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Silhouette v4 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 the 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 4.16.
- SilhouetteConnect version 4.16.
- SilhouetteStar 2 software version 1.10.
- SilhouetteLite version 1.13.
- SilhouetteLite+ version 1.13.
- SilhouetteMobile version 4.0.

System Description

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

SilhouetteCentral is a web-based application, enabling users to, securely and centrally store, share, review and analyze the wound data collected using SilhouetteCentral, SilhouetteConnect, SilhouetteStar, SilhouetteMobile, SilhouetteLite+, and SilhouetteLite devices and applications. SilhouetteCentral can collect images directly with a SilhouetteStar 2 scanner or using built-in cameras on mobile devices.

SilhouetteCentral has four main interfaces:

- 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, roles, data fields, 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.
- SilhouetteTokenService Provides centralized user authentication services to the Silhouette suite of products. The token service can also support single sign-on (SSO) for enterprise users using the SAML2 protocol, typically by integrating with an enterprise's federated identity provider (e.g. AD FS).

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 most of the system settings are
 administered in SilhouetteCentral and then downloaded to SilhouetteConnect 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.

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 an 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.

SilhouetteMobile is an application for Apple[®] iPhone[®], and iPad[®] devices. SilhouetteMobile 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.

Intended Use

Silhouette is intended to be used as an external wound / skin condition measurement and documentation system on long term / chronic wounds or skin conditions. This is comprised of an internet-based application accessed by a non-medical imaging device (e.g., smartphone or tablet).

The imaging system is intended to be used by either trained clinical professionals or the public while the documentation system is intended to be used by trained clinical professionals.

Silhouette is not intended to be used in emergency settings.

Silhouette is not intended to make diagnostic decisions or in isolation for the monitoring of physiological processes. These must be undertaken by a trained clinical professional.

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 the system 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, the second measurement can be made in a second assessment or within a single assessment set-up with two separate image capture fields.

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

- The patient banner at the top of the patient screens includes the patient details required to positively identify the patient as well as access to the patient's image **Portfolio**.
- The **Sidebar** on the left-hand side contains links to the patient **Details**, **Notes**, and **Orders** as well as a list of both active and inactive **Wounds** defined for the patient. The sidebar can be collapsed and on small screens appears in-line with the page content.
- The Patient Summary shows all of the high-level information for the patient.
- The Wounds shows all active wounds defined for the patient.
- The **Orders** table shows the incomplete orders or requests for assessments that have been received from an integrated EHR system.
- 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 or the patient silhouette image shows The Wound Dashboard.

Guide Topics

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



Silhouette Help and About Pages



Logging In and Logging Out of Silhouette



Quick Start Workflows



Using SilhouetteStar



Using 2D and 3D Imaging in SilhouetteCentral



Using SilhouetteLite+ or SilhouetteMobile



Using SilhouetteLite



The Silhouette Clinical User Interface (UI)



The Silhouette Admin User Interface (UI)



Troubleshooting



CTEULA and Terms of Use

Silhouette Help and About Pages

Both SilhouetteConnect and SilhouetteCentral includes an About page, providing important labeling information and legal declarations, as well as links to this help documentation.

Topics



About SilhouetteCentral



About SilhouetteConnect

About SilhouetteCentral

The about page in SilhouetteCentral can be viewed by anyone who can access the website URL. It does not require them to have a user account for SilhouetteCentral.

The about page contains the information about a specific instance of SilhouetteCentral. An example is shown below:



A

Information about how to get help is shown here. The text and the help link can be customized by your system administrator.

Symbol	Meaning
e-IFU	Consult electronic instructions for use. The web address for the instructions for use is provided on the page.

The SilhouetteConnect Compatibility information is relevant only when you are deploying SilhouetteConnect with your use of SilhouetteCentral, e.g. to use SilhouetteStar in wired mode or to support off-line data review and input.

A download link for the customized SilhouetteConnect installer for this instance of SilhouetteCentral is provided.

Information on the synchronization database version is also provided. Your ARANZ Medical support person may ask for this information in order to provide assistance.



B

The product information provides the detailed information you need to identify the product you are using.

Symbol	Meaning	
REF	Manufacturers reference / Model number.	
MD	Medical Device. SilhouetteCentral is an accessory to the SilhouetteStar medical device. Silhouette Central is software as a medical device when Silhouette Central Imaging features are enabled.	
	Manufacture. Identifies the manufacturer of the product.	
	Date of Manufacture. Specifies the date this software version was built.	
EC REP	European (CE) Authorised Representative	
GB REP	UK (UKCA) Authorised Person	
UDI	The Unique Device Identifier (UDI) Carrier for the product is provided as a GS-1 Data Matrix and as plain text.	
	Information included in the data matrix is:	
	• (01) - Global Trade Identification Number (GTIN)	
	• (21) - Serial Number given to this instance of SilhouetteCentral	
	• (8012) - Software version number	
CE	CE mark. EU Declaration of Conformity and Notified Body Identifier	
UK CA	UKCA mark. UK Conformity Assessed Marking	

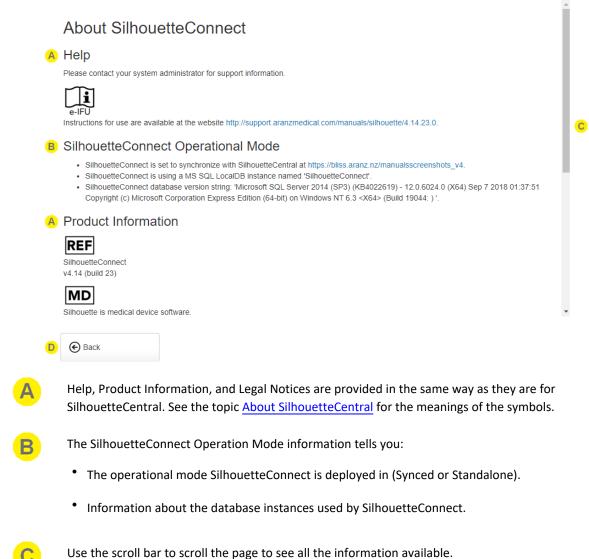
D

Links to legal notices include the license agreement for SilhouetteCentral and information about open-source licenses used in Silhouette components.

About SilhouetteConnect

The about page contains the information about a specific instance of SilhouetteConnect.

An example is shown below:



Ose the scroll bal to scroll the page to see all the information availab

Select **Back** to return to the SilhouetteConnect application.

Logging In and Logging Out of Silhouette

To use the Silhouette system, you need to first login. Once logged in, the permissions allocated to you govern both the data you can see and the operations you can perform.

The login workflow changes depending on the configuration of Silhouette and the Silhouette client you are using (e.g. SilhouetteCentral website vs. SilhouetteConnect application).

Topics



Accessing SilhouetteCentral



Accessing SilhouetteConnect



Logging In to Silhouette



License Warnings



Ending Your Silhouette Session

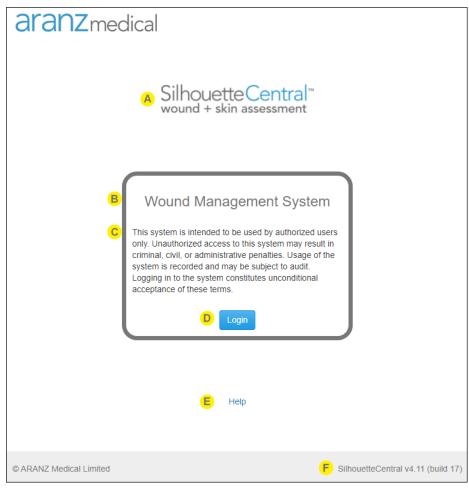
C

D

Accessing SilhouetteCentral

To access SilhouetteCentral, navigate to the URL of your SilhouetteCentral instance using your web browser.

If you are already authenticated to the system and have an active session, you will see the patient search screen. If you need to start a new user session in SilhouetteCentral, you will see the unauthenticated landing page.



The SilhouetteCentral word mark is shown to help you confirm you are accessing SilhouetteCentral rather than SilhouetteConnect.

The system identification is shown as configured by the system administrator. Use this to confirm that you are accessing the correct system or instance (e.g. training vs. production).

The login banner text is shown if an administrator has configured it. The login banner will contain any conditions or terms of use you are agreeing to by accessing the system.

If you are concerned about anything stated in the login banner, do not select the **Login** button and contact your system administrator to confirm the correct actions to take.

Select the **Login** button to confirm that you want to login to the system. See the help topic <u>Logging In</u> to <u>Silhouette</u> for more details.



Select the Help link to open the help documentation web pages. This link typically takes you to a web page where you can access the Silhouette user guides, however the link can be customized for your system.



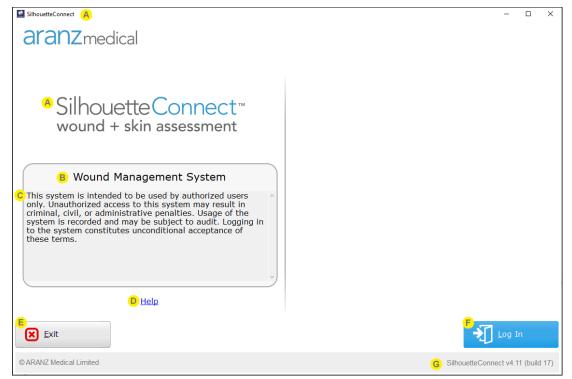
The footer of the page includes the Silhouette version number, which can be helpful if you require support.

B

Accessing SilhouetteConnect

To access SilhouetteConnect, open the Silhouette Connect application on your PC. The SilhouetteConnect start screen contains some helpful information to review before proceeding with the login.

Some of the information shown on the start screen can be configured by your system administrator. If SilhouetteConnect is set to Synchronized mode, the information shown on this screen is updated only after a successful sync with SilhouetteCentral.



- The application title and the SilhouetteConnect word mark is shown to help you confirm you are accessing SilhouetteConnect application.
- The system identification is shown as configured by the system administrator. Use this to confirm that you are accessing the correct system or instance (e.g. training vs. production).

If the SilhouetteConnect is setup to synchronize with SilhouetteCentral, the first time you start SilhouetteConnect the system identification is derived from the configured SilhouetteCentral URL.

C The login banner text is shown if an administrator has configured it. The login banner will contain any conditions or terms of use you are agreeing to by accessing the system.

If you are concerned about anything stated in the login banner, do not select the **Login** button and contact your system administrator to confirm the correct path forward.

- Select the **Help** link to launch the help documentation in your default web browser. This link typically takes you to a web page hosted at aranzmedical.com where you can access the Silhouette user guides, however the link can be customized for your system.
 - Select the **Exit** button to close the SilhouetteConnect application.

Select the **Login** button to confirm that you want to login to the application. The login flow depends on the operational mode and the previous state of Silhouette.

If using SilhouetteConnect in Standalone mode, you will be logged in using your Windows identity and will not be asked to enter any credentials.

If using SilhouetteConnect in Synchronized mode, you must be connected to a network and can browse to the SilhouetteCentral URL to be able to login to SilhouetteConnect. When you select the **Login** button, your default web browser will open to allow you to authenticate, see <u>SilhouetteConnect Web</u> Browser Login.

The online authentication can be skipped in a Synchronized mode SilhouetteConnect if all the following conditions are met:

- The Silhouette system is configured to Allow SilhouetteConnect Offline Operation.
- You have previously logged in to SilhouetteConnect.
- You have not exceeded the systems configured SilhouetteConnect Maximum Offline Session Time.
- You have not explicitly logged out.



E

The footer of the page includes the Silhouette version number, which can be helpful if you require support.

SilhouetteConnect Web Browser Login

When you select the **Login** button in Synchronized mode SilhouetteConnect, your default web browser will open to allow you to authenticate. Once the login process is completed in your web browser, most web browsers will prompt you asking if you want to allow the SilhouetteConnect application to open. Allowing this means that the SilhouetteConnect application will receive your authentication from the web site and complete the login.

If you have closed SilhouetteConnect it won't automatically open, you can reopen the application and initiate a new login request.

See the help topic Logging In to Silhouette for help with the login process in the web browser.

The SilhouetteConnect application will show a message to indicate it is waiting for confirmation of the login from the web browser, providing Cancel or Open Web Browser buttons. If the login takes too long, the request will timeout and SilhouetteConnect shows a message to try logging in again.

SilhouetteConnect	- 0	×
aranz medical		
SibouetteConnect™ wound + skin assessment Mound Management System Nis system is intended to be used by authorized users only. Unauthorized access to this system may result in criminal, civil, or administrative penalties. Usage of the system is recorded and may be subject to audit. Logging in to the system constitutes unconditional acceptance of these terms.	Log in via web browser Your default browser should open up automatically. If nothing happens try clicking the button below.	
Help		
Exit	Logging In	
© ARANZ Medical Limited	SilhouetteConnect v4.11 (build 1	7)

Select the **Cancel** button to cancel the login request. Canceling the login request enables the **Exit** and **Login** buttons again.

Select the **Open your browser** button to re-initiate the login request in your web browser.

Use the **Open your browser** button if the web browser does not open by itself, if you close the browser by mistake, if you cancel the request in the web browser, or if you cancel the web browser request to open the SilhouetteConnect application by mistake.

If you close SilhouetteConnect while it is waiting for the web page login it will not automatically relaunch. Re-open SilhouetteConnect and initiate another login.

?

Occasionally the confirmation of the login can get blocked between the web browser and the SilhouetteConnect application. If you have completed the login process in the web browser but SilhouetteConnect still appears to be waiting for the confirmation (or shows that the request has timed out), close the web browser, cancel the request from SilhouetteConnect, and then exit and restart SilhouetteConnect.

Logging In to Silhouette

Logging in to Silhouette always uses your web browser, regardless of the component of Silhouette that you are using. The only exception is when using SilhouetteConnect in Standalone mode, see <u>Accessing SilhouetteConnect</u> for more details.

It is important to log in using your unique identity. Silhouette records the names of users viewing, creating, and modifying patient records, and using the correct username ensures accurate auditing.

The exact login screens you will see vary depending on the system configuration, but can include:

- The Silhouette Login Screen
- Access Denied Screen

The Silhouette Login Screen

If your Silhouette system is configured to allow local user login or is configured with more than one SSO option, the Silhouette login screen will be displayed.

If there is only a single SSO option configured, you be immediately signed in or shown the SSO login page.

?

The Login screen will be skipped if your web browser still has an active login session. If you want to force a login flow for some reason, Logout from SilhouetteCentral and then try the login again.

this system may result in cri	e used by authorized users only. Unauthorized access to minal, civil, or administrative penalties. Usage of the v be subject to audit. Logging in to the system constitutes these terms.
	Login with Work ID
Usemame	
Password	
	Login

A

The system identification is shown as configured by the system administrator. Use this to confirm that you are accessing the correct system or instance (e.g. training vs. production).

The login banner text is shown if an administrator has configured it. The login banner will contain any conditions or terms of use you are agreeing to by accessing the system.

If you are concerned about anything stated in the login banner, do not select the **Login** button and contact your system administrator to confirm the correct path forward.



If there are SSO options enabled there will be a **Login with** button for each configured authentication provider. Select the appropriate **Login with...** button to use your SSO authentication provider.

If login with Silhouette local accounts is enabled, there are **Username** and **Password** fields available to enter your assigned Silhouette account details. Enter the Silhouette **Username** and **Password** supplied to you and select **Login**.

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

Many browsers prompt you to save a **Username** and **Password** for websites you log in to. Check your organizations policies on this feature, if in doubt do not permit the browser to save your login details for Silhouette.

E

Use the **Cancel** link if you wish to cancel the login request.

Use the **Forgot Password** link to reset the password using your email address that is associated to your Silhouette user account.

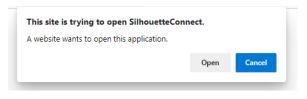
Forgot password emails are only available for Silhouette local accounts, not for user accounts provisioned through SSO authentication providers.

The Forgot Password link is shown if the Silhouette system is configured with appropriate SMTP emails settings and the Forgot Password email feature is enabled. See the troubleshooting topic <u>Recovering a</u> Forgotten Password for more details.

Completing the Login

Once login is completed successfully, you will be redirected back to the Silhouette client you used to initiate the login, e.g. the SilhouetteCentral website, the SilhouetteLite+ application, the SilhouetteMobile application or the SilhouetteConnect application.

- If using the SilhouetteCentral website, the redirect is seamless and happens in the same browser tab.
- If using the SilhouetteConnect application, your browser may prompt you to allow the application to open. Different web browsers have different prompts, but an example is provided below. Select Allow or Open to complete the login to SilhouetteConnect. Selecting Cancel prevents SilhouetteConnect from completing the login.





When logging in to the SilhouetteConnect application, the application is typically not be bought to the foreground. Once you respond to the web browser prompt, close the web browser tab and select SilhouetteConnect from the Windows Taskbar to use the application.

Access Denied Screen

If your account has no access assigned in Silhouette you will see a message stating Access Denied. If you see this message, it means that your account has not been assigned any permissions within Silhouette. Contact your system administrator to be granted the correct access.



License Warnings

Once logged in to SilhouetteConnect or SilhouetteCentral you may see license warnings if the license is nearing expiry. The warning is shown in a banner near the top of the screen.

 Warning! Your SilhouetteCentral license will expire in 28 days.
 Check for update
 X

 A
 B



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.



Select the **X** on the warning banner to dismiss it. The banner will be dismissed until the user logs in again.

Ending Your Silhouette Session

The way you end your login session varies depending on the Silhouette client application you are using. See the following topics:

- Logging Out From SilhouetteCentral
- Logging Out From SilhouetteConnect
- Logging Out From SilhouetteLite ,SilhouetteLite+ or SilhouetteMobile

Logging Out From SilhouetteCentral

To Logout from SilhouetteCentral, select Logout from the application menu.

Logging out from SilhouetteCentral, ends your session on the SilhouetteTokenService as well but does not end your session with any SSO authentication provider.

Closing the Web Browser completely is similar to logging out of SilhouetteCentral. Closing just the SilhouetteCentral Web Browser Tab, while other tabs are open, will mean that your session stays active and you will not be asked to re-authenticate when you next browse to the SilhouetteCentral website.

The system may time out your SilhouetteCentral session if you are not using it. Contact your system administrator if you would like to know what the SilhouetteCentral Idle Session Timeout is set to. Before your session is terminated there will be a message shown in the application.

You will be logged	out in 24 secs due to
inactivity.	

P If you have unsaved work when the idle session timeout expires that work is not saved.

Logging Out From SilhouetteConnect

When using SilhouetteConnect in Standalone mode then there is no **Logout** option available as the session is your Windows login session. When you have finished using SilhouetteConnect you can just close it.

When using SilhouetteConnect in Synchronized mode there are both **Close** and **Logout** options available in the application menu. Logging out will end your SilhouetteConnect session and you will need to be connected to the network to login using your web browser the next time you want to use SilhouetteConnect.

If your Silhouette system is configured to allow SilhouetteConnect offline operation, rather than logging out you can close the application. Closing the application will allow you to open it later without having to be connected to the network to re-authenticate. You will be allowed to use the application without re-authenticating until the configured maximum offline session time configured for your system or until you select **Logout**.

Contact your system administrator if you would like to find out what the SilhouetteConnect Maximum Offline Session Time is set to. The SilhouetteConnect Maximum Offline Session Time is typically set in the order of days rather than hours and a warning is provided whenever you start SilhouetteConnect if you are within 20% of the expiry time, i.e. if the maximum offline session time is set to 2 days then you will see a warning if you start SilhouetteConnect and you haven't synced or logged in for approximately 39 hours.

Warning! It looks like you have been working offline for a long time and soon you will be required to be online to login again. Performing a Sync will refresh your offline session.

 \mathbf{O}

Your offline session time is restarted each time you perform a Sync with SilhouetteCentral or whenever you go to the Manage Patient screen and successfully get a list of available patients from SilhouetteCentral.

Logging Out From SilhouetteLite ,SilhouetteLite+ or SilhouetteMobile

When using the iOS applications SilhouetteLite, SilhouetteLite+ or SilhouetteMobile you can end your session by selecting Logout from the navigation bar on the patient select screen. If you have data captured that needs to be uploaded to SilhouetteCentral, logging out will block access to the application until that data has uploaded successfully.

Once you select logout then you will need to be connected to the network and able to navigate to SilhouetteCentral before you can login again.

The application can be closed without logging out if you need to operate offline. In this scenario, your Silhouette system can be setup to require you to enter the device owner authentication (passcode or biometric id) before opening the application again.

Quick Start Workflows

The workflow for each organization can differ depending on the specific wound care protocols in place. However, some typical workflows are provided below to give you quick links the relevant help topics.

A user is always required to login to complete any actions within Silhouette, see Logging In to Silhouette.

A number of common workflows are described in short form in the following help topics.



Quick Start - Wound Assessment using SilhouetteStar



Quick Start - Wound Assessment using 2D or 3D Imaging



Quick Start - Wound Assessment using the SilhouetteLite+ or SilhouetteMobile



Quick Start - Wound Assessment using the SilhouetteLite



Quick Start - Send Assessment to EMR System using Orders

Quick Start - Wound Assessment using SilhouetteStar

See Using SilhouetteStar for more details on the use of the SilhouetteStar scanner.

A typical wound assessment workflow when using the SilhouetteStar scanner is:

- 1. Search for and select the patient you are assessing, see <u>The Patient Selection Screen</u>. Alternatively, if using an orders driven system, you can find an active order for the patient, see <u>Search Orders</u>.
- 2. Connect the SilhouetteStar scanner, see <u>Connecting a SilhouetteStar 2 using Wi-Fi</u> or <u>Connecting a</u> SilhouetteStar using USB.
- 3. Take images of the wounds or areas of interest, see Take Wound Images using SilhouetteStar.
- 4. Document the observations for each wound (including making measurements by tracing images), see <u>Create</u> an Assessment using an Image from the Portfolio.

When using EHR integration with orders, the typical workflow includes additional steps:

- 1. Link the assessment to the relevant order, see Linking Assessments and Orders.
- 2. Optionally, mark the order as completed, see Completing an Order.

When using SilhouetteConnect in Synchronized mode then these workflows typically require a sync step at both the beginning and/or the end.

Quick Start - Wound Assessment using 2D or 3D Imaging

See Using 2D and 3D Imaging in SilhouetteCentral for more details on the use of the 2D and 3D Imaging features.

A typical wound assessment workflow when using the 2D or 3D Imaging feature is:

- 1. Search for and select the patient you are assessing, see <u>The Patient Selection Screen</u>. Alternatively, if using an orders driven system, you can find an active order for the patient, see <u>Search Orders</u>.
- 2. Prepare the wound for imaging by placing a reference sticker on the skin near the wound, see <u>Silhouette 2D</u> and 3D Imaging Best Practice Guidelines.
- 3. Open the patient's image portfolio and select the 2D or 3D button to take images of the wounds or areas of interest, see SilhouetteCentral 2D and 3D Imaging Workflow.
- 4. Document the observations for each wound (including making measurements by tracing images), see <u>Create</u> an Assessment using an Image from the Portfolio.

When using EHR integration with orders, the typical workflow includes additional steps:

- 1. Link the assessment to the relevant order, see Linking Assessments and Orders.
- 2. Optionally, mark the order as completed, see Completing an Order.

Quick Start - Wound Assessment using the SilhouetteLite+ or SilhouetteMobile

<u>See Using SilhouetteLite+ or SilhouetteMobile</u> for more details on the use of the SilhouetteLite+ App and Sensor or the SilhouetteMobile App.

A typical wound assessment workflow when using the SilhouetteLite+ or SilhouetteMobile App is:

- 1. Sync the patient list from SilhouetteCentral.
- 2. Select the patient you are assessing, see <u>Select or Create a Patient in SilhouetteLite+ or SilhouetteMobile</u>.
- 3. Select or create the wound, see Select or Create the Wound to Assess.
- 4. Complete the assessment by taking images and documenting observations, see <u>Performing an Assessment in</u> <u>SilhouetteLite+ or SilhouetteMobile</u>
- 5. Allow the assessment to sync to SilhouetteCentral before closing the app.

Quick Start - Wound Assessment using the SilhouetteLite

See Using SilhouetteLite for more details on the use of the SilhouetteLite App.

A typical wound assessment workflow when using the SilhouetteLite App is:

- 1. Sync the patient list from SilhouetteCentral.
- 2. Select the patient you are assessing, see <u>Select or Create a Patient in SilhouetteLite</u>.
- 3. Complete the assessment by taking images and documenting observations, see <u>Perform an Assessment in</u> <u>SilhouetteLite</u>.
- 4. Allow the assessment to sync to SilhouetteCentral before closing the app.

Quick Start - Send Assessment to EMR System using Orders

See Orders in Silhouette for more details on the use of orders in Silhouette.

When using Silhouette in an order driven setup, once you have an assessment or assessments ready to share with the EMR system:

- 1. Select the order you wish to result against, see Search Orders.
- 2. Link the assessment(s) to the order, see Linking Assessments and Orders.
- 3. Optionally complete the order if you do not wish to send more assessment data using it, see <u>Completing an</u> Order.

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 an 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 Scanner

SilhouetteStar Wound Imaging Workflow

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

To use the SilhouetteStar you must first be logged in have a patient selected. Refer to the <u>The Silhouette Clinical</u> <u>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 using SilhouetteStar
- 3. Create an Assessment using an Image from the Portfolio

Connecting a SilhouetteStar 2 using Wi-Fi

Use the following process to connect a SilhouetteStar 2 to SilhouetteCentral with a Wi-Fi connection. Only users with the "Can Connect SilhouetteStar using WiFi" permission will be able to perform this operation.

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 to take images* link to show the barcode if it is not visible.

If there is no link or barcode available, it may be that you do not have the required permission to connect the SilhouetteStar using Wi-Fi.

 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, 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.

4 Once the device has decoded the on-screen barcode, the lasers turn off and it shows "Connecting...".

If the device was previously in airplane mode, Wi-Fi is turned on and the Wi-Fi strength icon is shown.

⁵ Once SilhouetteStar 2 is connected successfully, the selected patients name, ID and date of birth appear on the device screen for positive identification.

(USB or WiFi)

Please Connect







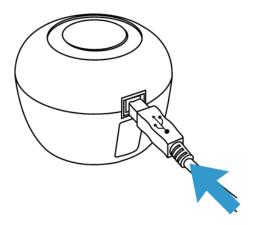
SilhouetteStar 2 is now ready to take wound images.



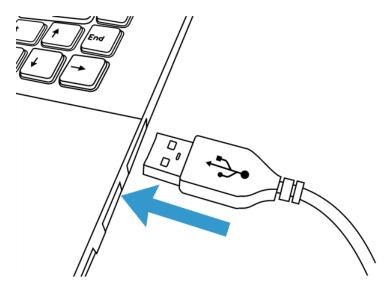
<u>See SilhouetteStar 2 Display</u> for more information regarding the different messages and icons shown on the SilhouetteStar 2.

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 scanner.



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 scanner via a powered USB hub.

2

Your computer automatically detects the SilhouetteStar 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.

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

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

34 • SilhouetteStar USB Cable

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, the lasers turn on to scan a barcode and the screen updates to show **Scanning for Silhouette barcode**. The scanner 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 scanners when they are initially plugged in or when the computer wakes up from sleep modes.

If the scanner 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

2

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

SilhouetteStar Model Name	Model Num- ber(s)	Label(s) present on the USB Cable
SilhouetteStar 1	2000.xx 2005.xx	SilhouetteStar TM USB Cable Manufacturer ARANZ Medical Christchurch, New Zealand.
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 using SilhouetteStar

To take wound images using SilhouetteStar:

- 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.

To get the best images from the SilhouetteStar, see the help topic Capturing Images with a SilhouetteStar.

Create an Assessment using an Image from the Portfolio

To use images from the patient's image portfolio to make wound measurements, add them to an assessment. The type of measurements available vary based on the type of capture made and the quality of the capture made.

- Create an assessment that has an image capture field by selecting the **chart +** button (b) for the relevant image in the image portfolio, which starts an assessment using that image.
 Alternatives to the **chart +** button are:
 - The + Add Assessment button on the patient banner, available in most patient screens when you haven't selected a wound or from the patient Action menu.
 - The + Wound Assessment from the patient banner, which is available when you already have a wound selected, providing a shortcut to create an assessment for that wound.
- 2. There maybe a create assessment wizard to work through, depending on your Silhouette configuration and role. See the help topic The Create Assessment Wizard for details.
- 3. Add the captured image(s) to a wound assessment.
 - a. Select the + placeholder image () in the image field to open the image portfolio in image assignment mode, see the <u>Portfolio Image Assignment Mode</u> topic.
 - b. Select the images you wish to add to the assessment by clicking or touching them. The selected images are highlighted by a blue border.
 - c. Close the image portfolio using the **Ok** button and the images you selected will show in the assessment.
- 4. Measure the wound by tracing around the wound in the image.
 - a. Select the image you wish to trace to open the image tracing screen.
 - Add an outline to the image. There is an on-screen stylus available for touch screens or the mouse can be used to directly interact with the outline. See the help topic <u>Making Measurements using</u> <u>Images</u> for a full description of the tracing tools available.
 - c. Once all tracing is complete apply the tracing using the **Accept** button.
 - d. Summary measurements from all images traced on the image capture field appear under the images in the assessment.
- 5. Add any notes you wish to capture in the notes fields and then select **Save** to save the assessment.

- 6. Once the assessment is saved it appears in the patient timeline. You can select the assessment from the patient timeline to view it in detail and:
 - Select the **Create Report** option from the other actions menu to generate a PDF report of the assessment.
 - Select the **Edit** option from the other actions menu to edit the assessment data or adjust tracings on images.
 - Select the **wound label** in the patient menu / sidebar to see the wound dashboard and the measurements from this assessment in the wound graph.

Maintaining SilhouetteStar Connections

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

The following topics discusses how to maintain the most reliable connection and do some basic troubleshooting if required.

- SilhouetteStar USB Connections
- SilhouetteStar 2 Wi-Fi Connections

SilhouetteStar USB Connections

The USB connection is generally uncomplicated and reliable.

By keeping in the USB cable and USB connectors clean and in good condition you will extend the life of the cable and keep the scanner working reliably. To keep the cable in good condition it is recommended to provide a place to keep the cable where it:

- Does not present a trip hazard.
- Does not get crushed or run over by other equipment.
- Does not get tangled with other cables.
- Does not place strain on the USB connectors of the computer or the SilhouetteStar.
- Is accessible when it is needed.

If something does go wrong with the USB interface on the computer or the SilhouetteStar, some simple troubleshooting checks are:

- You can check the connection with the SilhouetteStar by opening a patient's image portfolio.
- Ensure that the SilhouetteConnect software has a patient selected and is ready to accept an image capture. The SilhouetteStar does not connect to SilhouetteConnect until there is a user logged in and can only take images when there is a patient selected in SilhouetteConnect.
- If the computer being used goes to sleep, the scanner will loose connection and prevent the user from taking images until the computer is started again. Ensure that the sleep time of the computer is set appropriately to allow for image captures to be completed.

- If the SilhouetteStar scanner is not connecting to the SilhouetteConnect software, unplugging the USB cable and plugging it back in is typically enough to kick start it into action.
- The SilhouetteStar 2 does use a 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, review firewall settings to ensure the computer has been correctly configured to allow connections to TCP port 9874 on all network types.

SilhouetteStar 2 Wi-Fi Connections

The Wi-Fi connection is more convenient than the USB connection but the Wi-Fi network and additional mobility creates additional complex behaviors. There is more than one connection involved in the path between the SilhouetteStar 2 and your web browser where you see the SilhouetteCentral website.

- 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, 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.	

Scenario	SilhouetteStar 2 Device Behavior	Silhouette Web Site Behavior
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. Once the SilhouetteStar 2 moves back in to range of the Wi-Fi network then it will re- connect 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.	After approximately 30 seconds the Silhouette Web Site will lose 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 Measurements
- Lighting Requirements for Image Capture
- Holding a SilhouetteStar and Positioning the Lasers

The Mathematics of SilhouetteStar 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 to the SilhouetteCentral website using 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 to 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.

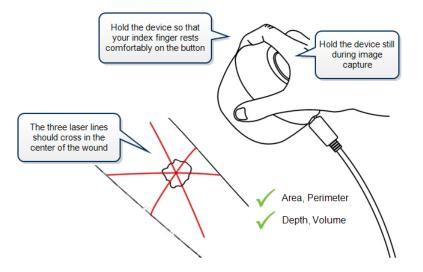
Once an image has been captured, you have the option of accepting or discarding the image.

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 Circumferential Measurements using Multiple Images.

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.

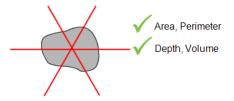
The set of measurements able to be made on a captured image depends on the positioning of the laser lines and the wound outline. Area and perimeter measures can be made under all circumstances. To determine depth and volume, the following conditions must be met:

- 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.

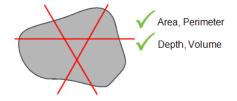
Preferred Laser Positioning

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.



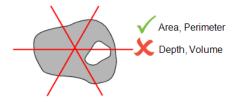
Acceptable Laser Positioning for Large Wounds

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



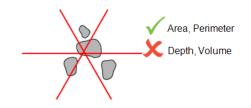
Preferred Laser Positioning for Wounds Containing Islands

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



Preferred Laser Positioning for Wounds With Multiple Outlines

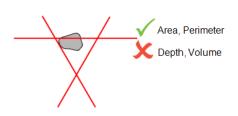
Depth and volume are not calculated when there is more than one wound outline in the same image. To allow depth and volume to be calculated, image each wound fragment and outline each wound separately.



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, the user should move SilhouetteStar to form a star and center it on a

wound.



The SilhouetteStar Scanner

There are two variants of SilhouetteStar, known as:

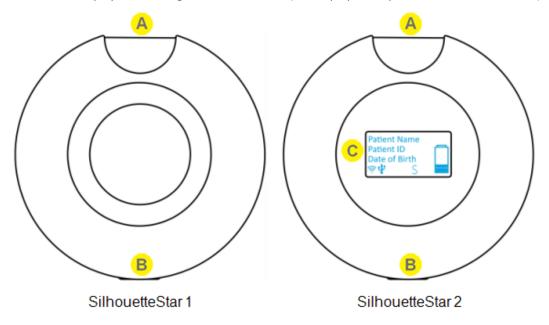
SilhouetteStar 1 has a 3 or 5 megapixel camera module (depending on the scanner model) and connects to SilhouetteConnect using a USB cable.

SilhouetteStar 2 has a 5 megapixel camera module, a display, and a speaker. It 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

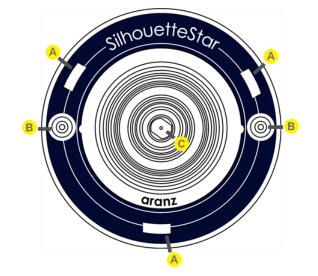
The USB port is on the side of the unit is used for data connection to SilhouetteConnect. It is also used for battery charging on the SilhouetteStar 2.



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 the help topic SilhouetteStar 2 Display for details.

Bottom View



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



Laser Aperture

SilhouetteStar devices contain three lasers.

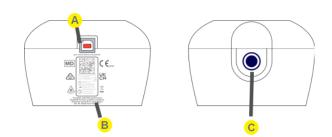


Illuminating LED

SilhouetteStar devices use illuminating LEDs to provide light for consistent wound imaging.

Camera Lens

Side Views



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USB Port

The USB port 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 <u>SilhouetteStar Trigger Button Operation</u>. The trigger can also be used to help orientate the device the same way to take consistent images.

SilhouetteStar Trigger Button Operation

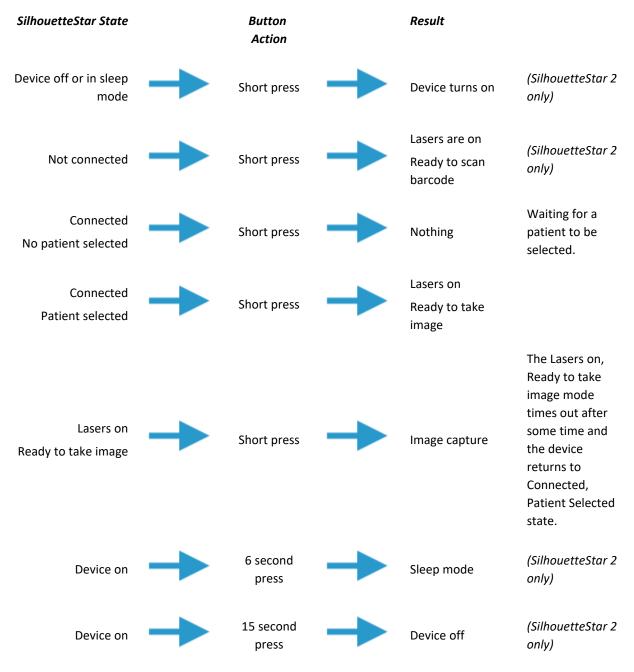
The trigger button on the side of SilhouetteStar is used for capturing images (single press); and in the case of SilhouetteStar 2, it is also used for powering on and off the device.

Whenever the SilhouetteStar is connected to SilhouetteConnect via USB or SilhouetteCentral via WiFi and there is a patient record selected, a short press of the trigger button turns the lasers on and then another short press captures the image.

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.

The exact behavior of the trigger button is dependent on the current state of the device and the connected software. The table below shows the detailed trigger button operations.





SilhouetteStar 2 Rescue Mode Restart

The SilhouetteStar 2 has a rescue mode restart that can be used to start the device using factory settings. Rescue mode is used to see the original device build information or to recover in the unlikely event of a failed upgrade. To restart the device into rescue mode:

- 1. Hold down the trigger button.
- 2. Insert and remove the USB cable.
- 3. Release the trigger button.

The device will restart with the walking kiwi bird marked with a + sign.

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), 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, 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 <u>SilhouetteStar 2 Screen Messages</u>.



Battery gauge.

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



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.

lcon	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 user's 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 device's 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. 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, contact your 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).

Connecting... Failed to connect to network Failed to connect to Central Please select patient

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.



Firmware upgrade is required 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 rese 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:

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- 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, 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.

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SilhouetteStar 2 Battery Management

SilhouetteStar 2 contains a Li-Ion 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, the battery requires a charge. Consider the following points when using or storing a SilhouetteStar 2.

- To charge the battery, use the supplied battery charger.
- The battery level bars on the screen animate an increasing change when the SilhouetteStar 2 is being charged. Once a full charge is reached, the device display goes blank, or the battery level bars stop animating.
- 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 as 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 most usage scenarios. However, poor or busy Wi-Fi environments can cause the battery to drain much faster than expected. Keeping the SilhouetteStar 2 on charge between assessments (but not longer than a week) is recommended to ensure that the device is ready to use when it is needed.
- Capturing consecutive images faster than they can upload to SilhouetteCentral in poor Wi-Fi conditions may cause the device to suddenly loose battery power. If this happens, the device will show a message that the battery is 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. If this happens frequently, consider measures that will improve Wi-Fi conditions or switch to use wired mode with SilhouetteConnect.

Fully charge SilhouetteStar 2 before leaving it unused for more than a few days.

Charge the SilhouetteStar 2 between uses and at least once a month when not being used to keep the battery at optimal performance and prevent long term damage. Do not leave the device connected to the charger for more than a week at a time.

See SilhouetteStar Warnings for more warnings relating to the SilhouetteStar 2 battery.

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
2000	Original SilhouetteStar models (refer to the applicable Quick Reference Guide for more details)
2005	
2010	SilhouetteStar 2 (5MP)



Manufacturer assigned device serial number



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



UKCA mark. UK Conformity Assessed Marking.



RCM mark. New Zealand and Australia Declaration of Conformity.

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

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

RC I

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.

Indicates that the SilhouetteStar is a Medical Device.



Unique Device Identifier Carrier is included on the SilhouetteStar label.



Consult electronic instructions for use (this guide).



Refer to instruction manual/booklet before use.

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.



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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.

- 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.
- Keep the SilhouetteStar 2 battery charged between uses.
- The SilhouetteStar 2 requires a full charge at least once a month when not in use, but should not be left charging while in storage.

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 2D and 3D Imaging in SilhouetteCentral

This section of the guide describes the use of the 2D and 3D Imaging features of SilhouetteCentral and how they are used to capture images and make measurements of wounds and skin features in Silhouette.

SilhouetteCentral 2D and 3D Imaging are optional features of SilhouetteCentral and can be enabled as part of the SilhouetteCentral license.

The SilhouetteCentral 2D and 3D Imaging features are designed to be used with mobile devices (smart phones and tablets), allowing you to safely and securely capture clinical images of wounds and skin features using the devices built in camera.

SilhouetteCentral 2D and 3D Imaging requires the placement of a reference sticker on the skin near the wound or the skin feature being imaged. Reference stickers are green dots that can be purchased off the shelf from most labeling suppliers. A full list of requirements for sourcing reference stickers can be found in the Administration User's Guide.

Once a reference sticker is sourced, it must be listed in the Silhouette system by a system administrator. See the Administration User's Guide for more information on configuring your system for 2D and 3D Imaging.

SilhouetteCentral Imaging Topics



SilhouetteCentral 2D and 3D Imaging Workflow



Silhouette 2D and 3D Imaging Best Practice Guidelines



Silhouette 2D and 3D Imaging Labels and Warnings

SilhouetteCentral 2D and 3D Imaging Workflow

This section of the guide describes the primary workflow to document a wound using 2D and 3D Imaging features available in SilhouetteCentral.

To use the 2D and 3D Imaging features, a system admin must have assigned the appropriate permissions to the role you are logging in as. Additionally, a system administrator must have completed the reference sticker configuration within Silhouette.

Once you are logged in with a patient selected:

- Place a reference sticker on the patient's skin near the wound or skin feature you wish to measure. See the topic <u>Silhouette 2D and 3D Imaging Best Practice Guidelines</u> for guidance on where to place the reference sticker.
- 2. Select the camera icon from the patient banner to open the patient's image portfolio.
- 3. Select the desired imaging method, (if these options are not available it is likely you have not been assigned permissions to use 2D or 3D Imaging).



for 2D Imaging

3	D

for 3D Imaging

- 4. Setup for image capture following <u>SilhouetteCentral 2D and 3D Imaging Setup</u>
- Capture images following the steps in either the <u>SilhouetteCentral 2D Imaging Capture Sequence</u> or the SilhouetteCentral 3D Imaging Capture Sequence
- Choosing Accept or Accept as Reference at the completion of the capture sequence will add the result to the patient's image portfolio.
- To use the image for measurements assign the image to an assessment, see the <u>Create an Assessment using</u> an Image from the Portfolio topic.

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SilhouetteCentral 2D and 3D Imaging Setup

The Imaging wizards guide you through the process of imaging a wound using your device's built in camera.

The wizard header is common to all wizard screens.

A	Mandarin Banana	
_	Patient ID: 258	
	Date of Birth: 1962-02-28 (60 years old)	

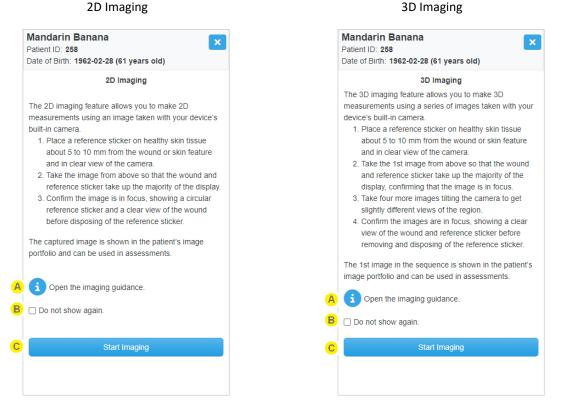


The header shows the positive patient identification details, allowing you to know that the image you are capturing will be assigned to the correct patient.



Select the **X** button to cancel the image capture at any stage in the wizard. Any images already captured will be discarded.

Intro Screen



The intro screen of the wizards give an overview of the process to successfully capture an image for measurement. It is intended for first time or infrequent users of the Imaging feature, giving a brief reminder of how to use the feature.



Select the **i** icon to see more detailed imaging guidance. See the <u>Silhouette 2D and 3D Imaging</u> Best Practice Guidelines for details.



Tick the **Do not show again** box to skip this first use screen in the future.

This option is saved as a user account preference and can be set or reset in the user preferences screen, see the <u>Preferences</u> topic for more details.

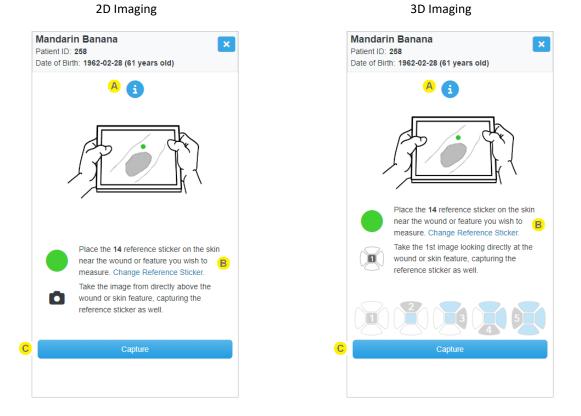
66 • Imaging Setup

Select the Start Imaging button to move the wizard to the next screen.

Imaging Setup

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The Imaging setup screen has the most important imaging reminders, lists the reference sticker you are using, and provides the capture button to launch your device's built-in camera.



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Select the i icon to see more detailed imaging guidance.

The short description of the currently selected reference sticker is shown in bold text.

It is important that the reference sticker selected in the Imaging wizard refers to the actual physical reference sticker you place on the patient. If they do not match, the measurements made from the image can have significant error.

If there is more than one reference sticker defined in the system, there is a **Change Reference Sticker** link available.

Selecting this link will give you a dialog listing the reference stickers defined to select from.

Select Reference Stick	ker
1/2" Fluro Green	
14mm Green Triarc	
	Cancel

Example of 2 reference stickers configured by a system administrator.

Select a reference sticker from the list. Selecting a reference sticker in this dialog sets your personal preference, which you can see and change in the preferences screen, see the Preferences topic.

If you do not see your currently selected reference sticker in the list, it may have been made inactive by a system administrator, i.e. if they can no longer source that sticker.

You will still be able to use the inactive sticker definition until you select a new one. Select **Cancel** on the dialog to continue using the existing selected sticker.

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Select the **Capture** button to launch your device's camera, see either <u>SilhouetteCentral 2D</u> <u>Imaging Capture Sequence</u> or <u>SilhouetteCentral 3D Imaging Capture Sequence</u> for guidance through the appropriate image capture and acceptance sequence.



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SilhouetteCentral 2D Imaging Capture Sequence

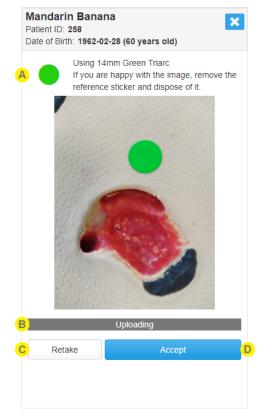
2D Image Capture and Confirmation

Once the <u>SilhouetteCentral 2D and 3D Imaging Setup</u> has been completed, your device's camera interface will have launched. The exact camera user interface is dependent on the make and model of the device you are using but the workflow typically has two steps, capturing the image and then confirming the capture. See the help topic <u>Mobile</u> Phone Camera User Interface Examples for some examples.

The 2D Imaging sequence requires the capture and review of a single image. The image should be captured from directly above and parallel to the wound or skin feature of interest, for detailed image capture guidance see <u>Silhouette 2D and 3D Imaging Best Practice Guidelines</u>.

Use the confirmation step offered by the camera to check that the important parts of the image are in focus and retake the image if necessary.

The confirmation step is a chance to review the image, see that it has uploaded correctly, and either retake it or accept it.



Α

The confirmation screen shows you the reference sticker selected in the Imaging setup but does not allow you to change it.

If you are happy with the image, remember to remove the reference sticker from the patient's skin and dispose of it in accordance with your organization's infection control procedures.

The status of the Imaging updates as the image uploads and completes processing on the server.

Possible statuses are:

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- Uploading, indicating that the image is still uploading to the server from your device.
- Success, indicating that upload and 2D image processing has been successful.



• Failed processing, indicating that something has gone wrong. The message includes some detail of the failure, e.g. uploading failed or reference sticker not detected.

Reference sticker not detected, image cannot be used for measurement.	
Retake	Accept as reference

• Error uploading, indicating that something has gone wrong attempting to transfer the image to the SilhouetteCentral server.

Error uploading the image		
Retake	Retry	

You do not need to wait until image uploading is completed before accepting the image, likewise an image that has failed 2D processing can be accepted as a reference image (image without measurement capabilities).



It is important to let the image upload complete before closing the web browser to ensure you do not loose the image.



Selecting **Retake** discards the current image and returns you to the start of the capture sequence.

Select **Accept** to accept the image as-is and close the Imaging wizard, returning to the image portfolio. The captured image will appear in the image portfolio after a small delay.

The **Accept** button can change to **Accept as reference** if the 2D image processing fails or **Retry** if the image upload fails.

- Use **Accept as reference** option to keep the image for reference, even though it will not be able to be used for measurement.
- The **Retry** option will not close the wizard but attempt to restart the upload of the image to the SilhouetteCentral server.

If you do not want to **Accept**, **Retake**, or **Retry** then use the **x** button at the top of the wizard to cancel the capture.

Once you accept the image the status of the image is included in the notification panel. An image upload failure can be retried by opening the notification panel from the application header.

You can accept the image before seeing the final status and continue to use the app. The notification panel will keep you up to date on upload and processing progress.

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If you are happy with the image, remember to remove the reference sticker from the patient's skin and dispose of it in accordance with your organization's infection control procedures.

SilhouetteCentral 3D Imaging Capture Sequence

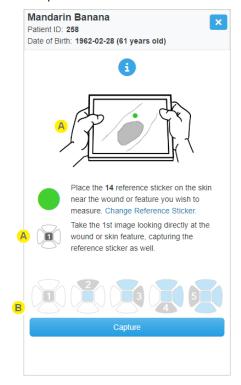
3D Image Capture and Confirmation

Once the <u>SilhouetteCentral 2D and 3D Imaging Setup</u> has been completed, your device's camera interface will have launched. The exact camera user interface is dependent on the make and model of the device you are using but the workflow typically has two steps, capturing the image and then confirming the capture. See the help topic <u>Mobile</u> Phone Camera User Interface Examples for some examples.

The 3D Imaging sequence requires the capture and review of five images. Use the confirmation step offered by the camera interface to check that the important parts of the image are in focus and retake the image if necessary.

The user interface guides you to the correct device position for each image capture while also providing feedback on the status of both the individual images and the processing of the image set, allowing you to accept or restart the sequence.

The confirmation step is a chance to review all images, see that they have been uploaded and processed correctly, and either accept the result or restart the sequence.





The capture guidance walks you through the image capture sequence, providing guidance on how to position the capture device for each of the five images required. See <u>Silhouette 2D and 3D Imaging Best</u> <u>Practice Guidelines</u> for further image capture guidance.

• Primary image **1**, taken from directly above the wound or skin feature of interest. Ensure the wound or skin feature is centered in the frame and that the reference sticker is visible.

This image will become available in the patient's image portfolio where it can be added to an assessment, see <u>Create an Assessment using an Image from the Portfolio</u>.



• 12 o'clock, image **2**, taken by tilting the camera away, while keeping the wound or skin feature centered in the frame.



• 3 o'clock, image **3**, taken by tilting the camera to the right, while keeping the wound or skin feature centered in the frame.



• 6 o'clock, image **4**, taken by tilting the camera towards you, while keeping the wound or skin feature centered in the frame.



• 9 o'clock, image **5**, taken by tilting the camera to the left, while keeping the wound or skin feature centered in the frame.



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Tracks the upload and processing status for individual images, and for the overall capture sequence. The results can reviewed and accepted or the sequence restarted if required.

Individual image status:

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• The status of each individual image is represented by four overlays. Uploading, Processing, Success and Failure.



Image capture sequence status and confirmation:

- The "Uploading and processing images" message indicates the images are being uploaded ready for processing.
- The "Performing 3D processing" message indicates the images have been successfully uploaded and processing has begun to create a 3D model.



Selecting **Accept** before the image upload and processing is complete allows you to continue to use the app, the status of the upload and processing will be visible in the notifications panel in the application header.

An image upload failure can be retried by opening the notification panel from the application header. If there is a processing error Silhouette will attempt to reprocess the images before automatically saving the primary image to the portfolio as a reference image, (image without measurement capabilities).

• The "Reference sticker not detected", "Upload error" and "Images did not successfully create a 3D model", error messages represent situations where a 3D model is not created

Referer	Reference sticker not detected.		Upload error. <u>Retry upload</u>		successfully create a 3D model.
		1	1 1 1	•	; ; ;
Restart Seq.	Accept as reference	Restart Seq.	Accept as reference	Restart Seq.	Accept as reference
8	the primary image to measurement capab To restart the sequer	the patient's i ilities). nce select Rest	en the option to select mage portfolio as a refe art Seq or to retry imag ss see <u>Silhouette 2D an</u>	erence image (ge upload selec	image without tt Retry upload .

• "3D processing completed successfully".





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It is important to let the image upload complete before closing the web browser to ensure you do not loose the image.

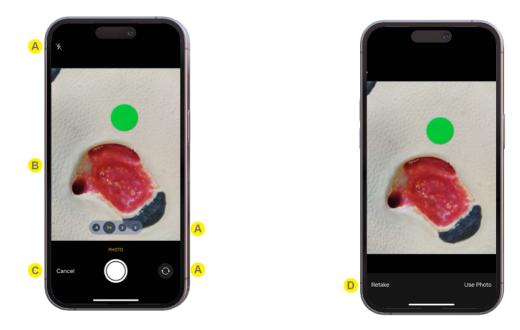
- Selecting either Accept or Accept as reference will close the Imaging wizard and return you to the
 patient's image portfolio where the primary image will appear after a small delay. The status of
 incomplete uploads or processing will be shown in the portfolio as well as in the notification panel of
 the application header.
- If you do not want to Accept, Accept as Reference, Restart Seq, or Retry Upload then use the x button at the top of the wizard to cancel the capture sequence.

If you are happy with the image, remember to remove the reference sticker from the patient's skin and dispose of it in accordance with your organization's infection control procedures.

Mobile Phone Camera User Interface Examples

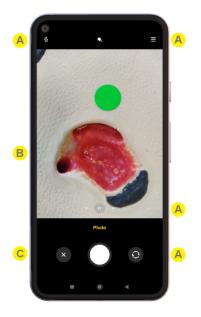
When using the 2D or 3D Imaging feature, the exact camera user interface is dependent on the device make, model, and operating system version. It typically has two steps, capturing the image and then confirming the capture.

Some examples of the camera user interface on different devices are shown below.



Example Apple iPhone image capture and review steps

Example Android based phone image capture and review steps





Mobile phones and tablet cameras can have lots of options.

When using an Apple iPhone or iPad, the camera settings available when used from a web app are simplified (when compared to the settings available in the standard camera app).

When using Android based devices, the camera settings available through a web app are more extensive than for an iPhone or iPad, more care should be taken to ensure the settings are appropriate for the wound image.

Important camera settings to get right are:

- Ensure the flash is off.
- Use the **1x** rear facing camera.
- Use the review step offered by the camera to check that the important parts of the image are in focus and retake the image if necessary.
- Use consistent camera settings when doing wound imaging.
- Ensure the wound is in focus and framed according to the imaging guidance, see the topic Silhouette 2D and 3D Imaging Best Practice Guidelines.

Common mobile device features like touch to focus can be used to adjust the focus and exposure.

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Capture and cancel buttons are usually provided at the capture stage.

In the review screen there is usually an unobstructed view of the captured image with accept and cancel (or retake) options.

Create an Assessment using an Image from the Portfolio

To use images from the patient's image portfolio to make wound measurements, add them to an assessment. The type of measurements available vary based on the type of capture made and the quality of the capture made.

- Create an assessment that has an image capture field by selecting the **chart** + button (b) for the relevant image in the image portfolio, which starts an assessment using that image.
 Alternatives to the **chart** + button are:
 - The + Add Assessment button on the patient banner, available in most patient screens when you haven't selected a wound or from the patient Action menu.
 - The + Wound Assessment from the patient banner, which is available when you already have a wound selected, providing a shortcut to create an assessment for that wound.
- 2. There maybe a create assessment wizard to work through, depending on your Silhouette configuration and role. See the help topic The Create Assessment Wizard for details.
- 3. Add the captured image(s) to a wound assessment.
 - a. Select the + placeholder image () in the image field to open the image portfolio in image assignment mode, see the Portfolio Image Assignment Mode topic.
 - b. Select the images you wish to add to the assessment by clicking or touching them. The selected images are highlighted by a blue border.
 - c. Close the image portfolio using the **Ok** button and the images you selected will show in the assessment.
- 4. Measure the wound by tracing around the wound in the image.
 - a. Select the image you wish to trace to open the image tracing screen.
 - Add an outline to the image. There is an on-screen stylus available for touch screens or the mouse can be used to directly interact with the outline. See the help topic <u>Making Measurements using</u> <u>Images</u> for a full description of the tracing tools available.
 - c. Once all tracing is complete apply the tracing using the **Accept** button.
 - d. Summary measurements from all images traced on the image capture field appear under the images in the assessment.
- 5. Add any notes you wish to capture in the notes fields and then select **Save** to save the assessment.

- 6. Once the assessment is saved it appears in the patient timeline. You can select the assessment from the patient timeline to view it in detail and:
 - Select the **Create Report** option from the other actions menu to generate a PDF report of the assessment.
 - Select the **Edit** option from the other actions menu to edit the assessment data or adjust tracings on images.
 - Select the **wound label** in the patient menu / sidebar to see the wound dashboard and the measurements from this assessment in the wound graph.

Silhouette 2D and 3D Imaging Best Practice Guidelines

This section of the guide provides the best practice imaging guidelines for the capture of images using 2D and 3D Imaging features of **SilhouetteCentral** and **SilhouetteMobile**.

This section contains the key instructions for a user learning and using Silhouette 2D or 3D Imaging, to ensure they get the maximum measurement accuracy and consistency.

On-Screen Detailed Imaging Guidance

A brief description of the best practice imaging guidance is available to the application user by selecting the icon in the 2D or 3D Imaging wizard.

Reference Sticker Placement

See the Administration User's Guide for details on selecting a reference sticker.

- Place the reference sticker on healthy skin tissue outside the wound boundary.
- Place the reference sticker beside the wound, approximately 5 to 10 mm away from the wound and in clear view of the camera. The reference should appear circular in the image.
- Be consistent with the reference sticker placement across assessments. Before each assessment, review where the sticker was placed for the last assessment of the wound and try to repeat the placement. e.g. if the placement was 10 mm north (towards the patient's head) last assessment, then place it 10 mm north for this assessment.



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To help with consistency, it is a good idea to agree a reference sticker placement protocol with all 2D Imaging users in your practice, e.g. always place the sticker to the north of the wound.



Take care when placing and removing reference stickers that you do not place or drop the sticker into the patients wound.

Reference stickers should not be reused. They should be removed and disposed of in accordance with your organization's infection control procedure.

Lighting

- Avoid extreme lighting conditions (e.g. very bright and very dark). Typical clinic, office, and home lighting is unlikely to cause problems.
- Try to avoid the shadow from your mobile device passing directly across the wound.
- Do not use the device's flash.

Composition / Framing

- For all images, ensure the wound and reference sticker take up the majority of the display, while keeping the image in focus.
 - The overall range from the skin to the camera should be between 100 400 mm (4 16 inches)
 - The center of the wound should be in the center of the camera's field of view.
 - For consistent results use the same camera orientation for each assessment.
- For 2D Imaging and the primary (first) image of a 3D Imaging sequence.
 - The scene should be captured from directly above.
 - Keep the camera parallel to the surface of the wound.
- For the secondary images (2,3,4 and 5) of a 3D Imaging sequence,
 - Maintain the same camera orientation as used for the primary image.
 - Shift the camera slightly towards 12 o'clock (image 2), then tilt the camera to recenter the wound in the field of view. You should be aiming for a camera tilt of between 5-15 degrees, relative to the primary image.
 - Repeat for 3, 6 and 9 o'clock, images 3,4 and 5 respectively, shifting the camera in each direction relative to the primary (first) image's position. Again you should end up with the camera tilted between 5-15 degrees relative to the primary image.
- Try to avoid capturing faces or identifiable marks in the background of the image, for either the patient or any one else present.



Take care when imaging that you do not allow the imaging device (mobile phone or tablet) to come into contact with the patient or with contaminated materials.

Examples of Good and Poor Image Composition

Example 1: Good composition



- The reference sticker is 5 to 10 mm outside the wound boundary.
- The reference sticker appears circular.
- The wound is in the center of the image.
- There is a clear view of the wound.
- There are no obvious shadows on the wound.

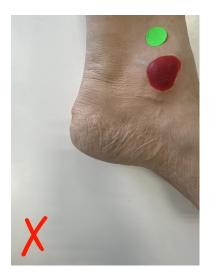
Example 2: Good composition



- The reference sticker is 5 to 10 mm outside the wound boundary.
- The reference sticker appears circular.
- The wound is in the center of the image.
- There is a clear view of the wound.
- There are no obvious shadows on the wound.

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Example 3: Poor composition



- The wound is not central.
- The reference sticker too close to edge of the image.

Example 4: Poor composition



• The reference sticker is not fully in frame (too close).

Example 5: Poor composition



• The wound and reference sticker appear very small in the image (too far).

Example 6: Poor composition



• The reference sticker doesn't appear to be circular (imaged on an angle).

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Example 7: Poor composition



• There is an obvious shadow across the wound.

Silhouette 2D and 3D Imaging Labels and Warnings

The labeling for the **SilhouetteCentral** 2D and 3D Imaging features and **SilhouetteMobile** is provided by the Help and About page of the SilhouetteCentral instance being used, see the Silhouette Help and About Pages topic.

2D Imaging Accuracy Statement

The 2D Imaging option on Silhouette produces better than 5% accuracy for linear measurements and better than 10% for area measurements when used in accordance with guidelines for use, and on flat parts of the body. When used outside of the guidelines, or on curved anatomy, performance may vary.

3D Imaging Accuracy Statement

The 3D Imaging feature of SilhouetteCentral when used in accordance with the guidelines for use, produces measurements likely to fall within 4% for area, 2% for perimeter and 10% for max depth and volume, 95% of the time.

When used outside the guidelines for use performance may vary.

2D and 3D Imaging Warnings

- Clinical judgment along with your organization's standard precautions / procedures must be followed when placing and removing a reference sticker.
 - Do not reuse reference stickers. Dispose of reference stickers in accordance with your organization's infection control procedure.
 - Take care when placing and removing reference stickers that you do not place or drop the sticker into the patient's wound.
- Take care when imaging that you do not allow the imaging device (mobile phone or tablet) to come into contact with the patient or with contaminated materials.
- Clean your imaging device according to your organization's standard procedures.

Using SilhouetteLite+ or SilhouetteMobile

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.

SilhouetteMobile is an application for Apple[®] iPhone[®], and iPad[®] devices. SilhouetteMobile 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.

To gain measurements, SilhouetteMobile uses a reference sticker placed in the scene near the wound or skin feature being imaged. Reference stickers are green dots that can be purchased off the shelf from most labeling suppliers. A full list of requirements for sourcing reference stickers can be found in the Administration User's Guide.

Once a reference sticker is sourced, it must be listed in the Silhouette system by a system administrator. See the Administration User's Guide for more information on configuring your system for 2D and 3D Imaging.

Topics



SilhouetteLite+ and SilhouetteMobile Wound Imaging Workflow



The SilhouetteLite+ Sensor



Setting Up SilhouetteLite+



Setting Up SilhouetteMobile

SilhouetteLite+ and SilhouetteMobile Wound Imaging Workflow

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

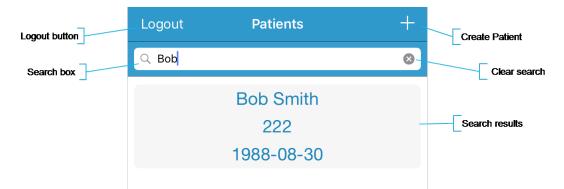
- 1. Select or Create a Patient in SilhouetteLite+ or SilhouetteMobile
- 2. Select the Assessment Type

2

- 3. <u>Select or Create the Wound to Assess</u>
- 4. Performing an Assessment in SilhouetteLite+ or SilhouetteMobile
- 5. <u>SilhouetteLite+ Guidelines for Use</u>

See Silhouette 2D and 3D Imaging Best Practice Guidelines for SilhouetteMobile imaging guidance.

Select or Create a Patient in SilhouetteLite+ or SilhouetteMobile



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.

	The patient list is updated (synchronized) from SilhouetteCentral when you initially log in to the app.
8	If the patient you are searching for doesn't appear to be in the list, you can attempt to refresh the list by swiping down on the screen.
	Refreshing the patient list on the device can take some time when the SilhouetteCentral database has a lot of patients.

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

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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+ or SilhouetteMobile

The assessment is split into groups of notes, each group of notes is presented on a separate screen within the workflow. The bottom of the screen shows the currently selected patient information to allow for positive identification.

If performing a wound assessment, 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+ and SilhouetteMobile you can only update the state of a wound by performing a wound assessment.

< Back		Next >
Details		
Etiology		
Wound Margins		
Surrounding Skin		
Signs of Critical Colonization or	Infection	
Exudate Volume		
Exudate Type		
Bob Smith	222	1988-08-30

- 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.

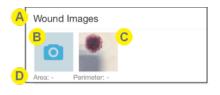
Assessments are sent to SilhouetteCentral once they are saved and when the device is online. Data is only uploaded while the App is open. Leave the App open until the offline data icon disappears from the bottom left of the patient selection screen.

The offline data icon:

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Using Image Capture Fields

Image capture fields show a camera icon in SilhouetteLite+ and a 2D icon in SilhouetteMobile. Thumbnails of any captured images will be displayed alongside.



SilhouetteLite+



SilhouetteMobile

The image capture field name is shown. Silhouette can be configured to have different image capture fields to capture different measurements. Ensure you are capturing images to the correct field if there is more than one.

Select the camera or 2D icon to capture images. A maximum of 10 images can be captured per image field.



Select an image thumbnail to edit tracings or to remove the image.

In **SilhouetteLite+** a thumbnail with a **blue** border indicates that the image has been set as having zero measurements.

In **SilhouetteMobile** a thumbnail with a **green** border indicates the a valid reference sticker has been detected and measurements can be made, an **orange** border indicates that a valid reference sticker was not detected and the image can only be saved as a reference without measurements.

Summary measurements from all the images appear below the images. Select an image thumbnail to see measurements specific to that image.

If more than one image is traced, the area and perimeter measurements are the sum of tracings on all images, see Taking Circumferential Measurements using Multiple Images.



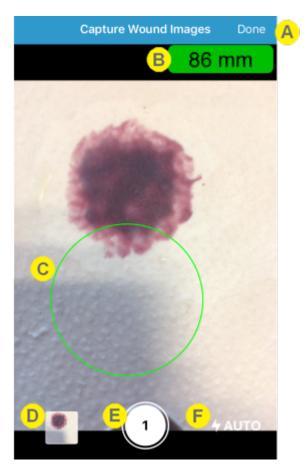
D

In SilhouetteMobile, tap **()** to see reference sticker and image guidance information.

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 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, 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.

SilhouetteMobile will not display this field.

SilhouetteLite+ displays the range to scene measurement reported by the SilhouetteLite+ sensor 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.

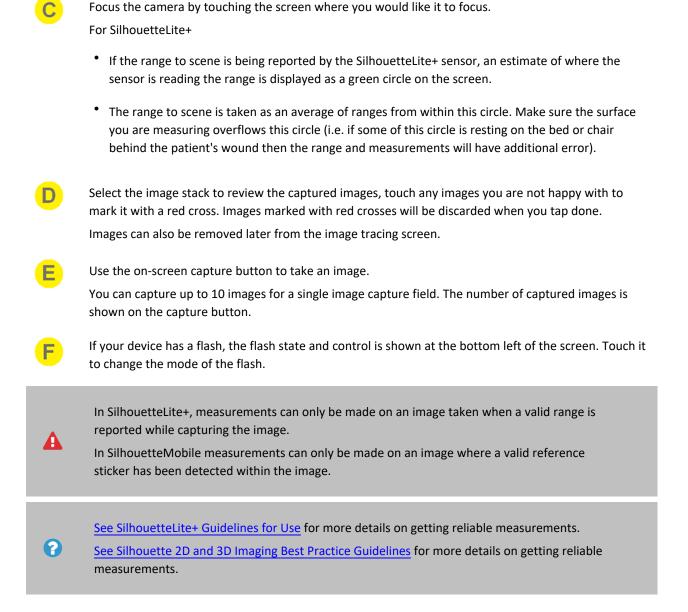
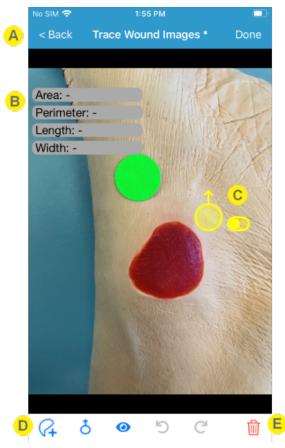


Image Tracing Screen

Selecting a thumbnail from the image capture field opens the Image Tracing Screen. This screen allows you to review, trace an outline or delete the image. However, you need to have been granted permission to trace images in order for the tracing tools to appear.

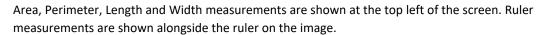




B

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.



For **SilhouetteLite+**, measurement capabilities are only available if there was a valid range measurement from the SilhouetteLite+ sensor when the image was captured.

For **SilhouetteMobile**, measurement capabilities are only available if there was a valid reference sticker detected within the image.

Images without a valid range measurement or reference sticker detection can be saved as reference images without measurements.



Use the stylus to trace wound outlines,

- With the stylus slider set to the left, individual points can be added to the outline by positioning and then tapping the stylus.
- With the stylus slider set to the right, points will automatically be added as the stylus is dragged around the screen.

You need to have the Can Trace permission to be able to use the outline and measure tools.

Multiple outlines can be added to a single image with the reported Area and Perimeter measurements equal to the sum of all outlines. Length and Width will not be displayed if multiple outlines are present. Outlines must not overlap.



The bottom tool bar provides access to the: **outline and ruler tools**, **stylus tools**, **outline and rulers visibility tools**, **undo** and **redo**

You need to have Can Trace permissions to be able to use the outline and measure tools.



Select the **trash can** icon to delete the image from the assessment. A confirmation dialog is shown before the delete is performed.

Using Non-Image Note Fields

The note fields are displayed in a single line on the screen until they are selected for data entry. Notes that are configured as persistent will show the values selected in the previous assessment, if there is a previous assessment for the same patient / wound.



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:





Manufacturers reference / Model number.

Model Number	SilhouetteStar Model
2100.01	The original SilhouetteLite+ sensor

Manufacturer assigned device serial number, a 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.



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

Made in New Zealand

ARANZ Medical Limited PO Box 3894 Christchurch 8140 New Zealand

Postal Address:

Delivery Address: ARANZ Medical Limited 47 Hereford Street Christchurch 8013 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+ Sensor is designated as a Class 1 laser product during all operational procedures. A Class 1 laser 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 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.

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

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.



Consult electronic instructions for use (this guide).



Refer to instruction manual/booklet before use.

SilhouetteLite+ Warnings

Laser Warnings

A

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.
- 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.

100 • Cleaning the SilhouetteLite+ Sensor

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. <u>Download the SilhouetteLite+ App</u>
- 2. Unbox the SilhouetteLite+ Sensor
- 3. Charging the SilhouetteLite+ Sensor
- 4. Attach the SilhouetteLite+ Sensor to Your Device
- 5. <u>Setup the SilhouetteLite+ App</u>
- 6. Changing SilhouetteLite+ Settings

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

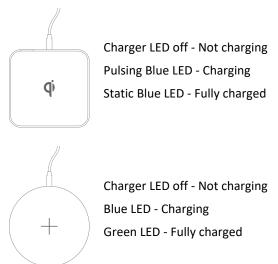
To turn the sensor on, before the initial use or if the SilhouetteLite+ App reports the sensor is not found, momentarily place the sensor on the charger.

If the SilhouetteLite+ App reports the sensor as having a low battery, leave the sensor on the charger to allow it to fully charge. A full charge from flat typically takes approximately 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.
- 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.
 - 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.





 Remove the SilhouetteLite+ sensor from the charger to initiate sensor communication and connect your device.

A

If the charger LED does not behave as expected the device is not charging. To initiate charging reposition the charger or sensor until the charger LED illuminates as expected.

▲

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, 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.



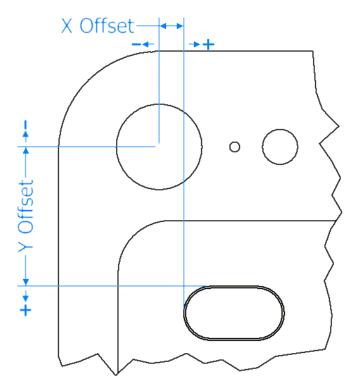
The sensor can only be attached to a device once. Removing the sensor can damage it, and it is not covered under warranty.

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.
 - 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, 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, 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.



When entering the SilhouetteCentral URL include the prefix 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.
- Log in to SilhouetteLite+ by entering the username and password provided to you by your system administrator. The application may ask you if you want to allow your SilhouetteCentral system to log you in. You must allow that in order to successfully use the application.



The App only allows you to log in when there is an active connection to SilhouetteCentral. Once logged in, the App can be used offline until you log 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.

	Settings	Close	
	SilhouetteLite+		
A	ARANZ Medical Limited Version: 1.2 (Build 54)		
	View End User License Agreement	>	1
	Log	>	
	Connection Status		
D	Network: Reachable (Wi-Fi)		
E	SilhouetteCentral: Reachable		
	Change SilhouetteCentral Address	\rightarrow	þ
	Sensor Status		
	G17C00174	\rightarrow	1
H	Battery Level: Medium		
	Change Sensor	\rightarrow	k
	Forget Sensor	>	k
	Turn Off Sensor To turn the sensor back on place the sensor on the charg	>	ŀ



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D

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, check:

- That the device Wi-Fi or mobile data is on and connected.
- If using mobile data, 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.

E

F

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.



H

The serial number of the connected SilhouetteLite+ sensor is listed. If the serial number is blue, 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 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 start-up 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 the SilhouetteLite+ App</u>.

Sensor Status	
No Sensor Selected	
Battery Level: n/a	
Select Sensor	>

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.

Setting Up SilhouetteMobile

This section provides the details required to download and setup the SilhouetteMobile App.

- 1. Download the SilhouetteMobile App
- 2. Changing SilhouetteMobile Settings

Download the SilhouetteMobile App

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



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

Changing SilhouetteMobile 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 the log in screen which allows access to only the **Change SilhouetteCentral Address** option.

	No SIM 🗢	1:01 PM	•	
		Settings	Close	
A	Silhouet	teMobile		
	ARANZ Med Version: 4.0 (Built			
	View End Us	ser License Agreement	>	B
	Log		>	C
	About		>	D
	Connect	ion Status		
E	Network: Re	eachable (Wi-Fi)		
F	SilhouetteC	entral: Reachable		
G	Change Silh	ouetteCentral Address	>	
_	Reference	e Sticker		
н	Selected:	NA - 14 - 14.0mr	n	

- SilhouetteMobile version and build
- Selecting the **View End User License Agreement** opens the SilhouetteMobile End User License Agreement in a web browser window.
- Selecting the **Log** option displays the SilhouetteMobile log file and provides a button to **Email** the log to your system administrator or to ARANZ Medical support at support@aranzmedical.com.
- Selecting **About** displays app details and a link to the help and about page of the SilhouetteCentral instance being synced to
- E 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, check:
 - That the device Wi-Fi or mobile data is on and connected.
 - If using mobile data, make sure that SilhouetteMobile is not restricted from mobile data use. The App mobile data access restrictions can be found in the iOS Settings App on your device.

F

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.



H

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.

Reference Sticker displays information about the currently selected reference sticker and allows you to select an alternative if available.

Reference stickers are defined in SilhouetteCentral by the system administrator and synced to the device.

If a reference sticker is not defined, images can be captured as reference only, without measurements.

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. <u>Setup SilhouetteLite</u>
- 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.



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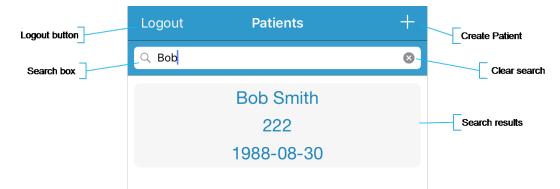
 $\mathbf{?}$

When entering the SilhouetteCentral URL include the prefix 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 application may ask you if you want to allow your SilhouetteCentral system to log you in. You must allow that in order to successfully use the application.

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.

8

The patient list is updated (synchronized) from SilhouetteCentral when you initially log in to the app.

If the patient you are searching for doesn't appear to be in the list, you can attempt to refresh the list by swiping down on the screen.

Refreshing the patient list on the device can take some time when the SilhouetteCentral database has a lot of patients.

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

Selecting a patient begins an assessment and shows the note fields available for entry.

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

- 1. Select the camera icon on the image capture field to capture images.
 - Focus the camera by touching the screen where you would like it to focus.
 - Take up to 10 images using the round capture image button.
 - Select the image stack to review the images and unselect any that should not be kept.
 - Once complete, select **Done** to finish capturing images.
- 2. Select the image thumbnails to review images and optionally delete them from the assessment.
- 3. Enter values for other note fields by selecting the title of the note field.
- 4. Select **Save** to complete the assessment.

2

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 can be found in the footer of the App and looks like: \mathbb{B}^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.

	Settings	Close	
	SilhouetteLite		
A	ARANZ Medical Limited Version: 1.1 (Build 37)		
	View End User License Agreement	>	в
	Log	>	c
	Connection Status		
D	Network: Reachable (Wi-Fi)		
E	SilhouetteCentral: Reachable		
	Change SilhouetteCentral Address	>	F



D

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 <u>CTEULA</u> 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, check:

- That the device Wi-Fi or mobile data is on and connected.
- If using mobile data, 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.

E

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, 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 is a web-based application, enabling users to, securely and centrally store, share, review and analyze the wound data collected using SilhouetteCentral, SilhouetteConnect, SilhouetteStar, SilhouetteMobile, SilhouetteLite+, and SilhouetteLite devices and applications. SilhouetteCentral can collect images directly with a SilhouetteStar 2 scanner or using built-in cameras on mobile devices.

SilhouetteCentral has four main interfaces:

- 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, roles, data fields, 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.
- SilhouetteTokenService Provides centralized user authentication services to the Silhouette suite of products. The token service can also support single sign-on (SSO) for enterprise users using the SAML2 protocol, typically by integrating with an enterprise's federated identity provider (e.g. AD FS).

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 most of the system settings are
 administered in SilhouetteCentral and then downloaded to SilhouetteConnect during the synchronization
 process.

Topics



Parts of the User Interface (UI)



Managing the SilhouetteConnect Patient List



The Patient Selection Screen



The Patient Dashboard



<u>Wounds</u>



Assessments



Working with Images



Clinical Data Administration

Parts of the User Interface (UI)

The following help topics are to help you become familiar with the general look and feel of the Silhouette application:

- Navigation within the Clinical UI (navigation around a patient record)
- Application Menu (navigation in the application outside of a patient record)
- Hidden Display (inactivity timeout)

Parts of the application outside of the clinical UI are largely discussed in the Administrator User's Guide.

Navigation within the Clinical UI

In most SilhouetteCentral and SilhouetteConnect clinical screens, you are be presented with three main navigation tools that are always available to you. There is:

- The header containing the application menu and an icon to get you back to the main patient search page.
- The patient banner to show the patient positive identification information for the currently selected patient, shown wherever there is a patient selected.
- The patient sidebar to navigate around the patient record.

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Patient > Details H			
Details			
Details			-
Patient ID	Unit	Last Name	First Name
258	Ward A / Site A	Banana	Mandarin
Middle Name	Date of Birth	Gender	Hospital Number
-	1962-02-28	Male	258
Address			+
Contact			+
	Details Patient ID 258 Middle Name - Address	Details Unit Patient ID Unit 258 Ward A / Site A Middle Name Date of Birth - 1962-02-28 Address Image: Comparison of the second sec	Details Unit Last Name 258 Ward A / Site A Banana Middle Name Date of Birth Gender - 1962-02-28 Male Address Image: Comparison of Comp

The screen layout changes based on the size of the screen. On the smallest screens (like mobile phones) the layout can change dramatically to optimize for the functions that are likely to be performed on those devices.

A 🧔 silhouette 🛛 🖁 Adam Nurse 🗸 🖪
C Mandarin Banana Patient ID: 258 Date of Birth: 1962-02-28 (60 years old) C + Add Assessment Actions C O
G 🛔 Overview
IH Investigation History
MH Medical History
Med Medication
Source State
Wounds
A: Right Calf
B: Right Elbow, Posterior
Mandarin
Middle Name



Patient Selection / Home

Selecting the icon or Silhouette word mark in the top left takes you back to the patient search screen.



Application Menu

The name of the logged in user is shown in the top right and selecting it shows the application menu to navigate between parts of the application. See the help topic <u>Application Menu</u> for more details.



Selected Patient Details / Positive Patient Identification

The currently selected patient is shown at the top of the screen in the patient banner.

The information displayed here is used for positive patient identification to help make sure you are taking images for the correct person. In clinical practice configurations this information typically includes:

- Patient Name
- The main patient identifier
- Patient date of birth

This information is the same as the information displayed on the patient and orders search screens when selecting patients and also on the SilhouetteStar 2 display.

When used for clinical research, operators tend to configure Silhouette without patient names or even date of birth.

On small screen the information can be condensed as the user scrolls down the page, allowing the screen size to be utilized effectively.



Main Action Button

The main action button provides easy access to the most common function in Silhouette for any given page. Other actions are available in the Action Menu.

If you don't have permissions to complete the action that would normally be the main action, the button is not shown.

The main actions are typically New Assessment or New Wound Assessment.



Action Menu

The action menu provides access to all other actions that are not the main action. The options available in the action menu are dependent on what page you are currently viewing and on your permissions.



Select the camera icon to open the patient's image portfolio, see the help topic <u>Portfolio -</u> <u>Image Review Mode</u> for more details.

The badge on the camera icon shows how many images are unassigned / unused in the patient's image portfolio.



Sidebar and Navigation

The Sidebar allows you to navigate between the various views of the patient. The sidebar contains:

- **Overview** the default view when selecting a patient. Selecting the overview option shows The Patient Dashboard.
- **Details** (and other patient level information) typically contains the main patient identification information. The number of patient information sidebar entries shown is configurable and will depend on your organization.
- **Orders** if orders are enabled then selecting the orders item in the sidebar shows the orders details page.
- Home User Access if the Home User optional feature is enabled and you have the Can Manage Home Users permission then selecting the Home User Access option takes you to screens to create and manage access to this patient record.
- **Wounds** The wounds section of the sidebar lists active and inactive wounds. Selecting a wound from the sidebar shows The Wound Dashboard.

The sidebar changes operation on smaller screens.

- On large screens then the sidebar can be squashed (③) to only show the icons for each item and then it can be expanded (④) to show the full description again.
- On smaller screens the sidebar is accessed using the hamburger menu icon (≡) in the patient banner and then hidden by pressing the X icon (×) of selecting an option.



Patient Breadcrumb

The breadcrumb shows you what you are viewing and the hierarchy of views to get to the current view.

All but the last part of the breadcrumb is click-able to navigate up the hierarchy.

Select the first (left most) part of the breadcrumb to get back to <u>The Patient Dashboard</u> screen.



Version

The version of Silhouette is displayed in the footer at the bottom-right corner of every page.

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. The options in the application menu provide a way to navigate away from a patient to more administrative parts of the application. The exact layout of the application menu depends on your permissions and application you are using. The typical application menu options for a clinical user using SilhouetteConnect are shown below.



Α

Search Patients

Navigates to the Patient Search or Patient Selection screen. Selecting this option is the same as selecting the icon in the top left of the page.

B Search Orders

Navigates to the Orders Search page, allowing you to find patients that have active orders. This option is only available in systems with EHR integration when orders are enabled.

Manage Patients

Opens the **Manage Patients** screen, allowing the selection of patients to download from SilhouetteCentral 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.

This menu item is not available in SilhouetteCentral.

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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.

This menu item is not available in SilhouetteCentral.



Admin

Sync

View and possibly 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.

Hide Display

Forces the display to be hidden to protect any private or personal information from being seen by unauthorized observers.

The display is also hidden automatically on an inactivity timeout, configurable by a system administrator.

The hide display feature is not a screen lock as you will not be required to authenticate again to unhide the display. The Silhouette hide display should be used in conjunction with the operating system screen lock.

If you have unsaved work in progress when the display is hidden, that work will still be available to you when you unhide the display providing that the session termination time hasn't been exceeded.



Help

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



Logout

Select this option to log out of SilhouetteCentral or SilhouetteConnect.

If you need to be use SilhouetteConnect without being connected to the network, just close the application without logging out. Provided that the system is configured to Allow SilhouetteConnect Offline Operation then you will be allowed to use SilhouetteConnect without logging in as long as the maximum offline time hasn't been exceeded.

See the help topic Logging Out From SilhouetteConnect for more details.



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

Hidden Display

The Silhouette display will be hidden to protect information after a period of inactivity, or by the user selecting Hide Display from the application menu, to help prevent unauthorized observers see personal information.

The inactivity period is configurable by the system administrator.

The hide display feature is not a screen lock as you will not be required to authenticate again to unhide the display. The Silhouette hide display should be used in conjunction with the operating system screen lock.

If you are using the SilhouetteCentral website, the hide display works independently between web browser tabs.

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The hidden display screen shows the application wordmark to help if you use both SilhouetteConnect and SilhouetteCentral clients. Other than this wordmark, the rest of the hide display screen looks the same in SilhouetteConnect and SilhouetteCentral.

The system identification is shown as configured by the system administrator. If you are a user that uses more than one Silhouette system, use this to confirm that you are unhiding the correct system or instance (e.g. training vs. production).

Select the **Unhide** button, or press the spacebar on the keyboard, to unhide the display and return to where you left off within Silhouette.

In most cases, unhiding the display does not require you to re-authenticate. You will be asked to reauthenticate when using SilhouetteConnect in a system configured to not allow SilhouetteConnect offline sessions or the Maximum Offline Session time has been exceeded. In this case you must be connected to a network, your web browser will open to allow you to perform a login using the web browser, see SilhouetteConnect Web Browser Login for details.

Managing the SilhouetteConnect Patient List

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

The patients available on SilhouetteConnect are updated whenever a **Sync** occurs (<u>See Synchronizing with</u> SilhouetteCentral).

To add Patients to SilhouetteConnect:

- Manually select patients to add to SilhouetteConnect via the Manage Patients application menu option (See Managing Patients).
- All patients on the user's patient shortlist are automatically added to SilhouetteConnect. (See Personal Shortlist
 <u>Criteria</u>
- Any patient that has an active Order is automatically added to SilhouetteConnect.

To remove Patients from SilhouetteConnect:

- Manually select patients to remove from SilhouetteConnect via the Manage Patients application menu option (See Managing Patients).
- Patients are removed automatically if they are no longer on the user's patient shortlist.
- Patients that were added automatically due to an active order can be optionally removed automatically once their orders are completed.

The **Sync** and **Manage Patients** options are only available in the application menu if your SilhouetteConnect software is configured to connect with SilhouetteCentral and your user account has the correct permissions. If do not see these options and think this could be an error, contact your system administrator.



See the Silhouette Installation and Configuration Guide for further details on the system configuration options relating to synchronization and patient management.

Synchronizing with SilhouetteCentral

The synchronization process coordinates the transfer of information between the SilhouetteConnect and SilhouetteCentral. Information transferred between the applications include:

- User account information.
- Patient information, including images and notes.
- 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. Not all patient data is downloaded to when a synchronization occurs, see Managing the SilhouetteConnect Patient List for more information.

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 manually 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 guide for further instructions on updating SilhouetteConnect.

Managing Patients

The **Manage Patients** screen is only available in SilhouetteConnect and only if it is operating in Synchronized mode 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:

SilhouetteConnect - N	Manage Patients	and and the second				Sec. 2	Ŀ	
Silhou	etteC	onnect				Main Ad	Ministr U All patie availabl	
	f patients in tteConnect	houetteConne	ect		Available	Patients	Silhouette	
Searc	$ \longrightarrow $	Unit A			py selected	🗙 Within U	nit A	•
Last Name	First Name	Middle Na			entral patients	First Name	Middle Na	Patient II
Berry	Clare	Judith	TF3 ^{IO}	Silnoue	etteConnect	Maria		TF02357
🗏 Bloom	Meredith	Cooper	TF32014	$\overline{}$	🗖 Dallas	Steven	Arthur	TF31098
Jones	Oliver	Wendell	ZW8023		Davidson	Peter		TF31947
Morrow	Alexandra	Mary	TF32007		🗹 Goodwin	Mark		TF32092
Moses	Olivia		TF32903	+	Gow Gow	Hilda		DF23682
Parker	Daniel	Maurice	TF32189		Grayson	Richard		TF00902
Singh	Alice		ZW0124		Petersen	Andrew	David	ZW3468
Smith	John		ZW8367		Probst	Terry		TF32473
Taylor	Marisa	(TE21065	\rightarrow	Rudd	Ashley	George	ZW0719
Watson	Judith	Click to remove	_	*	Smith	Tom		ZW6783
🔲 Wayne	Bruce	selected patients f			Stanford	Louis		TF32892
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White	Julia		TF31057		Warren	David	Arthur	TF33092
Wilkins	Jane		TF33235		Watson	Jonathon	Andrew	ZW0345
🔲 Wilkinson	Lois			k the le copy t	ect a patient, the ft arrow button he patient to letteConnect		Click to begin th synchronizatio process	
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Cancel		Select All Des	elect All		Select All	Deselect All	✓ ✓ <u>S</u> ync	

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 first screen you see is the patient selection screen. This page is the start point for all clinical workflows in Silhouette, allowing you to create a new patient record or to find and select an existing patient record. Select a patient to:

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

There are no patients shown for selection until you press the **Search** button.

In SilhouetteConnect, the patient search only looks at the patients that have been downloaded to the local PC, see <u>Managing the SilhouetteConnect Patient List</u>. To search the entire Silhouette patient list use the Manage Patients feature.

In SilhouetteCentral, the patient search looks for patients in the entire Silhouette database.

silhouette®					.) Adam Nurse 🗸
Search Name / Patient ID	×				+	Create Patient
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All Units -		-		-		<u> </u>
		-		× Rese	t Filter	Q Search
5) JI	wound + skin assessment earch Name / Patient ID nit filter	earch Name / Patient ID	earch Name / Patient ID nit filter All Units	earch Name / Patient ID ant filter All Units Save Filter	earch Name / Patient ID ant filter All Units Save Filter All X All	earch Name / Patient ID All Units Save Filter Save Filter K Reset Filter

You can return to the patient selection screen at any time by selecting the patient with the magnifying glass icon in the top left of the interface.

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Use the **search** box to find a patient. The search facility searches the following patient details:

- 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 **Search** button to perform the search and show results. Selecting the Search button without entering anything in the **search** box results in all patients you have access to being shown.



Create Patient

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

Unit Filter

You can filter the patients you want to see to a limited set of Silhouette Units. Selecting **All Units** from the drop-down does not filter the results at all, which is the same as making no selection. Selecting one or more Units from the drop down will only show patients currently assigned to those Silhouette Units.

Your most commonly used Unit filter can be remembered as your default by selecting the **Save Filter** button.

Select the Save Filter button to save the current Unit filter selection as your default selection.

The Save Filter button is disabled if your current selection is the same as your default selection.

Your saved filter is applied whenever you load Silhouette or refresh the SilhouetteCentral website. The saved filter is also used in the SilhouetteConnect manage patients screen to give you a short list of selectable units.



E

Select the Reset Filter button to:

- Clear the search box.
- Clear any search results shown.
- Reapply your saved filter as the selection in the Unit filter.

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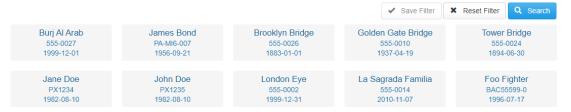
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Select the **Search** button to execute the search and see the list of available patient records matching your entered search criteria.

Selecting the **Search** button when there is no search criteria entered shows all the patient records available to you. If you update the search criteria, select the **Search** button again to show the updated results.



The information included on the tile depends on the Silhouette configuration. The default configuration is to show patient name, patient identifier, and date of birth.

There are up to 50 patients shown initially, with a **Load More** button shown to load further patients if required.

Select a patient tile to show the patient dashboard, see The Patient Dashboard.

Patient search results show below the search criteria. A helpful message is shown to remind you to press the search button to see the results or to let you know if the search resulted in no results.

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.

If the patient you are looking for does not show, the record may not exist in Silhouette or they may be associated to a Unit that you have filtered or do not have access to.

Alternative Configuration: Search By Active Order

You can also search for Orders by selecting if your Silhouette system has Orders functionality enabled and is integrated with an EMR system, **Application Menu > Search Orders**.

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**. Select **Cancel** to return without saving.

The Patient Dashboard

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

(3 Patient	
Cverview	Active Orders	Wounds G + Wound
Details	Order Number ÷ Account Number ÷ Scheduled ↑	
H Investigation History	0000000030 AC00000029 2021-04-10 10:55	Right Left
MH Medical History	Wound Assessment	
ed Medication		
Crders		
Home Users Access		8
/ounds		
B: Right Foot, Heel		
D: Spine, Lumbar	Patient Timeline D	
active -	Wound Assessment for Wound E (Spin	e, Lumbar)
	O a year ago B Healed Wound Images	



The patient banner provides information to positively identify 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 patient banner 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 status of the SilhouetteStar scanner.
- The connection barcode used to connect the SilhouetteStar 2 via Wi-Fi.
- The SilhouetteStar 2 sound mute control.
- 2D Imaging or 3D Imaging if your role has the required permissions.

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 sidebar provides the navigation around the patient record.

The sidebar is collapsible and appears in-line with the page content when viewed on small devices. The currently selected page is highlighted on the sidebar.

- **Overview** selecting overview shows the patient summary with the patient timeline.
- Patient Notes a list of the different patient notes that have been added to the patient, including
 patient demographic details. The **Details** section is always available, but the other patient notes
 shown will typically be configured by your system administrator.
- The fields available within each of the patients notes are configurable by your system administrator, changes to note configurations will be applied when the note is edited.
- Select the **Orders** item from the sidebar to see a list of all past (completed) and present (active) Orders for the patient.
- Wound List a list of wounds with their label and location. Select a wound from the list to open <u>The</u> <u>Wound Dashboard</u> for that wound.

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.

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 an assessment for the patient, see The Create Assessment Wizard
- If the Silhouette system is configured with EMR system Order integration, a paged table of active Orders for the patient are displayed on the overview.

Select an item from the table to display the order details.

A body silhouette image is shown with the wound labels giving the approximate locations for up to 18 active wounds.

Select a wound label from the body silhouette image to open The Wound Dashboard for that wound.

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.

Patie	nt Timeline			
8	Cover Limb Assessment			
	Comments -			
C	Wound Amputate	d for Wound C (Scalp, Post putated	erior)	
cA	Wound Assessme () an hour ago () Open	ent for Wound C (Scalp, Pos	terior)	
	Wound Images Area: 30.6cm ² Width: 64mm Ruler: -	Island Area: - Max Depth: 19mm Area Reduction: 0% (Baseline)	Perimeter: 204mm Mean Depth: 13mm	Length: 71mm Volume: 39cm ³
	Comments -			
C	🕚 an hour ago 🛛 Wound C b	paseline		



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, the state of the wound at the time of the assessment, and any linked order numbers.
- Assessments that include images show the image thumbnails and any summary measurements.
- The timeline dot is light gray for assessments where the wound state recorded is an inactive wound state, otherwise it is a darker gray. The dot contains the wound label for a wound assessment, or a patient icon for a patient assessment.
- The information displayed in each assessment type can be configured by your system administrator.

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, 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.

Wound baseline dates are shown on the timeline as a simple label with a light gray dot.

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.

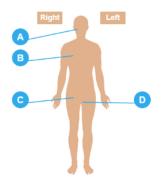
Wounds in Silhouette have a state or status recorded with them. Wounds are classified as either active or inactive based on their current wound state. Active wounds are wounds that are actively being managed in Silhouette and inactive wounds are less prominent in Silhouette as they are no longer being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

Wounds in Silhouette also have a baseline date and time. The baseline date and time are used specifically for the calculation of the baseline area measurement and the Area Reduction for the wound. Area reduction is the % change (reduction) of the wounds surface area with respect to the baseline area measurement and is generally represented as a % change along with a time period, i.e. 50.0% in 47 days.

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.

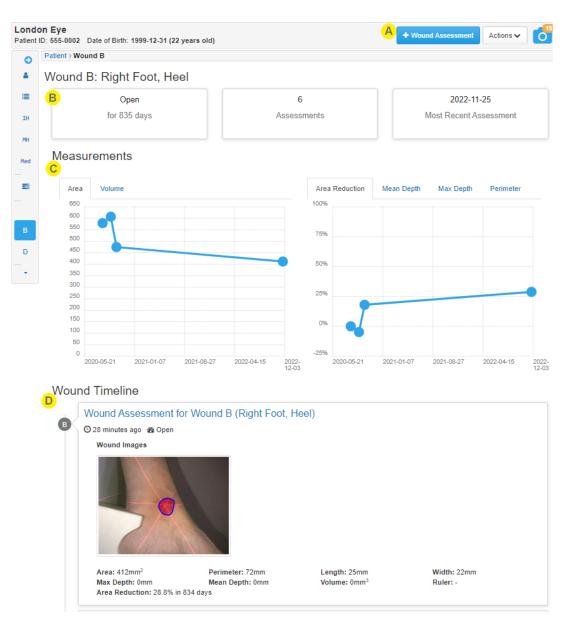
The list of wounds for a patient are available on <u>The Patient Dashboard</u> screen. All of the patient's wounds are listed on and can be selected from the patient sidebar under the **Wounds** heading. The Patient dashboard also shows a body silhouette with the wound labels and approximate locations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



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

The Wound Dashboard

Selecting one of the **Wounds** from the Sidebar or from the body silhouette image opens the **Wound Dashboard** for that selected Wound:



Α

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 The Create Assessment Wizard.



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.
- The Wound baseline date. To change the wound baseline date see <u>Setting the Wound Baseline</u>.
- Patient level assessments performed for the patient.

Creating a Wound

Create a new wound by selecting the + Wound option in the action menu.

Selecting the **+ Wound** option 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 (Synchronized 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

B

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

Group	
B 🖍 Head & Neck	
Gross Division	
B 🖍 Scalp	
Region	
B 🖍 Right Lateral	
Wound Auxiliary Text	
B 🖍	
	C, cia

Select the part of the wound description you want to change.

Select the **Close** button to close the dialog without making any changes.

C D

Setting a Wound State

A

B

C

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

Wound State for Wound A (Scalp, Right Lateral)

	🖌 Save	× Cancel
Wound State		
A Initial observation date *		
2019 08 05 11 : 43 🖬		
B Wound State *		
Healed		

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 wound timeline.

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.

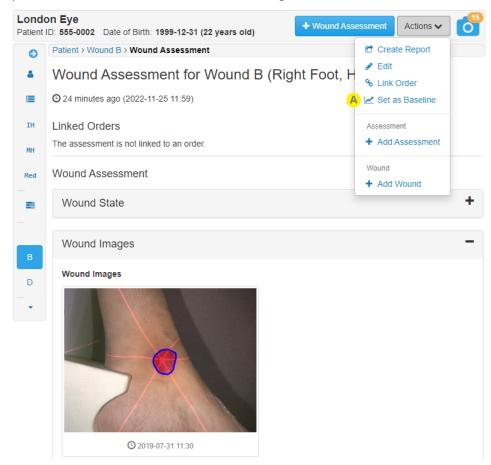
Setting the Wound Baseline

2

A wound baseline date is used to find the wound area baseline measurement. The wound area baseline measurement is the first non-zero area measurement on or after the wound baseline date.

When creating a wound, the baseline date is set as the initial observation date.

Users with the can set wound baseline permission can set the baseline date by selecting a wound assessment or wound state update from the wound timeline and then selecting **Set as Baseline** from the toolbar.



Use the **Set as Baseline** option when viewing a wound assessment or wound state record to set the wound baseline date to a new date.

A confirmation dialog is shown with the current baseline date and the new baseline date before any change is made.

Changing the wound baseline date changes the baseline measurement used for area reduction. There is only one baseline date for a wound and any assessments before the baseline date will no longer report an area reduction measurement.

The area reduction reported for assessments on or after the new date will change based on the new area baseline measurement, e.g. the assessment used to set the baseline date will now report 0% (Baseline) as the area reduction.

Changing the baseline date for the wound is not classed as a Wound Assessment edit and will not cause assessment edit actions to be triggered.

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.

A patient assessment appears on the timeline in both patient and wound overviews for all wounds.

• Wound Assessment for assessments specific to a single wound.

A wound assessment appears on the timeline in both the patient overview and the wound overview for the associated wound.

Wound assessments are where wound healing is tracked. A wound assessment will always show the current state of the wound and allow you to change it. You can even add an image of a healed wound and mark it as having been assessed by setting it to 'zero measurements'.

See the following help topics for more information.

- The Create Assessment Wizard
- Viewing and Editing Assessments
- Assessment PDF Report

The Create Assessment Wizard

To create a new Assessment use one of the following options:

- Select the Add Assessment button from the action menu toolbar or from within the Actions menu. The main toolbar button changes depending on the patient screen you are viewing.
- Select Wound Assessment from the action menu toolbar to create a wound assessment for the currently selected wound. This option is available when you have already selected a wound from the patient menu / sidebar.
- The **chart +** button (associated to an image in the patient's image portfolio.

Selecting one of these will present the assessment creation wizard which will allow creating either a **Patient Assessment** or a **Wound Assessment**.

Once the wizard is open there are **Back** and **Next** buttons available to move back and forward in the wizard. There is also a **Cancel** button to cancel the create assessment action.

Step 1: Select Assessment Type

Select Assessment Type	
Admission Assessment Patient admission	
Discharge Assessment	
Patient discharge	
Lower Limb Assessment	
Assessment of lower limb function	
Wound Assessment	
Back Next	Cancel

Α

The first step of the wizard will present a list of assessment types that can be created. If there is only one type of assessment that can be created, this step will be skipped.

B

Assessments that include image captures are marked with the picture icon.

If the create assessment wizard was started from the **chart** + button (🗟) in the image portfolio, only assessment types that have an image capture field are shown. There may also be an additional step available in the wizard if there is more than one image capture field in the assessment, allowing you to select the image field the image should be assigned to.

Step 2: Select Wound

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For a wound assessment there will be a second wizard step that will ask to select or create a wound. This step is skipped if you initially selected **Wound Assessment** from the wound overview.

Wound Assessment / Select Wound	
C Right Left B	Create New Wound
	A Scalp, Superior
	B Scalp, Posterior
Back Next	Cancel

The patient's active wounds are listed on the mannequin and as buttons.

Select the wound button or click the wound label on the mannequin to start an assessment for that wound.

The **Create New Wound** button will take the user through the wound creation wizard.

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.

🔇 an hour ago 🔮 Open				
Wound Images Area: 30.6cm ²	Island Area: -	Perimeter: 204mm	I	
			Length: 71mm	
Width: 64mm	Max Depth: 19mm	Mean Depth: 13mm	Volume: 39cm ³	
Ruler: -	Area Reduction: 0% (Baseline)			

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

	arin Banana D: 258 Date of Birth: 1962-02-28	(61 years old)		+ Wound Assessment	Actions -
€	Patient > Wound C > Wound As	ssessment			
+	Wound Assessment	for Wound C (Scalp, Po	osterior)		
:=	(\$ 2 hours ago (2023-09-12 13:39)		B ^ Hide a	issessment metadata
ІН	Created at 2023-09-12 13:39 Created by admin Assessment type version 1			0	
MH	Linked Orders				
Med	The assessment is not linked to a	n order.			
*=	Wound Assessment				
-	Wound State				^
	Wound State		Recurring		
A	Open				
B E	Wound Images				^
С	Wound Images Area: 30.6cm ² Width: 64mm Ruler: -	Island Area: - Max Depth: 19mm Area Reduction: 0% (Baseline)	Perimeter: 204mm Mean Depth: 13mm	Length: 71mr Volume: 39cr	



B

The actions you can perform when viewing an assessment are dependent on your assigned permissions.

Select Edit from the Action menu 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 <u>Making Measurements using</u> <u>Images</u>.
- Record other notes.

Select **Set as Baseline** to use this assessment as the new area baseline for the wound, see <u>Setting the</u> Wound Baseline.

Select **Create Report** to generate and download a PDF assessment report, see <u>Assessment PDF Report</u>. If you are using Orders, you can also select **Link Order** to link this assessment to an order, see <u>Linking</u> Assessments and Orders.

Selecting **Show/Hide assessment metadata** toggles display of the assessment type version, who created that version and when it was created. Assessment type templates can be added and configured by your system administrator.

If you are using Orders, the assessment orders which this assessment is linked to are displayed above the assessment.

A wound assessment will have the wound state as observed at the time of the assessment at the top of the assessment.

E

The remaining content of the assessment (including wound images, measurements, and notes) are shown below the wound state.

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

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

When measurements are displayed as a - this means that there is no valid measurement of that kind for the image field.

The area reduction measurement is calculated dynamically and depends on other assessments and the area baseline measurement for the wound.

- A typical area reduction is shown as a % area reduction with a number of days since the baseline measurement, e.g. 19.0% in 31 days.
- If the assessment is the area base line measurement, that is indicated by showing an area reduction of 0% (Baseline) as the area reduction measurement.
- If the assessment date is prior to the wound baseline date or there is no non-zero area baseline measurement, the area reduction measurement is shown as a (dash).

For more information about capturing images for circumferential wounds, see <u>Taking Circumferential</u> Measurements using Multiple Images.

Assessment PDF Report

The Create Report option in the Action Menu 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** option from the **Action Menu**. If the option is not available, 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 method, i.e. SilhouetteStar, SilhouetteLite+, SilhouetteMobile, or SilhouetteCentral 2D or 3D Imaging.

The fundamental image capture and measurement workflow is:

- 1. Select a patient.
- 2. Capture image(s).
 - See the topic Using SilhouetteStar for details on capturing images with the SilhouetteStar scanner.
 - See the topic <u>Using SilhouetteLite+ or SilhouetteMobile</u> for details on capturing images with the SilhouetteLite+ or SilhouetteMobile apps.
 - See the topic <u>Using SilhouetteLite</u> for details on capturing reference images (no measurements) with the SilhouetteLite application.
 - See the topic <u>Using 2D and 3D Imaging in SilhouetteCentral</u> for details on using the SilhouetteCentral web application to capture images for 2D or 3D measurements with a mobile device camera.
- 3. Assign the images to a wound in an assessment, see the topic Assessments.
- 4. Trace the wound images to identify and measure the wound.
- 5. Create a PDF assessment report to share images and measurements.

The imaging workflow changes based on the capture device you are using. However, once images are captured, 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
- Making Measurements using Images

Silhouette also allows you capture images by uploading JPEG images captured by generic cameras or capture directly from a mobile device camera. See the help topic Capturing Images from a Generic Camera for more details.

Viewing Images

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

In the image viewer you can control what you see overlaid onto the image both in the viewer and the exported image. The options available depend on the capture device used to obtain the image.

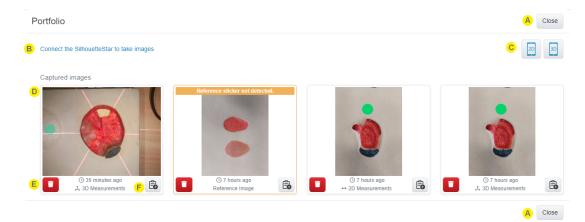
\times	Show or hide the lasers on SilhouetteStar captures.
×	Show or hide the laser detections (the points where the software has detected the laser) on SilhouetteStar captures.
	Use the laser detections to check the quality of the image captures for measurement. The laser detections should be almost solid lines within the visible laser lines in areas of the image where measurements are being made.
G	Show or hide the outlines drawn on the image.
1.	Show or hide the rulers drawn on the image.
	Show or hide the axes for the outlines drawn on the image. Showing the axes will also show the outlines if they are hidden.
	Showing the axes helps to see where the reported length and width are calculated from.
<u>.</u>	Export the current view of the image from Silhouette.

To edit the outlines and rulers on the image you need to edit the assessment. <u>See Making Measurements using</u> <u>Images</u> for more information on editing tracings.

Portfolio - Image Review Mode

B

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 <u>Portfolio - Image Assignment Mode</u>).



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

When imaging with a SilhouetteStar scanner, you can still collect images as long as there is a patient selected and the scanner is connected. You can reopen the image portfolio to review the images at any time.

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 you have the "Can Connect SilhouetteStar using WiFi" permission and there is no active connection between the current web browser tab and a SilhouetteStar 2 scanner. 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.

The **2D** and **3D** buttons will be available in SilhouetteCentral, provided:

- The 2D or 3D Imaging option is enabled in the SilhouetteCentral license.
- You have the correct permissions assigned by your system administrator.
- You are using a Mobile web browser (e.g. Safari on an iPhone). In some scenarios your system admin may allow 2D or 3D Imaging from non-Mobile web browsers.

Selecting the **2D** or **3D** button will start the appropriate imaging wizard, see the <u>SilhouetteCentral</u> <u>2D and 3D Imaging Setup</u> topic.

The available (unassigned) images are shown with the time since capture and the type of measurements that the image supports.

The type of measurements (2D or 3D) supported depends on the imaging method used to capture the image and the successful processing of that image. If no measurements are supported, the image shows as a Reference Image.

- SilhouetteStar images are capable of 3D Measurements.
- SilhouetteLite+ and SilhouetteMobile images can be capable of 2D Measurements or can be listed as a Reference Image, depending on the capture being made with a valid range from the SilhouetteLite+ Sensor.
- SilhouetteLite images are a Reference Image.
- Images captured with 2D Imaging may be capable of 2D measurements or can be listed as a Reference Image, depending on the successful detection of the reference sticker
- Images captured with 3D Imaging may be capable of 3D measurements or can be listed as a Reference Image, depending on the successful processing of the image sequence.
- Errors or warnings encountered during the processing of 2D or 3D Imaging captures are shown on the image.



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The measurement capability is a maximum capability. The actual measurements you will get from the image depend on image capture quality and the outlines you apply to the image.

Select an image to view it in larger image viewer (see the <u>Viewing Images</u> topic) and review the image quality and to see the full time of the image capture.

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.

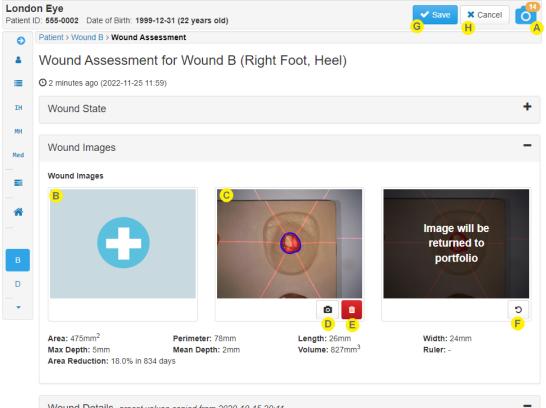


A **Create Assessment** button (a) is provided for each image. Select the button to start a new assessment using the image. This will launch the Assessment Wizard, see <u>The Create Assessment</u> <u>Wizard</u> topic, allowing selection of the assessment and wound that the selected image should be assigned to.

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 (The Create Assessment Wizard) or editing (Viewing and Editing Assessments) an assessment.



Wound Details preset values copied from 2020-10-15 20:11

Images captured using SilhouetteStar, 2D Imaging and 3D Imaging are initially 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.

Captured images need to be assigned to an assessment (usually Wound Assessments) to enable wound tracing and tracking of healing. The portfolio is designed for temporary storage of the captured images, allowing images of multiple wounds to be captured before completing the patient or wound assessments. The image portfolio is not designed for long term storage of a large number of patient images.

Images captured using SilhouetteLite, SilhouetteLite+ or SilhouetteMobile are already assigned 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.

The patient portfolio is not synchronized between SilhouetteConnect and SilhouetteCentral. Images captured in SilhouetteConnect will only appear in the image portfolio on that SilhouetteConnect. The images are uploaded to SilhouetteCentral on a synchronization, however, they will not show in the SilhouetteCentral portfolio until the patient record is removed from the SilhouetteConnect.

When editing or creating an assessment, 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 <u>Taking Circumferential Measurements using Multiple</u> Images.

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, add rulers or record zero measurements. See Making Measurements using Images for more information on image tracing.

If there are image validation rules set for the image capture field (e.g. there must be one image with a single outline) then an error message will be shown by the image capture field heading if the rules are not met. For the purposes of the image validation rules, recording zero measurements for an image is the same as recording an outline for the image.

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

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

If SilhouetteConnect is being used in Synchronized mode, 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.

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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.

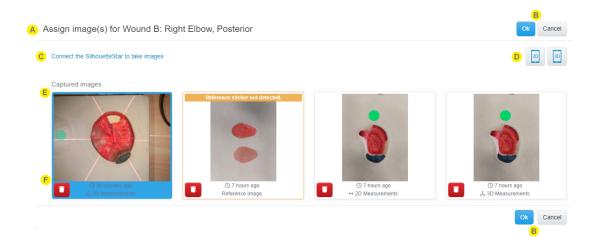


Select the Cancel button to cancel the assessment creation or edit.

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, see topic <u>Portfolio - Image Review Mode</u>). The key difference between the modes, is that when you select an image in image assignment mode it highlights the image with a blue border, indicating that it is selected for assignment, rather than opening the image viewer.

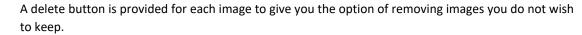


- The title of the portfolio dialog provides information about the assessment and wound you are assigning images to.
- B Ok and Cancel buttons are provided at the top and the bottom of the image portfolio. Select the OK button to confirm the selection and assign the images to the assessment.

Select the Cancel button to close the portfolio without assigning selected images.

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

- C There may be a link showing the connection of the SilhouetteStar scanner. See the topic <u>Portfolio -</u> <u>Image Review Mode</u> for details. You can continue to connect and capture SilhouetteStar images when the portfolio is in assignment mode.
- D There may be a 2D or 3D Imaging icon, see the topic <u>Portfolio Image Review Mode</u> for details. You can initiate a 2D or 3D Imaging capture and it will be automatically selected for assignment after completing the imaging wizard.
- The available (unassigned) images are shown with the time since capture and the type of measurements that the image supports. See the topic <u>Portfolio Image Review Mode</u> for details. 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.



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.

Making Measurements using Images

Measurements can be made using images captured with either the SilhouetteStar, SilhouetteLite+ or SilhouetteMobile. The measurements that can be made from images depend on the device used to capture the image, the quality of the image capture, and the complexity of the features to be measured. For details of the measurement process used by Silhouette, refer to the "How Silhouette Works" document available from ARANZ Medical support.

To make measurements using an image the image must be assigned to an assessment. The assessment must be in edit mode (i.e. not view mode) and the user must have permission to trace images.

Select the image thumbnails from an image capture field within an assessment to open the trace screen and to trace the wound outlines. The following topics help explain the use of the tracing screens:

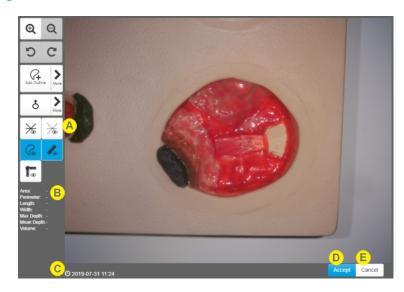
Using the Tracing Screen

F

- Adding Outlines to Images
- Taking Circumferential Measurements using Multiple Images

Selecting an image while viewing (not editing) an assessment or without tracing permissions, opens the image viewer without the trace tools present. See Viewing Images for more details on the image viewer.

Using the Tracing Screen



€ Q

Zoom in and Zoom out buttons are provided to zoom into features on the image. The image can be zoomed using pinch gestures by selecting the Pan tool first.

A disabled Zoom Out button indicates that the image is fully visible.

Once zoomed, the image can be panned by selecting the pan tool from the more tools button.



Undo and Redo buttons are provided to easily undo or redo any actions you perform on the image until you select either **Accept** or **Cancel**.

These buttons are always disabled when you first open the image tracing screen but get enabled as you perform actions that can be undone.



The currently selected tool or action is shown on the toolbar.

Selecting the button shows more actions and tools that are available. <u>See Tracing Tools</u> below for more details.



Toggles and rotates the on-screen stylus for accurate tracing on touch screens.

The button background is blue when the on-screen stylus is turned on, light gray when the onscreen stylus is available but turned off and dark gray when the on-screen stylus is not available for use.

- Select the main section of the button content to toggle the on-screen stylus.
- Select the More section of the button to show stylus rotation options.

In this version of Silhouette the on-screen stylus is only available for use when using the add outline tool.

See Using the On-Screen Stylus below for more details on the use of the on-screen stylus.

- The set of tools at the bottom of the toolbar provide control over what overlays are visible on the image. See View Controls below for more details.
 - The measurements generated by the outlines on this image are displayed below the toolbar on the left.

The measurements shown depend on the type of device used for capture and your organizations settings.

C

The image capture date and time is displayed under the image and is replaced with helpful messages about progress, the status of the tracings or tips on how to use the selected tools.

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**.

Tracing Tools

The currently selected tool is shown on the first large toolbar button which is used to switch between the tools. Selecting in the first large toolbar button shows a menu of tools that can be used for tracing and measuring the image.



- The selected tool has a blue background.
- A tool that can be selected has a light gray background.
- A disabled tool that can not be selected has a dark gray background.
- Measurements for the image are updated as you use the tools. In some scenarios the interface might block further actions while measurements are calculated.



Select the **Pan** tool to move the image when it is zoomed.



Select the **Add Outline** tool to add an outline to the image.

Outline a feature in the image to have Silhouette to report area, length, width, perimeter, mean depth, maximum depth, and volume of that feature. The type of measurements that can be made from an image depend on the scanner used to obtain the image and on the complexities of the image features. See help topics related to the scanner types for more information:

- SilhouetteStar for 3D measurement, see Using SilhouetteStar.
- SilhouetteLite+ or SilhouetteMobile for 2D measurement, see <u>Using SilhouetteLite+ or</u> <u>SilhouetteMobile</u>.
- SilhouetteCentral 3D Imaging feature for 3D measurement, see <u>Using 2D and 3D Imaging in</u> <u>SilhouetteCentral</u>.
- SilhouetteCentral 2D Imaging feature for 2D measurement, see <u>Using 2D and 3D Imaging in</u> <u>SilhouetteCentral</u>.

When you add an outline within another outline it is treated as an island and, depending on organizational settings, can be ignored when calculating area.

Use the **Add Outline** tool to identify regions of interest within the image when using the **Auto Boundary Detection** tool.

The Add Outline tool supports:

- Drawing by dropping discrete points of a polygon on the image.
- Drawing by dropping a continuous series of points as you move around the image.
- Drawing using a mouse, a stylus or the provided on-screen stylus for touch screens.

<u>See Adding Outlines to Images</u> for more help on using outlines to measure complex wounds or define regions of interest.



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

To add a ruler:

- 1. Select the start point for the ruler. A large point is drawn on the image
- 2. Select the end point for the ruler. A ruler line is drawn and the measurement for the ruler is displayed next to the ruler line.
- 3. Use the **Edit Point** tool to edit either end of the ruler as required.

Edit Point

Select the Edit Point tool to edit outlines and rulers.

To use the edit point 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.

If points are placed close together, you may need to move the topmost point before editing other points. Use the **Remove Point** tool if there are too many points in an outline.

Use **Add Point** tools to create an additional point to edit if there are not enough points in an outline.

Take care not to edit points so it creates outlines that cross over themselves or intersect with other outlines.



Select the **Delete** tool to delete outlines or rulers from the image.

Once the delete tool is selected then select the outline or ruler you wish to delete from the image.



Use the **Delete Point** tool to select and remove individual points from an outline.

+	
Add Point	

Use the **Add Point** tool to add points into an outline line segment by clicking or touching where you wish to add the point.

Once you have added a point into a line segment, use the **Edit Point** tool to move the point to the desired location.



Auto Boundary (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** 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:

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- 1. Use the **Add 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 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, 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, an error will be shown at the top of the screen. Make an edit to the ROI or delete it to clear the error. You can then retry the automatic wound boundary detection or trace the wound boundary manually.
- Once the automatic wound boundary detection is completed, use the Edit Point, Add Point and Delete Point tools to adjust the 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** 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** tool is dependent on your specific system configuration and it can be enabled or disabled by your system administrator.



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The **Auto Boundary** 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.



Use the **Record Zero** button to mark the image as having no wound and record measurements of 0.

The **Record Zero** button is disabled if there are already wound outlines on the image.

The **Record Zero** button is a toggle, selecting the button again removes the zero measurements from the image and allows you to draw wound outlines on the image again.

The record zero feature allows you to image a healed wound and record your observation that the wound measurements are 0.

When you record zero measurements for an image, a banner is added to the image showing that zero measurement has been recorded and you can no longer add wound outlines to the image.



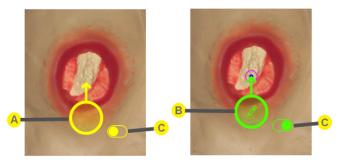
The banner is shown on the image in the image tracing and viewer screens and on the assessment timeline, but is not included in the wound assessment PDF report.

Using the On-Screen Stylus

The on-screen stylus allows accurate outline tracing on touch screens.

- Enable the on-screen stylus when using your finger or a large-tip stylus on a touch screen.
- Disable the on-screen stylus when tracing with a mouse, touch pad, or thin tip active stylus (e.g. Apple[™] Pencil).

The add outline tool can be used on touch screens without the on-screen stylus and the outline will be drawn where you touch the image. Using the on-screen stylus allows more accurate outlining and means that you can use pinch gestures to zoom the image and can pan a zoomed image by dragging the image.





The on-screen stylus in move and drop point mode is yellow with no icon.

- Drag the stylus around the image using the circle area.
- Tap the circle to drop a point at the current stylus location. Points are dropped at the tip of the stylus.

Points cannot be dropped too close to each other to prevent creating overlapping points by mistake. If you tap the stylus too close to the last point of an outline, the tap will be ignored. Move the stylus further away from the last point and tap it again. Points can be edited closer together using the Edit Point tool after the outline is completed.



The on-screen stylus in continuous draw mode is green with a drawing pencil icon.

- An initial point is dropped when the continuous draw mode is entered. Move the stylus to where you wish to drop a point before initiating continuous draw mode.
- Drag the stylus using the circle area. Points will be dropped at regular intervals as you move the stylus on the image.
- Drag the stylus into the finish target to complete the outline.

If you move the on-screen stylus off the image, zoom the image so the stylus moves or rotate the stylus then the stylus automatically changes to move mode.



Tap the toggle button beside the on-screen stylus to change between the move and continuous draw modes.

View Controls

The view controls allow you to change what you see on the image. The options available depend on the device used to capture the image but can include:

- Show / Hide Lasers (SilhouetteStar captures only)
- Show / Hide Laser Detections (SilhouetteStar captures only)
- Show / Hide Outlines
- Show / Hide Rulers
- Show / Hide Axis

Silhouette prevents you turning off some of the view controls when using the tracing tools, e.g. can not hide outlines when adding or editing outlines.

See Viewing Images for more information on each of the view controls.

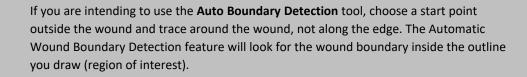
Adding Outlines to Images

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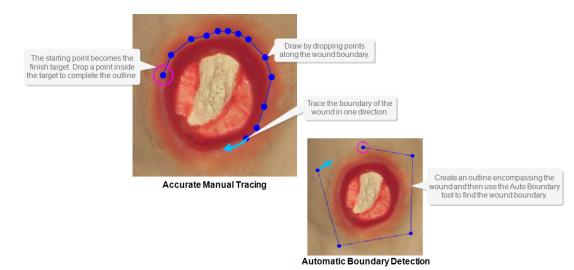
Outlines on an image are used by Silhouette to make measurements of area, length, width, max depth, mean depth, and volume from the image. The measurements available from any given image are dependent on the scanner used to capture the image, the quality of the image captured, and the complexity of the features being traced.

An outline is a non-intersecting polygon with any number of points and sides. To trace a wound boundary or a region of interest:

- 1. Zoom in so that the part of the image you wish to outline fills as much of the screen as possible.
- 2. Select the starting point of the outline by clicking on the image in the desired location or by dragging the onscreen stylus to the edge of the wound.



- 3. The first point of the outline becomes the finish target. The finish target is a dot with a circle around it.
- 4. Draw in one direction by dropping points along the wound boundary. Drawing in one direction ensures that you do not accidentally create an overlap within the outline.
- 5. Drop a point inside the finish target to complete the outline, at which point the outline can be edited.
- 6. Use the **Undo** button to remove the tracing point by point.



Multiple Wound Fragments

You can add multiple outlines to an image to identify individual fragments of a wound or feature by selecting the **Add Outline** tool and adding additional outlines to the image.

All outlines on a single image are treated as fragments of the same feature and the measurements are summarized by adding the area and perimeter of the outlines. When there are multiple outlines required to trace a wound on a single image then the depth and volume measurements can not be calculated or displayed for that wound.

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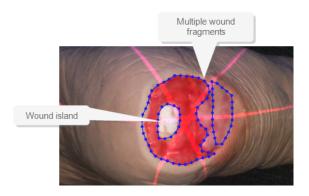
To trace different features in the same area multiple images need to be taken and assigned to separate assessments or to separate image capture fields within an assessment.

Excluding Wound Islands from Measurements

You can identify islands within another outline to exclude areas from the measurements.

To trace an island, select the **Add Outline** button and trace the island, ensuring the outline is closed and is not intersecting or crossing any other outline on the image. Silhouette automatically regards outlines inside other outlines as islands.

When you outline islands for a wound, depth and volume measurements can not be calculated or displayed for that wound.



Errors when Adding Outlines

Measurements can only be calculated if the outlines follow certain rules:

- An outlines can not cross itself at any point (e.g. a figure eight outline can not be used).
- An outlines can not intersect another outline.
- An island cannot be placed within another island.

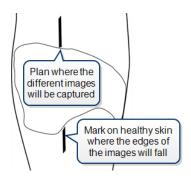
If there is a problem with the outlines or measurements, a message is presented at the top of the image window. The resolution to most errors is to remove or edit the offending outline and try again. See the example in the image below:



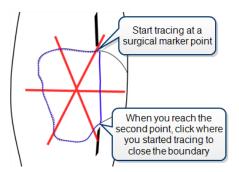
Taking Circumferential Measurements using Multiple Images

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.

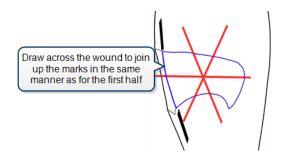
- **1.** Plan where the different images of the wound are to be captured.
- 2. Use a surgical marker to mark on healthy skin where the edges of the different images are.



- **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.

Capturing Images from a Generic Camera

Silhouette can be configured to allow the capture of images directly from a mobile device camera or by uploading JPEG format images captured by a generic digital camera which have already been transferred to your computer.

To enable this feature ask ARANZ Support to help configure an assessment type that includes an image capture note field which captures from the computing device. To capture or upload the images create an assessment that is configured to allow capturing images from the computing device.

all Spark NZ 🗢 🗺 10:39 PM	all Spark NZ 学 200 10:41 PM (二) 書 stheoet.ecentral.com	ati Spark NZ 후 253 10:48 PM
AA 🔒 silhouettecentral.com 💍		AA 🔒 silhquettecentral.com 🖒
🗞 silhouette® 🔝	Image Upload	
Bond James Patient ID: 1 Date of Birth: 1975-04-01	P Uploading intege	Bond James Patent ID: 1 Date of Birth: 1975-04-01
1 Overview	and and	1 Overview =
Admission Assessment		Admission Assessment
© 2021-06-20 22:38		@ 2021-06-20 22:46
Save X Cancel	B Cancel	C Save X Cancel
Admission Images -		Admission Images -
Admission Images		Admission Images
0		
	Details -	
	Expected Discharge	E a 💼
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Select the **+ Image** button to capture images from the mobile device camera or upload a JPEG image from your computer. Depending on the device you are using, this will either open your device camera or open a file selection dialog.

The **+ Image** button is available when creating, or editing, an assessment with an image capture field set to capture images from the computing device.

Proceed with capturing the image using the camera or selecting the image for uploading.

B Once captured, the image will be uploaded to Silhouette. The upload can be canceled if necessary. When successful, the image upload dialog will close and the image thumbnail will show in the image capture field.

Save the assessment to save the assessment and images, along with any other notes captured.

Select the + Image button to upload further images.

The uploaded image shows as a thumbnail and can be sent to the patient image portfolio or deleted using the buttons under the thumbnail.

Alternative Implementations

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The default configuration of Silhouette limits the size of images captured from mobile device cameras or uploaded JPEG images to approximately 10 MP. This configuration can be modified by ARANZ Medical Support.

Orders in Silhouette

Orders functionality is an optional Silhouette feature and requires EMR system integration.

An Order, in the context of Silhouette, is a request for an assessment to be preformed for a patient. An Order can only be created by integrating Silhouette with an EMR system and offers a good way to integrate information between the systems and manage a short list of active patients within Silhouette.

Key actions when using Orders in Silhouette are:

- Linking an Assessment to an Order. Linking an assessment to an order allows the details recorded in that assessment to be used when delivering observations from Silhouette back to an external EMR System, allowing the assessment observations to be correctly filed against the correct encounter or order.
- Completing an Order. Completion of an order within Silhouette prevents any additional assessments being linked to it, removes the order from the patient dashboard, stops automatically syncing the patient to SilhouetteConnect, and removes the order from the default orders search.

The typical workflow for orders is:

- An EMR system user creates an order for a Patient encounter in the EMR system.
- A Silhouette user performs an assessment for the patient.
- A Silhouette user links the assessment to the appropriate order for the patient.
- The Silhouette system sends the Assessment PDF Report back to the EMR system using information in the order and encounter to ensure it can be filed against the correct patient encounter.
- The Silhouette user marks the order as completed once they no longer expect to link any assessments to that order.

The design of the orders workflow is often organization specific and depends on the EMR system and clinical workflow needs. Common alternative workflows include:

- Orders can have an Expected Assessment Type, allowing only that assessment type to be used to fulfill the order.
- Order can have a Maximum Assessments specified, which limits the number of assessments that can be linked to an order when it is marked as completed.
- Silhouette creating phantom orders for Patient encounters based on EMR Admissions rather than EMR Orders.
- Use of EMR Admissions to create patient records in Silhouette and orders only created after the Assessment is completed in Silhouette and the user wants to send results to the EMR system.
- Use of Assessment Create and Update events to send PDF Assessment reports to the EMR system without any
 orders.

When the orders feature is enabled within Silhouette there are a number of changes to workflow and behavior. These are described in the following help topics:

- The <u>Search Orders</u> topic describes how to search Silhouette for active or completed orders for various facilities.
- <u>The Patient Dashboard</u>, the <u>Patient Timeline</u>, and <u>The Wound Dashboard</u> topics show how orders appear in general parts of the clinical UI.

- The <u>Viewing a Patients Orders</u> topic shows how to see all orders for a patient and all the details of the order and encounter that are recorded in Silhouette.
- The <u>Linking Assessments and Orders</u> topic describes how to link assessments to orders and describes why you might want to link an assessment to and order.
- The <u>Unlinking Assessments from Orders</u> topic describes how to unlink an assessment from an order if that is necessary.
- The <u>Managing Orders</u> topic describes additional Clinical Data Administration tools available relating to orders, including re-activating and deleting orders.

Search Orders

Orders functionality is an optional Silhouette feature and requires EMR system integration.

Selecting Search Orders from the Application Menu allows you to search Silhouette for Orders.

When you first select the search orders page there are no search results shown by default. You must select the **Search** button to see any search results.

Entering Search Criteria for Orders

Search for Orders					
Search Order Number /	Account Number / Patient ID				
Facility	Status		Scheduled Date from	to	
	- Active	•	yyyy mm dd 🖬	yyyy mm dd	
Hide advanced filters				E	F
				🔍 Searc	h 🗙 Reset

You can return to <u>The Patient Selection Screen</u> at any time by selecting the patient with the magnifying glass icon in the top left of the interface.



Use the **Search for Orders** box to find a patient. Entering text in the search box searches the following fields:

- Order Id
- Encounter Identifier (typically labeled the Account Number)
- Patient Identifier (typically labeled the MRN or NHI or Patient Id)

The search is a text search (not a number search) and searches anywhere in the field. For example:

- Entering an *001* into the search box finds order records with the text 001 in any of the fields listed above. It does not find order records with just the number 1 as the Order Id.
- Entering a *12345* into the search box finds all orders for patients that include the text 12345 in the patient identifier field and all orders for encounters that include the text 12345 in the encounter identifier field and all orders that include the text 12345 in the Order Id field.

Select the **X** to clear the search box of text.

D

The advanced filters can be shown and hidden by selecting the **Show advanced filters** or **Hide advanced filters** links.

The advanced filters allow you to restrict your search to:

- Only search for Orders relating to specific Encounter Facilities¹,
- Only search for Orders with a given Order status (Active and/or Completed), and
- Only search for Orders with a given range of Scheduled Dates.

By default, when first selecting the Order Search page, the filters are set to search for all Active Orders, in any Encounter Facility, scheduled for any date.

To quickly reset the Advanced filters to the default settings, a **Reset Filters** button is provided.

The Scheduled Date filter has a To and From entry. You can provide a From Date only, a To Date only, or both From and To dates. For example, setting a From Date of today's date with no other search or filter criteria will find all orders scheduled for today.

In the Facility and the Order Status filters, selecting no items in the drop-down is the same as selecting all items in the drop-down.

Select the **Search** button to execute the search and show the list of orders matching the entered search and filter criteria.

Selecting the **Search** button with an empty **Search for Orders** box and the default set of advanced filters shows all Active orders.



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Select the **Reset Filters** to clear the **Search for Orders** box and to reset the Advanced Filters to the default search for Active Orders in all Encounter Facilities and scheduled for any date.

¹The Encounter Facility label may be configured differently for your Silhouette system, e.g. a common configuration is to separate encounters by Service rather than Facility.



The paged search results are shown below the search criteria once the **Search** button is selected.

A blank search results area indicates that the **Search** button has not been selected. If the **Search** button has been selected and there are no Orders matching the criteria, a message is displayed indicating that there are no matching Orders to display.

Display of Orders Search Results

Once the **Search** button is selected, the matching Orders are displayed in a table below the search criteria.

	Search for Orders								
A)	Search Order Numb	oer / Account Number / Pa	atient ID						×
	Status: Active. Show advanced filters								C X Reset Filters
C	Order Number 🔺	Account Number 🜩	Facility 🖨	Status 🜩	Scheduled Date 🜩	Patient ID 💠	First Name 💠	Last Name 💠	Date of Birth 🜩
I.	000000023	AC00000023	Facility A	Active	2021-04-10 11:00	PA-MI6-007	James	Bond	1956-09-21
	000000030	AC000000029	Facility A	Active	2021-04-10 10:55	555-0002	London	Eye	1999-12-31
	000000039	AC00000035	Facility A	Active	2021-04-10 11:11	PX1234	Jane	Doe	1982-08-10
	0000000041	AC00000036	Facility A	Active	2021-04-10 11:11	PX1235	John	Doe	1982-08-10



The Orders search criteria are shown above the search results.

Selecting the Search button with the default search criteria shows all active Orders, as shown in the image above.



Selecting the **Search** button refreshes the search results shown.

Select the **Reset Filters** to reset the search criteria and clear the displayed results.



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Select the heading of the table column to sort the results shown.

The Orders matching the search criteria are displayed in a table. Select a row in the table to view the Order Details page.

If there are a lot of Orders matching the search criteria, they are shown across multiple pages with paging controls at the bottom of the table.

Viewing a Patients Orders

Orders functionality is an optional Silhouette feature and requires EMR system integration.

Selecting **Orders** from the patient sidebar opens up the **Patient Orders** page.

Patient Orders

The patient orders page shows all the orders for the currently selected patient in tables. The columns shown in the tables change depending on the size of the screen you are using to view them.

The tables show the configurable patient encounter identifier in the second column. It is shown in this manual as **Account Number** but is commonly reconfigured (e.g. Visit Number or Encounter).

The **Linked** column shows if there are any assessments linked to the order. A Yes means there has been at least one assessment linked to the order, while a No means that there are no assessments linked to this order.

The tables are paged if there are a large number of orders to show. The paging control (previous page / next page) are shown at the bottom of each table if they are needed.

Patient > Orders						
Patient Orde	ers					
Active (A)						
Order Number 🗢	Account Number 🗢	Scheduled 📩	Description	Linked		
000000030	AC00000029	2021-04-10 10:55	Wound Assessment	Yes		
000000052	AC00000001	2021-04-13 04:52	Wound Assessment	No		
Completed B						
Order Number 💠	Account Number ≑	Scheduled 👻	Description	Linked		
000000025	AC00000002	2021-04-10 11:00	Wound Assessment	No		
000000002	AC00000001	2020-08-12 04:13	Wound Assessment	Yes		

A

000000001

AC00000001

The first table shows all orders for the currently selected patient with an Active status. Select an order number from the table to see the full details of that order and the list of linked assessments.

Wound Assessment

Yes

The Active orders table is sorted by Scheduled date with the oldest shown first by default.

2020-06-23 04:13

B

The second table shows all orders for the currently selected patient with a Completed status. Select an order number from the table to see the full details of that order and the list of linked assessments.

The Completed orders table is sorted by Scheduled date with the most recent shown first.

Order Details

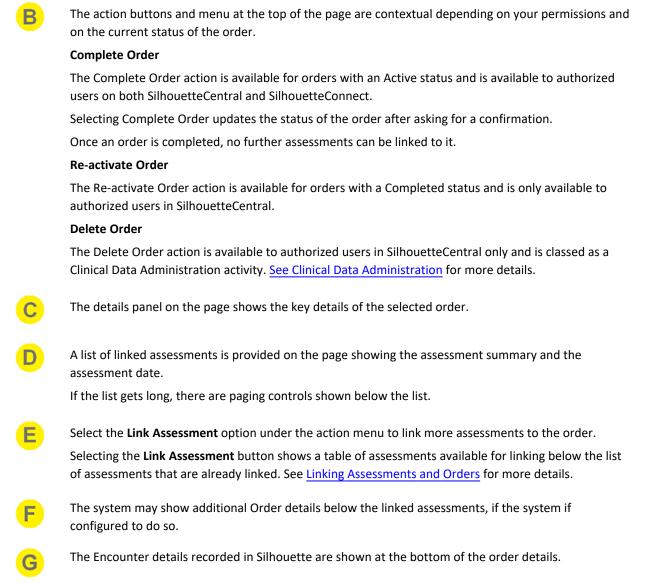
Α

Selecting an Order from the Orders Search or the list of orders for a patient shows the details for that order and encounter, along with a list of completed assessments.

	DI Eye ID: 555-0002 Date of Birt	h: 1999-12-31 (22 years old)		B Complete Order Actions V
Ð	Patient > Orders > Order	000000052		Orders
	Order 0000000	052 (Active) Α		E % Link Assessment
	Account Number: AC000	000001		Assessment Add Assessment
IH	Details C		Wound	
МН	Status	Scheduled Date	Assessment Type	+ Add Wound
Med	Active	2021-04-13 04:52	-	-
	Description Wound Assessment			
B D	Linked Assessme	ntsp		
- • A	Wound Assessment for O2021-03-19 20:23	Wound C (Left Foot, Sole)		
С	Encounter Details	G		
	Encounter			-
	Account Number		Facility	
	AC000000001		Facility A	

The heading for the page shows the Order Number and the current status (Active or Completed) for the order.

The encounter identifier is included as a subtitle on the page (shown above with the default label of Account Number). The encounter identifier is repeated in the Encounter Details further down the page as well.



Linking Assessments and Orders

Orders functionality is an optional Silhouette feature and requires EMR system integration.

A common way to integrate Silhouette output into an EMR system is to link Silhouette assessments to orders received from the EMR system.

An assessment in Silhouette, is the entity that holds your clinical observations and notes (including images and measurements). An order in Silhouette is used as a request for those observations and notes to be filed (integrated) in a specific location in the EMR system.

Silhouette puts the clinical user in control of which observations should be used to answer which request by letting the clinical user link the assessment to the order.

Silhouette allows an assessment to be linked to more than one order. This can be useful if the assessment needs to be seen on two different encounters in the EMR system or if different orders represent different stages in a multi-staged workflow.

Also, Silhouette allows more than one assessment to be linked to an order. This can be useful if an order needs to capture all assessments across all wounds on a single day or all assessments across an entire encounter.

Linking assessments to an order can be achieved from two places in the Silhouette UI.

- The Order Details page allows you to see all assessments already linked to an order and you can select assessments to link from a list of available assessments.
- The Assessment Details page allows you to see all orders that the assessment is already linked to. A Link Order action allows you can select an active order to link to.

Orders that have a Maximum Assessment count set will allow you to link more than the specified maximum number of assessments, however you will not be able to complete the order until you reduce the number of linked assessments below the set maximum. A - shown as the Maximum Assessment count indicates that there is no limit set; you can link as many assessments as you need to for the same order.



There is a method available to unlink Assessments from Orders after the links have been created and saved. Unlinking Assessments from Orders is covered in a separate topic and requires additional permissions.

Linking Assessments from the Order Details

The order details page (see <u>Viewing a Patients Orders</u>) shows all of the details of the order recorded in Silhouette. Selecting the **Link Assessment** button shows a table of assessments available for linking below the list of assessments that are already linked.

Wound Assessment for Wound A (Right Toe, Second) 2020-08-12 15:31			
Assessment	Date	Has Orders	Select <mark>E</mark>
Wound Assessment for Wound C (Left Foot, Sole)	2021-03-19 20:23	No	🔉 Unlin
Wound Assessment for Wound C (Left Foot, Sole)	2021-02-19 20:22	No	କ Lini
Wound Assessment for Wound C (Left Foot, Sole)	2021-01-19 20:20	No	କ Lini
Wound Assessment for Wound C (Left Foot, Sole)	2020-12-19 20:19	No	କ Lini
Wound Assessment for Wound C (Left Foot, Sole)	2020-11-19 20:17	No	କ Lini

Α

Select **Save** to complete the linking of assessments. A confirmation dialog is shown asking you to confirm the number of assessments to link.

Your system is configured with the linking of an assessment to an order as the trigger to initiate the transfer of data from Silhouette to your EMR system. If the linked assessment trigger is used, selecting the **Save** button initiates that trigger for all newly selected assessments.

Select **Cancel** to abort the link assessment action. None of the assessments selected will be linked to the order.

C

B

The assessment already linked to the order are listed above the table. Refer to this information if you want to select other assessments on the same day or for the same wound.



The assessments available to link are shown in a paged table.

If there is an Expected Assessment Type set on the order, only the assessments of that type are shown as available to link. For example, if the order is for a Lower Limb Risk Assessment, only Lower Limb Risk Assessments will be shown in the table.

The available assessments are always listed with the most recent assessment first.

The column Has Orders shows:

- No if that assessment has not been linked to any orders, and
- Yes if that assessment is already linked to a different order.

The **Select** column of the table has the buttons to select the assessment shown as one of the assessments to be linked.

Select assessments to link by selecting the corresponding Link button.

E

F

Once an assessment is selected, the row is highlighted and the Link button changes to an **Unlink** button. Select the **Unlink** button to unselect that assessment for linking.

The paging controls are shown at the bottom of the table if there are more than 5 assessments available to link.

You can move through the pages of the table and select assessments from different pages for linking. When you select the **Save** button you will be prompted to confirm the number of assessments you are linking.

Linking Orders from the Assessment Details

Authorized users are able to link orders to a given assessment when viewing the assessment in read-only mode, see Viewing and Editing Assessments.

>	Patient > Wound (> Wound Assessm	ent		Create Report			
	Wound As	 Edit Link Order 						
B	© 2 years ago (20 Linked Orders	Assessment + Add Assessment						
	Order Number	Account Number	Scheduled	Description	Wound			
d	000000030	AC00000029	2021-04-10 10:55	Wound Assessme	+ Add Wound			
	Wound Assessment							

The **Link Order** button is available in the action menu to users with the appropriate permissions. Select the **Link Order** button to link more orders to this assessment.

Selecting Link Order replaces the Linked Orders table with a table of orders available to be linked.

Any orders that are already linked to the assessment already are shown above the assessment details.

Selecting **Link Order** replaces the Linked Orders table with a table of orders available to be linked. The orders available for linking are the patient's active orders where they either have no Expected Assessment Type set or the Expected Assessment Type matches the current assessment.

Ð	Patient > Wound C	> Wound Assessm	ent					
	Wound Assessment for Wound C (Left Foot, Sole)							
	⊙ 2 years ago (2021-03-19 20:23)							
	Available Orders							
ł	Available Orde	ers						
	Available Orde	Account Number	Scheduled	Description	Select (
H H			Scheduled 2021-04-13 04:52	Description Wound Assessment	Select C			

Α

B

Δ

B

Select **Save** to create the links to the selected rows in the **Available Orders** table. If no rows are selected, there are no changes saved.

Select **Cancel** to cancel the linking without linking any orders to the assessment.

Selecting an order number from the Available Orders table will also cancel the operation and navigate to the Order Details page.

The **Select** column on the table has a **Link** button for each row.

Select the **Link** button related to the order you wish to link to this assessment. You can select more than one order to link.

Once a row is selected, the **Link** button changes to an **Unlink** button. Select **Unlink** to unselect the order for linking.

Unlinking Assessments from Orders

Orders functionality is an optional Silhouette feature and requires EMR system integration.

Authorized users can unlink assessments from orders where necessary.

Unlinking previously linked assessments and orders does not remove assessment data already sent to the EMR system and is not a common operation. However, there may be a number of reasons you might need to unlink an order and assessment, for example:

- To allow edits to be made to an assessment without sending updates to the EMR system until they are reviewed.
- To re-trigger the sending of the assessment information to the EMR system.
- Where the set Maximum Assessment count has been exceeded for an order.
- To resolve sync conflicts.

C

Unlink an order from an assessment by viewing the assessment in read-only mode, see <u>Viewing and Editing</u> Assessments.

Patient ID: 555-0002 Date of Birth: 1999-12-31 (22 years old)							
≡	+ v	Vound Assessment	Actions 🗸	0			
Patient > Wound C > Wound A		Create Report Create Report Edit S Link Order					
᠑ 2 years ago (2021-02-19 20 _inked Orders	0:22)	Set as Baselin	e				
Order Number	Account Numbe	+ Add Assessme	ent				
000000030	AC000000029	Wound					
Wound Assessment		+ Add Wound					
Wound Assessment		Data Correction	sment Date				
Wound State		 Delete Assess Move Assess 		•			
Wound State		A 🖏 Unlink Order					

A

The Unlink Order button is available in the Action Menu.

Select the Unlink Order button to remove order links from this assessment.

Selecting **Unlink Order** adds a Select column with **Unlink** buttons to the table of Linked Orders.

Wound Assessment for Wound C (Left Foot, Sole)

③ 2021-03-19 20: Linked Orders			A Save	B X Cancel
Order Number	Account Number	Scheduled	Description	Select <mark>C</mark>
000000052	AC000000001	2021-04-13 04:52	Wound Assessment	🔉 Unlink
000000030	AC00000029	2021-04-10 10:55	Wound Assessment	🗯 Unlink

A

Select **Save** to unlink the selected rows in the **Linked Orders** table. If no rows are selected, there are no changes saved.

Select **Cancel** to cancel without unlinking any orders from the assessment.

Selecting an order number from the Linked Orders table will also cancel the operation and navigate to the Order Details page.

The **Select** column on the table has an **Unlink** button for each row.

Select the **Unlink** button related to the order you wish to unlink from the assessment. You can select more than one order to unlink.

Once a row is selected, the **Unlink** button changes to a **Link** button. Select **Link** to not unlink the order when the **Save** button is selected.

Completing an Order

B

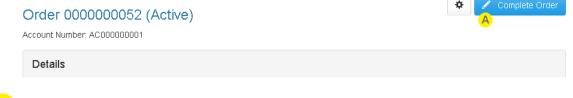
C

Orders functionality is an optional Silhouette feature and requires EMR system integration.

Completing an order within Silhouette:

- Removes it from the list of active orders on a patient dashboard.
- Prevents more assessments being linked to it.
- Can be used as a trigger to send results for linked assessments to the EMR system.
- Stops automatically syncing the patient to SilhouetteConnect (depending on synchronization settings)

Navigate to the Order Details of an Active order to complete it, see <u>Viewing a Patients Orders</u>. Authorized users will see a **Complete Order** button.



Once you have reviewed the order details, select **Complete Order** to complete the order.

A confirmation dialog is shown to ask you to confirm that you want to complete the order. The confirmation will highlight if you are trying to complete the order without linking any assessments to it.

If there are more than the set Maximum Assessments linked to the order, you will not be able to complete the order. Unlink some assessments and then attempt to complete the order again.

Clinical Data Administration

Silhouette provides the ability to administer clinical data (delete, merge, 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 "<u>Concurrency Considerations</u>" 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. <u>See Data Administration Confirmation Screens</u> 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
- Merge Patient, see <u>Managing Patient Records</u>
- Delete Wound, see Managing Wound Records
- Delete Assessment, see Managing Assessment Records
- Move Assessment, see <u>Managing Assessment Records</u>
- Change Assessment Date, see Managing Assessment Records
- Move Image, see Managing Images
- Re-activate Order, see Managing Orders
- Delete Order, see Managing Orders

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+ or SilhouetteMobile 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 user 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. Data administration changes will always be persisted, even if they are not recorded as the latest change.

- When a patient record has been merged SilhouetteCentral will attempt to attach any data captured by other users (wounds, assessments or images) onto the merged record.
- Other data administration actions (deletes, moves, and date changes) will cause changes submitted from offline users (using SilhouetteConnect, SilhouetteLite, SilhouetteLite+ or SilhouetteMobile) to be ignored.

A simple example of what can happen:

- 1. A duplicate patient record is created in error.
- 2. A SilhouetteConnect user downloads the duplicate patient record.
- 3. Another user asks that the duplicate patient record is deleted.
- 4. The clinical data administrator deletes the duplicate record in SilhouetteCentral. The offline users will not get the update until they sync.
- 5. The SilhouetteConnect user records some data on the duplicate record.
- 6. The SilhouetteConnect user syncs their changes to SilhouetteCentral.
- 7. The duplicate record remains deleted and the SilhouetteConnect user must re-record their data. If patient merge is used instead of patient delete, some of the data recorded in SilhouetteConnect (images, wounds, and assessments) can be kept and will be automatically moved to the merged patient.

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, SilhouetteLite+ and SilhouetteMobiledevices 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.

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• 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, 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.

All data administration confirmation screens follow a similar format. Specific examples of the confirmation screen are shown below.

A	Data Admin Action Do you want to?
B	Summary of the data affected by the data administration action.
С	Data Context
	Info about data context i.e. which patient the data belongs to.
D	Reason *
	Please enter a reason for performing this action
	E F Confirm Action Cancel



A title and question specifying the data administration action to be confirmed.

A summary of the data that will be affected by the data administration, i.e. what will be moved or deleted or changed.



D

Contextual information about the clinical record that is being changed. For example, the patient an assessment to be deleted belongs to.

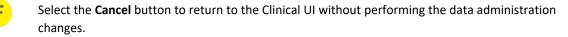
Reason

Enter a short reason for performing the data administration. The information needed is based on your own process requirements but is typically some information copied from the original data administration request.

The reason is saved in the database for audit purposes 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.



The button to confirm the action and save the changes is red to indicate that it will cause data changes that are not easily undone.



Confirmation Screen When Deleting Data

An example of the Delete Wound confirmation screen is below and is typical for other tools that delete clinical data.

Delete W	ound
Are you sure you w	ant to delete the following wound?
A: Scalp, Right	Lateral
1 assessment will	I be deleted:
 Wound As 	sessment for Wound A on Scalp, Right Lateral: 2019-06-17 13:33
Deleting from p	atient
Full Name	Max Zorin
B Patient ID	Px1234x 1944-02-29 Default Unit



The data affected summary above shows deleting the wound will also delete an associated wound assessment.

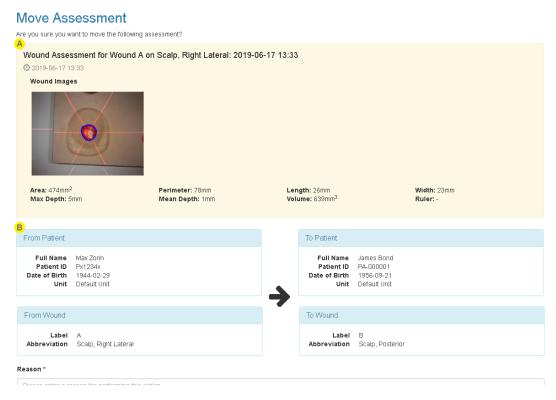
The information shown depends on what is being deleted. Review this information to check for unintended side effects of the delete operation.



The contextual information shows the patient record information that the wound to be deleted belongs to.

Confirmation Screen When Moving Data

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





B

The data affected summary shows the images that will also be moved with the assessment.

The contextual information shows that the assessment is moving between patients and wounds.

Confirmation Screen When Merging Data

An example of the Merge patient confirmation screen is below.

Merge Patients Do you want to move the data from the From Patient to the To Patient and delete the From Patient? A Full Name John Doe Patient ID PX1255 Date of Birth 1982-12-09 Unit Default Unit 1 wound will be moved to the destination patient and will be re-indexed: A: Right Foot, Sole (Open) 1 assessment will be moved to the destination patient: Wound Assessment for Wound A (Right Foot, Sole): 2020-02-27 07:06 No orders will be moved to the destination patient. 1 image will be moved to the destination patient: • 2020-02-27 07:56 B From Patient To Patient Full Name John Doe Full Name John Doe Patient ID PX1255 Patient ID PX1235 Date of Birth 1982-12-09 Date of Birth 1982-08-10 Unit Default Unit Unit Default Unit Reason *



The data affected summary shows the summary of the patient record that will no longer be available after the merge.

It shows lists of wounds that will be moved and re-indexed, assessments that will be moved, a list of orders that will be moved, and a list of unassigned images from the patient image portfolio that will be moved.



The contextual information shows a summary of the patient records that the data is being moved from and to as part of the merge.

Managing Patient Records

The functionality to manage a patient record is available in SilhouetteCentral and SilhouetteConnect when in Standalone mode. If SilhouetteConnect is being used in Synchronized mode, patient data administration must be performed in SilhouetteCentral.

To find the patient record administration options:

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

	arin Banana ID: 258 Date of Birth: 1962-02-28 (61 ye	ears old)		+ Add Ass	A Actions -
•	Patient				Wound + Add Wound
:=		Wounds		+ Wound	🛓 Export
IH		Right	Left		Data Correction
МН				B C	
Med					
^		8			



Actions Menu

If you have permissions to perform data administration tasks for the patient record. Selecting the **Actions** button on the wounds summary page will show the **Data Correction** available.



Delete Patient

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

The **Delete Patient** menu item is available to Silhouette users who have the Can Delete Patient permission.

See Delete Patient below for more details.



Merge Patient

Merges this patient record into another patient record. Merge means to move all images, wounds, assessments, encounters, and orders to another existing patient record and to delete the current patient record.

The **Merge Patient** menu item is available to Silhouette users who have the Can Manage Clinical Data permission.

See Merge Patient below for more details.

Delete Patient

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

Before the delete proceeds, you will be asked to confirm the action with a reason. <u>See Data Administration</u> <u>Confirmation Screens</u> 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.

Merge Patient

To merge data from one patient to another patient you need to select a 'From Patient' to take data from and a 'To Patient' to move the data to:

- The patient where you select Merge Patient becomes the 'From Patient'
- Use the patient search to select a second patient as the 'To Patient'

Merging a patient record moves all the associated wounds, assessments, images, encounters, and orders from the selected 'From Patient' record to the selected 'To Patient' and then deletes the originating 'From Patient' record.

The patient level details (e.g. Name, Unit association, Contact Details, and other Patient Notes) are not merged. The 'To Patient' patient level details remain unchanged and the 'From Patient' details are marked as deleted in the system.



Merging a patient record cannot be undone. Other data administration tools must be used to manually move individual assessments and images between patient records to un-merge a patient record.

A banner is shown while selecting the two patient records to merge.

Merge Pat From Patien A Full Name Patient ID Date of Birth Unit		To Patient B Full Name Patient ID Date of Birth Unit	Sam Johns 34565 2000-09-07 Default Unit		C	D	
				l	Apply	Cancel	
Sam Johns Patient ID: 34565	Date of Birth: 2000-09-	-07 (22 years old)		+ Add Assessment	Actions	- 0	



The **From Patient** is the patient that the wounds, assessments, images, orders, and encounters will be moved from.

The patient currently selected in Silhouette is shown as the **To Patient** and updates as you navigate in Silhouette.

The **To Patient** is the patient that the wounds, assessments, images, orders, and encounters will be moved to.



Select the **Apply** button to complete the patient merge. You will be asked to confirm the action and provide a reason, see Data Administration Confirmation Screens.

Select the Cancel button to cancel the merge patient action and close the banner.

Managing Wound Records

The functionality to manage wound records is available in SilhouetteCentral and SilhouetteConnect when in Standalone mode. If SilhouetteConnect is being used in Synchronized mode, 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 **Actions** menu on <u>The Wound Dashboard</u> page.

	arin Banana ID: 258 Date of Birth: 1962-02-28 (61 years old)		+ Wound Ass	essment Actions •
•	Patient > Wound A Wound A: Right Calf			Wound + Add Wound
IH MH	Open for 7 days	4 Assessments	Most	Edit Wound Set Wound State Assessment
Med	Measurements	And Deduction	Mara Darth - M	+ Add Assessment Data Correction
•	Area Volume	Area Reduction	Mean Depth	Delete Wound



Actions Menu

If you have permissions to perform data administration tasks for the wound.

Selecting the Actions button on the wounds summary page will show the Data Correction 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. <u>See Data Administration</u> 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.

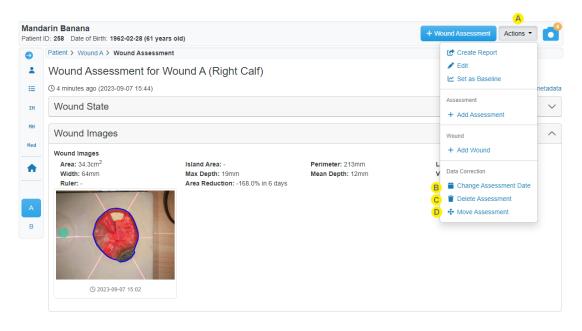
Deleting a wound means that the wound data is not accessible to any Silhouette users, however, the data is still in the system database. To permanently remove the data from Silhouette contact ARANZ Medical Support for assistance.

Managing Assessment Records

The functionality to manage assessment records is available in SilhouetteCentral and SilhouetteConnect when in Standalone mode. If SilhouetteConnect is being used in Synchronized mode, 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 Actions menu button on the assessment view.





Actions Menu

If you have the permission to perform data administration tasks for the assessment, such as deleting the assessment or managing clinical data the **Data Correction** options will be shown.



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.

C D

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.

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. <u>See Data Administration</u> <u>Confirmation Screens</u> 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

Α

R

C

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.

	Move Wou	und Assessment	: 2023-09-07 15	5:44
A	From Patie	nt	B To Patient	
	Full Name	Mandarin Banana	Full Name	Mandarin Banana
	Patient ID	258	Patient ID	258
	Date of Birth	1962-02-28	Date of Birth	1962-02-28
	Unit	Default Unit	Unit	Default Unit
	Label	A: Right Calf (Open)	C Please select a w	vound
				Cancel
В	Mandarin Bar Patient ID: 258	nana Date of Birth: 1962-02-28 (6	1 years old)	+ Wound Assessment Actions -
	Patient >	Wound A > Wound Asse	essment	

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.

	Move Wou	und Assessmen	t: 2023-09-07 15	5:44			
A	From Patie	nt	B To Patient				
	Full Name	Mandarin Banana	Full Name	Sam Johns			
	Patient ID	258	Patient ID	34565			
	Date of Birth	1962-02-28	Date of Birth	2000-09-07			
	Unit	Default Unit	Unit	Default Unit			
	Label	A: Right Calf (Open)	C Label	A: Right Temple (Open)			
					I	D Apply	E Cancel
B	Sam Johns Patient ID: 34565	Date of Birth: 2000-09-0	7 (22 years old)		+ Wound Assessment	Actions	•
	Patient >	Wound A					

The banner displayed at the top of the screen shows the context of the action being performed.

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

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

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 Selection screen and the Patient Sidebar.

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.

D

E

Before the move proceeds, you will be asked to confirm the action with a reason. <u>See Data</u> 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 of the application 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 Assesser			
A Wound Assessment for W © 2019-06-18 05:33 Wound Images	found A on Scalp, Right Lateral: 2019	-06-18 05:33	
Area: 474mm ² Max Depth: 5mm	Perimeter: 78mm Mean Depth: 1mm	Length: 26mm Volume: 639mm ³	Width: 23mm Ruler: -
B Patient			
Full NameMax ZorinPatient IDPx1234xDate of Birth1944-02-29UnitDefault Unit			
C Assessment's original date and tim Please enter the new date D New date *			
2019 06 17 13 : E Timezone *	33		
Pacific/Auckland	•		
F Some images were take	en on a different date		
G Reason *			
Please enter a reason for perfor	ming this action		
			H Change Date Cano

A

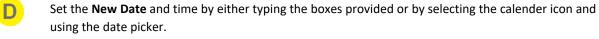
R

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.

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.



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

C

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 patient timeline. If you do not intend to adjust the order of the assessments on the timeline, 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 functionality to manage images is available in SilhouetteCentral and SilhouetteConnect when in Standalone mode. If SilhouetteConnect is being used in Synchronized mode, 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.

Mand	WOL	Portfolio	Close	h Administrator
Patient		Connect the SilhouetteStar to take images	2D 3D	ions 🔹 🚺
-	Wo	Captured images		
IIH				sment
MH Med	Me			
•	Ar 0.87	A , 3D Measurements		imeter
A	0.7	B Telete Image	Close	



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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.

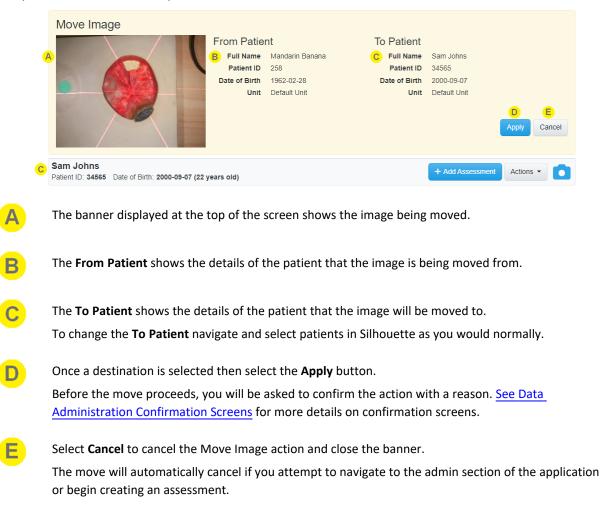
The move image menu item is available to Silhouette users who have been granted the Can Manage Clinical Data permission.

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.



Managing Orders

Orders functionality is an optional Silhouette feature and requires EMR system integration.

The functionality to manage orders is only available in the SilhouetteCentral application.

Re-activating an Order

A completed order can be re-activated within SilhouetteCentral if it was completed in error or if the EMR integration needs to be re-trigger.

When re-activating an order, there is no Data Administration Confirmation Screen because re-activating an order is easily undone by marking it completed it again.

Navigate to the Order Details of a Completed order in SilhouetteCentral to re-activate it, see <u>Viewing a Patients</u> Orders. Authorized users will see a **Re-activate Order** button.

Order 000000052 (Completed) Account Number: AC000000001	Image: A state of the state
Details	
Select Re-activate Order to re-activate the order.	

A confirmation dialog is shown to ask you to confirm that you want to re-activate the order.

Re-activating an order allows additional assessments to be linked to it.

Deleting an Order

A completed order can be re-activated within SilhouetteCentral if it was completed in error or if the EMR integration needs to be re-trigger.

Navigate to the Order Details of the order to be deleted in SilhouetteCentral, see <u>Viewing a Patients Orders</u>. Authorized users will see a cog button with a **Delete Order** option.



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Select Delete Order to delete the order.

A <u>Data Administration Confirmation Screens</u> is shown to ask you to confirm that you want to delete the order, showing any linked assessments and asks you to enter a reason.

Once an order is deleted, it cannot be used to send results back to the EMR system.

Deleting an order in Silhouette does not delete it in the EMR system, or remove assessment data already sent to the EMR system.



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

Deleting an order means that the order 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.

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:

- <u>Profile</u>. Allowing you to view and edit your own profile information, including the ability to change your password. See the <u>Changing Your Password</u> topic for more details.
- Preferences. Available to users who have access to features that have personal preferences.
- 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

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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 your 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:

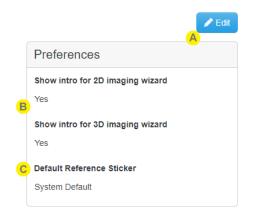
- 1. Navigate to the Admin -> Profile screen.
- 2. Select the Change Password button.
- 3. Enter your existing password in the Current Password box.
- 4. Enter your new password in both the New Password and Confirm Password boxes.
- 5. Select the Save button to update the system with your new password.

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, SilhouetteLite, SilhouetteLite+, SilhouetteMobile or SilhouetteConnect.

Preferences

In the **Preferences** screen you can see and edit your personal preferences for your account. The preferences only relate to SilhouetteCentral usage so the preferences screen is only available in SilhouetteCentral by selecting Admin > Preferences.

The preferences screen is only available if there are personal options to view or set. If you do not have permissions to any features that require personal preferences, you will not see the **Preferences** option in the **Admin** sidebar.



Select Edit to edit your preferences.

There are **Save** and **Cancel** buttons at the bottom of the page once you are editing to either save or cancel your changes.

The **Show intro for 2D imaging wizard** and **Show intro for 3D imaging wizard** options set whether the intro screen of the 2D or 3D Imaging wizard is shown or skipped. See the SilhouetteCentral 2D and 3D Imaging Setup topic for more information.

These options are only available if you have "Can Capture Mobile 2D Images" and or "Can Capture Mobile 3D Images" permission.

The default for all users is Yes, but is set to No if they tick the **Do not show again** option on the 2D or 3D Imaging wizard intro screen.

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The **Default Reference Sticker** option sets which of the defined reference stickers will be selected when ever the user uses the 2D or 3D Imaging feature of SilhouetteCentral.

The default option is **System Default**, which means that the user will use the reference sticker that the system admin has set as the default.

This option is set whenever the user selects a specific reference sticker while completing the 2D or 3D Imaging setup, see the help topic <u>SilhouetteCentral 2D and 3D Imaging Setup</u>.

Once set to a specific reference sticker, the 2D or 3D Imaging wizard will always use that sticker, even once it is disabled by the system admin, until they select a new one or they set the preference back to **System Default**.

Personal Shortlist Criteria

The shortlist filter is used to set the patients records made available offline in Silhouette Client applications. The patient shortlist can also be used to limit the set of results provided in the SilhouetteCentral and SilhouetteConnect patient search. The personal shortlist criteria page allows a user to override the default organization wide shortlist criteria.

Shortlist Criteria

The shortlist filter will return patients that matches any of the following criteria:

- Patients pinned by the user (not filtered by the units selected in the personalized shortlist).
- Patients moved to their current unit within the number of days specified in the shortlist criteria (filtered by units selected in the personalized shortlist).
- Patients viewed by the user within the number of days specified in the shortlist criteria (filtered by units selected in the personalized shortlist).

Personal Shortlist Criteria Configuration

Feisonai Falleni	Shortlist Criteria		
Pin Expiry (days)	Viewed Within Period (days)	Assigned to Unit (days)	Assigned to Unit filter
14	21	7	Default Unit
Default Patient Shor	tlist Criteria		
The default settings are se	t by system administrators on the	settings page and will be used if	you do not set your own.
Pin E	xpiry (days) 30		
Viewed Within F	eriod (days) 14		
Assigned to	o Unit (days) 7		
	a to remove your persona	al shortlist criteria and re	evert to using the
default patient sho		teria.	
default patient sho Select Edit to edit y Shows the current	rtlist criteria	. When these are set the	ey override the defa

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, 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:



```
<system.net>
```

```
<defaultProxy enabled="true">
<proxy proxyaddress="http://192.168.2.1:8888"/>
</defaultProxy>
</system.net>
```

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.

- <u>Recovering a Forgotten Password</u>
- Troubleshooting SilhouetteLite+ and SilhouetteMobile
- Troubleshooting SilhouetteStar

Recovering a Forgotten Password

Silhouette allows users with local user accounts to reset their password using the email address registered with their Silhouette user account. This feature is only available if the following conditions are met:

- The SilhouetteCentral system is configured to send emails using a valid SMTP Email sending service.
- The system administrator has enabled the password reset feature.
- Your email address is listed with your Silhouette user account.

If the reset password feature is not available, contact your system administrator for further advice on how to regain access to your account.

If you have forgotten your password, select the "Forgot Password" link on the login screen (see help topic <u>The</u> <u>Silhouette Login Screen</u>).

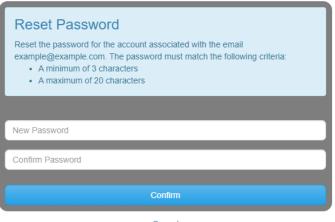
Once the "Forgot password" link is selected, you are prompted to enter your email address. You should enter the email address that is associated with your Silhouette user account and select the **Send password reset email** button. Select the **Cancel** link to return to the login screen.

Reset your password Enter your user account's email address and we will send you a password reset link
Enter your email address
Send password reset email
Cancel

Once you select the **Send password reset email** button, you are returned to the login screen and will see a message displayed to confirm that an email with instructions to reset your password has been sent to the email address you specified. For security reasons, the confirmation message is displayed even if the email you entered is not included in the Silhouette system.

An email has been sent with instructions for resetting your password.
Username
Password
Login

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 website and prompts you to enter a new password.



Cancel

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

Password change successful. You may now login with your new password.
Username
Password
Login

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. The password reset links emailed will always expire after some time. The default link expiry time is 60 minutes but can be changed by your system administrator.

Troubleshooting SilhouetteLite+ and SilhouetteMobile

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', 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+ or SilhouetteMobile 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, check the settings App to confirm that SilhouetteLite+ or SilhouetteMobile is allowed to use Mobile Data.
- Check that your device can reach your instance of SilhouetteCentral by putting the 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+ or SilhouetteMobile).
- If the app is constantly blocked showing Syncing Saved Data and the data upload is not occurring in the normal time, 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, turning the device to airplane mode and then opening the App will allow you to work offline.

If the problem persists, 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.

ISSUE: The SilhouetteLite+ or SilhouetteMobile App reports *Error Parsing JSON* when attempting to log in or sync with SilhouetteCentral

This error usually indicates that the application's SilhouetteCentral URL is set incorrectly or that there is a proxy between the mobile device and the SilhouetteCentral web application.

To check the SilhouetteCentral URL, attempt to navigate to the SilhouetteCentral URL in the web browser on the mobile device. You can either copy the URL out of the app or type it directly into the web browser. The URL should take you to the SilhouetteCentral web application.

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 the SilhouetteStar 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, rules to allow inbound TCP connections on ports 9874 and 9875 must be added to the configuration. If your firewall is centrally managed, 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 affected 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, 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, 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.