

bits BIOMEDICAL
CALIBRATION CERTIFICATE

ISO ACCREDITED

Scope as recognized under

Result	Expanded Uncertainty
Pass	0.50
Pass	0.50
Pass	0.50
Pass	0.50
Pass	0.50
Pass	0.50
Pass	0.50
Pass	0.50
Pass	0.50
Pass	0.50
Pass	0.50

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Per Limit	Result	Expanded Uncertainty
1,038	Pass	0.50
1,038	Pass	0.04
1,038	Pass	0.07
1,038	Pass	0.11
1,038	Pass	0.14

Limit	Result	Expanded Uncertainty
	Pass	0.04
	Pass	0.04
	Pass	0.04
	Pass	0.04
	Pass	0.06

after ISO/IEC 17025:2017 by the ANAB National

Microsoft Excel spreadsheet showing a calibration report table:

Measurement	Before		Upper Limit	Result
	Before	After		
32.0				
32.0			35.2	Pass
32.0			35.2	Pass
32.1			35.2	Pass
32.0			35.2	Pass
36.1			35.2	Pass
36.0			39.6	Pass
36.0			39.6	Pass
36.0			39.6	Pass
36.0			39.6	Pass
36.0			39.6	Pass
36.0			39.6	Pass

MEASUREMENT UNCERTAINTY MATTERS

A White Paper Series on Biomedical Metrology, Calibration, and Trust

BITS White Paper • Think About It - S05 •

WHY EVERY NUMBER NEEDS A MARGIN OF HONESTY

The Number We Trust Too Easily

A measurement result is often treated as a fact.

The reading appears.
The number is recorded.
The decision is made.

But one important question is rarely asked:
"How confident are we in this value?"

This is where measurement uncertainty becomes essential. Without it, confidence is replaced by assumption.

What Measurement Uncertainty Really Is

Measurement uncertainty does not mean doubt or mistake.

It is a quantified expression of confidence that describes the range where the true value is expected to fall.

In simple terms, uncertainty answers this question:

"How much could this result reasonably vary?"

Every measurement has uncertainty, whether it is stated or not.

"Uncertainty is not weakness. It is transparency."

Why Uncertainty Is Often Ignored

Measurement uncertainty can feel uncomfortable and it introduces:

- Ranges instead of single values
- Probability instead of certainty
- Questions instead of absolutes

A single number feels clear and decisive.

Uncertainty can feel like hesitation or lack of confidence.

But in reality, acknowledging uncertainty strengthens the reliability of a measurement. Precision without uncertainty can create a false sense of confidence, especially when important decisions depend on the result.

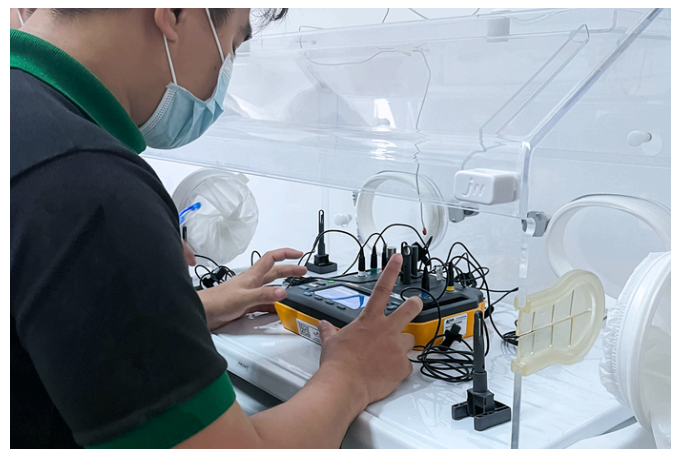
What Happens When Uncertainty Is Missing

When measurement uncertainty is not evaluated or reported, the result can appear more reliable than it actually is. Decisions may be based on numbers that seem exact, even though every measurement has a degree of variation.

Without uncertainty:

- Limits appear sharper than they truly are
- Margins are assumed rather than justified
- Decisions are made with false confidence

In regulated environments, this creates silent risk. Small measurement variations can affect compliance, product quality, equipment performance, and ultimately the reliability of critical decisions.



"A result without uncertainty looks confident, until it's challenged."

Why Accreditation Requires Uncertainty

ISO/IEC 17025 requires laboratories to:

- Evaluate measurement uncertainty
- Apply it consistently
- Use it in conformity decisions

These requirements are not simply added documentation or bureaucracy. They exist to ensure that measurement results can be trusted, especially when decisions involve safety, compliance, quality, and performance.

Measurement uncertainty provides the context behind every reported value. It allows decisions to be:

- Defensible
- Repeatable
- Transparent

Without uncertainty, even technically accurate measurements can be misinterpreted or applied with more confidence than they truly deserve.

Uncertainty and Decision-Making

Consider a measurement result that is very close to a specification limit. At first glance, the decision may seem straightforward. But without uncertainty, the result only tells part of the story.

Without uncertainty:

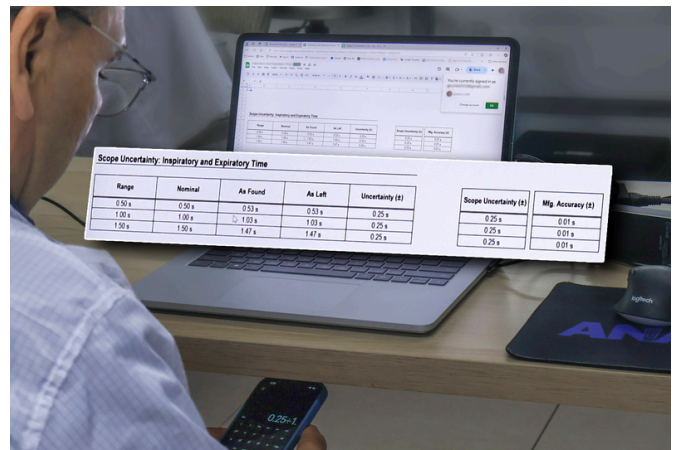
- The result appears clearly accepted or unacceptable

With uncertainty:

- The risk of a false pass or false fail becomes visible
- The level of confidence behind the decision can be properly understood

Measurement uncertainty does not complicate decisions.

It makes them more honest, realistic, and technically sound.



Why Auditors Care About Uncertainty

Auditors do not request measurement uncertainty to add complexity or formality.

They ask because:

- It demonstrates technical competence and understanding of its measurement.
- It shows control over measurement risk.
- It proves that results are not overstated or misleading.

When uncertainty is missing, it creates a gap in traceability and judgment. In such cases, auditors are often led to question not only the result, but also the reliability of the entire measurement process behind it.

“If uncertainty is not documented, confidence is not either.”

Uncertainty in Healthcare and Safety-Critical Systems

In biomedical and clinical environments, measurement uncertainty has a direct impact on critical decisions. It affects how results are interpreted in relation to safety and performance limits.

It influences:

- **Dosage thresholds**, where small variations can change treatment decisions.

- **Alarm limits**, where sensitivity and reliability depend on measurement confidence.
- **Safety margins**, which are defined by how much variation is acceptable.
- **Compliance decisions**, where acceptance or rejection depends on measured values near limits.

Ignoring uncertainty does not reduce risk. It only makes it less visible, which can lead to decisions being made without a clear understanding of their true reliability.

What Mature Systems Do Differently

Organizations with strong measurement systems treat uncertainty as part of the measurement itself, not as an optional add-on. It is built into how results are produced, reviewed, and applied in decision-making.

In practice, they:

- Evaluate measurement uncertainty systematically.
- Report it clearly alongside results, not separately or inconsistently.
- Apply it when making acceptance or rejection decisions.
- Review and update it regularly as methods, equipment, or conditions change.

This approach reflects a deeper understanding of measurement practice. Numbers alone drive actions, but uncertainty defines how far those numbers can be trusted. In that way, uncertainty does not weaken decisions, it protects their reliability and long-term outcomes.

Why Uncertainty Builds Trust

Counterintuitively, stating uncertainty:

- Increases credibility by showing transparency in how results are derived.
- Strengthens audit confidence by showing control over measurement quality.
- Demonstrates professionalism through accurate and responsible reporting.

Honesty about the limits of a measurement earns more trust than presenting results as more certain than they truly are.

Think About It:

A number without uncertainty is confidence without foundation.

Final Thoughts

- Measurement uncertainty doesn't weaken results, it strengthens decisions.
- Ignoring it doesn't make systems safer, it makes them fragile.



About the Authoring Organization

This paper is written from the perspective of an ISO/IEC 17025-accredited calibration & testing laboratory actively supporting healthcare institutions, laboratories, and engineering teams in meeting regulatory, accreditation, and patient safety requirements.

The purpose of this paper is to clarify the distinction and relationship between accuracy and precision, and to explain their importance in calibration.

Preserving Independent Assurance

When calibration must withstand audit scrutiny, independence and competence are critical.

Review which equipment truly requires accredited calibration and align your strategy with clinical risk and regulatory requirements.

For guidance on calibration, uncertainty, or audit readiness, consult an ISO/IEC 17025-accredited laboratory.