Use and Maintenance Manual

I-View Gold

Intraoral Sensor

trident

CE 0051

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The original version of this Manual has been written in English.
Please read and follow all the instruction in this Manual before positioning, installing and starting the equipment to avoid any damage to you and to the equipment.

TABLE OF CONTENTS

1 DOCUMENT STATUS

VERSION	DATE	PARTS/PAGES MODIFIED
0	June 18 2019	First release
1	11/11/2019	Manual updated according to OEM information
2	11/12/2019	Added paragraph 2.3 Usability 6.3 Imaging performance 6.8 Acceptance Test
3	23/01/2020	Added paragraph 3.4 Physical principles of operation
4	27/03/2020	Added Child definition and indications for pediatric use Changed the exposure parameters table inserting a guide to exposure time
5	16/10/2020	Changed Windows version
6	18/05/2021	Manual update

2 INTRODUCTION

Thank you for trusting our company and choosing I-View Gold as your Intraoral sensor unit. We appreciate your support and hope that I-View Gold serves you well. Our continued commitment lies in the complete customer satisfaction for each and every product we sell. This manual will assist you on the installation and general operation of your I-View. Please read carefully the warnings and instructions, and keep them for future reference.

2.1 Important notices

For USA users: United States Federal Law restricts this device to use by or on the order of physician.
For other countries users: This device to use by or on the order of a licensed person under the related laws in each country.

2.2 Scope of this Manual

This manual is intended to provide a general overview of the system and its technical characteristics; also, it provides a description of the operations necessary for a correct installation and proper use. For this reason, the manual is divided into the following sections:

- Introduction (this section)
- General description of the medical device and its parts
- Safety Aspects
- Technical Data
- Use
- Cleaning and disinfecting
- Error Messages
- Maintenance and Repair

2.3 Usability

All documentation supplied with the I-VIEW Gold systems has been designed to help the operator in performing the operations. The information contained in this manual call upon the knowledge requirements described for the user profile. Information on using the acquisition, storage and processing system for images captured using the I-VIEW Gold sensor is available in a specific manual, which should be read for further details.

	Read this manual carefully before using the sensor
	Always keep instructions for use near the sensor, so that they can be consulted even after the first use.
	The device must always be used in accordance with the procedures explained in the present manual, and shall never be used for purposes other than those it was designed for.
	This manual is updated to the state of the product with which it is sold to ensure the user an appropriate reference in the use of the device and with respect to all aspects related to safety. The manual may not reflect changes in the product without impact on operating procedures and on safe use.

2.4 Icons Used in this Manual

The following icons are used in this manual:

Symbol	Description
	Indicates a "**NOTE**"; all texts marked with this icon are very important and should be read carefully and understood.
	Indicates a "**WARNING**"; all texts marked with this icon relate to safety issues for the patient and/or operator.

2.5 Symbols Used in this Manual

The following symbols are used in this manual:

Symbol	Description
	Device with Type BF applied parts
	This symbol indicates I-View Gold sensor contains electrostatic-sensitive electronic parts susceptible to damage by electrostatic discharge. Refer to the section on Precautions for Use.
	The device contains solid materials which, at the end of its life cycle, must be disposed of at authorised recovery centres according to local regulations in order to prevent human health and environmental damages caused by improper disposal.
	NON-STERILE. I-View Gold is a non-sterile product and cannot be sterilised.
	Do not reuse
	Product identification reference
	Serial number
	Date of manufacture (year and month)
	Name and address of manufacturer
	Consult accompanying documents
	Conforms with EC Directive 93/42 and its amendments and supplements

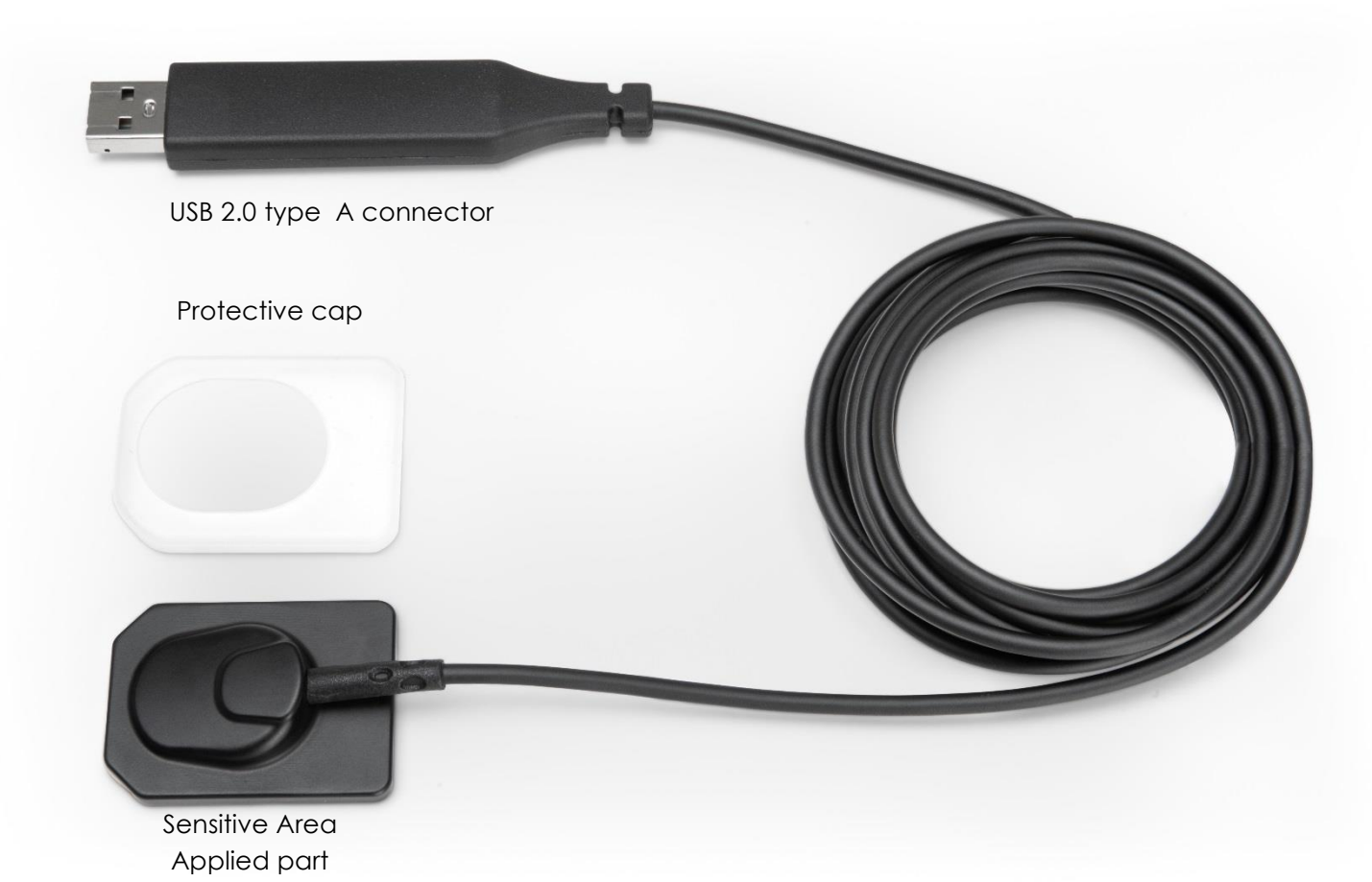
3 SENSOR PRESENTATION

3.1 About I-View Gold

I-View Gold is a receptor of intraoral digital radiographic images. The images are obtained from the exposure of the tissues of the mouth to a radiation source or X-ray generator. By interposing the tissue between the radiation source and the receptor, the densest parts appear with different tones within greyscale: structures that are dense, such as bones or metal, will block most X-ray particles and appear white, air-containing structures will look black, and muscles, fat and fluids will appear as shadows of grey color.

The sensor transmits the acquired image to the computer, instantly displaying it on the screen without additional processes. Subsequently, the specific software facilitates the identification of the images and allows to improve their analysis.

3.1.1 Sensor Parts



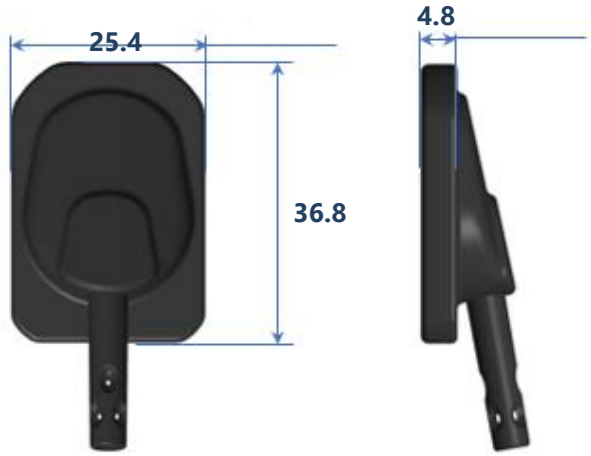
Body (sensitive area): it is composed of a rounded edge housing, with a thickness of 4.8 mm and constructed in black ABS, which contains the CMOS sensor.
Cable: highly flexible material, length 2,7 meters, black outer sheath.
USB 2.0 Type A connector: connect the sensor directly to the PC where the image acquisition software runs.
The sensor is protected by a flexible and lightweight cover that prevents scratches and damage from bumps or falls.

3.1.2 Sensor measures

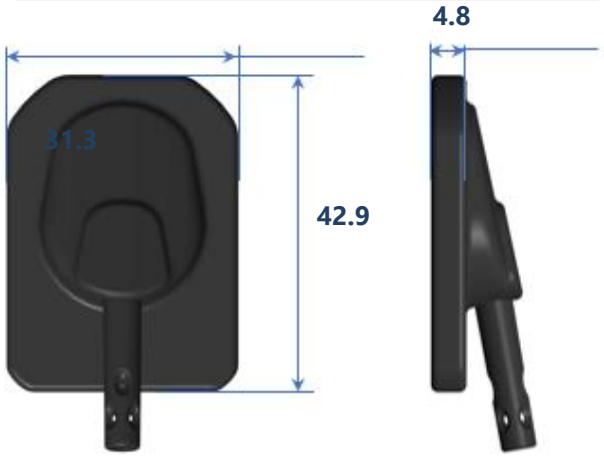
I-View Gold is available in two sizes:

	Measures (mm)	Active Area (mm)
Size 1	25,4 x 36,8 x 4,8	20 x 30
Size 2	31,3 x 42,9 x 4,8	26 x 38

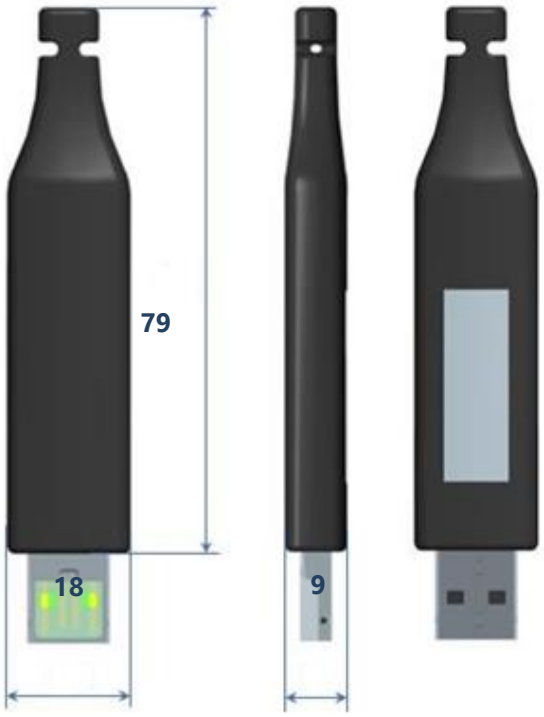
Size 1 (mm)



Size 2 (mm)



Connector (mm)



3.1.3 Type of Installation

I-View Gold is used as a temporary device and is not connected to the mains power source; power is supplied directly from the computer. The sensor connects directly to the USB port of the computer and is compatible with the standard USB 2. 0 type A.

3.1.4 Main advantages

Immediate images, without the use of films or chemicals.
Perfect exposure.
High resolution of images with the lowest radiation exposure possible.
Safe and efficient preservation of more information in digital archives.
Work space optimization.

3.2 Normal Intended Use

I-View Gold intraoral sensor is a digital image receptor, used to take X-rays of the teeth and surrounding tissues. The sensor requires an X-ray generator and a computer for its intended use; the sensor can be used on all patients, regardless of their age and gender.

The device is designed for the dental and radiological field. It can be installed and used in hospitals or clinics and in residential structures equipped with adequate protection systems.

The normal use and operation of this device does not imply:
- The administration of biological substances.
- Sterilization of parts of the product, since only regular cleaning is required.
- The interpretation of the final results.
- The update and modification of the control software.

3.3 Main Uses

- Conservative dentistry
- Diagnosis of caries, especially proximal lesions.
- Endodontics
- Periodontology
- Dental prostheses
- Surgical dentistry
- Implantology
- Orthodontics

Contraindications:
- Cartilage radiography
- Soft tissue radiography

3.4 Physical Principles of Operation

I-View Gold is based on CMOS (Complementary Metal-oxide Semiconductor) technology, allowing the user to obtain a small pixel size (18 µm), thereby ensuring excellent spatial resolution.

A major advantage that CMOS image sensors enjoy is the ability to integrate a number of processing and controlling functions, which lie beyond the primary task of photon collection, directly onto the sensor integrated circuit. These features generally include

timing logic, exposure control, analog-to-digital conversion, shuttering, white balance, gain adjustment, and initial image processing algorithms.

I-View Gold sensor works like a regular digital sensor, i.e. it transforms the measured dose which strikes each element of the sensor (pixel) in an electric signal that can be processed through an analog-to-digital converter.

The conversion process includes the following steps:

1) Conversion of incident x-rays into visible light; this conversion takes place in the CsI sensitive layer.
2) The visible light is transferred, through the Optical Fibre, onto the sensitive layer of the CMOS, short for complementary metal oxide semiconductor that is a widely used type of semiconductor. In a CMOS sensor, each pixel has its own charge-to-voltage conversion, and the sensor often also includes amplifiers, noise-correction, and digitization circuits, so that the chip outputs digital bits.
3) The CMOS sensor converts the light rays into electric charges which are stored in special structures until reading. In this way, each picture element (pixel) accumulates a number of charges proportional to both the quantity of incident light beams and to the exposure time.

3.5 Device Classification

I-View Gold, in all of its configurations, is an active medical device, invasive through natural orifices, for temporary use, and intended for diagnostic purposes. This device falls into **Class IIa** according to the classification rules set out in Annex IX of EC 93/42, amended by Directive 2007/47/EC.

3.6 Applicable Standards

The standards applicable to the device mainly concern rules on general safety (for the patient and operator) and electromagnetic compatibility. The following standards apply:

Applicable Directives and Decrees

Directive and Legislative Decree	Description
Directive 2007/47/EC	Directive amending and complementing Council Directive 93/42 / EEC on Medical Devices.
Directive 93/42/EEC	Council Directive 93/42 / EEC of 14 June 1993 concerning Medical Devices
Regulation (EU) N. 207/2012	Regulation of the EU Commission of March 9/12 concerning instructions on the use of Electronic Medical Devices.

Applicable Standards

Norma de Referencia	Descripción
IEC 60601-1:2005/A1:2012	Amendment 1 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2:2014	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
IEC 60601-1-3:2008	Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment
IEC 60601-1-6:2010	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 62366:2007/AMD1:2014	Medical devices - Application of usability engineering to medical devices
IEC 62304+AMD1:2015	Medical device software - Software life cycle processes
ISO 15223-1:2016	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements

Where applicable, the following national references must be applicable:
FDA: 21 CFR1020.30 Diagnostic X-Ray systems and their major components
1020.31 Radiographic equipment

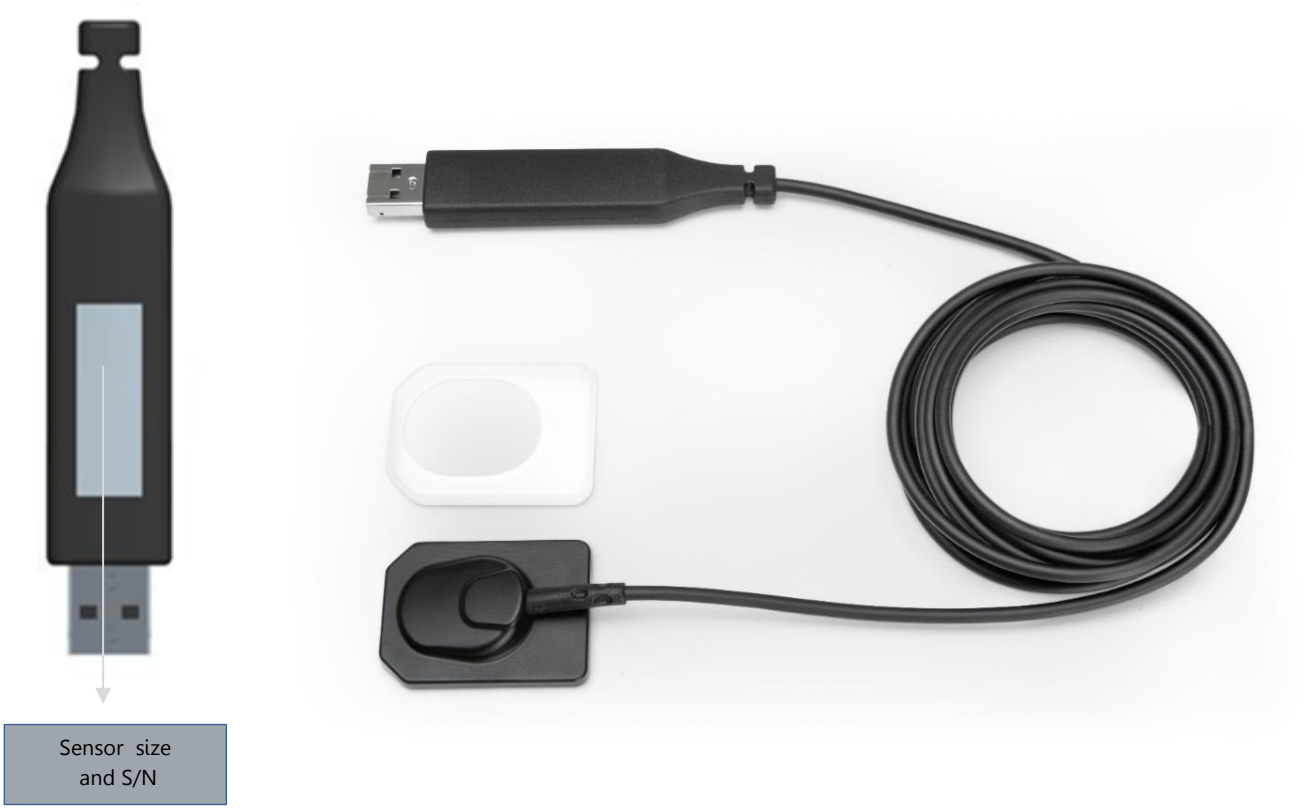
3.7 Manufacturer Address

Trident S.r.l.
Via Artigiani 4
25014 Castenedolo (BS)
Italy
Website: www.trident-dental.com

3.8 Device Identification and Labels

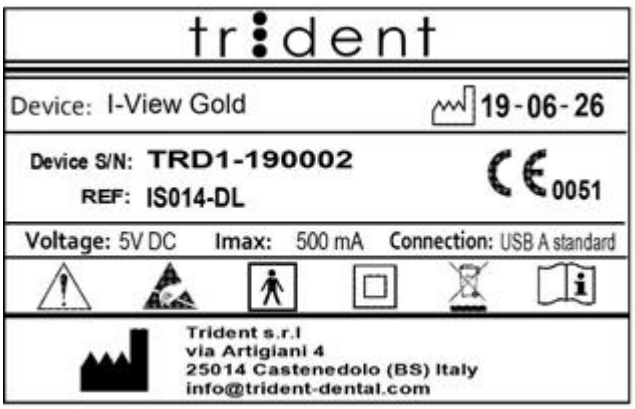
3.8.1 Identification

The sensor identification is fixed on the flat surface of the USB connector, it contains the serial number and sensor size.

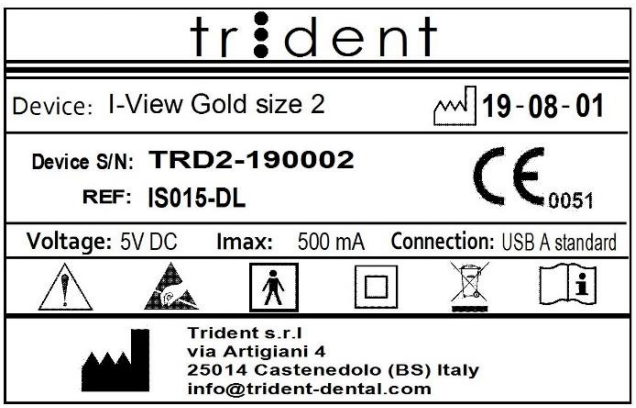


3.8.2 Labels

A silver label, stuck on the base of the black carton that contains the sensor, shows the device's main data:



Label for sensor size 1



Label for sensor size 2

- The company name in lowercase letters, font Century Gothic, with three points representing the "i" which identifies the company logo.
- Device name: I View Gold, for sensor size 1; I-View Gold size 2 for size 2.
- Manufacturing Date, in the year-month-day format.
- Device Serial number, SN, consisting of ten alphanumeric characters:

T R D	X	Y Y N N N N
Identifies the Manufacturer	X=1 size 1 X=2 size 2	The first two numbers identify the year of production, the following ones, show the progressive number of the sensor

- Reference: internal reference to identify the sensors

Reference	Name	Size	Software
IS014-DL	I-View Gold	1	Software Deep-View
IS015-DL	I-View Gold size 2	2	

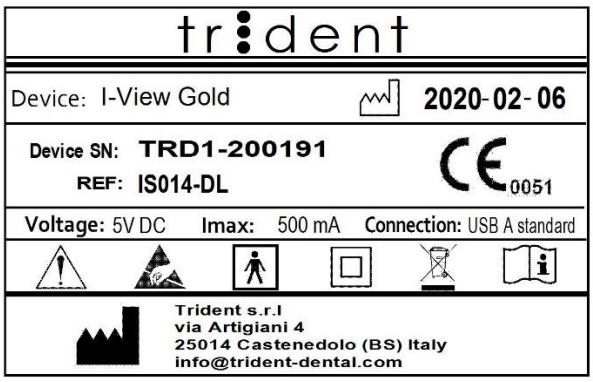
- CE Notified body (IMQ, identification code 0051)
- Voltage, maximum current and type of USB connector.

Other information shown in the label :

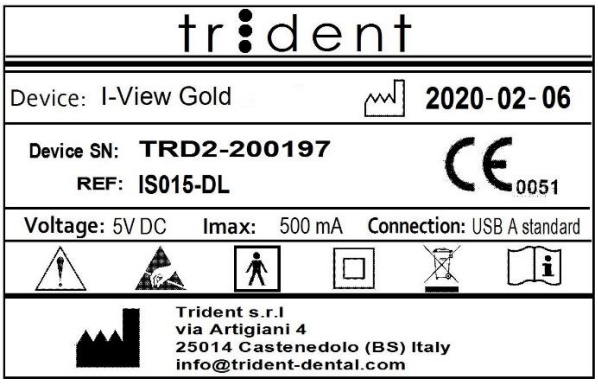
Icon	Meaning
	Risk warning for the patient and the operator.
	The sensor has some electro-static sensitive parts. Do not touch the sensor and computer screen at the same time. Do not touch the USB connector.
	Come into physical contact with the patient in order for the device to carry out its intended function.
	Double insulation Device in II security class
	Selective collection of electrical or electronic devices. At the end of its useful life do not throw this device in household waste
	Read instructions
	Manufacturer address

3.8.3 Label for USA market

A silver label, stuck on the base of the black carton that contains the sensor, shows the device's main data:

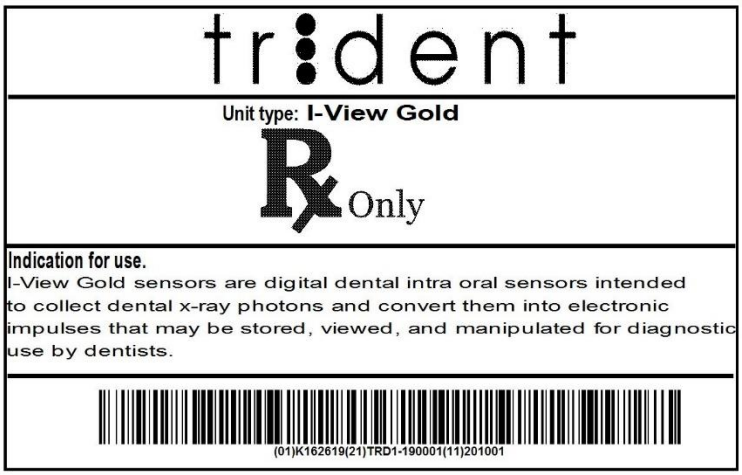


Label for sensor size 1



Label for sensor size 2

The following label, that states the restriction of use to the order of physician and holds the UDI, will be attached near the Identification label above.



The UDI shown has the following fields that completely identify the device:
(01): Manufacturer ID
(21): Device type and S/N
(11): Manufacturing date

3.9 Package and contents

I-View Gold is delivered in a solid black cardboard box with the Trident logo stamped in the cover.

Package			
Measures (cm)	**Weight (Kg)**	**Contents**	
		Qtty	**Item**
18 x 13 x 4,5	0.4	1	Sensor
		1	USB with software, drivers and manual
		1	Dongle with user license

4 SAFETY ASPECTS

	This chapter contains very important information concerning system, operator and patient safety. Read this chapter very carefully.

Trident S.r.l. designs and manufactures these devices in compliance with all relevant safety requirements. It also provides all necessary information for appropriate use and warnings on the risks associated with using X-rays for diagnostic purposes. Therefore, Trident S.r.l. shall not be held liable for:

1. Use of I-View Gold sensor for any purpose other those for which it has been designed,
2. Damage to the device, injuries to the operator or patient caused by either incorrect installation or maintenance that does not follow the procedures contained in the User and Service Manuals provided with the device, as well as incorrect operating techniques,
3. Mechanical and/or electrical changes, made during or after installation, differ from those listed in the Service Manual.

4.1 General Safety

	Before each usage, check the outer surface of the sensor for any signs of physical damage or defects. The surface of I-View Gold sensor should have a smooth finish, with no evidence of chipping or damage. Otherwise, contact your local product distributor for further instructions on how to proceed.
	I-View Gold must be used in radiography, dental or hospital facilities.
	To ensure the correct usage of I-View Gold sensor in a clinical environment, for which the intended purposes correspond to its design and application, only dentists or their designated operators are authorized to operate this system.
	This device can only be used in rooms or areas that comply with all laws and regulations applicable to electrical safety on medical premises, such as IEC standards for the use of an additional ground terminal for equipotential connections.
	For proper operation the sensor must be connected to a personal computer designed for image acquisition and image processing. The dedicated software must be installed on the personal computer.
	Water and other liquids must be kept at a distance to avoid penetration of the device. Liquids may cause corrosion or the device to short circuit. No protection is offered against liquid penetration.
	This device is not recommended for use in the presence of flammable gases or vapours. Some disinfectants evaporate and form explosive or flammable mixtures. If disinfectants of this kind are used, it is important to let the vapours disperse before using the device again.
	Do not sterilize the sensor in an autoclave or using dry heat as this could cause serious damage to the sensor. Do not sterilize with UV units.
	Do not immerse the USB connector of the sensor in cleaning fluids.

4.2 Electromagnetic Environment

Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to electromagnetic emissions information provided in this manual.

	I-View Gold meets the requirements of IEC 60601-1-2 concerning the electromagnetic emissions, and is therefore suitable for use in the electromagnetic environment that meet the conditions described below.

4.2.1 Guidance and manufacturer's declaration: Electromagnetic Emissions

	The device may cause radio interference and may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orientation or relocating of the equipment, or shielding the location.
	The system comes with all the cables needed for its operation. Using other cables not supplied by the manufacturer or in addition to those provided by the manufacturer can significantly influence the electromagnetic behaviour of this device. They may result in increased emissions or decreased immunity of the device.

I-View Gold is intended for use in the electromagnetic environment specified below. The customer or user of the device should assure that it is used in such an environment.

Emissions Test	Compliance	Emc Environment - Guidance
RF (Radio Frequency) Emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF (Radio Frequency) Emissions CISPR 11	Class B	The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuation / flicker IEC/EN 61000-3-3	Complies	

4.2.2 Guidance and manufacturer's declaration: Electromagnetic Immunity

I-View Gold is intended for use in the electromagnetic environment specified below. The customer or user of the device should assure that it is used in such an environment.

Immunity Test	Iec 60601 Test Level	Compliance Level	Emc Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/ burst IEC 61000-4-4	2 kV for power supply lines 1 kV for input/ output lines	2 kV for power supply lines 1 kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.

Surge *IEC 61000-4-5*	± 1 kV line to line ± 2 kV line to earth	± 1 kV line to line ± 2 kV line to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% Ut (> 95% dip in Ut) for 0.5 cycle 40% Ut (60% dip in Ut) for 5 cycles 70% Ut (30% dip in Ut) for 25 cycles <5% UT (> 95% dip in Ut) for 5 sec	<5% Ut (> 95% dip in Ut) for 0.5 cycle 40% Ut (60% dip in Ut) for 5 cycles 70% Ut (30% dip in Ut) for 25 cycles <5% UT (> 95% dip in Ut) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptable power supply or battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** d = 1,2 √P 80 MHz to 800 MHz d = 2,3 √P 800 MHz to 2.5 GHz d = 1,2 √P Where (P) is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with this symbol 
Radiated RF IEC 61000-4-3	3 Vrms 80 MHz to 2.5 GHz	3 V/m	

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

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

Notes:

- Ut is the AC mains voltage prior to application of the test level.
- At 80 MHz and 800 MHz, the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people

4.2.3 Recommended separation distances between portable and mobile RF communications equipment and I-View Gold.

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

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz d = 1,2 √P	80 MHz to 800 MHz d = 1,2 √P	800 MHz to 2.5 GHz d = 2,3 √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

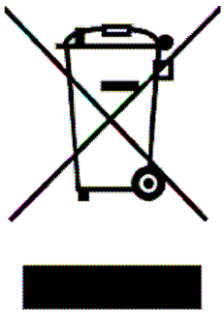
For transmitters rated at a maximum output power not listed above, the recommended separation distance **d** in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where **P** is the maximum output power rating of the transmitter in watts (W) according to the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

Notes:

- At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

4.3 Disposal at the end of the useful life

The symbol of the "crossed bin" as indicated on the label, means that when the product has reached the end of its useful life, it should not be disposed as household waste but must be collected separately and transferred to specialized operators for recycling or disposal of waste electrical and Electronic Equipment (WEEE), in accordance with the laws in force. This helps to avoid possible negative effects on health and environment, and promoting the recycling of the materials making up the product. The law provides penalties for illegal disposal.



5 TECHNICAL DATA

5.1 General Characteristics

Unit name	I-View Gold
Manufacturer 	Trident Srl Via Artigiani 4, Castenedolo, 25014 (BS) Italy
Classification according to Directive EC 93/42	Class IIa with Type BF applied parts

5.2 Technical Specifications

Parameter	Unit	Size 1	Size 2
Sensor Type	-	CMOS Photodiode Array	
X-ray convertor	-	FOS(FOP + CsI)	
Dimensions W x L x H)	mm	25.4 x 36.8 x 4,8	31,3 x 42,9 x 4,8
Pixel Size	µm	18	
Pixel shape		square	
Active Area	mm	20 x 30	26 x 38
Number of Active Pixels	pixels	1110 x 1666	1442 x 1998
Photodiode detector		Positioned outside of sensitive area	
Data output	-	USB 2.0	
USB cable length	m	2.7	
Electrical rating		DC 5V, 500 mA	
Operation mode		Global shutter	
Spatial resolution	lp/mm	20 typical (theoretical 25)	
Degree of Protection		IP68	

Parameter	Value
Supply voltage	5 V DC
Power Supply	Directly via USB connection
Maximum absorbed current	500 mA
Frame rate	0.7 fps
Typical dark current @23°C	350 LSB/s
Saturation level pixel (@70 kV)	340 µGy
Dynamic Range	57 dB
X-RAY response non uniformity (XRNU)	± 30 %
Total dose irradiation	50 Gy

Parameter	Unit	Size 1	Size 2
SNR	dB	≥ 35	≥ 35
Sensitivity [1]	ADU/µGy [2]	5,0 to 8,0	5,0 to 8,0
Resolution [3]	3lp/mm	≥ 50	≥ 50
	6lp/mm	≥ 25	≥ 25
	8lp/mm	≥ 15	≥ 15
Noise [4]	ADU	≤ 2,0	≤ 2,0
A/D	Bits	12	12
Energy Range [5]	kVp	60 ~ 70	60 ~ 70

1 Measured @ 60 kVp, 4mm Al filter
2 µGy is the unit of X-Ray exposure (1mR = 8.69 µGy)
3 Theoretical Spatial Resolution
4 RMS of dark current
5 Recommended Range, more than 70 kVp affects the sensor's life time

5.3 Recommended Environmental Operating Conditions

Parameter	Unit	Specification
Operating temperature	°C	+10 to +30
Operating humidity	%	30 to 80
Storage temperature	°C	-20 to +60
Storage humidity	%	10 to 80

6 HOW TO USE THE SENSOR

6.1 Precautions when using the sensor

	For a proper use of the sensor consult the manual.
	Before using the sensor, make sure it is in good condition (no cracks in the housing, orn cable, etc..). In case of problems or failures do not use the product and inform your dealer.
	Use a disposable protective sheath (not supplied) to prevent patients from cross infections. The lack of disposable protective sheats when using the sensor exposes the patient's health to adverse effects.
	Do not reuse the plastic protective sheath. Use a new one for each patient. For optimum performance, use protective sheaths specifically designed for the size of your sensor.
	Do not remove the protective cover by pulling the sensor cable.
	I-VIEW GOLD sensor has some electro-static sensitive parts: make sure to observe the precautions for use. Do not touch the sensor and computer screen at the same time. Do not touch the USB connector.
	When the sensor is not in use, store it away from static electricity.
	Do not use USB connectors/ports if they are dusty or damp.
	Keep free and clean the sensitive area of the sensor, do not attach stickers or tape to the sensor. Do not put pressure on the sensor's body. Do not twist, do not bend and do not pull the cable.
	When connecting / disconnecting the sensor, hold the connector, never pull the cable.
	The temperature of the sensor will rise considerably (even by 10°C) if it remains in operation for an extended period of time. Take care to use it only when the temperature is below 35° C.
	Although the sensor has been designed and engineered to be resistant to the entrance of liquids and powders, do not let the sensor immersed in liquid disinfectant, water or other chemicals for a long time.

6.2 About the user and patient

6.2.1 User Profile

I-View Gold, intraoral sensor was designed to be used in radiological and dental facilities. In both cases the primary user is a professional who has the knowledge required to properly weigh the risks and benefits associated with their radiological imaging technologies. End users must have basic knowledge about:

- Use of ionising radiation emissions

- Harmful biological effects related to excessive use of ionising radiation
- Methods to reduce the risk of excessive exposure to radiation as a patient (use of lead shields, etc.)
- The operator should be familiar with personal computers and the related software

Before installing the sensor, the operator should receive basic training on using the device and the image acquisition software. This training does not involve the use of special tools.

6.2.2 Patient Profile

The sensor is suitable for use on any type of patient. The different procedures for carrying out each exam, based on the type of patient, depend on the X-ray system used and are not included in this manual.

6.2.2.1 Child patients

Children are more radiosensitive than adults. Please follow the following indication for pediatric patients.

	The selection of the type of patient is at the discretion of professional dentistry, however, we recommend using the "Child" function, for children from 2 to 12 years old.

As a rule, next recommendations shall be observed in pediatrics:

	If children are to be examined, they should always be accompanied by an adult.
	Image only when there is a clear medical benefit and only the indicated area.
	Avoid multiple scans and use alternative diagnostic studies.
	Provide extra shielding of radiosensitive organs or tissues such gonads and thyroid glands.
	Apply a correct collimation will help to protect the patient against excessive radiation; if the X-Ray generator used is supplied with a rectangular collimator to reduce the irradiated area, please use it.
	X-Ray Generator must have short exposures times. If possible, use high kVp techniques.

6.3 Imaging Performance

I-View Gold is not used as an integrated X-Ray image detector integrated into a specific X-Ray device. As all digital intra oral sensors, I-View Gold achieves a good quality of the image also with a reduction of the emitted dose from X-Ray equipment. The balance of the benefit/risk ratio is part of the operator experience.

The dedicated acquisition software of I-View Gold contributes to the image quality with the specific features:

- Dose reduction to acquire the image
- Image processing to enhance the quality (noise reduction, brightness/contrast modification, enhancing filters, etc.)

	All manipulation are not applied in a permanent mode. All image processing can always be removed by returning to the "original image" under operator's request.

6.3.1 Exposures parameters

I-View Gold can be used with any kind of X-Ray generator technology. However, the best performance can be achieved using a DC type generator, due to the fact that this kind of generators reduce "soft emitted radiation".
We recommend the use of the following exposure parameters:

Parameter	Value
High voltage	from 60 to 70 kV
Focal spot (according to IEC 62336)	0.5 mm suggested, 0.7 mm
Focal spot to sensor	22 cm
Beam limiting device	maximum 6 cm at the beam limiting exit
Dose for Adult patient	From 300 to 500 µGy for incisor From 400 to 600 µGy for upper molar
Dose for pediatric use	Reduce the dose about 20%

6.3.1.1 X-Ray Exposure Guide

The required X-ray dose for the best image is dependent on the following:

- X-ray source (tube assembly, manufacturer, AC/DC, etc.)
- Distance between beam focus and sensor
- Tooth (object) to be X-rayed
- Bone density and age of patient

The X-ray dose influences image quality. Based on fundamental laws of physics, an insufficient dose generally means higher image noise, which leads to poor detail discrimination. On the other hand, an excessively high dose can cause the sensor to be overexposed. This is also perceptible by a decrease in detail discrimination, specifically in darker areas.

	Since the exposure time depends on the diagnostic as well as the clinical situation, the selection of an adjustment is the responsibility of the treating physician
	Image degradations caused by overexposure of the sensor cannot be compensated, but an insufficient dose can be partially compensated through image post processing.

The following table is a guidance to select the appropriate exposure time; it is based on a DC generator that have the possibility to select the high voltage values. Select exposure time according to the intra oral generator you are using.

Tooth/Patient size		70 kV		65 kV		60 kV	
		Adult	Child	Adult	Child	Adult	Child
Maxilla	Molars	0.100	0.063	0.125	0.071	0.200	0.125
	Premolars	0.080	0.050	0.100	0.063	0.160	0.100
	Incisors	0.063	0.032	0.080	0.040	0.125	0.063
Mandible	Incisors	0.056	0.020	0.063	0.025	0.110	0.040
	Premolars	0.063	0.036	0.090	0.045	0.125	0.071
	Molars	0.080	0.050	0.100	0.063	0.160	0.100

	A beam limiting device reducing the exposed area to image receptor can be further reduce the dose to patient.

6.4 PC and Monitor Requirements

	I-VIEW GOLD CMOS intraoral sensor connects directly to the type A USB port of the computer.
	The computer where I-VIEW GOLD sensor is installed, along with all equipment connected to it, must bear the CE marking (IEC 950)
	The computer and all other associated equipment must be placed outside of the patient environment (about 1.5 m away from the chair).
	Do not plug the PC used for the I-VIEW GOLD sensor in a power strip.

The minimum PC requirements to install the sensor are shown in the following table:

Component	Requirements
Operating System	– Windows 8 -1 – Windows 10
CPU	Intel i5-2520M 2.5 GHz or superior
RAM Memory	1 GB (ideally 2 GB)
Hard drive	10 GB RAM
Video card	1024 x 768 resolution in 65,000 colours (ideally 1280 x 1024 - 16 million colours, 32 bit)
USB Port	2.0 type A

The monitor characteristics are very important for the sensor performance since the video will significantly affect the image quality. Select a monitor that meets the medical safety and environmental standards, including the EN60601-1 medical certification and CE certification. The monitor must have the following characteristics:

- Anti-Scratch Surface.
- High Impact Resistance.
- Anti-Reflection.
- High Transmittance for perfect panel brightness.
- Water and dust resistance; easily cleaned and disinfected.

A high contrast and high definition monitor that has at least a 17" screen is preferable.

6.5 Deep-View Software Characteristics

Deep-View is the software used in all Trident intraoral sensors. The tools featured by Deep View software allow to efficiently create, organize, store and share, patients' data files and images:

- Multiple database management
- Easy images acquisition device configuration
- Advanced image filters
- Wide choice and customization of templates for Full Mouth Series exams
- Simulation of implant measurement and medical reports with teething preview
- Voice guidance option for image acquisition
- Images import/export in DICOM and other graphic formats
- Printing images with layout customization

	I-View Gold CMOS intraoral sensor only works when connected to a PC on which the software Deep-View has been previously installed.

Manufacturer 	Digital Imaging Srl – Nichelino (TO)
Operating system	Windows
Main functions available	Full size and/or multi image visualization Images magnification with dynamic zoom and scroll Image reverse and rotation Brightness and contrast adjustment Filters applicable type: median, logarithmic, noise reduction, dynamic and spatial LUT (look up table) and Gamma (grey scale compression) modification Grey scale inversion (positive/negative) Special filters application: harmonizer to optimize the visualization to all density present on image Histograms and density profile visualization Anatomic reference insertion based on international numbering standard Linear and angular measurement with dedicated calibration Images printer with or without overlays Database

6.6 Initial check and installation

	Before installing and using your sensor for the first time, it is mandatory to install the imaging software Deep-View

The sequence to install and use the sensor is as follows:

1. **Check the contents of the box**
   As indicated in paragraph 3.9, the contents of the box :
   - One (1)sensor

- One (1)USB key with Deep-View v4.0 software, drivers and manual.
- One (1) dongle with the user licence

Contact your dealer immediately if discrepancies arise.

2. Remove the sensor from the box

Check the condition of the sensor. Keep the serial number of the sensor and the software license in a safe place. In case of complaints or questions about the product, this information must be provided to the producer.
Keep the box for eventual claims or product return.

3. Install the software

Firstly, insert the key-shaped USB memory, which is inside the metal case, into a connection port on your PC or laptop. The USB memory can only be inserted one way into the connection port.

After inserting the USB wait a few seconds until the start-up window automatically appears. The installation process for this system entails:

- Installation of the main program
- Installation of the protection key drivers
- Installation of sensor drivers

When using the memory stick with the software, always:

- Avoid contact of the extremes with heat, cold, magnetic fields and liquids.
- Safely remove your memory stick and store it safely after use.

For Deep-View detailed information please refer to the software User Manual.

VERY IMPORTANT

The USB contains the software and calibration files for each single device.
In case 2 or more I-View Gold sensors are working on the same PC, be sure to run the installation setup for every serial number. The calibration files will be automatically installed.

4. **Insert in your computer the dongle with the user license**
   This USB should always be connected to the computer.
   In case you lost the USB (dongle) with the software license, you must request one to Trident(this new memory has an extra cost)

6.7 Image acquisition with I-View Gold

	**WARNING** During X-Rays emission, protection for operator and other personnel, must comply with the regulation in force. In any case, it is recommended that during X-Rays release, if bulkheads do not protect the operator, she/he should be located at least 2 meters away and in the opposite direction of X-Rays releasing.
	The patient must wear appropriate Individual protection devices; at least a leaded collar.
	Individual protective devices are not supplied with the sensor.

- Considering the type of patient and the tooth to be irradiated, configure the X-ray generator with the required exposure parameters, exposure time and voltage. Select the image receptor.
- Run the Deep-View image acquisition software (follow the instructions outlined in the software User Manual)and enter the patient information. Once the patient file has been created, prepare the sensor.
- Cover the sensor with the plastic sleeve and if you have the sensor holders, position the sensor in the appropriate holder(holder selection depends on the type of exam). We recommend to use the sensor support to ensure the sensor is parallel to the tooth and at the appropriate angle for exposure.
- Connect the sensor to the computer.
- Prepare the patient for the radiography and place the sensor in their mouth according to the characteristics of the required image. The flat side of the sensor ought to look towards the X-ray source.
- Once the patient and the sensor are ready, X-ray can be activated.
  Press the X-ray button.

After pressing the X-ray button, the message "*Optimizing image ... Please wait*" is shown. Once the image optimization is completed the image will appear on the monitor.

6.8 Acceptance Test

I-View Gold as an electro medical device is subjected to inspection and testing in compliance with laws, regulations and supervisory directives applicable in the country where the installation is carried out.

Trident recommends the following tests, to be performed after the installation of the acquisition software:

- Use special test tool for digital intra oral sensor that allows the acquisition of Line Pair up to 20 lp/mm [QUART dent/digitest M2]
- Insert I-View Gold into the relevant slot of the test tool and place it at the end of the beam limiting device, using the centering ring to correctly positioning it.
- Set the X-Ray generator for the acquisition of an image corresponding to 600 µGy, corresponding to Upper Molar
- Start the acquisition software and set it to acquire an image for a dummy test patient
- Acquire the image and display it on the monitor screen.
- Look at the line pair area; the 8 lp/mm should be visible.

Note: it is allowed to use the contrast/brightness adjustment to have a better image, but it is not advisable to use other image enhancement as the edge enhancement.

6.8.1 Q.A. Test frequency

Trident recommends to perform the above Q.A. test **at least once a year**, in order to check the absence of degradation of the digital sensor due to excessive absorbed radiation.

7 CLEANING AND DISINFECTION

7.1 Cleaning

To protect the health and safety of patients and prevent possible risks of contamination and/or cross-infection, please read and carefully follow the general following guidelines:

	I-View Silver and its accessories are supplied non-sterile. Do not sterilize the product using dry heat, autoclaves or UV devices.
	Cleaning operations must be performed with the device disconnected from the computer.
	Clean the sensor and the cable (at the output of the sensor) with a cloth moistened with 70% isopropyl alcohol for disinfection.
	Do not use other liquids or disinfectants and do not use too much rubbing.
	The sensor, cable (sensor side only), and any accessories used must be carefully disinfected before each use.
	Do not use a wet cloth or spray on the USB connector. The moisture will deteriorate with and can cause harm to the patient and / or operator.

7.2 Disinfection Procedures

I-View Gold sensor must be disinfected using a first or second level procedure, depending on the conditions observed and as described below:

7.2.1 First Level Disinfection

After each use, remove the disposable protective sheath and throw it away.
Carefully check the sensor and verify there are no traces of organic matter (residual tissues, blood, saliva and other type of secretions)
Prepare the disinfectant solution according to the manufacturer's instructions.
Carefully disinfect the sensor, following the instructions provided by the disinfectant manufacturer.

7.2.2 Second Level Disinfection

This procedure is required when one or more of the following issues are noted during a visual inspection:

1. The protective sheath is torn
2. Residues of organic matter are found on the sensor and/or the cable connection.

If any of these issues appear, follow the steps below for the second level disinfection procedure:

- Wash the sensor thoroughly with soap and water to remove all organic matter. Be careful not to immerse the end part of the cable with the USB connection.
- Prepare the disinfecting solution according to the manufacturer's instructions.
- Carefully disinfect the sensor, following the instruction provided by the manufacturer of the disinfectant.

7.3 Disinfection Products Compatible with I-View Gold

Use 70% isopropyl alcohol to properly clean and disinfect the I-View Gold sensor, tests carried out by the manufacture have shown that the sensor can be immersed in this disinfection solution without suffering any damage.

	Do not use disinfection products containing aldehydes.
	Trident Dental recommends that you only use disinfectants that are in compliance with EC Directive 93/42 on Medical Devices and that show the CE marking.

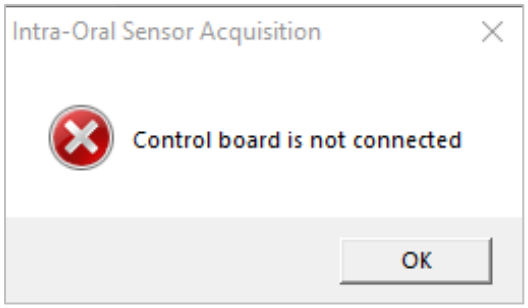
8 MAINTENANCE AND REPAIR

	I-View Gold intraoral sensor is not susceptible to be repaired.
	PLEASE DO NOT TRY TO OPEN THE SENSOR

In case you have any inconvenience with your sensor call your dealer and fully describe the problem.
Please follow these simple measures to prolong the useful life of your sensor:

- Do not drop sensor or allow objects to fall on sensor.
- Do not damage or break the power cord
- Do not drop or cause severe impact to your sensor.
- Properly positioning the sensor and instruct your patient to do not bite it.

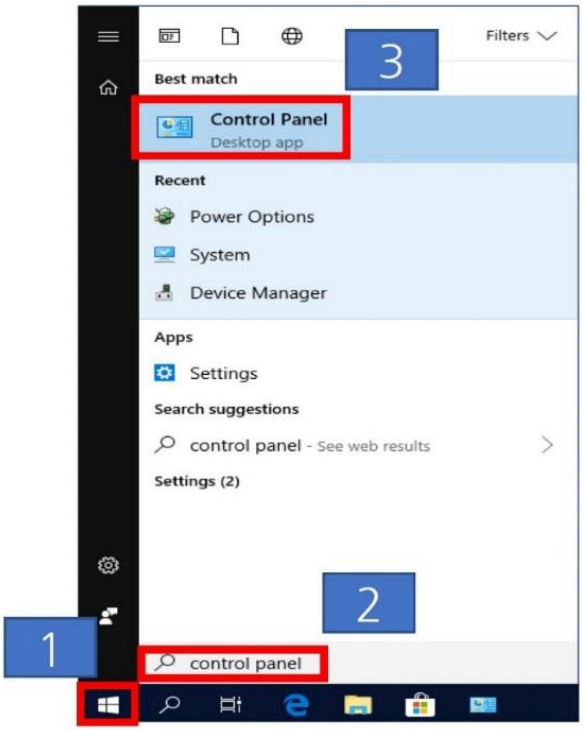
ANNEX 1
ERROR MESSAGES

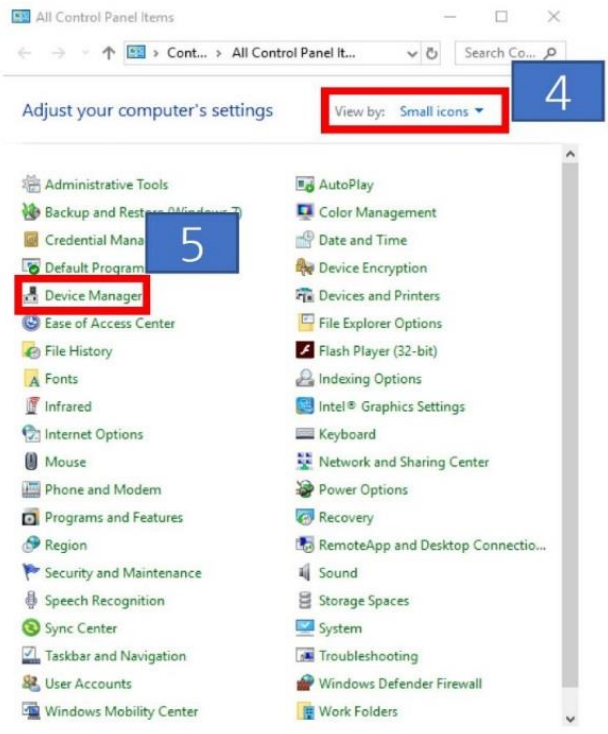
Message	Solution
Detector's configuration file "C:\IOSensor\CalibSensor\TRDX-AAYYYY\IOSensor.ini" does not exist	Please be sure that you launched the proper TRDX-AAYYYY installation folder and the proper calibration files has been correctly installed.
	Please check under "Device Manager" if the device is recorgnized by the PC. If not, please check the PC USB port. If the PC recorgnises the device, the driver is not correctly installed: reinstall it from the proper USB installer folder as administrator being sure to close any active antivirus or firewall
USB device driver is not working properly.	Re-install the driver.
Capture program is already running.	Please close any other programs.
Detector's response time-out.	Check and re-connect USB Box. Please try again. If the same message displayed again, contact Customer Service.
Data communication error.	Re-connect USB Box.
Cancelled image capturing.	This means that the user cancelled image capture. Please try again.
Can't find dark frame.	Restore the I-View Gold calibration data from the S/W installation CD or recalibrate the sensor. If the same message displayed again, contact Customer Service.
Can't find bright frames for calibration	Reinstall the I-View Gold driver.
Bad Pixels' Map correction error	Restore the i-View Gold calibration data from the installation CD or re-calibrate the sensor. If the same message displayed again, contact Customer Service.
Wrong image processing parameters.	Check the X-ray source. If the problem persists, call for technical assistance
Can't load 'Sensor.dll'	Please re-install acquisition software.
Require 'Sensor.dll' was damaged	Please re-install acquisition software

ANNEX 2
ERROR

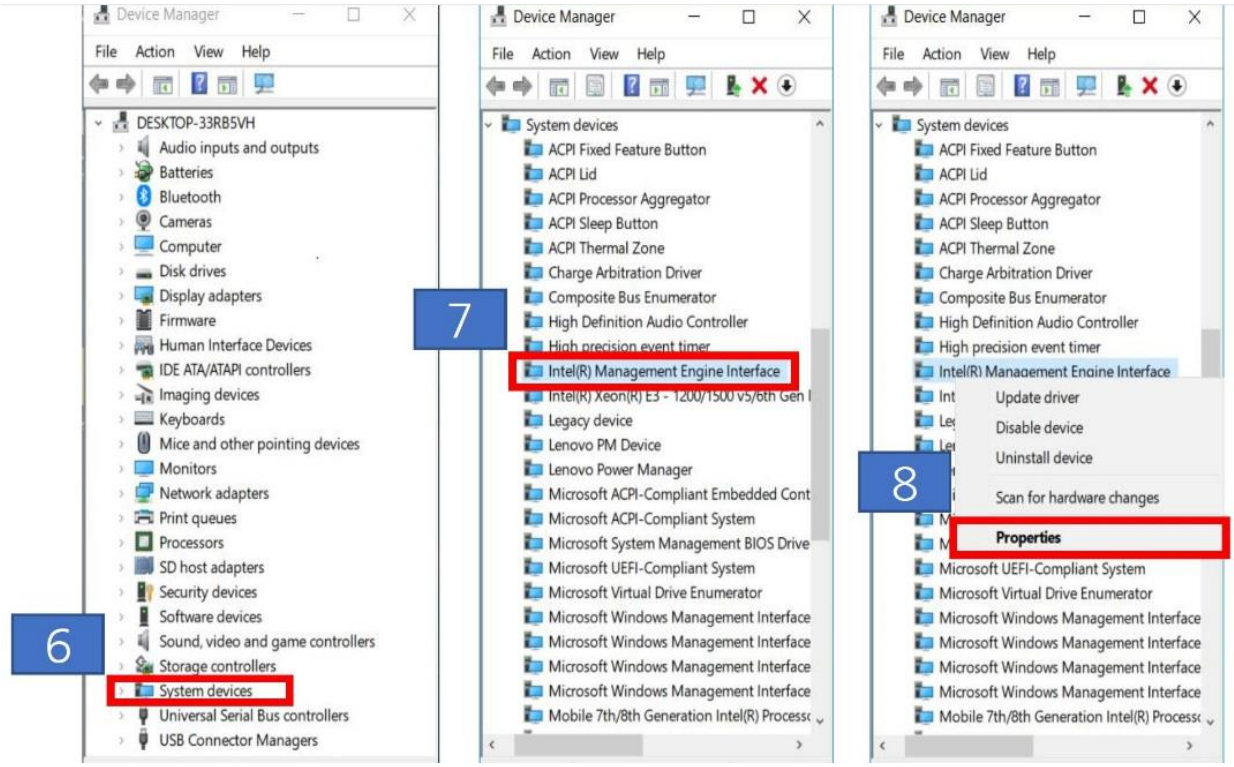
Image Error	Solution
Abnormal image received	Configuration of Control Panel*

Control Panel Configuration

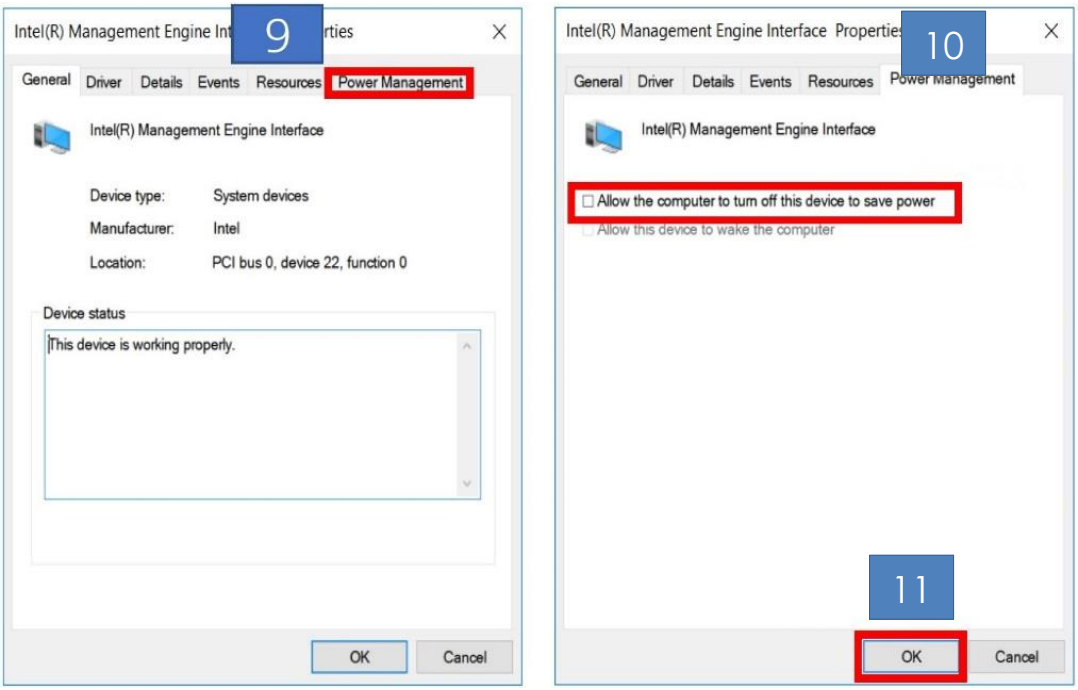




1. Click the Windows button
2. Write **Control Panel**
3. Click on **Control Panel**
4. Select **Small Icons**
5. Click on **Device Manager**



6. Double Click on **System Devices**
7. Right-click **Intel® Management Engine Interface**.
8. Click on Properties



9. Click on **Power Management**
10. Uncheck **Allow the computer to turn off this device to save power**
11. Click **OK**

ANNEX 3
SENSOR HOLDER USAGE

Name	Image	Teeth to be exposed
Bitewing		
Endo UL/LR		
Endo UR/LL		
Periapical UL/LR		
Periapical UR-LL		

Posterior UL/LR			
Posterior UR/LL