

Multi-frequency Non-contact Near Infrared Device for the Diagnosis of Pressure Ulcers

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Summary

Proper classification of existing pressure ulcers (PUs) is critical because it drives treatment recommendations. The proposed device will utilize DNIRS technology to quantify the tissue optical properties and concentrations of oxy (HbO_2) and deoxyhemoglobin (Hb) levels at multiple depths within skin regions likely to develop pressure ulcers. This will allow physicians to assess if a Deep Tissue Injury (DTI) exists. The proposed system may help prevent some surgical procedures altogether as well as engender a more judicious use of expensive wound care therapies thereby having the potential to reduce the overall cost of wound care management.

Research Objective

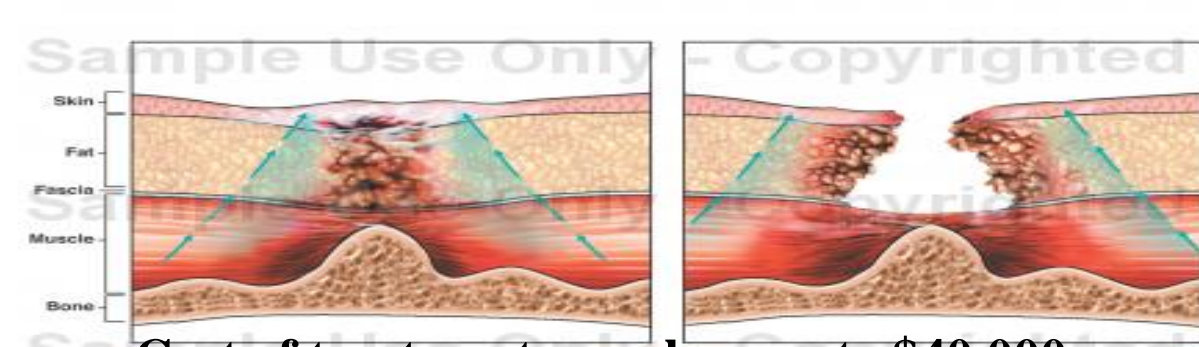
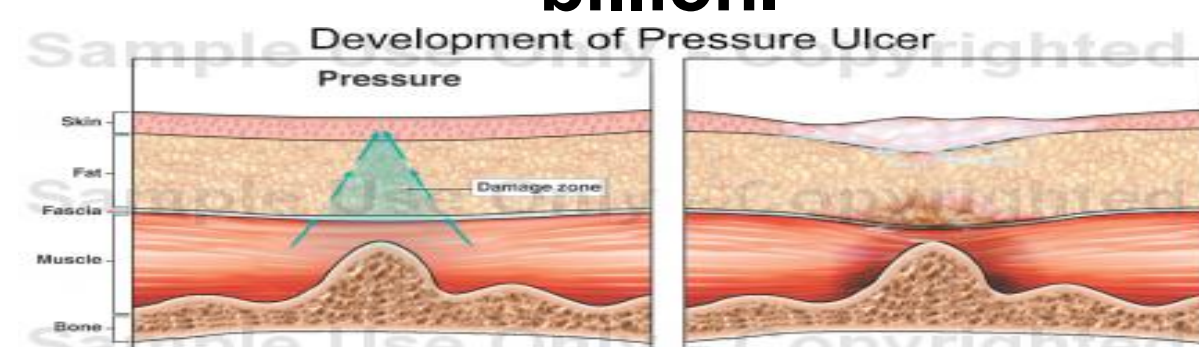
The goal of the proposed research is to implement a non-invasive optical system enabling healthcare professionals to:

- Objectively measure the health of skin, subcutaneous fat, and muscle.
- Provide an evidence-based method for non-invasively assessing depth of tissue damage at multiple depths.
- Determine if a suspected Deep Tissue Injury exists under high risk areas using a non-contact approach.
- Allow proper classification of existing pressure ulcer.

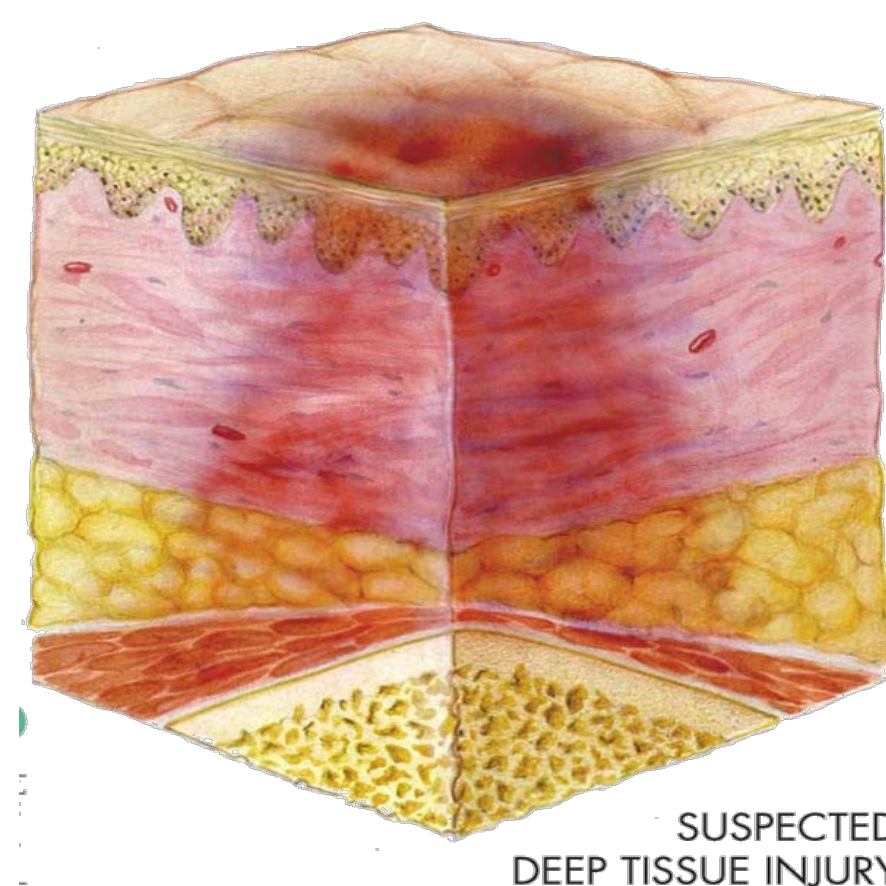
Background

~ 2.5 million PUs treated in U.S. acute care facilities alone.

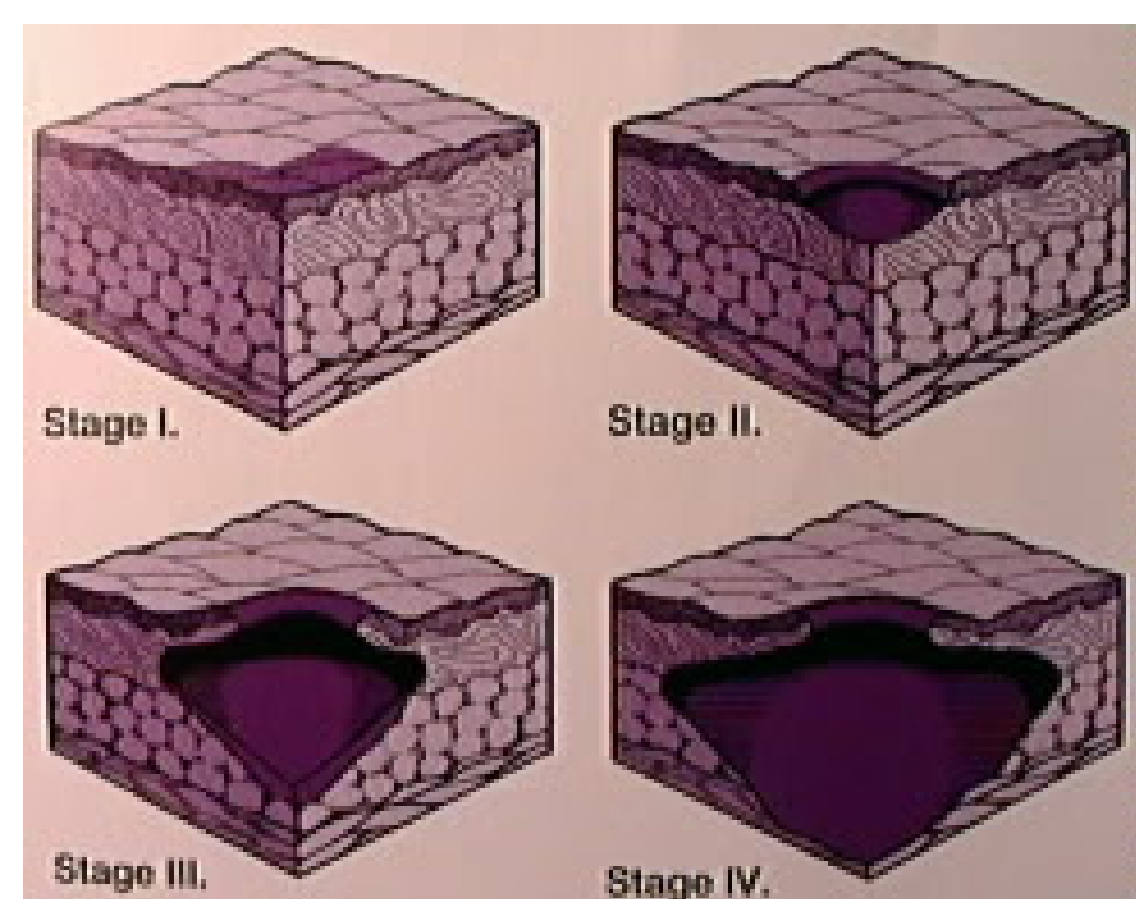
Annual treatment cost ~ \$11 billion.



Cost of treatment per ulcer up to \$40,000. Depending on the stage.



~ 60,000 patients die yearly from hospital-acquired PU complications.



Difficult to differentiate stage one PUs from suspected Deep Tissue Injuries.

Both manifest as intact skin with redness or discoloration.

Hypothesis

The hypothesis underlying this research is that changes in hemoglobin oxygenation can be used to distinguish non-viable tissue from the living dermal tissue. Pressure ulcers were chosen as an initial application for this system due to the difficulty of PU classification and differentiation (specifically between Stage I and Deep Tissue Injury).

State of the Art

Braden Scale	General Scale	Norton Scale	Waterlow Scale
Subscore with scores of 1 to 4 include sensory perception, mobility, activity, moisture, and nutrition.	Mental status subscale is scored from 1 to 5. Subscale with score of 1 or 2 include continence, mobility, and activity.	Subscore with score of 1 to 4 include physical condition, mental state, activity, mobility, and incontinence.	Subscore scores vary but include weight, height, visual assessment of the skin, gender, age, continence, mobility, appetite, medications, and special risk factors.
Total possible points range from 6 to 23. Lower scores mean higher risk.	Variables assessed but not scored include vital signs, skin appearance, diet, fluid balance, medications, and other medical.	A score of 16 or less means high risk for pressure ulcers.	The score of 10 to 14 indicates risk for pressure ulcers. A score of 10 is the critical score level.
Critical risk score cut-off score is 16 for younger clients and 18 for older adults.			
Alfred-Amerians, Asians, and Latinos. High risk scores range from 12 to 13 and lower risk scores are from 14 to 18.			
Sensitivity 52% Specificity 100%	Sensitivity 82% Specificity 87%	Sensitivity 81% Specificity 59%	Sensitivity 87% Specificity 81%
Positive Predictive Value 100% Negative Predictive Value 18%	Positive Predictive Value 89% Negative Predictive Value 92% Accuracy 82%	Positive Predictive Value 67% Negative Predictive Value 61% Accuracy 64%	Positive Predictive Value 61% Negative Predictive Value 94% Accuracy 77% ¹¹
Accuracy 66% ^{11,12}			

Scales do not objectively assess health of skin and subcutaneous tissue unlike our system.

Risk of formation currently assessed with qualitative tools such as Braden, Norton, and Waterlow scales.

BRADEN SCALE - For Predicting Pressure Sore Risk	
Subscore	Item
1	1. Sensory perception
2	2. Moisture
3	3. Activity
4	4. Mobility
5	5. Nutrition
6	6. Continence
7	7. Shear
8	8. Friction
9	9. Incontinence
10	10. Nutrition
11	11. Mobility
12	12. Activity
13	13. Moisture
14	14. Sensory perception
15	15. Continence
16	16. Nutrition
17	17. Mobility
18	18. Activity
19	19. Moisture
20	20. Sensory perception
21	21. Continence
22	22. Nutrition
23	23. Mobility

Previous DNIRS System (licensed to Emunamedica)

- Contact device
- Single frequency
- Limitations:
 - Poor depth resolution
 - Fixed measurement locations
 - Cannot measure $R < 4$ mm

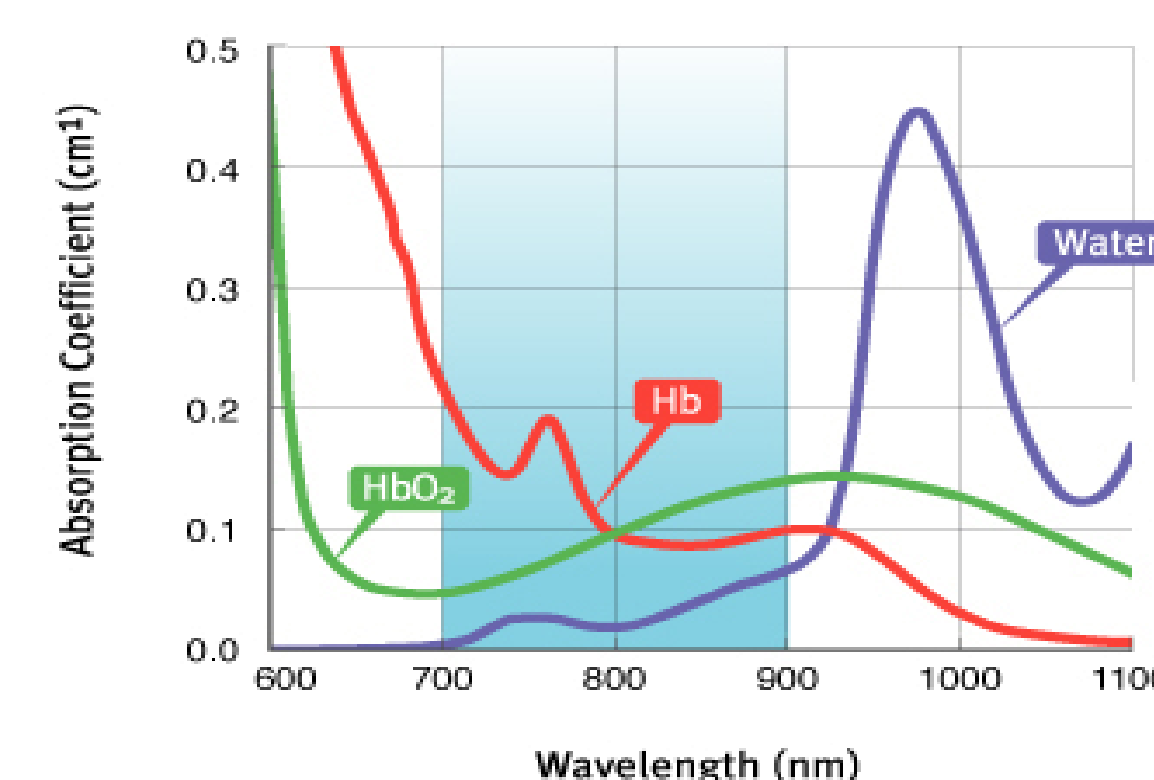
Proposed DNIRS System

- Non-contact device
- Multiple frequencies
- Advantages:
 - Precise depth resolution
 - Flexible measurement locations
 - Wide range of depths (0.15 mm to 1 cm)

Frequency-Domain Near Infrared Spectroscopy (DNIRS)

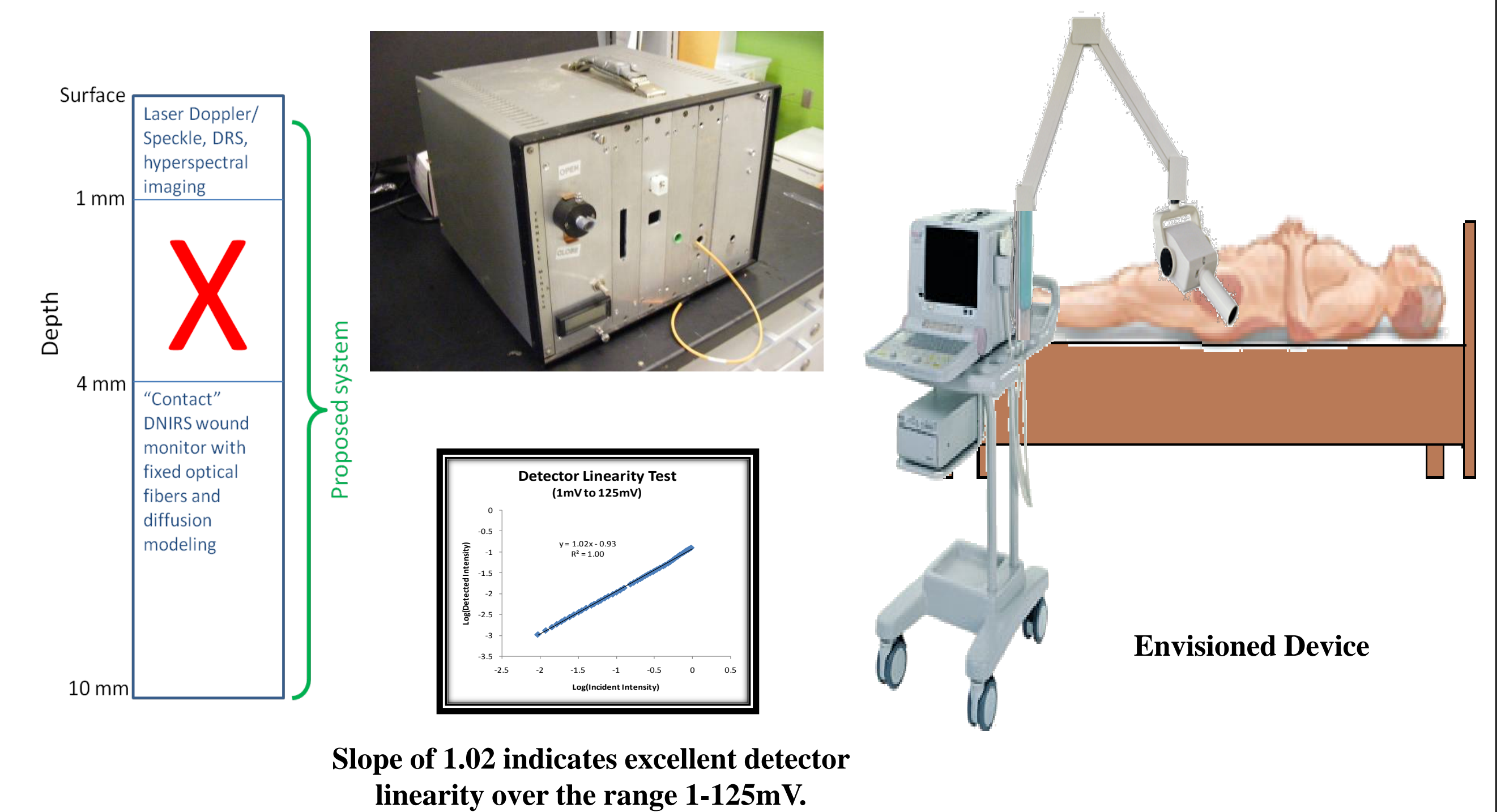
DNIRS provides quantitative information about tissue beneath the surface of the skin.

- Optical Absorption Coefficient (μ_a) at NIR wavelengths is determined mainly by deoxygenated and oxygenated hemoglobin.
- Optical Reduced Scattering Coefficient (μ_s') gives information about tissue structure (organization, composition).



Oxy and deoxyhemoglobin concentrations ($[HbO_2]$ and $[Hb]$) are calculated from measured values of μ_a

Non-Contact Device



Slope of 1.02 indicates excellent detector linearity over the range 1-125mV.

Future Work

OPTICAL PHANTOM TESTING

- Single Layer Phantom – Repeatability
- Multi-Layer Phantom – Efficacy to assess of depth



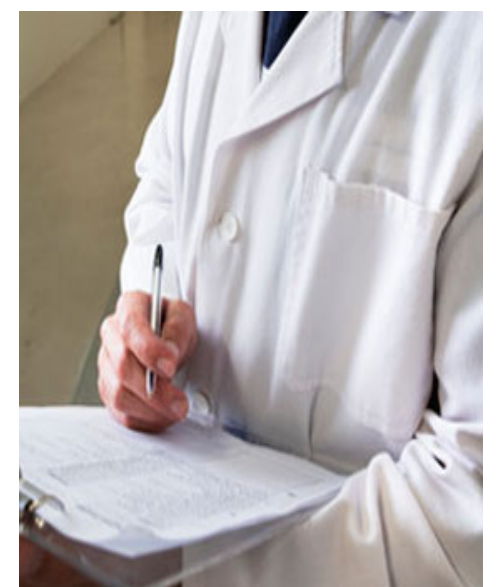
ANIMAL STUDY

- Burn Model
- Test efficacy of device in-vivo
- Assessment of depth of tissue damage



CLINICAL TRIALS

- Pilot Study
- Test efficacy of device in clinical setting



Additional Applications

There are many clinical applications for a non-contact system that can quantify tissue damage at multiple depths beyond the ones examined above. Some of the additional clinical applications include:

- Predicting healing of chronic wounds, burns, and surgical flaps.
- Provide objective information to direct initial treatments.
- Assessing the wound healing process and effectively evaluate the efficacy of treatments.
- Assessing the extent of sub-surface tissue damage in burn wounds.

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