

HEMOGLOBIN-POLYMER PHANTOMS FOR BIOPHOTONIC DEVICE PERFORMANCE EVALUATION

Technology Summary

Researchers at FDA have developed tissue-simulating phantoms that can accurately mimic the absorption and the scattering optical properties of biological tissue. The phantoms comprise silicone and hemoglobin, and can be shaped to accurately mimic a broad range of living tissue and corresponding organ shapes, such as breast, skeletal muscle, brain, and kidney tissue.

This technology is the first stable bio-photonic phantom that can provide realistic spectral characteristics of hemoglobin in its oxygenated and deoxygenated forms. The phantoms achieve superior accuracy simulating the optical properties of different tissues, along with improved long-term stability over preexisting phantom technology. Although several phantoms currently exist for biophotonic imaging systems, none are solid, stable, and contain hemoglobin in its native conformation. The FDA hemoglobin-polymer biophotonic phantoms are optimal for clinical use and can be used to calibrate or to test optical imaging systems.

Potential Commercial Applications

- Bio-photonic diagnostic device evaluation
- Endoscopic fluorescence imaging systems
- Clinical trial standardization
- Manufacturing quality assurance
- Regulatory evaluation

Competitive Advantages

- Long-term stability
 - Stable for up to one year
 - Will not typically change more than 10% for at least 2 months following construction
- Non-toxic preparation
- Can be manufactured in layers through sequential casting with varying oxygenation levels of hemoglobin

Development Stage: *In vivo* applications; prototype

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Publications:

“Solid hemoglobin-polymer phantoms for evaluation of biophotonic systems” *Opt Lett.* 2015 Sep 15;40(18) 4321-4. PMID: [26371926](https://pubmed.ncbi.nlm.nih.gov/26371926/)

Intellectual Property:

United States patent: US [10,024,785](https://www.uspto.gov/patent/publications/details/10024785) B2, issued 07.17.2018

Product Area: medical devices; optical measurements; calibration

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