

In a typical mammogram, any tumors found cannot be immediately assessed without further diagnostic testing. High Precision Devices set out to change all that with its Quantitative MRI (qMRI) Breast Phantom which was funded in part by the NIST SBIR program.



HIGH PRECISION DEVICES, INC.

While mammograms are widely recognized as a necessary means to detect breast cancer, the actual results of a mammogram do not tell the doctor anything about what is found. If a lump is detected, there is no way to know, without further diagnostic testing, if that lump is cancerous, benign, or something altogether different. Diagnostic testing involves biopsies and/or surgeries and it can take months for the patient to have any definitive results.

PHASE III SUCCESS

High Precision Devices has sold over 100 of its Phantom systems to customers around the world, including the Top 5 hospitals in the United States; \$6 million in total revenue from all of its SBIR funded technologies.

AGENCIES

DoC (NIST), DOD, NSF, HHS

SNAPSHOT

High Precision Devices (HPD) developed an imaging standard called the qMRI Breast Phantom that helps develop imaging protocols to identify breast tumors as either cancerous or benign without invasive, diagnostic testing. Funding for this initiative was provided by the Department of Commerce through NIST.

HIGH PRECISION DEVICES, INC.

1668 Valtec Lane, Suite C
Boulder, CO 80301
www.hpd-online.com

High Precision Devices (HPD), a precision instrument R&D and manufacturing small business, wanted to change this dynamic and so it set out to create a standard to enable non-invasive diagnostic testing. In doing so, it is raising the bar on improving imaging standards throughout the medical industry.

“Imaging diagnostics produce an anatomical grayscale picture, but MRI has an unharnessed capability to differentiate cell types,” explains Dr. Elizabeth Mirowski, VP of Imaging Standards Division at High Precision Devices, Inc. “Let’s say a woman goes in and the doctor detects a lump. It could be six months before she gets conclusive results. With MRIs and most imaging systems, you don’t have any sort of real ground truth standards that would allow you to correlate image data to biomarkers of a disease, which would tell you whether a lump is benign or potentially cancerous.”

HPD had long been in the field of precision instrument development, and has been selling its systems, called the Phantoms, to customers all over the world. The company’s product line includes the System Phantom and the Diffusion Phantom, which provide a standard for identifying new biomarkers associated with neurological and other diseases.

HPD wanted to see if the same technology could be applied for breast imaging, so they utilized the Small Business Innovation Research (SBIR) program through the National Institute of Standards & Technology (NIST). Through back-to-back Phase I and II grants, the company launched its newest Phantom – the Quantitative MRI (qMRI) Breast Phantom.



HPD's qMRI Breast Phantom consists of an anthropomorphic set of pliable silicone shells with rigid polycarbonate internal structures.

"So now, we are collaborating with researchers to see if we can identify that lump as cancerous or benign," says Mirowski. "If it is possible we can then reduce the number of biopsies performed in a year, which currently stands at about 1 million."

The technology provides a ground truth standard by which data from multiple sites and across time can be compared to determine what values of the various MRI parameters correspond to normal and abnormal tissue. The Breast Phantom can fit into most detection coils for breast imaging and all components are traceable to NIST, providing for accurate standardization of MRI scanners and breast coils as well as imaging protocols and procedures.

"We already commercialized two Phantoms prior to this, so it was in line with our goals for imaging standards," recalls Mirowski. "We had originally worked on some basic mechanical parts but with the SBIR funding, we were really given the leeway to create stable and nonbiological mimics of human tissue."

HPD is currently targeting software development around the Breast Phantom, to allow the end user to have as little interface as possible and enable a rapid QC program. The software aims to make doctor's jobs easier and faster, as well as answers the questions of whether the machine is functioning properly, and if all the protocols are working.

Clinical trials are still in the works for the Breast Phantom to test its accuracy, but based on the commercialization of the previous Phantom systems, HPD is confident the device will be widely used in the diagnostics market.

"We have engaged investors to accelerate the phantom efforts, and have gotten some great feedback," says Mirowski. "It's amazing how far we've come with our product, without the help of anything except the SBIR program. Eventually we'd like to work with our customers to develop Phantoms for other regions of the body."

This isn't the first time HPD has realized success from the SBIR program. In an unrelated SBIR technology area that was originally funded by the Department of Defense (DOD), HPD now has the expertise and capability to design and manufacture custom, ultra-low temperature (ULT) cryogenic systems for its customers, which include government agencies, academia, and private industry. The company's specialty is the integration of millikelvin cryogenics with precision mechanics, optics and electronics for a wide range of research applications. Revenues from this technology exceed \$4 million.

With customized precision instrumentation, high demand for its product line within the medical diagnostics industry, and innovative new ideas spawned from the SBIR program, High Precision Devices is an exemplary small business which has turned government funding into life-saving and sought after technologies.

"We had originally worked on some basic mechanical parts but with the SBIR funding, we were really given the leeway to create stable and nonbiological mimics of human tissue."

DR. ELIZABETH MIROWSKI
VP OF IMAGING STANDARDS DIVISION

