

MoleView Instructions For Use



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1. Welcome to MoleView

This document contains important information regarding safe operation of the MoleView system

Important

Please thoroughly acquaint yourself with the instructions for use before using the MoleView system. It is intended to describe the set-up and use of the MoleView software with the SIAscope V.

Important

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

Important

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. Papers written by independent scientists and clinicians describing how SIAscans can aid diagnosis are available from Astron Clinica.

Further information on each MoleView module can be found in the appropriate user guides supplied with your MoleView system. The documents contain additional detail on how to get the most from MoleView. These documents are also available to download from the MoleView website (www.MoleView.com).

2. 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.

3. Cautions and Warnings

Warning

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

Warning

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

Warning

The MoleView hardware 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).

Important

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

Important

Print outs 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 MoleView software to view fully detailed SIAscans.

Important

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

Important

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

Important

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 Astron Clinica Limited for advice.

Important

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

Important

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

 **Important**

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

4. How to take a contact SIAscan

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 V as described in the [Cautions and Warnings](#) section.

1. **Cleaning the SIAscope V** - Before each patient examination, wipe the end of the nose cone with an Isopropyl wipe.
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. Additional matching fluid is available from Astron Clinica or your local distributor.
3. **Place the SIAscope V on the patient** - Using the on-screen viewfinder centre the handset on the lesion. Pressing down lightly to prevent light from the room contaminating the scan.
4. **Hold the SIAscope V still and press the button** - Hold the handset still, then press and release the handset button and wait while the SIAscope V takes its measurements. The software will indicate when scanning is complete.

5. Correct use of the SIAscope V

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

- SIAscan contains unusual black edges
- Blotches on images
- Consecutive scans contain a similar mark or spot
- Blood SIAscan appears patchy
- Colour view has green and red areas or featureless images
- Unusual colored dots in the SIAscan

Important

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

5.1. 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.

5.2. 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.

5.3. 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. (Suitable Isopropyl wipes available from Astron Clinica and its distributors).

5.4. 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.

5.5. 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.

5.6. Unusual coloured dots in the SIAscan

In some circumstances MoleView 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 Warning](#) section.

6. Technical Details

6.1. System components

The MoleView system consists of a SIAscope V.

The SIAscope V consists of a unit with a 11mm diameter sensing window. It incorporates control buttons that allow navigation through the MoleView software. The SIAscope V is supplied with a standard USB 2.0 cable.

7. Care of MoleView system Hardware

7.1. Use Windows to shutdown MoleView PC

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

7.2. Care during operation

Before each patient examination, wipe the handset window with an Isopropyl wipe.

7.3. Usage conditions

The MoleView hardware should only be used in the following conditions;

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

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

7.4. Inappropriate conditions

The MoleView hardware should NOT be used in the following conditions:

- Avoid use in direct sunlight and very brightly lit rooms
- Avoid use in areas of dust concentration
- Avoid use in areas of extreme vibration

7.5. Transport and storage

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

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

8. Technical specification

8.1. SIAscope V

- **Function** - Non-invasive skin imaging device displaying the distribution and relative concentration of blood, pigment (such as melanin), and collagen within the papillary dermis and/or epidermis. Data is displayed as colour bitmaps known as SIAscans.
- **Sensing technology** - Spectrophotometric Intracutaneous Analysis
- **Sensor** - Hand held sensor with a 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
- **Data display format** - Processed data displayed as colour bitmaps (SIAscans) representing relative concentration and distribution of selected chromaphores.
- **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.
- **Calibration** - Factory Calibrated
- **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.

9. Electromagnetic Interference

The SIAscope V has been tested to ensure full compliance with the relevant sections of EN60601 (Electromagnetic Compatibility and Safety of Medical Electrical Equipment).

10. Feedback

At Astron Clinica Ltd, we strive to produce the highest quality products and welcome your feedback. If you have comments or suggestions about MoleView please do not hesitate to contact us.

If you have a technical query, please contact support:

support@astronclinica.com

11. Troubleshooting

11.1. Common problems

There are a number of foreseeable faults or problems that may affect the operation of MoleView. 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.

Further support information can be found on the MoleView website :

www.astronclinica.com/support

Table 1. Trouble shooting

Problem	Check	Action
Artifact on all scans.	The Handset window is clean.	Clean the SIAscope V 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 blue light emanating from the end. If there is not it is likely that the illumination has failed.	Contact technical support.

12. MoleView Warranty and Support

Features

- Comprehensive cover of the components of the MoleView product is included in the warranty, as long as they have been used in accordance with the terms and conditions in the warranty document. Items included are: MoleView SIAscope V Handset and associated components; MoleView software.
- A dedicated technical support team will be available for UK and EMEA customers during UK office hours (excluding Bank Holidays) to help with any issues relating to the installation and operation of the MoleView Product. Astron Clinica can be contacted by phone on +44 (1)223 265001 or via email support@astronclinica.com
- A dedicated technical support team will be available for Australian and ASIA-PAC customers during office hours 9:00 am. and 5:00 pm AEST (Australian Eastern Standard Time) excluding public holidays to help with any issues relating to the installation and operation of the MoleView Product. Astron Clinica can be contacted by phone on 1300 889 340, outside Australia (61) +7 3303 8472 or via email support@astronclinica.com.au
- If in the event that the MoleView SIAscope V handset needs to be shipped back to Astron Clinica the cost will be met by Astron Clinica. Approval must be sought from Astron Clinica before any shipment of the device is made.
- Any components found to be faulty under the terms and conditions of the contract will be repaired or replaced at no cost to the customer.
- No charge for parts, labour, during the warranty period.
- Upgrades to the MoleView software and relevant applications, within the current major version of the software that is released within the valid warranty period.

Limitations

- As detailed in the MoleView user documentation.

13. MoleView Extended Warranty and Support

Features

- Comprehensive cover of the components of the MoleView product is included in the warranty, as long as they have been used in accordance with the terms and conditions in the warranty document. Items included are: MoleView SIAscope V Handset and associated components; MoleView software.
- A dedicated technical support team will be available for UK and EMEA customers during UK office hours (excluding Bank Holidays) to help with any issues relating to the installation and operation of the MoleView Product. Astron Clinica can be contacted by phone on +44 (1)223 265001 or via email support@astronclinica.com
- A dedicated technical support team will be available for Australian and ASIA-PAC customers during office hours 9:00 am. and 5:00 pm AEST (Australian Eastern Standard Time) excluding public holidays to help with any issues relating to the installation and operation of the MoleView Product. Astron Clinica can be contacted by phone on 1300 889 340, outside Australia (61) +7 3303 8472 or via email support@astronclinica.com.au
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- Any components found to be faulty under the terms and conditions of the contract will be repaired or Replaced at no cost to the customer.
- No charge for parts, labour, during the warranty period.
- Upgrades to the MoleView software and relevant applications, within the current major version of the software that is released within the valid warranty period.

Limitations

- The warranty will only be in force after payment of the invoice for the extended warranty period has been received in full by Astron Clinica Ltd
- As detailed in the MoleView user documentation

14. Acknowledgements and Notices

SIA, SIAscanner, SIAscope, SIAscan, SIAscopy, COSMETRICS, Astron Clinica, SIAscope V, MoleView and Powered by SIAscopy are registered trademarks of Astron Clinica Ltd.

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The SIA technology is protected by patents in most major territories around the world including Australia (Patent No. 725 766), UK (Patent No. 2 334 099) and USA (Patent No. 6 324 417).

The MoleView software is subject to a separate license agreement and must not be copied or distributed to third parties.

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A. Revisions

Table A.1. Revisions

Revision No	Revision Description	Date
Revision 0.1	First draft composed	10/03/2009