Digital DOC®

Blū

Intraoral Sensor

Use and Maintenance Manual

1.800.518.1102
digi-doc.com

CE 0051

Date:10/19/2020
Language: English
Rev: 3-8
Code Blu12.r3-EN

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	18/06/2019	First issue
1	11/11/2019	Manual updated according to OEM information
2	11/12/2019	Added paragraph 6.3 (Usability), 6.5 (Imaging performance) and 6.11 (Acceptance Tests)
3	14/01/2020	Added paragraph **Errore. L'origine riferimento non è stata trovata.**, Labels for USA market (par. **Errore. L'origine riferimento non è stata trovata.**) changed labels for USA market only, par 6.4 (Principle of operations)

2 INTRODUCTION

Thank you for trusting our company and choosing Blu as your Intraoral sensor unit. We appreciate your support and hope that Blu 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 Blu. Please read carefully the warnings and instructions, and keep them for future reference.

2.1 Important notices

For U.S.A. users: United State 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

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 the correct installation and for proper, safe, and efficient use.

For this reason, the manual is divided into the following sections:

1) Introduction (this section)
2) System Presentation - General description of the medical device and its parts
3) Safety Aspects
4) Technical Data
5) Use
6) Cleaning and disinfecting
7) Error Messages
8) Maintenance and Repair

2.3 Scope

This manual is intended to provide a general overview of the system and its technical characteristics; also provides a description of the operations necessary for the correct installation and for proper, safe, and efficient use.

For this reason, the manual is divided into the following parts:

1) Introduction (this section)
2) System presentation. General description of the medical device and its parts
3) Safety Aspects
4) Technical Data
5) Use
6) Cleaning and Disinfection
7) Maintenance and Repair

2.4 Icons used on the manual

On this manual are used the following icons:

	Shows a "**NOTE**"; We recommend the user pay particular attention to the instructions identified by this icon because they refer to an equipment condition and can be hazardous to the device if ignored.
	**Shows** a "**WARNING**"; the instructions identified by this icon relate to patient and operator safety, security, and health.

2.5 Use of this Manual

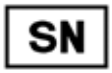
All documentation supplied with Blu intraoral sensor, has been designed to help the operator in performing the operations. Information using the acquisition, storage and processing system for images captured using Blu sensor is available in a specific manual, which should be read for further details.

	Read this manual carefully before using the device
	Always keep instructions for use near the unit for future reference, 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.

2.6 Symbols Used in this Manual

The following symbols are used in this manual:

SYMBOL	DESCRIPTION
	Device with Type BF applied parts
	This symbol indicates Blu 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 centers according to local regulations in order to prevent human health and environmental damages caused by improper disposal.

SYMBOL	DESCRIPTION
	NON-STERILE. Blu is a non-sterile product and cannot be sterilized.
	Do not reuse
	Product identification code
	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

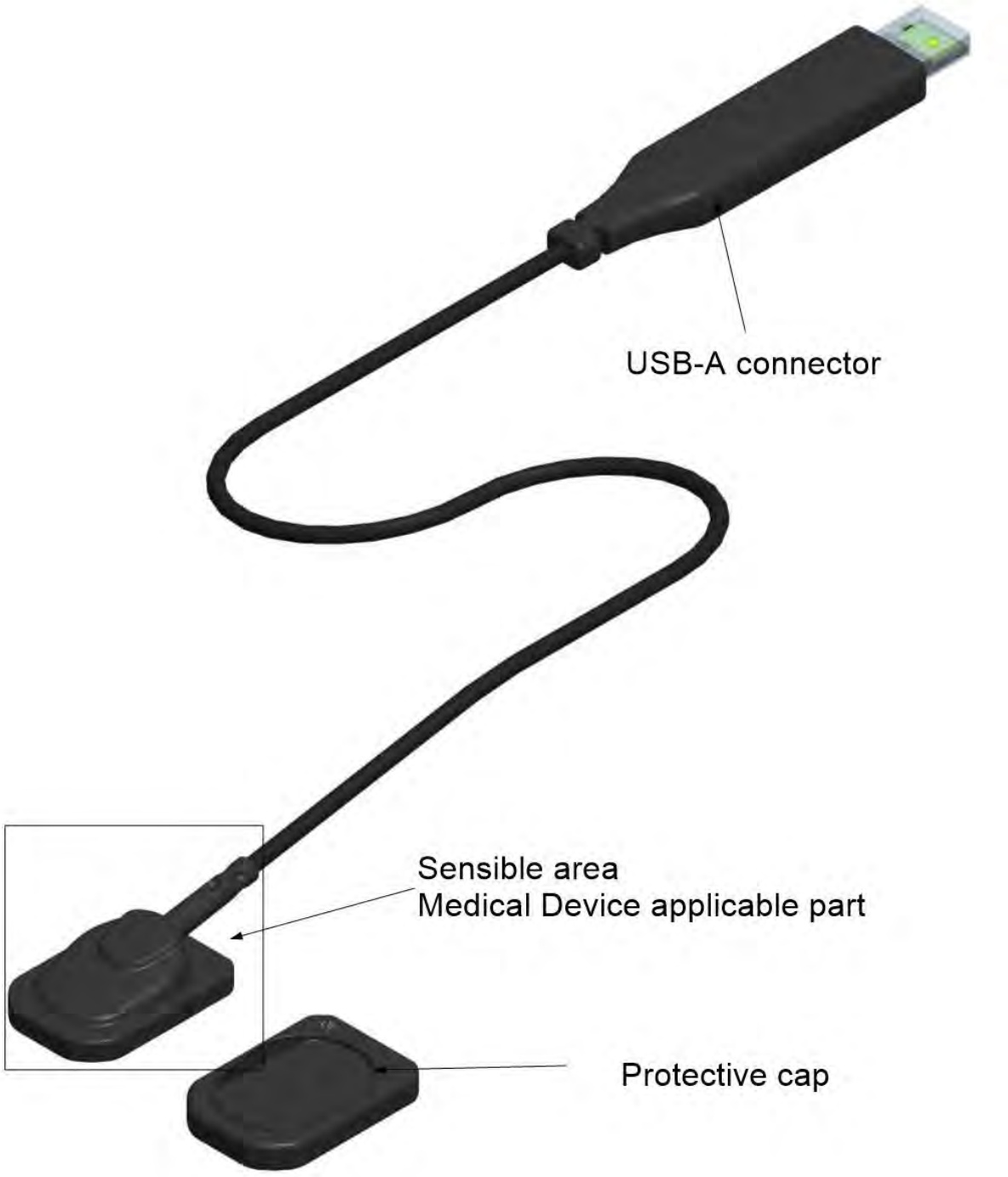
3 SYSTEM PRESENTATION

3.1 About Blu

Blu 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. The provided software facilitates the identification of the images and allows for improved image analysis.

3.1.1 Sensor's part



Body (ESD 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 meters, black outer sheath.

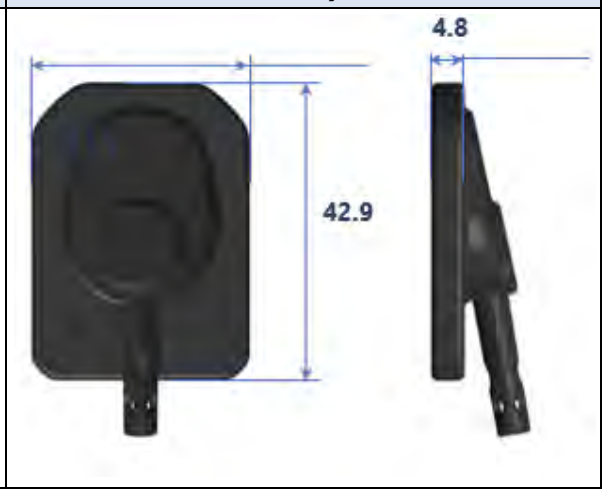
USB Type A connector: connects the sensor directly to the PC where the image acquisition software runs.

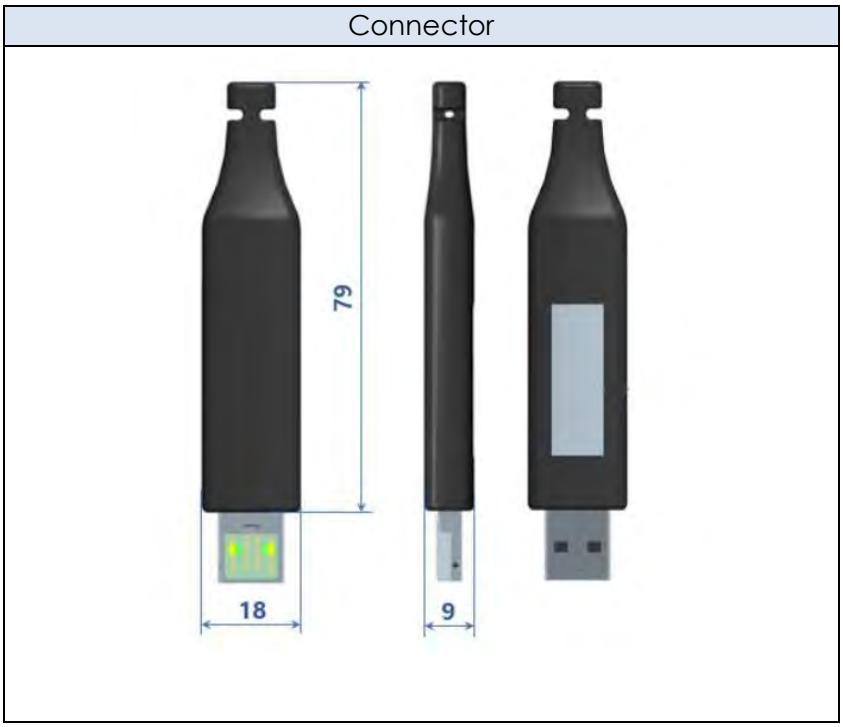
The sensor is protected by a flexible and lightweight cover that prevents scratches and damage from bumps or falls.

3.1.2 Sensor measures

Blu 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 36

Size 1 (mm)	Size 2 mm)
	

Connector


3.1.3 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 Physical Principles of Operation

Blu sensor works like a regular digital sensor, i.e. it transforms the measured dose which strikes each element of the sensor (pixel) with an electric signal that can be processed with 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 Fiber, 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.

3.3 Normal Intended Use

Blu sensors are digital dental intraoral sensors intended to collect dental x-ray photons and convert them into electronic impulses that may be stored, viewed, and manipulated for diagnostic use by dental professionals. The image receptor is designed to be used together with an X-Ray generator device; the sensor is intended for use for all patients, regardless of their age and/or gender.

The device is designed for both the dental and radiology market. It can be used and installed in dedicated facilities (hospitals or clinics) and in residential structures equipped with appropriate shielding systems.
Normal use and operation of this device does not imply:

- The administration of biological substances
- The sterilisation of parts of the product, since only regular cleaning is required
- The interpretation of the final results
- The updating and modification of the control software.

3.4 Main Uses

- Conservative dentistry
- Diagnosis of caries, especially proximal lesions.
- Endodontics
- Periodontology

- Dental prostheses
- Surgical dentistry
- Implantology
- Orthodontics

Contraindications

- Representation of cartilaginous structures.
- Representation of soft tissues.

3.5 Type of Installation

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

3.6 Device Classification

Blu, 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. For FDA purposes the Blu sensor is a regulatory class II device, product code: MUH

3.7 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:

3.7.1 Applicable Directives and Decrees

Directive and Legislative Decree	Description
Directive 93/42/EEC	Council Directive 93/42 / EEC of 14 June 1993 concerning Medical Devices
Directive 2007/47/EC	Directive amending and complementing Council Directive 93/42 / EEC on 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.

3.7.2 Applicable standards

Reference standard	Description
IEC 60601-1:2005/A1:2012	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
ISO 10993:2009	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
IEC 62304+AMD1:2015	Medical device software - Software life cycle processes Amendment 1 - 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

3.7.3 National Standards

Where applicable, the following national references must be applicable:

- FDA: 21CFR1020.30 Diagnostic x-ray systems and their major components, 1020.31 Radiographic equipment.

3.8 Manufacturer Address

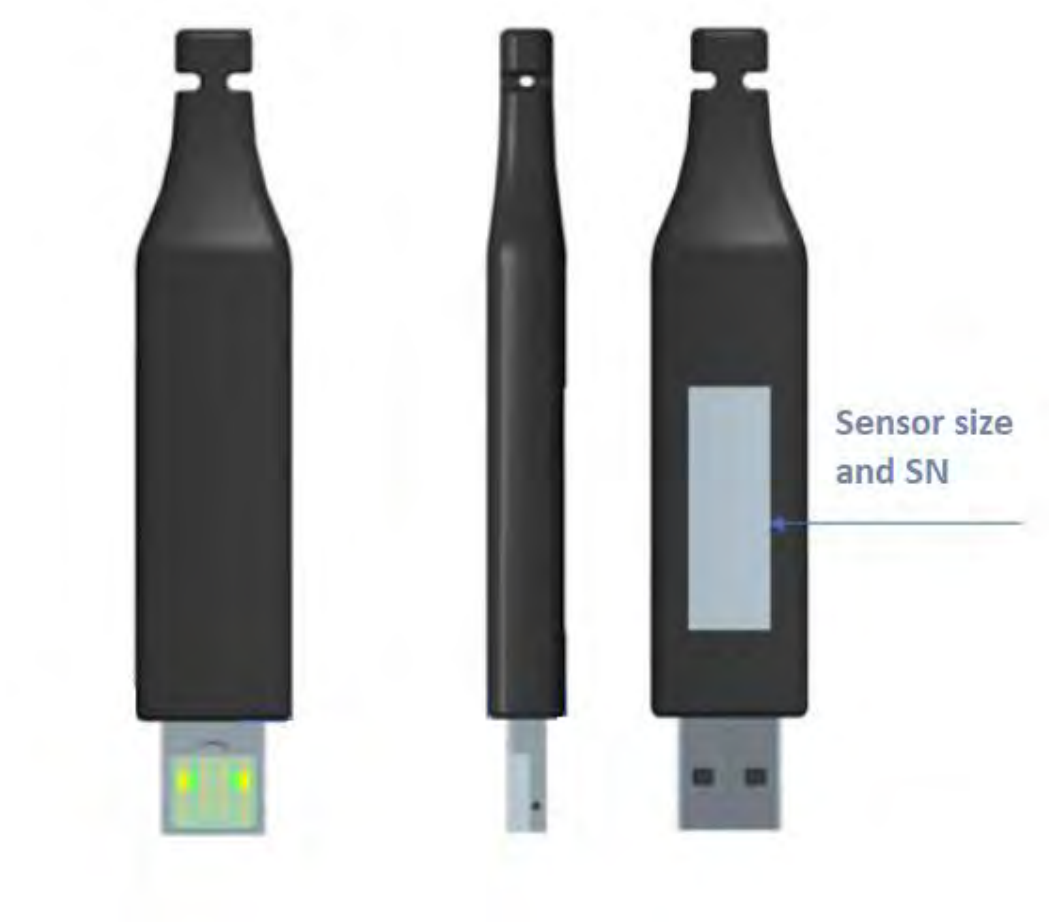
Trident
SEDE LEGALE
VIALE VITTORIO VENETO, 6
MILANO 20124
Italy

3.9 Device Identification and Labels

Due to its size, the sensor has no labels or name-plate on it.

3.9.1 Identification

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

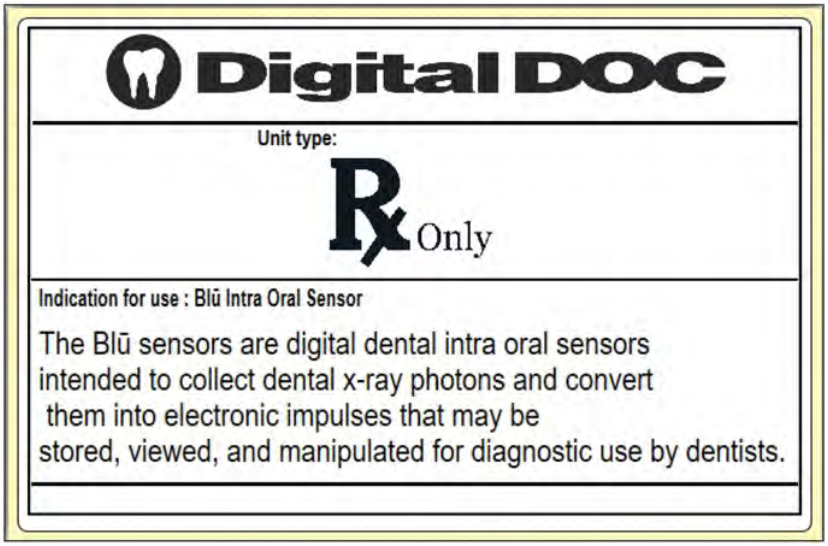


3.9.2 Label for USA market

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

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.

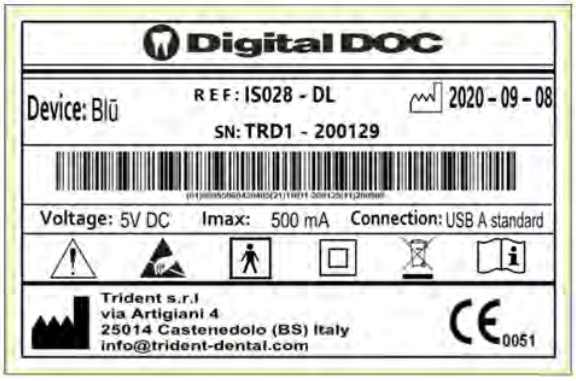
RX only label



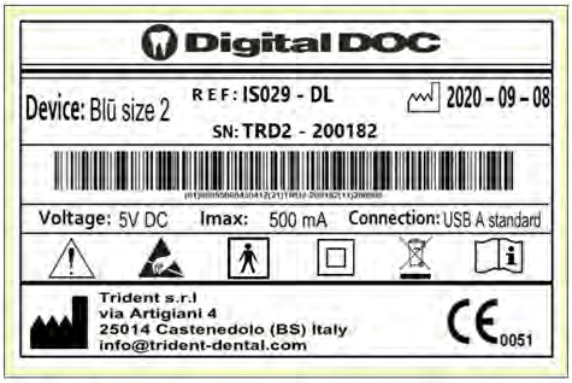
The UDI shown has the following fields that completely identify the device:
(01): Manufacturer ID
(21): Device type and S/N
(11): Manufacturing date

3.9.3 Label for non-USA Market

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



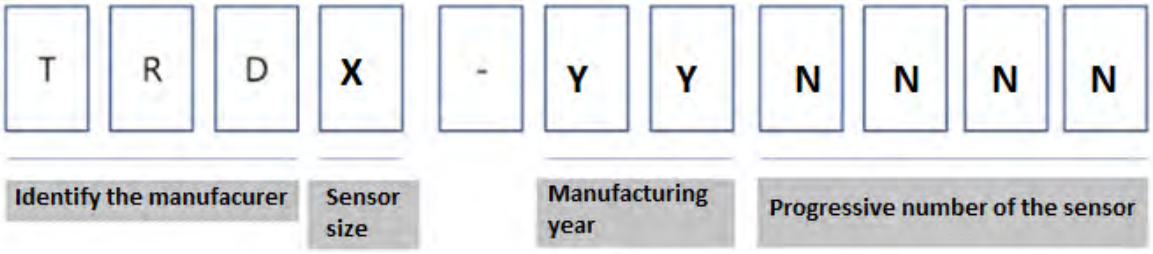
Label for size 1



Label for size 2

All the above labels contains:

- The company's name in lowercase letters, font Century Gothic, with three points representing the "ï" which identifies the company logo.
- Device name: Blu
- Manufacturing Date, in the year-month-day format.
- Device Serial number, SN, consisting of ten alphanumeric characters:



Where:

- X = 1for Size 1, 2 for size 2
- YY =last two digit of manufacturing year
- NNNN= Progressive number of sensor

- Internal reference for identify the sensor

Reference	Name	Size	Software
IS028-S	Blu Intraoral Sensor	1	Software TwainCapture
IS029-S	Blu Intraoral Sensor	2	

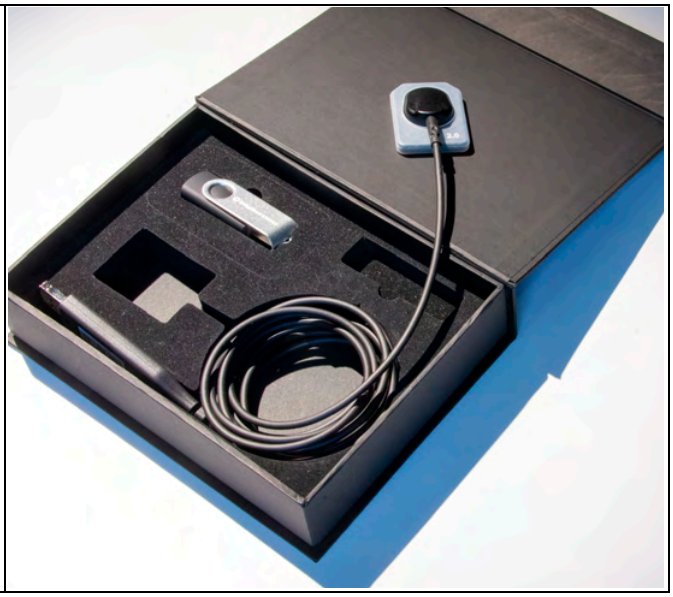
- Notified Body of the CE mark: IMQ (0051)
- Voltage, maximum current and connector type

Other symbols used on 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.
	Type BF. Come into physical contact with the patient in order for the device to carry out its intended function.
	Class II equipment Double insulation
	Selective collection of electrical or electronic devices. At the end of its useful life do not throw this device in household waste
	Read instructions

Icon	Meaning
	Manufacturer address

3.10 Package and contents.

Blu is delivered in a solid black cardboard box with the Digital Doc logo on the cover. Box Measures: 30 x 20 x15 cm Box Weight: 0.5 Kg Box Contents: (1)The sensor with 2 m USB cable length. (1) Dongle with the 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 Blu 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, that differ from than those listed in the Service Manual.

4.1 General Safety

For U.S.A. 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.

	Before each usage, check the outer surface of the sensor for any signs of physical damage or defects. The surface of the Blu 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.
	To ensure the correct usage of the Blu device 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.
	Blu must be used in dental or hospital facilities.
	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. This device must always be disconnected from the power supply before cleaning or disinfecting.
	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.
	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.

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.

	Blu 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.

Blu 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 A	Blu is suitable for use in domestic establishments and in those directly connected to the public low-voltage power supply 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	

Blu 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 in wood, concrete or ceramic tile. If floor is cover 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 > 3 mm	2 kV for power supply lines 1 kV for input/ output lines > 3 mm	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 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 s	<5% UT (> 95% dip in UT) for 0.5 cycles 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 s	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 phototherapy 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.
Note : UT is the A.C. mains voltage prior to application of the test level.			

4.2.2 Guidance and manufacturer's declaration – electromagnetic immunity

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	EMC ENVIRONMENT - GUIDANCE
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.

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	EMC ENVIRONMENT - GUIDANCE
Radiated RF IEC 61000-4-3	3 Vrms 80 MHz to 2.5 GHz	3 V/m	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 the symbol shown on the right			
NOTE 1) At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people			
NOTE: UT is the AC. mains voltage prior to application of the test level.			
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 Blu is used exceeds the applicable RF compliance level above, the Blu should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Blu Gold b. Over the frequency range 150kHz to 80MHz, field strengths should be less than [V1] V/m.			

4.2.3 Recommended separation distances between portable and mobile RF communications equipment and Blu.

The Blu device is intended to use in an electromagnetic environment in which radiated electromagnetic 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 equipment.

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

NOTES

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.

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 WEEE information according to directive 2002/96/EC

The crossed-out wheeled bin symbol, that is present on the device, means that within the European Union the product must be taken to a separate collection at the product end-of life. Therefore, at the end of the life-cycle of the device, the user should deliver the device to the proper collection facilities of the Waste Electrical and Electronic Equipment Directive (WEEE Directive). Alternatively, the user can return the device to the seller, on a one-to-one basis, as long as he or she is buying a new one of equivalent type and has the same functions as the old one.

Disposing the device separately avoids possible negative consequences for the environment and health deriving from inappropriate disposal; this also enables the constituent materials to be recovered, which helps obtain significant savings in energy and resources.

Anyone who disposes any electronic equipment as unsorted municipal waste rather than collecting it separately violates the administrative sanctions in accordance with the law.

5 TECHNICAL DATA

5.1 General characteristics

CHARACTERISTIC	VALUE
Unit name	Blu
Manufacturer 	Trident Srl Castenedolo, 25014 , (BS) Italy
Class (according to IEC 60601-1 classification)	Class I with Type BF applied parts

5.2 Technical Specifications

Parameter	Unit	Size 1	Size 2
Sensitive area structure	--	CMOS array of photodiodes	
Sensitive area structure	--	FOS: FOP + CsI	
Degree of Protection	--	Equivalent to IP68	
Dimensions W x L x H	mm	25.4 x 36.8 x 4,8	31,3 x 42,9 x 4,8
Sensitive (active) surface)	mm	30 x 20 mm	33 x 25 mm
Pixel size	µm	18	
Pixel shape	--	Square	
Number of Active Pixels	pixel	1110 x 1666	1442 x 1998
Number of effective Pixels	pixel	1100 x 1656	1432 x 1998
Photodiode detectors	---	Positioned outside of sensitive area	
Data output	---	USB 2.0	
Electrical rating	---	DC 5V, 500 mA	
Operation mode	---	Global shutter	
Spatial resolution	---	20 lp/mm typical (theoretical 25 lp/mm)	
USB cable length		2 m	

5.3 Electrical and Optical Specifications

CHARACTERISTIC	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
Sensitivity	15 LSM/µGy
X-RAY response non uniformity (XRNU)	± 30 %
Total dose irradiation	50 Gy

5.4 Sensor performance specifications

CHARACTERISTIC		VALUE	
	Unit	Blu	Blu size 2
SNR	dB	≥35	≥35
Sensitivity[1]	ADU/µGy[2]	5.0 to 8.0	5.0 to 8.0
Spatial resolution[3]	3 lp/mm	≥50	≥50
	6 lp/mm	≥25	≥25
	8 lp/mm	≥15	≥15
Noise[4]	ADU	<2.0	<2.0
A/D converter	bits	12	12
Energy range[5]	kVp	From 60 to 70	From 60 to 70

5.5 Environmental Characteristics

CHARACTERISTIC	VALUE
Operating temperature	10 / 35°C
Storage temperature	-20/+60°C
Sensor protection rating	Equivalent to IP68
Storage humidity	From -30 to95% not condensing70

[1] Measured at 60 kV, 4 mm Al
[2] µGy is the measuring unit for exposure: 1mR= 8.69 µGy
[3] Theoretical spatial resolution
[4] RMS of dark current
[5] Recommended Energy range; higher values can reduce sensor life.

6 USE

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 protective part of the sensor, cord ripped, etc..)In case of any problems or fault do not use the product and inform to your dealer.
	Use a disposable protective device (not supplied) to prevent patients from exposure to infections. Failure to use a disposable protective device may cause serious danger to the health of the patient.
	Use a new protective sheath for each patient. For optimum performance, use protective sheaths specifically designed for the size of your sensor.
	Do not remove the disposable sheath by pulling on the sensor cable. Remove the protective sheath by carefully cutting it or using the tear-off strip (if provided on the sheath).
	Blu 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.
	Do not attach or hang anything on the sensor, especially on the sensitive part. Do not exert pressure on the head of the sensor (tight sensor holders, clamps, etc.) Do not forcibly twist, bend, pull or pinch the cable. Do not pull the cable to remove the disposable protective sheath.
	When connecting/disconnecting the sensor, grasp the connector itself—never pull on 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's profile

Blu, intraoral sensor was designed to be used in radiography 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 programs.

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 device 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.

6.3 Usability

All documentation supplied with the Blu 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 Blu sensor is available in a specific manual, which should be read for further details.

	Read this manual carefully before using the device. Keep this manual near the device for future reference

6.4 Principle of operations

The Blu device uses a scintillator. This has an extremely linear response of light output with X-Ray exposure for a given X-Ray spectrum over a wide range of X-Ray exposure in the range appropriate for radiography.
The X-Ray passes through the substrate and interact in the scintillator. The quantum efficiency of the detector is a function of X-Ray energy.

The X-Ray interacting in the scintillator is converted directly to light. This light exits from the scintillator passes coupling material (between scintillator and photodiode arrays) and will be absorbed at photodiode arrays.
The photodiode arrays convert light to electrical signals proportional to the intensity of the light. The signal readout circuit makes digital image data from the electrical signals from photodiode arrays.
The detector outputs raw image data to the workstation, via USB. The acquisition software in the workstation receives the 12-bit digital image data and processes it. It is stored on hard disk with a 16-bit format.

6.5 Imaging performance

Blu is not used as an integrated X-Ray image detector integrated into a specific X-Ray device.

As with all digital intra oral sensors, it achieves good image quality while minimizing the emitted dose from the X-ray generating equipment.

Blu among with the dedicated acquisition software, contributes to the image quality with the specific features:

- Reduction of the dose 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.

6.5.1 Exposure parameters

Blu can be used with all X-Ray generator technology (i.e. traditional AC single phase), 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:

• 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:	• ranging from 300 to 500 µGy for Scissors/incisor and from 400 to 600 µGy for upper molar

• Dose for children patient:	• Reduce dose by 20%

• Dose for edentulous patients	• Reduce dose by 20%

• Exposure time at 60 kVp, 7 mA:	• 0.5 mm suggested, 0.7 mm
• Focal spot to sensor:	• 22 cm

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

6.6 Minimum PC Requirements

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

COMPONENT	REQUIREMENTS
Operating System	Windows 7 (32/64 bit) SP1, Windows 8-1, Windows 10
CPU	Intel
RAM Memory	1 GB (ideally 2 GB)
Hard drive	10 GB RAM
USB Port	2.0
Available space on HD	80 GB
Video card	1024x768 resolution in 65,000 colours (ideally 1280x1024 - 16 million colours, 32 bit)

	Blu CMOS intraoral sensor connects directly to the type A USB port of the computer. The sensor is compatible with the standard USB 2 and the system is able to recognise up to three different sensors connected at the same time to the PC.
	The computer where Blu CMOS intraoral 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 Blu sensor in a power strip.

6.7 Monitor Specifications

The characteristics of your monitor are very important for your sensor performance since your 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.

6.8 TwainCapture Software Characteristics

	Blu CMOS intraoral sensor only works when connected to a PC on which you have previously installed the software TwainCapture.

CHARACTERISTIC	VALUE
Manufacturer 	Digital Doc LLC
Operating system	Windows 7 and up
Main functions available	Single page and Multipage image acquisition through Twain Framework 2.4. 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

6.9 Initial check and installation

Before installing and using your sensor for the first time, it is mandatory to install the software TwainCapture for the image acquisition and management.

6.9.1 Software Installation

- Insert the USB disk that arrived with your Blu sensor into a workstation which is intended to acquire X-Ray images.
- Run the included setup.exe file
- Accept any requests for elevated privledges
- Once complete, please refer to the Integration guide section for your preferred Dental Imaging Application.

	Please carefully read and follow the instruction of the TwainCapture software Manual before using your sensor for the first time .

6.9.2 Installing and using Blu

Remove the system from the original package. Please save the original box and packing materials if you ever need to ship your Blu sensor.

- Check that the supplied sensor corresponds to the one specified in your order.
- The device and its accessories should be visually checked for scratches and missing parts. Verify the package contents and check all the parts. Please contact us immediately whether the product does not corresponds to the expectations.
- Place the system and its components in order to guarantee an ergonomic and safe use.
- Connect the USB cable to the PC. Blu sensor connects directly to the type A USB port of the computer. The sensor is compatible with the standard USB 2 and the system is able to recognise up to three different sensors connected at the same time to the PC.

6.10 Image acquisition with Blu

- Turn on the computer.
- Run your preferred Dental Imaging software as described in the Software Manufacturer's User Manual.
- Configure the required X-ray parameters (exposure time, etc.) for the X-ray generator.
- Put a new sensor cover on the Blu and connect this to the sensor positioning system.
- Position the Blu at the appropriate area of the mouth .
    - The flat, receptor side of the sensor must face the X-ray source. Note that the receptor side is marked with a label for ease of recognition.
    - The use of the sensor positioning aid is recommended to guarantee that the sensor is parallel to the tooth and at the appropriate angle for exposure.
    - The use of the parallel technique with a positioning system, if possible, is highly recommended.
- After preparing the sensor for exposure in your preferred Dental imaging application, acquire an image by pressing the exposure button for your X-ray source.

	
Using the Blu with intraoral X-ray	**Using the Blu with a Sensor positioning system (optional)**

- The message, "Optimizing Image… Please wait" appears while the image is being optimized.
- The image will appear after optimization is complete.

6.11 Acceptance tests

Blu 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 Blu into the relevant slot of the test tool and place it at the end of the beam limiting device, using the centring 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 not use other image enhancement as edge enhancement.**

6.11.1 Frequency of the Q.A. test

The manufacturer recommends that the QA test is **performed at least once per year.**

7 CLEANING AND DISINFECTION

7.1 Cleaning

	Blu and its accessories are supplied non-sterile and cannot be heat sterilized. 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

	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.
	Do not sterilize the product using dry heat, autoclaves or UV devices.
	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 because it will deteriorate with moisture and can cause harm to the patient and / or operator.

7.2 Disinfection solutions compatible with Blu

To clean the sensor, the following solutions are listed below. Please observe the precautions noted.

- Mild soap and water
- Isopropyl alcohol (70%)
- Most alcohol and ammonia based cleaners
- Mild, non-abrasive cleaners

	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.

7.3 Cleaning Procedure

Blu sensor must be disinfected using the following instruction.

In order to prevent infection, wipe the front plate of the sensor unit with ethanol or glutaraldehyde solution to disinfect it prior to using the instrument with a new patient. If you plan to use a disinfectant other than those specified above, or you are mixing another disinfectant with ethanol, please consult a specialist because it may damage the plate.

This cleaning procedure must be followed when the sensor is used for the first time or when after used, it is clear that the protective sheath is not damaged.

- Remove the protective sheath from the sensor and check there are not residues of blood, saliva, tissue or secretions.
- Carefully check the sensor and accessories used to make sure that there are no traces of organic matter on them.
- Prepare the disinfecting solution according to the instructions.
- Carefully disinfect the sensor, following the instruction provided by the manufacturer of the disinfectant.

	Do not soak or immerse the system, and be sure to dry it completely after cleaning.
	Clean the surface of the system by moistening it with a soft cotton swab dipped in one of the cleaning solutions listed above.
	Gently wipe the surface end-to-end in straight lines, without applying any pressure. Make sure the liquid does not penetrate the system through the USB cable or the sensor cable connectors.
	After cleaning the surface of the sensor, use a clean lint-free cloth to dry the system, as required, until the surface is clean.
	**Clean the silicone cover using the same method.**

Do not use the following cleaning materials.

- Hard brushes or scrapers of any kind
- Strong acids or alkaloids

8 ERROR MESSAGES

Message	Solution
USB device driver is not installed	Please install device driver again.
Control box can't be initialized.	Check and re-connect USB Box (USB connector).
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 Blu 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 Blu driver.
Bad Pixels' Map correction error	Restore the Blu 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

9 MAINTENANCE AND REPAIR

	Blu intraoral sensor is not susceptible to be repaired.
	Please do not try to open or attempt to repair neither the sensor housing nor the USB connector.

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.

Blū

Intraoral Sensor

Use and Maintenance Manual

Manufactured for

Digital DOC®

1.800.518.1102
digi-doc.com

CE 0051

Date:10/19/2020
Language: English
Rev: 3-8
Code Blu12.r3-EN