CALCIVIS®
Imaging Device

USER MANUAL

CALCIVIS®

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1 CALCIVIS® Imaging System: Overview

The wireless enabled CALCIVIS® Imaging System (CISw) 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 CISw 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 CISw 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, Dock, and associated software, which allows both video streaming of images and the capture of still images, and a mechanism which applies a small amount (approximately 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® wireless Intra-oral Imaging Device handset
- CALCIVIS® Dock
- CALCIVIS® (Imaging) Software on USB card
- CALCIVIS® User Manual
- Power Supply Unit
- Device cover
- USB cable

1.2 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 (including light shield attachment)
- 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.

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1.3 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.

Storage cover

HANDSET

Handset stand / charger

Photoprotein chiller

5°C Chiller temperature

DOCK

Applicator

Light shield

Syringe

Applicator release

CISw Handset

Keypad detail

Capture button

Charge / status indicators

Up button

Select button /
Power on / off (long press)

Down button

User interface navigation
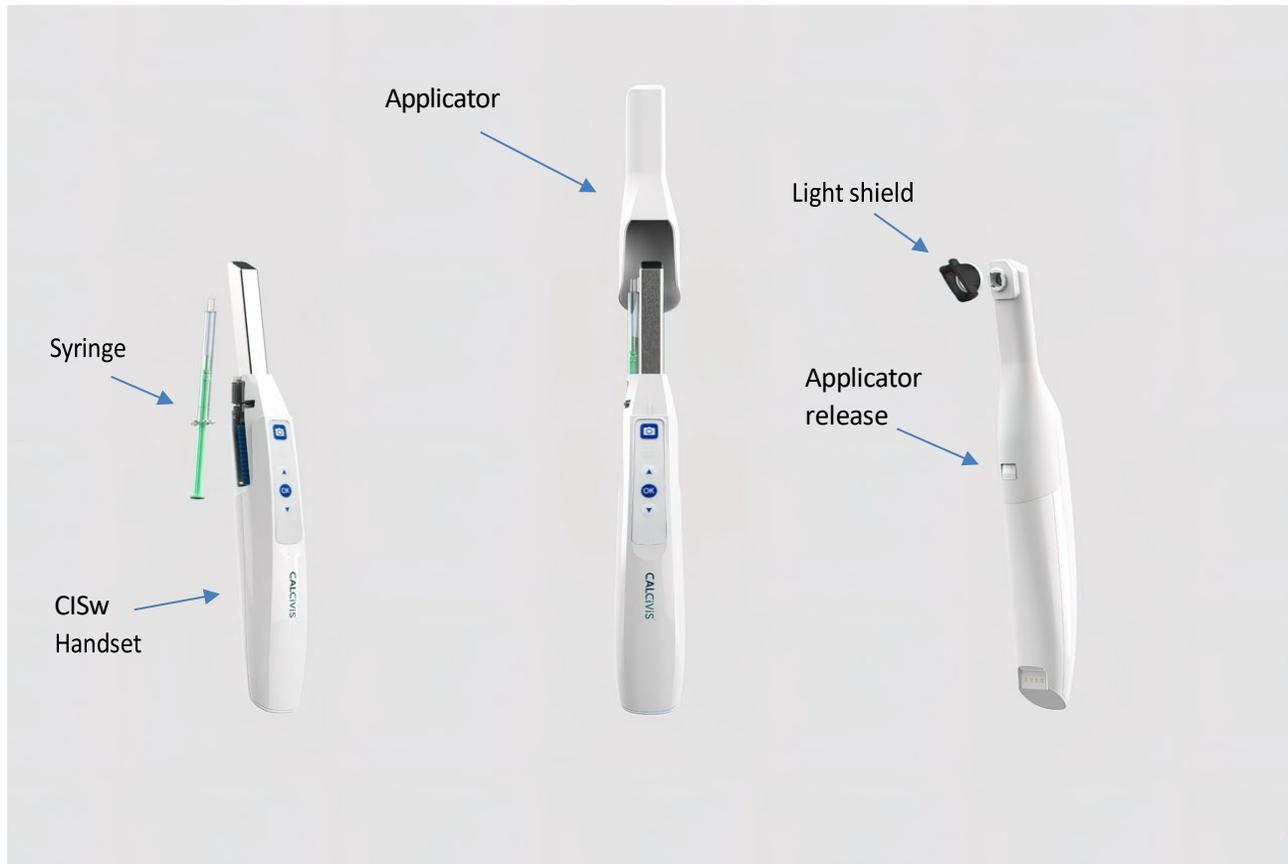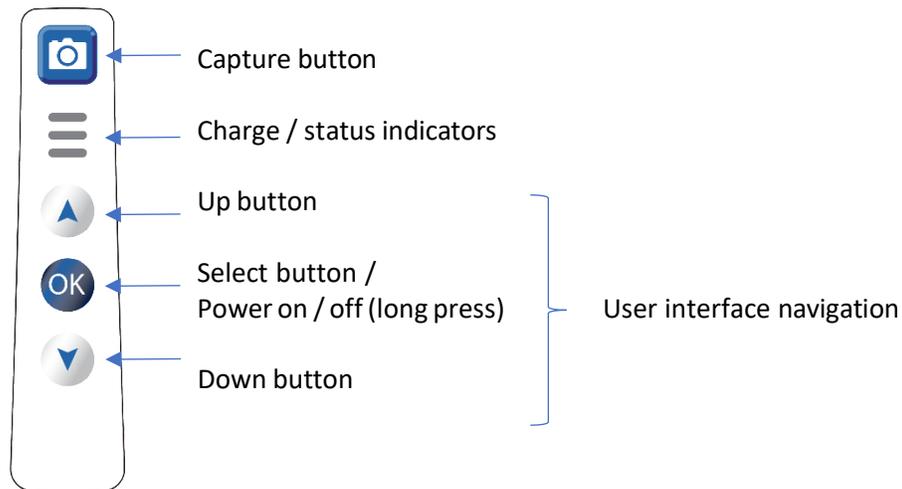
LED status indications
- Solid Lights: charge status, (3 lights indicates fully charged → 1 light indicates low charge).
- Flashing lights: charging (in combination with solid lights shows partially charged)
- Cycling lights: attempting to connect to dock

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1.4 SYMBOLS

The following symbols have been used on the system labels:

	CALCIVIS® Imaging Device Symbols		
SEE INSTRUCTIONS FOR USE	See instructions for use	LOT	Lot number
REF	Catalogue number (US-CID)	0°C—25°C TEMPERATURE LIMITS	Storage temperature limits
(Manufacturer symbol)	Manufacturer	(Hourglass symbol)	Expiry date
(Crossed-out wheelie bin symbol)	Waste must be controlled according to local regulation and collection schemes for disposal of batteries	②⃠	SINGLE USE Do not re-use
SN	Device serial number	2°C—8°C (thermometer)	Storage temperature limits
⚠	Warning/Caution	⎓	Direct current
(Date of manufacture symbol)	Date of manufacture	(Person symbol)	Type B applied part
Rx Professional use only	Professional use only	IPXX	Ingress Protection Rating
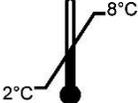
1.5 INDICATIONS FOR USE

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.

1.6 SAFETY INSTRUCTIONS

- DO NOT expose the CALCIVIS® Imaging Device to water spray and do not store it in a humid environment (to prevent risk of electrocution).
- Handset and dock should NEVER be immersed in any liquid, NOR should either be autoclaved.
- Do not use the device if any cables appear frayed or damaged as this could result in electric shock or fire.
- When handling camera and dental barriers, always take the appropriate hygiene measures and precautions in order to prevent cross contamination risks. Infection control procedures must be observed when using accessories such as the CALCIVIS® applicators and dental barriers. When using accessories always follow the manufacturer's instructions on how to use said accessory and prevent cross contamination risk from one patient to another.
- For each new patient, it is essential to use a fresh set of consumables especially the CALCIVIS® applicator as this enters the patient's mouth.
- Before using the camera, and accessories make sure there are no sharp edges.
- Install the device in a clean, dry, and well-ventilated place.
- DO NOT expose the product to high vibrations.
- DO NOT drop the device.

1.7 CONTRAINDICATIONS

There are no known contraindications for the use of the CALCIVIS® Imaging System.

1.8 WARNINGS AND PRECAUTIONS

1.8.1 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 as an aid to the assessment, diagnosis, monitoring and treatment planning for demineralization associated with caries lesions and should always be used in addition to other methods of assessing caries (such as visual / tactile examination), before subsequent treatment planning.
- The CALCIVIS® Imaging System may only be used with CALCIVIS® accessories.
- No modification of the equipment is allowed.

1.8.2 ELECTRICAL SAFETY:

- The CALCIVIS® Imaging Device has been tested for compliance to IEC 60601-1-2:2015.
- 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.

1.8.3 ELECTROMAGNETIC INTERFERENCE AND EMISSIONS:

- As a Class B medical device, the EMISSIONS characteristics of this equipment make it suitable for use in industrial areas, hospitals and residential areas.
- Risk from electromagnetic fields. Electromagnetic fields might interfere with the functions of implanted systems (such as pacemakers).
- Electromagnetic interference could reduce quality of the video stream, however there are no essential performance characteristics of the device that are affected by electromagnetic interference.
- Not to be used in or near an MRI scanner
- 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 authorization of the manufacturer.
- If this equipment is modified, appropriate inspection must be conducted to ensure continued safe use of the equipment.

Guidance And Manufacturer's Declaration – Electromagnetic Emissions		
CALCIVIS® Imaging Device is intended for use in the electromagnetic environment specified below. The user of the CALCIVIS® Imaging Device should assure that the device is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	Device use RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	Device suitable for use in all establishments, including domestic establishments and
Harmonic emissions IEC 61000-3-2	Class A (<75 W)	those directly connected to the public low- voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Applicable (Pass)	

1.8.4 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.

This equipment is intended for use in the electromagnetic environment of a typical location in a typical commercial or hospital environment and residential environment.

> ⚠️
>
> 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.

Guidance and manufacturer's declaration – electromagnetic immunity			
CALCIVIS® Imaging Device is intended for use in the electromagnetic environment specified below. The user of the CALCIVIS® Imaging Device should assure that the device is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete, vinyl or ceramic tile. Portable and mobile RF communications equipment should be used no closer to any part of the CALCIVIS® Imaging Device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Device suitable for use in all establishments, including domestic establishments and those directly connected to the public low- voltage power supply network that supplies buildings used for domestic purposes.
Electrical fast transient/ burst IEC 61000-4-4	±2 kV	Pass	
Surge IEC 61000-4-5	±0.5 kV ±1 kV ±2 kV	Pass	
Voltage dips, short interruptions and voltage variations on power supply IEC 61000-4-11	90 V and 264 V ac	Pass	
Power frequency (50/ 60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m 50/60 Hz	

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Guidance and manufacturer's declaration – electromagnetic immunity			
CALCIVIS® Imaging Device is intended for use in the electromagnetic environment specified below. The user of the CALCIVIS® Imaging Device should assure that it each are used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6	150 kHz – 80 MHz	3 V rms + 4 bands at 6 V rms	Portable and mobile RF communications equipment Should be used no closer to any part of the device including cables, than the recommended calculated from the equation appropriate to the frequency of the transmitter. **Recommended separation distance** d = 1.2 √P d = 1.2 √P 80 MHz to 800 MHz d = 2.3 √P 800 MHz to 2.7 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters as determined by an electromagnetic site survey, a should be less compliance level in each frequency range b. Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC 61000-4-3	3V/m 80 MHz to 6 GHz 10 V/m 1000MHz to 2700 MHz	3 V/m 10 V/m 1000MHz to 2700 MHz 1kHz 80% AM	
Note 1: At 80MHz and 800MHz, the higher frequency range applies. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			
Field strengths from fixed transmitters, such as base stations for radio (cellular/ cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device are used exceeds the applicable RF compliance level above, Device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re- orienting or relocating the device.			

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Recommended separation distance between portable and mobile RF communications equipment and the CALCIVIS® Imaging Device.			
CALCIVIS® Imaging Device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customers or the user of the Device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter in Watt:	**Separation distance according to frequency of transmitter in meters**		
	150 kHz to 80 MHz d = 1.2 √P	80 MHz to 800 MHz d = 1.2 √P	800 MHz to 2.7GHz d = 2.3 √P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. **Note 1:** At 80 MHz and 800MHz, the separation distance for the higher frequency range applies. **Note 2:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

A brief summary of the tests carried out in accordance with IEC / EN 60601-1-2 is shown below.

Section	Specification Clause	Test Description	Modification State	Result	Comments/Base Standard
Configuration and Mode: Docked - Video Streaming					
2.1	7.1	Radiated RF Emissions, 30 MHz to 1 GHz	0	Pass	CISPR 11: 2009 A1: 2010
2.3	Table 4	Immunity to Electrostatic Discharge (Enclosure Port)	0	Pass	IEC 61000-4-2: 2008
2.4	Table 4	Immunity to Radiated RF Electromagnetic Fields (Enclosure Port)	0	Pass	IEC 61000-4-3: 2006 A2:2010
2.5	Table 4	Immunity to Proximity Fields from RF Wireless Communication Equipment (Enclosure Port)	0	Pass	IEC 61000-4-3: 2006 A2:2010
Configuration and Mode: Undocked - Solenoid Operation					
2.1	7.1	Radiated RF Emissions, 30 MHz to 1 GHz	0	Pass	CISPR 11: 2009 A1: 2010
2.3	Table 4	Immunity to Electrostatic Discharge (Enclosure Port)	0	Pass	IEC 61000-4-2: 2008
2.4	Table 4	Immunity to Radiated RF Electromagnetic Fields (Enclosure Port)	0	Pass	IEC 61000-4-3: 2006 A2:2010
2.5	Table 4	Immunity to Proximity Fields from RF Wireless Communication Equipment (Enclosure Port)	0	Pass	IEC 61000-4-3: 2006 A2:2010

A brief summary of the tests carried out in accordance with EN 55032 is shown below.

Section	Specification Clause	Test Description	Modification State	Result	Comments/Base Standard
Configuration and Mode: Docked - Video Streaming					
2.2	Annex A, Section A.2	Radiated RF Emissions, 1 GHz to 6 GHz	0	Pass	EN 55016-2-3: 2017
Configuration and Mode: Undocked - Solenoid Operation					
2.2	Annex A, Section A.2	Radiated RF Emissions, 1 GHz to 6 GHz	0	Pass	EN 55016-2-3: 2017

1.8.5 WIRELESS ENVIRONMENT:

- The WIFI protocol used in the equipment is IEEE 802.11ac/n with an operational bandwidth of 40MHz at channel 36 (5180MHz / U-NII-1).
- The equipment uses its own network with hidden SSID and WPA2-PSK security to prevent any other devices connecting to the network. The equipment is incapable of joining any other WIFI network.
- There are no user-configurable parameters for the WIFI network.
- Other equipment could cause interference with the wireless connection, leading to a reduction in video quality or loss of connection. If connection problems are seen move the interfering equipment further away.
- If wireless connection is lost the WiFi symbol 📶 on the PC will become greyed out and the PC application will display a "Handset disconnected" error message and audible tone, and the handset will start "cycling" its LEDs, if not docked.
- See Section 7. Troubleshooting for help with reestablishing the wireless connection.
- Any loss of connection on the handset is always user-safe.

1.8.6 BATTERY:

- The CALCIVIS® handset contains a 1050mAh Lithium-ion Polymer Battery.
- The battery must only be charged by placing the handset in the CALCIVIS® dock.
- At full charge the battery will last for at least a day's intensive use, however it is recommended that the handset is placed in the dock whenever not in use to keep the battery fully charged.
- If the battery is damaged do not use the device. The battery is fully sealed and cannot be replaced.

System Hardware Components Handset

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 and Relative Humidity Range	Operating: Ambient +10°C to +30°C & 10% to 80% relative humidity non-condensing. Transportation: -20°C to 38°C & 10% to 80% relative humidity non-condensing. Storage: -20°C to 38°C & 10% to 80% relative humidity non-condensing.
Protection Against Ingress of Water	IP42

Dock

Physical Attributes	
Size (HxWxD)	15 cm x 15 cm x 15 cm
Weight	0.5 kg
Electrical Specifications	
Rating Voltage	DC 12 V
Power Consumption	0.9 W
Standby Power Consumption	0.1 W
Max Power Output	N/A
Environmental Specifications	
Temperature and Relative Humidity Range	Operating: Ambient +10°C to +30°C & 10% to 80% relative humidity non-condensing. Transportation: -20°C to 38°C & 10% to 80% relative humidity non-condensing. Storage: -20°C to 38°C & 10% to 80% relative humidity non-condensing.
Protection Against Ingress of Water	IP21

1.8.7 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 around 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

1.8.8 CALCIVIS® IMAGING DEVICE:

- Do not immerse the CALCIVIS® Imaging Device in water – follow the Cleaning Instructions provided.
- The CALCIVIS® Imaging Device should only be charged using the CALCIVIS® dock.
- The CALCIVIS® dock should only be used at the voltage stipulated using the power supply provided.
- Ensure the storage cover is in place whenever the handset is placed in the dock.
- Do not attempt to repair the product. Contact CALCIVIS® if you have any concerns regarding the product.

1.8.9 CALCIVIS® KIT AND CALCIVIS® PHOTOPROTEIN:

- Wear gloves.
- Do not use any components not supplied with the CALCIVIS® Imaging Kit.
- 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 (2oC to 8oC); 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.
- There are no Materials of Concern within the device or the kit.

1.9 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

2.1 PHYSICAL Setup

- Position the Laptop / PC so that the screen is clearly visible when imaging. The live video feed is used to accurately position and focus the camera over the tooth so good visibility of the screen is critical.
- Position the dock so that it may be connected to the PC by USB cable. The dock requires good air flow for correct operation of the photoprotein chiller unit so must be at least 10cm from any wall or large objects.
- Connect the power supply unit (PSU) provided to the dock and plug into an outlet. Turn on the power. The temperature display LEDs will light up and in 10-20s the temperature will be displayed. Ensure the dock is positioned so that the PSU can be easily disconnected at the mains plug.
- Connect the dock any USB port on the PC with the provided USB cable.
- Place the CALCIVIS® Imaging Device in the dock. Allow the device to charge for 4 hours before first use.
- Always place the device in the dock, with the cover in place, between uses. The device contains sensitive electronic and imaging components that can easily be damaged by heavy jolts such as dropping the device.
- For best results avoid direct illumination of the mouth during the actual imaging process by ensuring the main overhead illumination lights are switched off.
- Additional light shielding may be necessary in very bright operatories.
- 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.
- The dock requires good air flow for correct operation of the photoprotein chiller. It must be positioned at least 10cm (4 inches) from any solid surfaces that could block airflow.

2.2 MINIMUM SYSTEM REQUIREMENT

PC	2.0GHz processor, Intel i3 or better; 4GB of RAM 200GB Hard Drive 1366 x 768 or better screen resolution Graphics card / integrated graphics supporting at least DirectX 10 in hardware with at least 512MB video memory and supporting at least 24-bit color. At least one accessible USB 2 port
Operating System	Windows 10

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.

- 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 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, only images are created that are then used by the operating institution.

2.3 APPLICATION INSTALLATION INSTRUCTIONS

The CALCIVIS® Imaging System can be installed as either standalone (not integrated to other image management system) or integrated (integrated to Software of Excellence Examine Pro Image Management System). This option is selected during installation.

- Ensure all other programs are closed before starting installation.
- Download the latest Calcivis software from the Calcivis website http://www.calcivis.com/downloads.
- Double-click the setup.exe file to run the installer and follow the on-screen instructions.
- 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 on the screen below. This will be selected by default. If you do **NOT** wish to install the Examine Pro integration, deselect this option and click 'Next'.

Note: If performing integration, Examine Pro MUST be installed before installing the CALCIVIS® software

- If you wish to install the optional TWAIN driver, allowing images to be captured through TWAIN compatible imaging software, ensure Install as a TWAIN scanner is selected and click next.
- Chose the location to install the software. 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.
- Click next to begin installation

2.4 Starting The CALCIVIS® Application

Before starting the software, connect the CALCIVIS® dock by plugging into a **USB2 port**. The temperature display should light up and after about 10 to 20 seconds display the current temperature of the chiller unit. To start the application, double click on the CALCIVIS® shortcut icon or start menu icon:

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

2.4.1 THE WELCOME SCREEN (LOGIN):
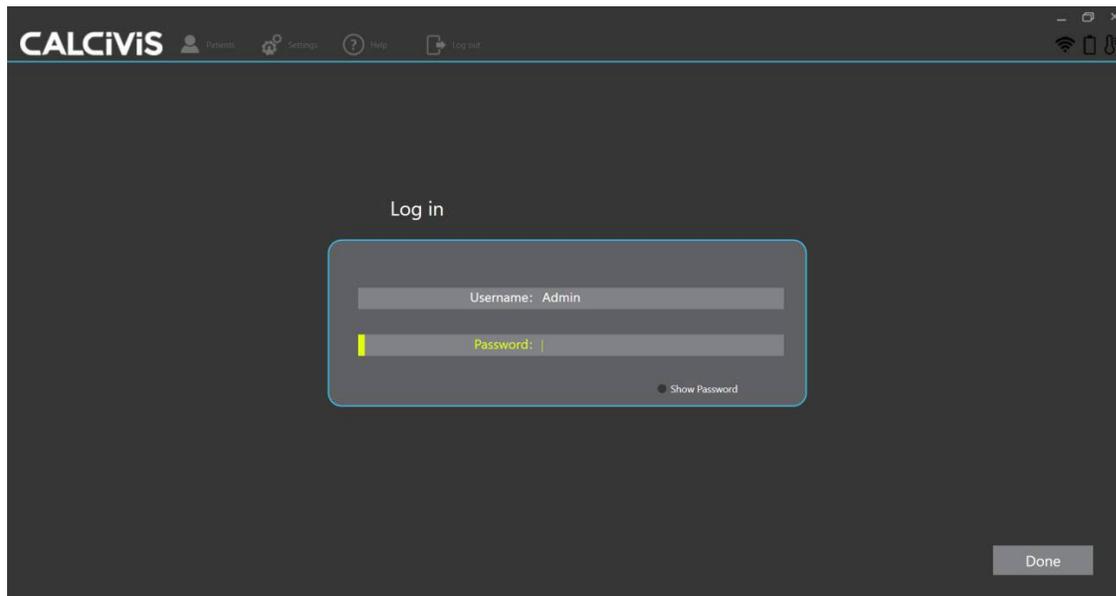
The Welcome screen allows authorized users to log on to the CALCIVIS® application. On first use log on to the application as administrator:

- Enter username: Admin
- Enter password: Calcivis
- Click on **Done** when ready. You will be taken to the patients' screen from where you can take and view images.

2.5 APPLICATION WINDOW
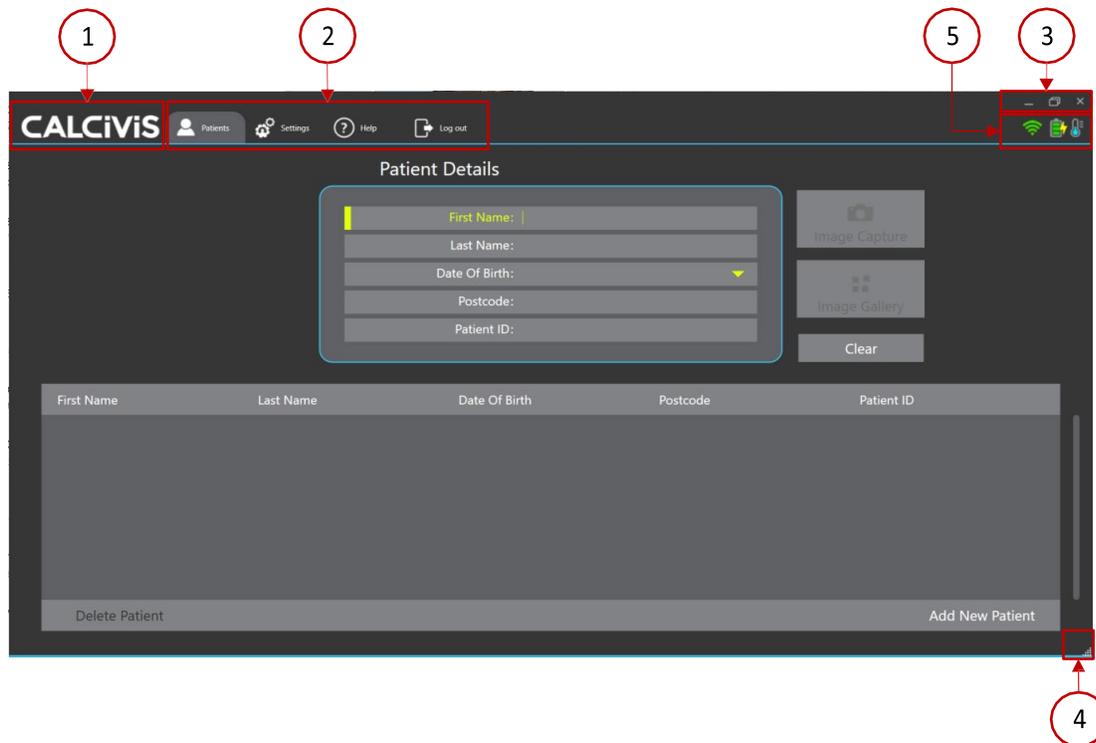
The following elements are always active

1   CALCIVIS® Logo – click to show software version and link to CALCIVIS® website.

2   Navigation bar – used to select different operations

3   Window type buttons, from left to right:

- Minimize – hide the window
- Maximize – click to make the window fill the screen. CTRL + click to toggle full screen mode (windows taskbar will be covered)
- Close window – exit the CALCIVIS® application

4   Resize window – click and drag to resize window

5   CISw status indicators

- If no dock is connected the icons will all be greyed out
- WIFI connection to the handset
- Charge status of the handset
- Chiller temperature – blue thermometer indicates chiller is down to temperature, red flashing thermometer indicates that the temperature is too high

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2.6 THE SETTINGS SCREEN
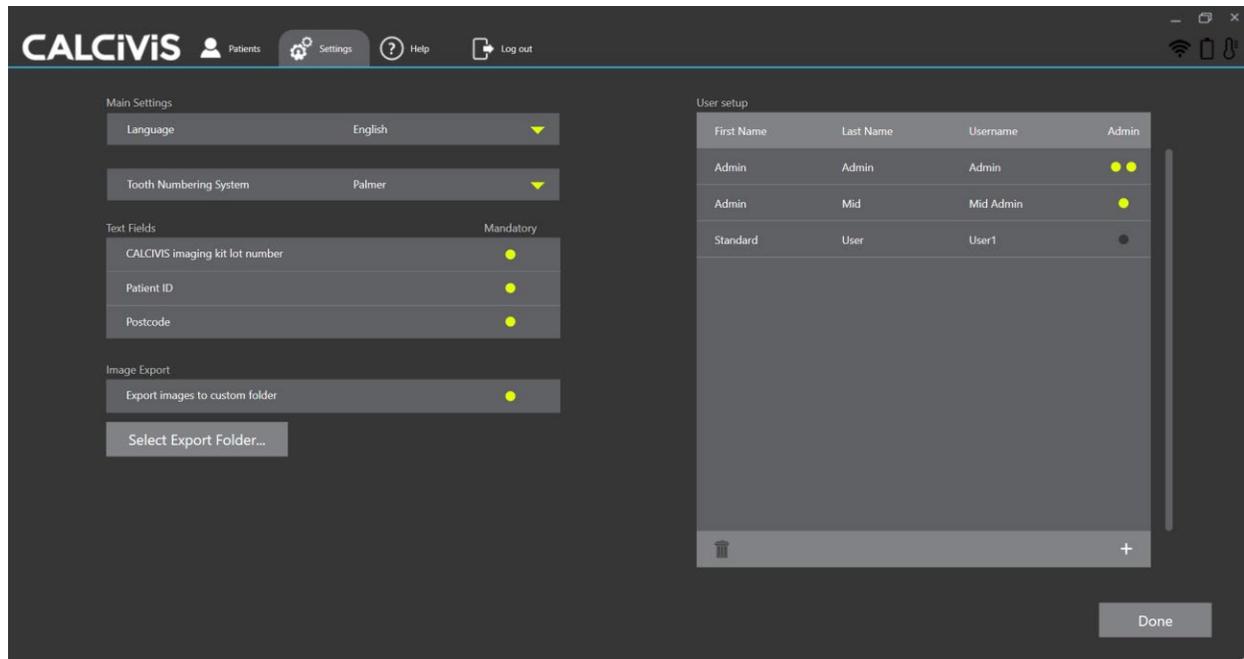
2.6.1 APPLICATION SETTINGS:

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.

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.

There are 3 user levels:

- Standard – can carry out imaging and view images in the gallery but not change settings or edit users (except to change their own password)
- Admin – As standard but can also change most settings but cannot add, remove or edit other users
- High level – as Admin but can also add, remove or edit other users

To delete a user (high level admin only), select the user and click the trash icon. Note: you cannot delete a user that is currently logged in.

To edit a user (high level admin only), 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 username 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

2.7 HELP

The help screen gives contact details in case of any technical problems. Clicking the 'Device info' button displays details of the connected device and logs to assist in troubleshooting. Updates to the Application can be checked for and installed from the help screen.

2.8 LOGOUT

To logout from the CALCIVIS® application, the user should click on **_Logout_**. This will return the user to the Login Screen

3 Image Capture

3.1 Photoprotein Preparation

Preparation of the CALCIVIS® photoprotein can be carried out in advance of the imaging sequence to save time. The prepared photoprotein solution can be stored in the chiller unit (or in a fridge at 2 -8 °C) for up to 2 weeks after reconstitution:

1. Wear disposable gloves
2. Check the integrity of the packaging of the vial adaptors and vials of CALCIVIS® photoprotein and CALCIVIS® diluent.
3. Do not use if the primary packaging has been breached or wet.
4. Remove flip off top from CALCIVIS® diluent vial (clear vial with blue cap).
5. Remove the green adaptor from packaging and fit to the CALCIVIS® diluent vial.
   Whilst fitting ensure the adaptor pushes straight down and not at an angle.
6. Remove flip off top from CALCIVIS® photoprotein vial (amber vial with white cap).
7. Remove the translucent blue adaptor from packaging and fit to the CALCIVIS® photoprotein vial.
   Whilst fitting ensure the adaptor pushes straight down and not at an angle.
8. Fit BLUE adaptor to vial of CALCIVIS® diluent.
9. Fit CLEAR adaptor to vial of CALCIVIS® photoprotein.
10. Remove the cap from the green vial adapter.
11. To reconstitute CALCIVIS® photoprotein with CALCIVIS® diluent, screw together in a vertical position ensuring the photoprotein (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.
12. Detach CALCIVIS® diluent from CALCIVIS® photoprotein by unscrewing (Discard empty CALCIVIS® diluent bottle)
13. Gently mix by swirling. Leave to stand for 30 seconds before withdrawing fluid
14. Write date of reconstitution and expiry date (2 weeks after reconstitution) on label on side of vial.
15. If not being used immediately, place residual CALCIVIS® photoprotein vial in the chiller unit of the dock or in a refrigerator (2-8°C). Always return vial to chiller unit directly after use.

CALCiViS®

Instructions for Preparation

1. Wear Gloves
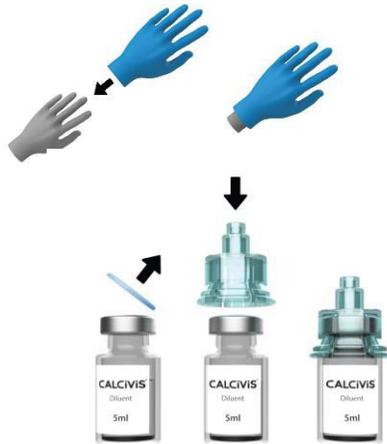
2. Remove cap from diluent (clear vial) and attach green vial adapter

3. Remove cap from photoprotein (Amber vial) and attach blue vial adapter
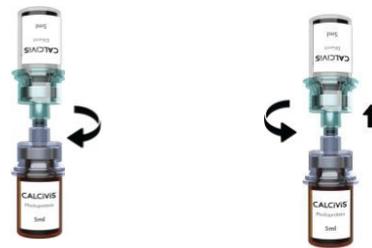
4. Remove cap from green vial adapter

5. Place photoprotein vial on flat surface

6. Connect the two vials by screwing the diluent vial into the photoprotein vial

7. Check that the liquid has passed into the photoprotein vial and unscrew the adapters

8. Mix gently and then leave for 30s before use

9. Place in chiller unit when not in use

3.2 DEVICE PREPARATION

- If not already in the 'Patients' screen, click the 'Patients' icon in the Navigation bar. (In integrated mode this screen is skipped as the patient is selected through the image management software)
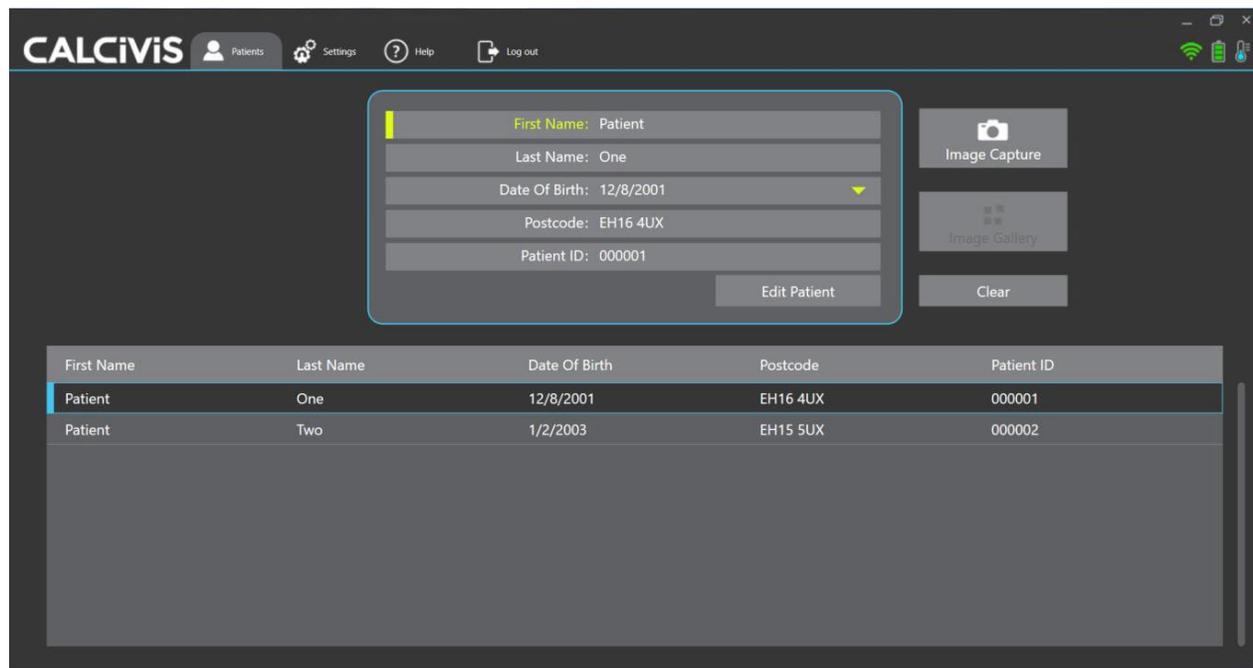
- Select the desired patient from the list. Start typing in any of the Patient details fields to filter the list.
- If the patient is not in the list enter the patient details and click 'Add New Patient'
- Click on the image capture icon initiate an imaging sequence.
- On the first screen, enter the Imaging Kit lot number and then click "done" (if this has been deactivated in settings then this screen will be skipped)
- Preparation of the CALCIVIS® Imaging Device should be carried out as follows:
  o Wear gloves
  o Remove the camera cover from the CALCIVIS® Imaging Device.
  o Check CALCIVIS® Imaging Device is clean, if not perform cleaning as in section 5.
  o Take the photoprotein vial from the chiller unit and check that it is in date.
  o Wipe top of adaptor with an isopropyl alcohol wipe and leave for 20 seconds to dry.
  o Insert syringe into vial adaptor and with vial upside down withdraw exactly 0.3 ml solution from vial. **If required, move syringe plunger back and forth to remove any air bubbles.**

0.30 ml
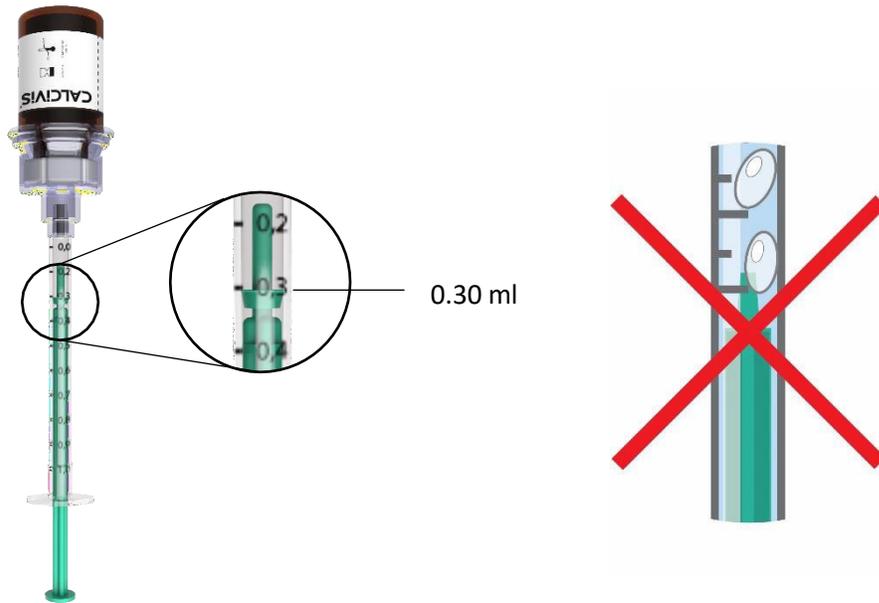
- The CALCIVIS® photoprotein syringe is now ready to be inserted into the CALCIVIS® Imaging Device.
- Insert the filled syringe into the side compartment, locating the T-bar in the yellow holder. IMPORTANT: Check that the end of the plunger lines up with the marker on the device and there are no bubbles in the syringe
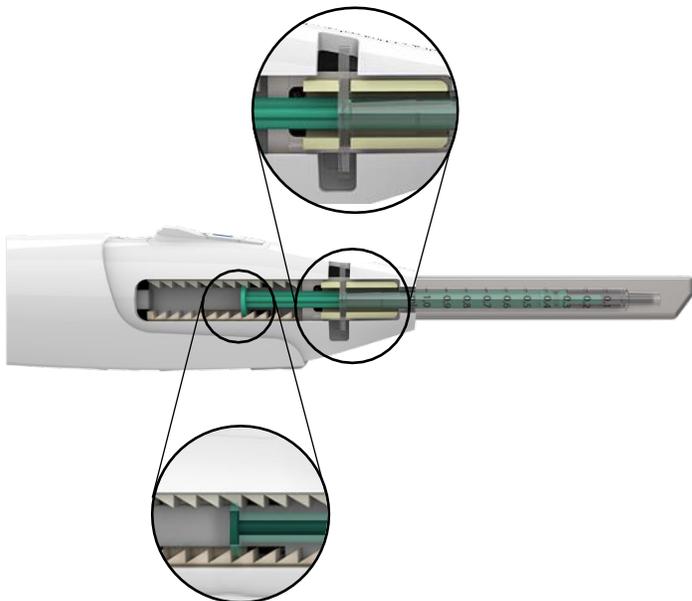
- Remove the applicator from the packaging and slide over the end of the camera until it clicks

firmly in place.
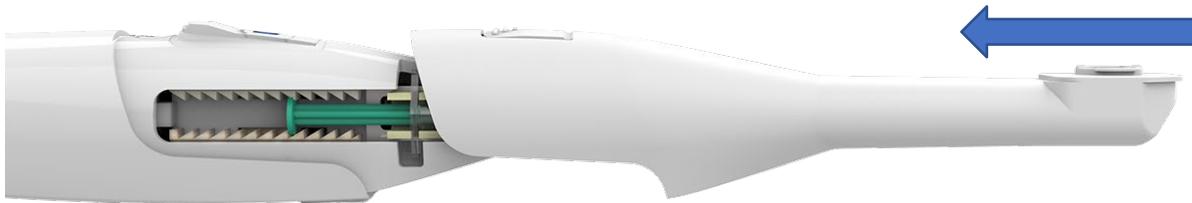
- Click done on the device preparation screen.3.3

3.3 CALCIVIS® Imaging Device Priming

- Position the end of the device over a piece of tissue paper.
- Press the camera button on the device.
- The device will click 4 times. Fluid should be dispensed onto the tissue on the final click.
- Confirm that fluid has been dispensed by clicking "Yes". If no fluid was dispensed click "no" to enable an extra priming shot.
- On completion of successful priming insert the CALCIVIS® applicator light shield and clip into place by rotating 90 degrees

3.4 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 for **5 – 10 seconds**.

3.5 Tooth Imaging Process

On completion of priming the CALCIVIS® Imaging System is ready for imaging. Imaging screen:
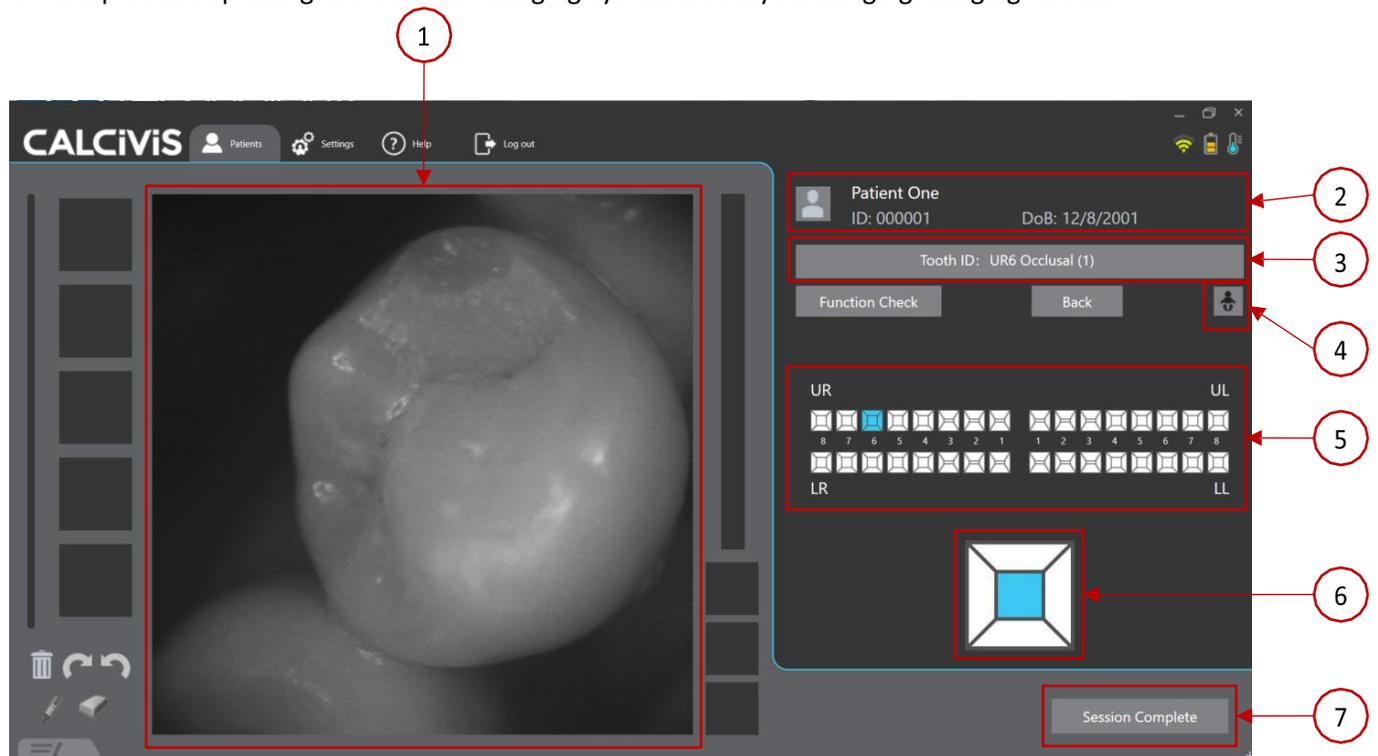
1) Live video feed
2) Patient details
3) Selected tooth and surface
4) Toggle deciduous teeth
5) Tooth selection grid
6) Surface selection
7) Session complete

Select the tooth and surface to be imaged:
Using the mouse:

- Click on the desired tooth from the tooth chart
- Click on the desired surface using the handset:
- Use ▲ and ▼ to highlight a quadrant and OK to select it
- Use ▲ and ▼ to cycle through the teeth and OK to select the desired tooth.
- Use ▲ and ▼ to cycle through the tooth surfaces and OK to select the desired surface. Once the tooth and surface are selected video stream will start. This video stream is used to view the positioning and focus prior to image capture.

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 is viewed on the screen to ensure correct positioning over and focus of the tooth surface of interest.
- Press the camera button on the handset to capture an image. When ready capture an image of the tooth surface of interest by pressing the capture button.

Note: A click will be heard as the photoprotein is dispensed. The imaging process continues for approximately 0.5 seconds after this and it is important to ensure the CALCIVIS® Imaging Device is held still during imaging until the images appear on the screen to avoid blurred images due to camera shake.

In addition, for best results avoid direct illumination of the mouth during the imaging process by ensuring the main overhead illumination lights are switched off. Additional light screening may be required in very bright surgeries, e.g. using rubber dam.

- When the image has been taken it will be displayed on the screen for review

3.6 ADDITIONAL INFORMATION ON IMAGING

- Having previously cleaned all teeth to be assessed (as detailed above in 3.4), air-dry the tooth surface 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 it can help if 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 monitor carefully center the display directly over the area of interest (e.g. white spot lesion). To initiate imaging press Camera actuator button on upper side of the CALCIVIS® Imaging Device.
- Hold the CALCIVIS® Imaging Device steady for approximately 0.5 seconds 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.

3.7 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 5. A new syringe of CALCIVIS® photoprotein can be inserted and the same applicator used if for the same patient.

4 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.
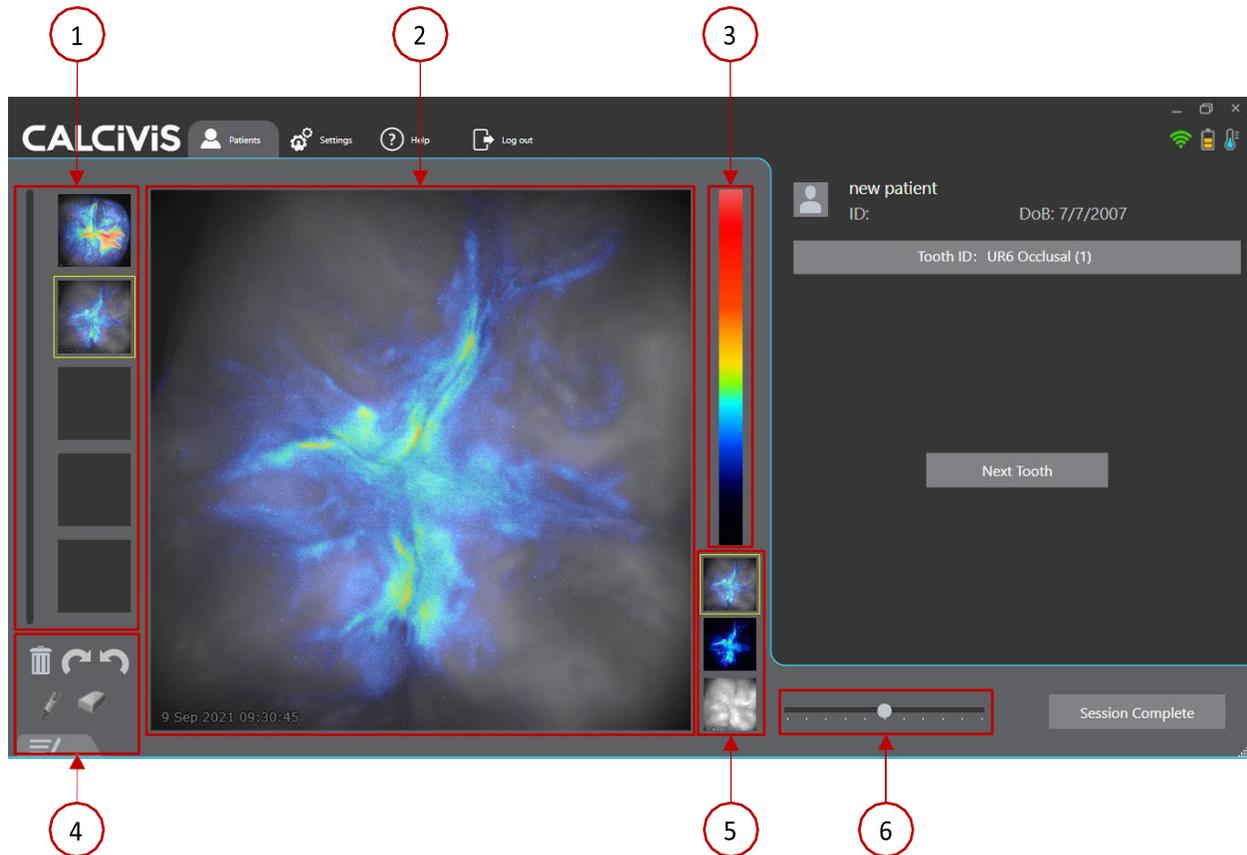
1) Image thumbnails
   - Select which image to view
2) Main image view
   - Large view the selected image
3) Intensity scale
   - Shows the color scale used to represent the level of signal from no signal at the bottom to strong signal at the top.
   - Left-click the mouse anywhere on the image to bring up a marker on the scale.
4) Image editing tools
   - 🗑 Delete image
   - ↻↺ rotate image 90°
   - Add or delete annotations
   - Add or edit notes.

5) Image mode thumbnails

 Blended image

 Luminescent image

 Visible light image
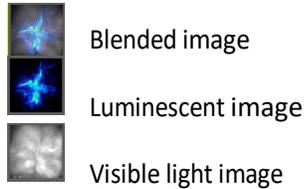
6) Blend slider
- When blended image is selected use the slider to adjust the % blend (this can be useful for demonstrating exactly where on the tooth the signal is seen.

When all images have been taken click on session complete. This will save the images from the session.

IMPORTANT: If session complete is not clicked images will not be saved.

4.1 THE IMAGE GALLERY

(Only available in "standalone" version. Not available when integrated to practice image management software).

At the end of an imaging session the Image Gallery will be displayed. The image gallery can also be accessed from the patients' screen.
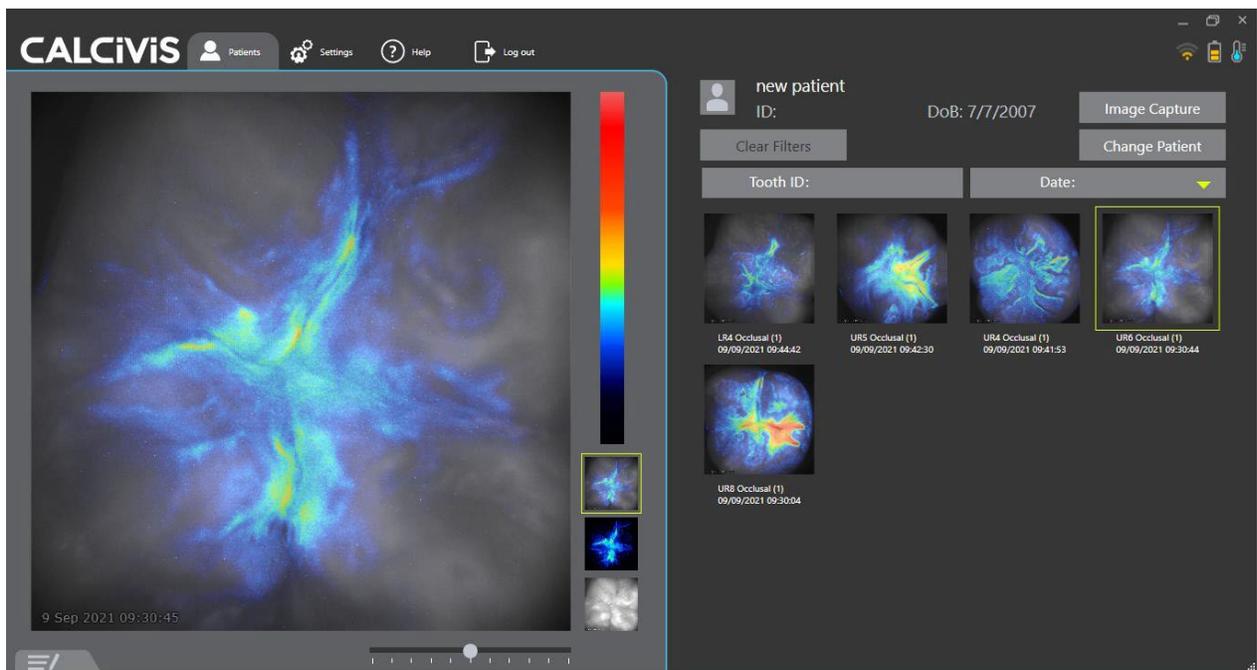
All images for the selected patient are shown on the righthand panel. The images can be filtered by date or Tooth ID. The selected image will be displayed on the left where the user can select between visible, luminescent and blended images and change the blend percentage of the blended image as described in Image Review (section 4)

Multiple images (up to 4) can be displayed side by side on the main screen for comparison by holding CTRL while clicking on the required images.

To capture more images from the same patient, click the image capture button in the top right. To switch to a different patient, click the change patient button or click on the patients tab on the navigation bar.
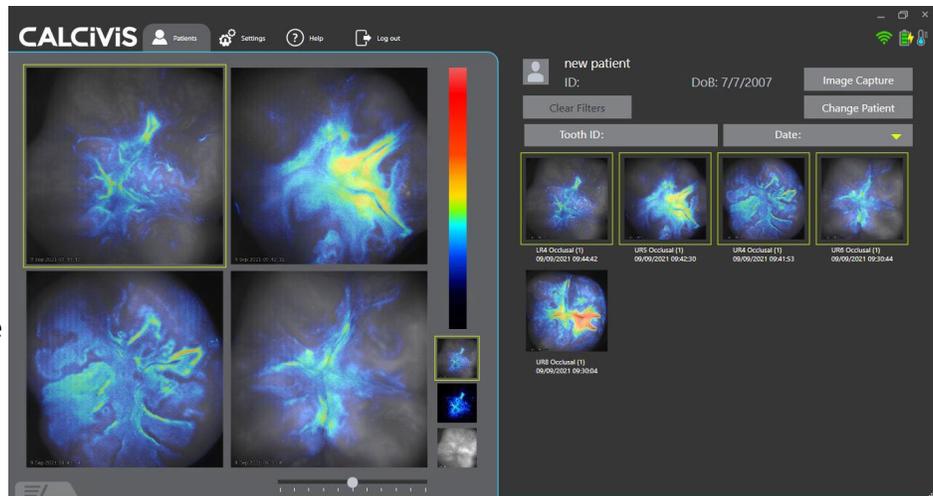
4.2 IMAGE INTERPRETATION AND ANALYSIS

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 demineralization. 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**.

4.2.1 TYPICAL IMAGES SEEN WITH THE CALCIVIS® IMAGING SYSTEM:

Active Demineralization

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 intensive demineralization (not highlighted as the specific area of interest in initial visual examination (see purple drawing in next image)	CALCIVIS® blended image clearly shows luminescence in central fissure entrance and upper white spot region, indicative of active demineralization in both these areas	CALCIVIS® raw images

Arrested Lesion

Area around caried yellow / brown indicative of arresting lesion	CALCIVIS® blended image show no luminescence in this area	CALCIVIS® raw images

4.2.2 EXAMPLE IMAGES OF POTENTIAL CONFOUNDING ISSUES:

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
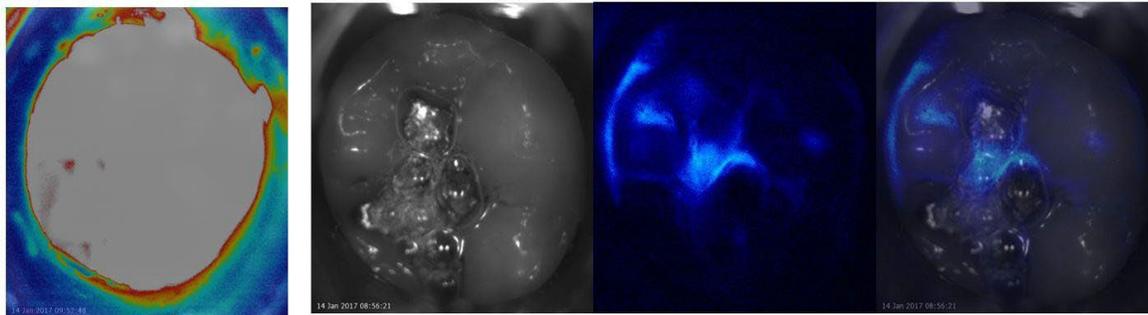
Ambient Light ingress

Gross saliva contamination evidenced by bubbles in visible image

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After each patient use, the CALCIVIS® Imaging Device should be dismantled and cleaned according to the following protocol:

- Remove gloves and de-contaminate hands.
- Use fresh pair of gloves.
- Remove the applicator by depressing the latch button and pulling off the Applicator.
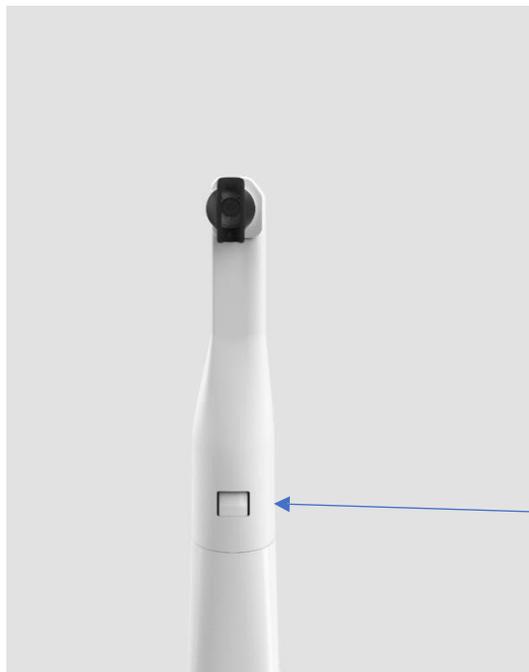
Depress latch to remove applicator

- Dispose of Applicator to clinical waste.
- Remove syringe. Dispose in clinical waste container
- Wipe <u>all</u> surfaces of the CALCIVIS® Imaging Device thoroughly, with hospital grade disinfectant wipes, taking care to wipe all molded parts.

6 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® Inc.
2 Granite Ave. • Suite #260
Milton, MA 02186
Office: (617) 322-1706
Toll Free: (866) 273-1711

7.1 PLEASE CONNECT THE CAMERA ERROR MESSAGE

- If the dock connection is not found (temperature icon is grey) check the power to the dock is on (temperature displayed on the front of the dock) and check the USB lead from the dock to the PC.
- If the dock connection is still not showing turn the dock power off, wait for 10s and then turn it back on.
- If the dock is connected but the handset is not connected (Wi-Fi indicator grey) then check that the handset is on (LEDs on handset lit) if not turn the handset on by pressing OK button on handset.
- If the handset is on but not connected hold the OK button for 10s to power down the handset. Press the OK button again to turn the handset back on.
- If these do not work exit the CALCIVIS® software and restart the application.
- If still unable to establish connection contact the vendor.

7.2 DOCK TEMPERATURE OUT OF RANGE

- The photoprotein should be stored at 2-8°C. If the dock temperature rises above 8°C or drops below 2°C, the indicator on the dock will display H or L respectively and the thermometer icon on the software will flash red.
- If the dock has only just been turned on it may take a few minutes to come down to temperature.
- Check that there are no obstructions to airflow in front or behind the dock. Good airflow is critical to the chiller performance
- The operating temperature range of the dock is 5 – 25°C, above this the dock may not be able to maintain a low enough temperature.
- If the temperature remains above 8°C move the photoprotein vial to a fridge.

8 Notes