PROGNOST ES

Radiographic Table with stand

Model/ID: 7049-5-1706L
7049-5-1707L
7049-5-1708L

User Manual

Ident. Nr. 5045-0-0002

CE

These accompanying documents were created and distributed by the documentation department. 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 updates distributed to the PROTEC GmbH & Co. KG Technical Service Organization.

Dokument Version

Revision #	Date	List of revised pages	Comments
0	14/08/2014	All	Original
01	15/10/2014		Turn Tube new
02	16/03/2015		General revision
03	06/05/2015		TP carbon 200x65,5 not applicable Tabletop defined to be an applied part
04	11/09/2015	21	Definition of operating position and possible hazards

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 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

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** 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.

Improvement Recommendations

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

1 Product Description

1.1 Introduction

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

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

1.2 Intended use

The radiographic table with stand PROGNOST ES is made up of an X- Ray table with floating tabletop and an integrated column system, which serves as the moving support for a complete X-Ray tube assembly. The radiographic table is designated as a component to be used for the creation/ assembly of a diagnostic X-Ray system for use in the medical sector (human medicine)

1.3 Intended user group

The radiographic table with stand PROGNOST ES is exclusively designated for use by professionals who are trained, in accordance with the corresponding national regulations, in the use of diagnostic X-Ray 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.

1.4 Conformity

CE 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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1.5 Product Description

1.5.1 Description

The radiographic tables within the PROGNOST ES series are constituted of a fixed elevating patient positioning table with floating tabletop and a completely integrated non- ceiling based column stand (without X-Ray components).

The floating tabletop is fixed in place by a motor activated braking system in the longitudinal and transverse directions. Both the tabletop brakes and height adjustment of the table is controlled using an integrated foot switching unit.

The table is prepared for the installation of a longitudinally sliding (manually movable) Bucky and/or Detector-Grid-Unit, an anti-scatter grid and a 3-field measuring chamber intended for use with an automatic exposure control. Through the easy to remove front panels it is possible to fully integrate an X-Ray generator by installing a compatible under-table unit.

The non-ceiling based column stand is guided by two rails, which are integrated into the table itself. All movements of the column stand are well guided and therefor smooth. The movements of the column stand (horizontal, vertical and rotational) and desired positions are fixed using an electromagnetic braking system. The carrying arm is prepared for the installation of an X-Ray tube assembly (X-Ray tube, collimator and command arm with integrated controls).

1.5.2 Product specific characteristics

- Prepared for the installation of X-Ray generator (under table)
- Variable table height
  - PROGNOST ES High Speed (56.3 cm- 86.3 cm)
  - PROGNOST ES Standard (58.3cm – 88.3 cm)
- Floating tabletop
- Tabletop color – white
- Motor activated tabletop brake for effortless patient positioning
- A low (optimized) distance between the tabletop surface and the film (detector) surface
- Large adjustment range of the tabletop for position of the patient
- Reliable construction
- Lateral rails of the tabletop prepared to accept a number of table accessories
- Prepared for the installation of a Bucky with anti-scatter grid and 3-field measuring chamber intended for the use with automatic exposure control
- Extensive cassette program including Format 13 cm x 18 cm up to Format 35.6 cm x 43 cm
- Ceiling-free column stand intended for use within rooms with a ceiling height of at least 2.3 meters
- Control elements within the command arm well placed and easy to activate
- Reproducible positioning of the X-Ray tube assembly (positions resulting from rotation around the axis of the carrying arm) through angle indicator
- Vertical range of travel of the focus height from 25 cm up to 189 cm during horizontal beam projection
- Electromagnetic brakes for the longitudinal movement of the column stand, the vertical movements of the carrying arm as well as the rotational movements of the X-Ray tube assembly around the axis of the carrying arm with integrated latching every 90°
- Integrated safety connector for automatically centering the X-Ray tube assembly and the Bucky in the longitudinal direction

1.5.3 Product Variations

PROGNOST ES	7049-5-1707L
PROGNOST ES classic	7049-5-1706L
PROGNOST ES TOUCH	7049-5-1708L

The listed versions are equipped with the "Standard" elevation speed of 11 mm/s

The classic and TOUCH versions can be delivered with an optional "High Speed" elevating speed of 27 mm/s

1.5.4 Product components

The PROGNOST ES can be equipped or customized with the following components:

- Horizontal, height adjustable patient positioning table with floating tabletop and integrated column stand.

- **Tabletop versions (Choose one)**

Model ID	Material	L	W	Tabletop color
7301-0-5900	Carbon fiber	200 cm	75,5 cm	white
7301-0-2200	Carbon fiber	226 cm	75,5 cm	white
7301-0-6000	Composite fiber	200 cm	75,5 cm	white
7301-0-6010	Composite fiber	226 cm	75,5 cm	white
7301-0-6020	Composite fiber	200 cm	65,5 cm	white

- **Optional Accessories:**
  - **Long hand grip RAL6018** *(ID: 7301-0-0610)*, to be mounted onto the backside of the tabletop to aid the patient in getting onto and off of the table.
  - **Short hand grip** *(ID: 7303-0-1100)*, **Short hand grip (moveable)** *(ID: 7303-0-1150)*, to be mounted on the front side of the tabletop to aid in the positioning of the tabletop.
  - **Tabletop corner protection set** *(ID: 7303-0-1700)*
  - **Bumper Profile-** ***light grey*** *(ID: 7303-0-1510)*, for the rear lateral tabletop rail.
  - **Compression band** *(ID: 7755-0-4001)*
  - **Mattress- 225X20x2cm** *(ID: 7765-0-4014)*
  - **Rails long; Prognost ES** *(ID:7602-0-2000)* for 3m exposure distance
  - **Turn Tube +/-90°**

1.6 Compatible components (stand-alone products) and combination possibilities

The below mentioned components/products are not included with the standard delivery of the PROGNOST ES radiographic table but nevertheless can be combined with the PROGNOST ES.

- Bucky with cassette tray or detector- grid unit
- 3-field measuring chamber
- Anti-scatter grid
- Collimator
- X-Ray tube assembly with housing
- X-Ray generator

1.7 Labels

The company label (Figure1-1;1) and the safety label –see user manual (Figure 1-1;2) can be found on the side of the table near the bottom rear.

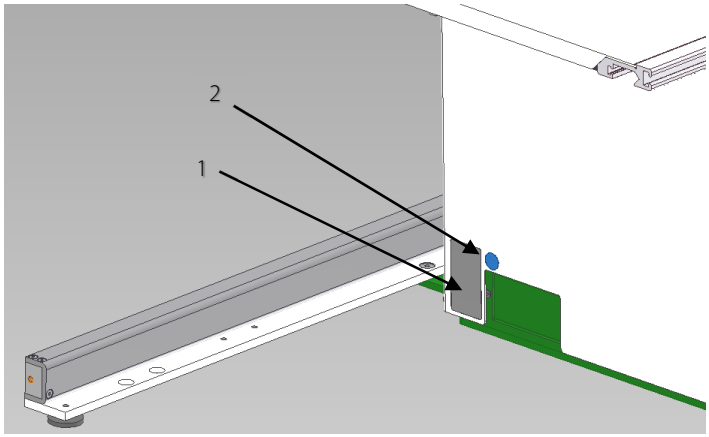


Figure 1- 1

2 Safety Instructions

2.1 General safety notice

Adjustments and calibrations that are described within the user manual must be made, with the aid of the technical description for PROGNOST ES, by the **PROTEC** customer service department or a PROTEC authorized service technician.

The operator(s) are required, prior to initial use of the product; to become acquainted with all control elements and their functionality.

All care and maintenance work should always be completed as suggested by the manufacturer.

The maintenance work must be recorded.

2.1.1 Requirements for operation

The radiographic table is a component of a complete X-Ray system. This product is to be outfitted and operated with a commercially available X-Ray tube and image acquisition unit, for which the high voltage, low voltage and ground will be supplied through direct connection to the X-Ray generator. All components within this system are required to fulfill the requirements of the MDD (Medical Device Directive 93/42/EEC) and contain the CE label.

Warning!

Class I ME device

To reduce the risk of electric shock, this unit is designated exclusively for connection to a supply network with protective earth.

The power for the radiographic table with stand PROGNOST ES is designated to be exclusively supplied through a direct connection to the available X-Ray generator. The X-Ray generator is required to offer a minimum of two connecting ports with 230V 50/60 Hz. . . . *(See Doc. #5045-0-0003 Technical Description)*

The PROGNOST ES radiographic table with stand is a ME Class I product.

This device contains no on/off switch. The PROGNOST ES is directly connected to the X-Ray generator and is switched on /off through the switching on and off of the generator itself. In order to disconnect the PROGNOST ES from power the connected X-Ray generator must be shut off.

A complete X-Ray system containing the radiographic table PROGNOST ES is only allowed to be taken into normal operation by customers when the PROTEC customer service department or PROTEC authorized service technician has successfully completed the installation and the system has been officially handed over to the customer.

It is important to ensure that all required registration activities are completed prior to initial use.
The national regulations regarding the approval of newly installed X-Ray Units as well as additional monitoring of the unit throughout its operational life by official testing organizations must be followed.
Additionally, it is absolutely necessary to follow the Maintenance specifications as set out in Chapter 5.

2.1.2 Operation of the product

It is essential to make sure that, while the tabletop is being positioned, no person or object (chairs, tables, pushcarts, etc.) is in an obvious area that could be dangerous (table adjustment area)
Failure to pay attention can lead to bodily harm (crushing, pinching, bruising, etc.) and damage to the table and/ or external objects.

In the case of disrupted functionality, use of the product should be discontinues and the customer service department from **PROTEC** or an service technician authorized by **PROTEC** should be informed.

2.1.3 Operating type

The PROGNOST E radiographic table is not designated for continuous use.

Duty Cycle: S3 15% - maximum continuous operation of 1.5 minutes

2.1.4 Operating personnel

The PROGNOST ES radiographic table with stand should 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.

Only properly trained and authorized personnel are allowed to work with the PROGNOST ES

The user, as well as the service personnel, must pay attention to 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.

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.

2.1.5 Emergency stop switch

An emergency stop switch is provided on the front of the table, thus the following must be considered:

- Actuate the emergency stop switch immediately if the patient, operator and or device is in danger. The electrically driven actuators for the tabletop brake and the elevating columns for height adjustment well be disconnected from power resulting in immediate interruption of all table movements.
- Only when the hazard has been clearly identified and removed can the emergency stop switch be switched off and normal system function be resumed. In all other cases (e.g. error of the table control) the PROTEC customer service department or a PROTEC authorized service technician should be notified.

The PROGNOST ES has no on and off switch. The radiographic table with stand will be switch on (off) directly through the switching on and off of the connected X-Ray generator. In order to completely disconnect the PROGNOST ES from power the connected X-Ray generator must be switched off or disconnected from power.

2.1.6 Explosion protection

This product is not designated for use within areas with explosion hazards.

2.1.7 Radiation protection

X-Ray radiation can pose a hazard to patients and other people when the regulations regarding the operation of X-Ray systems are not followed.

For this reason, the basic principles of radiation protection are of the highest priority and must be followed without exception:

- **Distance from the radiation source**
  The dosage is reduced as a factor of the square of the distance from a (dot shaped) radiation source. Double the distance ¼ dose, triple the distance 1/9 dose
- **Keep the exposure time as short as possible**
  The dosage is directly correlated with the exposure time. A half exposure time results in a radiation dose half that of a full exposure. (This is especially pertinent with fluoroscopy, as X-Ray images have predetermined mAs)
- **Utilize shielding and protective clothing**
  The protective value grows exponentially with the thickness of the shielding. Two half-value layer thickness (HVL) weaken (homogeneous) radiation to ¼, 3 HVL to 1/8, und 10 HVL to less than 1/1000 of the original value.
- **Do not reach into the direct X-Ray beam**
  The dosage in a un-weakened-Ray beam is around 100 times larger than that in the scattered radiation.
- **Use personal dosage meters**
  In working with radiation (X-Rays), the use of personal dosage monitors is suggested.

The X-Ray images are principally triggered from behind a protective wall. For the creation of images near the reproductive organs use the maximum available protection (e.g. Testicular shielding or lead covers)
People that must remain close to the patient are required to wear protective clothing (e.g. lead apron). This counts for maintenance and installation work as well.

2.1.8 Ventilation

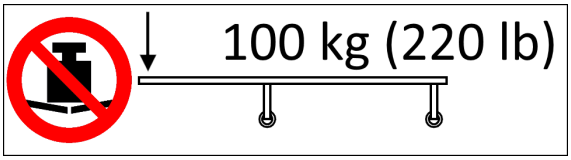
It is important to ensure that the air exchange of the X-Ray generator within the PROGNOST ES is not hindered. The ambient air temperature is not allowed to exceed 40°C.

2.1.9 Interaction with external devices

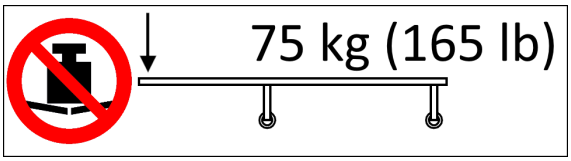
Unwanted interaction with external devices is not known.

2.1.10 Warning notifications and safety signs

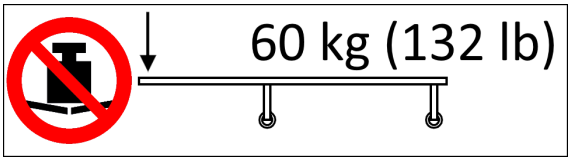
Tabletop version: Carbon fiber

	In the case that the tabletop is positioned completely to one side (front, back, left, right), the corresponding outer edge of the tabletop can be loaded with a maximum of 100 kg. With patients with a weight exceeding 100 kg, center the tabletop over the table base prior to the patient getting onto and off of the table.

Tabletop version: composite fiber, 2m length

	In the case that the tabletop is positioned completely to one side (front, back, left, right), the corresponding outer edge of the tabletop can be loaded with a maximum of 75 kg. With patients with a weight exceeding 75 kg, center the tabletop over the table base prior to the patient getting onto and off of the table.

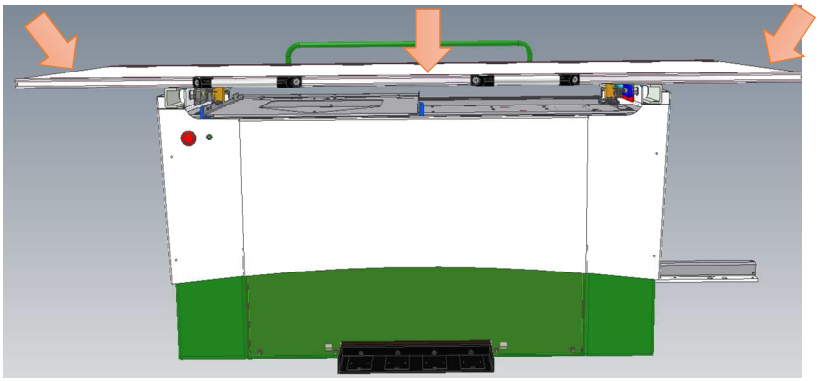
Tabletop version: composite fiber, 2.26 m length

	In the case that the tabletop is positioned completely to one side (front, back, left, right), the corresponding outer edge of the tabletop can be loaded with a maximum of 60 kg. With patients with a weight exceeding 60 kg, center the tabletop over the table base prior to the patient getting onto and off of the table.

2.1.11 Pinching and Collision Hazards

Caution!

Pinching of the fingers, hands and/or feet is possible within the areas marked in the following picture. Please pay close attention and ensure that neither the patient nor the operating personnel find themselves in known areas of movement during movement of the tabletop



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 (areas of movement).
Remove all objects (e.g. chairs, pushcarts) from known collision areas.

Be aware that careless or improper adjustment of the PROGNOST ES (height adjustment of the table & horizontal movement of the tabletop) can lead to damage of the X-Ray tube, unusable X-Ray images and injury to the patient (crushing injuries, bruising, etc…). Failure to pay attention can lead to damage of the PROGNOST ES as well as external objects.

3 Control elements and device displays

3.1 Footswitch

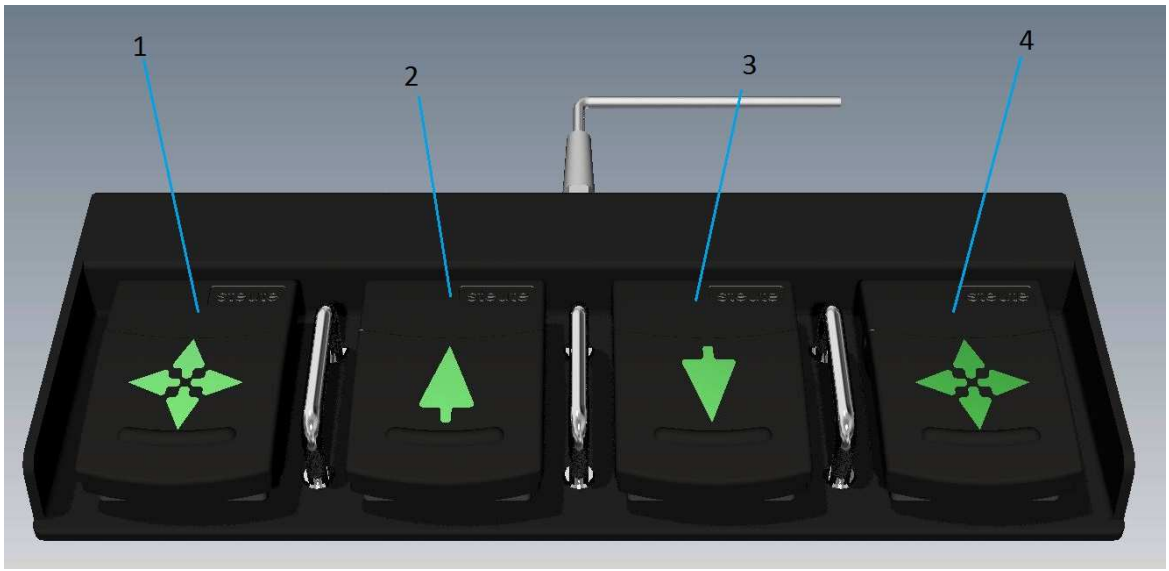


Figure 3- 1 (Footswitch-PROGNOST ES)

Pos.1 Release for tabletop brakes. The (floating) tabletop can move freely in all (horizontal) directions
Pos2 Height adjustment. The table (tabletop) moves upwards
Pos3 Height adjustment. The table (tabletop) moves downwards
Pos4 Release for tabletop brakes. The (floating) tabletop can move freely in all (horizontal) directions

Attention!

All functions operated through activation of the foot switches can only be activated using the proper "Double Click" activation.

The corresponding foot switch must be activated two times within 1.5 seconds in order to activate the function. As soon as the pedal is released the function/movement will immediately stop.

3.2 Accessories

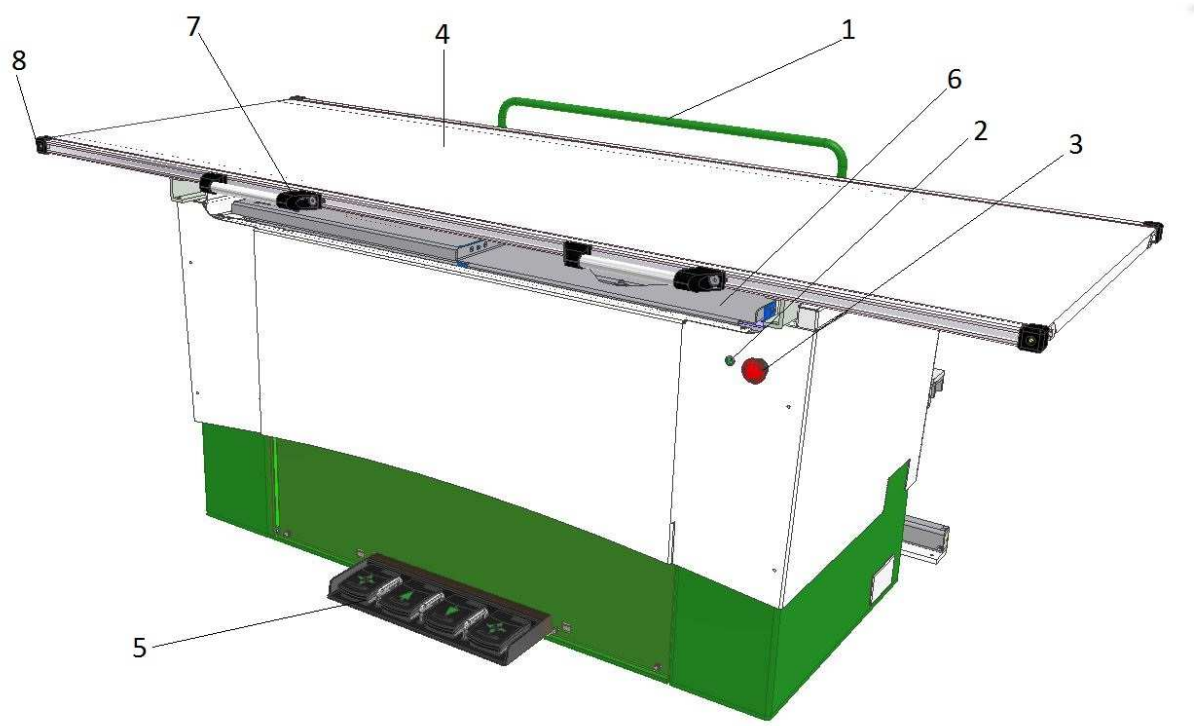


Figure 3- 2

Pos.	Component
1	Long hand grip RAL 6018 (optional)
2	Signal-LED
3	Emergency Stop switch
4	Tabletop
5	Footswitch
6	Bucky Wagon
7	Short hand grip (optional)
8	Corner protectors (optional)

3.2.1 Hand grips (optional)

Available options include a long hand grip (Figure 3-2; 1) for the back side of the tabletop and two short hand grips (Figure 3-2; 7) for the front side of the tabletop. Both handgrips can only be moved (removed) using the proper tools. The long hand grips eases the process of getting on to and off of the table for the patient. Use of the short hand grips allows for better positioning of the tabletop.

3.3 Emergency stop switch, Signal-LED and acoustic signals

Actuation of the emergency stop switch (Figure 3-2; 3) results in the disconnection of the following components from the power supply

- Linear actuator (2X) within the tabletop brakes
- Elevating columns (tabletop height adjustment)
- Central control unit (PCB)

The emergency stop switch is unlatched from the actuated position through clockwise rotation of the switch.

Located directly to the side of the emergency stop switch is a two color Signal – LED (Figure 3-2; 2). The Signal-LED communicates whether the PROGNOST E is operational (green) or if an error is present within the system. Errors are communicated by rhythmic blinking of the LED (red)

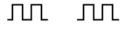
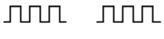
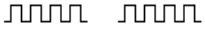
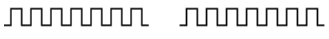
Caution!
Even when the emergency stop switch has been activated and the Signal LED is no longer illuminated, parts of the PROGNOST ES can still be connected to power.
Only by switching off (or disconnection from) the X-Ray generator is the PROGNOST ES 100% disconnected from power.

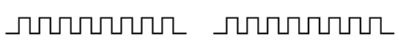
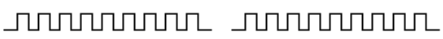
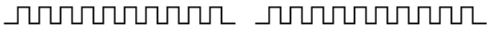
3.3.1 Status/ Error Notification – Signal-LED

The following is an overview of the status signals sent out by the signal-LED

Signal-LED green	Table is ready for use

Status/ Error notifications
Status of the table and its internal systems can be ascertained from the cyclic (red) blinking of the Signal-LED.

Error	Blink rhythm - Red	Description	Required action
1	**1x** 	Overheating of the power output components as a result of adjusting the tabletop height with a large patient load.	Allow the table to cool down until the Signal-LED is no longer blinking and has switches to a constant bright green illumination (ready for use). Reduce the load on the table
2	**2x** 	Actuator blocked	• Check to see if something is trapped between the tabletop and the ground, drive the table upwards and remove the object. • Inform a Protec authorized service representative
3	**3x** 	Overload- The Patient weight has exceeded the allowable maximum. Current draw for the elevating columns is too large.	Reduce the load on the table and allow the table to cool down. Once the load is removed the error status can be deleted by actuating the table up or table down footswitch one time.
4	**4x** 	Unwanted movement (e.g. due to unacceptably large load on the table)	Reduce the load on the table Contact a Protec authorized service representative
5	**7x** 	The central control has recognized that one of the end switches within	The unit should be taken out of service and switched off

		the elevating columns is out of order.	Contact a Protec authorized service representative
6	**8x** 	Height difference between the elevating columns The difference in the height of the elevating columns is greater than 10 mm.	• Complete a Nullification of the table as described in chapter 4.1.3 • Contact a Protec authorized service representative should the error remain following the nullification process
7	**9X** 	Tabletop brakes (linear actuator) is blocked	The unit should be taken out of service and switched off Contact a Protec authorized service representative
8	**10X** 	The allowable continuous operation of the table has been exceeded.	Allow the table to cool down until the SIGNAL LED stops blinking and is again illuminated green. ,3

Status /Error notifications 2 and 4
In the event that these error notifications cannot be erased by actuation of the footswitch (table up or table down) and/ or appear again following the erasure of the initial error, it is absolutely necessary to remove the unit from service and contact a PROTEC authorized service member.

3.3.2 Acoustic Status/ Error notifications

In addition to the notifications of the Signal-LED as described in chapter 3.31, a one-time acoustic notification (beep) will signal the emergence of an error/status notification. The signal is generated by a buzzer, which is integrated into the central control unit.

Beep tone	Meaning
2x 	General warning

3.3.3 Acoustic and optical status/error notifications – Blocked elevating columns

Caution!

In the event that one or both of the elevating columns becomes blocked and the source of the blockage is obvious, the height of the elevating columns (height of the table) should be adjusted in order to allow for the removal of the object/item (e.g. Chair which is trapped between the tabletop and the floor)

If the source of the blockage is not obvious (e.g. internally blocked elevating column), the height adjustment function of the table should be considered out of order and a Protec authorized service member should be contacted.

In the case that one or both of the elevating columns become blocked, the central control unit will issue a status/error notification (Signal- LED) and an acoustic warning (see chapters 3.31 6 3.32).

Should the difference in the height of the two elevating columns exceed 1cm, adjustment of the table height will no longer be allowed (the central control unit will automatically block the movements of the elevating columns)

3.4 Bucky --PROTEC- series *

The manual cassette tray (figure 4) serves as a receptacle for the X-Ray film cassette.

Once the cassette tray (Figure 3-3; 1) has been pulled out to the maximum position using the provided handgrip (Figure 3-3; 3), the cassette can be inserted. The cassette will be held into place by the integrated clamping mechanism (Figure 3-3; 2). This mechanism automatically centers the cassette in the transverse direction. The cassette can then be brought into the proper position (longitudinal) by bringing it in line with the provided middle marker by hand or by setting the cassette positioner (Figure 3-3; 4) to the corresponding cassette size.

The maximum longitudinal movement of the Bucky is 545 mm.

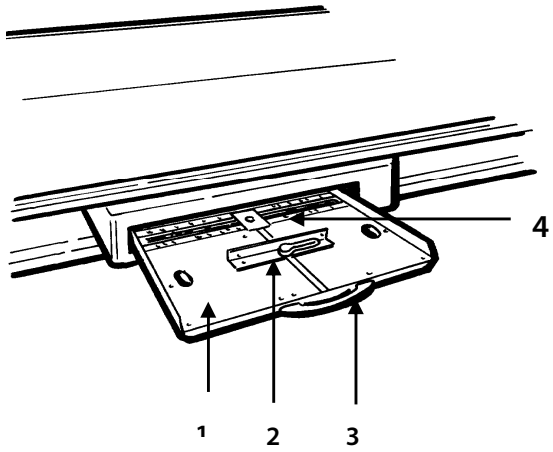


Figure 3- 3

*Not included with delivery of the Standard PROGNOST ES

3.5 Safety connector

The column stand (and corresponding X-Ray tube) are connected and aligned by the safety connector. This connector ensures that the X-Ray tube assembly (line of radiation) and the Bucky (image detection unit) remain correctly aligned when the column is being moved in the longitudinal direction (along the table). As soon as the column is moved outside of the allowable movement area of the Bucky, the connector will automatically disconnect the Bucky from the column assembly. Once the column is brought into the Bucky's range, the connector will automatically become latched and the Bucky is once again aligned with the X-Ray tube assembly.

Caution!

It is essential to ensure that the safety connector is correctly/fully latched prior creating X-Ray images. When not correctly latched, the focus of the X-Ray will not correspond to the middle of the X-Ray film/detector.

3.6 Column stand

1. Command arm
2. Collimator*
3. Film focus distance indicator for the working height of the radiographic table
4. Turn Tube +/-90° *

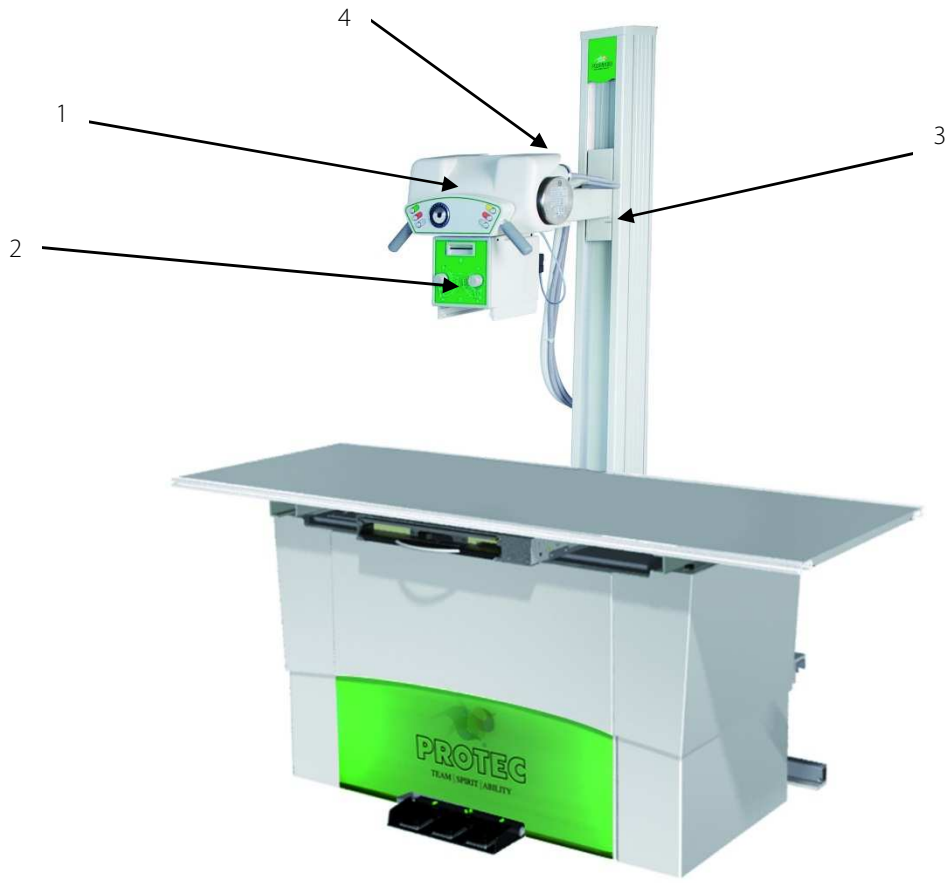


Figure 3- 4

* Not included with delivery of the Standard PROGNOST ES

3.7 Command arm

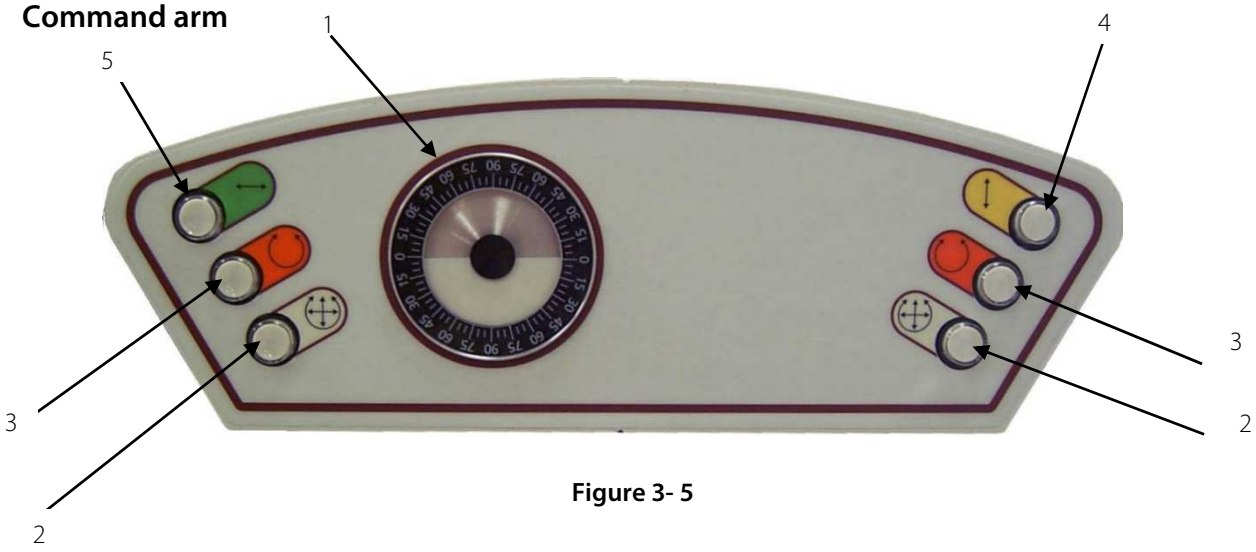


Figure 3- 5

1. Angle indicator for adjustment (rotation) of the X-Ray tube assembly.
2. Central brake release; when activated, all movements (including rotation of the X-Ray tube assembly) are released
3. Brake release for rotation of the X-Ray tube assembly
4. Brake release for vertical adjustment of the X-Ray tube assembly
5. Brake release for longitudinal adjustment of the column assembly

The unit is operated from the frontside (operators side) of the the column stand.
When gripped on the two handles (located on either side of the operational interface) one or more electromagnetic brake(s) can be released by actuating the corresponding button on the commandoarm with the thumb. Once released, the X-Ray tube assembly can be brought into the desired position.

3.8 Turn tube +/-90° *

1. Tube arm
2. Control lever
3. Arrester (3 pieces)

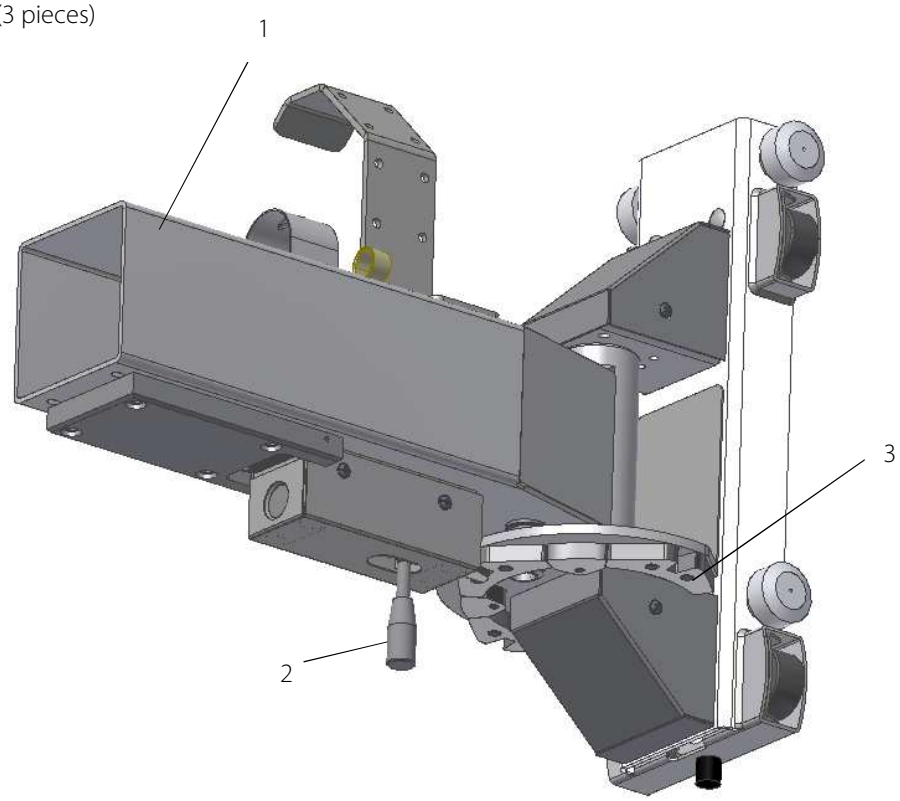
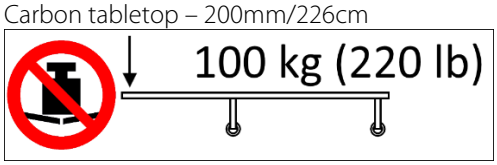


Figure 3- 6

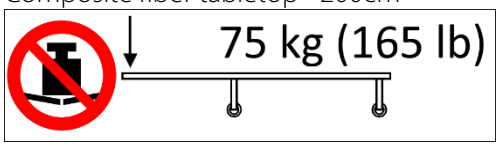
***** is not included with the Prognost FS and may vary depending on system

3.9 Labels at the head and foot of the tabletop

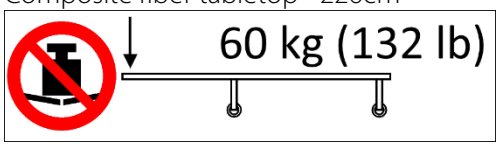
Carbon tabletop – 200mm/226cm



Composite fiber tabletop - 200cm



Composite fiber tabletop - 226cm



Caution:

If the tabletop is positioned completely to one side (right, left, front or back) the maximum given load for the corresponding outer edge **cannot** be exceeded. Failure to adhere to this can result in damage to the tabletop and/or injury to the patient.

3.10 Tabletop Labels

Caution: Pay careful attention to all possible pinching/crushing hazards for the fingers and hands while moving the tabletop, adjusting the table height and moving the column stand.

Maximum allowable patient weight (distributed weight) of the tabletop (Composite fiber tabletop)

Maximum allowable patient weight (distributed weight) of the tabletop (Carbon tabletop)

4 Handling/ Operation

4.1 Operation

4.1.1 Release the tabletop brakes (position the tabletop)

By actuating one of the two footswitches corresponding to the tabletop brakes (Figure 3-1; 1 & 4) using the double click activation (see chapter 3.1), the tabletop brakes are released. Once released the tabletop can be manually positioned.

Caution:

The corners of the tabletop are relatively sharp.

It is important to pay attention to the corners of the tabletop while positioning the tabletop as well as when the patient is getting onto and off of the table. Additional protective pieces are available as an optional addition (see chapter 3.2)

The movement of the tabletop from the middle outwards in the:

Transverse direction	±150 mm
Longitudinal direction	±330 mm (2m tabletop)
	±460 mm (2.26 m tabletop)

4.1.2 Adjusting the table height

By actuating the footswitch corresponding to height adjustment in the desired direction, table up (Figure 3-1; 2) and table down (Figure 3-1; 3) the height of the table can be adjusted. The footswitch must be actuated using the double click activation as defined in chapter 3.1). Once the table has reached the end position (upper and lower), the elevating columns will automatically stop.

Caution:

The table is to be operated with the user in a standing position, facing the front of the table.

Operating the table while seated should be avoided, as it is possible for the operators' leg to become trapped between the tabletop and the foot pedal if the tabletop is in the foremost position.

If the table must be operated from a sitting position, the tabletop must be pushed completely towards the back of the table.

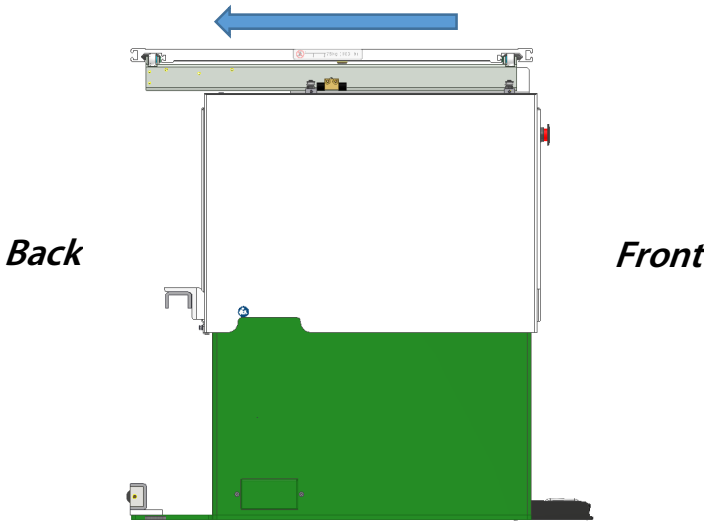


Figure 4 - 1

4.1.3 Nullification (calibration) of the table height (elevating columns)

During the initial set up of the unit or when a difference in the height of the elevating columns becomes noticeable (tabletop no longer level) the control/elevating columns need to be calibrated.

Caution:
It is possible for the tabletop to begin moving on its own if the tabletop brakes are released and there is an obvious difference in the height between the two sides of the tabletop (tabletop not level)

4.1.3.1 Nullification (calibration) using the footswitch

To nullify the elevating columns the follows steps should be followed.

1. Depress and hold down the "table-down" pedal (Figure 3-1; 3). After 4 seconds of continuous activation the central control will issue an acoustic notification (1x beep)
2. Following the acoustic notification, depress and hold the "table up" pedal (Figure 3-1; 2). After a short pause, the elevating columns will begin to drive slowly upwards. The nullification of the elevating columns takes place in the uppermost position of the table. Once the elevating columns have reached the uppermost position and the nullification is complete, the central control until will issue another acoustic notification (long beep). The nullification is now complete and the "table up" pedal can be released. *The "table up" pedal must remain depressed until the nullification is complete. If released the process must be repeated..*

Caution:
Never nullify the elevating columns with a patient on the table

Prior to positioning the patient, bring the X-Ray unit into position for the required exposure.

4.2 Adjusting the exposure position

4.2.1 Exposures with the PROGNOST ES

- To ease the process of getting onto the table (for the patient), adjust the table height to an appropriate height.

Caution:
The PROGNOST ES serves only as a support for the patient during the examination.
Patients are only allowed to get onto and off of the table under the supervision or with the help of those completing the examination. Failure to comply increasing the risk of injury.
Offer help to the patient when getting onto and off of the table.
In the case that the bodyweight of the patient exceeds 150 kg it is absolutely necessary to follow the steps regarding getting onto and off of the table, as outlined in Chapter 4.2.1.

- Getting onto and off of the table (*see figure 4-2*)
  - Move the tabletop completely to one side (left or right)
  - Move to the Bucky/ Bucky wagon completely to the side in the opposite direction as the tabletop.
  - Center the Tabletop as much as possible (front to back)
  - The patient should get onto the table in the middle of the tabletop (shown here as a green arrow)

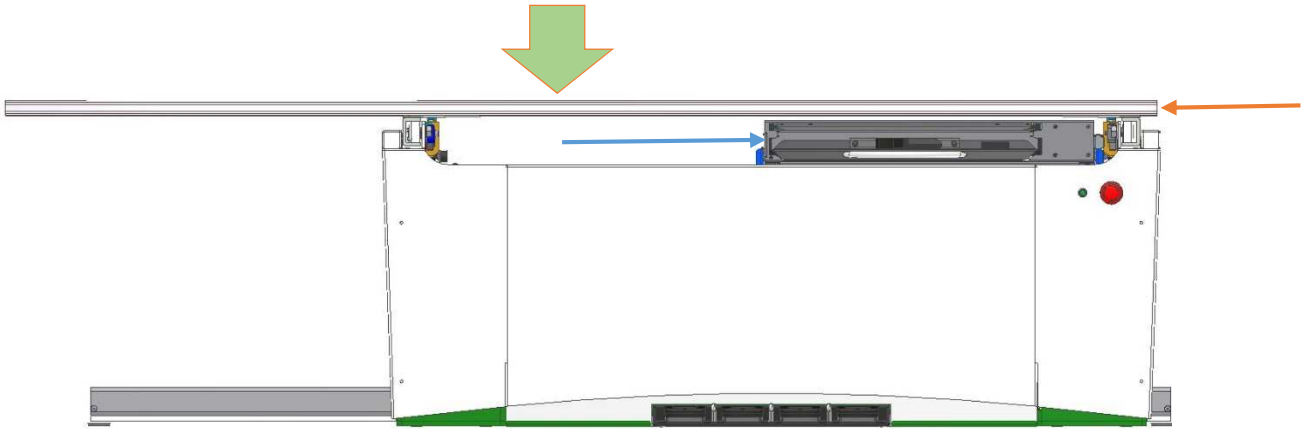


Figure 4 - 2

- Allow the patient to lay down on the tabletop. When required (e.g. patient has open wounds)) cover the surface of the tabletop using appropriate towels or one time use health care towels.

Caution:

Crushing danger around the edges of the tabletop and pinching hazard above and below the tabletop!

When positioning the tabletop, horizontally, it is possible for extremities to become trapped between the tabletop and a fixed object (wall, column, X-Ray tube assembly). It is therefore necessary to check that neither the patient nor the operator find themselves within the area within which the tabletop is being positioned. It is particularly important to ensure, for each patient, that no extremity (arms, hands, fingers, feet) extend beyond the edges of the tabletop. Each patient should be correspondingly informed and told that once on the tabletop they are to remain still unless told to change position.

- Release the tabletop brakes and move the tabletop and patient into the exact position needed for the exposure. Fix the tabletop by releasing the corresponding foot pedal.

4.2.1.1 Aligning the X-Ray tube assembly with Bucky (centerline)

- Release the brakes for longitudinal movement of the column stand by actuating the corresponding button (Figure 3-5; 5) on the command arm.
- Grab hold of both handles located on the command arm.
- Move the column stand in the longitudinal position in the direction of the radiographic table until the safety coupling latches, thus aligning the Bucky and the column. It is important to ensure that the coupling has properly latched, as incorrect or incomplete latching results in the misalignment of the image detector and the X-Ray tube.

4.2.1.2 Adjusting the Film Focus Distance

- Drive the table to the desired working height.
- Bring the X-Ray tube assembly into the desired film focus distance using the integrated measuring tape (collimator) or the indicator located on the column stand (Figure 3-4; 3).
- The vertical position of the X-Ray tube assembly can be adjusted by actuating the appropriate button on the command arm (Figure 3-5; 4)

4.2.1.3 Inserting a cassette into the cassette tray*

- Following adjustment of the X-Ray tube (see chapter 4.2.1.1 and 4.2.1.2), a cassette can be inserted into the Bucky's cassette tray.
- Using the grip provided (Figure 3-3; 3), pull the cassette tray (Figure 3-3) outwards from the Bucky until it reaches its maximum position.

- Rotate the latching lever on the clamping mechanism (Figure 3-3; 2), used in the lateral fixation of the cassette, in the counterclockwise direction.
- Open the clamping mechanism (Figure 3-3; 2) as needed to accommodate the insertion of the desired cassette.
- Insert the cassette in such a way that its middle is aligned with the centerline notch of the clamping mechanism (Figure 3-3; 2) or latch the cassette positioner (Figure 3-3; 4) into the position corresponding to the cassette size (13 cm, 24 cm, 30 cm, 35 cm, 40 cm or 43 cm) and push the cassette against the positioner (Figure 3-3; 4).
- Close the clamping mechanism (Figure 3-3; 2) onto the cassette and rotate the latching lever in the clockwise direction to lock into place.
- Push the cassette tray (Figure 3-3) into the Bucky until it stops.

* Not included with delivery of the standard PROGNOST ES

4.2.2 Operation Turn Tube +/-90°

For the purpose of this description, the tube arm is arranged in the 0°-position in which the tube arm is positioned in line with the vertical carriage. The position of the X-Ray tube assembly, which is to be assembled at the end of the tube arm, is not important. The tube header can be pointed downwards to either side.

Warning!

When rotation of the swing arm takes place, the brakes both for the vertical adjustment and for the rotation of the X-Ray assembly should be fixed. Only lateral rotation of the tube arm should be possible!

4.2.2.1 Operation instructions

1. With one hand, pull the control lever in direction the X-Ray tube. The tube arm is now free to move (no longer fixed).
2. With the other hand, swing the tube arm into the new position (+/-90°)

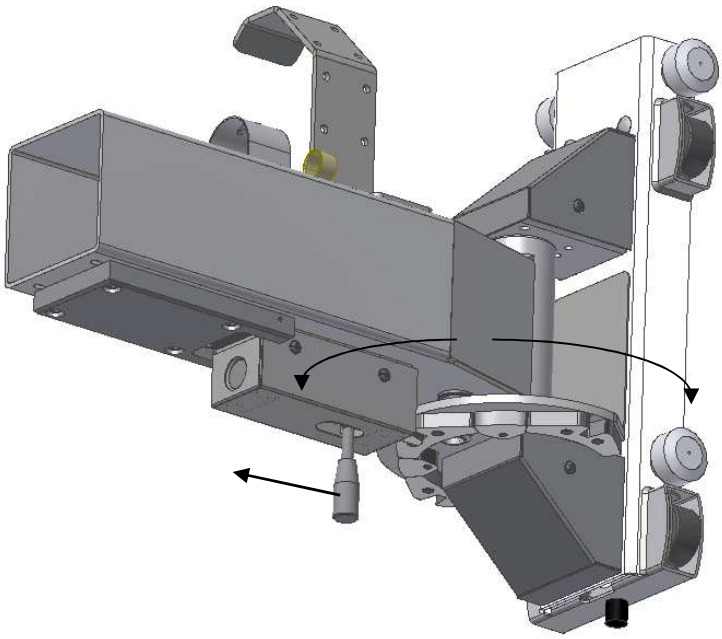


Figure 4 - 3

3. Release the control lever. The tube arm is fixes into the place through spring force.

Warning!

While rotating the swing arm, both hands should be contact with the tube arm and move along with it. Never reach into the access cover or into the area surrounding the latch-possible risk of injury!

For reasons of safety, ensure that the latching mechanism engaged and the swing arm is fixed.

* Not included with delivery of the standard PROGNOST ES

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 radiographic table with stand following initial installation.

5.2 Cleaning and disinfection

Caution:

Electrocution hazard

Prior to cleaning or disinfection, switch of the X-Ray generator. As a result, the X-Ray tube and the PROGNOST ES will be disconnected from power and the danger of electric shock is eliminated.

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

Caution:

Changes to material are possible

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 buildup.

All components within the PROGNOST ES, 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 Checkup and maintenance

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

- Check the ease of movement for the tabletop (horizontal) when the tabletop brakes are released.
- Check the tabletop brakes when fixed. (Table should not be able to be moved)

- Check that the tabletop is level. If the tabletop is noticeably uneven, the elevating columns should be nullified as described within chapter 3.2.3.
- Check the state of the steel cables within the column stand. Drive the command arm into its lowermost position and inspect the cable along its visible length. Drive the command arm slowly upwards and observe the two steel cables, they should both remain taut (straight) while moving the command arm.

5.3.2 Regular controls

5.3.2.1 Quality control measures completed by operator

Quality control activities for X-Ray units are to be undertaken in regular intervals according to the corresponding national guidelines.

- Check the surface of the tabletop for damage (dents, scratches, tears. . .)
- Check the functionality of the safety coupling between the Bucky Wagon and the column stand
- Check that the Collimator (X-Ray beam) is correctly centered.

5.3.2.2 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.

All components within the PROGNOST ES, which, through wear and tear, could present a hazard, are required to be checked, and when needed replaced, every 12 Months by the PROTEC service department or a Protec authorized service provider.

In the case that the required safety- related control activities and checks are 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 safety related controls. The checklist for safety related controls is located within the "Technical Description" Document # 5045-0-0003, Chapter 3.

5.3.3 Maintenance

The required Maintenance and Inspection (See Document #5045-0-0003, Technical Description- Chapter 3) 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 from PROTEC authorized service and when components (related to the safety of the unit) are replaced, in the case of component failure, with original spare parts

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

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 unit is overall operationally ready.
The Signal-LED is to be visually inspected for proper function.

5.3.4 Product life time

The PROGNOST ES 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 be completed.

5.3.5 Disposal

The PROGNOST ES does not contain toxic substances. All mechanical and plastic components are to be disposed of in accordance with the corresponding national guidelines. As users of electro- and electronic devices, you are responsible for utilizing the local collection system. In cases of doubt, contact PROTEC.

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

The PROGNOST ES is consistent with the requirements for electromagnetic compatibility according to EN 60601-1-2, Limit class B
The EMC clause within guidline2004/ 108 EWG has been fulfilled by the PROGNOST ES.

- The PROGNOST ES is, as a mechanical electrical 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 electrical devices
- The X-Ray generator integrated into the PROGNOST ES radiographic table with stand sends out electromagnetic waves during operation, which could cause interference with other devices. For EMC guidelines and manufacturers declaration for the generator according to EN 60601-1-2, see the separate User Manual for the corresponding generator.
- Only exclusively listed accessories and wiring are allowed, with exception to the spare parts as defined by the manufacturer.

6.4 Guidelines and Manufacturers declaration- electromagnetic interference *(non-life supporting device)*

The PROGNOST ES is intended for use in the electromagnetic environment specified below. The customer or the user of the **Equipment** should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic Environment**
RF emissions CISPR 11	Group 1	This equipment uses RF energy only for its internal function. Therefore, the RF emission is very low and unlikely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	This **Equipment** is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: **Warning:** This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the **Equipment** or shielding the location.
Harmonic emissions EN 61000-3-2	Class A	
Voltage fluctuation/ flicker emission EN 61000-3-3	Complies	

The **Equipment** is intended for use in the electromagnetic environment specified below. The customer or user of the **Equipment** should assure that it is used in an electromagnetic environment.			
Immunity Test	**EN 60601-1-2 Test level**	**Compliance level**	**Electromagnetic Environment - guidance**
Electrostatic discharge (ESD) EN 61000-4-2	± 6 kV contact ± 8 kV air	EN 60601-1-2 Test level	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst EN 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output	EN 60601-1-2 Test level	Mains power quality should be that of a typical commercial or hospital environment.
Surge EN 61000-4-5	± 1 kV differential mode ± 2 kV common mode	EN 60601-1-2 Test level	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines EN 61000-4-11	<5 % U_T for 0,5 cycle (>95 % dip in U_T) 40 % U_T for 5 cycles (60 % dip in U_T) 70 % U_T for 25 cycles (30 % dip in U_T) <5 % U_T for 5 s (>95 % dip in U_T)	EN 60601-1-2 Test level	Mains power quality should be that of a typical commercial or hospital environment. If the user of the **Equipment r**equires continued operation during power mains interruptions, it is recommended that the **Equipment** be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field EN 61000-4-8	3 A/m	EN 60601-1-2 Test level	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the alternating supply voltage prior to application of the test levels			

The **Equipment** is intended for use in the electromagnetic environment specified below. The customer or the user of the **Equipment** should assure that it is used in such an environment

Immunity Test	**EN 60601-1-2 Test level**	**Compliance level**	**Electromagnetic Environment**
Radiated RF EN 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the **Equipment,** including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter **Recommended separation distance** $d = 1.2 \times \sqrt{P}$ 80 MHz to 800MHz $d = 2.3 \times \sqrt{P}$ 800 MHz to 2.5GHz $d = 1.2 \times \sqrt{P}$ Where *P* is the maximum output rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths for fixed RF transmitter, as determined by an electromagnetic site survey, should be less then the compliance level in each frequency range Interference may occur in the vicinity of equipment marked with the following symbol: 
Conducted RF EN 61000-4-6	3 V 150 kHz to 80 MHz	3 V	

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structure, objects and people.

[a] Fields strengths from fixed transmitters, such as base stations for radio telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters , an electromagnetic site survey should be considered. If the measured field strength outside the shielded location in which the **Equipment** is used exceeds **[field strength]** V/m, observe the **Equipment** to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as relocating the **Equipment** or using a shielded location with a higher RF shielding effectiveness and filter attenuation

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.

The **Equipment** is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the **Equipment** can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitter) and the **Equipment** as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of the transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150kHz to 80MHz $d = 1.2 \times \sqrt{P}$	**80MHz to 800MHz** $d = 1.2 \times \sqrt{P}$	**800MHz to 2.5GHz** $d = 2.3 \times \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at the maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note:

(1) at 80MHz and 800MHz, the separation distance for the higher frequency range applies

(2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people

7 Technical Data

7.1 Physical dimensions

Tabletop dimensions (L x W):	200 cm x 75, 5 cm or 226 cm x 75, 5 cm or 200 cm x 65, 5 cm
Max. Patient weight (Distributed weight)	230 kg (Standard) 250 kg (High speed)
Table height	563mm - 863 mm (High Speed) 583mm - 883 mm (Standard)
Transverse movement of the tabletop (from the middle):	± 150 mm
Longitudinal movement of the tabletop (from the middle):	± 330 mm (200 cm tabletop)
Longitudinal movement of the tabletop (from the middle):	± 460 mm (226 cm tabletop)

The tabletop brakes are electromechanically released.

7.2 Attenuation equivalent of the tabletop

The tabletop is defined as an applied part.
The aluminum attenuation equivalent of the tabletop is typically 0, 7 < 0, 8 Al mm for carbon / 0, 85 mm Al for composite fiber, according to EN 60601-1-3. Tested at 100 kV with a first half-value layer thickness (HVLT) of 3, 7 mm Al and typically 0, 6 mm Al und <0,8mm Al according 21CFR § 1020-30 (n) with 100 kV and a first half-value layer thickness (HVLT) of 2,7mm Al.

7.3 Bucky

Longitudinal movement:	533 mm
Min. distance from film center to the head of the table*	330 mm
Min. distance from film center to foot of the table	440 mm
Tabletop to film distance*:	67 mm

** Head of the table is to the left when facing the front side of the table*
** This tabletop to film distance is calculated for a Panel with a thickness of 17 mm*

The Bucky with grid and measuring chamber are to be directly connected to the generator.

7.3.1 Attenuation equivalent of the Bucky housing

The aluminum attenuation equivalent of the Bucky housing (when present) is ≤0,2 mm Al according to EN60601-1-3 using 100 kV and a first half-value thickness layer of 3,7 mm Al.

7.4 Column stand

Vertical focus – range of travel (horizontal beam projection):	250 - 1892 mm
Vertical focus – film distance:	max. 1267 mm
Vertical focus – Table distance:	max. 1200 mm
Rotation of the X-Ray tube assembly (around carrying arm axis):	± 120°
Latching at:	- 90°, 0°, + 90°
Vertical travel- carrying arm:	1642 mm
Longitudinal range of travel, column stand:	1285 mm
Longitudinal range of travel, column stand with 3m m rail extension:	1985 mm

7.5 Complete Weight

Without patient	ca. 400kg

7.6 Electrical data

7.6.1 Type of protection and protection class

The PROGNOST ES is consistent with a protection class 1 device and contains applicable parts Type B (according to EN 60601-1)

7.6.2 Power input

It is intended that the PROGNOST ES radiographic table with stand always be connected to an X-Ray generator.
The three possible internal power supplies must be hard wired to the X-Ray generator.
The X-Ray generator is required to offer a minimum of three 230V connections which are collectively protected by an internal 10 A circuit breaker.

PROGNOST ES mains connections:

Column transformer: 1 x 230 V 50/60Hz, 2A
Main switching power supply: 1x 230V 50/60Hz, 2,4A
Optional Illumination: 1x 230V 50/60Hz, 0,2A

7.7 Environmental conditions

7.7.1 Environmental conditions during operation

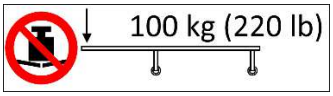
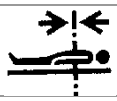
Ambient Temperature	+ 10°C to + 40°C
Relative humidity	30% to 70% (non-condensing)
Atmospheric pressure	700 hPa to 1060hPa

7.7.2 Environmental conditions during Transport und Storage

Ambient Temperature	- 15°C to + 70°C
Relative humidity	10% to 95% (non-condensing)
Atmospheric pressure	500 hPa to 1060hPa

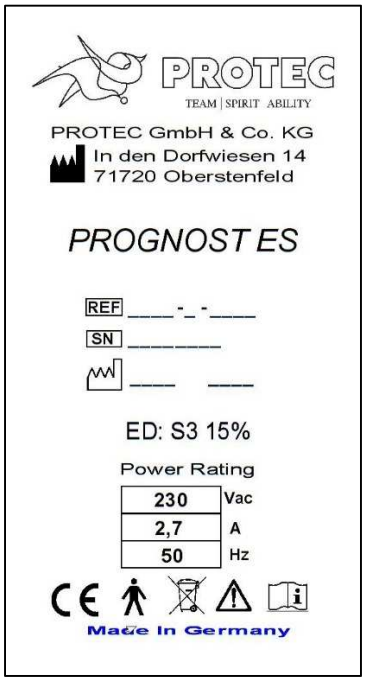
8 Description of symbols, labels and abbreviations

8.1 Symbols

	Caution, Observe accompanying documents
	Refer to user manual
	CE-Mark
	Classification according to EN 60601-1 (Type B)
	Caution: pinch-/crushing hazard for hands and fingers
	Do not exceed the maximum indicated weight
	Do not exceed the maximum indicated weight
	Tabletop movements for exposure
	Longitudinal movement of the tabletop
	Transverse movement of the tabletop
	Table height adjustment – table up
	Table height adjustment – table down
	Release tabletop brakes

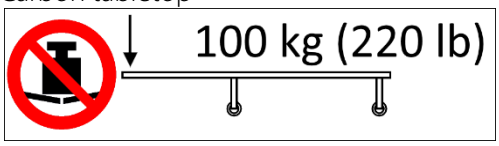
8.2 Labels

Identification label

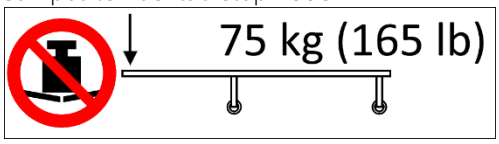


Labels on the side of the tabletop

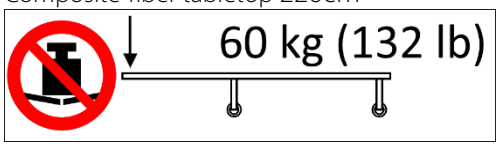
Carbon tabletop



Composite-fiber tabletop 200cm



Composite-fiber tabletop 226cm



Labels on top of the tabletop

Caution: Possible pinch-/crushing hazard fort he hands and fingers while moving the tabletop, table and or X-Ray tube assembly unit.

Maximum allowable Patient weight (distributed load) for the tabletop (Composite-fiber tabletop)

Maximum allowable Patient weight (distributed load) for the tabletop (Carbon tabletop)

8.3 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