

OptiGauge by Lumetrics *Dimensional Measurement Authority*

Lumetrics OptiGauge for Tubing Applications

The OptiGauge is a versatile precision measurement system that improves product yields, provides repeatable accurate measurements of most medical tubing, and can be integrated into the manufacturing process. Lumetrics has provided systems for some of the largest providers and users of medical tubing for uses as diverse as balloon, catheter, shrink wrap, drainage, and other medical applications.



In the past, most medical companies have relied on inspection tools developed in the 19th century and earlier to provide acceptance and rejection results for their advanced medical products. Razor blades, pin gauges, the micrometer and microscope are the predominant tools of the trade.

Medical companies are realizing the requirement for gauging the wall thickness, inside and outside diameter, ovality, and concentricity of their tubing is critical to product performance.

OptiGauge by Lumetrics is fast becoming the industry standard for high speed, repeatable, accurate, non-contact measurement of a variety of tubing in both on-line and laboratory settings.

OptiGauge Features

- Non-contact precision gauging
- Super luminescent infrared optical measurement beam
- Requires no liquid medium for accurate operation
- Single or multiple layer material
- Repeatable measurements from 12 microns to 8mm thick
- Sub-micron accuracy
- Lightweight probes can be used up to hundreds of feet from controller
- Easily replaced and adjusted probes can be installed in minutes on the production line
- Multiple points can be measured using Lumetrics' optical switch
- High speed data acquisition 50Hz – 200Hz
- Ethernet ready

QA tubing application

A prominent medical tubing and balloon manufacturer approached Lumetrics with a need for a non-contact, waterless inspection system for at-line measurement of their tubing products. The system was required to provide at-line QA inspection and approval of product. Lumetrics provided its Automated Tubing measurement system, and then integrated it into the customers' internal parts database.

Lumetrics:

- Designed and built a self centering, automated tubing manipulation stage and software

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- Provided an easy to operate user interface with minimal operator adjustment
- Used dimensional information from the customer's database
- Simultaneously measured tube wall thickness, inner diameter, outer diameter, ovality and concentricity
- Provided pass fail acceptance criteria through simplified user interface for each inspected part
- Automatically downloaded test results to a central data storage system.

The system was installed in a clean room environment although any manufacturing environment is acceptable. The customer found that they had much more accurate measurements in less time, with reduced operator error. Additional systems were installed and integration into their online production process is underway.

Production Line startup and qualification

One customer used the OptiGauge to bring a new production line online in record time. The customer, a developer of bio-absorbable polymeric medical implants, dramatically reduced product development time of complex medical tubing. The use of the OptiGauge provided never-before obtainable data regarding physical attributes of custom polymer-based tubing under development at the customer's site. Using Lumetrics OptiGauge thickness measurement system, including an Automated Tubing System, the customer was able to quickly and accurately determine size and form characteristics of a challenging new product design.

“Originally intended to be a QC instrument for monitoring production, the OptiGauge has allowed us to quickly and easily determine the geometry of our tubing during development”, said the company president. “This information has enabled us to immediately identify abnormalities in prototypes, isolate the cause, and take corrective actions. The speed with which we were able to make changes to the process as we moved from startup to fine-tuning, reduced the time to produce qualified product from 4-6 months to just weeks.”

The company's challenge was to provide very precise dimensions and geometry for their customer, utilizing new raw materials and manufacturing methods. “The Lumetrics' OptiGauge can identify very small product irregularities, which our manufacturing equipment supplier then used to fine-tune their systems, dramatically reducing the time required to produce tubing that met our customer's specifications,” said the president.

Luminescent Technology uses optical, non-contact techniques to provide highly accurate dimensions and form characteristics of thin-walled medical devices. This eliminates human error in associated manufacturing and quality control processes of products such as stents, catheters and balloons.

As a part of the customer's OptiGauge system, Lumetrics also provided a semi-automated tubing fixture to simultaneously measure wall thickness, ID, OD, concentricity and ovality of their tubular product in seconds, -- to sub-micron accuracies. These metrics could be integrated into a quality control database,

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where comparisons with expected dimensions can be used to generate pass/fail recommendations in real time. Speed, accuracy, and reliability all far exceed traditional measurement methods. Lumetrics worked closely with this customer to provide individualized fixturing and software in an integrated manufacturing environment and prides itself in providing full solutions as part of a partnership with our customers, to meet their specific measurement needs.

OptiGauge inspection installations

Numerous additional customers have since installed the OptiGauge and the Automated Tubing System to provide them with improved inspection capabilities. Many are using the system because of its unique ability to accurately measure the exact dimensions of the tubing walls. This becomes crucial in the production of many medical products especially medical balloons and biodegradable stents and similar products. Wall thickness of the initial tubing has a direct correlation with the resulting measurements of the finished product, and this has an impact on how the system operates within the patient.



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OptiGauge Specifications

OptiGauge

Model	OptiGauge DI-340
Measurement Method	Low Coherence Interferometry
Target Materials	Single or Multi-Layer Glass, Plastic, Tubing, Silicon, Coated Metals
Maximum # of Layers	Up to 20
Thickness Measurement Range	12 μ m to 8mm Mechanical Thickness (Refractive Index - \approx 1.5)
Accuracy	\pm 0.1 μ m
Repeatability	0.1 μ m 1 σ
Measurement Scan Rate	50Hz - 200Hz
Power Requirements	AC 110V - 240V 50/60Hz
Light Source	1310nm SLED
Dimensions	419mmW x 457mmD x 133mmH/16.5"W x 18"D x 5.25"H
Weight	20lbs./9kg
Operating Temperature Range	15 $^{\circ}$ to 30 $^{\circ}$ C (59 $^{\circ}$ to 86 $^{\circ}$ F)*
Non-Operating Temperature	-15 $^{\circ}$ to 60 $^{\circ}$ C (5 $^{\circ}$ to 140 $^{\circ}$ F)
Operating Relative Humidity	10 to 90% (non-condensing)
Maximum Altitude	2000 meters (6560 Ft.)
Data Outputs	RS-232, Ethernet via .NET Remoting

* Published accuracy at temperature range 20 $^{\circ}$ to 30 $^{\circ}$ C

OptiGauge PC Controller

Operating System	MS Windows XP, Microsoft Dot Net Remoting
Processor	Intel Core-2 Duo
RAM	1GB
Hard Disk	80GB SATA
Power Supply	500W Universal Input
Video	ASUS EXP1600PRO w/256mb DDR RAM
Software	Lumetrics OptiGauge Control Center
Dimensions	432mmW x 533mmD x 178mmH/17"W x 21"D x 7"H
Weight	28Lbs./13kg

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OptiGauge Measurement Probes

Focal Length (Working Distance)	25mm and 50mm
Optical Fiber Length	8M standard, up to 1000M Maximum
Vertical Z-Axis Tolerance	±5mm
Angular Tolerance	25mm Probe - ±2° 50mm Probe - ±1°
Probe Dimensions	25mm Probe - 21.6mm Diameter X 108.7mm Length 50mm Probe - 21.6mm Diameter x 78.2mm Length
Operating Temperature Range	0°C - 100°C
Optical Fiber Bend Tolerance	50mm Minimum Bend Diameter

Optical Multiplexer Switch

Capacity	Up to eight probes on one OptiGauge system
Switch Time	≈100ms
Dimensions	432mmW x 254mmD x 45mmH/17"W x 10"D x 1.75"H
Weight	4.2lbs./1.3kg