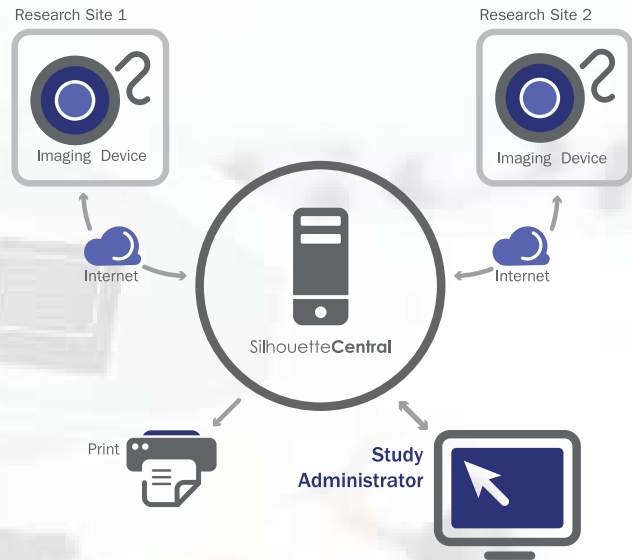


Silhouette™

The gold standard
for wound
assessment
data collection



The Silhouette™ Product Suite seamlessly integrates the flow of data enabling the collection of electronic data from multiple research sites at the time of patient assessment improving the efficiency of data collection, providing more complete, consistent and accurate records that can be reviewed remotely. Imaging devices include SilhouetteMobile™ and SilhouetteStar™ + SilhouetteConnect™.

Organizations that are responsible for conducting clinical trials with wound care patients and wound care products have recognized a pressing need to increase the efficiency, accuracy and reliability of the way in which they measure wound dimensions and monitor progress. The natural contours of the body present challenges for traditional methods of measurement; invasiveness can lead to patient discomfort and non-compliance; processing of mechanical measurements can be tedious and costly and inter/intra-rater variability can be problematic.

Silhouette can measure wounds and track wound healing progression in a way that is quick, secure, accessible, user-independent and accurate – automatically taking into account the skin's curvature and the camera position. Data is collected efficiently at the time of patient assessment from multiple research sites and centralized. This process improves the speed of data collection, providing more complete, consistent and accurate records.

Silhouette is the wound assessment solution choice for a number of clinical studies in the United States and more than 15 other countries worldwide. Studies vary greatly in size, from one to over 120 sites; they are multi-center and multi-national, Pre-Clinical to Phase III, with subjects including pigs, rats and humans.

Key Features and Benefits

- » Training is minimal. In less than 2 hours, users are confident in operating an imaging device.
- » Data collection is quick and efficient. In less than 3 minutes a clinician can capture an image, and perform an area and depth assessment.
- » Measurements are repeatable and accurate. Have confidence, even between different users. With Smart Calibration technology, the skin's curvature is 'unwrapped' so measurements are significantly more accurate than other methods.
- » Data is immediately accessible for study administrators via the internet.
- » Robust, automated and seamless information transfer. At the touch of a button information is sent to the centralized database, SilhouetteCentral for long-term storage and review from anywhere in the world.
- » Study data is easily exported into a standard format for further analysis and statistical processing.
- » Support for CFR Title 21 Part 11 compliance including system access password, data encryption and audit logging of user activities.

Silhouette Product Suite

SilhouetteCentral™

A database for longer-term storage of collected wound information, SilhouetteCentral manages and stores all information collected from the imaging devices in one central location. Assessment details can be reviewed and edited remotely.

Data Capture

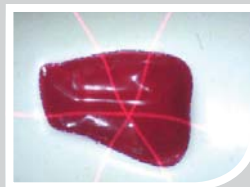
Capture a photograph, measure surface area and depth, calculate volume and record clinical notes at the point-of-care.

SilhouetteStar™ + SilhouetteConnect™

SilhouetteStar is a small, lightweight image capture device for imaging wounds. SilhouetteStar connects via USB to a computer, capturing all information required in one photograph, using only one button. SilhouetteConnect, the software application that



controls SilhouetteStar, enables the collection of wound assessment information directly to a computer. SilhouetteStar + SilhouetteConnect



provide a fast and easy way to collect wound information and review active patients at a later date.

SilhouetteMobile™

A compact and portable device, SilhouetteMobile provides a convenient way to assess a wound. The device uses a small hand-held computer (PDA) and custom camera to capture wound information. SilhouetteMobile is provided as part of a Kit and can be used immediately when received.



Other Products and Services

ARANZ Medical provides a variety of products and services to support organizations conducting clinical trials including training, customer support, customization and data review services. Please enquire directly to learn more.

Technical Information

SilhouetteMobile includes a standard Pocket PC running Windows Mobile operating system and requires Microsoft ActiveSync or Windows Mobile Device Center to synchronize to a PC. SilhouetteStar connects via USB to a computer with SilhouetteConnect installed. SilhouetteConnect operates on a tablet, laptop or desktop PC computer with Windows XP or later. 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.