

Dear Customer,

Thank you for your trust in the inpasso product. The inpasso products represent the perfect combination of functionality, quality, design, and craftsmanship. Our gravity position system, **einstein**, is exclusively manufactured in Germany and bears the quality seal "Made in Germany." We hope you enjoy it.



Please read this user manual carefully before using the **einstein**, as it contains important information and safety-related instructions. This is especially important for caregivers and companions of the user. The safety of the user/patient may be compromised if the instructions in this manual are not followed.

If you have any questions regarding usage, maintenance, or cleaning, please first contact your local specialist dealer from whom you have purchased our product. For further information, our inpasso team is also available to assist you (Email: info@inpasso.de).

**We aim to impress you with the highest quality – this is our philosophy.
Try out the **einstein** and experience the difference!
The **einstein** is an investment in health and well-being that is worth it.**



The areas marked with this warning symbol contain important information, including safety-related details, and must be strictly observed when using the **einstein**.

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1 Legal Product Notice and Manufacturer Information

Our products comply with all applicable German and European safety and performance requirements according to:

- Medical Device Law Implementation Act "MPDG"
- Regulation (EU) 2017/745 on Medical Devices - Medical Device Regulation "MDR (EU)".

Please also refer to the EU Declaration of Conformity attached to the product.

 <p> manufacturer inpasso GmbH Heideweg 35 D-49086 Osnabrück E-Mail: info@inpasso.de Homepage: www.inpasso.de SRN: DE-MF-000035766 </p>	 <p> Made in Germany Country of manufacture </p>		 <p> Medical Device </p>
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2 Product Description

The **einstein** is designed in the form of a lowered reclining chair and utilizes the gravitational force, which is universally present on our planet. Since the user's center of gravity is very low in the **einstein**, the stability of the sitting or reclining position is significantly enhanced. With the additional close lateral body support provided by the **einstein**, body segments (e.g., torso, limbs) are positioned in therapeutically supportive postures and maintained there. This primarily serves to alleviate pain, relieve joints, and prevent and/or treat contractures and spasms. It can also provide temporary pressure relief for specific body areas, for example, during the postoperative phase.

The **einstein** is ideal for individuals with physical and mental disabilities, as well as for children, adolescents, and adults who require support in their sitting or reclining position. It can be easily used both at home and in care facilities due to its straightforward handling.

2.1 Areas of Application

Innovative solutions for healthy and comfortable body posture are in demand in many areas. Particularly, individuals with physical and mental disabilities often require individualized support to sit comfortably and healthily. The **einstein** is designed to provide these individuals with any kind of physical impairment a comfortable and simultaneously therapeutic aid in their daily lives. It can be used as a primary seating and positioning system or as an additional positioning alternative (e.g., in combination with a seating shell). By individually adjusting the seat with the help of accessories (leg rest, therapy table, pelvic belt, swing, etc.), additional support can be tailored to the specific needs of the user.

The unique design of the positioning system allows for a homogeneous distribution of body weight across the seating and reclining surfaces, providing stable and comfortable body support, particularly for the user's spine and pelvis. This promotes a relaxed body posture and reduces pressure on stressed body areas.

Especially after prolonged sitting in seating shells, relief and relaxation of affected body parts are important, and the **einstein** provides exactly that. Through repositioning and the accompanying transition from tension to relaxation, the **einstein** can help alleviate discomfort and pain while providing a refreshing change. Particularly in children and adolescents, the **einstein** can help develop and promote a more vital body posture through regular changes in positioning systems.

The **einstein** offers another therapeutic aspect through physical relief and relaxation. A relieving and supportive body posture can promote mobility, positively influence joints, and thus contribute to improving overall well-being, enhancing joy of life, vitality, and participation.

The **einstein** can also be used for further treatment/rehabilitation measures upon medical and therapeutic recommendation, for example, for individual support in speech and occupational therapy.

2.2 Indications

The gravity position system **einstein** is used by individuals who are mobility-impaired due to illness, accident, or other circumstances. The medical conditions are characterized by significant immobility, accompanied by physical misalignments that the patient can hardly or cannot correct by their own strength. The positioning system supports conservative treatment of orthopedic problems and damages in the posture and movement apparatus, body misalignments, and instabilities, and is used in conditions such as:

- Infantile cerebral palsy
- Myelodysplasia
- muscular dystrophy
- Or diseases with scoliotic spinal deformities.

Positioning systems enable users with significantly reduced or absent trunk stability or pronounced trunk deformity to achieve (partially) corrective and relieving or supportive sitting or lying. They provide support and/or positioning effects such as pelvic elevation, lateral support of the pelvis and thorax through their body-embracing construction. The **einstein** supports the compensation of pronounced body misalignments and postural instabilities. The goal is pain-free sitting/lying in a physiological posture. The daily usage duration depends on the diagnosis and medical and therapeutic recommendations.



Please note that the positioning system **einstein** should be used as part of a comprehensive therapeutic concept. To prevent deterioration of the patient's physical condition in terms of contractures and deformities (secondary disabilities), regular active physiotherapeutic treatment, as well as other forms of care, such as nursing or psychological support, and additional corrective aids are of immense importance. Therefore, always seek the assistance of a doctor, physiotherapist, occupational therapist, etc., regarding usage and duration of provision.

2.3 Contraindications



The **einstein** should not be used for the treatment/therapy of existing pressure ulcers. For patients at risk of pressure ulcers, consult a doctor or therapist.

3 Usage Area and Storage Conditions

The **einstein** is designed for indoor use. It should only be used on flat surfaces. Ensure that the **einstein** is always stored dry and not exposed to direct sunlight. Clean soiled parts immediately after use.

4 Safety and Risks

When used according to the intended purpose and all instructions described in this user manual are followed, the use of the **einstein** gravitational positioning system is safe. Possible risks are unknown with proper application. However, the following safety notes must be observed.

4.1 Important Safety Instructions



- The **einstein** is approved for use by one person.
- Use on a base/ wheelchair is not intended.
- The use of the **einstein** in a motor vehicle (MV) is not intended.
- Avoid use in water, saltwater, and contact with acids, alkalis, and solvents (exception: washing/cleaning the cover).
- Do not leave users unattended in the **einstein**. If the user attempts to rise or stand, the **einstein** may become unbalanced, tip over, and the user may fall and injure themselves. The same applies to users with spasms and sudden movements.
- Ensure that the **einstein** is not used as a toy, climbing frame, or stepping stool.
Warning: Uncontrolled tipping poses a risk of serious injury.
- The **einstein** should only be lifted and transported by the handles when empty. When occupied, lifting may cause the handles to tear, posing a risk of injury to the occupant.
- Prolonged direct skin contact with the cover fabric may, in rare cases, especially due to heavy sweating, lead to skin irritations during use. Therefore, we recommend wearing loose-fitting textile clothing that covers the upper body, torso, and legs (e.g., T-shirt, long pants, socks). If unexpected reactions occur, please consult your treating physician.
- The user should regularly relieve pressure and change their sitting or lying position during prolonged unilateral sitting or lying. Partial immobilization of the muscles can



- lead to long-term weakening and shortening of the muscles or pressure zones on the body (pressure ulcers).
- If a seating shell is also used alongside the **einstein**, we recommend regular switching between the two aids. This relieves and protects pressure zones on the body from damage (pressure ulcers). Your doctor or therapist can provide further guidance on this.
 - Individuals who cannot reposition themselves should have access to nursing assistance when using the product.
 - Only supplement and combine the positioning system with other accessories such as anti-decubitus cushions upon medical or therapeutic advice.
 - Use the product only with an appropriate cover.
 - In cases of incontinence, it is advisable to use an incontinence pad or an appropriate incontinence cover. Penetrating urine and feces can render the positioning system unusable.
 - Do not place the positioning system near heat sources (fireplace, stove, heater, etc.). Avoid open flames, candles, lighters, or cigarettes near the **einstein**. Avoid use at high temperatures, such as in saunas or direct sunlight, as heat buildup can cause skin burns. High temperatures can also lead to loss of shape in the foam.
 - In cases of weight gain, growth-related body changes, or changes in the medical condition, the intended purpose of the positioning system may no longer be fulfilled. A modification or new production may be necessary. Consult your local specialist retailer (medical supply store) for fitting issues! Especially in children, growth may render the fit of the positioning aid inadequate over time and require readjustment.
 - Users with visual or cognitive impairments must have the user manual explained to them by suitable persons.

4.2 Materials Used

Special attention has been given to the materials used for the cover fabric. They have been tested and selected for skin compatibility and biological safety.

4.3 Electrostatic Charging and Discharging

Contact or friction with the cover fabric may lead to electrostatic charging. Clothing with insufficient conductivity (synthetic fibers) promotes charging. The charging process is not noticeable to humans. Generally, electrostatic fields do not pose a danger to humans.

However, with hearing aids or headphones, electrostatic charging may discharge through earplugs onto the user, posing a risk of startling and resulting in erroneous actions. Electrostatic discharges may potentially affect electronic components in sensitive electronic devices (e.g., hearing aids, insulin pumps, or other aids) that lack internal protection.

4.4 Reporting Incidents

All serious incidents occurring in connection with the product that have led or could have led to death or serious deterioration in the health of people must be reported to the specialised dealer, the manufacturer and the competent authority in the respective country.

The following authorities are responsible for receiving and processing reports of incidents involving medical devices in accordance with the EU Medical Devices Regulation (EU) 2017/745

- Deutschland: Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM)
- United Kingdom: Medicines and Healthcare products Regulatory Agency (MHRA)

- Österreich: Bundesamt für Sicherheit im Gesundheitswesen (BASG)
- Norge: Norwegian Medicines Agency (NOMA) = Statens legemiddelverk
- Sverige: Läkemedelsverket (Swedish Medical Products Agency)
- Suomi: Fimea (Finnish Medicines Agency)
- Nederlande: Inspectie Gezondheidszorg en Jeugd (IGJ)
- France: Agence Nationale de Sécurité du Médicament et des Produits de Santé (ANSM)
- Italia: Agenzia Italiana del Farmaco (AIFA)
- España: Agencia Española de Medicamentos y Productos Sanitarios (AEMPS)
- Luxemburg: Direction de la Santé - Division de la Pharmacie et des Médicaments
- Schweiz: Swissmedic (Schweizerisches Heilmittelinstitut)
- Liechtenstein: Amt für Gesundheit
- Belgique: FAGG/AFMPS (Federal Agency for Medicines and Health Products)
- Danmark: Danske Lægemiddel- og Medicinproduktstyrelse (Danish Medicines Agency)

The aforementioned authorities are responsible for receiving and evaluating reports on safety risks, incidents and adverse events in connection with medical devices in their respective countries. They work together with manufacturers, users and other relevant stakeholders to minimise risks and ensure patient safety.

5 Textile and care instructions

The protective cover of the einstein positioning system requires regular care, cleaning or disinfection, just like normal clothing. Poor hygiene can lead to infections.



IMPORTANT: The einstein positioning system consists of a foam element (foam core) and a protective cover. The foam element must not be washed, as the adhesive bonds may come apart and moisture will be stored in the foam. When cleaning the protective cover, make sure that the foam does not absorb any water. Do not use the einstein without the protective cover.

5.1 Care of the protective cover

The protective cover is removable (zip fastener) and consists of various textiles and imitation leather-based materials that are sewn together. Therefore, the following care instructions apply to the entire cover. Partial cleaning or material-specific care procedures can only be carried out on small areas by hand with a soft, slightly damp cloth (not wet) (e.g. with a microfibre cloth) if necessary.

Please note the following care instructions

- Washable at 30°C / delicate cycle (washing machine)
- Do not bleach
- Do not tumble dry
- Do not iron
- Do not dry clean
- No solvents or alcohol > 10%
- No alcohol- or chlorine-based disinfectants
- Do not use abrasive cleaning agents, hard cleaning brushes or scouring pads. These agents can damage the surface and cause colour changes
- Wipe imitation leather parts with a slightly damp cloth, do not soak
- Dry in the air only, do not place on radiators, do not use hot steamers or hairdryers for drying
- Do not dry in direct sunlight
- Only put the cover back on the foam core when it is completely dry.

The above care instructions also apply to the softshell protective covers of accessory components such as neck cushions, headrests and positioning arms.

5.2 Disinfection

Only use alcohol-free and chlorine-free disinfectants!

Suitable disinfectants include the 'Alcohol-free rapid disinfectant cleaner (item no. 800 x 310)' or the 'Cleaning set for imitation leather (item no. 800 x 301)' from mah-ATN GmbH.

6 Inspection

To ensure long-lasting enjoyment of the product, we recommend regular care and inspection of the **einstein** according to the inspection plan (see table). The **einstein** should be regularly checked for fit, functionality, defects, and wear. Please contact your specialist retailer (e.g., local medical supply store) where you purchased the product.

The inpaso maintenance protocol can be used for documenting inspections performed.

Inspection Checkpoints	Regular use by users or caregivers	at least every 6 months by a medical supply store
Follow care and cleaning instructions in this user manual	X	
Check (cover and foam element) for damage (e.g., tears, wear, strength or material fatigue) and functionality (zipper)	X	X
Check fit and accuracy ⁽¹⁾	X	X ⁽¹⁾

Table: Inspection Plan

(1) Seating or positioning aids for children should be checked for fit by your local rehabilitation specialist at least every 3 to 6 months.

7 Quality Assurance

Our aids leave our facility in perfect and ready-to-use condition. We continuously work on improvements and process optimizations to prepare the **einstein** as best as possible for you. Should any issues arise unexpectedly, please do not hesitate to reach out (Email: info@inpaso.de).

8 Product Lifespan

The **einstein** is designed for long-term use. Although special attention was given to selecting high-quality materials during development, the product is subject to natural wear and tear.

The product lifespan is the average duration of usability of the product without loss of quality. Ideally, the foam or cushion adapts precisely to the body when pressure is applied to the foam. The so-called restoring force ensures that the foam returns to its original shape when the load from lying or sitting is removed.

Various factors play a role in product lifespan: it is strongly dependent on age, usage, duration of use, and care. Every foam, cushion, or mattress eventually reaches its lifespan, becomes worn out, no longer provides seating or lying quality, and thus loses its therapeutic effect.

When the foam has permanently deformed and does not return to its original shape after the load is removed, this is referred to as "sagging." This effect results from a gradual material fatigue over the years. Due to the depressions (sagging), the foam can no longer optimally adapt to the body, and further use is thus called into question (similar to mattresses).

The product lifespan of the **einstein** is at least 5 years under normal use. We recommend having the positioning system regularly checked for further usability by a specialist retailer, considering the information in the following table "Product Lifespan."

The year of production is indicated on the product label under the cover at the bottom of the seat.

Type of Use	Average Product Lifespan
Light Use: Less than 3 hours/day	Approximately 5 years
Moderate Use: 3 to 5 hours/day	Approximately 3 years
Heavy Use: Over 5 hours/day	Approximately 2 years

Table: Product Lifespan



Important: Damaged or worn seating and positioning systems must not be used for safety reasons!

Warning: Especially in children, growth may render the fit inadequate over time and require readjustment. Please note that seating and positioning aids for children typically have a much shorter lifespan of about one to two years. Therefore, they should be checked for fit by your local rehabilitation specialist every 3-6 months.

8.1 Disposal and Environmental Protection

At inpaso, protecting people and the environment is our highest priority. To ensure proper and environmentally friendly disposal or recycling of materials after the end of the product's lifespan, you can dispose of the retired product directly through household or bulky waste.

9 Product Labeling

The product or manufacturer label is usually attached to a suitable location under the cover at the bottom of the foam element. Warning labels, stickers, tags (textile labels, side inserts), etc., must remain legible and are very important for identifying the product. They must not be removed, altered, or damaged.

10 Complaints and Warranty

For complaints or issues, please contact your local medical supply store immediately where you purchased the product. The statutory warranty for this product is 24 months from the date of purchase.

Please keep the sales documents with the date. Warning labels, stickers, tags, markings (textile labels, side inserts), etc., must remain legible and are very important for identifying the product. Warranty claims become void if they are removed, altered, or damaged. Warranty claims relate to defects in the product that are demonstrably due to material or manufacturing errors.

Unusable or defective parts will be repaired and replaced free of charge within the warranty period, considering the points mentioned below. Warranty claims must be made in writing immediately after the defect occurs, along with proof of purchase. The disputed parts must be sent to inpaso GmbH free of shipping costs. If a material or manufacturing defect is demonstrably present, defective parts will be replaced free of charge. Repairs are to be carried out exclusively by inpaso GmbH.

Inpaso GmbH cannot accept liability for defects and damages resulting from the following circumstances:

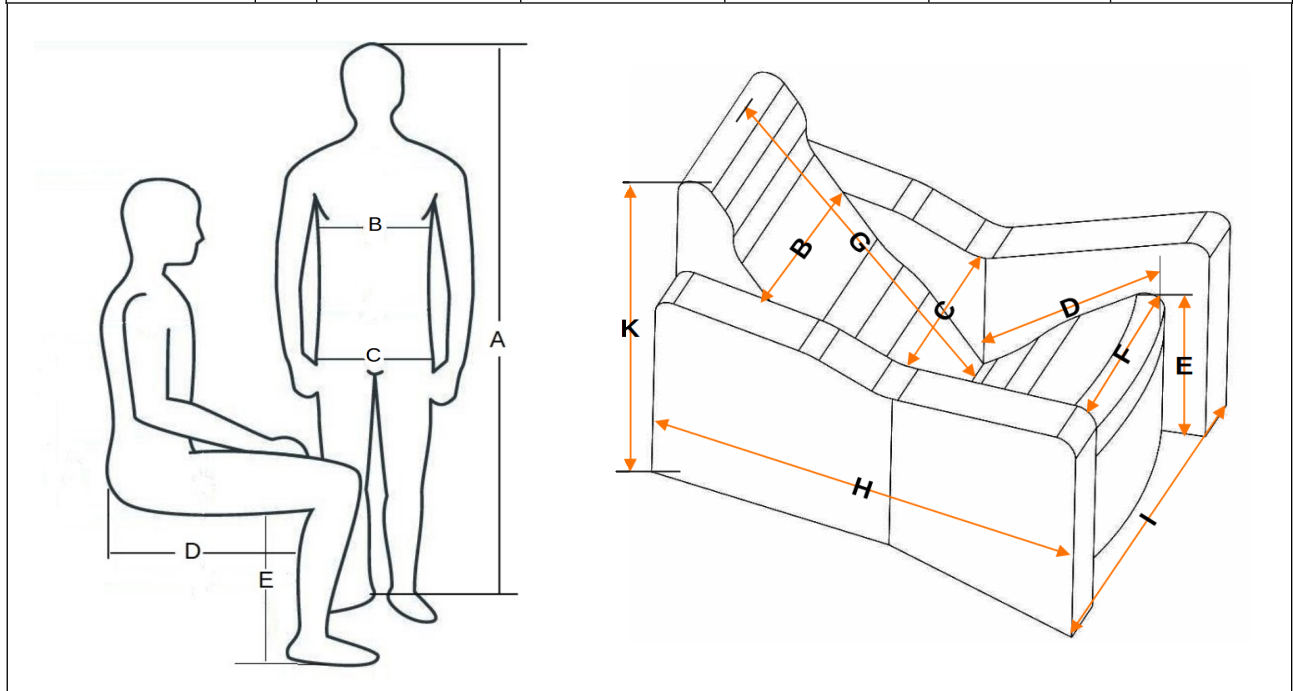
- Inadequate or improper care, cleaning, or non-compliance with the instructions in the user manual
- Use of non-original or non-approved replacement parts and accessories by inpaso GmbH
- Unauthorized modifications or interventions on the product by users or third parties
- Natural wear and tear or excessive use
- Improper use or intentional damage
- Damage resulting from improper or unprofessional assembly and/or repair
- Non-compliance with maintenance or inspection intervals or poorly performed maintenance
- Accident damage
- Fit issues arising during use due to weight fluctuations, growth, changes in medical conditions, etc.

11 Which model size is right for me?

The required model size is determined based on the user's body measurements and the size overview table. Please consult your specialist retailer (medical supply store) to determine the appropriate size.

Size Overview all dimensions in cm (product dimensions may vary due to manufacturing)

model size →		1 (XS)	2 (S)	3 (M)	4 (L)	5 (XL)
body size	A	90 - 110	111 – 130	ca. 131-150	ca. 151-170	171-180
chest width	B	20	23	27	30	40
rear seat width	C	20	23	27	30	40
seat depth	D	26	32	38	43	48
lower leg length	E	24	29	34	38	43
front seat width	F	30	36	44	50	60
back height	G	58	65	70	76	90
total length	H	60	70	79	88	100
total width	I	42	50	61	69	85
total height	K	52	59	66	74	86



12 EU Declaration Of Conformity



EU-Konformitätserklärung EU Declaration of Conformity

Die Firma inpasO GmbH erklärt als Hersteller in alleiniger Verantwortung, dass das **einstein** Schwerkraftlagerungssystem den Bestimmungen der Verordnung (EU) 2017/745 (Medical Device Regulation - MDR) entspricht. Anwendbare harmonisierte Normen wurden angewendet.

Entsprechend den Klassifizierungsregeln der MDR, ANHANG VIII ist das Objekt, auf die sich diese Erklärung bezieht, in der **Risikoklasse I** eingestuft.

Zweckbestimmung: Das **einstein** Schwerkraftlagerungssystem ist dafür gemacht, Menschen mit körperlichen Beeinträchtigungen jeglicher Art eine komfortable und gleichzeitig therapeutische Hilfe in ihrem Alltag zu geben. Er kann als primäres Sitz- und Lagerungssystem oder als zusätzliche Lagerungsalternative (z. B. in Kombination mit einer Sitzschale) eingesetzt werden.

*The company inpasO GmbH as manufacturer declares with sole responsibility that the **einstein** gravity positioning system complies with the provisions of Regulation (EU) 2017/745 (Medical Device Regulation - MDR). Harmonized European Standards have been applied.*

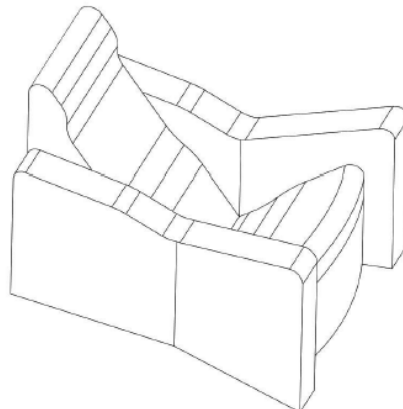
*According to the classification rules of the MDR, APPENDIX VIII, the object to which this declaration refers is classified in **risk class I**.*

*Intended purpose: The **einstein** gravity positioning system is designed to provide people with any kind of physical impairment with a comfortable and at the same time therapeutic help in their everyday life. It can be used as a primary seating and positioning system or as an additional positioning alternative (e.g. in combination with a seat shell).*

Name und Adresse des Herstellers /
name and adress of manufacturer:
inpasO GmbH
Heideweg 35
49086 Osnabrück
Germany

SRN / actor ID: DE-MF-000035766

Produkt-Handelsname / trade name: **einstein**
Artikel-Nr. / item number: 2002-100x
Basic UDI-DI: 4262430780017Y




Die Konformität wird durch die Anbringung des CE Zeichens bestätigt.
The conformity is confirmed through adjustment of CE sign.

Diese Erklärung gilt für alle Produktversionen und den dazugehörigen Zubehören und wird verantwortlich für den Hersteller abgegeben durch:

This declaration is valid for all product versions and their accessories and issued in responsibility- for the manufacturer by:

Osnabrück, 15.11.2023, J. Wördemann

Ort, Datum, Unterschrift Geschäftsführer / Place, date, signature CEO



Stand: 15.11.2023 / © inpasO GmbH, Heideweg 35, 49086 Osnabrück / www.inpasO.de / E-Mail: info@inpasO.de / Tel: +49 0541/33095615