# 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:<br>• Length<br>• Width<br>• Perimeter<br>• Area<br>• Mean Depth<br>• Max Depth<br>• Volume<br>• Tissue Type Area %*<br>• Area Reduction* |
| SilhouetteLite+ | Image capture and non-contact 2D planimetry modeling with support taking 2D measurements:<br>• Length<br>• Width<br>• Perimeter<br>• 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<br>(recorded per patient, per visit) | Admission Details, Discharge Details, Vital Signs, Related Pain (non-wound), Edema, Factors Affecting Healing |
| Wound Assessment Notes<br>(recorded per wound, per visit) | Anatomical Site, Images, Measurements, Wound Details, Wound Pain, Comments, Wound Etiology |
| 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:<br>• Area<br>• Area Reduction*<br>• Max Depth<br>• Mean Depth<br>• Volume |
| Reporting | PDF Assessment Report |
| **Security** | |
| Access Control | Username and Password, LDAP* |
| 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) |
| **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 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 | 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 | - |
| 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) - 1.8 m (5' 11"), 3 m (9' 10"), 5 m (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 a network connection. Data is synchronized with SilhouetteCentral when a network connection is available.

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| **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 |
| Disk | 10 GB available space (Recommended Minimum) |
| 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 ynchronized 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 4.5.2 |
| **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 |

## 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 | No |
| 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<br>+20mm Maximum |
| Y Offset (Vertical offset between the sensor window to the center of the device camera) | -12mm Minimum<br>+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)<br>Medium Term (< 1 month): 0°C (32°F) min to 45°C (113°F)<br>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<br>iPod Touch 6th Gen<br>iPad Mini, iPad Standard, iPad Pro<br>Contact ARANZ Medical for advice on device recommendations |
| Security | A passcode must be enabled on the device to encrypt data-at-rest<br>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 | No |
| 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.

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