Application Note

Consistent Formulation Quality

Preventing Errors in the Dispensing Room

Wrong measurements caused by unsuitable scales, incorrect selection of raw materials, false labeling of materials and incorrect documentation. What do these problems have in common?

They are top reasons for quality problems and inefficiencies during the dispensing process. However, the correct design and set-up of a dispensing station can reduce those error sources significantly, while and at the same time, improving the workflow efficiency of the weighing tasks.

This Application Note describes two weighing systems designed to ensure the highest formulation accuracy in the dispensing room. Both systems address the challenges of ensuring accurate measurements, of preventing operating errors and of fulfilling documentation requirements.

However, the approach taken with the two systems differs:

- The first application example shows how a traditional recipe-weighing process can be enhanced to improve the quality of dispensing and facilitate documentation requirements.
- The second application example examines a weighing system based on formulation software, which is integrated to the company's production and resource-management systems providing improvements in process automation.



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METTLER TOLEDO

1 Selecting the right scales

The dispensing room usually includes several scales with different capacities and resolutions toweigh different amounts of materials, such as APIs and excipients. Choosing the right scales is critical to ensure each amount of raw material is weighed accurately. The right scales are chosen with consideration of measurement uncertainty, possible environmental influences and the required weighing tolerances.

The scales in the following examples have been selected according to Good Weighing Practice™ (GWP®), assuming a weighing tolerance of 1% and applying a safety factor of 2 to compensate for measurement uncertainty and environmental influences. METTLER TOLEDO developed GWP as a standardized methodology for safe selection, calibration and operation of weighing equipment. The safe weighing range for each scale is determined based on the calculated minimum weight for each device. The detailed documentation provides written proof of risk-based weighing equipment selection, as required by GMP guidelines.



Accuracy and versatility with high-precision

The installations consist of two METTLER TOLEDO PBK989 bench scales and one PFK989 floor scale to weigh materials from 0.5 grams to 1,200 kilograms at the highest accuracy. The weighing platforms offer a wide weighing range, which allows for accurate measurements of small amounts into or out of heavy containers. The set-up also reduces the number of scales required in a comparable analog weighing system. That is a real benefit, considering the constrained space of dispensing stations.

High-accuracy weighing platforms

	PBK989-XS	**PBK989-AB30**	**PFK989-ES1500**
			
Safe Weighing Range* (at 1% Weighing Tolerance)	0.4 g – 600 g	40 g – 30 kg	2 kg – 1,500 kg
Readability	0.001 g	0.1 g	2 g
Ingress Protection	IP54	IP68	IP68

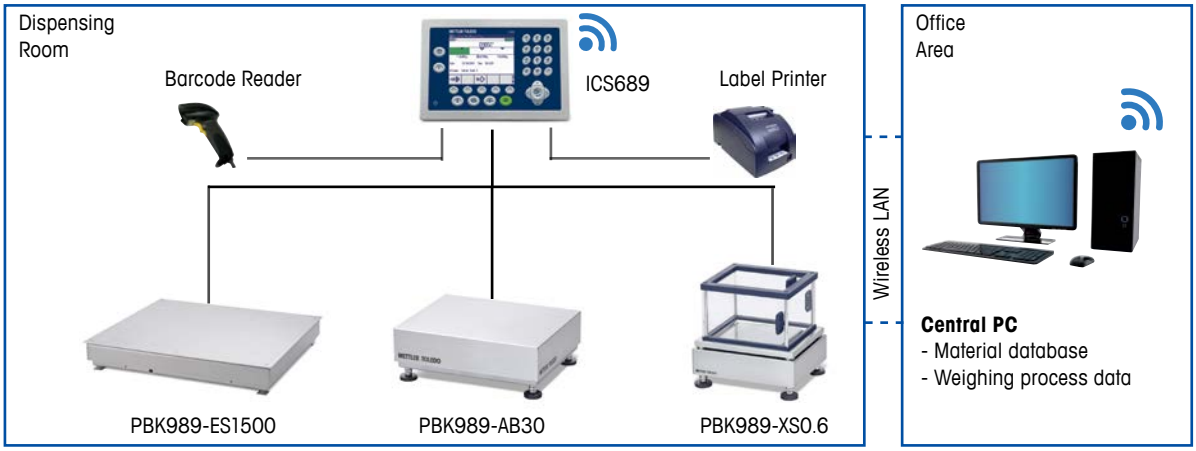
*includes a safety factor of 2

All weighing platforms provide a high level of ingress protection to ensure integrity from dust and water. The electro-polished stainless-steel surface enables easy cleaning to prevent cross-contamination. In addition, the weighing platforms notify the operator when calibration or adjustments are necessary due to environmental changes. Adjustments can even be performed automatically via internal calibration weights to ensure consistently accurate weighing results.

2 Application 1: Recipe Weighing

The first weighing application describes a recipe-weighing system that is designed to provide maximum weighing process accuracy without the support of a formulation software.

The floor scale and both bench scales are connected to an ICS689 weighing terminal. Depending on the dimensions of the dispensing room and the location of the scales, a second terminal might be required for the floor scale for better usability. Furthermore, a barcode reader and label printer are connected to each of the terminals to ensure accurate material selection and traceability of the dispensed materials. The terminals are connected via wireless LAN to a PC in the office area.



The PC contains the central material database (databICS) in which all material data is maintained. When changes are made to material data, they can be easily transferred to the weighing terminals. Weighing process data, including information, such as measurement result, date, time, operator ID, scale ID and other data, is captured in a secure database on the weighing terminal. While the weighing process data is protected from alterations on the weighing terminal, it can be transferred to the central PC for analysis and report generation.

Operator guidance

The operator is guided through the entire weighing process, according to the standard operating procedures (SOPs), by user prompts on the weighing terminal. He then scans the material ID barcode of each recipe component to load the respective weighing tolerances from the material database. Next he places the vessel on the scale and tares it. Then the operator weighs the material according to its tolerances. Finally, the operator confirms the measurement on the weighing terminal to store the weighing data and to print a label for further identification of the material.



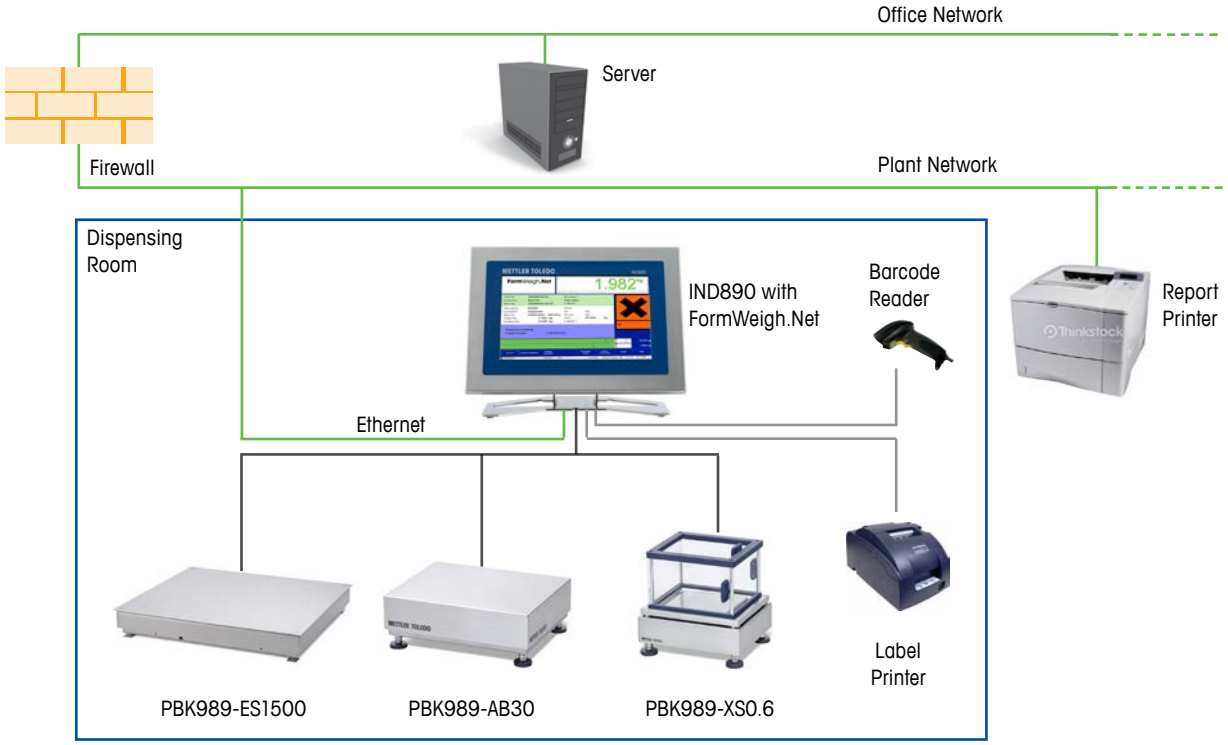
Step-by-step guidance of the operators, central management of material data with tolerances and secure storage of weighing process data reduce operating errors and ensure accurate recipe weighing.

3 Application 2: Formulation Solution

The second application example describes an advanced formulation solution, which can be operated alone or fully integrated into existing manufacturing and data-management systems.

All three weighing platforms are connected to a single IND890 PC weighing terminal, which can be mounted onto the wall to gain working space and facilitate easy cleaning. The large touchscreen is easy to use and read because weighing data from each of the three scales and the sum scale are displayed simultaneously. Simple icons allow for intuitive control of the weighing process.

In addition to the weighing platform, a barcode reader and a label printer are connected to the IND890. The barcode reader is used to identify the production order and raw materials, while the label printer ensures traceable identification of the weighed materials later in the production process. The terminal is also connected via Ethernet to the LAN, which enables data exchange with the MES/ERP system and allows batch-report printing on an office printer.



Full formulation control

The entire dispensing process is controlled via FormWeigh.Net formulation software, which runs on the IND890 weighing terminal. This software guides the operator through the recipe-weighing process. Through multi-level user authentication, each user only sees the information and user interface required for the task at hand. Raw materials are verified via barcode scanning of the material ID attached to the containers. Furthermore, the system verifies the quality status and expiry dates of the dispensed materials. The software automatically selects the suitable scale to ensure the most accurate weighing results.

During weighing, FormWeigh.Net graphically and numerically displays the distance to target weight. The required tolerances are clearly displayed as limits and weighing results that exceed or fall below those limits are highlighted in color, thereby making it easier to weigh accurately.

FormWeigh.Net fulfills the technical 21 CFR Part 11 requirements needed for an in-process control system as stated by the U.S. Food and Drug Administration (FDA). All batch-relevant information is automatically recorded and verified. It also can be electronically signed; a second operator is no longer needed to fulfill the four-eye requirement. The audit-trail function ensures that notifications are sent when relevant data is changed. Additionally, all audit-relevant information modification is documented, including who did what, when and where.



IND890 PC Weighing Terminal
with FormWeigh.Net

Validation manuals allow the user to easily assess the quality of the formulation software and simplify the validation process. They guide users through the necessary steps to conduct effective acceptance testing of the system.

FormWeigh.Net can be used on its own, but it can also be connected to an existing MES or ERP system to provide real-time availability of process data, including production orders, quality data and material consumption.

4 Summary

Both systems provide a series of features that guide operators and prevent errors, such as incorrect selection of raw materials, weighing outside defined tolerances, wrong labeling of materials, incorrect documentation of the weighing process and others. The system based on FormWeigh.Net goes a step further. It offers more flexibility in operator guidance, it can cover several dispensing stations throughout the site, it provides GMP-compliant process documentation and it can be integrated into the company's manufacturing and resource-planning systems.

www.mt.com/ind-formulation

For more information

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