silhouette®
wound assessment + management

Proven wound care solutions
for Clinical Practice
Delivering the precision you need in practice.

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 is a proven clinical practice tool that is revolutionizing clinical wound management while enabling enterprise-wide risk mitigation.

**Easy to Implement and Use**
- Silhouette is easy to implement and integrate with your existing EMR system.
- Users are able to quickly learn how to use the camera and software to complete accurate wound assessments every time.
- The Silhouette system generates a comprehensive progress note for each wound assessment, making it easy for health care professionals to monitor their patients’ healing over time.

**Accurate, Precise and Secure**
- Silhouette ensures that you capture accurate, reproducible measurements to reliably track complex wounds, and the documentation proves that consistent assessment techniques and appropriate standards of care have been applied.
- Silhouette assessments are precise and consistently provide high quality images and data regardless of the skill-level of the person assessing wounds.
- The documentation and images are available instantly in the electronic medical record, and the data is securely assigned to the correct patient.

**Proven in Practice**
- Silhouette is used by a number of the world’s largest medical organizations, such as the US Department of Veterans’ Affairs, Kaiser Permanente, and the National Health Service in the UK to streamline their wound management.
- Silhouette is non-invasive, so there is no physical contact with a patient required, which significantly reduces infection risks during assessments.
- Silhouette provides a complete audit trail of accurate, high quality wound images and information about a patient’s healing progress, reducing the risks of litigation.
- Silhouette is used for telehealth assessments and workflows, providing a precise method of assessment and supporting preventative and curative decision-making for health organizations, practitioners and multi-disciplinary teams.

*Silhouette connects people throughout an organization.*
Proven Risk Mitigation

FDA approved Silhouette is the gold standard for reliable data, and is your best defense against wound related liability. A complete, accurate wound story exists for each patient, providing evidence of quality of care and a deterrent against litigation.

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 Efficiency

Silhouette’s pioneering wound assessment workflow frees practitioners to care for their patients with electronic imaging and documentation occurring instantly at the bedside. All information is automatically transferred to the EMR, so the images and notes are collected in just a few minutes compared to manual documentation methods, which can take considerably longer.

Proven EMR integration

Wound assessment data is automatically transferred to the EMR and available to all wound stakeholders instantly via a secure Internet connection. EMRs integrated with Silhouette include EPIC, Cerner and Meditech. EMR orders drive Silhouette, integrating with existing workflows.
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, project management, customization, configuration, training, hardware, and software support, as well as maintenance services including second-tier support for both users and administrators.

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. The wound images are integrated into the patient’s notes as soon as they are taken and they are not stored in the camera. Silhouette supports HL7 and DICOM standards, and provides audit trails to track both hardware and software usage.

Proven Infection Control

With Silhouette there is no need to have any direct contact with any wounds. The wound camera can be disinfected and there are options to ensure that computers need not enter a patient’s room.

Proven Services and Support

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.
Leading organizations are turning to Silhouette for its unique combination of risk mitigation, productivity enhancement, and precision. No other system is proven by practitioners to offer the comprehensive combination of risk protection, accuracy, EMR integration, and infection mitigation.

<table>
<thead>
<tr>
<th>Proven and designed for:</th>
<th>Manual assessment &amp; imaging</th>
<th>Mobile applications</th>
<th>Wound documentation systems</th>
<th>Other wound imaging and assessment systems</th>
<th>Silhouette</th>
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<tr>
<td>Non-contact operation</td>
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<td>❌</td>
<td>Some</td>
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<tr>
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<tr>
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<tr>
<td>Consistent good images</td>
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<td>❌</td>
<td>❌</td>
<td>❌</td>
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<tr>
<td>3D measurement</td>
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<td>❌</td>
<td>❌</td>
<td>Few</td>
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<tr>
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<td>❌</td>
<td>❌</td>
<td>✓</td>
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<tr>
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<td>✓</td>
<td>Some</td>
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<td>Efficient &amp; timely reporting</td>
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<tr>
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<td>Few</td>
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<td>❌</td>
<td>❌</td>
<td>❌</td>
<td>✓</td>
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</table>
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 providers 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.

**SilhouetteLink™**

SilhouetteLink is the interface between SilhouetteCentral and Health Information Systems, assisting data exchange between systems.

**Other Products and Services**

Clinical practices using Silhouette are supported by a number of other products and services, including training, customer support and customization.

**Regulatory Approvals**

Silhouette has the following regulatory approvals:

- FDA 510(k) approval
- CE Mark
- Health Canada – Therapeutic Products Directorate
- TGA approval (Australia)
- WAND registration (New Zealand).
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.

About ARANZ Medical

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