

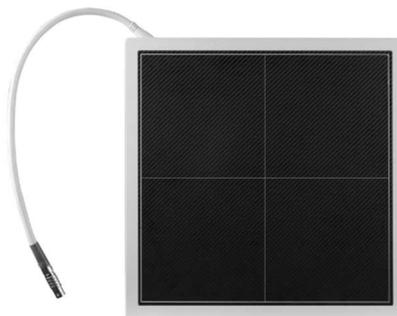
RAPIXX 4343M1i Set RAPIXX 4343M2i Set RAPIXX 4343V1i Set RAPIXX 4343V2i Set

Digital X-ray detector system

Model/ID: 4495-9-0000L
4496-9-0000L
4495-9-1000L
4496-9-1000L

Installation & User Manual

Ident. Nr. 5441-0-0004



CE 0297

Please note:

The CE marking is an EU directive compliance mark and may only be affixed to products for which a directive applies, which provides the CE marking.

At PROTEC these are medical devices that are intended for use in human medicine. For the identical products which are intended for use in veterinary medicine, the CE marking is excluded.

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Note

The information contained in this document conforms to the configuration of the equipment as of the date of manufacture. Revisions to the equipment subsequent to the date of manufacture will be addressed in service notes distributed by PROTEC GmbH & Co.KG.

Document Version

Revision	Date	List of revised pages	Comments
1.0	January 2015	---	First edition Installation Manual
2.0	29/01/2016	all	Widening to Installation and User Manual
3.0	04/05/2016	6, 9, 20, 23	Safety instructions, chapter 13
4.0	Sept. 2016	Title page, 6, 8, 20	CE note, note residual risk, use note, caution handling

Mechanical and Electrical Warning

All of the **movable assemblies and parts of this equipment** should be operated with care and routinely inspected in accordance with the manufacturer's recommendations contained in the equipment accompanying documents. Maintenance and service is only to be performed by technicians authorized by **PROTEC GmbH & Co. KG**.

Touching electrical live parts can be lethal.

Do not remove flexible high-tension cables from X-ray tube housing or high-tension generator and/or access covers from X-ray generator.

For all components of the equipment protective earthing means must be provided in compliance with the national regulations.

Failure to comply with the foregoing may result in serious or fatal bodily injuries to the operator or those in the area.



Caution! Electrostatic sensitive device.
Handling instructions have to be respected!

Radiation Warning

The component of the equipment described within this document is part of a system for the intended generation of X-rays for medical diagnosis.

X-rays generate a potential risk for both patients and operators.

For this reason the application of X-rays for a given medical purpose must aim at the minimization of radiation exposition to any persons.

Those persons responsible for the application must have the specific knowledge according to legal requirements and regulations and must establish safe exposure procedures for these kind of systems.

Those persons responsible for the planning and installation of this equipment must observe the national regulations.

To the User

The user of this document is directed to read and carefully review the instructions, warnings and cautions contained herein prior to beginning operation, installation or service activities. While you may have previously operated equipment similar to that described in this document, changes in design, manufacture or procedure may have occurred which significantly affect the present operation.

The installation and service of equipment described herein is to be performed by authorized, qualified **PROTEC GmbH & Co. KG** technicians.

Although the product was subject to a risk analysis and the design corresponds to the current state of the art, residual risk will remain in clinical use. These are displayed in the following user manual by application limitations, contraindications, warnings and precautions.

Technicians and other persons not employed by nor directly affiliated to **PROTEC GmbH & Co. KG** technical services are directed to contact the local **PROTEC GmbH & Co. KG** office before attempting installation or service procedures.

Improvement Recommendations

Users of this document are encouraged to report errors, omissions and improvement recommendations to **PROTEC GmbH & Co. KG**.

1 General

1.1 Inspection of delivery packaging

Check the packaging for any damages.

1.2 Inspection of the scope of delivery

Please check if the system has been completely delivered.

Following parts should be included:

- Detector RAPIXX 4343M1i or RAPIXX 4343M2i
- Power supply
- Syncbox
- Network interface card
- Cables (5m Sub-D, 2m network)
- USB to RS232 Converter cable
- Handle grip
- Connection cable for detector (7m)
- CONAXX 2-CD
- Ferrite core

1.3 System requirements

For an optimal use of the DR detector it is necessary that the PC fulfils the system requirements described in the document "System requirements".

Note:

To ensure a correct image transmission please only use the delivered network card.

For an optimal adjusted installation, the following things are recommended:

- Deactivate WLAN adapter
- Uninstall the Antivirus program
- Detector cable & network cable should not be in the same cable channel together with the HVG cable from the generator. The HVG cable from the generator should be placed differently
- Using the ferrite core
- The Detector must be separately grounded in the Bucky
- Firewalls should not influence the system performance of the PC. This effects software firewalls the same as hardware firewalls.

1.4 Environmental Conditions

1.4.1 Operating Conditions

Temperature: 5 °C – 40 °C

Humidity: 30% RH - 75% RH

Atmospheric pressure: 700 hPA – 1060 hPA

1.4.2 Storage Conditions

Temperature: -20 °C – +60 °C

Humidity: ≤ 93% RH

Atmospheric pressure: 700 hPA – 1060 hPA



Caution!

When the flat panel sensor is used in high temperature condition for long period of time, it may cause image artefacts and/or failure of the device.

2 Description of the RAPIXX DR-systems

2.1 General Description

The digital X-ray detector systems of the RAPIXX series are assembled of single components, which are separate medical devices. To fulfil their intended use they must be combined together. The system components are listed under point 1.2 in this manual.

2.2 Intended Use

The digital X-ray detector systems of the RAPIXX series are intended for acquisition, processing and data transfer of digital conventional X-ray images. They are used as a system component of digital X-ray system, which is used. In the diagnostic human medicine (e.g. radiology departments, orthopaedics, surgery, emergency surgery and urology) in a healthcare facility.

2.3 Intended User Group

The digital X-ray detector systems of the RAPIXX series are only intended for the usage by professional users, which are specially trained on the operation of diagnostic X-ray units, according to the correspondent national requirements and which are instructed into the appropriate operation (usage and operations as well as in permitted connection with other medical devices, objects and accessories). Adequate user groups could be radiologists, X-ray technicians, radiological assistants, orthopaedists, surgeons, emergency surgeon, urologists and other medical trained staff.

2.4 Use Note

The digital X-ray detector systems of the RAPIXX series are also adapted and ready to use for the veterinary area. The CE marking is only for use in the human medicine and is excluded for use in the veterinary medicine.

2.5 Combination with other products

The digital X-ray detector systems of the RAPIXX series are subsystems, which must be put together/combined with other products to an X-ray system to fulfil their intended use.

Required combination products:

- High-frequency generator
- X-ray tube
- Collimator
- PC and monitor

Optional combination products:

- Ionisation measuring chamber
- Anti-scatter grid
- Dose area product meter
- Bucky (for moving anti-scatter grid) / grid entity (for fixed anti-scatter grid)
- X-ray table
- X-ray stands (wall stand/table stand/ceiling suspension)
- PACS software

3 Important notes for the preparation of the detector installation

3.1 General Information

- Do not use cable extensions
- Use only the delivered network cables or at least CAT 6 cables
- Anti-scatter grid:
 - o Use grid with ratio 12:1 and 40 lines/cm
 - o For radiology use source image distance (SID) 120cm and 180cm. For orthopaedics use 120cm SID or 150 cm if chest X-rays are taken as well. Just one grid for all SIDs is not sufficient.



PROTEC GmbH & Co KG is not liable for the selection of the used anti-scatter grid

3.2 Notes for installing a new digital X-ray system

- The generator cut-off dose should be in the range between 3.0 and 3.3 μ Gy.

3.3 Notes for upgrading an existing CR- or analogue X-ray system

- Increase the generator cut-off dose to 3.2 μ Gy at least.
- Adjust the values of the organ programs for exposures under table, which had been exposed on the table before.
- Check all old components on site which are located inside the ray path:
 - Replace wood cover plate by new cover plate made of carbon
 - Use state-of-the-art HF generators
 - Check grounding of detector grid entity/Bucky and panel
 - Check the swivel of swivel arm installations if there are any kinks in the cables
 - Check measurement chamber if it is capable for DR

4 Installation

4.1 Check list

If PROTEC GmbH & Co. KG already prepared the installation, only the following sub-chapter from this chapter must be considered:

- 4.5 Modification of the x-ray unit
- 4.6 **Fehler! Verweisquelle konnte nicht gefunden werden.**

Then proceed with chapter 5 *Calibration of the DR system* on page 17.

4.2 Installation of the network interface card (NIC)

Switch of the PC and open the chassis. Plug in the NIC at the free PCI Express slot and close the chassis. Please be aware of the possibility of electrostatic discharging.

4.3 Placing the Ferrite core

Please place the ferrite core to the detector cable at the power box to minimize the electronic interference.



4.4 Installation of CONAXX 2

Install the CONAXX Software. During installation of CONAXX please select the driver "RAPIXX 4343M1i/-M2i".

Note:

Check the "CONAXX 2 Installation Manual" for detailed CONAXX installation information.

4.5 Modification of the x-ray unit

4.5.1 Installation with automatic exposure detection

In this mode no synchronization between detector and X-ray generator is needed.

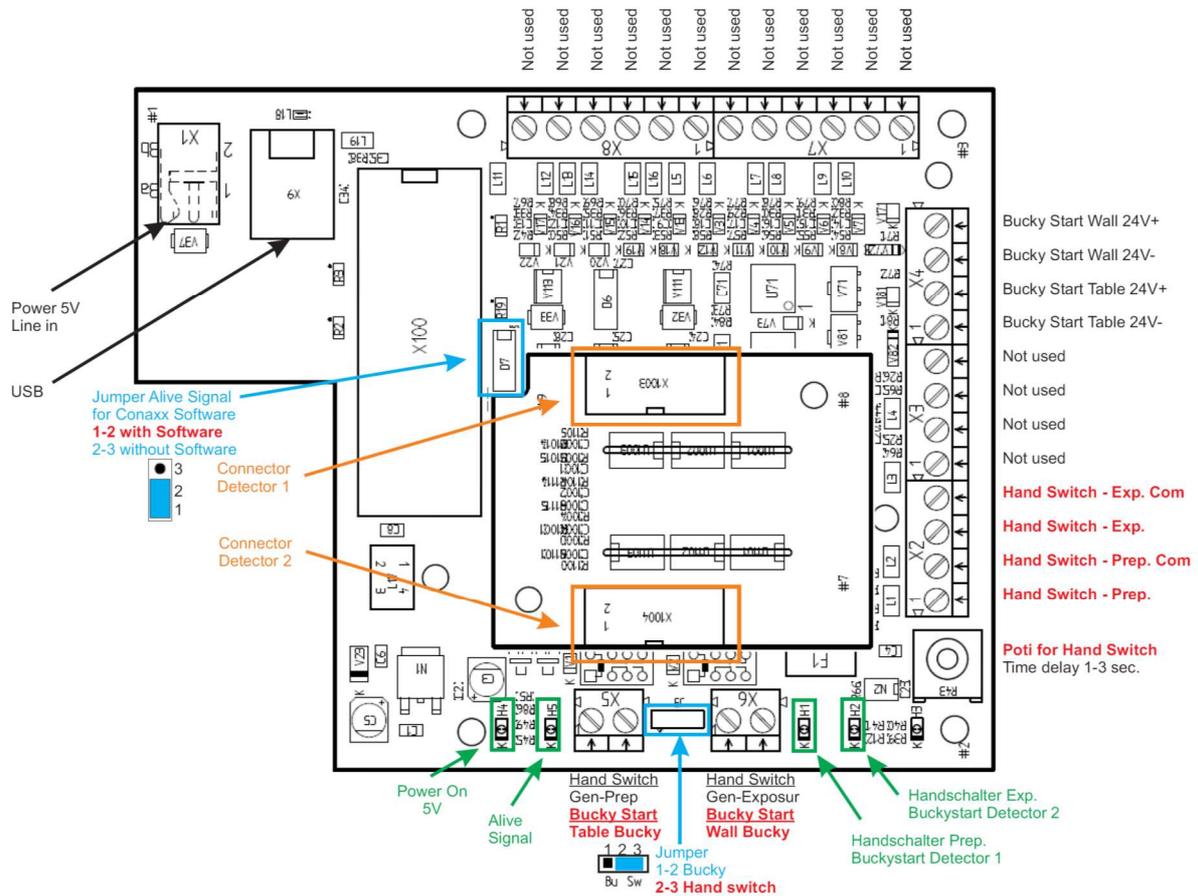
4.5.2 Installation with hand switch

Connect the delivered generator cable between Sync Box and X-ray generator. For the generators side use the following pin definition:

Red:	Preparation	(PREP)
Black:	Common	(COM)
White:	Exposure	(RAD)

4.5.3 Installation with hand switch (Interface-Box)

Connect the hand switch and the x-ray equipment inside the Interface box as labeled at the connectors.

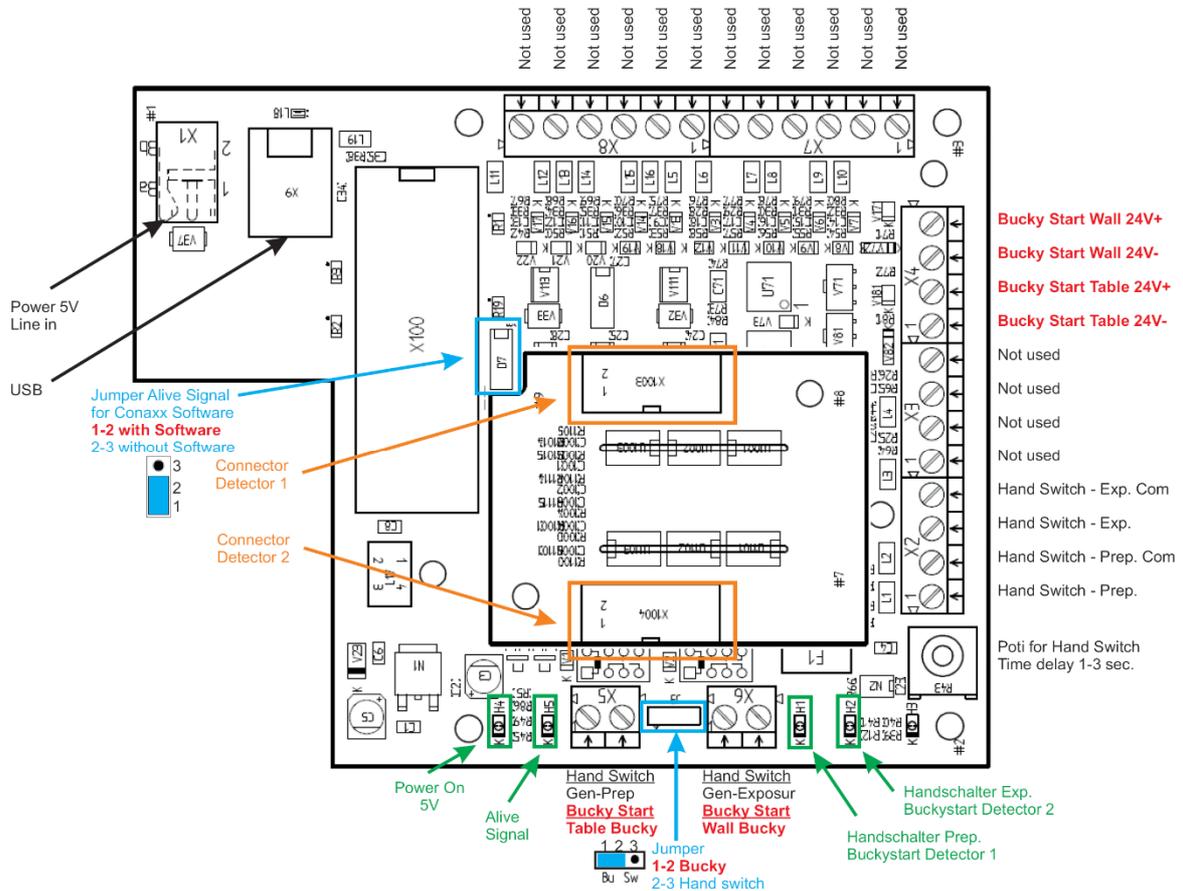


Proceeding:

1. The Interface box has to be disconnected from the electrical power.
2. Open the Interface box by unscrewing the screws.
3. Guide the cable from the hand switch and from the x-ray equipment through the cable feed through.
4. Connect the cables to the screw terminals according to the connecting diagram.
5. Now close the Interface box with the screws.

4.5.4 Installation with BUCKY START

Connect the bucky and the x-ray equipment inside the Interface box as labeled at the connectors.



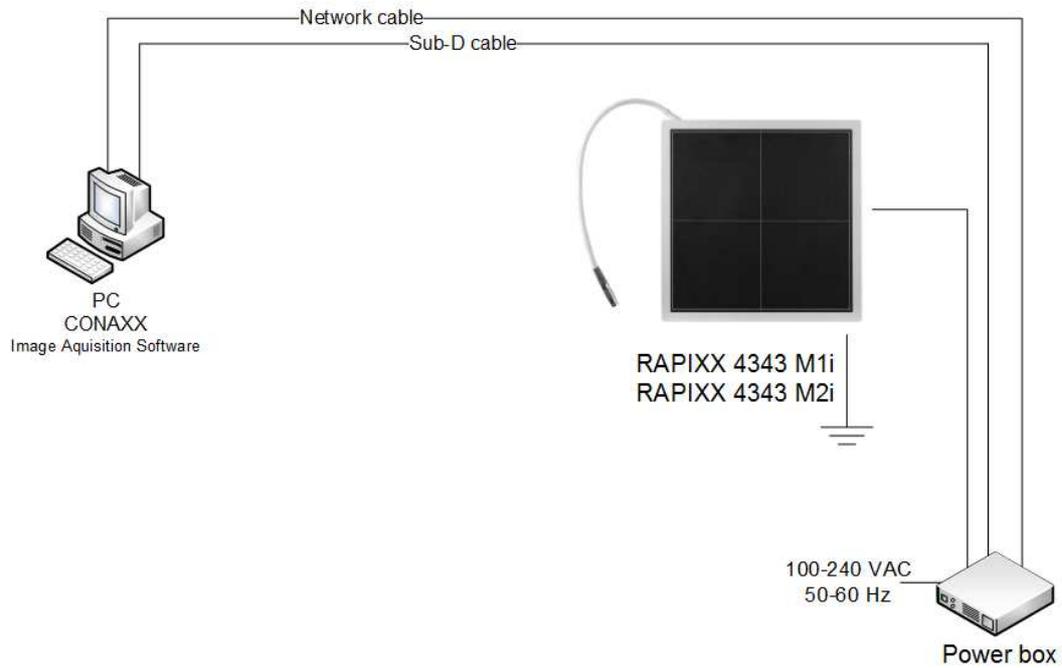
Proceeding:

6. The Interface box has to be disconnected from the electrical power.
7. Open the Interface box by unscrewing the screws.
8. Guide the cable from the bucky and from the x-ray equipment through the cable feed through.
9. Connect the cables to the screw terminals according to the connecting diagram.
10. Now close the Interface box with the screws.

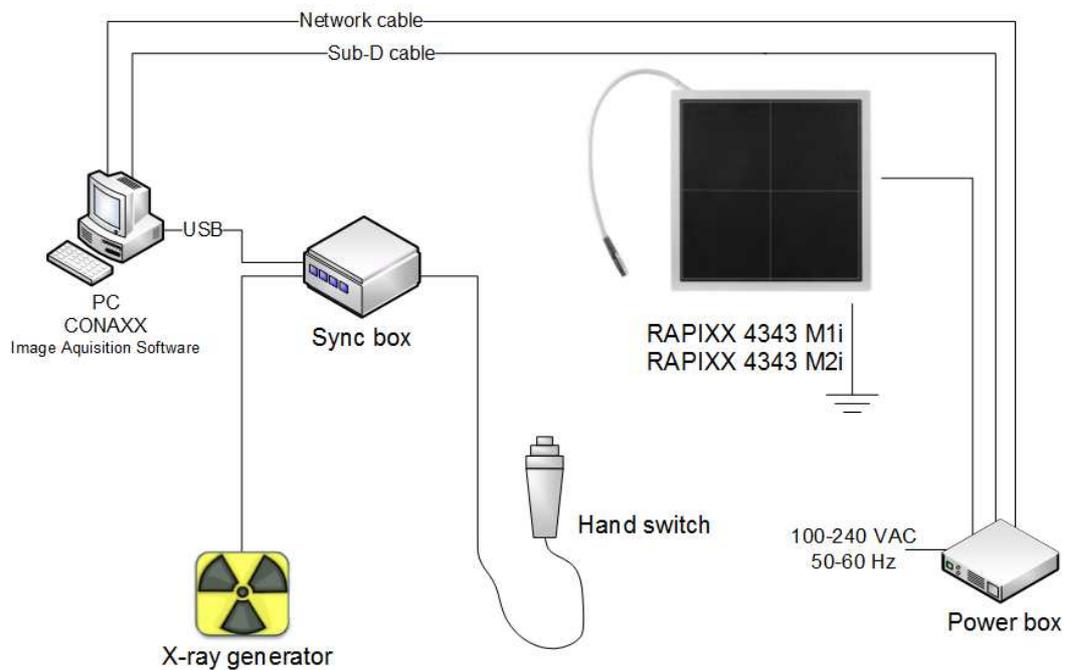
4.6 Connection of the components

Connect the components as described in the following diagrams.

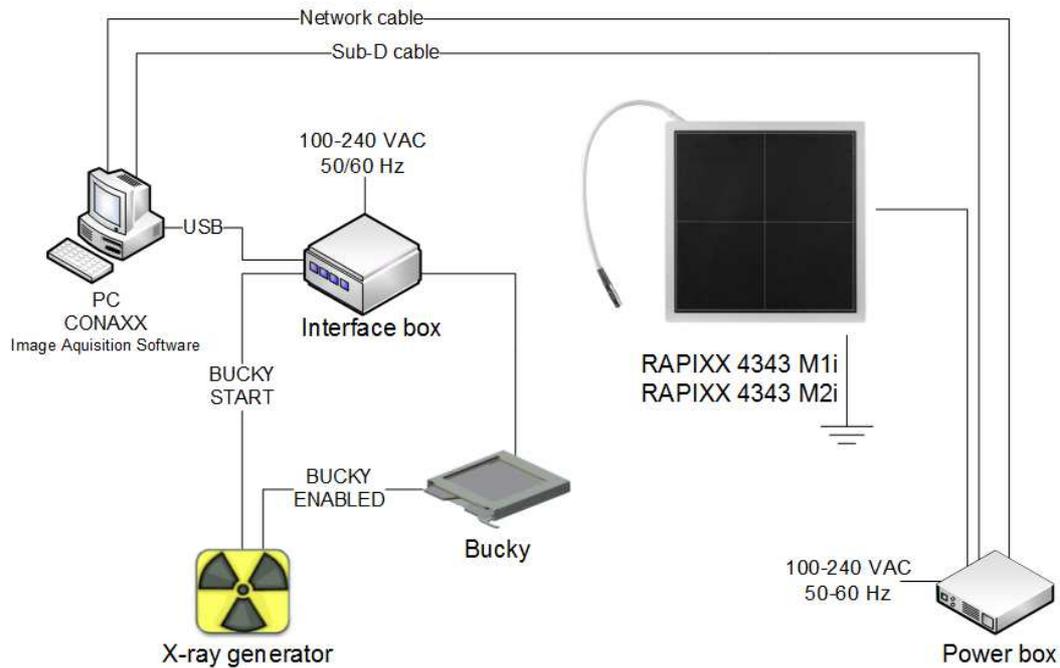
4.6.1 Installation with automatic exposure detection (RAPIXX 4343 M1/M2i)



4.6.2 Installation with hand switch (RAPIXX 4343 M1/M2i)



4.6.3 Installation with BUCKY START (RAPIXX 4343 M1/M2i)



4.7 First start of CONAXX 2

Start CONAXX 2 with a double click on the desktop icon. Check the document "CONAXX 2 User Manual" for more details.

4.7.1 Necessary settings in CONAXX 2

After the first start of CONAXX open the configuration by clicking the button "Configuration" in the start menu of CONAXX and change to the section "System > Modality".

Select in the area "Selected Modality" the Detector that you would like to use, e.g. „RAPIXX 4343 M1i“

Depending on how the detector is build in it might be necessary to rotate the acquired images in CONAXX. This can be changed in "Rotation of images" in the same configuration section.

For the detector "RAPIXX 4343 M1i/M2i" you have to select the used "serial port".

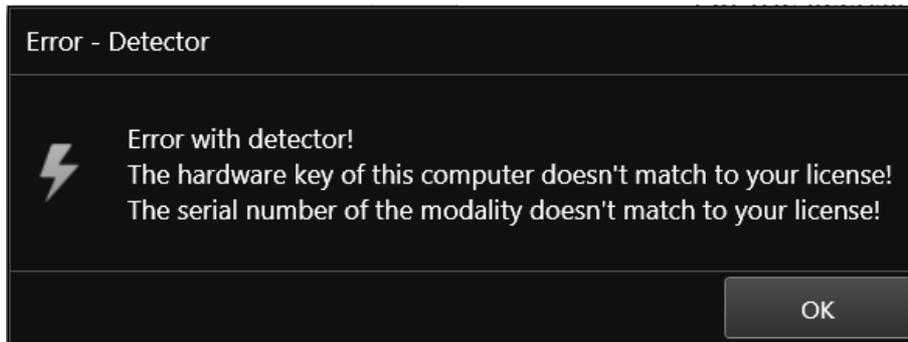
In case of using the Interface Box and for synchronization via the signal BUCKY START instead of a hand switch activate the option "InterfaceBox uses BuckyStart".

In case of using automatic exposure detection activate the according option.

Afterwards please restart CONAXX.

4.7.2 Licensing of CONAXX 2

After the restart of CONAXX 2 a message that the license does not fit to the system appears.



Confirm this message.

Note:

For the licensing procedure it is necessary that CONAXX 2 can communicate with the detector. Please do not change the system environment (network card, connected detectors ...) because this can make the license invalid. In case of using more than one detector please connect all detectors to the computer.

Open the configuration of CONAXX 2 by clicking the button "CONFIGURATION" in the start menu of CONAXX 2 and change into the section "SYSTEM > REGISTRATION". In the section "GENERATE HARDWARE KEY" select the function "SAVE KEY AS..." to create a license request. In the next step please choose the type of licensing.



CONAXX 2 supports two different types of licensing:

Type of licensing	Properties
Detector-based	This type will linking the license with the detector.
Computer-based	This type will linking the license with the computer.

In case of having no question to choose the type of licensing, the detector supports computer-based licensing only.

Note:

The module "Advanced image processing (AIP)" is always linked to the computer. It is not possible to use it on other computers, even if the detector-based licensing is used.

There are two ways to send the hardware key:

- a) Online with the licensing page of the dealer backroom or
- b) by e-mail

For the online licensing, please login to the dealer backroom and navigate to the page "LICENSING". Select the desired license and upload the hardware key with the function "SET". Download the license afterwards with "GET".

For the licensing by e-mail, send the hardware key to mis@protec-med.com. You will then get the valid license key by e-mail.

This license file can be imported with the function "Import license..." in the section "SYSTEM > REGISTRATION" of the CONAXX 2 configuration.

Now restart CONAXX 2. CONAXX 2 is now ready to acquire images with the detector. The proceeding with the DR system is described in the document "CONAXX 2 User manual".

4.8 Setup dose indicator for detector

For each detector the document "RAPIXX calibration values" is included. Follow the instructions in the document to setup the dose indicator.

5 Calibration of the DR System

Note:

For the calibration make sure that the detector runs at least 2 hours so that a sufficient operating temperature is reached.

General note for calibration:

- use the maximum SID that you might use for a real exposure
- open the collimator so that the complete area of the detector is exposed
- try to always use 70kV for all calibration exposures
- In case a fixed anti-scatter grid is installed, please take it out for calibration. A movable grid is not supported. The ionization chamber can also remain in the system for calibration.
- perform "Gain calibration" every 6 months

Start the program "RAPIXX Calibration" from the start menu "CONAXX2\DR-Panel". In the "Configuration" menu the Interface Box must be configured. For the RAPIXX 4343 M1i/M2i the serial port must be configured. After saving the settings the connection to the detector can be established with "Calibrate Detector 1".

In the first step the offset calibration must be done ("Create offset file"). The detector will acquire multiple images without x-ray radiation. After the offset calibration a status window will be shown.

The gain calibration will be started with "Create gain file" and each exposure must be prepared with the button "Prepare". Please follow the screen instructions and perform 9 exposures without any object on the detector. After the gain calibration a status window will be shown.

While the defect calibration the detector will acquire multiple images without radiation. After that please follow the screen instructions and perform 5 exposures with radiation. After finishing the defect calibration the whole calibration is complete.

The software "RAPIXX Calibration" can be closed.

6 Status information

Status area of CONAXX 2

This area provides status information and tools for different components:



- **System:**
This functions shows status information of the system (e.g. used disk space)



- **Modality:**
This function opens the tool box for the connected modality. It provides functions to recover or close the connection to the modality, calibration functions or status information for the battery charge level.

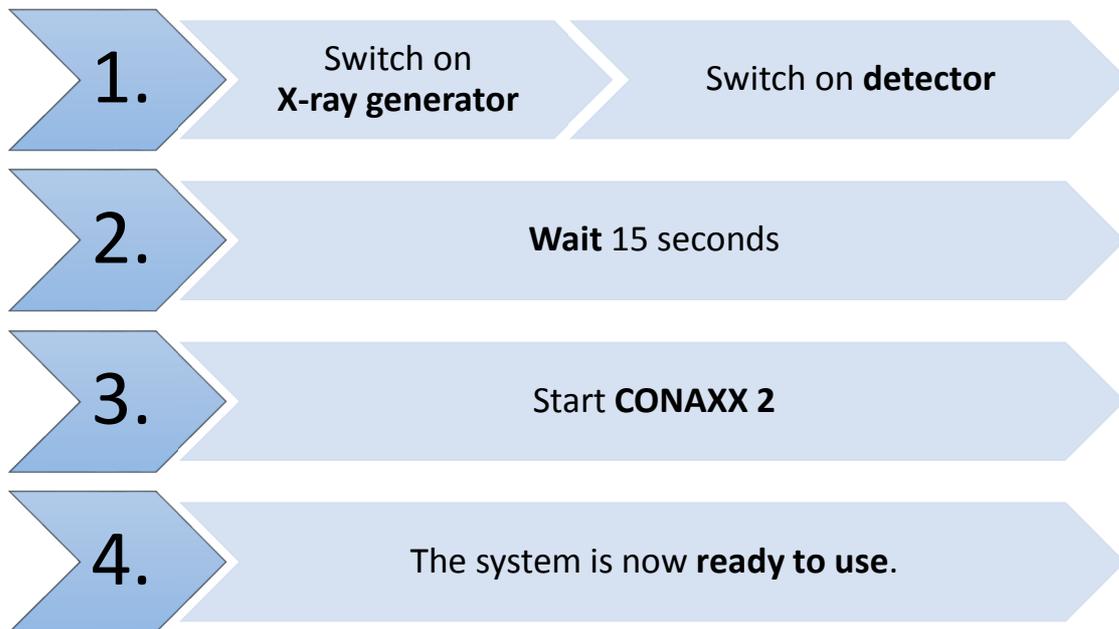


- **X-ray generator:**
This functions opens the x-ray generator control. It can be used for exposures without using the modality.

7 Handling of the RAPIXX 4343M1i and RAPIXX 4343M2i system

7.1 Operation of the RAPIXX DR system

7.1.1 Startup order for daily use



If CONAXX 2 cannot connect to the modality or generator after launching the program there will appear an error message. In this case, CONAXX 2 has to be restarted to initiate a new connection. Further hints you can find in the indicated error message.

If no error message appears after starting the program, the connection was established successfully.

7.1.2 Error during operation with the X-ray generator

Should an error appear during the daily operation with the X-ray generator, the error message will show hints to solve the problem.

Is the connection to the generator during operation with CONAXX 2 interrupted, CONAXX 2 has to be restarted to establish a new connection. If no error message appears after the restart, the connection has been established successfully and the generator can be used.

7.1.3 Error during operation with the modality

Should an error appear during the daily operation with the modality (e.g. communication error, power blackout), the error message will show hints to solve the problem.

Is the connection to the modality during operation with CONAXX 2 interrupted, CONAXX 2 has to be restarted to establish a new connection. If no error message appears after the restart, the connection has been established successfully and the modality can be used.

7.2 Operation of the CONAXX 2 software

Detailed information please find in the enclosed user manual of the CONAXX 2 software.

Note

To keep the image quality and the battery power in wireless detector systems optimally, it is recommended to click the "Start exposure" button in the CONAXX 2 software first, when everything is prepared for the exposure (e.g. patient positioning) and the X-ray system is ready to release.

7.3 Operation of the detector with accessories

Detailed information please find in the enclosed original user manual *UserManual Venu 1717M Manual* of the detector manufacturer.



Caution!

In case of receiving technical incorrectly images (e.g. missing image content, stripes structures) the complete X-ray system must be restarted. Please make afterwards a test exposure without any patient. For a further regularly usage of the system please ensure that the taken exposure is correct. If not inform your technical contact person.

8 Safety and Maintenance

8.1 Introduction

In this chapter, you will find details regarding safety and maintenance, which is required to ensure the correct and reliable function of the system after the initial installation.

8.2 Cleaning and disinfection

Please turn off power of the Detector and unplug power cord of adapter before cleaning.

Never use alcohol ether and other flammable cleaning agent for safety. Never use methanol, benzene and acid because they would corrode the equipment.

Proper disinfection requires that a disinfectant solution be used; such as Sani-Cloth® Plus, a hospital grade, EPA registered low to intermediate-level product for hard, non-porous surfaces and equipment.

Don't dip the product into liquid.

Please make sure that the surface & plugs are dry before turning on.



Caution!

The use of corrosive or abrasive cleaning agents as well as solvents is not allowed. These materials can cause damage to the outer surface of the unit or to the coating of the individual components.

Do not use an excessive amount of ethanol (or neutral detergent), as doing so may allow the liquid to enter from the gap on the outer surfaces, resulting in the damage to the flat panel sensor, or cause the labels to come off.

Do not use a solvent such as thinner or benzene, as it corrodes the outer surfaces.

8.3 Checkup and maintenance

8.3.1 Daily controls prior to or during the unit operation

The detector surface must be daily checked before operating start if there are any visible damages. In case of visible damages, a technical homogeneity X-ray (without any patient) should be taken to ensure that the damages are not visible inside the image. If damages are visible inside the image, please contact a PROTEC dealer.

8.3.2 Safety-related controls

In the interest of the safety of the patient, operator and external 3rd parties, the check /control activities related to maintaining the operational safety and /or functionality of the unit are required to be undertaken in regular **12 month** intervals by the **PROTEC** service department or a **PROTEC** authorized service provider. This includes the control of the image quality as well.

It is recommended to calibrate the RAPIXX DR system every six months at least. The instruction for the calibration you can find under the chapter *5 Calibration of the DR system* in this manual.

8.3.3 Maintenance



Before opening the device always switch off the device, pull out the mains plug and check that the parts are de-energised.

Secure the device against restarting.

The required maintenance and inspection must be completed every 12 months by the PROTEC service department or a **PROTEC** authorized service provider in order to ensure the reliable operation of the unit.

As the manufacturer, PROTEC is responsible for safety-related characteristics/performance of the unit as long as the maintenance, repair and corresponding changes are undertaken by PROTEC or an expressly

by PROTEC authorized technicians and when components (related to the safety of the unit) are replaced, in the case of component failure, with original spare parts.



Only use original spare parts in case of component replacement is required.

In the case that the required maintenance is not completed as intended, **PROTEC** is no longer responsible for damages/injury to the operator and/or third party, provided that the damage is the result of improper or missing maintenance.

Prior to operation (creation of X-Ray images), the operator must ensure that all safety related mechanisms, indicators and/or switches described within the user manual are fully functional and that the RAPIXX DR system is overall operationally ready.

Detailed information about safety and maintenance you can find in the enclosed original user manual *UserManual_Venu 1717M Manual* of the detector manufacturer.

9 Liability

We hereby expressly point out, that under following mentioned situations any liability of PROTEC is excluded:

- Breach of maintenance intervals
- Operation by not trained staff
- Service and maintenance work not made by PROTEC service department or PROTEC authorized service technicians.

10 Guarantee

A 24-month full guarantee of the material and relevant corresponding components, for the entire contents of delivery, is granted from the delivery date (date the product leaves the factory). All repairs and replacement of components because of misuse and/or incorrect operation are excluded from the guarantee.

PROTEC service department or PROTEC authorized technicians may only do service and maintenance work.

11 Disposal



Do not dispose the RAPIXX DR system with household waste. All mechanical and plastic components are to be disposed of in accordance with the corresponding national guidelines. Correctly disposing of this product will help to save valuable resources and prevent any potential negative effects on human health and the environment, which could otherwise arise from inappropriate waste handling. In cases of any doubt, contact PROTEC.

12 Electromagnetic compatibility (EMC) according to EN 60601-1-2

12.1 General

- The RAPIXX DR system is, as a medical electric device, subject to particular precautionary measures in regard to EMC and is required to be installed and prepared for initial use as described within the accompanying documents.
- Portable and mobile HF- communication units can have an influence upon medical electric devices
- The RAPIXX DR system sends out electromagnetic waves during operation, which could cause interference with other devices or it could be interfered by other devices.

12.2 Detector with accessories

Detailed information to the electromagnetic compatibility of the detector and its accessories you can find in the enclosed original user manual *UserManual_Venu 1717M Manual* of the detector manufacturer.

12.3 Interface Box

Detailed information to the Interface Box you can find in the original user manual "Installation- and user manual RAPIXX Interface Box".

13 Description of symbols and abbreviations

13.1 Symbols

	Attention, consult accompanying documents
	Refer to user manual
	CE-Mark
	Classification according to EN 60601-1 (Type B)
	Electrostatic sensitive device
	Large focus
	Small focus
	System (CONAXX 2)
	Modality (CONAXX 2)
	X-ray generator
	Electrical product. Do not dispose in the household waste.

13.2 Abbreviations

mm	Millimeter
cm	Centimeter
lb.	Pound
kg	Kilogram
°C	Degree -Celsius
hPa	Hectopascal
DIN	German Industry Standard
EN	European Standard
CE	CE-Mark
Hz	Hertz
ED	Duty cycle
A	Ampere
SN	Serial number