

User Manual

**Models 2640-01XLE, 2640-01XL/H,
2645-01XLE, 2645-01XL/H,
2648-01XLE**

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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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
- DIN EN 60601-2-52 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.

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 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.

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 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.


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.
-  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.

1.8 Model designation and type labelling

The exact model designation depends on the selectable type of height adjustment:












E = electromotive;

/H = hydraulic

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	

1.9 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, - upholstery. Depending on the respective version, these assemblies can feature further attachment parts. The surfaces of the welded design are plastic coated. The height adjustment unit 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, 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. The lifting motor is activated by a low control voltage.

2.2 Height adjustment

Height adjustment (all models with electromotive 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.

Height adjustment using foot switch rails (optional)

The electric motor for height adjustment is operated by a switch rail attached to the long side of the table, which can be operated with your foot.

Press the switch rail down = the table is lifted

Lift the switch rail up = the table is lowered.

Here, too, brief activation (double tap) must take place beforehand (see section 7). Alternatively, the switch rails can also be led out to the short side of the table. This facilitates height adjustment from the short sides of the table. The lifting motor is equipped with a freewheeling clutch as standard. This ensures automatic declutching if an obstacle is encountered when lowering. 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 reduced.



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.

Height adjustment (with hydraulic height adjustment)

At tables equipped with hydraulic height adjustment, the height is adjusted by repeatedly depressing (pumping) the foot lever on one side of the table. To lower the table, the foot lever is simply lifted with your foot. If the table is only lifted slightly each time the foot lever is depressed after transport or a longer period of non-use, air bubbles have formed in the hydraulic system. To remove the air bubbles, pump the table upwards under load and perform an additional 20 - 30 strokes of the pump when the table is in the uppermost position. This will force air out of the system.

2.3 Upholstery adjustment



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

Head part adjustment

Head part adjustment is enabled by two metal ratchets. Hold the head part in the middle at the upper end and pull it up to the desired inclination, the ratchets will 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.

Middle part adjustment

Middle part adjustment is enabled by a rack-and-pinion mechanism. Lifting the middle section to the desired position reveals a support bracket which, depending on the degree of adjustment, engages into specified position notches (inter-rack space). This ensures that the middle part is held securely under load.

Please note: Before applying load, please ensure that the support bracket is engaged securely.

To lower the middle part, lift it slightly with one hand (this disengages the support bracket), press the support bracket underneath the upholstery with the other hand and lower the middle part.

Seat part adjustment

Seat part adjustment is enabled by a mechanical clamping lever. The seat part can thus be adjusted steplessly. To release, turn the lateral clamping lever while holding the seat part with your hand and move it to the desired position. Then tighten the clamping lever and fix the seat part in place.

Rectoscopy insert adjustment (models 2640-01XLE, 2640-01XL/H)

To extract the rectoscopy insert, release the two clamping levers on both sides of the table. Hold the rectoscopy insert in the middle and pull it out and upwards until the desired height has been reached. By tightening the released clamping levers with the other hand, the rectoscopy insert is fixed in place in its position. To slide in the rectoscopy insert, hold it with one hand, release the clamping levers with the other hand and slide in the rectoscopy insert downwards.

Please note: When the middle part is raised, it is not possible to slide in the rectoscopy insert.

2.4 Standard accessories

There is an extractable stainless steel tray underneath the seat part. The tray can be pulled out centrally underneath the seat part using the handle and can also be removed completely for cleaning purposes. To do so, press against the tray from below and remove it from the holder from above.

Two fastening clamps are attached to the left and right of the seat part end of the underframe. These are designed for leg holders (with a guide tube diameter of 18 mm). To do so, loosen the knurled screw, insert the leg holder, hold it at the desired height and fix the knurled screw in place. For transport, the fastening clamps can be removed and kept loose with the table. In this case, please use a hexagon socket wrench to fasten the clamps at the points provided on the frame of the foot part using the provided screws.

On the side of the seat part, two handles are firmly attached and enable the patient to hold on firmly to the table during the examination. For transport, both handles can be removed and kept loose with the table. In this case, please use a hexagon socket wrench to fasten the handles at the points provided on the side of the seat part using the provided screws. The open ends of the handles must point towards the foot end.

2.5 Inclination adjustment of the entire lying surface (model 2648-01XLE)

Inclination adjustment of the lying surface is carried out by an electric motor. By operating the hand switch, the inclination can be varied steplessly. Please also refer to section 7.

2.6 Movability

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. Transporting patients is not considered as intended use.

Central movability (optional)

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.

3. Further optional accessories

Foldable side guard

Folding down the side guard: Grasp the side guard with one hand in the middle of the guard frame (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 turn it outwards slightly, thereby releasing the lock. Subsequently hold the side guard loosely and fold it up until it engages.

Please note: Do not use the side guard as a push handle.

4. Technical data

4.1 Technical data for individual models

Models	2640XLE	2645XLE	2648XLE
Length (mm)	1980	1950	1950
Head part length (mm)	550	550	550
Back part length (mm)	930	930	930
Rectoscopy insert length (mm)	100	/	/
Seat part length (mm)	400	450	450
Width (mm)	650	650	650
Weight (approx., depending on equipment) kg	120	115	130
Min. – max. height (mm)	620 - 1060	620 - 1060	630 - 1070
Adjustment time (motor) (s)	22	22	22
Adjustment time, inclination (motor) (s)	/	/	23
Head part adjustment range	0° to +30°	0° to +30°	0° to +30°
Back part adjustment range	0° to +50°	0° to +50°	0° to +50°
Seat part adjustment range	0° to -20°	0° to -20°	0° to -20°
Electromotive inclination adjustment	/	/	0° to +15°
Max. patient weight (kg)	220	220	200

Models	2640XL/H	2645XL/H
Length (mm)	1980	1950
Head part length (mm)	550	550
Back part length (mm)	930	930
Rectoscopy insert length (mm)	100	/
Seat part length (mm)	400	450
Width (mm)	650	650
Weight (approx., depending on equipment) kg	120	115
Min. – max. height (mm)	640 - 1060	640 - 1060
Head part adjustment range	0° to +30°	0° to +30°
Back part adjustment range	0° to +50°	0° to +50°
Seat part adjustment range	0° to -20°	0° to -20°
Max. patient weight (kg)	220	220

Technical data subject to change

The motor is equipped with a thermal protective switch as standard. This causes the motor to cut out if the weight load is too extreme or the motor's duty cycle (DC: 25 s/400 s) 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 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
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: 850 W, model 2648XLE: 1700W
Current consumption: 3.7A, model 2648XLE: 5.0A
Protection class: II (protective insulation), connecting cable without protective conductor
Protection rating: IPX4 – resistant to water splashes,
Degree of protection: B

The motor is maintenance free.

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.

Model 2648-01XLE is equipped with a second electric motor. Both motors are connected to the mains by a power cable.

4.3 Technical data for hydraulic system

Manufacturer: Power-Packer Europa B.V., NL-7575 AT Oldenzaal
Type: Compact MK5 long
Mode of operation: Hydraulic cylinder with pump

The hydraulic unit is maintenance free.

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

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, set all the adjustable sections to the horizontal position.

At tables with electromotive height adjustment, disconnect the power plug from the mains socket beforehand.

At tables with hydraulic height adjustment, block the foot levers.

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. 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
- Function check
- Check all swivel joints for completeness.
- Check proper fit of the screw connections.
- 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.



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

When lowering, the motor declutches automatically if an obstacle is encountered, and automatic declutching 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.

In addition, the table can be equipped with another option:

Foot switch cover

The top of the foot switch is fitted with a protective cover. This makes unintentional or unauthorised operation more difficult.

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	Swiss medic	https://www.swissmedic.ch/swissmedic/de/home.html

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: Electromotive adjustable treatment table

Model designation:	2640-01XLE, 2645-01XLE, 2648-01XLE	2640-01XL/H, 2645-01XL/H
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.

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.

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, 02 November 2021

K.H. DEWERT GmbH

A handwritten signature in black ink, appearing to be 'A. ...' followed by a stylized flourish.

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? _____
 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
<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	<input type="checkbox"/>	

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?

<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	<input type="checkbox"/>	

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)

<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	<input type="checkbox"/>	

Gas spring inspection: Lifting the lying surface segment:

Does the gas spring respond when released?
 Is the segment held properly and securely at every height?
 Is the piston rod of the gas spring free of grease and not leaking?
 Clean the piston rod with a cloth

<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	<input type="checkbox"/>	
<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?
 All necessary toggle screws present?

<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	<input type="checkbox"/>	

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

<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	<input type="checkbox"/>	

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

<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	<input type="checkbox"/>	
<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"/>	
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Checking the side guard:

Easy adjustment possible without clamping?
 Proper locking during setup/lowering?

<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	<input type="checkbox"/>	

Laterally lowerable side guard:

No adjustment possible without pulling the locking knob?
 Proper engagement in the end positions?

<input type="checkbox"/>	<input type="checkbox"/>	
<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:

<input type="checkbox"/>	<input type="checkbox"/>	
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Protective conductor measurement
 (protection class I, degree of protection B, telescopic column tables)

Final assessment

Everything error free?
 Device put out of operation until it has been repaired?
 Comments

<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	<input type="checkbox"/>	

Place / Date / Signature of inspector

Next inspection: