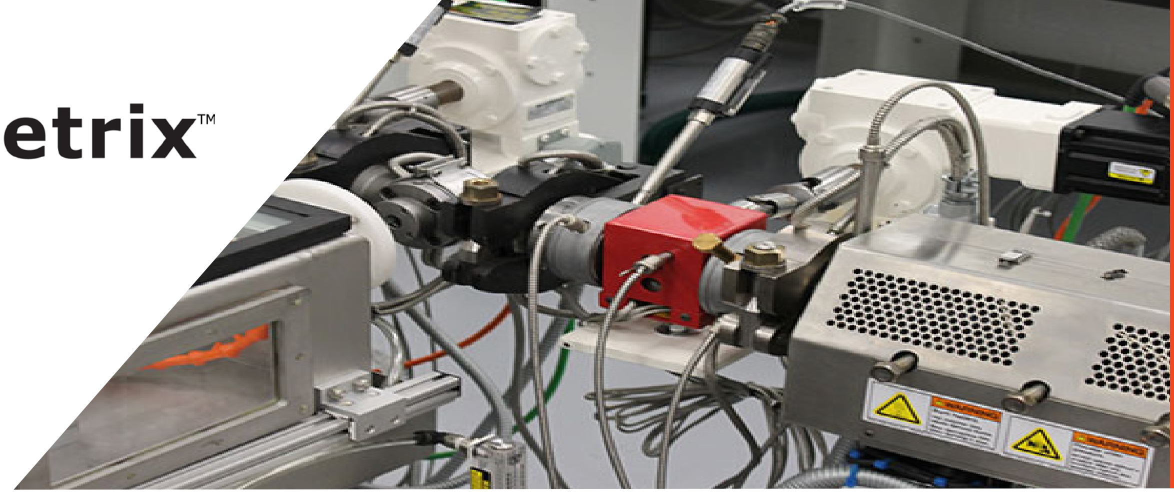
TeraMetrix™



On-Line Measuring and Control Solutions:

Tubing THz Applications

SUMMARY

Catheter / tubing manufacturers are under pressure to provide precise control of multiple product parameters; tubing wall thickness for single and multilayer walls, concentricity, increased physical property controls (e.g., material density) all with tighter manufacturing and validation tolerances. And in many newer products, smaller diameter tubing with thinner walls, and more complex walls and lumens (multichannel) products are also challenges. These demands also apply to coated metal catheters used for invasive procedures. For example, the consistency of the coating thickness affects the ease of guiding the catheter.

Ideally, measurements of all these parameters would be available in a single easily deployed sensor. Current measurement solutions typically involved multistep vacuum or water tank solutions for wall thickness measurements and other sensors for tubing OD, concentricity and physical property measurements. Solutions for multi lumen products are uncertain.

A Time-Domain Terahertz sensor is capable of making very high precision, very fast measurements of all of these product parameters with a single non-contact reflection sensor unit. The measurement concept is similar to ultrasound while operating in air and other locations ultrasound cannot.

ADVANTAGES

- Non-Contact
- Simultaneously measures both Front and Rear tubing walls
- Measures all tubing and coating materials, even black or opaque materials
- Simultaneous multilayer measurements
- Simultaneous multi lumen measurements
- Easily measure coating thickness on metal catheters
- Can additionally measure OD, ID, Concentricity with same sensor / data
- Very precise, accurate measurements
- Very fast, 1000 meas/sec
- Easily adapted to online or offline measurements
- Insensitive to tubing manufacturing motion, diameter, temperature, environment
- Large standoff distances (up to 150 mm)
- Completely safe
- Possible two measurement axes per sensor or easily rotate sensor around tubing
- Very low sensor maintenance required

BACKGROUND

A typical tubing creation process

Most high performance tubing products are being produced in an extrusion processes. A hopper of raw polymer pellets feeds into a heater element to melt the material to a liquid form. The liquid polymer is then forced (e.g., threaded screw) through a die to create the tubing. The formed tube is kept at a constant extrusion rate and tension, while either passing into either a vacuum sizing chamber or haa pressurized air pumped into the lumen space to prevent the still hot low strength tubing walls from collapsing. The product dimensions are set at this step. The product is typically passed next through a water cooling bath. This process is used to create both single layer and multilayer tubing wall products.

As the demand for more complex precisely controlled tubing increases, it's ever more important to have monitoring methods that can provide the full range of product information necessary for the manufacturers to profitably manufacture and validate their products. Typical monitoring of the critical product parameters (single and multilayer wall thickness, concentricity, outside diameter (OD), inside diameter (ID) is typically performed by a combination of laser microns for dimensions and ultrasound for wall thickness measurements. Ideally, the closer the measurements are made to the extruder, the more responsive the whole system can be and quickly correct for variations in product.

Ultrasound measurements require contact with the sample through a couplant. The water in the downstream cooling tanks functions well for this purpose. However, ultrasonic methods can only measure the contact surface, measurement on the opposite tubing wall are not possible without adding more sensors. Laser systems, outside of the cooling tank, are combined with the ultrasound thickness results to provide dimensional measurements.

A NEW ALTERNATIVE

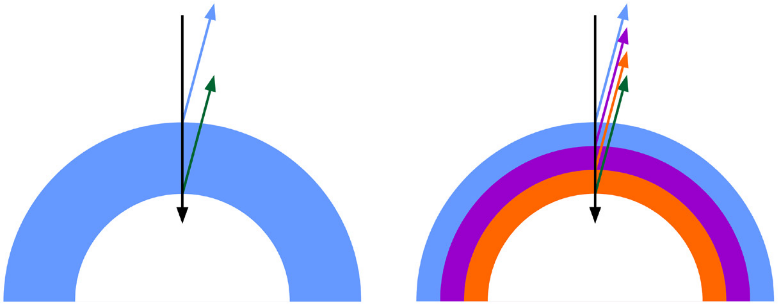
An ideal sensor would measure all the tubing critical parameters with better precision, provide simultaneous multilayer measurements, especially for thinner layers and smaller diameter products, is non-contact, has a very fast measurement rate and is completely safe.

A demonstrated solution to these measurement needs is a Terahertz (THz) sensor. The sensor's concept and operation is somewhat similar to Ultrasound. The main difference is a THz sensor emits a very narrow completely safe low energy pulse which travels through air. Thus the probe is non-contact and operates with long standoff distances (25mm, 75mm or 150mm). All materials used for tubing and catheter coatings are transparent to THz.

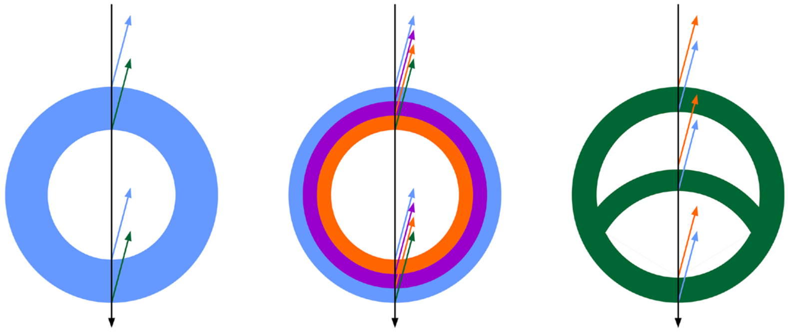
The emitted THz pulse will reflect off interfaces in the sample, such as the air / outer wall and the internal interfaces between materials in a multilayer wall. The Time-of-Flight (ToF) between the reflections are measured and the layer thickness is calculated from these values. Measurements are collected up to 1000 Hz. The THz beam spot size is approximately 2 mm. Because the sensor operates in reflection, for round tube objects the bulk of the return signal is off the highest point of the tubing surface which will be perpendicular to the sensor. As long as the tubing does not wander outside the 2 mm wide THz beam, the measurement will be insensitive to tubing motion.

The 5 × 7 × 2.5 inch sensor is connected to a control unit with a highly flexible umbilical cable (up to 30+ m long) and thus can be freely positioned in the manufacturing process. The most likely position is at a fixed set standoff from the tubing, but the sensor could be continuously scanned around the circular tubing to give full 360° monitoring.

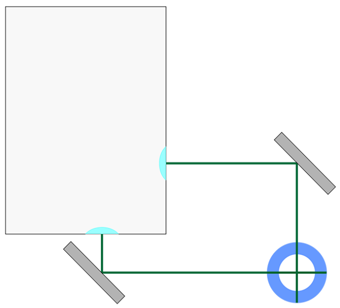
The emitted THz beam passes through air to the tubing sample. If the wall is a single material, two reflections, one from the wall outer surface and one from the wall inner surface would be expected. If the tubing was multilayer, then N+1 reflections would be seen for an N layer material.

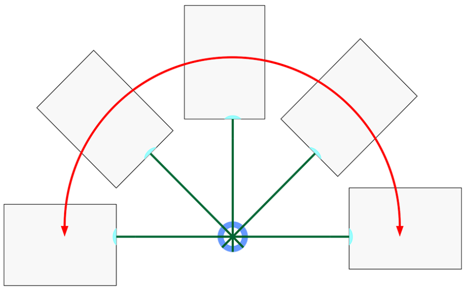


An important advantage of THz is the pulse continues through the tubing front wall and through the ID air space. Thus simultaneous measurements of the rear wall are also obtained from the same sensor. This capability can be deployed in a number of ways:
A fixed sensor measuring a set point and the 180° opposite position, for both single layer and multilayer products.

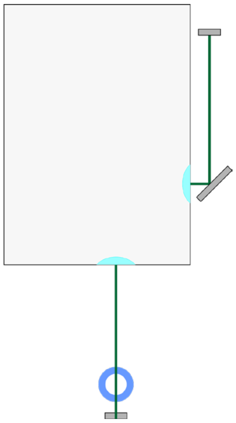


With the addition of two mirrors, a second beam from the same sensor can simultaneously monitor the 90° and 270° orientations. With the use of a circular scanner over 180° around the tubing, a full 360° of monitoring is possible.





It is also possible to use the two port sensor in a different configuration to measure the sample OD without any calibration and from that data, tubing ID can always be measured and with OD and ID information, the tubing wall material average density can be found.



Cross section tubing samples were sectioned and examined under a microscope to examine the structure. Figure 1 shows the cross section and the measurements that were made on one of the samples.

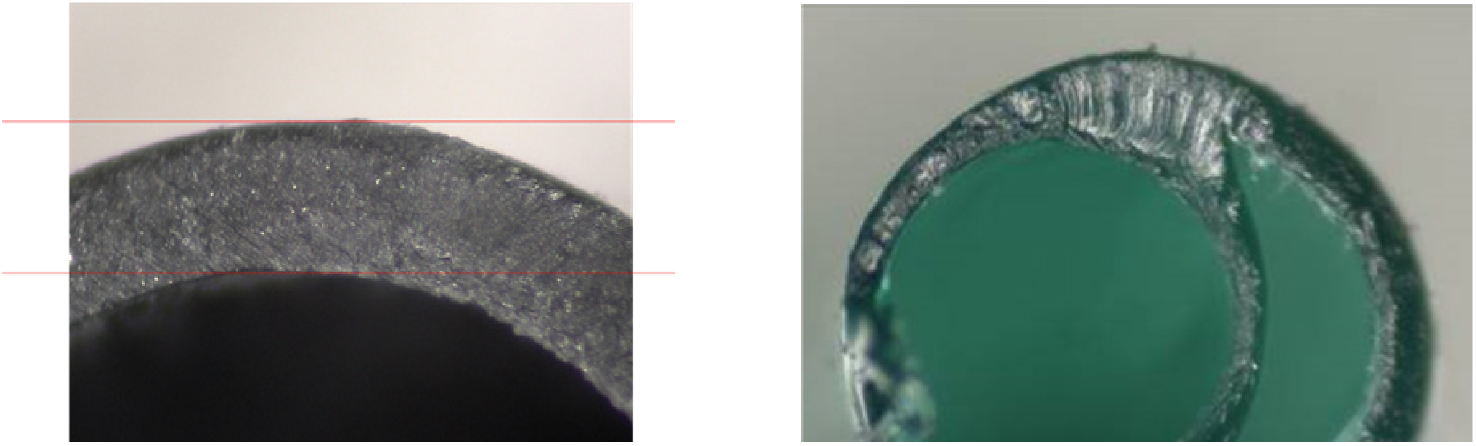


Figure 1: Using THz we are able to measure the thickness of both walls of this thin medical tubing. Currently no other methods exist to measure the interior wall of this material.

ON-LINE APPLICATION

In operation, the THz pulse is focused onto the tube and the reflections off the tube and its interior interfaces are detected by the sensor. The measurement is immune to radial axis flutter, dirt or gum build up on the lens and works well in dusty or fume generating environments.

Multilayer coatings with vastly different Refractive Index's will be easy to measure. The larger the diameter the tube is, the easier it will be to measure. Tubes with a large diameter have the reflections look almost like perpendicular surfaces, which is the ideal shapes to measure for THz. We can measure changes in types of materials far easier when the speed of light in the material changes from material to material.

We have measured total wall thickness as low as 240 microns in the past. We have previously measured individual wall thickness down to 50 microns in thickness at 1000 measurements per second.

With a spot size of approximately 2mm we will need stability in order to measure tubes of very small diameter and thin layer thickness. Layers with similar RI may need similar precautions if multilayer thickness are required. For small diameter tubing surface reflections of a similar diameter will be needed to calibrate our equipment. With tubes with metal interiors, we will be able to measure the other surfaces, but will struggle to measure surfaces inside metal walls, as metal reflects THz.

CERTIFIED SAFETY US-CA SÉCURITÉ US-CA E363955 INSPECTION EQUIPMENT

INVISIBLE LASER RADIATION AVOID DIRECT EYE EXPOSURE CLASS 3R LASER PRODUCT

Industry Leading Regulatory Compliance
The T-Ray® 5000 intelligent TCU has been certified by Underwriters Laboratories has received the CE mark, is fully compliant with FDA CDRH laser safety regulations, and has been tested to meet FCC part 18 regulations.

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