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Blood Pressure Measurement

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75.1 Introduction

Blood pressure measurements have been part of the basic clinical examination since the earliest days of modern medicine. The origin of blood pressure is the pumping action of the heart, and its value depends on the relationship between cardiac output and peripheral resistance. Therefore, blood pressure is considered as one of the most important physiological variables with which to assess cardiovascular hemodynamics. Venous blood pressure is determined by vascular tone, blood volume, cardiac output, and the force of contraction of the chambers of the right side of the heart. Since venous blood pressure must be obtained invasively, the term *blood pressure* most commonly refers to arterial blood pressure, which is the pressure exerted on the arterial walls when blood flows through the arteries. The highest value of pressure, which occurs when the heart contracts and ejects blood to the arteries, is called the systolic pressure (SP). The diastolic pressure (DP) represents the lowest value occurring between the ejections of blood from the heart. Pulse pressure (PP) is the difference between SP and DP, i.e., $PP = SP - DP$. The period from the end of one heart contraction to the end of the next is called the cardiac cycle. Mean pressure (MP) is the average pressure during a cardiac cycle.

Mathematically, MP can be decided by integrating the blood pressure over time. When only SP and DP are available, MP is often estimated by an empirical formula:

$$MP \approx DP + PP/3 \quad (75.1)$$

Note that this formula can be very inaccurate in some extreme situations. Although SP and DP are most often measured in the clinical setting, MP has particular importance in some situations, because it is the driving force of peripheral perfusion. SP and DP can vary significantly throughout the arterial system whereas MP is almost uniform in normal situations.

The values of blood pressure vary significantly during the course of 24 h according to an individual's activity [1]. Basically, three factors, namely, the diameter of the arteries, the cardiac output, and the state or quantity of blood, are mainly responsible for the blood pressure level. When the tone increases in the muscular arterial walls so that they narrow or become less compliant, the pressure becomes higher than normal. Unfortunately, increased blood pressure does not ensure proper tissue perfusion, and in some instances, such as certain types of shock, blood pressure may seem appropriate when peripheral tissue perfusion has all but stopped. Nevertheless, observation or monitoring of blood pressures affords dynamic tracking of pathology and physiology affecting the cardiovascular system. This system in turn has profound effects on the other organs of the body.

75.2 Measurement Techniques

The basis of any physiological measurement is the biological signal, which is first sensed and transduced or converted from one form of energy to another. The signal is then conditioned, processed, and amplified. Subsequently, it is displayed, recorded, or transmitted (in some ambulatory monitoring situations). Blood pressure sensors often detect mechanical signals, such as blood pressure waves, to convert them into electric signals for further processing or transmission. They work on a variety of principles, for example, resistance, inductance, and capacitance. For accurate and reliable measurements a sensor should have good sensitivity, linearity, and stability [2].

75.3 Indirect Blood Pressure Measurement

Indirect measurement is often called noninvasive measurement because the body is not entered in the process. The upper arm, containing the brachial artery, is the most common site for indirect measurement because of its closeness to the heart and convenience of measurement, although many other sites may have been used, such as forearm or radial artery, finger, etc. Distal sites such as the wrist, although convenient to use, may give much higher systolic pressure than brachial or central sites as a result of the phenomena of impedance mismatch and reflective waves [3]. An occlusive cuff is normally placed over the upper arm and is inflated to a pressure greater than the systolic blood pressure. The cuff is then gradually deflated, while a detector system simultaneously employed determines the point at which the blood flow is restored to the limb. The detector system does not need to be a sophisticated electronic device. It may be as simple as manual palpation of the radial pulse. The most commonly used indirect methods are auscultation and oscillometry, each is described below.

Auscultatory Method

The auscultatory method most commonly employs a mercury column, an occlusive cuff, and a stethoscope. The stethoscope is placed over the blood vessel for auscultation of the Korotkoff sounds, which defines both SP and DP. The Korotkoff sounds are mainly generated by the pulse wave propagating through the brachial artery [4]. The Korotkoff sounds consist of five distinct phases. The onset of Phase I Korotkoff sounds (first appearance of clear, repetitive, tapping sounds) signifies SP and the onset of Phase V Korotkoff sounds (sounds disappear completely) often defines DP [5].

Observers may differ greatly in their interpretation of the Korotkoff sounds. Simple mechanical error can occur in the form of air leaks or obstruction in the cuff, coupling tubing, or Bourdon gage. Mercury can leak from a column gage system. In spite of the errors inherent in such simple systems, more mechanically complex systems have come into use. The impetus for the development of more elaborate detectors has come from the advantage of reproducibility from observer to observer and the convenience of automated operation. Examples of this improved instrumentation include sensors using plethysmographic principles, pulse-wave velocity sensors, and audible as well as ultrasonic microphones [6].

The readings by auscultation do not always correspond to those of intra-arterial pressure. [5]. The differences are more pronounced in certain special occasions such as obesity, pregnancy, arteriosclerosis,

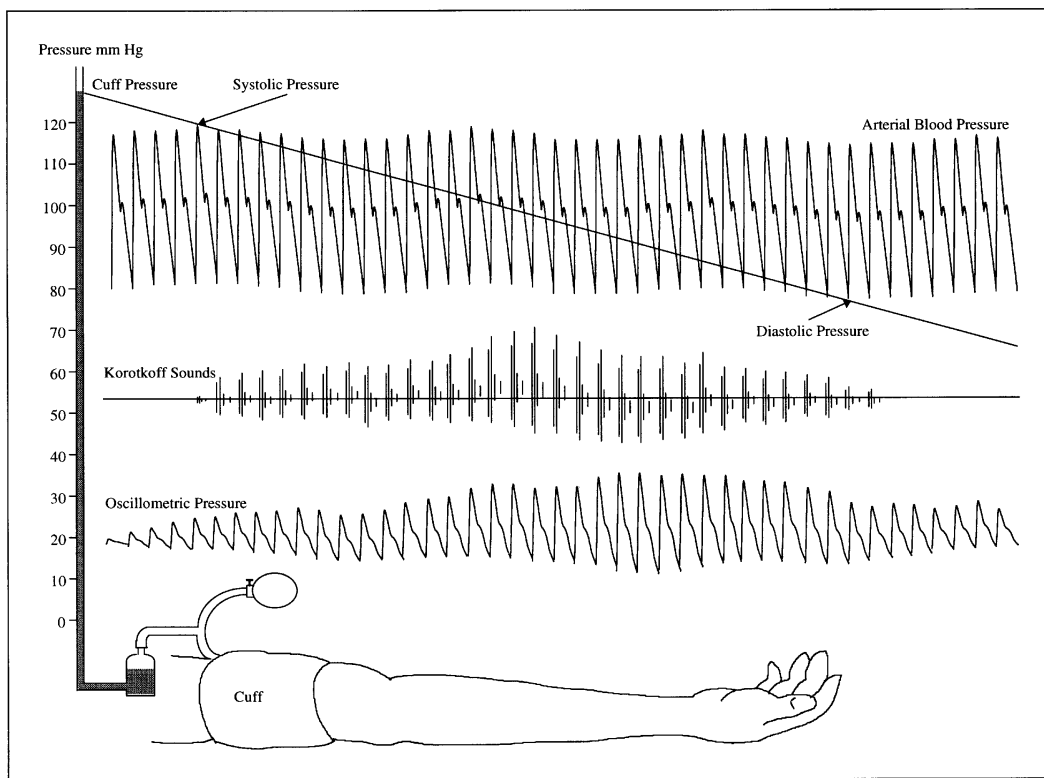


FIGURE 75.1 Indirect blood pressure measurements: oscillometric measurement and auscultatory measurement. (Adapted from Current technologies and advancement in blood pressure measurements — review of accuracy and reliability, *Biomed. Instrum. Technol.*, AAMI, Arlington, VA (publication pending). With permission.)

shock, etc. Experience with the auscultation method has also shown that determination of DP is often more difficult and less reliable than SP. However, the situation is different for the oscillometric method where oscillations caused by the pressure pulse amplitude are interpreted for SP and DP according to empirical rules [7].

Oscillometric Method

In recent years, electronic pressure and pulse monitors based on oscillometry have become popular for their simplicity of use and reliability. The principle of blood pressure measurement using the oscillometric technique is dependent on the transmission of intra-arterial pulsation to the occluding cuff surrounding the limb. An approach using this technique could start with a cuff placed around the upper arm and rapidly inflated to about 30 mmHg above the systolic blood pressure, occluding blood flow in the brachial artery. The pressure in the cuff is measured by a sensor. The pressure is then gradually decreased, often in steps, such as 5 to 8 mmHg. The oscillometric signal is detected and processed at each step of pressure. The cuff pressure can also be deflated linearly in a similar fashion as the conventional auscultatory method.

Figure 75.1 illustrates the principle of oscillometric measurement along with auscultatory measurement. Arterial pressure oscillations are superimposed on the cuff pressure when the blood vessel is no longer fully occluded. Separation of the superimposed oscillations from the cuff pressure is accomplished by filters that extract the corresponding signals. Signal sampling is carried out at a rate determined by the pulse or heart rate [7]. The oscillation amplitudes are most often used with an empirical algorithm to estimate SP and DP. Unlike the Korotkoff sounds, the pressure oscillations are detectable throughout

the whole measurement, even at cuff pressures higher than SP or lower than DP. Since many oscillometric devices use empirically fixed algorithms, variance of measurement can be large across a wide range of blood pressures [8]. Significantly, however, MP is determined by the lowest cuff pressure of maximum oscillations [9] and has been strongly supported by many clinical validations [10, 11].

Self-Measurement

From the growing number of publications on the topic in recent years, it is evident that the interest in self-measurement of blood pressure has increased dramatically. There is also evidence that the management of patients with high blood pressure can be improved if clinic measurements are supplemented by home or ambulatory monitoring. Research has shown that blood pressure readings taken in the clinic can be elevated, by as much as 75 mmHg in SP and 40 mmHg in DP, when taken by a physician. The tendency for blood pressure to increase in certain individuals in the presence of a physician due to stress response is generally known as “white-coat” hypertension [12]. When reasonably priced and easy to use, oscillometric devices became commonly available in the early 1970s, public interest in the self-measurement of blood pressure increased and this has made it possible for greater patient involvement in the detection and management of hypertension [13]. Health care costs may also be reduced by home monitoring. Indeed, a recent study found that costs were almost 30% lower for patients who measured their own blood pressure than those who did not [14]. Measurements taken at patient’s home are more highly correlated to 24-h blood pressure levels than clinic readings are. It has also been shown that most patients are able to monitor their blood pressure and may be more relaxed as well as assured by doing so, particularly when experiencing symptoms [15].

Ambulatory Monitoring

There is great significance for ambulatory monitoring of blood pressure. Over a period of 24 h, blood pressure is subject to numerous situational and periodic fluctuations [1]. The pressure readings have a pronounced diurnal rhythm in an individual, with a decrease of 10 to 20 mmHg during sleep and a prompt increase on getting up and walking in the morning. Readings tend to be higher during working hours and lower at home and they depend on the pattern of activity. After a bout of vigorous exercise or strenuous work, blood pressure may be reduced for several hours. The readings may be raised if the patient is talking during the measurement period. Smoking a cigarette and drinking coffee, especially if they are combined, may both raise the pressure [16]. When assessing the efficacy of antihypertensive drugs, ambulatory blood pressure monitoring can provide considerable information and validation of the drug treatment [17].

Although the technique of noninvasive ambulatory blood pressure monitoring was first described more than three decades ago, it has only recently become accepted as a clinically useful procedure for evaluation of patients with abnormal regulation of blood pressure. It gives the best evaluation for patients who have white-coat hypertension. Technical advances in microelectronics and computer technology have led to the introduction of ambulatory monitors with improved accuracy and reliability, small size, quiet operation, and reasonable low price. They can take and store several hundred readings over a period of 24 h while patients may not be compromised with their normal activities, thus becoming usable for purposes of clinical diagnosis [18]. Theoretically, ambulatory monitoring can provide information about the level and variability covering the full range of blood pressure experienced during day-to-day activities. It is now recognized to be a very useful procedure in clinical practice since blood pressure varies significantly during the course of 24 h, especially useful in detecting white-coat hypertension. However, many studies have found that accuracy of monitoring using current ambulatory monitors is acceptable only when patients are at rest but not during physical activity [19] or under truly ambulatory conditions. Report of error codes during operation in the latter situations is much higher [20].

TABLE 75.1 AHA Acceptable Bladder Dimensions for Arm of Different Sizes^a

Cuff	Bladder Width (cm)	Bladder Length (cm)	Arm Circumference Range at Midpoint (cm)
Newborn	3	6	≤6
Infant	5	15	6–15 ^b
Child	8	21	16–21 ^b
Small adult	10	24	22–26
Adult	13	30	27–34
Large adult	16	38	35–44
Adult thigh	20	42	45–52

^a There is some overlapping of the recommended range for arm circumferences in order to limit the number of cuffs; it is recommended that the larger cuff be used when available.

^b To approximate the bladder width:arm circumference ratio of 0.40 more closely in infants and children, additional cuffs are available.

Adapted from the *Recommendations for Human Blood Pressure Determination by Sphygmomanometers*, Dallas: American Heart Association, 1993. With permission.

Cuff Size

Both the length and width of an occluding cuff are important for accurate and reliable measurement of blood pressure by indirect methods. A too-short or too-narrow cuff results in false high blood pressure readings. Several studies have shown that a cuff of inappropriate size in relation to the patient's arm circumference can cause considerable error in blood pressure measurement [21]. The cuff should also fit around the arm firmly and comfortably. Some manufacturers have designed cuffs with a fastener spaced so that a cuff of appropriate width only fits an arm of appropriate diameter. With this design, the cuff will not stay on the arm during inflation unless it fits accordingly.

According to American Heart Association (AHA) recommendations [5], the width of the cuff should be 40% of the midcircumference of the limb and the length should be twice the recommended width. [Table 75.1](#) presents the AHA cuff sizes covering from neonates to adults.

Recommendations, Standards, and Validation Requirements

The AHA has published six editions of the AHA recommendations for indirect measurement of arterial blood pressure. The most recent edition [5] included the recommendations of the joint national committee on the diagnosis, evaluation, and treatment of hypertension for classifying and defining blood pressure levels for adults (age 18 years and older) [22], as shown in [Table 75.2](#). The "Report of the Second Task Force on Blood Pressure Control in Children" [23] offered classification of hypertension in young age groups from newborns to adolescents, as shown in [Table 75.3](#).

The AHA recommendations provide a systemic step-by-step procedure for measuring blood pressure, including equipment, observer, subject, and technique. It extends considerations of blood pressure recording in special populations such as infants and children, elderly, pregnant and obese subjects, etc. It also provides recommendations of self-measurement or home measurement of blood pressure, as well as ambulatory blood pressure measurement.

The Association for the Advancement of Medical Instrumentation (AAMI) and American National Standard Institute (ANSI) published and revised a national standard [24, 25] for evaluating electronic or automated sphygmomanometers. This standard established labeling requirements, safety and performance requirements, and referee test methods for electronic or automated sphygmomanometers used in indirect measurement of blood pressure. Specific requirements for ambulatory blood pressure monitors were also included. Recently, AAMI/ANSI amended this SP10 standard to include neonatal devices as well [26]. Some of the specific requirements, procedures, and limits were modified to fit neonatal

TABLE 75.2 Recommendations of the Joint National Committee on the Diagnosis, Evaluation, and Treatment of Hypertension for Classifying and Defining Blood Pressure Levels for Adults (age 18 years and older)^a

Category	Systolic Pressure (mm Hg)	Diastolic Pressure (mm Hg)
Normal ^b	<130	<85
High normal	130–139	85–89
Hypertension ^c		
Stage 1 (mild)	140–159	90–99
Stage 2 (moderate)	160–179	100–109
Stage 3 (severe)	180–209	110–119
Stage 4 (very severe)	≥210	120

^a Not taking antihypertensive drugs and not acutely ill. When systolic and diastolic pressures fall into different categories, the higher category should be selected to classify the individual's blood pressure status. For instance, 160/92 mmHg should be classified as stage 2, and 180/120 mmHg should be classified as stage 4. Isolated systolic hypertension is defined as a systolic blood pressure of 140 mmHg or more and a diastolic blood pressure of less than 90 mmHg and staged appropriately (e.g., 170/85 mmHg is defined as stage 2 isolated systolic hypertension). In addition to classifying stages of hypertension on the basis of average blood pressure levels, the clinician should specify presence or absence of target-organ disease and additional risk factors. For example, a patient with diabetes and a blood pressure of 142/94 mmHg plus left ventricular hypertrophy should be classified as having “stage 1 hypertension with target-organ disease (left ventricular hypertrophy) and with another major risk factor (diabetes).” This specificity is important for risk classification and management.

^b Optimal blood pressure with respect to cardiovascular risk is less than 120 mmHg systolic and less than 80 mmHg diastolic. However, unusually low readings should be evaluated for clinical significance.

^c Based on the average of two or more readings taken at each of two or more visits after an initial screening.

Adapted from *The fifth report of the Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure (JNCV)*, Arch. Intern. Med., 153, 154–183, 1993.

applications, such as the maximum cuff pressure, ranges of age and weight, reference standards for validation, minimum sample size of data, etc. The overall system efficacy for both neonatal and adult devices requires that for systolic and diastolic pressures treated separately, the mean difference between the paired measurements of the test system and the reference standard shall be ± 5 mmHg or less, with a standard deviation of 8 mmHg or less.

For manual or nonautomated indirect blood pressure measuring devices, ANSI/AAMI SP9 standard [27] applies.

The British Hypertension Society (BHS) also published and revised a protocol for assessing accuracy and reliability of blood pressure measurement using automatic and semiautomatic devices [28, 29]. Many automatic and semiautomatic devices, including ambulatory devices, have been evaluated according to the BHS protocol. Such evaluation provided a quality-control mechanism for manufacturers and an objective comparison for customers. However, there are many more devices available on the market, which have not been accordingly evaluated. Different from the AAMI SP10 standard in which either indirect or direct blood pressure may be used as a reference standard, the BHS protocol relies exclusively on references of sphygmomanometric blood pressure measurement, and does not recommend comparison with intra-arterial blood pressure values [30]. This could make accurate validation of ambulatory devices difficult because sphygmomanometric measurements during exercise and under ambulatory conditions are not accurate [31].

Significantly, the BHS protocol emphasized the need on special-group validation, such as children, pregnancy, and the elderly for the intended use. It also emphasized the need for validation under special circumstances, such as exercise and posture. The accuracy criteria use a grading system based on the percentages of test instrument measurements differing from the sphygmomanometric measurements by ≤ 5 , ≤ 10 , and ≤ 15 mmHg for systolic and diastolic blood pressure, respectively, as shown in Table 75.4.

TABLE 75.3 Classification of Hypertension in the Young by Age Group^a

Age Group	High Normal	Significant Hypertension	Severe Hypertension
	(90–94th percentile) mmHg	(95–99th percentile) mmHg	(>99th percentile) mmHg
Newborns (SBP)		96–105	≥106
7 d	—	104–109	≥110
8–30 d	—		
Infants (≥2 y)			
SBP	104–111	112–117	≥118
DBP	70–73	74–81	82
Children			
3–5 y			
SBP	108–115	116–123	≥124
DBP	70–75	76–83	≥84
6–9 y			
SBP	114–121	122–129	≥130
DBP	74–77	78–85	≥86
10–12 y			
SBP	122–125	126–133	≥134
DBP	78–81	82–89	≥90
13–15 y			
SBP	130–135	136–143	≥144
DBP	80–85	86–91	≥92
Adolescents (16–18 y)			
SBP	136–141	142–149	≥150
DBP	84–91	92–97	≥98

^a SBP indicates systolic blood pressure; DBP, diastolic blood pressure.

Adapted from the Report of the Second Task Force on Blood Pressure Control in Children — 1987, *Pediatrics*, 79, 1–25, 1987. With permission.

TABLE 75.4 Grading Criteria of the 1993 British Hypertension Society Protocol^{a,b}

Grade	Absolute Difference between Standard and Test Device (mmHg)		
	≤5	≤10	≤15
	Cumulative Percentage of Readings		
A	60	85	95
B	50	75	90
C	40	65	85
D	Worse than C		

^a Grades are derived from percentages of readings within 5, 10, and 15 mmHg. To achieve a grade all three percentages must be equal to or greater than the tabulated values.

^b Grading percentages changed from the 1990 British Hypertension Society protocols due to changes in sequential assessment of blood pressure references.

Manufacturer, Product, Price, Efficacy, and Technology

The annual publication of the *Medical Device Register* is a comprehensive reference work that provides a wealth of detailed information on U.S. and international medical devices, medical device companies, OEM suppliers, and the key personnel in the industry. Blood pressure devices are listed in the sphygmomanometer

directory. Price information of specific models for some providers is also published. For example, A&D Engineering, Inc. listed price from \$51.95 (model UA701) to \$179.95 (model UA-751) for a whole line of sphygmomanometers in the 1997 *Medical Device Register* [32]. Since technology and market can change rapidly, models, features, specifications, and prices may change accordingly. More specific and updated information may be available by contacting the manufacturers or distributors directly.

Table 75.5 lists only a limited number of indirect blood pressure devices from a literature review. Many of the listed blood pressure devices have multiple evaluation studies and only a few study results are presented here. In view of reference standards for comparison, although direct and indirect methods yield similar measurements, they are rarely identical because the direct method measures pressure and the indirect method is more indicative of flow [5]. Egmond et al. [33] evaluated the accuracy and reproducibility of 30 home blood pressure devices in comparison with a direct brachial arterial standard. They found average offsets of all tested devices amounted to -11.7 mmHg for systolic and 1.6 mmHg for diastolic blood pressure, which were close to those of the mercury sphygmomanometer (-14.2 mmHg for systolic and -0.1 mmHg for diastolic pressure), indicating a significant difference between the two assessment standards. When selecting a blood pressure device for a specific application, the evaluation using the reference that is of a common practice in the intended population or environment may be practically more informative, since that reference has been the common basis for decision making in blood pressure diagnosis and treatment.

Different evaluation results for the same brand product can also be due to different versions of a model used for validation, where a later version may have performance improvement over the earlier one [34]. Another source of discrepancies can come from utilizing different study protocols or only partially following the same protocols. It is recommended that the original clinical evaluation report be carefully examined in determining the desired efficacy that may meet the users' requirements. If the devices were FAD approved for marketing in the U.S., one may request a copy of their clinical validation report directly from the manufacturer.

In addition to the fundamental categories such as intended use, efficacy, and acquisition technology, listed in Table 75.5, many other categories are also very important in evaluating, selecting, purchasing, using, and maintaining blood pressure devices. These include but are not limited to the following items: measurement range of each pressure (systolic, diastolic, and mean) for each mode of intended use (i.e., neonates, children, adults); maximum pressure that can be applied by the monitor and cuff for each mode of intended use; cuff size range for the target population of the intended use; cost; measurement and record failure rate; noise and artifact rejection capability; mode of operation (manual, automatic, semiautomatic); data display; recording, charting, reporting, and interfacing; physical size and weight; power consumption; operation manual; service manual; labels and warnings; etc.

Advancement of Indirect Blood Pressure Measurement

Since the introduction of Dinamap™, an automated blood pressure monitor based on the oscillometric principle [9], many variants of oscillometric algorithms were developed. However, the fixed or variable fractions of the maximum oscillations are still the fundamental algorithms of the oscillometry [10, 53, 54]. Typically, mean blood pressure was determined by the lowest cuff pressure with greatest average oscillation [11]. Systolic and diastolic blood pressure were determined by the cuff pressure with the amplitude of oscillation being a fixed fraction of the maximum. Performance of the algorithms may be improved by introducing a greater level of complexity or variables into considerations. The Dinamap™ 1846SX (Critikon, Tampa, FL) oscillometric device offered two measurement modes. The normal mode uses two matching pulse amplitudes at each cuff pressure step to establish an oscillometric envelope or curve. Therefore, measurement time is heart rate dependent. The second mode, which the manufacturer refers to as “stat mode,” is capable of faster determination by disabling the dual pulse-matching algorithm which was designed for artifact rejection. The stat mode does not appear to compromise accuracy in anesthetized patients [55], in which rapid measurement of blood pressure is often more desirable, particularly during induction and management of anesthesia.

TABLE 75.5 Survey of Indirect Blood Pressure Device Manufacturer, Product, Intended Use, and Efficacy

Manufacturer	Model	Technology	Intended Use	Reference Standard	Efficacy								Ref.		
					BHS Protocol Grading		AAMI SP10 Comparison (Device - Reference) mmHg		Other Validations (Device - Reference) mmHg						
					SBP	DBP	SBP	DBP	SBP	DBP	SBP	DBP			
A&D, Tokyo, Japan	TM-2420/ TM-2020	Korotkoff	Health Care: Ambulatory	MC	D	D	D	-4 ± 11	-2 ± 11						35
	TM-2420 Version 7	Korotkoff	Health Care: Ambulatory	MC	B	B	B	-1.8 ± 5.0	-3.5 ± 6.8						36
Colin Medical Instruments, Plainfield, NJ	ABPM 630	Korotkoff (primary mode) Oscillometry (backup mode)	Health Care: Ambulatory Ambulatory	AC						1.4 ± 7.1	-0.1 ± 5.6				37
			Health Care: Ambulatory	MC						-0.4 ± 4.6	-6.0 ± 5.9				
			Health Care: Ambulatory	AC						4.5 ± 6.6	-1.2 ± 6.3				
			Health Care: Ambulatory	MC						1.9 ± 4.0	-6.9 ± 5.1				
Del Mar Avionics, Irvine, CA	Pressurometer IV	Korotkoff (ECG R-wave gating)	Health Care: Ambulatory	MC	C	D	D	-2 ± 11	-3 ± 11						38
Disetronic Medical Systems AG Burgdorf, Switzerland	CH- Druck/Pressure Scan ERKA	Korotkoff	Health Care: Ambulatory	MC	A	A	A	-3 ± 4	-2 ± 4						39
Novacor, France	DIASYS 200	Korotkoff	Health Care: Ambulatory	MC	C	C	C	-1 ± 8	0 ± 8						40
Oxford Medical, Abingdon, Oxford, U.K.	Medilog ABP	Korotkoff	Health Care: Ambulatory	AC				-8 ± 8	6 ± 6						41
			Health Care: Ambulatory	MC				-4 ± 6	-2 ± 8						42
Disetronic Medical Systems AG, Burgdorf, Switzerland	Profilmomat	Korotkoff	Health Care: Ambulatory	MC	B	A	A	-3 ± 5	-1 ± 5						43
SpaceLabs Medical, Redmond, WA	90207	Oscillometry	Health Care: Ambulatory	MC	B	B	B	-1 ± 7	-3 ± 6						44
Suntech Medical Instruments, Raleigh, NC	Accutracker II (v30/23)	Korotkoff (ECG R- wave gating)	Health Care: Ambulatory	MC	A	C	C	-1.3 ± 6.5	-4.5 ± 7.3						45 ^b
Tycos-Welch-Allyn, Arden, NC	QuietTrack	Korotkoff	Health Care: Ambulatory					0.3 ± 5.0	-1.5 ± 7.5						46 ^c
Colin Medical Instruments, San Antonio, TX	BP8800MS	Oscillometry	Health Care: Children Health Care: Adults	MC				3.2 ± 6.0	-0.8 ± 5.2						47
			Health Care: Adults	MC				2.8 ± 5.4	0.0 ± 4.9						

Matsushita, Osaka, Japan	Denko EW 160	Oscillometry	Self Care: Home Measurement	MC	1.8 ± 5.2	-1.7 ± 5.5	52
Nissei, Tokyo, Japan	DS 91 ^f	Korotkoff	Self Care: Home Measurement	MC	-2.5 ± 7.4	2.8 ± 10.8	52
Omron, Tokyo, Japan	HEM 439 ^f	Korotkoff	Self Care: Home Measurement	MC	-0.2 ± 5.3	6.2 ± 9.9	52
	HEM 719K	Korotkoff	Self Care: Home Measurement	MC	-2.3 ± 5.6	2.4 ± 4.7	52
	401C ^f	Oscillometry	Self Care: Home Measurement	MC	-1.6 ± 7.7	2.4 ± 6.1	52
Sharp, Osaka, Japan	MB 305H ^f	Korotkoff	Self Care: Home Measurement	MC	0.5 ± 4.5	9.6 ± 14.3	52
	MB 500A	Oscillometry	Self Care: Home Measurement	MC	-1.8 ± 6.7	0.7 ± 6.3	52
A&D, Tokyo, Japan	Takeda UA 751	Oscillometry	Self Care: Home Measurement	MC	-4.1 ± 5.6	0.4 ± 7.8	52

^a MC: mercury column; AC: arterial catheter.

^b Data quoted for the standing position; grading was the same as for pooled data of three positions (supine, seated, and standing).

^c Data quoted for the three positions of supine, seated, and standing.

^d Efficacy quoted was determined in adult population.

^e Efficacy quoted was determined in neonate and adult populations, respectively.

^f Semiautomatic; all other listed are automatic.

^g Only partially followed AAMI and BHS protocol and only validated one size (median) of three cuffs (small, median, large).

Adapted from Current technologies and advancement in blood pressure measurements-review of accuracy and reliability, Biomed. Instrum. Technol., AAMI, Arlington, VA (publication pending). With permission.

Another variant of the oscillometric algorithm was developed by Protocol Systems [56]. In addition to using pulse amplitude for primary artifact rejection, it further calculated impulse value, a principal area of pulse waveform, in constructing an oscillometric curve. This curve is smoothed by employing a Kalman filter that also provides an expected mean and acceptable upper and lower bounds of prediction for the principal area of subsequent pulse waveform. Smoothing of the oscillometric curve is accomplished by using the difference between the predicted and calculated area data of pulse waveform for each cuff pressure step. Blood pressures are derived from the final smoothed oscillometric curve.

In more recent study, oscillometric algorithms using an artificial neural network have been reported to produce better estimates of reference blood pressures than the standard oscillometric algorithm [57]. By using neural network training and processing, subtle features and nonlinear relationships of the oscillometric envelope have been modeled. Empiricism of the oscillometric fixed fraction criteria is overcome and variances of measurements are greatly reduced.

Because of its low risk and cost, noninvasive continuous blood pressure monitoring represents another need in critical-care monitoring to supplement invasive arterial catheterization. A significant development in this field is the arterial counterpulsation principle, proposed by Penaz [58], and further developed by two major groups of people [59, 60]. Finapres™, a continuous finger arterial blood pressure monitor was engineered and developed by Ohmeda, Denver, CO. Many clinical evaluation reports of these devices have been published since then.

Recently, a number of other continuous blood pressure monitors have been made commercially available. Examples of these are Cortronic APM770 [61], which monitors pulsation of the brachial artery with a slightly pressurized arm cuff and calibrates it to a continuous pressure waveform; Sentinel ARTRAC 7000 [62], which monitors pulse transit time and correlates that to pressure change; Colin CBM-3000 and JENTOW (Colin Electronics, Komaki, Japan) [63, 64] and Nellcor NCAT N-500 (Nellcor, Hayward, CA) [65], which are tonometric devices monitoring the radial artery pulse waveform by a matrix pressure sensor. All of these monitors require a frequent calibration reference. Except for a few favorable reports with the tonometric method and devices, many reports so far are unfavorable. Nevertheless, noninvasive continuous monitoring represents an important and growing field of biomedical sensor and instrumentation research and development. Continuous monitors, which maintain cuff pressure, must periodically relieve pressure to prevent the risk of venous congestion, edema, swelling, and tissue damage.

75.4 Direct Blood Pressure Measurement

Direct measurement is also called invasive measurement because bodily entry is made. For direct arterial blood pressure measurement an artery is cannulated. The equipment and procedure require proper setup, calibration, operation, and maintenance [66]. Such a system yields blood pressures dependent upon the location of the catheter tip in the vascular system. It is particularly useful for continuous determination of pressure changes at any instant in dynamic circumstances. When massive blood loss is anticipated, powerful cardiovascular medications are suddenly administered, or a patient is induced to general anesthesia, continuous monitoring of blood pressures becomes vital.

Most commonly used sites to make continuous observations are the brachial and radial arteries. The femoral or other sites may be used as points of entry to sample pressures at different locations inside the arterial tree, or even the left ventricle of the heart. Entry through the venous side of the circulation allows checks of pressures in the central veins close to the heart, the right atrium, the right ventricle, and the pulmonary artery. A catheter with a balloon tip carried by blood flow into smaller branches of the pulmonary artery can occlude flow in the artery from the right ventricle so that the tip of the catheter reads the pressure of the left atrium, just downstream. These procedures are very complex and there is always concern of risk of hazard as opposed to benefit [67].

Invasive access to a systemic artery involves considerable handling of a patient. The longer a catheter stays in a vessel, the more likely an associated thrombus will form. The Allen's test can be performed by pressing on one of the two main arteries at the wrist when the fist is clenched, then opening the hand to see if blanching indicates inadequate perfusion by the other artery. However, it has proved an equivocal

predictor of possible ischemia [68]. In the newborn, when the arterial catheter is inserted through an umbilical artery, there is a particular hazard of infection and thrombosis, since thrombosis from the catheter tip in the aorta can occlude the arterial supply to vital abdominal organs. Some of the recognized contraindications and complications include poor collateral flow, severe hemorrhage diathesis, occlusive arterial disease, arterial spasm, and hematoma formation [69].

In spite of well-studied potential problems, direct blood pressure measurement is generally accepted as the gold standard of arterial pressure recording and presents the only satisfactory alternative when conventional cuff techniques are not successful. This also confers the benefit of continuous access to the artery for monitoring gas tension and blood sampling for biochemical tests. It also has the advantage of assessing cyclic variations and beat-to-beat changes of pressure continuously, and permits assessment of short-term variations [70, 71].

Catheter–Tubing–Sensor System

A large variety of vascular catheters exist. Catheter materials have undergone testing to ensure that they have a minimal tendency to form blood clots on their surface. The catheter chosen may be inserted percutaneously over a hollow stylet into the blood vessel. Guide wires can be useful to facilitate longer or larger-diameter catheters into vessels, after the guide wires have been placed through a smaller catheter or needle. Less often, entry to a vessel requires a “cutdown,” a direct exposure of the vessel after a skin incision. Ultrasonic devices may assist locating the vessels not readily apparent at the skin surface.

Although pressure sensors can be located at the catheter tip, this presents a problem for calibration if left in place and a clot forms near the tip of the catheter, damping the pressure signal. Instead, most catheters connect to an external pressure sensor via fluid-filled low-compliance tubing. The signal from the sensor then undergoes transformation for display or recording. The sensor may take one of several forms, from a variable resistance diaphragm to a silicon microchip. A basic system can consist of an intravascular catheter connected to a rigid fluid-filled catheter and tubing which communicates the pressure to an elastic diaphragm, the deflection of which is detected electrically. There is a direct relationship between the deflection of the diaphragm and the voltage. The higher the voltage, the greater the pressure. Continuous low-rate infusion of heparinized saline is carried out to keep the catheter patent or free from coagulation. The advent of disposable sensor kits have greatly simplified the clinical use of intravascular monitoring [72]. With the cost continually being lowered with the development of semiconductor industry, disposable sensors become more and more cost-effective.

Although direct recording is considered the most accurate method, its accuracy may be limited by variations in the kinetic energy of the fluid in the catheter or dynamic frequency response of the measurement system. The hydraulic link between the patient and the sensor is the major source of potential errors and hazard for the monitoring. Damping and degrading the system's natural frequency, caused by trapped air bubbles, small catheters, various narrow connections, compliant and too long tubing, and too many components connected, are the two characteristic problems with a pressure sensor system. Extreme care should be exercised to eliminate all air bubbles from the fluid to provide adequate dynamic response. The sensor should be zeroed at the level of the heart to eliminate hydrostatic error [73]. A fast flush testing is easy to use for inspection of the dynamic response of the whole system of catheter–tubing–sensor. It can also help direct adjustments for the system to minimize dynamic artifacts [74, 75].

75.5 Reproducibility, Accuracy, and Reliability Issues and Recommendations for Corrective Measures

For each blood pressure assay technique, there is an issue of reproducibility of measurements given approximately similar conditions. Reproducibility quantifies the internal uncertainty of an individual method and instrument, whereas accuracy quantifies the external uncertainty when compared with a reference. [Table 75.6](#) presents estimated uncertainties of reproducibility for three blood pressure–measuring techniques: auscultation, oscillometry, and umbilical arterial catheter [50]. When dealing with

TABLE 75.6 Estimated Uncertainties of Reproducibility for Blood Pressure Measuring Techniques of Auscultation, Oscillometry, and Umbilical Arterial Catheter^a

	Auscultation	Oscillometry ^b	Umbilical Arterial Catheter
Neonate			
Systolic pressure (mmHg)	N/A	3.3	2.2
Diastolic pressure (mmHg)	N/A	3.4	1.8
Adult			
Systolic pressure (mmHg)	2.8	3.2	N/A
Diastolic pressure (mmHg)	2.2	3.5	N/A

^a From Reference 50.

^b Evaluated from SpaceLabs Medical Oscillometric monitor [50].

blood pressure measurement, it is important to bear in mind that even for standard methods, there is a certain amount of nonrepeatable random error. Consequently, taking the average of repeated measurements or multiple readings is always advised before any serious recommendation or management is made.

Table 75.7 presents a review of common problems associated with accuracy and reliability in both indirect and direct blood pressure measurements. Consequences of these problems are analyzed and recommendation of preventive action or alternative solutions are provided. Hazard or safety analyses and review are also very important.

75.6 Blood Pressure Impact, Challenge, and Future

Hypertension is one of the most common and important risk factors of health in industrialized countries [82]. It is the leading cause of death in the U.S. It is treatable by a variety of effective medications. It can cause serious damage to the heart and arteries leading to cardiac infarct, stroke, or renal failure. Significant sudden changes in blood pressure may also precede a major physiological catastrophe such as cardiac arrest. There is now almost universal acceptance that basic physiological parameters such as blood pressure should always be monitored in the clinical setting.

There has been increasing interest in automatic blood pressure monitoring devices in recent years and some clinicians are now advising patients to record their blood pressure at home over a period of up to 3 months before starting antihypertensive medication [83]. Self-monitoring of blood pressure has become very common with the development of microchip technology and oscillometric monitors. The patients no longer have to learn how to listen for Korotkoff sounds. This has also removed bias and observer errors, allowing more accurate measurement than by conventional techniques using a stethoscope and a mercury sphygmomanometer [84].

Special populations have unique blood pressure assessment requirements. Newborns require miniaturized equipment. The act of taking a blood pressure in a newborn may stimulate a series of movements causing motion artifact. The very obese may be hard to fit properly with a cuff at the upper arm, if the upper arm is too conical rather than cylindrical. In pregnancy, auscultatory and oscillometric methods, although useful to follow trends, may correspond poorly with central pressures [85] and even the proper Korotkoff sound (IV or V) to designate as diastolic pressure is uncertain [86].

Observing blood pressures has limitations. It may suggest what is happening with blood volume, but sometimes does not reveal that blood volume has become inadequate until circulatory collapse has occurred. Venous and left atrial pressures are often used in an attempt to clarify blood volume problems but with uncertain results [87]. Similarly, a satisfactory blood pressure does not always indicate adequate tissue perfusion. Some medications that increase blood pressure can do so at the expense of general perfusion. Since blood pressure is measured at specific sites in the arterial tree, if circulation has become nonhomogeneous, such as can happen in arteriosclerosis, the region distal to the arteriosclerosis can be compromised without warning from blood pressure readings sampled at another site. Even mean blood pressure, so useful otherwise, can fail in these circumstances.

TABLE 75.7 Common Issues of Accuracy and Reliability in Blood Pressure Measurement and Recommendations of Preventive Action or Alternative Solution in Both Indirect and Direct Measurements

Source	Problem	Result	Recommendation
Indirect Measurement			
Subject	Obesity, peripheral edema, peripheral vascular disease	Weak Korotkoff sounds and diminished sound transmission may reduce the accuracy and reliability of auscultatory measurement; oscillometric measurement may also be affected	Verify with a second indirect method such as oscillometry; direct blood pressure measurement may be elected to use in severe conditions that indirect measurement does not warrant sufficient accurate and reliable measurement
	Shock, severe peripheral vasoconstriction, diminished peripheral circulation resulting from shunting of blood to central organs; Korotkoff sounds and pulses may be absent even in presence of normal pressure [76]	Any of the indirect methods, including auscultatory, oscillometric and Doppler techniques may not provide accurate and reliable reading; indirect measurement may be impossible or may give misleading results	Direct measurement should be considered
	Arrhythmias, respiratory effect	Pronounced variation in beat-to-beat blood pressure and waveform	Take multiple measurements and average
	Subject shivering, pain, anxiety, discomfort, motion artifact	Shivering and motion artifact may cause either false high or false low reading, whereas pain, anxiety, and discomfort may cause false high reading	Minimize pain, anxiety, and discomfort; reduce shivering and movement
	Physical activity within 5 min of measurement; talking, moving, arm unsupported, back unsupported, legs dangling, and any other isometric activities	False high reading that does not reflect subject's resting blood pressure	Subject should rest at least 5 min in the same position that blood pressure is going to be taken; subject should not talk and involve any isometric activities during measurement; arm should be supported at heart level
	Arm supported at above heart level	Hydrostatic pressure causes false low reading by 0.78 mmHg for each centimeter of offset [77]	Support the arm with midpoint of upper arm at heart level
	Arm supported at below heart level	Hydrostatic pressure causes false high reading by 0.78 mmHg for each centimeter of offset	Support the arm with midpoint of upper arm at heart level
	White-coat hypertension during clinical measurement	Psychological or stress response causes blood pressure temporarily elevated and unrepresentative of subject's true condition	Take multiple self-measurements at home or ambulatory monitoring as desired and provide record to care providers
"Pseudo-hypertension" with calcified or stiffened arteries	Reduced arterial compliance, often occurring in the elderly, causes cuff blood pressure falsely too high or unable to be measured accurately	Use Osler maneuver for screening; direct method is recommended for those who test positive [78,79]	
Operator	Hose kinked	Will cause reading error or operation failure	Rearrange hose to avoid kink
	Cuff used too narrow for arm	Will cause false high reading	Select appropriate cuff size that its width encircles 40% of arm circumference
	Cuff used too wide for arm	May cause false low reading; may not fit on arm	Select appropriate cuff size that its width encircles 40% of arm circumference

TABLE 75.7 (continued) Common Issues of Accuracy and Reliability in Blood Pressure Measurement and Recommendations of Preventive Action or Alternative Solution in Both Indirect and Direct Measurements

Source	Problem	Result	Recommendation
	Cuff wrapped too loosely	Will cause false high reading; may introduce artifact of inter cuff–arm abrasion if placed for long-term monitoring	Cuff should be snugly applied; one should not be able to insert two fingers between the cuff and arm for adult
	Cuff wrapped too tightly	May cause false low reading; will restrict and impair limb circulation if placed for long-term monitoring	Cuff should be snugly but not restrictively applied; one should be able to insert one finger between the cuff and arm for adults
	Cuff pressure inflated too high	Patient discomfort; may induce increase in systolic blood pressure during inflation period, so called “cuff-inflation hypertension” [80]	Inflate cuff pressure to 30 mmHg above palpatory blood pressure
	Cuff pressure inflated too low	Will either miss or have false low systolic pressure reading	Inflate cuff pressure to 30 mmHg above palpatory blood pressure
	Cuff pressure deflated too fast	May degrade the accuracy of the reading	Deflate cuff pressure at 2–4 mmHg per heart beat or 3 mmHg/s
	Cuff pressure deflated too slow	May cause discomfort or forearm congestion	Deflate cuff pressure at 2–4 mmHg per heart beat or 3 mmHg/s
	Repeated cuff pressure measurement too frequently	May cause discomfort and forearm congestion	A sufficient time should elapse (at least 60 s) before the next reading to allow the return of normal circulation
	Miss identifying auscultatory gap between systolic and diastolic pressure	Will cause false low systolic or false high diastolic pressure	Listen to Korotkoff sounds carefully for a wide pressure deflation range or use oscillometric method
	Stethoscope head or sensor not over the brachial artery	Will not hear clear sounds or detect sufficient signal for blood pressure determination	Place the stethoscope head or sensor over the brachial artery at least 1.5 cm above the antecubital fossa
	Noise and artifact created by accidentally touching or bumping the cuff, hose, stethoscope, or sensor	May cause inaccurate reading or failure of reading	Avoid incidence of extraneous noise and artifact
Equipment	Leaky hose, bladder/cuff, or pneumatic components	Will cause inaccurate reading or failure in operation	Require service or replace equipment
	Faulty valves	Will cause inaccurate reading or failure in operation	Require service or replace equipment
	Limited selection for different size of cuffs	Will cause false low or false high reading if cuff is too large or too small, respectively	Manufacturer should provide appropriate label/labeling for the intended use and arm size; blood pressure measurement beyond the intended use of the device should be warned against and prohibited
	Device zero-shifted, out of calibration	Will create systematic bias or uncertainty in blood pressure reading	Require routine calibration and maintenance
Direct Measurement			
Subject	Subject position change (e.g., body position change, bed lowered or elevated, etc.) in relation to pressure sensor	Subject heart level change in relation to pressure sensor will introduce bias of hydrostatic pressure in blood pressure recording	Move the sensor zero port to the heart level and zero the sensor/monitor
	Catheter whip in pulmonary artery, catheter impact in aorta or ventricle	Catheter whip can result in superimposed waves of ± 10 mmHg; catheter impact can cause high-frequency transients to occur in waveform [81]	Catheter whip and catheter impact are difficult to prevent; evaluation of pressure waveform and reading should consider the effect of these events

TABLE 75.7 (continued) Common Issues of Accuracy and Reliability in Blood Pressure Measurement and Recommendations of Preventive Action or Alternative Solution in Both Indirect and Direct Measurements

Source	Problem	Result	Recommendation
	Subject severe shivering, pain, anxiety, discomfort, moving	Severe shivering and moving may cause artifact on blood pressure waveform whereas pain, anxiety, and discomfort may elevate blood pressure	Minimize pain, anxiety, and discomfort, reduce shivering and moving
Operator	Tubing kinked	Will change dynamic response of tubing system and distort pressure waveform	Use short and low compliant tubing, and place tubing appropriately to avoid kink
	Sensor zero port higher than heart level when zeroing	Hydrostatic pressure causes false low pressure measurement by 0.78 mmHg for each centimeter of offset	Move the sensor zero port to heart level and zero the sensor/monitor
	Sensor zero port lower than heart level when zeroing	Hydrostatic pressure causes false high pressure measurement by 0.78 mmHg for each centimeter of offset	Move the sensor zero port to heart level and zero the sensor/monitor
	Air bubbles entrapped in the tubing system	Air bubbles will decrease natural frequency and increase damping coefficient; therefore they damp and distort the waveform, causing high-frequency components to loss in pressure waveform	Eliminate air in both tubing system and flush solution bag; light tapping while fluid is filling the tubing system is an effective method for removing air
	Tubing too long, too thin, and with too many components	All of these will degrade the system dynamic response and result in distorted waveform and erroneous reading	Use tubing of large inner diameter, short length, and reduce the number of components as much as possible
	Connectors not tightly connected	Will decrease natural frequency of tubing system and cause pressure waveform to be distorted	Check loose luer-lock connection and cracked connection; replace cracked components and secure tight connection of all components
	Failure to flush the arterial line adequately after blood draw	May cause the catheter tip partially clotted by the blood and pressure waveform over damped and distorted	Flush the arterial line adequately; may need to replace with a new catheter if dynamic response cannot be improved to meet the minimum requirement
	Failure to zero the sensor/monitor after subject position change in relation to pressure sensor	Subject heart level change in relation to pressure sensor will introduce bias of hydrostatic pressure in blood pressure recording	Move the sensor zero port to the heart level and zero the sensor/monitor
Equipment	Failure to provide constant infusion of anticoagulation/saline solution	May cause catheter tip partially clotted by the blood and pressure waveform overdamped and distorted	Check the constant infusion device to have sufficient flow rate; flush the arterial line adequately; may need to replace with a new catheter if dynamic response cannot be improved to meet the minimum requirement
	Failure to test dynamic response at least once a shift and anytime after blood draw or component change	This leaves the system dynamic performance unknown, which may affect the accuracy of systolic pressure the most, diastolic pressure the second; mean pressure is hardly affected	Routinely perform the fast flush test to evaluate the dynamic response visually according to Gardner's chart of natural frequency vs. damping coefficient [73]
	Not equipped with an appropriate flush device	May not be able to generate quality test waveform to evaluate the adequacy of dynamic response of the catheter-tubing-sensor system	Select appropriate flush device that permits fast flush test for the system dynamic response
	Tubing or component not transparent	Unable to see entrapped air bubbles	Use transparent tubing and components

TABLE 75.7 (continued) Common Issues of Accuracy and Reliability in Blood Pressure Measurement and Recommendations of Preventive Action or Alternative Solution in Both Indirect and Direct Measurements

Source	Problem	Result	Recommendation
	Tubing, sensor, or constant flush device too compliant	Will decrease natural frequency of the system and cause pressure waveform to be distorted	Use only high-quality and low-compliance tubing, sensor, and constant flush device
	Stopcocks not tightly sealed	Will decrease natural frequency of the system and cause pressure waveform to be distorted	Replace with tightly sealed, high-quality stopcocks
	Monitor failure to zero the sensor electronically, sensor zero drift, or pressure amplifier zero drift	Will introduce unknown offset or bias in pressure measurement	Require service or replacement of the equipment
	Natural frequency and damping coefficient of the catheter-tubing-sensor system failure to meet minimum dynamic response requirement	Fidelity of pressure waveform recording suffers and accuracy of systolic and diastolic pressure measurement degrades	Need to optimize the catheter-tubing-sensor system by replacing part or all of the components; use low-compliance pressure sensor, tubing, and all other components; use short and large tubing and reduce the number of components as much as possible
	Blood pressure monitor failure to identify special events such as sensor zeroing, fast flush testing, blood drawing, as well as artifacts	Blood pressure monitor displays false digital reading of blood pressure without warning sign or error message	Health care provider needs to exercise care in viewing the digital results with waveform display; quality control or screening process is needed in dealing with monitoring database

Adapted from Current technologies and advancement in blood pressure measurements-review of accuracy and reliability, *Biomed. Instrum. Technol.*, AAMI, Arlington, VA (publication pending). With permission.

In spite of inherent problems, observation of blood pressure through both old and new technologies retains more than enough usefulness to have remained an essential aspect of patient care. The promise of improved technology to solve problems such as those of motion artifacts, noninvasive continuous monitoring, long-distance telemetry, rapid analysis of accumulated or concurrent data, and assessment of new inaccessible regions of blood flow represent continued challenges for future biomedical research and development.

Recently, exciting research has revealed that comparing pressures taken at the arm and the ankle results in a simple but extremely useful index for assessment of lower extremity vascular disease, with implications for general cardiovascular risk factors [88]. The possibility of obtaining noninvasive blood pressures from arteries in the forehead by stick-on oscillometric patches has also been proved. At least in anesthetized patients, the forehead noninvasive blood pressure corresponded reasonably well with central arterial pressures [89]. Finger blood pressure monitors have found some applications in continuous ambulatory and sleep blood pressure assessments [90]. A technology that is capable of continuously monitoring brachial or even central blood pressure continues to be a clinical demand and future challenge.

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