

## Mobile-Series

EN	<b>General Safety Instructions and Warnings</b>
DE	Allgemeine Sicherheits- und Warnhinweise
FR	Consignes de sécurité et mises en garde générales
IT	Istruzioni e avvertenze generali di sicurezza
ES	Indicaciones generales de seguridad y advertencias
PT	Instruções gerais de segurança e advertências
HU	Opće sigurnosne upute i upozorenja
NL	Algemene veiligheidsaanwijzingen en waarschuwingen
NO	Generelle sikkerhets- og advarselmerknader
DK	Generelle sikkerheds- og advarseloplysninger
SE	Allmänna säkerhetsanvisningar och varningar
FI	telineen yleiset turvallisuus- ja varoitushjeet



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## 1. General

Thank you for choosing a product in the UDAPTION®-series.

Please read these safety instructions and warnings before using the product.

Correct use requires you to note the further information in the 'Installation and operation' instructions and the cleaning instructions. Please also note any instructions that might be placed on the products themselves.

If the product is passed on, all the documents stated here must be passed on with the product so that the subsequent user has all the necessary information.

The Udaption® series are accessories to medical aids in the field of supported communication (SC) information gathering (IT) and environmental control (ECU).

### Symbols used

#### Safety Instructions and Warnings



Warning of considerable risk of injury to the user, the adapted aid or the Udaption® series product itself if these instructions are disregarded.



Warning of considerable risk of injury to the user if these instructions are disregarded.



Warning of possible damage or malfunction of the product if these instructions are disregarded.



Reference to the invalidation of the warranty if the prohibition is disregarded.



Note that the user needs to pay particular attention here.



Instruction for correct handling or setting



Reference to handling or settings that are within the accepted range.



Reference to incorrect/impermissible setting or handling.



Close / tighten



Open / loosen



Half open or close / half tighten or loosen.



Reference to accessories/attachments with separate operating instructions.

**Labelling** on instructions, packaging, products and accessories.



UKCA is the product mark that confirms that the product may be marketed in England, Scotland and Wales as it meets the requirements in effect there.



The CE mark is an indication that a product has been tested by the manufacturer and that it meets all EU-wide safety, health protection and environmental protection requirements.



Follow operating instructions!



Item number



Serial number



Batch Identifier



Medical device



Unique Device Identification



Choking hazard (user exclusion / accessibility warnings)



Protect against moisture



Do not re-use



Manufacturer



Date of manufacture

### **Purpose / Intended use**

**Intended use / Application** The models in the Udaption® “Mobile Series” (Mobile L, Mobile M, Mobile S, Mobile Friction, and Headswitch) are mounting systems with stepless positioning options for attaching medical devices from the fields of AAC (augmentative and alternative communication), environmental control systems, IT (information technology), and control elements for electric wheelchairs to mobility aids. The medical devices mentioned above are used when the usual means of operation are not available to users due to a disability (compensation for the disability). Only with the mounts of the Udaption Mobile Series can these medical devices be used on mobility aids, thus enabling the medical devices to be used by the intended user group. The Mobile series consists of coupling points (adaptation interface for the Udaption® frame connection, which is attached to the mobility aid), tubes, joints, swivel devices, and adaptation points for the medical devices/aids to be carried (PIN adapters, trapezoidal adapters, or ¼-inch mounts). It is a modular system that can be freely configured (in terms of tube lengths) within the model-specific specifications provided by Insors GmbH. The trapezoidal and pin adapters are quick-release fasteners that allow the aids to be quickly attached and detached. The counterpart (the pin, trapezoid or ¼ inch mount) is semi-permanently connected to the aid. The combination of the continuously adjustable joints and the various tube lengths allows the aid to be adapted optimally to the user's operating position and operating movements. The optimally aligned aid is operated by the user from the body position specified for the mobility aid. A swivel mechanism allows adapted aids to be swiveled out of the way by 90° (e.g., to exit the mobility aid) or 270° (to “park” the aid on the side of the mobility aid). The technical specifications can be found in the respective “Assembly and Operation” instructions. The Udaption® “Mobile Series” is an accessory for non-active medical devices in Group I and is neither life-sustaining nor life-supporting.

**Places of use:** Corresponding environmental conditions of the connected mobility aids. For interior and exterior use.

For further technical data and information, please refer to the 'Installation and operation' instructions and the instructions for cleaning and disinfecting the Udaption® series.

**Indications:** Persons who rely on mobility aids and adaptive technologies to communicate (SC), access information technology (IT) or control their environment (ECU).

**Contra-indications:** None

**Patient target group:** People with significant motor impairments, also linked with communication impairments due to illnesses and disabilities (whether acquired, hereditary or degenerative).

These include:

Infantile cerebral palsy -neuromuscular diseases such as ALS, muscular dystrophy, MS, - Damage to the spinal cord with tetraplegic character, multiple amputation, - Acquired brain damage due to strokes, TBI or inflammatory processes, - Rett syndrome, Angelman syndrome or other severe multiple disabilities

**Intended users:**

- **Set-up and commissioning:** Qualified specialist dealers or other suppliers with the appropriate expertise.
- **Operation:** Assistants, carers, family members, therapists and other people working with patients and who are familiar with how to use the Udaption® 'Mobile series'.  
Where there are indications with suitably pronounced motor skills, operation, or at least partial operation, by the user him- or herself may be possible.

**Scope of delivery**

Check the scope of delivery against the information in the 'Installation and operation' instructions for the respective product. Additional supplementary products may be required in order to utilise the product to its full extent. If these are not available or incomplete, please contact your supplier.

## 2. Safety

The products in the Insors® GmbH Udaption® series comply with all specifications and standards for medical devices. However, to ensure safe installation, operation and reuse of the Udaption® series, the following safety instructions and warnings must be observed:

### General Safety Instructions and Warnings



**Using unauthorised accessories** or making unauthorised modifications to the product may result in danger and/or injury to persons and damage to property. Therefore, **only** use **accessories** that are approved **by Insors® GmbH** for combination with the respective product or that have standardised connection options. Only make **changes** to the product **in accordance with** the associated **installation and operating instructions** or if the **changes** have been **authorised in writing** by Insors® GmbH.



Ensure **correct installation** in accordance with the installation instructions. Incorrect assembly can impair the stability and function of the product and can also cause damage to the adapted aid or even lead to physical injury.



**Small parts** and packaging material included in the scope of delivery must be kept **out of the reach of children**. There is a choking hazard.



Observe the **maximum permissible adaptation weight** of the product and the item being adapted (wheelchair, bed, wall, etc.) to **prevent** damage to the Insors® GmbH product or the item being adapted.



**Do not use force.** This could damage the Insors® GmbH product or the adapted aid.



**Caution Pinching Hazard!** When installing / using Insors®GmbH products, always ensure that body parts are not touched by the moving parts of the brackets.



Products in the Udaption® series are delivered ready for use. Do **not** use any **lubricants, solvents** or similar. Such agents may **only** be used as part of maintenance/repair by **trained specialist personnel**. See chapter "Servicing and Repair"



**Before transporting** the mobility aid (e.g. wheelchair) or **loosening the screws and levers**, **remove** all **adapted aids** to prevent them from being damaged.



Do not permanently attach any objects that are not part of the scope of use to the Udaption® series product, as this may adversely affect its function and stability.

All safety and warning notices on the product must always remain clearly visible.



When using the **swivel unit**, ensure that the swivel tube is aligned vertically. **If the swivel tube is tilted** forwards (away from the user), the resulting pivoting under gravity, can lead to **damage to the aid** (Udaption® and adapted aid). There is also a risk of injury to the user. **The swivel tube must not be tilted towards the user!**



When selecting the mounting point on the mobility aid, make sure that no functionally relevant equipment on the mobility aid is negatively affected by the mounting itself and the operation of the bracket and adapted aid.



These include, for example, brakes, adjustment levers, tilting mechanisms, wheels, adjustable footrests, seat depth adjustment, seat height adjustment, swivelling armrests and much more.



When positioning the bracket for use, avoid the bracket protruding significantly and overhangs of the adapted aid in relation to the base of the mobility aid to prevent the risk of tipping and collisions.



Align the adjustable handles of the clamping levers so that they run alongside the tubes. If possible, also ensure that the end of the handle points against the direction of travel or downwards.



The spring tubes can rebound. This harbours a risk of injury if disregarded.



When using the swivel unit, pay attention to the left and right mounting. This involves reaching the optimum lever position of the quick-release lever (when the lever is closed, its end points against the direction of travel). The quick-release lever is used to adjust the swivel unit without play (the swivel tube can still be moved easily, but no longer has any play). The quick-release lever allows removal of the swivel tube from the unit.



**When changing the screw connection type (screw or clamping lever) on joints with RKN50, ensure that the spring assembly, spacer washer, and O-ring are installed correctly. Incorrect installation will impair the function of the joint. Observe the "Assembly and operation" instructions.**

### 3. Assembly



Ensure **correct and stable installation** so that the product can be used as intended. Insors®GmbH accepts no liability for incorrect installation.

**Ensure that the product is correctly and securely installed so that it can be used as intended.**

Insors®GmbH accepts no liability for improper installation.

The responsibility for installation, commissioning, and instruction lies with the qualified personnel of the supplier. The users are responsible for safety and functionality during use.



### 4. Safety for persons with impaired judgement



Insors®GmbH products are not toys! They must not be used for play by children or persons with limited judgment.

Otherwise, there is a risk of injury or damage to Insors®GmbH products or the adapted aids.

When assembling or modifying products from the Udaption® series, small parts may become detached (risk of swallowing) or other situations that could cause injury may arise. Small children



or persons with limited judgment should not be allowed to modify Udaption® products without supervision by a responsible adult.

## 5. Report serious cases

Please report all incidents to the following e-mail address (customer@insors.de).

An 'incident' means a malfunction or deterioration in the properties or performance of the Insors®GmbH product, including application errors due to ergonomic features, or any inadequacy in the information provided by Insors®GmbH or the supplier or an undesirable side effect (source MDR). All serious incidents occurring in connection with the product must be reported to Insors®GmbH.

## 6. Installation

Insors®GmbH products must be installed in accordance with the instructions in the 'Installation and operation' manual and in compliance with the general safety and warning instructions (this document).

Modification of Insors®GmbH products may only be carried out in accordance with the instructions of the aid manufacturer and/or the specifications of Insors®GmbH.

The safety and function of the item being adapted (wheelchair, bed, chair, etc.) must not be impaired by improper assembly of Insors®GmbH products (e.g. shifting of the centre of gravity with subsequent tipping, exceeding load limits, blocking of folding mechanisms, etc.). Please contact the supplier of the item being adapted if you have any doubts about maintaining its safety and performance.

## 7. Servicing and Repair

A damaged product or worn components can injure users or third parties. Please only use the product if you can rule out any defects/wear. If you are unsure, please contact your supplier. Repairs/maintenance or safety checks may only be carried out by trained specialists. Depending on the intensity of use, annual maintenance is recommended (heavy use). In accordance with Sections 3 and 7 of the Ordinance on the Installation, Operation, and Use of Medical Devices (MPBetreibV), a safety inspection = **maintenance is recommended at least every 2 years**. In accordance with Section 7 (MPBetreibV), the responsibility lies with your medical device supplier. Therefore, please contact them in good time.

## 8. Checking the intended use:

To ensure proper use, all connections on Insors®GmbH products must be adjusted in accordance with the 'Installation and operation' instructions. Screw connections must not be tightened with excessive force. If an unusual amount of force is required to clamp a connection, arrange for the product to be checked by trained specialists.

Check regularly that safe use is guaranteed. For detailed information and assistance with questions relating to maintenance and service, please contact your aid consultant/supplier or Insors®GmbH directly.

## 9. General Cleaning Instructions:

Products in the Udaption® series should be cleaned at regular intervals, depending on the intensity of use and the environment in which they are used.

This ensures perfect hygiene and functionality.

Responsibility for cleaning Udaption® products lies solely with the user or their carers. Ignoring this request may invalidate the product warranty and affect the clinical condition and safety of users and/or carers.

The necessary instructions 'Cleaning and disinfection guidelines' can be found on our website ([www.udaption.com](http://www.udaption.com)) for the respective product.

**Summary:** Wear protective gloves. Ensure that no water can penetrate into tubes, bearings or joints.

Wipe all parts with warm water and a non-abrasive cleaning agent using a damp cloth. Then wipe / dry with a dry, lint-free cloth. Disinfect all surfaces that users come into contact with (alcohol wipes 70%). The Udaption® product can then be dried with a paper towel to avoid staining.

## **10. Service life**

The expected service life (taking into account normal usage intensity and number of reuses) is 5 years.

This assumes intended use, proper use, timely maintenance, and compliance with the instructions in the “Assembly and Operation,” “General Safety and Warning Instructions,” and “Cleaning and Disinfection Guidelines.”

The specified service life of 5 years is not a guaranteed service life and is subject to individual inspection by qualified personnel, e.g. in the event of reuse.

If the product is to be used beyond the 5-year period, it must be inspected/overhauled by qualified personnel. The service life may also be shortened depending on the frequency of use, the operating environment, and maintenance. The service life does not refer to wear parts such as wheels and plastic parts, which are subject to material-specific aging and/or wear. This specified service life has no relation to the warranty or guarantee.

## **11. Re-use**

Please contact your supplier or Insors®GmbH before reuse. The Udaption® product may only be passed on for reuse if it has been tested and reconditioned in accordance with the safety and performance requirements of Insors®GmbH.

## **12. Disposal**

Insors®GmbH Udaption® products must be disposed of in accordance with the regulations applicable in the respective country.

## **13. Guarantee Conditions**

Insors®GmbH guarantees all Udaption® brand products fully against any form of product defect for a period of two years from the date of purchase, evidenced by a proof of purchase (with reference to the serial number, if the item has one).

This 2-year guarantee covers all components supplied with the product and also includes the consequences of wear and tear, improper operation or incorrect installation. Within this 2-year warranty period, Insors®GmbH will replace defective parts or the complete product with new or as-new components free of charge. Shipping costs shall be borne by Insors®GmbH, but on-site assembly services are excluded from the warranty. Damage caused by deliberate use contrary to the intended use or by wilful damage is also excluded.

Insors®GmbH accepts no liability for indirect damage to objects or persons resulting from the use of Udaption® products. Insors®GmbH accepts no liability for compensation for damage to adapted aids, adapted items (wheelchair, bed, chair, etc.) or furniture, or any liability for personal injury. No compensation can be claimed for loss of use due to faulty Insors®GmbH products.

Extended but limited 5-year warranty on all Insors®GmbH products. Insors®GmbH guarantees all Udaption® brand products against defects in materials and workmanship for a period of 5 years from the original date of purchase of the product, evidenced by a proof of purchase showing the serial number, if provided, for the product. Within the 5-year warranty Insors®GmbH will, at its discretion, replace defective parts or the complete product with new or like new components or repair the original product free of charge.

Shipping costs shall be borne by the customer; there are no on-site assembly services. This limited warranty applies to all components supplied with the product and only covers problems caused by defects in materials or workmanship of the product during its intended use. Indications of non-compliance will invalidate the warranty for the product. Excluded from the warranty are consumable parts such as screws, levers and all threads, as well as the consequences of improper use.

## **14. Customer service**

If you have any technical questions, please contact your medical aid consultant/supplier or [customercare@insors.de](mailto:customercare@insors.de). So that you can be helped as quickly as possible, you should have your Udaption® products at hand and know which product you are using (article number / instructions, delivery note or similar showing the exact designation / configuration of the product).