PAUSCH technologies

# Ceiling support

# TOPLIFT

CE 1275

## Operating Instructions

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Pausch technologies Graf-Zeppelin-Str.1 D-91056 Erlangen

# 1 General

## 1.1 Warning Statements and Symbols

The following safety precautions in this Operating Instruction call attention to potentially dangerous conditions. These symbols for especially important tasks are used:

Note!

Attention! Particular statements regarding commandment or interdiction for damage protection

Danger! Radiation

Red emergency switch

Danger!
If you use a disinfectant that can form an explosive gaseous mixture, they must have evaporated before the system is switched on again!!

The equipment is classified an marked according to the type of protection against electric shock as CLASS I Equipment and according to the degree of protection against electric shock as TYPE B Equipment.

Danger! Pinch points.

For power connection it is important, that the notes in the Mounting Instructions are followed.

## 1.2 Principle of proper use

The TOPLIFT ceiling suspension is only build for stationary use. Other or over that exceeding use is considered as improper use. For hereby resulting damage the manufacturer will not take any responsibility. It will be the owner's risk only.

Proper use also means to pay attention to the operating manual as well as to follow up on inspections- and maintenance schedules.

This radiographic unit may only operated by persons who have the required technical understanding of radiation safety and who have been instructed in the use of the radiographic unit. The user is always responsible for maintaining regulations that apply for operation of the radiographic unit.

Safety Note:
Use only the TOPLIFT ceiling suspension in safe condition.

If there is any danger for patient or operator in a emergency situation and in connection with malfunctioning of the TOPLIFT you must immediately press the red emergency off button.

### 1.3 Warranty and Liability

Basically our „general sales and terms of delivery" are valid. The user when signing the contract knows these. Warranty and liability claims by person- and material damage are excluded when one or more of the following causes can be conducted:

- Improper use of the TOPLIFT and its components
- Improper mounting, take in operation, operation and service of the TOPLIFT and its X-ray equipment
- Operating the TOPLIFT under unsafe condition or improper installed safety guards or protection device
- Not observing the notes in the operating instructions regarding transportation, storage, assembly, initial start up, operating, maintenance and preparation time of the TOPLIFT
- Unauthorized constructional changes of the TOPLIFT
- Unauthorized changes to the e.g. drive controls: power, pressure and rpm
- Inadequate observation of machine parts, which are subject to wear improper performed repair
- Disaster cases through foreign bodies and higher authority.

Warranty: 12 Month
Life time: approx. 10 Years

## 2 PRODUCT SAFETY

### 2.1 Electrical Safety

Only trained service personal may remove covers and enclosures of the TOPLIFT.

### 2.2 Examinations at and around the heart

Prior to examinations at and around the heart in connection with any other machines a ground connection between the equipment and the main ground stud must be made. E.g. Bucky wall stand and ceiling guide rails.
Only if this connection is made you are allowed to make any connection between patient and equipment.

### 2.3 Mains connection

For this product the line power must be established via regulated power supply (i.g. SBA Elektrogreätebau Type EGS 074-316 with a capacitor 4700µF/40V) or must come from a CE approved generator who is able to supply a medical low voltage of 24 V.
For this product power input must be made via 6,3 A ground fault circuit breaker that is installed on site. The room installation must correspond to VDE 0107.
In all countries outside the Federal Republic of Germany, the legal specified country regulations must be observed.

### 2.4 Mechanical Safety

Please make sure that the patient is not in the uncontrolled movement area.

Caution

Please take care, that on products which can be moved in different directions, raised, lowered or tilted neither the patient nor yourself are in the movement area of the product. Always watch where you standing. Remove all objects from the collision area.

## 2.5 Cleaning the TOPLIFT

Always switch off unit before cleaning.
Water or any other liquid may not get into the inside of the unit because this can cause short-circuits in the electrical installation and to avoid corrosion of parts.

## 2.6 EC Conformance

This radiological unit meets the general requirements according to the specifications of the EC Guideline 93/42 of the Council for Medical Products per Article 11, Section 3 and to the procedure listed in Appendix II.
**The CE - Mark applies only for the product without X-ray components.**

## 2.7 Velocity of the TOPLIFT

Do not drive the TOPLIFT to hard in its end stop position when moving the unit by hand.

Additional information can be obtained by request from:

*Pausch*
*technologies*
QC Department
Postfach 28 60
D-91056 Erlangen
Fax: +49 9131 99 24 22
E-Mail:info@pausch.de

## 3. Pinch Points

Danger!

The following sketch indicates dangerous locations where patient or operator can be injured or pinched. Please pay attention that neither the patient nor yourself get pinched or hurt in this area.

# 4 Radiation Protection

In all countries outside the Federal Republic of Germany the corresponding national regulations must be met.
We recommend to maintain safety to operator, patient and third parties to follow up this rules in addition to the local and national regulations.

## 4.1 Regulations in Germany:

Constant test § 16

Before start- up:

- Acceptance test
- Expert inspection
- Constant test (according the time intervals specified)

## 4.2 The following notes should be observed:

- Limit radiation field as small as possible
- Make sure to protect patient against radiation during examinations in the gonadal and / or crotch area..
- In the restricted area wear protective clothing during examinations.
- Keep maximal possible distance to the radiation source.
- No outher persons are to be allowed in the restricted area.

# 5 Environmental Conditions for Operation

| | |
|---|---|
| Ambient temperature range: | 10° C to 40° C |
| Relative humidity: | 20% to 80% |
| Atmospheric pressure: | 700 hPa to 1100 hPa |

# 6 Technical Data

## 6.1 Electrical Data

| Input power Tolerance ±10% | F1 terminal strip | T1 terminal strip |
|---|---|---|
| 24 V | 4 - 6 | 24 |
| Possible transformer type | SBA-Elektrogerätebau GmbH Typ Nr. EGS 074-316 with capacitor 4700 µF/40V | |

## 6.2 Component weights and temperatures

| | weight | temperature |
|---|---|---|
| Top Lift with longitudinal rails | approx. 288 Kg | 200 Watt |
| 2 longitudinal rails<br>4 m Standard (6 m Option) | 48 Kg (68 Kg) | |
| Telescope carriage compl. | approx. 240 Kg | |
| Lateral rails | approx. 43 Kg | |

## 6.3 Environmental conditions

| | Operation | Transport | Storage |
|---|---|---|---|
| Ambient Temperature range | +10°C to +40°C | - 20°C to +60°C | - 20°C to +60°C |
| relative humidity | 20% to 70% | 10% to 90% | 10% to 90% |
| atmospheric pressure | 700hPa to 1060hPa | 500hPa to 1060hPa | 500hPa to 1060hPa |

## 6.4 Packing weights and transport lane

| | | | | |
|---|---|---|---|---|
| Crate 1<br>Crate 2 | Length 1,20 m<br>Length 4,69 m | Width 0,75 m<br>Width 0,68 m | Height 1,25 m<br>Height 0,40 m | Weight 330 kg<br>Weight 225 kg |
| Heaviest single component | 240 Kg | | | |
| Minimum door size for transport | 0,90 m | | | |

## 7 Electromagnetic Compatibility (EMC) acc. EN 60601-1-2: 1994

The unit meets: the Collateral Standard of Electromagnetic compatibility – Requirements and tests EN 60601-1-2 (IEC 601-1-2) the limits and methods of measurement of electromagnetic disturbance characteristic of industrial, scientific and medical radio frequency equipment EN 55011 Group 1, Class B.

## 8 Classification per IEC 601-1

The equipment is classified and marked according to the type of protection against electric shock as CLASS I Equipment and according to the degree of protection against electric shock as TYPE B Equipment.

## 9 CONFORMANCE PER IEC 601-2-32

The associated equipment TOPLIFT meets the requirements of IEC 601-2-32.

## 10. Compatibility

At the moment the following x-ray tube and collimator assemblies can be adapted:

| | |
|---|---|
| Tube | Dunlee |
| | Varian |
| Collimator | Dunlee |
| | Siemens |
| | Ralco |

If the user wants to combine the TOPLIFT with other x-ray tubes or collimators he must make sure or consult us as manufacturer or expert that the safety of the patient or operating staff and the environment is not affected by the proposed combination.
The user is responsible adhere to the DIN EN60601-1-1.
The max. load for tube and collimator combination of 48 Kg (tube 37 Kg, collimator 11 Kg) can be adapted.

## 11 Risk analysis

According to the conducted risk analysis this product is classified to be safe whereby it can not excluded, that a hitherto unknown remaining risk anymore can exist.!

## 12 Disposal

Gather information from the authorities before placing the system in operation about all applicable disposal regulations.
Care about proper environmental utilization!

## 13 Council Directive 93/42 EEC concerning medical devices, Article 12

Particular Procedure for Systems and Procedure Packs.

1) By way of derogation from Article 11 this Article shall apply to systems and procedure packs.

2) Any natural or legal person who puts devices bearing the CE marking together within their intended purpose and within limits of use specified by their manufacturers, in order to place them on the market as a system or procedure pack, shall draw up a declaration by which he states that:

    - he has verified the mutual compatibility of the devices in accordance with the manufacturers instructions and has carried out operations in accordance with these instructions and
    - he has packaged the system or procedure pack supplied relevant information to users incorporating relevant instructions from the manufacturers and
    - the whole activity is subjected to appropriate methods of internal control and inspection.

Where the conditions above are not met, as in cases where the system or procedure pack incorporate devices which do not bear a CE marking or where the chosen combination of devices is not compatible in view of their original intended use, the system or procedure pack shall be treated as a device in its own right and such be subjected to the relevant procedure pursuant to Article 11.

The user is responsible for observance and enforcement of the national deviations in the European Economic Community.

## 14 Product Description

The ceiling support TOPLIFT is a radiological exposure system with a high technical specification level for hospitals and practice.
In addition, free exposure technique on table or bed exposures as well as emergency exposures are possible.
With the Easy Drive System you can approx. do 10 times more cycles as on conventional systems possible.
This means drastically reducement of service and maintenance inspections as well as low costs and time loses.

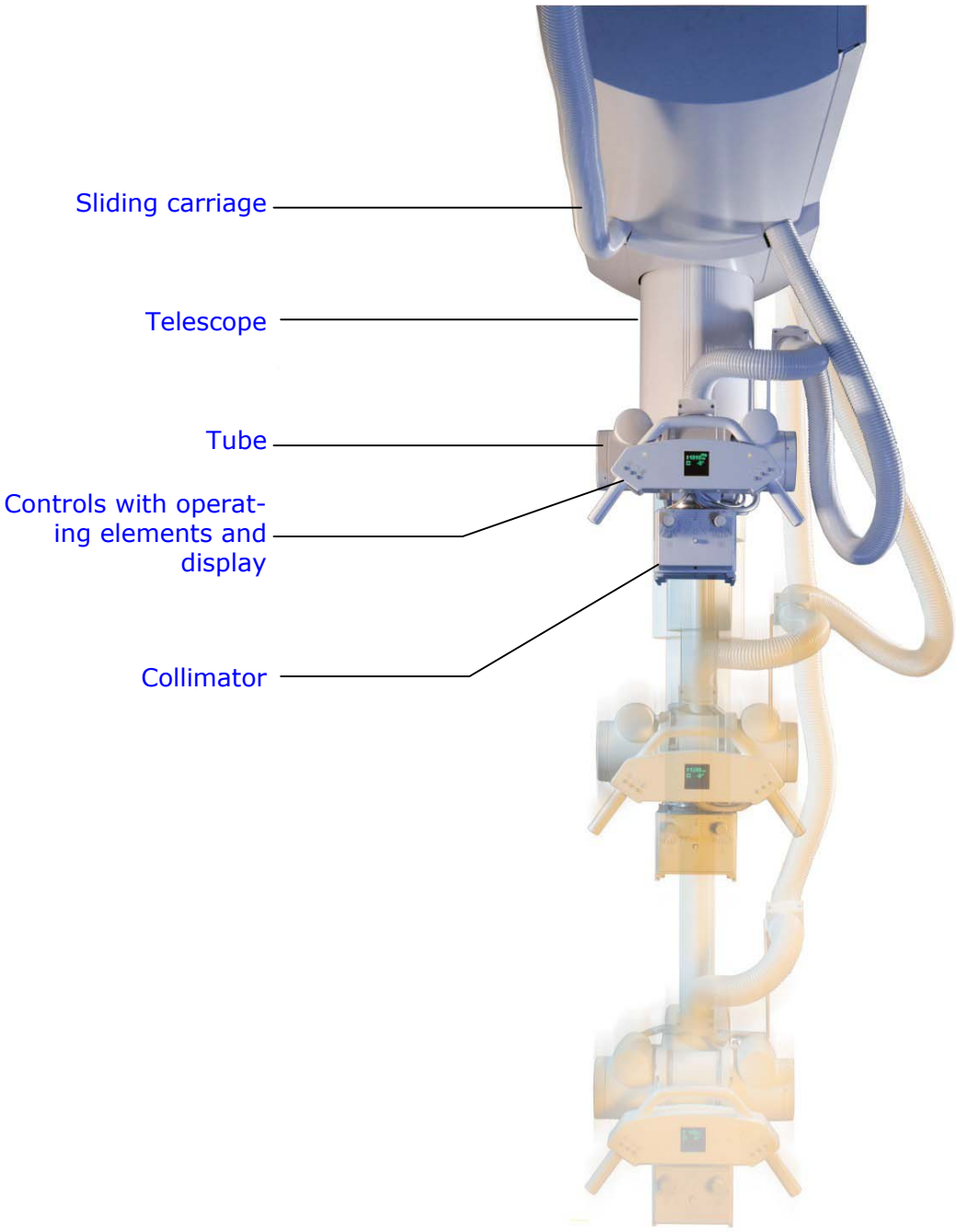
### 14.1 Balanced Ergonometry

The main goal during engineering was ergonometry with a simple use of operation.

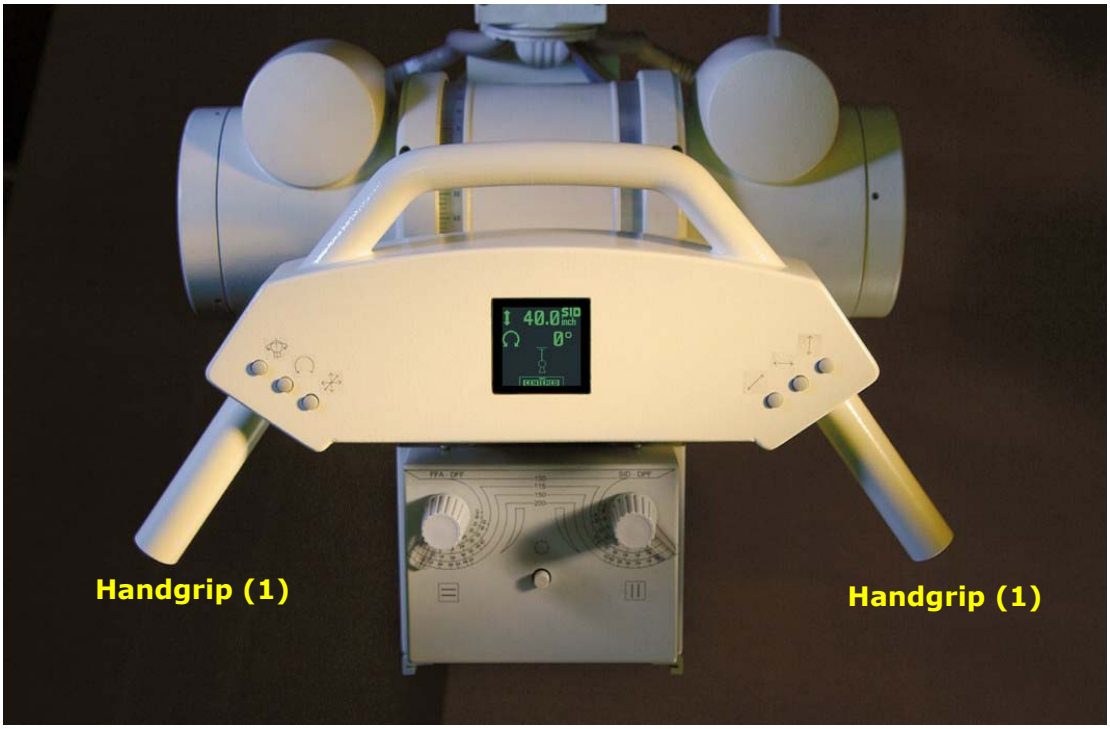
### 14.2 The Highlights are:

- Easy movement of the TOPLIFT
- Ergonometrical working with easy operation
- High precision in positioning as well as individual adoption to the described tube and collimator combinations.
- Self levelling digital display
- Weight differences up to 20 Kg can be balanced.

## 15 General View



## 16 Control Elements for TOPLIFT




All movements of the TOPLIFT are done direct and manually.

To rotate the tube assembly around the telescope vertical axis (+180° to -160 °) or to rotate the tube around the horizontal axis (±135°) the handles (1) are to be used to move into the desired position.

Detent in vertical axis: every 45°
Detent in horizontal axis: at 0° and ± 90°

The longitudinal (380 cm), lateral (max.300 cm) and vertical (lift) movement (up to 152 cm) of the TOPLIFT are also be operated via the handles to move the tube assembly in desired direction.

**WARNING**

In case of a blocking in longitudinal, lateral or vertical direction up or down or turning the tube please do not use any force.!

Please contact your service immediately in case of a defect on the wire ropes. You will notice this if the mechanical movement is blocked. Also on the display a broken wire will be shown (page 17) and a acoustical signal will alert you.

## 17 Operation with the Control Handle


Attention: The display does not indicate a true measurement. It is only for your information.

By pressing one of the buttons (1 to 6) the following movements can be done:

**1** Move the TOPLIFT in all directions including up and down

**2** Lateral movement of TOPLIFT

**3** Rotate tube assembly around horizontal axis

**4** Longitudinal movement of TOPLIFT

5 Rotate tube around the vertical axis

**6** Move tube assembly up or down

Note: If the SID is not changing while moving up or down there might be an error in the display or potentiometer.

# 18 Set up Exposure Position

Note: Basically the operator must place the patient in all exposure positions correctly and must control the field light as close as possible.

## 18.1 Exposures to patient - table

Tube: vertical position
Table and Bucky horizontal

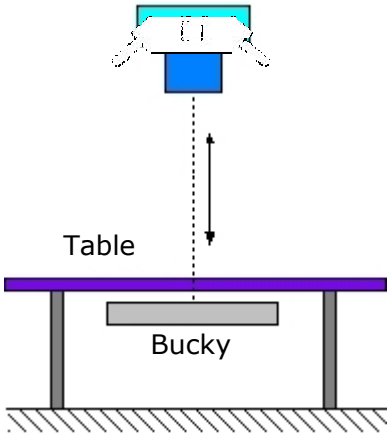
TOPLIFT lateral- and longitudinal and tube movement up or down



TOPLIFT in longitudinal direction only



Move tube up or down




To avoid quality image through grid shadows or lines always set proper SID.

Note: Always check SID distance with means of the tape measure to the cassette in the cassette tray.

## 18.2 Exposures to Bucky wall stand

Tube: horizontal position
Bucky: vertical

TOPLIFT lateral- and longitudinal and tube movement up or down

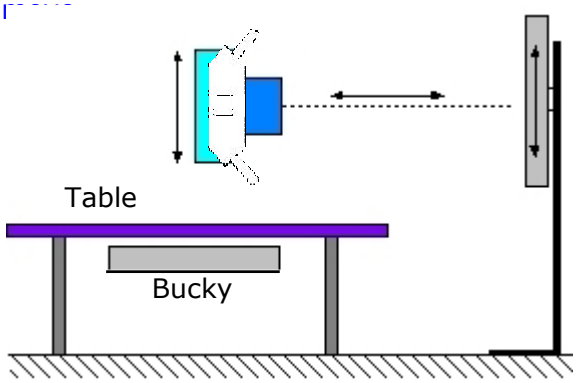


TOPLIFT in longitudinal direction only



Move tube up or down

Rotate tube around horizontal axis to 90° position

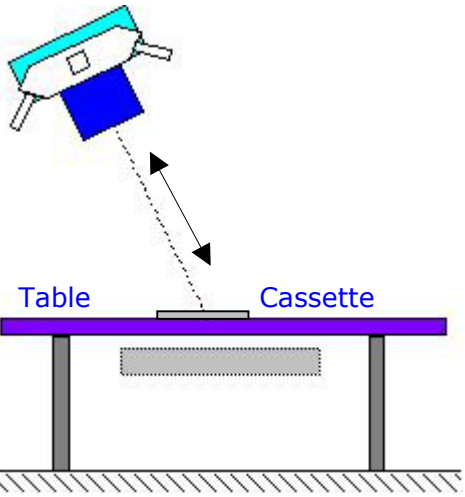



Move the TOPLIFT into preselected exposure position A or B.
(Standard: 115 cm re. 180 cm to wall stand)
To avoid quality image thru grid shadows or lines always set proper SID.

Note: Always check SID distance with means of the tape measure to the cassette in the cassette tray.

## 18.3 Oblique exposures with „cassette on table"

Tube: vertical position ± 135°




TOPLIFT lateral- and longitudinal and tube movement up or down

TOPLIFT in longitudinal direction only

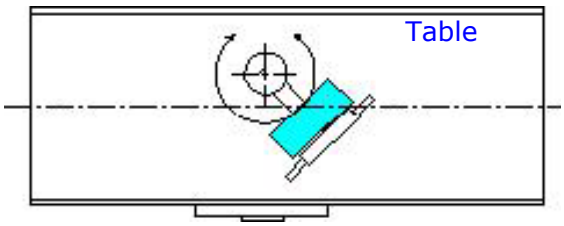
Move tube up or down

Rotate tube around horizontal axis to 90° position

Note: When doing oblique exposures the SID in the display is not active. Check SID distance with tape measure.

## 18.4 „Over-Table-Exposures" with tube rotated around the vertical axis

Tube: vertical position
Detent: every 45°




TOPLIFT lateral- and longitudinal and tube movement up or down

TOPLIFT in longitudinal direction only

Move tube up or down

Rotate tube around horizontal axis to 90° position

Note: Check SID distance to the cassette with means of a tape measure.

## 19 Display Functions on Control Panel


Source to Image Distance (SID) 41 Inch to Table

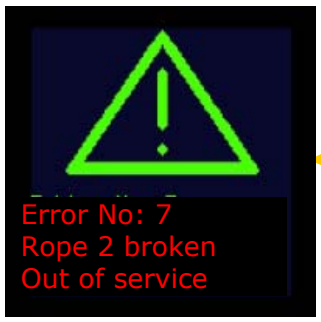
Angle indication / tube rotation

Patient - Table


Source to Image Distance (SID) 40 Inch to Bucky Wall Stand


Source to Image Distance (SID) 72 Inch to Bucky Wall Stand


Indication wire rope broken




Indication wire rope broken

If the SID is not working please measure the distance with a tape measure and contact field service.
In case of malfunction of the display call field service immediately.

# 20 Accessories

For safety reasons please use only accessories manufactured by Pausch or accessories from other manufacturer which is officially released by Pausch.
It is the owners risk when using accessories which are not released or intended for this unit.

# 21 Maintenance

Like any other technical equipment, this radiographic unit and its accessories requires a regular maintenance and care to ensure the operating reliability of the unit.
The user must check the radiographic unit and accessories for deficiencies as described:
Check all brakes and the display for proper function. In case of defects or other problems do not operate the TOPLIFT and call field service. Use the TOPLIFT only after all the problems are corrected and the unit is safe again.

## 21.1 Maintenance Intervalle

To maintain trouble-free operation of the unit as well as to ensure safety for patients and operating personal, technical maintenance should be performed by customer service in 12-month intervals.
See chapter "*Technical Maintenance*" in the mounting instructions. Especially all wire ropes must be inspected every 12 month.

Note: The wire ropes **must** be replaced every 5 years.

# 22 Disinfection of the Unit

**Note!**
Only those disinfection methods that correspond to applicable regulations and guidelines as well as to explosion protection measures may be used..

**Caution!**
No caustic, solvent or volatile disinfectants may be used**!**

**Danger!**
If you use a disinfectant that can form an explosive gaseous mixture, they must have evaporated before the system is switched on again!!

All parts of the X-ray equipment, including the accessories and connecting cables may be disinfected by wiping only.
Spray-disinfection is not recommended because the disinfectant may enter the equipment.
If you perform room disinfection with an atomizer, you must switch off the X-ray equipment first. When the X-ray equipment has cooled down, cover it carefully with a plastic sheet. When the mist of disinfectant has subsided you can remove the plastic sheets and disinfect the X-ray equipment by wiping.

**The following disinfectants can be used:**

Mild soapy solution
Misty Multi-Purpose Disinfectant Cleaner - Amrep Inc.
Misty Multi-Purpose Disinfectant Cleaner II - Amrep Inc.
Misty Disinfectant and Deodorant RTU - Amrep Inc.
Virex II 256 - Johnson Professional
Tego 1103
Kosolin

## 23 Name Plate Location

PAUSCH technologies

Graf-Zeppelin-Str. 1
D-91056 Erlangen

| | | |
|---|---|---|
| Type | 04100001 | |
| S.-Nr. | | |
| Datum | | |
| Spanng. | 24 ⚠ | Volt DC |
| Frequenz | ——— | Hertz |
| Strom | 4,3 | Ampere |

Made in Germany

Name Plate

Typ B

Identification of Labels

CE 1275

Specifications are subject to change without notice.