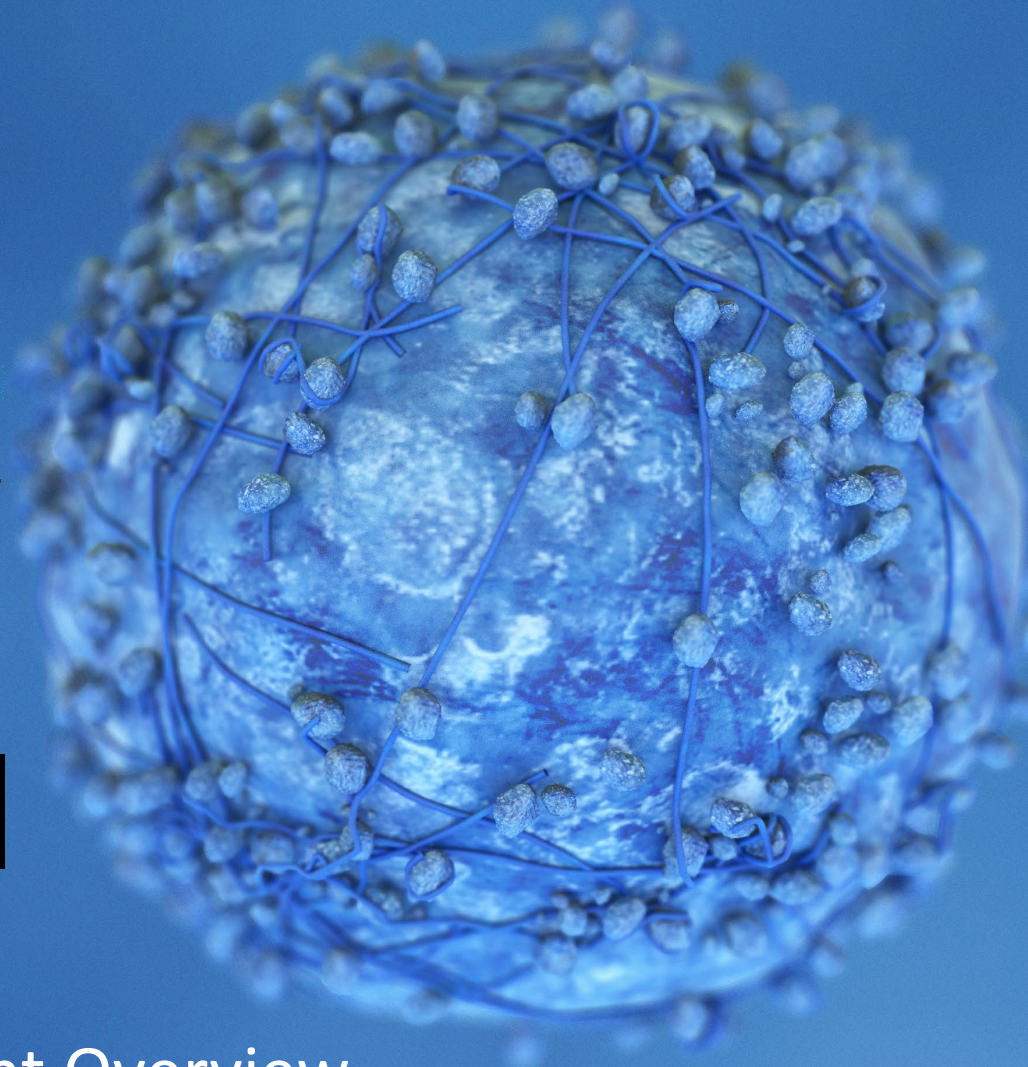


UMM

ULTRASONIC MEDICAL MAPPING

Revolutionizing Cancer Detection

2019 Technical Development Overview

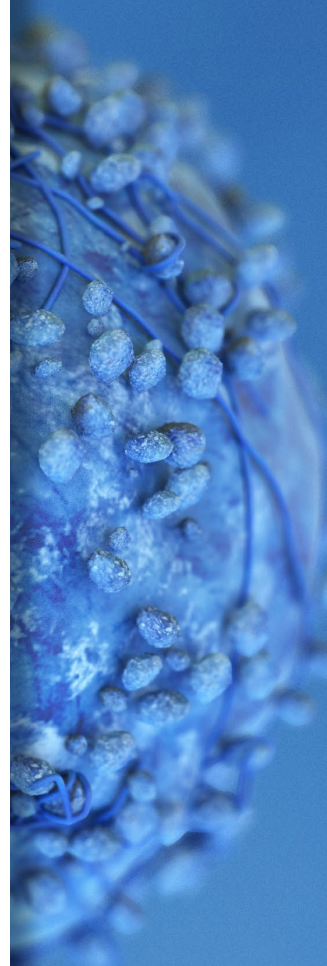


All significant breakthroughs are break -
“withs” old ways of thinking.

– Thomas Kuhn

“Listening for Tumors”

Ultrasonic Medical Mapping was created to take advantage of millions of dollars spent over several decades and transfer a mature diagnostic technology from the Aerospace/Defense Industry to Medicine.



A Change of Paradigm

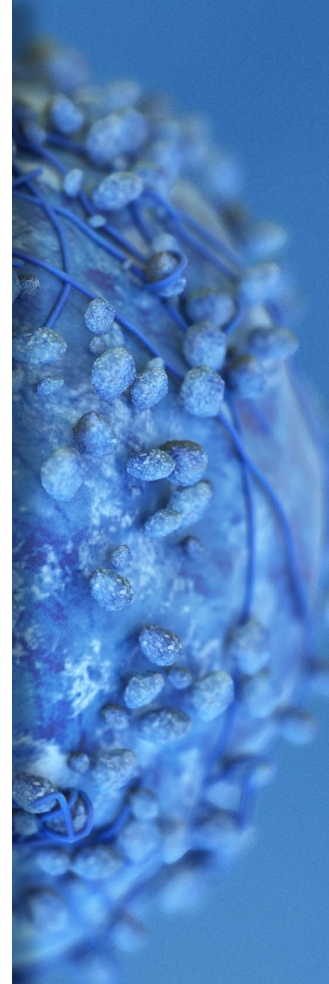
What we are not doing:

We are not using a planar phased array of transducers to send and receive a signal that will be converted into an “image” for the user.

What we are doing:

We are using Ultrasonic Scattered and Through Transmission for volumetric scanning.

Our mapping technology operates on the very simple premise that a low-frequency ultrasonic signal will be altered in different ways as it passes through different materials and that these differences can provide significant and detailed information about the target.

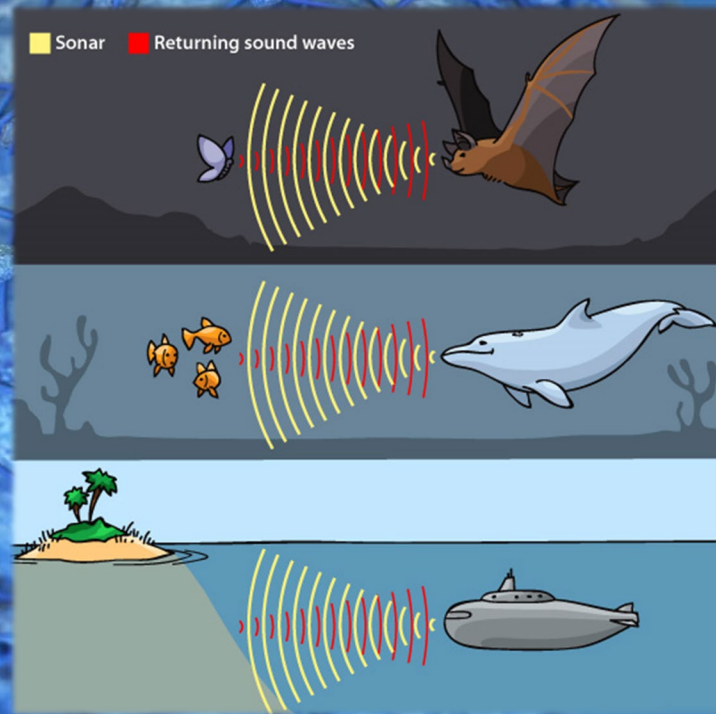


“Mapping” vs. “Imaging”

Bats, dolphins and submarines are able to recognize targets and navigate without imaging.

Ultrasonic Mapping is a mature and highly developed application currently used in Materials Science for non-destructive evaluation and testing of complex structures.

Mapping techniques enable the use of acoustic information that is lost in the imaging process.



Limitations of Current Technologies

X-Ray – CT Scan, Mammography (“Mx”)

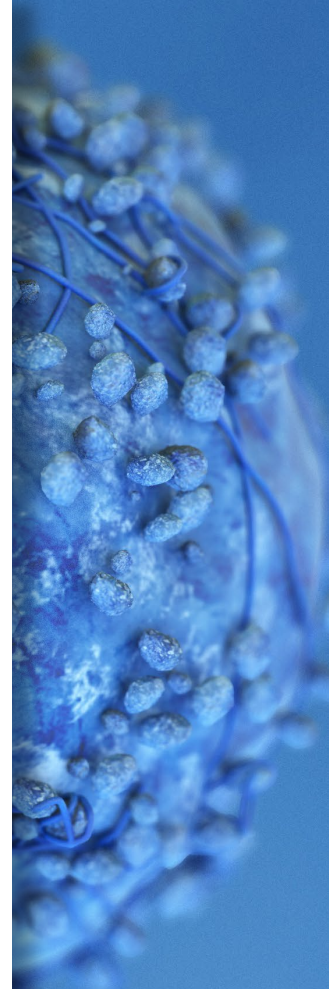
- Detects only density changes, becomes steadily less useful as average density increases
- Exposes patient to potentially harmful ionizing radiation

Imaging Ultrasound

- Has penetration limitations at the high frequencies needed for medically relevant pixel size (resolution)
- Results are dependent upon operator skill and judgement

MRI

- Cost prohibitive, often not covered by insurance



Initial Proof of Concept

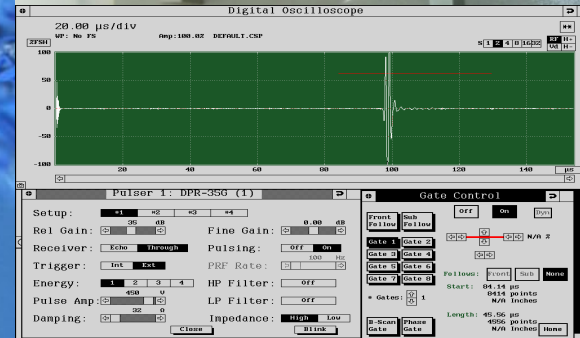
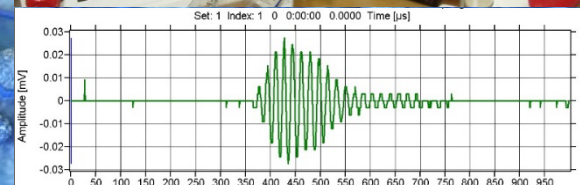
UMM is applying techniques used for non-destructive testing in Materials Engineering:

- Low-frequency ultrasound is capable of sending high quality signals through complex materials.
- Initial bi-static testing against a lung tissue proxy (at right) proved the ability of the technique to deliver high fidelity signals through expected target densities across an “air gap”.

Subsequent water-coupled (immersion) testing against a standard breast phantom was conducted with the following results:

- High signal fidelity confirmed.
- Contact with the target is not required.

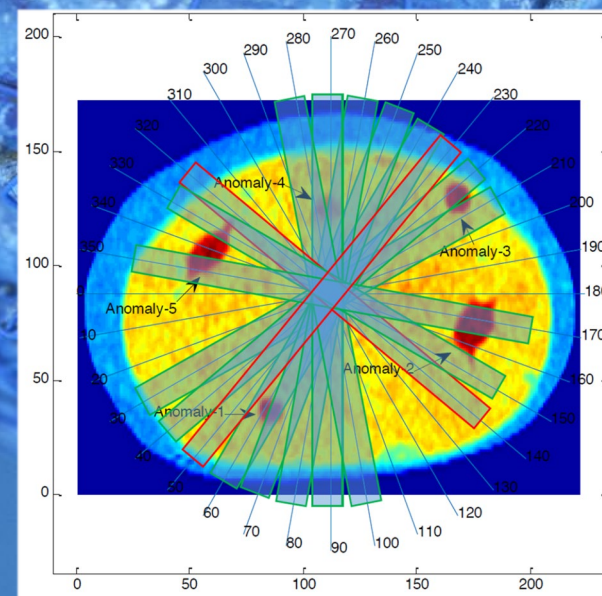
Lack of contact paves the way towards a fully automated system reducing the operator dependencies inherent in traditional imaging.



Technical Progress – Gen 1

Building upon the initial proof of concept demonstrations, UMM partnered with Dynaflo, Inc. to build the Gen1 prototype based upon the technical language in the UMM patent.

Testing against a standard breast phantom resulted in detection of all anomalies. The figure to the right shows detections overlaid on a CT image of the phantom.

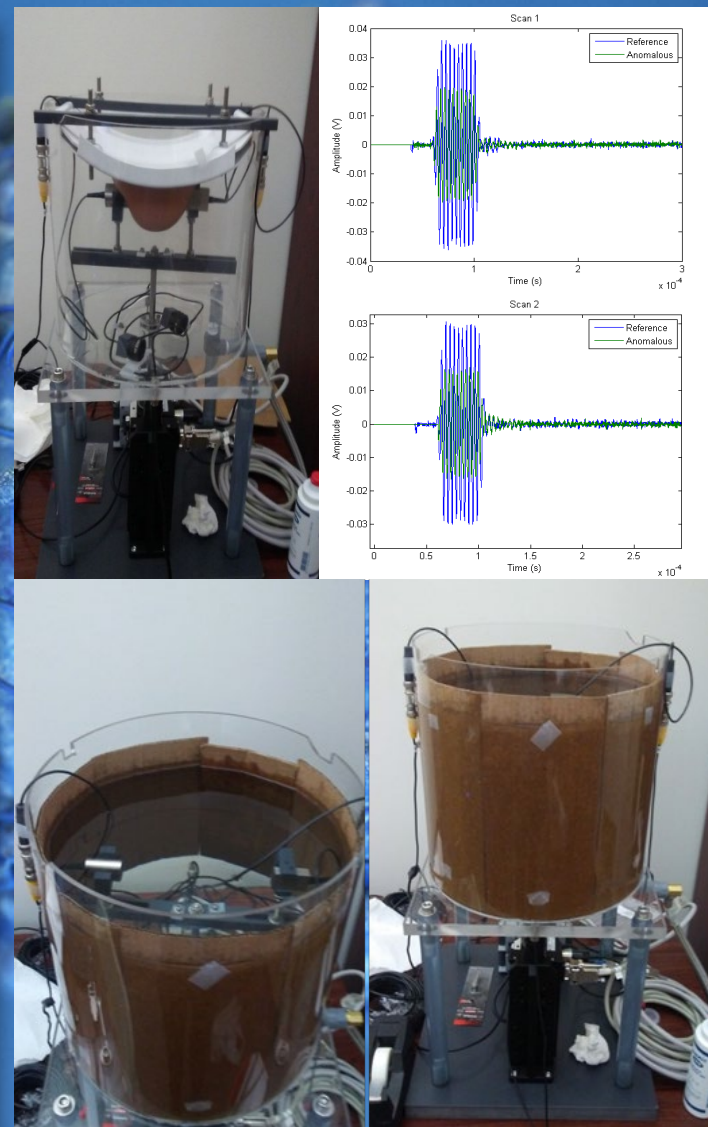


Technical Progress – Gen 2/3

The Gen2 iteration introduced enhanced transducer elements (transmit and receive) along with lowering the testing frequency.

Testing and evaluation, using direct contact and water immersion, confirmed both signal quality and repeatability of results using a standard breast phantom.

The wider beam of the Gen2 transmitter element required the addition of sound absorbent material on the inner surface of the tank as indicated to the right (Gen3).

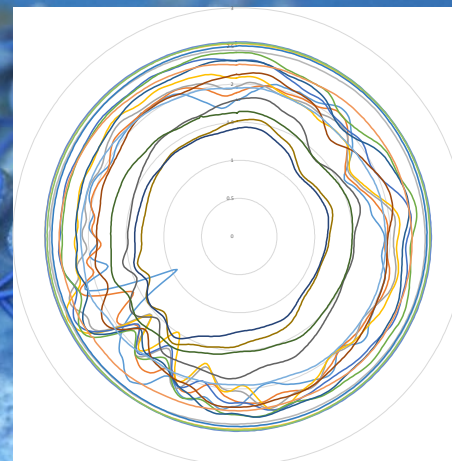


Technical Progress – Gen 4

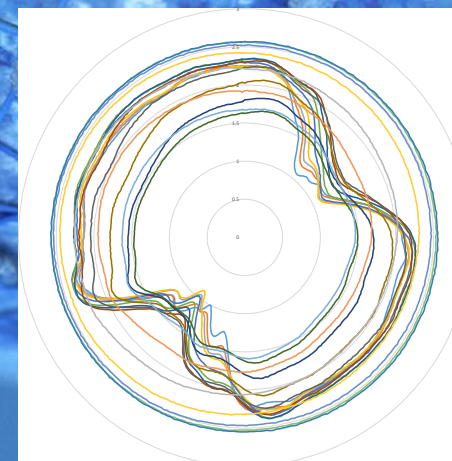
The Gen4 iteration introduced mechanical filters to the transmit and receive units in an attempt to narrow the detection window and improve data quality.

As can be seen in the charts to the right, adding filters resulted in a noticeable improvement in the quality and consistency of the data.

While representing the limit of azimuth resolution enhancement in the current configuration, this confirmed the feasibility for continued localization enhancement through optimization of the physical size of the transducer array.



Without Filters



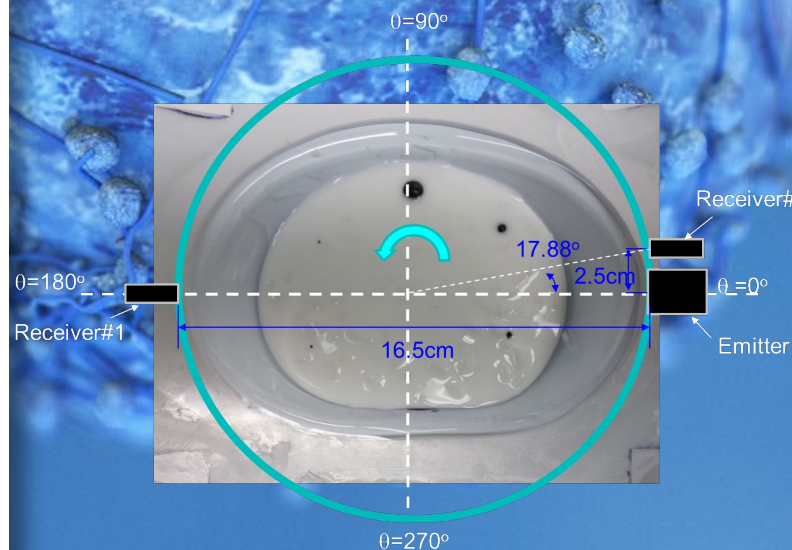
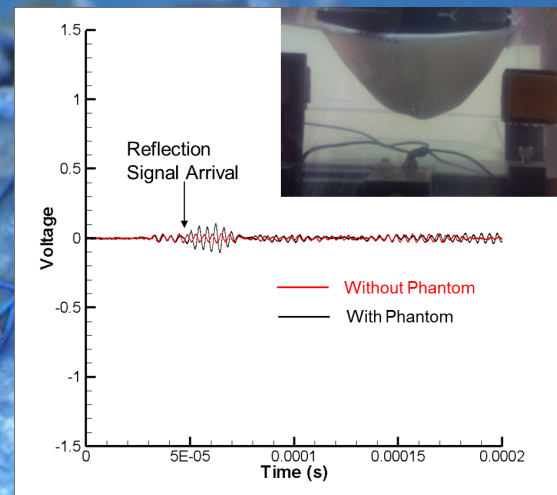
With Filters

Technical Progress – Gen 5

The Gen5 iteration repurposed the second receiver in order to allow for target contour mapping.

Mapping the external contour is a requirement that enables the following:

1. The contour map allows for a graphical representation of the target. This is needed to place any detected anomalies to be localized within it.
2. The contour enables precise calculations of Time of Arrival (ToA) by differentiating the portion of the sound path in water vs tissue. Expected vs Actual ToA variances are used along with received amplitude to detect presence of anomalies.

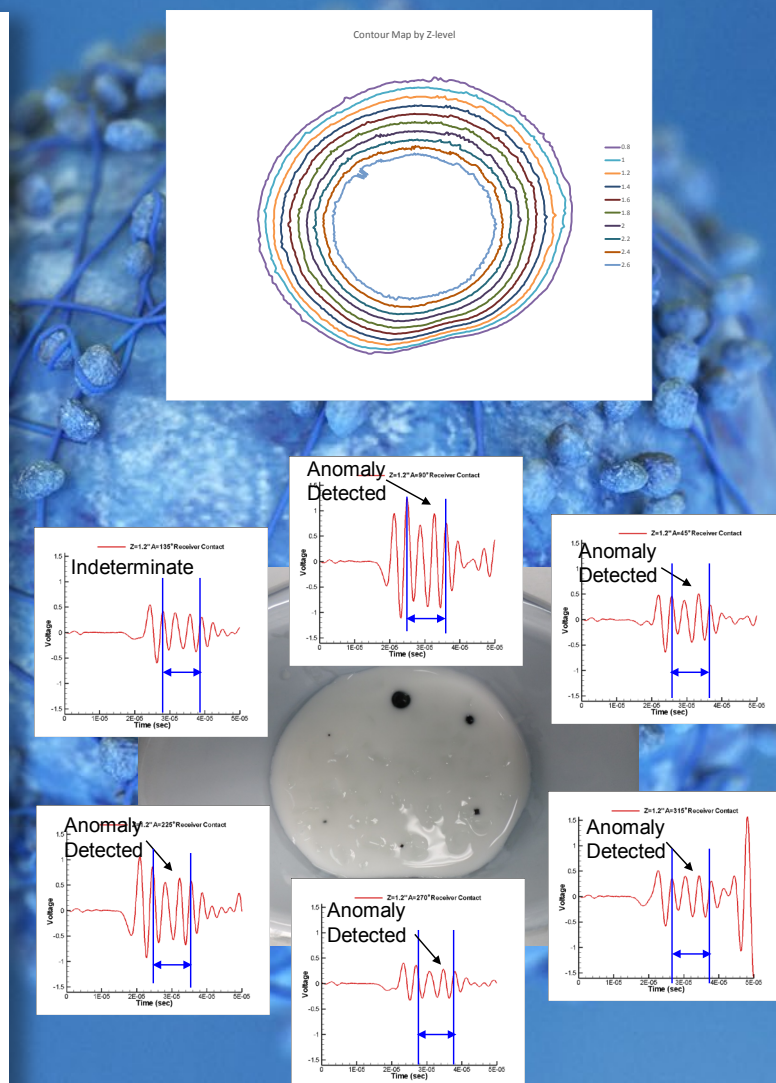


Gen 5 Test Results

The results from Gen 5 testing exceeded expectations with 9 detections at the primary (through-transmission) receiver. Follow up tests against the secondary (offset reflection) receiver confirmed 7 of the primary 9 while adding an additional 5 for a total of 12.

The 12 detections included 5 out of 6 on the two largest cross sections of the phantom (see next slide for detail) only missing the 0.5mm anomaly in each case. Interference due to the anomaly placement prevented better results at the third level.

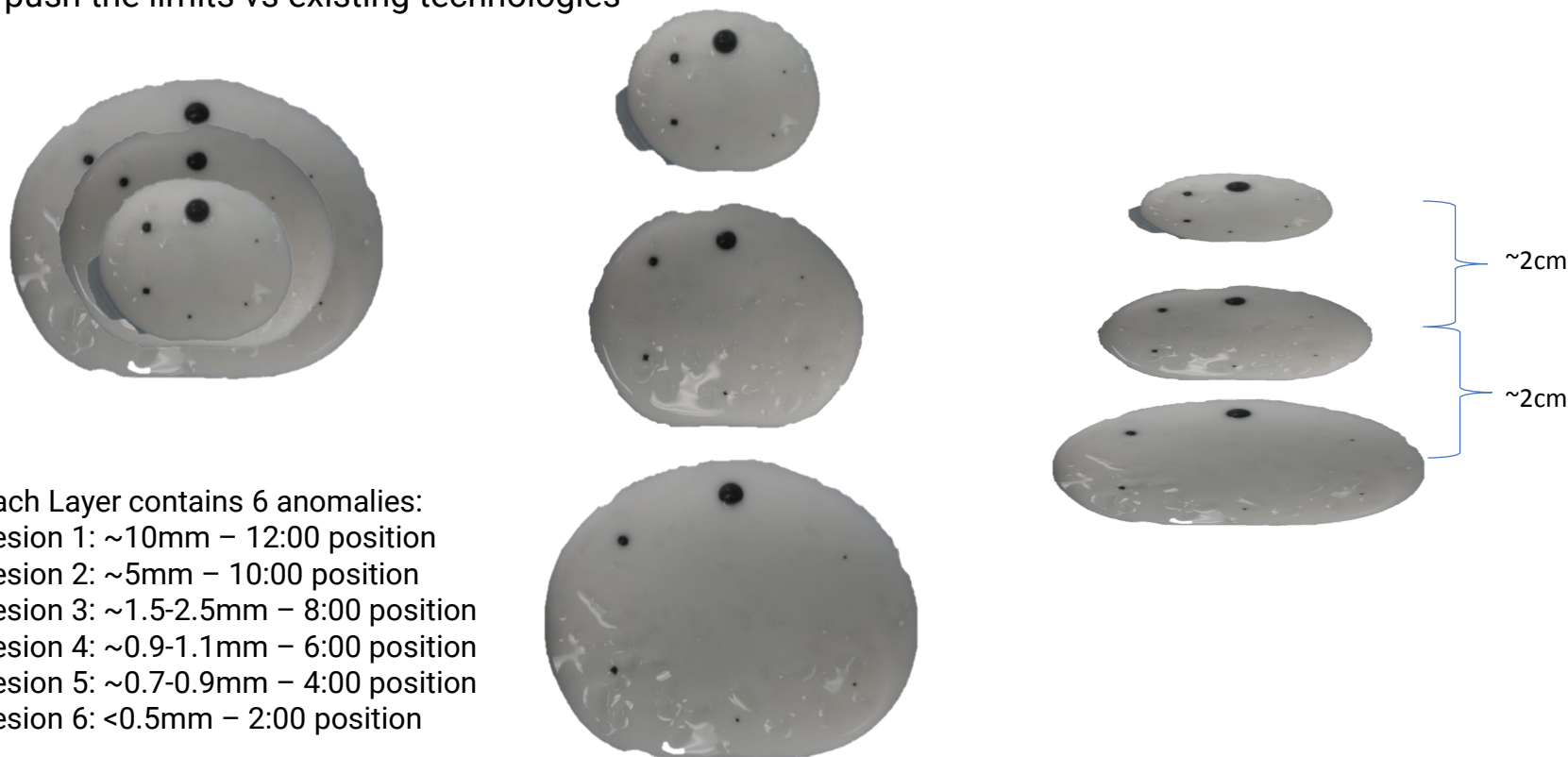
Overall the results were outstanding and point to a clear and inexpensive pathway to continued improvement in both resolution and location.



Clinically Relevant Test Protocol

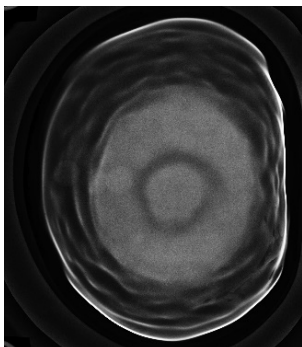
CIRS Custom Dense Breast Phantom

UMM has conducted comparative testing using a customized “dense breast” phantom designed to push the limits vs existing technologies

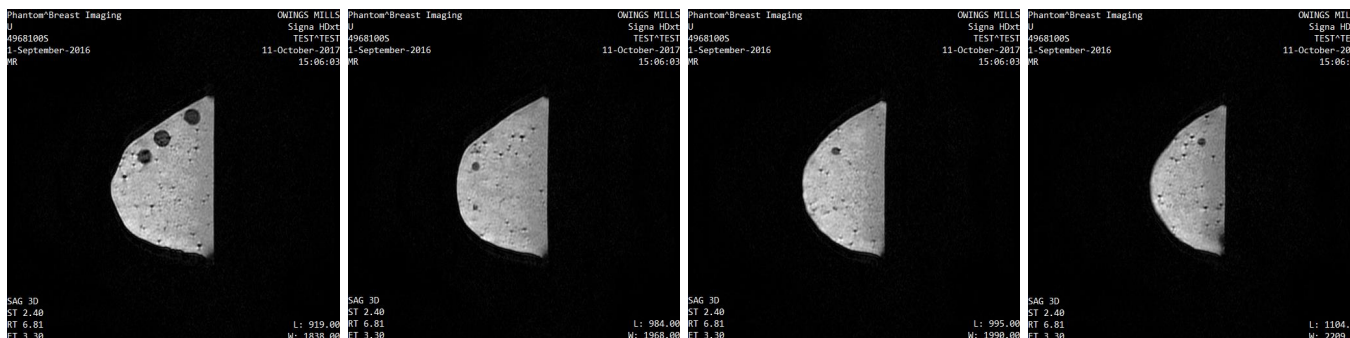


Anomalies detected by Competing Tech

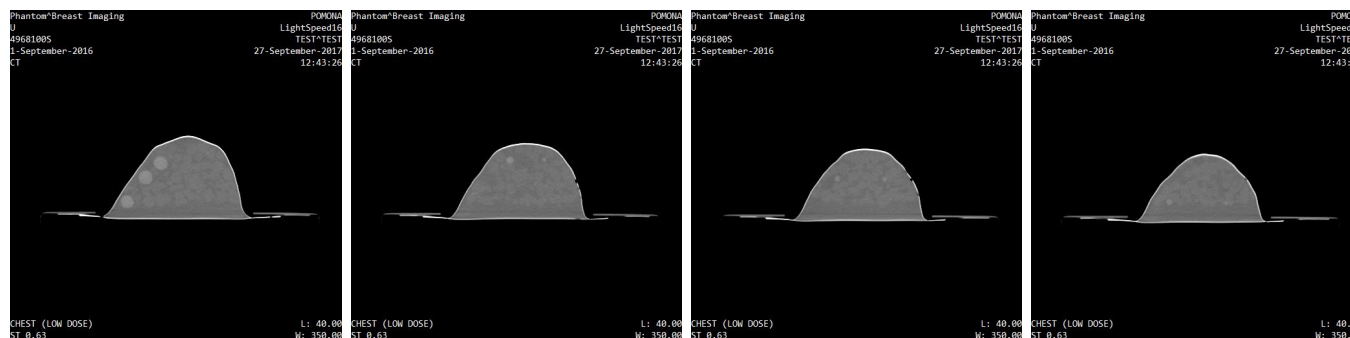
UMM Prototype detected 12 out of 18 anomalies



Mammography both 2D (FFDM) and 3D (Tomography) detected 5 out of 18 anomalies



Breast MRI detected 7 out of 18 anomalies



CT (not generally used for breast) detected 9 out of 18 anomalies

Lessons Learned and Path Forward

Lessons Learned from Preclinical Prototype

- Size of transducers used placed limits on our ability to localize smaller anomalies
- Number and Placement of transducers limited our ability to discriminate between anomalies in a direct line
- Working with raw (unfiltered) signals decreased available signal to noise.
- Mechanical apparatus was not designed around rapid scanning

Improvements Planned for Clinical Prototype

Optimization of Transducer Array

UMM will make several modifications to the transducer array based upon the results achieved in the preclinical validation including:

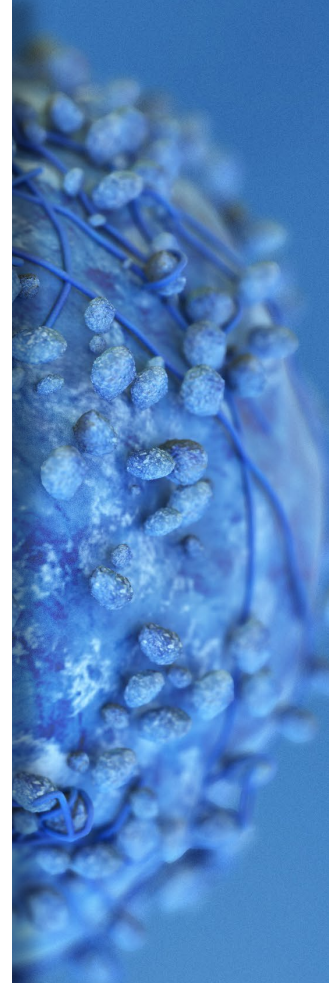
- Increasing the number of transducers in the array
- Placement of the transducers
- Reduced transducer size

Optimization of Signal Processing

UMM has a detailed roadmap to guide the optimization of data capture. This will significantly increase the signal-to-noise ratio and allow for more sophisticated analysis.

Optimization of Physical Assembly

The preclinical prototype was not optimized for scanning speed and UMM has several concepts that would bring the “time in machine” down to acceptable durations for a patient.



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