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OPERATOR'S MANUAL
X-VS E

NewTom

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

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1. INTRODUCTION AND INDICATIONS FOR USE

X-VS E 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 digital intraoral sensor X-VS E 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, these sensors allow an easy intraoral positioning. The smoothed edges and rounded corners comfortably adapt to the shape of the patient's mouth, ensuring an easy positioning. X-VS E sensors are available in two interchangeable sizes to meet different diagnostic needs.

The sensor electronic module is compatible with the 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 E is designed as a portable device (stand-alone).

USB® connection makes the X-VS E device 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.

A computer and program to view x-ray images are required for use. 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 is based on 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 the iCapture software, to guarantee that X-ray images are correctly transferred from the electronic module to the computer.

Indications for Use for US market
The Digital Intra-Oral X-Ray Imaging System is used in conjunction with dental Radiography in medical units. The product is used for dental X-ray examination and the diagnosis of structural diseases. The product is expected to be used in hospitals and clinics, operated and used by trained professionals under the guidance of doctors. This device is not intended for mammography and conventional photography applications.
This device is suitable for providing dental radiography imaging for both adult and pediatric.

Dental X-rays are part of the diagnostic process in clinical dentistry. Appropriate radiographic selection and interpretation together with clinical information and other tests are essential for the formulation of a strong differential diagnosis.
X-rays will help the dentist in making a diagnosis and identifying the type and extent of the disease.
Clinical benefits include the ability to aid and support the dentist in identifying and/or ruling out dental problems and diseases; to determine when dental interventions are needed and to plan them; to guide treatment of common dental conditions.
The sensor itself does not provide any diagnosis but supports the dentist in identifying and evaluating diseases and is used for a wide variety of clinical purposes.

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

Third-party software can be used 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 regardless of the user's will.

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

For operators in Europe: any serious accident occurred in relation to the device must be reported to CEFLA s.c. and to the competent authority of the Member State where the user and/or patient lives.

Since the X-ray exposure condition can be changed depending on the age, gender and bone density of the patient, in case of Pediatric, X-ray exposure condition can be changed by expert's judge.
For further information, please refer to FDA Pediatric X-ray Imaging webpage (http://www.fda.gov/radiation-emittingproducts/radiationemittingproductsandprocedures/medicalimaging/ucm298899.htm).

1.1. MANUAL DESCRIPTION

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.
This operator's manual refers in general to the X-VS E device (indicated 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 E sensor and the iCapture software have been developed and manufactured by CEFLA s.c. - via Selice Provinciale 23/A - 40026 Imola (BO) Italy, hereinafter referred to as the Manufacturer, which is the manufacturer and distributor in compliance with the EC Medical Device Directive.

These instructions explain how to correctly use the X-VS E 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 E sensor, software for capturing and saving the images is needed that is not part of the sensor X-VS E. 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 the program is installed, acceptance of the contract will be explicitly requested. If the contract is not accepted the program cannot be installed.

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 Regulation (EU) 2017/745 concerning Medical Devices, based on which it is classified as **class IIa** medical device.

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The CE mark certifies the conformity of the product with the Medical Device Regulation (EU) 2017/745, as described here.

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.) + A1:2015 - 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 device 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 in compliance with the essential requirements of (EU) Regulation 2017/745 on Medical devices.
Notified body: IMQ spa.

 — Applied part of type BF, 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.

 — Symbol: dispose under directive 2012/19/EU. This symbol indicates that this product is not to be disposed of with your residential or commercial waste.

 — USB® 2.0 connection (as specified on USB® cable).

Ukraine compliance mark.

MD — Medical device.

 — The operator’s manual is provided in electronic format.

— Model.

IP68 — Protection against dust and temporary immersion in water up to 1 meter for 40 minutes.

Rx only — Important: Federal law restricts this device to sale by or on the order of a physician.

1.5. WARNINGS FOR USE

Use only computers and image display monitors that comply with IEC 60601-1 or IEC 60950-1.

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 E sensor and relevant software in conjunction with other commercial devices is not assured or recommended.

The digital sensor adopts the TWAIN® protocol for data transmission. It can be used with 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 the image acquisition software. After installing new programs in the computer or updating the operating system, check device 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.

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. To recover the image, follow the manual procedure described in paragraph “Recovering the last image acquired” of the iCapture operator's manual. 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 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.

The USB® 2.0 connection required for the operation of the device is not a simple electrical connection but requires special cables (recognisable by USB® HiSpeed® marking).
To ensure perfect operation, a single USB® cable cannot exceed the total length of 4.5 m. Should it be necessary to install the sensor with longer cables, a USB® repeater must be installed every 4.5 m, up to a maximum of three cable sections (two repeaters).

The sensor used to capture images is fragile and sensitive to electrostatic discharge. 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 “Description of operation”.

1.6. GENERAL SAFETY WARNINGS

The instructions inform the user on how to properly operate the device. 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 (see paragraph “Standards and Regulations”).
Do not use the device for tasks other than those described in the intended use (see paragraph “Introduction and indications 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 device must not be used if it shows any electrical or mechanical defect. Like for any electrical medical equipment, 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 device 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.

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

1.6.2. USE CONDITIONS

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.

Installation and environment of use:
- Do not use or store the equipment near flammable chemicals such as thinner, benzene, etc.If chemicals are spilled or evaporate, it may result in fire or product damage through contact with electric parts inside the equipment.
- Do not connect the equipment with anything other than specified.Doing so may result in personal injury or product damage.
- Do not install or use in the following environment, or it may cause fire, personal injury or product damage:
  - Facilities near water sources
  - In direct sunlight
  - Close to air conditioning or ventilation systems
  - Close to a heat source such as a heater
  - In salty or acidic environments
  - In case of high temperatures and high humidity
  - In case of ice or condensation
  - In an environment subject to vibration
  - On a slope or in an unstable area
- Ensure that the cable is not knotted or wound during use. Or it may cause the equipment damage or personal injury.

Handling:
- Never disassemble or modify the equipment. No modification of this equipment is allowed.
- Follow the instructions below to prevent damage to the sensor (detector) and cable.
- Do not twist, bend, pull and pinch the cable strongly.
- Do not strike or drop the equipment.
- Do not touch the pin of the USB connector.
- Do not put the equipment and pointed objects together.

When a problem occurs:
- Please unplug the USB connector when a problem happened and contact the supplier or local dealer:
- When there is smoke, an odd smell or abnormal sound.
- When liquid has been spilled into the equipment or a metal object has entered through an opening.
- When the equipment has been dropped and damaged.

Use the X-ray system associated with the sensor in compliance with national provisions on protection from ionising radiation, such as:
- **Each examination must be justified by evidence that the benefits outweigh the risks.**
- **Patients must wear leaded aprons with collar for thyroid protection.**
- **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.**
- **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.**
- **Inform the patient of the risks associated with the examination, acquire its informed consent and store the related document.**

For users in Brazil: for any claims or technical assistance, please 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, the PC should be on and the sensor cable connected to a USB® port.
Insert the A-type USB® connector inside a free USB® port of the PC.

Operation is only possible if iCapture is activated (see the iCapture manual for details about installation and use).

1.6.3. USE OF THE CENTRING DEVICE

The sensor must be held in the correct position using a centring device in order to obtain good x-ray images.
Kits of special centring 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 centring devices.
In addition, universal centring devices such as RINN® Uni-Grip or KerrHawe® Bite Senso series or similar can be used.
Always refer to the instructions included with the centring kit for details on use, cleaning and sterilization of the centring device.

NEVER grasp the sensor with grippers to avoid irreparable damage. Always use centring devices specifically designed for use with digital X-ray sensors.

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

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 itself;*
- *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. CYBERSECURITY INFORMATION

Medical devices capable of connecting (e.g. Via Ethernet port) to another device are vulnerable to cybersecurity.
The intended use of the device limits for its nature the intended use environment (health care facility, medical surgery, hospital, etc.) and intended users (health care worker, paediatrician, etc.).
This condition limits the probability that the device may be subject to cyber-attack.

In every case some precautions are recommended:

- The device and the workstations must be used in a controlled access environment (e.g. radiology department) so that they are accessible to authorised personnel only;
- the workstations must belong to a medical network, where the cybersecurity countermeasures are correctly and effectively implemented in accordance with national and regional regulations in force;
- the infrastructure must manage functions for access protection, therefore a login must be executed to access the workstation with correct User Id and Password. The passwords must be maintained reserved, not easily identifiable and they must be changed periodically;
- the infrastructure must provide the protection from unauthorised accesses with firewall;
- the infrastructure must manage functions for data protection;
- the infrastructure must manage functions for logging and detecting accesses.

1.6.4.3. LIMITATION OF LIABILITY

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 E device is designed to operate in the electromagnetic environment specified below. The customer or user of the X-VS E device should ensure that it is used in such environment:		
Emission test	**Conformity**	**Electromagnetic Environment**
RF emissions CISPR 11	Group 1	The X-VS E 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 E device is suitable for use in all environments, including households and those directly connected to the public low-voltage power network that supplies buildings used 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 E device is designed to operate in the electromagnetic environment specified below. 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	contact ± 8 kV 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 relevant 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 between phases ± 2 kV phase(s) to 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 E user requires a continuous operation also in case of blackout, it is recommended to power the X-VS E 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 E is designed to operate in the electromagnetic environment specified below. The customer or user of X-VS E should ensure that it is used in such environment.			
Immunity test	**Test level under IEC 60601**	**Conformity level**	**Electromagnetic environment - guide**
Conducted RF EN 61000-4-6	3 V 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 E and its components, including cables, lower than the recommended distance calculated 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 80 MHz to 2.7 GHz	IEC 60601-1-2 Test level	$d = 1.2 \times \sqrt{P}$ 80 MHz at 800MHz $d = 2.3 \times \sqrt{P}$ 800 MHz at 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 portable and mobile RF communication equipment and X-VS E			
X-VS E is designed to operate in an electromagnetic environment where radiated RF interference is under control. The customer or the user of X-VS E can help prevent electromagnetic interferences by ensuring a minimum distance between mobile and portable RF communication equipment (transmitters) and X-VS E, 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)**		
	150 kHz to 80 MHz d = 1.2 x √P	**80 MHz to 800 MHz** d = 1.2 x √P	**800 MHz to 2.7 GHz** d = 2.3 x √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 cannot 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 RADIATIONS

The digital sensor must be used together with an intraoral x-ray system. As such, the device 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

- **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 device 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 infection control sheaths. Disposable infection control sheaths 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 infection control sheaths 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, centring 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.**
- **Pay attention to the sensitivity of the patient 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 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 device malfunction is present or suspected.

Preventive maintenance
Inspect PC connection cables 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 device does not work as described in this manual, contact the technical service immediately.

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

Component	Activity	Time interval
Global device	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 device	Conduct a test by capturing x-ray images using a phantom.	Once a month
Global device	Check image quality as required by local regulations, using for instance a Quart Phantom 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”.

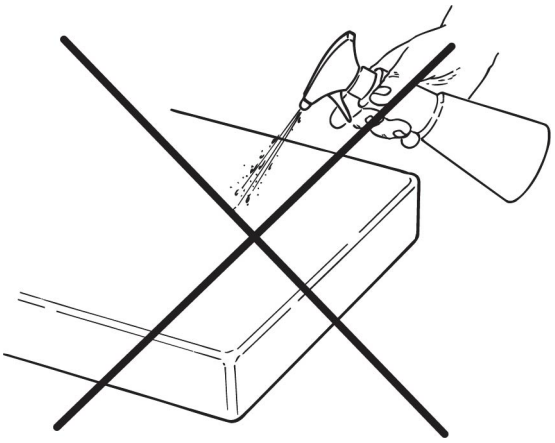
In compliance with Directives 2011/65/EU and 2012/19/EU regarding restriction of the use of certain hazardous substances in electrical and electronic equipment along with waste electrical and electronic equipment, it is forbidden to dispose of this equipment in the municipal waste stream as unsorted 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 symbol indicating separate collection for electrical and electronic equipment consists of the crossed out bin marked on the equipment. Under local legislation, fines can be imposed if the equipment is disposed in an illegal manner.

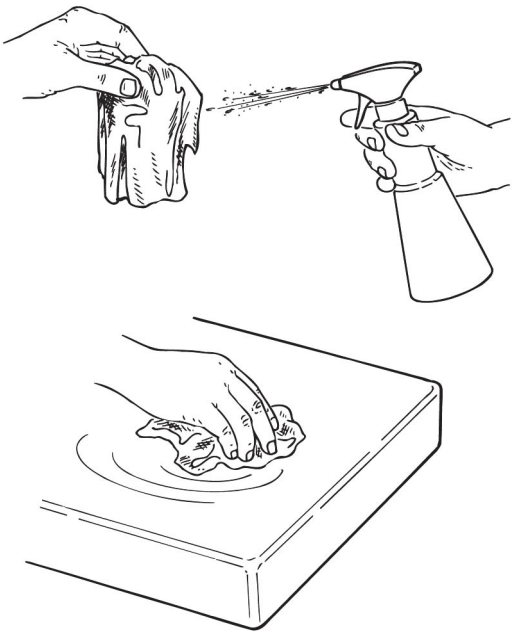
1.6.9. CLEANING AND DISINFECTION

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 micro-organisms. 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.

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





- **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.**
- **All materials used for cleaning and disinfection 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.

For centring device cleaning and sterilization instructions, follow the conditions specified by centring device manufacturer.

Warnings 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.

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

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 **IP68** rating.
Pay special attention to avoid the risk of damage when cleaning the sensor(detector).
The sensor(detector) should be cleaned frequently.

For the external cleaning and/or disinfection of the sensor and its power cable (USB® connector excepted), **use gauze or cotton soaked in** 70% isopropyl alcohol when the USB connector is not connected. Do not apply any liquid or disinfectant to the product except 70% isopropyl alcohol. Do not immerse the sensor(detector) in disinfectants or any other chemicals.

Warnings 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.

All materials used for cleaning and disinfection must be thrown away upon completing the procedure. Observe current regulations when disposing the material.

1.6.10. HYGIENE PROCEDURES FOR PATIENT PROTECTION

Disposable hygienic infection control sheaths 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 infection control sheaths. Disposable infection control sheaths are class I medical equipment and cannot be replaced with other protections having lower specifications.
Disposable infection control sheath 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 infection control sheaths before positioning a new patient.
Disposable hygienic infection control sheaths must be stored in a dry and clean area and must not be exposed to direct sunlight or UV radiation.
Cover with disposable infection control sheaths 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 centring device guarantees that the sensor is perpendicular to the x-ray tube and its sensitive area is centred. Use of a centring device is strongly recommended. The clinician should choose the most suitable one based on his/her own experience.

The centring device must comply with ISO 10993 standards concerning biocompatibility. For further information on use of the centring device, refer to paragraph "Use of the centring device".

1.6.11. APPLIED PARTS

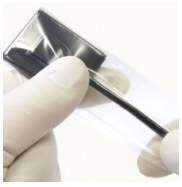
The parts of the device or its accessories that, during standard use, necessarily come into contact with the patient, so that the device may carry out its functions correctly, are: digital sensor, centring device and hygienic covers.
The part not applied that might come into contact with the patient is the 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 (Size 1 or Size 2)	
Package containing a USB® drive with software, driver and electronic user's manual	
Quick Start Guide for sensor use	
Support for sensor and related wall-mounting instructions	
USB® 2.0 hub (4 ports)	
Package containing no. 100 disposable infection control sheaths for the sensor	
Introduction package of centring devices (Size 1 or Size 2) (OPTIONAL)	
USB® 2.0 PC extension and additional USB® 2.0 hub (4 ports) (OPTIONAL)	 
2D image acquisition workstation (OPTIONAL)	

Multiple-workstation hardware keys for the activation of additional licenses (1, 5, 10, 25, 50, 250) on LAN network (OPTIONAL)	
22” / 24” medical monitor for image displaying (OPTIONAL)	

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

3. DESCRIPTION OF THE OPERATION

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

3.1. TURNING THE SENSOR ON AND OFF

To use the device, the X-ray sensor must be connected to the USB® port of a personal computer.
Please check whether the USB connector is dry or clean before connecting the USB connector.
Please hold the control box of the USB when plugging the USB connector, do not touch the pin of USB connector.

Connect the sensor to the USB® port of the PC.

To disengage the sensor from its housing, gently pull the USB® connector of the cable out of the USB® port of the personal computer. Do not exert lateral movements or stress, and do not pull the cord.
After the USB port is pulled out, please take care of the USB connector to avoid the risk of damage.

The sensor(detector) should be stored in a place free of chemicals or gases and free from adverse factors such as pressure, high temperature, humidity, direct sunlight, dust, oxides or sulfides.
When the sensor(detector) is out of using, it is recommended to put it into the product package box, to avoid damage.

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

3.2. SENSOR CONNECTION AND CONTROL

Sensor status is displayed on the Personal Computer. For further details on colour-coding and status symbols, also refer to “Status indications”.

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 TWAIN® driver will be automatically started for device initialisation.

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

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

If the sensor is NOT connected, after a few seconds the MyRay® Driver TWAIN® window will show “SENSOR NOT CONNECTED” on a red background.

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

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

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 centring 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 paragraph "Use of the centring device".

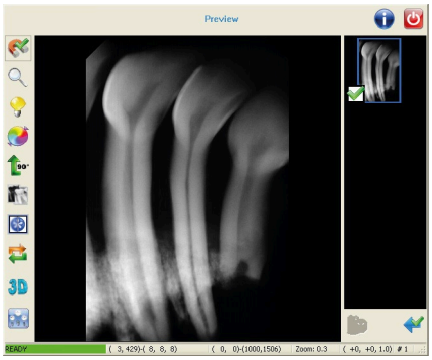
Remember to change the disposable infection control sheaths before positioning a new patient.

3.4. ACQUIRING AN X-RAY IMAGE

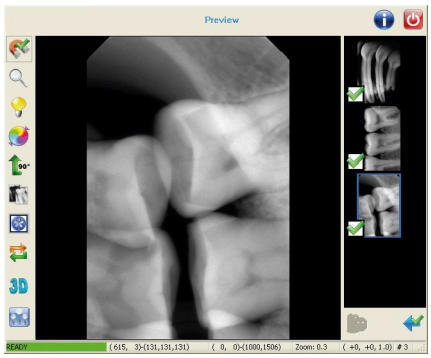
To acquire an X-ray image, run the image acquisition program by selecting image acquisition from iCapture.

Do not take x-ray pictures on a patient when testing the device 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 MyRay® 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.



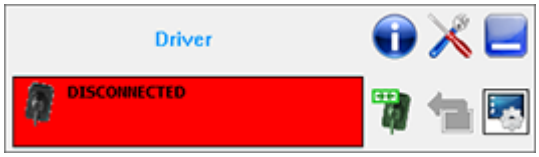
After the acquisition of an image, it is possible to acquire a second image after 5 seconds.

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.

Always check device 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.

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 “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.

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. TECHNICAL 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		
Outer dimensions (mm)	38.5 x 25	45 x 31.6
Thickness (mm)	4.5 mm	4.5 mm
Pixel Array	1500 x 1000	1800 x 1300
Pixel Size (µm)	20	20
Maximum resolution (lp/mm)	25	25
AD Conversion	≥ 14 bits	
Sensitivity	> 401 sb/nGy	
Max linearity dose	> 300 uGy	
Gray level depth	16-bit acquisition - max. 65535 grey levels	
Sensor technology	CMOS APS	
Scintillator technology	Direct-deposit CsI (Caesium Iodide)	
Case protection rating	IP68 (Guaranteed against the penetration of liquids and dust)	
Compatibility with X-ray generators	Any AC or DC generator with technical factors in the 60-70 kV and 1-8 mA range and precision control of exposure times.	
Connectivity	Direct USB connection to PC	
Port	USB 2.0 or higher	
Cable length	＜3 m	
Power supply	5 VDC, 400 mA (via USB)	
Acquisition software (for PC)	iCapture with dedicated filters for third-party software	
Image management software (for PC)	NNT compliant with ISPD©10003:2020 scheme according to EN ISO/IEC17065:2012 certificate number 2019003109-2)	
Supported protocols	DICOM 3.0, TWAIN, VDDS	
DICOM nodes	Compliant with IHE (Print; Storage Commitment, SR document; WorkList; MPPS; Query/ Retrieve)	

Timing and Electrical characteristics				
	Condition	Min	Type	Max
Integration time		0.05 s		4 s
Current consumption	Image sensor(detector) head		30 mA	50 mA
	USB driver		200 mA	350 mA
Readout time			1 s	1.5 s
AcqDelay	Can be Configured			50 ms
Image cycle time				6 s

Operating conditions	
Temperature	10 °C to +35 °C (temperature variation ≤1℃/min)
RH (humidity)	20% to 90%
Atmospheric pressure	700 to 1060 hPa (barometric variation ≤10 mbar/hour)

Do not operate the sensor (detector) at an altitude above 3000 m; the system connected to the sensor (detector) can also operate at an altitude below 3000 m.
Do not expose the sensor(detector) to a hot and humid environment, otherwise it may result in product damage.

Transport and storage conditions	
Temperature	-10 °C to 55 °C (temperature variation ≤1℃/min)
RH (humidity)	10% to 95%
Atmospheric pressure	700 to 1060 hPa (barometric variation ≤20 mbar/hour)

4.2. COMPATIBILITY WITH X-RAY GENERATORS

The features and some of the key functions of the device 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". Considering the high sensitivity of the sensor, 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 DC X-ray units manufactured by CEFLA s.c., a sensitivity value of F15 is recommended, with pre-setting left at 8 mA 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.

		30cm (12")	20cm (8")
	UPPER MOLARS	0.25 s 0.16 s	0.16 s 0.10 s
	PREMOLARS / UPPER CANINES	0.20 s 0.125 s	0.125 s 0.08 s
	UPPER INCISORS	0.16 s 0.10 s	0.10 s 0.063 s
	BITEWING	0.20 s 0.125 s	0.125 s 0.08 s
	LOWER INCISORS	0.16 s 0.10 s	0.10 s 0.063 s
	PREMOLARS / LOWER CANINES	0.20 s 0.125 s	0.125 s 0.08 s
	LOWER MOLARS	0.25 s 0.16 s	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 SYSTEM REQUIREMENTS

Minimum system requirements	
Supported operating systems	Microsoft® Windows® 10 (Professional 64 bits) or 11
Processor	Intel Core 2 Duo / AMD Athlon X2 or higher
RAM	4 GB (8 GB recommended)
Graphics Card	Discrete 3D Video Card or integrated GPU
Display settings	1280 x 1024; 1344 x 768 or higher, 16 million colours
Port	USB 2.0 or higher
Power supply	5 VDC, 400 mA (via USB)

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.

PC connected to the sensor(detector) must be approved by local authorities: for example, by IT equipment safety certificate, NRTL approval, etc..

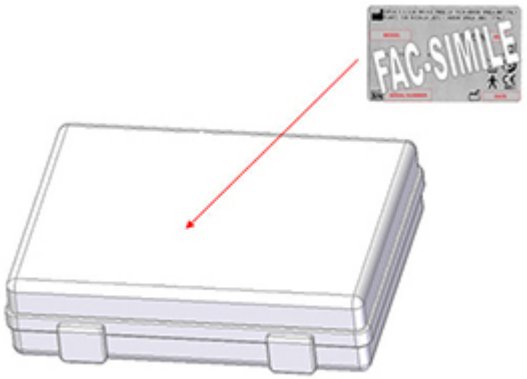
5. PRODUCT IDENTIFICATION

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 the paragraph “Stylistic conventions”.

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

Position: applied to both the inner case containing the sensor and the lower part of the outer packaging.
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 acquired image can be recovered by downloading it again from the sensor via the window " TWAIN® data source" (see paragraph "**Recovering the last image acquired**" of the iCapture operator's manual). Do not turn the PC off or disconnect the interface from the USB® port: the image will be definitely lost.
The device does not switch on.	USB® cable not connected.	Connect the USB® cable to a PC port.
The device 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 mass storage device (Pen drive). Test the equipment on another PC. The status light should be on (flashing yellow) even without installing the software.
The device does not switch on.	Faulty device.	Do not use the sensor, contact the Technical Service Centre.
The device 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 device connection.
The device is not recognised.	The PC contains a version of iCapture released prior to the introduction of the digital X-ray sensor.	The device is recognised starting from version 2.2 of iCapture. Close iCapture and install an updated version.
Message *ERROR31* appears on the PC.	Data image loss.	In the device advanced setting menu, disable Processor Idle (refer to iCapture manual).
An ERROR message followed by a number (other than 31) appears on the PC.	Sensor malfunction	Write down the message and inform technical personnel. Do not use the sensor, contact the Technical Service Centre.
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.

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