

# VivoSight Clinical Training Program

This training plan is designed for new VivoSight owners. If you are instead undertaking a 2 week clinical evaluation of VivoSight, it is suggested that you follow this training programme but dip into and out of the modules, rather than follow them week by week.



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## PART 1 – USING VIVOSIGHT

### MODULE 1 - MEET YOUR VIVOSIGHT SCANNER & THE BASICS OF IMAGE INTERPRETATION

#### SUGGESTED TIME TO COMPLETE: 1 WEEK

#### MODULE GOALS

At the end of this Module you will

1. Be familiar with using the probe on the skin of patients
2. Know how to optimise image quality
3. Understand the features of an OCT image

#### RESOURCES

A Michelson Diagnostics Trainer

VivoSight Instructions for Use (printed & comes with machine)

VivoSight Quick Scan Guide (printed & comes with machine)

VivoSight [‘How to take a basic scan?’](#) video (5mins)

#### LET’S BEGIN

When your VivoSight is installed you will be shown how to operate the equipment and use the VivoSight patient management and image capture software. The software is intuitive and designed so that you can easily begin using the scanner but handling the probe and optimising the images you capture will take some practice.

The following tasks will give you an introduction to the VivoSight handheld probe and to OCT images of the skin. The key here is to get lots of experience and to intensively practice as you gain new skills.

#### 1. Image Acquisition Practice

- Start out by watching [‘How to take a basic scan?’](#) video, which will teach you to do basic ‘EnFace scans’.
- Now begin with a colleague by capturing 10 EnFace images of their face (you can scan yourself if necessary but someone else is better).
  - Begin with easy areas such as the cheek and forehead and progress onto the ears, nose and periocular areas.

Make sure that:

1. You can see the live image on the VivoSight’s screen at all times without moving excessively.
2. The ‘patient’ is comfortable for the duration of the exam.
3. That you get used to changing standoffs to ensure that your images are at the optimal distance from the skin surface – see page 13 of the VivoSight Instructions for use for more details.
4. You capture plenty for Dynamic scans (if you purchased this option) – get used to keeping the handheld probe stationary and the pressure on the skin light during the scan.

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## MODULE 1 (CONTINUED)

### 2. OCT Image Interpretation Basics

With patients or colleagues, capture some images of diverse skin anatomies, try:

1. Skin in different condition:
  - a. Old skin
  - b. Young skin
  - c. Heavily sun exposed skin
2. Skin in different locations:
  - a. Face
  - b. Scalp
  - c. Forearm
  - d. Hands and limbs
3. A few common conditions:
  - a. Nevi
  - b. Eczema
  - c. New and old scars and wounds

Things to note:

1. The thickness of the epidermis varies considerably. On the palm, sole and back-of-hand the layers of the epidermis are distinguishable to varying degrees. Elsewhere the basal membrane is visible as a dark line. In other areas the dermal-epidermal junction is signified only by a change in brightness and texture.
2. The imaging depth of the VivoSight device varies with anatomical location, adnexa density scarring and sun exposure.
3. The following adnexa: Sebaceous glands, hair follicles, sebaceous ducts.
4. Artefacts:
  - a. The air-skin boundary signal
  - b. Surface flare
  - c. Hairs and other shadow-sources
  - d. Mirror images
  - e. Vessel projection

Using the on screen image annotation tools, if you wish you can mark up each of these scans with identifying features and export this as a pdf. This way, you can build you own collection of notes.

## END OF MODULE 1

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## MODULE 2 – THE BASICS OF (NODULAR) BCC RECOGNITION

**SUGGESTED TIME TO COMPLETE: 1 WEEK / 10-20 PATIENTS**

### MODULE GOALS

At the end of this Module you will:

1. Understand key diagnostic criteria for Nodular BCC.
2. Be able to spot the signs of NBCC in real images.
3. Have diagnosed your first case.

### RESOURCES

Training Video (10mins): [How are OCT Images of the skin interpreted?](#)

The [VivoSight Atlas pages describing BCC](#)

OCT image interpretation clips video [playlist](#)

### LET'S BEGIN

Image interpretation takes time to learn, in this first stage you're going to identify the simplest lesions before beginning to build on differential skill.

1. Watch [How are OCT Images of the skin interpreted?](#) Nodular BCC is covered. Cross reference what you learn with the [VivoSight Atlas web pages on BCC](#) in order to further build your understanding. These resources are always available.
2. Pick out 10-20 patients with clear Nodular BCCs that are going to be biopsied.
3. Scan the whole lesion using EnFace or Dynamic scans.
4. Review the scans to identify the features of a BCC. If you used Dynamic mode to capture the images, be sure to review the scans with Dynamic turned off as well as with blood vessels visible (red).

The key features of Nodular BCCs are summarised here for convenience.

Typical BCCs:

- Ovoid structures with clear dark borders separating them from the surrounding tissue
- Bulges/cones intruding into the dermis
- Epidermal thickening is a counter-indicator of Nodular BCC.

Specific to the Nodular subtype:

- Ovoid structures in the dermis.
- A thinned epidermis covering larger ovoid nests.
- Black areas (cysts) at the centre of larger ovoid structures

5. Capture one or two images of healthy nearby or contralateral skin to rule out normal adnexa (label the scans of healthy skin appropriately in the VivoSight software).
6. Record your findings using VivoSight's Post-OCT diagnosis field, annotation and bookmark tools and create a PDF report.
7. When the biopsy results return, compare your results.

### END OF MODULE 2

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## MODULE 3 – BCC: SUPERFICIAL AND NODULAR SUBTYPES

**SUGGESTED TIME TO COMPLETE: 1 WEEK / 20 PATIENTS**

### MODULE GOALS

At the end of this Module you will:

1. Recognise the key diagnostic criteria for Superficial BCC.
2. Have experience spotting the signs of SBCC in real images.
3. Be able to diagnose and differentiate Superficial and Nodular BCCs.

### RESOURCES

Training Video (10mins): [How are OCT Images of the skin interpreted?](#)

The [VivoSight Atlas pages describing BCC](#)

OCT image interpretation clips video [playlist](#)

### LET'S BEGIN

This week you're going to take what you learned in the previous one and extend your skills to include differentiation of Superficial BCC.

1. Review the training materials from the previous Module, as necessary.
2. Pick out 10-20 patients (per week) with clear Nodular BCCs that are going to be biopsied.
3. Scan the whole lesion using EnFace or Dynamic scans.
4. Review the scans as before to identify the features of a Nodular BCC and Superficial BCC.

The distinguishing features of Superficial BCC:

- Epidermally-bound ovoid structures – “pearl-like chains”
- A thickened appearance to the epidermis in the presence of the ovoid structures
- The presence of bulges/cones extending from the epidermis into the dermis.
- Absence of parakeratosis (particular to AK)

Note that in OCT images, mixed subtype are more frequently seen than in histology reports.

5. Capture and label some normal healthy scans if you feel it is necessary.
6. Record your findings using VivoSight's Post-OCT diagnosis field, annotation and bookmark tools and create a PDF report.
7. When the biopsy results return, compare your results.

## END OF MODULE 3

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## MODULE 4 – INFILTRATING BCC

**SUGGESTED TIME TO COMPLETE: 2 WEEK / 20 PATIENTS**

### MODULE GOALS

At the end of this Module you will:

1. Recognise the key diagnostic criteria for Infiltrative BCC.
2. Have experience spotting the signs of IBCC in real images.
3. Be able to diagnose and differentiate Infiltrative BCCs from other lesions.

### RESOURCES

Training Video (10mins): [How are OCT Images of the skin interpreted?](#)

The [VivoSight Atlas pages describing BCC](#)

OCT image interpretation clips video [playlist](#)

### LET'S BEGIN

You should now be capable of diagnosing Nodular and Superficial BCC, with practice comes accuracy! The final task is to learn to differentiate Infiltrative BCC.

1. Review the training materials from the previous Module, as necessary.
2. Pick out 10-20 patients (per week) with clear or suspected Infiltrative BCCs.
3. Scan the whole lesion using EnFace or Dynamic scans.
4. Review the scans as before to identify the features of an Infiltrative BCC.

The distinguishing features of Infiltrative BCC:

- The "shoal of fish" or micronodular BCC nest appearance.

Note again that in OCT images, mixed subtype are more frequently seen than in histology reports.

5. Capture and label some normal healthy scans if you feel it is necessary.
6. Record your findings using VivoSight's Post-OCT diagnosis field, annotation and bookmark tools and create a PDF report.
7. When the biopsy results return, compare your results.

## END OF MODULE 4

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## PART 2 - INTEGRATING VIVOSIGHT INTO YOUR CLINIC

### MODULE 5 – WORKFLOW INTEGRATION

The way in which you organise your clinic and adapt your workflow to accommodate VivoSight is, of course, unique. Our user like how VivoSight [has benefitted their workflow](#), especially with regard to triaging patients. Below are some things to consider when deciding how to do things and who should do them.

If you have not yet got familiarised with VivoSight by completing at least modules 1 and 2, then do not be intimidated by this module. Attempting to think about your workflow without first getting to grips with scanning and interpreting images will be very difficult indeed! For this reason, it is suggested to work few modules 1-4 first and let the answer to your workflow questions just 'come' to you as you go along.

#### GOALS

In this section you should get an idea how to:

1. Organise your practice workflow with streamlined integration of VivoSight.
2. Assign new tasks and responsibilities for maximum efficiency.

#### ORGANISATIONAL MODELS

##### VIVOSIGHT MODEL WORKFLOW

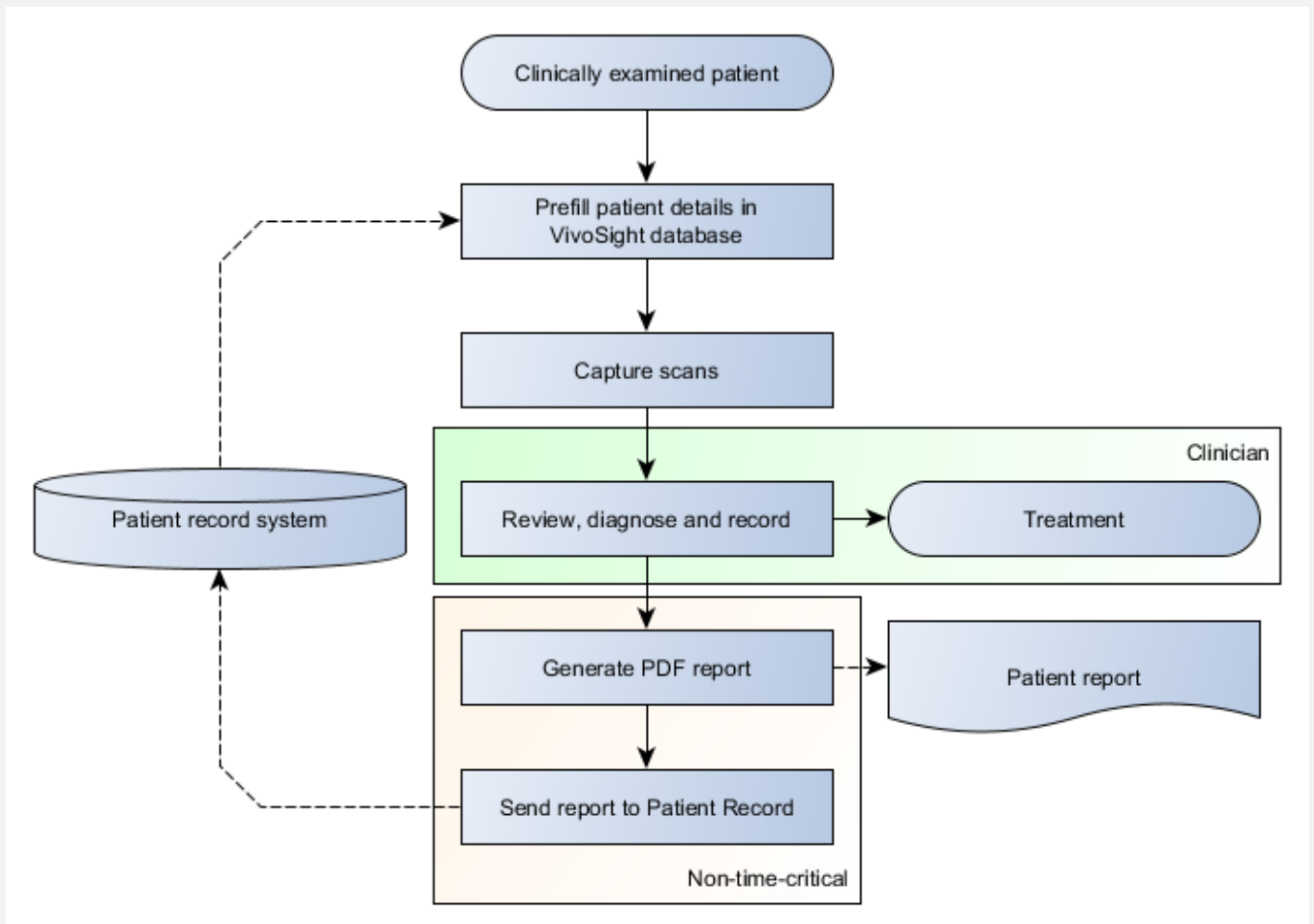
The basic workflow of essential tasks is represented in the flowchart below, together with data flow to and from your patient record database. In the graphic, the following groupings of tasks have been made:

- Tasks highlighted as "Non-time-critical":
  - Can be done at a later time or
  - In a batch after a number of patient exams

Whichever suits your clinical workflow.

- Items which must be done by a clinician are labelled "Clinician".





## RESPONSIBILITIES

The use of VivoSight can be broken down into a few main tasks; these are arranged in a responsibility matrix below. The table has been made in consultation with experienced VivoSight owners who organise their practices in the suggested ways. Every practice is different, however, so if you would like more detail or additional guidance, contact your VivoSight representative who may be able to put you in contact with a user whose practice organisation matches yours.

		Staff			
		Clinician	Clinical assistant, nurse	Administrative staff	Cleaning, support staff
T a s k	Pre-filling patient and lesion details		*		
	Scanning the patient		*		
	Interpreting the images and recording the results	*			
	Producing a PDF report for your patient		*		
	Updating your patient record system with the results			*	

	Cleaning the device and sterilising standoffs				*
	Data backup management			*	

More discussion is given to the tasks in the following paragraphs.

### Pre-filling the VivoSight database with patient and lesion details

This is a task commonly given to assistive staff in order to reduce the amount of time spent by a clinician.

In the most laborious form, the task may include looking up the patients details in a patient record system, printing them in order to transfer them to the VivoSight and then manually typing them in.

In the workflow with the greatest streamlining, the patient record is retrieved using an instance of the patient record system on the VivoSight itself, and automatically copied into the VivoSight database using the German Gerätedatentransfer (GDT) data exchange format.

To get your patient record system set-up on your VivoSight, consult your IT administrator or the supplier of your patient record database.

Automation of record filling is currently only available in Germany. For more information about this and to get it set-up, consult your VivoSight representative.

### Scanning the patient

Scanning of patients doesn't have to be carried out by clinicians; it can be undertaken by clinical specialists or nursing staff in order to free-up valuable doctor-time for other tasks. The same level of equipment training will be required for all staff; this training is provided in your practice when your VivoSight is installed and there's no limit on the number of staff who attend it. This said, scanning is very quick so you may wish to just do it all yourself, as many of our users have chosen to do.

If required, we can advise you on local contacts with experience of operating in this manner.

### Interpreting the images and recording the results

This task can only be undertaken by a trained doctor.

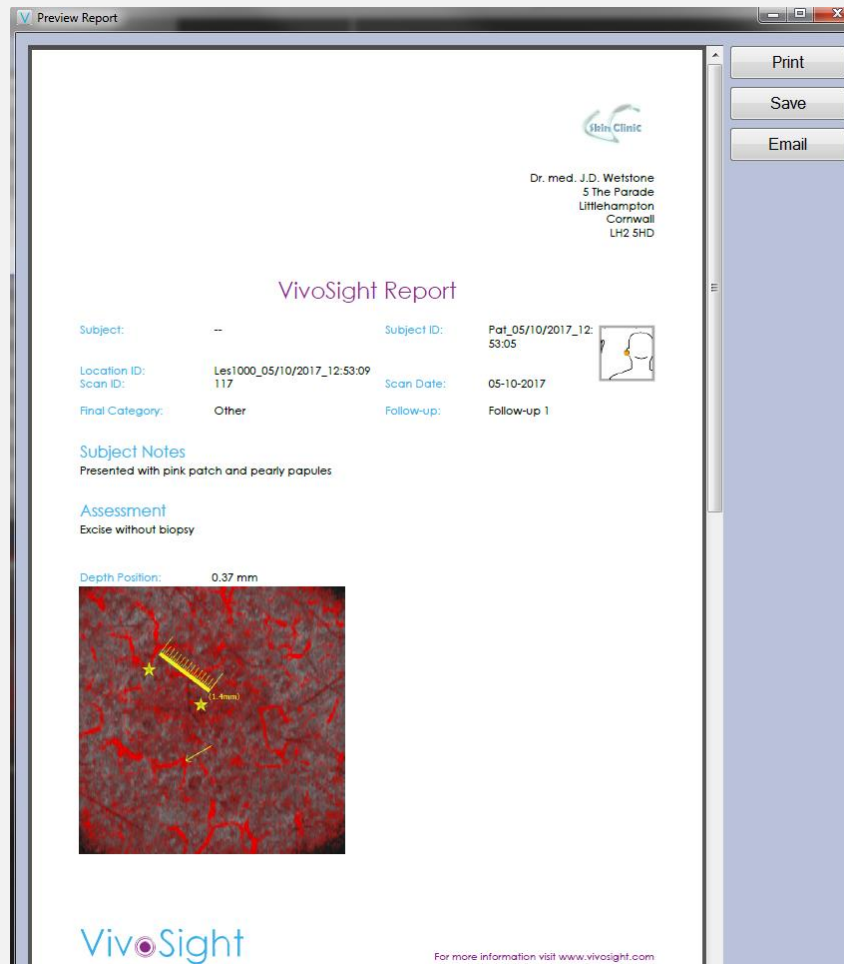
### Producing a PDF report for your patient

A printed PDF report of their exam is valuable for patient information and engagement and is reimbursed in many healthcare systems.

The PDF report feature allows you to quickly commit your findings to file and save or print it. Making the report is straightforward:

- Highlight relevant image features with annotations, symbols and descriptive notes
- Select a pre-defined diagnosis or type your own
- Select a reason for performing the VivoSight examination
- Generate the PDF

The details are automatically placed in a template customised to your clinic.



Instructions on producing a PDF can be found in the VivoSight Software Training Manual.

Provided the relevant information is recorded, these steps can be performed by anyone with access to the VivoSight and a little experience to prevent errors. Therefore, the task can be delegated to the assistant who captured the scan with instruction from the diagnosis doctor.

### Updating your patient record system with the results

The PDF can also be used to store your findings in your patient record system. If you have the PRS software on your VivoSight, it's just a matter of attaching it to a record. If the PRS software is on another PC, someone is required to transport the PDF across your network (or carried on a flash drive) and uploaded to the correct patient record. Please contact us to make sure we get this sorted for you.

All of the details required to identify the correct patient record are stored in the file. So this task can be safely undertaken by an assistant passing the data to an administrator or secretary.

### Cleaning the device and sterilising standoffs

Cleaning of the VivoSight and its standoffs is detailed in the VivoSight Instructions for Use.

### Archiving

Given enough time and patients, your VivoSight will begin to fill-up with data. It's important to regularly review the data usage on your VivoSight and decide how to manage this *before* your system fills up.

An Archiving service is offered by VivoSight engineers in which space-hungry image data is moved from your VivoSight's disk-drive onto your practice servers. We recommend scheduling Archiving before you have less than 25% disk space.

If you have 10% or less disk space available, your VivoSight will display a warning and prevent capture of any more data until you contact a VivoSight engineer. The engineer may be able to help you to temporarily begin scanning again, but an urgent Archiving operation will have to be completed to ensure you can continue capturing and backing-up data on your VivoSight.

### **Data backup management**

Data is stored and backed-up on your VivoSight's internal hard drives. Additional details and precautions are documented in the Appendix to this document.

The VivoSight backups protect you against data loss in a large number of scenarios including hard-drive failure and power loss, but additional data redundancy is required to ensure complete security. It is your responsibility to manage and verify data backup on your own servers. The scheduling and responsibilities for managing this process should be decided with the assistance of IT professionals possessing relevant experience. Your VivoSight representative will be able to supply relevant information and technical descriptions for you and your IT management to make the right decisions.

## **END OF MODULE 5**

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## MODULE 6 – GETTING THE MOST OUT OF YOUR VIVO SIGHT

### **Marketing**

Making potential patients aware that your practice is using VivoSight is important for attracting both privately and publicly insured patients as well as patients from overseas. Michelson Diagnostics can provide you with resources for publicising VivoSight through the press and on your website. If you would like to feature on the [vivosight.com](http://vivosight.com) find a scanner webpage, please contact us and we will add details of your practice.

You may also like to participate on our new [testimonials page](#), where several of our satisfied customers have started feeding back to the clinical community about exactly how they are using, and getting the most out of VivoSight.

### **Reimbursement**

Please contact your rep directly for the most up to date info about reimbursement for OCT scans in your country.

**END OF MODULE 6**

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## APPENDIX

### DATA BACKUP

A backup of your VivoSight data is created automatically on the Backup drive of your VivoSight using software called MDLBackup. The features and limitations of this software, as well as your responsibilities for data security are described here.

### MDLBackup

This is a piece of software on your VivoSight which creates, manages and restores backups of the VivoSight database. Data which is held in the VivoSight database (i.e. which has been entered and captured using the VivoSight software) is stored on the D: drive of your VivoSight (labelled "Data") and an additional hard drive (E:, labelled "Backup") holds backups of the VivoSight database.

### What's backed-up?

The backup data consists of the following:

- OCT images
- Dynamic OCT images
- Context camera images
- Image annotations
- The database tables, consisting of user-entered:
  - Patient data
  - Lesion data
  - Scan data
- Catalogue files which log the backed-up data
- "Fingerprint" files for checking the backup's integrity.

This information is everything which is required to restore your VivoSight database in event of a fault.

### Backup schedule

From the factory, your backup software is configured to create two independent backups of your data and to store 40 separate days' worth of database tables.

Data is backed-up on the following schedules:

- The database tables (see above) are backed-up the first time your VivoSight is started each day.
- Image and annotation data is backed-up continuously in the background.

This (necessary) schema means that a small amount of data may be lost if a fault occurs between data entry and backup the following day.

### Limitations and recommendations

What's not backed up

The following items are not backed-up:

- Copies of data which has been exported to another format:
  - TIFF
  - DICOM
  - Snapshots
  - PDF reports
  - OCTAnalyse scans

- OCT and Dynamic OCT image data of scans which have been Archived (see 3.2 below). The storage and backup of Archived data is your responsibility. However, the Patient, Lesion and Scan records of Archived data are backed-up.
- Other files stored on the computer (My Documents, Desktop etc.)

### Scope of Protection

MDLBackup creates "local" backups of your data, meaning that the backup is stored on the same machine as the data. This protects you from the following scenarios:

- Single hard drive failure
- Equipment failure
- Database corruption
- Accidental deletion of data

In the following scenarios, MDLBackup alone will not prevent data loss:

- Multiple hard drive failure
- Destruction of the equipment (e.g. in a fire)
- Theft of the equipment.

To protect against these eventualities, we recommend that a further backup of at least backup folder is made on a remote backup server. This is a simple matter for your IT management. Helpful details are available for them upon request.

**END**