

Table

EN	General Safety Instructions and Warnings
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



Insors® GmbH
Struthof 2
55595 Münchwald- Germany
TEL: 0049 6706 915 6130
FAX: 0049 6706 915 1640
info@insors.de
www.insors.de



General Safety and Warning Instructions for the "Table" Mounts

1. General

Thank you for choosing a product from the UDAPTION® series. Please read these safety and warning instructions before using the product. Proper use requires further information from the "Assembly and Operation" manual and the cleaning instructions. You can find these on the website under the respective product. Please also take note of any instructions that may be placed directly on the products. When transferring the product, all documents mentioned here must be enclosed with the product so that the subsequent user can have all the necessary information. The Udaption® series is an accessory for assistive devices in the fields of Augmentative and Alternative Communication (AAC), Information Technology (IT), and Environmental Control Units (ECU).

Symbolism

Safety and Warning Instructions



Warning of significant risk of damage to the user, the adapted aid, or the product of the Udaption® series itself if these instructions are ignored.



Warning of significant risk of injury to the user if these instructions are not followed.



Warning about potential damage or malfunctions to the product if these instructions are disregarded.



Notice of loss of warranty claim in case of violation of the prohibition.



Notice the special attention paid to the user that is available here!



Note on proper handling or adjustment



Note on handling or settings that are within the scope of acceptance.



Note on incorrect / inadmissible setting or handling.



Close/Turn to close



Open/Turn to open



Half-open or close/Half-open or turn to open or close.



Notice regarding accessories/ attachments with separate operating instructions.

Labels on manuals, packaging, products, and accessories



UKCA is the product labeling that confirms that the product may be marketed in England, Scotland and Wales because it meets their requirements.



The CE marking indicates that a product has been assessed by the manufacturer and meets all EU-wide requirements for safety, health, and environmental protection.



Observe operating instructions!



Article Number



Serial number



Batch identification



Medical device



Unique Device Identification



Choking hazard (User exclusion / Warning notices Accessibility)



Protect from moisture



Do not reuse



Manufacturer



Date of Manufacture

Purpose / Intended Use

The models of the Udaption® series "Table" are table mounts that are either intended for placing on a table (or other furniture with storage options) or "Clamp" for attaching to tabletops or similar surfaces. Their purpose is to mount/adapt adaptive technologies (AAC (augmentative and alternative communication), IT (information technology), or ECU (environmental control units)) on tables or comparable fixed locations. These mentioned medical devices are used when standard control methods are not accessible to users due to a disability (disability compensation). It is only through the mounts of the Udaption Table series that these medical devices can be utilized, thereby fundamentally enabling the usability of the medical devices for the intended user group.

The included trapezoidal adapters, pin adapters, or ¼-inch mounts are quick-release fasteners that allow the assistive device to be quickly attached and removed. The counterpart (the pin, trapezoid, or ¼-inch thread) is semi-permanently connected to the assistive device. The various tubes, flexible arms, and joints of the differently equipped bracket types allow the accessory to be adapted optimally to the user's operating position and operating movements.

For technical details, please refer to the "Assembly and Operation" instructions.

The Udaption® "Table" series is an accessory for assistive devices and is neither life-sustaining nor life-supporting.

Usage locations: The mounts of the "Table" series can be used indoors and outdoors.

For further technical details and instructions, please refer to the "Installation and Operation" manual, as well as the "Cleaning and Disinfecting" guide for the Udaption® series.

Indicators: Individuals who rely on mobility aids and adaptive technologies to communicate (AAC), to access information technologies (IT), or to control their environment (ECU).

Contraindications: None

Target patient group: People with significant motor impairments, also related to communication ability limitations, due to diseases and disabilities (both acquired, hereditary, or degenerative in nature).

Including among others:

Infantile cerebral palsy, - neuromuscular diseases such as ALS, muscular dystrophies, MS, - spinal cord injury with tetraplegic development, multiple amputations, - acquired brain injury from strokes, traumatic brain injuries, or inflammatory processes, - Rett syndrome, Angelman syndrome, or other severe multiple disabilities.

Intended users:

- **Setup and Commissioning:** Qualified dealers or other suppliers with the appropriate expertise.
- **Operation:** Assistants, caregivers, family members, therapists, and other individuals operating in a patient environment who are knowledgeable about the handling of the Udaption® "Mobile Series."

For indications with correspondingly pronounced motor skills, operation by the user themselves cannot be ruled out, at least in parts.

Scope of Delivery

Verify the contents of the delivery with the information provided in the "Assembly and Operation" guide for the respective product. Additional complementary products may be necessary to fully utilize the product. If these are not present or incomplete, please contact your supplier.

2. Safety

The products from the Udaption® series by Insors® GmbH comply with all specifications and standards for medical devices. However, to ensure safe assembly, operation, and re-use of the Udaption® series, the following safety and warning instructions must be adhered to:

General Safety and Warning Instructions



The **use of unauthorized accessories or unauthorized modifications** to the product can lead to endangerment and/or injury to **persons and property damage**. Therefore, **only use accessories approved by Insors® GmbH** for use with the respective product or that have standardized connection options. Make **changes to the product only** in accordance with the corresponding installation and operating instructions, or if the changes have been approved in writing by Insors® GmbH.



Ensure the **correct assembly according to the installation instructions**. Improper assembly can compromise the stability and function of the product, and may further cause damage to the adapted aid or even result in physical injuries.



Small parts and packaging materials included in the scope of delivery must be kept out of the reach of children. **There is a risk of suffocation.**



Please observe the **maximum permissible adaptation weight** of the product and the adaptation base (wheelchair, bed, wall, etc.) to prevent damage to the Insors® GmbH product or the adaptation base.



Do not exert force or use excessive strength. This can damage the Insors® GmbH product or the adapted aid.



Caution! Risk of pinching! When assembling or using Insors® GmbH products, always ensure that body parts do not come into contact with moving parts of the mounts whenever possible.



Products from the Udaption® series are delivered ready for use. **Do not use any lubricants, solvents, or similar substances.** The **use of such substances** should only be carried out during maintenance/repair by trained professionals. See chapter "**Maintenance and Repair**"



"Before transporting the "Table" holder or loosening screws and levers, remove all adapted aids to prevent their damage."



Do not permanently attach any items that are not part of the intended use to the product of the Udaption® series, as this can negatively impact its function and stability.

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



Ensure that the "Table" brackets, which are to be placed on the table, are positioned on the flattest possible surfaces.



Position the brackets of the "Clamp" series so that the adapted aid is located above the table surface/furniture surface.



With the exception of the MiniClamp and Friction brackets, the brackets are not designed for round tubes, as the clamping force is otherwise insufficient (rotation resistance).

The use as wheelchair mounts is also not intended for this reason.



Ensure the integrity of the anti-slip bases on the table stands to maintain the stability of the Udaption® product.

3. Responsibility



Ensure **proper and stable installation** of the product to be able to use it as intended.

Insors®GmbH disclaims any liability for improper installation.

The **responsibility for assembly, commissioning**, and briefing rests with the trained **personnel of the supplier**. The **users** are **responsible** for safety and functionality **during use**.

4. Lifetime



The use of a Udaption® product beyond the intended period of use carries increased risks.

Therefore, an assessment should be made by professionals (medical equipment supplier) beforehand to evaluate the extent to which the product can be refurbished/serviced and used for an extended period.

5. Safety for persons with impaired judgment



Insors®GmbH products are not toys! Therefore, they must not be used for play by children or individuals with impaired judgment.

There is otherwise 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 separated (risk of swallowing), or other potentially hazardous situations can arise. Small children or individuals with impaired judgment should not be able to modify Udaption® products without supervision by responsible persons.

6. Report serious cases



Please report all incidents to the following email address (customercare@insors.de).

An "incident" refers to a malfunction or deterioration in the characteristics or performance of the Insors®GmbH product, including application errors due to ergonomic features, as well as an inadequacy of the information provided by Insors®GmbH or the source, or an undesirable side effect (source MDR). All serious incidents related to the product must be reported to Insors®GmbH.

7. Assembly

The assembly of Insors®GmbH products must be carried out according to the instructions in the "Assembly and Operation" manual and in compliance with the general safety and warning notes (this document).

The adaptation of the accessories to Insors®GmbH products is permitted solely in accordance with the specifications provided by the accessory manufacturers and/or the specifications set by Insors®GmbH. The safety and functionality of the adaptation base (table, wheelchair, bed, etc.) must not be compromised by improper installation of Insors®GmbH products (e.g., shifting of the center of gravity leading to potential tipping, exceeding load limits, blocking of folding mechanisms, etc.). Please contact the source of the adaptation base if there are any doubts regarding the maintenance of its safety and performance.

8. Maintenance and Restoration

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.

9. Checking proper usage:

To ensure proper use, all connections on Insors® GmbH products must be adjusted in accordance with the instructions "Assembly and Operation." Screwed connections must not be tightened with force. If an unusual amount of force is required to clamp a connection, arrange for an inspection of the product by trained professionals.

Make sure regularly that safe use is ensured. Detailed information and assistance with questions about maintenance and service can be obtained from your assistive device consultant or supplier, or directly from Insors® GmbH.

10. General cleaning instructions:

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

This ensures impeccable hygiene and functionality.

The responsibility for cleaning Udaption® products lies solely with the user or their supporting environment. Ignoring this instruction may result in the loss of the product warranty and potentially compromise the clinical condition and safety of users and/or caregivers.

The necessary instructions "Cleaning and Disinfection Guidelines" can be found on our website (www.udaption.com) under the respective product.

Summary: Please wear protective gloves. Make sure that no water can enter pipes, bearings or joints. Wipe down all parts with warm water and **non-abrasive detergent using** a wrung-out cloth. Then wipe/dry with a dry, lint-free cloth. Disinfect all surfaces that come into contact with users (alcohol wipes 70%). The Udaption® product can then be dried with a paper towel to avoid staining.

11. Lifetime

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.

12. Reuse

Before reuse, please contact your medical supply provider or Insors® GmbH. The Udaption® product may only be passed on for reuse if it has been tested and reconditioned according to the safety and performance requirements of Insors® GmbH.

13. Disposal

The Udaption® products by Insors® GmbH must be disposed of according to the regulations applicable in the respective country.

14. Warranty terms

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

This 2-year warranty includes all components supplied with the product and also covers consequences of wear, improper operation, or faulty installation. Within this 2-year warranty period, Insors®GmbH provides free replacement of defective parts or the complete product with new or refurbished components. Shipping costs are borne by Insors®GmbH, but on-site assembly services are excluded from the warranty services. Also excluded are damages resulting from deliberate application contrary to the intended use or from intentional damage.

Insors®GmbH does not assume liability for indirect damages to objects or individuals resulting from the use of Udaption® products. Claims for compensation concerning damages to adapted aids, adaptation bases (wheelchair, bed, chair, etc.), or furniture are excluded by Insors®GmbH, as well as liability for personal injuries. Compensation for loss of use due to defective Insors®GmbH products cannot be claimed.

Extended, yet limited 5-Year Warranty on all Insors®GmbH products. Insors®GmbH guarantees all Udaption® branded products against material and workmanship defects for a period of 5 years from the original purchase date of the product, evidenced by a purchase receipt stating the serial number, where applicable. Within the 5-Year Warranty period, Insors®GmbH, at its sole discretion, will provide free replacement of defective parts or the entire product with new or like-new components, or make repairs to the original product.

Shipping costs are the responsibility of the customer, and assembly services on-site are excluded. This limited warranty applies to all components delivered with the product and only covers issues that arise from material or workmanship defects during proper use of the product. Indications of misconduct will void the warranty on the product. The warranty excludes wear parts, such as screws, levers, and all threads, as well as consequences from improper use.

15. Customer Service

For technical questions, contact your aid consultant/supplier or customercare@insors.de. To ensure you receive assistance as quickly as possible, have your Udaption® products ready and be aware of which product you have (item number/manuals, delivery note, etc. that indicate the exact designation/configuration of the product).

16. Responsible person

UK	REP
----	-----

Patient Guard Ltd, Lancaster House, Amy Johnson
Way, Blackpool, Lancashire, FY42RP. United
Kingdom