UDAPTION®

INSORS® GMBH

Wall

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CE UKCA

General safety and warning information for the **"Wall"** series

1. General

Thank you for choosing a product from the **UDAP**TION® series.
Please read these safety and warning instructions before using the product.
Proper use requires further information from the "Installation and Operation" manual and the cleaning instructions. These can be found on the homepage www.udaption.com under the respective product.
Please also observe any instructions that may be placed on the products themselves.
If the product is passed on to another user, all documents mentioned here must be included with the product so that the subsequent user has all the necessary information.
The Udaption® series is an accessory for assistive devices in the fields of assisted communication (AC), information acquisition (IT), and environmental control (ECU).

Symbolism

Safety and warning notices


Warning of significant risk of damage to the user, the adapted assistive device, or the Udaption® series product itself if these instructions are not followed.


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


Warning of possible damage or malfunction of the product if these instructions are not followed.


Warning of loss of warranty if the prohibition is disregarded.


Notice of the special attention required by the user in this case!


Note on correct handling or adjustment


Note on handling or settings that are acceptable.


Warning about incorrect/impermissible settings or handling.


Close / Turn off


Open / Turn open


Half open or close / Half open or close.


Reference to accessories/attachments with separate instructions for use.

Markings on instructions, packaging, products, and accessories

UKCA is the product marking that confirms that the product may be placed on the market in England, Scotland and Wales because it complies with their requirements.

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

Follow the instructions for use!

REF Item number

SN Serial number

LOT Batch identification

MD Medical device

UDI Unique device identification

Choking hazard (user exclusion / accessibility warnings)

Protect from moisture

Do not reuse

Manufacturer

Date of manufacture

Intended use

The models in the Udaption® "Wall" series are wall mounts that can be attached to a wide variety of surfaces with sufficient load-bearing capacity using 4 screws. A wide variety of screw types with and without dowels can be used. For this reason, NO screws are included with the mounts; instead, they must be provided by the installation team and adapted to the circumstances.
The wall mount is designed to hold 22 mm pipes (pipe combinations J-pipe with max. 400 mm pipe) with joints and a quick adapter (trapezoid or PIN).
The resulting mounting system serves the purpose of attaching/setting up adaptive technologies (AAC (augmentative and alternative communication), IT (information technology), or ECU (environmental control units)) to a table or similar fixed locations. 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 from the Udaption Wall series can these medical devices be used, thus enabling the intended user group to use the medical devices.

The included trapezoidal or pin adapters are quick-release fasteners that allow the aids to be adapted to be quickly attached and detached again. The counterpart (the pin or trapezoid) is semi-permanently connected to the aid. The tube combination with joints and quick-release fasteners allows the aid to be adapted to be optimally adjusted to the user's operating position and operating methods.
The sliding block joint included in the scope of delivery allows the wall mount to also be used as a bearing point for the "Mobile" series (22 mm clamping ring additionally required).
For technical details, please refer to the "Assembly and Operation" manual.
The Udaption® "Wall" mounts are accessories for assistive devices and are neither life-sustaining nor life-supporting.

Places of use: Indoors
For further technical data and information, please refer to the "Assembly and Operation" manual and the instructions for cleaning and disinfecting the Udaption® series.
Indications: People who rely on mobility aids and adaptive technologies to communicate (AAC), access information technologies (IT), or control their environment (ECU).
Contraindications: None
Target patient group: People with significant motor impairments, including those related to communication impairments, due to illness and disability (whether acquired, hereditary, or degenerative in nature).
These include, among others:
Infantile cerebral palsy, - Neuromuscular diseases such as ALS, muscular dystrophy, MS, - Spinal cord injury with tetraplegia, multiple amputation, - Acquired brain damage due to stroke, traumatic brain injury, or inflammatory processes, - Rett syndrome, Angelman syndrome, or other severe multiple disabilities.
Intended users:

- **Setup and commissioning**: Qualified specialist dealers or other providers with the relevant expertise.
- **Operation**: Assistants, caregivers, family members, therapists, and other people involved in the patient's care who are familiar with the operation of the Udaption® "Mobile Series." In cases where the patient has sufficiently developed motor skills, operation by the user themselves, at least in part, cannot be ruled out.

Scope of delivery

Check the scope of delivery against the information in the "Assembly and Operation" instructions for the respective product. Additional products may be necessary in order to use the product to its full extent. If these are not available or are incomplete, please contact your supplier.

2. Safety

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

General safety and warning information

The **use of unauthorized accessories** or unauthorized 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 use with the respective product or that have standardized connection options. Only make **modifications** to the product **in accordance with** the relevant **installation and operating instructions**, **or** if the **modifications** have been **approved in writing** by Insors® GmbH.

Ensure **correct assembly** in accordance with the assembly instructions. Incorrect assembly can impair the stability and function of the product and 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 risk of suffocation.

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 use **force** or excessive force. This can damage the Insors® GmbH product or the adapted aid.

Caution: risk of entrapment! When installing/using Insors® GmbH products, always ensure that body parts do not come into contact with moving parts of the mountings.

Udaption® series products are delivered ready for use. **Do not** use **lubricants, solvents**, or similar substances. Such substances may **only** be used **by trained specialists** during maintenance/repair work. See the "Maintenance and Repair" section.

Before loosening the **screws and levers**, **remove** all **adapted aids** to prevent damage.

Do not permanently attach any objects that are not included in 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 remain clearly visible at all times.

The wall brackets must not be mounted on ceilings.

When mounting, ensure that the surface is sufficiently load-bearing. Use the appropriate screws and, if necessary, dowels for the existing surface. The load capacity of the associated 22 mm joint is max. 8 kg. Please note that the weight of the Udaption mount to be adapted must be deducted from the 8 kg in order to calculate the max. adaptation weight (e.g., mount 2.1 kg = max. adaptation weight 5.9 kg).

3. Responsibilities

Ensure that the product **is installed correctly and securely** so that it can be used as intended. Insors®GmbH accepts no liability for improper installation.

Responsibility for installation, commissioning, and instruction lies with **the specialist personnel** of the source of supply. **Users** are responsible for safety and function during use.

4. Service life

Using an Udaption® product beyond its intended period of use carries increased risks. Therefore, a professional (aid supplier) should first assess the extent to which the product can be refurbished/maintained for further use.

5. Safety for persons with limited judgment

Insors®GmbH products are not toys! They must therefore 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 posing a risk of injury may arise. Small children or persons with limited judgment should not be able to modify Udaption® products without supervision by a caregiver.

6. Report serious incidents

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

An "incident" refers to a malfunction or deterioration in the properties 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 of supply, or an undesirable side effect (source: MDR). All serious incidents related to the product that occur in the context of must be reported to Insors®GmbH.

7. Assembly

Insors®GmbH products must be assembled in accordance with the instructions in the "Assembly and Operation" manual and in compliance with the general safety and warning instructions (this document).

The adaptation of aids to Insors®GmbH products may only be carried out in accordance with the specifications of the aid manufacturer and/or the specifications of Insors®GmbH.

The safety and function of the adaptation base (wheelchair, bed, chair, etc.) must not be impaired by improper installation of Insors®GmbH products (e.g., shift in center of gravity with subsequent tipping, exceeding load limits, blocking of folding mechanisms, etc.). Please contact the source of supply for the adaptation base if you have any doubts about the safety and performance of the base.

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 source of supply.
Repairs, maintenance, or safety inspections 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**.
According to §7 (MPBetreibV), your medical device supplier is responsible for carrying out this inspection. Therefore, please contact them in good time.

9. Checking for intended use:

To ensure proper use, all connections on Insors®GmbH products must be adjusted in accordance with the "Assembly and Operation" instructions. Screwed connections must not be tightened with force. If unusual force is required to clamp a connection, have the product checked by trained specialist personnel.
Regularly check that safe use is guaranteed. Detailed information and assistance with questions about maintenance and service can be obtained from your medical device consultant/supplier or directly from Insors®GmbH.

10.General cleaning instructions:

Products in the Udaption® series should be cleaned at regular intervals, depending on the intensity and environment of use.
This ensures proper hygiene and functionality.
The user or their care team is solely responsible for cleaning Udaption® products. Ignoring this request may void the product warranty and 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) for the respective product.

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

11.Service life

The expected service life (taking into account normal usage intensity and number of reuses) is 5 years.
This assumes intended use, compliance with service and maintenance intervals, and adherence to the specifications in the "Installation and Operation," "General Safety and Warning Instructions," and "Cleaning and Disinfection Guidelines" manuals.
The specified service life of 5 years is not a guaranteed service life and is subject to individual assessment 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 apply 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 device supplier or Insors®GmbH. 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.

13.Disposal

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

14.Warranty

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 proof of purchase (with reference to the serial number if the item has one).
This 2-year warranty covers all components supplied with the product and also includes the consequences of wear and tear, improper operation, or faulty installation. Within this 2-year warranty period, Insors®GmbH will replace defective parts or the entire product free of charge with new or as-new components. Shipping costs shall be borne by Insors®GmbH, but on-site installation services are excluded from the warranty. Damage resulting from deliberate use contrary to the intended use or intentional damage is also excluded.
Insors®GmbH accepts no liability for indirect damage to property or persons resulting from the use of Udaption® products. Insors®GmbH excludes compensation for damage to adapted aids, adaptation bases (wheelchairs, beds, chairs, etc.), or furniture, as well as liability for personal injury. Compensation for loss of use due to defective Insors®GmbH products cannot be claimed.

Extended, but limited, 5-year warranty on all Insors®GmbH products. Insors®GmbH provides a warranty for all Udaption® brand products covering material and manufacturing defects for a period of 5 years from the original date of purchase of the product, as evidenced by a proof of purchase with the serial number, if provided for the product. Within the 5-year warranty period, Insors®GmbH will, at its sole discretion, replace defective parts or the entire product with new or refurbished components free of charge, or repair the original product.
Shipping costs shall be borne by the customer; on-site installation services are excluded. This limited warranty applies to all components supplied with the product and covers only problems resulting from material or manufacturing defects in the product during normal use. Any indication of misuse will void the warranty for the product. Wear parts such as screws, levers, and all threads, as well as consequences of improper use, are excluded from the warranty.

15.Customer service

If you have any technical questions, please contact your medical device consultant/supplier or customercare@insors.de. In order to help you as quickly as possible, please have your Udaption® products ready and be aware of which product you have (item number/instructions, delivery note, or similar, showing the exact name/configuration of the product).

16. Responsible person

UK	REP

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