical apparatus* (normative reference 2.2) establishes the risk current limits for an "isolated patient connection" to provide a safe environment for a patient with a direct conductive pathway to the heart. The use of indwelling catheters or direct puncture for blood pressure measurements establishes a conductive pathway.

A.4.2.4.3 Defibrillator withstand

To prevent the transducer from failing and to ensure continuous monitoring of the patient through and after a defibrillation procedure, the transducer should withstand the worst-case conditions of defibrillation. When both the defibrillator and the pressure monitor are grounded, the transducer sees the full potential of the defibrillator. Most available energy, however, is shunted by the 50-ohm patient load. Because the damage to the transducer may accumulate as a result of self-heating, five repeated discharges at a rate of one per minute are introduced. It should be noted that the American National Standard, *Cardiac defibrillator devices* (normative reference 2.1) requires the delivery of 15 charges within 5 minutes.

A.4.3 Requirements for the cable

The cable between the transducer and the pressure monitor may consist of a continuous cable or of two parts, a short pigtail from the transducer itself, and the main cable for connection to the pressure monitor. For the purpose of this standard, both parts of the cable are considered in combination for each of the standards's applicable sections.

a) Transducer mounting varies with the type. The transducer may be mounted on the patient or on a pole adjacent to the bed or table, necessitating cables of different lengths. Thus available lengths should be disclosed.

b) Because blood pressure is conventionally measured relative to atmosphere, the transducer shall be appropriately vented. Although venting may be at the transducer itself, it was believed that by venting through the cable, one could prevent clogging due to fluid entering the vent during plumbing connection or flushing.

c) The cable shall withstand the environmental requirements of the transducer. Thus, it should also meet the defibrillation requirements established.