silhouette®
wound + skin assessment

aranzmedical

Silhouette v4 System Specifications

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

Whether you work in skin and wound care or research, Silhouette has been designed to make your job easier. First launched in 2007, Silhouette is a widely used wound assessment, documentation, and management system, proven to collect high quality, repeatable, and reliable information. Now with a wireless camera and new applications that operate on Apple devices, Silhouette version 4 provides greater flexibility and usability than ever before.

Wound and Skin 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

- Support for secure telehealth workflows with home user access and asynchronous 'store and forward' data sharing
- Fewer hospital admissions and visits
- Shorter hospital stays
- A reduction in the total cost of patient care

Wound and Skin Research

Silhouette's ability to reliably capture, measure, and manage wound data has been proven in more than 190 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
- Data exports at any time

- 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 with electronic signatures can be used as source documentation
- An easy-to-use solution for sites

System Feature Overview   Silhouette V4

Image Capture Devices	
SilhouetteStar	Image capture and non-contact 3D modelling with support for making 3D measurements: • Length • Width • Perimeter • Area • Mean Depth • Max Depth • Volume • Area Reduction
SilhouetteMobile	Image capture and non-contact 3D modelling with support for making 3D measurements. Measurements require a fiducial marker to be placed on the skin next to the wound. With the 2D Imaging option measurements are: • Length • Width • Perimeter • Area The 3D Imaging option adds measurements of: • Mean Depth • Max Depth • Volume
SilhouetteLite	Image capture with no measurement capability
SilhouetteCentral Web App	Secure JPEG image capture from generic cameras with no measurement capability. 2D image capture from mobile devices using reference stickers with support for making 2D (planimetry modelling) measurements (length, width, perimeter, area, area reduction). 3D image capture from mobile devices using reference stickers with support for making 3D measurements (length, width, perimeter, area, mean depth, max depth, volume, area reduction).
Medical Notes	
Wound Tracing	Manual – determined by clinical judgment. Automatic Boundary Detection - optional manual adjustment if necessary.
Patient Identifiers	Patient Information and Patient Identifiers.
Patient Notes (recorded per patient)	Investigation History, Medical History, Medication.
Patient Assessment Notes (recorded per patient, per visit)	Admission Details, Discharge Details, Vital Signs, Related Pain (non-wound), Edema, Factors Affecting Healing.
Wound Assessment Notes (recorded per wound, per visit)	Anatomical Site, Images, Measurements, Wound Details, Wound Pain, Comments, Wound Etiology.
Wound Outcomes	Healed, Amputated, Released from Follow-up.
Multiple assessment Types	Yes.
Configuration	Configurable fields and conditional validation rules available.**
Auto Email Wound Assessments	Yes.
Customizable Notes	Yes.**
Calculated fields	Yes.**
Analysis and Reporting	
Trend Graphs	The following trend graphs are available depending on capture device used: • Area • Area reduction • Max depth • Mean depth • Volume
Assessment Reporting	PDF wound assessment report.
Security	
Access control	Username and password, SAML2 SSO.
Application timeout	Configurable.
Audit records	Available for login attempts, changes and patient data, data viewed, and data exported from Silhouette (enterprise deployment only).
Deployment Models	
Enterprise – on premises / customer managed	Yes.
Enterprise – cloud hosted / ARANZ managed	Yes.
Standalone PC software	Yes – SilhouetteConnect standalone.
Integration and Data Export	
EMR (Electronic Medical Record)	Order receipt and results (assessment report, discrete observations, and images) (enterprise deployment only).
Export	Images, wound and assessment data.
Services, Support, and Warranty	
Established services offered	Project management, system documentation, data management, technical training, and clinical training.
Hardware warranty	Return to base.
Software upgrades	Support agreement defines level of upgrade support.
Support locations and hours	International support – support agreement defines hours.

SilhouetteStar Scanner Specifications

The SilhouetteStar scanner captures wound images and non-contact 3D measurements of wounds at the point of care. The images and data captured with SilhouetteStar are uploaded to SilhouetteCentral either over a secure Wi-Fi network (SilhouetteStar 2 only) or via USB cable to SilhouetteConnect.

	Model 2010.xx SilhouetteStar 2 (Wireless and Wired)	Model 2005.xx SilhouetteStar 5MP (Wired)	Model 2000.xx SilhouetteStar 3MP (Wired)
Imaging			
Sensor resolution	5 MP (nominal)		3 MP (nominal)
Working distance (from the base of the scanner)	190 mm (typical). 275mm (nominal max).	190mm (typical). 275mm (nominal max).	190mm (typical). 275mm (nominal max).
FOV – horizontal	41°. (Nominally 182mm at the typical working distance.	40°. (Nominally 171mm at the typical working distance).	40°. (Nominally 174mm at the typical working distance).
Aspect ratio	4:3.		
Focus	Fixed.		
Guided image capture	Formation of laser star for consistent imaging.		
Exposure	Automatic (dual LED flash).		
Picture format	Exportable in png or jpg formats.		
Wound measurement			
Minimum wound size	2 mm x 2 mm typical.		
Accuracy[1] (95% confidence internal)	Area (cap measurement): 2% Perimeter: 1% Depth: 5% Volume: 5%		
Precision	Area: $1mm^2$ Perimeter: 1mm Depth: 1mm Volume: $1mm^2$		
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	4s typical[2].	3s typical.	3s typical.
Image transfer time USB	2s typical.	Included in the time above.	
Transfer (Wi-Fi)	4s typical.	-	
Scanner start-up time	< 25s from off, 1s from sleep.	-	
Wi-Fi connection time	< 15s typical.	-	
Lighting and lasers			
Lasers	Class 1 per IEC60825–1.		
Flash	High power LED flash, approx. 10,000 lux.		
User interface			
Audio	Shutter + image transfer.	(audible feedback via connected computer).	
Screen	Patient name, patient ID, Wi-Fi status, image transfer status, system messages.	(status of camera available via connected computer).	
Control	Single button.		
Capture guidance	Laser star.		
Power Requirements			
Power Consumption	Compatible with USB 2.0 power specifications and USB battery charging specifications v1.2.	Compatible with USB 2.0 power specifications 500mA @ 5V.	
	Li – ion, 6.5Wh	-	
Battery Shift Life	8 hrs[3].	-	
Battery Lifetime	> 2 years[4].	-	
Environmental			
Operating Temperature	10°C (50°F) min to 30°C (86°F) max.		
Storage Temperature	-5°C (23°F) min to 50°C (122°F) max (short term).		
Operating Humidity	0% RH min to 80% RH max.		
Lighting[5]	100 lux min – 400 lux nominal – 1000 lux max.		

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[1] Based on the material presented at http://www.aranzmedical.com/silhouette/wound-measurement-accuracy-study/ using v3 Silhouette for wound tracing and 3MP camera.

[2] Transfer via WiFi depends on WiFi network quality.

[3] Depends on usage pattern. Estimate is based on 10 patient assessments over 8 hours, with 5 images per assessment.

[4] Depends on usage and charge pattern. Estimate is based on 1 shift and 1 change per day when in use and with regular monthly charges when in storage.

[5] 100 lux is equivalent to a dark, heavily overcast day. 500 lux is equivalent to typical office lighting and 1,000 lux is equivalent to TV studio lighting levels. Direct sunlight can easily exceed 30,000 lux.

Connectivity		
Offline Support (wire USB with SilhouetteConnect)	Yes.	
USB	USB 2.0 – uses IP networking over USB (RNDIS).	USB 2.0
USB Connection Time	<15ms.	
Offline Support (direct Wi-Fi to SilhouetteCentral	Yes.	No.
Wi-Fi	802.11 b,g,n (2.4 GHz only) Minimum 14 Mbps uplink to SilhouetteCentral. Maximum 300ms round trip latency.	-
Wi-Fi Security	WPA2 PSK. 802.1x Authentication with MAC Authentication Bypass with WPA2 PSK.	-
Wi-Fi TLS Support	Up to TLS1.2 for connection to SilhouetteCentral.	-
Compliance		
Laser	Class 1 Designation – IEC 60825-1	
EMC	IEC 60601-1-2:2014.	IEC 60601-1-2:2007.
Medical Device	IEC 60601 3rd Edition.	
Cleaning		
Alcohol (Isopropyl) based wipes	Yes.	
Bleach based wipes	< 1:50 concentration, limited use.	
Mild detergent	Yes.	
Water based wipes	Yes.	
Hydrogen peroxide-based wipes	Yes.	
Physical		
Dimensions	100mm x 67mm typical.	
Weight	300g typical.	240g typical.
Accessories		
Charger	Yes.	-
Cradle	Yes.	Yes.
Cables	USB-A to USB-B – 5m/16' 5".	USB-A to USB-B – 1.8m/5' 11", 3m/9' 10", 5m/16' 5".

SilhouetteConnect Specifications (Client Software)

SilhouetteConnect is the software installed on a Windows tablet, laptop, or desktop computer. SilhouetteStar connects via USB to a computer with SilhouetteConnect. It enables wound assessments to be performed without connection to a network, and the data is synchronized with SilhouetteCentral when a network connection is available.

Key System Times	
Capture to Measurement Complete Time	<2 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).
Computing Platform Requirements	
Supported devices	Windows laptop, desktop, or tablet.
Supported Operating Systems	Windows 10 or Windows 11 (64-bit).
Processor	x86 compatible Intel or AMD processor running at 2.0 GHz minimum (multi-core recommended).
Disk	10GB available space recommended minimum for approx. 2000 images and assessments.
Memory	8 GB minimum.
Browser	N/A
Database	SQL Server LocalDb for sync mode or SQL Server Express for standalone mode. SQL Server LocalDb 2022 is included with SilhouetteConnect installer. Other versions of SQL Server can be used but must be deployed manually.
Software dependencies	Included with SilhouetteConnect Installer: .NET framework 4.8 and SQL Server LocalDb 2022.
USB requirements	USB 2.0 or 3.0 port.
Display resolution	1024x768 minimum.
Security	
Data-at-rest encryption	To enable data-at-rest encryption, the software must be deployed using Bitlocker encryption or similar.
Data-in-transit encryption	To enable data-in-transit encryption, the software is synchronized to SilhouetteCentral using the HTTPS protocol.

SilhouetteCentral Specifications – Server Software

SilhouetteCentral enables users to review, report, securely share, and analyze the wound data collected by SilhouetteStar 2, SilhouetteConnect, SilhouetteMobile. SilhouetteCentral is accessed using a web browser.

Infrastructure Types	
On premises	Yes. Note: use of the SilhouetteCentral 3D imaging feature requires that images be sent to a Silhouette Surface Modelling Service hosted in the cloud for processing.
Cloud	Yes.
Client Software Supported	
Web browser Support	Chrome, Firefox, Safari, Microsoft Edge. (Each release of SilhouetteCentral is tested on the latest version of these browsers.) (Note: Microsoft Internet Explorer is not supported.) Note: if using an Apple device to access the SilhouetteCentral web app, the iOS version must be 15 or later. Note: the version of Safari for iOS/iPadOS is linked to the version of iOS/iPadOS. Effort is made to keep compatibility with the previous major versions for at least one year after a new iOS/iPadOS major version is released.
Thick Client Support	SilhouetteConnect (Windows), SilhouetteMobile (iOS devices), SilhouetteLite (iOS devices)
Screen Sizes Supported	
Home user workflow	Minimum viewport with 360px (current iPhone models).
Clinician and admin user workflow	Minimum viewport width by height is 360px by 667px for clinical screens (current iPhone models). Minimum viewport width of 768 pixels for administration screens.
Enterprise on Premises Deployment Platform Requirements	
OS	Windows Server 2016 or later (2019 or later recommended).
Processor	2.4 GHz dual core, 64 bits minimum.
Desk	100 GB available space (recommended minimum).
Memory	16 GB recommended; 4 GB minimum.
Database	SQL server 2016 SP3 (work group, standard, enterprise, web) or later.
Software Dependencies	Internet information services (IIS) with SSL alias certificates for HTTPS. .NET framework 4.8. SQL Server LocalDB 2022 for SilhouetteConnect synchronisation. ASP.NET Core v8.0 IIS Hosting Bundle (ASP.NET Core v8.0 Runtime + ASP.NET Core Module v2). NextGen Connect v4.0 or later for integration with EMR Systems. VC++ 14.0 Runtime.
Network	Ethernet TCP/IP Connection. Static IP Address.
Security	
Username and Password	Configurable password rules and expiration.
Authentication	SAML2 SSO Support with Just-In-Time provisioning, compatible with Active Directory Federated Services (AD FS).
Data-in-transit	To support data-in-transit encryption, SilhouetteCentral is deployed with HTTPS transport.
Data-at-rest	To support data-at-rest encryption, SilhouetteCentral must be deployed with Bitlocker or similar. Microsoft SQL Enterprise Transparent Data Encryption or similar can be used to encrypt databases.
SilhouetteCentral 2D/3D Imaging	
Reference sticker colour	Neon/fluoro green.
Reference sticker size	10 mm minimum, 20 mm maximum, typical sizes are ½ inch, ¾ inch or 14 mm.
Reference sticker recommendations	Available on request.
Mobile device support	Apple devices running iOS/iPadOS 15 or greater supported where they meet the screen size specifications above. Android mobile devices running the latest Google Chrome browser are supported where they have at least an 8 MP rear camera, have a minimum of 4 GB of RAM, and meet the screen size specifications above. ARANZ Medical has tested the 2D and 3D imaging feature with both Apple devices and Android devices. The specific list of tested devices is available on request.
Measurement accuracy	Contact ARANZ Medical for an accuracy statement relating to SilhouetteCentral 2D and 3D imaging.
EMR Interfaces	
Standards	HL7 (Health Level 7), Email.
Key Functionality	Patient Management, Order Management, Order Results.
Key Vendors Supported	Cerner, Concerto, Epic*, Meditech, VistA Imaging*.
Data Export	
File export	PDF wound export report with images, CSV files.
Reporting	
Dashboard Reporting	Includes a reporting engine to generate reports across the population of patients in the database. Report templates can be created for varied reporting scenarios.

SilhouetteMobile Specifications - Application

SilhouetteMobile is an application designed for Apple® iPhone® and iPad® devices that enables users to take wound images, obtain non-contact 2D measurements, and record patient notes on their Apple device. The data collected at the patient's bedside is synchronized with SilhouetteCentral over a secure connection when available. Measurements are made using a reference sticker that is placed on the patient's skin adjacent to the wound.

App	
IOS/iPadOS version	15 (minimum).
Device support	iPhone 6s or newer. iPad mini, iPad standard, iPad Pro. Contact ARANZ Medical for advice on device recommendations.
Security	A passcode must be enabled on the device to encrypt data at rest. HTTPS must be used on SilhouetteCentral to encrypt data in transit.
Maximum number of patients	4,000.
Maximum number of images per assessment	10.
Network	
Minimum network uplink to SilhouetteCentral	1.5 Mbps.
Measurement Capabilities	
Area, perimeter, length, width and rulers	Yes.
Depth and volume	Yes - with a 3D measuring option.*
Minimum size	2 mm x 2 mm.
Measurement accuracy	Contact ARANZ Medical for accuracy statement relating to SilhouetteMobile.

SilhouetteLite Specifications - Application

SilhouetteLite is an application designed for Apple® iPhone® and iPad® iOS devices that enables users to add patients, take wound images, and simple notes (without measurements) on their Apple device. The data collected at the patient's bedside is synchronized with SilhouetteCentral over a secure connection when available.

App	
IOS/iPadOS version	15 (minimum).
Device support	iPhone 6s or newer. iPad mini, iPad standard, iPad Pro. Contact ARANZ Medical for advice on device recommendations.
Security	A passcode must be enabled on the device to encrypt data at rest. HTTPS must be used on SilhouetteCentral to encrypt data in transit.
Maximum number of patients	4,000.
Maximum number of images per assessment	10.
Network	
Minimum network uplink to SilhouetteCentral	1.5 Mbps.
Measurement Capabilities	
Area, perimeter, and rulers	No.
Depth and volume	No.

System Regulatory Approvals

FDA 510k – approval number K070426.
ISO 13485.2016 certified.
Health Canada – Therapeutic Products Directorate.
Wand registration (New Zealand).
UKCA Mark.

TGA approval (Australia).
CE Mark.
Supports HIPAA compliance.
Singapore regulatory clearance.

Footnotes

*   Planned in a future release, not available in the current release.

**   Configuration notes available via services in the current release.

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