

# Operating Guide





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## 1.0 WELCOME TO SIASCOPE - SIMSYS

This document contains important information regarding the safe operation of the SIMSYS SIAscopy system.



Read through the entire operating guide before using the SIAscope handset or SIMSYS software for the first time. It describes the installation, set-up and use of the SIMSYS software with the SIAscope and provides important safety information.



Before operating the SIMSYS software and the SIAscope it is imperative that the user has received proper training and is familiar with the Cautions and Warnings section of the manual.



Contact SIAscans are intended to be used as an aid to diagnosis. The user must understand the meaning and implications of SIAscans before attempting to use them clinically. Clinical White Papers written by independent scientists and clinicians describing how SIAscans can aid diagnosis are available from MedX Health Corp. (MedX).

### 1.1 System Components

The following components should be included with your SIMSYS SIAscopy system:

- SIAscope V Model Handset Scanner
- Base Stand
- SIMSYS Software Installation (on CD or USB memory stick)
- SIAscope Calibration Data (on CD or USB memory stick)
- Clinical Training (on CD or USB memory stick)
- Clinical Training Guide
- SIMSYS Operating Guide (this booklet)
- SIMSYS Installation Guide
- USB Licence Key
- USB Cable
- Matching Fluid
- Lens Cleaning Cloth

## 1.2 Indications for Use

The SIAscope, together with the SIMSYS software, is a non-invasive system used to analyse skin conditions and skin health. It provides colour bitmaps called 'SIAscans' that show the relative location and concentration of blood, collagen, melanin and dermal melanin within the papillary dermis and/or epidermis.

The device is for external application only and should only be used to scan a patient's skin.

The device is intended for professional use only in general clinical examination room environments.

### Contra-indications

The SIAscope should **NOT** be used under the following conditions:

- Over open wounds or sores,
- Directly over a pacemaker.
- On skin or lesions containing light absorbing pigments (see Warnings).

## 1.3 How SIAscans Provide Information on Skin Histology

Unlike biopsy, the SIAscans use patented SIA technology to provide an array of quantitative measurements that are displayed in graphical form creating a synthesized 'image' showing how the parameter varies spatially over the skin area.

Contact SIAscans provide information about:

- **Concentration:** The relative concentration of various skin components, including pigment (such as melanin), blood and collagen, in the plane of the skin.
- **Location:** The location relative to the dermal / epidermal junction of selected components.

Each contact SIAscan isolates a single component viewed over an approximately 11mm diameter area and displays it as a colour bitmap.

## 1.4 SIMSYS

SIMSYS allows you to bring SIAscopy into consultations within your practice. SIMSYS is designed as an introduction to SIAscopy (our skin imaging technology) that is backed up with the Hunter scoring system; also known as the 'Primary Care SIAscopy Algorithm'. Developed by Dr. Jude Hunter and first presented in poster format at the British Association of Dermatology 2006 titled

**“The diagnostic characteristics of SIAscopy versus dermoscopy for pigmented skin lesions presenting in primary care”,**

SIMSYS has been designed for the clinician that is not an expert in either SIAscopy or Dermoscopy but who wants to increase diagnostic accuracy as well as patient satisfaction within lesion specific consultations.

SIMSYS has been designed to help you identify some common benign lesions, as well as identify features in suspicious lesions. With SIMSYS as a diagnostic tool to back up your clinical expertise along with the patient history you can reassure both yourself as well as your patients that the correct course of action has been taken.

The Hunter scoring system presents specific questions regarding the captured SIAscan. The questions are aimed at assisting you to identify specific features within the lesion that are visible using SIAscopy. Any presence of these features in melanin, dermal Melanin, blood or collagen views can be key indicators regarding the status of the lesion. After progressing through the Hunter scoring system a recommendation will be displayed to aid your diagnosis.

After regular use, you may find that you do not need to use the scoring system and simply assess the SIAscans looking at other characteristics within the individual views, therefore improving your sensitivity and specificity for suspicious lesions even further.

Further information regarding SIMSYS, clinical papers or any of MedX's products can be found at the following website:

<http://www.medxhealth.com/>

## 1.5 SIAscope Handset

The SIAscope handset used in conjunction with SIMSYS captures detailed SIAscans of the skin. The centre button marked **SIA** is used to capture a SIAscan. The four buttons with the directional arrows are not used with the SIMSYS program.

















The centre button also lights up blue indicating that the SIAscope is on.

The SIAscope is designed such that it uses a USB 2.0 cable and USB2.0 or 3.0 port on the computer. This is particularly useful as the SIAscope can be unplugged and transported along with the Computer to a different room or even a different building without involving any complicated set up each time.



## 1.6 Labelling Symbols and Markings

	Use-by date		Serial number
	Keep dry		Fragile, handle with care
	Temperature limit		Humidity limitation
	Caution		Consult instructions for use
	Type BF applied part, device makes physical contact with patient		Class II electrical device
	Recycle separately from other waste		Manufacturer
	Batch Code		Authorized representative in European Community

## 2.0 CAUTIONS AND WARNINGS



The SIAscope V is for **EXTERNAL USE ONLY** and should not be used on open wounds or sores.



The SIAscope V is not to be used over a pacemaker.



The SIAscope V is intended for use by healthcare professionals only.

The SIAscope V may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as reorienting or relocating the equipment or shielding the location.



The SIAscope does not generate a significant source of electro-magnetic interference. However, the system is not intended for use in areas of high electro-magnetic radiation (e.g. MRI).



No modification of this equipment is allowed.



The use of cables other than those specified, with the exception of cables qualified and sold by the manufacturer of the SIAscope V, may result in increased emissions or decreased immunity of the equipment and may cause the system to be non-compliant with the requirements of IEC 60601-1-2:2007.



The SIAscope V should not be used adjacent to or stacked with other equipment and if adjacent or stacked use is necessary, the SIAscope V should be observed to verify normal operation in the configuration in which it will be used.



In order to avoid cross contamination, the nosecone of the SIAscope must be cleaned between each patient use with an Isopropyl wipe.



The SIAscope V emits light of wavelength 440-960nm. Check with a patient's existing treatments to ensure compatibility.



Do not look directly into the light from the SIAscope. When scanning skin on a patient's face, ensure that their eyes are closed.



SIAscopy (Contact or Non-Contact) does not function correctly on skin or lesions containing light absorbing pigments including haemasiderin, eschar, scales, jaundice, tattoos, inks, cosmetics, and other conditions that give rise to the presence of unusual chemicals in the skin. In very dark lesions such as some Seborrhoric Keratoses, Contact SIAscans may also give incorrect information. In these special cases refer to MedX for advice.



The SIAscope V needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this document.



Portable and mobile RF communications equipment can affect the SIAscope V.



Untrained or unqualified personnel must not use the system. All users must read and understand these instructions fully before using the device.



Printouts of SIAscans are intended for reference only as they are of reduced resolution and colours may not be reproduced accurately. Refer to SIAscans displayed in the SIMSYS software to view fully detailed SIAscans.



Do not disconnect the SIAscope from the PC when it is scanning.



The SIAscope contains no user serviceable parts. Please contact MedX or your local distributor if your system requires maintenance.



Take care in handling the SIAscope. These pieces of equipment are liable to be damaged if dropped.



Take care when packing/unpacking the equipment. The SIAscope contains delicate components which should not be subjected to undue forces. Take care to store each item carefully.



It is up the clinician/operator to take proper measures in order to ensure appropriate security of patient information as the SIMSYS system does not incorporate any security features.



Any measurements taken are for relative indication purposes only and are not to be considered as an accurate or precise measurement.



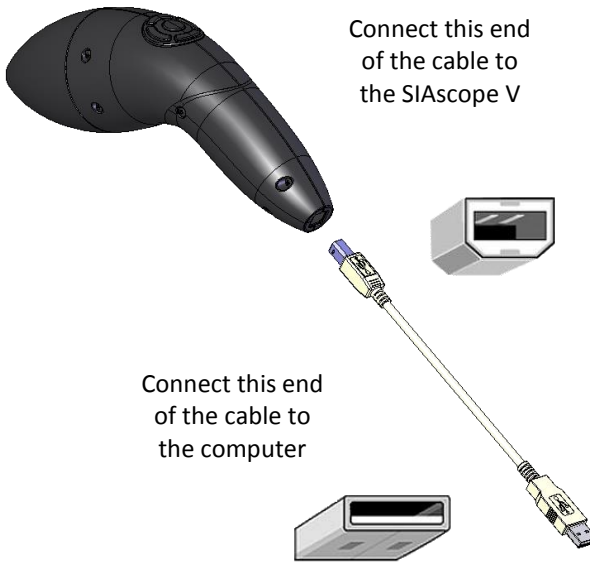
To safely terminate operation, you should always close the SIMSYS application first by clicking on "X" in the upper right hand corner or by selecting Exit from File menu (File>Exit) before you unplug SIAscope V scanner and License Key from their USB ports.

### 3.0 OPERATING INSTRUCTIONS

#### 3.1 Connecting the SIAscope and USB Licence Key

The SIMSYS software must be installed before proceeding with this section.

- (a) Plug the USB 2.0 cable into the SIAscope and into an available USB 2.0 port on your computer.



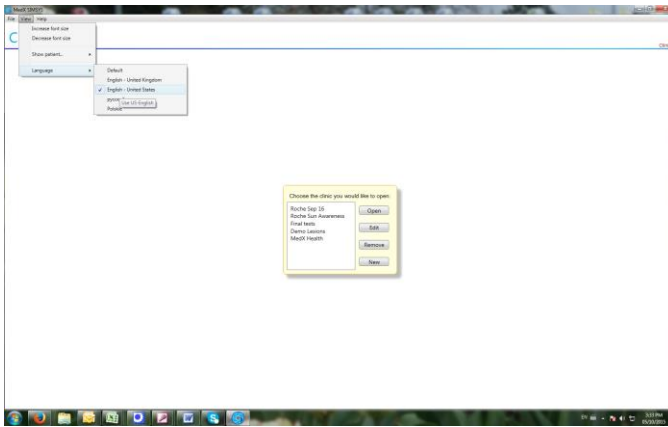
- (b) Plug the USB Licence Key into an available USB 2.0 port on the computer.

**NOTE:**

**Both the SIAscope and License Key have to be plugged in at all times while running the SIMSYS program.**

### 3.2 Starting SIMSYS

To start the SIMSYS software, ensure that the Licence Key and SIAscope are plugged into the USB 2.0 ports before double clicking on the SIMSYS icon. **It is recommended to always plug the License key and SIAscope into same ports as when they were originally installed.** The software will open displaying the default **Clinics** page. Before you proceed with setting up your Clinic’s details you can select one of available software languages under “View>Language” menu.



### 3.3 Setting Up a New Clinic

Click on **New** and complete the on-screen form (see below) and then click **OK**. The details are automatically saved and the name of the clinic will now be listed in the **Clinics** window.

Name

Address

Phone

Phone

...

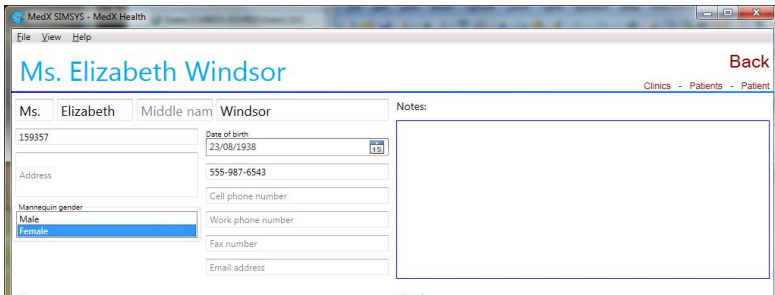
Ok Cancel

Click **Back** to return to the Clinics page.

## 3.4 Patients

### 3.4.1 Creating a New Patient Record

To create a new patient record, select the appropriate clinic and click on **New** on the Patients screen. Enter as much data as you require into the form. The patient number is optional and determined by your own, existing patient records system or, for instance, a National Insurance number. Notes can be added directly into the Notes section at any stage.

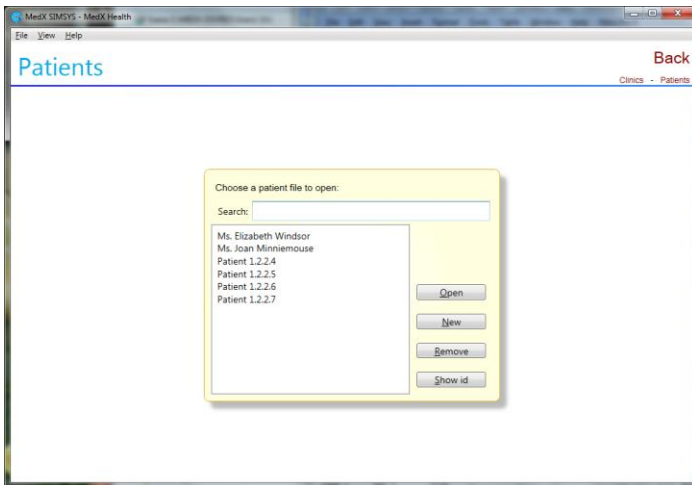


The screenshot shows the 'MedX SIMSYS - MedX Health' application window. The title bar includes 'File View Help' and a 'Back' button. The main header displays 'Ms. Elizabeth Windsor' and a breadcrumb trail 'Clinics > Patients > Patient'. The form contains the following fields:

- Ms. Elizabeth | Middle nam | Windsor
- 159357 | Date of birth: 23/08/1938
- Address | 555-987-6543
- Mannequin gender: Male (selected), Female
- Cell phone number
- Work phone number
- Fax number
- Email address
- Notes: (empty text area)

### 3.4.2 Accessing Patient Records

Open the required Clinic. All patients' names or ID numbers associated with the Clinic selected are then displayed. Highlight the name required and click **Open**.



The screenshot shows the 'MedX SIMSYS - MedX Health' application window with the 'Patients' screen. A search dialog box is open, titled 'Choose a patient file to open:'. It contains a search field and a list of patient records:

- Ms. Elizabeth Windsor
- Ms. Joan Minniemouse
- Patient 1.2.2.4
- Patient 1.2.2.5
- Patient 1.2.2.6
- Patient 1.2.2.7

Buttons at the bottom of the dialog include 'Open', 'New', 'Remove', and 'Show id'.

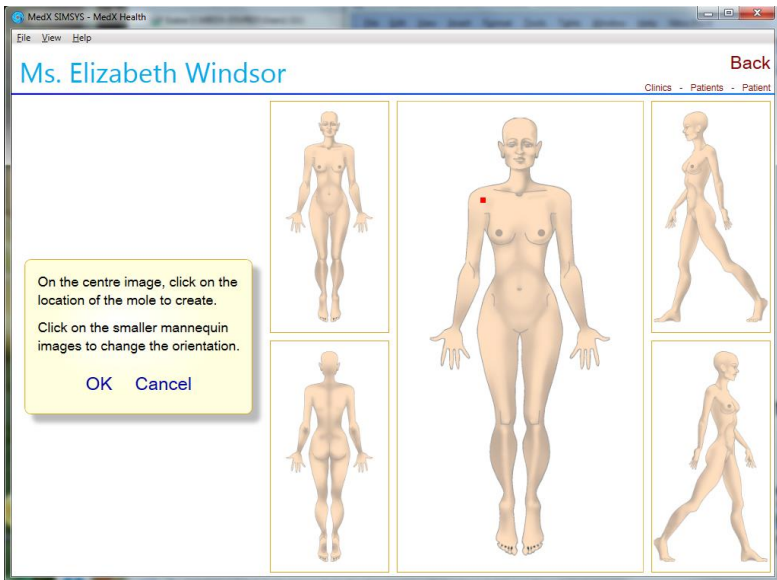
For patient privacy, patients may be listed by number instead of name. Click on the **Show Names/Show ID** to switch between options. The **Search** function can also be used to locate patient records.

### 3.4.3 Deleting a Patient Record

Open the **Clinic** screen and select the appropriate clinic. From the **Patients** screen select the name of the patient. Click to highlight and click on **Remove**. Confirmation window will pop-up before deleting the patient files.

### 3.5 Locating a Mole or Lesion on the Mannequin

SIMSYS provides a mannequin onto which the exact location of the mole or lesion is recorded. The mannequin gender is determined when the new patient record is created. To create and locate a new mole or lesion record, under the **Body map** section, click on **New** to access the mannequin. The following screen will appear.



Moles or lesions can only be marked on the central mannequin view. If the mole or lesion concerned is located on one of the alternative views, click on the alternative view which will then occupy the larger, central view. Position the cursor on the location desired and **Click**. The mole or lesion location will now be marked with a red dot. Click **OK** to confirm. A new mole or lesion record

has now been created; ready to be populated with images of the specific mole or lesion identified in the graphic and any associated documents.

**Note:**

If you have a wheel on your mouse you can zoom-in the central mannequin view for more precise locating of the lesion.

### 3.6 Creating a New SIAscan of a Mole or Lesion

Before conducting a scan clean the patient's skin, removing cosmetics etc with a sterile swab. Check for unusual conditions that may adversely affect the performance of the SIAscope as described in the Cautions and Warnings section.

- (1) *Cleaning the SIAscope* - Before each patient examination, wipe the end of the nosecone with an Isopropyl wipe and the Lens Cleaning Cloth provided.



In order to avoid cross contamination, the SIAscope must be cleaned between each patient use.

- (2) *Applying matching fluid* - Apply optical matching fluid to the area of skin to be examined. A single squirt from the applicator should be sufficient. Should you need to order additional matching fluid please contact MedX or your local distributor.



In order to obtain the best possible SIAscan it is essential that matching fluid is used whenever a SIAscan is taken. This is to help the light being emitted from the SIAscope to penetrate the skins surface. To apply matching fluid simply use the spray dispenser supplied to cover the area being examined with the SIAscope. Do not apply too much matching fluid as this can cause bubbles to appear in the final image. It is well worth taking some time to practice how much is needed to achieve the best results.



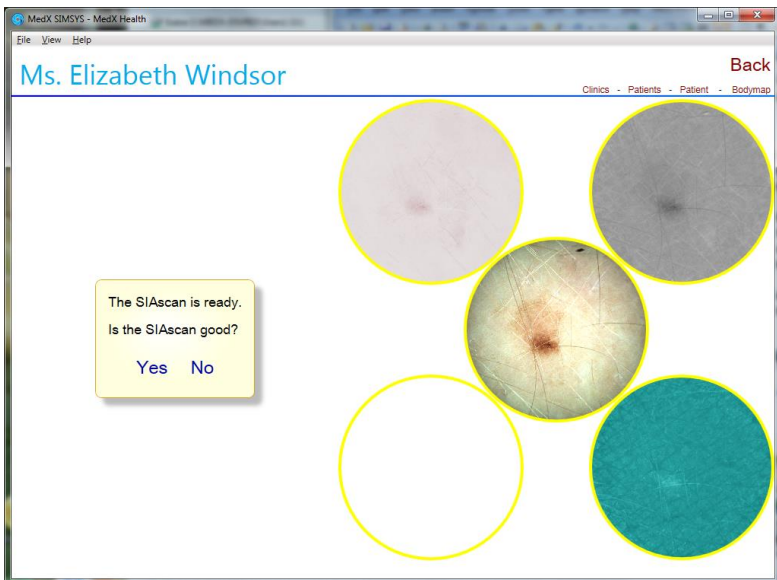
For best results, matching fluid recommended and supplied by the manufacturer should only be used.



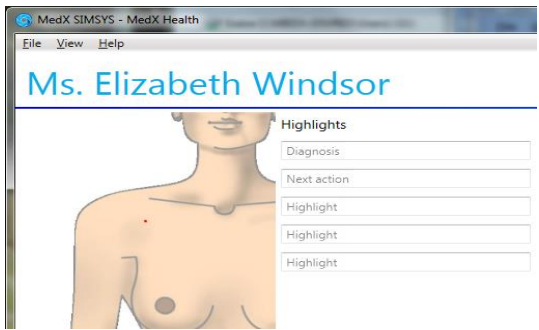
Do not apply matching fluid to open wounds or sores.



- (3) *Start a New Scan* - Within the **Images** section, click on **New Scan**. The SIAscope will now be active and begin to flash from the nosecone. Wipe the nosecone with an isopropyl wipe and follow the direction on the screen.
- (4) *Positioning the SIAscope* - Apply matching fluid to patient's skin and place the SIAscope on the patient. Using the on-screen viewfinder centre the handset on the lesion. Press down lightly to prevent light from the room contaminating the scan.
- (5) *Acquiring a scan* - Hold the handset still, then press and release the handset button and wait while the SIAscope takes the scan. The software will indicate when scanning is complete. Ensure that the scope is held in place while the SIAscope logo on the screen turns. A tone will sound when the scan is complete and the scope can be removed.
- (6) *Review and accept* – The colour view of the mole or lesion is then displayed alongside the four images. If you are satisfied with the quality of the image taken, click on **Yes**.



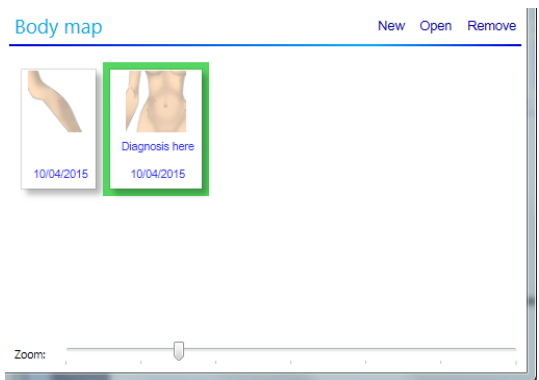
The SIAscan is then presented in a new window ready for assessment with the fade and zoom tools (see section 3.8). If you wish to assess the lesion later, click on **BACK** to return to the lesion record/body map or select any other program location from the “bread crumb” menu located below the **BACK** button in upper right section of the window.



**Note:**

All fields entered under **Highlights** section will be printed in your PDF patient/detailed report (see section 3.11 Saving and Printing Reports)

When the **Diagnosis** field is entered this will become name within the **Body map** thumbnail under the Body map section on the patient screen.



### 3.7 Correct Use of the SIAscope

The following symptoms may indicate inaccurate use of the SIAscope, producing inconsistent contact SIAscans. Check the precautionary notes below and repeat the scan to ensure the SIAscans contain accurate indications.

- I. SIAscan contains unusual black edges
- II. Blotches on images
- III. Consecutive scans contain a similar mark or spot
- IV. Blood SIAscan appears patchy
- V. Colour view has green and red areas or featureless images
- VI. Unusual coloured dots in the SIAscan



Refer to the Cautions and Warnings section for limitations relating to unusual skin pigmentation conditions such as jaundice, tattoos, inks and cosmetics.

- I. SIAscan contains unusual black edges

A shadow effect around the edge of the scan area, normally on the Blood or Collagen SIAscans, is likely to have been caused by light ingress during scanning. To rectify the problem, repeat the scan ensuring the window on the handset is fully in contact with the skin to exclude light.

- II. Blotches on images

Blotches may be caused by bubbles in the matching fluid. The Blood SIAscan scan highlights these bubbles particularly well. To rectify the problem, clean off the current layer of matching fluid, apply a thinner layer and re-take the scan.

- III. Consecutive scans contain a similar mark or spot

A re-occurring mark or spot on the scans is likely to have been caused by dirt or debris on the window. It is important to ensure that the window is always clean. It is often difficult to spot this kind of problem when heavily featured or freckled areas are being scanned. One method recommended to avoid this problem is to wipe the end of the handset after every scan with an Isopropyl wipe. This serves to both clean and sterilize the window.

#### IV. The Blood SIAscan appears patchy

A patchy Blood SIAscan is often a symptom of excessive pressure being applied to the skin. This pressure tends to whiten the skin surface pushing the blood into a blotched formation.

#### V. Colour view has a green and red areas or featureless images

This is most likely caused by handset movement during scanning. Ensure that the lesion is steady on the viewfinder before starting a scan, and hold the handset in position until after the scan finishes. Excessive use of optical matching fluid can make it difficult to keep the handset still.

#### VI. Unusual coloured dots in the SIAscan

In some circumstances SIMSYS cannot process the data collected. In areas where this occurs the SIAscans contain bright dots, which are easily distinguishable. Such scans should be retaken. If the dots appear consistently ensure that the skin is clean and free of cosmetics. Refer to the Cautions and Warnings section.

### 3.8 Using SIMSYS Tools to Assess a Mole or Lesion

SIMSYS provides tools to aid an accurate assessment of the mole or lesion.

**Zoom In/Out** - The zoom slider bar is located to the right hand side of the screen. The zoom function can also be used with the Blood, Melanin, Dermal Melanin and Collagen views.



To view the lesion in one of the specific views, click on the icons to the left of the page until yellow highlighting bars appear around the title.

Using the **Fade colour in/Fade colour out** slider to the right of the screen, the colour view can be wholly or gradually removed to enable the blood, melanin and collagen views to be seen in isolation or superimposed onto the colour view.

Using the **Rotate** slider will rotate the image. This is particularly useful when comparing images as it is easy to line them up as the positioning of the scanner will probably not be exactly the same when taking follow up scans.

The **Mark** feature will allow you to place a marker on the scan. This tool will allow the clinician to identify specific area of concern within the mole/lesion with a marker (circle or arrow). To add the marker use the *Insert* key on your keyboard or left click on **Mark** and then select Add mark. Configure the marker type by selecting desired options in the pop-up window

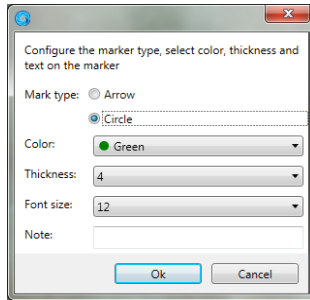
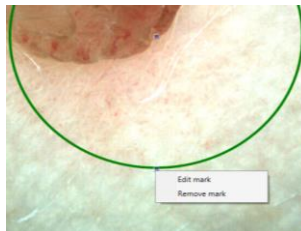


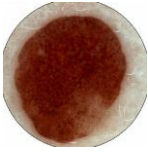
Figure: Mark editing pop-up window

This will place marker on the scan in all five views. To move the marker into desired position use centre/top mark-end icon (little blue square icon) – place the mouse over this point, left-click and drag. To change the size of the marker, place the mouse over the bottom mark-end icon (another little blue square icon), left-click and drag to change the size. To save the selections use the *Escape (Esc)* key on your keyboard or click on **Mark** and select Stop editing marks.

To Remove or Edit already added/saved marker, left-click on **Mark** and select Edit marks. This will bring back mark-end icons (two little blue squares icons) on the marker. Place the mouse over either one of mark-end icons (little blue square icons) and right-click to open new menu (see below).



Select Remove mark which will remove the marker from all five SIAscan views, or select Edit mark which will open the Mark editing pop-up window to make any desirable changes. Click on the *Escape (Esc)* key on your keyboard or select Stop Editing marks to save the changes you have made.



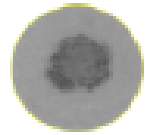
Colour

Colour view of Lesion



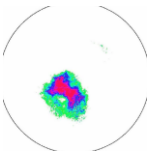
Blood

View blood vessels



Melanin

View of melanin distribution



Dermal melanin

View dermal melanin levels



Collagen

View collagen indicators

### 3.9 Compare SIAscans in Parallel or Overlay

SIMSYS allows the comparison of two images taken of the same mole or lesion.

From the mole or lesion record, select the two images that are to be compared by **clicking** on the first image, then push and hold down the **CTRL key** and select the second image by **clicking** on it. Both images will now be highlighted with a green border.

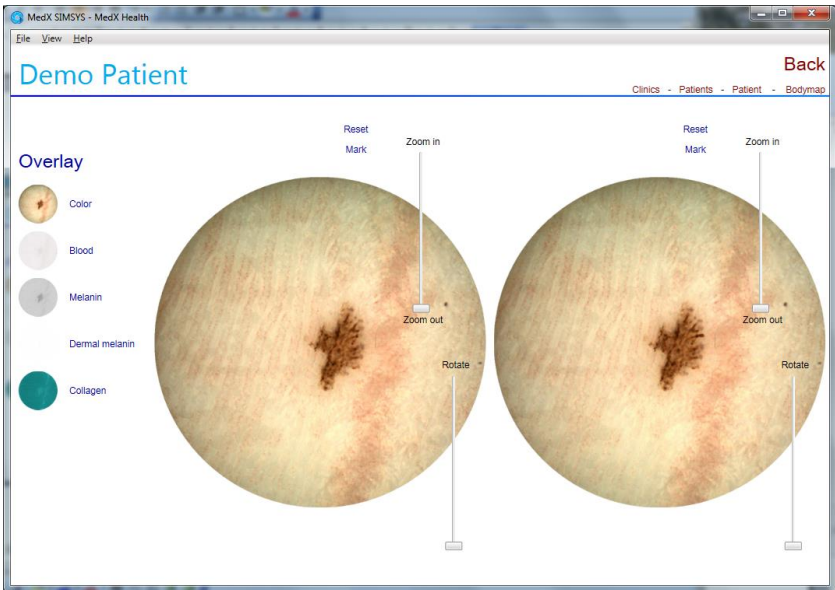
**Click** on the **Compare** button. The two images will be displayed in Overlay. Click on **Hide newer** to zoom in the older image first, and then click on **Show newer** to zoom in and line up newer image. **Rotate** feature will come in handy at this point to achieve the closest possible “alignment” of the two scans.



**Overlay View**

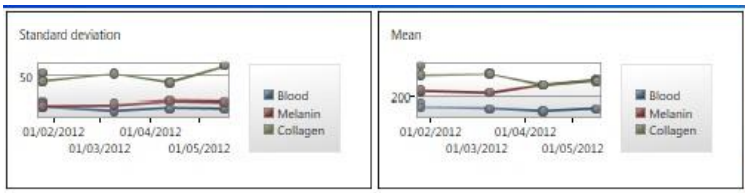
Use the function tools on the top left side of the screen to change view from Overlay to Parallel View.





**Parallel View**

**Note:** In a mole or lesion record that contains 2 or more SIAscans of the same mole or lesion, an automatic graph of the blood, collagen and melanin levels of the separate images is displayed.



### 3.10 Scoring a SIAscan

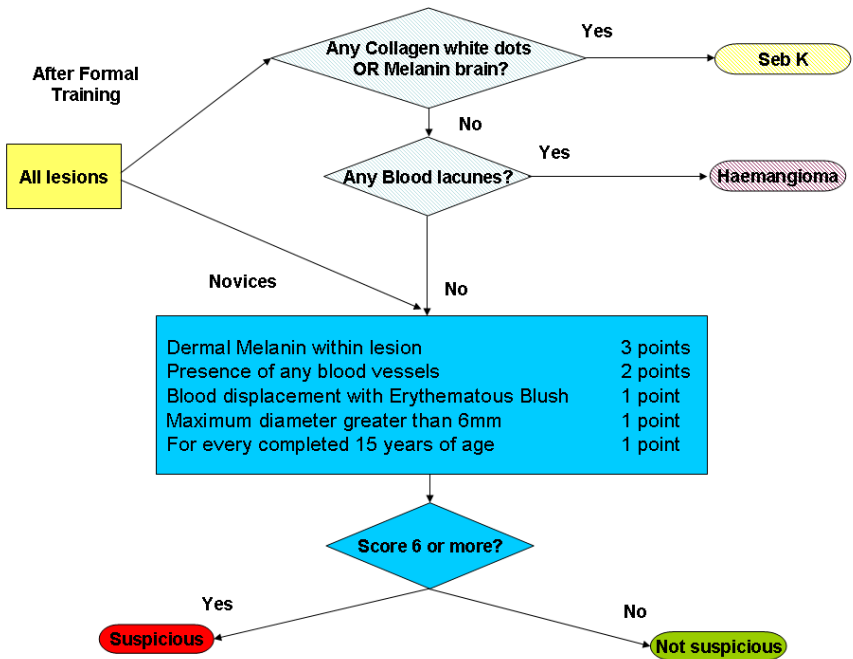
SIMSYS offers three standard scoring systems used with a Dermatoscope to assess a mole or lesion:

1. Primary Care Scoring System,
2. 7 Point Scoring System,
3. 3 Point Scoring System.

In the patient record, click on a SIAscan and click on **Score**. Choose which system to use and then follow the on-screen instructions to complete the assessment.

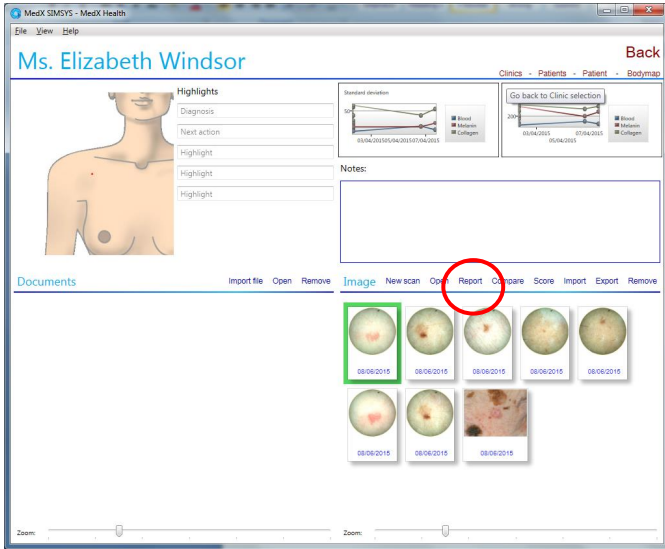
The scoring tool will automatically display the correct chromophore to the question being asked. In order to proceed through the scoring tool select the appropriate answer to the question, this will automatically load the next one. For each question a set of example SIAscans has been provided for reference. To access an example SIAscan navigate to the Example 1 button. This will display the example image on the screen in place of the patients SIAscan, repeat as necessary for the other example images. To return to the patients SIAscan Click on the Current button. On completion of the steps a **Summary** pane will appear with an overall score for the lesion and a recommendation as to whether the lesion is suspicious or not.

The Hunter Scoring System (Primary Care SIAscopy algorithm) is shown below. This shows the decision making path and outcome along with how a score is calculated and is taken directly from the poster associated to the scoring system.

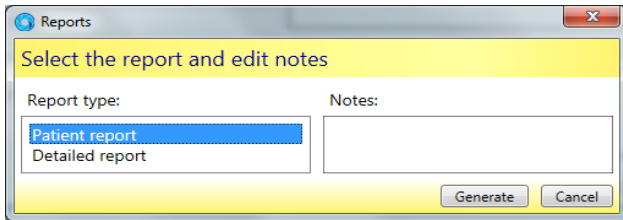


### 3.11 Saving and Printing a Report

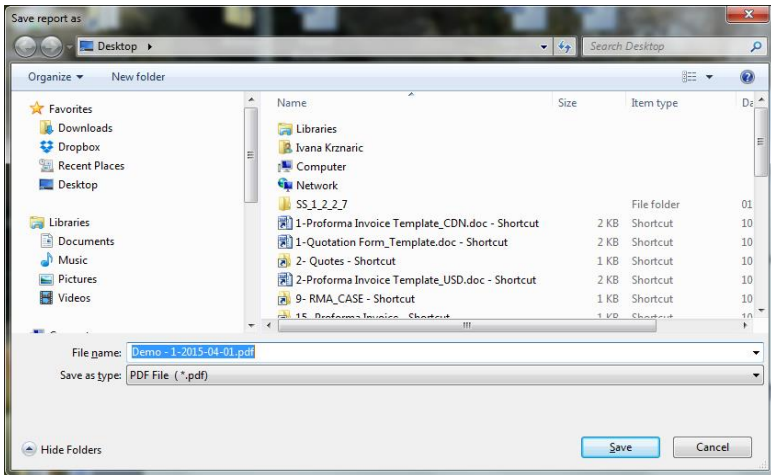
Select patient and scan you want to print/save the report for. Click on the **Report** tab to open a new window.



Select the type of the report, **Patient** or **Detailed** and click **Generate**.



This will open the "Save Report as" window.



Chose the location where you want to save and rename the file if necessary and click **Save**. The report is saved in PDF format in a location you have specified.

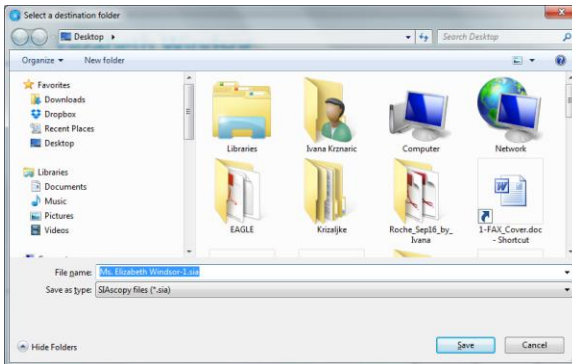
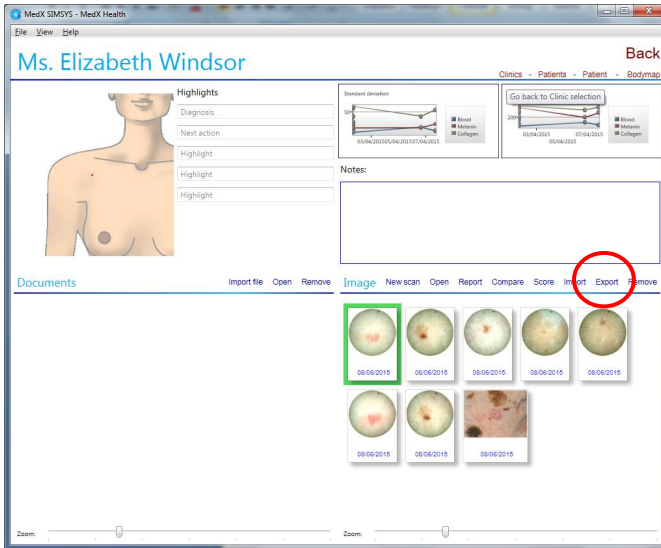
Now you can view, print or email your report.



All data should be backed up on a regular basis in order to reduce the risk of loss of data.

### 3.12 Saving/Exporting SIA file

If you wish to export SIA file images you can do so by using **Export** feature. Select patient and scan you want to export .SIA file for. Click on the **Export** tab to open a new window.



Select the location where you wish to save the file to and re-name the file if necessary before clicking on **Save** button.

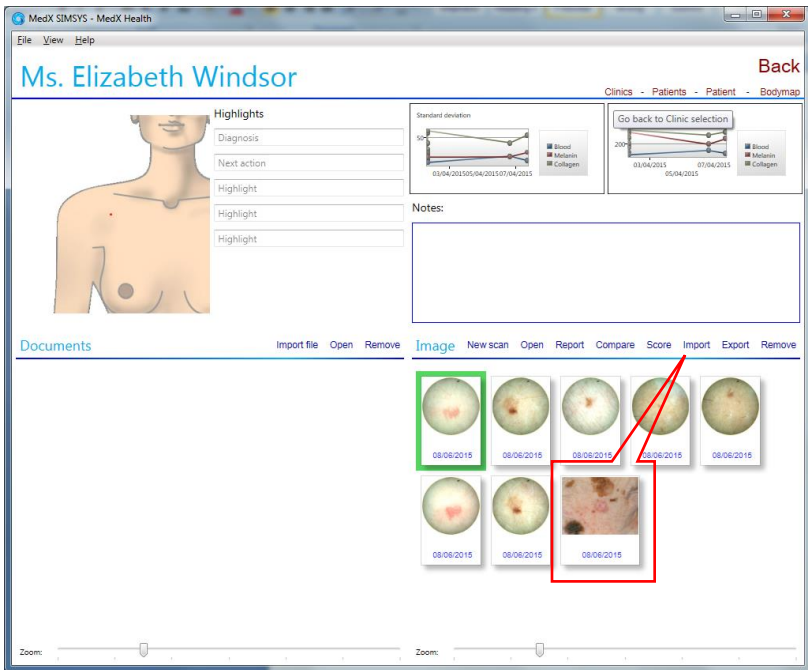
If you wish to send the .SIA file electronically, simply attach or upload the files accordingly.

**NOTE: The receiver must have SIMSYS application installed.**

Upon receipt of the .SIA file, the user needs only to double-click on the .SIA file icon and it will automatically open up in SIMSYS. Image quality will be identical as if the SIAscan was taken by the end user or operator.

### 3.13 Importing Images into a Mole or Lesion Record

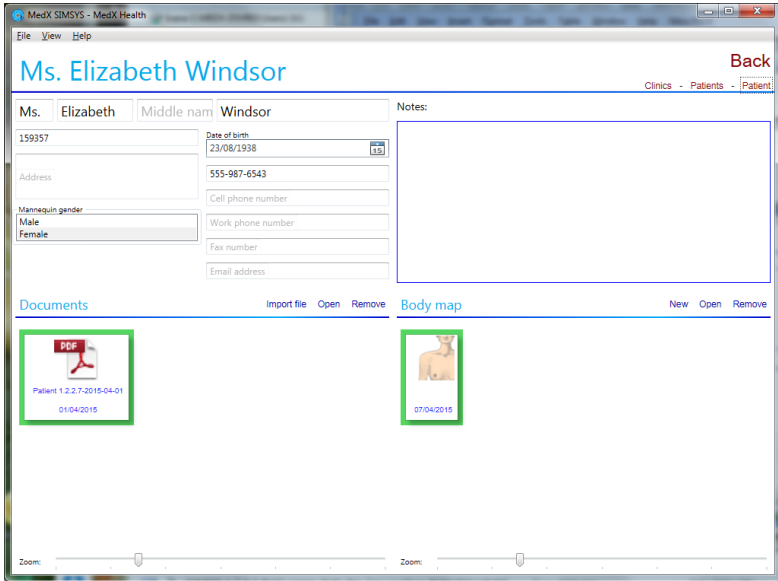
The clinical image in jpg, jpeg or png format could be imported to Images section and added to the report. Click on **Import Image** to add clinical image of the mole or lesion and Browse your files and click on **Open** to save the file to SIMSYS. Or you can use “drag and drop” technique to add clinical images here.



To include the clinical image on the PDF report select both SIA image and clinical image (hold “CTRL” button while clicking on each file) and then click on **Report** to save Patient or Detailed report (see section 3.11 Saving and Printing a Report).

### 3.14 Importing Other Documents into the Patient Record

Click on **Import File** to add any pre-existing file relevant to the patient. Files of any format can be dropped into the record.



To remove any record from documents or from the Body Map view, click on the item to select and click on **Remove**. Confirmation window will pop-up before the file is deleted.

## 4.0 CARE & MAINTENANCE OF SIMSYS SYSTEM

### Use Windows to Shutdown SIMSYS & PC

Data corruption can occur if power is suddenly removed from the system. Always use Windows to turn off your computer.

### Care During Operation

Before each patient examination, wipe the handset lens with an Isopropyl wipe. A Lens Cleaning Cloth is provided with each device.

### Usage Conditions

The SIAscope should only be used in the following conditions:

- Temperatures between 10°C and 40°C,
- Relative humidity between 30% and 80%.

The SIAscope should NOT be used in the following conditions:

- In direct sunlight and very brightly lit rooms,
- In areas of dust concentration, and
- In areas of extreme vibration.

The SIAscope is not intended for use in areas of high electromagnetic radiation (e.g. MRI and CT scanning rooms)

### Transport and Storage

The SIAscope should be stored and transported in the following conditions:

- Temperatures between 10°C and 40°C,
- Relative humidity between 30% and 80%.

The Matching Fluid should be stored and transported in the following conditions:

- Temperatures between 10°C and 40°C,
- Relative humidity between 30% and 80%.





Matching fluid should be used within the use-by date indicated on its label.

### Maintenance and Calibration

In order to ensure optimal performance of your SIAscope V unit, it is recommended that it be sent to the manufacturer or authorized service centre annually for maintenance and calibration. No maintenance or calibration is to be performed by unauthorized personnel.

### Disposal of Device

At the end of its service life, the SIAscope should not be disposed of in the general waste. You should consult your local regulations for the proper disposal of medical electronic devices in your area. Alternately, the SIAscope may be returned to MedX for disposal (see address on back cover).

## 5.0 TROUBLESHOOTING

There are a number of foreseeable faults or problems that may affect the operation of SIMSYS. These problems are often easy to solve. The following table highlights these problems, suggests a check to diagnose them and then suggests an action to amend the fault.

<b>Problem</b>	<b>Check</b>	<b>Action</b>
Artefact on all scans.	The Handset window is clean.	Clean the SIAscope window with an Isopropyl wipe.
SIAscope V will not connect.	Check that the SIAscope V has been connected properly to a USB 2.0 port.	Try connecting to another USB 2.0 port.
Droplets of water on the inside of the handset window.	Are the droplets on the inside of the scanning window? If not clean the window.	If moisture is on the inside of the window, leave the handset in a warm room for the moisture to evaporate. If the problem persists then contact technical support.
Viewfinder screen is black.	Examine the handset and note if there is a white light emanating from the end and if the "SIA" button on the scope is lit up blue. If there is not it is likely that the illumination has failed.	Contact technical support.
"The licence will expire in x days" message appears.		Contact MedX customer support to purchase a licence renewal.

## 6.0 TECHNICAL SPECIFICATIONS

- **Classification** - Class II Medical Equipment (IIa for EU – (CE<sup>0086</sup> )
- **Sensing technology** - Spectrophotometric Intracutaneous Analysis
- **Sensor** - Hand held sensor with an 11mm diameter sensing area, linked by a standard USB 2.0 cable to the system unit.
- **Emitted wavelengths** - 440nm to 960nm
- **Resolution** - Features larger than 25 microns
- **Scan time** - Approximately 3 seconds data collection, 3 seconds data processing (depending on your computer)
- **Data display format** - Processed data displayed as colour bitmaps (SIAscans) representing relative concentration and distribution of selected chromophores.
- **Reference image format** - Enhanced colour ELM (dermatoscopic) image. Image calibrated for repeatability and optimized for maximum colour discrimination in both light and dark areas of the image.
- **Dimensions** - 240mm in length x 65mm in diameter at its widest point.
- **Weight** - 250g.
- **Viewfinder** - Colour viewfinder mode allows accurate positioning of the sensor on the skin.
- **Hygiene** - Easily disinfected sensor window. Wipe clean with an Isopropyl wipe before each scan.
- **Power supply** - Power provided via the standard USB 2.0 connection.

## 7.0 LIFETIME OF PRODUCT

The SIAscope handheld scanner has been manufactured to exacting standards with high quality components to ensure excellent performance and durability. However, in the course of normal usage as laid out in this Operating Guide, normal wear and tear and degradation of such components could potentially affect the clarity of the images taken. As manufacturers, we therefore state that the lifetime of the SIAscope is three (3) years.

## 8.0 DECLARATION OF CONFORMITY

MedX Health Corp. declares that the following medical devices:

- SIAscope (model name: SIAscope V)
- SIAscopy Software (model name: SIMSYS)

conform to the Medical Device Directive 93/42/EEC as amended by Directive 2007/47/EC and comply with the following standards:

- EN 60601-1: 2006/A1:2013
- EN 60601-1-2: 2007
- IEC 62471: 2006
- IEC 62366: 2007
- IEC 62304: 2006
- IEC 60529:2001
- ISO 10993-1:2009
- ASTM D4169-16

EC Certificate 543441 – Directive 93/42/EEC on Medical Devices, Annex V (Notified Body Number 0086)


## 9.0 EMC REQUIREMENTS

The SIAscope V is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The equipment uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The equipment is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: Warning: This equipment/system is intended for use by healthcare professionals only. This equipment/ system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the equipment or shielding the location.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

The SIAscope V is intended for use in the electromagnetic environment specified below. The customer or the user of the Equipment should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 UT = 230 Vac	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles  <5 % UT (>95 % dip in UT) for 5 sec	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles  <5 % UT (>95 % dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the equipment requires continued operation during power mains interruptions, it is recommended that the equipment be powered from an uninterruptible power supply or a battery.
Power frequency (50 Hz and 60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

The SIAscope V is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-2	3 Vrms 150 kHz to 80 MHz	3 Vrms	<p>Portable and mobile RF communications equipment should be used no closer to any part of the equipment including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = \left[ \frac{3.5}{V_1} \right] \sqrt{P} \quad 150 \text{ kHz to } 80 \text{ MHz}$ $d = \left[ \frac{3.5}{E_1} \right] \sqrt{P} \quad 80 \text{ MHz to } 300 \text{ MHz}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = \left[ \frac{7}{E_1} \right] \sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz}$ <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey<sup>a</sup> should be less than the compliance level in each frequency range<sup>b</sup>.</p> <p>Interference may occur in the vicinity of known RF transmitting devices and equipment marked with the following symbol: </p>

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the equipment is used exceeds the applicable RF compliance level above, the equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the equipment.

b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

**Recommended separation distances between portable and mobile RF communications equipment and the SIAscope V.**

The SIAscope V is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the SIAscope V can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the SIAscope V as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter [W]	Separation distance according to frequency of transmitter [m]		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800MHz to 2.5 GHz
	$d = \left[ \frac{3.5}{V_1} \right] \sqrt{P}$	$d = \left[ \frac{3.5}{E_1} \right] \sqrt{P}$	$d = \left[ \frac{7}{E_1} \right] \sqrt{P}$
0.01	0.35	0.12	0.24
0.1	1.11	0.37	0.74
1	3.5	1.17	2.34
10	11.07	3.69	7.38

## **10.0 ACKNOWLEDGEMENTS AND NOTICES**

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## 11.0 REVISIONS

<b>Table A.1. Revisions</b>		
<b>Revision No</b>	<b>Revision Description</b>	<b>Date</b>
Revision 0.1	First draft composed.	10/03/2009
Revision 0.2	Biocompatibles changes.	16/04/2010
Revision 0.3	MedX Health changes.	15/02/2012
Revision 1.0	Reformatting of manual and addition of installation instructions, warnings and EMC requirements.	21/10/2013
Revision 1.1	Change of address for manufacturer and EU Rep.	28/04/2014
Revision 1.2	Added clinical image to reports, rotation feature and some other minor software changes	20/05/2015
Revision 1.3	Added software language selection and Mark the lesion feature	05/10/2015
Revision 1.4	Added CE0086 label to the manual	14/01/2015
Revision 1.5	Replaced applicable symbols with ones conforming to harmonized standards for medical device symbols. Added computer and OS system requirements to indicate Windows 10 compatibility. Standards applied – updated. Added note about safely terminating application.	19/10/2016

Revision 1.6	<p>New feature added i.e. exporting .SIA file</p> <p>Added on Sec 1.6 new symbols: EC REP and LOT</p> <p>On Sec 9.0, indicated EC certificate number and corrected MD directive number to 93/42/EEC.</p> <p>Updated information on compliance to latest issue/edition of following standards: EN 60601-1,; ISO10993-1, and ASTM D4169, Added IEC 60529:2001,</p> <p>Change of Authorized EU Rep, from TGM Medical Technology Consultants Ltd. in Berkshire, UK, to AJW Technology Consulting GmbH with office in Dusseldorf, Germany.</p> <p>Added required information pertaining to the newly-designated Australia Sponsor: Pharmadev Consulting Pty Ltd. with office in Sydney, NSW, Australia</p> <p>Added MedX Health Corp email address as part of company contact information</p> <p>Pg.9 Changed length of the USB cable supplied from 1.83m (6') to 3m (9.84')</p>	31/10/2017
Revision 1.7	<p>Separated Installation Guide from Operating Guide</p> <p>Added New Zealand sponsorship to Pharmadev Consulting Pty</p>	14/3/2018

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Method and apparatus Claims of U.S. and Worldwide Patent numbers: US6324417, US7916910, US2008075340, WO9822023, WO0075637, EP2393063, EP1768060, EP1185853, EP1006876, JP4856872, JP2001504020, JP2003501651, JP2007190364, GB2334099, GB2367125, GB2429385, GB2439469, CA2272290, CA2560364, AU2006220441, AU2006220441, AU4961597, AU5232100, AU725766 licensed for limited viewing uses only.

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