PROTEC
TEAM | SPIRIT | ABILITY

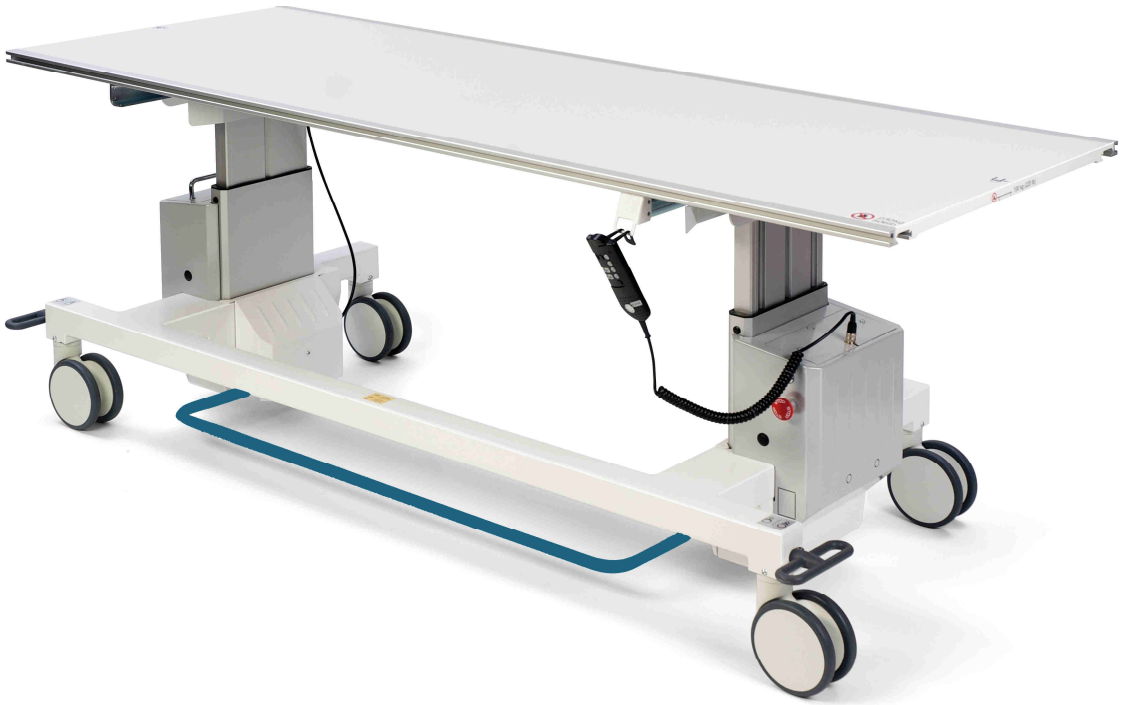
PROGNOST XPE-Akku

Mobile Patient Table

with floating table top
and motorized elevation

Instruction for Use

Ident. Nr. 5033-0-0002



CE

2020-07-03 PROTEC GmbH & Co. KG, In den Dorfwiesen 14,
71720 Oberstenfeld, Germany

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 – 92 55 60

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

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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 GmbH & Co. KG Technical Service Organization.

Document Effectivity

Revision No.	Date	List of effective pages	Comments
	18/06/2007		Original issue
01	23/01/2008	all	UL Label changed, options supplemented
02	23/11/2009		Change from GmbH & Co. KG & Co. KG to GmbH & Co. KG
03	02/12/2010	All	Modified address
04	19/08/2011	All	Protec Lable
05	01/12/2011		New Lable
06	03/05/2012		
07	01/08/2013	33	New Standards / new labels
08	07/01/2014		Technical Safety check interval 2 years
09	12/02/2015		New Control unit
10	08/06/2016	6	Missing error messages added
11	20/09/2017	Capture 2.12	Text duty cycle new
12	30/10/2019	Page 28	Changed table height
13	2020-07-03	Capture 2.12	Changed % and times

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 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 PROGNOST XPE-Akku.

It is suggested that you review the operation instructions, the safety notes and the controls described in this “Instruction for Use” before using the PROGNOST XPE-Akku. Each control device and each display is described in order to make you acquaint with its function.

1.2 Intended Purpose

The battery powered PROGNOST XPE-Akku is a patient table for examinations with X-ray units (e.g. L/U-arms) for general radiography in diagnostic human medicine use. It most only be used in medically rooms.

The PROGNOST XPE-Akku is not suitable for patient transportation.

The PROGNOST XPE-Akku is not suitable for use in mobile vehicles or mobile clinic.

The **PROGNOST XPE-Akku** must be operated by qualified users trained in the use of human diagnostic X-ray equipment in conformity with the respective national regulations.
An introduction of the product is necessary for the user.

1.3 Declaration of 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

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 – 92 55 60
e-Mail: protec@protec-med.com
Internet: www.protec-med.com

1.4 Features

- Power line independently battery powered usage with two exchangeable accumulator-boxes
- Separate accumulator-box charge-station
- Wide range of application
- Motor driven elevation table with smooth start and stop and convenient patient access
- Automatic stop at pre programmed working heights
- High reliability
- Easy movement
- Floating flat table top, carbon fiber type, high transparency with high rigidity
- Long hand grip at rear side (optional)
- Short hand grips at front side of table top (optional)
- Large range of table top displacement for convenient patient positioning
- Minimized table top thickness for short image receptor to object distance
- Control elements are arranged for easy access

1.5 Unit versions

See chapter 7.1 „Model versions and measurements“

1.6 Optional Equipment

- **Handle** *(ID: 7301-0-0600)*, mounted on the long side of the table top in order to ease the patient's getting on and off
- **Hand grips** *(ID: 7303-0-1100)***,** mounted on the long side of the table top in order to ease shifting of the table or of the table top
- **Fixing mechanism** *(ID: 7303-0-1450)***,** left or right mountable, for moving the table around the corresponding elevating column axis
- **Deflector** *(ID: 7303-0-0190)*, for easier positioning of the table above digital detector
- **Side edge guard** *(ID: 03030182)*, for protection of the detector
- **Bumper profile** *(ID: 03030187)*, for rear accessory rail of table top
- **Protection foil** *(ID: 03030184)*, for internal covers
- **Center stop** *(ID: 7519-0-0000)***,** for transverse table top movement

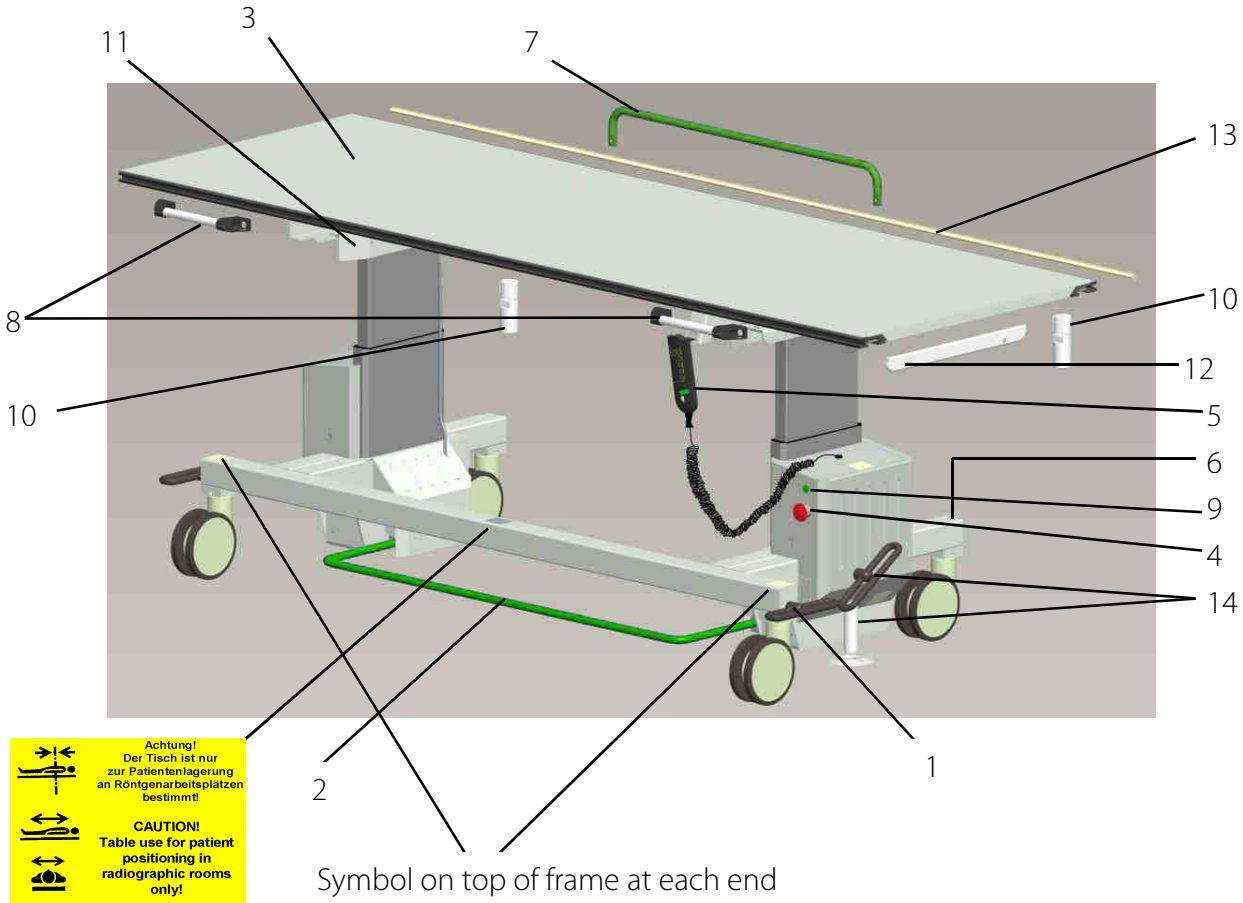
1.7 Nameplate

For nameplate location refer to Fig. 2-1/6.

2 Control Elements and Indicators

2.1 Brakes

In order to fix the patient table in all directions, it is fitted with 2 brake wheels at the front, which have to be fixed with a fastener (Fig. 2-1/1) on the left or right side before a patient gets on or off the table top.



Symbol on top of frame at each end

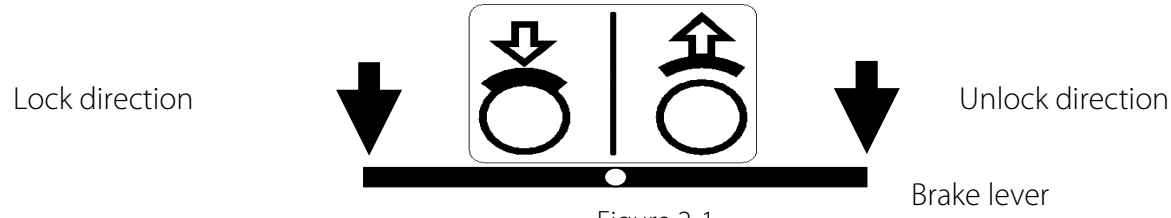


Figure 2-1

Description to Figure 2-1:

1: Fastener for brake wheels

2: Table top brake foot-pedal

3: Table top

4: Emergency stop switch

5: Hand control + holding device

6: Nameplate, UL and FDA Label (version depending)

7: Long handgrip

8: Short handgrips

9: Ready for use indicator lamp

10: Deflector

11: Protection foil

12: Side edge guard

13: Bumper profile

14: Fixing mechanism

2.2 Brake for Table top

By pressing the brake foot-pedal (Fig. 2-1/2) the table top brakes are released. Then the floating table top can be moved manually.
Movement of the table top (from the middle):

Transverse direction	± 100 mm
Longitudinal direction	± 330 mm (2 m table top)
	± 426 mm (2,26 m table top)

2.3 Hand grips (optional)

As options a long handgrip at rear side of the table top (Fig. 2-1/7) and short hand grips (Fig. 2-1/8) at front side of the table top are available. The hand grips can be removed with tools only. The long hand grip can be used for patient to easier getting ON and OFF the table top. The short hand grips allow more convenient movement of table and table top

2.4 Fixing mechanism (optional)

As option a left or right mountable fixing mechanism (Fig. 2-1/14) is available.
With the fixing mechanism it is possible to position the PROGNOST XPE accurate in the X-ray examination room and to turn around the according column axis.

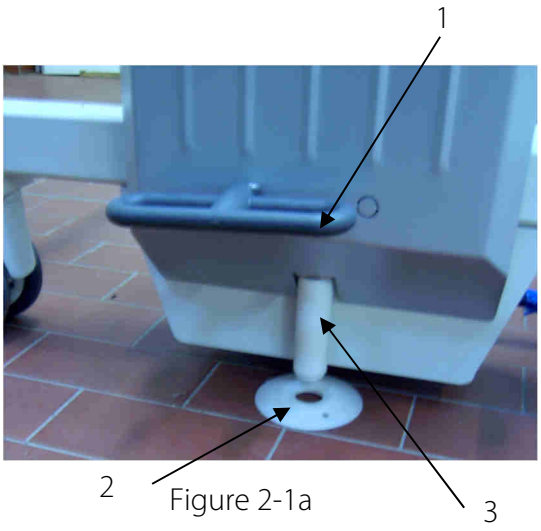


Figure 2-1a

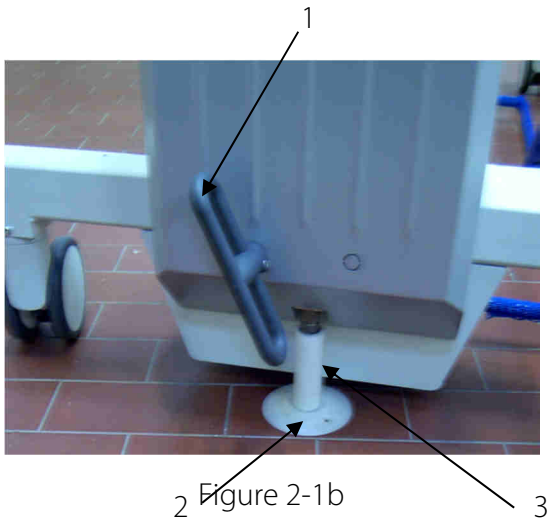


Figure 2-1b

The PROGNOST XPE has to be positioned above the floor mounted position-disk (Fig. 2-1a/2), so that the springy-pivot (Fig. 2-1a/3) locks in place into the position-disk (Fig. 2-1a/2) by pressing the fastener according to (Fig. 2-1a/1).
Pressing the fastener according to (Fig. 2-1b/1) the springy-pivot will loosen (Fig. 2-1a).

2.5 Deflector (optional)

The deflectors (Fig. 2-1/10) at the transverse carriage avoid contact of the u-rail of transverse carriage with detector housing and consequently facilitate the positioning of the table.

2.6 Side edge guard (optional)

The side edge guards (Fig. 2-1/12) avoid direct contact of detector housing with the z-angle.

2.7 Bumper profile (optional)

The bumper profile (Fig. 2-1/13) avoids a direct contact of rear accessory rail of the table top with the stand or detector support.

2.8 Protection foil (optional)

The protection foil on internal covers (Fig. 2-1/11) increases the slippage at contact with detector housing.

2.9 Center stop (optional - not shown -)

The center stop for transverse movement of table top improves alignment of the table to x-ray tube assembly.

2.10 Emergency Stop Switch and indicator lamp

By depressing the emergency stop switch (Fig. 2-1/4) the controller and the motor for the elevation of the table top are switched off.

The emergency stop switch will be released by clockwise rotation.

The three color indicator lamp (Fig. 2-1/9) is placed near the emergency stop switch. It indicates that the table elevation controller is ready for use and the actual status of the PROGNOST XPE-Akku.

Attention

If the emergency stop switch is <u>not</u> activated and the green ready for use indicator is <u>off</u>, the electronic inside the table controller box can be still under voltage! The table is disconnected from power only by removing the accumulator-box out of the power supply box.

2.10.1 Status of indicator lamp

indicator lamp low green	XPE energy-saving mode (see chapter 2.15), depress the Release switch (Fig. 2-2/6) to activate the XPE to full power mode.
indicator lamp bright green	XPE ready for operation
indicator lamp orange	Accumulator discharged to first level, normal operation possible
indicator lamp red	Accumulator discharged, only slow moving possible. After reaching low power mode it is not possible to switch on to full power mode back. Change discharged accumulator against newly charged one.

table 2.1

Further status messages are displayed with red blinking cycles of indicator lamp

Stat.	red blinking cycle	Description	Take action
1	1x	Overtemperature of power amplifier. Caused by to frequent up and down moving or too heavy patient load.	Cool down unit in standby until red blinking cycle is finished and indicator lamp is bright green again. Reduce patient load
2	2x	Drive blocked	Remove blocked reason. Call Protec authorized, qualified technical service
3	3x	Drive overload	Reduce patient load
4	4x	Unintentional moving down	Reduce patient load. Call Protec authorized, qualified technical service
	5x 	Internal voltage breakdown	Call Protec authorized, qualified technical service
	6x 	Discharged accumulator battery	Change accumulator battery
5	7x 	Internal limit switch error	Call Protec authorized, qualified technical service
	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 2.13 Contact a Protec authorized service representative should the error remain following the nullification process
	9X	Tabletop brakes (linear actuator) is blocked	The unit should be taken out of service and switched off Contact a Protec authorized service representative
	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.

table 2.2

Trouble shooting of Status 3:
Cool down unit in standby. Reduce patient load
After removing source of fault reset the status message by pressing the release button

(Fig. 2-2/6).

Status 2, 4 and 5:
Call Protec authorized, qualified technical service, if after reset of status message by pressing the release button (Fig. 2-2/6) the failure status is indicated during next moving again.

2.10.2 Acoustic status message

With all indicator lamp messages (see chapter 2.10.1) an acoustic beeper message is generated.

Beep cycle	Description
2x	General warning
3x	Accumulator nearly discharged
6x	Accumulator discharged

table 2.3

2.10.3 Acoustic and indicator lamp message if drive blocked

Attention!!
If during moving one drive is blocked (e.g. collision of table top), stop motion and remove blocked reason
If drive is blocked and reason not found (e.g. internal blocked drive), stop table top elevating and call Protec authorized, qualified technical service

If one drive is blocked, an optical indicator lamp message and acoustic warning sound take place (see table 2.2 and 2.3)

If after reset of indicator message with release button (Fig. 2-2/6) the drive blocked reason is not removed, the drive in function will move only in direction of the blocked drive, independently if up or down (Fig. 2-2/1, 2 or 7, 8) is commanded. This will prevent inclination of table top.

If the difference between both drives is more than 1cm (0.394inch), moving of drives will be disabled.

The indicator lamp shows cyclic red flashing and the acoustic beeper warning will become also cyclic peep

2.11 Hand Control

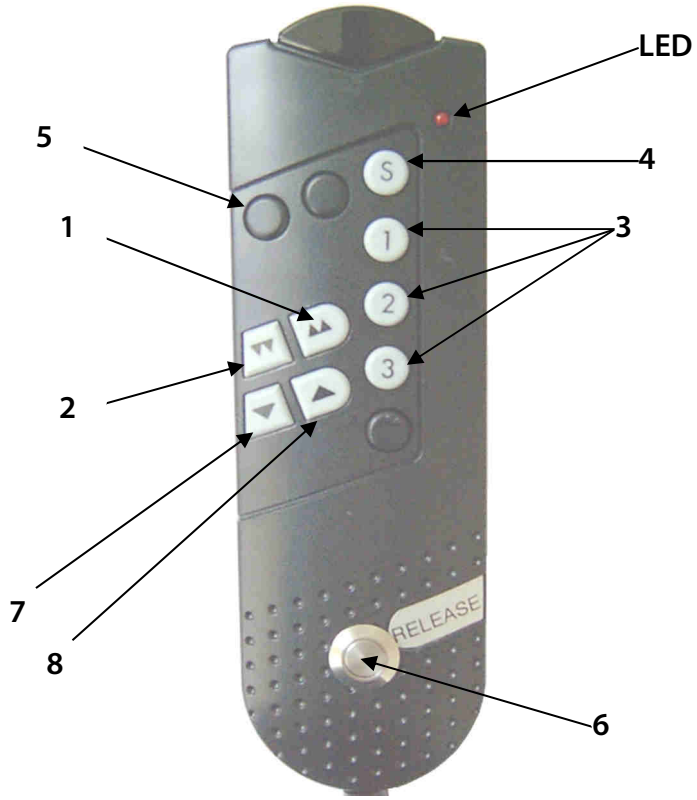


Figure 2-2

Pushbutton description of the hand control:

1 drive table top upwards fast, together with pushbutton 6
2 drive table top downwards fast, together with pushbutton 6
3 memory 1, 2 and 3 for stored heights
4 store, intermediate height
5 push button to drive the table down used in combination with pushbutton 4 for column synchronization
6 up/down motion-release
7 drive table top downwards slow, together with pushbutton 6
8 drive table top upwards slow, together with pushbutton 6

LED flashes if a key is depressed

Pushbuttons special functions see technical description.

Note:
To move the table top up/down, it is necessary to depress at first the motion-release button (Fig. 2-2/6) before any other motion button (Fig. 2-2/1, 2, 3 or 7, 8).

To stop motion it is necessary to release at first the motion button (Fig. 2-2/1, 2, 3 or 7, 8) before the motion-release button (Fig. 2-2/6).

If not used place hand control into holding device (Fig. 2-1/5).

2.12 Table top UP and DOWN movement

By depressing one of the arrow pushbuttons ▲▲ , ▲ or ▼▼ , ▼ (Fig. 2-2/1, 2 or 7, 8) in conjunction with the motion-release button (Fig. 2-2/6), the table top moves up or down. At end positions the movement stops automatically.

A maximum duty cycle (ED) of 10% for the drive columns is required to avoid overloading of the columns and to achieve a long service life. This is implemented in the control unit, that the height adjustment of the table is inhibited after the factory-set time, and a fault message (10x flashing, see table) is displayed. This forces a 4 minute break of height adjustment of the table. The internal time is then reset to such an extent that the table height can again be adjusted again (for at least 45 seconds). In order to have the complete travel time (210 seconds) continuously available again, the table must be left in the switched on state for at least 20 minutes without adjusting the height of the table.

2.13 Column synchronization

At first time or after a long time without usage and at visible heights differences between the columns, the controller must be synchronized.
If not synchronized the 2 columns can have different heights and therefore the table top can move automatically to the lower side if the table top brakes are leased.

For synchronization depress pushbutton „S" (Fig. 2-2/4) three times and then pushbutton (Fig. 2-2/5) in conjunction with the motion-release button (Fig. 2-2/6) to drive the table completely down until both columns stops. The control unit confirms this with a single 'beep' the columns elevation controllers are synchronized now.

Attention:
Never make column synchronization with patient in position on table top!

2.14 Adjustment and storage of preferences table heights

It is possible to store and memorize three different intermediate table heights to pushbuttons 1, 2 and 3. Move table height to desired position. Depress pushbutton "S" (Fig. 2-2/4) three times and then the memory pushbutton 1, 2, or 3 (Fig. 2-2/3).
By this the current height is stored to the selected pushbutton. The Storage will be confirmed by a beep. It is recommended that the stored table heights are sequential as e.g. for pushbutton 1 the lower height, for pushbutton 2 the medium height and for pushbutton 3 the highest table position.

For selecting a stored position, press key 1, 2 or 3 in conjunction with the motion-release button (Fig. 2-2/6) until table top stops.

2.15 Energy-saving mode

To reduce discharging of accumulator box in standby, the PROGNOST XPE-Akku switches into energy-saving mode after 20sec of last table top elevating and pressing of the motion-release button (Fig. 2-2/6).
The indicator lamp (Fig. 2-1/9) switches from bright green to low green.

The PROGNOST XPE-Akku switches from energy-saving mode back to normal operating mode by pressing the motion-release button (Fig. 2-2/6) again.

The indicator lamp (Fig. 2-1/9) switches back to bright green or to the status before energy-saving mode (see chapter 2.10.1 table 2.1 and 2.2).

If the PROGNOST XPE-Akku is not in operation over a longer time (e.g. weekend), it is recommended to switch off via emergency stop switch (Fig. 2-1/4).

2.16 Accumulator-box

Two accumulator-boxes (Fig. 2-3) are delivered in the composite fiber configuration

Figure 2-3

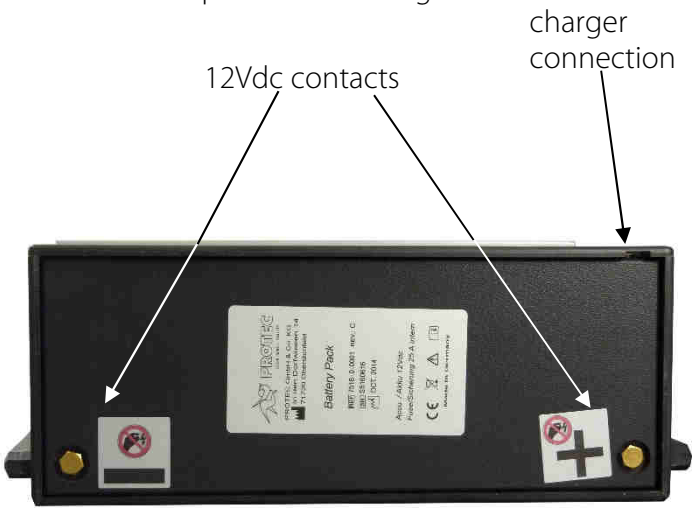


Figure 2-4

For the operation of the PROGNOST XPE-Akku one charged accumulator-box (Fig. 2-3) must be inserted into the power supply box of the table (Fig. 2-5).

Attention!
Before replacement of accumulator-box, switch OFF PROGNOST XPE-Akku with emergency stop switch (Abb. 2-1/4). After insertion of new charged accumulator-box switch ON.

Figure 2-5

Autofuse rated
32dc 20A
Use UL listed
types only.

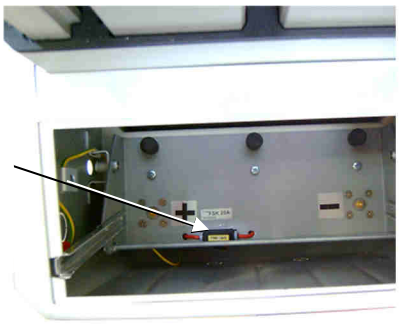
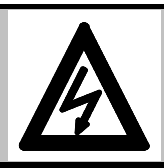


Figure 2-6

Attention!
Charging of accumulator-boxes only allowed with chargers which are released by Protec (see also chapter 2.17).

To protect the 12Vdc voltage a 20A fuse is mounted inside the power supply box (Fig. 2-5) of the PROGNOST XPE-Akku. The fuse is accessible from inside of the box (Fig. 2-6).



Attention!
The accumulator-box has on the bottom two contacts (Fig. 2-4) for connection to the 12Vdc voltage of the inside mounted accumulator.

Never short-circuit these contacts!
To prevent a short-circuit of the accumulator, never place an accumulator-box on metal-plates, metal parts or conductive parts!!

Inside the accumulator-box is a 25A fuse for additional protection (Autofuse rated 32dc 25A Use UL listed types only).
In case of defect of this fuse (no voltage at the contacts (Fig. 2-4)) call the Protec authorized service to check the PROGNOST XPE-Akku

2.16.1 Accumulator state of charge

When the lower discharge-limit of the accumulator-box is reached, an acoustic tone comes out of the electronic controller box and the indicator lamp changes from color green to orange.
This usually takes place at first when the table moves up with patient load.

In order to ensure the further correct table up and down moving function, it is necessary to change the discharged accumulator-box against a new charged accumulator-box, before placing the next patient.

NOTE
In case of ignoring the acoustic and optical discharge-limit tone the XPE controller allows up and down moving of the table until the discharge safety-limit of the accumulator-box is reached.
If the discharge safety-limit is reached, all moving are disabled to prevent the accumulator against complete discharging.

To set the PROGNOST XPE-Akku again in correct function, a new charged accumulator-box has to be inserted into the power supply box

To prevent discharging of the accumulator-box when the PROGNOST XPE-Akku is not used over a longer time, it is recommended that it will be switched off with the emergency stop switch (Fig. 2-1/4)

NOTE
As known as characteristic of accumulators, the maximum charging capacity is reached after several cycles of discharging and charging.
The accumulator-boxes are charged when delivered by Protec.
In any case it is recommended to charge the accumulator-boxes with the charger (Fig. 2-7) before first use of PROGNOST XPE-Akku

2.17 Accumulator-box charge station (option)

One charger station (Fig. 2-7/1) is delivered in the composite fiber configuration of the PROGNOST XPE-Akku.

Attention!
Use charger station Protec Id. 7517-0-0300 only
With the charger it is only allowed to charge accumulator-boxes which are released by Protec (see also chapter 2.14)

Place the charger (Fig. 2-7/1) that it can be reached easily from the diagnostic room.

Attention
The charger has to be placed out of the patient area!!

Attention!

When charging lead-acid batteries explosive gases can be produced. Ensure sufficient ventilation and avoid open fire or sparks.

The charger is for indoor use only. In order to avoid the risk of fire and/or electric shock, the charger must be protected against high humidity and water

To clean the charger, disconnect it from the mains and use only a dry cloth. Do not plug in the charger if there are signs of damage to the housing or power cable and call Protec authorized service.

Always disconnect charger from mains before connection or removing accumulator-box

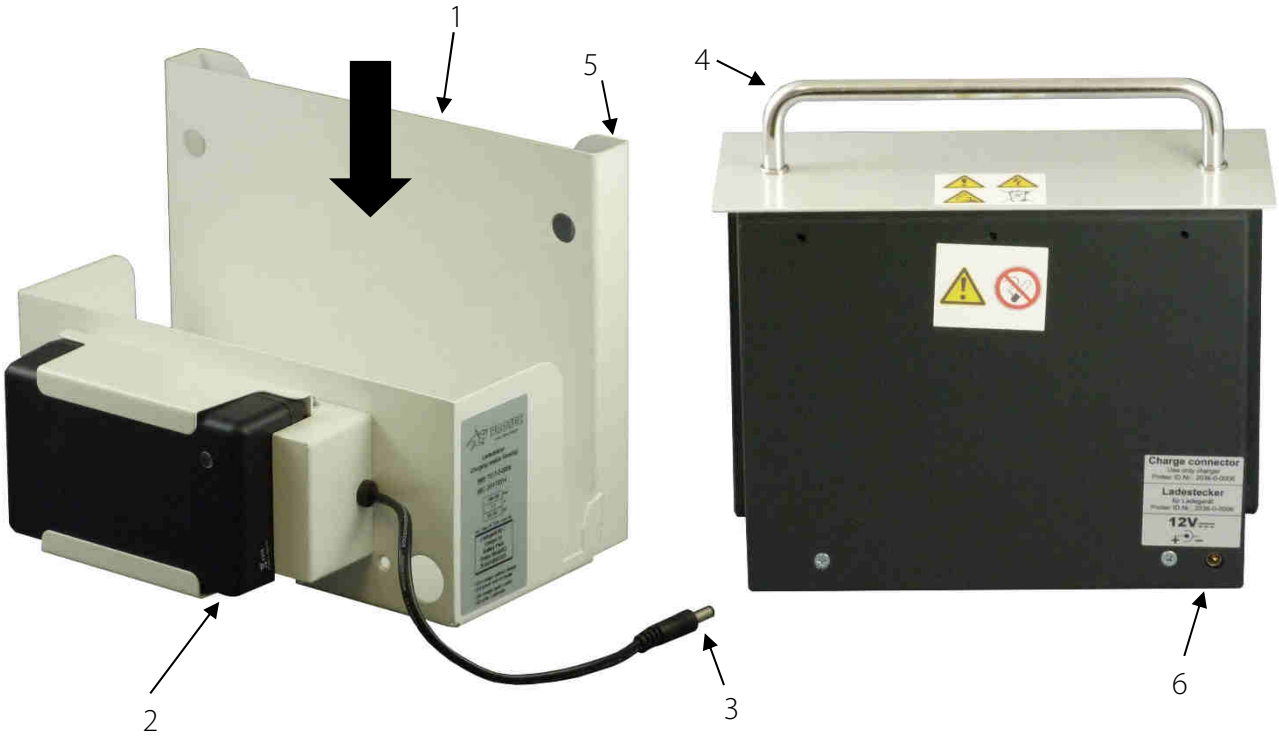


Figure 2-7

Description to Figure 2-7: 1: charge station 2: charger 3: charge connector
4: accumulator-box 5: wall holder 6: charge socket

The optional charge station (Fig. 2-7/1) is for positioning of a discharged accumulator-box.

Place charge-station that it can be reached easily from the diagnostic room.
Wall mounting of charge-station is possible with wall holder (Fig. 2-7/5)

Attention
The charge-station has to be placed out of the patient area!

After placing one accumulator-box inside charge-station connect at first charge connector and then connect charger to mains.

Follow also description of chapter 2.17.

Before removing of charged accumulator-box, disconnect charger from mains and then remove charge connector out of accumulator-box. After this remove accumulator-box.

2.17.1 Charging of accumulator-box

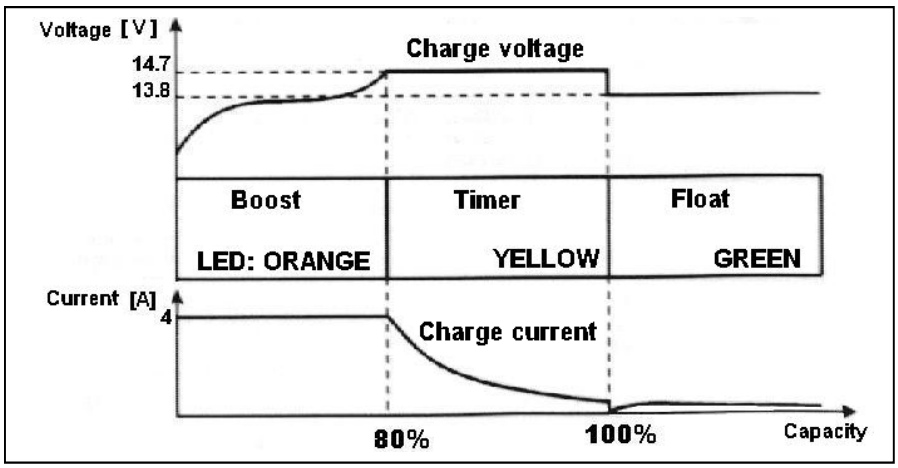
Place accumulator-box on a **non-conductive** stable underground.

Before connection of the charger with accumulator-box, make sure that charger is disconnected from mains.

Insert charge connector (Fig. 2-7/3) into connection input (Fig. 2-7/5) of accumulator-box.
Connect charger with mains.

After charging of accumulator-box disconnect at first charger from mains, wait until control LED is off. Then disconnect charge connector (Fig. 2-7/3) from charge input of accumulator-box (Fig. 2-7/5).

2.17.2 Charge cycle and meaning of charge status LED



LED orange: Mode boost charging:
Maximum and constant charging current until the load voltage is reached. The status LED changes from orange to yellow and the charge timer is switched on.

LED yellow: Mode charge timer:
The charger is for 2 hours in time-controlled mode.
Charge voltage is constant and charge current will decrease. At this time battery capacity is between 80-95% of maximum.
The charger remains in this mode until the time interval is completed

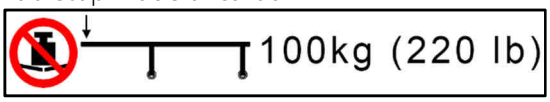
LED green: Mode trickle charge (standby):
The battery is fully charged

Charger switches over to trickle charge, if accumulator-box is not removed after fully charged.

Attention!!
Remove charge connector (Fig. 2-7/3) from accumulator-box, if charger is disconnected from mains, to prevent discharging of accumulator to low energy level.

2.18 Labels on head and foot end of table top

Tabletop made of carbon



Tabletop Composite fiber 200cm

Tabletop Composite fiber 226cm

Attention

When the table top is completely moved forwards, backwards, to head or foot end, the maximum permissible load on the outside edges are:

max 100 kg for tabletop made of carbon

max 75 kg for 200 cm table top length Composite fiber

max 60 kg for 226 cm table top length Composite fiber

Otherwise whole table may tilt or can tip over!

For heavier patients move table top to approx. center position before they get ON and OFF the table top

Before a patient get ON or OFF the table, the PROGNOST XPE brake wheels must be fixed in all directions with brake lever (Fig. 2-1/1)

3 Operating Instructions

3.1 Safety Aspects

3.1.1 Requirements for Operation

The mobile patient table is a component of X-ray systems, as e.g. L/U-arms

Such systems are prepared for the use of commercial standard X-ray tubes and image receptors (e.g. Bucky's) which are, concerning grounding, high and low voltage, directly connected to X-ray generators. All parts of the system must meet the applicable Medical Device Directive and applicable standards.

X-ray systems with the mobile patient table PROGNOST XPE-Akku must be completely installed and officially handed over by **PROTEC** Customers or by service Customers, authorized by **PROTEC,** before it can be used.

National regulations have to be observed.

Maintenance has to be carried out according to the instructions in chapter 4.

3.1.2 User

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 Emergency-Stop switch

- Activate the emergency-stop switch (Fig. 2-1/4) immediately in case of hazard to the patient, the operator or the unit. This disconnects the power supply to the control box and all movements are stopped.
- The emergency-stop switch may be reset only after the hazard has been positively identified and the problem is solved. Notify the **PROTEC** customer service department in all other cases (such as a malfunctioning of the unit).

3.1.4 Explosion protection

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

3.1.5 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) for the patient.

The operator shall always stand behind a shielded area during x-ray exposures.

Persons who must be near the patient during x-rays shall wear protective clothing (as e.g. lead aprons). The same applies for maintenance and repair work.

3.1.6 Interferences to other devices

There are no interferences to other devices known.

3.1.7 Warnings

	Keep enough distance between moving parts during movements.
	When tabletop is completely shifted forwards, backwards, to the left or right, the maximum permissible load on the outside edges is as indicated on head or foot end of table top. Otherwise whole table may tilt!

References regarding the maximum permissible load of the table, attached on the tabletop of the **PROGNOST XPE**, have to be observed especially when patients get on or off the table.
For heavier patients move tabletop to center position above the table base frame!

3.1.9 Exposures with PROGNOST XPE-Akku

For use the operator has to insert a charged accumulator-box (Fig. 2-3) into the power supply box (Fig. 2-5).
Switch power-supply ON with emergency-stop switch (Fig. 2-1/4).
Out of the controller box comes a short acoustic tone. The green ready for use indicator lamp (Fig. 2-1/9) must lit.

Attention:

If the green ready for use indicator lamp (Fig. 2-1/9) does not lit:

- **check correct insertion of accumulator-box into the power supply box**
- **make sure that emergency-stop switch (Fig. 2-1/4) is switched on**
- **make sure that accumulator-box is charged**

If not possible to solve the problem call Protec authorized service

If the green ready for use indicator lamp (Fig. 2-1/9) lit only for approx. 5sec after power supply is switched ON with emergency-stop switch (Fig. 2-1/4):

- **Switch power supply with emergency-stop switch (Fig. 2-1/4) OFF**
- **Remove accumulator-box (Fig. 2-3) out off power supply box (Fig. 2-5)**

call Protec authorized service to check function of electronic inside controller box

Note:

Before removing an discharged accumulator-box, switch power-supply OFF with emergency-stop switch (Fig. 2-1/4). Out of the controller box comes a short acoustic tone and the green ready for use indicator lamp do not lit.

The following sequence is necessary in order to avoid a collision between X-ray image receptor and table top.

- For exposures with the PROGNOST XPE-Akku bring X-ray unit into desired position.
- Adjust height of X-ray image receptor to table top height or adjust height of mobile table to image receptor.

Attention:

The table elevating system is designed for intermittent use only…

- Move mobile table carefully to desired exposure position and check that there is no collision between table top, table and image receptor.
- Move table to position for patient getting ON the table top.
- Lock brake wheels of mobile table and check that brakes are fixed.
- Assist patient to get ON the table top.
- Unlock the brake wheels and move table to previous desired exposure position and lock the brake wheels.
- Switch ON collimator light.
- Move floating table top with patient to final exposure position.
- Lock brake wheels
- Collimate the organ and take an exposure.

- Unlock brake wheels and move table to position for patient to get convenient OFF the table top.
- Lock brake wheels of mobile table and check that brakes are fixed.
- Assist patient to get OFF the table top

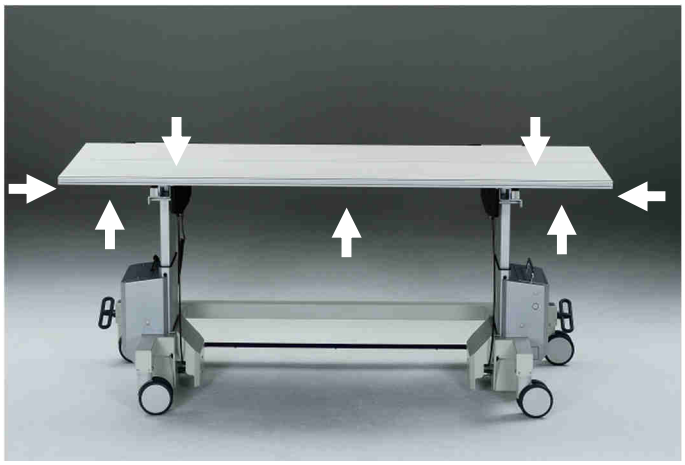
Attention:

The PROGNOST XPE-Akku is not suitable for patient transportation.
It only can be used as a support for the patient during examination.
Patients are only allowed to get on or off the table top if the brakes are fixed (chap. 3.1.7) and under supervision and assistance from the examining Customers, as otherwise the whole table may tilt.

3.1.10 Pinch points and danger of collisions

Danger!

Hands and fingers may be squeezed at the shown arrow positions.
Be sure that during movement of the table and the table top neither the patient or personal are within the uncontrolled movement area.



Warning!

Take care that at equipment, which can be raised or lowered or which can be moved in different directions yourself or other persons are not within the movement area.
Remove objects, as e.g. chairs, out of the collision area, before using the table.

Pay attention that careless movements of the PROGNOST XPE-Akku table and table top may injure patients, users or other persons and may cause damages to the X-ray tube assembly or the X-ray image receptor.
Non-observance can cause bodily injuries and damages of the x-ray unit.

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** Customers or expressly by **PROTEC** authorized service Customers.

Before operating this X-ray unit, users 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 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, do not longer use the mobile table and notify immediately **PROTEC** service or the expressly authorized service provider.

4.3 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 24 months by **PROTEC** service or expressly authorized service providers.

All parts of this equipment that could create a hazard through wear and tear must be checked in intervals of at least 24 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 occurred by the user or third parties if such damages are the result of improper or missing maintenance.

4.4 Maintenance schedule

4.4.1 General

Prior to cleaning or disinfecting, ensure that the system power is turned off, that the emergency-stop switch is actuated, and that no liquids can penetrate into the equipment.

4.4.1.1 Cleaning

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.

4.4.1.2 Disinfection

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.

4.4.2 User's daily maintenance before and during operation

- Check that brake wheels are locked if brake lever is turned into locking position (Fig. 2-1/1).
- Check fixing and easy movement of table top by using the brake foot-pedal (Fig. 2-1/2).
- Check if there are visible height differences of elevation columns for table top.
- If yes perform synchronization according to 2.13.

4.4.2.1 Check of motion-release function

- Depress the motion-release button (Fig. 2-2/6) without pressing any other of the motion buttons (Fig. 2-2/1, 2, 3 or 7, 8).
  No motion may start.
- Depress one of the motion buttons (Fig. 2-2/1, 2 or 7, 8) without pressing the motion-release button (Fig. 2-2/6).
  No motion may start.

If table height motion starts during this check, put the table out of order and call service.

4.4.3 Regular Checks

4.4.3.1 Quality Control

X-ray equipment should be quality-controlled at regular intervals 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.

4.4.4 Technical safety checks and maintenance

Required technical safety checks and maintenance (see “Maintenance check list” in the manual “Technical Description”) must be performed at 24-months intervals by **PROTEC** Service or authorized service providers to ensure the safe and reliable operation of the equipment.

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

4.4.5 Disposal Remarks

The accumulator-boxes of the PROGNOST XPE-Akku, all mechanical, electrical and plastic components have to be disposed according to local or national regulations. In case of doubt contact **PROTEC.**

5 Electromagnetic Compatibility (EMC) acc. IEC 60 601-1-2: 2007

The unit meets the Collateral Standards of Electromagnetic compatibility – Requirements and tests EN 60601-1-2 (IEC 601-1-2) the limits and methods of measurement of electromagnetic disturbance characteristics of industrial, scientific and medical radio frequency equipment EN 55011 Class B and the requirements for interference resistance are in compliance.
Medical electrical equipment is subject in regard to the electromagnetic compatibility (EMC) and its special precautionary measure.
The unit must in reference to the mentioned EMC-hints in the accompanying documents be installed and operated.
Portable and mobile RF – communicating systems (such as cell phones) can have influence to medical electrical equipment.

NOTE:
This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

5.1 General Regulation for safety acc. IEC 60601-1-2

Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
The PROGNOST XPE-Akku is intended for use in the electromagnetic environment specified below. The customer or the user of the PROGNOST XPE-Akku should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF-emissions Acc. CISPR 11	Group 1	The PROGNOST XPE-Akku uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF-emission Acc. CISPR 11	Class B	
Harmonic emissions Acc. IEC 61000-3-2	Not applicable	
Voltage fluctuations/ Flicker emissions Acc. IEC 61000-3-3	Not applicable	

Table 201

Guidance and Manufacturer's Declaration - Electromagnetic Emissions			
The PROGNOST XPE-Akku is intended for use in the electromagnetic environment specified below. The customer or the user of the PROGNOST XPE-Akku should assure that it is used in such an environment.			
Immunity test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic Discharge (ESD) acc. IEC 61000-4-2	± 6 kV Contact ± 8 kV Air	± 6 kV Contact ± 8 kV Air	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/ bursts acc. IEC 61000-4-4	± 2 kV for Power supply lines ± 1 kV for I/O lines (input/output)	Not applicable	
Surges acc. IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	Not applicable	
Voltage dips, short interruptions and voltage variations on power supply input lines acc. IEC 61000-4-11	< 5 % UT (> 95 % dip in U_T) for 0,5 cycle 40 % UT (60 % dip in U_T) for 5 cycles 70 % UT (30 % dip in U_T) for 25 cycles < 5 % UT (> 95 % dip in U_T) for 0,5 cycle	Not applicable	
Power frequency (50/60 Hz) magnetic field acc. IEC 61000-4-8	3 A/m	Not applicable	
NOTE :	U_T is the AC mains voltage prior to application of the test level.		

Table 202

Guidance and Manufacturer's Declaration - Electromagnetic Emissions			
The PROGNOST XPE-Akku is intended for use in the electromagnetic environment specified below. The customer or the user of the PROGNOST XPE-Akku should assure that it is used in such an environment.			
Immunity test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment – guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the PROGNOST XPE-Akku, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance: 3m (118,11inch)**
Conducted RF acc. IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	Not applicable	
Radiated RF acc. IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m measured until 300Mhz *	$d = 1{,}2\sqrt{P}$ *80 MHz bis 800 MHz*
			$d = 2{,}3\sqrt{P}$ *800 MHz bis 2,5 GHz*
			Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey **a** , should be less than the compliance level in each frequency range **b**. Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1	At 80 MHz and 800 MHz, the higher frequency range applies.		
NPTE 2	These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.		
a	Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast ant TV broadcast cannot be predicted theoretically with accuracy. To access the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the PROGNOST XPE-Akku is used exceeds the applicable RF compliance level above, the PROGNOST XPE-Akku should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocation the PROGNOST XPE-Akku.		
b	Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.		

Table 204

* As a result of risk analysis, it has been determined, that the PROGNOST XPE-Akku has no essential performance on which electromagnetic disturbances may have influence. On this a lower compliance level can be used, or measures are not necessary (DIN EN 60601-1-2:2001, 6.8.3.201 i), 1)

Recommended separation distance between Portable and mobile RF communications equipment and the PROGNOST XPE-Akku

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

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz bis 80 MHz $d = 1{,}2\sqrt{P}$	80 MHz bis 800 MHz $d = 1{,}2\sqrt{P}$	800 MHz bis 2,5 GHz $d = 2{,}3\sqrt{P}$
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 a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using 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 To calculate the recommended separation distance of transmitters in the frequency range at 80 MHz to 2,5 GHz an additional factor of 10/3 was used , to limit the possibility for the patient area that unintentional brought in mobile or portable communication equipment cab cause any disturbance.

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

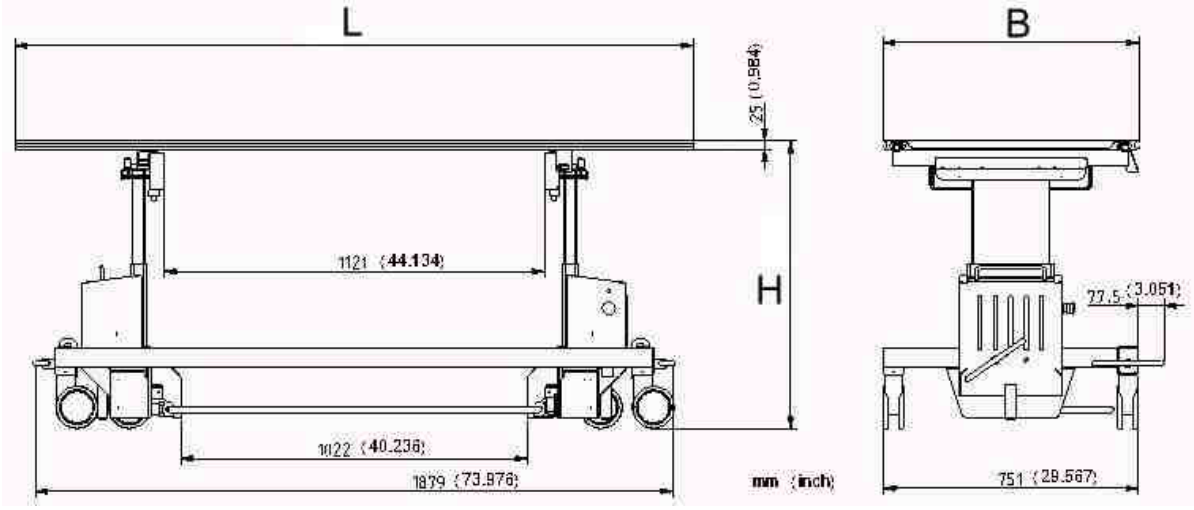
Table 206

6 Combination with other equipment

- The PROGNOST XPE-Akku is normally prepared for the use with X-ray units as e.g. L/U-arm series for general radiographic in diagnostic human medicine use.
- For combination with other equipments please contact **PROTEC** for compatibility tests and release.

7 Technical Data

7.1 Model versions and measurements



PROGNOST XPE-Akku base

Model ID	Max. patient weight	H m (inch)	color
7033-9-XXXXL	230kg (506lb) or 250kg (550lb)	0,607 – 0,873 (23.8976 – 34.3701)	RAL 9003

Table Top versions

Model ID	Material	L cm (inch)	W cm (inch)	Table top color
7301-0-5900	Carbon	**200 (78.74)**	75,5 (29.72)	white
7301-0-2200	Carbon	**226 (88.97)**	75,5 (29.72)	white
7301-0-6000	Composite fiber	**200 (78.74)**	75,5 (29.72)	white
7301-0-6010	Composite fiber	**226 (88.97)**	75,5 (29.72)	white
7301-0-6020	Composite fiber	**200 (78.74)**	65,5 (25.78)	white

Max. patient weight 230kg (506lb) table top composite fiber
250kg (550lb) table top carbon

Total weight without patient 98 kg (216lb)

Table top transverse movement from center pos. ± 100 mm (3.937inch)

Table top longitudinal movement from center pos.:

2m (78.74 inch) table top ± 330 mm (12.992 inch)

2,26m (88.976 inch) table top ± 460 mm (18.110 inch)

Distance between stroke columns below table top: 1121 mm (44.134 inch)

Manual table top and wheels brake.

Accumulator-box for PROGNOST XPE-Akku

Model ID	color
7516-0-0001	RAL 9006

7.2 Electrical Characteristics

7.2.1 Equipment Classification

The PROGNOST XPE-Akku is an internally powered equipment type B (according to EN 60601-1).

7.2.2 Power requirements

Power supply	12Vdc accumulator-box (exchangeable)
Fuses	1x Auto fuse rated 32Vdc 20A, Use UL listed types only,

7.3 Attenuation equivalent of Table top

The aluminum attenuation of the table top is typical 0,7 and <0,8 mm Al according to EN 60601-1-3 at 100kV and a first half value of 3,7 mm Al and typical 0,6 and <0,8 mm Al according to 21CFR § 1020-30 (n) at 100 kV and a first half value layer of 2,7 mm Al.

7.4 Product Life Time

The PROGNOST XPE-Akku is designed for a useful lifetime of ten years if used according to specifications and regular maintenance through **PROTEC** service or authorized service providers.

7.5 Environmental Conditions

7.5.1 Operating Environment

Temperature range	+ 10°C to + 40°C (50°F to 104°F)
Relative humidity range	30% to 70% (not condensing)
Atmospheric pressure range	700 hPa to 1060hPa

7.5.2 Transport and stock environment

Temperature range	- 10°C to + 70°C (14°F to 158°F)
Relative humidity range	10% to 95% (non condensing)
Atmospheric pressure range	500 hPa to 1060hPa

8 Description of Symbols, Labels and Abbreviations

8.1 Symbols


Wheel brake unlocked


Wheel brake locked


Attention, consult accompanying documents


Attention, High Voltage


CE-marking


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


EMC interference


Special refuse, separate collection

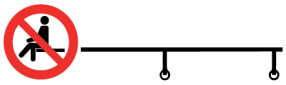

No smoking


Warning against battery risk


Don’t touch electric contacts


Danger of violent pressure to hands and fingers


Don´t exceed maximum weight, risk of breakage


Don´t exceed maximum weight, tilting danger

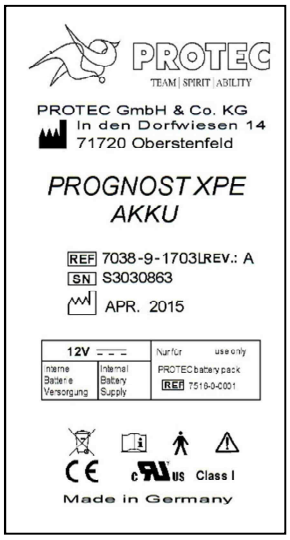

Positioning into examination position


Positioning in longitudinal

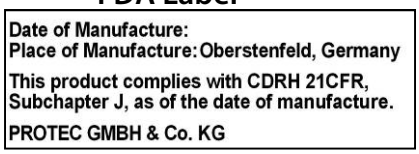

Positioning in transversal

8.2 Labels

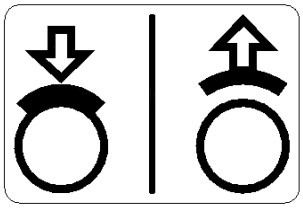
Nameplate table



FDA Label



Labels brake release/activate

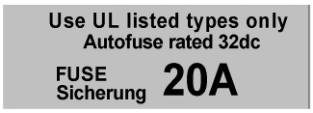


Labels inside power supply box and near contacts of accumulator-box

Plus pole of 12dc

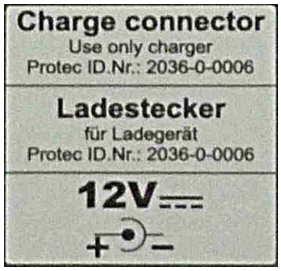
Minus pole of 12dc

Labels inside power supply box

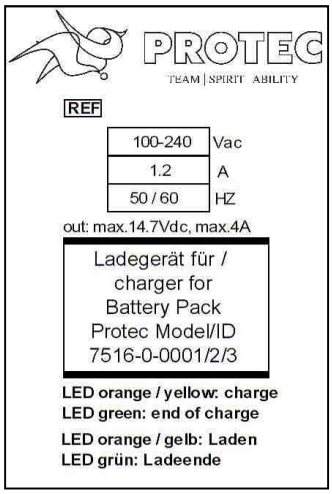


Labels Akku-Box

nameplate



Label on charger



Warning (background yellow)

At lower front frame of table (background yellow)

EMERGENCY-STOP

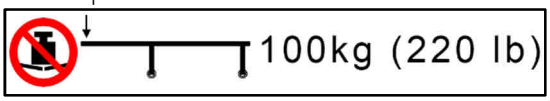
On table top

Maximum allowable weight patients (line load) on tabletop
Composite fiber tabletop

Maximum allowable weight patients (line load) on tabletop
Carbon tabletop

Labels on head and foot end of table

Tabletop made of carbon



Tabletop Composite fiber 200cm

Tabletop Composite fiber 226cm

8.3 Abbreviations

mm	millimeter
cm	centimeter
kg	kilogram
°C	Degree centigrade
hPa	Hektopascal
DIN	German Industrial Standard
EN	European Norm
CE	CE-marking
V	Voltage
A	Ampere
Hz	Frequency
int.2min/18min	Intermittent duty 2min ON, 18min Off