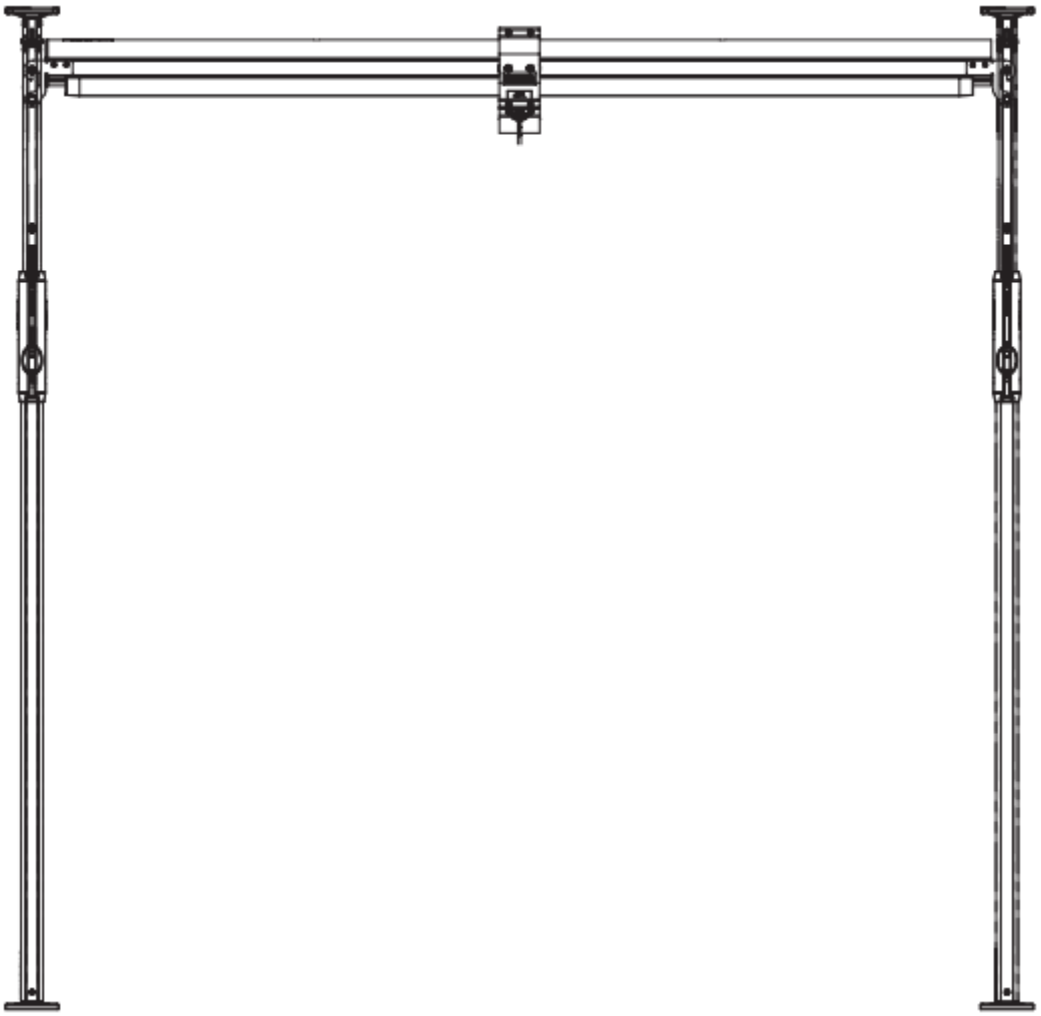
Pressure Fit 200 Gantry



User Manual

Doc No. 999091

Revision of document: A
Revision Date: 02.08.2022

Contents

1.0 Safety Instructions and Warnings

1.1 Introduction

Please read and understand this manual in its entirety before using your Pressure Fit System 200.

The information in this manual is important for the safety of anyone near the PFS 200 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 gantry or related components.

Store this manual with the documents included with the PFS200. 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.

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

Table 1

1.5 Contraindications / Limitations

There are no known “contraindications” associated with the usage of the PFS200 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

For internal use only.

The PFS200 gantry system together with a portable hoist, shall be used for transferring an elderly or disabled person; e.g. in the private homes sector as a portable/temporary track system.

The gantry system is a portable rail system which can be set up practically anywhere but requires a ceiling to be pressurised up against. The gantry system should only be used on solid ceilings. Do not use with a false ceiling or any other fragile construction. The rail system is length and height adjustable, to suit all needs regarding installation and accessibility.

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 gantry, to ensure safe use can be established.

- The PFS200 is intended to be installed on a flat and levelled surface prior to use.
- The PFS 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 PFS200 and its associated Hoist, be put in control of a person who has not been properly trained in the use of the PFS200. 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 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 PFS200, 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 PFS200.
- To maintain optimum function, the gantry should be inspected and maintained on a regular basis. See section ‘General Inspection, Maintenance and Cleaning’ within this user manual.
- The PFS200 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 PFS200 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 PFS200. 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 PFS 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 PFS200, 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 Warning Notes

Your 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. PFS200 are less stable on sloping surfaces. Prism medical recommend that the install of the PFS200 is on a flat and level surface, as well as a flat and level ceiling.
2. ALL PFS200 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 PFS200 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 PFS200 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 Components / Key Parts

Please see below to familiarise yourself with the components of the PFS200 Gantry System. The image below show the contents of the 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.

Item	Description
1	Adjustable track
2	Support Post
3	Foot
4	Post Pins
5	Pin “R” Clips
6	Ceiling Plates
7	User Manual

Table 2

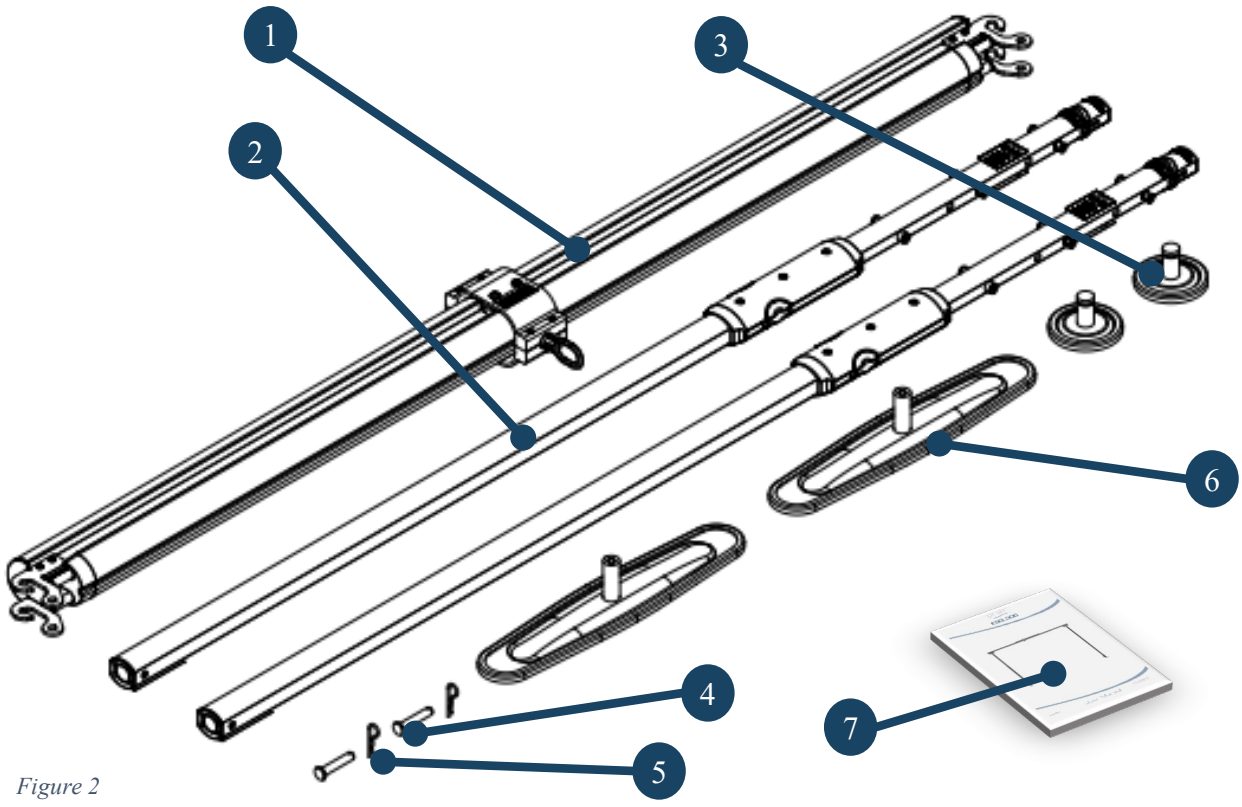


Figure 2

3.0 Final Inspection

Before first operation of the PFS 200:

- Confirm that the PFS is level. This can be done using the built in spirit 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 and ceiling.
- 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 PFS200 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 PFS200, 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 PFS200.

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 PFS200.

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.

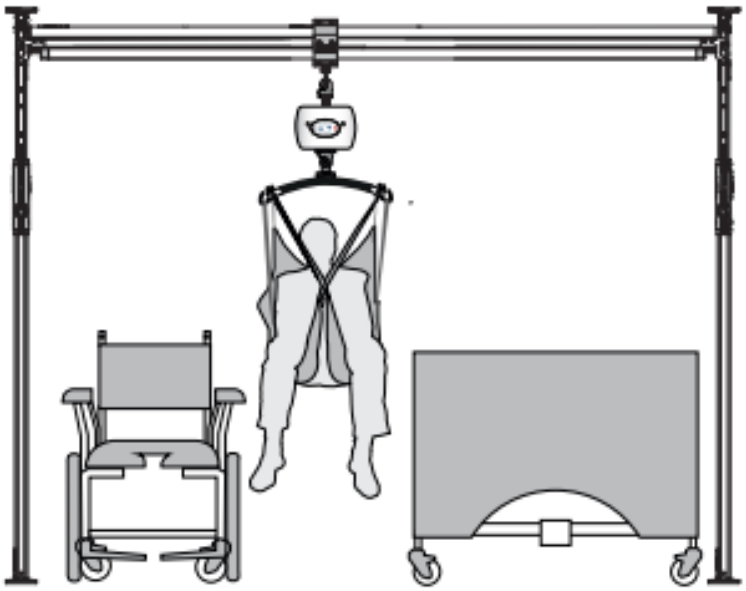


Figure 3

4.0 Technical Specification

4.1 PFS Gantry Dimensions

All dimensions below are shown in millimetres.

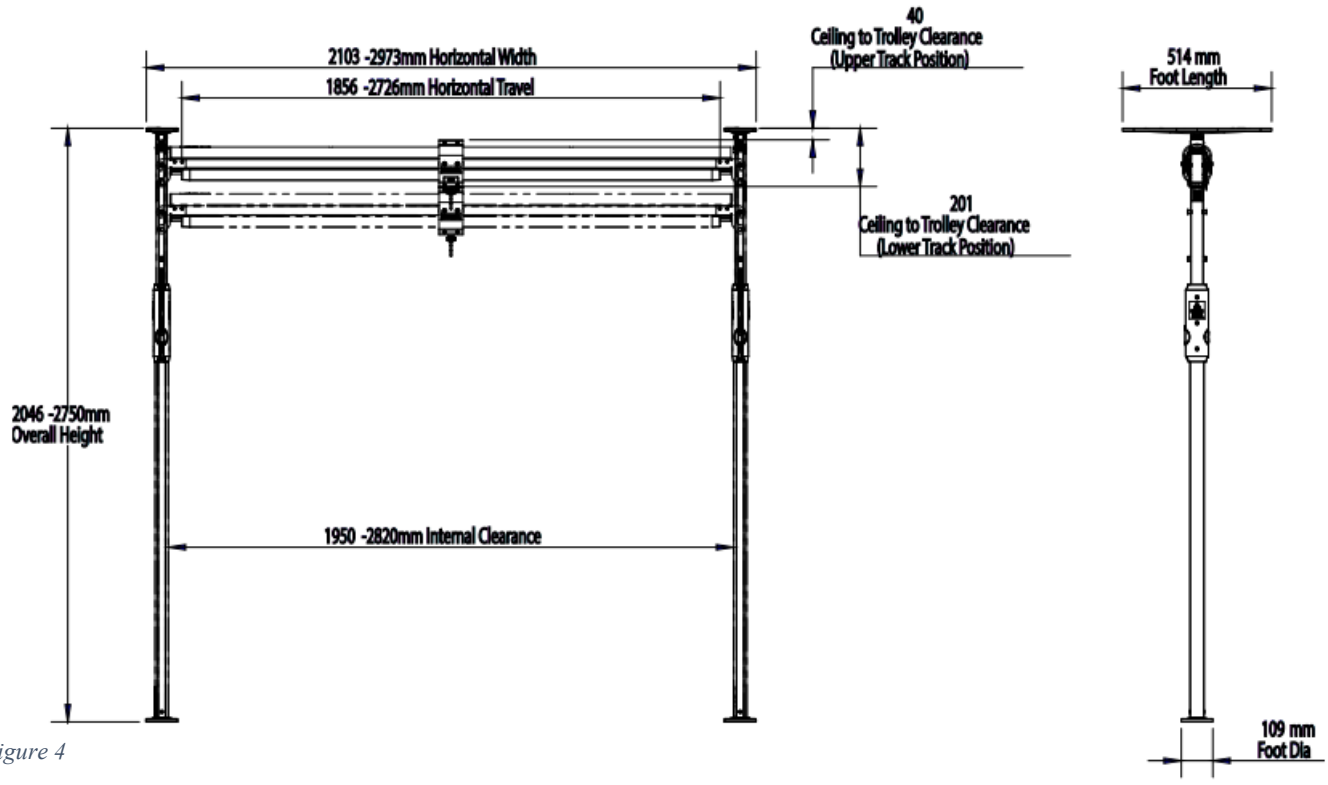


Figure 4

4.2 Specifications

Dimensions	
Maximum Height	2750mm
Lowest Height	2046mm
Maximum Length	514mm
Minimum Length	514mm
Maximum Width	2973mm
Minimum Width	2103mm
Internal maximum clearance	2820mm
Internal minimum clearance	1950mm

Table 3

Weights	
Track	6.8 kg
Support post, ceiling plate & foot	9.4 kg
Ful product	23 kg

Table 4

Operational Forces	
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 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 (-13ºF to 41ºF) 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 (95ºF to 158ºF) non-condensing at a water vapour pressure up to 50hPa.

6.0 Disposal

When the PFS200 has completed its life cycle and can no longer perform to its intended use safely the 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	Rubber
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 7.3 ‘Cleaning’ for details of how to do this.

7.0 General Inspection, Maintenance and Cleaning

7.1 Service

No service is to be carried out on a Prism PFS200, 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 gantry, routine service must be performed on your PFS200. 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 PFS200.
Service Manual Document Number: 995091
Spare Parts Manual Document Number 992091
The Service must be completed every 6 months after installation of the Hoist to comply with LOLER Regulations.

The Prism PFS200 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.

7.2 Inspection and Fault Finding

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.

Fault	Reason	Recommended Solution
Visually the system is not aligned straight.	1. Level is not working. 2. Floor is not levelled. 3. Level is damaged. 4. Post is knocked with impact	Do not use the system. Contact your local authorised dealer immediately.
Feet are slipping after installation	1. Feet are not cleaned. 2. Floor is not cleaned. 3. The fit between floor and ceiling is not at the required pressure.	Do not use the system. Contact your local authorised dealer immediately.
Lever is not engaged with magnet.	1. Support Post assembly instructions not followed correctly 2. Clutch bearing function fails. 3. Lever not cleaned.	Do not use the system. Contact your local authorised dealer immediately.
Pressure gauge is not in safe zone.	1. Post assembly instructions not followed. 2. Barrel nut is loose or not secured tightly. 3. Top plate Spring broken or bent.	Do not use the system. Contact your local authorised dealer immediately.
The adjustable track does not extend smoothly or doesn't extend up to required limit.	1. Physical damage to track. 2. Track slots are not cleaned.	Do not use the system. Contact your local authorised dealer immediately.
Trolley does not move smoothly along the adjustable track.	1. Physical damage to track or trolley wheels. 2. Track slots or trolley wheels are not cleaned.	Do not use the system. Contact your local authorised dealer immediately.
The Adjustable Track is not locking on the Post Pins.	1. One or more track connector bracket(s) are damaged or broken. 2. Track lock pin(s) is(are) broken or damaged.	Do not use the system. Contact your local authorised dealer immediately.
Misalignment of Adjustable Track on the post pins. (for example; track is not sitting straight on the post assembly)	1. Track connector hooks are not Sitting right on the post pins.	Do not use the system. Contact your local authorised dealer immediately.
Safety lock not working.	1. Red button is not pressed in enough. 2. Physical damage to safety lock cover. 3. Lock latch Spring breaks	Do not use the system. Contact your local authorised dealer immediately.
Track connector brackets are loose.	1. Rivets are broken or loose.	Do not use the system. Contact your local authorised dealer immediately.
Parts missing	1. Locking pin missing. 2. Locking clip missing	Do not use the system. Contact your local authorised dealer immediately.

Table 8

7.3 Cleaning

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

7.3.1 General cleaning

It is recommended to clean the PFS200 and accessories before the use by a different patient, reducing the risk of cross–contamination.

The exterior of the PFS200 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.

7.3.2 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.

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.

Dilution chart					
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
	-	-	-	-	-

*** Dilution is made with water. DO NOT dilute within any other medium.** • **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

8.0 Warranty

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

1. Prism Medical UK guarantees the Prism PFS200 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. 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.

9.0 Service Record History

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: ..... (*printed name*). ..... (*signature*) **Company:** .....
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*). ..... (*signature*) **Company:** .....
Remarks & Action Taken:
Device left in a safe usable condition: YES. ☐ NO ☐ (if "NO" explain in remarks the action taken)

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

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Remarks & Action Taken:	
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Date: ______________________	**Time:** ______________________
Service Type: ☐ Periodic inspection ☐ Monthly inspection ☐ 6-month inspection ☐ Repair ☐ Yearly inspection ☐ Other	
Completed by: .... (*printed name*). .... (*signature*) **Company:**	
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*). .... (*signature*)

Company: ....

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*). .... (*signature*)

Company: ....

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*). .... (*signature*)

Company: ....

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*). .... (*signature*)

Company: ....

Remarks & Action Taken:

Device left in a safe usable condition: YES.☐ NO☐ (if "NO" explain in remarks the action taken)

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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