Accuracy Results Following a Multiple-Angle Drop Test Comparing the ELEMANO™ Blood Pressure Monitor with Leading Aneroid Sphygmomanometers

Background:

The benefits of dependable and accurate blood pressure monitoring are well understood, and are critical to reducing the risk of stroke, heart attacks and arrhythmias. Healthcare professionals rely on the accuracy of their blood pressure measurements. If a blood pressure monitor fails to consistently provide accurate measurements, there is increased risk of misdiagnosis or altered course of medical therapy. Therefore, the blood pressure monitoring equipment must be regularly calibrated, which can be time-consuming, inconvenient and costly.

ELEMANO™ Monitor vs. Aneroid Technology

It is well-accepted that, even with the greatest of care, portable blood pressure monitors are sometimes dropped in use, thrown into drawers, or otherwise mishandled. These activities can affect the accuracy of these units by creating changes in calibration. In an effort to understand the effect of "normal use" on the calibration of digital and aneroid blood pressure monitors, a team of Terumo's research engineers conducted drop tests involving the digital ELEMANO™ Blood Pressure Monitor (Terumo Corporation) and each of three aneroid blood pressure monitors (Welch-Allyn). The objective of this test was to determine the impact of stress on the accuracy of each unit under identical conditions.

Drop Test Methodology:

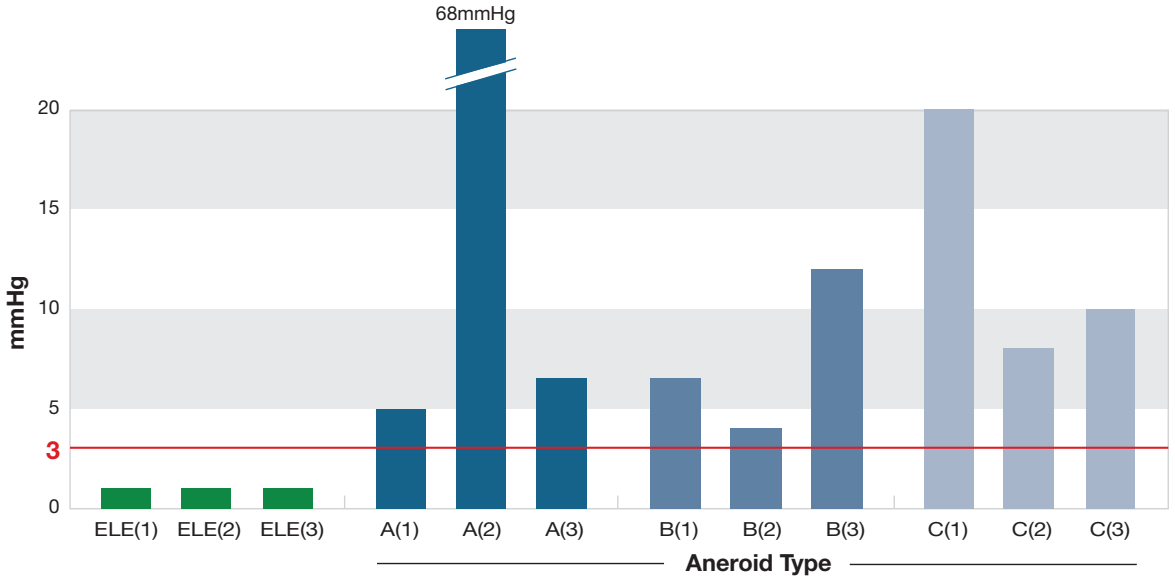
To determine how these units would fare under stress-induced conditions, researchers sought to determine the effect of a uniform drop test performed according to uniform protocols[1].

- Three units of each blood pressure monitor model were dropped according to established protocol, each one from the same six different angle positions.
- The distance of each drop from release to impact on a 5cm oak board floor was one meter (3.28 feet).
- The units were dropped without an attached cuff.
- Maximum absolute error pressure is shown in Chart A.
- Results of each drop test are listed in Chart B.

1. Method protocols are based on Japan Industrial Standard (JIS) T 0601-1: 1999 21.5 and JIS T 1115: 2005.

Chart A. Maximum Absolute Error Pressure at Pre-Determined Points (from 0 to 300mmHg each 50mmHg)

The ELEMANO Blood Pressure Monitor demonstrated low variability across multiple units and across multiple drops when compared to three different competitive aneroid sphygmomanometers.



Results:

The ELEMANO Monitor maintained its calibration within the Pressure Transducer Accuracy standards[2] of +/- 3mmHg, with a maximum pressure error of 1mmHg during the multi-unit, multi-drop protocol. Under the same protocol, the aneroid models all demonstrated maximum pressure errors exceeding the standards:

- Aneroid A (Welch-Allyn)
  Maximum pressure error of 68mmHg
- Aneroid B (Welch-Allyn)
  Maximum pressure error of 12mmHg
- Aneroid C (Welch-Allyn)
  Maximum pressure error of 20mmHg

In aggregate, the aneroid sphygmomanometers performed outside of the standard acceptable range of +/-3mmHg after 43 of the 63 drop tests, while the ELEMANO Monitors performed inside of the standard acceptable range after every drop test.

Chart B. Maximum Pressure Error Post-Drop

Multiple drops of various aneroid sphygmomanometers demonstrated substantial variance, and the direction of the variance shifted on several occasions.

Sample		No.	Drop Directions and Error (mmHg)							
			Initial	1	2	3	4	5	6	Max
ELEMANO BP Monitor		1	-1	0	0	0	0	0	0	**-1**
		2	0	-1	0	0	0	0	0	**-1**
		3	0	+1	+1	+1	+1	+1	0	**+1**
Aneroid	A[3]	1	-2	-3	-4	-4	-4	-4	-5	**-5**
		2	+3	+2	+2	+2	+2	-68	-67	**-68**
		3	+4	+5	+6	+5	+5	+5	+5	**+6**
	B[3]	1	-1	+6	+6	+6	+5	+5	-2	**+6**
		2	+2	+4	+3	+4	+4	+2	+2	**+4**
		3	-2	+2	-9	-11	-12	-12	-12	**-12**
	C[3]	1	+2	-3	-6	-5	-6	-6	-20	**-20**
		2	-2	-8	-4	-3	-4	-5	-6	**-8**
		3	-3	-8	-8	-8	-8	-9	-10	**-10**

Conclusions:

Based on the results of this comparative drop test involving the ELEMANO Blood Pressure Monitor (ES-H55) and three aneroid models, the ELEMANO Monitor consistently demonstrated its ability to maintain accuracy within the standard range of +/- 3mmHg under stress.

2. Pressure Transducer Standards: Association of Advancement of Medical Instrumentation SP 10 and Japan Industrial Standard T1115.
3. Aneroid A: Bronze Series Integrated Aneroid (Welch-Allyn), Aneroid B: Tycos® Classic Hand Aneroid (Welch-Allyn), Aneroid C: Tycos® Classic Pocket Aneroid (Welch-Allyn).

Elemano™

Blood Pressure Monitor

So Accurate. So Easy.

The ELEMANO™ Blood Pressure Monitor is the only monitor that combines gold standard accuracy with digital ease of use.

- Rapid BP and pulse readout in 30 seconds
- Accurate, automatic BP readout to ± 3 mmHg
- Encourages standardized measurements with multiple users
- No stethoscope required

ELEMANO is a trademark of Terumo Medical Corporation, Somerset, N.J.
and Terumo are registered trademarks owned by Terumo Corporation, Tokyo, Japan. © 2009

TERUMO®

TERUMO MEDICAL PRODUCTS