

# Detecting Flaws in Medical Devices with Acoustic Micro Imaging

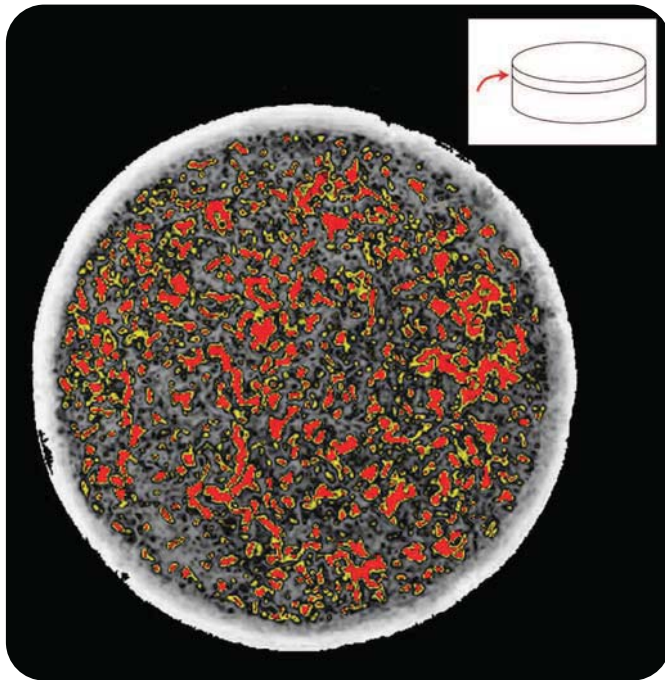
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Reliability in medical devices is a serious concern because of the impact of device failure or device anomaly on the welfare of the patient. A flaw in an x-ray system can pose a risk to the patient, as can a misdiagnosis caused by the malfunction of a microfluidic blood analysis system. Reliability is even more critical in devices such as surgical instruments and pacemakers that are used inside the patient's body.

These and thousands of other medical devices are imaged and inspected by acoustic micro imaging systems in order to ensure long-term reliability. Like medical ultrasound, acoustic micro imaging uses ultrasonic pulses, but at much higher frequencies and much higher resolution. Acoustic micro imaging provides very detailed images of the interior of solid materials, but is not suitable for examining living tissue.

Acoustic imaging of medical devices can be carried out during the development of a device, during production, or after a field failure. In each of these scenarios, the purpose of acoustic imaging is to see and analyze internal anomalies and defects. An advantage of acoustic micro imaging is that it is nondestructive and leaves the sample

being imaged intact for use (replacement hip joints are one example) or for other types of analysis. The internal anomalies and defects typically consist of delaminations, cracks, and voids. The acoustic image gives the engineer considerable insight into the root cause of the problem.



**Fig. 1** — Acoustic image of the tungsten-copper interface in an x-ray target. Red features are multiple voids at the interface.

## Acoustic Microscopy

Acoustic microscopes pulse very high frequency ultrasound into the sample and receive the echoes from internal interfaces. Most samples have at least one flat surface for the ultrasonic transducer to scan, but cylindrical samples (a shaft bonded within a tube, for example) can also be imaged.

A frequently imaged sample having a flat surface is the metal target used in hot-cathode high-vacuum x-ray tubes. High-energy electrons produce x-rays when they strike the target. In the example shown in **Figure 1**, the target consists of a tungsten plate bonded to a copper substrate. To function properly, the bond between tungsten and copper must be free from defects such as voids or delaminations.

The ultrasound that is pulsed into the x-ray target by the scanning transducer is reflected to some de-

gree by the top surface of the tungsten. The reflected echoes go back to the transducer where they are received and used to locate the top surface of the sample. The unreflected portion of the pulse then travels through the tungsten without creating echoes (because there are no interfaces) until it reaches the tungsten-copper interface.

If the pulse strikes a location where the tungsten-copper bond is good, it will reflect a medium-amplitude echo. Because the transducer is scanning, several thousand echoes are reflected per second from the bond area. If the ultrasonic pulse strikes a void (air or a vacuum) between the tungsten and the copper, the amplitude of the return echo is extremely high – actually more than 99% of the pulse energy. Since the amplitude of the echo at each of the thousands or millions of locations being scanned determines the brightness of the pixels in the acoustic image, the high-amplitude reflections from voids and other gap-type defects are the brightest features in the image.

Figure 1 is the acoustic image of a tungsten-copper x-ray target. Since echoes from different depths within the target arrive back at the transducer at different times, this image was made using only the echoes from the tungsten-copper interface, indicated by the red arrow in the diagram. Echoes from above the interface (i.e., in the bulk tung-

sten) and from below the interface (the bulk copper) were discarded. This procedure is known as gating and is used in most acoustic imaging in order to highlight the image produced at the depth of interest and to eliminate echoes from other depths.

### Defect Identification

The red areas within the acoustic image of the x-ray target are voids between the two metals. Their red color identifies them as highest-amplitude (>99% reflection) echoes. The number and distribution of the voids immediately tell the engineer that some process error has interfered seriously with the tungsten-copper bonding process. Since the long-term functioning of the x-ray system depends on a well bonded interface, this x-ray target is clearly a reject.

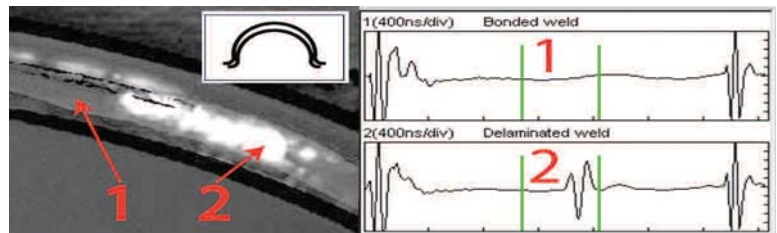
**Figure 2** shows a very different device, but with a somewhat similar problem. The slightly curved feature running from left to right in the acoustic image is one small segment of a circular seal in a polymer blood filtering device. The seal should be firmly bonded to its substrate, and its acoustic image should be a medium gray. The inset shows a cross-section through the tongue-in-groove seal. The gap between the two layers in the diagram is an unwanted defect.

The gray region indicated by arrow #1 in Figure 2 is a well bonded region. Arrow #2 points to a gap whose bright white tone represents the highest echo amplitude (>99%, as in the x-ray target, but white rather than red in this image). The whole circular seal had numerous similar gaps that seriously compromised its integrity and created the potential for leakage.

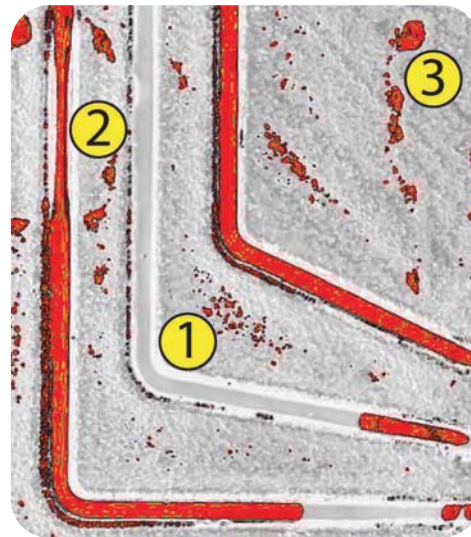
The acoustic image at the left of Figure 2 was made using only echoes returned from the depth of the intended seal. The two waveforms at right show, at their extreme right and left, the echoes from the top and bottom surfaces of the seal. Note that these portions of the waveforms are very similar at both locations 1 and 2. The two vertical green bars mark the time window defining the depth of interest; only echoes from this depth, where the seal should be bonded, were used in imaging. Waveform #1 shows little variation between the two green bars, which is consistent with a good bond. But waveform #2 shows the high amplitude that is characteristic of a gap.

**Figure 3** is the acoustic image of one portion of a cartridge designed for automated blood analysis. Acoustic micro imaging was carried out during the development of the cartridge. The solid plastic body of the cartridge has channels in its surface for directing the blood to sensors located in wells. Over these channels a very thin polymer/foil film has been bonded to close the tops of the channels. The cartridge was imaged acoustically using a time window that included echoes from just below the top surface of the film to just below the bottom of the channels.

In the color map used in Figure 3, red represents the highest amplitude echoes – that is, gaps. The covered channels should appear red, because they are intentional gaps, but in some areas, such as area #1, the channels show the gray tone that indicates



**Fig. 2** — Good (#1) and bad (#2) bonds in the polymer-to-polymer seal in a blood filtering device.



**Fig. 3** — Open (red) and closed (gray) channels in a development-stage blood analysis cartridge. Scattered red features are delaminations of top film from cartridge body.

that no gap is present. Instead, the channel has been filled in, probably during injection molding. In area #2, the channel is present but is narrowed, probably as a result of injection molding. Outside of the channels themselves, the acoustic image shows – at #3, for example – areas where the film is not bonded to the body of the cartridge. These delaminations might be acceptable because they tend not to occur along the channels. Multiple anomalies such as these are not uncommon during the development of a new medical device.

The devices shown here are only three out of thousands of device types that have been imaged acoustically. Although most acoustic micro imaging has as its purpose the interrogation of an interface between materials, it can also be used to examine a homogeneous material for possible defects. The tungsten layer in the x-ray target, for example, can be imaged by using only the echoes, if any, from the bulk of the tungsten to make the acoustic image. The desired result in this case is a blank image, meaning that no cracks or other anomalies are present in the tungsten. A crack or other defect within the tungsten will be very conspicuous in the acoustic image. ○

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