Accurate & Efficient Weighing
Good Weighing Practice in Modern Industry

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<td>Performance Verification – Assuring Accuracy</td>
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<td>How and how often should a scale be tested? Can costs be reduced without compromising compliance?</td>
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1946

The first METTLER scale that was developed following the substitution principle:

Only one weighing pan instead of two!

Thank you Dr. Erhard Mettler
Evolution: The E M F R Weighing Cell

1973:
The first time presented to the public:
The electronic precision balance METTLER PT1200.
Electro Magnetic Forced Restoration
Electromagnetic compensating analytical balance

1 weighing pan
2 hanger
3 guide
4 flexible joint
5 coupling
6 lever
7 lever bearing
8 compensation coil
9 permanent magnet
10 magnetic flux
11 optical position sensor
12 position vane
13 temperature sensor
Accurate weighing: Essential for your processes
Guaranteed Accuracy – Reduced Costs – Secure Audits

- We want to produce high-grade products.
- We want to save costs and reduce expenses.
- We want to meet ISO and other regulations.

How can your weighing systems help and meet the above requirements?

Avoid the following pain points....
Avoid These Pain Points

Prevent bad batches and OOS*?

Prove scales are consistently accurate to the auditor!

Appropriate testing at appropriate intervals

Problem source:
- Inaccurate weighing - QUALITY -

Missing adequate documentation - COMPLIANCE -

Testing is costly and a lot of effort - COST -
“Say what you do, do what you say, and be able to prove it.”

Good people + Good equipment + Good processes = Good products
3. The calibration of instruments was not always conducted at suitable intervals.

21 CFR 211.160(b)(4)

and a [ ] used for sterilization of [ ] during the qualification of [ ] processed in these [ ].

Your response indicates you will qualify and calibrate these pieces of equipment and identify all critical and non-critical GMP equipment in order to have a more comprehensive qualification and calibration program.
Mr./Mrs. Customer: I have assessed, recorded data, and performed adjustments on all of your weighing devices. They are within manufacture's specifications. Here are the calibration reports for your file.

-Qualified Service Provider

I have a Calibration Report from my service provider, but are my balances and scales appropriate for my weighing process?
"My SOP says I need to weigh 1kg of this **key** ingredient"

Capacity: 3'000kg  
Readability: 1kg

What you see is not what you get! Each measurement comes with measurement uncertainty. In order to weigh in a reproducible manner, this should be known.

± 80% uncertainty  
0.4 kg  1.5kg
How do you guarantee Accurate weighing?

**Wrong ideas:**
- “What you see is what you get” → Inaccurate measurement results
- "I test my scales every day"… but incorrect or redundant tests cause unnecessary costs
Accurate & Efficient Weighing
Life Cycle Management
Life Cycle Management

The weighing community should have a science-based standard for efficient **life-cycle management of weighing equipment**.

Clear answers should be available on: how you calibrate each device, how you establish of limits, and sound scientific rationale covering every step in the life cycle management of a weighing device.
The requirements for the scale are documented transparently and scientifically.

In particular the most important are:

- **The smallest and largest initial weight**

- **Accuracy requirements**

- **Quality standards to be met**

- **Don't buy a device based readability alone**
New Equipment Selection

Which scale can weigh 200 g with an accuracy of at least 1%?

200g/0.01mg  4000g/0.01g  60kg/1g  600kg/50g

The knowledge about the measurement uncertainty and the minimum weight is the requirement for the selection of a suitable, accurate measurement instrument.
Installation by a trained technician

A professional **installation** and **qualification** ensures good measurement results from the beginning.

**Training** assists users in the correct handling of your measuring instruments.
Calibration of each weighing device

The determination of the measurement uncertainty and the minimum weight ensures that the instrument supplies measurements with the required accuracy.

The weighing device is calibrated and appropriate for the weighing process.
Routine Operation / Performance Checks

- Appropriate testing during the entire life cycle of the weighing system assures accurate weighing measurements.

- Establish scientific rationale for routine testing, based on the risk of the weighing process:
  - How is the weighing instrument to be checked?
  - How often?
  - To what extent can the expenses for tests be reduced?

- Minimization of risk and cost savings are achieved by testing what is required. This way good weighing results are consistently achieved.
The Measurement Uncertainty of a Weighing Device
Measurement Uncertainty – what is it?

“Measurement uncertainty

[...] Parameter that describes the dispersion of the quantity values that is assigned to a scale [...]”

International Vocabulary Of Basic And General Terms In Metrology (VIM) JCGM 200:2008, entry 2.26

- The measurement uncertainty takes of account of the circumstance that no measurement is perfect
- The measurement uncertainty indicates how accurate the measured value is – how close it is to the destination
- The indication of the measurement uncertainty is a part of quality systems, such as ISO, GLP/GMP or pharmacopoeia such as the USP
- The accuracy of measurements can be checked during an inspection and needs to be documented
We would like to formulate 100 kg of fragrance in a drum with a weight of 20 kg. We need the following ingredients:

- Water: 70 %
- Oil: 20 %
- Emulsifier: 5 %
- Moisturizer: 3 %
- Stabilizer: 1.5 %
- Fragrance: 0.5 %

Each component is to be weighed with an accuracy of 1 %.

If possible, we would like to work with a single scale.

Which scale do you recommend?
Can I use a scale with a **readability of 100 g** to weigh a substance having a weight 500 g with an **accuracy of 1 %**?

Example: Quality Assurance in the formulation

This scale can indicate 500 g; is it still accurate to ± 5 g? Of course not!
Accuracy = Readability?

Or do I need a scale with a higher readability, such as 10 g or even 1 g?

But what about the accuracy?
Accuracy ≠ Readability

Display: The readability of a scale can be electronically set to any value.

Sensor: To increase the accuracy, a better sensor must be selected (e.g. EMFR instead Strain Gauge technology)

The accuracy of a scale is expressed by its measurement uncertainty.
A scale is ACCURATE if it satisfies the requirements of the user.

In other words:

MEASUREMENT UNCERTAINTY < PROCESS TOLERANCE
Accurate, reliable Measurement results

Accuracy means that the MEASUREMENT UNCERTAINTY of the instrument is always less than/equal to the PROCESS TOLERANCE.
“Measurement uncertainty

[...] Parameter that describes the dispersion of the quantity values that is assigned to a scale [...].”

International Vocabulary Of Basic And General Terms In Metrology (VIM) JCGM 200:2008, entry 2.26

What are the main contributors to uncertainty of measurement in a weighing device?
## Measurement Uncertainty of a Scale

<table>
<thead>
<tr>
<th>Nominal Property</th>
<th>Readability</th>
<th>Sensitivity</th>
<th>Non-linearity</th>
<th>Corner Load</th>
<th>Repeatability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Measurement Properties</td>
<td></td>
<td>SE</td>
<td>NL</td>
<td>EC</td>
<td></td>
</tr>
</tbody>
</table>

All these properties contribute to the measurement uncertainty of the scale.
The perfect Scale
Measurement uncertainty By readability, ... (RD)
Sensitivity Deviation, ...  (SE)

Load vs. Indication graph with a shaded area representing the sensitivity deviation.
Non-linearity, …
Corner Load/Eccentricity/Shift… (EC)
Repeatability (RP)

Indication vs. Load plot for METTLER TOLEDO scale with various load indications and their respective repeatability ranges.
Determination of the measurement uncertainty

Calibration of non-automatic electronic measurement instruments:

\[ U = K \cdot W^2 + V_{\text{a}} \cdot W^2 + V_{r} \cdot W^2 + V_{w} + V_{e} + V_{K} \]

- Measurement uncertainty
- Weight
- Deviation of the repeatability
- Rounding error deviation
- Deviation of the corner load
- Deviation of the non-linearity
- Effect of the deviation of the calibration weight
Relative measurement uncertainty [%] = Absolute measurement uncertainty / weight
Focus: Minimum Weight and Safety Factor
Establishing Accuracy Limitations
Accuracy limit = Minimum weight

If there is weighing below the minimum weight, the measurement uncertainty is greater than the required accuracy:
→ Inaccurate results
When weighing above the minimum weight, the measurement uncertainty is always smaller than the accuracy required: Accurate results

Accuracy limit = Minimum weight
Minimum weight increases as process % gets tighter

The greater the accuracy, the tighter the process tolerance - the higher the minimum weight.
The minimum net sample weight, $m_{\text{min}}$, of a balance can be expressed by the equation:

$$m_{\text{min}} = \frac{k \cdot s}{\text{required weighing tolerance}}$$

For materials that must be accurately weighed, *Balances 41* stipulates that repeatability is satisfactory if two times the standard deviation of the weighed value, divided by the net desired smallest weight, does not exceed 0.10%. For this criterion the equation above simplifies to:

$$m_{\text{min}} = 2000 \cdot s$$

If not subject to the requirements of *Balances 41*, the minimum weight value may vary depending on the required weighing tolerance and the specific use of the balance.

This methodology describes an alternative for determining the minimum weight of balances.
Test Weight for Repeatability/Minimum Weight?

At the lower end of the measurement range, the repeatability is almost constant.

Test weight up to a few percent of the balance's capacity.

Smaller weight: Feasible, but difficult to handle (especially for micro and analytical balances)
"In order to satisfy the required weighing tolerance, when samples are weighed the amount of sample mass (i.e., the net weight) must be equal to or larger than the minimum weight. The minimum weight applies to the sample weight, not to the tare or gross weight."

The net sample weight has to fulfill the minimum weight requirement.

GC 1251 wants to overcome the misconception that a tare weight can be used to fulfill the minimum weight requirement.
"Factors that can influence repeatability while the balance is in use include:

- The performance of the balance and thus the minimum weight can vary over time because of changing environmental conditions
- Different operators may weigh differently on the balance—i.e., the minimum weight determined by different operators may be different
- The standard deviation of a finite number of replicate weighings is only an estimation of the true standard deviation, which is unknown
- The determination of the minimum weight with a test weight may not be completely representative for the weighing application.
- The tare vessel also may influence minimum weight because of the interaction of the environment with the surface of the tare vessel."

"For these reasons, when possible, weighings should be made at larger values than the minimum weight."

The above information stipulates the application of a "safety factor".
What is the Safety factor?

- **Safety factor < 1**
  Weighing results are inaccurate and process fails

- **Safety factory Between 1 and 2**
  Weighing process is temporarily functioning properly, but the reproducibility cannot be guaranteed over the long term.

- **Safety factor ≥ 2**
  (depends on risk)
  Accuracy ensured over the long-term
Variability of the Minimum weight – safety factor

Minimum weight

SAFETY AND SECURITY

Smallest net weight

Calibration range

Adjustment (by Service)

Calibration range

Time

Initial calibration
"As Found" calibration
"As Left" calibration

SAFETY AND SECURITY
## Traceable Documentation of Minimum Weight

**What is the minimum weight for an accuracy of 1%?**

### Table of minimum net weight display values (minimum weights) for different weighing accuracies and various safety factors

<table>
<thead>
<tr>
<th>Weighing Accuracy</th>
<th>1x (no safety factor)</th>
<th>2x (safety factor of 2)</th>
<th>3x (safety factor of 3)</th>
<th>5x (safety factor of 5)</th>
</tr>
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<tbody>
<tr>
<td>0.10</td>
<td>12.042 g</td>
<td>24.169 g</td>
<td>36.382 g</td>
<td>61.069 g</td>
</tr>
<tr>
<td>0.20</td>
<td>6.011 g</td>
<td>12.042 g</td>
<td>18.095 g</td>
<td>30.265 g</td>
</tr>
<tr>
<td>0.50</td>
<td>2.402 g</td>
<td>4.807 g</td>
<td>7.215 g</td>
<td>12.042 g</td>
</tr>
<tr>
<td><strong>1.00</strong></td>
<td><strong>1.200 g</strong></td>
<td><strong>2.402 g</strong></td>
<td><strong>3.604 g</strong></td>
<td><strong>6.011 g</strong></td>
</tr>
<tr>
<td>2.00</td>
<td>0.600 g</td>
<td>1.200 g</td>
<td>1.801 g</td>
<td>3.003 g</td>
</tr>
<tr>
<td>5.00</td>
<td>0.240 g</td>
<td>0.480 g</td>
<td>0.720 g</td>
<td>1.200 g</td>
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</table>
We recommend using a safety factor >1 to assure accuracy over time.

### Minimum Weight Certificate

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Focus: Performance Verification
Ensuring accuracy
Calibration: Evaluation of the overall performance of the scale by testing all relevant weighing parameters, including integrated safety functions (e.g. automatic calibration)

⇒ Instrument

Routine testing: Evaluation of the requirements for the weighing accuracy

⇒ Weighing process

FACT: Compensation of external (temperature) and internal effects (drafts)

⇒ Environment

Risks during weighing are reduced and accurate results at minimal costs are ensured by the combination of the 3 test procedures.
Calibration by Service technician

Benefits
- Evaluation of the overall performance of the scale by testing all relevant weighing parameters
- Determination of the measurement uncertainty and the minimum weight
- Output of recognized and verifiable certificates according to ISO 17025/USP/A2LA

Restrictions
- Unknown status of the scale between several calibrations if they were not frequently executed
- High costs if they were frequently executed
Self-testing by Intelligent scales

Benefits
- Automatic adjustment compensates for drafts and corrects temperature effects
- Reduction of costs and effort, because on scales having FACT fewer routine tests are required.

Restrictions
- Weights are formally not verifiable for national or international standards and guidelines.
- No determination of repeatability or corner load errors
Functionality of Auto-Calibration / Adjustment

- At the end of the assembly process in the factory, the built-in weight of the balance is being calibrated with an external reference weight ("primary reference calibration").

- The value of this calibration is stored in the memory of the balance. The built-in weight is used to calibrate or adjust the sensitivity of the balance during any subsequent auto-calibration / adjustment.
Functionality of Auto-Calibration / Adjustment

- Internal adjustment mechanisms are a great compliment to a weighing quality process
- They should **not** be used in place of a routine testing
- They should be used in **conjunction** with routine testing
- They should be challenged by appropriate routine testing performed by end users and appropriate service providers
- For most weighing equipment, only OEM service technicians have the ability to adjust these mechanisms
Routine testing by User

Benefits
- Effortless and rapid checking of the required accuracy
- Immediate determination of deviations
- Minimization of risks by testing at appropriate intervals between the calibrations

Restrictions
- Incomplete testing of the properties of the scale
- Weights must be recalibrated at regular intervals
GWP: A risk-based Test strategy

Weighing accuracy

Impact

Higher Risk = More Testing

0.01%
0.1%
1%
10%
Which checks should I perform to effectively test my measuring instruments and minimize risks?

Let us first consider the properties that actually affect your weighing results, i.e., that mainly contribute to measurement uncertainty.

We recommend that you check only these relevant properties.
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</table>

All these properties contribute to the measurement uncertainty of the scale.
Suggested Uncertainty Testing

Indication vs. Load

Load: 0 kg, 1 kg

Indication: 0, 1 kg

Data Points:
- 260.076
- 259.947
- 259.922
- 260.068
- 260.190
- 260.002
- 259.905
- 259.791
- 259.889
- 260.035

Graph showing the range of uncertainty for different loads.
Effect of the weighing Parameters on the accuracy

Scale XP 204: Individual effects on the uncertainty (@k = 2)

- Repeatability dominates uncertainty
- Sensitivity and corner load dominate uncertainty
Summary: Influence of Weighing properties

**Repeatability**
Dominant influence on samples with low mass

**Sensitivity** and **eccentricity load**
Dominant influence on samples with high mass; Influence on samples with low mass negligible

**Non-linearity**
Not dominant with samples having high mass; generally not dominant over the entire sample mass range

Normally it is not required that users test the non-linearity. This test is performed in the context of the service technician.
Which weight for The sensitivity test?

- Test the sensitivity with a weight that corresponds to the capacity (weight 1).
- The use of a low test weight leads to a lower detectable sensitivity deviation. The measurement is influenced in part by repeatability (pink marking).
- If an even smaller test weight is used, the sensitivity deviation is completely covered by the repeatability.
The assessment of the repeatability is much easier with weight 2 than with a much lower weight (weight 2 is less prone to operating errors).
Test weights For user tests

**Weight 1**: Maximum OIML/ASTM weight, that is less than or equal to the capacity of the scale (except scales with high capacity)

**Weight 2**: Maximum OIML/ASTM weight that is less than or equal to 5% of the capacity of the scale

- **XP205**: 200 g and 10 g
- **PBA430x-60**: 50 kg and 2 kg
Accurate & Efficient weighing processes

Questions to ask a quality manager…
4 Simple Questions to Answer

Are my balances/scales accurate?

Am I performing too many or too few tests?

Is our documentation complete?

Do I have an overview of the status of all devices?
Analysis of the scales and their accuracy in the process

Recommendations for measuring equipment monitoring based on risk analysis

Complete documentation

Overview of the status of all scales

Training
GWP® - The Global Weighing Standard

Metrology ✓
Quality management ✓
Process requirements ✓

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