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1 CALCIVIS IMAGING SYSTEM: OVERVIEW

The CALCIVIS imaging system is intended to be used by dental healthcare professionals on patients (6 years and older) with, or at risk of developing, demineralization associated with caries lesions, on accessible coronal tooth surfaces.

The CALCIVIS imaging system is indicated for use to provide images of active demineralization on tooth surfaces, as an aid to the assessment, diagnosis, monitoring and treatment planning of demineralization associated with caries lesions.

The CALCIVIS Imaging System consists of two main components which are used in conjunction to enable a Dental Practitioner to obtain images of active demineralization on tooth surfaces: The CALCIVIS Imaging Device and the CALCIVIS imaging kit.

The CALCIVIS Imaging Device includes an intra-oral camera and associated software, which allows both video streaming of images and the capture of still images, and a mechanism which applies a small amount (25µl) of CALCIVIS photoprotein on to the tooth under investigation.

The key component of the CALCIVIS imaging kit is the CALCIVIS photoprotein which contains a non-therapeutic recombinant photoprotein which, in routine use, is applied at approximately 3µg per tooth with a maximum of 20 teeth (for example all molar and pre-molar occlusal surfaces) examined at any one visit.

The CALCIVIS Imaging System comprises:

1.1 CALCIVIS IMAGING DEVICE

Consists of:

- CALCIVIS Intra-oral imaging device
- CALCIVIS Device cradle
- CALCIVIS (Imaging) Software on USB card
- CALCIVIS User Manual

1.2 ACCESSORY - CALCIVIS FUNCTIONAL CHECK KIT

Consists of:

- CALCIVIS Functional Check Kit
- Instructions for use

1.3 ACCESSORY - CALCIVIS APPLICATOR MAIN BODY

Consists of:

- Applicator main body
- Instructions for use

1.4 ACCESSORY - CALCIVIS IMAGING KIT

Consists of:

- CALCIVIS photoprotein (Freeze dried in vials)
- CALCIVIS diluent for reconstitution (containing 0.9% anti-microbial preservative Benzyl Alcohol)
- Vial Adaptors to allow for needle-less reconstitution
- Device syringes
- Medical wipes used to clean the top of the multi-use vial adaptor
- CALCIVIS applicator single use components
- Instructions for use

The photoprotein in the reconstituted CALCIVIS photoprotein solution binds with free calcium ions at the tooth surface and emits light (in visible spectrum) which is captured by the imaging system.

Photographs of the product

Figure 1 example photographs of device loading and fully assembled device on stand

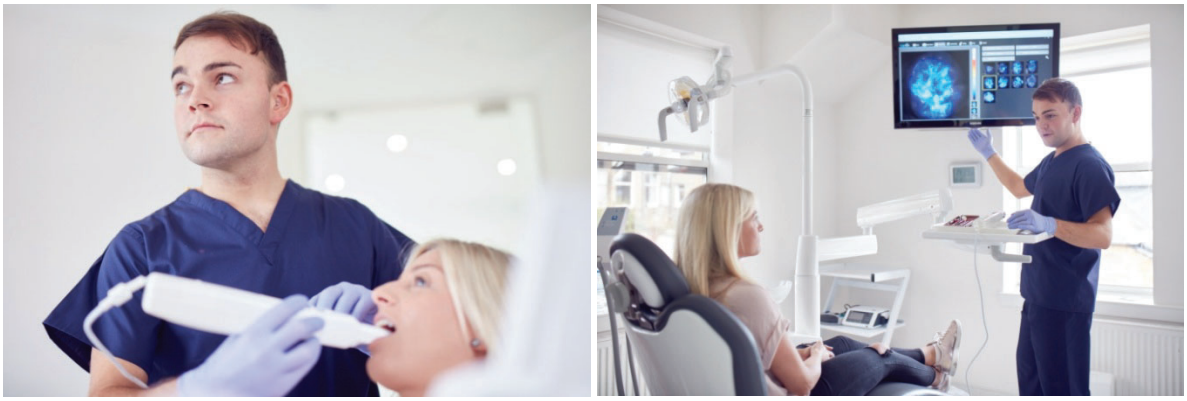


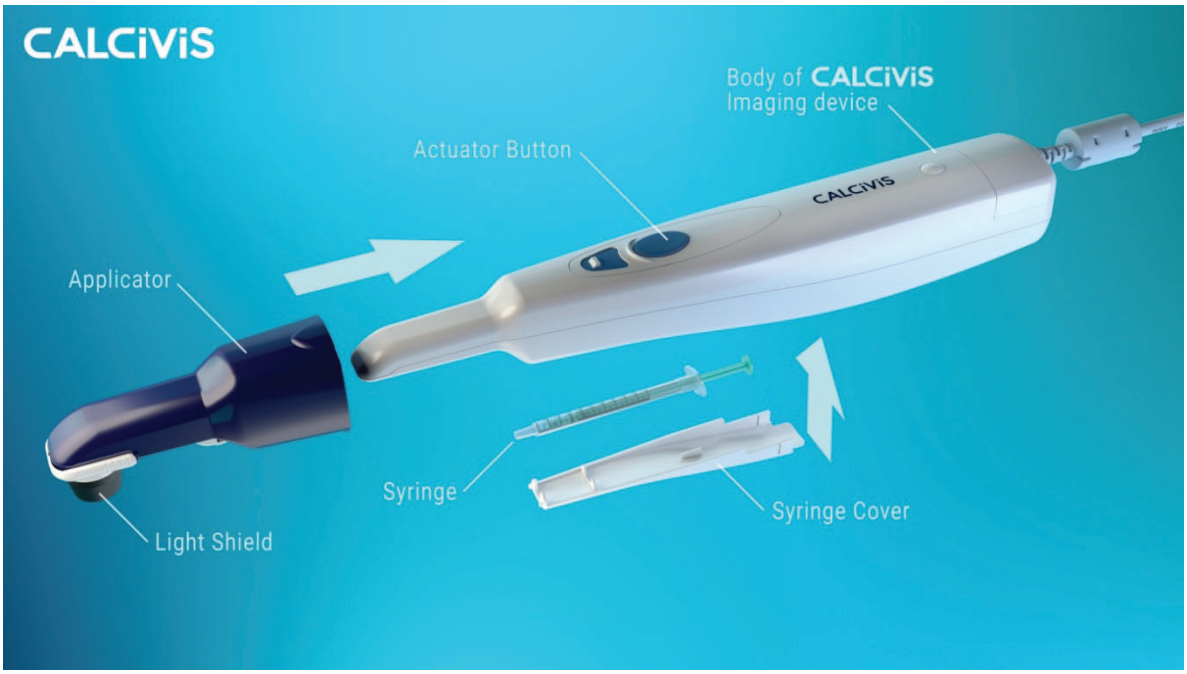
Figure 2 example photographs of device in use

The CALCIVIS imaging system is indicated for use to provide images of active demineralization on tooth surfaces, as an aid to the assessment, diagnosis, monitoring and treatment planning of demineralization associated with caries lesions. The CALCIVIS imaging system is for use by trained dental healthcare professionals.

The sequence of image capture and CALCIVIS photoprotein application are controlled using the custom application software. This also features the set-up of patient information within a database which allows sets of images to be captured. These are easily saved and a number of images can be compared for a number of patients over a period of time.

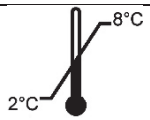
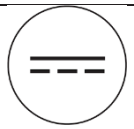
1.5 CALCIVIS IMAGING DEVICE: OVERVIEW

The picture shown below indicates the locations for the parts of the CALCIVIS imaging device which require the user to perform an action, and the component parts which will be removed and replaced after each set of assessments on individual patients have been completed.



1.6 SYMBOLS

The following symbols have been used on the system labels:

CALCIVIS imaging device Symbols			
	See instructions for use.		Lot number.
	Notified body CE mark.		Storage temperature limits.
	Manufacturer.		Expiry.
	Waste must be controlled according to local regulation and collection schemes for disposal of batteries.		SINGLE USE Do not re-use
	Device serial number.		Storage temperature limits.
	Warning/Caution		Direct current.
	Date of manufacture.		Type B applied part.
	Professional use only	IP42	Ingress Protection Rating

Operating temperature: 5 degrees C to 30 degrees C,

Humidity: 20% to 85% relative humidity, non-condensing

Storage temperature: Store away from sources of moisture below 35 degrees C

1.7 INDICATIONS FOR USE

The CALCIVIS imaging system is intended to be used by dental healthcare professionals on patients (6 years and older) with, or at risk of developing, demineralization associated with caries lesions, on accessible coronal tooth surfaces.

The CALCIVIS imaging system is indicated for use to provide images of active demineralization on tooth surfaces, as an aid to the assessment, diagnosis, monitoring and treatment planning of demineralization associated with caries lesions.

1.8 CONTRAINDICATIONS

There are no known contraindications for the use of the CALCIVIS imaging system

1.9 WARNINGS AND PRECAUTIONS

1.9.1 GENERAL:

- The CALCIVIS imaging system should only be used in accordance with (CALCIVIS Instructions for Use and CALCIVIS User Manual).
- Read all the Instructions carefully before use. Failure to properly follow the instructions, warnings and precautions may lead to serious consequences or injury for the patient and user.
- The CALCIVIS imaging system should only be used by trained dental healthcare professionals.
- Do not use on patients with known sensitivities or allergies to photoproteins.
- Patients using recent tooth bleaching (within previous two weeks of treatment with the CALCIVIS imaging system) may affect quality of images.
- The CALCIVIS imaging system is an aid to the diagnosis, monitoring and assessment of caries lesions and should always be used in addition to other methods of assessing caries (such as visual / tactile examination), before subsequent treatment planning.

1.9.2 ELECTRICAL SAFETY

- The CALCIVIS imaging device has been tested for compliance to IEC 60601-1-2:2015.
- Equipment connected to this product must conform to IEC standards (i.e. IEC 60601-1 for Medical electrical equipment, IEC 60950-1 for Information technology equipment, IEC 60065 for Audio, video and similar electronic apparatus). In addition, the combination and installation shall conform to IEC 60601-1. Any person who connects this product is responsible for ensuring that the system conforms to IEC 60601-1-1.
  To conform to IEC 60601-1, equipment connected to this product should be connected to the power supply via an isolation transformer and have at least basic insulation.
  For clarity; the Calcivis imaging device is powered via a **USB 3 port** of laptop or PC (not supplied with Calcivis imaging device kit).

WARNING: DO NOT PLUG THE CALCIVIS DEVICE DIRECTLY IN TO MAINS SUPPLY OR MAINS ADAPTOR.

WARNING: To protect the patient against the possibility of unwanted shock due to malfunction of the parent PC to the Calcivis intraoral camera via the USB3 cable, it is recommended the computer mains be connected to the Calcivis components using either a “medical isolation transformer”, or power the laptop using an IEC60601-1 conforming “medical grade power supply”.

When connecting to other devices, there is a risk that the leakage current may increase. If there is anything that you do not understand, please contact the dealer where this product was purchased.

1.9.3 Electromagnetic Interference and Emissions

- The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals. If it is used in a residential environment this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
- Risk from electromagnetic fields. Electromagnetic fields might interfere with the functions of implanted systems (such as pacemakers).
- No modification of this equipment is allowed. This includes the USB cable. Only use the cable supplied with the device.
  Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Do not modify this equipment without authorisation of the manufacturer.
- If this equipment is modified, appropriate inspection must be conducted to ensure continued safe use of the equipment.

1.9.4 ELECTROMAGNETIC IMMUNITY

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30cm (12 inches) to any part of the CALCIVIS imaging device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

This equipment is intended for use in the electromagnetic environment specified below. The user of this equipment should assure that it is used in such an environment.		
Immunity Against:	Compliance Level	Electromagnetic Environment
Radiated RF EM fields (IEC 61000-4-3: 2006 (+A1, A2))	3V/m 80-2700MHz Plus Proximity Fields	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Power Frequency Magnetic Field 50/60Hz (IEC 61000-4-8:2009)	30A/m	

SYSTEM HARDWARE COMPONENTS

Physical Attributes	
Size (HxWxD)	30 cm x 5 cm x 4 cm
Weight	0.5 kg
Electrical Specifications	
Rating Voltage	DC 5 V
Power Consumption	0.9 W
Standby Power Consumption	0.1 W
Max Power Output	N/A
Environmental Specifications	
Temperature Range	Operating: 5°C (41°F) to 35°C (95°F) Storage: 0°C (32°F) – 40°C (104°F)
Relative Humidity	<95%
Protection Against Ingress of Water	IP42

1.9.5 SAFE ACCESS

- Not suitable for use if teeth cannot be accessed without causing trauma or upset to patients

There are several clinical conditions which could preclude the use of the CALCIVIS imaging system, in addition to many other dental instruments, devices and procedures, as they prevent the mouth opening wide enough to accommodate these devices, instruments and procedures. Such clinical conditions include:

- Radiation induced fibrosis – preventing mouth opening wide
- Scleroderma – skin hardening / tightening round mouth
- Medial pterygoid (masseter) muscle very strong - resulting in muscular pain and inability to open mouth
- Temporal Mandibular Joint (TMJ) disorder - when the disc moves forward at the mandibular joint preventing the amount the jaw can open
- Trismus (lockjaw) – reduced opening of jaw

1.9.6 CALCIVIS IMAGING DEVICE

- Do not immerse the CALCIVIS imaging device in water – follow the Cleaning Instructions provided.
- The CALCIVIS imaging device should only be used with the cabling provided
- The CALCIVIS imaging device should only be used at the voltage stipulated
- Do not attempt to repair the product. Contact CALCIVIS if you have any concerns regarding the product

1.9.7 CALCIVIS KIT AND CALCIVIS PHOTOPROTEIN

- Wear gloves
- Do not use the CALCIVIS kit if primary packaging has been breached in any way or is wet.
- Do not use the sterile syringe provided if the primary packaging has been breached in any way.
- Do not use the vial of freeze-dried CALCIVIS photoprotein or vial of CALCIVIS diluent if they have been damaged in any way or show signs of leakage.
- Do not fill the syringe with any solution other than the CALCIVIS photoprotein or CALCIVIS diluent.
- Always make up the CALCIVIS photoprotein according to the manufacturer's instructions.
- Once reconstituted CALCIVIS photoprotein should be stored refrigerated (2^{o}C to 8^{o}C); discard any unused CALCIVIS photoprotein after 2 weeks beyond reconstitution.
- The CALCIVIS photoprotein must only be used in conjunction with the CALCIVIS imaging system.
- Follow the instructions carefully for fitting the CALCIVIS applicator to the end of the CALCIVIS imaging device and check it is fitted correctly by gently pulling to ensure it does not dislodge.

1.10 ADDITIONAL INFORMATION

Dental imaging examinations should be performed by a range of trained dental healthcare professionals. Interpretation of these results must be a matter for a specialist. The clinic needs to be suitably equipped and have staff capable of carrying out standard clinical procedures. Interpretation and reporting of the results should be done by a Dentist or a member of staff with suitable qualifications.

2 CALCIVIS IMAGING SYSTEM INSTALLATION AND SETTINGS

Note: **As the video stream on the laptop or monitor is used to position the CALCIVIS imaging device over the teeth in-mouth it is important to ensure the viewing screen is clearly visible when using the device in the patient's mouth.**

In addition, for best results avoid direct illumination of the mouth during the actual imaging process by ensuring the main overhead illumination lights are switched off.

It is recommended to turn sleep mode off on the PC or set it to >1hr as entering sleep mode may disrupt connection to the device.

- Unpack the CALCIVIS imaging system and place the CALCIVIS imaging device on the cradle provided.

Note: **Always place the device on the cradle between uses. The device contains sensitive electronic and imaging components that can easily be damaged by heavy jolts such as dropping the device**

Note: **The Calcivis imaging system can be installed as either standalone (not integrated to other image management system) or regular (integrated to Software of Excellence ExaminePro Image Management System)**

2.1 MINIMUM SYSTEM REQUIREMENTS

- PC — 2.0GHz processor, Intel i3 or better;
  4GB of RAM;
  200GB Hard Drive
  1366 x 768 or better screen resolution
  Graphics card supporting at least DirectX 10 in hardware with at least 512MB video memory and supporting at least 24-bit colour
  At least one accessible **USB 3** port
- Operating System: Windows 7 or 10
- Available USB 3 port

- The CALCIVIS imaging device has been tested for compliance to IEC 60601-1-2:2015.
- Equipment connected to this product must conform to IEC standards (i.e. IEC 60601-1 for Medical electrical equipment, IEC 60950-1 for Information technology equipment, IEC 60065 for Audio, video and similar electronic apparatus). In addition, the combination and installation shall conform to IEC 60601-1. Any person who connects this product is responsible for ensuring that the system conforms to IEC 60601-1-1.

To conform to IEC 60601-1, equipment connected to this product should be connected to the power supply via an isolation transformer and have at least basic insulation.
For clarity; the Calcivis imaging device is powered via a **USB 3 port** of laptop or PC (not supplied with Calcivis imaging device kit).

WARNING: DO NOT PLUG THE CALCIVIS DEVICE DIRECTLY IN TO MAINS SUPPLY OR MAINS ADAPTOR.

WARNING: To protect the patient against the possibility of unwanted shock due to malfunction of the parent PC to the Calcivis intraoral camera via the USB3 cable, it is recommended the computer mains be connected to the Calcivis components using either a “medical isolation transformer”, or power the laptop using an IEC60601-1 conforming “medical grade power supply”.

When connecting to other devices, there is a risk that the leakage current may increase. If there is anything that you do not understand, please contact the dealer where this product was purchased.

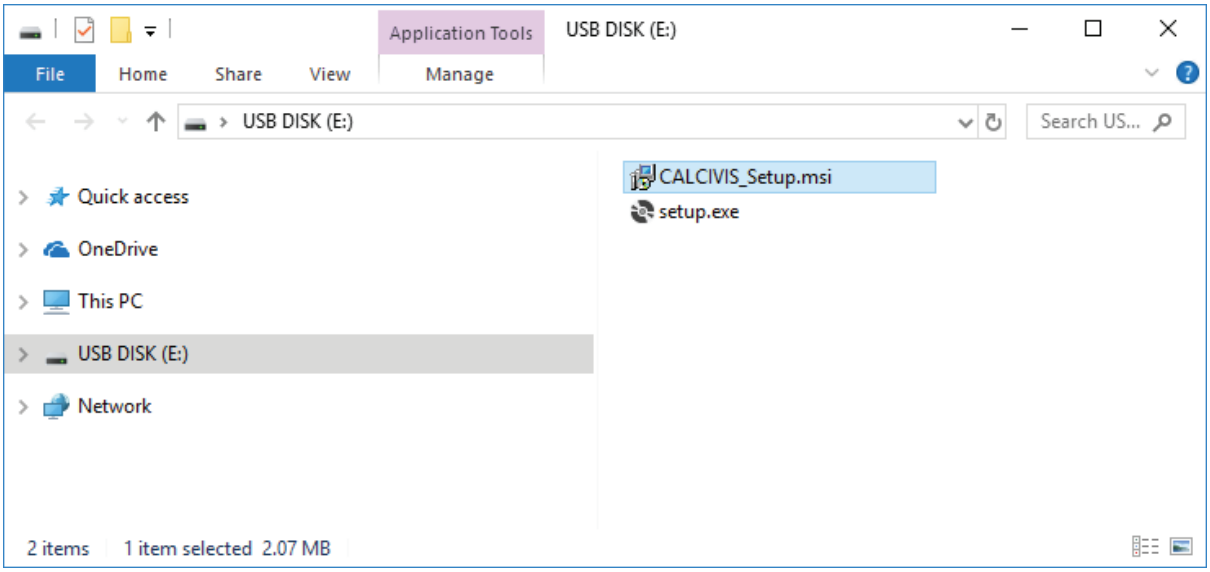
About Cybersecurity

CALCIVIS imaging device can be installed on regular Windows PCs (Operating System Windows 7 or 10). The operating institution is responsible for installing antivirus software and a firewall on the PC, for installing critical Windows updates regularly, and for keeping the PC otherwise secure.

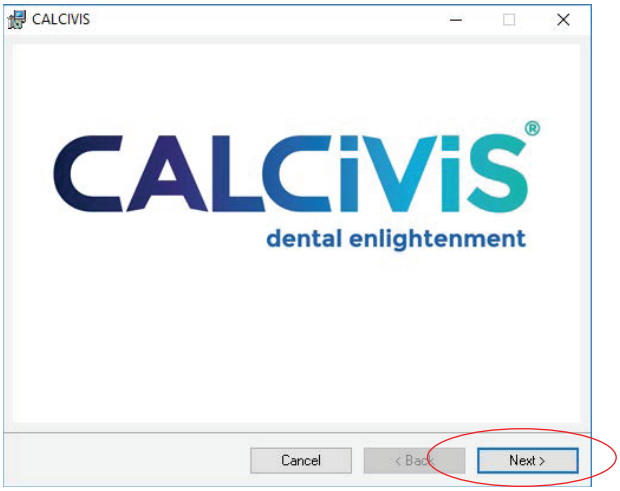
CALCIVIS imaging device itself is not directly connected to the network. CALCIVIS imaging device can be connected to a network via a PC/laptop for various purposes but can also function stand-alone without network access. No Patient data is held on the firmware of the device or the application software, only images are created that are then used by the operating institution.

2.2 APPLICATION INSTALLATION INSTRUCTIONS

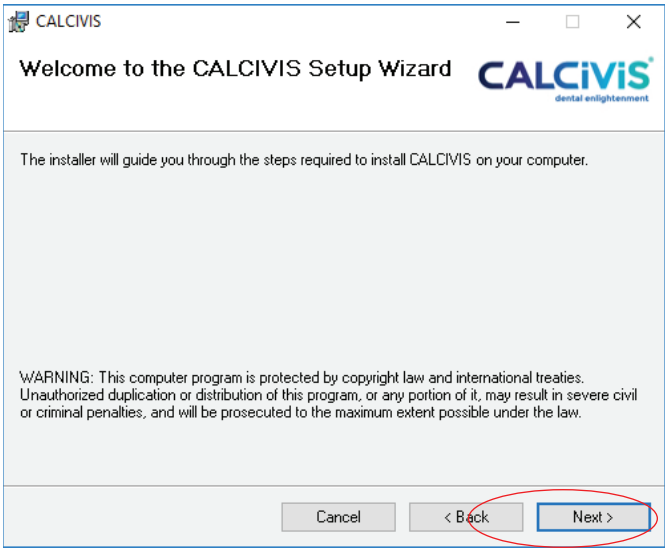
- Ensure all other programs are closed before starting installation.
- Insert the CALCIVIS application software card into any available USB port and navigate to the USB card folder.
- Double-click the setup.exe file to run the installer.



- The following window will appear. Click ‘Next’.

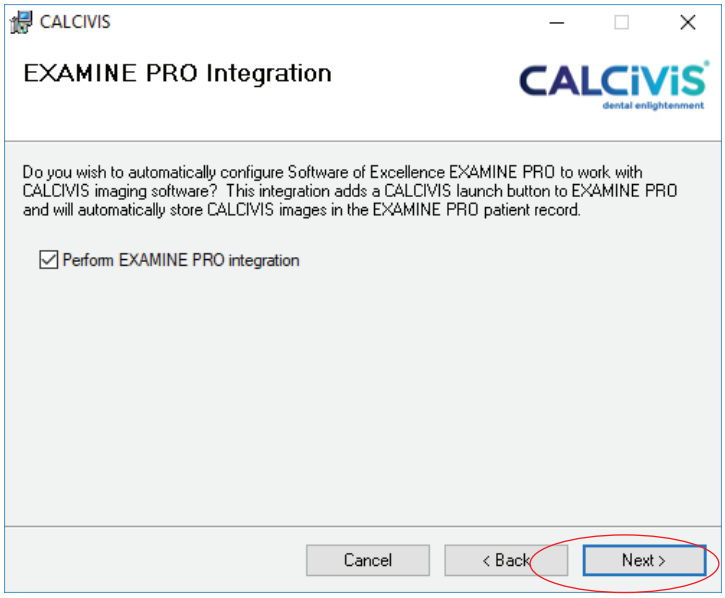


- The following view will appear. Click ‘Next.



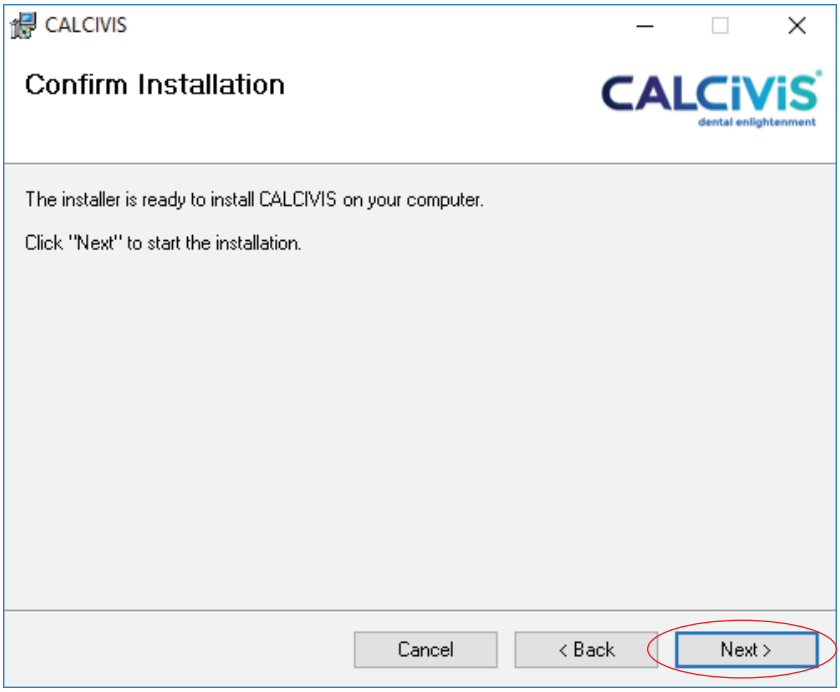
- The following view will appear. If you wish to install the optional Examine Pro integration, allowing the CALCIVIS app to be launched within Examine Pro and the images to be stored within its patient record, ensure ‘Perform EXAMINE PRO integration’ is selected and then click ‘Next’. This will be selected by default.

Note: Examine Pro MUST be installed before installing the CALCIVIS software.

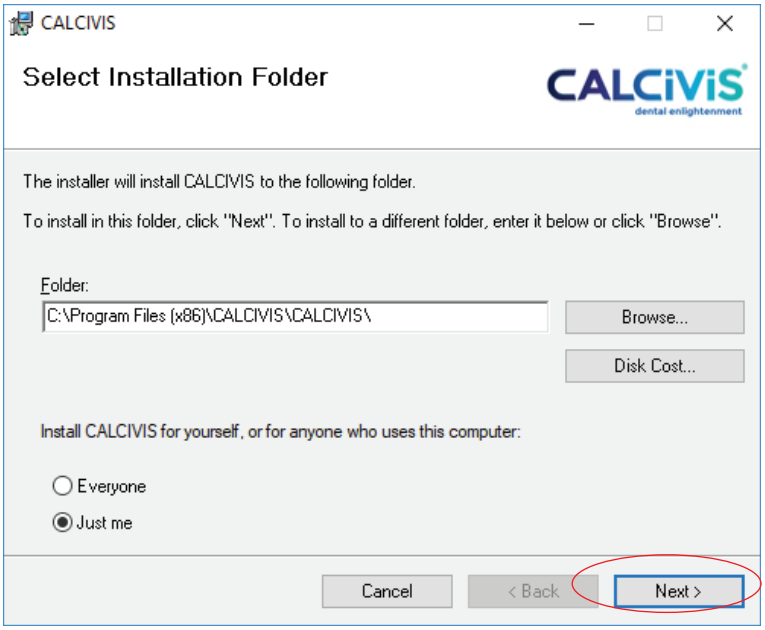


If you do **NOT** wish to install the Examine Pro integration, deselect this option and click ‘Next’.

- The following view will appear. Click ‘Next’.



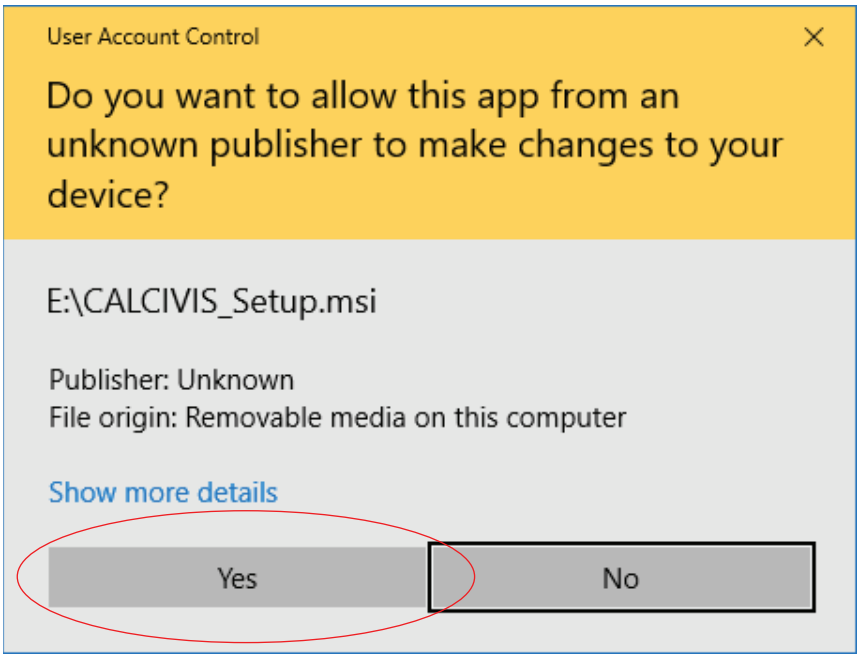
- The following view will appear, allowing you to select where the installed application will be stored. The default folder (on a 64-bit machine) is C:\Program Files (x86)\CALCIVIS\CALCIVIS. If you want to install the App in a different file location select ‘Browse…’ and navigate to the desired file location.



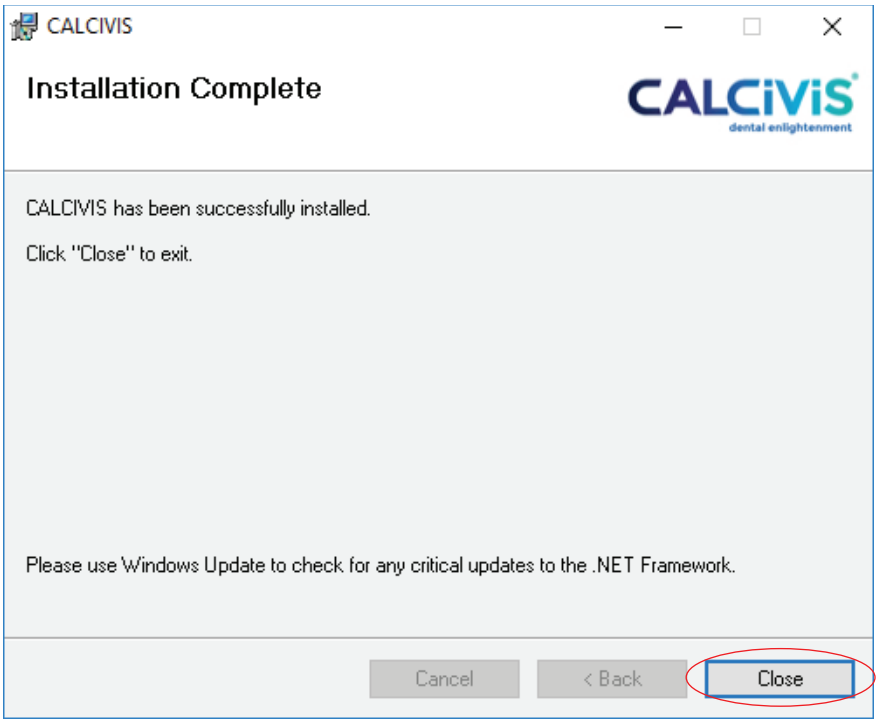
- If you wish to install the application for use on all user accounts on your PC, select ‘Everyone’. If you only want to install the application on the current users account, select

‘Just me’. This option will be selected by default. When you have selected the desired settings, click ‘Next’.

- The following User Account Control pop-up warning may appear. If so, click on ‘Yes’.



- Installation is now complete, click on ‘Close’ to finish. A shortcut to the CALCIVIS app will now appear on your desktop and start menu.

- 
CALCIVIS
Installation Complete
CALCIVIS
dental enlightenment
CALCIVIS has been successfully installed.
Click "Close" to exit.
Please use Windows Update to check for any critical updates to the .NET Framework.
Cancel
< Back
Close

2.3 STARTING THE CALCIVIS APPLICATION

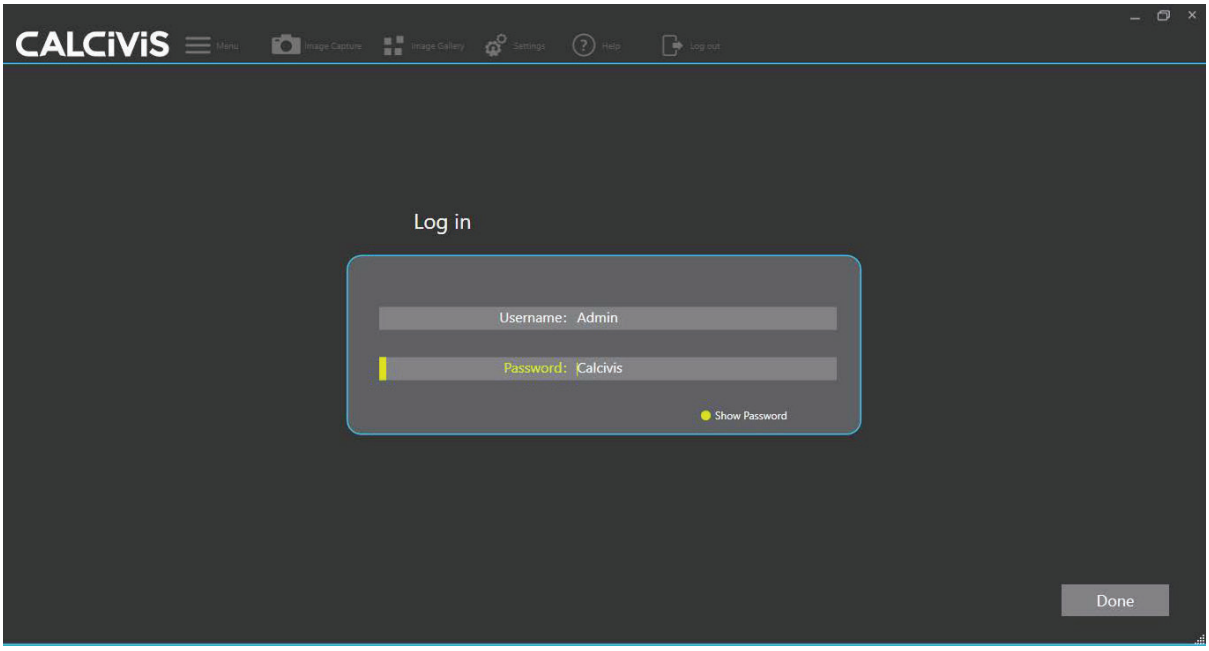
Connect the CALCIVIS device by plugging into a **USB3 port**. Check the port is USB 3 (USB3 ports are identified by this symbol and/or blue colouration inside the port). The LED lights should flash 3 times and the mechanism move to its home position.

Note: Ensure device is powered on and connected prior to starting application to avoid error message.

To start the application, double click on the CALCIVIS application icon:

The application will start, and the ***Welcome*** (login) screen will be displayed.

2.3.1 THE WELCOME SCREEN (LOGIN)

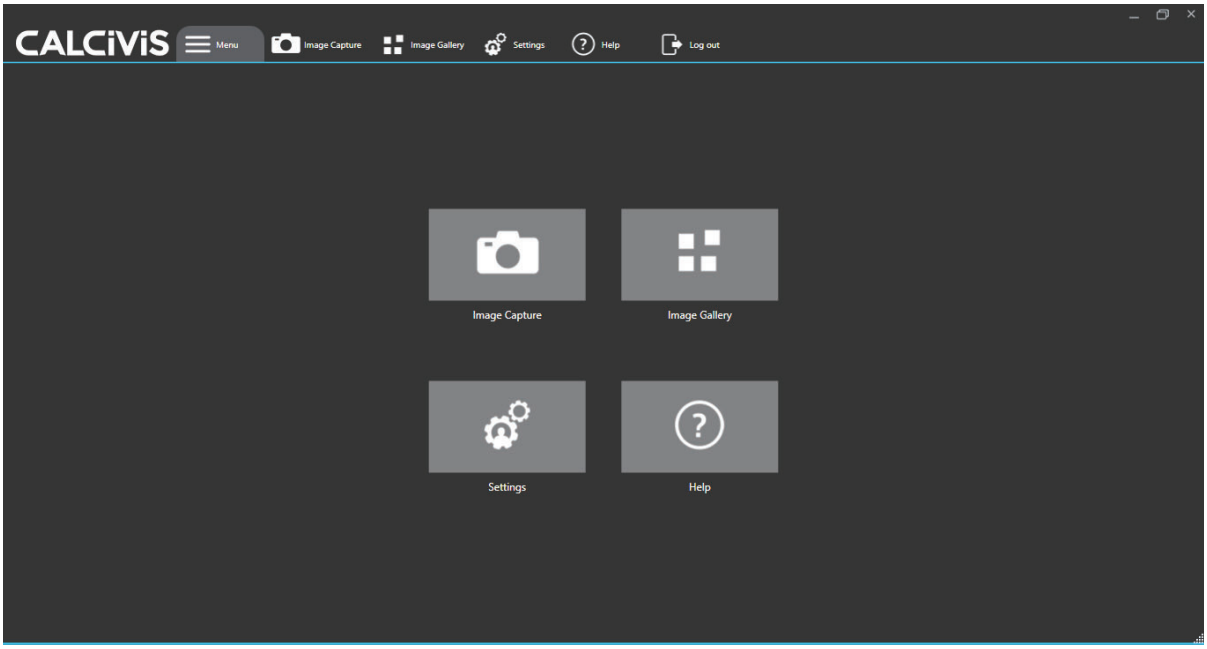


The Welcome screen allows authorised users to logon to the CALCIVIS application.

On first use logon to the application as administrator:

- Enter user name: Admin
- Enter password: Calcivis
- Click on ***Done*** when ready

2.4 Welcome Screen and Navigation Bar

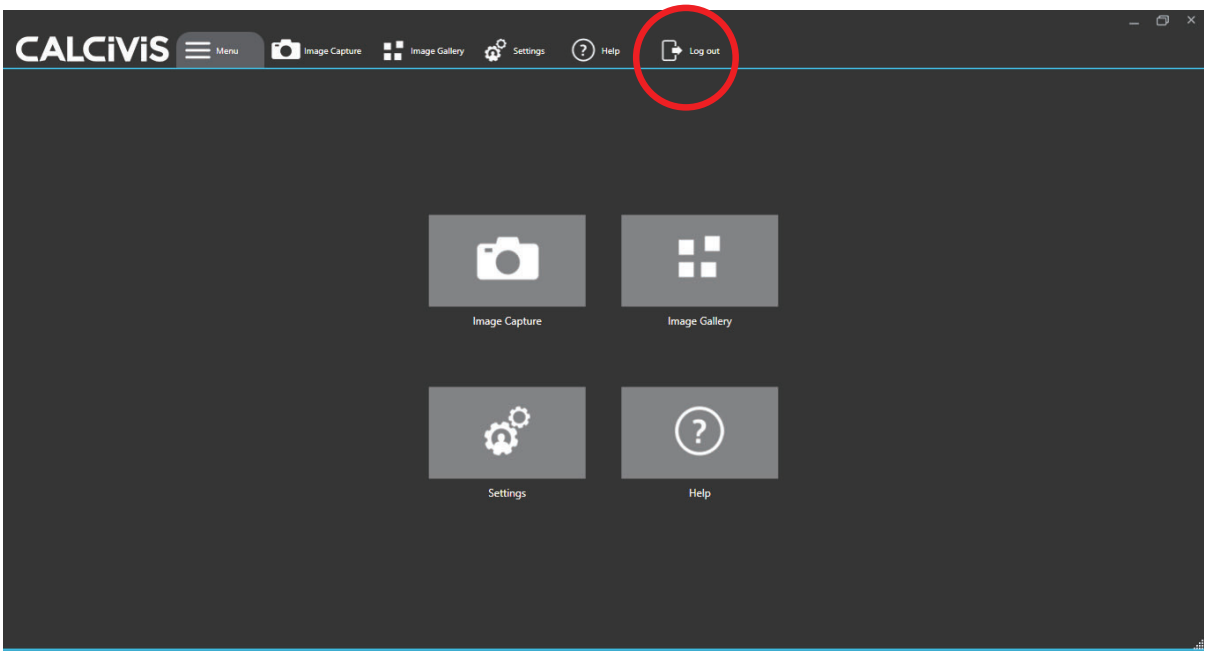


The Navigator bar appears along the top of each of the screens and enlarged icons appear on the screen immediately after login.

It allows the user to select which of the screens to display:

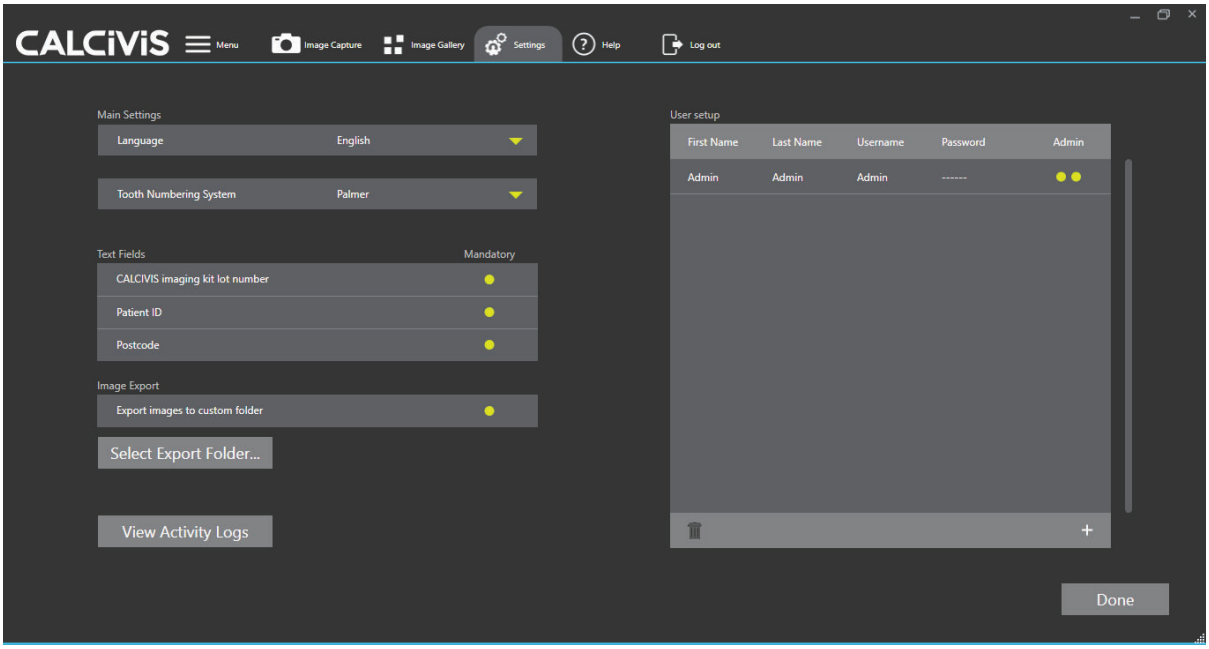
- Image capture
- Image Gallery
- Settings
- Help
- Log out

2.5 LOGOUT



To logout from the CALCIVIS application, the user should click on ***Logout***.

2.6 THE SETTINGS SCREEN



2.6.1 APPLICATION SETTINGS

The settings screen is an area for users with Administration rights only where users can be assigned passwords and various software settings can be selected.

Main settings allow you to choose from drop down boxes:

- Language
- Tooth numbering system.

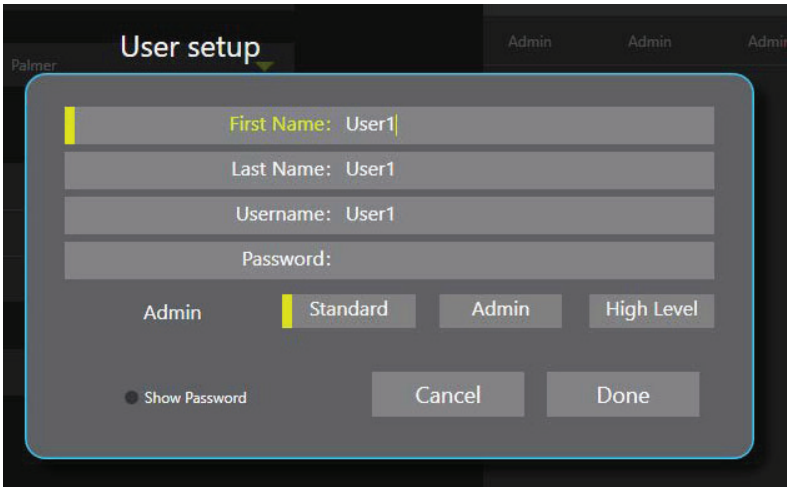
Text fields allow you to determine which patient details are mandatory

Image export allows you to select a folder to export a copy of all images to for use outside the CALCIVIS software.

Activity log may be required by CALCIVIS technical support and can be accessed by clicking the 'View Activity Logs' button

2.6.2 USER SETUP

- New users are added by clicking the '+' symbol. The user setup dialogue box will appear. Complete all fields and click done.



- To delete a user, select the user and click the trash icon. Note: you can not delete the user that is currently logged in.
- To edit a user double-click the user. The User setup dialogue box will open allowing details to be updated.

2.6.3 PASSWORDS

Users can use a combination of user name and password in order to control access to CALCIVIS imaging device. It is the responsibility of the operating institution to apply the appropriate password policies (for example, password strength and password renewal intervals). CALCIVIS imaging device does not include functionality for password strength and password expiration requirements. In case user handling is deactivated a default, password is used to restrict access to certain functionalities. Follow these general recommendations on password strength in case your institution does not have a more specific policy:

- Use a minimum password length of 8 characters.
- Include lowercase and uppercase alphabetic characters, numbers and symbols.
- Generate passwords randomly where feasible.

Follow this general recommendation for a password renewal interval in case your institution does not have a more specific policy:

- Passwords should be renewed after 90 days.

Note: It is advisable to change the Admin Password to avoid non-administrators accessing editing rights in settings

For continued secure use, perform Windows software updates regularly

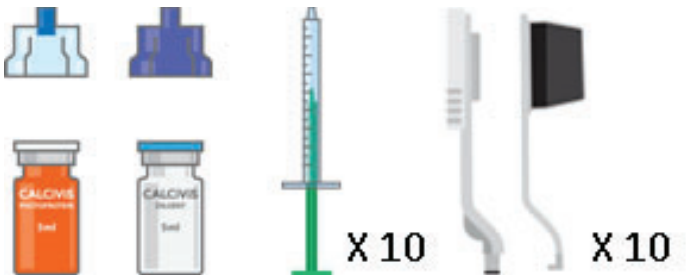
3 ACCESSORY AND DEVICE PREPARATION

3.1 SYRINGE PREPARATION

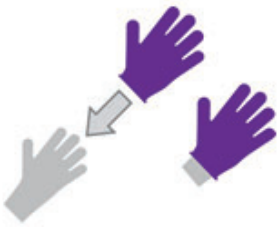
Preparation of the CALCIVIS photoprotein and filling the syringe should be carried out as follows:

1. Wear disposable gloves
2. If CALCIVIS photoprotein has already been reconstituted proceed directly to 11.
3. Check the integrity of the packaging of all components of the CALCIVIS imaging kit: CALCIVIS single use applicator components, syringes, vial adaptors, vial of CALCIVIS photoprotein and CALCIVIS diluent.
4. Do not use if the primary packaging has been breached or wet.
5. Remove flip off tops from CALCIVIS photoprotein (white cap) and diluent vials (blue cap).
6. Remove adaptors from packaging and fit to vials of CALCIVIS photoprotein and diluent. **Whilst fitting ensure the adaptor pushes straight down and not at an angle**.
   Fit BLUE adaptor to vial of CALCIVIS diluent.
   Fit CLEAR adaptor to vial of CALCIVIS photoprotein.
7. To reconstitute CALCIVIS photoprotein with CALCIVIS diluent, screw together in vertical position ensuring the opaque (amber) vial is at the bottom.
   Note: Ensure fluid passes from the CALCIVIS diluent vial to the CALCIVIS photoprotein vial. A small residual amount may remain in the diluent vial.
8. Detach CALCIVIS diluent from CALCIVIS photoprotein by unscrewing (Discard empty CALCIVIS diluent bottle)
9. Gently mix by swirling. Leave to stand for 30 seconds before withdrawing fluid
10. Write date of reconstitution and expiry date on label on side of vial.
11. Wipe top of adaptor with IPA wipe and leave for 20 seconds to dry. Insert syringe into vial adaptor and withdraw 0.37ml solution from vial
12. **If required, push Syringe plunger to empty fluid back into vial to remove any air bubbles**. Carefully withdraw 0.37ml using syringe (avoiding bubbles).
    If bubbles are present, gently tap the side of the syringe to dislodge.
13. The CALCIVIS photoprotein syringe is now ready to be inserted into the CALCIVIS imaging device.
14. Place residual CALCIVIS photoprotein vial (in its box) in refrigerator (2-8°C).

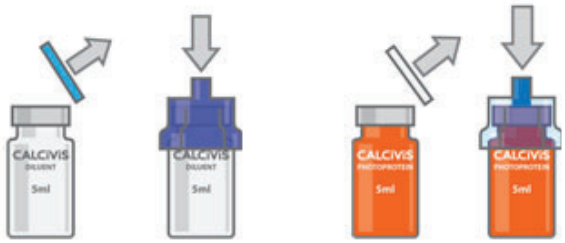
CALCIVIS imaging kit components



Instructions for Preparation

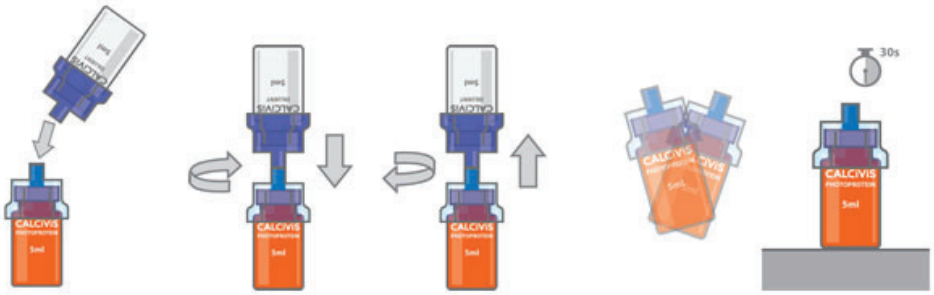


1) Wear Gloves



2) Flip off vial caps and attach adapters:

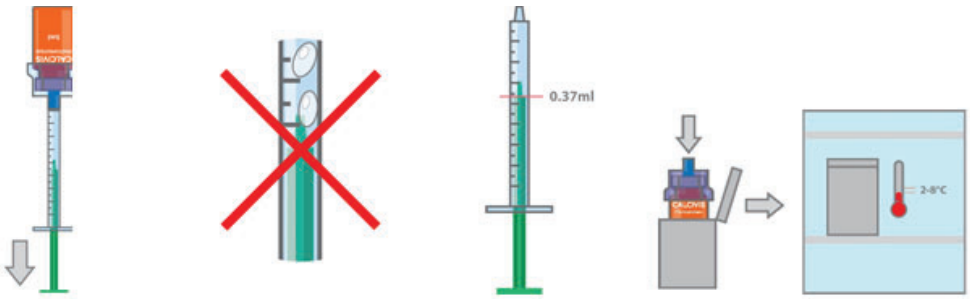
Blue → Diluent; Clear → Photoprotein



3) Place photoprotein on flat surface and bring diluent to photoprotein.

4) Screw the applicators together to draw the fluid through and unscrew to disconnect

5) Mix gently and let sit for 30s



6) Connect the syringe to the adapter and with the vial upside down draw photoprotein into syringe

7) Ensure there are no bubbles in the syringe. Move the plunger up and down to remove bubbles

8) Fill to 0.37 ml and remove vial. Return the vial to the fridge.

3.2 Device Preparation

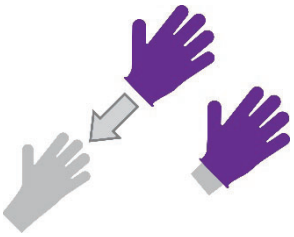
Preparation of the CALCIVIS imaging device should be carried out as follows:

- Wear gloves
- Check CALCIVIS imaging device is clean, if not perform clean as in section 7.
- With the CALCIVIS imaging device upside down (syringe door up) in its storage cradle, remove the syringe compartment cover, on the underside of the device body.
- Insert the pre-filled syringe into the underside compartment, locating the T-bar and end of plunger into the matching slots on underside of the device.
- Re-fit the syringe compartment cover (front end first).

3.3 CALCIVIS Applicator Preparation

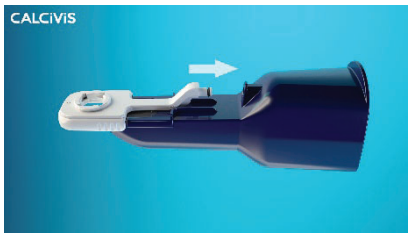
Preparation of the CALCIVIS applicator should be carried out as follows:

- Wear disposable gloves
- Obtain CALCIVIS applicator main body.
- Firmly push the CALCIVIS applicator main body into place over the CALCIVIS imaging device – an audible or tactile ‘click’ should be heard or felt when correctly attached.
- Remove the single use CALCIVIS applicator fluid channel from its pouch and slide into place over the CALCIVIS applicator main body
- The device is now ready for priming



Wear gloves

Fit main body to device



Fit fluid channel to Applicator main body

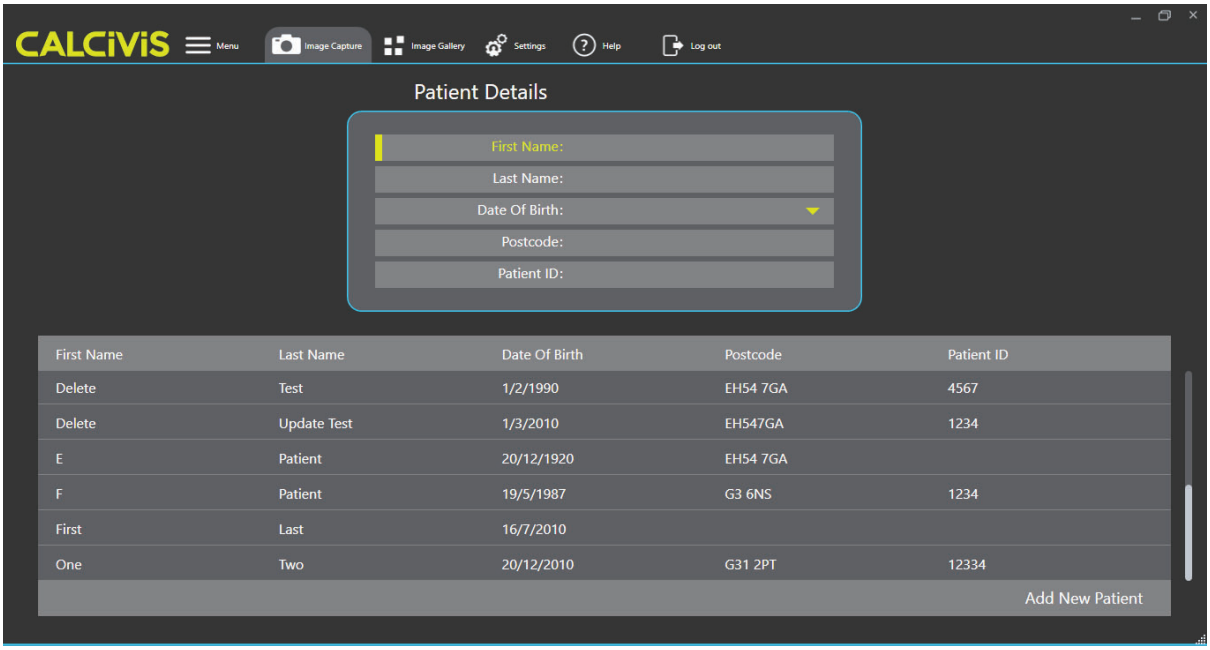
4 ENTERING PATIENT DETAILS USING IMAGE CAPTURE SCREENS

4.1 STANDALONE MODE (NOT INTEGRATED TO OTHER IMAGE MANAGEMENT SYSTEM)

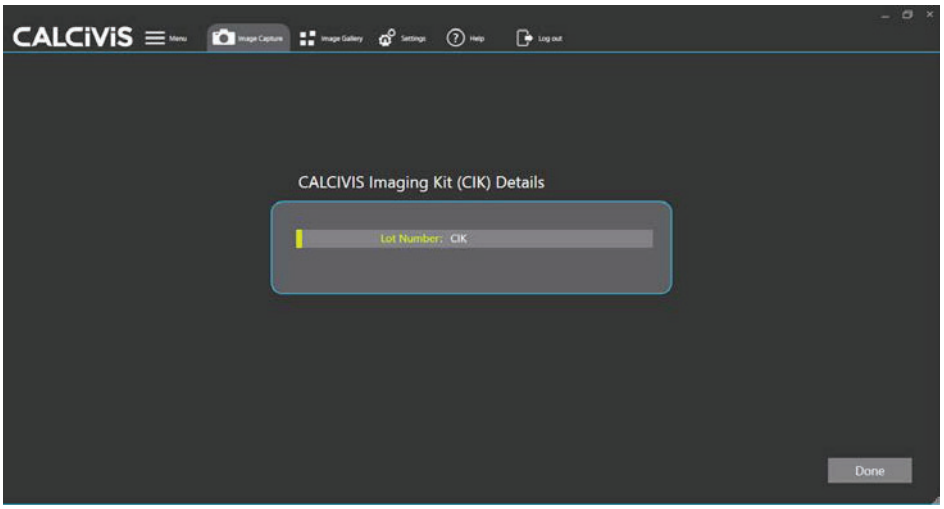
In standalone mode (i.e. when not integrated to other Image Management System) the Image Capture screens allow the user to:

- Select a pre-existing patient via list of patients or search function.
- Enter a new patient's details
- Enter CALCIVIS imaging kit lot numbers
- Enter patient ID
- Prime the CALCIVIS imaging device
- On completion of successful priming, capture images

4.1.1 ENTER PATIENT DETAILS



4.1.2 CALCIVIS IMAGING KIT DETAILS



Enter CALCIVS imaging kit lot number found on kit packaging (if required by administrator settings).

4.2 Integrated Mode (integrated to Software of Excellence Image Management System)

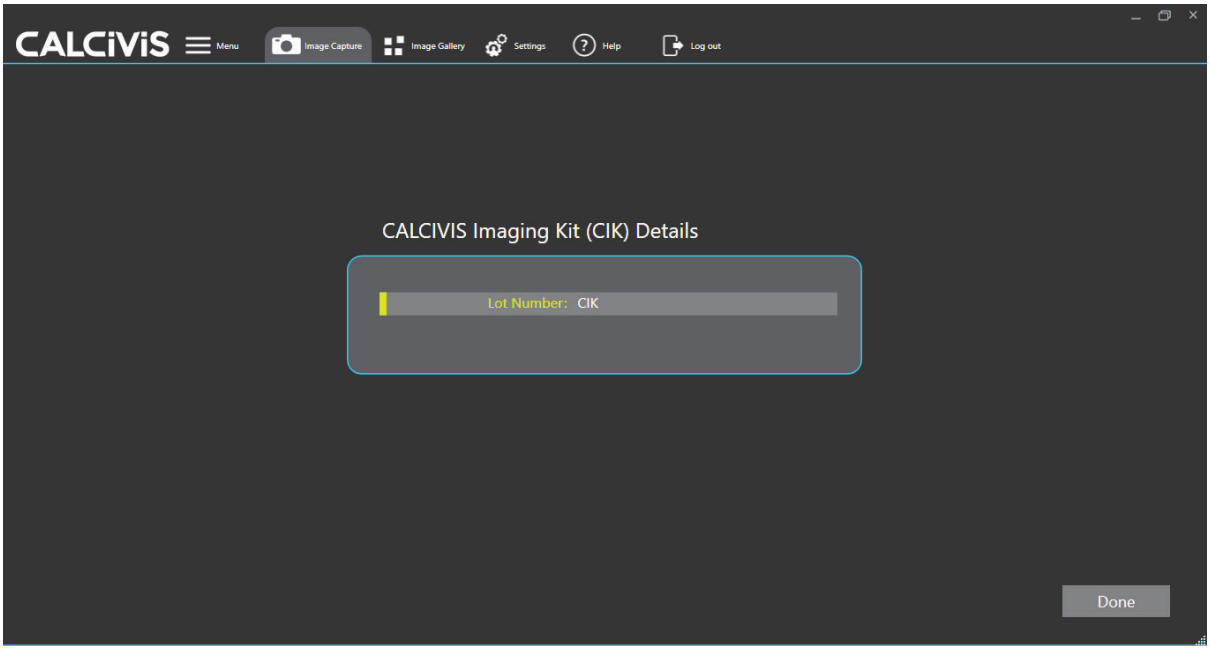
In Integrated mode (i.e. when integrated to other Image Management System [IMS]) the Image Capture screens allow the user to:

- Enter CALCIVIS imaging kit lot numbers
- Prime the CALCIVIS imaging device
- On completion of successful priming, capture images

4.2.1 Patient Details

Patient details that have been selected in the IMS will follow through to the CALCIVIS software, therefore it is not necessary to re-enter patient details.

4.2.2 CALCIVIS imaging kit Details



Enter CALCIVS imaging kit lot number found on kit packaging (if required by administrator settings).

4.3 PRIMING THE CALCIVIS IMAGING DEVICE

After loading syringe containing reconstituted CALCIVIS photoprotein and fitting main body of the applicator along with the single use fluid channel of the applicator, confirm the operation has been completed by clicking ‘DONE’

Prime the CALCIVIS imaging device by pressing the actuator Button.

CAUTION: the CALCIVIS imaging device will dispense some fluid while priming. Ensure it is held over tissue paper to visually confirm fluid is dispensed.

Ensure fluid is dispensed before moving to next stage. If fluid is not dispensed it indicated something is wrong with the set up. Remove the applicator and syringe and replace with new CALCIVIS photoprotein filled syringe and CALCIVIS applicator.

If any doubt over the priming or overall set up a function check test may be performed as detailed in the Troubleshooting Section;

On completion of successful priming insert the CALCIVIS applicator light shield and clip into place

5 IMAGING OF TEETH

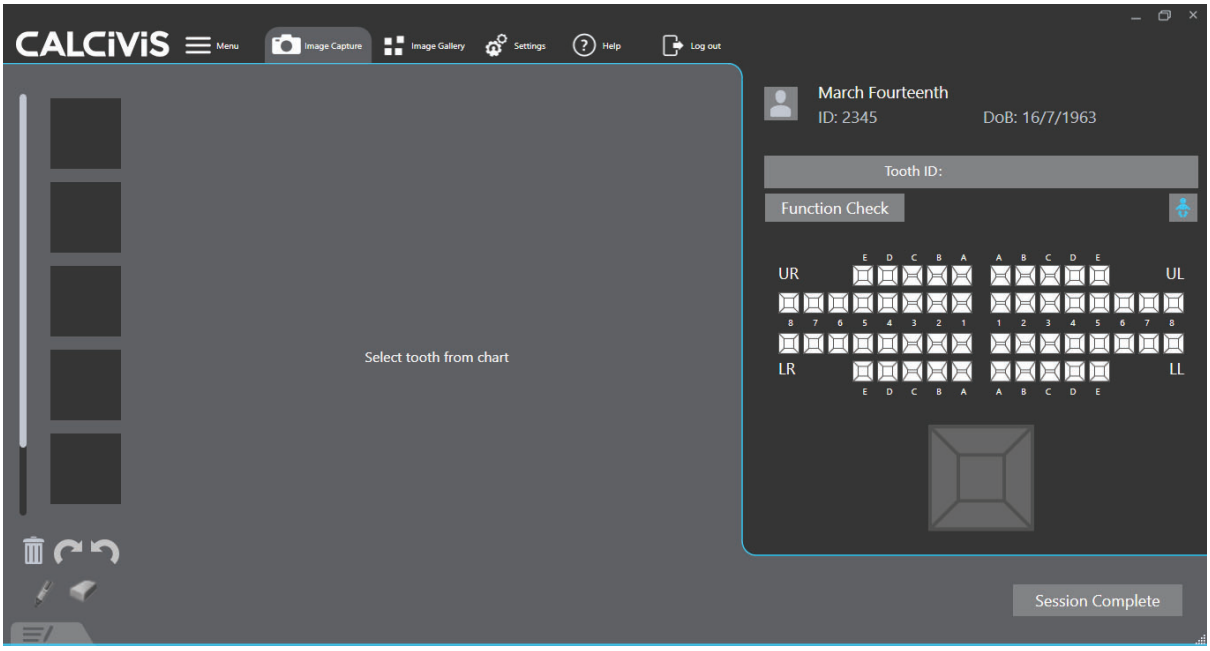
5.1 PREPARATION OF TEETH

Once a tooth surface of interest has been identified and selected for assessment with the CALCIVIS imaging system, the following procedure should be followed:

- Use a blunt / ball ended probe to remove gross accumulations of debris and dental plaque from the tooth surface if required
- For each tooth surface to be imaged brush the entire exposed tooth surface with a toothbrush and water (dental paste may be used if required and followed by brushing with water)
- Thoroughly rinse the tooth surface with a 3-in-1 (water only, then air-water spray). The patient should be asked to spit out residual water after the 3-in-1 rinse.
- As saliva contains calcium ions any gross contamination of the tooth surface under investigation, may interfere with the results. Where possible isolate the tooth from saliva with the use of isolation items such as mini-dams, cotton rolls, dry tips, saliva ejectors etc.
- Dry the tooth with compressed air.

5.2 TOOTH IMAGING PROCESS

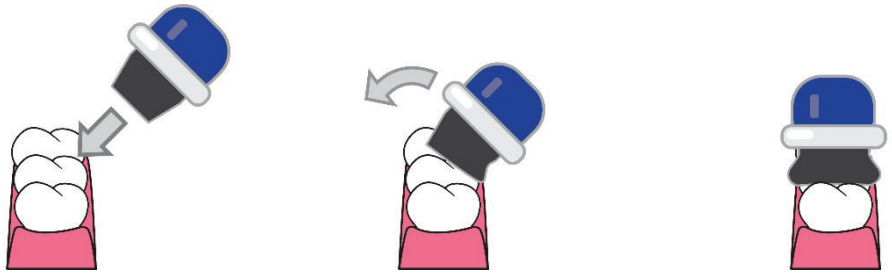
On completion of priming the CALCIVIS imaging system is ready for imaging.



Click on the tooth ID chart to identify which tooth is to be imaged, followed by surface to be imaged.

Note: Ensure the tooth surface to be imaged is clean, rinsed and thoroughly air-dried before imaging. Air-dry the tooth for approximately 5 - 10 seconds immediately prior to imaging.

Position the tip of the applicator over the tooth surface of interest. Ensure the surface is in focus and ambient light has been eliminated. Envelop the chosen accessible surface of interest by approaching from the lingual side of the tooth at an angle of about 45 degrees and working the light shield over the tooth surface until the chosen accessible surface is completely covered then press firmly to get correct focus.



A live video stream can be viewed on the screen to ensure correct positioning over the tooth surface of interest. When ready capture an image of the tooth surface of interest.

Note: Imaging takes approximately 1 second and it is important to ensure the CALCIVIS imaging device is held still during imaging to avoid blurred images due to camera shake. In addition, for best results avoid direct illumination of the mouth during the actual imaging process by ensuring the main overhead illumination lights are switched off.

To trigger the start of the sequence, press the Sequence Activation Button on the CALCIVIS imaging device

Note: An audible 'whirl' indicates that the system is about to apply CALCIVIS photoprotein and image. Ensure the CALCIVIS imaging device is correctly positioned and held still until imaging has finished and the image displayed on screen.

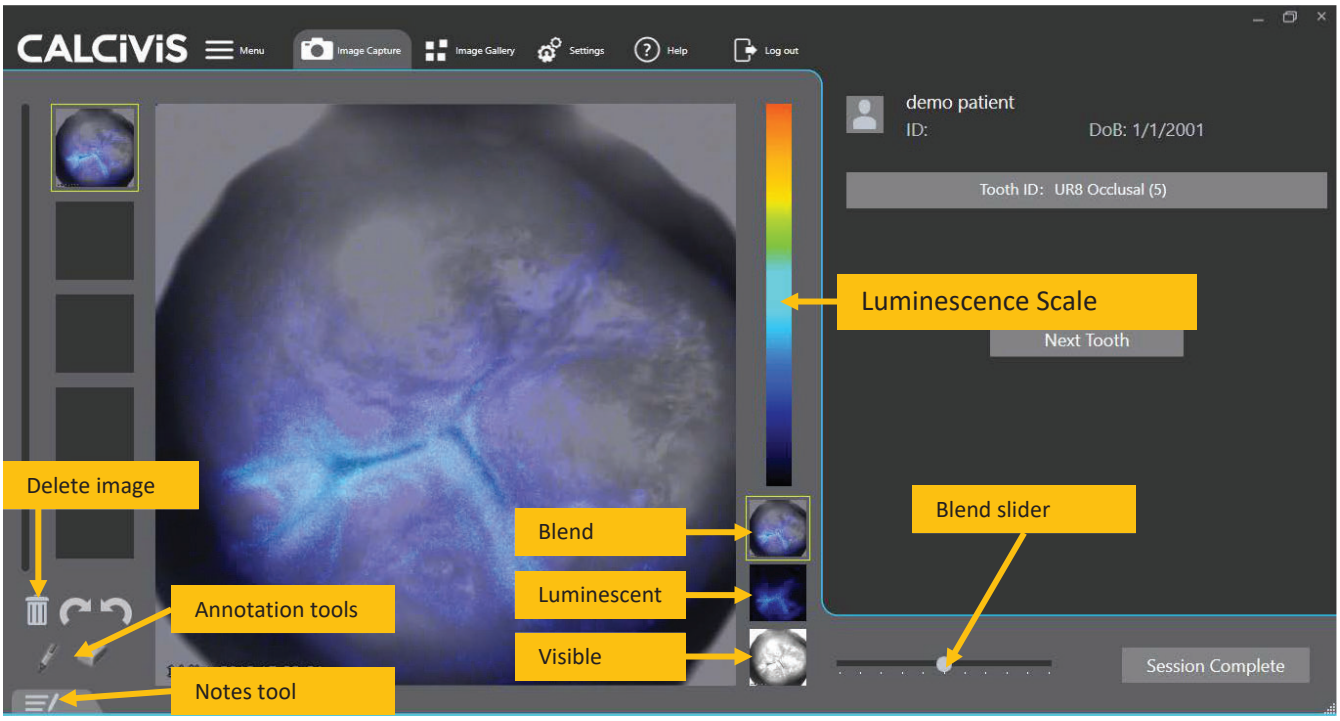
5.3 Additional Information on imaging

- When imaging multiple teeth in one sitting ensure all lower teeth are imaged first.
- Having previously cleaned all teeth to be assessed (as detailed above in 5.1), **air-dry the tooth for approximately 5 - 10 seconds immediately prior to imaging**.
- **As the** CALCIVIS imaging device **is detecting very faint transient luminescence from teeth, for best results the device should be used in a low light setting. Avoid sources of direct light into patients' mouth, ensuring the main overhead illumination lighting is switched off.**
- **When imaging upper teeth ensure the patient is in the fully reclined position.**
- To ensure best surface coverage, wherever possible, place the CALCIVIS applicator black tip fully over the tooth to be assessed. This will ensure optimal focus, best tooth surface coverage of CALCIVIS photoprotein and exclusion of ambient light that could spoil the image.
- Do not attempt to image teeth if the tooth cannot be accessed without causing trauma or upset to the patient.
- Using the video stream on the laptop or surgery monitor carefully centre the display directly over the area of interest (e.g. white spot lesion). To initiate imaging press actuator button on upper side of the CALCIVIS imaging device.
- Hold the CALCIVIS imaging device steady for approximately 1 second until imaging is complete.
- Remove CALCIVIS imaging device from patient's mouth and ask patient to rinse any residual photoprotein solution from their mouth.
- Repeat as necessary for other teeth, beginning with the air-drying procedure, **up to a maximum of 5 teeth**.
- **If greater than 5 teeth (up to a maximum of 20 per sitting) are to be imaged a new syringe will need to be fitted.**

Image Count

The software will allow a maximum of 5 applications per session. If additional images are required end current session and the device should be dismantled and cleaned according to section 7. A new syringe of CALCIVIS photoprotein can be inserted and the same applicator used if for the same patient.

6 IMAGE REVIEW (AVAILABLE FOR BOTH INTEGRATED AND STANDALONE MODES)



On capturing an image the live camera feed will stop and the captured image will be displayed in the image review screen.

The Review screen allows the user to toggle between:

- Visible light images
- Luminescent images
- Blended images

The user is able to:

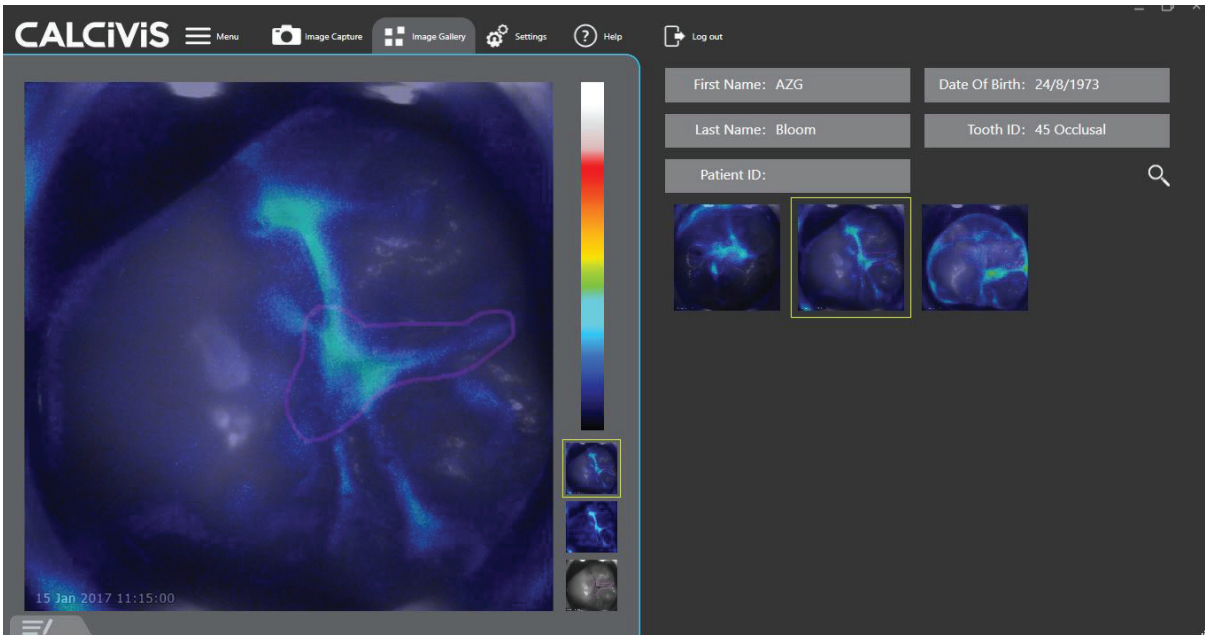
- Adjust the blending level of the visible and luminescence images
- Rotate images
- Delete the image (the image can be deleted if unsuitable, otherwise it will automatically be saved when the session is complete).
- Visualise the level of luminescence on the scale by left clicking on the mouse when hovering over an area of interest
- Annotate the image using the annotation tools

- Add notes to the image using the notes tool

When all images have been taken click on session complete. This will save the images from the session.
<u>IMPORTANT:</u> If session complete is not clicked images will not be saved.

<u>IMPORTANT: Images will be saved at the blend level set (a warning will be provided if out with 25 – 75% blend)</u>

6.1 THE IMAGE GALLERY (ONLY AVAILABLE IN "STANDALONE" VERSION. NOT AVAILABLE WHEN INTEGRATED TO PRACTICE IMAGE MANAGEMENT SOFTWARE).



The Image Gallery allows the user to:

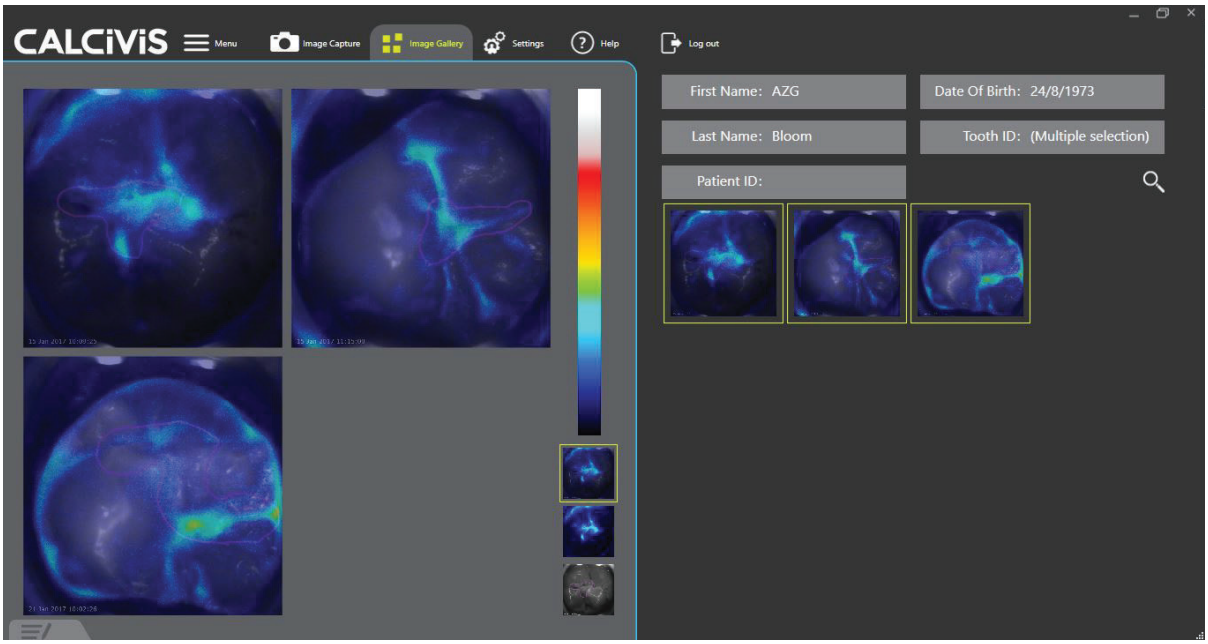
- Search previously captured images using patient details
- Select multiple images to view side by side and compare
- Review
    - Visible light images
    - Luminescent images

- Blended images

The user is able to:

- Toggle between blended, visible and luminescence images in the main window
- Add notes to the images using the notes tool
- Search by clicking the search symbol (magnifying glass) and entering patient details
- Select patient from drop down menu
- Select image from drop down menu
- Confirm patient details using ‘details tab’
- View images using ‘image tab’

Multiple images can be displayed side by side on the main screen for comparison.



6.2 IMAGE INTERPRETATION AND ANALYSIS

Image interpretation and analysis should only be performed by trained professionals. Areas of luminescence represent areas of greatest concentration of free calcium, which is indicative of on-going demineralisation.

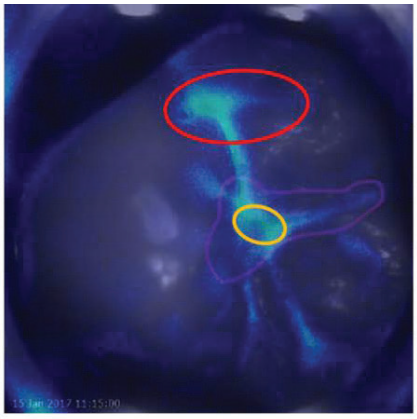
Very high levels of apparent luminescence in unexpected areas may be due to ambient light leak. If this is seen repeat imaging ensuring all **main overhead illumination** lights are off and no external light source is entering the mouth during imaging.

Very high levels of apparent luminescence in unexpected areas may also be due to gross contamination with saliva. If this is seen repeat imaging ensuring tooth surface is **thoroughly rinsed and dried**.

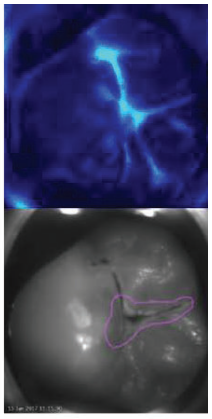
6.2.1 TYPICAL IMAGES SEEN WITH THE CALCIVIS IMAGING SYSTEM

Active Demineralisation

Central fossa white spot (circled in orange) in fissure entrance (noted at visual examination) along with distal (upper) white spot areas (circled in red) indicative of more intense demineralisation (not highlighted as the specific area of interest in initial visual examination (see purple drawing in next image).

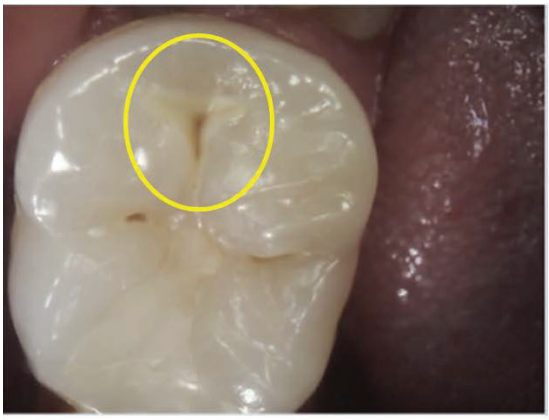


CALCIVIS blended image clearly shows areas of luminescentce in central fissure entrance and upper white spot region, indicative of active demineralisation in both these areas.

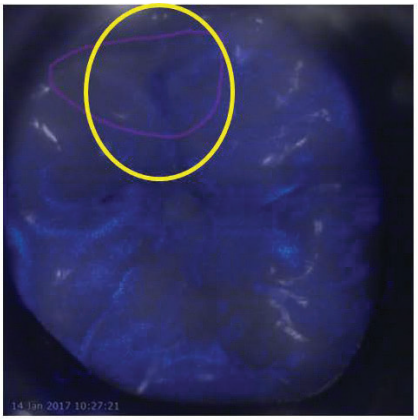


CALCIVIS raw images

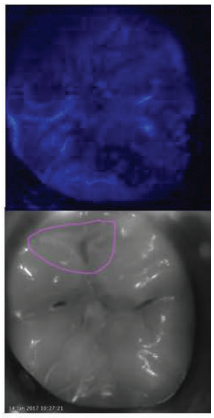
Arrested lesion



Area around caries yellow/brown indicative of arresting lesion.

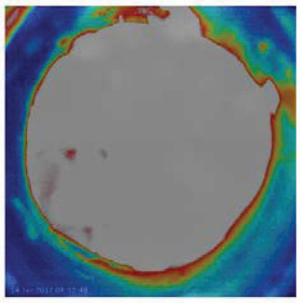


CALCIVIS blended image shows no luminescence in this area

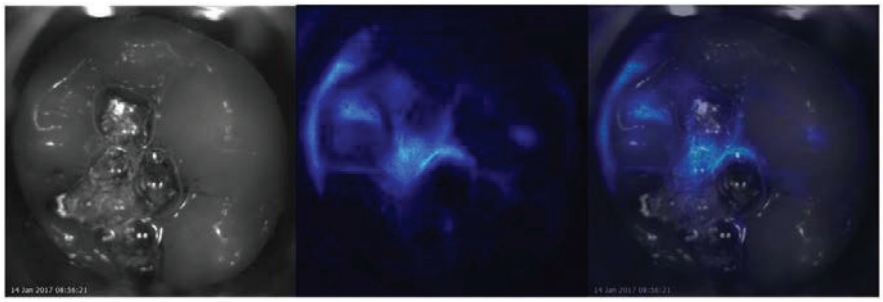


CALCIVIS raw images

6.2.2 EXAMPLE IMAGES OF POTENTIAL CONFOUNDING ISSUES



Ambient Light ingress



Gross saliva contamination evidenced by bubbles in visible image

If these sort of images are seen or there is any doubt over the images a repeat should be taken ensuring the tooth surface is clean and dry and sources of external light have been eliminated.

7 DISMANTLING, CLEANING AND DISPOSAL INSTRUCTIONS

After each patient use, the CALCIVIS imaging device should be disconnected from the USB 3 port and dismantled and cleaned according to the following protocol:

- Detach CALCIVIS imaging device cable from USB 3 port.
- Remove gloves and de-contaminate hands.
- Use fresh pair of gloves.
- Remove the applicator by twisting to unclip the light shield, depressing the latch button and pulling off the Applicator. The applicator should easily detach. If difficult to remove the thumb guard can be used to apply additional leverage.

- Dispose of Applicator to clinical waste.

- Open lower case of CALCIVIS imaging device and remove syringe.
- Dispose in clinical waste container

- Wipe all surfaces of the CALCIVIS imaging device thoroughly, including the housing and the inside and out of lower case cover with hospital grade disinfectant wipes, taking care to wipe all moulded parts.

8 MAINTENANCE, REPAIR AND DISPOSAL

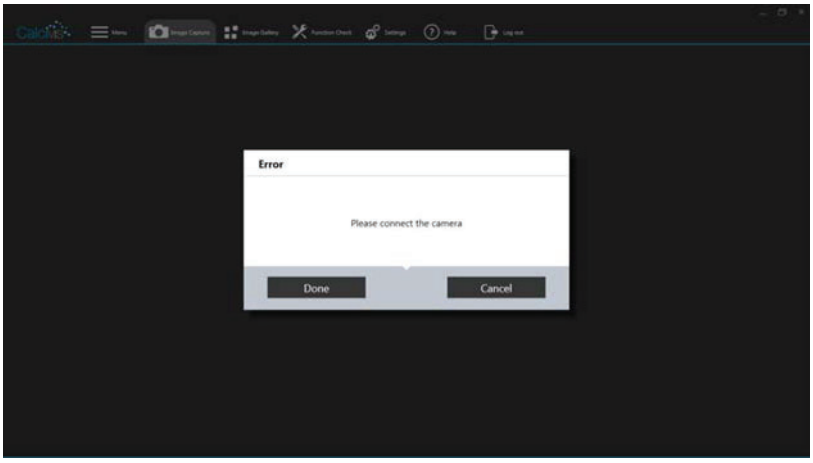
The CALCIVIS imaging device does not contain any user serviceable parts. Servicing and maintenance should only be carried out by qualified personnel. In the event of any failure, damage or misfunction the device should be returned to:

CALCIVIS Ltd.

Nine Edinburgh BioQuarter
9 Little France Road
Edinburgh
EH16 4UX
Tel: +44 131 658 5152

9 TROUBLESHOOTING

9.1 NO CAMERA FOUND ERROR MESSAGE



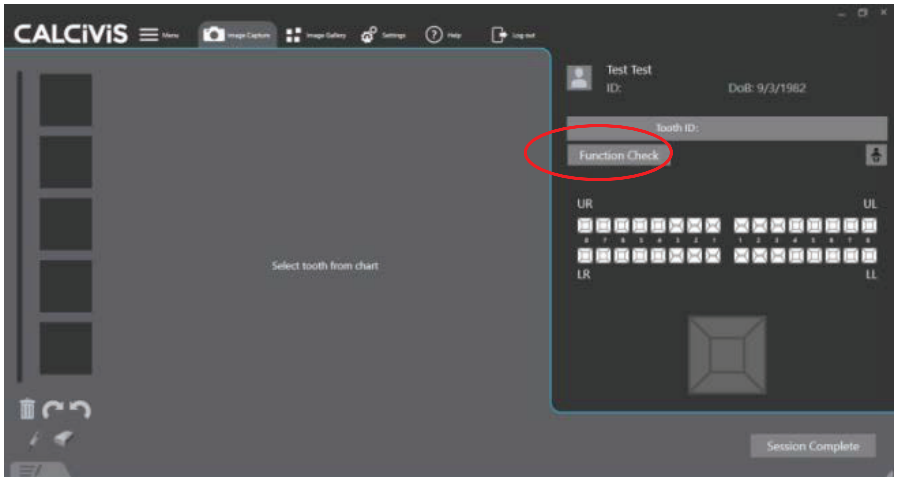
1. Exit software
2. Unplug camera from USB 3 port. Check the port is USB 3 (USB 3 ports are identified by this symbol SS and/or blue connection in port)
3. Check all connections from instrument
4. Power up camera by reactivating via the USB3 port.
5. Wait at least 15 seconds (to allow camera driver to start-up)
6. Re-start software

9.2 FUNCTION CHECK

The Function check kit consists of a plastic tray with thermoformed wells containing a deposit of calcium chloride, which is used in conjunction with the CALCIVIS Imaging System to detect free calcium ions within the well. A positive result for the test confirms to the user that the system is functioning as intended.

The Function check kit should be used at any time the operator has doubts about the CALCIVIS imaging system set up or function.

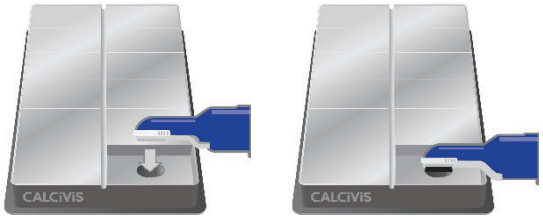
Select the **Function Check** tool on the Image Capture Screen.



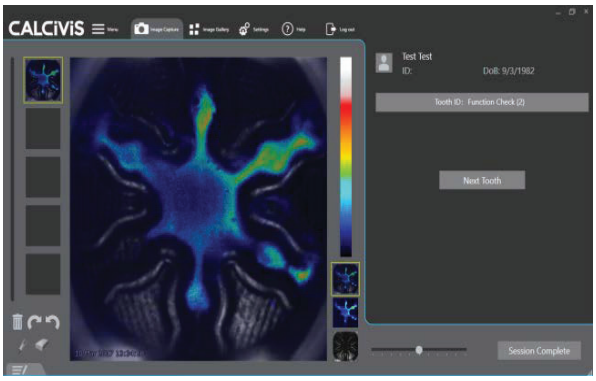
While wearing gloves, remove the cardboard sleeve and carefully remove the foil cover from one of the test wells.

Firmly place the applicator tip into the test well.

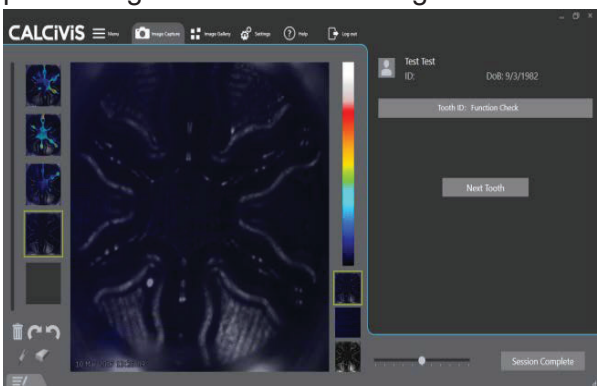
NOTE: The function check is to be performed without the CALCIVIS applicator light shield in place.



Press the **activation button** on the device.
If the function check has passes a luminescent image similar to the one below is displayed.



If **no** luminescence is observed, or a blank image is displayed (below), this indicates something is wrong with the set up. Click session complete, re-load with fresh Photoprotein solution before performing the function check again.



10 NOTES