Silhouette Digital Wound Assessment and Information Management System (#1817)

(Innovation Elevator Pitch)

Electronic wound imaging, 3D measurement, documentation, reporting, data sharing and informatics system. An enabling technology to support objective wound assessment, quantitative outcomes monitoring and evidence-based treatment.

Overview of Innovation

Silhouette is an easy-to-use wound imaging, 3D measurement & documentation system providing accurate wound information at the point of care to support effective clinical management of patients. Silhouette wound informatics are available as a wound assessment PDF report and on a secure web-enabled database and for easy access and sharing across the entire care team.

The wound images and wound healing progress charts are highly visual and provide immediate and clear indication of a patient's response to treatment.

This award-winning system includes an imaging 3D camera that precisely and consistently measures the area, depth & volume of wounds to track and report healing progress. Silhouette enables wound assessment activity and wound outcomes to be monitored, providing wound information that is available instantly to key stakeholders, integrated with your EMR system. Silhouette is proven in both clinical research & clinical practice.

Silhouette supports pro-active management of wound-related risk & improves communication, helping practitioners to be more productive & effective in their delivery of wound care. Silhouette is suitable for all settings, including acute out-patient clinics, community-based care, home health & telehealth wound care.

The Silhouette system is made up of three main parts – a point of care wound camera, smart software for measuring wounds, & a wound information database:

- The SilhouetteStar® specialized camera (pictured right) captures the wound image;
- SilhouetteConnect® software for accurate 3D measurements of the wound based on the data acquired by SilhouetteStar (see below), together with healing progress charts & electronic wound assessment summary reports.
- SilhouetteCentral®, a secure Internet-accessible database that stores & consolidates the information obtained from the organisation's SilhouetteStar + SilhouetteConnect devices, including integration with the EMR.

Unlike non-3D and traditional methods, which are imprecise & unreliable, Silhouette provides meaningful information for better clinical decisions. It is also extremely easy to use & is ready to integrate with EMR systems. Silhouette was first established in clinical research, which requires rigorous source documentation, & is now available for widespread use in clinical practice.
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Stage of Development
Market ready and adopted - Fully proven, commercially deployable, market ready and already adopted in some areas (in a different region or sector)

Online Discussion Rating - 5 (votes 3)

Initial Review Rating - 4.2 (votes 1)

Compelling proposition - 5
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Innovation fit - 5
Health outcome potential for the region - 3
Wealth creation opportunity for WM region - 3
Innovation stage - 5

WMAHSN priorities and themes addressed
Long term conditions: a whole system, person-centred approach / Digital health / Person centred care

Benefit to NHS
Silhouette is an enabling technology to support safe, cost-effective care for patients with chronic and acute wounds such as diabetic foot ulcers, pressure ulcers and leg ulcers and complex wounds. Currently, the burden of wound care on the NHS is estimated at £3 billion per annum, with unacceptable variances reported in practice standards and outcomes achieved so that thousands of patients are not receiving the standard of care that should be possible.

Silhouette technology transforms how wound status is assessed, documented and reported. Better quality of wound information available in a connected and interoperable system means that clinicians are better supported for effective and timely clinical decisions and actions. Silhouette facilitates data sharing across an entire care pathway to reduce the risks of fragmented care across silos.

Silhouette equips, empowers and enables healthcare professionals and patients to collaborate for best practice to achieve optimal wound outcomes.

There is significant potential for the NHS to drive for cost savings, greater efficiencies and clinical effectiveness with the adoption of the Silhouette wound informatics solution.

Benefit to WM population
As well as assuring patients of best practice and quality of care, patients can actively engage in their care plan and outcomes due to the highly visual nature of Silhouette wound healing data and charts displayed on the software screens.

The benefits of rapid and effective wound healing for the patient should not be underestimated. The psychological consequences of living with a chronic wound are well documented. Upton and Hender (2012) suggest that patients with chronic wounds may experience negative emotions such as:

- Stress
- Concern about physical symptoms
- Lack of self-worth
- Despair

See featured Silhouette Patient Story which demonstrate the power of Silhouette informatics in motivating a patient with a debilitating pressure ulcer to recovery. [http://www.aranzmedical.com/patient-pressure-ulcer/](http://www.aranzmedical.com/patient-pressure-ulcer/)

Current and planned activity
Entec Health is an appointed distributor to ARANZ Medical for the Silhouette solution in the UK. Our partnering goals are to inform & engage NHS stakeholders on the advantages of adopting digital wound assessment & wound informatics to address the “best practice, clinical excellence & cost-effectiveness gap” in wound management. Entec has supported 5 field Silhouette evaluations in acute & community care with considerable investment of time, expertise & resource. Entec has successfully established early adopters of Silhouette across the NHS:

Clinical Practice: King’s College Hospital London Diabetic Foot Clinic, North Bristol Trust Enablement Centre
Clinical Research: 10 NHS centres of excellence in diabetes foot care are currently using Silhouette in a multi-centre clinical trial sponsored by EdixoMed

Planned activity: A Diabetes Foot Pathway demonstrator project supported by EMAHSN to be announced & 2 further Silhouette collaborations are in progress, information to follow.

What is the intellectual property status of your innovation?
Product family: Silhouette Mobile, Silhouette Connect
US patent: 8,755,053
Chinese patent: ZL 200680037626.3
Product family: Silhouette Star, Silhouette Connect
US patents: 9,179,844, 8,755,053, D662,122
Chinese patent: ZL 200680037626.3
Other patent(s) pending

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 is quality assured as an ISO 13485 (Medical Devices) and ISO 9001 certified company and is audited annually by a notified body.

Health information protocols and privacy: Silhouette supports a variety of protocols and functionality, including:

- HL7 patient demographic information exchange or transfer
- DICOM image transfer
- DICOM Encapsulated PDF report creation and transfer

Silhouette is designed to support HIPAA and HITECH compliance.

Return on Investment (£ Value)
medium

Return on Investment (Timescale)
2 years

Ease of scalability
2

Detailed submission

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Commercial information

The Silhouette wound imaging, assessment and information management system is a proven, established in-market solution used across world-wide markets. The Silhouette solution is supporting wound outcomes documentation, reporting and informatics for effective and efficient wound care service delivery. Silhouette is enabling transformation of wound care pathways in acute, community and integrated care settings. Early market for Silhouette is the US with UK, Europe and Asia as emerging markets.
Investment activity
Entec Health, as an appointed distributor of Silhouette in the UK, has invested considerable time, effort and funds to introduce the Silhouette to the NHS/UK market since 2011. ARANZ Medical, the developer and manufacturer of Silhouette has invested significant funds, effort and expertise in R&D and bringing the Silhouette solution to the global market. There is continued investment in partnering with the NHS and UK healthcare provider market by Entec Health. ARANZ Medical has a commitment to on-going investment in R&D for Silhouette to ensure that the solution meets the future needs of healthcare professionals.

Regional Scalability
The Silhouette solution is highly and easily scalable across the West Midlands region for transformation of wound care services within the NHS sector. Silhouette can help to address delivery of greater clinical effectiveness and productivity in managing patients with chronic and acute wounds, including Diabetic Foot ulcers, Pressure Ulcers, Leg Ulcers and complex wounds. Silhouette is an enterprise system designed to be interoperable and connected within the NHS/Provider IT infrastructure to enable support of multi-disciplinary care of patients across a diverse range of care settings. Silhouette can be incorporated into telehealth/teleconsultation models of service delivery to support new models of care that improve patient experience, outcomes and cost-effectiveness.

Measurement of outcomes

**Measures**

**Quality outcomes/measure**
The target outcomes of adoption of the Silhouette solution for the Healthcare Provider Organisation are:
Organisation will demonstrate objective, evidenced-based practice to support timely and appropriate treatment planning and care for delivery of optimal wound outcomes.
Measure: Silhouette wound informatics available; quantifies and reports wound healing outcomes for individual patient, patient-population, clinical pathway and treatment type.

**Safety outcomes/measure**
Organisation will have consistent standard of wound care practice and transparency on wound care outcomes to demonstrate accountable care provision to the required safety standards.
Measure: Silhouette wound informatics available; including digital wound images, wound healing data/charts and wound assessment reports available electronically for audit and management reporting.

**Cost outcomes/measure**
Organisation will have wound care outcomes data available to support assessment of cost-effectiveness of wound care treatments, service delivery and wound outcomes by treatment type.
Measure: Silhouette wound outcomes and assessment activity data available; to feed into cost-planning and cost-assessment of wound care service.

**People outcomes/measure**
Organisation will be supported to ensure high levels of staff and patient satisfaction of wound care services through equipping and empowering with quality clinical information on wound progress. The objective wound outcomes data generated with Silhouette will enable joint, evidence-based conversations on care plan and treatment goals with patients and the multi-disciplinary care team.
Measure: Silhouette patient and population-level reporting available; combined with patient/staff surveys before and after deployment of Silhouette.

Adoption target
Over next 2 years, we would like to aim to partner with 6 NHS Trusts/other healthcare providers in the West Midlands region for adoption of Silhouette.

Investment sought
The Silhouette enterprise system is a modular system and investment level is dependent on scope of deployment. An enterprise level Silhouette system based on 5 Silhouette assessment devices and SilhouetteCentral database package starts
from £45,000 (net, excluding VAT) for a capital purchase plan. Data integration, IT services, project management and annual software maintenance/support fees are additional costs, dependent on requirements. Silhouette pricing can be offered as an annual subscription model or a capital purchase model to suit different budgetary requirements.

User Comments

See update on EMAHSN Technology-enabled transformation of Diabetes Foot Service. A great success story of EMAHSN, NHS Partners and industry working together to deliver improved diabetes foot care in the East Midlands. This digital telehealth solution (Silhouette) supports improved diabetes foot service access and lower service costs and is ready for replication across the NHS. Come and see us at the Entec Health, Silhouette stand at Meridian Live on Wed 15th February, Birmingham event. We look forward to partnering with NHS Innovators in the West Midlands to transform management of diabetes foot ulcers, pressure ulcers, leg ulcers and complex wounds to support better patient experience and outcomes.

Submitted by Achala Patel on 14 February, 2017 - 11:34.
Watch this 3 minute BBC Regional News Report to find out how the EMAHSN Diabetes Foot Service, enabled by Silhouette, is improving service access, patient experience and joining up integrated diabetes foot care. This solution supports NHS Providers to comply with NICE Guidelines for managing patients with diabetes foot ulcers by enabling rapid escalation/de-escalation and MDT management based on objective DFU progress data. A key clinical goal of diabetes foot care is to achieve rapid healing of foot ulcers to prevent secondary complications such as unnecessary amputations.
Watch the video: [https://vimeo.com/195309682](https://vimeo.com/195309682)

Entec Health is proud to let everyone know that a successful Silhouette telehealth demonstrator has been established for the management of patients with diabetes foot ulceration.
The initiative is supported by the East Midlands Academic Health Science Network.
This Silhouette technology-enabled initiative went live in July 2016 in the Royal Derby Hospital out-patient clinic and in the Derbyshire Community Healthcare Services Trust in Sept 2016.
The EMAHSN Diabetes Foot digital solution is releasing pressure on an over-booked out-patient DF clinic, improving access to MDIT care and reducing tariff costs across the integrated pathway. The patient response has been very positive to the reduced travel time, wait time and convenience. The Derbyshire team are now working on securing funding for expansion of the model to additional community sites.