

# Optical Metrology User Case Study: In production measurement of Pharmaceutical Packaging



Bruker alicona

Bruker Alicona is a leading global supplier of optical metrology solutions based on the principle of Focus Variation.

Focus Variation works on the basis of moving a focal plane over a surface and collecting robust 3D data which can then be used to measure geometric form and surface finish from a single optical sensor.

Measurement processes can be fully automated and provide GD&T measurement capabilities across all industrial & medical sectors.

The systems are in use in Industry, Industrial Research, Universities and production facilities globally.

Pharmaceutical packaging must be optimally sealed to prevent foreign substances from entering and it must also follow all legal guidelines on counterfeit protection and traceability. When it comes to the production of pharmaceutical packaging, priority is given to the protection of the high-quality ingredients and formulations while maintaining complete functionality.

Based in Germany, Uhlmann Pac-Systeme GmbH & Co. KG is one of the world's leading suppliers of pharmaceutical packaging systems. Uhlmann's product portfolio includes machines for all process steps: from blister machines and bottling lines to cartoners and end-of-line packaging machines. This range is complemented by extensive services for the systems' entire life cycle.

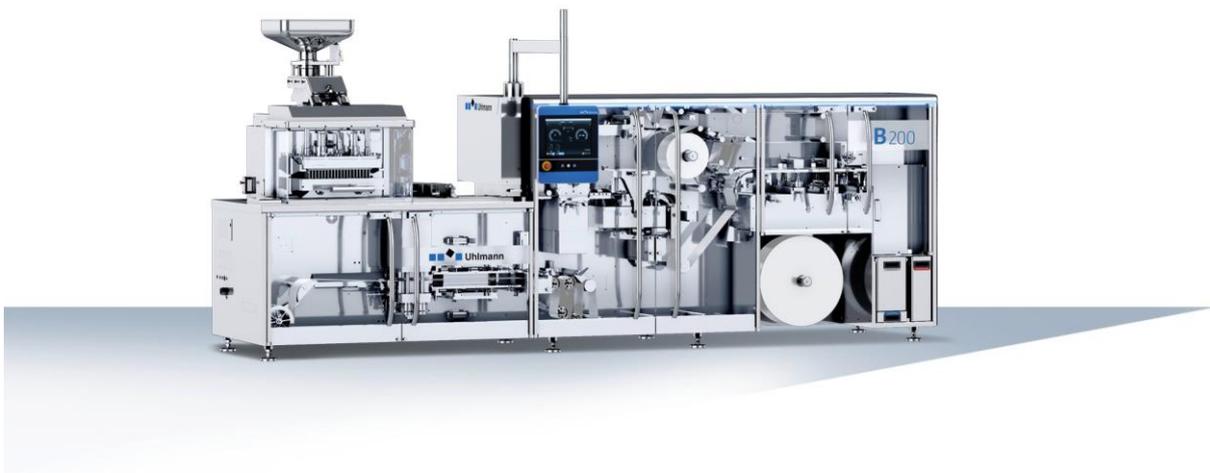
Product safety is particularly important in the production of pharmaceutical packaging and is subject to stringent requirements. Uhlmann – experts in the field of pharmaceutical packaging – use Alicona to verify the quality of machine components, thus gaining knowledge on the reproducibility of manufacturing processes.

## **New knowledge on the reproducibility of manufacturing processes**

When manufacturing special pharmaceutical machines, the focus is to implement professional quality assurance processes at all stages of production. Uhlmann use Bruker Alicona InfiniteFocus system to test the machine components and the packaging products they fabricate. Matthias Obert, a member of Uhlmann's Quality Management team states "Alicona allows us to gain new knowledge on the reproducibility of our manufacturing processes. Besides this, the measurements also enable us to verify supplier specifications for purchased parts, predict the functional behaviour of products and carry out cause analyses on the functionality of products".

Monitoring measurements in the manufacturing process of blister machines

Blister machines are used to produce blister packaging, better known as "blister packs". These packs contain the pre-sorted medicine and are hygienically sealed using plastic or aluminum composite foils. Each separate drug unit has its own "cup", from which the tablet or capsule can be popped out with your fingers and it is critical that a permanent seal is obtained during production.



*Figure 1 an example of a Blister Packaging machine from Uhlmann Pac-Systeme GmbH & Co. KG*

Material parameters for the evaluation of the functional surface behavior

The process steps of a blister packaging machine include, first and foremost, the shaping of the cup-shaped depressions into the base, which is made of aluminum foil.

The product, tablets or capsules, are then filled into the cups and a cover film is fed through the sealing station and placed on the base foil.

The cover film is warmed up by means of hot plates to enable it to mould to the base foil, thus enclosing the product in the cup-shaped depression.

In order to prevent sticking to the hot plates and to ensure optimum heat distribution on the hot plates, it is important to understand the surface parameters of the hotplate (Figure 2). Uhlmann use the InfiniteFocus to

determine surface parameters ( $S_a$ ,  $S_z$ ) and material parameters ( $S_k$ ,  $S_{pk}$ ). Surfaces with similar  $S_a$  values can have completely different structures.

This provides a sound statement about the functional behaviour of the surface after evaluating the material ratio parameters.”



*Figure 2: 3D measurement, from the InfiniteFocus of the hot plate surface in true color. The hot plates warm up the cover film before sealing it onto the base foil. Alicona enables Uhlmann to determine the surface finish parameters ( $S_a$ ,  $S_z$ ) and material parameters ( $S_k$ ,  $S_{pk}$ ).*

Sealing rollers made of tool-grade steel or high-quality aluminium are used for bonding the film to the foil. The contact surfaces of the rollers have inclined surfaces and tips, i.e. pyramid-shaped corrugation (Figure 3) The distribution density of these "pyramids" dictates how deep the tips penetrate in the foil composite and thus provides a contact face adapted to the surface pressing requirements. "Before we switched to the measuring technology of Alicona, we could not measure these corrugated geometries. The analysis of the pyramid stump dimensions, such as the angle, height and distance to each other, gives us indispensable information." Once the sheet is sealed air-tight, each tablet is enclosed by two longitudinal sealing gutters and two transverse sealing gutters. The seal shape of the blisters is checked in the course of the packaging process. The shape measurement and color evaluation enable Uhlmann to check the homogeneity of the impression and lacks gutter width and height.

After sealing the carrier foil and cover film, it is possible to emboss specific safety features (e.g. batch number) permanently on the blister reel. The serial numbers are punched in using die stamps. Uhlmann use InfiniteFocus to ensure the correct letter height of the die stamp, measure the surface roughness and perform a visual inspection.



*Figure 3; 3D measurement of a blister sealing area in true color*

### Simple handling and extensive applicability

The cut areas of the punched blister packages are then evaluated. "About Alicona, we particularly appreciate the ease of use of the system and its extensive applicability. The color-coded height representation comes in very helpful to communicate surface properties easily and intelligibly to other interfaces in the company", explains Obert.

In order to ensure the quality of the production process of the blister machines, Uhlmann also require information on the slip properties of the tablets and capsules. To do this, one needs to know the surface roughness of the medicine. Tactile measuring methods are not suitable for this application because the surface of the measuring object can alter or get damaged in direct contact with the medicine. Alicona helps determine

surface characteristics of the tablets (e.g. Sa and Sz) without touching the surface.

## Summary:

It can be clearly seen that Optical 3D metrology can offer a versatile tool in the pharmaceutical packaging industry.

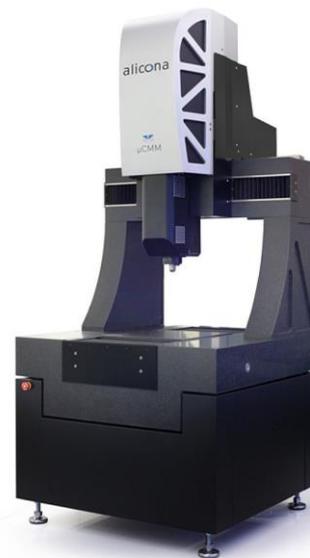
In a simple to use package, and not requiring any metrology knowledge to operate users can easily scan a surface and measure the features required.

## Equipment Available

These measurements can be made using one of the 2 products shown below from Bruker Alicona. the InfiniteFocusG5 plus will measure up to 200 x 200mm and the  $\mu$ CMM up to 300 x 300mm.



InfiniteFocusG5 plus system with 200 x 200mm XY stage and fitted with rotation device. Info at <https://bit.ly/2TF9ctH>



$\mu$ CMM 300 x 300 mm XY stage. Info at <http://bit.ly/34ht4tk>