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# Integration of Sartorius Cubis® II Premium Balances into STARLIMS™ from Abbott Informatics

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## Abstract

Laboratory Information Management Systems (LIMS) is becoming increasingly important in GMP regulated environments in order to ensure data integrity and faster working practices. When introducing a LIMS, direct instrument integration is an essential task to reduce the need for manual recording, which negates the potential for errors, gives back operator time, and reduces data redundancy.

Sartorius and Abbott Informatics, supplier of the world-class LIMS solution STARLIMS™, have developed a complete computerized solution for a professional integration of Sartorius Cubis® II premium laboratory balances into STARLIMS™ covering all cGMP/cGLP aspects.

## Introduction

The completeness and accuracy of data is important for a safe product development and production. Violation of data integrity could have serious implications for human health and safety. In recent years the number of data integrity violations in the pharmaceutical industry has risen significantly. Over 65% of all FDA Warning Letters in 2017 address data governance and data integrity deficiencies<sup>1</sup>. Therefore, an increasing number of companies are turning to integrated informatics solutions, like ELN, LIMS, SDMS or SCADA systems, to manage their data handling and to ensure data integrity throughout the laboratory workflow. A complete solution can only be achieved if the laboratory equipment is fully integrated into the computerized system to help prevent errors caused by manual data handling or disregarding of Standard Operating Procedures (SOP) or instructions.

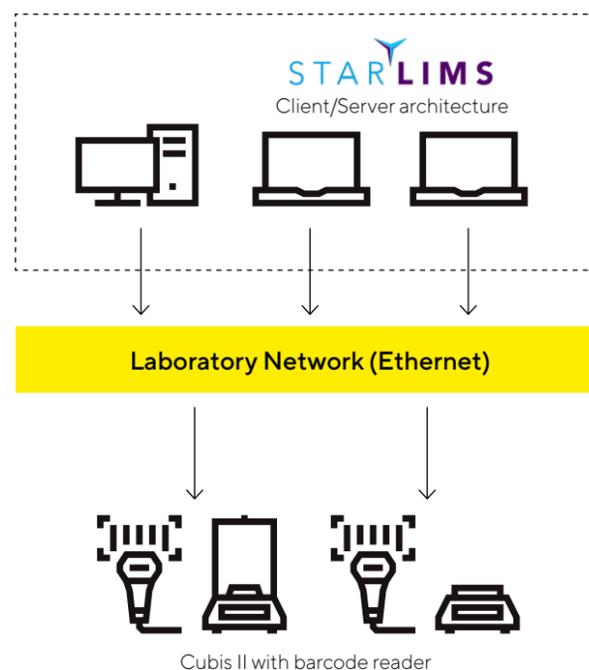
The problem with integrating laboratory equipment into a computerized system is the absence of an industrial standard which meets all compliance requirements with a plug and play interface as an attractive alternative to implementing external middleware. Another point is the non-consistent handling, when changing from the computerized system to the laboratory equipment inside a laboratory workflow. This is confusing for the user and harbors potential for risks.

Abbott Informatics and Sartorius have developed a solution that makes it easy to integrate Sartorius Cubis® II into STARLIMS™ offering customized comprehensive laboratory workflows with a plug-and-play connection via recognized IT standards and sufficient protection against data integrity problems.

Sartorius Cubis® is the first series of lab balances to feature a completely modular design, Cubis® enabling you to combine your choice of display and control unit, weighing module, data interface module, and much more. The unique Cubis® individual concept lets you create a customized profile for your specific app requirements – without having to use a laptop! Start off by integrating data into your software infrastructure and continue right on up to implementing complete control of your weighing process. The premium lab balances have become the benchmark for use in regulated sectors that impose the highest requirements, such as in global pharmaceutical labs.

Abbott Informatics is a subsidiary of Abbott Laboratories and a leading provider of laboratory information management solutions with more than 1000 implementations in over 45 countries. The Abbott Informatics' STARLIMS™ can or may improve the reliability of laboratory sampling processes, support compliance with global regulatory requirements and industry standards, and provide comprehensive reporting, monitoring and analysis capabilities.

## Flexible System Architecture with STARLIMS™ & Cubis®



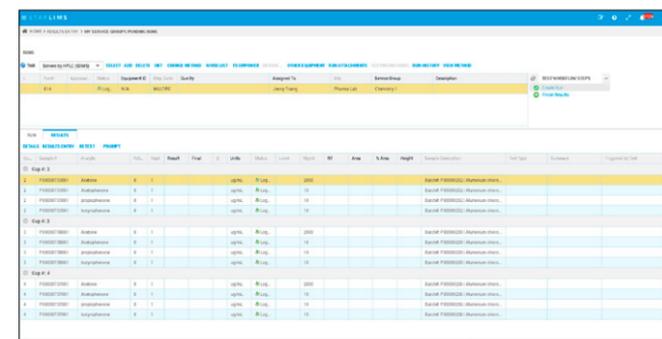
The STARLIMS™ client/server architecture is well designed and flexible. The client side is running in a standard web browser and the server side consists of a scalable and extensible application and database server. Communications between the client and server are achieved through standard Web service messaging over hypertext transfer protocol (HTTP) or optionally secure HTTP (HTTPS) for a more protected environment.

Each Cubis® scale is an independent unit which can communicate over REST Web Services with STARLIMS™ without any additional middleware between. With the standardized device interface a new Cubis® can be quickly connected to STARLIMS™ without complex configuration effort or additional software license.

To read and verify sample identification tags, a hand scanner, which can read different types of matrix codes, can be connected directly to the Cubis® II.

On the Cubis® II, run QApps; small customer specific embedded applications which extend the standard weighing functions by weighing-related workflows to guide a user step by step through a particular process. To connect the Cubis® II Balance, a QApp was developed, allowing a seamless integration of a laboratory workflow. This QApp application can be customized to meet the customer SOP to 100%. Another benefit of these small embedded applications is the low validation effort. Instead of complex PC software, only the app itself needs to be validated, resulting in both greatly reduced cost and risk for the end customer.

## Workflow Implementation

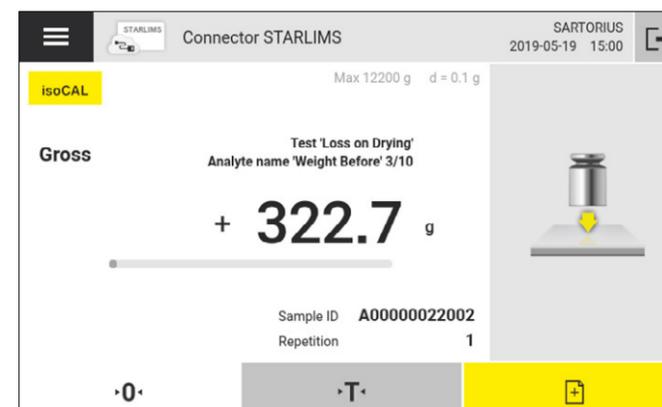


A typical laboratory workflow for differential weighing applications e.g loss on drying was chosen as example for the integration.

The process starts in STARLIMS™ where the samples are created and assigned to the analytical method and a specific Cubis® II Balance. The samples themselves will be labeled with a barcode that contains the sample ID from STARLIMS™ to track them during the whole process.

After the job is created in STARLIMS™ and transferred to the balance, the user logs onto the Cubis® II with their personal login and scans a sample with the barcode reader. The balance verifies directly that the scanned sample is included in the sample list and that the logged in user is allowed to work with this sample otherwise he will receive an error message and the job will not be performed.

The User is guided step by step through the weighing process on the display of the balance. This protects against incorrect operation, improper use or violation of the weighing related SOP. This step can be completely customized according to the customer's requirement for additional functions such as ionization of the sample.



At the end, the Cubis® II sends the weighing result together with all required metadata to STARLIMS™. STARLIMS™ automatically calculates the difference between the initial and residual weights and stores the raw data securely.

STARLIMS™ offers many possibilities to document and evaluate the results, and control the progress of the sample or batch throughout its lifecycle.

## Our Guarantee: Best Solution for Regulated Laboratories

The trustworthiness of data is essential in regulated laboratories. By fully integrating Cubis® II into STARLIMS™ we demonstrated that we can successfully minimize data integrity issues and increase the degree of automation with this solution.

### No Manual Data Handling

WHO Data Integrity guidance states that data integrity risks are higher when processes are performed manually or paper based. Our outlined solution reduces manual data entry to a minimum. The weighing process comprises no manual data entry steps. The identification of a sample is done via its barcode and results are automatically transmitted to STARLIMS. Thus, the probability for transmission errors or loss of data from paper-based recording is significantly reduced.

### Data Integrity Over the Entire Life Cycle

The fully integrated solution with Cubis® II individual and STARLIMS™ helps to ensure that the regulations are complied with cGMP and cGCP compliance regulations. It was designed to cover all aspects of the ALCOA principles from the important FDA, PIC/s and MHRA guidelines. The Cubis® II balances generate the data with all required meta data and transfer the data immediately to STARLIMS™, which is designed for automated data collection and long term data storage.

### Device Monitoring & Calibration

Regular monitoring and calibration of laboratory equipment is required in order that specifications are being maintained. STARLIMS™ gives the possibility to set up a service status for maintenance or calibration of lab equipment and to record all maintenance and calibration activities. This service status is checked by the Cubis® II before the weighing process starts which protects against the use of a faulty balance.

### Personal User Accounts

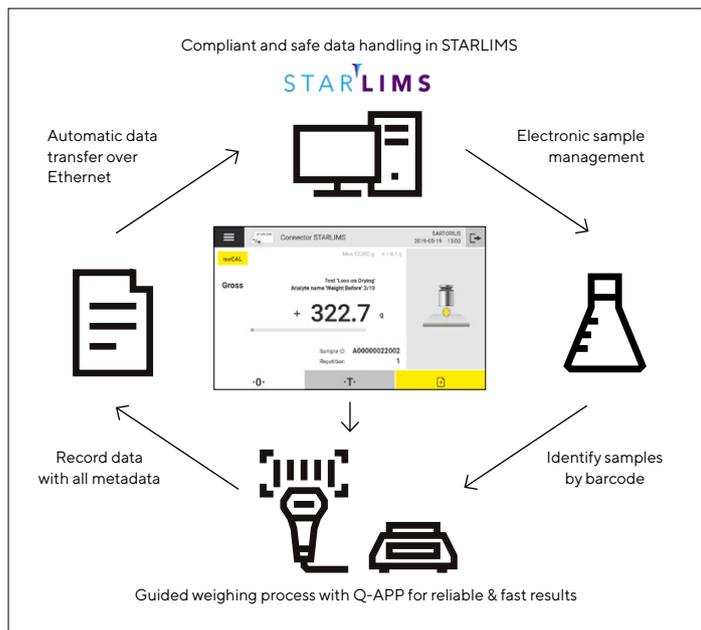
If someone is logged in using a shared user account then it is not registered which specific user was responsible for creating or changing a data record. This then leads to a breach of data integrity. This situation can be prevented by using personalized accounts, which is supported by Cubis® II and STARLIMS™. The users of the two systems are synchronized and rights can be assigned, which prevents the unauthorized user from starting a weighing process.

## Conclusion

In this note, we have demonstrated the ideal suitability of integrating Sartorius Cubis® II balance into Abbott Informatics STARLIMS™ for the use in a GMP regulated environment. We have demonstrated a flexible, user friendly and robust system that helps to meet and monitor your specific laboratory workflow and at the same time delivers time savings and efficiency gains for laboratory staff in their day to day work.

## Follow the written SOPs

Not following SOPs is often criticized by the FDA. This can be prevented by the seamless integration of Cubis® II into STARLIMS™. The user is guided and monitored step by step through the whole weighing process without any break between STARLIMS™ and Cubis® II. This ensures SOPs and business rules are being followed.



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