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# SOPROCARE

## User's manual

IMAGING
ACTEON

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# 1 FOREWORD

To optimize the use of this device, whilst taking all the necessary precautions, we recommended you read carefully and follow the owner's manual.

Please carefully consider the messages "CAUTION", "WARNING", and "NOTE" when using the system.

⚠ WARNING: the term WARNING describes potential incidents likely to jeopardize safety.
⚠ CAUTION: the term CAUTION refers to the incidents likely to conduct to minor injury.

NOTE: the term NOTE highlights particular points in order to facilitate the system maintenance or to clarify important information.

⚠ CAUTION: Federal law restricts this device to sale by or on the order of a dentist

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# DENTAL CAMERA INTRODUCTION

The SOPROCARE 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 that are invisible to the naked eye or with a mirror (thanks to its magnification).

It provides the following benefits:

- Aids in the detection of pit and fissure caries
- Information about patient dental hygiene
- Highlight dental plaque and gingival inflammations (restricted to gingival inflammations which lead to bleeding upon probing)
- Show the difference between "before" and "after" care.

In CARIO mode, the camera helps the dental practitioner to highlight carious warning on pits and fissures of 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 (thanks to its magnification).
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.
This fluorescence Imaging device is composed of a handpiece (SOPROCARE) and a connection box (DOCK M_USB2, DOCK M_VIDEO, DOCK MU_USB2, DOCK U_USB2, DOCK MU_VIDEO, DOCK USB2) as well as various accessories necessary for it to work.

SOPROCARE

- 1 handpiece integrating the camera electronics and lighting.
- 1 handpiece holder.
- 4 SOPROTIPS.
- 10 dental barriers.
- CD of SOPRO Imaging software (in basic version) including documentations.
- A quick start of SOPROCARE and SOPRO-Imaging software


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DOCK M_USB2
- A connection box with integrated image memory.
- Power supply.
- A 2.5 meters cable to connect the handpiece to the connection box (5 meters and 7 meters optionally).
- A S-video Y/C cable
- A RCA video cable.

DOCK M_VIDEO
- A connection box with integrated image memory.
- Power supply.
- A 2.5 meters cable to connect the handpiece to the connection box (5 meters and 7 meters optionally).
- A S-video Y/C cable
- A RCA video cable.

DOCK USB2
- A USB2 connection boxwith a 3.5 meters connecting cable.
- CD of SOPRO Imaging software (in basic version) including documentations.
- A quick start of SOPRO-Imaging software

DOCK MU_VIDEO
- A connection box with integrated image memory.
- A 2.5 meter cable to connect the handpiece to the connection box (5 meters and 7 meters optionally).
- An installation manual. (Note: the installation of the docking station into the unit must be done by trained technician)

DOCK U_USB2
- A connection box with USB2 digital output.
- A 2.5 meter cable to connect the handpiece to the connection box (5 meters and 7 meters optionally).
- An installation manual. (Note: the installation of the docking station into the unit must be done by trained technician)

DOCK MU_USB2
- A connection box with integrated image memory and USB2 digital output.
- A 2.5 meter cable to connect the handpiece to the connection box (5 meters and 7 meters optionally).

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• An installation manual. (Note: the installation of the docking station into the unit must be done by trained technician)

This device has been packaged in a custom carton. This carton should be kept for future possible transportation. As a complement to the dental camera, we provide some dental barriers necessary for intra-oral use of the dental camera. For more details about these products, please refer to our catalogue or contact our commercial service.

NOTE :

*This device and its accessories have been designed to maximize performance and safety. The use of accessories from different origins may reduce the performance and safety of this device. Only use SOPRO accessories and authorized SOPRO After-Sales.*


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# 3 SAFETY INSTRUCTIONS

⚠ WARNING:

• For each new patient, it is essential to use the dental barriers provided with the handpiece. Cleaning/disinfection INSTRUCTIONS of the handpiece must be performed between all appointments, even though a barrier is used. Failure to do this could result in cross contamination of patient.

• Infection control procedures must be observed when using accessories such as SOPROTIPS and dental barriers. When using accessories always follow the manufacturer's instructions on how to use said accessory and prevent cross contamination risk from one patient to another. Failure to do this could result in cross contamination of patient.

• When handling camera and dental barriers, always take the appropriate hygiene measures and precautions in order to prevent cross contamination risks.

• Handpiece should NEVER be immersed in any liquid, NOR should it be autoclaved. This could result in electric shock.

• Before using the camera, make sure it does not have any sharp edges. This could result in injury.

• DO NOT expose the SOPRO camera to water spray and do not store it in a humid environment This could result in electric shock.

• DO NOT pull on the 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.

• Install the camera in a clean, dry, and well-ventilated place. This cloud result in an electric shock.

! CAUTION:

• Disconnect the connection box from the power supply if you are not going to use it for several days. This will save energy.

• The surface temperature in the light emission area can reach above 41 °C (after several minutes of use). Therefore avoid maintaining this emission area in contact with the patient's mouth. This could result in pain for patient

• The camera is a product using group 1 LEDs according to IEC 62471. To avoid any ocular risk do not look directly at the light.

NOTE :

*If the hygienic protection is torn while examining a patient or if the handpiece was "infected" while withdrawing the hygienic protector, it is essential to totally disinfect the handpiece. In order to do this: please refer to the maintenance chapter.*

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⚠ WARNING:

Modification of the product, without the permission of the manufacturer, is prohibited. This could result in electric shock If the medical equipment is modified, an appropriate control and test should be performed to ensure that the medical equipment still can be used safely. Risk of electric shock or injury due to sharp edge.


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# 4 REGULATORY REQUIREMENTS

## 4.1. COMPLIANCE WITH STANDARDS AND REGULATIONS

This product was designed and manufactured by a company having an authorized quality system. It meets the European directive 93/42/EEC requirements relative to medical devices. Therefore, it particularly meets electrical safety and electromagnetic compatibility standards (IEC) (CEM).

## 4.2. ELECTROMAGNETIC INTERFERENCE AND ELECTROSTATIC DISCHARGES

Electromagnetic compatibility (EMC) is the ability of electronic device elements to correctly interact in an electronic environment. Although the SOPRO system was designed according to this compatibility and complies with the electromagnetic interference thresholds established by the regulatory agency, there is no guarantee about interference likely to occur on a particular installation. If the device generates interference with radio communication services (which can be determined by switching it off and on), it is recommended to try to correct this phenomenon by taking whole or part of the following measures:

- Change the receiving antenna orientation
- Reposition the product according to the receiver.
- Take the computer away from the receiver.

The SOPRO camera is designed and tested to be used in a home environment, class B Group 1, according to the CISPR11 standard.

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4.3. MEDICAL DEVICE VIGILANCE

As with any medical device, this device is subjected to medical device vigilance dispositions; any serious dysfunction should then be the subject of a description to the competent authorities and to the manufacturer as soon as possible and as precisely as possible.

4.4. END OF LIFE

This device bears the recycling symbol according to the European directive 2002/96/EC about electric and electronic equipment waste (DEEE or WEEE). By correctly disposing of this device, you will avoid any damage to the environment and human health.

The symbol  on the device or on the accompanying documentation indicates this product cannot be, in any case, treated as household waste. Therefore, it should be transferred to a waste collection centre that handles electric and electronic equipment recycling. Please respect the standards relative to waste disposal in force in the installation country . For more details about the device treatment, recuperation and recycling, please contact your dental device distributor (or failing that, the group ACTEON site www.acteongroup.com), so that you can be informed of the procedure.


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4.5. ELECTROMAGNETIC COMPTABILITY

| Guide and declaration of the manufacturer - electromagnetic emissions | | |
|---|---|---|
| SOPRO device is intended to be used in the electromagnetic environment specified below. The user should make sure it is used in this environment. | | |
| Emission trial | Compliance | Electromagnetic environment - Guide |
| RF emissions CISPR 11 | Group 1 | SOPRO device only uses radio energy for its internal functions. Therefore, its RF emissions are very low and are unlikely to cause interference with nearby electronic devices. |
| RF emissions CISPR 11 | Class B | SOPRO device may be used in all domestic environments, including the ones directly connected to the public low voltage power distribution network used to supply household buildings. |
| Harmonic emissions EN 61000-3-2 | Not applicable | |
| Voltage fluctuations / Flicker EN 61000-3-3 | Applicable | |

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| Guide and declaration of the manufacturer - electromagnetic immunity | | | |
|---|---|---|---|
| SOPRO device is intended to be used in the electromagnetic environment specified below. The user should make sure it is used in this environment. | | | |
| Immunity trial | IEC 60601 Severity level | Compliance level | Electromagnetic environment Guide |
| Electrostatic discharges EN 61000-4-2 | ± 6 kV when in contact<br>± 8 kV in the air | ± 6 kV<br>± 8 kV | The floor should be wooden, concrete or tile. If the floor is covered with a synthetic material, the relative humidity should be at least 30%. |
| Far transient bursts EN 61000-4-4 | ± 2 kV for the feed cables<br>± 1 kV for the input/output cables | ± 2 kV<br>± 1 kV | The main power supply quality should be one of a traditional commercial or hospital environment. |
| Voltage shocks EN 61000-4-5 | Differential mode ± 1 kV<br>Common mode ± 2 kV | ± 1 kV<br>N.A. | The main power supply quality should be one of a traditional commercial or hospital environment. |
| Dips, brief outages and power voltage variation EN 61000-4-11 | • <5% Ut - for 10 ms<br>• 40% Ut - for 100 ms<br>• 70% Ut - for 500 ms<br>• <5% Ut - for 5 s | <5% Ut 10 ms<br><40% Ut 100 ms<br><70% Ut 500 ms<br><5% Ut 5 s | The main power supply quality should be one of a traditional commercial or hospital environment. If the user of SOPROCARE device requires it to continue to operate during main power supply outages, it is recommended SOPROCARE device is fed by an inverter or a battery. |
| Magnetic field with the network frequency (50/60 Hz) | 3 A/m | 3 A/m | The magnetic field with the network frequency should be at a characteristic level of a location in a traditional commercial or hospital environment. |
| Note: Ut is the power voltage nominal value applied during the trial. | | | |


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| Guide and declaration of the manufacturer - electromagnetic immunity | | | |
|---|---|---|---|
| SOPRO device is intended to be used in the electromagnetic environment specified below. The user should make sure it is used in this environment. | | | |
| Immunity trial | IEC 60601 Severity level | Compliance level | Electromagnetic environment Guide |
| Conducted RF EN 61000-4-6 | 3 Vrms 150 kHz to 80 MHz | 3V | Portable and mobile RF communication devices should not be used at a distance from SOPRO device including the cables, lower than the recommended separation distance, calculated with the applicable formulas depending on the emitter frequency.<br><br>Recommended separation distance<br>d = 1.16/P<br><br>d = 1.16/P 80 MHz to 800 MHz<br>d = 2.33/P 800 MHz to 2.5 GHz<br>where $P$ is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).<br>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a] should be less than the compliance level in each frequency range[b].<br>Interference may occur in the vicinity of equipment marked with the following symbol:  |
| Radiated RF EN 61000-4-3 | 3 V/m 80 MHz to 2.5 GHz | 3V/m | |
| Note 1 : At 80 MHz and 800 MHz, the higher frequency range applies.<br>Note 2 : These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. | | | |

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the ele tromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the equipment is used exceeds the applicable RF compliance level above, the equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the equipment.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between the portable and mobile RF communication devices and SOPROCARE device

The SOPROCARE is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the SOPROCARE can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the SOPROCARE as recommended below, according to the maximum output power of the communications equipment.

| Rated maximum output power of transmitter W | Separation distance according to frequency of transmitter - m | | |
|---|---|---|---|
| | 150 kHz to 80 MHz | 80 MHz to 800 MHz | 800 MHz to 2.5 GHz |
| | d = 1.6 /P | d = 1.6 /P | d = 2.33 /P |
| 0.001 | 0.116 | 0.116 | 0.233 |
| 0.1 | 0.366 | 0.366 | 0.736 |
| 1 | 0.16 | 1.16 | 2.33 |
| 10 | 3.66 | 3.66 | 7.36 |
| 100 | 11.6 | 11.6 | 23.3 |

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1 : At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2 : These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.


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# 5 INSTALLATION

The device is intended to be used by a dental practitioner. Its installation does not require any special training. Consult the instructions in this manual.

## 5.1. CONNECTING

Fastening the handpiece holder:

1. Choose a plain area that can be easily accessible for use.
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 that is on the support, place it, and then press it into place several times. The maximum sticking performances are obtained after two hours,so avoid any stress on the holder during this two hour period.

⚠ CAUTION :

*This holder is equipped with magnets that can damage devices sensitive to magnetic fields. Make sure you do not install this holder near these devices (cathode ray tube video screen, magnetic videotapes, etc.)*

## 5.2 FURTHER CONNECTION BOXES (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. When you disconnect the handpiece connecting cable to take it to another chair (or when you put the handpiece in its holder), the last stored image is displayed on the screen or the last four if you were in four-images mode, or the color-bar pattern if no image was stored (except on Dock USB2 and Dock U_USB2).

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5.3. FOCUSING ADJUSTMENT

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.

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


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# 6 CONNECTING TO A VIDEO SCREEN

## 6.1. CONNECTION OF DOCK M_USB2 OR DOCK M_VIDEO

- Connect the video cable (preferably Y/C "S-video") between the connection box and the monitor video input
- Connect the connecting cable between the connection box and the handpiece.
- If you prefer using a footswitch rather than SoproTouch to freeze the image, you just have to connect the footswitch (optional) to the connection box. With this configuration, SoproTouch is inhibited.
- Connect the power supply to the outlet, and then to the connection box (the green indicator light should be on).
- Only use the power supply provided with the connection box.

## 6.2. CONNECTION OF DOCK MU_USB2 OR DOCK MU_VIDEO

- Please refer to DOCK MU_USB2/DOCK MU_VIDEO integration manual for its connections.
- Connect the connecting cable to the handpiece.
- Connect the video cable (preferably Y/C "S-video") between the connection box and the monitor video input.

## 6.3. OPERATION OF SOPROTOUCH IMAGE FREEZE ON CAMERA

- When powering on, the camera automatically selects the one-image mode.

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• To switch to four-image mode, press SoproTouch for more than three seconds (until a black flash appears on the screen or, if you have chosen to use a footswitch, press it for more than three seconds).

• Perform the same procedure to switch back to one-image mode.

• In one-image mode, you just have to slightly touch SoproTouch (or briefly press the footswitch once) as soon as the desired image appears on the monitor. The image is automatically stored in the camera and displayed on the screen. If you want to return to direct mode, you just have to slightly touch SoproTouch once more (or press the footswitch).

• Another little gentle touch on SoproTouch (or press on the footswitch) will freeze another image by deleting the previous one.

• In four-image mode, the image is stored in one of the quarters of the screen when you slightly touch SoproTouch (or press the footswitch) and remains displayed on the screen. Another little slight touch on SoproTouch (or press of the footswitch) will return the image to direct mode. A third little slight touch (or press) will store a second image in another quarter of the screen and so on until obtaining the four images.

NOTE :
*The footswitch must be rated IPX1 according to IEC 60529 standard (Article 15.4.7.3 of IEC 60601-1 ed3 standard).*


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# 7 CONNECTING TO A COMPUTER

## 7.1. REQUIRED CONFIGURATION FOR THE COMPUTER

To use the SOPRO device, you must make sure the computer and its peripherals do not have any usage limitation that could concern personal safety. It should also meet the following requirements:

Windows® configuration:

| | Minimum Configuration | Recommended Configuration |
|---|---|---|
| Operating system | Windows® XP Pro SP3 | Windows® 7 Pro SP1 |
| Processor | Intel® Pentium IV - 1,3 GHz | Intel® Core 2 |
| Memory | 512 MB | 2 GB or more |
| Hard disk | 250 GB | 320 GB or more |
| USB ports | 2 USB2.0 Hi-Speed ports | 4 USB2.0 Hi-Speed ports |
| Video board | Graphic board 32 MB of unshared video RAM compatible with DirectX 9 | Chipset Nvidia or ATI / 512 MB RAM unshared video RAM compatible with DirectX 9 or higher. |
| USB Chipset | Intel or NEC® / RENESAS® | Intel or NEC® / RENESAS® |
| Screen resolution | 1024 x 768 | 1280 x 1024 or more |

MAC® configuration:

| | Minimum Configuration | Recommended Configuration |
|---|---|---|
| Computer | MAC® Book Pro 13.3" or iMac® 21.5" | iMac® 27" |
| Operating system | MAC® OS X 10.6 Snow Leopard | MAC® OS X 10.7 Lion |
| Processor | Intel® Core 2 | Intel® Core i7 |
| Memory | 2 GB | 4 GB |

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7.2. DOCK M_USB2 CONNECTION

- Connect the USB cable between the connection box and one of the computer USB ports.
- Connect the connecting cable between the connection box and the handpiece.
- If you prefer using a footswitch rather than SoproTouch to freeze the image, you just have to connect the footswitch (optional) to the connection box. With this configuration, SoproTouch is inhibited.
- Connect the power supply to the outlet, and then, to the connection box (the green indicator light should be on).

7.3. DOCK MU_USB2 OR DOCK U_USB2 CONNECTION

- Refer to DOCK MU_USB2 / DOCK U_USB2 integration manual.
- Connect the connecting cable to the handpiece.
- Connect the USB cable between the connection box and one of the computer USB ports.

7.4. DOCK USB2 CONNECTION

- Connect the USB cable to one of the computer USB ports.
- Connect the connecting cable to the handpiece.

7.5 SOPRO IMAGING SOFTWARE INSTALLATION

Refer to the Sopro Imaging installation manual that is on the Sopro Imaging CD-ROM in the document directory.

7.6. SOPRO IMAGING SOFTWARE CONFIGURATION WITH THE CAMERA

Refer to the USB connection for camera SOPRO manual that is on the Sopro Imaging CD-ROM in the document directory.


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# OPERATION PROTOCOL OF THE CAMERA IN PERIO MODE AND CARIO MODE

The SOPROCARE is used as an aid in the prevention practice thanks to its technology based on fluorescence phenomenon (given by its LED lamps) and chromatic amplification, this camera will permit a large and time efficient oral examination of the patient.

The optics and the charge coupled device (CCD) sensor in the SOPROCARE pick up the images containing this fluorescence, highlight it and converts them to a video signal that is sent to a video monitor or computer monitor. The result 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, any changes in fluorescence color should direct 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 to formulate an appropriate treatment plan.

NOTE:
*The SOPROCARE is an aid in your diagnosis by providing additional information to supplement the dentist's visual observations, patient history and information from other diagnostic techniques, resulting in overall determination. The camera does not provide a diagnosis. Diagnosis subsequent to the use of the camera is performed by the dental practitioner.*

Any use that is not described in this manual as correct usage is considered as incorrect usage. The manufacturer is not to be held liable for any damage caused as a result of incorrect usage. The operator bears all risks.

## 8.1. PERIO MODE

This fluorescent mode associated with chromatic amplification permits to have information about patient dental hygiene and to highlight dental plaque and gingival inflammations (restricted to gingival inflammations which lead to bleeding upon probing). The images provided are displayed with colors that can be interpreted following the tab below:

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| | Normal signal | | Alert signal | |
|---|---|---|---|---|
| Displayed color | Natural color of the tooth | Natural color and aspect of the gum | Presence of deposits from white, yellow, orange to red | Coloration of the gum in purplish red |
| Supposed state of tissue | No presence of deposits on the tooth | Healthy gum | Presence of dental plaque | Presence of gingival inflammation |
| Examine for | Healthy tooth | Healthy tooth | Use gold standard techniques to examine for patient's hygiene | Use gold standard techniques to examine for gingival inflammation |

The camera needs to be used with a SOPROTIPS, it must be put on the camera's head. This accessory provided with the camera enables displacement of ambient lighting.

NOTE: the clinical sign of non-bleeding on probing is not a safe criteria for evaluating gingival health. An absence of alert signal for gingival inflammation in inspected area can't be considered as a sign of healthy area.

8.2. CARIO MODE

In this fluorescent 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 a 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 color | Colorless | Red |
| Supposed state of tissue | Healthy dentine | Suspicious area |
| Examine for | Healthy tooth | 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 fluor-paste that can interfere with caries detection. Then perform a new examination.

Diagnosis subsequent to the use of the SOPROCARE is performed and provided by the general practitioner and/or dental hygienist.


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Alert signal is only an indication, the dental practitioner is the only expert to judge and adapt his/her treatment's option to the situation and also decide to stop treatment based on his/her clinical sense.

8.3. MODE SELECTION



Button 1: Pressing on this button makes it possible to switch from DAYLIGHT mode to PERIO mode and inversely.

Button 2: Pressing on this button makes it possible to switch from DAYLIGHT mode to CARIO mode and inversely.

9

# DESCRIPTION OF THE CONNECTION BOXES

⚠ WARNING:
*Devices that connect to the inputs / outputs must conform to the IEC 60950-1 standard. Risk of electrical shock.*

## 9.1. DOCK M_USB2 AND DOCK M_VIDEO POWER SUPPLY

SOPROCARE power supply is connected to the power outlet. The other end of the cord is connected to the connection box where the symbol 6 V ⎓ is located (PHIHONG, PSA 10R-060 Model or FRIWO, MPP15 FW 7555M/06 model).
The power supply automatically adapts to the electric networks 115 V~ - 230 V~; 60 Hz - 50 Hz; 0.5 A. SOPROCARE voltage is powered by 6V ⎓ of a continuous low voltage type.

## 9.2. DOCK MU_USB2 / DOCK MU_VIDEO POWER SUPPLY

The electrical connection of this connection box should be performed by the installer. SOPROCARE power supply is powered through the connection box that should be connected to 24 V~; 50 Hz - 60 Hz; 10 VA.

## 9.3. DOCK U_USB2 POWER SUPPLY

The electrical connection of this connection box should be performed by the installer. SOPROCARE power supply is powered through the connection box that should be connected to 24 V~; 50 Hz - 60 Hz; 15 VA.

## 9.4. DOCK USB2 POWER SUPPLY

The dental camera electrical supply is directly powered through the computer USB port. The voltage powering the camera is of continuous 5 V low voltage type ⎓ (0.5 A).


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9.5. VIDEO AND USB OUTPUTS

These connection boxes have two independent video outputs* - a composite one and a Y/C "S-Video" one.
One of these two outputs should be connected to the monitor video input (preferably Y/C "S-Video"). This connection box has a digital USB 2.0 output that can be connected to a computer USB2 port.
*Except on Dock USB2 and DOCK U_USB2.

9.6.FOOTSWITCH

The footswitch should be connected* here  if you have selected it to freeze the image. (*Except on DOCK USB2)

9.7. IDENTIFICATION

The symbols on the boxes identify the SOPROCARE according to the international standards IEC 60601-1, IEC 60601-2-18 and IEC 60417.

 Class II power supply not grounded. The plug of the power supply is used as the disconnecting device on the network. Only for M_USB2 and M_VIDEO docking stations.

 Dental barriers for single use.

 Video output.

 Handpiece connection.

 Footswitch connection.

 Continuous voltage.

 USB2 output.


Type BF applied part


Follow instructions for use.


Disposal of electric and electronic equipment marketed after 13/August/2005. This symbol indicates that the product cannot be disposed as domestic waste.


For medical devices, this symbol is associated to the manufacturing year (expressed with four digits).


For medical devices, this symbol is associated to the manufacturer name and address.



Product compliance according to the European directive 93/42/EEC relative to medical devices.


Functional earth ground (for MU_USB2 and MU_VIDEO docking stations).

The devices that connect to video or USB outputs should comply with the IEC 60950 standard.


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# SOPROTIPS STERILIZATION

SOPROTIPS must be clean before sterilization.

SOPROTIPS can be immersed in a disinfection bath and be subjected to a manual or automatic cleaning device (ultrasonic cleaner).

It must then be rinsed, dried and packaged before sterilization in an autoclave.

Package should be double-pouche, with as an example SPS Medical Selg-Seal Sterility assurance pouches; part #SSP-380- (inner pouch) and part # SSP-382 (outer pouch).

For pre-vacuum steam sterilizer the following parameters have been validated: 132˚C (270˚F) for 4 minutes,20 minutes dry time.

For Gravity-displacement steam sterilizer the following parameters have been validated:121˚C (250˚F) 30 minutes, 30 minutes dry times.

! CAUTION: Nevertheless, it is important to note that sterilization of SOPROTIPS in an autoclave will cause wear on these accessories. Therefore it is recommended to replace the SOPROTIPS on average, every fifty sterilization cycles (to avoid distorted diagnosis).

NOTE:
The SOPROTIPS can be cleaned with a disinfecting wipe e.g. Septol Wipes from Pierre Rolland.

⚠ WARNING:
Infection control procedures must be observed when using accessories such as SOPROTIPS and dental barriers in order to prevent cross contamination risk from one patient to another.

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# 11 MAINTENANCE

The camera does not need any maintenance if it is used according to the manufacturer's use and cleaning instructions.
Before first using it, it is imperative to follow the complete disinfecting procedure.

Any camera returned from servicing or maintenance should be completely disinfected before being used.

⚠ WARNING:
*Do not use products containing:*
- *Ammoniac, trichloroethylene*
- *Dichloroethylene*
- *Ammonium hydrochlorid*
- *Chlorinated and aromatic hydrocarbon*
- *Ethylene dichloride*
- *Methylene chloride*
- *Ketones*

*Use of these chemicals subject plastic parts to risk of deterioration.*

! CAUTION:
*Do not directly spray disinfecting products on SOPRO products. This could damage the product.*

⚠ WARNING:
*Infection control procedures must be observed when using accessories such as SOPROTIPS and dental barriers in order to prevent cross contamination risk from one patient to another.*


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11.1. HANDPIECE OR CONNECTION BOX MAINTENANCE

NOTE:

*In case of contact with blood or excessive soiling, it is strongly recommended to follow a disinfecting process. First, clean the handpiece with disinfecting wipes, then wrap the handpiece in several disinfecting wipes and leave for 15 minutes.*

| DESCRIPTION | RECOMMENDATIONS | USE INSTRUCTIONS AND PRECAUTIONS | |
|---|---|---|---|
| | | ✓ | x |
| Disinfecting | Surface cleaning and disinfecting wipes e.g. Septol™ Wipes from Pierre Rolland. | ✓ Take the wipe, remove excess moisture, and then wipe the equipment until visible cleanliness is obtained.<br>✓ Allow to dry in the open air.<br>✓ Carefully close the packaging box. | x Do not scrub<br>x Do not rinse.<br>x Do not immerse in a disinfecting liquid. |

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# 12 AFTER-SALES SERVICE

## 12.1. WARRANTIES

SOPRO ensures 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, or 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 its convenience when replacing or repairing, free of charge the defective product, if it has been sent to SOPRO After-Sales Service. This applies for the warranty period.

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 REMEDY. IT REPLACES ANY OTHER WARRANTY, FOR EXAMPLE, A WARRANTY OF ADEQUACY TO A PARTICULAR AIM, SHOULD IT BE 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, NON-CONTRACTUAL 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.


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12.2. IN CASE OF FAILURE

| PROBLEMS | CAUSES | SOLUTIONS |
|---|---|---|
| With a video monitor | | |
| No image displays on the screen and SOPROCARE LEDs are not on. | • Defective power supply.<br>•connection problem. | 1. Check the power supply is correctly connected to the network and to the connection box.<br>2. Check 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. | • Defective monitor power supply.<br>• Connection problem. | 1. Check the video cable is correctly connected to the monitor and to the connection box.<br>2. Check the monitor is switched on. |
| An image displays on the screen, but the quality is not satisfac-tory. | Monitor configuration. | Check the video monitor configuration is correctly set up (brightness, contrast, saturation, etc.) |
| An image displays, but it is not really clear (blurry) | • Rotating ring.<br>• Hygienic protector. | 1. Check the rotating ring is correctly positioned (Extra oral, Intra oral, CARE, macro).<br>2. Check the hygienic protector is correctly positioned on the camera head. |
| With a computer | | |
| No image displays on the screen and the SOPROCARE LEDs are not on. | • Defective power supply.<br>•connection problem. | 1. Check the power supply is correctly connected to the network and to the connection box.<br>2. Check 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<br>•Driver<br>• Connection problem. | 1. Check the SOPROCARE is correctly set up in Sopro Imaging (please, refer to Sopro Imaging user's manual).<br>2. Check the camera is correctly detected in the device driver (correct installation of its driver).<br>3. Check the USB cable coming from the DOCK is correctly connected to the HUB. |

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| | | |
|---|---|---|
| An image displays on the screen, but the quality is not satisfactory. | Camera driver configuration | Check the camera configuration in the Sopro Imaging software (brightness, contrast, saturation, etc.). Please refer to Sopro Imaging user's manual. |
| An image displays, but it is not really clear (blurry) | • Rotating ring.<br>• Hygienic protector. | 1. Check the rotating ring is correctly positioned (Extra oral, Intra oral, CARE, macro).<br>2. Check the hygienic protector is correctly positioned on the camera head. |

The camera should be sent to us in its totality (connection box, handpiece, cables). Please enclose your packing list with a brief explanatory note relative to the noticed defect.

If some parts constituting the camera happen to break, it is imperative to send in everything so that the defective parts can be replaced.

When your material is returned to you, you should 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 deny 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.


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# TECHNICAL FEATURES

SOPROCARE

- High sensitivity CCD 1/4".
- Resolution: (752 x 582) PAL; (768 x 494) NTSC.
- Definition: 470 lines.
- Sensitivity: 2 lux.
- Lighting: seven LEDs.
- Adjustment: four preset positions (Extra-oral, Intra-oral, Tooth, Macro).
- 3 positions: PERIO mode, CARIO mode and DAYLIGHT mode.
- Non-inverted image.
- Image capture through SoproTouch or footswitch (optional).
- Angle of view: 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.

DOCK M_USB2

- Memory one and four images.
- Power supply: 115 V~ - 230 V~; 60 Hz - 50 Hz
- 1 PAL or NTSC video output.
- 1 PAL or NTSC S-video output.
- 1 digital USB output 2.0.
- Controller dimensions: L: 145; W: 130; H: 35 mm.
- Controller weight: 245 g.

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DOCK M_VIDEO
- Memory one and four images.
- Power supply: 115 V~ - 230 V~; 60 Hz - 50 Hz
- 1 PAL or NTSC video output.
- 1 PAL or NTSC S-video output.
- Controller dimensions: L: 145; W: 130; H: 35 mm.
- Controller weight: 245 g.

DOCK U_USB2
- Power supply: 24 V~; 50 Hz - 60 Hz.
- Consumption: 15 VA.
- 1 digital USB output 2.0.
- Controller dimensions: L: 50; W: 75; H: 36 mm.
- Dock weight: 76 g.

DOCK MU_USB2
- Memory one and four images.
- Power supply: 24 V~; 50 Hz - 60 Hz.
- Consumption: 10 VA.
- 1 PAL or NTSC video output.
- 1 PAL or NTSC S-video output.
- 1 digital USB output 2.0.
- Controller dimensions: L: 100; W: 72; H: 36 mm.
- Dock weight: 190 g.

DOCK MU_VIDEO
- Memory one and four images.
- Power supply: 24 V~; 50 Hz - 60 Hz.
- Consumption: 10 VA.
- 1 PAL or NTSC video output.
- 1 PAL or NTSC S-video output.
- Controller dimensions: L: 100; W: 72; H: 36 mm.
- Dock weight: 190 g.

DOCK USB2
- Cable length: 3.5 m.
- 1 digital USB output 2.0.
- Controller dimensions: L: 100; W: 46; H: 20 mm.
- Dock weight: 165 g.

- BF-type applied part.
- Operating temperature: +10˚C to +40˚C.
- Storage temperature: -20˚C to +45˚C.
- Relative humidity: 10 % to 90 %.
- Atmospheric pressure: 900 hPa to 1060 hPa.
- Continuous service.
- Not protected against water ingress (IPX0).
- Not adapted to the use in presence of an anaesthetic mixture flammable with air, oxygen or dinitrogen monoxide.
- Complies with the European directive 93/42/EEC.
- Complies with IEC60601-1 standard.
- Complies with IEC60601-2-18 standard.
- Complies with UL 60601-1 and CSA 60601-1 standard.

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ZAC Athélia IV - Avenue des Genévriers - 13705 LA CIOTAT cedex • FRANCE
Tel + 33 (0) 442 98 01 01 • Fax + 33 (0) 442 71 76 90

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SOPRO • A company of ACTEON Group • ZAC Athélia IV - Avenue des Genévriers - 13705 LA CIOTAT cedex • FRANCE
Tel : + 33 (0) 442 98 01 01 • Fax : + 33 (0) 442 71 76 90
E-mail : info@sopro.acteongroup.com • www.acteongroup.com

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