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NON-CONTACT MEASUREMENT AND ANALYSIS OF SIX MICRON+ THIN WALL COATINGS ON MEDICAL BALLOONS AND CATHETERS USING LOW COHERENCE INTERFEROMETRY

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1. Abstract

This paper describes a method of analysis of wall thickness of medical balloons and tubing of all sizes using a revolutionary white light interferometry system. Measurements can be taken at all critical dimensions of medical balloons including the balloon sleeves, main balloon body, the shoulder or cone. For main body and tube thickness, values are given for both top and bottom walls, outside and inside diameter.

In operation, infrared light (1310nm) is directed through a measurement probe via optical fiber to the material to be measured. At each juncture of refractive index, some portion of the transmitted light will be reflected back into the probe and some portion will continue through the material. In the case of a catheter, some IR energy will be reflected back to the device at the top and bottom surfaces of the tubing walls, generating measurements of not only the thickness of the walls themselves, but also the inside diameter distance between the walls.

Accurate measurements can be obtained from almost any flat or formed material that allows passage of 1310nm infrared light. Glass, plastic, silicone, or molded parts that are clear, translucent, dyed, and possibly opaque are good candidates for this measurement approach.

This presentation will illustrate advances in measurement of thinner materials than previously reported and discuss measurement of various medical and industrial components such as silicone implants, medical adhesives, capillary flow cells, and medical liquid (blood, saline, etc.) handling bags that can benefit from this new technology. There will be discussion of Research & Development, Quality Assurance, and online process monitoring and control applications.

2. Introduction

The ability to perform non-contact, repeatable thickness measurements with high precision is essential in a wide range of applications in the medical device manufacturing industry. There is a trend towards moving critical measurement activities out of the R&D/QA environment and into a manufacturing setting and the need for instruments to perform these measurements in a real-time mode is increasing. Optical non-contact interferometry can be used to perform these measurements faster and more accurately than existing contact and other methods.

The demand for a robust, accurate, user-friendly, and precise instrument for use in an industrial setting led to the development of the instrument described in this paper. Early work on a robust high precision interferometer was done by Marcus *et al.* [1-4] of Eastman Kodak for a variety of industrial applications, including liquid layer thickness monitoring on coating hoppers, film base thickness uniformity, digital camera focus assessment, optical cell path length assessment, and CCD imager and wafer surface profile mapping.[1]

Building on previous technology, we will discuss developments that provide users with the ability to detect and measure very thin materials and coatings, to a lower limit of six microns.

3. Description of Instrument

This section briefly outlines the theory behind low-coherence interferometry and describes the principle of operation of the instrument and the instrument layout. Advances in hardware and software technology has led to development of the current interferometer which uses piezoelectric (PZT) optical fiber stretchers enabling a system with no moving parts and utilizes telecom-grade 1310nm infrared (IR) Super Luminescent Diode (SLED) and a 1550nm diode laser with long service lifetimes and high reliability. The thin film and coating measurement instrument described in this paper also incorporates additional features such as real-time data acquisition and computation to allow for rapid measurements of thickness in an industrial environment.

Light is projected from the IR SLED onto a surface of the material being measured. When the IR light contacts the surface, a portion of the energy is reflected back and a portion continues through the material. At each new surface or layer where there is a change in refractive index, a small amount of light is reflected back and these reflections are retro-reflected back into the system to fiber stretchers, which causes them to oscillate and generate measurement peaks.

The 1550nm laser acts as an internal clock and reference to measure the distance between these peaks. A signal converter and processor contain the specialized algorithms and application software that produce extremely accurate physical measurements. These calculations are all executed in real time and displayed on the user interface screen. Measurement information can be transferred to software that controls the production process. Figure 1 shows a representation of the flow of light and measurement signals.

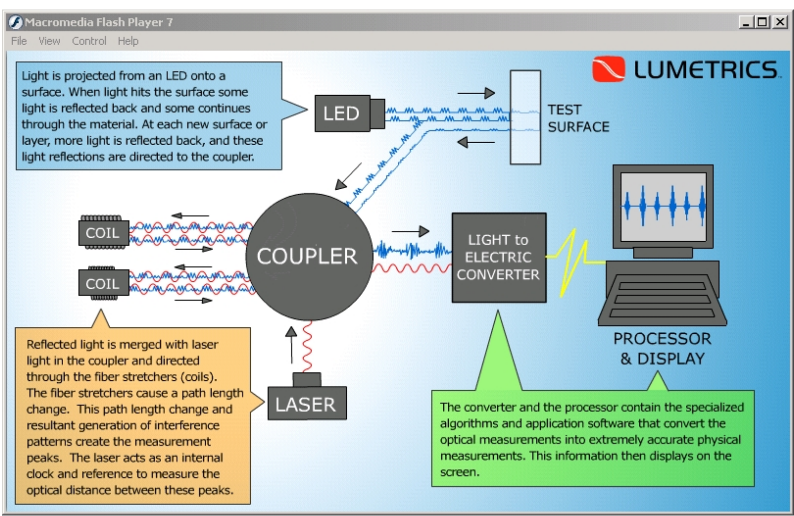

Fig. 1. Basic light flow diagram

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A base system is comprised of an OptiGauge, Controller, and Probe with fiber optic cable. Specific fixtures are designed to accommodate the particular application process or part that is to be measured. Some standard fixturing is appropriate for a number of similar applications. Figure 2 shows the base system with optical measurement probe; fixturing will be described in a later section.

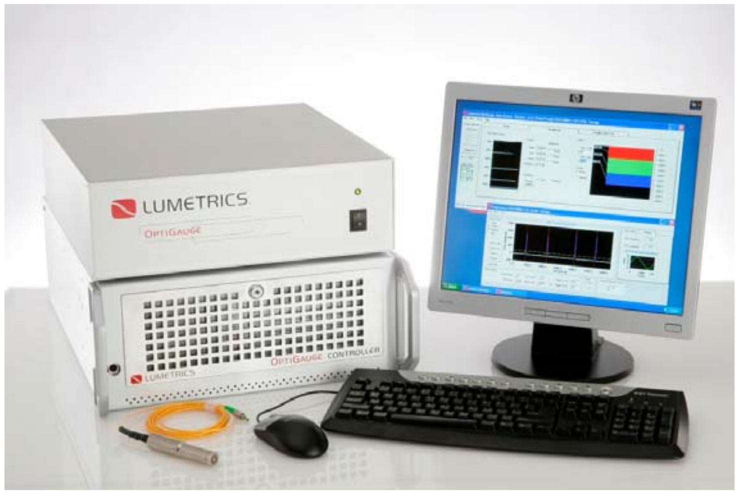

Fig. 2. Basic Interferometer System

4. Theory of Operation

This technology utilizes the well known optical phenomenon of Fresnel reflection which essentially states that when light travels from or through one medium to another (such as from air to plastic), a fixed amount will be reflected back from the interface between the two media based on the change of refractive index if the intervening materials. Figure 3 illustrates the process of Fresnel Reflection for a sample with 2 layers of different refractive index. For an interface between air and plastic, the index will change from approximately 1.0 to 1.5, and the amount of reflected IR light will be about 4%.

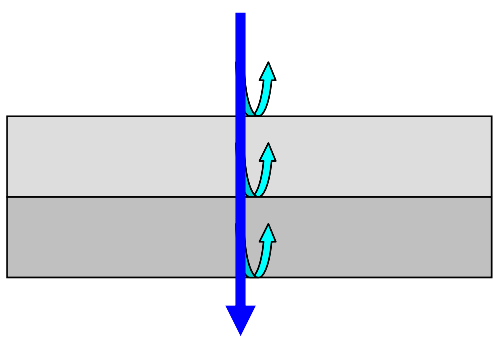

Fig. 3. Fresnel reflection from 2-layer sample

Building on this transmission and reflection of light from internal boundaries of the material being measured, the OptiGauge combines these reflections with an internal laser (1550nm) light source that provides extremely tight timing to that results in very accurately measured single layer or multi-layer material thickness.

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4.1.Angular Alignment of the Probe

In order to measure thickness of a sample, light from the probe must be retro-reflected off the sample and back into the probe, where it is re-coupled into the same optical fiber. Therefore, the sample surfaces must be perpendicular (or nearly so) to the probe beam. Figure 4 illustrates the angular alignment of the probe. In practice, the angular tolerance of the probe is ±1.5°.

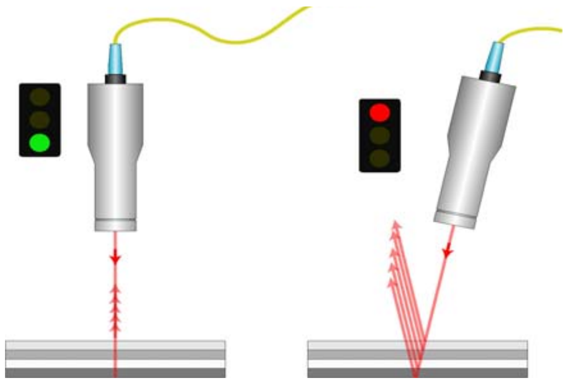

Fig. 4. Angular Alignment of TheProbe

Note: The Measurement probe is an intrinsically safe light delivery and gathering component and does not actually measure thickness of subject materials.

4.2. Measurement of Round Tubing and Balloons

In the case of round tubing and balloons, Fresnel reflections from all surfaces of the tube or balloon will be parallel only when the probe beam is aligned with the center of the sample. Figure 5 illustrates this condition.

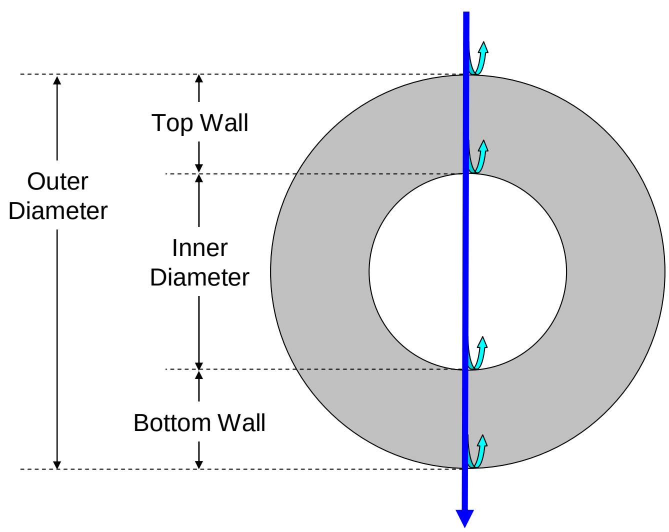

Fig. 5. Fresnel Reflection from Single-Layer Round Sample

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5. Instrument Display

The OptiGauge controls are straightforward and provide operators with real-time measurement data on the parts of interest.

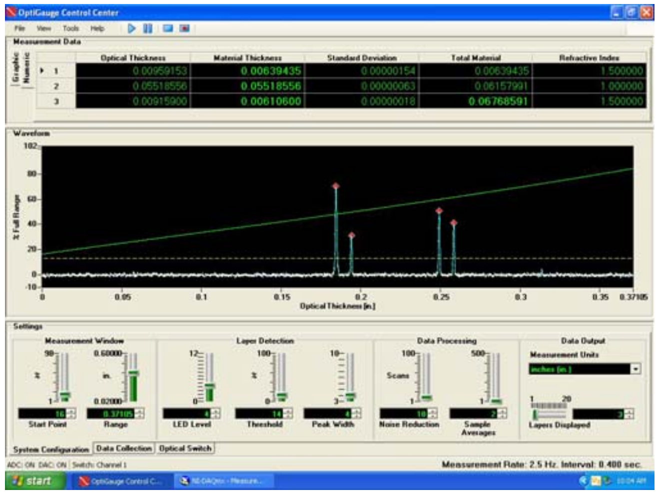

Figure 6. - OptiGauge Control Interface

6. Component-Specific Positioning Fixtures

As described above, positioning of the optical probe is critical to obtaining sufficient reflections to generate correct measurement of flat material, tubing or balloons. Figure 7 represents a simple manually positioned v-block stage that was used to measure the balloons in this study. Others were measured using a variable-angle platform shown in Figure 8 which rotates to measure irregular angles from the tubing to the neck of the balloon. The third fixture shown in Figure 9 is a fully automated station that rotates samples through different angles where measurements are taken. The system automatically displays Upper/Lower Wall Thicknesses, ID, OD, Ovality and Concentricity of the sample. Figure 10 is a screen display of tubing measurement information generated with the automated measurement fixture.

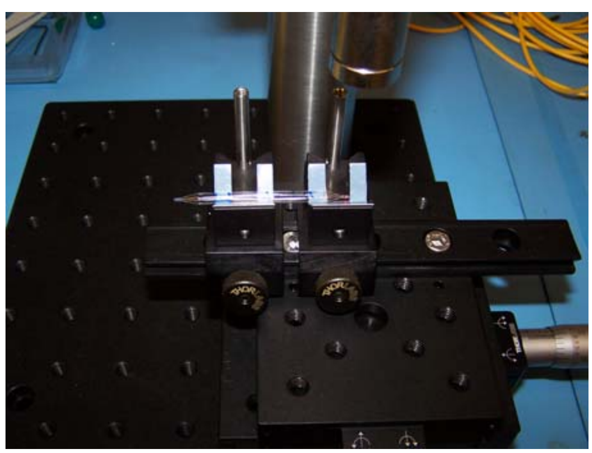

Fig. 7. Manually Positioned Balloon Body & Sleeve Measurement

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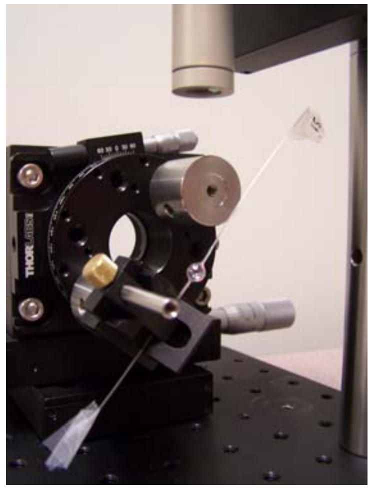

Fig. 8. Rotational Balloon Cone Measurement

Application-specific measurement fixtures have been created to assist medical device research and quality assurance teams in understanding the physical characteristics of new angioplasty products. In this photograph, an off-the-shelf rotational stage has been fitted with positioning clamps to allow measurement of critical dimensions on a variety of irregularly shaped molded components.

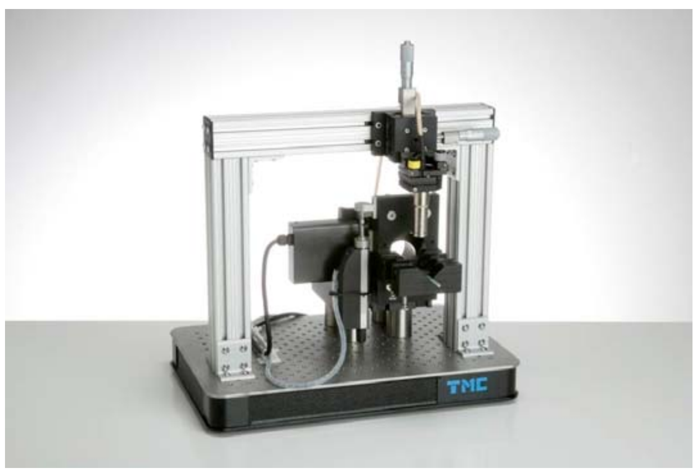

Fig. 9. Automated Tubing Measurement Apparatus

With low coherence interferometry, it is possible to automate the catheter and balloon characterization process by quickly delivering key data on medical products, including Wall Thickness, ID, OD, Concentricity, and Ovality. Recently developed opto-mechanical systems provide all key measurements simultaneously to ensure product quality and safety.

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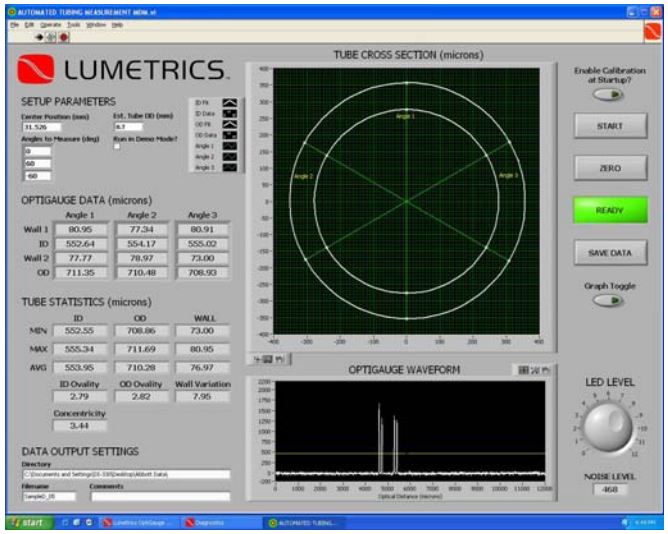

Figure 10. Cross Section Data from Automated Tubing Measurement

Where traditional measurements are provided by touch gauges which measure both sides and assume they are the same thickness, this interferometry approach measures each side individually and simultaneously. The technology is also able to gauge irregularly shaped positions such as cone thickness of a balloon.

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7. Six Micron+ Thin Coating & Wall Measurement

Recent technology development of the OptiGauge-6 variant represents an improvement over the existing OptiGauge and is optimized to measure thin layers down to 6 microns in thickness. The resolution improvement is achieved using technological advances in the field of the super-luminescent diodes (SLED's).

The spectral width of the new light source in OptiGauge-6 reaches 120 nm, compared to 55 nm in a standard OptiGauge. The spectral width determines the minimum thickness resolution of the system. The high spectral width corresponds to a narrow coherence function which defines the resolution of the system.

In addition to using the new SLED, Lumetrics also implemented polarization controlled illumination and data collection. The need for this technology is dictated by the presence of birefringence in many thin wall balloons. Birefringence manifests itself through apparent shifting of the refractive index of the material being measured and appears due to strain in plastic during the manufacturing process. If polarization control is not implemented, it may lead to uncertainty in thickness measurement and subsequent measurement error.

To take advantage of polarization control and minimize operator error, the optical probe is oriented axially along the balloon. The fiber connecting the probe to the OptiGauge is a specialized polarization fiber and the probe housing contains marks that indicate correct orientation of the main optical axis.

Figure 11 shows the typical measurement waveform for a balloon with a 7 micron coating. The group of peaks (b) corresponds to the balloon wall and the coating. Peak (a) is a reference peak; it is always present on the waveform and is required to obtain the topographical images of the balloon using the technique developed by Lumetrics. Occasionally, more peaks (c-e) can be visible on the waveform which are artifacts of the polarization control technology, and should be disregarded. They do not affect the thickness measurements when the "Threshold" level (dashed brown line) is positioned above the peaks.

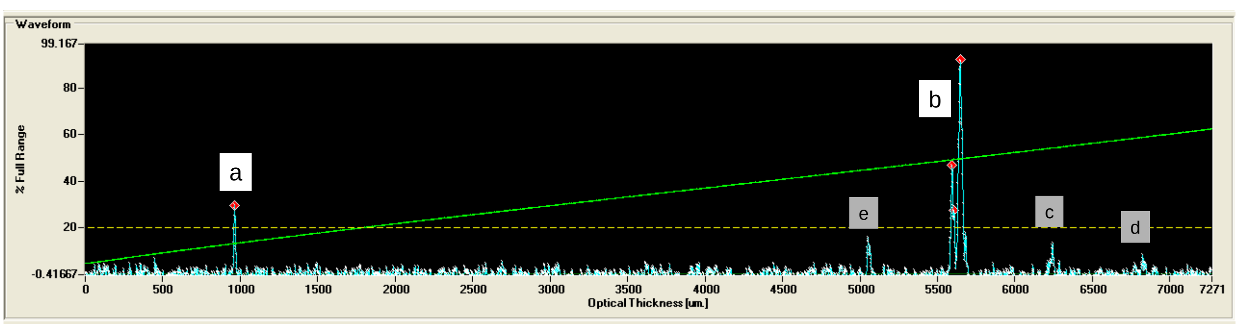

Figure 11. Typical Waveform for Balloon Measurement

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Figure 12 is the zoomed-in view of the group of peaks that correspond to the wall and the coating of the balloon. The curve contains three main peaks (a, b and c) and several smaller peaks. Peak (a) corresponds to the interface between the coating and the air. Peak (b) corresponds to the interfaces between the coating and the wall of the balloon. Peak (c) corresponds to the interface between the inside wall and the air. The distance between peaks (a) and (b) corresponds to the thickness of the coating, and the distance between (b) and (c) corresponds to the thickness of the balloon wall.

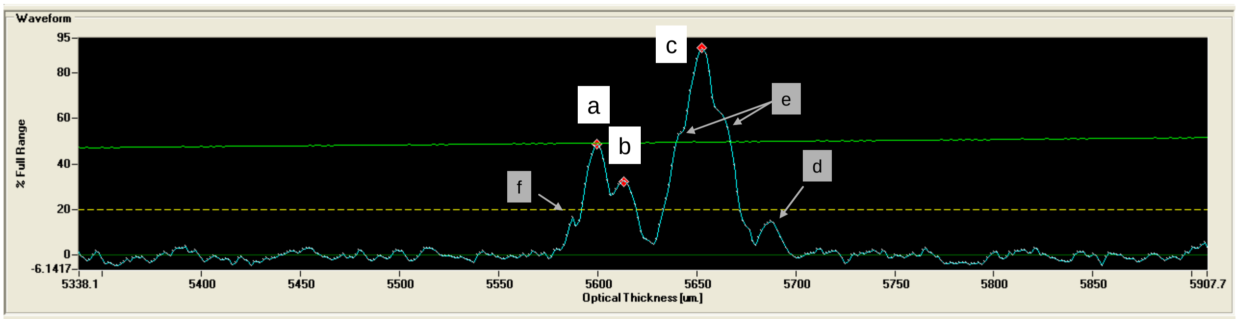

Figure 12. The group of peaks that represent the balloon wall and the coating.

Due to the nature of this new light-source technology, the appearance of measurement artifacts corresponding to minor side-lobes on the measurement peaks may be evident. In the figure above, peaks (d – e) appear due to the spectral shape of the SLED not being an ideal Gaussian form.

- The presence of the side peaks does not affect the distance primary measurement capability of the system and with operator training and experience, the presence of irrelevant side peaks becomes readily apparent and measurement of the "real" coatings and walls becomes relatively straightforward.

8. Other Measured Products

Various medical products have been measured using this approach including plastic and silicone dipped, blown, and extruded products. These include breast implants, medical balloons of various types, coatings on stents, medical fluid bags such as blood bags, and other soft products. Additionally, numerous glass products have been measured including molds, components, flow cells, and tubing of many sizes. This new measurement approach provides rapid peak identification resulting in extremely accurate measurements both on line and in a lab environment.

9. System Applications

Overall, OptiGauge interferometric technology has proven extremely useful in the areas of Research & Development, Quality Assurance, and online process monitoring and control applications.

As an R&D tool it provides engineers the ability to make measurements that were completely impossible prior to this technology. In the area of medical balloons for instance, engineers are able to measure wall thickness continually along a balloon as the balloon is undergoing burst testing. This allows the engineer to determine uneven heating and stretching along a balloon during manufacture and provides an in depth view of the structure of the balloon. Having immediate measurement capabilities provides rapid analysis of product failures and speeds up development in general by identifying problems early in the development process.

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Additionally, this tool provides process control engineers a tool to quickly move new products from the lab to the factory by identifying and eliminating problems in the production process. Prior to this instrument, identifying thickness problems was time consuming and measurements were difficult to obtain. Once a process is identified and established, the system provides an effective tool to monitor the process and provide a process control loop.

The third use for this approach is in the area of Quality Assurance of produced products. The system, in conjunction with fixturing such as shown in Figure 9, allows repeatable, accurate measurements of products. This tubing fixture allows a tube to be rotated to three or more different positions around a tube and provide enough measurements that a confident maximum wall thickness, I.D., O.D., Ovality, and concentricity can be provided. A tube can be scanned along the fixture so that longitudinal measurements can be recorded along its length. These measurements can be done in a fraction of the time, and significantly more accurately, than those using manual comparator and pin gauge methodologies. Figure 10 shows a typical results screen of a single tubing sample.

10. Conclusion

The varied measurement approaches demonstrated throughout this paper show the accuracy, repeatability, and consistency of interferometric measurement of balloons and catheters of various types. With proper fixturing and integration into process control systems this technology provides advances in the production of medical components that increase quality, and decrease costs while providing critical dimensions earlier in the production process. Measurements can be obtained quickly and with less operator variability with this technology than with traditional manual (destructive) pin gauge and micrometer methods. This technology also provides considerable advances in the development of new products and processes by providing engineers with critical information on components that up till now they have not been able to obtain.

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3. M. A. Marcus, J-R Lee, H.W. Harris and R. Kelbe, "Apparatus for Measuring Material Thickness Profiles," U.S. Patent #6,067,161, 2000.
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