

User Manual

Heavy-weight tables Models 208, 209 without height adjustment
Models 7209E, 7255E with height adjustment

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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K.H. DEWERT GmbH
Vollmestr. 7
33649 Bielefeld
Germany
Tel. +49 / 521 400 27-0
Fax +49 / 521 400 27-27
info@khdewert.de
www.khdewert.de

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 this user manual 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
- DIN EN IEC 60601-1
- DIN EN ISO 14971
- Pre standard DIN VDE V 0750-2-52-2 (VDE V 0750-2-52-2):2021-10 partly based on
- DIN EN IEC 62353
- DIN EN ISO 10993-5/-10
- DGUV Regulation 3


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 and 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 be secured in such a way that unauthorised adjustment is impossible.
Important: Never leave the device unattended or accessible to third parties when it is ready for operation.

Keep a sufficient safety distance to the device during all adjustment procedures. Special attention must be paid to the arms, hands, legs and feet of the user and the patient - RISK OF CRUSHING!



Make sure that there are no objects located directly around or above / underneath the device!

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 (not wheel-lifting/fixing mechanism), 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 or 100,000 drive cycles (double stroke = 1x up and down).

1.5 Information on setup and use

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

Transport and storage temperature: -20° to + 50°

Operating temperature: +10° to +40°

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.



When setting up the device, do not lift it at the head part, as this may damage the head part and/or the release mechanism.

Hold and lift the table on the left and right-hand side of the frame.

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 and make sure they are working properly.

When transporting the table, take hold of the underframe, NOT the upper frame.

1.6 Commissioning

The device is ready for use upon delivery.

Remove the power cable from the film packaging on the underframe of the table and connect it properly to a permanently installed mains socket. When routing the power cable, make sure the cable cannot be crushed, rolled over or otherwise damaged.

Lock the castors (optional) 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. Make sure that no connecting cables from the hand or foot switch to the motor are trapped in the mechanism and thus damaged.

Operation in potentially explosive atmospheres is not permitted.

Installation instructions: In order to exclude possible jamming / crushing between the device or one of its parts and an object, no objects must be located in the movement area of the device.
















1.7 Safety instructions



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.

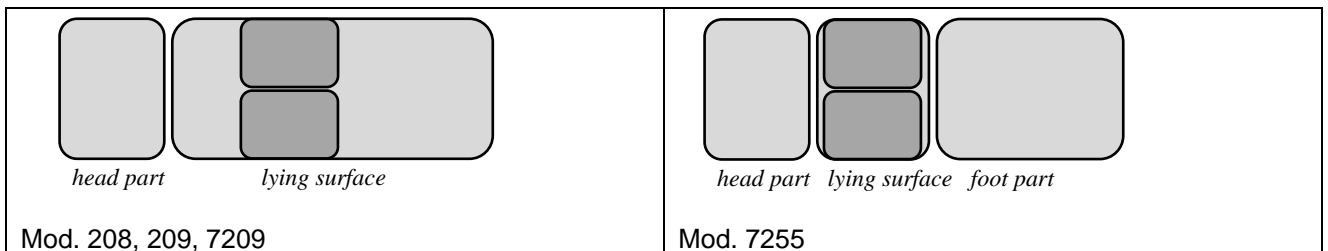
Patients may only be positioned in preparation for treatment/examination by professionally trained persons.

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

-  Prior to and when adjusting the height of the table, make sure that no persons or objects are located in the adjustment range of the table and that nobody has their hands on the underframe.
-  The following basically applies: Never reach into or under the frame of the table when adjusting the height. Height adjustment can result in injury if the user does not pay due care and attention. Therefore, take great care when performing this procedure.
-  When adjusting the upholstery parts, make sure that no persons or objects are in the adjustment range. 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.
-  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 so-called 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.
-  Disconnect the device from the mains (power supply) in the event of a fault or during maintenance work. To disconnect, be sure to grasp the plug, not the power cable.
-  This device must not be modified without the express permission of the manufacturer.
-  When transporting the table, only take hold of the underframe, **NOT** the upper frame.
-  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.
-  When the table is ready for use, it is forbidden to stay under the table or its parts.
-  Do not stand on the foot switch rail (optional).

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);
- 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	 Serial no.	 Applied part Type B
 Caution, potential hazard	 = Kg Max. load capacity	 CE mark
 Date of manufacture	 Product may only be used in dry rooms	 Do not dispose of with household waste
 Address of manufacturer	 Protective insulation, protection class II	

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 following assemblies: underframe, scissor section, upper frame or additional adjustment frame and upholstery. The surfaces of the welded design are plastic coated.

The lifting motor for height adjustment is located between the scissor section and the underframe, which guarantees very high power transmission even in the lowest adjustment range (min. height). By extending or retracting the lifting tube of the motor, the scissors are pushed apart or together, thus enabling adjustment of the lying surface. The electrical adjustment system does not pose a hazard to the health and safety of the user or the patient when used as intended. Correspondingly, the motors for the head part and the foot part adjustment are located on the upper frame and independently adjust the sections by extending or retracting. The lifting motor is activated by a low control voltage.

Due to the special stresses placed on the tables by heavy patients, these tables are specially designed for very heavy weights and feature a 4-fold safety factor.

2.2 Height adjustment

To adjust the height, the enclosed foot switch (optionally also hand switch) is operated according to the marking. Beforehand, brief activation (double tap) must take place via the foot switch (or the hand switch). Please refer to section 7. The table is lifted or lowered.



Note on operation

The electric motor is to be operated in intermittent duty mode. This means that a maximum duty cycle of 25 s must not be exceeded. Before switching the motor back on, an interruption time of at least 400 s must be observed. If the maximum duty cycle is exceeded, an internal thermal switch (protective temperature limiter) in the motor interrupts the power supply to the actuator. After the electric motor has cooled down, the thermal switch automatically reconnects the power supply to the actuator.

2.3 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 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.

Head part adjustment using an electric motor (optional or model 7255E)

The head part is adjusted using a separate electric motor. By operating (usually) a hand switch, the inclination of the head part can be varied steplessly and adjusted according to your needs.

Always observe: There must be no persons in the adjustment range of the head part.

Foot part adjustment (model 7255E)

The foot part is adjusted using an electric motor similar to the head part. By operating (usually) a hand switch, the inclination of the foot part can be varied steplessly and adjusted according to your needs.

Always observe: There must be no persons in the adjustment range of the foot part.

2.4 Movability (model dependent or optional)

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.

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

Stage 3: 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.

This castor system has been designed for the high loads caused by heavy patients.

2.5 Additional equipment

Nose opening

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 (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 (optional):

Foldable side guard

Folding down the side guard: 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). Now 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).

Folding up the side guard: 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 frame. Press down or pull up the side guard using the rail until the locking pin engages audibly. 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. Ballistol).

3. Additional accessories (for user-specific table configuration), in extracts

- Heavy-weight castors Ø 125 mm, centrally lockable
- Paper roll holder
- DIN rails
- Fastening clamp for DIN rail
- Infusion pole for fastening clamp
- Armrest for DIN rail and fastening clamp
- Push handle
- Nose opening in the head part and cushion
- Electromotive head part adjustment
- Wall protection bumpers / impact protection
- Additional foot switch
- Additional hand switch
- Foot switch fixation on the underframe

4. Technical data

4.1 Individual models

	208	209	7209E	7255E
Models				
Max. length (mm)	1950	1950	1950	1990
Width (mm)	650	800	800	800
Head part length (mm)	540	540	500	540
Weight (approx., depending on equipment) kg	60	70	110	130
Min. – max. height (mm)	/	/	540 – 890	590 – 930
Fixed height (mm)	650	650	/	/
Adjustment time, height (motor) (s)	/	/	36	36
Head part adjustment range (gas spring)	0° / +40°	0° / +40°	0° / +40°	/
Head part adjustment range (motor)	Optional	Optional	Optional	0° / +55°
Foot part adjustment range (motor)	/	/	/	0° / +30°
Max. patient weight (kg)	400	400	400	350

Technical data subject to change

The motors are equipped with a thermal protective switch as standard. This causes the motors to cut out if the duty cycle (DC: 25 s / 400 s) is exceeded. The table should be ready for use again after a 15-minute rest period. There is, therefore, no risk of overloading the motor. The engine has been specially designed for this high weight load.

The mechanics of the tables have been designed with extensive safety margins in mind. The max. patient weight is provided with a 4-fold static safety factor, i.e. the design has been fully tested for a 4-fold load.

4.2 Technical data for electric motor

Manufacturer:	Hanning Elektro-Werke GmbH & Co, D-33813 Oerlinghausen
Type of motor:	SL 95 heavy-load version (height adjustment) SL56 (head part adjustment model 7255E) SL 80 (foot part adjustment model 7255E)
Type of actuator:	Brushless asynchronous industrial motor
Mode of operation:	Electromechanical linear motor with maintenance-free lifetime lubrication Intermittent duty – installed thermal switch Electronic activation with internal supply for the control element Duty cycle (DC): 25 s / 400 s i.e. move the table for max. 25 seconds under nominal load, then observe a break of at least 400 seconds.
Nominal voltage:	220 – 240 V, 1-50/60 Hz
Nominal consumption:	Model 7209E: 900W, model 7255E: 1720W
Current consumption:	Model 7209E: 4.0A, model 7255E: 7.5A
Protection class:	II (protective insulation), connecting cable without protective conductor
Protection rating:	IP X4 – resistant to water splashes,
Degree of protection:	B

The motors are maintenance free. The maximum sound power level is 52 dB (A).

When operated with sinusoidal alternating voltage, the motors used do not cause field or line-borne interference within the meaning of EN 50081, Part 1 and 2, nor can their function be impaired by electromagnetic influences within the meaning of EN 50082, Part 1 and 2.

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.

Not oil-resistant, not antistatic!

A different upholstery covering is necessary for these requirements.

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

The plastic-coated table frame can be cleaned with mild household cleaners, if necessary. Do not use aggressive, abrasive or corrosive agents. 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 hydraulic height adjustment as well as for the 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.



Caution:

When cleaning, secure the table against unintentional lowering of the lying surface. To do so, place the head part horizontally and disconnect the power plug from the mains socket.

The power plug must not come into contact with water or cleaning agents.

The electrical components must not display any external damage through which liquid could enter. 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 or 100,000 drive cycles (double stroke = 1x up and down).



Regular maintenance procedures 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.

The maintenance procedures can be carried out by qualified personnel/instructed personnel.

The scope of maintenance includes, for example:

- Thorough visual inspection of all components, especially motor and switch with mains supply line or hydraulic system
- Check all swivel joints for completeness.
- Check 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.
- Lubricate the roller guides with a little bearing grease or similar using a brush, if necessary.

Insufficient lubrication is noticeable through noise development.
A checklist for maintenance/technical inspection can be found in the appendix.



**In addition to maintenance in accordance with the legal requirements of DGUV Regulation 3 / IEC 62353, a technical inspection must be carried out every two years at the latest on tables with electromotive adjustment.
This technical inspection may only be carried out by authorised and trained specialists.
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.



**All drive components must not be opened! Risk of electrocution!
Work on the electrical system may only be carried out by qualified and authorised personnel in compliance with all relevant provisions and safety regulations!**

Foot and hand switches for adjusting the electric motor as well as gas springs are wearing parts whose function may be impaired over the years depending on the frequency of use. Both can be replaced without too much effort. Please request the corresponding installation diagram, if required.
Replacement parts can be obtained directly from Dewert.

7. Safety devices

Tables with electromotive adjustment must have an automatic device to deactivate the control elements when moving the table. Reactivation of the control elements must be designed in such a way that they cannot be triggered accidentally by patients, users or third parties.

The actuator of this table is equipped with an integrated safety device to protect against unauthorised/unintentional operation. This device goes into "sleep mode" 3 seconds after the last operation and can only be reactivated with a defined switching sequence, the so-called double tap.

To "wake up" the actuator or the control unit, first press the desired direction of travel for approx. 1 second on the control element. After a short waiting time (1-2 seconds), press the desired direction of travel again and the actuator can be moved for a maximum of 30 seconds in this direction of travel.

If the switching cycle of the double-tap function is not observed, the actuator cannot be operated. After 30 seconds of operation in one direction of travel, the actuator switches off and goes into sleep mode. The actuator can still be operated for up to 3 seconds after the last operation to ensure fine adjustment. Within this time window, it is possible to move in each direction of travel again for a maximum of 30 seconds. The actuator always goes into "sleep mode" automatically 3 seconds after the last operation.

The lifting motor is equipped with a **safety freewheeling clutch** as standard:

When lowering, the motor declutches automatically if an obstacle is encountered, and the flow of power is interrupted. In other words, the active tractive force of the motor no longer acts; instead, simply the weight of the upper part of the table is applied. In the event of unforeseen entrapment, the risk of injury is significantly limited.

8. 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.

9. 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, e.g. by disconnecting the power cable.

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

Tables with electromotive height adjustment are subject to WEEE Directive 2012/19/EU. These old devices must be collected, recycled and disposed of in an environmentally sound manner. Use the return and collection systems available to you for this purpose.

10. Declaration of Conformity

EU Declaration of Conformity for medical devices

Manufacturer: K.H. DEWERT GmbH
Vollmestr. 7
D-33649 Bielefeld

SRN: DE-MF-000005967

Product: Heavy-weight table

Model designation*:	7209E, 7255E	208, 209
Basic-UDI-DI:	4063907KHDewertELiegenE4 Active medical device	4063907KHDewertLiegenP2 Non-active medical device
Classification:	Class 1 medical device according to Annex VIII, Chapter III, rule 1 (No. 4.1) and rule 13 (No. 6.5) of Regulation (EU) 2017/745.	Class 1 medical device according to Annex VIII, Chapter III, rule 1 (No. 4.1) of Regulation (EU) 2017/745.

* The numerical codes -00, -03, -04 appended to the individual model designation only indicate the colour of the frame (-00 = white frame, -03= white aluminium frame, -04= grey aluminium frame).

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 (not wheel-lifting/fixing mechanism), 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.

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:



Bielefeld/Germany, 01 March 2023

K.H. DEWERT GmbH

A handwritten signature in black ink, appearing to be 'R. ...', is written over a circular stamp or seal.

Management

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



Device _____
 Model designation _____
 Manufacturer K.H. Dewert GmbH _____
 Serial no. _____
 Location _____
 Responsible person _____
 Date, inspector _____
 Actuator designation _____

Inspections	OK	FAIL	Description of defects
Visual inspection			
Overall impression of the table OK?	<input type="checkbox"/>	<input type="checkbox"/>	_____
Labels, CE mark, type plate present?	<input type="checkbox"/>	<input type="checkbox"/>	_____
Manufacturer's operating manual available and accessible?	<input type="checkbox"/>	<input type="checkbox"/>	_____
Sufficient space available when carrying out all adjustment functions?	<input type="checkbox"/>	<input type="checkbox"/>	_____
Mechanical structure undamaged:	<input type="checkbox"/>	<input type="checkbox"/>	_____
Welds without obvious damage?	<input type="checkbox"/>	<input type="checkbox"/>	_____
Screw connections correct and complete?	<input type="checkbox"/>	<input type="checkbox"/>	_____
Upholstery undamaged?	<input type="checkbox"/>	<input type="checkbox"/>	_____
Upholstery attachment correct?	<input type="checkbox"/>	<input type="checkbox"/>	_____
All mechanical elements intact and complete?	<input type="checkbox"/>	<input type="checkbox"/>	_____
Electrical system and power cable undamaged?	<input type="checkbox"/>	<input type="checkbox"/>	_____
All switches and supply lines undamaged?	<input type="checkbox"/>	<input type="checkbox"/>	_____

Function check

With electromotive adjustment:

Move all motors with the foot switch or the hand switch to both limit positions until automatic switch-off to ensure that:

* the table operates smoothly without any collisions or blockages	<input type="checkbox"/>	<input type="checkbox"/>	_____
* no cable/connection can be overstretched, crushed or otherwise damaged	<input type="checkbox"/>	<input type="checkbox"/>	_____
* the motors run without noticeable noise development	<input type="checkbox"/>	<input type="checkbox"/>	_____
* the end position switch-off of the actuators works properly	<input type="checkbox"/>	<input type="checkbox"/>	_____
Foot switch / hand switch / foot switch rails work(s) without interference	<input type="checkbox"/>	<input type="checkbox"/>	_____
Power cables and power plugs undamaged?	<input type="checkbox"/>	<input type="checkbox"/>	_____
Correct and safe routing of the power cable and connection?	<input type="checkbox"/>	<input type="checkbox"/>	_____
Checking the safety device: Double-tap function given?	<input type="checkbox"/>	<input type="checkbox"/>	_____
Freewheeling motor: Freewheeling is maintenance free	<input type="checkbox"/>	<input type="checkbox"/>	_____

With hydraulic height adjustment:

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