RAPIXX 4336M1V v4 Wifi Set
RAPIXX 4336M2V v4 Wifi Set
RAPIXX 4336V1V v4 Wifi Set
RAPIXX 4336V2V v4 Wifi Set

Digital X-ray detector system

Model/ID: 4470-9-0000L
4474-9-0000L
4470-9-1000L
4474-9-1000L

Installation & User Manual

Ident. Nr. 5420-0-0004

CE 0297

Comments and questions about the documentation please contact:

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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	August 2016	---	First edition Installation & Operation Manual
2.0	November 2017	7 8 9 10, 11, 12 12, 13 19 27	Chapter 1.2: edit Chapter 2.2: edit Chapter 3.1: edit Chapter 4.4: new Chapter 4.5: new Chapter 5: edit Chapter 14.1: edit
3.0	February 2018	22	Chapter 7: edit
4.0	2020-06-30	8; 20; 29	NOTE Calibration new; Conformity added; Warranty changed

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 4336M1V v4 Wifi / RAPIXX 4336M2V v4 Wifi or RAPIXX 4336V1V v4 Wifi / RAPIXX 4336V2V v4 Wifi
- Battery charger incl. power supply
- 2 batteries
- Back-up cable for image recovery
- Access Point (optional for Vet)
- Network card (optional for Vet)
- Network cable (optional for Vet)
- Detector CD
- CONAXX 2 CD

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: 10 °C – 35 °C
Humidity: 10% RH - 90% RH
Atmospheric pressure: 70 kPA – 106 kPA

> ⚠️ **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.**

1.4.2 Storage Conditions

Temperature: -20 °C – +70 °C
Humidity: 15% RH - 80% RH
Atmospheric pressure: 70 kPA – 106 kPA

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.
The RAPIXX detector is intended to be used in a grid entity, which is well insulated.
The RAPIXX system is not intended for mammography or dental applications.

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

C€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:

PROTEC GmbH & Co. KG
In den Dorfwiesen 14 | 71720 Oberstenfeld
Telephone: +49 (0) 7062 – 92 55 0
Fax: +49 (0) 7062 – 92 55 60
E-Mail: protec@protec-med.com
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
- 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 3.3µGy.

3.3   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

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:

- ❑ 4.6 Modification of the x-ray unit
- ❑ 4.7 Connection of the components

Then proceed with chapter *5 Calibration of the DR System* on page 20.

4.2 Installation of the network interface card (NIC) if using an access point

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

4.3 Installation of CONAXX 2

Install the CONAXX 2 Software. During installation of CONAXX 2 please select the driver "RAPIXX 4336M1V/-M2V/-V1V/-V2V v4 Wifi".

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

4.4 Configure the WiFi Access point

The WiFi Access point is delivered with a working configuration. There are no adjustments required. The following settings are factory-set:

Access:
Name:	`admin`
Password:	`protec`

LAN:
IP-Address:	`192.168.2.21`
Subnet:	`255.255.255.0`

WLAN:
Band:	`5 GHz`
Channel:	`44`
SSID:	`VMSV4`
Key:	`abcd1234`
Authentication:	`WPA2 Personal`

4.4.1   LAN configuration

4.4.2 WiFi configuration

4.5 Setup the network
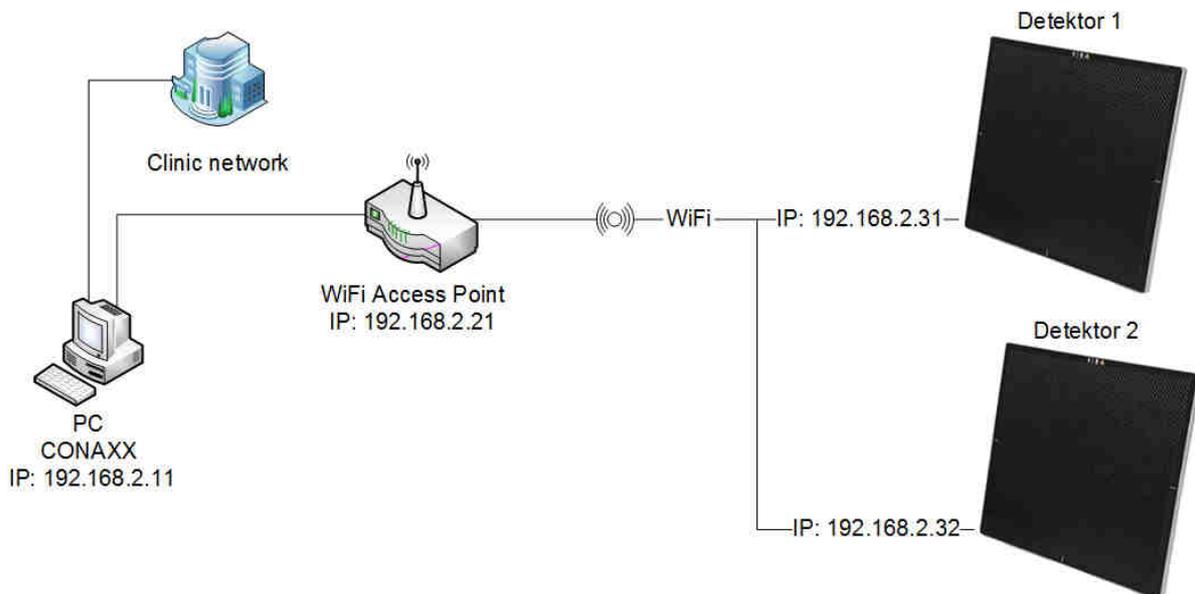
The default IP address of the detector is 192.168.2.31. Please setup the computer network configuration to ensure that a connection to the detector is possible. Open the "Windows Control Panel", open "Network and Sharing Center" and afterwards "Change adapter settings".

In case of using an Access point, select the network adapter where the Access Point is connected with the right mouse button and press "Properties".

In case of using the wireless adapter of the computer, select the wireless adapter 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 192.168.2.11 and for the subnet mask 255.255.255.0.

The setup of the network adapter is now complete.
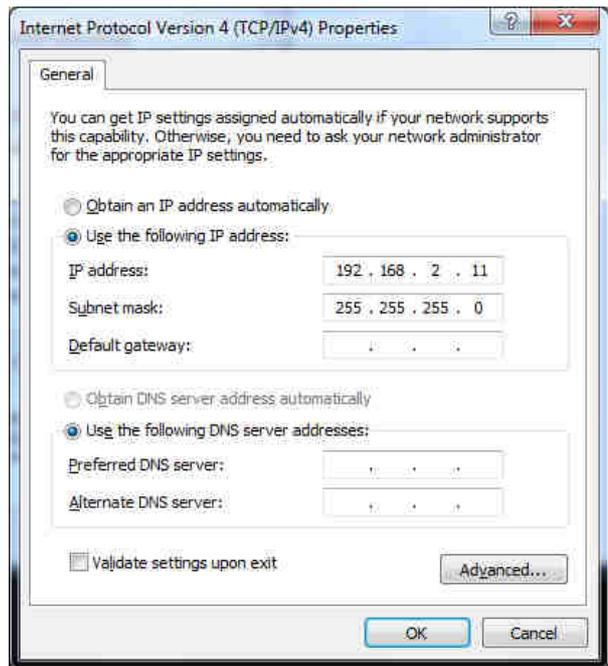
Hint:
Please make sure that the clinic network is not in the address range 192.168.2.*.

4.6   Modification of the x-ray unit

4.6.1   Installation with hand switch

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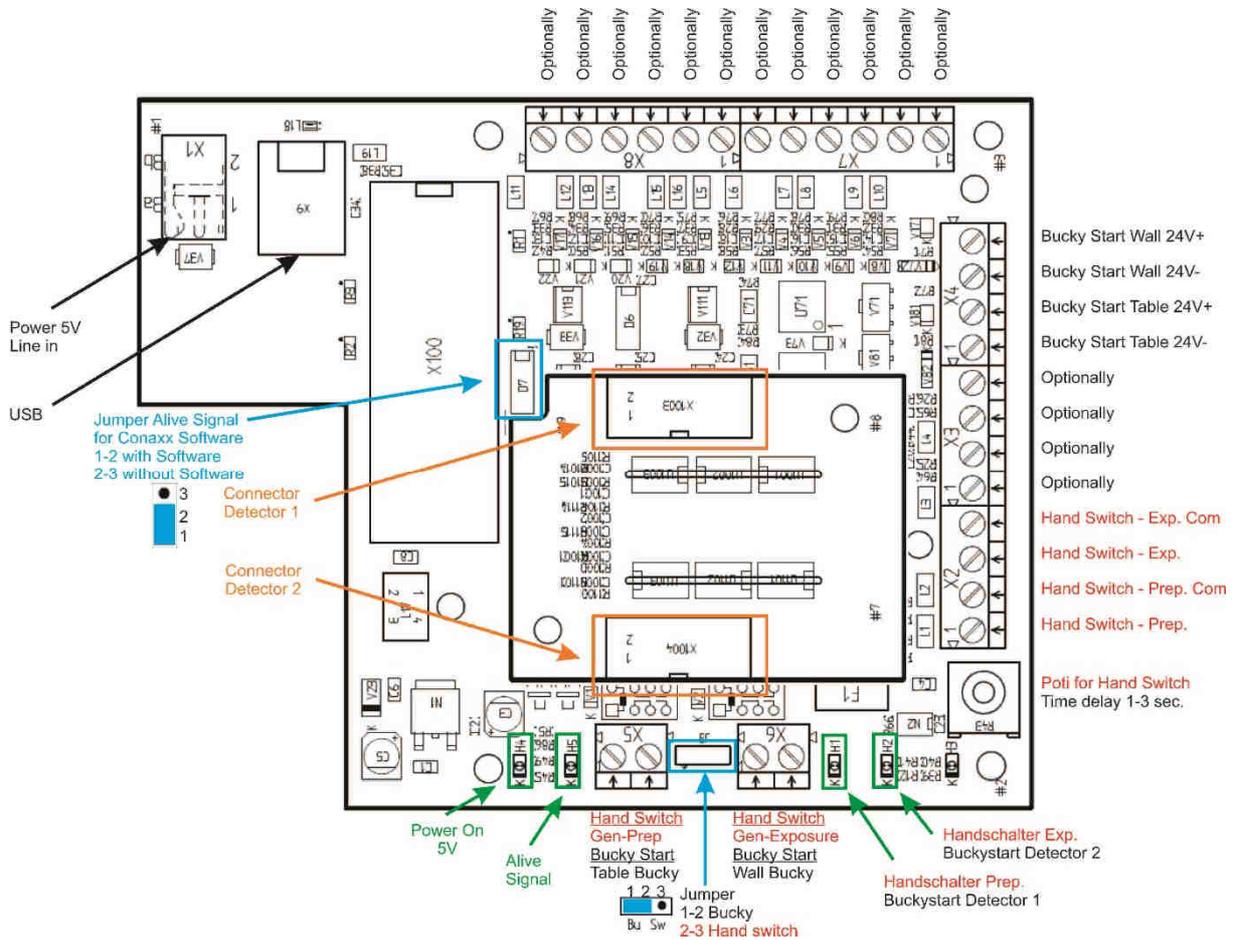
Proceeding:
1.   The Interface box has to be disconnected from the electrical power.
2.   Open the Interface box by unscrewing the screws.
3.   Guide the cable from the hand switch and from the x-ray equipment through the cable feed through.
4.   Connect the cables to the screw terminals according to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

4.6.2   Installation with BUCKY START

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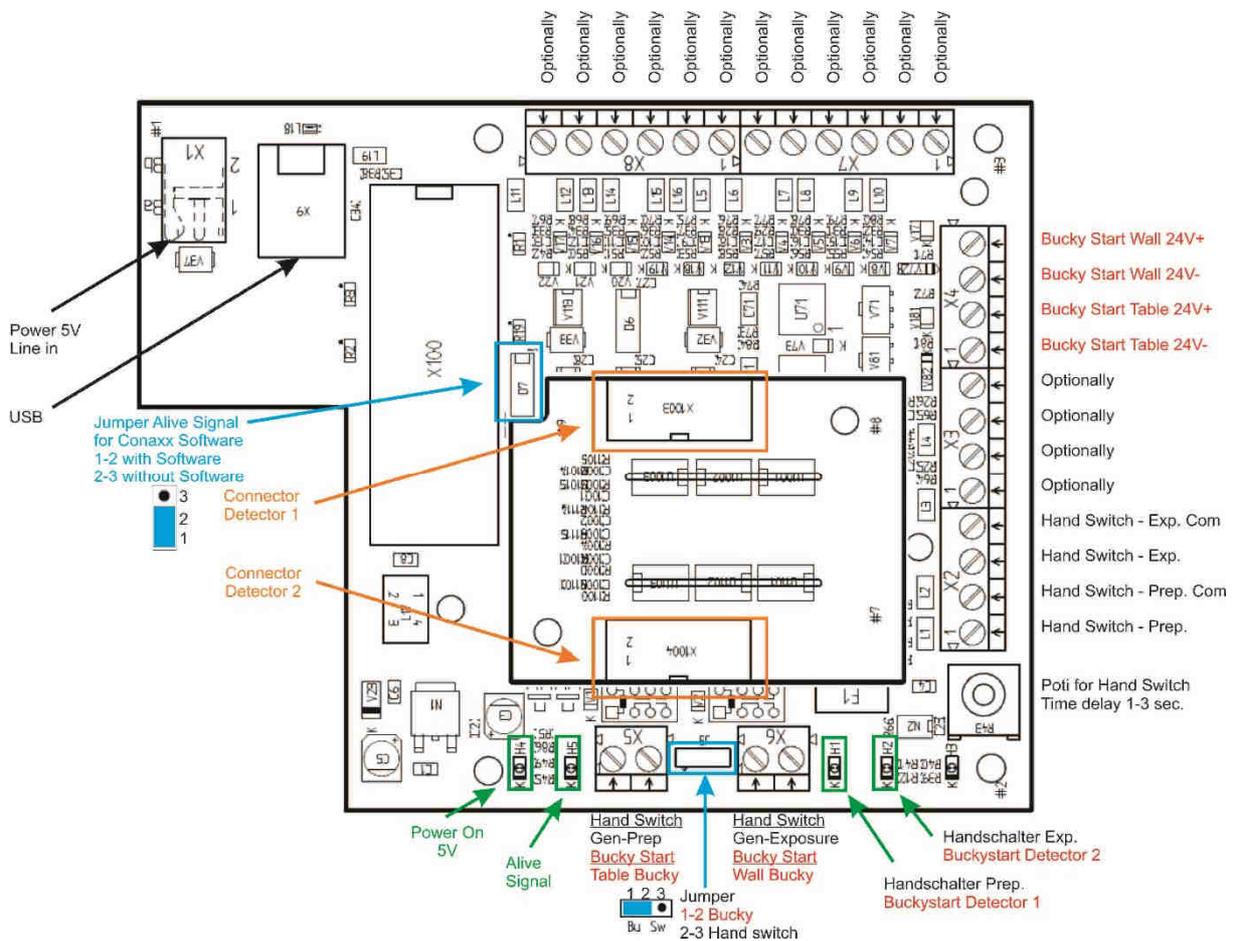
Proceeding:
1. The Interface box has to be disconnected from the electrical power.
2. Open the Interface box by unscrewing the screws.
3. Guide the cable from the bucky and from the x-ray equipment through the cable feed through.
4. Connect the cables to the screw terminals according to the connecting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

4.7 Connection of the components

Connect the components as described in the following diagrams.

4.7.1 Installation with automatic exposure detection and without Access point

PC
CONAXX
Image Aquisition Software

WiFi

Hand switch

X-Ray generator

RAPIXX 4336M1V v4 WiFi
RAPIXX 4336M2V v4 WiFi
RAPIXX 4336V1V v4 WiFi
RAPIXX 4336V2V v4 WiFi

4.7.2 Installation with automatic exposure detection and with Access point

PC
CONAXX
Image Aquisition Software

WiFi Access
Point

WiFi

RAPIXX 4336M1V v4 WiFi
RAPIXX 4336M2V v4 WiFi
RAPIXX 4336V1V v4 WiFi
RAPIXX 4336V2V v4 WiFi

Hand switch

X-Ray generator
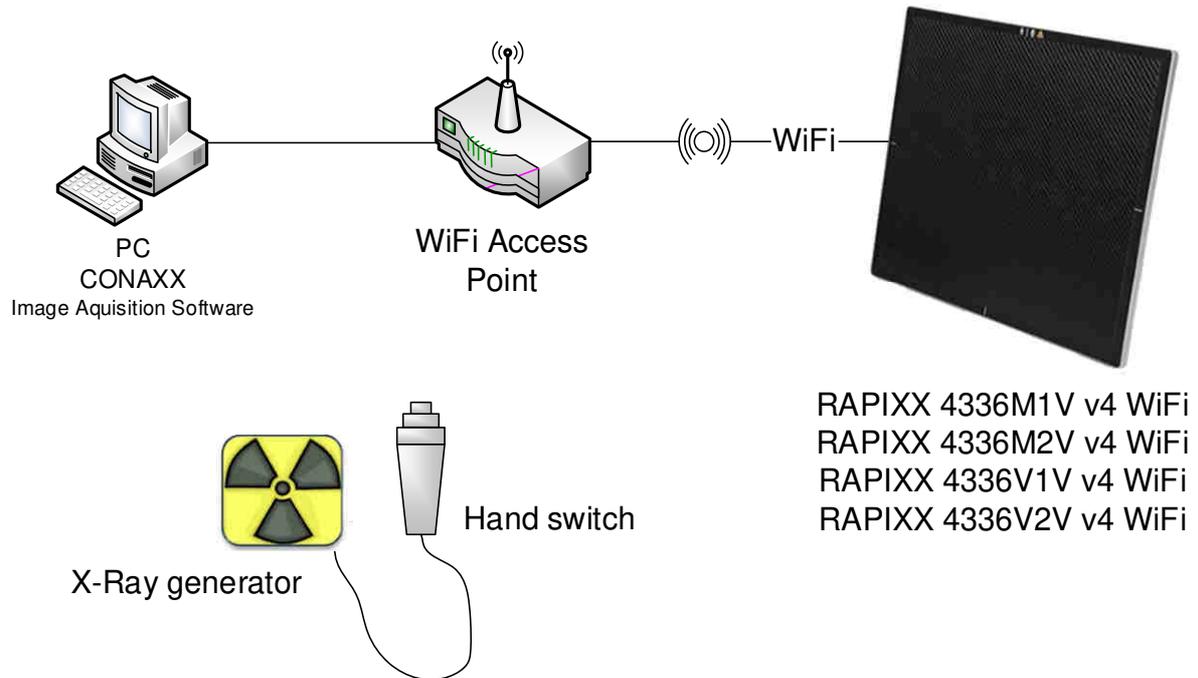
4.7.3   Installation with hand switch and without Access point

WiFi

USB

100-240 VAC
50/60 Hz

PC
CONAXX
Image Aquisition Software

Interface box

Hand switch

X-Ray generator

RAPIXX 4336M1V v4 WiFi
RAPIXX 4336M2V v4 WiFi
RAPIXX 4336V1V v4 WiFi
RAPIXX 4336V2V v4 WiFi
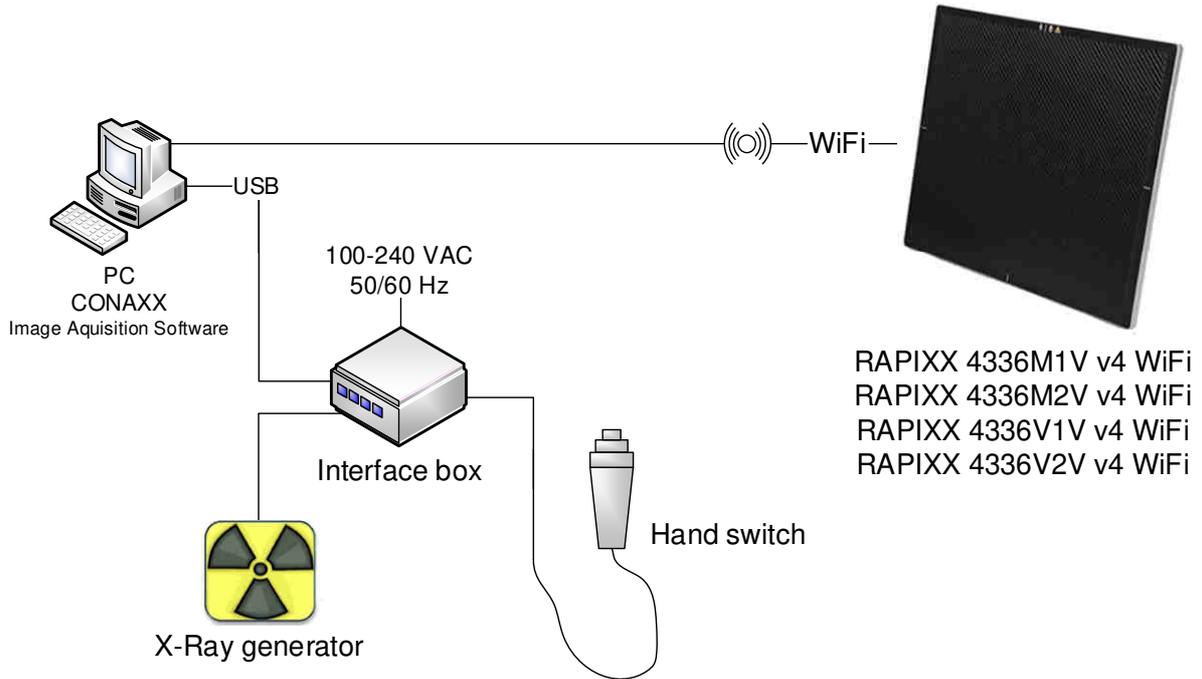
4.7.4   Installation with hand switch and with Access point

Network cable

100-240 VAC
50/60 Hz

USB

WiFi

PC
CONAXX
Image Aquisition Software

Interface box

Access Point

Hand switch

X-Ray generator

RAPIXX 4336M1V v4 WiFi
RAPIXX 4336M2V v4 WiFi
RAPIXX 4336V1V v4 WiFi
RAPIXX 4336V2V v4 WiFi
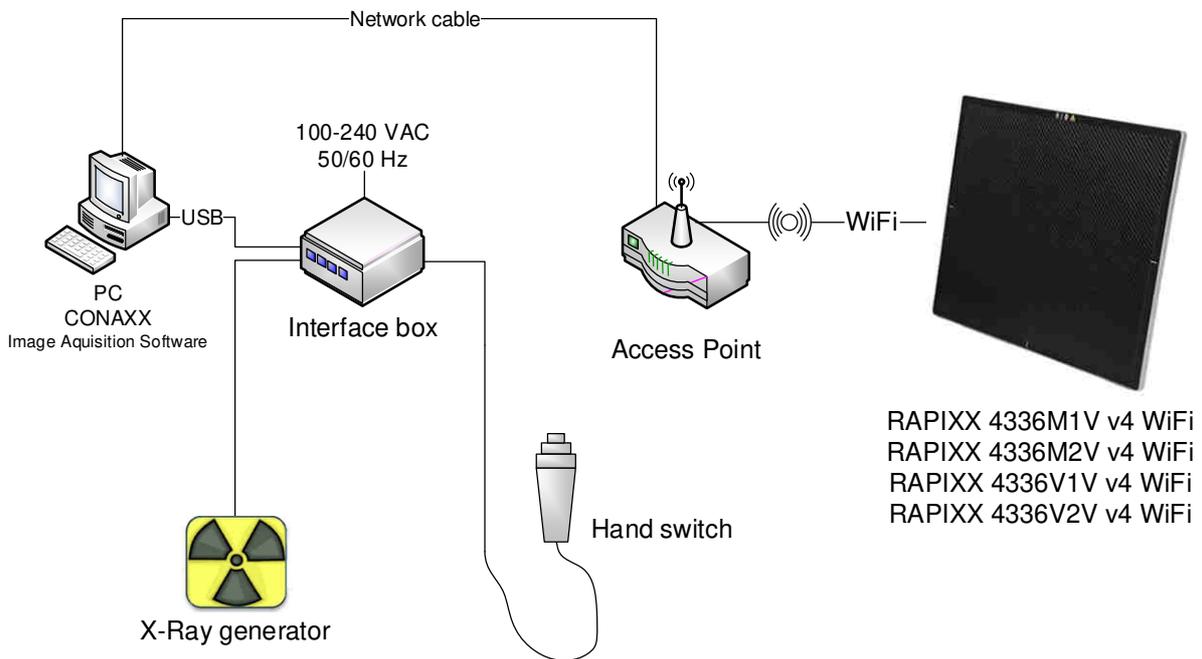
4.7.5 Installation with BUCKY START and without Access point

PC
CONAXX
Image Aquisition Software

USB

100-240 VAC
50/60 Hz

Interface box

BUCKY
START

BUCKY
ENABLED

Bucky

X-Ray generator

WiFi

RAPIXX 4336M1V v4 WiFi
RAPIXX 4336M2V v4 WiFi
RAPIXX 4336V1V v4 WiFi
RAPIXX 4336V2V v4 WiFi
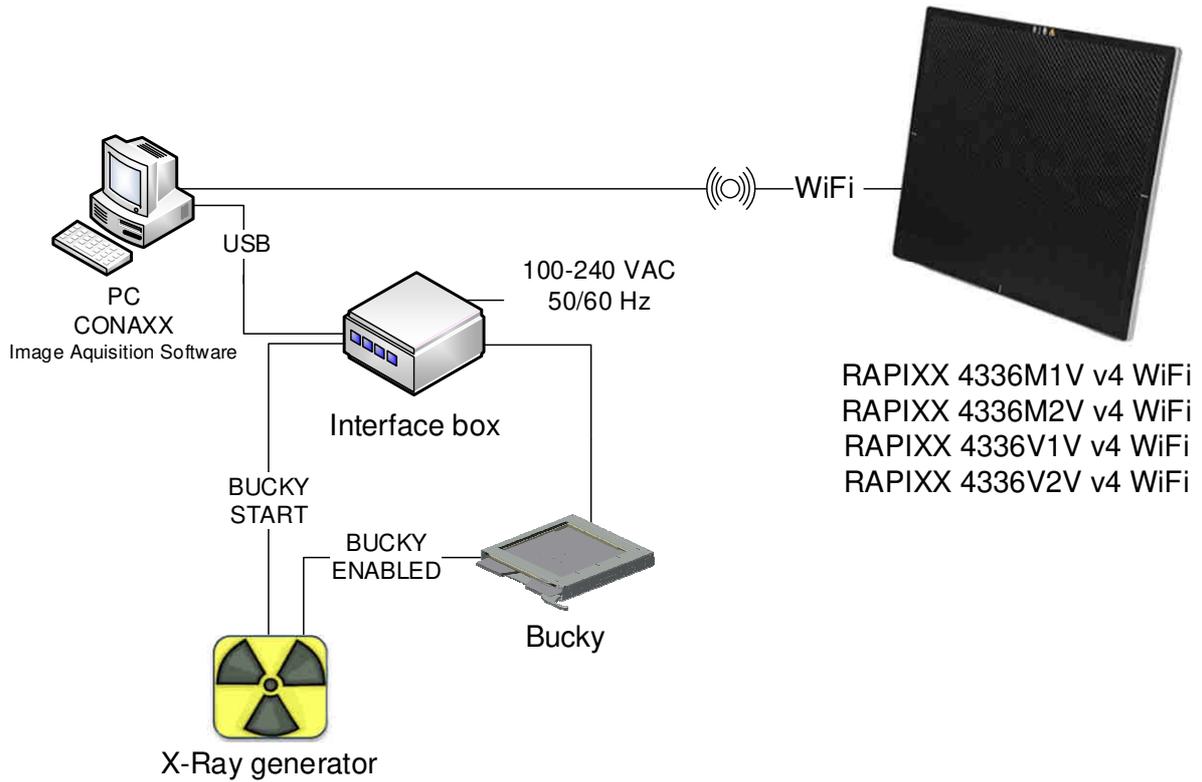
4.7.6 Installation with BUCKY START and with Access point

Network cable

100-240 VAC
50/60 Hz

Interface box

PC
CONAXX
Image Aquisition Software

USB

BUCKY
START

BUCKY
ENABLED

Bucky

X-Ray generator

AccessPoint

WiFi

RAPIXX 4336M1V v4 WiFi
RAPIXX 4336M2V v4 WiFi
RAPIXX 4336V1V v4 WiFi
RAPIXX 4336V2V v4 WiFi
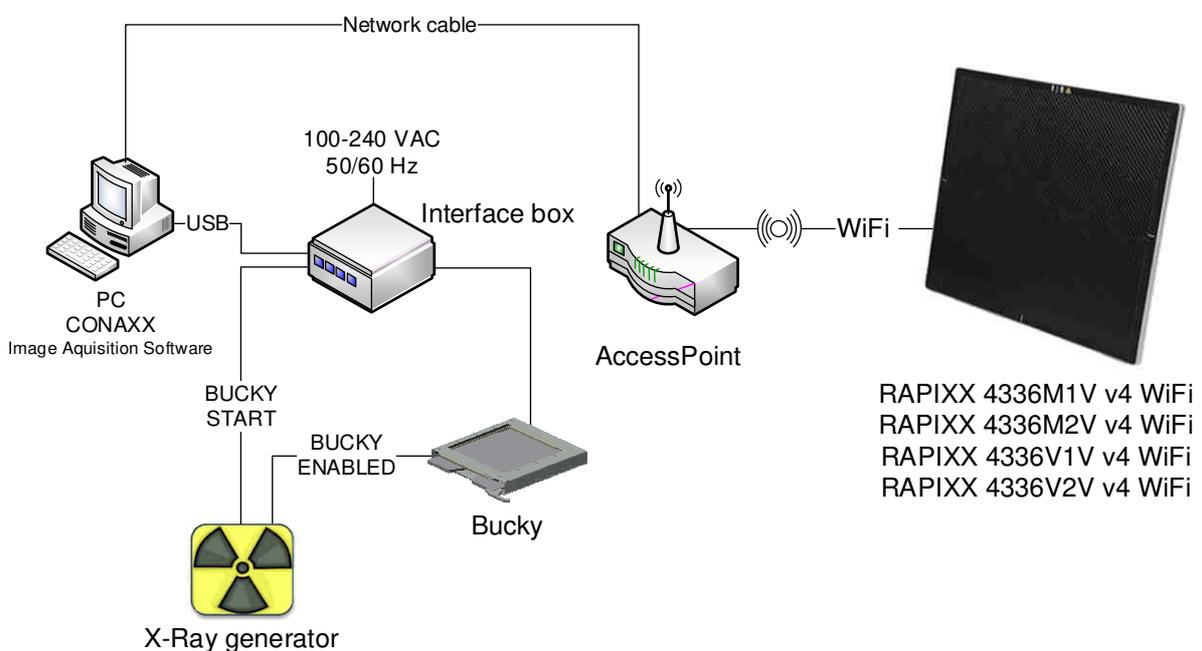
5   Calibration of the DR System

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 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

Go to "START MENU" and open in the folder "CONAXX2\DR-PANEL" the program "RAPIXX CALIBRATION". Make sure that you configured the detector connection in CONAXX 2 successfully. The calibration can be started by using the button "CALIBRATE DETECTOR A" (or "CALIBRATE DETECTOR B").

The offset calibration will be started with "START OFFSET CALIBRATION". The offset calibration is performed automatically. After the offset calibration, a status window will be shown.

The gain calibration will be started with "START GAIN CALIBRATION". Please follow the screen instructions and perform 8 exposures without any object in the beam. After the gain calibration, a status window will be shown.

Please close the software "RAPIXX Calibration".

(i)   NOTE

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

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6   Startup of the DR system

6.1   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.

6.2   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 4336M1V v4 WiFi".

The "Mode" property specifies the duration of the exposures for the detector.
Installation with automatic exposure detection:

        1000ms: Mode 2
        2200ms: Mode 3

Installation with hand switch or BUCKY START:

   1000ms: Mode 0
        2200ms: Mode 1

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

Now restart CONAXX 2.

6.3   Licensing of CONAXX 2

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


Error - Detector

Error with detector!
The hardware key of this computer doesn't match to your license!
The serial number of the modality doesn't match to your license!

OK
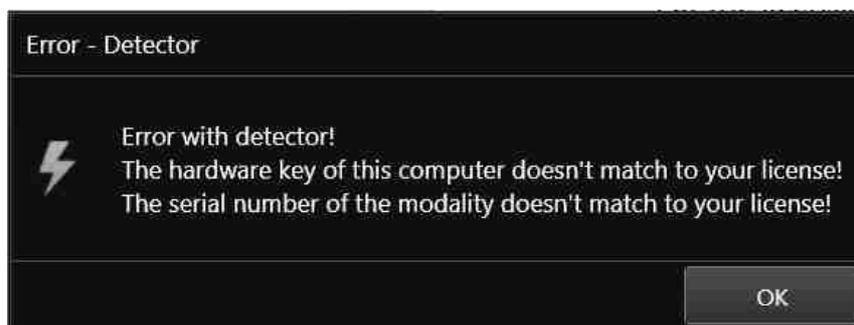
Confirm this message.

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.
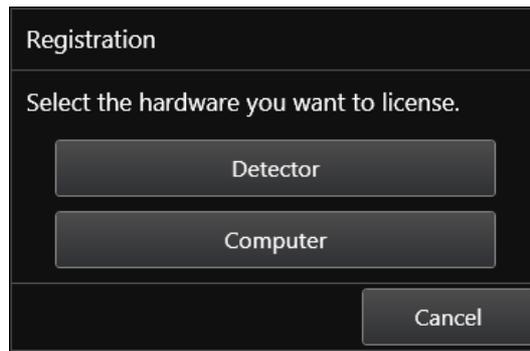
CONAXX 2 supports two different types of licensing:

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".

6.4   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.

7 Status information

7.1 Daily Operation

To start up the system perform the following steps:

1. Switch on the detector

   The status LED goes through the following states:

   - Orange   (permanent)
   - Green   (slowly flashing)
   - Green   (fast flashing; 1x per second)

   The start of the detector can take up to 60 seconds.

2. Wait until the green LED is flashing fast (1x per second)

3. Start CONAXX 2

4. If the LED is permanently green, the communication is ready

If there is no error when starting CONAXX 2, the connection is established correctly and the system is ready for use.

If no connection can be established, proceed as described in 7.3 **Troubleshooting**.

7.2 Switch on sequence after changing the battery

To change the battery perform the following steps:

1. Open "Toolbox" ( ) in CONAXX.

2. Change the battery

   The status LED goes through the following states:

   - Orange   (permanent)
   - Green   (slowly flashing)
   - Green   (fast flashing; 1x per second)
   - Green   (permanent)

   The start of the detector can take up to 60 seconds.

3. As soon as the new battery level is displayed, the connection is ready and you can close the toolbox.

If no error message appears, the connection is established correctly and the system is ready for use.

If no connection can be established, proceed as described in 0

Troubleshooting.

7.3   Troubleshooting

If the connection cannot be established you can be set up it manually in the tool box.

1.   Open Toolbox ( )

2.   Press the button "Disconnect"

3.   Make sure that the detector is switched on

4.   Please press the button "Connect"

If no error message appears at CONAXX 2 start up the connection is established correctly and the system is ready for use.


⚠	**Observe following notes when there are permanent problems with the wireless connection:**
	  - **Is any obstacle, which is in the transmission path, reducing the signal?**
	  - **Is there a jammer close to the wireless connection (mobile or DECT phone, baby monitor, wireless speakers etc.)?**
	  - **Is the wireless function switched on at the detector?**

8   Handling of the RAPIXX DR system

8.1   Operation of the RAPIXX DR system

8.1.1   Startup order for daily use

| 1. | Switch on **X-ray generator** | Switch on **detector** |

| 2. | **Wait** 15 seconds |

| 3. | Start **CONAXX 2** |

| 4. | The system is now **ready to use**. |
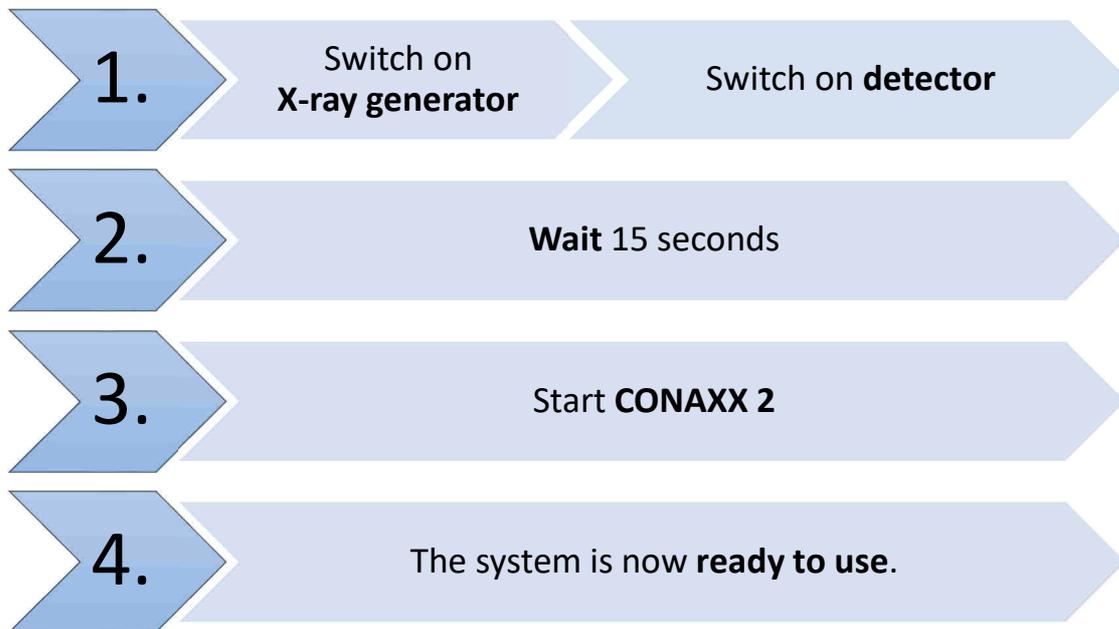
If CONAXX 2 cannot connect to the modality or generator after launching the program there will appear an error message. In this case, CONAXX 2 has to be restarted to initiate a new connection. Further hints you can find in the indicated error message.

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

8.1.2   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.

8.1.3   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.

8.2   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.**

8.3   Operation of the detector with accessories

Detailed information please find in the enclosed original user manual *VAREX Pax Scan 4336Wv4 Operating Instructions* of the detector manufacturer.

8.3.1   Handling and change of the battery

Detailed information about the handling of the battery and the battery charger, as well as the battery change, please find in the enclosed original user manual *VAREX Pax Scan 4336Wv4 Operating Instructions* 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.**

9   Safety and Maintenance

9.1   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.

9.2   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*

> ⚠️ **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 benzine, as it corrodes the outer surfaces.**
> **Do never submerge any components during cleaning.**

9.3   Checkup and maintenance

9.3.1   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.

9.3.2   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.

9.3.3   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 *VAREX PaxScan 4336Wv4 Operating Instructions* of the detector manufacturer.

10 Liability

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

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

11 Warranty

(i) 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.

12 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.

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

13.1 General

- o 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.
- o Portable and mobile HF- communication units can have an influence upon medical electric devices
- o 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.

13.2 Detector with accessories

Detailed information to the electromagnetic compatibility of the detector and its accessories you can find in the enclosed original user manual *VAREX PaxScan 4336Wv4 Operating Instructions* of the detector manufacturer.

14 Description of symbols and abbreviations

14.1 Symbols

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

14.2   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