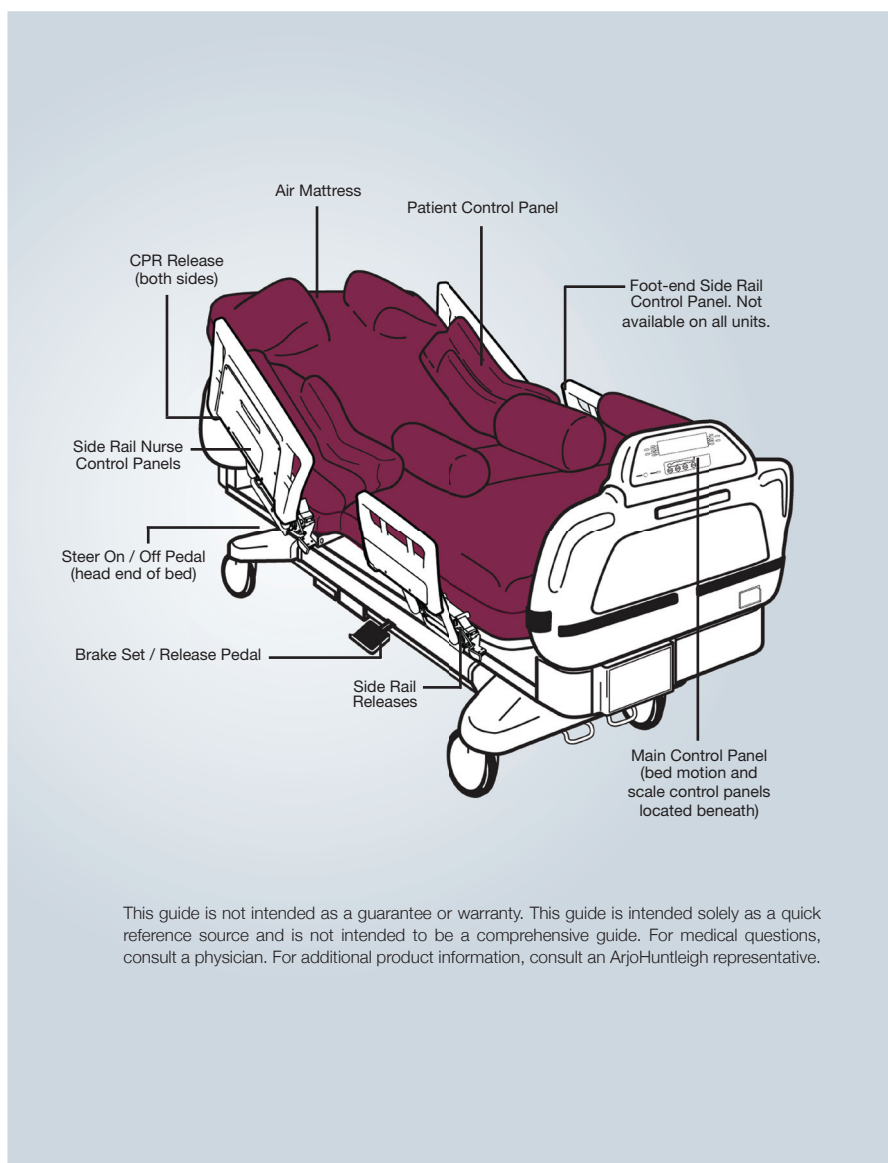


TriaDyne Proventa Critical Care Therapy System Quick Reference Guide

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Introduction

Introduction

The TriaDyne Proventa™ Critical Care Therapy System provides a comprehensive system of pulmonary therapies clinically proven to help improve outcomes and advanced skin care therapies for the critically ill, immobilized patient.

Indications for Use

TriaDyne Proventa Critical Care Therapy System is indicated for complications associated with immobility:

- Prevention or treatment of pulmonary complications
- Prevention or treatment of pressure ulcers
- Any other use where medical benefits may be derived from Continuous Lateral Rotation Therapy or percussion / vibration therapy.

Contraindications

- Unstable vertebral, pelvic, skull* or facial* fractures
- Cervical and / or skeletal traction
- Unstable spinal cord injury
- Uncontrolled intracranial pressure (ICP)*

*Only contraindicated for prone therapy

- Contraindications for Percussion Therapy:
 - Multiple rib fractures
 - Persistent intracranial hypertension
 - Bronchospasm
 - Post-operative periods following cardiac surgery

Risks and Precautions

Side Rails / Patient Restraints - Whether and how to use side rails or restraints is a decision that should be based on each patient's needs and should be made by the patient and the patient's family, physician and caregivers, with facility protocols in mind. Caregivers should assess risks and benefits of side rail / restraint use (including entrapment and patient falls from bed) in conjunction with individual patient needs, and should discuss use or non-use with patient and / or family. Consider not only the clinical and other needs of the patient but also the risks of fatal or serious injury from falling out of bed and from patient entrapment in or around the side rails, restraints or other accessories. In the US, for a description of entrapment hazards, vulnerable patient profile and guidance to further reduce entrapment risks, refer to FDA's Hospital Bed System Dimensional and Assessment Guidance To Reduce Entrapment. Outside the US, consult the local Competent Authority or Government Agency for Medical Device Safety for specific local guidance. Consult a caregiver and carefully consider the use of bolsters, positioning aids or floor pads, especially with confused, restless or agitated patients. It is recommended that side rails (if used) be locked in the full upright position when the patient is unattended. Make sure a capable patient knows how to get out of bed safely (and, if necessary, how to release the side rails) in case of fire or other emergency. Monitor patients frequently to guard against patient entrapment.

It is recommended that electrically operated beds conform to IEC 60601-2-38. Medical Electrical Equipment Part 2: particular requirements for the safety of electrically operated hospital beds.



Serious injury or death can result from the use (potential entrapment) or non-use (potential patient falls) of side rails or other restraints. See related Safety Information section of this guide.

When selecting a standard mattress, ensure the distance between top of side rails (if used) and top of mattress (without compression) is at least 8.66 in (220 mm) to help prevent inadvertent bed exit or falls. Consider individual patient size, position (relative to the top of the side rail) and patient condition in assessing fall risk.

Side rails must be in the full upright and locked position before bed rotation.

Patient Migration - Specialty surfaces have different shear and support characteristics than conventional surfaces and may increase the risk of patient movement, sinking and / or migration into hazardous positions of entrapment and / or inadvertent unit exit. Monitor patient frequently to guard against patient entrapment.

Percussion - Chest physiotherapy should be used with precaution in patients without sputum production. Adjust duration and intensity of percussion depending upon patient's condition and response to therapy.

Skeletal Traction or Unstable Fracture (if not contraindicated) - With skeletal traction, unstable pelvic fracture, or any other unstable fracture (to the extent not contraindicated), maintain physician directed angle of articulation and guard against risks of patient migration or inadvertent deflation of surface.

Electromagnetic Interference - Although this equipment conforms with the intent of the directive 89 / 336 / EEC in relation to electromagnetic compatibility, all electrical equipment may produce interference. If interference is suspected, move equipment away from sensitive devices and contact the manufacturer.

Shock Hazard - Electrical shock hazard; do not remove covers. Refer to qualified service personnel.

Proning (using *Triadyne Proventa* Proning Accessory Kit) - Proning may present inherent risks of serious injury. For instance, some studies and caregiver experience have suggested or reported risk of the following in relation to proning in general:

- skin breakdown and / or pressure necrosis
- wound dehiscence
- cardiac arrest
- loss of invasive lines or tubes or extubation (endotracheal and oral)
- edema and / or swelling
- splenic rupture
- blindness and other consequences of damage to the ocular nerve
- corneal abrasion
- myositis ossification
- venous air embolism
- increased intraorbital pressure

- central retinal artery occlusion
- pain and discomfort
- difficulty performing CPR
- patient in prone position with open sternal wound or thoracic post-surgical incision
- patient in prone position with open abdomen

Precautions may also need to be taken when using this product with certain patient conditions, including, but not limited to:

- hemodynamic instability
- severe agitation
- uncontrollable claustrophobia or fear of confinement
- uncontrollable diarrhea
- intolerance to face down position
- any implant that potentially increases the risk of skin breakdown including, but not limited to, breast implants or penile prosthesis
- pregnancy
- extensive facial trauma
- any other unstable fracture not listed in the **Contraindications** section
- ICP monitoring or intracranial drainage devices



Caregivers should make sure to discuss safety information and risks and precautions with patient (or patient's legal guardians) and patient's family.

Safety Information

General Protocols - Follow all applicable safety rules and institution protocols, concerning patient and caregiver safety.

Skin Care - Monitor skin conditions regularly, especially at bony prominences and in areas where incontinence and drainage occur or collect, and consider adjunct or alternative therapies for high acuity patients. It is recommended that skin pressure points be assessed at least every two hours. Early intervention may be essential to preventing serious skin breakdown.

Brakes - Lock all steer casters in line and set all caster brakes before transferring patient.

Bed Height - To minimize the risks of falls or injury the unit should always be in the lowest practical position when the patient is unattended. Make sure area under and around bed frame is clear of objects, persons and parts of body before adjusting height.

Bed Exit Alarm - Activation of the bed exit alarm is recommended whenever patient is unattended. Be sure to reactivate the bed exit alarm each time patient returns to unit.



Bed exit alarm is triggered by dramatic weight reduction and may not alarm if patient is only partially exited from unit.

Ambulatory Patient Entrance and Exit - Caregiver should always aid patient in entering and exiting the unit. Lower patient surface completely during assisted patient entrance / exit and patient turning.

Arm Cushions - If Kinetic Therapy™ patient turning is to be provided, it is recommended that the patient be secured with the straps on the arm cushions when they are used. Maintain a one-inch clearance (approximately two fingers' width) between the end of the arm cushion and the patient's axilla. Never place arm cushion snugly against patient's axilla. Undue pressure on axillary blood vessels and brachial plexus may result.

Rotation Pack Support - Do not remove rotation pack supports which must be used to help position the patient when rotation angles are more than 20° to either side. Rotation pack supports (or body packs) include the head pack, side support packs and leg abductor pack. Also refer to side rails in the **Risks and Precautions** section.

Tube and Line Management - Prior to activating rotation, assess the security of all invasive lines and tubes to accommodate a full 60° angle of rotation and minimize the risk of binding, disconnecting or dislodging. Tubes and lines should always have slack for rotation and patient movement.

Fluids - Avoid spilling fluids on unit controls. If spills do occur, unplug unit, clean fluid from unit, wearing rubber gloves to avoid any possibility of shock. Once fluid is removed, check operation of components in area of spill.



Fluids remaining on controls can cause corrosion, which may cause components to fail or to operate erratically, possibly producing hazards for patient and staff.

Oxygen Use - DANGER: Risk of explosion if used in the presence of flammable anesthetics. Use of this product in an oxygen-enriched environment may produce potential of fire hazard. This equipment is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.



When using half-bed-length-type oxygen administering equipment, ensure that side rails are outside of oxygen tent and not contained within the oxygen environment. Hand control not available with this product.

Lock-Outs - Lock-outs for bed functions and air functions should be used at staff's discretion to ensure against unintentional operation of system settings.

Moving Parts - Powered bed mechanisms can cause serious injury. Keep all equipment, tubes and lines, loose clothing, hair and parts of body away from moving parts and pinch points.

Power Cord - Ensure power cord is kept free from all pinch points, moving parts and is not trapped under casters. Improper handling of power cord can cause damage to the cord, which may produce risk of fire or electric shock.

Avoid Fire Hazards - To minimize the risk of fire, connect the unit's power cord directly into a wall-mounted outlet. Do not use extension cords or multiple outlet strips. In the US, review and follow FDA's Safety Tips for Preventing Hospital Bed Fires. Outside the US, consult the local Competent Authority or Government Agency for Medical Device Safety for specific local guidance.

Scale Readings - Scales / patient weights are for reference only. Scale readings should not be relied upon for medication dosage. All equipment on the weighed portion of the unit is included in weight displayed.

Tobacco Smoke - If routine laundering and cleaning procedures are not followed, tobacco smoke buildup may conceivably reduce the amount of air flow through the product. Severe air restrictions (whatever the source) may cause the unit to overheat and deactivate automatically.

Blank Display - If main control panel remains blank, call for service immediately.

Batteries - Unit contains batteries and must be plugged in when not in service.

Disposal - At the end of useful life, dispose of waste according to local requirements or contact the manufacturer for advice. There may be special requirements for disposal of batteries, leaded foam and / or angle sensors (if present in this product).

Patient Placement Check

- Verify casters are in the locked position.
- Verify patient is positioned in center of unit and rotating properly.
- Verify one-inch clearance between end of arm cushions and patient's axilla.
- Verify patient's legs are positioned correctly between leg abductor cushions.
- Verify pressure settings allow 40% depression into cushion where patient lies, and there is 1 in to 1.50 in (25 mm to 38 mm) minimum clearance below patient's buttocks.
- Verify head of unit is not elevated over 35° angle. (Elevations over 35° angle cause alarm to sound and rotation to be deactivated. This includes a combination of Fowler and Trend angles.)
- Verify side rails are not lowered. (Lowered side rails will cause alarm to sound and rotation to be deactivated.)
- Prior to activating rotation, assess security of all invasive lines and tubes to accommodate programmed angle of rotation and minimize risks of binding, disconnecting or dislodging.
- Verify unit is in lowest practical position before leaving patient unattended.

Alarms

An audible alarm will sound under the following conditions:

- Patient has exited unit (when bed exit alarm is selected).
- Side rail is down and rotation is active.
- Instaflate™ function has been activated for 20 minutes.
- Seat deflate has been activated for 20 minutes.
- Head of unit is elevated over 35° angle and rotation is active.

To silence alarm:

- View main control panel or **Nurse** display for cause of alarm.
- Disarm bed exit alarm on scale control panel.
- Correct cause of alarm.

Operating Tips

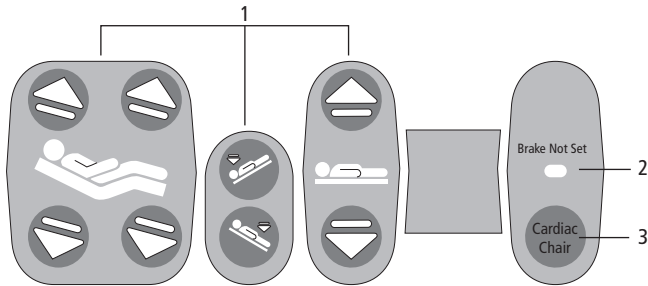
- Battery back-up may provide two hours of static air support. Rotation, percussion and pulsation will be suspended.
- Use **Cardiac Chair** button on side rail control panel to achieve cardiac chair position.
- Rotation will be deactivated if head of unit is elevated over 35° angle or if a side rail is lowered.
- Patient will automatically be returned to center position if side rails are lowered during rotation.

Side Rail Control Panels

BED POSITIONING BUTTONS (located outside of headend side rails)



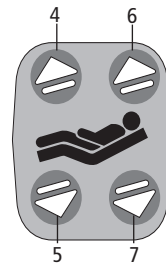
Height of bed automatically adjusts to accommodate Trendelenburg and Reverse Trendelenburg angles.



1. **Bed Positions** - Back up / down and knee gatch up / down, Trendelenburg / Reverse Trendelenburg, bed up / down.
2. **Brake Not Set** - LED light will flash when brake is not set.
3. **Cardiac Chair** - Press button to position patient to 51° fowler angle, 20° knee gatch and 9° Reverse Trendelenburg.

BED POSITIONING BUTTONS (inside of headend side rails)

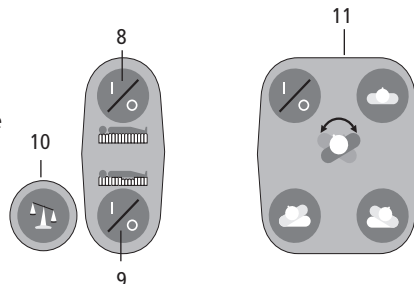
4. **Knee Up** - Press button to raise knee gatch up to 30° angle.
5. **Knee Down** - Press button to lower knee to level position.
6. **Back Up** - Press button to raise back up to 90° angle.
7. **Back Down** - Press button to lower back to level position.



BED POSITIONING BUTTONS (located outside of footend side rails)

This footend side rail control panel is not available on all units

8. **Instaflate function** - Press to increase air pressure in all cushions and create a firm surface.
9. **Seat Deflate** - Press to reduce air pressure in seat section cushion by 50%.
10. **Scale** - Press to display patient weight in the Nurse display.
11. **Bed Rotation** - Press buttons for rotation On / Off, center hold, left hold and right hold.



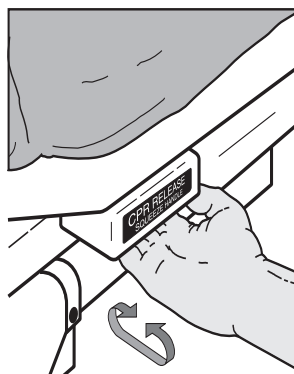
CPR

1. Squeeze and hold red CPR handle located on underside of head-end of unit frame. Air is switched off; cushions will deflate.



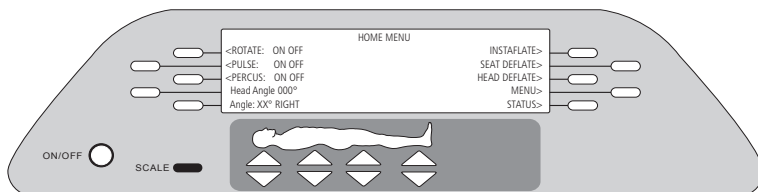
Head-end of unit frame (if elevated) will drop abruptly when CPR handle is squeezed.

2. Lower side rails.
3. Begin CPR. Crash board is not needed.
4. After CPR is performed and patient is clinically stable:
 - Raise and lock side rails (if using).
 - Press **Cancel CPR** button on **Main** display to inflate cushions and resume unit functions.



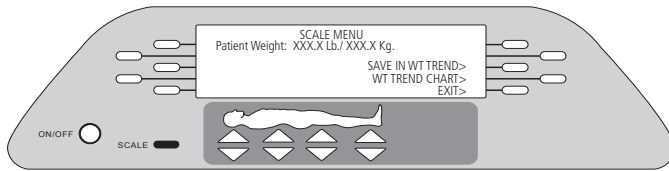
Main Control Panel

Use **Home Menu** Display to:



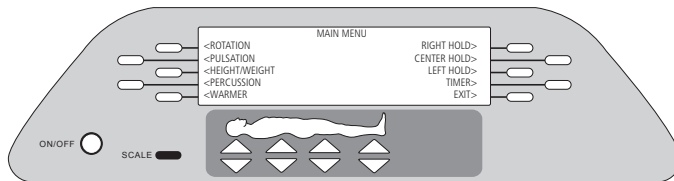
- Turn rotation On / Off
- Turn pulsation On / Off
- Turn percussion On / Off
- View current angle and direction of rotation
- Activate *Instaflate* function
- Activate seat deflate
- Activate head deflate
- Access **Main** menu
- Access **Status** display

Use **Scale Menu** display to:



- **SAVE in WT Trend** - Use the **Save in WT Trend** button to enter patient's most recent weight reading into the weight trend chart, with date and time each reading was taken.
- **WT TREND CHART** - Use **Wt Trend Chart** button to view patient's weight trend chart which shows initial weight and the four most recent weight readings, with date and time each reading was taken.

Use **Main Menu** display to access:



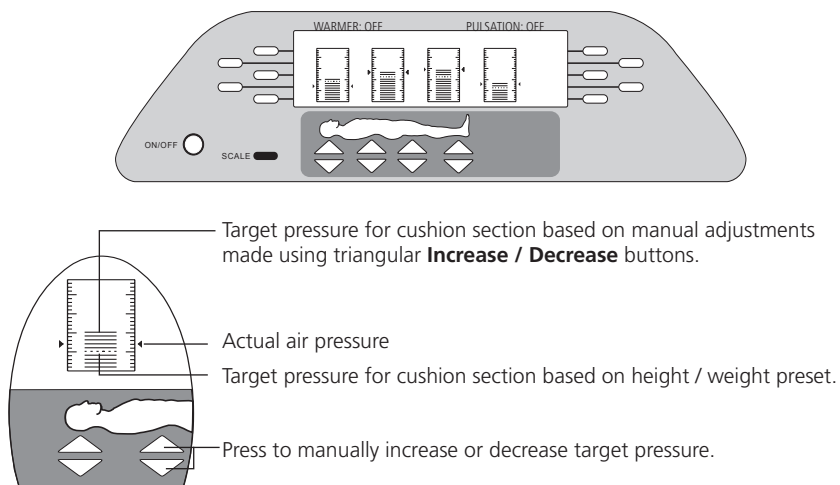
- **Rotation Menu** - Use to view and adjust:
 - Current status
 - Rotation angles
 - Pauses
- **Pulsation Menu** - Use to view and adjust:
 - Current status
 - Intensity
 - Cycle time
- **Height / Weight Menu** - Use to set air pressures in each section of cushions based on patient's height and weight. (Use **Air Pressures** display for additional manual adjustment.)
- **Percussion Menu** - Use to view and adjust:
 - Current status
 - Intensity
 - Duration
 - Frequency

- **Warmer Menu** - Use to view and adjust:
 - Current status
 - Warmer settings
- **Right Hold** - Use to interrupt rotation and turn patient to selected right position and hold the patient there.
- **Center Hold** - Use to interrupt rotation and turn patient to center (level) position and hold patient there.
- **Left Hold** - Use to interrupt rotation and turn patient to selected left position and hold patient there.
- **Timer Menu** - Use to view total:
 - Rotation hours above and below 40° angle
 - Percussion hours

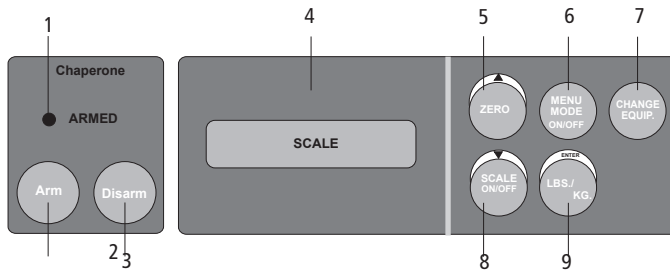
Use Air Pressures display to:

View a bar graph representation of air pressures in each section of cushions (head, back, seat and leg).

Current status of pulsation and warmer are also shown.



Scale Control Panel



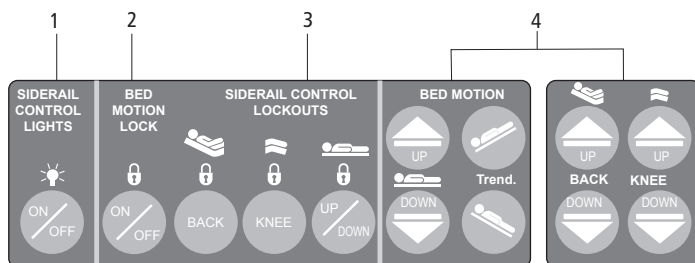
1. **Bed Exit Indicator Light** - Illuminates when bed exit alarm is activated.
2. **Arm** - Press button to activate bed exit alarm.



Monitor patient frequently to guard against patient entrapment.

3. **Disarm** - Press to deactivate bed exit alarm or to silence exit alarm. Be sure to reactivate each time patient returns to bed.
4. **Scale Display** - Displays patient weight and current Trendelenburg angle.
5. **Zero (▲)** - Press button to zero scale. Use ▲ to toggle options in **Menu Mode**.
6. **Menu Mode** - Press button to access patient weight change option and to view Trendelenburg and fowler angles.
7. **Change Equip.** - Press button to hold current patient weight during addition or removal of linens, equipment, etc.
8. **Scale On / Off (▼)** - Press button to display current patient weight. Use ▼ to toggle options in **Menu Mode**.
9. **LB / KG (Enter)** - Press button to convert weight display from pounds to kilograms. Use as **Enter** button in **Menu Mode**.

Bed Motion Control Panel



- 1. Side Rail Control Lights** - Press button to sequentially turn patient control panel backlight on low, medium, high and off.
- 2. Bed Motion Lock** - Press button to lock-out all bed motion functions.
- 3. Side Rail Control Lockouts** - Press button to lock-out side rail control for back up / down, knee gatch up / down, and bed up / down functions.
- 4. Bed Positioning Buttons** - Bed Up / Down, Trendelenburg / Reverse Trendelenburg, Back Up / Down and Knee Gatch Up / Down.



Height of bed automatically adjusts to accommodate Trendelenburg and Reverse Trendelenburg angle.

Scale Displays

Zero

Use **Zero** button to recalibrate the scale to 0.0 lb (0.00 kg) prior to patient placement, with linens and all equipment, etc. already on the weighed portion of the unit.

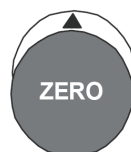


The I.V. pole at the head of the unit frame and the foley bag holders are not on the weighed portion of the unit. The I.V. pole supports at the foot end of the patient support surface are on the weighed portion of the unit.



Do not use **Zero** button while a patient is on the unit. An inaccurate weight reading will result.

- With the patient weight showing in the **Scale** display, **press and hold the Zero** button shown at right.



Hold to Zero WT display will appear temporarily, as shown at right.

HOLD TO ZERO WT

Release to Zero display will appear temporarily, as shown at right.

RELEASE TO ZERO

2. Release **Zero** button.
Do Not Touch Bed display will appear temporarily, as shown at right.

DO NOT TOUCH BED



Do not touch unit until the **0.0 lb (0.0 kg)** display appears. The bed exit armed light will flash temporarily.

Change Patient Weight Reading



The I.V. pole at the head of the unit frame and the foley bag holders are not on the weighed portion of the unit. The I.V. pole supports at the foot end of the patient support surface are on the weighed portion of the unit.

1. With the patient weight showing in the **Scale** display, **press and hold** the **Menu Mode On / Off** button shown at right.

MENU
MODE
ON/OFF

For Options display will appear, as shown at right.



FOR OPTIONS

2. Press **Scale On / Off** button to select the patient weight change option.
Chng. Ptnt. Wgt. display will alternately appear, as shown at right.

CHNG. PTNT. WGT.

PUSH ENTER

3. Press **Enter LB / KG** button shown at right.



Hold to Dec. / Hold to Inc. display will alternately appear., as shown at right).

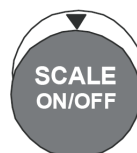
HOLD ▼ TO DEC.

HOLD ▲ TO INC.

4. Adjust as needed:
- **Press and hold Zero** button to increase patient weight.
 - **Press and hold Scale On / Off** to decrease patient weight.
5. Press **Enter LB / KG** button to save new patient weight.

View Fowler and Trendelenburg Angles

1. With the patient weight showing in the **Scale** display, press **Scale On / Off** button shown at right.



The **Exit Scale** display will appear temporarily, as shown at right.

EXIT SCALE

2. The **Fowler Angle X°** display will appear, as shown at right.

FOWLER ANGLE X°

3. To view Trendelenberg angle press either **Trend.** button on the bed motion control panel as shown at right.



The **Trend Angle X°** display will appear, as shown at right.



4. Press **Scale On / Off** button to exit **Trend / Fowler** display.



To view Fowler and Trend angles on beds with the old style (rounded) side rails, use the Trend / Fowler Angle button on the Scale Control Panel.

Change Equipment

Use **Change Equip** button to hold current weight value in memory while other weight (traction, etc.) is added or removed. Added / removed weight will not be reflected in weight reading.

1. With the patient weight showing in the **Scale** display, **press and hold** the **Change Equip** button shown at right.



The **Hold to Start** display will appear temporarily, as shown at right.



The **Release to Start** display will appear, as shown at right.



2. Release **Change Equip** button. **Add / Remove Equipment** display will appear, as shown at right.



3. Press **Change Equip** button.
Do Not Touch Bed display
will appear temporarily, as
shown at right. Do not touch
unit until patient weight
returns in **Scale** display.



Specifications*

Maximum Recommended Patient Weight	350 lb (160 kg)
Total Weight of all Accessories	50 lb (23 kg)
Total Unit Weight (includes scale, IV poles and mattress)	825 lb (375 kg)

Dimensions:

Overall Length.....	91 in (231 cm)
Overall Width.....	42.50 in (107.95 cm)
Patient Surface Length	82.50 in min to 93.50 in max (210 cm min to 237 cm max)
Patient Surface Width	35 in (89 cm)
Height (to litter top)	22.50 in min to 33 in max (57 cm min to 84 cm max)

Articulation:

Knee Gatch	6.5° to 30°
Fowler	0° to 90°
Trendelenburg / Reverse Trendelenburg	+9° / -9°

Cardiac Chair:

Head.....	51°
Knee.....	20°
Reverse Trendelenburg.....	-9°
Electrical Data (115 V).....	115 VAC, 60 Hz, 12 A
Electrical Data (230 V).....	230 VAC, 50 / 60 Hz, 7 A
Maximum Electrical Leakage	Less than 100 / 200 Microamps
Scale Accuracy	±2% of Patient Weight

Scales / patient weights are for reference only. Scale readings should not be relied upon for medication dosage.

*Specifications subject to change without notice.

Customer Contact Information

For questions regarding this product, supplies, maintenance or additional information about ArjoHuntleigh products and services, please contact ArjoHuntleigh or an ArjoHuntleigh authorized representative or visit: www.ArjoHuntleigh.com. In the US, call 1-800-343-0974.

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Getinge Group is a leading global provider of products and systems that contribute to quality enhancement and cost efficiency within healthcare and life sciences. We operate under the three brands of **ArjoHuntleigh**, **Getinge** and **Maquet**. **Getinge** provides solutions for infection control within healthcare and contamination prevention within life sciences. **Maquet** specializes in solutions, therapies and products for surgical interventions, interventional cardiology and intensive care.

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ArjoHuntleigh focuses on patient handling and hygiene, disinfection, DVT prevention, medical beds, therapeutic surfaces and diagnostics.



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