# **User Manual**

# Not height adjustable tables

#### Dear customer,

Congratulations on purchasing a product of outstanding quality.

Use of the best materials from renowned suppliers guarantees years of trouble-free operation, provided the device is handled correctly and as intended in accordance with the conditions described in the user manual. In the unlikely event you need to make a claim, please contact us.

We welcome suggestions from the users of our products.

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Subject to changes in materials and construction as a result of technical progress.

This product is not approved for the American market. Distribution and use of the product in these markets, including through third parties, is prohibited by the manufacturer.

#### 1. Safety information

#### 1.1 Applied symbols



Safety instructions and key sections in these operating instructions are marked with the exclamation mark symbol on the left. Please pay particular attention to these instructions and sections. Other symbols possibly used on the device:

Observe instructions for use:

Risk of pinching when adjusting:

Risk of hazard zone:

# 1.2 Applied standards

This device has been designed and manufactured in accordance with national and international regulations. This ensures a very high level of equipment safety.

The models described here comply with the following regulations and directives:

□Regulation (EU) 2017/745
□ Pre standard DIN VDE V 0750-2-52-2 (VDE V 0750-2-52-2):2021-10 partly based on
□DIN EN ISO 14971
□DIN EN ISO 10993-5/-10

This device is a Class 1 medical device according to Regulation (EU) 2017/745 (MDR).

#### 1.3 Safety regulations

This section contains a summary of the most important safety information.



Correct operation of the device is essential for safe operation. Therefore, please familiarise yourself with the contents of these instructions for use before using the device. We recommend that you keep these instructions for use near the device for future reference.

The device may only be used by authorised instructed (competent) persons who are sufficiently familiar with its adjustment mechanism or have read and understood the operating manual fully. The manufacturer cannot be held responsible for damage caused by or involving unauthorised persons. No third-party devices may be installed without consultation with us or brought in the direction of movement of the table in such a way that a possible hazard potential arises.



The user must ensure that the device is not accessible to unauthorised persons or cannot be operated by unauthorised persons even when left unattended. When leaving the device, it should always be secured in such a way that unauthorised adjustment is impossible.

#### 1.4 Intended purpose

The table is used for the ideal positioning of patients for the purpose of curative and disease treatment, examination, massage and health therapy. Table operation and patient positioning on the table may only be performed by professionally trained persons who have been instructed in its use or who, through experience with other similar medical devices, have knowledge of its proper use, taking into account possible hazards. Equipped with the options of movability, side guards and push handle, the intended purpose of the table is extended and also provides for the ideal positioning of patients for the purpose of transport to pre-treatment or post-treatment locations. Patient positioning during the recovery phase after a medical procedure is also permitted under supervision. Otherwise, the device must only be moved within the room for cleaning or patient access. This device has been developed exclusively for use indoors and in normal ambient conditions

and can be used in the following areas: laboratories, medical practices, examination and treatment rooms, hospitals, clinics, physiotherapy practices, occupational therapy centres and doctors' surgeries. This table is not classed as surgical furniture and must, therefore, not be used for surgical purposes. The expected service life is 10 years.

#### 1.5 General information on setup and use

When packed, the device may be exposed to the following environmental conditions for approx. 3 months:

Transport/Storage temperature: -20° to +50°C

Operating temperature: +10° to +40°C Relative humidity: 30% to 75% Air pressure: 800hPa to 1060hPa

When transporting the device in a vehicle, it must be secured properly against moving. To do so, lock the castors (optional equipment) and ensure further safety measures.



The table must stand securely on its feet or castors on a level, flat and solid surface. Before use, activate the brakes on the castors (optional) and make sure they are working properly.

# 1.6 Assembly of folding table: Models 16; 17; 20; 21; 22; 30; 31; 32; 36; 60; 61; 70; 71; 113; 114\*

- 1) Carefully open and remove the packaging.
- 2) Place the table on the upholstery with the folded-in feet pointing upwards. Make sure beforehand that there are no objects underneath the upholstery that could damage and destroy it.
- 3) Using a size 13 spanner, unscrew the upward-facing lock nut from the frame.
- 4) Undo the nut on the side of the feet inside the frame.
- 5) Move the table foot (i.e. pair of feet connected by a cross brace) for one side of the table to a vertical position. The steel bracket of the table foot must now lie flat on the frame, the bolts must protrude from the top of the slotted holes of the foot.
- 6) Screw the lock nuts loosened under point 3) onto the bolts mentioned under point 5); the locking ring of the nut (plastic) must point upwards. Using the size 13 spanner, tighten the lock nuts and the nuts loosened at the sides.
- 7) Repeat points 5) and 6) for the second table foot.
- 8) Turn over the table over and stand it up.
- 9) Check: Have the nuts been tightened properly?

If necessary, a longitudinal brace can also be fitted. It helps to hold the two pairs of feet together when exposed to very high loads. This results in greater table stability.

Slip the u-shaped clips of the longitudinal brace over the two cross braces of the pairs of feet and align them. Use the supplied bolts to fix the clips in place.

# 1.7 Commissioning

Prior to commissioning, lock the castors or the wheel system (optional). As the operator, carry out a thorough and precise function check once the device has been set up. Prior to commissioning, clean the device and remove any contamination from transport.

# 1.8 Safety notices



This table may only be used for its intended purpose. Any other use is strictly prohibited and possibly dangerous. The manufacturer cannot be held responsible for damage caused by improper use. Patients may only be positioned in preparation for treatment/examination by professionally trained persons.

Please note: This table is not classed as surgical furniture.



When adjusting the upholstery parts, make sure that no persons or objects are in the adjustment range. Further, make sure that no persons reach under the upholstery part or lean on the underframe.



Important for the user: When adjusting the upholstery parts, do not reach under the spacers located beneath the upholstery parts.

<sup>\*</sup>For the model designation, see point 1.10



Always use both hands when adjusting the lying surface elements: Use one hand to operate the adjustment mechanism and the other hand for the lying surface adjustment.



The lying surfaces and the underframe are not anti-static as standard.

Our products are not intended for use in wet rooms and must under no circumstances be cleaned using socalled bed washers. This would irreparably destroy the product.



The head part and armrests are only intended to support the patient and must not be used for sitting.



Do not stand on the table or its parts.



If the underframe is designed with movability (optional), all the castors must always be locked before using the table.



Do not put a damaged device into operation.



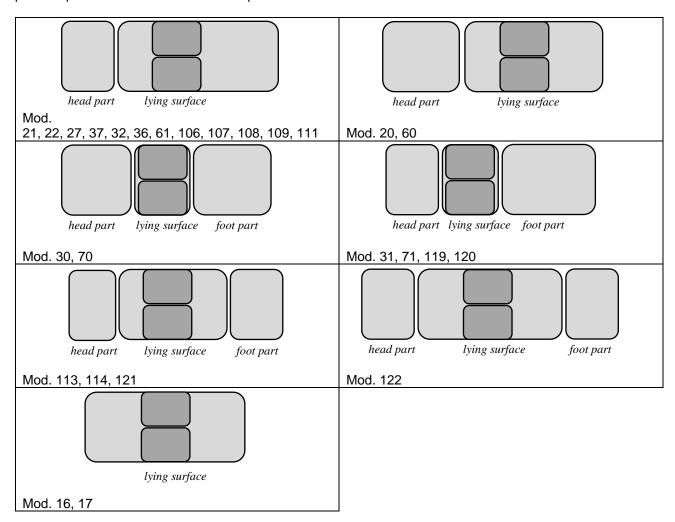
This device must not be modified without the express permission of the manufacturer.



Persons who are not familiar with the use of the table or who do not have knowledge of its proper use through experience with other similar medical devices must not be left unattended with the table.

#### 1.8 Entrance area

The following pictures show, depending on the number and adjustment of the upholstery parts, the table's entrance area. This is characterized by a dark grey surface. The entrance area represents the area in which a patient / person can sit down or stand up when used as intended.



#### 1.9 Model designation and type labelling

The exact model designation depends on the choice of frame colour:

- -00 white powder coated (RAL 9010);
- -01 chrome plated;
- -03 white aluminium powder coated (RAL 9006);
- -04 grey aluminium powder coated (RAL 9007)

The type plate is attached to the underframe on one long side of the table. It provides information about key table data.

The following symbols are listed there (by way of example), their meanings are:

Read the operating manual	SN Serial no.
Caution, potential hazard	Max. load capacity
Date of manufacture	Product may only be used in dry rooms
Address of manufacturer	CE mark

#### 1.10 Meaning of the serial number

The serial no. is located on the type plate or shown separately next to the type plate of the table. This number is unique and firmly linked to this specific individual product. It enables us to identify this table model and trace back assemblies/safety-relevant components at any time.

Please always state this serial number when enquiring about spare parts.

#### 2. Operating manual

#### 2.1 Table design

When designing the table frames, special emphasis was placed on functional and operational safety. The number of possible pinching points has thus been minimised, while remaining ones have been covered or protected with spacers to prevent injury, thus ensuring safe and yet simple operation. Nevertheless, necessary caution must always be exercised when using the table. The table consists of the frame and upholstery assemblies. Depending on the respective version, these assemblies can feature further attachment parts. The surfaces of the welded design are plastic coated or chrome plated.

# 2.2 Head part adjustment



Despite the very robust and strong design of the gas spring, the head part must not be used for sitting.

#### Head part adjustment using ratchets

Head part adjustment is enabled by two metal ratchets. Grasp the top of the head part in the centre and lift it up to the desired inclination, the ratchets engage automatically. To lower the head part, lift it up as far as it will go, the ratchets disengage. Subsequently lower the head part to the bottom end position.

#### Head part adjustment using a gas spring

The head part is adjusted using a gas spring. To operate, press the release lever, which is located at the end of the head part underneath the upholstery part, in the direction of the upholstered surface. The head part is lifted slowly to the positive end position. To lower, press down the head part and operate the release lever at the same time. Once the desired position has been reached, let go of the release lever.

#### 2.3 Adjustment of other sections

# Foot part adjustment using a gas spring

The foot part is adjusted using a gas spring. To operate, press the release lever at the end of the foot part in the direction of the upholstery. The foot part is lifted slowly to the positive end position. To lower, press down the foot part upholstery and operate the release lever at the same time. Once the desired position has been reached, let go of the release lever. The strength of the gas spring ensures ease of adjustment despite the patient's weight. Consequently, when unloaded, more force is required to adjust the foot part horizontally again.

# 2.4 Movability (model dependent or optional)

## Individually lockable castors

The castors can be locked using the foot-operated brake on the castor housings. In this case, the castors can neither be moved nor rotated. To release, operate the brake on each castor again.

Please note: Standard castors are not electrically conductive = optional equipment.

You can recognise conductive castors via the respective marking = yellow dot on the side of the running surface or a yellow ring.

With this movability option, access to the patient is improved during examination and treatment thanks to easy positioning within the room.

#### **Central movability**

By operating a lever (on the outside of the table feet), all four castors are activated simultaneously. The following moving options exist:

Stage 1: The castors of the table are locked and can neither be moved nor rotated.

<u>Stage 2:</u> = centre position: The castors are released and can be moved and rotated, the table can be moved in all directions.

<u>Stage 3:</u> Three castors are released (= can be moved and rotated). The fourth castor is locked and cannot be rotated (directionally locked castor), i.e. the wheel rolls in a fixed position and helps to steer the table in the intended direction.

**Please note:** Rotational movement is only prevented when the castor is swivelled parallel to the lying surface. This then allows the table to be moved in a straight line without pulling off to the side.

# 2.5 Further equipment

### Nose opening (optional equipment)

If a nose opening is upholstered in the head part as an optional equipment feature, the opening can be closed with a cushion (optional). To open up the nose opening, reach under the head part when the table is standing still and press the cushion out from the bottom upwards (a slight amount of pressure is required). To close it, simply insert the cushion into the opening (a slight amount of pressure is required).

# Paper roll holder (optional equipment)

The paper roll holder consists of a holding bar and, depending on the model, angle mount brackets or retaining brackets. In addition to the stainless steel bar, the paper roll holding bar consists of a spring-loaded stainless steel sleeve featuring a round steel gripping disc at the end. To insert the holding bar, feed the guide cotter pin of the stainless steel bar into the rear hole of the angle mount bracket/retaining bracket. Then push the sleeve with the gripping disc against the spring force and feed the front guide cotter pin into the second hole. Then relieve the spring tension on the sleeve. To release the paper roll holder, proceed in the same way.

# Push handles (model dependent or optional)

Depending on the actual equipment, push handles are located either at the end of the head part or the foot part, or on both sides. When moving the table, always use both hands on the push handles to push/pull the table.

# Side guard (model dependent or optional)

## Insertable side guard

To remove the side guard, undo the two black knurled screws underneath the upholstery and pull out the side guard. To insert the side guard, place the two guide pins in the locating holes and push the side guard forward up to the stop/upholstery. Tighten both knurled screws. Before using the side guard, make sure the two knurled screws are tightened properly (proceed in the same way with the second side guard, if

applicable). When not in use, the side guard can also be inserted into the mount the other way round, i.e. with the rail pointing downwards. Remember to fix the side guard in place by tightening the two knurled screws even when not in use.

Please note: Never use the side guard as a push handle. It has not been designed for this purpose.

#### Foldable side guard

<u>Folding down the side guard:</u> Grasp the side guard with one hand in the middle of the guard frame at the top (or with two hands on the left and right at the top). Then pull up the side guard evenly, thereby extracting the two guide pins from the grooves. Subsequently turn the side guard outwards slightly and hold it loosely, allowing the side guard to fold down through its own weight. Allow the side guard to fold all the way down until it engages automatically.

**Please note:** Due to the two grooves and guide pins, a small amount of force is only necessary when releasing the lock (= briefly removing the side guard guide pins from the grooves). Do not pull or push when allowing the side guard to fold down (hardly any force is required).

<u>Folding up the side guard:</u> Grasp the side guard with one hand in the middle of the guard frame at the end facing downwards (or with two hands on the left and right at the top). Push the side guard upwards and outwards slightly, thereby releasing the lock. Now hold the side guard loosely and fold it up until it engages. **Please note:** Never use the side guard as a push handle.

# Laterally lowerable side guard

Operating the side guard:

Hold the centre of the rail of the side guard with one hand and release it by moving it minimally sideways (either towards the head or foot part). At the same time, use your other hand to pull out and turn the locking pin (red knob) located in the centre of the side guard underneath the upholstery. Press down or pull up the side guard using the rail until the locking pin engages. After the locking pin has engaged, the side guard is secured in place. To check whether the side guard has engaged properly, move it sideways on the rail (either towards the head or foot part). Only limited movement should then be noticeable.



Always operate the side guard with the necessary caution. Never operate the side guard if the hands, fingers, etc. of another person are located between the bars or on the mechanism of the side guard. Risk of being crushed/pinched!!!

The laterally lowerable side guard is completely screwed in place. If the side guard becomes too loose or has excessive lateral play over time due to use, it can be readjusted by tightening the screws. The moving parts of the side guard should be re-lubricated slightly at regular intervals (spray oil, e.g. WD 40).

## Side quard, lowerable, for side rail

This side guard can be placed and fixed on any side rail using a clamp. By loosening the toggle screw of the clamp, the position and height of the inserted side guard can be shifted and adjusted respectively. Complete lowering below the upholstery level can only be achieved if the guide points in the direction of the upholstery when the side guard is inserted into the clamp.

Please note: Never use the side guard as a push handle. It has not been designed for this purpose.

#### 2.6 Special features of echocardiography tables

The table for echocardiography treatment has a cut-out on the left-hand side in the upholstered surface. It can be closed with a cushion. The cushion can be pushed out from the bottom upwards (a slight amount of pressure is required). To close the cut-out, first place the cushion in the rear of the cut-out and then press it down into the upholstered surface (a slight amount of pressure is required). The lower side of the cut-out is not parallel to the upper side. There is a visible slant. The position of the cushion in the cut-out is thus clearly identifiable and there is no risk of it being accidentally pushed out.

#### 3. Additional accessories

#### (for user-specific table configuration)

- Foldable side guard

- Laterally lowerable side guard
- Individually lockable castors, Ø 100 mm / Ø 125 mm / Ø 150 mm
- Twin castors Ø 100 mm, centrally lockable, non-conductive or conductive
- Comfort castors Ø 125 mm, centrally lockable, non-conductive or conductive
- Comfort castors Ø 150 mm, centrally lockable, conductive
- Nose opening in the head part and cushion
- Side rails
- Infusion pole for fastening clamp
- Push handles
- Head part adjustment using a gas spring
- Elastic soft upholstery
- Wall protection bumpers
- Medium soft upholstery

- Fastening clamp for side rail

- Armrest for side rail and fastening clamp

- Paper roll holder

- Push bar

- and much more

# 4. Technical data: Individual models

Models	16;17	20	21;22	27;37
Max. length (mm)	1450	1950	1950	1950
Width (mm)	650/800	650	650	650/800
Height (mm)	650	680	680	650
Head part length (mm)		750	1950	550
Overall length (mm)	1450	1950	550	1950
Overall width (mm)	650/800	650	650	650/800
Weight (approx. value in kg)	40/45	45	45	65
Head part adjustment range (ratchets)			0° to +30°	/
Head part adjustment range (gas spring)		0° to +75°	0° to +60°	-25° to+28°
Foot part adjustment range			/	/
Max. patient weight (kg)	250	250	250	250

Models	30; 30 with optional width	31; 31 with optional width	32;36	60; 60 with optional width	61; 61 with optional width
Max. length (mm)	1950	1950	1950	1950	1950
Width (mm)	650/800	650/800	800	650/800	650/800
Height (mm)	680	680	680	690	690
Overall length (mm)	1950	1950	1950	750	550
Head part length (mm)	750	550	550	2080*	2080*
Overall width (mm)	650	650	800	800/950**	750/900**
Weight (approx. value in kg)	55/60	55/60	50	65/70	65/70
Head part adjustment range (ratchets)	/	0° to +30°	0° to +30°	/	0° to +30°
Head part adjustment range (gas spring)	0° to +75°	0° to +60°	0° to +60°	0° to +75°	0° to +60°
Foot part adjustment range	0° to +30°	0° to +30°	/	/	1
Max. patient weight (kg)	250	250	250	250	250

Models	<b>70</b> ; <b>70</b> with optional width	<b>71; 71</b> with optional width	106; 108	107; 109
Max. length (mm)	1950	1950	1950	1950
Width (mm)	650/800	650/800	650	800
Height (mm)	690	690	650	650
Head part length (mm)	750	550	550	550
Overall length (mm)	750	550	1950	1950
Overall width (mm)	2080*	2080*	650	800
Weight (approx. value in kg)	70/75	70/75	60	65
Head part adjustment range (ratchets)	/	0° to +30°	0° to +30°	0° to +30°
Head part adjustment range (gas spring)	0° to +75°	0° to +60°	0° to +45°	0° to +45°
Foot part adjustment range	0° to +30°	0° to +30°	/	/
Max. patient weight (kg)	250	250	250	250

Models	116; 176	117; 177	119	120
Max. length (mm)	1950	1950	1950	1950
Width (mm)	650/800	650/800	650	650
Height (mm)	650	650	650	650
Head part length (mm)	800	800	550	550
Overall length (mm)	1950	1950	1950	1950
Overall width (mm)	650/800	650/800	650	650
Weight (approx. value in kg)	70/75	70/75	65	65
Head part adjustment range (ratchets)	0° to +30°	0° to +30°	/	0° to +30°
Head part adjustment range (gas spring)	0° to +45°	0° to +45°	-25° to +55°	0° to +45°
Foot part adjustment range	1	/	0° to +28°	0° to +28°
Max. patient weight (kg)	250	250	250	250

Models	111	113; 114	121	122
Max. length (mm)	1950	1950***	1970***	2020****
Width (mm)	650	650/800	650	650
Height (mm)	650	800	800	800
Head part length (mm)	550	550	550	550
Overall length (mm)	1950	1600***	1550***	1300****
Overall width (mm)	650	650/800	650	650
Weight (approx. value in kg)	65	45/50	60	60
Head part adjustment range (ratchets)	/	0° to +30°	0° to +30°	1
Head part adjustment range (gas spring)	-25° to +28°	0° to +60°	0° to +45°	-90° to +25°
Foot part adjustment range	/	-90° to +10°	-90° to +25°	-90° to +25°
Max. patient weight (kg)	250	250	250****	250****

Technical data subject to change

- \* incl. push handle/push handles
- \*\* incl. side guards
- \*\*\* foot part in horizontal/vertical position
- \*\*\*\* foot and head part in horizontal/vertical position
- \*\*\*\*\* foot and/or head part in vertical position

# 5. Cleaning instructions

# **Upholstery covering**

There are two different collections of upholstery covering to choose from:

- Skai Pandoria Plus (manufactured by Hornschuch/Continental in Germany)
- Skai Toronto EN (manufactured by Hornschuch/Continental in Germany)

For cleaning and disinfection, a selection of agents from various manufacturers has been tested for compatibility. Please refer to the separate enclosed sheet.

The table is equipped as standard with the **Dewert hygiene standards**, which enable optimal cleaning and disinfection:

- All undersides of the upholstery parts are coated with an upholstery covering and can thus be cleaned and disinfected
- Vent holes underneath the upholstery:
  - For the homogeneous foam to recover quickly, a rapid exchange of air is necessary. To ensure this, there are individual vent points on the underside of the upholstery, which are hygienically sealed with special air compensation caps that assume a valve function.
- Easy hygiene due to an open design
- Optional: Upholstery covering Skai Toronto EN with staynu

#### Table frame cleaning

The plastic-coated table frame and the chrome-plated bars and levers can be cleaned with mild household cleaners, if necessary.

Do not use aggressive, abrasive or corrosive agents.

Heavily soiled chrome-plated parts can be cleaned with a chrome polish (e.g. Sidol).

After cleaning, dry the frame with a soft dry cloth.

Seal deep scratches and worn areas with suitable repair agents to prevent moisture penetration.

#### Important:

At tables with gas springs, wipe the piston rod with a soft cloth at regular intervals. This prevents dust from entering through the dust lip and preserves the service life of the unit.

Do not clean the table with water jets, a high-pressure cleaner or with a so-called bed washer. Only use moist cloths.

#### 6. Maintenance and technical inspection

The device has been designed and manufactured in such a way that it will operate safely over a very long period of time if used as intended and in a correct manner. Depending on the conditions of use, place of use and care, the expected operating service life is 10 years.



**Regular maintenance procedures** and technical inspections are required to ensure patient, user and product safety. They must be carried out every two years at the latest, with frequent use even after 1 year. Both tasks can be carried out by instructed personnel.

Extensive maintenance and technical inspection, incl.:

- Thorough visual inspection of all the components
- Function check
- Checking the proper fit of the screw connections, especially the screw connection of the optional roller system
- Lubricate the swivel joints and operating levers slightly with low viscosity spray oil, if necessary.

A checklist for maintenance/technical inspection can be found in the appendix.



Despite regular maintenance/technical inspection, the **user** is also responsible for patient safety and proper and reliable functioning. As the user, make sure that the table is in good working order prior to each use (visual inspection). In the event of any abnormalities, take the table out of service immediately and inform the operator.



Replace damaged or worn components immediately and do not use the table until it has been repaired.



The table complies with the safety regulations prescribed at the time it was placed on the market. Improper repairs and structural modifications (disassembly of original parts, installation of third-party parts, etc.) may result in hazards for patients and users. In the event of uncoordinated modifications to the table, the Declaration of Conformity loses its validity and the warranty shall become null and void. We cannot be held liable for damages resulting from uncoordinated modifications. Only original Dewert spare parts may be used.

Gas springs and ratchets are wearing parts whose function may be impaired over the years depending on the frequency of use. These components can be replaced without too much effort. Please request the corresponding installation diagram, if required. Replacement parts can be obtained directly from Dewert.

# 7. Reporting obligation

All serious incidents occurring in connection with the product shall be reported to the manufacturer (**K.H. Dewert GmbH**) and to the **competent authority** of the Member State in which the user and/or the patient resides.

Member State	Competent authority	Web
Estonia	Health Board Terviseamet	https://www.terviseamet.ee/en
Finland	Fimea	https://www.fimea.fi/web/en
Iceland	Iceland Medicines Agency	https://www.ima.is/
Luxembourg	CNS	https://cns.public.lu/en
Malta	MCCAA	https://mccaa.org.mt/
Switzerland	Swissmedic	https://www.swissmedic.ch/swissmedic/de/home.html

Swiss authorised representative (CH-REP):



A serious incident is an incident that directly or indirectly had, could have had, or may have had any of the following consequences:

- death of a patient, user or other person,
- temporary or permanent serious deterioration of the state of health of a patient, user or other person,
- serious threat to public health.

#### 8. Disposal

#### Packaging

Safety notice: Pay attention to sharp edges and pointed objects during disposal!

The packaging materials produced are mainly:

- Cardboard/Paper - Plastic - Wood (when delivered on a pallet)

Please observe the local regulations for waste disposal and preferably recycle the materials. As a manufacturer, we are licensed as a participant in the Dual System in accordance with the German Packaging Act (VerpackG) and therefore bear the disposal costs, meaning you can dispose of the packaging free of charge.

#### Product

Safety notices:

- Pay attention to sharp edges and pointed objects!
- When transporting the table, only take hold of the underframe, **NOT** the upper frame.
- In order to prevent accidents later on, the no longer used product must be rendered unusable immediately.

Please observe the local regulations for waste disposal and preferably recycle the materials.

#### 9. Declaration of Conformity

# EU Declaration of Conformity for medical devices

Manufacturer: K.H. DEWERT GmbH

Vollmestr. 7 D-33649 Bielefeld

SRN: DE-MF-000005967

The product: Examination/Treatment table

**Model** 16, 17, 20, 21, 22, 30, 31, 32, 36, 60, 61, 70, 71, 113, 114, 106, 108, 107, 109, 27, 37,

**designation\*:** 111, 117, 177, 116, 176, 119, 120, 121, 122

Basic-UDI-DI: 4063907KHDewertLiegenP2

Non-active medical device

Classification: Class 1 medical device according to Annex VIII, Chapter III, rule 1 (No. 4.1) of

Regulation (EU) 2017/745.

#### Intended purpose:

The table is used for the ideal positioning of patients for the purpose of curative and disease treatment, examination, massage and health therapy. Table operation and patient positioning on the table may only be performed by professionally trained persons who have been instructed in its use or who, through experience with other similar medical devices, have knowledge of its proper use, taking into account possible hazards. Equipped with the options of movability, side guards and push handle, the intended purpose of the table is extended and also provides for the ideal positioning of patients for the purpose of transport to pre-treatment or post-treatment locations. Patient positioning during the recovery phase after a medical procedure is also permitted under supervision. Otherwise, the device must only be moved within the room for cleaning or patient access. This device has been developed exclusively for use indoors and in normal ambient conditions and can be used in the following areas: laboratories, medical practices, examination and treatment rooms, hospitals, clinics, physiotherapy practices, occupational therapy centres and doctors' surgeries. This table is not classed as surgical furniture and must, therefore, not be used for surgical purposes. The expected service life is 10 years.

complies with the relevant provisions of Regulation (EU) 2017/745, Article 19, Annex IV of 5 April 2017.

We hereby declare conformity with the aforesaid directive.

As the manufacturer, we bear sole responsibility for issuing this EU Declaration of Conformity.

Mark:

 $\epsilon$ 

Bielefeld/Germany, 01 March 2023

K.H. DEWERT GmbH

Management

<sup>\*</sup> The numerical codes -00, -01, -03, -04 appended to the individual model designation only indicate the colour of the frame (-00 = white frame, -01 = chrome-plated frame, -03= white aluminium frame, -04= grey aluminium frame).

# **Checklist for maintenance/technical inspection** to IEC 62353 and DGUV Regulation 3

Device					WEDT
Model designation				DE	WERT
Manufacturer	K.H. Dewert GmbH			D.	
Serial no.					äzisions- rohrmöbel
Location					
Responsible person					
Date, inspector					
Actuator designation		_			
Inspections		ОК	FAIL	Description of	defects
Visual inspection		•		•	
Overall impression of the table OK?					
Labels, CE mark, type plate present?	·				
Manufacturer's operating manual ava	ailable and accessible?				
Sufficient space available when carry	ying out all adjustment functions?				
Mechanical structure undamaged:					
Welds without obvious damage?					
Screw connections correct and comp	olete?				
Upholstery undamaged? Upholstery attachment correct?					
All mechanical elements intact and c	omplete?				
Electrical system and power cable ur	ndamaged?				
All switches and supply lines undama	aged?				
Function check					
With electromotive adjustment: Move all motors with the foot switch	or the hand switch to both limit positions un	til auton	natic sv	vitch-off to ensu	e that:
* the table operates smoothly withou	t any collisions or blockages				
* no cable/connection can be overstr	etched, crushed or otherwise damaged				
* the motors run without noticeable n	oise development				
* the end position switch-off of the ac	ctuators works properly				
Foot switch / hand switch / foot switch	h rails work(s) without interference				
Power cables and power plugs unda	maged?				
Correct and safe routing of the powe					
Checking the safety device: Double-Freewheeling motor: Freewheeling is	· ·				
With hydraulic height adjustment:					
Function given? Check by operating the pedals until t	he table reaches the uppermost position				

Continue to operate the pedals approx. 5-10 times (any air is pressed out of the system)

	OK	FAIL	Description of defects
Height retained?			
Hydraulic pump leaking?			
Smooth lowering possible?			
Check by operating the pedals to lower the table			
Strong noise development?			
Wipe the piston rod with a cloth			
Lying surface adjustment functions:			
Metal ratchets - arrester - gas spring			
Metal ratchet inspection: Lifting the lying surface segment:			
Do the two metal ratchets engage properly and securely?			
Do they engage evenly?			
Is this ensured in every adjustment position?			
Arrester inspection: Lifting the lying surface segment:			
Is the segment held properly and securely at every height?			
Perform the test also with a load			
Is the function smooth without clamping?			
(= move the lying surface segment without fixing the clamping lever)			
Gas spring inspection: Lifting the lying surface segment:			
Does the gas spring respond when released?			
	$\vdash$		
Is the segment held properly and securely at every height?	$\vdash$		
Is the piston rod of the gas spring free of grease and not leaking?			
Clean the piston rod with a cloth			
Accessories:			
Accessories such as belts, belt pads, belt guides, paper roll holders,			
armrests, etc. undamaged, and is proper and secure fixing/function possible?	$\vdash$		
All necessary toggle screws present?			
Possible movability:			
Castors undamaged, freewheeling given? Connection to frame undamaged?			
•			
Re-tighten all screw connections (with central locking system, also the grub screws of switch levers)			
Safe braking effect?	-		
Check with locked brakes by pulling and pushing the table			
Central Movability			
Levers must be in contact with the frame, tighten the fastening screws			
Shift levers on the subframe must be centered in the groove			
Tighten the grub screws on the shift levers			
Structural inspection:			
Checking the scissor fittings:			
Use a wrench to check the six fixing screws of the scissors (remove the black c	aps for	this puri	pose)
and the hexagon socket head screws for a very tight fit			,
Checking the side guard:			
Easy adjustment possible without clamping?			
Proper locking during setup/lowering?			
Laterally lowerable side guard:			
No adjustment possible without pulling the locking knob?			
Proper engagement in the end positions?			
Electrical testing			
Leakage current measurement (protection class II, degree of protection B)			
(max. 0.1 mA permissible) Measured va	lue:		
Due to atiliza a con divertan managarina			
Protective conductor measurement (protection class I, degree of protection B, telescopic column tables)			
<u></u>			
Final assessment			
Everything error free?			
Device put out of operation until it has been repaired?			
Comments			
Place / Date / Signature of inspector	Nevt i	nspectio	on:
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