INSTRUCTIONS FOR USE

C50
& ACCESSORIES

CONTENTS

1 FOREWORD

Thank you for your confidence and for buying the C50 intraoral camera. It is essential that you familiarize yourself with the contents of these instructions for use. It will help you get the best out of the C50 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 C50 and accessories.

Note with regard to UDI codes: custom products have a different UDI from the one shown on the cover of this manual. 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 C50 and its accessories.

The instructions for use are 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.

1.1 ASSOCIATED DOCUMENTATION

These instructions for use must be used in association with the following documents:

- Quickstart: 011809

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 C50 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 user instructions are available in PDF format (Portable Document Format). You will need to have PDF reader software installed to read the electronic version of the user instructions. It is important for you to read and understand the content of the user instructions 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 C50 instructions for use can be consulted at the following address:
www.acteongroup.com

As soon as you receive the C50 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 C50 instructions for use. Keep the documents on hand for consultation when necessary. All printed and electronic documentation relating to the C50, and its accessories must be retained for the devices' entire service life.
Please retain all original documentation relating to the C50 and its accessories for reference at a later date. When loaning out or selling the C50, the documentation must be provided with it.

2 SAFETY INSTRUCTIONS

Caution: United States Federal law restricts medical devices to sale by or on the order of a dentist." (21CFR 801.109(b)(1))

2.1 CONTRAINDICATIONS

None known.

2.2 WARNINGS

- The maximum temperature at the light emission is 52°C.
- When handling C50, C50TIPS and the single-use FDA-cleared protective sheaths of your choice, such as the UNiPACK Barrier Sleeves catalog number UBC-820855 recommended by Sopro, always take the appropriate hygiene measures and precautions to prevent cross-contamination.
- Follow the Cleaning / Disinfection / Sterilization procedures described in §6 between each patient; failure to do this could result in cross-contamination.
- Make sure that the C50 camera is covered throughout the procedure by the single-use FDA-cleared protective sheaths of your choice, such as the UNiPACK Barrier Sleeve catalog number UBC-820855 recommended by Sopro. Take care to not damage the protective sheath. If the protective sheath is torn while examining a patient or if you suspect the handpiece was contaminated while withdrawing the protective sheath, it is essential to disinfect the C50 in accordance with the instructions provided in §6 .
- Make sure that the C50TIPS is put on the C50 camera head (previously covered by the protective sheath) throughout the procedure in all operating modes (DAYLIGHT / DAYLIGHT+ / PERIO / CARIO).
- The C50 handpiece should NEVER be immersed in any liquid nor autoclaved: this could result in electric shock.
- Do not pull on the C50 cable; 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.
- Do not drop the handpiece. This could damage the housing and could result in electric shock.
- C50 camera is classified as a low-risk LED lamp in accordance with IEC 62471. To avoid risk of ocular damage, do not look directly at the light.
- Do not insert metal objects into the device to avoid any risk of electric shock, fire, short-circuit or hazardous emissions.
- Do not use the device in an oxygen-rich environment.
- Do not use the device if it is damaged. Prior to each use, make sure the devices do not have any rough surfaces, sharp edges or protuberances which could lead to safety problems.
- Do not use products containing: Ammoniac, trichloroethylene Dichloroethylene, Ammonium, Hydrochloride, Chlorinated and aromatic hydrocarbon, Ethylene dichloride, Methylene chloride, Ketones. Use of these chemicals subject plastic parts to risk of deterioration.
- Do not place heavy objects on top of the device.
- Do not splash water on the device nor store it in damp areas.
- Never place the device near a heat source or in a location where it is exposed to vibration and/or shock.

2.3 PRECAUTIONS

- If the caries is not located on a surface accessible to DAYLIGHT / DAYLIGHT+ modes or to the naked eye, the camera will not highlight the lesion.
- C50TIPS are not provided sterile: they must be cleaned, packaged and steam sterilized before use.
- The C50 intraoral camera is not suitable for use in the presence of a flammable anaesthetic mixture containing air, oxygen or nitrous oxide.
- The surface temperature in the light emission area can reach above 43°C (after several minutes of use). Therefore, avoid maintaining this emission area in contact with the patient's mouth.
- For the professional healthcare environment, the medical device should not be used in the vicinity of electrosurgical or diathermy equipment or in the vicinity of an electromagnetically shielded room for magnetic resonance imaging (MRI) equipment where the intensity of electromagnetic disturbances is high.
- Install the camera in a clean, dry, and well-ventilated place.
- Use only the accessories supplied with the device or recommended by SOPRO.
- The devices that connect to video or USB outputs should comply with the IEC 62368-1 standard.
- C50 intraoral camera is not provided sterile: the C50 must be wipe disinfected before use. The C50 camera is not sterilisable.
- FDA-cleared protective sheaths for intraoral cameras are not provided sterile: they do not need cleaning and sterilization before use.
- Throw away the protective sheath after use.
- Do not submit the device to excessive dust.
- Do not apply excessive force on the medical device.

- Do not pull on the connection cable to disconnect the device.
- Where 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 adapter.
- Unplug the C50 intraoral camera before decontaminating it.
- The camera must always be stored on its handpiece holder after use.
- This device must not be modified without the manufacturer's authorization.
- The camera must not be bitten by the patient.
- Respect the conditions of use and storage.

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:

- 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, the C50 intraoral camera was designed and developed together with its 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.
During clinical use, the C50 camera must always be covered by a single-use protective sheath cleared by FDA for use as a disposable barrier for dental instruments to reduce the risk of cross contamination between patients, such as the UNiPACK Barrier Sleeve UBC-820855 recommended by SOPRO.
Even if the manufacturer or dealer of your accessory claims full compatibility with SOPRO 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 SOPRO after-sales service team.

2.6 UNDESIRABLE SIDE EFFECTS

There is no known undesirable side effect associated with the camera.

2.7 DEVICE ASSEMBLY AND DISASSEMBLY

The C50 intraoral camera must only be opened by a competent technician approved by the manufacturer.

3 REQUIRED INFORMATION

The following notice 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 this user manual are C50 intraoral camera (handpiece) and C50TIPS designed for dental applications.
Congratulations on your purchase of the ACTEON's camera.

The box contains the following items:
• 1 C50 intraoral camera integrating the camera electronics and lighting
• 1 USB cable
• 1 handpiece holder
• 1 intraoral camera quick start guide
• 4 C50TIPS

3.2 INDICATIONS FOR USE

C50 is intended for clinical practice of general dentistry, as an aid in the diagnosis of pit and fissure caries, as an aid to highlight dental plaque and gingival inflammations (restricted to gingival inflammations which lead to bleeding upon probing) and as intra-oral camera to visualize anatomical details invisible to the naked eye or with a mirror (thanks to magnification).

3.3 PRINCIPLE OF OPERATION

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.

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 Complementary Metal Oxide Semiconductor (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.

3.4 USER POPULATION RECOMMENDATIONS

3.4.1 USER POPULATION

The devices are intended for use by:

- A qualified and certified dentist.
- A qualified and certified dental hygienist
- A qualified and certified nurse
- 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 devices are not intended for self-treatment.
The device can be used by any adult practitioner of any weight, age, height, gender, and nationality.

3.4.2 SPECIFIC USER TRAINING

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

3.4.3 DEVICES IN CONTACT WITH THE USER

The C50 intraoral camera and C50TIPS are in indirect contact with the user, who wears gloves during use of the device.
The C50 intraoral camera does not enter in direct contact with the patient's mouth.
C50TIPS are in direct contact with the patient's mouth and are biocompatible in accordance with the requirements established by ISO 10993-1:2018 Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process.

3.5 PATIENT POPULATION RECOMMENDATIONS

3.5.1 PATIENT POPULATION

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

- Adults
- Elderly persons

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

3.5.2 PATIENT POPULATION RESTRICTION

The user is the only person who can decide whether or not to treat his/her patients.

3.5.3 APPLIED PART(S)

The C50 handpiece, the connection cable and the connector are considered applied parts within the meaning of international standard IEC 60601-1.

3.6 BASIC SAFETY AND ESSENTIAL PERFORMANCE

3.6.1 NORMAL CONDITIONS OF USE

The normal conditions of use of the C50 are the following:

- Storage
- Installation
- Use
- Maintenance
- Disposal

3.6.2 ESSENTIAL PERFORMANCE

Within the meaning of the applicable electromedical device safety standard, the manufacturer has determined that none of the functions of the C50 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.

3.7 INFORMATION FOR PERFORMANCE

3.7.1 DEGRADATION OF PERFORMANCE DUE TO EM DISTURBANCES THAT IS CONSIDERED ACCEPTABLE

Within the meaning of the applicable electromedical device electromagnetic compatibility (IEC 60601-4-2), the manufacturer has determined during immunity tests that if the displayed image is altered, but in a way that is not affect diagnosis (established by the dental practitioner), this degradation of performance is acceptable.

3.7.2 ACTIONS THE OPERATOR COULD TAKE TO PREVENT OR MITIGATE THE DEGRADATION OF PERFORMANCE

To prevent or mitigate the degradation of performance, we recommend that you:

- Ensure that the product is not damaged.
- Keep the device away from sources of electromagnetic interference (e.g., compressor, motor, transformer, HF generator, etc.).

3.7.3 RECOVERY TIME FOLLOWING TRANSIENT PHENOMENON

The maximum recovery time defined by the manufacturer is 3 seconds.

3.8 LIFETIME

- C50 intraoral camera lifetime is 7 years.
- C50TIPS lifetime is 50 steam sterilization cycles.

4 DEVICE INSTALLATION

No special training is required to install the device.

4.1 CONNECTING THE C50 TO A COMPUTER

4.1.1 REQUIRED COMPUTER CONFIGURATION

To use the C50, 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
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 port	USB 3.0 Super-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

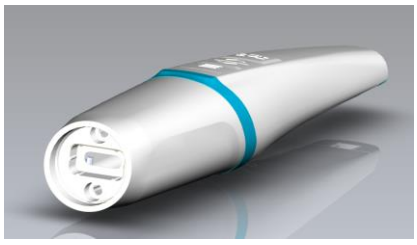
MAC® Configuration:

	Minimum Configuration	Recommended Configuration
Computer	MacBook® Pro 13'' or iMac® 21.5''	iMac® 27''
Operating system	MacOS® Monterey Catalina	MacOS® X Big Sur
Processor	Intel® Core i5– At least 4 cores	Intel® Core i7– At least 4 cores
Memory	8 GB	16 GB
USB port	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.

4.1.2 CONNECTING THE C50 HANDPIECE TO THE COMPUTER

A USB cable is provided to connect the C50 (USB-C) to a computer (USB-A).
It is recommended to set up IT security controls for the operating environment (e.g.. antivirus software and a firewall).



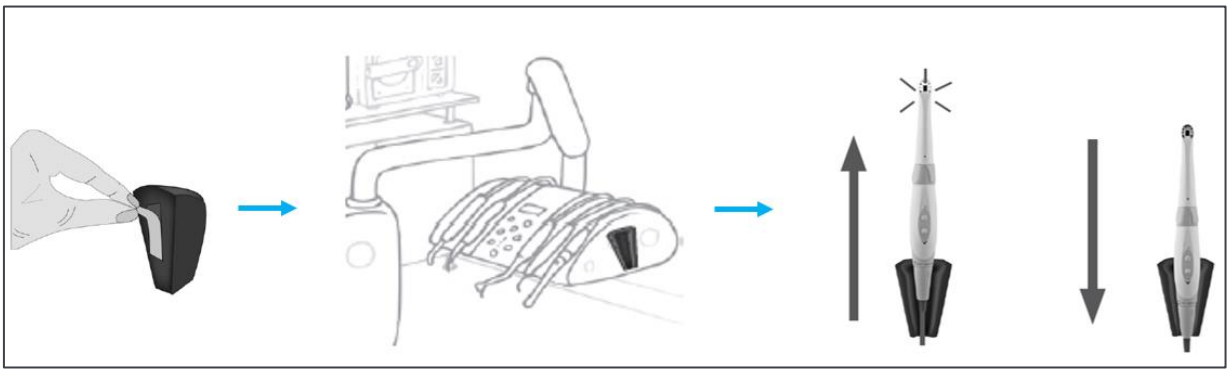
The USB port must be at least an USB 3.0. The following symbol must be shown on the computer connection:

4.2 IMAGING SOFTWARE INSTALLATION AND CONFIGURATION

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

4.3 INSTALLATION OF THE HANDPIECE HOLDER

1. Use a wipe such as CaviWipes™ to clean the handpiece holder.
2. Discard the used wipe.
3. Use a new wipe such as CaviWipes™ to disinfect the handpiece holder. Discard the used wipe.
4. Leave the surface wet for 3 minutes.



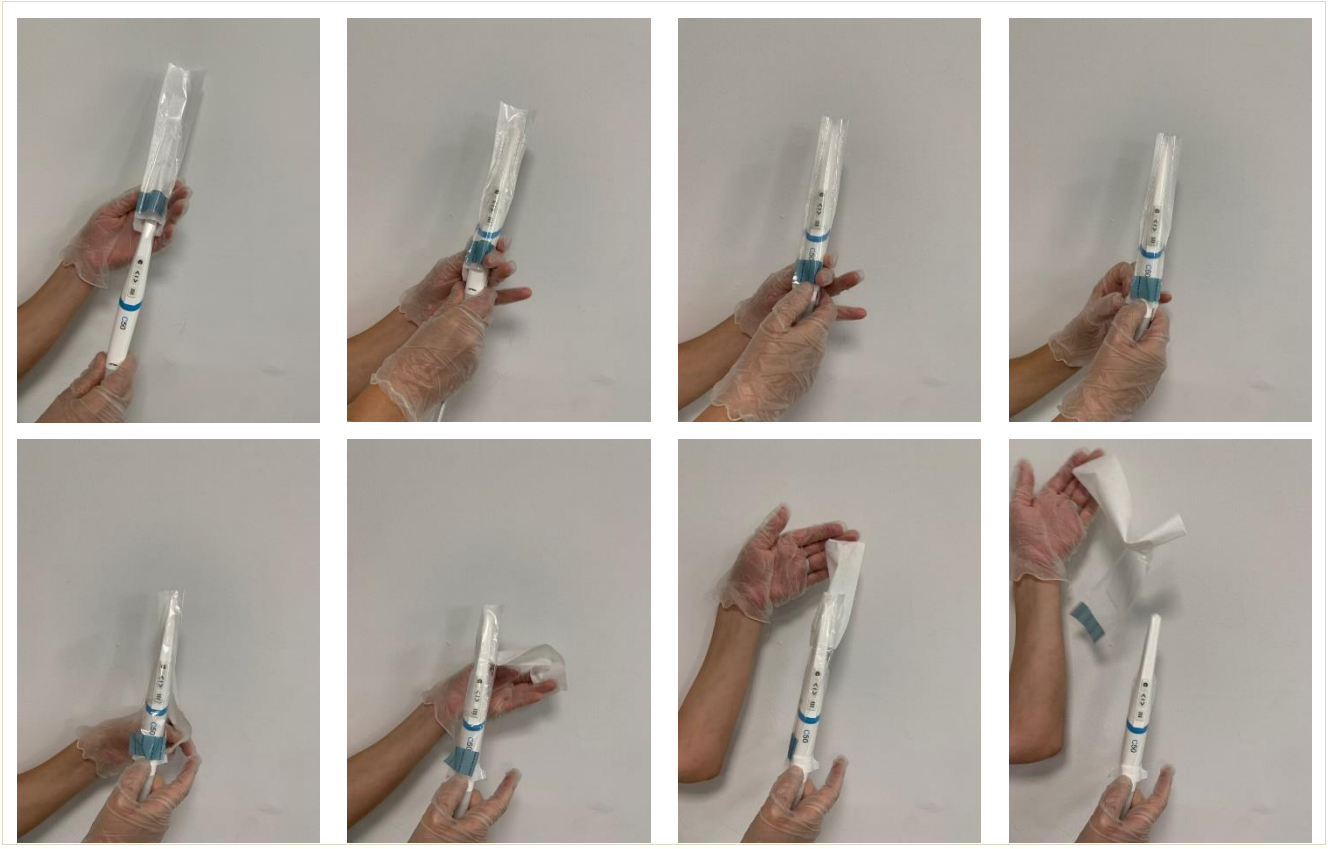
5. Choose an easily accessible flat surface.
6. Use the wipe provided to clean the surface on which you are going to fasten the holder.
7. Remove the double-sided adhesive tape protection from the handpiece holder and press it on the desired surface for a few seconds. Full adhesion of the handpiece holder is achieved after 2 hours, so avoid any stress on the handpiece holder during this two-hour period.
8. After a minimum of 2 hours, the C50 camera can be stored in the handpiece holder.
   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.

4.4 USE OF THE SINGLE USE PROTECTIVE SHEATH

Cover the C50 camera with a single use protective sheath before introducing the camera into the patient's mouth, as shown on the pictures below.
Make sure that the sheath that you use is a legally marketed protective sheath cleared by FDA for use as a disposable barrier for dental instruments, specifically for intraoral cameras.

SOPRO has tested use and functionality of the C50 intraoral camera successfully using UniPack single use Disposable Barrier Sleeves UBC-820855, which are manufactured of polyethylene film with a thickness of 0.02-0.06mm, a width of 2.5 mm at the tip and a total length of 21 cm. If you will be using a different protective sheath with your C50 camera, make sure that the product has equivalent specifications.

CAUTION: When inserting the camera head into the protective sheath, be sure to insert the tip first (lens down) and make sure that the sheath covering the tip is not folded or wrinkled. Otherwise, the dental image may be blurred.



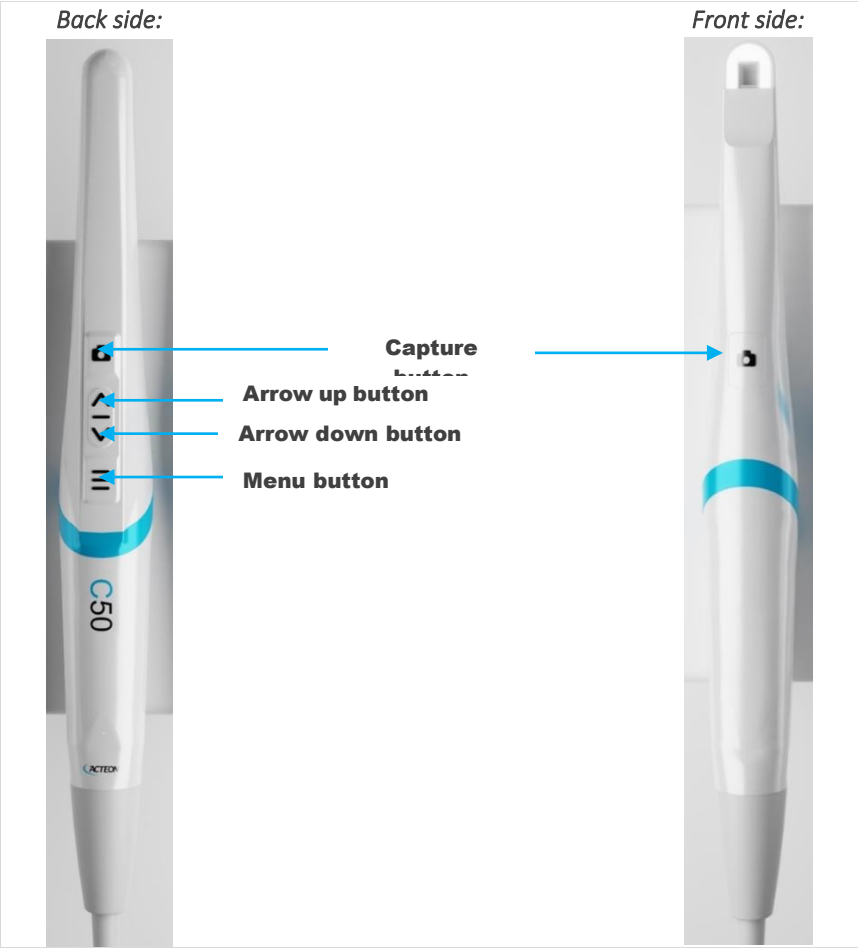
4.5 USE OF C50TIPS

Immediately before use, place a clean and sterile C50TIPS on the camera head over the protective sheath.

5 USE OF THE DEVICE

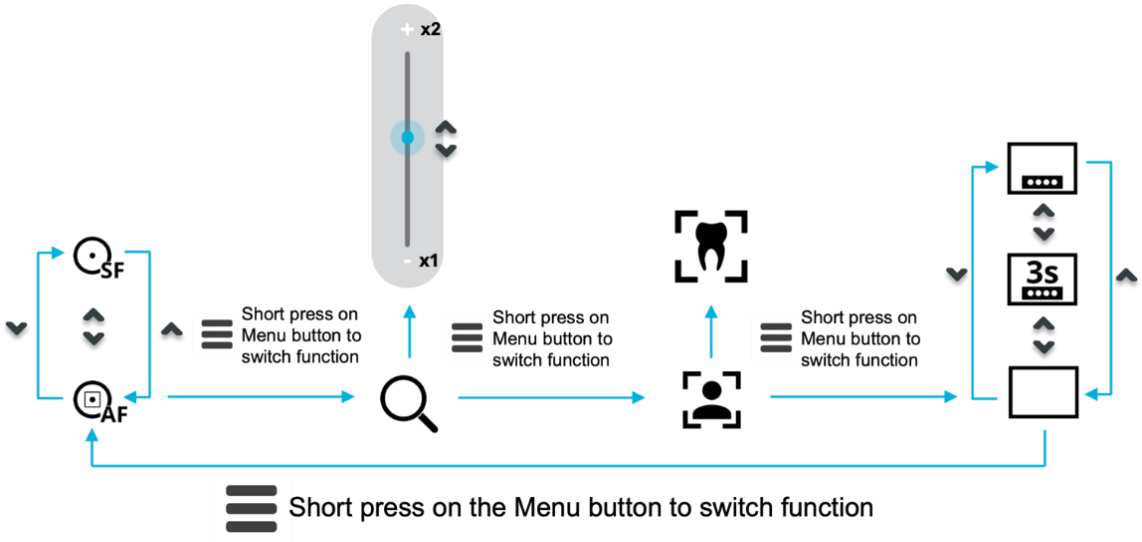
5.1 USE OF C50

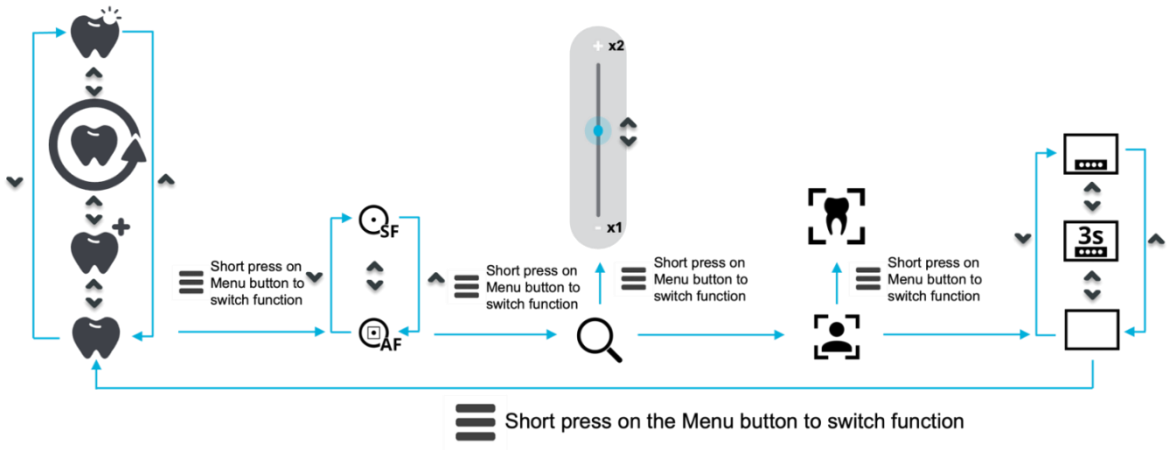
5.1.1 BUTTON LOCATION AND DESIGNATION



5.1.2 ON-SCREEN DISPLAY (OSD)

If you are using the C50 with other imaging software (OIS) instead of the 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.





5.1.3 ICON DESCRIPTION

Function	Picture	Designation	Available on OIS
Focus	AF	**Automatic Focus** The camera focuses automatically.	Yes
Focus	SF	**Single Focus** To focus the image, short press the capture button.	Yes
DAYLIGHT Mode		**DAYLIGHT** The camera produces an image with natural colour.	Yes
DAYLIGHT+ Mode		**DAYLIGHT+** This mode adds higher contrast to daylight mode.	Yes
PERIO Mode		**PERIO** Diagnostic aid to highlight plaque and gingival inflammation by chromatic amplification	Yes
CARIO Mode		**CARIO** Diagnostic aid to highlight caries – by fluorescence	Yes
Zoom		**Digital zoom** Magnifies the picture from x1 to x2 with step od 0.1	Yes
Self-timer		**Self-Timer** The self-timer can be set according to your needs to Off, 1s, 3s or 5s.	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
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

6 CLEANING, DISINFECTION AND STERILIZATION

In accordance with EN ISO 17664, this section provides users with instructions for cleaning and disinfection or sterilization of SOPRO reusable medical devices. All cleaning, disinfection and sterilization instructions provided by SOPRO for the company's medical devices and accessories have been validated. This section is applicable only to devices manufactured by SOPRO.
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 product free of viable microorganisms with a Sterility Assurance Level (SAL) of 10^{-6}.

6.1 DEVICES AND PROCESS TO APPLY

6.1.1 WARNINGS & PRECAUTIONS

WARNINGS:

- Change gloves between each patient to avoid cross contamination.
- The C50 handpiece should NEVER be immersed completely in any liquid nor autoclaved. This could result in electric shock, in addition to causing irreparable damage to the device itself.
- The bottom half of the device is not waterproof.
- Never splash water on the non-waterproof part of the camera (bottom half of the device); i.e., between the USB connection and the tip portion. Splashing it with water could result in electric shock, in addition to causing potentially irreparable damage to the device itself.

C50 back side:

C50 front side:

PRECAUTIONS:

- The C50 camera is a reusable medical device intended to be cleaned and disinfected before use.
  The C50 camera is not autoclavable. Do not immerse in a disinfecting liquid.
  Do not touch the USB cable during use on the patient to avoid any contamination. Do not splash water on the USB cable.
  The USB cable should NEVER be immersed completely in any liquid nor autoclaved.
  - ➢ Follow the procedure described in section “Processing instructions for C50 and the USB cable”.
- C50TIPS is a reusable medical device supplied non-sterile and intended to be cleaned and sterilized before use.
  - ➢ Follow the procedure described in section “Processing instructions for C50TIPS”.
- Protective Sheath is a single use device intended to be used on one patient only. The Protective Sheath is not intended to be cleaned or sterilized before use.
  Immediately before use, remove the Protective Sheath from its packaging and place it on the C50 camera.
- If a device requires servicing, it must be decontaminated in accordance with these processing instructions prior to sending it to the after-sales service department.

6.1.2 REPROCESSING PROCEDURES TO APPLY ACCORDING TO THE DEVICE

Processing Procedures		C50 waterproof part		C50 non-waterproof part	USB Cable	Handpiece Holder	C50TIPS
		*If protective sheath **compromised** and / or **delayed reuse***	*If protective sheath is **not compromised**, **immediate reuse***				
1	Cleaning with **wipes** and **water**	✓	✓	×	×	×	×
	High-Level Disinfection	✓	×	×	×	×	×
2	Clean with **wipes without water**	×	×	✓	✓	✓	×
	Intermediate-Level Disinfection using wipes	×	✓	✓	✓	✓	×
3	Cleaning	×	×	×	×	×	✓
	Steam sterilization	×	×	×	×	×	✓

6.1.3 CLEANING AGENTS AND DISINFECTANTS

The reprocessing instructions described below were validated by the manufacturer using CaviWipes Disinfecting Towelettes intended for cleaning and intermediate level disinfection of hard, non-porous surfaces in the healthcare setting. If you will be using a different product, make sure it has equivalent specifications and intended use and is compatible with devices made of polymer materials.

Always follow the instructions provided by the manufacturer of your cleaning and disinfection wipes regarding product application and dwell time.

Do not use disinfection wipes containing ammoniac, trichloroethylene Dichloroethylene, Ammonium, Hydrochloride, Chlorinated and aromatic hydrocarbon, Ethylene dichloride, Methylene chloride, Ketones., which can damage product surfaces if used repeatedly in the long term.

6.2 PROCESSING INSTRUCTIONS FOR HANDPIECE HOLDER

6.2.1 CLEANING BEFORE DISINFECTION

1. Put on new, clean gloves before performing the following steps.
2. Clean all accessible surfaces of the handpiece holder 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.
3. Dispose of used wipes in accordance with Federal, State, and local regulations for infectious materials disposal.

6.2.2 DISINFECTION AFTER CLEANING

1. Pull out a fresh disinfectant wipe from its container.
2. Disinfect all accessible surfaces of the handpiece holder with the disinfectant wipe. Leave the surface wet for 3 minutes.
3. The Handpiece Holder is now ready for storage of the clean and disinfected C50 Camera.
4. Dispose of used wipes in accordance with Federal, State, and local regulations for infectious materials disposal.

6.3 PROCESSING INSTRUCTIONS FOR C50 & USB CABLE

6.3.1 AFTER EVERY USE INSTRUCTIONS

6.3.1.1 PREPARING FOR CLEANING

After completing work with a patient, immediately take the C50 Intraoral Camera to the reprocessing area.

1. Remove the C50TIPS.
2. Carefully pull the Protective Sheath up toward the tip end of the camera to partially uncover the bottom half of the camera.
   CAUTION: DO NOT touch the uncovered portion of the camera with soiled gloves or hands!
3. Put on clean gloves to grip the uncovered portion of the camera.
4. Remove the Protective Sheath completely and set it aside for inspection as described in the section "Inspection of the Protective Sheath".
5. Unplug the USB cable from the camera.
6. Set the camera aside on a clean and disinfected surface.
   WARNING: DO NOT return the camera into the handpiece holder until the reprocessing procedure has been completed.
7. Immediately proceed to cleaning and disinfection of the USB cable.

6.3.1.2 CLEANING AND DISINFECTION OF THE USB CABLE

Once the C50 camera is set on a clean and disinfected surface, put on clean gloves to reprocess the USB cable.

Cleaning before Disinfection:

1. Put on new, clean gloves before performing the following steps.
2. 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.
3. Dispose of used wipes in accordance with Federal, State, and local regulations for infectious materials disposal.

Disinfection after Cleaning:

1. Pull out a fresh disinfectant wipe from its container.
2. 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. If the disinfected cable is not to be reused immediately, store it in a clean and dry place.
3. Dispose of used wipes in accordance with Federal, State, and local regulations for infectious materials disposal.

6.3.1.3 INSPECTION OF THE SINGLE USE PROTECTIVE SHEATH

During use, the tip portion of the C50 camera is doubly protected from contamination by a single-use FDA-cleared protective sheath, such as the UNiPACK Barrier Sleeve catalog number UBC-820855 recommended by SOPRO, and the C50TIPS. The camera can only be contaminated during use if the integrity of the Protective Sheath has been compromised.

1. To inspect the Protective Sheath, fill it 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 C50 is to be reused immediately on another patient) or DELAYED REUSE Procedure (if the C50 is not reused immediately on another patient).

6.3.2 REPROCESSING PROCEDURE

Follow the instructions below when the integrity of the Protective Sheath has been compromised during use.

6.3.2.1 PRE-CLEANING

CAUTION: Put on new clean gloves before performing the following steps.

1. Clean the tip portion of the C50 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.
2. Using a new cleaning/disinfection wipe such as CaviWipes™, pre-clean the remaining parts of the device.
3. Dispose of used wipes in accordance with Federal, State, and local regulations for infectious materials disposal.

6.3.2.2 MAIN CLEANING

1. 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.
2. Hold the C50 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.
3. Rinse the device tip portion under running tap water for 1-2 minutes.
4. As you rinse, thoroughly brush the device tip and lens area with a soft brush to remove any contamination.
5. After conclusion of the rinsing and brushing process, inspect the device tip to ensure that it is visibly clean.
6. Should any visible contamination remain, repeat the above steps.
7. When the device is visibly clean, use a clean and dry lint-free tissue to rough dry the device.
8. Using a new cleaning/disinfection wipe such as CaviWipes™, clean the non-waterproof part of the device.
9. Dispose of used wipes in accordance with Federal, State, and local regulations for infectious materials disposal.
10. Proceed to disinfection.

6.3.2.3 DISINFECTION

1. Prepare a suitable container (glass) to disinfect the tip portion of your C50 camera. The container must be approximately 1.9” (5 cm) wide and 4.7”-5.9” (12-15 cm) high.
2. Fill the container to a height of 2.7”-3.1” (7-8 cm) with an FDA-cleared 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)!

3. Turn the C50 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.)

4. 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.

5. 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.
6. Hold the C50 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.
7. 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.
8. Let the C50 camera air-dry completely on a disinfected surface.
9. Discard your gloves used for the previous step and put on new ones.
10. Disinfect the non-waterproof part of the C50 camera carefully and thoroughly with a ready-to-use, lint-free cleaning/disinfection wipe (such as CaviWipes™).
11. Leave the surface wet for 3 minutes.
12. Dispose of used wipes in accordance with Federal, State, and local regulations for infectious materials disposal.

6.3.3 IMMEDIATE REUSE PROCEDURE

If the Protective Sheath was not compromised during use and the C50 camera is to be reused immediately on another patient, prepare the device for use by wiping the C50 camera carefully and thoroughly with a ready-to-use, lint-free cleaning/disinfection wipe (such as CaviWipes™). Discard the wipe.

1. 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.
2. Hold the C50 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.
3. 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.
4. Place the camera on a clean, disinfected surface to dry completely.
5. Using a new cleaning/disinfection wipe such as CaviWipes™, clean the non-waterproof part of the device. Discard the wipe.
6. To prepare the C50 handpiece holder, use a new cleaning/disinfection wipe to thoroughly wipe all its surfaces, starting from the inside. Discard the wipes after use.
7. Cover the dry C50 camera with a protective sheath and a C50TIPS as described in section “Use of the Single Use Protective Sheath” and in section “Use of C50TIPS”.
8. Place the C50 camera into the previously disinfected C50 handpiece holder.
9. The camera is now ready for use.

6.3.4 DELAYED REUSE PROCEDURE

If the C50 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.

1. After completion of the reprocessing procedure, store the reprocessed C50 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.
2. Before use on a new patient, prepare the device for use by following the Immediate Use Procedure described above.

6.4 PROCESSING INSTRUCTIONS FOR C50TIPS

6.4.1 MANUAL CLEANING

Only C50TIPS are concerned by the cleaning procedure described hereafter:

1. Wash hands using correct technique and mild foam soap and dry with disposable paper towels.
2. Wear appropriate PPE (disposable gloves, goggles, surgical mask, face shield etc.).
3. Immediately after use, rinse the C50TIPS 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.

4. Submerge the 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 devices and possessing demonstrated antimicrobial efficacity and a pH of 7.4 at 0.5% dilution in mains water.

5. 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.
6. 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).

CAUTION: Do not use steel wool or wire brushes.

7. Visually inspect the device to ensure that all contamination has been removed.
8. Let the C50TIPS dry completely.

6.4.2 PACKAGING

1. Package the individual C50TIPS in a single use sterilization pouch made of high medical grade paper and multilayer PET/PP copolymer film, in compliance with the ISO 11607-1 standard and cleared by FDA for the sterilization parameters prescribed below. Please refer to manufacturer's Instructions for Use for proper sizing and use of sterilization pouches.

Note: SOPRO 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.

2. Proceed to sterilization immediately.

6.4.3 STERILIZATION

Only C50TIPS are concerned by the steam sterilization procedure describer hereinafter.

CAUTION: The approved sterilisation settings apply only to sterilization equipment which is properly serviced and calibrated. Any deviation from the recommended sterilization settings must be validated by the user.

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

2. Autoclave using the following parameters:

Steam Sterilization Prevacuum Cycle validated by SOPRO:	Temperature	Time	Drying time
USA cycle	132°C	4 minutes	30 minutes
Maximum number of sterilization cycles:	50 cycles		

3. Sterile devices 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, discard the packaging. Clean, package and sterilize the device again before use.

7 MAINTENANCE AND AFTER-SALES SERVICE

7.1 MAINTENANCE

The only preventive maintenance the medical device requires is:
• Checking of accessories
• Cleaning, disinfection, and sterilisation as described above.

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 and the power supply cable). Make sure to include an explanation of the problem you have encountered with your shipping form.

7.2 AFTER-SALES SERVICE

WARRANTIES: SOPRO guarantees its products to be free from material and manufacturing defects for a period of one (1) year 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 SOPRO.
The entire liability of SOPRO is limited to discretionary replacement or repair ofthe defective product free of charge, if it has been sent to SOPRO 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 SOPRO 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. SOPRO 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 returning 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 connecting cable 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 your imaging software (please refer to the imaging software's user manual). 2. Check whether the camera is correctly detected by the device driver (correct installation of its driver). 3. Check whether the USB cable 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 your imaging software (brightness, contrast, saturation, etc.). Please refer to the imaging software's user manual.
An image displays, but it is not really clear (blurry).	Protective sheath	Check whether the protective sheath is correctly positioned on the camera head.

The camera should be sent to ACTEON in its totality (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 receive a 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 48 hours) or to the recipient. Check as soon as possible whether all components are working correctly.

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 standards IEC 60601-1-2 and IEC/TR 60601-4-2.
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: Use of accessories, transducers, and cables other than those specified or provided by SOPRO of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

8.1 CABLE LENGTH

Cables and accessories	Maximum length
USB connection cable	< 3 m

8.2 APPLICABLE TESTS

Test type	In compliance with	Applicable (A)/ Non-applicable (N/A)
Conducted disturbances (conducted emissions)	CISPR 11	A
Electromagnetic radiation disturbance (radiated emissions)	CISPR 11	A
Harmonic current emissions	IEC 61000-3-2	*NA*
Voltage changes, voltage fluctuations and flickers emissions	IEC 61000-3-3	*NA*
Electrostatic discharge immunity test	IEC 61000-4-2	A
Radiated radiofrequency electromagnetic field immunity test	IEC 61000-4-3	A
Immunity to proximity fields from RF wireless communications equipment	IEC 61000-4-3	A
Electrical fast transient/burst immunity test – A.C and/or D.C POWER PORT	IEC 61000-4-4	*NA*
Electrical fast transient/burst immunity test – SIP/SOP PORT	IEC 61000-4-4	A *NA for IEC 60601-4-2*
Surge immunity test	IEC 61000-4-5	*NA*
Immunity to conducted disturbances, induced by RF fields – A.C and/or D.C POWER PORT and/or PATIENT COUPLING PORT	IEC 61000-4-6	A
Immunity to conducted disturbances, induced by RF fields – SIP/SOP PORT	IEC 61000-4-6	A *NA for IEC 60601-4-2*
Power frequency magnetic field immunity test	IEC 61000-4-8	A
Voltage dips immunity test	IEC 61000-4-11	*NA*
Voltage short interruptions and voltage variations immunity test	IEC 61000-4-11	*NA*
Proximity magnetic fields immunity test	IEC 61000-4-39	A *NA for IEC 60601-4-2*
Electrical transient conduction along supply lines	ISO 7637-2	*NA*

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
Conducted disturbances (conducted emissions) *CISPR 11*	Group 1	The medical device uses RF energy for its internal functioning.
Electromagnetic radiation disturbance (Radiated emissions) *CISPR 11*	Class B	
Harmonic current emissions *IEC 61000-3-2*	*N/A*	Professional healthcare facility environment and home healthcare environment
Voltage changes, voltage fluctuations and flicker emissions *IEC 61000-3-3*	*N/A*	

This medical device is intended for use in a professional healthcare environment (hospital, clinic, dental office) and in the home healthcare environment (dental office in a home setting).
The user and installer must ensure that the medical device is used in the environment described below, if applicable.

For the professional healthcare environment, the medical device should not be used in the vicinity of electrosurgical or diathermy 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.

Immunity test	Test level applied (IEC 60601-1-2)	Deviations	Electromagnetic environment - comments
Electrostatic discharge immunity test *IEC 61000-4-2*	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	/	Professional healthcare facility environment and home healthcare environment
Radiated radiofrequency electromagnetic field immunity test *IEC 61000-4-3*	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	/	Professional healthcare facility environment and home healthcare environment
Immunity to proximity fields from RF wireless communications equipment *IEC 61000-4-3*	9 V/m 710 MHz, 745 MHz, 780 MHz 5240 MHz, 5500 MHz, 5785 MHz 27 V/m 385 MHz 28 V/m 450 MHz, 810 MHz, 870 MHz, 930 MHz, 1720 MHz, 1845 MHz, 1970 MHz 2450 MHz	/	Professional healthcare facility environment and home healthcare environment
Electrical fast transient/burst immunity test SIP/SOP port *IEC 61000-4-4*	± 2 kV 100 kHz repetition frequency	/	Professional healthcare facility environment and home healthcare environment

Immunity test	Test level applied (IEC 60601-1-2)	Deviations	Electromagnetic environment - comments
Immunity to conducted disturbances induced by RF fields Patient coupling port and SIP/SOP port *IEC 61000-4-6*	3 V 0,15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	/	Professional healthcare facility environment and home healthcare environment
Power frequency magnetic field immunity test *IEC 61000-4-8*	30 A/m 50 Hz or 60 Hz	/	Professional healthcare facility environment and home healthcare environment
Proximity magnetic fields *IEC 61000-4-39*	8 A/m - 30 kHz 7.5 A/m – 13.56 MHz 65 A/m - 134.2 kHz	/	Professional healthcare facility environment and home healthcare environment

Immunity test	Test level applied (IEC TR 60601-4-2)	Deviations	Electromagnetic environment - comments
Electrostatic discharge immunity test *IEC 61000-4-2*	± 4 kV contact ± 2 kV, ± 4 kV, ± 8 kV air	/	Professional healthcare facility environment and home healthcare environment
Radiated radiofrequency electromagnetic field immunity test *IEC 61000-4-3*	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	/	Professional healthcare facility environment and home healthcare environment
Immunity to proximity fields from RF wireless communications equipment *IEC 61000-4-3*	3 V/m 710 MHz, 745 MHz,780 MHz 6 V/m 5240 MHz, 5500 MHz, 5785 MHz 6 V/m 385 MHz 9 V/m 450 MHz 810 MHz, 870 MHz, 930 MHz, 1720 MHz, 1845 MHz, 1970 MHz , 2450 MHz	/	Professional healthcare facility environment and home healthcare environment
Power frequency magnetic field immunity test *IEC 61000-4-8*	3 A/m 50 Hz	/	Professional healthcare facility environment and home healthcare environment

9 TECHNICAL DESCRIPTION

9.1 ENVIRONMENTAL CONDITIONS:

Storage temperature	-20 °C / +45 °C
Operating temperature	+10 °C / +35 °C
Relative humidity	10% to 90%
Transport, storage and operating atmospheric pressure	700 hPa to 1060 hPa
Electrical classification (IEC 60601-1)	Class 2
Applied part	Type BF
Photobiological risk group (IEC 62471)	Group 1 “Low risk”
This medical device complies with the following international standards:	IEC 60601-1, IEC 60601-1-2, IEC/TR 60601-4-2, IEC 60601-2-18; IEC 60601-1-6, ISO 23450, ISO 14971, ISO 15223-1, IEC 62304, IEC 62366-1

9.2 TECHNICAL CHARACTERITICS:

Sensor	CMOS
Resolution	1920 x 1080
Sensitivity	2 lux
Distortion	6% maximum
FPS	25 – 30
Aspect Ratio	16/9
Lighting	6 LEDs
Focus adjustment	Automatic focus or Single focus
4 Visions Mode	PERIO CARIO DAYLIGHT DAYLIGHT+
Image capture	Capture button or footswitch (optional)
Angle of view	75°
Cable length	3m
USB output	3.0
Consumption	4,5W max
Handpiece dimensions	200; W: 30; H: 24 mm
Handpiece weight	100g
Continuous service	/
Not protected against water chutes	IP53

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 information in this user manual is based on the requirements of standards to which the manufacturers of medical devices must adhere (as stated in standard IEC 62366-1).
The C50 was tested according to the recommendations of IEC TR 60601-4-2: Medical electrical equipment – Part 4-2: Guidance and interpretation – Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems.

11.2 MEDICAL DEVICE CLASSIFICATION

The devices concerned by this user manual and manufactured by SOPRO are Class II medical devices in accordance with U.S. Food and Drug Administration regulations.

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 manual.

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

REF	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.
SN	Indicates the manufacturer's serial number so that a specific medical device can be identified.
	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.
	To indicate 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.
	To indicate on product or product packaging that relevant information for use of the product is available in electronic form rather than, or in addition to, printed paper form.
	Follow instructions for use.
UDI	Indicates a carrier that contains Unique Device Identifier information.
	To indicate on the rating plate that the equipment is suitable for direct current only; to identify relevant terminals.
	On medical equipment. To identify a type 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 center designated for the recycling of electrical and electronic equipment.
MD	Indicates the item is a medical device.
	Indicates a medical device that needs to be protected from moisture.
	Indicates a medical device that can be broken or damaged if not handled carefully.
	To indicate correct upright position of the transport package.
	To indicate that a device that the manufacturer intends to be sterilized has not yet been through the sterilization process.
Rx Only	Prescription use only (Caution: United States Federal law restricts medical devices to sale by or on the order of a dentist." (21CFR 801.109(b)(1))).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