



SCHUPP
PHYSIO · FITNESS · WELLNESS



EN INSTRUCTIONS FOR USE



TEDAVI

Therapy couches



140025, 140035, 140040, 140235, 140240



BASIC

Therapy Couch ELECTRIC
4027887THERAPIELIEGEe6Z

Therapy Couch HYDRAULIC
4027887THERAPIELIEGEh77



[Current Instructions For Use]





Imprint



Manufacturer



DE-MF-000010127

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Warranty / Liability



These instructions for use are obligatory before carefully and completely before putting the product into operation!

For correct use of the medical device, observe all instructions and safety notes!

The instructions for use must always be accessible to all users!

You can call up the current status of the instruction manual online:



We reserve the right to make technical changes within the scope of further development of the therapy couch without prior notice. All information is non-binding. Misprints excepted.

We accept no liability for damage and malfunctions caused by operating errors and non-compliance with these operating instructions.





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1.0 General

With the requirements and specifications of physiotherapists, this therapy couch was developed in close cooperation for the professional therapy area. Special attention was paid to the safety of the couch, the components of the integrated safety, the comfort of the couch as well as durability and service life.

The design and manufacture of the therapy couch comply with the current safety principles of the BfArM and take into account the generally accepted state of the art. The couch does not impair the safety or condition of patients or the safety and health of users or third parties.

"Made in Germany" as well as the use of the highest quality materials guarantee a long and reliable functionality of the therapy couch when used as intended.

All therapy tables from SCHUPP GmbH & Co.KG are developed in the Black Forest / Baden Württemberg and manufactured with regional suppliers. The assembly of the therapy tables takes place in our ISO certified production facility and thus guarantees a high and always consistent processing quality.

2.0 Safety regulations

2.1 Safety signs - Symbols

Safety-relevant sections, instructions or notes are highlighted by the following symbols. Please familiarize yourself with the definitions before reading the operating instructions.



DANGER

Indicates an immediate danger for users, patients and third parties, which can result in death or serious injury.



Warning

Indicates a potentially hazardous situation which may result in a low or moderate injury to the user, patient or third party or to damage to the medical device or on other objects.



Warning

Warning of danger of trapping and crushing when adjusting the therapy couch



Warning

Warning of electrical voltage



Caution

Indicates a possible danger to property which may result in property damage.



It is essential to follow the instructions for use



Additional notes, application tips, useful information





2.2 Standards applied

The therapy couch has been developed and manufactured according to the latest state of the art and in compliance with national/international guidelines. It complies with the following guidelines:

EU MDR (Medical Device Regulation) 2017/745	This product is a class I medical device according to the EU Medical Device Regulation.
DIN EN ISO 10993-1:2021-05	Biological evaluation of medical devices
DIN EN ISO 15223-1:2022-02	Medical devices - Symbols for use in providing information
DIN EN ISO 20417:2022-03	Medical devices – Requirements for the information to be provided
DIN EN 60601-1:2022-11	Medical electrical equipment: General requirements for safety including essential performance characteristics
DIN EN 62366-1:2021-08	Medical devices - Application of fitness for use to medical devices
Machinery Directive 2006/42/EC	Medical hydraulic equipment - General requirements for safety

2.3 Intended use

The therapy couch of the company Schupp GmbH & Co KG is a medical device of class 1.

EU MDR 2017/745) and is intended exclusively for professional use by medically trained personnel and instructed users for the proper positioning and support of patients during diagnostic or therapeutic measures in physiotherapy, chiropractic, osteopathic, or general medical treatments of patients in the rooms provided for this purpose.

“Electrically adjustable medical couch for positioning patients for diagnostic and/or therapeutic purposes”

The Schupp company does not give any guarantee regarding the suitability of the therapy couch for a specific therapeutic or diagnostic purpose. The therapist determines the appropriate form of application.

The therapy couch is not intended or equipped for hydrotherapy or for domestic or radiological applications. Also, the electrically operated couches must not be used in areas with flammable gases, vapours or increased humidity. In case of non-observance, this can lead to considerable damage to the couch as well as endanger the patient, user or third parties.





3.0 Safety instructions

3.1 General

For your own safety as well as the safety of the patient and third parties, familiarize yourself with the limits and dangers associated with the use of the "electrically height-adjustable therapy couch" before using it for the first time.

Observe all safety and warning instructions! Also observe the safety and warning instructions when using devices together!



These operating instructions contain important information on safe handling, operation, care and maintenance.

The instructions are an integral part of the therapy couch and must always be kept within reach for all users.

In the event of a change of ownership or location, these instructions must be handed over with the couch. Failure to comply with these instructions will result in the loss of warranty and guarantee claims!

Observe the additional regional and country-specific rules and regulations for occupational safety and accident prevention that apply to the place of use.



The operator may only use the therapy couch within its intended purpose for therapy and treatment.

The operator may only allow qualified personnel or persons instructed and authorised in work safety and accident prevention regulations to work on the therapy couch.

The operator must ensure that all users have read and understood the instructions, warnings and safety notes in these instructions and are sufficiently informed about their operation. This must be checked at regular intervals.



The operator must ensure that the therapy couch cannot be operated by unauthorised persons when unattended.

The user must ensure that children are always supervised and do not stay in the area of the therapy couch. This can lead to serious accidents.

The operator may only allow trained persons to work on the therapy couch for cleaning and care. When leaving the therapy couch, it must be secured in such a way that unauthorised adjustment is not possible. This can lead to serious accidents.

The therapy couch / pads are not sterile. Open wounds or skin irritations must not come into contact with the padding material.

When leaving the therapy couch, it must be secured in such a way that unauthorized adjustment is not possible. For absolute safety, we recommend pulling the mains plug out of the socket when the therapy couch is unattended.

When using additional devices (e.g. red light or heat emitters), the user must ensure that the therapy couch cannot be adjusted unintentionally or accidentally. Safety distances must be observed exactly.

The operator has a duty of care towards his employees. We therefore recommend safe footwear to prevent the risk of injury.





3.2 Safety instructions for delivery / unpacking



The therapy couches are 100% visually inspected and checked for electrical and mechanical function before shipment. The couch has left the factory in perfect and operational condition.

Remove the transport securing strap under the head section and in the frame!

Attention when opening the packaging! Do not use pointed or sharp objects, the padding could be directly damaged.

Check immediately after receipt of the shipment for completeness of the delivery as well as for packaging damage. In the event of damage, this must be claimed immediately from the carrier and must be noted immediately on the shipping documents.

If damage to the medical device is detected, this must be reported in writing to Schupp GmbH & Co. KG within 2 working days.

After this period, warranty claims arising from transport damage can no longer be asserted.

3.3 Safety instructions for commissioning



Warning

Treatments may only be carried out on a therapy couch that is in perfect condition in terms of safety; there is no danger from electrical energy.

The therapy couch may only be actively connected to the mains during treatment.

The voltage and frequency of the house mains supply must correspond to the specifications on the type plate. Otherwise operation is prohibited.

The couch was designed exclusively for use under normal conditions indoors.

The therapy couch should be placed on a firm and level surface with adequate free space for the user.

Observe the acclimatisation time before commissioning.

The power cable must be positioned in such a way that it does not get jammed between the moving parts of the couch - and - so that nobody can trip over it. Strong tensile loads as well as running over with the couch must be avoided.

Do not fix any cables or hoses to the frame, as they can be torn off by the couch movement.

The mains plug must be disconnected for all activities inside the couch.

When using additional devices (e.g. red light or heat emitters), safety distances must be strictly observed. Uncontrolled adjustment may result in burns to the skin or upholstery.



Caution

When moving or lifting the wheel frame of the couch, no patient may be on the couch (overloading and danger of tipping over).

Treatments are only allowed with the wheel frame retracted.

Personally keep a sufficient distance when adjusting and driving the couch.



Warning

Before or during each position adjustment of the couch, make sure that no persons or objects (children, animals, chairs, stools....) are in the moving area of the couch.

Also do not store any objects for use (e.g. covers, towels, belts, cushions....) in the area of the frame!

Never load the arm, foot and/or head section with the total weight of the patient (danger of tipping over) - a maximum load of 30kg is permitted.

Neither the therapist nor the patient may misuse the arm or headrest as a seat, knee support, or climbing aid—a maximum load of 30 kg is permitted



**Warning**

There is a risk of entrapment when adjusting the height!

Observe during each position adjustment, that no part of the patient's own or body parts or third parties between the moving parts or between the upholstered part and the frame.

The danger points are marked on the couch with marked with appropriate warning signs.



Never exceed the maximum static load capacity of:

175kg (140025) of 200kg (140035, 140235) as well as 250kg (140040, 140240)!

**Caution !**

Regular inspection of the technical condition by the operator is required.

Regular monitoring or maintenance of wear parts such as operating and adjustment elements, gas springs, hydraulic cylinders, motors and pads.

Faults must be rectified immediately, damaged components must be replaced immediately and the couch must not be used until it has been repaired.

To ensure safety, only use original accessories from Schupp. Incorrect accessories can lead to material damage to the couch or to injuries!

Repair and maintenance only by the manufacturer or personnel authorized by the manufacturer.

The couch may not be modified without the written permission of the manufacturer. Conversions and technical modifications are not permitted.

When used outside the intended purpose or when using additional devices, it is the responsibility of the operator to comply with the limit values for the safety of medical electrical systems in accordance with DIN EN 60601-1 and following.



The customary national laws / regulations must be observed when operating this therapy couch. Observe the necessary safety inspections according to MPBetreibV (Medical Devices Operator Ordinance), BetrSichV (Operational Safety Ordinance) and DGUV (German Social Accident Insurance).

4.0 Warranty / Guarantee

Schupp GmbH & Co KG guarantees you a therapy couch free of material and processing defects. The couch was thoroughly tested before shipment and 100% approved in the final production test.

The warranty period is 60 months on the couch frame, 12 months on upholstered parts, 24 months on all other components of the therapy couch, with the exception of wear parts, and begins at the time of delivery. Please be sure to keep the invoice as proof of purchase.

Parts or components of the couch that prove to be defective within these periods can be sent in for compensation after prior consultation with the service department. The product liability ends 10 years after the product has been placed on the market. The manufacturer is no longer obliged to provide replacement parts or accessories.

The General Terms and Conditions for Deliveries and Services as well as the guarantee and warranty provisions of Schupp GmbH & Co. KG [current version at: www.schupp.shop] shall apply.

The therapy couch may only be repaired or modified by the manufacturer or by a person or company authorised by the manufacturer! Otherwise the warranty claim will expire!

5.0 Disclaimer

We expressly draw your attention to the fact that no liability is accepted for personal injury and/or damage to property caused by failure to observe the instructions for use, by incorrect or negligent operation, maintenance, servicing and repair or by improper use of the therapy couch or its accessories, or by exceeding the performance limits of the couch. This also applies to the effects of foreign bodies, modifications, additions and conversions to the table which impair or could impair safety.





6.0 Function and operation

6.1 Set-up and installation

Place the therapy couch at the desired treatment location and remove the protective foil from the couch. Do not use a cutter, knife or similar pointed tools for this. The upholstery could be damaged.

The packaging is made of environmentally friendly and recyclable materials and can be disposed of properly at a collection point. Also note when setting up:

- Carry the couch only by the lower metal frame, under no circumstances use the railing / all-round switch bar, head section or arm sections as a carrying handle!
- Remove the transport securing tape under the head section and in the frame before commissioning!
- Couch can be positioned in the room via activated wheel frame! Then retract the wheels again. The couch must stand firmly on the floor for use!
- Note the width of the couch - Do not push the couch against a door frame! Upholstery can burst open!

The stability in case of small unevenness in the floor can be improved by unscrewing the level adjustment at the feet of the couch frame.



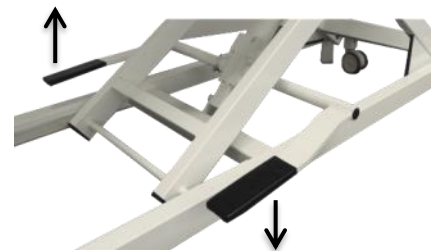
- In the case of an energetically operated therapy couch, it should be positioned near a power socket!
- Lay the mains cable in such a way that there is no danger, use cable bridges if necessary!
- Check whether the operating voltage of the therapy couch (label) corresponds to the mains voltage!

The therapy couch is immediately ready for operation after connection to the mains voltage.

6.2 Height adjustment with lifting cylinder

The height is adjusted by means of a hydraulic lifting cylinder via a foot pedal on both sides of the couch.

To **raise or lower the lying surface**, press the foot pedal down or up and then release the pedal. Repeat this until the lying surface is in the position you desire. In the upper end position, the pedal can be depressed freely. Damage to the lifting cylinder cannot occur. In the lower end position, the movement stops automatically.



Warning.



- ▶ Please inform patient beforehand and secure against slipping if necessary!
- ▶ The patient must always keep his limbs on the upholstered surfaces of the couch!
- ▶ Moving parts - Do not use the pedals of the lifting cylinder as a step or climbing aid!

▶ The adjustment of the lying surface can and may be carried out under load!
When lowering the pad (without patient) from the highest position, additional pressure can initially be applied to the pad with the hand in order to initiate the lowering process more quickly!





6.3 Height adjustment with electric motor

The height is adjusted by means of an electric motor using a hand switch, foot switch, three-point foot switch, or a railing/all-round switch bar on all sides of the bed.

In this range of tables, we have installed a motor with release coding and, from version 140035 onwards, additional collision protection and a freewheel clutch. This mechanical ratchet function is designed to prevent damage to the device and increase safety. The ratchet function prevents the drive from generating tensile forces when movement is blocked. The table is therefore only pressed down by the weight of the upholstery | upholstery frame or the patient. By eliminating the motor tensile force and adding release coding, this table series complies with the highest current safety standards.

HAND & FOOT SWITCH

The electric height adjustment is operated by double-pressing of the **hand switch** (release coding) or the **foot switch** to prevent unintentional or unauthorised adjustment.

To adjust the height, the same direction button on the handset or foot switch must be pressed twice in **quick** succession. The drive is already enabled with the second actuation.

Now the lying surface can be raised or lowered. With the buttons:

- +** Lying surface moves upwards
- , -** Lying surface moves downwards

the drive moves in the desired direction as long as the switch remains pressed. Releasing the button immediately interrupts the adjustment process.

Once the height adjustment has been completed, within **3 seconds**, before the couch switches off automatically.

If the interruption is longer than **3 seconds**, you must execute the double-pressure release again. For wiring diagram see technical data.

The times are permanently coded in the drive and cannot be changed.

The foot switch is also available in a 3-stage version with an additional stop function. Description of the different activation stages:

1. No pressure on the foot switch – NO Activation
2. Normal pressure on the foot switch to adjust the therapy table – Activation

With the buttons:

- +** Lying surface moves upwards
- , -** Lying surface moves downwards

The drive continues to move in the desired direction as long as the switch remains pressed. Releasing the button immediately interrupts the adjustment process.

3. Increased pressure on the foot switch stops the movement of the table – STOP Activation

Hand switch



Foot switch



3 Stage Foot Switch



**DANGER!**

- The therapy couch must not be operated by unauthorised persons when unattended!
Children must always be supervised and are not allowed to stay in the area of the therapy couch!
- ▶ Cleaning and care staff must always be instructed in occupational safety.

**Warning.**

- ▶ Moving parts - keep your distance when adjusting the position!
- ▶ Always detach the hand control from the frame to adjust the couch!



- ▶ When adjusting, make sure that the cable of the hand switch, foot switch cannot be crushed or otherwise damaged!
- ▶ Make sure that no one gets trapped between the arm section, head section and floor when the therapy couch is at a low height.
- ▶ Accidental, single or permanent actuation by a weight of an object or a person does not cause the frame to lower.





ALL-ROUND SWITCH BRACKET, RAILING

The electrical height adjustment is also operated by a double-pressure actuation of the rotary switch bracket or the **rail switch** (release coding) in order to prevent unintentional or unauthorised adjustment.

To adjust the height, the railing must be actuated twice in **quick** succession in the same direction. After the second actuation, the drive is released.

Now the lying surface can be raised or lowered. With

- Press down with the foot: Lying surface moves upwards
- Lift the railing with your foot - lying surface moves downwards

the drive moves in the desired direction as long as the railing switch remains pressed. Releasing the button immediately interrupts the adjustment process.

If the height adjustment is finished, a correction can be made within 3 seconds before the couch switches off automatically. If the interruption is longer than 3 seconds, you have to execute the double-press release again. For switching diagram see technical data.



The therapy couch must not be operated by unauthorised persons when unattended!
Children must always be supervised and are not allowed to stay in the area of the therapy couch!
 ► Cleaning and care staff must always be instructed in occupational safety.

DANGER!



Warning.

- Moving parts - keep your distance when adjusting the position!
- Never use the all-round switch bracket or railing as a step or climbing aid!

► Accidental, single or permanent actuation by a weight of an object or a person does not cause the frame to lower.

► Make sure that no one gets trapped between the arm section, head section and floor when the therapy couch is at a low height.



The lifting screw motor is designed for short-time operation. In case of strong and continuous overload, the motor is automatically switched off by the integrated thermal fuse to prevent further damage. After approx. 20-30 minutes the motor is ready for operation again!

When adjusting the lying surface with very heavy patients, the motor works more slowly than with light patients. This condition is due to the design and does not represent faulty operation of the adjustment drive.



- Observe the maximum dynamic load capacity of the couch of:
 175kg (140025), of 200kg (140035, 140235) as well as of 250kg (140040, 140240)!





6.4 Adjustment of the headrest upholstery (1 & 3 parts)

You can raise or lower the headrest upholstery continuously by pressing the operating lever under the headrest upholstery in the direction of the upholstery surface and simultaneously moving the headrest up and down.

After releasing the actuating lever, the gas pressure spring, which is blocked in the direction of tension and compression, holds the headrest cushion securely in its newly adjusted position.

The nose slot insert can be inserted or removed depending on the application.



Warning.

- **Moving parts - Do not press the operating lever of the head section upwards in an uncontrolled manner!**
- Neither the therapist nor the patient may sit, kneel or stand on the head section of the couch!
- The head section may be loaded with a maximum of 30kg!

6.5 Adjustment of the arm part upholstery (3 parts)

With the 3-piece headrest (optional), both armrests can be adjusted completely independently of each other.

The lowering of the armrest cushions is infinitely variable over a range of up to 18 cm.

After releasing the arm section, it locks itself in the desired position. The arm section can be additionally fixed in the individual position by means of the star grip.



In addition to the infinitely variable height adjustment, the respective arm rests can also be rotated and swivelled. This is used for individual positioning of the arms during therapy in the prone position.

The armrest upholstery can be infinitely swivelled (up to 180°) and can be brought up to the side of the couch as an upholstery extension.

In addition, the armrest pads can be infinitely rotated (360°) on the bracket to ensure optimum positioning.

The locking is done with a star knob underneath the arm part.



Warning.

- **Watch your hands when adjusting the armrest cushions!**





6.6 Adjustment of the roof / kyphosis - position

Press down the locking levers located on both sides next to the upholstery center section with one hand and hold the body section upholstery with the other hand.

The now unlocked gas pressure spring supports the adjustment process of the cushion depending on the patient's weight load. As a rule, the cushion must be pulled up slightly with the second hand.

Release the locking lever as soon as the pads are in the desired roof position. Lowering the upholstery parts is done by simultaneously pressing the locking lever down and pushing the body part upholstery down.



In the case of the electric motor version, which is also optional, the roof position is realised with a manual switch and the UP/DOWN adjustment with an all-round handle.



- ▶ Watch out for hands and objects when adjusting the body part pads!
- ▶ Position adjustment - inform patient beforehand and secure against slipping if necessary!

Warning.

6.7 Adjustment of the footrest upholstery

The adjustment of the footrest is damped by means of the gas spring in order to avoid sudden and rapid movements of the cushion.

You can raise or lower the footrest upholstery by pressing the operating lever under the footrest upholstery towards the upholstery surface and simultaneously moving the footrest upholstery up and down.

Release the operating lever as soon as the pad is in the desired position.

The gas pressure spring, which is blocked in the direction of tension and compression, holds the footrest cushion securely in the newly adjusted position.



- ▶ Watch out for hands and objects when adjusting the body part pads!
- ▶ Do not press the locking lever of the footrest upholstery upwards in an uncontrolled manner!
- ▶ Position adjustment - inform patient beforehand and secure against slipping if necessary!
- ▶ Do not load the foot section pad with the maximum patient weight!

Warning.





6.8 Adjusting the chair position

To set the couch as a chair, both the footrest and the headrest cushions must be set to the maximum deflection.

The operating lever on the side of the footrest allows you to adjust the footrest to a treatment position of your choice.

The headrest is adjusted by releasing the operating lever under the headrest cushion.



6.9 Adjustment of the Trendelenburg position

To adjust the Trendelenburg position, both the head and body section and the foot section cushion must be brought into deflection.

The headrest is adjusted by releasing the operating lever under the headrest cushion.

The locking levers located on both sides next to the upholstery centre section allow the body part upholstery to be adjusted.

The operating lever on the side of the footrest allows the footrest to be adjusted to the appropriate treatment position.



Warning.

- ▶ Do not press the operating lever of the headrest cushion upwards in an uncontrolled manner!
- ▶ Do not press down the operating lever of the body part cushion in an uncontrolled manner!
- ▶ Watch out for hands and objects when adjusting the body part pads!
- Do not press the operating lever of the footrest upholstery upwards in an uncontrolled manner!
- ▶ Position adjustment - inform patient beforehand and secure against slipping if necessary!
- ▶ Do not load the foot section pad with the maximum patient weight!



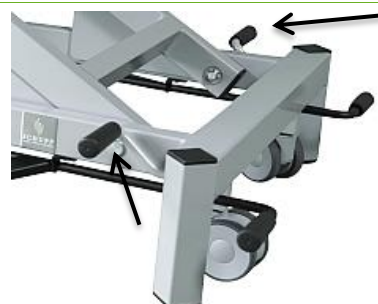


6.10 Wheel frame

For better positioning during treatment, for easier relocation in the practice or for cleaning and care, the couch can be equipped with a cushioned wheel frame.

The wheel frame must be extended on both the headboard side and the footboard side of the couch.

Operating pedals are located on both sides of the couch so that the castors can be easily extended and retracted.



"Active" - wheels extended:

Push the operating pedal of the wheel frame on the head **and** foot section side of the couch downwards with your foot as far as it will go.

The couch is lifted at the head and foot end and can now be moved in any direction with the castors.



"Inactive" - wheels retracted:

Pull up the operating pedal of the wheel frame on the head **and** foot section side of the couch with your foot.

The couch is lowered onto the feet in a cushioned manner and now stands firmly on the floor again.



Warning.

The wheel frame is designed for moving the couch without patient (overload)!

- ▶ For stability, treatments must only be carried out with the wheel frame inactive!
- ▶ Never extend or retract the wheel frame while a patient is on the couch!
- ▶ The impact caused by lowering can lead to pain and injuries in sensitive patients (e.g. with spinal disease)!
- ▶ Only operate the gearshift pedals with your feet, there is a risk of crushing if you operate them with your hands!

6.11 Paper roll holder

The therapy couch can be equipped with the option "paper roll holder".

The paper roll holder is mounted under the upholstery or on the frame on the narrow side of the foot section. The holder can accommodate paper rolls with a width of up to 59cm.





6.12 Equipment, optional assemblies

Type of couch	TEDAVI one	TEDAVI 2 200	TEDAVI 3 200	TEDAVI 4 200	TEDAVI 5 200	TEDAVI Elle 3-200	TEDAVI Elle 5-200
item no:	140025	140035	140035	140035	140035	140235	140235
Medical device	●	●	●	●	●	●	●
Integrated safety [IS], enable coding of the drive	●	●	●	●	●	●	●
Foot switch	○	○	○	○	○	○	○
Manual switch	●	●	●	●	●	●	●
All around switch bracket, railing		○	○	○	○	○	○
Height adjustment, hydraulic, operable from both sides	●	●	●	●	●	●	●
Height adjustment, electric, 8000N		○	○	○	○	○	○
Height adjustment, electric, 10000N, extra fast		○	○	○	○	○	○
wheel frame, damped release, with antistatic rollers, ball bearing guided	○	○	○	○	○	○	○
Special frame, colour		○	○	○	○	○	○
Load capacity 175kg	●						
Load capacity 200kg		●	●	●	●	●	●
Load capacity 250kg		○	○	○	○	○	○
Cushion	2	2	3	4	5	3	5
Pad width 65 cm	●	●	●	●	●	●	●
Pad width 80 cm		○	○	○	○	○	○
imitation leather, 6cm, durable composite structure	●	●	●	●	●	●	●
imitation leather, 8cm, Comfort de Luxe padding, extra soft		○	○	○	○	○	○
Head section incl. nose slot adjustable with GDF, +50° / -70°	●	●	●			●	
Head section 3 pcs. incl. nose slit adjustable with GDF, +50° / -70°, arm sections swivel-swivel adjustable up to 18cm				●	●		●
Nose slit insert	●	●	●	●	●	●	●
Headboard Pro Comfort, one-piece with 3 different inserts. Inserts		○	○	○	○	○	○
Lying surface 2 parts	●	●					
Lying surface 4 parts				●			
Lying surface 3 parts, head part, foot part adjustable with GDF, +85°.			●			●	
Lying surface 5 parts, head section, foot section adjustable with GDF, +85°.					●		
Lying surface 5 parts, head part, foot part adjustable with GDF, +85°, roof kyphosis with GDF							●
Lying surface widening due to swivelling armrest upholstery				●	●		●
Upholstery colours	3	37	37	37	37	37	37
Special upholstery, motif, embroidery		○	○	○	○	○	○
Paper roll holder	○	○	○	○	○	○	○
Lounger protective cover 600x400	○	○	○	○	○	○	○

● Standard equipment

○ optional





Type of couch	TEDAVI 2 250	TEDAVI 3 250	TEDAVI 4 250	TEDAVI 5 250	TEDAVI Elle 3-250	TEDAVI Elle 5-250
item no:	140040	140040	140040	140040	140240	140240
Medical device	●	●	●	●	●	●
Integrated safety [IS], enable coding of the drive	●	●	●	●	●	●
Foot switch	○	○	○	○	○	○
Manual switch	●	●	●	●	●	●
All around switch bracket, railing	○	○	○	○	○	○
Height adjustment, hydraulic, operable from both sides	●	●	●	●	●	●
Height adjustment, electric, 8000N	○	○	○	○	○	○
Height adjustment, electric, 10000N, extra fast	○	○	○	○	○	○
wheel frame, damped release, with antistatic rollers, ball bearing guided	○	○	○	○	○	○
Special frame, colour	○	○	○	○	○	○
Load capacity 175kg						
Load capacity 200kg						
Load capacity 250kg	●	●	●	●	●	●
Cushion	2	3	4	5	3	5
Pad width 65 cm	●	●	●	●	●	●
Pad width 80 cm	○	○	○	○	○	○
imitation leather, 6cm, durable composite structure	●	●	●	●	●	●
imitation leather, 8cm, Comfort de Luxe padding, extra soft	○	○	○	○	○	○
Head section incl. nose slot adjustable with GDF, +50° / -70°	●	●			●	
Head section 3 pcs. incl. nose slit adjustable with GDF, +50° / -70°, arm sections swivel-swivel adjustable up to 18cm			●	●		●
Nose slit insert	●	●	●	●	●	●
Headboard Pro Comfort, one-piece with 3 different inserts. Inserts	○	○	○	○	○	○
Lying surface 2 parts	●					
Lying surface 4 parts			●			
Lying surface 3 parts, head part, foot part adjustable with GDF, +85°.		●			●	
Lying surface 5 parts, head section, foot section adjustable with GDF, +85°.				●		
Lying surface 5 parts, head part, foot part adjustable with GDF, +85°, roof kyphosis with GDF						●
Lying surface widening due to swivelling armrest upholstery			●	●		●
Upholstery colours	37	37	37	37	37	37
Special upholstery, motif, embroidery	○	○	○	○	○	○
Paper roll holder	○	○	○	○	○	○
Lounger protective cover 600x400	○	○	○	○	○	○

- Standard equipment
- optional





6.13 Accessories

7.0 Liegentyp	Art-Nr:	TEDAVI one	TEDAVI 2	TEDAVI 3	TEDAVI 4	TEDAVI 5	TEDAVI elle 3	TEDAVI elle 5
Art-Nr:		140025	140035	140035	140035	140035	140235	140235
Art-Nr:			140040	140040	140040	140040	140240	140240
Handshalter Linak	443135	●	●	●	●	●	●	●
Fußschalter Boden Li.	443136	●	●	●	●	●	●	●
3 Fußschalter Boden Li.	443144	●	●	●	●	●	●	●
Netzkabel PVC Linak	443137	●	●	●	●	●	●	●
Handshalter Hanning	448582		●	●	●	●	●	●
Fußschalter + Boden H.	448583		●	●	●	●	●	●
3 Fußschalter Boden H.	448587		●	●	●	●	●	●
Netzkabel PVC Hanning	448584		●	●	●	●	●	●
Gasdruckfeder Kopfteil	402065	●	●	●	●	●	●	●
Gasdruckfeder Fußteil	448608			●		●	●	●
Gasdruckfeder Kyphose	402067							●
Schutzauflage 600x400	190999	●	●	●	●	●	●	●

● Zubehör für Liegentyp / ● Zubehör für Liegentyp mit Kollisionsschutz

8.0 Spare and wear parts

Repairs must not impair the safety of the couch. Therefore, they may only be carried out by the manufacturer or persons authorized for this purpose. Only original spare parts from the manufacturer may be used for repairs.

If you notice any defects or wear on your therapy couch, please inform us using the contact details provided (see last page). This also applies to type plates and labels.

When contacting us, always state the couch type, the article number and the serial number. This data can be found on the type plate on the frame of the foot section end of the couch (see chapter 10).

Our service staff will be happy to assist you in defining the fault and in selecting the correct spare and wear parts such as: Arm, foot, head or body pads, swivel castors, foot plugs, arm section guides as well as operating parts for the electric height adjustment.

9.0 Service life, maintenance and care

The therapy couch you have purchased is designed for an extremely long service life. The limiting factor here is the drive, which is designed for a lifetime of max. 10 years or 100000 cycles. After this time, depending on the condition of the table, the drive can be replaced by our service department, provided regular inspection and maintenance.

9.1 Maintenance

In order to ensure the safety of the patient and user and to protect the therapy couch from damage, expert use and regular maintenance in accordance with DIN 31051 are required. We recommend that you have the table serviced every 1-2 years by professionally trained Schupp employees or by authorised specialist dealers. As part of the maintenance, all prescribed safety checks are carried out in accordance with current safety regulations:



- ▶ Testing of medical technology according to DIN EN 62353 (VDE 0751-1), annually and in case of changes
- ▶ BetriebSichV (Ordinance on Industrial Safety and Health)
- ▶ MPBetreibV (Medical Devices Operator Ordinance)
- DGUV (German Social Accident Insurance); Regulation 3 (formerly BGV A3)

carried out.



- ▶ Electrical voltage - keep your distance!
- ▶ Before carrying out any maintenance work, disconnect the couches with electric motor from the power supply by removing the mains plug of the motor connection cable from the mains socket!

Warning.





9.2 Personal precautions

To maintain functionality and comfort, it is recommended to check the therapy couch regularly by visual inspection (at least 4 times per year). You can take some precautions yourself to prolong the life of the couch. These are:

Guides and joints

The therapy couch you have purchased is designed for an extremely long service life. The guides and joints are therefore low-maintenance. If the height adjustment is not used for a longer period of time or after very intensive use, the proper function should be checked regularly. If necessary, the joints can be lightly re-oiled with a fine-mechanical oil. Also visually check the screw connections, weld seams, locking pins and bolts for completeness and mechanical integrity.

Couch drive

The electric motor is maintenance-free and does not need to be oiled or greased. The piston rod of the drive should be regularly cleaned of dust with a soft cloth.

When not in use for a longer period of time, disconnect the electric motor / therapy bed from the mains supply.

Power cable

Check the power cord regularly. If it is damaged, it must be replaced immediately. Please contact the Schupp service department for this purpose.

Wheeled frame

To ensure smooth running of the wheel frame or wheels, the axles of the wheels can be lightly re-oiled with a fine mechanical oil if necessary.



- ▶ Electrical voltage - keep your distance!
- ▶ Before carrying out any maintenance work, disconnect the couch with electric motor from the power supply by removing the mains plug of the motor connection cable from the mains socket! Make sure that no water or moisture gets into the plugs or plug connections during cleaning.

Warning.



- ▶ Regular inspection/maintenance and compliance with technical tests do not relieve the user of his responsibility for the safety of the patient and the proper functioning of his treatment systems!

Heads up!



No tools are to be used during the visual inspection. In case of any abnormalities, inform the service department immediately!





9.3 Care and cleaning

The upholstery of the therapy couch must be treated very gently despite the highest leather quality. The surfaces should be cleaned or disinfected after each treatment.

In case of light soiling, clean the upholstery immediately with a soft cloth, a household sponge or a soft household brush in combination with lukewarm soapy water. The use of a commercially available microfibre cloth is particularly recommended.

For heavy soiling, soapy water can be used in concentrated form. Repeat brushing if necessary. After cleaning, wipe with clean water until there is no more cleaner on the artificial leather.

Moisture residues must be dried off with a soft cloth!

To avoid stains penetrating the material, they should be removed immediately. The use of abrasive cleaning agents (scouring agents) or solvents (nitro, acetone, etc.) will damage and after a short time lead to brittleness and discolouration of the artificial leather surface.



- ▶ The upholstery must not be cleaned with alcoholic or chemical solvents such as thinner, petrol or similar!
- ▶ Do not use chlorides, synthetic detergents, wax polishes or aerosol sprays for cleaning.

Warning.



- Always disconnect the mains plug before cleaning!
- ▶ Electrical voltage - never clean the therapy couch with water jets!

Warning.



Cleaning and disinfection of the couch, including the upholstery, may only be carried out with a suitable and approved disinfectant cleaner.



Discoloration - The manufacturer is not responsible for material discoloration of the synthetic leather due to contact with denim or other textiles.

9.4 Surface disinfection

The cleaning and disinfection of the couch, including the upholstery, may only be carried out with suitable disinfectant cleaners (observe application concentration!).

The currently released disinfectants / disinfectant cleaners vary depending on the manufacturer and leather type. Our sales and/or service staff can provide you with the latest release documents if required. You can also call up the current status online:



[SKAI – Evida, Palma, Plata, Pandoria, Tundra]

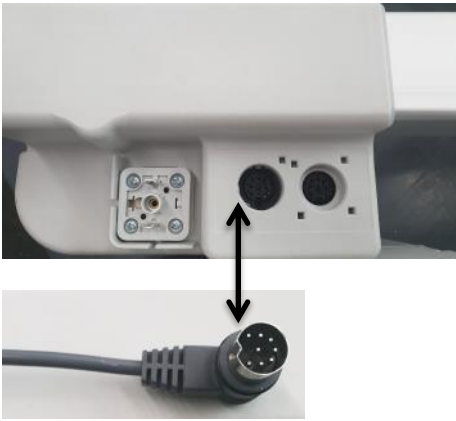
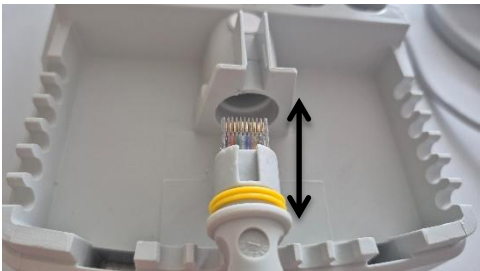


[AKV – Amalfi, Peri, Sileather]





10.0 Assistance in case of malfunctions

Symptoms	Possible causes	Measures
Cushions cannot be aligned mechanically	If the couch has not been used for a longer period of time, the supporting gas pressure springs can become stiff. Gas strut defective.	In this case, the lever of the gas pressure spring must be pulled completely upwards. With the other hand, move the lying surface completely up and down several times. Exchange gas strut
No function of the couch drive	Motor is not connected to the power supply Fuse is defective Cables are damaged	Check that the couch is properly connected to a 230V socket and that this socket is live. Check the fuse in the house distribution box. Check the power cable for damage. Check supply line of hand or foot switch for damage. Check whether the connecting cables of the switching elements are correctly plugged into the motor.
	Engine noise	Contact the Schupp service department (see last page).
No or limited function Hand or foot switch	Wear Pollution Switching elements defective	Exchange hand / foot switch Disconnect the plug of the hand or foot switch from the motor. Plug the plug of the new switching element back onto the Motor connection: 
	Switching elements defective	





Symptoms	Possible causes	Measures
No function of the hydraulic drive	Hydraulic drive defective Couch in lowest position	Check if the couch can still be pumped up properly or if it keeps collapsing. Attention ! Danger of slipping ! Please watch out for leaking oil! Contact the service department of Schupp (see last page)
No function of the electric drive	Activated motor protection due to overheating	If the motor is operated for too long without interruption (> 1 minute), the internal protective device can switch off the drive when the couch is under maximum load. Wait until the drive has cooled down again.
Problem cannot be fixed	Unknown	Contact the Schupp service department (see last page). Make sure you pay attention to the following features of your therapy couch: Type, part number Serial number You will find this data on the type plate on the frame of the foot section end of the couch.

11.0 Product Label

Applied Symbols:



MD	Medical device
REF	Part number
SN	Type no. - Date of manufacture -Serial number
SRN	Single Registration Number
UDI	Unique Device Identification
	Manufacturer, address
	Attention ! Warnings present
	Read operating instructions carefully, observe warnings
	Product for internal use only
CE	CE Conformity Marking
	Product must not be disposed of with household waste
	Product compliant according to ROHS II Directive 2011/65/EU





12.0 Disposal

Do not dispose of this device with normal household waste !

In order to ensure environmentally friendly disposal of the therapy bed, optional assemblies and spare parts at the end of their service life or after decommissioning, please contact the Schupp service department. We will be happy to help you with the disposal of your therapy bed.

If you are disposing of the couch yourself, the following information is important for you:

- Couch frame , is made of lacquered steel
- Upholstery parts, consist of a wooden board (MDF), composite foam, PU foam, imitation leather covering
- Drive, consists of electric motor, hydraulic cylinder, gas springs

The resulting waste must be recycled or disposed of in a manner that is safe for people and the environment^(*). Please inform yourself in principle about the regulations applicable in your country or also about the local regulations for the disposal of old devices and accessories.

^(*) Watch out for physical hazards such as sharp edges during disassembly / disposal.

13.0 Technical data

Medical Devices classification	EU MDR	Class 1 medical device
Dimension lying surface	Length	195 cm
	L..Head section upholstery	45 cm
	L..Body section upholstery	149 cm
	L..Middle section upholstery	51 cm
	L..Footrest cushion	97 cm
	Wide	65 , 70 , 80cm
	Reference	Faux leather
	Base plate	Wood fibre board P2 - 19 mm E1 [EN13986:2004, A1:2015]
	Upholstery: Standard	6 cm cushion thickness foam composite, padded edges
	Upholstery: Comfort de luxe	8 cm cushion thickness foam composite, padded edges
The 2 part lying surface includes	Body section upholstery	1 part
	Head section upholstery	1 part Nose slot opening and cover Manually adjustable with gas pressure spring
	Adjustment range	+50° to -70°
The 3 part lying surface includes	Body section upholstery	2 parts
	Adjustment range	+0° to +85° Manually adjustable with gas pressure spring
	Head section upholstery	1 part Nose slit opening and cover
	Adjustment range	+50° to -70° Manually adjustable with gas pressure spring
The 4-piece reclining surface includes	Armrest upholstery	Armrests are independently adjustable up to 18 cm, rotate 360° and swivel up to 180°. Soft locking by means of star handles.
	Body section upholstery	1 part
	Head section upholstery	3 parts Nose slit opening and cover Manually adjustable with gas pressure spring
	Adjustment range	+50° to -70°





The 5-piece reclining surface includes	Armrest upholstery	Armrests are independently adjustable up to 18 cm, rotate 360° and swivel up to 180°. Soft locking by means of star handles.
	Body section upholstery	2 parts
	Adjustment range	+0° to +85° Manually adjustable with gas pressure spring
	Head section upholstery	3 parts Nose slit opening and cover Manually adjustable with gas pressure spring
	Adjustment range	+50° to -70°
The 5-piece couch surface with roof position includes	Armrest upholstery	Armrests are independently adjustable up to 18 cm, rotate 360° and swivel up to 180°. Soft locking by means of star handles.
	Body section upholstery	2 parts
	Adjustment range 1	+0° to +85° Manually adjustable with gas pressure spring
	Adjustment range 2	+0° to +40° Adjustable by motor or manually with gas pressure spring
	Head section upholstery	3 parts Nose slit opening and cover Manually adjustable with gas pressure spring
	Adjustment range	+50° to -70°
Adjustment range Lying surface	Height	140025 - TEDAVIone 39 cm - 89 cm + selected cushion thickness (45 cm – 95 cm Standard) 140035/140040 - TEDAVI 46 cm - 89 cm + selected cushion thickness (52 cm – 95 cm Standard) 140235/140240 - TEDAVielle 49 cm - 89 cm + selected cushion thickness (55 cm – 95 cm Standard) optionally with lifting cylinder or electric motor
Load capacity (load evenly distributed over the entire lying surface)	Static load	Lifting cylinder / electric motor: Max. 175kg (140025) Max. 200kg (140035, 140235) Max. 250kg (140040, 140240)
	Lifting capacity	Lifting cylinder / electric motor: Max. 175kg (140025) Max. 200kg (140035, 140235) Max. 250kg (140040, 140240)
Weight	2-part	65 kg (without optional equipment)
	3-piece	67 kg (without optional equipment)
	4-piece	67 kg (without optional equipment)
	5-piece	69 kg (without optional equipment)
Wheels-Frame	Ground clearance	8-10mm
	Load capacity / roll	Single swivel castors on head and foot section side 90kg
Accessibility		YES, but not in version with railing; Recommendation SST and SSU Tripod





Motor drive Actuator	Voltage	230V, 50 Hz
	Power	1,5 A
	Duty cycle	Short-term operation
	Operating time	25 seconds operation / 400 seconds pause
	Service life max.	100 000 cycles (↑↓) or 10 years
	Protection class	Protective insulation class II
	Protection class	Degree of protection IPx4
	Low voltage	EN60034-1:2010+AC2010 EN60034-5:2001+AC2007
	EMC / ESD	EN 61000-6-3:2007 + AC2012 + A1:2011 EN 61000-6-4:2007 + A1:2011 EN 61000-6-1:2007 EN 61000-6-2:2005 + AC2015 EN55014 / CISPR 14
	Security tested according to:	EN 60601-1:2006 + AC2010 + A1:2013 EN 60601-1-2:2007 + AC2010
Noise Emission		50 dB (A), DIN EN ISO 3746:2011-03
Application climate	Temperature	+5 to +40 °C
	Humidity	20 % to 90 % RH (at 30 °C)
Transport climate	Temperature	-10 °C to +50 °C
	Humidity	20 % to 90 % RH (at 30 °C)



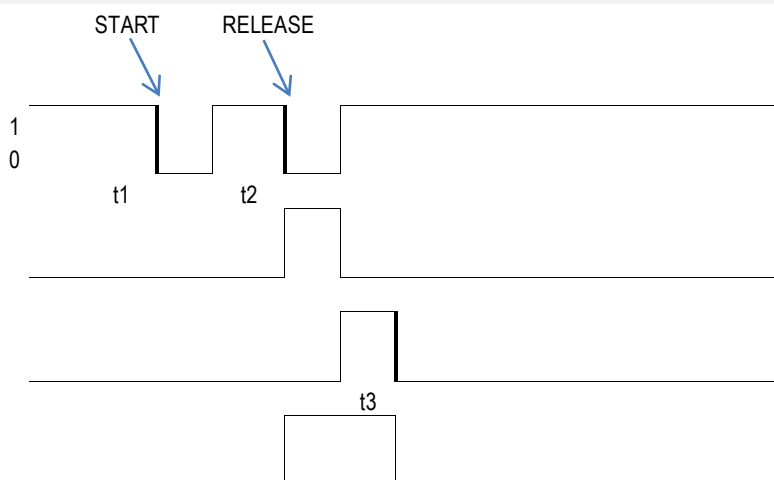


13.1 Switching diagrams - Enable coding

Share

with double
Click

Switching element
Manual pushbutton
Foot switch
Railing



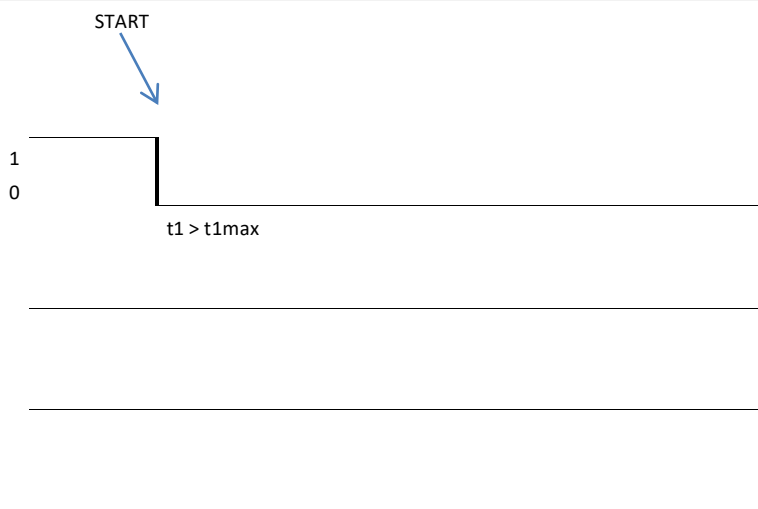
Timing diagram

Time	min (s)	max (s)	Explanation:
t1	0,3	1,5	t1 = Switch-on time at first pressure Switching unit
t2	0,3	2	t2 = Waiting time until second pressure switching unit
t3		3	Waiting time until the enable is switched off

If the maximum times are exceeded or t1 and t2 are not reached, the release procedure at **START** starts again.

no release with single Click

Switching element
Manual pushbutton
Foot switch
Railing



14.0 Declaration of Conformity



**EU-Konformitätserklärung**

EC-Declaration of Conformity
CE-Déclaration de conformité
CE-Dichiarazione di conformità

THIS DECLARATION OF CONFORMITY IS ISSUED UNDER THE SOLE RESPONSIBILITY OF THE MANUFACTURER

**Name, Hersteller**

Name, manufacturer | nom, producteur | nome, produttore

SRN | Single Registration Number

Adresse

Address | adresse | indirizzo

Wir erklären in alleiniger Verantwortung, dass das Medizinprodukt

We declare under our sole responsibility that the medical device
Nous déclarons sous notre seule responsabilité que le dispositif médical
Dichiariamo sotto la nostra esclusiva responsabilità che il dispositivo medico

Typ, Modell

type, model | type, modèle | tipo, modello

Basic-UDI | Unique Device Identification

Zweckbestimmung

intended purpose
usage prévu
destinazione d'uso

die grundlegenden Sicherheits- und Leistungsanforderungen erfüllt.

Meets the essential safety- and performance requirements
Répond aux exigences essentielles de sécurité et de performance
Soddisfa i requisiti essenziali di sicurezza e prestazione

Schupp GmbH und Co. KG

DE-MF-000010127

D - 72280 Dornstetten | Glattalstrasse 78
Germany | Allemagne | Germania

Therapieliege, elektrisch höhenverstellbar

Therapy couch, Treatment table, electric height adjustable
Table de physiothérapie, électrique de traction
Letini per terapia, elettrico regolabile in altezza

Achat, Bolani, Opal, Opal Plus, Phoenix, Rubin, Tedavi, Topas, Trendino

4027887THERAPIELIEGEe6Z

Elektrisch justierbare medizinische Liege zur Positionierung des Patienten im Rahmen von Diagnosen und/oder zu Therapiezwecke
Electrically adjustable medical couch for positioning patients for diagnostic and/or therapeutic purposes
Table médicale réglable électriquement pour le positionnement du patient dans le cadre de diagnostics et/ou à des fins thérapeutiques
Letino medico regolabile elettricamente per il posizionamento del paziente nell'ambito di diagnosi e/o a fini terapeutici

EU-MDR 2017/745 [Anhang 1]

EU-MDR 2017/745 [annex 1] | [annexe 1] | [appendice 1]

Konformitätsbewertung | Assessment details | Evaluation de la conformité | Valutazione della conformità**Konformitätsbewertungsverfahren**

Conformity assessment procedure
Procédure d'évaluation de la conformité
Procedura di valutazione della conformità

Klasse | class | classe | classe

Klassifizierung nach Anhang VIII

Classification according to annex VIII
Classification selon l'annexe VIII
Classificazione secondo l'allegato VIII

Gültig bis

Valid until | Valable jusqu'à | Valido fino a

Technische Dokumentation

Technical documentation | Documentation technique | Documentazione tecnica

Post Market Surveillance System

Post market surveillance | Surveillance post-marché | Sorveglianza post mercato

wurden erstellt und sind implementiert.
have been created and are implemented.
ont été créés et sont mis en œuvre.
sono stati creati e sono implementati.

EU-MDR 2017/745 [Artikel 52 Absatz 7, Artikel 19]

EU-MDR 2017/745 [article, article, articolo 52, paragraph, paragraphe, paragrafo 7] | [article, article, articolo 19]

Klasse 1 | Class 1 | Classe 1 | Classe 1

Regel 13

Rule 13 | Terme de règle 13 | Regola 13

26.05.2028

EU-MDR 2017/745 [Anhang II und III]**EU-MDR 2017/745 [Artikel 83-85]**

EU-MDR 2017/745 [annex, annexe, appendice II + III]

EU-MDR 2017/745 [article, article, articolo 83-85]

Erstellt: 20250917 | SCHUPP GmbH & Co. KG | D - 72280 Dornstetten | Glattalstrasse 78

Karin Schupp

Geschäftsführerin | Managing Director | Présidente Directrice Générale | Direttore Generale

20250917-06 | SCHUPP GmbH & Co. KG | D - 72280 Dornstetten | Glattalstrasse 78 | T: +49 (0) 7443/243-0 | info@schupp-gmbh.de | www.schupp.shop



**EU-Konformitätserklärung***EC-Declaration of Conformity**CE-Déclaration de conformité**CE-Dichiarazione di conformità*

THIS DECLARATION OF CONFORMITY IS ISSUED UNDER THE SOLE RESPONSIBILITY OF THE MANUFACTURER



Typ, Modell type, model type, modèle tipo, modello	Artikel-Nummer Item number numéro d'article numero articolo	UDI-DI Unique Device Identification - DI
ACHAT	131035	(01) 04027887000097 
BOLANI	138635	(01) 04027887000172 
OPAL	OPAL 139435	(01) 04027887000011 
	OPALplus 136435	(01) 04027887000028 
PHOENIX	PHOENIX [2] 139935	(01) 04027887000127 
	PHOENIX [4] 139335	(01) 04027887000134 
	PHOENIX [5] 139135	(01) 04027887000141 
RUBIN	131435	(01) 04027887000110 
TEDAVI	TEDAVI [200] 140035	(01) 04027887016104 
	TEDAVI [250] 140040	(01) 04027887000059 



**EU-Konformitätserklärung***EC-Declaration of Conformity**CE-Déclaration de conformité**CE-Dichiarazione di conformità*

THIS DECLARATION OF CONFORMITY IS ISSUED UNDER THE SOLE RESPONSIBILITY OF THE MANUFACTURER

TEDAVI	TEDAVielle [200]	140235	(01) 04027887016126	
	TEDAVielle [250]	140240	(01) 04027887000073	
	TEDAVlone	140025	(01) 04027887000035	
	TEDAVivojta	140345	(01) 04027887000189	
TOPAS		131235	(01) 04027887000103	
TRENDINO		139235	(01) 04027887000158	



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intended purpose
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DE-MF-000010127

D - 72280 Dornstetten | Glattalstrasse 78
Germany | Allemagne | Germania

Therapieliege, hydraulisch höhenverstellbar

Therapy couch, Treatment table, hydraulically height adjustable
Table de physiothérapie, hydrauliques de traction
Lettini per terapia, idraulico regolabile in altezza

Achat, Bolani, Opal, Opal Plus, Rubin, Tedavi, Topas

4027887THERAPIELIEGEh77

Hydraulisch justierbare medizinische Liege zur Positionierung des Patienten im Rahmen von Diagnosen und/oder zu Therapiezwecke
Hydraulically adjustable medical bed for positioning patients for diagnostic and/or therapeutic purposes
Table médicale à réglage hydraulique pour le positionnement du patient dans le cadre de diagnostics et/ou à des fins thérapeutiques
Lettino medico regolabile idraulicamente per il posizionamento del paziente nell'ambito di diagnosi e/o a fini terapeutici

die grundlegenden Sicherheits- und Leistungsanforderungen erfüllt.

Meets the essential safety- and performance requirements
Répond aux exigences essentielles de sécurité et de performance
Soddisfa i requisiti essenziali di sicurezza e prestazione

EU-MDR 2017/745 [Anhang 1]

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Post Market Surveillance System

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wurden erstellt und sind implementiert.
have been created and are implemented.
ont été créés et sont mis en œuvre.
sono stati creati e sono implementati.

EU-MDR 2017/745 [Artikel 52 Absatz 7, Artikel 19]

EU-MDR 2017/745 [article, article, articolo 52, paragraph, paragraphe, paragrafo 7] | [article, article, articolo 19]

Klasse 1 | Class 1 | Classe 1 | Classe 1

Regel 1

Rule 1 | Terme de règle 1 | Regola 1

26.05.2028

EU-MDR 2017/745 [Anhang II und III]**EU-MDR 2017/745 [Artikel 83-85]**

EU-MDR 2017/745 [annex, annexe, appendice II + III]
EU-MDR 2017/745 [article, article, articolo 83-85]

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