

# 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 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		V3.x
<b>Image Capture</b>		
Guided Image Capture		Formation of laser star for consistent imaging
Controlled Artificial Lighting		Dual LED Flash
Managed Camera Settings		Auto-exposure fixed focus
Camera Resolution*		3MP or 5MP
<b>Measurement</b>		
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
<b>Medical Notes</b>		
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)
<b>Analysis and Reporting</b>		
Trend Graphs		Area, Area Reduction, Max Depth, Mean Depth, Volume, Tissue Types
Reporting		Configurable PDF Assessments
<b>Security</b>		
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)
<b>Integration and Data Export</b>		
EMR		Order receipt and response (assessment report) (Enterprise Deployment Only)
Export		Images and Assessment Data
<b>Services, Support and Warranty</b>		
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 Specifications – Camera	Model 2000.xx (SilhouetteStar 3MP)	Model 2005.xx (SilhouetteStar 5MP)
SilhouetteStar is a non-contact camera 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.		
<b>Imaging</b>		
Sensor Resolution	3MP (nominal)	5MP (nominal)
Working Distance	235mm (typical), 285mm (max)	235mm (typical), 285mm (max)
Depth of Field	60 mm	100 mm
FOV - Horizontal	180mm min, 250mm max	170mm min, 230mm max
Aspect Ratio	4:3	4:3

SilhouetteStar Specifications – Camera	Model 2000.xx (SilhouetteStar 3MP)	Model 2005.xx (SilhouetteStar 5MP)
Focus	Fixed	Fixed
Exposure	Automatic	Automatic
Picture Format	Exportable in png or jpg formats	Exportable in png or jpg formats
Image Size (px)	2048 x 1536	2560 x 1920
<b>Wound Measurement</b>		
Maximum Wound Size	250mm x 180mm typical	230mm x 170mm typical
Minimum Wound Size	2mm x 2mm typical	2mm x 2mm typical
Accuracy (95% confidence interval)	Area (Cap measurement): 2% Perimeter: 1% Depth: 5% Volume: 5%	Area (Cap measurement): 2% Perimeter: 1% Depth: 5% Volume: 5%
Ref: <a href="http://www.aranzmedical.com/silhouette/wound-measurement-accuracy-study/">http://www.aranzmedical.com/silhouette/wound-measurement-accuracy-study/</a>		
Precision	Area: 1mm <sup>2</sup> Perimeter: 1mm Maximum Depth: 1mm Volume: 1mm <sup>3</sup>	Area: 1mm <sup>2</sup> Perimeter: 1mm Maximum Depth: 1mm Volume: 1mm <sup>3</sup>
Inter-rater Reliability	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% for area and perimeter, 2% for max depth and volume	1% for area and perimeter, 2% for max depth and volume
<b>Image Times</b>		
Image Capture Time	1.2 s typical	1.2 s typical
Image Transfer Time (USB)	Included in time above	Included in time above
<b>Lighting and Lasers</b>		
Lasers	Class 1 per IEC 60825-1	Class 1 per IEC 60825-1
Artificial Lighting	Dual torch mode LED	Dual torch mode LED
Flash	High Power LED Flash, 10,000 Lux	High Power LED Flash, 10,000 Lux
<b>User Interface</b>		
Audio	N/A <sup>1</sup>	N/A <sup>1</sup>
Screen	N/A <sup>1</sup>	N/A <sup>1</sup>
Controls	Single Button	Single Button
Capture Guidance	Laser Star	Laser Star
<b>Power Requirements</b>		
Power Consumption	500mA @ 5V	500mA @ 5V
<b>Connectivity</b>		
USB	USB 2.0	USB 2.0
<b>Compliance</b>		
Laser	Class 1 Designation – IEC 60825-1	Class 1 Designation – IEC 60825-1
EMC	IEC 60601-1-2: 2007	IEC 60601-1-2: 2007
Medical Device	IEC 60601 3rd Edition	IEC 60601 3rd Edition
<b>Cleaning</b>		
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
<b>Physical</b>		
Dimensions	100mm x 67mm typ.	100mm x 67mm typ.
Weight	240g typical	240g typical
<b>Environmental</b>		
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	-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 <sup>2</sup>	100 lux min – 400 lux nominal – 1000 lux max	100 lux min – 400 lux nominal – 1000 lux max

SilhouetteStar Specifications – Camera	Model 2000.xx (SilhouetteStar 3MP)	Model 2005.xx (SilhouetteStar 5MP)
<b>Accessories</b>		
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")

## SilhouetteConnect Specifications – Client Software Specifications

SilhouetteConnect is the software that operates on a tablet, laptop or desktop computer with Windows 7 or later. SilhouetteStar connects via USB cable to a computer with SilhouetteConnect.

<b>Key System Times</b>	
Successive Image Capture Time	1.2 s typical
Capture to Measurement Complete Time	< 1 minute typical (includes tracing)
Synchronization Time	17 s minimum. < 1 minute typical (dependent on database size, active patient list size, number of images, network speed and network reliability)
<b>Security</b>	
Access Control	Username and Password, Use Active Windows Credentials (Enterprise Deployment with LDAP only)
Data Encryption	SHA-256 and AES128 encryption on database
<b>Computing Platform Requirements</b>	
Supported Devices	Windows laptop, desktop or tablet
Supported Operating Systems	Windows 7,8,8.1 or 10
Processor	2.0 GHz
Disk	10 GB available space
Memory	4 GB recommended, 2 GB 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 Specifications

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.

<b>Infrastructure Types</b>	
Self-Hosted Enterprise	Yes
Cloud	Clinical Trials Only
<b>Self-Hosted Enterprise Platform Requirements</b>	
OS	Windows Server 2008/ 2008 (R2) or later. 2012 R2 64-Bit Recommended
Processor	2.4 GHz Dual Core Minimum
Disk	100 GB Available Space
Memory	16 GB Recommended. 4 GB Minimum
Database	SQL Server 2008 or later
Software Dependencies	Internet Information Services (IIS), IIS URL Rewrite 2.0 module .NET framework 4.5.2 Microsoft Report Viewer 2010 Redistributable
<b>Security</b>	
Username and Password	Configurable password rules and expiration
LDAP Authentication	Compatible with Active Directory and Posix LDAP implementations

## SilhouetteCentral Specifications – Server Software Specifications

### EMR Interfaces

Standards	HL7, DICOM, Email
Key Functionality	Patient Management, Order Management, Order Results
Key EMR Vendor Supported	Epic, Cerner, Meditech, 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 13485:2012 certified	WAND registration (New Zealand)
CE Mark	Singapore regulatory clearance
Health Canada – Therapeutic Products Directorate	HIPAA compliant system

### Footnotes

1. The camera uses the Silhouette Connect PC to play shutter sounds, display live previews and review image captures.
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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