

Accuracy and reproducibility of device-based stickerless digital wound measurement software

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Introduction.

- Accurate measurement and tracking of wound size over time is important to evaluate wound healing.1
- Standard clinical practice uses a paper ruler to measure the length and width of a wound; however, this approach is known to greatly overestimate wound area and often results in inconsistent measurements between users.^{2,3}
- Digital wound measurement applications accurately measure and track wound size and reduce the variability in measurements across users.
- This application uses stereographic imaging to eliminate any need for calibration stickers and patient contact, which is an advantage over other technologies.

Objective: to validate the accuracy and reproducibility of a digital measurement application on the MolecuLight $\mathbf{D}\mathbf{X}^{\text{TM}}$ wound imaging device, which also facilities detection of regions with high bacterial loads.

Methods.

MolecuLight**DX** device with digital wound measurement software was used to measure wounds in a 2-part statistically powered experimental design:

Part 1: Benchtop wound models

- 17 wound models measured in triplicate by 5 users
- Auto and manual trace modes validated
- Paper wound models placed onto flat, slanted, and convex surfaces to simulate anatomical locations & positions of wounds typically imaged in a clinical setting

Part 2: Real clinical wounds

- 17 clinical wounds measured in triplicate by 5 users
- Auto and manual trace modes validated
- Measured real wound images previously captured at clinical sites

Calculations

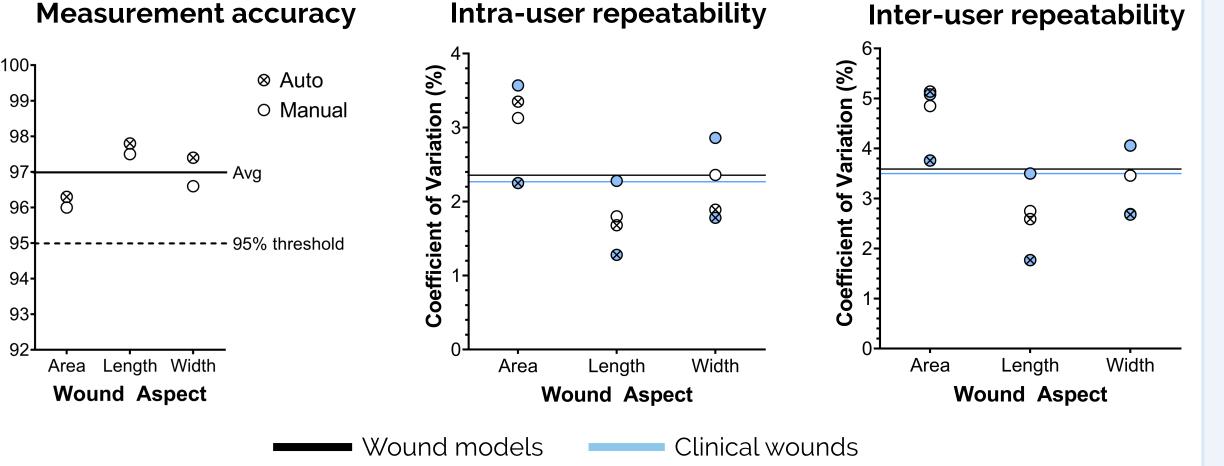
- Number of users, models, replicates were prospectively powered to validate accuracy above 95% and variation less than 10%
- Calculated coefficient of variation (CV) for intra- and inter-user repeatability using a multivariate regression model
- Measurement accuracy (%) calculated for wound models only

Results.

• Example measurements of clinical wounds using the MolecuLight**DX** (below)



- Validation data from benchtop wound models and clinical wounds (below)
- Target values are >95% accuracy and <10% coefficient of variation for repeatability



erms:

- **Accuracy** (calculated vs actual measurements)
- **Inter-user** (measurements by different users)
- Intra-user (one user taking multiple measurements)
- **Auto trace** (algorithm outlines wound border)
- Manual trace (user traces wound border with stylus)



Summary.

Part 1: Benchtop testing of wound models

- Mean measurement errors for wound area, length and width were all <4%, the intra-user variability <4% and the inter-user variability <6%.
- Demonstrates highly accurate and reproducible measurements.

Part 2: Testing on real clinical wounds

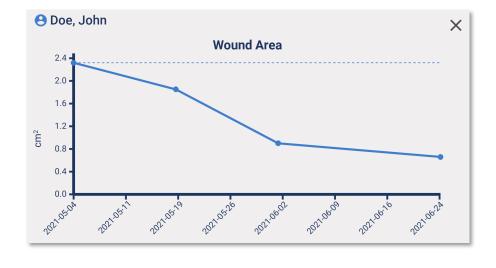
- Intra-user variability for wound area, length and width of clinical wound images was also <4% and the inter-user variability was <6%.
- Demonstrates equal reproducibility between users for real clinical wounds.

Conclusions.

Wound model schematic

These results validate the high accuracy and reproducibility of the wound measurement software and demonstrate that the implementation of software in clinical practice can be used to improve tracking of patients wound size, in addition to their bacterial loads.





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