

Dear Customer,

Thank you for your trust in the inpaso product. The inpaso 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 these instructions for use carefully before using **einstein**, as they contain important information and safety instructions. This applies in particular to care staff or persons accompanying the user.

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 inpaso team is also available to assist you (Email: info@inpaso.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.

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Symbols



Safety Notice



Manufacturer



Country of manufacture



Medical Device

2 Product Description

The **einstein** has the shape of a lowered reclining chair and utilises the physical force of gravity that is present everywhere on our planet. Since the user's centre of gravity is very low in the **einstein**, the stability of the sitting or reclining position is also increased. With the additional close lateral body support provided by the **einstein**, parts of the body (e.g. torso, extremities) are brought into therapeutically supportive positions and held there. This serves primarily to relieve pain, relieve pressure on joints, and prevent and/or treat contractures and spasms. Temporary pressure relief of individual body parts can also be achieved, e.g. in the post-operative phase.

The **einstein** is ideal for physically and mentally impaired persons, as well as for children, adolescents and adults who need support in their sitting or lying position. It can be used both at home and in care facilities due to its ease of use.

2.1 Areas of Application

Innovative solutions for healthy and comfortable posture are in demand in many areas. Physically and mentally impaired individuals in particular often require individual support in order to sit comfortably and healthily. The **einstein** is designed to provide people with physical impairments of all kinds with comfortable and therapeutic assistance in their everyday lives. 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). The seat can be individually adjusted with the aid of accessories (headrest, therapy table, pelvic belt, rocker, etc.) to provide additional support tailored to the user's specific needs.

The special design of the positioning system enables the body weight to be distributed evenly across the seating and reclining surfaces and also ensures stable and comfortable body support, especially for the user's spine and pelvis. This promotes a relaxed posture and reduces pressure on stressed areas of the body.

Relief and relaxation of affected body parts is particularly important after prolonged sitting in seat shells, and **einstein** offers exactly that. By repositioning and the accompanying change from tension to relaxation, **einstein** can help alleviate discomfort and pain and provide a soothing change. For children and young people in particular, the **einstein** can help at an early stage to develop and promote a more vital posture by regularly changing the positioning systems.

The **einstein** offers a further therapeutic aspect through physical relief and relaxation. A relieving and supportive posture can promote mobility, have a positive effect on the joints and thus contribute to improving general well-being and ensuring more joie de vivre, vitality and participation.

On medical and therapeutic recommendation, the **einstein** can also be used for further treatment/rehabilitation measures, e.g. for individual support in speech therapy 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 frame/wheelchair is not intended.
- Use of the **einstein** in a motor vehicle is not intended.
- Avoid use in water, salt water 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 sit up or stand up, the **einstein** could lose its balance, tip over and the user could fall out and injure themselves. The same applies to users with spasms and jerky movements.
- Ensure that the **einstein** is not used as a toy, climbing frame or step stool.
- Caution: Uncontrolled tipping over poses a risk of serious injury.
- The **einstein** may only be lifted and transported by the handles when empty. When occupied, the handles may tear when lifted, posing a risk of injury to the occupant.
- In rare cases, prolonged direct skin contact with the cover fabric may cause skin irritation during use, especially when sweating heavily. We therefore recommend wearing loose-fitting clothing that covers the upper body, torso and legs (e.g. T-shirt, long trousers, socks). If unexpected reactions occur, please consult your doctor.
- Users should regularly relieve pressure and change their sitting or lying position when sitting or lying on one side for long periods of time. Partial immobilisation of the



muscles can lead to long-term weakening and shortening of the muscles or pressure zones on the body (decubitus).

- If a seat shell is used in addition to the **einstein**, we recommend alternating between the two aids on a regular basis. This relieves pressure on the body and protects it from damage (decubitus). Your doctor or therapist can provide you with further information on this.
- People who are unable to move themselves should be able to seek nursing assistance when using the product.
- Only supplement and combine the positioning system with other accessories such as anti-decubitus cushions on the advice of a doctor or therapist.
- In case of incontinence, it is advisable to use an incontinence pad or incontinence cover. Urine and faeces can render the positioning system unusable.
- Do not place the positioning system near heat sources (fireplace, stove, heater, etc.). Refrain from using it at high temperatures, e.g. in a sauna or in direct sunlight, as heat accumulation can cause burns to the skin. High temperatures can also cause the foam to lose its shape.
- For safety reasons, avoid open flames, burning candles, cigarettes or similar items near the **einsteins**.
- In the event of weight gain, growth-related physical changes or changes in the clinical picture, the positioning system may no longer be fit for purpose. It may need to be modified or replaced.
- If you have any problems with the fit, please consult your local medical supply store!
- In children in particular, growth may mean that the positioning aid no longer fits properly depending on the period of use and must be readjusted accordingly.
- Users with visual or cognitive impairments must have the instructions for use explained to them by a suitable person.

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

5.1 General information

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.

5.2 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 may only be carried out on small areas by hand using a soft, slightly damp cloth (not wet) (e.g. a microfibre cloth).

Please observe the following care instructions

- Removable covers are washable at max. 30 °C by hand or on a gentle cycle (washing machine).
- Do not bleach.
- Do not tumble dry.
- Do not iron.
- Do not dry clean.
- Do not use solvents or alcohol > 10%.
- Do not use 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.
- Dry only in the air. Do not place on radiators. Do not use a hairdryer or similar devices 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.

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

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

Please retain the sales documents with the date.

Warranty claims shall lapse if product stickers, labels or markings used to identify the product are removed, altered or damaged. Warranty claims relate to product defects that can be proven to be due to material or manufacturing faults.

If a material or manufacturing defect can be proven, defective parts will be repaired or replaced free of charge within the warranty period, taking into account the points mentioned below. Warranty claims must be made in writing immediately after the defect occurs, enclosing proof of purchase. Repairs will only be carried out by inpasso GmbH or authorised companies.

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

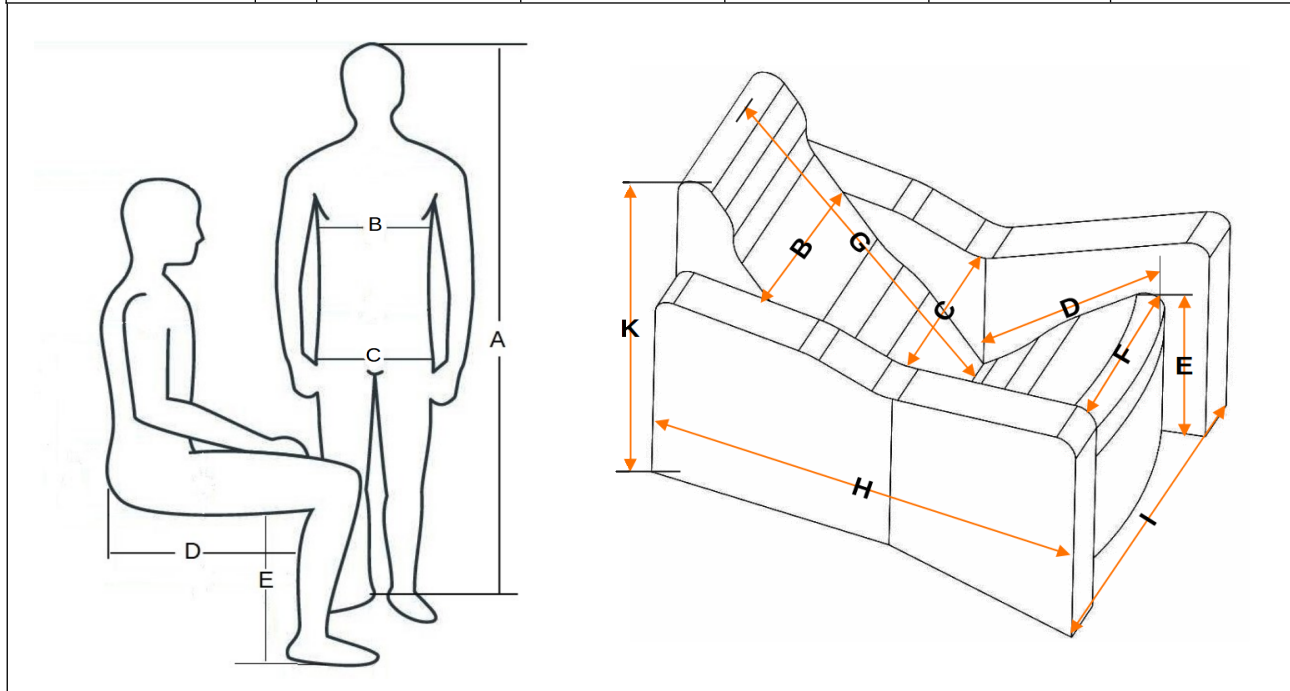
- Inadequate or improper care, cleaning, or non-compliance with the instructions in the user manual
- Use of non-original or non-approved replacement parts and accessories by inpasso GmbH
- Unauthorized modifications or interventions on the product by users or third parties
- Natural wear and tear or 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.

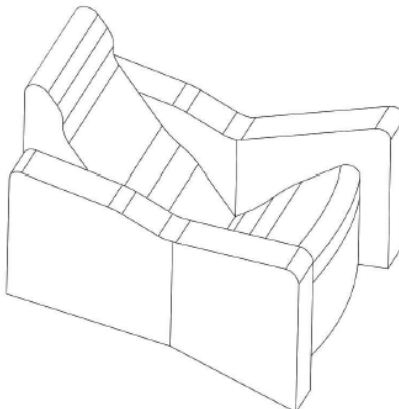
*The company inpaso GmbH as manufacturer declares with sole responsibility that the **einstein** gravity positioning system complies with the provisions of Regulation (EU) 2017/745 (Medical Device Regulation - MDR). Harmonized European Standards have been applied.
According to the classification rules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



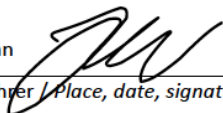
Die Konformität wird durch die Anbringung des CE Zeichens bestätigt.
The conformity is confirmed through adjustment of CE sign.

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



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