Functional Images of Hemoglobin and Blood Oxygen Saturation Co-registered with Ultrasound Provide Accurate Differentiation of Breast Tumors

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Disclosures:

- P. Otto
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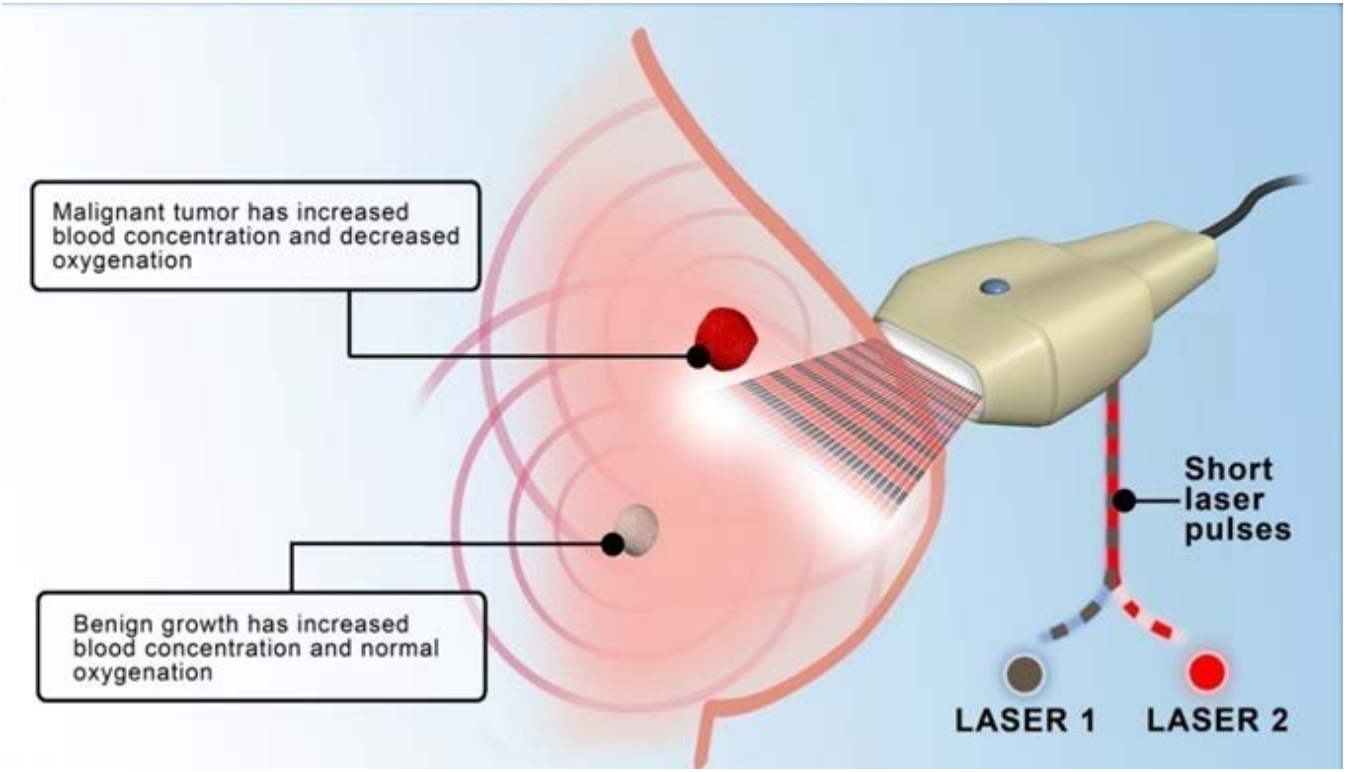
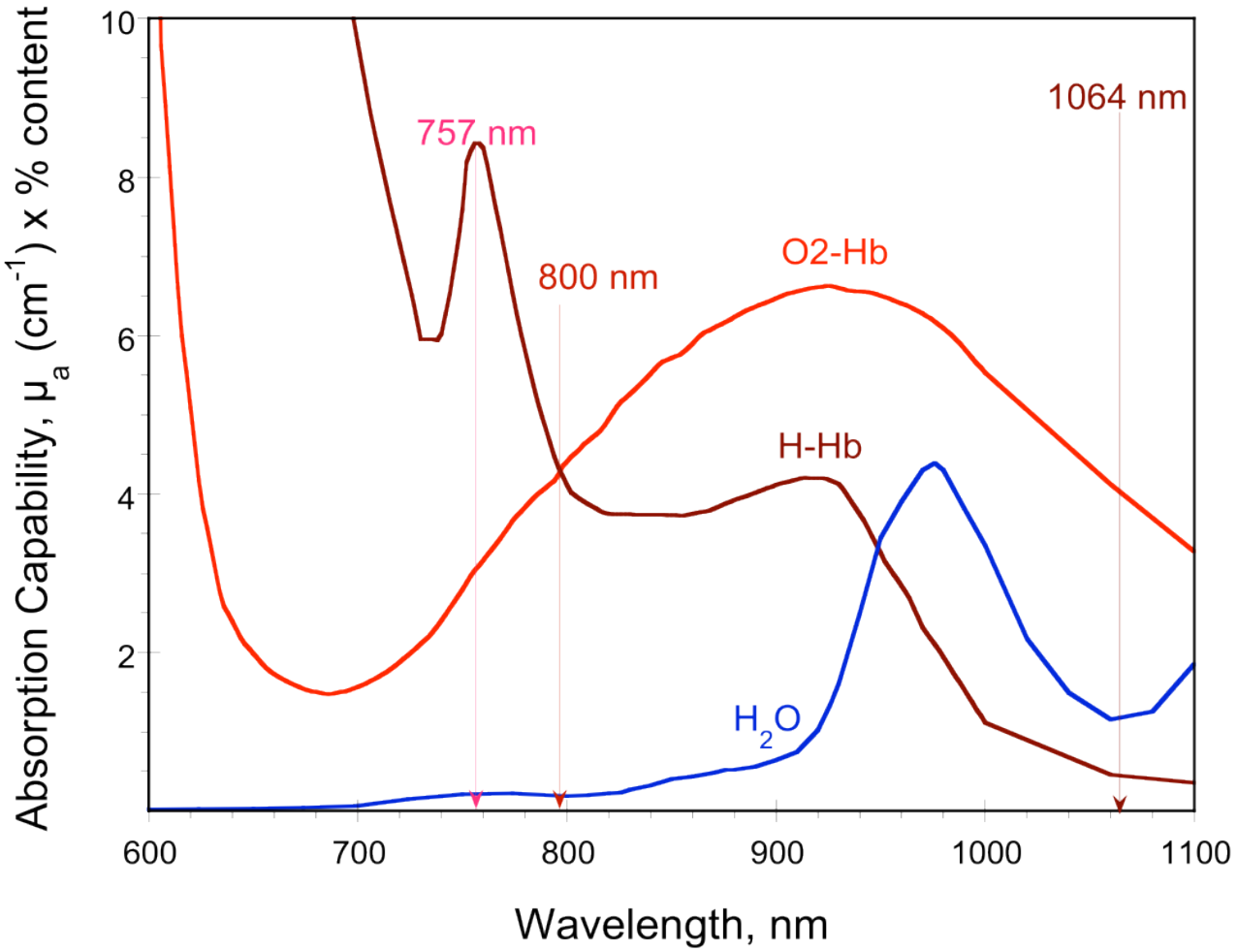
- T. Stavros, M. Ulissey, D. Herzog, B. Clingman, J. Zalev, P. Lavin and A. Oraevsky
  - Employees of Seno Medical Instruments

Co-registration of Opto-Acoustic and Ultrasound Images

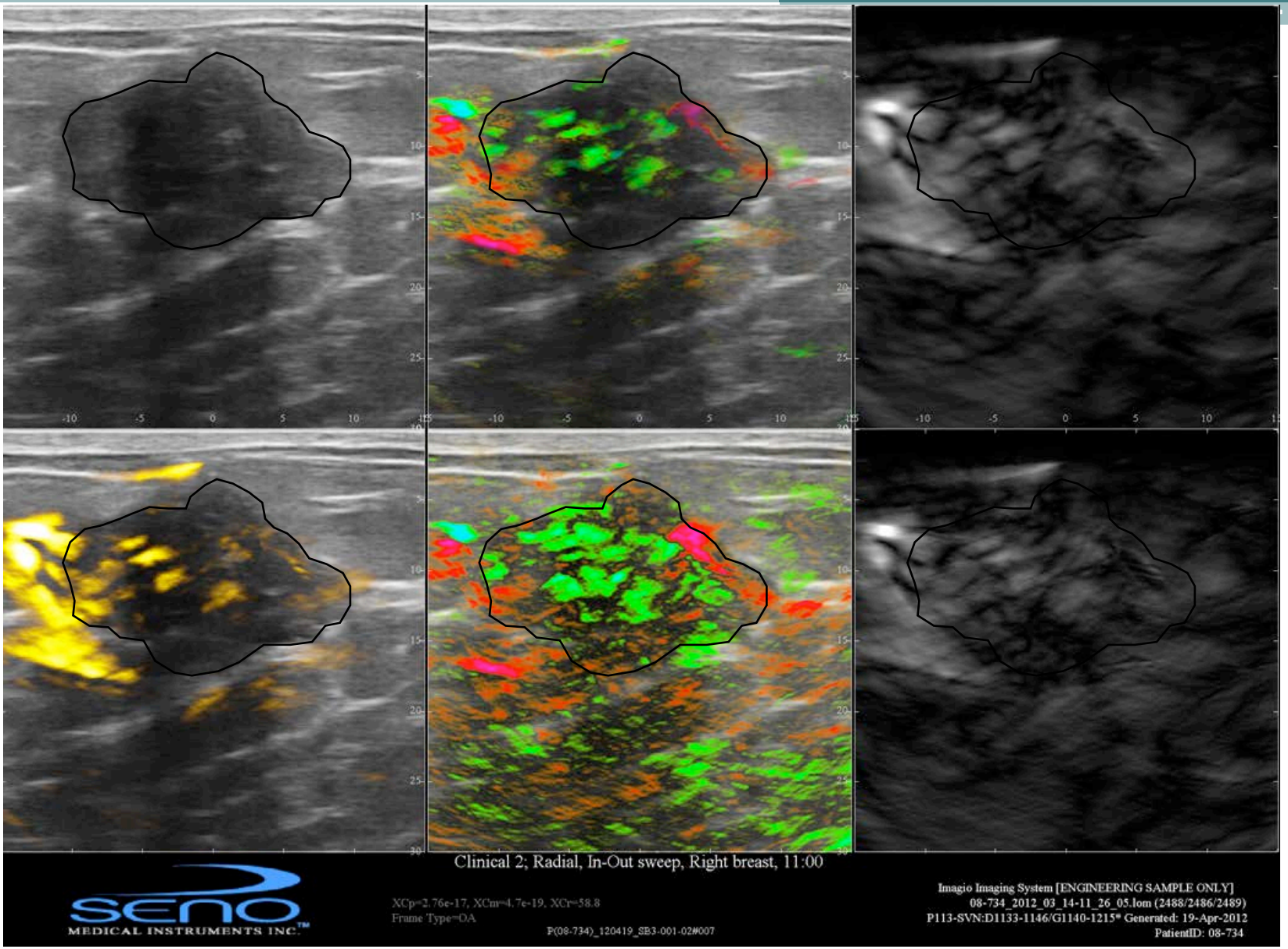
- OA technology combines and co-registers images based on optical and acoustical contrast.
- Co-registered OA+US imaging has the merit of providing both functional information based on specificity of optical contrast in blood and morphological information due to the high resolution of ultrasonic imaging



Molecular Components of Optical Absorption in Breast Tissue

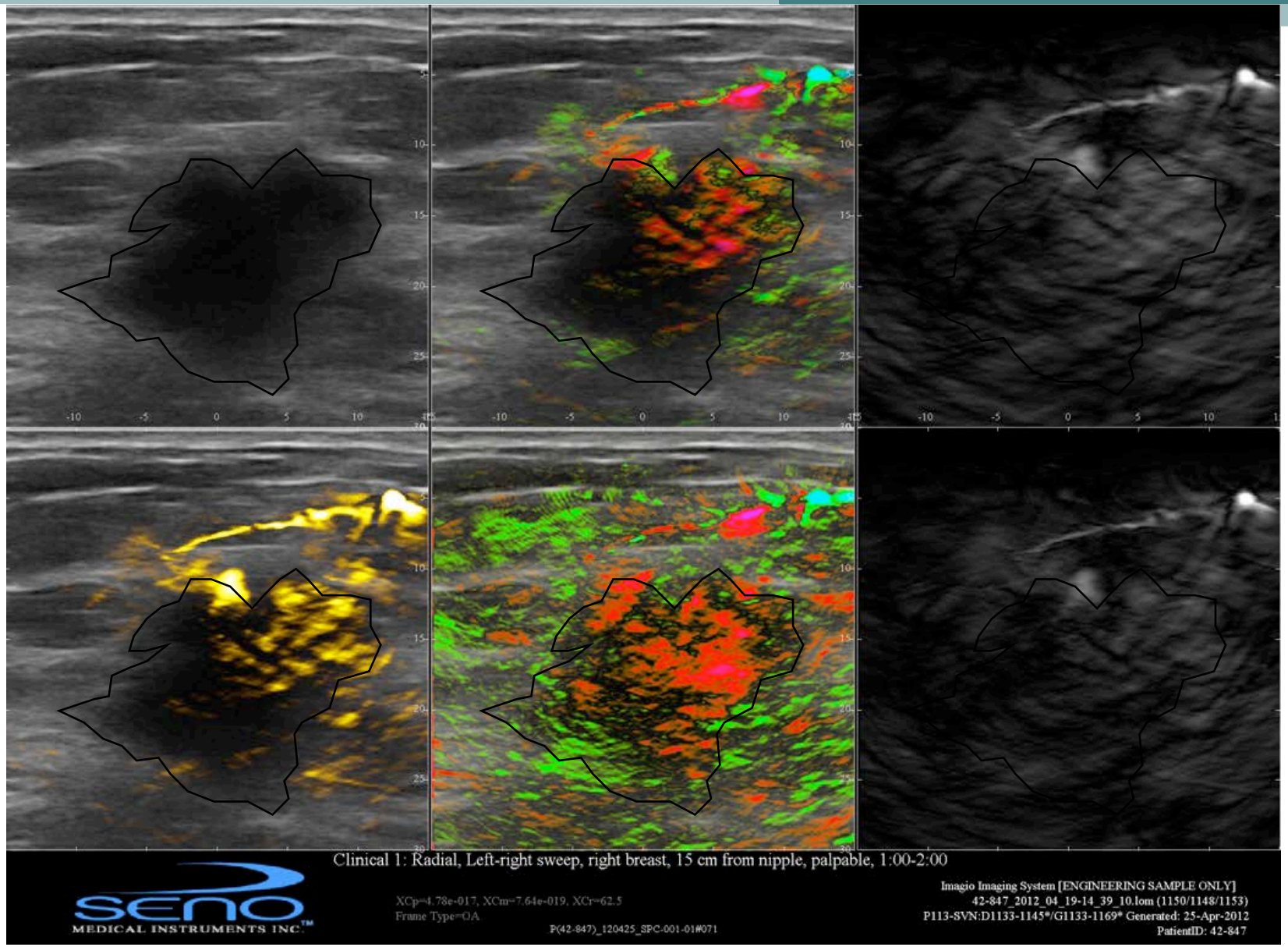


Fibroadenoma



1) normally polar branching feeding and draining vessel 2) mostly green internal signal

Invasive ductal carcinoma



1) internal red vessels 2) internal red blush 3) internal increased Hgb 4) superficial draining vein

Study Design

- 155 subjects (two TX sites) assessed
  - 73 biopsies: 39 benign, 34 cancers
- All had OA imaging prior to biopsy
- Biopsy was the gold standard
- Images read by 5 independent readers
  - Blinded to clinical data
  - No site guidance

Image Sets

- CDU
- IUS
- OA + Mammography
- OA + Mammography + CDU
- Mammography + CDU

Effectiveness Endpoints

- Probability of malignancy (POM)
  - Benign vs. malignant
  - BI-RADS 4ab: benign vs. malignant
  - Reader consistency
- ROC AUC (primary) from POM
- Sensitivity
- Specificity

Results: POM ROC AUC

- **All image sets produced AUC > 0.8 (0.5 random)**

Results: ROC Curves

- **OA had an advantage for POM<2%**

Results: Mean POMs

- **Mean POM**

	n	OA	IUS	I+M	CDU	H+M	All Images
BENIGN	39	**31.5**	19.9	**29.6**	19.9	18	**21.7**
MALIGNANT	34	**73.6**	64.1	**79.8**	62.1	68.3	**80.7**
Difference		**42.1**	44.2	**50.2**	42.2	50.3	**59**

OA is helpful in confirming cancer

Results

Sensitivity and Specificity by POM

POM Cut Point	OA Spec	OA Sens	IUS Spec	IUS Sens	CDU Spec	CDU Sens
0	0	1	0	1	0	1
1	0.058	1	0.058	1	0.026	1
2	**0.237**	**0.988**	**0.183**	**1**	**0.161**	**1**
3	0.368	0.976	0.351	0.988	0.363	0.994
4	0.389	0.976	0.356	0.988	0.389	0.988
5	0.4	0.976	0.366	0.988	0.389	0.988
10	**0.437**	**0.976**	**0.524**	**0.976**	**0.513**	**0.976**
15	0.5	0.929	0.644	0.94	0.606	0.898
20	0.526	0.929	0.66	0.934	0.622	0.886
25	**0.547**	**0.923**	**0.691**	**0.922**	**0.658**	**0.867**

Limitations of Study

- Number of patients
- Real time Imagio imaging did not have co-registered images available to the physician scanning

Summary

- OA POM ROC AUC exceeds 0.80
- OA IUS scores higher than CDU
  - IUS is non-inferior to CDU
  - OA may be superior to CDU
- OA has a higher POM for malignant lesions than CDU

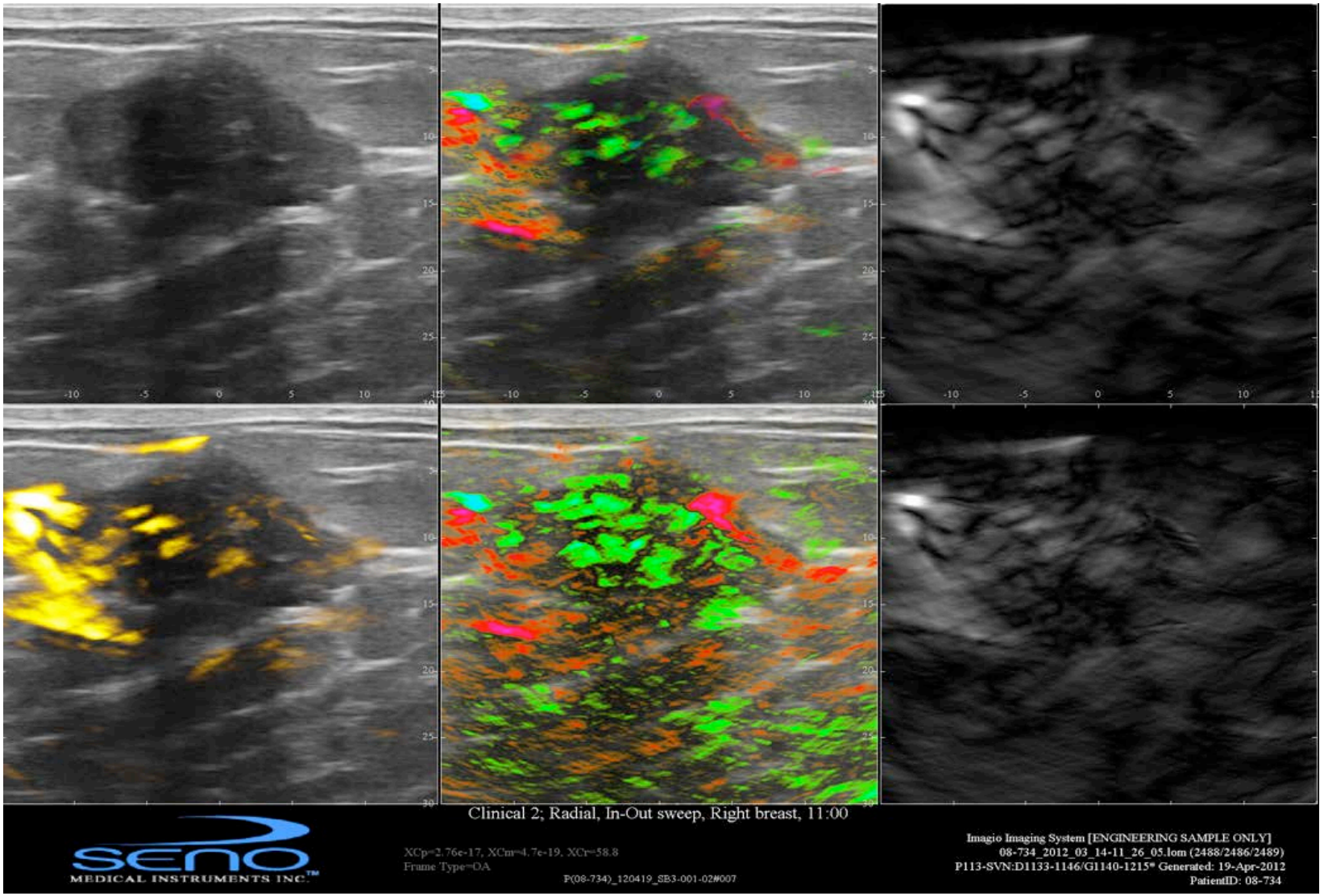
Summary
OA+US Imaging as a Clinical Technology

Preliminary Statistical Analysis of Clinical Feasibility Study:
(5 blinded readers, adjudicated and independently analyzed)

- Potential to spare 40% more biopsies
- Provides >42.1% mean POM difference between benign and malignant tumors for all variety of lesions
- Detects BIRADS 5 malignancies 10% higher mean POM vs. mammography + conventional diagnostic ultrasound

Co-registered OA + US may substantially improve Sensitivity and Specificity compared to the present standard of care

Thank you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SENO
MEDICAL INSTRUMENTS INC.
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