

RAPIXX 4336M1i WiFi Set

RAPIXX 4336V1i WiFi Set

Digital X-ray detector system

Model/ID: 4564-9-0000L
4564-9-1000L

Installation & User Manual

Ident. Nr. 5514-0-0004



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	December 2019	---	First edition Installation Manual
2.0	08.04.2020	Front age / page 9, 21	picture / note network isolator
3.0	2020-06-30	8; 18;24	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 4343M1i Wifi or RAPIXX 4343M2i Wifi
- Power supply for detector and power cable
- Battery charger with power supply
- 2 Batteries
- Network cable for detector
- Access point (optional)
- Syncbox
- 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: 5 °C – 30 °C

Humidity: 45% RH - 85% RH

Atmospheric pressure: 700 hPa – 1000 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.

1.4.2 Storage Conditions

Temperature: -20 °C – +40 °C

Humidity: 45% RH - 85% RH

Atmospheric pressure: 700 hPa – 1060 hPa

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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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:
 - Use grid with ratio 12:1 and 40 lines/cm or 90 lines/cm. Depends on the detector type.
 - 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



If the detector of the RAPIXX system is operated via data cable and with direct patient contact, it must be ensured that the data cable is equipped with a network isolator according to EN 60601-1.

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:

- ☐ 4.4 Modification of the x-ray unit
- ☐ 4.5 Connection of the components
- ☐ **Fehler! Verweisquelle konnte nicht gefunden werden. Fehler! Verweisquelle konnte nicht gefunden werden.**

Then proceed with chapter 5 *Calibration of the DR System* on page 18.

4.2 Installation of CONAXX 2

Install the CONAXX 2 Software. During installation of CONAXX 2 please select the driver "RAPIXX 4336M1i/-M2i WiFi".

Note:

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

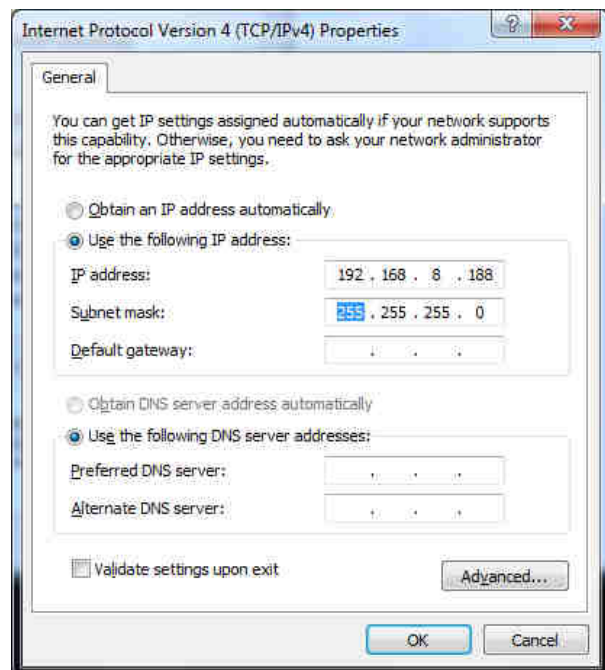
4.3 Setup of the network adapter

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".

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 192.168.8.188 and for the subnet mask 255.255.255.0.

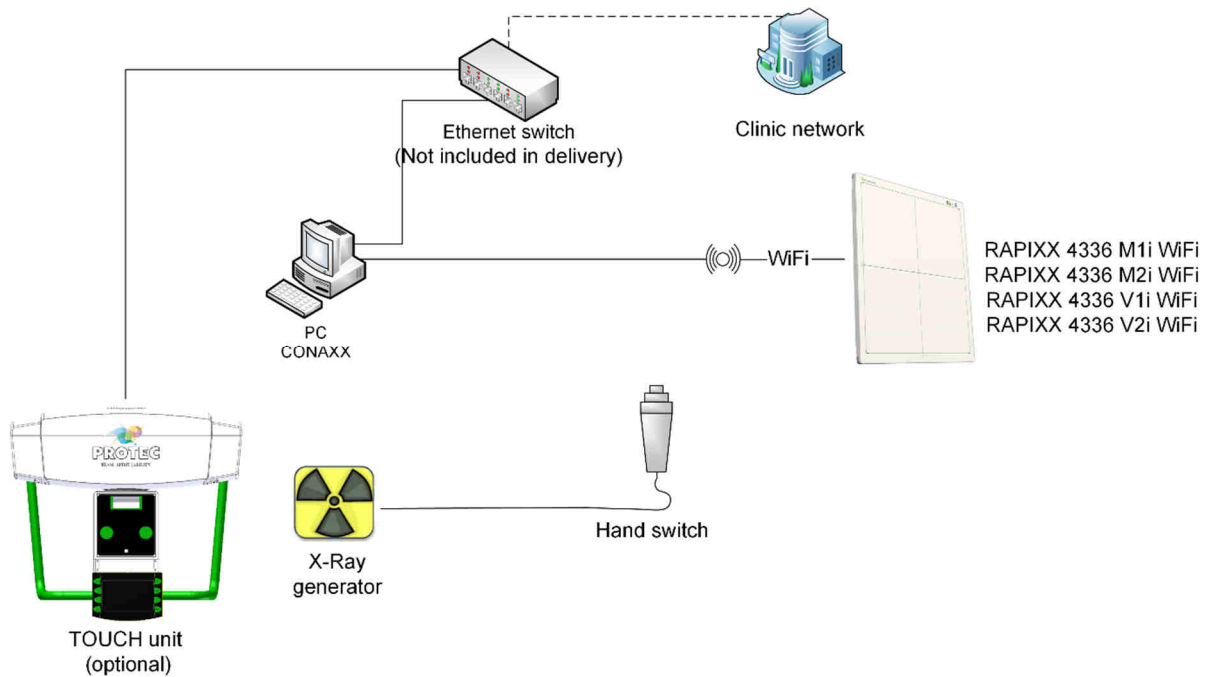


The setup of the network adapter is now complete.

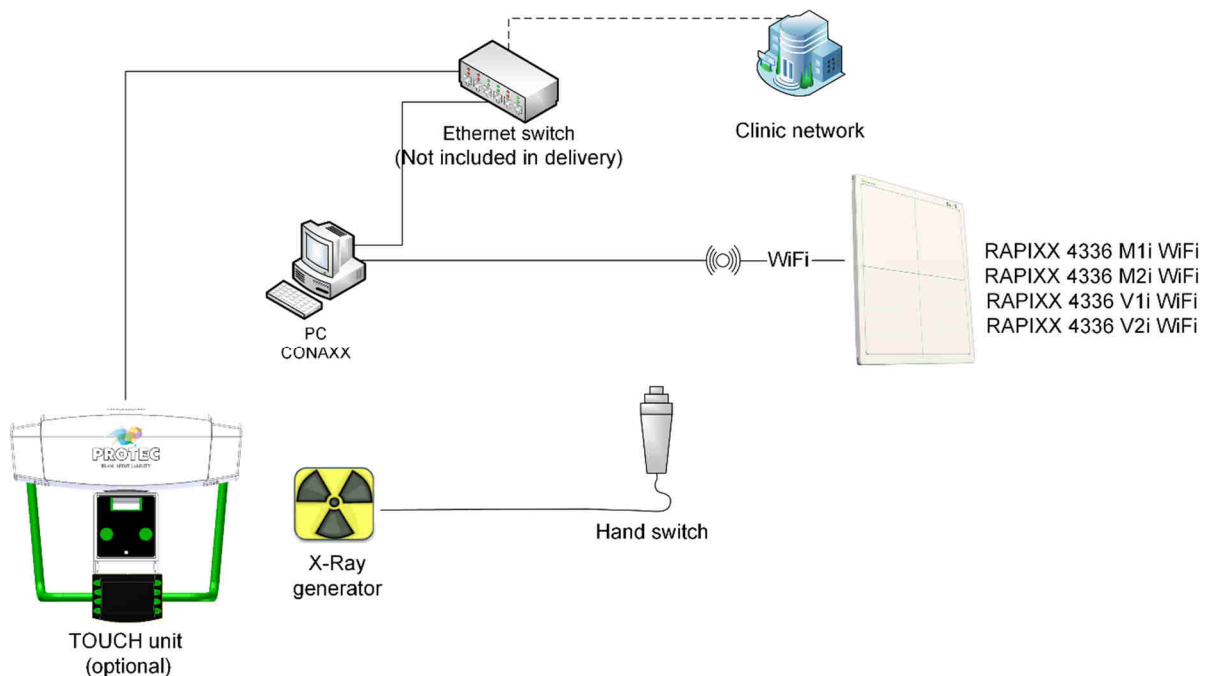
4.5 Connection of the components

Connect the components as described in the following diagrams.

4.5.1 Installation without Access point



4.5.2 Installation with Access point



4.6 Connection to the wireless detector

In case of using the wireless adapter of the computer to establish the connection to the detector you have to setup this connection once.

Open the list with the available wireless networks. The name of the network provided by the detector is equal to the serial number of the detector, e.g. "KV0704A294138". The password for this network is "Mars1417V".



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 2 open the configuration by clicking the button "Configuration" in the start menu of CONAXX 2 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 WiFi“

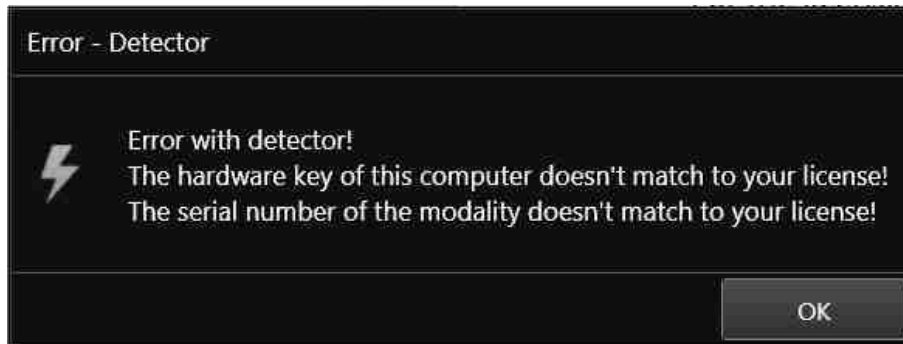
Depending on how the detector is build in it might be necessary to rotate the acquired images in CONAXX 2. This can be changed in "Rotation of images" in the same configuration section.

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

Afterwards please restart CONAXX 2.

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.

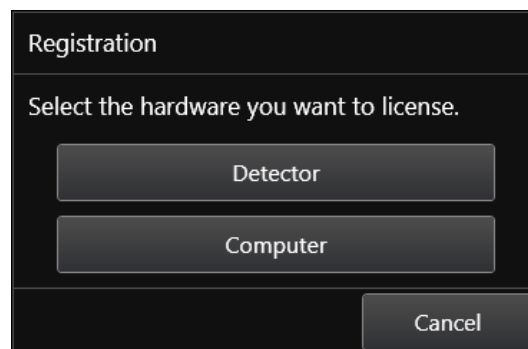


Confirm this message.

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:

- Online with the licensing page of the dealer backroom or
- 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

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
- perform the calibration on the table
- perform "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.

Please close the software "RAPIXX Calibration".

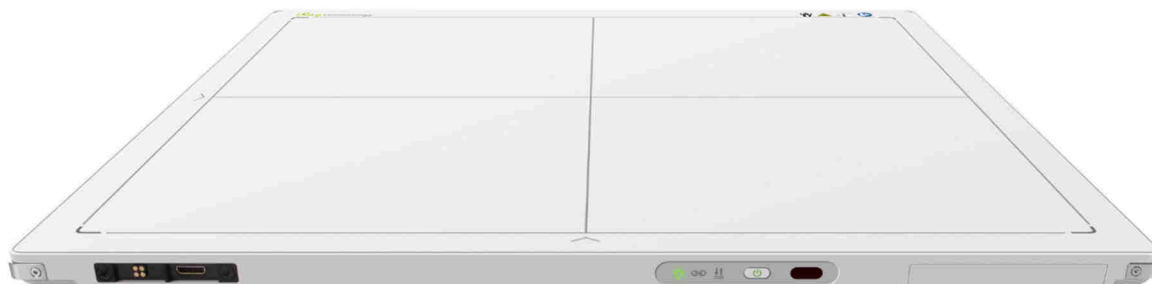


NOTE

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

6 Status information

6.1 Status LEDs of the detector



6.1.1 Power supply

LED	Description	Status
	Off	Detector switched off
	Orange	Detector switched on– Battery level under 10%
	Green	Detector switched on– Battery level over 10% or usage of power supply
	Orange (flashing)	Detector switched off – Battery level under 10%
	Green (flashing)	Detector switched off – Battery level over 10%

6.1.2 Connection

LED	Description	Status
	Off	Detector switched off
	Blue (flashing)	Detector switched on – Wireless signal available
	Blue	Detector switched on – Wireless connection with detector possible or established
	Green (flashing)	Detector switched on – Initialization
	Green	Detector switched on – Connected with network cable

6.1.3 Transmission

LED	Description	Status
	Off	No transmission
	Green (flashing)	Active transmission
	Orange	Initialization
	Orange (flashing)	Transmission error



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?**

6.2 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, calibration functions or status information for the battery charge level.



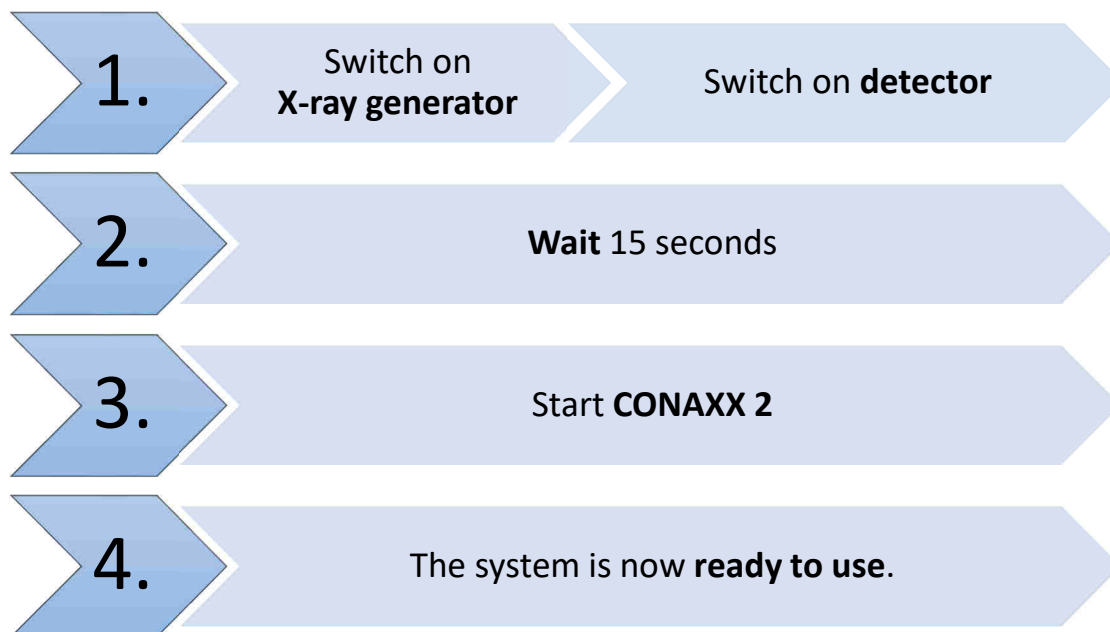
- **X-ray generator:**

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

7 Handling of the RAPIXX Wifi

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_Mars1417V* of the detector manufacturer.



If the detector of the RAPIXX system is operated via data cable and with direct patient contact, it must be ensured that the data cable is equipped with a network isolator according to EN 60601-1.

7.3.1 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 *UserManual_Mars1417V* of the detector manufacturer.

Note

Before changing the battery it is recommended to switch off the detector. Switch on the detector after battery change.



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_Mars1417V* 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 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.

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_Mars1417V* of the detector manufacturer.

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