PROVERT

Model/ID: 7401-5-XXXX

Instructions for Use

Ident. Nr. 5401-0-0002

CE

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Send inquiries regarding this document to the following address:

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

Content

NOTE

The information contained in this document conforms to the configuration of the equipment as of the date of manufacture. Revisions to the equipment subsequent to the date of manufacture will be addressed in service updates distributed to the PROTEC Technical Service Organization.

Document Effectivity

Revision No.	Date	List of effective pages	Comments
	25/01/1999		Original Issues
Rev. 1	05/02/2001	all	completely revised
Rev. 2	30/04/2003	all	Completely revised (digital bucky added)
Rev. 3	09/03/2005	all	Layout adjustment
Rev. 4	15/12/2010	All	Modified address
Rev. 5	01/12/2011		New Lable
Rev. 6	16/03/2015		Kpl überarbeitet
Rev. 7	30/06/2015	Chapter 6.7	Drawing revised

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**.

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

Improvement Recommendations

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

1 Equipment Description

1.1 Introduction

This “Instructions for Use” describes the features of the PROTEC wall bucky stands PROVERT and provides operational instructions for its efficient and effective use.

It is suggested that you review the operating instructions, the safety notes and the controls described in this “Instructions for Use” before using the PROVERT.
Each control is described to acquaint you with its function.

1.2 Intended Purpose

The PROVERT are wall bucky stands for vertical x-ray exposure technique on standing or seated patients for diagnostic within the human medicine.

The PROVERT 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 to the requirements of the European Community Medical Device Directive 93/42/EWG from 06/14/1993.

You can get the declaration of conformity directly from

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

1.4 Functioning

1.4.1 Description

The Vertical Wall Bucky Stands PROVERT (Figure 2-1) are designed for radiography of standing and seated patients.
The counterbalanced Bucky assembly is easily movable and permits simple, exact positioning. A brake serves to securely maintain the selected position.

1.4.2 Features

- Cassette loading from the right or left side (specified at installation).
- Cassette sizes from 13 x 18 cm (5 x 7 in) to 35 x 43 cm (14 x 17 in).
- Space saving with minimal footprint.
- Wall--floor mounting or floor mounting**.**
- Prepared for mounting of bucky’s with digital panels

1.5 Equipment Components

- Column
- vertical carriage

- counterweight
- bucky
- Tilting device for PROVERT

1.6 Optional Equipment

- Rails for accessory attachement
- Compression band
- Patient extending handle
- Baseplate incl. triangular

1.7 Nameplate, Manufacturing Date

The nameplate of the PROVERT is located at the uper front side of the column.
The manufacturing date is provided on the nameplate.

2 Controls

2.1 Vertical carriage

1. Vertical brake control handles are located on either the right or left side of the Vertical Bucky Stand, depending on left or right hand version. For the PROVERT with digital bucky's the control handles are on the left side only.

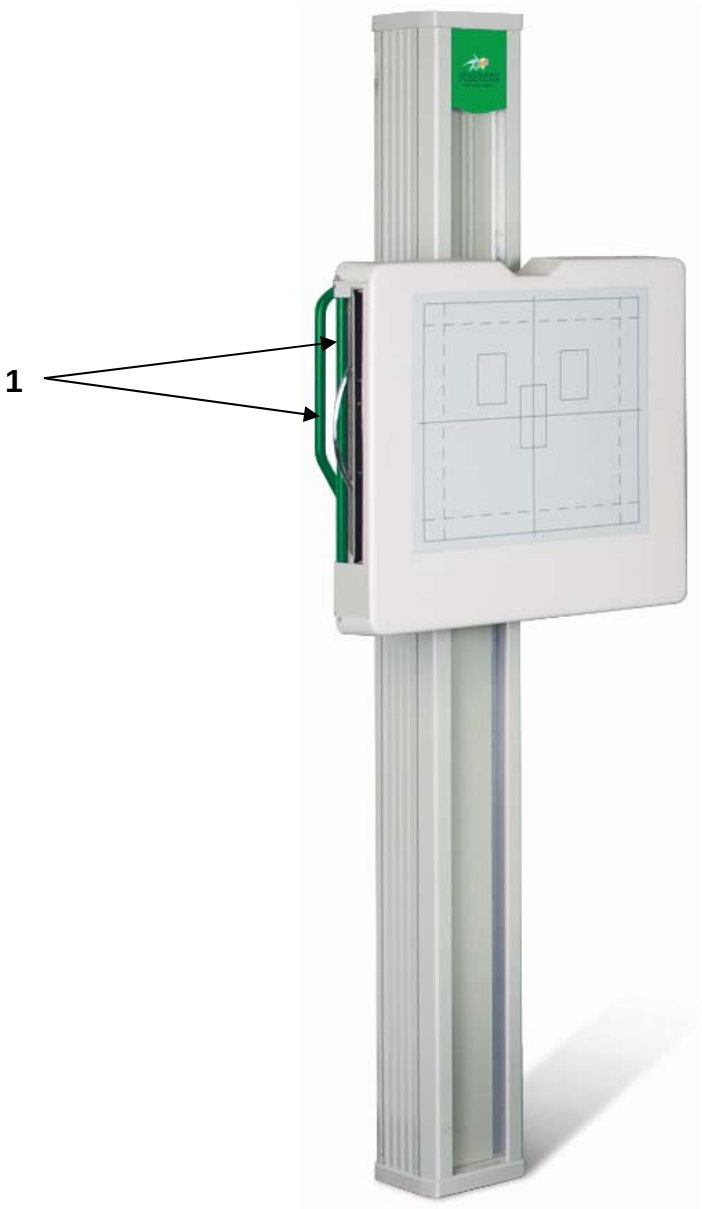

Figure 2-1

3 Operating Instructions

3.1 Safety Aspects

3.1.1 Requirements for Operation

The PROVERT must to be completely installed and officially handed over to the customer before it can be used by the customer.

The national regulations concerning announcement of new installed X-ray equipment and monitoring of the operating system must be met.

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

3.1.2 Users

The PROVERT 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 users is necessary.

3.1.3 Explosion Protection

3.1.4 Radiation Protection

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

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.

3.1.5 Maintaining 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.

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

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

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

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.

3.1.6 Interferences to Other Devices

There are no interferences to other devices known.

3.2 General Hints

The bucky mounted on a vertical carriage is counterbalanced, moveable without effort and locks automatically in place.

3.3 Vertical carriage

Two brake handles (refer to Fig. 2-1/1) pressed together will release a lock and allow vertical manual movement of the vertical carriage.

3.4 PA-accessory rails (Optional)

The two PA-accessory guide rails on both sides of the front cover are for the attachment of accessories as e.g. compression band or fixing parts for e.g. head clamps.

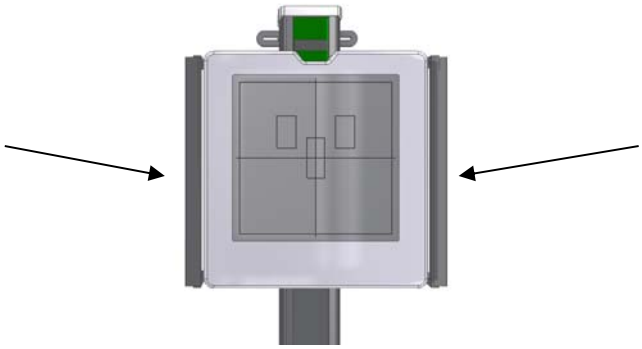

Figure 3-1

4 Maintenance through the User

4.1 Introduction

This chapter provides a maintenance schedule to ensure proper and safe operation after installation. Any further adjustments or calibration not contained in this "Instructions for Use", is permitted only from PROTEC service or the expressly authorized service providers according to the applicable "Technical Description".

4.2 Safety Information

The user and the service Customers are reminded to observe all CAUTIONS and WARNINGS as they appear throughout the text of this "Instructions for Use". Failure to comply may result in serious or fatal bodily injury.

In the event of a malfunction, turn the equipment off and notify PROTEC service or the expressly authorized service providers.

4.3 Technical Safety Information

To protect the safety of patients, users, and third parties, it is absolutely essential that the equipment be subjected to tests by PROTEC service according to the intervals displayed at chapter 4.4.5.1 to ensure its reliable function and operational safety.

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

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

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

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

4.4 Maintenance Schedule

4.4.1 User’s Maintenance Schedule

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

4.4.1.1 Cleaning

WARNING

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
Dry-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 Disinfecting

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

WARNING

For safety reasons, no spray disinfectants may be used.

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.
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 Prior to Operation

No daily maintenance check is required prior to operation.

4.4.3 User's Daily Maintenance During Operation

No daily maintenance check is required during operation.

4.4.4 Monthly checks

4.4.4.1 Quality control

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

4.4.5 Maintenance

Required maintenance must be performed at 6--month intervals by PROTEC Service or specifically authorized service provider 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 incurred by the user or third parties if such damages are the result of improper or omitted maintenance.
Required maintenance must be performed by PROTEC service or a specifically authorized service provider to ensure the safe and reliable operation of the equipment.

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

4.4.6 Duration of Life Time of the Product

The PROTEC PROVERT wall bucky stand is designed for a useful life of ten years, when used as intended and the regular maintenance schedule will be performed by the PROTEC service organization or by expressly authorized service providers.

PROTEC guarantees the supply of spare parts during these 10 years.

4.4.7 Disposal Remarks

The PROVERT does not contain any toxicological materials.
All mechanical, electrical and plastic components have to be disposed according to local or national regulations.

5 Combination with other Equipment

The PROVERT wall bucky stands can be combined with:

- Bucky`s from PROTEC
- X-ray Systems from PROTEC

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6 Technical data

6.1 PROVERT vertical bucky stands

	PROVERT
Column height	2133 mm
Vertical Travel	1310 mm
Dimension	Figure 6-1

6.2 Electrical

The Bucky unit has to be connected at the control cabinet of the X-ray generator or in case of a digital bucky to the digital system.

6.3 Weight

Weight (Vertical Bucky Stand with Bucky): approx. 128 kg
Weight (Vertical Bucky Stand with tiltable Bucky): approx. 180 kg
Weight (Vertical Bucky Stand with tiltable Bucky, digital): approx. 220 kg

6.4 Attenuation Equivalence

The aluminum attenuation equivalence of the front cover is typical 0,6mm and < 0,7mm Al according to EN 60601-1-3 at 100kV and a first half value layer of 3,7mm Al or according to FDA § 1020.30 measured at 100 kV and a first half value layer of 2,7mm Al.

6.5 Product Lifetime

The PROVERT is designed for a useful lifetime of ten years if used according specifications and regular maintenance through PROTEC service or expressly authorized service providers by PROTEC.

6.6 Environmental Conditions

6.6.1 Operating Environment

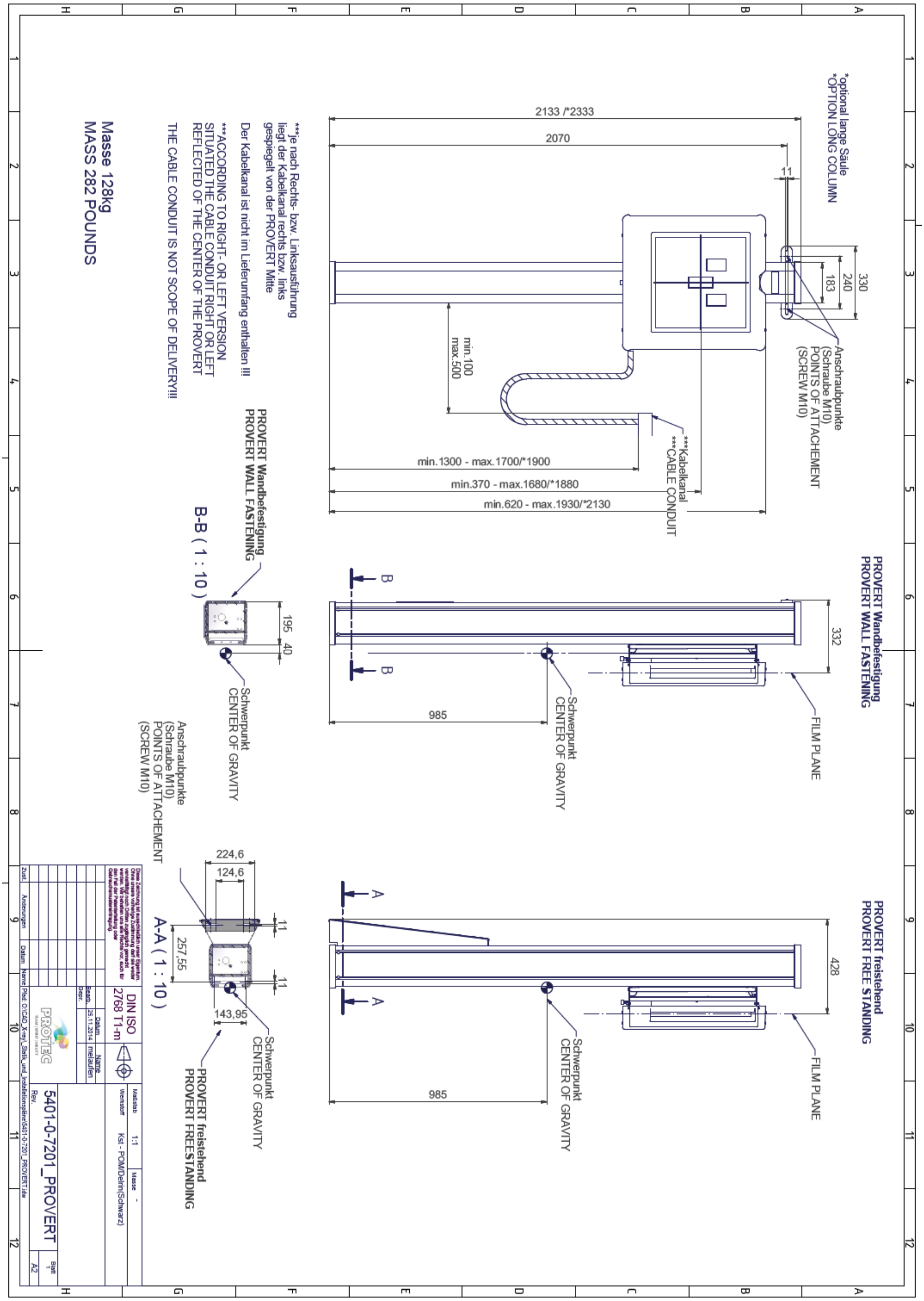
Temperature range: + 10 °C to + 40 °C
Relative humidity range: 30 % to 75 %
Atmospheric pressure range: 700 hPa to 1060 hPa

6.6.2 Transport and Stock Environment

Temperature range: - 10 °C to + 70 °C
Relative humidity range: 10 % to 95 % (not condensing)
Atmospheric pressure range: 500 hPa to 1060 hPa

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

6.7 Dimensions of the PROVERT



*optional lange Säule
*OPTION LONG COLUMN
2133 /*2333
2070
11
330
240
183
Anschraubpunkte
(Schraube M10)
POINTS OF ATTACHEMENT
(SCREW M10)
min.100
max.500
***Kabelkanal
***CABLE CONDUIT
min.1300 - max.1700/*1900
min.370 - max.1680/*1880
min.620 - max.1930/*2130
***je nach Rechts- bzw. Linksausführung liegt der Kabelkanal rechts bzw. links gespiegelt von der PROVERT Mitte
Der Kabelkanal ist nicht im Lieferumfang enthalten !!!
***ACCORDING TO RIGHT- OR LEFT VERSION SITUATED THE CABLE CONDUIT RIGHT OR LEFT REFLECTED OF THE CENTER OF THE PROVERT
THE CABLE CONDUIT IS NOT SCOPE OF DELIVERY!!!
Masse 128kg
MASS 282 POUNDS
PROVERT Wandbefestigung
PROVERT WALL FASTENING
332
FILM PLANE
985
Schwerpunkt
CENTER OF GRAVITY
B-B (1 : 10)
195
40
PROVERT freistehend
PROVERT FREE STANDING
428
A-A (1 : 10)
224,6
124,6
257,55
143,95
PROVERT freistehend
PROVERT FREESTANDING
DIN ISO 2768 T1-m
5401-0-7201_PROVERT
PROTEC

Figure 6-1

7 Description of Symbols, Labels and Abbreviations

7.1 Symbols


Attention, consult accompanying documents


CE-Marking


Protective Earth connection


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


Potential equalization conductor connection

7.2 Labels

Nameplate

7.3 Abbreviations

mm	millimetre
cm	centimetre
kg	kilogram
°C	Degree centigrade
hPa	Hektopascal
DIN	German Industrial Standard
EN	European Norm
CE	CE-marking