97055438
Rev. 03
2023-09

OPERATOR'S MANUAL
NewTom DCiS

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

EN

INDEX

1. FOREWORD

1.1. INFORMATION ON NewTom DCiS

NewTom DCiS is an intraoral sensor using a wireless communication protocol for reliable and quick transmission of X-ray images. NewTom DCiS uses direct conversion X-ray technology that converts photons directly into digital image data without photon scintillation in visible light.
This process ensures the highest possible Modulation Transfer Function (MTF), a measurement that expresses the true resolution and sharpness, which is achieved natively.
Manufacturer information:

Cefla S.C. - Via Selice Prov.le 23/A – 40026 Imola (BO) – Italy
PLANT: Via Bicocca 14/C – 40026 Imola (BO) – Italy

1.2. INTENDED USE

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

NewTom DCiS is intended to be used by a legally qualified veterinarian for X-ray examinations to support the diagnosis of diseases of the teeth, jaw and oral structures.
NewTom DCiS is a wireless digital sensor intended to acquire diagnostic X-ray images of animal teeth.
The NewTom DCiS sensor must be used by qualified veterinary radiology technicians and practitioners and other legally qualified professionals, trained and competent in taking diagnostic veterinary dental X-rays.
The NewTom DCiS sensor is used together with special positioning devices to facilitate the alignment with the X-ray beam.

1.2.1. FURTHER INFORMATION ON USE OF NewTom DCiS

Suitability for use of NewTom DCiS is limited by the anatomy and size of patient's oral cavity.
It is necessary to perform a professional evaluation to determine whether the sensor is suitable for use for a specific patient with minimum discomfort, based on the patient's anatomy and size.

1.3. GENERAL WARNINGS

This device is not designed, sold or intended for any use other than that indicated.
This device must be installed by a professional appointed by the authorised dealer.
The user cannot replace or remove any part of the system.
Only the USB cable and the antenna provided by the manufacturer are authorised for use with the system.

Patient or operator safety-related warnings.

Warnings concerning the potential risks related to exposure to radiation.

Important information on product use.

1.4. ESSENTIAL PERFORMANCE

The essential performance of NewTom DCiS sensor system allows to generate an X-ray image with acceptable quality. The essential performance depends on the functionality and performance of NewTom DCiS intraoral sensor.

1.5. SAFETY PRECAUTIONS

WARNING
Take the necessary measures to protect yourself from radiation. For correct operator positioning, refer to the “Operator's manual” of your intraoral X-ray equipment.

WARNING
In no case the professional must hold the sensor in his/her hands during X-ray exposure.

Changes or modifications not expressly approved by the party responsible of compliance of this device may cancel the user’s authorisation to use the equipment.

1.6. ABOUT THIS MANUAL

This manual describes the NewTom DCiS intraoral sensor system. The revision number on the cover refers to the release version of this document.
The original language of this manual is Italian.

1.6.1. PRINTED COPY OF THE MANUAL

A paper copy of this manual will be provided on request. Contact the distributor of this product and request the manual in your language.

1.6.2. CONVENTIONS USED IN THIS MANUAL

The terms Service or Service Personnel refer to service personnel trained by CEFLA s.c. or a service provider trained and authorised by CEFLA s.c.
In this manual, the NewTom DCiS intraoral sensor is named NewTom DCiS intraoral sensor or intraoral sensor or sensor.
In this manual, the NewTom DCiS docking station is named NewTom DCiS docking station or docking station.
When referring to different sections of this manual, section names are enclosed double quotation marks.
All illustrations contained in this manual are intended solely for purposes of example.

2. PRODUCT OVERVIEW

2.1. DESCRIPTION OF THE EQUIPMENT

The NewTom DCiS sensor is a direct conversion X-ray detector, that directly converts X-ray photons into digital image data. The NewTom DCiS sensor system supports the wireless communication protocol and USB 2.0/ 3.0 connectivity to Personal Computers (PCs).

Wireless interface features

Parameter	Description
Technology:	Wireless Low Energy
Frequency:	2.4GHz: 2402 - 2480 MHz (channels 0 - 39) | USA, Canada, EU, China, Japan, United Kingdom, South Korea
Modulation technology:	Frequency Hopping Spread Spectrum (FHSS)
Modulation type:	Gaussian Frequency Shift Keying (GFSK)
Wireless data transmission speed:	LE 1M PHY: 1Mbps or LE 2M PHY: 2Mbps
Safety protocols:	LE Security Manager
Effective radiated power:	Sensor: < 0.5mW, Docking Station: < 3.5mW

Imaging performance

The NewTom DCiS sensor has an excellent MTF that reproduces the details of small objects with high accuracy and sharpness.
The MTF is approx. 80% at 2 lp/mm, 40% at 10 lp/mm and 20% at 16 lp/mm.
The DQE of zero spatial frequency NewTom DCiS sensor (that describes X-ray use efficiency) is between 5 and 10% depending on the thickness and density of the material (teeth) to be acquired.

2.2. NewTom DCiS INTRAORAL SENSOR SYSTEM

The NewTom DCiS intraoral digital sensor system comprises NewTom DCiS sensor, docking station and USB cable(s).
NewTom DCiS is supplied together with a number of additional components, some of which come as standard while others are optional:

Image	Description	Quantity	Always present / optional
	DCiS WL sensor (size 2)	1	ALWAYS PRESENT
	Docking Station *(base, antenna, 2m USB-C/USB-A cable for connection to PC/laptop)*	1	ALWAYS PRESENT
	System for wall-mounting of docking station with sensor	1	ALWAYS PRESENT
	Dedicated positioning and centring system for DCiS WL sensor (size 2)	1	ALWAYS PRESENT
	USB Pen Drive including Instruction Manual, Drivers and Software for image display	1	ALWAYS PRESENT
	Quick Start Guide for use of DCiS WL Sensor (size 2)	1	ALWAYS PRESENT
	Quick Start Guide for use of centring devices for DCiS WL Sensor (size 2)	1	ALWAYS PRESENT
	Disposable infection control sheaths, size XL (100-piece package)	1	ALWAYS PRESENT

Image	Description	Quantity	Always present / optional
	Centring system for positioning of sensor size 2	1	OPTIONAL
	2D image acquisition workstation	-	OPTIONAL
	Multiple-workstation hardware keys for the activation of additional licenses (1, 5, 10, 25, 50, 250) on LAN network	-	OPTIONAL
	22” / 24” medical monitor for image displaying	-	OPTIONAL
	Quality control system for 2D examinations	-	OPTIONAL

2.2.1. NewTom DCiS SENSOR

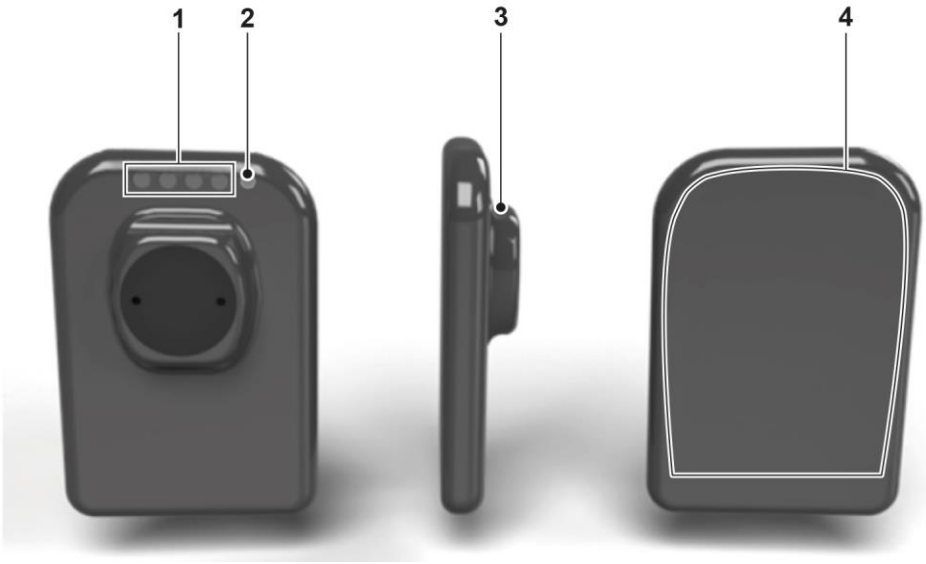


Figure 1: *Rear, lateral and front view of NewTom DCiS sensor. (1) contact points for sensor recharge, (2) sensor light (green or yellow), (3) sensor connection hub and (4) active sensor area (35.1 X 24.7 mm^2)*

Sensor statuses

The sensor light (green or yellow) is located on the rear side of the sensor near the contact points and above the battery compartment (see Figure 1, point (2) above).
It indicates various sensor statuses, as shown in the table:

Colour:	Signal:	Meaning:
Green	Activated: always on	Sensor ready for use.
Green	Activated: flashing; 2s	Sensor charging/Data transfer.
Green	Deactivated: flashing; non-specific frequency	Data transfer (wireless or USB).
Green	Deactivated: flashing; 1 x 50ms on - 4s off	Sensor warning. Sensor not ready.
Green	Deactivated: flashing; 2 x 50ms on - 4s off	Sensor connected. Sensor ready.
Yellow	Activated: flashing; 2s	Sensor charge. Battery flat.
Yellow	Deactivated: flashing; always on	Sensor warning. Battery flat. Sensor not ready.
Yellow	Deactivated: flashing; 2 x 50ms on - 4s off	Sensor connected. Battery flat. Sensor ready.
Yellow	Activated/deactivated: always on	Sensor error. Sensor not ready.
Yellow	Deactivated: flashing; approx. 0.25s	Sensor error. Power supply failure. Sensor not ready.
Yellow	Activated/deactivated: Flashing: non-specific frequency	Data transfer (wireless or USB). Battery flat.
Green/Yellow	Activated/deactivated: flashing; 2 x 0.1s yellow and 2 x 0.1s green	Sensor reset.
Green/Yellow	Activated/deactivated: flashing; 0.5s green, 0.1s pause, 0.5s yellow	Sensor bootloader mode.

2.2.2. NewTom DCiS DOCKING STATION

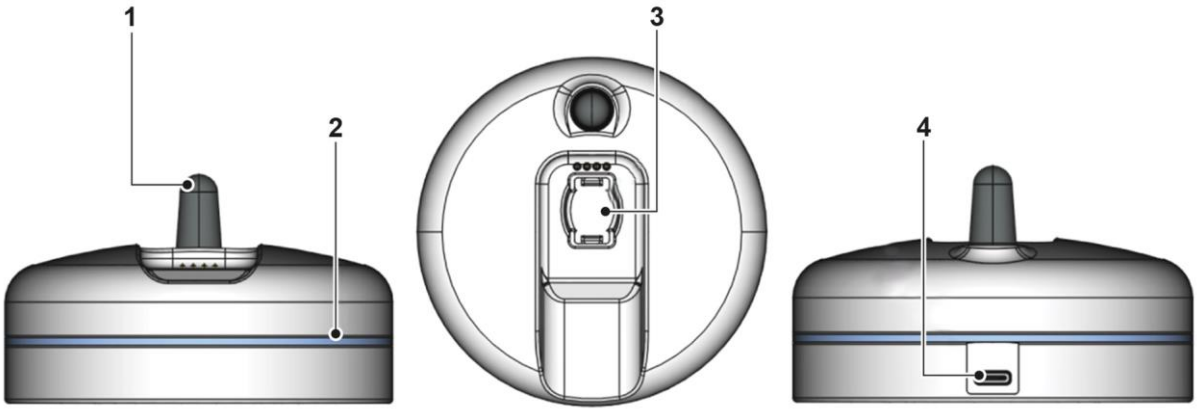


Figure 2: *Front, upper and rear view of NewTom DCiS docking station. (1) docking station antenna, (2) docking station light (blue), (3) docking station sensor port and (4) docking station USB-C port.*

Docking station statuses

The docking station light (blue) is visible around it (see Figure 2 (2) above) and indicates its various statuses, as shown in the table below:

Colour:	Signal:	Meaning:
Blue	Sensor activated: LED brightness decreases; 1s	Sensor on the docking station.
Blue	Sensor deactivated: cyclical movement; 0.5s	Docking station scanning.
Blue	Sensor deactivated: All LEDs are on	Docking station connected to the sensor.
Blue	Sensor deactivated: All LEDs are off	Docking station off. No scanning, no error, no connection.
Blue	Sensor activated/deactivated: all LEDs flash; 1s	Docking station error.
Blue	Sensor activated/deactivated: diagonal flashing; 1s	Docking station bootloader mode.
Blue	Sensor activated/deactivated: flash sequence; left 0.5s, left 0.5s, pause 0.5s, right 0.5s, right 0.5s	Docking station reset.

2.2.3. NewTom DCiS USB-C CONNECTION CABLES

Use the NewTom DCiS docking station with the USB type A to USB-C cable supplied. The cable length is 2m (~6.5 ft.).

2.3. MINIMUM AND RECOMMENDED SYSTEM REQUIREMENTS

The NewTom DCiS sensor system is compatible with the following minimum specifications of PCs, operating systems and components.

All IT components used together with the NewTom DCiS sensor system must comply with the applicable safety standards. Refer to the "Appendix A: Specifications and standards" and "Appendix B: EMC information" for more information.

2.3.1. PERSONAL COMPUTER

The supported operating system is Windows 10 and 11. The minimum mandatory requirements for the combination of sensors and software are an Intel i5 6th generation processor or equivalent. At least 4 GB RAM and 100 GB hard disk space must be available to store:

- software,
- space required to store the images generated by iCapture backup,
- logging of errors and messages.

The PC must be equipped with a USB 2.0/ 3.0 port.
Finally, the PC must meet all the requirements (if exceeding the above) of the Practice Management Software (PMS) or imaging software used, if installed on the same PC.

2.3.2. DISPLAY

The minimum requirements of the display used with the sensor system are a pixel resolution of 1920x1080 and 24bit RGB Full HD (high definition).

2.4. COMPLIANCE WITH STANDARDS

All X-ray equipment for intraoral dental radiography used with the NewTom DCiS sensor system must comply with the requirements of standard IEC 60601-2-65.
The NewTom DCiS sensor and NewTom DCiS docking station comply with the safety requirements of standard IEC 60601-1.
The power supply of any IT components electrically connected to the NewTom DCiS sensor system must use a power supply unit approved according to IEC/UL 60950-1/62368-1 CAT II.
This device complies with part 15 of the FCC rules.
Operation is subject to the following two conditions: (1) This device cannot cause harmful interference. (2) This device must accept any interference received, including interference that may cause undesired operation.

USA federal law restricts this device to sale by or on the order of a dentist or another qualified practitioner.

2.5. CONSIDERATIONS ON SAFETY

All external surfaces of the NewTom DCiS sensors and their supports and barriers are considered applied parts and are safe for normal or accidental contact with the patient during use.
The repairable parts of the NewTom DCiS sensor include the sensor battery.
The battery may only be replaced by service personnel.
Do not attempt to open the device for maintenance or repair.
All sensor elements that are intended to be handled by the operator are accessible without opening the internal components of the device.
If a problem occurs, contact a qualified representative of the dealer service or the NewTom DCiS technical support.

2.5.1. INSULATION FROM THE POWER MAINS

Disconnection from the power mains occurs at the computer input (PC or laptop). The NewTom DCiS docking station can also be disconnected from the computer.

2.5.2. X-RAY PROTECTION

The rules of dental radiography also apply to digital X-ray systems. Continue to use the protection for your patients.
The operator must clear the surrounding area when exposing the sensor.

2.5.3. CROSS-CONTAMINATION PREVENTION

To help prevent cross-contamination between patients, place a new hygienic barrier on the sensor for each new patient. The hygienic barrier must cover the sensor. For information on sensor cleaning, refer to section "Cleaning and disinfection of NewTom DCiS sensor".

2.5.4. DISPOSAL PROTOCOLS

Dispose of the sensor barriers and the other consumables according to the standard procedure of the dental practice for biomedical waste. Improper disposal of biomedical waste can result in spread of diseases.

Properly dispose of the sensor and docking station when they have reached the end of their useful life. For information, refer to the explanation of this symbol in “Appendix C: Symbols / Stylistic conventions”.

2.5.5. SENSOR INSPECTION

Always inspect the sensor and the positioning devices to check the presence of physical damage before each use. Do not use the sensor if its housing shows visible damage in the form of open cracks or puncture dents.

Put the sensor out of service in case of damage to its housing in the form of open cracks or puncture dents. Failure to comply with these instructions may result in incorrect operation.

2.5.6. END OF OPERATION

To end operation of the NewTom DCiS docking station, disconnect the USB cable from the power supply source (PC or laptop).

Operation of the NewTom DCiS sensor cannot be interrupted.
Do not use the sensor if you doubt that it is not fully functioning.
Contact the NewTom DCiS technical support.

2.6. PROTECTION AGAINST CYBER SECURITY THREATS

Protection of the practice against cyber security threats is a shared responsibility between Cefla S.C., as manufacturer of NewTom DCiS, and the customer, as user of the device and the healthcare practitioner.
Cefla S.C. has adopted precautions to ensure that NewTom DCiS, as shipped from its factory, is protected against such threats. However, it cannot protect the network system.
We strongly recommend to make sure that the office network system is properly protected against viruses, malware and intrusions (e.g. with antivirus software and/or using firewalls) and that IT equipment is properly protected against unwanted and inappropriate access (e.g. access control to the IT system/office).

Failure to maintain cyber security may result in impairment of device functionality, loss of availability or integrity of data (medical or personal), or exposure to security threats to other connected devices or networks.

2.7. CONFIGURATION INSTRUCTIONS

2.7.1. SETTING UP THE DEVICE

When the NewTom DCiS system is connected to a PC or laptop for the first time, the user must contact the NewTom DCiS technical support to install and activate the licence for iCapture interface, as well as download the calibration files from the cloud.
The docking station and its sensor can be positioned inside the dental practice in two different modes:

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

Vertically, leaning against a wall, using the appropriate wall support.

2.7.2. NewTom DCiS DOCKING STATION CONNECTION

Place the NewTom DCiS docking station in the desired position on a work surface, which must be in front of the surgical table or, if this is not possible, next to it.
The distance between NewTom DCiS and docking station must not exceed 2.5 metres.
Connect the USB cable supplied in the docking station package to the USB port of the docking station and the USB port of the PC or laptop.

Avoid positioning the NewTom DCiS docking station behind the surgical table in a position behind the head and neck of a patient. Any obstacles between sensor and docking station reduce the quality of the signal and slow down transmission.

The length of NewTom DCiS connection cables is 2m (~6ft.).
Other lengths may be available.
Contact the technical support for the options.

2.7.3. INSERTING THE SENSOR INTO THE DOCKING STATION

For correct insertion of the sensor into the docking station, follow the steps in the figure below:

Place the sensor directly on the docking station.

Gently push the sensor down until it clicks correctly in place.

2.7.4. PAIRING THE NewTom DCiS SENSOR TO THE DOCKING STATION

To pair any NewTom DCiS sensor with any NewTom DCiS docking station, place the sensor on the docking station and wait that the iCapture interface software displays the status message "Sensor ON BASE".
In some cases, the status message switches temporarily to "Sensor ON BASE" before the pairing, then to "Busy" and after a few seconds to "Sensor ON BASE".
Repeat these steps when moving a NewTom DCiS sensor from one room to another.
Every time a sensor is moved to another room, it must be paired with the relevant docking station.

When the status message "Sensor ON BASE", is displayed, wait three (3) seconds before removing the sensor from the docking station.

After removing the NewTom DCiS from the docking station, wait the status message "Sensor ready" before acquiring a X-ray image. Refer to the user guide of iCapture interface.

Never acquire a X-ray exposure if the iCapture interface does not indicate the green "Sensor Ready" status. Refer to the user guide of iCapture interface.

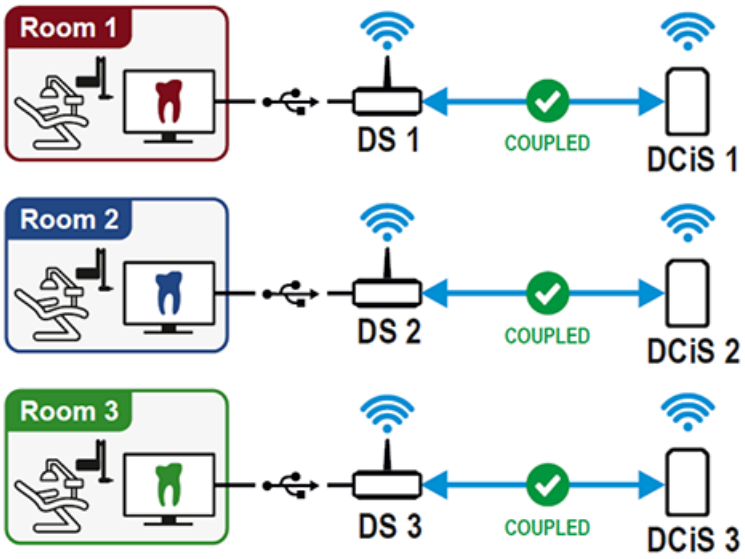
Never attempt to acquire a X-ray image with the docking station positioned behind a wall or in another room.

Pairing and operation mode between sensor and docking station

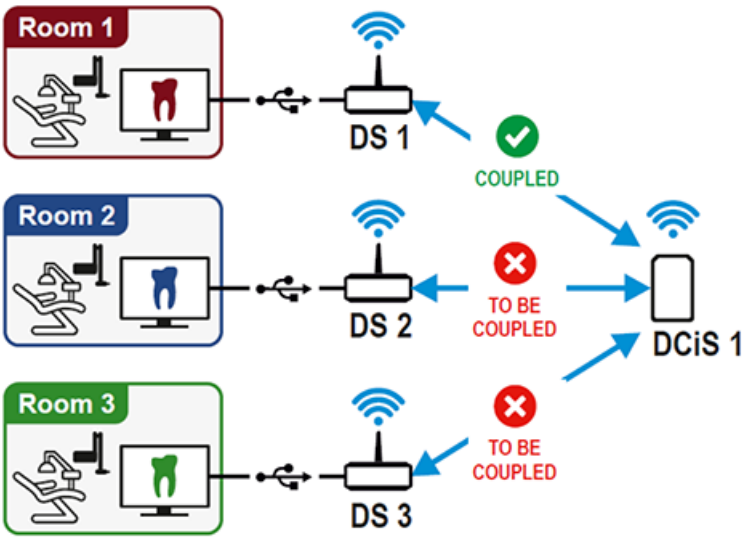
To pair the sensor with its docking station, it is first necessary to bring the 4 contact points on the rear side of the sensor into contact with the 4 USB pins of the docking station.

After this operation, there are three modes of use that can be applied within outpatient clinics (always consider that simultaneous use of several sensors with the same docking station is currently not possible):

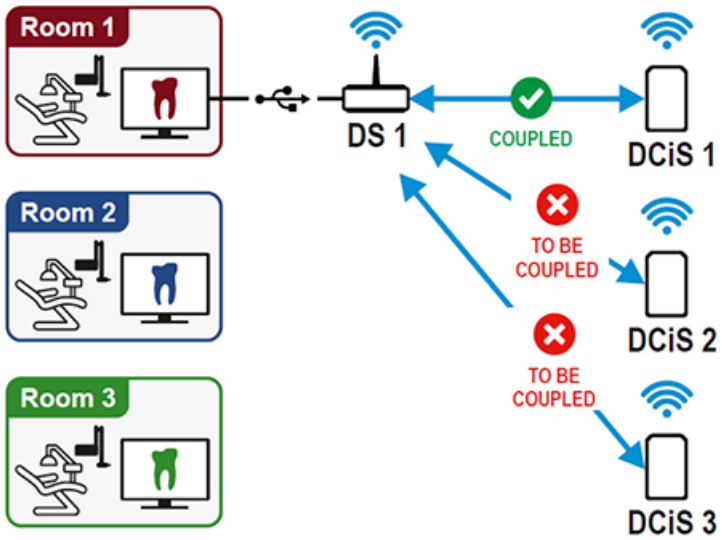
1 each sensor is only used with its docking station:



2 one sensor can be used with several docking stations (in this scenario it is important to remember that the sensor must first be paired with the new docking sensor in case it was already paired with another one):



3 one docking station can be used with several sensors (in this scenario it is important to remember that the docking station must first be paired with the new sensor in case it was already paired with another one):



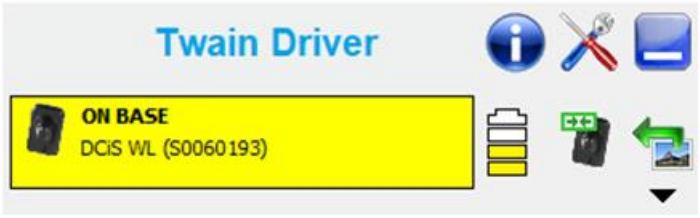
2.7.5. CALIBRATION

When connecting the NewTom DCiS to the PC or laptop for the first time and when replacing the PC or laptop previously used with another one, enable the NewTom DCiS and wait 30 seconds to download the calibration files from the cloud to the specific PC or laptop.
If there is no Internet access available in the dental practice, contact the technical support to receive the calibration files in a flash memory.
If the calibration file is not found the iCapture interface displays an error.
Refer to the user guide of iCapture interface.

2.8. OPERATING MODE

The NewTom DCiS sensor system features the following operating modes.
For more information, refer to the user guide of iCapture interface

ON BASE | Charging | Recovering the Last Image



This mode is used when the NewTom DCiS sensor is positioned on the docking station.
The sensor battery will charge in this mode.
When connected, the NewTom DCiS sensor is also viewed by the USB port of the PC or laptop.
Every time the technical support accesses the PC remotely, the NewTom DCiS sensor must be connected in the default position.
When it is connected via USB or disconnected via wireless connection, the last image saved in the NewTom DCiS sensor memory can be recovered through the iCapture interface.

Connected | Wireless Link

In this mode the sensor is waiting for X-rays. The iCapture interface indicates the sensor status as ready for exposure.

When the exposure is performed, the iCapture interface indicates the automatic activation of incoming X-rays, followed by the wireless transfer indication status bar.
When the image is received, it is processed and displayed.
The iCapture interface will send the image to the imaging software recalled by iCapture.
The imaging software can start a new iCapture request as single exposure or as part of a default model, and the iCapture interface will indicate that the sensor is ready for the next exposure.

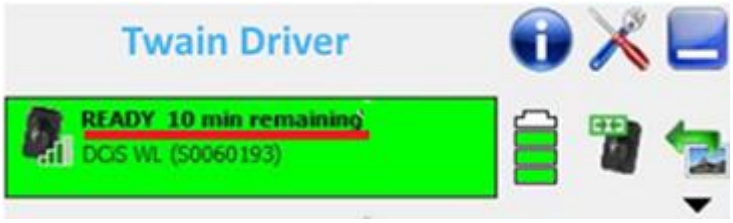
Never acquire a X-ray exposure until the iCapture indicates the green "Sensor Ready" status. For more information, refer to the user guide of iCapture interface.

The last image will be automatically downloaded both with the NewTom DCiS in wireless connection mode and with the sensor activated on the docking station.

Once the X-ray is taken, the operator must remove the sensor from the patient's mouth to optimise data sending time.

Sleep, Standby (POWER OFF)

When connected via wireless connection, the NewTom DCiS sensor switches to Sleep or Standby mode (this mode is indicated as "Power OFF" in iCapture) after a user-defined period of inactivity.
The time left to Power OFF is indicated during the Ready period.



While in Sleep mode (Power OFF), the battery charge is maintained more effectively.
To quit the Sleep mode (Power OFF), place the sensor on the NewTom DCiS docking station until "ON BASE" is displayed on the iCapture interface.

When the sensor sets to POWER OFF mode, the image stored in the sensor will be lost.

Loss of signal (DISCONNECTED)
When the sensor leaves the connection field, the base starts searching for the sensor; if it still cannot find it, the message Sensor NOT Connected is shown after a few seconds:

If you bring the sensor back within signal detection range before 20 minutes, the base will automatically detect the sensor, thus setting it back to the green “Sensor Ready” status. After 20 minutes, however, it is necessary to pair the sensor again by placing it on the base.

2.9. BATTERY MANAGEMENT

2.9.1. CORRECT MANAGEMENT OF THE BATTERY CHARGE

For proper battery management, always follow the instructions below when using the sensor:
1 When the sensor is not in use, ALWAYS place it on the docking station.
2 Between work sessions, ALWAYS place the sensor on the docking station.
3 Leave the sensor on the docking station overnight with the PC connected and switched on.
4 Follow battery status warnings on iCapture.

2.9.2. BATTERY FLAT

When the NewTom DCiS sensor battery is low, the sensor light (see also “Sensor lights”) on the rear side of the sensor starts flashing in yellow. When no longer charged, the NewTom DCiS sensor requires approx. 3.5 hours for the complete recharge, while a 15-minute recharge will allow performing at least one FMX (Full Mouth Series).

It is in any case recommended to fully recharge the sensor at least once every 5 months.

The BATTERY LOW message (together with the battery symbol with a red notch), indicates that the battery is low and it is necessary to place the sensor on the base WITHOUT taking any further X-rays:

Continuing to use the sensor during the BATTERY LOW message is not recommended because the sensor may shut down during an X-ray and the image will be lost.

When the BATTERY LOW message is displayed, place sensor NewTom DCiS back on the docking station for at least 15 minutes.

15 minutes is the time deemed necessary to charge the sensor and be able to make at least one FMX dental status.

2.9.3. BATTERY RECHARGE WITH DISCHARGED SENSOR

When storing the NewTom DCiS sensor fully discharged on the docking station, the BATTERY LOW message will appear for 15 minutes (along with the flashing flat battery symbol):

After 15 minutes, the ON BASE indication is shown again and the sensor has sufficient charge to make an FMX full status.

DO NOT lift the sensor from the base if the BATTERY LOW indication is still shown.

Always follow the instructions in section 2.9.1 for correct battery charge management. However, if you happen to leave the sensor outside the base for more than a month, the battery may become very low: in this case, when you put the sensor back on the base, the BATTERY LOW signal will be displayed for 45 minutes.

2.10. SYSTEM FAILURE

On rare occasions, the NewTom DCiS sensor system may fail and an acquired X-ray image is not sent to the PC or iCapture interface, or the imaging software crashes. In this case, follow the steps below:

1 Place the NewTom DCiS sensor on the docking station.
2 Close iCapture.
3 Quit the GUI on the application bar by right-clicking on the icon and selecting "Close NewTom DCiS service".
4 If the icon does not respond, perform a forced exit from NewTom DCiS using the Windows Task Manager function.
5 Close the imaging software.
6 Disconnect the USB cable of the docking station on the PC side.
7 Wait 10 seconds.
8 Reconnect the USB cable of the docking station to the PC.
9 Restart the imaging software and restart the iCapture interface.

After restarting the imaging software, recover the last X-ray image in the memory of the NewTom DCiS sensor by placing the sensor on the docking station. Refer to the user guide of iCapture interface.

Do not repeat the X-ray image. Recover the last X-ray image from the NewTom DCiS sensor memory by clicking on "Download last image" icon (or similar) on the imaging software. Refer to the user guide of iCapture interface.

3. X-RAY EXECUTION AND WORKFLOW FOR OPTIMAL USE

Refer to the user guide of iCapture interface for instructions on how to use iCapture and acquire images.

3.1. SENSOR POSITIONING IN A DISPOSABLE BARRIER

Place the sensor in a disposable barrier before each use, before placing the sensor on the support and in the patient's mouth.

Never use or place the NewTom DCiS sensor in a patient's mouth without using an approved barrier for sensors.

Use new and intact infection control sheaths only. Remove and dispose of the infection control sheaths after each use.

3.2. POSITIONING IN THE SUPPORT

Place the sensor in its support according to the instructions provided by the support manufacturer or distributor.

The sensor must be held in the correct position using a centring device in order to obtain good x-ray images.
Kits of special centring devices for front, rear, bite-wing periapical images and for endodontics are available on the market.
The individual components in the kits are also available as spare parts.
Contact your authorised dealer to purchase spare centring devices.
In addition, universal centring devices such as Dentsply Rinn® or TrollDental UK LTD® can be used.
In any case, it is recommended to use centring devices supplied by Cefla S.C..
Always refer to the instructions included with the centring kit for details on use, cleaning and sterilization of the centring device.

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

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

3.3. SENSOR EXPOSURE

The NewTom DCiS sensor captures X-rays using a direct conversion layer.
Direct conversion produces images with the highest brightness.

The NewTom DCiS sensor system can be used with any intraoral X-ray generator, and with portable X-ray generators (provided that they allow to deliver a minimum dose sufficient for proper sensor operation).
The types of X-ray systems that integrate with the NewTom DCiS sensor system are wall-mounted or wheeled X-ray generators (both AC and DC) with a tube current between 2 and 10 mA and a tube voltage between 60 and 70 kV included, with integrated controls to set the exposure parameters.
Otherwise, the NewTom DCiS sensor system can be used together with a portable and hand-held X-ray generator with a tube current between 2 and 10 mA included and a tube voltage between 60 and 70kV included.

In addition, the CMOS behind the direct conversion layer features the High Dynamic Range (HDR) function that facilitates the user in the workflow by allowing him/her to select a single exposure setting for an entire set of Full Mouth X-rays (FMX).
For example, considering a wall-mounted (or wheeled) X-ray generator operating in the 6-8 mA range with a 20 cm (8") cone, a recommended exposure time is between 0.1 and 0.25 seconds for any position in an FMX.

The exposure time setting must always be evaluated according to the reference levels (LDR) defined in the regulations in force in the country of use.

The rated kerma range of the sensor air for the intended use is between 450 uGy and 4500 uGy.

The **optimal exposure time of the NewTom DCiS sensor will depend on the mA** available from the X-ray generator.

*For X-ray units manufactured by CEFLA s.c., to ensure optimal exposures, a sensitivity value of **F26** is recommended, with pre-setting left at 8mA as default. Exposure times and kV values will be automatically set according to the anatomical area selected on the X-ray unit by the operator*

For other types of X-ray units, to ensure exposure optimisation, it is recommended to use the table below referred to a high frequency DC 70 kV and 8mA generator.

70KV – 8mA		Cone length 12” (30 cm)		Cone length 8” (20 cm)	
					
	UPPER MOLARS	**0.36 s**	**0.14 s**	**0.18 s**	**0.14 s**
	UPPER PREMOLARS	**0.28 s**	**0.18 s**	**0.14 s**	**0.09 s**
	UPPER CANINES / INCISORS	**0.20 s**	**0.14 s**	**0.10 s**	**0.07 s**
	LOWER CANINES / INCISORS	**0.20 s**	**0.14 s**	**0.10 s**	**0.07 s**
	LOWER PREMOLARS	**0.28 s**	**0.20 s**	**0.14 s**	**0.10 s**
	LOWER MOLARS	**0.28 s**	**0.25 s**	**0.14 s**	**0.125 s**

If using 4mA, double the exposure time. If using 7mA, increase the exposure time by 15%.

NOTE: the dose values on single patients may vary according to the patient’s build and the specific diagnostic work-ups.
Therefore, when necessary, it is possible to use higher doses than those recommended without overexposure effects, thanks to the HDR function of NewTom DCiS.

The **docking station** with the receiving PC or laptop must be placed at **no more than 2.5m (8 feet)** from the dental chair where the X-ray examination is performed and, if possible, **to the side or in front of the patient**.

Avoid placing the docking station behind the patient's head as the signal would be significantly reduced in that position.
The docking station can be positioned at a maximum distance of 2m (6ft.) from the PC using the USB cable supplied by the manufacturer.

After pressing the exposure button and **to optimise the return time and the user comfort, remove the NewTom DCiS sensor from the patient’s mouth**, wait for the preview and reposition the sensor for the next exposure.

Usually, in case of a the docking station direct view field on the NewTom DCiS, the preview image is available in approx. 4sec - 8sec.
In rare cases and usually when the NewTom DCiS remains inside the mouth, up to 30 seconds may be required for the preview.

Never proceed with the next X-ray exposure before the previous X-ray image has been successfully transferred through the iCapture interface to the imaging software.
If for any reason (for example, loss of wireless connection or crash of the imaging software or iCapture interface) the preview image and the final image are not sent to the imaging software, follow the steps described in paragraph “System Failure” and then recover the last image with the “Download last image” button on the iCapture interface software.

With **battery fully charged**, the NewTom DCiS sensor can perform at least **140 continuous X-ray exposures (e.g. one image every 40 seconds)**.

After completing an FMX or other set of X-ray operations and between patients, the sensor must always be repositioned on its docking station to be recharged.
When not used, the sensor must always be put back in place on its docking station.
When no longer charged, the NewTom DCiS sensor requires approx. 3.5 hours for the complete recharge, while a 15-minute recharge will allow performing at least one FMX (Full Mouth Series).
If left away from the docking station, the NewTom DCiS sensor will switch to **Sleep mode after a user-defined time** after the last X-ray to preserve the battery.
A special “ENDO” mode is available that prevents the sensor from switching to Sleep mode.
To quit the Sleep mode, place the sensor on its docking station for 10 seconds.

3.4. PiE (Powerful image Enhancer) FILTERS

A new filter set has been created for the NewTom DCiS to highlight all the details required for different clinical needs:

Soft tissue preserving: preserves areas at risk of blackening to highlight soft tissue.

High contrast: enhances contrast if the image is low in contrast for anatomical reasons or radiological parameters.

Default: balances interference, contrast and sharpness.

High details: emphasises image details.

Caries revealing: improves the contrast level of bitewing images allowing easier detection of interproximal caries.

To select the above-mentioned filters, refer to the iCapture manual.

4. MAINTENANCE

4.1. CARE AND MAINTENANCE

4.1.1. NewTom DCiS SENSOR

The NewTom DCiS sensor is reusable and can be used with several patients. Clean the sensor after each use by following the disinfection protocols described in this manual in section “Cleaning and disinfection”.
Always place the NewTom DCiS sensor in its docking station after use to recharge it and avoid that the sensor is in an incorrect position.
Do not drop or place the NewTom DCiS sensor with force on any surface.
Do not use the sensor if its housing has been damaged and shows visible deep cracks or puncture dents.

Battery

The NewTom DCiS sensor contains a rechargeable lithium-ion battery.
The battery may only be replaced by service personnel.
Do not attempt to open the battery compartment of the sensor for maintenance or repair.

Do not attempt to open the battery compartment or replace the battery inside the housing.
All battery repairs or replacements must be carried out by authorised service personnel.

Recharging the NewTom DCiS sensor

The NewTom DCiS sensor contains a rechargeable lithium-ion battery.
For battery recharge, place the sensor on the relevant docking station port.

4.1.2. NewTom DCiS DOCKING STATION

Only use the USB cable supplied with the NewTom DCiS docking station to connect the docking station to a PC or laptop.
Do not drop or place the NewTom DCiS docking station with force on any surface. Do not use the docking station if its housing has been damaged.

4.2. CLEANING AND DISINFECTION

When cleaning the NewTom DCiS sensor or the docking station, follow the cleaning and disinfection protocol described in this section.

4.2.1. NewTom DCiS SENSOR CLEANING AND DISINFECTION

Only use the disinfectants approved for NewTom DCiS sensors.
The use of non-approved disinfectants may create aesthetic problems to the product and potentially to its operation.

The NewTom DCiS sensor must be thoroughly cleaned after each use.
The purpose of the following recommendations for cleaning and disinfection is to achieve an intermediate level disinfection and prepare the product to be used and reused in a safe manner throughout its life.

Approved disinfectants

The following surface disinfectants have proven effective in achieving an adequate level of disinfection and are available from dental product dealers:

Commercial name	Manufacturer
CaviWipes™ (original)	Metrex Research
Disinfectant wipes for surfaces ADVANTACLEAR	Hu-Friedy Manufacturing Co Inc
Wipes OPTIM® 1	COLTENE SciCan
Wipes for surfaces Opti-Cide3®	Micro-Scientific
Isopropyl (70%)	Various

Cleaning and disinfection protocol

The NewTom DCiS sensor must be cleaned and disinfected after each patient.

Always follow the instructions of the manufacturer of the cleaning and disinfection product when disinfecting the NewTom DCiS sensor.

Never submerge the NewTom DCiS sensor in any liquid.
Do not sterilize the NewTom DCiS sensor in an autoclave, as the device would be irreparably damaged.

The following procedure is recommended before using the sensor for the first time and after each patient:

1 Remove and dispose of all the protective hygienic barriers and/or sheaths from the sensor before removing the disposable gloves.
2 Place the sensor on a tray covered with a disposable liner or in a container that can be thoroughly disinfected.
3 Remove and dispose of the gloves.
4 Wash your hands and wear a new pair of disposable gloves.
5 If the sensor is visibly dirty (e.g. with blood or saliva), clean it with a soapy cloth or a paper towel or using a recommended disinfectant wipe and dry it with a clean, lint-free cloth or blotting paper.
6 Thoroughly clean the sensor (min. 30 seconds) with one of the disinfectants recommended above.
Make sure that all impurities have been removed and the sensor is thoroughly disinfected.
If necessary, use several wipes.
7 Repeat step 6.
8 Place the sensor on the docking station to recharge it.

9 Store the sensor and/or the docking station in a clean place for future use.

4.2.2. NewTom DCiS DOCKING STATION CLEANING

The NewTom DCiS docking station is not intended to be moved or to come into contact with the patient during clinical use.
Therefore, it does not require routine cleaning.
If the NewTom DCiS docking station gets dirty or comes into contact with a patient, it must be cleaned using the detergents recommended for the NewTom DCiS sensor indicated in section "Cleaning and disinfection of NewTom DCiS sensor".

Never submerge the NewTom DCiS docking station in any liquid.
Do not sterilize the NewTom DCiS docking station in an autoclave, as the device would be irreparably damaged.

4.2.3. SUPPORT CLEANING AND DISINFECTION

Sensor supports and the other related elements must be cleaned and disinfected according to the instructions provided by the manufacturer of the support and/or related elements.

4.2.4. BARRIERS AND INFECTION CONTROL SHEATHS FOR SENSORS

Barriers and infection control sheaths for sensors (sensor covers) are disposable and must never be reused. Remove and dispose of the cover after each patient.

5. APPENDIX A: SPECIFICATIONS AND STANDARDS

Specifications of NewTom DCiS sensors

SENSOR ARCHITECTURE	Direct conversion of dental IO X-ray sensor linked to CMOS 1350 x 950 pixel pixel pitch 26 µm 19 lp/mm visible MTF: 90% at 2lp/mm, 70% at 5lp/mm, 40% at 10lp/mm, 10% at 16lp/mm
X- RAY PARAMETERS	The sensor can be used with dental X-ray generators in the range from 60 to 70 kV; with a minimum incident dose of 40µGy.
SOFTWARE ARCHITECTURE	Wireless interface and wired with the NewTom DCiS docking station
ELECTRICAL VALUES	Battery-operated, rated voltage 3.5V - 4.2V, 19mAh
CONNECTION TO THE DOCKING STATION	Wireless, USB
IMPACT PROTECTION	Type BF applied part 
OPERATING MODE	Continuous
STERILIZATION METHOD	The sensor is not suitable for sterilization

ENVIRONMENTAL CONDITIONS	Humidity	Air pressure	Ambient temperature
USE The NewTom DCiS sensor is not suitable for use in oxygen-rich and/or explosive environments	From 30%RH to 95%RH	From 70kPa to 106kPa	From +10°C to +35°C
TRANSPORT AND (STORAGE) Transport in the protective packaging provided	From 5%RH to 95%RH		From -20°C to +50°C
Protection from water/substances - IP67, IP64			

NewTom DCiS docking station specifications

ELECTRICAL VALUES	5V DC 0.5A 
PC CONNECTION	Compliant with USB 2.0 / 3.0
OPERATING MODE	Continuous
STERILIZATION METHOD	The docking station is not suitable for sterilization

ENVIRONMENTAL CONDITIONS	Humidity	Air pressure	Ambient temperature
USE The NewTom DCiS docking station not suitable for use in oxygen-rich and/or explosive environments	From 30%RH to 95%RH	From 70kPa to 106kPa	From +10° to +35°C
TRANSPORT AND (STORAGE) Transport in the protective packaging provided	From 5%RH to 95%RH		From -20°C to +50°C

6. APPENDIX B: INFORMATION ON ELECTROMAGNETIC COMPATIBILITY

The NewTom DCiS sensor and the NewTom DCiS docking station are subject to electromagnetic interactions with other electronic devices.
The information on electromagnetic compatibility in this chapter refers to the medical system obtained through the connection between the NewTom DCiS sensor and the NewTom DCiS docking station and between the NewTom DCiS docking station and the computer (PC or laptop).
Computer power supply must be approved according to IEC/UL 60950-1/62368-1 CAT II, evaluated for secondary outputs accessible to the operator that meet the requirements of SELV/ES1.
Power supply must be certified for reinforced insulation between primary and secondary.
The NewTom DCiS sensor system is suitable for use in hospitals, except in the vicinity of active HF surgical equipment and in the RF shielded room of an ME system for magnetic resonance (MR) imaging, where the electromagnetic interference intensity is high.

Portable/mobile radio frequency communication equipment may affect the operation of the NewTom DCiS sensor system, as well as any other electrical medical equipment.
This influence may prevent image acquisition or impair its quality.

The NewTom DCiS docking station is a USB-compliant device and must be used with USB-compliant cables suitable for maximum speed/USB 2.0/3.0. These cables are marked as "USB 2.0" or “USB 3.0” or "USB full speed".
Certified USB hubs can be used to increase the distance to the USB host/computer.
The connection cable to the hub or between hubs must not be longer than 5m (~16.4ft.).

The use of additional components, transducers and cables other than those specified or supplied by the manufacturer of this equipment may lead to an increase in its electromagnetic emissions or a decrease of its electromagnetic immunity and result in incorrect operation.

Using non-USB cables or hubs or exceeding the maximum number of USB hub devices to increase the distance, may reduce the immunity of the NewTom DCiS docking station to electromagnetic fields or increase the emission of electromagnetic fields from the NewTom DCiS docking station.
Contact the technical service for more details on cable lengths and USB hubs.

The use of this equipment near or stacked on other equipment must be avoided because it may cause incorrect operation.
If such use is necessary, this and other equipment should be checked to verify their normal functioning.

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

Guidance and Manufacturer's declaration - Electromagnetic emissions		
The NewTom DCiS sensor system is intended for use in the electromagnetic environment specified below. The customer or user of the NewTom DCiS sensor system must ensure that it is used in such environment.		
Emission test	**Conformity**	**Electromagnetic Environment**
RF emissions CISPR 11	Group 1	The NewTom DCiS sensor system uses a wireless communication protocol for data transmission. RF emissions are expected in the ISM band when the system is in transmission phase. This may cause interferences in adjacent electronic equipment operating in the same band. RF emissions in other frequencies are very low and should not cause any interference.
RF emissions CISPR 11	Class B	The NewTom DCiS sensor system is suitable to be used in all environments, including the domestic ones and those directly connected to the public low-voltage power mains supplying domestic buildings.
Harmonic emissions IEC 61000-3-2	Class A (*)	
Voltage fluctuations/ Flickering IEC 61000-3-3	Compliant (*)	

(*) The computer used with the NewTom DCiS sensor system must respect this value.

Guidance and Manufacturer's declaration - Electromagnetic immunity			
The NewTom DCiS sensor system is intended for use in the electromagnetic environment specified below. The customer or user of the NewTom DCiS sensor system must ensure that it is used in such environment.			
Immunity test	**IEC 60601 Test level**	**Conformity**	**Electromagnetic Environment**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2kV, ±4 kV, ±8 kV, ±15 kV air	Compliant	Floors must be made of wood, concrete or ceramic tiles. If floors are covered with synthetic material, the relevant humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Compliant (*)	The mains power supply should be that of a typical commercial or hospital environment.
Pulse IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	Compliant (*)	The mains power supply should be that of a typical commercial or hospital environment.
Voltage drops, short blackout or voltage variations on the input supply lines IEC 61000-4-11	0% UT; 0.5 cycles at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0% UT; 1 cycle 70% UT; 25/30 cycles for 50 Hz and 60 Hz, respectively Single-phase: at 0° 0% UT; 250/300 cycles for 50 Hz and 60 Hz, respectively Single-phase: at 0° 0% UT; 250/300 cycles for 50 Hz and 60 Hz, respectively Single-phase: at 0° **VDI specifications for the 3rd edition:** <5% UT (>95% drop in UT) per 0.5 cycles 40% UT (60% drop in UT) per 5 cycles 70% UT (30% drop in UT) per 25 cycles <5% UT (>95% drop in UT) per 5 s	Compliant (*)	The mains power supply should be that of a typical commercial or hospital environment.
Network frequency electromagnetic field (50/60 Hz) IEC 61000-4-8	Not Applicable	Not Applicable	-

(*) The computer used with the NewTom DCiS sensor system must respect this value.

<table>
<tr><th colspan="4">Guidance and Manufacturer's declaration – ELECTROMAGNETIC IMMUNITY (IEC 60601-1-2)</th></tr>
<tr><td colspan="4">The NewTom DCiS sensor system is intended for use in the electromagnetic environment specified below.
The customer or user of the NewTom DCiS sensor system must ensure that it is used in such environment.</td></tr>
<tr><th>Immunity test</th><th>IEC 60601
Test level</th><th>Degree of conformity</th><th>Electromagnetic Environment</th></tr>
<tr><td>Conducted RF
IEC 61000-4-6</td><td>AC mains power supply:
3 V, 0.15 MHz – 80 MHz
6 V in ISM band between
0.15 MHz and 80 MHz
80% AM at 1 kHz
SIP/SOPS:
3 V, 0.15 MHz – 80 MHz
6 V in ISM band between
0.15 MHz and 80 MHz
80% AM at 1 kHz</td><td>Compliant
(*)</td><td rowspan="2">The RF communication equipment (portable and mobile) must not be used at a distance from any point of the NewTom DCiS sensor lower than the recommended distance calculated using the equation applicable to the transmitter frequency.
Recommended distance:
$d=\left(\frac{3.5}{V_1}\right)\sqrt{P}$ From 150 kHz to 80 MHz
$d=\left(\frac{3.5}{E_1}\right)\sqrt{P}$ From 80 MHz to 800 MHz
$d=\left(\frac{7}{E_1}\right)\sqrt{P}$ From 800 MHz to 2.5 GHz
where P is the maximum output power of the transmitter in Watt (W) according to the transmitter Manufacturer, and d is the recommended distance in metres (m).
$V_1=3V_{rms}$</td></tr>
<tr><td>Radiated RF</td><td>3 V/m
from 80 MHz to 2.7 GHz</td><td rowspan="2">Compliant
(*)</td></tr>
<tr><td>IEC 61000-4-3 Ed. 3.0 (with A1:2007 + A2:2010)</td><td>80% AM at 1 kHz</td><td>$E_1=3\frac{\mathrm{V}}{\mathrm{m}}$
Field intensities of fixed RF transmitters, as determined by an electromagnetic survey on site [a]
must be lower than the conformity level in each frequency range. [b]
Interferences may occur near the equipment marked with the following symbol:
  </td></tr>
<tr><td colspan="4">Note:
1 These guidelines could not apply to all situations.
The electromagnetic propagation is influenced by the absorption and reflection of structures, objects and people.
The ISM (Industrial, Scientific, and Medical) bands between 0.15 MHz and 80 MHz range from 6,765 MHz to 6,795 MHz; from 13,553 MHz to 13,567 MHz; from 26,957 MHz to 27,283 MHz; and from 40.66 MHz to 40.70 MHz.
The radio amateur bands between 0.15 MHz and 80 MHz range from 1.8 MHz to 2.0 MHz, from 3.5 MHz to 4.0 MHz, from 5.3 MHz to 5.4 MHz, from 7 MHz to 7.3 MHz, from 10.1 MHz to 10.15 MHz, from 14 MHz to 14.2 MHz, from 18.07 MHz to 18.17 MHz, from 21.0 MHz to 21.4 MHz, from 24.89 MHz to 24.99 MHz, from 28.0 MHz to 29.7 MHz and from 50.0 MHz to 54.0 MHz.</td></tr>
<tr><td colspan="4">[a] The field intensities of fixed transmitters, such as base stations for radio (cellular phones/cordless) telephones and land mobile radios, amateur radios, AM and FM radio broadcasts and TV broadcasts cannot theoretically be accurately predicted.
To assess an electromagnetic environment due to fixed RF transmitters, consider an electromagnetic survey of the site.
If the field intensity measured in the place where the NewTom DCiS sensor is used exceeds the applicable RF conformity level mentioned above, it is necessary to check the NewTom DCiS sensor to make sure of its normal operation.
If abnormal performance is observed, further measures may be required, such as reorienting or repositioning the NewTom DCiS sensor.
[b] In the frequency range from 150 kHz to 80 MHz, the field intensity must be lower than 3 V/m.</td></tr>
</table>

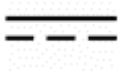
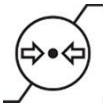
(*) The computer used with the NewTom DCiS sensor system must respect this value.

Recommended distances between the RF portable and mobile communication equipment and the NewTom DCiS sensor			
The NewTom DCiS sensor system is intended for use in an electromagnetic environment where RF irradiated disturbances are controlled. **The customer or the user of the NewTom DCiS sensor system can contribute in preventing electromagnetic interferences by ensuring a minimum distance between RF portable and mobile (transmitters) communication equipment and the NewTom DCiS sensor system as recommended below, according to maximum power output of the communication equipment.**			
Transmitter maximum nominal output (W)	**Distance according to the transmitter frequency (m)**		
	from 150 kHz to 80 MHz $d=\left(\frac{3.5}{V_1}\right)\sqrt{P}$	**80 KHz to 800 MHz** $d=\left(\frac{3.5}{E_1}\right)\sqrt{P}$	**800 KHz to 2.5 MHz** $d=\left(\frac{7}{E_1}\right)\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33
For transmitters having a maximum nominal output power not listed above, the recommended distance d in metres (m) can be estimated using the equation applicable to the transmitter frequency, where P is the maximum output power of the transmitter in Watt (W) according to the transmitter Manufacturer specifications. Note: **1** At 80 MHz and 800 MHz, it is necessary to apply the distance for the highest frequency range. **2** These guidelines could not apply to all situations. The electromagnetic propagation is influenced by the absorption and reflection of structures, objects and people.			

7. APPENDIX C: SYMBOLS / STYLISTIC CONVENTIONS

Symbols used on device labelling and/or packaging

Symbol	Meaning	Reference no.:	Standard containing the symbol:	Standard title:	Symbol description:
CE	CE mark	-	-	The sensor is designed to meet the requirements of Directive 2014/30/EC (EMC Directive) and Directive 2014/35/EU (LVD Directive).	Equipment complies with the requirements of Directive 2014/30/EC (EMC Directive) and Directive 2014/35/EU (LVD Directive)
	Important	5.4.4	ISO 15223-1 [FR Recognition no.5-117]	Medical devices - Symbols to be used in the medical device labels, in the labelling and in the information to be supplied - Part 1: General requirements.	It indicates that the user has to consult the operator's manual for important safety information such as warnings and precautions that, due to a number of reasons, cannot be indicated on the device.
	Type BF applied part	Table D.2, symbol 20 (IEE 60417-5333)	ANSI AAMI ES60601-1 [FR Recognition no.19-4]	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.	To identify a type BF applied part compliant with IEC 60601-1.
	Recycle electronic waste	N/A	EN 50419	Marking of electrical and electronic equipment in accordance with Article 11(2) of Directive 2002/96/EC (WEEE).	This device must not be disposed of as unsorted municipal waste, but must be sent to a separate collection centre for recovery and recycling.
	Manufacturer	5.1.1	ISO 15223-1 [FR Recognition no.5-117]	Medical devices - Symbols to be used in the medical device labels, in the labelling and in the information to be supplied - Part 1: General requirements.	It indicates the date of manufacture of the device. It indicates the manufacturer of the device.
IP 67 **IP 64**	IP code	(IEC 60529) Table D.3; Code 2 6.3; Table D.3; Code 2	ANSI AAMI ES60601-1 [FR Recognition no.19-4]	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.	The sensor is fully protected against penetration of dust and airborne particles. The sensor is protected from water and liquids up to and including immersion in one metre of water.
Rx ONLY	Subject to prescription	N/A	21 CFR 801.15(c)(1)(i)(F)	Labelling - Medical devices; evidence of required label statements.	It requires a prescription in the Unites States of America.
		N/A	21 CFR 801.109	Labelling - Prescription devices.	Important: In the United States of America, federal law restricts this device to sale by or on the order of a physician.
REF TYPE	Device model number	6050	IEC 60417 DB [FR Recognition no.5-102]	Graphical symbols for use on equipment.	It identifies the model number or type number of a product. In the application of this symbol, the model number or type number of the product comes with this symbol.
SN	Device serial number	5.1.7	ISO 15223-1 [FR Recognition no.5-117]	Medical devices - Symbols to be used in the medical device labels, in the labelling and in the information to be supplied - Part 1: General requirements.	It indicates the serial number of the product so that a specific device can be identified.
	See the operator's manual	5.4.3	ISO 15223-1 [FR Recognition no.5-117]	Medical devices - Symbols to be used in the medical device labels, in the labelling and in the information to be supplied - Part 1: General requirements.	It indicates that the user must refer to the operator's manual.

Symbol	Meaning	Reference no.:	Standard containing the symbol:	Standard title:	Symbol description:
	Follow the operator's manual	Table D.2, safety symbol 10 (ISO 7010-M002)	ANSI AAMI ES60601-1 [FR Recognition no.19-4]	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.	It indicates that the operator's manual/booklet must be read.
FCC ID	FCC identifier	N/A	47 CFR Chapter J §2.925	Identification of equipment.	This device complies with part 15 of the FCC rules. Operation is subject to the following two conditions: **1** This device cannot cause harmful interference, and **2** This device must accept any interference received, including interference that may cause undesired operation. For NewTom DCiS intraoral sensor FCC ID: 2AX53DC015 For NewTom DCiS docking station FCC ID: 2AX53DCDS1
		N/A	47 CFR Chapter J §2.926	FCC identifier.	
	Non-ionizing electromagnetic radiation	5140	IEC 60417 DB [FR Recognition no.5-102]	Graphical symbols for use on equipment.	It indicates generally high, potentially hazardous levels of non-ionizing radiation, or equipment or systems, for example in the electrical medical sector, that include RF transmitters or that intentionally apply RF electromagnetic energy for diagnosis or treatment.
	Direct Current	IEC 60417-5031	ANSI AAMI ES60601-1 [FR Recognition no.19-4]	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.	It indicates that the equipment is only suitable for use with direct current.
	Keep dry	5.3.4	ISO 15223-1 [FR Recognition no.5-117]	Medical devices - Symbols to be used in the medical device labels, in the labelling and in the information to be supplied - Part 1: General requirements.	It indicates a device that must be protected against humidity.
	Temperature limit	5.3.7	ISO 15223-1:2016 [FR Recognition no.5-117]	Medical devices - Symbols to be used in the medical device labels, in the labelling and in the information to be supplied - Part 1: General requirements.	It indicates the temperature limits to which the device can be safely exposed.
	Atmospheric pressure limitation	5.3.9	ISO 15223-1 [FR Recognition no.5-117]	Medical devices - Symbols to be used in the medical device labels, in the labelling and in the information to be supplied - Part 1: General requirements.	It indicates the atmospheric pressure range to which the device can be safely exposed.
	Humidity limitation	5.3.8	ISO 15223-1:2016 [FR Recognition no.5-117]	Medical devices - Symbols to be used in the medical device labels, in the labelling and in the information to be supplied - Part 1: General requirements.	It indicates the humidity range to which the device can be safely exposed.

Information on the label

The main label of NewTom DCiS sensor is available outside the package in which the sensor is delivered.
The NewTom DCiS docking station type label is applied to the bottom of the docking station. For further information, refer to the figure below.

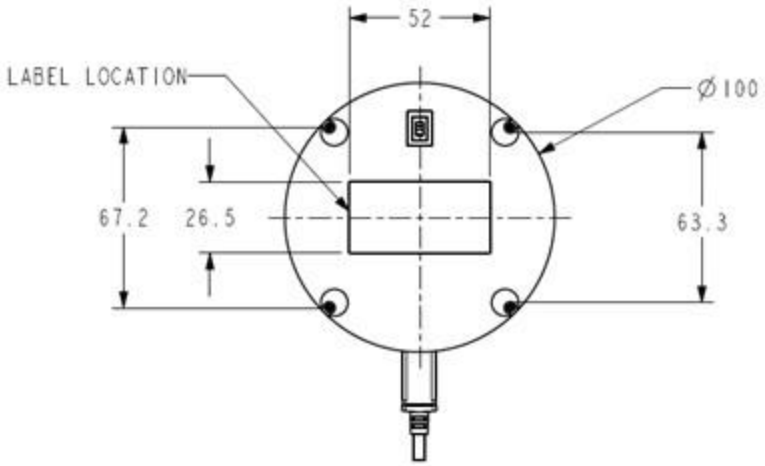


Figure 3*: Position of the label on NewTom DCiS docking station (bottom view*).

www.cefla.com