Spatial Frequency Domain Imaging (SFDI): Enabling Point-of-Care Microvascular Assessment to Guide Clinical Care

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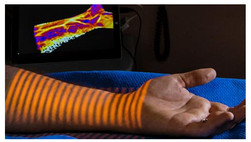
Microcirculation: A Barometer of Tissue Health

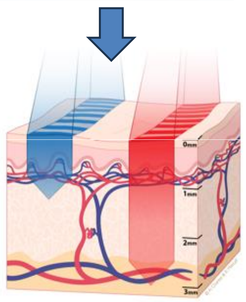
Need: Quantitative assessment of tissue health

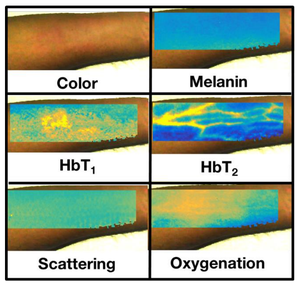
- Clinicians lack an on objective measure of circulation and tissue health at the point of care.
- **CURRENT STANDARD:** Subjective visual check, often by a non-expert.
- **NEED:** Rapid assessment of tissue health at the point-of-care

Solution: Spatial Frequency Domain Imaging (SFDI)



- Patented method to characterize tissue health
- Rapid (<1s) acquisition
- Non-contact and widefield
- Optical (non-radiative)
- Quantitative biomarkers





Solution Ecosystem

Clarifi® Imaging System

Cart-based, FDA-cleared microvascular imaging hardware outputs biomarkers to help identify circulatory issues below skin.

Magnifi Viewer

HIPAA-compliant cloud-based workflow to facilitate remote patient management by specialist care team.

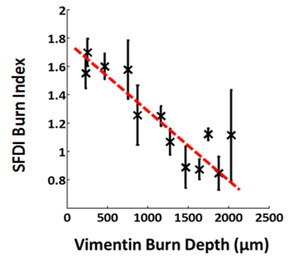
Burn Digital Assessment

MTEC-22-08-BDA: Field-deployable device builds on established burn research foundation

- **Military need**: Handheld assessment tool to help healthcare teams triage and manage burn patients at far-forward point of care settings

MTEC Medical Technology Enterprise Consortium

1. Unique SFDI biomarkers correlate with histological burn depth at day 1



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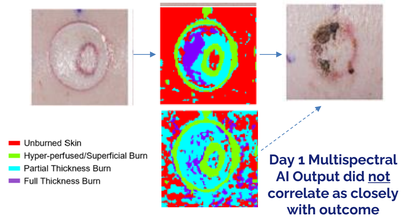
2. SFDI biomarkers enhance AI algorithms for predictive insights

Day 1 SFDI-based AI Output correlates with eventual outcome



Day 1 Multispectral AI Output did not correlate as closely with outcome

Year 1: Deliver a handheld prototype

- ~80% reduction in size[1]
- ~70% reduction in weight[1]
- ~5x reduction in cost of goods[1]
- On-board processing
- On-board visualization

[1] compared to cart system imaging head

	Clarifi Cart System	m-Clarifi Handheld System
Imaging Head (weight)	5 lbs	1.5 lbs
Imaging Head (size)	20 cm x 19 cm x 10 cm	8.5 cm x 22.5 cm x 3.5 cm
Total System (weight)	105 lbs	1.5 lbs
Total System (size)	46 cm x 46 cm x 127 cm	8.5 cm x 22.5 cm x 3.5 cm
Processor	Surface tablet	On board compute platform
Camera	COTS	Custom
Light Source	COTS w/ motorized projector	Custom w/ no moving parts
Methods	Multi-image SFDI	Snapshot SFDI

Year 2+: Validation + clinical data collection

- Hardware Verification and Validation (2024)
- Software development (2024-2025)
- Clinical burn study at Institute of Surgical Research (2024-2025)
- FDA submission for broad clearance of biomarkers (2025)

Biomarkers: SFDI Platform Impact

Functional biomarkers have broad utility across the entire continuum of burn care

1. SFDI Data capture with AI support for data quality → *2. Model based extraction of tissue properties* → *3. Biomarkers of tissue function and structure displayed by Clarifi* → *4. Biomarkers used by clinicians as an aid to manage multiple aspects of burn care* → *5. Enhanced predictive AI models to scale biomarker insights*

$\mu_a(\lambda)$

$\mu_s'(\lambda)$

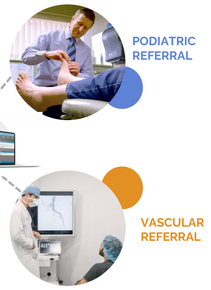
Oxygenation (StO2)
Perfusion (HbT_1, HbT_2)
Melanin
Scattering

Burn depth (thermal)
Burn Surface Area
Burn outcome
Healing time
Burn depth (electrical) Burn severity(radiation)
Debridement
Fluid resuscitation
Scarring

Index / Predictive Map

Outside DoD: Preventing limb complications

~700 Patients assessed



MICROVASCULAR ASSESSMENT

Patients w/potential circulatory issues identified remotely and referred to specialist

- Technician-acquired data in diabetes patients at clinical point-of-care
- Specialist remotely reviews cloud data to determine care path
- High risk patients are provided specialists care based on insights
- Proactive specialist care provided at the appropriate time & known to reduce complications by up to 50%

Limb care collaborators & publications

[1]Lee, et al. *Journal of Diabetes and its Complications* (2020): 107624.
[2]Weinkauf, *Journal of Vascular Surgery* 69.2 (2019): 555-562.
[3]Murphy et al. *BMJ Open Diabetes Research and Care (2020)*
[4]*Jett et al. Journal of Diabetes Science and Technology (2021)*

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modulim

- Founded by Beckman Laser Institute. researchers
- Core technology originally developed under SBIR/STTR funding
- Delivered FDA-cleared devices to assess circulatory compromise
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