

The ARANZ Medical Silhouette™: An Innovative Wound Measurement And Documentation System

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Introduction

Accurate and reliable wound measurement is an essential component of wound assessment within clinical practice. It provides objective data that assists in establishing wound progress, alerts the clinician to evidence of deterioration, enhances communication between health providers and between health provider and patient, aids in the selection of advanced treatment modalities and provides a concise account of the patients progress.^{1,2} The demand for practitioners to validate their interventions is increasing, thus providing robust rationale to support their practice is imperative. Emerging technologies, such as the ARANZ Medical *Silhouette*™ product suite are providing health professionals with new tools to support their practice.

Traditional wound measurement techniques

Simple measurement using a ruler is common within clinical practice. The linear dimensions of the maximum length and maximum perpendicular width are measured using a disposable ruler. These measurements can then be used to calculate the surface area, using various mathematical formulas, for example surface area calculation based on the formula of an ellipse.³ The drawback of this method is that it assumes the wound has a simple geometric shape, and therefore will not capture the non-symmetrical wound profiles in such wounds as leg ulcers.^{4,5}

Depth can be calculated using a probe. The assessor holds a ruled probe at right angles within the wound and documents the reading. These measurements are crude and small changes are difficult to measure accurately. Furthermore, the wound bed does not necessarily have a uniform depth throughout and may require multiple recordings.

Acetate tracing is a cheap and simple two-dimensional wound measurement modality. The wound is covered with a

clear, disposable plastic wrap allowing the clinician to trace the wound margins using an indelible marker. The outline is then transcribed onto an acetate sheet marked with a grid of squares. Surface area is then determined by counting the squares within the traced outline, with partial squares added together to form complete squares. Limitations of this method include risk of error during the transcribing process, the ability of the assessor to accurately estimate partial squares and discomfort for the patient during the tracing process.⁶ Variants of the above method also exist, such as use of digital planimetry as an alternative to square counting.⁷

Photography provides an excellent visual record of the wound. Additionally a disposable ruler can be placed alongside the wound to provide scale, and to give a reference point for the assessor to infer surface area. Image clarity is dependent upon the clinician's skills in focusing the camera and using functions such as the macro setting. Pale or shiny backgrounds can lead to the capturing of poor images and thus difficulty in interpreting the area. Furthermore, the angle and distance of the image recorded needs to be standardized to assist in appropriate interpretation, which can be difficult to achieve within the clinical setting.⁵

SilhouetteMobile™

The ARANZ Medical *SilhouetteMobile*™ is a secure electronic, hand-held, non-contact wound measurement and documentation device that is used to accurately measure both wound surface area and depth,⁸ and is the point-of-care component of the *Silhouette* product suite. It consists of a scanner head that attaches to a standard Personal Digital Assistant (PDA). The scanner comprises a digital camera used to capture an image of the wound and structured lighting that includes two fan laser beams. *SilhouetteMobile* software runs on the PDA, allowing the user to operate the scanner and performs all the necessary computation at the patient's bedside.

The process begins with the users identifying themselves on the PDA via a login procedure (username and password) and selecting the appropriate patient. Two images are taken, the first captures the wound surface area and the second records wound depth. On the first image, the operator traces the wound margin on

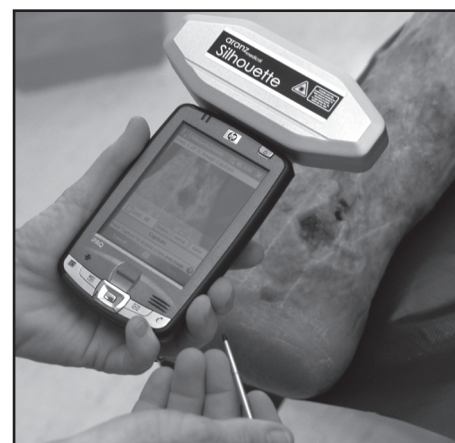


Figure 1: The ARANZ Medical *SilhouetteMobile*: Capturing the image for surface area measurement (top) and user-drawn wound boundary (bottom). Note the stylus in the top image (held in the clinician's right hand), which is used, for drawing the wound boundary on the PDA touch-screen.





Figure 2: The morphed image is produced in a few seconds, showing scale (cm tick marks) and surface area (cm²).

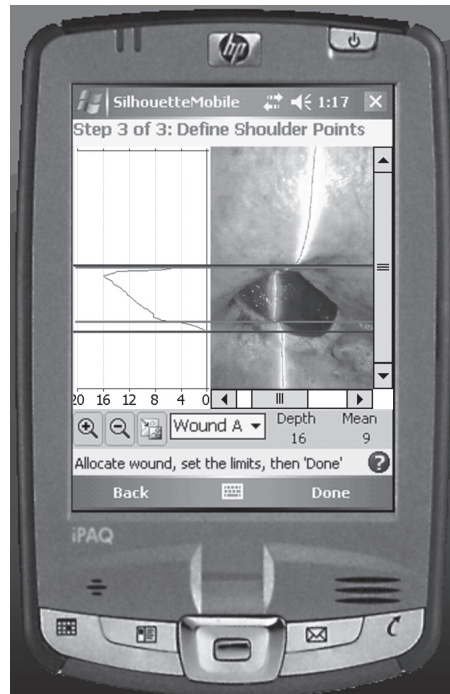


Figure 3: Depth profile of a wound, showing maximum and mean depth (mm).

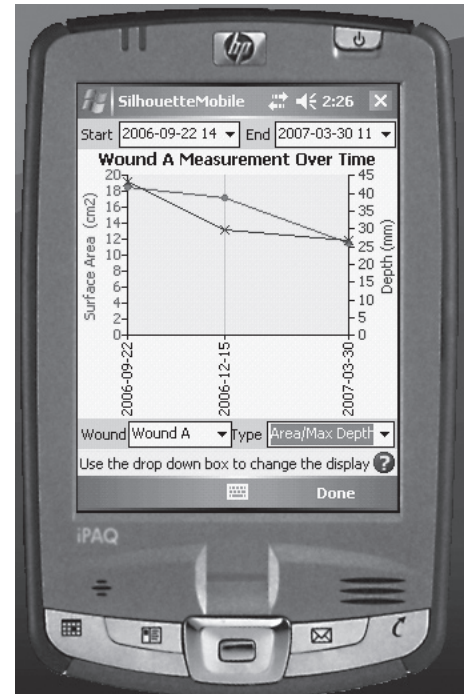


Figure 4: The *SilhouetteMobile* graph showing the changes of surface area and depth over time.

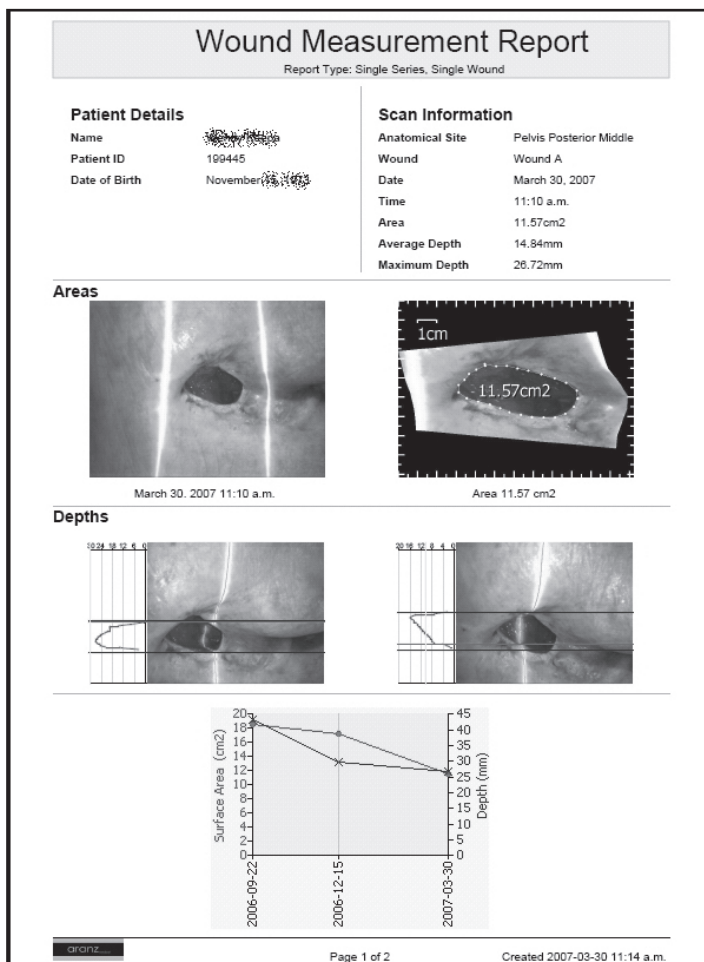


Figure 5: The PDF report that is automatically generated by the *SilhouetteMobile* software running on the PDA.

the PDA's touch screen using the PDA stylus (Figure 1). The structured lighting enables a three dimensional model to be created, thereby compensating for the skin curvature; the distance and orientation of the camera from the wound; and scale and perspective distortions in the image. A morphed photographic image is therefore created, akin to unwrapping the anatomy onto a flat surface, thus enabling an accurate and repeatable measurement of surface area to be made (Figure 2). Wound depth is captured by a second image where the laser beam is repositioned along the wound base (Figure 3). As historic data from earlier assessments are stored on the PDA, the results from the current assessment can be compared to those of the previous assessments in the form of a graph showing progress over time (Figure 4).

The software produces a comprehensive report (Figure 5) containing digital images of the wound, wound measurements (surface area, depth and volume), a graph of changes over time, and progress notes recorded on the wound assessment tool (Figure 6). The report can then be downloaded into the patient's electronic notes or printed for filing in paper notes.

The practicalities of equipment in the clinical setting require them to be efficient and user friendly in order for them to be adopted. *SilhouetteMobile* is easy to operate and can be easily transported in both hospital and community settings. It also provides immediate clarification of wound progress in the form of graphs and a standardized wound assessment tool.

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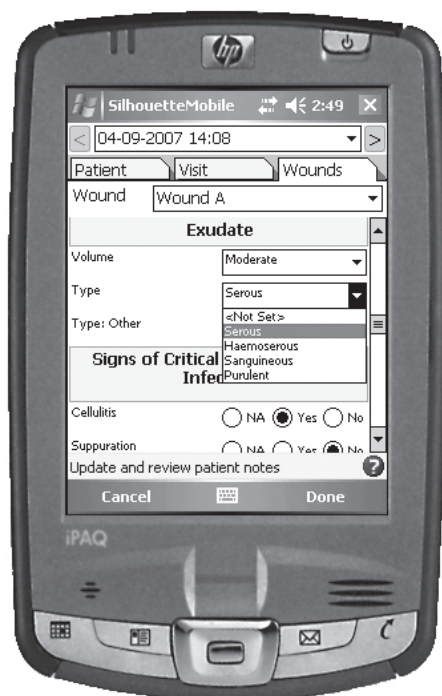


Figure 6: Extract from the *SilhouetteMobile* wound assessment notes.

The *SilhouetteCentral*™ Database

Once the data are collected on the PDA, they can be transferred (i.e., downloaded or synchronized) to a database on the clinic's computer network. The ARANZ Medical *SilhouetteCentral*™ software tool performs the synchronization function and stores all the information in a secure database. *SilhouetteCentral* also transfers to the PDA (i.e., uploads) information pertaining to any patient that may have been collected by another user on a different PDA. Thus patient information is seamlessly transferred between different users with different *SilhouetteMobile* systems (Figure 7).

Evidence to demonstrate good patient outcomes is an essential part of the audit process. An audit tool is built into *SilhouetteCentral*, enabling a user to examine the data present in the database. This enables the clinician or clinic manager to analyze patient outcomes on an individual, unit or clinic basis.

Accuracy and Repeatability

The accuracy and repeatability of *SilhouetteMobile* was assessed on wound models in a study undertaken by Nixon et al.⁹ Circular discs of a known size (4cm in diameter) were placed on a mannequin leg (Figure 8). Each disc was measured

five times with *SilhouetteMobile* and five times by transparent film tracing. For *SilhouetteMobile* the largest mean error for any one disc was 1.5% and the largest standard deviation was 0.5%. The largest error for any one single disc surface area measurement was 1.9% (0.2cm²). In comparison, for transparent film tracings using digital planimetry to calculate the area, the largest mean error for any one disc was 2.6%, the largest standard deviation was 2.7%, and the largest error for any one single surface area measurement was 6.2% (0.8cm²). The accuracy of depth measurement was assessed by repeated measurements of wound models at three known depths. The largest mean error for any of the depth models was 0.8% and the largest standard deviation was 0.5%. The largest error for any given depth measurement was 1.3% (0.3mm). Therefore, overall *SilhouetteMobile* was found to be accurate to within 2% on wound models for both area and depth measurements. Note that this also represented a significant improvement over wound tracings.

To assess inter and intra-rater repeatability of *SilhouetteMobile* within the clinical setting a study was carried out to perform repeated measurements (5) of the surface area and depth of a variety of wounds (5) and a number of users (3). The study found that inter- and intra-rater variability measurements for non-malleable wounds was within up to $\pm 0.2\text{cm}^2$ (± 2 to 5%) for surface area and up to $\pm 1.4\text{mm}$ for depth.⁸

A further study by Kapp et al. reinforced previous studies demonstrating good repeatability for surface area tracings, with an intra-class correlation coefficient (Cronbach alpha) of 0.93 and an inter-class correlation coefficient between the raters of 0.83.¹⁰

Conclusion

The demand for accurate wound measurements is increasing. Traditional wound measurement and documentation techniques include linear measurements, acetate tracings and photography. Although these approaches are cheap and reasonably convenient, they often are neither accurate nor repeatable ways of

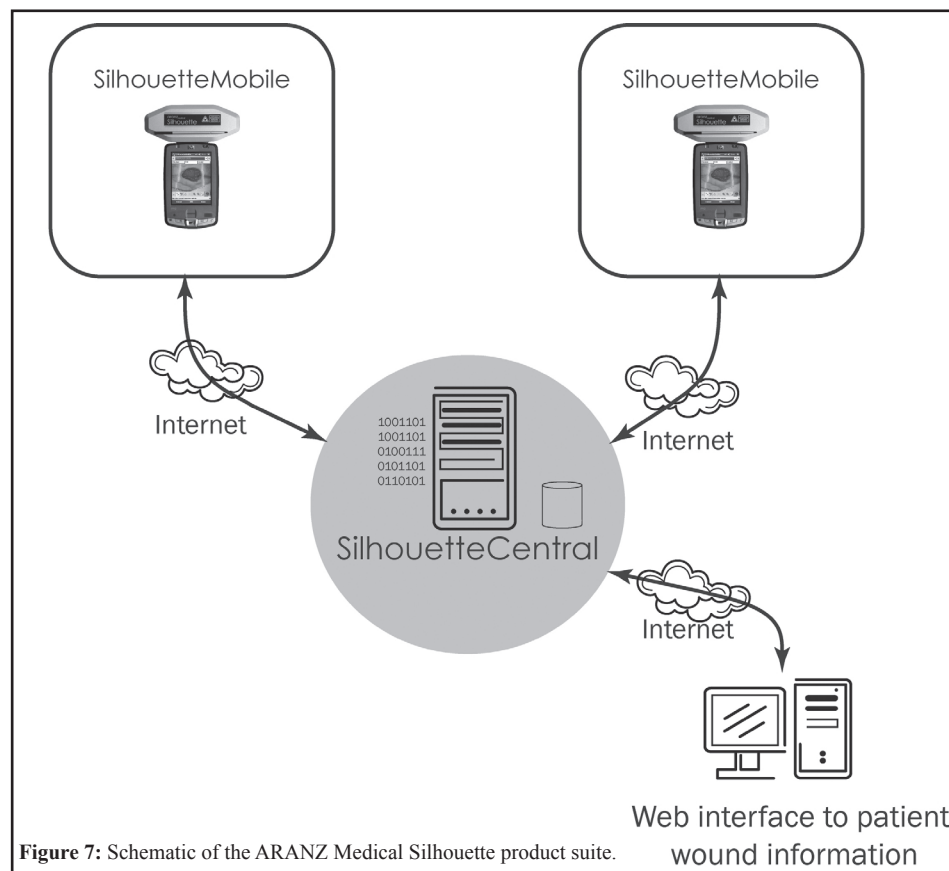


Figure 7: Schematic of the ARANZ Medical Silhouette product suite.

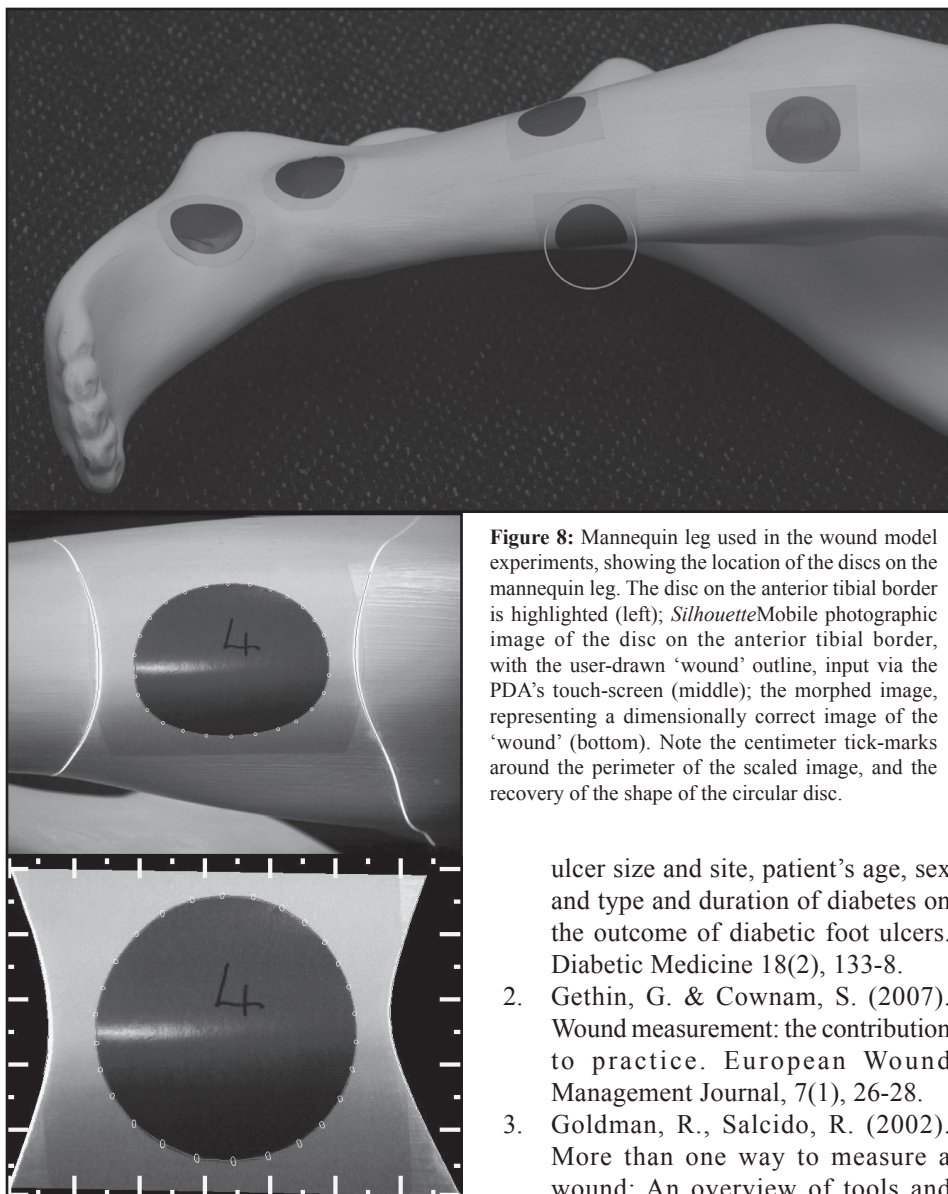


Figure 8: Mannequin leg used in the wound model experiments, showing the location of the discs on the mannequin leg. The disc on the anterior tibial border is highlighted (left); *SilhouetteMobile* photographic image of the disc on the anterior tibial border, with the user-drawn 'wound' outline, input via the PDA's touch-screen (middle); the morphed image, representing a dimensionally correct image of the 'wound' (bottom). Note the centimeter tick-marks around the perimeter of the scaled image, and the recovery of the shape of the circular disc.

performing measurements, and are prone to subjectivity. The ARANZ Medical *Silhouette* is a new and innovative wound imaging, measurement and documentation system combining digital camera, laser technology with software to produce accurate and reliable documentation that supports health professionals to make timely and appropriate wound management decisions.

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Manufacturer information

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