Weighing Guide

Ingeniously Practical

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1. HOW A BALANCE WORKS

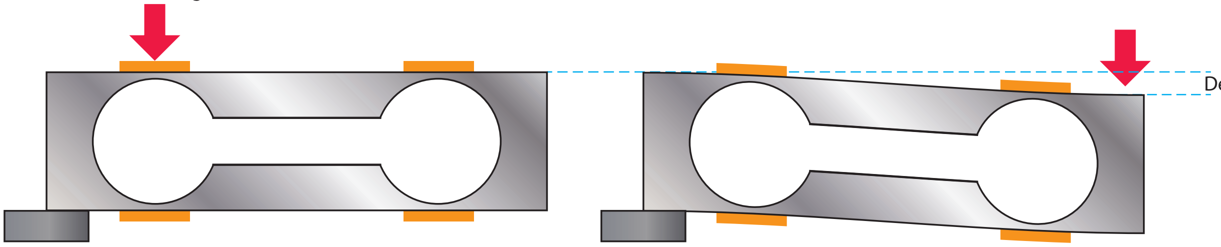
1.1 LOADCELLS

Electronic balances use an electromechanical transducer called a loadcell whose basic function is to convert a mechanical force exerted by an object (and the gravitational force acting upon it) into an electrical signal that can be measured and quantified by a process which converts an analog signal (such a voltage) into a digitally encoded value that a computer can process. Two basic types of loadcells exist. Loadcells with different names exist but they are usually a variant of these two basic types. The two types of loadcells are strain gauge, and magnetic force restoration or MFR for short.

1.1.1 Strain Gauge Loadcells

A strain gauge is a simple device that is used to measure force; they do so by changing their resistance as they stretch or compress. One of the basic electrical principles, Ohm's law gives a formula that equates voltage (V) equal to the current (I) times the resistance (R) in a circuit: $V = IR$. From this simple equation, we can see that if the current (I) remains constant, and the resistance (R) increases then the voltage (V) will also increase. Conversely, if the resistance decreases then the voltage will decrease.

A strain gauge loadcell is a metal object that deflects or bends when a load is applied. The amount by which a loadcell deflects correlates to a particular weight within the weighing range of that balance or loadcell. The loadcell as shown below uses 4 strain gauges mounted at the point where the metal beam deflects as marked in orange in the figure. The change in resistance at each point will cause the voltage output of the system to change in relationship to the downward force applied by the weight on the pan of the balance.



1.1.2 Magnetic Force Restoration Loadcells

A Magnetic Force Restoration or MFR Loadcell essentially uses a lever, which moves an armature up and down as a force (exerted by an object placed on the balance's pan) is applied to one side (Fig. 1 & Fig. 2).

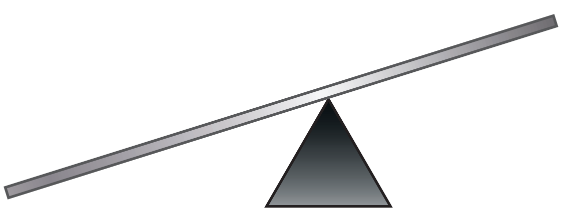


Fig. 1

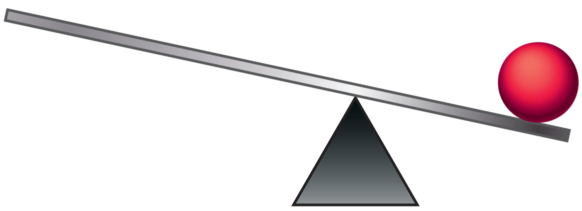


Fig. 2

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An electromagnet, mounted above the free end of the armature creates enough magnetic force to bring the arm back into an equilibrium position (Fig. 3). The amount of power it takes to sustain the equilibrium position can be measured and correlated to the weight on the pan.

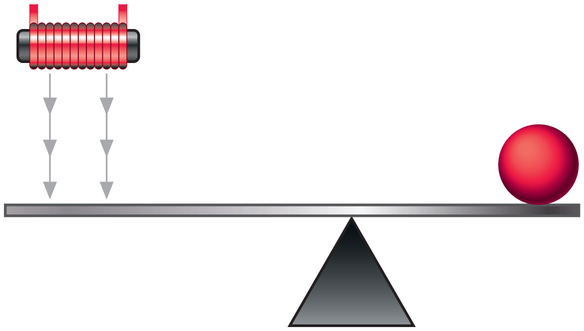

Fig. 3

1.1.3 Strain Gauge vs. MFR Loadcells

Strain Gauge and MFR Loadcells fundamentally both accomplish the same task; they convert a force (weight) into an electrical signal that can be measured, quantified, and further processed to ultimately display a useable weight value on the balance's display. They each accomplish this task in different ways so one may ask "which is better?". As with many thing of this nature, they each have their strengths and weaknesses and have applications for which they are better suited. In general, strain gauge loadcells tend to be cheaper to produce, more robust and are typically found in industrial scales and smaller portable devices. As a rule of thumb, strain gauge loadcells typically have a maximum resolution of up to 100,000 to 150,000 points. MFR loadcells on the other hand can have a much higher maximum resolution (in some cases several million points), and are typically found in tabletop balances or light industrial applications.

1.2 *BALANCE CONSTRUCTION & ARCHITECTURE*

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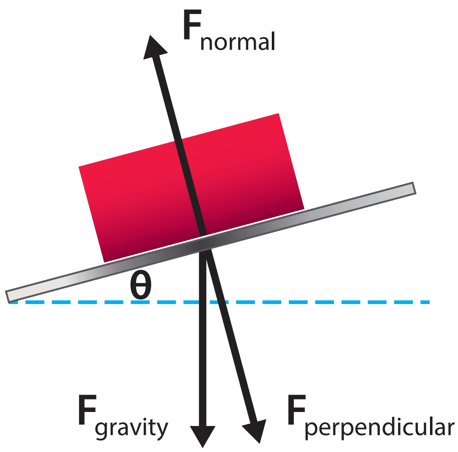
A typical balance is constructed with a housing, onto which the other components are assembled. A metal bottom housing typically offers more stability and provides a better mounting location for a loadcell than a plastic bottom housing. A loadcell is mounted to the housing, on to which a downward force is applied by the pan structure, which transfers any additional load placed upon it to the loadcell.

Some balances have adjustable leveling feet so that the balance can be leveled to provide accurate readings. In order to understand the importance of leveling a balance, lets look at a classical inclined plane diagram. In the following diagram, the plane on which the object sits is elevated at an angle θ from the plane perpendicular to the force of gravity.

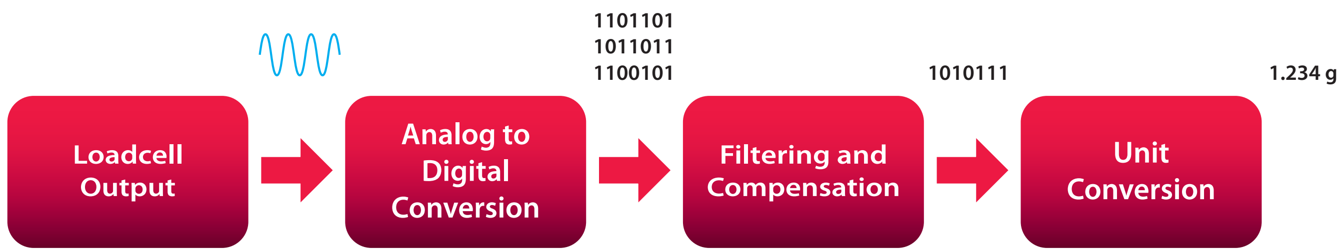


The normal force (Fnormal) is a force exerted perpendicular to the plane (i.e. the pan in this case), gravity (Fgravity) will always be exerted directly downward, therefore the downward force on the loadcell will be mass × gravity × cos(θ) or weight × cos(θ).

For example, if the weight of the object on the pan is 100.000 g and θ = 5° the weight in the downward direction will be 99.619 g

1.3 *FROM ELECTRICAL SIGNAL TO WEIGHT DISPLAY*

So now that we understand how a loadcell converts a physical weight into an electrical signal, how does an electronic balance process that signal in order to get it to appear as a final, readable weight on the display? The journey from the loadcell to display in an important one, the process in which an analog signal (in this case a voltage) converts not only to a raw digital value but to a final end result. This process plays a critical role in the overall performance, accuracy, and stability of the balance and reduces error from certain environmental factors such as changes in temperature, vibrations, etc.



1.3.1

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1.3.2 Analog to Digital Conversion

Analog-to-Digital converters (ADC) translate analog signals, real world signals like temperature, pressure, voltage, current, distance, or light intensity, into a digital representation of that signal. This digital representation can then be processed, manipulated, computed, transmitted or stored. [1]

1.3.3 Filtering and Compensation

Once the analog signal has been digitized, it can then be further manipulated. This critical step in the process of converting the loadcell's analog output to a final digital value for output is frequently overlooked and contributes significantly to the accuracy of the weighing instrument. In this step the individual values are filtered to reduce noise and reduce high frequency incoming values into a single average value. These lower frequency averaged values are then passed along the processing chain and are further manipulated by applying temperature compensations and calibration factors to produce a single compensated value.

1.3.4 Unit Conversion

Once a final value is reached, it can then be converted to a unit (e.g. grams, pounds, etc.) and displayed to the user, used in an internal calculation or operation or printed.

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2. BASIC TERMINOLOGY & CONCEPTS & BALANCE FUNCTIONS

2.1 BALANCE TYPES & NOMENCLATURES

Balance Type	Readability	Other terms
Micro balance	0.001 mg (1µg)	"6 place" or "6 digit" balance
Semi-micro balance	0.01 mg	"5 place" or "5 digit" balance
Analytical balance	0.1 mg	"4 place" or "4 digit" balance
Precision balance	0.001 g	"Milligram" or "3 place" or "3 digit" balance
	0.01 g	"2 place" or "2 digit" balance
	0.1 g	"1 place" or "1 digit" balance

2.2 TERMINOLOGY

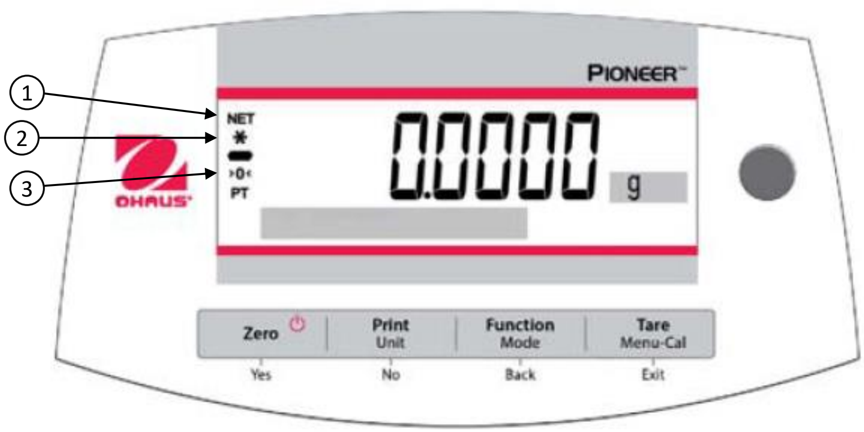

Fig. 4

Weight & Mass: The terms mass and weight are often used interchangeably. The mass of an object is a measure of the quantity of matter or material of which the object is comprised. The weight of an object is the measure of force that is applied to the object when acted upon by gravity, or in more general terms the strength of its gravitational attraction to other objects. A balance can determine the mass of an object by measuring the weight or force of gravity acting upon an object.

Capacity: Capacity is the maximum weight measurable by the balance or the maximum weight that can be placed on the pan before an overload error is shown.

Readability: Readability is the smallest difference in mass that can be displayed on a scale. The readability is commonly noted as "d" — also called divisions or increments. In Fig. 4 above, this particular balance shows a weight reading of "0.0000 g". Therefore, it is an analytical balance with a readability or d equal to 0.0001 g or 0.1 mg.

More officially, the readability or "d" is defined as "The value of the scale division, expressed in units of mass, is the smallest subdivision of the scale for analog indication or the difference between two consecutively indicated or printed values for digital indication or printing."

Resolution: Resolution is the number of unique weight values that a balance can display. This term is often confused with

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readability. The resolution of a balance is equal to the capacity divided by the readability. So for example, a balance that can weigh up to 500 grams and a readability of 0.01 g has a resolution of 50,000 points. Resolution can also be referred to as the "number of scale divisions".

Gross/Net/Tare

The gross weight is the sum total of the all the items or objects on the balance at any given time.

A tare weight is a value stored in the balance that represents a container or essentially something to be ignored. A tare value can be recorded by placing an object on the balance and pressing the tare key or in some cases; a "pre-tare" value can be entered directly by either keying it in on the balance or recalling a stored value.

The net weight is the item or items of interest (i.e. without the weight of a container). If a tare value exists then the weight will be displayed (and printed) with an indication that it is a net weight. If a tare value exists and the displayed weight is a net weight it will typically be indicated on the display. Fig. 4 item 1 shows the "NET" symbol that will appear on the display when a net weight is being displayed. If the container is removed and the balance is zeroed the "NET" indicator will disappear.

Net Weight = Gross Weight – Tare Weight

Stability: Stability is indicated when the weight on the pan is considered to be stable according to the balance's stability criterion. When a stable weight reading is achieved the balance will indicate this by showing an indicator on the display. Fig. 4 item 2 shows the stability indication symbol that will appear on the display when a stable condition is reached. This indicator will disappear if the balance is disturbed.

Dead Load: Dead Load is the combined weight of the pan or weighing platform, including any sub-pan or platform supporting structure that rests on the loadcell before any weight is placed on the pan.

Zero & Initial Zero

Zeroing the balance sets the Gross Weight to zero. When the balance is turned on it will attempt to take an Initial Zero, ideally this is the state of the balance with only the dead load pushing down on the loadcell, i.e. nothing on the pan (zero gross). Generally the initial zero point must be within some range of the balance's production zero point or else an error condition will occur. The balance can be re-zeroed during operation to indicate a new gross zero or empty pan state.

Auto Zero Tracking: Auto Zero Tracking (or AZT) is a feature that will maintain a zero point by automatically performing a zero operation in the case that the balance drifts slightly around the zero point. This value is usually given in divisions (d) per second. For if the selected AZT setting is 0.5d per second that means that if the balance drifts less than ½ of a scale division within one second, the balance will zero itself. Depending on the balance this value can be changed or switched off.

Dual Range: A dual range (or multi range) balance essentially divides the weighing range (from zero to its capacity) into two (or more) ranges. In each range the readability of the balance will change in each range allowing lighter (typically smaller) samples to be weighed with a finer, more suitable readability and larger samples to be weighed with a larger one.

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For example a balance might have a total capacity of 220 g with a fine range from 0-100 g where the weight is displayed in increments (d) of 0.01mg, and a coarse range from 100-220 g where the weight is displayed in increments (d) of 0.1 mg.

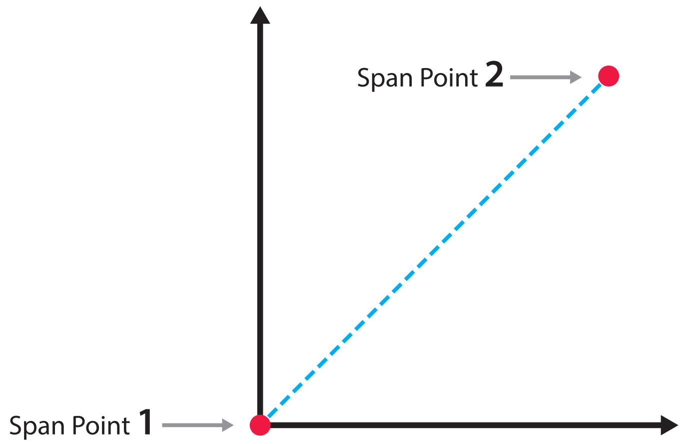
2.3 *CALIBRATION & ADJUSTMENT*

Calibration is a process of comparing measured values to a 'true' value. A calibration is essentially a test; it does not alter the behavior of a measurement device

Adjustment is the process of altering a measuring instrument's performance, so that the values indicated correspond to reference point or standard unit of measure.

Balances can be calibrated and adjusted using reference (calibration) weights (see section 6 for more information on calibration weights). This essentially tells the balance that a given weight correlates to a particular electrical signal. A balance must have at least 2 reference points in order to perform a calibration. From 2 points a line can be formed and values between (or beyond) the two known points can be inferred.

A calibration that uses 2 points is known as a "span calibration", and is typically done with the zero point (empty pan), and a weight close to the capacity of the balance.



A calibration can be done with more than 2 points, which defines one or more mid points (see section 3.4.2 for information on linearity uncertainty). Performing a linearity calibration will typically reduce the uncertainty due to linearity (or non-linearity) throughout the weighing range.

2.3.1 Internal and Automatic Calibration

Nearly all balances can be calibrated or adjusted using external weights, however some balances have an internal calibration mechanism. This consists of a small motor and set of internal weights that can be raised and lowered within the housing of the balance in order to perform a calibration. Some advanced balances have an automatic calibration feature that will autonomously perform an adjustment of the balance after a certain amount of time has elapsed or a temperature change is detected.

3. BASIC INSTALLATION & SETUP

3.1 ENVIRONMENTAL FACTORS & LOCATION

In order to achieve the best possible performance out of a balance it is critical to setup and use the balance in a controlled and stable environment. In general, balances are sensitive to environmental effects that would cause physical vibration, changes in temperature and humidity, and static electric charges. To avoid these negative influences and resulting effects on the balance choosing a suitable location should take into account the following factors.

3.1.1 Vibration

Balances should be placed on solid, rigid surfaces. These surfaces should be either free standing or anchored to the floor but avoid contact with more than one surface of the room (such as an adjoining wall). They should be placed and used away from sources of vibration such as local foot traffic, HVAC equipment, and other machinery or instruments. Ideally, the table used for weighing should not be used simultaneously for other activities.

Balances should be kept out of the path of any potential drafts, either directly from a vent or fan, or in an environment with more than one opening that could create a wind tunnel effect.

3.1.2 Static charges

The buildup of static charges can aversely effect a balance's weighing performance. Static charges can create either an attracting or repelling force on an object which can ultimately lead to erroneous weight results or have a negative impact on stability. Balances with smaller readabilities (e.g. analytical and semi-micro balances) are effected more than precision balances with larger readabilities. Elimination of static charges might require increasing relative humidity in the room, changing the way sample materials are stored or handled, using tare containers that are less prone to accumulating a static charge (e.g. glass over plastic), or using external devices such as a static ionizer.

3.1.3 Temperature & Humidity

Expansion and contraction of materials such as metals and adhesives due to changes in temperature and humidity might seem negligible and without consequences. However, in high precision applications, this can create challenges. If possible, balances should be used in a controlled environment with a constant ambient temperature and humidity. They should be kept out of direct sunlight and away from heating or cooling vents. In the event of a change in ambient conditions, the balance should be re-adjusted

3.1.4 Drafts

Drafts can cause high levels of instability and have a negative effect on weighing performance therefor balances should be kept away from air drafts. Obvious sources of air movement can be caused by interior doorways, windows, fans or HVAC vents however even in a closed room slight variations in temperature can cause air to move and circulate within the room especially in environments where other equipment is being used. Some balances are equipped with draftshields that enclose the pan, preventing disruptions caused by drafts.

3.2 SETUP PROCEDURE

1. Unpack and assemble the balance. Check for any damage that may have occurred during shipping or storage/handling of the instrument. Make sure all parts are included as specified in the user manual.
2. Place the balance on a suitable weighing surface (refer to the guidelines given in the previous section)
3. Level the balance
4. Connect power and allow the balance to warm up before use for optimal performance. It is suggested to switch off a balance but leave it plugged into the wall when not in use. Appropriate warm up times are as follows:
    a. At least 30 minutes for a precision balance
    b. At least 1 hour for analytical balances

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c. At least 2 hours for semi-micro balances.

d. Or according to the manufacturers specifications.

5. Perform a calibration and adjustment if necessary using either external calibration weights or the internal calibration mechanism the balance is equipped with one. It is recommended to calibrate and readjust the balance when moving to a new location or if the environment changes.
6. Perform a cursory functional inspection of the balance. Ensure that the display and user interface (mechanical buttons, touch screen, sensors, etc.) are working correctly. Ensure that the weighing is responsive and stable.
7. If necessary, perform relevant metrological tests on the balance as defined in Appendix A of this guide.
8. Configure the balance's various settings in the menu so that it operates and behaves as desired for the intended environment and application.

3.3 *MAINTENANCE & CLEANING*

Proper maintenance and cleaning of a balance is essential for ensuring proper operation and performance as well as maximizing the longevity of the balance in operation. Balances should be kept clean, stored properly when not in use, and calibrated periodically.

Balances should be cleaned regularly to avoid the buildup of dust and debris on balance surfaces and on internal components. Balances should be wiped down after use with a soft cloth, a damp cloth with a mild, nonabrasive household cleaner (soap) can be used. Dot use alcohol or solvents on the balance. Any spills of materials on balance surfaces should be cleaned up immediately before further use of the balance; balances should not be allowed to sit with chemical residue for any period of time as it risks corroding metal and weakening plastic parts.

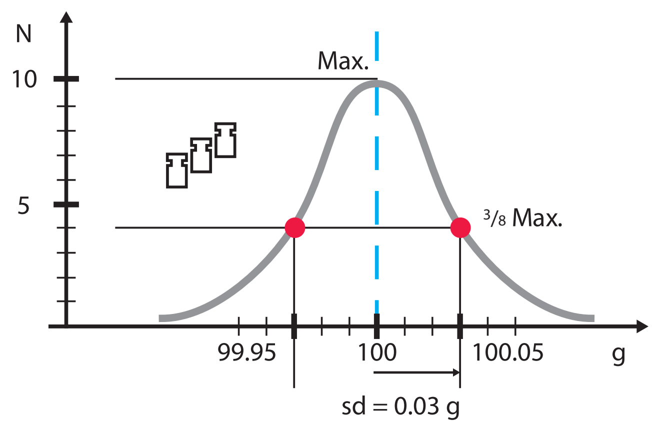
It is good practice to routinely check the balance's performance with a calibration weight and adjust the balance if any deviation occurs. Balances should be calibrated and adjusted if they are moved for any reason.

When storing a balance it is best to use the original packaging if available. Balances should be stored on a level surface and stored oriented as it would be used (i.e. not upended or on it's side). When in storage items should not be placed on top of the balance's pan.

3.4 *SOURCES OF UNCERTAINTY*

3.4.1 Repeatability

Repeatability is the ability of a balance to provide the same result for repeated weighing of the same load under the same measurement conditions. The uncertainty due to repeatability is a statistical measurement and is represented by the standard deviation of several measurements taken in succession without interruption.



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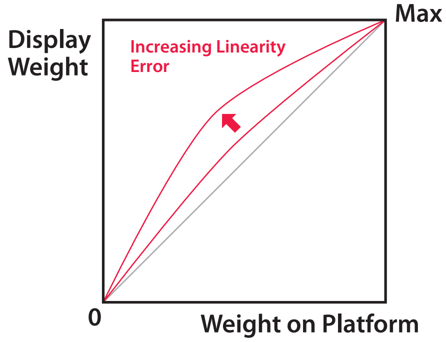
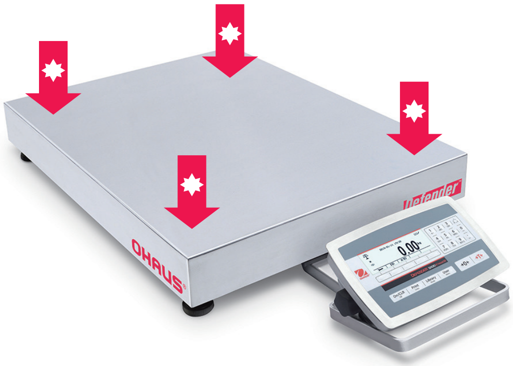
3.4.2 Linearity

Linearity (or nonlinearity) is the capability (or inability) of a balance to follow a linear relation between the load and the displayed value. It is the deviation of the scale's displayed results compared to a theoretical straight line between 0 and maximum capacity. A higher value indicates more deviation and greater uncertainty. Linearity deviation or uncertainty will vary throughout the weighing range and will likely be the greatest between the various calibration points.



3.4.3 Eccentricity or corner load

Eccentricity (corner load) is the deviation of a measurement result when the weight is placed at various points on the pan. Poor corner load performance is often a result of bad design and poor quality of a loadcell and platform assembly construction.



4. METROLOGY & ACCURACY

4.1 MEASUREMENT UNCERTAINTY

Measurement, or measurement science, is something that is used daily by all individuals in order to quantify and describe the world around us. The applications are nearly infinite and we rely on them for all sorts of reasons ranging from measuring the portion of food you ate for breakfast, to how much has is in your gas tank as you drove to work, to complex global positioning satellite systems which guided you on your route. Without the ability to not only measure but measure "accurately" life would become very difficult. For this reason, measurement science or "Metrology" is of vital importance to every individual.

What is "Metrology"? The International Bureau of Weights and Measures (BIPM) is an inter-governmental organization whose mandate is "to provide the basis for a single, coherent system of measurements throughout the world". The BIPM defines metrology as "the science of measurement, embracing both experimental and theoretical determinations at any level of uncertainty in any field of science and technology". Note that the definition specifically acknowledges measurement uncertainty as a fundamental principle of metrology.

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"No measurement is exact. When a quantity is measured, the outcome depends on the measuring system, the measurement procedure, the skill of the operator, the environment, and other effects. Every measurement is subject to some uncertainty. A measurement result is only complete if it is accompanied by a statement of the uncertainty in the measurement. Measurement uncertainties can come from the measuring instrument, from the item being measured, from the environment, from the operator, and from other sources." [3]. Measurement uncertainty represents the variance of measured values by an instrument or the degree to which a measured value can deviate from the true value.

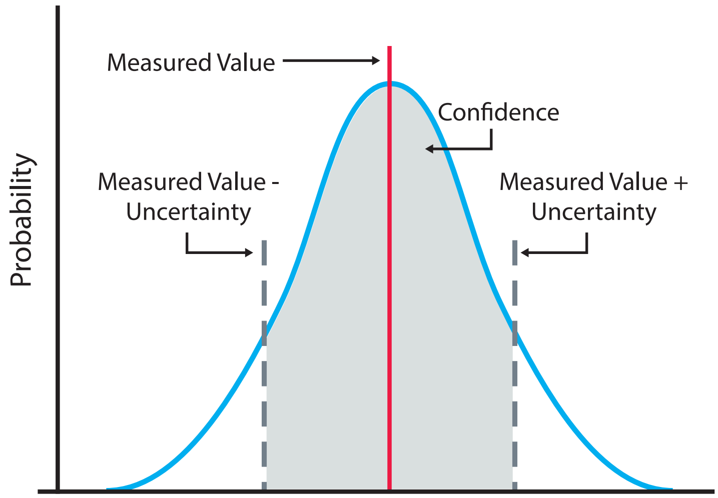
All measurement values are in essence approximations or estimations of how closely a measured value compares to a 'true value'. The best we can do is to give an estimation of a measurement and say something about how confident (or not confident or uncertain) we are with the estimate. Therefore, a complete "measurement" would actually look something like this:

Measurement = Estimated Value ± Uncertainty

That is to say, that for our purposes, we are confident that the 'true value' of whatever we are trying to measure falls somewhere in the range of:

(Estimated Value – Uncertainty) to (Estimated Value + Uncertainty)

Repeated measurements will vary within a given range if plotted based on frequency of occurrence will typically (although not always) form a normal distribution or a "bell shaped" curve.



From this we can form a 'confidence interval' that is, how confident are we that a measured value does fall with a finite and defined range? To simplify this concept consider the following example. If you were asked to measure the length of the given object with a ruler, you'd probably look and see that the end of the object fell somewhere in between the 3.0 and 3.1 markings so you might split the difference and say that the length is approximately 3.05 centimeters, give or take 0.05 centimeters. You would probably be fairly confident that estimate or measurement is "accurate". Would you be more or less confident saying that the length of the object is 3.07 centimeters give or take 0.01 centimeters, so that the length of the object is between 3.06 and 3.08 centimeters? You would probably be less confident in this estimation as it has a much smaller range of uncertainty. Now how confident would you be that the object is exactly 3.07 centimeters? In this case probably not very confident at all.

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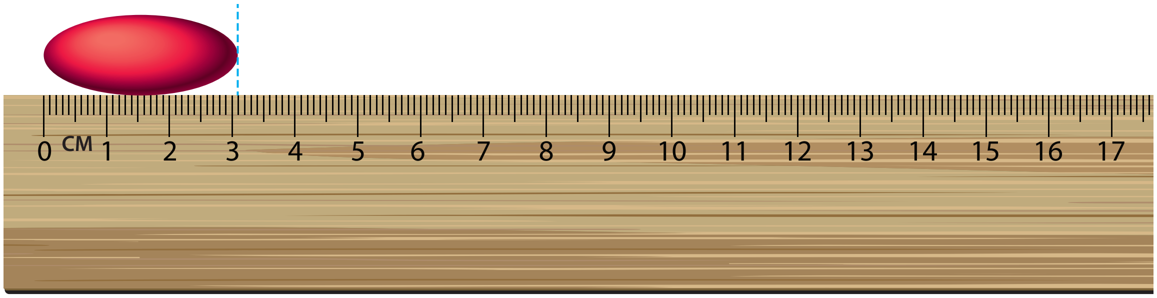
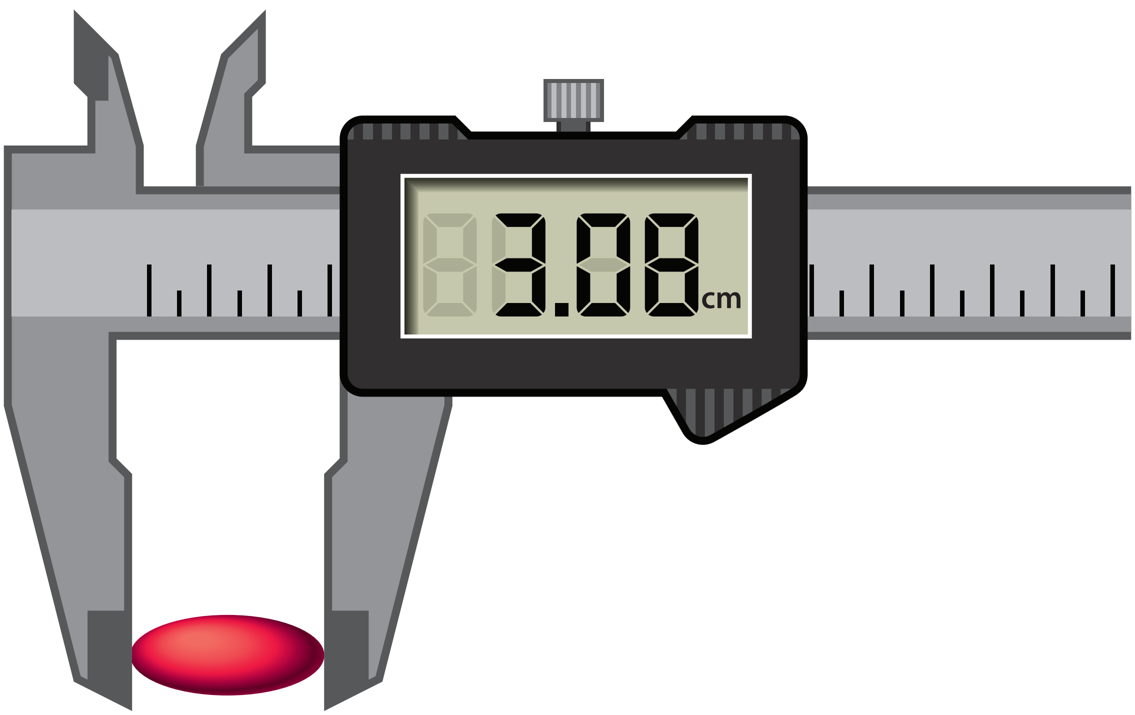


So in the previous example, what are the factors that would cause you to be more uncertain of the accuracy of the measurement. What if the other end of the object wasn't lined up exactly at the zero position? What if you were not observing the end of the object and the markings on the ruler in a straight line? What if the ruler itself wasn't manufactured to a very small tolerance and the markings are ever so slightly off? These are all factors that could lead you to question the "accuracy" of the measurement or factors that contribute to measurement uncertainty.

Taking the linear measurement example a step further, let's say that instead of a basic ruler we used a digital caliper to measure the object. After tightening the arms on the object, the caliper reads 3.08 centimeters. So again how confident would you be that the actual value is exactly 3.08 centimeters? What if the caliper isn't calibrated correctly? What if the caliper wasn't zeroed exactly at the zero point? What if the caliper is poorly made and there is play in the slider? All these factors contribute to some degree of uncertainty in the measurement.



In this example, simply because we moved from a simple ruler to a digital instrument does not mean that some degree of uncertainty does not exist. Furthermore, the readability of the instrument in no way guarantees the accuracy of the measurement. In this example, just because the caliper reads by increments of 0.01 centimeters does not mean that the displayed measurement is "accurate" to the displayed value.

Readability does not equal accuracy! A measurement instrument is not necessarily accurate to within one displayed division.

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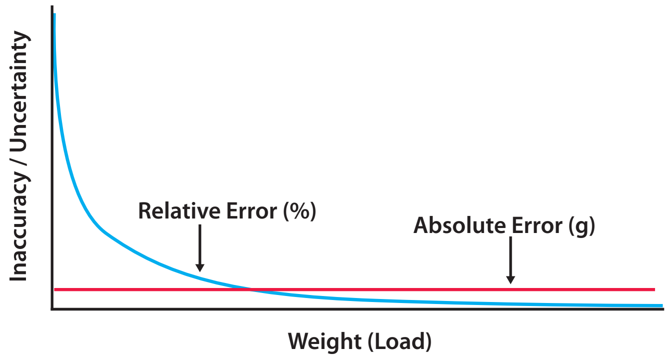
4.2 *BALANCE ACCURACY & MINIMUM WEIGHT*

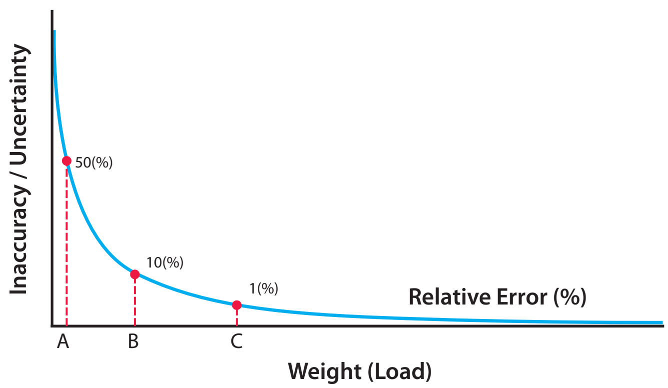
So how do we apply all of these concepts to weighing and how can we ensure that we are weighing accurately? Fortunately, there are methods to quantify the measurement uncertainty when using a balance. Additionally it is important to note that when dealing with balances measurement uncertainty values are absolute not relative; that is to say that they do not scale in magnitude with the amount of weight on the balance. For example if the sum of the measurement uncertainty on a particular balance is 1.5mg, then it is true for a 10 g weight or a 500 g weight.

To further illustrate this point let's consider a golfer who, no matter where he is on the course will always land his golf ball within 3 yards of the hole. So if he drives a ball on his first shot from 200 yards away from the hole and the ball lands within 3 yards of the hole one would say that he is a very good golfer. However if the same golfer starts 10 yards away from the hole and the ball lands 3 yards away one might argue that he is not such an accurate golfer. Similarly, as the weight on a balance increases, the relative accuracy (that is the proportion of uncertainty to the weight of the sample) increases. Conversely, as the weight on a balance decreases the uncertainty becomes larger relative to the sample. It is therefore reasonable to refer to the "accuracy" of a balance in relative terms (i.e. as a percentage of the sample being weighed).



One way to guarantee a minimum accuracy is to use a concept known as *minimum weight*. **Minimum weight is a widely misunderstood concept. It is not the smallest thing that can be weighed on a balance, but rather the smallest thing that can be weighed on a balance while guaranteeing a maximum level of uncertainty. Second, there is no standard or one size fits all minimum weight; the minimum weight can vary based on the desired tolerances, which can vary from application to application**. For example, an application such as pharmaceutical manufacturing would likely require smaller tolerances and greater accuracy than weighing materials for industrial manufacturing.

Given the relative error curve, it is apparent that as the weight or load increases the relative error (again the measurement uncertainty in proportion to the weight of an item) decreases. As it is possible to quantify the measurement uncertainty, it is therefore possible to calculate the relative measurement uncertainty at a given weight. Similarly, it is possible for a given weight to calculate the relative measurement uncertainty. It is also reasonable to assume that all weights heavier than a given weight will have a lower relative uncertainty or higher relative accuracy. For example, in the figure below, all weights heavier than B will have a relative uncertainty less than 10%.



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Given an accuracy tolerance (typically denoted by the letter U and is given as a percentage, e.g. 0.1%), the absolute measurement uncertainty value for a particular instrument a minimum weight value is easily be calculated using the following formula:

Sample Weight $_{(Min)}$ = Instrument uncertainty / (U $_{(Max)}$ $\times$ 100)

4.3 *CALCULATING THE MINIMUM WEIGHT*

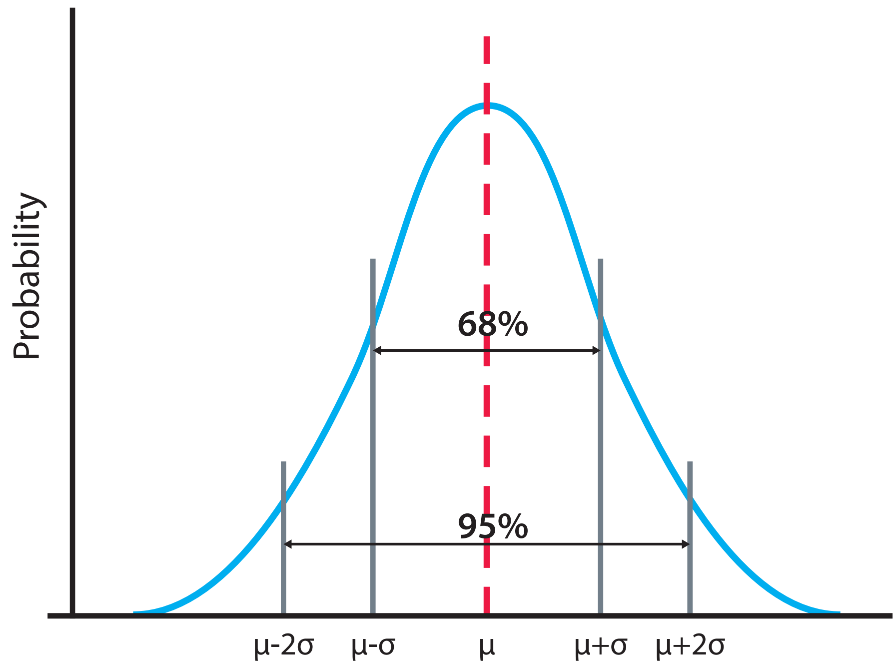
There are several sources of measurement uncertainty as previously described in this document; however measurement uncertainty due to repeatability (or non-repeatability) has the most impact by far at the beginning of the weighing range. For this reason, in practice, the minimum weight value is typically calculated using the repeatability as the instrument uncertainty value. It is best practice to use a measured, calculated value once the balance is been installed and in the operating environment in which the balance will be used.

4.3.1 Coverage factor

Frequently a factor (or multiplier, typically denoted by the letter k, e.g. 2) will be applied to the minimum weight formula, thereby making the calculation:

Sample Weight $_{(Min)}$ = Instrument uncertainty / (U $_{(Max)}$ $\times$ 100) * k

Since the repeatability is calculated using the standard deviation of multiple measurements (denoted by the Greek letter sigma σ) if we assume a normal distribution of weight values, then one standard deviation from the mean value (plus or minus) would give an area under the curve of about 68%. This means that on average 68% of the time the measurement error due to repeatability would be smaller than or equal to this value, but 32% of the time it wouldn't be. By applying a coverage factor of 2, it increases the probability to 95% that the error due to repeatability would fall within this range.



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5. LEGAL METROLOGY & APPROVED WEIGHING

5.1 INTRODUCTION

In essence, a legal metrology system exists to protect consumers from false or inaccurate measurements. Inaccurate measurements can have a variety of negative effects from health and safety (e.g. the production and preparation of medication) to financial (e.g. paying too much or too little for a particular good). Various organizations worldwide have been established to ensure the accuracy of measurements and adherence to global standards and conventions. This is done through various guidelines, certification (type evaluation) programs, and audits.

5.2 OIML

The International Organization of Legal Metrology (or in French Organisation Internationale de Metrologie Legale or OIML) is a worldwide, intergovernmental organization who aims to harmonize regulations and metrological controls of its 57 member countries. It promotes global harmonization of the legal metrology procedures that underpin and facilitate international trade.

OIML R76 is a document that defines metrological and technical requirements for "Non-automatic weighing instruments" (i.e. Scales and Terminals). It is a comprehensive set of performance and functionality requirements. Additionally OIML has a certification system, which certifies that a particular balance has been tested, and conforms to guidelines and requirements including metrological performance, set forth in R76. [3]

5.3 NVLAP

The National Voluntary Laboratory Accreditation Program (NVLAP) "provides third-party accreditation to testing and calibration laboratories in response to legislative actions or requests from government agencies or private-sector organizations. NVLAP-accredited laboratories are assessed against the management and technical requirements published in the International Standard, ISO/IEC 17025:2017." [4]

5.4 2014/31/EU

The Directive 2014/31/EU of the European Parliament and of the Council of 26 February 2014 apply to Non-Automatic Weighing Instruments. This Directive covers non-automatic weighing instruments and gives the guidelines each manufacturer has to follow to ensure their conformity to the terms of the directive. The "EC marking" affixed by the manufacturer indicates that the instrument is in conformity with the applicable requirements set out in Union harmonization legislation providing for its affixing. [5]

5.5 ASTM

Formerly known by its full name, American Society for Testing and Materials, ASTM International "is an international standards organization that develops and publishes voluntary consensus technical standards for a wide range of materials, products, systems, and services." [6] ASTM puts forth standards as recommendations as developed by its various member committees and does not verify conformance or enforce compliance with its standards however they are frequently adopted into various industry standards created and enforced by other organizations.

5.6 TYPE APPROVALS

What is a type approval? A type approval is a generic term that is essentially a certificate of conformity. The Directive 2014/31/EU mention categories of use of non-automatic weighing instruments which shall be distinguished, there are 7 uses that require certification. The balances concern by those specific usage will be marked with "M"/ EC Type Approved [5]

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5.7 BALANCE CLASSES

Balance classes are defined in OIML R76:

Name	Symbol marked on instrument	Denomination used in this Recommendation
Special accuracy	I	I
High accuracy	II	II
Medium accuracy	III	III
Ordinary accuracy	IIII	IIII

Class	*Value of the Verification Scale Division (d or e[1])*	*Number of Scale[4] Divisions (n)*	
		Minimum	*Maximum*
		SI Units	
I	*equal to or greater than 1 mg*	*50 000*	*--*
II	*1 to 50 mg, inclusive*	*100*	*100 000*
	equal to or greater than 100 mg	*5 000*	*100 000*
III[2,5]	*0.1 to 2 g, inclusive*	*100*	*10 000*
	equal to or greater than 5 g	*500*	*10 000*
III L[3]	*equal to or greater than 2 kg*	*2 000*	*10 000*
IIII	*equal to or greater than 5 g*	*100*	*1 200*

According to OIML R76 " Equipment shall be suitable for the service in which it is used with respect to elements of its design, including but not limited to, its capacity, number of scale divisions, value of the scale division or verification scale division, minimum capacity, and computing capability." [7].

Scale classes are often referred to in weights and measures guidelines; they help indicate the suitability of a scale for a particular application.

5.8 APPROVED READABILITY & LEGAL FOR TRADE APPLICATIONS

OIML R76 defines the "verification scale division" or "verification scale interval" as "A value, expressed in units of weight (mass) and specified by the manufacturer of a device, by which the tolerance values and the accuracy class applicable to the device are determined. The verification scale division is applied to all scales, in particular to ungraduated devices since they have no graduations. The verification scale division (e) may be different from the displayed scale division (d) for certain other devices used for weight classifying or weighing in pre-determined amounts, and certain other Class I and II scales." It then goes on to say "If e ≠ d, and both "e" and "d" are continuously displayed during normal operation, then "d" shall be differentiated from "e" by size, shape, color, etc. throughout the range of weights displayed as "d.""

To translate:

- "d" is the normal readability or interval of the scale.
- "e" is the smallest division or interval that is allowed to be used if the balance is being used in an application where a price (to a consumer) is being calculated based on weight. Also referred to as a "legal for trade" application.

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- "d" and "e" can be but are not always the same value, in these cases "e" is usually equal to 10d. For example, An OHAUS AX223M balance has a "d" value of 0.001g and an "e" value of 0.01g.
- When "d" and "e" are not equal, "d" can be displayed but must be differentiated. For example, when in "legal for trade mode" a balance (again using the OHAUS AX223M) can show 20.00[1]g; the final digit is displayed with a bracket to differentiate it from the more significant digits which can be used for computing price.

5.8.1 How to select a legal-for-trade scale

When selecting an appropriate scale for a legal-for-trade application it is important to first check the measures guidelines that define the requirements for a particular use. Frequently, the guidelines will identify the class of balance required, the (approved) readability, and in some cases specify or recommend an appropriate or minimum capacity. In nearly all cases, the scale will be required to have a local type approval (e.g. EC Type Approved)

Once the requirements are known, select a balance that meets the specified criteria. A balance's specs usually can be easily found in a manufacturer's catalog or in a datasheet. For example:

Model	EC Type Approved	AutoCal™	Capacity	Readability (d)	(e)	Platform	Cal. weight, class
AX124		•	120g	0.1mg		Ø 90mm	100g, E2
AX224		•	220g	0.1mg		Ø 90mm	200g, E2
AX324		•	320g	0.1mg		Ø 90mm	200g+100g, E2
AX124M	•	•	120g	0.1mg	1mg	Ø 90mm	100g, E2
AX224M	•	•	220g	0.1mg	1mg	Ø 90mm	200g, E2
AX324M	•	•	320g	0.1mg	1mg	Ø 90mm	200g+100g, E2

The excerpt from the OHAUS catalog has several models in a particular family that could be used as "legal for trade" balances, however not every scale will work for every application. In the example above, the "M" in the model name identifies it as an EC Type Approved model, the class for each model is given, and both the normal interval or readability (d) and the certified readability (e) are given. Note that they may or may not be the same value. It is important to go by the certified readability if the scale will be used to weigh items for which a price will be calculated based on its weight..

6. CALIBRATION WEIGHTS

Scale calibration weights are typically available according to either ASTM or OIML classes. OIML R111 and ASTM E617 publications each provide recommendations and metrological specifications and requirements for their respective calibration weights.

6.1 *TYPICAL APPLICATIONS BY CLASS:*

ASTM	OIML	Typical Uses:
Class 0, 00, 000	E1	Reference weights used nearly exclusively by metrology labs and are used for calibrating other weights; they are rarely used to calibrate balances directly.
Class 1	E2	Typically available in smaller weights for applications that require ultra-high accuracy such as calibrating analytical (balances with a readability of 0.1 mg readabilities) and semi-micro (balances with a readability of 0.1 mg readabilities) balances.
Class 2	F1	Typically used to calibrate precision balances with readabilities of 0.001 - 0.01 grams.
Class 3	F2	Typically used to calibrate precision balances with readabilities of 0.01 – 0.1 grams.
Class 4	F3	Typically used to calibrate larger balances with readabilities above 0.1 grams
Class 5, 6, 7	M1, M2, M3	Typically used for large industrial scales

See Appendix A for tolerances by class and weight

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6.2 *WEIGHT TRACEABILITY & CERTIFICATES*

Even the highest quality balances are only as accurate as the reference weights used to calibrate them. It is therefore very important to use appropriate calibration weights relative to the application.

With regards to weights, traceability refers to the ability to track (or trace) a particular weight back to the laboratory in which it was manufactured, calibrated, or adjusted and links that weight to the weights that were used to calibrate it, and so on. In this case it is an assurance that the weight being used can be traced back to a laboratory or manufacturer that is NVLAP certified and abides by NVLAP measurement standards.

"There are two types of calibration reports, accredited and non-accredited. While both provide traceability to the International System of Measurement (SI), the differences are significant. The accredited calibration process meets the quality standards required of ISO/IEC 17025. In addition, the measurement process is inspected by an independent assessor group like NVLAP to insure compliance. Accredited calibration certificates provide more detailed information about the measurement to meet the calibration requirements of regulatory agencies like the FDA, ISO and cGMP compliant manufacturing processes. Non-accredited certificates are controlled solely by the calibration laboratory." [8]

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7. REGULATED WEIGHING ENVIRONMENTS & APPLICATIONS

7.1 INTRODUCTION

There are several organizations and regulatory agencies that are responsible for creating and enforcing rules and regulations by which companies or organizations working within a particular industry must abide. Some examples of such organizations are the Federal Drug Administration, the United States Pharmacopeial Convention (USP), and the European Medicines Agency (EMA), to name a few. The primary objective of these organizations is to protect the public by requiring that certain procedures are followed and standards are met. This is typically done through a published guideline or compendium and a licensing or auditing system that makes sure the guidelines are being adhered to on a complete and regular basis. In many cases, these organizations have the ability to impose fines, halt certain functions of a business, revoke operating licenses etc.

Typically, the guidelines put forth by these various agencies are very broad with regards to the aspects of the business that they cover from facility layout to waste management to product labeling. Within that broad scope there are usually guidelines that relate to how things are measured, how equipment is calibrated and maintained, and sometimes even general specifications for the equipment itself. **It is a common misconception however that a piece of equipment (such as a balance) is "compliant" or "approved" with regards to a particular regulation. This is almost never the case; as long as the instrument is suitable for use within a given industry (i.e. it is in compliance with the requirements and specifications if any are given), it is not the instrument that is compliant but it is up to the organization to use it in a way that conforms to the relevant procedures.** However, when it comes to scales and balances, there are a few popular guidelines that govern certain aspects of equipment qualification, maintenance, and calibration, record keeping, and usage practices.

7.2 FDA CFR 21 & GMP/GLP

The Code of Federal Regulations Title 21 (CFR 21 for short) is the FDA's rules and regulations for Food and Drugs. It consists of over 1400 sections governing almost every aspect of the development, testing, production, and distribution of food and drugs in the US. Within it there are a few sections that have implications on the use of balances.

7.2.1 cGMP/GLP

Within the CFR21, there are some sections that define "Good Manufacturing Practices" (GMP or CGMP, the 'C' stands for Current), and "Good Laboratory Practices" (GLP). "The CGMP regulations for drugs contain minimum requirements for the methods, facilities, and controls used in manufacturing, processing, and packing of a drug product. The regulations make sure that a product is safe for use, and that it has the ingredients and strength it claims to have.". [9]

"Good Laboratory Practice or GLP is a quality system of management controls for research laboratories and organizations to ensure the uniformity, consistency, reliability, reproducibility, quality, and integrity of products in development for human or animal health (including pharmaceuticals)" [10]

Similar to the rest of CFR Title 21, GMP and GLP are vast collections of requirements and guidelines that addresses many different aspects of the manufacturing process including, facility layout and management, equipment usage and maintenance, guidelines for sanitation, material handling, personnel qualifications, etc. Furthermore, the guidelines are typically quite general and there is a lot of flexibility with regards to how the guidelines are complied with. It is up to the particular company to implement processes in a way that makes sense and best serves the industry or market with which they are affiliated. Once again, **a single piece of equipment (e.g. a balance) is not GMP or GLP compliant on its own; it is entirely up to the company using the equipment to use and handle the equipment in a way that is in accordance with its approved procedures**.

7.2.2 Data Integrity

There are however certain elements within the GMP and GLP guidelines that are applicable to balances (and other analytical equipment), and while a balance in and of itself is not "GMP or GLP compliant". However there are certain features to look

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for that can help a facility do things in a way that are in accordance with the GMP or GLP guidelines (should they choose to use them and incorporate them into their operating procedures). One area of particular interest is known as Data Integrity. Data Integrity is a large part of compliance for the FDA and other regulatory agencies. It is defined as the degree to which collected data is complete, consistent, and accurate.

It is required that collected data be:

- Attributable (Who made the measurement and when?)
- Legible
- Contemporaneous (Documented at the time of measurement)
- Original
- Accurate

There are many different ways to achieve this and as long as the method for collecting and storing specified by a company's internal procedures is deemed effective or complaint.

7.2.3 CFR 21 Part 11 – Electronic Records and Electronic Signatures

One particular chapter of CFR 21 is part 11, which deals with electronic records and signatures (as opposed to handwritten or printed records) for capturing and submitting data to the FDA. Again, there is some degree of flexibility in the implementation of these guidelines, however they are typically more narrowly interpreted than some other sections of CFR 21. CFR 21 is typically only enforced when the use of paper or physical records are not being used (at all).

In the part 11 guideline, it states "electronic records, electronic signatures, and handwritten signatures executed to electronic records to be trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper." For this reason, the entire system of record creation and storage must be evaluated for compliance.

In summary, the integrity of electronic records must be proven, that is that it must be possible to prove conclusively that a piece of data was generated accurately and by whom it was generated and when, and that at no point from generation to submission to the FDA it was compromised, altered or falsified in any way.

7.3 *USP GENERAL CHAPTERS 41 & 1251*

USP is an independent, scientific nonprofit organization focused on building trust in the supply of safe, quality medicines. [11]

The United States Pharmacopeia (or USP for short) is a document published by the United States Pharmacopeial Convention. Within it, there are several general chapters on various topics such as testing procedures, labeling, etc. Two chapters in particular, Chapter 41 – Balances, and Chapter 1251 – Weighing on an Analytical Balance, provide guidelines for the use of a balance.

7.3.1 USP General Chapter 41

USP General Chapter 41 provides a guideline for "materials that must be accurately weighed". It states "Repeatability is satisfactory if two times the standard deviation of the weighed value, divided by the desired smallest net weight (i.e., smallest net weight that the users plan to use on that balance)". In other words, the guideline calls for the usage of a minimum weight standard with a maximum measurement uncertainty of 0.10%. This guideline specifies that the repeatability value (established by taking the standard deviation of 10 sequential measurements) is to be used as the instrument uncertainty and uses a coverage factor of 2.

7.4 *TRACEABILITY (ISO 17025)*

ISO/IEC 17025 is a guideline issued by the International Organization for Standardization and specifies requirements for laboratories to ensure reliability and traceability in its testing and calibration procedures and ultimately help ensure accurate sampling and measurement results. As with other large standards, **a single piece of equipment (e.g. a balance) is not ISO17025 compliant or certified on its own; it is entirely up to the company using the equipment to use and handle the equipment in a way that is in accordance with its approved procedures**.

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8. IQ/OQ/PQ

In order to be put into service and used routinely, a balance (or any measurement instrument for that matter), must be tested to ensure that it meets accuracy and reliability standards for the purposes for which it is being used. These tests or qualifications must be performed and documented to ensure the quality of the results that it produces. An "IQ/OQ/PQ" is a set of activities that should be performed during various stages of a balance's use.

IQ stands for "Initial Qualification" which is done upon receiving and setting up the balance for initial use. It will covers delivery, unpacking and initial installation of the new balance. The installation qualification should be performed before operational qualification. The IQ typically involves the following steps:

- Unpacking the balance and checking for all parts (as typically listed in the user manual or operating instructions) and ensuring that no parts are damaged
- Selecting an installation site for the balance, taking into account the environmental factors outlined previously in this guide
- Setting up the balance, including any peripherals (such as printers, etc.) and verifying the initial startup occurs without error.

OQ stands for "Operational Qualification" and contains procedures and tests which will verify that the balance is ready to be put into operation. Operational Qualification is directly linked to the current location of the balance. If the location is changed, the balance must be requalified before putting it back into routine operation. The OQ typically involves the following steps:

- General functional tests of the instrument including the user interface, under and overload behavior, calibration mechanism, etc.
- General performance tests of the instrument such as the stability of the balance
- Metrological tests:
    - Verification of eccentricity
    - Verification of repeatability
    - Verification of linearity
- Recording the minimum sample weight if applicable based on the metrological test results

PQ stands for "Performance Qualification" details the ongoing procedures and tests, these tests are used demonstrate the performance of the balance throughout its life cycle. The basic performance checks need to be performed by the end user to ensure the balance is in accordance with the specifications. The user needs to define and maintain a standard operating procedure. It is recommended the periodic functional and performance tests are performed by trained service technicians to ensure the balance is within specified tolerances. The steps in a routine performance qualification can vary based on the needs of the organization. It can be as simple as checking the balance with a series of test weights and recording the results and verifying that the results are within a set tolerance or can be essentially a repeat of the OQ procedure outlined above.

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9. APPENDIX A—WEIGHT TOLERANCE CHARTS

9.1 OIML

	Class E0*	E1	E2	F1	F2	M1	M2	M3
2000 kg				10 g	30g	100g	300g	1000g
1000 kg			1.6 g	5	16	50	160	500
500 kg			0.8	2.5	8	25	80	250
200 kg			0.3	1	3	10	30	100
100 kg			160mg	0.5	1.6	5	16	50
50 kg	12.5 mg	25 mg	80	250 mg	800 mg	2.5	8	25
20 kg	5	10	30	100	300	1	3	10
10 kg	2.5	5.0	16	50	160	500 mg	1.6	5
5 kg	1.3	2.5	8.0	25	80	250	800 mg	2.5
2 kg	0.5	1.0	3.0	10	30	100	300	1
1 kg	0.25	0.5	1.6	5.0	16	50	160	500 mg
500 g	0.13	0.25	0.8	2.5	8.0	25	80	250
200 g	0.05	0.10	0.3	1.0	3.0	10	30	100
100 g	0.025	0.05	0.16	0.5	1.6	5	16	50
50 g	0.015	0.03	0.10	0.3	1.0	3.0	10	30
20 g	0.013	0.025	0.08	0.25	0.8	2.5	8.0	25
10 g	0.010	0.020	0.06	0.20	0.6	2.0	6.0	20
5 g	0.008	0.016	0.05	0.16	0.5	1.6	5.0	16
2 g	0.006	0.012	0.04	0.12	0.4	1.2	4.0	12
1 g	0.005	0.010	0.03	0.10	0.3	1.0	3.0	10
500 mg	0.004	0.008	0.025	0.08	0.25	0.8	2.5	
200 mg	0.003	0.006	0.020	0.06	0.20	0.6	2.0	
100 mg	0.003	0.005	0.016	0.05	0.16	0.5	1.6	
50 mg	0.002	0.004	0.012	0.04	0.12	0.4		
20 mg	0.002	0.003	0.010	0.03	0.10	0.3		
10 mg	0.002	0.003	0.008	0.025	0.08	0.25		
5 mg	0.002	0.003	0.006	0.020	0.06	0.20		
2 mg	0.002	0.003	0.006	0.020	0.06	0.20		
1 mg	0.002	0.003	0.006	0.020	0.06	0.20		
0.5 mg	0.002	0.003	0.006					

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9.2 *ASTM*

	000	00	0	1	2	3	4	5	6	7
2000 kg					10 g	20 g	40 g	100 g	200 g	300 g
1000 kg					5	10	20	50	100	150
500 kg					2.5	5	10	25	50	75
300 kg					1.5	3	6.0	15	30	45
200 kg					1	2	4.0	10	20	30
100 kg					500 mg	1	2.0	5	10	15
50 kg	13 mg	25 mg	63 mg	125 mg	250	500 mg	1.0	2.5	5	7.5
30 kg	7.5	15	38	75	150	300	600 mg	1.5	3	4.5
25 kg	6.25	12.5	31	62	125	250	500	1.2	2.5	4.5
20kg	5.0	10	25	50	100	200	400	1.0	2	3.8
10kg	2.5	5.0	13	25	50	100	200	500 mg	1	2.2
5 kg	1.3	2.5	6.0	12	25	50	100	250	500 mg	1.4
3 kg	0.75	1.5	3.8	7.5	15	30	60	150	300	1.0
2 kg	0.5	1.0	2.5	5.0	10	20	40	100	200	750 mg
1 kg	0.25	0.5	1.3	2.5	5.0	10	20	50	100	470
500 g	0.13	0.25	0.60	1.2	2.5	5.0	10	30	50	300
300 g	0.075	0.15	0.38	0.75	1.5	3.0	6.0	20	30	210
200 g	0.05	0.10	0.25	0.50	1.0	2.0	4.0	15	20	160
100 g	0.025	0.05	0.13	0.25	0.50	1.0	2.0	9	10	100
50 g	0.015	0.030	0.060	0.12	0.25	0.60	1.2	5.6	7	62
30 g	0.014	0.026	0.037	0.074	0.15	0.45	0.90	4.0	5	44
20 g	0.013	0.025	0.037	0.074	0.10	0.35	0.70	3.0	3	33
10 g	0.010	0.020	0.025	0.050	0.074	0.25	0.50	2.0	2	21
5 g	0.005	0.010	0.017	0.034	0.054	0.18	0.36	1.3	2	13
3 g	0.005	0.010	0.017	0.034	0.054	0.15	0.30	0.95	2.0	9.4
2 g	0.005	0.010	0.017	0.034	0.054	0.13	0.26	0.75	2.0	7.0
1 g	0.005	0.010	0.017	0.034	0.054	0.10	0.20	0.50	2.0	4.5
500 mg	0.002	0.003	0.005	0.010	0.025	0.080	0.16	0.38	1.0	3.0
300 mg	0.002	0.003	0.005	0.010	0.025	0.070	0.14	0.30	1.0	2.2
200 mg	0.002	0.003	0.005	0.010	0.025	0.060	0.12	0.26	1.0	1.8
100 mg	0.002	0.003	0.005	0.010	0.025	0.050	0.10	0.20	1.0	1.2
50 mg	0.002	0.003	0.005	0.010	0.014	0.042	0.085	0.16	0.50	0.88
30 mg	0.002	0.003	0.005	0.010	0.014	0.038	0.075	0.14	0.50	0.68
20 mg	0.002	0.003	0.005	0.010	0.014	0.035	0.070	0.12	0.50	0.56
10 mg	0.002	0.003	0.005	0.010	0.014	0.030	0.060	0.10	0.50	0.40
5 mg	0.002	0.003	0.005	0.010	0.014	0.028	0.055	0.080	0.20	
3 mg	0.002	0.003	0.005	0.010	0.014	0.026	0.052	0.070	0.20	
2 mg	0.002	0.003	0.005	0.010	0.014	0.025	0.050	0.060	0.20	
1 mg	0.002	0.003	0.005	0.010	0.014	0.025	0.050	0.050	0.10	
0.5 mg	0.002	0.003	0.005	0.010	0.014	0.025	0.050	0.050	0.10	
0.2 mg	0.002	0.003	0.005	0.010	0.014					
0.1 mg	0.002	0.003	0.005	0.010						
0.05 mg	0.002	0.003	0.005	0.010						

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10	7.2.1	Good laboratory practice - Wikipedia
11	7.2.3	About U.S. Pharmacopeia (usp.org)

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OHAUS Corporation

Headquartered in Parsippany, NJ, OHAUS Corporation manufactures an extensive line of high-precision electronic and mechanical balances and scales that meet the weighing needs of virtually every industry. We are a global leader in the laboratory, industrial, and education channels as well as a host of specialty markets, including the food preparation, pharmacy and jewelry industries. An ISO 9001:2008 manufacturer, OHAUS products are precise, reliable and affordable, and are backed by industry-leading customer support.

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