

## **Modulated Imaging Receives FDA Clearance for its New Clarifi Imaging System**

Irvine, CA—July 31, 2018—[Modulated Imaging](#), the leader in optical imaging solutions powered by Spatial Frequency Domain Imaging (SFDI) for noninvasive assessment of tissue health, announced today that it has received FDA 510(k) clearance for its new medical device, the Clarifi™ Imaging System.

Clarifi is the first and only commercialized diagnostic medical device to use SFDI, a patented technology based on structured light, that helps clinicians assess tissue function and compromised circulation by measuring oxygenation and hemoglobin levels in superficial tissue. This essential information can be used in the assessment, management and treatment of several challenging conditions, including peripheral vascular diseases, diabetic foot ulcers, burns, skin flaps, and chronic wounds.

Clarifi is a non-contact noninvasive system that measures tissue oxygen saturation (StO<sub>2</sub>), oxyhemoglobin (HbO<sub>2</sub>), and deoxyhemoglobin (HbR). In addition, it is the first noninvasive diagnostic technology to quantitatively display total hemoglobin levels in superficial (0-1mm) and subsurface (1.5-3 mm) layers—HbT<sub>1</sub> and HbT<sub>2</sub>, respectively. Clarifi's exclusive capabilities gives clinicians greater understanding of tissue perfusion, oxygen supply, and utilization. This critical information can be used for earlier identification of patients who are at risk for developing wounds, and to guide clinical interventions to prevent their onset or escalation.

Optimized for seamless integration into a variety of care delivery environments, Clarifi is designed to address shortcomings of existing spectral imaging systems (multispectral and hyperspectral) by incorporating structured light into the process. Clarifi is smaller, faster, and lighter than its predecessor, Ox-Imager CS®, and it offers the largest optical imaging field available—approximately 225 mm x 300 mm—and can image the entire plantar aspect of a foot. The system displays color-coded images of each biomarker to help clinicians assess oxygenation and hemoglobin delivery to superficial and subsurface tissue in any region of interest, with clarity and confidence.

“The ability to separately quantify and display in total hemoglobin and distribution in superficial and subsurface layers of tissue is a significant advancement,” said Anand S. Patel, MD, Chief of Interventional Radiology at Providence Little Company of Mary Medical Center. “Modulated Imaging’s technology should enable us to better diagnose and treat patients with compromised circulation who may be at risk for lower limb diabetic complications, peripheral arterial disease, or similar conditions.”

“With much of our daily practice dedicated to limb salvage, this technology is so exciting because I know it will provide information that will allow us to prevent ulcers before they

occur, heal them more efficiently when they do occur, and ultimately limit amputations," said Jeffrey Lehrman, DPM, Medical Director at the Crozer Wound Healing Center in Pennsylvania.

"Clarifi is a powerful example of how cutting edge optical imaging and computational technologies can be combined to create new, accessible tools for Precision Medicine," said Bruce Tromberg, PhD, Director of the Beckman Laser Institute and Medical Clinic at UC Irvine. "Clarifi delivers more insight into oxygen delivery, availability, and utilization at the microvascular level than any other diagnostic technology. Unlike other optical imaging devices used for assessing tissue, Clarifi quantifies and displays hemoglobin concentration and distribution in the superficial and subsurface. Every person is different, and this new information reveals individual biomarkers that clinicians can use to optimize health and clinical outcome for each patient."

"We're proud to be able to provide meaningful information that advances patients' health and wellness. FDA clearance is a major milestone for our company, and for the patients and physicians within the vascular treatment communities," said David Cuccia, PhD, Modulated Imaging's CEO and CTO. "Clarifi can lead to significant preventive care actions as well as over \$6 billion per year in savings to the US healthcare system."

The Clarifi imaging system demonstrates Modulated Imaging's continuing mission to deliver technology that provides clinically actionable information for early intervention, enabling caregivers to prevent the onset or escalation of conditions related to circulatory compromise.

The company is currently ramping up production of the Clarifi imaging system and expects to start fulfilling orders by the end of Q4.

**About Modulated Imaging:** Modulated Imaging leverages medical photonics and informatics to help clinicians assess tissue health. Powered by Spatial Frequency Domain Imaging (SFDI), the company's disruptive technology identifies compromised circulation and perfusion by measuring microvascular tissue oxygenation and hemoglobin concentration and distribution. As a result, the company's optical imaging system can identify patients with tissue health problems early enough for clinicians to intervene. With widespread adoption, this approach could save thousands of limbs and lives, not to mention billions of dollars in treatment costs.

Spatial Frequency Domain Imaging was invented by researchers at UC Irvine's Beckman Laser Institute, including Dr. David Cuccia, CEO/CTO of Modulated Imaging. Dr. Cuccia and Dr. Amaan Mazhar, VP Research & Development, are internationally-recognized experts in medical photonics.

Clarifi and Ox-Imager are trademarks of Modulated Imaging.

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