



User Manual

RADIOVIDEOGRAPHY SENSOR

RX2 HP

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INDEX	page
GENERAL NOTICE	3
MARKING AND LABELLING SYMBOLS.....	3
TRADEMARKS	3
TECHNICAL CHARACTERISTICS.....	4
LIST OF SPARE PARTS RX2 HP	4
HEALTH AND DISINFECTION INFORMATION.....	5
INSPECTIONS AND VERIFICATION OF THE IMAGING SYSTEM ACCORDING TO CURRENT STANDARD	6
DIRECTIVE 93/42/ECC CONCERNING MEDICAL DEVICES	6
HARDWARE INSTALLATION	8
ELECTROSTATIC DISCHARGES.....	10
MINIMUM SYSTEM REQUIREMENTS	10
MONITOR QUALITY.....	10
DECLARATION OF CONFORMITY	11

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

A warning standardised label (see figure 1: symbol 1) (supplied with each kit) must be placed so as to be clearly visible on any medical apparatus, such as the PC containing the RX2HP card, which is part of the system and liable pose a risk of electric shock.

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 RX2HP 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 RX2HP sensor is a type BF applied part, it is reported the corresponding standardised label

TRADEMARKS

RX2 and RX2 Mega Px are 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.

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	Continuous

Functioning and storage conditions

Functioning	Temperature: 0°C to +50°C Relative humidity: 30 to 75%
Storage	Temperature: -20 to +70°C
USB port power supply	USB1.1 : DC 4,5÷5,5 V (420mA max)
	USB2.0 : DC 4,5÷5,5 V (480mA max)
External card power supply (<i>option</i>)	5 VDC ≥1A EIAJ RC5320A connector, voltage class 2; internal device.
Classification	Class I, Type B

LIST OF SPARE PARTS RX2 HP

Consumables	Disposable protection sheaths
Options	- 1.5 m (around 5') sensor extension cable - 8 m (around 26') sensor extension cable
Spare parts	- Sensor - Support kit - USB cable - Low tension power supply (option)

CSN Industrie engage himself to give to all the user, on demand, the list of the components or any other helpful information.

HEALTH 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.

Never place an RX2 HP sensor in an autoclave: it will be seriously damaged.

The RX2 HP sensor and accessories must be carefully disinfected for 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.

Disinfection products

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.

First level of disinfection:

MICRO 10 PLUS or similar product:	Watery disinfectant containing quaternary ammonium compounds, not ionic surface-active agents and cleansing alkaline compounds.
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Second level of disinfection:

HELIPUR H PLUS N or similar product:	Watery concentrated disinfectant for instruments with aldehydes, surface-actives and alcohol.
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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.

The RX2HP imaging card has been designed to comply with the European and international medical standards.

To avoid any risk to the user and to the patient, any system associated to the RX2HP must be CE marked (see details on – Hardware installation chapter).


Content of kits: refer to the check list delivered with the hardware.

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

	<p>RX2HP is a product 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). RX2HP is considered as an ordinary device according to the degree of protection against harmful penetration of water.</p>
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HARDWARE INSTALLATION

Environment

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 RX2HP 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 RX2HP 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: the supplied boards are PCI standard, that means it has been taken into account all the standard characteristics at the design time, particularly the size of the slots. Despite this, some PC and computer material manufacturers are producing motherboards with inaccessible slots PCI because of a wrongly positioned component on the motherboard.

Csn Industrie s.r.l. therefore does not consider himself responsible in case of such wrong configurations (PC, motherboards).

However for information only, in case it is impossible to insert the board RX2HP PCI CE in one of the available slots relative to one of these configurations, it is recommended to try and to verify the other slots PCI.

Additional earth connection

No specific installation is required.

Additional safety measures to be applied on installation

Mobile mains socket outlets for multiple sockets:

Radiovideography sensor RX2 HP
User manual

Depending on the power consumption of RX2 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.

The mobile mains sockets outlets supplied with the system must only be used to provide power to apparatus which is part of the RX2HP system.

If another piece of apparatus is plugged into the RX2HP 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 acquisition USB box of the RX2 HP system

The PC must be equipped with a suitable USB interface. Connect the USB module to an USB port using the USB cable included with the RX2 HP sensor.

Installing the sensor

Insert the RX2 HP sensor connector into the external unit (ref. 2).

Power supply for RX2 HP cards

It is possible a personal computer can't supply the USB modul necessary power. In this case is necessary to use an external power supplier.

We recommend to switch off the low tension power supply when you finish to work.

Switching on and switching off

To use the RX2 HP sensor the USB module must be switched on (position I of the On/Off power button).

To connect or disconnect the system parts is necessary they are all switched off (PC and external unit).

Switch

It has 3 positions:

left:	switched on, powered by USB cable;
middle:	switched off;
right:	switched on, powered by external unit.

Light indicator (LED)

On USB module there is a LED indicating the follow operative modalities:

switched off:	suspend mode (USB module not active);
red:	idle/sleep mode (the module is switched on but it isn't powering the sensor);
orange:	standby mode (the module is waiting for acquire an image);
green:	data transfer mode (the module is sending to the PC the acquired image).

ELECTROSTATIC DISCHARGES

- When the RX2HP 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 RX2HP sensor simultaneously as this may severely damage the sensor.

MINIMUM SYSTEM REQUIREMENTS

Operative system	Windows XP®
CPU	Pentium4® o later
Memory	512MB RAM (1.024MB reccomended)
USB port	2.0 (with eventually compatibility 1.1)
Free space on HD	20GB, 80GB reccomended
VRAM	32MB, 128MB reccomended

The RX2 HP image display needs a minimal resolution of 1024x768 and 16M colours (colours 32 bit).

Caution:

when you use SVGA Plug & Play cards and Plug & Play monitors, the monitor's refresh rate is gauged on the maximum supported frequency (between 75 and 100 Hz).

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. RX2HP image quality is proportional to tube quality. To obtain the highest level of performance, you should use a high contrast and high definition monitor which can be recognised by its deep black tube. As the monitor is the last link in the digital radiology chain you should pay very close attention to it.