

GxP-compliant Printing and Archiving of
Initial Weights and Related Weighing Data

White Paper

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Introduction

Sartorius Lab Instruments GmbH & Co. KG has been operating globally as a manufacturer of laboratory and process equipment and a provider of these technologies for over 140 years. One of its core areas of expertise is in the sector of high-quality laboratory balances that focus on processes and maximizing their efficiency.

The balances in the Cubis® product range are designed for use in this highly demanding environment based on the rules of "Good Manufacturing Practices" (GMP) and "Good Laboratory Practices" (GLP). With the Advanced Pharma Compliance (APC) design, function and service package installed inside, they provide exceptionally customer-friendly solutions to meet the process and quality requirements of this sector.

Thermal Printing Processes

Determining reliable and highly accurate weights and related weighing data is essential in every measurement. Besides this requirement, there are also high demands on how the resulting raw data is handled. If a printout is created for documenting and archiving this data, its integrity and readability must be ensured in a regulated environment. With this requirement in mind, Sartorius Lab Instruments GmbH & Co. KG has developed the YDP30 label printer, which operates based on two technologically different thermal printing processes.

Both of these processes are based on the same basic functional principle: using partial heat application to create the desired printed image on the print medium. Based on simple technology, the most commonly used process in the non-regulated industry is direct thermal printing, which uses special heat-sensitive paper, also known as thermal paper. The printout is

the result of an interaction between the paper roll, which is electrically operated, and the print head or thermal array. The thermal array has fields with a number of small heat resistors, which electrically apply the heat to the thermal paper selectively in order to print the correct image. Selective heating releases a leuco dye in the thermal paper, generating the printed image (see Figure 1).

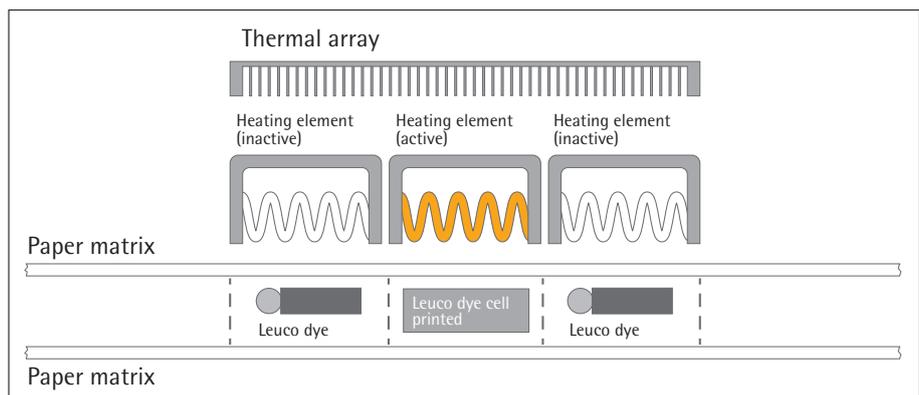


Figure 1: Direct thermal printing (schematic diagram)

A major disadvantage of this technology using thermal paper is that the printed images do not last long enough. So far, there have been no technological improvements to this type of paper to counteract its sensitivity to UV radiation and extreme ambient temperatures. As a result, the printed image fades as early as within a few weeks if subjected to such conditions. Often, even meeting the requirements for retaining batch documents in line with GMP requirements, such as the European Union GMP Guide, cannot be guaranteed. These requirements stipulate that records of pharmaceuticals must be kept at least one year after the expiration date of the batch in question or at least five years after this batch has been certified by qualified personnel under Article 51, Paragraph 3, of European Directive 2001/83/EC for medicinal products.

Printouts on special thermal paper, such as those showing weighing results, must therefore be copied in a second step onto fade-resistant paper to provide a GxP-compliant, permanent record to ensure that raw data is sufficiently documented for the required duration.

The use of thermal transfer printers is a significantly better choice for raw data recording by measurement devices. In thermal transfer heating, an ink ribbon is run through the printer synchronously with the print medium, and the ink is transferred exactly onto the print medium by selectively heating the print head (see Figure 2).

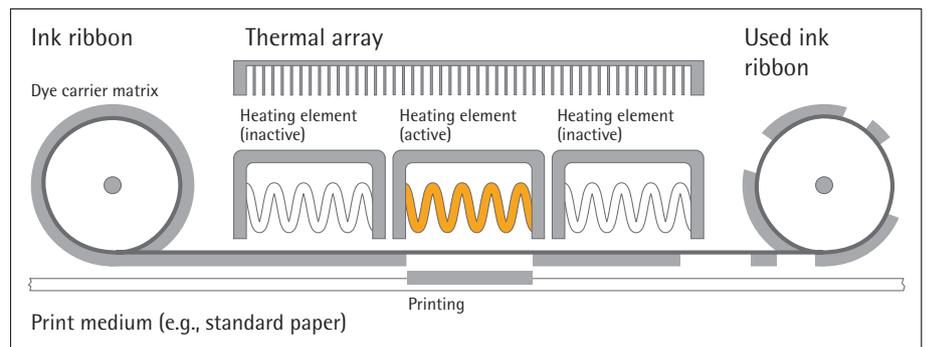


Figure 2: Thermal transfer printing (schematic diagram)

Thermal transfer printing can be used on most conventional print media, such as standard paper or films, and produces a stable, non-fading printed image. The printout is appropriate as a permanent record, just like printouts from dot matrix printers or office printers. The considerable advantage of thermal printers is that they do not use small components that have a tendency to cause problems. Thermal transfer printers are also compact and easy to clean.

Advanced thermal transfer printers generate GxP-compliant documents in an especially economical way. The print head of the Sartorius YDP30 premium printer lasts up to four times longer than conventional direct thermal printers. Buffering the ink ribbon between the thermal elements of the print head and the print medium protects the components from contamination by chemicals, making the thermal transfer printer a very robust device.

Another advantage is the flexible ways in which the Sartorius thermal transfer printer can be used. For standard applications outside the regulated sector, YDP30 can also be easily operated as a direct thermal printer just by removing the ink ribbon and changing the paper to the standard type. In addition, it can be used to print conventional barcodes, 2D codes and pre-prepared labels, for example, when operated in combination with a Cubis® balance that has an MSA display and control unit with the Q-App "QR/Barcode and Label Print" installed.

Synopsis

When choosing a balance for a regulated production environment, it is important to consider the right aspects for automatic documentation.

Sartorius Lab Instruments GmbH & Co. KG offers the ideal accessory for GxP-compliant documentation: the YDP30 premium printer. As part of the modular-design system provided by the Cubis® balance series, the YDP30 features a compact design and is easy to clean. This leading-edge, full-featured thermal printer can be used in a wide range of applications, from printing standard labels to generating fade-resistant printouts of weights and

other values for long-term archiving of raw data. The thermal transfer printing components make the YDP30 premium printer a high-quality product that can be operated independently, without needing to be connected to a computer, in a GxP-regulated environment.

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