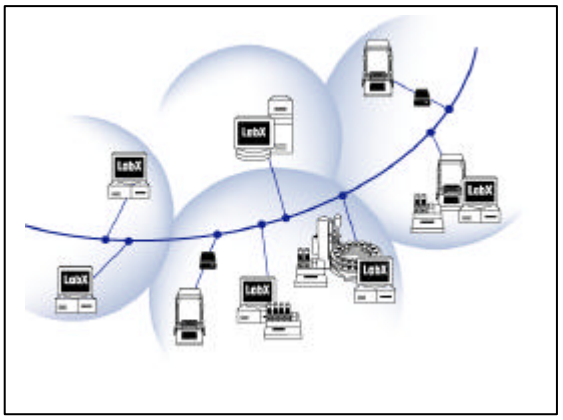
Embedding quality in your weighing processes



Weighing data is critical. In almost every lab, balances are the first precision instruments used in the analysis chain.

Standardization of weighing practices is a topic in validated areas. Weighing tasks typically involve a high number of users as well as instruments of different types, which makes compliance to internal and external quality standards more difficult.

Latest generations of balances are highly sophisticated with numerous settings and interfaces. Transforming complexity into better performance and increased security is a daily challenge.

If you have already encountered those topics in your everyday life in the lab, then take the opportunity to give your balances the weight they deserve in your quality assurance system.

In this article, we will first review customers' requirements for weighing data management focusing on Quality Management considerations. Then, we will check if and how the solutions currently available on the market fulfill these requirements. Finally, we will briefly mention some features of LabX, the METTLER TOLEDO instrument control software, that brings an immediate benefit in regards to weighing data reliability and overall process security.

1. Requirements review

Interviews of customers in regulated areas on weighing data management systems lead to various requirements that are classified hereafter in 3 levels, from basic to most sophisticated requirements:

Level 1- Traceability. The system should allow full traceability of weighing tasks (date / time, user ID, sample ID, balance ID, method ID, balance settings that influences the weight value, weight value, unit) and calibration data (date / time, balance ID, method reference, result/status, calibration weight ID if applicable, user ID if applicable)

Level 2- Standardization. The system should allow the implementation of Standard Operating Procedures for weighing tasks and balance calibration. The system must be validated.

Level 3- Security enhancement. Further tools are welcomed to increase weighing data reliability.

2. Evaluation of software solutions against requirements

2.1 Stand-alone balance (embedded software) or balance connected to a printer

Level 1- Traceability

The latest generation of METTLER TOLEDO balances relies on solid Quality Management features. To mention just a few of them, it is equipped with user management, calibration history, settings protection and audit trail. Nevertheless, this best in class does not reflect the average installed base of our users. So it is easy to conclude that full traceability is not achieved by almost all balances when used stand-alone or when connected to a printer.

Level 2- Standardization and

Level 3- Security enhancement

These requirements can in principle not be fulfilled in case the of multiple balances. Multiple user managements on standalone balances and different settings for the same weighing method lead to data redundancy, inconsistency and to mistakes.

2.2 Balance connected to PC Software

In general, PC software is well adapted to increasing traceability, standardization, and security. A desktop computer solves memory capacity issues inherent to embedded software and a PC can also better handle data management complexity thanks to easier navigation with a larger screen, keyboard, and mouse. PC software also brings immediate productivity gains and eliminates transcription mistakes by implementing automatic data capture from all balances in the laboratory.

Nevertheless, not all types of PC software completely satiate customer quality requirements. The aspects of a PC software solution that could lead to a non-compliance are pointed out in the following paragraphs.

Level 1- Traceability

User ID. In a multi-user and distributed environment (networked balances), the user ID must be captured by the system for each weighing task. This is ensured only if the user is prompted for his User ID (and password) before each weighing task.

Instrument related data**.** To be able to capture all relevant instrument-related data, the system must rely on a very tight instrument integration. As an example, LIMS-type Software (Laboratory Information Management System) cannot offer full traceability because it does not control instruments with the requested product granularity. Indeed, if balances are often considered as simple devices, control and capture of balance settings and capture of local calibration history are technical challenges even for balance manufacturers like METTLER TOLEDO. Naturally, LIMS-type software supports the simplest and most sophisticated balances in a uniform way, thus excluding the unique features supported in professional-level balances.

Level 2- Standardization

Networkability. Prerequisites for standardization are that all balances connect to one system (networkability) and that system administers all users centrally. The weighing methods must

also be administered centrally and must go through a review and approval process. The calibration practices require the same diligence. If requested, all changes within the system are subject to electronic signature.

Validation. In order to validate both weighing methods and calibration procedures, off-the-shelf software solutions offer standard validation manuals whereas highly customized solutions based on script languages are hardly validatable.

Level 3- Security enhancement

A profound understanding is needed to bring added security into the weighing process. This advanced understanding is available mainly among instrument manufacturers (for practical examples, read section 3).

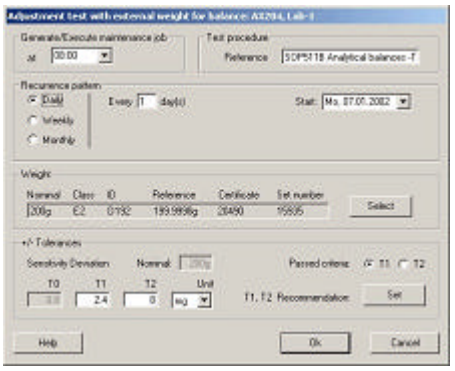
2.3 Summary

This table summarizes how customers requirements are supported by the different solutions. They are ranked from 1 (limited support) to 3 (best support).

Type of software solution		**Level 1- Traceability**	**Level 2- Standardization**	**Level 3- Security enhancement**
Stand-alone balance (embedded software) or balance connected to a printer		1	1	1
Balance connected to one-place PC Software		2	1	1
Networkable PC Software solutions	LIMS	1 Missing User ID, Instrument related data	2 If customized difficult to validate	1
	Balance control Software	3	3 If customized difficult to validate	1-3 depending of solutions

3. Enhance weighing process security

Using LabX balance Quality Management-related features helps to avoid mistakes and supports the weighing process as a whole (non-exhaustive list):



- **Scheduling / controlling of calibration** over the installed base of balances (Sensitivity adjustments, sensitivity adjustment tests, repeatability tests can be scheduled and controlled)
- **Instrument tolerance management**. METTLER TOLEDO balance tolerances are made available from a built-in tolerance database. The user additionally sets tolerance levels appropriate for his industry.
- **Job-dependant instrument release control**. According to the level of security required for a particular weighing task, the balance may be locked for job processing if calibration data is not valid. Non-critical jobs can still be processed on the same balance.
- **Balance suitability check**. The right balance for the job according to the SOP.
- **MinWeigh incident history**. While operating, the user is informed when the measured weight is under the minimum weight allowed on the balance. Weights captured under the minimal weight are tracked.

4. Conclusion

In this article, it has been shown that:

- Only a networkable instrument control PC-software provides the tight instrument integration needed for full traceability and standardized weighing and calibration practices.
- LabX, the lab instrument control software of METTLER-TOLEDO, is designed to go beyond traceability and standardization to enhance weighing process security.

If you are willing to challenge LabX against your own requirements, please contact your METTLER TOLEDO representative.

Emmanuelle Billard

METTLER TOLEDO Switzerland

http://www.mt.com/