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Silhouette v4.7 Clinical User's Guide

Note: This device is developed for use only by qualified medical professionals trained and experienced in its use. Do not use the device before reading and understanding this user's guide.

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Introduction

This Clinical User's Guide describes how to use Silhouette™ for capturing images of wounds, making wound measurements, and documenting healing progress over time. It describes how to use the clinical features and functions of the Silhouette system.

The Silhouette Administration User's Guide and Silhouette Installation and Configuration Guide are available for non-clinical users.

This guide is applicable to following versions of Silhouette Components:

- SilhouetteCentral version 4.7.
- SilhouetteConnect version 4.7.
- SilhouetteStar 2 software version 1.8.
- SilhouetteLite version 1.6.
- SilhouetteLite+ version 1.6.

System Description

Silhouette is a computerized wound imaging, analysis, and documentation system.

SilhouetteCentral enables users to review, report, securely share and analyze the wound data collected by SilhouetteConnect, SilhouetteLite+ and SilhouetteLite applications. SilhouetteCentral is accessed via a web-based application and can collect wound data directly with a SilhouetteStar 2 device.

SilhouetteCentral is divided into three parts:

- Clinical Provides access to the patient medical data stored in the Silhouette database for reviewing, editing, and updating. Reports, images, and wound measurement data can also be exported for further processing and importing into other applications.
- Administration Provides facilities to manage units, groups, patients, and system users. SilhouetteCentral can also be used to configure and customize the Silhouette system.
- Integration Interfaces SilhouetteCentral allows integration of assessment data with other health IT systems using the Silhouette Integration Interface.

SilhouetteConnect is the software installed on a Microsoft Windows tablet, laptop or desktop computer. SilhouetteStar devices connect via USB to a computer running 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.

SilhouetteConnect can be used in two modes of operation:

- Standalone mode provides the power of Silhouette on a single PC. Data is collected and stored on the PC. PDF reports can be generated to share the results.
- Synchronized mode provides offline and wired SilhouetteStar device support for SilhouetteCentral systems. Data
 collected by SilhouetteConnect can be uploaded to SilhouetteCentral and data stored in SilhouetteCentral can be
 downloaded and used offline in SilhouetteConnect. In synchronized mode the system is mostly administered in
 SilhouetteCentral and the appropriate settings are downloaded during the synchronization process.

SilhouetteStar 2 is a device 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 over a secure Wi-Fi network or to SilhouetteConnect over a USB cable.

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SilhouetteStar 2 has software running on it. The software version for SilhouetteStar 2 is typically compatible with a limited range of SilhouetteCentral and SilhouetteConnect software versions. The software on a SilhouetteStar 2 upgrades or downgrades when it is connected to Silhouette to ensure it is compatible.

SilhouetteStar 2 is an IP network device. In wired mode, the device uses a IP network that is local to the computer running SilhouetteConnect. The USB device appears as a network interface in Microsoft Windows using the RNDIS protocol. In wireless mode, the device communicates over the Wi-Fi IP network directly to SilhouetteCentral.

SilhouetteStar 1 is a device that captures wound images and non-contact 3D measurements of wounds at the point of care. SilhouetteStar 1 operates over a USB cable connected to a computer running SilhouetteConnect software.

SilhouetteLite+ is comprised of an application and a range finding sensor for Apple® iPhone®, iPod® touch and iPad® devices. SilhouetteLite+ enables users to take wound images, obtain non-contact 2D measurements, and record patient notes on their mobile device. The data collected at the patient's bedside is synchronized with SilhouetteCentral over a secure connection when available.

SilhouetteLite is an application designed for Apple® iPhone®, iPod® touch and iPad® 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 network connection when available.

The Organization of Patient Data

In Silhouette, the region of interest for assessment is the wound. For each patient, each wound is designated with an identifying label, starting with the letter A or the number 1 (as defined in your organizations settings by your system administrator). Once assigned, the identifying label for a particular wound does not change.

Wounds created for a patient have a state. Typically a wound is created in the Open state (an active state) and then it is changed to an inactive state (e.g. Healed or Amputated) once it is no longer present or is no longer being actively cared for.

Information about the patient that is not likely to change from encounter to encounter is captured as patient notes. Patient notes are accessible through the left-hand sidebar when viewing any patient pages. Information that is captured about the current state of the patient or of a particular wound is organized into assessments, either patient assessments or wound assessments, and is accessible in the patient or wound timeline:

- A patient assessment contains information collected at a patient's appointment that doesn't relate to a specific wound, such as general patient health or patient risk assessments.
- A wound assessment is made for each wound and contains all the information collected about a particular
 wound, at that point of time. This information includes images, measurements, and notes specific to the single
 wound being assessed.

If a wound needs to have another measurement taken during an appointment, such as pre- and post-debridement, then the second measurement is contained in a second assessment or within a single assessment with two separate image capture fields.

The Patient Dashboard summarizes information about a single patient, such as:

- The **Patient Summary** shows all of the high level information for the patient.
- The **Wounds** shows all active wounds defined for the patient.
- The **Sidebar** on the left-hand side contains links to the patient **Details** and **Notes** as well as a list of both active and inactive **Wounds** defined for the patient.
- The **Patient Timeline** shows all the assessments that have been made on the patient, with the newest assessment at the top. Images and wound summary information are shown on the timeline where appropriate.

Selecting a wound from the left-hand sidebar shows the Wound Dashboard.

Guide Topics

This user's guide is divided into the following high level topics:



Using SilhouetteStar



Using SilhouetteLite+



Using SilhouetteLite



The Silhouette Clinical User Interface (UI)



The Silhouette Admin User Interface (UI)



Troubleshooting



CTEULA and Terms of Use

Using SilhouetteStar

SilhouetteStar 2 is a device 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 over a secure Wi-Fi network or to SilhouetteConnect over a USB cable.SilhouetteStar 2 has software running on it. The software version for SilhouetteStar 2 is typically compatible with a limited range of SilhouetteCentral and SilhouetteConnect software versions. The software on a SilhouetteStar 2 upgrades or downgrades when it is connected to Silhouette to ensure it is compatible.SilhouetteStar 2 is an IP network device. In wired mode, the device uses a IP network that is local to the computer running SilhouetteConnect. The USB device appears as a network interface in Microsoft Windows using the RNDIS protocol. In wireless mode, the device communicates over the Wi-Fi IP network directly to SilhouetteCentral.

SilhouetteStar 1 is a device that captures wound images and non-contact 3D measurements of wounds at the point of care. SilhouetteStar 1 operates over a USB cable connected to a computer running SilhouetteConnect software.

This section of the guide describes the components of a SilhouetteStar and how it is used to capture wound images and measurements in Silhouette. The information in this guide is relevant to all models of SilhouetteStar, unless otherwise stated.

Topics



SilhouetteStar Wound Imaging Workflow



Capturing Images with a SilhouetteStar



The SilhouetteStar Device

SilhouetteStar Wound Imaging Workflow

This section of the guide describes the primary workflow to capture a wound assessment with a SilhouetteStar device in wireless mode with SilhouetteCentral and in wired mode with SilhouetteConnect.

To use the SilhouetteStar you must first be logged in have a patient selected. Refer to the <u>The Silhouette Clinical User Interface (UI)</u> section for details on these operations.

Once you are logged in with a patient selected then the following is the basic workflow.

- 1. Connecting a SilhouetteStar 2 using Wi-Fi or Connecting a SilhouetteStar using USB
- 2. Take Wound Images
- 3. Create an Assessment

Connecting a SilhouetteStar 2 using Wi-Fi

Use the following process to connect a SilhouetteStar 2 to SilhouetteCentral with a Wi-Fi connection.

You must have already logged in to SilhouetteCentral and selected a patient. Once you have a patient selected in SilhouetteCentral, use the camera icon (in the left-hand sidebar to open the image portfolio and show the connection barcode.

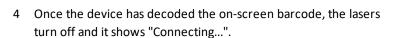
- The barcode contains encrypted connection information allowing a SilhouetteStar 2 to connect to the Wi-Fi and to select the correct patient. Use the Connect the SilhouetteStar link to show the barcode if it is not visible.
 - 1 Push the button on the SilhouetteStar 2 to turn the device on. The device displays a kiwi bird walking while it is starting up.



- 2 When the SilhouetteStar 2 is ready, the screen displays a prompt to make a connection.
 - If the device has been previously connected to the Wi-Fi network then it may show Wi-Fi signal strength rather than the airplane mode icon.



- 3 Press the button on the SilhouetteStar 2 to start scanning for the Silhouette connection barcode. The screen updates to read Scanning for Silhouette barcode and the guide lasers turn on.
- Point the lasers towards the on-screen barcode, with the device button facing up.



- If the device was previously in airplane mode then Wi-Fi is turned on and the Wi-Fi strength icon is shown.
- Once SilhouetteStar 2 is connected successfully, the selected patients name, ID and date of birth appear on the device screen for positive identification.







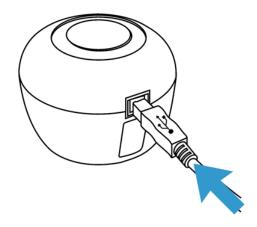
SilhouetteStar 2 is now ready to take wound images.



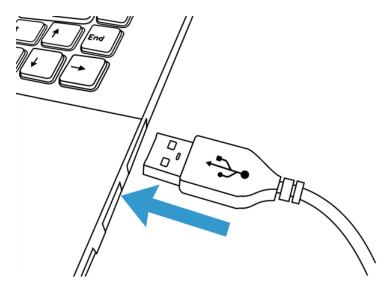
<u>See "SilhouetteStar 2 Display"</u> for more information regarding the different messages and icons shown on the SilhouetteStar 2.

Connecting a SilhouetteStar using USB

To connect a SilhouetteStar (SilhouetteStar 1 or SilhouetteStar 2) directly to a computer running SilhouetteConnect, insert the square end of a SilhouetteStar USB cable into the port on the device.



Insert the flat end of a SilhouetteStar USB cable into one of the USB 2.0 or 3.0 ports on your computer:



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

Your computer automatically detects the SilhouetteStar device and installs the required drivers. If the computer's sound is on, the computer chimes to indicate successful connection.

A SilhouetteStar connection to SilhouetteConnect takes place once the user is logged in to SilhouetteConnect.

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The SilhouetteConnect application may pause momentarily when a SilhouetteStar 1 device is connected.

The SilhouetteStar devices will disconnect and reconnect after SilhouetteConnect finishes a sync with SilhouetteCentral.

A SilhouetteStar can be used to capture images whenever a patient is selected. The lasers will not appear until you have selected a patient.

If the button is pressed on a SilhouetteStar 2 before it initiates a connection with SilhouetteConnect, then the lasers turn on to scan a barcode and the screen updates to show **Scanning for Silhouette barcode**. The device does not connect to SilhouetteConnect until the barcode scan times out and the lasers turn off.



USB connections are typically very reliable, however computers occasionally fail to recognize devices when they are initially plugged in or when the computer wakes up from sleep modes.

If the camera is not connecting to SilhouetteConnect, the first troubleshooting step is typically to unplug the USB cable and then plug it back in again.

SilhouetteStar USB Cable

Always use an approved SilhouetteStar USB Cable to connect a SilhouetteStar to the USB port on the computer. As there are three models of SilhouetteStar available there are also three cables. Use the table below to identify which cable is to be used with which device.

SilhouetteStar Version	Model Number	Label(s) present on the USB Cable	
SilhouetteStar 1	2000.xx	SilhouetteStar TM USB Cable Manufacturer ARANZ Medical Christchurch, New Zealand.	
SilhouetteStar 1 (5MP)	2005.xx	Manufacturer ARANZ Medical	This cable is designed only for use with SilhouetteStar model 2005.xx
SilhouetteStar 2	2010.xx	This cable is designed only for use with SilhouetteStar Model 2010.xx Manufacturer aranzmedical Christchurch New Zealand	WARNING! USB cable only for use with SilhouetteStar® models 2010.xx with display screen on top. See User Guide.

Take Wound Images

To take wound images:

- 1. Press and release the button on a SilhouetteStar device to turn the lasers on.
- 2. Point the device at the wound so that the lasers form a star in the wound and at least one laser crosses the deepest part of the wound.
- 3. Press and release the button on the device to take an image. Hold the device steady while the image is being captured.
- 4. Once an image is captured, a camera icon () is shown on the device screen (SilhouetteStar 2 only) to indicate images are captured and transferring to Silhouette. More images can be taken while previous images are uploading.

For more information see Capturing Images with a SilhouetteStar.

Create an Assessment

To use SilhouetteStar images to make wound measurements add them to an assessment.

- 1. Add the captured image(s) to create a wound assessment in SilhouetteCentral.
 - a. Close the image portfolio using the **close** button, if it is open.
 - b. Select the wound that has been imaged by selecting the **wound label** in the left-hand sidebar. If it is a new wound, then create a new wound in Silhouette using the **+ Wound** button in the left-hand sidebar.



c. Create an assessment using the **+ Wound Assessment** button at the top of the wound dashboard or wound timeline.



d. To open the image portfolio, select the + sign in the image field.



- $e. \ \ Select the images you wish to add to the assessment by clicking or touching them.$
- f. Close the image portfolio using the **close** button and the images will show in the assessment.

- 2. Measure the wound by tracing around the wound in the image.
 - a. Select the image you wish to trace.
 - b. Move the on-screen pencil to the edge of the wound. To move the pencil without drawing, use a dragging motion (rather than a select and hold motion).
 - c. Select the **pencil** and hold it in one spot to start tracing (a dot with a finish target appears on the screen to indicate the tracing has started).
 - d. Move the **pencil** around the wound in one direction until the finish target is reached. Once the outline tracing has begun, moving the **pencil** continues the tracing until the wound boundary is complete, i.e. the **pencil** is moved back to the start of the tracing.
 - e. Use the tools available to make edits as required, see <u>Tracing Wound Outlines</u>.
 - f. Once all tracing is complete apply the tracing using the **Apply** button.
 - g. Measurements from the wound tracing appear under the images in the assessment.
- 3. Add any notes you wish to capture in the notes fields and then select **Save** to save the assessment.
- 4. Once the assessment is saved you can:
 - Select the **Create Report** button to generate a PDF report of the assessment.
 - Select the Edit button to edit the assessment data or adjust tracings on images.
 - Select the **wound label** in the left-hand sidebar to see the wound dashboard and the measurements from this assessment in the wound graph.
 - Select the **Sync** option from the Application Menu (if using SilhouetteConnect) to synchronize the assessment and associated images to SilhouetteCentral.

SilhouetteStar Connection Behavior

A SilhouetteStar requires a connection to either SilhouetteCentral (Wi-Fi and SilhouetteStar 2 only) or SilhouetteConnect (USB) to operate and safely capture images for wound assessments.

This topic discusses some of the connection behaviors you may see and how to maintain the most reliable connection in your scenario.

USB Connection

The USB connection is generally uncomplicated and reliable. If something does go wrong with the USB interface on the computer or the SilhouetteStar then some simple troubleshooting is possible:

- Unplugging the USB cable and plugging it back in is typically enough to kick start it into action.
- The SilhouetteStar devices do not connect to SilhouetteConnect until there is a user plugged in and can only take images when there is a patient selected.
- If the computer being used goes to sleep then the camera will loose connection and prevent the user from taking images until the computer is started again.
- The SilhouetteStar 2 does use an local IPv4 Network and appears as if it is connected to an Ethernet connector on the computer. If initial connections fail when you first attempt to use the SilhouetteStar 2 then review firewall settings to ensure the computer has been correctly configured to allow connections to TCP port 9874 on all network types.

Wi-Fi Connection

The Wi-Fi connection is more convenient than the USB connection but the Wi-Fi network and additional mobility creates additional complex behaviors. There are generally a multitude of connections involved in a SilhouetteStar 2 wireless connection.

- 1. The connection from the SilhouetteStar 2 to the SilhouetteCentral server will contain at least one Wi-Fi connection and a combination of wired LAN and possibly WAN connections.
- 2. The connection from the end user computing device (laptop or tablet) used to browse to the SilhouetteCentral server can also contain Wi-Fi and a variety of wired LAN and WAN connections.

Any of the connections may go down or become unavailable in some locations where you wish to use the SilhouetteStar 2 device.

As well as that both user devices (the SilhouetteStar 2 and the laptop or tablet) can sleep at different times, becoming unresponsive to the other device.

To get reliable wireless device behavior:

- Have high quality Wi-Fi access points with good coverage in the areas you wish to use the connection.
- Set sleep times on the end user computing devices (laptop or tablet) to a time that is longer than the time it takes to perform a typical wound assessment.
- Set the application timeout in Silhouette to a time that is longer than the time it takes to perform a typical wound assessment.
- If using a tablet to access the Silhouette website and connect the SilhouetteStar 2, then don't put the web browser in the background while attempting to use the SilhouetteStar 2.

Understanding the behavior of wireless SilhouetteStar 2 connection can help to know what to expect and to get the best use from the device.

Scenario	SilhouetteStar 2 Device Behavior	Silhouette Web Site Behavior
SilhouetteStar 2 is out of range of the Wi-Fi network when attempting to connect.	The SilhouetteStar 2 will show "Failed to connect to network" and will not form a connection with Silhouette.	The SilhouetteStar 2 connection barcode will not disappear.
SilhouetteStar 2 is attempting to connect, is in Wi-Fi range but some other part of the wired network is not working.	The SilhouetteStar 2 will show "Failed to connect to SilhouetteCentral" and will not form a connection with Silhouette.	
SilhouetteStar 2 moves out of the Wi-Fi network range after being connected to Silhouette.	The SilhouetteStar 2 will maintain the last known patient selection and will allow images to be captured for that patient.	After approximately 30 seconds the Silhouette Web Site will lose
	Once the SilhouetteStar 2 moves back in to range of the Wi-Fi network then it will reconnect and upload the images taken. Reconnecting to the Wi-Fi network may take some time (minutes) once the Wi-Fi network is within range again.	connection and will allow a SilhouetteStar 2 connection barcode to be displayed again.
SilhouetteStar 2 has been 'sleeping' and wakes up out of range of the Wi-Fi network.	The SilhouetteStar 2 will not be able to reconnect to Silhouette. It will need to be manually reconnected by scanning a Silhouette connection barcode.	-
SilhouetteStar 2 has been 'sleeping' and wakes up when the corresponding web browsing session is unavailable (computing device sleeping, web browser has been closed or put in the background when using a tablet).	The SilhouetteStar 2 will show "Failed to connect to SilhouetteCentral" and will not form a connection with Silhouette. It will need to be manually reconnected by scanning a Silhouette connection barcode.	-
Silhouette web browser device moves out of Wi-Fi range after a SilhouetteStar 2 connection has been made.	After a short time (approximately 30 seconds) the SilhouetteStar 2 will realize that the Silhouette web browsing session isn't available and will become	The web browser will not be able to be used while the device is out of Wi-Fi range.
Silhouette web browser gets closed or the web browser get pushed into the background (tablet operation).	disconnected. It will need to be manually reconnected by scanning a Silhouette connection barcode.	-
Silhouette web browsing device goes to sleep while the SilhouetteStar 2 is connected.		
Silhouette application timeout expires.	The SilhouetteStar 2 will become disconnected and will need to be manually reconnected by scanning a Silhouette connection barcode.	The user is returned to the login page.

Capturing Images with a SilhouetteStar

This section describes:

- The Mathematics of SilhouetteStar's Measurements
- Lighting Requirements for Image Capture
- Holding a SilhouetteStar and Positioning the Lasers
- Taking a Multiple Image Measurement

The Mathematics of SilhouetteStar's Measurements

SilhouetteStar projects laser lighting onto the body surface in order to gain 3D information about the wound and surrounding tissue. SilhouetteStar consists of:

- Three lasers
- White LEDs for illuminating the body surface
- A digital camera for capturing the image

SilhouetteStar connects to your computer using one of its USB ports or through a wireless Wi-Fi connection. Images captured using SilhouetteStar are displayed in the Silhouette software (SilhouetteCentral or SilhouetteConnect), where you can outline the wound boundary and make surface area, depth, perimeter, and volume measurements.

- For concave wounds that have depth, the wound area is the area of an elastic sheet that could be pinned along and stretched across the boundary of the wound. Depth is the distance between the virtual elastic sheet and the wound bed, and volume is the volume enclosed by the sheet.
- For convex wounds and other pathologies (e.g. cellulitis) that rise above the wound outline as drawn in Silhouette, depth and volume have no meaning. In such cases, area is the actual (physical) surface of the wound. One example of a convex surface is the heel.

For further details on the measurement process used by Silhouette, refer to the "How Silhouette Works" document available from ARANZ Medical support.

Lighting Requirements for Image Capture

When capturing images with SilhouetteStar, it is important that lighting is at normal office or household lighting levels. SilhouetteStar should not be used in direct sunlight.

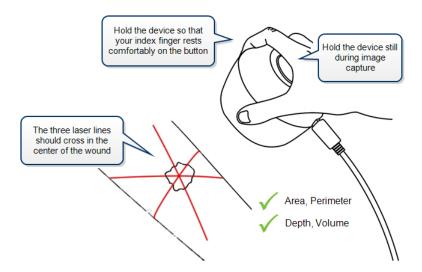
Once an image has been captured, you have the option of accepting or discarding the image.

Refer to the Silhouette Administration Manual for further details regarding operating conditions for SilhouetteStar.

Holding a SilhouetteStar and Positioning the Lasers

To capture images with a SilhouetteStar, ensure that the device is connected to SilhouetteConnect or SilhouetteCentral and a patient is selected. Press the capture button so that the lasers are activated.

Hold the device so that your hand sits comfortably, with your index finger in reach of the button:



Position the SilhouetteStar device facing the wound so that the laser lines cross inside the wound to form a star shape. The laser lines do not need to cross in a perfect star shape.

For wounds with an uneven wound bed, position the star so that at least one laser line lies across the deepest part of the wound.

The length of the laser line indicates the approximate maximum wound size that can be captured in one image. It is acceptable to move the SilhouetteStar device away from the wound, forming a small triangle with the laser lines, in order to capture a large wound in one image. If it is not possible to capture the entire wound in a single image, follow the instructions in Taking a Multiple Image Measurement.

Gently press and release the button to capture the image, keeping the device still until you hear the shutter sound or, if the sound is off, until the lasers come back on. Continue capturing as many images as required.

If the image capture fails (due to overexposure, or similar issue), the device plays a buzzer sound instead of the shutter sound. In this case, re-attempt the image capture. No sound will be heard if the device has been muted.

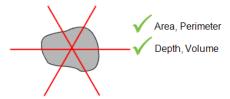
The set of measurements able to be made on a captured image depends on the positioning of the laser lines and the wound outline. Area and perimeter measures can be made under all circumstances. To determine depth and volume, the following conditions must be met:

- The star-point must be positioned within the wound outline. The star-point is the point where the three laser lines cross, or if there is a triangle, the point at the center of the triangle.
- There must be some laser line within the wound outline.
- There must be only a single outline.
- The outline must contain no islands.

This is illustrated in the following examples.

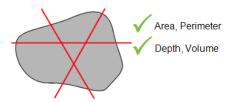
Preferred Laser Positioning

For a typical wound, it should be possible to place the star-point inside the wound with a laser line through the deepest part of the wound.



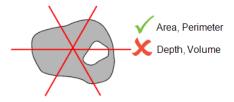
Acceptable Laser Positioning for Large Wounds

It has been necessary to pull SilhouetteStar away from the wound in order to capture the entire wound.



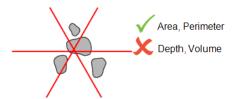
Preferred Laser Positioning for Wounds Containing Islands

Depth and volume are not calculated when there is an island inside the wound outline.



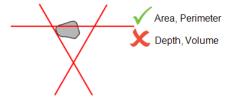
Preferred Laser Positioning for Wounds With Multiple Outlines

Depth and volume are not calculated when there is more than one wound outline in the same image. An alternative strategy that allows depth and volume to be calculated, is to image each wound fragment and outline each wound separately.



Poor Laser Positioning

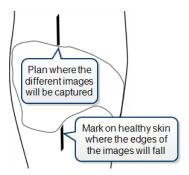
Depth and volume are not calculated if the star-point is not inside the wound outline. This is typically because the laser lines have been positioned poorly, and the user should move SilhouetteStar to form a star, and center it on a wound.



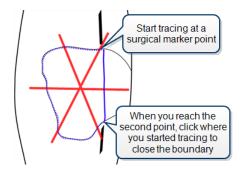
Taking a Multiple Image Measurement

If it proves difficult to capture a wound in one image, you can capture a series of images and individually outline the separate segments. Silhouette then automatically calculates wound area for the different segments of the wound. This is useful for large wounds, or a wound that occurs on a part of the body that is curved, or a circumferential wound, which can all be difficult to capture in a single image.

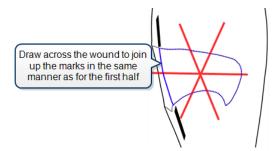
- 1. Plan where the different images of the wound are to be captured.
- 2. Use a surgical marker to mark on healthy skin where the edges of the different images are.



- **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.** For 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 where you started tracing 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 are combined to give overall measurements for the wound. Maximum depth and volume are not calculated.

The SilhouetteStar Device

There are two variants of SilhouetteStar, known as:

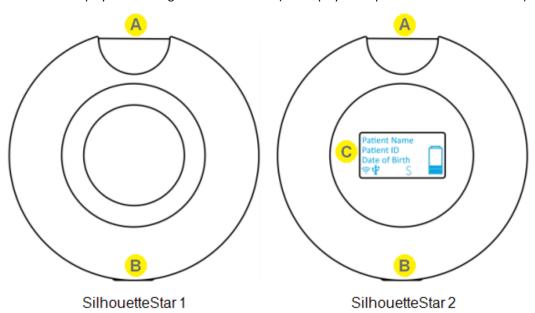
SilhouetteStar 1 has a 3 megapixel camera module and connects to SilhouetteConnect using a USB cable.

SilhouetteStar 2 has a 5 megapixel camera module, a display, a speaker and connects to SilhouetteCentral using Wi-Fi or to SilhouetteConnect using a USB cable.

SilhouetteStar Components

Top View

SilhouetteStar 2 has a display for showing status information (the display is not present on SilhouetteStar 1):





Trigger Button

The trigger button is on the side of the device. The trigger button is used for all the functions of the device, see <u>SilhouetteStar Trigger Button Operation</u>. The trigger can also be used to help orientate the device the same way to take consistent images.



USB Port

The USB port is on the side of the unit is used for data connection to SilhouetteConnect. It is also used for battery charging on the SilhouetteStar 2.



Display

The SilhouetteStar 2 has a display to show the current status of the device and to show the patient images are being captured for. See "SilhouetteStar 2 Display" for details.

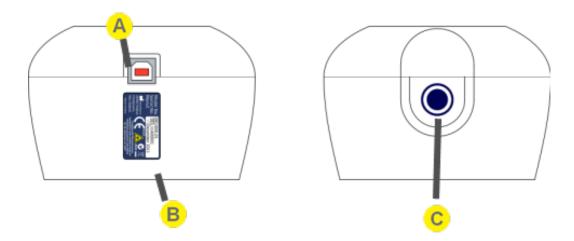
Bottom View

The location of SilhouetteStar's laser lights, LEDs, and camera lens are shown below:



- A Laser Aperture
 SilhouetteStar devices contain three lasers.
- B Illuminating LED
 SilhouetteStar devices use illuminating LEDs to provide light for consistent wound imaging.
- Camera Lens

Side Views



USB Port

The USB port is on the side of the unit is used for data connection to SilhouetteConnect. It is also used for battery charging on the SilhouetteStar 2.

- Product Label

 See "SilhouetteStar Label Information" for more information.
- Trigger Button

 The trigger button is on the side of the device. The trigger button is used for all the functions of the device, see SilhouetteStar Trigger Button Operation. The trigger can also be used to help orientate the device the same way to take consistent images.

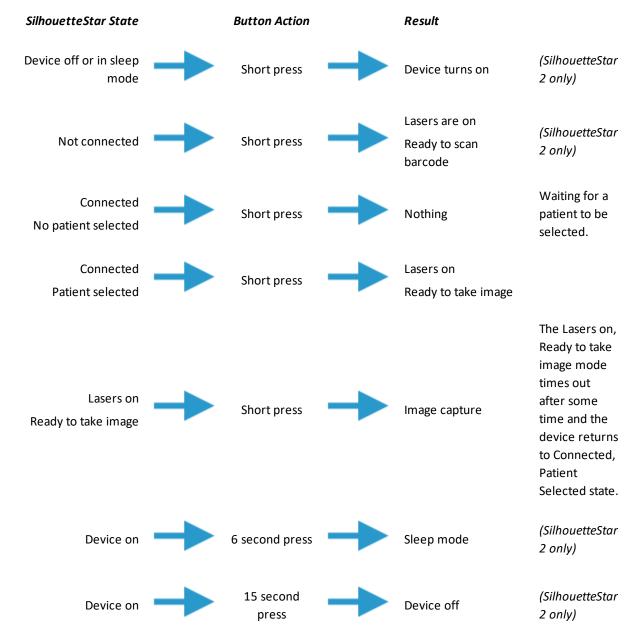
SilhouetteStar Trigger Button Operation

The trigger button on the side of SilhouetteStar is used for capturing images (single press); and in the case of SilhouetteStar 2, it is also used for powering on and off the device.

In general, the usage of the trigger button is a short press to turn the lasers on and then another short press to capture an image. The exact action of the trigger button is dependent on the current device state and what the next action needs to be.

On the SilhouetteStar 1 the trigger is activated when the trigger button is pressed.

On the SilhouetteStar 2 the trigger is activated when the trigger button is released.



SilhouetteStar 2 Inactivity Timeouts

The SilhouetteStar 2 uses a battery to provide wireless operation and has a sleep or standby mode to allow the conservation of battery.

The SilhouetteStar 2 does not have a specific off button so also uses an inactivity timeout to turn off.

Sleep Mode

If the device is left idle for 2 minutes (default) then it will enter sleep mode. In sleep mode the device display shows a snoring Kiwi bird.

- The device waits for longer (10 minutes as a default) if there are images captured, waiting to be uploaded.
- The device inactivity timeouts can be changed by the Silhouette system administrator.
- The device does not sleep at all when it is connected over the USB to SilhouetteConnect and when there is a user logged in.

Press the trigger button to wake the device out of sleep mode. The device waking up from sleep mode is faster than starting the device from off.

The device remembers the SilhouetteCentral connection that was active before it entered sleep mode and will attempt to automatically reconnect when it wakes up.

The automatic reconnection to SilhouetteCentral when coming out of sleep mode can fail for a number of reasons:

- The iPad or laptop used to connect SilhouetteStar 2 has gone to sleep.
- The web browser used to connect the SilhouetteStar 2 has been closed or pushed to the background (e.g. home key pressed on iPad).
- The application lock timeout has occurred for the user in SilhouetteCentral.
- The user has logged out of SilhouetteCentral.
- The Wi-Fi network conditions do not allow connection.

If the automatic reconnection fails then the device can be manually connected to a session by scanning a connection barcode again.

The device also retains any images that did not get uploaded to SilhouetteCentral before it entered sleep mode and will attempt to upload them once it has been woken up and has a Wi-Fi connection again. The device only needs a Wi-Fi connection to be established to allow for image upload, i.e. a failure to reconnect to a SilhouetteCentral session for other reasons does not necessarily prevent image upload.

Off Mode

After 15 minutes (default) of sleep time the device turns off.

Any images and patient details are removed from the device when it turns off.

The amount of sleep time before the device turns off can be changed by your system administrator.

SilhouetteStar 2 Display

There are several parts to the display:



Main message area of the display.

Displays device instructions and patient information depending on the status of the device, see SilhouetteStar 2 Screen Messages.

Battery gauge.

Shows the current charge level of the device battery, see SilhouetteStar 2 Battery Gauge.

C Icon bar.

Shows icons to display the current status of the device, see SilhouetteStar 2 Icons.

The display above shows the status when the device is ready to take an image for the patient shown on the screen. Other messages shown on the display are listed below.

SilhouetteStar 2 Icons

A number of icons can be shown on the SilhouetteStar 2 display.

Icon

Icon Meaning

Wi-Fi Status



Indicates that the device is in airplane mode, the Wi-Fi is off.

The Wi-Fi gets enabled again by attempting a wireless connection to SilhouetteCentral.



Indicates that the Wi-Fi is on but that it is not connected to a Wi-Fi network.



Shows the strength of the Wi-Fi signal.

Can show a minimum of 0 bars and up to a maximum of 4 bars. A consistently scrolling 1, 2, 3, 4 bars indicates that the Wi-Fi is searching for a connection.

USB Status



Indicates that the USB cable is plugged in and that there is a data connection to a computer.

Mute Status



Indicates that the device sound has been muted. When this icon isn't shown the user will hear audible feedback when the device captures images and when image upload is completed.

Image Capture Status



Indicates that an image is being captured or that there are captured images that are not yet uploaded to either SilhouetteCentral or SilhouetteConnect.

Silhouette Connectivity Status



Indicates that the device has an active connection and is synchronized to a users session within SilhouetteCentral or SilhouetteConnect.



Indicates that the device has lost the connection to SilhouetteCentral (typically due to poor Wi-Fi). The device maintains the current selected patient so that images can be taken and uploaded once the connection is re-established.

SilhouetteStar 2 Battery Gauge

The battery gauge gives an approximation of the remaining charge in the devices battery.



The battery gauge indicator shows the battery level in the Star 2 as up to 5 bars in 1/2 bar steps.

The battery gauge animates the top bars when it is charging and the rate of animation shows the rate of charge.



The battery gauge shows an exclamation mark when the device needs to be charged.

SilhouetteStar 2 Screen Messages

Display Shows



SilhouetteStar 2 State

The Kiwi birds feet walk as the device is in powering up.

If the walking kiwi bird has a broken heart symbol it indicates that the device has rebooted to recover from a problem with the device operation. If this happens frequently then contact you system administrator to determine if some troubleshooting is necessary.



The Kiwi bird is snoring as the device has gone into sleep mode after being left inactive.



The device is fully powered up and is waiting for a connection.

The user can initiate a Silhouette barcode scan, which enables it to connect to the wireless network, or the user can log in to SilhouetteConnect on a computer can connect the device to it via a USB cable.



The device is scanning for a barcode to allow either:

- a Wi-Fi connection to SilhouetteCentral.
- an update of the DHCP configuration.
- enabling of SSID display.
- enabling of Wi-Fi MAC address display.
- enabling of airplane mode (turning off Wi-Fi).



The device is attempting to connect to a Silhouette user session (either in SilhouetteConnect over USB or in SilhouetteCentral over Wi-Fi).



The device was unable to connect to the Wi-Fi network. Either the network is out of range, or the wrong password has been entered when the network was configured.



The device was unable to connect to SilhouetteCentral or SilhouetteConnect. One possible cause is the browser session it is attempting to connect to has expired or is in-active.



The device is connected and waiting for a patient to be selected in the Silhouette. This includes any time that the admin (non-patient) sections of the application are being used.

When this screen is showing then pressing the trigger button doesn't activate the lasers and images cannot be taken.

When connected on Wi-Fi, the patient selection on the device is synchronized to the patient selected in the SilhouetteCentral web browser tab that it was initially connected to.

When connected on USB, the patient selection on the device is synchronized to the patient selected in SilhouetteConnect.



The device is connected to the network and a patient is selected. The device is ready to take images.



An update to the internal operating system is required for the device to continue to function correctly with Silhouette.

The upgrade will proceed automatically, showing various progress indications while downloading and installing the upgrade.

Once the upgrade is complete the device will reboot and it will need to be connected to Silhouette again.

If the download gets interrupted the device can be reset manually by pressing and hold the trigger button for 15 seconds.



The device has detected there is not sufficient battery level to boot. A battery charge is required before it can start.

Disconnecting SilhouetteStar

Logging out of SilhouetteCentral or SilhouetteConnect will immediately disconnect SilhouetteStar.

When operating on Wi-Fi, you may leave a SilhouetteStar 2 device connected to SilhouetteCentral and it will automatically disconnect after a period of inactivity.

In some scenarios (e.g. poor Wi-Fi connectivity) you wish to force disconnect a SilhouetteStar 2 by sending it to sleep and waking it again or by turning it off and on again. See "SilhouetteStar Trigger Button Operation" for details.

Resetting SilhouetteStar 2

A SilhouetteStar 2 can be put to sleep by holding the trigger button down.

6 seconds	Sleep mode (sleeping kiwi)
15 seconds	Deep sleep mode (screen off)
45 seconds	Hard power reset (must have power supplied through USB cable to hard power reset the device)

SilhouetteStar 2 Airplane Mode

You are able to turn off the Wi-Fi function of the SilhouetteStar 2 (airplane mode) if you need to use the device in an RF sensitive area or if you only ever intend to use the device in wired (USB) mode.

To enable Airplane mode:

- 1. With the SilhouetteStar 2 showing "Please Connect (USB or WiFi)"
- 2. Press the trigger to activate "Scanning for Silhouette barcode"
- 3. Scan the barcode below.
- 4. The Wi-Fi signal strength icon will be replaced by the airplane icon when the device is in airplane mode.



Once the device is in airplane mode it will remain in airplane mode until a connection barcode is scanned to attempt a Wi-Fi connection to SilhouetteCentral.

If the device is used primarily in USB mode then it is recommended that you do enable airplane mode.



The **Enable Airplane Mode** barcode is available by logging in to SilhouetteCentral and navigating to **Admin -> SilhouetteStar 2 -> Enable Airplane Mode**.

The barcode can be printed and posted at the entrance to any RF sensitive areas to allow easy access to turn Wi-Fi off.

SilhouetteStar 2 Battery Management

SilhouetteStar 2 contains a Li-lon battery to enable wireless use. If the device fails to turn on or if there is an exclamation mark flashing in the battery indicator on the screen then the battery requires a charge.

To charge the battery, use the supplied battery charger and leave the device off. The device does not charge while it is being used. The battery indicator bars flash when the device is changing.

Ensure that the battery is fully charged before first use - this should take approximately 2 hours. Ensure there is some charge in the battery before attempting an image capture. Images waiting to transfer to Silhouette are lost if the battery goes flat.

A SilhouetteStar 2 battery is designed to last a full shift in a busy clinic. However, poor or busy Wi-Fi environments can cause the battery to drain much faster than expected.

In poor Wi-Fi conditions, while attempting to capture a second image while attempting to upload a first image the device may reset due to lack of power. If this happens, the device will show the battery as suddenly depleted. Charge the device, reconnect it to Silhouette and recapture the images one at a time, allowing each to upload before capturing the next image.

SilhouetteStar Label Information

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



Manufacturers reference / Model number

Model Number	SilhouetteStar Model
2001	Original SilhouetteStar models (refer to the applicable Quick Reference Guide for more details)
2005	
2010	SilhouetteStar 2 (5MP)



Manufacturer assigned device serial number



Date of Manufacture



Manufacturer ARANZ Medical Limited Tel +64-3-374-6120, 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-mark. EU Declaration of Conformity and Notified Body Identifier

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C-Tick. New Zealand and Australia Declaration of Conformity and Identifier



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



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



Federal Communications Commission logo. SilhouetteStar 2 contains transmitter module FCC ID: 2ACMW-MX6

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

SilhouetteStar Warnings

References to SilhouetteStar apply to all SilhouetteStar models, except where a specific model is specified.

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 the Silhouette Administration User Guide.
- 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 (if used) to come into contact with the patient or with contaminated materials.
- When using SilhouetteStar in wired configuration, 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.

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- 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.
- Ensure the computer power supply, and any USB hubs used are approved for medical use according to IEC60601-1.
- Ensure the computer power supply is 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.

Warnings specific to Model 2010.xx SilhouetteStar (SilhouetteStar 2):

- Use only the charger supplied with the SilhouetteStar 2 for charging its internal battery. Use of any other charger voids the product warranty and could damage the unit.
- The internal Lithium-ion battery pack is rated at 3.8v, 1.7Ah and is charged at 5.00v dc through the USB port on the SilhouetteStar 2 either via the supplied charger or an approved USB port.
- SilhouetteStar 2 contains an internal Lithium-ion battery pack, which is compliant with IEC62133 and UN38.3 standards.

Care of a SilhouetteStar

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

- Do not drop, knock, or shake a SilhouetteStar.
- Ensure there is no dirt, moisture, or scratching over the camera, laser and LED apertures.
- Do not let a SilhouetteStar come into contact with the patient.
- Keep SilhouetteStar and the USB cable (if used) clean at all times by regularly wiping them with an antiseptic cloth. Ensure SilhouetteStar and the USB cable are thoroughly dry before use.
- Do not submerge a SilhouetteStar in liquid.
- A SilhouetteStar should be placed face-down on a clean, dry, flat surface when not in use.

Cleaning a SilhouetteStar

The exterior of a SilhouetteStar can be cleaned with a range of common cleaning agents. All cleaning should be performed with the camera disconnected from the host computer. The use of pre-impregnated cleaning wipes is recommended since they do not physically scratch the camera's optical surfaces.

Please note the following:

- Cleaning products should always be used according to the manufacturers' specifications.
- Cleaning agents or techniques not listed in this document should not be used.
- It is your responsibility to ensure product cleaning achieves the desired result.
- Certain cleaning agents may cause discoloration of the housing. Any such discoloration is cosmetic only and does not affect the SilhouetteStar operation and is not covered by warranty.



When cleaning a SilhouetteStar, ensure excess fluid from wipes does not enter any openings on the device.

Compatible cleaning agents are:

- Mild detergent. Do not submerge.
- Water-based wipes.
- · Alcohol (isopropyl) based wipes.
- · Hydrogen peroxide-based wipes.



Use caution if cleaning with:

- Manual physical cleaning. Avoid abrasive materials. Scratching of the optical covers may negatively impact measurement accuracy.
- Bleach based wipes, low effective concentration (1:50, 1:100).*
- Bleach based wipes, high effective concentration (1:10).*

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*Use bleach based wipes only where required for decontamination or infection control purposes, not for day to day cleaning. We suggest that a SilhouetteStar be wiped down with these wipes and allowed to thoroughly dry. Do not allow the unit to sit on the wipes, or on a wet bleached surface.



Do not use:

- Ultrasonic cleaning SilhouetteStar is not designed for liquid submersion.
- Ultraviolet cleaning SilhouetteStar is not designed for exposure to high levels of ultraviolet light. Damage to the optical components could occur.
- Steam SilhouetteStar is not designed for contact with steam.
- Thermal disinfection SilhouetteStar is not designed for thermal disinfection.

Using SilhouetteLite+

SilhouetteLite+ is comprised of an application and a range finding sensor for Apple® iPhone®, iPod® touch and iPad® devices. SilhouetteLite+ enables users to take wound images, obtain non-contact 2D measurements, and record patient notes on their mobile device. The data collected at the patient's bedside is synchronized with SilhouetteCentral over a secure connection when available.

Topics



SilhouetteLite+ Wound Imaging Workflow



The SilhouetteLite+ Sensor



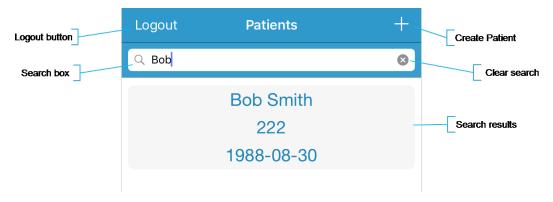
Setting Up SilhouetteLite+

SilhouetteLite+ Wound Imaging Workflow

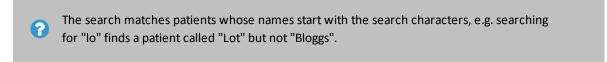
This section provides guidance on how to capture a wound assessment with the SilhouetteLite+ App and Sensor.

- 1. Select or Create a Patient in SilhouetteLite+
- 2. Select the Assessment Type
- 3. Select or Create the Wound to Assess
- 4. Performing an Assessment in SilhouetteLite+
- 5. SilhouetteLite+ Guidelines for Use

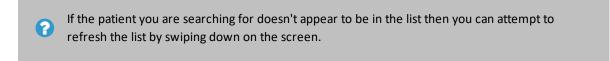
Select or Create a Patient in SilhouetteLite+



1. Search for the patient by entering part of the patient's name or patient identifier in the **search** box.



2. Select the patient you want to create an assessment for by touching the patient's name on the screen.



3. Use the + in the top right of the Navigation bar (top of screen) to create a new patient record.

Select the Assessment Type

Before performing an assessment you may be asked to select which assessment you wish to perform. The assessments available depend on the system configuration. This step is skipped if your system is configured with only one assessment type available.

The assessments are split into Patient Assessments and Wound Assessments.

- Patient Assessments are assessments which relate to the patient as a whole, not a particular wound.
- Wound Assessments are assessments which relate to a given wound on a patient. These are typically the assessments where you image and measure individual wounds to track healing.

Select the assessment that you are performing with the patient.

Select or Create the Wound to Assess

The Select Wound screen presents a list of wounds that are already created for the patient. These are listed in two groups, with active wounds at the top and inactive wounds at the bottom.

- Select a wound from the list or select the + button in the top right of the screen to create a new wound for the patient.
- The Select Wound screen is skipped if you are performing a patient assessment.
- Wounds are given a letter or number designator that appears at the beginning of the wound label. Wounds with a '-' designator have been created on the device and have not been uploaded to SilhouetteCentral yet.
- When creating a wound you will be asked to set the initial state of the wound. In most systems this will default to open with the current date and time and you do not need to change it before selecting **Save**.

The create wound option is only available if you have permission to create wounds.

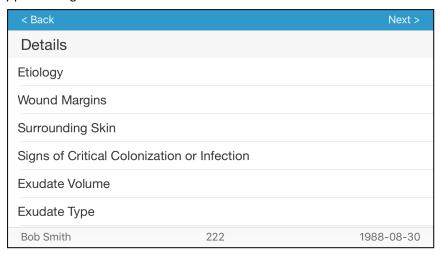


The create wound button guides you through a set of screens to specify the anatomical site of the wound. There is a chance to enter some auxiliary text at the end of the structured anatomical site selection. The auxiliary text appears on the wound label.

Performing an Assessment in SilhouetteLite+

The assessment is split into groups of notes. SilhouetteLite+ presents each group of notes on a separate screen. The bottom of the screen shows the currently selected patient information to allow for positive identification.

If performing a wound assessment then the first set of notes always asks to confirm the current wound state. You can either accept the current state without changes or change the state. In SilhouetteLite+ you can only update the state of a wound by performing a wound assessment.



- A field with a * next to name is a required field.
- The Next and Back buttons on the top of the screen can be used to move between the note groups within the assessment.
- The first note group has a Cancel button at the top left of the screen. Select the Cancel button to cancel the current assessment, all captured notes and images will be removed. There is a warning message that must be accepted to confirm the cancel action.
- The last note group has a Save button at the top right of the screen. Once the Save button is pressed the assessment is queued for upload to SilhouetteCentral and is no longer visible within the App.

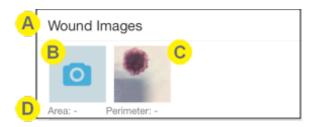


Assessments are sent to SilhouetteCentral once they are saved and when the device is online. Data is only uploaded while the App is open. Leave the App open until the offline data icon disappears from the bottom left of the patient selection screen.

The offline data icon: \Box^1

Using Image Capture Fields

Image capture fields show thumbnails of the images captured and show a camera icon allowing you to launch the device camera to capture an image.



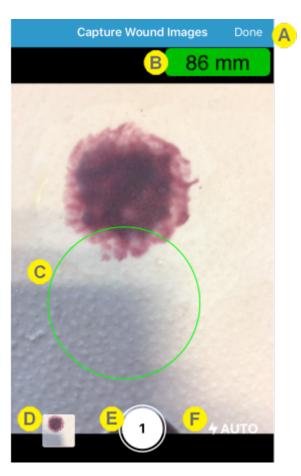
- The image capture field name is shown. The system can be configured to have different image capture fields to capture different measurements.
- Select the **camera icon** to launch the camera.
- Thumbnails for already captured images appear in the image capture field. Select a thumbnail to edit tracings or to remove the image.
- Summary measurements for all the images captured appear below the images. Select an image thumbnail to see measurements specific to that image.

If more than one image is traced, then the area and perimeter measurements are the sum of tracings on all images, see <u>Taking a Multiple Image Measurement</u>.

The Camera Screen

The Capture screen shows the live stream from the devices camera and allows images to be captured for Silhouette.

The first time the SilhouetteLite+ app is used to take images it asks for permission to access the device camera. Select **Allow**. If you selected to not allow the app permission to the device camera then a black screen will display, instead of the live stream from the camera. The permissions you have given an app can be reviewed in the iOS Settings app.





Select **Done** to finish capturing images.

The title of the screen shows the name of the images capture field used to launch the camera.



The range to scene measurement reported by the SilhouetteLite+ sensor is in the top right of the screen. If the range measurement is valid the range measurement is shown with a green background.

A valid range measurement must be shown when capturing an image to allow measurements to be made from the image later.

A sensor error or connection progress may be reported in place of the range.

- "Connecting..." is shown when attempting a connection to the paired sensor.
- "Out of Range" is shown if the sensor is not working or if the scene is too close or too far.
- "Sensor not Found" is shown if the sensor is not configured or if the sensor battery is flat.



Focus the camera by touching the screen where you would like it to focus.

If the range to scene is being reported by the SilhouetteLite+ sensor, then an estimate of where the sensor is reading the range is displayed as a green circle on the screen.

The range to scene is taken as an average of ranges from within this circle. Make sure the surface you are measuring overflows this circle (i.e. if some of this circle is resting on the bed or chair behind the patient's wound then the range and measurements will have additional error).



Select the image stack to review the images and touch any to put a red cross on any that should not be kept.

Images can also be removed later from the image tracing screen.



Use the on-screen capture button to take an image.

You can capture up to 10 images for a single image capture field. The number of captured images is shown on the capture button.



If you device has a flash then the flash state and control is shown at the bottom left of the screen. Touch it to change the mode of the flash.



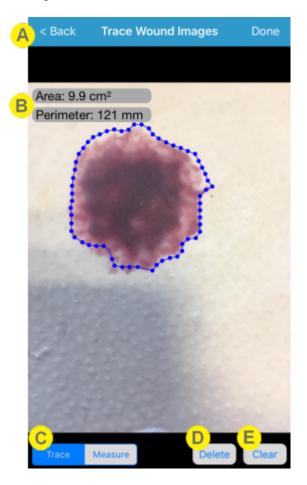
Measurements can only be made on an image taken when a valid range is reported while capturing the image.



See "SilhouetteLite+ Guidelines for Use" for more details on getting reliable measurements.

Image Tracing Screen

Selecting a thumbnail from the image capture field opens the Image Tracing Screen. The image tracing screen allows you to review, trace, or delete the image.





The navigation is provided at the top of the screen along with the name of the image capture field currently being used.

- Select **Done** to accept changes to the tracings.
- Select **Back** to close the tracing screen without saving any changes.



Area and Perimeter measurements are shown at the top right of the screen. Ruler measurements are shown along side the ruler on the image.

The length and width of the traced wound is only calculated on SilhouetteCentral once the assessment is uploaded.

The measurement capabilities are only available if there is a valid range measurement from the SilhouetteLite+ sensor along with the image.



Use the tools available at the bottom right of the screen to trace a wound or make a measurement (add a ruler).

- The **Trace** tool is used to trace wound outlines.
- The **Measure** tool is used to measure between two points (a ruler).

Trace by dropping points around the wound (or by tracing around the wound in one direction) until the starting point is reached.

Only one wound outline is allowed per image. Additional tracings can be added in SilhouetteCentral once the assessment is uploaded.



The **Delete** button is used to delete the image from the assessment. A confirmation dialog is shown before the delete is performed.



The **Clear** button is used to clear all measurements on the image.

Using Non-Image Capture Notes Fields

The notes fields are displayed in a single line on the screen until they are selected for data entry.



The following points describe the operation of the text entry fields, the selection list fields, boolean (yes/no) fields, date fields, integer fields and the decimal fields:

- Touch the field name to open the data entry for the field.
- Enter data into the field using the device keyboard or by selecting the option(s) required.
 - On some fields it may be necessary to scroll the screen to allow all options to be seen.
 - On date fields it may be necessary to select the year, then the month, then the day.
- Touch the field name again to close the data entry. A summary of the data entered is displayed next to the name of the field.

SilhouetteLite+ Guidelines for Use

Follow these guidelines to get the best and most consistent measurements from SilhouetteLite+:

- Use indoors, out of direct sunlight.
- Use on clean, bare skin.
- Hold device parallel to the wound being imaged.
- Ensure the surface being measured overflows the target circle, i.e. don't let the target circle fall off the side of the anatomy being imaged.
- Frame the wound in the camera view in a consistent fashion for every capture (i.e. put the patient in a consistent position and take the image so the top of the image is toward the patient's head).
- Ensure that the optical window on the sensor is clean and unobstructed.
- Use with an unmodified device with no additional camera lens elements (e.g. don't use with clip-on lenses or transparent sleeves).

The SilhouetteLite+ Sensor

This section provides information about your SilhouetteLite+ sensor, including the safety information. It is important that this information is read and understood before using the sensor.

- 1. SilhouetteLite+ Label Information
- 2. SilhouetteLite+ Warnings
- 3. Care of the SilhouetteLite+ Sensor

SilhouetteLite+ Label Information

The marking on the SilhouetteLite+ sensor provides information about your SilhouetteLite+ sensor. The symbols on the label have the following meanings:

Model	Model Number	SilhouetteStar Model
	2100.01	The original SilhouetteLite+ sensor

Serial Number 9-digit code printed on to the bottom bezel of the sensor.

The year and month of manufacture is encoded in the first 3 characters of the serial

number.

Made in New Zealand Manufacturer: ARANZ Medical Limited

Tel +64-3-374-6120, Fax +64-3-374-6130

Delivery Address: Postal Address:

ARANZ Medical Limited **ARANZ Medical Limited**

PO Box 3894 47 Hereford Street Christchurch 8140 Christchurch 8013

New Zealand **New Zealand**



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



C-Tick. New Zealand and Australia Declaration of Conformity and Identifier



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



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



Federal Communications Commission logo. The SilhouetteLite+ sensor contains FCC ID: 2AA9B04

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

SilhouetteLite+ Warnings

Laser Warnings



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

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

SilhouetteLite+ sensor 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. The SilhouetteLite+ sensor laser uses IR light (not visible light). However, the following precautions are recommended:

• Never stare into the laser beam (i.e. the black window on the SilhouetteLite+ sensor) or use SilhouetteLite+ in a manner that causes the laser to shine into people's eye.

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

Other Warnings

- The SilhouetteLite+ sensor includes a Bluetooth LE transmitter, which is activated when first placed on the charger. It should be treated as always on. Do not use in an RF Sensitive area.
- Ensure that the mobile device being used with the sensor is approved for use in your medical environment. Clean the SilhouetteLite+ sensor with the same cleaning protocol used to clean the device to which the sensor is attached, i.e. use a slightly damp lint free cloth for cleaning.
- Do not use sensor in humidity or temperature conditions outside those listed in the specifications (see the Silhouette Installation and Configuration Guide for the operating conditions).
- Do not touch the optical plastic covering the sensor range finder (i.e. black window in the sensor). Wipe any condensation, dirt, or smudges from the protective optical plastic cover with a lint free cloth.
- Avoid contact with sharp objects.
- Handle the sensor and attached device with care to minimize physical shock.
- The sensor should be placed face-down on a clean and dry surface when not in use.
- The sensor can only be placed onto a device once. If it is removed from a device, the sensor can be damaged and is not covered under warranty.
- The sensor contains no user serviceable parts.
- This product is designed to have a nominal operational life of two years.

- At end of unit life, please recycle in accordance with local government regulations.
- The sensor contains an internal Lithium-ion battery pack rated at 3.7v, 180mAh and is charged using a wireless (inductive) charger.
- Only use the wireless charger supplied with the sensor for charging the internal battery. Use of any other charger voids the product warranty and could damage the unit.
- · Keep the charger at least 20 cm away from implantable medical devices to avoid potential interference with the medical device.
- Do not place the charger too close to cards with magnetic strips or chips (e.g. bank cards) as card failure may occur.

Care of the SilhouetteLite+ Sensor

The SilhouetteLite+ sensor is a precision optical instrument and must be handled with care at all times.

- Do not drop or knock the SilhouetteLite+ sensor.
- Ensure there is no dirt, moisture, or scratching on the sensor window.
- Do not let the SilhouetteLite+ sensor come into contact with the patient.
- Keep the SilhouetteLite+ sensor clean at all times by regularly wiping it with an antiseptic cloth.
- Do not submerge the SilhouetteLite+ sensor in liquid.

Cleaning the SilhouetteLite+ Sensor

The exterior of the SilhouetteLite+ sensor can be cleaned with a range of common cleaning agents. Cleaning should be performed with the same protocols used to clean the device to which the sensor is attached. The use of preimpregnated cleaning wipes is recommended since these do not physically scratch the sensor's optical surfaces.

Please note the following:

- Cleaning products should always be used according to the manufacturers' specifications.
- Cleaning agents or techniques not listed in this document should not be used.
- It is your responsibility to ensure product cleaning achieves the desired result.
- Certain cleaning agents may cause discoloration of the housing. Any such discoloration is cosmetic only and does not affect sensor operation and is not covered by warranty.
- Continue to use the cleaning protocol used to clean the device to which the sensor is attached.

Compatible cleaning agents are:

- Mild detergent. Do not submerge.
- Water-based wipes.
- · Alcohol (isopropyl) based wipes.
- · Hydrogen peroxide-based wipes.



Use caution if cleaning with:

· Manual physical cleaning. Avoid abrasive materials. Scratching of the optical covers may negatively impact measurement accuracy.

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- Bleach based wipes, low effective concentration (1:50, 1:100).*
- Bleach based wipes, high effective concentration (1:10).*
- *Use bleach based wipes only where required for decontamination or infection control purposes, not for day to day cleaning.

A Do not use:

- Ultrasonic cleaning the sensor is not designed for liquid submersion.
- Ultraviolet cleaning the sensor is not designed for exposure to high levels of ultraviolet light. Damage to the optical components could occur.
- Steam the sensor is not designed for contact with steam.
- Thermal disinfection the sensor is not designed for thermal disinfection.

Setting Up SilhouetteLite+

This section provides the details required to perform the initial setup of both the SilhouetteLite+ sensor and the SilhouetteLite+ App.

- 1. Download the SilhouetteLite+ App
- 2. Unbox the SilhouetteLite+ Sensor
- 3. Charging the SilhouetteLite+ Sensor
- 4. Attach the SilhouetteLite+ Sensor to Your Device
- 5. Setup the SilhouetteLite+ App

Download the SilhouetteLite+ App

- 1. Visit the Apple App Store on your device.
- 2. Search for SilhouetteLite+.



3. Download the SilhouetteLite+ App to install it on your device.

Unbox the SilhouetteLite+ Sensor

The SilhouetteLite+ Sensor comes in a box with the following items:

- Quick Start Guide
- Wireless Charging Pad
- USB Cable for the Wireless Changing Pad

The Quick Start Guide contains helpful information to get you started as well as the relevant safety warnings (see <u>SilhouetteLite+ Warnings</u> and <u>SilhouetteLite+ Label Information</u>). Please review this information before using the device.

Before using the SilhouetteLite+ sensor it needs to be placed on the charger.

Charging the SilhouetteLite+ Sensor

To turn the sensor on, before the initial use or if the SilhouetteLite+ App reports the sensor is not found, momentarily place the sensor on the charger.

If the SilhouetteLite+ App reports the sensor as having a low battery, then leave the sensor on the charger to allow it to fully charge. A full charge from flat typically takes 90 minutes and once charged it is designed to operate for approximately 80 assessments.

The sensor is charged using the supplied Wireless Charging pad. To charge the sensor:

- 1. Use the supplied USB cable to plug the Wireless Charging Pad into a USB power supply or a USB socket on a computer. A green LED on the charger indicates that the charger has power but is not charging a sensor.
- 2. Place the SilhouetteLite+ sensor face down on top of the charger to charge it.
 - The sensor must lie flat on top of the charger for charging to take place.
 - The bottom 2/3 of the sensor should be centered on the charger.
 - A blue charger LED indicates that the sensor is correctly placed on the charger and is charging.
 - To charge the sensor once it is attached to a device, place the device and sensor on the charging pad so the sensor surface is lying flat on top of the charger. If you are having difficulty placing the sensor flat on the charger, consider placing the device and sensor with the screen down and put the charger face down on the sensor.
- 3. The charger LED turns off once the sensor reaches full charge.
- 4. Remove the SilhouetteLite+ sensor from the charger to initiate sensor communication and connect your device.



If the sensor is still on the charger and the charger LED is green, this indicates that the charge 🛕 connection has broken and the sensor is no longer being charged. Reposition the charger or the sensor until the LED turns blue.



Attaching the SilhouetteLite+ sensor directly to a device that also supports wireless charging will prevent your device from being charged wirelessly. If you wish to wirelessly charge both the device and the SilhouetteLite+ sensor, then place the sensor on a removable case.

There is no charge indication on the physical SilhouetteLite+ sensor. The current charge state of the sensor can be seen in the SilhouetteLite+ App. The battery indication in the App shows:

- High means the sensor has been recently charged.
- Medium means the sensor has plenty of charge and can be used for days under normal usage conditions.
- Low the sensor has reached low charge. It still operates for a number of assessments but eventually stops giving range measurements. The App continues to report Low sensor battery until the sensor reaches full charge again.

When the SilhouetteLite+ sensor is on the charger it can not communicate with the SilhouetteLite+ App and the App reports "Sensor not found" when taking images. Remove the sensor from the charger to enable communication.

Attach the SilhouetteLite+ Sensor to Your Device

- 1. Determine the best position for the sensor on your device. The best position for the sensor is on a flat surface (not overhanging any edges), with the black window on the sensor directly below and as close as practical to the camera lens of your device.
 - Make sure the whole sensor is on a flat surface of the device, not overhanging any edges or sitting on any protruding items.
 - Do not place the sensor over any lenses, microphones, or other sensors on the device.
 - The sensor can be placed directly on your device or onto a hard case or cover, as long as it remains flat. Attaching the sensor to a soft case or cover may cause the sensor to detach as the case is removed.
 - The sensor can not be used under a case or protective sleeve.
- 2. Ensure the surface of the device is clean.
- 3. Remove the adhesive backing from the SilhouetteLite+ sensor and attach it to your device.



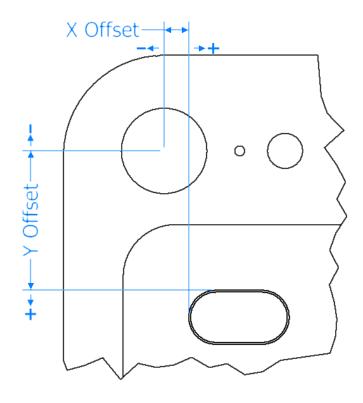
The sensor can only be attached to a device once. Removing the sensor can damage it, and it is not covered under warranty.

The figure below shows an example of the sensor placement on an iPad.



Setup the SilhouetteLite+ App

- 1. Ensure that the SilhouetteLite+ sensor has been removed from the charger.
- 2. Enable the Bluetooth functionality on your device.
- 3. Open the SilhouetteLite+ App on your device.
- 4. The first time the App is opened, it prompts you to select a sensor. Select the SilhouetteLite+ serial number that matches the serial number on the sensor attached to your device. If you don't have your sensor yet you can **skip** this step and complete it later by accessing the settings menu once logged into the App.
 - 1. Select the SilhouetteLite+ serial number that matches the number on the sensor attached to your device. If there is more than one sensor in range, the closest sensor is typically listed at the top of the list. If your sensor doesn't appear in the list then charge the sensor for at least 3 minutes, remove it from the charger and try again.
 - 2. Follow the instructions in the App to enter the information about how the sensor is placed on the device.
 - The x and y offsets are entered in mm and are measured from the center of the device camera to the edge of the black window on the sensor. A picture is provided in the App to assist with the measurement. These measurements allow an indication of where the range sensor is working when taking an image.
 - A positive value for the x offset means that the left edge of the sensor window is to the left of the device camera. A negative value for the x offset means that the left edge of the sensor window is to the right of the device camera.



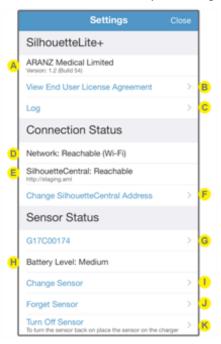
- A positive value for the y offset means that the top edge of the sensor window is below the device camera. A negative value for the y offset means that the top edge of the sensor window is above the device camera.
- If your device has two cameras then take the measurements from the wide angle lens (i.e. the lens closest to the edge of the iPhone 7 Plus).
- Select if the sensor is placed directly on the device or on a case. This selection allows for an adjustment to the range reported by the sensor.
- 5. After the selection of the sensor, then the App asks for **Your organization's SilhouetteCentral URL**. Enter the URL of the SilhouetteCentral instance for your organization.

- 8
- When entering the SilhouetteCentral URL include the prefix http:// or https://. The URL can be edited at any time by selecting the settings cog in the App.
- 6. Ensure the device is online and there is a network connection available.
- 7. Log in to SilhouetteLite+ by entering the **username** and **password** provided to you by your system administrator.
 - 0
- The App only allows the user to log in when there is an active connection to SilhouetteCentral. Once logged in, the App can be used offline until the user logs out.

Changing SilhouetteLite+ Settings

App settings can be viewed and changed in the settings menu.

Select the settings cog icon () on the bottom right of the Patients screen to access the settings menu. There is also a settings cog icon on log in screen which allows access to only the **Change SilhouetteCentral Address** option.



- A SilhouetteLite+ version and build
- Selecting the **View End User License Agreement** opens the Silhouette Suite End User License Agreement in a web browser window.
- Selecting the **Log** option displays the SilhouetteLite+ log file and provides a button to **Email** the log to your system administrator or to ARANZ Medical support at support@aranzmedical.com.
- Displays the status of the network connection. **Reachable** means that the App can send data on a network, **Not Reachable** means that the App can not send data on a network. If the network is reported as Not Reachable then check:
 - That the device Wi-Fi or mobile data is on and connected.
 - If using mobile data then make sure that SilhouetteLite+ is not restricted from mobile data use. The App mobile data access restrictions can be found in the iOS Settings App on your device.



Displays the status of the connection to SilhouetteCentral and the URL that it is trying to reach SilhouetteCentral on. **Reachable** means that the App can send and receive data to and from SilhouetteCentral. **Not Reachable** means that the App can not send or receive data from SilhouetteCentral and the App is operating in offline mode.

If the network is listed as Reachable, but SilhouetteCentral is listed as Not Reachable, then check:

- The network the device is using (Wi-Fi or mobile data) is able to connect to SilhouetteCentral. Some public networks might not be able to reach SilhouetteCentral servers which are behind corporate firewalls.
- The URL listed is the correct URL for your organization's SilhouetteCentral.
- SilhouetteCentral may be down for maintenance, check with your system administrator.
- One way to confirm if the SilhouetteCentral can be reached on your network is to put the listed SilhouetteCentral URL into your devices web browser.



The **Change SilhouetteCentral Address** option allows you to change the SilhouetteCentral URL. This should only be changed if requested by your system administrator. Changing it deletes any offline data and will log you out of the App.

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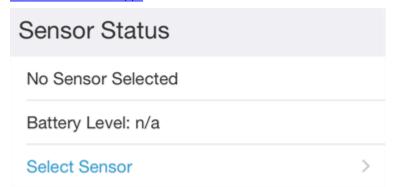


The serial number of the connected SilhouetteLite+ sensor is listed. If the serial number is blue then you can select the serial number to open the SilhouetteLite+ sensor information screen, which shows:

- Sensor model number.
- · Sensor serial number.
- Sensor battery level.
- Current range reported by the sensor with a status value. The range is reported without the Z offset adjustment and the a status of 0 means good. A status of any other value means that the sensor is operating outside the design values (e.g. the object is too far or too close for the range sensor).
- Firmware revision of the sensor.
- Hardware revision of the sensor.
- Software revision of the sensor.
- The X, Y and Z offsets set in the App for the sensor are also listed. To change these select **Change Sensor** from the App Settings menu.

If the App can not currently communicate to the sensor (e.g. the sensor is flat or on charge) then the sensor serial number is shown in gray and the sensor information screen can not be accessed.

If there is no sensor currently configured in the App (e.g. the sensor selection was skipped on App startup or the Forget Sensor option has been used) then **No Sensor Selected** is displayed instead of a serial number and an option **Select Sensor** is available to go through the sensor selection process. <u>See "Setup</u> the SilhouetteLite+ App".





Indicates the battery level of the sensor or **n/a** if a sensor cannot be found.

The battery level is shown as High, Medium or Low (requires charge). The sensor is still able to perform a number of assessments with a Low battery, but the sensor should be placed on charge at the earliest convenience.

Once the sensor is reporting a Low battery level, it continues to report a Low battery level until it receives a full charge.

See "Charging the SilhouetteLite+ Sensor" for information on charging the sensor.



Use the **Change Sensor** option to select a new sensor or to change the X, Y, or Z offset values being used. See "Setup the SilhouetteLite+ App" for details.



Use the Forget Sensor option to remove the association between the mobile device and the sensor.

This option can be useful if one sensor is shared between a number of devices (i.e. when the sensor is attached to a removable case). When one device has the sensor selected and the App open then the sensor can not communicate with a second device.



Use the **Turn Off Sensor** option to stop the sensor from broadcasting Bluetooth advertisements.

This option can be useful if you want to ship the sensor or want to attempt to reset the sensor.

Once the sensor is off, turn it on again by placing it on the charger.

Using SilhouetteLite

SilhouetteLite is an application designed for Apple® iPhone®, iPod® touch and iPad® 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 network connection when available.

This section of the guide goes through the main workflow to capture a wound assessment with the SilhouetteLite App.

- 1. Download the SilhouetteLite App
- 2. Setup SilhouetteLite
- 3. Select or Create a Patient in SilhouetteLite
- 4. Perform an Assessment in SilhouetteLite
- 5. Changing SilhouetteLite Settings

Download the SilhouetteLite App

- 1. Visit the Apple App Store on your device.
- 2. Search for SilhouetteLite with the icon shown below.



3. Download the SilhouetteLite App to install it on your device.

Setup SilhouetteLite

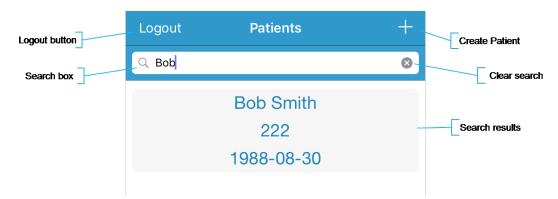
1. Open the SilhouetteLite App on your device.



2. The first time the App is opened, it asks for **Your organization's SilhouetteCentral URL**. Enter the URL of the SilhouetteCentral instance for your organization.

- 8
- When entering the SilhouetteCentral URL include the prefix http:// or https://. The URL can be edited at any time by selecting the settings cog icon in the App.
- 3. Ensure the device is online and there is a network connection available.
- 4. Log in to SilhouetteLite by entering the **username** and **password** provided to you by your system administrator.
 - The App only allows the user to log in when there is an active connection to SilhouetteCentral. Once logged in, the App can be used offline until the user logs out.

Select or Create a Patient in SilhouetteLite



- 1. Search for the patient by entering part of the patient's name or patient identifier in the **search** box.
 - The search matches patients whose names start with the search characters, e.g. searching for "lo" finds a patient called "Lot" but not "Bloggs".
- 2. Select the patient you want to create an assessment for by touching the patient's name on the screen.
 - If the patient you are searching for doesn't appear to be in the list then you can attempt to refresh the list by swiping down on the screen.
- 3. Use the + in the top right of the Navigation bar (top of screen) to create a new patient record.

Perform an Assessment in SilhouetteLite

Once a patient is selected then the device camera opens to allow you to capture wound images.

- 1. Focus the camera by touching the screen where you would like it to focus.
- 2. Take up to 10 images using the round capture image button.
- 3. Select the image stack to review the images and unselect any that should not be kept.
- 4. Once complete, select **Done** to finish capturing images.
- 5. Select the note title to enter text into the notes.
- 6. Select **Save** to complete the assessment.



Assessments are sent to SilhouetteCentral once they are saved and when the device is online. Data is only uploaded while the App is open. Leave the App open until the offline data icon disappears from the bottom left of the patient selection screen.

The offline data icon: 1

Changing SilhouetteLite Settings

App settings can be viewed and changed in the settings menu.

Select the settings cog icon () on the bottom right of the Patients screen to access the settings menu. There is also a settings cog icon on log in screen which allows access to only the **Change SilhouetteCentral Address** option.



- SilhouetteLite version and build.
- Selecting the **View End User License Agreement** opens the Silhouette Suite End User License Agreement in a web browser window. The same content is also contained in this manual, see CTEULA and Terms of Use.
- Selecting the **Log** option displays the SilhouetteLite+ log file and provides a button to **Email** the log to your system administrator or to ARANZ Medical support at support@aranzmedical.com.
- Displays the status of the network connection. **Reachable** means that the App can send data on a network, **Not Reachable** means that the App can't send data on a network. If the network is reported as Not Reachable then check:
 - That the device Wi-Fi or mobile data is on and connected.
 - If using mobile data then make sure that SilhouetteLite is not restricted from mobile data use. The App mobile data access restrictions can be found in the iOS Settings App on your device.

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Displays the status of the connection to SilhouetteCentral and the URL that it is trying to reach SilhouetteCentral on. **Reachable** means that the App can send and receive data to and from SilhouetteCentral. **Not Reachable** means that the App can not send or receive data from SilhouetteCentral and the App is operating in offline mode.

If the network is listed as Reachable but SilhouetteCentral is listed as Not Reachable then check:

- The network the device is using (Wi-Fi or mobile data) is able to connect to SilhouetteCentral. Some
 public networks might not be able to reach SilhouetteCentral servers which are behind corporate
 firewalls.
- The URL listed is the correct URL for your organization's SilhouetteCentral.
- SilhouetteCentral may be down for maintenance, check with your system administrator.
- One way to confirm if the SilhouetteCentral can be reached on your network is to put the listed SilhouetteCentral URL into your devices web browser.



This option allows you to change the SilhouetteCentral URL. This should only be changed if requested by your system administrator. Changing it deletes any offline data and logs you out of the App.

The Silhouette Clinical User Interface (UI)

The Silhouette Clinical User Interface (UI) is available in both SilhouetteCentral and SilhouetteConnect products.

Silhouette is a computerized wound imaging, analysis, and documentation system.

SilhouetteCentral enables users to review, report, securely share and analyze the wound data collected by SilhouetteConnect, SilhouetteLite+ and SilhouetteLite applications. SilhouetteCentral is accessed via a web-based application and can collect wound data directly with a SilhouetteStar 2 device.

SilhouetteCentral is divided into three parts:

- Clinical Provides access to the patient medical data stored in the Silhouette database for reviewing, editing, and updating. Reports, images, and wound measurement data can also be exported for further processing and importing into other applications.
- Administration Provides facilities to manage units, groups, patients, and system users. SilhouetteCentral can also be used to configure and customize the Silhouette system.
- Integration Interfaces SilhouetteCentral allows integration of assessment data with other health IT systems using the Silhouette Integration Interface.

SilhouetteConnect is the software installed on a Microsoft Windows tablet, laptop or desktop computer. SilhouetteStar devices connect via USB to a computer running 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.

SilhouetteConnect can be used in two modes of operation:

- Standalone mode provides the power of Silhouette on a single PC. Data is collected and stored on the PC. PDF reports can be generated to share the results.
- Synchronized mode provides offline and wired SilhouetteStar device support for SilhouetteCentral systems. Data collected by SilhouetteConnect can be uploaded to SilhouetteCentral and data stored in SilhouetteCentral can be downloaded and used offline in SilhouetteConnect. In synchronized mode the system is mostly administered in SilhouetteCentral and the appropriate settings are downloaded during the synchronization process.

Topics



Logging In to SilhouetteCentral or SilhouetteConnect



Parts of the User Interface



Managing the SilhouetteConnect Patient List



The Patient Selection Screen

66 • Topics



The Patient Dashboard



<u>Assessments</u>



Wounds

Logging In to SilhouetteCentral or SilhouetteConnect

To login to SilhouetteCentral, navigate to the website address of your SilhouetteCentral instance using your devices web browser.

As an alternative to SilhouetteCentral, you may be able to use the installed SilhouetteConnect application for offline data access and wired (USB) SilhouetteStar connections. To login to SilhouetteConnect, go to the Windows start menu and launch the SilhouetteConnect application.

When the log in screen appears, enter the User Name and Password supplied to you and select Login.



It is important to log in using the **User Name** and **Password** assigned to you. Silhouette records the names of users viewing, creating, and modifying patient records, and using the correct user name ensures accurate auditing.

Many browsers prompt you to save a **User Name** and **Password** for websites you log in to. If using a shared computer, it is recommended that you do not permit the browser to save your login details for SilhouetteCentral. Doing so means that anyone using your computer can log in, access and potentially modify patient medical records, which will be recorded as having been completed by you.

While logging in, you may occasionally be prompted to change your password if a system administrator has made use of the password expiry features. In this case you need to pick a new password that meets the password complexity requirements and enter it before Silhouette allows you to log in.

If logging in to SilhouetteConnect then you may be prompted to synchronize the database prior to login. Follow the prompts to login.



If you are having trouble logging in then use the **Forgot your password?** link available in SilhouetteCentral to reset your password, see <u>Recovering Forgotten Password</u>.

License Warnings

License warnings are displayed in both SilhouetteConnect and SilhouetteCentral if the license is nearing expiry. The warning is shown in a banner near the top of the screen once any user is logged in.





Select the **Check for Update** link to query the ARANZ Medical licensing server for an update.

The **Check for Update** function can also be accessed through the Admin pages.

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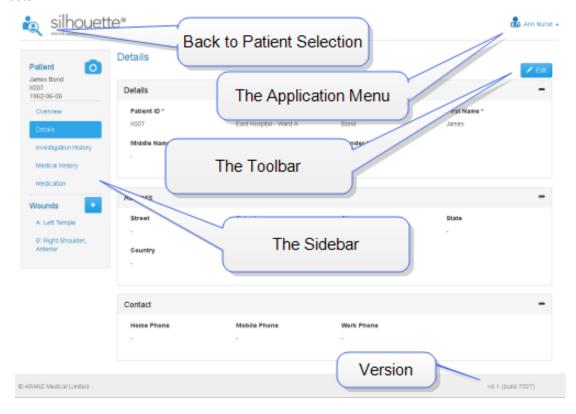


Select the \mathbf{x} button to dismiss the warning banner. The banner will be dismissed until the user logs in again.

Parts of the User Interface

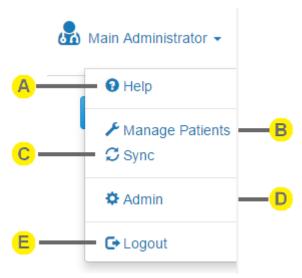
Navigation

In most SilhouetteCentral and SilhouetteConnect screens, you are be presented with three menu groups as well as a page footer:



Application Menu

Once you have logged in to Silhouette, your name is shown in the top right-hand corner, with a drop down menu, known as the Application Menu:





Help

Contains links to the User Guides to help you use Silhouette. It also contains the links to legal and licensing information for Silhouette.

Manage Patients

Opens the Manage Patients screen on SilhouetteConnect, allowing the selection of patients to download to this instance of SilhouetteConnect.

This menu item is only shown in SilhouetteConnect if it is running in Synchronized mode and if the current user has the Can Manage Patients permission.



Sync

Initiates a Sync to SilhouetteCentral.

This menu item is only shown in SilhouetteConnect if it is running in Synchronized mode and if the current user has the Can Synchronize permission.



Change your account settings such as your name, email address and password.

Also, if your account has the correct permissions, then you can administer settings for the application. See the separate Administration User's Guide for more details.



Logout

Log out of SilhouetteCentral or SilhouetteConnect.



There may also be an Export option available in the application menu when SilhouetteConnect is operating in Standalone mode and the optional feature for Clinical Data Export is enabled. See the Silhouette Administration User's Guide for more details on clinical data exports.

The Toolbar

Options such as Edit, Save, Cancel, Import, Export, Delete, Close can be found in the toolbar area.

The options displayed are dependent on the page you are viewing and the permissions assigned to you by your System Administrator.

The Sidebar

The Sidebar contains a summary of the selected patient, with the ability to select / create features.

On small screens the sidebar might be off screen to the side and can be bought on screen by swiping or dragging it into view.

Version

Note that the version of Silhouette is displayed at the bottom-right corner of every page.

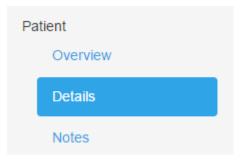
Return to Patient List (Home)

Selecting the Silhouette logo or the Patient search icon at the top-left corner of the screen at any stage returns you to The Patient Selection Screen.

Selecting Items

Selected items in a list are colored with a blue highlight.

Selected items such as wound labels and images are indicated by a blue outline (below the **Patient > Details** are selected):



Quick Start Workflow

A typical workflow comprises:

- 1. Logging In to SilhouetteCentral or SilhouetteConnect
- 2. The Patient Selection Screen (selecting a patient)
- 3. Connecting a SilhouetteStar 2 using Wi-Fi or Connecting a SilhouetteStar using USB
- 4. Take Wound Images
- 5. Create an Assessment

See "SilhouetteStar Wound Imaging Workflow" for more detailed workflow steps.

Managing the SilhouetteConnect Patient List

If SilhouetteConnect is set to synchronize (sync) to a SilhouetteCentral instance then the patients available offline on SilhouetteConnect are typically a subset of the full set of patients.

The patient list is managed via the application menu options Manage Patients (See "Managing Patients") and Sync (See "Synchronizing with SilhouetteCentral"). The Sync and Manage Patients options are only seen in the application menu if your SilhouetteConnect software is configured to connect with SilhouetteCentral and your user account has the correct permissions. If you have SilhouetteCentral and do not see these options, contact your system administrator.

Synchronizing with SilhouetteCentral

The synchronization process coordinates the transfer of information between the SilhouetteConnect and SilhouetteCentral. Information transferred between the user application and SilhouetteCentral includes:

- User account information
- All patient information, including images and notes
- · Any wound assessment reports
- · Additional configuration information for Silhouette

Information is transferred from SilhouetteConnect to SilhouetteCentral and vice-versa. For example, new images captured in SilhouetteConnect are transferred to SilhouetteCentral, and updates to patient information made in SilhouetteCentral are transferred to Silhouette.

There are three ways to initiate synchronization with SilhouetteCentral:

- Select the **Sync** option in the application menu. Synchronization begins immediately.
- Select the Manage Patients option in the application menu to choose patients to add to and remove from Silhouette. See Managing Patients for more information.
- Automatically when you log off, if this functionality has been enabled by your system administrator.

The time required for synchronization depends on the amount of data to be transferred and the speed of the communication path between SilhouetteConnect and SilhouetteCentral. As synchronization proceeds, SilhouetteConnect displays progress at each stage.

If a compulsory update to SilhouetteConnect software is available, a message appears asking you to update SilhouetteConnect before synchronization can continue. The updated SilhouetteConnect software can be downloaded from SilhouetteCentral at <SilhouetteCentral URL>/install, e.g. https://silhouettecentral.myorganisation.com/install.

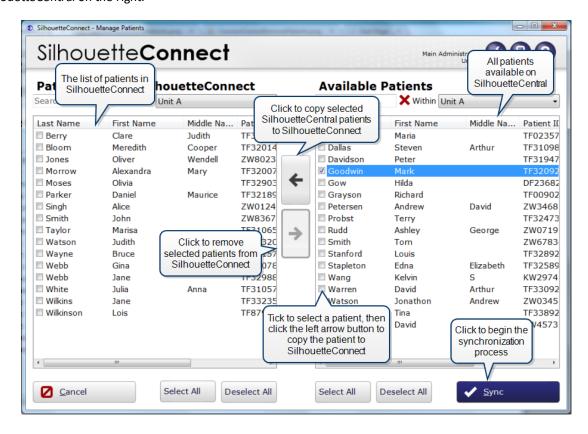
See the Silhouette Configuration and Installation manual for further instructions on updating SilhouetteConnect.

Managing Patients

The **Manage Patients** screen is only available in SilhouetteConnect and only if it is configured to synchronize with SilhouetteCentral.

In the **Manage Patients** screen, you can choose patients to add or remove from the user application before starting the synchronization process.

When the **Manage Patients** screen first opens, SilhouetteConnect establishes a connection with SilhouetteCentral and retrieves the list of patients available on SilhouetteCentral. The **Manage Patients** screen shows the list of patients available on this installation of SilhouetteConnect on the left and the list of patients only available in SilhouetteCentral on the right:



To copy patients from SilhouetteCentral to SilhouetteConnect, check the boxes for the required patients in the **Available Patients** list, then click on the left arrow button to move the selected patients to the **Patients on this SilhouetteConnect** list. Patient information remains on SilhouetteCentral after synchronization.

To remove patients from the user application, check the boxes for those patients in the **Patients on this SilhouetteConnect** list, then click on the right arrow button to move the selected patients to the **Available Patients** list. Patient data is preserved on SilhouetteCentral, but the patient does not appear in the SilhouetteConnect.

Click the **Sync** button to begin the synchronization process. The time required for synchronization depends on the amount of data to be transferred and the speed of the communication path between SilhouetteConnect and SilhouetteCentral. As synchronization proceeds, SilhouetteConnect displays progress at each stage.

Setting the group permissions to add or remove patients

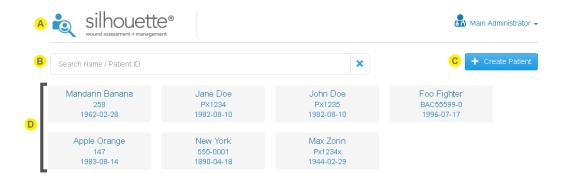


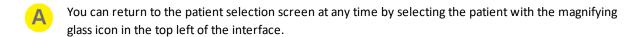
The permissions to add or remove patients can be configured via the Silhouette Central **Groups**. By editing a group, users belonging to that group may be given permissions to add patients, remove patients, or both. For more information, see the **Silhouette Administration User's Guide**.

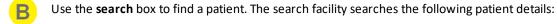
The Patient Selection Screen

After you log on, the list of patients in the database is displayed. This page is the start point for all clinical workflows in Silhouette. Select a patient to:

- Create wounds or assessments for that patient.
- Review and edit patient information.
- To capture images for a patient.







- First name
- Last name
- · Patient ID

When searching, the search looks for matches starting at the beginning of any name field and looks for matches anywhere within the Patient ID. For example:

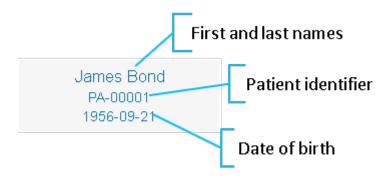
- Entering an *M* into the search box finds names Mary but not Amy.
- Entering a 12 into the search box finds patients with Ids PA123 and 123.



Select the Create Patient button to add a patient to the database. See <u>Creating a New Patient</u> for more information.



The patients available to you in the system are shown in a series of tiles. The information included on the tile depends on the Silhouette configuration. The default configuration is to show patient name, identifier, and date of birth



The patients shown are filtered as search terms are entered. There are up to 50 patients shown initially, with a **Load More** button shown to load further patients if required.

Select the a patient tile to show that patients dashboard.

- If the patient you are looking for does not show, then they may not exist in Silhouette or they may be associated to a Unit that you do not have access to.
- Select the patient search icon or the Silhouette logo at the top left of the screen to return to the patient search screen at any time.

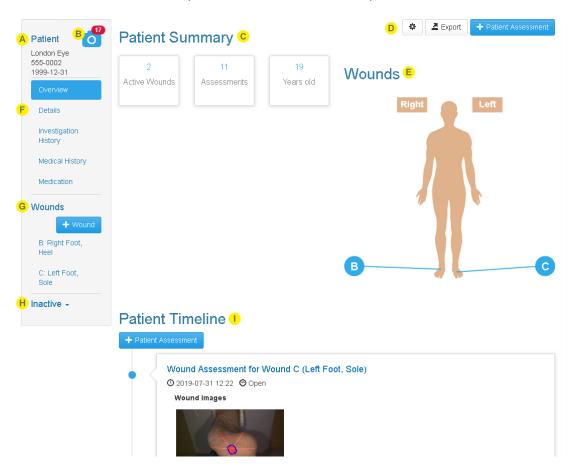
Creating a New Patient

To create a new patient, select the **Create** button in the **Patient Selection** screen. In the screen that appears, fill out the required fields, which are indicated by an asterisk (*).

To save the information select **Save**, or **Cancel** to return without saving.

The Patient Dashboard

The patient dashboard shows a summary of information about a selected patient:





The sidebar provides information to positively identify the patient and provides navigation to view different pages of information about the patient.

On a small screen the sidebar may be hidden off screen. Drag it on and off screen from the left as needed.



Select the camera icon on the sidebar to open the patient's image portfolio in image review mode. The patient's image portfolio provides access to:

- Captured images that haven't been used in an assessment.
- The connection barcode used to connect the SilhouetteStar 2 via Wi-Fi.
- The SilhouetteStar 2 sound mute control.

The camera icon shows a badge with the number of images that are available to be used in an assessment.

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The Patient Summary section provides a high level overview of the patient, including:

- The number of active wounds.
- The number of assessments performed for the patient.
- The patient's age.



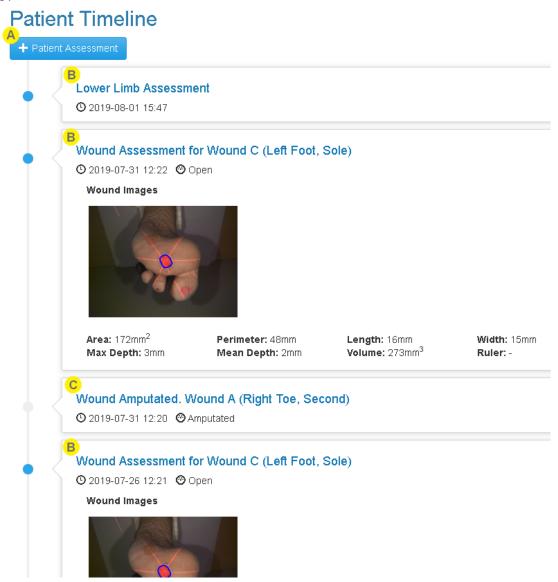
Most of the actions available for you to perform on the selected patient are available at the top right of the screen. The actions available to you depend on your permissions but may include:

- Patient data administration, see Managing Patient Records.
- Export, see the Administration User's guide for more details.
- Start a patient assessment for the patient, see Creating a Patient Assessment.
- A body silhouette is shown with the wound labels giving the approximate locations for up to 18 active wounds.
- Patient Notes a list of the different patient notes that have been added to the patient, including patient demographic details.
- Wound List a list of wounds with their label and location. Inactive wounds are grouped together below a collapsed Inactive header that can be expanded.
- Inactive wounds are listed under an expandable section of the sidebar. Select the **Inactive** heading to expand or collapse the list.
 - Inactive wounds are wounds that are in states that are no longer being actively cared for (e.g. Healed, Amputated, Released from follow-up)
- The Patient Timeline shows all events for the patient in chronological order, with the most recent at the top. See "Patient Timeline" for more details.

Patient Timeline

The patient timeline shows all the assessments and observations recorded for the patient, in order of occurrence (newest assessment at top).

The wound timeline is similar to the patient timeline except that it filters out assessments for other wounds, only showing patient assessments and wound assessments for the selected wound.





Select the + Patient Assessment button to start a new patient assessment.

The wound timeline has a + Wound Assessment button in place of the + Patient Assessment button.

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Each assessment in the timeline has:

- A title, showing the type of the assessment and the wound information (if it is a wound assessment).
- A subtitle, showing the date and time of the assessment and the state of the wound at the time of the assessment.
- Assessments that include images show the image thumbnails and any summary measurements.
- The timeline dot is gray for assessments where the wound state recorded is an inactive wound state, otherwise the dot is blue.

The date and time shown in the timeline are localized to the time zone of your computer. If you have users using the system in multiple time zones then other users will see the assessment localized to their time zone. Assessment date and times on PDF reports and in data exports are shown in the time zone they were created in.

Select the assessment tile to view the assessment in greater detail (captured notes or larger images) or to generate an assessment PDF report, see <u>Viewing and Editing Assessments</u>.



Wound states that have been set without performing an assessment are also shown on the timeline.

Wounds

Silhouette allows you to track different wounds on a patient. You do this by creating wounds for the patient in Silhouette and then all wound assessments for that wound are grouped together.

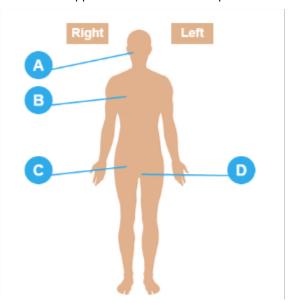
Silhouette assigns a unique wound label to the wound. These labels are alphabetical or numerical depending on the Silhouette system configuration.

Wounds in Silhouette have a state or status recorded with them. Wounds are classified as either active or inactive based on their current wound state. Active wounds are wounds that are actively being managed in Silhouette and inactive wounds are somewhat hidden in Silhouette as they are no longer being actively managed.

The active and inactive wound states available may differ based on system configuration, however the states are typically:

- Open. An active state and the default starting point when a wound is created in Silhouette.
- Healed. An inactive state, indicating that the wound healed so no longer needs to be monitored.
- Amputated. An inactive state, indicating that the wound is no longer there as it was amputated.
- Released from follow-up. An inactive state, indicating that the wound is no longer being monitored but the actual outcome for the wound may be unknown.

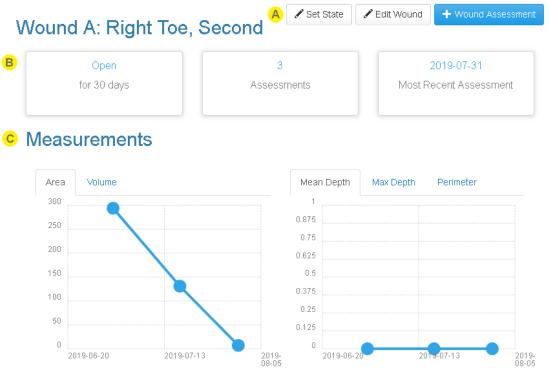
The list of wounds for a patient are available on the <u>The Patient Dashboard</u> screen. All of the patients wounds are listed on and can be selected from the patient sidebar under the **Wounds** heading. The Patient dashboard also shows a body silhouette with the wound labels and approximate locations for up to 18 active wounds.



Selecting on the wound label from either the body silhouette or the sidebar opens the Wound Dashboard.

Wound Dashboard

Selecting one of the Wounds from the Sidebar opens the Wound Dashboard for that selected Wound:



Wound Timeline





The actions available for you to perform on the selected wound are available at the top right of the screen. The actions available to you depend on your permissions but may include:

- Wound data administration, see Managing Wound Records.
- Set State, see Setting a Wound State.
- · Edit Wound, see Editing a Wound.
- Start a wound assessment for the wound, see Creating a Wound Assessment.



The wound summary panels show:

- The current wound state and how long the wound has been in that state.
- How many assessments have been made.
- The date of the most recent wound assessment.



The Measurements section contains graph(s) showing how the wound has changed over time.

Select the required graph by using one of the tabs above the graph.

Selecting a data point on the graph opens the relevant assessment.



The **Wound Timeline** section shows events relevant to the selected wound on a timeline with the most recent event at the top. Selecting an item on the timeline opens a detailed view of the item.

The wound timeline includes:

- Wound state records from when the wound was created and when the Set State button has been
 used to change the wound state.
- Wound assessments performed on the wound with thumbnail images and summary details.
- Patient level assessments performed for the patient.

Creating a Wound

Create a new wound by selecting the + Wound button in the sidebar beside the wounds heading.

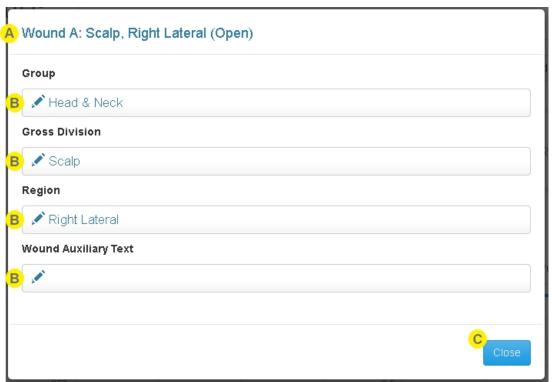


Selecting the + Wound button shows a dialog allowing you to specify the location for the wound (anatomical site), some Wound Auxiliary Text and an initial state of the wound. The Wound Auxiliary Text is a short piece of free text which is added to the wound description allowing you to distinguish between wounds on the same anatomical site.

The wound label is unique with respect to the patient record and is assigned automatically by Silhouette. When creating a wound in SilhouetteLite+ or SilhouetteConnect (syncing mode) the wound label is not assigned until the wound is synced with SilhouetteCentral. A - is displayed for the label until the wound label is assigned.

Editing a Wound

To edit wound details select the **Edit Wound** button on the <u>Wound Dashboard</u>. The **Edit Wound** button is only available to users with the Can Edit Wound permission.



- The title of the dialog contains the current wound label and state.
- Select the part of the wound description you want to change.
- Select the **Close** button to close the dialog without making any changes.

Setting a Wound State

A wound state can be set when performing a wound assessment or by selecting **Set State** from the Wound Dashboard. The **Set State** button is available to users with the Can Edit Wound permission.



- Set the **Initial observation date** to the date to record the wound state change.

 The current state will be updated only if the date set is the latest date on the wounds timeline.
- B Select the new **Wound State** and enter any additional notes that appear.
- Select **Save** to record the wound state and update the wound.
- Select **Cancel** to close the view without updating the wound.

Assessments

An assessment is the main data capture and wound tracking mechanism in Silhouette. Silhouette can be configured with many different assessments each capturing different data. The assessments available to your organization will typically be tailored to your requirements.

All assessments fall into two main assessment types:

- Patient Assessment for assessments about the patient as a whole person, e.g. risk assessments.
- Wound Assessment for assessments specific to a single wound. Wound assessments are where wound healing is tracked.

Creating a Patient Assessment

To create a new **Patient Assessment**, select the **Patient Assessment** button at the top of the page, or in the **Patient Timeline**, the information regarding the patient that can be stored is:

- Admission and discharge information.
- Physician details.
- Patients vital signs.
- General pain levels, etc.

Note: The only type of assessment that can be created from the patient dashboard is a patient assessment. To create an assessment of a particular wound see Creating a Wound Assessment.

Creating a Wound Assessment

A new wound assessment can be created from the **Wound Dashboard**. Selecting the new assessment button at the top right of the screen or the top of the **Wound Timeline** causes a new assessment form to appear.

If there is more than one type of wound assessment available you will see a list of options. Select the type of assessment you are performing from the list, and fill in the details.

A wound assessment will always show the current state of the wound and allow you to change it.

When you have completed the assessment select **Save**. The assessment will be added to the top of the **Wound Timeline**.

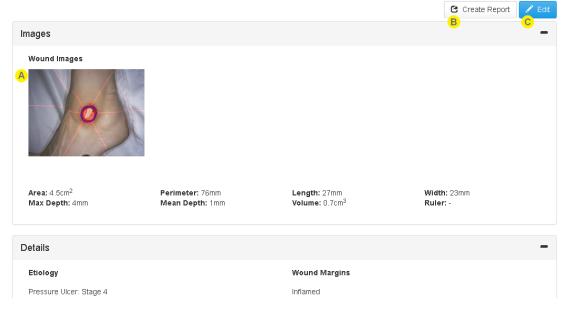
Viewing and Editing Assessments

Once assessments are created, assessment summaries are shown on the applicable patient timeline and wound timeline. The summaries include the thumbnails of all the images assigned to the assessments and the associated measurements.



Selecting the assessment summary from the timeline will open the full assessment in a read-only view.







Select the individual images to review them in the image viewer and export them as image files, see Viewing Images.

To edit tracings on the images, or assign new images from the portfolio to the assessment then first select **Edit** on the assessment.

The measurements shown underneath the images are the sum of all measurements from all the images in that image capture field. Tracing more than one image is useful when imaging and measuring circumferential wounds. To see the measurements for just one image, open it in the image viewer, which displays the measurements from just the image.

For more information about capturing images for circumferential wounds, see <u>Taking a Multiple Image</u> <u>Measurement</u>.

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Select Create Report to generate and download a PDF assessment report, see Assessment PDF Report.



Select **Edit** to edit the assessment. Editing the assessment allows you to:

- Add images to the assessment (and wound) from the image portfolio.
- Remove images from the assessment (and wound).
- Trace images to identify and measure wounds within the image, see Tracing Wound Outlines.
- Record other notes.

Assessment PDF Report

The Create Report button at the top right of the screen lets you create PDF reports.

Create an assessment report by navigating to the desired assessment and selecting the **Create Report** button. If the button is not available then you may not have sufficient permissions to create reports.

The report is generated and downloaded. When using SilhouetteCentral the download location is the default set by your web browser. When using SilhouetteConnect you will be prompted to choose the save location.

The PDF report includes a footer referencing the time zone used to display the dates and times in the report. The PDF report time zone is selected based on the time zone where the assessment was initially created.

Working with Images

Images in Silhouette are used as a visual record of the wound over time and allow measurement of the wound as long as they are captured by a measurement capable capture device, e.g. SilhouetteStar or SilhouetteLite+.

The fundamental image capture and measurement workflow is:

- 1. Select a patient.
- 2. Capture image(s) of wound(s).
 - See "Using SilhouetteStar" for details on using the SilhouetteStar device.
 - See "Using SilhouetteLite+" for details on using the SilhouetteLite+ device.
 - See "Using SilhouetteLite" for details on using the SilhouetteLite application.
- 3. Assign the images to a wound in an assessment, see Assessments.
- 4. Trace the wound images to identify and measure the wound.
- 5. Create a PDF assessment report to share images and measurements.

The workflow changes based on the capture device you are using. However, working with images in the Silhouette Clinical UI is largely independent of the capture device. The following topics explain the different parts of the UI when working with images:

- Viewing Images
- Assigning Captured Images
- Tracing Wound Outlines

Viewing Images

The image viewer is accessed by selecting an image in the portfolio (see <u>Portfolio - Image Review Mode</u>) or from an assessment in non-edit mode by selecting the image thumbnail.

In the image viewer you can control what you see overlaid onto the image and you can also export the image. The following describes the icons in the Image viewer that can be toggled on and off.



Show or hide the lasers. Select the **Show/Hide Lasers** button in the full-screen view.



Show or hide the laser detections (the points where the software has detected the laser). Select the **Show/Hide Laser Detections** button in the full-screen view.



Show or hide the wound outline. Select the **Show/Hide Outline** button in the full-screen view.



Show or hide the rulers. Select the **Show/Hide Rulers** button in the full-screen view.



Show or hide the axes. Select the **Show/Hide Axes** button in the full-screen view.

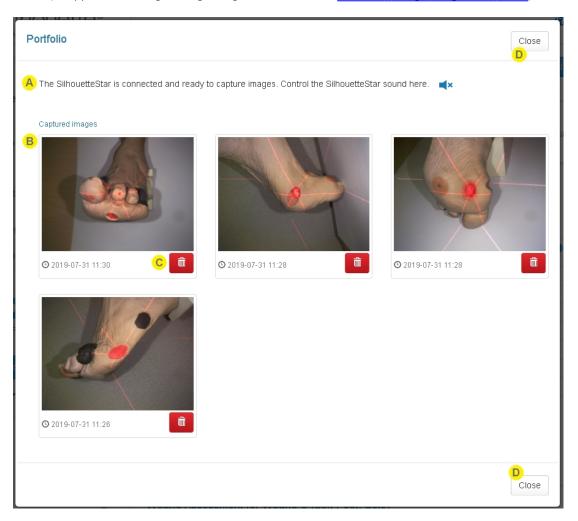


Export the image. Select the **Export Image** button in the full-screen view.

To edit the image tracings or adjusting the wound outline edit the assessments. See "Tracing Wound Outlines" for more information on editing tracing.

Portfolio - Image Review Mode

When you have opened the image portfolio by selecting the camera icon from the patient sidebar it is in image review mode (as opposed to being in image assignment mode, see Portfolio-Image Assignment Mode).





The status of the connected SilhouetteStar is displayed at the top of the portfolio with any sound mute controls available. The messages you might see here are:

- Connect the SilhouetteStar using the supplied USB cable to take images.
 This message is shown in SilhouetteConnect when there is no USB connected SilhouetteStar 1 or SilhouetteStar 2.
- Connect the SilhouetteStar to take images.
 This message is shown in SilhouetteCentral when there is no active connection between the current web browser tab and a SilhouetteStar 2 device. The message is a hyperlink that can be selected to show a Wi-Fi connection barcode for the SilhouetteStar 2.
- The SilhouetteStar is connected and ready to take images. Control the SilhouetteStar sound here. This message is shown in SilhouetteCentral or SilhouetteConnect when any SilhouetteStar is connected. Select the speaker icon to mute or unmute the device sound.

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The available images are shown with the time they were captured.

Select an image to view it in larger image viewer (see the <u>Viewing Images</u> topic) and review the laser detections.



A delete button is provided for each image to give you the option of removing images you do not wish to keep.

It is good practice to take a couple of images, review which to keep and which to discard.

Selecting the **Trash Can** button turns the button into an undo button. You have about 5 seconds to use the undo button before the image is deleted.



Select the **Close** button to close the image portfolio.

Images can still be collected with a SilhouetteStar device as long as there is a patient selected. You can reopen the image portfolio to review the images at any time.

Images are not automatically removed from the image portfolio, however the images in the image portfolio are not synchronized between SilhouetteConnect and SilhouetteCentral.

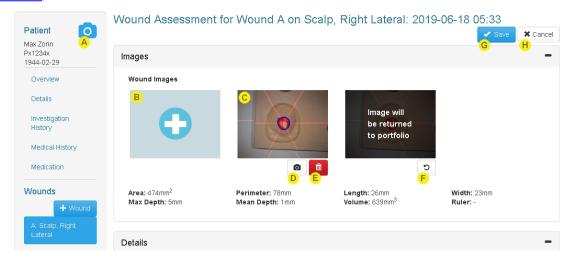


The images captured in SilhouetteConnect must be assigned to assessments before they are synchronized to SilhouetteCentral. If a patient is removed (see Managing the SilhouetteConnect
Patient List) from SilhouetteConnect then any unused images remaining in the image portfolio will not be kept.

Assigning Captured Images

Images in Silhouette are linked to a specific patient.

To assign images to a specific wound for the patient you assign them to designated image capture fields within a wound assessment, either when creating (<u>Creating a Wound Assessment</u>) or editing (<u>Viewing and Editing Assessments</u>) an assessment.





Images captured using SilhouetteStar are initial stored in the patient portfolio. The patient portfolio can be accessed in an image review mode by selecting the camera icon on the sidebar, see Portfolio-Image Review Mode.

Images captured using SilhouetteLite or SilhouetteLite+ are already linked to an assessment when they are uploaded to SilhouetteCentral, therefore they do not appear in the image portfolio unless they have been returned to the portfolio after being uploaded.

Images in the patient portfolio are not synchronized between SilhouetteConnect and SilhouetteCentral. The portfolio is for temporary storage of the captured images, allowing images of multiple wounds to be captured before completing the individual wound assessments.

Captured images need to be assigned to assessments (usually Wound Assessments) to enable wound tracing and tracking of healing.



Select the + button on an image capture field you wish to assign the images to.

Selecting the + button on the image capture field shows the portfolio dialog in an image assignment mode with the images available for selection.

Multiple images can be assigned to a single image capture field. This is useful when capturing area measurements for circumferential wounds, see Taking a Multiple Image Measurement.

The measurements shown underneath the images always pertain to all the images. Select an image to open the image tracing screen to see the measurements pertaining to a single image.



Select the image to open the tracing screen to trace the wound boundary or add rulers. See "Tracing Wound Outlines" for more information on image tracing.

If there are multiple image capture fields available (e.g. pre-debridement and post-debridement) in the assessment then images can be dragged between the different capture fields.

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Select the camera button under each image to return the image back to the patients portfolio.

The camera button is always available in SilhouetteCentral or SilhouetteConnect in standalone mode.

If SilhouetteConnect is being used in synchronized mode, then only images that haven't yet been saved with the assessment are available to return to the portfolio. Once the assessment has been saved you will need to synchronize to SilhouetteCentral and edit the assessment in SilhouetteCentral to remove an image without deleting it.



Select the **trash can** button to delete the image.

Deleted images are no longer available to view or assign to other assessments.



Using the **camera** button to return an image to the portfolio or using the **trash can** button to delete an image only completes the action when the assessment is saved.

The image is overlaid with a message regarding what will occur and an **undo** button is provided.



Select the **Save** button to save the assessment.

Saving the assessment saves all the edits made, including:

- Assigning images to the assessment.
- Removing images from the assessment.
- Deleting images.
- · Adding or editing wound outlines.
- · Adding or editing tracings.



Select the Cancel button to cancel the assessment creation or edit.

When canceling an assessment edit or creation the assessment and images are left as they were. No images are assigned or removed or deleted, unless they were deleted from the image portfolio dialog. Any wound tracings or rulers that have been edited or added are not saved.

Portfolio - Image Assignment Mode

When you have opened the image portfolio from an image capture field in an assessment it is in image assignment mode (as opposed to being in image review mode).



- The banner in the portfolio dialog provides information about the wound you are assigning images for.
- B The available images are shown with the time they were captured.

 Select the images you want to assign to the wound assessment image capture field. You can select multiple images and selected images are highlighted with a blue border.
- A delete button is provided for each image to give you the option of removing images you do not wish to keep.

It is good practice to take a couple of images and then review which to keep and which to discard.

Selecting the **Trash Can** button turns the button into an undo button. You have about 5 seconds to use the undo button before the image is deleted.

Select the **OK** button to confirm the selection and assign the images to the assessment.

The image assignment is not completed until you save the assessment. If you subsequently Cancel the assessment creation or editing then the images appear back in the patient portfolio.

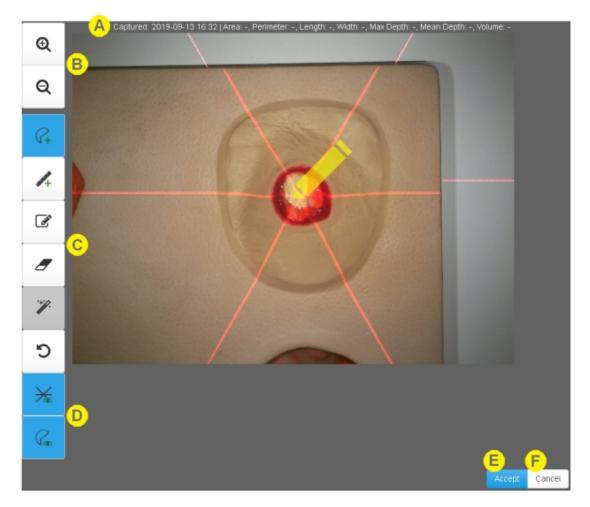
Tracing Wound Outlines

Select the image thumbnails from an image capture field within an assessment to open the trace screen and to trace the wound outlines. The assessment must be in edit mode (i.e. not read mode) to trace. The following topics help explain the use of the tracing screens:

- Using the Tracing Screen
- Using the Tracing Tools

Selecting an image in read mode, opens the image viewer without the trace tools present. See "Viewing Images" for more details.

Using the Tracing Screen



- The image capture date and time and the measurements for this image are displayed at the top of the screen.
- The first set of buttons provide controls to zoom in and out of the image. See "Zoom Controls" below for more details.
- The next set of tools are the tracing tools. See "Tracing Tools" below for more details.



The final set of tools provide control over what overlays you see on the image. See "View Controls" below for more details.



Accept

Select the **Accept** button once you have finished outlining and measuring all the wounds in the image. The **Accept** button accepts the tracings, however, the tracings are not saved until the associated assessment is saved.

If you do not trace an image, it can be kept as a reference image. Reference images are useful if you wish to capture an image of the surrounding tissue to demonstrate, for example, redness or swelling extending beyond the measured wound image.



Cancel

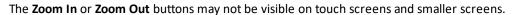
Select the **Cancel** button to close the image viewer without accepting the changes. The changes are lost if you select **Cancel**.

Zoom Controls



Zoom In and **Zoom Out** buttons.

To trace wounds, zoom into the image either by selecting the zoom image button, using the scroll wheel on your mouse, or by using pinch to zoom gestures on a touch interface.





Once zoomed, the image can be panned by selecting the image away from the on-screen pencil and dragging it around.

Tracing Tools

The color of the toolbar button shows which tool is selected and which tools can be selected.

- The selected tool has a blue background.
- A tool that can be selected has a light gray background.
- A disabled tool has a dark gray background.



New Outline

Select the **New Outline** tool to add an outline to the image. An outline can be used to:

- Trace one or more wound boundaries.
- Trace an island of healthy skin within a wound boundary.
- Identify a region of interest when using the **Auto Boundary Detection** tool.

The **New Outline** button is highlighted when the tool is selected and active. When the tool is selected an on-screen pencil appears that is used to draw the outline. <u>See "Using the Tracing Tools"</u> for more help on moving and using the pencil to draw the outline.



New Ruler

Select the **New Ruler** tool to add a ruler to the image. A ruler is used to measure the distance between two points.

The New Ruler button is highlighted when the tool is selected and active. An on-screen pencil is used to draw the ruler and appears when the tool is selected . To use the on-screen pencil to draw a ruler:

- 1. Drag the pencil to the start point of the ruler.
- 2. Hold the pencil in one place for appropriately 1 second to set the start of the ruler.
- 3. Drag the pencil to the desired location on the image and release it to set the end of the ruler.
- 4. The **Edit Outline** tool is automatically selected once the ruler is completed. Edit either end of the ruler as required.

The measurement for the ruler is displayed on the screen next to the ruler line.



Edit Outline

Select the **Edit Outline** tool to edit points on outlines and rulers.

The Edit Outline button is highlighted when the tool is selected and active.

To use the edit outline tool:

- 1. Use your finger or mouse pointer to select the point you wish to move.
- 2. Drag the point to the desired location and let it go.



Delete Outline

Select the **Delete Outline** tool and then select the ruler or outline you wish to delete.

The **Delete Outline** button is highlighted when the delete tool is selected and active.

Use the **Undo** tool to undo a delete if you delete the wrong item.



Auto Boundary Detection (Automatic Wound Boundary Detection)

The automatic wound boundary detection feature does not replace a clinician's judgment. A clinician with appropriate expertise is still required to review and edit the auto outline before accepting it. The more complex the wound boundary the more likely the user will need to manually edit the automatic boundary or revert to manually tracing the image.

Use the Auto Boundary Detection tool to reduce the time it takes to trace a wound. The automatic wound boundary detection feature allows you to use a manually drawn outline as a region of interest (ROI) and then instruct Silhouette to automatically detect the wound boundary within the ROI. The automatic wound boundary detection algorithm works best when used on wounds with well defined boundaries (e.g. a typical diabetic foot ulcer).

To use the tool:

- 1. Use the New Outline tool to draw a region of interest around the wound. This helps the automatic detection by identifying the approximate area of the image where the wound is. Always draw the region of interest so that the wound is fully encapsulated inside of the drawn outline.
- 2. Select the Auto Boundary Detection tool.
- 3. Select the outline you want to use as the ROI from the image. If there is only one outline on the image it is automatically used as the ROI.
 - If the wound boundary is able to be detected automatically inside the ROI, then the ROI outline will be replaced with the automatically detected boundary outline.
 - If the wound boundary can not be detected inside the ROI for any reason, then an error will be shown at the top of the screen. Make an edit to the region of interest or delete it to clear the error. You can then retry the automatic wound boundary detection or trace the wound boundary manually.
- 4. Once the automatic wound boundary detection has taken placed you can use the Edit **Outline** tool to adjust the automatically generated outline.



The Automatic Wound Boundary Detection feature provides best effort detection of the wound boundary. The automatic detection can be confused by foreign objects or complex features in and around the wound.

Make sure you review the generated boundary using your clinical judgment, and only accept it if you agree it is an accurate outline of the wound boundary.

You can use the **Undo** button to undo the Automatic Wound Boundary Detection.

The Auto Boundary Detection button is disabled if there are no outlines on the image or if there is an error shown on the screen.

The availability of the **Auto Boundary Detection** tool is dependent on your specific system configuration and it can be enabled or disabled by your system administrator.



The Auto Boundary Detection tool can be selected multiple times. Each time the wound outline will get smaller until a boundary can not be discovered inside the existing boundary.

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Undo

Use the **Undo** button to undo the last tracing action.

View Controls

The view controls allow you to change what you see on the image.



Show Lasers

Select the **Show Lasers** button to show or hide the SilhouetteStar lasers on and off in the image. The button is highlighted if the lasers are currently shown.



Show Outlines

Select the **Show Outlines** button to show or hide the rulers and outlines that are drawn on the image. The button is highlighted if the outlines are currently shown.

Using the Tracing Tools

Selecting the New Outline tool shows an on-screen pencil in the middle of the image.

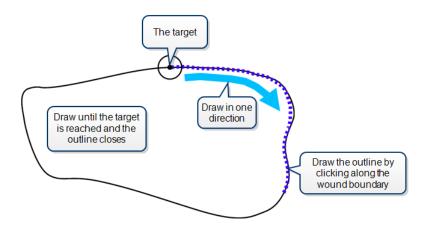
To trace a wound boundary or a region of interest:

1. Drag the pencil to the edge of the wound. Do not hold the pencil in one location on the image while dragging it because that will cause the pencil to begin drawing.

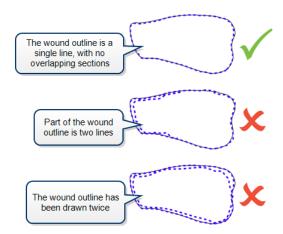


If you are intending to use the **Auto Boundary Detection** tool then drag the pencil outside the wound and trace around the wound, not along the edge. The Automatic Wound Boundary Detection feature will look for the wound boundary inside the outline you draw (region of interest).

- 2. Hold the pencil in one spot for approximately 1 second to start the tracing. The target (a dot with a circle around it) appears to indicate that the tracing has started.
- 3. Move the pencil along the edge of the wound and it will automatically drop points as you go.
- 4. Draw in one direction until the circular target (the starting point) is reached.

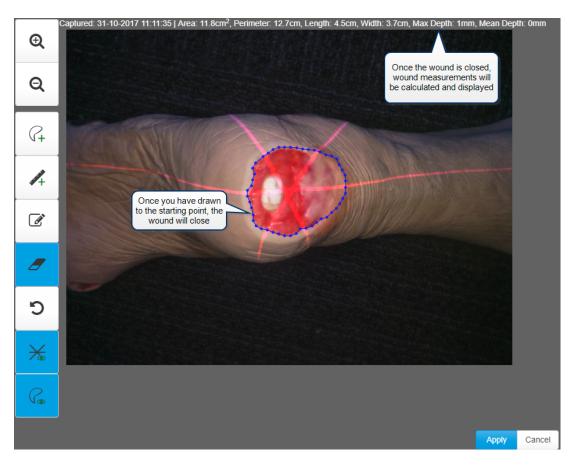


When tracing the wound boundary, it is important to draw in one direction. For example, draw in the clockwise direction or the counterclockwise direction, but do not draw in one direction then switch to the other direction. Ensure that the different parts of the outline do not overlap:



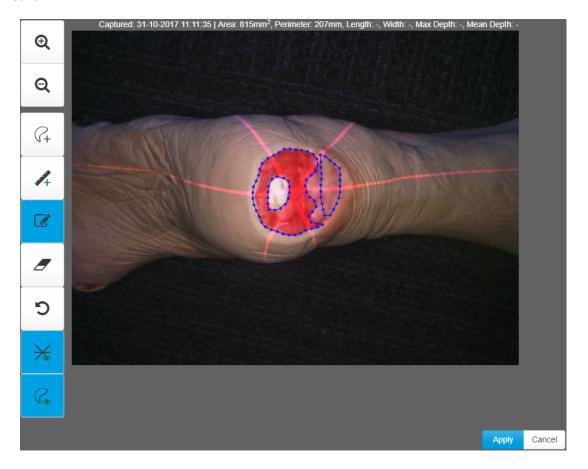
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Once you have reached the target, the outline closes and the wound's area and perimeter are displayed at the top of the screen. The maximum depth and volume may also be displayed for some wounds. See the example in the image below:



You can also draw outlines of any wound fragments or islands. To do this, select the **Add Outline** button and trace the island or fragment, ensuring the outline is closed. Silhouette automatically regards outlines inside other outlines as islands and separate outlines as fragments.

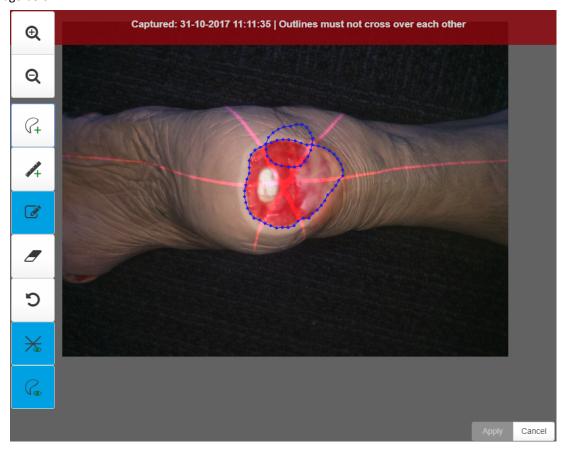
When you outline islands or fragments for a wound, maximum depth and volume are not calculated or displayed for that wound.



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Use the **Undo** button to remove the tracing point by point.

If there is a problem with the outlines or measurements, a message is presented at the top of the image window. Typically, the resolution to most errors is to remove or edit the offending outline and try again. See the example in the image below:



Clinical Data Administration

Silhouette provides the ability to administer clinical data (delete, move, or change dates). The administration of clinical data should only be performed by adequately trained staff as the changes are not able to be automatically undone.

When performing data administration on active records there is an opportunity for clinicians to be capturing or modifying data related to the same record elsewhere in the Silhouette system. Silhouette protects the system and data integrity by managing concurrent change requests to records, see "Concurrency Considerations" for more details.

To confirm data administration changes you will be asked to enter a reason, which can be a code to a request form or simply a short statement about why this data is being changed. See "Data Administration Confirmation Screens" for more details.

ARANZ Medical can provide data administration services if you are uncertain of data administration impacts or do not have adequately trained staff.

Clinical data administration includes the following data administration functions:

- Delete Patient, see Managing Patient Records
- Delete Wound, see Managing Wound Records
- Delete Assessment, see Managing Assessment Records
- Move Assessment, see Managing Assessment Records
- Change Assessment Date, see Managing Assessment Records
- Move Image, <u>See "Managing Images"</u>

Concurrency Considerations

Silhouette is a distributed system. The central store for patient records is the SilhouetteCentral database however multiple users might be using a patient record in different places within the system. All of these activities might occur concurrently:

- Users can be interacting with the patient record in their web browsers.
- Users can be viewing the patient record or capturing data using SilhouetteConnect offline.
- Users can be capturing data for the patient record using SilhouetteLite+ offline.
- A clinical administrator can be cleaning up the database by performing clinical data administration tasks.

In a distributed system where data is being changed concurrently there is always a choice about whose data to keep and how to merge that data.

Silhouette's typical data concurrency policy is that the person to make the latest change to a Patient, Wound or Assessment record has their change preserved and concurrent changes made earlier will be discarded, images will be preserved on the SilhouetteCentral disk but will not be available to Silhouette users.

The data concurrency policy is different when a data administration task has been performed on a record. Data administration tasks can only be performed directly on SilhouetteCentral. If a clinical data administrator has performed a modification to a record, this will always be persisted. Changes submitted from offline users (using SilhouetteConnect, SilhouetteLite, or SilhouetteLite+) will be ignored. A simple example of what can happen:

- A duplicate patient record is created in error.
- A SilhouetteConnect user downloads the duplicate patient record.
- Another user asks that the duplicate patient record is deleted.
- The clinical data administrator deletes the duplicate record in SilhouetteCentral. The offline users will not get the update until they sync.
- The SilhouetteConnect user records some data on the duplicate record.
- The SilhouetteConnect user syncs their changes to SilhouetteCentral.
- The duplicate record remains deleted and the SilhouetteConnect user must re-record their data.

It is good practice to implement usage policies that aim to reduce the risk of concurrent changes becoming an issue.

- Do not download more patient records that you need to into SilhouetteConnect.
- Synchronize SilhouetteConnect and SilhouetteLite+ devices regularly.
- Schedule data administration activities for an off-peak usage time.
- Rather than directly deleting patient records, setup a 'pending deletion' unit which only clinical data administrators have access to, move patients into the 'pending deletion' unit and leave them until you are confident no one is using those records.
- Use the auxiliary text on a wound to mark it as 'pending deletion' while you make sure all data recorded for that wound is collected before deleting it.

If you believe you have lost access to some data due to concurrency issues then the ARANZ Medical support team may be able to help attempting to recover it.

Data Administration Confirmation Screens

The clinical data administration tools all present a confirmation screen before completing the task. The confirmation screen describes the change to be made and any other relevant data that may be impacted by the change.

Confirmation Screen When Deleting Data

The screen below shows the Delete Wound confirmation screen, but is typical for other tools that delete clinical data.

Delete Wound Are you sure you want to delete the following wound? A: Scalp, Right Lateral A: 1 assessment will be deleted: • Wound Assessment for Wound A on Scalp, Right Lateral: 2019-06-17 13:33 Deleting from patient Full Name Max Zorin PATENTIA 1944-02-29 Unit Default Unit Reason * Please enter a reason for performing this action

- The detail of the item being deleted. This section lists any related data that will also be deleted.
- Contextual information about the clinical record that the item is being deleted from. The example in the image above shows that the wound is being deleted from a patient.
- Reason

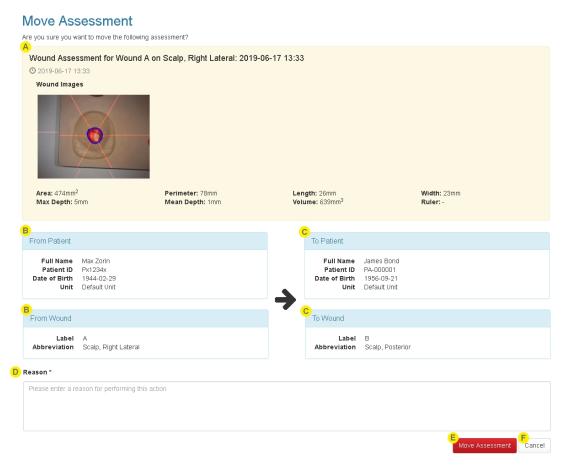
Enter a short reason for performing the delete action.

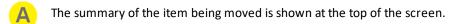
The reason is saved in the database for audit reasons but cannot be seen within the Silhouette web site. ARANZ Medical can provide the information required to retrieve the reason from the database for you if you need it.

- Select the **Delete** button to confirm and save the changes.
- Select the **Cancel** button to return to the Clinical UI without saving any changes.

Confirmation Screen When Moving Data

The screen below shows the Move Assessment confirmation screen, but is typical for other tools that move clinical data.





From Patient and From Wound are the patient and wound the item being moved currently belongs to.

From Wound is only displayed if the item being moved belongs to a wound (e.g. an image in the portfolio or a patient assessment are not assigned to a wound).

A single **Patient** box is shown to provide context for the data being moved if the data being moved between wounds on the same patient.

To Patient and To Wound are the patient and wound the item is being moved to.

To Wound is only displayed if the item being moved belongs to a wound (e.g. an image in the portfolio or a patient assessment are no assigned to a wound).

Reason

Enter a short reason for performing the move action.

The reason is saved in the database for audit reasons but cannot be seen within the Silhouette web site. ARANZ Medical can provide the information required to retrieve the reason from the database for you if you need it.



Select the **Move** button to confirm and save the changes.



Select the **Cancel** button to return to the clinical UI without saving any changes.

Managing Patient Records

The ability to manage a patient record is available in SilhouetteCentral and SilhouetteConnect in standalone mode only. If SilhouetteConnect is being used in synchronized mode then the patient data administration must be performed in SilhouetteCentral.

Delete patient is the only patient record data administration option available in the current version of Silhouette.

To find the patient record administration options:

- 1. Select the patient in Silhouette (see The Patient Selection Screen).
- 2. Select the data administration cog menu on the The Patient Dashboard page.





Patient Record Administration Menu

The button with the cog icon is available on the Patient Summary page if you have permissions to perform data administration tasks for the patient record.

Select the button to show the data administration options available.



Delete Patient

Deletes the currently selected patient record and all associated clinical data (wounds, images and assessments).

The delete patient menu item is available to Silhouette users who have been granted the Can Delete Patient permission.

See "Delete Patient" below for more details.

Delete Patient

Deleting a patient record also deletes all clinical data (images, wounds and assessments) associated to that patient record.

Before the delete proceeds, you will be asked to confirm the action with a reason. See "Data Administration Confirmation Screens" for more details on confirmation screens.



Deleting a patient record is not easily undone, contact ARANZ Medical Support for assistance if you need to recover deleted data.

Deleting a patient record means that patient data is not accessible to any Silhouette users, however, the patient data is still in the system database. To permanently remove the patient data from Silhouette contact ARANZ Medical Support for assistance.

Managing Wound Records

The ability to manage wound records is available in SilhouetteCentral and SilhouetteConnect in standalone mode only. If SilhouetteConnect is being used in synchronized mode then the wound data administration must be performed in SilhouetteCentral.

Delete wound is the only wound data administration option available in the current version of Silhouette.

To find the wound data administration options:

- 1. Select the patient in Silhouette (see The Patient Selection Screen).
- 2. Select the wound from the Patient Sidebar.
- 3. Select the data administration cog menu on the Wound Dashboard page.





Wound Data Administration Menu

The button with the cog icon is available on the Wound Summary page if you have permissions to perform data administration tasks for the wound.

Select the button to show the data administration options available.



Delete Wound

Deletes the currently selected wound and all related clinical data (including assessments, images and tracings) for the wound.

The delete wound menu item is available to Silhouette users who have been granted the Can Delete Wound permission.

See "Delete Wound" below for more details.

Delete Wound

Deleting a wound also deletes all clinical data (wound assessments and images) associated to that wound.

Before the delete proceeds, you will be asked to confirm the action with a reason. See "Data Administration Confirmation Screens" for more details on confirmation screens.

Deleting a wound does not allow the wound label to be reused.



Deleting a wound is not easily undone, contact ARANZ Medical Support for assistance if you need to recover deleted data.

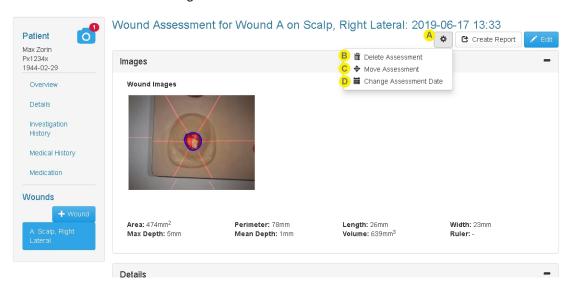
Deleting a wound means that the wound data is not accessible to any Silhouette users, however, the data is still in the system database. To permanently remove the data from Silhouette contact ARANZ Medical Support for assistance.

Managing Assessment Records

The ability to manage assessment records is available in SilhouetteCentral and SilhouetteConnect in standalone mode only. If SilhouetteConnect is being used in synchronized mode then the assessment data administration must be performed in SilhouetteCentral.

To find the assessment data administration options:

- 1. Select the patient in Silhouette (see The Patient Selection Screen).
- 2. Select the assessment from the Patient Timeline or the Wound Timeline.
- 3. Select the data administration cog menu on the assessment view.





Data Administration Menu

The button with the cog icon is available on the Assessment page if you have permissions to perform data administration tasks for the assessment, such as deleting the assessment or managing clinical data. Select the button to show the data administration options available.



Delete Assessment

Deletes the currently visible assessment and all associated clinical data, including images and tracings.

The delete assessment menu item is available to Silhouette users who have been granted the Can Delete Assessment permission.

See "Delete Assessment" below for more details.



Move Assessment

Moves the currently visible assessment to a different wound, which can be for the same patient or a different patient. Moving the assessment moves all associated clinical data, including images and tracings.

The move assessment menu item is available to Silhouette users who have been granted the Can Manage Clinical Data permission.

See "Move Assessment" below for more details.



Change Assessment Date

Changes the assessment date and time.

The change assessment date menu item is available to Silhouette users who have been granted the Can Manage Clinical Data permission.

See "Change Assessment Date" below for more details.

Delete Assessment

Deleting an assessment also deletes all data contained within that assessment, including images and tracings. Deleting a wound does not allow the wound label to be reused.

Before the delete proceeds, you will be asked to confirm the action with a reason. See "Data Administration Confirmation Screens" for more details on confirmation screens.



Deleting an assessment is not easily undone, contact ARANZ Medical Support for assistance if you need to recover deleted data.

Deleting an assessment means that the assessment data is not accessible to any Silhouette users, however, the data is still in the system database. To permanently remove the data from Silhouette contact ARANZ Medical Support for assistance.

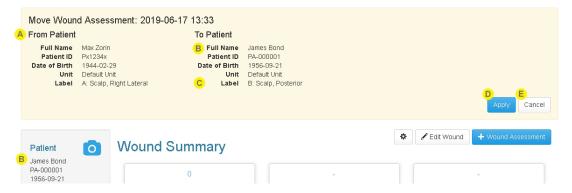
Move Assessment

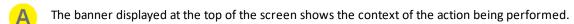
Moving an assessment also moves all data contained within that assessment to the new patient and/or wound, including images and tracings.

Moving an assessment requires that a destination is selected. Once Move Assessment is selected a banner is shown to allow you to select a destination patient and wound, if necessary.



The figure above shows the move assessment banner without a destination selection completed. The figure below shows the move assessment banner with a destination patient and wound selected.





The current patient and wound label is also shown on the left as the **From Patient** to provide continued context as you complete the action.

If moving a Patient assessment then the Label is not shown.

Selection screen and the Patient Sidebar.

- The banner also shows the patient currently selected in Silhouette as the **To Patient**.

 To change the **To Patient** navigate in the Silhouette Clinical UI as you would normally, using the Patient
- Instructions are shown in a dark orange color if the current patient or wound selection is not a valid place to move the assessment.
- Once a destination is selected then select the **Apply** button.

 Before the move proceeds, you will be asked to confirm the action with a reason. See "Data Administration Confirmation Screens" for more details on confirmation screens.



Select **Cancel** to cancel the Move Assessment action and close the banner.

The move will automatically cancel if you attempt to navigate to the Admin section or begin creating another assessment.

Change Assessment Date

Changing an assessment date is useful if the assessment was recorded in Silhouette at a time that wasn't the actual time of assessment. This may be because the assessment was completed on paper and then entered retrospectively or if some details of the assessment are pre-filled and saved prior to the assessment being completed.

The assessment date and time (not the image date and time) is used as the date and time to graph wound measurements made during the assessment.

Assessments have the time zone details recorded with them based on the time zone of the computer or mobile device used to create the assessment. Changing the assessment date also allows the user to change the assessment time zone.

When you select the **Change Assessment Date** data administration option you will see a confirmation screen which allows you to select a new date, time and timezone.

Change Assessment Date Are you sure you want to change the assessment date? Wound Assessment for Wound A on Scalp, Right Lateral: 2019-06-18 05:33 O 2019-06-18 05:33 Wound Images Perimeter: 78mm Length: 26mm Width: 23mm Volume: 639mm³ Max Depth: 5mm Mean Depth: 1mm Ruler: B Patient Full Name Max Zorin Patient ID Px1234x Date of Birth 1944-02-29 Unit Default Unit C Assessment's original date and timezone: 2019-06-17 13:33 US/Eastern Please enter the new date D New date ' 2019 06 17 13 : 33 E Timezone * Pacific/Auckland Some images were taken on a different date G Reason * Please enter a reason for performing this action

- The summary of the assessment being modified is shown. This summary is similar to the summary that appears on the Patient timeline. The summary includes the current assessment date and time as viewed in the main clinical UI, i.e. in the local timezone of the user viewing the record.
- B The relevant **Patient** details are shown to provide confirmation that you are changing the assessment for the correct patient.



The assessment's current date, time and timezone are shown as they are recorded in the database.

The assessment's current date and time may differ from the date and time displayed on the assessment summary if you are viewing the assessment from a computer in a different timezone compared to the timezone where the assessment was captured.

- D
- Set the **New Date** and time by either typing the boxes provided or by selecting the calender icon and using the date picker.
- E

Set the **Timezone** by using the drop-down list to select the timezone you wish to use for the assessment. The timezone you select will be used in the PDF assessment report and data exports.



Warnings

A number of warnings may be shown to alert you to a change that you may not intend.

- Some images were taken on a different date or Some images have more than a 12 hour difference There are images on the assessment which have a capture time that differs significantly from the date
 and time you are setting. This is unusual as the measurements made from the images will be shown as
 having be measured at the new assessment date and time on any graphs. Setting this too far out might
 skew the representation of the healing.
- There is a 5 day difference with the current date You are attempting to change the assessment date by more than 5 days. Check the year and month selected to confirm you are making the change you intend to make.
- The new date will cause the patient's timeline to change The new date you have selected will cause this assessment to show either before or after other items that are already on the patients timeline. If you do not intend to adjust the order of the assessments on the timeline then go back and review the other items on the timeline before confirming the change.



Reason

Enter a short reason for changing the date.

The reason is saved in the database for audit reasons but cannot be seen within the Silhouette web site. ARANZ Medical can provide the information required to retrieve the reason from the database for you if you need it.



Select the **Change Date** button to confirm and save the changes.



Select the **Cancel** button to return to the Clinical UI without saving any changes.

Managing Images

The ability to manage images is available in SilhouetteCentral and SilhouetteConnect in standalone mode only. If SilhouetteConnect is being used in synchronized mode then the image data administration must be performed in SilhouetteCentral.

Move images is the only image administration option available in the current version of Silhouette.

To find the image administration options:

- 1. Select the patient in Silhouette (see The Patient Selection Screen).
- 2. Select the camera icon from the patient sidebar to open the image portfolio in image review mode.





Data Administration Menu

The button with the cog icon is available for each image in the portfolio if you have permissions to manage clinical data. Select the button to show the image administration options available.



Delete Image

Delete image is not treated as a data administration task. All users who capture images have the rights to remove images before they are assigned to a wound. See "Assigning Captured Images" for more details.



Move Image

Moves the associated image to a different patient. Moving the image moves all associated tracing data.

The move image menu item is available to Silhouette users who have been granted the Can Manage Clinical Data permission.

See "Move Image" for more details.

Move Image

Moving an image also moves all associated tracings.

Moving an image requires that a destination patient is selected. Once **Move Image** is selected a banner is shown to allow you to select a destination patient.



- The banner displayed at the top of the screen shows the image being moved.
- The **From Patient** shows the details of the patient that the image is being moved from.
- The **To Patient** shows the details of the patient that the image will be moved to.

 To change the **To Patient** navigate and select patients in Silhouette as you would normally.
- Once a destination is selected then select the **Apply** button.

 Before the move proceeds, you will be asked to confirm the action with a reason. See "Data Administration Confirmation Screens" for more details on confirmation screens.
- Select **Cancel** to cancel the Move Image action and close the banner.

 The move will automatically cancel if you attempt to navigate to the Admin section or begin creating an assessment.

The Silhouette Admin User Interface (UI)

The options available under the Silhouette Admin in the Application Menu are dependent on your permissions, the application (SilhouetteConnect or SilhouetteCentral) in use, the application deployment mode and the application license. For most clinical users the only options available are:

- · Profile. Allowing you to view and edit your own profile information, including the ability to change your password. See "Changing Your Password" for more details
- License. Allowing you to check and update the licensing for the application.

See the Silhouette Administration User's Guide for more information about other Silhouette administration features.

Profile

In the Profile screen, you can:

- Change the password you use to log on to Silhouette. See Changing Your Password.
- Change other account settings, such as your name, contact details or email address.



You may not be able to access the Account screen if your user account is administered centrally via our IT infrastructure. In this case you should contact your systems administrator if you need to change any details of your user account displayed within Silhouette.

Changing Your Password

To change your Silhouette password:

- 1. Navigate to the Admin -> Profile screen.
- 2. Select the Change Password button.
- 3. Enter your existing password in the Current Password box.
- 4. Enter your new password in both the New Password and Confirm Password boxes.
- 5. Select the Save button to update the system with your new password.

User names and passwords are used across the Silhouette Product Suite, so you will need to use the new password when logging in to SilhouetteCentral, SilhouetteConnect, SilhouetteLite or SilhouetteLite+.

License

The **Admin > License** screen allows you to update the license for the current Silhouette component. For example, the **License** screen in SilhouetteCentral shows details about the licensing of SilhouetteCentral and the **License** screen in SilhouetteConnect shows details about the licensing for that install of SilhouetteConnect. The following license details are displayed:

- **1. Client Code**: The client code that the product is licensed against. If there is no client code in the text box, then the Silhouette instance is unlicensed and operating in a trial mode.
- 2. Created: The creation date of your license.
- 3. Expires: This is the expiry date of your license. The word 'Never' is displayed if you have a perpetual license.
- **4. Features**: Any optional software features that have been licensed are listed here.

Licensing Silhouette

A **Check for Update** section with an **Update** button is provided below the license details. To license Silhouette for the first time, enter your client code and select the **Update** button. To subsequently update your license, for example if you have purchased additional features or extended your warranty, it is only necessary to select the **Update** button.

In order for the automatic license update process to function, access to the Internet is required. If there is no Internet access, instructions on obtaining the license file manually are provided once the **Update** button is pressed.

HTTP Proxy Configuration

The ARANZ Medical licensing server is hosted on the internet. When attempting communication with the licensing server, SilhouetteCentral uses .NET's default proxy settings. If your network environment requires the use a different proxy server, update the defaultProxy setting within the SilhouetteCentral web.config file.

As an example if you desire SilhouetteCentral to make use of a proxy server located at 192.168.2.1 port 8888 you could update the relevant section of the web.config file as follows:



Please refer to Microsoft's online .NET framework configuration documentation for further details.

SilhouetteConnect Admin

The Administration features available in SilhouetteConnect depend on the mode of operation.

In standalone mode, the administration of SilhouetteConnect includes:

- Users
- Groups
- Assessments
- Patient Notes
- Units
- SilhouetteStar 2
- License

In synchronized mode, the administration of system settings is controlled in SilhouetteCentral. The settings available in SilhouetteConnect are:

- Profile (see Profile)
- SilhouetteStar 2
- License (see License)

Refer to the Silhouette Administration User's Guide for details on all of the above items.

There are also some hidden SilhouetteConnect settings that can be configured by ARANZ Medical support users. Contact ARANZ Medical Support before changing these settings. These hidden settings include:

- Synchronization Settings
- Organization Settings (includes display formats and application lock time for standalone installs)

Troubleshooting

The troubleshooting section provides solutions for common problems you may have using the Silhouette clinical tools. For any issues you experience with Silhouette that are not resolved by following the instructions in this topic, please contact your organization's IT support team or ARANZ Medical customer support.

- Recovering Forgotten Password
- Troubleshooting SilhouetteLite+
- Troubleshooting SilhouetteStar

Recovering Forgotten Password

If you have forgotten your password, select the "Forgot your Password?" link on the log on screen. If you do not see this link, your administrator may have chosen to disable this feature, in which case contact your system administrator for further advice on how to regain access to your account.



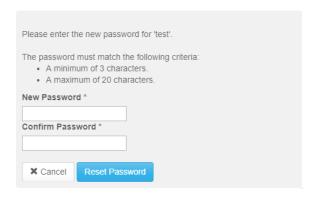
Once the "Forgot your password?" link is selected, you are prompted to enter your email address. You should enter the email address that is associated with your Silhouette user name.



A message is displayed to confirm that an email with instructions to reset your password has been sent to the email address you specified.

Password reset request Information on how to complete your password reset request has been sent to your email address.
Please check the email for instructions on how to complete the password reset.

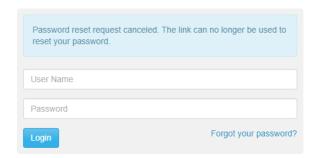
Check your email account for the email sent by Silhouette. Use the link in the email to reset your password. Selecting the link loads the Silhouette website and prompts you to enter a new password.



You will receive confirmation that your password has been changed. You can now proceed to log on with the new password.



If you receive a password reset request email and do not remember requesting it, an additional link in the email may (depending upon system configuration) be provided that allows you to cancel the password reset request so any other person who manages to view the email can not reset your password.



In some circumstances you may get a password reset email that indicates your user account is not able to have its password reset via email. In this scenario contact your system administrator for further instructions on how to reset your password.

Troubleshooting SilhouetteLite+

ISSUE: The SilhouetteLite+ sensor does not show in the SilhouetteLite+ App

If the SilhouetteLite+ sensor either does not show in the 'Select Sensor' list or if the App reports 'Sensor Not Found' then try placing the sensor on the charger. A 10 minute charge should give enough charge for an assessment to be completed.

The sensor must be removed from the charger before it communicates with the App again.

ISSUE: The SilhouetteLite+ App is not uploading data to SilhouetteCentral

Go through the following checklist to confirm that the App can upload data to SilhouetteCentral:

- Check that your device has a Wi-Fi or a Mobile Data network connection.
- If using Mobile Data then check the settings App to confirm that SilhouetteLite+ is allowed to use Mobile Data.
- Check that your device can reach your instance of SilhouetteCentral by putting the SilhouetteLite+ sync URL into the web browser on the device.
- Check with your system admin to confirm your user account is not locked or disabled.
- Check to see if the patients, wounds, or assessments you expect to be uploaded to SilhouetteCentral are uploaded (i.e. determine if the problem is uploading data or just in the reporting of offline data on SilhouetteLite+).
- If the app is constantly blocked showing Syncing Saved Data and the data upload is not occurring in the normal time, then force close the App and then reopen it and give it more time to upload.
- If you have not previously logged out of the App and the Syncing Saved Data message is showing, then turning the device to airplane mode and then opening the App will allow you to work offline.

If the problem persists then open the settings menu in the App (cog icon in the Patients screen) and select Logs. There is an email link in the logs screen and this can be emailed to your system administrator to provide further help.

ISSUE: The SilhouetteLite+ App reports Bluetooth off even if device bluetooth is on

The SilhouetteLite+ App does not detect the bluetooth state from the device correctly on some devices. This can be a device error and can be remedied by switching the device bluetooth off then on again.

Troubleshooting SilhouetteStar

ISSUE: SilhouetteStar is not detected on a USB connection

If SilhouetteConnect reports that the SilhouetteStar device is not connected when it is plugged in, or if SilhouetteStar's lasers or LEDs do not turn on during image capture:

- Check that the USB cable is connected properly at both ends. Unplug it and plug it back in.
- Check that the USB cable is not damaged. Use a different SilhouetteStar branded USB cable, if one is available.
- Try a different USB port on your computer.
- Check that the port your cable is connected to supports USB 2.0.
- Ensure that your USB port is not locked. If you think your USB port might be locked, contact your organization's IT administrator.
- Exit SilhouetteConnect and restart the computer.

A SilhouetteStar 2 in wired mode also requires some PC firewall rules to be added. These firewall rules are added to the Microsoft Windows™ firewall by the SilhouetteConnect installer. If a different firewall is being used then rules to allow inbound TCP connections on ports 9874 and 9875 must be added to the configuration. If your firewall is centrally managed then you will need to contact your organization's IT administrator.

ISSUE: Laser detections are poor

The ability for the laser lines to be detected in the image can be effected by excessive ambient light or by operating the camera outside of focus length. Poor laser detection can be seen in the Image Viewer as either little blue dots (indicating laser detection points) placed randomly on the image or by excessive brightening of parts of the image. If poor laser detections are found then try the following:

- Reducing the amount of ambient light on the scene. The camera is designed to work in typical indoor florescent lighting. Closing curtains or having someone stand so they create a shadow on the scene can help provide better laser detections and a generally good image.
- Make sure that the image is taken at the correct focal length by ensuring the lasers form a star patten on the scene.
- Reduce the depth in the scene by placing something behind what is being imaged. If the body part being imaged is very small and the background is distant then placing something behind the body part can help with the laser detection. For example, instead of imaging a finger 1 meter above the floor, have the patient place the finger on a desk or hold something behind the finger that will show the lasers.

ISSUE: The PC Wi-Fi connection drops when the SilhouetteStar 2 device is connected via USB

A feature of Microsoft Windows[™] allows the PC to automatically turn off Wi-Fi if there is another network connection present. In Windows 8 and above, the group policy "Prohibit connection to non-domain networks when connected" must be left "Not configured" or be set to Disabled. Some third party network management software may also offer similar network adapter switching features. Care must taken to determine compatibility.

The opposite problem can also occur, where a wired IP network (SilhouetteStar 2 connection) may not be allowed if there is a mobile or metered connection in place. This is typically a rule enforced by 3rd party networking or mobility software. You will need to contact your IT administrator to resolve this issue.

ISSUE: The SilhouetteStar 2 gets stuck with "Downloading..." on the screen.

The SilhouetteStar 2 device will not recover automatically if the download of a firmware update gets interrupted. An interrupted download will usually occur by removal of the USB cable or by Wi-Fi network failure mid download.

Press and hold the device trigger button for approximately 15 seconds to manually recover the device.

CTEULA and Terms of Use

The CTEULA and Terms of Use for the Silhouette suite of products are available at https://www.aranzmedical.com/silhouette-legal.