# COSMETRIČS... USER GUIDE

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### 1. Introduction

Welcome to COSMETRICS, the Clinical Trials Manager for SIAscopy. COSMETRICS utilizes the power of SIAscopy to quantify change in Blood, Melanin and Collagen concentration up to 2mm below the surface of the skin. COSMETRICS performs statistical analysis on each chromophore, tracking changes over time allowing you to visualise and validate the performance of your product with reproducible accurate results. Ideal for any Clinical Trial.

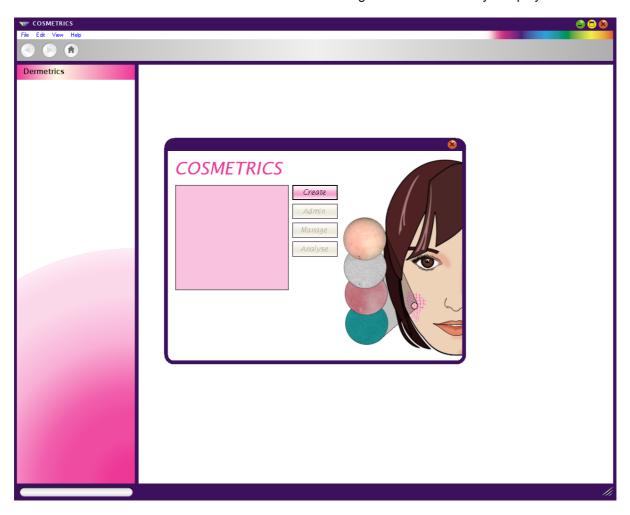
COSMETRICS is part of Astron Clinica's Skin Cosmetics Family. This means that it shares parts of the underlying DERMETRICS platform with the other families, in the case of COSMETRICS it shares the **Patient Management System**. This means that the appearance of the Patient Manager as can be seen in the section Using the Patient Manager contains text used by other families and all reference to **Participants** will be seen as **Patient**.

# 2. Getting started

To begin using COSMETRICS, Double Click on the COSMETRICS icon located on the desktop of the computer being used.



When the COSMETRICS software is loaded the main navigation screen is always displayed.



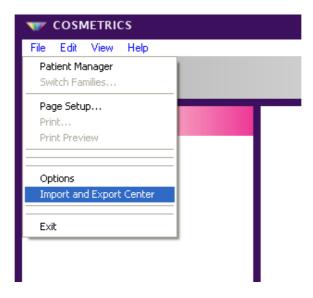
### 2.1. Importing the SIAscope IV Calibration Data

# ! Important

The calibration data for the handset must be imported before using the SIAscope IV

Begin by putting the calibration data CD into the CD drive of the computer being used.

Next Click on the File menu option from the COSMETRICS tool bar.



The **Import and Export Center** page will be displayed.

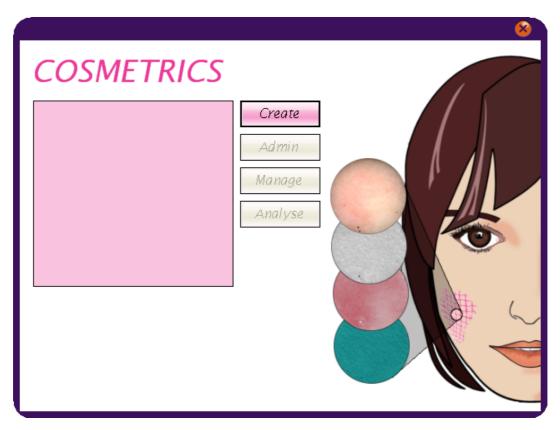


Click on the option Import Calibrations from file. This will display a browse window and using this navigate to the location of the CD. Double Click on the CD and then select the calibration folder and Click on OK to start the import process. Once completed successfully a message confirming a successful import will be displayed. Close the Import and Export Center.

If the Calibration import fails first check that the file located contains the calibraion data required and repeat the process. If the process repeatedly fails please contact Astron Clinica Technical Support.

### 2.2. Navigating COSMETRICS

The COSMETRICS window is used to navigate to the features available within the software. If the COSMETRICS window is not displayed, **Click** on the **Home** button in the tool bar and it will be displayed.



**Create - Clicking** on the **Create** button will open the **New Trial Wizard** so that a trial can be created. For instructions on using the new trial wizard go to the **Creating a New Trial** section.

**Admin - Clicking** on the **Admin** button will open the **Administration Tool** for the selected trial. For instructions on using the Administration Tool go to the Administration Tool section.

**Manage** - To open an existing trial, **Click** on the name from the list displayed and then **Click** on the **Manage** button. This will display the **Trial Manager** window for the trial. For instructions on using the Trial manager go to the **Trial Manager** section.

**Analyse** - To analyse the data captured for an existing trial **Click** on the name from the list displayed and then **Click** on the **Analyse** button. The analysis window will open for the chosen trial. For instructions on using the new trial wizard go to the **Trial Analysis** section.

### 3. Creating a new trial.

COSMETRICS uses an intuative wizard to guide users through the trial set up process. During this process a list of participants will be required to complete the set up of the trial. There are two methods for adding participants to the trial. The first is by importing the data from from an external .csv file, the second is using the participant manager that exists within the COSMETRICS platform.

The example followed in this section will use a .csv file to import the participants and will explain how to add participants using the **Import Participants from the Participant database** part of the wizard. Instructions on how to manage the patient database within COSMETRICS can be found in this manual under the section Patient Database.

### 3.1. New Trial Wizard

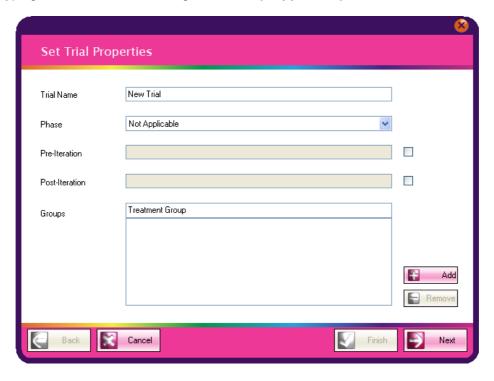
To set up a new trial **Click** on the **Create** button in the COSMETRICS window. This will open the New Trial set up wizard.



### Note

Once the trial has been set up it possible to edit some of the settings. Please refer to the Administration Tool section of this guide on how to do this.

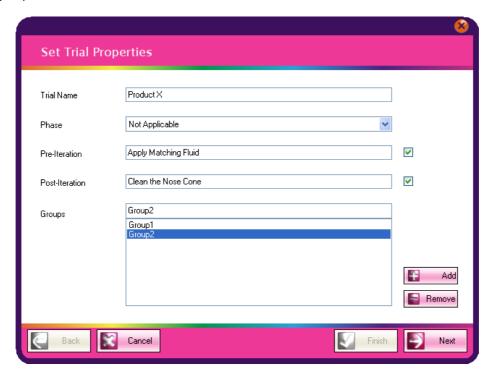
Begin by typing a Trial Name and setting the Phase (if applicable).



The fields for **Pre-Warning Text** and **Post-Warning Text** can be added by checking the boxes at the end of each text box and then entering the text required.

- Pre Iteration The text entered will be displayed on the screen at the beginning of each trial iteration.
- Post Iteration The text entered will be displayed on the screen at the end of each trial iteration.

Now add a Treatment Group. Click in the **Treatment Groups** text box and type in the new group name then **Click** on the **Add** button. The new group will appear in the window below. Repeat to add multiple groups.



To remove a Treatment Group Click on the name in the list and then Click the Remove button.

To move to the next window **Click** on the **Next** button.

The **Custom Trial Data** can be set up in this section. These fields are used when the data collected in the trial is exported from COSMETRICS.



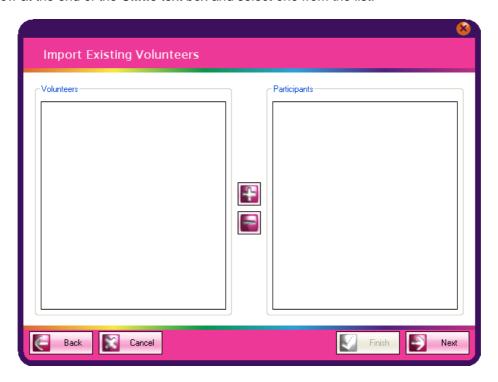
Custom Text Globals - Sets any text fields that may be needed in the spreadsheet if the trial data
is exported. An example using the Custom Text Field would be to set the Name field to Company Name and set the corresponding Value to your company name. This text would then be added to the spreadsheet.

Custom Numerical Globals - Sets any numerical fields that may be needed in the spreadsheet if
the trial data is exported. In a similar way to the custom text fields set the name of the field and the
numerical value to be displayed.

When the required fields have been entered **Click** on the **Next** button.

The next step is to import participants into the trial. This is done using two methods. The first is from the database within the COSMETRICS software. To use this method continue with the wizard page displayed. The second method is from an external data source such as a spread sheet. To use this method **Click** on the **Next** button to move to the correct wizard page and go to the section Import Participants from an external data source.

The **Import Patients from the DERMETRICS database** wizard window is divided in two. The left hand side shows a list of participants for the chosen clinic. To choose another clinic **Click** on the drop down arrow at the end of the **Clinic** text box and select one from the list.

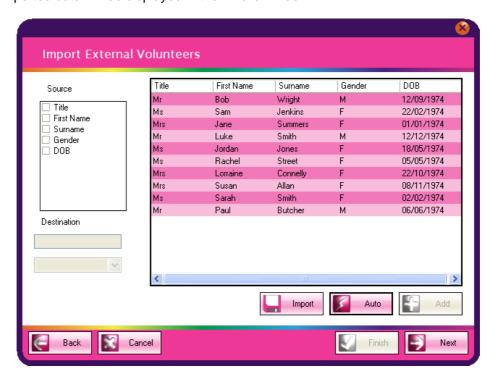


When the required participants are displayed in the list they need to be moved across to the trial. This is done by **Clicking** on the name so that it is highlighted. Then **Click** on the + button to move them across. Repeat the process for all the required participants. Multiple participants can be selected by **Clicking** and dragging down the list and then **Clicking** on the + button.

If a participant has been added to the trial by mistake they can be removed by selecting the name from the participant list on the right and **Clicking** on the - button.

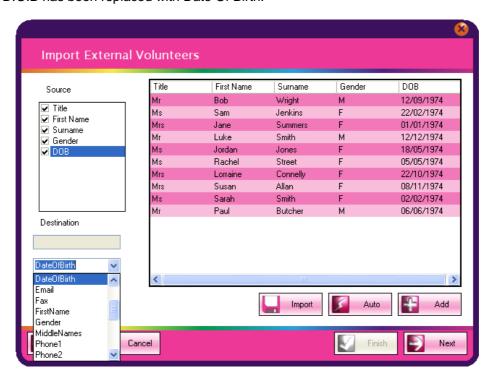
Once complete **Click** on the **Next** button. To skip the next wizard page for importing from an external data source **Click** on **Next** button again.

The first step when importing participants from an external source is to locate the .csv file containing the participant data. **Click** on the **Import** button and navigate to the file and **Click** on the **Open** button. The imported data will be displayed in the wizard window.



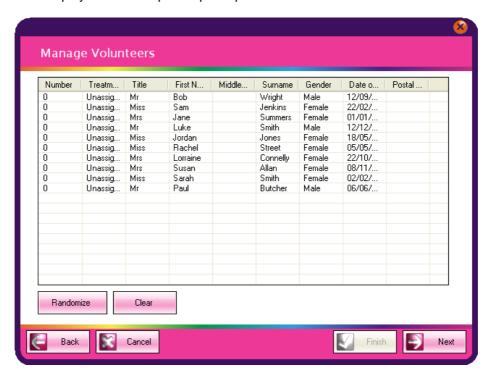
Now the imported data source column titles need to be matched with those stored in the COSMET-RICS software. **Click** on the **Auto** button to begin the check. Any matches will be shown by the check box next to each source column having a tick placed in it. Any Source columns left blank could not be matched and so will have to be completed manually.

To match a source column manually **Click** on the empty check box, a tick will be placed inside. This will activate a selection box under the heading **Destination**. **Click** on the drop down arrow and choose the column name that identifies the source column name that will be used in the software. In this case D.O.B has been replaced with Date Of Birth.

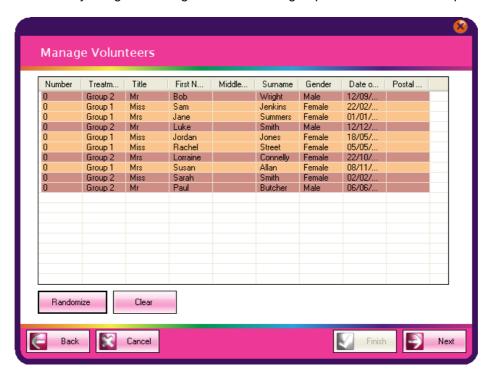


Once complete Click on the Add button. Then Click on Next to move to the Manage Participants window.

This window will display all of the imported participants.



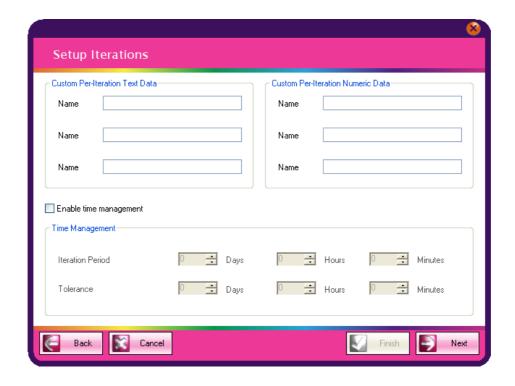
The Participants need to be assigned a group. To do this **Click** on the **Randomize** button. The Participants will be randomly assigned amongst the number of groups that have been set up.



If required selected columns can be hidden. **Right Click** anywhere on the table and a list of the column headings will be displayed. **Click** on the heading to uncheck it, the tick will be removed and it will be hidden from the main list. To show a hidden column repeat the process and a tick will be added and the column will be displayed again in the main list.

All of the participants can be removed by **Clicking** on the **Clear** button. Going back to the import window allows the process to be started again.

Once completed **Click** on the **Next** button to set up the Trial Iterations.



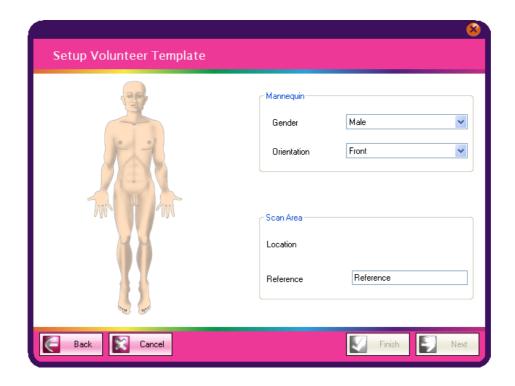
The Setup Iterations page is divided into three sections.

- Custom Per-Iteration Text Data Adding a name to one of the fields creates a text box that is displayed on the scanning page in the Additional Data section so that textual data can be added at the time of scanning.
- Custom Per-Iteration Numeric Data Adding a name to one of the fields creates a text box that is
  displayed on the scanning page in the Additional Data section so that data of a numerical value
  can be added at the time of scanning.
- Time Management Sets the iteration periods of the trial and the tolerence for the collection of data. As default the Time Management feature is disabled. This means that data can be gathered at any time during the trial. To enable Time Management check the **Enable Time Management** box.

**Iteration Period** - Setting an Iteration Period means that once a participants SIAscan has been acquired then that participant will not be available until the Iteration Period has lapsed.

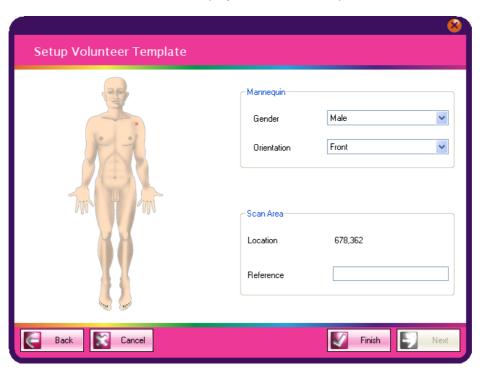
**Tolerence** - Setting a Tolerence creates some flexibility in the Iteration Period. If the Iteration Perdiod is 1 day and the Tolerence is 1 day it means the participant can still be scanned up to one day after the Iteration Period has lapsed.

Once complete **Click** on the **Next** button to move to the **Setup Volunteer Template**.



The **Setup Volunter Template** page configures the test locations on the body. To switch the gender and the view **Click** on the drop down arrows in the text boxes. The mannequin will be updated to reflect the changes.

To position a test location on the mannequin **Right Click** on the mannequin in the correct location and select **Create lesion**. A locator will be displayed on the mannequin.



If multiple test locations are needed then repeat the process until they are all positioned on the mannequin.

A textual reference can be made to scan areas. The reference is then used in the analysis area of the software to help distinguish the different scan areas. Simply **Click** inside the **Reference** text box and enter the text required.

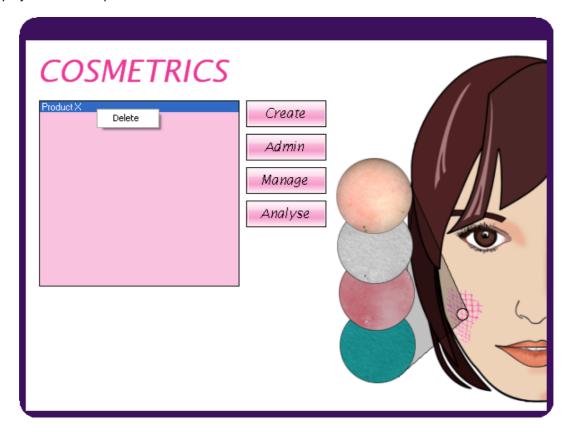
Once complete **Click** on the **Finish** button. The Trial Manager will be automatically loaded and the new trial displayed. Instructions on how to use the Trial Manager can be found in the section Manage Trial.



If the trial is not starting instantly **Click** on the **Home** button to display the Navigation screen or close COSMETRICS until needed.

# 3.2. Deleting a Trial

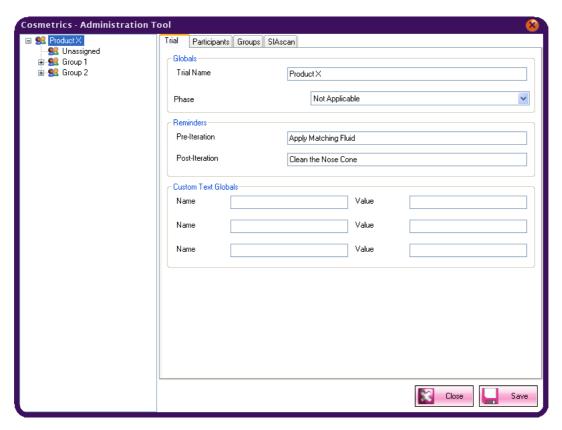
To delete a trial that has been created **Right Click** on the name of trial from the list of trials. This will display the **Delete** option. **Left click** on the **Delete** text and the trial will be removed.



### 4. Administration Tool

The Administration Tool displays information about the selected trial and also allows some of the settings to be changed once the trial has begun.

The general trial information is displayed when the trial name is selected from options displayed down the left hand side.

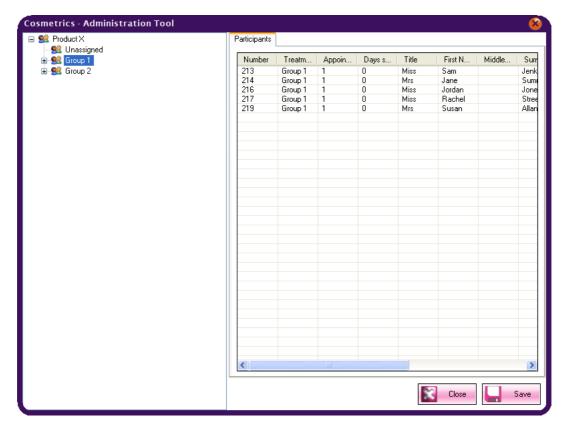


All of the information displayed on the **Trial** tab is configurable. This is done by **Clicking** in the required text box and editing the information. When complete **Click** on the **Save** button to commit the changes.

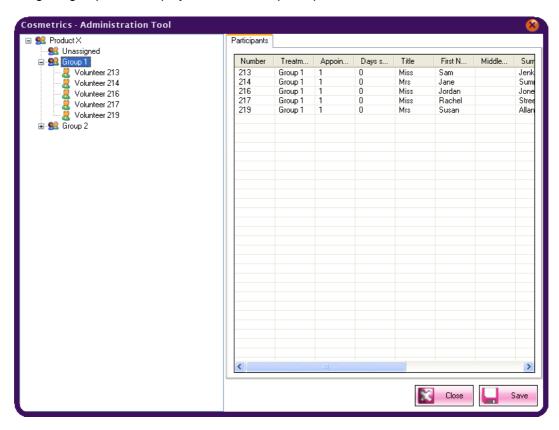
The **Participants** tab displays all of the participants which are included in the trial.

The **SIAscan** tab allows contrast of the SIAscan chromophore to be adjusted and the values saved.

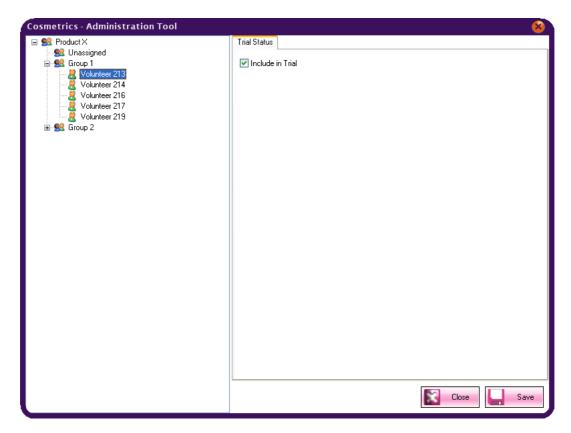
**Clicking** on a trial **Group** name displays the information about the participants in that group.



Expanding the group name displays the individual participants in the left hand view.



Clicking on an individual participant will display their Trial Status.

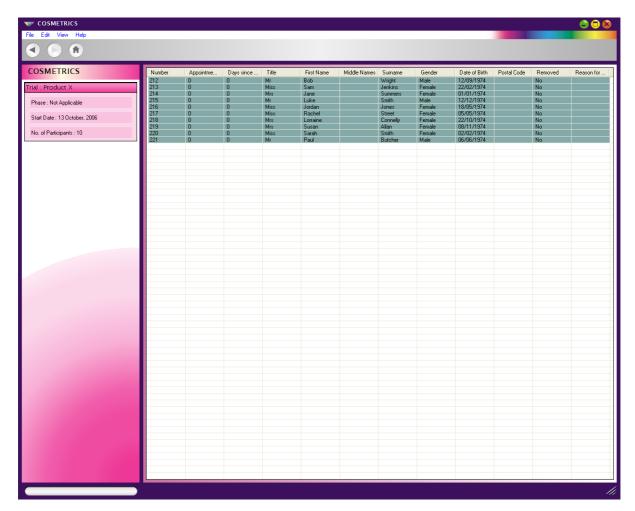


The participant can be excluded from the trial if required by unchecking the **Include in Trial** box and then **Clicking** on the **Save** button. They can be included in the trial by checking the box again and **Clicking** on the **Save** button.

### 5. Trial Manager

The Trial Managers role is to provide an overview of the whole trial. It shows all of the participants for the chosen trial and by using the trial iterations setting completed in the trial set up wizard it can either allow a participant to be scanned or not. It also captures a SIAscan for a chosen participant within the trial and collects any additional data required.

After having clicked on the Manage button the **Trial manager** page will be displayed for the selected trial.



On the right hand side is a list that contains all of the participants associated to this trial. At the top of each column is a description of its contents.

On the left hand side under the heading COSMETRICS are details about the trial being displayed.

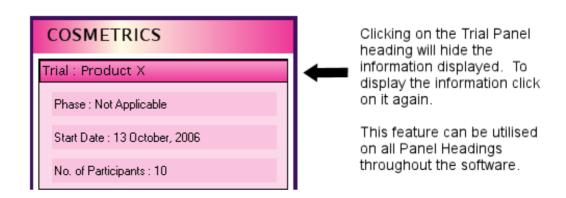
To view trial information about a participant, select one from the list by **Clicking** on the line required in the right hand window. This will display the participants status on the left.



The participants ID is displayed along with their status for taking part in the Trial. In this instance the participant has not been seen before so the message **Available**, **ready for initial iteration** is displayed. This will be updated when a Contact SIAscan has been captured for this participant. If the participant is not available at that time then the following status will be displayed along with the next date of availability.



# Note



### 5.1. Taking a SIAscan

To ensure that the SIAscans are captured correctly it is important to adhere to the following information

### ! Important

Always use the Matching Fluid supplied when capturing a SIAscan. Simply squirt a little matching fluid onto the scan area and then place the handset onto the skin. It is advisable to practice using the matching fluid as using too much can cause bubbles to form between the skin and the handset.

# Warning

Do not apply matching fluid to open wounds or sores.

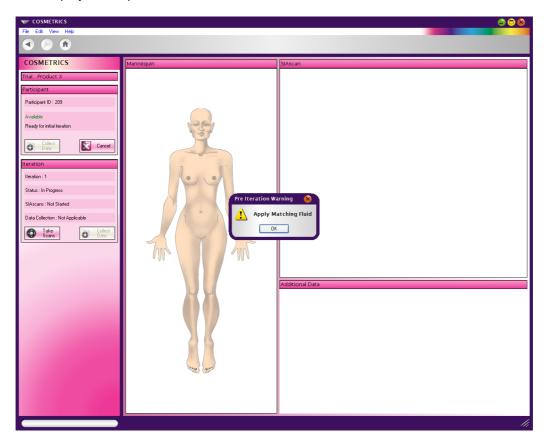
# ! Important

The SIAscope IV must be held steady during the scanning process and should not be removed until the SIAscans are displayed on the screen.

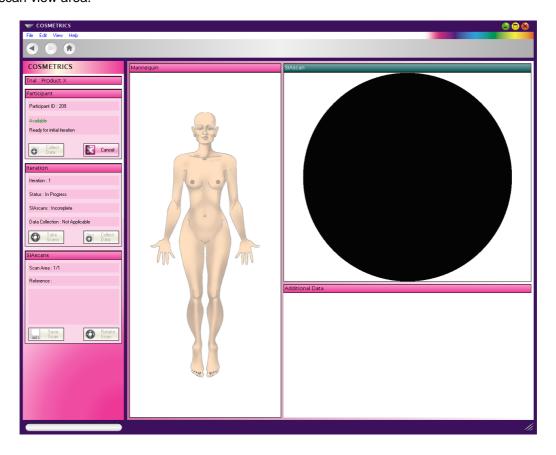
# Warning

Hold the SIAscope IV gently against the skins surface whilst scanning. Applying to much pressure will cause blanching of the scan area.

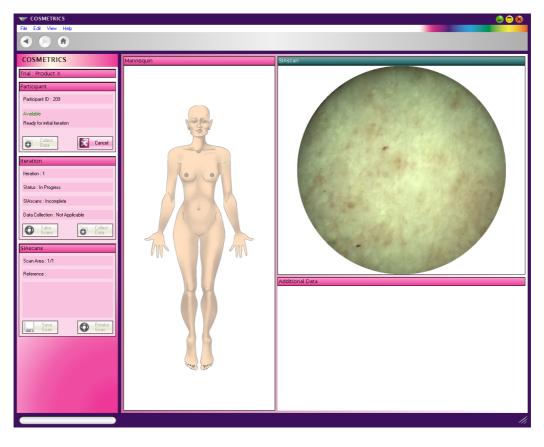
To add a Contact SIAscan to the selected participant **Click** on the **Collect Data** button. The screen view will change to the SIAscan capture page and if a Pre-Iteration reminder has been set a pop up window will display the required text. **Click** on the **OK** button to continue.



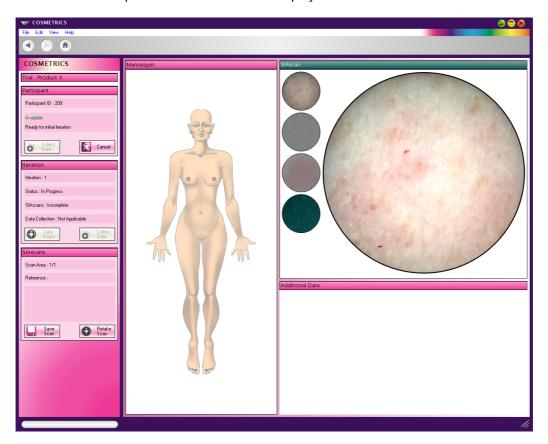
Now **Click** on the **Take Scans** button. This will intialise the SIAscope IV and display a live view in the SIAscan view area.



Using the live view position the SIAscope IV so that the area being scanned is central in the viewfinder. When positioned correctly press the button marked SIA on top of the SIAscope IV.



It will take a few moments to process the SIAscan and messages about the progress will be displayed on the screen. When complete the SIAscan will be displayed in the SIAscan section.



By default the Colour view is displayed as the larger view. To switch the view to either the Melanin, Blood or Collagen view **Click** on the smaller image, this will be displayed as the larger view.

To keep the SIAscan **Click** on the **Save Scan** button. If the image needs to be retaken **Click** on the **Retake Scan** button. This will initialise the SIAscope and display a live view. Repeat the process until an acceptable image is acquired.

# **(F)**

### Note

If multiple test locations have been set up then each time a SIAscan is saved the software will automatically select the next test location and show this on the mannequin. Repeat the scanning process until all the SIAscans have been captured.

If additional data is to be collected **Click** on the **Collect Data** button. The **Additional Data** text boxes will be unlocked and allow the data to be entered. Once complete **Click** on the **Done** button. If a Post-Iteration reminder has been set a pop up window will display the required text. To continue **Click** on the **OK** button.

# 1

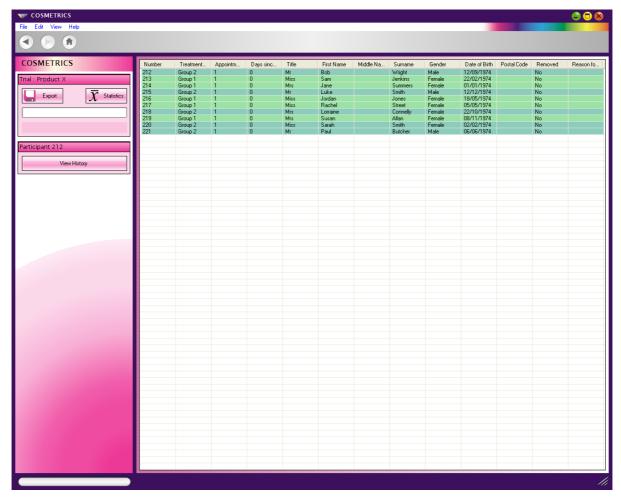
## **Important**

A value must be entered into all of the Numerical Data fields set up to complete this participants scan.

This participant will be unavailable until the next available date and the status will display this. The next participant can be selected and the process repeated until the all of the participants for this trial have been seen.

### 6. Trial Analysis

After having clicked on the **Analyse** button the **Trial Analysis** page will be displayed for the selected trial.



All of the participants for the selected trial will be displayed on the right hand side of the page. Down the left hand side are the tools available to analyse the trial. The buttons **Export** and **Statistics** are explained below.

### 6.1. Export

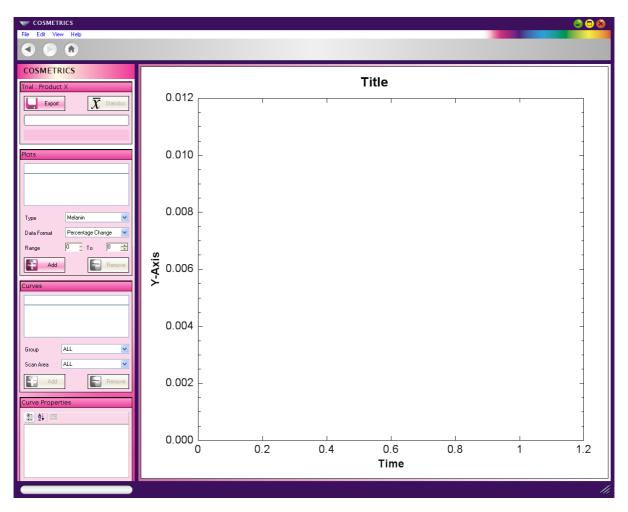
Using COSMETRICS it is possible to export the data for the trial to an external .csv file. To use this function begin by **Clicking** on the **Export** button.

A location will have to defined for the files to be saved to. If one already exists then navigate to it using the tree view displayed and then **Click** on **OK**. If a new one is needed first navigate to the required location and **Click** on **Make New Folder** and then **OK**. In both instances the exported data will be saved in a folder by the same name as the trial.

The data will be saved in the respective groups used in the trial within the folder.

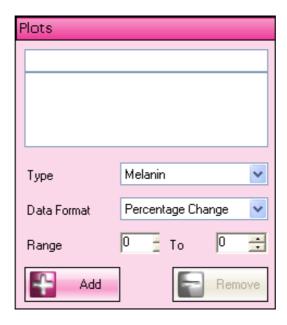
### 6.2. View Statistics

To view various statistics of the trial **Click** on the **Statistics** button. This will display the statistics page for the chosen trial.

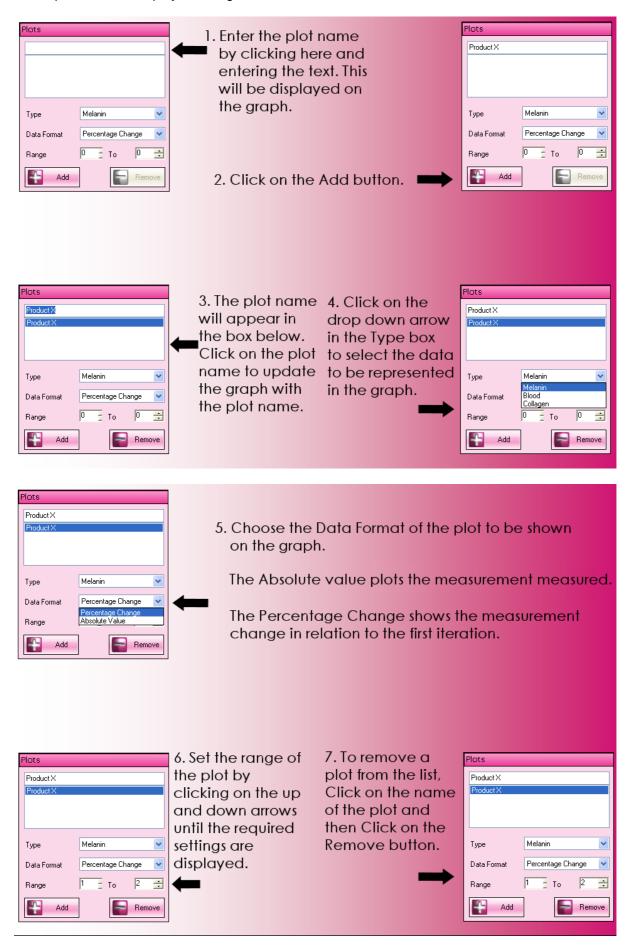


The statistics settings are divided into three sections, **Plots**, **Curves** and **Curve Properties**. Each statistic setting is described below.

**Plots** - The Plots section allows the content of the graph to be set.

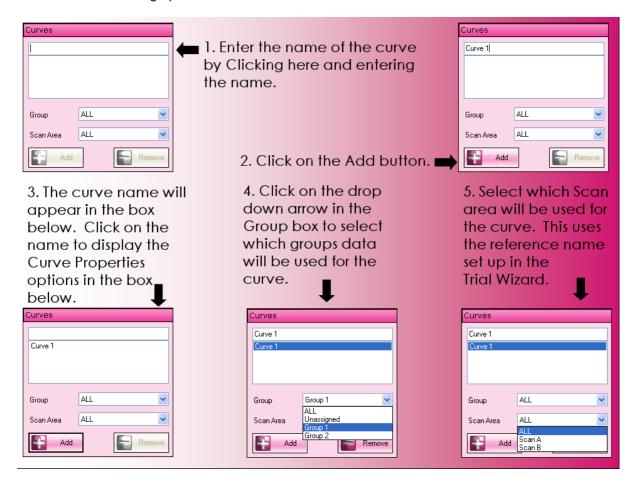


A new plot can be set up by following the instructions below.

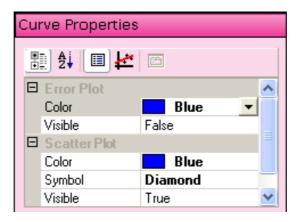


Curves - Sets an identity for each curve which will be fitted to the data and displayed on the graph.

To add a Curve to the graph:



Curve Properties - This sets the general appearance of the curve that will be displayed on the graph.



The settings are accessed by **Clicking** on the text in the left hand column. This will unlock the right hand side and display a drop down arrow in the box. **Clicking** on the arrow displays a list of options for that selection and they can be chosen by **Clicking** on the one required.

The Error Plot shows the Standard Deviation of the pixel values over the SIAscan.

- Color Sets the color of the Error curve to be displayed on the graph.
- Visible Sets whether the error curve will be visible on the graph.

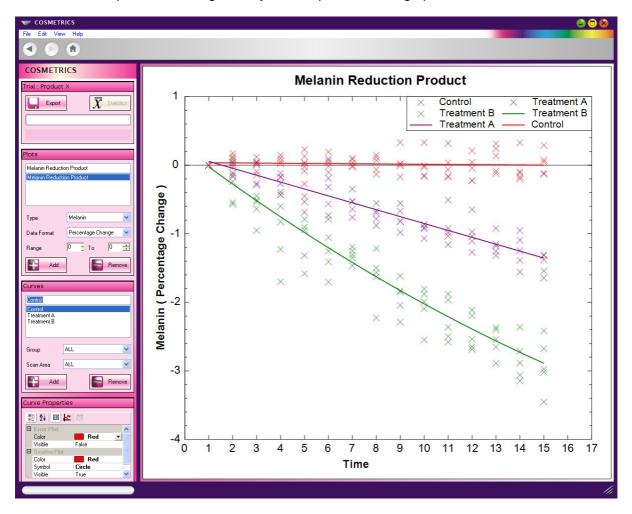
The Regression shows overall trend in the data over time.

- Color Sets the color of the Regression curve to be displayed on the graph.
- **Degree** The degree of Polynomial used to perform the regression. Setting 1 would perform a straight line fit. Setting 2 would perform a Quadratic regression.
- Type Either set to a Linear type or none.

The Scatter plots the data values.

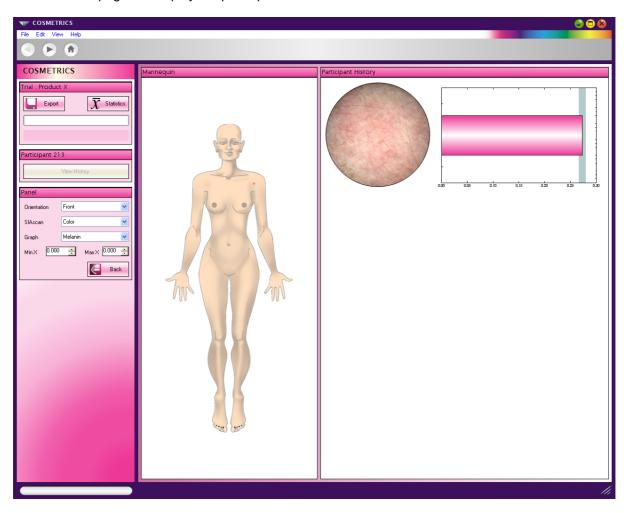
- Color Sets the color of the Scatter plots to be displayed on the graph.
- **Symbol** Sets the symbol that will be used to represent the scatter points on the graph.
- Visible Sets whether the Scatter plots will be visible on the graph.

As the Curve Properties are being set they will be updated on the graph.

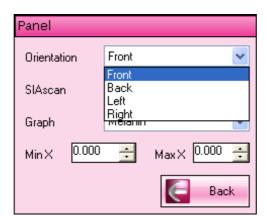


# 6.3. View History

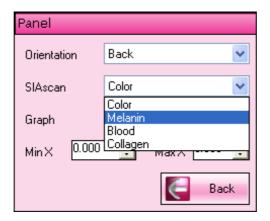
Each participants trial history can be viewed by **Clicking** on the **View History** button. First a participant must be selected from the list by **Clicking** on the one required, then **Click** on the **View History** button. A new page will display the participants details.



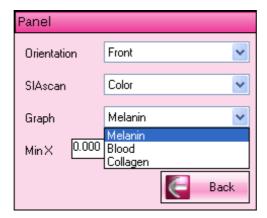
The Mannequin section displays the trial locations. The orientation of the mannequin can be changed by **Clicking** on the drop down arrow in the **Orientation** box and choosing the required orientation from the list.



The Participant History section shows the colour SIAscan as default. To change the SIAscan to either the Melanin, Blood or Collagen views **Click** on the drop down arrow in the **SIAscan** box and choosing the required view from the list.



The Chromophore that is used for the graph can be changed by choosing Color, Melanin, Blood or Collagen from the drop down menu.



The graph to the right of the SIAscan shows the Mean melanin value of the participants SIAscans. The value ranges can be specified by adjusting the **MinX** and the **MaxX** values as required. The graph will be updated instantly.

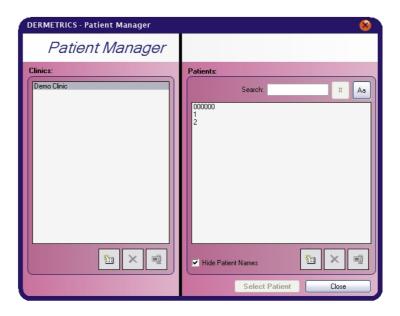
To exit the history of the selected participant **Click** on the **Back** button. The list of participants will be displayed again.

### 7. Using the Patient Manager

The Patient Manager allows new participants to be added to the COSMETRICS database and existing ones to be managed. Once participants have been added they can be imported into a trial during the trial setup.

Participants imported into a trial from a .csv file will automatically be added to the Patient Manager.

Start by **Clicking** on **File** from the Menu options at the top of the screen and from the list displayed **Click** on **Patient Manager**.

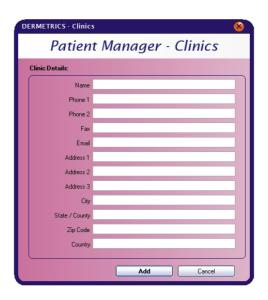


### 7.1. Creating a new clinic

To create a new clinic Click on the Add button located at the bottom of the Clinic list.



This will display a details page for the clinic.

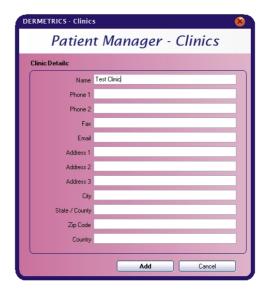


The name of the clinic should be entered into the name field box. For completness the rest of the information can be entered but this not neccesary by default. Once complete **Click** on the *Add* button located at the bottom of the screen. The new clinic will be displayed in the list.

If the clinic details need to be edited **Click** on the clinic name and then the **Edit** button.



This will display the clinic details. Make any changes needed and **Click** on the *Save* button at the bottom of the page to keep the changes.



To delete a clinic from the software Click on the Delete button.



# Warning

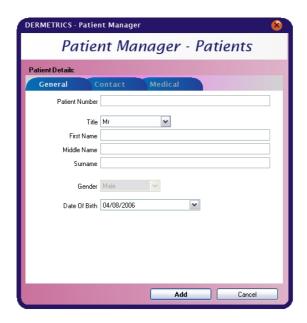
Deleting a clinic will remove associated data to it permanently.

## 7.2. Adding a new patient

First Click on the Add button under the list of patients.



This will open a new patient details window.



Enter information about the patient on each of the sections General, contact and medical.

### Note

To naviage between the sections **Click** on the heading of each of the tabs.

When the information has been entered Click on the Add button.

# Note

If the New patient is not needed then **Click** on the **Cancel** button which can also be found in the bottom right hand corner of the patient manager. This must be done before using the Save button.

### 7.3. Updating patient details

Select the patient whose details need to be updated by **Left Clicking** on their name. This will unlock the three Tabs to the right and allow the patients details to be updated. Once the details have been updated **Click** on the **Save** button at the bottom of the page. This will save the details to the database.

### 7.4. Deleting a patient

Find the patient who is going to be deleted from the Patient Manager.

Once the correct patient has been found **Click** on the **Delete** button at the bottom of the Patients section.

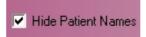
DERMETRICS will then ask for confirmation that the patient records are to be deleted.

# Warning

The delete function will remove any records associated to the patient permanently

### 7.5. Displaying and searching for patients by name or number

To switch between displaying patient names and numbers check the box **Hide Patient names** that can be found at the bottom of the patient list.



# ! Important

If a patient number has not been entered then the message No Patient Number will be displayed in the list.

Searching for a patient can be done by using either the Patients name or number.

The buttons that control this selection can be found at the top of the patient list next to the heading patients



To display patients by their number **Left click** on this button.



To display patients by their name **Left click** on this button.



Once the search format has been set, **Click** inside the text box at the top of the patient list and enter either the name or number. The patient that matches the criteria will be highlighted in the patient list. To open the patient file **Click** on the **Select Patient** button.

### 8. COSMETRICS Questions and Answers

- Q Matching fluid, what is it for?
- A In SIAscopy we are interested only in the light that has entered the skin, interacted with the skin and then exited into the lens system.

For wavelengths shorter than around 800nm, (high red light), we can use cross polarised light. The light is polarised before it hits the skin, and then only light that has the opposite polarisation can penetrate the lens system. Light that reflects from the surface of the skin retains its polarisation and therefore does not make it to the image sensor. However, light that has entered the skin loses its polarisation and can then make it to the sensor.

Unfortunately, for technical reasons this method cannot be used for wavelengths of light longer than 800nm, infra-red light. To stop surface reflections in the infra-red image, matching fluid is used. This creates an optical bridge between the skin and the glass, preventing any infra-red reflection from the skin surface.

- Q What is the effect of using and not using matching fluid?
- A If matching fluid is not used the infra-red image will contain artefacts due to surface reflections. As the infra-red image is very important in collagen measurement, this means that without matching fluid, we are unable to measure collagen. The melanin and blood images are affected to a much lower extent, but are not as accurate.
- Q How much do we use? Different amounts appear to have different results?
- **A** There should be enough matching fluid to prevent any air bubbles between the SIAscope and the skin. This often involves several squirts of the bottle, and ensuring that the SIAscope is placed on the correct area. If not enough is used, the images will look different. Different amounts will not affect the results if enough is used to ensure the optical coupling.
- **Q** Can we optically separate the layers of the skin?
- A No each pixel is a measurement of the gross histology being viewed, the melanin value is the amount melanin containing in a tube the size of a pixel extending from the surface of the skin to the bottom of the collagen.
- Q What type of melanin do we see, can we look at the different types?
- **A** We see eumelanin which is the most common form of melanin in human skin. The system measurements are invariant to the amount of pheomelanin.
- Q Can we see elastin?
- **A** Not directly. We measure the quantity of collagen in the papillary dermis of the skin. If the amount of elastin/collagen ratio changes we will see this as a drop in collagen.
- Q Could we measure the effect of Sunscreen?
- A It depends what the effect of the sunscreen is, if it has an effect on the blood and melanin content of the skin then yes. You could run a trial with a sunscreen and measure that the area with sunscreen experienced a lower increase in melanin over time. If you wanted to replace the MED test then you could detect changes in blood.
- **Q** Can we analyze the tone and size of a specific age spot rather than just the whole SIAscan?
- A This is possible however this will not be available in the first release of COSMETRICS
- **Q** Is COSMETRICS the best AC solution to use for temporal management of a freckle (pigmentation)?
- A Yes, COSMETRICS is the only solution that is able to quantify the data contained within SIAscans.
- **Q** If I wanted to compare collagen images side by side is the only way to buy Mole View. Could/Will COSMETRICS have compare and overlay features in it at some point on the road map?

- **A** This is in the process of being developed at the moment, Although this is not in the initial release, this will be implemented into the next release.
- **Q** What other papers other than Paul Matts, (Proctor and Gamble;), combined paper on Chromophore mapping do we have reference anti-aging?
- **A** Paul Matts paper is the only one that references anti-aging that we are aware of at the moment. All the clinical papers that we are involved with are on our website at http://www.astronclinica.com
- **Q** We are interested in collagen comparisons and are planning on looking at collagen in lips. What features can we see in an image of lips in the collagen view with COSMETRICS? Can we see stacked collagen?
- A The skin model used in COSMETRICS is designed for normal skin with end-points for blood and melanin within a common range. While we have had some promising results for scanning and measuring scars and lips we have not performed any in-depth studies.
- **Q** How well does COSMETRICS handle scars and lips? What do the scans tell us about these areas of the body? Should we never test on a scar or lips?
- A The skin model used in COSMETRICS is designed for normal skin with end-points for blood and melanin within a common range. While we have had some promising results for scanning and measuring scars and lips we have not performed any in-depth studies.
- Q Are there any plans to make a smaller diameter nose cone? Is it physically/technically possible?
- A The current cone size is used as COSMETRICS is designed to measure changes due to local area product application. There have been enquiries into using smaller nose sizes. While a hardware change is unlikely, it is possible that in future releases of COSMETRICS it will be possible to configure the system to use a sub-section of the scan area for analysis. This will have the same results as using a smaller nose cone.
- **Q** We are undertaking research on pores. What information can hope to gain and interpret about the depth of a pore with SIAscopy? What might be possible with COSMETRICS or Mole View i.e. contact SIAscopy?
- **A** At present there is no mechanism in any Astron Clinica software product to measure the depth of pores.
- **Q** COSMETRICS offers an ability to randomize the participants and allocate them to groups. In some current trials the files are already pre-randomised or assigned. How would we manage this on the current User Interface? Could we have an option in the product for this?
- **A** This is information that we are now finding out from our Beta trials, until a solution is built into a release version of the software. A way to avoid the problem is to assign them to 1 group in the software and reference your pre assigned groups in the actual trial, referencing the participant id only
- **Q** We need to have participants scanned more frequently more than once a day in some trails at the beginning of the trial and then daily or bi-weekly further into the trial. How could we manage this is the current interfaces when we set up the trial?
- A This will be available in the full release version
- **Q** Can we export the images so we can compare them and keep them together with the exported stats? Is it planned in COSMETRICS? Save to BMP files?
- A Exporting of the SIAgraphs is planned the exact file format is still to be determined
- **Q** Can we export the graphs themselves?
- A Yes, you can right click the graph on the screen and 'Save As' this will save the screen out to a separate file
- Q Is there a plan to have an export wizard for these above elements?
- A Not at the moment, although this may be implemented at a latter stage
- Q When the data is exported the reference shows the number of the participant not the name. Can it

show both fields?

- A This will be implemented in an upcoming release
- Q Will COSMETRICS be available as a Local Area Network (LAN) solution?
- **A** Yes, this is being planned at the moment, a single user version is already available (to assist with data backup)
- Q How do we quantify melanin?
- A The SIAscope is based around a mathematical model of the interaction of light with the constituents of skin especially melanin, haemoglobin and collagen. By utilizing an in-depth understanding of the scattering and absorption properties of these constituents it is possible to create an inverse model linking spectral measurements with their quantity and position. The SIAscope performs this operation at every point in the image creating maps of the chromophores called SIAscans. Good references are http://www.astronclinica.com/research/papers/miccai2002.pdf which gives an overview or http://www.astronclinica.com/research/papers/sdcthesis.pdf for an in depth analysis.
- **Q** How deep does the light travel?
- A This depends on both the wavelength of the light with longer wavelength light penetrating further and the anatomy of the skin. The maximum penetration depth is governed by the thickness of collagen within the dermis. Typically from stratum corneum this is around 2 mm being less for thin skin, such as under the eye and more for thick skin such as the sole of the foot.
- **Q** What wavelengths go in and come out?
- A Four wavebands are used centred on 450nm, 550nm, 700nm and 950nm none of which are harmful to the skin.
- Q What is the accuracy of the SIAscans?
- **A** The accuracy of the scans then for blood and melanin the error on each pixel measurement is around 1%, for collagen this error varies non-linearly between 1% and 5% with total collagen.
- Q What CCD chip information is available No of Pixels?
- A We use a 3 Mega Pixel Imaging chip.
- Q What is the number of LED's in handset and wavelength of LED's?
- A There are over 30 LEDS in the handset; with wavelengths ranging from blue up to IR (300 to 1100 nm).
- **Q** What is the best advice on repositioning issues?
- **A** Marking the skin with something semi permanent such as pen is good or you have to use natural landmarks such as moles or scars or distances from joints.
- ${\bf Q}$  What research or information is available about time series of lesions e.g. time management and repositioning?
- ${\bf A}$  http://www.astronclinica.com/research/papers/DIORPosterEnglish.pdf is the only publication. We have done other unpublished work under contract.
- **Q** What is the LAB space for colour values?
- **A** It is important to realize that the SIAscope doesn't use this. The SIAscope works as a broadband spectrometer, and therefore does not use any specific colour space.
- **Q** What calibration details are required for recalibration?
- **A** We have to know the amount of each wavelength of light which is incident on the skin during each capture sequence. A factory calibration is done to measure this and a calibration check is performed during every scan to ensure accuracy.
- **Q** Polarisation coating in capture mode (parallel and cross)?

- **A** Cross polarised light is used to cut down surface reflections. By doing this we know that the light returned to the camera has interacted with the skin and not simply been reflected off the surface.
- Q Can the mannequin face be made larger?
- A This will be incorporated into an upcoming release.
- Q Reproducibility data for cosmetic applications effect of surface film?
- **A** Any surface film such as makeup may lead to incorrect results. The model used is based on the interaction of light with skin and its natural components. Make up is not taken into account and so its presence will cause false readings.
- Q Can you custom label files during capture?
- A Not at the moment.
- Q What are the export function options from within COSMETRICS?
- **A** COSMETRICS will export mean and standard deviation values for each of Blood, Melanin and Collagen SIAscans for each scan captured. This is in comma separated value (csv) file format, which can be imported into Excel. COSMETRICS does not currently export SIAscans as image files as this functionality is part of Dermetrics, however future releases may include this function if requested.

### 9. Acknowledgements and Notices

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# A. Revisions

# **Table A.1. Revisions**

Revision No	Revision Description	Date
Revision 0.1	First draft composed	01.05.2006
Revision 0.2	Front Cover and Formating changed	24.05.2006
Revision 0.3	Final Version for release	17.10.06

### **B. Third Party Software Licenses**

COSMETRICS dynamically links the following libraries:

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