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Silhouette**Connect** v3.22
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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Contents

Introduction **3**
Warnings **4**
Laser Warnings 4
Other Warnings 4
SilhouetteStar Label Information 4
Installation and Getting Started **6**
Installing SilhouetteConnect 6
Uninstalling SilhouetteConnect 6
Obtaining a License 6
Activating Your License 7
Logging On to SilhouetteConnect 8
Logging Off SilhouetteConnect 8
Connecting a SilhouetteStar 9
SilhouetteStar USB Cable 9
The SilhouetteStar Device **11**
SilhouetteStar Components 11
Bottom View 11
Top View 11
Side View 12
SilhouetteStar Trigger Button Operation 13
SilhouetteConnect Concepts **14**
Navigation 14
Selecting Items 14
Workflow 14
The Organization of Patient Data 15
The Patient Selection Screen **17**
Creating a New Patient 18
Deleting Patients 18
Exporting Patient Data 18
Assessment Summary 19
Image Summary 19
Patient Notes 19
Visit Notes 19
Wound Notes 20
Synchronizing with SilhouetteCentral 20
Managing Patients 20
Managing Patients for Groups with only Add Patient Permission 21
Managing patients without permission to add patients 22
The Patient Dashboard **24**
Wound List 24
Visits 25
Visit Timeline 26
Tissue Types Graph 27
Wound Measurement Overview 28
Area Reduction 28
Tissue Type Percentages Overview 29
Wound Images 29
Report Buttons 30
Notes Button 32
Orders Button 32
Assigning Multiple Assessments to an Order 35
Resending an Assessment 36
Healing a Wound 37
Changing the Baseline 38

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Exporting Images from SilhouetteConnect 39
Capturing Images 41
The Mathematics of Silhouette's Measurements 41
Lighting Requirements for Image Capture 41
Holding a SilhouetteStar and Positioning the Lasers on the Wound 41
Preferred Laser Positioning 43
Acceptable Laser Positioning for Large Wounds 43
Preferred Laser Positioning for Wounds Containing Islands 43
Preferred Laser Positioning for Wounds With Multiple Outlines 43
Poor Laser Positioning 43
Disconnecting a SilhouetteStar 44
The Image Assignment Screen 44
Assigning the Captured Images to a Wound 44
Split and Merge: Creating More Than One Assessment for a Wound at the Same Visit 46
Tracing Wound Boundaries 47
Tracing Tissue Outlines 52
Taking a Multiple Image Measurement 60
SilhouetteConnect Administration 62
The Administration Screen 62
Login 63
Synchronization 63
Organization Settings 64
Organization 64
Display Formats 64
Parameters 64
Axis Method 64
Database Backups 65
Power 65
Users 65
Licensing 65
Calibration Check 65
Tissue Type Classification 66
Backing Up Patient Information 66
If Backing Up Without SilhouetteCentral 66
If Synchronizing with SilhouetteCentral 67
Care of SilhouetteStar 68
Cleaning SilhouetteStar 68
Appendices 69
Appendix A: Troubleshooting 69
SilhouetteStar is not detected 69
Cannot synchronize with SilhouetteCentral or synchronization fails 69
Laser detections are poor 69
"No Database Present" error displayed 70
Appendix B: Getting Support 70
Appendix C: Operating Conditions 70
Appendix D: System Requirements 71

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Introduction

This user's guide describes how to use SilhouetteStar™ and SilhouetteConnect™ for capturing images of wounds, making wound measurements, and documenting healing progress over time. It describes how to get started with SilhouetteStar and SilhouetteConnect and how to use the system's features.

Warnings

Laser Warnings

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

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

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

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

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

Other Warnings

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

SilhouetteStar Label Information

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

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Manufacturers reference / Model number

Model Number	SilhouetteStar Model
2001	SilhouetteStar (3MP)
2005	SilhouetteStar (5MP)

Manufacturer assigned device serial number

Date of Manufacture

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

Postal Address:	Delivery Address:
ARANZ Medical Limited	ARANZ Medical Limited
PO Box 3894	47 Hereford Street
Christchurch 8140	Christchurch 8013
New Zealand	New Zealand

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

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

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

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

Federal Communications Commission logo. The 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.

Installation and Getting Started

This section describes:

- Installing SilhouetteConnect
- Obtaining a License
- Activating Your License
- Logging On to SilhouetteConnect
- Connecting a SilhouetteStar

Installing SilhouetteConnect

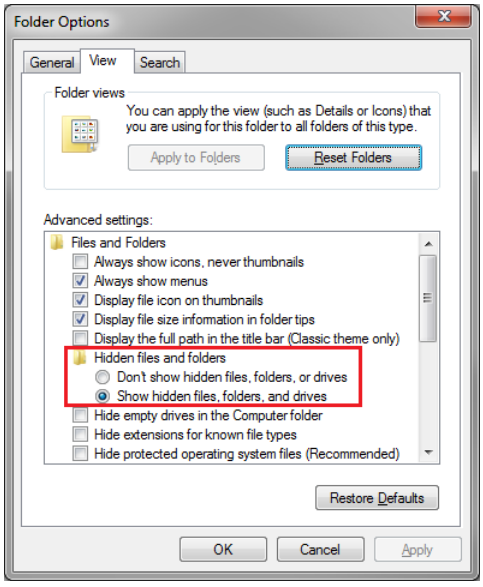
There are two files required to install SilhouetteConnect: setup.exe and SilhouetteConnect.msi. These files can be obtained from ARANZ Medical support, or alternatively directly from your SilhouetteCentral installation. Once obtained:

1. Navigate to the folder that contains the installation files.
2. Double click the setup.exe file to start the installation process.
3. Follow the on-screen instructions.

On Windows 8 the SilhouetteConnect install file may be prevented from running by the Windows SmartScreen filter. In order to run the setup, click on the **More Info** link, and then on the **Run anyway** button.
Once the installation is complete, launch SilhouetteConnect by double-clicking on the icon created on your desktop or by selecting SilhouetteConnect from the **All Programs** menu.

Uninstalling SilhouetteConnect

Should you need to uninstall SilhouetteConnect, this can be done via **Programs and Features**, which is accessible via the **Control Panel**. Please ensure that you have first backed up all information to SilhouetteCentral or an alternative location.
Uninstalling SilhouetteConnect removes the application software, but leaves all clinical data on your machine. If you also want to remove clinical data from a device delete the following folder on your computer
C:\ProgramData\ARANZ Medical Limited\SilhouetteConnect
Note that this folder may be hidden - if so, ensure the **Show hidden files, folders, and drives** folder option is selected:



Obtaining a License

In order to use SilhouetteConnect, you must first obtain and activate a license.
To obtain a SilhouetteConnect license, contact Customer Support using the details provided in Appendix B: Getting Support.

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Activating Your License

Once a license has been obtained, Customer Support will provide you with a unique client code. When you first launch SilhouetteConnect, a screen will appear prompting you to enter your **Client Code**. There are two options:

- If you have a client code, ensure your computer is connected to the internet, enter the code, and click **Check for License**.
- If the automatic license update process fails, or you have received a license file instead of a client code, click **Import License** to locate the file.

If you click **Continue** without entering a client code or importing a valid license, you can use SilhouetteConnect for a 30-day trial period.

Once licensed the license activation screen will not be displayed when SilhouetteConnect is started, unless your license expires at which point the screen can be used to re-license your copy of SilhouetteConnect.

OR

If you have downloaded the installation package for SilhouetteConnect from SilhouetteCentral the license details will be pre-populated and you will not see the activation screen on first login.

Logging On to SilhouetteConnect

SilhouetteConnect with either attempt to use your Windows credentials to log on or will present you with a log on prompt. To log on to SilhouetteConnect, enter the **User Name** and **Password** assigned to you.
If your **User Name** has been assigned recently or if SilhouetteConnect has not synchronized with SilhouetteCentral for some time, SilhouetteConnect will contact SilhouetteCentral via the network to validate the new **User Name** and **Password** and will then prompt you to synchronize.

Multi-unit implementation
If your user account has permission to view patients within multiple units you may be prompted to select which unit you wish to log on to. For more information see The Patient Selection Screen.

Logging Off SilhouetteConnect

You can log off SilhouetteConnect by clicking the log off button in the bottom left which will take you back to the log on screen.

If you have LDAP integration enabled and use the authentication mode "Automatic sign-on only" the log off button is replaced with an exit button that will close the application. For a different user to log on, that user must first log on to Windows.

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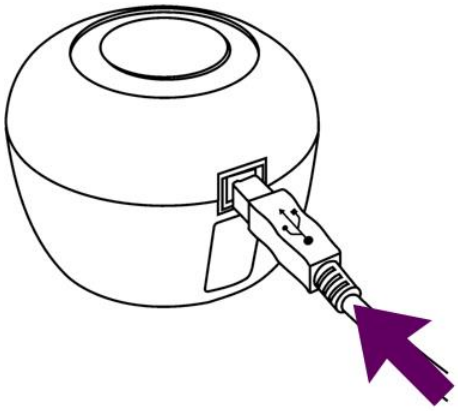
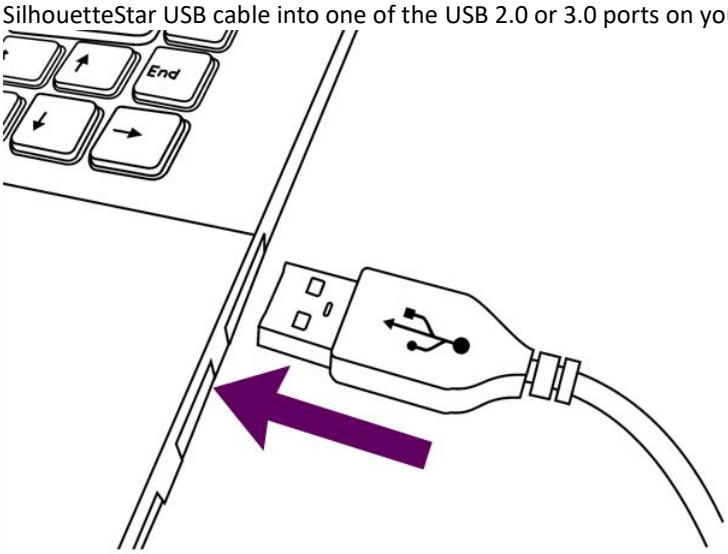
Connecting a SilhouetteStar

To connect SilhouetteStar, insert the square end of the SilhouetteStar USB cable into the corresponding port on the device. The SilhouetteStar USB cable has a protective foam gasket fitted to the end of the cable (not shown in diagram). This foam gasket compresses to seal the gap between the cable plug and SilhouetteStar devices.



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



You can also connect the device via a powered USB hub.
Your computer will automatically detect the device and install the required drivers. If the computer's sound is on, the computer will chime to indicate successful connection.
The device lasers and illumination LEDs will not operate until you initiate image capture from SilhouetteConnect.

SilhouetteStar USB Cable

Always use an approved SilhouetteStar USB Cable to connect the SilhouetteStar to the USB port on the computer, these cables can be identified by an attached label, as shown below for the different models.

SilhouetteStar Version	Model Number	Label(s) present on the USB Cable
SilhouetteStar (3MP)	2000.xx	
SilhouetteStar (5MP)	2005.xx	

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The SilhouetteStar Device

SilhouetteStar is the device used to capture images of wounds. SilhouetteStar connects to SilhouetteConnect through a USB cable and contains laser lights, LEDs, and camera lens. This section of the help describes the SilhouetteStar device, covering:

- SilhouetteStar Components
- SilhouetteStar Trigger Button Operation

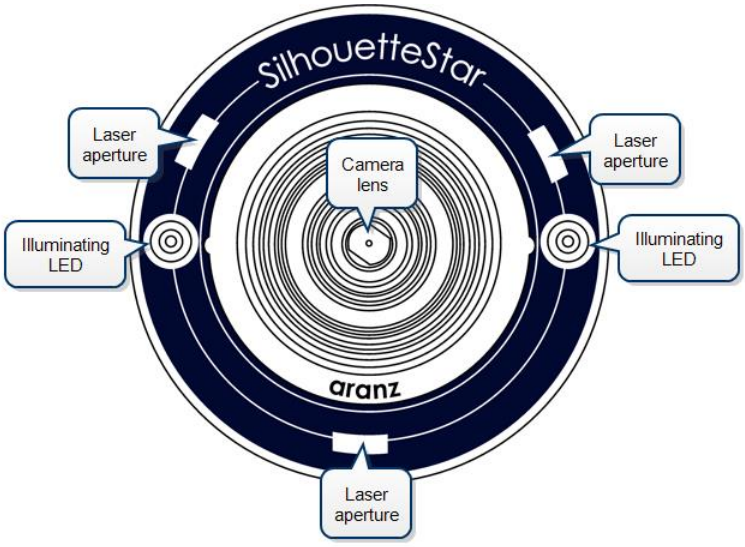
Connecting the device to SilhouetteConnect and capturing images are both covered in other help topics.

- Connecting the device to SilhouetteConnect is covered in "Connecting a SilhouetteStar".
- Capturing images and making measurements is covered in "Capturing Images".

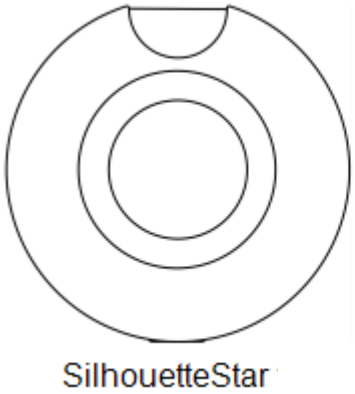
SilhouetteStar Components

Bottom View

SilhouetteStar connects to SilhouetteConnect through a USB cable supplied with the device, see help topic Connecting a SilhouetteStar. SilhouetteStar includes laser lights, LEDs, and camera lens as shown below:

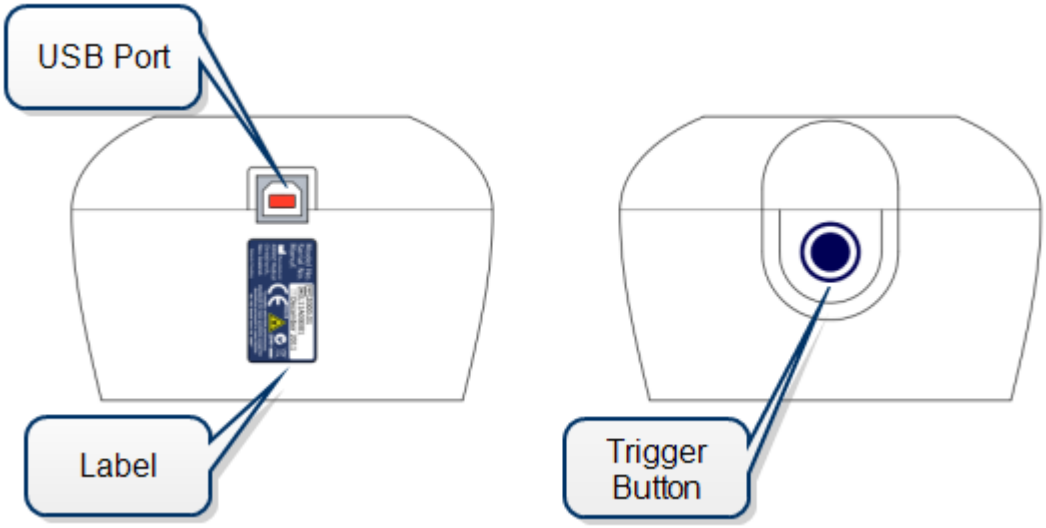


Top View



Side View

The USB port is used to connect the SilhouetteStar to SilhouetteConnect using the cable supplied with the device, see Connecting a SilhouetteStar.
The trigger button is used to operate the device.



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SilhouetteStar Trigger Button Operation

The trigger button on the SilhouetteStar is used for capturing images when SilhouetteConnect is in the image capturing screen. The different trigger button actions are described in the table below.

The trigger action is activated when the trigger button is pressed.

SilhouetteStar and SilhouetteConnect Status	Trigger Button Press	Result
Connected to SilhouetteConnect. SilhouetteConnect is not in the Image Capture screen.	Short Press	Nothing happens, waiting for image capture screen to be active in SilhouetteConnect.
Connected to SilhouetteConnect SilhouetteConnect is in the Image Capture screen. Live preview is showing. Device lasers are on.	Short Press	Image capture performed.

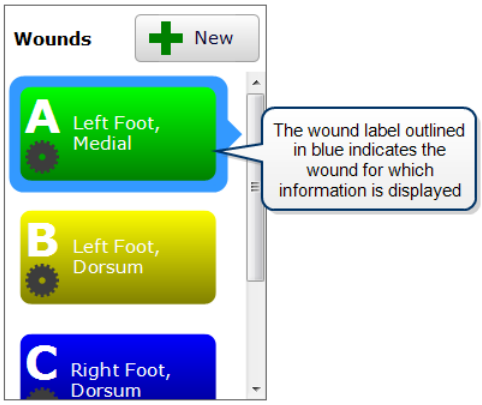
SilhouetteConnect Concepts

Navigation

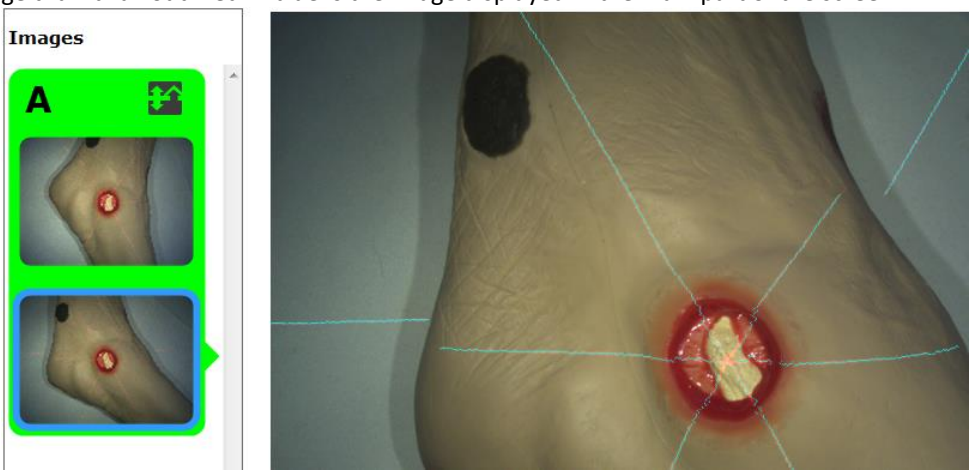
In most SilhouetteConnect screens, you can move on to the next step by clicking the large blue button in the lower right-hand corner. You can return to the previous screen by clicking on the arrow button in the lower left-hand corner.

Selecting Items

Selected items in a list are colored with a blue highlight.
Selected items such as wound labels and images are indicated by a blue outline:



Here, the image thumbnail outlined in blue is the image displayed in the main part of the screen:



Workflow

A typical workflow comprises:

1. Logging on to SilhouetteConnect
2. Selecting a patient from the list or creating a new patient
3. Capturing images
4. Assigning images to wounds, tracing outlines around the wound boundaries, and reviewing the measurements
5. Synchronizing with SilhouetteCentral
6. Logging off

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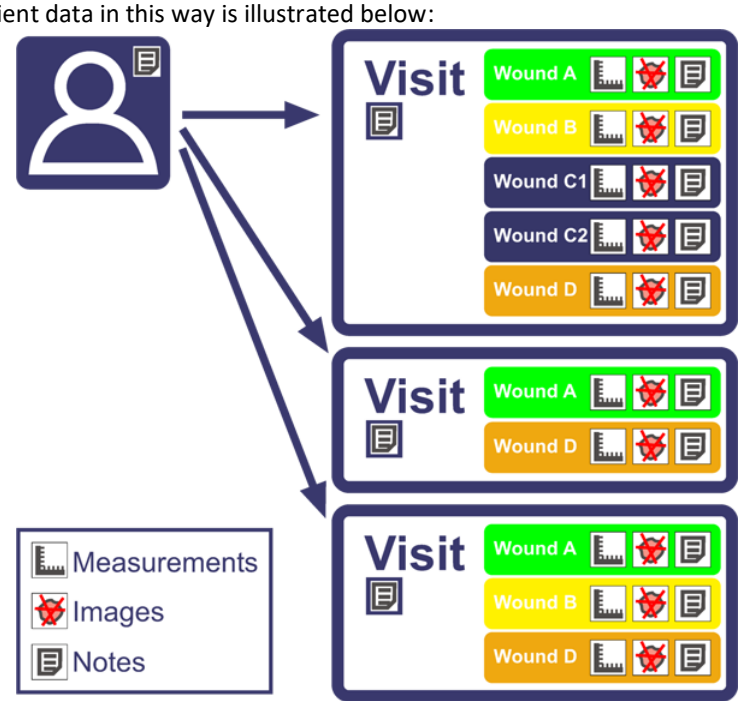
The Organization of Patient Data

In Silhouette, the region of interest that is assessed 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 Settings). Once assigned, the identifying label for a particular wound does not change.
Information is organized into assessments and visits:

- A visit contains all the information collected during the patient's appointment with the healthcare provider. This information includes the assessments and visit notes.
- An assessment is made for each wound and contains all the information collected about a particular wound during a visit. This information includes images, measurements, and notes specific to a single wound being assessed.

If a wound needs to have another measurement taken during an appointment, such as pre- and post-debridement, then the second measurement will be contained in a second assessment.
The organization of patient data in this way is illustrated below:



This is reflected in the patient dashboard, which summarizes information about a single patient:

The **Wounds** list shows all wounds defined for the patient, and the **Visits** list below that shows all visits for that patient. Visits will be grayed out if no information about the selected wound exists for those visits. In the screen above, Wound A is selected, and the latest visit (at the top of the list) is grayed out, indicating that no information was collected about Wound A in the most recent visit.

The **Visit Timeline** shows the assessments that have been made of Wound A during different visits. Images and **Wound Measurement** information shown belong to the assessment and visit indicated by the blue dots on the graph and the highlighted visit in the **Visit Timeline**. The gray dot on the timeline indicates that no assessments were made of Wound A during the latest visit and matches the grayed out visit in the **Visits** list.

Typically, a wound will be assessed only once during a visit. There may be cases, though, where a wound is assessed more than once during a visit, such as when a wound is debrided. In such cases, images can be captured before and after debridement and assigned to the same wound label, for example, Wound C. The assessment will be labeled Wounds C1 and C2 and saved as different assessments. See The Image Assignment Screen for more information.

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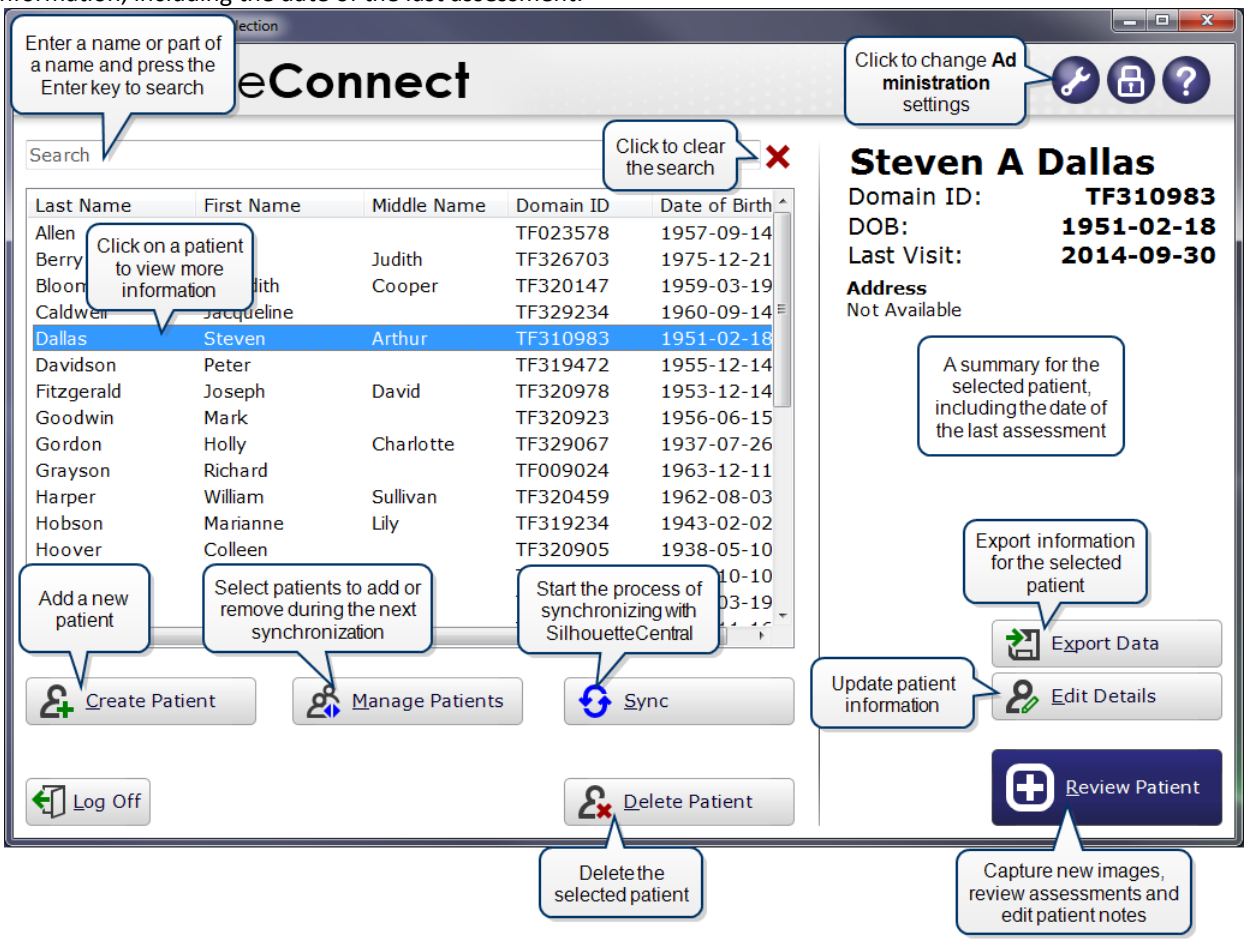
The Patient Selection Screen

After you log on, the list of patients in the database is displayed. Click on a patient to view a brief summary of information, including the date of the last assessment:



You can:

- Filter the list of patients. Enter part of a patient's name or Patient ID in the **Search** box.
- Start capturing images for a patient. Click on that patient, then click the **Review Patient** button to open the **Patient Dashboard**. Alternatively, double-click the patient to go straight to the **Patient Dashboard**.
- Add a patient to the database. Click the **Create Patient** button. See Creating a New Patient for more information.
- Edit the details for an existing patient on SilhouetteConnect. Click the **Edit Details** button.
- Export information for the selected patient. Click the **Export Data** button. See Exporting Patient Data for more information.
- Delete a patient for whom no data has been collected. Select the required patient, then click the **Delete Patient** button. See Deleting Patients for more information.
- Select existing patients to add to or remove from SilhouetteConnect and synchronize with SilhouetteCentral. Click the **Manage Patients** button. See Managing Patients for more information.
- Synchronize with SilhouetteCentral. Click the **Sync** button. See Synchronizing with SilhouetteCentral for more information.

The difference between clicking the **Manage Patients** button and the **Sync** button is that clicking **Sync** starts the synchronization process immediately, whereas clicking **Manage Patients** lets you first choose patients to add or remove from SilhouetteConnect.

The **Manage Patients** and **Sync** buttons only appear on this screen if synchronization is enabled. See Synchronization for more information.

Multi-unit implementation

If using SilhouetteCentral your user account may have access to patients in multiple units you may be prompted to select which unit you wish to log on to. When you log on to a particular unit:

- Only the patients that belong to the selected unit will be displayed.
- The patient identifiers displayed, and the label of the Patient ID column will reflect those used by the selected unit.

You can change the display to show all patients by changing the **Within** drop-down box from the selected unit to **All Units**. However the style of the Patient ID will remain that of the unit selected at log on.

Creating a New Patient

To create a new patient, click the **New Patient** 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:

- click **Save** to return to the **Patient Selection** screen or
- click **Save and Review Patient** to proceed directly to the **Patient Management** screen.

Multi-unit implementation

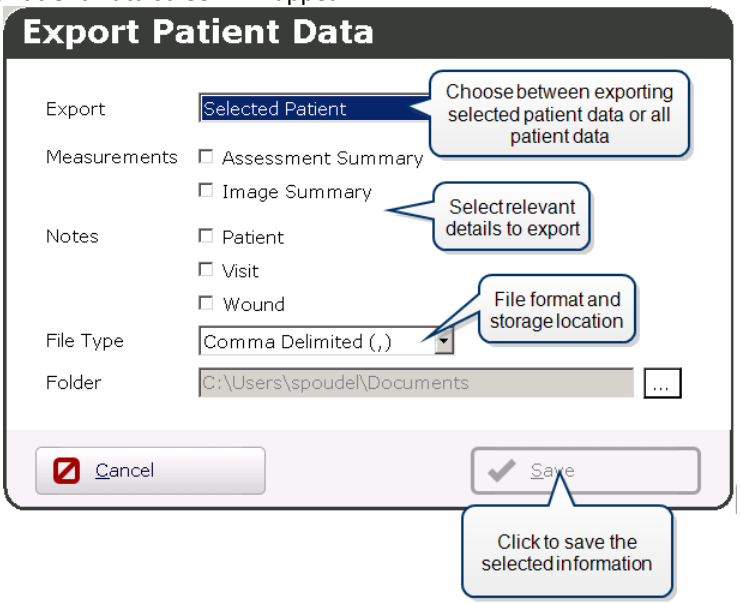
If your user account has access to multiple units, patients that are created will be assigned to the unit you selected during log on. If you wish to assign a patient to a different unit, log off and then log on to the correct unit.

Deleting Patients

To delete a patient for whom no data has been collected, click on the patient in the **Patient Selection** screen and click the **Delete Patient** button. You will be asked to confirm your choice.
Once data has been collected against a patient, you cannot delete that patient. However, you can remove the patient from SilhouetteConnect during synchronization with SilhouetteCentral. Patient data will be preserved on SilhouetteCentral, but the patient will not appear in SilhouetteConnect. See Managing Patients for more information.

Exporting Patient Data

To export patient data for use in an external application, select a patient in the **Patient Selection** screen and click **Export Data**. The **Export Patient Data** screen will appear:



You can use the **Export** drop down box to create a file for the **Selected Patient** or for **All Patients**.
Select the appropriate **File Type**. You can chose to export the file as an Excel spreadsheet (.xml) file, or as a delimited text (.csv) file. Each selected Data check box will produce a separate file containing the relevant exported contained in the Folder specified.

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Assessment Summary

The **Assessment Summary** option exports a wound assessment level summary of all assessments captured with SilhouetteStar. For each wound assessment the export contains:

- Patient details, including name, address, Patient ID, date of birth, and gender
- The wound label, anatomical site, assessment number, assessment date and time, and state (open or healed)
- The wound's area, perimeter, depth (max and mean) and volume
- The wound's tissue types and their percentages
- Wound notes, if enabled via the **Include Wound Notes in Summary Export** organization setting in SilhouetteCentral

Note that the **Assessment Summary** presents the wound measurements as the *assessment* level. For example, when two or more images are required to assess the area of a large wound, a single area measurement figure is displayed.

Image Summary

The **Image Summary** option exports an image level summary of all assessments captured with SilhouetteStar. For each image the export contains:

- Patient details, including name, address, Patient ID, date of birth, and gender
- The wound label, anatomical site, assessment number, and assessment date and time
- The image number, capture date and time, the number of fragments, the number of islands, and state (open or healed)
- The wound's area, perimeter, depth (max and mean) and volume
- The wound's tissue types and their percentages
- The axes (length and width) of each fragment and each ruler measurement

So in contrast to the **Assessment Summary** which presents measurements at the *assessment* level, the **Image Summary** presents measurements at the *image* level.

Customizing the Displayed Measurements

If using SilhouetteCentral the types of measurements displayed is configurable via the Organization Settings. Any number of measurement types can be chosen (or hidden) from the following list: time, area, area reduction, island area, perimeter, axes (length and width), rulers, maximum depth, mean depth, volume, and tissue types. For the measurement type to be included in the exported data file, it must be displayed somewhere within the Silhouette user interface.

For details on how the individual image and assessment level measurements are calculated, refer to the **How Silhouette Works** document.

Patient Notes

The **Patient Notes** option exports information extracted from the patient notes fields. In addition to the patient identity fields (name, address, Patient ID, date of birth, and gender), there are four columns:

- Group
- Item
- Value
- Changed

Each entry in the patient notes will appear as a row in the exported report, with the note's section label in the **Group** column, the label for the note in the **Item** column, the note's selected option or measurement in the **Value** column, and the date of the last update in the **Changed** column.

Visit Notes

The **Visit Notes** option exports information extracted from the visit notes fields. In addition to the patient identity fields (name, address, Patient ID, date of birth, and gender), there are five columns:

- Visit
- Group
- Item
- Value

- Changed

Each entry in the visit notes will appear as a row in the exported report. The date of each visit is listed in the **Visit** column, the note's section label in the **Group** column, the label for the note in the **Item** column, the note's selected option or measurement in the **Value** column, and the date of the last update in the **Changed** column.

Wound Notes

The **Wound Notes** option exports information extracted from the wound notes fields. In addition to the patient identity fields, there are seven columns:

- Wound
- Assessment
- Visit
- Group
- Item
- Value
- Changed

Each entry in the wound notes will appear as a row in the exported report. Each wound is identified in the **Wound** column, and alongside in the **Assessment** column is the date and time for each assessment. The note's section label appears in the **Group** column, the label for the note in the **Item** column, the note's selected option or measurement in the **Value** column, and the date of the last update in the **Changed** column. Note that if using SilhouetteCentral the **Wound Notes** can also appear in the **Assessment Summary** if enabled via the **Include Wound Notes in Summary Export** organization setting.

Synchronizing with SilhouetteCentral

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

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

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

There are three ways to initiate synchronization with SilhouetteCentral:

- Click the **Sync** button in the **Patient Selection** screen. Synchronization will begin.
- Click the **Manage Patients** button to choose patients to add to and remove from SilhouetteConnect. See Managing Patients for more information.
- Automatically when you log off - if this functionality has been enabled by your system administrator.

The **Sync** and **Manage Patients** buttons are only seen on the **Patient Selection** screen if your SilhouetteConnect software is configured to connect with SilhouetteCentral. If you have SilhouetteCentral and do not see these buttons, contact your system administrator as described in Appendix B: Getting Support.

The time required for synchronization depends on the number of patients and images to be transferred and the speed of the communication path between SilhouetteConnect and SilhouetteCentral. As synchronization proceeds, SilhouetteConnect will display progress at each stage.

If a compulsory update to SilhouetteConnect software is available, a message will appear before synchronization begins asking whether you wish to update SilhouetteConnect.

- If you wish to update SilhouetteConnect, click **Yes** and follow the instructions. Once the update has been installed, you will need to synchronize with SilhouetteCentral again.
- If you do not wish to update SilhouetteConnect, click **No**. Synchronization will be canceled.

If you cannot synchronize with SilhouetteCentral, follow the steps outlined in Appendix A: Troubleshooting.

Managing Patients

The **Manage Patients** screen is only available if SilhouetteConnect is configured to connect with SilhouetteCentral. In the **Manage Patients** screen, you can choose patients to add or remove from SilhouetteConnect before starting the synchronization process.

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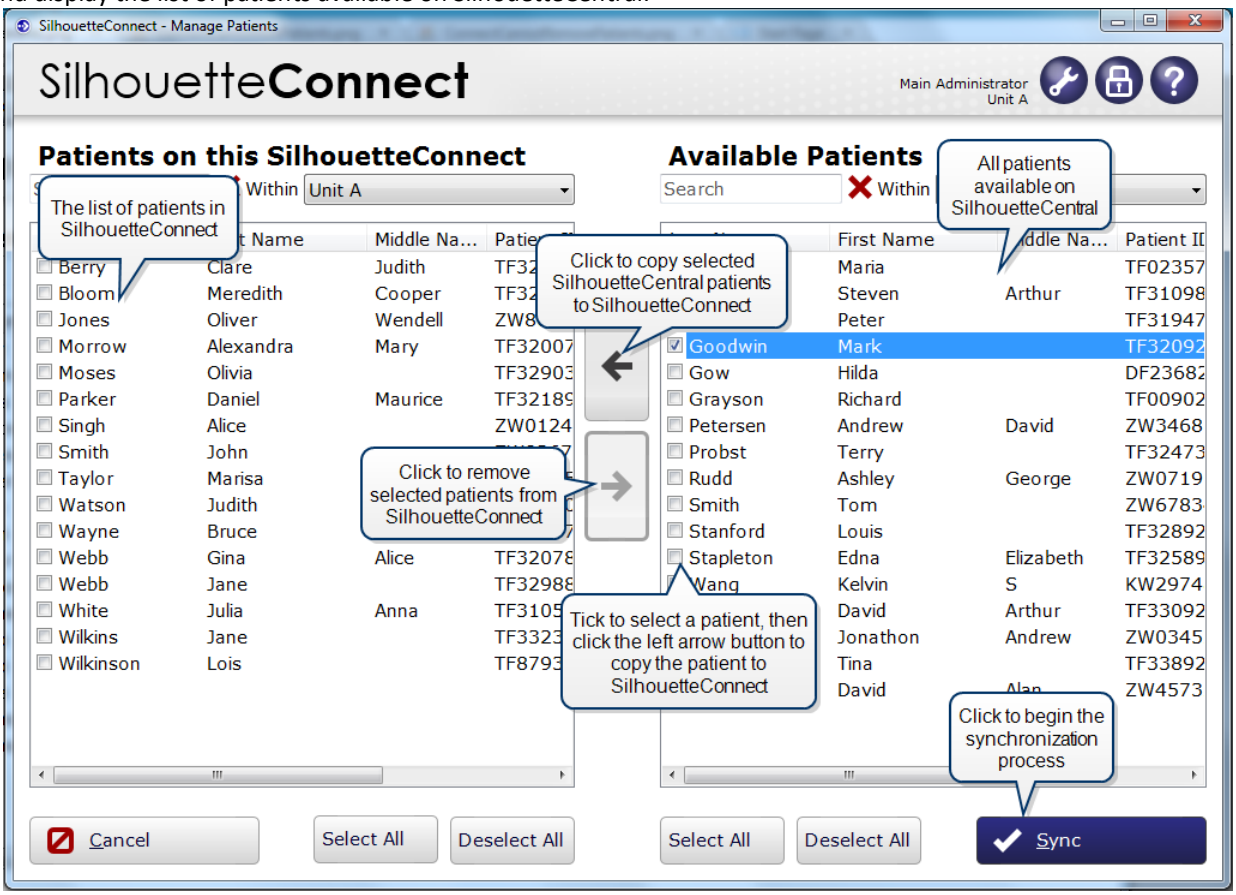
When the **Manage Patients** screen first opens, SilhouetteConnect will establish a connection with SilhouetteCentral and display the list of patients available on SilhouetteCentral:



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 SilhouetteConnect, 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 will be preserved on SilhouetteCentral, but the patient will not appear in SilhouetteConnect.

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

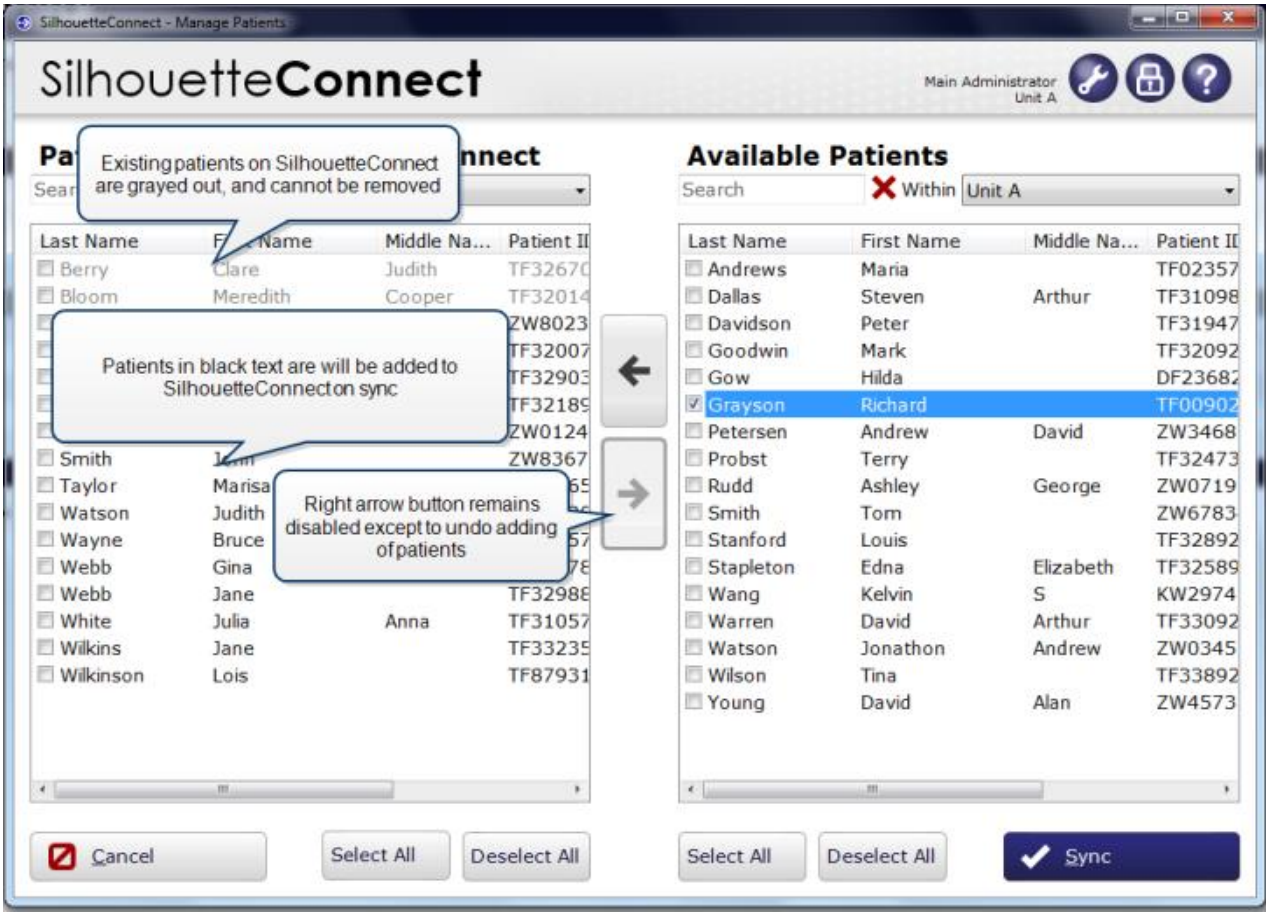
If you cannot synchronize with SilhouetteCentral, follow the steps outlined in Appendix A: Troubleshooting.

Setting the group permissions to add or remove patients

The permissions to add or remove patients can be configured via the SilhouetteCentral **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 **SilhouetteCentral User's Guide**.

Managing Patients for Groups with only Add Patient Permission

In some cases the group permissions may be set so that the user has permissions to add patients to SilhouetteConnect, but does not have permission to remove patients. For these users the Manage Patients screen will behave slightly differently. As shown in the screenshot below, all the patients that are currently on SilhouetteConnect are listed under the **Patients on this SilhouetteConnect** list are grayed out, preventing them from being removed from SilhouetteConnect.



Patients can still be added to SilhouetteConnect by selecting them from the **Available Patients** list and using the left arrow button to move them to the **Patients on this SilhouetteConnect** list. These newly added patients will be shown in black text on the **Patients on this SilhouetteConnect** list, and can be removed again before syncing. This allows the user to undo the accidental adding of a patient.

Managing patients without permission to add patients

In some cases the group permissions may be set so that the user has permission to remove patients from SilhouetteConnect, but does not have permission to add patients. For these users the Manage Patients screen will behave slightly differently. As shown in the screenshot below, all the patients on SilhouetteCentral are shown as grayed out on the **Available Patients** list, preventing them from being added to SilhouetteConnect.

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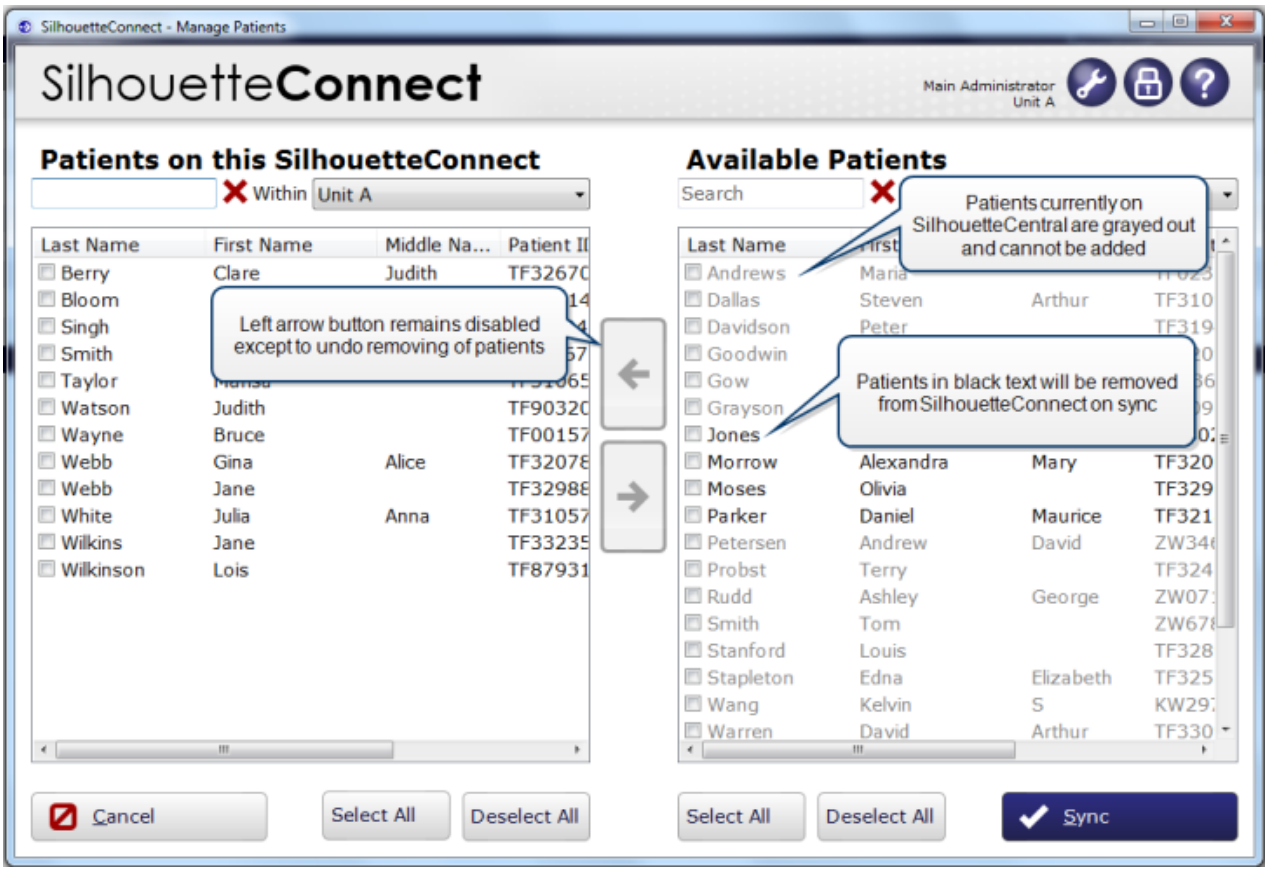


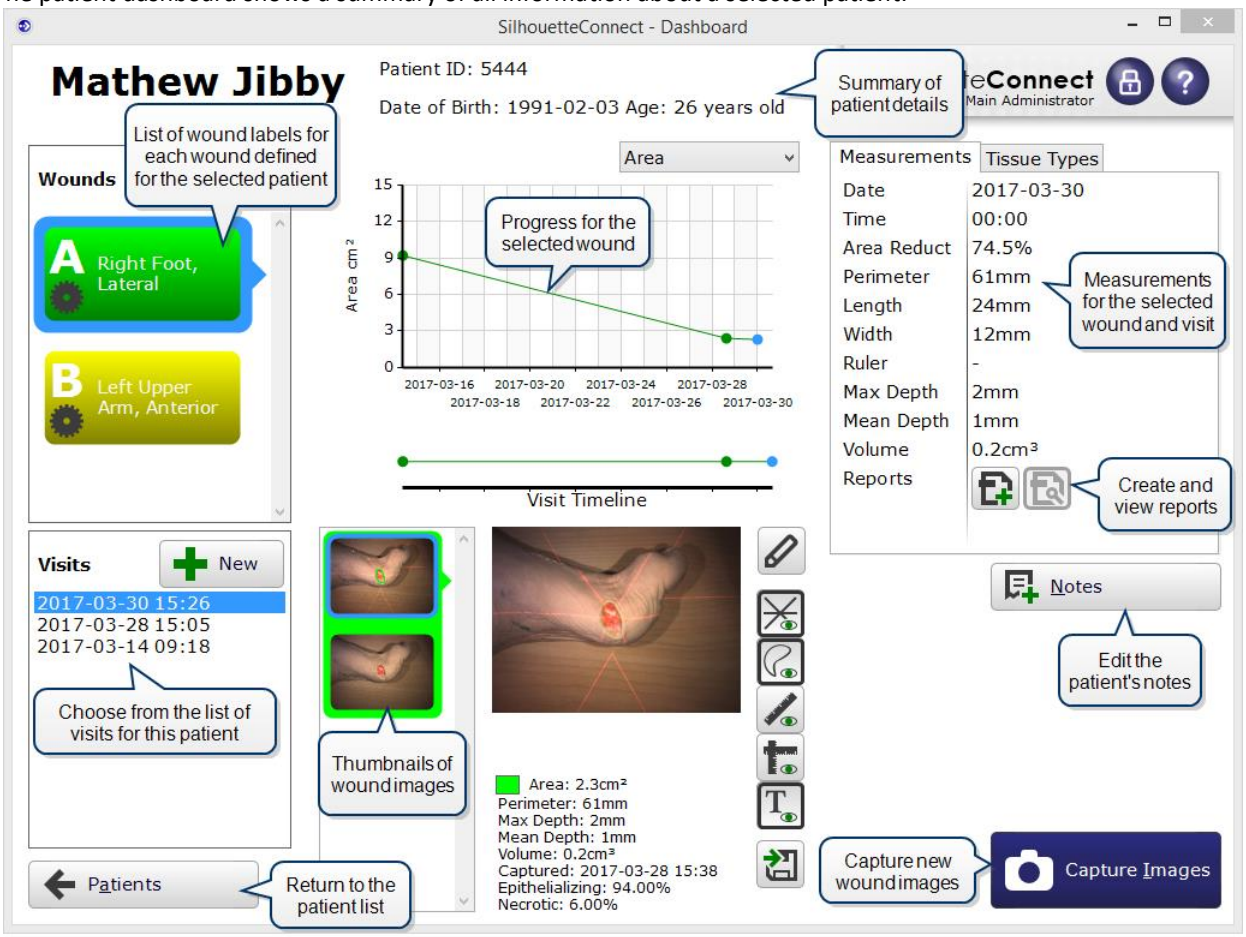
Patients can still be removed from SilhouetteConnect by selecting them from the **Patients on this SilhouetteConnect** list and using the right arrow button to move them to the **Available Patients** list. These removed patients will be shown in black text on the **Available Patients** list, and can be added back before syncing. This allows the user to undo the accidental removing of a patient.

In this case, the left arrow button will remain disabled unless you want to undo removing a patient from SilhouetteConnect.

If your organization uses Assessment Orders then patients may appear in bold, or grayed out and unavailable, regardless of your permissions.

The Patient Dashboard

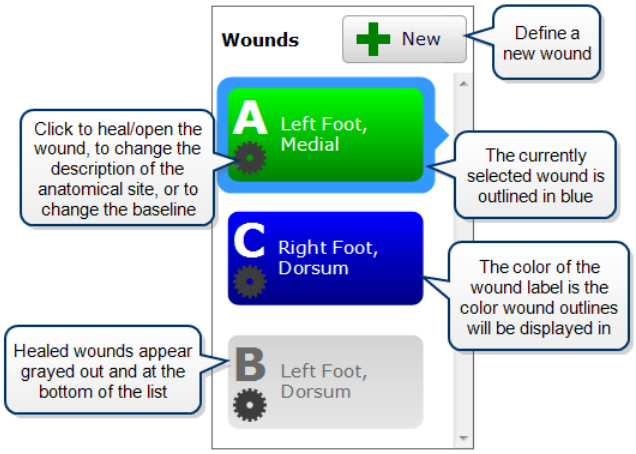
The patient dashboard shows a summary of all information about a selected patient:



Click on a wound in the **Wounds** list and select a visit to view images for that wound.

Wound List

The wound list shows all of the wounds defined for the patient:



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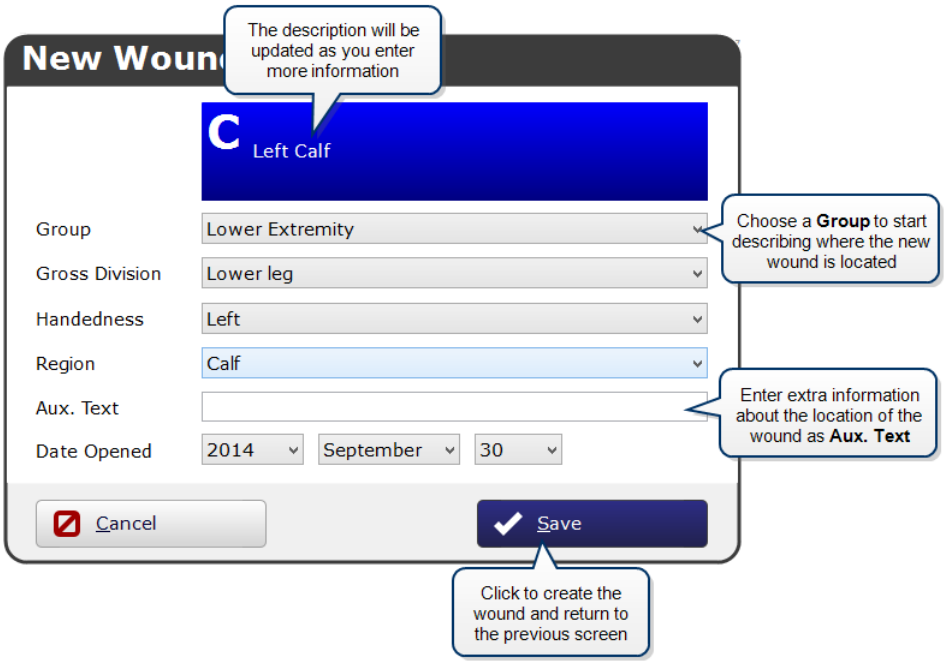
The currently selected wound is outlined in blue. The color of each wound label is the color used to display the outline for each wound. Healed wounds are grayed out and appear at the bottom of the wound list.
To add a new wound, click the **New** button and use the drop-down boxes to describe the wound's location:

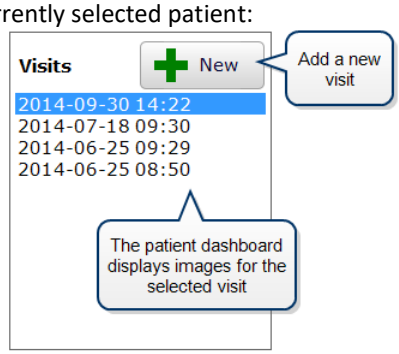


You may have permission to see the ▪ button on a wound label. Click on the ▪ button to change the wound's anatomical site, to indicate that the wound has healed, or to change the baseline:

See Healing a Wound and Changing the Baseline for more information on these options.

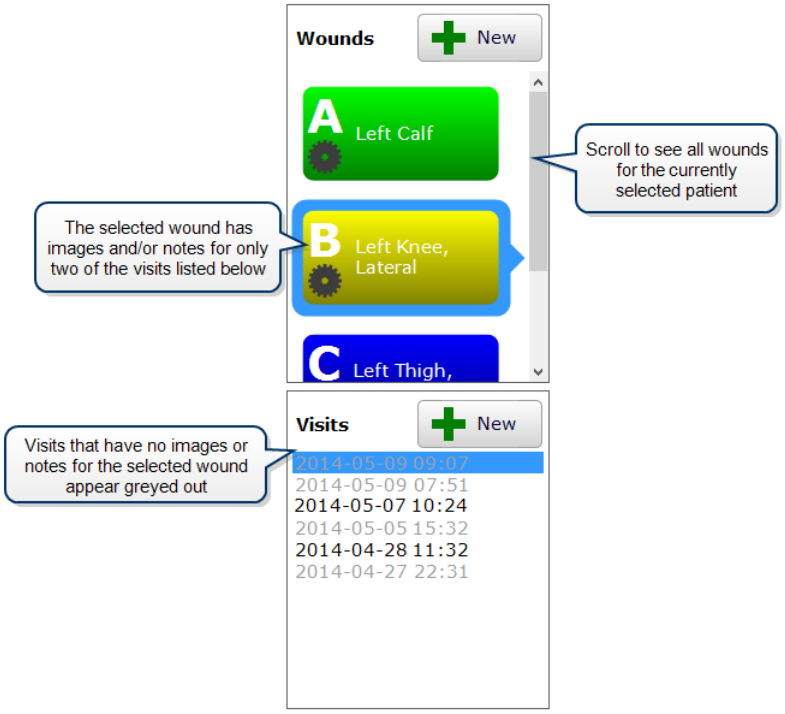
Visits

The **Visits** shows the list of visits for currently selected patient:



The images displayed are those for the currently selected visit and wound.

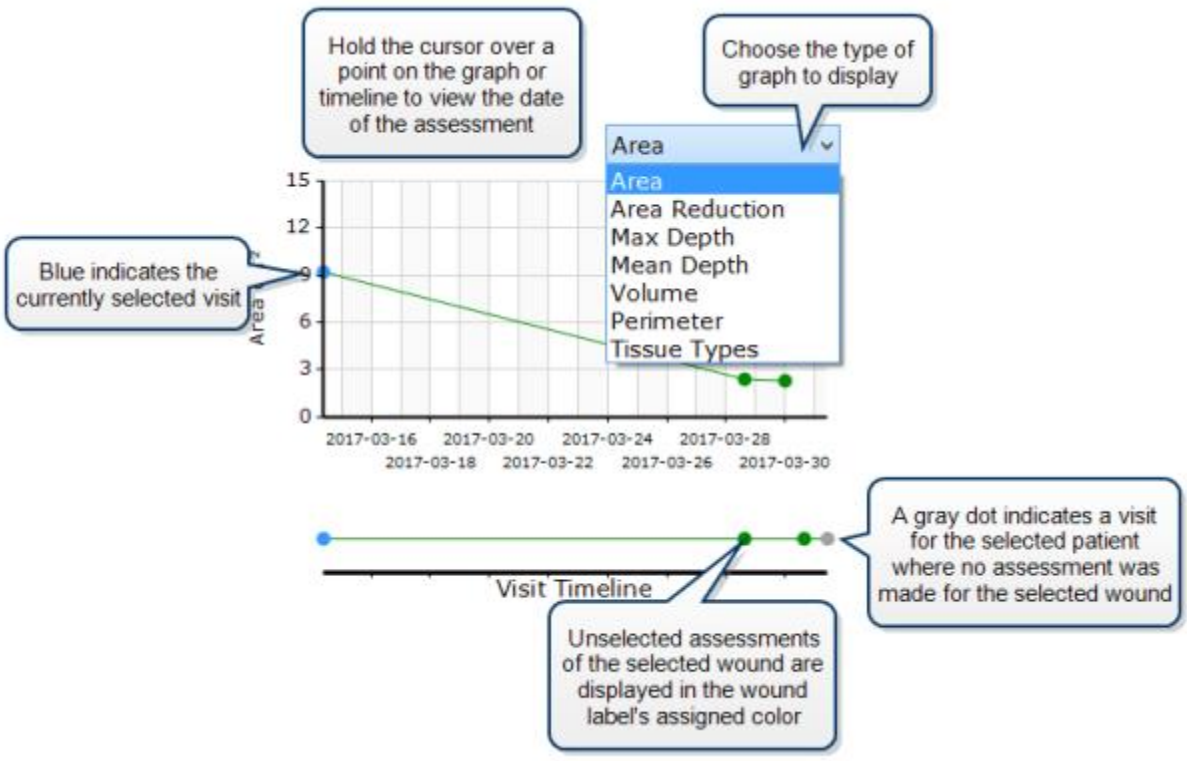
Visits that have no images or notes for the currently selected wound will appear grayed out. For example, here Wound B has images and/or notes for only two of the visits recorded for the selected patient:



Click on a visit to view the wound images captured for that visit.
To add a new visit, click the **New** button. A new visit will be created using the current date and time. Note that once you create a visit, you cannot delete it; however, visits that contain no assessments or notes will be automatically removed when you return to the **Patient Selection** screen.

Visit Timeline

The **Visit Timeline** shows the history of the currently selected wound:



The different points on the graph indicate different visits.

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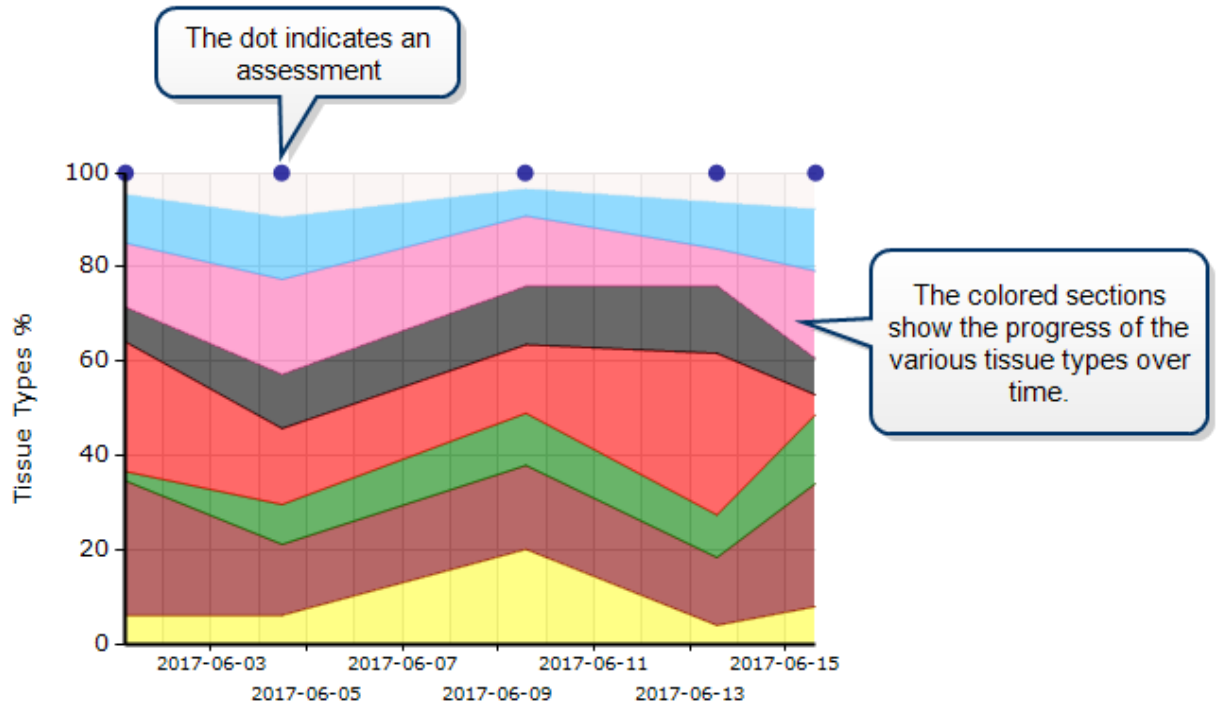
- A blue dot indicates the currently selected visit.
- Dots in the wound label's assigned color indicate other visits for which assessments of the selected wound were made.
- A gray dot indicates a visit for the selected patient where no assessment was made of the selected wound.

Hold the cursor over the different points to view the time and date of the visit.
Click on the different points to change the selected visit.

Tissue Types Graph

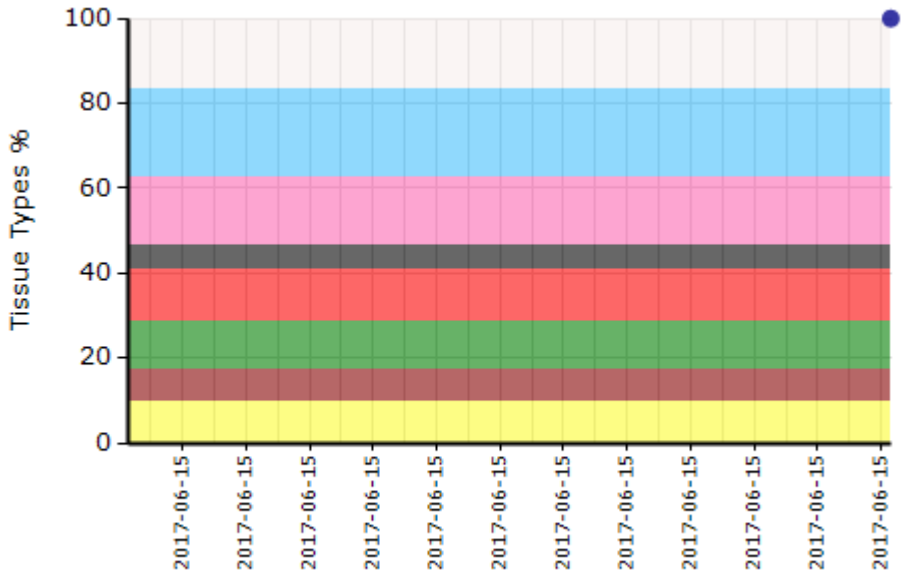
The **Tissue Types graph** shows the progress for the tissue types over time for the currently selected wound:



The different points at the top of the graph indicate different assessments.
The stacked sections show percentages of the tissue types that were represented in the wound for the various assessments. The order that the sections are displayed in are the same as the graph order on the Tissue Type Classification screen, with the highest number at the bottom and the lowest at the top. Hover over a section to see the name of the tissue type in a tooltip.

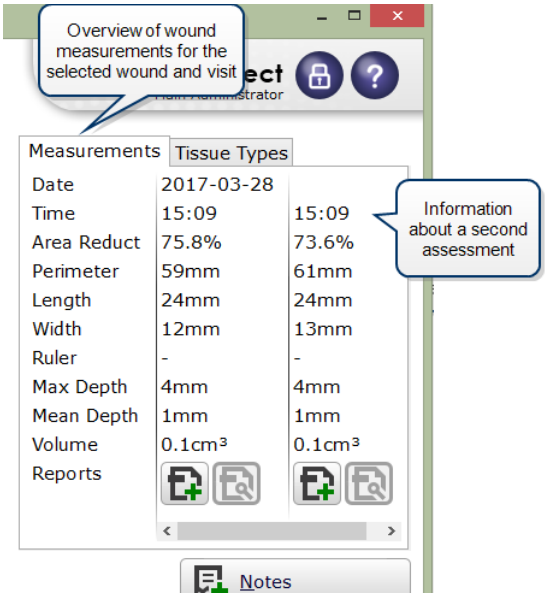
Hovering the mouse over the assessment dot will not show the assessment date and time.

Another way in which this graph is different from the other graphs, is that it will only show the assessments with wounds that have any tissue types assigned. This is to make sure that, when tissue types are enabled for a patient with months or years of data, that the graph won't have a large amount of white space on the left. For the same reason, this graph will not show the Visit Timeline. The graph will also always take up all the space that is has, so if the patient only has 1 assessment with tissue types, the data will show as horizontal lines, with the assessment dot on the far right.



Wound Measurement Overview

The **Wound Measurement** overview shows information about the selected wound:



If there is more than one assessment for the selected wound in the selected visit, the assessments will appear in additional columns. This may represent pre and post-debridement measurements, for example, that occurred during the same patient visit.

This tab also contains the generate/view report buttons for each assessment belonging to the selected visit.

Area Reduction

The **Area Reduction** expresses the percentage reduction in the wound's surface area with reference to the wound's baseline area measurement. **Area Reduction** appears in the **Wound Measurement** summary and has its own graph type.
Area Reduction is calculated as the difference between the baseline area, A_b, less the current area measurement, A_c, divided by the baseline area measurement, and expressed as a percentage:
Area Reduction (%) = $(A_b - A_c)/A_b \times 100$

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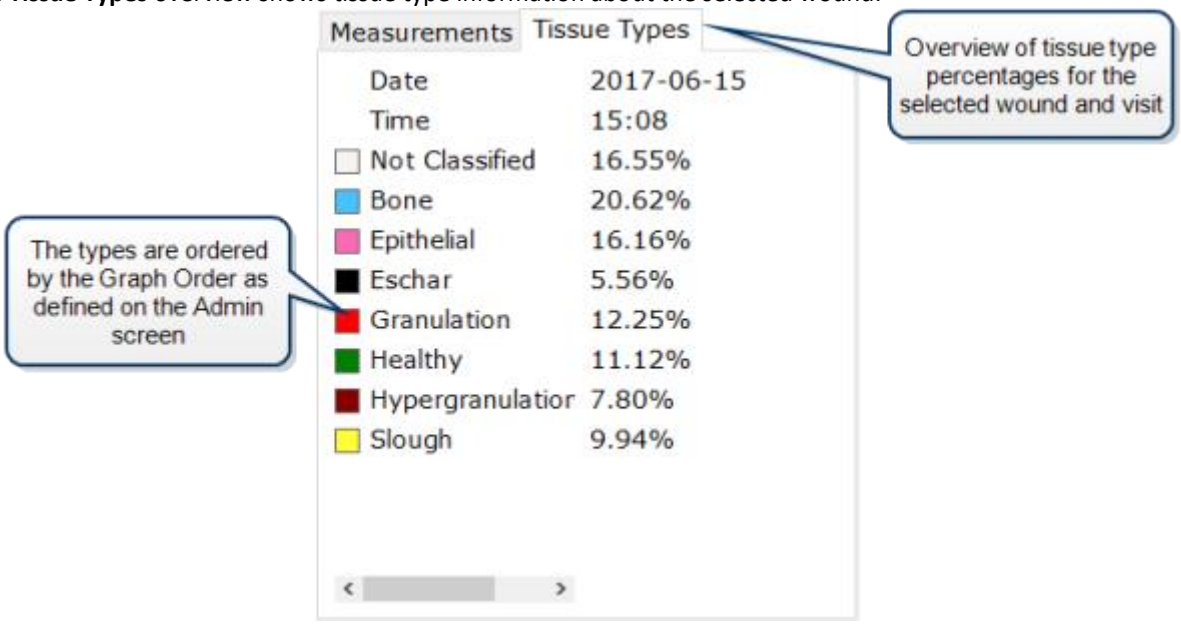
Note that when a wound starts, the **Area Reduction** is 0%, and when a wound is healed, the **Area Reduction** is 100%.
The default baseline area measurement is chosen to be the first area measurement that is made for a wound. For more information on the baseline and changing the baseline see Changing the Baseline.

Tissue Type Percentages Overview

The **Tissue Types** overview shows tissue type information about the selected wound:

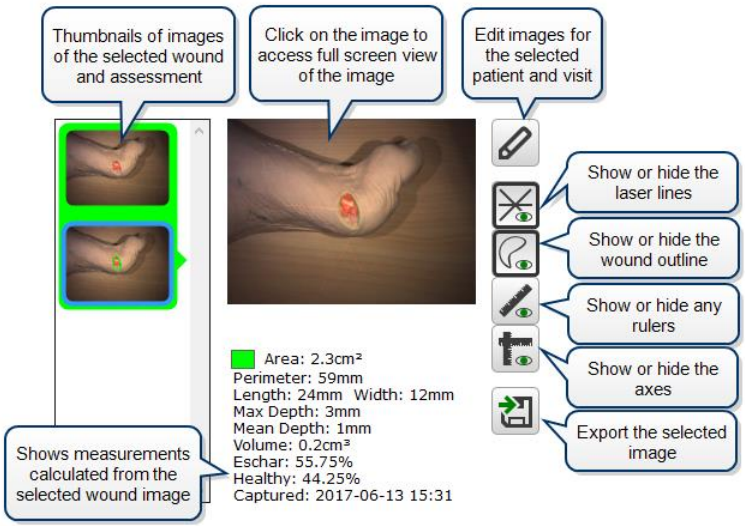


If there is more than one assessment for the selected wound in the selected visit, the assessments will appear in additional columns. This may represent pre and post-debridement measurements, for example, that occurred during the same patient visit.

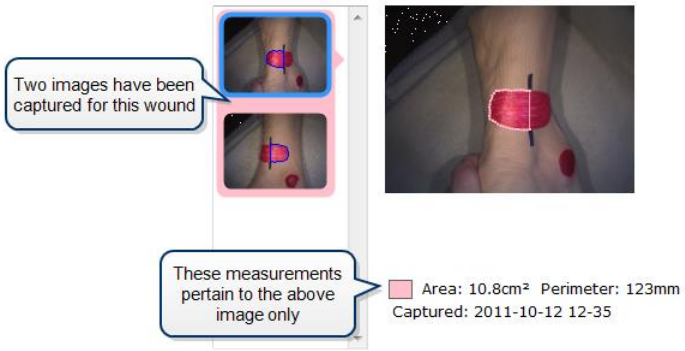
Customizing the Displayed Measurements
The type of measurements displayed can be configured via the SilhouetteCentral **Organization Settings**. Any number of measurement types can be chosen (or hidden) from the following list: time, area, area reduction, island area, perimeter, axes (length and width), rulers, maximum depth, mean depth, volume, and tissue types. For more information see the **SilhouetteCentral User's Guide**.

Wound Images

Thumbnails of all the images for the currently selected assessment are shown:



If the wound selected is a circumferential wound, for example, there may be more than one image associated with the assessment. In this situation, the Wound Measurement Overview overview at the top right of the **Patient Dashboard** shows the measurement for the wound as a whole. However, the measurements *below* the wound show the measurements for the wound fragments in the selected image. For example, two images have been captured for the wound shown below; the measurements pertain to the fragments in the immediately above image only.



Customizing the Displayed Measurements
The type of measurements displayed can be configured via the SilhouetteCentral **Organization Settings**. Any number of measurement types can be chosen (or hidden) from the following list: time, area, area reduction, island area, perimeter, axes (length and width), rulers, maximum depth, mean depth, volume, and tissue types. For more information see the **SilhouetteCentral User's Guide**.

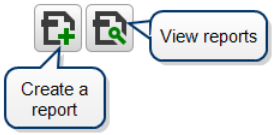
For more information about capturing images for circumferential wounds, see Taking a Multiple Image Measurement.

You can also:

- Edit the image by redrawing or adjusting the wound outline. Click the **Edit** button .
- Change the outline or assign the image to a different wound. Click the **Edit** button .
- Show or hide the lasers. Click the **Show/Hide Lasers** button .
- Show or hide the wound outline. Click the **Show/Hide Outline** button .
- Show or hide the rulers. Click the **Show/Hide Rulers** button .
- Show or hide the axes. Click the **Show/Hide Axes** button .
- Export the image. See Exporting Images from SilhouetteConnect.

Report Buttons

The **Report** buttons let you create and view reports. The buttons are located on the Measurements tab.



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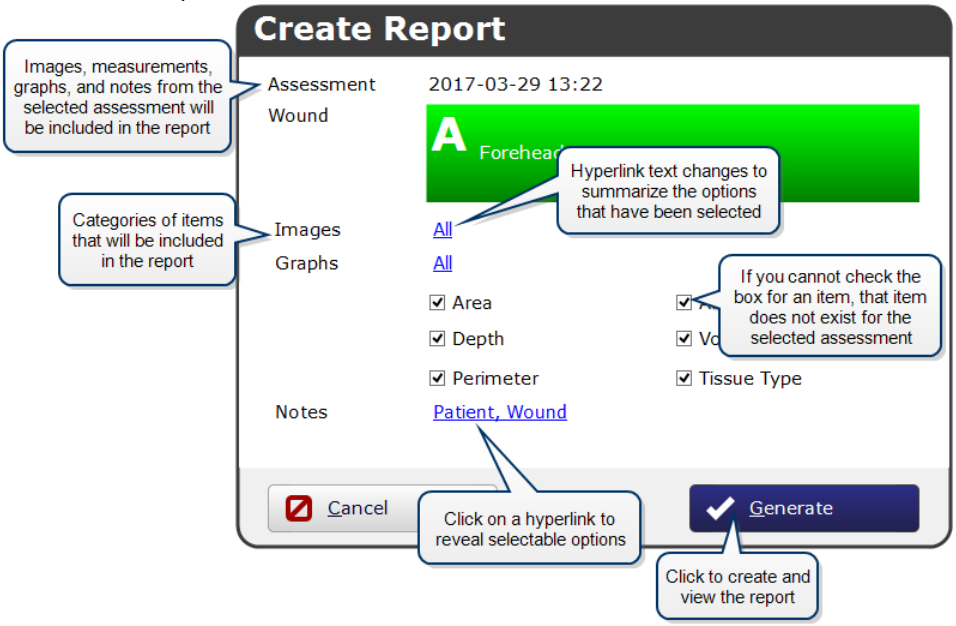
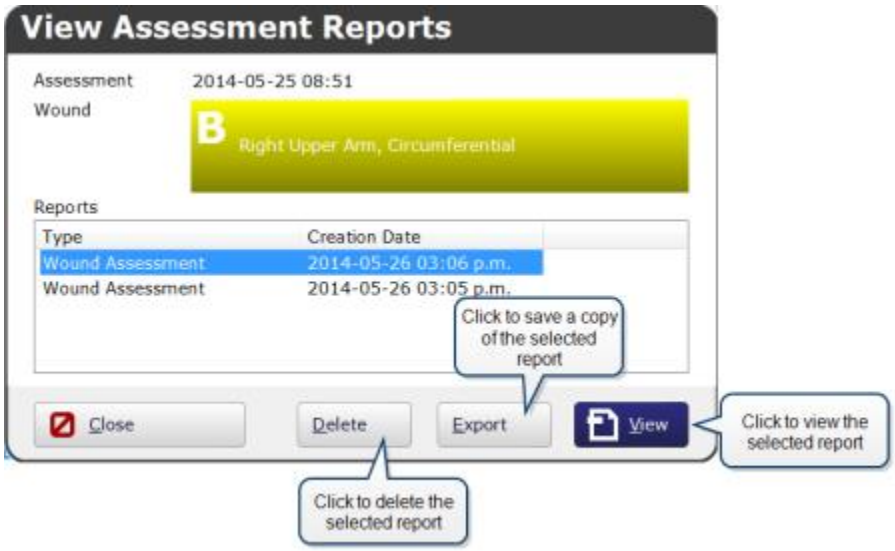
To create a report, select the visit for which you wish to create a report, then click the **Create Report** button under the list of measurements for the specific assessment you want. In the window that appears, choose what information to include in the report from that assessment:



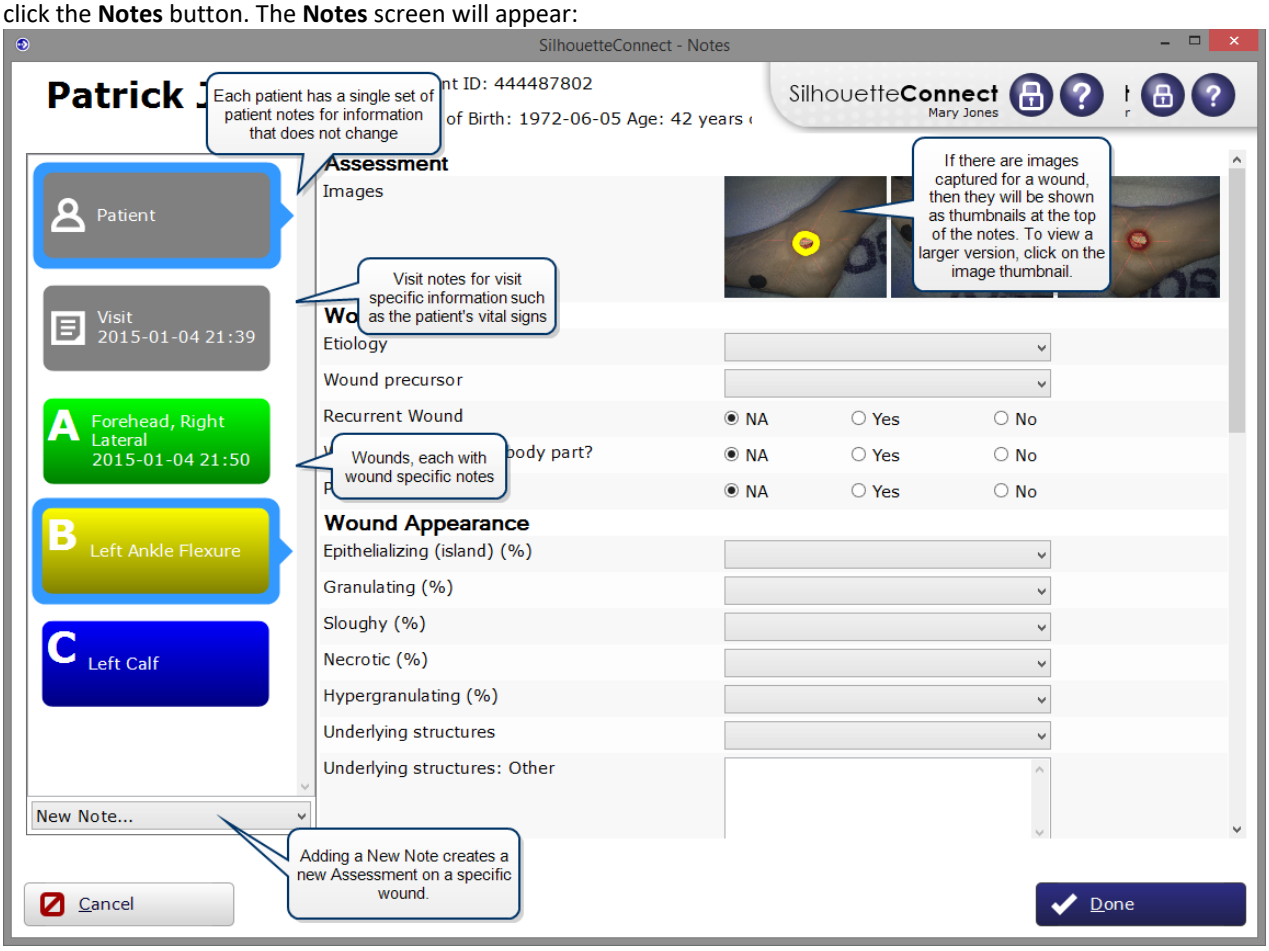
Options are grouped into three categories: **Images**, **Graphs**, and **Notes**, with the currently selected options listed. Click on the options to view check boxes letting you choose from the available options.
Some options may be grayed out and cannot be ticked. For example, the **Wound** options under **Notes** will only be available if notes have been created.
The image options available will depend on the types of images captured for the selected assessment. Reference images are images for which wound boundaries have not been traced. Reference images are useful if you wish to capture an image of surrounding tissue to demonstrate, for example, redness or swelling extending beyond the measured wound image.
Select **Generate** to create the report. If you have Adobe Reader installed, the report will be opened so you can view it.
You can view all existing reports for the assessment by clicking the **View Reports** button. Select from the list of reports available:



Clicking **Delete** will delete the selected report. This can be useful if a report is a duplicate or if it contains incorrect information.
You can also save a copy of a SilhouetteConnect report in PDF format to your PC. Before saving a report, make sure that exporting reports complies with your organization's patient data security policy. If you are permitted, click the **Export** button, and in the window that appears, select the location where you wish to save the report.

Notes Button

To view and edit notes for a patient, select the visit for which you wish to edit notes in the patient dashboard and click the **Notes** button. The **Notes** screen will appear:



For each patient, there is a single set of patient notes for information that does not tend to change from visit to visit. Information you can enter when the **Patient** tab is selected includes wound etiology, investigation history, medical history, the wound management supplier and the patient's medication. If using SilhouetteCentral this may differ as these items are configurable.

Click on the **Visit** tab to enter information for the currently selected visit about the patient's vital signs and factors affecting wound healing progress. If you wish to edit the notes for a different visit, click on that visit in the **Visits** list, found in the dashboard before clicking the **Notes** tab.

Each wound assessment within the Visit has it's own set of notes. Click on the wound to enter specific wound notes. To add a second assessment for a wound click **New Note** and select the required wound to create a new set of notes for a wound's assessment in the selected visit. If the **New Note** function is not available this is because the Visit window has closed.

Orders Button

> **Optional Feature: Assessment Orders**
> Depending on the licensed features and configuration of your system, you may see an **Orders** button on the **Patient Dashboard**. This is described in the following section.

Assessment orders are instructions to obtain one or more wound assessments for a specific wound on a specific patient. An assessment order contains a unique order number that can be use to uniquely identify the order, a scheduled date when the assessment(s) should occur and a description field containing details provided by the EMR which describe what needs to be assessed.

Once assessment orders have been obtained via synchronization with SilhouetteCentral, patients for whom orders have been created are indicated in bold on the **Patient Selection** screen.

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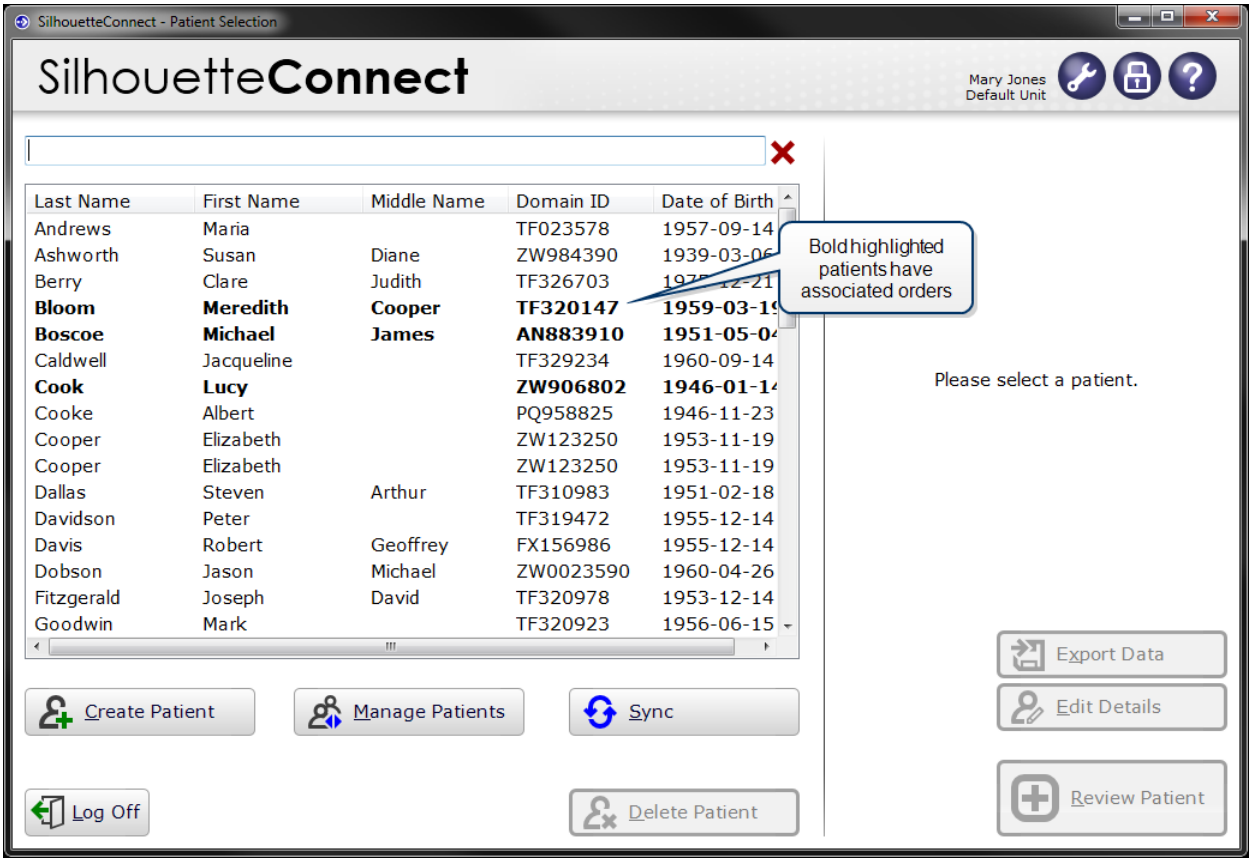
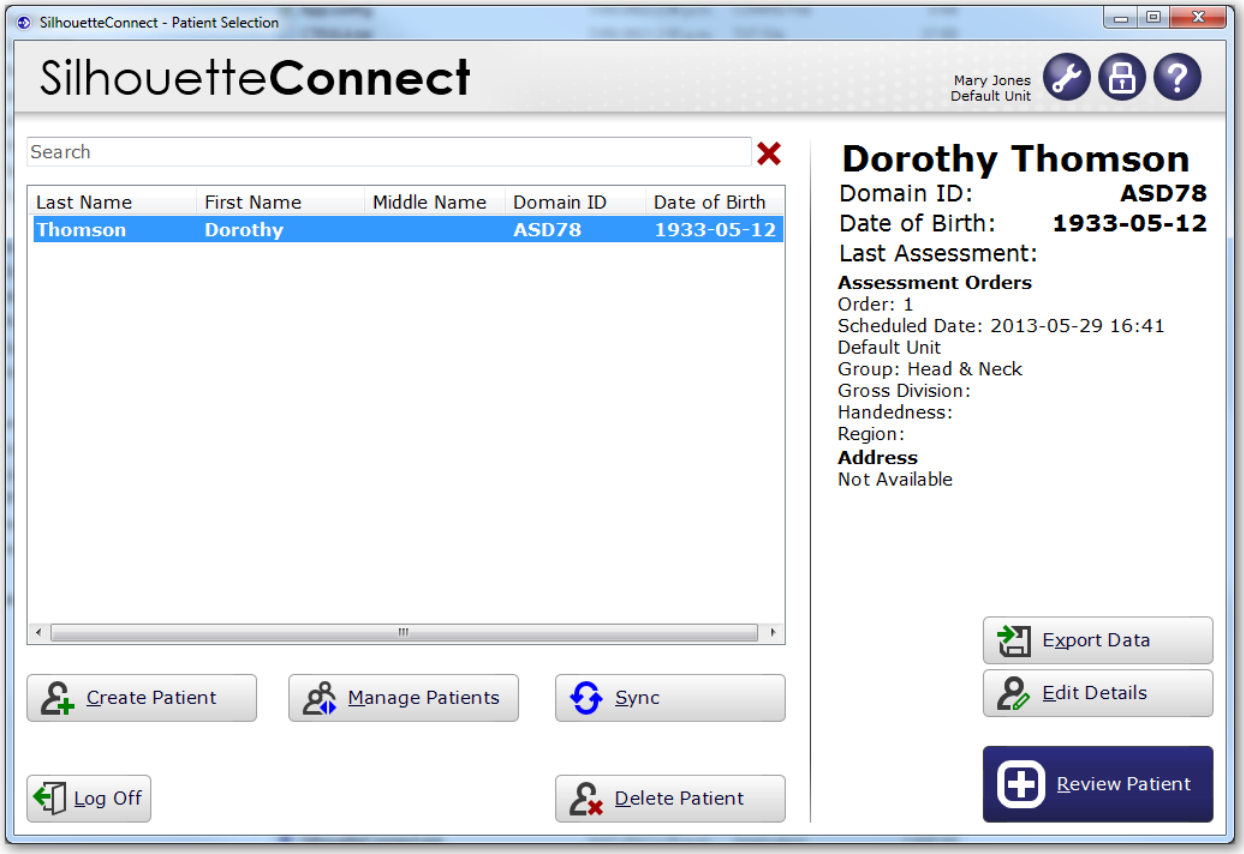
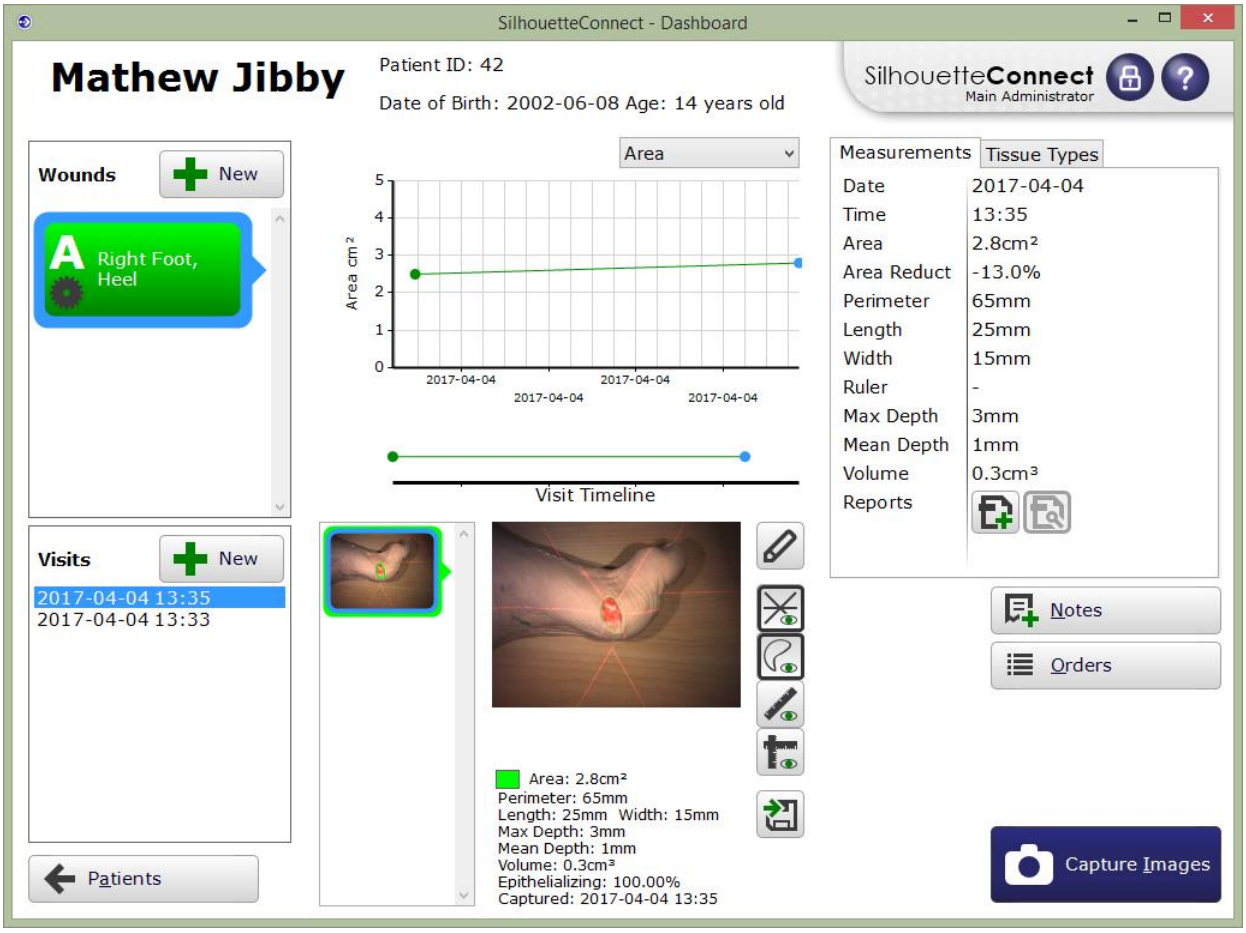


Selecting a patient with active orders in this screen will display information about the orders on the right side of the screen, including the date the order was issued and the wound that is to be assessed.



To action an assessment order, first perform the required assessments with Silhouette. Next the assessment(s) are assigned to their respective assessment order. This can be done either on SilhouetteConnect or SilhouetteCentral

(once the data has been synchronized). To perform the assignment on SilhouetteConnect, select the patient and then click the **Orders** button on the **Patient Dashboard** screen.



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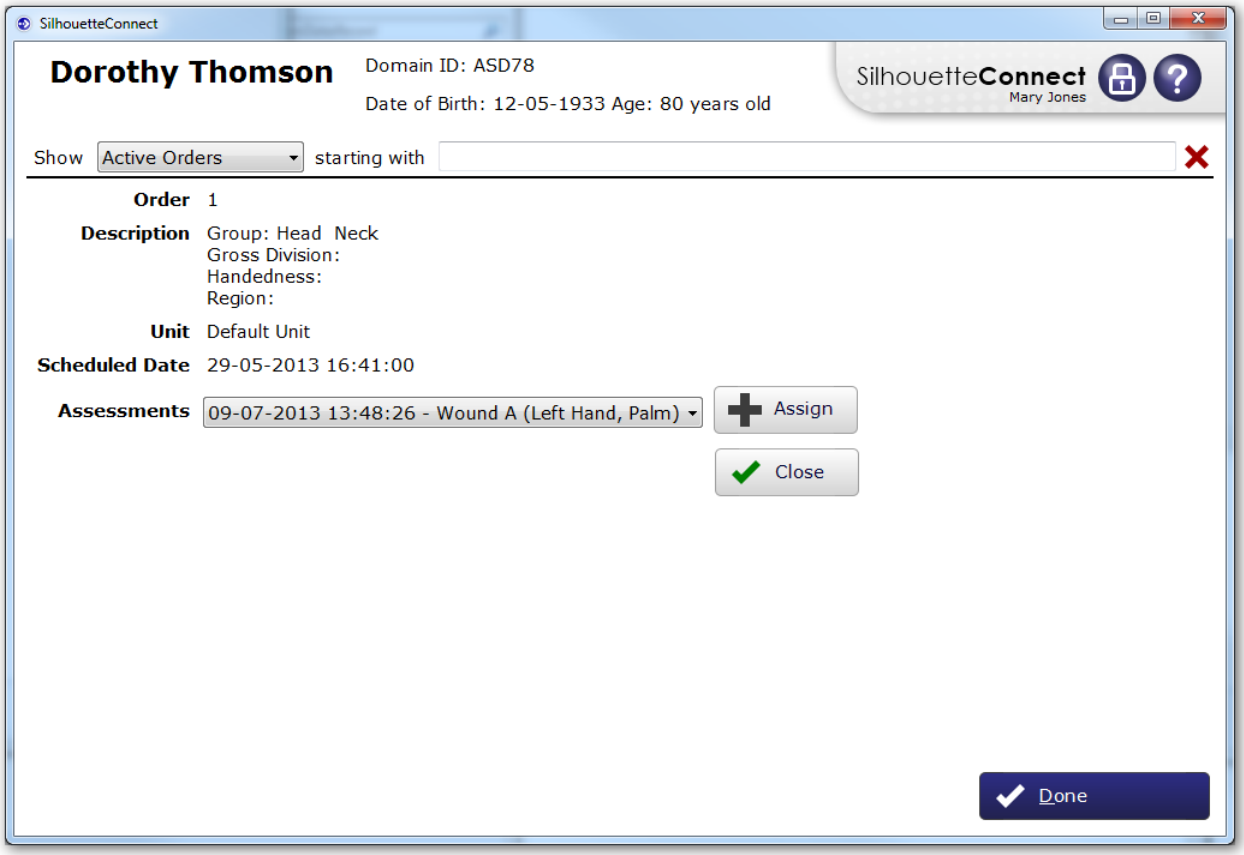
The **Orders** screen shows the orders for the selected patient, with a filter that defaults to displaying all currently active orders. Each order that has not been completed will display a drop down list containing suitable assessments that can be used to fulfill the order.



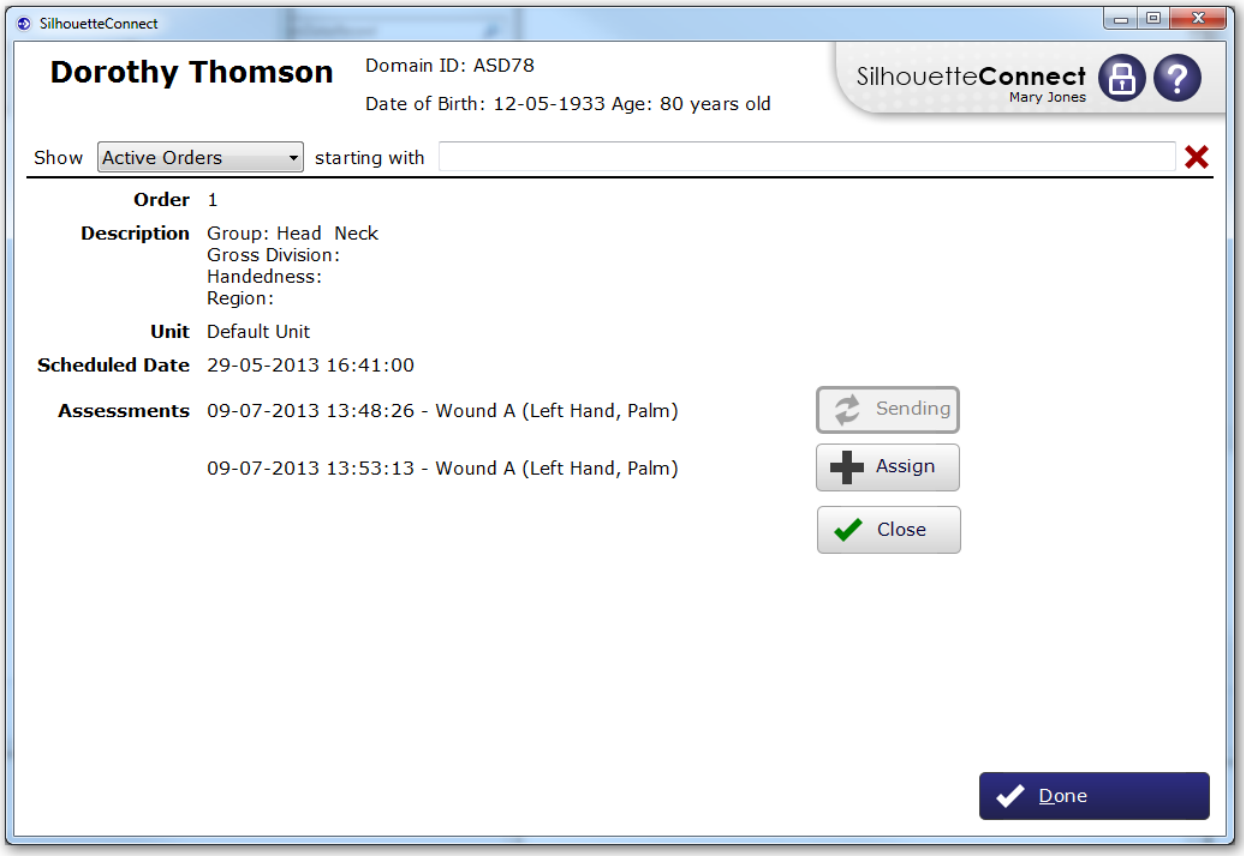
Find the appropriate assessment for the order in the drop-down list then click the **Assign** button to link the assessment to the order. The button will change to a disabled **Sending...** button, indicating that the assessment is being sent to the institution's electronic medical record system the next time a synchronization with SilhouetteCentral is performed. As soon as SilhouetteCentral has accepted responsibility for passing the assessment order results through to the EMR system the disabled **Sending...** button will change to a **Resend** button.
When an assessment order has been satisfied click **Close** button to mark the assessment order as completed. No more assessments can be added after the assessment order is closed. Note that it is possible to close an assessment order without assigning any assessments to it. It would be appropriate to close an assessment order in this way if the assessment order was generated in error. It is also possible that such assessment orders may automatically be closed by your institution's electronic medical record system when the order is canceled elsewhere. If this occurs the status change for the assessment order will be detected the next time a synchronization with SilhouetteCentral is performed.
Other filter options on the assessment orders screen allow the user to display:

- All Orders - irrespective of their status
- Active Orders - orders which are "new" or "in progress"
- New Orders - orders which have been received from the EMR but have yet had a wound assessment assigned to them.
- In Progress Orders - orders which have had 1 or more wound assessments assigned to them, but have not been marked as closed (completed).
- Closed Orders - orders which have been marked as closed by a user in Silhouette, or canceled by the EMR.

Assigning Multiple Assessments to an Order

Depending upon configuration it may be possible to assign multiple assessments to a single assessment order. For example an assessment order may have a description requesting 1 assessment be made each week for the following 3 weeks. First, select and assign the first wound assessment as described in the previous section. Additional unassigned assessments for the same wound will then automatically be listed below the assigned assessment, each

with an **Assign** button. Click the **Assign** button for each assessment you want to associate with the assessment order.
Note when a wound assessment has been assigned to an active assessment order this will mean all subsequent assessments for the same wound must be assigned to the same order. If you want to assign future wound assessments to a different assessment order the currently active assessment order must first be closed.



Resending an Assessment

In some cases you may wish to change information or generate an updated report for a wound assessment that has already been assigned to an assessment order. This means the order results will already have been sent through to your institutions electronic medical record system. Once you have edited the assessment using the standard SilhouetteConnect editing tools, navigate to the **Orders** screen. On the orders screen, the modified assessment will

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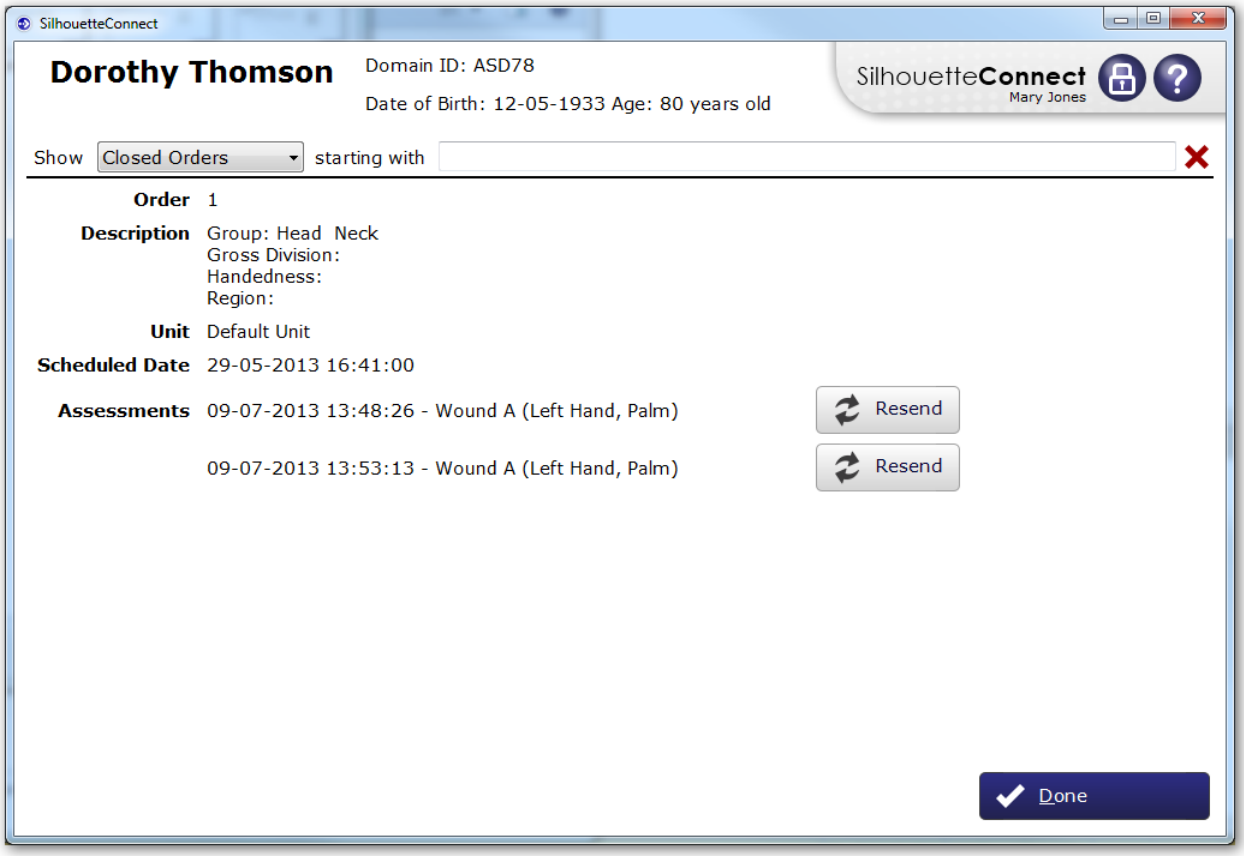
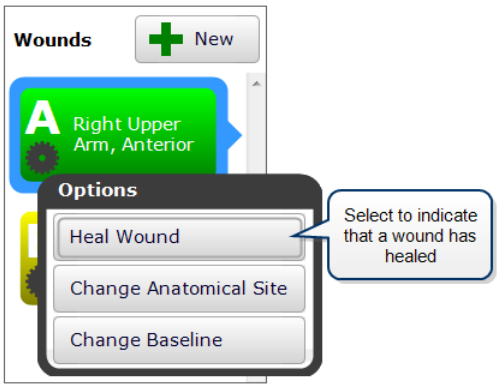
appear with a **Resend** button. Click the **Resend** button to have the updated assessment order results re-sent to the electronic medical record system.
Note if a change has been made to an assessment and the **Resend** button is not pressed this may mean that out of date results will be displayed within the EMR when the assessment order is reviewed. Always ensure that after a change is made in Silhouette that the **Resend** button is used.



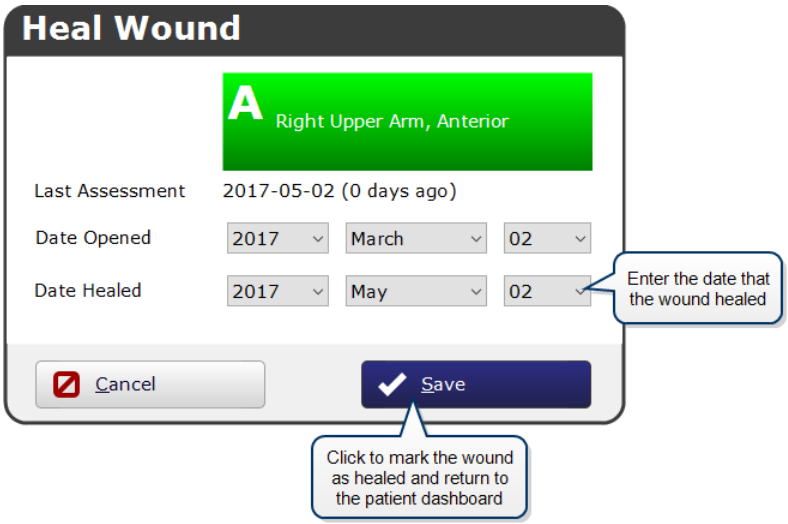
Healing a Wound

To indicate that a wound has healed:

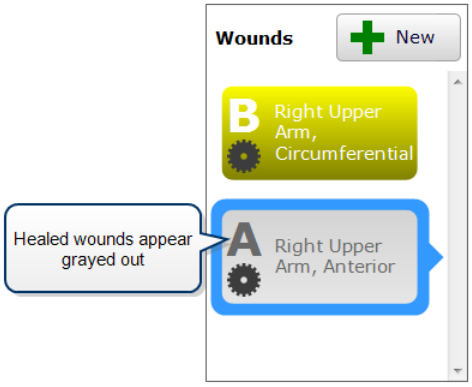
1. Select the required patient and go to the patient dashboard.
2. For the wound that has healed, click on the . button and select the **Heal Wound** option:



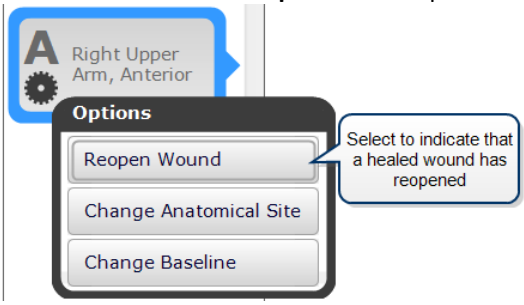
3. In the window that appears, change the **Date Opened** and **Date Healed**, if required, then click **Heal**:



You cannot heal a wound that has the same date entered for **Date Opened** and **Date Healed**.
Healed wounds appear in the wound list grayed out:



If a wound reopens, click on the ▪ button and select the **Reopen Wound** option:



Enter the date the wound reopened and click **Reopen**. Note that you cannot reopen a wound on the same day the wound has been healed. When reopened, the wound will again appear as open in the wound list.
To change the Healed Date, reopen the wound as above then find the wound, click on the ▪ button and select the **Heal Wound** option. Enter the new **Date Healed** and click on **Save**

Changing the Baseline

Area reduction expresses the percentage reduction in the wound's surface area with reference to the wound's baseline area measurement. It appears in the Wound Measurement summary and has its own graph type.
If you would like to change the baseline area measurement:

1. Select the required patient and go to the patient dashboard.
2. Click on the ▪ button on the wound label for which you wish to change the baseline, and select the **Change Baseline** option:

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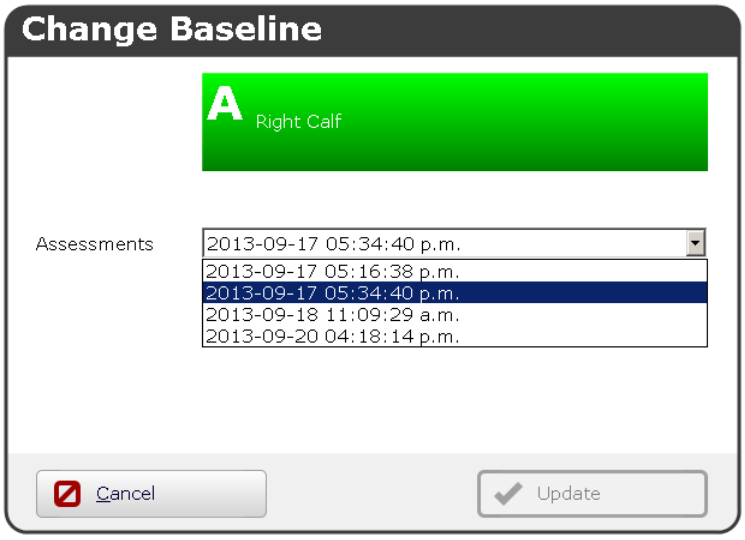
3. In the window that appears, select the desired assessment from the drop-down list that contains the area measurement that you would like to be the baseline:



The default baseline area measurement is chosen to be the first area measurement that is made for a wound. While this is usually the area of a wound's first assessment, it may not be. For example, say you create a wound and immediately make two assessments - a pre-debridement assessment and a post-debridement assessment. If you draw an outline on the post-debridement (which is the second assessment) first, then this second assessment will be the baseline.

If you want to change a baseline manually, then you can do so as described above.

SilhouetteConnect will also change the baseline automatically in the special circumstance that you remove all the outline(s) that were defining the baseline area measurement. This can happen if the outline(s) are all deleted, or the image(s) are all assigned to a different wound. In such circumstances, the new baseline will be chosen as follows:

1. the wound's earliest area measurement in the same visit will be chosen as the baseline (if one exists)
2. otherwise the wound's earliest area measurement will be chosen (if one exists)
3. otherwise the wound will have no baseline area measurement

If display of Area reduction is disabled from all areas, then **Change baseline** option will not be visible. For more information on display of measurements, see Customizing the displayed measurements.

Exporting Images from SilhouetteConnect

To export images from SilhouetteConnect:

1. Select a patient and go to the patient dashboard.
2. Select the visit you wish to export images from.
3. Click the thumbnail for the image you wish to export.
4. The appearance or otherwise of the annotations on the image (laser lines, outline, rulers and axes) are determined by the state of the
   - **Show/Hide Lasers** button
   - **Show/Hide Outline** button
   - **Show/Hide Ruler** button

- **Show/Hide Axes** button

In other words, if they appear on the main image in the **Patient Dashboard** they will appear in the exported file. Therefore click on these to set your desired configuration.

5. Click the **Export** button .
6. In the window that appears, choose the folder option and then click **Save**.

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Capturing Images

This section describes:

- The Mathematics of Silhouette's Measurements
- Lighting Requirements for Image Capture
- Holding a SilhouetteStar and Positioning the Lasers on the Wound
- Disconnecting a SilhouetteStar
- The Image Assignment Screen
- Tracing Wound Boundaries
- Tracing Tissue Outlines
- Taking a Multiple Image Measurement

The Mathematics of Silhouette's Measurements

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

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

SilhouetteStar connects to your computer using one of its USB ports. Images captured using SilhouetteStar are displayed in SilhouetteConnect, where you can outline the wound boundary and make surface area, depth, perimeter, and volume measurements.

- For concave wounds that have depth, the wound area is the area of an elastic sheet that could be pinned along and stretched across the boundary of the wound. Depth is the distance between the virtual elastic sheet and the wound bed, and volume is the volume enclosed by the sheet.
- For convex wounds and other pathologies (e.g. cellulitis) that rise above the wound outline as drawn in SilhouetteConnect, 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.

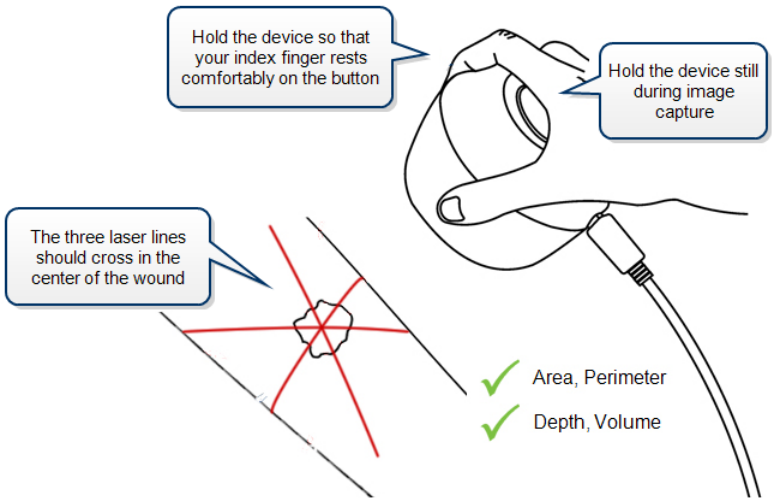
For further details on the measurement process used by SilhouetteStar, refer to the "How Silhouette Works" document available from ARANZ Medical support.

Lighting Requirements for Image Capture

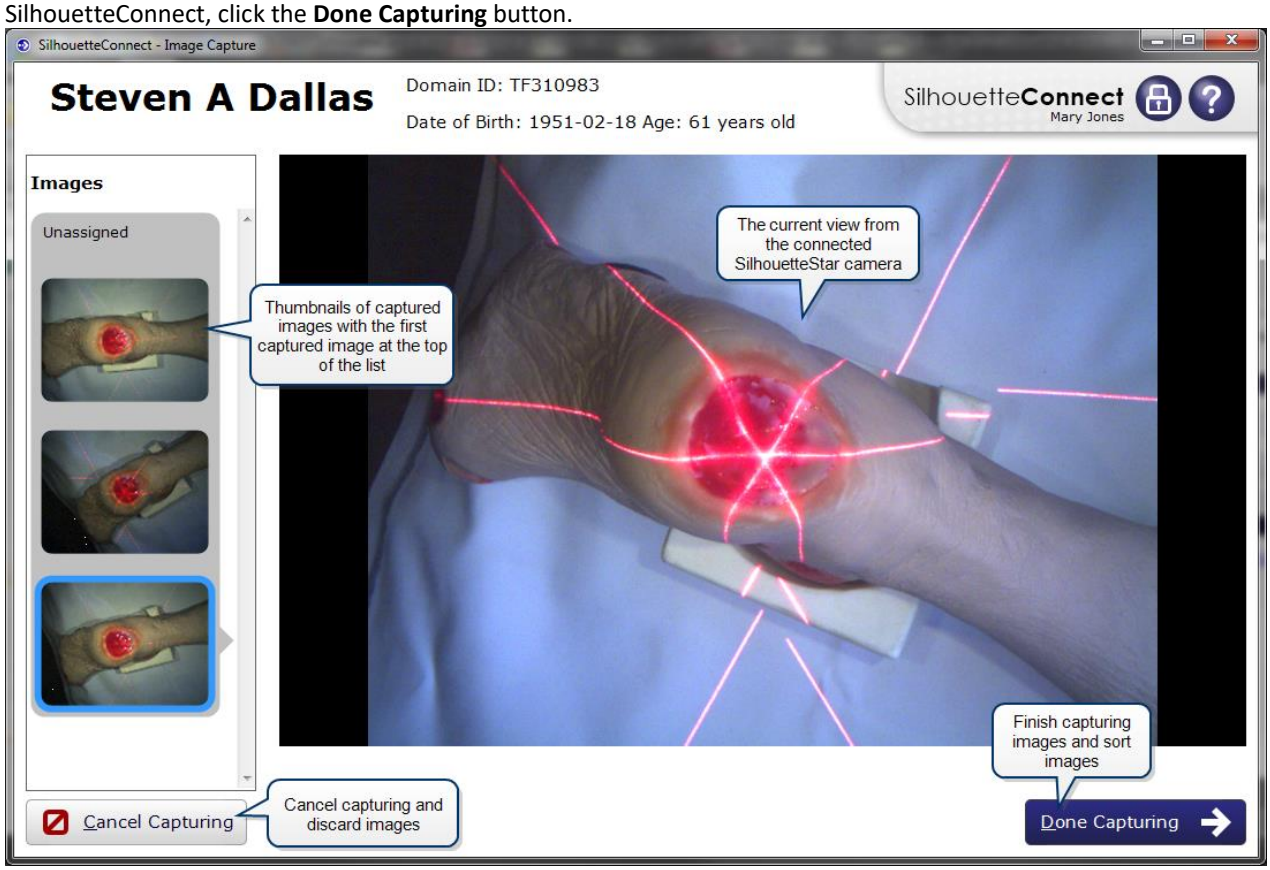
When capturing images with SilhouetteStar, it is important that lighting is at normal office or household lighting levels. SilhouetteStar should not be used in direct sunlight.
Once an image has been captured, you have the option of accepting or discarding the image if it looks overexposed, blotchy or if the laser detections look bad, see The Image Assignment Screen.
See Appendix C: Operating Conditions for further details regarding operating conditions for SilhouetteStar.

Holding a SilhouetteStar and Positioning the Lasers on the Wound

To capture images with SilhouetteStar, ensure that the device is connected to your computer via the USB cable provided. Then click the **Capture Images** button in the patient dashboard. The device's lasers and illumination LEDs will be activated and a preview image will appear on-screen.
Hold the camera so that your hand sits comfortably, with your index finger in reach of the button:



Position the camera facing the wound so that the laser lines cross on or near the center of 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 camera away from the wound, forming a small triangle with the laser lines, in order to capture a large wound in one image. If it is not possible to capture the entire wound in a single image, follow the instructions in Taking a Multiple Image Measurement.
Gently squeeze and release the button (or alternatively, tap or click the image on the screen) to capture the image, keeping the camera still until you hear the shutter sound from SilhouetteConnect or, if your computer's sound is off, until the image appears on-screen in SilhouetteConnect. Continue capturing as many images as required, then, in SilhouetteConnect, click the **Done Capturing** button.



If you cancel capturing, the images will be discarded and cannot be recovered.

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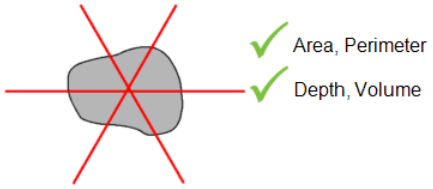
The set of measurements able to be made on a captured image depends on the positioning of the laser lines and the wound outline. Area and perimeter measures can be made under all circumstances. To determine depth and volume, the following conditions must be met:

- 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.

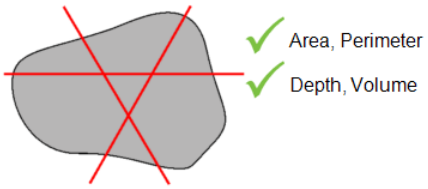
Preferred Laser Positioning

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.



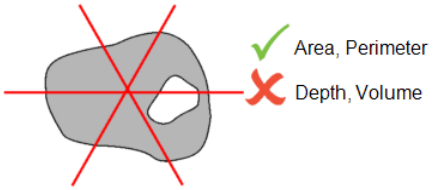
Acceptable Laser Positioning for Large Wounds

It has been necessary to pull SilhouetteStar away from the wound in order to see the entire wound in the field of view of the camera.



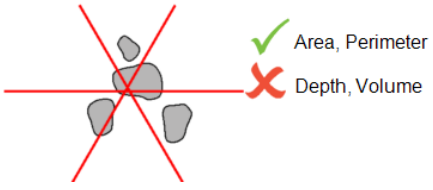
Preferred Laser Positioning for Wounds Containing Islands

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



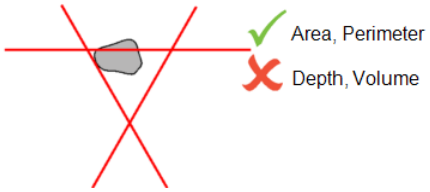
Preferred Laser Positioning for Wounds With Multiple Outlines

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



Poor Laser Positioning

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



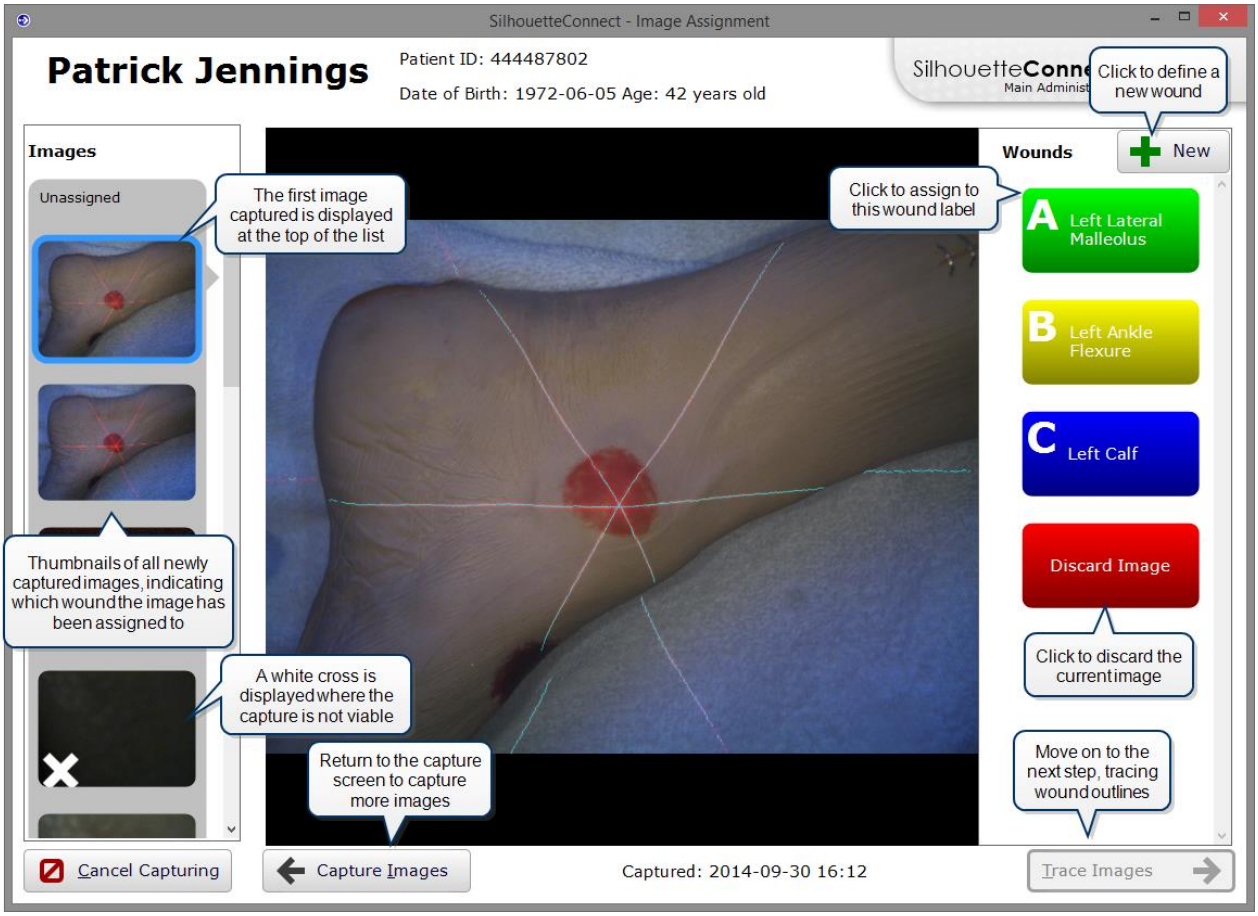
Disconnecting a SilhouetteStar

You may leave a SilhouetteStar connected to your computer, but if you do wish to remove the device, you can do this at any time that the lasers are not on.
If the lasers are on, it will mean that you are in the **Image Capture** screen, in which case before disconnecting the device from your computer, click the **Done Capturing** button to exit the **Image Capture** screen. The lasers will switch off, and it will be now safe to remove the USB cable from your SilhouetteStar and/or the computer's USB port.

The Image Assignment Screen

Assigning the Captured Images to a Wound

Once image capture is complete, the next step is to choose which images to keep and assign them to wounds. When this screen first opens, the wound images shown down the left-hand side have not yet been assigned to wounds:



If you need to define a new wound, click the **New** button and use the drop-down boxes to describe the wound's location. Defined wounds will appear on the right-hand side of the screen.
Review the quality of the image. The important things to check on the image are:

- The wound boundary is able to be seen. The wound tracing screen allows zoom to assist accurate tracing but if the image is under or over exposed the wound boundary can be hard to identify.
- The laser detections (little blue dots/blue line) appear where the lasers were on the skin. Poor or false laser detections in and around the wound can cause additional errors in the wound measurements, see Appendix A: Troubleshooting.

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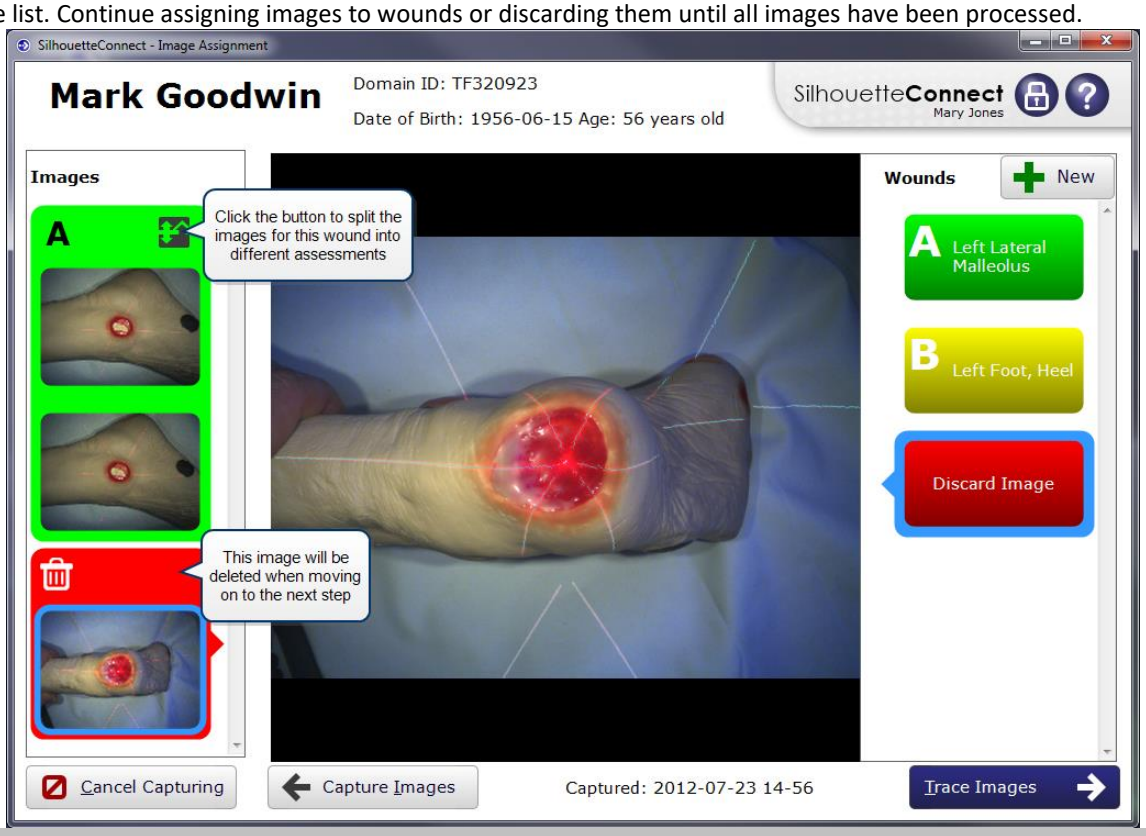
If you are not satisfied with the quality of the image, click the **Discard Image** button. When you exit this screen, any discarded images will be permanently deleted. Click the **Capture Images** button to return to the capture screen. Assign captured images to wounds by:

- Selecting the required image from the **Images** list on the left-hand side of the screen
- Assigning the image to a wound by selecting a wound label from the **Wounds** list on the right-hand side of the screen

As you assign images to wounds, the **Images** list will be updated, with the next unassigned image moved to the top of the list. Continue assigning images to wounds or discarding them until all images have been processed.

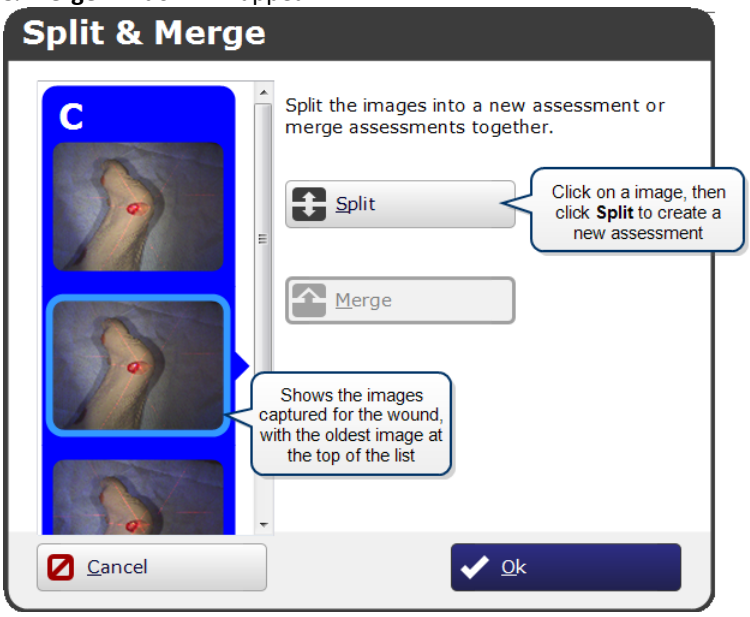


Alternative workflow

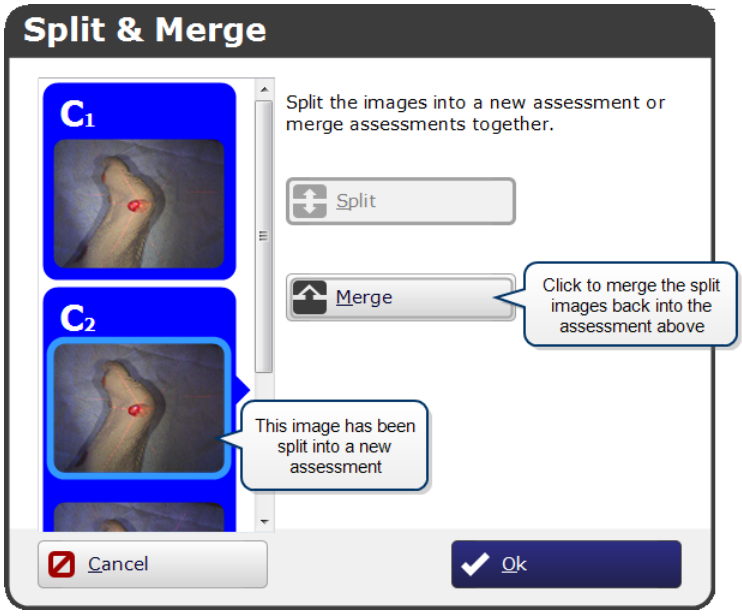
Your SilhouetteConnect may be configured to finish the image capture sequence after you have assigned the images. If this is the case, the **Trace Images** button above will be a **Done** button instead. Selecting **Done** will take you back to the **Patient Dashboard**. Once you are ready to trace the outlines, from the **Patient Dashboard** select the **Edit** button . This will take to you the Image Tracing screen.

Split and Merge: Creating More Than One Assessment for a Wound at the Same Visit

If you have a series of images of a wound you wish to split into different assessments, click on the button on the wound label. The **Split & Merge** window will appear:



This can be useful if you wish to capture images before and after debridement.
The oldest image appears at the top of the list, and additional assessments can be created from younger images.
Click on any image in the list other than the oldest image, then click **Split** to create a new assessment for that image and all newer images.



If you then wish to create a third assessment, click on one of the younger images in the second assessment and click **Split**.
Click **Merge** to merge the split images back together again. Click **OK** to return to the **Assign Images** screen.
Only once you have either assigned each image to a wound or marked it to be discarded can you click the **Trace Images** button to begin tracing the wound boundaries for each image.

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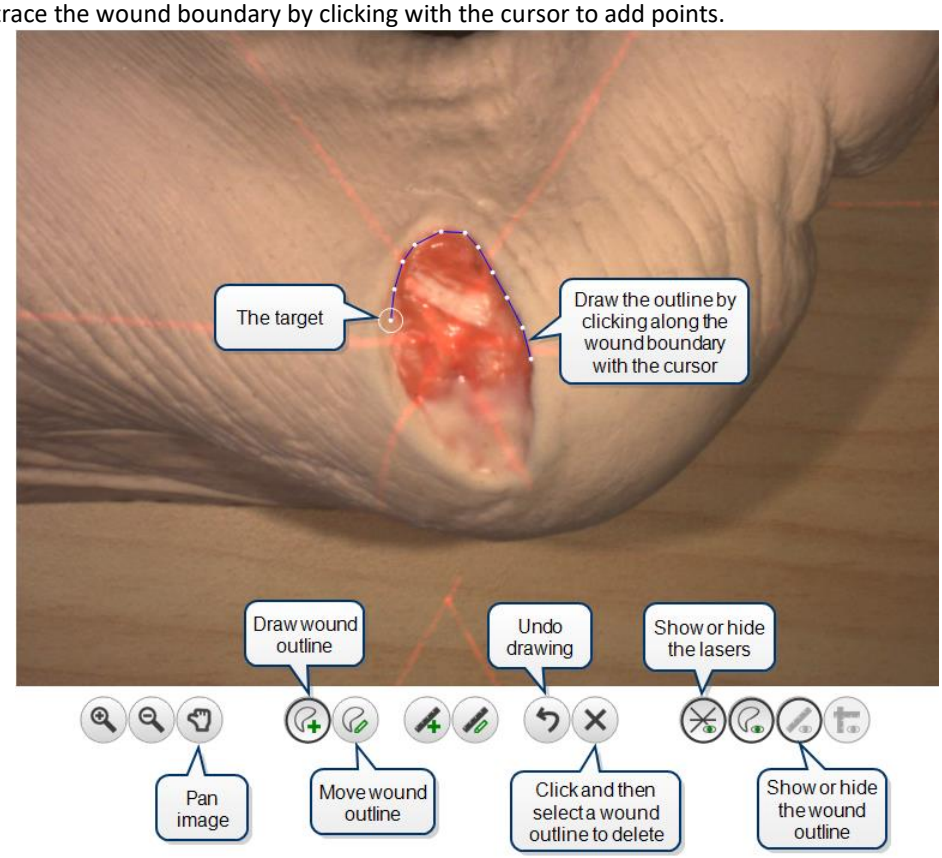
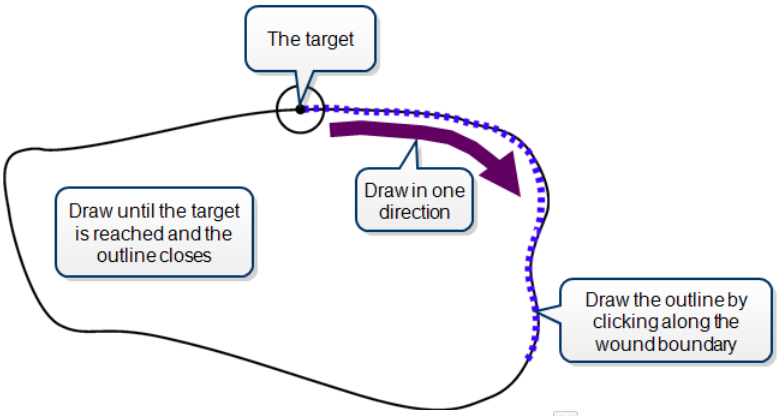
Tracing Wound Boundaries

Once the captured images have been assigned to wounds, the next step is to trace the wound boundaries. To do this, zoom into the image, if required, either by clicking the zoom image button or using the scroll wheel on your mouse. Then trace the wound boundary by clicking with the cursor to add points.

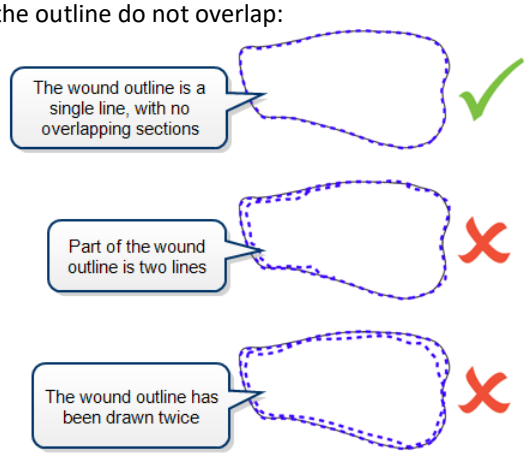


Draw in one direction until the circular target (the starting point) is reached:

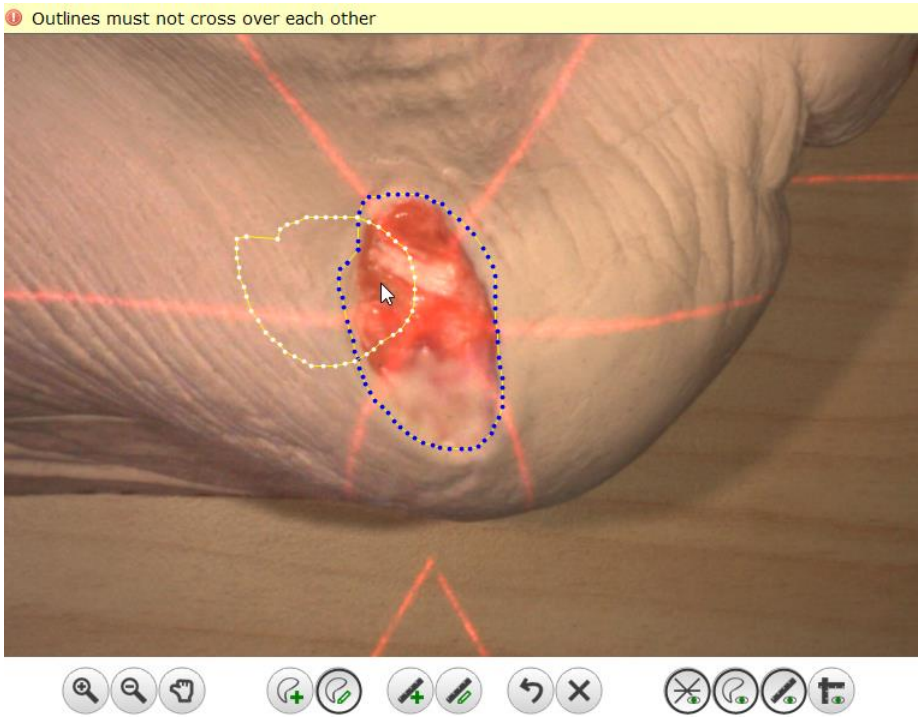


If you wish to delete the whole outline, click on the **Clear outline** button, then on the outline you wish to delete. To start drawing again, click on the **Draw outline** button.

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



SilhouetteConnect will advise you if there is a problem with the tracing of a wound boundary with a message at the top of the image window:



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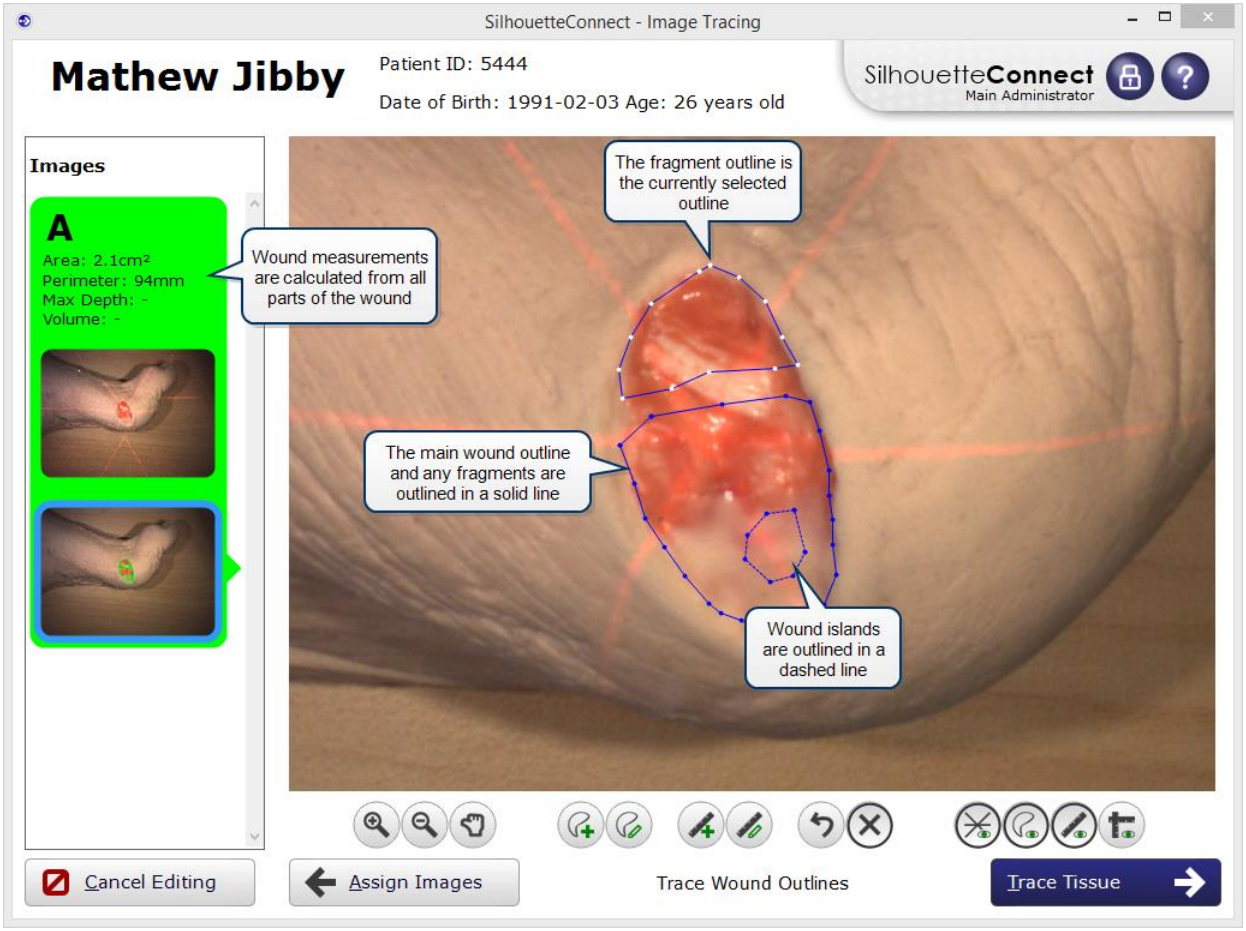
Once you have reached the target, the outline will close and the wound's area and perimeter will be displayed:

Maximum depth and volume may also be displayed for some wounds.

You can also draw outlines of any wound fragments or islands. To do this, click on the **Draw outline** button and trace the island or fragment, ensuring the outline is closed. SilhouetteConnect automatically regards outlines inside the main wound outline as islands and those outside the main outline as fragments:



When you outline islands and/or fragments for a wound, maximum depth and volume will not be displayed for that wound.

If the image has any **tissue outlines** defined (for example because the image is being edited again after being traced first), then those outlines will appear in green, and will not be editable on this screen.

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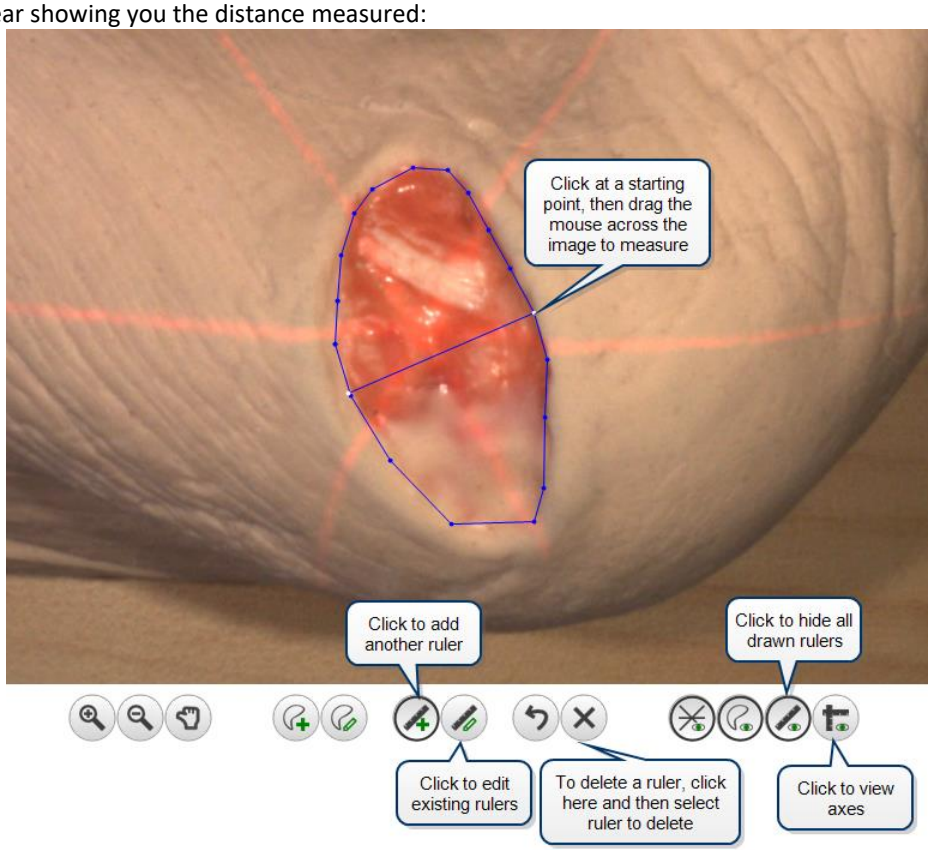
You can also draw rulers on the image to measure different parts of the wound. To do this, click on the **Draw rulers** button and then click and drag across the distance you wish to measure. When you release the mouse button, a menu will appear showing you the distance measured:

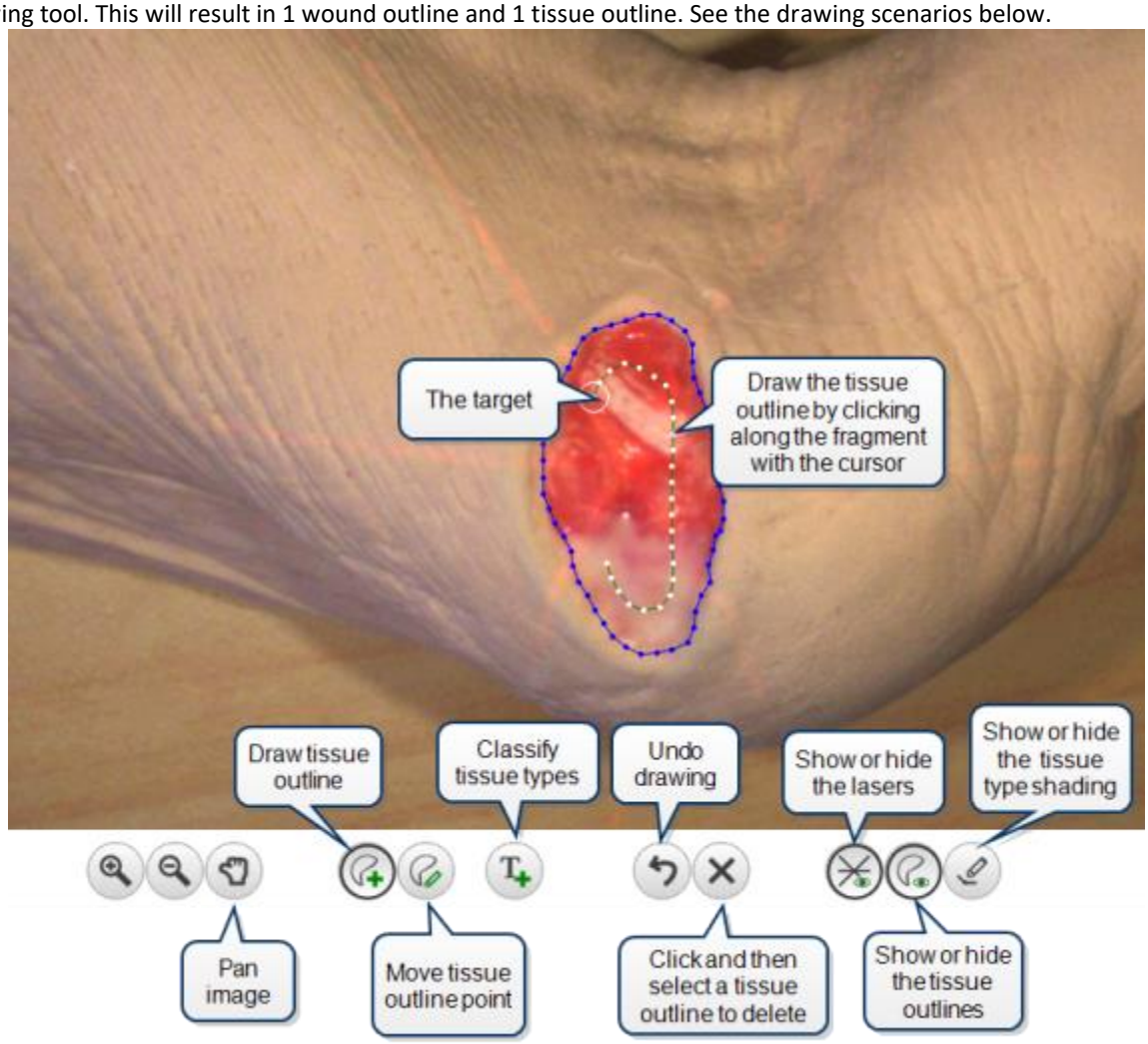


You can draw additional rulers, if required. If you wish to edit a ruler, click on the **Edit rulers** button, then click on one of the end points of a ruler and drag to move it.
Axes can be drawn on the wound. Depending on your settings, they may be drawn automatically, or you may have to click the **View axes** button to show the axes.
Once you have finished outlining and measuring all the wounds, click the **Done**/**Trace Tissue** button (if Tissue Type Classification is enabled, it will be *Trace Tissue*. Otherwise, it will be *Done*). If you do not trace an image, it will be regarded 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.
If you decide to discard an image, click the **Assign Images** button to return to the screen where this can be done.

Tracing Tissue Outlines

Once the wound boundaries have been traced, and the tissue types have been enabled, the next step is to trace the tissue outlines. To do this, zoom into the image, if required, either by clicking the zoom image button or using the scroll wheel on your mouse. Then trace the tissue outlines by clicking with the cursor to add points.

The wound outlines (as defined on the Image Tracing page) will show as blue, whereas the tissue outlines will show as green. The wound outlines cannot be edited by either deletion or point moving, but can be bisected using the drawing tool. This will result in 1 wound outline and 1 tissue outline. See the drawing scenarios below.



NOTE: Incomplete tissue outlines cannot be removed with the **Delete** button. Use the **Undo** button instead (or close the outline, after which it can be deleted).
NOTE: **Undo** will only work on drawing actions. Assigning tissue types to outlines cannot be undone.

SilhouetteConnect will advise you if there is a problem with the tracing of a tissue outline with a message at the top of the image window:

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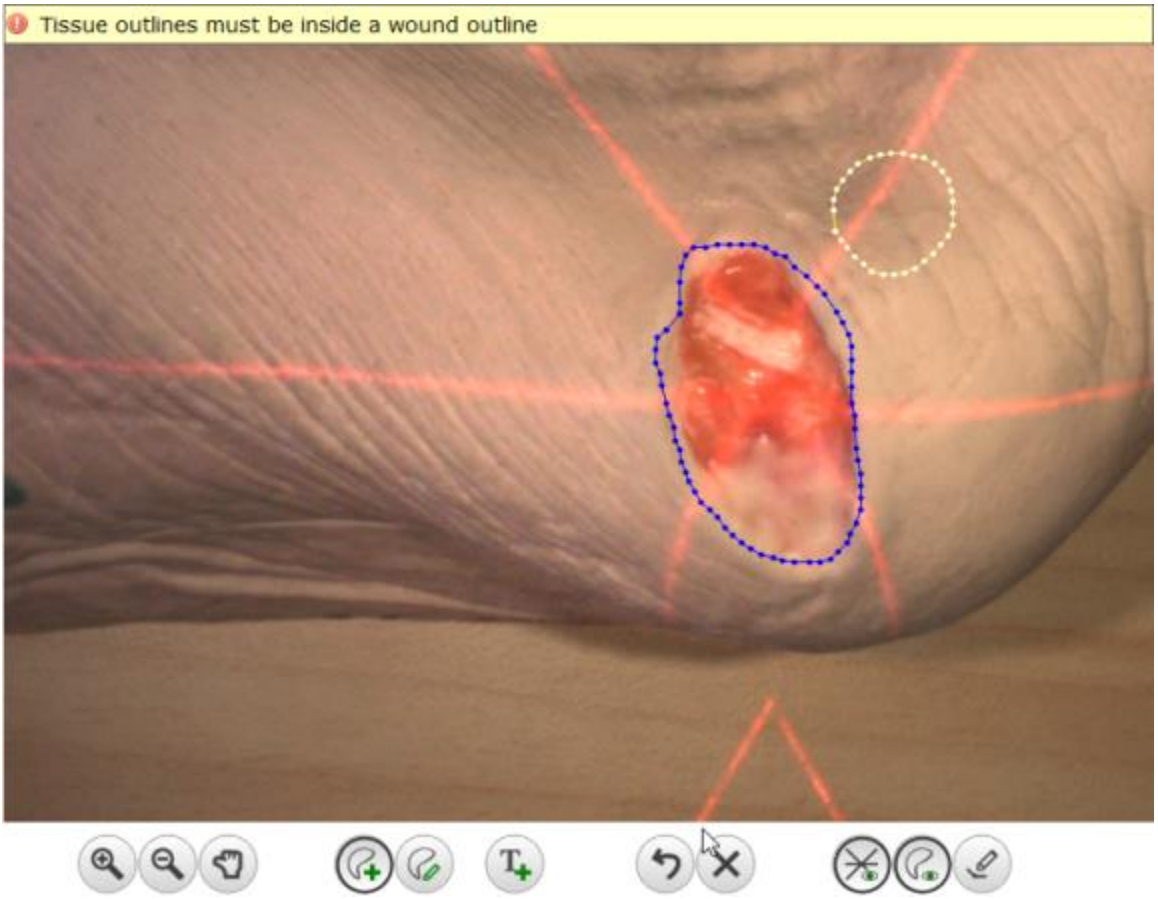
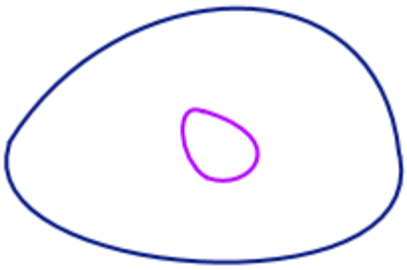


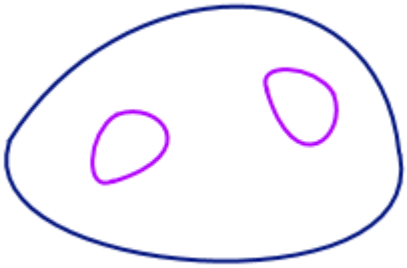
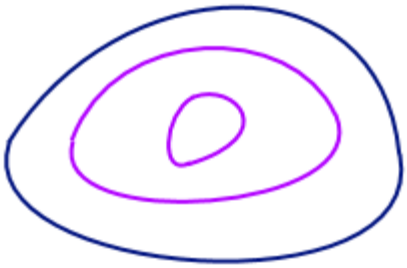
In addition to drawing the tissue type outline, it is also possible to cut existing wound/tissue outlines. Do this by selecting the **Draw Tissue Outline** button and dividing 1 outline at a time.

Tips for drawing successful tissue outlines:

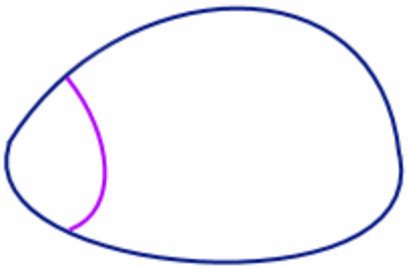
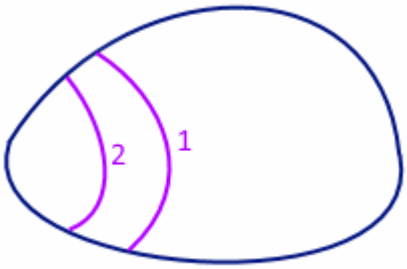
- Having many tissue outlines can start to impact performance. Try to avoid this by clicking around the fragment, rather than dragging the mouse. This will result in the outline having less points
- Start by dividing the main into large outlines, and then add the smaller details. See scenario 5 below
- Sometimes, dividing the outlines will not work. Undo and try again

Drawing outlines as islands inside the wound outline

 **1.**	1. Create wound outline 2. Create tissue outline inside wound outline

 **2.**	1. Create wound outline 2. Create multiple tissue outlines inside wound outline
 **3.**	1. Create wound outline 2. Create nested tissue outlines inside wound outline

Drawing outlines by dividing either the main outline or other tissue outlines

 **4.**	1. Create wound outline 2. Draw arc that crosses the wound outline to create a tissue outline
 **5.**	1. Create wound outline 2. Draw arc that crosses the wound outline to create the tissue outline 3. Draw arc that crosses the wound outline, which is inside the tissue outline **NOTE**: Once a wound outline has been divided, only the resulting tissue outline can be divided again, NOT the wound outline again.

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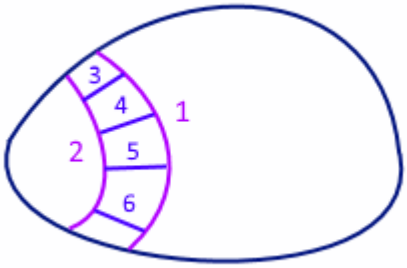
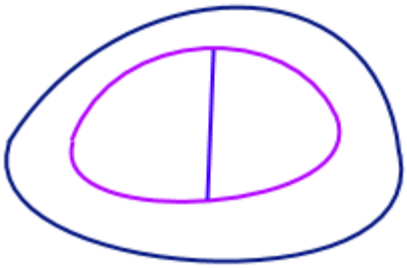
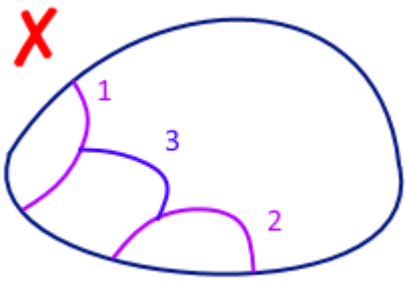
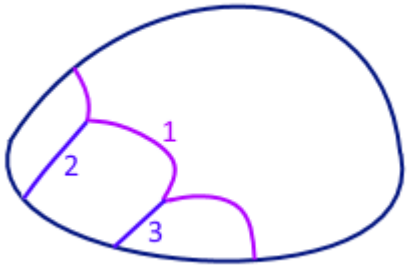
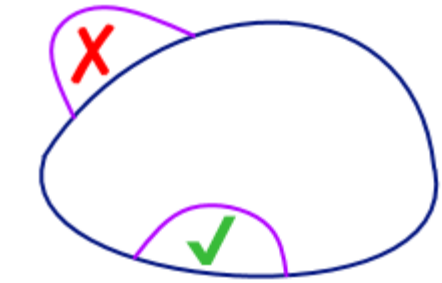
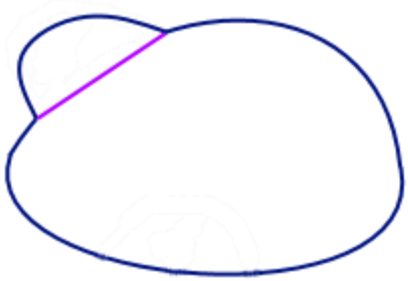
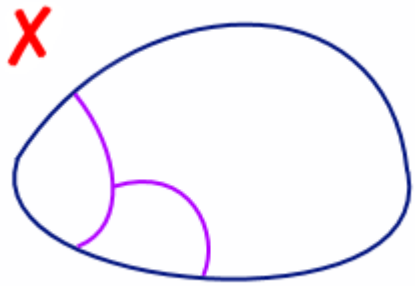
 **6.**	1. Create wound outline 2. Draw arc that crosses the wound outline to create the tissue outline 3. Draw arc that crosses the wound outline, which is inside the tissue outline 4. Draw lines between the first and the second tissue outline
 **7.**	1. Create wound outline 2. Create tissue outline inside wound outline 3. Draw line to divide tissue outline into 2 tissue outlines
 8.	1. Create wound outline 2. Create tissue outline inside wound outline 3. Draw outlines that cross the new outline on both the outside and the inside

There are also scenarios that aren't currently supported, namely the 'bridged' outline and drawing tissue type outlines that increase the wound size

 **9.**	**Invalid scenario** 1. Create wound outline 2. Draw arc that crosses the wound outline to create the tissue outline 3. Draw another arc in the same way that does not touch the first outline 4. Draw a 'bridge' between the 2 outlines **Valid alternative** 1. Create wound outline

	2. Draw curved arc that follows the outside shape required 3. Draw arcs from the outline to the wound outline to split the outline into sections
10.  	**Invalid scenario** 1. Create wound outline 2. Draw arc that crosses the wound outline to create the tissue outline (still valid) 3. Draw arc that crosses the wound outline on the outside, which is invalid **Valid alternative** 1. Create wound outline that incorporates the outside outline 2. Draw arc that bisects the wound outline to denote the tissue outline
11. 	**Invalid scenario** 1. Create wound outline 2. Draw arc that crosses the wound outline to create the tissue outline 3. Draw arc that crosses the tissue outline on one side, and the wound outline on the other **Valid alternative** 1. Create wound outline 2. Draw curved arc that follows the outside shape required 3. Draw arc from the outline to the wound outline to split the outline into sections

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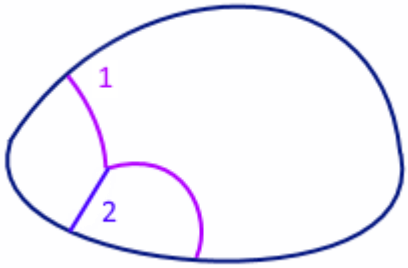
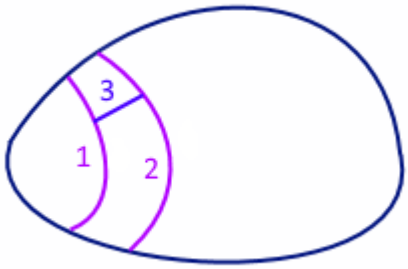
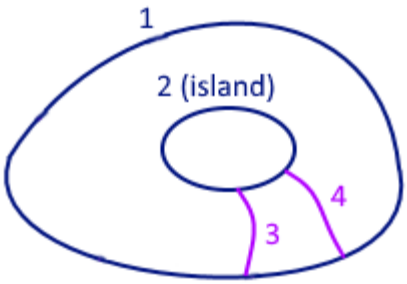
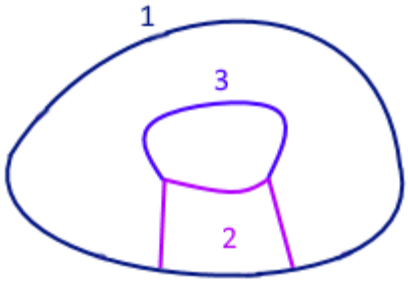
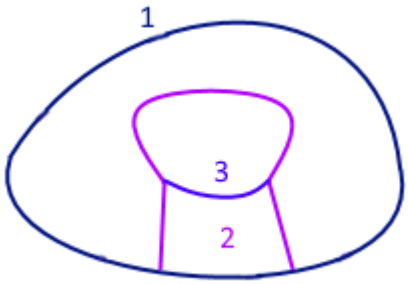
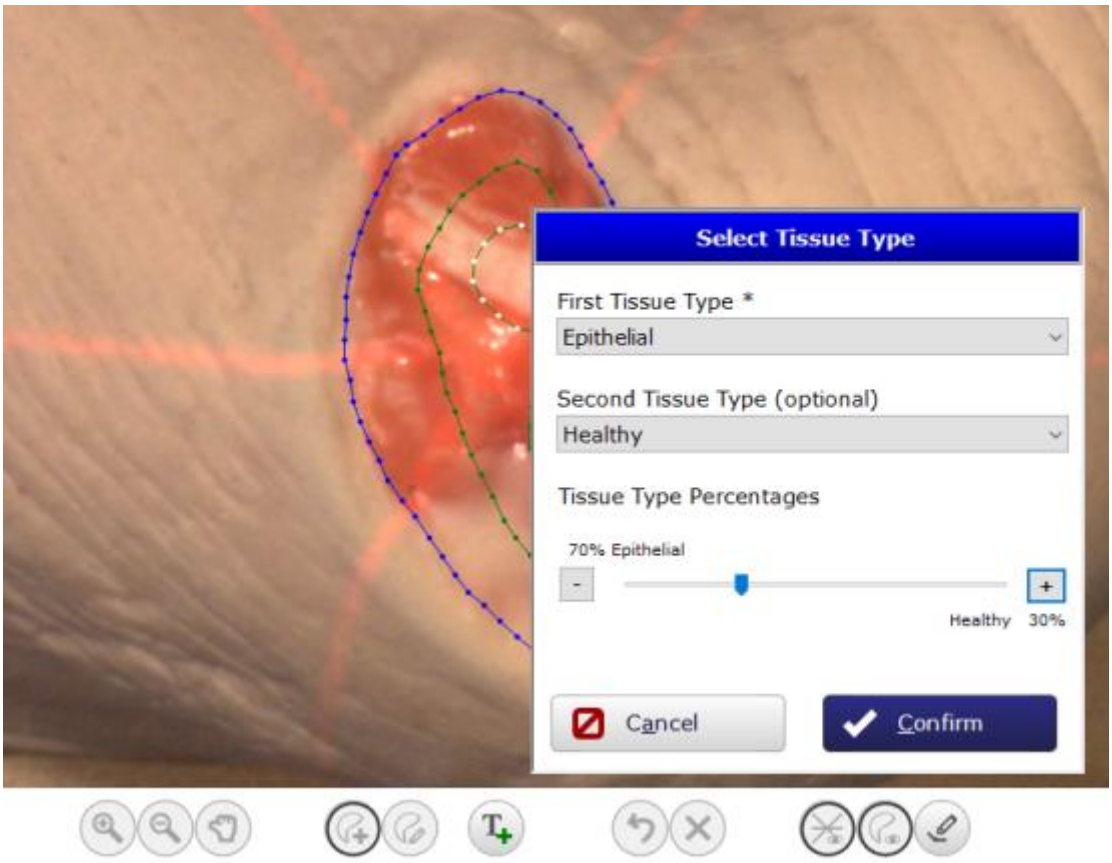
	
12. 	**Invalid scenario** 1. Create wound outline 2. Draw arc that crosses the wound outline to create the tissue outline 3. Draw arc that crosses the wound outline on the outside of the created tissue outline 4. Draw a line between the 2 tissue outlines **Valid alternative** See scenario 5 above
 **13.** 	**Invalid scenario** 1. Create wound outline 2. Create island inside wound outline (on the Trace Wound screen) 3. Draw arcs that cross from the wound outline to the island **Valid alternative** 1. Create wound outline 2. Create tissue outline that follows the bottom part of the outline 3. Create second tissue outline that crosses the first outline at the bottom, and follows the rest of the outline at the top **Valid alternative** 1. Create wound outline

	2. Create tissue outline that follows the entire outline 3. Draw a dividing line that splits the tissue outline into 2 segments

If there is a default tissue type defined, then that type will be assigned to the outline as soon as it is closed. If there is no default type, or you want to assign a different type, you can either:

- right-click inside the outline
- click the **Classify Tissue Types** button and select the outline with a left-click

This will cause the 'Select Tissue Type' window to pop-up, in which you can select the first and (optional) second tissue type for the outline, and define the percentages of each (if the second type has been defined). When this window is open, you will not be able to add/edit any tissue outlines, but can turn the shading on and off.



All the tissue outlines need to have a type assigned before the **Done** button can be clicked. For a visual overview of which outlines have a tissue type assigned, click the **Tissue Type Shading** button This will add a transparent overlay to the outlines , based on their corresponding tissue type color. For any outline that has two types defined, the main type's color will be used.

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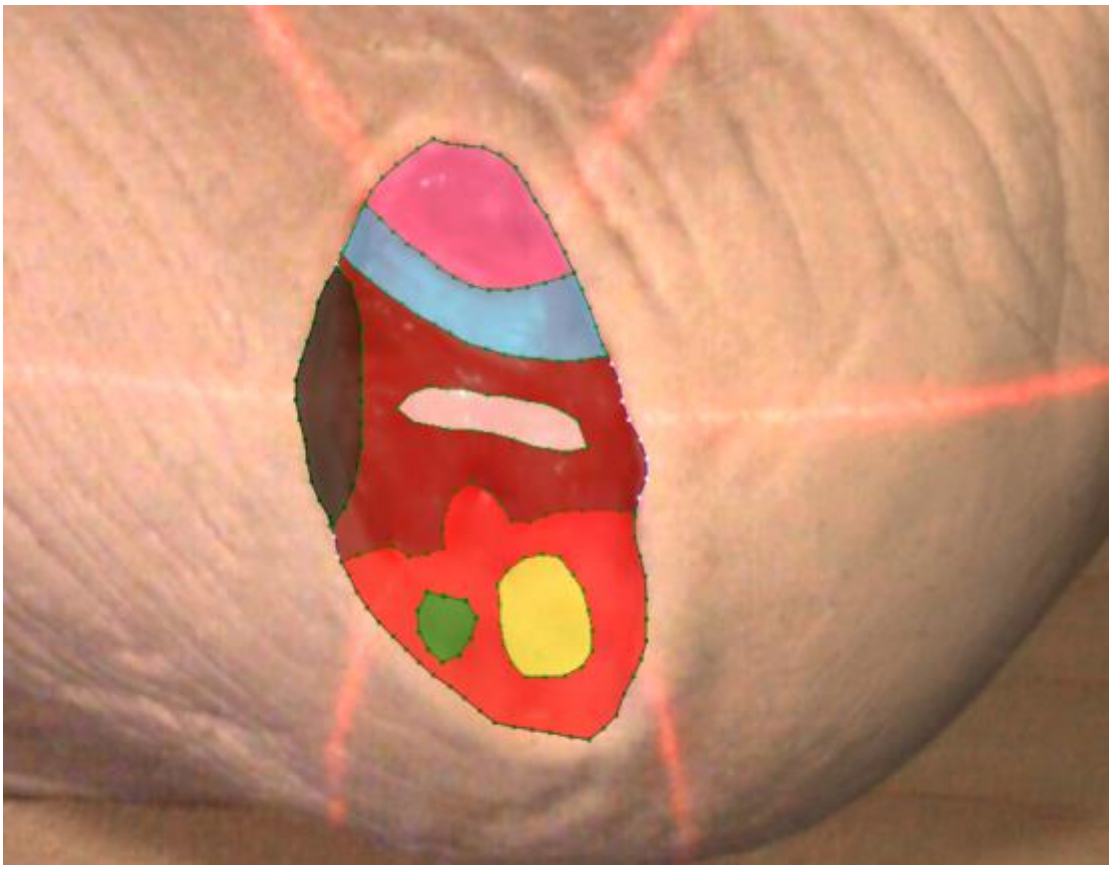
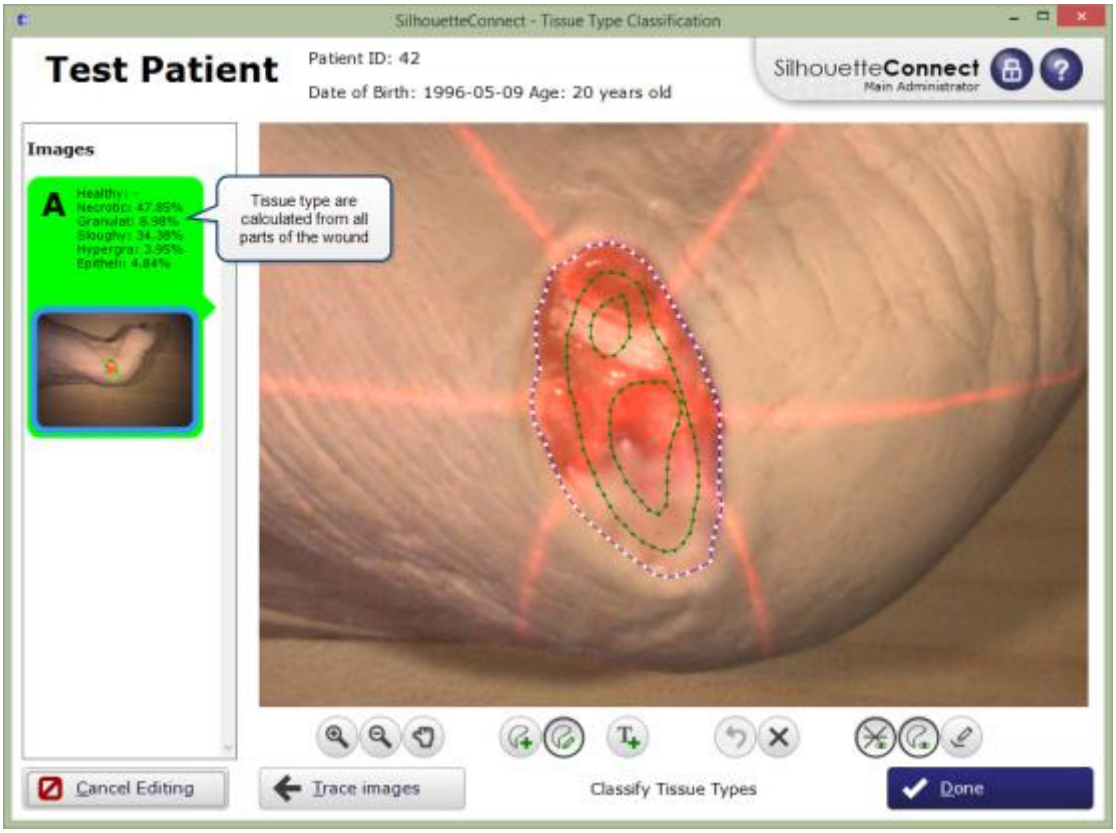


The percentages for the tissue types will always be displayed on the left-hand side with the image, unless the outlines are in an invalid state (not closed, crossing over each other, etc.)



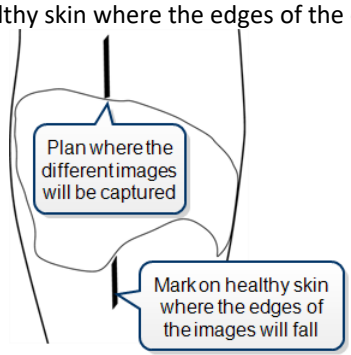
If the selected image has no wound outlines, SilhouetteConnect will show an information message at the top of the screen, and all the buttons related to tracing the tissue outlines will be disabled.

Once you have finished outlining and assigning all the tissue types, click the **Done** button.

Taking a Multiple Image Measurement

If it proves difficult to capture a wound in one image, you can capture a series of images and individually outline the separate segments. SilhouetteConnect will then automatically calculate wound area for the different segments of the wound. This is useful for large wounds, or 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.
Follow these steps:

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



3. Capture an image of each segment of the wound and the surgical marker lines. Make sure the laser crossing point is located within the wound segment.
4. Assign each image to the same wound.

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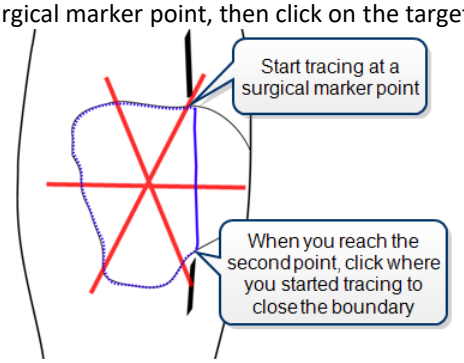
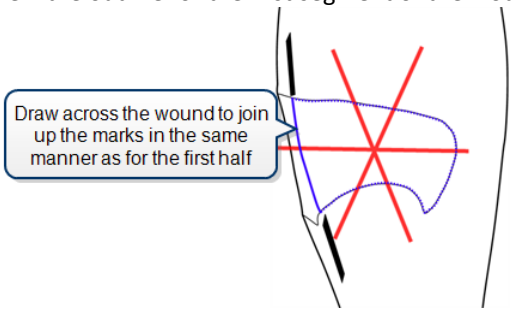
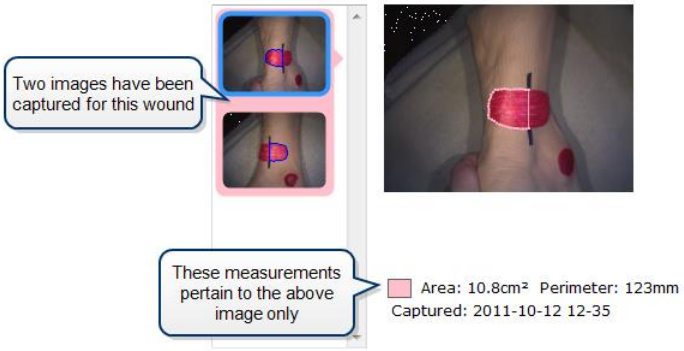
5. For the first image, start at a surgical marker point and trace the wound boundary for the first segment. Stop when you reach the other surgical marker point, then click on the target to close the wound boundary.



For the next image, trace the second segment of the wound in the same manner as the first. Try to draw the outline as close as possible to where you drew the outline for the first segment of the wound.



When wound area is calculated, the measurements for the different parts of the wound will be combined to give overall measurements for the wound:



Maximum depth and volume will not be calculated.

SilhouetteConnect Administration

This section describes how to

- Configure SilhouetteConnect via the Administration Screen
- Backing up your data

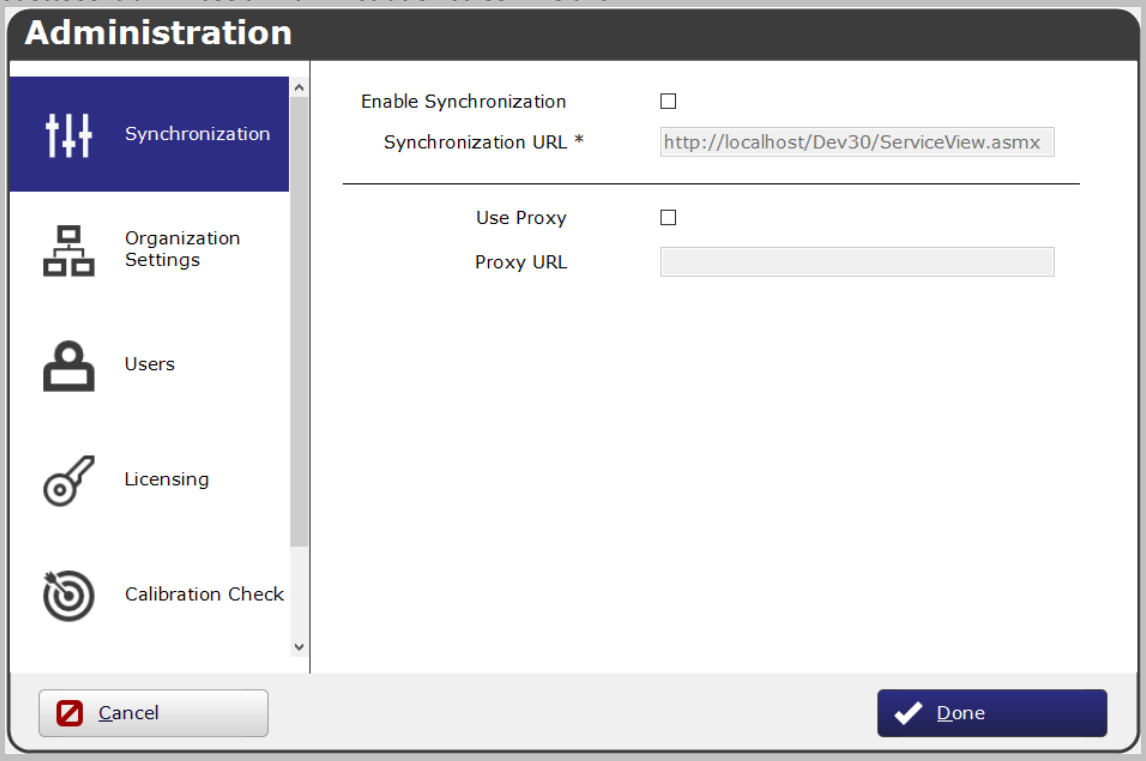
The Administration Screen

To open the **Administration** screen, click the **Administration** button in the **Patient Selection** screen:

Alternative Implementations

The appearance of the **Administration** screen will depend on user permissions and whether your SilhouetteConnect is synchronizing with SilhouetteCentral.

For example, an *administrative* user for a SilhouetteConnect installation that is *not* synchronizing with SilhouetteCentral will see an **Administration** screen like this:



A *non*-administrative user with a SilhouetteConnect installation that *is* synchronizing with SilhouetteCentral will see an **Administration** screen like this:

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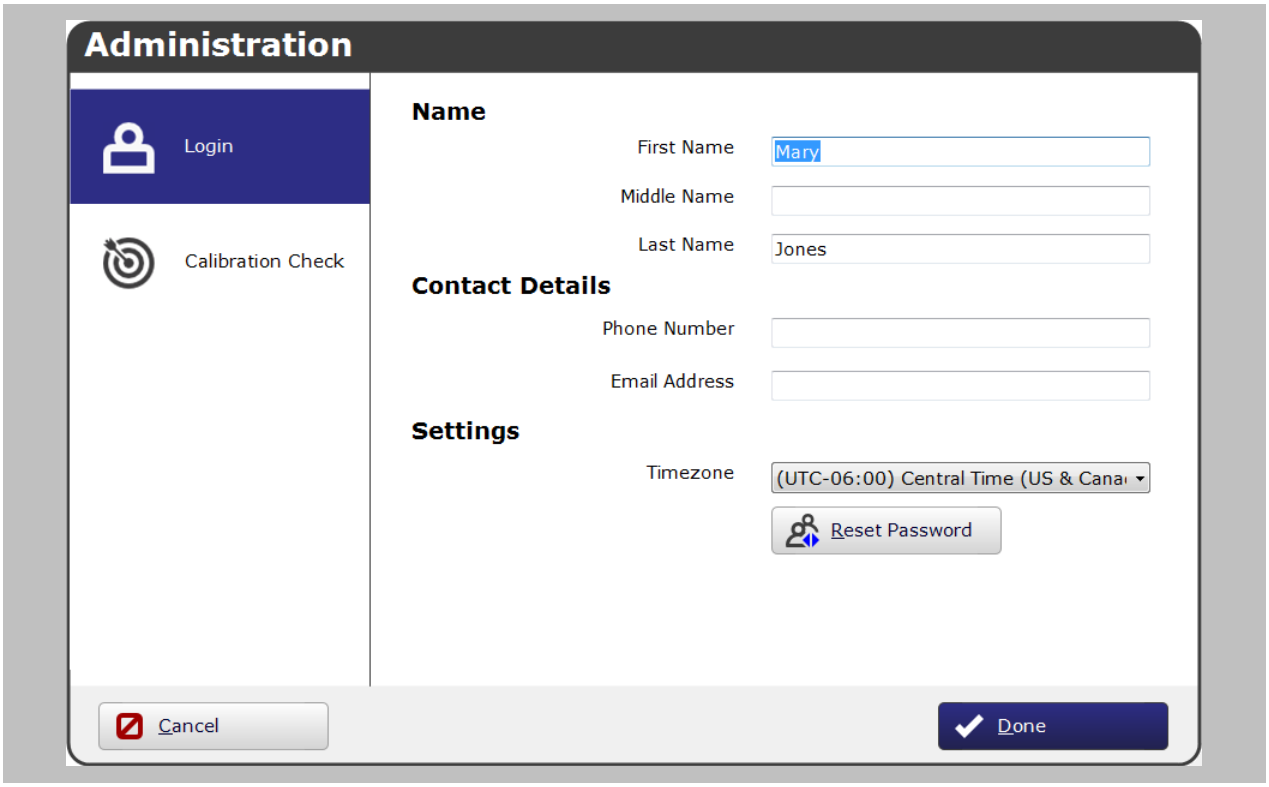

The functions of the various tabs that can appear in the **Administration** screen are explained below.

Login

In the **Login** tab, you can update your personal details and change your password.
Administrators of SilhouetteConnect will not see the **Login** tab. Administrators can update personal details in the Users tab.
You will be prompted to change your password on the first login and if your password expires in the future.

Synchronization

The connection to SilhouetteCentral is controlled in the **Synchronization** tab. Here you can change settings related to how SilhouetteConnect communicates with SilhouetteCentral.

- Check the box to enable synchronization.
- Enter the URL for communicating with SilhouetteCentral.
- Tick **Use Proxy** and enter the URL for your organization's proxy server, if this is necessary to access the SilhouetteCentral server.

When configuring the synchronization settings, please note the following:

- If you enter the URL for SilhouetteCentral, SilhouetteConnect will test the connection when you click **Done**. If the connection test fails, a warning box will appear. If you continue to have difficulties, check the Troubleshooting section.
- If you are changing the SilhouetteCentral that you synchronize with to a different SilhouetteCentral these steps should be followed:
  - Perform a synchronization to the existing SilhouetteCentral.
  - Change the URL to the new SilhouetteCentral.
  - A prompt will remind you that the current database will be deleted. Proceed if you have synced this data already to the original SilhouetteCentral. If you have not synced then cancel and do the first step above. If you do not the data will be lost. Contact Customer Support if you require assistance with this step.
  - You will then be returned to the logon screen where you will be prompted to synchronize with the new SilhouetteCentral.

Organization Settings

In the **Organization Settings** tab, you can change settings related to SilhouetteConnect display formats and features. This tab will show where SilhouetteConnect is being used in a standalone situation. If you are connecting to SilhouetteCentral, Organization Settings will not show in SilhouetteConnect. Contact your SilhouetteCentral administrator for more information.

Organization

You can change the **Name** of your organization. This is displayed on the Wound Assessment Report footer.
You can change the **Patient ID** label. This is useful where you use a different terminology for patient identifying codes, for example Subject ID, Visit Number, Domain ID, MRN, NHS Number.

Display Formats

The **Display Formats** settings relate to how SilhouetteConnect displays filenames and measurement units. Select the formats used by your organization. The settings related to Tissue Types will be hidden if the Tissue Types are disabled.

Parameters

The **Visit Length** defines the length of time, in hours, after which a new visit will automatically be created without requiring the user to select the new visit button on the patient dashboard. The default visit length is 12 hours and 0 minutes.
Prior to the **Visit Length** duration occurring the user would need to manually select the **Add New Visit** button to place subsequent assessments into a new visit.

Axis Method

The axes are two perpendicular rulers automatically drawn on each wound outline drawn on an image. The **Axis Method** setting defines the technique used to orient the axes. The options available are:

- **Longest Axis**. The axes are oriented such that one of the pair of rulers transects the wound at the longest point across the wound. The second ruler is drawn perpendicular to the first, where the greatest width is found.
- **Smallest Rectangle**. The orientation of the smallest rectangle that can completely enclose a wound is calculated, and the axes are oriented across the middle of the rectangle, perpendicular to the rectangle's edges.
- **North South East West (East/West is length)**. A rectangle is drawn completely enclosing the wound, with the edges of the rectangle being vertical and horizontal as seen on the wound image. The axes are oriented across the middle of the rectangle, perpendicular to the rectangle's edges and constrained to fit within the wound outline. The measurement from east to west is considered as length of the axis and the measurement from north to south is considered its width.
- **North South East West (North/South is length)**. A rectangle is drawn completely enclosing the wound, with the edges of the rectangle being vertical and horizontal as seen on the wound image. The axes are oriented across the middle of the rectangle, perpendicular to the rectangle's edges and constrained to fit within the wound outline. The measurement from north to south is considered as length of the axis and the measurement from east to west is considered its width.

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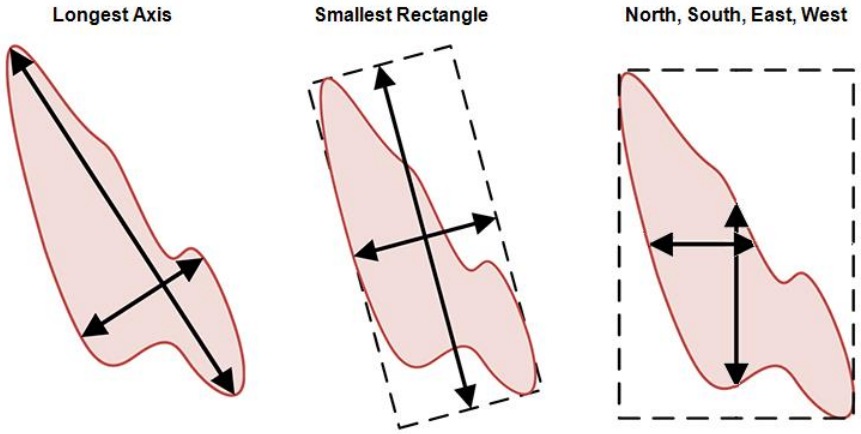
These different methods are illustrated for a wound outline as follows:



The **Application Lock Time** defines the length of time, in minutes, after which SilhouetteConnect will lock following a period of inactivity. You will then be required to log on again. The default lock time is 10 minutes.

Database Backups

The **Database Backups** setting determines how often SilhouetteConnect creates a backup of the SilhouetteConnect database on your computer:

- When **Never create** is selected, no backups are made.
- When **Create on start up** is selected, a backup is made whenever SilhouetteConnect is started.
- When **Create daily** is selected, a backup is made when SilhouetteConnect is started and the software detects that a backup has not yet been made for that day.
- When **Create weekly** is selected, a backup is made when SilhouetteConnect is started and the software detects that a backup has not been made in the last seven days.

The default is **Create daily**.

Power

The **Power Frequency** setting determines the power frequency used for image capture. If horizontal banding is observed on captured images, change this setting to suit regional lighting conditions. There are three options:

- When **Auto** is selected, the power frequency is determined by your PC's locale settings.
- The **50Hz** setting is for capturing images under 50Hz lighting.
- The **60Hz** setting is for capturing images under 60Hz lighting (USA and Canada).

Users

In the **Users** tab, administrators can add users to the system and change user settings. User passwords can be reset from the **Edit User** screen.

Licensing

In the **Licensing** tab, you can review your current SilhouetteConnect license and the optional features you have purchased. To update your license click the **Relicense** button.

Calibration Check

It is recommended that you periodically perform a calibration check of your SilhouetteStar device. You can do this in the **Calibration Check** tab. The **Calibration Check** tab will show the results for the SilhouetteStar that is currently connected.

To carry out a calibration check, click the **Test Calibration** button and capture an image of the Silhouette test target. This does not perform a device calibration, but checks if the device is still within calibration.

If the calibration check fails, try the sequence again. If the test fails a second time, contact Customer Support using the details provided in Appendix B: Getting Support.

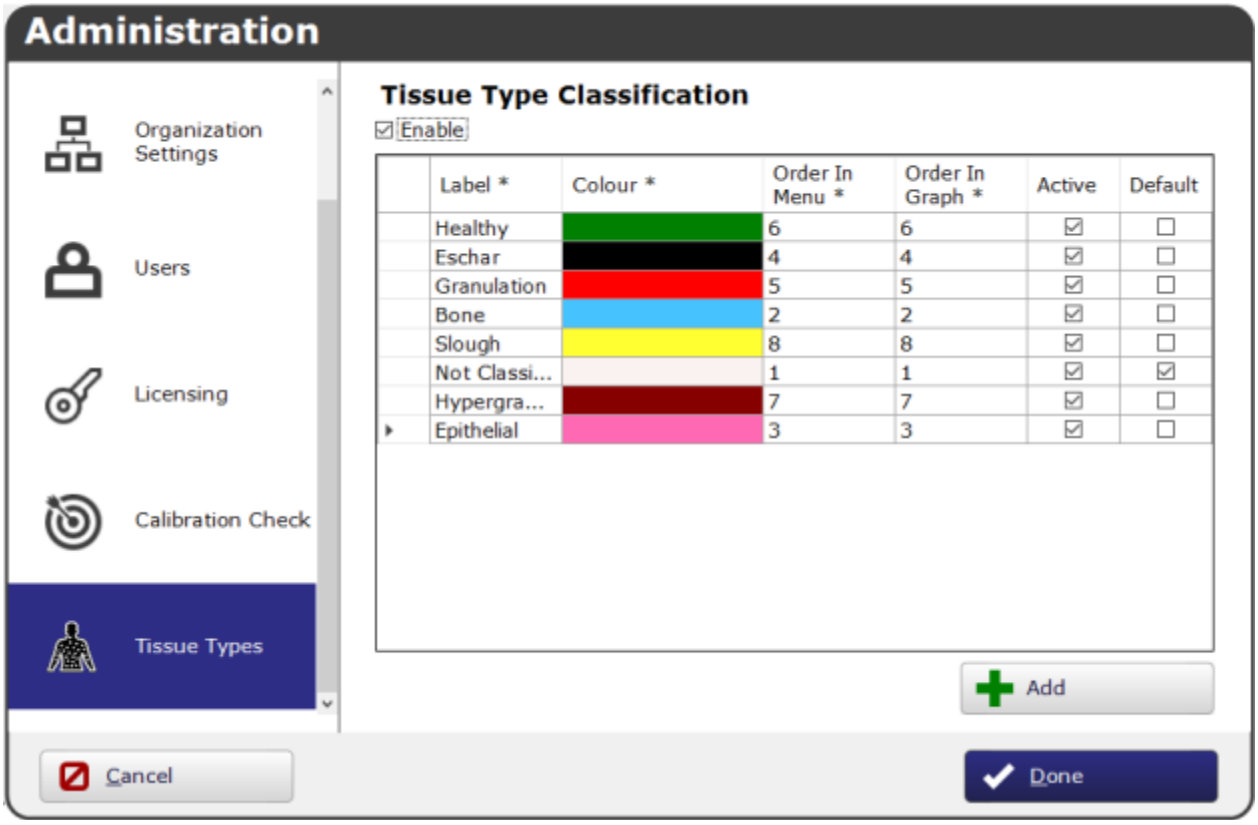
If the test target card that was provided with the device has been mislaid, contact Customer Support.
An **Export** button is provided so a record of calibration checks can be provided to auditors, where required.

Tissue Type Classification

In the **Tissue Types** tab, you can enable/disable the Tissue Type Classification setting, and edit the various types related to SilhouetteConnect. By default the Tissue Type Classification will be **disabled**. The 8 initial types are: *Not Classified* (default), *Bone*, *Epithelial*, *Eschar*, *Granulation*, *Healthy*, *Hypergranulation*, and *Slough*.

Here you can edit the

- Name (no duplicate names are allowed)
- Colour (no duplicate colours are allowed)
- Menu order - this defines the order that the tissue types are displayed in on the Trace Tissue screen, for both the displayed percentages, as the Tissue Type Selector control
- Graph order - this defines the order that the tissue types are displayed on the Tissue Types graph, on the Tissue Type Percentages Overview, and underneath the image on the Patient Dashboard
- Whether the tissue type is active (inactive types aren't shown in SilhouetteConnect). Only 10 active types are allowed, and there needs to be at least 1 active for the tissue types to work correctly. **NOTE**: deleting tissue types is not supported. Inactive types will still be shown for any assessments that they were included in
- The default type. Any tissue outlines will become this type when they are traced (only 1 default type is allowed)



Backing Up Patient Information

It is recommended that you regularly back up patient information stored in the SilhouetteConnect database. There are multiple strategies for achieving this:

If Backing Up Without SilhouetteCentral

If you do not have SilhouetteCentral, you can back up the patient database by copying SilhouetteConnect data from your computer onto another storage medium. Before copying data, however, make sure that copying data complies with your organization's patient data security policy.

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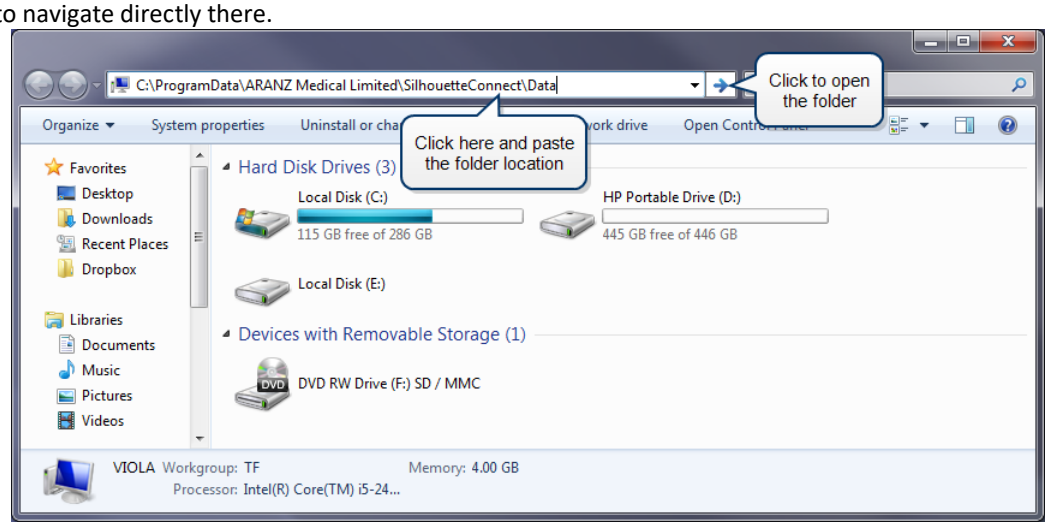
The patient database files are stored in a folder called C:\ProgramData\ARANZ Medical Limited\SilhouetteConnect\Data.
If you cannot find the folder, it may be a hidden folder. You can copy the folder location above and paste it into File Explorer to navigate directly there.



Ensure SilhouetteConnect is closed, then simply copy the Data folder to another folder on your computer or onto another storage medium. Copying the Data folder also backs up all reports, images, and backups stored on your computer.

> ⚠ Do not move or delete the Data folder, this is required for SilhouetteConnect to operate.

If Synchronizing with SilhouetteCentral

If SilhouetteConnect is set up to synchronize with SilhouetteCentral, the patient database will be backed up each time you synchronize.
In the **Patient Selection** screen, you can start the synchronization process in two ways:

- To start synchronizing immediately, click the **Sync** button.
- To select patients to add to or remove from SilhouetteConnect, click the **Manage Patients** button.

See Synchronizing with SilhouetteCentral for more information.

Care of SilhouetteStar

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

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

Cleaning SilhouetteStar

The exterior of SilhouetteStar can be cleaned with a range of common cleaning agents. All cleaning should be performed with the device disconnected from the host computer. The use of pre-impregnated cleaning wipes is recommended since these will 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 will not affect SilhouetteStar operation and is not covered by warranty.

When cleaning SilhouetteStar, ensure excess fluid from wipes does not enter device openings.

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). Avoid long term exposure.
- Bleach based wipes, high effective concentration (1:10). Avoid long term exposure.

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.

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Appendices

The appendices include:

- Appendix A: Troubleshooting
- Appendix B: Getting Support
- Appendix C: Operating Conditions
- Appendix D: System Requirements

Appendix A: Troubleshooting

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 as described in Appendix B: Getting Support.

SilhouetteStar is not detected

If a message appears saying the SilhouetteStar camera is not connected, when it is, or if SilhouetteStar's lasers/LEDs do not turn on automatically during image capture:

- Check that the USB cable is connected properly at both ends.
- Check that the USB cable is not damaged. Use a different SilhouetteStar-branded USB cable, if one is available. (See Warnings.)
- 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.

Cannot synchronize with SilhouetteCentral or synchronization fails

If SilhouetteConnect cannot synchronize with SilhouetteCentral:

- Check that you are connected to the internet.
- Check that the SilhouetteCentral URL is correct in the **Administration > Synchronization** screen. See Synchronization for more information.

If SilhouetteConnect still cannot synchronize with SilhouetteCentral, note the step at which synchronization fails. Synchronization may fail due to network issues that prevent uploading or downloading files. Check that your network connection is working properly and try synchronizing again. If the problem persists, check that your network's firewall or proxy settings allow the uploading and downloading of files. See your organization's IT support team if synchronization continues to fail or for further assistance contact ARANZ Medical customer support as described in Appendix B: Getting Support.

Laser detections are poor

The ability for the laser lines to be detected in the image can be effected by excessive ambient light or by operating the camera outside of focus length. Poor laser detection can be seen in the Image Assignment screen as either little blue dots (indicating laser detection points) placed randomly on the image or by excessive brightening of parts of the image.

If poor laser detections are found then try the following:

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

"No Database Present" error displayed

If you attempt to log into SilhouetteConnect and get an error message stating "No Database Present" this is due to the SilhouetteConnect Data folder not being found.
This is caused by removal of the SilhouetteConnect Data folder. This may happen because someone has tried to back up the Data folder but moved the folder instead of copying it. Locate where the Data folder has been moved to, and restore the folder to the correct location. See If Backing Up Without SilhouetteCentral for Data folder locations and instructions on backing up correctly.

Appendix B: Getting Support

You can reach the**About** screen by clicking the icon at the top of any screen on SilhouetteConnect™. From there, you can also access the **Help** screen by clicking on the **Help** button.
In the **About** dialog box of SilhouetteConnect™, you will find a **Support** tab that displays customized support information that is specific to your organization. Following this information will be the most expedient way to get support, as it may refer you to a local IT support desk.
The **General** tab on the About dialog contains information that may be useful for diagnosing common issues. It displays your details, permissions related to image capture and synchronization and your connectivity status.
Failing this you can contact ARANZ Medical support by using the contact information listed below:

Customer Support	**Sales Enquiries**
Please contact your system administrator for support information.	Phone (International): +64-3-374-6120 Phone (US customers): 866-467-0934 Fax: +64-3-374-6130 Email: sales@aranzmedical.com

ARANZ Medical Website

www.aranzmedical.com

An ARANZ Medical Support representative may ask you to download a remote access tool from http://support.aranzmedical.com. A download link to this tool is also present on the General tab of the **About** screen. This page links you to a tool that enables us to temporarily share your screen. We use this to interact directly with your screen's display of our software, to troubleshoot issues, and to access and securely transfer authorized files to and from your computer.

Appendix C: Operating Conditions

Parameter	Min	Nominal	Max
Operating temperature	10°C (50°F)		30°C (86°F)
Storage temperature	-5°C (23°F)		50°C (122°F)
Long term (> 1 week) storage temperature	5°C (41°F)		35°C (104°F)
Operating humidity	0% RH		80% RH
Lighting	100 lux	400 lux	1000 lux

For lighting, 100 lux is considered equivalent to a dark, heavily overcast day. 500 lux is equivalent to typical office lighting and 1000 lux is equivalent to TV studio lighting levels.

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Appendix D: System Requirements

Component	Requirement
Computer operating system	Windows 10 Windows 7, 8 or 8.1 can be supported where extended support is in place. Contact support@aranzmedical.com for details.
RAM	2 GB (minimum)
CPU	2 GHz (minimum)
Free hard disk space	10 GB (minimum) for data files
Display resolution	1024 x 768 (minimum)
Other	Functioning USB 2.0 or 3.0 port SilhouetteConnect is optimized for mouse/keyboard use NOTE: Recommendations are based on AML tested systems. System Performance may vary depending on hardware quality, we recommend validating system performance.