

Sample Measurement Testing - Medical Balloons

Lumetrics' OPTIGAUGE™ Thickness Measurement System is ideal for measuring balloons, catheters, and other medical devices. It is in use by medical device companies throughout the US. The system is comprised of the OPTIGAUGE, a control unit, and probe. The OPTIGAUGE™ Thickness Measurement System is non-contact and uses light reflections from an infrared source directed at the sample to accurately calculate up to 50 measurements per second. An internal calibration source maintains an accuracy of 0.1 micron (.000004"). Continuous measurements can be directed to a statistics program or provide feedback to a process control system for automated operation.

Where traditional measurements are provided by touch gauges which measure both sides and assume they are the same thickness, the OPTIGAUGE measures each side individually. The OPTIGAUGE also measures those impossible to reach locations like the beginning angle of a balloon.

In one application, medical balloons were tested for thickness at various points along the balloon and catheter and all were measured with very consistent results. The balloons were measured at 6 locations and a scan was performed on one of the balloons as well. All measurements showed the greatest thickness on the tube, then gradually thinning on the edge of the balloon and decreasing to a minimum thickness of 14 microns.

The probe is positioned perpendicular to the surface of the balloon or tube to give the best signal returned to the system. Figure 1 shows the fixture which allowed the measurements to be taken from approximately the same location.

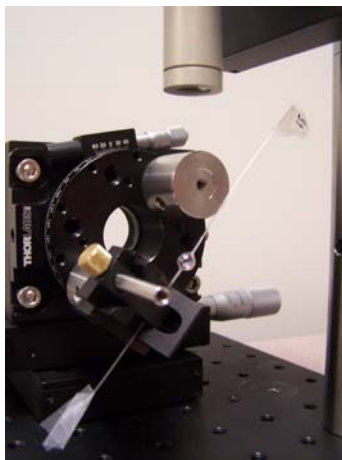


Figure 1 – Fixture with balloon

OptiGauge Precision Thickness Measurement

The balloons were blown up with a syringe to maintain a round shape and allow easy measurements. This measurement could also be performed on a manufacturing fixture to provide real-time measurements and feedback to the process. Figure 2 shows the Lumetrics instrument display screen with the wave form representing the walls and ID of the tube. Figure 3 shows the physical measurements of the tube walls, ID, and OD.

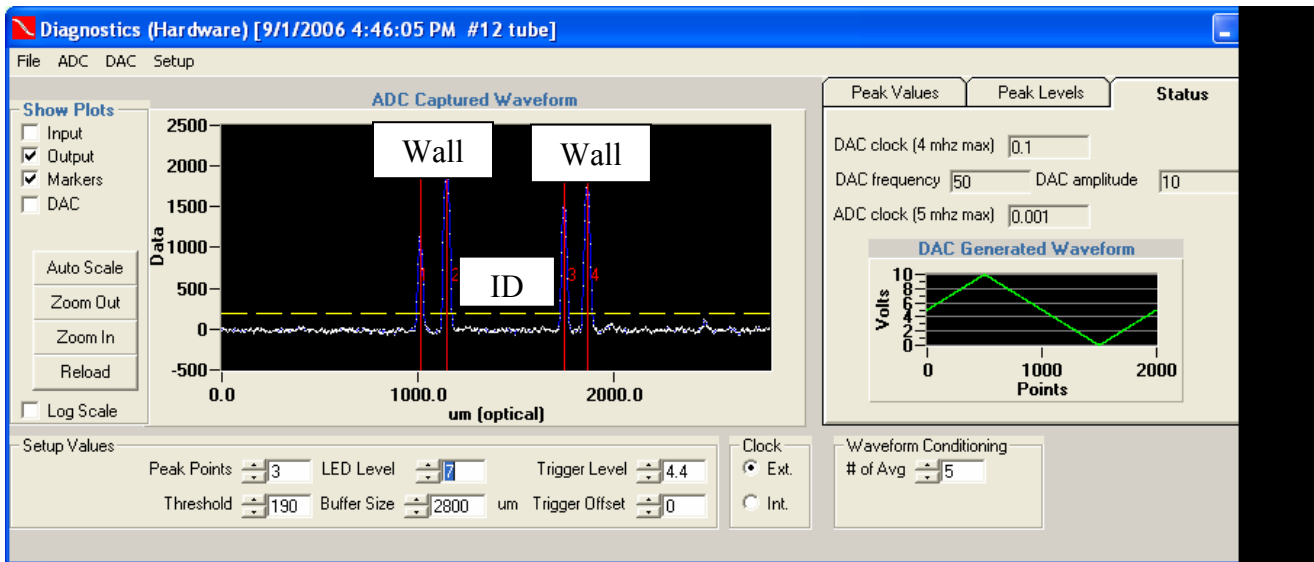


Figure 2 – Diagnostic screen showing wall thickness and balloon ID

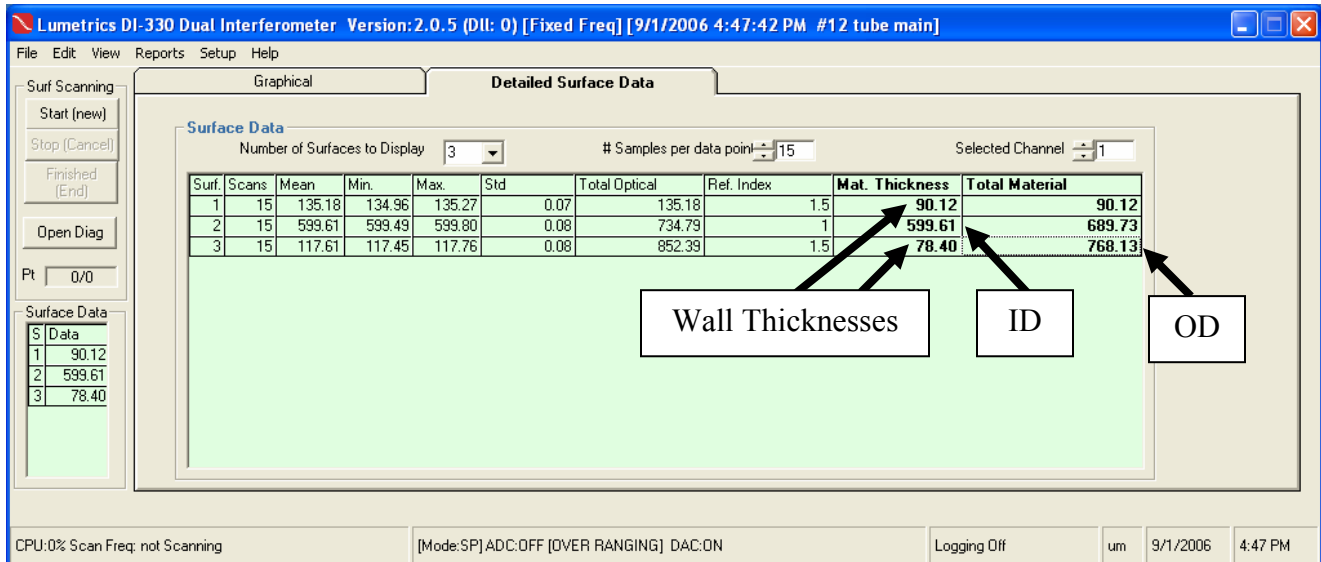


Figure 3 – Main screen measurements

OptiGauge Precision Thickness Measurement

Figure 4 represents the balloon and the respective locations of each of the measurements. Figure 5 represents the raw data from each of the measurement points on the balloon and Figure 6 is a graphical representation of those data points.

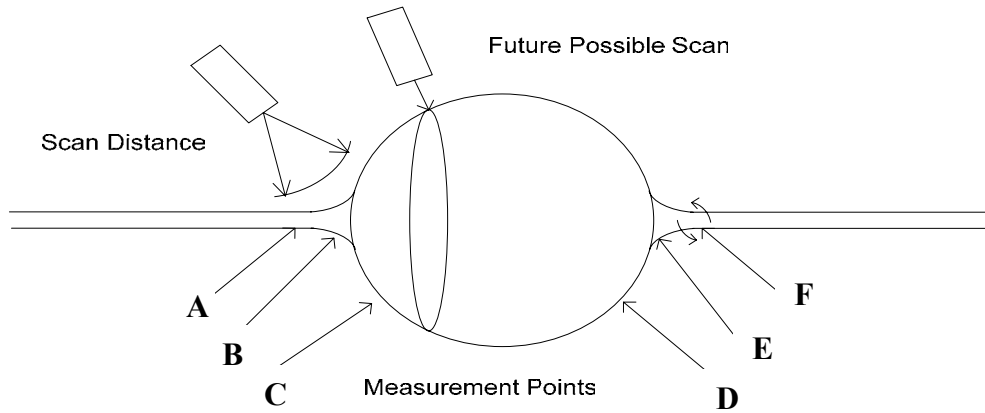


Figure 4 - Balloon scan

Sample	A	B	C	D	E	F
1	79	59	16	14	84	92
2	91	75	16	16	68	78
3	83	61	14	18	82	98
4	90	79	18	15	77	83
5	97	60	24	15	58	104

Figure 5 - Sample Data

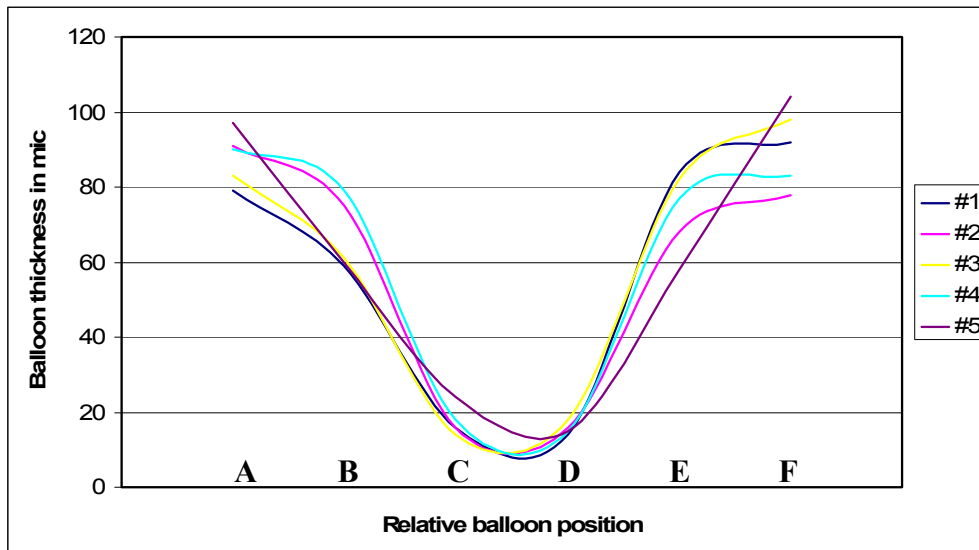


Figure 6 - Raw Data chart

OptiGauge Precision Thickness Measurement

The raw data points were consistent with the expected thickness change from the catheter to the balloon. There was minimum variability between the thicknesses of the tubes. The data showed a consistent method for measuring the thicknesses of balloons. This data can be extrapolated to different shapes and sizes of any balloon.

Additionally, two scans were taken of one side of a tube, with consistent results between the scans and with the individual point measurements. The balloon was measured from the tubing wall near the balloon and up into the balloon; from position A up to position C with a second scan from position C back to position A. See Figure 4 for a diagram of the balloon scan. Figure 7 shows a graph of the data.

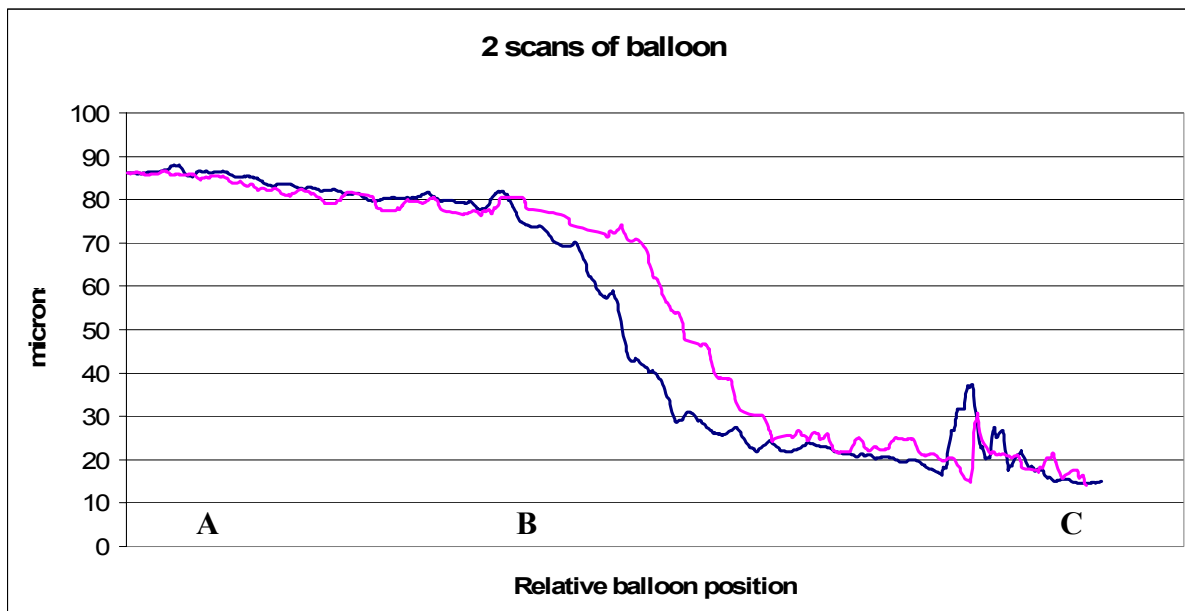


Figure 7 – 2 simultaneous scans of single balloon

These data points showed the accuracy and consistency of Lumetrics' OPTIGAUGE in measuring balloons and catheters of various types. The OPTIGAUGE provides more accurate and consistent measurement of balloons and with automated processing can provide quicker evaluation as well. We look forward to working further with our balloon customers to ensure the highest quality product to their customer as well as the most efficient way to measure these products both in the lab and on line during production.