

OPTICAL THICKNESS MEASUREMENT OF CORONARY BALLOONS AND MEDICAL TUBING

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Abstract—Medical device manufacturers often struggle when inspecting balloons, tubes, stents, and other medical products with many simplistic measurement devices in use today. There are limitations when using micrometers, microscopes, pin gauges, and razor blades that limit accuracy, repeatability, and general ease-of-use.

Lumetrics' low-coherence interferometer, OptiGauge II, is a device capable of measuring the simultaneous wall thickness, inner-diameter, and outer-diameter thickness of medical devices. Combined with custom software and automated scanners, a medical balloon or tube can be fully profiled quickly and accurately, on-line or off-line.

I. INTRODUCTION

Medical grade tubing and balloons must be held to extremely tight tolerances for wall thickness, concentricity, and ovality. Manufacturer's need a system that has repeatable measurements, high accuracy, easy to use, and could be used either online or offline.

Lumetrics offers off-the-shelf solutions to address the metrology needs associated with these products, as well as providing opto-mechanical or software development expertise required to develop a custom measurement solution.

II. LUMETRISCAN 360

The LumetriScan 360 is an automated measurement system designed for clean rooms (ISO Class 7) for off-line inspection of medical tubes and balloons. The system is designed to:

- Easily load the parts into a rotating fixture with interchangeable mounts
- Inflate a part up to 120psi
- Load a part-specific scan routine from a library to profile the part for wall thickness, ID, and OD
- Take multiple measurements at any location along the length of a part and at various angular positions
- Provide a customized inspection report
- Reduce product development cycle time by providing data quickly to engineers

- Increase measurement productivity by reducing inspector variability
- Less waste due to non-destructive testing
- Increase product compliance as well as the ability to meet quality requirements

Many different sized tubes and balloons can be used in the LumetriScan 360. The system provides replaceable clamps to allow for tube sizes from .030" to .520" (Figure 1). An adjustable support structure placed along a sliding rail gently supports the product when inserted into the pneumatic clamp and while rotating. The optical probe is mounted in a carriage that traverses along the tube length to positions defined by recipes (Figure 2).



Figure 1: Rotational Stage with Removable Collet



Figure 2: Traversing Measurement Probe

The LumetriScan 360 provides a fully programmable menu structure to allow any number of measurement points across the product you are measuring. Around the product or along its length, the LumetriScan 360 provides a method to obtain multiple measurements with no manual intervention.

A balloon sample was measured in the LumetriScan 360 at ten different points along the length of the balloon's body. The thickness of the first wall, air gap, and second wall are easily measured along the length of the balloon. Figure 3 and 4 show the results of the testing.

Customers have used the LumetriScan 360 to provide precise dimensions and geometry of balloons and tubing during development. Customers are able to identify potential issues and deliver products that meet customer requirements.

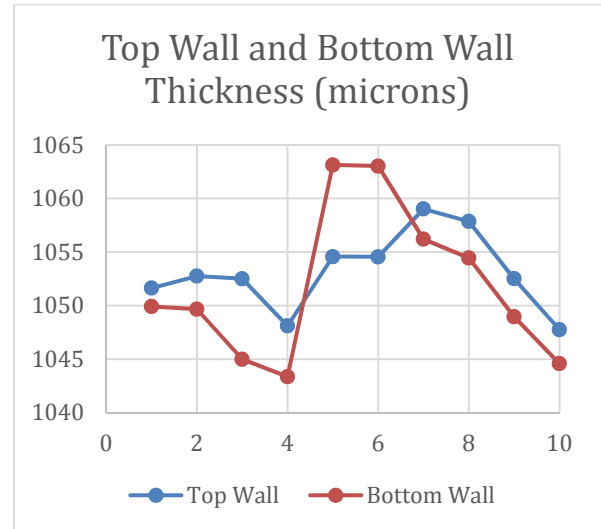


Figure 3: Wall Thickness Measurements

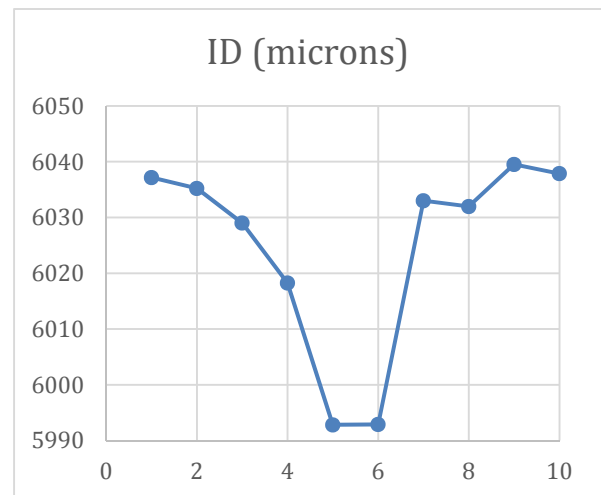


Figure 4: ID Thickness Measurements

III. CONCLUSION

The LumetriScan 360 is a powerful non-contact optical measurement instrument. It can precisely measure wall thickness, ID, OD, concentricity, and ovality of transparent and even visually opaque materials, like medical tubing or balloons.

Lumetrics' engineers can quickly answer any questions pertaining to software communication with these products, mechanical mounting, or any other technical question to help you evaluate your metrology options.

Contact Lumetrics for additional information

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