VivoSight
The Whole Picture ™

VivoSight Dx Instructions for Use

The Whole Picture®

Michelson DIAGNOSTICS

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1 APPLICATION SPECIFICATION SUMMARY

Optical Coherence Tomography (OCT) is a cross-sectional imaging technique that is applicable to in-vivo medical examination. The technique is analogous to ultra-sound scanning, but because it uses Near Infra-Red (NIR) light it has much finer resolution (<10μm) for the same imaging depth. OCT allows one to see, in-vivo, in real time and non-invasively, tissue microstructure, without exposing the subject or user to ionizing radiation.

The VivoSight Dx will enable the user to:

1. Enter and manage patient and descriptive data
2. Acquire single and multiple 2-dimensional 16-bit OCT images of sub-surface tissue
3. Produce 3D volumes from multiple 2D images which can be rendered using third party software
4. Export OCT images as TIFF and as DICOM compliant image files

Expected locations of use are in-patient and ambulatory care settings. The complete system is suitable for use within the patient environment.

Users of the equipment need to be computer literate healthcare professionals, and have undergone the appropriate level of training for the different areas of operation. At a minimum it is expected that the user will be at nurse practitioner level.

There are no restrictions on patient population, and no restrictions related to the intended part of the body to which imaging can be applied.

2 INDICATIONS FOR USE

The VivoSight Dx is indicated for use in the two-dimensional, cross-sectional, real-time imaging of external tissues of the human body.

This indicated use allows imaging of tissue microstructure including skin, and enables detection and display of regions within the scanned area that are in motion (Dynamic OCT) to aid trained and competent clinicians in their assessment of a patient's clinical conditions.

3 CONTRAINDICATIONS

The VivoSight Dx is contraindicated for:

- Invasive procedures including use on open wounds
- Use on the eyeball

4 WARNINGS AND PRECAUTIONS

- Ensure that this manual has been read and understood before using the VivoSight Dx.
- If the VivoSight Dx shows signs of damage or is suspected of malfunction it should be taken out of service immediately and returned to the manufacturer or their authorised service centre for repair.
- The VivoSight Dx contains no user serviceable parts and should not be opened except by authorised service personnel of the manufacturer.
- The VivoSight Dx
    - Is **NOT** MRI safe and should **NOT** be taken into an MRI environment.
    - Is **NOT** defibrillator proof.
    - Must **NOT** be used in the presence of flammable anaesthetic mixtures with oxygen or nitrous oxide.
- If it is necessary to use the VivoSight Dx adjacent to other equipment, observe both the VivoSight Dx and the other equipment to make sure they are operating normally. Ensure the umbilical is separated from other cables. Only use cables supplied with the device.

  The emissions characteristics of this equipment make it suitable for use in professional health care facility environments. It is not intended for use in a residential environment, and might not offer adequate protection to radio frequency communication services. The user may need to take mitigation measures, such as moving or reorienting the equipment.
- The VivoSight Dx is a CLASS 1 Laser Product and is safe to use without additional eye protection. However, inside the VivoSight Dx is a CLASS 1M laser. If unauthorised maintenance is attempted then the user may potentially be exposed to hazardous Class 1M invisible laser radiation.
- If at any time the covers of the main unit of the VivoSight Dx have been removed, do **NOT** disconnect or handle or cut any exposed yellow or white sleeved fibre optic cables, as this may result in uncontrolled emission of invisible CLASS 1M laser radiation from the fibre aperture, which if viewed with magnifying or telescopic optical instrument could result in eye damage.
- If the VivoSight Dx does not operate as expected, consult section 8 “Setup Guide”. If it continues not to operate as expected, stop using the system immediately and contact the manufacturer or their approved agents for service
- The VivoSight Dx images may only be used to supplement other clinical information and should **NOT** be used to replace current clinical information, practice or judgment, and should be used in accordance with appropriate clinical guidelines e.g. Guidelines issued by the European Dermatology Forum (http://www.euroderm.org/edf/index.php/edf-guidelines).
- The VivoSight Dx is **NOT** intended to provide direct diagnosis or to make clinical decisions and is not intended to replace trained staff or existing test and assessment procedures.
- The VivoSight Dx should only be cleaned and disinfected as specified in these instructions (section 13).
- If the VivoSight Dx is used in a manner **NOT** specified by the manufacturer, the protection provided by the equipment may be impaired.

	• Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure. • **NO** modification of this equipment is allowed. Do **NOT** modify or make any new connections to the monitor. • Do **NOT** operate the VivoSight Dx outside the rated power supply range specified. Ensure the it is only connected to an earthed supply.

	• Use the green on/off switch on the cart do power the device up and to power it down. Do **NOT** power down the device by disconnecting from mains power at the wall socket.
	• Do **NOT** touch any USB connections on the cart shelf or connections to the Monitor and the Patient at the same time
	• Do **NOT** block the cooling vents on the rear of the VivoSight Dx
	• Keep the mains plug accessible at all times in order to isolate the device from the mains in an emergency
	• The VivoSight Dx is **NOT** to be used with USB devices with a separate connection to the mains such as printers, externally powered storage devices and other accessories that may compromise isolation during clinical procedures
	• Only cables <3m long should be used to connect acceptable devices to the USB ports on the cart shelf.
	• When using the VivoSight Dx, ensure that the mains lead and umbilical are **NOT** a trip hazard.
	• The recommended operating temperature range of the VivoSight Dx is +15°C to +30°C.
	• The VivoSight Dx should be placed on a stable level surface, away from direct sunlight.
	• Before moving the VivoSight Dx:
	  ○ Clear the top shelf of the cart of any items other than the keyboard and mouse
	  ○ Stow the mains cable and topical probe.
	• Grasp the monitor from the front when positioning.
	• It is recommended that at least two people move the system when the terrain is uneven or inclined, or when moving the system over thresholds.
	• Contact the manufacturer if attempting to move the device between buildings.
	• Do **NOT** place loads in excess of 10kg on the top shelf of the cart.
	• Do **NOT** apply loads to the umbilical in excess of 1.5 kg shear force, and 5 kg tensile force. If the umbilical shows any signs of splitting, contact the manufacturer.
	• Windows Defender antivirus software is installed on delivery. However, it is recommended that the user checks that the software conforms to the user's IT security and internet policy.
	• Do not install third party software on the device, it may interfere with the device operation.

5 FORESEEN MISUSES

Misuses of the probe

- **DO NOT** use on broken skin, due to the risk of cross-infection if blood is transferred to the standoff and not adequately disinfected (contraindicated).
- **DO NOT** attempt to scan inside the mouth or inside the ear canal or inside the vagina. The device is NOT intended for internal use (contraindicated).
- **DO NOT** attempt to scan the eyeball (contraindicated).
- **DO NOT** use the device for clinical applications for which there is insufficient clinical evidence. **ALWAYS** follow the locally applying Clinician Guidelines provided by your dermatology professional body for the clinical application.
- **DO NOT** place the probe on top of the shelf, it may fall off onto the floor and damage the delicate internal optics; **ALWAYS** re-holster the probe when not in use
- **DO NOT** continue to use if there is visible damage or cracks to the probe covers or umbilical
- **DO NOT** attempt to remove probe covers, due to risk of exposure to electrical or laser hazards
- **DO NOT** continue to use if the camera image is absent or has become very blurry due to dirt or contamination

Misuses of the standoff

- **DO NOT** use the device without cleaning and disinfecting the standoff between patients. The device is not intended for use as a sterile device.
- **DO NOT** use the device without a standoff fitted; it will not be possible to obtain a useable image
- **ALWAYS** use the device with the correct size standoff to achieve a good focus (see section 9.3 of this manual, Setting the Correct Working Distance); if this is not done, the image quality will be reduced resulting in poor performance.
- **DO NOT** use a standoff if it has visible damage, is cracked or is dirty or is visibly contaminated.

Misuses of the software

- **DO NOT** fail to enter the patient details for the scan about to be performed and **ALWAYS** ensure that they are correct when scanning to avoid risk of scan data being saved to the wrong patient record
- **DO NOT** delegate scanning or interpreting scans to an untrained or inexperienced user without direct supervision, to avoid risk of incorrect use of software or probe
- **DO NOT** leave the device unattended in public area with Windows or Wifi password bypassed or disabled due to risk of malicious access
- **DO NOT** install 3rd party software on the device as it may interfere with correct operation of the VivoSight software
- **DO NOT** ignore warnings supplied by the VivoSight software such as 'Disk nearly full' and always seek assistance
- **DO NOT** share user names or disclose your password to anyone else

Misuses of the cart and peripherals

- **DO NOT** disconnect the device from power at the wall socket while it is switched on due to risk of corruption of data; always turn off first using the green power button and wait for the green illumination to go off before disconnecting from the wall socket
- **DO NOT** connect the device to a 3rd party display monitor
- **DO NOT** subject the device to major shocks or vibration when transporting it to a new location as it may affect the device function
- **DO NOT** place an excessive weight > 10 kg on the shelf, for example a young child or cot, due to the risk of mechanical failure of the shelf
- **DO NOT** pull on the probe umbilical to try to move the entire device as it may cause the device to topple, or cause damage to the umbilical and internal fibres

Misuses from operating environment

- **DO NOT** use the device in very humid conditions exceeding the specification (80% RH) due to the risk of condensation on the lens and of malfunction of the electronics
- **DO NOT** use the device in very cold conditions or very hot conditions outside the specified ideal working range (15 to 30 ºC); due to risk of malfunction of the laser or electronics

General misuses

- **DO NOT** continue using the device if it is suspected to be faulty in any way or if the image quality is consistently worse than normal (too dim or reduced depth penetration); cease using it and seek support.
- **ALWAYS** ensure that the device is adequately maintained with annual checks by the manufacturer
- **DO NOT** use the device for clinical indications other than those provided in Section 2

6 RESIDUAL RISKS

1. Risk of loss of Essential Performance of Degraded Image Quality

The image quality provided by the device may be affected by any of the causes listed below. There is a residual risk that the user may not notice the degraded performance and continue using the device resulting in poorer than optimal results for the patient:

- Incorrect standoff fitted by user resulting in image out of focus
- Optics damaged by dropping of probe or excessive shocks/vibration
- Use in very humid conditions outside specified operating range
- Optics or internal fibre assemblies manufactured incorrectly and not adequately tested
- Damage to internal fibres caused by umbilical failure or internal abrasion during use
- Malfunction of the internal electronics including drift of calibration
- Image is somehow corrupted by software malfunction

2. Risk of incorrect positioning of probe

- The camera and LED illumination enable the user to position the probe accurately on the lesion. If the camera malfunctions or becomes dirty then this capability will be degraded; if the user nevertheless continues to use the device then inaccurate probe placement may happen resulting in poorer than optimal results for the patient

3. Risk of device misuse

- Due to misuse by the user, a result which is not optimal for the patient may result. See preceding section 5 Foreseen Misuses for a list of misuses and related risks;

4. Risk of mixing up patient records

There is a risk that data is stored in the wrong patient record, leading to later confusion over a patient's actual condition and then to incorrect treatment, if:

- The user enters the wrong patient details for the scan they are about to perform and does not notice their error;
- There is a software malfunction causing data to be saved to the wrong record

5. Risk of cross-infection:

The device is not sterile and should be disinfected between patients. There is a risk of cross-infection between patients if:

- The device is used on broken skin (contraindicated) and the standoff becomes contaminated with infected blood from a diseased patient and is not replaced and is used on another patient also with broken skin (contraindicated) enabling infected blood to be transferred to the second patient
- The device is used on broken skin (contraindicated) with a dirty/non-sterile standoff enabling bacteria to enter and infect the wound
- The device is used on a patient with a contagious skin disease and the standoff is not disinfected before use on the next patient

	6. Risk of mechanical injury or minor cuts: • There is risk that the device could tip onto the patient if the device is misused by excessive pulling on the umbilical when the wheels are locked; • There is risk that the shelf could collapse causing injury to user or patient if a weight well in excess of the specified maximum is placed on the shelf; • There is a risk of cuts to the user or patient if the device is used when the covers or standoff are damaged or broken and exposing sharp edges **7. Risk of biotoxicity:** • Although the device parts that come into contact with the patient and user have been evaluated for biotoxicity to EN 10993, there is residual risk of biotoxicity from contact with subject's skin. **8. Risk of electrical shock:** • There is residual risk from electrical shock due to multiple internal failures of the power electronics including failure of fuses to blow leading to exposed parts becoming electrically live. **9. Risk of eye damage from laser:** • There is residual risk of eye damage from exposure to laser light if the installed laser significantly exceeds maximum specified power output and this is somehow not detected in final testing and the probe is then used to scan the eyeball (contraindicated) **10. Risk of EMC affecting other equipment:** • There is residual risk of the device emitting RF emissions causing nearby equipment to be affected or vice versa, if either device malfunctions to cause such RF emissions outside its normal working EMC conditions **11. Risk of loss of data or loss of data confidentiality** • There is residual risk of loss of all patient data if both of the hard drives that make up the D: mirrored volume fail simultaneously • There is residual risk of loss of patient data confidentiality, or of permanent loss of patient data, if the user disables Windows security features or if the device is affected by malware infecting the user's computer equipment which is then connected to the device (including USB sticks, Wifi-LAN etc.) • There is residual risk of loss of patient records caused by accidental deletion by the user

7 ICONS AND SAFETY LABELS

7.1 LASER SAFETY LABEL

Label	Description
	Laser Classification (BS EN 60825-1: 2007) Location: Top of probe above objective lens

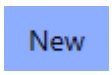
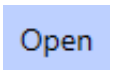
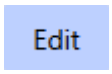
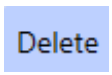
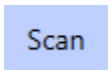
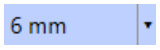
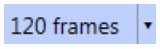
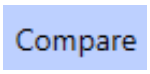
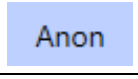
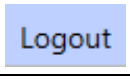
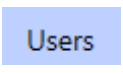
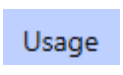
7.2 ICONS USED ON THE SYSTEM LABELS

Icon	Description
	Attention, consult accompanying documents
	Refer to Instructions For Use
	Signifies that this is a medical device
	Type BF Applied Part
	Type Number
	Serial Number
	Date and country of Manufacture
	Manufacturer
	Importer
	Batch number (standoffs only)
	Non-Ionizing Electromagnetic Radiation
	Standby / On
	USB
	Computer Network

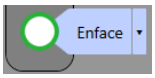
Icon	Description
	Alternating Current
	Protective Earth
	Temperature Limitation
	Humidity Limitation
	Atmospheric Pressure Limitation
	Fragile
	Keep Away from Sunlight
	Keep Dry
	MR Unsafe
	Waste Electrical and Electronic Equipment recycling (WEEE)
	FCC certification
CE 2797	Confirms compliance with relevant EU legislation. The number “2797” is the identification number of the “notified body”.
	Weight

7.3 ICONS AND FREQUENTLY USED FUNCTIONS IN THE VIVOSIGHT SOFTWARE

Icon	Description
	Icon to start the VivoSight Software
	Info - Displays VivoSight system and software version
	Info with alert - display alert messages
	Minimize - minimize the VivoSight window
	Close - close the VivoSight Software

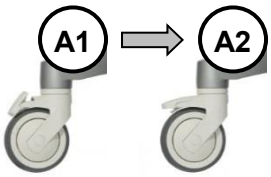
Icon	Description
	Home – go to home page with filters unset
	Back – navigate to previous screen
	Search – Start search
	Clear – Clear text field
	Create a new item
	Open the selected item
	Edit the selected item
	Delete the selected item
	Start Freerun
	Set Scan Width
	Set number of frames
	Export OCT images as Tiff
	Export OCT images as DICOM
	Export PDF Report
	Compare OCT scans
	Export the current OCT frame, Enface slice, 3D skin surface image (if enabled), and camera image as PNG
	Toggle on/off anonymization of patient names to initials only in patient list
	Log current user out of the application
	Open dialog for managing users, resetting passwords (admin users only)
	Create 12-month VivoSight usage report (count of patients, lesions, scans)
	Play-pause button in the middle (►) “jump to previous/next annotated frame” buttons to the left and right
	(yellow) **annotation marker** on the (blue) **navigation slider**

Icon	Description
	No Camera image. ⚠ If this appears, stop using and seek assistance.
	Import Dermoscopy image
	Annotation “Select” tool
	Annotation “Text” tool
	Annotation “Ruler” tool
	Free-Run “Trim” button
	Annotation “Arrow” tool
	Annotation “Star” tool
	Annotation “Bookmark” tool

Function	Screen and Probe	Keyboard
Start Freerun Stop scanning	 Black Circle  	F7
Start Enface or Start Dynamic	 White Circle  	F8

8 SETUP GUIDE

CLEAN PRIOR TO PATIENT USE



B

SYSTEM SETUP

A Move the cart into its final position and apply the cart brakes

B Plug the mains cable into the mains supply

C Position the monitor

D Turn on the system by briefly pressing the Standby / On button on top of the main unit

E If required, turn on the monitor by pressing the Standby / On button

F Log in to the system

Start the software using the VivoSight icon 

G Remove the probe from the cart tray

SYSTEM SHUTDOWN

G Replace the probe in the cart tray when all scans are complete

F Exit the VivoSight software

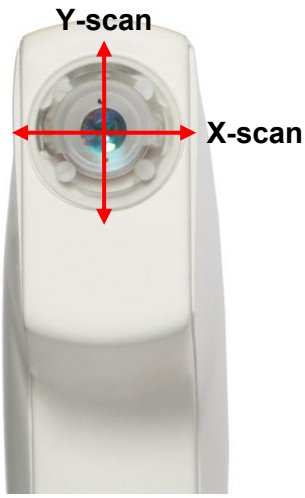
D Shut down the system by briefly pressing the Standby / On button, ensuring the shutdown process completes

B Unplug the mains cable, and stow at the back of the top shelf

A Release the cart brakes

	The VivoSight Dx must complete shutting down before mains power is disconnected. In the event of a temporary unplanned disruption to mains power, the device will continue to function for approximately 60 seconds before shutting down automatically.

9 VIVOSIGHT TOPICAL PROBE



The topical probe has been designed to be held comfortably in either the left or right hand, and operates in any orientation for ease-of-access to the region being imaged. It incorporates a colour camera (with white LED illumination) which shows on-screen the area of skin being imaged and the exact location of the scan line, to assist the user with positioning the scan on the area of interest.

9.1 PROBE BUTTON FUNCTIONS

There are 2 buttons located on the back of the probe which provide the following functions:

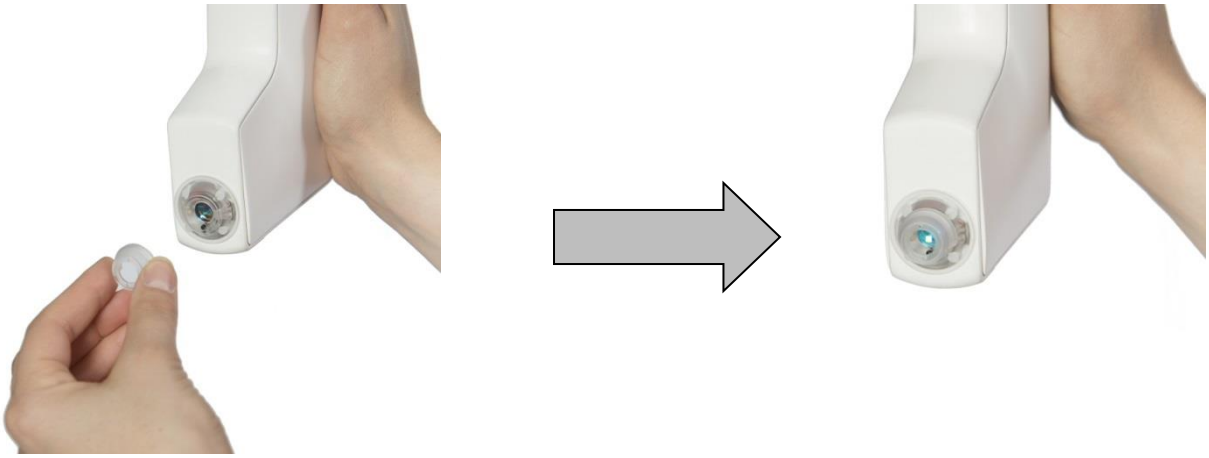
Start Freerun / Stop scanning

Start Enface

9.2 FITTING OF THE STANDOFF

A probe standoff is provided with the VivoSight Dx to aid positioning the probe on the skin surface and setting the correct scan distance. Probe standoffs are provided in 6 different sizes, each identified by between 1 and 6 small holes on the front face, to enable the skin surface to be positioned correctly (see below).

The standoff is fitted to the probe by clipping it sideways onto the retaining ring on the objective lens mount.



The standoff can be removed by doing the reverse, and simply unclipping it from the objective lens mount.

The standoff can also be rotated to set the most appropriate orientation for the skin area being scanned.

9.3 SETTING THE CORRECT WORKING DISTANCE

The correct working distance is set as follows:

1. Set the software to capture a scan (see section 10 for a detailed description of software operation).
2. Position the probe so that the standoff is gently pressing against the patient's skin around the region-of-interest (see figures below); use the camera view to locate the scan exactly as desired on the lesion or skin area.

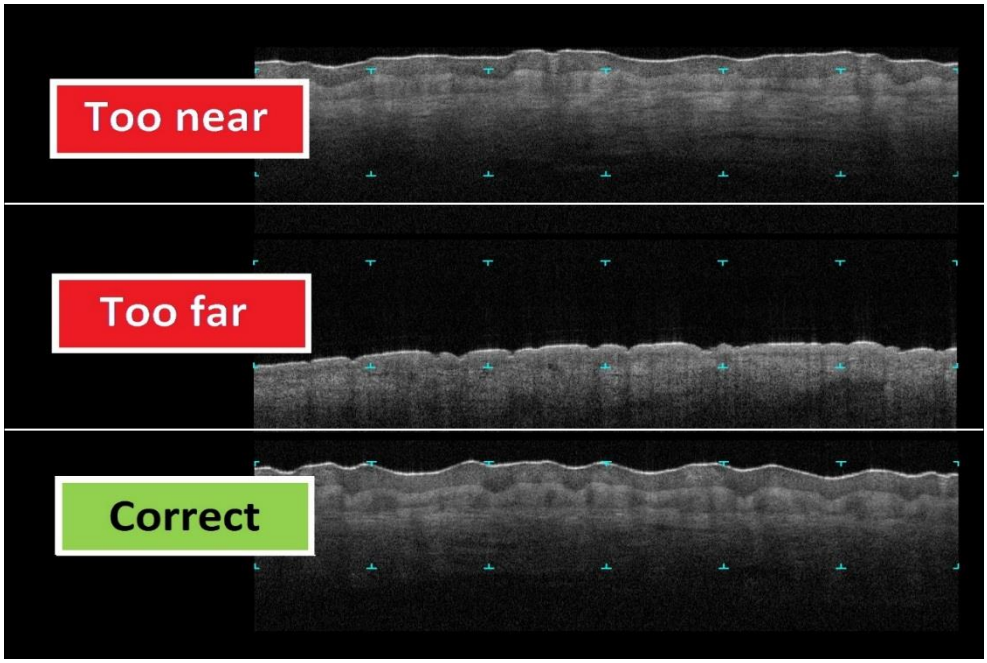
Probe placed with standoff touching the skin. The free hand not holding the probe is used to steady the probe on the patient.

Note how the VivoSight display is easily visible to the user during the scan.

3. By observing the image in the VivoSight software, adjust the working distance so that the region of skin you wish to see is within the region demarcated by the onscreen 'T' shape markers (see figures below). The image of the skin is moved vertically within the frame by:
   i. Changing the fitted stand-off for a different length (see 9.2 for the correct procedure).
   ii. Slightly varying the pressure applied to the probe. Do not press hard, but use some pressure; after completing the scan a circular imprint of the standoff will be visible on the skin surface for a short period. This is nothing to worry about and will clear naturally within minutes. The probe should not slide about on the skin; if it is then you are probably not pressing enough.
5. Use a standoff with more holes (i.e. a larger standoff) if the skin surface is too high / mostly above the blue tick marks. Use a standoff with fewer holes (i.e. a smaller standoff) if the skin surface is too low / mostly in bottom half of the focus region. Optimum image quality is achieved with skin surface positioned at the top of the tick mark boxes. See below.

⚠	Ensure that the correct working distance is set with the correct standoff so that the tissue region of interest is located within the blue tick marks as shown in the diagram below. If this is not done, then the tissue will be out of focus and details of the image will be unclear and will be difficult to interpret.

6. Ensure that the patient is comfortable before proceeding with the scan.



In the top image, the skin surface is above the top row of tick marks and so is out of focus.

In the middle image, the skin surface is near the bottom row of tick marks and so most of the tissue is outside the tick mark area and is out of focus

In the bottom image, the skin surface is located approximately at the top row of tick marks and all of the tissue image is in the tick mark area and is in focus.

Often the skin surface bulges or slopes and is not possible to always achieve these optimal conditions. In that case, do not rely on image features located outside the tick mark area which indicates the region of focus.

9.4 DYNAMIC OCT

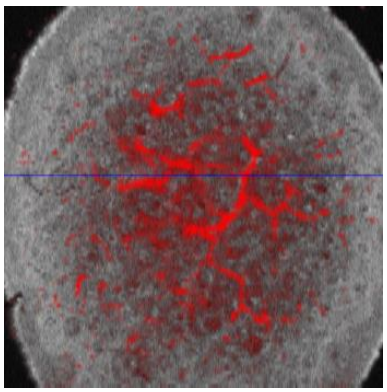
	Ensure that the correct working distance is set as in section 9.3 above, and that the Dynamic OCT Signal is clearly visible in the resulting EnFace View at top right with vessel shapes visible.

Enable Dynamic OCT by clicking on the down arrow next to the white button marked Enface: 

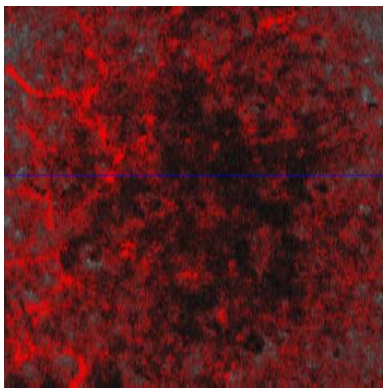
The label will change to Dynamic: 

To disable, click on the down arrow to change it back to Enface.

EnFace View



Dynamic OCT Signal
Bright Red linear or dotted features of vessels



Dynamic OCT Noise
Dim Red cloud

If the Dynamic OCT image resembles the lower image ‘Dynamic OCT Noise’ then the enface depth is too deep to provide reliable vessel images or the focus is set incorrectly with the wrong standoff fitted.

10 USING THE VIVOSIGHT SOFTWARE

Start the VivoSight software using the VivoSight **Icon**.

1. At the user login, enter your User name and your password.

2. Patients Management (Home) Screen – Selecting or adding patients

   For an Existing Patient:

   Use the search fields in the Header Bar to find an existing patient. Double click the Patient to enter the Patient Screen.

   OR for a New Patient:

   To define a new patient, fill-in the patient details in the Header Bar (this can be completed later in the Patient Screen). Click the New button.

3. Patient Screen – Selecting or adding Lesions

   For an Existing Lesion:

   Use the search fields in the Lesion Bar to find an existing Lesion, click the Lesion and then the Scan button.

   OR for a NEW Lesion

   Define a new Lesion by filling in the Lesion details (this can be completed later) and click on the **Lesion Map** to define the location of the Lesion. Finally specify the Lesion's Clinical Diagnosis from the selection and click the Scan button.

4. Scan Screen - Acquiring and Reviewing scans

⚠ Check that the patient details displayed at the top of the screen are correct, otherwise data may be saved to the wrong patient record.

⚠ Select the appropriate stand-off in accordance with the Instructions for use (see Section 9.3)

i. Position the stand-off against the skin.
ii. To change the width of the scan click the 6 mm **Scan Width** button and adjust the vertical slider.
iii. To change the number of frames click the 120 frames **Frames** button and adjust the vertical slider.
iv. To change between Dynamic mode on or off click on the 

arrow next to the white button at bottom right of the screen

⚠ It is important that a sufficient number of slices is set. A reduced number of slices will affect the resolution of the Enface view. 120 is recommended.

v. Using the context camera and OCT image, locate the Lesion to be scanned and press the **White** button on the probe. This captures a square area surrounding the Lesion. The Default settings are 120 frames 6 mm wide.
vi. On completing the scan, the probe illumination will turn off automatically and it will be possible to review the completed scan. The blue line displayed on the Enface window can be dragged to take you through the B-scan frames. The green line displayed on the B-scan can be used to alter the depth of the Enface slice.
vii. Use the annotation functions as required to make annotations of the images in the captured scan. It is also possible to modify the scan description and lesion description for lesions and scans created in the current session. However, only 'admin' level users can do so for previously captured lesions and scans, and only admin users can delete them or delete patient records.

⚠ The nominal depth of the Enface slice indicated by the green line is shown at bottom left. Note that this depth is approximate and is for indication only.

5. To acquire an additional scan of the same Lesion, press the **Black** button, repeat the steps above.
6. Once scanning is complete, click **Back** to return to the previous screen or **Home** to return to the Patients Management Screen.

7. To review a previously captured scan:
   - vii. in the Patient Management Screen, click on the Patient record of interest and then on 'Open'. This will display the Patient Screen record with a list of Lesion records at right.
   - viii. Click on the Lesion of interest and 'Open' which will display a list of scans performed on that lesion
   - ix. Click on the scan of interest and 'Open' which will show it in the Scan Screen. Follow steps (vi) above to review the scan.
   - x. It is also possible to then perform more scans as described above.

11 USE WITH OTHER EQUIPMENT

The VivoSight Dx is not intended to be used with other equipment.

12 CONNECTION TO AN IT-NETWORK AND DATA SECURITY

12.1 USE OF VIVOSIGHT WITHOUT CONNECTION TO AN IT-NETWORK

VivoSight Dx does NOT have to be connected to an IT-Network for its Intended Purpose, and it can be utilised as a stand-alone device without any IT connection, if so desired. Data output, if required, can be accomplished by connecting a USB memory storage device (thumb drive) to one of the USB sockets in the shelf.

USB devices that do **NOT** require additional drivers or a separate connection to the mains may be connected to the USB ports on the Cart shelf. These include:

USB flash drives (Including U3)
USB powered disk drives
USB wireless receivers for use with remote keyboards, mice, and printers.
DermoGenius dermatoscope devices

⚠	Do NOT connect USB devices with a separate connection to the mains including: Printers Externally powered storage devices Any other accessories that may compromise isolation during clinical procedures Only cables <3m long should be used to connect acceptable devices to the USB ports on the Cart shelf Do NOT modify or make any new connections to the monitor

Some user IT security policies require that the device is NOT connected to the internet for any purpose, including servicing. If this applies to your device, be aware that:

	If VivoSight Dx is not connected to the internet: • VivoSight Dx Windows Operating System may not be kept automatically up to date with security patches • VivoSight Dx Defender Anti-virus may not be kept automatically up to date to protect against the most recent malware • VivoSight Dx remote servicing will not be possible and may give rise to added costs and delays caused by the requirement for an in-person service visit.

Follow the user's IT security policies to ensure that if internet connection is prohibited, the above risks are addressed by alternative measures.

12.2 REQUIREMENTS FOR CONNECTION TO AN IT-NETWORK

Connection to an IT-Network is possible:

- To enable the user to transfer VivoSight output files, such as the .pdf reports or exported graphics files over Windows-LAN to a local networked Windows server if required;
- To enable the user to print pdf reports to a networked printer if required;
- To enable the manufacturer to remotely access the device for remote servicing (diagnosis, check-up, data archiving support or VivoSight software update) by connection to internet
- To enable the device to automatically update its antivirus protection by connection to internet

There are no data or information flows between VivoSight Dx and IT Network that are essential for the Intended Purpose.

Connection is possible via:

- Standard Ethernet cable IEEE 802.3 compatible, RJ45 connector, via ethernet socket at rear of Main Unit.
- Standard WiFi connection 802.11, 2.4 GHz. (WPA2 Security is recommended)

VivoSight Dx has an internal PC which runs on Windows 10 Operating System and can be connected to by the user to a Windows Local Area Network (LAN) compatible with Windows 10, using the Windows Network Settings and connecting by ethernet cable or Wifi. If this is done, VivoSight Dx will provide access to and from the LAN, and by extension, to and from the internet, according to the set-up network configured by the user. However, access to the data on the hard disk is not provided to externally connected users unless specifically enabled using Windows administration app; and VivoSight Dx will not be able to access other equipment or servers on the IT-network unless this is enabled by the user.

The Manufacturer is NOT responsible for validating the user's IT-network or for validating the VivoSight Dx connection to it or any networked other device.

The user is wholly responsible for managing data security of the user's IT network and for any damage to, or unauthorised access to, or loss of data on VivoSight Dx or on other devices connected to the VivoSight, caused by connection of VivoSight to the user's IT network and its misuse.

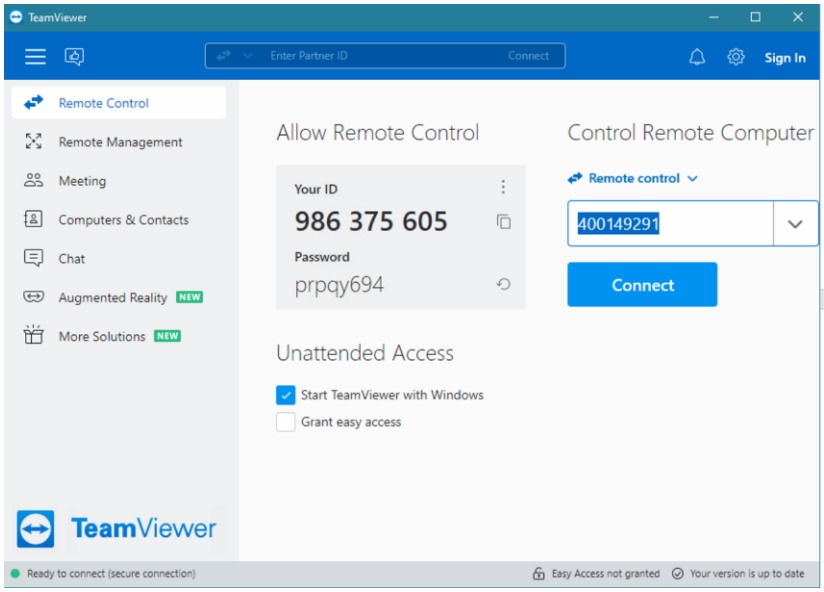
⚠	Connection to the internet is at the user's risk. If the VivoSight Dx is connected to the internet, it is the user's responsibility to ensure that local IT data security policy and procedures are appropriately followed and enforced to ensure security of patient data. VivoSight Dx is **NOT** intended to be connected to a public access network. Do **NOT** connect VivoSight Dx to an IT-network to which are also connected any safety-critical devices Do **NOT** provide access from VivoSight via the IT network to user data servers containing confidential or safety-critical data. Confidentiality of patient data may be compromised if Windows security features are disabled or if the VivoSight Dx is connected to a public access network or if malware is installed on the device intentionally or otherwise

If the user connects the VivoSight to the internet, the user is responsible for ensuring that the connection is adequately secure. The VivoSight Dx Windows Firewall should be left enabled, and Windows Defender Antivirus software left enabled and configured to auto-update when connected.

12.3 INTERNET CONNECTION FOR REMOTE SERVICING

In order to perform remote diagnosis, remote check-up maintenance, VivoSight software update, or support for data archiving (See section 17.2), the Manufacturer's service engineer may request the user to connect the VivoSight to be connected to the internet, and then to start the TeamViewer application by clicking on the TeamViewer icon on the TaskBar (See www.TeamViewer.com), and provide the TeamViewer ID and one-time-password. Example shown below – ID and password appear under 'Allow Remote Control'. This will enable the Service Engineer to connect to the device and provide service functions. These service functions and the Service Engineer procedures are HIPAA compliant and will not involve transfer of any patient data from the VivoSight. Always be sure that the engineer requesting TeamViewer connection is from the Manufacturer by telephoning or emailing the manufacturer directly.

TeamViewer icon



Example of TeamViewer login screen

12.4 IT SECURITY MEASURES

The following security measures are supplied with the installed device:

- The Anon button Anon when toggled, replaces all patient names in the patient list with initials only, so that patients looking at the screen cannot see the names of other patients
- Windows account password is enabled so that on start-up, access to the device requires knowledge of the password.
- After 30 minutes of no use, Windows password must be re-entered to regain access to the device
- All users have their own login credentials (user name and password) in the VivoSight application. The password must meet minimum complexity requirements (8 characters, both upper and lower case, and 2 numerical digits), and all passwords much be changed at least every 180 days
- After 10 minutes of non-use, users are logged out of the application and must re log-in
- Non-admin users are unable to delete or modify previously created patient records, to protect against unauthorised modification
- User activities are logged with name, date and time, to ensure traceability
- Windows Firewall is enabled providing protection against hostile internet-based actions
- Windows Defender is enabled, providing protection against malware infected files or USB devices

⚠	Do **NOT** share the VivoSight passwords with anyone else. Do NOT share or disable the Windows login password Do NOT share user names between multiple users Do NOT disable Windows Defender Do NOT disable Windows Firewall It is good practice to ensure that internet connection is regularly enabled so that Windows OS security patches & Windows Defender updates are kept up-to-date

12.5 IT SECURITY & SAFETY RISKS

The following risks may arise if VivoSight Dx is connected to an IT-network which has weak or no security or to which unauthorised persons have or may gain access:

- Risk of unauthorised access to confidential patient data stored on VivoSight
- Risk of partial or total loss of stored patient data on VivoSight
- Risk of software virus infection of VivoSight data
- Irreversible total loss of function of VivoSight due to virus infection of VivoSight Windows Operating System
- Misuse of VivoSight to gain unauthorised access to other devices or data servers on the IT-network
- Loss of access to VivoSight due to unauthorised change of security settings eg. Windows password

There are no identified risks resulting from failure of the IT-network to operate as intended or meet the above specifications in section 12.2. However, connection of the VivoSight to an IT-network that includes other equipment could result in previously unidentified risks to patients, operators or 3rd parties, and subsequent changes to the connected IT-network might result in new risks arising that require analysis (eg. changes to the IT network configuration, adding or disconnecting items, updating or upgrading connected items) and it is the responsibility of the user to ensure that any such changes are analysed and addressed.

	It is good practice to only enable the IT-network functions on VivoSight specifically required for the user's purpose, e.g. for printing reports or for remote servicing. Do **NOT** enable network access **from** VivoSight **to** network servers containing critical or confidential patient data Do **NOT** enable unnecessary control or access to other medical devices on the network Do **NOT** allow VivoSight to be used for purposes other than its intended use, e.g. email, browsing the internet, social media etc.

Exported data files from VivoSight may contain confidential patient data, including their names, dates of birth, and notes on their diagnosis. Therefore, the user should implement security policies to ensure that exported data files that are copied from the device are controlled and do not result in unauthorised access to the confidential data.

	VivoSight exported data files contain patient data including patient id, name, date of birth Exported TIFF and DICOM files contain patient name, date of birth within the file body

In the event of a data security breach causing loss of data or loss or impairment of function of VivoSight, contact the manufacturer or their authorised service representative for support.

12.6 DATA BACKUP & ARCHIVING

VivoSight Dx is equipped with an internal RAID back up hard disk. If the main hard disk fails or is corrupted, the lost data can be recovered from the back-up drive. If on start-up, Windows reports that it

cannot access the D: drive, then contact the manufacturer or authorised service representative for support in replacing the drive and recovering data from backup drive.

12.7 MANAGING USERS

There are 3 types of users:

- 'Normal' users have limited capabilities. They can create new patients, new lesions and perform scans. They can modify, annotate or delete newly created lesions and scans. However, they cannot modify or delete lesions or scans created in previous sessions, and they cannot delete patient records. They cannot manage users.

- 'Admin' level users can additionally do all of the above steps that normal users cannot. They can also access the 'Manage Users' dialog (see below).

- 'Engineer' level user can do all of the steps that Admin users can, except they cannot create Normal Users. In addition, Engineer users are prevented from seeing patient names and Dates of Birth on the patient list, for patient confidentiality reasons. Engineer user is reserved for use by authorised service engineers for maintenance procedures.

To access the 'Manage Users' dialog, an admin user clicks on Users button.

In this dialog, it is possible to create or delete new users (Admin or Normal level) and reset a user password if they have forgotten it

⚠	To preserve patient data confidentiality: Do NOT share user names between multiple users Delete users who have left the user's organisation Caution users to use complex passwords

13 CLEANING AND DISINFECTING

⚠	The VivoSight Dx including, cables and or other parts may **NOT** be immersed in water or other liquids. Do **NOT** use solvents or abrasive cleaners on plastic parts or the display screen

Cleansers and disinfectants must be CE marked indicating an intended purpose of medical devices & specified for use on plastics.

Before cleaning, disconnect from the mains electrical supply. Always apply the liquid to the cloth and squeeze out surplus liquid before applying to the device. Never make contacts of connectors wet.

13.1 TOPICAL PROBE, STANDOFF AND UMBILICAL

The topical probe, standoff and umbilical should be cleaned and disinfected prior to patient use with standard hospital disinfectant appropriate to the materials. Ensure all joints on the probe are disinfected thoroughly. The topical probe, standoff and umbilical should also be cleaned and disinfected after patient use to remove any contamination.

Contact cleaning of the objective lens should be minimised. However, if it is required, use a lens cloth or clean air duster. Should further cleaning be required, use a soft cloth moistened in Isopropyl alcohol and then polish with a lens cloth.

The standoff is not intended for use on broken skin. However, if the standoff is contaminated and cleaning is not considered to be adequate, the contaminated standoff should be disposed of to clinical waste and a fresh standoff used for the next patient.

13.2 KEYBOARD, MOUSE

The keyboard and mouse should be cleaned and disinfected at regular intervals in line with your establishment's infection control policy

13.3 CART AND MONITOR

All accessible surfaces on the cart and monitor may be cleaned regularly using a cloth dampened with water and detergent that is indicated for use on plastic. Apply the liquid to the cloth and squeeze out surplus liquid. Do **NOT** apply liquid to the system or its cables.

Alcohol lens wipes may be used to clean the screen.

The cart and monitor are **NOT** intended to be disinfected regularly. Only disinfect when required due to contamination of external surfaces.

14 PRODUCT LIFECYCLE

The VivoSight Dx product lifetime is **7 years**, based on the expected lifetime of the laser used in the device.

Other parts of the device that may incur wear and may require replacement during the device lifetime include:

Standoff. It is recommended that these are replaced annually as precaution against wear and possible breakage.

Hard disks. The hard disk manufacturer specifies a 5 year lifetime. If the device software starts to run slowly, this may be a sign that the hard disk(s) are wearing out and need replacement.

Umbilical. The probe umbilical outer sleeve may split from repeated flexing. If this is observed, report it immediately so that it can be repaired.

Power unit. The power unit contains capacitors which may degrade if the device is stored unused for more than 2 years, or if the device is kept in humid conditions > 70% RH; resulting in reduced capability to continue operating during a momentary mains electricity supply interruption (brownout). If the device is stored unused for more than 2 years or in humid conditions, contain the manufacturer before reusing the device so that the power unit can be maintained.

In all cases, contact your local representative for VivoSight, or Michelson Diagnostics, for advice and support if the device requires service or replacement parts.

15 TECHNICAL DATA

The following technical data relates to the VivoSight Dx

15.1 SYSTEM SPECIFICATION

Key Part References

VivoSight	Dx1302
Monitor	HP 22”
Keyboard	UK: KG22295 or Perixx 10904 DE: KG22294 or Perixx 10901 US: KG22296 or Perixx 10905
Mouse	KH22219 or as supplied with Perixx keyboard

Applied Parts

Standoff Set of 6 sizes	1191.MD.317

Performance

System Type	Swept-source Fourier-Domain OCT
Laser centre wavelength	1305 ± 10 nm
Laser frequency sweep range	≥ 147 nm
Axial optical resolution (in tissue)	< 10 µm
Lateral optical resolution	< 7.5 µm
Scan area	6mm x 6mm
Imaging depth	Tissue dependent, typically 1 mm for skin
A-line rate	20 kHz
Scan time	< 15s (6mm x 6 mm, 120 frames, enface mode) < 40 s (6mm x 6 mm, 120 frames, dynamic mode)

Safety

Medical Device Classification	Class IIa (Active diagnostic, may come into contact with injured skin)
Basic Safety	Complies with EN ISO 60601-1:2006+A1:2013+A12:2014
Type of Protection against Electric shock	Class I (Safety Earth)
Degree of Protection against Electric shock	Type BF Applied Parts
Method of mains isolation	Disconnection of the mains plug from the electrical supply
EMC/EMI compliance:	Complies with IEC60601-1-2 Ed 4 Emissions Standard and Immunity Standard for Medical Equipment, Professional Health Care Facility Environment Complies with EN 301 489-1 V2.2.1:2019 Emissions, and Immunity Standard for radio equipment and services – Professional

Laser Safety:	CLASS 1 Laser Product Contains a CLASS 1M Laser device emitting up to 25 mW of invisible laser radiation Complies with EN 60825-1:2014+A11:2021

Water & Dust Protection

The topical probe and umbilical have been designed to reduce ingress of liquids. However, do **NOT** place under running water or immerse in liquids.

All parts of the system are IPX0. No water or dust protection is claimed.

Power

Supply Voltage	100-240V~ 50-60Hz Nom. (Earthed supply)
Maximum Power	250VA
Mains Input Connector	IEC 320 C13 Socket 10A
Fuse	T 5AL 250V

Weight and dimensions

Dimensions (W x D x H) (Monitor at maximum height)	0.55 x 0.57 x 1.61 m
Weight	54 kg with no additional load added to the shelf
Load	Max shelf load 10 kg

Exclusions

- Not a sterile device and not intended for use in a sterile environment
- Not for use in an oxygen-rich environment or in the presence of flammable anaesthetics or agents
- Not for invasive use

Environmental

Operating

- Temperature of 15°C to 30°C
- Humidity of 20% to 80% non-condensing
- Height above sea level to be less than 2000m
- Floor to be level to within 10° of horizontal during use

Movement and storage between use

- Temperature of 10°C to 40°C
- Humidity of 20% to 80% non-condensing
- Atmospheric Pressure 50kPa - 106kPa
- Floor to be level to within 10° of horizontal when being moved
- Thresholds should be less than 20mm in height during transport conditions

Transportation and Storage in original packaging

- Temperature of 0°C to 40°C
- Humidity of 20% to 80% non-condensing
- Atmospheric Pressure 50kPa - 106kPa
- Prior to transportation, the monitor and monitor support must be removed from the cart by the manufacturer or their approved agents and packed in the original packaging
- If stored for extended periods in humidity > 70%, or for more than 2 years without operation, the capacitive energy store unit should be replaced before use

15.2 FCC

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

1. this device may not cause harmful interference, and
2. this device must accept any interference received, including interference that may cause undesired operation.

16 TESTING INCLUDING PRE-USE CHECKS

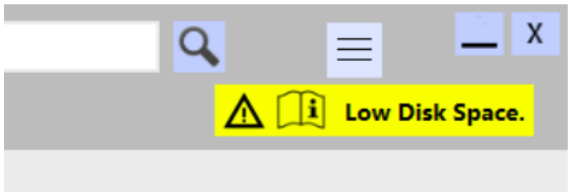
16.1 PRE-USE CHECKS

Before each use the VivoSight Dx, including cables must be inspected for wear & damage. Systems showing wear or damage should **NOT** be used. If device has not been operated for more than 2 years, or if in any doubt as to device safe operation, contact the manufacturer or authorised service representative for advice.

When connecting VivoSight Dx to a mains supply, ensure that the mains plug is accessible at all times so that it can be easily disconnected or switched off at the wall socket to ensure isolation from the mains supply is easily possible.

To verify that the VivoSight Dx is installed and ready for normal use, follow the steps A to F described in Section 8 and then view the display. If there is a major fault detected in the electronics, a warning will be prominently displayed and it will not be possible to perform any scans.

Alternatively, a warning may be displayed in yellow or red at the top right of the display, as shown below. If it appears in red, it will not be possible to perform any scans. If it appears in yellow, then the device may be used but a service or maintenance action is required and the manufacturer or its authorised service agent should be contacted.



Example of yellow warning message requiring service agent action.

⚠	Do **NOT** ignore yellow warning messages. Always contact the manufacturer or authorised service representative to report the problem and request support.

16.2 ELECTRICAL SAFETY TESTING

Electrical safety tests should be performed using a Rigel Medical or similar test system to the requirements of BS EN 62353 including.

- Earth Bonding
- Insulation
- Patient applied parts leakage Type BF
- Signs of damage which may lead to the exposure of live parts

Connect the safety tester earth clip to the bottom plate of the VivoSight underneath the main housing.

After testing check the VivoSight Dx for correct operation.

Frequency of the electrical safety tests should be at least annual or more frequently in the event of actual or potential damage or if your establishment's code of practice specifies.

17 MAINTENANCE & ACCESSORIES

17.1 MAINTENANCE

The VivoSight Dx does **NOT** include any user serviceable parts. Therefore, the manufacturer or their approved agents for service should be contacted in the event of damage, malfunction or change in performance.

If the VivoSight Dx does not operate as expected, consult section 8 Setup Guide. If the VivoSight Dx continues not to operate as expected, stop using the system immediately and contact the manufacturer or their approved agents for service.

	Repair of the VivoSight Dx is to only be carried out by the manufacturer or their approved agents for service. Do not attempt to open any cover; the device is not user-serviceable.

Test system performance at least every year or shorter period if specified in your medical establishment's code of practice. Annual maintenance is recommended to be carried out by the manufacturer or their approved agents for service including electrical safety testing as defined in section 16.2.

17.2 DATA ARCHIVING

After approximately 2,000 scans have been performed, the VivoSight hard disk may become full and it will no longer be possible to perform any more scans. Prior to this happening, the VivoSight Dx will detect low disk space and will warn the user (See Section **Error! Reference source not found.**). When this happens, c ontact the manufacturer or authorised service representative for support with data archiving.

Data archiving is a procedure in which scans performed prior to a set date are moved off the VivoSight Dx drive to an external archive drive. This can be a large capacity (at least 10 TB) external USB drive, or a server on the Wifi or ethernet LAN. The archived data can be accessed at a future date if required by reconnecting it to the VivoSight Dx.

	Due to the potential risk of data loss if done incorrectly, data archiving should only be performed by the manufacturer or its authorised service representative. Do **NOT** attempt to delete or move database files from VivoSight Dx, as this may result in permanent loss of data and or corruption of the VivoSight database

17.3 ACCESSORIES

Probe standoffs 1191.MD.317 are provided with the VivoSight Dx to aid in positioning the probe on the skin surface at the correct scan distance. Replacement sets will be supplied annually to customers with warranty or service contracts for their device, or can be ordered when required.

Standoffs should be replaced if they show any sign of damage or if contaminated with blood or bodily fluids.

18 WARRANTY

The manufacturer warrants the product, when new, to be free from defects in materials and workmanship and to perform in accordance with manufacturers specification for a period of one year from the date of purchase. The manufacturer will repair or replace at their discretion any components found to be defective or at variation from the manufacturer's specification within this time at no cost to the purchaser.

Your original supplier will administer this warranty on behalf of the manufacturer; and initial contact relating to a claim under this warranty must be made to the distributor.

After contacting your original supplier to agree warranty cover it shall be the purchaser's responsibility to return the product.

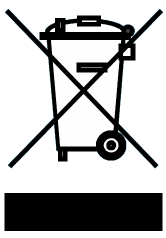
The warranty does not include breakage or failure due to tampering, misuse, neglect, accidents or modifications. This warranty is also void if the product is not used in accordance with the manufacturer's instructions or is repaired during the warranty period by any person other than the manufacturer or their approved service agent.

The date of purchase / delivery determines the commencement of this warranty. No other expressed or implied warranty is given and no consequential claims will be accepted.

19 DISPOSAL

Damaged or contaminated standoffs should be disposed of in containers intended for low-risk clinical waste. If waste receptacles are provided for recycling of plastics, these may be used, as the standoffs are made from recyclable polycarbonate plastic.

Information on Disposal of Waste Electrical & Electronic Equipment (Europe Only)



This symbol on the products and / or accompanying documents means that used electrical and electronic products should not be mixed with general waste.

Disposing of this product correctly will save valuable resources and prevent any potential negative effects on human health and the environment which could otherwise arise from inappropriate waste handling. If you are unsure of your national requirements with respect to disposal please contact your local authority, dealer or supplier for further information.

Penalties may be applicable for incorrect disposal of this waste, in accordance with national legislation.

The above information is based on the European waste electrical and electronic equipment directive 2012/19/EU.

20 REPORTING OF ADVERSE AND SERIOUS INCIDENTS

	If any **adverse or serious incident** occurs in relation to the VivoSight Dx, then it should be **immediately reported** to the manufacturer at the address below and its authorised representative and to the competent health safety authority of the EU Member State where the device is located.

Michelson Diagnostics Ltd
Units 1 & 2, Maidstone Innovation Centre
Gidds Pond Way
Maidstone, Kent, ME14 5FY

Tel: +44 (0)20 8308 1695
Email: support@vivosight.com

EC REP

Medical Device Management Ltd
Block B, The Crescent Building,
Northwood, Santry,
Dublin 9, DO9 C6X8
Ireland

Australian Sponsor

Emergo Australia
Level 20, Tower II
Darling Park
201 Sussex Street
Sydney, NSW 2000
Australia

CE 2797

Compliant with Medical Device Directive 93/42/EEC

Compliant to RoHS 2011/65/EC