User Manual
CAP02-CS0131-SIE01

(Describes the operation and support carried out by the user)

Patient positioning table for Siemens Lithoscope

CE

- hardware-version: 03
- software-version: VC02A
- originally issued in German

Valid starting as from serial no. M01107970

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Abbreviations used

PPT: Patient positioning table

1 Appropriate Use, Product Overview

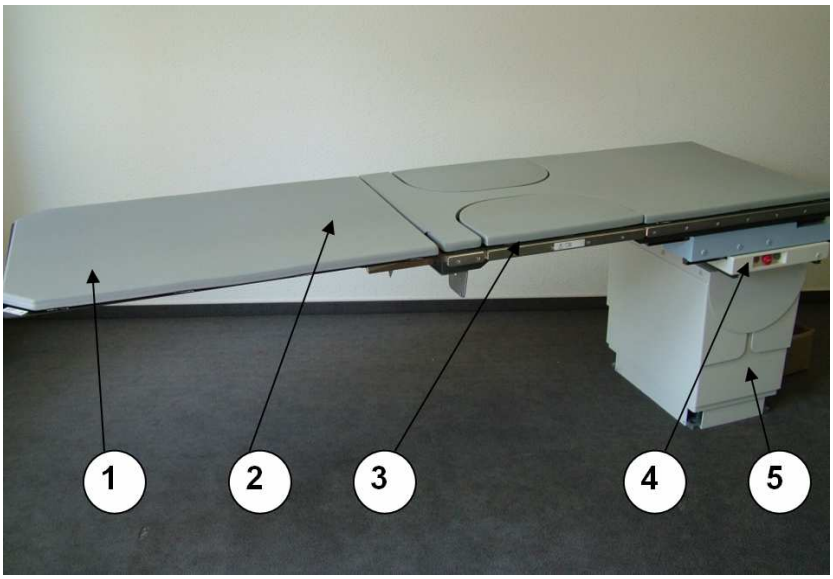
The patient positioning table is an integral part of the Siemens-Lithoscope-System for endourological and lithoscopical treatments. According to the requirements of the customer it was developed and customized for the use within this system

The microcontroller, which is integrated in the table, directs decentred its four movable axes in speed and position.

The power supply is effected within the voltage range. The user interfaces consist of a power supply and a digital in- and output and a CAN-Open-interface.

The patient positioning surface consists of a multilayer system of CFK-sandwich-boards. A novel kind of patient pad allows the patient to lie comfortably.
To fasten the accessories a rail has been attached as usual in urology.

There are an emergency stop button, a so-called decollision button and a socket plug at the table to connect a Siemens- handheld control.



1. Leg extension
2. Patient pad
3. Table top with lithotripsy slot
4. Operating elements
5. Table column

Figure 1: Patient positioning table

2 General Instructions

2.1 Legend

Below-mentioned symbols label the possible risks and important indications.

This symbol shows actions and states leading to risks for people and items. Exactly observe the instructions!

This symbol shows the relevant and useful indications.

2.2 How to use the instruction manual

This instruction manual is written for technical experts installing the PPT in medical systems.

3 Law, Conformity, Standards and Safety

3.1 Law

The device meets the requirements of the

- German Medical Product Law (MPG Medizinproduktegesetz) and of the
- American Code of Federal Regulations CFR 21, Chapter I,
  Part 801 Labeling
  Part 820 Quality System Regulation
  Table top and Lithotripsy slots also fulfil
  Part 1020.30 Performance Standards for Ionizing Radiation Emitting Products

3.2 Conformity

The device meets the basic requirements of Directive 93/42 EEC for medical products of category 1. It has been labelled by the appropriate CE-Label and developed and checked according to the following standards:

- EN 60601-1
- EN 60601-2-32
- EN 60601-2-36
- EN 60601-1-2
- UL 94 UL 60601-1

This device cannot be operated independently and is provided for the integration into a medical system. The initial operation is allowed only if the user notes that the regulations of the applicable EU-directives, national law and standards for the related end-product have been fulfilled.

3.3 Operational Safety

Only skilled personnel install and operate the device.

In case of trouble (collision movement, bruise, and unexpected movement,)all movements of the PPT can be stopped by pushing the red emergency stop button. Collision detection within the entire system is recommended.

The PPT may only be used when supervised. It is to secure that in any case of trouble the emergency stop button can be reached in time.

The hardware-signal reports the missing of the litho-slot to the superior system and there it has to be analysed.

If the litho-slots are placed, attention has to be paid so that the patient is not bruised.

If the table is tilted the patient pad has to be fixed so that it is non-slipping and operational.

The PPT is not in conformity with the categories AP or APG and may not be used in any environment showing inflammable compounds of respiratory anaesthesia drugs together with air and oxygen.

The operator has to observe that the PPT can move freely and that no attached items can cause bruises and cuttings.

3.4 Location of the type label and the warning notices

1. **Type label of the table (underneath the shutter)**
2. **Caution label: Attention! Observe the instructions in the manual.**
3. **Caution label: max. table load**
4. **Caution label: max load extension board**

Figure 2: Patient positioning table

4 Operation

The operation of the table is made by the Siemens-Lithoscope-System and is therefore described in that Siemens operator manual.

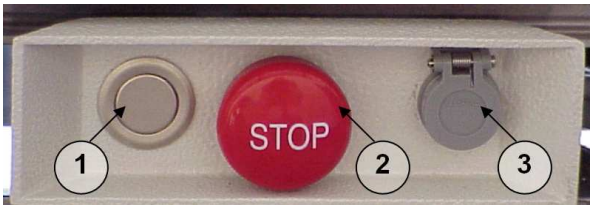
4.1 Operating Elements

There are three operating elements at the PPT:

Decollision button:	The system control can identify an eventual collision with the entire system. In this case the entire system is stopped. After being informed by the system control this key must be pressed to re-operate the system out of the collision.
Emergency stop button:	Stops the PPT immediately via the system control. The emergency stop can be released if the button is turned and pulled out.
Connector socket for the Handheld-control:	Here the Siemens- handheld-control can be plugged in.

For further descriptions of these operating elements refer to the operator manual of the entire system.

⚠ The signals of all elements are transmitted to the superior control where they are analysed. There is no autarkic handling at the PPT.



1. Decollision button

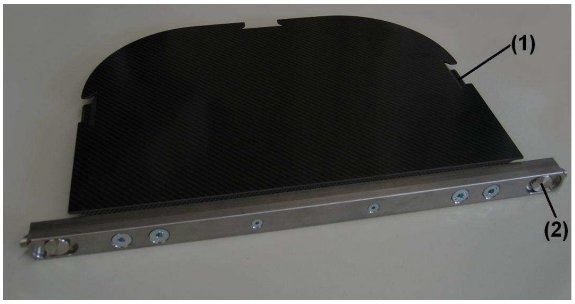
2. Emergency stop button

3. Connector socket

Figure 3: Operating elements

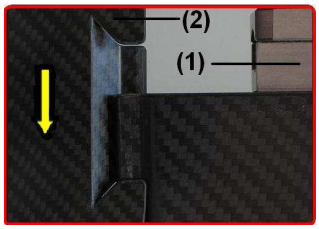
4.2 Attached Elements

4.2.1 Tabletop inserts



On both of the tabletop inserts there are 3 clips on the insert plate and 2 latches on the side rail.

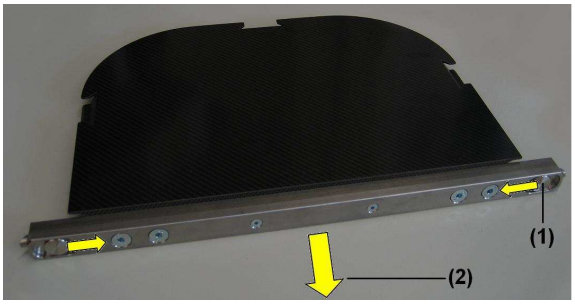
(1) Clip
(2) Latch



(1) Patient table
(2) Tabletop insert without mat

Accessories (e.g. Coxafix leg supports) can be attached to the removable tabletop inserts.

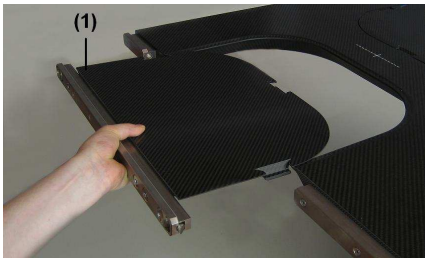
4.2.1.1 Abnehmen der Tischplatteneinsätze



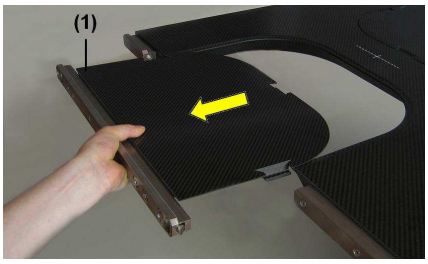
Push both of the latches toward the middle of the tabletop insert (see arrow 1) and at the same time pull the tabletop insert away fro the patient table (see arrow 2)

Do not lean the detached tabletop insert against the lifting column of the patient table.

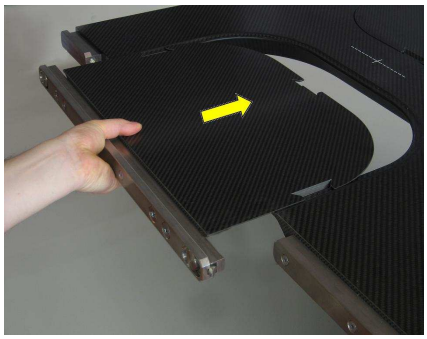
4.2.1.2 Detaching the tabletop inserts



Place one side of the tabletop insert (1) on the edge of the cut-out in the tabletop.



Withdraw the tabletop insert (1) a small distance away from the patient table (see direction of arrow). The tabletop insert should fall into the correct position.

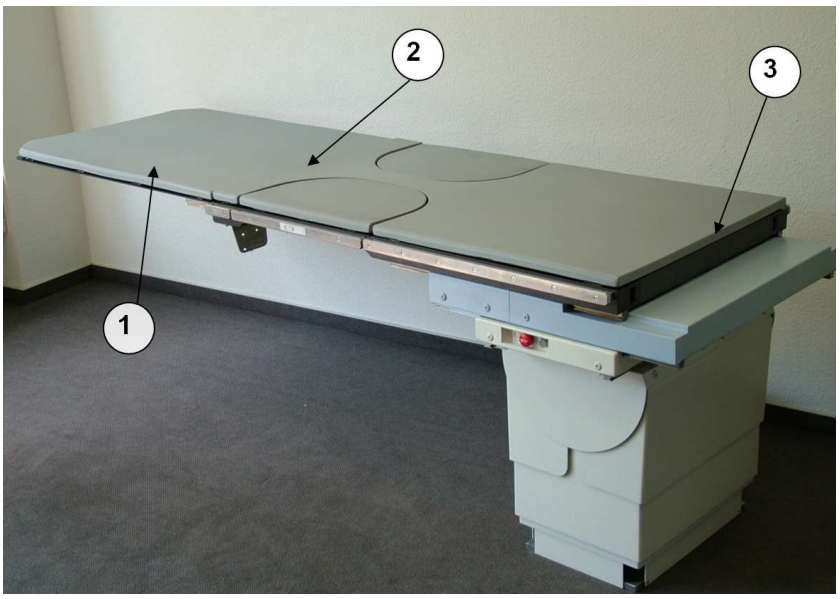


Push the tabletop insert with the 3 clips toward the middle of the patient table (see direction of arrow) until the latch snaps into the rails.

4.2.2 Use of the Extension Boards

An extension board can be attached with a length of 950mm/ 400mmand a weight of 6 kg/ 3.5kg including the patient pad, both, at the head or perineal end of the main board of the table.

⚠ It is to observe that these boards are inserted till they reach the mechanical stop. Before operating the correct locking has to be checked.
The extension board may only be loaded to a max. 80kg/m linearly decreasing at the foot end. This applies to the legs of a heavy patient of 205 kg sitting on the main board and having his legs laid down on the foot end.
Any further or different load (e.g. sitting on the extension board, …) can cause a breakage of the suspension at the main board



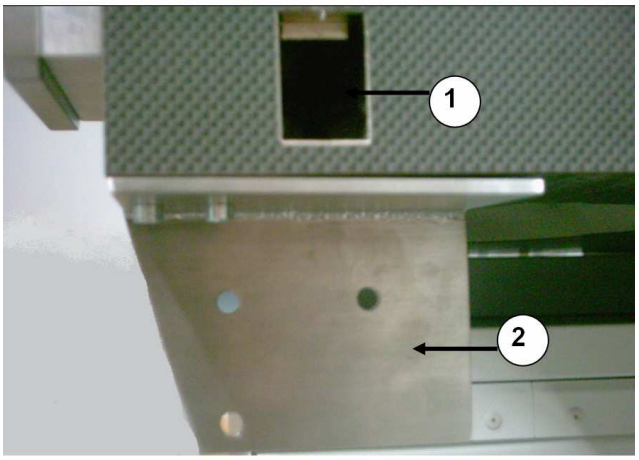
1. Extension Board
2. Perineal End
3. Head Side

Figure 4: Patient positioning table

4.2.3 Fastening of Accessories

There is a standard rail on both long sides of the table top on which the accessory parts, defined by Siemens, can be added by clamped-connexions and screwed- connexions. Furthermore there is a fastening profile at the perineal end on which the so-called usual Siemens blocks can be mounted for the arm support and the kidney dish.

⚠ Attaching the accessories may not lead to an excess of the total load compared to the safety work load (see paragraph 7).



1. Insertion slot for the leg extension
2. Fastening profile

Figure 5: Fastening profile for Siemens blocks

5 Cleaning and Disinfection

5.1 Cleaning

Prior to the examination, clean all parts which come into contact with the patient.

Equipment:

Use a damp cloth or cotton pad to clean the unit parts. For moistening, use water or a lukewarm, diluted aqueous solution consisting of water and household cleaning agent. Do not use scouring cleaning agents or organic solvents or cleaning agents such as benzine, pure alcohol, spot remover etc. Because of possible material incompatibility.

Ventilation slots:

Keep the ventilation slots of all components clear.

Dust deposits:

Dust deposited on moving parts can impair unit movements. Regulary clean the dust off all rails and joints etc.

CFK Boards:

Only special acrylic glass agents, washing-up liquid, soap sud or petroleum ether have to be used as agents. Acid agents as tri-acetone, alcohol/raw spirits and others containing these ingredients can cause fissures and can therefore break at even the slightest load.

Accessory parts:

Please note that for some accessory parts, special instructions on cleaning are given in the corresponding chapters. If no special reference is given, then the following applies generally:

- Use a lukewarm detergent solution and a soft cloth for removing slight contamination.
- Remove major contamination first with a cloth soaked in alcohol, then wipe off with clear water.
- Remove blood spots best of all with cold water.
- Remove contrast medium spots best of all with warm water.
- After using desinfectants, always wipe off with clear water.

5.2 Disinfection

To disinfect surfaces, we recommend aqueous solutions of commercially available aldehyde and/or amphotenside-based surface disinfectants such as Tensodur 103, Korsolin, Cidex. Certain substituted phenol-based or chlorine-splitting disinfectants can attack materials and are therefore not recommended. The same restrictions apply to undiluted solutions with a high alcohol content, for example, for disinfecting hands. Please also observe the instructions of use of the disinfectant.

Some substances contained in disinfectants are known to be hazardous to health. The concentration of such substances in the air must not exceed the statutorily defined limit. We recommend that you follow the manufacturers operating instructions for these products.

- Do not use any sharp-edged tools and aggressive solvents.
- Observe the instructions of the solvents or disinfectants.
- Before you clean or disinfect, assure yourself that the device is at zero-potential.
- If disinfectants or solvents are used which create explosive endangered or highly inflammable gas, it must be assured that the gas has volatilised.

6 Safety Inspections

We recommend an inspection of the ground wire resistance and the compensatory leakage current before the initial operation, after installation work and within regular intervals of one year, to assure safety during the entire life-cycle. For the procedure we refer to VDE 0751-1. In some countries of the EC these inspections are regulated by law.

- The operator of the system has to find out the country related circumstances.
- Only technical experts are allowed to carry out these measurements by using appropriate measuring instruments.

6.1 Attendance

To safe the economic life-time we recommend to lubricate the Z-spindle with grease all two years once with “BERULUB FB 38”. As well as to lubricate the slide rail with grease all two years once with „FAG Arcanol Multi3 K3N-30“.

7 Technical Data

Supply voltage	100-240V~ ±10% 50-60Hz
Max. charging rate	8.4 A (100V) 7.0 A (120V) 3,6 A (230V)
Power consumption at standstill (Standby)	0,41 KW
Max. Power consumption	850 W
Protection against insertion of liquid	Protected against „spillage“ according to paragraph 44.3 EN 60601-1
Environment requirements storage and transport	Temperature: Category 2K4, exemption Temp. -20…+60°C Mech. ecological damage: class 2M2
Environmental requirements operation	Temperature: +10…+40°C Rel. humidity: 45 %...75% Air pressure: 860 hPa...1060hPa
Protection against electric shock	Device of protection category I Application part type B
weight	approx. 280kg
dimensions	See 13. Dimensions and fixing holes
Power-on time	Intermittent operation 1min/9 min (1 min. Operation, 9 min standstill)
Max. speed longitudinal (y-direction)	20mm/s
Max. speed transversal (x-direction)	20mm/s
Max. speed vertical (z-direction)	16mm/s
Max. speed tilting	0,78°/s
Max. Lift longitudinal (y-Direction)	±250mm
Max. Lift transversal (x-Direction)	±150mm
Max. Lift vertical (z-Direction)	470mm from715mm to1185 mm
Max. tilting angle	±14°
Safety work load	225 kg (205kg patient +20kg accessories)
Repeat accuracy	±0,15mm unidirectional

Table 1: Technical Data

7.1 Functional features

- The PPT has been designed for multifunctional use. Beside the lithotripsy as a main application also urological diagnostics, end urological and minimum invasive applications as well as ESTW treatment can be performed.
- The PPT allows any lithotripsy-treatment provided by two cut-outs on both sides of the table top which are easy to install and take off.
- The PPT allows any urological treatment at the perineal end of the table while tilting the table with an isoclinic tilt.
- Trouble-free climbing of a mobile patient is as possible as a putting into another bed of an immobile patient.
- The PPT has been ergonomically designed
- The table can be moved on four different axes.
- The PPT allows a Trendelenburg-tilt at the perineal end of the table (isoclinic tilt) and also at the isocentre for the Litho-operation (isocentre tilt).
- X-rays are possible as the PPT has got 70 cm – 90cm of X-ray fluoroscopy measured from the perineal end to the head side.

8 Trouble Shooting and Malfunction

In case of trouble or malfunction inform the customer service of the entire system (see operator manual of the entire system).

9 Waste Disposal Management

The PPT consists of materials which are recyclable and can be used again. Specialized companies can recycle this product in order to gain re- usable material and to reduce the amount of disposal material
The waste disposal management should be done by a service technician.

⚠ The device cannot be disposed along with industrial waste and domestic waste. Please observe your local regulations for the waste disposal of old devices.

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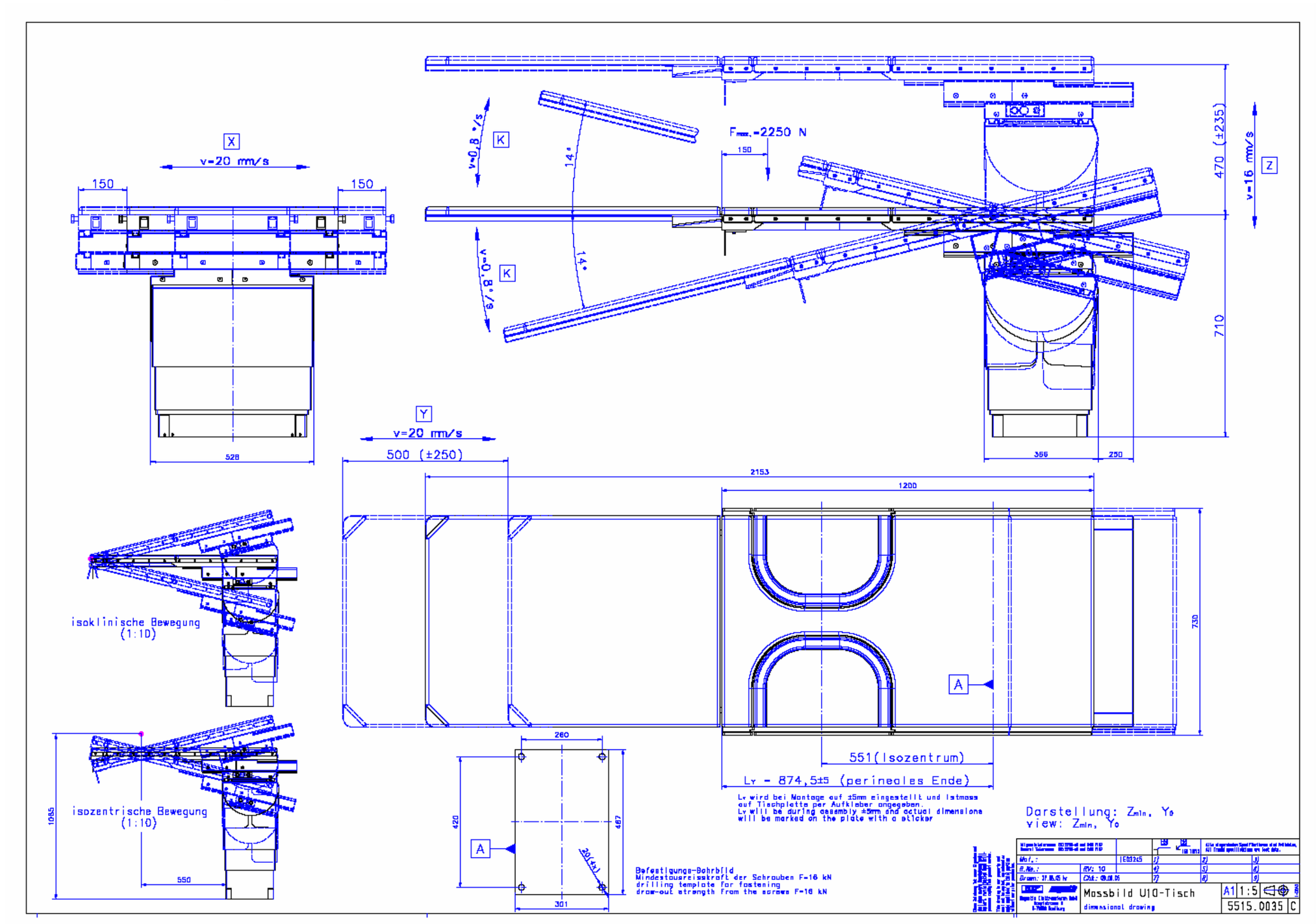
10 Annex

Annex1: Dimensions and fixing holes PPT
Annex2: CE evidence of conformity

10.1 Dimensions and fixing holes



10.2 CE evidence of conformity

CE **Declaration of conformity**
Konformitätserklärung

We declare under our sole responsibility that the following medical device of Class I
Wir erklären in alleiniger Verantwortung, dass das folgende Medizinprodukt der Klasse I

MagSys CAP02-CS0131-SIE01 — **Patientenlagerungstisch** / **Patient positioning table**

meets all applicable provisions of the directive 93/42/EEC.
allen anwendbaren Anforderungen der Richtlinie 93/42/EWG entspricht.

Applied standards Angewandte Normen	**EN 60601-1:1990 + A1:1993 + A2:1995** **IEC 60601-1:1988 +A1:1991 + A2:1995** **EN 60601-2-32:1994** **IEC 60601-2-32:1994** **EN 60601-2-36:1997** **IEC 60601-2-36:1997** **EN 60601-1-2:2001** **IEC 60601-1-2:2001** **UL 60601-1, 1st Edition, 2006-04-26** **CAN/CSA-C22.2 No. 601.1-M90, 2005**

If used in combination with other instruments or equipments, start of operation is only permitted after assuring by the user, that the relevant requirements of all applicable directives, national laws and standards are met.
Bei Verwendung in Kombination mit anderen Geräten oder Einrichtungen ist die Inbetriebnahme erst erlaubt wenn durch den Anwender festgestellt wurde, dass die relevanten Anforderungen aller zutreffenden Richtlinien, nationale Gesetze und Standards erfüllt sind.

CH-4410 Liestal 03.03.2008

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