EN

INSTRUCTIONS FOR USE

SOPRO 617
SOPRO 717FIRST
SOPROCARE
C50
C20
& ACCESSORIES

CONTENTS

1 FOREWORD

Thank you for your confidence and for buying this medical device. It is essential that you familiarize yourself with the contents of these Instructions for Use. It will help you get the best out of your equipment and its accessories and ensure that all necessary safeguards are in place. We have tried to make these Instructions for Use as straightforward as possible to help with installation and use of the medical device and accessories.

NOTE UDI-DI: custom products have a different UDI from the one shown on the cover of these Instructions for Use. You will find the UDI of your camera on the product label and labels on the packaging. In these Instructions for Use we do not use any text, brand names, pictures, figurative signs, or other items liable to mislead you or the patient regarding the purpose, safety and performance of the device and its accessories.

The Instruction for Use is an integral part of the medical device. The document must be made available to the user. Proper use and correct handling of the device entail following these instructions. You are responsible for any damage that may result from improper use.

Medical device Picture	Device Name	Basic UDI-DI
	SOPROCARE	801337602782D0006CZ
	S617	801337602782D0004CV
	SOPRO 717FIRST	
	C50	801337602782D0006CZ
	C20	801337602782D0004CV
	MINI DOCK USB2	01337602782D0007D3
	MINI DOCK U_USB2	
	SOPROTIPS	801337602782P0002GV
	C50TIPS	
	INTRAORAL DENTAL CAMERA SINGLE-USE PROTECTIVE SHEATHS	801337602782P0001GT

1.1 ASSOCIATED DOCUMENTATION

These Instructions for Use must be used in association with the following documents:

- ACTEON Imaging Suite (AIS) User Manual
- QuickStart 011809 and 011827, 011822

The Quick Start document is a simplified summary designed to help you get started but cannot replace these Instructions for Use.
The only official instructions are these Instructions for Use and the regulatory documents accompanying the medical device and accessories.

1.2 ELECTRONIC DOCUMENTATION

The Instructions for Use are provided in electronic format on the website. If you cannot access the website, please try again later. To obtain a free copy of the documentation in printed form within 7 days, please submit a request by filling in the request form on our website, by phone or in writing.
The electronic Instructions for Use are available in PDF format (Portable Document Format). You will need to have PDF reader software installed to read the electronic version of the Instructions for Use. It is important for you to read and understand the content of the Instructions for Use relating to the use of your device and its accessories prior to using the device.

WARNING: DO NOT USE YOUR DEVICE WITHOUT FIRST FAMILIARIZING YOURSELF WITH THE INSTRUCTIONS FOR USE.
The device's Instructions for Use can be consulted at the following address: www.acteongroup.com

As soon as you receive the device, it is important that you print and download all documents or sections of documents that you may need to consult in the event of an emergency, if you are unable to connect to the Internet or if your electronic display device (computer, tablet, etc.) stops working. We recommend that you visit the website regularly to view and download the latest version of your device's Instructions for Use. Keep the documents on hand for consultation when necessary.
All printed and electronic documentation relating to the medical device and its accessories must be retained for the devices' entire service life.
Please retain all original documentation relating to the medical device and its accessories for reference at a later date. When loaning out or selling the device, the documentation must be provided with it.

2 SAFETY INSTRUCTIONS

2.1 CONTRAINDICATIONS

None known.

2.2 WARNINGS

- Not suitable for use in the presence of a flammable anaesthetic mixture containing air, oxygen or nitrous oxide.
- Not suitable for use in an oxygen-rich environment.
- The high-energy light emitted may come from the product's light emission window, giving rise to high temperatures in front of the light emission window: 53°C for the SOPROCARE camera, 51°C for the SOPRO 717FIRST camera, 52°C for the C50 camera and 59°C for the C20 camera. This emission zone should not be kept in contact with the patient's mouth. This could cause the patient pain. (Not applicable to SOPRO 617 intra-oral cameras).
- Intraoral cameras are a product using Group 1 LEDs according to IEC 62471. To avoid risk of ocular damage, do not look directly at the light (Non-applicable for SOPRO 617 and C20 intraoral camera).
- Intraoral camera is not provided sterile. It must be wipe disinfected before use. The camera is not sterilisable.
- The protective sheaths are not provided sterile. They do not need cleaning and sterilization before use.
- SOPROTIPS & C50TIPS intraoral tips are reusable medical devices that are supplied non-sterile. They must be cleaned, and steam sterilized before first use and after each use thereafter Intraoral cameras, USB cable, docking station and the handpiece holder are reusable devices. These devices must be disinfected before first use and after each use with a disinfecting wipe only.
- Cleaning / disinfection of intraoral cameras, the USB cable and the handpiece holder must be performed between all appointments. Follow the CLEANING / DISINFECTION procedures described in chapter 6 CLEANING, DISINFECTION AND STERILIZATION Failure to do this could result in cross contamination.
- The intraoral camera and docking station should NEVER be immersed in any disinfecting liquid nor autoclaved. This could result in electric shock.
- Use a single-use protective sheath on the camera throughout the procedure. Infection control procedures must be observed when using accessories such as single use protective sheaths.
- Before use, check that the protective sheath is not damaged. Failure to follow the manufacturer’s instructions could result in cross contamination
- If the protective sheath is torn while examining a patient or if the handpiece was “contaminated” while withdrawing the protective sheath, it is essential to disinfect the camera with a disinfectant wipe. For instructions on disinfection, please refer to the chapter 6 CLEANING, DISINFECTION AND STERILIZATION.
- Before cleaning, the medical device must be disconnected from its power source.
- When handling camera and intraoral tips (SOPROTIPS or C50TIPS), always take the appropriate hygiene measures and precautions to prevent cross contamination.
- Do not use corrosive or abrasive products to clean the device, but only the disinfectant liquids recommended in the chapter 6 CLEANING, DISINFECTION AND STERILIZATION.
- Do not use products containing: Ammoniac, Trichloroethylene Dichloroethylene, Ammonium, Hydrochloride, chlorinated and aromatic Hydrocarbon, Ethylene Dichloride, Methylene Chloride or Ketones.
  Use of these chemicals subject plastic parts to risk of deterioration.
- Before each use, check the outer surface of the medical device parts for any rough surfaces, sharp edges or undesired protrusions that could cause damage or could deteriorate the single use protective sheaths.
- This medical device must not be modified without the manufacturer’s authorization. If the medical device is modified, a test and inspection must be carried out to ensure that the medical device satisfies the safety requirements.
- Backup your data at regular intervals. It is the responsibility of the user to perform and maintain data backups in order to prevent loss of data.
- Protect your data against loss, unauthorized access and unauthorized use.
- The devices that connect to video or USB outputs should comply with the IEC 62368-1 standard."
- Computer systems connected to the docking station have to comply with the international safety standard for Information Technology Equipment, IEC 62368-1.

2.3 PRECAUTIONS

- Use only the accessories supplied with the device or recommended as options by ACTEON. The use of accessories from other sources could put you and your patients at risk and could damage your medical device. Please refer to the chapter 2.5 USE OF ACCESSORIES PROVIDED BY ANOTHER MANUFACTURER.
- If the medical device is damaged, do not use it.

- If the packaging of the protective sheaths is damaged, do not use it.
- Do not expose the medical device to splashed water or store in damp areas.
- Do not submit the medical device to excessive dust.
- Never place the device near a heat source or in a location where it is exposed to vibration and/or shock.
- Install the medical device in a clean, dry, and well-ventilated place.
- It is obligatory to respect the conditions of use and storage defined by the manufacturer.
- Do not insert metal objects into the device to avoid any risk of electric shock, fire, short-circuit or hazardous emissions.
- Do not place heavy objects on top of the device.
- Do not apply excessive force on the medical device. The intraoral camera must not be bitten by the patient.
- To avoid the risk of falling, the medical device must always be stored on its handpiece holder after use.
- Do not pull on the cable and do not pull on the connection cable to disconnect the device. This could damage the cable and could result in electric shock.
- Do not compress or nip the handpiece cable; this could damage the cable and could result in electric shock.
- When you are using multiple adapters, the requirements of IEC 60601-1 must be observed. Do not place the multiple adapters on the ground. Other systems must not be connected to the same multiple adapters. It is recommended to turn off the medical device before unplugging it.
- Disconnect the medical device from the computer if you are not going to use it for several days.
- It is strongly recommended to have IT security controls in place for the operating environment (e.g. antivirus software and firewall).
- Before use or after changing any settings, the user should check that the live image is displayed properly in the camera preview window of the program.

2.4 ELECTROMAGNETIC INTERFERENCES AND ELECTROSTATIC DISCHARGE

Although this product meets the requirements of international standards related to electromagnetic compatibility, it may under very specific circumstances cause interference with other devices or itself be affected by other devices or an unfavourable electromagnetic environment. To avoid such situations, we recommend that you:

- Ensure that the electrical supply network is of good quality (in particular, make sure that all devices and trolleys are earthed).
- Keep the device away from sources of electromagnetic interference (e.g., compressor, motor, transformer, HF generator, etc.).

2.5 USE OF ACCESSORIES PROVIDED BY ANOTHER MANUFACTURER

To guarantee maximum safety and optimal performance, cameras were designed and developed together with accessories, including accessories offered for optional use. The use of accessories obtained from other sources could put you and your patients at risk and could damage your medical device.
Even if the manufacturer or dealer of your accessory claims full compatibility with ACTEON devices, it is advisable to exercise caution with regard to the origin and safety of the product offered. Look out for warning signs such as lack of information, information in a foreign language, very attractive prices, suspect appearance, mediocre quality, or premature wear. In the event of doubt, contact an approved dealer or the ACTEON after-sales service team.

2.6 UNDESIRABLE SIDE EFFECTS

No known adverse side effects linked to the use of intraoral camera and accessories.

2.7 DEVICE ASSEMBLY AND DISASSEMBLY

The cameras must only be opened by a competent technician approved by the manufacturer.

3 REQUIRED INFORMATION

NOTE: The following note is only applicable for the United States of America.
United States Federal Law restricts the use of this medical device within its territory to health professionals who are qualified, fit, and certified, or to those under their control.
CAUTION: U.S. federal law restricts this device to sale by or on the order of a dentist.

3.1 CONTENTS

Devices concerned by these Instructions for Use are intraoral cameras (handpieces), docking stations (MINI DOCK USB2 or MINI DOCK U_USB2), SOPROTIPS or C50TIPS and protective sheaths designed for dental applications.
Congratulations on your purchase of ACTEON camera(s).

3.1.1 SOPRO 617 AND SOPRO 717FIRST INTRAORAL CAMERAS BOXES CONTENT

The box contains the following items:
• 1 handpiece (intraoral camera)
• 1 handpiece holder
• 10 single-use protective sheaths
• 1 USB stick of Acteon Imaging Suite (AIS)* software
• 1 intraoral camera quick start guide

** Manufactured by DE GÖTZEN S.R.L, a company of ACTEON Group.*

3.1.2 SOPROCARE INTRAORAL CAMERA BOX CONTENT

The box contains the following items:
• 1 handpiece (intraoral camera)
• 1 handpiece holder
• 10 single-use protective sheaths
• 1 USB stick of Acteon Imaging Suite (AIS)* software
• 1 intraoral camera quick start guide
• 4 SOPROTIPS
** Manufactured by DE GÖTZEN S.R.L, a company of ACTEON Group.*

3.1.3 DOCKING STATIONS BOXES CONTENT

The MINI DOCK USB2 box contains the following items:
• 1 USB2 docking station with 2.5 meters connecting cable
• 1 USB stick of Acteon Imaging Suite (AIS)* software
** Manufactured by DE GÖTZEN S.R.L, a company of ACTEON Group.*

The MINI DOCK U_USB2 box contains the following items:
• 2.5-meter cable to connect the handpiece to the docking station *(5 meters and 7 meters optionally)*
• An Installation quick start (NOTE: must be done by trained technician)

Note: The docking stations can only be used with the following intraoral cameras: SOPRO 617, SOPRO 717FIRST & SOPROCARE.

3.1.4 C50 INTRAORAL CAMERA BOX CONTENT

The box contains the following items:
• 1 handpiece (intraoral camera)
• 1 USB cable
• 1 handpiece holder
• 20 single-use protective sheaths
• 1 USB stick of Acteon Imaging Suite (AIS)* software
• 1 intraoral camera quick start guide
• 4 C50TIPS
** Manufactured by DE GÖTZEN S.R.L, a company of ACTEON Group.*

3.1.5 C20 INTRAORAL CAMERA BOX CONTENT

The box contains the following items:
• 1 handpiece (intraoral camera)
• 1 USB cable
• 1 handpiece holder
• 20 single-use protective sheaths**
• 1 USB stick of Acteon Imaging Suite (AIS)* software
• 1 intraoral camera quick start guide
** Manufactured by DE GÖTZEN S.R.L, a company of ACTEON Group.*
*** Manufactured by MINITUBE company.*

As a complement to the dental camera, we provide some single-use protective sheaths necessary for intra-oral use of the dental camera. For more details about these products, please refer to our catalog or contact our customer service.

The camera has been delivered to you in cardboard packaging to be retained for use if transporting the device.
NOTE: Any other consumable or accessory not sold by ACTEON will have its own manual. Please refer to it before using the product. Keep the packaging in case you need to transport the equipment later

3.2 DESCRIPTION

SOPRO's devices concerned are optical handpieces for use in the oral cavity of the patient to assist with diagnosis and facilitate patient information.

3.3 INDICATION

No indication is claimed for intraoral cameras and accessories associated.

3.4 INTENDED PURPOSE

3.4.1 SOPRO 617 AND SOPRO 717FIRST INTRAORAL CAMERAS

SOPRO 617 and SOPRO 717FIRST intraoral cameras, with the essential accessories such as docking station and single-use protective sheath, are intended to visualize anatomical and pathological details that cannot be seen with the naked eye, as well as pathology control and post-treatment.
SOPRO 617 and SOPRO 717FIRST cameras do not provide a diagnostic.

3.4.2 SOPROCARE INTRAORAL CAMERA

The SOPROCARE intraoral camera with its essential accessories such as docking station, single-use protective sheath and SOPROTIPS is intended:

- as intraoral camera, to visualize anatomical details that are invisible to the naked eye or with a mirror (thanks to its magnification) in DAYLIGHT mode. This mode allows the dentist to show difference between "before" and "after" care.
- to aid in the diagnosis of pit and fissure caries on the occlusal side of the teeth in CARIO mode.
- to help identify the presence of dental plaque but also to highlight gingival inflammations (restricted to gingival inflammations which lead to bleeding upon probing) in PERIO mode.
- to offer to the dentist a tool for an improved communication, motivation and education of the patients who will then become aware of their oral health condition (PERIO mode).

IMPORTANT: SOPROCARE does not provide diagnosis but constitutes a diagnostic aid by providing additional information to supplement visual observations, patient history, and information from other diagnostic techniques. The camera does not provide a diagnosis. Diagnosis after using the camera is performed by the dentist.

3.4.3 C50 INTRAORAL CAMERA

3.4.3.1 WITH **DIAGNOSTIC AID** OPTION DISABLED

C50 Intraoral Camera and its single-use protective sheath is intended to visualize anatomical and pathological details that cannot be seen with the naked eye or with a mirror (thanks to its magnification) in DAYLIGHT mode. This mode allows the dentist to show difference between "before" and "after" care, as well as pathology control and post-treatment.
C50 Intraoral Camera does not provide a diagnostic.

3.4.3.2 WITH **DIAGNOSTIC AID** OPTION ENABLED

C50 Intraoral Camera with the DIAGNOSTIC AID option enabled and its essential accessories such as single-use protection sheath and C50TIPS are intended:

- as intraoral camera, to visualize anatomical details that are invisible to the naked eye or with a mirror (thanks to its magnification) in DAYLIGHT or DAYLIGHT+ mode. These modes allow the dentist to show difference between "before" and "after" care.
- to aid in the diagnosis of pit and fissure caries on the occlusal side of the teeth in CARIO mode.
- to aid to see the presence of dental plaque but also to highlight gingival inflammations (restricted to gingival inflammations which lead to bleeding upon probing) in PERIO mode.
- to offer to the dentist a tool for an improved communication, motivation and education of the patients who will then become aware of their oral health condition (all modes).

IMPORTANT: C50 Intraoral Camera does not provide diagnosis but constitutes a diagnostic aid by providing additional information to supplement visual observations, patient history, and information from other diagnostic techniques. The camera does not provide a diagnosis. Diagnosis after using the camera is performed by the dentist.

3.4.4 C20 INTRAORAL CAMERA

C20 intraoral camera, with its single-use protective sheath are intended to visualize anatomical and pathological details that cannot be seen with the naked eye, as well as pathology control and post-treatment.
C20 intraoral camera does not provide a diagnostic.

3.4.5 ACCESSORIES (PROTECTIVE SHEATHS AND INTRAORAL TIPS (SOPROTIPS AND C50TIPS))

The single-use protective sheath is intended to be used on the camera head as a hygienic protection between each patient.

SOPROTIPS and C50TIPS are intraoral tips placed on the camera head (itself protected by the protective sheath) to improve fluorescence imaging quality by shielding the camera from ambient light.

Any use outside of these areas constitutes improper use of the product, and the user will therefore be considered responsible for such use. The manufacturer does not accept any liability in this case.

3.5 BENEFIT

Cameras and accessories associated (intraoral tips, protective sheaths, and mini docks) are intended to visualize anatomical and pathological details that cannot be seen with the naked eye, as well as pathology control and post-treatment.
No clinical performance is claimed for these cameras, neither direct clinical benefit but an indirect clinical benefit which consists of allowing a faster response and a more effective action of the treatment for the patient, thanks to technical performances allowed by each camera’s technical specification.

3.6 PRINCIPLE OF OPERATION

3.6.1 SOPRO 617 INTRAORAL CAMERA

The optics and electronics developed around a CCD sensor in SOPRO 617 pick up the images, enhance them and convert them into a video signal which is sent to the video monitor or to a computer screen.

3.6.2 SOPRO 717FIRST INTRAORAL CAMERA

The optics and electronics developed around a CCD sensor in SOPRO 717FIRST pick up the images, enhance them and convert them into a video signal which is sent to the video monitor or to a computer screen. The focus is possible thanks to 3 pre-set positions corresponding to the main camera uses (extra-oral, intra-oral, macro).

3.6.3 SOPROCARE INTRAORAL CAMERA

Thanks to its technology based on the phenomenon of fluorescence (caused by LED lighting) and chromatic amplification, the camera SOPPROCARE will make it possible to carry out an overall assessment of the patient's oral health.
The optics and the charge coupled device (CCD) sensor in the SOPROCARE generate images displaying this fluorescence. These images are sent to a video or computer monitor and can be used by the dental team as an aid for diagnosis. The resulting image can be used by dental practitioner and/or hygienist as an aid for diagnosis. As an aid in the detection of dental plaque, gingival inflammations (restricted to gingival inflammations which lead to bleeding upon probing), and pit and fissure caries, SOPROCARE will display any changes in fluorescence directing the dental professional to examine the warning area

using gold standard techniques. The image information, together with results of gold standard examination, can be used to identify pathological symptoms and formulate an appropriate treatment plan.
In CARIO mode, the camera (thanks to its magnification) helps the dental practitioner to detect potential caries on pits and fissures on the occlusal side of the teeth.
In DAYLIGHT mode, the camera enables you to visualize anatomical details invisible to the naked eye or with a mirror.
In PERIO mode, the camera helps the dental practitioner to see the presence of dental plaque but also to highlight gingival inflammations (restricted to gingival inflammations which lead to bleeding upon probing). This mode offers to the dentist and/or hygienist a tool for an improved communication, motivation, and education of his/her patients, who will then become aware of their oral health condition.

3.6.4 C50 INTRAORAL CAMERA

3.6.4.1 WITH OR WITHOUT DIAGNOSTIC AID OPTION

The optics and electronics developed around a CMOS sensor in C50 capture images, enhance them, and convert them into a video signal which is sent to the computer screen. The camera is provided with autofocus (AF) or single focus (SF) capabilities.

3.6.4.2 WITH DIAGNOSTIC AID OPTION

Thanks to its technology based on the phenomenon of fluorescence (provided by LED lighting) and chromatic amplification, the camera makes it possible to carry out an overall assessment of the patient's oral health. The optics and the CMOS sensor in this camera generate images displaying the natural fluorescence of the site under observation. These images are sent to a computer and displayed on a computer monitor and can be used by the dental team as an aid for diagnosis. As an aid in the detection of dental plaque, gingival inflammations (restricted to gingival inflammations which lead to bleeding upon probing), pit and fissure caries, C50 will display any changes in fluorescence, alerting the dental professional to the need to examine the affected area using gold standard techniques. The information provided by the image, together with results of gold standard examination, can be used to identify pathological symptoms and formulate an appropriate treatment plan.
In CARIO mode, the camera helps the dental practitioner detect potential caries on pits and fissures on the occlusal surface of the teeth thanks to its magnification.
In DAYLIGHT or DAYLIGHT+ mode, the camera enables visualization of anatomical details invisible to the naked eye or with a mirror.
In PERIO mode, the camera helps the dental practitioner identify dental plaque, in addition to highlighting gingival inflammations (restricted to gingival inflammations which lead to bleeding upon probing). This mode offers the dentist and/or hygienist a tool for improved communication, motivation, and education of his/her patients, heightening their awareness of their oral health condition.

3.6.5 C20 INTRAORAL CAMERA

The optics and electronics developed around a Complementary Metal Oxide Semiconductor (CMOS) sensor in C20 pick up the images, enhance them and convert them into data which is sent to a computer screen.

3.6.6 DOCKING STATIONS

The MINI DOCK U_USB2 module is built-in docking station for SOPRO 617, SOPRO 717FIRST, SOPROCARE cameras.
The MINI DOCK U_USB2 docking station is to be powered directly by a USB 2.0 compatible port.
The docking station is turned ON/OFF according to the computer electrical supply. In case of use of a handpiece holder, connect the strap on the ON/OFF selector (*cf. installation diagram*).
Its compact size and light weight allow an easy installation into different dental units. This product is composed of a docking station and a linking cable to the handpiece.

The electrical supply for all cameras is directly performed through the computer USB port. The voltage powering the camera is of continuous 5 V low voltage type (0.5 A).

3.6.7 SINGLE-USE PROTECTIVE SHEATH

A single-use protective sheath is put on the intraoral camera’s head as a hygienic protection between each patient.

3.6.8 INTRAORAL TIPS (C50TIPS AND SOPROTIPS)

C50TIPS and SOPROTIPS intraoral tips are respectively used with C50 and SOPROCARE intraoral cameras when using their DIAGNOSTIC AID mode.
Intraoral tips are placed on the camera head (itself protected by the protective sheath) to improve fluorescence imaging quality by shielding the camera from ambient light.

3.7 USER POPULATION RECOMMENDATIONS

3.7.1 USER POPULATION

The devices are intended for use by:

- A qualified and certified dentist / dental surgeon
- A qualified and certified dental hygienist
- A qualified and certified dental assistant
- A qualified and certified nurse
- A qualified and certified decontamination / sterilisation processing personnel

The following requirements must be fulfilled by the user: Any vision problems must be corrected by glasses or contact lenses / Colour perception is mandatory.
The user must wear gloves.
The device is not intended for self-treatment.
The user is not the patient.
The device can be used by any adult practitioner of any weight, age, height, gender, and nationality.

3.7.2 SPECIFIC USER TRAINING

No specific training other than initial professional training is required to use this medical device.

3.7.3 DEVICES IN CONTACT WITH THE USER

The intraoral cameras and accessories associated are in indirect contact with the user, who wears gloves during use of the device.
The intraoral cameras do not enter in direct contact with the patient's mouth.
The protective sheaths, C50TIPS and SOPROTIPS are in direct contact with the patient mouth and are biocompatible according to the ISO 10993-1:2018 standard.

3.8 PATIENT POPULATION RECOMMENDATIONS

3.8.1 PATIENT POPULATION

This medical device is designed to be used with the following patient populations:

- Children (2 years to 11 years)
- Adolescents (12 years to 17 years)
- Adults (from 18 years)

This medical device can be used irrespectively of the patient's details such as weight, age, height, gender, and nationality.

3.8.2 PATIENT POPULATION RESTRICTION

The user is the only person who can decide whether to treat his/her patients.

3.8.3 APPLIED PART(S)

The handpiece (including distal part) and the connexion cable are considered applied parts within the meaning of international standard IEC 60601-1.

3.9 BASIC SAFETY AND ESSENTIAL PERFORMANCE

3.9.1 NORMAL CONDITIONS OF USE

The normal conditions of use the cameras are the following:

- Storage
- Installation
- Use
- Maintenance
- Disposal

3.9.2 ESSENTIAL PERFORMANCE

Within the meaning of the applicable electromedical device safety standard (IEC 60601-1), the manufacturer has determined that none of the functions of the cameras are essential performance.

A lack of performance such as loss of image does not lead to unacceptable risk, because the procedure can be continued either by changing the camera or by direct observation with the naked eye assisted by a mirror.
A degradation of performance such as an erroneous image does not entail an unacceptable risk because the analysis of the image lies in the responsibility of the dental practitioner and his or her clinical judgment, experience, and training. The device solely functions as an aid to visualization. In case of non-performance, the clinical procedure can be continued either by exchanging the camera for another one or by direct observation using a dental inspection mirror.

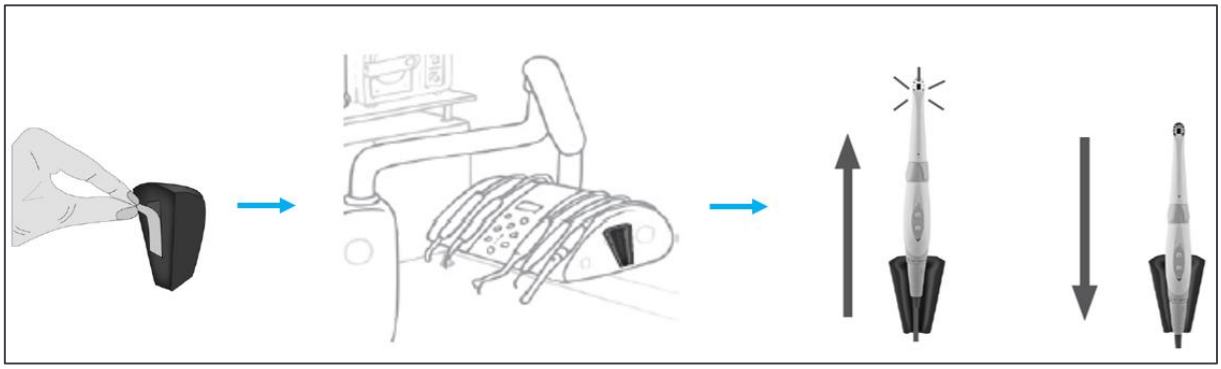
3.10 LIFETIME

- The intra-oral cameras C20, C50, SOPROCARE, SOPRO617, SOPRO717First and docking stations' lifetime is 7 years.
- SOPROTIPS and C50TIPS' lifetime is 50 steam sterilization cycles.
- The protective sheaths are single-use devices with a lifetime of maximum 1 minute.

4 DEVICE INSTALLATION

No special training is required to install the device.
Note: Setting up IT security controls for the operating environment (e.g., antivirus software and a firewall).

4.1 INSTALLATION OF THE HANDPIECE HOLDER



1. Choose an easily accessible flat surface.
2. Use the wipe provided to clean the surface on which you are going to fasten the holder.
3. Remove the double-sided adhesive tape protection from the handpiece holder and press it on the desired surface for a few seconds. Full adhesion of the handpiece holder is achieved after 2 hours, so avoid any stress on the handpiece holder during this two-hour period.

CAUTION: The handpiece holder is equipped with magnets that can damage devices sensitive to magnetic fields. Make sure you do not install the handpiece holder near devices such cathode ray tube video screens, magnetic videotapes, etc.

4.2 CONNECTING SOPRO 617, SOPRO 717FIRST, SOPROCARE INTRAORAL CAMERAS TO A COMPUTER

4.2.1 REQUIRED COMPUTER CONFIGURATION

This paragraph is linked to the cameras below:

- SOPRO 617
- SOPRO 717FIRST
- SOPROCARE

To use the cameras, you must make sure the computer, and its peripherals do not have any usage limitations that could affect personal safety. The following requirements should be met:

Windows® configuration:

	Minimum Configuration	Recommended Configuration
Operating system	Windows® 10 PRO	Windows® 11 PRO 64 bits
Processor	Intel® Core i5 – 4 cores 4 thread	Intel® Core i5 – 6 cores 6 thread
Memory	8 GB	8 GB or more
Hard disk	250 GB	300 GB
USB ports	2 ports USB2.0 Hi-Speed ports	2 ports USB2.0 Hi-Speed ports
Graphic card	OpenGL 2.1 or Direct X 9 or 11 graphics card	OpenGL 2.1 or Direct X 9 or 11 graphics card
Video board	512 MB unshared RAM – Memory compatible with DirectX 9	Chipset Nvidia or ATI / 2 GB of unshared RAM – Memory compatible with DirectX 9 or higher
USB Chipset	Intel or NEC® / RENESAS®	Intel or NEC® / RENESAS®
Screen resolution	1280 x 1024	1280 x 1024 or higher

MAC® configuration:

	Minimum Configuration	Recommended Configuration
Computer	MacBook® Pro 13'' or iMac® 21.5''	iMac® 27''Retina
Operating system	MacOS® Ventura	MacOS® Sonoma
Processor	Intel® Core i5 or from Apple M1	Intel® Core i7 or from Apple M1
Memory	8 GB	8 GB

4.2.2 MINI DOCK U_USB2 CONNECTION WITH A COMPUTER

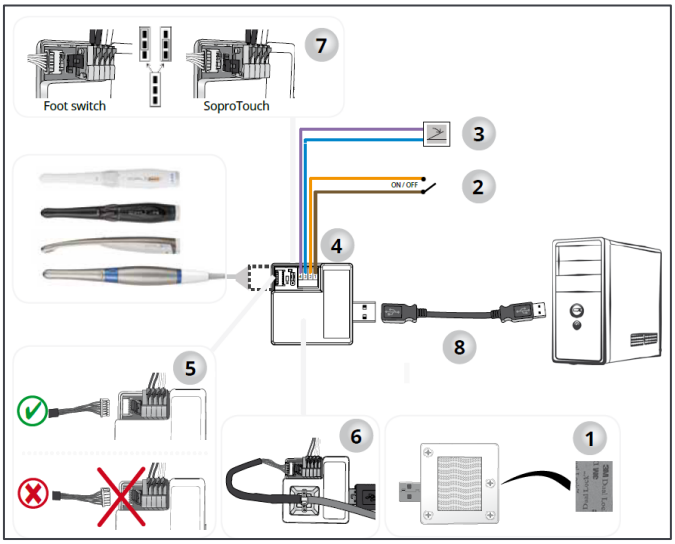
The following section is only applicable for cameras for which a docking station is mandatory.
To integrate the MINI DOCK U_USB2, you must follow the process described hereinafter:

- Fixation of cable on the docking station
- Fixation of the docking station into the unit

Necessary material:

- Cutter
- Flat screwdriver
- ESD Grounding strap

Installation diagram:

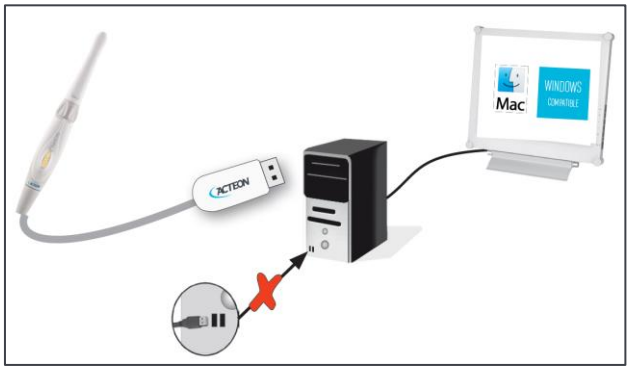


The footswitch should be connected to MINI DOCK U_USB2  if you have selected it to freeze the image.

4.2.3 MINI DOCK USB2 CONNECTION WITH A COMPUTER

The following section is only applicable for cameras for which a docking station is mandatory.

Connect the USB cable to one of the computer USB ports.
Connect the connecting cable to the handpiece (e.g., for SOPROCARE camera here below):



4.2.4 FURTHER DOCKING STATIONS *(OPTIONAL)*

You can install a connection box near each dental chair (no limitation). You will just have to transport the handpiece from one chair to the other.
The handpiece holder is intended to maintain the connecting cable connector when the cable is not linked to the handpiece.

4.3 CONNECTING THE C50 INTRAORAL CAMERA TO A COMPUTER

4.3.1 REQUIRED COMPUTER CONFIGURATION

To use the C50, you must make sure the computer, and its peripherals do not have any usage limitation that could concern personal safety. The following requirements should be met:

Windows® configuration:

	Minimum Configuration	Recommended Configuration
Operating system	Windows® 10 PRO	Windows® 11 PRO
Processor	Intel® Core i5 – At least 4 cores	Intel® core i7 or more – At least 6 cores
Memory	8 GB	16 GB or more
Hard disk	250 GB	1 TB or more
USB ports	USB 3.0 Super-Speed*	USB 3.1 Super-Speed*
Video board	1 GB unshared RAM	Chipset Nvidia or ATI / 2 GB of unshared RAM – Memory compatible with DirectX 9 or higher
USB Chipset	Intel or NEC® / RENESAS®	Intel or NEC® / RENESAS®
Screen resolution	1920 x 1080	1 920 x 1 080 or higher

MAC® configuration:

	Minimum Configuration	Recommended Configuration
Computer	MacBook® Pro 13'' or iMac® 21.5''	iMac® 27''
Operating system	MacOS®Ventura	MacOS® Sonoma
Processor	Intel® Core i5 – At least 4 cores or at least Apple M1 with Rosetta2	Intel® Core i7 – At least 4 cores or at least Apple M1 with Rosetta2
Memory	8 GB	16 GB
USB ports	USB 3.0 Super-Speed*	USB 3.0 Super-Speed*

*: The C50 must be connected to a USB root hub to ensure use of maximum available bandwidth.

4.3.2 CONNECTING THE C50 INTRAORAL CAMERA TO A COMPUTER

Unlike the other cameras, the C50 is not associated with a MINI DOCK USB2 or MINI DOCK U_USB2.
A USB cable is provided to connect the C50 (USB-C) to a computer (USB-A).

The USB port must be at least an USB 3.0. The following symbol must be shown on the computer connection:

4.4 CONNECTING THE C20 INTRAORAL CAMERA TO A COMPUTER

4.4.1 REQUIRED COMPUTER CONFIGURATION

To use the C20, you must make sure the computer, and its peripherals do not have any usage limitation that could concern personal safety. The following requirements should be met:

Windows® configuration:

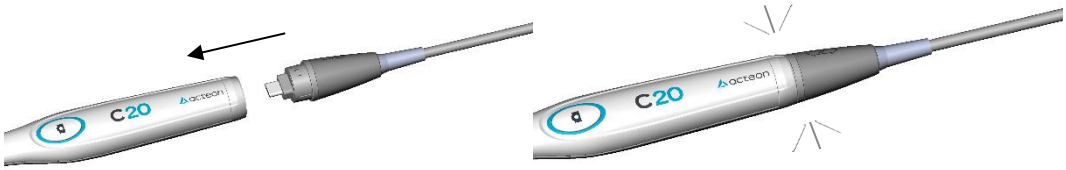
	Minimum Configuration	Recommended Configuration
Operating system	Windows® 10 PRO	Windows® 11 PRO
Processor	Intel® Core i5 – At least 4 cores	Intel® core i7 or more – At least 4 cores
Memory	8 GB	16 GB or more
Hard disk	250 GB	1 TB or more
USB ports	USB 2.0 High-Speed*	USB 3.0 Super-Speed*
Video board	1 GB unshared RAM	Chipset Nvidia or ATI / 2 GB of unshared RAM – Memory compatible with DirectX 9 or higher
USB Chipset	Intel or NEC® / RENESAS®	Intel or NEC® / RENESAS®
Screen resolution	1920 x 1080	1 920 x 1 080 or higher

MAC® configuration:

	Minimum Configuration	Recommended Configuration
Computer	MacBook® Pro 13'' or iMac® 21.5''	iMac® 27''
Operating system	MacOS®Ventura	MacOS® Sonoma
Processor	Intel® Core i5 – At least 4 cores or at least Apple M1 with Rosetta2	Intel® Core i7 – At least 4 cores or at least Apple M1 with Rosetta2
Memory	8 GB	16 GB
USB ports	USB 2.0 High Speed	USB 2.0 High Speed

4.4.2 CONNECTING THE C20 INTRAORAL CAMERA TO A COMPUTER

Like the C50 cameras, the C20 is not associated with a MINI DOCK USB2 or MINI DOCK U_USB2.
A USB cable is provided to connect the C20 (USB-C) to a computer (USB-A).



4.5 IMAGING SOFTWARE INSTALLATION AND CONFIGURATION

4.5.1 IMAGING SOFTWARE INSTALLATION FOR SOPRO 617, SOPRO 717FIRST, SOPROCARE INTRAORAL CAMERAS

The SOPRO 617, SOPRO 717FIRST, and SOPROCARE cameras can be used with ACTEON® Imaging Suite (AIS) software.

The video acquisition module is installed when AIS, or OIS (with SDK) is installed.
The video acquisition module is a software that can captures films and images from ACTEON cameras video stream, according to dentist's needs for patient's oral heath follow-up.

4.5.2 IMAGING SOFTWARE INSTALLATION FOR C50 INTRAORAL CAMERA

The C50 can be used with ACTEON® Imaging Suite (AIS) software or any Other Imaging Software (OIS) supporting USB Video Class (UVC).

The video acquisition module is installed when AIS or OIS (with SDK) is installed.
The video acquisition module is software that can capture films and images from ACTEON cameras video stream, according with the dentist's needs for patient oral heath follow-up.

4.5.3 IMAGING SOFTWARE INSTALLATION FOR C20 INTRAORAL CAMERA

The C20 can be used with any Imaging Software (IS) supporting USB Video Class (UVC).

4.5.4 ACTEON CAMERA CAPTURE BUTTON (C20 & C50 ONLY)

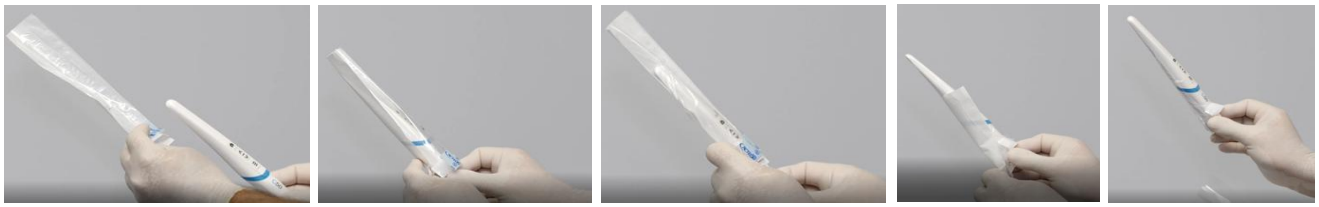
ACTEON® Imaging Suite (AIS) software or any Other Imaging Software (OIS) using our video acquisition module (through SDK implementation or TWAIN) can access the camera capture functionality without any specific configuration.
The video acquisition module is software that can capture films and images from ACTEON cameras video stream, according with the dentist's needs for patient oral heath follow-up.

If you are not using our SDK neither our TWAIN, please contact our assistance to configure the camera capture button into a third-party software: cs@acteongroup.com

4.6 USE OF THE SINGLE-USE PROTECTIVE SHEATH

CAUTION: When inserting the camera head into the protective sheath, be sure to insert the tip first. Otherwise, the dental image may be blurred.

SOPROCARE, SOPRO717First, SOPRO 617 or C50 camera placement into the protective sheath: for these cameras, the lens must be positioned facing the protective sheath, as shown in the figure below:



C20 camera placement into the protective sheath: For the C20 intraoral camera, the lens must be positioned facing the user, as shown in the figure below:

4.7 USE OF C50TIPS AND SOPROTIPS FOR THE DIAGNOSTIC AID OPTION (C50TIPS WITH C50 INTRAORAL CAMERA AND SOPROTIPS WITH SOPROCARE INTRAORAL CAMERAS)

Immediately before use, place a clean and sterile SOPROTIPS or C50TIPS on the camera head over the protective sheath. SOPROTIPS and C50TIPS are intended to improve fluorescence imaging quality by shielding the camera from ambient light.

5 USE OF THE DEVICE

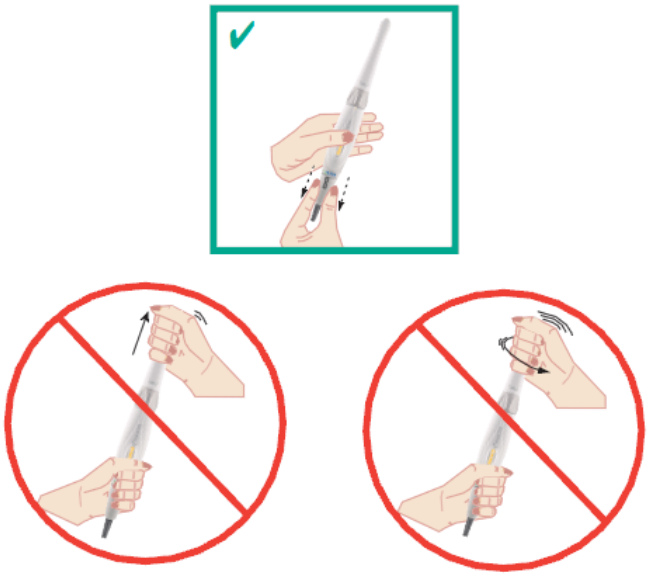
5.1 USE OF SOPRO 617, SOPRO 717FIRST AND SOPROCARE INTRAORAL CAMERAS

5.1.1 FREQUENTLY USE FUNCTION

The SOPRO 617, SOPRO717FIRST and SOPROCARE intraoral cameras have a slightly touch “SoproTouch” to capture image, a rotating ring to adjust the focus (only for SOPRO 717 First and SOPROCARE) and two button on the front of handpiece to perform various functions (only SOPROCARE).
Each function is described in the following paragraphs. Their frequency of use is summarised in the table below:

	SoproTouch for Image capture	Rotating ring for focus adjustment	button on the front of handpiece for various function
SOPRO 617	Frequently used	NA	NA
SOPRO 717First	Frequently used	Frequently used	NA
SOPROCARE	Frequently used	Frequently used	Frequently used

WARNING:



5.1.2 IMAGE CAPTURE

Operation of SoproTouch *image capture on camera*
To capture an image, you have just to slightly touch SoproTouch as soon as the desired region of interest appears on the screen. The image is automatically captured on the computer - only when used with Acteon Imaging suite (AIS) (if another imaging software is used, please refer to its Instructions for Use). During the capture, the video live stream flashes white, confirming the image capture.

Operation of FOOTSWITCH *image capture on camera*

- By the built-in Docking Station: If you prefer using a footswitch rather than SoproTouch to capture an image, connect the footswitch (optional) to the docking station and place the jumper on footswitch position. With this configuration, SoproTouch is disable.
- By the computer: If you prefer using a footswitch rather than SoproTouch to capture an image, connect the footswitch (optional) to the computer and configure it into your imaging software (please refer your imaging software manual). With this configuration, SoproTouch is still functional. To disable the SoproTouch, please refer your imaging software manual.
  NOTE: When used with the medical device, the footswitch must comply with IEC 60601-1 standard and must be rated IPX1 according to IEC 62368-1 standard.

5.1.3 FOCUS ADJUSTMENT ON SOPRO 717FIRST AND SOPROCARE INTRAORAL CAMERAS ONLY

On the handpiece, there is a rotating ring used to focus from “0” to infinite. To simplify handling, we have pre-set four positions corresponding to the main camera uses.

Picture	Designation
	Extra-oral (Portrait)
	Intra-oral (1 to 5 teeth)
	Tooth (diseases observations)
	Macro (details that cannot be seen with the naked eye)

5.1.4 OPERATING PROTOCOL FOR SOPROCARE INTRAORAL CAMERA

PERIO MODE

This fluorescence mode (associated with chromatic amplification) helps provide information about the patient’s dental hygiene and highlights dental plaque and gingival inflammations (restricted to gingival inflammations which lead to bleeding upon probing).

The images provided are displayed with colours that can be interpreted following the table below:

	NORMAL SIGNAL		ALERT SIGNAL	
Displayed colour	Natural colour of the tooth	Natural colour and aspect of the gingiva	Presence of deposits from white, yellow, orange to red	Coloration of the gingiva in purplish red
Supposed state of tissue	No presence of deposits on the tooth	Healthy gingiva	Presence of dental plaque	Presence of gingival inflammation
Examine for	Healthy tooth	Healthy tooth	Use Gold Standard techniques to examine patient hygiene	Use Gold Standard techniques to examine gingival inflammation

The camera needs to be used with SOPROTIPS, which must be placed on the camera’s head to improve fluorescence imaging quality by shielding the camera from ambient light.

NOTE: Non-bleeding during probing is not a sure criterion for assessing gum health. The absence of a warning signal corresponding to gingival inflammation in the area examined should not be taken as a sign of a healthy area.

CARIO MODE

In this fluorescence mode the obtained image gives a warning in red while the rest of the picture remains in black and white. It is advised to use SOPROTIPS in CARIO mode. It is necessary to move the dental light in order to avoid light in the patient’s mouth.

	NORMAL SIGNAL	ALERT SIGNAL
Displayed colour	Colourless	Red
Supposed state of tissue	Healthy dentine	Suspicious area
Examine for	Healthy dentine	Use Gold Standard techniques to examine for potential caries

In case of this alert signal, always perform a professional cleaning using a prophy brush, powder jet cleaner, or other acceptable means to remove any debris, meal deposits, dental plaque, plaque detection agents, and preventative materials such as fluoride paste that can interfere with caries detection. Then perform a new examination.

Diagnosis after using the SOPROCARE is performed and provided by the general practitioner and/or dental hygienist. The alert signal is only an indication. The dental practitioner should make a professional judgment about the proper treatment, or to stop treatment, based upon his or her clinical expertise and analysis.

SELECTION MODE

To switch from DAYLIGHT mode to PERIO mode press the top button of the handpiece.
To switch from DAYLIGHT mode to CARIO mode press the bottom button of the handpiece.

Picture	Designation
	Button 1: Press button to switch between DAYLIGHT and PERIO modes.
	Button 2: Press button to switch between DAYLIGHT and CARIO modes.

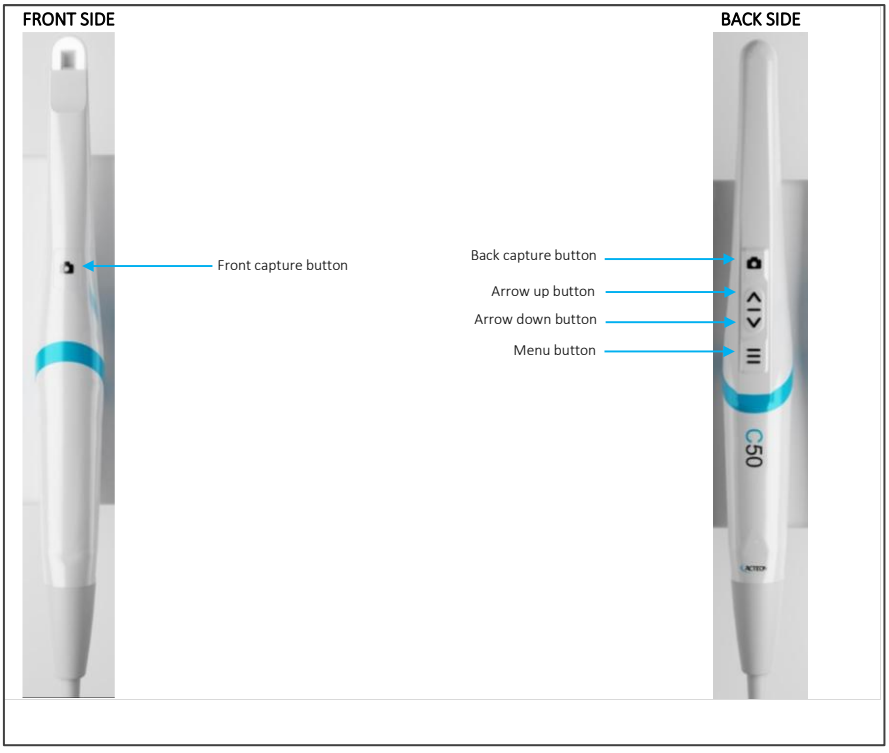
5.2 USE OF C50 INTRAORAL CAMERA

5.2.1 FREQUENTLY USE FUNCTION

The C50 intraoral cameras have a press and hold button to capture image, an arrow up and arrow down button for various function and a menu button to switch functions.
Note: Automatic face detection allows the C50 intraoral camera to be switched to portrait mode automatically.
Each function is described in the following paragraphs. Their frequency of use is summarised in the table below:

	Press and hold button to capture image	Arrow up and arrow down button	Short press on menu button to switch functions
C50	Frequently used	Frequently used	Frequently used

5.2.2 BUTTON LOCATION AND DESIGNATION



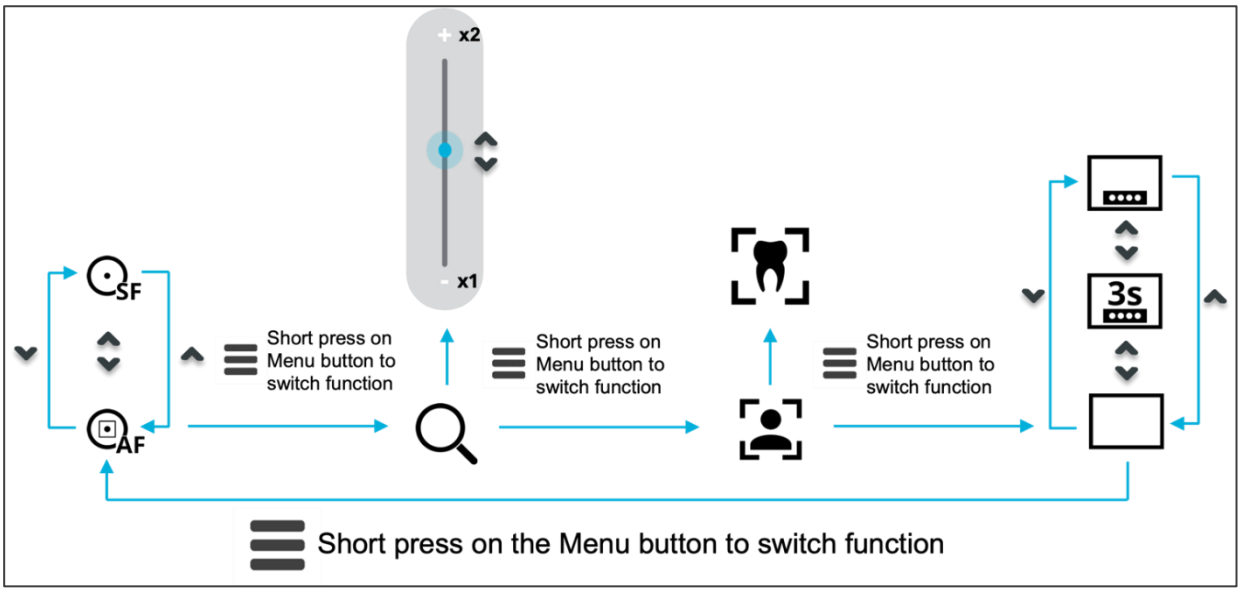
5.2.3 IMAGE CAPTURE

To capture an image, you have just to press and hold the capture button as soon as the desired region of interest appears on the screen. The image is automatically captured on the computer - only when used with Acteon Imaging suite (AIS) (if another imaging software is used, please refer to its Instructions for Use). During the capture, the video live stream flashes white, confirming the image capture.

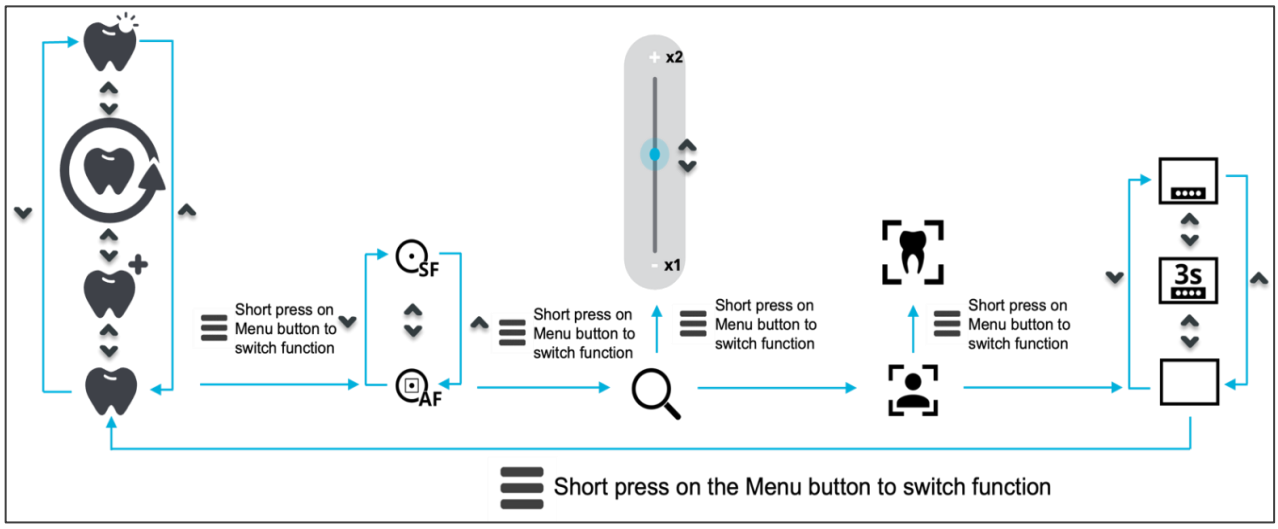
5.2.4 ON-SCREEN DISPLAY (OSD)

If you are using the C50 with another imaging software (OIS) different from ACTEON® Imaging Suite (AIS) and you are not using our TWAIN nor our SDK, you will have access to the camera OSD.
To access the OSD, please refer to the instructions provided on the picture below.

WITHOUT **DIAGNOSTIC AID** OPTION



WITH **DIAGNOSTIC AID** OPTION



5.2.5 ICON DESIGNATION

Function	Picture	Designation	Available on AIS or TWAIN or SDK	Available on OIS
Focus		**Automatic Focus** The camera focuses automatically.	Yes	Yes
Focus		**Single Focus** To focus the image, short press the capture button.	Yes	Yes
DAYLIGHT Mode		**DAYLIGHT** The camera produces an image with natural colour.	Yes, but here after the new icon. 	Yes
DAYLIGHT+ Mode		**DAYLIGHT+** This mode adds higher contrast to daylight mode.	Yes, but here after the new icon. 	Yes
PERIO Mode		**PERIO** Diagnostic aid to highlight plaque and gingival inflammation by chromatic amplification.	Yes, but here after the new icon. 	Yes
CARIO Mode		**CARIO** Diagnostic aid to highlight caries – by fluorescence.	Yes, but here after the new icon. 	Yes
Zoom		**Digital zoom** Magnifies the picture from x1 to x2 with step od 0.1.	Yes	Yes
Self-timer		**Self-Timer** The self-timer can be set according to your needs to Off, 1s, 3s or 5s.	Yes	No
Portrait Mode		**Portrait** Portrait mode helps you capture a portrait image of your patient using ambient room AWB. (The handpiece light is turned OFF in this mode. Use the single focus function to focus).	Yes	Yes
Intraoral Mode		**Intraoral** Intraoral mode allows you to take an intraoral image of your patient using ambient mouth AWB. (The handpiece light is turned ON.)	Yes	Yes

Note: Automatic face detection allows the C50 intraoral camera to be switched to portrait mode automatically.

5.3 USE OF THE C20 INTRAORAL CAMERA

5.3.1 FREQUENTLY USE FUNCTION

The C20 intraoral cameras have a press and hold button to capture image.
Note: Due to its design, the C20 intraoral camera is intended to be used in a horizontal position.
Each function is described in the following paragraphs. Their frequency of use is summarised in the table below:

	Press and hold button to capture image
C20	Frequently used

5.3.2 IMAGE CAPTURE

Operation of image capture on camera

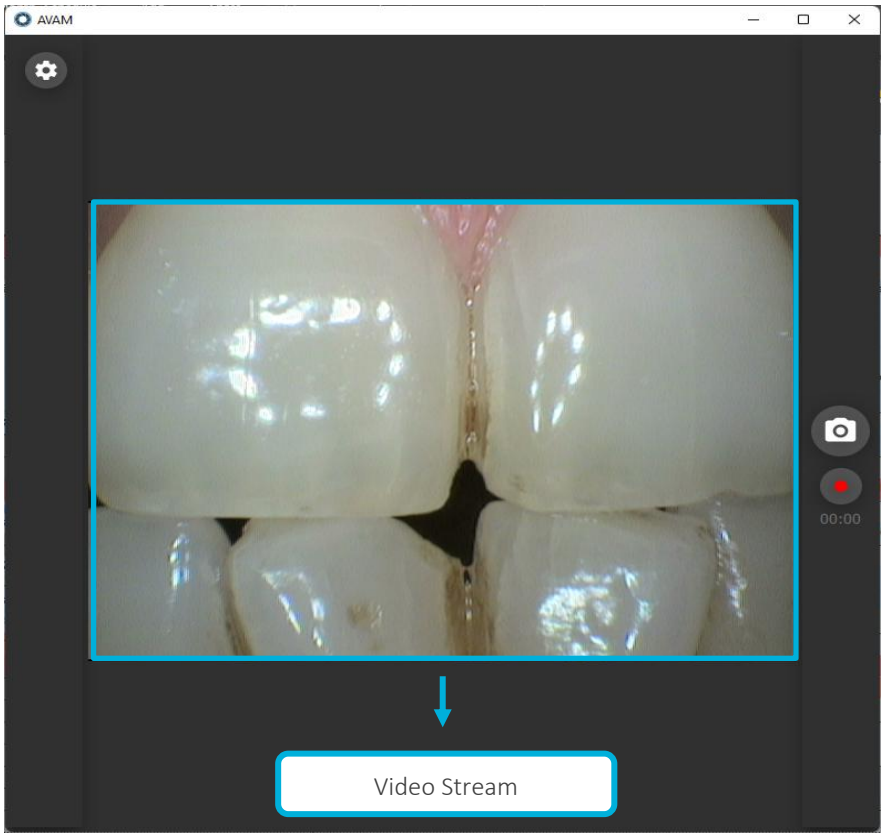
To capture an image, simply press and hold the capture button as soon as the desired region of interest appears on the screen. The image is automatically captured on the computer - only when used with Acteon Imaging suite (AIS) (if another imaging software is used, please refer to its Instructions for Use). During the capture, the video live stream flashes white, confirming the image capture.

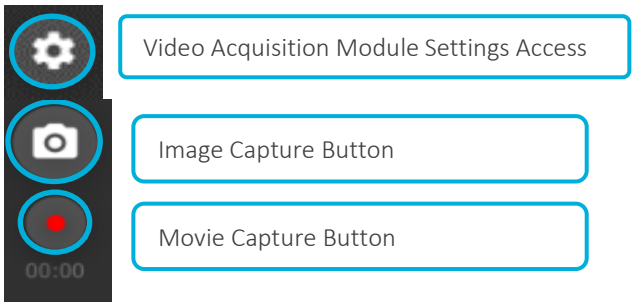
5.3.3 AUTOMATIC FLIPPING

The part of the mouth visible at the top of the image must always be the maxillary (both for the two sides left and right)
The automatic flipping is managed by C20 camera allowing to always display the maxillary arch on the top of the live video stream.
Note: for more information, follow the guide supplied with each camera (For info: a QR code giving access to videos, how to use C20)

5.4 USE OF THE VIDEO ACQUISITION MODULE

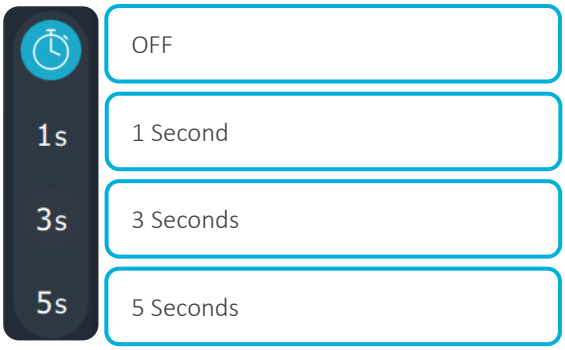
5.4.1 MAIN INTERFACE OF SOPRO 617, SOPRO 717FIRST AND SOPROCARE INTRAORAL CAMERAS





5.4.1.1 SELF-TIMER

To access the Self-Timer menu, use your mouse.
The menu offers four options:

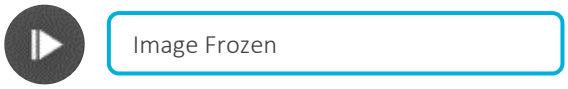


The option selected is highlighted in blue.
The Self-Timer option is set to OFF when video acquisition module is used for the first time.
If you modify the Self-Timer setting, the option selected will be applied by default until a new option is selected.
To change the Self-Timer option, select the desired option with a mouse click.
Your selection is applied immediately.

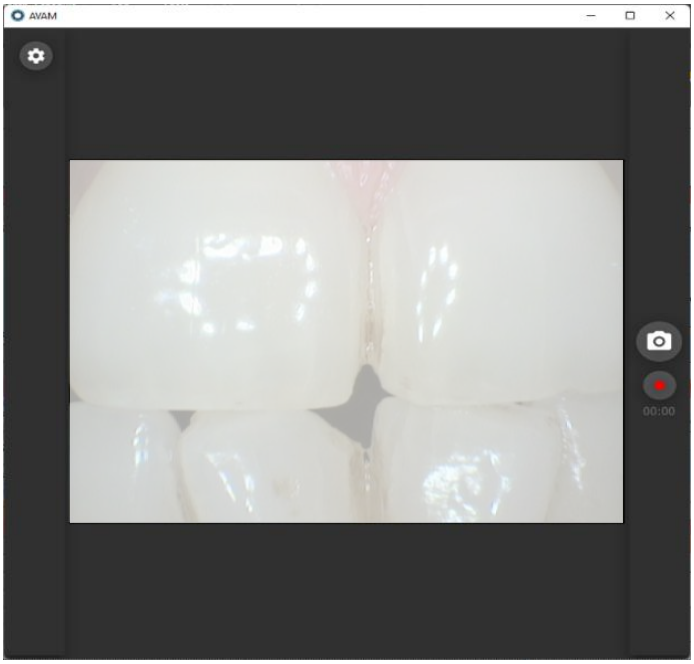
If no action is taken during 3s, the system automatically exits the menu.

5.4.1.2 IMAGE CAPTURE

The default option present in the Advanced Settings of the video acquisition module is Freeze After Capture.
When this option is enabled and an image is captured, either via the camera capture button or the video acquisition module Capture button , the image captured appears frozen and the capture button on the video acquisition module displays the following message:



As soon as an image is captured a white flash lasting less than a second appears on the video stream (see image below), denoting that an image has been taken.



5.4.1.3 MOVIE CAPTURE

When the record button is pressed in the video acquisition module or if the imaging software is running in movie mode, filming can be controlled via the camera capture button . As soon as the recording is in progress the movie capture button appears as below:

Movie Recording

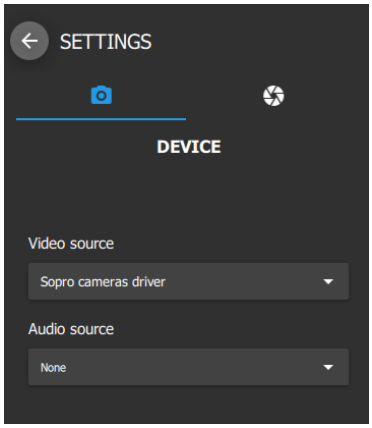
Record duration

5.4.1.4 SETTINGS

To access to the video acquisition module setting, press the dedicated button present in the top left corner of the video acquisition module.

5.4.1.5 DEVICE SETTINGS

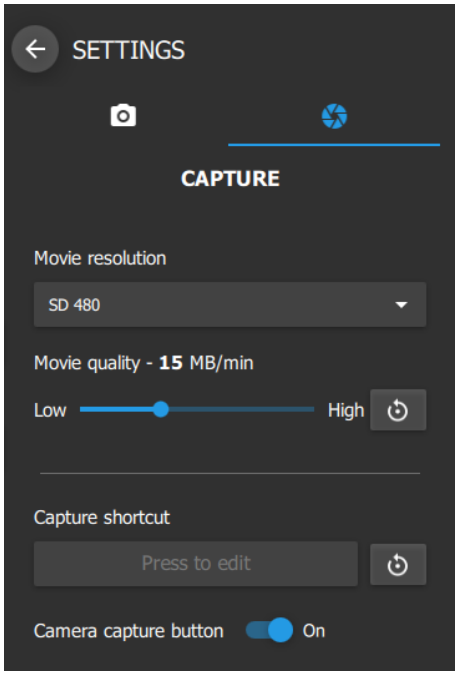
If a camera is already connected to the computer, the video source should be configured automatically.
NOTE: Only ACTEON cameras can be used with the video acquisition module.



Video source selection

Audio source selection

5.4.1.6 CAPTURE SETTINGS



Movie Resolution: define the resolution of the movie

Movie Quality: define the movie compression quality

Capture shortcut: to define a shortcut to capture an image or a movie

Camera capture button: Enable or Disable

5.4.1.6.1 Movie resolution

The movie resolution is displayed:

- SD 480

5.4.1.6.2 Movie quality

Video quality compression can be adjusted from 7,5MB/minute to 30MB/minute.
The default value is 15MB/minute.

5.4.1.6.3 Capture shortcut

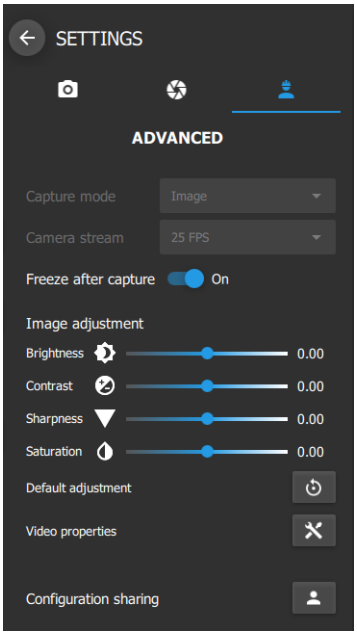
In accordance with the capture mode used (still image or movie), an image or a film can be captured by means of a shortcut defined in the dedicated field.
Select “Press to edit” and create a shortcut to use either the keyboard or the optional USB footswitch (ref.# 009009).

5.4.1.6.4 Reset to default settings

To return to the default value after having changed a setting, press the reset button .

5.4.1.7 ADVANCED SETTINGS

To access the Advanced Settings, use the toggle button “Advanced mode” option depicted below.
The following parameters can be adjusted on this menu:



Capture Mode: Define by the imaging software calling the video acquisition.

Camera Stream: Define by the user camera (PAL: 25FPS; NTSC: 30FPS).

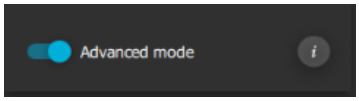
Freeze After Capture (see 5.3.3.1. Above)

Image Adjustment

Reset to default settings

Camera Video properties

Configuration sharing: to share the AVAM configuration with all computer’s users.



Advanced Mode: Enable/Disable

5.4.1.7.1 Capture mode

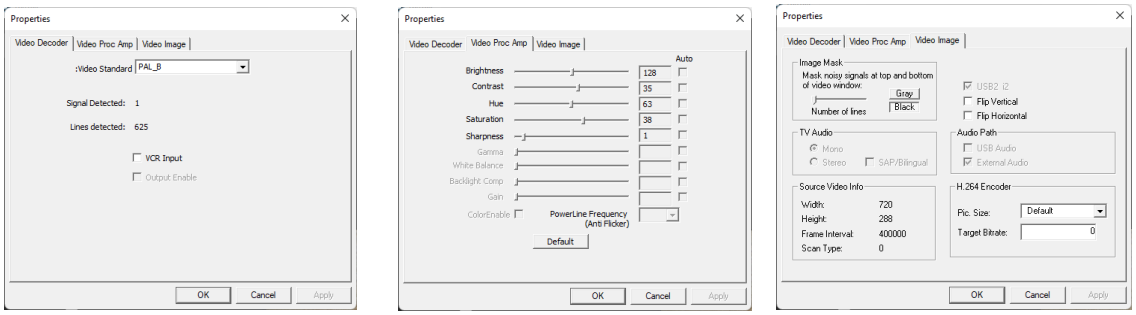
When the imaging software is opened in Image mode, an image can be taken by pressing the camera capture button or by means of the user-defined shortcut.
When the imaging software is opened in Video mode, a movie is acquired by pressing the camera capture button or use the defined shortcut.

5.4.1.7.2 Camera stream

This option displays information with regard to the camera that is connected to the module.

5.4.1.7.3 Video properties

Video properties related to the device are displayed.



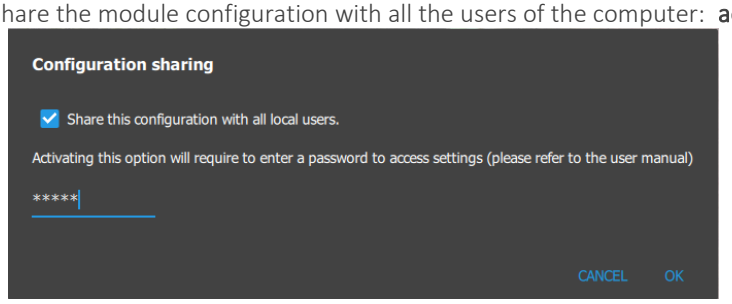
These settings should be adjusted by qualified technician only.

5.4.1.7.4 Reset to default settings

To return to the default value after having changed a setting, press the reset button .

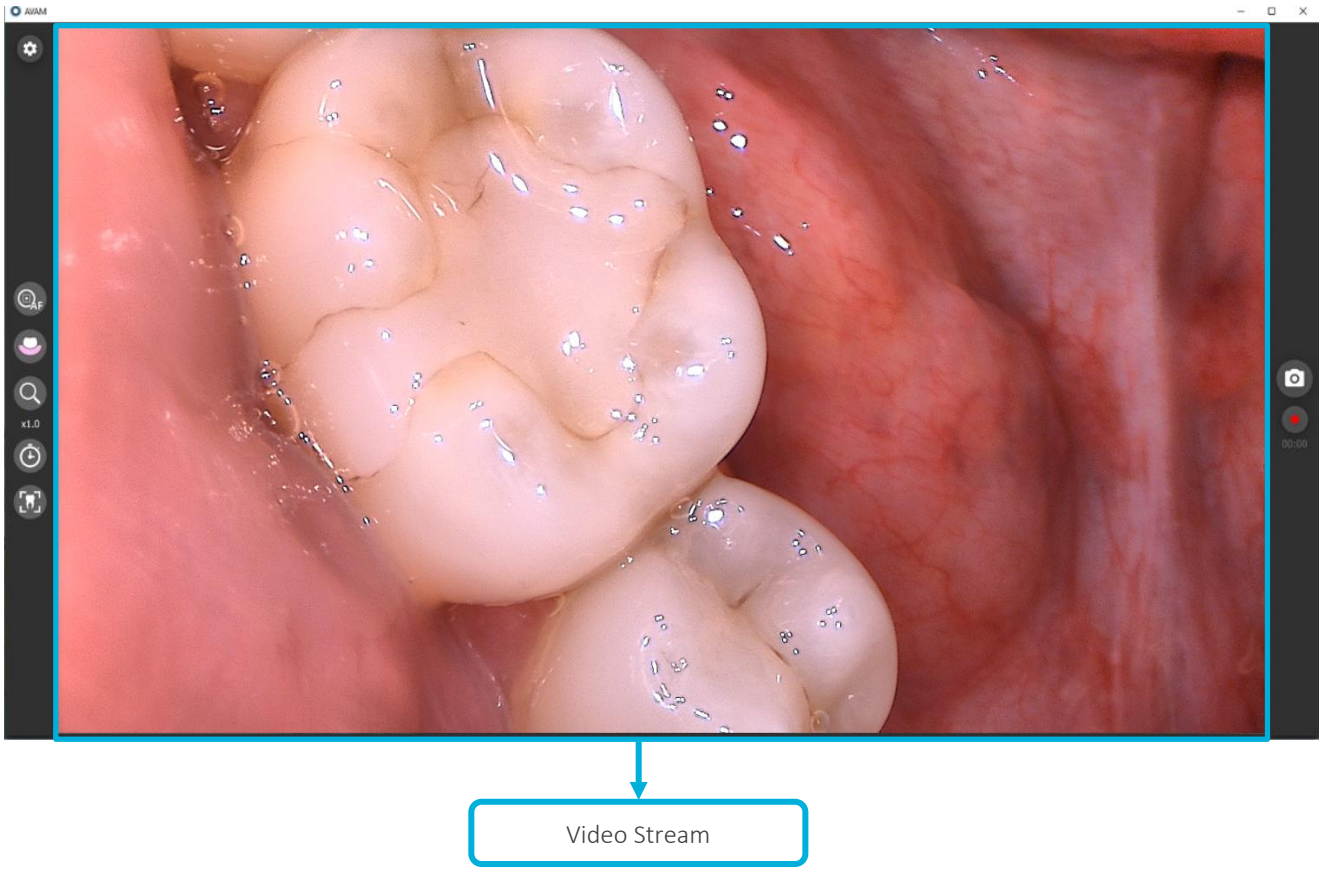
5.4.1.7.5 Configuration sharing

A password is required to share the module configuration with all the users of the computer: **admin.**



5.4.2 MAIN INTERFACE OF C50 INTRAORAL CAMERA

5.4.2.1 With Or Without Diagnostic Aid Option



Video Acquisition Module Settings Access

Focus Function used

Vision Mode Function used

ZOOM Function factor used

Self-Timer Function used

Camera Mode Function used

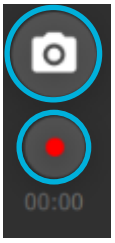


Image Capture Button

Movie Capture Button

5.4.2.2 FOCUS MODE

To access the focus menu, use the camera menu button or your mouse.
The menu displays two options:

Automatic Focus

Single Focus

The option selected is highlighted in blue.
AF is the default option selected when the video acquisition module is used for the first time.
If you change the focus to SF this option will be the one applied by default until you switch back to AF.

To change the focus option, press the camera arrows buttons or select the desired option with a mouse click.
The selected option is applied immediately.

If no action is taken during 3s, the system automatically exits the focus menu.

5.4.2.3 VISION MODE

5.4.2.3.1 Without DIAGNOSTIC AID option

With the DIAGNOSTIC AID option disabled the default vision is the DAYLIGHT mode.

5.4.2.3.2 With DIAGNOSTIC AID option

DAYLIGHT

DAYLIGHT+

PERIO

CARIO

The option selected is highlighted in blue.
DAYLIGHT Mode is the default option applied when the video acquisition module is used.

To change the option, press the camera arrows buttons or select the desired option with a mouse click.
The selection option is applied immediately.

If no action is taken during 3s, the system automatically exits the menu.

5.4.2.4 DIGITAL ZOOM

To use the ZOOM:

- ZOOM IN
- ZOOM OUT

The video acquisition module interface indicates the ZOOM factor as depicted bellow:

Long press the up/down arrows to increase or diminish the ZOOM factor fluently from x1 to x2.
It is possible to define the ZOOM function as Quick Access in the advanced settings menu of the module. If this is done, a short press on the camera up/down arrows will increase or diminish the ZOOM factor step-by-step from x1 to x2 or vice versa.

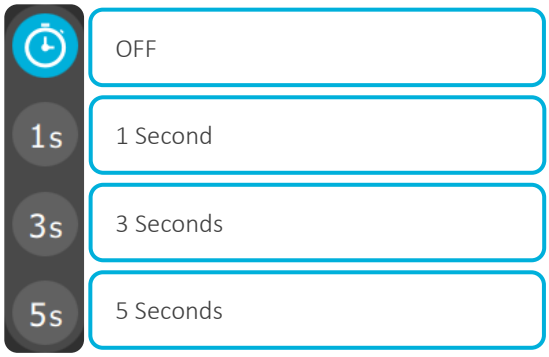
If the camera menu button or your mouse is used, the behaviour is the following one:

To change the zoom factor, use the camera arrows buttons or select the blue slider dot with a mouse to increase or decrease the magnification.
By default, the ZOOM factor is x1 each time you run the application.
The maximum digital zoom is “x2”.

If no action is taken during 3s, the system automatically exits the menu.

5.4.2.5 SELF-TIMER

To access the Self-Timer menu, use the camera menu button or your mouse.
The menu offers four options:



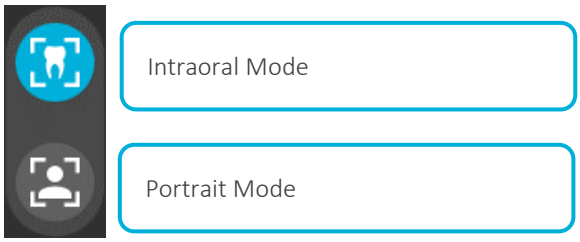
The option selected is highlighted in blue.
The Self-Timer option is set to OFF when video acquisition module is used for the first time.
If you modify the Self-Timer setting, the option selected will be applied by default until a new option is selected.

To change the Self-Timer option, press the camera arrows buttons or select the desired option with a mouse click.
Your selection is applied immediately.

If no action is taken during 3s, the system automatically exits the menu.

5.4.2.6 CAMERA MODE

To access the Camera Mode menu, use the camera menu button or your mouse.
The menu offers two options:



The option selected is highlighted in blue.
The Intra-Oral Mode is the default option in the video acquisition module.

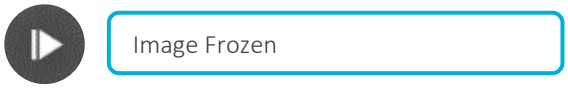
To change the option, press the camera arrows buttons or select the desired option with a mouse click.
Your selection is applied immediately.

If no action is taken during 3s, the system automatically exits the menu

5.4.2.7 IMAGE CAPTURE

The default option present in the Advanced Settings of the video acquisition module is Freeze After Capture.

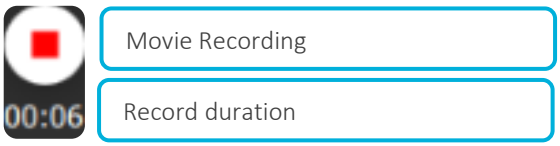
When this option is enabled and an image is captured either via the camera capture button or the video acquisition module Capture button , the image captured appears frozen and the capture button on the video acquisition module displays the following message:



As soon as an image is captured a white flash lasting less than a second appears on the video stream (*see image below*) denoting that an image has been taken.

5.4.2.8 MOVIE CAPTURE

When the record button is pressed in the video acquisition module or if the imaging software is running in movie mode, filming can be controlled via the camera capture button . As soon as the recording is in progress the movie capture button changes colour:

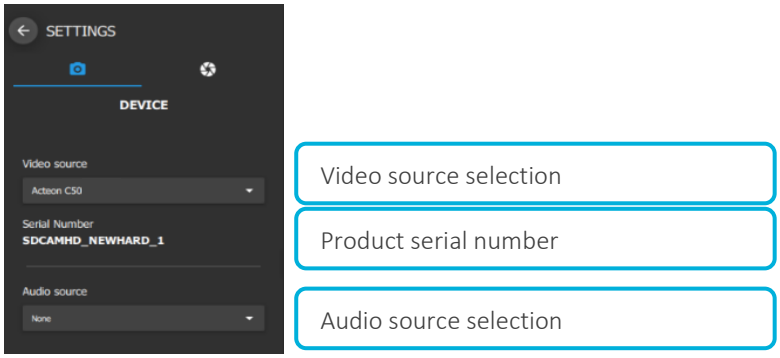


5.4.2.9 SETTINGS

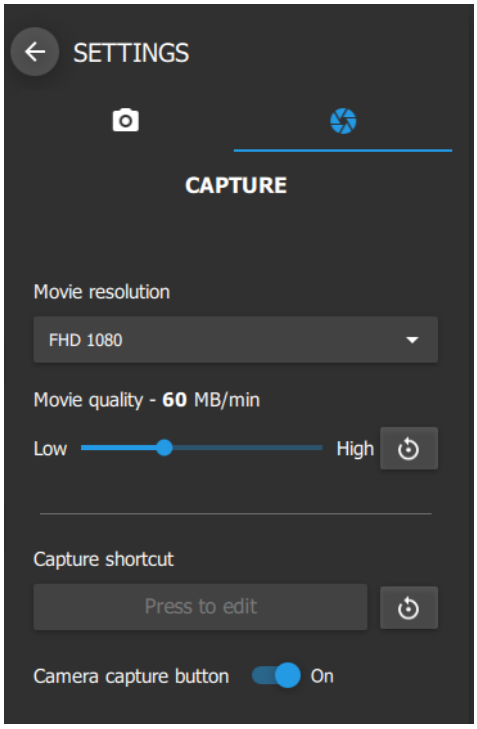
To access to the video acquisition module setting press the dedicated button present in the top left corner of the video acquisition module.

5.4.2.10 DEVICE SETTINGS

If a camera is already connected to the computer, the video source should be configured automatically.
NOTE: Only ACTEON cameras can be used with the video acquisition module.



5.4.2.11 CAPTURE SETTINGS



Movie Resolution: define the resolution of the movie

Movie Quality: define the movie compression quality

Capture shortcut: to define a shortcut to capture an image or a movie

Camera capture button: Enable or Disable

5.4.2.11.1 Movie resolution

The movie resolution can be defined in this setting:

- FHD 1080
- HD 720
- SD 540

5.4.2.11.2 Movie quality

Video quality compression can be adjusted from 30MB/minute to 120MB/minute.
The default value is 60MB/minute.

5.4.2.11.3 Capture shortcut

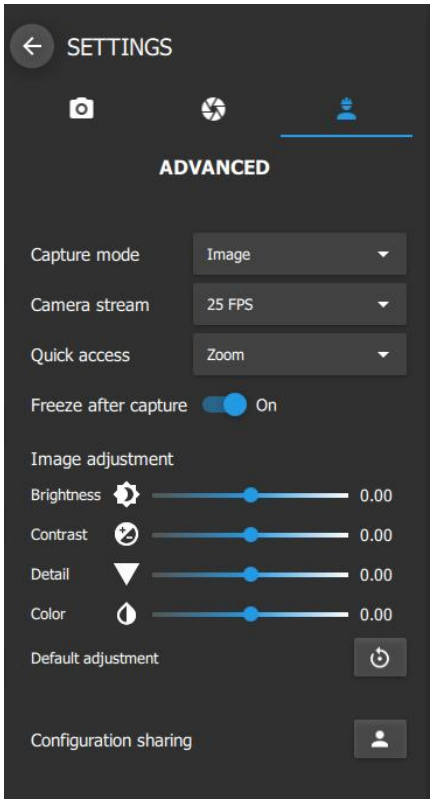
In accordance with the capture mode used (still image or movie), an image or a film can be captured by means of a shortcut defined in the dedicated field.
Select “Press to edit” and create a shortcut to use either the keyboard or the optional USB footswitch (ref.# 009009).

5.4.2.11.4 Reset to default settings

To return to the default value after having changed a setting, press the reset button .

5.4.2.12 ADVANCED SETTINGS

To access the Advanced Settings, use the toggle button “Advanced mode” option depicted below.
The following parameters can be adjusted on this menu:



Capture Mode: Define by the imaging software calling the video acquisition.

Camera Stream: Define by the user to fit the power line software frequency.

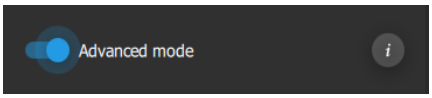
Quick Access: to define the default mode action for the camera arrows.

Freeze After Capture (see 5.3.2.6. Above)

Image Adjustment

Reset to default settings

Configuration sharing: to share the AVAM configuration with all computer's users.



Advanced Mode: Enable/Disable

5.4.2.12.1 Capture mode

When the imaging software is opened in Image mode, an image can be taken by pressing the camera capture button or by means of the user-defined shortcut.
When the imaging software is opened in Video mode, a movie can be taken by pressing the camera capture button or by means of the user-defined shortcut.

5.4.2.12.2 Camera stream

This option is defined by the computer region and language and can be changed if needed. Two options are provided:

- 25 FPS
- 30 FPS

5.4.2.12.3 Quick Access

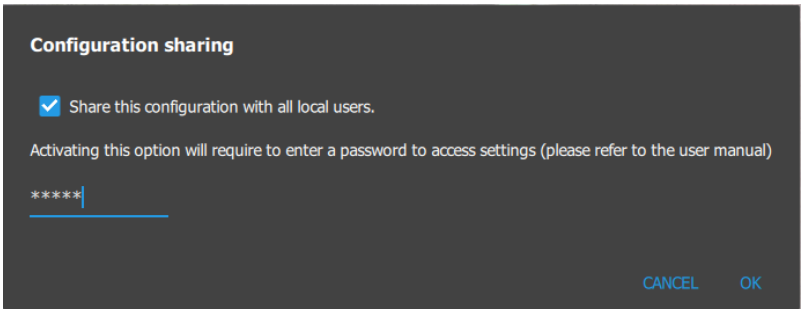
C50 with Fluorescence option disabled: default option ZOOM.
C50 with Fluorescence option enabled: default option DIAGNOSTIC AID.

5.4.2.12.4 Reset to default settings

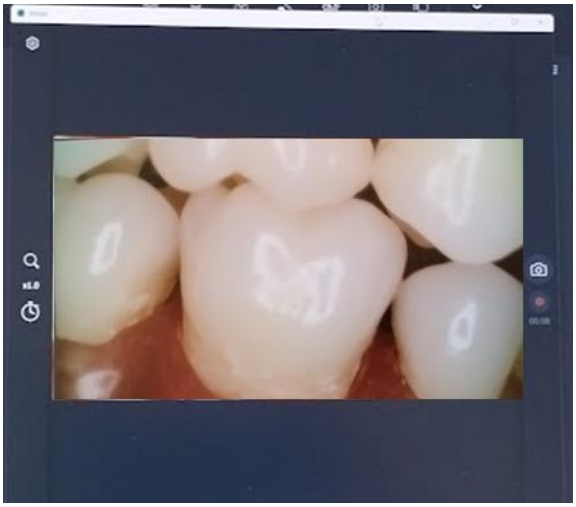
To return to the default value after having changed a setting, press the reset button .

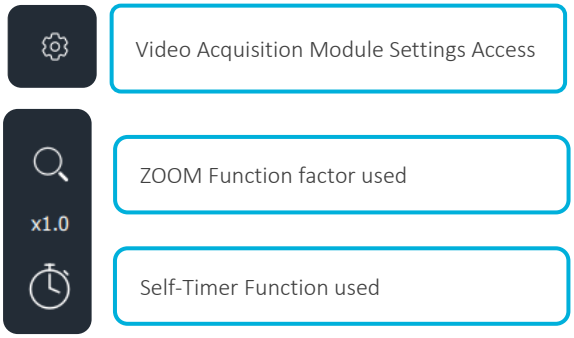
5.4.2.12.5 Configuration sharing

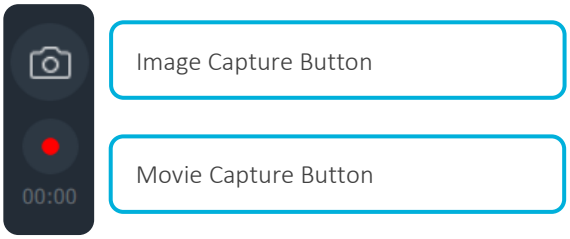
A password is required to share the module configuration with all the users of the computer: **admin.**



5.4.3 MAIN INTERFACE OF C20 INTRAORAL CAMERAS







5.4.3.1 DIGITAL ZOOM

To use the ZOOM:

The video acquisition module interface indicates the ZOOM factor as depicted bellow:

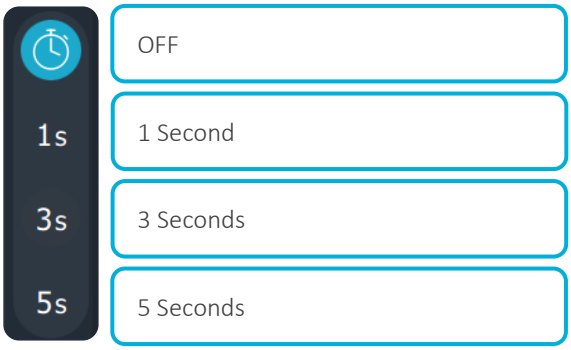
If the zoom menu thanks to the mouse, the behaviour is the following one:

To change the zoom factor, select the blue slider dot with a mouse to increase or decrease the magnification.
By default, the ZOOM factor is x1 each time you run the application.
The maximum digital zoom is x2.

If no action is taken during 3s, the system automatically exits the menu.

5.4.3.2 SELF-TIMER

To access the Self-Timer menu, use your mouse.
The menu offers four options:



The option selected is highlighted in blue.
The Self-Timer option is set to OFF when video acquisition module is used for the first time.
If you modify the Self-Timer setting, the option selected will be applied by default until a new option is selected.

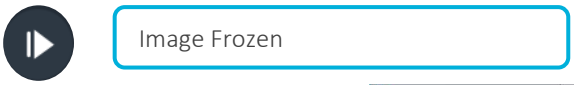
To change the Self-Timer option, select the desired option with a mouse click.
Your selection is applied immediately.
If no action is taken during 3s, the system automatically exits the menu.

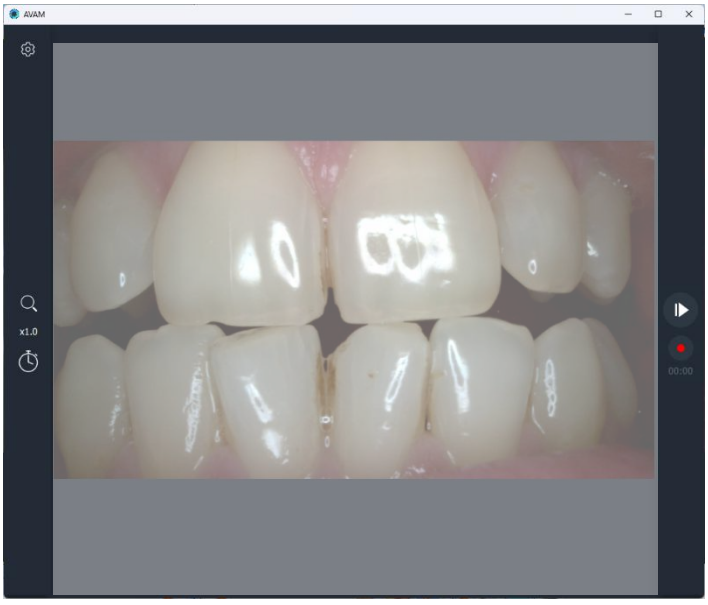
5.4.3.3 IMAGE CAPTURE

The default option present in the Advanced Settings of the video acquisition module is Freeze After Capture.

When this option is enabled and an image is captured, either via the camera capture button or the video acquisition module Capture button , the image captured appears frozen and the capture button on the video acquisition module displays the following message:

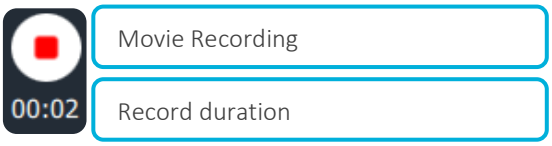
As soon as an image is captured a white flash lasting less than a second appears on the video stream (see image below), denoting that an image has been taken.





5.4.3.4 MOVIE CAPTURE

When the record button is pressed in the video acquisition module or if the imaging software is running in movie mode, filming can be controlled via the camera capture button . As soon as the recording is in progress the movie capture button appears as below:



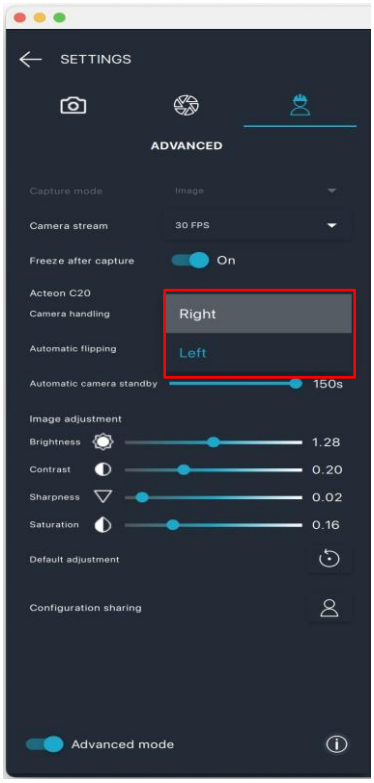
5.4.3.5 SETTINGS

To access to the video acquisition module setting, press the dedicated button present in the top left corner of the video acquisition module.

5.4.3.6 CAMERA HANDLING

The camera handling position help users to define their position according to patient left or right in order to get the object moving accordingly on the live video streaming.
If users are placed to the patient left, then the object will move from right to left on the live video streaming. While if they are on patient right, the object will move from left to right on the live video streaming.

This option can be adjusted through the AVAM advanced settings as below:

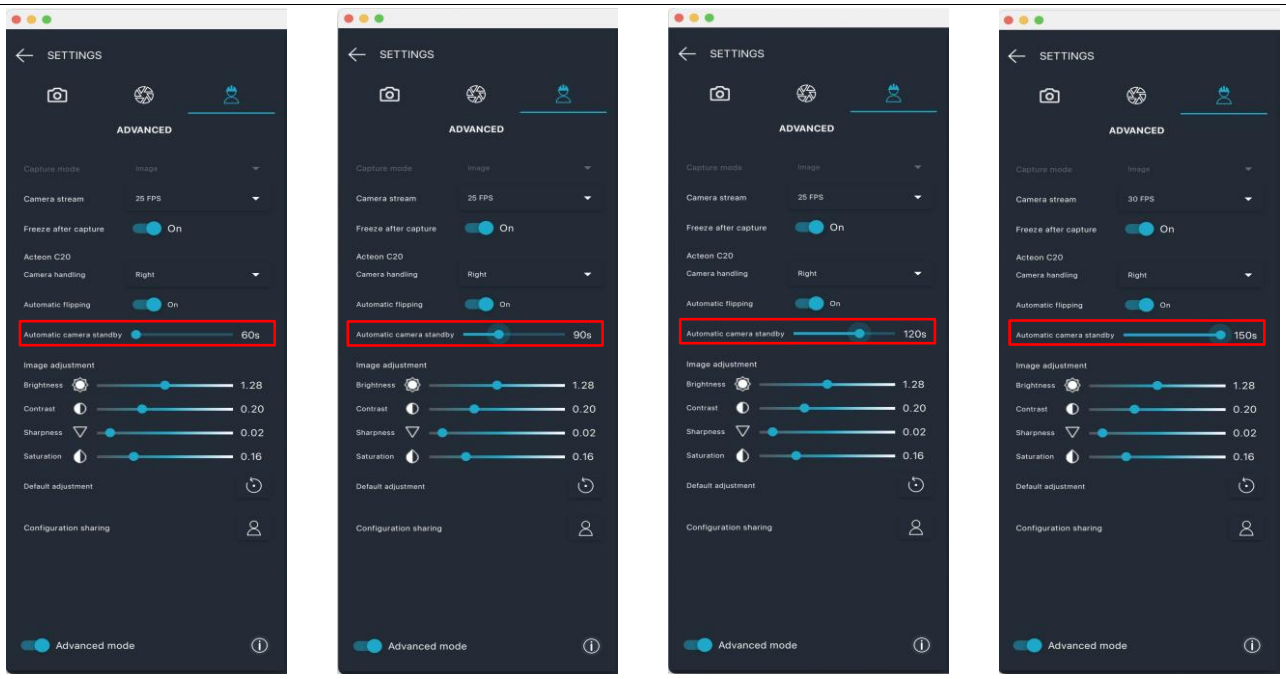


5.4.3.7 AUTOMATIC CAMERA STANDBY

The automatic camera standby allows to change the delay before the camera is going in eco-mode.

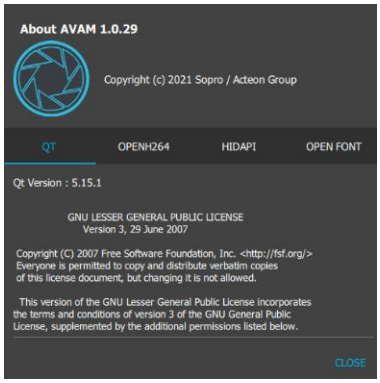
This option can be adjusted through the AVAM advanced settings. There are 4 steps adjustable possible through a slider from 60s to 150s with steps of 30s. The default value is set at 150s.

60s 90s 120s 150s



5.4.4 “ABOUT AVAM” WINDOW

Within the “Advanced Mode” is enabled, information about the video acquisition module can be accessed by pressing the icon. From the next window that opens, information on the video acquisition module version and all the licenses used by this application can be consulted.



5.5 STOP THE DEVICE

After use, disconnect the USB cable from the computer without pulling on the power cord.
Store the device in the handpiece holder.

6 CLEANING, DISINFECTION AND STERILIZATION

In accordance with EN ISO 17664, this section provides users with instructions for cleaning, disinfection, and sterilization of ACTEON reusable medical devices. All cleaning, disinfection and sterilization instructions provided by ACTEON for the company's medical devices and accessories have been validated. This section is applicable only to devices manufactured by ACTEON.
In countries where the reprocessing requirements are more stringent than those detailed in these Instructions for Use, the user must always comply with national guidelines, laws, and regulations.
Always follow the recommendations of the manufacturers of the products and equipment used.

Cleaning is defined as the removal of visible soil (e.g., organic, and inorganic material). Cleaning reduces the initial population of microorganisms, preventing blood proteins and other contaminants from drying on the devices, facilitating subsequent processing steps, and protecting personnel who handle medical devices, in addition to preventing contamination of the environment.
Disinfection reduces the number of pathogenic microorganisms, except bacterial spores.
The sterilization process is used to render a product free of viable microorganisms with a Sterility Assurance Level (SAL) of 10^{-6}.

6.1 DEVICES AND PROCESS TO APPLY

Handpiece and docking station must be disinfected before first use and after each use with a disinfecting wipe only. Do not immerse in a disinfecting liquid. Handpiece and docking station are not autoclavable.
SOPROTIPS & C50TIPS intraoral tips are reusable medical devices that are supplied non-sterile. They must be cleaned, and steam sterilized before first use and after each use thereafter.
The device must always be decontaminated before sending it to the after-sales service department.

6.2 CLEANING AND DISINFECTION OF SOPROCARE, SOPRO 617FIRST AND SOPRO 717FIRST INTRAORAL CAMERAS

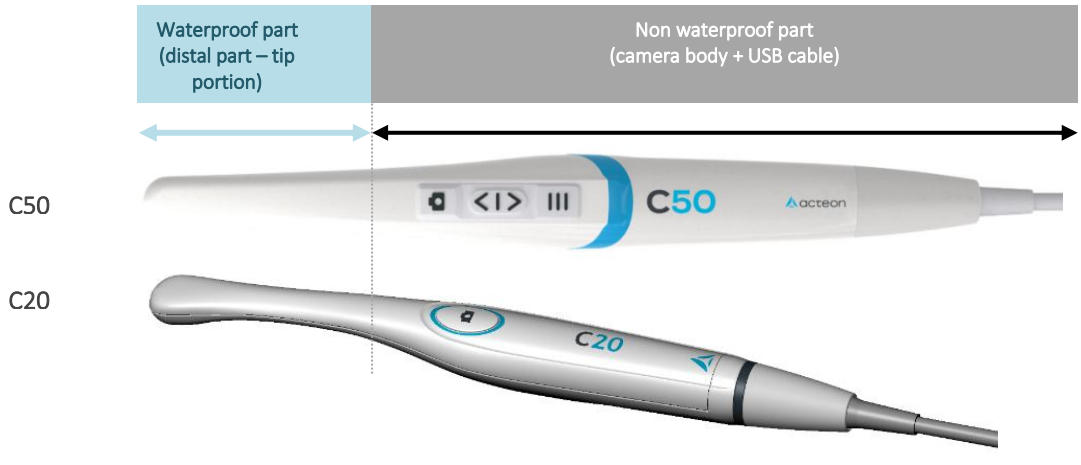
Only the handpiece is affected by the disinfection procedure described below.

In case of contact with blood or excessive soiling, it is strongly recommended to follow a disinfecting process.

Clean the handpiece with disinfecting wipes.
Wrap the handpiece in several disinfecting wipes and leave for 15 minutes.
Take off the wipes and remove excess moisture.
Wipe the equipment until visible cleanliness is obtained.
Allow to dry in the open air.
Carefully close the packaging box.
CAUTION: Do not scrub. Do not rinse. Do not immerse in a disinfecting liquid.
.

6.3 CLEANING AND DISINFECTION OF C50 AND C20 INTRAORAL CAMERAS

The design characteristics for reprocessing purposes are the same for C20 camera and C50 camera as illustrated below:



The reprocessing procedures to apply on the C20 handpiece (distal part / camera body), C20 USB cable and the C20 handpiece holder are the same procedures as for the C50 handpiece (distal part / camera body), C50 USB cable and the C50 Handpiece Holder.
For C20 and C50 cameras, the following procedures must be performed according to camera's part concerned:

Processing Procedures to follow:	**Waterproof part** of the cameras (C50/C20)		**Non waterproof part** of the cameras (C50/C20)	**USB Cable** of the cameras (C50/C20)	**Handpiece Holder** of the cameras (C50/C20)
	*If protective sheath **compromised** and / or if the camera is not reused immediately on another patient: **"Reprocessing Procedure / Delayed Reuse Procedure***	*If protective sheath is **not compromised : "Immediate Reuse Procedure"***			
Cleaning with wipes (*CaviWipes™*) then water	✓	✓	✗	✗	✗
High-Level Disinfection *(Cidex OPA)*	✓	✗	✗	✗	✗
Cleaning without water with wipes *(CaviWipes™)*	✗	✗	✓	✓	✓
Intermediate-Level Disinfection using wipes *(CaviWipes™)*	✗	✓	✓	✓	✓

6.3.1 CLEAN AND DISINFECT THE HANDPIECE HOLDER:

a) Put on new, clean gloves before performing the following steps.
b) Clean all accessible surfaces of the handpiece holder thoroughly with ready-to-use, lint-free cleaning, and disinfectant wipes for intermediate-level disinfection.
c) Dispose of used wipes.
d) Pull out a fresh disinfectant wipe from its container.
e) Disinfect all accessible surfaces of the handpiece holder with the disinfectant wipe. Leave the surface wet for 3 minutes. The handpiece holder is now ready for storage of the cleaned and disinfected intraoral camera.
f) Dispose of used wipes.

6.3.2 PREPARING THE INTRAORAL CAMERA FOR CLEANING:

a) After completing work with a patient, immediately take the intraoral camera to the reprocessing area.
b) Carefully remove the protective sheath toward the tip end of the camera to partially uncover the bottom half of the camera. DO NOT touch the uncovered portion of the camera with soiled gloves or hands!
c) Put on clean gloves to grip the uncovered portion of the camera.
d) Remove the protective sheath completely and set it aside for inspection.
e) Set the camera aside a clean and disinfected surface. DO NOT return the camera into the handpiece holder until the reprocessing procedure has been completed.
f) Immediately proceed to clean and disinfect the USB cable.

6.3.3 CLEAN AND DISINFECT THE USB CABLE:

a) Put on clean gloves to reprocess the USB cable.
b) Clean the USB Cable thoroughly with ready-to-use, lint-free cleaning, and disinfectant wipes for intermediate-level disinfection, making sure to remove any visible soil in accordance with the product manufacturer's instructions. Pay particular attention to the proximal end of the cable, i.e., the connector and the first 6" (15 cm) of the cable.
c) Dispose of used wipes.
d) Pull out a fresh disinfectant wipe from its container.
e) Disinfect the surface of the USB Cable connector and the first 6" (15 cm) of the cable with the disinfectant wipe. Leave the surface wet for 3 minutes. The USB Cable is now ready for reuse.
f) Dispose of used wipes.

6.3.4 INSPECTION OF PROTECTIVE SHEATH

a) To inspect the protective sheath, fill I with water and inspect it carefully for leaks:

- If water drops appear on the outside surface of the Protective Sheath or you observe water leaking or dripping from the sheath, its integrity has been compromised during use.
  Pour away the water, discard the sheath and follow the REPROCESSING Procedure below to reprocess the device prior to use on another patient.
- If no water drops, leaks, or dripping is observed, the integrity of the Protective Sheath was not compromised during use.
  Pour away the water, discard the sheath and follow the instructions for IMMEDIATE REUSE Procedure (if the intraoral camera is to be reused immediately on another patient) or DELAYED REUSE Procedure (if the intraoral camera is not reused immediately on another patient).

6.3.5 CLEANING AND DISINFECTING THE C20 AND C50 CAMERAS FOLLOWING THE SHEATH'S INTEGRITY

6.3.5.1 OPTION 1 "REPROCESSING PROCEDURE" - WHEN THE INTEGRITY OF THE PROTECTIVE SHEATH HAS BEEN COMPROMISED DURING USE:

a) Precleaning – Put on new gloves before the following steps:
- Clean the tip portion of the intraoral camera carefully and thoroughly with a ready-to-use, lint-free cleaning/disinfection wipe such as CaviWipes™ until it is visibly clean. Discard the wipe.
- Using a new cleaning/disinfection wipe such as CaviWipes™, pre-clean the remaining parts of the device.
- Dispose of used wipes in accordance with Federal, State, and local regulations for infectious materials disposal.

b) Main Cleaning
- Turn on the faucet and let the water run at room temperature 70°F - 75°F (20-25°C). Adjust the water pressure to low to avoid splashing during the cleaning process.
- Hold the intraoral camera angled downward. You will only be introducing the device tip portion into the running water. The device tip portion consists of the camera lens and the smooth white part of the device above the control buttons.
- Rinse the device tip portion under running tap water for 1-2 minutes.
- As you rinse, thoroughly brush the device tip and lens area with a soft brush to remove any contamination.
- After conclusion of the rinsing and brushing process, inspect the device tip to ensure that it is visibly clean.
- Should any visible contamination remain, repeat the above steps.
- When the device is visibly clean, use a clean and dry lint-free tissue to rough dry the device.
- Using a new cleaning/disinfection wipe such as CaviWipes™, clean the non-waterproof part of the device.
- Dispose of used wipes in accordance with Federal, State, and local regulations for infectious materials disposal
- Proceed to disinfection.

c) High Level Disinfection
- Prepare a suitable container (glass) to disinfect the tip portion of your intraoral camera. The container must be approximately 1.9" (5 cm) wide and 4.7"-5.9" (12-15 cm) high.
- Fill the container to a height of 2.7"-3.1" (7-8 cm) with an high-level disinfection solution for semi-critical medical devices (such as CIDEX™ OPA Solution). CAUTION: Do not go above a level of 3.1" (8 cm).
- Turn the intraoral camera upside down and immerse the tip portion of the device in the disinfection solution to destroy all pathogenic microorganisms. CAUTION: Carefully follow the disinfectant manufacturer's instructions with regard to temperature and dwell time. (For instance, CIDEX™ OPA Solution requires a minimum dwell time of 12 minutes at 20°C (68°F) or higher.)
- Remove the device from the solution and rinse thoroughly following the rinsing instructions below. CAUTION: If possible, use sterile water to rinse the device. If sterile water is not available, potable water may be used. Preferably, the potable water system should include a bacterial retentive (0.2 micron) filter. CAUTION: NEVER immerse the non-waterproof part of the camera (between tip portion and USB connection) in the disinfectant.
- Turn on the faucet and let the water run at room temperature 70°F - 75°F (20-25°C). Adjust the water pressure to low to avoid splashing during the cleaning process.
- Hold the intraoral Camera angled downward. You will only be introducing the device tip portion into the running water. The device tip portion consists of the camera lens and the smooth white part of the device above the control buttons.
- Thoroughly rinse the device tip portion under running water for 2-3 minutes. Turn the device as you rinse the tip to ensure that the disinfection solution is rinsed off completely.
- Let the intraoral camera air-dry completely on a disinfected surface.
- Discard your gloves used for the previous step and put on new ones.

- Disinfect the non-waterproof part of the intraoral camera carefully and thoroughly with a ready-to-use, lint-free cleaning/disinfection wipe (such as CaviWipes™).
- Leave the surface wet for 3 minutes.
- Dispose of used wipes in accordance with Federal, State, and local regulations for infectious materials disposal.

6.3.5.2 OPTION 2 "IMMEDIATE REUSE PROCEDURE" - IF THE PROTECTIVE SHEATH WAS NOT COMPROMISED AND THE INTRAORAL CAMERA IS TO BE REUSED IMMEDIATELY:

Prepare the device for use by wiping the intraoral camera carefully and thoroughly with a ready-to-use, lint-free cleaning/disinfection wipe (such as CaviWipes™). Discard the wipe.

- Turn on the faucet and let the water run at room temperature 70°F - 75°F (20-25°C). Adjust the water pressure to low to avoid splashing during the cleaning process.
- Hold the intraoral camera angled downward. You will only be introducing the device tip portion into the running water. The device tip portion consists of the camera lens and the smooth white part of the device above the control buttons.
- Thoroughly rinse the device tip portion under running water for 2-3 minutes. Turn the device as you rinse the tip to ensure that the disinfection solution is rinsed off completely.
- Place the camera on a clean, disinfected surface to dry completely.
- Using a new cleaning/disinfection wipe such as CaviWipes™, clean the non-waterproof part of the device. Discard the wipe.
- To prepare the intraoral handpiece holder, use a new cleaning/disinfection wipe to thoroughly wipe all its surfaces, starting from the inside. Discard the wipes after use.
- Cover the dry intraoral camera with a protective sheath and a SOPROTIPS as described in section "Use of the Single Use Protective Sheath" and in section "Use of SOPROTIPS".
- Place the intraoral camera into the previously disinfected intraoral camera handpiece holder.
- The camera is now ready for use.

6.3.5.3 OPTION 3 "DELAYED REUSE PROCEDURE" - IF THE INTRAORAL CAMERA IS NOT TO BE REUSED IMMEDIATELY ON ANOTHER PATIENT FOR INSTANCE AT THE END OF A WORKDAY, THE DEVICE MUST BE REPROCESSED IN ACCORDANCE WITH THE REPROCESSING PROCEDURE PROVIDED ABOVE.

- After completion of the reprocessing procedure, store the reprocessed intraoral camera in a designated, limited-access, closed storage cabinet that is clean and dry and provides protection from dust, moisture, insects, vermin, and extreme temperatures.
- Before use on a new patient, prepare the device for use by following the Immediate Use Procedure described above.

6.4 CLEANING, DISINFECTION AND STERILIZATION OF INTRAORAL TIPS (C50TIPS AND SOPROTIPS)

6.4.1 CLEANING AND DISINFECTION

a) Wash hands using correct technique and mild foam soap and dry with disposable paper towels.

Wear appropriate PPE (disposable gloves, goggles, surgical mask, face shield etc.). Immediately after use, rinse the intraoral tip for 1 minute with warm (not hot) tap water at 20-25°C taking care to brush the inside surface of the tip with a small nylon brush.
CAUTION: Do not use steel wool or wire brushes. Be sure to remove all blood, fluids, and tissue.

b) Submerge the SOPROTIPS or C50TIPS in a detergent and disinfectant solution freshly prepared with ANIOS's Clean Excel D diluted to 0.5 %, which was used for cleaning validation. If ANIOS Clean Excel D is not available, be sure to select a detergent and disinfectant designed to reduce the risk of surface biofilm formation on medical device, possessing demonstrated antimicrobial efficacity and a pH of 7.4 at 0.5% dilution in mains water.
c) Leave the device to soak for at least 15 minutes. Please refer to the detergent manufacturer's instructions for use. This step is intended to reduce the risk of surface biofilm formation on the medical device.
d) Manual cleaning: Brush the intraoral tip with a stiff plastic (nylon) cleaning brush in a detergent solution prepared in accordance with the manufacturer's instructions (for instance, a 0.5% solution of ANIOS's Clean Excel D).
e) CAUTION: Do not use steel wool or wire brushes.
f) Visually inspect the device to ensure that all contamination has been removed.

g) Let it dry completely, then package the SOPROTIPS or C50TIPS in a single sterilization pouch compatible with steam sterilization and complying with the ISO 11607-1 and EN 868-5 standards in force. If possible, proceed immediately to sterilization.

6.4.2 STERILIZATION OF INTRAORAL TIPS (C50TIPS AND SOPROTIPS)

SOPROTIPS and C50TIPS must be carefully cleaned prior to sterilization (all visible organic material, blood and cleaning solution must be completely eliminated).
SOPROTIPS and C50TIPS must be packaged in an individual single-use sterilization pouch. The approved sterilisation settings apply only to sterilisation equipment which is properly serviced and calibrated.
Any deviation from the recommended sterilisation settings must be validated by the user.

6.4.3 STEAM STERILIZATION STEPS

a) Place the intraoral tips in a single-use sterilization pouch compatible with steam sterilization complying with the ISO 11607-1 standard. Please refer to manufacturer's instructions for use for proper sizing and use of sterilization pouches.

NOTE: ACTEON recommends the use of self-seal sterilization bags for routine steam sterilization in dental offices. Self-seal pouches are pre-folded and assure accurate and fast closing without the requirement of a heat-sealing device. They are especially suited for use in small general practices, dental surgeries and by users who want to avoid the cost of additional sealing equipment and they are made of high-grade medical paper and multilayer PET/PP copolymer film.

b) Place the packaged device correctly and loosely into a prevacuum class B sterilizer so as not to impede penetration of the sterilant (moist heat).

c) Autoclave using with the following parameters:

Steam Sterilization Prevacuum cycles validated by the manufacturer	Temperature	Time	Drying time	Maximum number of sterilization cycles
USA cycle	132°C	4 minutes	30 minutes	50 cycles
UK cycle	134°C	3 minutes		
FRANCE cycle		18 minutes		
CHINA cycle		5 minutes		

d) Sterile device should be stored in a manner that does not compromise packaging.

CAUTION:

- ☞ Packages should always be inspected and evaluated before use for loss of integrity (e.g., torn, punctured or wet).
- ☞ Any package that has fallen on the floor must be inspected for damage to the packaging and its contents.
- ☞ If the package is heat-sealed in impervious plastic and the seal is still intact, the package can be considered not contaminated. If undamaged, items in packaged plastic need not be reprocessed.
- ☞ If the integrity of the package is compromised, repack, and reprocess the pack before use.

7 MAINTENANCE AND AFTER-SALES SERVICE

7.1 MAINTENANCE

No preventive maintenance for cameras.
The camera must be used as intended by the manufacturer by:
• Checking associated accessories.
• Following cleaning, disinfection, and/or sterilisation procedures described previously.

WARNING: Any incorrect use of the device is not covered by the guarantee.
If a problem persists and the device needs to be returned to the after-sales department, make sure it is sent in its original packaging. Please return all components of the device (the camera, the power supply cable, and the control unit). Make sure to include an explanation of the problem you have encountered with your shipping form.

7.2 AFTER-SALES SERVICE

WARRANTIES: ACTEON guarantees its products to be free from material and manufacturing defects for a period of two (2) years from the date of purchase. This warranty does not apply to misused, modified, untended, or accidentally damaged products nor to products subject to abnormal use and handling conditions. The distributors, other than ACTEON Group's subsidiaries, are not authorized to apply an extended warranty period on behalf of ACTEON.
The entire liability of ACTEON is limited to discretionary replacement or repair of the defective product free of charge if it has been sent to ACTEON After-Sales Service. This applies to the warranty period only.
Outside of France, access to the warranty is only possible if the product was bought at a point of sale by an authorized ACTEON dealer in the country where it will be used.
THIS WARRANTY APPLIES ONLY TO THIS UNIQUE RECOURSE. IT REPLACES ANY OTHER WARRANTY, FOR EXAMPLE, A WARRANTY OF ADEQUACY TO A PARTICULAR AIM, EXPLICIT OR IMPLICIT. ACTEON SHALL NOT BE LIABLE FOR ANY PARTICULAR DAMAGE, INDIRECT, ACCIDENTAL OR CONSEQUENTIAL NOR FOR ANY DETERIORATION OR DATA LOSS, ON A CONTRACTUAL, NONCONTRACTUAL OR OTHER BASIS.
The liability exclusion or limitation for direct or indirect damages does not apply under the regulatory or legal rules in force in some countries and the present exclusion may not apply to a purchaser in those countries.

WARNING: The equipment must be disinfected prior to return for repairs. When returning the equipment, check its condition and note down any anomalies on the shipping form as necessary. Confirm those anomalies to the carrier by recorded letter within 48 hours. If equipment shipped by us suffers damage during transport, the total cost of repairs will be billed to the carrier if exceptions have been communicated within the deadline, otherwise such charges will be billed to the addressee.

7.3 TROUBLE SHOOTING

Problems	Causes	Solutions
No image displays on the screen and the camera LEDs are not on.	•Defective power supply •Connection problem	1. Check whether the power supply is correctly connected to the computer and to the connection box. 2. Check whether the connecting cable is correctly connected to the handpiece and to the connection box.
The camera switches on but no image displays on the screen.	•Configuration •Driver •Connection problem	1. Check whether the camera is correctly set up in the imaging software. 2. Check whether the camera is correctly detected by the device driver (correct installation of its driver). 3. Check the USB cable coming from the DOCK is correctly connected to the HUB.
An image displays on the screen, but the quality is not satisfactory.	Camera driver configuration	Check the camera configuration in the imaging software (brightness, contrast, saturation, etc.).
An image displays, but it is not really clear (blurry).	Protective sheath	Check whether the protective sheath is correctly positioned on the camera head.
poor image colour (blue)	video settings are not correct in the third-party software	When using a third-party imaging software, it is necessary to go in the Video Settings and click on the Default button

		to get the correct default settings from the camera and obtain an image with the actual hue

The camera should be sent to ACTEON in its totality (docking station, handpiece, and cables). Please include a brief explanatory note with regard to the defect you have encountered. If some parts constituting the camera happen to break, it is imperative to send in everything so that all defective parts can be replaced. When you received repaired product, check its condition, and note any discrepancies on the delivery slip, if necessary. You will then have 48 hours to confirm by registered letter sent to the carrier. After 48 hours, the carrier will be able to reject these discrepancies. If any material we sent was damaged during transportation, the repair charges will be billed either to the carrier (if the discrepancies were made within the period) or to the recipient. Check as soon as possible that all material is correctly working.

For any other problems, contact your nearest after-sales service department.

8 ELECTROMAGNETIC COMPATIBILITY

All the information below is based on the requirements of standards to which the manufacturers of electrical medical devices must adhere, as stated in standard IEC 60601-1-2.
The medical device complies with the electromagnetic compatibility standards in force.
However, the user must make sure that any electromagnetic interference does not create an additional risk, such as radio-frequency transmitters or other electronic devices.
This chapter contains the information required for you to install and use your medical device in optimum conditions in terms of electromagnetic compatibility.
Different medical device leads must be kept separate from each other.
Sometimes mobile telecommunication devices such as mobile phones can interfere with the medical device. The recommended separation distances in this chapter must therefore be strictly observed.

WARNING: The use of accessories, transducers, and cables other than those specified or sold by ACTEON as replacement parts, may have as a consequence an increase of emission or decreased immunity of the medical device and result in inadequate operation.

8.1 CABLES LENGTH

CABLES	MAXIMUM LENGTH
USB connection cable	< 3 m

8.2 APPLICABLE TESTS

TEST TYPE	IN COMPLIANCE WITH	APPLICABLE (A) NON-APPLICABLE (N/A)
EMISSION STANDARDS		
Terminal disturbance voltages	CISPR 11	A *N/A for C50 intraoral camera* *N/A for C20 intraoral camera*
Radiation disturbance	CISPR 11	A
Terminal disturbance voltages	CISPR 14-1	*N/A*
Disturbance Power	CISPR 14-1	*N/A*
Radiated disturbances	CISPR 14-1	*N/A*
A.C Mains Harmonic	IEC 61000-3-2	*N/A*
AC-Mains Voltage fluctuations and flicker	IEC 61000-3-3	*N/A*
IMMINUTY STANDARDS		
Electrostatic discharge	IEC 61000-4-2	A
Radiated RF electromagnetic field	IEC 61000-4-3	A
Electrical fast transient/burst	IEC 61000-4-4	A *N/A for C20 intraoral camera*
Surge	IEC 61000-4-5	*N/A*
Conducted disturbances induced by RF fields	IEC 61000-4-6	A
Rated power frequency magnetic fields	IEC 61000-4-8	A
Voltage dips	IEC 61000-4-11	*N/A*
Voltage interruptions	IEC 61000-4-11	*N/A*
Electrical transient conduction along supply lines	ISO 7637-2	*N/A*
Immunity to proximity fields from RF wireless communications equipment	IEC 60601-1-2 (Table 9)	A
Immunity to proximity magnetic fields	IEC 61000-4-39	A

8.3 RECOMMENDED SEPARATION DISTANCES

The medical device is designed to be used in an electromagnetic environment in which interferences due to RF radiation are controlled.
The user or installer of the medical device can help prevent any electromagnetic interference by applying a minimum distance, according to the maximum power of the radio-frequency transmission equipment.

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.

WARNING: Portable RF communications devices (including peripherals such as antenna cables and external antennas) should not be used closer than 30 cm (12 inches) to any part of the medical device, including specified cables by the manufacturer. Otherwise, the performance of these devices could be impaired.

8.4 ELECTROMAGNETIC EMISSIONS

The medical device is designed for use in the electromagnetic environment described in the table below. The user and/or installer must therefore ensure that the medical device is used in the environment described below.

EMISSION TEST	CONFORMITY	ELECTROMAGNETIC ENVIRONMENT - COMMENTS
Applied limit group	Group 1	The EMISSIONS characteristics of this device allow it to be used in industrial areas and hospitals (Class A as defined in CISPR 11). When used in a residential environment (for which Class B as defined in CISPR 11 is normally required), this device may not provide adequate protection to radio frequency communications services. The user may need to take corrective action, such as relocating or reorienting the equipment.
Applied limit class	Class B	
A.C Mains Harmonic *IEC 61000-3-2*	Applicable	Professional healthcare facility environment and home healthcare environment.
AC-Mains Voltage fluctuations and flicker *IEC 61000-3-3*	Applicable	

The medical device is intended for use in a professional healthcare environment (hospital, clinic) and in a home healthcare environment (dental office in a residential area).
The user and installer should therefore ensure that the medical device is used in the environment described below.

For the professional healthcare environment, the medical device should not be used in the vicinity of electrosurgery equipment or in the vicinity of an electromagnetically shielded room for magnetic resonance imaging (MRI) equipment where the intensity of electromagnetic disturbances is high.

8.5 MAGNETIC AND ELECTROMAGNETIC IMMUNITY

The medical device is designed for use in the magnetic and electromagnetic environment described in the table below. The user and/or installer must ensure conformity of the electromagnetic environment.

ELECTROMAGNETIC ENVIRONMENT	Professional healthcare facility environment and home healthcare environment.

IMMUNITY TEST	TEST LEVEL APPLIED	TEST LEVEL (IEC 60601-1-2)
Electrostatic discharge *IEC 61000-4-2*	Contact discharge voltage: ± 8 kV Air discharge voltage : ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV	
Radiated RF electromagnetic field *IEC 61000-4-3*	Test level: 10 V/m Frequency bandwidth: 80 MHz to 2700 MHz Modulation: 80 % AM at 1 kHz Frequency step: 1%	
Immunity to proximity fields from RF wireless communications equipment *IEC 60601-1-2 (Table 9)*	Immunity level :9 V/m Test frequency: 710 MHz, 745 MHz, 780 MHz, 5240 MHz, 5500 MHz, 5785 MHz Immunity level: 27 V/m Test frequency: 385 MHz Immunity level: 28 V/m	

IMMUNITY TEST	TEST LEVEL APPLIED	TEST LEVEL (IEC 60601-1-2)
	Test frequency: 450 MHz, 810 MHz, 870 MHz, 930 MHz,1720 MHz, 1845 MHz, 1970 MHz, 2450 MHz	
Electrical fast transient/burst Port : D.C. mains & SIP/SOP *IEC 61000-4-4*	Test level (DC port): 2 kV Coupling Method: Direct injection Repetition frequency: 100 kHz Test level (SIP/SOP port): 1 kV Coupling Method: Capacitive clamp Repetition frequency: 100 kHz	
Conducted disturbances induced by RF fields Port : D.C. mains & SIP/SOP *IEC 61000-4-6*	Level: 3 V RMS outside the ISM band, 6 V in the ISM and amateur radio bands Frequency step: 1% Modulation: 80% Am with 1 kHz	
Rated power frequency magnetic fields *IEC 61000-4-8*	Test level: 30 A/m Frequency: 50 and 60 Hz	
Immunity to proximity magnetic fields *IEC 61000-4-39*	8 A/m - 30 kHz 65 A/m - 134.2 kHz 7.5 A/m – 13.56 MHz	

9 TECHNICAL DESCRIPTION

9.1 ENVIRONMENTAL CONDITIONS

Transport temperature	-20 °C / +45 °C
Storage temperature	+10 °C / +40 °C
Operating temperature	+10 °C / +40 °C
Relative humidity (transport, storage and operating)	10% to 90%
Transport, storage and operating atmospheric pressure	700 hPa to 1060 hPa
Electrical classification (IEC 60601-1)	N/A (Powered by USB port from an external IT equipment)
Applied part	Type BF
Photobiological risk group (IEC 62471)	Risk 1 (Exempt for SOPRO 617 and C20 intraoral camera)
This medical device complies with the following international standards: IEC 60601-1, IEC 60601-1-2, IEC 60601-4-2; IEC 60601-2-18 ; IEC 60601-1-6, ISO 14971, ISO 15223-1, IEC 62304, IEC 62366-1 ; IEC 62471 & IEC 80601-2-60	

9.2 TECHNICAL CHARACTERITICS

9.2.1 SOPRO 617 INTRAORAL CAMERA

Sensor	CCD 1/4”
Resolution	(752 x 582) PAL; (768 x 494) NTSC
Definition	470 lines
Lighting	8 LEDs
Adjustment	Automatic
Image	Non-inverted
Image capture	SoproTouch or footswitch (optional)
Field Of View Diagonal (FOVD)	80°
Cable length	2.5m
Handpiece dimensions	L: 205; W: 28; H: 24 mm
Usable part dimensions	W: 16 x D: 11.10 mm
Handpiece weight	55 g
continuous service	/
IP Protection	IPX0 - Not protected against water chutes

9.2.2 SOPRO 717FIRST INTRAORAL CAMERA

Sensor	CCD 1/4”
Resolution	(752 x 582) PAL; (768 x 494) NTSC
Definition	470 lines
Lighting	8 LEDs
Adjustment	3 pre-set positions (Extra-oral, Intra-oral, Macro)
Image	Non-inverted
Image capture	SoproTouch or footswitch (optional)
Field Of View Diagonal (FOVD)	70°
Cable length	2.5m

Handpiece dimensions	L: 200; W: 28; H: 24 mm
Usable part dimensions	W: 14.25 x D: 8.75 mm
Handpiece weight	78 g
continuous service	/
IP Protection	IPX0 - Not protected against water chutes

9.2.3 SOPROCARE INTRAORAL CAMERA

Sensor	CCD 1/4"
Resolution	(752 x 582) PAL; (768 x 494) NTSC
Definition	470 lines
Lighting	7 LEDs
Adjustment	4 pre-set positions (Extra-oral, Intra-oral, Tooth, Macro)
3 positions	PERIO mode, CARIO mode and DAYLIGHT mode
Image	Non-inverted
Image capture	SoproTouch or footswitch (optional)
Field Of View Diagonal (FOVD)	70°
Cable length	2.5m
Handpiece dimensions	L: 200; W: 28; H: 24 mm
Usable part dimensions	W: 14.4 x D: 8 mm
Handpiece weight	78 g
continuous service	/
IP Protection	IPX0 - Not protected against water chutes

9.2.4 C50 INTRAORAL CAMERA

Sensor	CMOS
Resolution	1920 x 1080
Distortion	6% maximum
FPS	25 – 30
Aspect Ratio	16/9
Lighting	6 LEDs
Focus adjustment	Automatic focus or Single focus
4 Visions Mode	DAYLIGHT, DAYLIGHT+ If option enabled: PERIO, CARIO
Image capture	Capture button or footswitch (optional)
Field Of View Diagonal (FOVD)	75°
Cable length	3m
USB output	3.0
Consumption	4,5W maximum
Handpiece dimensions	L: 200; W: 30; H: 24 mm
continuous service	/
Handpiece weight	100g
IP Protection	IP53

9.2.5 C20 INTRAORAL CAMERA

Sensor	CMOS
Resolution	1920 x 1080
Distortion	-8%
FPS	25 – 30
Aspect ratio	16/9
Lighting	8 LEDs
Adjustment	Fixed focus
Image	DAYLIGHT
Image capture	Capture button or footswitch (optional)
Field Of View Diagonal (FOVD)	70°
Cable length	3m
USB output	2.0
Consumption	2,5W maximum
Handpiece dimensions	L:200,9 ; W: 26,9 ; H: 23,3 mm
Handpiece weight	35 g
continuous service	/
IP Protection	IP53

9.2.6 MINI DOCK USB2

Cable length	2.5 m
Digital USB output 2.0	X1
Controller dimensions	L: 64.50; W: 26; H: 11 mm
Dock weight	97 g
continuous service	/
IP Protection	IPX0 - Not protected against water chutes

9.2.7 MINI DOCK U_USB2

Consumption	2.5 VA
Digital USB output 2.0	X1
Controller dimensions	L: 48; W: 48; H: 30 mm
Dock weight	22 g
continuous service	/
IP Protection	IPX0 - Not protected against water chutes

10 DISPOSAL AND RECYCLING

This device bears a recycling symbol. By correctly disposing of this device, you will help prevent any harm to the environment and to human health.

The symbol  present on the device or in the accompanying documentation shows that this product cannot under any circumstances be processed as domestic waste. It must therefore be disposed of at a waste centre designated for the recycling of electrical and electronic equipment.

For disposal, please comply with current rules concerning waste disposal in the country of installation.
To obtain further detailed information about the processing, salvage, and recycling of this device, please contact your nearest retailer who will tell you how to proceed.

11 REGULATORY INFORMATION

11.1 APPLICABLE STANDARDS AND REGULATIONS

The medical devices comply with the requirement on medical devices.
They were designed and manufactured in accordance with an EN ISO 13485-certified quality assurance system.
The information in these Instructions for Use is based on the requirements of standards to which the manufacturers of medical devices must adhere, as stated in standard IEC 62366-1.

11.2 MEDICAL DEVICE CLASSIFICATION

The devices concerned by these Instructions for Use and manufactured by ACTEON are class I medical devices in accordance with the European regulation on medical devices.

11.3 VIGILANCE

Any serious incident concerning the medical device or its accessories, except for the expected secondary effects must be reported to the relevant competent authorities and to the manufacturer as soon as possible. Generally, the notification period should consider the seriousness of the incident.
Consult local applicable regulations.
Manufacturer's contact details: please see the last page of the Instructions for Use.

11.4 MANUFACTURER'S RESPONSIBILITY

Failure to comply with the recommendations provided by the manufacturer in this document and those supplied subsequently in written, electronic, or whatever other form will render the warranty null and void. The manufacturer shall be released from any liability, including for direct or indirect injuries to persons or damage to property and the environment. Furthermore, the managers of the facility, customers or collaborators shall be held liable for any damage and/or accidents and/or deterioration of patients' or operators' health or of the surrounding environment.

12 SYMBOLS

	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Indicates the medical device manufacturer.
	Indicates the date when the medical device was manufactured.
	Indicates the manufacturer's serial number so that a specific medical device can be identified.
	Indicates a medical device that has not been subjected to a sterilization process.
	Indicates a medical device that should not be used if the package has been damaged or opened and that the user should consult the Instructions for Use for additional information.
	Indicates the temperature limits to which the medical device can be safely exposed.
	Indicates the range of humidity to which the medical device can be safely exposed.
	Indicates the range of atmospheric pressure to which the medical device can be safely exposed.
	Indicates a medical device that is intended for one single use only.
	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action to avoid undesirable consequences.
	Indicates on product or product packaging that relevant Instructions for Use of the product is available in electronic form rather than, or in addition to, printed paper form.
	Follow Instructions for Use.
	Indicates a carrier that contains Unique Device Identifier information.
	Indicates on the rating plate that the equipment is suitable for direct current only; to identify relevant terminals.
	On medical equipment. To identify a type of BF applied part complying with IEC 60601-1. *B: Body / F: Floating applied part*
	Indicates the product (put on the market after 13/08/2005) cannot under any circumstances be processed as domestic waste. It must therefore be disposed of at a waste centre designated for the recycling of electrical and electronic equipment.
	Indicates the item is a medical device.
	Indicates correct upright position of the transport package.
	Indicates a medical device that can be broken or damaged if not handled carefully.
	Indicates a medical device that needs to be protected from moisture.

SOPRO a company of ACTEON Group | ZAC Athélia IV | Av. Des Genévriers |
13705 LA CIOTAT Cedex | FRANCE
Tel. +33 (0) 442 980 101 | Fax. +33 (0) 442 717 690
E-mail: info@acteongroup.com
www.acteongroup.com