VivoSight

VivoSight Dx Instructions for Use

Diagnosis at the speed of light

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 directly on the eye

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
    - 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. Do **NOT** attempt to stare directly into the beam. Do **NOT** attempt to insert a mirror or other reflecting device into the beam.
- The VivoSight Dx contains a 660nm 3mW fibre coupled laser. No laser radiation is accessible within the system.
- If the VivoSight Dx does not operate as expected, consult section 6 “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 10).
- 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.

- 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 if required
- The VivoSight Dx is **NOT** intended 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, umbilical, and footswitch cable 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, footswitch, and topical probe.
- Grasp the monitor from the front when positioning. Do **NOT** insert fingers into any potential pinch points on the pillar.
- 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.
- 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 1.5Kg shear force, and 5Kg tensile force.
- 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.
- Only software specified in this manual may be safely installed on the system without consulting the manufacturer or authorised service representative for advice.

5 ICONS AND SAFETY LABELS

5.1 LASER SAFETY LABEL

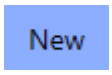
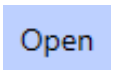
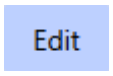
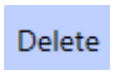
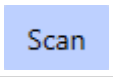
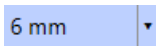
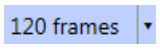
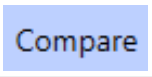
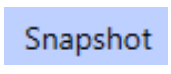
Label	Description
	Laser Classification (BS EN 60825-1: 2007) Location: Top of probe above objective lens

5.2 ICONS USED ON THE SYSTEM LABELS

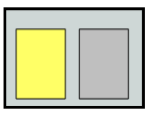
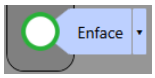
Icon	Description
	Attention, consult accompanying documents
	Consult Instructions For Use
	Refer to Instructions For Use
	Type CF Applied Part
	Type Number
	Serial Number
	Date of Manufacture
	Manufacturer
	Non-Ionizing Electromagnetic Radiation
	Standby / On
	USB
	Computer Network
	Alternating Current
	Protective Earth

Icon	Description
	Temperature Limitation
	Humidity Limitation
	Atmospheric Pressure Limitation
	Fragile
	Keep Away from Sunlight
	Keep Dry
	MR Unsafe

5.3 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
	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

Icon	Description
Calculate	Calculate estimated Plexus Depth, Vessel Diameter, and Vessel Density
	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**
	No Camera image
	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	Footswitch	Keyboard
Start Freerun Stop scanning	 Black Circle  	 Yellow	F7
Start Enface or Start Dynamic	 White Circle  	 Green	F8

6 SETUP GUIDE

CLEAN PRIOR TO PATIENT USE

SYSTEM SETUP

A1 Move the cart into its final position and apply the cart brakes

Plug the mains cable into the mains supply

B Position the footswitch (if supplied)

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 Stow the footswitch (if supplied)

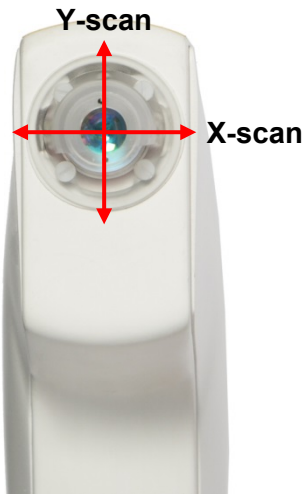
Unplug the mains cable, and stow at the back of the top shelf

A2 Release the cart brakes

⚠	The VivoSight Dx must complete shutting down before mains power is disconnected

7 VIVOSIGHT TOPICAL PROBE

The VivoSight topical probe has a visible red spot to enable the user to position the scan on the required area of skin. It enables X-Y scanning to be performed to produce 2D images, and 3D volume renders.



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. A low-power red laser projects light from the scanning lens at all times when the VivoSight Dx is powered-up. This laser helps the user to position the probe correctly on the region-of-interest.

7.1 PROBE BUTTON FUNCTIONS

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

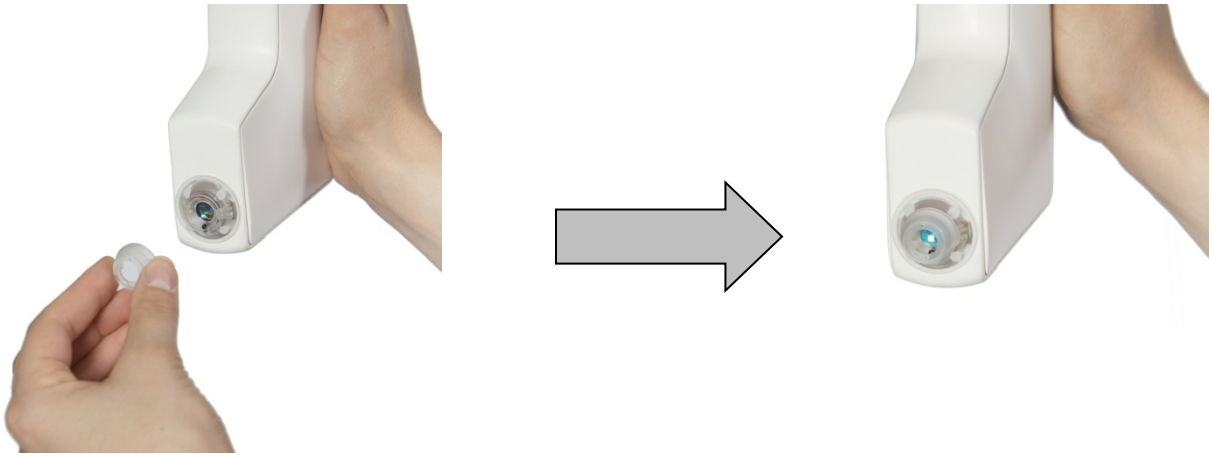
Start Freerun / Stop scanning

Start Enface

7.2 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.

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.

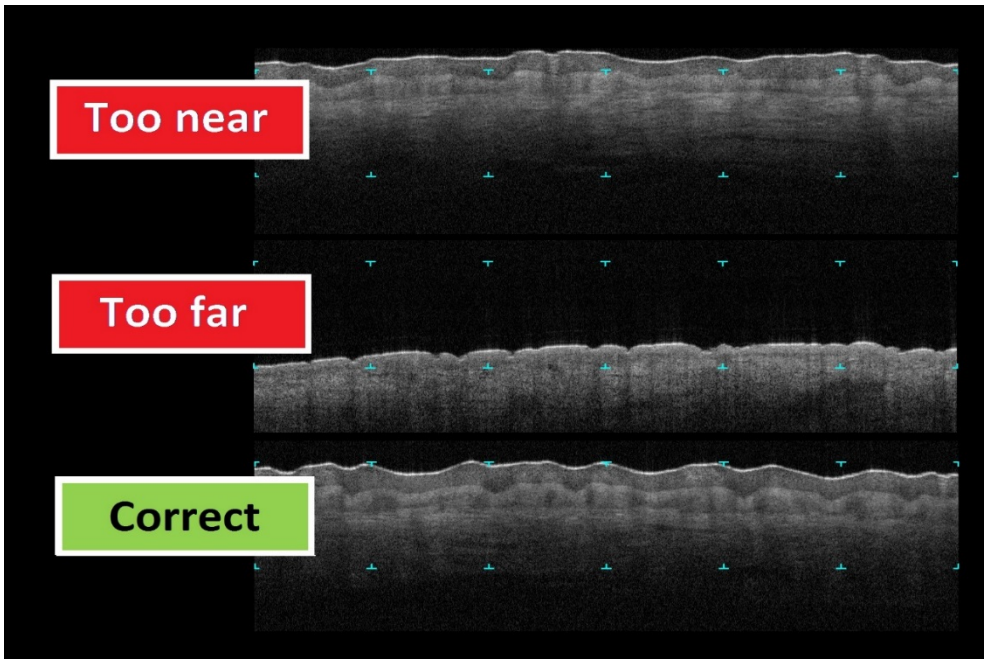
The standoff can also be rotated to set the most appropriate orientation for the skin area being scanned.

7.3 SETTING THE CORRECT WORKING DISTANCE

The correct working distance is set as follows:

1. Set the software to capture a scan (see section 8 for a detailed description of software operation).
2. Position the probe so that the patient-facing edge of the standoff is gently pressing against the patient's skin around the region-of-interest (see figures below); use the red laser light to guide the position of the imaged section.

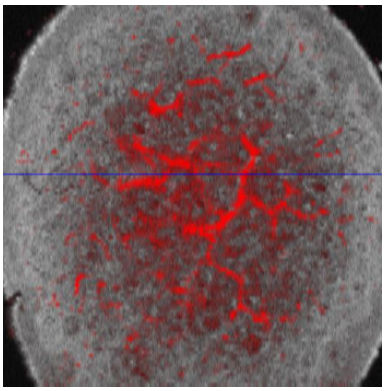
3. By observing the image in the VivoSight software, adjust the working distance so that the region of skin you wish to see is within the region demarcated by the onscreen 'T' shape markers (see figures below). The image of the skin is moved vertically within the frame by:
   i. Changing the fitted stand-off for a different length (see 7.2 for the correct procedure).
   ii. Twisting the probe and/or detachable stand-off to adjust the way it fits the contours of the patient's skin.
   iii. Varying the angle at which the probe is pressed onto the patient's skin.
   iv. Varying the pressure applied to the probe.
4. Ensure that the patient is comfortable before proceeding with the scan.



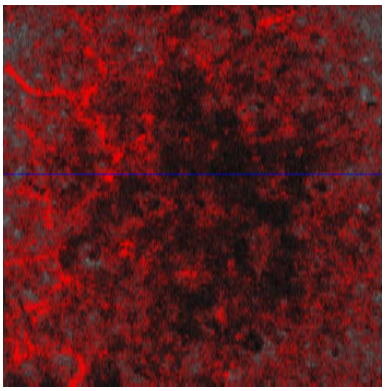
7.4 DYNAMIC OCT

⚠	Ensure that the correct working distance is set as in section 7.3 above, and that the Dynamic OCT Signal is clearly visible in the EnFace View

EnFace View



Dynamic OCT Signal
Bright Red linear or dotted features



Dynamic OCT Noise
Dim Red cloud

7.5 ESTIMATED PLEXUS DEPTH, VESSEL DIAMETER, AND VESSEL DENSITY

⚠	Ensure that the correct working distance is set as in section 7.3 above. Failure to do so could result in increased inaccuracy of the estimated Plexus Depth, Vessel Diameter, and Vessel Density Always perform a visual check from the Dynamic OCT Signal to confirm the estimated values.

8 USING THE VIVOSIGHT SOFTWARE

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

1. If the Patients Management Screen is not visible, click **Home**.

2. Patients Management 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 scans

   ⚠ Select the appropriate stand-off in accordance with the Instructions for use.

   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.

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

   iv. 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.
   v. 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.

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.

9 USE WITH OTHER EQUIPMENT

The VivoSight Dx may only be used with the following items:

Additional Software such as:

- Microsoft Office
- Tiff compatible image viewers
- Antivirus software

⚠	Antivirus software is installed on delivery. However, it is recommended that the user checks the software conforms to the user's IT security an internet policy. Only software specified in this manual may be safely installed on the system without consulting the manufacturer or authorised service representative for advice

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.

A network connection with galvanic isolation is provided on the rear of the VivoSight Dx to connect the system your local area network. Consult your IT department for connection and configuration.

⚠	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

10 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.

10.1 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.

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.

10.2 KEYBOARD, MOUSE, AND OPTIONAL FOOTSWITCH

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

10.3 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.

11 TECHNICAL DATA

The following technical data relates to the VivoSight Dx

11.1 SYSTEM SPECIFICATION

Key Part References

VivoSight Dx1302	1191.PL.122
HP Z22n G2 Monitor	1JS05AT#ABU
Keyboard	UK: KG22295 or Perixx 10904 DE: KG22294 or Perixx 10901 US: KG22296 or Perixx 10905
Mouse	KH22219
3 Pedal Footswitch	6224-0047
2 Pedal Footswitch	6226-0032

Applied Parts

Standoff Set	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
Maximum scan width	6mm x 6mm to a depth of ~2mm
A-line rate	20 kHz
Frame rate	≥11 fps (6 mm scan width / 1,333 A-lines) ≥35 fps (1.5 mm scan width / 333 A-lines) ≥69 fps (0.3 mm scan width / 67 A-lines)

Mode of Operation

Continuous operation
NOT suitable for use in the presence of flammable anaesthetic mixtures with oxygen or nitrous oxide.

Safety

Type of Protection against Electric shock	Class I (Safety Earth)
Degree of Protection against Electric shock	Type CF Applied Parts
Method of mains isolation	Disconnection of the mains plug from the electrical supply

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	56 kg

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 main and power units must be removed from the cart enclosure, and the monitor and monitor support must be removed from the cart by the manufacturer or their approved agents and packed in the original packaging

11.2 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.

12 TESTING INCLUDING PRE USE CHECKS

12.1 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 in doubt, contact the manufacturer or authorised service representative for advice.

12.2 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 CF
- Signs of damage which may lead to the exposure of live parts

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.

13 MAINTENANCE & ACCESSORIES

13.1 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 6 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.

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 12.2.

The preventative maintenance of cleaning the objective lens should be carried out as and when required to maintain system performance. Refer to section 10 for details. Before cleaning, disconnect from the mains electrical supply.

13.2 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. Other types may become available. Please consult the manufacturer or distributor with your requirements.

14 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.

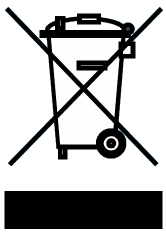
After contacting your original supplier to agree warranty cover it shall be the purchaser's responsibility to return the product.

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.

15 DISPOSAL

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.

EU Representative - Medical Device Management Ltd
Block B, The Crescent Building
Northwood
Santry
Dublin 9
DO9 C6X8
Ireland
Tel: +353 (0) 1893 4143
Email: EU-Rep@MedicalDeviceManagement.com

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

Michelson Diagnostics Ltd
Ground Floor Eclipse House
Eclipse Park, Sittingbourne Rd
Maidstone, Kent ME14 3EN, UK

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

CE 2797

Compliant with
Medical Device Directive
93/42/EEC

CE Compliant with
RoHS 2011/65/EC

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