

Stand-Serie

EN	General Safety Instructions and Warnings
EN	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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General Safety and Warning Instructions for the "Stand" Series

1. General Information

Thank you for choosing a product from the UDAPTION® series.

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

A proper use requires further information from the "Assembly and Operation" manual and the cleaning instructions. You can find these on the homepage under the respective product. Please also pay attention to any notices placed directly on the products themselves.

When passing on the product, all documents mentioned here must be enclosed with the product to ensure that the subsequent user has 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 Udaption® series product itself if these instructions are disregarded.



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



Warning on potential damage or malfunctions to the product if these instructions are not followed.



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



Note the special attention given to the user here!



Notice on Proper Handling or Adjustment



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



Notice of incorrect/ improper setting or handling.



Close / Turn off



Open / Unscrew



Half open or close / Half turn or close.



Notice on accessories / attachments with separate operating instructions.

Labels on instructions, 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 is an indication that the product has been tested by the manufacturer and that it meets all EU-wide requirements for safety, health protection, and environmental protection.



Observe the instruction manual!



Article number



Serial Number



Batch designation



Medical device / médical



Unique Device Identification



Choking Hazard (User Exclusion / Accessibility Warnings)



Protect from moisture



Do not reuse



Manufacturer



Manufacture date

Purpose / Intended Use

The Udaption® “Stand-Series” (V-Stand, U-Stand, Star-Stand) are stationary devices on casters designed to facilitate the usability of medical products in fields such as AAC (Augmentative and Alternative Communication), environmental control systems, and IT (Information Technology). They consist of a base (wheeled support), a height-adjustable vertical column placed on it, and a horizontally adjustable holding unit with an adaptable device head. Both the vertical column and the device holding unit with the adaptable head are adjustable. This allows the assistive device being adapted to be optimally adjusted to the user's operational position and interaction paths. The optimally aligned assistive device can be operated by the user from various positions: in front of or under the stand, sitting or lying down. The device head features a quick adapter (trapezoidal mount) that allows fast and secure connection/adaptation, through a corresponding counterpart (trapezoid) firmly screwed onto the assistive device. Detaching this connection is equally simple and swift. The aforementioned medical products come into use when usual operational paths are unavailable due to an existing disability (disability compensation). Only by using the stands of the Udaption Stand-Series do these medical products become operable, thereby enabling their usability for the intended user group.

The Udaption® “Stand Series” is an accessory for assistive devices and is neither life-sustaining nor life-supporting.

Usage Areas: Dry Indoor Spaces

For further technical data and information, please refer to the operation and assembly manual, as well as the instructions for cleaning and disinfecting the Udaption® series.

Indications: Individuals who rely on assistive technologies to communicate (AC), to access information technology (IT), or to control their environment (ECU).

Contraindications: None

Patient target group: people with significant motor impairments, including those associated with communication limitations, due to diseases and disabilities (whether acquired, hereditary, or degenerative in nature).

Among these include, among others:

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

Intended Users:

- **Setup and Commissioning:** Qualified specialist dealers or other suppliers with the appropriate expertise.
- **Operation:** Assistance, care, relatives, therapists, and other individuals operating in the patient's environment who are knowledgeable about the handling of the Udaption® "Stand Series."
- For indications with correspondingly pronounced motor abilities, operation by the user themselves cannot be completely ruled out, at least in part.

Contents of Delivery

Check the included items against the instructions in the manual "Assembly and Operation" for the respective product. Additional supplementary products may be necessary to fully utilize the product. If these are missing 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 installation, operation, and re-use of the Udaption® series, the following safety and warning instructions must be observed:

General Safety and Warning Instructions



The use of **unauthorized accessories** or improper modifications to the product can lead to hazards and/or injuries to persons and property damage.



Therefore, **only use accessories that have been approved by Insors® GmbH** for use with the particular product or that have standardized connections.



Make **modifications** to the product **only** in accordance with the associated **installation and operating instructions**, or if the modifications have been **explicitly approved in writing by Insors® GmbH**.



Ensure correct assembly according to the assembly instructions. Incorrect assembly can impair the stability and function of the product and may also cause damage to the adapted equipment or even lead to personal injury.



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



Please note 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 apply excessive force or violence. This can damage the Insors® GmbH product or the adapted accessory.



Caution, risk of pinching! When installing or using Insors® GmbH products, always ensure that body parts do not come into contact with moving parts of the fixtures.



We urge **you not to allow the adapted accessory** to extend beyond the **base areas** of the "Stand" series (base frame with castors). If it does, there is an increased **risk of tipping over**. Furthermore, the protruding accessory poses an increased **risk of collision during the transfer** of the unit.



When moving the stand from the "Stand" series over rough, uneven surfaces, **please remove any adapted equipment beforehand** to prevent damage.



"When moving the "Stand" series rolling stand, be sure to firmly grasp the column with both hands to prevent the stand from wobbling or tipping over."



When **moving** the stand, pay attention to the chassis to **avoid collisions** with objects and people. Use the "Stand" series only on level surfaces **without slopes**.



The 'Stand' series is suitable for use **only in dry indoor areas**.



Navigate around the "Stand" series **with enough distance** to avoid tripping or injuries.



The height-adjustable column and the gas spring-assisted Hoover arm can execute rapid upward movements when unlocking or removing the adapted tool, which can lead to injuries. Therefore, **do not place any body parts over the stand or the tool when performing these actions**.



Use the 'Stand' series only with the caster brakes engaged. Also remember to **engage all the brakes after moving the stand**.



The Udaption® series products are delivered ready for use. Do **not use** any **lubricants, solvents, or similar substances**.



The use of such substances should **only be carried out by trained professionals** during maintenance or repair work. Refer to the chapter "Maintenance and Repairs."



Before transporting the Udaption® Stand product or loosening the screws and levers, remove all adapted aids to prevent damage.



Please do not permanently attach items unrelated to the intended functionality to a product from the Udaption® series, as this may negatively affect its function and stability.

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

3. Accountability



Ensure **correct and stable installation** of the product to use it as intended. Insors®GmbH disclaims any liability for improper installation.



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

4. Service life



Using a Udaption® product beyond its intended service life carries increased risks. Therefore, a prior assessment should be made by qualified personnel (aid supplier) to determine the extent to which the product can be restored to a further service life by possible reconditioning / maintenance.

5. Safety for individuals with impaired judgment

Safety for individuals with impaired judgment

Insors®GmbH products are not toys! Therefore, they should 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.

During the assembly or modification of products from the Udaption® series, small parts may become detached (risk of swallowing), or other hazardous situations that could cause injury may occur. Small children or individuals with impaired judgment should not be able to modify the Udaption® products without supervision from a responsible person.

6. Report serious cases

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

An "incident" is defined as a malfunction or deterioration of the characteristics or performance of the Insors®GmbH product, including application errors due to ergonomic features as well as

inadequacy of the information provided by Insors®GmbH or the source, or an undesirable side effect (source MDR). Any serious incidents associated with the product must be reported to Insors®GmbH.

7. Assembly

The installation of Insors®GmbH products must be carried out according to the instructions in the 'Assembly and Operation' manual and with due regard to the general safety and warning instructions (this document).

The adaptation of tools and equipment to Insors®GmbH products must be carried out solely according to the instructions of the tool manufacturers or/and according to the specifications of Insors®GmbH.

8. Maintenance 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.

9. Inspection of proper use:

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

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

10. General cleaning instructions:

Products from the Udaption® series should be cleaned regularly depending on the frequency and environment of use.

This ensures impeccable hygiene and functionality.

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

You can find the necessary instructions, "Cleaning and Disinfection Guidelines," on our website (www.udaption.com) under the respective product.

Summary: Please wear protective gloves. Ensure that no water can enter the pipes, bearings, or joints.

Wipe all parts with warm water and a **non-abrasive cleaning agent** using a wrung-out cloth.

Then, wipe and dry with a lint-free cloth. Disinfect all surfaces that users might come into contact with, using 70% alcohol wipes. The Udaption® product may then be dried with a paper towel to prevent streaking.

11. Service life

The expected lifespan (considering the usual intensity of use and number of reuses) is 5 years.

The intended and proper use, adherence to service and maintenance intervals, and compliance with the guidelines in the "Installation and Operation" manual, "General Safety and Warning Instructions," and the "Cleaning and Disinfection Guidelines" are assumed.

The specified service life of 5 years is not a guaranteed service life and is subject to individual case assessment by qualified personnel, for example, in case of reuse.

If the product is to be used beyond the 5-year period, an inspection/overhaul of the product by qualified personnel is necessary. The lifespan may also be shortened depending on the frequency of use, the operational environment, and maintenance. The lifespan does not apply to wear parts, such as wheels and plastic parts, which are subject to material-specific aging and/or wear. This specified lifespan is not related to warranty or guarantee.

12.Re-use

Before re-use, please contact your assistive device supplier or Insors® GmbH. The Udaption® product may only be passed on for re-use if it has been checked and refurbished according to the safety and performance requirements of Insors® GmbH.

13.Disposal

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

14.Warranty Specifications

Insors® GmbH provides a comprehensive 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 (referencing the serial number if the item carries one).

This 2-year warranty includes all components supplied with the product and also covers consequences of wear and tear, 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 like-new components. Shipping costs are covered by Insors® GmbH, however, on-site assembly services are excluded from the warranty services. Also excluded are damages arising from deliberate use contrary to intended purpose or from intentional damage.

Insors® GmbH assumes no liability for indirect damage to objects or persons resulting from the use of Udaption® products. Insors® GmbH excludes compensation for damage to adapted aids, adaptation bases (wheelchair, bed, chair, etc.), or furniture, as well as liability for personal injury. Compensation for loss of use due to faulty Insors® GmbH products cannot be claimed.

"Extended but Limited 5-Year Warranty on all Insors® GmbH Products. Insors® GmbH warrants all Udaption® brand products against defects in material and workmanship for a period of 5 years from the original date of purchase, proven by a purchase receipt that specifies the serial number, if applicable. Within the 5-Year Warranty, Insors® GmbH, at its discretion, provides free replacement of defective parts or the entire product with new or reconditioned components, or performs repairs on the original product."

Shipping costs are the responsibility of the customer, and on-site assembly services are excluded. This limited warranty applies to all components supplied with the product and only covers issues that arise due to material or workmanship defects of the product during proper usage.

Indications of non-compliance will void the product's warranty. Wear parts such as screws, levers, and all threads, as well as consequences from improper use, are excluded from the warranty.

15.Customer service

For technical questions, please contact your facilitation consultant/supplier or customercare@insors.de. To ensure you receive assistance as quickly as possible, have your Udaption® products ready and be informed of which product you have (article number/instructions, delivery note, etc., specifying the exact name/configuration of the product).

16.Responsible Person

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