aranz medical

Silhouette v4.6

Installation and Configuration Guide

This document has been prepared by ARANZ Medical Limited for its customers. The content of this document is confidential. It may be reproduced only with written permission from ARANZ Medical Limited. Specifications contained herein are subject to change, and these changes will be reported in subsequent revisions or editions. The device described in this document cannot substitute for the knowledge, skill and experience of the competent medical personnel who are its intended users. Its use as such a substitute is prohibited.

Copyright © 2019 ARANZ Medical Limited

All rights reserved. Unauthorized use, reproduction, or disclosure is prohibited. Patents pending. No patent liability is assumed with respect to the use of the information contained herein. While every precaution has been taken in the preparation of this user's guide, ARANZ Medical assumes no responsibility for errors or omissions. Neither is any liability assumed for damages resulting from use of the information contained herein.

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

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

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

CE Authorised Representative
mdiEUROPA
Phone +49 (0)511 39089530
werner.sander@mdi-europa.com
Langenhagener Str. 71
30855 Langenhagen

EC REP

FDA Authorised Representative
MDI Consultants
Phone +1 (516) 482 9001
alan@mdiconsultants.com

TGA Sponsor #55050
Brandwood Biomedical Pty Ltd
Phone +61 (0) 2 9906 2984
help@brandwoodbiomedical.com

ARANZ Medical Limited documentation often refers to hardware or software products by their trade names. In most, if not all, cases these designations are claimed as trademarks or registered trademarks of their respective companies. The trade names are used here for identification purposes only.

Document Number: 2018-00262 Rev4.0

Contents

Introduction **1**
Notation Convention 1
SilhouetteCentral Installation **2**
Pre-Installation Planning 3
Installing Internet Information Services (IIS) 4
Windows Server 2012 4
Windows Powershell 4
SilhouetteCentral Web Application Installation 5
Software Prerequisite Installation 5
Extract SilhouetteCentral 5
Configure IIS 6
Configure IIS via IIS Manager 6
Configure IIS via Windows Powershell 6
File System Permissions 7
SilhouetteCentral Web Application Configuration 8
Patient Assessment Data File Location 8
SilhouetteConnect Synchronization Related Settings 8
Automatic Email Application Settings 9
Assessment Data Export Related Settings 10
File clean up schedule 10
Preparing a SQL Server Database 11
Using an existing SQL Server Installation 11
Installing SQL Server 11
Creating a SilhouetteCentral Database 12
Creating a Database using SQL Management Studio 12
Creating a Database using Windows Powershell 13
Synchronization Database Configuration 13
SilhouetteCentral Configuration Wizard 14
SilhouetteCentral Backup 17
SilhouetteCentral Upgrade 18
Versions 18
SilhouetteConnect Installation and Initial Configuration **21**
Installing SilhouetteConnect 22
SilhouetteStar 2 Firewall Rules and Networking 23
Upgrading SilhouetteConnect 24
Uninstalling SilhouetteConnect 25
Logging In to SilhouetteConnect 26

Copyright © 2019 ARANZ Medical Limited

Licensing for SilhouetteConnect 27
Obtaining a License 27
Activating Your License 27
Logging Out of SilhouetteConnect 28
Licensing **29**
Licensing Silhouette 29
System Configuration **30**
Assessment and Note Configuration 31
Wound State Configuration 32
Support Information Configuration 33
Measurement Calculation and Display Settings 34
Display Settings 34
Measurement Calculation Settings 34
Application Lock Configuration 35
SilhouetteStar 2 Sleep Timeouts 36

Copyright © 2019 ARANZ Medical Limited

Introduction

This Installation and Configuration Guide focuses on the pre-planning, installation and initial configuration of the Silhouette™ system.

The intended audience for this guide includes Project Managers, Systems Administrators and IT Personnel.

Other useful sources of help:

- For general usage of the Silhouette system, refer to the Silhouette Clinical User's Guide or the Silhouette Administration User's Guide.
- The Silhouette Administration User's Guide contains a system description with information on the system components, the system security and the optional features.
- For the latest system requirements and operating conditions refer to the www.aranzmedical.com web site. If you need the system requirements for a specific Silhouette version, please contact ARANZ support with your request.

This guide is applicable to the following versions of the Silhouette components:

- SilhouetteCentral version 4.6.
- SilhouetteConnect version 4.6.
- SilhouetteStar 2 version 1.7.
- SilhouetteLite version 1.5.
- SilhouetteLite+ version 1.5.

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.

Copyright © 2019 ARANZ Medical Limited

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. Topics covered are:

- Pre-Installation Planning
- Installing Internet Information Services (IIS)
- SilhouetteCentral Web Application Installation
- SilhouetteCentral Web Application Configuration
- Preparing a SQL Server Database
- SilhouetteCentral Configuration Wizard
- SilhouetteCentral Backup
- SilhouetteCentral Upgrade

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.

Copyright © 2019 ARANZ Medical Limited

Pre-Installation Planning

The following pre-installation steps should be performed before commencing the installation of SilhouetteCentral:

- Review the Silhouette CTEULA and Terms of Use, see the ARANZ Medical website (https://www.aranzmedical.com/silhouette-legal/). Installing and using SilhouetteCentral means that you accept these conditions.
- The SilhouetteCentral application uses the Microsoft .NET framework and is hosted by Microsoft Internet Information Services (IIS) on Windows Server machines. Patient demographic and assessment data is stored in a Microsoft SQL Server database, while images are stored outside of the database. Review the latest system requirements and operating conditions from www.aranzmedical.com to ensure the targeted installation platforms and networks are adequate.
- Define the desired URL of the SilhouetteCentral website.
- Plan the network location and network firewall configurations for SilhouetteCentral, considering where users will need to access the system from (e.g. nurses may need to use the system from patient's homes or remote clinics).
- Prepare the server certificates to allow HTTPS to be used. HTTPS communication is required to encrypt data between SilhouetteCentral and the other Silhouette system components.
- The encryption requirements for the server file system and the database are understood and any required keys and recovery mechanisms are prepared.
- 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 and backup systems are prepared.
- Silhouette users and their system access is determined.
- Gather the SMTP server details, for use by SilhouetteCentral to send password reset emails.

Aside from the technical installation considerations, to gain 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 enabling wound data capture at the point of care, which can assist in the achievement of great clinical results. Spending time defining what data you want to collect can help achieve the desired results, while optimizing workflow for clinical staff.

Copyright © 2019 ARANZ Medical Limited

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 and configured. IIS is an optional component of the Windows operating system.

The precise installation instructions are operating system version specific. The instructions are included below for Windows Server 2012.

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**.
11. Tick the **ASP.NET 4.5**, the **Application Initialization** and the **WebSocket Protocol** checkboxes and confirm you want to add the additional features.
12. Click **Next** until you reach the **Confirmation** page, and the click **Install**.

Windows Powershell

If installing on a Windows 2012R2 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-Net45,Web-Mgmt-Console,Web-AppInit, Web-WebSockets
```

Installing using the powershell command above includes the minimum set of features required to run Silhouette. It does not include all components selected by default when installing using the Server Manager UI. For example, the components Web-Dir-Browsing, Web-Http-Errors, Web-Http-Logging and Web-Stat-Compression are selected by default when installing using the Server Manager UI.

If you receive an error message stating “The source files could not be downloaded” insert the Windows installation DVD into your DVD drive and use the following command where the drive letter is your DVD drive:

```
Import-Module ServerManager –Source D:\Sources\Sxs
```

Copyright © 2019 ARANZ Medical Limited

SilhouetteCentral Web Application Installation

The following steps install the SilhouetteCentral web application on IIS.

Software Prerequisite Installation

In order to run SilhouetteCentral, Microsoft .NET 4.8 (https://dotnet.microsoft.com/download/dotnet-framework/net48) 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.

It can be hard to known which versions of the .NET Framework are already installed. Refer to Microsoft's website for "How to: Determine which .NET Framework versions are installed?"

It is also known that Windows updates can occasionally cause problems with the installed .NET frameworks. Microsoft offer a "Microsoft .NET Framework Repair Tool" that detects and repairs frequently occurring .NET Framework issues. This repair tool should be run if SilhouetteCentral reports non-Silhouette related errors when trying to start.

Extract SilhouetteCentral

Unzip the SilhouetteCentral zip file into a sub directory within the main wwwroot folder used by IIS. The name of this folder becomes 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.

If upgrading an existing SilhouetteCentral installation, check the instructions in the SilhouetteCentral Upgrade section.

Copyright © 2019 ARANZ Medical Limited

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:

Configure IIS 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 Application 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 the Managed Pipeline mode as Integrated.
    5. Click OK.
    6. Right-click on the new Application Pool in the list and select Advanced Settings…
    7. Set the Start Mode property to AlwaysRunning.
    8. 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.
    6. Right-click the folder again (which is now an application) and select Manage Application > Advanced Settings…
    7. Set the Preload Enabled property to True.
    8. Click OK.

Configure IIS via Windows Powershell

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"

Set-ItemProperty –path IIS:\AppPools\Silhouette –name "startMode" –value "AlwaysRunning"

New-WebApplication –Name Silhouette –Site "Default Web Site" –PhysicalPath
c:\inetpub\wwwroot\Silhouette –ApplicationPool Silhouette

Set-ItemProperty -path "IIS:\Sites\Default Web Site" -name "preloadEnabled" -value "True"
```

Copyright © 2019 ARANZ Medical Limited

If upgrading an existing SilhouetteCentral installation most of the IIS configuration should already be completed and can be left unaltered. Check through the configuration of the Application Pool and the site to ensure settings are correct.

File System 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 is automatically 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 also requires the following subdirectory specific permissions

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

If SilhouetteConnect as part of your system, then the service account used to run the SQL Server synchronization instance will need to permission to access the folder where SilhouetteConnect databases are stored during the synchronization process (this folder may not exist until after the website has been started). For our default install where the instance name is Silhouette, the user account will be "NT SERVICE\MSSQL$SILHOUETTE".

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

Copyright © 2019 ARANZ Medical Limited

SilhouetteCentral Web Application Configuration

There are a number of web application settings available in the <Main Application Directory>\Files\Settings\machinesettings.xml file. In most installations there is no need to adjust the Web Application settings.

Any adjustments to the MachineSettings file should be made with care and by first taking a copy of the original settings. If an invalid file or invalid settings are detected then the initial SilhouetteCentral setup wizard is displayed when accessing the web site.

Changes to the application settings in the machinesettings.xml are only applied when the associated SilhouetteCentral application pool is recycled.

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 in the MachineSettings configuration 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>
```

Changing this setting does not transfer any existing images and reports to the new location. To change this setting:

1. Stop the SilhouetteCentral application pool,
2. Move the contents of the existing folder to the new location,
3. Update the DataDirectory setting, and
4. Restart the SilhouetteCentral application pool.

SilhouetteConnect Synchronization Related Settings

Synchronization Database Configuration

The connection string used by SilhouetteCentral to connect to the synchronization SQL Server instance can be customized in the MachineSettings configuration file.

```
<SilhouetteConnectDatabaseInstanceConnectionString>Data Source=.\Silhouette;Integrated
Security=SSPI;</SilhouetteConnectDatabaseInstanceConnectionString>
```

Number of days to keep SilhouetteConnect databases

SilhouetteCentral keeps an archived copy of the SilhouetteConnect database when it is uploaded during a synchronization. The SilhouetteConnect database copies are only kept for 10 days by default and are then deleted. The number of days the databases are kept can be customized in the MachineSettings configuration file with a minimum of 1 day.

```
<DaysToKeepArchivedConnectDatabases>10</DaysToKeepArchivedConnectDatabases>
```

Copyright © 2019 ARANZ Medical Limited

Automatic Email Application Settings

When using the automatic assessment email feature there are a number of settings that can be adjusted in the MachineSettings configuration file.

System Event Queue Processing

The following settings allow the period of the System Event processing job and how many system events will be processed in one go. If the email log shows that the system event job is commonly taking more than 30 seconds to run then you should consider reducing the batch size. The batch size given in the configuration is per system event type (assessment create and assessment update).

```
<ProcessAssessmentSystemEventsCronSchedule>* * * * *</ProcessAssessmentSystemEventsCronSchedule>

<ProcessAssessmentSystemEventsBatchSize>1000</ProcessAssessmentSystemEventsBatchSize>
```

Email Attachment Storage

If emails are configured to be sent with attached PDF reports then these reports are generated and stored on the file system.

```
<EmailAttachmentsDirectory>~/Files/Data/EmailAttachments</EmailAttachmentsDirectory>
```

Modifying the Email Attachments Directory doesn't move or clean up the old directory. Clean up must be done manually.

Email Queue Processing

The email queue processing allows you to control how many emails will be attempted in any one period (the period is set by the System Event Queue Processing settings) and how many emails are sent concurrently. These settings may need to be adjusted to fit within sending limits of the SMTP service being used.

```
<ProcessEmailQueueMaximumNumberOfEmailsToSendPerJob>20</ProcessEmailQueueMaximumNumberOfEmailsToSendPer
Job>

<ProcessEmailQueueMaximumNumberOfEmailsToSendConcurrently>5</ProcessEmailQueueMaximumNumberOfEmailsToSe
ndConcurrently>
```

The maximum age for an email in the queue is also adjustable. Any emails still pending after they have been in the queue for more than the maximum age are not sent.

```
<ProcessEmailQueueMaximumAgeOfEmailsInDays>10</ProcessEmailQueueMaximumAgeOfEmailsInDays>
```

Purging System Events and Email Queue

The system event queue and email queue are stored in the database. Silhouette has a daily job that removes old emails and system events. If there is a reason to keep data for longer then the configuration can be adjusted.

```
<PurgeEmailAndSystemEventsIsEnabled>true</PurgeEmailAndSystemEventsIsEnabled>

<PurgeEmailAndSystemEventsCronSchedule>0 1 * * *</PurgeEmailAndSystemEventsCronSchedule>

<PurgeEmailAndSystemEventsBatchSize>500</PurgeEmailAndSystemEventsBatchSize>
```

The minimum age of an item to be purged can be set from 35 to 400 days. Setting a value outside of this range causes the default of 35 days to be used.

```
<PurgeEmailAndSystemEventsMinimumAgeInDays>35</PurgeEmailAndSystemEventsMinimumAgeInDays>
```

Copyright © 2019 ARANZ Medical Limited

Assessment Data Export Related Settings

When using the assessment data export feature there are a number of settings that can be adjusted in the MachineSettings configuration file.

Days to keep data exports

This setting controls how long Silhouette keeps data exports after they are created. Valid settings are from 1 to 7 days. Any non-valid setting will cause the default of 3 to be used.

```
<DefaultMaximumAgeOfExportedDataInDays>3</DefaultMaximumAgeOfExportedDataInDays>
```

Data exports file location

This setting tells where on the file setting to create and store data exports before they are downloaded.

```
<DefaultAssessmentExportDirectory>~/Files/Data/Exports</DefaultAssessmentExportDirectory>
```

Modifying the Default Assessment Export Directory doesn't move or clean up the old directory. Clean up must be done manually.

Data exports stored in this directory will contain patient information. Ensure this directory is adequately protected against unauthorized access.

File clean up schedule

The file clean up schedule controls when the job which cleans up synchronized SilhouetteConnect databases and expired data exports is run.

```
<DefaultCleanUpFilesCronSchedule>0 0 * * *</DefaultCleanUpFilesCronSchedule>
```

Copyright © 2019 ARANZ Medical Limited

Preparing a 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 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 the authentication method selected is "SQL Server," you need the associated username and password.
- Database name, i.e. Silhouette.

Your Database Administrator (DBA) should be able to create the database and provide these details to you. The database can be created empty and SilhouetteCentral populates it during the installation procedure.

Installing SQL Server

If SilhouetteConnect is being supported, then SilhouetteCentral will need access to a SQL Server 2014 instance to be used for the Synchronization process. There are two common cases for the synchronization instance:

1. The main database is hosted on an external server, and only the synchronization instance will be hosted on the server running the SilhouetteCentral website. In this case SQL Server 2014 Express should be installed as the named instance "Silhouette" as documented below.
2. Both the main database and the synchronization instance will be hosted on the server running the SilhouetteCentral website.
    1. If the main database server instance is SQL Server 2014, then this instance will able to be used for both the main and synchronization instance.
    2. If the main database server instance is not SQL Server 2014, then both the main server instance and an instance of SQL Server 2014 Express should be installed as documented below. By default the synchronization instance should be the named instance "Silhouette".

The use of SQL Server Express is not recommended for production installations due to limitations on database performance, size and features.

The exact instructions to install SQL Server depend on the SQL server edition and version. The basic steps are provided below, derived from SQL Server 2014, but it is recommended to read and follow the instructions that come with SQL Server.

1. Run the SQL Server installation executable and click the **OK** button on the “Choose Directory For Extracted Files” dialog.
2. 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).

Copyright © 2019 ARANZ Medical Limited

3. The SQL Server 2014 Setup wizard starts.
4. 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 an appropriate name, e.g. SQLSILHOUETTE, 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 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:

- SQL Server Management Studio
- Windows Powershell

Creating a Database using 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 .\<SQL SERVER NAME> (e.g. .\SQLSILHOUETTE) 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**.

Copyright © 2019 ARANZ Medical Limited

Creating a Database using Windows Powershell

Creation of the SilhouetteCentral database may also be scripted via a powershell command prompt:

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

Invoke-Sqlcmd –ServerInstance .\SILHOUETTE –Query "CREATE LOGIN

[IIS AppPool\Silhouette] FROM WINDOWS WITH DEFAULT_DATABASE=Silhouette"

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

Required permissions on the main database:

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

Required permissions on the synchronization instance:

```
Invoke-Sqlcmd –ServerInstance .\SILHOUETTE –Query "exec sp_addsrvrolemember [IIS AppPool\Silhouette] ,
'sysadmin'"
```

If securing database access using the IIS AppPool\Silhouette user account the database server must be running on the same server as IIS. You may need to 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.

Synchronization Database Configuration

By default SilhouetteCentral expects the synchronization instance to be installed as the named instance "Silhouette" on the same machine. However if this is not the case, then the connection string used by SilhouetteCentral will need to be customized by editing the MachineSettings configuration file, see SilhouetteCentral Web Application Configuration.

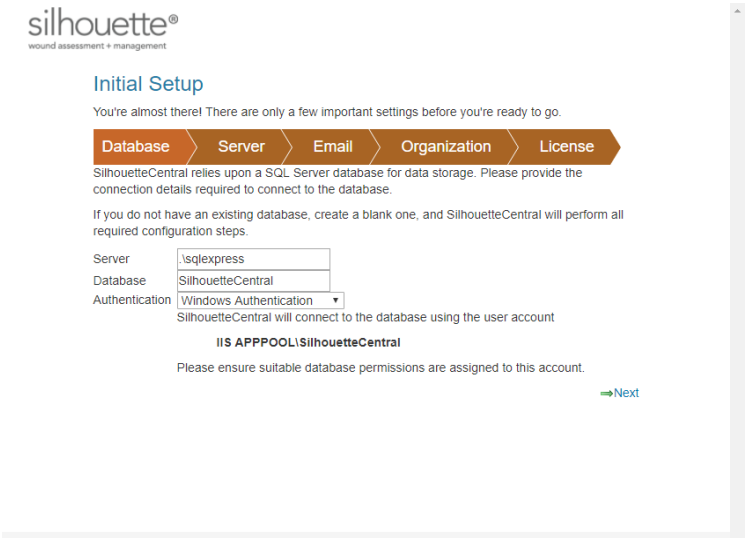
Copyright © 2019 ARANZ Medical Limited

SilhouetteCentral Configuration Wizard

After you have completed the install process, you need to perform some additional setup. The setup automatically runs 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).

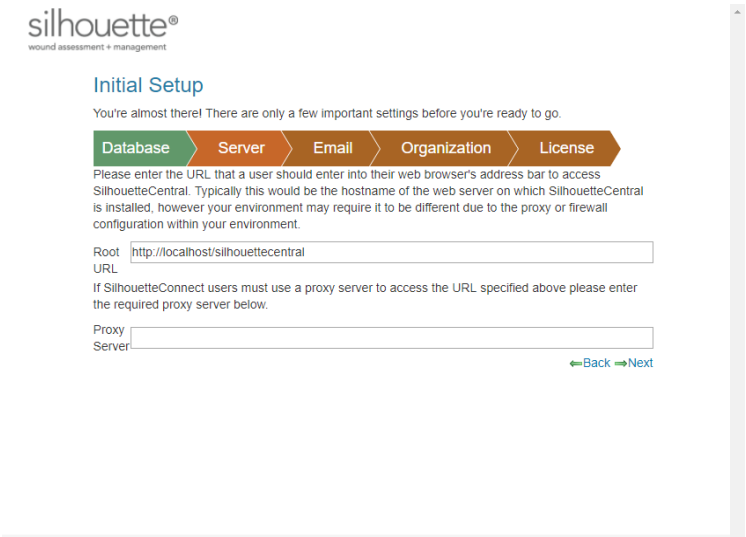
This wizard configures the basic settings required for SilhouetteCentral to run correctly.



Step 1 Database

Enter the connection details to the SQL Server instance and database that Silhouette uses. The database entered here must already exist and it should be a new blank database, see Preparing a SQL Server Database instructions.

The account used to authenticate must have database owner permissions.

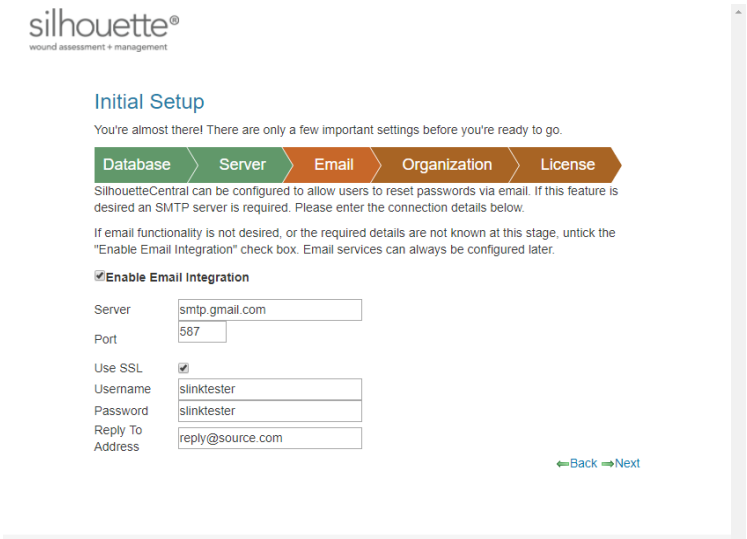


Step 2 Server

The Root URL is the URL of the SilhouetteCentral instance.

The root URL must be a resolvable hostname on your network. Please make sure this is correctly entered here. Failure to enter the correct value for the Root URL causes a SilhouetteStar 2 Wi-Fi connection failure and possibly a user login failure.

Copyright © 2019 ARANZ Medical Limited



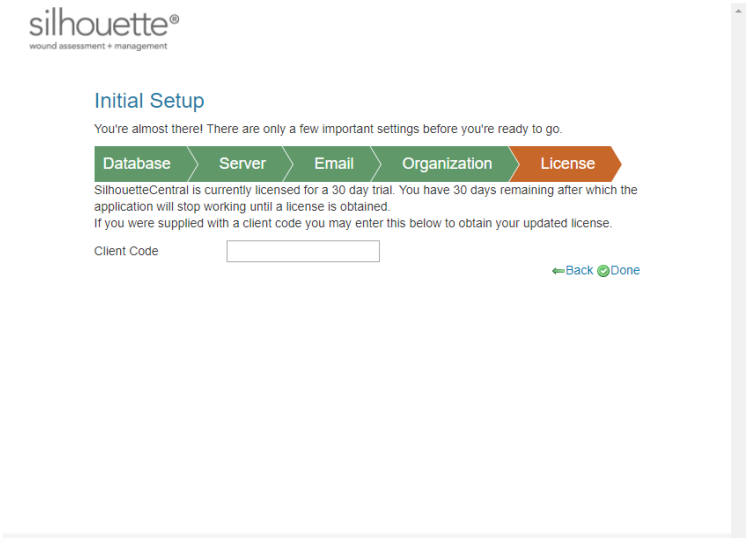
Step 3 Email

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 should be displayed to the systems users. It can include contact details of a support person.

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



Step 5 License

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

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

This step may complete automatically, depending on how you obtained your SilhouetteCentral installation files .

Copyright © 2019 ARANZ Medical Limited

Step 6 Initial Log on

With the web browser window opened at the SilhouetteCentral login page, login using the default credentials:

User name = admin

Password = aranz

On the next screen you are prompted to change this password.

Step 7 Password Change

This step changes 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.

Copyright © 2019 ARANZ Medical Limited

SilhouetteCentral Backup

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

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 should be similar to:

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

Copyright © 2019 ARANZ Medical Limited

SilhouetteCentral Upgrade

In order to upgrade extract the contents of the SilhouetteCentral ZIP file and replace the existing contents in inetpub wwwroot folder (refer to SilhouetteCentral 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, it is possible a "database is upgrading" screen is displayed as the existing database content is converted to the newer format. SilhouetteCentral is not accessible to any users while the database is upgrading.

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 (the wizard is automatically populated with all originally specified information).

After an upgrade which changes the major version number (e.g. v3 to v4) then the system settings should be reviewed for desired configuration, e.g. users, groups, units, notes definitions, etc.

Versions

The method specified above can be used to upgrade SilhouetteCentral from any version greater than v3.10. The following notes are provided as there are some versions where additional care must be taken.

From v3.x To v4.x	Upgrading from v3.x to v4.x is a major upgrade and the following points need consideration. If you have any queries or concerns please contact ARANZ Medical Limited before upgrading, at: support@aranzmedical.com • For versions prior to v3.10 of the software, it is recommended that a customer support representative be contacted to assist with this process. • Tissue Type Classification feature is not available in v4.6. Any tissue type outlines need to be segregated in the data before upgrading. • The storage format of the image captured date is converted based on the Default Timezone specified in the Organization Settings. As such, you should verify that the Default Timezone setting is correct prior to starting the upgrade. If an adjustment has to be made, then synced the change to all SilhouetteConnect devices before proceeding with the upgrade. The automatic upgrade process assumes that all image capture dates are from a single timezone. If data should be split into multiple timezones this needs to be performed by a customer support representative. • Data consistency issues (e.g. duplicate wound IDs for a single patient) this may cause upgrades to fail. These data consistency issues must be fixed before an upgrade can complete.

Copyright © 2019 ARANZ Medical Limited

- SilhouetteLink is not compatible with v4.6.

From pre-v4.3

To v4.3+

Upgrading to v4.3 or beyond requires that a synchronization instance of SQL Server be available on SilhouetteCentral to support the SilhouetteConnect synchronization process. The synchronization instance of SQL Server needs read and write access to the appropriate files\mdfcreation directory.

It is also recommended to modify the SilhouetteCentral web site configuration in IIS to set Preload Enabled to True and to set the Application Pool Start Mode property to Always Running. The optional IIS Application Initialization feature is required to enable these properties.

See the following topics for more details:

- Installing Internet Information Services (IIS)
- Preparing a SQL Server Database.
- SilhouetteCentral Web Application Installation.

From pre-v4.4

To v4.4+

Upgrading to or beyond v4.4 changes the way assessment dates are stored. Assessment creation dates are changed to record the local time plus an offset from UTC, as well as recording the time zone name of where they were created.

The time zone database used by Silhouette is the iana time zone database. Information on the iana time zone database can be found on the website https://www.iana.org/time-zones.

During the upgrade to v4.4 the upgrade will ask you to select an appropriate time zone to use for historical assessments. Selecting the correct time zone is important as the offset from UTC applied is dependent on any seasonal clock changes for that time zone.

The upgrade will ask you to specify a time zone per unit in the database. The assumption is that if you do use the system between time zones then the patients seen in different time zones will be in different units.

If the assumption above does not hold for your system then you will need to contact ARANZ Medical for support while upgrading.

From pre-v4.6

To v4.6+

Version 4.6 reintroduces the concept of Wound State which was part of version 3 Silhouette but had previously been missing from the version 4 product.

If you are upgrading from a v3 Silhouette then the wound state records will be upgraded. These upgraded entries will appear as wound state changes on the relevant patient and wound time lines. The time given to the wound state records is 00:00, in some case if a wound was healed on the same day as an assessment was completed for that wound then the healed state will show earlier than the assessment on the time line.

All wounds created in previous v4 versions of Silhouette are given an Open state based on the creation date and time of the wound.

This wound state upgrade requires the time zone mappings mentioned above in the v4.4 upgrade. If the time zone to unit mappings are not present or are incomplete then you will be asked to specify them during the first start of SilhouetteCentral.

Copyright © 2019 ARANZ Medical Limited

Version 4.6 wound state also allows you to update the current wound state as part of a wound assessment. When upgrading any assessments will have a blank associated wound state record.

Copyright © 2019 ARANZ Medical Limited

SilhouetteConnect Installation and Initial Configuration

This section describes the basic installation of SilhouetteConnect and the initial configuration. The process is the same for either standalone or synchronized modes of operation. See the Silhouette Administration manual for further configuration options.

Topics covered in this section are:

- Installing SilhouetteConnect
- SilhouetteStar 2 Firewall Rules and Networking
- Upgrading SilhouetteConnect
- Uninstalling SilhouetteConnect
- Logging In to SilhouetteConnect
- Licensing for SilhouetteConnect
- Logging Out of SilhouetteConnect

Copyright © 2019 ARANZ Medical Limited

Installing SilhouetteConnect

There are two files required to install SilhouetteConnect: setup.exe and SilhouetteConnect.msi. These files can be obtained from ARANZ Medical support.

Download SilhouetteConnect from SilhouetteCentral

The SilhouetteConnect installer can be downloaded from an instance of SilhouetteCentral by using a web browser to navigate to https://<SilhouetteCentral URL>/install.

When the SilhouetteConnect installer is downloaded from a SilhouetteCentral instance, it includes a third file, CustomProperties.xml, which bootstraps the installation of SilhouetteConnect with the initial configuration. The initial configuration which can be set by the CustomProperties.xml file includes:

- The client code
- Synchronization URL
- License Service URL
- The time zone unit mappings required to upgrade data.

Once the installation files are obtained:

1. Navigate to the folder that contains the installation files.
2. Double click the setup.exe file to start the installation process.
3. The install requires admin permissions to install.
4. Follow the on-screen instructions, which includes the acceptance of the Silhouette CTEULA and Terms of Use, see the ARANZ Medical website (https://www.aranzmedical.com/silhouette-legal/).

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.

The installer includes the drivers for SilhouetteStar, as well as, any necessary SilhouetteStar 2 software patches. These drivers are installed per USB port when a SilhouetteStar is connected to the computer.

The firmware in a SilhouetteStar 2 upgrades or downgrades to the latest compatible version when it is connected to SilhouetteConnect. See the Clinical User Manual for information on connecting a SilhouetteStar and getting started with Silhouette.

Copyright © 2019 ARANZ Medical Limited

SilhouetteStar 2 Firewall Rules and Networking

The SilhouetteStar 2 in wired mode uses RNDIS drivers to communicate. This means that when the SilhouetteStar 2 is connected to a computer using the USB cable, the device is seen as a IP Network interface with an Ethernet device appearing in the networking section of windows.

The IP Network interface gets assigned a known IPv4 address by the SilhouetteStar 2. By default this address is a link-local address, 169.254.0.2. The addresses used can be changed, see the Administration User's Guide for details.

The SilhouetteConnect installer inserts firewall rules into the default Windows firewall to allow the SilhouetteStar 2 to connect to the computer on TCP port 9874. If a firewall other than the default Windows firewall is being used then the user must manually add a firewall rule to allow connections on TCP port 9874 for all network profiles (domain, public and private PCs).

The SilhouetteStar 2 appears to the computer as a wired network with no internet access.

Some third party network management software can offer network adapter switching features, either turning off Wi-Fi if there is a wired connection present or not allowing a wired connection if also using a Mobile connection. Care must taken to determine the correct compatibility and configuration to allow both a network connection and a SilhouetteStar 2 connection.

Copyright © 2019 ARANZ Medical Limited

Upgrading SilhouetteConnect

If the computer has, or has had, a previous version of SilhouetteConnect installed, then the installer will attempt to use the SilhouetteConnect clinical data and related settings already present on the computer. To remove the clinical data and SilhouetteConnect settings from a computer see the uninstall instructions.

When upgrading a standalone SilhouetteConnect to v4.4 or beyond, then when you first start SilhouetteConnect you will be asked to select which time zone your historical assessments were captured in. You will be asked to select a time zone per unit, however, for a standalone SilhouetteConnect it is expect that all time zone selections are the same. See "SilhouetteCentral Upgrade" for more details on why the time zone mapping is requested.

If you are upgrading a synchronized SilhouetteConnect then it is required that you obtain the specific installer from your SilhouetteCentral instance, via https://<SilhouetteCentral URL>/install. This installer contains specific information to ensure that the data in SilhouetteConnect is upgraded in the same way as the data in SilhouetteCentral.

SilhouetteConnect v4.6 and beyond reintroduces wound state recording in Silhouette. See "SilhouetteCentral Upgrade" for details on how existing wounds are updated to include state information during the upgrade.

Copyright © 2019 ARANZ Medical Limited

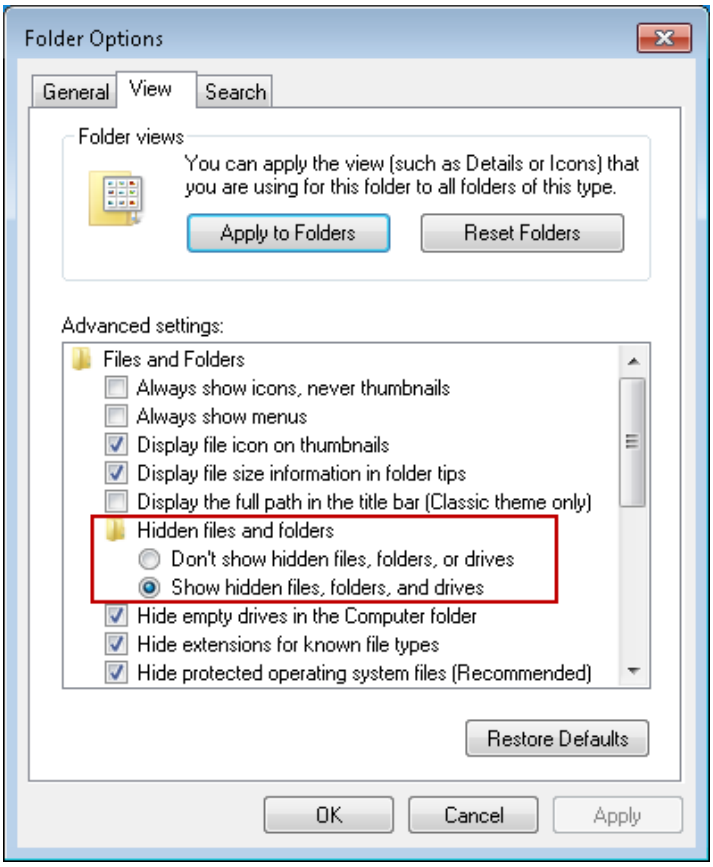
Uninstalling SilhouetteConnect

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. Hidden folders can be shown by selecting the **Show hidden files, folders, and drives** folder option:



Copyright © 2019 ARANZ Medical Limited

Logging In to SilhouetteConnect

SilhouetteConnect presents a **login** prompt when starting the application. To log in 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.

For standalone, fresh installs of SilhouetteConnect, a default login is provided:

- **User Name**: admin
- **Password**: aranz

The system prompts for the default password to be changed when initially logging in. New user accounts can be created once logged in.

Copyright © 2019 ARANZ Medical Limited

Licensing for SilhouetteConnect

Obtaining a License

In order to use SilhouetteConnect, you must first obtain and activate a license.

To obtain a license call your ARANZ Medical representative or contact support@aranzmedical.com.

Activating Your License

Once a license has been obtained, you are provided a unique client code. When you first launch and login to SilhouetteConnect, a screen appears, 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.

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

The license activation screen is no longer displayed on application start once SilhouetteConnect is licensed. The screen reappears and can be used to re-license your copy of SilhouetteConnect once your license expires.

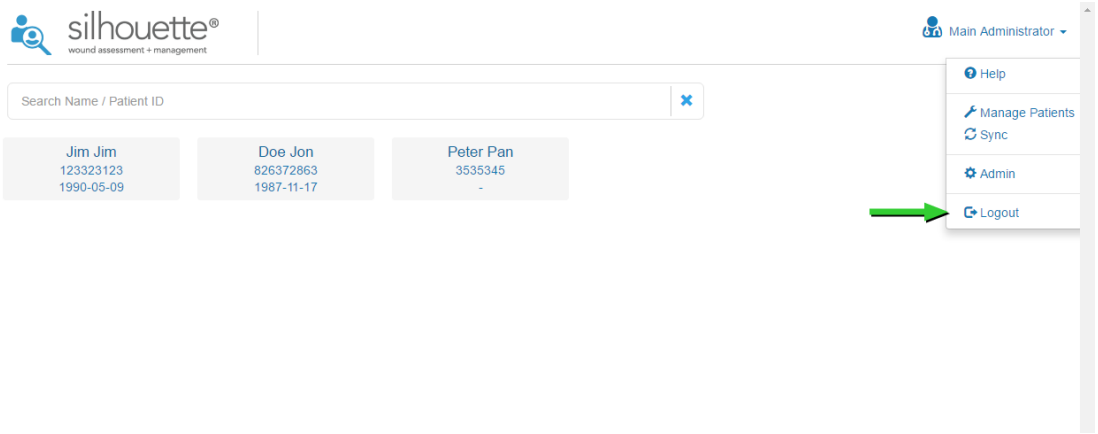
Pre-populated client code

If you have downloaded the installation package for SilhouetteConnect from a SilhouetteCentral instance, the license details are pre-populated and the activation screen does not display on first launch.

Copyright © 2019 ARANZ Medical Limited

Logging Out of SilhouetteConnect

You can log out of SilhouetteConnect by clicking the **Logout** button in the bottom left. Logging out takes you back to the log in screen.



If you leave the application unattended for the application lock time, then the application automatically logs you out. The default application lock time is set to 10 minutes. See "System Configuration" to change the default application lock time.

Copyright © 2019 ARANZ Medical Limited

Licensing

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

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

Licensing Silhouette

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

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

HTTP Proxy Configuration

The ARANZ Medical licensing server is hosted on the internet at www.silhouettecentral.com. When attempting communication with the licensing server Silhouette uses .NET's default proxy settings. If your network environment requires Silhouette to use a different proxy server this can be specified by updating the defaultProxy setting within Silhouette's web.config file.

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

```
<system.net>
  <defaultProxy enabled="true">
     <proxy proxyaddress="http://192.168.2.1:8888"/>
  </defaultProxy>
</system.net>
```

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

Copyright © 2019 ARANZ Medical Limited

System Configuration

Silhouette can be configured to match clinical needs. Configuration of users, groups, units, and SilhouetteStar 2 settings can be performed via the admin interface. For details please see the Silhouette Administrator's User Guide.

In SilhouetteConnect, some of the configuration available depends on the mode SilhouetteConnect is operating in. For example, if SilhouetteConnect is operating in synchronized mode then the configuration is mostly contained in SilhouetteCentral.

Other settings and features are available for configuration by ARANZ Medical Support users. The other settings are listed below. The items listed in bold text are items that should be reviewed with ARANZ Medical and set up when the system is first installed. These settings are ideally locked down before clinical user training is undertaken, as they can effect user workflow significantly.

- **Assessment type configuration**, see Assessment and Note Configuration.
- **Patient and Wound Notes configuration**, see Assessment and Note Configuration.
- **Wound State configuration**, see Wound State Configuration.
- SilhouetteLite and SilhouetteLite+ Touch ID configuration (SilhouetteCentral Only).
- Branding Logo (SilhouetteCentral Only).
- **Support information** (SilhouetteCentral Only), see Support Information Configuration.
- **Measurement calculation and display settings**, see Measurement Calculation and Display Settings.
- Data export settings (SilhouetteCentral Only).
- Report settings (SilhouetteCentral Only).
- Password settings (SilhouetteCentral Only).
- **Application lock settings**, see Application Lock Configuration.
- SilhouetteStar 2 connection RootURL (SilhouetteCentral Only).
- **SilhouetteStar 2 sleep timeouts**, see SilhouetteStar 2 Sleep Timeouts.
- Synchronization settings.
- Log access (SilhouetteCentral Only).

The items in bold above are items that should be reviewed with ARANZ Medical and set on installation. These settings are ideally locked down before clinical user training is undertaken as they can effect user workflow significantly.

Copyright © 2019 ARANZ Medical Limited

Assessment and Note Configuration

Assessments provide the core workflows and charting for the Silhouette system. Creating the right set of assessments and notes is important for optimizing clinical efficiency and providing key metrics for clinical review later on. Working through what and when information needs to be recorded as part of initial system configuration is important to encourage consistent use and aids in change management.

The Administration User's Guide contains an appendix with the default configuration of assessments and notes which can be reviewed.

Copyright © 2019 ARANZ Medical Limited

Wound State Configuration

Silhouette has the ability to record wound state, including if a wound is Open, Healed, Amputated or Released from Follow-up. It is also possible to include data capture when setting the wound state (e.g. minor amputation vs. major amputation).

The labels for the selectable wound states and the associated notes you wish to record with the selection can be changed but only by direct database manipulation. Setting these as part of initial system configuration is important to provide consistent data capture.

The Administration User's Guide contains an appendix with the default configuration of wound state values and associated notes which can be reviewed.

Copyright © 2019 ARANZ Medical Limited

Support Information Configuration

Custom support information can be configured to give your end users the correct contact details for first line support when they need help using Silhouette.

A custom message can also be displayed on the login page if you wish.

Copyright © 2019 ARANZ Medical Limited

Measurement Calculation and Display Settings

Silhouette allows the configuration of measurement display and calculations. The following is a list of variables that can be configured on initial system deployment.

Display Settings

- Date format
- Time format
- Wound Label format
- Show Area
- Show Island Area
- Show Perimeter
- Show Axis
- Show Rulers
- Show Max Depth
- Show Mean Depth
- Show Volume
- Area Units
- Depth Units
- Length Units
- Volume Units
- Rounding of measurements in CSV exports

Measurement Calculation Settings

- Axis Method
- Ignore Islands in Area Computations
- Ignore Islands in Perimeter Computations

Copyright © 2019 ARANZ Medical Limited

Application Lock Configuration

The application lock sets the time the application will remain available without any user interaction before it will timeout the user session.

If the user session times out, the user is logged out and must log in again before continuing with the Silhouette operation.

Copyright © 2019 ARANZ Medical Limited

SilhouetteStar 2 Sleep Timeouts

The SilhouetteStar 2 timers can be adjusted. There are three values that can be changed

Idle time before sleep (no images)	Sets the time that the SilhouetteStar 2 device will wait with no user interaction before going into sleeping Kiwi mode. Set in seconds between 60 and 1200 seconds. The default value is 120 seconds.
Idle time cycles before sleep (with images)	The time before entering sleeping Kiwi mode can be extended by up to 10 cycles of the idle timer if there are images waiting to upload. The default setting is 5 cycles. This means that, given the **Idle time before sleep (no images)** is set to 120 seconds, the device will wait 5 x 120 seconds before going into sleep mode.
Sleep time before turning off	Sets the time the device is in sleeping Kiwi mode before turning off. Set in seconds between 60 to 3600 seconds. The default value is 900 seconds (15 minutes).

To optimize the device battery shift life, set the timers to their minimum values.

To optimize the device for operational convenience, set the timers to higher values.

The Silhouette application lock time must also be considered when setting the **Idle time before sleep**. If the application lock times out, the user is logged out and the SilhouetteStar 2 will need to be manually reconnected.

The sleep time of the end user computing devices being used to browse to the SilhouetteCentral web site and connect the SilhouetteStar 2 must also be considered. If the device being used to browse to SilhouetteCentral goes to sleep (or locks the screen in the case of a tablet), the SilhouetteStar 2 will need to be manually reconnected.

It is recommended that the SilhouetteStar 2 timers be set shorter than the application lock and the computing device timers.

Copyright © 2019 ARANZ Medical Limited