RAPIXX 4343M1i X CC Set
RAPIXX 4343V1i X CC Set

Digital X-ray detector system

Model/ID: 4552-9-0000L
4552-9-1000L

Installation & User Manual

Ident. Nr. 5502-0-0004

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 exclude

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NOTE

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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 updates distributed to the PROTEC Technical Service Organization.

Document Effectivity

Revision No.	Date	List of effective pages	Comments
1.0	21/01/2019	all	Original issue
2.0	2020-06-30	19; 27	NOTE Calibration new; Warranty changed

Mechanical – Electric Warning

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 Customers authorized by PROTEC GmbH & Co. KG.
Live electrical terminals are deadly.
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

WARING!

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

To the User

NOTE

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

Assemblers and other Customers not employed by nor directly affiliated with **PROTEC GmbH & Co. KG** technical services are directed to contact the local **PROTEC GmbH & Co. KG** office before attempting installation or service procedures.
For Installations and service procedures it is necessary to read the „technical description" of the product and to observe any containing point in it.

NOTE

The usage of the product in combination with accessories which aren't authorized by PROTEC is forbidden.

1 General

1.1 Inspection of delivery packaging

Check the packing 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
- Power supply with cable
- Control box with detector cable
- Network card
- Detector CD
- CONAXX 2 CD
- Documentation CD iRay
- Interface Box iRay (not included in VET)
- Network cable 15m (not included in VET)

1.3 System requirements

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

1.4 Environmental Conditions

1.4.1 Operating Conditions

Temperature: 5 °C – 35 °C
Humidity: 30% RH - 80% RH
Atmospheric pressure: 70 kPA – 106 kPA

1.4.2 Storage Conditions

Temperature: -10 °C – +55 °C
Humidity: 10% RH - 90% RH
Atmospheric pressure: 70 kPA – 106 kPA

NOTE

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 Conformity

CE 0297

This product is in conformity with the requirements of the European Community Medical Device Directive 93/42/EEC from 06/14/1993 including all current revision standards.

The declaration of conformity is available directly from PROTEC:

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Internet: www.protec-med.com

2.5 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.

2.6 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 40 lines/cm
- Dose area product meter

- Grid entity (for fixed anti-scatter grid)
- X-ray table
- X-ray stands (wall stand/table stand/ceiling suspension)
- PACS software

3 Safety Instructions

	**NOTE** xxx	Contains information that are relevant to the usage.
	**CAUTION!** **xxx**	Contains information that can cause damage to properties at non conformity.
	**WARNING!** **xxx**	Contains information that can cause personal injuries at nonconformity.
	**WARNING!** **xxx**	Warning of radioactive substances or ionisating rays. Contains information that can cause personal injuries at non conformity.

Adjustments and calibrations that are described within the user manual must be made, with the aid of The technical description for the system, by the **PROTEC GmbH & Co. KG** customer service department or a PROTEC GmbH & Co. KG authorized service technician.

NOTE

Every delivered manual has to be read and the safety notes have to be observed.

NOTE

The commissioning of the digital X-ray detector system can only be done if all safety notes and user securities have been met. The user securities can be: door contact, marked area, dosimeter, safety clothings …

CAUTION!

The manual contains every safety relevant information's for the commissioning of the digital X-ray detector system. Operating the device is exclusively for special trained staff. In this context there are on every operating element relevant safety symbols. Further information's are on the delivered document-CD. Those information's count as additional information's and have to be observed.

4 Important notes for the preparation of the detector installation

4.1 General Information

- ❑ Do not use cable extensions
- ❑ Use only the delivered network cables or at least well-shielded 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.

NOTE

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

4.2 Notes for installing a new digital X-ray system

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

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

- ❑ Increase the generator cut-off dose to 3.2µGy 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

5 Installation

5.1 Check list

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

0

- ❑ Modification of the x-ray unit
- ❑ 5.5 Connection of the components

Then proceed with chapter *0*
Calibration of the DR System on page 19.

5.2 Installation of CONAXX 2

Install the CONAXX 2 Software. During installation of CONAXX 2 please select the driver "RAPIXX 4343M1i X CC" or "RAPIXX 4343V1i X CC".

NOTE

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

5.3 Setup the network

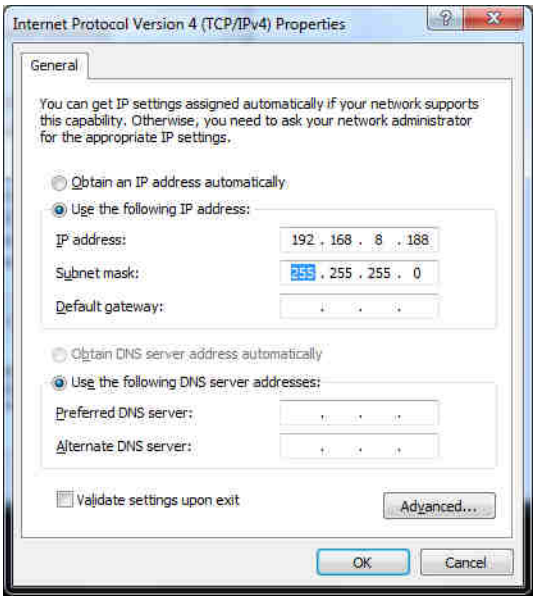
The default IP address of the detector is `192.168.8.8`. Please setup the computer network configuration to ensure that a connection to the detector is possible.

Open the "WINDOWS CONTROL PANEL", open "NETWORK AND SHARING CENTER" and afterwards "Change adapter settings".

Select the network adapter where the detector is connected with the right mouse button and press "PROPERTIES".

Select the list entry "INTERNET PROTOCOL VERSION 4 (TCP/IPv4)" and press "PROPERTIES". Please enter in the following window the IP address `192.168.8.188` and for the subnet mask `255.255.255.0`.

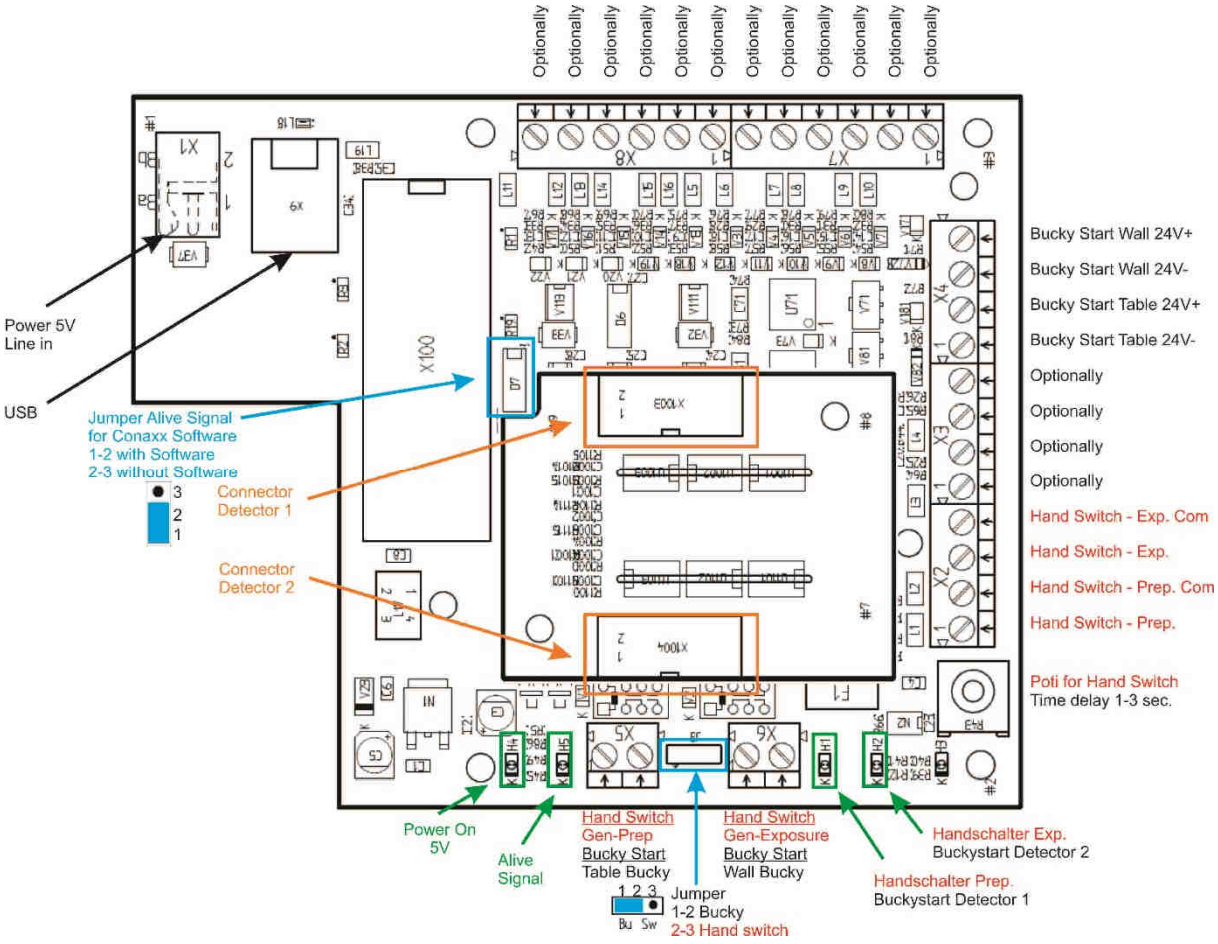
The setup of the network adapter is now complete.



5.4 Modification of the x-ray unit

5.4.1 Installation with hand switch

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

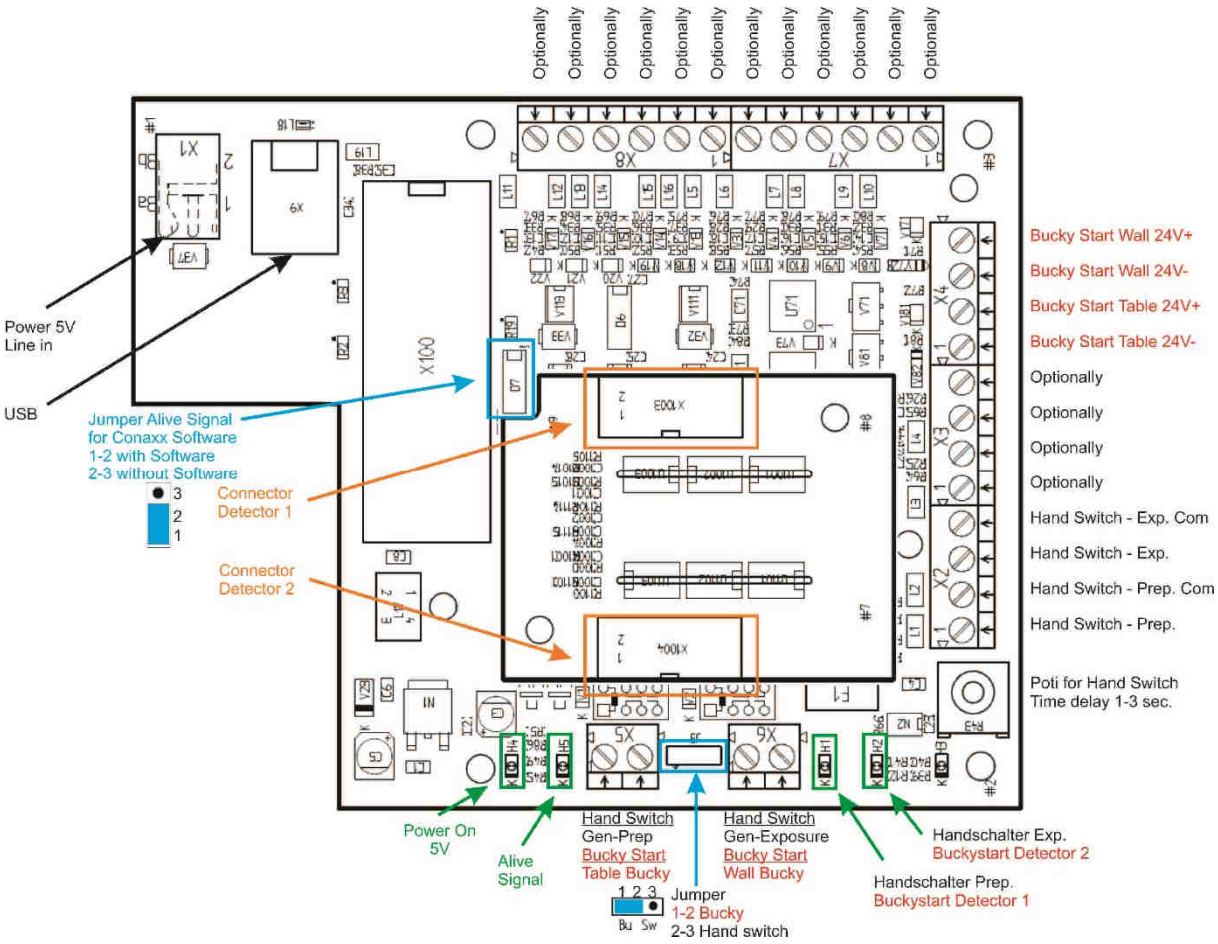


Proceeding:

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.

5.4.2 Installation with BUCKY START

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



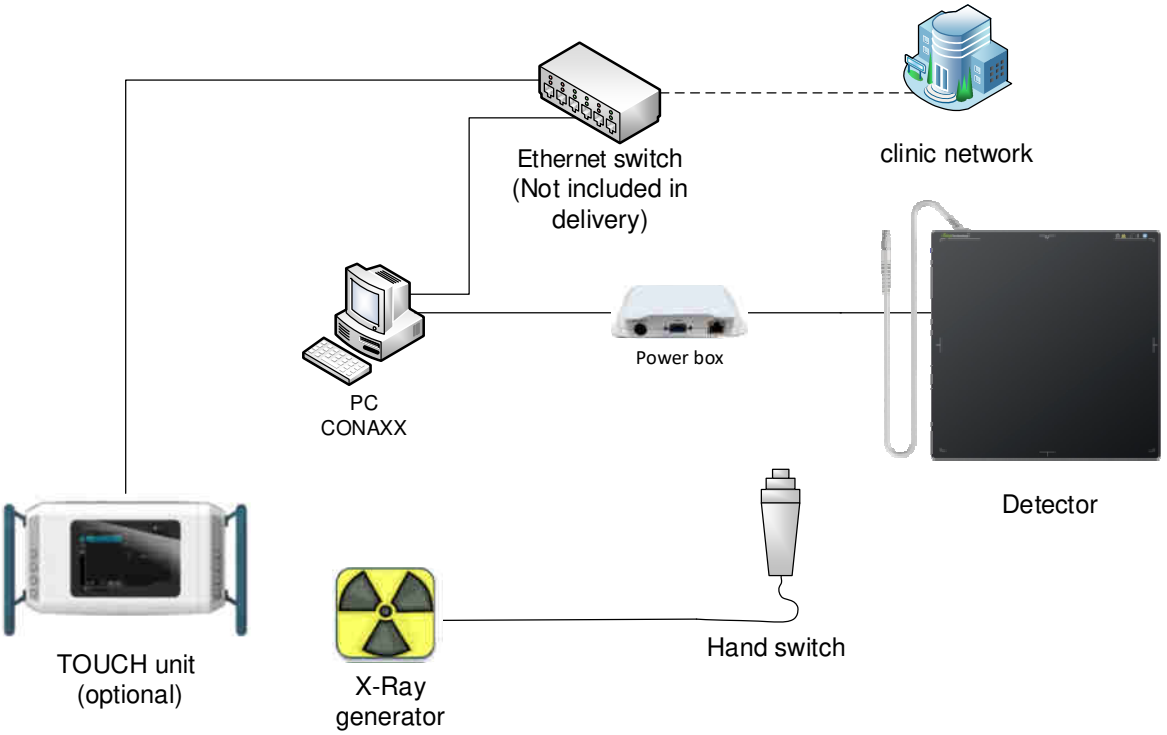
Proceeding:

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 bucky 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.

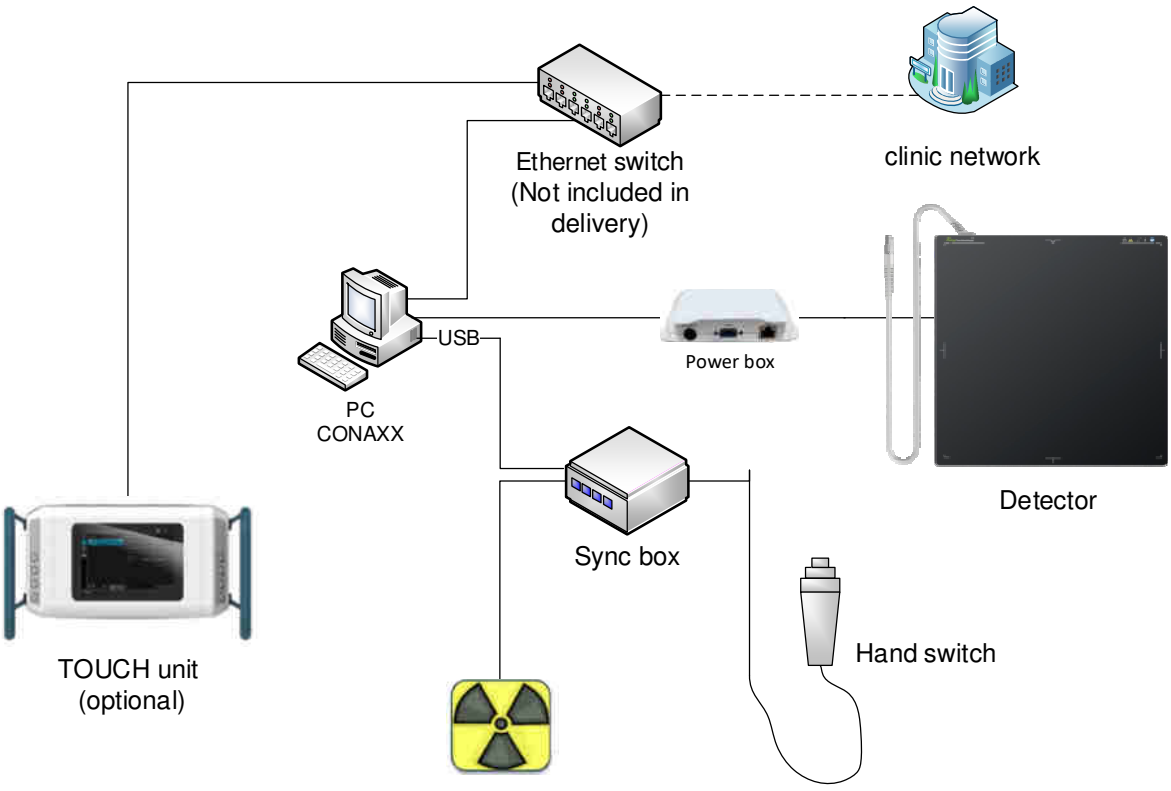
5.5 Connection of the components

Connect the components as described in the following diagrams.

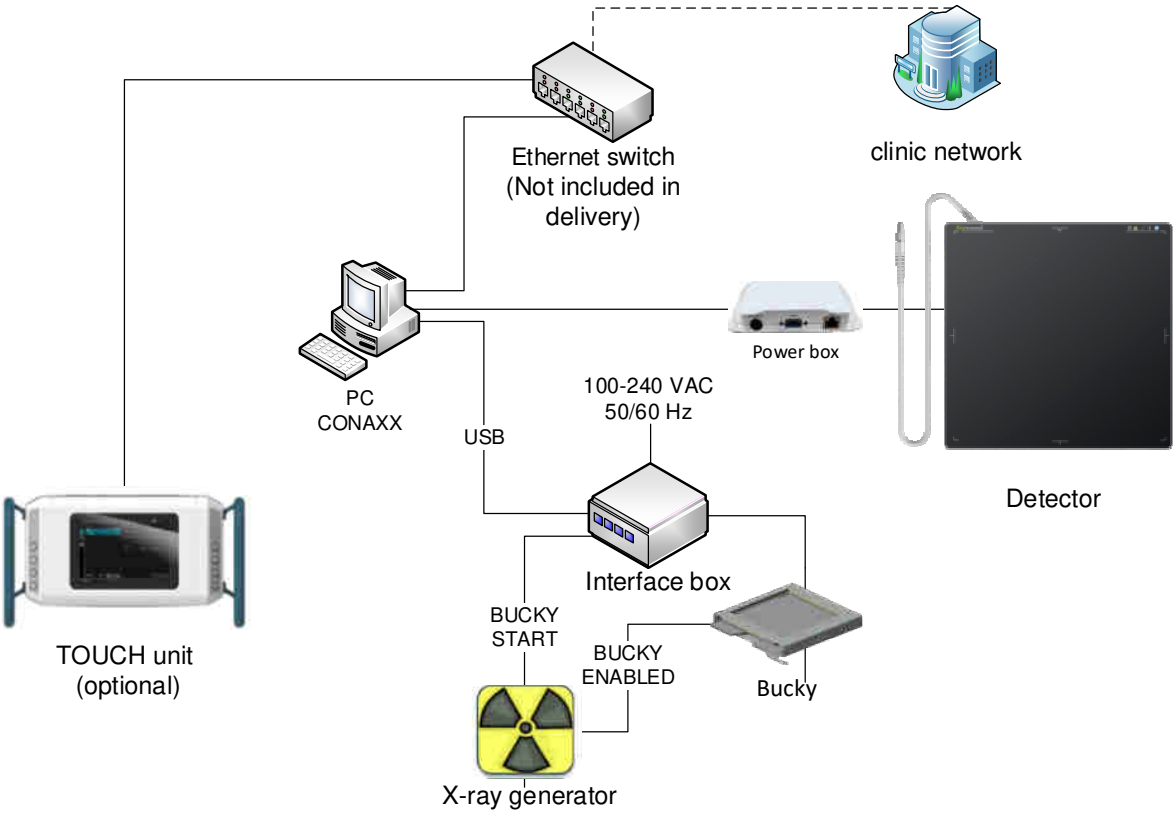
5.5.1 Installation with automatic exposure detection



5.5.2 Installation with hand switch

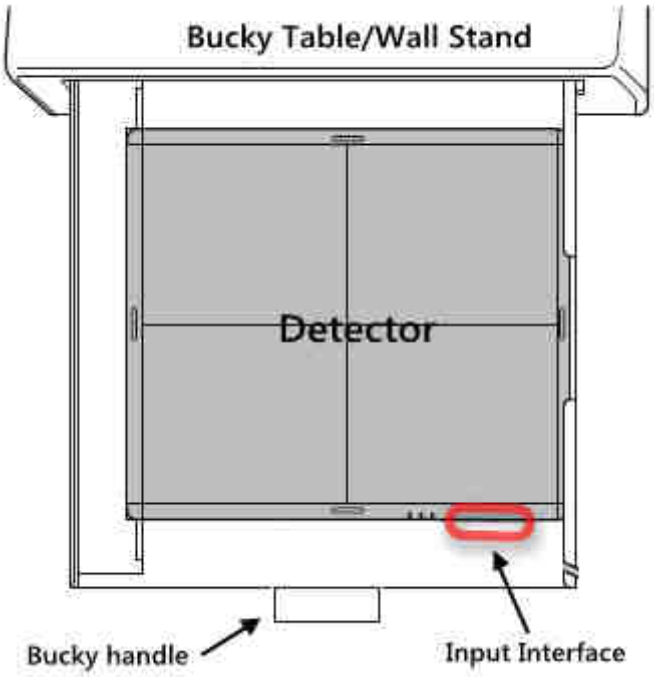


5.5.3 Installation with BUCKY START



5.6 Alignment of the detector when using a grid entity/Bucky

When using a grid entity/Bucky the detector must be positioned inside the Bucky that the detector DC Input Interface is at the same side like the handle of the Bucky drawer.



Hint:
The use of a moving anti-scatter grid is not possible! It is recommended to use a fixed anti-scatter grid (90L/cm) in combination with the CONAXX 2 module "Grid Line Suppression".

6 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 of portable detectors, which are used at several workstations, the calibration is carried out on the table.
- For fixed detectors: In case a fixed anti-scatter grid is installed, please take it out for calibration. A movable grid can stay in the system. The ionization chamber can also stay in the system for calibration.
- complete "Gain calibration" every 6 months

Start the program "RAPIXX Calibration" from the start menu "CONAXX2\DR-Panel" and press "Start".

The gain calibration will be started with "Start" in the section "Gain". Each exposure must be prepared with the button "Prepare". Please follow the screen instructions and perform 5 exposures without any object on the detector. After the gain calibration, a status window will be shown.

The defect calibration will be started with "Start" in the section "Defect". Each exposure must be prepared with the button "Prepare". Please follow the screen instructions and perform 19 exposures without any object on the detector. After the defect calibration, a status window will be shown.

To finish the calibration it is necessary to upload the calibration files ("gain*.gn" and "defect*.dft") to the detector. To upload the files use the function "Upload" for each file. The files are stored in the subfolder "\Correct\Default". Select this folder in the appearing "file open" dialog.

Please close the software "RAPIXX Calibration".

NOTE

If problems occur when calibrating the detector, please calibrate according to the included user manual provided by the detector manufacturer.

7 Startup of the DR system

7.1 First start of CONAXX 2

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

7.2 Necessary settings in CONAXX 2

After the first start of CONAXX 2 open the configuration by clicking the button "Configuration" in the start menu of CONAXX 2 and change into the section "System > Modality".

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

Depending on how the detector is built in it might be necessary to rotate the acquired images in CONAXX 2. This can be changed in "Rotations" in the same configuration section.

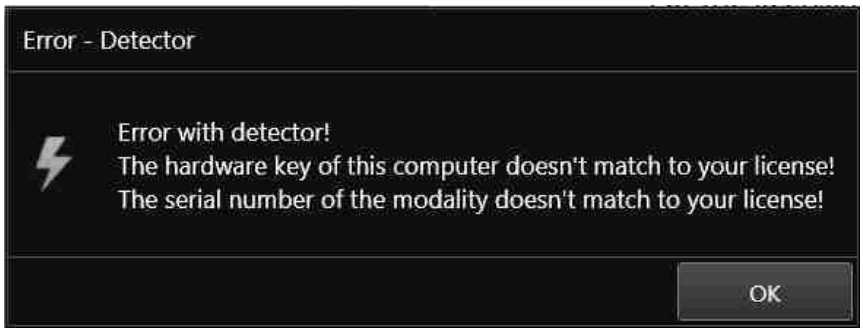
In case of using automatic exposure detection activate the according option.

In case of not using automatic exposure detection specify the synchronisation in the option "Interface box".

Now restart CONAXX 2.

7.3 Licensing of CONAXX 2

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

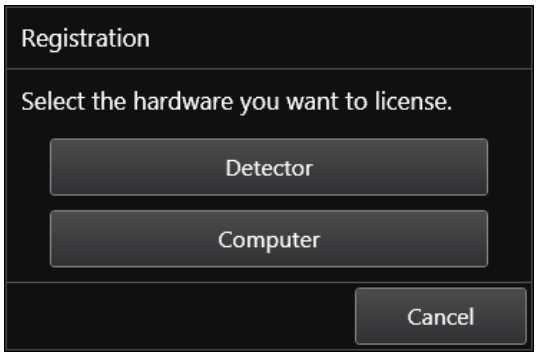


Confirm this message.

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 links the license with the detector.
Computer-based	This type links 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".

NOTE

For detailed information on CONAXX 2 licensing please refer to the document "CONAXX 2 User Manual".

7.4 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.

8 Status information

8.1 Status LEDs of the detector

LED	Status	Description
Power supply 	Off	Detector switched off
	On	Detector switched on
Connection 	Off	Detector switched off or no connection
	On (blue)	Connected with the power box
	On (green)	Connected with the software
Transmission 	Off	Detector switched off or detector ready
	Flashing (green)	Data transmission
	Flashing (blue)	Error

8.2 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)

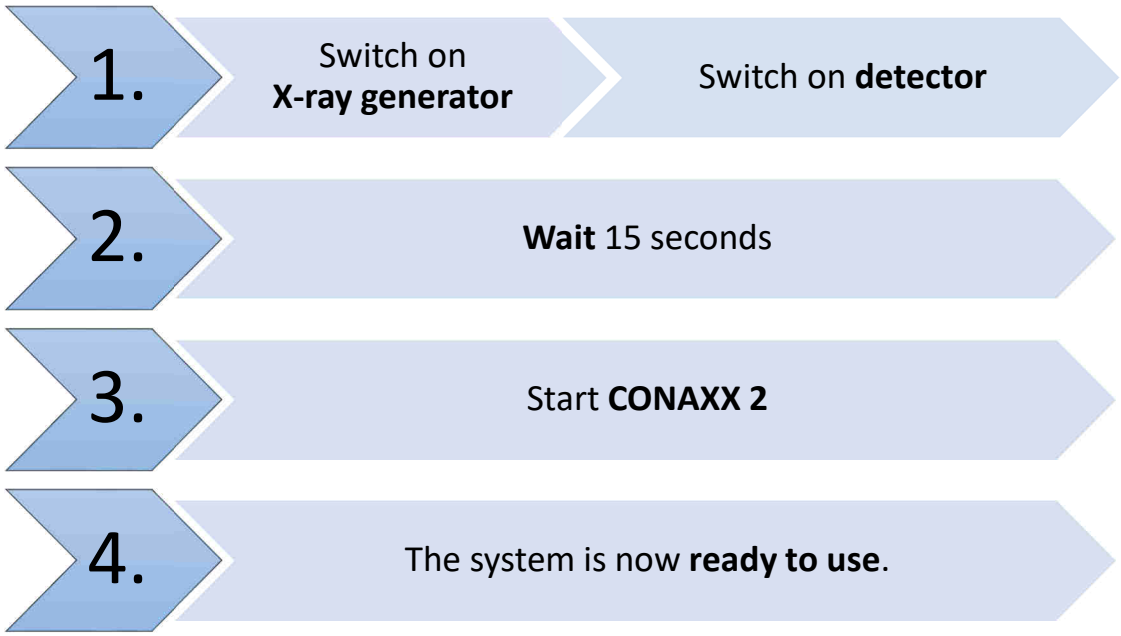
- **Modality:**
  This function opens the tool box for the connected modality. It provides functions to recover or close the connection to the modality or calibration functions.

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

9 Handling of the RAPIXX DR system

9.1 Operation of the RAPIXX DR system

9.1.1 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.

9.1.2 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.

9.1.3 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.

9.2 Operation of the CONAXX 2 software

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

9.3 Operation of the detector with accessories

Detailed information please find in the enclosed original *Venu1717X User Manual* of the detector manufacturer.

HINWEIS

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.

10 Safety and Maintenance

10.1 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.

10.2 Cleaning and disinfection

The flat panel receptor and connected cables are likely to be soiled during use. The specific material most likely to become soiled is the X-ray grade carbon fibre input window and aluminium/magnesium housing.

Cleaning and disinfecting of the input window should be performed as needed. Wiping the surfaces with a soft cloth dampened with soap and water will generally clean the surfaces.

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. Use disinfectants in accordance with the manufacturer's instructions. Alternatively, the below chemical cleaning solutions may also be used.

Cleaning and disinfecting of the battery and battery compartment should also be performed as needed using the same practices described above. Care should be taken when cleaning the battery contacts, use a non-abrasive cleaner that will not damage the copper contact material.

The battery charger can be cleaned with a wet cloth using one of the chemicals below. The battery charger cannot be submerged any time during cleaning.

Chemical Cleaning Solutions Recommended:

- Isopropyl alcohol, 70% aqueous solution.
- Mild soap and water.
- Chlorine bleach, 3% aqueous solution. *Do not clean electrical contacts or connector with bleach.*
- Quaternary ammonium compounds, such as Steris "Coverage Plus NPD" (one part Coverage Plus NPD to 255 parts water).
- CaviWipes®. *Use in accordance with the manufacturer's instructions*

NOTE

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 benzine, as it corrodes the outer surfaces.

Do never submerge any components during cleaning.

10.3 Checkup and maintenance

10.3.1 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.

10.3.2 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.

10.3.3 Maintenance

WARNING

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.

NOTE

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 *Venu1717X User Manual* of the detector manufacturer.

11 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.

12 Warranty

NOTE

The current conditions of guarantee are deposited in the order papers or in the valid pricelist to the time of purchase.

All repairs and replacement of components because of misuse and/or incorrect operation are excluded from the warranty.

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

13 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.

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

14.1 General

- The PRAPIXX 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.

14.2 Detector with accessories

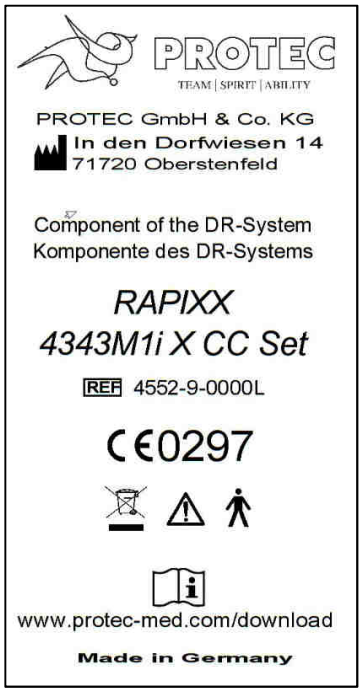
Detailed information to the electromagnetic compatibility of the detector and its accessories you can find in the enclosed original *Venu1717X User Manual* of the detector manufacturer.

15 Description of symbols and abbreviations

15.1 Symbols

CE 0297	CE-Mark
	Attention, consult accompanying documents
	Classification according to EN 60601-1 (Type B)
	Manufacturer
	Order number
 www.protec-med.com/download	With this symbol we point out that Usage instructions of the corresponding product is on out Homepage
	Electrostatic sensitive device
	System (CONAXX 2)
	Modality (CONAXX 2)
	X-ray generator
	Electrical product. Do not dispose in the household waste.

15.2 Type label



15.3 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