Reference Paper

Management of Weighing Data

From Paper to Digital

Integrated lab: Data is electronically transferred to/from the instruments

Weighing is often the most important step of an analytical lab procedure, even if it may not seem like the most exciting step. This is because accurate weighing and error-free data transfer is absolutely essential for accuracy in subsequent process steps, whether you are taking aliquots of samples for analysis or are preparing solutions, buffers, high-performance liquid chromatography (HPLC) mobile phases, or analytical reference solutions.

METTLER TOLEDO

3 Ways of Data Management
From Paper to Digital

In this reference paper, we will look at both manual transcription and three potential solutions for improving the accuracy and ease of data transfer and management, assessing the strengths and weaknesses of each. As such, this paper may be particularly interesting for labs that are still largely reliant on handwritten results or which use manual processing, including keyboard entry, at any stage of data notation, storage or analysis.

Data quality and integrity.
Using real-world examples, we will explore how systematically relying on our powers to remember and transmit data can generate significant errors, even when we are certain of our accuracy. Manual data transcription and report creation are also time-consuming and keep laboratory analysts from focusing on value-added lab work.

In short, it is no longer enough to say, "But that's the way we've always done it." It is essential that any method chosen to gather, transmit, and analyze data ensures data quality as well as data integrity.

Why are data quality and integrity so important?
The majority of data that we take down in our day-to-day living is manual, either using a pen and paper or a note-taking application on a smartphone or laptop. But have you ever written down a phone number then dialed it later, only to discover it was wrong? Whether you copied it down wrong or someone recited it to you incorrectly, humans are known to make mistakes when it comes to numbers.

Other more scientific analyses show that people make errors every day with all kinds of data – when typing, when trying to remember words, when attempting to read signs and charts, and more. And people make these errors in situations where they know accuracy is critical and they are convinced of their own accuracy.

Take, for example, a case from 2004 that involved a study of blood records for 100 consecutive patients in the intensive care unit (ICU) of a Glasgow Royal Infirmary, Glasgow, UK. Researchers looked at 954 results sets that included 4664 value sets. Complete, accurate transcription occurred in only 67.6% of cases. In 23.6% of cases, data sets were missing. 8.8% of cases had transcription errors. The study also showed that transcription was more accurate in

Figure 1: Laboratory processes – data acquisition, generation and transfer

Data definied

Data quality – ensuring data is generated without errors through use of proper, calibrated equipment, following SOPs, identifying and training users, and using the right materials. Systems should be designed in a way that encourages compliance with the principles of data integrity.

Data integrity – ensuring data is transcribed without errors and cannot be manipulated through proper set-up of data flow, integration of data and metadata, proper archiving, and ensuring accessibility. Good Manufacturing Practice (GMP) defines data integrity through the acronym ALCOA, which stands for attributable, legible, contemporaneous, original, and accurate.

Metadata – data that provides information about other data, considered attributes of the measured values (e.g. sample identification, date, time, study number) and technical properties (e.g. instrument, calibration history, SOP, method version, etc.).

Audit trail – ensures traceability of electronic data. An audit trail is a complete historical record of who did what, when and why. Computer system design should always provide for the retention of full audit trails to show all changes made to the data without obscuring the original data.
It should be possible to associate all data changes with the persons who made those changes, for example, by use of timed and dated (electronic) signatures. Reason for changes should be given.

Further definitions: See References [3] and [4]

the morning, pointing to the fact that operator fatigue can also affect accuracy later in a work shift. [Reference 1]

Let us reiterate that this was in an ICU: a place where poor data capture can not only affect health outcomes, but could in extreme cases result in a patient's death. These data sets were also created by dedicated medical professionals. Because of this, the number of incorrect or incomplete results made a strong case for computerized data capture and records maintenance.

Another study looked at errors in clinical research. Results from a single unnamed academic center were analyzed to assess frequency, distribution, and features of data-entry errors to determine if these errors were large enough to skew results. Errors detected by double-entry ranged from 2.3% to 26.9% and were attributed to both data entry error and misinterpretation of original information. [Reference 2]

These examples – situations where errors had the potential to directly impact quality either on direct care or via research results – mirror our personal experience. And it is no different when writing down weighing results in a lab journal or keying them into a computer.

Do you want to subject your results to this kind of error potential – particularly in processes where errors expand exponentially as additional analytical actions are performed downstream? We suspect the answer is no.

As scientists, engineers, operators, and researchers, we must seek out better solutions than writing down weighing data manually in a lab notebook or paper form. This is because, while weighing can appear to be a simple procedure, we know that even the everyday act of writing down a phone number contains significant error potential.

Data Management Option 1: Add a Printer

One basic way to eliminate a certain amount of transcription error risk is to simply add print-out capabilities to your balance, scale, or other analytical instrument. This is a simple way to document and store data.

Data flow in many labs that use printers looks like this:

1. Results generated by analytical instruments are printed on paper. Some limited metadata, as ong as it is maintained in the instrument, can be added to the print-out.

2. Printed records are then used to manually transcribe figures into reports using programs such as Excel.

3. In certain situations, reports are double-checked for errors and perhaps a few results are recalculated to check if they are plausible. Some records also require checking by a second person – the "4 eyes principle".

4. Data may also be manually transcribed into the lab information management system (LIMS) or enterprise resource planning (ERP) system.

Traceability ensured	(✓)
Low risk of transcription errors	✓
Efficiency of weighing process	(✓)
Transfer of metadata	(✓)
Audit trail (system & data)	✗
Centralized data storage	✗
Paperless lab	✗
Electronic signatures	✗
Data integrity	✗

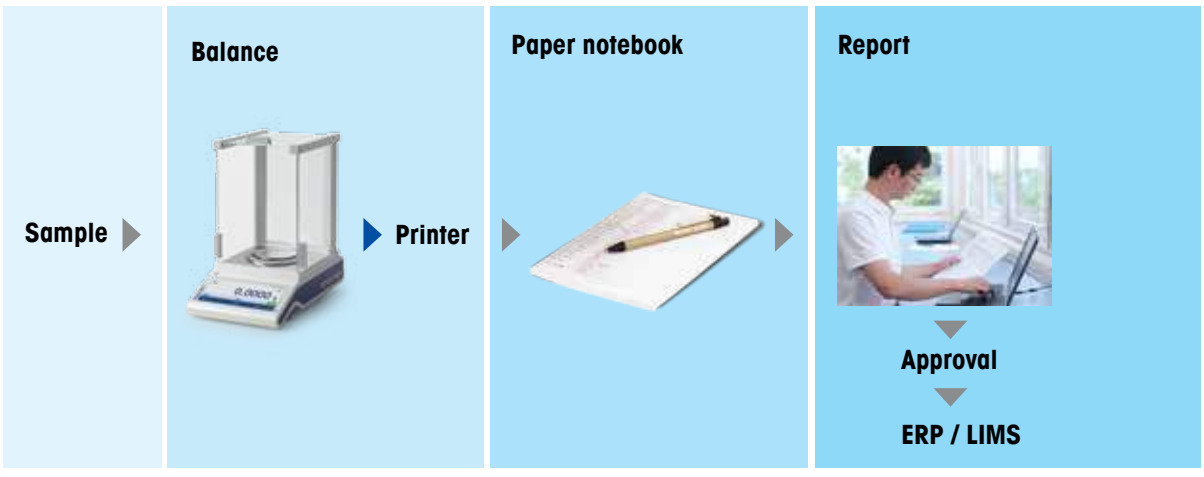

Figure 2: Data flow in a lab with weighing results documentation and storage on a print-out, eliminating one source of transcription error. However, further data processing with manual copy/paste retains the risk of making transcription errors and losing metadata.

Digital sample identification

Data quality and integrity can be improved by automated sample identification, e.g. by connecting a barcode or RFID reader. Sample ID data – as part of measurement metadata – can be printed on strips or labels, or stored on a sample RFID tag. This allows it to be transferred electronically to the next analysis step to help eliminate sample mix-ups. Automatic matching of samples and results also saves time.

- **Barcode reader** (read only), for sample identification and transfer to the balance
- **RFID reader** (read & write), for sample identification, transfer to the balance, storage and transfer of measurement results

As you can see, printing results eliminates the error inherent when we read and note results off a terminal screen. However, this is still a manually intensive process that requires a significant amount of time and attention, leaving the process open to error.

Pros: Direct printing is a simple way to document and store measurement data without transcription errors.

Cons: The information is not ready for digital processing and analyzing. Manual transcription is still necessary.

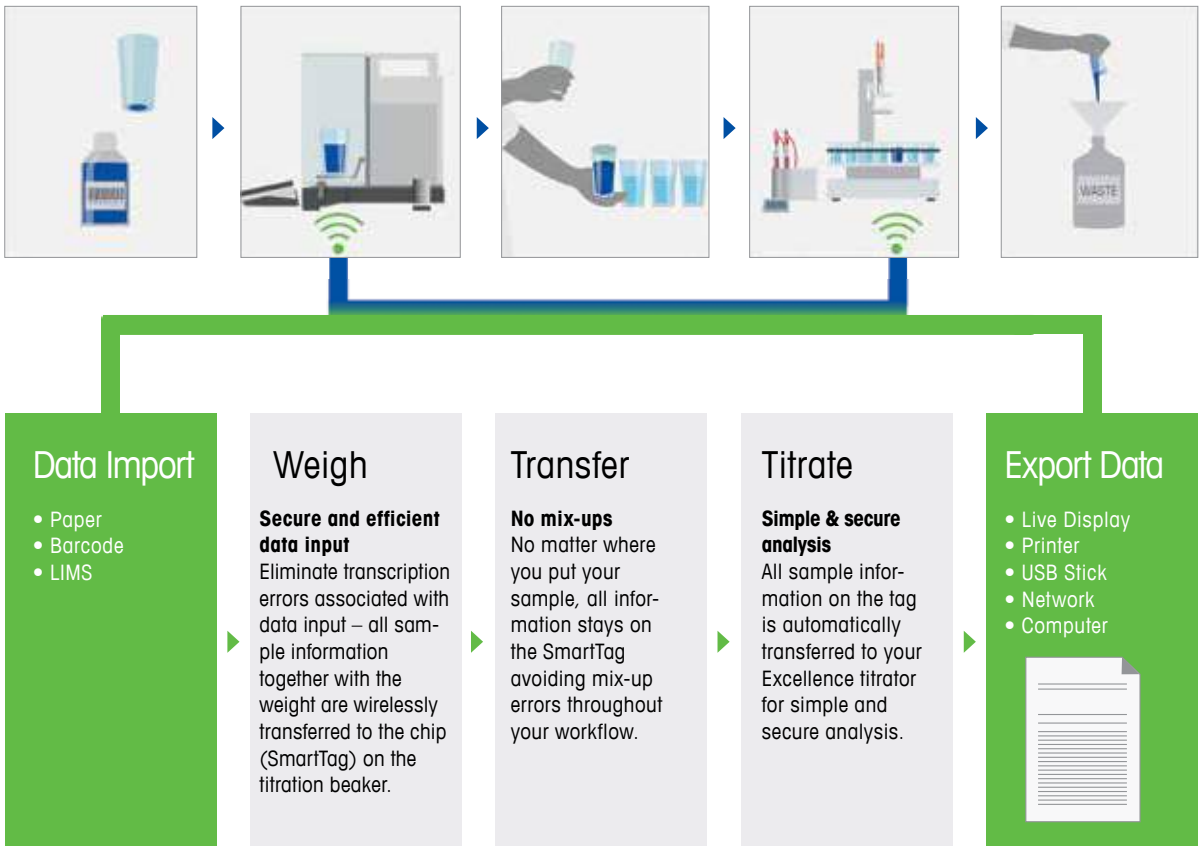

Figure 3: The SmartSample™ weighing system for titration automation increases sample identification and efficiency with RFID technology. RFID tags attached to the beakers transfer sample information wirelessly from the balance to the titrator – errors due to data transcription and mix-ups on the sample rack are eliminated.

Data Management Option 2: Transfer to a Stand-alone Computer

To eliminate manual steps and related transcription errors, a balance or other so-enabled lab equipment can be connected to a computer allowing direct, unidirectional collection of data in a program such as Microsoft Excel. Data is submitted as a serial ASCII text protocol.

Without additional communication software, the weight value – the value only, without unit or further metadata – is "dropped at the cursor" into the open file in the computer.

Data communication software, such as METTLER TOLEDO's LabX® direct or BalanceLink allow a simple data transfer including some metadata such as value with unit, time and date, sample ID (if entered into the balance), net/gross, and tare. Layouts are configurable. Input masks, validation rules, and calculations are possible.

The connection of an optional barcode or RFID reader to the balance eliminates an additional error source by automatically transferring sample IDs as part of measurement-result metadata.

Traceability ensured	(✓)
Low risk of transcription errors	✓
Efficiency of weighing process	✓
Transfer of metadata	(✓)
Audit trail (system & data)	(✓)
Centralized data storage	✗
Paperless lab	✗
Electronic signatures	✗
Data integrity	✗

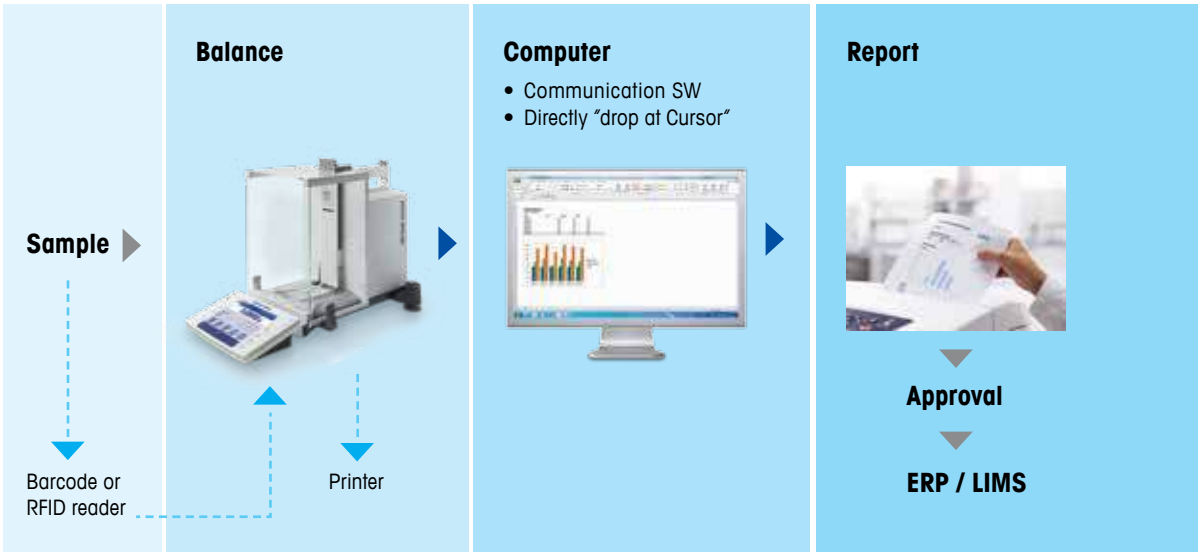

Figure 4: Direct connection of a balance to a computer: One-way data transfer "drop at cursor," with communication software allowing the inclusion of some metadata and a configurable layout. Transcription errors are eliminated and data quality is improved.

Figure 5: Transfer results from a XPR balance to a computer without separate software using USB to eliminate transcription errors and improve data integrity

Note: Newer generations of METTLER TOLEDO lab balances including the XPR line can transfer weight results, applications, methods or even complete configurations directly to a connected computer for use in Microsoft Excel, Word, or third-party applications without additional supporting data communication software.

Pros: Direct transfer from the balance to a computer eliminates manual transcription. Adding simple communication software allows transfer of the value along with unit, time and date, and sample ID (if entered). For weighing, net, gross and tare are also recorded. Data layout is configurable, and validation rules and calculations are possible.

Cons: There is no centralized data storage. Not all metadata is captured, and values can still be changed or omitted when reporting without traceability. This lack of an audit trail – essentially, not being able to determine who changed what, when – potentially reduces data accuracy and integrity.

Data Management Option 3: Integrate Into a Network

Instrument control software such as METTLER TOLEDO's LabX® offers more than data capture. Users are fully guided through the complete workflow according to the SOP, data including metadata is stored centrally and all steps are fully tracked. In this way the accuracy of results is highly improved and traceability is assured back to the origin of data.

1. The sample information is displayed automatically on the balance screen.
2. The analyst weighs the sample according the directions given on the screen. Results including metadata are sent seamlessly to the PC. All user activities are logged by the system.
3. Reports are generated automatically and all results can be approved by the lab manager.
4. All data is stored securely in the database and can optionally be transferred to ERP or LIMS systems.

Traceability ensured	✓
Low risk of transcription errors	✓
Efficiency of weighing process	✓
Transfer of metadata	✓
Audit trail (system & data)	✓
Centralized data storage	✓
Paperless lab	✓
Electronic signatures	✓
Data integrity	✓

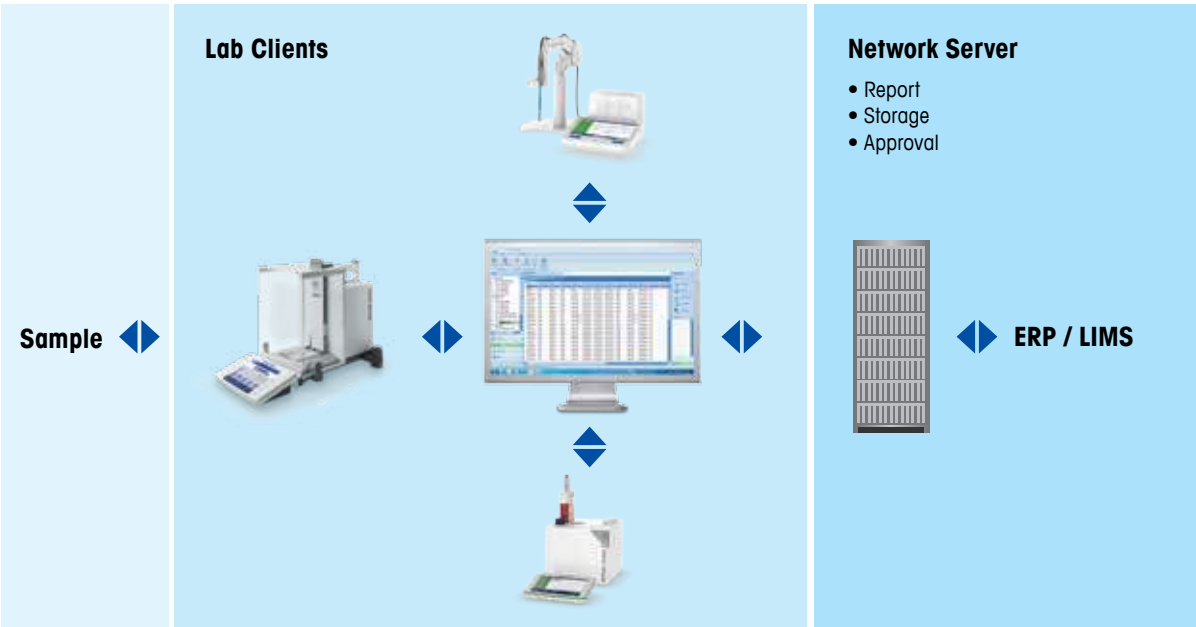

Figure 6: Data flow in a digital lab with automated transfer of data from the balance to the network server

Figure 7: LabX software integrates data capture for many laboratory instruments. LabX works behind the scenes to take care of all your data while you concentrate on your analyses.

When considering true data integrity, particularly in regulated environments or for high-risk applications, full integration of lab equipment into instrument control software is highly desirable. However, whether it is used in its complete system format or as individual methods and data modules, LabX also provides a robust solution for non-regulated labs where accuracy and ease of use are desired.

Pros: Data can be automatically transferred to eliminate transcription errors and increase productivity. Processes and calculations are guided, ensuring each user is guided through the same analytical process, helping to eliminate rework and waste. Metadata is linked to results, supporting full traceability. A variety of import/export options allow transfer of data into existing networks, data archives, LIMS, ERP and other knowledge-management systems.

Cons: Complete solutions such as LabX tend to cost more than either paper records or direct-to-PC solutions at the outset. However, initial expense is usually made up in due course in error reduction, time saved, and traceability (which eases both internal and external audits). This is particularly true for high-volume or high-risk labs.

Digitalisation of Weighing Data
Reduces Error Risks

As shown, humans are capable of error, even when stakes are high and accuracy is desired. While paper logs have historically been the norm, some level of automating results capture and storage is desirable to help reduce error risk.

There are essentially three levels of non-manual data capture that labs can take advantage of today. While there is not a "right" or "wrong" way to capture data, each level offers a certain level of security, error mitigation, and time savings not afforded by a primarily hand-written, paper-based system. Whether you choose to add a printer, connect to a PC, or provide full integration with a workflow and data management system such as LabX, capturing data at the point of origin is the foundation of any effort to enhance data accuracy and integrity. Capture at this point – without manual transcription – helps to eliminate errors. Heightened levels of automation in data capture, including the implementation of simplified, self-documenting processes, can further eliminate transcription errors and avoid unnecessary data retyping. It can also help ensure metadata is captured in a structured way so that it has meaning for future analysis and audits.

Management of weighing data	Traditional: Data recording by observation	Option 1: Data output	Option 2: Data transfer, peer-to-peer, decentralized	Option 3: Data integration, client-server, centralized
Gateway	**Eyes, pen**	**Printer, RFID**	**Computer, tablet**	**Network, software such as LabX®**
Traceability ensured	(✓)	(✓)	(✓)	✓
Low risk of transcription errors	✗	✓	✓	✓
Efficiency of weighing process	✗	(✓)	✓	✓
Transfer of metadata	✗	(✓)	(✓)	✓
Audit trail (system & data)	✗	✗	(✓)	✓
Centralized data storage	✗	✗	✗	✓
Paperless lab	✗	✗	✗	✓
Electronic signatures	✗	✗	✗	✓
Data integrity	✗	✗	✗	✓

Tab. 1: Comparison of three levels of data management to the traditional process of manual ording and transcription.
(✓): Only partially possible or only reachable with extra effort.

References

1. Black R., Woolman P. and Kinsella J., Variation in the transcription of laboratory data in an intensive care unit, Anaesthesia, 2004, 59, pages 767-769
   http://onlinelibrary.wiley.com/doi/10.1111/j.1365-2044.2004.03834.x/pdf

2. Goldberg Saveli I., Niemierko Andrzej, Turchin Alexander, Analysis of Data Errors in Clinical Research Databases, AMIA 2008 Symposium Proceedings Page – 242
   http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.668.8354&rep=rep1&type=pdf

3. MHRA GMP Data Integrity Definitions and Guidance for Industry March 2015
   https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/412735/Data_integrity_definitions_and_guidance_v2.pdf

4. WHO Good Data & Records Management Practice, June 2016
   http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex05.pdf

Further reading

1. Webinar: "The Importance of Data Integrity in a GXP Regulated Laboratory", May 2015
   www.mt.com/lab-data-webinar

2. White paper, "The Unknown Sources of Error in the Weighing Process", September 2013
   www.mt.com/lab-accurate-analytical-weighing

3. White paper: "Power the Bench – an Enhanced Strategy for Data Integrity", January 2015
   www.mt.com/lab-data-integrity-wp

4. Data Integrity Guide: "Secure Your Measuring Processes with LabX Software". June 2015
   www.mt.com/qc-security

METTLER TOLEDO product information

Lab Weighing:
www.mt.com/balances

Printers:
www.mt.com/lab-printers

LabX® Direct communication software:
www.mt.com/LabXdirect-balance

BalanceLink communication software:
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