

Seating

Standing

Sleeping

Therapy

Instruction for use part 1 of 2

Safety, Care & Warranty Information

October 2020. Version 012



Read part 1 and part 2 before use.



Please always refer to the manufacturer or distributor you purchased the product from in order to obtain copies of instructions for use manuals or safety, care and warranty information.

Jenx

Every position a child adopts has an effect on their development and functional movement now and in the future.

As a leading global supplier of paediatric postural support equipment, we're committed to providing our distributors with outstanding service and after sales support, so rest assured in the knowledge that our after sales care is designed to offer support and peace of mind with every purchase from the Jenx range.

This booklet contains all the safety, care and maintenance information for your product, along with the Jenx warranty information.

Need some help? Visit www.jenx.com to find your local Supplier/Distributor details.

Alternatively email: export@jenx.com

Important Information.















These instructions must be kept with the product at all times. This product is a prescribed Medical Device. To be used only under the guidance of a Therapist or Prescribing Practitioner. You must read these instructions carefully before use.

What's in this booklet?

1. Important safety information.
2. Care and cleaning instructions.
3. Maintenance and Inspection.
 - a. Why regular checks and inspections are necessary.
 - b. Information for stores.
 - c. Monthly checks.
4. Warranty information (Jenx manufacturer's warranty).

1. Important Safety Information

The following information is for the benefit of you, the carer and the user of this Medical Device, therefore please read thoroughly before using the Device.

-  It is essential that Jenx products are thoroughly inspected at least annually and periodically reviewed by a qualified prescriber for their suitability to the user and the user's needs. The reviewer is responsible for ensuring any product is safe and stable during use with particular consideration being given to users whose clinical presentation or body size may have changed since initial provision or where the user now displays challenging behaviour or patterns of movement that may compromise the stability of the product such as exaggerated rocking.
-  Ensure that the Prescriber has confirmed that the product is correctly set up, if the product has not been set up by your Prescriber DO NOT USE.
-  Jenx Ltd. recommends that children are never left unattended whilst using this Medical Device. Children may slip or fall when unattended and may suffer serious injury. It is the sole responsibility of the person caring for the child using this Medical Device to ensure the safety of the child in the Device should they be left alone.
-  Always read the instructions before operating. Failure to read and follow the Instruction for Use, especially with regard to moving parts, may pose a risk to the user.
-  Do not use this product if you suspect or know that it is broken or faulty. Please contact your supplier.
-  This product contains small parts which could present a choking hazard to small children.
-  All Jenx Ltd. products are tested to meet current Fire Safety regulations. Always keep products away from; naked flames, cigarettes and sources of heat such as heaters.
-  Assemble product fully before use. Please contact your supplier if you have any problems.
-  Ensure that good care is taken of your product: clean regularly. Do not use abrasive cleaners. When not in use, store this product in a dry place that is not subject to extreme temperatures. Please DO NOT store this product in garages, attics or garden sheds.
-  All belts and harnesses should be used at all times. For therapy purposes it may be necessary to deviate from this rule and any deviation should be fully documented as part of a Risk Assessment or Therapy Program and all relevant staff and carers appropriately trained. Secure user with straps before adjusting product. Ensure there is a finger's width between safety strap and user to prevent over tightening or user moving to inappropriate position. Adjust straps for each user and changes of clothing. Minimum hook and loop fastener overlap: 3 inches (7.5cm) on all straps. If strap is not long enough: DO NOT USE PRODUCT.
-  This product conforms to the EU Medical Device Regulation. It has not been tested in conjunction with other manufacturer's products. Do not add any accessories other than Jenx Ltd. approved accessories to this product. Only use the charger supplied with the original product or a replacement charger supplied by Jenx Ltd. If in doubt, contact your supplier.
-  Any changes or alterations carried out by persons other than a Jenx Ltd. authorised service person will invalidate the warranty and Jenx Ltd. can accept no liability for any injury or damage so caused.
-  All Jenx Ltd. products are Medical Devices and are sold on the understanding that they will be prescribed, issued and maintained in line with current national device management guidelines.
-  Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the country in which the user and/or patient is established.

Safety Labels

There are various labels and symbols on your Medical Device that indicate safety instructions and also the Serial Number and CE Certification of the Device. Please make sure you are familiar with these.

Serial Number/ CE Certification

The serial number is written on the CE label attached to the product (see picture). Please quote this number on all correspondence.

The diagram shows a CE label with the following fields and markings:

- Unique Device Identifier (UDI):** (01) 0 5056235 20000 0, (11) 210101, (10) 123456, (21) JX10000PRO01, (240) PROCODE
- Date of Manufacture:** Date: 01/21
- Serial Number:** SN: JX10000PRO01
- Manufacturer's Details:** Jenx Limited, Wardsend Road, Sheffield, S6 1RQ, UK
- EU Authorised Representative:** EC REP, Jenx Limited, Building, Street, Town, AB 123, Country
- Medical Device Product Identifier:** PROCODE
- CE Marking:** CE
- UK Conformity Assessed Marking:** UKCA
- Jenx Logo:** Jenx Positioning for life

Product Labels

Each Jenx product has a number of pictorial safety labels attached, please refer to the explanations below.



Attention / Warning.



Do not leave child unattended.



Please read Instruction for Use.



DO NOT USE as a mobility device
Never use product on rough ground or uneven surface.



Only for indoor use.



User Weight Limit (changes per model and size).



Always fasten and adjust positioning straps and belts to suit the child.
Adjust to suit changes in clothing. Allow one fingers width between the belt and the child.



Conforms to CE Marking Regulations Medical Device Regulation (MDR) (EU) 2017/745.



Conforms to UKCA Marking Regulations.



Refer to Linak handbook on WEEE Disposal requirements.

2. Care and Cleaning Instructions

Fabrics, Vinyl and PU (polyurethane)

- Minor spills can be removed with a damp cloth.
- Spillages should be removed as quickly as possible. Dab the stain, do not rub.
- Do not over wet the stain.
- Do not use organic solvents, dry cleaning fluids, abrasive cleaners or industrial bleaches.
- Antibacterial spray or wipes can be used.
- Always ensure that the product is dry before use.
- Some fabrics may be suitable for cleaning in a washing machine and / or tumble dryer. See label for further information.
- If disinfection is necessary, clean with a solution of disinfectant with a damp cloth.
- When using bleach a 5% (50,000ppm) solution is acceptable. A 5% solution of alcohol is also suitable.

Metal Frames, Plastic and Coated Parts

- For deep cleaning, a low pressure steam cleaner can be used.
- Do not use organic solvents, dry cleaning fluids, abrasive cleaners or industrial bleaches.
- Soap and water or antibacterial spray can be used.
- Daily cleaning: Wipe framework down with a damp cloth as necessary.

Wooden Products and Parts

- For deep cleaning, a low pressure steam cleaner can be used.
- Do not use organic solvents to clean Jenx Products.
- Soap and water or antibacterial spray can be used.
- Check for breaks or splintering of the wood before re-issuing.
- Daily cleaning: Spray polish or wax polish can be used.

Batteries, Actuators and Gas Springs

- Use damp cloth only. To avoid degreasing of the piston rod, the actuator should be retracted to minimum stroke before cleaning.
- Do not steam clean.
- Do not submerge in water.

- The following directions regarding cleaners and disinfectants must be complied with:
- They must not be highly alkaline or acidic (pH value 6-8).
- They must not contain caustic agents.
- Their contents must not be able to change the structure of the surface or adhesion of the plastic.
- They must not break down grease.

3. Maintenance & Inspection

All Jenx Ltd. products are expected to have a life of 5 years.

Each Jenx Ltd. product must be checked and inspected in line with the advice given in the relevant product IFU. Failure to complete these regular checks will invalidate your warranty and pose a risk to the user. Every year, each product must be thoroughly inspected by a person competent to assess faults and have the ability to either rectify any faults discovered, or to outsource this requirement.

The maximum period that should elapse between full product inspections is 1 year. After 3 years, or from purchase where a product is subject to heavy use*, this should be increased to six monthly full inspections.

Daily Checks:

Daily checks of the equipment should be carried out by carers. These checks are not technical but a basic understanding of the product is needed. Multiple daily checks may be needed in schools or therapy rooms where the products are used by multiple users. The checks should include the following points:

- Replace any lost or worn washers or bolts.
- Check tray for damage. Ensure that the tray edging is secure and that the tray is clean and free of any rough or sharp corners.
- Check all upholstery for any signs of wear and tear.
- Brush hook and loop fastener to remove fluff.
- Check straps for fraying and missing or broken buckles.
- Clean any stains or spillages..
- Contact your Supplier/Distributor/Jenx Ltd. if any accessories not approved by Jenx Ltd. have been attached to the product. Unauthorised accessories may affect the safety of this product and invalidate your warranty.
- Check that gas spring levers are not bent. Do not use the product if any levers are bent. Contact your supplier to arrange replacement.

*More than 4 hours a day continuous use, or used by children with excessive movement or extension and within the top 20% of the weight or size limit.

Monthly Checks:

We recommend that on a monthly basis a competent person who is familiar with this piece of equipment and who has been trained in its use should carry out a more detailed check.

- Check that all nuts and bolts are in place and secured.
- Check that all mechanical movements operate fully.
- Check the structure of the product for signs of fatigue.
- Castors: Lift base and check each wheel to ensure it is not loose or worn. Remove any grease or dirt that has built up on the wheels, check that the brake stops the wheels rotating (where applicable).
- Check gas springs for normal operation and resistance. Slow descent (creeping) of the gas spring can be checked by observing the position of the unit over a period of time.
- Check that gas spring levers are not bent. Do not use the product if any levers are bent. Contact your supplier to arrange replacement.

This product must be thoroughly inspected by a qualified person at least annually. Please read note overleaf regarding products over 3 years old, or products subject to heavy use*.

*More than 4 hours a day continuous use, or used by children with excessive movement or extension and within the top 20% of the weight or size limit.

Maintenance & Inspection information and guidelines for Stores:

Stores should follow the national competent authority guidelines for the recording, issuing, servicing or repairing of products in their charge. Check the competent body website for the latest bulletins.

- Structure: is the product structurally sound, no wobbles or loose parts?
- Safety: is the product safe and fit for use?
- Straps: are the straps in good condition and not showing any signs of wear?
Check straps for fraying and missing or broken buckles. Ensure all webbing end clips are in place.
- Stability: is the product stable on an even surface, no rocking?
- Screws, Nuts and Bolts: Are there nuts and bolts missing or damaged?
- Castors: are the castors in good order? Do swivels and brakes work?
- Springs: do all gas springs work and hold pressure and weight?
- Sandals: are the sandals in good condition? Do straps and hook and loop fastener show signs of wear?
- Upholstery and PU: is the upholstery and PU in good, clean condition with no rips, wear or gaping of the cushions?
- Steel, Plastic and Woodwork: is the steel, plastic and wood work in good order?
Check for deformities, splinters or breaks.

If there is any doubt about the safety of the product, do not hesitate to contact your supplier/Jenx Ltd. for advice. Products should be thoroughly decontaminated in line with national guidelines prior to inspection, storage and re-issue.

Jenx Ltd. can take no responsibility for re-issue of products.

Re-issue of Jenx Ltd. products

Jenx Ltd. products are usually assessed for an individual user, therefore the following points must be adhered to prior to the re-issuing of any Jenx Ltd. products to a new user. Please note all Jenx products are expected to have a life of 5 years.

- Check with issuing Therapist that the product is standard and no special attachments or modifications have been made. If modifications have been made: contact Jenx Ltd. for advice.
- Check that the product has been fully cleaned, taking into account the condition of the fabric and the foam inside.
- Check that all hand wheels and levers are in good condition and fitted securely.
- Check the product and any accessories fully for any sign of wear and tear or distortion.
- Check that all the functions of the product are working correctly e.g. tilt, height adjustment or back recline, etc.
- Always ensure that the Instruction For Use stays with the product and is passed on to the new user. For new sets of instructions please email export@jenx.com or visit www.jenx.com.
- If the product is being delivered, always ensure that the product is packed securely.
- We strongly recommend that all straps and harnesses are replaced with new ones before re-issue. Only genuine Jenx Ltd. parts should be fitted.

This product must be thoroughly inspected by a qualified person at least annually. See earlier for advice on daily/monthly checks.

Note:

Each Jenx Ltd. product, whether re-issued or not, must be checked and inspected in line with the advice given in this Safety, Care and Warranty Information booklet. Failure to complete these regular checks poses a risk to the user. Every year, each product must be thoroughly inspected by a person competent to assess faults and have the ability to either rectify any faults discovered, or to outsource this requirement. The maximum period that should elapse between full product inspections is 1 year. After 3 years, or from purchase where a product is subject to heavy use*, this should be increased to six monthly full inspections.

Jenx Ltd. can take no responsibility for re-issue of products.

4. Jenx Manufacturer's Warranty

The Instruction for Use of this product should be followed carefully. It is impossible to eliminate all risks inherently associated with the use of this product. Product failure or other unintended consequences may result because of such factors as improper storage, use or maintenance, unauthorised and inappropriate alteration or repair or improper or violent treatment, excessive strain, use of improper replacement parts, or because of normal wear and tear, all of which are beyond the control of the Manufacturer and Seller. Buyer and User assume all such risks.

Manufacturer and Seller warrant that this product will be free from defects in material and workmanship for a period of 24 months from the date of purchase and is reasonably fit for the purposes stated in the Instruction for Use, subject to the inherent risks under normal use conditions. This Warranty does not extend to the use of the product contrary to the Instruction for Use, or under abnormal conditions, or under conditions not reasonably foreseeable to or beyond the control of the Manufacturer or Seller. Buyer and User assume the risk of any such use. **MANUFACTURER MAKES NO WARRANTIES OF SATISFACTORY QUALITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.**

In no event shall Manufacturer or Seller be liable for any incidental, consequential or special damages resulting from the use of this product. **THE EXCLUSIVE REMEDY OF THE USER OR BUYER AND THE EXCLUSIVE LIABILITY OF MANUFACTURER AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR THE REPLACEMENT OF THE PRODUCT.**

Manufacturer and Seller offer this product, and Buyer and User accept it, subject to the foregoing conditions of sale and limitations of warranty and liability, which may not be modified except by written agreement signed by a duly authorised representative of the Manufacturer.