PROSLIDE 32 SR System

Mobile radiographic unit with DR-System

Model/ID: 7016-9-0000
Basis UDI-DI: 426050264X027ZV

System instructions for use
shortform

Ident. Nr. 5016-0-0002

(Example configuration without RAPIXX-DR System)

Responsible for putting devices together
to this system acc. to Article 22 of
Regulation (EU) 2017/745:

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Version: 4.0
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Subject to change

NOTE

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Table of content

NOTE

The information this document is containing conforms to the configuration of the equipment as of the date manufacture. Revisions to the equipment subsequent to the date of manufacture will be addressed in service updates distributed to the Protec GmbH Technical Service Organization.

Document effectivity

Revision	Date	List of effective pages	Comment	Author
1.0	2017-03-13	all	Original issue	ML
2.0	2019-11-29	3, 4, 8	NOTE changed; Cap. 1 new; Cap. 3.1 WARNING new	ML
3.0	2020-11-03	Title page, 5	Model/ID, Intended use	ML
4.0	2021-07-20	Title page, 5, 6	change to article 22	ML

Radiation warning

WARNING!

The system described in this document is for intended generation of X-rays for medical diagnostics.

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 person.
Those persons responsible for the application must have the specific knowledge according to legal requirements and regulations and must establish sage exposure procedure for these kind of systems. The responsible persons for planning and installation of this equipment must observe the national regulations.

1 Product description

1.1 Introduction

This System Quick Guide summarizes the most important information for efficient and effective operation of the PROSLIDE 32 SR system.

NOTE

Before you work with the PROSLIDE 32 SR System, it is imperative that you read the applicable instructions for the two system components PROSLIDE 32 SR and RAPIXX DR System with detailed safety and handling instructions. These documents are in charge and valid in their current version.

1.2 Intended use

The PROSLIDE 32 SR Systems as mobile general-purpose diagnostic X-ray systems with DR-System are intended in a variety of routine planar x-ray imaging applications in human medicine. They are used in hospitals and enable the acquisition, image processing and transmission of digital, conventional X-ray images at various locations within the hospital.

1.3 Clinical Benefit

The clinical benefit of using diagnostic X-ray systems in human medicine is the generation of conventional two-dimensional X-ray images for creation or specification of findings as a basis for treatment decisions.

1.4 Patient target group

The intended patient group includes all people for whom a justifying indication for a medical X-ray has been given by a physician with the necessary expertise in radiation protection.
There are no general or fundamental restrictions on the patient group regarding age, gender, origin and patient condition.

1.5 Medical conditions to be diagnosed

A complete list of indications is unrealisable for conventional radiography, because the spectrum of conventional X-rays is very diverse and can vary in the course of medical-technical progress.

Some examples of indications for an X-ray examination may be:

- For the diagnosis of a bone fracture or bony injuries of the skeletal system or pathological changes of hard tissues.
- To control the bone setting.
- For the diagnosis of luxations and ligament ruptures of the locomotor system.
- For the diagnosis of degenerative, inflammatory, traumatic and tumorous diseases and changes of the locomotor system.
- For diagnostic of malformations and malalignments of the skeletal system.
- For the diagnosis of thoracic and pulmonary symptoms (thorax exposures)
- For the diagnosis of sclerotherapy.
- For the diagnosis of inflammatory and expansive processes of the mucosa, cranial bones and paranasal extension.
- For the diagnosis of the abdomen (e.g. acute abdomen, plain abdominal radiography, urethrogram, cystogram).

1.6 Indications and Contra Indications

1.6.1 Indications

According to §83 of the German radiation protection law (StrlSchG), an X-ray examination is only justified if the patients benefit from x-ray diagnostics outweighs the radiation risk. The examination method, means the conventional X-ray with the PROSLIDE 32 SR System, must be suitable to answer the diagnostic question and no other more suitable alternative method is available.

Accordingly, it is also described by the International Atomic Energy Agency (IAEA) in the document Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards (Requirement 37: Justification of medical exposures). It also refers to the need to consider national or international guidelines for the justification of a medical exposure.

NOTE

Even if, according to the justifying indication, the benefit predominates the radiation risk, it must not be disregarded that there are residual risks due to ionising radiation and that undesirable side effects may occur. Ionising radiation (X-radiation) can damage the genome and, in the long term, lead to cancer and mutations and thus damage the human body.

1.6.2 Contra Indications

There are no absolute contraindications for conventional X-rays But it is not allowed to make any exposures on humans when they are not medically indicated (see Justification of medical exposures,). For pregnant women and children it is important to consider if the exposure is really necessary. It should be avoided if possible.

1.7 Intended user group

The mobile radiographic system PROSLIDE 32 SR is exclusively designated for use by professional who are trained, in accordance with the corresponding national regulations, in the use of diagnostic X-Ry equipment and its proper intended use in connection with other medical devices, objects and accessories.

Suitable users could include the following: Radiologist, radiology assistants, radiology technicians, doctors and other medically trained personnel.

1.8 Declaration according to Article 22

The Declaration according to Article 22 of Regulation (EU) 2017/745 is available on request from PROTEC:

PROTEC GmbH & Co. KG
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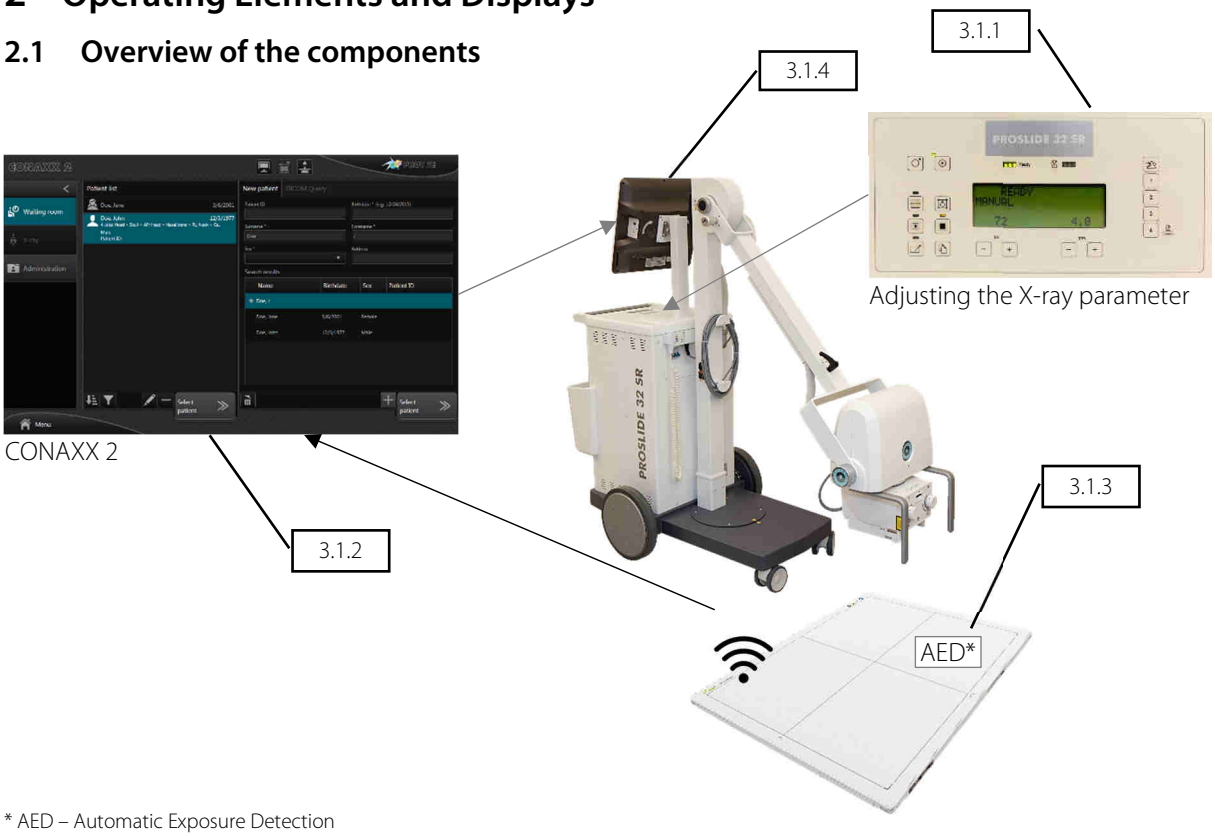
2 Operating Elements and Displays

2.1 Overview of the components



* AED – Automatic Exposure Detection

2.1.1 Operating Elements and Displays PROSLIDE 32 SR

You can find further information of the mobile X-ray unit in the user manual for this component.

2.1.2 Operating Elements and Displays of the CONAXX 2 Software

You can find further information of the CONAXX 2 in the user manual for this component.

2.1.3 Operating Elements and Displays of the RAPIXX System

You can find further information of the RAPIXX-systems in the user manual for this component.

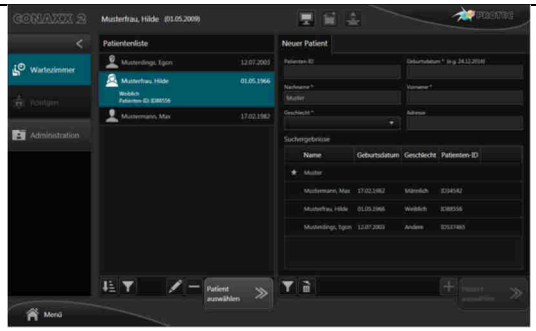
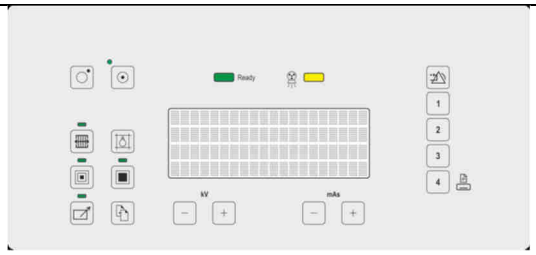
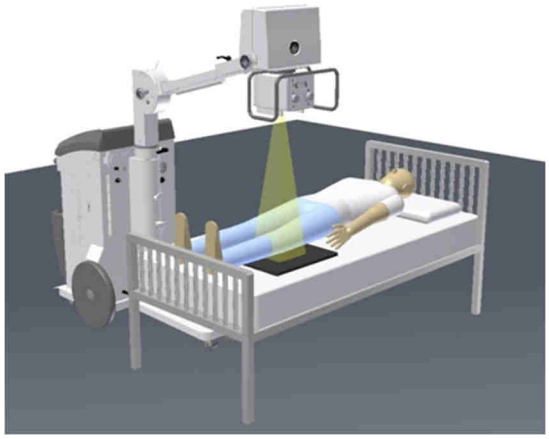
2.1.4 Operating Elements and Displays of the Panel-PC/Tablet*

You can find further information of the Panel-PC/Tablet in the user manual for this component.

* Not included in delivery. Please order separately.

3 Handling

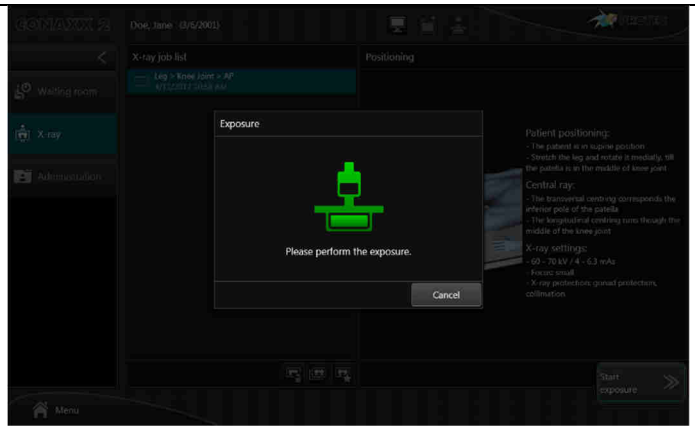
3.1 Operation

Description	Picture
Switch on the PROSLIDE 32 system	Switch-on sequence: - Generator - RAPIXX DR-System - Panel-PC/Tablet*
Start CONAXX 2	
Chose patient and region of interest in CONAXX 2	
Prepare exposure in CONAXX 2	
Set up generator values	
Position detector, y-ray tube and patient	

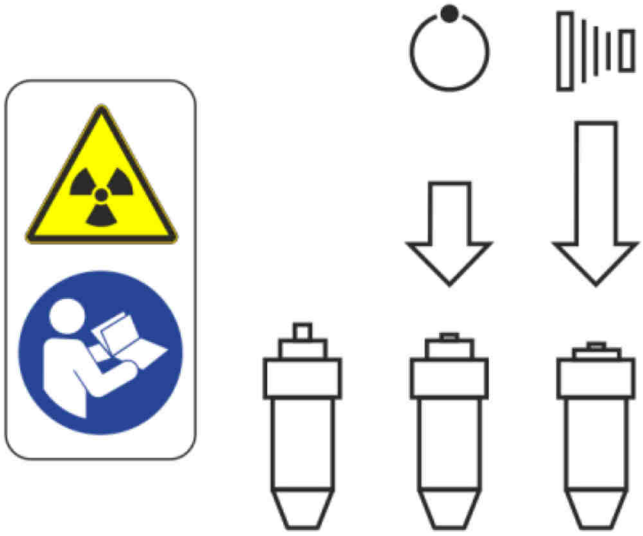
WARNING!

The central beam and the detector surface (or CR or film) should always be positioned orthogonally to each other and centrally in the beam field for optimum imaging. The active surface of the detector (or CR or film) must always point towards the radiation field.

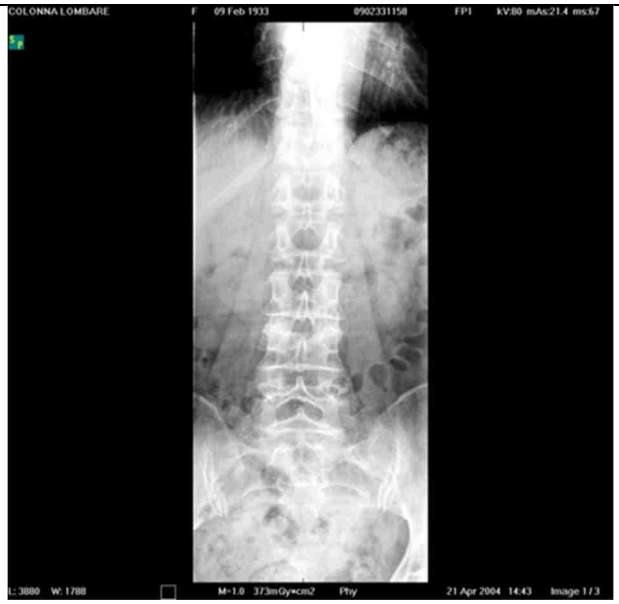
Prepare CONAXX for exposure

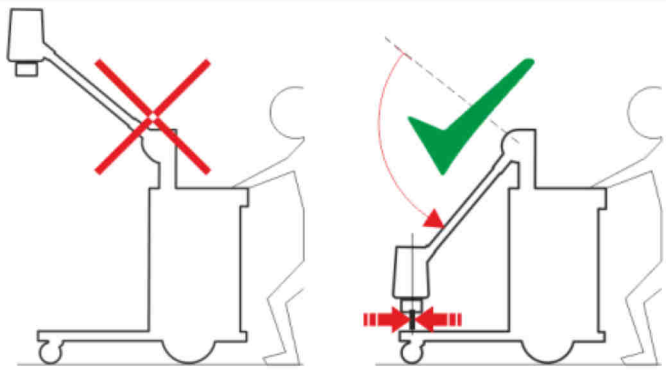


Make the exposure



View the image



Prepare X-ray tube and detector for next exposure or bring them into transport position	
Copy exposures to the clinical system	

Detailed information of using the components can be found in the respective user manual.

3.1.1 Operation of PROSLIDE 32 SR

Detailed information of using the PROSLIDE 32 SR can be found in the user manual.

3.1.2 Operation of CONAXX 2

Detailed information of using the CONAXX 2 can be found in the user manual.

3.1.3 Operation of the RAPIXX-DR System

Detailed information of using the RAPIXX-DR system can be found in the user manual.

3.1.4 Operation of Panel-PC/Tablet*

Detailed information of using the PANELPC/Tablet can be found in the user manual.

3.2 Functions of the PROSLIDE 32 SR SYSTEM

3.2.1 Switching the PROSLIDE 32 SR system OFF and ON

To switch on the complete PROSLIDE 32 SR system it has to be switched on 3 components. We recommend the following sequence of switching on:
1. Generator (PROSLIDE 32 SR)
2. RAPIXX DR-System
3. Panel-PC/Tablet* (depends on configuration)

Detailed information about switching on the component can be found in the respective user manual.

* Not included in delivery. Please order separately.