aranzmedical

silhouette®
wound assessment + management

Silhouette v3 System Specifications

A proven wound assessment and management solution for both clinical practice and clinical research.

Whether you work in wound care or wound research, Silhouette has been designed to make your job easier. First launched in 2007, Silhouette is the most widely used wound assessment, documentation, and management system available and is proven to collect high quality, repeatable, and reliable information.

Wound Care

Silhouette is used in clinical practice by some of the world's largest healthcare providers, including the department of Veteran's Affairs in the US, the NHS in the UK, and many other clinics and hospitals in more than 30 countries. For clinical practice, Silhouette delivers:

- Reliable, accurate and timely wound documentation
- An easy to use solution for staff
- A non-invasive solution for patients
- Reduced commercial and litigation risk
- Improved patient satisfaction
- Fewer hospital admissions and visits
- Shorter hospital stays
- A reduction in the total cost of patient care.

Wound Research

Silhouette's ability to reliably capture, measure, and manage wound data has been proven in more than 180 clinical studies globally. For clinical research, Silhouette delivers:

- High quality data to support study endpoints
- Highly accurate, reliable, and repeatable measurements (inter and intra-operability)
- Reliable data collection for pre-clinical through phase IV, post-marketing surveillance, and observational studies
- A scalable solution for studies from one site to 250+ investigator sites
- Immediate access to images, data, and reports for sponsors, CROs, adjudicators, and sites
- One-click PDF assessment reports can be used as source documentation
- Data exports at any time
- An easy to use solution for sites.

System Feature Overview	V3.x
Image Capture	
Controlled Artificial Lighting	Dual LED Flash
Managed Camera Settings	Auto-exposure fixed focus
Camera Resolution*	3MP or 5MP
Measurement	
Measurement Dimensions	3-D
Image Scale Calculation	Automatic and Non-contact
Measurements Calculated	Length, Width, Perimeter, Surface Area, Mean Depth, Max Depth, Volume, Area Reduction, Tissue Type %
Wound Tracing	Manual – determined by clinical judgment
Medical Notes	
Patient Identifiers	Patient Information and Patient Identifiers
Patient Notes	Medical History, Diagnostic History
Visit Notes	Admission Status, Physicians, Vital Signs, Pain Assessment, Limb Assessment, Healing Factors Assessment
Wound Notes	Anatomical Site, Status, Measurements, Wound Etiology, Tissue Types, Tissue Appearance, Infection and Pain
Configuration	Configurable fields and conditional validation rules available. (Enterprise Deployment Only)
Auto Email Wound Assessments	Yes (Enterprise Deployment Only)
Protocol Engine	Guided Workflow (Optional - Enterprise Deployment Only)
Customizable Notes	Yes (Enterprise Deployment Only)
Analysis and Reporting	
Trend Graphs	Area, Area Reduction, Max Depth, Mean Depth, Volume, Tissue Types
Reporting	Configurable PDF Assessments
Security	
Access Control	Username and Password, LDAP (Enterprise Deployment Only)
Application Timeout	Configurable
Audit Records	Available for logon attempts, synchronizations, camera calibration checks, changes in patient data, data viewed, and data exported from Silhouette. (Enterprise Deployment Only)
Integration and Data Export	
EMR	Order receipt and response (assessment report) (Enterprise Deployment Only)
Export	Images and Assessment Data
Services, Support and Warranty	
Established Services Offered	Project Management, System Implementation, Data Management, Technical Training and Clinical Training
Hardware Warranty	Hardware – Return to base
Software Upgrades	Software – Support agreement defines level of upgrade support
Support Locations and Hours	International Support - Support agreement defines hours

*Dependent on the model of SilhouetteStar used.

SilhouetteStar Scanner Specifications	Model 2000.xx SilhouetteStar 3MP (Wired)	Model 2005.xx SilhouetteStar 5MP (Wired)	Model 2010.xx SilhouetteStar 2 (Wired and Wireless)
SilhouetteStar is a non-contact scanner that connects via USB cable to a computer with SilhouetteConnect software to capture wound images and data for 3D wound measurements at the point of care. SilhouetteStar 2 wireless use requires SilhouetteCentral v4.			
Imaging			
Sensor Resolution	3MP (nominal)	5MP (nominal)	5MP (nominal)
Working Distance (from the base of the scanner)	190mm (typical) 240mm (nominal max)	235mm (typical) 285mm (nominal max)	190mm (typical) 280mm (nominal max)
Depth of Field	-30mm, +50mm at typical working distance	100 mm	-50mm, +90mm at typical working distance
FOV - Horizontal	42.5° (Nominally 183mm at the typical working distance)	170mm min, 230mm max	42° (Nominally 180mm at the typical working distance)
Aspect Ratio	4:3	4:3	4:3
Focus	Fixed	Fixed	Fixed
Guided Image Capture	Formation of laser lines for consistent imaging	Formation of laser lines for consistent imaging	Formation of laser lines for consistent imaging
Exposure	Automatic (Dual LED Flash)	Automatic	Automatic (Dual LED Flash)
Picture Format	Exportable in png or jpg formats	Exportable in png or jpg formats	Exportable in png or jpg formats

SilhouetteStar Scanner Specifications	Model 2000.xx SilhouetteStar 3MP (Wired)	Model 2005.xx SilhouetteStar 5MP (Wired)	Model 2010.xx SilhouetteStar 2 (Wired and Wireless)
Wound Measurement			
Maximum Wound Size	250mm x 180mm typical	230mm x 170mm typical	250mm x 180mm typical
Minimum Wound Size	2mm x 2mm typical	2mm x 2mm typical	2mm x 2mm typical
Accuracy (95% confidence interval) Ref: http://www.aranzmedical.com/silhouette/wound-measurement-accuracy-study/	Area (Cap measurement): 2% Perimeter: 1% Depth: 5% Volume: 5%		
Precision	Area: 1mm^2 Perimeter: 1mm Maximum Depth: 1mm Volume: 1mm^3		
Inter-rater Reliability	1% for area and perimeter, <2% for max depth and volume		
Intra-rater Reliability	1% for area and perimeter, <2% for max depth and volume		
Timings			
Image Capture Time	3s typical	3s typical	4s typical
Image Transfer Time (USB)	Included in time above	Included in time above	2s typical (when used in conjunction with SilhouetteConnect)
Scanner Start-Up Time	-	-	<25s from off 1s from sleep
Lighting and Lasers			
Lasers	Class 1 per IEC 60825-1	Class 1 per IEC 60825-1	Class 1 per IEC 60825-1
Flash	High Power LED Flash, 10,000 Lux	High Power LED Flash, 10,000 Lux	High Power LED Flash, 10,000 Lux
User Interface			
Audio	Audible feedback via connected computer		Shutter + Image Transfer
Screen	Audible feedback via connected computer		Patient Name, Patient ID, WiFi Status, Image Transfer Status, System Messages
Controls	Single Button	Single Button	Single Button
Capture Guidance	Laser Star	Laser Star	Laser Star
Power Requirements			
Power Consumption	Compatible with USB 2.0 power specifications 500mA @ 5V		Compatible with USB 2.0 power specifications and USB battery charging specifications v1.2
Battery Type and Capacity	-	-	Li-Ion, 6.5 Wh
Battery Shift Life	-	-	8 hrs
Battery Lifetime	-	-	>2 years
Connectivity			
Offline Support (wired USB with SilhouetteConnect)	Yes	Yes	Yes
USB	USB 2.0	USB 2.0	USB 2.0 - Uses IP networking over USB (RNDIS)
USB Connection Time	<15s	<15s	<15s
Online Support (direct WiFi to SilhouetteCentral)	No	No	Yes
WiFi	-	-	WiFi ready for use with Silhouette v4

SilhouetteStar Scanner Specifications	Model 2000.xx (SilhouetteStar - wired 3MP)	Model 2005.xx (SilhouetteStar - wired 5MP)	Model 2010.xx (SilhouetteStar 2 - wired and wireless)
Compliance			
Laser	Class 1 Designation – IEC 60825-1	Class 1 Designation – IEC 60825-1	Class 1 Designation – IEC 60825-1
EMC	IEC 60601-1-2: 2007	IEC 60601-1-2: 2007	IEC 60601-1-2: 2014
Medical Device	IEC 60601 3rd Edition	IEC 60601 3rd Edition	IEC 60601 3rd Edition
Cleaning			
Alcohol (Isopropyl) Based Wipes	Yes	Yes	Yes
Bleach Based Wipes	< 1:50 concentration, limited use	< 1:50 concentration, limited use	< 1:50 concentration, limited use
Mild Detergent	Yes	Yes	Yes
Water Based Wipes	Yes	Yes	Yes
Hydrogen Peroxide Based Wipes	Yes	Yes	Yes
Physical			
Dimensions	100mm x 67mm typ.	100mm x 67mm typ.	100mm x 67mm typ.
Weight	240g typical	240g typical	300g typical
Environmental			
Operating Temperature	10°C (50°F) min to 30°C (86°F) max	10°C (50°F) min to 30°C (86°F) max	10°C (50°F) min to 30°C (86°F) max
Storage Temperature	-5°C (23°F) min to 50°C (122°F) max	-5°C (23°F) min to 50°C (122°F) max	-5°C (23°F) min to 50°C (122°F) max (short term)
Operating Humidity	0% RH min to 80% RH max	0% RH min to 80% RH max	0% RH min to 80% RH max
Lighting[2]	100 lux min – 400 lux nominal – 1000 lux max	100 lux min – 400 lux nominal – 1000 lux max	100 lux min – 400 lux nominal – 1000 lux max
Accessories			
Charger	-	-	Yes
Cradle	Yes	Yes	Yes
Cables	USB-A to USB-B (Active) 1.8 m (5′ 11″), 3 m (9′ 10″), 5 m (16′ 5″)	USB-A to USB-B (Active) 1.8 m (5′ 11″), 3 m (9′ 10″), 5 m (16′ 5″)	USB-A to USB-B 5 m (16′ 5″)

SilhouetteConnect Specifications – Client Software

SilhouetteConnect is the software that operates on a Windows tablet, laptop or desktop computer.
SilhouetteStar connects via USB cable to a computer with SilhouetteConnect.

Key System Times	
Successive Image Capture Time	1.2s typical
Capture to Measurement Complete Time	<1 minute typical (includes tracing)
Synchronization Time	17s minimum. <1 minute typical (dependent on database size, active patient list size, number of images, network speed and network reliability)
Security	
Access Control	Username and Password, Use Active Windows Credentials (Enterprise Deployment with LDAP only)
Data-at-rest Encryption	Full data-at-rest encryption requires deployment of full disk encryption using Bitlocker or similar. Database is protected with SHA-256 and AES128 encryption.
Data-in-transit Encryption	Supports the use of TLS (up to TLS1.2) when synchronizing with SilhouetteCentral.
Computing Platform Requirements	
Supported Devices	Windows laptop, desktop or tablet
Supported Operating Systems	Windows 10 (Support for Windows 7, 8, and 8.1 where extended support is in place)
Processor	2.0 GHz Minimum (Multi-core recommended)
Disk	10GB available space recommended minimum for approx. 2,000 images and assessments
Memory	4GB Minimum
Browser	N/A
Database	SQL Compact
USB Requirements	USB 2.0 or 3.0 Port
Display Resolution	1024 x 768 (minimum)

SilhouetteCentral Specifications – Server Software

SilhouetteCentral is an integrated electronic wound information management system that enables providers to review, report, securely share, and analyze data collected by SilhouetteStar and SilhouetteConnect.

Infrastructure Types	
Self-Hosted Enterprise	Yes
Cloud	Yes - For Clinical Research Customers Only
Self-Hosted Enterprise Platform Requirements	
OS	Windows Server 2012 (R2) or later.
Processor	2.4 GHz Dual Core Minimum
Disk	100 GB Available Space
Memory	16 GB Recommended. 4 GB Minimum
Database	SQL Server 2012 or later
Software Dependencies	Internet Information Services (IIS), IIS URL Rewrite 2.0 module .NET framework 4.7.2 Microsoft Report Viewer 2010 Redistributable SSL Certificates for HTTPS bindings
Network	Ethernet TCP/IP Connection Static IP Address
Security	
Username and Password	Configurable password rules and expiration
LDAP Authentication	Compatible with Active Directory and Posix LDAP implementations
Data-in-transit	To support data-in-transit encryption, SilhouetteCentral must be deployed with SSL certificates. SilhouetteCentral supports up to TLS1.2.
Data-at-rest	To support data-at-rest encryption, SilhouetteCentral must be deployed with full disk encryption using Bitlocker or similar MS SQL Enterprise Transparent Data Encryption or similar can be used to encrypt databases
EMR Interfaces	
Standards	HL7, DICOM, Email
Key Functionality	Patient Management, Order Management, Order Results
Key EMR Vendor Supported	Epic, Cerner, Meditec, VistA Imaging
Data Export	
File Export	Text files (Comma/Pipe/Asterix/Underscore separated), XML (Microsoft Excel), PDF wound assessment report with images
Database	Query Database Export (Optional)

System Regulatory Approvals

FDA 510k – approval number K070426	TGA approval (Australia)
ISO 13485:2016 certified	WAND registration (New Zealand)
CE Mark	Singapore regulatory clearance
Health Canada – Therapeutic Products Directorate	HIPAA compliant system

Footnotes

1. Transfer via WiFi depends on network quality.
2. 100 lux is equivalent to a dark, heavily overcast day. 500 lux is equivalent to typical office lighting and 1000 lux is equivalent to TV studio lighting levels. Direct sunlight can easily exceed 30000 lux.

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