FSG200 Portable Gantry





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1.0 <u>Safety Instructions and Warnings</u>

1.1 Introduction



Please read and understand this manual in its entirety before using your FSG200 free-standing gantry.

The information in this manual is important for the safety of anyone near the FSG200 product and must be read and understood to help prevent injuries. It is also crucial to the proper operation and maintenance of the gantry.

Should any questions arise from reviewing this manual, contact your local authorised representative.

Failure to comply with warnings in this manual may result in; injury to the operator and/or client and/or damage to the freestanding gantry or related components.

Store this manual with the documents included with the FSG200. Contents of this manual are subject to change without prior written notice.



Do not attempt to use this equipment without first understanding the contents of this manual.



Unauthorised modifications on any Prism Medical UK product may affect its safety. The manufacturer will not be held responsible for any accident, incident or deficiencies of performance that occur as a result of any unauthorised modification to its products.

1.2 Manufacture

The Gantry is manufactured at the address below:



Prism Medical UK Unit 1, Tir Llwyd Industrial Estate, St Asaph Avenue, Kinmel Bay, Conwy, LL18 5JZ Telephone number: 01924 840 100

1.3 European Authorised Representative

The address of the European Authorised Representative for this product:



European Healthcare & Device Solutions (Ireland) Ltd. Stratton House, Bishopstown Road, Cork, Ireland. T12 Y9TC. Telephone number: +353(86)2280846

1.4 Symbols Used

The Table below includes all Symbols from BS EN ISO 15223-1:2016 that can be found in this Manual and on the Product and what they represent. Refer back to this Table when you are unsure of what a symbol represents.

ĺĺĺ	Consult instructions before use	\triangle	Caution – see instructions for use
	Manufacturer	SWL	Safe Working Load represents the maximum load rated for safe operation
THIS WAY UP	Packaging indicator – This way up		Date of manufacture
SN	Serial number	Ţ	Packaging indicator – Keep dry
X	Please observe local laws on recycling		For internal use only
X	Temperature range	MD	Medical Device
<u>%</u>	Humidity range	EC REP	European Authorised Representative
	Atmospheric pressure range	REF	Catalogue number

Table 1

1.5 <u>Contraindications / Limitations</u>

There are no known "contraindications" associated with the usage of the FSG200 Free-standing gantry, provided they are used as per manufacturer's recommendations and guidelines. However, it is recommended that a client specific assessment is completed by a trained and knowledgeable health care professional to determine the method of transfer.



Prism Medical UK does not recommend a required number of care givers for the use of our products. This information and recommendation can only be provided after a thorough personalized, case specific assessment, as there are many factors that can influence these decisions.

1.6 Intended Use



The FSG200 rail system together with a portable hoist, shall be used for transferring an elderly or disabled person; e.g. in the private homes sector.

The free-standing rail system is a portable rail system which can be set up practically anywhere and requires no mounting on walls, ceiling or to the floor. The free-standing rail system is length and height adjustable.



The device is used under instruction, and the operation of the aid is undertaken by a trained carer. A risk assessment must be performed before using any other manufactured slings or Gantry, to ensure safe use can be established.

- The FSG200 is intended to be installed on a flat and levelled surface prior to use.
- The FSG200 must be installed only by persons authorised by Prism Medical UK or who have the rights to install and commission the Gantry safe for use.
- Under no circumstance should the FSG200 and its associated Hoist, be put in control of a person who has not been properly trained in the use of the FSG200. Failure to adhere to this warning may result in serious injury to the operator, and / or the individual being transferred.
- In facilities where more than one operator will be responsible for using the free-standing gantry and hoist it is imperative that all such members be trained in the proper use. A training program should be established by the facility to acquaint new operators with this equipment.
- The FSG200, and associated hoist are not toys. Do not use it for unsafe practices. Do not allow children to play with the Hoist or any of its components.
- Your guarantee is void if persons unauthorised by Prism Medical UK perform servicing work on the FSG200.
- To maintain optimum function, the Free Stand Gantry should be inspected and maintained on a regular basis. See section 'General Inspection, Maintenance and Cleaning' within this user manual.
- The FSG200 and its associated hoist are intended only for transferring of a person. Prism Medical UK will not be responsible for any damage caused by the misuse, neglect or purposeful destruction of the Unit, and/or its associated components.
- The FSG200 and its associated parts are certified to a maximum load of 200kg. Do not exceed the maximum rated load of any of the components.
- Ensure that a clear space is maintained around the FSG200. Before performing a transfer, check for and move all obstacles out of the way.
- Your Product is for aiding and transferring a patient. Do not use it, or allow it to be used, for any other purpose.
- In areas where children are prone to be present be vigilant when carrying out a transfer.

- To reduce the risk of unintended use, when the FSG and Hoist is not in use, remove the sling(s) from the product to prevent entrapment or strangulation should the device be tampered with.
- Between FSG200, Hoist, Spreader Bar and Body-Support Unit, the lowest maximum load shall always be used.



You may need to seek specialist advice on how to assist some people with specific moving and handling needs. Sources of advice include, but is not limited to, professional bodies and organisations, occupational therapist, physiotherapists, manual handling advisers and ergonomist with experience in health and social care.

1.7 <u>Warning Notes</u>



Your Free-Standing Gantry has been manufactured and tested to exceed BS EN 10535:2006. This does not mean that it can be used without care. ALL OPERATORS should have read the operating instructions and appreciate this warning section.

- 1. FSG200 are less stable on sloping surfaces. Prism medical recommend that the install of the FSG200 is on a flat and level surface.
- 2. ALL FSG200 are dangerous to the person being transferred when used without training.



If, during the use of this device or as a result of its use a serious incident has occurred, please report it to the manufacturer and to your national authority

1.8 Operating Environment

The FSG200, Free-Standing Gantry is suitable for use within the professional health care facility environment as well as the following listed:

- Home environment
- Hospital and/or treatment centre
- Residential care home
- Education institute

The FSG200 is not suitable for any special environments.

This product is not intended to be used in environments where there are rapid changes in the environmental temperature and humidity during intended use.

1.9 Labeling

The serial number label shown in figure 1 is located on both support posts. The information which is present is:

- Manufacturer address
- Manufacturing Date
- Reference number
- Serial number
- Safe working load





Figure 1



2.0 <u>Components / Key Parts</u>

Please see below to familiarise yourself with the components of the FSG200 Gantry System. The image below show the contents of the free standing gantry. If you have not received all the components contact Prism Medical UK dealer immediately – contact details are provided on the last page of this manual.

ltem	Description
1	Adjustable track
2	Support Post
3	Foot
4	Star handle bolts
5	User Manual







3.0 Final Inspection

Before first operation of the FSG200:

- Confirm that the FSG is level.
- Ensure that the safety pins are installed in both support posts.
- Ensure that all fixing point are all tight and no parts are broken or bent.
- The feet are located on a stable, level surface.
- Make sure that the trolley moves easily from one end of the track to the other.
- Ensure that the adjustable track is located at the correct length.
- Ensure that attachment procedure of their portable hoist is carried out correctly, in accordance with manufactures installation instructions.



Prior to each lift, this will be completed by the user, the FSG200 and associated hoist, accessories and sling(s), must be visually inspected. Refer to the hoist, accessory and sling user guides for specific details regarding their inspection.



Prior to mounting the portable lift onto the trolley of the FSG200, please read the owner's manual of the portable lift. Be sure that the instructions on the use of the lift and any accessories, such as slings are thoroughly understood before attempting to use them with the FSG200.

Failure to comply with this may result in injury to the individual being lifted and/or the caregiver or damage to the lift and/or the FSG200.

Following the instructions for the portable lift, attach the carabiner, (or other similar attaching device) located at the end of the lift strap. Be sure that the carabiner is securely attached to the trolley prior to proceeding with the transfer.

Proceed to transfer the individual in the manner described in the owner's manual for the portable lift and sling. When the transfer is completed the lift may be removed from the trolley.



Figure 3



4.0 Technical Specification

4.1 FSG Gantry Dimensions

All dimensions below are shown in millimetres.



Figure 4

4.2 Specifications

Dimensions	
Maximum Height	2508mm
Lowest Height	2141mm
Maximum Length	3387mm
Minimum Length	2445mm
Internal maximum clearance	3052mm
Internal minimum clearance	2102mm

Table 3 Weights	
Track	6.8 kg
Support Post & foot	9.1 kg
Ful product	22.7 kg

Table 4

Operational Forces	
Latch	3N
Moving Trolley – with hoist (0Kg)	6N
Moving Trolley (200kg)	97N

Table 5



4.3 Expected Product Lifetime

10 yrs. depending usage and compliance to maintenance, servicing and LOLER inspections.

4.4 Standards Applied

The standards that have been applied to the device are as follows:

• EN 10535:2006 Hoists for the transfer of disabled persons. Requirement and test methods

5.0 Environmental - Storage and Operating Conditions

The Prism Free-Standing gantry is intended for internal use within normal environmental conditions.



It is not intended to be used in environments where there are rapid changes in the environmental temperature and humidity during use.

5.1 Normal operating conditions

+5°C to +40°C (41°F to 104°F) at a relative humidity between 15% to 90% RH, non-condensing but not requiring a water vapour pressure greater than 50hPa and atmospheric pressure between 700hPa to 1060hPa.

5.2 Shipping and storage conditions

-25°C to +5°C (-13°F to 41°F) with any humidity level.
+5°C to +35°C (41°F to 95°F) at a relative humidity up to 90%.
+35°C to 70°C (95°F to 158°F) non-condensing at a water vapour pressure up to 50hPa.

6.0 Disposal



When the FSG200 has completed its life cycle and can no longer perform to its intended use safely the Freestanding Gantry must be disposed correctly. The following specifies the importance of correct disposal procedure including local laws and being environmentally friendly.

Please observe the local laws on recycling and respect the current laws for disposal within the community the device is being used within. If there is any uncertainty of the below guidelines, contact your local authorities to determine the proper method of disposal of potentially biohazardous parts and accessories.

The relevant components utilised in the manufacture of the device that can be recycled at the end of the device life are:

Fully recyclables:	Consideration when Recycling:
Aluminium structure (Track, support posts, feet)	Plastic parts (end caps, foot covers)
Steel trolley	
Initial packaging of the device (cardboard)	
Metallic fixing – screws etc.	

Table 6



The product may be contaminated and has to be disinfected before recycling or disposal. See section 10.3 'Cleaning' for details of how to do this.



7.0 Fault Finding

If a problem arises with the Gantry, the Table below will hopefully assist in determining the fault and what actions you can take. If the fault cannot be found or the fault is found and the action guide does not provide a fix (e.g. – a damaged wire would need replacement), contact your local Prism Medical UK authorised dealer immediately, a service engineer will be required to repair the Hoist. Contact details can be found on the last page of this manual.

Fault	Action
Trolley does not transverse	 Check the track profile is clean and free from any obstructions. Check the wheels are free and regular servicing has been undertaken. Check the telescopic track profiles are all aligned.
Hoist transverse without assistants	 Check the FSG is located on a level surface. Check that the installation of the FSG has been carry out correctly. Check the traversing track is level.
FSG is unstable	 Check the FSG is located on a level surface. Ensure all foot contact points are in contact with the floor. Ensure that track attachment star handle bolt is all secure.

Table 7

8.0 General Inspection, Maintenance and Cleaning

8.1 Service



No service is to be carried out on a Prism FSG200, while transferring a person to reduce the risk of injury. Service must be completed by a Prism Medical UK authorised Service Engineer. Do not attempt to service the product yourself, or warranty is void.

To ensure the safety and continued good function of your Hoist, routine service must be performed on your FSG200. Service should be completed by a Prism Medical UK approved service engineer every 6 months to ensure the products required standard is maintained. The service history of the product should be documented each service in the Service Log at the back of this User Manual.



When the Gantry is serviced, the 6-month service checklist must be completed for the FSG200.

Service Manual Document Number: 995018

Spare Parts Manual Document Number 992018

The Service must be completed every 6 months after installation of the Hoist to comply with LOLER Regulations.

The Prism FSG200 Gantry has an expected Service Life of 10 Years.

Contact your local authorised Prism Medical UK dealer if you:

- Need more information.
- Have any questions about the use or service of your Gantry.
- Notice any change in the performance.
- Want to report an unexpected occurrence.
- Want to arrange a service.
- Need to ascertain necessary information for replacement parts and components.

Contact details of your local Prism Medical UK dealer are shown on the last page of this manual.

8.2 Inspection

Check List before Lise

Inspection is to be completed prior to each use by the user of the Gantry.



Should any of the components in the table below fail the inspection, DO NOT use gantry. Contact your local authorized dealer for service – contact details are on the last page of this manual.

Ensure all component inspections in the Table below are completed prior to each use of the Hoist.

Check List before Use	
Component	Service/Inspection required
Generic	Visual inspection of the external of the Gantry. Significant damage that may affect
	the function of the Gantry along with a clear safety hazard is unacceptable.
	Check the Labelling on the Gantry to ensure they are all still legible, this includes
	the Serial Number and other important markings. If labels are not legible, then
	contact your local authorised dealer immediately.
	Check all main nuts and bolts to see if they are loose, If they are not tight or you
	have concerns, then contact your local authorised dealer immediately.
Certification	An authorised/competent service company or person will issue a test certificate
	after satisfactory completion of the LOLER inspection. The certificate will be valid
	for 6 months.
Telescopic track	Check the smooth opening and closing of the track.
Telescopic legs	Ensure the telescopic legs are fully engages into each foot
Track	Check the attachment of the track to the Legs, ensure all fixing points are secure
	and free from wear.
Trolley	Check the trolley rotates and traverses freely. Check the central pivot bolt and
	nylon lock nut for excessive wear. Check the fixing point for excessive wear and
	inspect the hooks for any damage, sharp edges and excessive wear.

Table 8

8.3 <u>Cleaning</u>

Please follow the cleaning guidelines below on cleaning and disinfecting the Gantry.

8.3.1 General cleaning



It is recommended to clean the FSG200 and accessories before the use by a different patient, reducing the risk of cross–contamination.

The exterior of the FSG200 can be cleaned using a damp soapy cloth for general cleaning duties. Please ensure the cloth is damp and not wet. Ensure the exterior of the device is dry after cleaning. Dry using a clean dry cloth.



8.3.2 Disinfecting (if necessary)

Should the Gantry require a more thorough clean, the use of the Actichlor[™] disinfectant product (which is widely available in tablet form and used throughout the health care industry) is recommended.



Dilution chart

Follow the manufacturer's safety instructions for the use of the cleaning product before use to ensure safe use for the operator and the patient.

Ensure the cloth is damp before the cleaning process.

Application is through a clean damp cloth applied to wipe the device down. Use in the following dilutions to ensure an effective clean:

- Actichlor[™] dissolvable chlorine tablets provide a concentration of 1000 ppm of available chlorine (0.1%) per 1 tablet
- 1 tablet (1.7g formed tablet (x1)) will create a virucidal solution, diluted in 1 litre of water to provide effective means to clean a "dirty" device. This is also ideal for use after an outbreak of the Norovirus/winter vomiting and can be used as a precaution against C.Diff. It is effective against viruses, bacteria, spores, yeasts and moulds.
- The contact time against the outer components of the device should be for 5 minutes to prevent any virucidal infections without a degradation to the functionality of the device. 5 minutes is a recommended contact time. The device can withstand a longer contact period but the 5 minute recommendation as a minimum must be followed to provide an effective cleaning regime.
- Blood spills should be dealt with by an increased concentration of the solution please refer to the instructions on the manufacturers product labelling.

Product used as	Device condition	Concentration (ppm)	Dilution qty* (l)	Tablets per 1l (0.26gal)	Contact time (minutes)
Bactericidal	Clean	200	5 (1.32gal)	1	1
	Dirty	1000	1 (0.26gal)	1	5
Yeasticidal	Clean	200	5 (1.32gal)	1	1
	Dirty	1000	1 (0.26gal)	1	5
Fungicidal	Clean	2000	1 (0.26gal)	2	15
	Dirty	5000	1 (0.26gal)	5	15
Mycrobactericidal	Clean	1000	1 (0.26gal)	1	15
	Dirty	5000	1 (0.26gal)	5	15
Virucidal	Clean	500	2 (0.53gal)	1	5
	Dirty	1000	1 (0.26gal)	1	5
Sporcidal (C.Diff)	Clean	1000	1 (0.26gal)	1	10
	-	-	-	-	-
Sporcidal	Clean	5000	1 (0.26gal)	5	10
	-	-	-	-	-

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When diluted in water, one tablet gives 1000ppm of available chlorine.

• The concentration of the solution depends upon whether the object being cleaned is noticeably dirty (indicated in the table by "Device condition".

Table 9



Handling and storage safety precautions when using this cleaning agent:

Advice on Safe Handling

Avoid contact with skin and eyes.



Do not breathe dust/fumes/gas/mist/vapours/spray. Use only with adequate ventilation. Wash hands thoroughly after handling.

Mixing this product with acid or ammonia releases chlorine gas.

Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice. Remove and wash contaminated clothing before re-use. Wash face, hands and any exposed skin thoroughly after handling.

Conditions for safe storage, including and incompatibilities



Keep out of reach of children. Keep container tightly closed. Store in suitable labelled containers. Storage temperature: 0-25°C (32-77°F).

Individual protective measures

Hand protection: Gloves

Dissolve

Dissolve in cold water – With no agitation, 1 tablet will take approximately 10 minutes to fully dissolve in the water used.

The information above has been extracted from the Actichlor[™] MSDS (Manufacturers Safety Data Sheet). For a full review of the data please follow the link below:

http://www.nhsggc.org.uk/media/236215/msds-actichlor-plus.pdf

9.0 <u>Warranty</u>

This guarantee does not affect or in any way limit your Statutory Rights.

- 1. Prism Medical UK guarantees the Prism FSG200 Gantry, supplied as new, against failure within the period of 12 months from the date of purchase by virtue of defects in material or workmanship.
- 2. The liability of Prism Medical UK under terms of this guarantee shall be limited to the replacement or the defective part(s) to the sales distributor, dealer, agent, person or entity which purchased the equipment from Harvest. In no event shall Prism Medical UK incur liability for any consequential or unforeseeable losses.
- 3. This equipment guarantee shall be void if the equipment is not serviced by Prism Medical UK or its authorized agents, in accordance with manufacturer's recommendations, or if any unauthorized persons carry out work on the equipment.
- 4. This guarantee does not apply to failure attributable to normal wear and tear, damage by natural forces, user neglect or misuse or to deliberate destruction.
- 5. Do not attempt to service the product yourself, or warranty is void.



10.0 <u>Service Record History</u>

Complete this section after each service, repair inspection and/or maintenance.

Date: Time:
Service Type: Periodic inspection Monthly inspection 6-month inspection Repair Yearly inspection Other
Completed by:
Remarks & Action Taken:
Device left in a safe usable condition: YES. NO (if "NO" explain in remarks the action taken)
Date: Time:
Service Type: Periodic inspection Monthly inspection 6-month inspection Repair Yearly inspection Other
Completed by:
Remarks & Action Taken: Device left in a safe usable condition: YES. NO. (if "NO" explain in remarks the action taken)
Date: Time:
Service Type: Periodic inspection Monthly inspection 6-month inspection Repair Yearly inspection Other
Completed by:
Remarks & Action Taken:
Device left in a safe usable condition: YES. NO. (if "NO" explain in remarks the action taken)



Date: Time:
Service Type: Periodic inspection Monthly inspection 6-month inspection Repair Yearly inspection Other
Completed by: (printed name)
Remarks & Action Taken:
Device left in a safe usable condition: YES. NO. (if "NO" explain in remarks the action taken)
Date: Time:
Service Type: Periodic inspection Monthly inspection 6-month inspection Repair Yearly inspection Other
Completed by: (printed name)
Remarks & Action Taken:
Device left in a safe usable condition: YES. NO (if "NO" explain in remarks the action taken)
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User notes:

Dealer/service contact details:

Prism Medical UK Contact details:

Address: Unit 1• Tir Llwyd Industrial Estate • St Asaph Avenue • Kinmel Bay • Conwy • LL18 5JZ

Telephone Number: 01924 840 100

Disclaimer

While every effort has been made to ensure the accuracy of information contained in this assembly and installation manual, no liability can be accepted by Prism Medical UK for any errors or omissions. Prism Medical UK operates a policy of continuous improvement. Specifications and other data are subject to change without notice.







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