

Validation of a Stickerless, Digital Automatic-Depth Measurement Feature within a Multi-Modal Wound Imaging Device



Danielle Dunham¹, Claudio Irrgang¹, Ben Gidalevich¹, Jeffrey Kirman¹, Nikola Andric¹, Desmond Hirson¹, Micaela D Gray¹, Carolina Wuesthoff¹

UNMET CLINICAL NEED

There is significant inaccuracy & inconsistency associated with manual wound depth measurements (probe + ruler) . This inaccurately reflects a wound's healing progress.

Why?

- Deepest point of a wound is subjective
- Pressing on tissues (tissue distortion) leads to overestimation
- Incorrect technique or differences in technique between providers

Digital methods for wound depth measurement **produce more reliable & consistent results**, with less patient discomfort.

STUDY DESIGN

- A statistically powered validation study of stickerless digital wound depth measurement using MolecuLightDX[®]

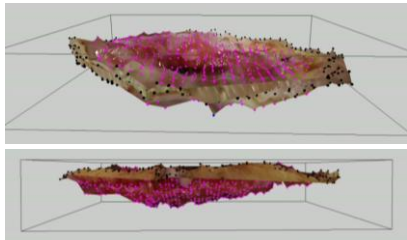
Study Elements	Part 1: Benchtop testing of wound models	Part 2: Clinical testing of real wounds
True depth reference	Calibrated, highly accurate Artec Leo 3D scanner ³	
N testers (intended users)	Five (5)	Four (4)
N wounds tested	17 (range of sizes, skin tones, wound types)	34 (range of sizes, skin tones, wound types)
N depth measurements per wound	Three (3)	Two (2)
Performance measures assessed	<ul style="list-style-type: none">• Accuracy (Error%)• Intra-user and inter-user reliability (interclass correlation coefficients, or ICC)	



Artec Leo 3D Scanner
Accuracy: ± 0.1 mm



Some of the 3D Vata Wound Models² used:
(left to right) Annie, Seymour, Wilma



Autodepth 3D renderings of
a real wound.



STUDY RESULTS

MolecuLightDX AutoDepth measurement was **highly accurate with excellent reproducibility**.

Measure	Part 1: Benchtop testing	Part 2: Clinical testing
Error	± 0.87 mm	± 0.97 mm
Intra-user ICC	0.999 (95% CI 0.997, 1)	0.992 (95% CI 0.984, 0.996)
Inter-user ICC	0.998 (95% CI 0.996, 0.999)	0.997 (95% CI 0.994, 0.998)

Intra-user = measurement variability from same user; Inter-user = measurement variability between users; 95% CI = 95% confidence interval; ICC = interclass correlation coefficient.



Wound Model

Real Patient Wounds

Overall Impressions: This feature speeds up the clinical workflow by providing contactless digital wound depth measurements alongside co-registered bacterial fluorescence images & wound length, width, and area measurements.

Objective, bedside information from MolecuLightDX[®] enhances wound care.

STUDY AIM

A two-part study validating the performance of a stickerless digital automatic-depth measurement feature within a multi-modal wound imaging device (MolecuLightDX[®]).

STUDY PROCEDURE

- Prior to testing, all study participants were trained on MolecuLightDX[®] wound measurement, including AutoDepth
- True depth wound measurements for wound models & clinical testing were taken with Artec Leo 3D scanner³

Benchtop testing of wound models:

Five intended users...

1. Capture 3D scans & wound measurement images.
2. Refine the wound border, perform AutoDepth measurement.
3. Record wound measurements & repeat until each model is imaged 3 times.

Clinical testing of real wounds:

Two clinical users...

1. Capture 3D scans & wound measurement images in a clinical setting

Four intended users...

1. Re-measure each wound image, refine the wound border, perform AutoDepth measurement.
2. Record wound measurements & repeat for a total of two depth measurements

Data analysis:

1. Accuracy measures were determined using the depth reference measurements*.
2. Intraclass correlation coefficients (ICC) for intra- and inter-user variability were also calculated using a 2-way random effects ANOVA model*.

¹MolecuLight, Inc., Toronto, ON Canada; ²VATA Inc., Oregon USA; ³Artec 3D, Senningerberg, Luxembourg.

*R Statistical Software Package (2024).