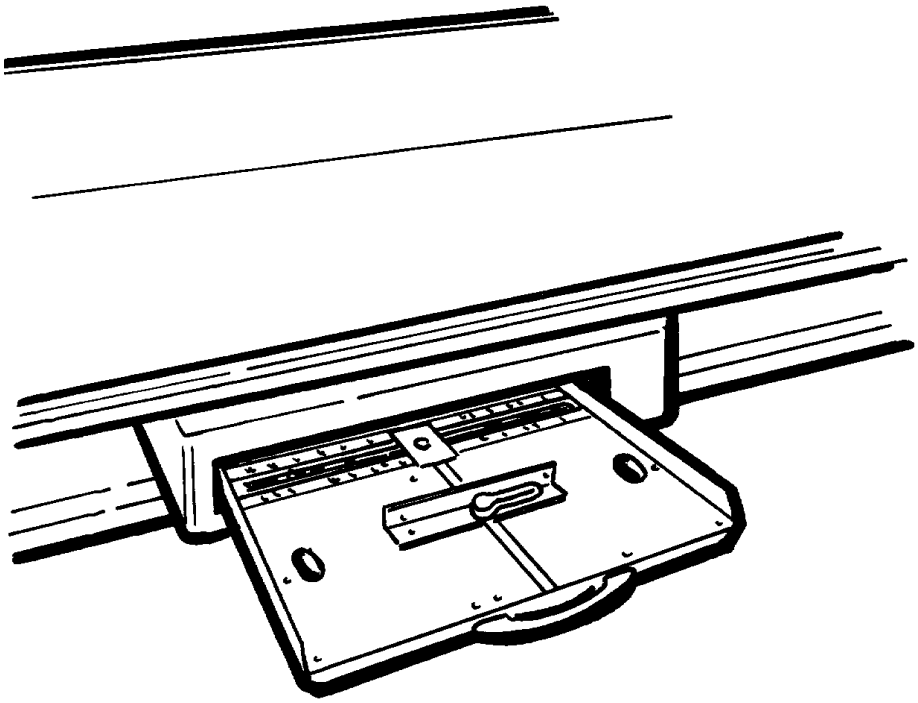
PROTEC
TEAM | SPIRIT | ABILITY

Cassette Size Sensing Tray KLFA

Model/ID: 7503-0-0000
7503-0-0002

Instruction for Use

Ident. Nr. 5051-0-0012



CE

This document is prepared and distributed by Publications Department.
Send inquiries regarding this document to the following address:

PROTEC GmbH & Co. KG
In den Dorfwiesen 14 | 71720 Oberstenfeld

Telefon: +49 (0) 7062 – 92 55 0
Fax: +49 (0) 7062 – 22 68 5

e-Mail: protec@protec-med.com
Internet: www.protec-med.com

Content

Page

NOTE

The information contained in this document conforms with 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
	21/10/1998	all	Original Issue
Rev 1	31/01/2005	all	re-Layout
Rev 2	10/07/2007	all	Fail Safe added
Rev 3	25/11/2010		Modified address
Rev 4	03/08/2011		Lable Protec
Rev 5	30/11/2011		New Lable
Rev 6	03/05/2012		New nameplate

Mechanical - 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 personnel 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

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** personnel. Assemblers and other personnel not employed by nor directly affiliated with **PROTEC** technical services are directed to contact the local **PROTEC** office before attempting installation or service procedures.

Improvement Recommendations

Users of this Document are encouraged to report errors, omissions and improvement recommendations to the following address:

PROTEC GmbH & Co. KG
In den Dorfwiesen 14 | 71720 Oberstenfeld

Telefon: +49 (0) 7062 – 92 55 0
Fax: +49 (0) 7062 – 22 68 5

e-Mail: protec@protec-med.com
Internet: www.protec-med.com

1 Equipment Description

1.1 Introduction

This „Instruction for Use“ describes the special, characteristic features and the correct operational instructions which are necessary for the efficient and effective use of the Cassette Size Sensing Tray KLFA.
It is suggested that you review the operation instructions, the safety notes and the controls described in this “Instruction for Use” before using the Cassette Size Sensing Tray KLFA. Each control device and each display is described in order to make you acquaint with its function.

1.2 Intended Purpose

The Cassette Size Sensing Tray KLFA is for use with an x-ray cassette

1.3 Description

The cassette size sensing tray is designed for use in conjunction with automatic collimators to provide positive beam limitation of emitted X-rays. The cassette Tray KLFA senses the size of any cassette for film sizes from 13 cm x 18 cm (5" to 7") to 35,5 cm x 43 cm (14" x 17") when placed in either direction in the cassette Tray KLFA.
The cassette Tray KLFA has a film cassette locking mechanism which automatically centers the film cassette from front to back. The cassette Tray KLFA has a cassette side support to support the cassette when the cassette Tray KLFA is used in a vertical position. The size of the film cassette is measured by two potentiometers, one of which is mechanically connected to a side arm for left to right (width) measurements. The second potentiometer is mechanically connected to the clamping mechanism for front to back (length) measurements. In addition the cassette Tray KLFA is equipped with an auxiliary switch which is mechanically operated when the cassette Tray KLFA is inserted in the Bucky with a film cassette installed. This switch is an isolated circuit and can be incorporated to perform various functions; such as switching from automatic to manual collimation when a cassette Tray KLFA has been inserted in the Bucky without a film cassette.
A 14 pin connector is provided on the rear of the cassette Tray KLFA which mates with an 14 pin receptacle installed on the Bucky. The signals **"cassette size"**, **"cassette inserted"** and **Fail Safe** (version 05030002) are present at the 14 pin receptacle on the Bucky.

1.4 Declaration of Conformity

CE

This product is in conformity to the requirements of the European Community Medical Device Directive 93/42/EEC from 06/14/1993.

You can get the declaration of conformity directly from:

PROTEC GmbH & Co. KG
In den Dorfwiesen 14 | 71720 Oberstenfeld
Telefon: +49 (0) 7062 – 92 55 0
Fax: +49 (0) 7062 – 22 68 5
e-Mail: protec@protec-med.com
Internet: www.protec-med.com

1.5 Equipment components

The Cassette Tray KLFA consists of the following equipment components:

- Cassette tray
- Cassette clamps
- Cassette positioner
- Cassette size sensing

1.6 Optional Equipment

The Cassette Tray KLFA requires no optional equipment.

1.7 Nameplate

The name plate for the Cassette Size Sensing Tray KLFA is located at the front on the right side, readable from the bottom side.

2 Control Elements and Indicators

The controls of the Manual Cassette Tray KL are shown in Figure 2-1: Cassette Tray and their functions are briefly described on the following page.

Warning

Pinch points are present. Grip only the handle to pull out or to push in the Manual Cassette Tray KL.
Failure to comply may cause injury to operator's hands.

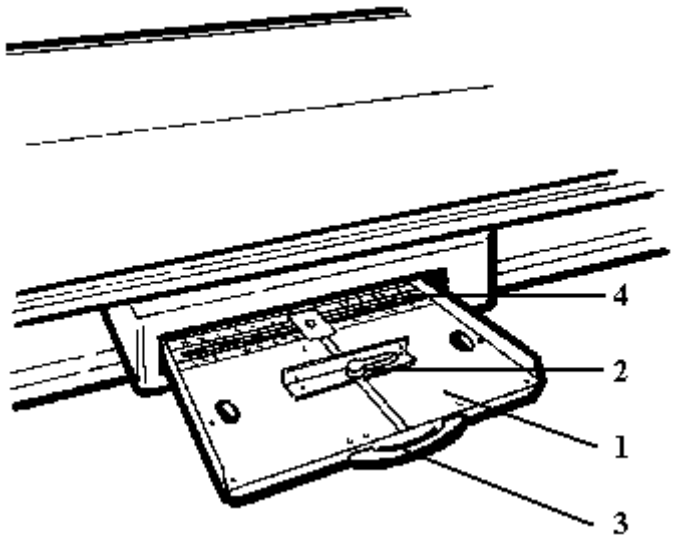


Figure 2-1: Cassette Tray

2.1 Cassette tray KLFA

The cassette tray KLFA (Figure 2-1, item 1) positions the film cassette in the Bucky.

2.2 Cassette clamps

Two cassette clamps (Figure 2-1, item 2) center the film cassette transversely within the cassette tray KLFA (Figure 2-1, item 1).

2.3 Handle

A film cassette may be inserted, when the cassette tray KLFA (Figure 2-1, item 1) is pulled out by its handle (Figure 2-1, item 3) from the Bucky to the forward stop.

2.4 Cassette positioner

The film cassette may be longitudinally centered within the cassette tray KLFA (Figure 2-1, item 1) with its transverse center line aligned with the notch in the cassette clamps (Figure 2-1, item 2) or by pushing the film cassette against the cassette positioner (Figure 2-1, item 4) positioned into the locking corresponding to the inserted film cassette.

3 Operating Instructions

3.1 Safety Aspects

3.1.1 Requirements for Operation

Prior to operating the system, the user must ascertain that all devices are in safe operation and proper working condition, and that the product is ready for use.

3.1.2 Users

The system must be operated by qualified users, trained in the use of human diagnostic X-ray equipment in conformity with the respective national regulations.
A product introduction for the user is necessary.

3.1.3 Explosion protection

This unit is not designed for operation in potentially explosive atmospheres.

3.1.4 Radiation Protection

X-rays represent a hazard to both patients and operator if the rules for the use of such systems are not observed.
For this reason the principles of radiation protection must have the highest priority and they shall be observed at all times.

- **Keep distance from the radiation source**
  The dose declines with the square of the distance from a (point-like) radiation source, i.e. doubling the distance reduces the dose to one quarter, tripling the distance reduces the dose to one ninth, etc.
- **Keep exposure periods short**
  The dose rises linear to the exposure time, i.e. halving the exposure period will halve the dose (this is applicable particularly for fluoroscopy; when making X-ray films the current time product (mAs value) is prescribed in the most cases).
- **Use shielding and protective clothing**
  The protective factor rises exponentially with the thickness of the shielding. This means that two half-value layers will reduce (homogeneous) radiation to 1/4, three half-value layers to 1/8, and 10 half-value layers will reduce the radiation to less than 1/1000 of the original value.
- **Never reach into the direct X-ray beam**
  The dose in the direct, non-attenuated X-ray beam is some 100 times higher than the scattered radiation.
- **Personal dose meters**
  During work with X-ray use corresponding personal dose meters for measurement of the accumulated dose.

When taking X-rays near the reproductive organs, pay attention to using the best possible protection (testicle shielding cup or lead apron).

The operator shall always stand behind a shielding panel or partition when taking exposures.

Persons who must be near the patient during fluoroscopy shall wear protective clothing (a lead apron, for instance). The same applies for maintenance and repair work.

3.1.5 Interferences to other devices

There are no interferences to other devices known.
The system meets the requirements of EN 60601.

3.1.6 Warnings

	Pinch points are present. Grip only the handle to pull out or to push in the cassette tray. Failure to comply may cause injury to operator's hands.
	Observe all general precautions to protect the patient against hazard from unwanted or excessive radiation.

3.2 Inserting a film cassette into the cassette tray KL

- A film cassette may be placed into the cassette tray KLFA, when the X-ray tube assembly is positioned.
- Pull out the cassette tray KLFA (Figure 2-1, item 1) by its handle (Figure 2-1, item 3) from the Bucky until it hits the forward stop.
- The cassette clamps (Figure 2-1, item 2) center the film cassette transversely within the cassette tray KLFA. Rotate its latch counterclockwise to unlock it.
- Open the cassette clamps (Figure 2-1, item 2) far enough to insert a film cassette of the desired size.
- Insert the film cassette with its transverse center line aligned with the notch in the cassette clamps (Figure 2-1, item 2) or push the film cassette against the cassette positioner (Figure 2-1, item 4) positioned into the locking corresponding to the inserted film cassette (13 cm, 18 cm, 24 cm, 30 cm, 35 cm, 40 cm, or 43 cm).
- Push the cassette clamps (Figure 2-1, item 2) against the film cassette, and rotate the latch into the locked position.
- Push the cassette tray KLFA (Figure 2-1, item 1) fully into the Bucky.

4 Operator Maintenance

4.1 Introduction

This chapter provides a maintenance schedule to ensure proper and safe operation after installation.
Further adjustments or calibrations not contained in this “Instructions for Use”, refer to the applicable “Technical Description” and have to be made by **PROTEC** personnel or expressly by **PROTEC** authorized service personnel.

Before operating this x-ray unit, user have to make themselves acquaint with all control elements and their functions.

The preventative maintenance procedures required to ensure the operational integrity and safety of the equipment are listed in the following paragraphs. It is the owner/user's responsibility to perform preventative maintenance at the specified intervals or arrange for such service with an authorized service representative.

Maintenance has to be recorded.

4.2 Operating

1. Prior to service or maintenance ensure that the system is turned off and completely separated from voltage (FI-switch or room emergency OFF switch)
2. Covers may only be opened by service personnel, as there may be high voltage behind them.

4.3 Safety Information

The user and the personal have to follow the warnings and safety information, placed on the device, disregarding may lead to injury.

Personal must make itself familiar with all warnings, placed on the device.

They are necessary for the safety and ensure the correct operation.

In the event of a malfunction, turn the equipment of and notify **PROTEC** service or the expressly authorised service provider.

4.4 Technical Safety Information

To protect the safety of patients, users and third parties, it is absolutely necessary that Checks, which ensure the reliable function and operational safety are made in intervals of 12 months by **PROTEC** service or expressly authorised service providers.

All parts of this equipment that could create a hazard through wear and tear must be checked in at least intervals of 12 months and if necessary, replaced by **PROTEC** service or by expressly authorized service providers at regular intervals.

As the manufacturer, we are responsible for the technical safety aspects of the equipment if any maintenance, repairs and/or modifications are performed by our staff or by expressly authorized service providers. Likewise, if component parts that affect the safety of the equipment are replaced by original replacement parts in the event of a failure, we are responsible for the technical safety aspects of the equipment.

In the event that scheduled maintenance is not performed, **PROTEC** will not be responsible for damages incurred by the user or third parties if such damages are the result of improper or omitted maintenance.

Before the start of examination operations, the operator must ensure that all the equipment, which is listed in the Instructions for Use and which is relevant to safety, is functioning properly and that the product is ready for use. A visual check shall be made to insure that all displays and indicator lamps are functioning correctly.

4.5 Preventative maintenance

The preventative maintenance procedures required to ensure the operational integrity and safety of the equipment are listed in the following paragraphs. It is the owner/user's responsibility to perform preventative maintenance at the specified intervals or arrange for such service with an authorized service representative.

4.6 Users maintenance

4.6.1 Daily maintenance prior to operation

Check "User's maintenance schedule" for equipment compliance.

4.6.2 Daily maintenance during operation

No checking of the equipment is required during operation.

4.6.3 Monthly maintenance

Check "User's maintenance schedule" for equipment compliance.

4.6.4 Service maintenance

Required maintenance must be performed at twelve month intervals by **PROTEC GmbH & Co. KG** service or a specifically 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.

4.7 Users maintenance schedule

4.7.1 Daily maintenance

1. Clean the Cassette Tray KLFA using a clean cloth and common household cleaner.
2. Check the controls for proper function.

4.7.2 Cleaning

Prior to cleaning or disinfecting, ensure that the system power is turned off (remove power cord), that the emergency OFF switch or safety switch is actuated, and that no liquids can penetrate into the equipment.

Do not use water for cleaning.

Water causes short circuits in the electrical portion of the system, and corrosion in the mechanical components.

Do not use corrosives, solvents or abrasive cleaning materials.

Clean painted and plastic surfaces only with a cloth and common household cleaners and wipe surfaces with a clean, dry, lint-free cloth.

Clean chrome-plated parts by wiping with a clean, dry, lint-free cloth.

4.7.3 Disinfection

Prior to disinfecting, ensure that the system is turned off, that the emergency OFF switch or safety switch is actuated, and that no liquids can penetrate into the equipment.

All components, including accessories and connecting cables, may be disinfected only by wiping with a disinfectant solution. Please contact **PROTEC** if detailed information is needed concerning appropriate disinfection materials.

The equipment must be well covered with plastic sheets during room disinfection.

For safety reasons, no spray disinfectant may be used.

Recommendations and instructions regarding the use of disinfectants and methods of disinfection may be derived from the most recent rules and guidelines concerning disinfection and explosion safety.

4.7.4 Quality Control

X-ray equipment should be quality-controlled at regular intervals, at least monthly, or as required by applicable regulations to determine that the image quality remains in accordance to national regulations, e.g. by a monthly consistency testing.

4.7.5 Service Maintenance Schedule

To be performed by properly trained and equipped service personnel.

12 Months intervals:

1. Check all mechanical stops for damage and firm seating.
2. Check the performance of all mechanical parts.
3. Tighten loose screws and nuts.
4. Check guide rails for damage and traces of wear.
5. Check micro switches and potentiometer for damage and firm seating.
6. Check connector and cables for damage and firm seating.

4.7.6 Disposal Remarks

The **Manual Cassette Tray KLFA** does not contain any toxicological materials.
All mechanical and plastic components have to be disposed according to local or national regulations.
In case of doubt contact **PROTEC GmbH & Co. KG**

5 Combination with other equipment

The Cassette Tray KLFA can only be combined with the following equipment:

- **PROTEC** type Bucky for cassette size sensing
- 3-field measuring chamber for Bucky
- Grid for Bucky

Combination with alternative equipment on inquiry only. For combination with other equipments please contact **PROTEC GmbH & Co. KG** for compatibility tests and release.

6 Technical Data

6.1 Measurements

Length: 586 mm
Width: 471 mm
Weight: 5,38 kg

6.2 Mechanical Characteristics

The Cassette Tray KLFA is made for continuous operation.

6.3 Electrical Characteristics

The Cassette Size Sensing Tray KLFA system incorporates two separate, but identical, electrical circuits to sense information related to cassette width and length measurements. The potentiometers are connected to act as voltage dividers for the automatic collimating voltage supplied by the collimator system. The electrical characteristics for these circuits are the following:

Impedance:	1 kΩ each potentiometer
Input voltage from collimator:	24 V max
Power dissipation:	1.2 W

2 micro switches are integrated to sense the an inserted cassette:
1. Cassette present switch: Supply's an external signal for an automatic collimator
2. Fail Safe switch: Interrupts the exposure release signal in case no cassette is inserted.

6.4 Compatibility requirements

The Cassette Size Sensing Tray KLFA is designed to be compatible with any automatic collimating system which provides the following parameters for positive beam limitation:

Input impedance:	100 kΩ
Sensing voltage:	24 V max

6.5 Environmental Conditions

6.5.1 Operating Environment

Temperature range	+10°C to +40°C (50°F to 104°F)
Relative humidity range	30% bis 75% (not condensing)
Atmospheric pressure range	700 hPa bis 1060hPa

6.5.2 Transport and stock environment

Temperature range	-15°C to +70°C (5°F to 158°F)
Relative humidity range	10% bis 95% (non condensing)
Atmospheric pressure range	500 hPa bis 1060hPa

6.6 Standards

The CE-labeling of this product is in conformity to the requirements of the European Community Medical Device Directive 93/42/ECC according to Article 11 Appendix VII

7 Description of Symbols, Labels and Abbreviations

7.1 Symbols

CE-marking

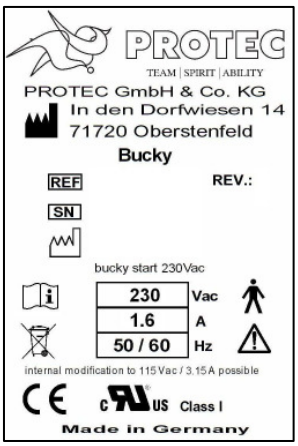
Attention, consult accompanying documents

Classification according to EN 60601-1, Class 1 Equipment, Type B

Attention, Pinch points are present

Observe all general precautions to protect the patient against hazard from unwanted or excessive radiation.

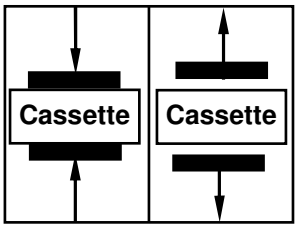
7.2 Labels



Nameplate

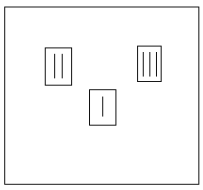
Bucky start may contain the following voltage specifications
230 Vac
115 Vac
24 Vdc

Voltage specifications may contain the following voltage specifications
230 Vac
115 Vac
24 Vdc



Cassette clamp

3-Field measuring chamber



7.3 Abbreviations

mm	millimetre
cm	centimetre
”	inch
kg	kilogram
%	Percent
hPa	Hektopascal
℃	Degree centigrade
℉	Degree Fahrenheit
CE	CE-marking
V	Volt
W	Watt
Ω	Kiloohm