Application Note

#AN700

Measuring Thickness of Biologically Active Films for Medical Devices and Sensors

Biologically active films play a pivotal role in the realm of medical devices and sensors, where precision, reliability, and compatibility are paramount. These films, often composed of biomaterials or functional coatings, are integrated into a diverse array of applications, ranging from implantable medical devices to diagnostic sensors. The accurate measurement of film thickness is not merely a technical necessity; it is a fundamental requirement that directly influences the performance and safety of these critical biomedical tools.

For instance, in the development of implantable medical devices such as drug-eluting stents or bioresorbable scaffolds, the controlled deposition of biologically active coatings dictates their drug release kinetics and biocompatibility. In diagnostic sensors, the precise thickness of functional layers is essential for ensuring optimal sensing performance, sensitivity, and selectivity. Consequently, the characterization of these films extends far beyond the realm of metrology; it becomes an indispensable facet of the design and quality assurance processes in the biomedical field.

This application note explores the importance of film thickness control in the manufacturing of glucose sensors, tissue sealers, and blood sensors and highlights the benefits of advanced reflectometry and ellipsometry technologies for ensuring the quality, consistency, and performance of these medical devices.

Whole-wafer mapping of film thickness for glucose sensors

Continuous glucose monitoring (CGM) technology has revolutionized the management of diabetes by providing real-time, continuous insights into blood glucose levels. Central to the effectiveness of CGM devices are biologically active films integrated into the glucose sensors. These films are engineered to selectively respond to glucose molecules while minimizing interference from other substances in the physiological environment. Consequently, the thickness of these films directly influences the sensor's sensitivity, response time, and overall performance. Meticulous film thickness control and the ability to measure thickness accurately and repeatably is essential for consistent sensor output.

In general, optical techniques are well-suited for process control in medical device manufacturing environments where film thickness measurement must be non-contact and non-destructive. However, the two most common optical techniques encounter challenges in these environments:

- Optical profilometry methods are tricky because the films are quite thick (several microns or more) and a clear step is not readily available.
- Standard reflectometry and ellipsometry techniques are difficult to accurately decipher because biologically active films are, by design, deposited on rough metal electrode surfaces, causing incoherence in the reflected light from local non-uniformity of film thickness over the measurement spot size.

To achieve coherent, specular reflection from a thick film and rough metal interface, the ideal optical method must have a small spot size and a nearly collimated beam.

The Bruker FilmTek™ 2000M spectroscopic reflectometer is ideally suited to address these challenges. A patented optical design provides a measurement spot size as small as 1 x 2 µm and a nearly collimated beam. This approach allows accurate, non-contact measurement of very thick films, even on rough substrates. With automated wafer handling, 1D/2D barcode scanner, and pattern recognition, straightforward measurements from an entire device wafer can be obtained, eliminating the need to infer broader performance from a limited sample area. Integrated SECS/GEM software allows automated factory control of recipe selection (including recipe change control) and output data.

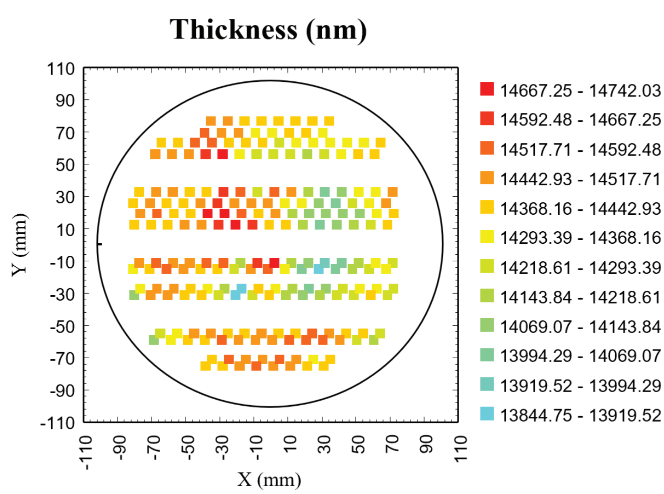

FIGURE 1.

Film thickness data for many implantable glucose sensors over an entire wafer.

In the Figure 1 example, FilmTek 2000M is used to enable the manufacture of implantable glucose sensors for diabetes patients. Film thickness is automatically measured at the active sensor region for each device over the entire product wafer.

Coating thickness mapping on the surface of metal jaws

Tissue sealers play a pivotal role in laparoscopic surgeries by addressing the crucial task of sealing and dividing blood vessels and tissue structures. These devices are designed to optimize hemostasis, reduce postoperative complications, and enhance the overall precision of the surgical process. The integration of tissue sealers into laparoscopic techniques offers surgeons a reliable means to achieve effective hemostasis while minimizing tissue damage. Films or coatings are often applied on the surface of these devices for added lubricity and protection. The precise measurement of film thickness is critical for ensuring biocompatibility, device performance and consistency, minimizing tissue trauma, and regulatory compliance.

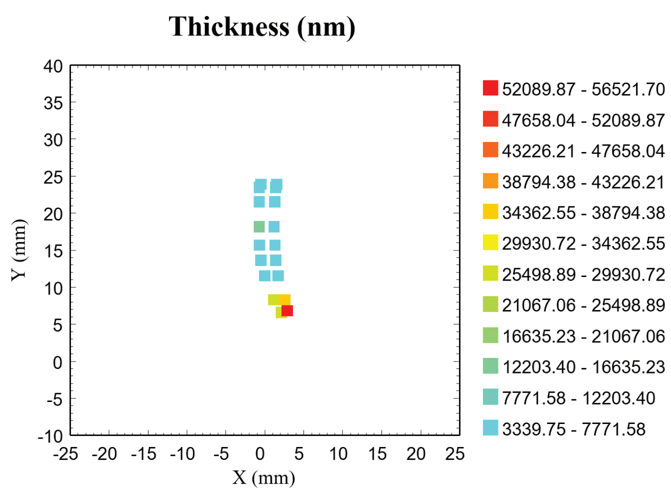

FIGURE 2.

Film thickness data for a nonstick coating on metal jaws, mapped over the surgical device.

The use of small, collimated beam technology in FilmTek metrology tools is applicable to a wide range of substrates including silicon, metal, and glass. In the given example, the thickness of a nonstick coating deposited on the surface of a tissue sealer device was mapped over the metal jaw (Figure 2). FilmTek optical technology provides nanometer thickness accuracy even for film coatings that vary by many thousands of microns over the device.

Film thickness determination for multi-layer stacks in single-use blood sensors

Handheld blood sensors have emerged as pivotal instruments in hospital settings, providing healthcare professionals with a rapid and precise means of analyzing crucial blood parameters, including troponin levels—a critical biomarker for cardiac health. In the context of cardiac care, troponin response serves as a key indicator of myocardial injury, aiding in the timely diagnosis and management of cardiovascular conditions. This point-of-care capability is particularly critical in emergency departments, where immediate assessment and diagnosis are essential for patients presenting with chest pain or symptoms indicative of potential cardiac issues.

The reliability of these handheld blood sensors depends significantly on the meticulous manufacturing processes involved, where film thickness metrology plays a pivotal role. The thin films applied to the sensors serve as critical interfaces between the device and the blood sample, influencing the accuracy and sensitivity. Consequently, precision in each individual film thickness is essential, as it directly impacts the sensor’s ability to interact optimally with blood constituents and provide the correct output. This introduces a crucial need for advanced metrological techniques to measure and control the thickness of these films during the manufacturing process. In this context, film thickness metrology becomes not merely a quality control step but a cornerstone in ensuring the efficacy of handheld blood sensors.

Reflectometry and ellipsometry methods are well suited for non-contact thickness measurement. Spectroscopic ellipsometry is sensitive to very thin films (<250 nm), and reflectometry can quickly measure thicker films (>5 nm). However, the thickness accuracy and the ability to resolve multi-layer stacks ultimately depends on refractive index accuracy, which may be unknown for advanced biologically active films. Multiple solutions are a common problem when characterizing refractive index with these methods, and this uncertainty limits both thickness accuracy and the ability to unambiguously resolve multi-layer stacks.

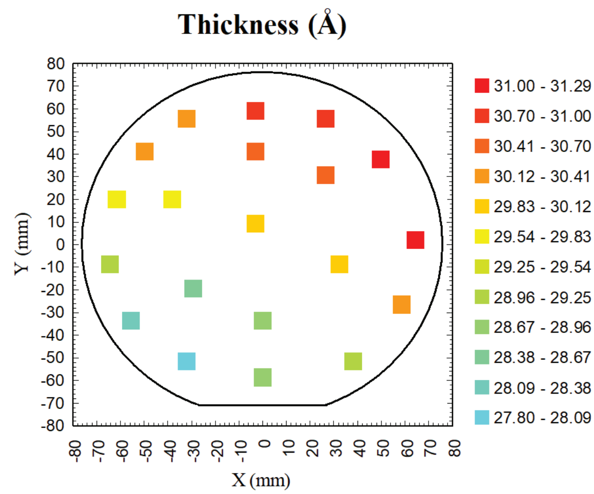

FIGURE 3.

Film thickness mapping for a very thin film in a blood sensor device.

In Figure 3, FilmTek 2000 PAR-SE is used to support the manufacture of single-use blood sensors on silicon wafers. FilmTek's multi-angle and multi-modal measurement technology is well-suited for accurately measuring the very thin films and multi-layer stacks that comprise the active sensor region of these devices. Simultaneous multi-angle measurements introduce a wavelength shift between spectra that is only a function of refractive index. In combination with proprietary modeling algorithms, this additional information content allows the unambiguous characterization of unknown materials and multi-layer stacks. In Figure 3, a very thin 30 Å film is mapped over the wafer with a standard deviation of ~1 Å.

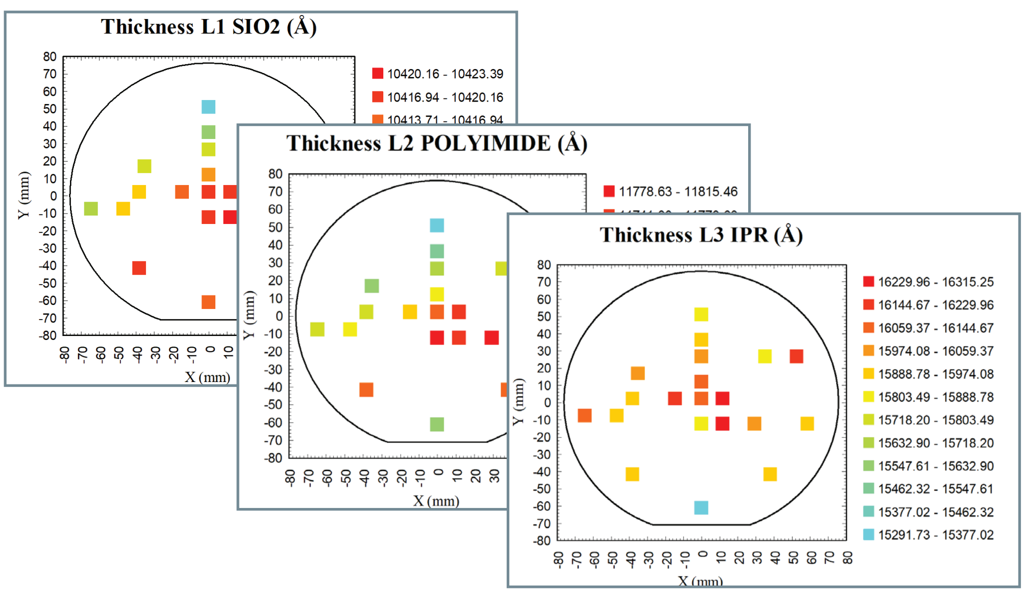

FIGURE 4.

Layer-by-layer analysis (three layers) for a multilayer film in a blood sensor device.

In Figure 4, the thicknesses of a multi-layer stack at the active sensor region are unambiguously determined across the wafer. Accurate and reliable film thickness measurement contributes to consistent manufacturing, regulatory compliance, and the overall quality of these medical devices.

Conclusion

Film thickness metrology tools play a pivotal role in the precision manufacturing of medical devices and sensors. This application note reviewed the application of advanced reflectometry with small, collimated beam technology and multi-angle reflectometry/ellipsometry technology for accurate and robust thickness measurement to the sub-angstrom level. By incorporating these advanced metrology tools and solutions into manufacturing processes, companies can enhance the quality, consistency, and performance of their products. This not only contributes to advancements in healthcare technology but also ensures the safety and reliability of medical devices in real-world applications.

The information in this application note is based on case studies presented in the webinar: Thin Film Characterization Using Spectroscopic Reflectometry and Ellipsometry Techniques | Bruker.

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