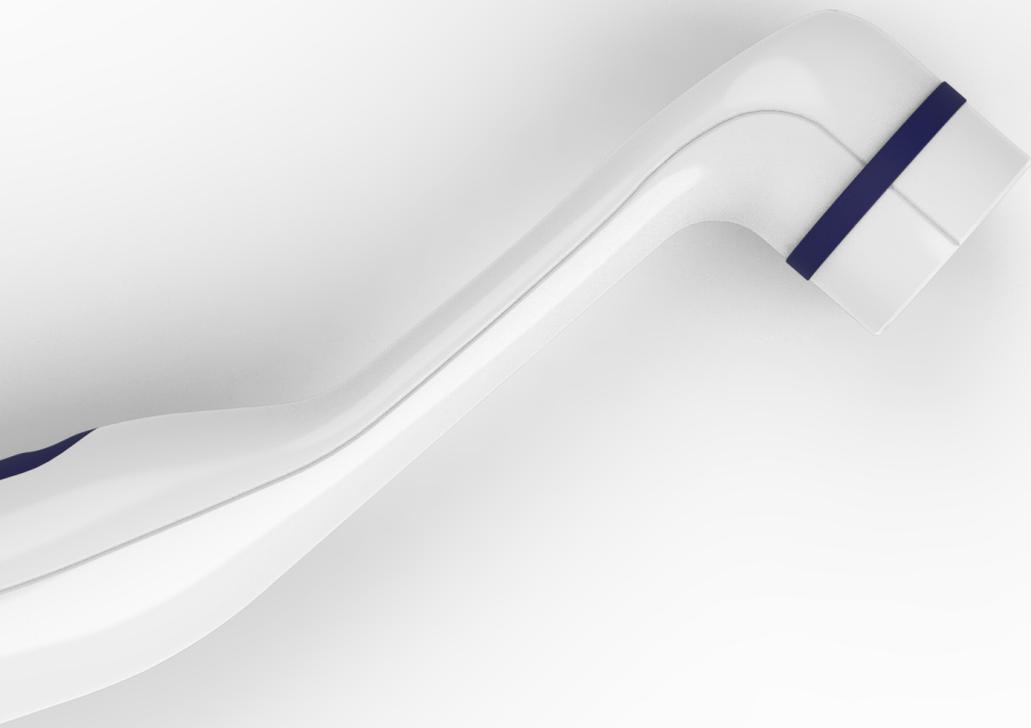


INSTRUCTIONS FOR USE



OralScan[®]

An oral cancer screening device

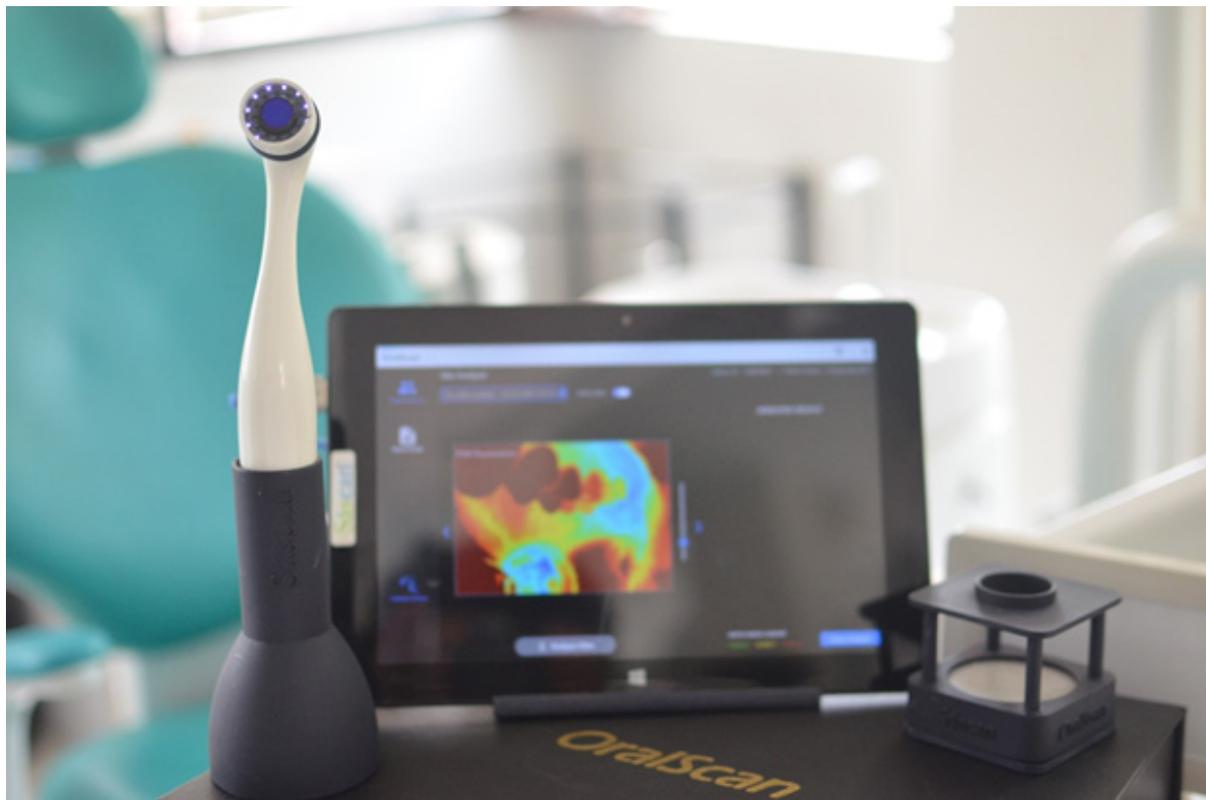
Developed and distributed by Sascan Meditech Pvt. Ltd



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Introduction



Model: S10

OralScan is a multi-modal camera (Figure 1) in a multi-spectral imaging platform consisting of LEDs emitting at violet (400 nm), green (540-545 nm), and red (610-620 nm) wavelengths for tissue illumination, a 5MP monochrome camera with collimating optics and electronics hardware for screening and detection of OPMLs. This hand-held non-invasive device is controlled through proprietary software, installed on a 64-bit Tablet or laptop computer with Windows 10 operating system, for sequential firing of LEDs and image capture. The captured images are processed in real time in the computer to provide information on the level of tissue abnormality or malignancy with the help of a cloud-based machine learning algorithm. OralScan works as an intra-oral screening tool for early detection of oral cancers and helps the clinician to locate the most malignant site in the lesion for tissue biopsy, thereby minimizing false negatives (under diagnosis) and false positives (unnecessary biopsies). Being cloud enabled, the captured images and patient data can be easily accessed through the Internet by healthcare providers and oncologists in any part of the world for follow up.

Abbreviations

1. IFU - Instructions for use
2. LED - Light Emitting Diode
3. OPML - Oral Potentially Malignant Lesion
4. CMOS - Complementary Metal Oxide Semiconductor
5. MRN - Medical Record Number
6. PCM - Pseudo-Color Map
7. DR - Diffuse Reflectance
8. ROI - Region of Interest
9. CCCD - Color-coded Circular Display
10. IPA - Isopropyl Alcohol
11. CIS - Carcinoma In Situ
12. SCC - Squamous Cell Carcinoma
13. USB - Universal Serial Bus
14. PC - Personal Computer
15. MP - Mega Pixel

Designed & Manufactured By

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Intended use

- To screen for oral precancerous tissue and detect OPML of the oral cavity
- To demarcate regions of tissue abnormality
- To provide real time feedback on the tissue status
- To guide the clinician to the optimal site for tissue biopsy

Product Specifications

OralScan Probe

- Multi-spectral imaging probe with high resolution monochrome camera (Ximea model: MU9PM-MH) featuring 5MP CMOS sensor (2592x1944 pixel, 2.2 um, 5.8fps, 70dB)
- Tissue illumination with LEDs emitting at 400 nm, 545 nm, and 620 nm wavelengths
- Live view of tissue fluorescence with violet light illumination
- Captures fluorescence and diffuse reflectance images of potentially malignant tissues of the oral cavity
- Provides real time assessment of tissue status using a cloud-based ML algorithm
- Locates the most appropriate/malignant site in the lesion for tissue biopsy

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Standard Accessory

- Probe Holder
- Calibration Unit (supplied with one tissue phantom of 58 mm dia.)

Optional Accessory

- 10-inch LapTab (Tablet with Keyboard) and 64-bit Windows10 Operating System.

Product Dimensions

- OralScan probe: 15 cm (L), 2.8 cm (dia at probe tip) and 3.2 cm (dia at handle).
- Cable length: Probe to Laptop/Tablet – 140 cm
- Carry-case of dimensions: 28.5 x 15.5 x 8.5 cm (L x W x H)

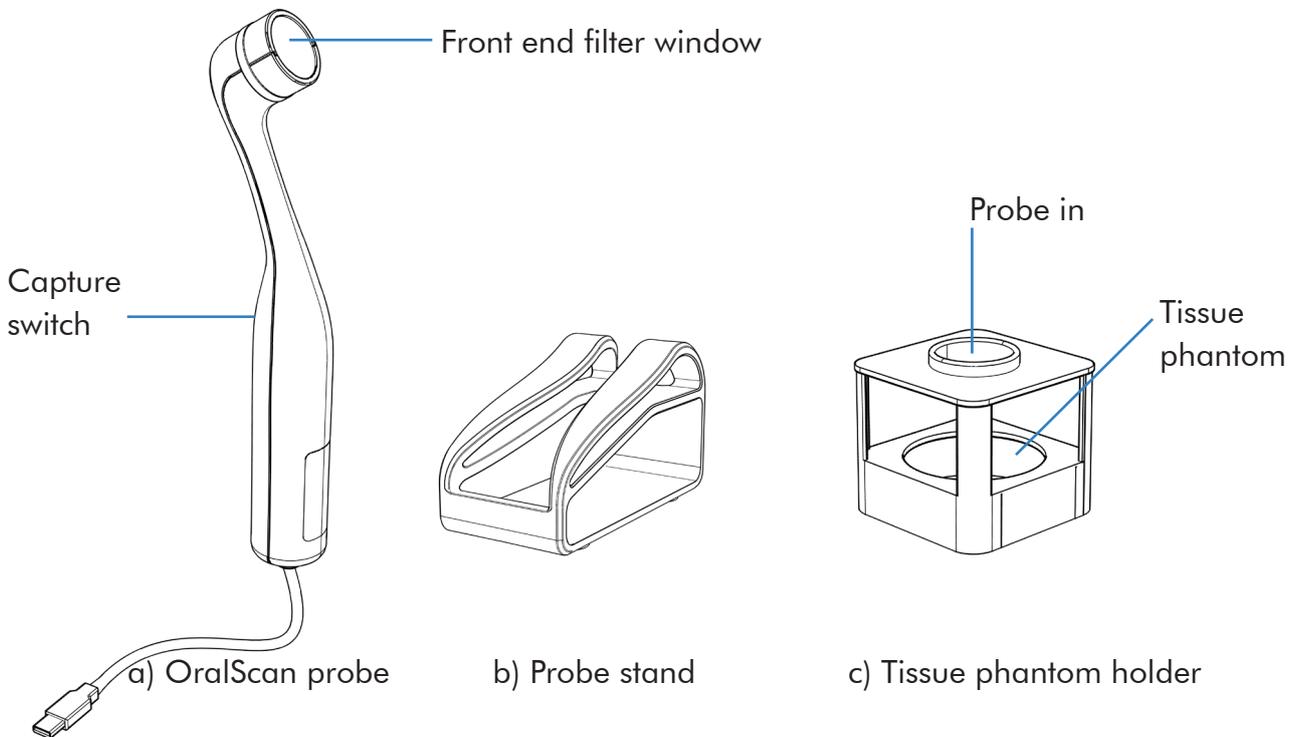


Figure 1. (a) OralScan probe, (b) Probe Stand and (c) Tissue Phantom holder

Installation

The XIMEA API Software Package program needs to be pre-installed in the LapTab or laptop before installation of the OralScan software.

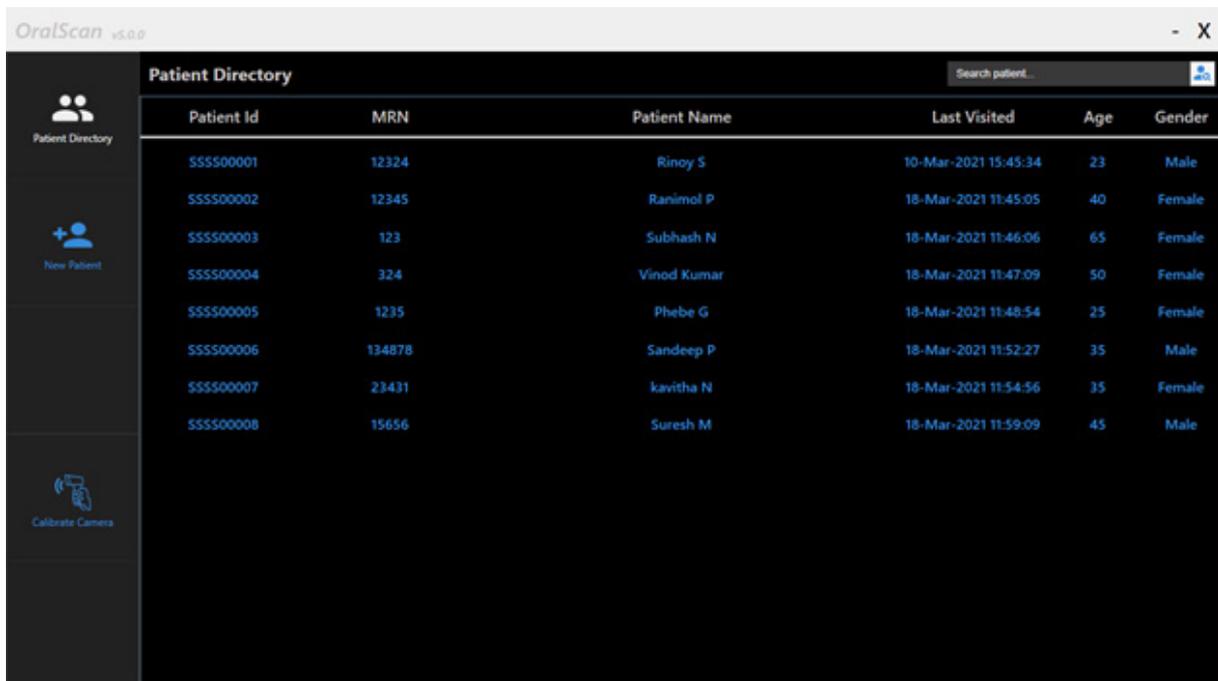
https://www.ximea.com/support/wiki/apis/XIMEA_Windows_Software_Package.

Double click on the SascanInstaller.msi file provided. During installation enter hospital/username and click install (Fig. 2). On completion of the installation process, XiCamTool and OralScan shortcuts will be created on the desktop.

Initial Setup

Connect the USB connector of the probe to the USB port of the Laptop or Laptop. The default LED (violet) will get turned on. Run the OralScan program by double clicking on the windows shortcut created during installation. The program will now ask for the Passcode supplied to the user as per the chosen usage plan, such as Outright Purchase, the Pay-per-use (PPU) and Unlimited Lifelong Plan (ULP).

The Main Menu Screen can now be accessed (Figure 2), which displays the Patient Directory, and icons to add new patients and Calibrate the Camera, and a search button on the right top corner. The Patient Directory has columns displaying Patient ID, MRN, Patient Name, Last visit date, Age and Gender.



Patient Id	MRN	Patient Name	Last Visited	Age	Gender
SSSS00001	12324	Rinoy S	10-Mar-2021 15:45:34	23	Male
SSSS00002	12345	Ranimol P	18-Mar-2021 11:45:05	40	Female
SSSS00003	123	Subhash N	18-Mar-2021 11:46:06	65	Female
SSSS00004	324	Vinod Kumar	18-Mar-2021 11:47:09	50	Female
SSSS00005	1235	Phebe G	18-Mar-2021 11:48:54	25	Female
SSSS00006	134878	Sandeep P	18-Mar-2021 11:52:27	35	Male
SSSS00007	23431	kavitha N	18-Mar-2021 11:54:56	35	Female
SSSS00008	15656	Suresh M	18-Mar-2021 11:59:09	45	Male

Figure 2. Main Menu Screen

Calibration

Dark light condition is a prerequisite for using the device for accurate measurements and the device needs to be calibrated to the ambient dark light conditions before any measurement. This is achieved with the help of the calibration unit consisting of a tissue phantom, supplied with the device. Place the calibration unit on the sideways position on the table and insert the probe head through the hole provided, with the probe handle resting on the table. The calibration button on the Tablet screen is now pressed to initiate the calibration process (Figure 3). The LED lights up one after the other to calibrate the camera with respect to the intensity of the on-LED and corresponding colour dots light up displaying the calibration status. Once the calibration process is over, the Calibration completed message appears on screen. The device is now ready to use. The device needs to be calibrated again if the room light conditions change.

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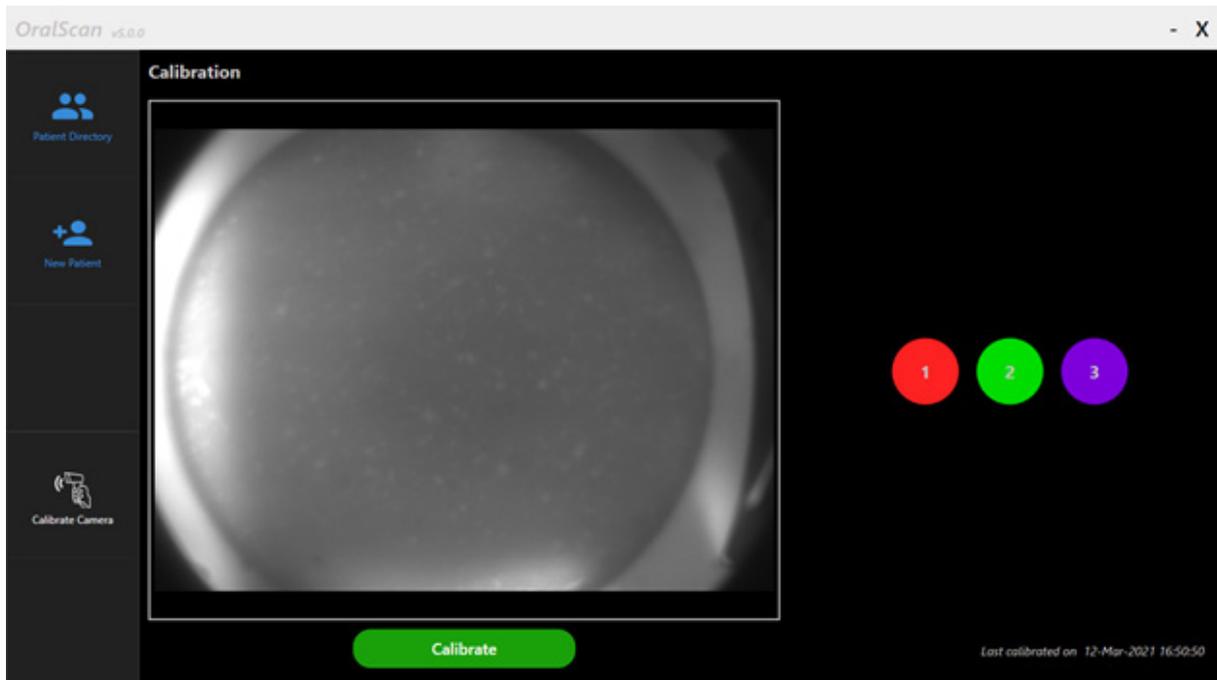


Figure 3. Calibrate Camera Window

Patient Registration

Click on the New Patient Icon on the main menu and the new patient registration window opens up (Figure 4), where one can enter complete details of the patient, such as Name, Age, Gender, Email ID, Clinical diagnosis, MRN, Contact Number, Aadhar Number and Habits.

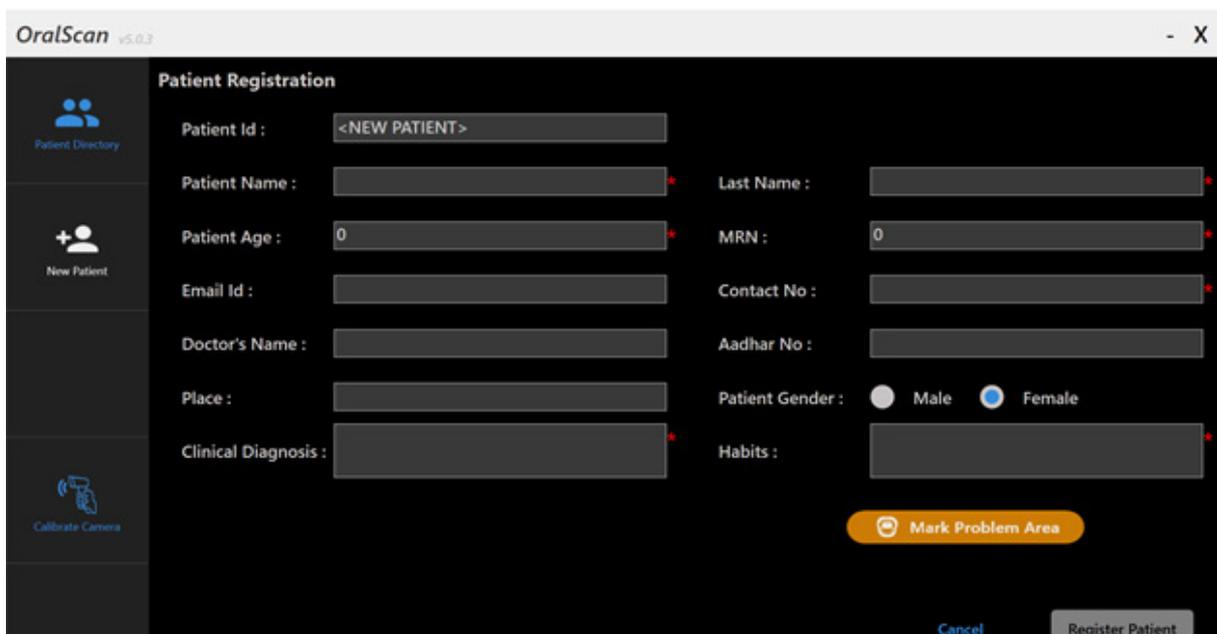


Figure 4. New Patient Registration Window

The mandatory items are shown by red Asterisk. This menu provides an option to mark the problem area in a separate window (Figure 5), which opens up on clicking the “mark problem area” button. After all the clinically suspicious sites are marked, click the continue button

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that saves the data and takes you back to the Patient Registration Window. On clicking the Register Patient button, a unique Patient ID is automatically generated and the complete data gets saved in the system. Now the user can either Proceed to Screening or go back to the Patient Directory to register other patients by clicking on the Back button. While Clicking on the Proceed to Screening button, the Patient Screening window opens up and the live image is visualized on the screen. If the camera is not connected properly to the USB port, of the Tablet/PC, the user gets a message to reconnect the camera and retry onscreen visualization of the image (Figure 6).



Figure 5. Oral cavity image for lesion sites marking

Patient Directory

The name of the newly registered patient appears in the patient directory along with the rest of the patients who are already registered (Figure 2). Now, by selecting any one of the patient names, the patient details gets displayed and the user can now proceed to imaging or review the already recorded images of any patient by clicking on the Patient Studies icon.

Probe Hygiene

In order to maintain hygiene, the probe shall be cleaned using a soft cotton tissue wetted with isopropyl alcohol (IPA). It is then wrapped with a fully transparent, thin, and stretchable polyethene film (food quality). While covering, ensure that the film portion over the optical window of the probe is stretched flat, without any wrinkles, (such that the captured images are not distorted and that the film covers the probe handle). On completion of the patient examination, the polyethene film is discarded and a new piece is used for the next patient. Under no circumstance the probe be exposed to any other standard sterilization procedures, as it will cause irreparable damage to the

Standard Operating Protocol

The patient is asked initially to wash/gargle their mouth with chlorhexidine or saline solution to remove food particles remnants, if any, from the oral cavity. Following visual examination, a clinical photograph of the oral cavity lesion is taken using the Tablet Camera or any other available suitable device. The probe is now connected to the USB port of the computer. The device needs to be calibrated, as per Sec 3.2, under the prevalent dark or semi-dark light conditions for patient examination.

The patient details are gathered before examination and the probe head is inserted into the open oral cavity of the patient, wrapped with polyethylene film (Sec 3.5). With the violet light on, the changes in tissue fluorescence can be visualised directly or on the Tablet screen in monochrome or pseudo colors based on toggle switch position for mode selection. In the Color mode the user will be able to adjust the colour saturation by moving the slider up or down. Once a suspicious lesion for screening is located, multispectral images are captured by clicking on the capture button, which opens up a window to select the anatomical site of the suspected site. Afterwards, click OK to sequentially capture the 3 monochrome images of the tissue on sequential illumination with the LED light sources at 400, 545 and 620 nm.

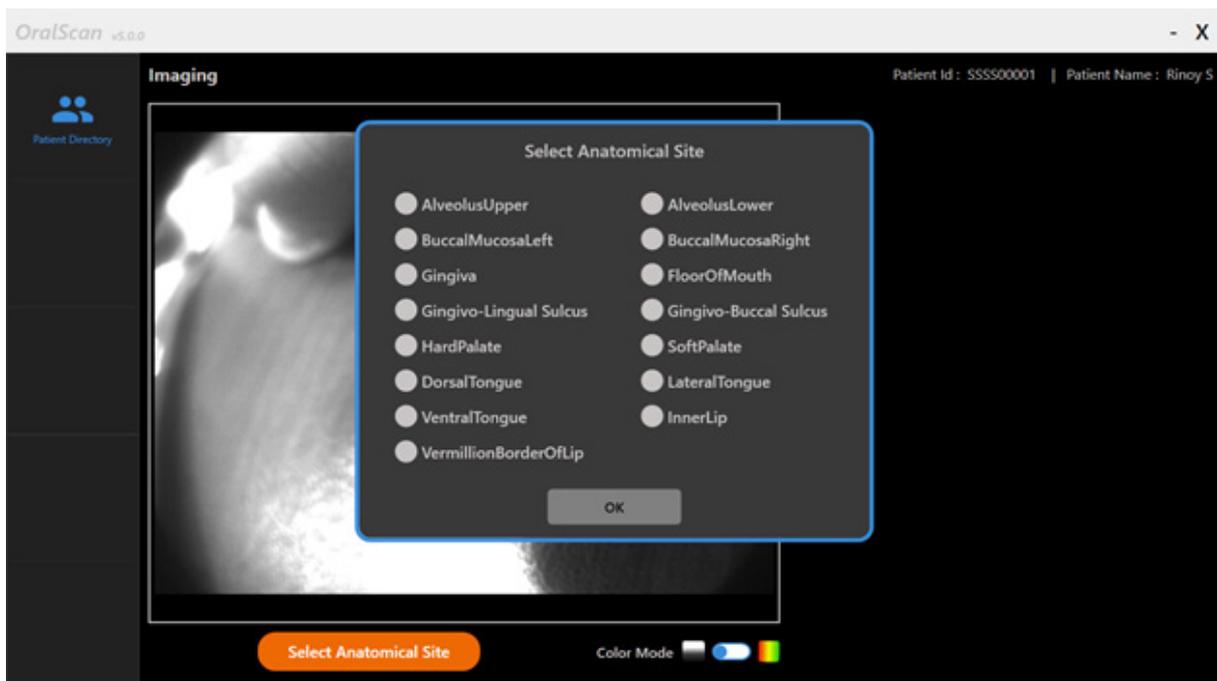


Figure 6. Window for Anatomical site selection

In order to minimize specular reflection from saliva, dry the lesion to be screened with cotton gauze or tissue. The camera is now moved back and forth to visualize the focused image of the lesion on the display screen of the Laptab. If unwanted reflections are still noticed from the tissue surface, adjust the tilt of the probe to avoid surface reflections. Multispectral images of the lesion are captured by a single click of the button on the probe holder or on the software window, as per one's convenience, while keeping the hand holding the camera steady. It is a good idea to rest the hand holding the camera on some stationary object or the patient body during image capture to avoid any patient/camera movement. The patient may also be asked to remain stationary during image capture. The captured and processed images get displayed on screen in no time. On clicking one of the captured images, the user will be able

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to review the images in full screen mode. If the images are not sharp due to camera shake or some other reason, these are discarded by pressing the discard button and a new set of images are captured.. The discarded images will not be saved.

The 3 monochrome images of the lesion captured, representing the tissue autofluorescence (with violet LED illumination) and diffuse reflectance (DR) images with the green and red LEDs, and the red/green image ratio gets displayed on screen. Any number of images can be captured from the same site and all these files will get saved in the Tablet memory under different file names. The same step may be repeated to capture multiple sets of images of the affected area in the same anatomical site or other sites. When the user presses the continue button, the program moves to the Site Analysis window, where the user can visualize the captured and processed images one after the other by pressing the arrow buttons on either side of the image. The colour gradation in PCM of the R620/R545 image ratio, representing the HbO₂ absorption changes in the tissue, and the PCM-Fluorescence map can be adjusted by up or down movement of the slider on the right side of the image. This helps to evaluate changes in tissue abnormality across the lesion and locate the most malignant site for biopsy. The user shall also have an option to analyze all of the captured set of images in the analysis screen by selecting the image set from the drop down option provided above the displayed image (Figure 8).

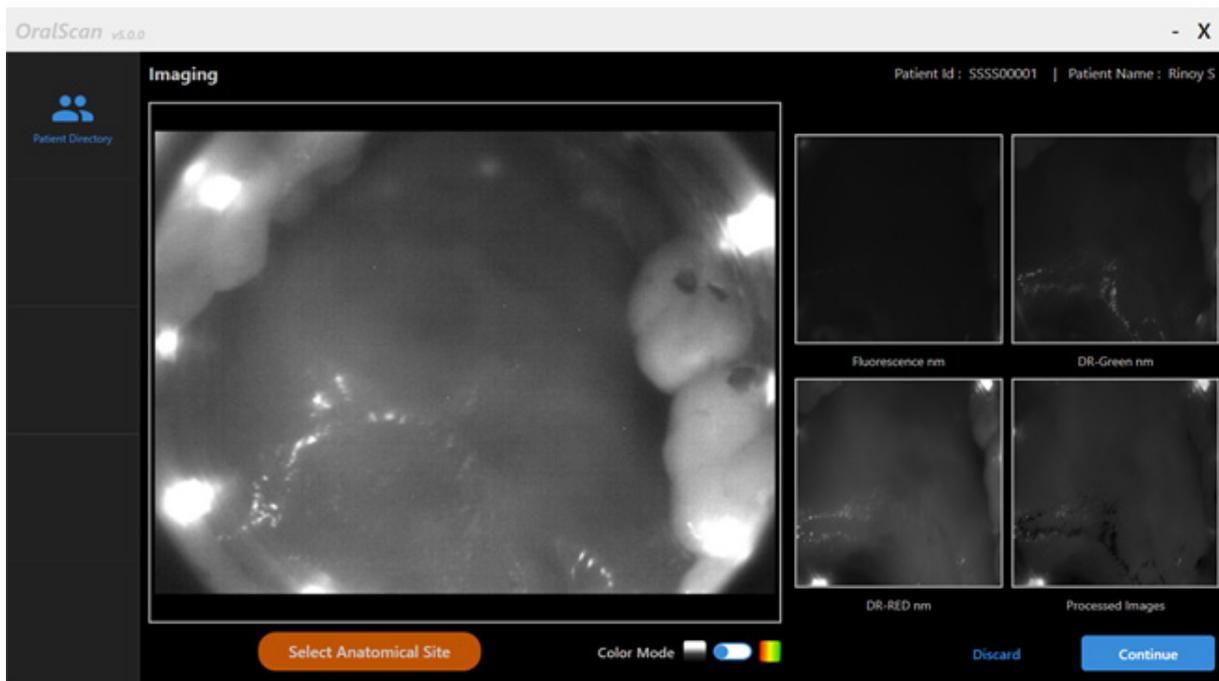


Figure 7. Patient Screening Window with the captured monochrome images such as the fluorescence, DR green, DR red and Processed DR ratio image R620/R545

Region of Interest (ROI) marking

On completion of the image capture, the monochrome and processed images are viewed on screen and the user marks the area surrounding the abnormal lesion by observing the PCM of tissue fluorescence and the processed DR red/green (R620/R545) ratio image. After the ROI is marked with the stylus pen or the mouse pointer on the fluorescence image, the Analyze Sites button is clicked (Figure 8) and the R620/R545 PCM ratio is viewed. The program will now automatically locate the site (black spot) with most malignancy based on the DR ratio

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value. If there are more than one ROI marked, all the results will get displayed one after the other in the Analysis Result section for all ROIs marked. The colour designations for tissue status are: Green for healthy, Yellow for precancerous or oral potentially malignant lesions (OPML) and Red for squamous cell carcinoma (SCC) sites. Now, by moving the cursor across the DR ratio image (Figure 9), the user can view the ratio value in any point in the oral cavity at the cursor tool-tip. By clicking with the right mouse button or by long pressing of the image display window (on touch screens) the previously marked ROIs can be removed and new ROIs can be drawn. Pressing of the analyze button refreshes the Analysis result. Clicking on the Close analysis button takes the program back to the Patient Directory screen. This completes the screening process for a particular patient.

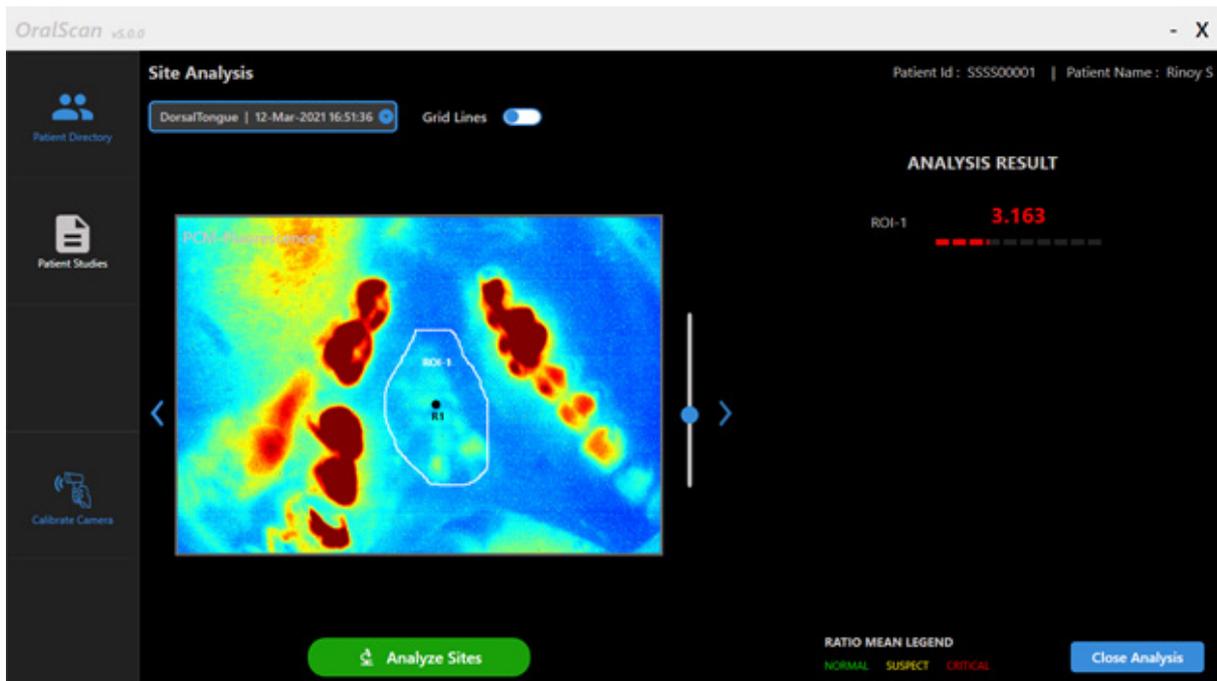


Figure 8. PCM of HbO₂ absorption map with Rols marked and the most malignant site marked as a black spot with the R620/R545 ratio value displayed on screen.

Biopsy Guidance and Patient Review

The DR ratio value represented in Figure 8 serves as an indicator to assess the tissue status and helps in deciding whether follow-up is required or not, and/or a biopsy is warranted for pathological confirmation of the cancer grade. Higher DR ratio values are indicative of higher levels of tissue abnormality. Also, the site marked representing the highest value of DR ratio in the ROI shall be considered for the biopsy.

Another important application of the DR ratio value is in the assessment of tissue status following surgery or during normal reviews of oral precancers that doesn't warrant surgery. Mapping of HbO₂ absorption in tissue and detection of an increase in R620/R545 (red/green) ratio can help the user to decide on whether a surgery is mandated in the case of OPMLs or to decide on whether radiation/chemo treatment is needed when an increase in the DR ratio is noticed at the tissue margins.

Use of grid lines for biopsy guidance

The user can access the Site Analysis screen by clicking on the respective row on the Patient Directory. In the site Analysis screen the user can draw grid lines on the processed image ratio and enhance the accuracy of biopsy, by activating the toggle switch. Any number of grid lines can be entered and drawn on the images (Figure 9). The grid lines automatically get applied on all the images and helps to locate the disease spread and ease biopsy guidance. Once the biopsy is taken, the sample is sent for histopathology following standard procedures.

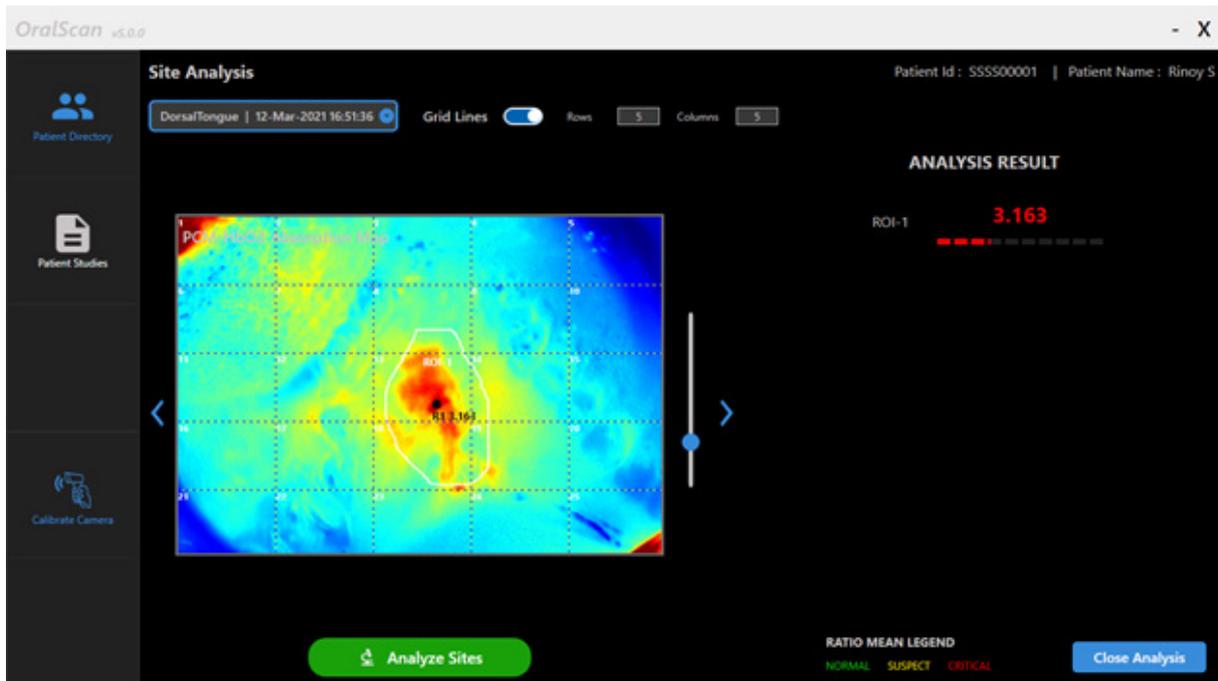


Figure 9. ROI marked on the PCM of R620/R545 image ratio representing HbO₂ absorption in tissue, with black spot representing the most malignant site and white spot representing an adjoining patient normal site. The gridlines can be referenced to permanent tooth structures seen on the image, to ease biopsy guidance.

Cloud Support and Machine Learning algorithm

On completion of the screening process, the patient screening data gets saved in the computer/tablet, which will later get uploaded to the Amazon Cloud server, when the Tablet gets connected to the internet. By clicking on the respective patient row in the Patient Directory and Patient Details can be reviewed. On clicking on the Patient Studies icon, a new screen opens showing the various measurements/visits of the patient along with the anatomical site of measurement. Now on clicking on the anatomical site of measurement, a new screen opens up for uploading clinical photographs, and for report downloading (Figure 10). The pathology report of biopsy taken during the measurement is scanned and saved in pdf format shall also be uploaded to the cloud for safe upkeep and algorithm refinement. Drop down menus are provided for each of the ROIs marked, so that a comprehensive report can be generated (Figure 11). Clicking on the Save and Continue buttons after uploading all reports, takes the screen back to the Patient Study window. The view button helps to review the pathology report at any time.

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The screening data is saved, referenced to the patient ID and the screening center, which will be accessible to all users, through the web portal (<https://sascanmeditech.com>) via personal login IDs created. The personal particulars of the patient are not extracted/stored in the cloud server.

Patient Review and Report Generation

The ROI and biopsy sites can also be marked during the review process, after all the recordings are completed. This is done by clicking on the ID of the Patient whose images are reviewed. Now click on the Patient Studies on the left column.

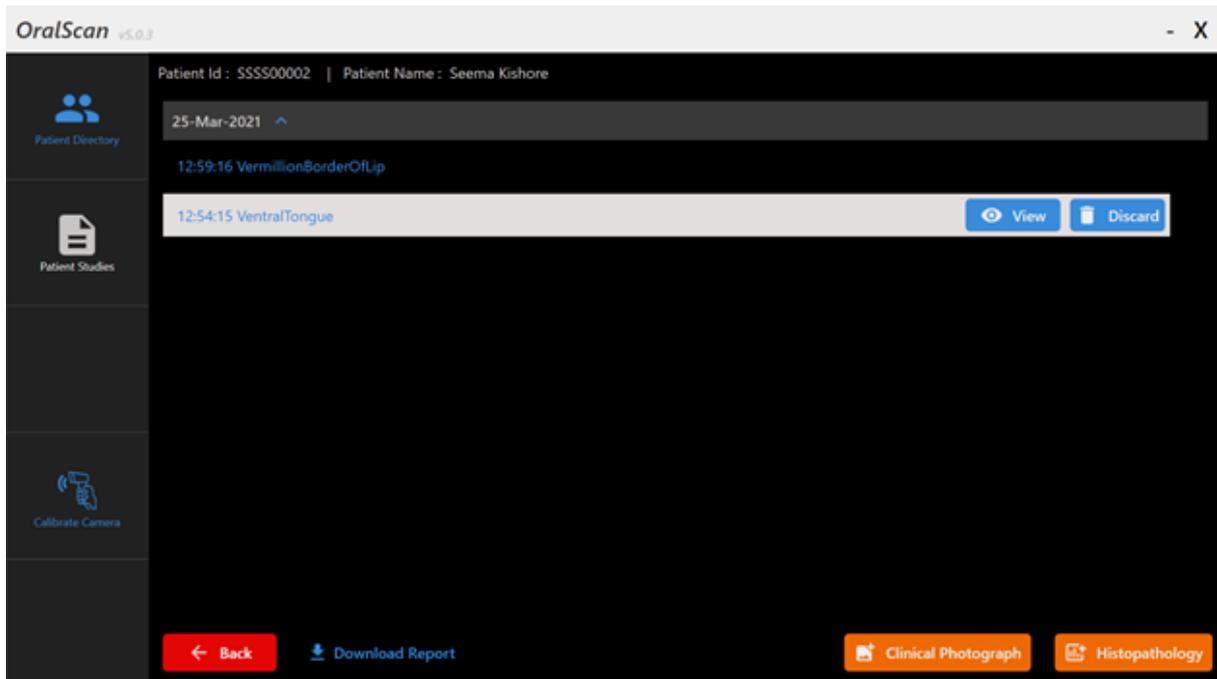


Figure 10. Window for uploading of clinical photo and histopathology report to the cloud

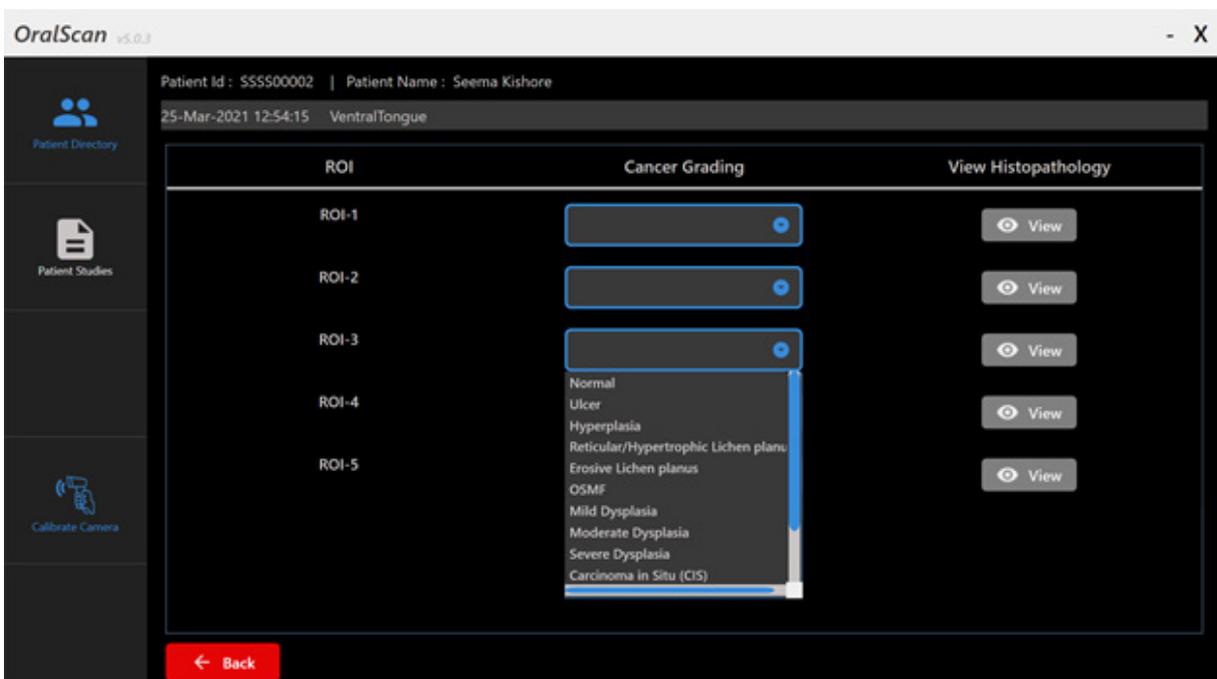


Figure 11. Uploading of pathology reports for each ROI marked on the DR ratio image

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The new window shows all visits of the patient and the user can choose the visit date to open up the data sets for editing, listed as per the anatomical site and the time of screening. Now, click on the anatomical site or screening time button, and the view or discard button appears on the right side. Also displayed at the bottom are the icons for inserting clinical photographs of the lesion and the histopathological report for each of the ROIs biopsied. There is provision to download the report in PDF format for sharing with the patient via email and for its printing (Figure 9).

All the images captured, the video files, the ROI values and the screening report are saved under C:\Program Files(x86)\Sascan\Data\Patient ID path, in the computer. In areas without internet connectivity, the data saved in the computer gets uploaded whenever the device gets connected to the internet.

Enabling collection of normal tissue characteristics

In the default mode, the user can only mark ROIs surrounding the abnormal sites only. Whenever, the DR ratios (R620/R545) of the adjoining normal tissues or of healthy volunteers need to be recorded, the user has to click on the Settings icon, and enable the slider switch for collection of healthy tissue data. Afterwards, when a set of monochrome images are captured, the user will have the possibility to mark ROIs for both healthy (appears as dark line) and abnormal sites (appears as white line) with reference to the PCM of the fluorescence or the HbO₂ absorption map (Figure 12).

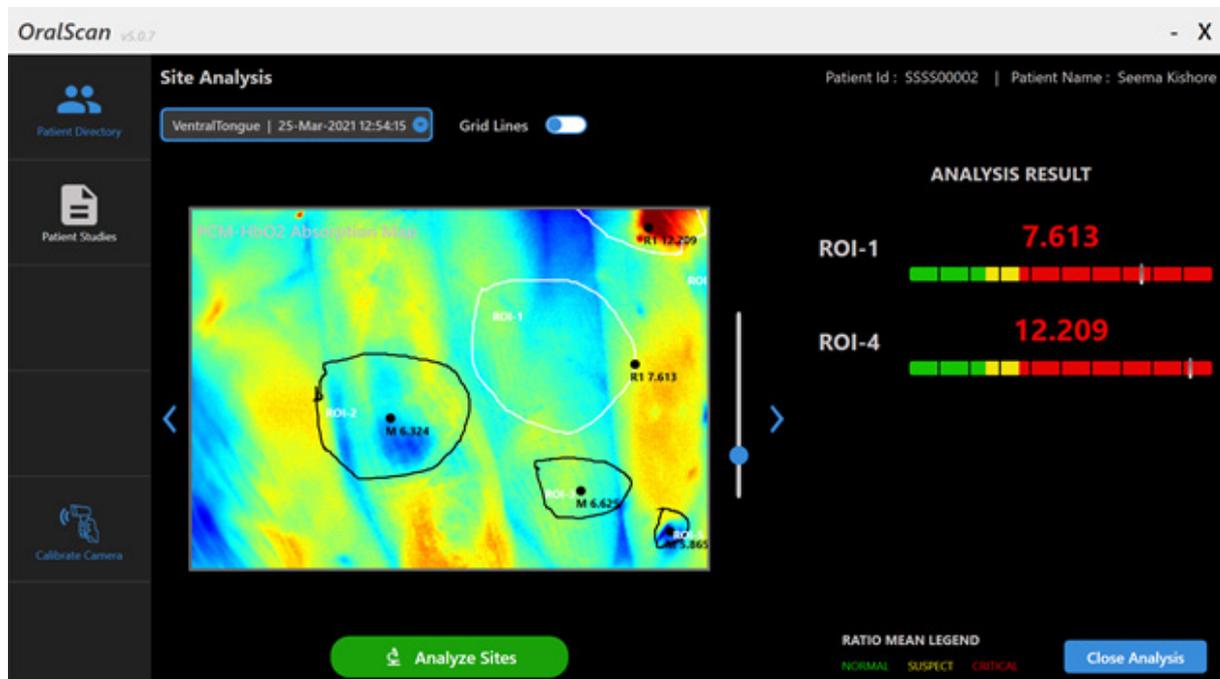


Figure 12. After marking an ROI on the captured image, the user will select either abnormal or normal in the Popup window and click OK. Now, on clicking the Analyse Sites button, all the ratio values corresponding to the marked Rols get displayed on screen

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The program is set to display the mean of pixel intensities within the marked RoIs on the PCM-HbO₂ absorption map as Mxxx, whereas the peak ratio value gets displayed as R1-2 xxx for the abnormal sites on the processed HbO₂ absorption map, which also gets displayed on a color coded horizontal bar, with green for healthy, yellow for OPML and red for SCC. for each RoI marked on screen. Any number of RoI can be drawn for healthy/abnormal data sampling on the same image.

Cleaning Procedure

- The body of the device is wiped clean with isopropyl alcohol (IPA) or any laboratory sanitizer / disinfectant solution (hand sanitizer, wetted on tissue paper).
- The optical window at the front end should be cleaned using lens cleaning solution or with soft tissue/microfiber cloth. Do not touch the optical window to avoid fingerprints on the coating. The window needs to be handled with care to avoid scratches and other blemishes..

Caution

- Do not immerse or dip the probe in water or any other liquid.
- Do not use harmful or corrosive chemicals or soap solution for disinfection
- Do not use steam autoclave or use other modes of sterilization for the probe.

Software Upgrades

The software automatically checks for the latest version and downloads it onto the PC/ LapTab used for data collection.. Upon starting the Oralscan application, if a new version of is available a prompt is shown to the user to install the latest version. We highly recommend you to install the latest version and stay up to date.

Labeling

The following labels are used on the device:

Labels	Description	Labels	Description
	Conformity to European Standards		Manufacturer
	Date of Manufacturing		Serial Number
	Fragile		Storage temperature
	Instructions for use		Do not accept if broken
	Keep away from sunlight		Keep dry

Warranty & Support

Thank you for purchasing the OralScan product, which is designed and manufactured to ISO 13485:2016 standards and is expected to deliver high-quality performance, ease of use and ease of installation. In case you encounter any difficulty while installing or using our product, we recommend you to first consult the operating instructions or contact us for installation support.

The period of warranty is for one year and begins from the date of purchase of the product. If your product turns out to be defective, the customer needs to return the product in its original packaging to the company and Sascan will arrange to repair or replace defective parts off site and return the product in good working condition as per the warranty terms. If any defect occurs due to faulty materials and/or workmanship during the warranty period, Sascan will repair or replace the product at its expense. Even if the product is replaced, the warranty start date remains the date as that of the original product purchase. This warranty does not cover consequential damage, and does not apply if:

- The purchase documents have been altered in any way or made illegible.
- The model- and/or serial number (if available) on the product has been altered, removed or made illegible.
- Repairs or product modifications and alterations have been carried out by unauthorized organizations or persons.
- The product is not used correctly according to the instructions included in the operating manual (IFU).
- The defect is caused by abuse or misuse of the product or due to environmental conditions that are not in conformance with the recommended operations of the product.
- Damage is caused by accidents including but not limited to lightning, abnormal voltage, water or fire, natural disaster or transport accident or caused by animals.
- The warranty does not cover products and/or product parts that are subject to wear, that can be considered as consumable parts by their nature (e.g. power bank) or that are made of glass (optical components). Integrated light sources (e.g. LED-components) are not considered as consumable parts.

The life expectancy of the product is 7 years. Whenever the product malfunctions or any service is required, please contact us at the following address:

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