97050942
Rev. 04
2019-12

X-VS

CEFLA S.C. VIA SELICE PROVINCIALE 23/A - 40026 IMOLA (BO) ITALY
PLANT: VIA BICOCCA 14/C - 40026 IMOLA (BO) - ITALY

EN

Contents

1. INTRODUCTION AND INDICATIONS FOR USE

X-VS is a digital intraoral sensor intended for acquiring intraoral digital images when exposed to X-rays, for diagnostic radiographic examination of the human dentition (teeth, maxillary area and oral structures).
The produced digital images are automatically transmitted via digital connection to a PC.
The device can be used as an accessory to legally marketed components such as conventional X-ray tubes and software for the acquisition of images.
The device is managed and used by doctors, dentists, radiologists and other legally qualified professionals.

The intraoral sensor X-VS has been developed to simplify the entire intraoral x-ray acquisition procedure and display the images on a computer screen. Thanks to the new shape ergonomics, this sensor allows an easy intraoral positioning. The smoothed edges and rounded corners comfortably adapt to the shape of the patient's mouth, ensuring an easy positioning. The sensor X-VS is available in two interchangeable sizes to satisfy various diagnostic requirements.

The sensor electronic module is compatible with the extremely fast USB® 2.0 standard, thereby cutting down the time that elapses between x-ray exposure and display of the image on the computer screen to a few seconds.
X-VS is designed as a stand-alone device or as an accessory to be fitted to mechanically compatible dental units.

In stand-alone version, the USB® connection makes the system convenient and portable. In fact, no power supply adapters are needed as power is fed directly through the USB® port, thanks to the low consumption requirements.

In the version integrated in the dental unit, the x-ray sensor is placed on-board the dental unit like any other instrument on the dentist's board.

A computer and program to view x-ray images are required for use of both versions. If used in conjunction with a dental office practice management software, the x-ray images can be associated to each patient and saved for processing and viewing when required.

The sensor system makes use of a communication standard called TWAIN®, adopted by many electronic products such as scanners and digital cameras. TWAIN® ensures product compatibility with all the best programs for digital image management and processing.

Regardless of the selected program, refer to the manual supplied together with the program for all the warnings, precautions and operating instructions.

The sensor is supplied together with software called iCapture, that assures the x-ray images are correctly transferred from the electronic module to the computer.

USA federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

Use a third-party software for the management and treatment of digital images acquired with the intraoral sensor only as long as such software does not alter the content of the images provided by iCapture independently from the user's will.

The Manufacturer's website contains a list of authorised agents.

1.1. DESCRIPTION OF THE MANUAL

This Manual is an essential consultation tool and contains important information and instructions for the use of the digital sensor.
These instructions describe how to properly and safely use the sensor.
Carefully read and familiarise yourself with the entire contents of the Manual before attempting to use the product.
To use the software, refer to the specific manual.

The Manual is only provided in electronic format and can be consulted directly on the PC screen during use. It is advisable to keep a copy of this manual within reach with the aim of training the operators and as guide for consultation during the use of the device. This manual also contains all the essential information for the safety of patient, operator and device.

It is therefore advisable to read carefully the paragraphs on the safety rules.

The original text is in Italian; this is a translation from the original in Italian.

The manual refers to sensor X-VS as “the sensor”, “the digital sensor”, “the device” indifferently.
The manual refers to a “computer”, Personal Computer, “work post”, WorkStation or WS indifferently. In all cases, the computer used will have to satisfy the technical requirements indicated.

1.2. GENERAL WARNINGS

Please pay particular attention to the sections in the manual where the following symbols appear:

Patient or operator safety-related warnings.

Important information on product use.

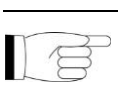
The X-VS sensor and the relevant software iCapture are developed and manufactured by Cefla S.C. – Via Selice Prov.le 23/A 40026 Imola (Italy), hereinafter referred to as the Manufacturer, which is the manufacturer and distributor in compliance with the EC Medical Device Directive.

WARNING: These instructions explain how to correctly use the X-VS sensor. As regards the iCapture software instructions, consult the specific manual. Carefully read
both manuals before attempting to use the sensor and program.

In order to use the X-VS sensor, software for capturing and saving the images is needed that is not part of the X-VS sensor. Consult the relative manual for information about installation and use of the image management software.

- The contents of this publication are valuable trade secrets and must not be given to third parties, stored, copied, reproduced, disclosed or transferred in any manner (via computer, photocopies, translations or other means) without the prior written consent of the Manufacturer.
- The Manufacturer pursues a policy of continual improvement of its products; therefore, some specific instructions and images contained in this manual may differ from the product purchased.
- The Manufacturer reserves the right to make changes without prior notice.
- The information, technical specifications and illustrations contained in this publication are not binding. The Manufacturer reserves the right to make technical modifications and improvements without modifying these instructions.
- All the registered trademarks and the product names mentioned are the property of the respective owners.
- Carefully read the USER LICENSE AGREEMENT before using the product. When installing the program, you will explicitly be asked to accept the agreement; if you do not accept, the program cannot be installed.

WARNING: In accordance with privacy laws in force in several countries, all sensitive personal information must be adequately protected. In addition, patients must sign a consent form before personal information or images are transmitted across networks. If required by the laws in force, dentists are obliged to protect data using a protection password. Refer to the Microsoft® Windows operating system manual for data access protection methods by means of password.



It is recommended to regularly (at least once a week) make a **backup copy of the databases**. This will allow restoring the data in the event of damage to the hard disc of the PC or the databases themselves.

1.3. STANDARDS AND REGULATIONS

The sensor was designed to meet the requirements of Directive 93/42/EEC as amended (namely Directive 2007/47/EC) concerning Medical Devices, based on which it is classified as **class IIa** medical device.

CE 0051

The CE marking certifies compliance of the product as described herein with Medical Device Directive 93/42/EEC and subsequent amendments.

The sensor has been manufactured in compliance with the IEC standards on safety of electro-medical devices of similar type and particularly with the following technical standards:

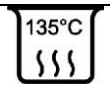
- IEC 60601-1:2005 + A1:2012 - General requirements for basic safety and essential performance.
- IEC 60601-1-2:2014 (4th Ed.) - General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.
- IEC 60601-1-6:2010 + A1:2013 (3rd Ed.) - General requirements for safety - Collateral Standard: Usability including IEC 62366: Application of usability engineering to medical devices.
- IEC 62304:2006 (1st Ed.) - Software life cycle processes.
- ANSI/AAMI ES60601-1: 2005 / A2:2010 - US NATIONAL DIFFERENCES Medical electrical equipment, Part 1: General Requirements.
- CAN/CSA-C22.2 No. 60601-1:2008 - CA - CANADIAN NATIONAL DIFFERENCES to CAN/CSA-C22.2 No. 60601-1:2008.

The system is classified as **Class II and Type B** as far as safety is concerned, under IEC 60601-1.

1.4. STYLISTIC CONVENTIONS

The following symbols may be found on the device and in the manual:

CE 0051	Equipment compliant with directive 93/42/EEC as amended. Notified body: IMQ S.p.A.
	Applied part of type B, according to IEC 60601-1.
REF	Product/equipment identification code.
SN	Product serial number.
	Manufacturer.
	Date of manufacture (month / year).
	It is necessary to read the user's manual before using the device.
	Class II insulation.
II	Stand-by position, indicated on sensor support (only for the model integrated in dental unit).
	Operating position, shown on the sensor support (only for the model integrated in dental unit).
	Position for extraction of sensor support (only for the model integrated in dental unit).
	Rest position, shown on the sensor support (only for the model integrated in dental unit).

	The symbol on the sensor support indicates that the part can be autoclaved at a maximum temperature of 135°C (only for the model integrated in dental unit).
	Symbol: dispose under directive 2012/19/EU.
	USB® 2.0 connection (as specified on USB® cable).
	Ukraine compliance mark.

1.5. WARNINGS FOR USE

The device is designed to work only when connected to accessories equipped with adequate software interface. For this reason, neither the sensor, electronic interfaces nor software components (“drivers” installed in computer and “firmware” in the devices) are compatible with other commercial devices. Therefore use of the X-VS sensor and relevant software in conjunction with other commercial devices is not assured or recommended.

The digital sensor makes use of the TWAIN® protocol for data transmission. It can be used through any program able to acquire images from TWAIN® peripherals (e.g. scanners, digital cameras). Medical programs should be used as they assure data security and quality of the images.

Even though other software interfaces are compatible with the sensor and relevant software components, it is not advisable to use other x-ray image acquisition software simultaneously in the same computer employed to capture images with the sensor or use other software simultaneously for acquiring images in general (scanners, digital cameras, etc.).

Some manufacturers of dental surgery management programs protect their products by purposely making them incompatible with equipment manufactured by third parties. For this reason, it is not possible to guarantee full compatibility of the sensor with all programs currently available.

We recommend to regularly make backup copies of all acquired images.

The PC should have adequate antivirus software and be used only as a work instrument.

The installation of new programs on the PC and the update of the operating system may interfere with the TWAIN® driver or with the image acquisition software. After installing new programs in the computer or updating the operating system, check system operation before attempting to use it on a patient.

Electronic apparatuses may cause or be subject to interferences when used near other electromagnetic equipment such as mobile phones, personal computers equipped with Wireless LAN cards, microwave ovens. Keep the parts of the sensor and Personal Computer used to acquire and save the x-ray images away from RF sources such as wireless LAN cards, other radio devices, Home RF devices, microwave ovens; the recommended distance is at least 1 metre, 2 metres in the case of microwave ovens.

WARNING: In the event of Personal Computer failure while the x-ray image is being transferred (software “crash”), in many cases the x-ray picture is stored in the electronic interface memory until it is successfully transferred or the interface is shut off or disconnected. The manual procedure described in paragraph “Recovering the last image acquired” of the iCapture user instructions can be carried out to recover the image. This event is extremely unlikely as it takes just a few seconds to transfer the image from the electronic control to the computer.

Consult the manuals that deal with the individual devices for instructions on how to use the equipment in conjunction with the sensor (computer, x-ray unit, etc.).
Only specially trained technicians should install the other system components (computer or computer network, software to manage and save images, x-ray generator, etc.). In particular, keep in mind that installation of x-ray equipment must be checked and inspected by a qualified technician.

WARNING: The USB® 2.0 connection required for the operation of the device is not a trivial electrical connection but requires special cables (recognisable by USB® HiSpeed® marking).

To ensure its perfect operation, a single USB® cable cannot exceed the total length of 4.5m. Should it be necessary to install the sensor with longer cables, a USB® repeater must be compulsorily installed every

4.5m, and for a maximum of three cable sections (two repeaters).

WARNING: The sensor used to capture images is fragile and bothered by electrostatic discharges. Handle it with care. Do not deform or squeeze it. Do not touch the electric contacts when the connector is not plugged into the electronic control module.

Do not disconnect it while the interface is on; see paragraph 3 “DESCRIPTION OF OPERATION”.

1.6. GENERAL SAFETY WARNINGS

The instructions inform the user on how to properly operate the system. Read this manual thoroughly before using the device.

The owner or manager of the installation site is responsible for verifying the compliance with local requirements and/or requesting advice from a Qualified Expert. Pay special attention to compliance with legal obligations regarding the protection of workers, the population and patients from radiation.
The main regulations are listed in this manual (1.3 - Standards and Regulations).
Do not use the system for tasks other than described as intended use (1 – Foreword and instructions for use), and do not use it if you are not an expert in dentistry and radiology.

Law restricts sale and use of this device only to doctors, dentists or radiologists.

USA federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

1.6.1. INSTALLATION CONDITIONS

- The system must not be used if it shows any electrical or mechanical defect. Like for all medical electrical systems, this device requires proper installation, use, maintenance and service with the aim of assuring safe and efficient operation.
- For Europe, the electric system in the room where the device is installed must comply with the IEC 60364-7-710 standards (requirements for electric systems in rooms used for medical purposes).
- Before installing the sensor software and drivers, ensure that programs using TWAIN® for image management (cameras, digital cameras, scanners) are installed on the personal computer. Keep in mind that any system drivers installed may interfere with operation of the programs and vice versa.
- It is recommended to use a dedicated computer for the device. This computer should be used only as a work tool and any software programs that are not needed should be uninstalled.
- In order to use the device, the sensor software components have to be installed. Consult the iCapture manual and refer to the relevant instructions.
- If the sensor is integrated in Manufacturer's dental chairs equipped with an incorporated Workstation, no installation procedures are required as all the drivers and software needed are factory-installed.
-

For further details, refer to the installation template and the detailed instructions given in the service manual.

1.6.2. CONDITIONS OF USE

The equipment may only be used by authorised and adequately trained staff (physicians and paramedics).

Comply with all safety use requirements:

- Do not forget to turn off the main switch on the equipment before leaving the surgery.
- The equipment is not suitable for use in the presence of a mixture of flammable anaesthetic gas with oxygen or nitrous oxide.
- This equipment must be stored properly so that it is kept in top working order at all times.
- The user must be present at all times when the equipment is turned on or ready for start-up. In particular, never leave the equipment unattended in the presence of children or other unauthorised personnel in general.
- The Manufacturer shall not be held responsible (under civil and criminal law) for misuse, carelessness or improper use of the equipment.
- If any person who is not an authorised technician changes the product in any way by replacing parts or components with other ones not used by the Manufacturer, they shall assume responsibility for the product. Do not tamper with the equipment unless authorised by the Manufacturer.

- Any computer, monitor, printer, mouse, keyboard and any other device connected to the device must be compliant with ISO, IEC, EN or local standards.
- The Manufacturer is not responsible for problems or malfunction of parts and/or components not approved by itself, not complying with the regulations and not installed by qualified technical personnel acknowledged by the Manufacturer.
- Do not use electronic equipment in proximity of life support equipment (e.g. pacemakers or heart stimulators) and hearing aids. Before using any electronic device in health facilities, always check that it is compatible with the other equipment present.

Use the X-ray system associated with the sensor in compliance with national provisions on protection from ionising radiation, such as:
(a) Each examination must be justified by evidence that the benefits outweigh the risks.
(b) Patients must wear leaded aprons with collar for thyroid protection.
(c) Before the examination, ask women of childbearing age if they are pregnant or if there is a possibility that they can be. If so, the patient should not undergo the examination, unless she has seen a radiologist belonging to an accredited hospital facility in order to evaluate, together with the patient and operator, the benefits and risks associated with this type of procedure, taking into consideration the possibility to make other types of examination.
(d) The operators must keep a safe distance, protect themselves with proper shielding and stay close to the patient in the examination room only in the rare cases where the patient needs assistance. In the event that the operators must remain in the examination room, they must protect themselves with a leaded apron featuring a collar for thyroid protection.
(e) Inform the patient of the risks associated with the examination, acquire its informed consent and store the related document.

In case of claims or for technical assistance, users in Brazil are required to contact the following email address: servico.odontologico@cefla.it.

Users in the US are required to use the following contact information:
Cefla North America Inc.,
6125 Harris Technology Blvd., Charlotte, NC, 28269 United States
Phone: +1 704 598 0020, e-mail: info@ceflaamerica.com

The sensor system is directly powered by the Personal Computer USB® port. Therefore, it is necessary that the PC is turned on and the sensor cable (in the case of stand-alone model) or the electronic interface (in the case of the model integrated in the dental unit) is connected to a USB® port. If the sensor is installed in a dental chair equipped with integrated Workstation, the connections have already been made inside the dental chair's system; therefore, just turn on the workstation.
Insert the A-type USB® connector inside a free USB® port of the Personal Computer.

WARNING: It is possible to operate only if iCapture is turned on (see the iCapture manual for details about installation and use).

1.6.3. USE OF THE CENTERING DEVICE

The sensor must be held in the correct position using a centering device in order to obtain good x-ray images.
Kits of special centering devices for front, rear, bite-wing periapical images and for endodontics are available on the market. The individual components in the kits are also available as spare parts. Contact the dealer who supplied the sensor to purchase spare centering devices.
In addition, universal centering devices such as RINN® Uni-Grip or KerrHawe® series Bite Senso or similar can be used.
Always refer to the instructions included with the centering kit for details on use, cleaning and sterilization of the centering device.

WARNING: NEVER grasp the sensor with grippers to avoid irreparable damage. Always use centering devices specifically designed for use with digital x-ray sensors.

Always sterilize the centering device before using it with a patient. For centering device cleaning and sterilization instructions, follow the conditions specified by centering device manufacturer.

1.6.4. WARRANTY

The Manufacturer stands behind its products warranting safety, reliability and performance.
The warranty is effective from the date of installation of the product.
The product is covered for the warranty period indicated in the installation report and, in any case, not less than 12 months.

WARNING: The Manufacturer shall not be held liable for any personal injury or property damage arising from failure to heed the following clauses.

The warranty is valid only under the following terms:

- closely observe the conditions specified in the warranty certificate;
- the equipment is only to be used as instructed in this manual;
- equipment installation, upgrade and technical support must be performed exclusively by personnel authorised by the Manufacturer to carry out these operations;
- never open the equipment casing. Installation, repairs and, in general, any other operations requiring the casing to be opened are to be performed exclusively by personnel authorised by the Manufacturer to carry out these operations;
- equipment is to be installed in rooms that satisfy the requirements specified in the manual.

1.6.4.1. SOFTWARE NOT COVERED BY WARRANTY

The Software is supplied in its original condition and the Manufacturer shall not be held liable or warrant any original defects or defects originating over time and shall not guarantee quality and proper operation of the software. In addition, the manufacturer shall not honour or provide any warranty regarding conformity of the software to the information given on-line or in electronic documentation or in any case made available except for the warranty on the physical support, if damaged or unusable.
Any warranty is also excluded for Software integrated in - or otherwise being a part of - other Software applications developed by third parties. As far as these applications are concerned, the Manufacturer also expressly declares not to have carried out and not to carry out any inspection activity or other activities to guarantee the software operation.

1.6.4.2. LIMITS OF RESPONSIBILITY

In no case shall the Manufacturer or its suppliers be responsible for direct or consequential damages (including damages for profit loss or lost earnings or savings, interruption of business activities, loss of data or information or other economic losses) affecting the User or third parties as a consequence of the use or failure to use the Software, also in the event that the Manufacturer had been warned of the possibility of such damages.
The present limitation of liability is applicable not just to cases of software use not in compliance with the Manufacturer's recommendations but also to cases of software use in compliance with the Manufacturer's recommendations.

1.6.5. ELECTROMAGNETIC SAFETY

It is recommended not to use electronic equipment in proximity of life support equipment (e.g. pacemakers or heart stimulators) and hearing aids.
Before using any electronic device, always check that it is compatible with the other equipment present.

The device is intended for use in home healthcare environments, as described in **IEC 60601-1-2**. The device belongs to CISPR 11 Class B Group 1 and complies with immunity test levels specified by IEC 60601-1-2 for home healthcare environments.

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.

Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Do not subject the device to strong electromagnetic disturbances. These disturbances could degrade the following essential performance of the device:

- Capturing and transferring X-ray images without alteration in image quality;
- Correct maintenance of the “Ready” or “Stand-by” status.

Guidance and Manufacturer's declaration - Electromagnetic emissions		
The X-VS device is designed to operate in the electromagnetic environment specified below. The customer or user of the X-VS device should ensure that is used in such environment:		
Emission test	**Conformity**	**Electromagnetic Environment**
RF emissions CISPR 11	Group 1	The X-VS device uses RF energy only for its internal operation. Therefore, its RF emissions are very low and they probably do not interfere with the electronic devices nearby.
RF emissions CISPR 11	Class B	The X-VS device is suitable to be used in all rooms, including the domestic ones, and places directly connected to a public low-voltage line that supplies buildings for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker IEC 61000-3-3	Not applicable	

Guidance and Manufacturer's declaration - Electromagnetic immunity			
The X-VS device is designed to operate in the specified electromagnetic environment. The customer or the user of the device must ensure its use in an electromagnetic environment with the following features:			
Immunity test	**IEC 60601-1 test level**	**Conformity**	**Electromagnetic Environment**
Electrostatic discharge (ESD) IEC 61000-4-2	with contact ±8 kV in air ±15 kV	IEC 60601-1-2 Test level	Floors must be made of wood, concrete or ceramic tiles. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Transients/burst IEC 61000-4-4	±2 kV for power lines ±1 kV for input/output lines	IEC 60601-1-2 Test level	The power supply line quality should be that of a typical commercial or hospital environment.
Over-voltage IEC 61000-4-5	±1 kV across phases ±2 kV across phase(s) and ground	IEC 60601-1-2 Test level	The power supply line quality should be that of a typical commercial or hospital environment.
Voltage drops, short blackout or voltage variations on the input supply lines IEC 61000-4-11	U_t = 0% (at 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315°) for 0.5 cycles U_t = 0% for 1 cycle U_t = 70% (at 0°) for 25/30 cycles U_t = 0% for 250/300 cycles	IEC 60601-1-2 Test level	The power supply line quality should be that of a typical commercial or hospital environment. If the X-VS user requires a continuous operation also in case of blackout, it is recommended to power the X-VS with uninterruptible power supply or batteries.
Magnetic field at network frequency (50/60 Hz) IEC 61000-4-8	30 A/m	IEC 60601-1-2 Test level	The magnetic fields at network frequency should feature levels typical of a standard commercial or hospital environment.
NOTE: U_t is the AC grid voltage before test level application.			

Guidance and Manufacturer's declaration - Electromagnetic immunity			
X-VS is designed to operate in the electromagnetic environment specified below. The customer or user of the X-VS device should ensure that is used in such environment.			
Immunity test	**Test level under IEC 60601**	**Level of conformity**	**Electromagnetic environment - guide**
Conducted RF EN 61000-4-6	3 V from 150 kHz to 80 MHz 6V ISM frequencies	IEC 60601-1-2 Test level	The RF communication devices (portable and mobile) must not be used at a distance from X-VS and its components, including cables, lower than the recommended distance using the corresponding equation applicable to the transmitter frequency. **Recommended distance** $d = 1.2 \times \sqrt{P}$
Radiated RF EN 61000-4-3	10 V/m From 80 MHz to 2.7 GHz	IEC 60601-1-2 Test level	$d = 1.2 \times \sqrt{P}$ 80 MHz to 800MHz $d = 2.3 \times \sqrt{P}$ 800 MHz to 2.7GHz Where P is the maximum output power of the transmitter in Watt (W) according to the transmitter Manufacturer, and d is the recommended distance in metres (m). The field intensity of the fixed RF transmitters, determined based on an electromagnetic site, could be lower than the conformity level in each frequency interval. Near the equipment with the following symbol interferences can be caused: 

Recommended distance between the RF portable and mobile communication devices and X-VS			
X-VS is designed to operate in the electromagnetic environment with control of the RF irradiated disturbances. The customer or the user of the X-VS device could help in preventing electromagnetic interferences ensuring a minimum distance between the RF mobile and portable communication devices (transmitters) and X-VS, as indicated below, in relation to the maximum output power of the radio-communication equipment.			
Transmitter maximum nominal output (W)	**Distance according the transmitter frequency (m)**		
	from 150 kHz to 80 MHz $d = 1.2 \times \sqrt{P}$	**from 80 MHz to 800 MHz** $d = 1.2 \times \sqrt{P}$	**From 800 MHz to 2.7 GHz** $d = 2.3 \times \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters having a maximum nominal output power not listed above, the recommended distance d in metres (m) can be determined using the corresponding equation applicable to the transmitter frequency where P is the maximum output power of the transmitter in Watt (W) according to the transmitter Manufacturer. NOTE 1 At 80MHz and 800MHz it is necessary to apply the distance defined for the highest frequency interval. NOTE 2 These guidelines could not be applicable to all situations. The electromagnetic propagation is influenced by the absorption and reflection of structures, objects and people.			

1.6.6. PROTECTION AGAINST RADIATION

The digital sensor must be used together with an intraoral x-ray system. As such, the system exposes the patient and the operators to the risks deriving from radiation. It must be used in compliance with the safety regulations set out in the radiation protection standards in force in the country of use. Some requirements are listed below:

- Start X-ray emission only from the control room. The radiation room must be adequately shielded (if required by regulations currently in force in the country of use).
- Make sure the radiation room's doors are closed before starting the examination.
- Only the patient shall be present in the radiation room during X-ray emission. If the presence of a person is necessary during the examination (for example to help patients who are not self-sufficient), personal equipment must be used to protect the individual against scattered radiation. In any case, no body parts should be exposed directly to the X-rays. Patients may not be assisted by pregnant women or minors.
- The following points must always be observed:
  - During exposure, keep a distance of at least 2 metres from the X-ray source. For installations in Canada, the required distance is 3 metres.
  - Anyone not directly involved with the patient should be outside the room where the examination is carried out or stand behind a lead shield or lead glass panel during exposure.
  - Make sure that the operator can communicate verbally and visually with the patient.
  - If required, use a dosimeter for personal monitoring.
- Full use must be made of all radiation protection devices, accessories, and procedures available to protect the patient and operator from X-ray radiation, especially for children.

1.6.7. SAFETY AND HEALTH CARE

HAZARD:

- The digital sensor is a medical device for the acquisition of intraoral X-rays. It is intended for use only by qualified dental professionals. Do not use the system for tasks other than the acquisition of intraoral X-rays, and do not use it if you are not an expert in dentistry and radiology.
- Do not use electronic equipment in proximity of life support equipment (e.g. pacemakers or heart stimulators) and hearing aids. Before using any electronic device in health facilities, always check that it is compatible with the other equipment present.
- In order to prevent the transmission of infectious diseases between patients, it is essential to always use disposable hygienic covers. Disposable covers are class I medical devices and cannot be replaced with other protections having lower specifications. Contact the dealer who supplied the sensor or disposable covers to obtain additional disposable covers.
- Cover with disposable covers all components that will be in contact with dental personnel's hands and might be contaminated by indirect contact with the mouth of the patient. In particular, be careful when handling the Personal Computer mouse, keyboard or touch screen.
- Never use the device in the presence of mixtures of flammable anaesthetic gas with air, oxygen or nitrogen protoxide.
- Some parts (USB® cable, silicone rubber protection, disposable covers, centering device components, packing components, x-ray sensor) may cause choking if ingested or improperly used. Avoid unintended, inappropriate and misuse and keep out of reach of children.
- Take care to the sensor temperature when applied in the oral cavity: the sensor can reach a temperature up to 12 degrees higher than the ambient temperature. The software coming with the sensor implements, during periods of non-use, timing for sensor switch-off/stand-by modes, in order to limit the temperature increase. Assess the sensor temperature and decide whether it is necessary to allow it to cool down after heavy usage, before reactivating it for use on patients with dressings, wounds or those particularly sensitive (e.g., paediatric patients).

1.6.8. MAINTENANCE AND DISPOSAL

The device does not contain parts that can be repaired directly by the user. In the event of a malfunction, do not attempt to carry out maintenance operations, but directly contact the Manufacturer or its local distributor at the numbers indicated in the warranty certificate. If the apparatus has to be returned to the Manufacturer or Service

Centre for any reason, completely disinfect the outside of the apparatus with a specific product (see paragraph “Cleaning and disinfecting”) and send it back preferably in its original box.

No electronic parts of the sensor require maintenance. If the sensor or interface casings are opened to reach the circuits inside, devices may be broken, the protective means for electric safety may be disabled and the warranty will become null and void.

Do not use the sensor on a patient if a system malfunction is present or suspected.

Preventive maintenance

Inspect PC connection cables or the dental unit at regular intervals. Check the connection cable to the computer, the monitor, the keyboard, the mouse and the printer according to the Manufacturer instructions.

Component and accessory storage

Components and accessories must be stored and handled with care.
Any provided components and accessories must be stored and handled in compliance with the relevant technical specifications.

Malfunctions

In case the system does not work as described in this manual, contact the technical service immediately.

System inspection checklist

The following checklist indicates the recommended time intervals of the various system checks.
For further information contact your local distributor.

Component	Activity	Time interval
Global system	Visually inspect the system to find any damage or physical defect of the sensor or connection cables.	Once a week
Labelling	Visually check label for damage and readability.	Once a month
Global system	Conduct a test by capturing x-ray images using a phantom	Once a month
Global system	Check image quality as required by local regulations, using for instance a phantom Quart or similar device.	Once a month
Personal Computer	Check proper transfer of an image from sensor to PC.	Once a month

In case of failure of the prescribed checks, contact your local distributor.

Scrapping

At the end of its lifetime, dispose of the device in accordance with the regulations in force. It is also advisable to disinfect all the external parts of the device before disposal and to separate the materials for differentiated waste collection.

Dispose of disposable covers as “special waste”.

In compliance with Directives 2011/65/EU and 2012/19/EU regarding restriction of the use of certain hazardous substances in electrical and electronic equipment along with waste electrical and electronic equipment, it is forbidden to dispose of this equipment in the municipal waste stream as unsorted municipal waste. When purchasing a new device of an equivalent type, one for one, the device that has come to the end of its lifetime should be returned to the distributor for disposal. As regards reuse, recycling and other forms of recovery of waste electrical and electronic equipment, the Manufacturer carries out the functions defined by current local laws. Appropriate differentiated waste collection for subsequent recycling treatment and environmentally friendly disposal contributes to preventing possible negative effects on the environment and health and encourages recycling of the materials of which the device is made up. The crossed-out bin symbol on the device indicates that the product must be collected separately from other waste at the end of its useful life. Under local legislation, fines can be imposed if the equipment is disposed in an illegal manner.

1.6.9. CLEANING AND DISINFECTION

Cleaning is the first step required for any disinfection process. Physically scrubbing with detergents and surface-active substances and rinsing with water removes a considerable amount of microorganisms. If the surface is not first cleaned, the disinfection process cannot be successful.

If a surface cannot be adequately cleaned, it should be protected with barriers.

1.6.9.1. CLEANING AND DISINFECTION OF THE INTERFACE SUPPORT ON DENTAL UNIT

The outside of the interface on dental unit, if any, must be cleaned and disinfected with a hospital disinfectant labelled as effective against human immunodeficiency virus (HIV) and hepatitis B virus (HBV) (i.e. low-level) or a hospital tuberculocidal disinfectant (i.e., intermediate-level) specifically designed for small surfaces. Follow the manufacturer’s operating instructions.

The great variety of medical and chemical products used in a dental practice may damage painted surfaces or plastic materials parts. Researches and tests performed show that the surfaces cannot be fully protected against the harsh action of all products available on the market. We therefore recommend protecting with barriers whenever possible.

The harsh actions of chemical products also depend on the amount of time they are left on the surfaces. It is therefore important not to leave the product on the surfaces longer than the time specified by the manufacturer.

Given the aggressiveness of the active principles used in disinfectants, we recommend to use products containing the following maximum quantities of:

- **96% ethanol.** Concentration: maximum 30 g per 100 g of disinfectant.
- **Propanol.** Concentration: maximum 20 g per 100 g of disinfectant.
- **Combination of ethanol and propanol.** Concentration: the combination of the two should be maximum 40 g per 100 g of disinfectant.

The Manufacturer performed tests on the compatibility between the most common disinfectants and its own plastic materials.
The test results indicated that the least aggressive agents are:

- Incidin Spezial (Henkel Ecolab).
- Omnizid (Omnident).
- Plastisept (ALPRO) (not tuberculocide as not an alcohol-based disinfectant).
- RelyOn Virkosept (DuPont).
- Green and Clean SK (Metasys) (not tuberculocidal as it is not an alcohol-based disinfectant).

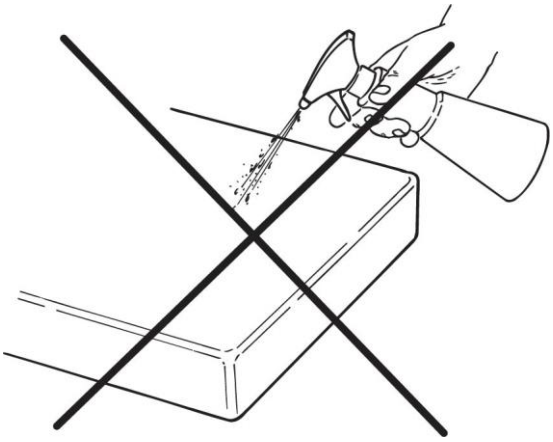
WARNING: The same tests showed that the above-mentioned products can therefore be used by adopting, however, the following precautions:

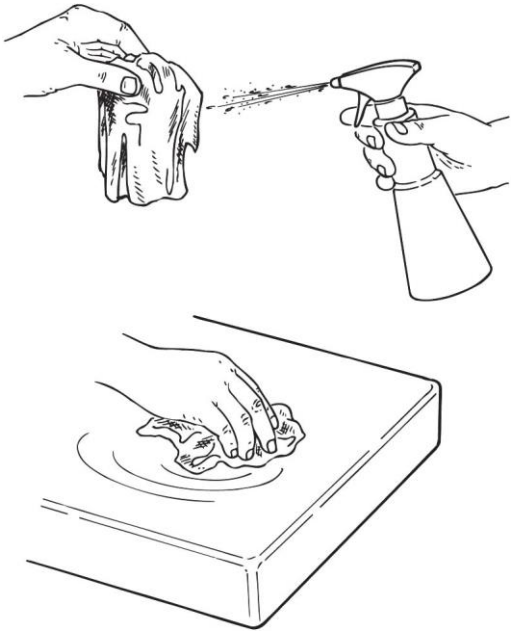
- Do not use products containing isopropyl alcohol (2-propanol, iso-propanol).
- Do not use products containing sodium hypochlorite (bleach).
- Do not use products containing phenols.
- Do not spray the selected products directly on the surfaces.
- Never combine products with each other or with liquids other than the products listed above.

- All products must be used as directed by the manufacturer.

Cleaning and disinfecting instructions.

Clean and disinfect with disposable non-abrasive paper (avoid using recycled paper) or sterile gauze.
Do not use sponge cloths or, in any case, any material that can be reused.





WARNING:

- In order to clean equipment connected to the power mains, shut off the devices and disconnect the power supply from the outlet before attempting to clean and disinfect the outside.
- Also the sensor support integrated in the dental chair works through a USB® connection; it is therefore mandatory to switch off the PC/WS it is connected to before removing the sensor support.
- All material used to clean and disinfect must be thrown away upon completing the procedure. Observe current regulations when disposing the material.

Sterilize the sensor support only in an autoclave at a maximum sterilization temperature of 135°C.

WARNING:

- The sensor support is able to withstand 500 autoclave sterilization cycles.
- Always contact the Manufacturer to purchase genuine spare parts.

Recommendations for waste disposal.
Follow the manufacturer's instructions when disposing whole disinfectant bottles.
Do not let the product into the municipal sewer systems and/or waterways.

1.6.9.2. CLEANING AND DISINFECTION OF THE SENSOR AND ITS POWER CABLE

WARNING:
The sensor is NOT suitable for autoclave sterilization.

The sensor and its power cable (USB® connector excepted) are protected against harmful penetration of water and special substances and have therefore been assigned an **IP67** rating.
For the external cleaning and/or disinfection of the sensor and its power cable (USB® connector excepted), **use gauze or cotton soaked in ethyl alcohol 70% v/v**.

Recommendations for waste disposal.
Follow the manufacturer's instructions when disposing whole disinfectant bottles.
Do not let the product into the municipal sewer systems and/or waterways.

WARNING:
All material used to clean and disinfect must be thrown away upon completing the procedure. Observe current regulations when disposing the material.

1.6.10. HYGIENE PROCEDURES FOR PATIENT PROTECTION

WARNING: Disposable hygienic protections are the main protection means against cross contamination between patients. **In order to prevent the transmission of infectious diseases between patients, it is essential to always use disposable protections. Disposable protections are class I medical equipment and cannot be replaced with other protections having lower specifications.**
Disposable covers must comply with ISO 10993 standards on biocompatibility and be approved by control bodies where required (e.g. FDA, EC).

Always replace sensor disposable hygienic covers before positioning a new patient.

Disposable hygienic protections must be stored in a dry and clean area and must not be exposed to direct sunlight or UV radiation.

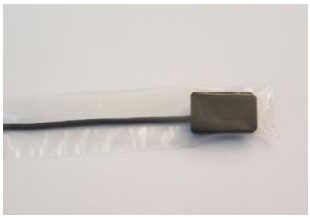
Cover with disposable protections all components that will be in contact with dental personnel's hands and might be contaminated by indirect contact with the mouth of the patient. In particular, be careful when handling the Personal Computer mouse and keyboard.

Before positioning the patient for a radiological examination, always cover the sensor with a new (non-sterile) plastic protection in order to prevent cross contamination.

Note for users in Canada: ask your trusted dental material distributor for any plastic barrier that is suitable in size and is marketed in Canada according to the local regulations in force.

In compliance with the provisions of Health Canada, bite protections are Class I equipment supplied by authorised distributors as per MDEL database.

Disposable cover application instructions:



1) Place a disposable cover complete with its protective sheet on a flat surface. Introduce the sensor through the opening at one end.
2) Push the sensor all the way into the disposable cover, paying attention not to break the transparent material.
3) If present, remove the protective support sheet.
4) The operation is now completed.
5) After use, dispose of the disposable covers as “special” waste.

Use of a centering device guarantees that the sensor is perpendicular to the x-ray tube and its sensitive area is centred. Use of a centering device is strongly recommended. The clinician should choose the most suitable one based on his/her own experience.
The centering device must comply with ISO 10993 standard concerning biocompatibility. For further information on use of the centering device, refer to paragraph 1.6.3.

1.6.11. APPLIED PARTS

The parts of the device or its accessories that, during standard use, necessarily come into contact with the patient, so that the device may carry out its functions correctly, are: digital sensor, centering device and hygienic covers.

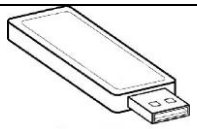
Not applied parts that might come into contact with the patient are the dental unit interface (only for version built in the dental unit) and USB® cable.

2. DESCRIPTION OF DEVICE AND BOX CONTENTS

The X-ray sensor can be purchased in two different sizes (Size 1 and Size 2) in order to adapt to different sizes of oral cavity.

The package contains:

Sensor package

	X-ray sensor
	USB® key with software, driver and electronic user's manual
	Warranty certificate

Accessory to be integrated to dental unit

	Interface for dentist’s board with sensor support and cable ring

Only use spare parts supplied or approved by the Manufacturer.
Do not connect standard USB® extensions to the digital sensor.

3. DESCRIPTION OF OPERATION

Refer to the paragraphs below for information on X-ray sensor operation.

3.1. TURNING THE SENSOR ON AND OFF

For using the device, it is necessary to connect the X-ray sensor to the USB® port of a Personal Computer or to the appropriate connector on the interface integrated in the dental unit.

Connect the sensor to the USB® port of the PC (stand-alone sensor)

Connect the sensor to the interface integrated in the dental unit
(sensor integrated in dental unit)

To disengage the sensor from its housing, gently pull the cable from its USB® connector to disconnect it from the USB® port of the Personal Computer (stand-alone version) or of the interface (version integrated to dental unit). Do not exert lateral movements or stress, and do not pull the cord.

The X-ray sensor is a delicate component, sensitive to electrostatic discharge. For this reason, it is recommended to always extract the sensor from the interface in the dental unit when the interface is not active. Always use the **stand-by** position to extract the sensor connector from its housing.

Do not unplug the USB® connection cable before the transfer of newly acquired images is completed.

3.2. SENSOR CONNECTION AND CONTROL

Sensor status is indicated by warning lights (only for the sensor integrated in dental unit) and displayed on the Personal Computer. For further details on colour-coding and status symbols, also refer to 3.5 – “Status indications”.

3.2.1. STAND-ALONE SENSOR

This paragraph explains connection and control methods for the stand-alone sensor, which can be directly connected to the Personal Computer.

The sensor does not have any control button. As soon as it is connected to a PC, if iCapture Monitor is running (factory default setting), the Driver TWAIN® will be automatically started for system initialisation.

At first, Driver TWAIN® window will show a “WAIT” message on yellow background.

If sensor is connected, "WAIT" will be displayed on a yellow background on Driver TWAIN® window and, after a few seconds, "READY" will be displayed on a green background on Driver TWAIN® window.
At this point, the sensor is ready to receive an x-ray image.

If the sensor is NOT connected, “SENSOR NOT CONNECTED” will be displayed on a red background on Driver TWAIN® window.

If the sensor is connected to a PC where Driver TWAIN® is NOT active (factory default settings have been changed by the user), it will not be possible to acknowledge and initialise it. In this case it is not possible to take x-rays.
Consult the iCapture manual to start Driver TWAIN®.

When Driver TWAIN® is activated, drivers are automatically acknowledged and activated and, after a few seconds, the system will be ready to work.

3.2.2. SENSOR INTEGRATED IN DENTAL UNIT

As sensor is installed on the dentist’s board as the sixth instrument, it may be to the right or left of the dentist’s board, depending on the particular case. For this reason, two indicator lights are provided. They are placed so that the operator can always see at least one of them under regular work conditions.

The sensor support can be turned and placed in four distinct positions. The position of the sensor support, combined with the PC features, controls the activation and deactivation of the sensor.
The colour of this indicator on the sensor support indicates to the user if the sensor is ready to acquire images.

Description of the sensor support positions

Enabled

Stand-by

Door closed

Extraction

Image acquisition

To capture images using the sensor, rotate the sensor support in "Enabled" position, pull the sensor from its housing and wait until the light on the sensor support becomes green. The captured image will be immediately transferred at the end of the X-ray exposure.

WARNING: positioning the sensor support on the symbol **does not necessarily imply** that the sensor is active and ready to receive images. In order to avoid exposing the patient to unnecessary radiation, it is recommended to always make sure that the light on the sensor support is green before each X-ray exposure.

Sensor stand-by

To set the sensor in stand-by mode, turn the sensor support in the "Stand-By" position: the light on the sensor support will turn blue.

WARNING: In order to minimise the temperature on the active surface of the sensor, during periods of non-use it is recommended to disconnect it or take it in stand-by mode, by rotating the sensor support to stand-by position.

WARNING: Always use the stand-by position to disconnect the sensor connector.

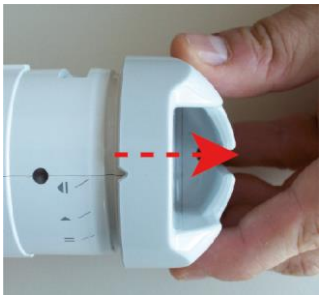
Closing the door

Turn support to O position in order to close the door.

As sensor is physically attached to the dental chair dentist's board, dirt and sprays may reach the USB® connector when the sensor is not connected to the USB® connector of sensor support.

WARNING: It is recommended to close the door by rotating the sensor support until covering the opening with the appropriate appendix, both for reasons of hygiene and to prevent damage to the electronic parts.

Removing the sensor



The sensor support can be taken out of the interface when in position ⏏, so that cleaning and disinfecting operations can be performed.

WARNING: Clean and disinfect the sensor support on a regular basis. The sensor mount can be sterilized in autoclave. It is recommended to have an adequate number of sensor supports so that a clean one can be used for each patient for whom x-rays need to be taken. Additional supports can be ordered from the dealer who supplied the equipment.

Disconnecting the sensor from the USB® port

To disconnect the sensor from the sensor from the USB® port of the sensor support, turn the sensor support in "Stand-By" II position, and disconnect the USB® connector.

For a legend of the colour-coding of the light on the sensor support in the version integrated in the dental unit, see 3.5 "STATUS INDICATIONS".

3.3. PATIENT POSITIONING

Having the patient correctly positioned for an X-ray is extremely important for the quality of the image. The size and shape of the captured area depends on the correct positioning of the patient.

Instruct the patient to remain still for the entire duration of the examination. The slightest movement can affect the quality of captured images.

A positioner or centering device specific for the selected image receiver should always be used to assure the x-rays are correctly aligned regardless of the position of the patient's head. Position the x-ray head so that the collimator is aligned with the sensor.

For further information, refer to 1.6.3 - “Use of the centering device”.

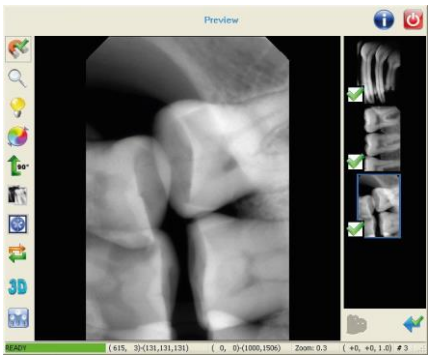
Remember to change the disposable covers before positioning a new patient.

3.4. ACQUIRING AN X-RAY IMAGE

To acquire an x-ray image, run the image acquisition program by selecting image acquisition from iCapture.

WARNING: Do not take x-ray pictures on a patient when testing the system for the first time or verifying correct operation. Use phantoms to conduct tests.

Take X-ray picture.
The image will appear on the computer screen after a few seconds and, if enabled, it can be seen in the iCapture Monitor preview window and right-hand column, next to the main window.



No other steps are required to capture further images after the first x-ray picture has been taken.
The last image captured is shown in the preview window.
The new images will appear under the first one in the right-hand column of the main window.

After the acquisition of an image, it is possible to acquire a second image after 5 seconds.

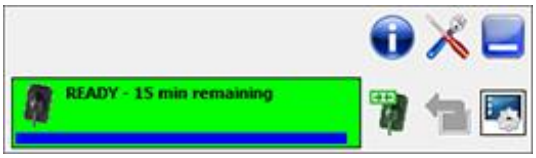
To prevent data loss, regularly make a backup copy of the acquired X-rays.

3.5. STATUS INDICATIONS

The sensor status is displayed on the screen of the personal computer and can be identified by the following colours:

A **red** signal indicates that the sensor is disconnected from the PC and it is therefore impossible to acquire x-ray images. Do not make acquisitions as long as the sensor is in this status.

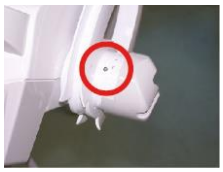
A **yellow** signal indicates a situation of stand-by. You need to reactivate the sensor before x-ray image acquisition, for example by clicking the yellow box on screen or by extracting the sensor from its support.



A **green** box indicates that the sensor is enabled and ready to acquire an image. Make an acquisition only when the sensor is in this status.
The software also indicates the remaining time before the sensor goes into stand-by mode.

WARNING: Always check system status before attempting to take x-rays on a patient. Make sure the operation light is **green** before taking an x-ray on a patient.

The supplied sensor software implements sensor standby timing during periods of non-use:
- when connected to a Personal Computer, the digital sensor remains active for 10 minutes, during which it is possible to acquire images.
- after the acquisition of an image, the device returns to stand-by after 3 minutes of inactivity.
- when in stand-by mode, the user can reactivate the sensor for another 10 minutes, by clicking on the status window displayed.



The model of the sensor integrated in the dental unit also includes an additional status indicator, located on dental unit interface. This indicator has the function to report device status and any anomalies in the system:
- A **red** light indicates an error situation for which it is impossible to capture images.
- A **yellow** light (flashing or steady on) indicates a temporary situation (initialisation, image transfer) or a fault which the user should be aware of (e.g.: sensor not connected);
- A **blue** light (flashing or steady on) indicates that the system is connected to the Personal Computer but not on;
- A **white** light indicates non-use when sensor is not active and not connected;
- A **green** light indicates that the system is connected to the Personal Computer and is on;

Consult the sensor status table in the next page for a detailed description of the messages.

STATUS CHART OF THE SENSOR BUILT IN THE DENTAL UNIT	
GREEN	**Sensor ready**: sensor support is in “Active” position and sensor is connected. **In this condition, sensor is ready to acquire images.**
BLUE	**Sensor in stand-by** since sensor support is NOT in “Active” position. **In this condition it is NOT possible to acquire images.** For the sensor to get ready to acquire images, turn sensor support to “Active” position and wait until light becomes green.

BLUE FLASHING	**Sensor in stand-by** since sensor support is in “Active” position, but the sensor remained unused for a long time. **In this condition it is NOT possible to acquire images.** For the sensor to get ready to acquire images, reactivate the sensor by turning sensor support to “Active” position or clicking on the window displayed on PC, then wait until light becomes green.
YELLOW	**Sensor being initialised.** **In this condition it is NOT possible to acquire images.**
YELLOW FLASHING	**Sensor not connected**: sensor support is in “Active” position but is waiting for the user to connect the sensor. **In this condition it is NOT possible to acquire images.**
WHITE	**Sensor not used**: sensor support is NOT in “Active” position and sensor is not connected. **In this condition it is NOT possible to acquire images.**
RED	**Sensor in error.** User must disconnect and reconnect the sensor to run a new initialisation. **In this condition it is NOT possible to acquire images.**

3.6. QUALITY OF THE X-RAY IMAGES

Unlike common x-ray film, the digital x-ray sensor tends to automatically correct any exposure errors, providing images that are always usable. Although the sensor allows images with a wide range of grey levels to be captured, standard computer monitors display only 256, therefore in most cases the software will obtain a satisfactory image even from a picture taken with incorrect exposure. However, keep in mind that there are boundaries beyond which results cannot be corrected.

The x-ray sensor is more sensitive than x-ray film therefore exposure times usually have to be reduced.
See the information given in paragraph 4.2 “COMPATIBILITY WITH X-RAY GENERATORS”.

To obtain top performance of digital x-ray sensors, it is important to keep in mind that there are some differences compared to film.
Insufficient exposure is clearly seen on x-ray film as the areas corresponding to soft tissues are less dark. On the other hand, when a digital sensor is used, the image background noise increases (salt and pepper noise) and the tonal range is insufficient.
Excessive exposure (time too long) on x-ray film causes the image to be too dense (dark) while the image will lose contrast with a digital sensor.
It is a common mistake to confuse excessive exposure with insufficient exposure therefore further increase the exposure time rather than reducing it.

It is important to check and note this limit with your own x-ray system in order to be sure not to exceed it during dental treatment as the images obtained under these conditions will be of poor quality or even unusable.

WARNING: Before attempting to take x-ray pictures on patients, it is advisable to take some test pictures on phantoms, comparing the results obtained to the usual ones. Identify the best exposure conditions for your own x-ray system through trial and error.

4. SPECIFICATIONS

4.1. TECHNICAL SPECIFICATIONS

The device is designed to operate in environmental conditions that are typical of covered working areas and within the parameters under IEC 60601-1.

General characteristics	
Image format	Bitmap file 4096 grey levels, compatible with Windows / Mac (PNG, JPG)
Image transfer	via USB cable, according to TWAIN® standard, in single and multiple picture mode
Power input	5V DC 500mA max, USB powered Stand-alone sensor: 1 W Sensor integrated in dental unit: 2.5 W
USB interface characteristics	USB 2.0 High Speed
Protection class	IP67 (only the sensor and its cable, not the USB connector) IPX0 (for all the other parts of the product)
Operation	Continuous

Sensor general characteristics	
Technology	CMOS
Type of scintillator	Caesium Iodide scintillator: CsI(Tl)
Pixel dimensions (H x V)	20 x 20 µm
Pixel pitch	20 µm
Maximum nominal resolution	25 lp/mm
Dynamic range	57 dB
Tensile strength	100 N
Maximum irradiation	57.6 Gy (@ T = 25°C, 60 kVp)
Air Kerma necessary for intended use	min 0.4 mGy, max 1.1 mGy
Cable length	2.5 ± 0.1 m
Cable diameter	3.7 ± 0.3 mm
Useful lifespan	50,000 shots at max 1.1 mGy

Sensor characteristics: Size 1	
Image dimensions (H x V)	20 x 30 mm
Number of pixels (H x V)	1000 x 1500
Dimensions (H x V x T)	39.0 x 25.0 x 12.5 mm (tolerance: ± 0.3 mm)

Sensor characteristics: Size 2	
Image dimensions (H x V)	26 x 34 mm
Number of pixels (H x V)	1300 x 1700
Dimensions (H x V x T)	41.9 x 30.4 x 12.8 mm (tolerance: ± 0.3 mm)

Characteristics of the interface on dental unit	
Dimensions (H x V x T)	162 x 122 x 109 mm excluding sensor cable
Weight	approx. 220g

Operating conditions	
Temperature	from 0°C to +35°C
RH (humidity)	from 0% to 70%

Atmospheric pressure	from 700 to 1060 hPa

Transport and storage conditions	
Temperature	from -20°C to +70°C.
RH (humidity)	from 0% to 70%.
Atmospheric pressure	from 700 to 1060 hPa

4.2. COMPATIBILITY WITH X-RAY GENERATORS

The features and some of the key functions of the system will largely depend on the characteristics of the X-ray generator and of the software used to display and store the images.
To obtain the best results, it is preferable to use a constant-potential (DC) radiographic generator with long rectangular collimator (focus-to-skin distance not below 30cm).
Old x-ray models that do not permit the exposure times to be sufficiently reduced may not be suitable for use with the device.

The digital sensor can work correctly both with conventional X-ray generators, known as "AC", and with the most recent high-frequency generators called "DC". As the sensor is very sensitive, it is necessary to reduce the exposure times compared to those normally used for conventional x-ray film.

To obtain the required performance for intended use, it is recommended to carry out acquisitions with Air Kerma ranging between 0.4 and 1.1 mGy.

The table below shows the focus-to-skin distance and the maximum exposure time to be observed.

EXPOSURE TIMES

For X-ray units manufactured by Cefla S.C., a sensitivity value of F15 is recommended, with pre-setting left at 8mA as default. Exposure times, kV and mA values will be automatically set according to the anatomical area selected on the X-ray unit by the operator.

For other types of X-ray units, use the table below referred to a high frequency DC 60-65 kV and 8mA generator. If a 70 KV generator is used, the time given in the table has to be reduced by approximately 1/4. Instead, double the times if 4mA is selected.

Length of the cone 12" (30 cm)			
	UPPER MOLARS	**0.25 s**	**0.16 s**
	PREMOLARS / UPPER CANINES	**0.20 s**	**0,125 s**
	UPPER INCISORS	**0.16 s**	**0.10 s**
	BITEWING	**0.20 s**	**0,125 s**
	LOWER INCISORS	**0.16 s**	**0.10 s**
	PREMOLARS / LOWER CANINES	**0.20 s**	**0,125 s**
	LOWER MOLARS	**0.25 s**	**0.16 s**

Length of the cone 8" (20 cm)			
	UPPER MOLARS	**0.16 s**	**0.10 s**
	PREMOLARS / UPPER CANINES	**0,125 s**	**0.08 s**
	UPPER INCISORS	**0.10 s**	**0,063 s**
	BITEWING	**0,125 s**	**0.08 s**
	LOWER INCISORS	**0.10 s**	**0,063 s**
	PREMOLARS / LOWER CANINES	**0,125 s**	**0.08 s**
	LOWER MOLARS	**0.16 s**	**0.10 s**

- If edentulous areas are irradiated, the device may provide images that are too blackened in the missing areas of the irradiated radiographic subject. In these cases, reduce the time indicated in the table by about 1/4.
- The best results are achieved with a high frequency generator with square collimator and 30cm focus-to-skin distance (refer to the relevant table).
- For a better distance control, we suggest using a centring device with fixed spacer between centring ring and sensor.
- Before attempting to use the product on a patient, practice by taking a few x-ray pictures on inanimate objects with your own x-ray unit.
- Do not exceed the dose in the chart.

In order to limit patient exposure to radiation, only use x-ray generators having a collimation compatible with the size of the sensitive area of the intraoral film.

4.3. MINIMUM PREREQUISITES

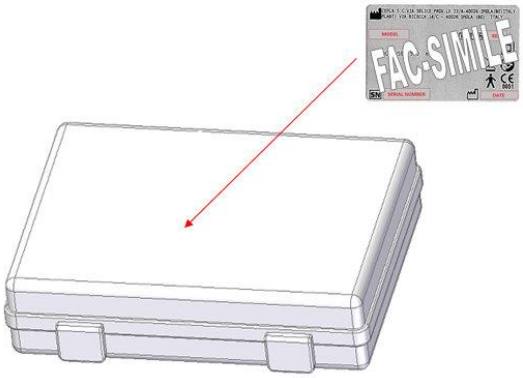
For more details on minimum and recommended hardware and software requirements for workstations directly connected to reference or additional devices, refer to the “Minimum and Recommended System Requirements” attachment.

5. EQUIPMENT IDENTIFICATION

WARNING: Do not remove the identification plates that accompany the product and its accessories.

This section includes an example of the identification plates used on the product.
For a thorough explanation of the symbols on the identification plates, see 1.4 “STYLISTIC CONVENTIONS”.

Position: directly applied on sensor USB® cable.
Contents:
- name and location of Manufacturer
- product name
- product brand
- CE marking
- type reference



Position: applied on the inner case of the sensor.
Contents:
- name and address of Manufacturer's registered office
- production plant address
- product name
- type reference
- sensor serial number
- label data
- type-approvals
- date of manufacture

The identification plates in this paragraph are shown only for illustrative purposes. Always refer to the plates actually present on the device.

6. TROUBLESHOOTING

PROBLEM FOUND	POSSIBLE CAUSES	SOLUTIONS
Doubts concerning the sensor efficiency.	Falling, banging, malfunctioning.	Do not use the sensor on a patient. Conduct tests by capturing an x-ray image using a phantom. If there are doubts about proper operation, do not use the sensor and contact the Service Centre.
Image loss.	Error in the management program or PC operating system.	The last image captured can be recovered by downloading it again from sensor through the "TWAIN® data source" window (see paragraph **"Recovering the last image acquired"** of the iCapture user instructions). Do not turn the PC off or disconnect the interface from the USB® port: the image will be definitely lost.
The system does not switch on.	USB® cable not connected.	Connect the USB® cable to a PC port.
The system does not switch on.	Faulty USB® cable or USB® port of the Personal Computer.	Check the USB® cable and the USB® port of the Personal Computer with another device, e.g. a Pen drive. Test the equipment on another PC. The status light should be on (flashing yellow) even without installing the software.
The system does not switch on.	Faulty system.	Do not use the sensor, contact the Technical Service Centre.
The status light on the interface integrated in the dental unit stays red.	Damaged or faulty sensor.	Do not use the sensor, contact the Technical Service Centre.
Sensor does not start; the light on interface integrated in the dental unit is yellow and flashes.	Driver not present, defective or damaged. New software has been recently installed in the PC or the PC has been used with external connections (Internet).	Run an antivirus check. Reinstall the software. Only use your PC as a working tool, avoiding connection to external networks.
The sensor integrated in dental unit cannot be started (it stays in stand-by) the light is flashing yellow.	The sensor support is not correctly inserted or is not turned to the correct position.	Check rotation and verify the sensor support is in the correct position.
The system switches on but the light stays yellow and flashes: a fault message appears on the computer.	Quality of USB cable not good enough or cable is too long. **The maximum length of a top quality USB cable is about 4.5m.**	Replace the USB cable; eliminate any extensions; try to use an externally-powered HUB in the last section before the x-ray system connection.
The device is not recognised.	A version of iCapture released prior to the introduction of the digital x-ray sensor is installed in the PC.	The device is recognised starting from iCapture version 2.2. Close iCapture and install an updated version.
Message *ERROR31* appears on the PC.	Data image loss.	In the device advance setting menu disable *Processor Idle* (refer to iCapture user instructions).
An ERROR message followed by a number (other than 31) appears on the PC.	Sensor or interface malfunction.	Write down the message and inform technical personnel. Do not use the sensor, contact the Technical Service Centre.

PROBLEM FOUND	POSSIBLE CAUSES	SOLUTIONS
An image is acquired but with poor tone range and/or massive background noise.	Underexposed image.	Use a longer exposure time, make sure the x-ray generator works correctly.
The image is captured but it is very light with little contrast.	Over-exposed image.	Use a shorter exposure time, check the settings of the x-ray generator.


cefla