

Grid entity

X-ray film cassette holder

Model/ID: 7051-0-xxxx

User Manual

Ident. Nr. 5051-0-0252



CE



NOTE

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These accompanying documents were created and distributed by the documentation department.
Comments and questions about the documentation, please contact:

PROTEC GmbH & Co. KG

In den Dorfwiesen 14 | 71720 Oberstenfeld
Deutschland

Phone: (+ 49) 7062 – 92 55 0

Fax: (+ 49) 7062 – 22 68 5

E-Mail: protec@protec-med.com

Internet: www.protec-med.com

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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	2017-09-20	all	Original issue, base to Gebrauchsanweisung V1.0
2.0	2020-09-22	7, 12, 15, 18	Chap. 1.2.1, 4.2, 6, 8: Detector charging added

General Notes



WARNING!

No changes of the ME device!

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.

Radiation Warning



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 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.

Improvement Recommendations

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

1 Product description

1.1 Introduction

This user manual describes the special features and operational aspects of the Grid entity, knowledge of which are required for efficient and effective use of the radiographic system.

Prior to working with the Grid entity, it is required that the user read the Safety Notes as well as the chapter regarding operation.

1.2 Description

The grid entity is designed for intended for use with a cassette load, a measuring chamber (for the operation of the x-ray generator with exposure machine) and a scattered-radiation screen.

The X-ray grid, cassette loader as well as measuring chamber with adapting parts must be ordered separately.

The grid serves to reduce the scattered radiation, which has a contrast-reducing effect on the recording.

1.2.1 Models

Grid entity
Grid entity FSE
Grid entity DL
Grid entity FSE DL

All models are available in left and right loading.

1.3 Product specific characteristics

Optional for use of standard cassette trays with or without anti-scatter grid.

1.4 Intended use

The Grid entity is intended for use with standard cassette trays in standard Bucky systems, used in examinations with X-ray units for general radiography in diagnostic human medicine use. It must be used only in locations designated for medical use.

1.5 Intended user group

The Grid entity 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 (certified) use in connection with other medical products, objects and accessories.

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

1.6 Conformity



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 Dorfswiesen 14 | 71720 Oberstenfeld
Telephone: +49 (0) 7062 – 92 55 0
Fax: +49 (0) 7062 – 22 68 5
E-Mail: protec@protec-med.com
Internet: www.protec-med.com

2 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 ionising 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 Grid entity 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 Grid entity. 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.



NOTE

Every operating element are descript in the corresponding manual.



WARNING!

It's not allowed to make any medical not indicated exposures on people. At pregnancy or children the question is if the exposure is really necessary. If possible it's better to abandon it.

2.1 General safety notice

2.1.1 Operating of the Grid entity

When having troubles with operating of the Grid entity, immediately call the Service of PROTEC or an authorized service and stop the using of the system.

2.1.2 Operating personnel

The Grid entity only be operated by personnel who are trained in accordance with the corresponding national regulations in the use and operation of diagnostic X-Ray systems.



NOTE

Only properly trained and authorized personnel are allowed to work with the Grid entity.

The user, as well as the service personnel, must observe the warnings, notices and safety instructions located on the device and in the user manual. Failure to comply with the information provided can lead to injury.



NOTE

Operating personnel are required to acquaint themselves with all warnings (warning signs) located on the device. They serve to ensure the safety of the operator as well as others and set a basis for orderly operation.

2.1.3 Pinching and Collision Hazards



CAUTION!

Ensure that while using any product that can be lowered, raised or moved in different directions, neither yourself (operator), the patient or any third party finds themselves in a hazardous position (area of movement). Remove all objects (e.g. chairs, pushcarts) from known collision areas. Failure to pay attention can lead to damage of the device as well as external objects.

2.1.4 Explosion protection

This Grid entity is not designated for use within areas with explosive hazards.

2.1.5 Interaction with external devices

Unwanted interaction with external devices is not known.

3 Control elements and device displays

Not available.

4 Handling / Operation

4.1 Operation Grid entity

Detailed information please find in the enclosed User Manual KL.

4.2 Panel einlegen in Ladeposition

Charging the 4343 panel only works if the panel is inserted in the drawer in the correct position. The charging connector must be on the rear left (for the 4343 panel) or rear right (for the 4336 panel) to make contact with the charging plug (image exemplary for 4343 panel).

When the detector load is closed and the system is switched on, the panel loads automatically. The display of the battery status depends on the applied software.



5 Safety and Maintenance

5.1 Introduction

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

5.2 Cleaning and disinfection



NOTE

Caution

Changes to material are possible!

Pay attention that, during cleaning and/ or disinfection, no fluids find their way into the main housing of the radiographic table. This reduces the risk of short circuits and corrosion.

5.2.1 Cleaning

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.

Clean the outer surfaces of the unit and all painted components using a damp towel and a mild – light alkaline cleaning agent (e.g. RBS* Neutral T). Dry the components off following cleaning.

Chrome components should be cleaned by being wiped down with a dry woolen cloth.

5.2.2 Disinfection

Disinfection must be performed in accordance with the applicable legal requirements and guidelines corresponding to disinfection and explosion protection.

For reasons related to safety, the use of spray disinfection is not allowed. The mist from such disinfection dispenser systems can find its way into the unit, resulting in short circuiting and/ or corrosive build up.

All components within the radiographic system, including unit accessories, should undergo a wipe down disinfection using appropriate surface disinfection agents (e.g. Melsept* SF, 15 min. reaction time with a concentration of 2%). The information provided by the disinfectant manufacturer in regard to concentration and reaction time must be closely followed.

No disinfection agent, which is classified as flammable, can be utilized.

Should explosive gas and / or vapors be created through the use of the chosen disinfection agents, the unit can only be switched on when the gas/vapors have 100% dispersed.

5.3 Check-up and maintenance



WARNING!

It's forbidden to make any checkup or maintenance services while the Grid entity is in use with a patient! Any checkup or maintenance services can only be done by people who got trained or authorized by PROTEC.

5.3.1 Daily Controls (prior to or during the unit operation)

No required.

5.3.2 Maintenance

Required maintenance must be performed at 6-month intervals by PROTEC Service or specific authorized service provider to ensure the safe and reliable operation of the equipment. In the event that scheduled maintenance is not performed, PROTEC GmbH & Co. KG will not be responsible for damages incurred by the user or third parties if such damages are the result of improper or omitted 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 unit is overall operationally ready.

See Technical Description off the system and off all integral components.

Only original spare parts are to be used in situations requiring component replacement.

5.3.3 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.

Only authorized technicians may do service and maintenance work.

5.3.4 Product life time

The Grid entity has an expected product life of 10 years when used in accordance with the product specifications/ limitations and provided that maintenance through the PROTEC service department or a **PROTEC** authorized service provider has been completed. After reaching the life span the further usage of the device happens on own risk.

5.3.5 Further Information

Further information's to the chapters and for a safe usage, transport or storage are in the technical description of the Grid entity.

5.3.6 Disposal



The Grid entity contains different plastics, oils and heavy metal (counterweight). At disposal of exchange parts or the whole system the current regulations have to be observed. Please contact your contractual partner or the service company, or a company specialized for disposing the components.

6 Electrical data

**NOTE**

The Detector charging is in need of the following power supply:

Power supply	230 Vac
Power frequency	50 - 60 Hz
Input current	1,5A Max

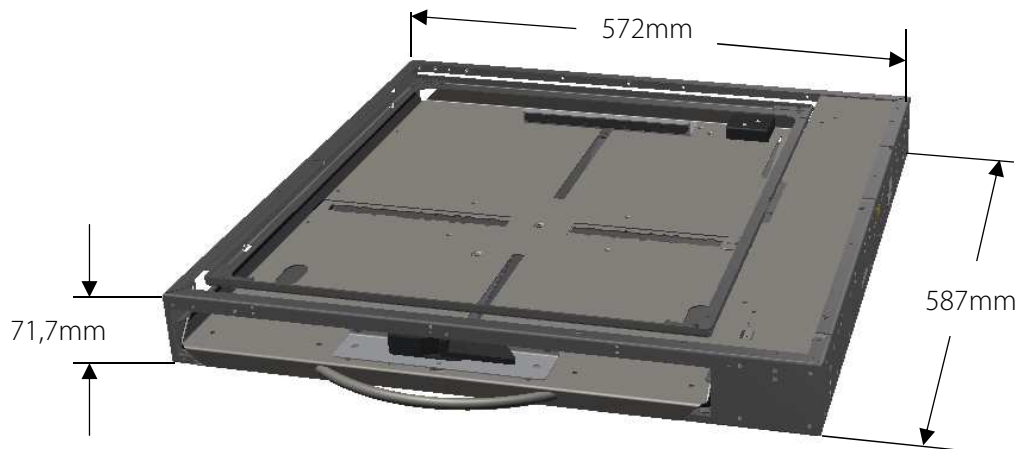
The power supply for the panel is provided by a power supply unit. This supplies 24Vdc, 3A.

**WARNING!**

To lower the risk of an electrical shock, the device can only be run on a power supply with a protective conductor.

7 Technical Data

7.1 Dimensions



7.1.1 Protection Art and Protection Class

The Grid entity is consistent with a protection class 1 device and contains applicable parts Type B (according to EN 60601-1). Environmental conditions.

7.2 Environmental

7.2.1 Environmental conditions during operation












Ambient Temperature	+ 10°C to + 40°C
Relative humidity	30% to 75% (non-condensing)
Atmospheric pressure	700 hPa to 1060hPa

7.2.2 Environmental Conditions for Shipping and Storage

Ambient Temperature	- 10°C to + 70°C
Relative humidity	10% to 95% (non-condensing)
Atmospheric pressure	500 hPa to 1060hPa

8 Description of symbols, labels and abbreviations

8.1 Symbols

	Attention, consult accompanying documents
	Classification according to EN 60601-1 (Type B)
	Protective ground (Earth)
	Refer to user manual
	CE-Mark
	Order number
	Serial number
	Manufacturer
	Date of manufacture
 www.protec-med.com/download	With this symbol we point out that Usage instructions of the corresponding product is on our Homepage
	Notes on disposal; WEEE , Waste of Electrical and Electronic Equipment

8.2 Identification label

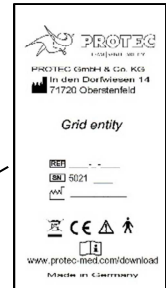


8.3 Labels



Refer to user manual.

8.4 Position symbols and labels



8.5 Abbreviations

mm	Millimeter
°C	Degree -Celsius
hPa	Hectopascal
EN	European Standard
RA	Grid detection
DL	Detector charging
FSE	Fail safe