



MEDICAL BALLOON SAMPLE MEASUREMENT REPORT

DISCUSSION

A leading medical device manufacturer provided Lumetrics with samples of two sizes of thin walled tube. The tube labelled 'A' was longer than the tube labelled 'B'. Both tubes are made of flexible, thin-walled material and have varying outer and inner diameters.



Figure 1 - Samples

The customer requested wall thickness, ID and OD measurements at specific locations. The tubes were requested to be inflated to 5Kpa during measurement.



Measurement points for balloon

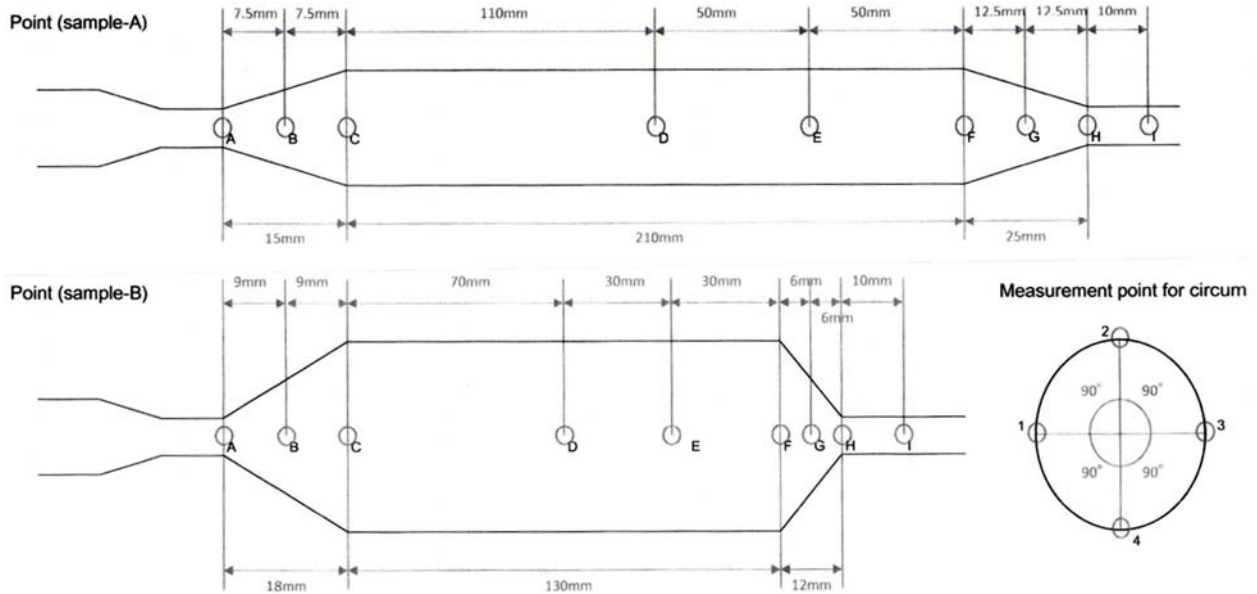


Figure 2 - Measurement Criteria and Positions

PROCESS

An OptiGauge EMS with a 100mm probe was used to do the sample testing. These samples require the use of the OptiGauge EMS and the 100 mm probe due to their ability to measure from 12 microns to about 50mm. With this equipment measurements were obtained for wall thickness, ID and OD all at the same time.

The samples were fixtured into the Manual Cone Thickness Inspection (MCTI) station. This fixture is specifically designed to hold tubes like these, inflate them to a desired pressure and position a probe to interrogate the samples. In addition the probe positioning is allowed to rotate to capture the areas where the walls are angled.

To hold the samples in the MCTI, small metal tubing was used in the ends of the sample to clamp them. This was because the samples have such flexible walls.

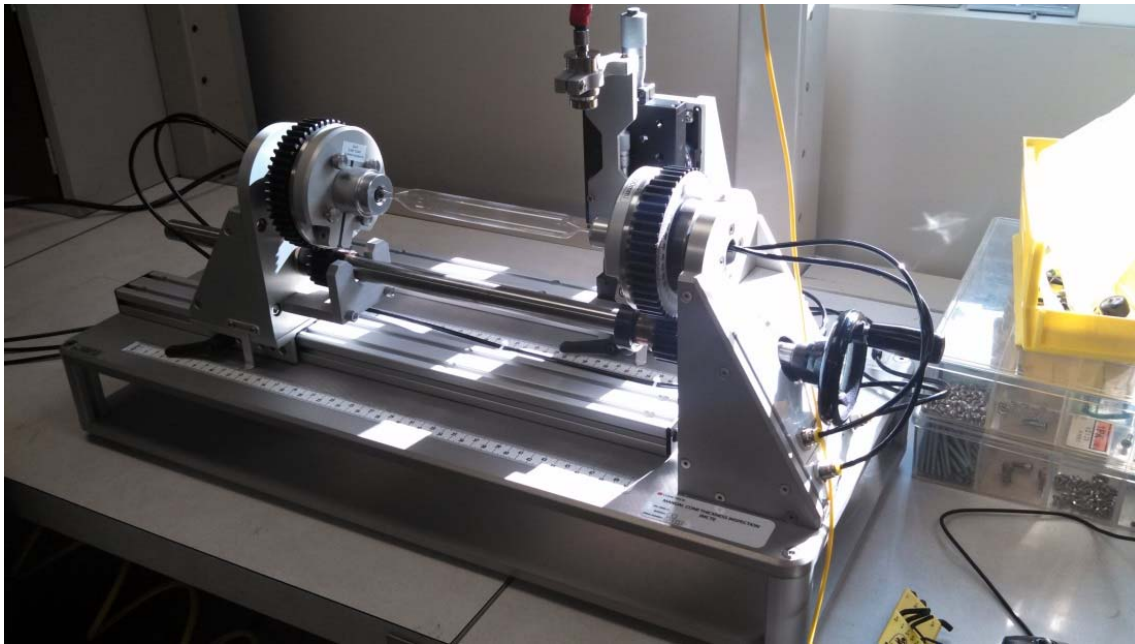


Figure 3 - Manual Cone Thickness Inspection Station with Sample B installed



Figure 4 - Metal Tubes to Allow Clamping in the MCTI



Figure 5 - Sample B with the Small Metal Tubes Installed

Both samples were tested to the criteria in Figure 2. For positions A, C, D, E, F, H and I the process was to position the probe above the sample to measure the near wall, ID, far wall and therefore OD. The sample was then rotated 90 degrees and the probe measured the near wall, ID, far wall and therefore OD. Since when the tube was inflated, the corner at position C and F was well rounded, the probe was positioned as close to the edge of the cone as possible. Also Position I was not spaced as requested from Position H because it would have been inside the clamp. The actual spacing is listed in the results for all points.

For positions B and G, the probe was rotated perpendicular to the cone and then 4 measurements were taken at 90 degree increments. It was not possible to use the same method as the other positions because the angle of the cone would prevent the light from returning to the probe for the far walls. Also the positions of these points were estimated between A and C and F and H.

The tube was requested to be inflated to 5 KPa. The system uses gauges that display PSI. 5 KPa is equivalent to ~0.75 PSI and the gauges resolution is 1 PSI. Therefore a pressure of inflation that was just high enough for the gauge to read 1 PSI was used. Sample A was long enough to sag in the middle. In order to prevent the sag, a small tripod with a bent piece of sheet metal was placed under the sample to bring it close to level.

All measurements were done with an RI of 1.5*.

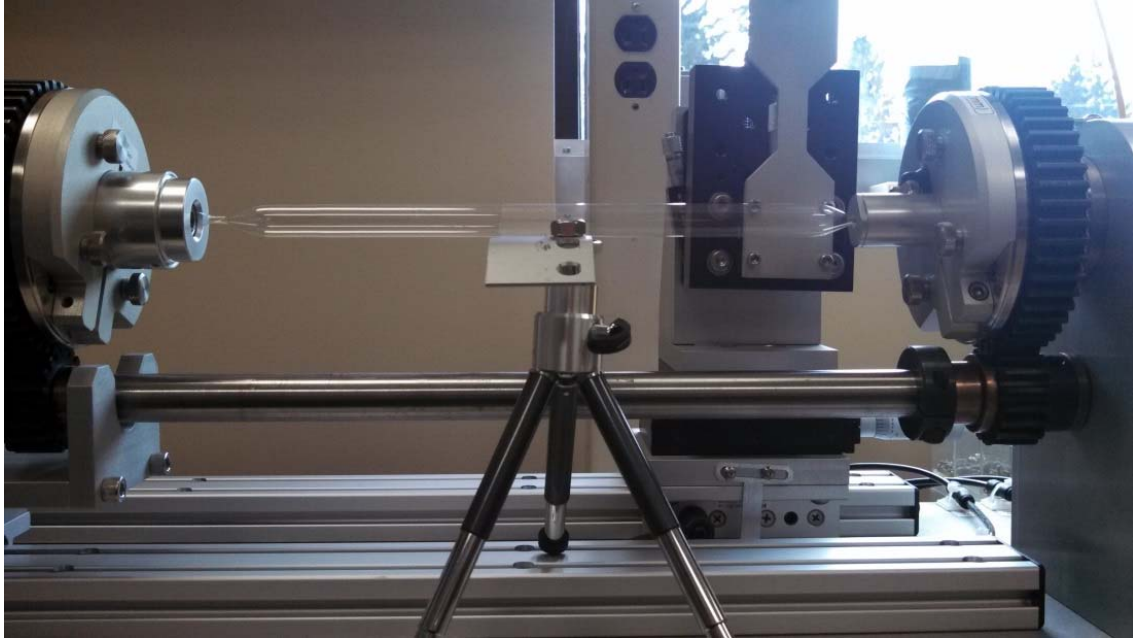


Figure 6 - Sample A in the MCTI with the Tripod Support

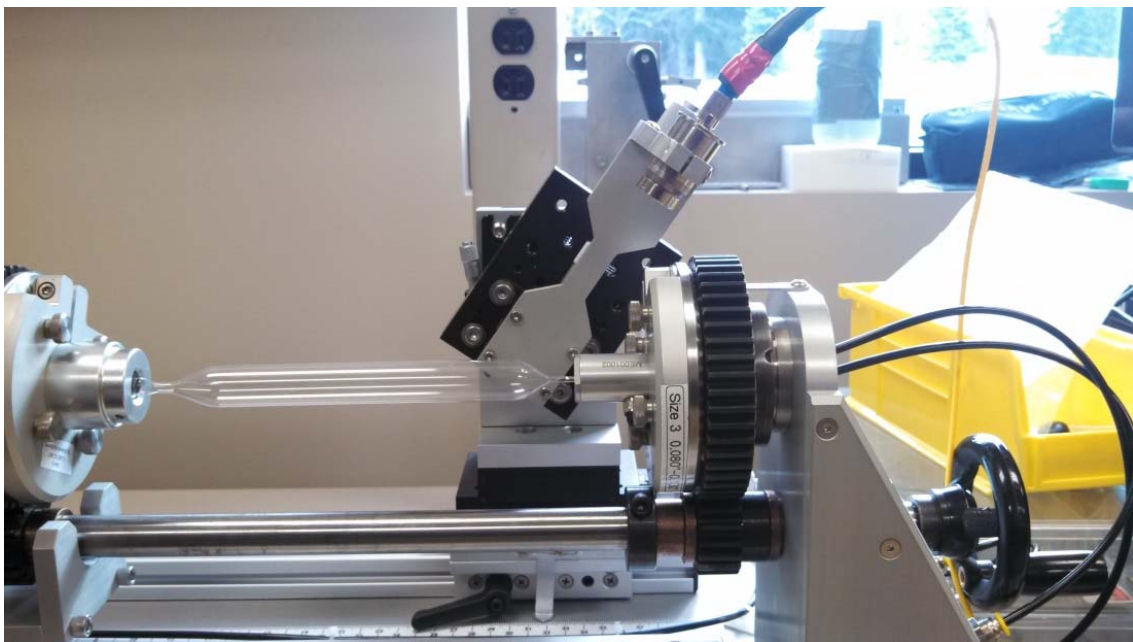


Figure 7 - Sample B in the MCTI with the Probe Positioned for Cone Thickness Measurement



RESULTS

Sample A

		Test Location								
		A	B	C	D	E	F	G	H	I
Position (mm)		8	85	102	212	262	312	325	330	335
Probe Angle (degrees)		0	340	0	0	0	0	20	0	0
		Dimensions (microns)								
Rotation	0	79.728	62.342	57.352	61.026	59.640	59.611	59.614	75.289	72.104
	90	82.969	65.628	56.780	63.772	62.799	62.346	68.823	101.393	91.042
	180	80.315	62.425	58.324	61.953	62.762	59.548	72.429	109.310	104.360
	270	80.590	63.051	56.725	63.490	62.060	62.519	59.496	82.557	87.587
ID		3042.105	na	13140.594	13011.075	13058.194	12954.934	na	1903.972	1903.788
OD		3203.907	na	13255.184	13136.195	13181.824	13075.904	na	2088.246	2081.335

Sample B

		Test Location								
		A	B	C	D	E	F	G	H	I
Position (mm)		153	159	176	241	271	301	318	318	324.5
Probe Angle (degrees)		0	339	0	0	0	0	35	0	0
		Dimensions (microns)								
Rotation	0	94.530	73.051	67.891	68.968	67.094	69.814	60.086	107.569	163.204
	90	87.018	72.269	69.602	66.215	66.009	66.786	55.565	92.415	148.853
	180	100.636	76.059	69.591	69.292	67.284	68.174	66.952	127.800	164.813
	270	79.993	74.040	67.738	71.424	65.317	64.257	53.725	97.913	161.007
ID		4557.793	na	17784.311	17778.514	17885.470	17868.604	na	2587.167	2587.808
OD		4738.881	na	17921.723	17916.464	18018.322	18003.119	na	2800.016	2906.746

In the above report the columns represent the measurement positions as described in Figure 2. The first two rows, the position represents the placement of the probe head along the fixture in millimeters and the probe angle represents the rotation of the probe where 0 is straight down.

The remaining rows in the report represent the wall thickness at the four quadrants from the measurements. Since ID and OD was found for positions A, C, D, E, F, H and I during both measurements, the ID and OD are averaged over both measurements.





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CONCLUSION

The balloon samples were easily measured with the OptiGauge EMS with 100 mm probe and Manual Cone Thickness Measurement system.

Lumetrics believes there could be considerable benefit to the balloon manufacturer due to the OptiGauge's high-accuracy and non-contact, non-destructive nature. In addition the ability of the fixture to provide quick and easy sample setup can provide them with high throughput. Call Lumetrics or email Sales@Lumetrics.com for more information on your balloon measurement challenges.

** Refractive index (RI) is a material-specific property. The OptiGauge measures the optical thickness of a sample. In order for it to calculate the mechanical thickness, the sample's refractive index must be entered. Until sample-specific RI data is obtained and taken into account, the data above is for proof-of-concept purposes only and approximate. However, air gap and inner tube diameter measurements are valid as the RI of air is a known value (1.000).*

Lumetrics sells the Refractive Index Calculation Systems (RICS) and has the capability to measure RI on-site if provided appropriate samples.

In order receive sample-specific RI measurements please provide a separate sample of each material originally sent in for testing sized approximately 1mm thick by 25mm x 25mm. If you are working with a multi-layer material we must receive a separate sample for each layer