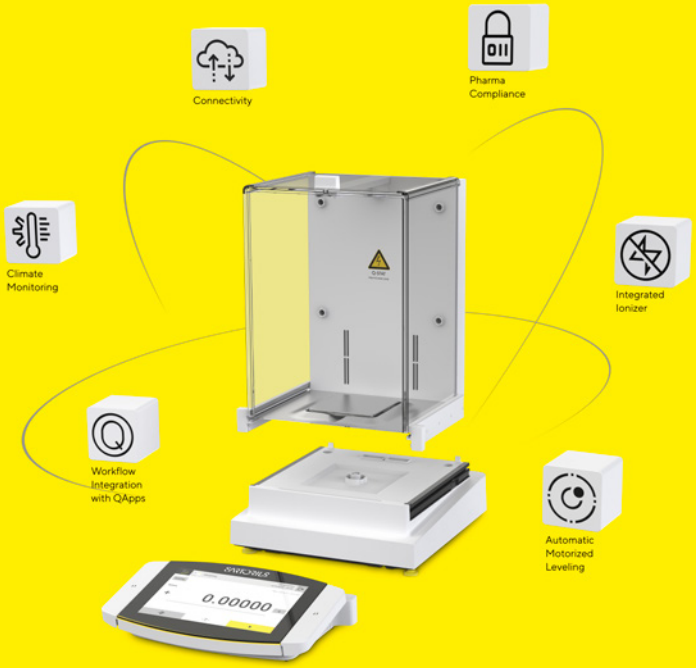


2020 Guide to Laboratory Balances and Scales

Simplifying Progress

SARTORIUS

Introduction

Balances are one of those foundational pieces of equipment in a lab that are often overlooked. Yet, since you use your balance in nearly every workflow in your lab, your choice of lab balance is one of the most important decisions you will make.

All researchers need confidence that their most fundamental lab equipment is accurate, efficient, and easy-to-use. Sartorius offers lab weighing solutions such as the Cubis® II balance, a completely configurable, high-performance, portfolio of balance hardware and software that will align with your unique demands and compliance requirements to maximize your operational efficiency and experimental outcomes.

Our weighing resources and solutions will increase your weighing accuracy and ensure your full compliance to the most rigorous standards and requirements. See our weighing resources and solutions, including:

- Achieving Accurate Weighing Performance
- Weighing in Compliance with Regulatory Standards and Requirements
- Integrating your lab balances with your LIMS
- How the Innovative Features of the Cubis® II Can Make Accurate Weighing Even Easier

Partner with Sartorius to achieve accuracy, repeatability, and efficiency with your most fundamental laboratory equipment and skills.

Chapter 1:
Advanced Compliance for Use in Regulated Sectors, such as Pharmaceutical Industries

Sartorius's Cubis® II is designed to follow US FDA data integrity principles that require data to be accurate, legible, contemporaneous, original, and attributable (ALCOA).

The Cubis® II balance, with pharma package, contains all the technical controls to support compliance with common regulations. Full compliance can be achieved with additional procedural controls and systems for long-term data storage.

Download White Paper

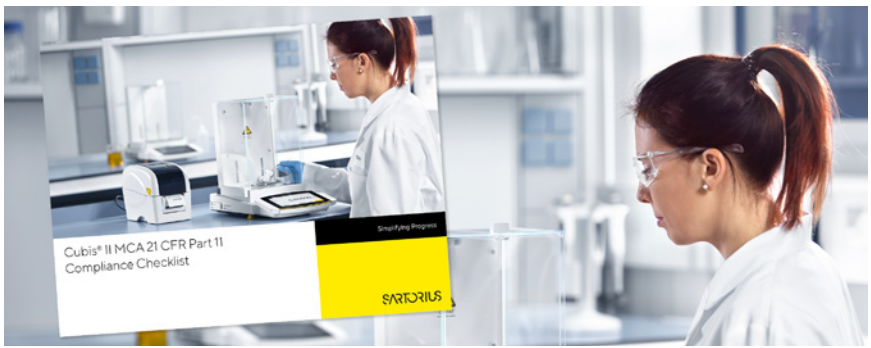
Chapter 2:
FDA 21 CFR Part 11: Our Compliance Checklist

FDA 21 CFR Part 11 lays out the criteria that the FDA uses to determine if electronic records and signatures are trustworthy, reliable, and generally equivalent to paper-based records. Your compliance is essential if you work in an FDA-regulated industry and want to use electronic quality records and electronic signatures in place of paper and ink-based records. Nevertheless, what constitutes compliant electronic records can be confusing.

Download our checklist to help you check the details of the regulations.

Our Cubis® II balance, with the pharma software package, contains all technical controls to support compliance with common regulations such as US FDA 21 CFR Part 11 or EU Annex 11.

Download Checklist



Chapter 3:
Data Integrity & the Next Level of Connectivity in a Modern Lab

The digital transformation of laboratories brings many advantages but also new challenges for the laboratory staff. Ensuring the integrity of data and the seamless integration of laboratory instruments into the IT landscape are two major challenges. Watch our webcast to learn how to fulfill data integrity in the paperless lab with an intelligent instrument design.

Key Objectives:

- Review why data integrity has become a hot topic in laboratories
- Understand the problems to integrate instruments into a laboratory environment
- Learn what is needed to document instrument results paperless under the aspects of data integrity

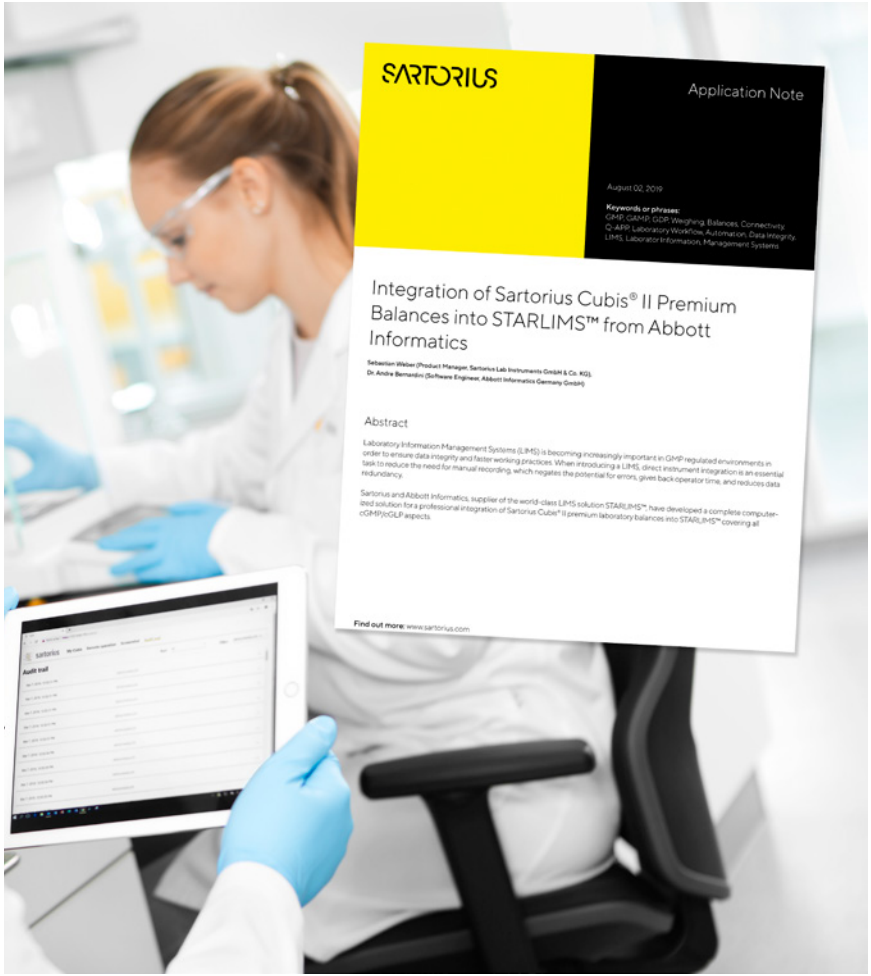
Watch Webinar

Chapter 4:
Integrate Your Lab Balance into LIMS System

Laboratory Information Management Systems (LIMS) are becoming increasingly important in GMP regulated environments to ensure data integrity and fast 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 Laboratory Balances into STARLIMS™ covering all cGMP/cGLP aspects.

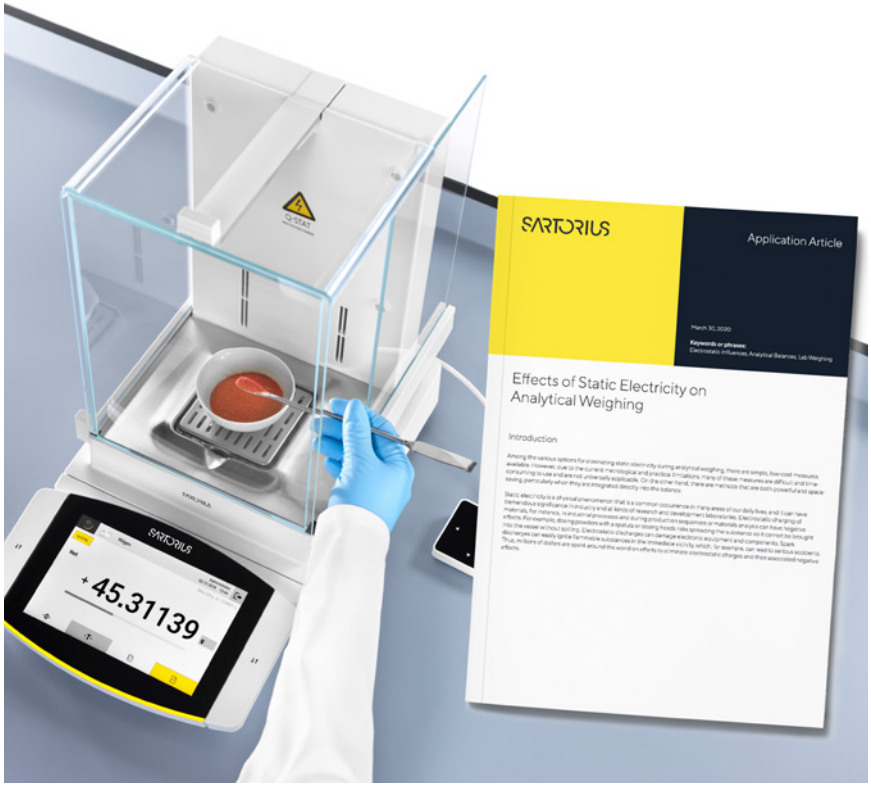
Download Application Note



Chapter 5:
Effects of Static Electricity on Analytical Weighing

Among the various options for eliminating static electricity during analytical weighing, there are simple, low-cost measures available. However, due to the current metrological and practical limitations, many of these measures are difficult and time-consuming to use and are not universally applicable. On the other hand, there are methods that are both powerful and space-saving, particularly when they are integrated directly into the balance.

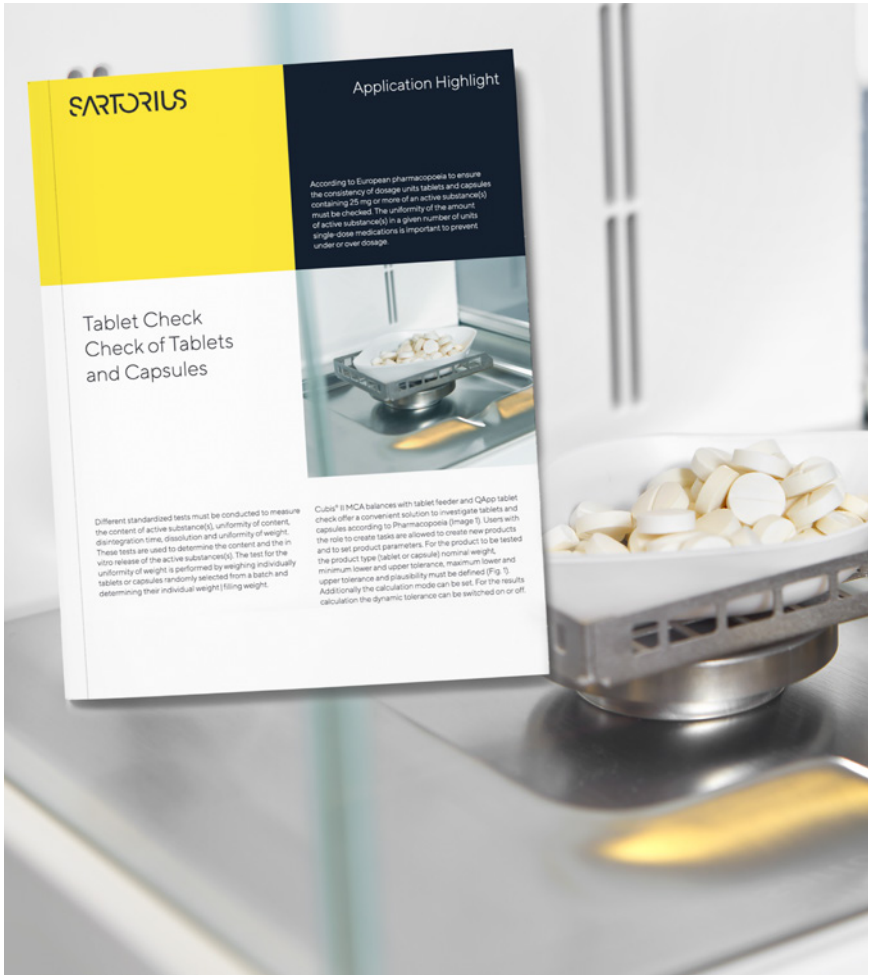
Download Application Article



Chapter 6:
Accurate Determination of Uniformity of Dosage with Cubis® II

According to European pharmacopoeia to ensure the consistency of dosage units tablets and capsules containing 25 mg or more of an active substance(s) must be checked. The uniformity of the amount of active substance(s) in a given number of units single-dose medications is important to prevent under or over dosage.

Download Application Highlight



Chapter 7:
Pipette Check to According Standard DIN with Cubis® II

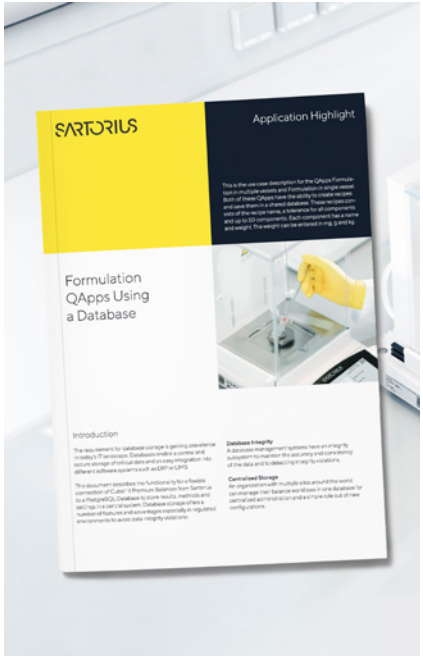
According to Standard DIN EN ISO 8655-2, volumetric measuring instruments such as piston pipettes must be checked at regular intervals (at least once per year). Shorter time intervals may be specified by the users depending upon the frequency of use, number of users, aggressive nature of the pipetted liquids, and the acceptable maximum permissible errors established by the user. This regular check is mandatory for all laboratories that have to work in compliance to standard DIN EN ISO 8655.

Download Application Highlight

Chapter 8:
Formulation QApps Using a Database with Cubis® II

This is the use case description for the QApps Formulation flexible tare and Formulation single vessel. Both of these QApps have the ability to create recipes and save them in a shared database. These recipes consists of the recipe name, a tolerance for all components and includes up to 50 components. Each component has a name and weight. The weight can be entered in mg, g and kg.

Download Application Highlight



Chapter 9:
Cubis® II in Action | Tutorial and Application Videos

Learn how Cubis® II can support you in your daily workflow with features like an ionizer to eliminate electrostatic charges or electronic signature, audit trail and user management for 21 CFR Part 11 compliance or how easy a balance can be levelled with just the click of a button .

Download Application Highlight

Chapter 10:
Advanced Software to Increase Repeatability and Workflow Efficiency

All modules of the Cubis® II balance were designed for an intuitive operation, further aided by intelligent diagnostic systems. These design elements guarantee a high degree of repeatability for different workflows, while lowering the probability of human error.

The software modules for our Cubis® II Lab Balance are called QApps. These QApps run lab applications, functions, or utilities. The licenses for QApps are bundled in specific QApp-Packages, clustered by topic area. It's part of what makes the Cubis® II Lab Balance customizable by design.

The benefits of QApps include:

- Long-term flexibility to extend and update—assuring its adaptability to the evolving regulatory landscape and your laboratory's needs
- They are modifiable if they do not fit into your workflow
- Easy to validate, with reduced testing efforts due to their compact and clearly structured design
- They have an iterative software development cycle for the complete life of the application, once again assuring their adaptability

Order QApp-Packages together with your Cubis® II Lab Balance. All packages are pre-installed on the balance and ready for use after delivery. In the QApp-Center, browse through the packages to get information about their content, in detail.

Learn more about how our QApps can upgrade your lab weighing experience.

Learn More about QApps

Sales and Service Contacts

For further contacts, visit **www.sartorius.com**

Sartorius Corporate Administration GmbH
Otto-Brenner-Straße 20
37079 Goettingen
Germany

Phone: +49 551 308 0
Fax: +49 551 308 3289
Email: info@sartorius.com

Sartorius Corporation
565 Johnson Avenue
Bohemia, New York 11716
United States

Phone: +1 631 254 4249
Fax: +1 631 254 4253
Email: info@sartorius.com