Prioma Birthing Bed





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1. WARNINGS & CAUTIONS



WARNING

Indicates possible hazard in procedures or conditions which, if not correctly followed, could result in death, injury, or other serious adverse reactions.



CAUTION

Indicates possible hazard in procedures or conditions which, if not correctly followed, could result in equipment damage or failure.

<u>Important</u> that this Information for Use Manual is read in its entirety prior to the operation of the bed. The manual is designed to ensure that users are equipped with the information required to competently and responsibly operate the bed and its accessories.

It is recommended that the Information for Use Manual be kept in an easily assessable place for quick reference. If required Arjo product specialists can provide additional training.

All warnings and cautions within this manual should be strictly adhered to. Failure to do so could result in harm to the patient, or operator.

<u>Warnings</u> highlighted throughout this manual identify possible hazards in procedures or conditions, which if not followed correctly could result in serious injury or fatality.

<u>Cautions</u> highlighted throughout this manual identify possible hazards in procedures or conditions, which if not followed correctly could result in equipment damage or failure.



GENERAL WARNINGS

- Electrical equipment can be hazardous if used incorrectly.
- Do not use electrically operated beds in the presence of flammable gases.
- Do not use electrically operated beds in operating theatres.
- Use the bed to support one patient only. The Prioma Birthing Bed is intended for one person use and may become unstable if used incorrectly.
- It is recommended that the bed be positioned at its lowest height when unattended by caregivers to minimise the risk of patient injury from falls when getting in and out of the bed.
- Residual current devices (RCD) are not supplied with the Prioma Birthing Bed. Please consult with your Biomedical Engineer/advisor concerning RCD requirements.
- The full safe working load (SWL) of the Prioma Birthing Bed is 200Kg with a maximum
 patient weight of 135Kg. The 200Kg SWL includes the mass of the patient, mattress and
 any accessories fitted to the bed.
- Do not place the handset if fitted, or the power cord across the mattress surface of the bed. When the bed is not connected to mains power always store the mains power cord within the power cord fixtures fitted to the bed.
- Do not use accessories that are not designed or approved for use with the Prioma bed.

1. WARNINGS & CAUTIONS - Continued

GENERAL SAFETY WARNINGS

- Always use the mattress sections designed for use with the Prioma Birthing Bed.
- Before operating the bed make sure that the patient is safely positioned to avoid entrapment.
- Before transporting the bed make sure the power cable is disconnected from mains power
 and stored within the power cord fixtures at the head end of the bed. Adjust the bed to a
 suitable height to move without stooping, or straining.
- Always apply the brakes when the bed is stationary.
- When the patient's condition could lead to patient entrapment the mattress support platform should be left in the flat position whilst unattended.
- The clinically qualified person responsible should consider the age, size and condition of the patient before using the bed and its accessories.
- Always ensure that all hospital lines and power cables are free from possible entanglement with mechanical parts of the bed.
- Always ensure that attendant and patient limbs are free from potential entrapment areas before operating any functions.

<u>⚠</u> WARNING

- Ensure that the patient, care givers and bedside equipment is not positioned to become either trapped or crushed during bed adjustment.
- Ensure that the power lead is not being stretched.
- Ensure that the handset cable (if fitted) and electrical supply cable cannot become entangled with moving parts of the bed.
- <u>DISCONNECT</u> the electrical power cable from the mains and store before transporting the bed.
- If the power cable shows any sign of damage, replace immediately.
- Some functions may cause injury to the patient if unintentional movement occurs. See Nurse Control Panel instructions for handset lockout to avoid unintentional movement.



• Do not operate the bed controls for more than the control systems prescribed duty cycle (i.e., no more than 6 minutes within a 60-minute period).

If in the event of a serious incident occurring in relation to the use of this medical device, affecting user, or patient then the user or patient should report the serious incident to the medical device manufacturer or the nominated distributor of the product. In the European Union, the user should also report the serious incident to the Competent Authority in the member state where they are located.

2. INTRODUCTION

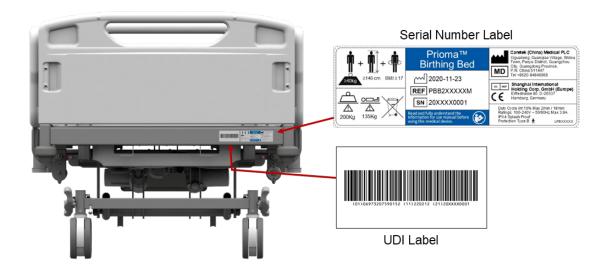
These instructions contain information for the installation, use and maintenance of the Prioma Birthing Bed. The bed includes a range of functions and positional movements that assist caregivers and provide for patient comfort. Ease of use, functionality, serviceability, and cleaning practicality are key features of the Prioma Birthing Bed. The bed has a fabricated steel structure with a powder coated finish. The plastic components are made from urethane, PP and POM nylon, ABS and HDPE plastic.

2.1 Prioma Birthing Bed Key Features

- The Prioma bed has as adjustable height range (fitted with twin 150mm diameter castors) of 48.5 cm low height to a maximum high height of 84.0 cm.
- Electrically actuated mattress platform Trendelenburg tilt (14°) and reverse Trendelenburg tilt (12°), which includes an electronic horizontal timed stop function on electric models.
- Castors: Central locking with foot pedal operated braking and steering function. Central locking castors are either 150mm, or 125mm diameter twin wheeled.
- Retracting backrest to help reduce abdominal squeezing.
- Integral mattress platform extension.
- Head end side rails: Light weight and durable HDPE (High-density polyethylene) blow moulded side rails.
- Light weight, strong and durable interchangeable HDPE blow moulded head and foot panels.
- If fitted: Under bed light.

<u>NOTE:</u> The battery back-up unit should be charged for 24 hours prior to first use. This requires the bed to be plugged into mains power.

The model and serial numbers can be found on the specification label; this is located at the head end of the bed below the moulded head panel.



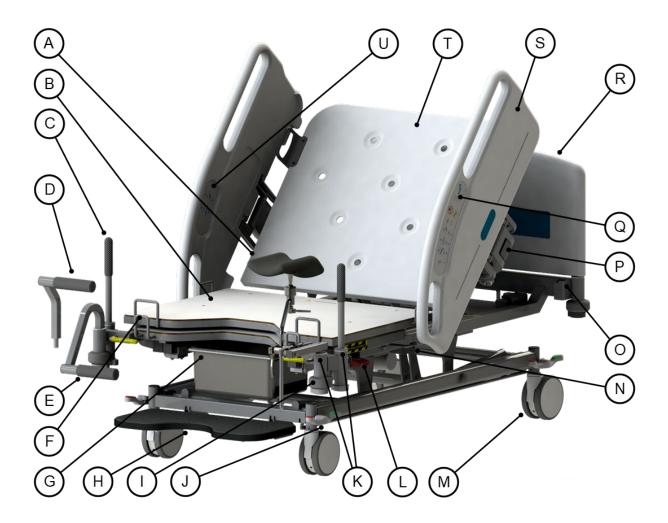


 Before using the Prioma Birthing Bed, ensure that the "Power in" rating on the specification label is compatible with the local electricity supply.

2. INTRODUCTION - Continued

2.2 Product Overview

Note: Mattress - The single sided two part mattress is a standard accessory to the Prioma Birthing Bed. It is not shown in the below overview for illustration purposes. For further information see sections **4.2 Mattress**, **4.3 Mattress and Side Rails** and **8.6 Mattress Sections**.



- A. Leg Stirrup
- B. Seat Panel
- C. Grab Handle
- D. Upper Leg Support
- E. Lower Leg Support
- F. Base Extension
- G. Under Tray
- H. Footrest Plate
- I. Roller Buffer
- J. Brake/Steer Pedal
- K. Accessory Sockets

- L. Backrest CPR Release Handle
- M. Castors
- N. Drainage Bag Rail
- O. IV Pole / Self Help Pole Socket
- P. Side Rail Release Handle
- Q. Nurse Control Panel
- R. Interchangeable Head/Foot Panels
- S. Drop Down Side Rail
- T. Backrest Panel
- U. Patient Control Panel

3. CLINICAL APPLICATION

3.1 Intended Area of Use

The Prioma Birthing Bed is appropriate for use in pre and post-natal ward and delivery rooms. The use of the Prioma Birthing Bed is appropriate for all stages of childbirth, pre and post-delivery and during delivery.



To ensure the patient can use the bed safely, their age, size and condition should be assessed by a clinically qualified person.

The Prioma Birthing Bed is a platform that transforms from bed to Obstetric configuration by retraction of the foot end base extension. The bed configurations are intended for patients that are not typically sick or ill and therefore are not at risk from falls.

3.2 Application Environment

The bed is suitable for use in Application Environment 2 as defined in IEC 60601-2-52.

Application Environment 2

Acute care provided in a hospital or other medical facility where medical supervision and monitoring is required, e.g., general medical and surgical wards.

3.3 Maximum Patient Weight

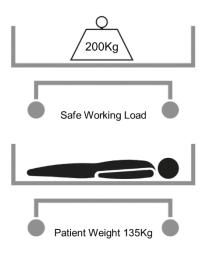
The safe working load (SWL) of the bed is calculated as follows: (In accordance with IEC60601-2-52)

Maximum Patient Weight	135Kg
Mattress	14Kg
Accessories (including attached permanent side rails)	50Kg
TOTAL SAFE WORKING LOAD (SWL)	200Kg



WARNING

If the combined weight of the mattress and accessories exceeds 65kg, the maximum patient weight must be reduced accordingly



4. INSTALLATION

The following chapter describes how to install the bed.

⚠ WARNING

- If the power supply cord or plug is damaged, the complete assembly must be replaced by authorised service personnel. Do not remove the fitted plug or use a rewireable plug or adapter.
- Make sure the power supply cord is not stretched, kinked, or crushed.
- Do not allow the power supply cord to trail on the floor where it may cause a trip hazard.
- Make sure the power supply cord does not become entangled with moving parts of the bed or trapped between the beds frame and moving parts.
- Disconnect the power cord from mains supply, and store as shown before moving the bed.

ACAUTION

Before the first use, or if the bed has been unused for more than three months, connect the bed to the electricity supply for at least 24 hours to allow the backup battery to recharge fully; failure to do this may reduce the life of the battery. After charging, check that the battery is fully serviceable by carrying out a battery test as shown in the Maintenance section of this manual.

4.1 Electricity Supply

Connect the mains plug to a suitable socket outlet. Make sure the plug is easily accessible so it can be disconnected quickly in an emergency.



The power supply cable should be wrapped around the Cable Retainer (1) when the bed is not in use or before moving the bed. To isolate the bed from the electricity supply, disconnect the power plug from the mains socket outlet.



A potential equalisation terminal is located behind the backrest fitted to the beds head end rail tube. When other electrical equipment is within reach of the patient or caregiver, potential differences between the equipment can be minimised by connecting together their potential equalisation terminals.

4. INSTALLATION - Continued

4.2 Mattress

WARNING

Always use the mattress designed for use with the Prioma Birthing Bed. Incompatible mattresses can create hazards.

4.3 Mattress and Side Rails.

It is important to consider the use of side rails based on clinical assessment of each individual patient and in line with local policy. When assessing the suitability of the use of side rails, the following factors should be considered.

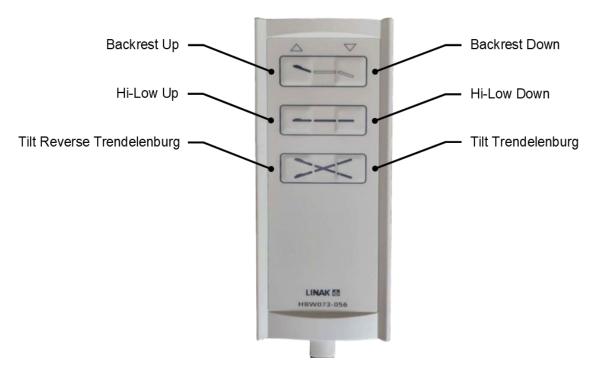
- The bed is designed to provide an acceptable side rail height when used with a mattress of up to 170mm thick.
- Mattress overlays are not recommended for use with this bed.
- To ensure compliance with IEC 60601-2-52, the specifically designed mattress designed for use with the Prioma Birthing Bed is to be used.

5. ELECTRONIC CONTROLS

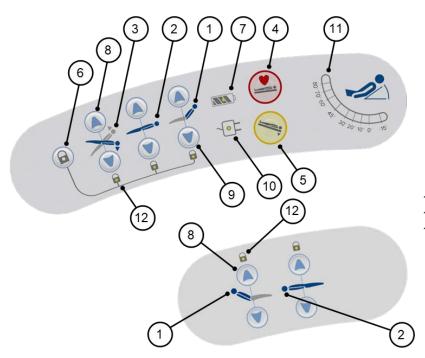
5.1 Control Handset - Optional

The Prioma Birthing Bed has the option of including a factory fitted control handset that is connected to the beds control system by an extendable curly cord. The handset can be used around the perimeter of the bed and can be hooked over the beds rails, or head and foot panels for storage.

Adjustment occurs only while a button is pressed. Adjustment will stop when the button is released, or the movement selection reaches the end of its range of adjustment.



5. ELECTRONIC CONTROLS - continued



- 1) Backrest
- 2) Hi-Low Bed Height
- 3) Trendelenburg Tilt
- 4) CPR Emergency Positioning
- 5) Emergency Head Down Tilt
- 6) Lock Out Function
- 7) Battery Charging
- 8) Function UP
- 9) Function DOWN
- 10) Power Plugged In
- 11) Backrest Angle Indicator
- 12) Locked Out Indicator

5.2 Nurse Side Control Panel

Single button press, to go for all functions. Lock out to hi-low, back rest and tilt positions. Emergency assist functions include Trendelenburg and bed levelling (CPR). Angle gauge is a ball bearing gravity movement type. Visual symbols include Power connected and battery indicator lights. Example is of the left-hand side controller.

5.3 Patient Side Control Panel

Single button press, to go for all functions. Limited functions for patient safety are back rest and hilow positioning. Visual symbols for function locked out.

The Prioma Birthing Bed adjustments are powered by three electronic actuators which are either controlled by handset, or by the inset buttons on both sides of the head end side rail panels.

NOTE: The following categories cover the range of electronic control devices and functions that are available to the Prioma Birthing Bed.

NOTE: Adjustment occurs only while a button is pressed. Adjustment will stop when the button is released, or the movement selection reaches the end of its range of adjustment.

6. ELECTRONIC CONTROLS DESCRIBED



6.1 Backrest Adjustment



WARNING

Care should be taken whilst operating the backrest function to ensure hands and fingers are away from potential squeeze hazards.

NOTE: This control function is available to all control devices fitted to the bed.

To move the backrest up or down, press and hold the appropriate button on the control device. The backrest can be adjusted through a range of between 0° and 70°

The retracting backrest provides additional comfort for the patient by allowing the mattress to expand. When operating the backrest buttons, the backrest slides progressively towards the head end of the bed. This action enlarges the seat section of the bed and helps prevent compression of the abdomen reducing shearing and risk of tissue damage.

The backrest adjustment actuator includes an inbuilt manual quick release CPR function as well as a disengaging spline drive that only uses force in the push direction.



6.2 Mattress Platform Height Adjustment



WARNING

It is recommended that the bed be positioned at its lowest height when unattended by caregivers to minimise the risk of patient injury from falls when getting in and out of the bed.

To move the mattress platform up or down, press and hold the appropriate button on the control device. The beds platform height can be adjusted through a range (fitted with twin 150mm diameter castors) of 48.5 cm low height to a high height of 84.0 cm.

The mattress frame height adjustment uses two actuators working in conjunction and separate to each other creating the vertical lift and enabling the bed to tilt in opposite directions.



6.3 Tilt Positioning – Trendelenburg / Reverse Trendelenburg



CAUTION

Trendelenburg function should only be used under professional supervision.

To move the tilt positioning press and hold the appropriate button on the control device. The tilt button allows the bed to be positioned in a foot or head down tilt position. Tilt positioning achievable is between 0° and 14° for head down tilt and between 0° and 12° for foot down tilt.

- In use the mattress platform may initially rise before tilting. The bed will automatically adjust to ensure that there is adequate clearance between the mattress platform and the mechanical structure of the bed before tilting.
- When reversing the tilt angle of the bed with the tilt button remaining depressed, the
 mattress platform will pause at horizontal for two seconds before continuing with the
 tilting movement.

6. ELECTRONIC CONTROLS DESCRIBED - Continued



6.4 Cardiopulmonary Resuscitation (CPR)

Note: For the electronically activated emergency patient positioning function, it is **NOT** necessary to press the 'up/down' buttons as the operation is programmed to operate directly from the associated button.



When electronic emergency patient positioning functions are activated, care should be taken over the potential of the beds moving parts to either trap or crush the patient, caregivers and or other equipment.

Pressing the <u>SINGLE BUTTON PRESS</u> button, the bed will automatically level all positioning functions back to a flat deck position whilst lowering the bed to a safe working height.



6.5 Emergency Trendelenburg (head down tilt) Function

Note: For the electronically activated emergency patient positioning function, it is **NOT** necessary to press the 'up/down' buttons as the operation is programmed to operate directly from the associated button.

Pressing the "**EMERGENCY TRENDELENBURG**" button will lower the head and raise the foot of the bed to the maximum tilt of 14°, while simultaneously lowering the back rest and knee break back to a flat deck position – **NO** pause if passing through horizontal.



6.6 Lock Out Functions

This facility allows users to selectively disable some of the electrical features of the bed. In normal operation the key functions of the bed should be in an (unlocked) state of use. This is indicated on the ACC panel by LED lights above the function buttons.

To lock and unlock each function hold the "key" or "lock" button and at the same time press the function button that is required to be locked or unlocked. An LED light will illuminate when the function is in the locked position.



6.7 Battery Charge Indicator - Battery Backup

LED light illuminates when the battery is in charge mode.

The battery backup system allows the electrically operated functions to be used for short periods when the bed is disconnected from mains power. The bed switches between mains and battery power automatically.

The battery is lead-acid and should be charged regularly and not be allowed to discharge fully. Fully discharging the battery will cause a reduction in battery life.

To charge the battery connect the power cord to the mains supply. This should be done as often as possible to maximise battery life. If the bed is not used for a long period of time, it is recommended that the batteries are charged in accordance with the section on Transportation and Storage within this manual.

6. ELECTRONIC CONTROLS DESCRIBED - Continued

WARNING

Do not expose the battery to open flame or immerse in liquid.

NOTE: The beds batteries should be charged for 24 hours prior to first use.

NOTE: Keep the bed plugged to mains power source for optimum performance.

NOTE: Bed adjustment will be slower when the power cord is unplugged, and the bed is powered from its batteries only.



6.8 Mains Power Indicator

NOTE: Power cord storage is located at the head end of the bed. The cable should be stowed when the bed is unplugged or in transport by wrapping around the "cord minder" hooks.

6.9 Backrest Angle Indicator

The backrest angle indicator is a ball bearing gravity-based indication of the backrest angle. When the back rest is in its flat position the angle indicator also provides an approximate tilt degree indication also.

6.10 Under Bed Lighting - Option

NOTE: <u>IF FITTED</u> the LED under bed light will be permanently on when connected to mains power.

The under-bed lighting feature provides a soft LED illumination of the floor beneath the bed carriage. This safety feature provides floor illumination for patients at night when getting in and out of bed. In the event the bed is operating on battery power (e.g., during transport) the lights will power down after approximately 2-3 minutes of no button use.

7. GENERAL BED OPERATION

7.1 Castor System

NOTE: The Prioma Birthing Bed has two castor options available (150mm twin or 125mm twin wheeled). This section covers the locking and steering mechanism that is used.



125mm Twin Wheeled Central Locking Castor



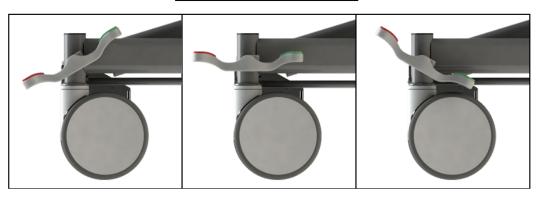
150mm Twin Wheeled Central Locking Castor

Central Locking Castors - Brake & Steer

The central locking castor system is operated by use of foot pedals found at the head and foot end of the bed. The pedal movement from horizontal is 30° both ways.

- With the pedals in the **Red Down Brake** position the brakes are applied to all four castors of the bed simultaneously and the bed is immobilised.
- With the pedals in the <u>Horizontal Free</u> position the brakes are released, and the bed can be moved in any direction.
- With the pedals in the <u>Green Down Steer/Track</u> position, a single steering castor at the head end of the bed is engaged to provide better control when pushing the bed in a straight line.
- When moving the bed, push from the foot end holding the panels top push rail.

Central Lock Pedal Positions



Brake Position

Neutral Position

Tracking Position



- Disconnect the bed power cord before moving the bed.
- Do not remove the power cord from the source by pulling on the cord.
- Do not use the beds side rails to manoeuvre the bed.
- Do not pull on the power cord, or handset cord to manoeuvre the bed.
- Always apply the brakes when the bed is in a stationary position.

7.2 Head & Foot Panels

The head and foot panels are easily removable from the bed allowing quick access to the patient. There are no clamps or screws that are required to be adjusted before removal.

Installation & Removal

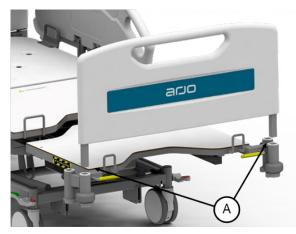
The panel includes a decorative infill to one side. There is no specific way in which the panels are to be fitted as they are both interchangeable and therefore cannot be placed incorrectly. Generally, the infill face of the panel is fitted to face towards the foot of the bed providing a more pleasing aesthetic appearance.

To Install:

Using two hands align the panels bottom tubes with the beds corner sockets as shown in the below diagram (A). Lower the panel gently until it seats at the bottom of the beds moulded corner sockets.

To Remove:

Reverse the above procedure.





Panel aligned ready for installation

Panel installed



Always install and remove the head and foot panels in line with the facilities Manual Handling Procedures and Policies.

7.3 Bed Extension

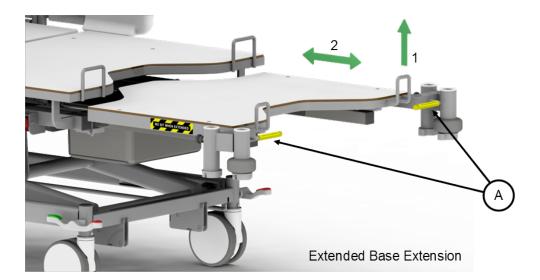
To Retract: Apply the central locking brake system (refer page 13) raise the mattress platform to a comfortable working height and remove the foot panel from the bed (refer page 14).

Next step is to remove the mattress leg section.

Grip both yellow coloured levers (A) at the foot end of the bed and lift upward (1) and begin pushing towards the head end of the bed (2). The bed extension automatically locks in position when fully retracted.

To Extend: Prepare the bed as described above.

Grip both yellow coloured levers **(A)** at the foot end of the bed, lift upward **(1)** and pull towards you **(2)** to fully extend. The bed extension automatically locks in position when fully extended.





To ensure maximum stability, do not sit or place loads greater than 90kg on the foot end of the mattress platform in the area indicated by this label.



7.4 Manual Cardiopulmonary Resuscitation (CPR) Function

A clearly marked emergency CPR release handle is available on both sides of the bed. The manual release function returns the beds backrest to a level position in the event of an emergency resuscitation being required.

Emergency Lowering: To lower the backrest in an emergency, pull up on the red CPR release handle. The handles are positioned at the side and towards the middle of the bed when the bed is fully extended. The lowering movement is assisted by a gas damper, but **CAUTION** is required as the backrest may lower quickly under patient weight.





The backrest can fall quickly on release - keep hands clear to avoid trapping.

7.5 Drop Down Side Rails

The drop down side rails have two positions, either fully raised or fully lowered. When the side rail is raised to its full height position it will automatically lock to its fully raised position. The lock position is clearly audible.

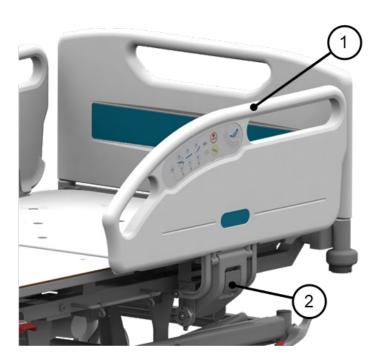
WARNING

Do not operate side rails when there is potential of entrapment or crushing to the patient, caregivers, visitors and/or other equipment.

Side Rail Operation

To raise the side: Grip the top of the rail (1) and lift until the spring loaded lock mechanism automatically clicks into its locked position at maximum height.

To lower the side: Hold the top of the rail near the middle (1) and gently pull forward the rail release handle (2). As the rail begins to lower the handle can be released and the rail can be gently lowered to its down position. The rails are mechanically dampened for safety and ease of use.



⚠ WARNING

- Care should be taken whilst operating the side rails to ensure hands and fingers are kept away from potential squeeze hazards.
- Side rails should only be used after clinical assessment and within organisational policy and guidelines.

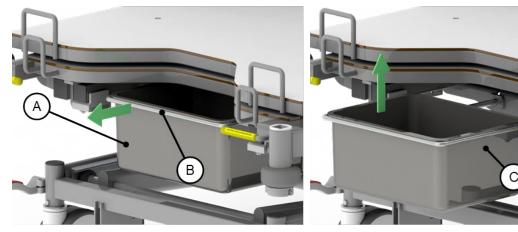
8. STANDARD ACCESSORIES

The Prioma Birthing Bed is supplied with a range of standard accessories. For installation locations on the bed, refer to product overview page 5.

8.1 Under Tray

To use or for removal of the stainless steel tray (A), using two hands to give even leverage, pull towards using the lip of the tray as the handle (B) and extend out until it comes to a stop position.

For complete removal of the tray, lift upwards and out from the underside steel support frame (C).

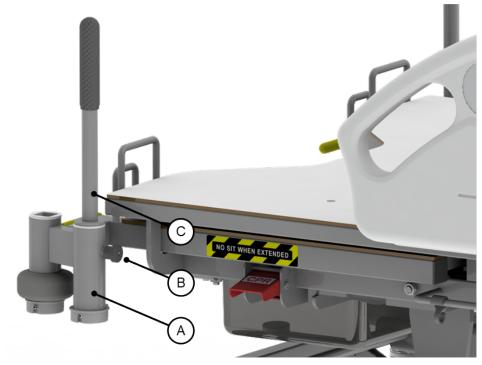


Fully Retracted Under Tray

Fully Extended Under Tray

8.2 Grab Handle

Both Handles fit in the accessory sockets (A) at the foot of the bed. Unscrew accessory socket locking handwheel (B) if necessary and fully insert Handles (C) inside the socket. Lock in position via handwheel (B).



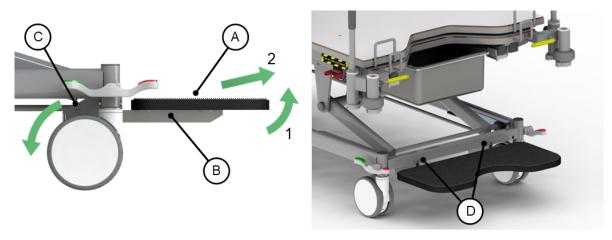
Grab Handle Installed

8. STANDARD ACCESSORIES - Continued

8.3 Footrest Plate

Footrest Plate (A) can be easily attached and removed from the bed as shown below. To remove the footrest plate, tilt the footrest arms (B) in direction (1) releasing it from its locked position (C) and slide out away for the bed in the direction of arrow (2).

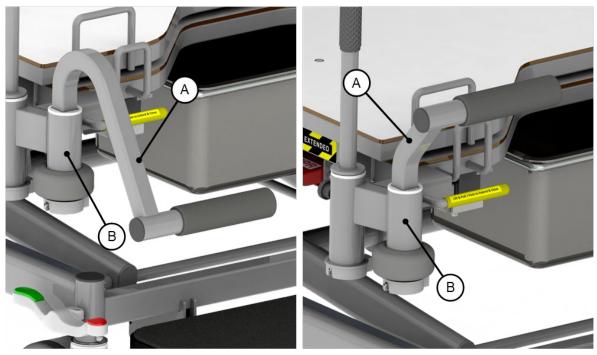
Installation is reversal of the above, ensuring footrest arms **(B)** are resting inside the location brackets **(D)** and the footrest arm slots are properly engaged with the locating pins **(C)** on the bed frame.



Foot Plate Removal and Installation

8.4 Upper & Lower Leg Supports

Both Upper and Lower Leg Supports (A) fit inside the corner accessory sockets (B) at the foot of the bed.



Lower Leg Support Installed

Upper Leg Support Installed

8. STANDARD ACCESSORIES - Continued

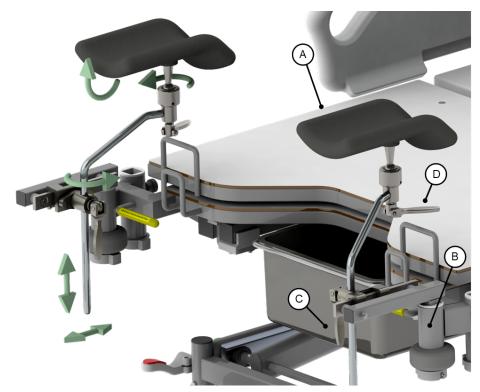
⚠ CAUTION

Be sure to push the supports all the way down inside the accessory sockets until contact with bottom stop pin is made.

8.5 Stirrups

Both Leg Stirrups (A) fit in to the corner accessory sockets (B) at the foot of the bed. Once Stirrup brackets are fully inserted inside the socket, stirrup height, horizontal position and orientation can be adjusted as required by loosening handwheel (C).

The stirrup pad can also be swivelled and tilted as required by loosening lever (D)



Leg Stirrups Installed

8. STANDARD ACCESSORIES - Continued

8.6 Mattress Sections

The mattress sections are specifically designed for use with the Prioma Birthing Bed which enables both standard bed and birth procedure configurations. The mattress sections are made from high resilience polyurethane foam and are covered with a two way stretch, water vapour permeable cover with fully welded seams.

The mattress sections are single sided use only with the correct side for use clearly marked on the mattress covers. The maximum patient weight of the mattress is 135kg.

Mattress Cover Specifications

Mattress covers are bi-elastic knitted polyamide, coated with a flame retardant and anti-microbial polyurethane coating. They are washable to 75°C and machine drying at 60°C maximum.

Specification of the covers include the following attributes: Halogen free, FR to BS7175 crib 5, Excellent Chlorine resistance, Hydrolysis resistant 1 year+, Oeko-Tex class 1, Cytotoxicity grade 1, Non-irritating to the skin, REACH compliant, Durable and Comfortable

Mattress size specifications can be found in section 10. of this document. To re-order the mattress sections please see the Prioma Birthing Bed Service Manual. Mattress cover replacement order code information can be found at page 32. of this manual.

Maintenance and Cleaning

To clean the cover, wipe with a soft cloth impregnated with mild detergent and lukewarm water, then using a sodium Hypochlorite solution (NAOCL) and Dichloroisocyanurate Sodium (NaDCC) diluted to 1000 ppm. It is possible to wash the cover at 75°C.

Disposal

Ensure that local regulations and, where appropriate, standard operating procedures for sanitary and health facilities are complied with. If the foam of the mattress is suspected of contamination it must be condemned as hospital waste and incinerated at temperatures exceeding 1,100°C. If the foam of the mattress is not suspected of contamination it can be disposed of in landfill.



⚠ WARNING

The mattress cover is permeable to water vapour while being air-impervious. It is therefore a risk of suffocation. Caregivers should ensure that the mattress is safe for the user.



Do not use the mattress without a cover. The cover is a protection and allows to prolong the time of use.

FIRE RETARDANCY

The mattress meets the specifications of GPEMDI 90: Class C; BS EN 597-1:1995 BSEN 597-2:1995 and BS EN 6807:1996 section 2, ignition sources 0, 1 and 5.

Laundering - Cover



Machine Washable 75°C Maximum



Do Not Iron



Do Not Use Phenol Based Solutions



Machine and cool drying at 60°C Maximum



Wipe clean with a damp cloth impregnated with a mild detergent.



Use a diluted solution NaOCI/NaDCC at 1,000 ppm

9. BED POSITIONING EXAMPLES



10. BED SPECIFICATIONS

Dimensions

Overall Length (Bed Configuration)	218.5 cm
Overall Length (Obstetric Configuration)	163.5 cm
Bed Extension Length	58.0 cm
Mattress Surface Length - Between Panel Faces	203.0 cm
Overall Width	100.0 cm
Deck Height Range - Twin 150mm Castors	48.5 cm to 84.0 cm +/- 5mm
Trendelenburg Tilt	0 to 14°
Reverse Trendelenburg	0 to 12°
Backrest Angle Adjustment	0 to 70°

Mattress

Mattress Size Seat & Backrest Section	W=85cm L=135cm H=12.5cm
Mattress Size Extension Bolster	W=85cm L=75cm H=17cm

Product Weight (approximate)

Bed Without Accessories	160 Kg
Mattress Sections	14 Kg
Safe Working Load (SWL)	200 Kg
Maximum Patient Weight	135 Kg

Power Ratings

Power In	100 - 240V ~ 50/60Hz Max 3.9A
Duty Rating	Intermittent 10%, Max 2 min / 18 min
Electric Shock Protection	Class 1 Type B 🏠
Liquid Ingress Protection	IPX4
Internally Powered Equipment (Battery Backup Only)	2 x 12V Series Connected Batteries Sealed, Rechargeable Lead/Acid Gel 1.2 amp hours.

Standards

The Prioma Birthing Bed has been built to comply with International Standard IEC 60601-1 Section 9 and IEC 60601-2-52 Section 9 (Edition 3.1 2012-08)

11. CLEANING

• Before cleaning always disconnect the bed from the mains power source.

NOTE: It is strongly recommended that protective clothing be used when carrying out any cleaning processes on the Prioma bed.

NOTE: The following procedure also applies to the beds accessories but does not include mattresses.

- Wipe the beds surfaces with a soft cloth moistened with hot water and mild detergent (or the
 hospital's recommended cleaning solution). It is recommended that the cloth be a white material to
 prevent bleeding of die colours to the bed. Take extra care in areas that can harbour dirt or dust.
- Rinse with clean water and a dry clean cloth.
- To remove potentially infectious materials such as body fluids, or when the bed has been used by someone with a known infection. Clean with NaDCC (e.g. Presept, Actichlor) at 10,000 ppm of available chlorine. Rinse and dry.
- Allow the cleaned parts to dry before replacing the mattress.



Do not use abrasive Hypo-carbonate or Phenolic compounds or pads.

12. MAINTENANCE

The following preventative maintenance procedures should be carried out every 12 months.

NOTE: Other than general maintenance activities all other service or repair work must be performed by qualified and trained persons who are approved by Arjo.

MARNING

The bed must be disconnected from the mains power supply before any maintenance activity.

GENERAL			
1	Examine the bed for obvious signs of damage. All aspects of the equipment should operate as intended. Check that all nuts, bolts, and other fasteners are tight and are not missing.		
2	Examine flexible cables and conduits for cuts, cracks, abrasions, or other deterioration.		
3	Check that the power supply plug is not damaged. If either the power cable or plug is damaged, then both the cable and plug must be replaced as a complete assembly by an approved service agent.		
ВАТТ	ERIES		
1	A beeping sound heard during normal bed operation means that the battery is at low charge. Reconnect the bed to the mains power supply for a minimum of 24 hours. If the problem reoccurs use step 2 below for verification.		
	Check the batteries condition every six months using the following procedure:		
	 Make sure that the bed has been connected to the mains power supply for an uninterrupted 24 hour period. 		
	Disconnect the bed from the mains power supply.		
2	3. Apply a load of approximately 80Kg to the mattress platform.		
	Raise and lower the mattress platform from minimum low height to maximum high height three times.		
	If the bed does not operate correctly in step 4, perform steps 1 to 4 again. If the bed continues to operate incorrectly the batteries may need replacing. In this situation consult an approved service agent.		
SIDE RAILS			
1	Inspect the side rails for general wear and tear on fittings and pivot joints every six months. Check for rust, structural integrity of welds and paint finish every twelve months.		
2	Raise the side rail to the upright position until the locking mechanism clicks into place. Refer to the operating procedures in this manual for further instruction.		
2	Ensure that the rail cannot be pulled out of the locked position without unreasonable force being applied.		

MAINTENANCE - Continued

BRAKE LOCKING SYSTEM

1

(Central Locking) Check the two steering lock castors for correct operation. If either the brakes or the steering locks are not working correctly contact an approved service agent.

HANDSET CHECKS

Between each patient, Arjo strongly advises that the Preventative Maintenance checks are conducted on the Handset.

When using a specific function staff should be aware of, and check for any of the symptoms listed in point 3 below.

Preventative Maintenance Checks

Arjo recommends that the full check and testing regime is conducted between each bed use, or worst case during annual preventative maintenance. This should take no more than one (1) minute to complete.

Visual Inspection of Control Panel & Handset Casing

1.1 Inspect the outer plastic casing for any obvious cracks or damage.

1

1.2 Inspect for damage to the front cover (outer label) particularly over the buttons where the label may be torn or indented.

If any damage is identified while conducting checks 1.1 and 1.2, immediately decommission the bed and report the damage to maintenance staff.

Visual inspection of the cable and Cable insulation

2.1 Inspect the cable for any nicks or cuts in the insulation.

2.2 Inspect for any evidence that the cable may have been squashed/flattened.

2

Squashed or flattened cables may indicate a possible break in the internal conductors or insulation causing conductors to short together, which could cause unwanted movement of the bed. Any handsets that are found with obvious damage to the cable insulation, immediately decommission the bed and report the damage to maintenance staff.

Tactile inspection of the buttons:

All buttons should be operated, and response tested.

Depress each button on the handset and control panels. Each button should have a positive click that is also felt. The function being pressed should also operate.

If the button:

3

- · does not have a click feel
- does not immediately operate the function
- · feels soft offering no resistance
- feels different to the rest of the buttons
- · travels further when depressed

Immediately report the damage to maintenance staff or quarantine the bed and contact an Arjo approved Technician.

13. TROUBLE SHOOTING

Symptom	Possible Cause	Action
All actuators fail to work	Power disconnected. or batteries discharged	Ensure mains supply lead is connected
	Control box and handset plugs disconnected	Check the plugs are fully inserted in the control box and any lock out devices fitted to the bed. Check that plugs are fully inserted in the sockets on the deck frame. Check that the handset controls are not deactivated on the patient lockout facility.
	Blown fuse	Contact your local Arjo Service Department.
	Damaged handset cable	Replace handset
One actuator fails to work	Actuator plug disconnected	Check that actuator plug is fully inserted in the control box. Check that the handset controls are not deactivated on the patient lockout facility if fitted.
Main lift actuators fail to work, and an audible beeping sound can be heard when handset is activated	Control box requires calibrating possibly due to bed being operated when batteries were fully discharged	Ensure mains power lead is connected and carry out calibration procedure.
Backrest CPR release not effective	Release mechanism not correctly adjusted	Check and re-adjust
Brakes or steering lock not effective	Wear or damage	Adjust or replace castor

14. TRANSPORTATION AND STORAGE

Handle with care.

The Prioma Birthing Bed should be stored in a clean, dry well ventilated area.

Do not drop and avoid shock or violent impact when transporting.

The following limits apply during transport and or for a storage period of up to 6 weeks duration:

Ambient temperature	-15°C	То	+60°C
Relative humidity	10%	То	75%
Air pressure	50 kPa	То	106 kPa

The following limits apply to normal operating conditions and or for periods of storage longer than 6 weeks:

Ambient temperature	+10°C	То	+40°C
Relative humidity	30%	То	75%
Air pressure	70 kPa	То	106 kPa

When storing the bed, or when the bed is not in use for prolonged periods of time it is recommended that the beds battery system be maintained periodically using the following guidelines:

Storage Temperature	Charging Interval
20°C or less	Charge batteries for 24 hours every 9 months.
20 to 30°C	Charge batteries for 24 hours every 6 months.
30 to 40°C	Charge batteries for 24 hours every 3 months.

15. PRODUCT LIFETIME & END OF LIFE DISPOSAL

Product Lifetime

The lifetime of this equipment is typically (10) years. "Lifetime" is defined as the period during which the product will maintain the specified performance and safety, provided it has been maintained and operated in conditions of normal use in accordance with the requirements provided in the instructions for use manual.

End of Life Disposal

- Equipment that has electrical and electronic components should be disassembled and recycled per Waste of Electrical and Electronic Equipment (WEEE) or in accordance with local or national regulation.
- All batteries in the product must be recycled separately. Batteries are to be disposed in accordance with national or local regulations.
- Components that are primarily made up of different kinds of metal (containing more than 90% metal by weight) for example bed frame, should be recycled as metals.

Safe Disposal of Gas Dampers

Gas dampers contain air and oil at high pressure and must be vented in accordance with the following instructions before being discarded.

Under no circumstances should any attempt be made to open the device.



DANGER OF EXPLOSION. DO NOT HEAT OR INCINERATE

High pressure gas. The sudden release of gas at high pressure could cause serious injury or death. Use suitable protective clothing, eye protection or a face shield. This procedure should be carried out in a well-ventilated room as the expelled gas may contain oil droplets.

- 1 Operate the valve at the end of the piston rod and allow the piston rod to fully extend.
- 2 Clamp the gas spring in a vice and drill a 3mm diameter hole, 15 to 20mm from the end of the gas spring housing (refer diagram below). Screen off the drilling point as metal chips and oil may be ejected due to the high internal pressure. Then drill a second hole at position 2 as shown. The holes should be drilled to a depth of approximately 10mm.

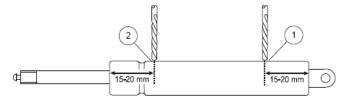
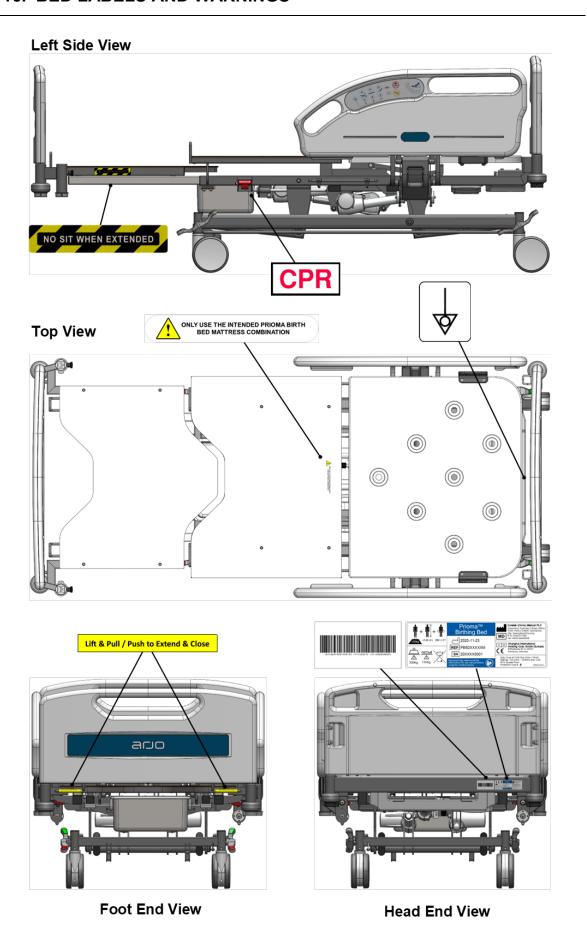


Figure 22: Disposal of Gas Spring

- Pump the piston rod in and out several times while holding the drilled hole over a container to collect the expelled oil.
- 4 Dispose of the gas spring and oil through special waste or recycling points in accordance with local regulations. Do not dispose of gas springs or oil in household refuse.
- 5 If correct disposal in accordance with these instructions is not possible, the unit should be returned to the supplier.

16. BED LABELS AND WARNINGS



16. BED LABELS AND WARNINGS - Continued

Explanation of Symbols

Serial Number Label	PROTOCON TO ANY CONTROL OF THE
UDI Bar Code Label	(01)26/7520/790112 (11)220212 (21)200000001
Manual Cardiopulmonary Resuscitation (CPR) Function Label	CPR
Mattress Caution Label	ONLY USE THE INTENDED PRIOMA BIRTH BED MATTRESS COMBINATION
Base Extension Warning Label	NO SIT WHEN EXTENDED
Grounding Equipotential Bonding Pin Location Label	
Base Extension Instruction Label	Lift & Pull / Push to Extend & Close
Manufacturer	
European Representative	EC REP
Date of Manufacture	
Product Code Reference	REF
Serial Number	SN
Bed Safe Working Load	200Kg
Maximum Patient Weight	<u>○□년</u> <u>↑</u> 135Kg
Read Instructions Before Use	
Indicates the Product is a Medical Device According to EU Medical Device Regulation 2017/745	MD
CE Marking	CE
WEEE - Waste Electrical and Electronic Equipment Symbol	

17. PRIOMA BIRTHING BED ACCESSORIES

Optional accessories that may be used on the Prioma Birthing Bed:

Code	Description
PBB-ST	Accessory Storage Trolley – (Powder Coated Finish)
PBBDC	Accessory Trolley Dust Cover
PBBMCS	Replacement Mattress Cover Set (backrest & foot section)
SP001	Self Help Pole - (Includes Strap & Handle, Powder Coated Finish)
SP002	Self Help Pole - (Includes Strap & Handle, Stainless Steel Finish)
IV110	IV Pole - Stainless Steel Finish
СТКО2	"C" Size Oxygen Bottle Holder - Clamps to Head or Foot End of Bed



Do not use accessories that have not been designed for use with the Prioma Birthing Bed

18. WARRANTY AND SERVICE

Arjo's standard terms and conditions apply to all sales. A copy is available on request. These contain full details of warranty terms and do not limit the statutory rights of the consumer.

19. REGULATORY INFORMATION



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At Arjo, we are committed to improving the everyday lives of people affected by reduced mobility and age-related health challenges. With products and solutions that ensure ergonomic patient handling, personal hygiene, disinfection, diagnostics, and the effective prevention of pressure ulcers and venous thromboembolism, we help professionals across care environments to continually raise the standard of safe and dignified care. Everything we do, we do with people in mind.



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