User Manual

RX4

RADIOVIDEOGRAPHY SENSOR

INDEX **page**

Radiovideography sensor RX4
User Manual

GENERAL NOTICE

The firm CSN Industrie s.r.l. shall not be held responsible for the consequences resulting from not applying the prescriptions contained in this installation manual or in the user manual, in particular for bodily damage, loss of profits, interruption of operations, loss of data or any other loss of a financial nature.

Given the continuous development of its products, CSN Industrie s.r.l. reserves the right to improve this manual and any of the products mentioned therein at any moment without need of justification or of notifying the persons concerned.

MARKING AND LABELLING SYMBOLS

SYMBOL 1

Caution, consult supporting documents
(Pic. 1)

This warning symbol "Caution, consult supporting documents" is a reference to the present document. The use of accessories which do not meet the equivalent RX4 safety requirements may incur a reduction in the level of safety of the whole system. The choice of accessories must take account of their use around the patient and the verification of their conformity with the harmonised standard EN 60 601-1 and EN 60 601-1-1. Strict adherence to the PC installation and usage requirements in this manual will ensure that the system complies with these standards.

SYMBOL 2
Type BF

(Pic. 2)

As the RX4 sensor is a type BF applied part, it is reported the corresponding standardised label on the package

This symbol means that RX4 sensor contains electronic components sensitive to electrostatic, which may damage them.
Please refer to precautions for use.

Radiovideography sensor RX4
User Manual

TRADEMARKS

RX4 is a trademark of CSN Industrie s.r.l. 's property.
Microsoft, MS-DOS and Windows are trademarks or registered trademarks of Microsoft Corporation.
All other names mentioned in this work are used only for the purposes of identification and may be trademarks or registered trademarks of their respective owners.

DESCRIPTION OF THE PRODUCT

RX4 is an intraoral sensor which is very simple to use: you just have to connect the cable to the USB port of the pc and you are ready to capture images of the highest quality.
Apical bevelled edges, rounded casing and highly flexible cable make RX4 the ideal tool for any type of positioning ensuring the highest possible comfort to your patient.
RX4 is managed by the powerful diagnostic software CSN OS which saves the scanned images directly into DICOM.

TECHNICAL CHARACTERISTICS

Applicable classifications according to standard EN 60 601-1

Type of protection against electric shock	CLASS I
Grade of protection level against electrical shock	TYPE BF
Grade of protection against penetration of liquids	Ordinary unit
Disinfection method	See the specific paragraph
Functioning method	Continous

Technical characteristics

Active area (mm):	30x20
Matrix:	CMOS
Scintillator:	CSI iodurum cesium
Resolution (pixels):	1500x1000
Line pair:	> 20
Pixel size (micron):	About 20x20
Cable length (m):	2
Image data (bit):	16

Radiovideography sensor RX4
User Manual

Functioning and storage conditions

Storage (with package)	Temperature : from -20°C to +70°C (recommended: from 15 to 35°C) Relative humidity: lower than 75% (without condensation)
Storage (sensor out of package)	It is recommended to store the sensor in a container in low humidity, away from electrostatic
Functioning	Temperature : from 0°C to +35°C **Warning** If the sensor works for a long period, its temperature could increase even of 10°C: avoid to operate with environment temperature over 35°C to prevent the sensor could exceed 45°C.
Supply through USB port	Minimum USB2.0 : DC 4,5÷5,5 V (480mA max)

LIST OF SPARE PARTS

Consumables	Disposable protection sheaths
Spare parts	- Sensor - Sensor holders

CSN Industrie, upon request, could supply the list of components as well as any other useful information to all users.

Radiovideography sensor RX4
User Manual

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CLEANING AND DISINFECTION INFORMATION

Caution: the sensors and accessories delivered are not sterile.
It is recommended that the following general rules are followed in order to guarantee maximum health safety for the patient:

– At each use, it is indispensable to apply a new protector on the sensor. This protector has the form of a finger stall that slips over the sensor.
– A new protective cover must be used for each patient. For maximum efficiency, it is recommended that protective covers which have been specially designed for the diameter and length of the sensor or handpiece be used.

Do not remove protective covers pulling the cable of the sensor. These covers have to be removed by cutting them gently or using the special tear (if provided by the covers' manufacturer).

Never place an RX4 sensor neither in an autoclave or dry heat: it will be seriously damaged. Do not sterilize with UV units.

Please carefully disinfect the sensor, the cable (the sensor side only) as well as the accessories before the use with each patient:

The disinfection procedure comprises two steps:

First level of disinfection:
- remove the protective cover from the sensor and the relevant accessories and make sure that there is no residues of blood, saliva, tissue or secretions on it.
After an accurate check:
- prepare a disinfecting solution in accordance with the manufacturer's instructions
- carefully disinfect the sensor, in accordance with the disinfection products manufacturer's instructions.

Second level of disinfection:
The final disinfection procedure must be carried out in the event the protector is torn or if there is any residue of blood, saliva, secretions or tissue on the sensor.
- prepare a disinfecting solution according to the manufacturer's instructions.
- remove any residue and clean the sensor by rubbing it carefully with soap and water
- carefully disinfect the sensor, in accordance with the disinfection products manufacturer's instructions.

Warning: avoid the immersion of the sensor in liquids for cleaning. It is allowed immersion in water, but only for few seconds.

Radiovideography sensor RX4
User Manual

Disinfection products

It is recommended cleaning with 70% isopropyl alcohol.

Note: According to the Medical Devices Directive, disinfection products are considered as "device accessories" and consequently fall within the scope of the Directive. First level disinfection products (this requirement does not relate to final disinfection) must not contain aldehydes.
CSN Industrie s.r.l. recommends the use of CE marked disinfectants.

Radiovideography sensor RX4
User Manual

INSPECTIONS AND VERIFICATION OF THE IMAGING SYSTEM ACCORDING TO CURRENT STANDARD

CSN Industrie s.r.l. does not consider himself responsible for the effects on safety, reliability and performances of the products if:

− Assembly operations, extensions, readjustments, modifications or repairs are not carried out by persons authorized by him
− The electrical installation of the relevant room does not comply with appropriate requirements
− The products are not used in accordance with the instructions for use.

RX4 sensor has been designed in compliance with the European and international medical standards.

To avoid any risk to the user and to the patient, any system associated to the RX4 must be CE marked (see details on – Hardware installation chapter).

Contents of the kit: sensor, sensor holders/protective sheaths, wall support.

Check the conformity of the electricity network with current standards in the country of installation.

Guarantee, transportation and safety conditions
Our products are guaranteed ex-works in their original packaging. The firm CSN Industrie s.r.l. may not be held responsible for any damages resulting from transportation.

DIRECTIVE 93/42/ECC CONCERNING MEDICAL DEVICES

RX4 sensors are products belonging to Class I of the Directive on Medical Device: it is an active device, invasive by natural orifice, for temporary use, and intended for diagnostic purposes. The applicable European norms are the General Safety and Electromagnetic Compatibility regulations (EN 60601-1 and collaterals). RX4 is considered as an ordinary device according to the degree of protection against harmful penetration of water.

CSN INDUSTRIE

HARDWARE INSTALLATION

Enviroment
After the installation, the system must not present any risk for the patient or the operator. That is why:

- The PC in which our imaging systems are installed, as well as all its peripherals, must be CE marked (IEC 950). Otherwise, all equipments not complying with its standard must be connected to an insulation transformer (IEC989 - holding voltage 1500 V) in a permanent manner (the piece or pieces of equipment must not be separable from the transformer except with the help of a tool).
- Verify in the documentation of the pieces of equipment associated with the RX4 that there is no limitation of use that might concern the safety of persons.
- The PC and all pieces of equipment connected to it must be placed outside of the patient's environment (more than 1.50 meters (5 feet) from the chair).
- Only the sensor, handpiece and x-ray generator can be in the patient vicinity (as they are marked CE/IEC 601-1).
- If the pieces of equipment to which the RX4 is connected are connected to the power supply via a multiple outlet extension, the latter must not be placed on the floor and only elements of the system may be connected to it.
- These elements must not be separable from the multiple outlet extension except with the help of a tool, or the multiple outlet extension must be connected to an insulating transformer (IEC989 – Holding voltage 1500 V).
- This multiple outlet must be designed for a current of at least 2200 VA.

Refer to your computer's installation manuals for instructions on the IT system (PC and screen). You must leave enough space around the central unit to allow it to be properly ventilated. For the best image quality and visual comfort, it is recommended that you turn your screen away from direct reflections (interior or exterior lighting).

CAUTION: all the standard USB characteristics have been taken into account at the design time. Despite this, some PC and computer manufacturers could produce PC partially compliant to these standards.
Csn Industrie s.r.l. therefore does not consider himself responsible in case of such wrong configurations (PC, motherboards).

Additional earth connection
No specific installation is required.

Additional safety measures to be applied on installation
Mobile mains socket outlets for multiple sockets:

Depending on the power consumption of RX4 system, ensure that it is compatible with the power which the outlet for multiple sockets can support.
Mobile mains sockets outlets for multiple sockets must not be placed on the ground.

Radiovideography sensor RX4
User Manual

The mobile mains sockets outlets supplied with the system must only be used to provide power to apparatus which is part of the RX4 system.

If another piece of apparatus is plugged into the RX4 system multiple socket, excess electrical consumption may cause damage, such as causing the cabling and the connectors to melt or creating a risk of electrocution.

Installing the sensors:
Insert the connector of RX4 into the USB port of the pc.
External unit:
It is possible that a pc could not supply necessary power to power the sensor through the USB port. In this case it is necessary the use of an external unit (hub).
It is recommended to switch off the low voltage power supply when you finish to work.
Switching on and switching off
To switch on or off the parts of the system it is necessary they are all switched off (PC and external unit, if any).

ELECTROSTATIC DISCHARGES

– When the RX4 sensor is not connected to the PC, it should be placed in its holder or in its case.
– Do not touch the display screen and the RX4 sensor simultaneously as this may severely damage the sensor.

MINIMUM SYSTEM REQUIREMENTS

Operative system	Windows XP® SP3, Windows Vista (32/64 bit) SP2, Windows 7 (32/64 bit) SP1
CPU	Intel Centrino Duo
Memory	4GB RAM
USB port	2.0
Free space on HD	80 GB
Video memory	512 MB

MONITOR QUALITY

Different monitor sizes (15", 17", 19", 21") as well as different tubes qualities (standard, high contrast, high definition) are available for computer today. RX4 image quality is proportional to tube quality. To obtain the highest level of performance, you should use a high contrast and high definition monitor.

Radiovideography sensor RX4
User Manual