

silhouette®
wound assessment + management

Proven wound care evidence

for Clinical Research



Delivering the evidence you need for a successful trial.

Silhouette® is an easy to use wound imaging, 3D measurement, and documentation system using non-invasive laser technology.

As an FDA approved medical device, Silhouette has been proven to provide accurate, precise, and repeatable wound assessments for all phases of clinical research in more than 70 studies globally.

High Quality Data

- Silhouette enables users to easily and quickly gather accurate and repeatable assessment data to prove study endpoints, and make defensible cases for regulatory approval.
- Patient, visit, and wound level notes are customizable to meet data collection requirements.
- Silhouette provides comprehensive and transparent reporting, ensuring the credibility of data throughout your study.
- Data precision and efficiency mitigate risks in evidence collection for clinical trials.

Easy to Use

- SilhouetteStar captures wound images and 3D measurements including area, volume, depth, and perimeter using innovative and proprietary technology superior to other methods.
- Data is instantly available through SilhouetteConnect, enabling timely review and assessment to quickly determine subject inclusion/exclusion.
- SilhouetteCentral increases the efficiency of data collection by centralizing the data, and providing Sponsors, CROs, and other key stakeholders with immediate access to the data gathered at the investigative sites.
- One-click reports, graphs, and custom note fields make it easy for researchers to analyze and track healing progress.

Proven

- Silhouette has gathered evidence for successful FDA approvals, to support significant funding for phase progression, and for studies published in peer-reviewed publications.
- Silhouette is the preferred wound assessment and documentation solution for wound studies in the US and globally.
- Silhouette has been used in a multitude of wound studies, including:
 - Diabetic Foot Ulcers (DFU), Venous Leg Ulcers (VLU), Arterial Leg Ulcers (ALU), and Pressure Ulcers (PU).
 - Acute Bacterial Skin and Skin Structure Infection (ABSSSI), Epidermolysis Bullosa, and Critical Limb Ischemia.
 - Pre-clinical through Phase IV studies.
 - Assessing Pharmaceutical, Biological, Wound Dressing, and Medical Device products.
 - Multi-center and multi-national studies.
 - Clinical trials that range in size from 1 to 250 investigator sites.
 - Human, porcine, equine, and rodent studies.



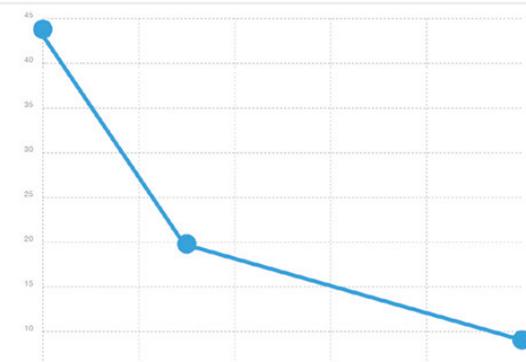
XFR123987



Measurements

Area Area Reduction Mean Depth Max Depth Volume

Perimeter



Patient

Overview

Details

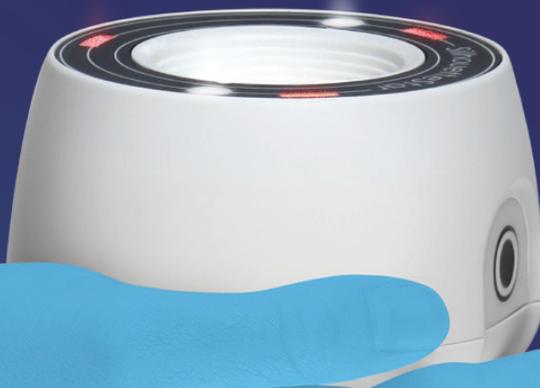
Investigation History

Medical History

Medication

Wound Management Supplier

Wounds





Proven Risk Mitigation

FDA approved Silhouette is the gold standard for reliable, credible evidence. The Silhouette system ensures study data is anonymous, private, and secure, mitigating risks to your study and business. Audit trails are available to track Silhouette hardware and software usage.



Proven Efficiency

Silhouette's pioneering wound assessment workflow supports investigators in delivering precise evidence that is instantly available to Sponsors and CROs. Corrections can be made instantly in the event of errors, and subjects can be excluded if they no longer meet trial criteria.



Proven Precision

Studies show that any single Silhouette-derived measurement is within approximately 2% for Area, 1% for Perimeter, 5% for Average Depth, and 5% for Volume. (95% confidence interval)



Proven Successful Outcomes

Silhouette data has supported numerous pre-clinical and Phase I-IV trials to successful outcomes, including progressions through all phases to successful FDA approvals, progression through funding stages, and acceptance of research by peer-reviewed and respected international journals.



Proven Repeatability

With Silhouette, all evidence gathered is transparent and repeatable. Inter- and intra-rater variability is extremely low - <1% for area and perimeter, and <2% for average depth and volume.



Proven Advanced Image Capture

The world's easiest-to-use wound camera, SilhouetteStar guides the user to focus the camera with laser lines, and consistently lights each wound using LED. Structured light software builds a 3D model of the wound.



Proven Data Security and Privacy

Silhouette supports the privacy and security compliance required by HITECH and HIPAA. Data is instantly integrated into the research notes and removed from the camera to the Silhouette software after the wound has been imaged. Silhouette ensures that all research data is anonymous, preventing any possibility of a privacy breach.



Proven Services and Support

Wherever a wound is being assessed, a comprehensive services and support portfolio is available. Our experienced Services team offers comprehensive implementation and project management services, customization and configuration services, training, hardware and software support, and maintenance services including second-tier support for both users and administrators.

Clinical Research

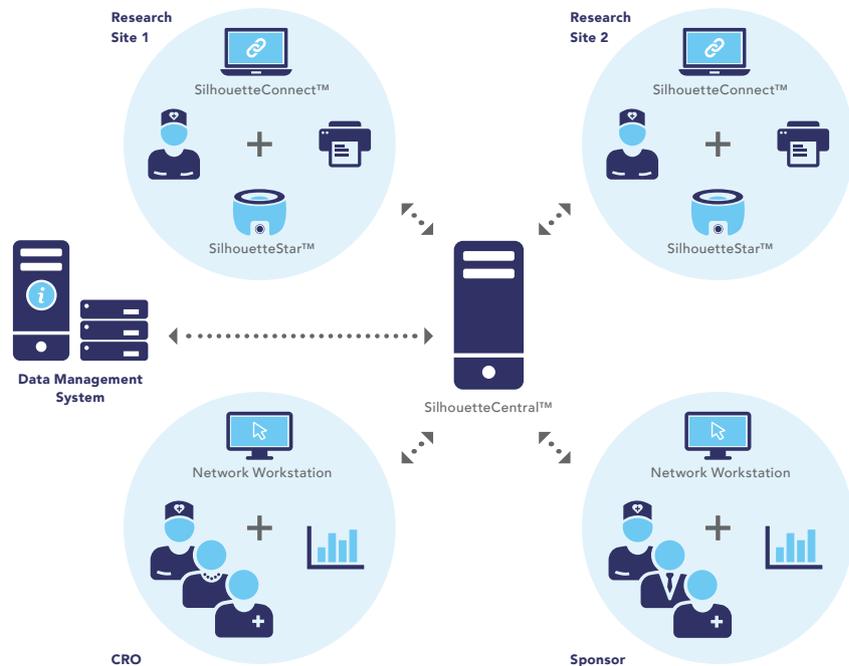
Silhouette is a family of products developed by ARANZ Medical for imaging, measuring and documenting wounds. It provides accurate and easily reproducible data across all investigator sites to a centralized database that can be accessed anywhere in the world.

The cost of monitoring and managing data in a clinical trial typically makes up around one third of the cost of the trial. Silhouette helps to reduce these costs by improving the wound assessment workflow, allowing investigators to quickly and consistently image and accurately analyze a wound and wound healing using Silhouette's portable, non-contact device.

All measurements are made without touching the subject's wound, eliminating discomfort and reducing the risk of infection. SilhouetteStar can be safely disinfected after use. All measurements are saved directly into an electronic database designed specifically for wounds, and can be viewed instantly by the Sponsor or CRO via the Internet.

The principle components in the Silhouette product suite are:

- The SilhouetteStar wound camera.
- SilhouetteConnect software to drive the imaging, measurement and documentation functions.
- SilhouetteCentral centralized database, accessible via a secure Internet connection typically hosted by ARANZ Medical.
- An optional software "engine" that controls the workflow of each wound assessment in accordance with the protocol.
- Optional auto-generated and auto-distributed emails to study personnel including Wound Assessment Reports, notifications of the arrival of new trial data, and custom information.



Technical Information

SilhouetteStar™ + SilhouetteConnect™

The SilhouetteStar camera is used with the SilhouetteConnect application software for fast and easy imaging, 3D wound measurement and clinical notes capture. SilhouetteStar connects via USB to a computer with SilhouetteConnect installed. SilhouetteConnect operates on a tablet, laptop or desktop computer with Windows Vista or later. Wireless and mobile device variants are being released in 2016.

With SilhouetteStar + SilhouetteConnect you can:

- Calculate accurate wound surface area, depth, perimeter and volume, as well as healing progression at the click of a button;
- Combine imaging and measurement with assessment information to generate comprehensive reports;
- Immediately store wound information in a secure environment.

SilhouetteCentral™

SilhouetteCentral is an integrated electronic wound information management system that enables trial managers to review, report, securely share, and analyze data collected by Silhouette point-of-care devices. SilhouetteCentral software can be accessed using Microsoft Internet Explorer web browser, version 7 or later. Silhouette exports data in a standard .csv file format, interfaces with other medical records systems using standard formats including HL7 and DICOM, and is designed to support HIPAA compliance.

With SilhouetteCentral you can:

- Access data remotely and provide feedback to the investigator
- Securely store wound information long-term in one location that is accessible anywhere in the world.

Regulatory Approvals

Silhouette has the following regulatory approvals:

- FDA 510(k) approved
- ISO 13485 Certified
- CE Mark
- Health Canada – MDEL
- TGA approval (Australia)
- WAND registration (New Zealand)

Code of Federal Regulations (CFR)

Silhouette supports compliance with 21 CFR Part 11.

Other Products and Services

Silhouette for clinical research is supported by a variety of other products and services, including:

- Clinical and Technical Training - an investigator can be trained to undertake a Silhouette wound assessment in a matter of hours. Silhouette training can be provided at investigator meetings.
- Implementation Support
- Configuration - assistance in ensuring that Silhouette is configured and used in a manner consistent with the requirements of 21 CFR Part 11.
- Second-tier Technical Support – for investigators, Sponsors and CROs.
- Secure Data Hosting
- Data Curation Services – which might include a quality control service to review images, the approved editing and deletion of wound images and notes, and the development of reports during the trial to track healing rates and other statistics.

About ARANZ Medical

ARANZ Medical's wound assessment and limb scanning technologies have pioneered electronic skin assessment for some of the world's largest clinical research and clinical practice companies over the last decade. Based in New Zealand with a subsidiary in the United States, ARANZ Medical offers world leading expertise in the improvement of wound assessment using structured light technologies. Our solutions are used in more than 30 countries, primarily the United States, the United Kingdom, Europe and Australasia. Many large organizations, such as Veterans Affairs in the US, and the National Health Service in the UK have chosen our systems as well as many wound research and development companies. ARANZ Medical is an ISO 13485 certified manufacturer of medical devices.



In 2015, ARANZ Medical was awarded a United Nations-sponsored World Summit Award recognizing innovations that benefit the development of communities.



In both 2015 and 2016, ARANZ Medical won awards at the AmCham – DHL Express Success & Innovation Awards.

ARANZ Medical Limited

866 467 0934 (USA & Canada)
 +64 3 374 6120 (International)
sales@aranzmedical.com

www.woundproven.com

Patents pending. Silhouette is approved for sale in the USA, Europe, Australia, Canada and New Zealand. Specific features of this solution may change without prior notice. Silhouette, Silhouette Product Suite, SilhouetteMobile, SilhouetteStar, SilhouetteConnect, SilhouetteCentral and SilhouetteLink are trademarks of ARANZ Medical Limited.

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