

# Gear-free, shock-resistant aneroid sphygmomanometer technology greatly improves ability to maintain accurate blood-pressure readings.

Reported by Thomas J. Grant, Group Product Director, Welch Allyn, Inc.

Data Analysis by Jiejing Qiu, Biostatistician, Welch Allyn, Inc.

## Background:

Aneroid sphygmomanometers have been used to safely and accurately measure blood pressure in humans and animals for more than 100 years. However, due to delicate gears at the core of an aneroid sphygmomanometer movement, these gauges can go out of calibration when subjected to rough handling or drops. In an effort to improve the ability of the common aneroid sphygmomanometer to maintain more-accurate blood pressure readings, Welch Allyn Inc. invented a gear-free, shock-resistant aneroid movement in 2001 and has subsequently released this patented<sup>1</sup> technology in several professional aneroid sphygmomanometer models worldwide. The intent of this investigation is to evaluate the ability of sphygmomanometers with gear-free Welch Allyn® DuraShock™ technology to maintain more-accurate blood pressure readings than traditional gear-based instruments when exposed to rough handling common in busy medical environments.

## Methodology:

An experiment organized and directed by Klaus Forstner, Physician, M.D. Dipl.-Ing.; Forschungsinstitut für klinische Medizintechnik, Tamm, Germany, utilized an independent organization to test aneroid sphygmomanometers of various brands and models (see Table A) for accuracy after being dropped ten times from a height of one meter onto a hard surface<sup>2</sup>. Dr. Forstner intends to publish his findings in a paper titled “*The Aneroid Drop Study: Evaluation of a New Gear-Free Aneroid Blood Pressure Technology and Clinical Relevance of Shock Stability*”.

To conduct the experiment, the Physikalisch-Technische Bundesanstalt (PTB) – national (German) metrology institute – purchased 13 different brands of aneroid sphygmomanometers from independently owned and operated medical-product distribution companies. Up to seven different models from each brand were acquired and five gauges for every model were drop tested.

Before the first drop, and after each of ten subsequent drops, every gauge was tested for accuracy both upscale (inflation) and downscale (deflation) at zero, 50, 100, 150, 200,

250, and 300 mm Hg using an electronic pressure meter calibrated to a known pressure standard. Hysteresis<sup>3</sup> was measured at every pressure listed above. Leakage rate was measured and visual inspection was conducted after each drop.

## Results:

Drop tests were conducted on 35 gear-free, shock-resistant DuraShock gauges (seven models x five gauges each) and 109 traditional gauges with gears (22 models x five gauges each, minus one out-of-box failure). Survival rate<sup>4</sup> for gear-free DuraShock gauges was 91.4% over ten drops while only 22.7% of traditional gauges with gears survived ten drops (see Graph A).

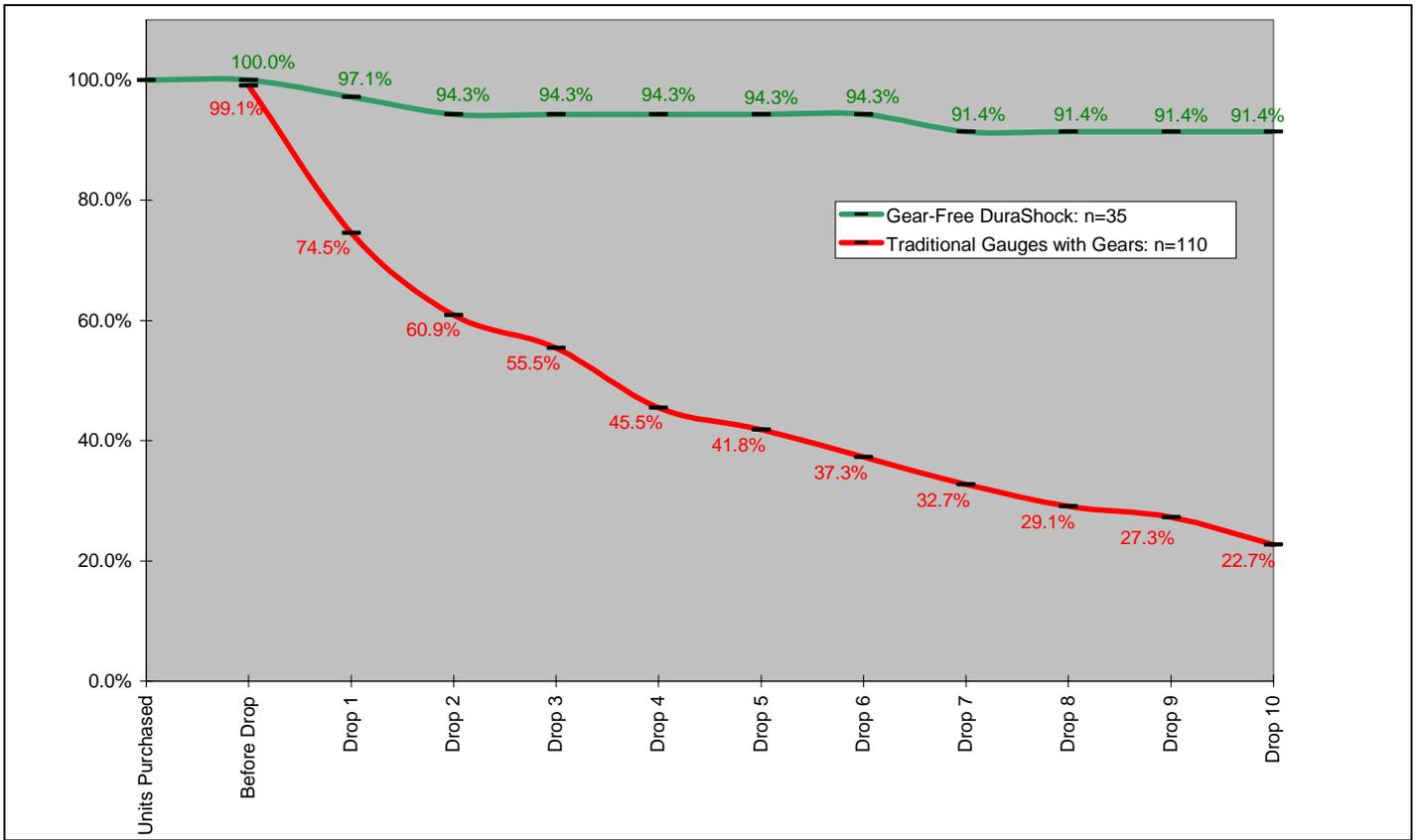
To evaluate accuracy, data was analyzed as long as a gauge was functional (survived). Accuracy data obtained after a gauge broke is not included in this analysis. Gauges with gear-free DuraShock technology maintained much better accuracy than surviving traditional gauges with gears. 75% of errors measured on gear-free gauges were within a range of 2.0 mm Hg, with reference to the known pressure standard, while 75 % of errors measured on traditional gear-based gauges were within a range of 3.5 mm Hg, with reference to the known pressure standard (see Graph B). Total error (excluding outliers<sup>5</sup>) ranged up to 4.25 mm Hg on gear-free models vs. 7.25 mm Hg on traditional gauges with gears.

In summary, the results of testing this sample of aneroid gauges show that the survival rate after 10 drops for gear-free gauges is more than four times greater than the survival rate for traditional gauges. And for the gauges that survive, the gear-free gauges exhibit a range of error that is 41.4% less than the range of error for traditional gauges.

## Conclusion:

Aneroid sphygmomanometers with gear-free DuraShock technology are far more capable of surviving rough handling and maintaining accurate blood pressure readings compared to traditional sphygmomanometers with gears. The results suggest that gear-free DuraShock gauges will not need to be repaired or replaced as often, resulting in lower lifetime-cost of ownership.

**Graph A: Sphygmomanometer Survival Rate – Ten Drops from One Meter.**



**Graph B: Box-and-Whisker Plot of Total Error (11,186 Readings<sup>6</sup>)**



**Table A: Sphygmomanometers Tested**

Gear-Free DuraShock™ Models	Traditional Models with Gears	
Welch Allyn DS58 Classic	Accoson Duplex	Heine Gamma G5
Welch Allyn DS66 Trigger	Accoson Limpet	KaWe Mastermed A1
Welch Allyn DS44 Integrated	ADC Diagnostix 700	KaWe Mastermed A2
Welch Allyn DS45 Integrated	Boso Classic	Mabis 01-149-011
Welch Allyn DS54 Hand	Boso Clinicus	Medline MDS9380
Welch Allyn DS44 Pocket	Boso Profitest	Riester Exacta 1350
Welch Allyn DS44 Pocket Trigger	Erka Perfect	Riester Exacta 1351
	Erka Switch	Riester Minimus III
	Generic Gauge (Asia)	Spengler Ergo-Sphyg II
	Gima London	Spengler Lian Classic
	Gima Rome	Spengler Vaquez-Laubry Classic

<sup>1</sup> Patents issued in the United States and other regions of the world include 6,615,666; 6,578,428; 6,481,291; 6,422,086; D457,632; D457,631; 6,234,972; 6,796,186; 6,783,500; 6,746,406; 6,120,458; 6,082,170; 5,966,829; and 3233645. Additional patents are pending.

<sup>2</sup> Hard surface used in this test was a concrete floor, with a screed leveling layer, covered by Linoleum tile. This is quite typical of floors found in hospitals and other clinical environments.

<sup>3</sup> Hysteresis in a mechanical sphygmomanometer is difference in a pressure reading taken on the inflation vs. on the deflation and is a measure of the amount of friction inherent in the mechanical movement.

<sup>4</sup> Survival is defined as a gauge capable of taking a pressure reading.

<sup>5</sup> Outlier in the box-and-whisker plot is defined as observations which are 1.5 inter-quartile ranges (IQR) above the 75<sup>th</sup> percentile or 1.5 IQR below the 25<sup>th</sup> percentile.

<sup>6</sup> 11,186 is the result of 14 readings per surviving gauge (0, 50, 100, 150, 200, 250, 300 mm HG upscale and downscale), after each of 10 drops.

**FOR IMMEDIATE RELEASE**

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## **Study Concludes Gear-Free Aneroid Technology Greatly Improves Ability to Maintain Accurate Blood-Pressure Readings.**

### **Patented Welch Allyn Blood Pressure Gauges with DuraShock™ Technology Get High Marks for Accuracy Over Time, Durability**

**Skaneateles Falls, New York, USA, December 08, 2006** — Welch Allyn, Inc., a leading global manufacturer of frontline medical products and solutions, today reported results of an important study that reveals that blood pressure gauges with gear-free Welch Allyn® DuraShock™ technology maintain accurate blood pressure readings better than traditional gear-based instruments when exposed to rough handling common in busy medical environments. The results of the study, organized and directed by Klaus Forstner, Physician, M.D. Dipl.-Ing.; Forschungsinstitut für klinische Medizintechnik, Tamm, Germany, evaluates and compares different brands of aneroid sphygmomanometers to withstand the rough handling common in busy medical environments.

“Aneroid sphygmomanometers have been used to safely and accurately measure blood pressure in humans and animals for more than 100 years,” explained Thomas Grant, group product director at Welch Allyn. “However, due to delicate gears at the core of an aneroid sphygmomanometer movement, these gauges can go out of calibration when subjected to rough handling or drops. In an effort to improve the ability of the common aneroid sphygmomanometer to maintain accurate blood pressure readings throughout the life of the gauge, Welch Allyn invented a gear-free, shock-resistant aneroid movement in 2001.”

To conduct the experiment, the Physikalisch-Technische Bundesanstalt (PTB) – national (German) metrology institute – purchased 13 different brands of aneroid sphygmomanometers from independently owned and operated medical-product distribution companies. Up to seven different models from each brand were acquired, and five gauges for every model were dropped ten times from one meter onto a hard surface, with accuracy checked at set intervals before and after each drop.

More than 10,000 readings were obtained by the German PTB for this experiment. The data substantiates the conclusion that aneroid sphygmomanometers with gear-free DuraShock technology are far more capable of surviving rough handling and maintaining accurate blood pressure readings longer than traditional sphygmomanometers with gears. For this reason, gear-free DuraShock gauges should not need to be repaired or replaced as often, resulting in lower lifetime-cost of ownership.

“Healthcare providers are under constant pressure to improve the quality and cost of care,” said Grant. “Worldwide, there are millions of mechanical aneroid sphygmomanometers with traditional gear-based technology being used to screen and monitor blood pressure every day. There are more than one billion people with hypertension. This study is important because it shows gear-free DuraShock technology can impact both the quality and cost of one of the most common diagnostic instruments in use today.”

In addition to the report being distributed today, Dr. Forstner intends to publish his findings early next year in a paper titled “*The Aneroid Drop Study: Evaluation of a New Gear-Free Aneroid Blood Pressure Technology and Clinical Relevance of Shock Stability*”.

**About Welch Allyn:** Welch Allyn, Inc. was founded in 1915 and is today a leading manufacturer of innovative medical diagnostic and therapeutic devices, cardiac defibrillators, patient monitoring systems, and miniature precision lamps. Headquartered in Skaneateles Falls, New York, USA, Welch Allyn employs more than 2,300 people and has numerous manufacturing, sales, and distribution facilities located throughout the world. Additional information on Welch Allyn and its products may be found at [www.welchallyn.com](http://www.welchallyn.com).

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*Organized and directed by Klaus Forstner, Physician, M.D.  
Dipl.-Ing.; Forschungsinstitut für klinische Medizintechnik, Tamm, Germany*

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# Background

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- Sphygmomanometers in use for 100+ years.
- All designed with delicate gears that cannot withstand drops or rough handling.
- Gauges often break or go out-of-calibration.
- Drives up cost and sacrifices accuracy.
- Welch Allyn Inc. invented a gear-free, shock-resistant aneroid movement in 2001.

# Objective

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- The intent of this investigation is to evaluate the ability of sphygmomanometers with gear-free Welch Allyn® DuraShock™ technology to maintain more-accurate blood pressure readings than traditional gear-based instruments when exposed to rough handling common in busy medical environments.

# Methodology

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- Organized and directed by Klaus Forstner.
- German PTB purchased 13 different brands of aneroids from independent distributors.
- Five gauges of each model, 35 gear-free gauges and 110 traditional gauges with gears.
- Gauges dropped ten times each from one meter.
- Accuracy measured after each drop both upscale and downscale (0, 50, 100, 150, 200, 250, and 300 mm Hg).

# Methodology

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- Sphygmomanometers Tested

Gear-Free DuraShock™ Models	Traditional Models with Gears	
Welch Allyn DS58 Classic	Accoson Duplex	Heine Gamma G5
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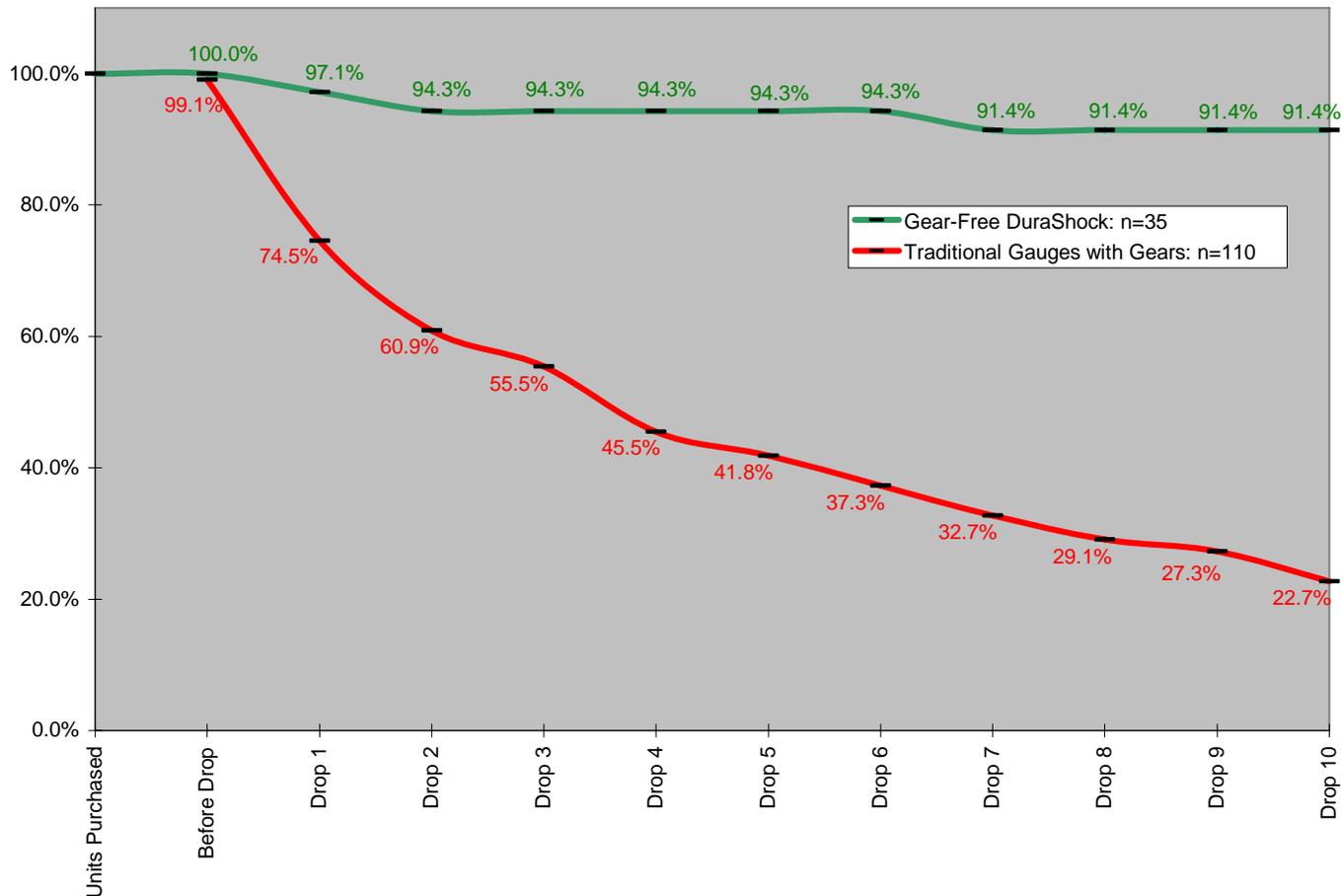
# Results

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- Survival rate for gear-free DuraShock gauges was **91.4%** while only **22.7%** of traditional gauges with gears survived ten drops from one meter (39.4 inches).

# Results

- Survival Rate



# Results

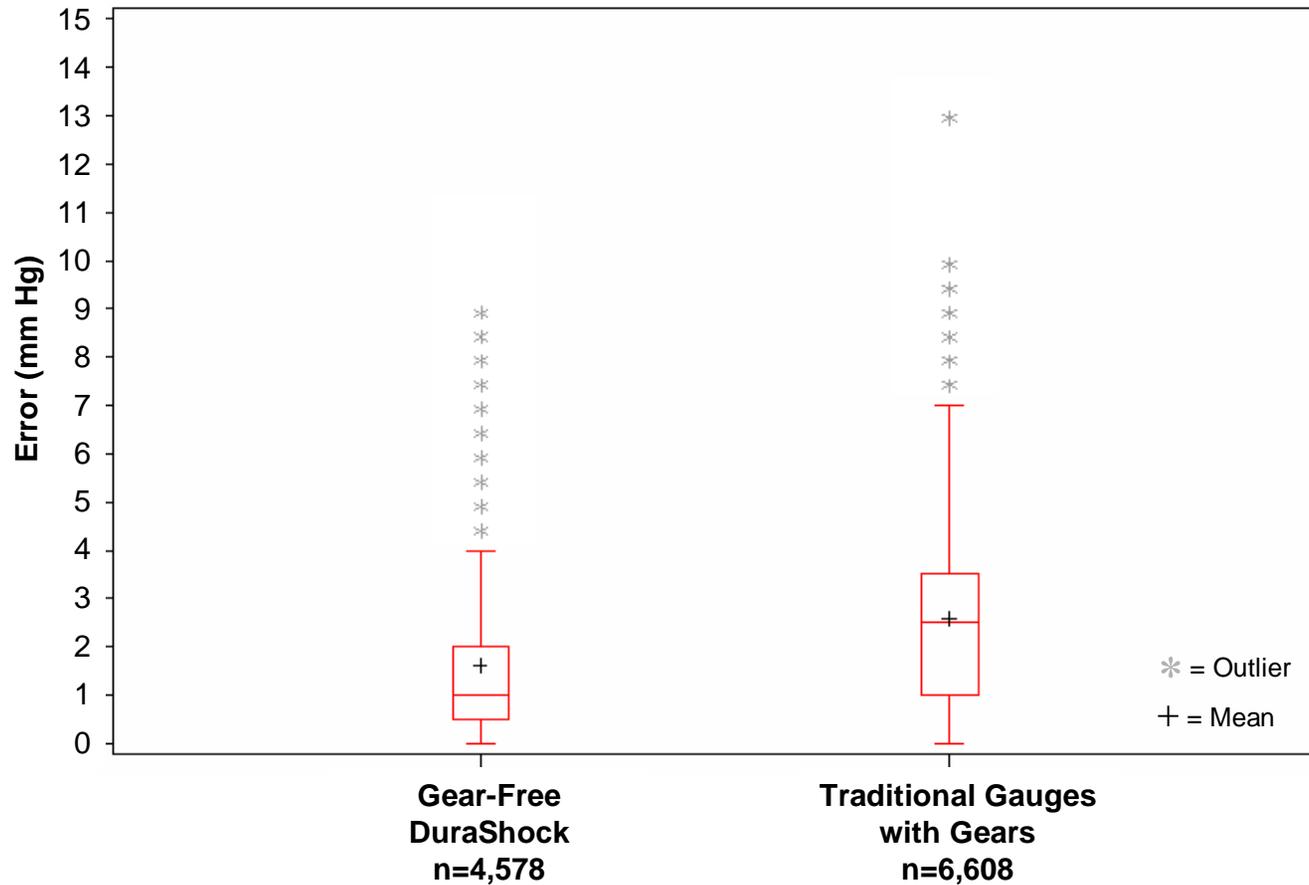
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- Gear-free gauges have a **four times greater rate of survival** compared to traditional gauges
- Gear-free gauges exhibit **41.4% less range of error** compared to traditional gauges.
  - 75% of errors measured on gear-free gauges were within a range of **2.0 mm Hg** vs. **3.5 mm Hg** for traditional gauges with gears.
  - Total error (excluding outliers) ranged up to **4.25 mm Hg** on gear-free models vs. **7.25 mm Hg** on traditional gauges with gears.

# Results

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- Box-and-Whisker Plot of Error



# Conclusion

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- Aneroid sphygmomanometers with gear-free DuraShock technology are:
  1. far more **capable of surviving** rough handling, and
  2. **maintaining accurate blood pressure readings** compared to traditional gauges with gears.
- Results suggest gear-free DuraShock gauges will not need to be repaired or replaced as often, **resulting in lower lifetime cost of ownership.**