MDDT Summary of Evidence and Basis of Qualification For MolecuLightDX

Background

MDDT Name:	MolecuLightDX
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Tool Description and Principle of Operation

The MolecuLightDX is a handheld imaging tool that allows users evaluating skin wounds to measure and digitally record the size of a wound. The MolecuLightDX is also an FDA-cleared device (K211901) intended to allow clinicians at the point of care to view and digitally record images of a wound, and to measure and digitally record the size of a wound. The MolecuLightDX is composed of a high-resolution color LCD display and touch-sensitive screen with integrated optical and microelectronic components. There are two cameras that are fixed in the housing of the device that are not shifted or moved relative to each other. The pixel dimension is determined from the shift of an object in the field of view from the 2 cameras. The device does not require direct contact with the patient or wound during operation.

The standard digital imaging capability can acquire and document standard digital images of dermatological wounds. The measurement process is initiated by taking an image of the wound. The digital built-in wound measurement software allows for the accurate determination and documentation of a wound's surface area, length and width. The MolecuLightDX has an Auto Trace mode and a Manual Trace mode, which enables the user to detect wounds for measurement automatically (Auto Trace) or enables the user to manually outline the wound borders (Manual Trace).

The device measurement mode outputs are wound area (cm^2), wound length (cm), and wound width (cm) which are objective measurements of wound size that can be used as a monitoring biomarker in clinical investigations that study medical devices intended to manage or heal wounds.

CONTEXT OF USE

"The MolecuLightDX can be used to capture images and document wound size measurements (specifically, length, width, and area) for surface wounds as a response biomarker for assessing wound healing in clinical trials studying medical devices intended to manage or heal wounds.

The tool is intended for use by healthcare professionals, who can outline wound borders using either the automatic (default) or manual trace mode. It is used in conjunction with clinical signs and symptoms to support the assessment of wound healing.

The tool is not intended for use in measuring wounds that encircle the body surface or for evaluating the extent of tunneling or undermining, or those with length of >18.5 cm, or a width of >13.5 cm as these wound characteristics fall outside the device's measurement capabilities."

SUMMARY OF EVIDENCE TO SUPPORT QUALIFICATION

MDDT Qualification of the MolecuLightDX is supported by a single-arm, prospective, paired, multicenter study (2 sites) that evaluated the accuracy and precision of the tool under both automatic and manual trace modes.

Patients were recruited based on the inclusion/exclusion criteria relevant to the context of use, namely wounds with well-defined borders (diabetic foot ulcer, venous, arterial, pressure ulcer, or traumatic wound) that were not circumferential and greater than 0.5 cm^2 in size. The full analysis set included 27 patients (between the ages 42 to 90 years) with a total of 33 wounds.

Wounds were located across various anatomical sites, including the ankle (n=12), forefoot (n=8), midfoot (n=6), shin/calf (n=4), hip (n=2), and knee (n=1) and minimum recruitment thresholds were achieved to ensure that there was representation of all skin tones, wound sizes, and wound ages within the samples.

Wound Type (minimum 3 per type, wound level)	
Diabetic foot ulcer	12
Venous leg ulcer	9
Arterial ulcer	3
Pressure ulcer	4
Traumatic wound	5
Wound Size (minimum 3 per group, wound level)	
<2 cm^2	13
2 cm^2 – 10 cm^2	14
>10 cm^2	6
Wound Duration (minimum 5 per group, wound level)	
<12 months	20
>12 months	13
Fitzpatrick Score (minimum 2 per group, patient level)	
I	5
II	5
III	9
IV	4
V	2
VI	2

Accuracy

The study assessed the accuracy of the device by comparing the measurements for the 33 clinical wounds obtained with MolecuLightDX to ground truth measurements. Each wound was measured by the manual mode and then the automatic mode and an established reference methodology. Standard of care (SOC) measurements made using the ruler method were also compared to ground truth measurements. The ground truth measurements were obtained by a separate panel of three expert clinicians who defined wound borders on images captured with a Canon EOS R10 camera and used ImageJ software to determine the wound area using reference stickers are markers of image scale. The measurement error of MolecuLightDX and SOC relative to the ground truth measurements is reported below.

Method	Mean Percent Error	95% Confidence Interval*
MolecuLightDX Manual Measurement	8.86%	[6.79%, 11.24%]
MolecuLightDX Automatic Measurement	8.16%	[5.89%, 11.28%]
Ruler Measurement (LxW)	63.97%	[39.00%, 88.93%]

*Two-sided 95% confidence interval (CI) based on the lower 2.5th percentile and the upper 97.5th percentile of distribution of 5000 bootstrap samples.

Intra- and inter- user variability

Each wound was measured by 5 clinical users three times under each mode to evaluate intra and inter-user variability. The variability is quantified by intra- and inter- user coefficients of variation (CV) averaged across all patients.

	Method	**Mean CV**	**95% Confidence Interval***
Inter-user	MolecuLightDX Manual Measurement	0.051	[0.0194, 0.0597]
	MolecuLightDX Automatic Measurement	0.0526	[0.0204, 0.0658]
Intra-user	MolecuLightDX Manual Measurement	0.0369	[0.0271, 0.0509]
	MolecuLightDX Automatic Measurement	0.038	[0.0237, 0.0597]

*Two-sided 95% confidence interval (CI) based on the lower 2.5th percentile and the upper 97.5th percentile of distribution of 5000 bootstrap samples.

DISCUSSION OF THE EVIDENCE STRENGTH TO SUPPORT QUALIFICATION

Use of the MolecuLightDX results in lower measurement error compared to SOC ruler measurements. Performance data further demonstrate that wound measurements obtained using the MolecuLightDX in both manual and automatic modes are comparable, with similar point estimates and overlapping confidence intervals across modes. The data also demonstrate that intra- and inter- user variability is similar between MolecuLightDX manual and automatic modes. The results are reported as descriptive statistics only with 95% confidence intervals. The primary qualification criterion specified a maximum acceptable error of 10% when comparing MolecuLightDX measurements obtained in manual and automatic modes to ground truth measurements. While point estimates of measurement accuracy for both modes were below the 10% error threshold, the upper bounds of the 95% confidence intervals slightly exceeded this criterion (11.24% for manual mode and 11.28% for automatic mode), indicating limited precision to definitely conclude that the qualification criterion was met. The intra- and inter- user variability met the qualification criterion of a maximum acceptable CV of 0.1, demonstrating repeatability and reproducibility of MolecuLightDX measurements across different users and repeated assessments. Due to the low sample size, statistically significant conclusions regarding tool accuracy, variability, and generalizability across subgroups could not be established.

ASSESSMENT OF ADVANTAGES AND LIMITATIONS OF QUALIFICATION

Advantages of Using the MDDT

The MolecuLightDX may serve as a valuable tool in the design of clinical trials focused on medical devices intended for wound care and healing. By offering a convenient and objective method for wound measurement, it supports accurate, reproducible assessments with low inter- and intra- rater variability—essential for reliably detecting treatment effects over time.

As the MolecuLightDX uses digital image capture to measure wounds, and can be used in Auto Trace mode, the MolecuLightDX can reduce bias and measurement error observed with other methods. The MolecuLightDX objective wound size measurements can enable repeated accurate assessments of wound size in a clinical trial evaluating a therapeutic's effect on wound size over time. Collectively, the reduction in bias, and ability to easily acquire accurate measurements can enable clinical trial designs that are more likely to detect a meaningful difference over time between treatment groups.

Limitations of Using the MDDT

This tool requires imaging of the wound area, with the device held at a specific distance (8 to 20 cm) for measurement mode. Therefore, for wounds which wrap around a body surface (e.g., around the leg), it may not be physically possible to capture the entire wound in the frame of the digital image. Thus, the tool cannot be used to measure circumferential wounds. The tool is also limited to wounds with defined borders and wounds with length and width below 18.5 cm and 13.5 cm respectively. This may mean that certain participants may not be suitable for measurement with the device, and therefore this limitation may alter the study eligibility criteria. This should be considered for a specific therapeutic to determine if clinical cases, where the wound(s) wrap around a body surface, are pertinent to the evaluation of its safety and effectiveness.

Moreover, the tool only assesses surface dimensions and does not account for wound tunneling or undermining. It has been tested only for wounds with well-defined borders, such as diabetic foot ulcers, venous leg ulcers, and traumatic wounds. Its performance on other wound types, particularly those with poorly defined edges, is not known.

The tool shows a slight systematic bias towards overestimation of wound area, with variable directional bias in linear measurements. Variability of bias increases as wound size increases. Due to low sample size for larger wounds, it is not possible to conclude that the bias is statistically significant. Overall, larger wound sizes within the specified range in the COU may be more challenging to measure.

The qualification study was not statistically powered; therefore, statistically significant conclusions regarding tool accuracy, intra- and inter-user variability, and generalizability cannot be drawn. Accordingly, the point-estimates and 95% confidence intervals are presented as

descriptive statistics. Based on the limited dataset, observed performance may vary from the overall estimates reported above.

CONCLUSIONS

The submitted qualification materials, including the clinical study, support the qualification of the MolecuLightDX within the specific context of use. The use of this tool in clinical studies may allow for additional collection of data in order to more fully characterize the performance of the tool and support the generalizability of its use.

CONTACT INFORMATION FOR ACCESS TO TOOL

MolecuLightDX is a commercially available device. More information about MolecuLightDX is available at https://moleculight.com/

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