

Closing the Loop Between In-process and Offline Measurements of Flexible Medical Tubing Products for Compliance Validation



Demand for medical device consumables, such as tubing, is increasing, creating production challenges for manufacturers. One critical challenge is how to accurately measure flexible products for compliance validation without sacrificing production speeds.

Due to increasing demands on production efficiencies and material savings, manufacturers need to ensure their medical tubes remain within specifications by verifying in-process and offline measurement consistency. For many flexible tubes, these two measurements yield different results and confirming product accuracy in-process becomes an ambiguous and in-consistent chore.

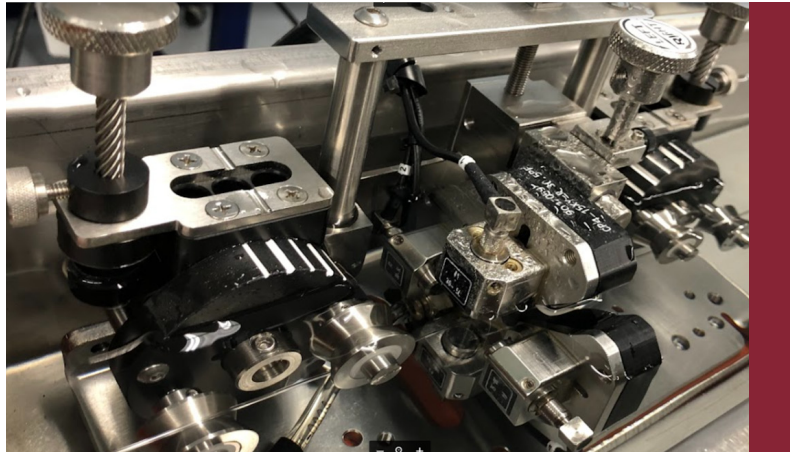
However, while in-process measurement alone may be a viable method for rigid components with fixed dimensions, it is not the most reliable method for measuring flexible products, such as medical tubing. This is because medical tubing properties can change once it leaves the manufacturing line, causing offline measurements to be dramatically different from in-process measurements.

When these two measurements are not consistent, it creates a validation loop, which can threaten compliance and cause manufacturing disruptions.

Challenges Unique to Flexible Products

Most dimensional measurement systems are based on the measurement of metals. However, when we look at a typical flexible PVC medical tube, it is incredibly elastic and more prone to thermal expansion than carbon steel.

Compared to metal components, medical tube extrusion lines also have many more production variables, such as the use of multiple materials, tooling, and settings. And since the tubing is “plastic,” measured dynamically, under tension, and still has residual temperature, the in-process measurements will be different from the offline measurements, which measure the product after it has cooled and is no longer under tension.



When these fluctuating properties are combined with other factors, such as operator error, the offline measurements can be dramatically different from the in-process measurements.

Compounding the problem is that most measurement equipment was not developed to measure flexible components. Consider the following:

- Nearly all measurement equipment is comparative and standardized to traceable calibrated SI standards
- Measurement standards are typically metal, generally developed for the measurement of metal components
- Readings are stationary and at 20°C

When it comes to flexible products, in-process dimensional measurement systems are actually measuring the dynamic representation of the static measurement, including effects from product movement, temperature, and elasticity.

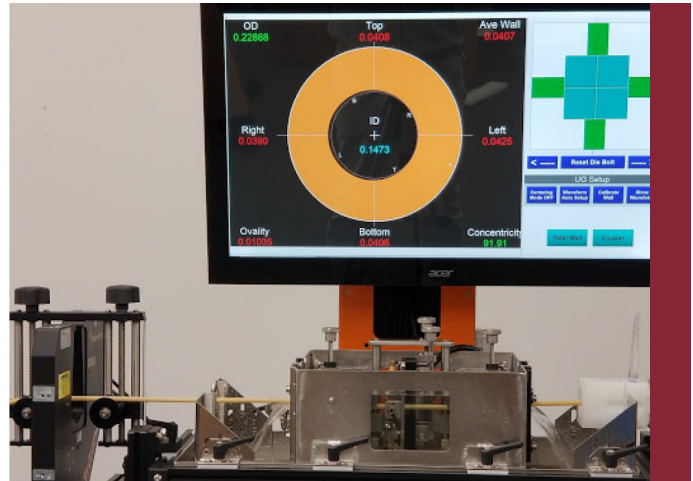


Closing the In-process and Offline Measurement Loop

To ensure dimensional quality compliance, medical tubing manufacturers must associate and verify offline with dynamic in-process readings and close the measurement “Validation Loop.”

One way to accomplish this is to measure flexible products with greater accuracy using “Non-Contact” offline sample measurement. This approach uses software-controlled measurement, elements, and servos to coordinate and improve performance to efficiently and consistently check product dimensions against a recipe.

Benefits from non-contact offline sample measurement include minimized operator influence, resulting in greater measurement consistency, accuracy, and efficiency. Examples of this technology from LaserLinc include:



BenchLinc-V

Outside diameter and ovality



BenchLinc-OD/ID

Inside, outside diameter, wall, and ovality



Metron-L

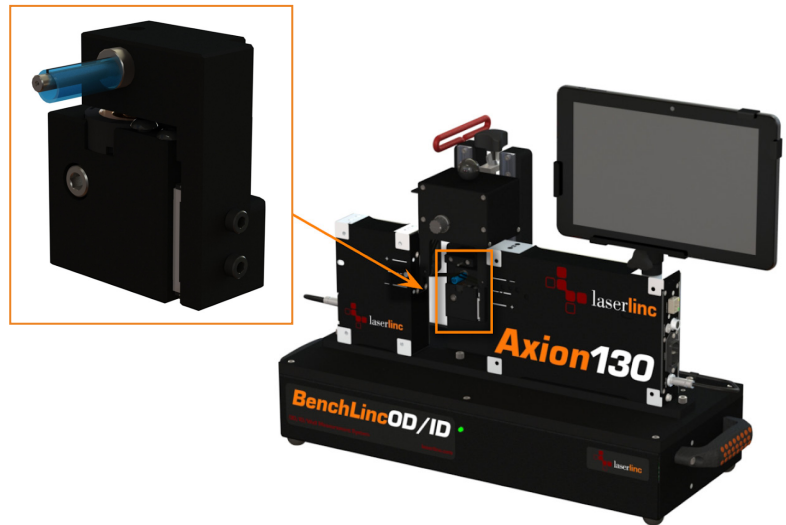
Outside diameter, ovality, and length

Systems that perform non-contact offline sample measurements have been around for a while, but recently there have been significant improvements, both to system functionality and usability.

A Two-Step Process

Let's take a closer look at how one of these systems delivers more accurate measurements.

First, the prepared tube sample is loaded onto a fixed mandrel and rotated with a controlled motor drive so that the tube can be measured in multiple positions and its true dimensions can be captured. The mandrel is zeroed before the measurement and acts as a datum point for the tube wall thickness dimension. The shadow captured by the laser represents the product's outside diameter measurement. The internal diameter is calculated using the two known outside diameter and wall dimensions.



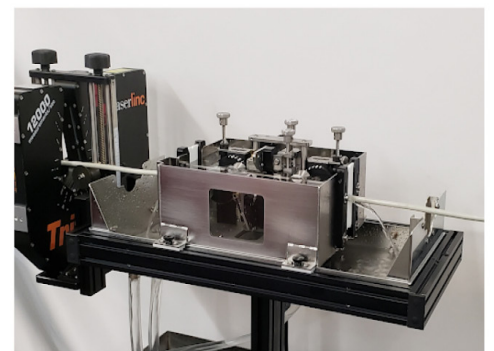
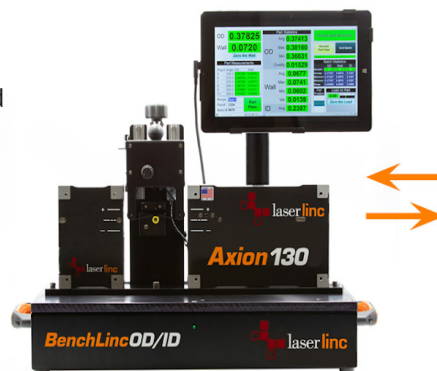
This technology is an improvement over past tools because an integrated load cell guarantees all tube samples are measured consistently and under identical conditions for more accurate results.

Further, the measurement mandrel has been designed to ensure high rigidity so that the wall datum is retained during operation. A low friction coating is added to ensure the tube samples rotate freely, and a new "quick-change" holder removes the need for a problematic three-jaw chuck.



Integrating Offline Measurements with the Inline Dynamic System

After accurately generating non-contact offline measurements, the next step is to transfer and compare these readings with the inline dynamic system. This is achieved via UltraLinc, an Ethernet connection between the two measurement systems. UltraLinc by LaserLinc sends the tube dimensions to the dynamic inline system on the tube extrusion line to automatically verify the wall thickness and diameter, closing the validation loop between in-process and offline measurements.

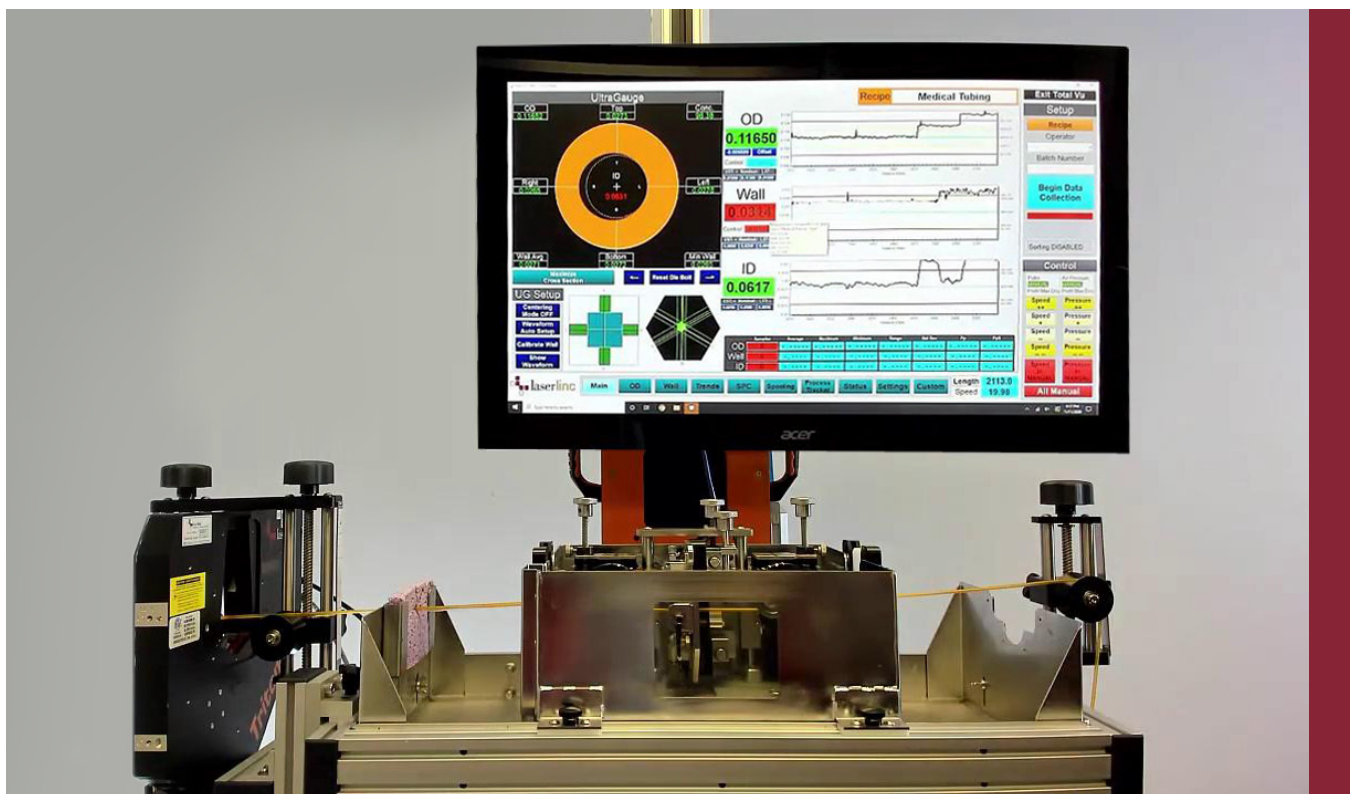


Conclusion

Medical device consumables manufacturers are looking for ways to increase production to meet the increasing demand for products, such as medical tubing. Inconsistent offline and in-process product measurements can hamper compliance validation and slow production.

New technologies enable precise non-contact offline measurement, which eliminate operator influence, generate more accurate offline measurements, and automatically compare offline measurements with the dynamic in-process readings.

Technologies, including those by LaserLinc, can help manufacturers “close the validation loop,” increase time to market, and boost production.



For more information on LaserLinc, please visit LaserLinc.com or contact us at info@laserlinc.com



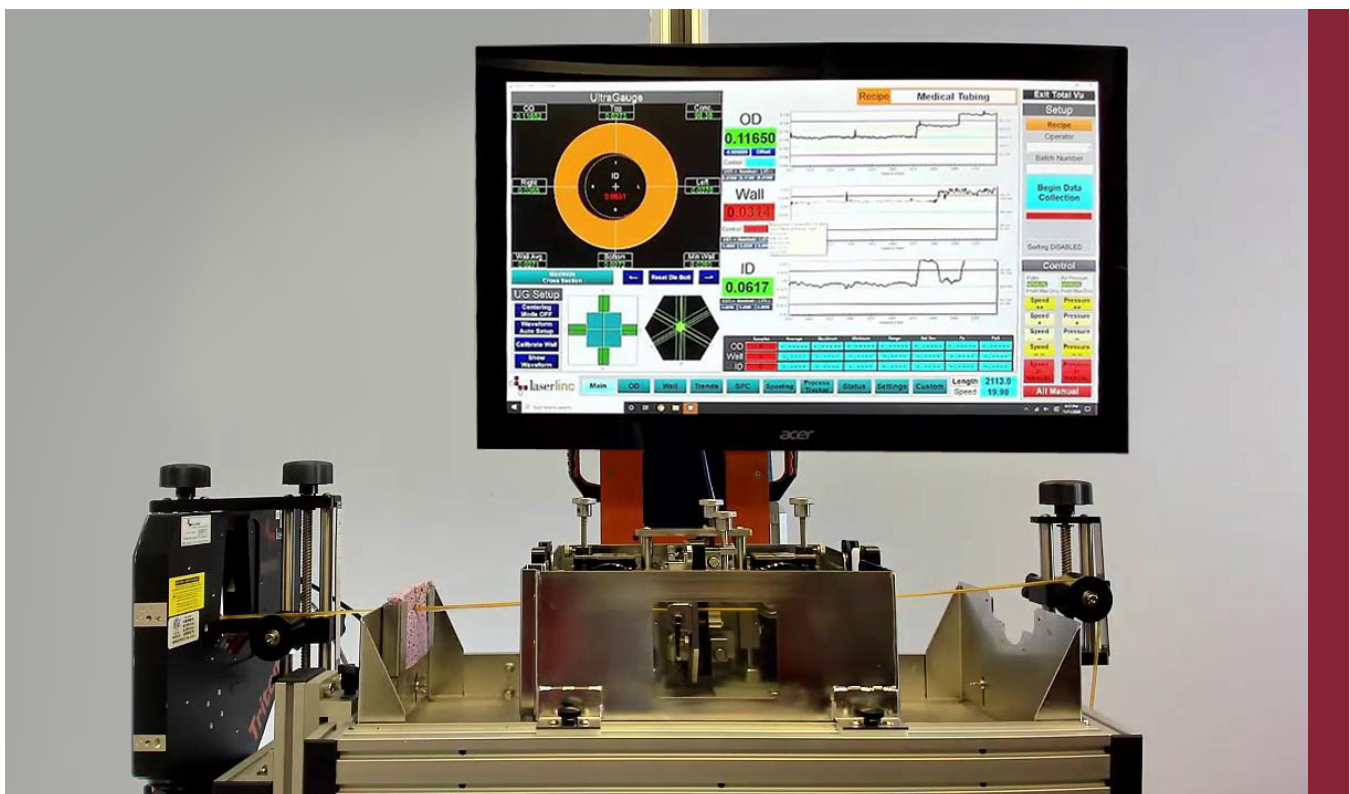
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