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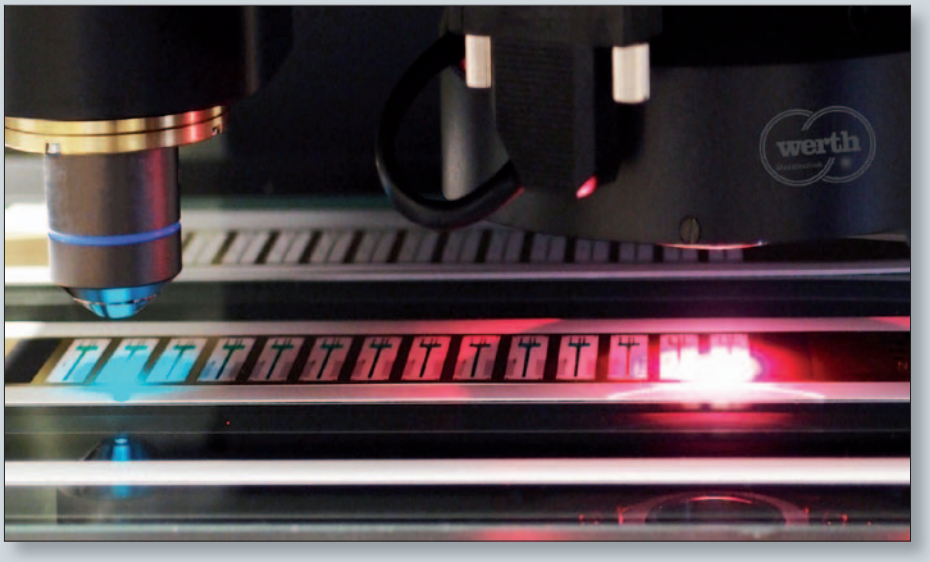
User´s report

Roche Diagnostics GmbH

Precise measurement results for research and development



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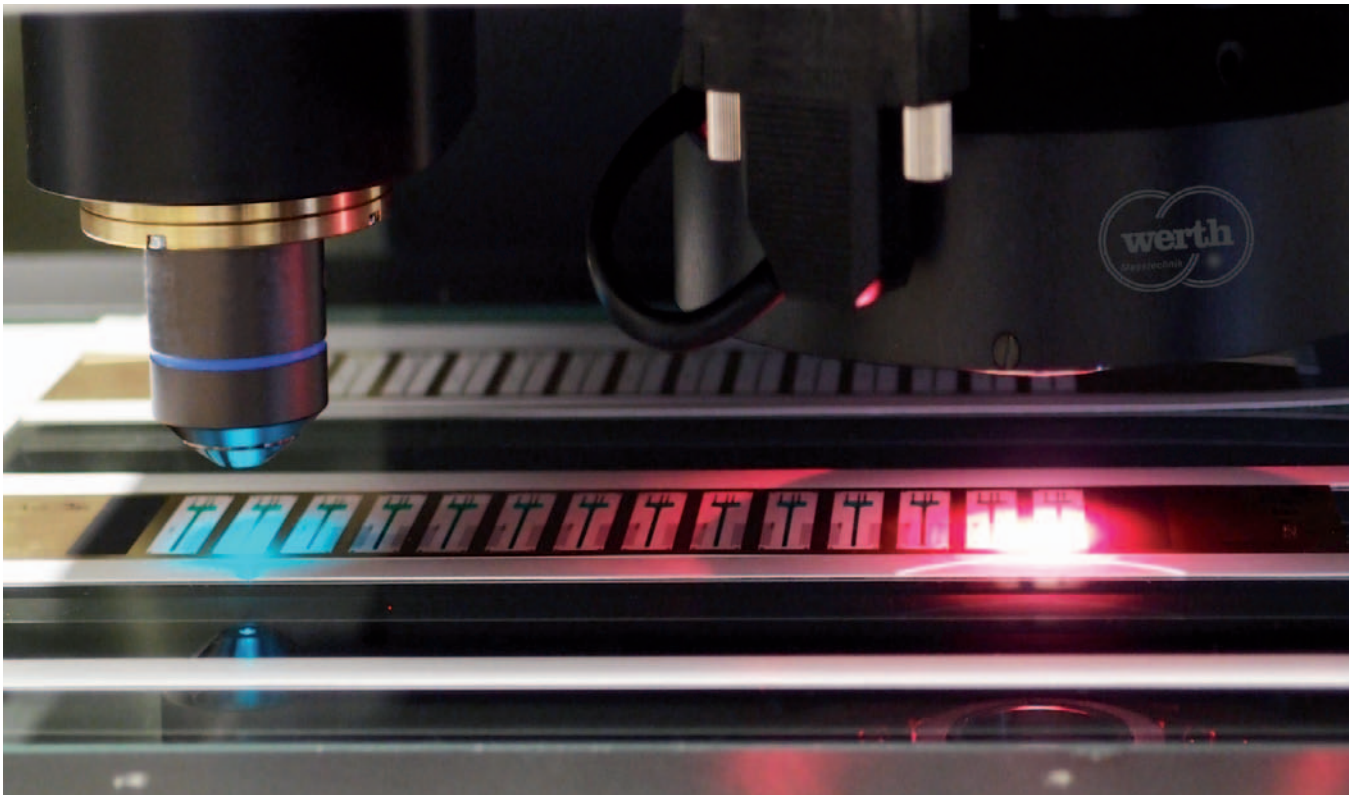

CMM CAPTURES GEOMETRY AND LAYER THICKNESSES IN MICROSTRUCTURES

Precise Measurement Results

Multisensor measuring machines are not just for use in quality assurance. Development can also benefit from their combination of different measurement techniques.

Roche Diabetes Care uses a Werth VideoCheck® IP unit equipped with an image processing sensor and a confocal sensor in its technology development. The machine captures the geometry and layer thicknesses of functional microstructure samples, contributing to efficient development of new products. The diagnostics division of the globally active healthcare company Roche develops and provides products and services for the prevention, diagnosis, and therapeutic treatment of various diseases. One business unit within Roche Diagnostics is Diabetes Care, which develops and produces systems and services for diabetes management such as insulin pumps and glucose monitoring systems, among other things. It has been very successful. The company is the global leader in the area of in-vitro diagnostics for diabetics.

Dr. Gregor Ocvirk, a team leader and project manager in technology development for Roche Diabetes Care in Mannheim, expresses the need to make it easier for diabetics to use improved and fundamentally new types of systems for monito-

Figure 1. VideoCheck® IP: The two sensors of the Werth VideoCheck® IP 400 can be seen in the photo. On the right is the image processing sensor (red light) and on the left is the Nanofocus measurement head (blue) in sequential operation. (Photos: Roche)

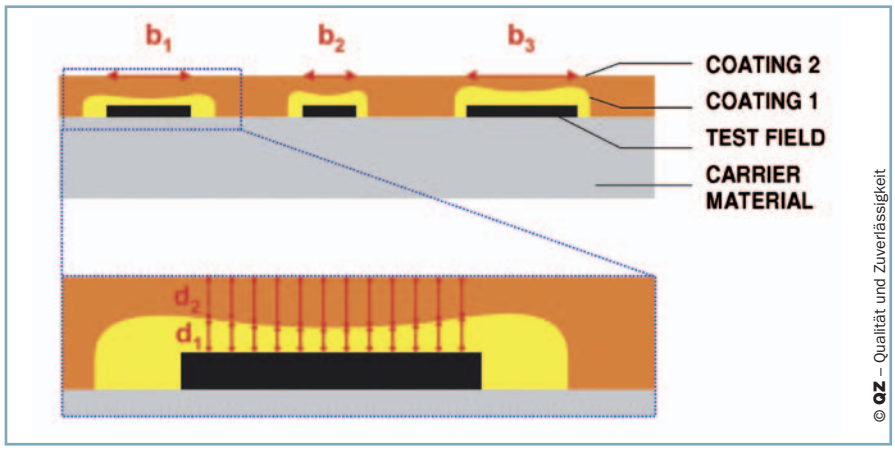

Figure 2. The graphic shows two transparent coatings on a test field, where the width (b1, b2, b3) and length of the test field and a layer thickness raster of the transparent coatings (d1(x,y),d2(x,y)) can be seen.

ring and treating their disease. This has resulted in the continued miniaturization of test elements for blood sugar measurement and minimally invasive subcutaneous measurement of glucose and also of drive systems for metering insulin.

Gregor Ocvirk and his colleagues in development explore many technologies to develop new test elements and dosing systems to bring products to market readiness through process development. He explains: "In order to be able to make reliable statements about the functionality of new test elements, we produce small batches of functional samples using manufacturing processes that allow high accuracy and precision. The subsequent process development can also be accelerated if the technology development process not only determines the capability of the test element, but also identifies the appropriate production process. This accelerates implementation of the idea through market readiness, which ultimately benefits the patient."

To make credible statements very early in the development process using near-production equipment to produce functional samples means that a significant number of functional samples must be produced and tested. It is ultimately the job of development to set the precise capability of the samples with respect to their functions to achieve changes with improved functionality.

Automated measurement is needed

The practical impetus for investing in a measuring machine was the development of new glucose sensors. Its core consists of an enzyme electrode that can be used to electrochemically determine the glucose content of the blood or other bodily fluids. To produce such an electrode, various layers are applied to a conductor. Typically, several microscopic protective plastic layers are added to a conductive base layer. To investigate the effects of these layers and combine them with the actual function of the electrode, the lateral extent of the electrode and the protective layers in the X-Y direction, which is in the sub-millimeter range, must be measured. The local thickness of the protective layers, which are generally between 5 and 50 µm, must also be determined.

For this reason, Gregor Ocvirk and his team at Roche Diabetes Care decided to introduce a Werth VideoCheck® IP multi-sensor coordinate measuring machine (see text box). This coordinate measuring machine can be equipped with a wide range of sensors. Roche Diabetes Care decided on two for now: an image processing sensor for geometric, non-contacting measurement of the electrodes and the con-focal sensor "Nano Focus Probe" for measuring the applied layers. The machine is thus suitable for quickly capturing the component completely at high resolution and high point density.

One measuring machine, one software package - fast results

Marcel Thiele, the responsible technician, reports: "From a method standpoint, these measurements are no problem. We have several different methods for this in house.

But those are time-consuming individual measurements, which would mean that as the number of electrodes to be measured increases, we would have time and resource constraints. We also have not been able to provide quick, reliable results of the tests of suitability of the test elements during the production process. We were therefore looking for a measuring machine that was fast enough and not only captured the contour, but also determined the thickness of the coating on this contour. Finally, we wanted a software package that would link and analyze the various measurement data. We found it all at Werth Messtechnik. The VideoCheck® IP with the image processing and confocal sensors, and the WinWerth® software package, meet our requirements."

To determine the layer thickness in a certain area on an electrode, Marcel Thiele first measures the contour of this sample. He illuminates the object with white or red light and captures the X-Y coordi- »

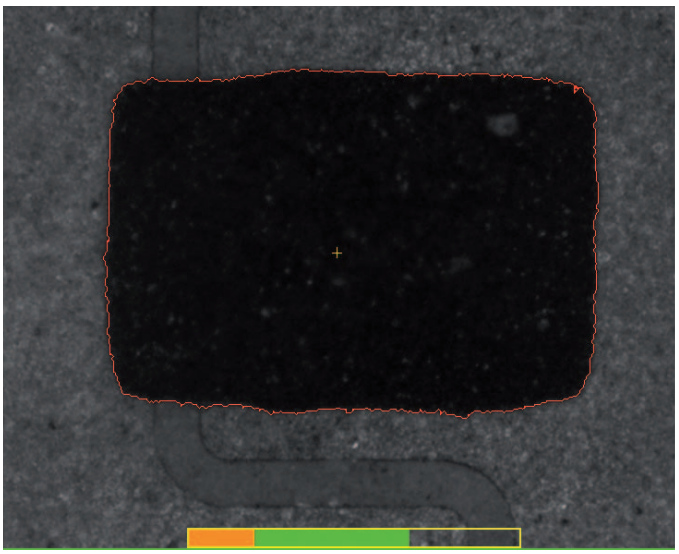

Figure 3. Contour capture with a sensor electrode

VideoCheck® IP provides nearly limitless measurement flexibility

The Werth VideoCheck® is a 3D CNC multisensor coordinate measuring machine that provides flexibility in the measuring room and in production control. It has a unique, stress-free guide system with a measuring range of X = 250 to 400 mm by Y = 125 to 200 mm, depending on the model. Larger measuring ranges are available in models with air bearings. Due to its modular machine concept, the Werth VideoCheck® IP can mount various sensor, such as the Werth image processing sensor, 3D Patch, laser sensor, touch probes and scanning probes, Fiber Probes, the Contour Probe, and others. The Nano Focus Probe from Werth Messtechnik uses the con-focal principle to measure the surfaces of microstructures with high-precision. The geometry, form, roughness of microstructures and layer thicknesses as well as cutting edges of tooling and can thus be measured for small and large work pieces. Werth Messtechnik integrates the Nano Focus Sensor exclusively in coordinate measuring machines in cooperation with the Nanofocus AG.

Innovation for health

Roche, a research oriented health care company based in Basel, Switzerland, centers its activities on the discovery and development of new diagnostics and medications. It producing significant value for doctors and patients in the prevention, diagnosis, therapy, and monitoring of illnesses. The company has about 80,000 employees, and sells its products in over 150 countries.Roche is based on two strong core businesses: pharmaceuticals and diagnostics. Roche Diagnostics employs about 26,000 people worldwide, over 10,000 of them in Germany. Sales of the Diagnostics unit were about 10 billion CHF in 2010. The product range includes products and services for the prevention, diagnosis, and treatment of illnesses for researchers, doctors, patients, hospitals, and laboratories around the world.

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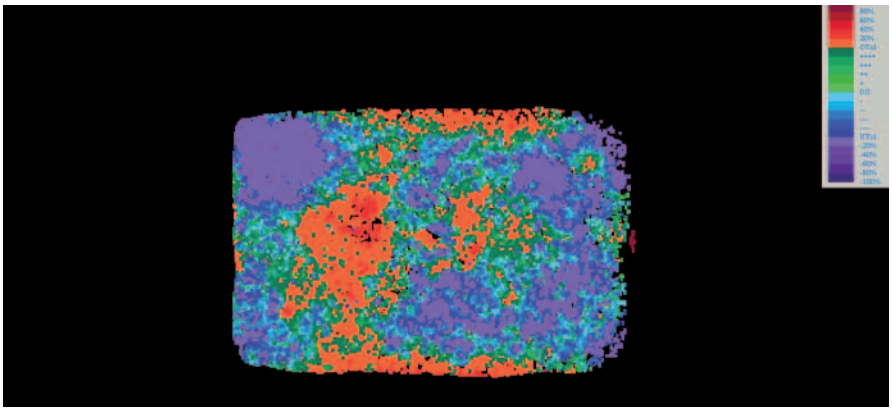

Figure 4. Color-coded representation of the thickness of the electrode layers (red: too thick, violet: too thin; blue and green: within tolerance)

nates with the image processing sensor. Based on the reference coordinate system generated by the optical sensor, the confocal sensor then performs surface measurements at precisely the desired locations. It scans the object in the Z direction and generates images of each individual layer. Marcel Thiele explains: "Using the differences in reflection, we can detect the boundary layers and calculate the distance between them. For every pixel that we address in X and Y, this gives us the distance between the two layers."

The WinWerth® software program, with its 3D CAD module, enables fast, easy analysis of the measurement data and a graphic representation of the 3D surface.

Improving the production process in real time

The measurement results were convincing for the preliminary developers who focus on practical value. The difference from the previous procedure is significant. Previously, X-Y coordinates were captured on a coordinate measuring machine and then each electrode was individually placed on a con-focal microscope to determine the thickness of the transparent layers. Today, the multisensor coordinate measuring machine from Werth performs both measurements automatically in one process step. Entire sheets of sensors with many electrodes can be measured at once. Such a complete analysis can even be run overnight. The Werth VideoCheck® IP works through a sensor sheet unattended, measuring the electrodes with great precision. In the morning, the development team has all of the measurement results available to them.

Marcel Thiele explains: "The high measurement speed also opens up the possibility for us to do a fast check during the manufacturing process, that is, while the individual layers are being deposited. Previously, this was not possible with our measurement equipment due to the time required. To raster a surface of 1 mm x 1 mm with our confocal microscope took at least 30 minutes. With the Werth machine and the raster scanning feature (patent), we are faster by about a factor of 10. This means it is possible to report the errors that we detect to the production process immediately, so that they can be corrected in real time."

Additional sensors can be integrated as needed

Employees in the technology development group at Roche Diabetes Care appreciate the process improvements that the Werth VideoCheck® IP has made possible. The expectations that Dr. Gregor Ocvirk has for a measurement system, however, go even further: "In technology development, we work with a wide range of applications and test systems.

It was thus important for us to have the option of expanding the VideoCheck® IP with other types of sensors, and to be able to adapt the CNC code accordingly, using variable programming, for example. The modularity of this system means that we are well equipped for new measurement tasks." □

Translated by Werth Messtechnik GmbH

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