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Silhouette v4.1

Installation and Configuration Guide

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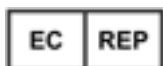
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Introduction

This guide focuses on the pre-planning, installation and configuration of the Silhouette™ system.

The intended audience for this guide are Project Managers, Systems Administrators and IT Personnel. For general usage of the Silhouette system, refer to the Silhouette Clinical or Administration User Guides.

 The details specified in this document assume that the SilhouetteCentral Installation is performed on one machine that contains the SQL Database, Web Server and all patient data. The SilhouetteCentral installation may be fragmented by having the data stored on another data server, or Network Attached Storage (NAS) device and also having a separate machine for the Web Server.

Notation Convention

Throughout this guide, screen, menu, and field names in SilhouetteCentral are displayed in a **bold font**. A series of actions are shown as follows:

Admin > Organization > Settings

which means to select the **Settings** option in the **Organization** menu in the SilhouetteCentral **Admin** section.

Topics

This guide contains information on the following topics:

Use the links to access



[System Description](#)



[System Requirements and Operating Conditions](#)

2 • Topics



[SilhouetteCentral Installation](#)



[System Configuration](#)



[CTEULA and Terms of Use](#)

System Description

Wound Care

Silhouette is used in clinical practice by some of the world's largest healthcare providers, including the department of Veteran's Affairs in the US, the NHS in the UK, and many other clinics and hospitals in more than 30 countries. For clinical practice, Silhouette delivers:

- Reliable, accurate and timely wound documentation
- An easy to use solution for staff
- A non-invasive solution for patients
- Reduced commercial and litigation risk
- Improved patient satisfaction
- Fewer hospital admissions and visits
- Shorter hospital stays
- A reduction in the total cost of patient care.

Wound Research

Silhouette's ability to reliably capture, measure, and manage wound data has been proven in more than 70 clinical studies globally. For clinical research, Silhouette delivers:

- High quality data to support study endpoints
- Highly accurate, reliable, and repeatable measurements (inter and intra-operability)
- Reliable data collection for pre-clinical through phase IV, post-marketing surveillance, and observational studies
- A scalable solution for studies from one site to 250+ investigator sites
- Immediate access to images, data, and reports for sponsors, CROs, adjudicators, and sites
- One-click PDF assessment reports can be used as source documentation
- Data exports at any time
- An easy to use solution for sites.

System Components

SilhouetteCentral is a computerized wound imaging, analysis, and documentation system. SilhouetteCentral enables users to review, report, securely share and analyze the wound data collected by SilhouetteStar 2, SilhouetteLite+ and SilhouetteLite applications. SilhouetteCentral is accessed via a web-based application.

SilhouetteCentral is divided into two parts:

- Clinical UI - Provides access to the patient medical data stored in the Silhouette database for reviewing, editing, and updating. Reports, images, and wound measurement data can also be exported for further processing and importing into other applications.

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- Administration - Provides facilities to manage units, groups, patients, and system users. SilhouetteCentral can also be used to configure and customize the Silhouette system.

The SilhouetteCentral application uses the Microsoft .NET 4.5.2 framework and is hosted by Microsoft Internet Information Services (IIS) on Windows Server 2008 or later machines. Patient demographic and assessment data is stored in a Microsoft SQL Server 2008 or later database (images and reports are stored outside of the database).



In this version of SilhouetteCentral there is limited configurability available via the main web app. Contact ARANZ support if configuration changes need to be made.

SilhouetteStar 2 is a camera that captures wound images and non-contact 3D measurements of wounds at the point of care. The images and data captured with SilhouetteStar 2 are uploaded to SilhouetteCentral over a secure Wi-Fi network.

SilhouetteLite+ is comprised of an application and a range finding sensor for Apple® iPhone®, iPod® touch and iPad® iOS 10+ devices. SilhouetteLite+ enables users to take wound images, obtain non-contact 2D measurements, and record patient notes on their mobile device. The data collected at the patient's bedside is synchronized with SilhouetteCentral over a secure connection when available.

SilhouetteLite is an application designed for Apple® iPhone®, iPod® touch and iPad® iOS 10+ devices. SilhouetteLite is a simplified application that enables users to add patients, wound images and simple notes (without measurements) to SilhouetteCentral. The data collected at the patient's bedside is synchronized with SilhouetteCentral over a secure network connection when available.

System Data Security

SilhouetteCentral Data Security

Patient demographic information and associated measurement data is stored in a Microsoft SQL Server 2008 or later database. The database uses standard SQL Server authentication mechanisms. SQL Server includes various mechanisms to encrypt both the database and the connection between the database and SilhouetteCentral.

Images are stored in a compressed, proprietary format with anonymized filenames. Reports are created and stored in PDF format. It is possible to configure the host server to use drive encryption where required.

Both the database and associated images and reports can be stored on the same or different machines depending on the installation criteria.

SilhouetteStar 2 Data Security

SilhouetteStar 2 captures images of wounds, creates a 3D model for measurements and uploads them to SilhouetteCentral over the Wi-Fi network. The images are uploaded and removed from the camera almost immediately. If there is a communications issue which prevents immediate uploading the images are kept on the camera only until the camera goes to sleep mode, typically after 2 minutes of no use.

To keep the data secure over the network, it is required to configure SilhouetteCentral to use HTTPS. It is typically not good enough to rely on the Wi-Fi network encryption.

The SilhouetteStar 2 displays the patient name, patient id and date of birth of the patient being assessed by a user via the SilhouetteCentral web interface. Once the clinician closes the web browser or navigates away from the patient the patient information is removed from the screen and is removed from the camera. If the camera is idle for 2 minutes, the device enters sleep mode and all patient information is removed.

SilhouetteLite and SilhouetteLite+ Data Security

The SilhouetteLite and SilhouetteLite+ apps support offline operation. A list of patients from Silhouette is stored on the mobile device as well as any assessments waiting to be uploaded. Once assessment data is uploaded to SilhouetteCentral it is deleted from the mobile device.

Apple devices offer FIPS140-2 validated encryption for data stored on the device. The Apple [iOS Security Guide](#) provides a description of the way file security works on the device and how it works with iTunes syncs and backups. To ensure the data displayed and stored on the device is safe the following configuration recommendations are made:

- Use Passcode security on the device to enable data file encryption and to protect the device from unauthorized users accessing it.
- Use Touch ID on the device to provide an additional authentication check when first launching the SilhouetteLite or SilhouetteLite+ apps. The use of Touch ID for access to the apps is enabled by default in SilhouetteCentral, but can be turned off if required.
- Use the Apple Configurator 2 app to supervise devices, in particular:
 - Disable screenshot capabilities.
 - Disable the Allow pairing to computers for content sync setting or enable the Force encrypted backups feature.

System Requirements and Operating Conditions

Not all system specifications are listed in this section. See the system specification sheet from ARANZ Medical for further information.

SilhouetteCentral Web Application - Minimum Requirements

Web Browsers Supported	Safari, IE, Edge, Firefox, Chrome
	Note: The web application is not designed to work on phone screens. An iPad mini or larger is recommended.

SilhouetteCentral - Minimum Server Requirements

Operating System	Windows Server 2008/2008 (R2) or later (Windows Server 2012 R2 64-bit recommended)
Processor	2.4 GHz Dual Core
Memory	4 GB RAM (16 GB Recommended)
Network	Ethernet or Wi-Fi TCP/IP Connection DHCP or static IP Address
Hard Disk	100 GB Available Space
IIS Versions supported	IIS versions that come with Windows Server 2008 or above are supported.
Required Components to be installed	.net 4.5.2

SilhouetteCentral - Database Requirements

SQL Server Versions Supported	SQL Server 2012 (Workgroup, Standard, Enterprise) or later (SQL 2014 recommended).
SQL Server Configuration	Windows Authentication (recommended) SQL Authentication (supported)
Estimated database size	Database size growth should be expected at approx. 1 MB per patient assessment stored. Total space requirements will depend on data size, testing volume and database maintenance.

SilhouetteStar 2 - Minimum Requirements

Wi-Fi Network Support	Wi-Fi 802.11 a,b,g at 2.4 GHz
Wi-Fi Security Supported	WPA/WPA2-PSK Note: Network passwords must be at least 8 characters long
Minimum bandwidth required	14 Mbps uplink and downlink between the exam room and the SilhouetteCentral server.
Maximum network latency	300 ms round trip between the exam room and the SilhouetteCentral server.
Lighting	100 lux minimum 400 lux nominal (normal office) 1000 lux max (bright office)
Operating Temperature	10 C (50 F) min 30 C (86 F) max
Operating Humidity	0% RH min 80% RH max
Storage Temperature	-5 C (23 F) min 50 C (122 F) max



The SilhouetteStar 2 uses Wi-Fi to send captured images to SilhouetteCentral. For a reliable user experience, the Wi-Fi network at the point of care (i.e. in the exam rooms) must be reliable. A reasonable heuristic for the Wi-Fi performance required is that the Wi-Fi should support a 10 minute video conference session with no glitches and good video quality.

The bandwidth and latency requirements above are minimum recommendations for end-to-end network performance requirements based on testing. They don't cater for the number of other services using the network or packet loss in the network. As part of the deployment it is recommended that some testing be carried out to confirm reliable and timely performance of the system.

SilhouetteLite and SilhouetteLite+ App - Minimum Requirements

iOS version	iOS 10 or newer
Device support	iPhone 5s and later The application interface is designed primarily for iPhone Plus and iPad Mini devices but has been tested on a wider range of device sizes.

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Security	Passcode / Touch ID enabled It is recommended that passcode / Touch ID is enabled on the device. Doing so enables the Apple to encrypt the SilhouetteLite files, protecting them from untrusted access.
Maximum number of patients	4000
Maximum number of images per image capture field	10

SilhouetteLite+ Sensor - Operating Conditions

x offset	-12 mm to +20 mm Horizontal offset for placement of the SilhouetteLite+ sensor optics relative to the device optics.
y offset	-12 mm to +30 mm Vertical offset for placement of the SilhouetteLite+ sensor optics relative to the device optics.
Sensor Operating Temperature	0°C to 40°C (32°F to 104°F)
Sensor Charging Temperature	0°C to 45°C (32°F to 113°F)
Sensor Storage Temperature	-5°C to 60°C (23°F to 140°F) for < 2 hours 0°C to 45°C (32°F to 113°F) for up to 1 month 0°C to 35°C (32°F to 95°F) for > 1 month

SilhouetteCentral Installation

This section describes the installation and initial configuration of Silhouette. It also covers the upgrade procedure for updating an existing installation to the latest version.

Pre-Installation Planning

The following items should be considered before commencing the installation of Silhouette:

- Review the Silhouette [CTEULA and Terms of Use](#). Installing and using SilhouetteCentral means that you accept these conditions.
- Review the [system requirements](#) to ensure the targeted installation platforms and networks are adequate.
- The URL of the Silhouette website is known.
- The location on the network and firewall configurations consider the access needs of the desired use (i.e. access for nurses to use the system from patients homes).
- Prepare the server certificates to allow HTTPS to be used. The system can run using HTTP but it is strongly recommended to use HTTPS to encrypt communications.
- The encryption requirements for the server file system and the database are understood.
- Gather the details of the SQL server to host the Silhouette database, including:
 - SQL Server name
 - Database name
 - Connection details
- Backup requirements for clinical data stored within Silhouette are understood.
- Silhouette users and their system access is determined.
- Gather the SMTP server details, for use by Silhouette to send password reset emails.

Aside from the technical installation considerations, to get the most out of Silhouette it is recommended that there is time spent planning how different users are going to use the different components of the system. A demonstration or trial of the system maybe appropriate in some cases to assist with this planning.

The Silhouette system is a powerful tool to enable data to be captured at the point of care, which can assist in the achievement of great clinical results. Spending some time defining what data is needed from the system can help achieve the desired results, while optimizing workflow for clinical staff.

Installing Internet Information Services (IIS)

Prior to the installation of SilhouetteCentral you must ensure the server you are installing onto has Internet Information Server (IIS) installed. This is an optional component of the Windows operating system.

The precise installation instructions are operating system specific.

Windows Server 2008

1. From the Start Menu, select **Administrative Tools**, then **Server Manager**.
2. In the tree-view on the left hand side, right-click the **Roles** item and select the **Add Roles** option.
3. A new window should appear called Add Roles Wizard.
4. Click **Next**, then select the **Web Server IIS** role.
5. A prompt will appear requesting permission to add additional features required for the Web Server IIS role to operate correctly. Click "Add Requested Features".
6. Click **Next** and under the Role Services select ASP.NET.
7. A prompt will appear requesting permission to add additional optional features of the Web Server IIS role required for ASP.NET applications to operate correctly. Click "Add Required Role Services".
8. Click **Next** and then **Install**.

Windows Server 2012

1. From the Start Screen select the **Server Manager**.
2. Click **Manage** menu at the top right, and select **Add Roles and Features**.
3. Click **Next** until you reach the **Server Roles** page.
4. If the **Web Server (IIS)** role is not labeled as Installed, then tick the checkbox beside it.
5. Click **Next** to go to the **Features** page.
6. Expand the .NET Framework 4.5 Features and ensure that the .NET Framework 4.5 and ASP.NET 4.5 is checked.
7. Click **Next** until you reach the **Confirmation** page, and the click **Install**.
8. Once this has completed run the **Add Roles and Features** wizard a second time.
9. Click **Next** until you reach the **Server Roles** page.
10. Expand the **Web Server (IIS)** role then the **Web Server** then **Application Development**. Tick the ASP.NET 4.5 checkbox and confirm you want to add the additional features.
11. Click **Next** until you reach the **Confirmation** page, and the click **Install**.

Windows Powershell

If installing on a Windows 2008 R2 or later server installation of IIS may also be scripted via a powershell command prompt running with administrator privileges:

```
Import-Module ServerManager
```

```
Add-WindowsFeature Web-Static-Content,Web-ASP-Net,Web-Mgmt-Console
```

NOTE: If installing on Windows Server 2012R2 or later the Add-WindowsFeature command line must be modified to add the windows feature `Web-ASP-Net45` instead of `Web-ASP-Net`.

NOTE: If you get an error message stating “The source files could not be downloaded” insert the Windows installation DVD into your DVD drive and add the parameter `-Source D:\Sources\Sxs` where D:\ is the drive letter assigned to your DVD drive.

SilhouetteCentral Installation Process

The following steps install the SilhouetteCentral web application on IIS.

Software Prerequisite Installation

In order to run SilhouetteCentral, Microsoft .NET 4.5.2 (<http://www.microsoft.com/en-us/download/details.aspx?id=42642>) must be installed on the server in addition to IIS. If not already installed, .net can be downloaded from the internet using the link provided. In some circumstances a reboot of the server may be required during installation.

NOTE: If .NET 4.5.2 was installed prior to IIS being configured (see the Installing Internet Information Services (IIS) section) you may need to re-register ASP.NET in order for IIS to be properly configured to serve ASP.NET 4.5.2 based applications such as Silhouette.

To re-register ASP.NET open up an administrator command prompt and type the following command:

```
C:\Windows\Microsoft.NET\Framework64\v4.0.30319\aspnet_regiis.exe -ir
```

If installing on a 32bit version of Windows replace Framework64 with Framework in the command listed above. This step should not be necessary if you installed IIS prior to Microsoft .NET 4.5.2 as the .NET 4.5.2 installer will take care of this step when it detects IIS is already installed.

Extract SilhouetteCentral

Unzip the SilhouetteCentral zip file into a sub directory within the main wwwroot folder used by IIS. The name of this folder will become part of the URL used to access SilhouetteCentral.

For example, if IIS is installed within the `C:\inetpub\wwwroot` folder and you want the SilhouetteCentral website to be accessible via `http://name-of-your-server/Silhouette` you would extract the zip file into a subdirectory called `C:\inetpub\wwwroot\Silhouette`.

NOTE: If upgrading an existing SilhouetteCentral installation first delete the entire contents of the `C:\inetpub\wwwroot\Silhouette` folder except for the sub-folder called Files.

Configure IIS

Once the SilhouetteCentral software has been placed in the wwwroot folder IIS must be configured to treat this folder as a web application. This can be configured in a number of ways including:

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Via IIS Manager

1. Open IIS Manager.
2. Create a new application pool for use by SilhouetteCentral:
 1. In the Connections pane, right-click the Applications Pools node.
 2. Select Add Application Pool.
 3. Give the pool a unique name (we recommend the same name as the directory extracted previously)
 4. Select .NET CLR Version v4.0.30319, and Managed Pipeline mode as Integrated.
 5. Click OK.
3. Convert the directory into an application
 1. In the Connections pane, expand the Sites node and then the node representing your website (Default Web Site by default).
 2. Find the node representing the folder you created in step 1.
 3. Right-click the folder, and click Convert To Application.
 4. Click Select, and choose the application pool you created above.
 5. Click OK.

Via Windows Powershell

If installing on a Windows 2008 R2 or later server creation of the Silhouette application pool and web application may also be scripted via a powershell command prompt:

```
Import-Module WebAdministration
New-WebAppPool -Name Silhouette
Set-ItemProperty
-path IIS:\AppPools\Silhouette
-name "managedRuntimeVersion"
-value "v4.0"
New-WebApplication
-Name Silhouette
-Site "Default Web Site"
-PhysicalPath C:\inetpub\wwwroot\Silhouette
-ApplicationPool Silhouette
```

NOTE: If upgrading an existing SilhouetteCentral installation most of the IIS configuration should already be completed and can be left unaltered. The only item which may require attention is to ensure the Application Pool used by SilhouetteCentral is set to use .NET CLR version v4.0.30319. Releases of SilhouetteCentral prior to v3.7 made use of .NET CLR version v2.0.50727 so this setting must be updated for correct operation of SilhouetteCentral.

Permissions

The user account used by the application pool created in the previous section (typically IIS AppPool\Silhouette) requires read permission to all files within the folder you extracted SilhouetteCentral to. Note that this user will automatically be a member of the local IIS_IUSRS group, which by default has read access to all web applications hosted in the wwwroot folder.

The application pool user account will also require the following subdirectory specific permissions

Folder Name	Permission	Notes
Files	Modify	All sub-files and folders must inherit this folder permission.

SQL Server Database

SilhouetteCentral stores all patient demographic and assessment data in a SQL server database. Depending upon your expected scale and existing IT infrastructure this database can be hosted on the same server running the SilhouetteCentral website, or it can be hosted on a dedicated database server.

Using an existing SQL Server Installation

If an existing instance of SQL Server has been designated to host the SilhouetteCentral database you will need to obtain the required connection details to access the database. These details include:

- SQL Server Instance name, i.e. serverName\instanceName
- Authentication method (Windows Authentication or SQL Server)
 - If SQL Server you will need the associated username and password
- Database name, i.e. Silhouette

Your Database Administrator (DBA) should be able to provide these details to you and create the blank database which SilhouetteCentral will populate during the installation procedure.

Installing SQL Server Express



The use of SQL Server Express is not recommended for production installations due to limitations on database performance, size and features. Instructions for SQL Server Express are provided here as a help for trial and demonstration purposes.

If you do not have an existing SQL server installation small SilhouetteCentral installations can install the latest SQL Server Express edition which is available as a free download from Microsoft. This can be installed directly on the server on which SilhouetteCentral will be installed.

Follow these steps to download and install SQL Server 2014 Express:

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1. Download SQL Server 2014 Express with Tools via the Microsoft Downloads website:
<http://www.microsoft.com/en-nz/download/details.aspx?id=42299>.
 1. If you are installing on a 32bit server you require the file SQLEXPRTW_x86_ENU.exe
 2. If you are installing on a 64bit server you require the file SQLEXPRTW_x64_ENU.exe
2. Run the executable and click the **OK** button on the “Choose Directory For Extracted Files” dialog.
3. On the “SQL Server Installation Center” dialog select the “New SQL Server stand-alone installation or add features to an existing installation” link (towards top right corner of dialog).
4. The SQL Server 2014 Setup wizard will start. Select “I accept the license terms” and click **Next**.
5. On the Feature Selection step ensure the following features are enabled and click **Next**.
 1. Database Engine Services
 2. Management Tools – Basic
6. On the Instance Configuration step select the “Named Instance” option and give the SQL server instance the name SQLEXPRESS then click **Next**.
7. On the Server Configuration step click **Next**.
8. On the Database Engine Configuration step select the “Windows authentication mode” option and click **Next**.
9. Follow any additional prompts that appear until installation is completed.

Creating a SilhouetteCentral Database

Once SQL Server Express has been installed a blank database must be created to store all clinical assessment data. This can be created in a number of ways including:

Via SQL Management Studio

- From the Windows start menu start **SQL Management Studio**
- A **Connect to Server** dialog should appear
 - If not select **Connect Object Explorer** within the **File** menu.
- Set the **Server type** drop down to **Database Engine** and in the **Server name** box type .\SQLEXPRESS then click **Connect**
- Within the object explorer pane (left side of screen), right click on **Databases** and select **New Database...**
- Within the **New Database** dialog type in the database name **Silhouette** and press OK
- Within the object explorer pane right click on **Security** and select **Login...** underneath the **New** submenu
- Type IIS AppPool\Silhouette into the **Login name** text box
- Select Silhouette within the **Default database** drop down
- Click **OK**

- Within the object explorer pane expand the **Databases** item and further expand the sub-item representing the SilhouetteCentral database.
- Right click on Security and select User... underneath the New submenu
- Type IIS AppPool\Silhouette into both the **User name** and **Login name** text boxes
- In the **Membership** section scroll down and place a tick beside **db_owner**
- Click **OK**

Via Windows Powershell

If installing on a Windows 2008 R2 or later server creation of the SilhouetteCentral database may also be scripted via a powershell command prompt:

```
Invoke-Sqlcmd –ServerInstance .\SQLEXPRESS –Query "CREATE DATABASE Silhouette"
```

```
Invoke-Sqlcmd –ServerInstance .\SQLEXPRESS –Query "CREATE LOGIN  
[IIS AppPool\Silhouette] FROM WINDOWS WITH DEFAULT_DATABASE=Silhouette"
```

```
Invoke-Sqlcmd –ServerInstance .\SQLEXPRESS –Query "USE Silhouette CREATE USER [IIS AppPool\Silhouette] FOR  
LOGIN [IIS AppPool\Silhouette];"
```

```
Invoke-Sqlcmd –ServerInstance .\SQLEXPRESS –Query "USE Silhouette exec sp_addrolemember 'db_owner', [IIS  
AppPool\Silhouette]"
```

NOTE: If securing database access using the IIS AppPool\Silhouette user account the database server must be running on the same server as IIS. You should also wait until step 1 of the SilhouetteCentral [configuration wizard](#) before securing database access as the IIS AppPool\Silhouette user account may not exist until this point of the installation process.

SilhouetteCentral Configuration Wizard

After you have completed install process you will need to perform some additional setup. This will automatically be run the first time you visit the SilhouetteCentral website. To run the wizard

1. Launch a Web Browser
2. Navigate to <http://localhost/Silhouette/> (or the location you installed the application to).

This wizard will configure the basic settings required for SilhouetteCentral to run correctly.

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Initial Setup

You're almost there! There are only a few important settings before you're ready to go.

Database Server Email Organization License

SilhouetteCentral relies upon a SQL Server database for data storage. Please provide the connection details required to connect to the database.

If you do not have an existing database, create a blank one, and SilhouetteCentral will perform all required configuration steps.

Server:
Database:
Authentication:

SilhouetteCentral will connect to the database using the user account
IIS APPPOOL\SilhouetteCentral

Please ensure suitable database permissions are assigned to this account. [Next](#)

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Step 1 Database

Enter the connection details to the SQL Server instance that Silhouette will use. Note that the database entered here must already exist. (It should be a new blank database)

The account used to authenticate must have database owner permissions.

Migrating from SilhouetteConnect – Additional Step

A single SilhouetteConnect “standalone” installation can be migrated to SilhouetteCentral while retaining all patient data and customized settings that were present within the SilhouetteConnect system.

The SilhouetteCentral Setup Wizard can import these settings and data, provided that they are copied into the specified location:

1. Copy the SilhouetteConnect data from C:\ProgramData\ARANZ Medical Limited\SilhouetteConnect*. * to [installation location]...Files\Setup\SilhouetteConnectData*. * these files will be deleted by the Setup Wizard if the migration is successful.
2. Follow the remaining steps, should an error be encountered by the wizard, such as an incompatible data file the migration will be aborted and an error message presented.

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Initial Setup

You're almost there! There are only a few important settings before you're ready to go.

Database Server Email Organization License

Please enter the URL that a user should enter into their web browser's address bar to access SilhouetteCentral. Typically this would be the hostname of the web server on which SilhouetteCentral is installed, however your environment may require it to be different due to the proxy or firewall configuration within your environment.

Root URL:
If SilhouetteConnect users must use a proxy server to access the URL specified above please enter the required proxy server below.

Proxy Server:

[Back](#) [Next](#)

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Step 2 Server

The Root URL is the URL of the SilhouetteCentral instance. Please make sure this is correctly entered here.

Step 3 Email

If you require any of the Email sending features like password reset emails, then enable the Email integration.

Step 4 Organization

Enter support information that will be useful for the users. It can include contact details of a support person.

If a logo is provided, then this will be displayed on the SilhouetteCentral website, and also in the standard Wound Assessment Report.

Migrating from SilhouetteConnect – Additional Step

Check that the details from your SilhouetteConnect Installation are correct before clicking **Next**.

Step 5 License

Enter your client code here. SilhouetteCentral will then try to contact the license server and download the required license file.

Leave this blank in order to proceed using a trial license.

Depending on how you obtained your SilhouetteCentral installation files this step may complete automatically.

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Step 6 Initial Log on

With the web browser window opened at the SilhouetteCentral login page you will be able to login using the default credentials:

User name = admin

Password = aranz

On the next screen you will be prompted to change this password.



Step 7 Password Change

This step will change the password of the admin user account from the default value of aranz.

Enter the password that you wish to use for the admin user account.

Patient Assessment Data File Location

By default SilhouetteCentral stores patient images and report files in the Files\Data folder under the main application folder. The location of this Data folder may be altered by updating the DataDirectory property located in the Files\Settings\machinesettings.xml file. This allows the data to be stored in a different location to the SilhouetteCentral application files. This can be either a local directory, or a UNC file share.

As an example updating the setting within machinesettings.xml as follows would store patient images and reports in the D:\Silhouette\Data folder.

```
<DataDirectory>D:\Silhouette\Data</DataDirectory>
```

NOTE: Any change in this setting will only be detected by SilhouetteCentral when the associated application pool is recycled. The setting also does not physical transfer any existing images and reports to the new location. Ideally the SilhouetteCentral application pool should be stopped, the contents of the existing folder moved to its new location, the DataDirectory setting updated and then the application pool restarted.

Backup

On completing the installation of SilhouetteCentral a backup plan and procedure should be put in place. To ensure no data is lost in the event of a hardware or software failure. The following items should be included in your backup plan:

1. SilhouetteCentral database (.mdf) and log (.ldf) files. This may be done using SQL Agent or a Windows Scheduled Task.
2. The Files folder under the SilhouetteCentral installation folder. This folder contains all of the assessment images, reports, license and other configuration files. With a default installation this will be similar to:

```
C:\inetpub\wwwroot\Silhouette\Files\
```

Upgrade

In order to upgrade extract the contents of the SilhouetteCentral ZIP file and replace the existing contents in inetpub wwwroot folder (refer to [manual installation](#) instructions for how the exact folder paths are specified/ described).

- Shutdown the IIS App Pool before extracting the files, then restart it after the files are copied across.
- Before extracting the new files make sure you delete everything except the "Files" folder (the "Files" folder contains all of the configuration and patient data).

After installation its possible a "database is upgrading" screen is displayed - as the existing database content is converted to the newer format. While this screen is present no users will have access to SilhouetteCentral.

Likewise after the database upgrade page dismisses itself automatically you may be placed part way through the [configuration wizard](#) as described previously. If this occurs it means that additional mandatory configuration (or options) have been added in the later version.

Specify the settings, as required and click Next -> Next -> Next, etc. to complete the wizard (all originally specified information will automatically be in place).

Versions

The method specified above can be used to upgrade SilhouetteCentral from v3.10 through to v4.0.



If upgrading from v3.19 or newer and you have tissue type classification data in your database (have used the Tissue Type Classification feature) contact ARANZ Medical Limited support before upgrading, at: support@aranzmedical.com.

For older versions of the software, it is recommended that a customer support representative be contacted to assist with this process - email customer support at: support@aranzmedical.com.

System Configuration

Silhouette can be configured to match clinical needs. Configuration of users, groups, units, and SilhouetteStar 2 Wi-Fi settings. For details please see the Silhouette Administration Manual.

Other settings and features are available for configuration by ARANZ Medical Support users. These other settings include:

- Assessment type configuration
- Patient and Wound Notes configuration
- SilhouetteLite and SilhouetteLite+ Touch ID configuration
- **Silhouette default timezone**
- Branding Logo
- **Support information**
- **Measurement calculation and display settings**
- Report settings
- Password settings
- Lockout settings
- SilhouetteStar 2 connection RootURL
- Log access

The items in bold above are items that should be reviewed with ARANZ Medical and set on installation.

CTEULA and Terms of Use

This section provides the Silhouette license information, consisting of:

- [Conditions of Transfer and End-User License Agreement](#)
- [ARANZ Medical Limited – Silhouette® Product Suite Terms of Use](#)

Conditions of Transfer and End-User License Agreement for ARANZ Medical Limited and Silhouette® Product Suite

Effective Date: 1 July 2017

IMPORTANT – READ CAREFULLY: This Conditions of Transfer and End User License Agreement (CTEULA) constitutes a legal agreement between You and ARANZ MEDICAL LIMITED, covering (1) the sale or leasing of one or more units of **Silhouette Hardware**, and (2) the licensing of **Silhouette Software**, in the SILHOUETTE® product suite. This CTEULA also covers the circumstance in which one or more unit(s) of Silhouette Hardware is/are loaned to You for evaluation, research or other purposes.

PLEASE READ THIS CTEULA CAREFULLY BECAUSE USING THE SILHOUETTE HARDWARE OR THE SILHOUETTE SOFTWARE WILL BE DEEMED TO BE ACCEPTANCE THAT THEY ARE BEING USED ON THE FOLLOWING TERMS.

1. Defined Terms. As used in this CTEULA and in the Terms of Use, the following terms have the following meanings:

AML means ARANZ Medical Limited.

Image Capture Unit means an image capture device, and includes a Silhouette Device, but also includes a smart phone or tablet provided by You running SilhouetteLite or SilhouetteLite+.

Module means an add-on, option or feature, which is associated with a Silhouette Software product but is licensed for an additional license fee.

Upgrade means a subsequent release of a Silhouette Software product which AML may offer to license holders with a current paid up Support Contract at no additional license fee and may include bug fixes and new functionality.

Order Form means the contract, quotation or purchase order accepted by AML designating which unit(s) of Silhouette Hardware (if any) are being sold, leased or loaned to You and which units of Silhouette Software (if any) are being licensed to You.

Point of Care Access License means a license to SilhouetteCentral that permits specified Image Capture Units to communicate with an instance of SilhouetteCentral.

Products means, collectively, any Silhouette Device or Silhouette Accessory sold, leased or loaned to You, any Silhouette Software licensed to You, and any Support or Services purchased by You.

Services means any additional services purchased by You from AML (and/or its distributor) over and above those services included in Your **Support Contract** (see Part 4 of the Terms of Use for more detail).

Silhouette Accessory means accessory hardware produced by AML, other than the Silhouette Devices, and includes the SilhouetteLite+ Sensor.

SilhouetteCentral means the executable code version of the application software for the storage and organization of wound data, produced by AML under the SILHOUETTECENTRAL™ trademark.

SilhouetteConnect means the executable code version of the application software for wound image processing and storage on a personal computer, laptop or tablet provided by You, produced by AML under the SILHOUETTECONNECT™ trademark.

Silhouette Device means one or more image capture devices in the Silhouette product suite produced by AML, including SilhouetteStar.

Silhouette Hardware means, collectively, the Silhouette Device(s) and the Silhouette Accessory(ies).

SilhouetteLite means the executable code version of the application software for wound image and data capture and processing, produced by AML under the SILHOUETTELITE™ trademark.

SilhouetteLite EULA means the End User License Agreement that the end user agrees to when he/she/it downloads SilhouetteLite or SilhouetteLite+ from the Apple App Store.

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SilhouetteLite+ means the executable code version of the application software for wound image and data capture and processing with the SilhouetteLite+ Sensor, produced by AML under the SILHOUETTELITE+™ trademark.

SilhouetteLite+ Sensor means the range finder accessory device, and associated battery charger, produced by AML under the SILHOUETTELITE+ SENSOR™ trademark.

Silhouette Software means collectively SilhouetteCentral and SilhouetteConnect, and also includes Upgrades and Modules with respect to each of same. The "Silhouette Software" also includes any documentation provided or made available to You by AML in connection with and pertaining to the Silhouette Software, whether in printed or electronic format, and any associated media or printed materials pertaining to the Silhouette Software. For clarity, as used herein, the term "Silhouette Software" does not include SilhouetteLite or SilhouetteLite+, as those products are licensed under the terms of SilhouetteLite EULA.

SilhouetteStar means the SILHOUETTESTAR™ image capture device.

Support means the support services that AML provides to license holders of the Silhouette Software who have paid for a Support Contract for the current support period (see clause 12 and the Terms of Use for more detail).

Support Contract means the contract that the holder of a license of the Silhouette Software must purchase as a precondition to receiving Support and Updates during a designated support period (see clause 12 and the Terms of Use for more detail).

Terms of Use means the ARANZ Medical Limited Silhouette® Product Suite Terms of Use, which are supplemental to and incorporated by reference into this CTEULA, as such Terms of Use may be revised from time to time.

You or Your means the person or entity that purchases, leases or borrows Silhouette Hardware and/or holds a license of the Silhouette Software.

- 2. Cover:** This CTEULA applies to all Products sold, leased, loaned or licensed by AML (and/or one of AML's distributors) to You. The Order Form will designate whether and which units of Silhouette Hardware are being sold, leased or loaned. The Order Form will also designate whether and which units of Silhouette Software (including any Modules) are being licensed to You. This CTEULA incorporates the Terms of Use all of which Terms of Use shall apply between AML and You as though set forth in this CTEULA in full.
- 3. Risk:** The risk of loss to the Products shall pass to You immediately upon delivery of the Silhouette Hardware unless otherwise agreed in writing.
- 4. Delivery.** Delivery of the Silhouette Hardware shall occur when the Silhouette Hardware arrives and is signed for at the address shown on the Order Form.
- 5. Title:** In the case of sale of one or more units of Silhouette Hardware, ownership of the Silhouette Hardware shall not pass to You, nor shall You have a license to use any Silhouette Software until You have paid for the Silhouette Hardware in full and also paid all license fees owing for the Silhouette Software. In the case of a lease or loan of one or more unit(s) of the Silhouette Hardware, ownership of the Silhouette Hardware shall at all times remain with AML (or its distributor in instances where AML's distributor has made the lease or loan), and, at the expiration or termination of the lease or loan term, You shall, at Your expense, return the Silhouette Hardware to AML (or its distributor, as the case may be) in the same condition as at the beginning of the term, reasonable wear and use excepted.
- 6. Non-Payment:** Where You fail to pay when due either the purchase price for the Silhouette Hardware, or any lease payment, license fee or other amount owing to AML (and/or its distributor), AML (and/or its distributor) may charge, and You shall be liable to pay, interest on any overdue account calculated on a daily basis from the due date until actual payment at an interest rate equal to the lesser of (i) 5% above the the "U.S. Prime Rate", as adjusted from time to time, as published in the Wall Street Journal, or (ii) the highest rate of interest permitted by law. In addition, You agree to reimburse AML (and/or its distributor) for any costs and expenses, including legal fees, incurred by AML (and/or its distributor) in collecting any amounts You fail to pay when due to AML (and/or its distributor). Further, You agree to return the Silhouette Hardware to AML (and/or its distributor) at Your expense if requested to do so by AML (and/or its distributor) following non-payment of any amount owing by You to AML (and/or its distributor) for the purchase or lease of Silhouette Hardware and without limiting any other right AML (and/or its distributor) may have.
- 7. Taxes:** All payments under this CTEULA shall be made free of deduction or withholding. In the event that You become liable to deduct or withhold an amount by way of tax or otherwise from payments due under this Agreement, You shall pay such additional amount as will be necessary to ensure that the price for the Products received by AML (and/or its distributor) equals the amount that would otherwise have been received in the absence of that deduction or withholding.

8. License: If the Order Form includes one or more licenses of Silhouette Software, AML grants You a non-exclusive, non-transferrable license to use the then current released version of the specified Silhouette Software Product in accordance with this CTEULA and this license shall continue for the term described in Paragraph 9, unless sooner terminated or revoked under the terms of this CTEULA. In addition to any other rights AML may have, AML may revoke the Silhouette Software licenses granted by notifying You in writing if You fail to pay when due, the purchase price for the Silhouette Hardware, or any lease payment, license fee or other amount owing to AML, or shall breach any provision of the CTEULA. Upon such revocation, or upon the expiration or termination of a Silhouette Software license, AML shall have the right to block Your access to and use of the licensed Silhouette Software or any part thereof. “Use” of the Silhouette Software means loading, installing, or running the Silhouette Software on the hardware provided by You, meeting a specification provided by AML; provided, however, in the case of a license of SilhouetteCentral with hosting by AML, “Use” means access to and use of the hosted instance.

9. Software License Term and Renewal: The license granted under this Agreement may be either for a Fixed Term or for a Continuous Term as follows:

- (a) If the Order Form specifies a fixed term, then this license is for the fixed term specified on the Order Form (**Fixed Term**) commencing on the date the license is issued. In such event, the renewal of the Fixed Term will be governed by clause 10 below. If the Order Form fails to specify a Fixed Term or a Continuous Term, the license shall be deemed to be for a Fixed Term of one month commencing on the date the license is issued.
- (b) If the Order Form specifies a Continuous Term, then this license is for a Continuous Term as specified in the Order Form (**Continuous Term**) commencing on the date the license is issued.
- (c) For clarity, where more than one Silhouette Software Product is licensed to You, the Order Form may specify a different Fixed Term and/or a Continuous Term for each.
- (d) Whether for a Fixed Term (or any Renewed Term thereof) or a Continuous Term, the license granted under this Agreement is subject to termination under the circumstances described in clause 8.

10. Renewal: If Your license is for a Fixed Term, then at the expiration of the Fixed Term (and any subsequent Renewed Term), AML may offer to renew Your license of the Silhouette Software for an additional term (**Renewed Term**) provided:

- (a) You are not in breach of this Agreement;
- (b) AML has received from You in cleared funds the then current license fee for the Renewed Term; and
- (c) You agree to any variation of this Agreement specified by AML in accordance with clause 23.

AML may offer You a Renewed Term by sending You a renewal invoice for the license fee for the Renewed Term during the last ninety (90) days of the then current term of Your license. You may accept such offer by paying the renewal invoice when due and agreeing to any such variations in the manner specified by clause 23. The Renewed Term may be effected by the issue of an executable or license file over the internet. If AML does not offer a Renewed Term or if You do not accept a Renewed Term in the above manner, the license of the Silhouette Software shall terminate at the end of the initial Fixed Term or the initial Fixed Term as previously renewed.

11. Restrictions on Use: You agree not to:

- (a) translate, adapt, reverse-engineer or modify the Silhouette Hardware or the Silhouette Software, or do anything to circumvent the operation of the Silhouette Hardware or the Silhouette Software, or combine or integrate the Silhouette Hardware or the Silhouette Software with any other products;
- (b) separate any component of the Silhouette Software or Silhouette Hardware for use with other than the hardware for which a license has been granted;
- (c) lend, rent, lease, transfer, assign or otherwise deal in the Products without the prior written consent of AML.
- (d) export or extract data from the Silhouette Software, except through a product or service provided by AML.
- (e) use any of the Products outside the field of human medicine or for any use or purposes for which governmental approvals have not been obtained.

Without limiting the generality of the foregoing, you agree that the Products may not be exported or re-exported (a) into any U.S.-embargoed countries or (b) to anyone on the U.S. Treasury Department's Specially Designated Nationals List or the U.S. Department of Commerce Denied Persons List or Entity List. By using the Products, you represent and warrant that you are not located in any such country or on any such list. You also agree that you will not use these products for any purposes prohibited by United States law, including, without limitation, the development, design, manufacture, or production of nuclear, missile, or chemical or biological weapons.

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In addition, (1) each license of SilhouetteConnect is restricted to use only on a single unit of computer equipment used by a single person at any time, and consisting of a personal computer, laptop or tablet, and You agree not to exceed this limitation, and (2) each Point of Care Access License will specify the specific Image Capture Unit(s) which may connect to an instance of SilhouetteCentral via that Point of Care Access License, and You agree not to circumvent this restriction.

- 12. Upgrades and Support:** AML may offer You Upgrades when they are released. In cases where new versions are offered with respect to the Silhouette Software, but are not accepted by You, AML shall have no obligation to provide Support for older versions. The Order Form may describe Upgrades and/or Support that AML has agreed to provide You with respect to the Products. Except as otherwise provided in the Order Form, Upgrades and Support will be available to You only if offered by AML and purchased by You at AML's applicable rates. AML may offer You Modules from time to time, subject to Your payment of such additional license fees and agreement to any terms and conditions applicable to the Modules. All Upgrades and Modules will form part of the Silhouette Software and must only be used in accordance with this CTEULA.
- 13. Protection of Proprietary Rights:** You acknowledge that all right, title and interest in the Silhouette Software and all Proprietary Rights in the Silhouette Hardware and the Silhouette Software are vested in AML or its licensors, and You agree that You will not dispute such ownership nor claim any intellectual property rights relating to the Silhouette Hardware or the Silhouette Software or any enhancements or modifications of the Silhouette Hardware or the Silhouette Software. For the purposes of this CTEULA, "Proprietary Rights" means all intellectual or industrial property rights in the Silhouette Hardware and the Silhouette Software and all rights to patents, trademarks, trade names, inventions, designs, trade secrets, copyright and know-how relating to the origin, manufacture, programming, operating and/or servicing of the Silhouette Hardware and the Silhouette Software and any enhancements or modifications of the Silhouette Hardware or the Silhouette Software. You must maintain all intellectual property notices appearing on the Products and must not remove the same. You must notify AML immediately if You know of any circumstances that suggest that any person may have unauthorised knowledge, possession or use of the Products.
- 14. Warranty - Silhouette Hardware:** If You have purchased or leased one or more unit(s) of the Silhouette Hardware, the Terms of Use sets forth the Limited Warranty applicable to the Silhouette Hardware. Except as set forth in the Terms of Use, all other representations or warranties (statutory, express or implied except any which may not lawfully be excluded) with respect to the Silhouette Hardware are expressly excluded. Without prejudice to the generality of the foregoing, the implied warranties of merchantability and fitness for a particular purpose are excluded.
- 15. Warranty - Software:** The Silhouette Software is licensed to You "as is" and all representations or warranties (statutory, express or implied except any which may not lawfully be excluded) are expressly excluded. Without prejudice to the generality of the foregoing, the implied warranties of merchantability and fitness for a particular purpose are excluded. You acknowledge that the Silhouette Software operates in a predictive manner relative to input of which AML has no control over the collection, use or interpretation, and You accept the entire risk as to the use and the results of the use of the Silhouette Software in the terms of correctness, accuracy, reliability and performance. You also accept the entire risk as to any conflict between Silhouette Software and other software on the hardware on which the Silhouette Software is installed.
- 16. Data:** If the Order Form includes a license of SilhouetteCentral with data to be hosted by You, You will be exclusively responsible for security and integrity of data, including regular back up of data. If the Order Form includes a license of SilhouetteCentral with data hosted by AML, then upon termination of Your license of SilhouetteCentral, AML will take Your instance of SilhouetteCentral off line, but will offer You an archive of images and wound assessment records, provided You pay for AML's usual commercial charges for the cost of preparing the archive. This archive will be in the form of jpg images, an export of the wound measurement data in a CSV (comma separated value) format file, and an export of SilhouetteCentral format data. This archive will be provided on an industry standard media (such as DVD) that AML will select at the time.
- 17. Government Licenses of Software.** The Silhouette Software and related documentation are "Commercial Items", as that term is defined at 48 C.F.R. §2.101, consisting of "Commercial Computer Software" and "Commercial Computer Software Documentation", as such terms are used in 48 C.F.R. §12.212 or 48 C.F.R. §227.7202, as applicable. Consistent with 48 C.F.R. §12.212 or 48 C.F.R. §227.7202-1 through 227.7202-4, as applicable, the Commercial Computer Software and Commercial Computer Software Documentation are being licensed to U.S. Government end users (a) only as Commercial Items and (b) with only those rights as are granted to all other end users pursuant to the terms and conditions herein. Unpublished-rights reserved under the copyright laws of the United States.

- 18. Liability:** TO THE EXTENT NOT PROHIBITED BY LAW, IN NO EVENT SHALL AML BE LIABLE FOR PERSONAL INJURY OR ANY INCIDENTAL, SPECIAL, INDIRECT, OR CONSEQUENTIAL DAMAGES WHATSOEVER, INCLUDING, WITHOUT LIMITATION, DAMAGES FOR LOSS OF PROFITS, LOSS OF DATA, BUSINESS INTERRUPTION, OR ANY OTHER COMMERCIAL DAMAGES OR LOSSES, ARISING OUT OF OR RELATED TO YOUR USE OR INABILITY TO USE THE PRODUCTS, HOWEVER CAUSED, REGARDLESS OF THE THEORY OF LIABILITY (CONTRACT, TORT, OR OTHERWISE) AND EVEN IF AML HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. SOME JURISDICTIONS DO NOT ALLOW THE LIMITATION OF LIABILITY FOR PERSONAL INJURY, OR OF INCIDENTAL OR CONSEQUENTIAL DAMAGES, SO THIS LIMITATION MAY NOT APPLY TO YOU. In no event shall AML's total liability to You for all damages (other than as may be required by applicable law in cases involving personal injury) exceed the amount of fifty US Dollars (US\$50.00). The foregoing limitations will apply even if the above stated remedy fails of its essential purpose.
- 19. Compliance with Law:** You will not use the Products for any unlawful purpose or in furtherance of any illegal activity. You warrant that You will comply with all applicable federal, state and local laws, executive orders, and regulations. You further warrant that at all times when using the Products you will have obtained all consents and/or permissions as required by law to receive, transfer, use or provide any personal information, Protected Health Information, and/or other data provided, entered, transferred or received by you using the Products, and that your use of the Products will be conducted in accordance with all applicable laws, including but not limited to HIPAA.
- 20. Notice:** Any notice to be given in terms of this CTEULA must be made in writing or by email sent to the address notified by either party to the other from time to time. Any communication by email will be deemed to be received when transmitted to the correct email address of the recipient and any communication in writing will be deemed to be received when left at the specified address of the recipient.
- 21. Force Majeure:** AML will not be liable to You for any delay or failure of AML to perform its obligations hereunder if such delay or failure arises from cause or causes beyond the reasonable control of AML.
- 22. Assignment:** You may not assign or transfer this Agreement or any of the rights or obligations under this Agreement without the prior written consent of AML.
- 23. Agreement:** This Agreement constitutes the entire agreement of AML and You with respect to the subject matter hereof and supersedes any and all prior negotiations and agreements between AML and You with the exception of terms listed in the Order Form and a non-disclosure agreement that may separately be in force between AML and You. The additional terms set forth in the Order Form and in the Terms of Use are incorporated by reference in this Agreement, and You agree to abide by all of such additional terms. In the event of any conflict between the terms of the Order Form and the terms of this CTEULA, the terms of the Order Form shall govern. This Agreement and/or the Terms of Use may be revised by AML from time to time. By accepting any Renewed Term, by paying Support fees or by accepting any Update or Module offered by AML, You will be deemed to have agreed to, and will be bound by, all the terms and conditions of this Agreement and the Terms of Use in its and/or their then most current form, as posted at www.aranzmedical.com. No variation to the terms of this Agreement or the Terms of Use made by You will be binding on AML unless it is in writing and signed by both parties.
- 24. Governing Law:** This Agreement is subject to the laws of New Zealand and You agree to submit to the exclusive jurisdiction of the New Zealand courts.

CTEULA Document Number: 2007-00204, Revision: 11.0

ARANZ Medical Limited – Silhouette® Product Suite Terms of Use

Effective Date: 1 July 2017

This document sets forth terms of use for the Silhouette® Product Suite, and is divided into the following Parts:

Part 1: Defined Terms

Part 2: Warranty Terms

Part 3: Use of Silhouette Software

Part 4: Technical Support Policies

Part 5: General Terms

Parts 1 and 5 apply to all Products, whereas Parts 2 through 4 are divided into sections applicable to individual Products, so you should review Parts 2 through 4 and your Order Form to determine the sections of Parts 2 through 4 applicable to the Products you are purchasing, leasing, licensing and/or borrowing from Us. These Terms of Use are supplemental to the Conditions of Transfer and End User License Agreement (CTEULA) applicable to the Products and all of terms of the CTEULA will apply to your purchase, lease, license and/or loan of the Products.

Part 1: Defined Terms

As used in these Terms of Use, the following terms have the following meanings:

AML means ARANZ Medical Limited.

Image Capture Unit means an image capture device, and includes a Silhouette Device, but also includes a smart phone or tablet provided by You running SilhouetteLite or SilhouetteLite+.

Module means an add-on, option or feature, which is associated with a Silhouette Software product but is licensed for an additional license fee.

Upgrade means a subsequent release of a Silhouette Software product which AML may offer to license holders with a current paid up Support Contract at no additional license fee and may include bug fixes and new functionality.

Order Form means the contract, quotation or purchase order accepted by AML designating which unit(s) of Silhouette Hardware (if any) are being sold, leased or loaned to You and which units of Silhouette Software (if any) are being licensed to You.

Point of Care Access License means a license to SilhouetteCentral that permits specified Image Capture Units to communicate with an instance of SilhouetteCentral.

Products means, collectively, any Silhouette Device or Silhouette Accessory sold, leased or loaned to You, any Silhouette Software licensed to You, and any Support or Services purchased by You.

Services means any additional services purchased by You from AML (and/or its distributor) over and above those services included in Your **Support Contract** (see Part 4 of the Terms of Use for more detail).

Silhouette Accessory means accessory hardware produced by AML, other than the Silhouette Devices, and includes the SilhouetteLite+ Sensor.

SilhouetteCentral means the executable code version of the application software for the storage and organization of wound data, produced by AML under the SILHOUETTECENTRAL™ trademark.

SilhouetteConnect means the executable code version of the application software for wound image processing and storage on a personal computer, laptop or tablet provided by You, produced by AML under the SILHOUETTECONNECT™ trademark.

Silhouette Device means one or more image capture devices in the Silhouette product suite produced by AML, including SilhouetteStar.

Silhouette Hardware means, collectively, the Silhouette Device(s) and the Silhouette Accessory(ies).

SilhouetteLite means the executable code version of the application software for wound image and data capture and processing, produced by AML under the SILHOUETTELITE™ trademark.

SilhouetteLite EULA means the End User License Agreement that the end user agrees to when he/she/it downloads SilhouetteLite or SilhouetteLite+ from the Apple App Store.

SilhouetteLite+ means the executable code version of the application software for wound image and data capture and processing with the SilhouetteLite+ Sensor, produced by AML under the SILHOUETTELITE+™ trademark.

SilhouetteLite+ Sensor means the range finder accessory device, and associated battery charger, produced by AML under the SILHOUETTELITE+ SENSOR™ trademark.

Silhouette Software means collectively SilhouetteCentral and SilhouetteConnect, and also includes Upgrades and Modules with respect to each of same. The “Silhouette Software” also includes any documentation provided or made available to You by AML in connection with and pertaining to the Silhouette Software, whether in printed or electronic format, and any associated media or printed materials pertaining to the Silhouette Software. For clarity, as used herein, the term “Silhouette Software” does not include SilhouetteLite or SilhouetteLite+, as those products are licensed under the terms of SilhouetteLite EULA.

SilhouetteStar means the SILHOUETTESTAR™ image capture device.

Support means the support services that AML provides to license holders of the Silhouette Software who have paid for a Support Contract for the current support period (see Part 4 below).

Support Contract means the contract that the holder of a license of the Silhouette Software must purchase as a precondition to receiving Support and Updates during a designated support period (see Part 4 below).

Terms of Use means these ARANZ Medical Limited Silhouette® Product Suite Terms of Use, as such Terms of Use may be revised from time to time.

You or Your means the person or entity that purchases, leases or borrows Silhouette Hardware and/or holds a license of the Silhouette Software.

Part 2: Warranty Terms

Section 1 - Silhouette Hardware

Overview

Each unit of Silhouette Hardware is covered by a limited warranty (the **Limited Warranty**) for a period of 12 months from the date that unit is delivered to you. The Order Form may offer you the option of purchasing a warranty extension, pursuant to which the Limited Warranty may be extended for either an additional 12 or an additional 24 months; but the annual rate charged for the Limited Warranty for a unit of Silhouette Hardware will increase as the age of that unit increases and we reserve the right to not offer warranty extension on any unit of Silhouette Hardware.

Scope of Limited Warranty

The Limited Warranty covers failure of the unit of Silhouette Hardware due to manufacturing error or component failure, but expressly excludes any damage or failure that could reasonably be considered to result from: (i) negligence or misuse of the unit of Silhouette Hardware, including dropping of the unit of Silhouette Hardware, (ii) improper operation, use, storage, repair or maintenance of the unit of Silhouette Hardware, (iii) any modification to the unit of Silhouette Hardware not performed by us, or (iv) connection of the unit of Silhouette Hardware to other equipment or software to which it is incompatible.

All other representations or warranties (statutory, express or implied except any which may not lawfully be excluded) with respect to the Silhouette Hardware are expressly excluded. Without prejudice to the generality of the foregoing, the implied warranties of merchantability and fitness for a particular purpose are excluded. We will not be liable to you under the law of tort, contract or otherwise for any direct, indirect or consequential loss or damage, including any loss of profits, however caused, arising out of the use of, loss of use of or disrepair of the Silhouette Hardware. If any limitation of liability is invalid for any reason and we become liable for loss or damage that would otherwise have been excluded, such liability to You for all damages will not (other than as may be required by applicable law in cases involving personal injury) exceed the amount of fifty US Dollars (US\$50.00).

Warranty Procedure

In order to receive warranty service for a unit of Silhouette Hardware, the Limited Warranty for that unit of Silhouette Hardware must be in effect on the date on which a warranty claim is lodged by you. You may lodge a warranty claim by email or by calling our technical support line during Support hours. When a warranty claim is lodged, we will assign your warranty claim a Case Number. In most cases it will be necessary for you to ship the unit of Silhouette Hardware to us for evaluation of your warranty claim. If your warranty claim is covered by the Limited Warranty, we will repair or replace the damaged or defective article and will pay for shipping in both directions. If your warranty claim is not covered by the Limited Warranty, you will be responsible for all shipping costs, and if you elect to proceed with repair, you will be responsible for the cost of repair at our usual rates as then in effect.

Section 2 - Silhouette Software

Disclaimer

If the Order Form includes one or more licenses of Silhouette Software, the Silhouette Software is licensed to you “as is” and all representations or warranties (statutory, express or implied except any which may not lawfully be excluded) are expressly excluded. Without prejudice to the generality of the foregoing, the implied warranties of merchantability and fitness for a particular purpose are excluded. You acknowledge that the Silhouette Software operates in a predictive manner relative to input of which AML has no control over the collection, use or interpretation, and you accept the entire risk as to the use and the results of the use of the Silhouette Software in the terms of correctness, accuracy, reliability and performance. You also accept the entire risk as to any conflict between Silhouette Software and other software on the hardware on which the Silhouette Software is installed.

Part 3: Use of Silhouette Software

Section 1 - SilhouetteCentral – Customer Hosted

Overview

This Section 1 applies if the Order Form includes a license of SilhouetteCentral where data is to be hosted by you on your server.

Installation

SilhouetteCentral is supplied by download from the internet or by other means. The software includes installation instructions for a person skilled in computer system administration to carry out the installation process. To assist in this installation, we will provide remote assistance by connecting to the server computer via the internet. You are responsible for coordinating within your organization to have a properly skilled person available at the site while our service person assists with the SilhouetteCentral installation.

Each Image Capture Unit connects to SilhouetteCentral in one of two ways: (1) an indirect connection via a Point of Care Access License that permits an instance of SilhouetteConnect installed on a personal computer, laptop or tablet to communicate with an instance of SilhouetteCentral, or (2) a direct connection via a Point of Care Access License that permits the Image Capture Unit to communicate directly with an instance of SilhouetteCentral. In either case, configuration is required as described below.

Connection via SilhouetteConnect

Each instance of SilhouetteConnect must be configured to connect with the specific SilhouetteCentral database to allow SilhouetteCentral to synchronize. This configuration is performed by you and all necessary setup information for configuring SilhouetteCentral will be provided to you by us. A Point of Care Access License is required to enable this connection.

ARANZ Medical will provide detailed instructions to you on how to configure an instance of SilhouetteConnect to connect to SilhouetteCentral. ARANZ Medical will provide telephone assistance in the setup of the first license of SilhouetteConnect at no charge. Any requested support for additional licenses of SilhouetteConnect will be considered as support for that license of SilhouetteConnect and processed accordingly.

You are responsible for the setup and maintenance of the connection of each personal computer, laptop or tablet on which SilhouetteConnect is installed to the internet and for ensuring that each instance of SilhouetteConnect is regularly synchronized with SilhouetteCentral. We highly recommend that you synchronize each instance of SilhouetteConnect on each day on which data is collected.

Direct Connection

Where an Image Capture Unit is connected directly to SilhouetteCentral via a Point of Care Access License, each Image Capture Unit must be configured to access your URL and instance of SilhouetteCentral. This configuration is performed by you and all necessary setup information is provided to you by us. You are responsible for the maintenance and performance (to our product minimum specifications) of your wireless internet connection to allow your Image Capture Unit(s) to communicate with your instance of SilhouetteCentral. Your Point of Care Access License will specify the specific Image Capture Unit(s) which may

connect to an instance of SilhouetteCentral via that Point of Care Access License, and You agree not to circumvent this restriction.

In addition, where the Image Capture Unit is a smart phone or tablet, it is necessary for the user to first download and install SilhouetteLite or SilhouetLite+. We will provide minimum specifications for Your smart phone or tablet, and you are responsible for the purchase and maintenance of the smart phone or table at your expense.

System Requirements

We will provide minimum specifications for the computer system for the server. You are responsible at your expense for the purchase and maintenance of all hardware for the server computer. Note: In smaller installations, for example a wound care center or office, SilhouetteCentral can sometimes be installed on an existing computer in the facility. In larger installations, dedicated higher performance servers will be required.

You are responsible at your expense for the Microsoft software required to support SilhouetteCentral including the operating system and SQL Server database. Note that Microsoft currently provides SQL Server Express Edition at no charge. The Express edition has certain performance and database size limitations and is suitable for smaller installations of SilhouetteCentral.

You are responsible at your expense for all hardware and network infrastructure at your site including any remote locations. This includes any network data connection costs. You are also responsible for security and regular backup of data.

Section 2 - SilhouetteCentral – AML Hosted

Overview

This Section 2 applies if the Order Form includes a license of SilhouetteCentral where data is to be hosted by us.

Set up and Use

SilhouetteCentral with data hosting by AML requires no software installation at your site for the SilhouetteCentral instance. Each Image Capture Unit connects to SilhouetteCentral in one of two ways: (1) an indirect connection via a Point of Care Access License that permits an instance of SilhouetteConnect installed on a personal computer, laptop or tablet to communicate with an instance of SilhouetteCentral, or (2) a direct connection via a Point of Care Access License that permits the Image Capture Unit to communicate directly with an instance of SilhouetteCentral. In either case, configuration is required as described below.

Connection via SilhouetteConnect

Each instance of SilhouetteConnect must be configured to connect with the specific SilhouetteCentral database to allow SilhouetteCentral to synchronize. This configuration is performed by you and all necessary setup information for configuring SilhouetteCentral will be provided to you by us. A Point of Care Access License is required to enable this connection.

ARANZ Medical will provide detailed instructions to you on how to configure an instance of SilhouetteConnect to connect to SilhouetteCentral. ARANZ Medical will provide telephone assistance in the setup of the first license of SilhouetteConnect at no charge. Any requested support for additional licenses of SilhouetteConnect will be considered as support for that license of SilhouetteConnect and processed accordingly.

You are responsible for the setup and maintenance of the connection of each personal computer, laptop or tablet on which SilhouetteConnect is installed to the internet and for ensuring that each instance of SilhouetteConnect is regularly synchronized with SilhouetteCentral. We highly recommend that you synchronize each instance of SilhouetteConnect on each day on which data is collected.

Direct Connection

Where an Image Capture Unit is connected directly to SilhouetteCentral via a Point of Care Access License, each Image Capture Unit must be configured to access your URL and instance of SilhouetteCentral. This configuration is performed by you and all necessary setup information is provided to you by us. You are responsible for the maintenance and performance (to our product minimum specifications) of your wireless internet connection to allow your Image Capture Unit(s) to communicate with your instance of SilhouetteCentral. Your Point of Care Access License will specify the specific Image Capture Unit(s) which may connect to an instance of SilhouetteCentral via that Point of Care Access License, and You agree not to circumvent this restriction.

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In addition, where the Image Capture Unit is a smart phone or tablet, it is necessary for the user to first download and install SilhouetteLite or SilhouetteLite+. We will provide minimum specifications for Your smart phone or tablet, and you are responsible for the purchase and maintenance of the smart phone or table at your expense.

General

We will provide instructions on web access to SilhouetteCentral. SilhouetteCentral can be accessed from a Microsoft Windows PC using Microsoft Internet Explorer (version 7 or later) web browser, which you will be required to provide at your expense.

We are responsible for connectivity charges relating to connecting SilhouetteCentral on our server to the internet. You are responsible for any other internet data charges – e.g. if there are charges for the connection of each personal computer, laptop or tablet on which SilhouetteConnect is installed to the internet, and/or for the connection of your Image Capture Unit directly to Silhouette Central via a Point of Care Access License, and for performance and cost of the internet network traffic of any computer system used to access SilhouetteCentral.

We will provide hosting of SilhouetteCentral on the internet and we have sole discretion as to the means of providing this data hosting service (we may host this service on our servers or on third party servers). However we choose to host this service, and provided you comply with the requirements imposed on you under the Section entitled "Security" below, we are responsible for the maintenance and backup of the data transferred to the server hosting SilhouetteCentral.

The SilhouetteCentral server will be off-line for short periods for scheduled (and in some cases unscheduled) maintenance so 100% up-time of the server is not guaranteed. We will back up the SilhouetteCentral server content regularly according to standard industry practice.

Security

We use standard industry practice employed in medical record systems to ensure the confidentiality of data stored on SilhouetteCentral.

You agree to configure SilhouetteConnect and SilhouetteCentral according to guidelines provided by us with regards to maintaining data confidentiality. All information is under username/password protection and you are responsible for selection and modification of all usernames and passwords and for ensuring that the confidentiality of this access information. You agree to allow us to access your instance of SilhouetteCentral for service purposes. You agree that you are responsible for any legal issues (other than our responsibilities with respect to confidentiality and back up described in the previous paragraph) relating to storage of data on SilhouetteCentral.

Termination

You are permitted to terminate your license of SilhouetteCentral only as of the last day of a calendar quarter, by giving us written notice of termination at least 15 days prior to the last day of the quarter, except that where the Order Form specifies a minimum number of quarters, you may terminate your licence only as of or after the last day of the last specified quarter. We will continue to invoice you quarterly for, and you agree that you will continue to pay, Quarterly License Fees for SilhouetteCentral until the effective date of termination of your license.

Following the effective date of termination, including any termination by us pursuant to the terms of the CTEULA or these Terms of Use, we will take SilhouetteCentral off line, archive all images and wound assessment records and provide these to you. (This will be in the form of jpg images, an export of the wound measurement data in CSV (comma separated value) format file, and an export of the Silhouette format data in the event that in future the customer may require this.) A Data Archival Fee will apply to this service. Once this data transfer has occurred, we may, at our discretion, delete all patient data. We reserve the right to provide an alternate means of providing this data hosting service or to discontinue providing SilhouetteCentral at any time; provided, however, that we will not discontinue this service during the period that you have committed to pay hosting fees in the accepted Order Form.

Customization

The software comprising SilhouetteConnect and SilhouetteCentral is standard, and without customization and configuration. Upon Customer request, a customization or configuration service can be made available for an additional charge.

Section 3 - SilhouetteConnect

Overview

This Section 3 applies if the Order Form includes a license of SilhouetteConnect.

Installation

SilhouetteConnect is supplied by download from the internet or by other means, and must be separately installed on each personal computer, laptop or tablet running SilhouetteConnect. The software includes installation instructions for a person skilled in computer system administration to carry out the installation process.

System Requirements

We will provide minimum specifications for the personal computer(s), laptop(s) and/or tablet(s) running SilhouetteConnect. You are responsible at your expense for the purchase and maintenance of the personal computer(s), laptop(s) and/or tablet(s). You are responsible at your expense for all other hardware and network infrastructure at your site including any remote locations, and for any network data connection costs. You are also responsible for security and regular backup of data.

Input/output Unit and Other Limitations

Each license of SilhouetteConnect is restricted to use only on a single personal computer, laptop or tablet. You agree not to exceed this limitation. Where an instance of SilhouetteConnect is not integrated to connect to an instance of SilhouetteCentral, a maximum of 2000 assessments (or other number of assessments specified in the Order Form) may be stored with that instance of SilhouetteConnect. Where that limit is exceeded, you must either purchase an additional license of SilhouetteConnect or a license of SilhouetteCentral.

Part 4: Technical Support Policies

These Technical Support Policies apply to technical support (**Support**) that we provide for the Silhouette Software:

- SilhouetteCentral
- SilhouetteConnect

Support Contracts

Each licence of the Silhouette Software will only be entitled to Support during periods that license is under a current Support Contract. You will not be entitled to Support or Updates for any license of Silhouette Software for which a Support Contract is not purchased. Three levels of Support are offered under different Support Contracts: Minimum Support, Enhanced Support and Premium Support. Unless otherwise provided in an accepted Order Form, if your license is an annual license or is for a shorter Fixed Term, a Support Contract providing Minimum Support is included in the license fees charged for the Fixed Term (or any offered and accepted Renewed Term); provided, if you wish to purchase Enhanced Support or Premium Support for that license, additional fees apply. Unless otherwise provided in an accepted Order Form, if your licence is for a Continuous Term, your license fee will not include a Support Contract. In the case of a license for a Continuous Term, (1) you will not be entitled to Support or Updates unless you purchase a Support Contract for each applicable Support period, at our then current rates, (2) the Support period (usually one year) will be the period for which we have invoiced and you have paid support fees in advance, (3) you will not be required to pay Support fees, but you acknowledge that without Support and Updates the functionality of the Silhouette Software will not progress and may degrade over time, and (4) you may purchase a Support Contract at one of our three offered levels: Minimum Support, Enhanced Support or Premium Support. Further if you and/or a related person or entity holds more than one licence of the Silhouette Software, you or they will not be entitled to Support unless a current Support Contract is maintained on all such licences.

Provision of Support

Support is provided through email and telephone during the Support hours designated in your Support Contract. We will provide you with a telephone number and email address for you to use in seeking Support. You are responsible for all telecommunications charges (telephone, internet, etc.) you incur in contacting us for Support. If a voicemail answers your call or you do not receive a response to your email request during your business hours, we will endeavor to respond within the applicable response time designated in your Support Contract. The person contacting us for Support on your behalf must be knowledgeable about the relevant Product and your environment in order to assist us in analyzing and resolving service requests, and must have a baseline understanding of the problem you are encountering and an ability to reproduce the problem in order to assist us in diagnosing and triaging the problem.

Scope of Support

Support that we provide is remote assistance with technical questions about the Products. It also includes Updates as defined below. The scope of Support (whether Minimum, Enhanced or Premium) is designated in your Support Contract. Regardless of the level of Support purchased by you, Support does not include the following Services: training, product integration, project integration, project implementation, consulting, data review, data processing, data correction or user administration services, data archival services, but these Services may be available for additional fees either directly by us or through our distributors or agents. Support and Services are delivered in English only.

Updates and Modules

Updates with respect to the Silhouette Software may be offered from time to time. Updates of our Silhouette Software Products are offered to license holders of those Products if your license is in effect, with a current paid Support Contract in effect, during the period the release is first offered. Updates and installation instructions are made available by download and you will be responsible for copying, downloading and installing the Updates. If we offer you an Update, but you do not accept it, we will have no obligation to provide Support of older versions. We may offer you Modules from time to time, subject to your payment of any additional license fees and agreement to any terms and conditions applicable to the Module. All Updates accepted by you and all Modules purchased by you will form a part of the Silhouette Software licensed to you and be subject to these Terms of Use and the CTEULA.

Lapsed Support

If Support lapses because you have failed to purchase a Support Contract prior to the commencement of an offered Support period, and you subsequently wish to be reinstated in the Support program, you must:

- a) pay all support fees that would have been payable during the period Support was lapsed had you kept a Support Contract in place on a continuous basis.
- b) update your Silhouette Software to the latest major release.

Discontinuation of Support

We may choose to discontinue Support of any of our Silhouette Software Products (or any release thereof) at any time in the future; however, if your licence is for a Continuous Term we will continue Support for a minimum period of three years from the date of your original purchase of your licence for a Continuous Term, so long as you have purchased a Support Contract for all Support periods during such three year period and have installed all Updates we have offered to you

Use of Information

You recognize that in the course of receiving Support, you or your representatives may furnish data or other information to us or to our distributors or support agents. By furnishing such information you irrevocably consent to the use, transfer and processing of this information by us, our distributors and agents for support purposes and keeping you apprised of Support and Update information.

Contact Us

We value your business and want you to experience success with Silhouette. If for any reason you are not satisfied with the Support you receive, please contact us at quality@aranzmedical.com.

Part 5: General Terms

The Products are supplied with the user interface and supporting documentation in English only.

We may perform any of our obligations under these Terms of Use through a distributor or agent.

These Terms of Use are subject to revision by us at any time, provided we will provide you with advance written notice of any such revisions.

Terms of Use Document Number: 2011-00017, Revision: 3.0