BIOMEDICAL METROLOGY

BACK TO THE BASICS OF TEST AND MEASUREMENT

DAVID HEISELT AND DONALD SHEPPARD

04/12/2023

MDEXPO
April 11–13, 2023 • Houston, TX

OVERVIEW

- Introduction and References
- Metrology Terms & Definitions
- Calibration Reference Standards
- Accuracy and Traceability
- Quality of Measurements
- Metrology Partnership with your Calibration Laboratory
- Verification of Services
- Practical Application and Demonstration

INTRODUCTION

DAVE HEISELT

QRS Calibrations, LLC

DONALD SHEPPARD

QRS Calibrations, LLC

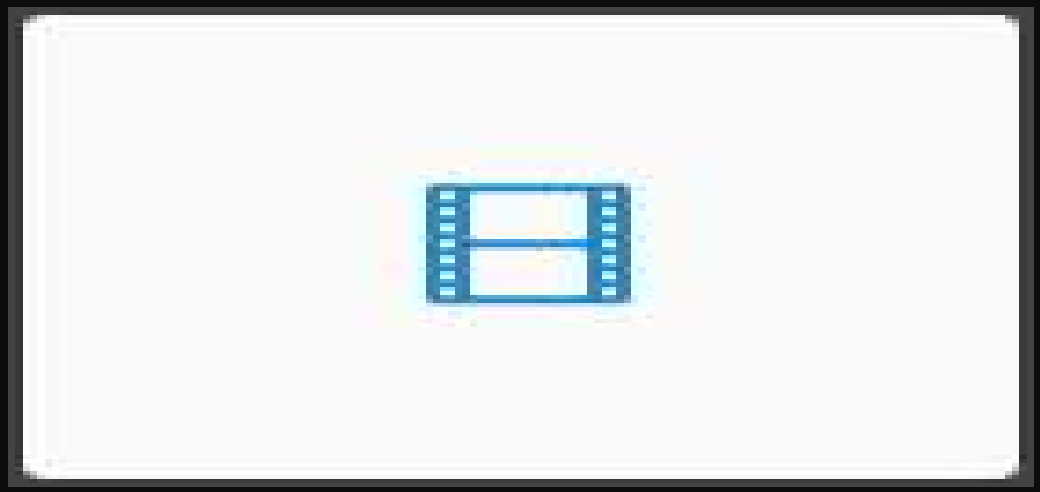
REFERENCES

- Metrology And Calibration Quality

- ***NIST TRACEABLE***
  - ***(NIST IS NOT A REFERENCE – it is a National Laboratory)***
- ISO/IEC 17025:2017
- ISO 9001:2015
- ISO 10012:2003
- ANSI Z540-1:1995
- ANSI Z540.3:2006
- SAE:AS9100
- JCGM 100:2008
- JCGM 200:2012
- NCSL RP-6:2023
- NIST QM-1

METROLOGY

LET'S DIVE IN



METROLOGY TERMS AND DEFINITIONS

METROLOGY

THE SCIENCE OF MEASUREMENT AND ITS APPLICATION

Metrology is a term that applies to all measurement processes, encompassing variables that affect the test being performed

METROLOGY TERMS AND DEFINITIONS

CALIBRATION

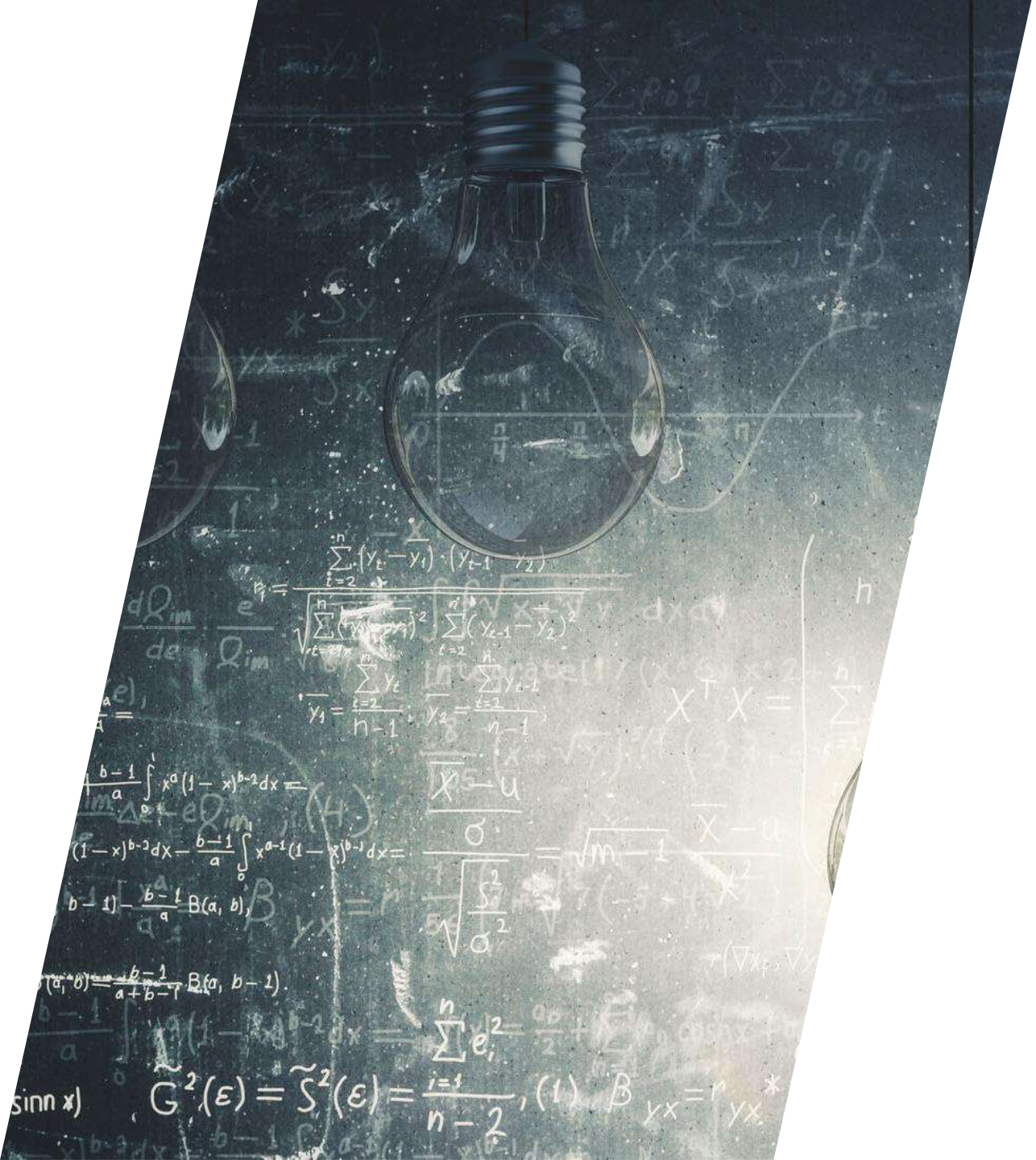
Operation that, under specified conditions, in a first step, establishes a relation between the quantity values with measurement uncertainties provided by measurement standards and corresponding indications with associated measurement uncertainties and, in a second step, uses this information to establish a relation for obtaining a measurement result from an indication (JCGM 200:2012, International Vocabulary of Metrology)

METROLOGY & CALIBRATION

At their core, both metrology and calibration are focused on ensuring measurements and measurement data are adequate for the intended purposes.

Accurate measurements and measurement data are integral to the success of any organization that makes decisions based upon measurements.

The goal of any metrology and calibration program (and laboratories) is to provide the necessary requirements and resources to ensure measurement data are adequate and contribute to safety and mission success.



METROLOGY TERMS AND DEFINITIONS

True Value vs Indicated Value

Calibration vs PM

Performance Test

Adjustment (calibration adjustment)

Uncertainty in Measurement

Traceability

Test Reports/Certificates of Calibration

Resolution

- The smallest division in which an indication may be made

Precision

- The relative closeness of repeated measurements

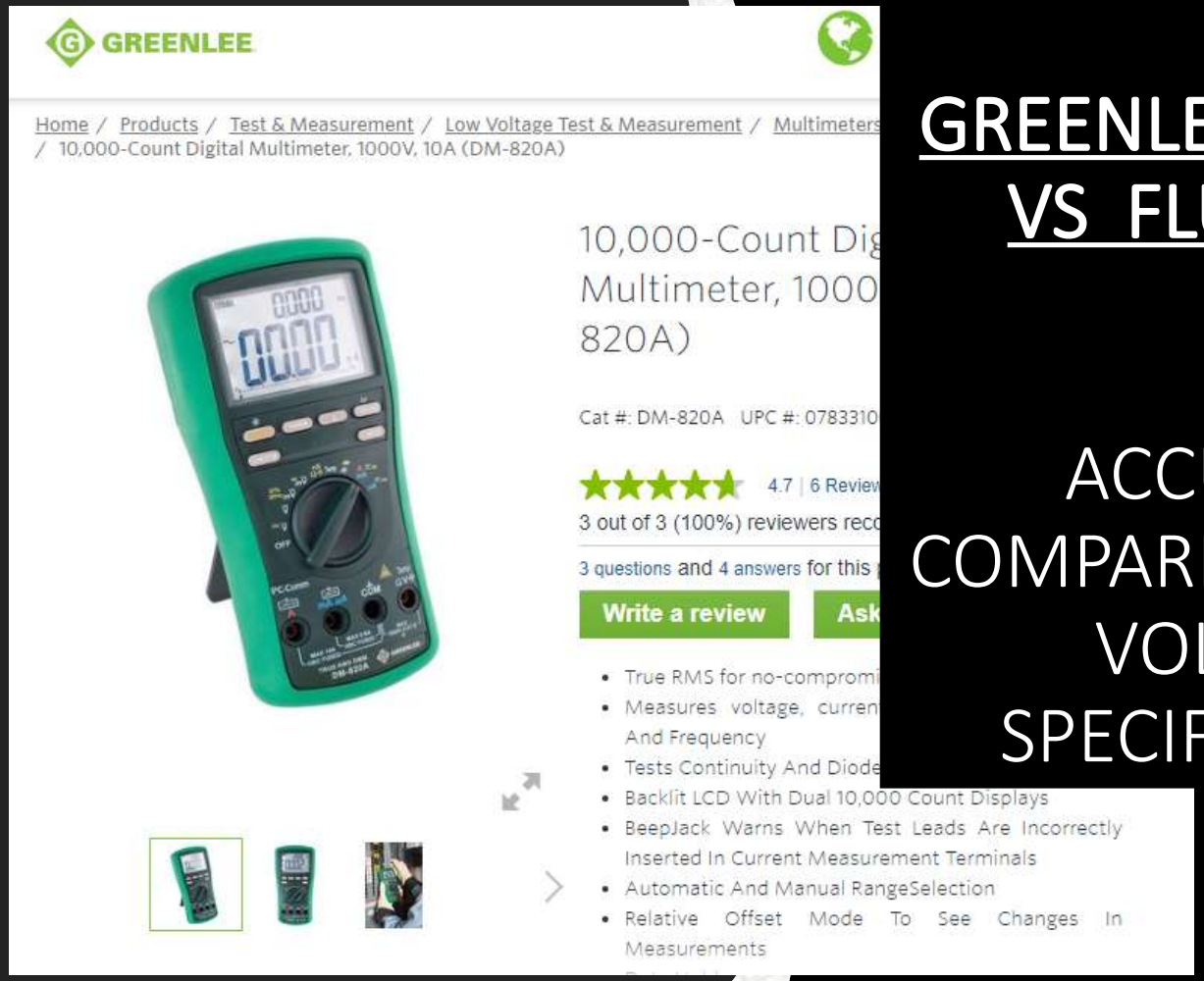
Accuracy

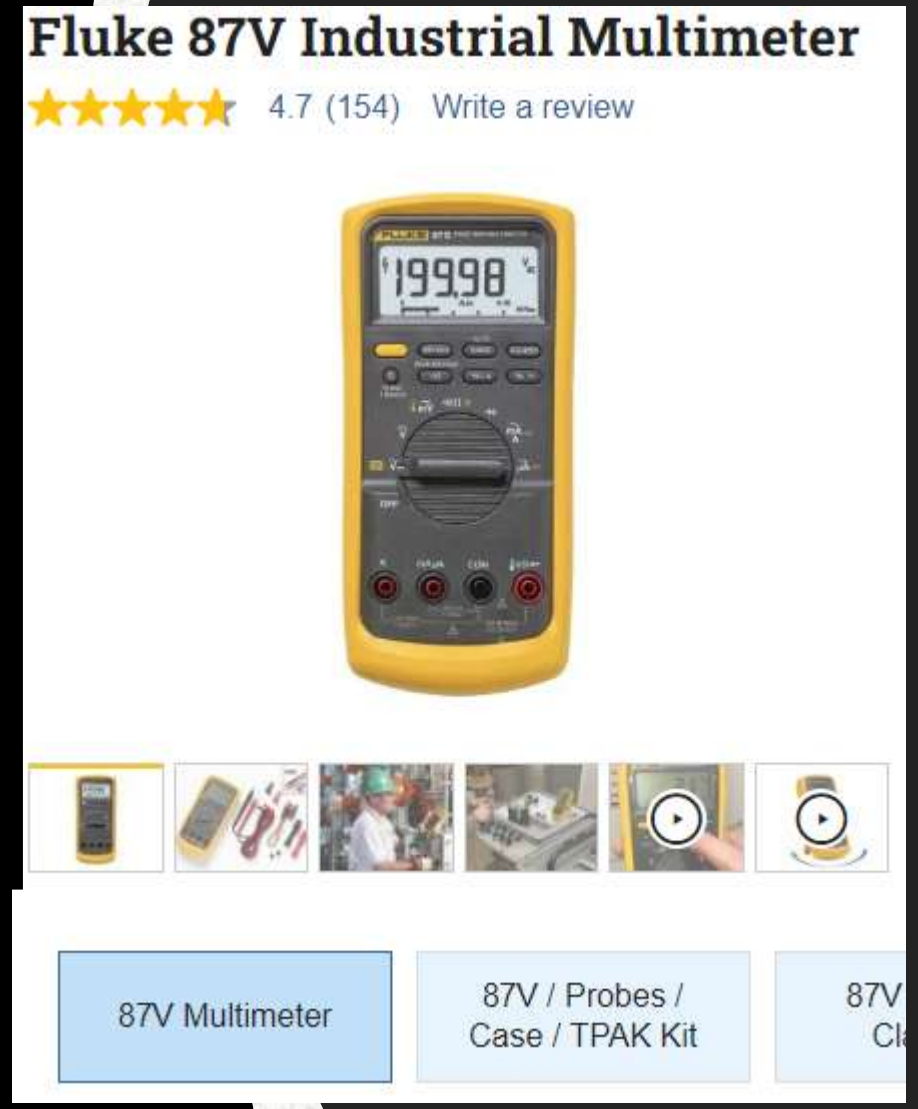
- The estimate of error from displayed measurement to the true value.
  - Usually reported as a percentage of indication or range.

- High Precision

GREENLEE DM-820 VS FLUKE 87V

ACCURACY COMPARISON OF AC VOLTAGE SPECIFICATION





COMPARISON OF GREENLEE DM-860 VS FLUKE 87 V

AC Voltage (AC + DC Voltage on DM-830A and DML-430A Only)

Range	Accuracy at 50 to 60 Hz	Accuracy at 40 to 500 Hz	Accuracy at 500 Hz to 1 kHz	Accuracy at 1 to 3 kHz	Accuracy at 3 to 20 kHz
60.00 mV	± (0.5% + 0.03 mV)	± (0.8% + 0.04 mV)	± (2.0% + 0.03 mV)	± (2% + 0.03 mV)	± (2% + 0.03 mV)(1)
600.0 mV	± (0.5% + 0.3 mV)	± (0.8% + 0.4 mV)	± (2.0% + 0.3 mV)	± (2% + 0.3 mV)	± (2% + 0.3 mV)(1)
9.999 V	± (0.5% + 0.003 V)	± (1.0% + 0.004 V)	± (1.0% + 0.004 V)	± (3% + 0.004 V)	3 dB(2)
99.99 V	± (± (0.5% + 0.03 V)	± (1.0% + 0.04 V)	± (1.0% + 0.04 V)	± (3% + 0.04 V)	3 dB
999.9 V	± (0.5% + 0.3 V)	± (2.0% + 0.4 V)	± (2.0% + 0.4 V)	± (3% + 0.4V)	Unspecified

(1) Specified from 30% to 100% of range
Input Impedance: 10 MΩ, 50 pF nominal (80 pF nominal for 600 mV range)
(2) Range bandwidth to 15kHz only

Table 2. Model 87 AC Voltage Function Specifications

Function	Range	Resolution	Accuracy					
			45 - 65 Hz	30 - 200 Hz	200 - 440 Hz	440 Hz - 1 kHz	1 - 5 kHz	5 - 20 kHz[1]
$\tilde{V}$ [2,4]	600.0 mV	0.1 mV	± (0.7 % + 4)	± (1.0 % + 4)			± (2.0 % + 4)	± (2.0 % + 20)
	6.000 V	0.001 V	± (0.7 % + 2)					
	60.00 V	0.01 V					± (2.0 % + 4)[3]	unspecified
	600.0 V	0.1 V						
	1000 V	1 V					unspecified	unspecified
	Low pass filter		± (0.7 % + 2)	± (1.0 % + 4)	+1 % + 4 -6 % - 4[5]	unspecified	unspecified	unspecified

1. Below 10 % of range, add 12 counts.
2. The Meter is a true rms responding meter. When the input leads are shorted together in the ac functions, the Meter may display a residual reading between 1 and 30 counts. A 30 count residual reading will cause only a 2-digit change for readings over 3 % of range. Using REL to offset this reading may produce a much larger constant error in later measurements.
3. Frequency range: 1 kHz to 2.5 kHz.
4. A residual reading of up to 13 digits with leads shorted, will not affect stated accuracy above 3 % of range.
5. Specification increases from -1% at 200 Hz to -6% at 440 Hz when filter is in use.

Greenlee DM-820A ($450) -- 10,000 counts						
Function	Frequency (Hz)	Applied (V)	Range	Accy (% of Reading)	Floor (V)	Tolerance
ACV	60	0.4	0.6	0.80%	400.000E-6	3.6mV
ACV	60	4	10	1.00%	4.000E-3	44mV
ACV	60	40	100	1.00%	40.000E-3	440mV
ACV	60	400	1000	2.00%	400.000E-3	8.4V

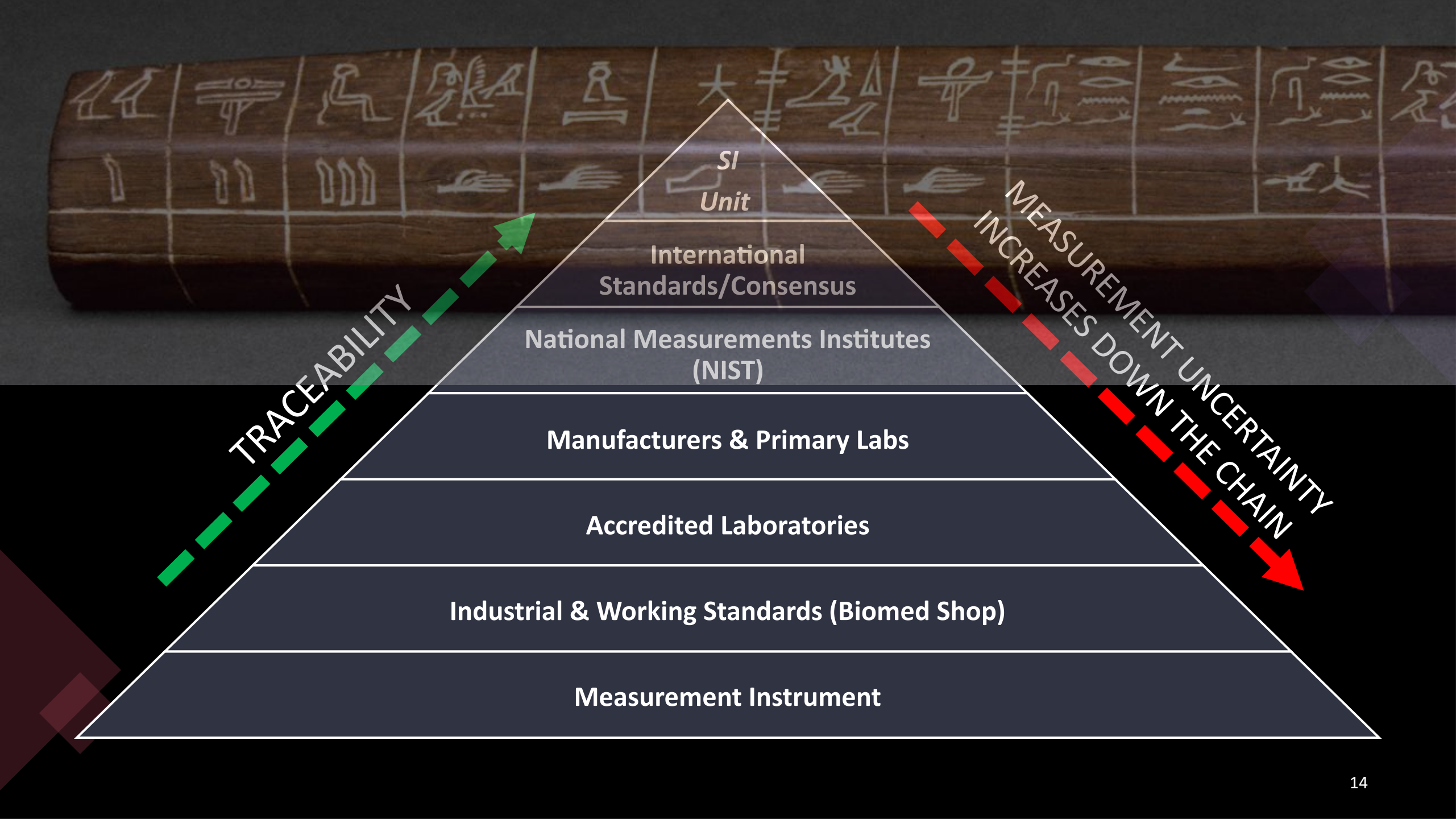
Fluke 87 V ($568) -- 6000 counts						
Function	Frequency (Hz)	Applied (V)	Range	Accy (% of Reading)	Floor (V)	Tolerance
ACV	60	0.4	0.6	0.70%	400.000E-6	3.2mV
ACV	60	4	6	0.70%	4.000E-3	32mV
ACV	60	40	60	0.70%	20.000E-3	300mV
ACV	60	400	600	0.70%	200.000E-3	3.0V

NIST AND TRACEABILITY

(Excerpt From NIST QM-1 Quality Manual)

6.5.2 Consistent with the CIPM, NIST measurements are directly traceable to the SI [International System of Units] as realized or represented by NIST or in rare cases by another NMI [National Measurement Institution]. For those measurements, e.g., ambient temperature, that do not provide a significant influence on the overall measurement uncertainty, traceability can also be obtained from a calibration laboratory that is accredited by an ILAC-signatory accreditation body.

6.5.3 For some NIST chemical or materials metrology measurement service activities, metrological traceability to SI units is not technically possible. In these cases, traceability is achieved to other recognized standards or consensus values, for example as determined through key comparisons, as described in supporting sub-level quality documents.


SI
Unit
International
Standards/Consensus
National Measurements Institutes
(NIST)
Manufacturers & Primary Labs
Accredited Laboratories
Industrial & Working Standards (Biomed Shop)
Measurement Instrument
TRACEABILITY
MEASUREMENT UNCERTAINTY
INCREASES DOWN THE CHAIN

METROLOGICAL TRACEABILITY

Example of an unbroken chain of calibrations

Digital Multimeter

Resolution: 0.01 volt

Accuracy: 0.02 volt

Multifunction Calibrator

Resolution: 0.000001 volt

Accuracy: 0.0000375 volt

Direct Voltage Standard

Resolution: 0.0000001 volt

Accuracy: 0.000005 volt

Josephson Voltage Standard

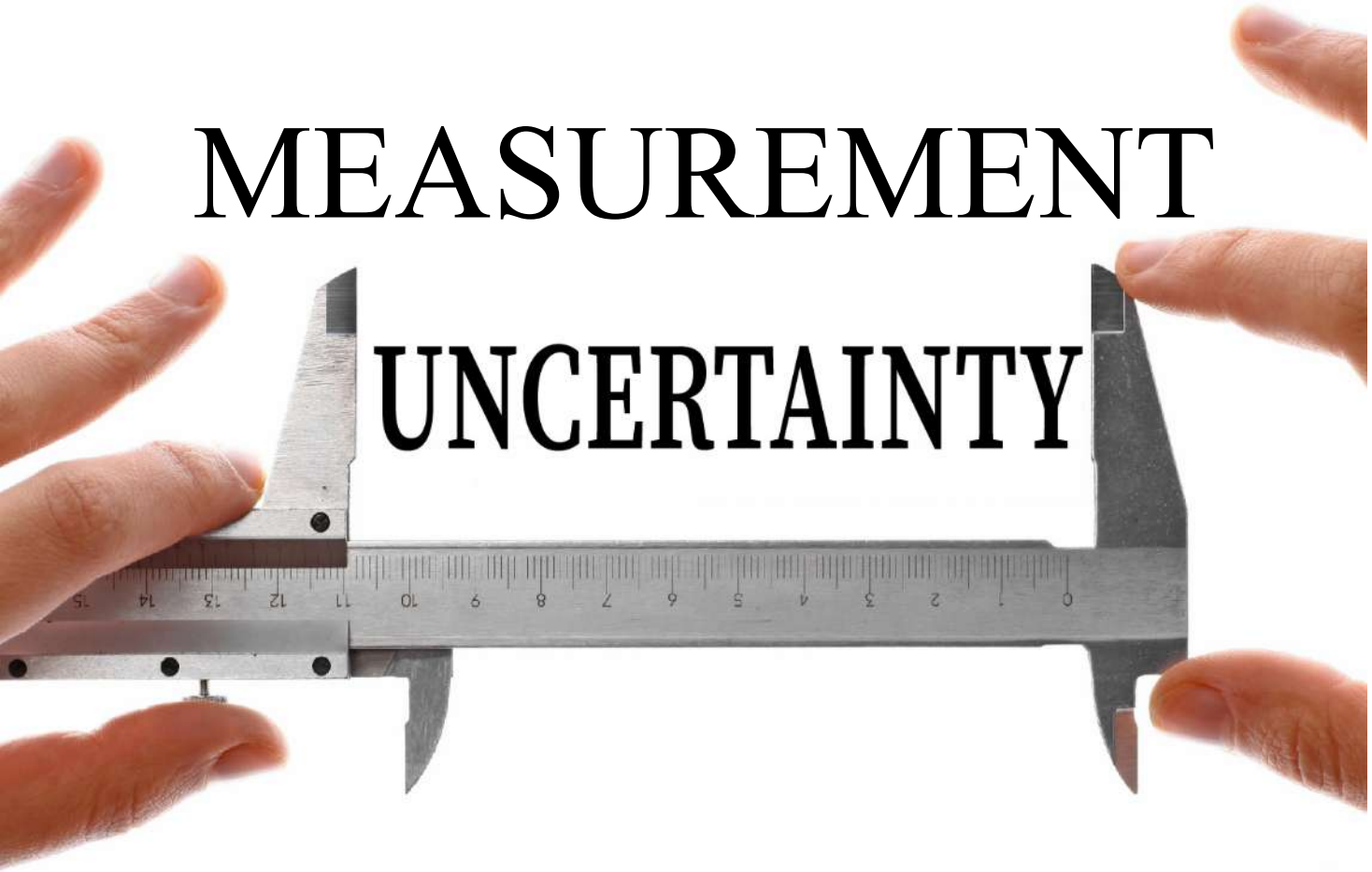
Resolution: 0.000000001 volt

Accuracy: 0.000000015 volt

Inter-comparison of Primary Standards by National Metrology Institutes ensures international equivalence

International Inter-comparison

Increasing accuracy at each level of the traceability chain (example at 10 volt DC)



COMMON UNCERTAINTIES

- Uncertainty of Measurement Reference reported on calibration certificate.
- Accuracy of Measurement Reference
- Resolution of Measurement Reference
- Environment of measurement
- Stability of setup and instrument under test
- User errors

Routine Calibration Provides a Level Of Confidence to Perform to Specifications for Service Interval

QUALITY OF MEASUREMENT

The most common causes of Out-of-Tolerance conditions for measurement devices:

- Inherent Nature of the Device (drift, mechanical wear, aging)
- Usage (environmental effects, mistakes in processes/procedures, user error or negligence)
- Transportation (shipping and handling problems)

METROLOGY PARTNERSHIP

Choose the Quality Management System that matches your requirements

Ensure the calibration laboratory understands your applications and requirements

Verify the services provided by your calibration laboratory

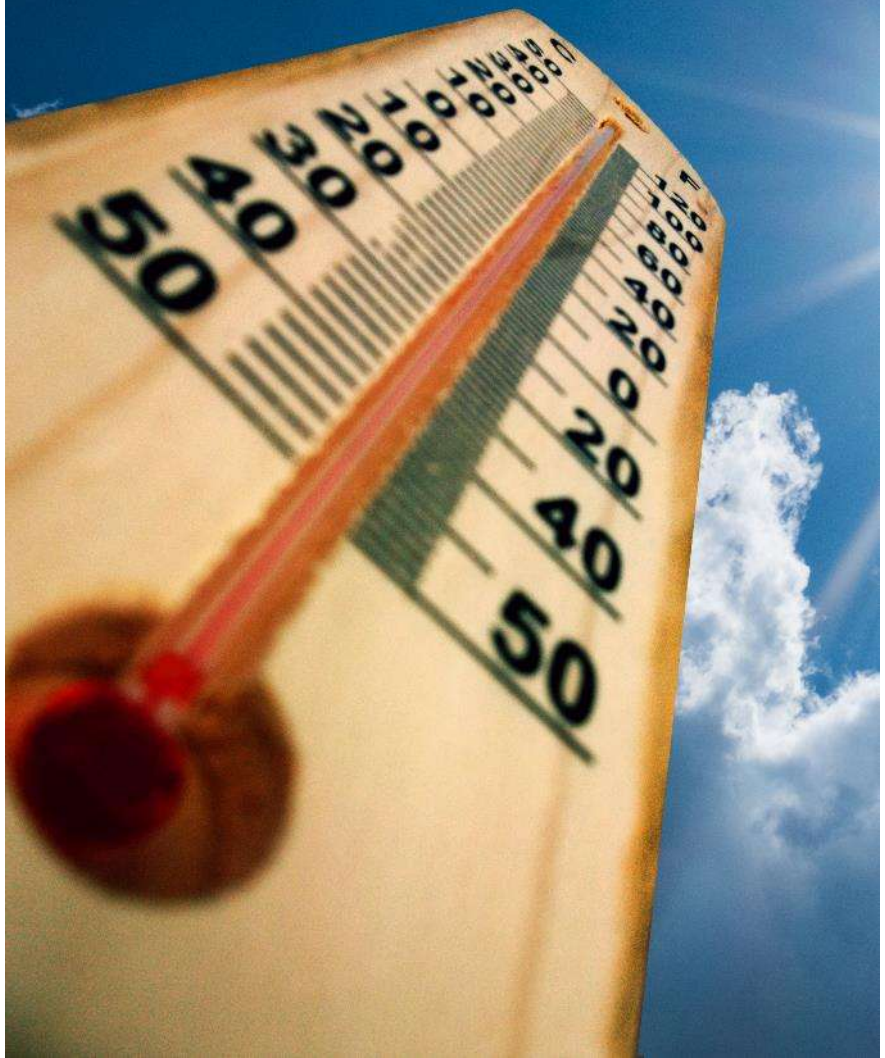
METROLOGY PARTNERSHIP

- PAYERS AND PURCHASERS ROLES:
  - Cost Avoidance/Reduction, selection of service provider, detailing requirements of service with contract
  - Cost vs Quality vs Service
- SERVICE PROVIDERS:
  - Measurement Accuracy and quality control for the items that do not meet specification. Secondary role as trainers and technical experts for the test equipment – can help diagnose equipment errors in setups.
  - If the payers and purchasers choose the wrong service provider, the measurement quality and subsequent measurement chain can be affected.
- MEASUREMENTS TRANSFER FROM THE SERVICE PROVIDER TO BIOMEDICAL DEPARTMENT, AND TO THE PATIENT FLOOR
  - Poor Measurements or Service can translate to misdiagnosis or death

QUESTIONS

Open Discussion

PRACTICAL APPLICATIONS & DEMONSTRATION



Thermometry

- PRT Probe (50 milli-kelvin accuracy)
- Thermocouple Probe (Meter 0.05% ± 0.3°C, Probe 1.1°C)
- Thermistor Probe (Meter 2 digits, Probe ± 0.1°C)

Resistance

- Resistance Decade
- Multimeter

DC Voltage

- Power Supply
- Multimeter

3 EASY STEPS TO WIN $100!

1. Take a picture
2. Post on social media using #MDExpo
3. The attendee who uses the hashtag the most throughout the conference will win a $100 giftcard!!