97055273
Rev. 01
2021-05

# X-PSP VET

Cone Beam 3D Imaging
NewTom
what's next

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

EN

Contents

# 1. FOREWORD

This manual refers to the following model:

- NewTom X-PSP VET - REF. 703D

The NewTom X-PSP VET system is a system for acquiring and processing digital X-ray images that can be used with all intraoral X-ray systems.

In order to manage the images, it is essential to use a personal computer and an image viewer program.

The NewTom X-PSP VET system was developed to simplify the process of acquiring and viewing images on a digital screen.

The phosphor plate acquisition system uses a very similar method to that of common radiographic film, but the technique is simplified and speeded up through the use of digital technologies.

The image is scanned on phosphor plates available in various sizes, to best fit the anatomical region to be examined. The flexibility and ergonomics of the shapes of phosphor plates allow an easy intraoral positioning, minimising patient discomfort during the examination.

Following exposure, the phosphor plate is inserted into the scanner, which thanks to a laser scans the image and transfers it to the PC, where it can be displayed, manipulated and stored.

The 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 image management program, refer to the manual supplied together with the program for all the warnings, precautions and operating instructions.

The phosphor plate acquisition system is supplied together with software called iCapture, that assures the x-ray images are correctly transferred from the electronic module to the computer. Refer to iCapture manual for details on proper use with this device.

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 device 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 phosphor plate acquisition system.
These instructions describe how to properly and safely use the device.
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 manual refers to NewTom X-PSP VET phosphor plate acquisition system as “the system”, “the scanner”, “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.

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

## 1.2. BOX CONTENTS

Package includes the following:

- Phosphor scanner
- Power supply
- USB key to install software, and electronic user's manual
- Ethernet cable
- Power cable
- Basic starter kit containing phosphor plates and related additional components (light covers and disposable bags)
- Quick Start Guide
- Disposable hygienic covers
- Additional Starter kit (optional - available formats 0,1,2,3,4)
- Wall bracket (option)
- Centring device for phosphor plates (optional)
- Touch device for "multi room" function (optional)

After opening the casing, check that the supply matches the order specifications and that all the contents of the package are undamaged.

Do not use the system if you find any damaged parts.

## 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 phosphor plate acquisition system and the relevant software iCapture are 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 applied EC Directives.

**WARNING:** These instructions explain how to correctly use the phosphor plate acquisition system. As regards the iCapture software instructions, consult the specific manual. Carefully read both manuals before attempting to use the device and program.

In order to use the scanner of the phosphor plate acquisition system, software for capturing and saving the images is needed that is not part of the device. 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.

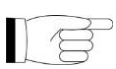
The Manufacturer reserves the right to make changes without prior notice.

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.

**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.

## 2.1. STYLISTIC CONVENTIONS

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

| | |
|---|---|
|  | It is necessary to read the user's manual before using the device. |
|  | Equipment compliant with the requirements set out by the applied Directives. |
|  | Product/equipment identification code. |
| SN | Product serial number. |
|  | Product batch number. |
|  | Symbol: dispose under directive 2012/19/EU. |
|  | Manufacturer. |
|  | Date of manufacture. |
|  | Ukraine compliance mark. |

## 2.2. INTENDED USE

The NewTom X-PSP VET system is a system for digital recording of images that are imprinted on phosphor plates exposed to X-rays, and then digitally acquired and sent to an external Personal Computer.

Since the phosphor plates are exposed to X-rays, the use of the device is limited to qualified personnel, aware of the dangers derived from ionising radiation.
During the execution and the acquisition of X-ray images, all the precautions for radiation protection of the patient and the operator must be in place because the phosphor plate is used in conjunction with an X-ray system.

**WARNING!**

- This device is intended for veterinary use only.
- This device is not intended to be used on human beings.
- The device is managed and used by radiologists and qualified operators in the veterinary field and by other legally qualified professionals.

## 2.3. CLASSIFICATION AND REFERENCE STANDARDS

| **IEC 60601-1 classification** (ed 3.1). | |
|---|---|
| Type of protection against electric shocks: | CLASS I |
| Degree of protection, IP: | IPX0 |
| Sterilization method: | The device is not subject to sterilization. |
| Use within an environment having a high oxygen content: | Not intended for use within an environment having a high oxygen content |
| Use conditions: | Continuous operation |
| Use with anaesthetic mixes: | This equipment has not been evaluated for use in the presence of a flammable anaesthetic mixture with air, oxygen or nitrous oxide |

**Reference standards.**

The device and its additional components are designed and constructed in compliance with the following standards:

- Directive 2014/30/CE - Electromagnetic compatibility.
- Directive 2014/35/EU - Low voltage devices.
- IEC 60601-1:2005 + A1:2012 (ed. 3.1) – General requirements for the safety of medical electrical equipment.
- IEC 60601-1-2:2014 (4th ed.) – Medical electrical equipment: Electromagnetic compatibility - Requirements and tests.
- Dir. 2011/65/EU – Directive of the European Parliament and Council of June 8, 2011, regarding restriction of the use of certain hazardous substances in electrical and electronic equipment (Rohs 2).

CE Equipment compliant with the requirements set out by the applied Directives.

## 2.4. ENVIRONMENTAL CONDITIONS

During the transport and the storage it is necessary to respect the conditions indicated below.

**Transport and storage temperature:**
from -10° to +70° (Celsius)

**Humidity conditions for transport and storage:**
min 10% - max 90% (non-condensing)

**Pressure:**
500 - 1060 hPa

The equipment must work in rooms with the following environmental conditions:

**Operating temperature:**
from +10° to +40° (Celsius)

**Operating humidity conditions:**
min 30%, max 75% (non-condensing)

**Pressure:**
710 – 1060 hPa

## 2.5. DISPOSING THE EQUIPMENT WHEN NO LONGER USED

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 dealer 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.

**WARNING:**
Under local legislation, fines can be imposed if the equipment is disposed in an illegal manner.

## 2.6. 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 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.

### 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.

### 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.

## 2.7. SAFETY GUIDELINES

- Carefully read the procedures described in this manual;
- Do not forget to turn off the main switch on the equipment before leaving the surgery;
- 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;
- Power up the system with a power supply in accordance with IEC 60601 (Ed.3.1) connected to ground;
- Use the system with phantoms before proceeding to the acquisition of images of patients;
- Apply the law relating to radiation protection as described in paragraph 2.10 – "Protection against radiations";
- Do not use the system at distances of less than 3 m from any equipment of which you do not know the level of electromagnetic emissions;
- Do not pour flammable substances on the system;
- Do not spill liquid of any kind on the system;
- Do not use the system in the presence of flammable or explosive gases or vapours;
- Do not use the system during the use of electric scalpels or similar in the vicinity;
- This equipment must be stored properly so that it is kept in top working order at all times;
- 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;
- Any computer, monitor, printer, mouse, keyboard and any other device connected to the phosphor scanner 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;
- Always make sure, before each start-up, that additional components cables to be connected to the system are in perfect condition;
- Use and store the device in rooms protected from dust, featuring the following conditions: - humidity between 30% and 75%; temperature between +10°C and + 40°C;
- Only qualified personnel authorised by the Manufacturer may perform technical operations on the system.
- Use only original additional components, supplied by the Manufacturer such as plates, power supply unit. Do not connect devices that are not compatible with the system.
- Some parts may be dangerous if used improperly. Avoid unintended, inappropriate and misuse and keep out of reach of children.

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**IMPORTANT:**
The device is delivered in its original packing which should be kept for future shipment.

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- Electromagnetic interferences: use of electrical equipment that does not comply with standard IEC 60601-1-2 in the office or nearby may cause electromagnetic or other types of interferences resulting in equipment malfunctions.

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**WARNING: Phosphor plates are toxic.**
The phosphor plates, if not packaged in a light cover, can cause intoxication when placed in the mouth or swallowed.
Place the phosphor plates in the patient's oral cavity only with a light cover and a disposable hygienic cover.
Do not swallow the phosphor plates, nor parts of them. In case of swallowing of phosphor plates or parts of them, immediately consult a specialist and remove the phosphor plates.
If the guard is damaged in the oral cavity of the patient, you must rinse your mouth with plenty of water. Be careful not to swallow the water.

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## 2.8. ELECTRICAL SAFETY DEVICE

**WARNING: To avoid the risk of electric shock, this equipment should be connected only to a power supply with a protective earthing system.**

The system is designed in compliance with regulations regarding electrical safety. Always observe the following safety precautions:

- Do not place containers containing liquid near the system.
- Do not tamper with the computer or the connected equipment.
- Only use original cables and additional components that come with the system. The use of additional components not supplied by the Manufacturer may cause fire, electric shock or injury.
- Check that the voltage on the label corresponds to the value actually available in the power mains to which the system will be connected.
- Place the system so that it can be quickly and conveniently accessed by the operator for connection/disconnection.
- Check that all cables are connected properly. Never remove a plug by pulling its cable and prevent excessive tension on the cable.
- Before connecting the system, make sure that the power outlet is properly grounded.
- Do not disconnect any cables while the system is running.
- Lay out the system (and its components) in order to ensure an ergonomic use.

## 2.9. ELECTROMAGNETIC SAFETY

It is recommended not to use the product 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.

| Guidance and Manufacturer's declaration - Electromagnetic emissions | | |
|---|---|---|
| **The 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:** | | |
| **Emission test** | **Conformity** | **Electromagnetic Environment** |
| RF emissions<br>CISPR 11 | Group 1 | The device uses RF energy only for its internal operation. Therefore, its RF emissions are very low and they do not interfere with any electronic devices nearby. |
| RF emissions<br>CISPR 11 | Class B | The 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<br>IEC/EN 61000-3-2 | Class A | |
| Voltage fluctuations/ flicker<br>IEC/EN 61000-3-3 | Compliant | |

| Guidance and Manufacturer's declaration - Electromagnetic immunity | | | |
|---|---|---|---|
| **The 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<br><br>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<br><br>±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<br><br>±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 | Ut = 0% (at 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315°) for 0.5 cycles<br><br>Ut = 0% per 1 cycle<br><br>Ut = 70% (a 0°) per 25/30 cycles<br><br>Ut = 0% per 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 user requires a continuous operation also in case of blackout, it is recommended to power the device with an 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 | | | |
|---|---|---|---|
| **The device is designed to operate in the electromagnetic environment specified below. The customer or user of the device should ensure that is used in such environment.** | | | |
| **Immunity test** | **Immunity test** | **Immunity test** | **Immunity test** |
| | | | The RF communication devices (portable and mobile) must not be used at a distance from the device and its components, including cables, lower than the recommended distance, calculated using the corresponding equation applicable to the transmitter frequency. |
| Conducted RF EN 61000-4-6 | 3 V from 150 kHz to 80 MHz<br><br>6V ISM frequencies | IEC 60601-1-2 Test level | **Recommended distance**<br>$d = 1.2 \times \sqrt{P}$ |
| Radiated RF EN 61000-4-3 | 3 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<br>$d = 2.3 \times \sqrt{P}$ 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).<br>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.<br>Near the equipment with the following symbol interferences can be caused:<br>  |

| Recommended distance between the RF portable and mobile communication devices and the device | | | |
|---|---|---|---|
| **The device is designed to operate in an electromagnetic environment with control of the RF irradiated disturbances. The customer or the user of the device could help in preventing electromagnetic interferences ensuring a minimum distance between the RF mobile and portable communication devices (transmitters) and the device, 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.<br>NOTE 1: At 80MHz and 800MHz it is necessary to apply the distance defined for the highest frequency interval.<br>NOTE 2: These guidelines cannot be applicable to all situations.<br>The electromagnetic propagation is influenced by the absorption and reflection of structures, objects and people. | | | |

## 2.10.PROTECTION AGAINST RADIATION

The phosphor scanner and intraoral plates 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 room must be manned on the outside by authorised personnel until projection is complete.
- 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.
  - 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, additional components, and procedures available to protect the patient and operator from X-ray radiation, especially for children.
- The phosphor plate, with or without its support, must be maintained in position by the patient or by special support devices.

**Risk of loss of image and subsequent nullification of the patient's exposure.** The scanner of phosphor plates erases the plate at the end of the scan, in order to make it ready for a subsequent exposure. Do not turn off the scanner of phosphor plates before the digitised radiography is transferred to the computer.

The image data on the phosphor plate are alterable. The image data are modified by light, natural radiation or scattered radiation. This can compromise the diagnostic result. Acquire the image data within 10 minutes after they were created. Never handle the phosphor plates without light cover. Do not expose the phosphor plates to any light radiation before, during and after the acquisition with the scanner. If the equipment is in the same room as the X-ray generators, do not perform X-rays during the scanning.

Adjust the X-ray exposure parameters in relation to the radiation source used, the anatomical region of interest, the purpose of the examination and the patient's age and size.

## 2.11.HYGIENE PROCEDURES FOR PATIENT PROTECTION

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 covers supplied with phosphor plates.**

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

Always protect the intraoral plates with the appropriate protective bags before inserting them into the patient's mouth.
The plastic protection of the phosphor plate is disposable and must be replaced from patient to patient. After examination, throw the cover away, it should never be reused.

## 2.12.EXPOSURE TO LASER RADIATION

The system contains a class 3B LASER diode, in compliance with IEC 60825-1.
Both the patient and the operator may be dazzled by laser beams.
Do not open the equipment.

Do not look directly into the laser beam. Make sure that the laser beam does not strike the eye of the patient or the operator, neither as direct beam nor as a reflected beam from a reflective surface.

The presence of the laser source is indicated by the label below, attached INTERNALLY to the body of the scanning unit:

## 3. DESCRIPTION OF THE EQUIPMENT

The device is a system for acquiring and processing digital images obtained by exposure to X-rays produced by an intraoral X-ray system.

The scanner can read different sizes of phosphor plates:


**Size 0**
22 x 31 mm
726 x 1024 pixel


**Size 1**
24 x 40 mm
792 x 1321 pixel


**Size 2**
31 x 41 mm
1024 x 1352 pixel


**Size 3**
27 x 54 mm
891 x 1783 pixel


**Size 4**
57 x 76 mm
2049 x 2730 pixel

Please use only original plates, available separately from your local distributor.

The phosphor plates, with the relevant light covers and disposable hygienic covers, are supplied by means of two specific optional kits, called Starter Kits.

The basic Starter Kit contains a first supply of plates, one of each size, accompanied by an adequate amount of light covers and disposable hygiene control sheaths.

The additional Starter Kits (optional), suitable for increasing the number of plates available to users, contain two plates of the same size with light covers and disposable hygienic infection control sheaths compatible with the chosen size.

The scanner can be positioned in two different ways:


horizontally, on a flat surface, for example on a table;

vertically, leaning against a wall, using the appropriate wall support (optional).

# 4. INSTALLATION

Some simple operations have to be performed before attempting to use the device for the first time:

1) Remove the system from the original packaging. The phosphor scanner can be placed on a horizontal surface or vertically, fixed to the wall by means of suitable support.

To verify the correctness of the supply, refer to paragraph 1.1 – “Package contents”.

2) Follow the instructions in the Software Installation Manual supplied with the device.

Before installation, check that the characteristics of the Personal Computer correspond at least to those indicated in the attachment “**Minimum and recommended system requirements**”.

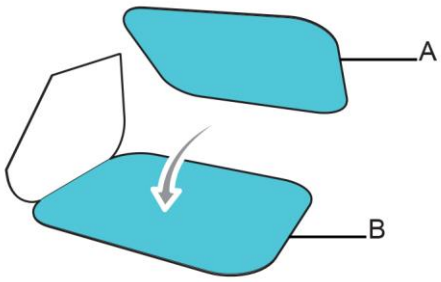
# 5. FUNCTIONING

## 5.1. PHOSPHOR PLATE PREPARATION

The phosphor plate stores energy from the X-rays that strike it, and is able to return this energy as a result of laser excitation. Using the scanner, the re-emitted light is converted into an image.
The phosphor plate has an active side (blue) and an inactive side (black). The X-ray exposure must be carried out on the active side (blue).
If used properly, the phosphor plate can be exposed, read and erased many times.

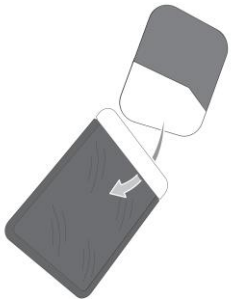
Before putting the phosphor plate in a bag, verify that the same has been deleted properly, and that there are no scratches or defects. In case of first use or if the plate has been idle for more than a week, it is recommended to repeat the deletion.

Always use light covers having dimensions equal to those of the plate. In case of mismatch, the plate may get stuck in the system.
In case of jam, refer to paragraph 9 – "Troubleshooting".

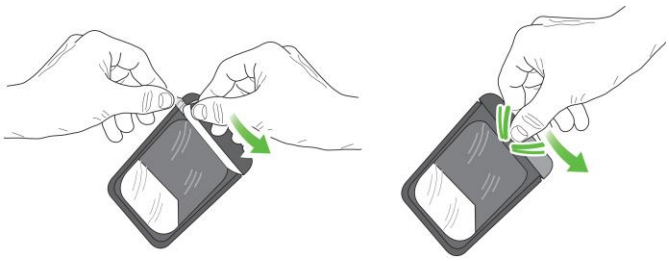



Place the phosphor plate (A) on the long part of the light cover (B). The blue side (active) of the phosphor plate must be aimed towards the blue side of the light cover.

Fold the short side of the light cover towards the phosphor plate.



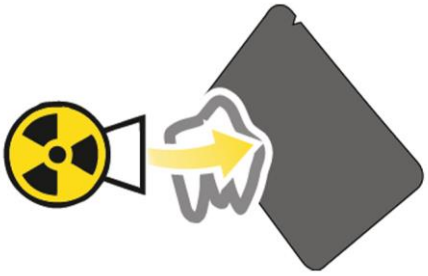
Place the phosphor plate, within the light cover, inside the hygienic cover (C) as shown.
The hygienic cover is disposable and must be changed from patient to patient.
It is not necessary to disinfect hygienic cover before use.



Make sure that the back of the light cover (black side marked "TUBE SIDE") is against the black side of the hygienic cover.

Remove the protective paper from the seal of hygienic cover and tightly close the hygienic cover.

## 5.2. PHOSPHOR PLATE EXPOSURE



Place the phosphor plate in the patient's mouth, in the position required to obtain the required image. The rear part of the hygienic cover (the part with the seal) must be away from the X-ray source.

It is recommended to use the optional centring devices - that can be purchased separately from your local distributor - to facilitate the positioning of the plate and therefore obtain better quality images.

Use an appropriate dose value, referring to the table below, and expose the plate to X-rays.

After exposure, remove the hygienic cover containing the phosphor plate from the patient's mouth and remove any water or saliva.
Before opening the hygienic cover, disinfect all elements with the appropriate solution (e.g., disinfectant soap and water).

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.

The phosphor system can work correctly both with conventional X-ray generators, known as "AC", and with the most recent high-frequency generators called "DC".

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).

The tables on the next page show the focus-to-skin distance and the maximum exposure time to be respected.

## 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.**

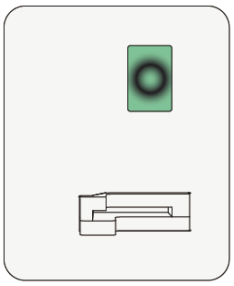
| | | Cone length 12" (30 cm) | | Cone length 8" (20 cm) | |
|---|---|---|---|---|---|
| | |  |  |  |  |
|  | UPPER MOLARS | **0.25 s** | **0.16 s** | **0.16 s** | **0.10 s** |
|  | UPPER PREMOLARS | **0.20 s** | **0,125 s** | **0,125 s** | **0.08 s** |
|  | UPPER CANINES / INCISORS | **0.16 s** | **0.10 s** | **0.10 s** | **0,063 s** |
|  | LOWER CANINES / INCISORS | **0.16 s** | **0.10 s** | **0.10 s** | **0,063 s** |
|  | LOWER PREMOLARS | **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 obtained with a high frequency generator with square collimator and 30 cm focus-skin distance (refer to the relevant table).
- For a better distance control, we suggest using a centring device with fixed spacer.
- 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.

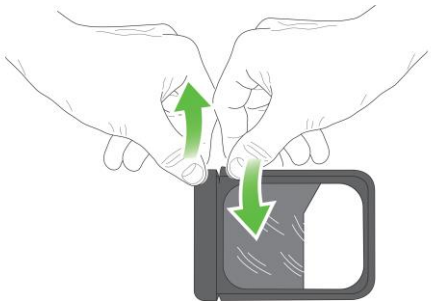
## 5.3. PHOSPHOR PLATE READING

In the extraction stages of the phosphor plate from light cover, do not expose the plate to light.

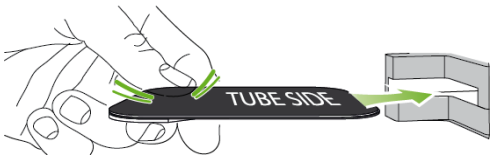
After exposure of the plate, it is recommended to immediately proceed with its reading. Do not exceed 10 minutes of waiting time. In case it is not possible to immediately proceed with the reading, avoid removing the plate from the light cover.

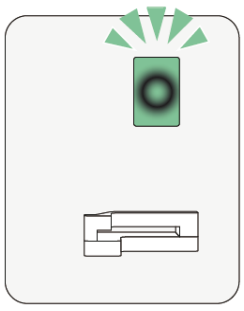


1. Make sure the Personal Computer connected to the phosphor scanner is turned on and functioning properly; in this case the system LED will be steady on and green.

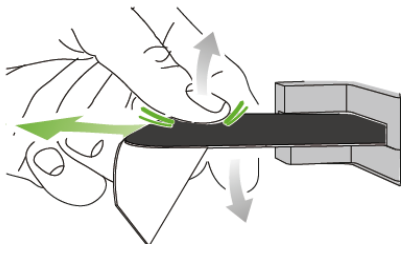


2. Open the hygienic cover and extract the phosphor plate, avoiding to expose it to light, and taking care not to contaminate the plate and the light cover.



3. Keeping the light cover in position as support, insert the plate so extracted into the slot on the phosphor scanner, making sure that the plate is properly aligned with the inserter. Gently push the plate into the slot until it stops. The green LED of the system will begin to flash.



4. As soon as the plate stops and the green LED flashes, decrease the pressure of your fingers on the light cover and remove the latter, leaving only the plate inserted into the phosphor scanner slot.

   **NOTE:** Do not pull out the light cover laterally but perpendicularly to the inserter as shown.

5. At this point, the phosphor plate will be engaged by the magnetic drive system and will be automatically dragged inside the scanner for scanning. The blue LED will come steady on and the automatic reading and erasing of the plate will start, as described in paragraph 5.4 - "LED Sequence".

6. At the end of the scanning and deletion procedure, the plate will be released automatically by the scanner. It is possible to remove the plate from the scanner, which is immediately ready for subsequent exposure. The plate must be grabbed through the light cover, for added protection. Store it in a dry and secure place to avoid exposure to shocks, scratches, dust and dirt.

The scanner starts reading only following the insertion of the plate with its light cover and after the subsequent removal of said protection. Any different insertion sequence will prevent the start of the reading stage.

In case of improper insertion of the plate, the red LED on the scanner will turn on. Before inserting another plate, wait for the red LED to go off and for the plate to be ejected.

Do not force the insertion of the plate: once the light cover is removed, the magnetic system automatically drags the plate inside the scanner, thereby starting the reading procedure described in step 5.

## 5.4. LED SEQUENCE

Through the software, the device can alert the operator about the different statuses of the system, such as errors, functions, or other.
The different statuses of the system can also be identified through the front-mounted LEDs.
The following table shows all situations that may occur during a normal work sequence.

| NORMAL OPERATION | | | |
|---|---|---|---|
| | LED COLOUR | | DESCRIPTION |
| 1 | Steady green light + flashing red light |  | System powered but not connected to software |
| 2 | Steady green light |  | System powered and connected to software (stand-by) |
| 3 | Flashing green light |  | Plate insertion detected; system waiting for removal of light cover to start reading |
| 4 | Steady blue light |  | Light cover was properly removed to start reading and the plate has been inserted properly |
| 5 | Flashing blue light |  | Scanner is reading the plate |
| 6 | Flashing white light |  | Scanner starts ejecting the plate |
| 7 | Steady white light |  | Deleting the plate |
| 8 | Flashing white light |  | Message: remove plate from scanner |

The most frequent use errors are indicated by the following LED combinations:

| POSSIBLE USE ERRORS | | |
|---|---|---|
| LED COLOUR | | DESCRIPTION |
| Flashing red light + steady green light + flashing green light |  | System will not capture plate: plate is inserted but scanner is disconnected |
| Flashing green light |  | System will not capture plate:<br>- plate was properly inserted, remove the light cover to start reading<br>- or, system detected that plate was inserted with the (blue) sensitive surface NOT facing the device reading side |
| Flashing white light |  | System will not capture plate: plate was inserted on proper side, but with no light cover |
| Flashing red light + steady red light |  | System will not capture plate: in the stage of removal of the light cover (steps 4 and 5 of normal use) the plate was held by user |

In case of LED sequences that are not described in this paragraph, remove the phosphor plate and wait for the automatic reset of the device. You can normally use the device as soon as the steady green light comes on.

After long periods of non-use, the system sets to waiting mode (SAVE POWER STATUS) and the steady green LED brightness will start decreasing.

To exit the SAVE POWER STATUS, insert a new plate to be read by the system, following the procedure detailed in paragraph 5.3 - "Phosphor plate reading".

## 6. MAINTENANCE

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 your local distributor at the numbers indicated in the warranty certificate. If the equipment has to be returned to the distributor or Service Centre for any reason, completely disinfect the outside of the apparatus with a specific product (see paragraph 7 - “Cleaning and disinfecting”) and send it back preferably in its original package.

If the phosphor sensor casings are opened to reach the circuits inside, device may be broken, the protective means for safety may be disabled and the warranty will become null and void.

All maintenance must be performed by a qualified technician and power must be disconnected.

Do not use the device if a system 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 instructions of their manufacturers.

### Additional component storage

Additional components must be stored and handled with care.
Any provided additional components 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 | Responsibilities |
|---|---|---|---|
| Global system | Visually inspect the system to find any damage or physical defect of the scanner or connection cables. | Once a week | Operator |
| Phosphor plates | Check intraoral plate for damage | Once a week | Operator |
| Personal Computer | Check PC operation.<br>Check proper transfer of an image from scanner to PC. | Once a week | Operator |
| Labelling | Visually check label for damage and readability. | Once a year | Operator |

If the operator should find any anomalies, during the above checks, it will be his/her responsibility to immediately contact the authorized Technical Service or the local distributor.

**WARNING!**
- Only technicians authorised by the Manufacturer can replace and/or repair the device.
- The warranty is automatically void if the device is altered in any way.

## 7. CLEANING AND DISINFECTION

The device does not contain parts that can be repaired directly by the user. The phosphor scanner does not require daily cleaning and disinfection, but the phosphor plates used by patients must be protected with hygienic covers before they are inserted in the mouth.
Particular attention must also be paid to the intraoral plate that, although protected by special disposable covers, is inserted into the patient's mouth.
No sterilization is necessary as the contact of the additional components with the patient and the operator is superficial and only through the skin.
The intraoral plates should not be placed in an autoclave.

Never use abrasive liquids containing alcohol or alkaloid substances for cleaning and disinfecting the phosphor scanner.
Never immerse any part in liquids.
Do not sterilize in an autoclave.
Always comply with the instructions in paragraph 2 – “General warnings”.

The outer parts of the equipment must be cleaned and disinfected using a product for hospital use with indications for HIV, HBV and tuberculocidal (medium-level disinfectant) specific for small surfaces.
The various drugs and chemical products used in dental surgeries may damage the painted surfaces and the plastic 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.

It is recommended to use the specific medium-level disinfectant, STER 1 PLUS (CEFLA s.c.), which is compatible with:

- **Coated surfaces and plastic parts.**
- **Upholstery.**
- **Uncoated metal surfaces.**

If you do not use STER 1 PLUS, it is recommended to use products that contain at maximum:
- **96% ethanol.** Concentration: maximum 30 g per 100 g of disinfectant.
- **1-Propanol (n-propanol, propyl alcohol, n-propyl alcohol)**. 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.

**WARNING!**
- **Do not use products containing isopropyl alcohol (2-propanol, iso-propanol).**
- **Do not use products containing sodium hypochlorite (bleach).**
- **Do not use cleaners containing phenols.**
- **Do not spray the selected product directly on the surfaces.**
- **All products must be used as directed by the manufacturer.**
- **Do not mix the STER 1 PLUS disinfectant with other products.**

**Cleaning and disinfecting instructions.**
Clean and disinfect the external housing of the phosphor scanner 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.

**WARNING!**
Unplug the power adapter and disconnect the Ethernet cable from the PC prior to cleaning and disinfecting the external parts.
All materials used for cleaning and disinfection must be thrown away upon completing the procedure.

## 8. TECHNICAL DATA

| **Characteristics**<br>*System classification* | |
|---|---|
| **Dimensions and weight** | |
| Weight | 5.7 Kg (with no power supply) |
| Height | 294 mm |
| Depth | 290 mm |
| Width | 163 mm |
| **Technical specifications** | |
| Pixel size | 30 µm |
| Spot size | 30 µm |
| A/D conversion | 16 bit input |
| **Scanner electrical features** | |
| Power supply | 24 V DC |
| Absorbed current | 1A |
| Absorbed power | 24 W |

| **Characteristics**<br>*Intraoral plate* | | |
|---|---|---|
| Dimensions | Size 0 | 22 x 31 mm |
| Dimensions | Size 1 | 24 x 40 mm |
| Dimensions | Size 2 | 31 x 41 mm |
| Dimensions | Size 3 | 27 x 54 mm |
| Dimensions | Size 4 | 57 x 76 mm |
| Phosphor composition | | BaSrFBr:Eu |
| Luminescence | | 400nm |
| Plate reading | | Within 1 h from exposure |
| Temperature (packed plate) | | <34°C (93°F) |
| Temperature (unpacked plate) | | 15÷34°C (59÷93°F) |

| **Characteristics**<br>*Laser* | |
|---|---|
| Manufacturer | MITSUBISHI |
| Model | ML101J18 |
| Wave length | 658 nm |
| Frequency | 200 Hz |
| Pulse duration | 500 ns |
| Indicative optical power | 15 mW |
| Laser power supply (voltage/current) | 2.5 V / 60 mA |

## 8.1. SYSTEM PC REQUIREMENTS

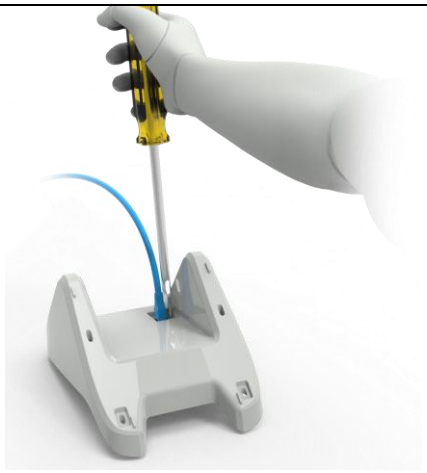
The PC on which the phosphor scanner system will be installed and all its related devices must meet the requirements for additional equipment, as specified in IEC 60601-1 (ed. 3.1).

For more details on minimum and recommended hardware and software requirements for workstations directly connected to reference device, refer to the "**Minimum and Recommended System Requirements**" attachment.

## 9. TROUBLESHOOTING

**WARNING!**
Do not try to solve the problem if the need for intervention by a specialist technician is indicated. This could cause injury to the operator or compromise the integrity of the system.

| Problem | Possible cause | Possible Solution |
|---|---|---|
| **The application installation is not possible** | Not compatible type of PC | Check PC characteristics against the minimum requirements specified in paragraph 9.1 |
| **The application is not properly running all functions** | Not compatible type of PC | Check PC characteristics against the minimum requirements specified in paragraph 9.1 |
| **The phosphor plate is not recognised** | Connection error.<br>Incorrect driver installation.<br>Incorrect system configuration | Check plate conditions. Repeat driver installation.<br>Check system configuration and proper connection of Ethernet cable. |
| **Poor image view** | System settings.<br>X-ray system | Make sure that X-ray parameters in use are the proper ones |
| **No X-ray image** | Failed X-ray emission.<br>Plate not exposed | Check X-ray system proper operation Check system proper connection |
| | | Possible fault of the X-ray system |
| **Out-of-focus images** | System settings.<br>Wrong plate position.<br>Movement during exposure | Make sure that X-ray parameters in use are the proper ones |
| | | Check that intraoral plate position is correct and that the patient does not move during exposure |
| | | Check that plate was exposed with the side marked as “tube side” of the light cover facing the X-ray source |
| | | Check that, during the X-ray exposure, plate was positioned with its blue side facing the blue side of the light cover |
| **Software operation shutdown** | Electrostatic discharge or processor fault | Unplug the scanner power supply, then plug it back in. |
| | | Ensure no wrong operations have been carried out. Shut off the PC and then turn it back on. |



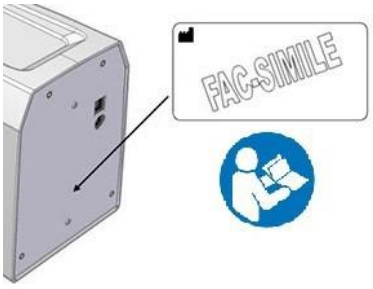
**WARNING!**

To avoid unwanted disconnections of the Ethernet cable, the connector has been placed deep; therefore it is not possible to disconnect the cable by manually pressing the reference tab.

After disconnecting the power supply, use a screwdriver (as shown in the figure) to press the tab and safely disconnect the cable.

## 10. IDENTIFICATION PLATE

**WARNING!**
Do not remove the identification plates that accompany the product and additional components.




The nameplate with product identification data and any other symbols are attached to the back of the product, near the power connectors.

For a thorough explanation of the symbols on the identification plate, see 2.1 “Stylistic conventions”.

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