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silhouette®
wound assessment + management

Silhouette v4 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. Now with a wireless camera and a new web-based application that operates on a range of mobile devices, Silhouette version 4 provides greater flexibility and usability than ever before.

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 70 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	V4
Image Capture Devices	
SilhouetteStar	Image capture and non-contact 3D modeling with support for making 3D measurements: • Length • Width • Perimeter • Area • Mean Depth • Max Depth • Volume • Tissue Type Area %* • Area Reduction*
SilhouetteLite+	Image capture and non-contact 2D planimetry modeling with support taking 2D measurements: • Length • Width • Perimeter • Area
SilhouetteLite	Image capture with no measurement capability
Medical Notes	
Wound Tracing	Manual – determined by clinical judgment
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**
Analysis and Reporting	
Trend Graphs	Depending on capture device used the following trend graphs are available: • Area • Area Reduction* • Max Depth • Mean Depth • Volume
Reporting	PDF Assessment Report
Security	
Access Control	Username and Password, LDAP*
Application Timeout	Configurable
Audit Records	Available for logon attempts, changes in patient data, data viewed, and data exported from Silhouette. (Enterprise Deployment Only)
Deployment Models	
Enterprise – On Premises	Yes
Enterprise – Cloud Hosted	Yes - For clinical research customers only
Standalone PC Software	Yes - SilhouetteConnect standalone
Integration and Data Export	
EMR	Order receipt and response (assessment report)* (Enterprise Deployment Only)
Export	Images, Wound and Assessment Data*
Services, Support and Warranty	
Established Services Offered	Project Management, System Implementation, 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 Camera Specifications	Model 2010.xx SilhouetteStar 2 (Wireless and Wired)	Model 2001.xx SilhouetteStar (Wired)

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

Imaging		
Sensor Resolution	5MP (nominal)	3MP (nominal)
Working Distance	From the base of the camera: 190mm (typical) 280mm (nominal max)	From the base of the camera: 190mm (typical) 240mm (nominal max)
Depth of Field	-50mm, +90mm at typical working distance	-30mm, +50mm at typical working distance
FOV - Horizontal	42° (Nominally 180mm at the typical working distance)	42.5° (Nominally 183mm at the typical working distance)
Aspect Ratio	4:3	4:3
Focus	Fixed	Fixed
Guided Image Capture	Formation of laser star for consistent imaging	Formation of laser star for consistent imaging
Exposure	Automatic (Dual LED Flash)	Automatic (Dual LED Flash)
Picture Format	Exportable in png or jpg formats	Exportable in png or jpg formats
Image Size (px)	2592 x 1944	2048 x 1536
Wound Measurement		
Maximum Wound Size	250mm x 185mm typical	250mm x 185mm typical
Minimum Wound Size	2mm x 2mm typical	2mm x 2mm typical
Accuracy[1] (95% confidence interval)	Area (Cap measurement): 2% Perimeter: 1% Depth: 5% Volume: 5%	Area (Cap measurement): 2% Perimeter: 1% Depth: 5% Volume: 5%
Precision	Area: 1mm^2 Perimeter: 1mm Depth: 1mm Volume: 1mm^3	Area: 1mm^2 Perimeter: 1mm Depth: 1mm Volume: 1mm^3
Inter-rater Reliability[1]	1% for Area and Perimeter <2% for max Depth and Volume	1% for Area and Perimeter <2% for max Depth and Volume
Intra-rater Reliability[1]	1% for Area and Perimeter <2% for max Depth and Volume	1% for Area and Perimeter <2% for max Depth and Volume
Image Times		
Image Capture Time	4s typical	3s typical
Image Transfer Time (USB)	2s typical (when used in conjunction with SilhouetteConnect)	Included in the time above
Image Transfer Time (WiFi)	4s typical[2]	-
Camera boot time	< 25s from off 1s from sleep	-
Lighting and Lasers		
Lasers	Class 1 per IEC 60825-1	Class 1 per IEC 60825-1
Flash	High Power LED Flash, approx. 10,000 Lux	High Power LED Flash, approx. 10,000 Lux
User Interface		
Audio	Shutter + Image Transfer	- (audible feedback via connected computer)
Screen	Patient Name, Patient ID, WiFi Status, Image Transfer Status, System Messages	- (status of camera available via connected computer)
Controls	Single Button	Single Button
Capture Guidance	Laser Star	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
Battery Type and Capacity	Li-Ion, 6.5 Wh	-
Battery Shift Life	8 hrs[3]	-
Battery Lifetime	> 2 years[4]	-

SilhouetteStar Camera Specifications	Model 2010.xx SilhouetteStar 2 (Wireless and Wired)	Model 2001.xx SilhouetteStar (Wired)
Connectivity		
Offline Support (wired USB with SilhouetteConnect)	Yes	Yes
USB	USB 2.0 - Uses IP networking over USB (RNDIS)	USB 2.0
USB Connection Time	< 15s	< 15s
Online Support (direct WiFi to SilhouetteCentral)	Yes	No
WiFi	802.11 b,g,n (2.4 GHz only), Minimum 14 Mbps uplink to SilhouetteCentral, Maximum 300ms round trip latency	-
WiFi Security	WPA2 PSK, 802.1x Authentication with MAC Authentication Bypass with WPA2 PSK	-
WiFi Connection Time	< 15s typical	-
Compliance		
Laser	Class 1 Designation – IEC 60825-1	Class 1 Designation – IEC 60825-1
EMC	IEC 60601-1-2: 2014	IEC 60601-1-2: 2007
Medical Device	IEC 60601 3rd Edition	IEC 60601 3rd Edition
Cleaning		
Alcohol (Isopropyl) Based Wipes	Yes	Yes
Bleach Based Wipes	< 1:50 concentration, limited use	< 1:50 concentration, limited use
Mild Detergent	Yes	Yes
Water Based Wipes	Yes	Yes
Hydrogen Peroxide Based Wipes	Yes	Yes
Physical		
Dimensions	100mm x 67mm typical	100mm x 67mm typical
Weight	300g typical	240g 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
Storage Temperature	-5°C (23°F) min to 50°C (122°F) max (short term)	-5°C (23°F) min to 50°C (122°F) max
Operating Humidity	0% RH min to 80% RH max	0% RH min to 80% RH max
Lighting[5]	100 lux min – 400 lux nominal – 1000 lux max	100 lux min – 400 lux nominal – 1000 lux max
Accessories		
Charger	Yes	-
Cradle	Yes	Yes
Cables	USB-A to USB-B - 5m/16' 5"	USB-A to USB-B (Active) - 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. SilhouetteConnect 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 (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	4 GB Minimum
Browser	N/A
Database	Included in SilhouetteConnect (SQL Express 2014)
USB Requirements	USB 2.0 or 3.0 Port
Display Resolution	1024 x 768 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 must be 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, SilhouetteLite+ and SilhouetteLite Applications. SilhouetteCentral is accessed via a web-based application.

Infrastructure Types	
On Premises	Yes
Cloud	Yes - For Clinical Research Customers Only
Client Software Supported	
Web Browser Support	Chrome, Firefox, Safari, IE, Microsoft Edge
Thick Client Support	SilhouetteConnect (Windows), SilhouetteLite (iOS devices), SilhouetteLite+ (iOS devices)
Enterprise On Premises Deployment Platform Requirements	
OS	Windows Server 2012 R2 or later
Processor	2.4 GHz Dual Core, 64 bit Minimum
Disk	100 GB Available Space (Recommended Minimum)
Memory	16 GB Recommended 4 GB Minimum
Database	SQL Server 2012 (workgroup, standard, enterprise) or later An instance of SQL Server 2014 SP2 (express, workgroup, standard, or enterprise) is required if syncing with SilhouetteConnect
Software Dependencies	Internet Information Services (IIS) .NET framework 4.8 HTTPS Certificates
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 HTTPS transport
Data-at-rest	To support data-at-rest encryption, SilhouetteCentral must be deployed with 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 Vendors Supported	Epic*, Cerner*, Meditec*, VistA Imaging*
Data Export	
File Export	PDF wound assessment report with images, CSV files

SilhouetteLite+ Application and Sensor

SilhouetteLite+ is comprised of an Application and a range finding Sensor for Apple® iPhone® and iPad® iOS devices. SilhouetteLite+ 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.

Application	
iOS version	11 (Minimum)
Device Support	iPhone 5s or Newer, iPod Touch 6th Gen, 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	Yes
Perimeter	Yes
Rulers	Yes
Depth and Volume	No
Minimum Wound Size	2mm x 2mm
Measurement Accuracy	Contact ARANZ Medical for accuracy statement relating to SilhouetteLite+

SilhouetteLite+ Application and Sensor cont.

Sensor	The SilhouetteLite+ Sensor is attached to an iOS device, close to the iOS device camera, enabling wound measurements to be taken from images.
X Offset (Horizontal offset between the sensor window to the center of the device camera)	-12mm Minimum +20mm Maximum
Y Offset (Vertical offset between the sensor window to the center of the device camera)	-12mm Minimum +30mm Maximum
Minimum range to wound	60mm
Maximum range to wound	400mm
Range to Wound Accuracy	<6% Error
Battery	Li-Ion
Battery Charging	Inductive Charger (Qi) Supplied
Battery Shift Life	Approx. 30 Calendar Days or 80 Images - depends on usage pattern
Connection to iOS Device	Bluetooth 4 (Bluetooth LE)
Attachment to iOS Device	One time adhesive attachment. The Sensor can be attached to a removable case. Not all cases are suitable size or material.
Sensor Size	90mm x 52mm x 5mm (nominal)
Sensor Environment	
Operating Temperature	0°C (32°F) min to 40°C (104°F) max
Sensor Charging Temperature	0°C (32°F) min to 45°C (113°F) max
Storage Temperature	Short Term (< 2 hours): -5°C (23°F) min to 60°C (140°F) Medium Term (< 1 month): 0°C (32°F) min to 45°C (113°F) Long Term (> 1 month): 0°C (32°F) min to 35°C (95°F)

SilhouetteLite Application

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

App	
iOS Version	11 (Minimum)
Device Support	iPhone 5s or Newer iPod Touch 6th Gen 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	No
Perimeter	No
Rulers	No
Depth and Volume	No

System Regulatory Approvals

FDA 510k – approval number K070426	TGA approval (Australia)
ISO 13485:2012 certified	WAND registration (New Zealand)
CE Mark	Singapore regulatory clearance
Health Canada – Therapeutic Products Directorate	HIPAA compliant system

Footnotes

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 20 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
5. 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.

* Planned for a future release, not available in the current release.
** Configuration of notes available via services in the current release.