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# Using Ultrasound Technology to Improve Device Reliability

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Using Ultrasound Technology to Improve Device Reliability

Acoustic micro imaging technology can identify latent defects in products during development and manufacture and prevent field failures.

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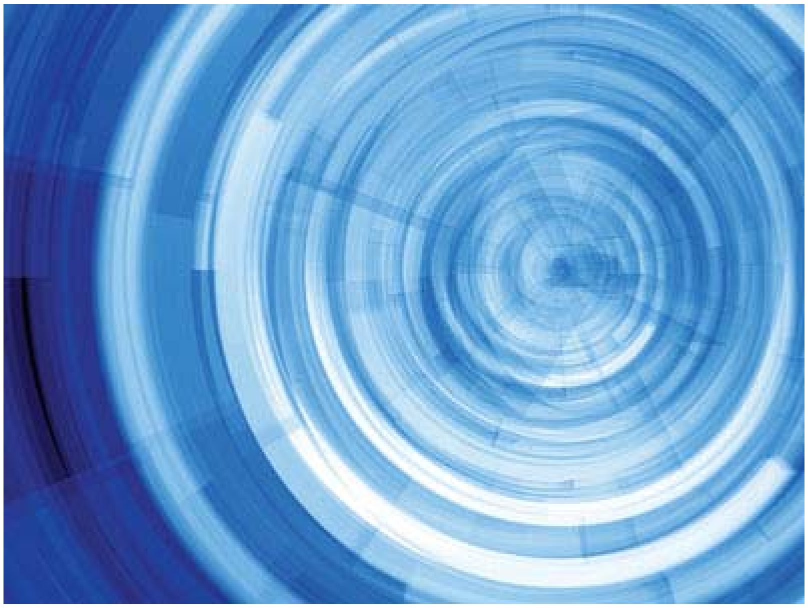
**A nondestructive method**



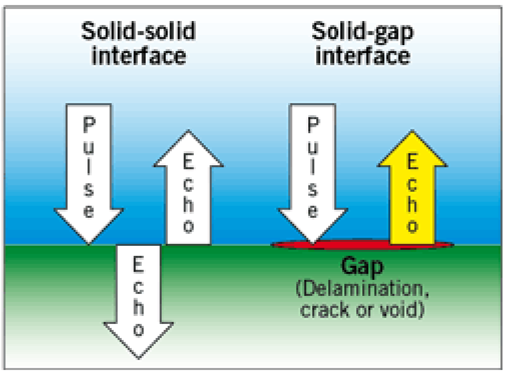
When a medical device fails during active use, the failure is often preceded by a latent defect of some type. If the failure is not electrical in nature—or even if it is—the latent defect often turns out to have been a structural flaw such as an internal crack, delamination or void. Given time, vibration and thermal stresses, these are the types of latent defects that can cause field failures in a variety of medical devices.

To avoid such failures, manufacturers may want to look for these types of defects at an early stage—during development of the device or on a sampling basis during production. Cracks, delaminations and voids are all gaps. They can be found by destructive physical analysis (DPA), in which the device is typically cut open and polished to provide a magnified optical view. They can also be found and imaged by acoustic micro imaging, which is nondestructive and especially sensitive to internal gaps.

Suppose that engineers want to gain some understanding of a medical device in which a layer of plastic is bonded to a layer of metal. Acoustic micro imaging systems use a moving ultrasonic transducer that scans over a flat or cylindrical surface. The transducer pulses ultrasound into the part and receives the echoes that come back from internal interfaces. Engineers would expect the plastic-to-metal interface to send back echoes of more or less medium amplitude if the two materials are well bonded. Any two well-bonded solids will return their own characteristic echo.

If there is a gap between the two materials, however, the interface at that location is no longer plastic-to-metal. Instead, it's plastic-to-vacuum, or perhaps plastic-to-air. The second material is not a solid, and the acoustic properties at the interface are so vastly different that the return echo is of extremely high amplitude (Figure 1) and larger than any echo produced by two well-bonded solids. Typically >99.99% of the pulse ultrasound is reflected, and engineers will see a very bright region where the gap is located, even if the gap is as thin as 0.01 µm.

**Figure 1**




If engineers see such a defect in an acoustic image of the device during development, they have the opportunity to modify materials or processes to eliminate it. They will probably want to DPA the device to see the defect optically; the acoustic image will show them exactly where to cut.

A variety of medical devices, ranging from pacemakers and abdominal implants to cartridges for blood analysis, have been inspected by acoustic micro imaging. The ultrasonic transducer needs to be able to scan one flat surface on the device. The flat surface may be as small as the width of the weld area on a pacemaker case, where the depth of interest is the whole thickness of the weld, and where there is no tolerance for anomalies. The transducer also can scan devices with a cylindrical exterior or other nonflat geometries.

**An incompletely bonded gasket**

**Figure 2**

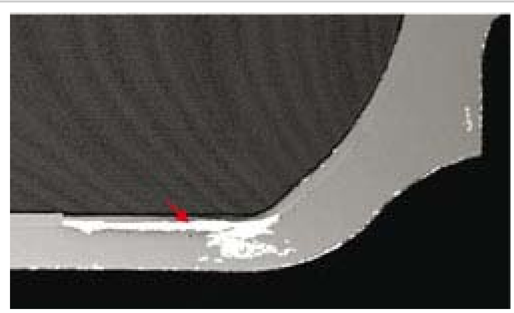


Figure 2 is the acoustic image of a gasket that has been bonded to the flat perimeter of a cavity in a microcassette through which blood is pumped as part of analysis. The solid grey region is the flat surface of the perimeter to which the gasket has been bonded. The echoes coming back to the transducer are “gated” to image the bond of the gasket to the wall of the microcassette—the “depth of interest.” Any echoes from other depths are easily excluded because they would arrive either before or after the echoes from the depth of interest. The region of wavy lines is a plastic/glass layer overlying the gasket and the microcassette.

Most of the flat perimeter surface is the same shade of grey, indicating that uniform bonding of the gasket to the surface has occurred. This is precisely what is needed to achieve long-term, leak-free reliability in this device. However, the white regions marked by the arrow reflect the ultrasonic pulse at much higher amplitude and are therefore bright white. Conclusion: these regions are not bonded to the perimeter surface.

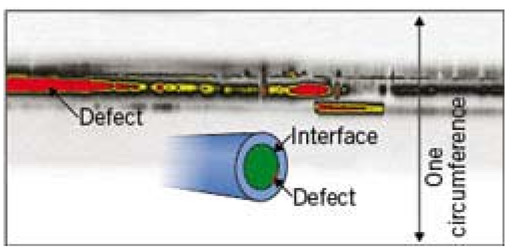
Even more serious, these disbonds come close to forming a continuous pathway from the interior of the cavity to the outside environment. If this device went into service in this condition, exposure to moisture, contaminants, thermal cycling and shock and vibration, might make the pathway continuous and cause unanticipated failure. In high-reliability devices, any amount of disbond at this interface may be cause for rejection. In devices where this type of failure is less critical, a defined small area of disbond might be permitted.

Because acoustic imaging is nondestructive, it leaves the part intact for other types of analysis. This part might be physically sectioned in order to get a close look at the bonded and nonbonded interfaces. The acoustic image shows where to section the part.

**Rod bonded inside tube**

The device imaged acoustically in Figure 3 is a polymer rod that has been ultrasonically welded within a larger polymer tube. The depth of interest in this case is the welded interface between the two polymers.

**Figure 3**




This cylindrical sample can be imaged by having the transducer scan the length of the sample once, and then rotating the cylinder a fraction of a degree for the next scan. (Imagine holding the cylinder horizontally in front of your eyes and slowly rotating it.) In this type of imaging, called rotational imaging, the sample is typically rotated through slightly more than 360° to ensure complete coverage. The echoes are gated on the depth of interest where the two pieces are welded together.

The long arrow in Figure 3 shows one full circumference of weld. Over most of the circumference, the colour is light grey, and indicates a uniform weld. But there is one horizontal zone in which red indicates the highest amplitude of reflection, meaning a gap. Yellow indicates the edges of a gap, and black to dark grey regions indicate tiny gaps or weld irregularities that have not resulted in gaps. The insert in Figure 3 shows how the tube, rod and defect would look if they were cross-sectioned.

What does this acoustic image tell engineers? It tells them that there may be some type of process flaw in the ultrasonic welding that affects one part of the circumference. Or it may tell them that there was some type of longitudinal material flaw in either the tube or the rod.

**Other applications**

The two examples illustrated above are typical medical device applications for acoustic micro imaging, where engineers are looking for the integrity—or lack of integrity—in a bond between materials. The diversity of medical devices means that there are also plenty of atypical applications. One example: a polymer film bonded to a plastic plate in which channels have been formed. Engineers making an acoustic image of such a sample are looking for two things. First, they want to see that the film-to-substrate interface has no acoustically bright unbonded regions. Ideally, this interface will be of a uniform grey tone.

Second, they want to see acoustically that the channels are open and have not been filled in by the bonding process. Good channels, since they are gaps, will be bright and will have the specified width.

In some cases, acoustic imaging is not used to look for bonding-related issues, but instead examines the structure of a material. Plastics are often filled with particles that give them added strength. An acoustic image can show the size and distribution of the particles. Irregular particle distribution can alter the strength or other properties of the material.

Return echoes from within the device being imaged are typically accepted only within a defined time window. For example, the transducer may use only echoes that arrive between x and y microseconds after being pulsed, because these echoes will be from the depth of interest. Echoes arriving earlier or later will originate above or below the targeted interface. If a device has multiple material interfaces at different depths, or if bulk materials are being investigated for anomalies such as cracks or voids, the sample may be imaged more than once using a different time window each time.

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