

Accuracy and reliability of disposable pressure transducers coupled with modern pressure monitors

Reed M. Gardner, PhD

Objective: To determine the bedside accuracy of direct patient pressure monitoring when used with new and clinically used disposable blood pressure (BP) transducers.

Design: Prospective study.

Setting: Laboratory bench and critical care units in an adult and children's hospital.

Subjects: Seventy-five bedside patient monitors (25 Marquette Electronics, 25 Spacelab Medical, and 25 Hewlett-Packard), and 100 disposable transducers (50 from Utah Medical Products and 50 from Abbott Critical Care Systems [25 new, 25 clinically used of each manufacturer]) were tested.

Interventions: None.

Measurements and Main Results: A $\pm 2\%$ accuracy requirement for bedside monitors and the $\pm 3\%$ American National Standards Institute accuracy standard for disposable BP transducers were used. To test the accuracy of the bedside monitors, a certified transducer simulator was used to apply 100 mm Hg to each bedside monitor. To test the accuracy of the disposable BP transducers, a very accurate ($\pm 0.05\%$) pneumatic dead weight tester was used to apply pressures to the transducer. A digital power supply and a $6\frac{1}{2}$ digit voltmeter were used. The average output of the bedside monitors when 100 mm Hg was applied was 99.90 ± 0.83

mm Hg, with the worst cases being 98 and 103 mm Hg. For all 100 disposable pressure transducers, the average output was 100.03 ± 0.55 mm Hg, with the worst cases being 98.53 and 101.36 when 100 mm Hg was applied. There was no important difference in the accuracy of the transducers obtained from the two vendors nor whether the transducers had been used clinically.

Conclusions: All disposable BP transducers tested were much more accurate than the American National Standards Institute standard for accuracy. Even the worst case transducers were twice as accurate as required by the American National Standards Institute standard. Only one bedside monitor was outside the $\pm 2\%$ accuracy range (103 mm Hg). Based on these findings, this author recommends that fixed calibration disposable transducers and fixed calibration bedside pressure monitoring systems be used. The clinical risks of air embolism and infection from the calibrating mercury manometer and the complexity of the calibration task are the overriding factors for making these recommendations. (Crit Care Med 1996; 24:879-882)

KEY WORDS: transducers, pressure; blood pressure; physiologic monitoring; instrumentation; apparatus and instruments; critical illness

Modern disposable pressure transducers are a result of a remarkable set of advances in technology (1-6). Just 15 yrs ago, blood pressure (BP) transducers were reusable devices that cost \$500 to \$700 each. The reusable transducers were hand fabricated, typically used fine wires (about the size of a human hair) as sensors, and were very fragile and unstable. However, in recent years, semiconductor technology has produced pressure transducers that are tiny, ~ 2.5 mm \times 2.5 mm \times ~ 0.4 mm

thickness, that are remarkably rugged and stable and cost $< \$20$ each, and thus become disposable. Pressure transducers for measuring direct BP have been standardized by the Association for the Advancement of Medical Instrumentation and the American National Standards Institute (7-9). The standard sensitivity is $5 \mu\text{V}/\text{V}$ of excitation/mm Hg applied. Thus, if 6 V of excitation is applied, an output of $30 \mu\text{V}/\text{mm Hg}$ pressure applied results—a small signal. By the nature of the semiconductor state-of-the-art, these transducers are rugged, have negligible temperature and time drift, and are accurately calibrated at the time of manufacture (5). Recently, data presented by Bailey, Bauer, and Yanos (10) challenged the accuracy and stability suppositions noted earlier. Bailey, Bauer and Yanos (10) tested the entire clinical pressure monitoring system—a system that included a

disposable BP transducer and the patient monitor.

Figure 1 is a block diagram of a typical direct BP monitoring system. The pressure transducer has an excitation voltage applied and its output signal is amplified before being displayed on a screen as a waveform with digital parameter display and/or placed on a strip recorder. The output signal detected by the monitor display and strip recorder is as follows: Output Voltage = Transducer Sensitivity \times Excitation Voltage \times Monitor Amplifier Gain, where typical values are: Transducer sensitivity = $5 \mu\text{V}/\text{V}/\text{mm Hg}$; Excitation voltage = 6 V; Monitor amplifier gain = 1000 V at the output per V applied at the input. For the above situation, for each mm Hg of pressure applied, there is 30 mV of output voltage. For each 100 mm Hg of pressure applied, there is 3 V of output voltage. Note from Figure 1

From the Department of Medical Informatics, LDS Hospital, Salt Lake City, UT.

Twenty-five new transducers were supplied by Utah Medical and 25 by Abbott Laboratories.

Address requests for reprints to: Dr. Reed M. Gardner, Department of Medical Informatics, LDS Hospital, 325 8th Avenue, Salt Lake City, UT 84143.

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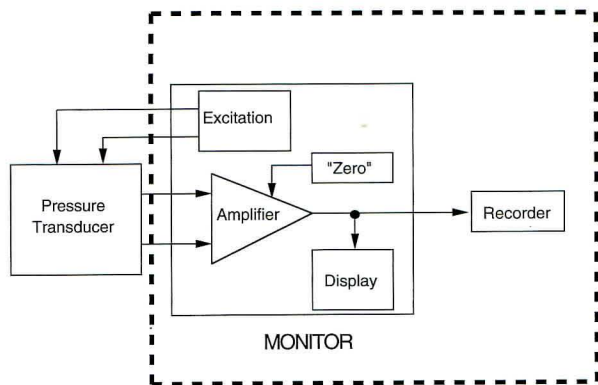


Figure 1. Block diagram of a direct blood pressure measurement system. At the left is the disposable pressure transducer. The excitation voltage for the transducer is supplied from the monitor. The monitor also provides amplification and zero capability, and displays the pressure results. Recorders are typically attached to the monitor after signal amplification.

and the above equation that the output voltage is dependent on three parameters: a) the transducer sensitivity; b) the excitation voltage applied by the monitor; and c) the monitor amplifier gain. Any one of these parameters not being in calibration could cause the output voltage to be incorrect. Calibration refers to the process of adjusting the sensitivity of the pressure transducer, adjusting the excitation voltage, and/or adjusting the gain of the monitor's amplifier system. Typical modern pressure monitoring systems fix the excitation voltage and monitor gain. The same microcomputer technology used in making transducers has made excitation voltages and amplifier gains of monitors very stable. However, some monitors allow the possibility to override the preset gain of the monitor by using a mercury manometer.

According to the latest Association for the Advancement of Medical Instrumentation/American National Standards Institute BP transducer standard, the sensitivity of the transducers must be $5 \mu\text{V/V}$ of excitation/mm Hg. The combined effect of sensitivity, repeatability, nonlinearity, and hysteresis errors should be within $\pm 3\%$ of reading over the range from 50 to 300 mm Hg (9). Methods for testing the transducers are also specified in the standard (9). National standards have not been developed for the gain accuracy of pressure monitoring systems. However, most institutions have specified a gain calibration accuracy of $\pm 2\%$ with a 6-month interval between testing (11).

If transducers meet the $\pm 3\%$ accuracy requirements and the monitors are within the $\pm 2\%$ gain accuracy requirement, the largest error possible when 100 mm Hg is applied to the transducer/monitor pair would be $95.06 = (100 \times 0.97 \times 0.98)$ at a minimum, or $105.06 = (100 \times 1.03 \times 1.02)$ at a maximum. In the worst case situation, a $\pm 5\%$ error might be expected. Bailey, Bauer, and Yanos (10) reported pressures as low as 83 mm Hg and as high as

110 mm Hg when 100 mm Hg was applied to disposable pressure transducers. Since 17% errors are *not* common in our clinical experience, a series of transducer, monitor, and mercury manometer testing was conducted.

MATERIALS AND METHODS

One hundred disposable pressure transducers were evaluated ($n = 50$, Utah Medical Products, Salt Lake City, UT; $n = 50$, Abbott Critical Care Systems/Sorenson Research, Salt Lake City, UT). For each manufacturer noted, 25 new transducers and 25 transducers that had been attached to patients and used in the clinical situation were tested. The 25 used Utah Medical transducers had been attached to patients (between February 2 and 22, 1995) for an average of 32.1 hrs (range 0.5 to 117) at Primary Children's Medical Center in Salt Lake City, UT, and the 25 used Abbott transducers had been attached to patients (between January 26 and February 4, 1995) for an average of 61.8 hrs (range 3.5 to 170) at LDS Hospital in Salt Lake City, UT. The new transducers from both Utah Medical ($n = 25$) and Abbott Critical Care Systems ($n = 25$) were donated by the manufacturers. Pressure transducers were tested using a Mansfield & Green Pneumatic Dead Weight Tester (model PK, Ametek, Largo, FL) pressure standard (accurate at 100 mm Hg to within $\pm 0.05\%$ or ± 0.05 mm Hg). A 6,000-V DC power supply (DVC-8500A, Datel Intersil Voltage Calibrator, Mansfield,

MA) was attached as excitation to each transducer. The voltage applied to the transducer and the output voltage of each transducer were measured with a $6\frac{1}{2}$ digit voltmeter (3457A, Hewlett-Packard Digital Multimeter, Palo Alto, CA). Each transducer initially had atmospheric pressure applied (0 mm Hg) and then 100 mm Hg from the pressure standard. The voltages obtained were then converted to mm Hg by using the $5 \mu\text{V/V/mm Hg}$ calibration factor as is done in bedside monitors.

The gain calibration factor for 75 pressure monitors was also tested ($n = 25$ each, Merlin Monitors, Hewlett-Packard, Andover, MA; PC-1, Spacelab Medical, Redmond, WA; and 7010 Monitor, Marquette Electronics, Milwaukee, WI). Both the Hewlett-Packard and the Spacelab monitors were tested at Primary Children's Medical Center, while the Marquette Electronics monitors were tested at LDS Hospital. A patient simulator (215A, Dynatech Nevada, Carson City, NV) was used as the certified pressure calibration source to test the calibration of each of the monitors. Bedside monitors only indicate integer results for BP (i.e., 99 not 99.3).

Finally, 25 mercury manometers, used at the bedside at LDS Hospital (Baumanometer wall mount, W.A. Baum, Copiague, NY), were tested. The required accuracy of a mercury manometer is ± 3 mm Hg over the range from 0 to 260 mm Hg according to the American National Standards Institute (12). A disposable pressure transducer that measured 100 mm Hg within ± 0.1 mm Hg was used as the testing device and was attached to a particular bedside monitor (Marquette Electronics) that was determined to be accurate at 100 mm Hg pressure, using the certified pressure source (Dynatech Nevada). The specific monitor and transducer were moved from bedside to bedside to test each mercury manometer.

RESULTS

Results of the testing are presented in Table 1 and also shown graphically in Figure 2. Several important findings become apparent: a) Both the Utah Medical and Abbott transducers are *very* accurate (worst case $\pm 1.5\%$), independent of whether they had been used in a clinical situation or not. The

Table 1. Transducer and monitor results

| | Used (hr) | 100 mm Hg ^a | 100 mm Hg (Min) | 100 mm Hg (Max) |
|--------------------------------------|-----------|------------------------|-----------------|-----------------|
| Transducers | | | | |
| Utah Medical | | | | |
| New (n = 25) | | 100.65 ± 0.34 | 99.94 | 101.36 |
| Clinically used (n = 25) | 32.07 | 100.16 ± 0.52 | 98.53 | 100.83 |
| Combined (n = 50) | | 100.40 ± 0.50 | 98.53 | 101.36 |
| Sorenson | | | | |
| New (n = 25) | | 99.63 ± 0.36 | 98.78 | 100.31 |
| Clinically used (n = 25) | 61.78 | 99.69 ± 0.19 | 99.23 | 99.96 |
| Combined (n = 50) | | 99.66 ± 0.29 | 98.78 | 100.31 |
| All transducers (n = 100) | | 100.03 ± 0.55 | 98.53 | 101.36 |
| Monitors | | | | |
| Hewlett-Packard (n = 25) | | 99.72 ± 0.60 | 99 | 101 |
| Marquette (n = 25) | | 99.96 ± 1.18 | 98 | 103 |
| Spacelabs (n = 25) | | 100.04 ± 0.53 | 99 | 102 |
| All monitors (n = 75) | | 99.90 ± 0.83 | 98 | 103 |
| Transducers and monitors (n = 7,500) | | 100.04 ± 0.99 | 96.56 | 104.40 |
| Mercury manometers (n = 25) | | 100.08 ± 1.23 | 98 | 103 |

^aMean ± SD.

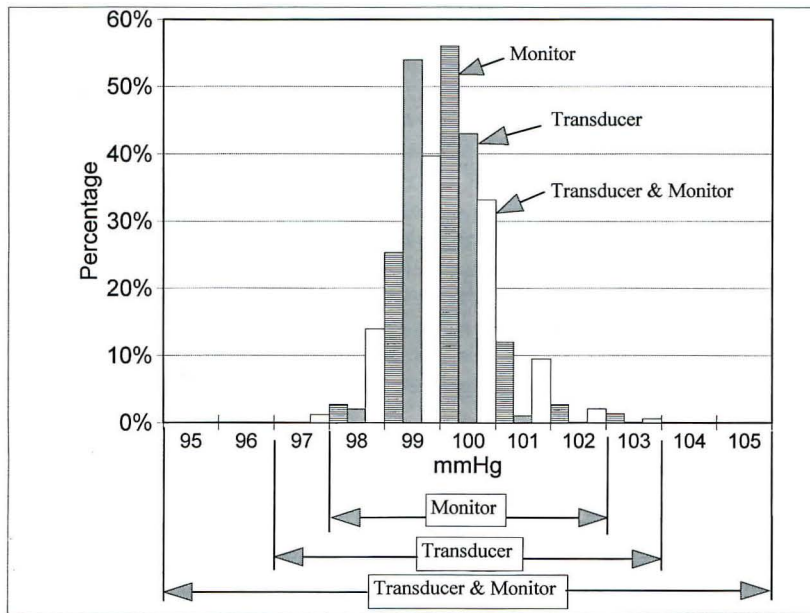


Figure 2. Histogram of results from testing 75 monitors (n = 25, Merlin model, Hewlett-Packard, Medical Division, Andover, MA; n = 25, model 7010, Marquette Electronics, Milwaukee, WI; n = 25, model PC-1, Spacelab Medical, Redmond, WA), 100 disposable blood pressure transducers (25 new and 25 used transducers each from Utah Medical Products, Deltran-II model, Salt Lake City, UT; Abbott Critical Care Systems, Transpac III model, Salt Lake City, UT), and data from the 7,500 transducer and monitor pairings. Vertical lines indicate the ±3% allowable error ranges for disposable transducers, ±2% allowable error ranges for monitors, and ±5% allowable error ranges for transducer-monitor pairings. Only one monitor with an output of 103 mm Hg with 100 mm Hg applied was outside the requisite accuracy range.

worst case output signal for all 100 transducers with 100 mm Hg applied was 98.53 mm Hg on the low end and 101.36 mm Hg on the high end. b) All of the pressure monitors performed well. When a 100 mm Hg pressure signal was applied to each monitor, the average output display was 99.90

mm Hg. The worst case outputs were 98 mm Hg on the low end and 103 mm Hg on the high end. c) Simulating the situation when each of the 100 transducers might have been used on any one of the 75 monitors, the average output was 100.04 mm Hg. In the worst case situation, the transducers

and the monitors that were furthest out of calibration resulted in an output of 96.56 and 104.40 mm Hg when 100 mm Hg was applied. Thus, the maximum error was ±4.4%.

DISCUSSION

The set experimental results presented here are dramatically different than those results reported by Bailey, Bauer, and Yanos (10). The results presented here for disposable transducers are in agreement with results presented in *Health Devices* (3, 5), a publication of Emergency Care Research Institute, a group that was founded in 1971 and has taken the consumer reports role of the health care instrumentation industry. The first *Health Devices* report on disposable transducers was made in September 1984 (3). At that time, *Health Devices* evaluated accuracy, cost, and many other parameters of a variety of disposable transducers. In a more recent evaluation, *Health Devices* devoted almost its entire 20-page issue to the evaluation of 12 different brands of disposable pressure transducers (5). All of the disposable pressure transducers *Health Devices* tested passed the ±3% mm Hg pressure calibration error criterion.

It is unclear why Bailey, Bauer, and Yanos (10) found such large pressure monitoring errors. Perhaps they did not have their pressure monitors properly calibrated. Since Bailey, Bauer, and Yanos (10) made the recommendation to perform a daily calibration check, perhaps the clinical staff had introduced monitor calibration errors. To be certain what caused the errors, a careful study of their raw data and a check of the calibration factors found in their bedside monitors should be conducted.

Bailey, Bauer, and Yanos (10) recommended daily calibration of pressure transducers, a recommendation that should be challenged. This author, as well as monitor manufacturers, have made strong recommendations that fixed gain monitors should be used (1, 2, 13). In addition, the calibration errors reported by Bailey and associates (10) did not change over time. As a consequence, making daily calibration corrections is not needed and the recommendation by Bailey,

Bauer, and Yanos (10) for performing daily calibration checks is unfounded.

Furthermore, the daily calibration methodology suggested by Bailey, Bauer, and Yanos (10) is dangerous for the following, well-documented reasons.

Air Embolism Risk. Air embolism is a serious problem that can result from having a mercury manometer connected to the transducer with improper positioning of the stopcock. *Health Devices* made the following recommendation, "Do not use a mercury or aneroid manometer to test the transducer after it is connected to the patient. Errors such as incorrect stopcock positions can result in pumping air into the blood vessel. We have received reports of fatal cerebral air embolism immediately following routine recalibration of invasive BP monitoring systems while connected to a patient" (14).

Infection Risk. Opening a pressure monitoring system is an invitation for infecting the patient. Several incidents of infection problems have been reported in the literature (15-20). Each time a monitoring system access is made, there is opportunity for contamination.

Recommendation. Based on the findings presented here, this author recommends the following steps be taken: a) Fixed calibration pressure monitoring systems should be purchased and their calibration maintained and verified every 6 months; b) fixed calibration disposable pressure transducers should be used; c) infusion systems should be manipulated as little as possible (19, 20); d) the number of stopcocks and the complexity of the plumbing part of the monitoring systems should be kept as simple as possible (1, 13, 20); e) use of

totally disposable transducer assemblies is preferable (20); f) if pressure transducer or monitor calibration errors are suspected, then the pressure transducer should be replaced and tested in a laboratory setting and the monitor pressure module replaced or tested with a high accuracy pressure transducer simulator.

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