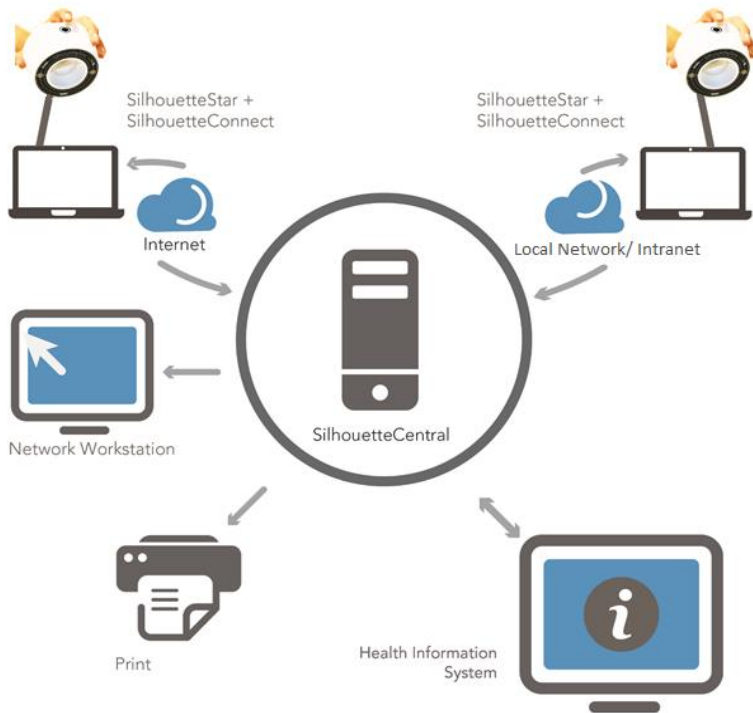# aranzmedical

Quick Reference Guide

SilhouetteStar 1

+

SilhouetteConnect

Welcome

SilhouetteStar™ is a non-contact device used to collect images, measurements and other information from all external wound types at the point of care; it is connected to a computer via a USB cable.

SilhouetteConnect™ is the software that runs on the computer; it controls the SilhouetteStar device and functions as a wound-focused electronic medical record system.

This quick reference guide is the reference for using SilhouetteStar + SilhouetteConnect. It summarizes important points in regards to wound imaging, measurement, and documentation.

You can find more detailed information in the user manuals or SilhouetteConnect help documentation or the Silhouette Clinical User's Guide.

Contents

Warnings

Laser Warnings

SilhouetteStar is designated as a Class 1 laser product during all operational procedures. A Class 1 laser product is safe under reasonably foreseeable conditions per the requirements in IEC 60825-1. However, the following precautions are recommended:

- Never stare into the laser beam.
- Do not view the laser with optical instruments.
- Do not use SilhouetteStar in a manner that causes the laser light to shine into people's eyes.
- Warn patients not to stare into the laser beam. Young children or subjects whose natural aversion reflex may be dulled due to medication or a medical condition may be advised to wear a blindfold.
- Operate the device so that it is pointing away from windows, doors, mirrors, and other shiny reflective surfaces, and areas where other people are working.
- There are no controls, adjustments, or user serviceable parts that can affect the laser output. In the event of equipment failure, contact the manufacturer or agent for repair and servicing.

SilhouetteStar complies with FDA performance standards for laser products except for deviations pursuant to Laser Notice No. 50, dated June 24, 2007.

CAUTION: Use of controls or adjustments or performance of procedures other than those specified in this guide may result in hazardous radiation exposure.

WARNING: Laser light Class 1 product. Do not view directly with optical instruments.

Other Warnings

- Do not use SilhouetteStar in humidity or temperature conditions outside those listed in Appendix A: Operating Conditions in SilhouetteConnect help.
- Wipe any condensation from the SilhouetteStar protective optical plastic covers.
- Do not touch the optical plastic covering the SilhouetteStar lasers, LEDs or camera lens. Avoid contact with sharp objects. SilhouetteStar should be placed face-down on a clean, dry, flat surface when not in use.
- Use standard sterility protocols. Do not allow SilhouetteStar or the USB cable to come into contact with the patient or with contaminated materials.
- When using SilhouetteStar, the operator and others in the room should use caution to avoid tripping when the USB cable is draped across the floor. When SilhouetteStar is not in use, the cable should be disconnected and stored.
- Use only a SilhouetteStar USB cable. Use of a non-factory cable may cause interference with other electronic devices and/or unreliable operation.
- If the USB cable becomes damaged, please contact ARANZ Medical for a replacement. Continued use with a damaged cable may cause interference with other electronic devices and/or result in incorrect measurements and/or cause permanent damage to SilhouetteStar or to the attached computer.
- SilhouetteStar can be plugged into any available USB 2.0 port that meets electrical specifications of the USB standard.

- Ensure the computer power supply, and any USB hubs used are approved for medical use according to IEC60601-1.
- SilhouetteStar has an Ingress Protection rating of IP40, which means it is protected against dust but not water ingress.
- SilhouetteStar contains no user serviceable parts.
- This product is designed to have a nominal operational life of five years.
- At end of unit life, please recycle in accordance with local government regulations.

SilhouetteStar Label Information

The warning label on the SilhouetteStar device shows information about your SilhouetteStar. The symbols on the label and their meanings are as follows:

Symbol	Meaning
e-IFU	Consult electronic instructions for use
	Refer to instruction manual/booklet before use
MD	Medical Device
UDI	Unique Device Identifier Carrier

Manufacturer reference / Model number

REF

Major Model Number	SilhouetteStar Model
2000	SilhouetteStar 1 (3MP)
2005	SilhouetteStar 1 (5MP)
There are other models of SilhouetteStar (e.g. SilhouetteStar 2 (2010)), refer to separate quick reference guides for details.	

SN Manufacturer assigned device serial number

Manufacturer

ARANZ Medical Limited
Tel +64-3-3 74-6120, Fax +64-3-374-6130

Postal Address:
ARANZ Medical Limited
PO Box 3894
Christchurch 8140
New Zealand

Delivery Address:
ARANZ Medical Limited
47 Hereford Street
Christchurch 8013
New Zealand

CE 0123 CE-mark. EU Declaration of Conformity and Notified Body Identifier

UKCA UKCA mark. UK Conformity Assessed Marking

RCM mark. New Zealand and Australia Declaration of Conformity

Warning: Laser light. SilhouetteStar is designated as a Class 1 laser product during all operational procedures.

See the Laser Warnings section of the guide.

CLASS 1 LASER PRODUCT

Waste Electrical and Electronic Equipment Directive (WEEE) Symbol. Separate collection for electrical and electronic equipment under WEEE EC Directive.

Installation and Getting Started

The files required to install SilhouetteConnect are delivered as a zip file, which will require extracting to a known location. Once you have downloaded these files:

1. Navigate to the folder that contains the installation files.

2. Right click on setup.exe, and run as Administrator to start installation.

3. Follow the on-screen instructions.

Once the installation is complete, launch SilhouetteConnect by double-clicking on the icon created on your desktop.

Obtaining and Activating Your License

To use SilhouetteConnect a license is required. You can use SilhouetteConnect for the 30-day trial period without adding a license.

To obtain a license or client code, contact Customer Support using the details provided on page 14 of this guide.
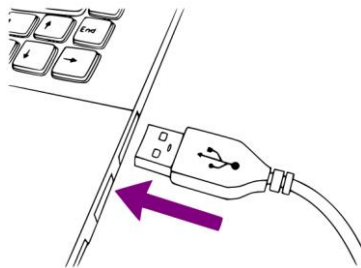
Connecting the SilhouetteStar

To connect SilhouetteStar, insert the square end of the cable into the port on the device.
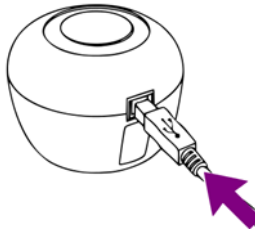
Insert the flat end of the cable into one of the USB 2.0 ports on your computer:

You can also connect the SIlhouetteStar via a powered USB hub.

Your computer will automatically detect the device and install the required drivers. If the computer's sound is on, the computer will chime to indicate successful connection.

The SilhouetteStar's lasers will not operate until you initiate image capture from SilhouetteConnect.

Performing a test image capture ensures that the correct drivers have been loaded and that the SilhouetteStar is working correctly. Please note that your system includes a Silhouette Test Target (a card with 4 dots supplied with SilhouetteStar). The Silhouette Test Target is used to perform a SilhouetteStar calibration test capture if your software provides the calibration test capture facility.

Disconnecting the SilhouetteStar

To disconnect the SilhouetteStar, make sure the lasers are off and simply remove the USB cable from your SilhouetteStar and/or the computer's USB port.

Typical Silhouette Data Collection Workflow

Silhouette captures images of wounds in order to generate dimensional information about the wound. A typical workflow is:

1.   Log on to SilhouetteConnect

2.   Select a patient from the list or create a new patient

3.   Create a new assessment

4.   Capture images

5.   Assign images to wounds, trace wound boundaries, and take measurements

6.   Generate an assessment PDF report or synchronize with SilhouetteCentral

8.   Log off

The user interface and exact operation depends on your system configuration and Silhouette software version. Refer to the SilhouetteConnect help or Silhouette Clinical User's Guide for more specific instructions.

Capturing Images

To capture images with the SilhouetteStar device, ensure that the device is connected to your computer via the USB cable provided and that you have the correct patient selected in SilhouetteConnect.

If using SilhouetteConnect software prior to v4.0, enter capture mode by selecting the **Capture Images** button in. If using SilhouetteConnect software v4.0 or greater, enter capture mode by pressing the button on the SilhouetteStar.

The SilhouetteStar lasers will be activated when in image capture mode. When using SilhouetteConnect v4.0 or greater, image capture mode will timeout and the device lasers will turn off. Reactivate them by pressing the button on the device.

Hold the SilhouetteStar so that your hand sits comfortably, with your index finger in reach of the button, this may take two hands. The device takes a series of images and it is important to keep it steady during the capture sequence to get the best results.
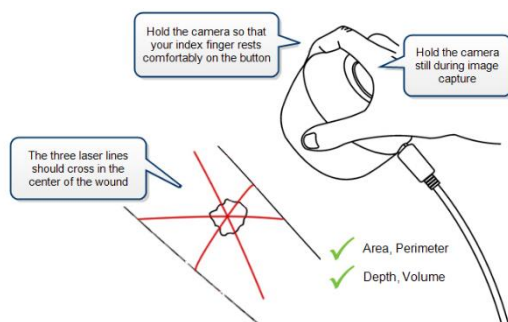
Position the SilhouetteStar facing the wound so that the laser lines cross near the center of the wound to form a star shape. The laser lines do not need to cross in a perfect star shape, but all the crossing points should be within the wound. One of the laser lines should cross the deepest part of the wound. For very large wounds, see the instructions in "Taking a Multiple Image Measurement" on page 11.
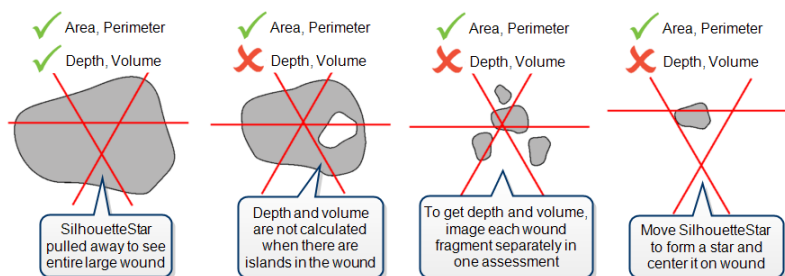

Gently squeeze the button on the SilhouetteStar to capture the image, keeping the device still until you hear the shutter sound from SilhouetteConnect or, if your computer's sound is off, until the image appears on-screen in SilhouetteConnect. Continue capturing as many images as required.

Tracing Wound Boundaries

Once the captured images have been assigned to wound assessments, the next step is to trace the wound boundaries. The following guidelines for tracing wounds are provided:

- Starting an outline create a target circle on the first point. The outline is completed by tracing back to the target circle.
- Use image zoom and pan to optimise the tracing accuracy.
- Trace the wound boundary by clicking to add points to the outline.
- When tracing the wound boundary, it is important to draw in one direction. For example, draw in the clockwise direction or the counter-clockwise direction, but do not draw in one direction then switch to the other direction.
- Always trace using a comfortable hand position. The tracing does not need to be completed in a single motion, reposition your hand or mouse to make tracing easy.
- Wound outlines are considered invalid if they cross themselves or other wound outlines.
- The drawing tools differ depending on the version of software you are using and the computing device you are using. Practice a little with the drawing tools to find the tracing method that works the best for you.
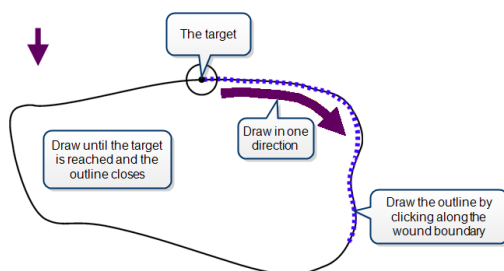

Once you have reached the target, the outline will close and the wound's area and perimeter will be displayed. Maximum depth and volume may also be displayed for some wounds.

You can also draw outlines of any wound fragments or islands. Outlines created inside the main wound outline are regarded as islands of that wound, and outlines outside the main outline are regarded as fragments. When you outline islands and/or fragments for a wound, maximum depth and volume will not be displayed for that wound.

Taking a Multiple Image Measurement

If it proves difficult to capture a wound in one image, you can capture a series of images and individually outline the separate segments. SilhouetteConnect will then automatically calculate wound area for the different segments of the wound. This is useful for large wounds or when a wound occurs on a part of the body that is curved and, therefore, difficult to capture in a single image.

1. Plan where the different images of the wound will be captured.

2. Use a surgical marker to mark on healthy skin where the edges of the different images will fall.
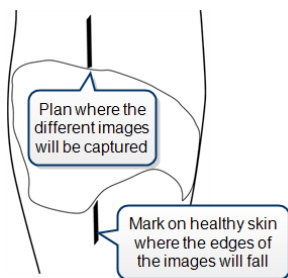
3. Capture an image of each segment of the wound and the surgical marker lines. Make sure the laser crossing point is located within the wound segment.

4. Assign each image to the same wound.

5. To trace the first image, start at a surgical marker point and trace the wound boundary for the first segment. Stop when you reach the other surgical marker point, then click on the circular target at the starting point to close the wound boundary.
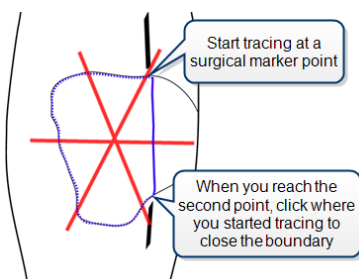
6. For the next image, trace the second segment of the wound in the same manner as the first. Try to draw the outline as close as possible to where you drew the outline for the first segment of the wound.
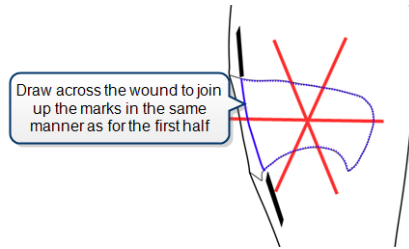
When wound area is calculated, the measurements for the different parts of the wound will be combined to give overall measurements for the wound. Maximum depth and volume will not be calculated.

Measurement Accuracy

A study on wound models with known dimensions and a variety of different shapes (flat, cylindrical, concave, and convex) has shown that any single Silhouette-derived measurement is within approximately 2% for area, 1% for perimeter, 5% for average depth, and 5% for volume (95% confidence interval). Inter- and intra-rater variability is extremely low; <1% for area and perimeter, and <2% for average depth and volume.

Reference: Nixon, Rivett and Robinson; Accuracy and repeatability of wound measurement
http://www.aranzmedical.com/wound-measurement-accuracy-study/

Good Habits

Backing Up Information on SilhouetteConnect

If using SilhouetteConnect standalone (not synchronized to SilhouetteCentral), then regularly back up patient information. Instructions to perform backups are provided in the help documentation.

If using SilhouetteConnect synchronized to SilhouetteCentral then synchronize regularly.

Exiting SilhouetteConnect

Close SilhouetteConnect when not using the application. This helps make sure there is no unsaved data and allows other PC users to open the application when they login to the PC.

Housekeeping

After using SilhouetteStar, ensure the device is cleaned and stored safely. Ensure the USB cable is tidied away following use to avoid tripping over the cable.

Care of SilhouetteStar

SilhouetteStar is a precision optical instrument and must be handled with care at all times.

- Do not drop, knock, or shake SilhouetteStar.
- Ensure there is no dirt, moisture, or scratching over the device, laser, and LED apertures.
- Do not let SilhouetteStar come into contact with the patient.
- Keep SilhouetteStar and the USB cable clean at all times by wiping them regularly with an antiseptic cloth. Ensure SilhouetteStar and the USB cable are thoroughly dry before use.
- Do not immerse SilhouetteStar in liquid.
- SilhouetteStar should be placed face-down on a clean, dry, flat surface when not in use.
- Do not leave the SilhouetteStar in places where it will be exposed to temperature extremes for extended periods of time, e.g. in a vehicle in the hot sun or in freezing conditions.

Getting Support

ARANZ Medical website: www.aranzmedical.com Fax: +64-3-374-6130

Customer Support	Sales Enquiries
Please contact your system administrator for support information.	Phone (International): +64-3-374-6120
	Phone (US customers): +1 866-467-0934
	Email: sales@aranzmedical.com

To report a serious incident involving an ARANZ Medical Silhouette product, please contact your local representative using the information provided below. When reporting an incident please provide detailed information about the incident, including the device model, lot number or software version, and a description of the event. Reports must be filed in a timely manner in accordance with the reporting requirements specified by the competent authorities in your country.

Regulatory contact details:

US REP	FDA Authorized Representative	MDI Consultants 55 Northern Blvd Great Neck, NY 11021 Phone +1 (516) 482 9001 alan@mdiconsultants.com
EC REP	European (CE) Authorized Representative	mdi EUROPA Langenhagener Str. 71 30855 Langenhagen Germany Phone +49 (0)511 39089530 werner.sander@mdi-europa.com
GB REP	UK (UKCA) Authorised Person	Qserve Group UK, Ltd 282 Farnborough Road, Farnborough, GU14 7NA United Kingdom globalreg@qservegroup.com
AU REP	Australian Representative	AA MED Pty Ltd Cencora PharmaLex Limited Suite 4, Level 10, 1 Chandos Street St Leonards NSW 2065 Phone +61 (0) 2 9906 2984

Appendix A: Operating Conditions

Parameter	Min	Nominal	Max
Operating temperature	10°C (50°F)		30°C (86°F)
Storage temperature	-5°C (23°F)		50°C (122°F)
Operating humidity	0% RH		80% RH
Lighting	100 lux	400 lux	1000 lux

For lighting, 100 lux is considered 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