SOPROLIFE

Light Induced Fluorescence Evaluator

User's manual

IMAGING ACTEON

Contents

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.

⚠ **CAUTION**: the term CAUTION describes potential incidents likely to jeopardize safety.

WARNING: the term WARNING refers to the incidents likely to disturb the smooth running of the imaging system.

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

2

DENTAL CAMERA INTRODUCTION

Congratulations on your purchase of the SOPROLIFE Caries Detection Aid System, the latest product from Sopro Acteon Imaging in the aid of detection of caries.

SOPROLIFE system provides the following benefits:
• Motivates the patient to carry out a professional tooth cleaning.
• Aids in the detection of caries.
• Ideal complement to an X-ray imaging system for patient care.

In mode I, diagnosis aid mode, SOPROLIFE helps the dental practitioner to detect damage at various clinical stages in very high resolution.

In mode II, treatment aid mode, SOPROLIFE helps dental practitioner to get a spatial map of unbroken tissue areas which are suspect.

In daylight mode », SOPROLIFE enables you to visualize anatomical details invisible to the naked eye or with a mirror. It allows the dentist to show the difference between «before» and «after» care.

This fluorescence Imaging device is composed of a handpiece (SOPROLIFE) 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.

SOPROLIFE
• 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 SOPROLIFE and SOPRO-Imaging software

DOCK M_USB2
- A connection box with integrated image memory and USB2 digital output.
- Power supply.
- A 2.5 metre cable to connect the handpiece to the connection box (5 metres and 7 metres optionally).
- An S-video Y/C cable
- An RCA video cable.
- A USB cable.

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

DOCK USB2
- A USB2 connection box with a 3.5 metre 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 metre cable to connect the handpiece to the connection box (5 metres and 7 metres optionally).
- An installation manual.

DOCK U_USB2
- A connection box with USB2 digital output.
- A 2.5 metre cable to connect the handpiece to the connection box (5 metres and 7 metres optionally).
- An installation manual.

DOCK MU_USB2
- A connection box with integrated image memory and USB2 digital output.

• A 2.5 metre cable to connect the handpiece to the connection box (5 metres and 7 metres optionally).
• An installation manual.

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 dental camera. For more details about these products, please refer to our catalogue or contact our commercial service.

NOTE :
The device was designed and developed with its accessories in order to guarantee to you safety and performance maximum. The use of different origin accessories can represent a risk for you, your patients and your device.

3 SAFETY INSTRUCTIONS

• DO NOT expose the SOPRO camera to water spray and do not store it in a humid environment (to prevent risk of electrocution).
• When handling camera and dental barriers, always take the appropriate hygiene measures and precautions in order to prevent cross contamination risks.
• Infection control procedures must be observed when using accessories such as 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.
• Install the camera in a clean, dry, and well-ventilated place.
• Disconnect the connection box from the power supply if you are not going to use it for several days. Do not pull on the cable.
• DO NOT compress or nip the handpiece cable.
• DO NOT expose the product to high vibrations.
• DO NOT drop the handpiece.
• Handpiece should NEVER be immersed in any liquid, NOR should it be autoclaved.
• For each new patient, it is essential to use the dental barriers provided with the handpiece. Before using the camera, make sure it does not have any sharp edges.
• 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.
• 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.

⚠ **CAUTION:**
Modification of the product, without the permission of the manufacturer, is prohibited.

⚠ **CAUTION:**
If the medical equipment is changed, an appropriate control and test should be performed to ensure that the medical equipment still can be used safety.

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 (CEM) 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 CISPR11 standard.

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 contribute to avoiding 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.

4.5. ELECTROMAGNETIC COMPTABILITY

<table>
<tr><th colspan="3">Guide and declaration of the manufacturer - electromagnetic emissions</th></tr>
<tr><td colspan="3">SOPRO device is intended to be used in the electromagnetic environment specified below.
The user should make sure it is used in this environment.</td></tr>
<tr><th>Emission trial</th><th>Compliance</th><th>Electromagnetic environment - Guide</th></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td>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.</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Class B</td><td rowspan="3">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.</td></tr>
<tr><td>Harmonic emissions
EN 61000-3-2</td><td>Not applicable</td></tr>
<tr><td>Voltage fluctuations / Flicker
EN 61000-3-3</td><td>Applicable</td></tr>
</table>

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	**CEI 60601 Severity level**	**Compliance level**	**Electromagnetic environment Guide**
Electrostatic discharges EN 61000-4-2	± 6 kV when in contact ± 8 kV in the air	± 6 kV ± 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 ± 1 kV for the input/output cables	± 2 kV ± 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 Common mode ± 2 kV	± 1 kV 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 • 40% Ut - for 100 ms • 70% Ut - for 500 ms • <5% Ut - for 5 s	<5% Ut 10 ms <40% Ut 100 ms <70% Ut 500 ms <5% Ut 5 s	The main power supply quality should be one of a traditional commercial or hospital environment. If the user of SOPRO device requires it to continue to operate during main power supply outages, it is recommended SOPRO 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.			

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	**CEI 60601 Severity level**	**Compliance level**	**Electromagnetic environment Guide**
			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. **Recommended separation distance**
Conducted RF EN 61000-4-6	3 Vrms 150 kHz to 80 MHz	3V	d = 1.16√P
Radiated RF EN 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3V/m	d = 1.16√P 80 MHz to 800 MHz d = 2.33√P 800 MHz to 2.5 GHz where P is the maximum rated output of the transmitter in watts (W) by the transmitter manufacturer and d the recommended separation distance in metres (m). The field levels emitted by the fixed RF transmitters, determined by an electromagnetic measurement of the sitea, should be lower than the compliance level in each frequency band b. Interference may occur in the vicinity of the devices bearing the following symbol:

Note 1 : At 80 MHz and 800 MHz, the higher frequency band applies.

Note 2 : These recommendations may not apply in every situation. Electromagnetic wave propagation is modified by the absorption and reflection due to the structures, objects and persons.

a The fixed transmitter field levels, such as the base stations of the radio telephones (cellular/wireless) and the terrestrial mobile radios, domestic radio, AM, FM, and TV radio communication cannot be theoretically assessed precisely. To obtain the electromagnetic environment due to the fixed RF transmitters, a site measurement should be performed. If a field level measured in the use environment of SOPRO device exceeds the compliance levels above applicable, the good operation of SOPRO device should be checked. If abnormal operations are proved, some further measures should be taken, such as reorientation or relocation of the standard device.

b Above the 150 kHz to 80 MHz frequency band, the field level should be lower than 3 V/m.

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

SOPRO device is intended to be used in an electromagnetic environment in which the irradiated RF disturbances are checked. The user of SOPRO device can help to avoid electromagnetic interference by maintaining a minimal distance between the portable and mobile RF communication devices (transmitters) and the recommended SOPRO device such as recommended below, depending on the maximum output power of the communication device.

Rated maximal output power of the transmitter W	Separation distance depending on the transmitter frequency - m		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2,5 GHz
	$d = 1.6 \sqrt{P}$	$d = 1.6 \sqrt{P}$	$d = 2.33 \sqrt{P}$
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 the transmitters whose maximal output is not listed above, the recommended separation distance d in metres (m) can be determined by using the equation applicable to the transmitter frequency, where P is the maximal output of the transmitter in watts (W) rated by the transmitter manufacturer.

Note 1 : At 80 MHz and at 800 MHz, the separation distance given in the higher frequency band applies.

Note 2 : These recommendations may not apply in every situation. The electromagnetic wave propagation is modified by absorption and reflection due to the structures, objects and persons.

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 on its holder), the last stored image is displayed on the screen or the last four if you were in four-image mode, or the colour-bar pattern if no image was stored (except on Dock USB2 and Dock U_USB2).

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).
- LIFE (diseases observations)
- Macro (details that cannot be seen with naked eye).

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.

• To switch to four-image mode, press SoproTouch or 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 conformed IPX1 according to IEC 60529 standard (Article 15.4.7.3 of IEC 60601-1 ed3 standard).

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:

	Minimal 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:

	Minimal Configuration	Recommended Configuration
Computer	MAC® Book Pro 13.3" ou 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

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 owner's 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 Sopro Imaging owner's manual that is on the Sopro Imaging CD-ROM in the document directory.

7.7 USING SOPRO IMAGING SOFTWARE WITH LIFE FUNCTION

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

8

OPERATION PROTOCOL OF THE CAMERA IN IN DIAGNOSIS AID MODE AND TREATMENT AID MODE

The Soprolife is used as an aid in the detection of caries. The light emitting diode (LED) lamps in the Soprolife emit blue- light (In diagnosis aid mode and treatment aid mode) which causes healthy dentin to fluoresce with a green color.

The optics and the charged coupled device (CCD) sensor in the Soprolife picks up the images containing this fluorescence, highlights it and converts them to an video signal that is sent to a video monitor or computer monitor. The result image can be used to aid the dental practitioner to perform diagnosis.

As an aid in the detection of caries, any color other than acid green, light green or blue displayed in the image should direct the dental professional to examine that area using Gold Standard techniques. The Soprolife image information together with results of visual Gold Standard examination and X-ray image inspections can be used to identify any caries and to formulate an appropriate treatment plan.

NOTE:
The Soprolife is an aid in the detection of caries by providing additional information to supplement the dentist's visual observations, patient history, and information from other diagnostic techniques, resulting in an overall treatment determination. The Soprolife does not provide a diagnosis. Diagnosis subsequent to the use of the Soprolife is performed and provided 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.

SOPROLIFE today has not been proven to detect incipient or just beginnings caries.

SOPROLIFE needs to be used with a SOPROTIPS in both diagnosis aid mode and treatment aid mode. This accessory provided with SOPROLIFE enable displacement of ambient lighting.

The SOPROTIPS must be put on the camera's head; when using this accessory it is necessary to move the dental light in order to avoid light in the patient's mouth.

8.1. DIAGNOSIS AID MODE

In mode I, diagnosis aid mode, SOPROLIFE helps the dental practitioner to detect damage at various clinical stages in very high resolution. DIAGNOSIS AID MODE is used to view the fluorescence of the tooth surfaces in order to quickly identify areas for the dentist to examine using Gold Standard methods. The images provided are displayed with colors than can be interpreted following the tab below:

	Normal signal		Alert signal
Displayed color	Acid green	Light green to blue according to the thickness of the enamel	Green/black or Bright red or black red or miss of color (grey area)
Supposed state of tissue	Healthy dentine	Healthy dentine	Suspicious area
Examine for	Healthy tooth	Healthy tooth	Use Gold Standard techniques to examine for potential caries

In case of 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 tartar, plaque detection agents and preventative materials such as fluor-paste that can interfere with caries detection. Then process to a new examination.

8.2. TREATMENT AID MODE

In mode II, treatment aid mode, SOPROLIFE helps dental practitioner to get a spatial map of unbroken tissue areas which are suspect. It helps to check the exeresis quality of damage tissue during or at the end of the preparation in several clinical situations common in general practice. Diagnosis subsequent to the use of the Soprolife is performed and provided by the dental practitioner. The images provided are displayed with colors than can be interpreted following the tab below:

In case of quick carious processus:

	Normal signal	Alert signal		
Displayed color	Light green to blue according to the thickness of the enamel	green / black or Bright red	dark green	dark green with red shadow
Supposed state of tissue	Healthy dentine	Completely decayed infected dentine or affected Interface	Affected dentine (end of treatment)	Affected dentine (end of treatment) there can still be a red shadow at the bottom of the cavity, linked to a very hard tissue. It represents the tertiary dentine and testifies of the answer of the pulp to the carious attack.
Examine for	Healthy tooth	Suspicious area*	Presumed end of treatment*	Presumed end of treatment*

*Diagnosis subsequent to the use of the Soprolife is performed and provided by the dental practitioner. Alert signal is only an indication, the dental practitioner is the only expert to judge and adapt his treatment's option to the situation and also decide to stop treatment based on his clinical sense.

In case of slow carious processus:

	Normal signal	Alert signal	
Displayed color	Acid green or Light green to blue according to the thickness of the enamel.	green / black or Bright red	dark green with red shadow
Supposed state of tissue	Healthy dentine	Completely decayed infected dentine or affected Interface	Affected dentine (end of treatment)
Examine for	Healthy tooth	Suspicious area*	Presumed end of treatment*

8.3. SELECTION MODE

Button I: Pressing on button “I” makes it possible to switch from daylight mode to diagnosis aid mode and inversely.

Button II : Pressing on the button II makes it possible to switch from daylight mode to treatment aid mode and inversely.

NOTE :
An alternated push on the button I then on the button II makes it possible to switch from diagnosis aid mode to treatment aid mode.

9

DESCRIPTION OF THE CONNECTION BOXES

⚠ **CAUTION:**
Devices that connect to the inputs / outputs must be conformed to IEC 60950-1 standard.

9.1. DOCK M_USB2 AND DOCK M_VIDEO POWER SUPPLY

SOPRO device 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. SOPRO device 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. SOPRO device power supply is performed through the connection box that should be connected 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. SOPRO device power supply is performed through the connection box that should be connected 24 V~; 50 Hz - 60 Hz; 15 VA.

9.4. DOCK USB2 POWER SUPPLY

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

9.5. VIDEO AND USB OUTPUTS

These connection boxes has 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 indications born on the boxes identify the SOPRO device 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.

“BF type camera”.

Follow instructions for use.

Disposal of electric and electronic equipment marketed after 13/August/2005. This symbol indicates that the product cannot be treated with 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.

Grounding (for MU_USB2 and MU_VIDEO docking stations).

The devices that connect to video or USB outputs should comply with 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.

It can be sterilized at 134°C and two bars (200 KPa) in an autoclave for 18 minutes.
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 fifteen 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.

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.

WARNING:
Do not directly spray disinfecting products on SOPRO products.

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.

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 of all, 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. ✓ Allow to dry in the open air. ✓ Carefully close the packaging box.	x Do not scrub x Do not rinse. x Do not immerse in a disinfecting liquid.

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, othVer 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.

12.2. IN CASE OF FAILURE

PROBLEMS	CAUSES	SOLUTIONS
With a video monitor		
No image displays on the screen and camera LEDs are not on.	• Defective power supply. •connection problem.	1. Check the power supply is correctly connected to the network and to the connection box. 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. • Connection problem.	1. Check the video cable is correctly connected to the monitor and to the connection box. 2. Check the monitor is switched on.
An image displays on the screen, but the quality is not satisfactory.	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. • Hygienic protector.	1. Check the rotating ring is correctly positioned (Extra oral, Intra oral, LIFE, macro). 2. Check the hygienic protector is correctly positioned on the camera head.
With a computer		
No image displays on the screen and the camera LEDs are not on.	• Defective power supply. •connection problem.	1. Check the power supply is correctly connected to the network and to the connection box. 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 •Driver • Connection problem.	1. Check the camera is correctly set up in Sopro Imaging (please, refer to Sopro Imaging user's manual). 2. Check the camera is correctly detected in the device driver (correct installation of its driver). 3. Check the USB cable coming from the DOCK is correctly connected to the HUB.

An image displays on the screen, but the quality is not satisfactory.	Camera driver configuration	Check the camera configuration in the 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. • Hygienic protector.	1. Check the rotating ring is correctly positioned (Extra oral, Intra oral, LIFE, macro). 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

SOPROLIFE

- High sensitivity CCD 1/4”.
- Resolution: (752 x 582) PAL; (768 x 494) NTSC.
- Definition: 470 lines.
- Sensitivity: 2 lux.
- Lighting: eight LEDs.
- Adjustment: four preset positions (Extra-oral, Intra-oral, LIFE, Macro).
- 3 positions: DIAGNOSTIC aid mode, TREATMENT aid 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.

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; l: 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 chutes (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 et CSA 60601-1 standard.

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IMAGING
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