turmedical

Instructions for Use

pronova·O2™
automated prone therapy system

Legal Statement

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The Pronova-O₂™ Automated Prone Therapy System and most other Turn Medical products are subject to patent and/or pending patents. A copy of patents and/or patents pending can be found at Turnmedical.com/patents.

Notes

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DISCLAIMER OF WARRANTY AND LIMITATION OF LIABILITY

This user manual provides the information required for the normal operation of the Pronova-O_2™ Automated Prone Therapy System (Pronova-O_2™) from Turn Medical. It is important that you read and strictly adhere to the aspects of safety contained in this manual. The statements, technical information and recommendations contained herein are believed to be accurate as of the date hereof. Since the conditions and methods of use of the product and of the information referred to herein are beyond our control, Turn Medical expressly disclaims any and all liability as to any results obtained or arising from any use of the product or reliance on such information; NO WARRANTY OF FITNESS FOR ANY PARTICULAR PURPOSE, WARRANTY OF MERCHANTABILITY OR ANY OTHER WARRANTY, EXPRESSED OR IMPLIED, IS MADE CONCERNING THE GOODS DESCRIBED OR THE INFORMATION PROVIDED HEREIN.

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Information in this publication may be subject to change at any time. Contact Turn Medical for updates at 1.855ASKTURN (1.855.275.8876).

IMPORTANT INFORMATION FOR USERS
Turn Medical recommends compliance with the following conditions in order for Turn Medical products to perform properly. Failure to comply with these conditions will void any applicable warranties.

- Operate this product only in accordance with these instructions and applicable product labeling. Please contact Turn Medical for product and competency training prior to operating the Pronova-O_2™.

- Contact Turn Medical for information regarding maintenance and repair. Any modifications, assembly, extensions, adjustments, technical maintenance, or repairs must be performed by qualified personnel who have completed product specific training and have been authorized by Turn Medical to perform.

- Ensure the electrical installation of the room complies with the appropriate national electrical wiring standards.

Specific indications, contraindications, warnings, precautions, and safety information exist for Turn Medical's Pronova-O_2™. It is important for users to read and familiarize themselves with these instructions and to consult the treating physician prior to patient placement and product use. Individual patient conditions may vary. Contact your local Turn Medical representative for product education and training.

Caution: Federal law restricts this device to sale by or on the order of a physician.

Introduction

This manual provides the required information for the operation of the Pronova-O₂™ Automated Prone Therapy System from Turn Medical.

Pronova-O₂™ provides the following therapies:

- Automated Prone Therapy with Prone Rotational Therapy up to 65° bilaterally
- Automated Supine Therapy with Supine Rotational Therapy up to 65° bilaterally

Additional features include:

- Integrated packs and accessories
- Single patient use Critical Line Management System
- Single patient use InteliDerm™ Face Pack and Chest Wedge
- Interactive touch screen User Interface designed by Intensive Care Unit (ICU) nurses
    - Patient therapy history, weight and microclimate history
    - Visibility of cumulative time in Prone Position to meet therapy goals
- Ergonomically designed low surface height
- Pressure relief hatch in occiput region of head support
- Intubation lever facilitates intubation
- Automated CPR and Manual CPR release
- 4 hour battery backup allows for use of Rest at Angle in any position
- Built in safety features such as integrated packs and accessories, buckle tension release, safety checklist and sensors

Indications for Use

The Pronova-O₂™ Automated Prone Therapy System is designed to treat and prevent pressure injuries and to assist in the management of patients experiencing pulmonary distress and/or complications due in part to patient immobility. Such pulmonary distress or complications can arise in immobile patients suffering from pneumonia, sepsis and ventilatory associated events, among others.

Intended Use

The Pronova-O₂™ Automated Prone Therapy System is a rotating hospital bed intended to allow for automated patient Supine and Prone Positioning with or without Continuous Lateral Rotational Therapy (CLRT). Pronova-O₂™ is intended to assist in the optimal positioning of a patient in a manner requiring fewer hospital staff. Patient positioning has been found to be highly effective in assisting in the treatment of certain conditions.

Intended Use Environment

The Pronova-O₂™ Automated Prone Therapy System is intended for use in the intensive/critical care and acute care environments where close medical supervision and monitoring is provided. It is not intended for use in long term care, outpatient care, or home care environments where close medical monitoring is not possible.

Intended Users

The intended users of this product are trained health care professionals who have completed required training set forth by the facility and Turn Medical. Facility safety protocols and competency checks should be followed prior to using the product.

Contraindications
Patient conditions which are contraindicated for the use of the Pronova-O_2™ Device include:
- Patient weight below 88 lbs./40 kg
- Patient weight above 400 lbs./181.4 kg
- Patient height below 4'6" (137.1 cm)
- Patient height above 6'6" (198.1 cm)
- Unstable spine (cervical, thoracic, lumbar)

Prone ONLY:
- Skull or severe facial fractures
- Uncontrolled Intracranial Pressure (ICP)
- Cervical and/or skeletal traction

Risks
Proning itself, either automated or manual, may present inherent risks of serious injury. A significant body of clinical evidence has reported risks associated with the Prone Position in general. Some of the most frequently reported risks include, but are not limited to:
- Loss of invasive lines
- Pressure injuries and skin breakdown
- Facial edema and swelling
- Increased pressures within the eyes (intra-orbital pressure); related to Prone Position duration
- Increased intra-abdominal pressures
- Increased intracranial pressures
- Intolerance to Prone Position
- Prone dependence
- Need for increased sedation
- Brachial plexus lesions (nerve damage)

Precautions
Certain precautions may need to be taken when using Pronova-O_2™ including, but not limited to:
- Open sternal or abdominal wounds
- Multiple traumas with unstable fractures
- Pregnancy
- Severe hemodynamic instability
- Multiple trauma/unstable fractures
- High dependency on airway and vascular access
- Open sternal wounds with patient in Prone Position
- Intracranial Pressure Monitoring systems
- Transient desaturation or transient hypotension; related to Prone Position change
- Extracorporeal Life Support or Extracorporeal Membrane Oxygenation
- Any implantable device such as, but not limited to hemodialysis access ports, chemotherapy ports, breast implants, penile implants and other prosthetics
- Chest tube drainage systems
- Body piercings

Prior to ordering the product, contraindications, risks and precautions should be discussed by the healthcare team with the patient's designated representative.

Safety Information

This section reviews the product functions and safety information related to the Pronova-O₂™ Automated Prone Therapy System. It is recommended clinicians interacting with the product participate in a device inservice and/or review this manual prior to operating the device. Contact your representative for further information on device inservicing and education.

Bed Height
To minimize risk of injury, bed height should be at lowest practical position when possible.

Lock Pin
The Lock Pin provides additional stability to surface and should be engaged when in 0° Supine Position.

Central Locking Brakes and Steer Lock Pedals
Once device is properly positioned in patient room, brakes should be engaged at all times.

Skin Care
Common pressure points for patients in the Prone Position include, but are not limited to, face, ears, shoulders, sides of body, knees and toes. Assess skin at frequent intervals according to hospital policy and procedures. Securing Pronova-O₂™ components such as InteliDerm™ Face Pack, Prone Support Surfaces, and Side Supports too tightly can cause increased risk for pressure injury. Do not leave patient stationary in the Prone or Supine Position for greater than 2 hours.

InteliDerm™ Face Pack
The Face Pack is for single patient use only. This Face Pack incorporates a powered microclimate feature to reduce risk for skin breakdown and should be plugged in to the face microclimate connection on the patient frame and turned on when possible. Ensure proper placement of Face Pack by ensuring visibility of eyes. Remove Face Pack at regular intervals while Supine to assess skin and eyes. Ensure safe placement of Face Pack by securing support straps, and pull up to ensure safe securement, as the Face Pack does not have a sensor. Do not place Face Pack tightly to avoid unnecessary pressure.

InteliDerm™ Chest Wedge
The Chest Wedge is for single patient use only. The Chest Wedge incorporates a powered microclimate feature to reduce risk for skin breakdown and should be plugged in to the chest microclimate connection on the patient frame and turned on when possible. Ensure proper placement of Chest Wedge by placing in line with the patient's shoulders and taking consideration for invasive lines/tubes near the Chest Wedge.

Tube and Line Management
Prior to placement, assess securement and length of all invasive lines to ensure safe movement into the Prone Position to reduce risk of dislodgement, disconnection or compression. All lines and tubes should be routed through the head or foot opening for safe rotation. Do not hang or place any devices, equipment or lines on surface, other than in designated areas.

Head Hoop
The Head Hoop should be opened to secure critical lines above midline, utilizing the Critical Line Management System. The Head Hoop shall remain closed when not actively securing invasive lines and must be closed to allow for rotation.

Ventilator Management
Rotation into the Prone Position should always be set to rotate towards the ventilator. Place ventilator tubing in Critical Line Management System opposite of ventilator to allow for slack during rotation. Ensure proper securement of Endotracheal tube (ETT) prior to placement on surface. It is recommended to not use plastic securement devices to reduce risk of skin breakdown.

Touch Points
Designated touch points are generally purple in color. Use the designated touch points when articulating parts of the device to avoid risk of pinch points.

Prone Surface Support
Each Prone surface support has a sensor to ensure safe placement. Keep in mind pressure points with each section and adjust as necessary to reduce risk for breakdown. If unable to release buckle, utilize the strap tension release lever located on the patient left Prone Support Arms.

Side Supports
Side supports should fit snugly beside patient's body to reduce friction and shearing. Allow for approximately a 2-inch clearance under the axilla of patient to reduce risk for injury. Adjust as required.

Foot Rest
Adjust Foot Rest as required to provide support without causing additional pressure.

Foot Opening
All invasive lines below midline should be routed through the foot opening. Utilize appropriate protocols to route safely through opening if disconnection is required.

Prone Panels
The two chest, seat and two lower leg panels have sensors to ensure safety. The Center Chest Panel does not have a sensor. Ensure all panels are secured prior to rotation to the Supine Position. Use caution when opening or closing panels, keeping objects, extremities, etc, clear of openings to avoid injury.

CPR and Manual Rotation
Clinicians and other hospital personnel are recommended to become familiar with automated and manual CPR operation and procedures to operate Pronova-O_2™ prior to use.

Scale
All items on the patient surface, Accessory Sockets and Accessory Racks, are included in scale reading. Weight is for reference only and should not be used for medication dosage.

Fluids
Use caution to avoid spilling fluids on unit controls to reduce risk of corrosion or shock. If spills occur, call technical support or refer to instructions to clean area safely.

Additional Equipment
Do not place additional equipment on surface. Keep in mind that any additional equipment will add weight to the scale.

Power Cord
Power cord should be plugged in at all times possible, taking care to avoid a trip hazard and avoiding compression of cord. Improper handling of cord can affect functionality and safety of cord. Pull the power cord out of the wall outlet to remove mains power from the device. Always position the Pronova-O_2™ device and surrounding equipment so that the power cord can easily be disconnected from the wall outlet, if necessary.

Fire Hazards
To reduce risk of fire, connect cord directly to wall-mounted outlet. Do not utilize extension cords or outlet strips.

Transport
Utilize the steer and neutral options of the central locking brakes to safely transport the device. Pronova-O_2™ is not intended for patient transport.

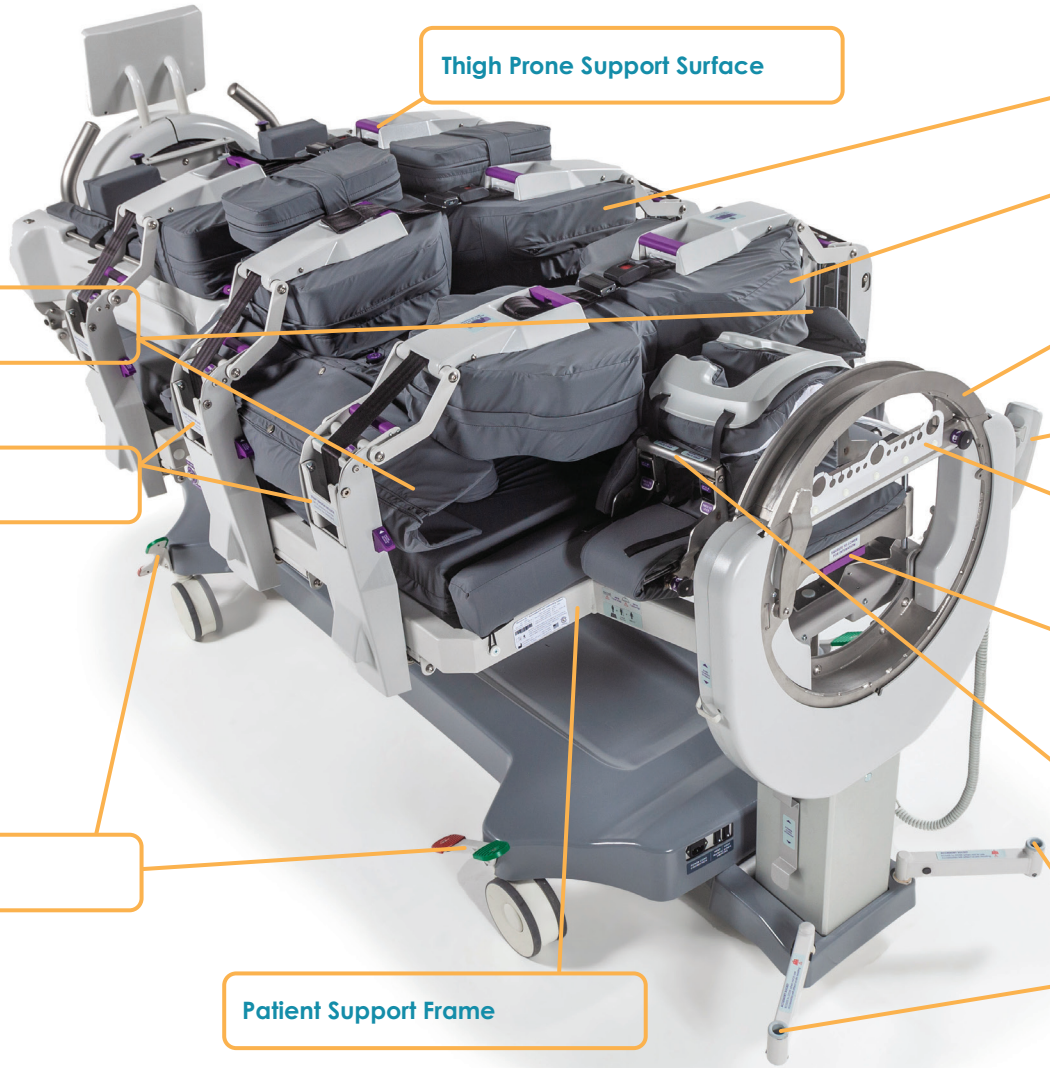
General Hospital Protocols
Follow all applicable hospital and safety protocols while using the Pronova-O_2™ surface.

Prone Occipital Panel
The Prone Occipital Panel is designed to reduce facial pressure in the Prone Position. The Prone Occipital Panel has a sensor to ensure safety.

Oxygen Rich Environment
Do not use this device in oxygen rich environments or with oxygen tents.

Pronova-O₂™ Device Components

This section reviews some of the major components of Pronova-O₂™ for ease of use. Please refer to Instructions for Use section for more detailed information regarding each component in this diagram or not mentioned below.



Thigh Prone Support Surface

Pelvic Prone Support Surface

Chest Prone Support Surface

Arm Slings

Head Hoop

Hand Control

Strap Tension Release

Critical Line Management System (single patient use)

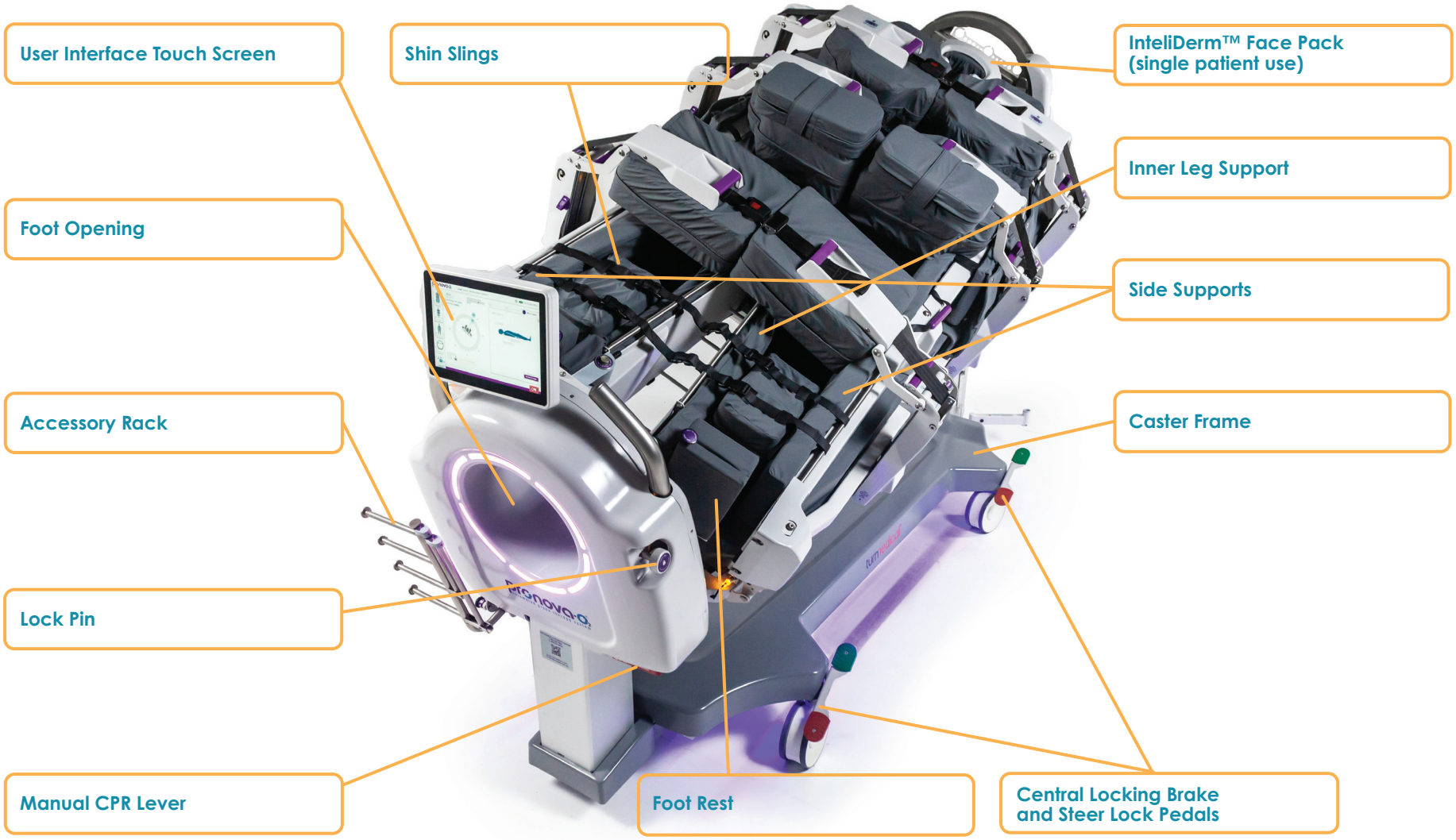
Intubation Lever

Central Locking Brake and Steer Lock Pedals

Head Support

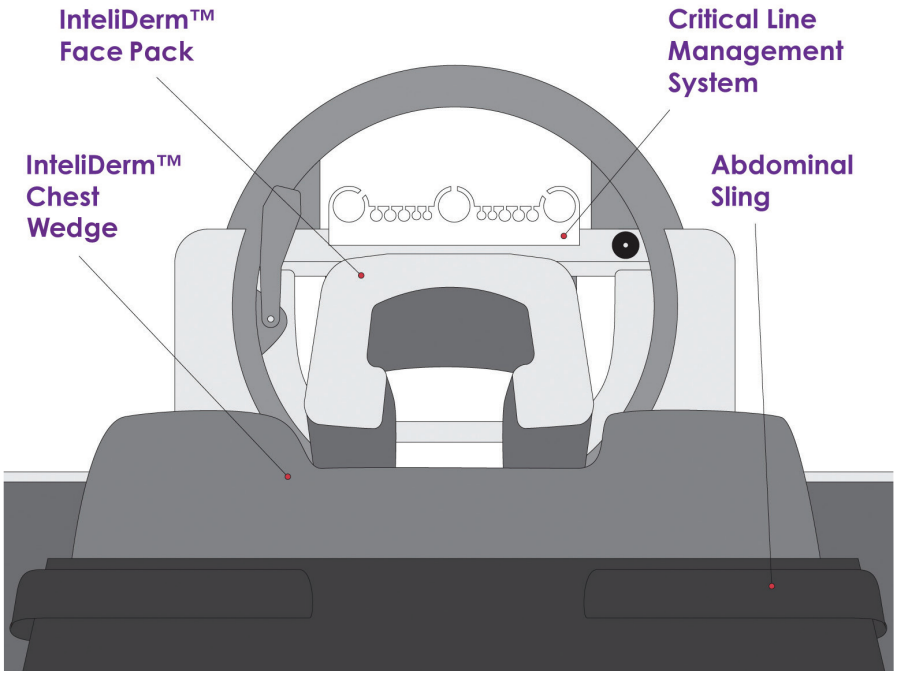
Patient Support Frame

Accessory Sockets


User Interface Touch Screen
Shin Slings
InteliDerm™ Face Pack
(single patient use)
Inner Leg Support
Foot Opening
Side Supports
Accessory Rack
Caster Frame
Lock Pin
Manual CPR Lever
Foot Rest
Central Locking Brake
and Steer Lock Pedals

InteliDerm™ Single Patient Use Kit

The InteliDerm™ Single Patient Use Kit contains all the single patient use items required for a patient placement. The kit consists of the following disposable items:



Quantity	Item
1	*InteliDerm™ Face Pack*
1	*InteliDerm™ Chest Wedge*
1	*Abdominal Sling*
1	*Critical Line Management System*

One InteliDerm™ Single Patient Use Kit is provided with each rental order. For customers that own Pronova-O_2™, InteliDerm™ Single Patient Use Kits are available for purchase in single or bulk quantities by contacting Turn Medical at 1-855-ASK-TURN (1-855-275-8876).

Each item is for single patient use. Discard after use.

Pronova-O₂™ Touch Screen User Interface

Home Screen

The Home Screen allows the user to visualize the current status of the Pronova-O₂™ Therapy System, quickly navigate to all functions and adjust the surface height and Trendelenburg angle.

1. **Current Date and Time**
   Displays current date and time. Time and date can be adjusted in the system settings menu.

2. **Battery/AC Status Indicator**
   Displays ⚡ when on AC power and displays % charge when on battery power.

3. **System Settings**
   Provides access to a list of system settings that can be adjusted.

4. **Total Daily Time in Prone Indicator**
   Displays time that patient has been in the Prone Position for the current calendar day. Each tick mark represents one hour.

5. **Navigation Menu**
   Provides easy navigation between major functions of the product.

6. **Time in Supine/Prone**
   Displays continuous time the patient has been in the Supine or Prone position. Displayed as HH:MM.

7. **Device Status Indicators**
   Displays the status of monitoring sensors.

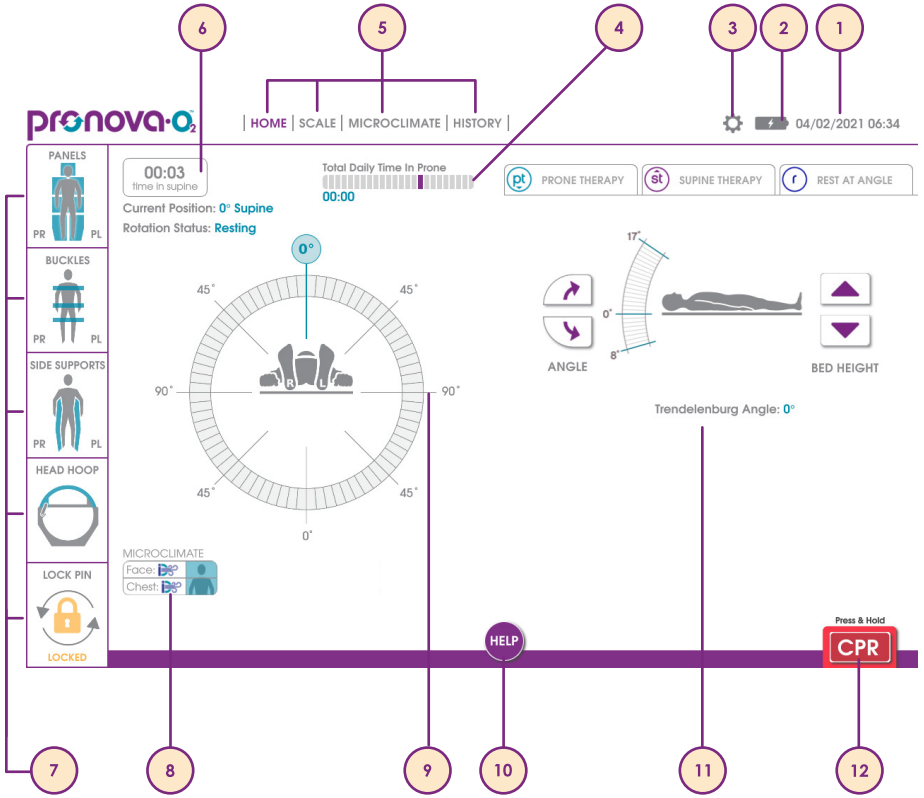
8. **Microclimate Indicator**
   Displays the status of the Microclimate pumps and provides shortcut access to the Microclimate screen.

9. **Rotation Status Indicator**
   Displays the rotational position of the patient surface.

10. **Help Button**
    Provides contextual help related to the current screen.

11. **Surface Position Indicator/Adjustment**
    Provides adjustment of surface height and adjustment and displays Trendelenburg angle.

12. **CPR Button**
    Provides adjustment of the device to lowest position and 0° Supine IF all indicators are in a safe position for patient rotation.



Pronova-O₂™ Touch Screen User Interface

Prone Therapy Screen

The Prone Therapy tab allows the user to enter settings for Prone Therapy, including rotation, pause times, Prone rotation direction, and Prone duration. The Prone Therapy tab also allows the user to initiate rotation into the Prone Position and initiate Prone Rotation Therapy.

1. **Set Turn Angle**
   Enter rotation settings by pressing up or down arrow or pressing and dragging the purple markers on the angle wheel for both patient left and patient right side. Angle adjusts by 5 degree increments.

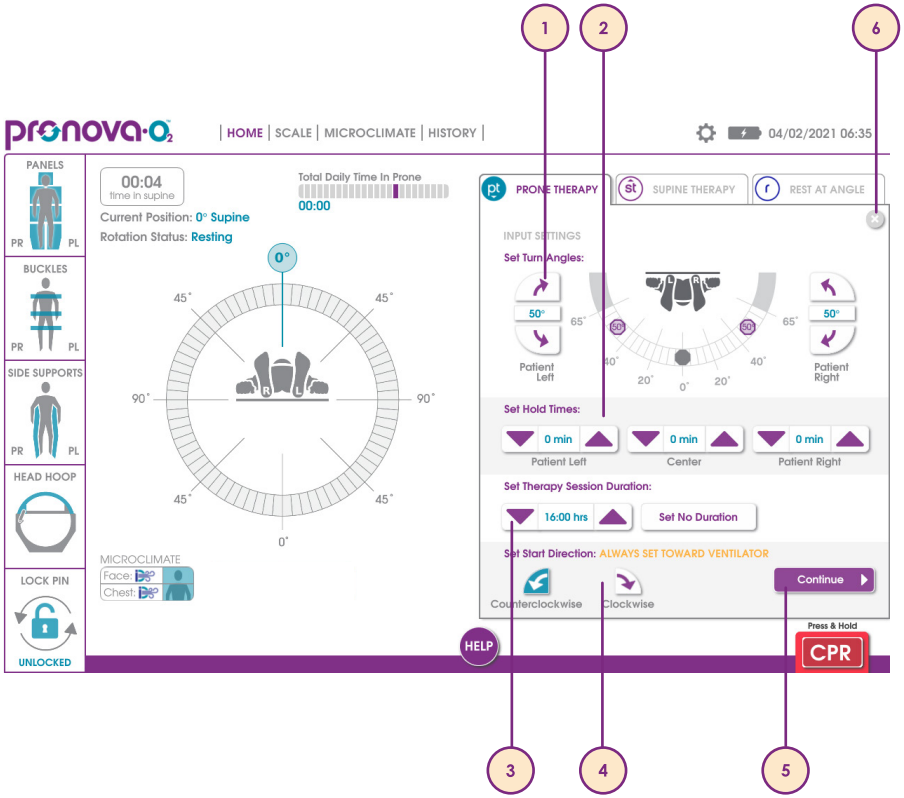
2. **Set Hold Times**
   Enter hold times for Patient Left, Center, and Patient Right by pressing the up or down arrows. Time adjusts in 5 minute increments up to 30 minutes.

3. **Set Therapy Session Duration**
   If desired, enter the physician order for Prone duration. If not desired to set duration, press **Set No Duration**. The Therapy Session Duration sessions can be set in increments of 30 minutes up to 24 hours. When Therapy Session is complete, a screen appears, stating Therapy Session Complete.

4. **Set Start Direction**
   Set the Prone direction based on the location of the ventilator. The surface should always rotate toward the ventilator. To set, press the desired direction, **clockwise or counterclockwise.**

5. **Continue**
   Once settings are entered and verified, press **Continue** to proceed with initiating Prone Therapy.

6. **X or Cancel**
   Press this button to exit to Home Screen if desired.

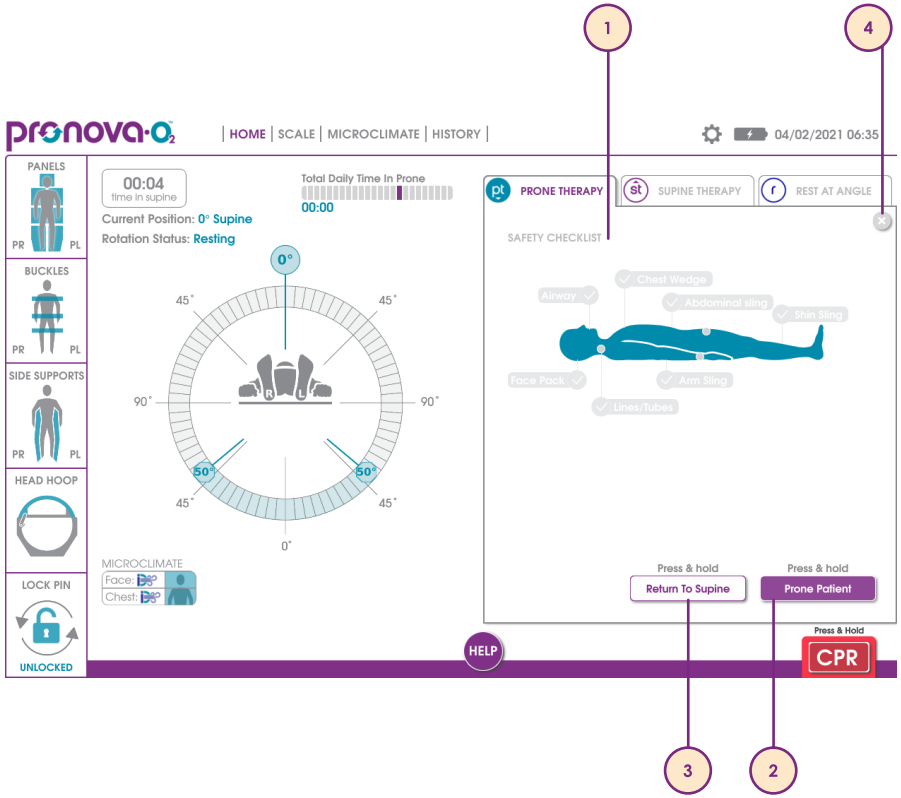


Pronova-O₂™ Touch Screen User Interface

Prone Therapy Safety Checklist - Supine to Prone

The Prone Therapy safety checklist screen appears after the user confirms Prone Therapy settings and pressing Continue on previous screen to initiate rotation in the Prone Position.

1. **Prone Safety Checklist**
   There are 7 items to check prior to rotation into the Prone Position. Check each item prior to pressing the icon:
   - Face Pack
     Ensure Face Pack is secured
   - Airway
     Ensure airway is secured and monitored
   - Chest Wedge
     Ensure Chest Wedge is secured over shoulders
   - Lines/Tubes
     Ensure all lines/tubes are routed through Head Hoop or Foot Opening and monitored
   - Arm Slings
     Ensure arms are in Arm Slings and secured
   - Abdominal Sling
     Ensure Abdominal Sling is secured to side supports
   - Shin Slings
     Ensure Shin Slings are buckled and secured to Inner Leg Support
2. **Prone Patient**
   Press and hold when checklist is complete to begin rotation. If you release, rotation will stop.
3. **Return to Supine**
   Press and hold to return to Supine Position if required. If you release, rotation will stop.
4. **X or Cancel**
   Press this button to exit to Home Screen if desired.



Pronova-O₂™ Touch Screen User Interface

Prone Rotational Therapy Safety Checklist - Prone Position

The Prone Therapy safety checklist screen appears after the user achieves the 0˚ Prone Position to initiate rotation in the Prone Position, or anytime Prone Therapy is initiated in the Prone Position.

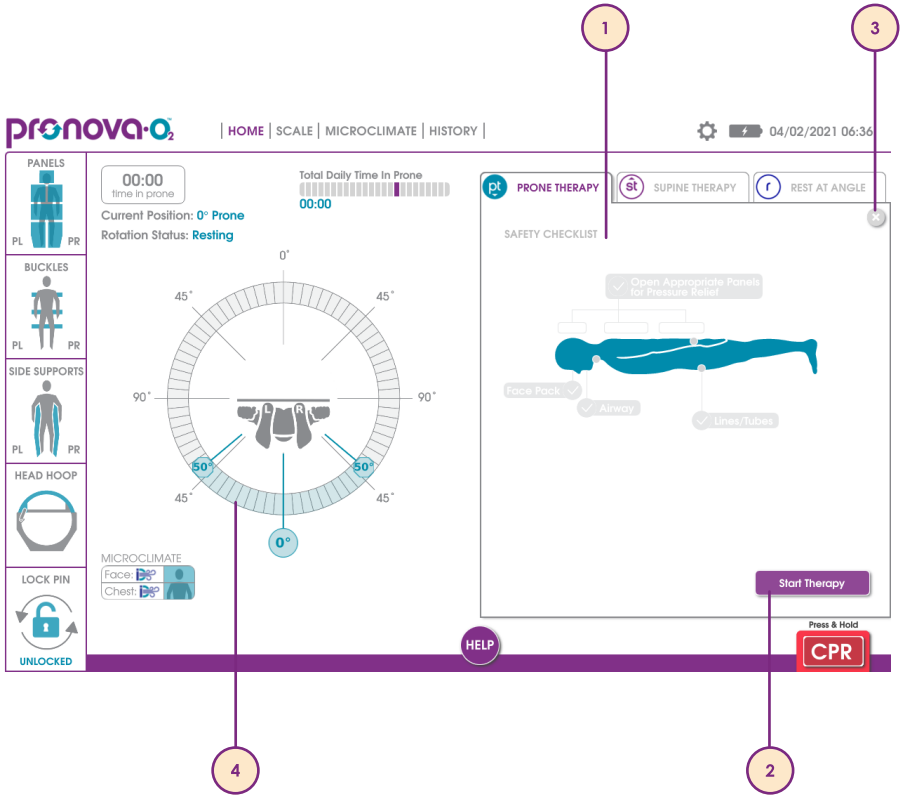
1. **Prone Safety Checklist**
   There are 4 items to check prior to starting rotation in the Prone position. Check each item prior to pressing the icon:

   - Face Pack
     Ensure Face Pack is secured
   - Airway
     Ensure airway is secure and monitored
   - Lines/Tubes
     Ensure all lines/tubes are routed through Head Hoop or Foot Opening
   - Open Appropriate Panels for Pressure Relief
     Prior to initiating rotation, it is recommended to open head, chest and seat panels to relieve temperature and pressure.

2. **Start Therapy**
   Press **Start Therapy** to initiate Automated Prone Rotational Therapy.

3. **X or Cancel**
   Press this button to exit to Home Screen if desired.

4. The Patient Status Wheel indicates the rotation settings entered in the previous screen.



Pronova-O₂™ Touch Screen User Interface

Supine Therapy Screen

The Supine Therapy tab allows the user to enter settings for Supine Therapy, including rotation and pause times. The Supine Therapy tab also allows the user to initiate rotation into the Supine Position and initiate Supine Rotation Therapy.

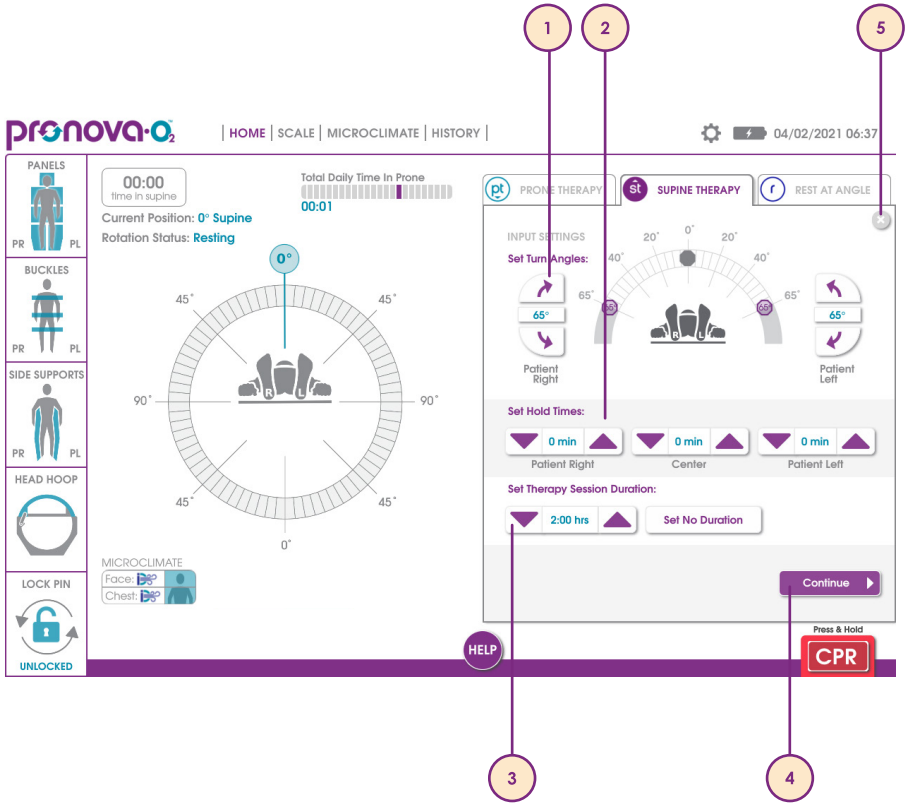
1. **Set Turn Angle**
   Enter rotation settings by pressing up or down arrow or pressing and dragging the purple markers on the angle wheel for both patient left and patient right side. Angle adjusts by 5 degree increments.

2. **Set Hold Times**
   Enter hold times for Patient Left, Center, and Patient Right by pressing the up or down arrows. Time adjusts in 5 minute increments up to 30 minutes.

3. **Set Therapy Session Duration**
   If desired, enter the physician order for Supine duration. If not desired to set duration, press **Set No Duration**. The Therapy Session Duration can be set in 30 minute increments up to 24 hours. When Therapy Session is complete, a screen appears, stating Therapy Session Complete.

4. **Continue**
   Once settings are entered and verified, press **Continue** to proceed with initiating Supine Therapy.

5. **X or Cancel**
   Press this button to exit to Home Screen if desired.



Pronova-O₂™ Touch Screen User Interface

Supine Rotational Therapy Safety Checklist - Supine

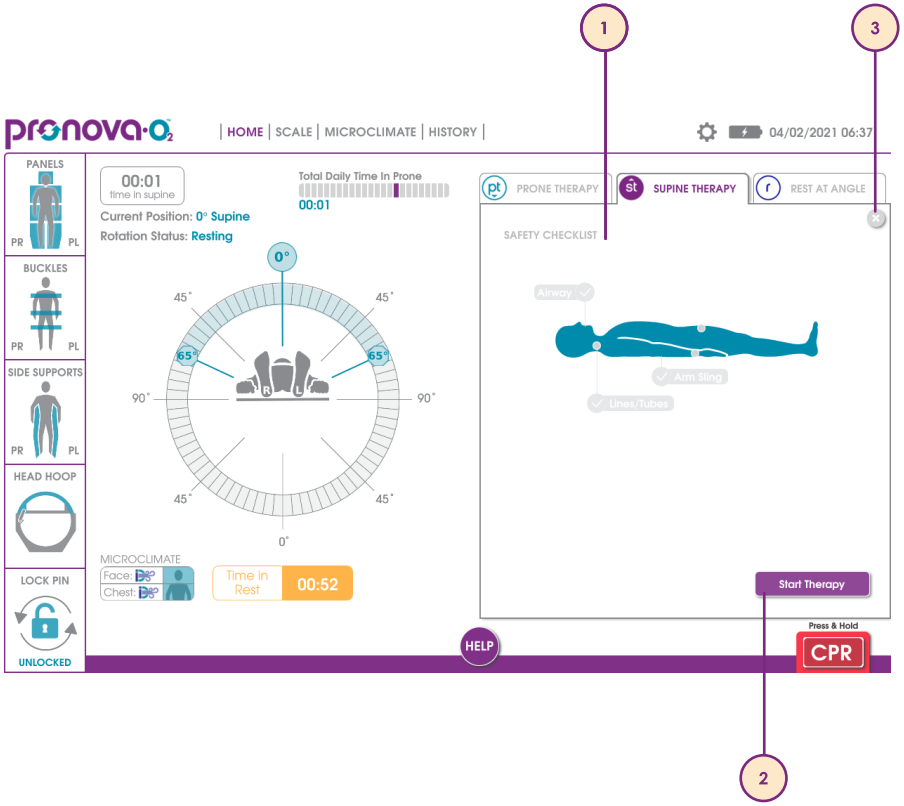
The Supine Therapy safety checklist screen appears after the user presses Continue on the Supine Therapy tab. This screen initiates Supine Rotational Therapy when the patient is in the Supine Position.

1. **Supine Safety Checklist**
   There are 3 items to check prior to starting rotation therapy in the Supine Position. Check each item prior to pressing the icon:

   - Airway
     Ensure airway is secure and monitored
   - Lines/Tubes
     Ensure all lines/tubes are routed through Head Hoop or Foot Opening and monitored
   - Arm Slings
     Ensure arms are in Arm Slings and secured

2. **Start Therapy**
   Press **Start Therapy** to initiate automated Supine rotational therapy.

3. **X or Cancel**
   Press this button to exit to Home Screen if desired.



Pronova-O₂™ Touch Screen User Interface

Supine Therapy Safety Checklist - Prone

The Supine Therapy safety checklist screen appears after the user presses Continue on the Supine Therapy tab. This screen initiates the Supine Therapy from the Prone Position.

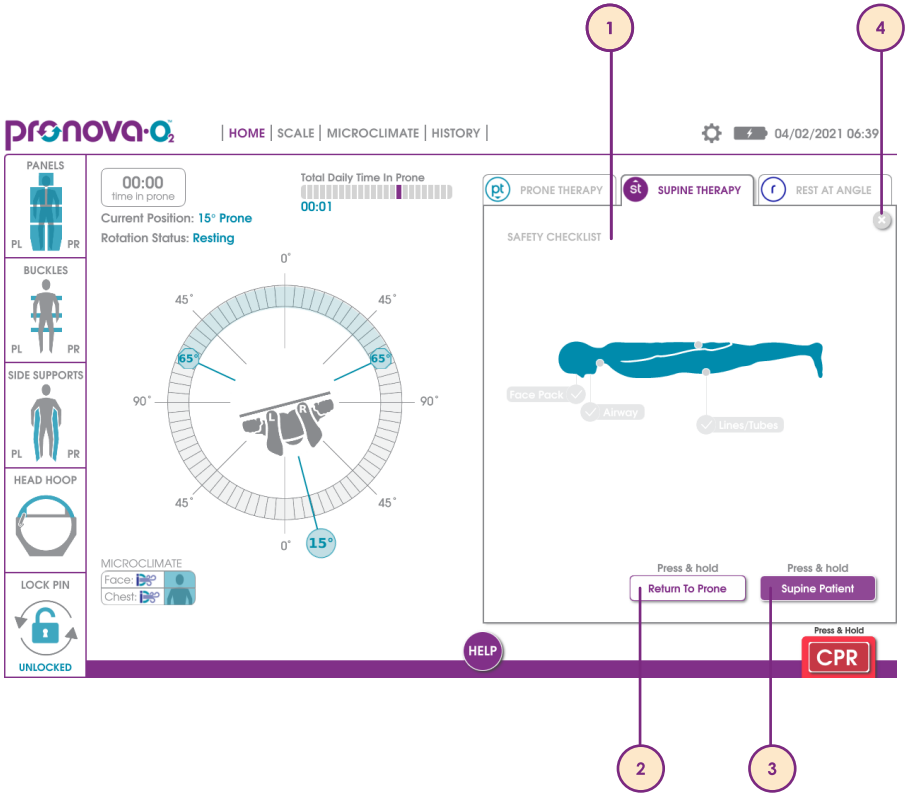
1. **Supine Safety Checklist**
   There 3 items to check prior to rotation into the Supine Position from the Prone Position. Check each item prior to pressing the icon:

   - Airway
     Ensure airway is secure and monitored
   - Lines/Tubes
     Ensure all lines/tubes are routed through Head Hoop or Foot Opening and monitored
   - Arm Slings
     Ensure arms are in Arm Slings and secured

2. **Return to Prone**
   Press and hold to rotate back into the Prone Position if required.

3. **Supine Patient**
   Press and hold to rotate into the Supine position.

4. **X or Cancel**
   Press this button to exit to Home Screen if desired.



Pronova-O₂™ Touch Screen User Interface

Rest at Angle Screen

The Rest at Angle tab allows the user to enter a desired angle to rest at for a short period of time. This screen is useful for procedures, assessments, etc. Once the Rest at Angle has been achieved, a timer will begin counting up. Once assessment/procedure complete, press the Prone Therapy or Supine Therapy tab to initiate rotation.

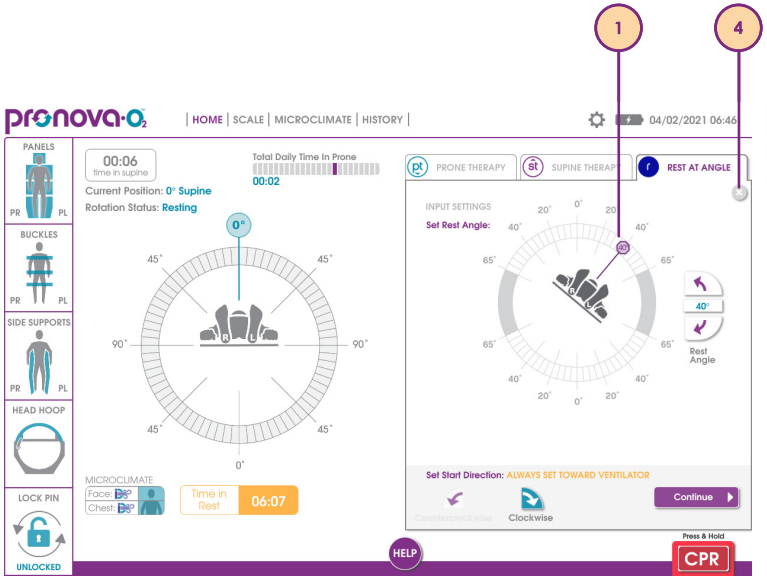
1. **Set Rest at Angle**
   Enter desired angle by pressing up or down arrow or pressing and dragging the purple marker on the angle wheel. Angle adjusts by 5 degree increments.

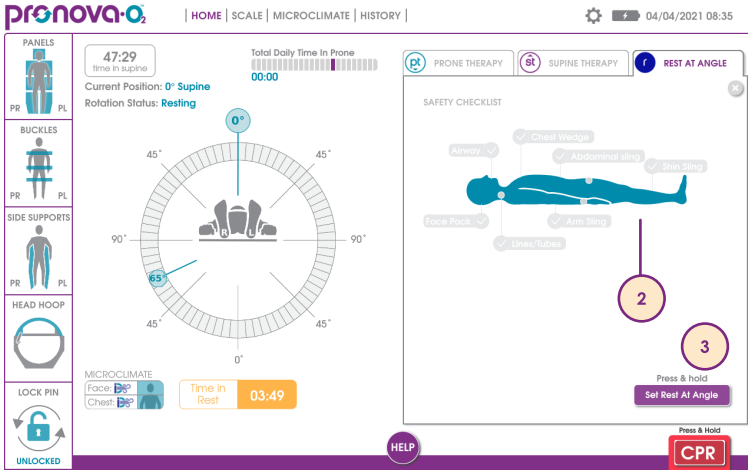
2. **Safety Checklist**
   Depending on the position selected, there are up to 7 items to check prior to initating rotation. Check each item prior to pressing the icon:

   - Face Pack
     Ensure Face Pack is secured
   - Airway
     Ensure airway is secure and monitored
   - Chest Wedge
     Ensure Chest Wedge is secured over shoulders
   - Lines/Tubes
     Ensure all lines/tubes are routed through Head Hoop or Foot Opening and monitored
   - Arm Slings
     Ensure arms are in Arm Slings and secured
   - Abdominal Sling
     Ensure Abdominal Sling is secured to side supports
   - Shin Slings
     Ensure Shin Slings are buckled and secured to inner leg support

3. **Set Rest at Angle**
   Press and hold when checklist complete to initiate rotation to desired angle to rest.

4. **X or Cancel**
   Press this button to exit to Home Screen if desired.





Pronova-O₂™ Touch Screen User Interface

Scale Screen

The scale screen provides options to view Current Weight, Zero Weight, Hold Weight, Manually Adjust Weight, and Save Weight.

1. Press **lbs/kg** to switch between displayed weight units per facility protocols.

If lbs/kg button is greyed out, you must change Scale Units to User Selectable in the Settings Screen before changing weight units.

2. Press **Save Weight** to save weight in Weight History. To access weight history, press Weight History tab.

3. Press **Zero** to set the scale to zero and press **Confirm** to accept changes.

Touching surface during zero can alter zeroing process.

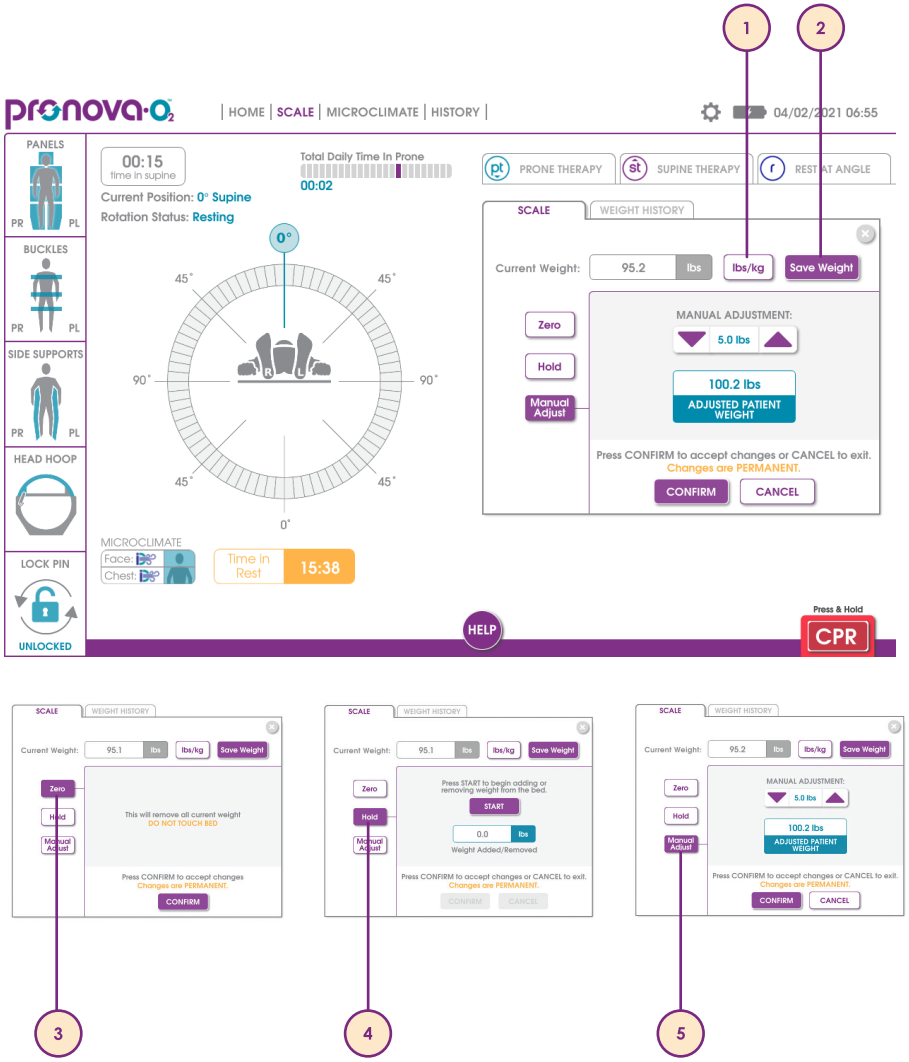
4. The **Hold** function can be utilized to add equipment to surface without altering patient weight, such as IV poles/pumps, or items stowed on accessory management system. Press **Hold**. Press Start to begin Hold. Press Confirm to accept weight addition or removal or Cancel to cancel.

5. The **Manual Adjust** function is useful if weight is added to the surface and the patient weight is inaccurate. Press **Manual Adjust** button and press the up or down arrows to adjust weight to appropriate weight. The adjusted weight will show below the arrows. Press Confirm to confirm adjustment or Cancel to cancel.

Weight is for reference only and should not be used for medication dosage.

The scale measures all weight on the device, including items that may be stowed on the Accessory Sockets and Accessory Rack.

Scale readings should be taken with the patient surface in the flat and level position to ensure the greatest accuracy.



Pronova-O₂™ Touch Screen User Interface

Microclimate Screen

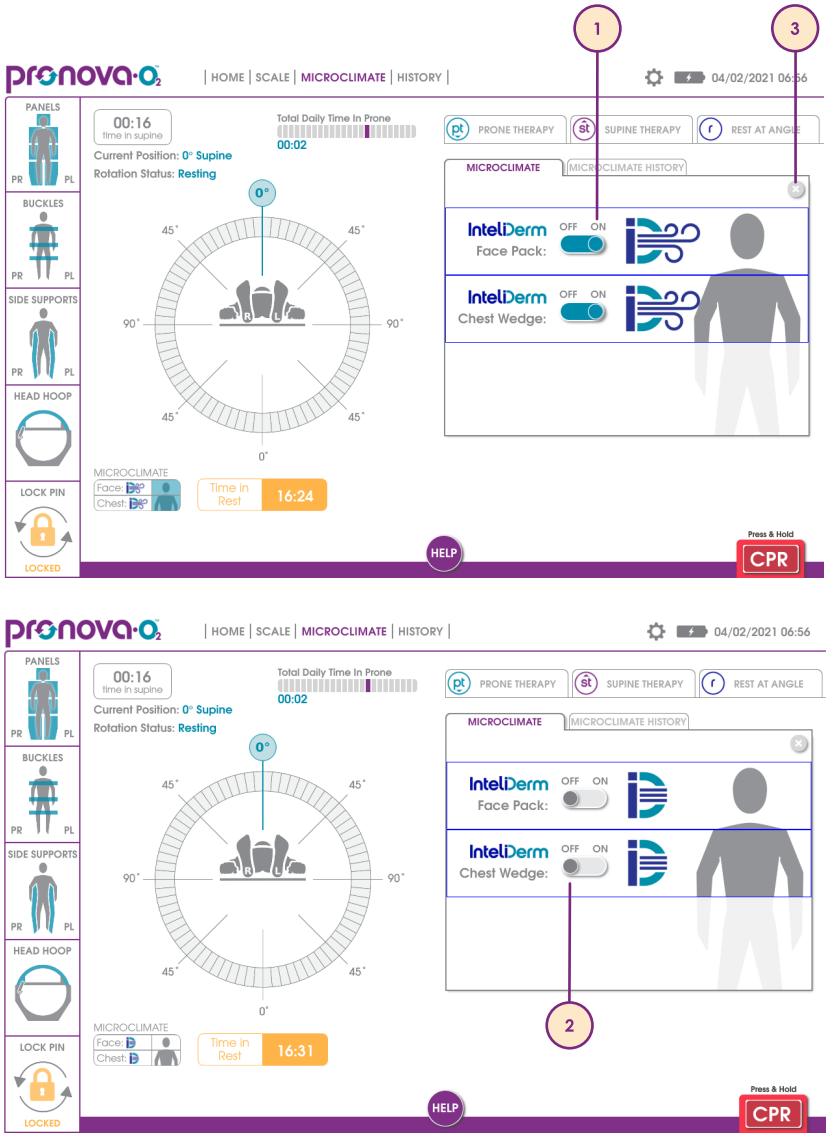
The InteliDerm™ Microclimate screen provides the ability to turn on the Microclimate for both the face and chest.

1. Press the **Off/On** switch to turn the **InteliDerm™ Face Pack** on. When the switch is green, the Microclimate is **ON**. Microclimate is **OFF** when the switch is grey.
2. Press the **Off/On** switch to turn the **InteliDerm™ Chest Wedge** on. When the switch is green, the Microclimate is **ON**. Microclimate is **OFF** when the switch is grey.

   Microclimate ON indicator

   Microclimate OFF indicator
3. Press **X or Cancel** to exit to Home Screen if desired.

The status of the InteliDerm™ Face Pack and Chest Wedge is also visible on the bottom left corner of the Home Screen.



Pronova-O₂™ Touch Screen User Interface

History Screen

*The history tab allows the user to view therapy, weight and microclimate data since the last time New Patient Setup or Clear History was used. Press **Clear History** in any of the History screens to remove saved data for a new patient.*

1. **Therapy History**
   Daily and cumulative patient history for Supine Rest, Supine Therapy, Prone Rest and Prone Therapy. If therapy duration is greater than 4 days, the user can scroll left and right to view additional therapy days. The Patient Total Therapy is always displayed on the right.

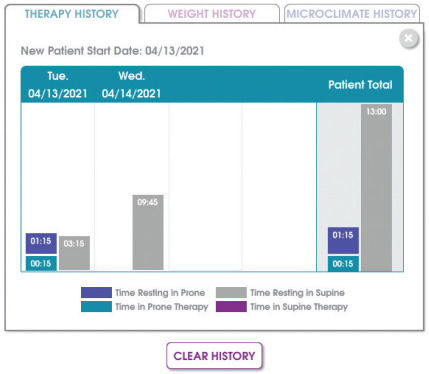
2. **Scale History**
   Daily and cumulative saved Weight History is displayed graphically and in tabular form. To view additional Weight History, the user can scroll up and down on the table.

Weight is for reference only and should not be used for medication dosage.

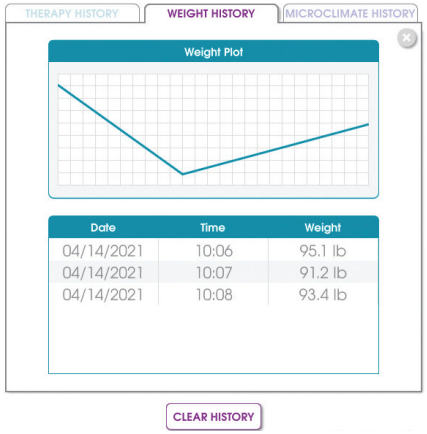
The scale measures all weight on the device, including items that may be stowed on the Accessory Sockets and Rack.

Weight is only added to Scale History when the user presses save weight in the Scale screen.

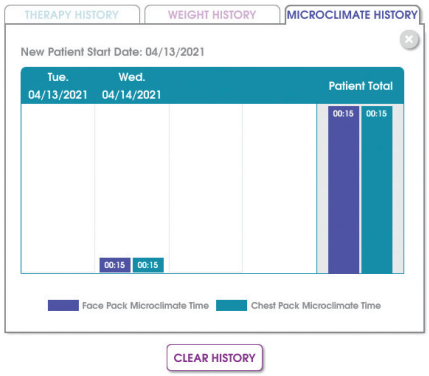
3. **Microclimate History**
   Daily and cumulative patient history for InteliDerm™ Face Pack and Chest Wedge. If therapy duration is greater than 4 days, the user can scroll left and right to view additional therapy days. The Patient Total Therapy is always displayed on the right.



Therapy History



Scale History



Microclimate History

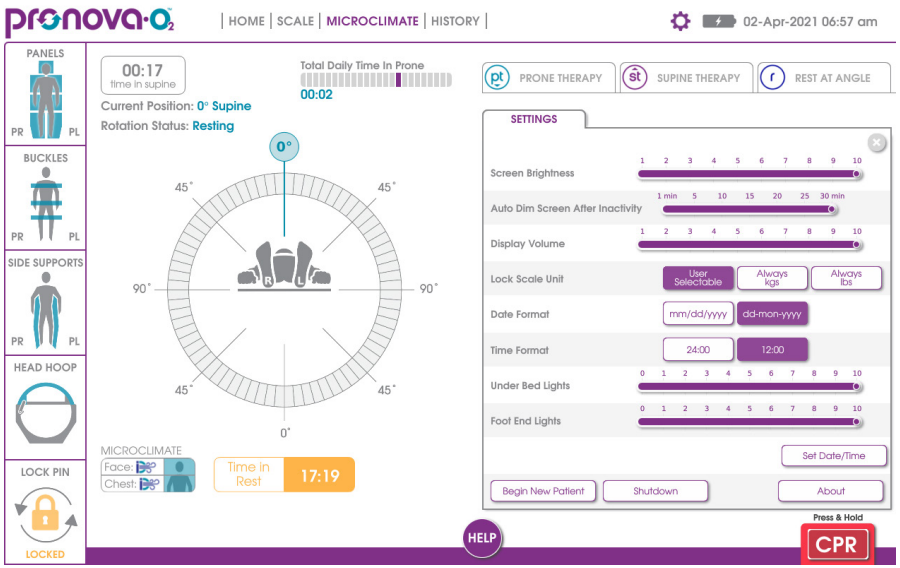
Pronova-O₂™ Touch Screen User Interface

Settings Screen

The settings screen can be accessed by pressing ⚙ *at the top right of the screen to adjust various settings for the interface.*

1. **Screen Brightness**
   Slide the **purple button** to adjust screen brightness to desired level. The default setting is 10.
2. **Auto Dim Screen after Inactivity**
   Slide the **purple button** to adjust to desired time. The screen will automatically dim after no buttons are pressed for the set amount of time and will resume regular brightness as soon as the screen is touched again.
3. **Display Volume**
   Slide the **purple button** to adjust display volume system notifications. Alerts and alarm volume will not be affected by this setting.
4. **Lock Scale Unit**
   Default for scale is **User Selectable**. To adjust, press desired button, either Always Kgs or Always Lbs to highlight the button purple, indicating that setting is active.
5. **Date Format**
   The default for time format is **mm/dd/yyyy**. To adjust to **dd-mon-yyyy** press the button to highlight purple, indicating the setting is active.
6. **Time Format**
   The default for time format is **24:00**. To adjust to **12:00** press the button to highlight purple, indicating the setting is active.
7. **Under Bed Lights**
   The default brightness is 5. To adjust, slide the purple button to desired setting.
8. **Foot End Lights**
   The default brightness is 5. To adjust, slide the purple button to desired setting.
9. **Set Date**
   Press to set appropriate date and time. History data is stored according to this date.
10. **Begin New Patient**
    Press to initiate a new patient and clear previous history and settings.
11. **Shutdown**
    Press to initiate Shutdown of Pronova-O₂™.
12. **About**
    Provides information about trademarks, patients, and software licenses.

Do not touch the touch screen user interface and patient at the same time.



Hand Control

The Hand Control is located at the head end of the surface and can be stored on the patient right or left side. The Hand Control In Use screen will appear when any button other than CPR is pressed on the Hand Control. Once the button is released, the screen will disappear. Pressing the CPR button on the Hand Control will cause the CPR screen to appear.

1. **Bed Up/Bed Down Buttons**
   The user can change the height of the surface by pressing and holding the desired button. This function is available with or without screen functionality as well as on battery power.

2. **Rev Trend/Trend**
   The user can change the head angle to Reverse Trendelenburg or Trendelenburg by pressing and holding the desired button. The surface will pause at 0° before continuing in the commanded direction. This function is available with or without screen functionality as well as on battery power.

Monitor all critical lines through Head Hoop while placing patient in Reverse Trendelenburg to ensure line securement and proper slack in lines.

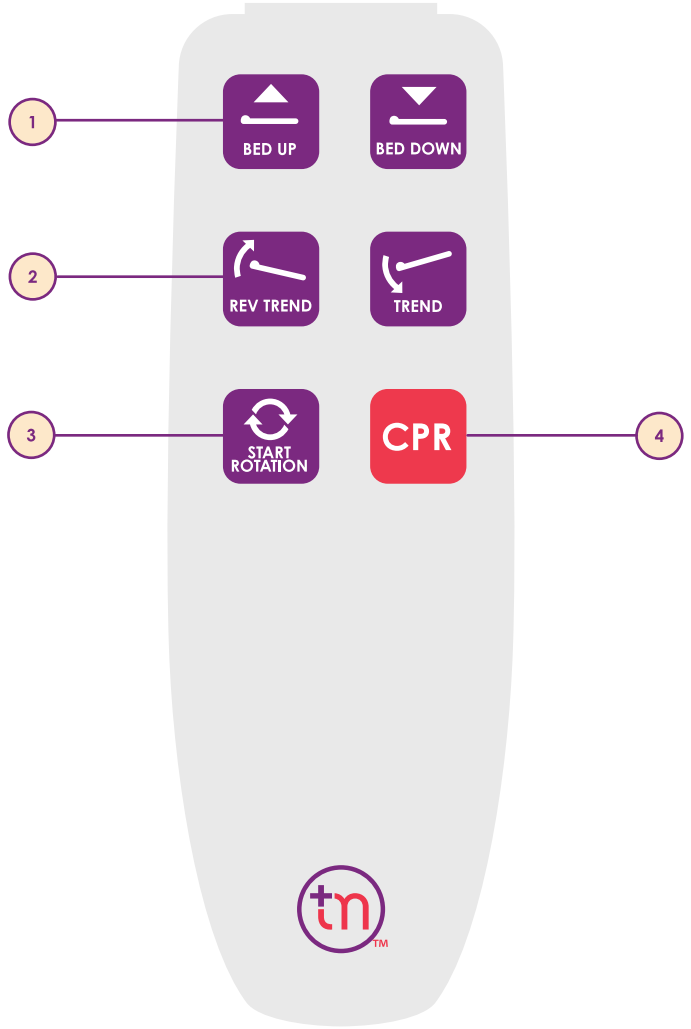
3. **Start Rotation**
   The user can utilize this button once all sensors are in "green" status and the checklist to initiate rotation is complete. Press and hold to rotate into the Supine or Prone Position.

4. **CPR**
   The user can utilize this button once all sensors are in "green" status. Press and hold to rotate and lower the surface to 0° Supine.

If rotation does not begin, check the User Interface and resolve all issues shown.

In the event of a Hand Control button being pressed longer than 70 seconds, the Hand Control button will be disabled until it is released.

Do not touch hand control and patient at the same time.



Instructions for Use

The following Instructions for Use Section will provide step by step guidance for clinicians to safely prepare, transfer, position, and rotate the patient into the Prone and Supine Position.

- Patient Preparation for Placement
- Preparation of Pronova-O_2™ for Patient Placement
- Patient Transfer and Securement onto Pronova-O_2™
- Initiate Automated Prone Position
- Initiate Prone Therapy
- Return to Supine Position
- Initiate Supine Therapy
- Rest at Angle
- Automated and Manual CPR
- Discontinuation of Pronova-O_2™ Therapy
    - Patient transfer from surface
    - Shutdown Procedures

Patient Preparation for Placement

The following items describe preparations and considerations to prepare the patient prior to Pronova-O₂™ placement.

- Prepare room to allow for patient transfer from left side to facilitate safe transfer of Critical Lines through open side of Head Hoop.
- Remove gown, allowing for privacy prior to transfer.
- Use of hard plastic Endotracheal Tube (ETT) securement devices are not recommended for use in the Prone Position. Consult with Respiratory Therapist and/or Attending Physician or Prescriber regarding alternative ETT securement methods.
- Secure patient's hair to prevent catching during rotation on surface.
- Remove any piercings to reduce risk for skin breakdown.
- Properly dress and secure any skin injury or surgical sites.
- Consult WOCN as appropriate prior to placement to discuss and plan to reduce risk for skin breakdown.
    - Consider high pressure points and prophylactic dressing for cheeks/face and chest among others.
- Detach any non-essential equipment to prepare for transfer. (ie: SCDs, enteral feedings NG suction, among others) Follow hospital policy and protocol.
- Reinforce any surgical dressings.
- Gather and consider the following supplies as needed:
    - Line extensions-Invasive lines, arterial lines, chest tubes, etc
    - Eye lubricant
    - Electrodes for EKG monitoring posteriorly
    - Slide board or Safe Patient Handling equipment for transfer

Refer to Special Considerations Section (pages 70-76) for additional considerations for patients with invasive treatments such as mechanical ventilation, ECMO or Dialysis.

Preparation of Pronova-O₂™ for Patient Placement

This section describes preparations and considerations to prepare the Pronova-O₂™ surface for placement. The following items provide a quick reference of steps required. For detailed information regarding each step, refer to the detailed text provided in this section. This checklist should only be used in conjunction with the detailed steps provided in this section.

- Plug in to properly grounded outlet
- Gather InteliDerm™ Face Pack, Chest Wedge, and Abdominal Sling, place on surface for zero
- Clear History
- Zero Scale
- Ensure Critical Line Management Securement on Head Hoop
- Open Head Hoop
- Stow Head Side Supports
- Remove Pelvic Pads from Pelvic Prone Support
- Stow Prone Surface Supports
- Unbuckle Shin Slings
- Stow Side Support Panels
- Stow Foot Rests
- Stow Inner Leg Support
- Lift Accessory Rack
- Lock brakes
- Ensure Lock Pin is in locked position

Preparation of Pronova-O₂™ for Patient Placement
continued

The following section reviews the procedures to prepare Pronova-O₂™ for patient transfer.

1. **Plug power cord** into a properly grounded wall outlet.

To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

Position the Pronova-O₂™ device and surrounding equipment so that the power cord can easily be disconnected from the wall outlet, if necessary.

2. **Clear History.** When the device is initially plugged in, the Pronova-O₂™ welcome screen appears. To prepare the device for a new patient, press **Clear History** button and **Confirm** to clear history. This will clear the previous settings, history, and scale. If the Welcome screen appears and it is not a new patient, press **Continue to Home.**

If surface is not at 0° Supine when plugged in, Lock Pin Calibration Screen may appear. Refer to page 64 for additional information.

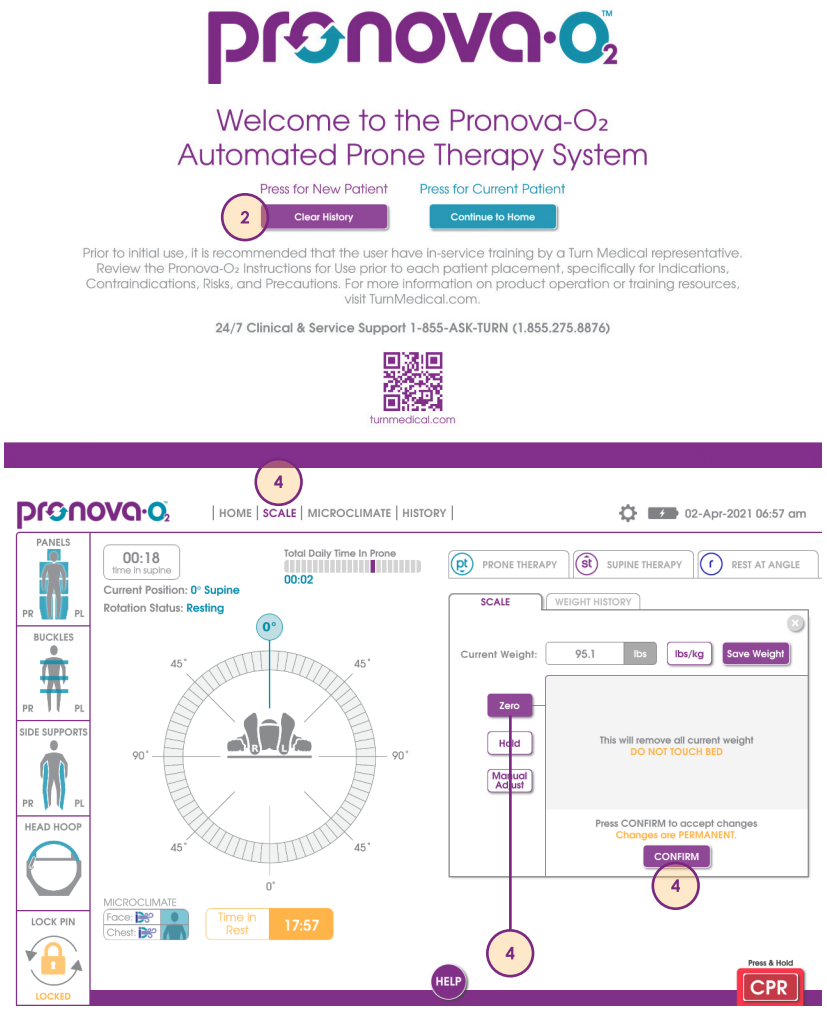
3. If you are not starting from the welcome screen, you can access **Begin New Patient** button in the settings menu.

4. **Zero Scale.** With all accessories (including **InteliDerm™ Single Patient Use Kit**) and equipment on the surface that will be utilized with the patient, including IV poles and pumps being utilized in the Accessory Sockets at the head or Accessory Rack at foot of the device, go to SCALE tab and press **Zero** then press **Confirm.**

The scale measures all weight on the device, including items that may be stowed on the accessory socket and rack.

Weight is for reference only and should not be used for medication dosage.

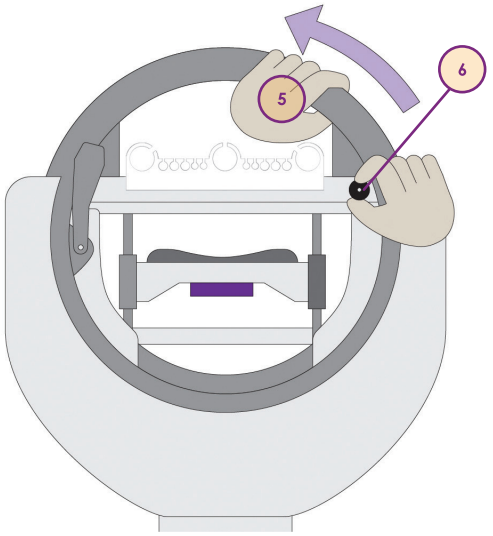
Touching surface during zero can alter zeroing process.

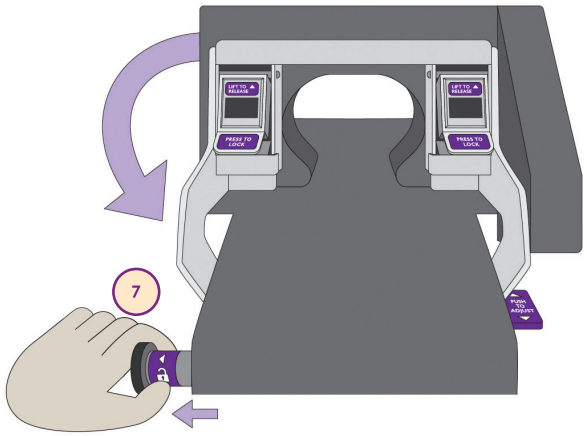


Preparation of Pronova-O₂™ for Patient Placement
continued

Ensure that two beds can fit side by side in room for patient transfer onto Pronova-O₂™. If space is limited, consider transferring patient to larger room or utilizing overhead lift for transfer.

5. **If not present, install Critical Line Management System** by inserting 5 rivets into holes on crossbar inside Head Hoop.
6. **Open Head Hoop** by pulling knob outward and rotating top of Head Hoop with opposite hand.
7. **Stow head side supports** by pulling knob under head side support on each side and pull Head Side Support down to rotate and stow.





Preparation of Pronova-O₂™ for Patient Placement
continued

Stow Prone surface supports:

8. Remove Pelvic Packs from Pelvic Prone Supports.

9. Unbuckle top of each support. Lift purple handle on support and pull outward and down to lock against Prone section arm.

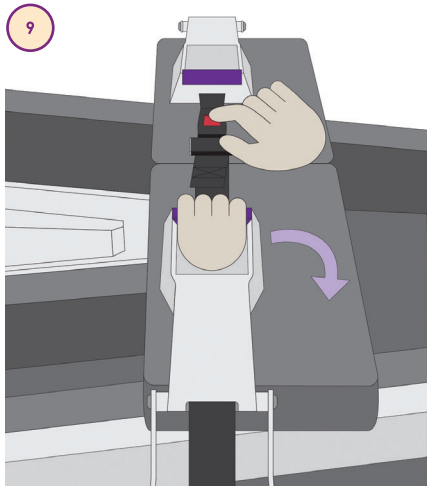
10. Press firmly against surface to latch on panel arm.

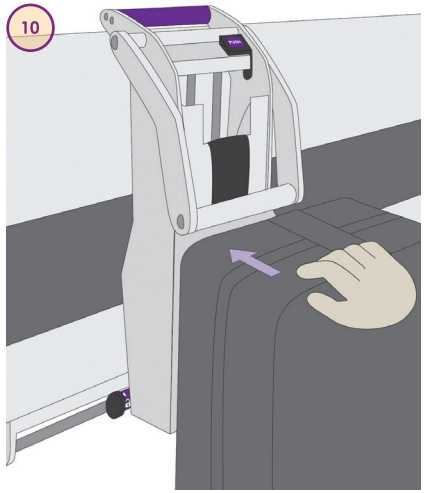
11. Hold purple handle on top of Prone Support Arm with right hand and pull knob on left side with left hand. The pack will lower and flatten. Slide the pack inward toward the surface to stow it beneath the surface.

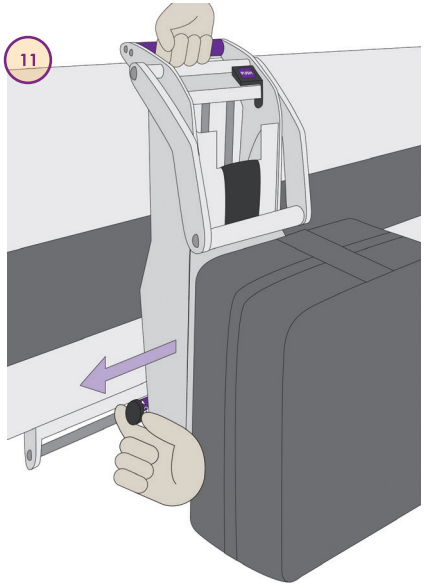
If proning surface does not slide into stowed position, lift up or down slightly to allow surface to slide inward.

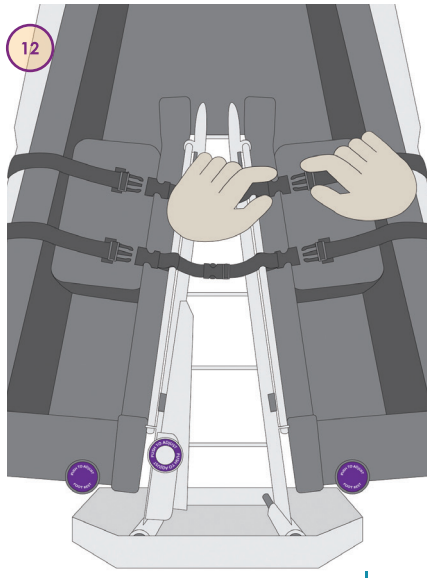
If Prone surface becomes disengaged from the arm, simply press the padding back into the arm to secure it.

12. Unbuckle Shin Sling buckles (4). These will stow with side supports.









Preparation of Pronova-O₂™ for Patient Placement
continued

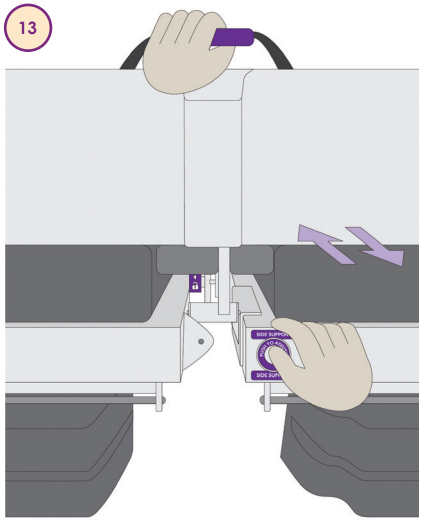
Stow the Side Support Panels:

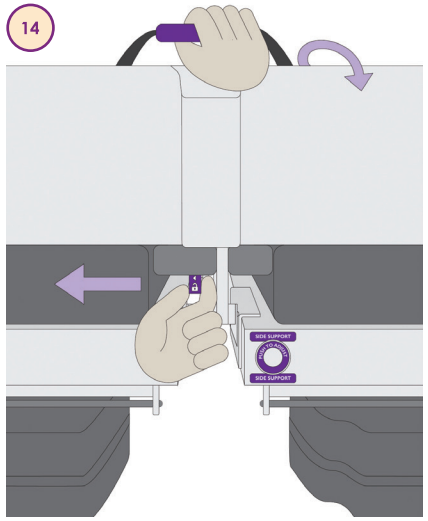
13. Press silver button on both sides of frame and pull each side support outward toward the surface edge.

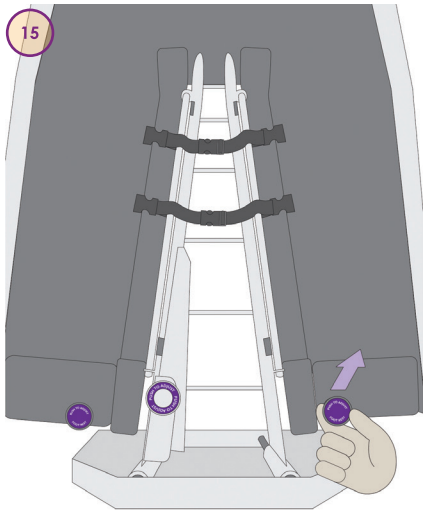
14. Pull knob under each side support panel out with left hand and lift side support using handle on top of side support with right hand. Pull handle outward and down until it fully extends and stows beneath surface.

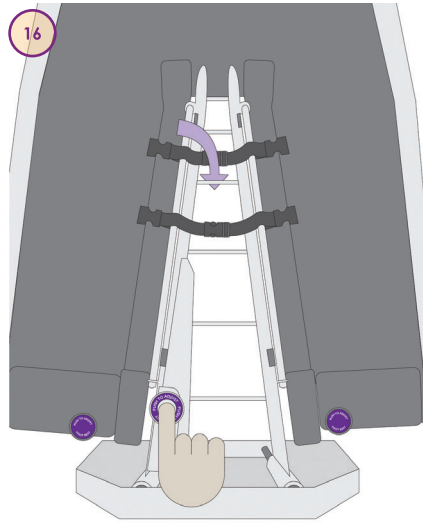
15. **Stow Foot Rest** if required, lift knob and press outward to slide Footrest to foot end of device.

16. **Stow Inner Leg Support** press button on foot end of Inner Leg Support and push downward until it is level with the surface. Ensure Shin Slings are unbuckled.









Preparation of Pronova-O₂™ for Patient Placement
continued

17. Pull knob at foot end of device to lift **Accessory Rack** to stow all critical lines that are routed through the foot end of device. If required, unclip additional Accessory Rack poles and for additional storage of accessories.

18. Align Pronova-O₂™ with the patient's bed, lock central locking brakes, and adjust bed height so that Pronova-O₂™ is slightly lower than the bed the patient will be transferred from when possible.

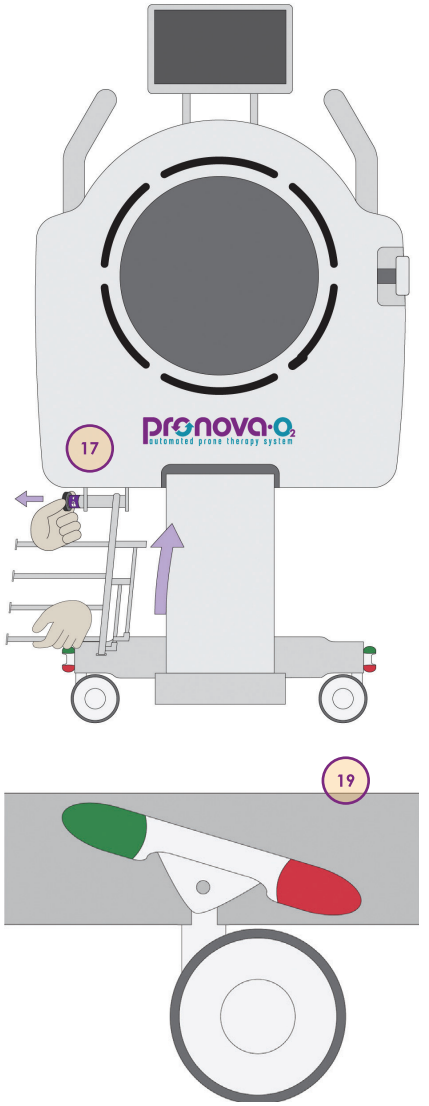
Once the device is properly positioned in patient room, brakes should be engaged at all times.

19. Press downward on red pedal to engage brakes.

20. Ensure that Pronova-O₂™ is at 0° Supine and secured with the **Lock Pin in the locked position.**

The Lock Pin provides additional stability to the surface and should be engaged when in 0° Supine Position.

Proceed to section **Patient Transfer and Securement onto** Pronova-O₂™.



Patient Transfer and Securement on Pronova-O₂™

The following section reviews the procedures to transfer the patient onto Pronova-O₂™ and the procedures to secure the patient in preparation for Prone or Supine Therapy. The items below provide a quick reference of steps required for patient transfer and securement on to Pronova-O₂™. For detailed information regarding each step, refer to the detailed text provided in this section. This checklist should only be used in conjunction with the detailed steps provided in this section.

- Ensure Lock Pin is fully secured in locked position
- Ensure brakes on both surfaces are set in locked position
- Gather appropriate staff and equipment for transfer
- Transfer patient, center patient on surface
- Raise and adjust Head Side Supports, center ears
- Ensure Head Hoop is open
- Secure invasive lines on Critical Line Management System or Accessory Rack and close hoop
- Raise Inner Leg Support, buckle inner leg securement straps.
- Secure Foot Rests
- Raise, secure and adjust Side Supports
- Secure Arm Slings
- Buckle Shin Slings
- Place and connect InteliDerm™ Chest Wedge
- Secure Abdominal Sling and Pelvic Pads
- Secure and connect InteliDerm™ Face Pack
- Raise and buckle Prone Support Surfaces
    - Lower leg support (over thigh or shin, avoid knees)
    - Pelvic support (over pelvis)
    - Chest support (slide to highest point)
- Turn on InteliDerm™ (Microclimate tab)

Patient Transfer and Securement onto Pronova-O₂™
continued

The following section reviews the procedures to transfer the patient onto Pronova-O₂™ and the procedures to secure the patient in preparation for Prone Therapy.

Prior to transfer, ensure brakes on both surfaces brakes are set in locked position.

Prior to transfer, ensure Lock Pin is engaged in the locked position.

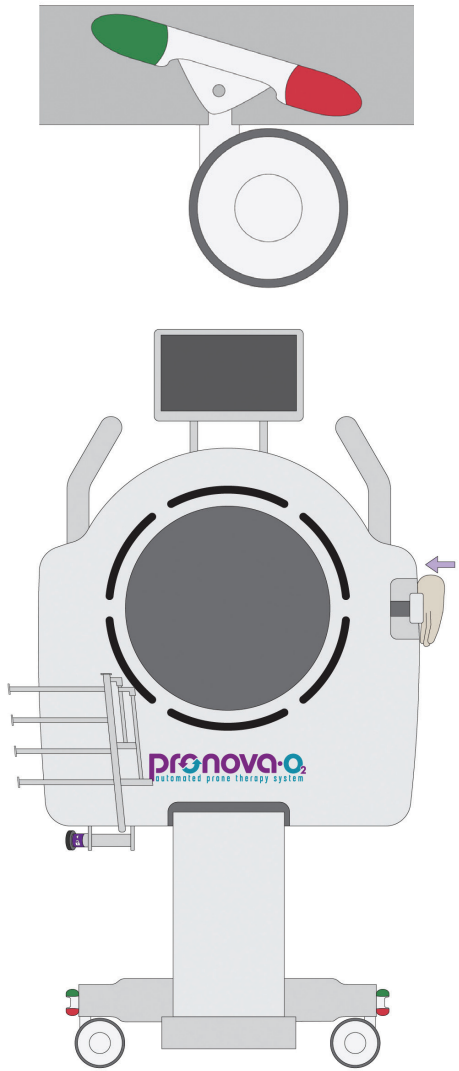
Refer to Special Considerations Section (page 70-76) for considerations related to patients with Mechanical Ventilation, Tracheostomy, ECMO, Dialysis and other Invasive Lines.

1. If possible, prepare to transfer patient from their left side onto Pronova-O₂™ so that all lines from upper chest to head will transfer into the open side of the hoop. Place ventilator and all IV pumps at the head of the device IV or Accessory poles can be placed in Accessory Sockets at the head of the device.

Anything added or subtracted from the Accessory Sockets will affect scale reading.

To ensure there is clearance for the patient surface to rotate without interference from IV poles. IV pole weight limit is 20lb (9.07 kg) and should not exceed 54" in height.

2. Ensure proper number of staff or Patient Handling Equipment/Lifts or slide boards are available to safely transfer patient onto Pronova-O₂™. Follow all facility policies and protocols for transfer procedures.



Patient Transfer and Securement onto Pronova-O₂™
continued

3. Transfer patient onto Pronova-O₂™. Slide the patient's head into the Head Support and center patient on surface.

Ensure that ETT and all critical lines are secure, visible and monitored during transfer.

Ensure at least two clinicians remain at bedside when side supports are stowed, and patient is in the surface.

4. Secure all lines and tubes above midline in the Critical Line Management System. Once all lines and tubes are secured, **close hoop.**

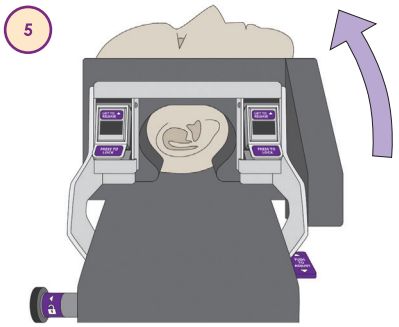
5. Rotate and **raise Head Side Supports** by lifting upward until you hear a click. Ensure ears are centered in the oval holes in the Head Side Support.

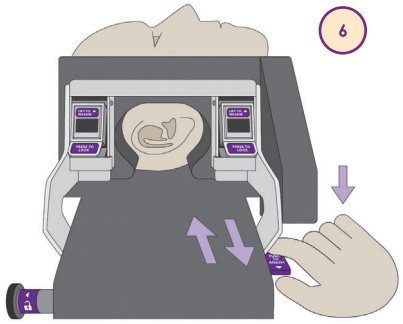
All equipment, lines, tubes and hair should be kept away from the head support, Head Hoop, and other moving parts for safety.

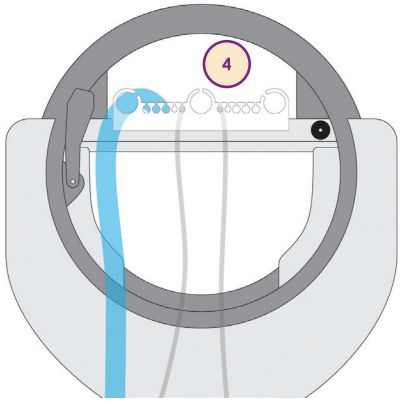
6. **Adjust Head Side Supports** by pressing purple Push to Adjust lever on front edge of head support to rest against patient's face, without causing excessive pressure.

Refer to Special considerations section for additional information on considerations related to patients with mechanical ventilation, tracheostomy, ECMO, Dialysis, and other invasive lines. (pages 70-76)

7. Tuck sheets or transfer assistive device just under patient posterior side for easy removal once patient is in the Prone Position.







Patient Transfer and Securement onto Pronova-O_2™
continued

8. **Raise Inner Leg Support** by depressing button located on top of the Inner Leg Support; pull up or press downward until desired position is reached.

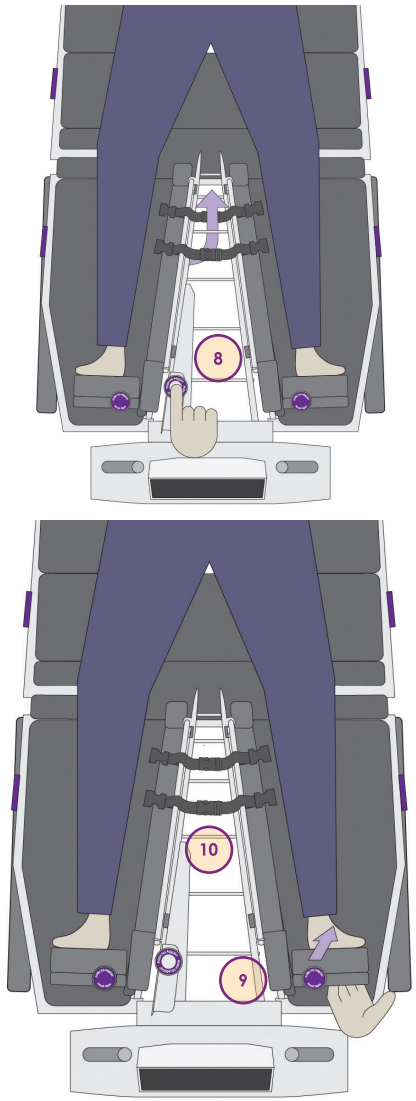
Always ensure Inner Leg Support is raised prior to rotation.

9. **Adjust Foot Rest** so that patient's feet are flat against the padding. To adjust Foot Rest, place your hand on the back side of the Foot Rest and push inward until the desired position is reached. To release, pull knob on top of Foot Rest and push outward until desired position is reached.

Refer to Special Considerations Section D and E for additional considerations for patients on dialysis and management of invasive lines. (page 75 and 76)

10. **Unbuckle Line Retention Straps** located on the Inner Leg Support and route all lines and tubes below mid chest through the foot opening of the device and rest on Accessory Rack. **Buckle Line Retention Straps** to prevent lines from dangling during Prone Position.

Do not secure the Foot Rest too tightly against the feet, causing undue pressure and risk for hyperextension of leg.



Patient Transfer and Securement onto Pronova-O₂™
continued

11. **Lift Side Supports** by using handle in the center of the Side Supports and rotate to rest on the surface.

12. **Lift patients arm** outward to allow for Side Support to rest firmly against the patient.

13. **Adjust both Side Supports** firmly against the patient's body. To adjust, press button located on frame and push inward on side supports.

Adjust side support to properly secure patient in surface. Patient may shift during rotation. Re-assess securement often and tighten side supports against body as needed. Adjustment can be made at any point in rotation.

Refer to Special Considerations Section E (page 76) for additional information on considerations related to invasive line management.

14. Unsnap Arm Slings and open sling to rest patient's arms inside slings.

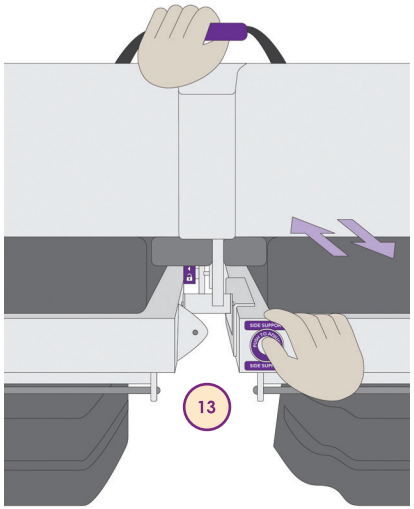
15. Press snaps to secure Arm Slings. (4 snaps located on top of each side support to secure Arm Slings)

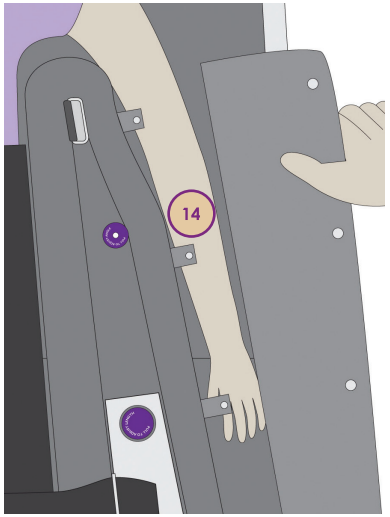
Ensure monitoring devices located in Arm Slings are assessed to protect patient's skin and risk for breakdown.

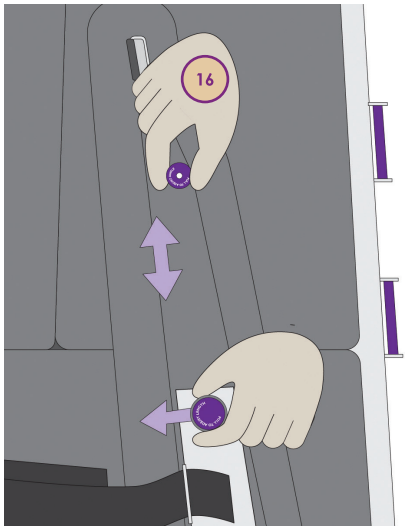
16. **Adjust Side Support Length**
Ensure that there are 2-3 finger breadths (approximately 2") clearance under axilla to avoid compression and provide the best fit. To lengthen, **pull the top portion of Side Support Panel** towards the head. To shorten, pull up on the lower knob labeled **Pull to Adjust Length** and push downward on the top portion of the Side Support.

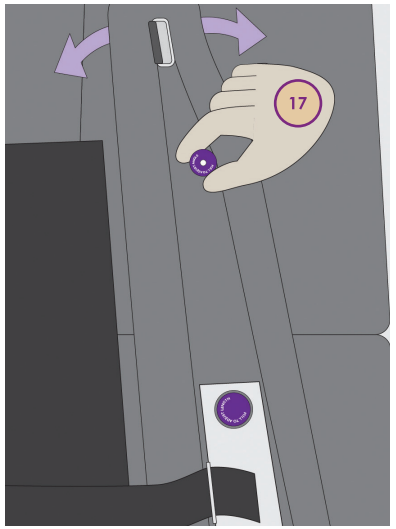
17. **Adjust Side Support Angle**
Ensure Side Supports fit snugly beside patient's torso to reduce risk of friction and shear from sliding when rotating. You can adjust Side Supports 5° out for patients with a wide chest, Neutral, or 5° in for patient with a narrow chest by lifting the smaller knob on each side of the Side Support.

Always ensure a minimum of 2 inches of clearance from patient axilla to side support panel to reduce risk for nerve damage and undue pressure.









Patient Transfer and Securement onto Pronova-O_2™
continued

18. Place **Shin Sling** on patient's shins and buckle in place. If using the lower Prone support over the shin, place the Shin Sling under Thigh Prone Support to provide additional shin support, or place Shin Slings below Foot Rest and buckle to secure if not needed for patient due to shorter patient height.

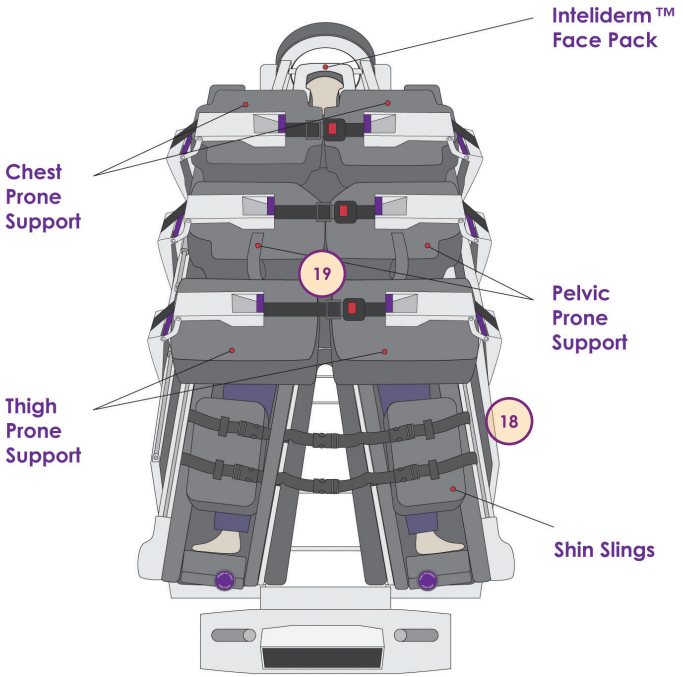
19. Place Pelvic Pads over iliac crest **using caution not to compress any lines or tubes.** Pelvic Pads are located in the pocket on the top of the Pelvic Prone Support Surface.

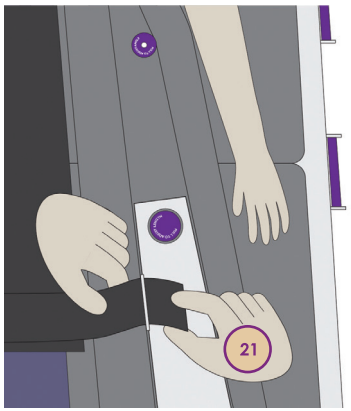
20. Place the **InteliDerm™ Chest Wedge** white side on patient so it is aligned with the patient's shoulders and connect Microclimate tubing by securing the tubing to the chest Microclimate connection located below the Head Support on the patient left. For additional information regarding the **InteliDerm™ Single Patient Use Kit**, refer to page 7.

See Special Considerations Section B (page 73) for additional considerations for a patient that has a tracheostomy.

21. Attach **Abdominal Sling** by sliding Velcro Straps through slots on each side support and securing to the fabric on the Abdominal Sling.

Ensure Velcro Straps are not in contact with the patient to reduce risk for skin breakdown.





Patient Transfer and Securement onto Pronova-O₂™
continued

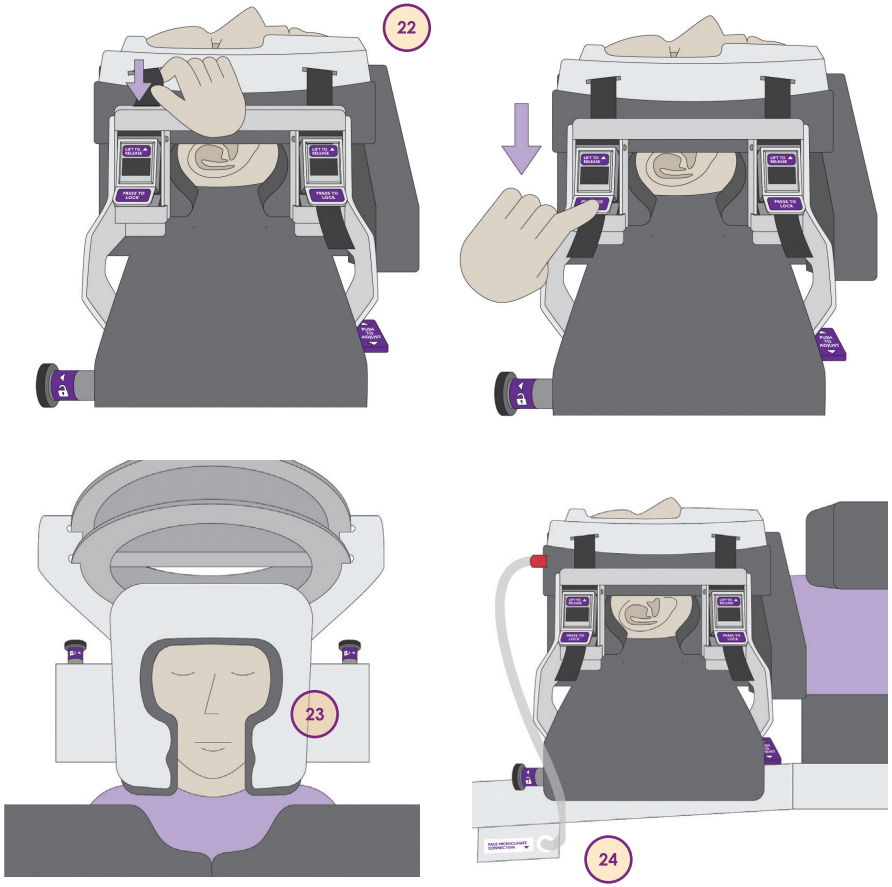
22. Rest the **InteliDerm™ Face Pack** over the patient's face, white side to patient. Slide straps into the securement slots located on top of Head Side Supports and secure in place by pressing tab down.

The Face Pack is not required for Supine Therapy.

Always ensure face pack is fully secured. Face pack does not have a sensor.

23. Ensure eyes are visible through opening in **InteliDerm™ Face Pack.**

24. Connect the **InteliDerm™ Face Pack** to the Microclimate connection located below the head support on the patient right.



Patient Transfer and Securement onto Pronova-O_2™
continued

Secure Prone Support Surfaces:

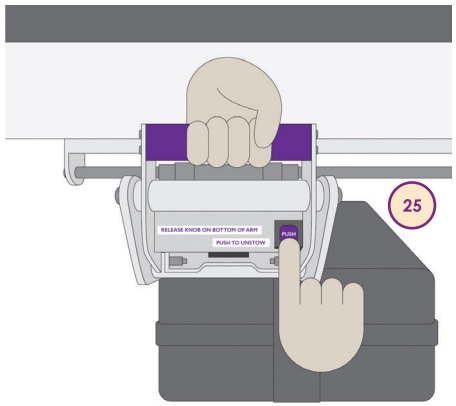
25. Depress lever on the Prone Support Arm and pull outward on purple handle. Once fully slid out, rotate upwards towards the patient to lock in place against the frame.

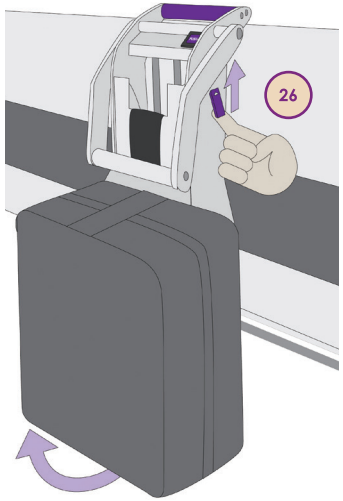
26. Lift purple lever on right side of each Prone arm to release Prone surface and lift surface to place over patient's body.

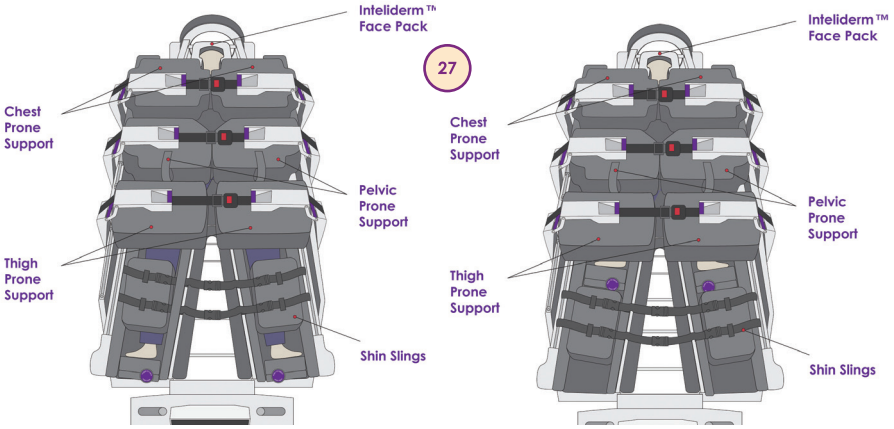
27. Laterally slide each arm to appropriate placement as described below:

- **Thigh Prone Support** slide along the surface to prevent direct pressure on knees if possible, either over the thighs or over the shins.
- **Pelvic Prone Support** place over pelvic bone, avoiding abdominal pressure when possible.
- **Chest Prone Support** slide section to the highest point, nearest to patient head, to allow for support of shoulders, unless patient condition does not allow for highest placement.

28. Buckle and tighten each Prone Support Surface.



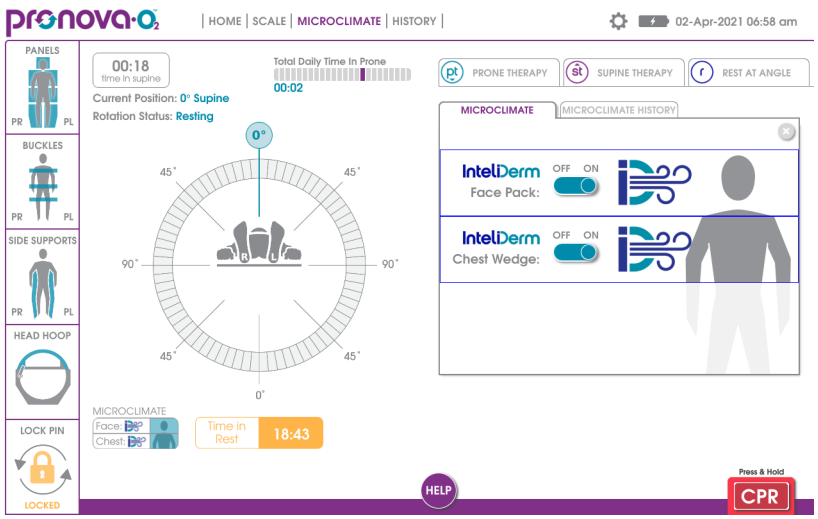




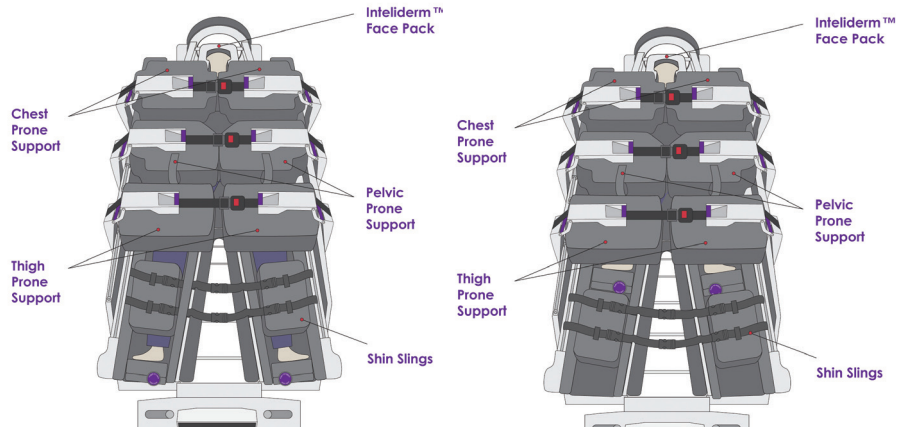
Patient Transfer and Securement onto Pronova-O₂™
continued

29. Complete final patient placement assessment:

- Ensure all lines and tubes are routed through either the Head or Foot Hoop of the device.
- Check head and ensure lines and tubes are properly secured in the Critical Line Management System.
- Ensure that Arm, Shin, and Abdominal Slings are properly placed and secure.
- Ensure all buckles are securely buckled and secure.
- Gather appropriate staff in preparation of position change.
- Turn Microclimate Therapy on for the InteliDerm™ Face Pack and Chest Wedge by pressing the Microclimate tab and turning the Microclimate on.



Proceed to **Initiate Prone Therapy (page 42) or Initiate Supine Therapy Section (page 48)** to initiate therapy.



Initiate Automated Prone Position

The following section reviews the procedures to initiate Prone Therapy. The items below provide a quick reference of steps required to initiate Prone Therapy. For detailed information regarding each step, refer to the detailed text provided in this section. This checklist should only be used in conjunction with the detailed steps provided in this section.

- Pull Lock Pin fully out to Unlocked position
- Press Stop if surface is in rotation
- Press Prone Therapy tab
- Input Physician orders
- Input Prone Direction (toward ventilator)
- Press Continue
- Verify items on Checklist
- Press and hold Prone Patient

Initiate Automated Prone Position
continued

The following section reviews the procedures to initiate Prone Therapy.

Two clinicians should be present to observe patient lines, tubes, and vital signs during initial rotation into the Prone Position.

Rotation into the Prone Position should always be set to rotate towards the ventilator. Place ventilator tubing in Critical Line Management System opposite of ventilator to allow for slack during rotation.

Prior to placement, assess securement and length of all invasive lines to ensure safe movement into the Prone Position to reduce risk of dislodgement, disconnection or compression. All lines and tubes should be routed through the Head or Foot Opening for safe rotation. Do not hang or place any devices, equipment or lines on surface, other than in designated areas.

Rotation cannot begin until the device is plugged in and all sensors are in "green" status.

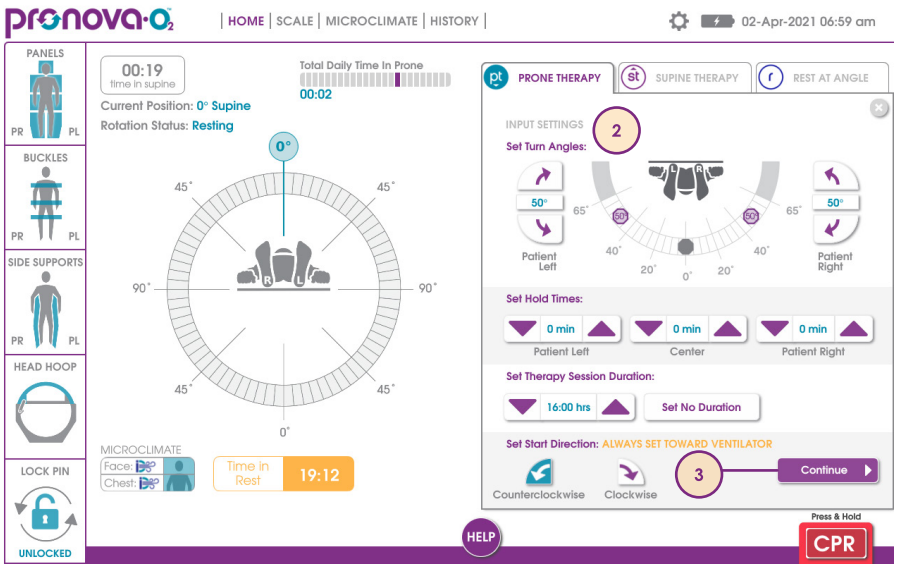
1. **Disengage Lock Pin** at foot of device by pulling outward if engaged.

If in rotation, press Stop to access the Prone Therapy tab.

2. **Press Prone Therapy** tab and input physician orders for rotation:
    - Set Turn Angle for right and left side (0-65°)
    - Set Hold times at each position (patient right, patient left and center)
    - Set Therapy Session Duration (Physician order for duration in Prone position, if desired)
    - Set Start Direction (toward ventilator)

The user can also access the Prone Position by using the Rest at angle tab. (Refer to Rest at Angle page 50)

3. Press **Continue.**



Initiate Automated Prone Position
continued

4. Complete the **safety checklist** by verifying securement of each item on the checklist: Face Pack, Airway, Lines/Tubes, Chest Wedge, Abdominal Sling, Arm Sling, and Shin Sling. Press each safety item once checked and it will grey out acknowledging securement/safety.

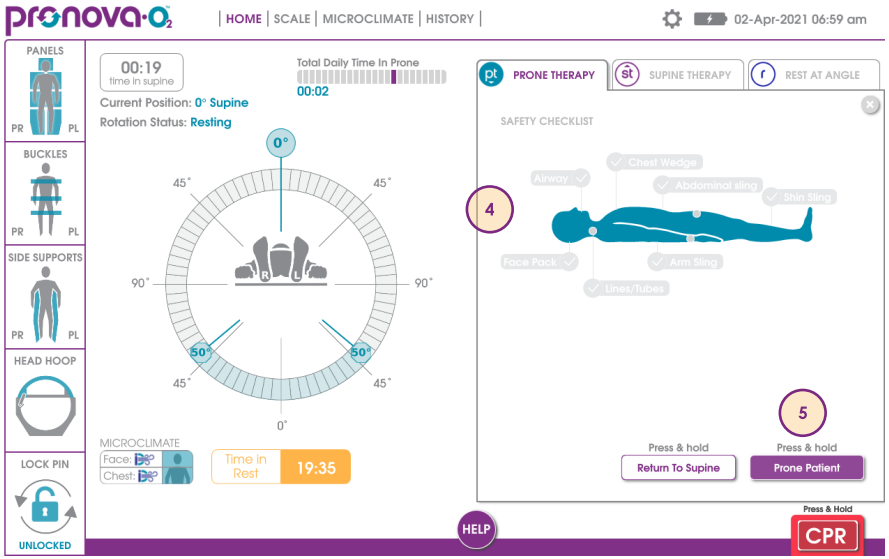
Items on the checklist do not have a safety sensor to ensure securement. Visually inspect that each item is safely secured.

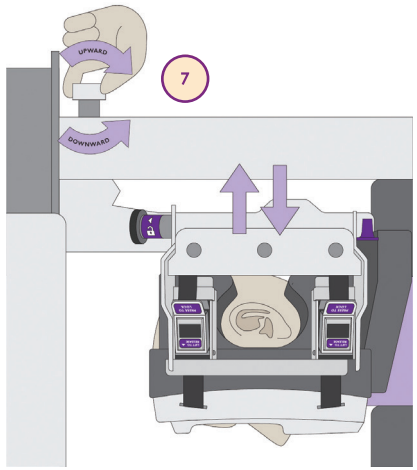
5. Once Safety Checklist is complete and all panels, buckles, side supports, Head Hoop, and Lock Pin are green, you can press and hold **Prone Patient** or utilize the Hand Control at the head of the device. Patient will begin rotating into 0° Prone Position as you continue to press and hold. An audible tone will sound when 0° Prone is reached and a checklist appears to initiate Prone Rotational Therapy. If it is required to go back to Supine Position, press and hold Return to Supine to go back to 0° Supine.

Observe all lines, tubes and vital signs during rotation. You can use the Hand Control at head of device to rotate patient and assess critical lines if additional clinician cannot visualize all lines.

6. **Prior to going through checklist to initiate Prone rotation**, ensure patient stability and line/tube securement post position change. The patient's body often shifts during position change. Assess securement of side supports against patient's body and re-tighten as needed. Ensure securement of lines and tubes, as well as Face Pack.

7. Ensure head and neck are in alignment with body. Make any adjustments necessary by using Head Alignment Adjuster located at the head of the device just between Head Panel and Thoracic Panels. Turn knob right to raise or left to lower Head Support.





Initiate Automated Prone Position
continued

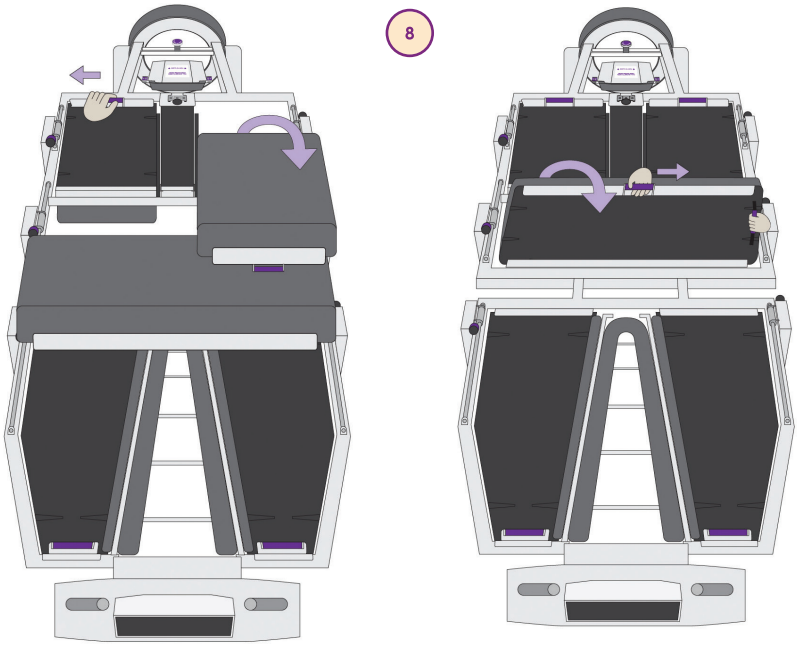
8. **Consider opening all panels** necessary to: release pressure, place EKG leads on back, remove transfer linens, allow airflow and provide patient access. All panels except Middle Panel can be opened by sliding panel handles away from midline; Middle Panel opens by sliding handle toward patient's right. Keep in mind patient stability prior to opening panels.

The Prone Occipital Panel can be opened in the Prone Position to relieve facial pressure. To open, pull black knobs located on outside of panel and lift.

9. If appropriate, place patient in Reverse Trendelenburg. Adjust to the appropriate angle by pressing the **up arrow** in the angle section of the Home Screen or on Hand Control.

Monitor all critical lines through Head Hoop while placing patient in Reverse Trendelenburg to ensure line securement and proper slack in lines.

Proceed to **Initiate Prone Therapy,** Step 3.



Initiate Automated Prone Therapy

The following section reviews the procedures to initiate Prone Rotational Therapy, once Prone Position has been achieved and patient status is stable. The below items provide a quick reference of steps required to initiate rotation in the Prone Position. For detailed information regarding each step, refer to the detailed text provided in this section. This checklist should only be used in conjunction with the detailed steps provided in this section.

- Open all appropriate panels
- Press Stop if surface is in rotation
- Press Prone Therapy tab
- Verify Physician orders
- Press Continue
- Verify items on Checklist
- Press Start Therapy

Initiate Prone Rotational Therapy
continued

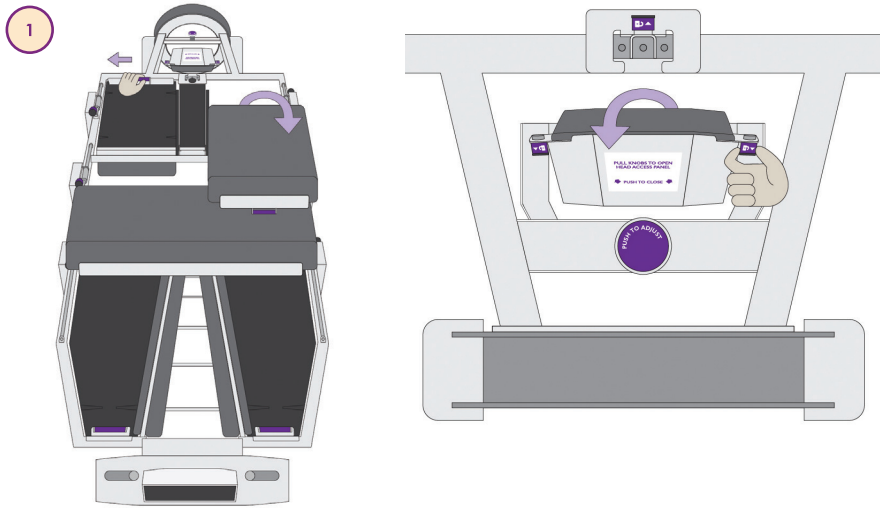
The following section reviews the procedures to initiate Prone Rotational Therapy, once Prone Position has been achieved and patient status is stable.

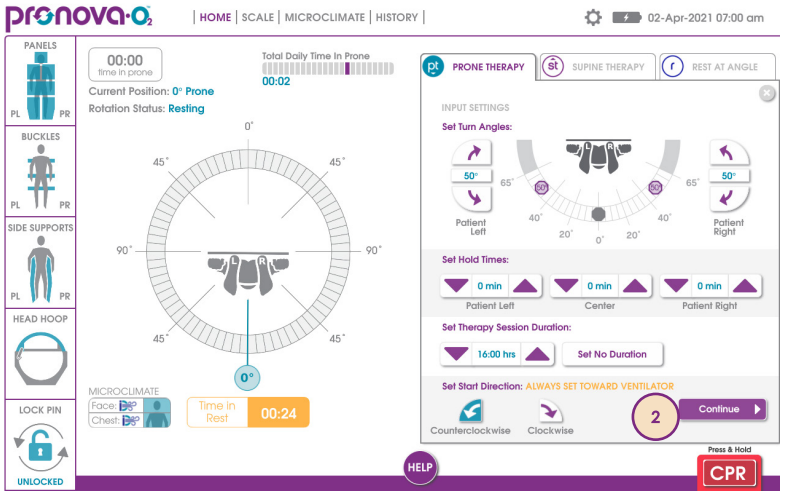
1. If panels are not already open, **consider opening all panels** necessary to: release pressure, place EKG leads on back, remove transfer linens, allow airflow and provide patient access. All panels except Middle Panel can be opened by sliding panel handles away from midline; Middle Panel opens by sliding handle toward patient's right. Keep in mind patient stability prior to opening panels.

The Prone Occipital Panel can be opened in the Prone Position to relieve facial pressure. To open, pull black knobs located on outside of panel and lift.

2. Once patient stability is verified and lines/tubes secure, press Prone Therapy tab and if required, verify orders, and press **Continue.**

If the patient is in rotation, press Stop to access the Prone Therapy tab.





Initiate Automated Prone Therapy
continued

3. Review Safety Checklist (Face Pack, airway, lines/tubes, and open appropriate panels) by pressing each icon when prompted and validated. Press **Start Therapy** to initiate rotation.

Always ensure Face Pack is fully secured. Face pack does not have a sensor.

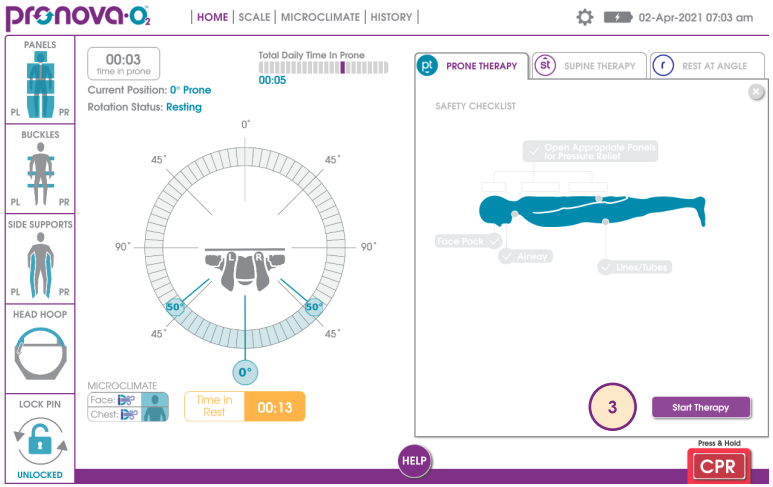
Observe 2-3 full rotation cycles to ensure all lines and tubes are secure with enough slack to complete fully programmed turns. Add extensions or move equipment as needed. Tighten side supports as needed to reduce friction and shearing.

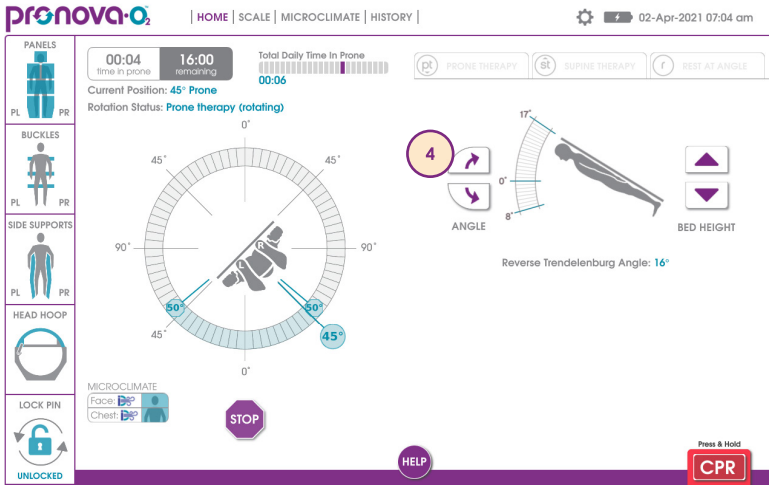
4. If appropriate, place patient in Reverse Trendelenburg. Adjust to the appropriate angle by pressing the **up arrow** in the angle section of the Home Screen or on Hand Control.

Monitor all critical lines through Head Hoop while placing patient in Reverse Trendelenburg to ensure line securement and proper slack in lines.

If the Home Screen is not visible, access the Home Screen by pressing "home" or "X" at the top right of any screen.

If the patient shifts while in rotational therapy, it is recommended to tighten the side supports closer to the patients' body. Place the patient at rest at 0° and press button located on frame and push inward on side supports.





Return to Supine Position

The following section reviews the procedures to return to the Supine Position during Prone Therapy. The below items provide a quick reference of steps required to initiate the Supine Position. For detailed information regarding each step, refer to the detailed text provided in this section. This checklist should only be used in conjunction with the detailed steps provided in this section.

- Press Stop if surface is in rotation
- Lower surface by pressing Bed Height Down on Hand Control or Home Screen
- Close all open panels
- Press Supine Therapy tab
- Verify Physician orders
- Press Continue
- Verify Checklist
- Press and hold Supine Patient
- Insert Lock Pin to locked position or initiate Supine Rotational Therapy

Return to Supine Position
continued

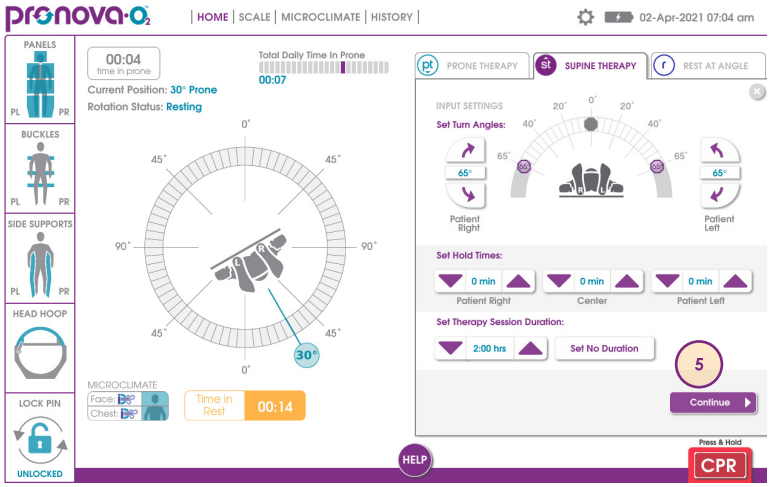
The following section reviews the procedures to return to the Supine Position during Prone Therapy. The Supine Position can be reached by using either the Supine Therapy tab or the Rest at Angle tab.

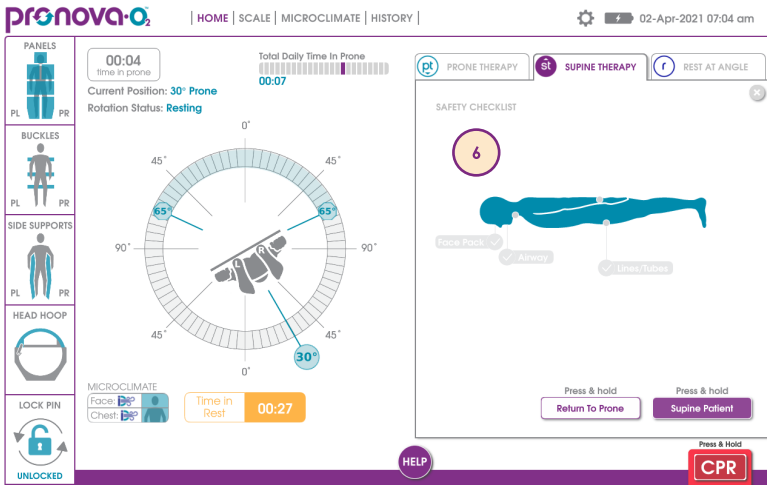
1. Press **Stop** button to stop rotation.
2. If desired, lower bed height by using the Hand Control or Home Screen on User Interface.
3. **Close all open panels**.
4. Press **Supine Therapy** tab to transition patient to the Supine Position.

The user can also initiate Supine Position by utilizing the Rest at Angle tab. Refer to Rest at Angle Section (page 50) for instructions on procedures.

5. Verify Supine Therapy settings. Press **Continue** on bottom right of screen.
6. Complete the **safety checklist**. Once action is complete, the appropriate icon will grey out.

Always ensure Face Pack is fully secured. Face pack does not have a sensor.





Return to Supine Position
continued

7. Press and hold **Supine Patient**. Patient will begin rotating into 0° Supine position as you continue to press and hold. If it is required to go back to Prone Position, press and hold Return to Prone to go back to 0° Prone.

Observe all lines, tubes and vital signs during rotation. You can use the Hand Control at head of device to turn patient and assess critical lines if additional clinician cannot visualize all lines.

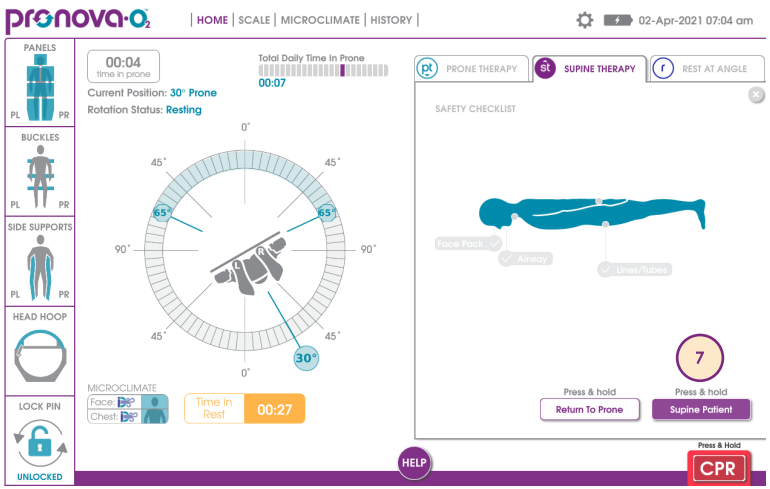
8. An audible tone will sound when 0° Supine is reached. Fully **insert Lock Pin** to locked position for Supine assessment, or initiate Supine Therapy, if desired (Refer to **Initiate Supine Therapy** Section, page 48).

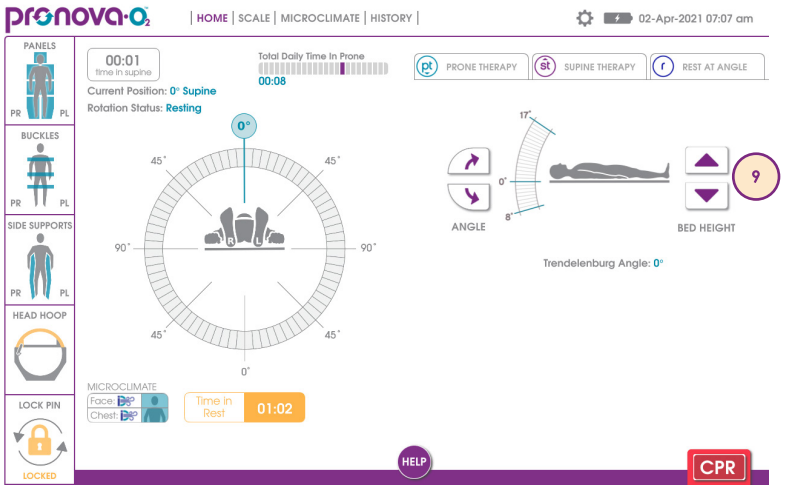
For Supine patient assessment: Once patient is ensured to be stable for assessment, open all Prone buckles, release Side Supports, disengage and disconnect Face Pack and Chest Wedge (Refer to Preparation of Pronova-O₂™ for Placement for additional directions on stowing these parts of the device for assessment)

Ensure at least two clinicians remain at bedside when Side Supports are stowed and patient is in device.

9. If desired, press **Home** to adjust surface height or use the **Hand Control**.

Monitor all critical lines through Head Hoop while changing surface height to ensure line securement and proper slack in lines.





Initiate Supine Rotational Therapy

The following section reviews the procedures to initiate Supine rotational therapy. The items below provide a quick reference of steps required to initiate Supine Therapy. For detailed information regarding each step, refer to the detailed text provided in this section. This checklist should only be used in conjunction with the detailed steps provided in this section.

- Press Supine Therapy tab
- Input Physician orders
- Press Continue
- Verify Checklist
- Press Start Therapy

Initiate Supine Therapy
continued

The following section reviews the procedures to initiate Supine rotational therapy.

1. Press **Supine Therapy** tab.
2. Input physician orders for rotation in the Supine Therapy tab:
   - Angle of rotation for right and left side (0-65°)
   - Rest times at each position (patient right, patient left and center)
   - Set Therapy Duration (Physician order for duration in Supine Position, if desired)
3. Press **Continue.**
4. Complete Safety Checklist is on Supine Therapy screen by pressing each icon when prompted and validated. (Airway, lines/tubes and Arm Slings).

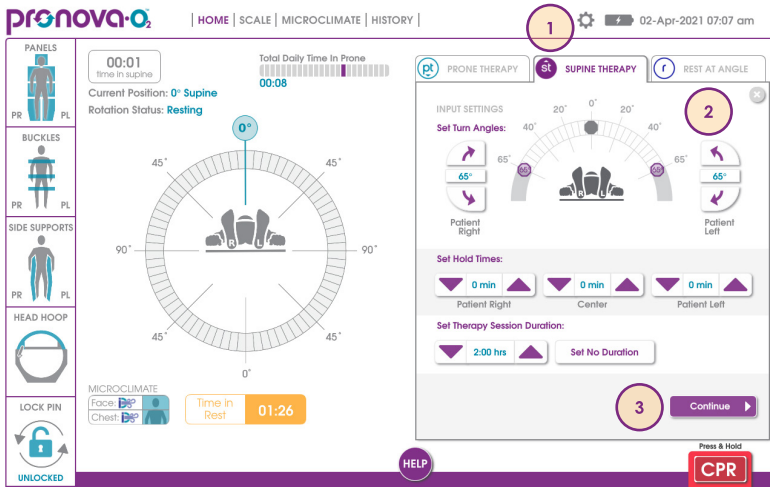
Items on the checklist do not have a safety sensor to ensure securement. Visually inspect that each item is safely secured.

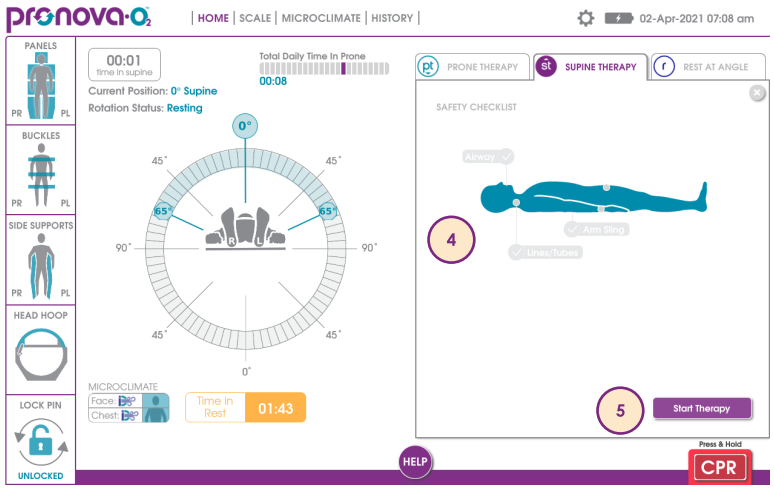
Rotation cannot begin until the device is plugged in and all sensors are in "green" status.

Face Pack is not required for Supine Therapy.

5. Once Safety Checklist complete, press **Start Therapy** to initiate continuous lateral rotation therapy in the Supine Position.

Observe 2-3 full rotation cycles to ensure all lines and tubes are secure with enough slack to complete fully programmed turns. Add extensions or move equipment as needed.





Initiate Rest at Angle

This section reviews the procedures for utilizing the Rest at Angle tab. The below items provide a quick reference of steps required to initiate Rest at Angle. For detailed information regarding each step, refer to the detailed text provided in this section. This checklist should only be used in conjunction with the detailed steps provided in this section.

- Press Rest at Angle tab
- Set desired angle
- Set desired direction of rotation if applicable
- Press Continue
- Verify items on Checklist
- Press and hold Rest at Angle

Initate Rest at Angle
continued

This section reviews the procedures for utilizing the Rest at Angle tab. Rest at Angle is utilized when procedures are required for the patient, such as patient care, line management, assessments, among others.

1. If in rotation, press **Stop** and press the **Rest at Angle** tab.

2. Determine the angle you would like the patient to rest at. To adjust angle, you can use arrows on right side of screen to adjust or press and hold purple circle in angle wheel to set desired angle. Press **Continue** when complete.

Rotation greater than approximately 300° is prohibited due to the rotation limiter system safety feature.

3. Complete the **safety checklist** on the screen, based on the position you desire.

Rotation cannot begin until all sensors are in "green" status.

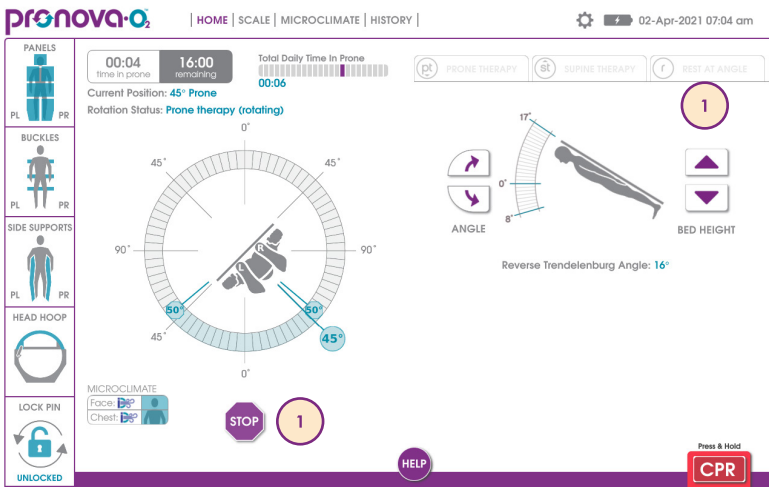
Always ensure Face Pack is fully secured. Face Pack does not have a sensor.

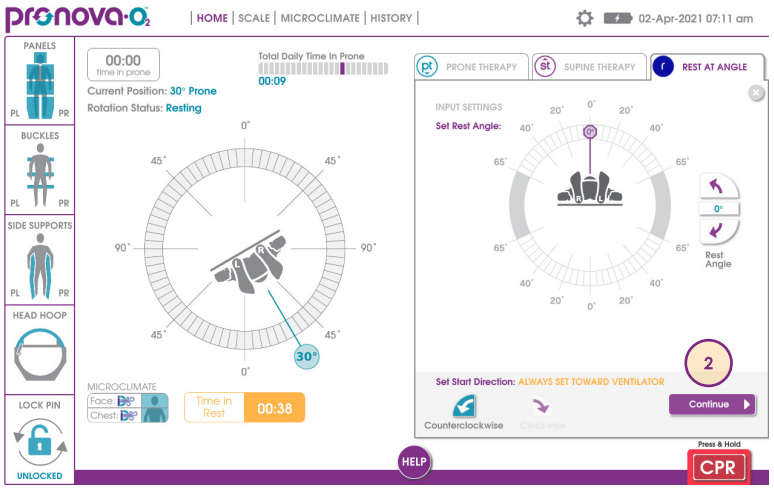
4. **Press and hold Set Rest at Angle** to place patient in desired position. Patient will begin rotating into desired position as you continue to press and hold. Once you release the Set Rest at Angle button, a timer will begin counting the time your patient remains at rest.

Monitor all critical lines during rotation.

It is recommended to have the patient in rotational therapy when possible to reduce risk for injury.

5. Once the requirement to rest is complete, press either Supine Therapy or Prone Therapy to initiate rotation based on the position the patient is in. For additional information refer to the **Initiate Prone Therapy** Section (page 42) or the **Initiate Supine Therapy** Section (page 48).





CPR Procedures

The below items provide a quick reference of steps required to initiate Automated CPR. For detailed information regarding each step, refer to the detailed text provided in this section. This checklist should only be used in conjunction with the detailed steps provided in this section.

- Close all open panels if in the Prone Position
- Press CPR and resolve any issues shown on status screen
- Press and hold CPR to rotate and lower surface to 0° Supine
- Monitor all invasive lines for rotation
- Engage Lock Pin
- Initiate CPR procedures
- Place CPR board under patient for proper compressions

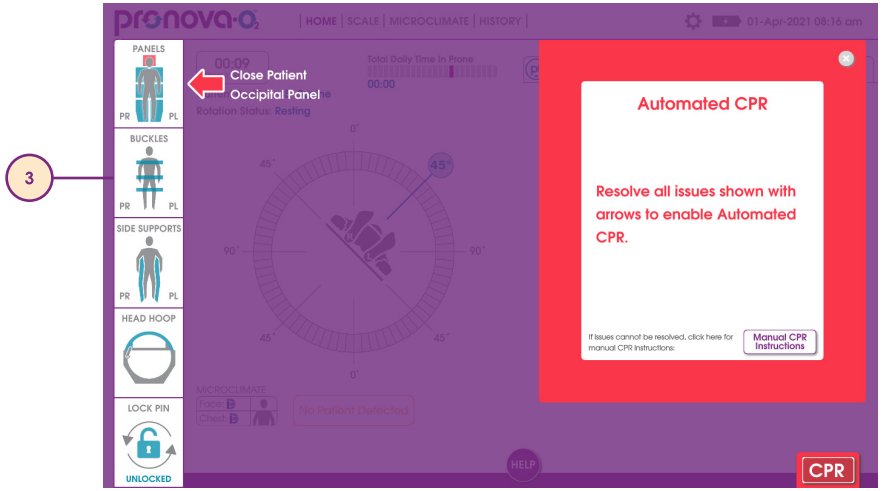
Automated CPR Procedures

The Automated CPR function is available by pressing and holding the CPR button on the Home Screen or Hand Control as long as all sensors on the sensor status screen are green.

1. If in the Prone Position, **close all open Prone Panels.**
2. **Press and hold CPR** button on User Interface or Hand Control.
3. Resolve any issues shown on left of screen. Once resolved, **press and hold CPR button** on User Interface or Hand Control.

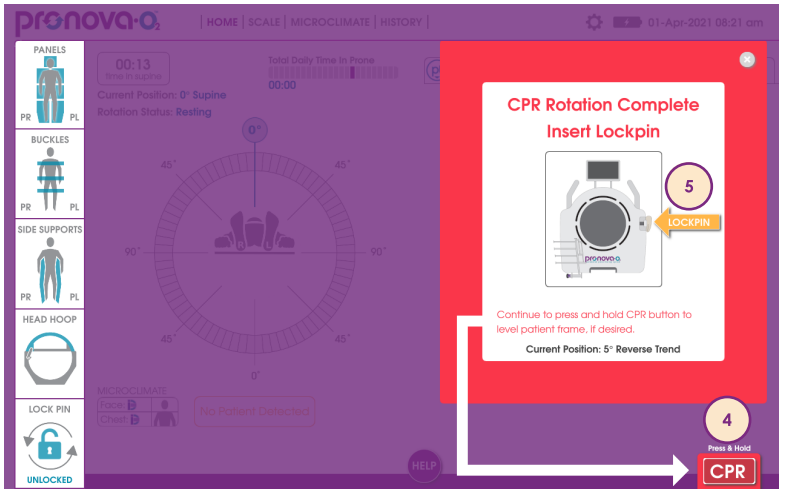
If there is an error with the sensors and all panels are closed to safely rotate patient into the Supine Position, proceed to Manual CPR/ Manual Rotation procedures (page 54) or press the Manual CPR Instructions button on the CPR screen.

If Prone, consider placing CPR board over patient's back prior to closing panels. Follow applicable facility protocols.



4. **Press and hold CPR button** until you reach 0° Supine. The surface will rotate and lower while you press and hold. Once patient surface is flat and at 0° Supine, an audible tone will sound to instruct user to insert Lock Pin.

Monitor all critical lines during rotation.



5. **Insert Lock Pin** in locked position. Ensure Lock Pin icon displays **locked**.
6. **Unbuckle chest buckles** to initiate CPR as per hospital protocol.

It is recommended to place a CPR board under patient to allow for appropriate compressions. Follow hospital protocols.

Manual CPR/Manual Rotation:

The below items provide a quick reference of steps required to initiate Manual CPR. For detailed information regarding each step, refer to the detailed text provided in this section. This checklist should only be used in conjunction with the detailed steps provided in this section.

- Gather 3 or more clinicians
- Place CPR board and close panels if in Prone Position
- Determine direction of rotation to Supine Position (toward ventilator)
- 2 clinicians support surface
- 1 clinician to release manual CPR Lever
- Monitor all invasive lines for rotation
- Guide surface to 0° Supine
- Engage Lock Pin in locked position
- Re-engage Manual CPR Lever
- Initiate CPR procedures per hospital/facility procotol

Manual CPR Procedures/Manual Rotation Procedures

The following section reviews procedures to initiate manual CPR or manual rotation in Pronova-O₂™ in the case of power failure or loss of automated rotation functionality.

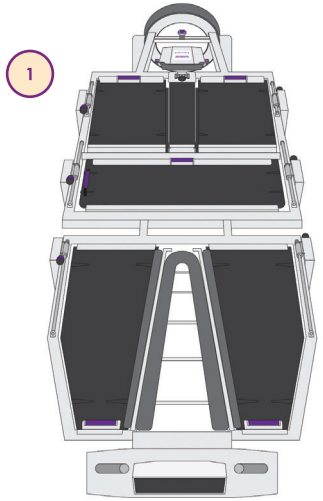
Consider placing CPR board over patients' back prior to closing panels. Follow applicable facility protocols.

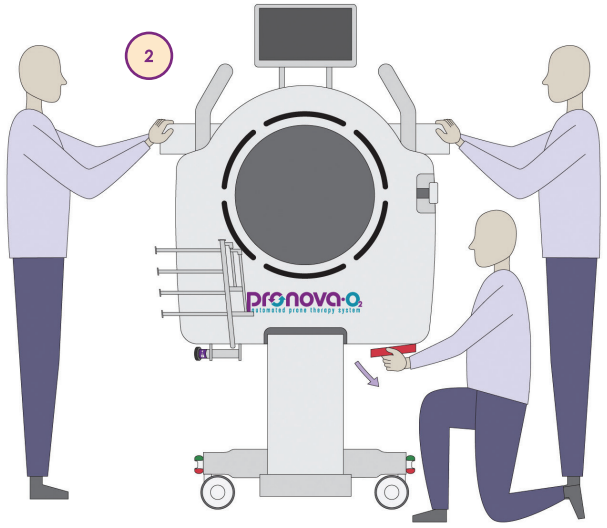
1. If in the Prone Position, **close all Prone panels**. Consider placing a CPR board over patient's back prior to closing panels if appropriate.

2. Gather a **minimum of 3 clinicians** to monitor manual rotation to Supine. Two clinicians should support the side of the surface to guide to Supine, while another should be at foot of the device to monitor maneuver and release manual CPR lever. Keep in mind that a clinician should also be monitoring the invasive lines at the head of device.

3. **Discuss and plan** for the direction of rotation to Supine, **toward the ventilator,** to reduce risk for tube/line dislodgement.

The device is designed with a rotation limiter safety feature that prevents the surface from rotating 360° in either direction to prevent critical lines and tubes being kinked or dislodged. Ensure that manual rotation into the Supine Position is in the opposite direction the surface went Prone. If the surface is rotated and the safety feature is reached, turn surface in opposite direction to reach 0° Supine. *For example, if the patient rotated into Prone clockwise, the patient should return to Supine counterclockwise.*





Manual CPR Procedures/Manual Rotation Procedures
continued

4. After appropriate staff is gathered and supporting surface, **pull manual CPR lever** outward to disengage and guide the surface to the 0° Supine position or desired position.

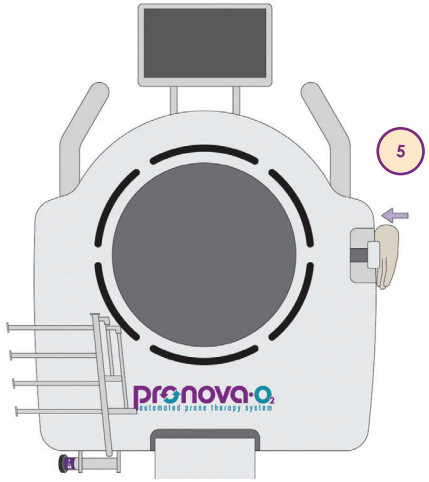
Monitor all critical lines during rotation.

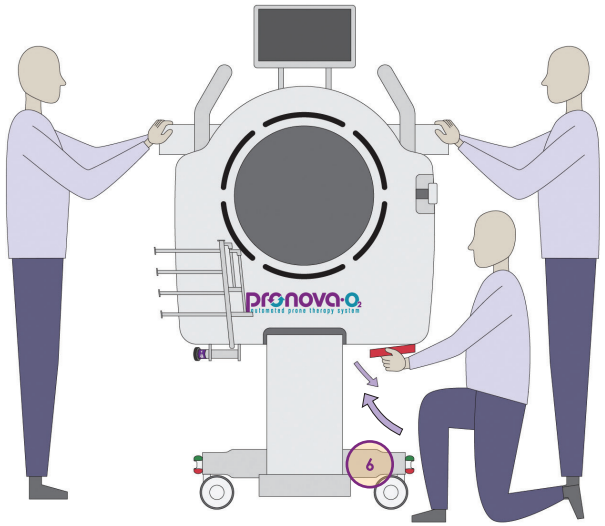
5. If in 0° Supine Position, insert Lock Pin in locked position. If User Interface is available, ensure Lock Pin icon displays **locked**.

6. Once desired position is reached, **re-engage manual CPR lever**.

7. If desired, the user can **lower surface height** by pressing down arrow on angle section of Home Screen. If the User Interface is not available, lower and flatten the surface using either the Hand Control or by locating the manual switches on the head end of the surface, near the Accessory Sockets.

8. If initiating CPR, unbuckle chest buckles and initiate CPR per hospital protocol.





Discontinuation of Pronova-O₂™ Therapy

Patient Transfer and Shutdown Procedures

The following items provide a quick reference of steps required to transfer the patient from the Pronova-O₂™. For detailed information regarding each step, refer to the detailed text provided in this section. This checklist should only be used in conjunction with the detailed steps provided in this section.

- Ensure brakes are in locked position
- Stow Prone Support Surfaces
- Remove and discard Abdominal Sling
- Disconnect and discard the InteliDerm™ Face Pack and Chest Wedge
- Remove and stow Pelvic Pads on Prone Supports
- Unbuckle Shin Slings
- Stow Side Supports
- Stow Inner Leg Support
- Unbuckle line securement straps to prepare for unstowing invasive lines below midline
- Stow Head Side Supports
- Bring invasive lines stored through the Foot Opening through Foot Opening and monitor for transfer.
- Open Hoop.
- Remove invasive lines stored on Critical Line Management System and monitor for transfer.
- Ensure Lock Pin is engaged at 0° Supine in the locked position.
- Gather Safe Patient Handling equipment or slide board for transfer.

Patient Transfer from Pronova-O₂™

The following section reviews the process for transferring the patient from the Pronova-O₂™ surface when therapy is discontinued.

1. **Fully insert Lock Pin** into locked position at 0° Supine.
2. Press downward on red pedal to **engage brakes.**
3. Unbuckle Prone Surface Supports, Shin Slings, Release and disconnect InteliDerm Face Pack, Stow Foot Rests and Inner Leg Support, Unsnap Arm Slings, disconnect InteliDerm Chest Wedge and Abdominal Sling, Stow Side Supports.

If unable to unbuckle Prone Surface Supports, refer to the Strap Tension Release Section in the Operation Instructions (page 106).

4. Discard of InteliDerm Single Patient Use Items: InteliDerm Face Pack and Chest Wedge and Abdominal Sling.

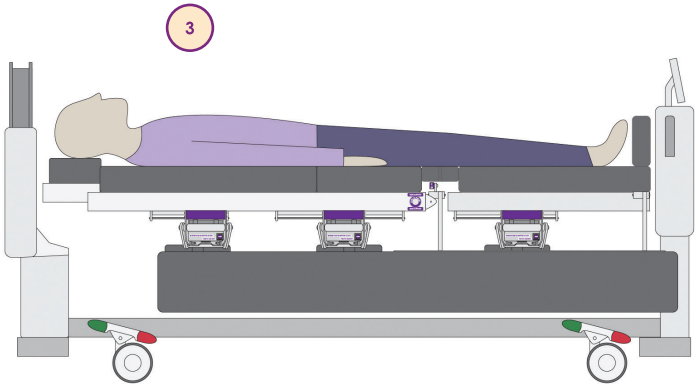
Ensure at least two clinicians remain at bedside when side supports are stowed and patient is in the device.

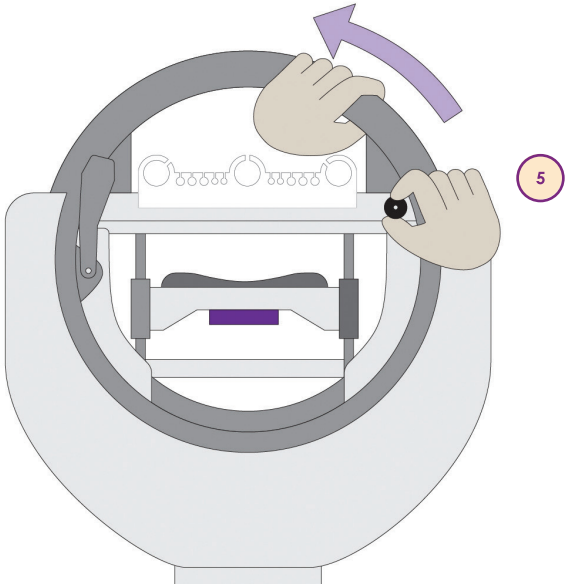
5. **Open Head Hoop.** Unstow and monitor all invasive lines and tubes from the Critical Line Management System and the Accessory Rack. Remove and Discard of Critical Line Management System.

Ensure that ETT and all critical lines are secure, visible and monitored during transfer.

6. Bring new patient surface to room and place surface next to patient right to allow for easy transfer of critical lines that were stowed in the Critical Line Management System.
7. Gather proper number of staff or ensure Patient Handling Equipment/Lifts/ Slide Board are available to safely transfer patient off of the Pronova-O₂™ device. Follow all applicable facility policies and protocols.
8. Transfer patient from Pronova-O₂™ Surface, following all applicable facility policies and protocols.

Prior to transfer, ensure brakes on both surfaces are set in locked position.





System Shut Down

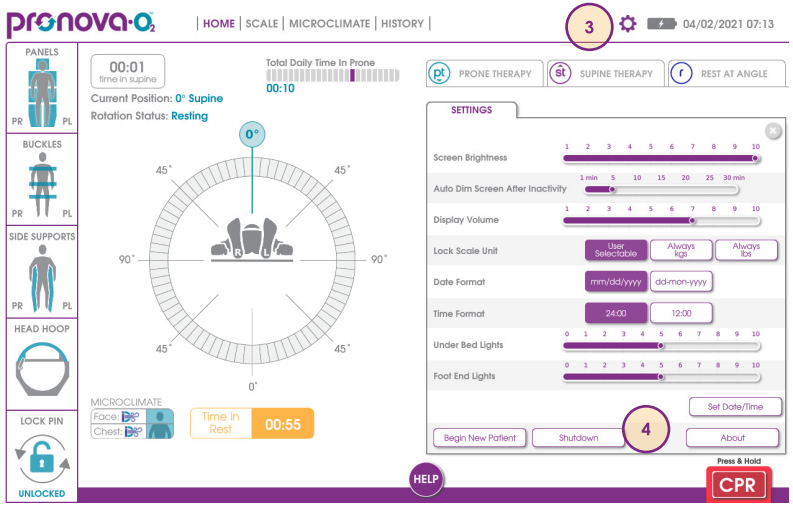
The following section reviews the steps to shutdown the Pronova-O₂™ when not in use.

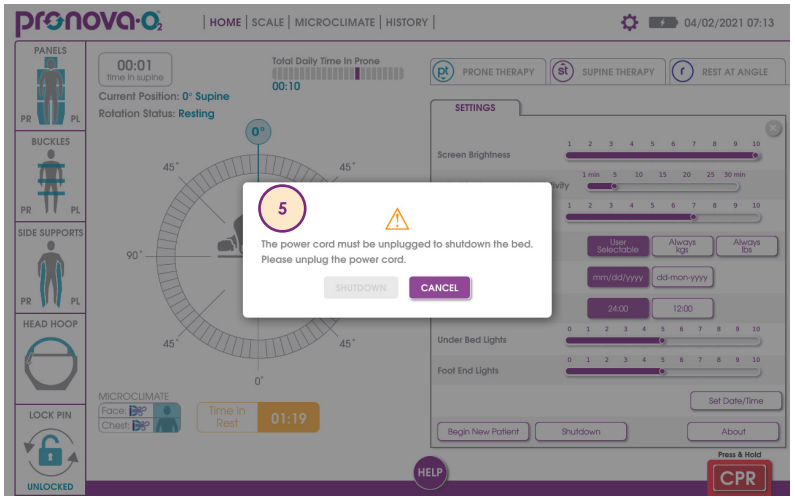
Ensure patient has been removed from surface prior to powering down.

1. Fully **insert Lock Pin** into locked position at 0° Supine.
2. Lower surface to lowest height.
3. Press **Settings** icon on top right of User Interface.
4. Press **Shutdown.** If power cord is not already unplugged, unplug power cord.
5. Once power cord is unplugged, Press **Shutdown**. The screen will begin counting down from 10 and an audible tone will sound.

To preserve battery power, Pronova-O₂™ should be plugged in at a minimum of 24 hours every 30 days.

If device is planned to be unplugged for a long period of time, greater than 30 days, the batteries should be removed from the system by a trained technician.



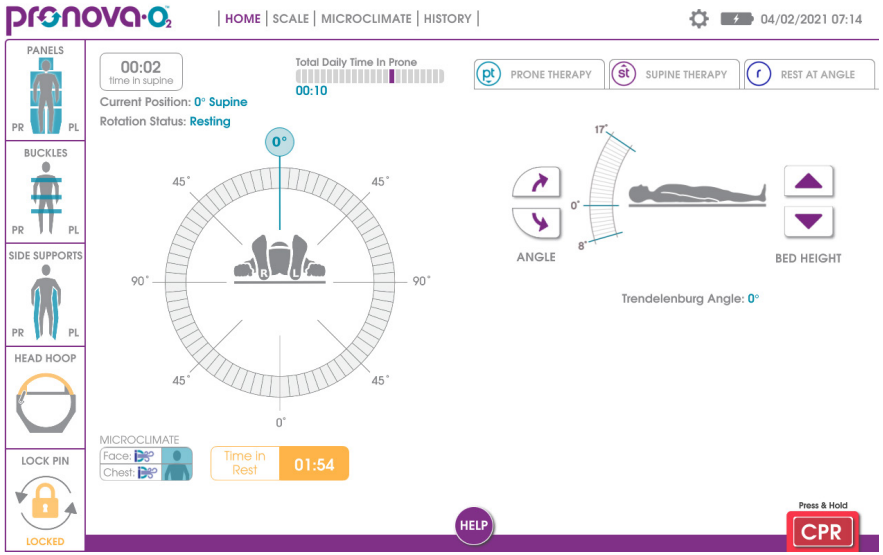


Indicator/Alarm Screens

The following section reviews the warning screens that can occur while your patient is on the Pronova-O_2™ device, and considerations to resolve warnings/alarms.

Surface Status Indicators

On the left side of the User Interface, the status of parts of the surface that are monitored for safety are always shown. When an item is indicated in green, the item is secured in a rotation ready position. When an item becomes yellow, the status needs to be resolved before beginning rotation.



Panels

To change the status to green, ensure each panel is in the locked and secured position. Latches are located on the bottom of each panel.

Buckles

To change status to green, secure and tighten each buckle (a total of 3 buckles) on the Prone support section until the indicator changes to green.

Side Supports

To change status to green, lift and place the side support on the surface and press the silver button located on the side of the surface to secure side support against patient.

Head Hoop

To change status to green, rotate the Head Hoop and push downward to latch closed.

Lock Pin:

Indicates when the Lock Pin is fully disengaged and ready for rotation.

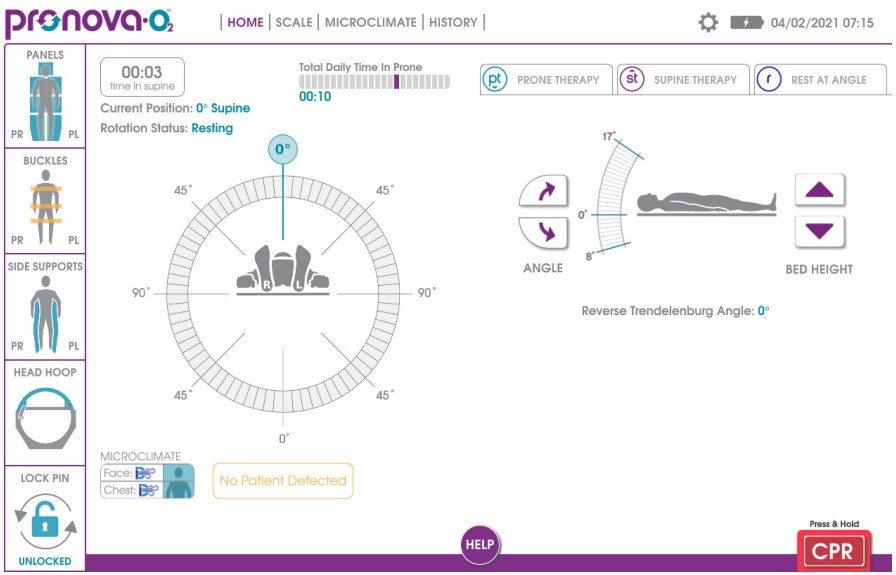
Indicates when the Lock Pin is in the locked position. This position is only possible when the surface is at 0° Supine. The locked position should be utilized for Supine assessments, CPR, and transferring on and off the surface, among others.

When the Lock Pin is in the Stopped position, the icon will flash between red and yellow, indicating the Lock Pin is partially engaged in the stopped position. This position can be used at any time to quickly stop rotation.

No Patient Detected Indicator

The No Patient Detected Indictor will show if the Pronova-O₂™ device scale reads less than 50 pounds (22.7 kg). When the indicator is present, the Rest Time Exceeded alarm is deactivated.

If the No Patient Detected Indicator is present when a patient is in the Pronova-O₂™, press the scale tab at the top of the User Interface, then use the manual adjust feature to enter the patient weight using the up and down arrows on either side of the weight indicator. Refer to page 16 to manually adjust the scale.

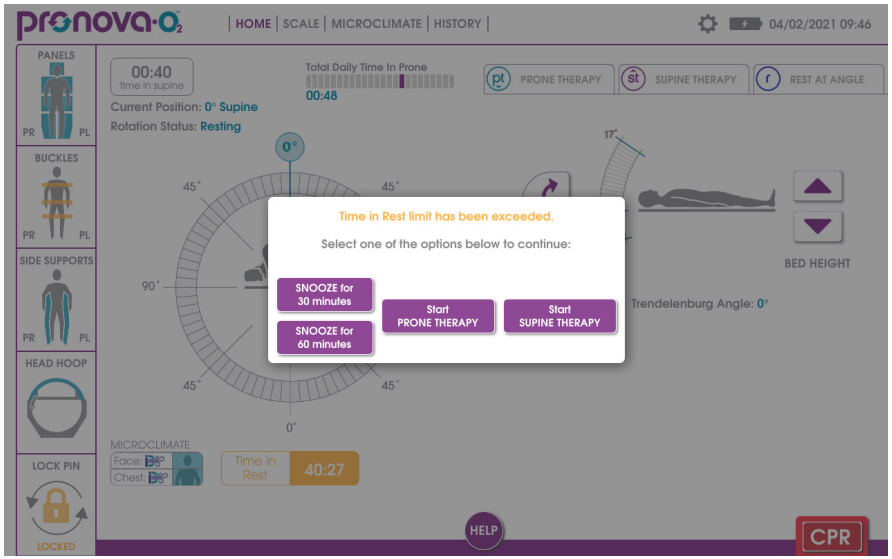


Rest Time Exceeded

The Rest Time Exceeded alert will occur if a patient has not been rotated for greater than 30 minutes. To reduce the risk for skin breakdown and maximize the benefits of the Pronova-O₂™ Therapy, it is recommended to have the patient in rotational therapy when possible. The Rest Time Exceeded alert will not activate if the No Patient Detected Indicator is present.

To snooze, press either **Snooze for 30 minutes** or **Snooze for 60 minutes.**

Press **Start Prone Therapy** if you would like to initiate Prone Therapy. Press **Start Supine Therapy** if you would like to initiate Supine Therapy.

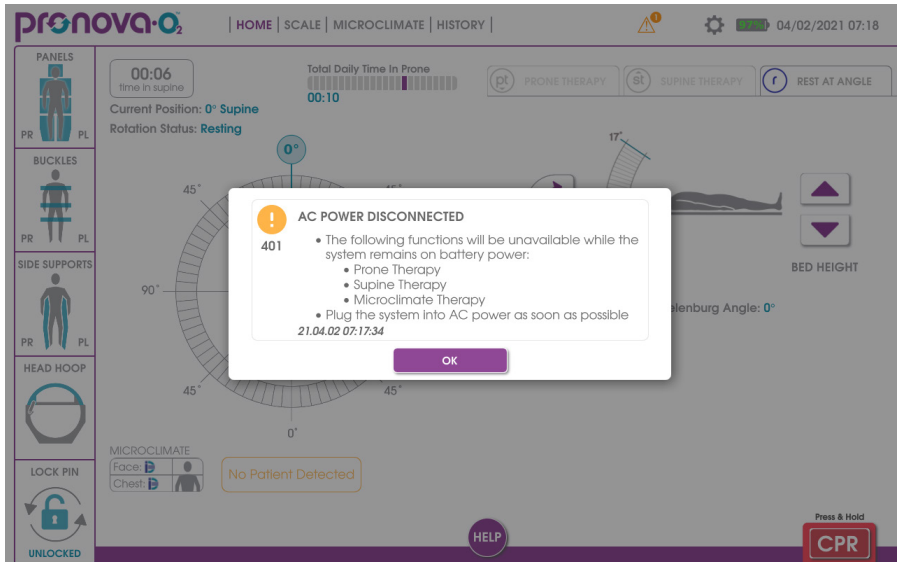


Pronova-O₂™ on Battery Power

The Battery Power alert will show if the device is unplugged during therapy.

To resolve, locate the power cord at head end of device and ensure the device is plugged into appropriate wall outlet and that the wall outlet has power.

Prone Therapy, Supine Therapy and Microclimate functions are not available when device is operating on battery power.

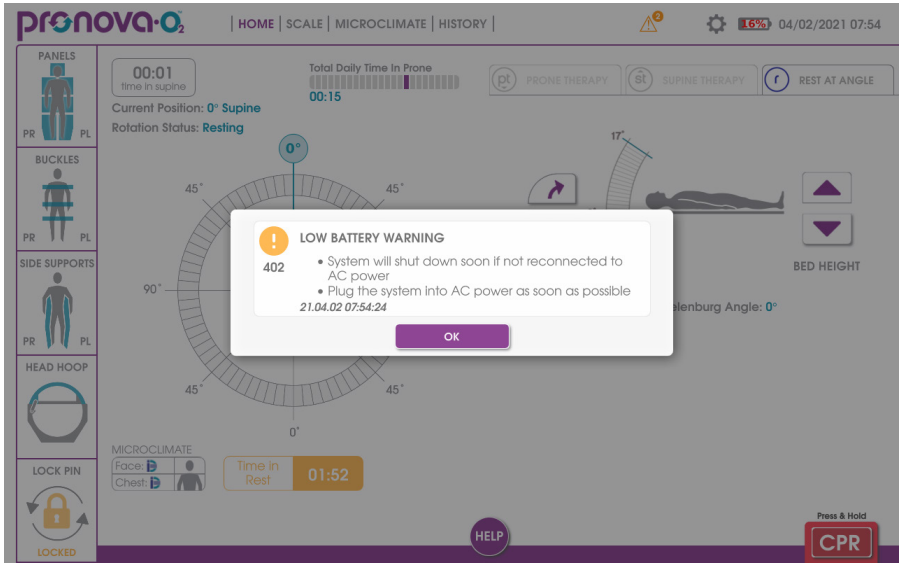


Pronova-O₂™ Battery Low

The Battery Power alert will show if the device is unplugged, and battery power is running low.

To resolve, locate the power cord at head end of device and ensure the device is plugged into appropriate wall outlet, and that the wall outlet has power.

If Battery Low alert shows and Pronova-O₂™ is plugged in, service may be required. Call 1-855-ASK-TURN (1-855-275-8876).



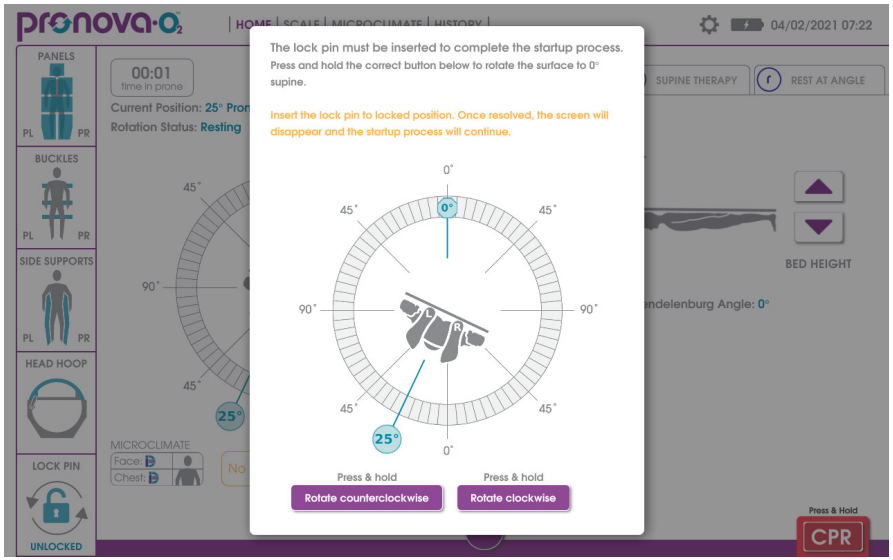
Lock Pin Calibration

The Lock Pin Calibration screen will appear during the device boot up process if the Lock Pin is not in the locked position at 0° Supine and the surface has been manually rotated while it was powered down.

Follow the prompts on the screen to guide the surface to 0° Supine and fully insert the Lock Pin in the locked position. All of the surface indicators must be in the green position to begin rotation during the calibration routine.

Always rotate the patient towards the ventilator.

There is a safety mechanism that will not allow the surface to rotate greater than about 300°. If this safety mechanism is engaged, rotate the surface in the opposite direction to reach 0° Supine.

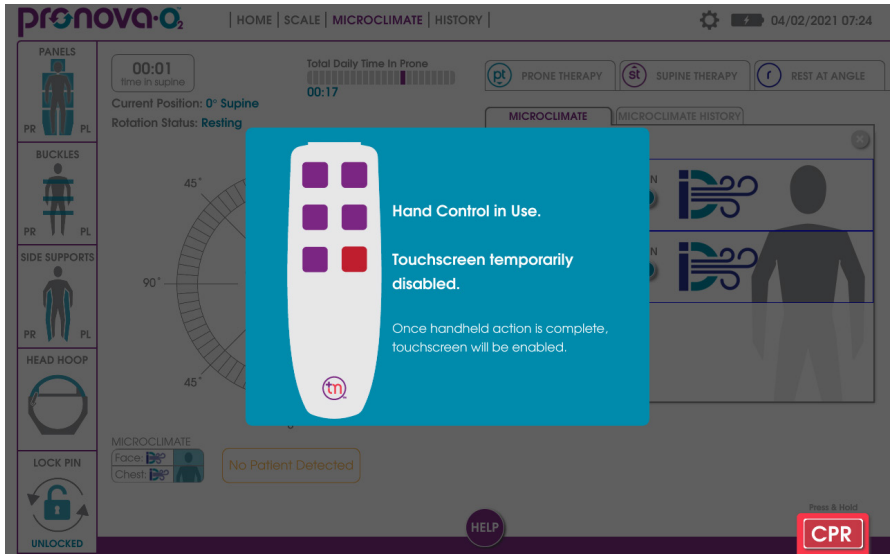


Hand Control in Use

The Hand Control In Use screen will appear when any button other than CPR is being pressed on the Hand Control. Once the button is released, the screen will disappear. Pressing the CPR button on the Hand Control will cause the CPR screen to appear.

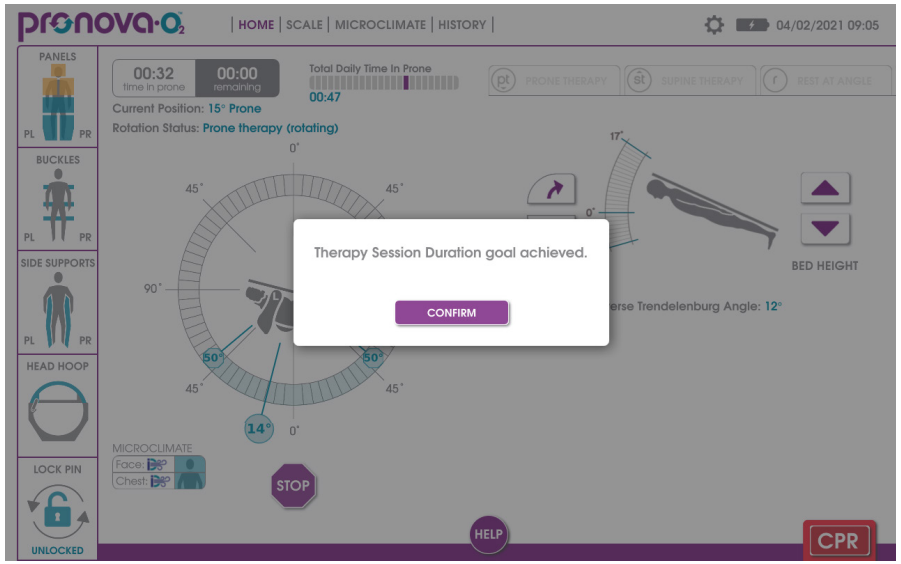
CPR Functionality will remain available on the User Interface during Hand Control use.

In the event of a Hand Control button being pressed longer than 70 seconds, the Hand Control button will be disabled until it is released.



Therapy Session Duration Goal Achieved

When therapy session duration is entered, once the duration is achieved, the therapy session duration achieved screen pops up. Press Confirm to acknowledge Therapy Complete.

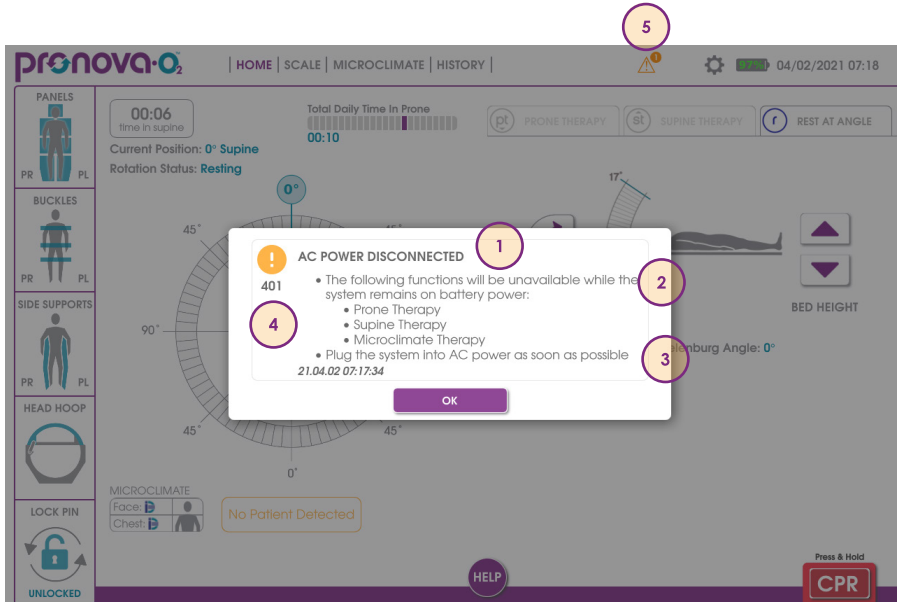


This alert is for information only; therapy will not be interrupted or stopped when therapy session duration is achieved.

Press **Confirm** to acknowledge Therapy Complete.

If an error occurs with the Pronova-O₂™ device, the system will present an audible alert and a pop-up window will appear listing the following information related to the error:

1. Description of the error
2. Impact of the error (e.g. are any features disabled because of the error)
3. Guidance on resolving the error
4. An error identification number
5. Error icon indicating error condition present



If the system can continue being used, the pop-up window will allow you to acknowledge the error by pressing the OK button. If the error prevents the system from being used, it will permanently be displayed on the screen blocking access to the rest of the User Interface and will only allow the system to be Shutdown.

In addition to the pop-up window, an orange triangle (item 5) will be displayed in the upper right corner of the user interface indicating that an error condition is present. The number next to the triangle indicates the number of errors that are currently active. When an issue is resolved, the triangle will disappear, or the number of errors listed will decrease.

The tables below list all of the errors for the Pronova-O₂™ Therapy System.

Errors that Require User Attention	
101 - Patient Frame Rotation Stall Detected - Ensure no obstacles are preventing rotation of the patient frame - Ensure patient is centered and secured between the side supports - If issue persists, contact Turn Medical for Technical Support	**402 - LOW BATTERY WARNING** - System will shut down soon if not reconnected to AC power - Plug the system into AC power as soon as possible
102 - Patient Frame Rotation Overspeed Detected - This may have occurred because the system was bumped during rotation - If the patient frame exhibited unexpected rapid rotation, or if this issue persists, use the Manual CPR Lever to place the patient surface in a safe position - Contact Turn Medical for Technical Support	**403 - REDUCED BATTERY CAPACITY** - The battery is recovering from a complete discharge or its capacity to support the system has been diminished. If possible, do not unplug the system until the battery has been charging for at least 1 hour. - If this issue persists, contact Turn Medical for Technical Support
103 - Patient Frame Rotation Stall Detected - The bed has reached the maximum rotation limit. To reach 0° Supine, rotate the surface in the opposite direction and insert the lock pin into the locked position. Once resolved, the screen will disappear, and the startup process will continue. - Ensure no obstacles are preventing rotation of the patient frame	**411 - SYSTEM POWERING DOWN due to critically low battery** - Plug the system into AC power as soon as possible to restart

401 - AC POWER DISCONNECTED
- The following functions will be unavailable while the system remains on battery power:
  - Prone Therapy
  - Supine Therapy
  - Microclimate Therapy
- Plug the system into AC power as soon as possible
	901 - Handset prolonged press
	- Hand Control button has been pressed longer than 70 seconds. This button will be deactivated until released.
	- If this issue persists, contact Turn Medical for Technical Support.

Errors that Require Prompt Service	
302 - SYSTEM REQUIRES SERVICE (FCUIO Data not Present) cA system error has occurred that may prevent the following functions from working: - Emergency Column Down switches - Under bed lighting - Contact Turn Medical for Technical Support	**804 - SYSTEM REQUIRES SERVICE (Emergency Column Down CPUV Fault)** - A system error has occurred that may prevent the following functions from working: - Emergency Column Down Switches - Contact Turn Medical for Technical Support
400 - SYSTEM REQUIRES SERVICE (Batteries not Detected) - A system error has occurred that may prevent the following functions from working: - Battery Back-up - Emergency Column Down switches - Under bed lighting - Contact Turn Medical for Technical Support	**805 - SYSTEM REQUIRES SERVICE (Emergency Column Down UVLO Fault)** - A system error has occurred that may prevent the following functions from working: - Emergency Column Down Switches - Contact Turn Medical for Technical Support
408 - SYSTEM REQUIRES SERVICE (UPS Communication Error) - A system error has occurred that may prevent the following functions from working: - Battery Back-up - Contact Turn Medical for Technical Support	**806 - SYSTEM REQUIRES SERVICE (Emergency Column Down Temperature Warning)** - A system error has occurred that may prevent the following functions from working: - Emergency Column Down Switches - Contact Turn Medical for Technical Support
410 - SYSTEM REQUIRES SERVICE (UPS Communication Modbus Error) - A system error has occurred that may prevent the following functions from working: - Battery Back-up - Contact Turn Medical for Technical Support	**807 - SYSTEM REQUIRES SERVICE (Emergency Column Down Unresponsive)** - A system error has occurred that may prevent the following functions from working: - Emergency Column Down Switches - Contact Turn Medical for Technical Support
500 - SYSTEM REQUIRES SERVICE (Scale Output Unresponsive) - A system error has occurred that may prevent the following functions from working: - Scale - Contact Turn Medical for Technical Support	**834 - SYSTEM REQUIRES SERVICE (Foot Emergency Column Down Open Fault)** - A system error has occurred that may prevent the following functions from working: - Foot End Emergency Column Down Switch - Contact Turn Medical for Technical Support
501 - SYSTEM REQUIRES SERVICE (Scale Output Error) - A system error has occurred that may prevent the following functions from working: - Scale - Contact Turn Medical for Technical Support	**835 - SYSTEM REQUIRES SERVICE (Head Emergency Column Down Open Fault)** - A system error has occurred that may prevent the following functions from working: - Head End Emergency Column Down Switch - Contact Turn Medical for Technical Support
610 - Touch Screen Unresponsive - A system error has occurred that may prevent the following functions from working: - Touch Screen - Use the Hand Control, Manual CPR Lever, and the Emergency Column Down Switches to control the system - To stop active rotation therapy, push the lockpin inward - Contact Turn Medical for Technical Support	**836 - SYSTEM REQUIRES SERVICE (Lift Actuator Controller Unresponsive)** - A system error has occurred that may prevent the following functions from working: - Adjustment of Patient Surface Height and Trendelenburg Angle - Contact Turn Medical for Technical Support
802 - SYSTEM REQUIRES SERVICE (Emergency Column Down Temperature Fault) - A system error has occurred that may prevent the following functions from working: - Emergency Column Down Switches - Contact Turn Medical for Technical Support	**837 - SYSTEM REQUIRES SERVICE (Lift Actuator Controller Fault)** - A system error has occurred that may prevent the following functions from working: - Adjustment of Patient Surface Height and Trendelenburg Angle - Contact Turn Medical for Technical Support
803 - SYSTEM REQUIRES SERVICE (Emergency Column Down Over Current Fault) - A system error has occurred that may prevent the following functions from working: - Emergency Column Down Switches - Contact Turn Medical for Technical Support	

Errors That Require the System to Shutdown	
300 - SYSTEM ERROR (RDIO Data not Present) - A system error has occurred and the system must be shutdown - Use the Manual CPR Lever and the Emergency Column Down Switches to place the patient surface in a safe position prior to shutdown - Contact Turn Medical for Technical Support before restarting the system	**702 - SYSTEM ERROR (RMCU Over Voltage Limit)** - A system error has occurred and the system must be shutdown - Use the Manual CPR Lever and the Emergency Column Down Switches to place the patient surface in a safe position prior to shutdown - Contact Turn Medical for Technical Support before restarting the system
301 - SYSTEM ERROR (RMCU Data not Present) - A system error has occurred and the system must be shutdown - Use the Manual CPR Lever and the Emergency Column Down Switches to place the patient surface in a safe position prior to shutdown - Contact Turn Medical for Technical Support before restarting the system	**703 - SYSTEM ERROR (RMCU Under Voltage Limit)** - A system error has occurred and the system must be shutdown - Use the Manual CPR Lever and the Emergency Column Down Switches to place the patient surface in a safe position prior to shutdown - Contact Turn Medical for Technical Support before restarting the system
303 - SYSTEM ERROR (RMCU Data not Present) - A system error has occurred and the system must be shutdown - Use the Manual CPR Lever and the Emergency Column Down Switches to place the patient surface in a safe position prior to shutdown - Contact Turn Medical for Technical Support before restarting the system	**704 - SYSTEM ERROR (RMCU Output Overload)** - A system error has occurred and the system must be shutdown - Use the Manual CPR Lever and the Emergency Column Down Switches to place the patient surface in a safe position prior to shutdown - Contact Turn Medical for Technical Support before restarting the system
404 - SYSTEM ERROR (UPS Mains Over Voltage) - A system error has occurred and the system must be shutdown - Use the Manual CPR Lever and the Emergency Column Down Switches to place the patient surface in a safe position prior to shutdown - Contact Turn Medical for Technical Support before restarting the system	**705 - SYSTEM ERROR (RMCU Emergency Stop Activated)** - A system error has occurred and the system must be shutdown - Use the Manual CPR Lever and the Emergency Column Down Switches to place the patient surface in a safe position prior to shutdown - Contact Turn Medical for Technical Support before restarting the system
405 - SYSTEM ERROR (UPS Battery Over Voltage) - A system error has occurred and the system must be shutdown - Use the Manual CPR Lever and the Emergency Column Down Switches to place the patient surface in a safe position prior to shutdown - Contact Turn Medical for Technical Support before restarting the system	**706 - SYSTEM ERROR (RMCU Setup Fault)** - A system error has occurred and the system must be shutdown - Use the Manual CPR Lever and the Emergency Column Down Switches to place the patient surface in a safe position prior to shutdown Contact Turn Medical for Technical Support before restarting the system
406 - SYSTEM ERROR (UPS Output Over Current Limit) - A system error has occurred and the system must be shutdown - Use the Manual CPR Lever and the Emergency Column Down Switches to place the patient surface in a safe position prior to shutdown - Contact Turn Medical for Technical Support before restarting the system	**707 - SYSTEM ERROR (RMCU Mosfet Fault)** - A system error has occurred and the system must be shutdown - Use the Manual CPR Lever and the Emergency Column Down Switches to place the patient surface in a safe position prior to shutdown - Contact Turn Medical for Technical Support before restarting the system
701 - SYSTEM ERROR (RMCU Over Temperature Limit) - A system error has occurred and the system must be shutdown - Use the Manual CPR Lever and the Emergency Column Down Switches to place the patient surface in a safe position prior to shutdown - Contact Turn Medical for Technical Support before restarting the system	**708 - SYSTEM ERROR (RMCU Configuration Fault)** - A system error has occurred and the system must be shutdown - Use the Manual CPR Lever and the Emergency Column Down Switches to place the patient surface in a safe position prior to shutdown - Contact Turn Medical for Technical Support before restarting the system

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Special Patient Considerations

This section reviews special patient considerations while in Pronova-O₂™ Therapy.

Section A
Mechanical Ventilation

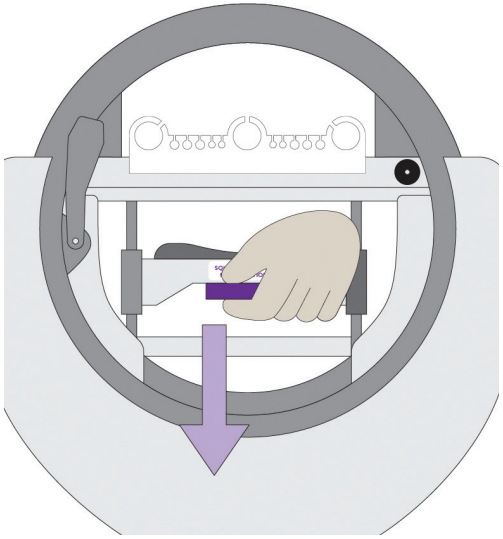
Pronova-O₂™ is designed to assist in the management of patients experiencing pulmonary distress and/or complications due in part to patient immobility. Such distress or complications can arise in patients suffering pneumonia, sepsis, trauma, Acute Respiratory Distress Syndrome (ARDS) and ventilatory associated events, among others.

- Patients with pulmonary distress related to sepsis, pneumonia, ventilator associated events and ARDS, among other conditions, often experience desaturations (reduced oxygen levels) while laying flat in preparation for position change to Prone. Consider ways to mitigate this risk such as preparations prior to placing the patient flat, having required staff available for transfer and position change, etc. Often, when patients reach the Prone Position, the oxygenation improves.
- Patients requiring the Prone Position with mechanical ventilation often require higher levels of PEEP. Do not disconnect ventilator when possible, to avoid potential loss of recruitment and damage to alveoli.
- Use of hard plastic Endotracheal Tube (ETT) securement devices are not recommended in the Prone Position. Consult with Respiratory Therapist and or Attending Physician or Prescriber regarding alternative ETT securement methods. Some practitioners have secured ventilator tubing with tape or velcro and a foam securement device.

Intubation on Pronova-O₂™ Device
For assistance with intubation, an intubation lever is located on the head panel. If required while the patient is in the Pronova-O₂™ device, pull purple handle to lower head panel and allow for visibility of patient airway. Refer to page 96 on intubation lever in Operating Instructions.

Follow all hospital/facility protocols during procedure.

Re-engage panel after use by lifting and locking panel in place, in line with surface.



Section A

Mechanical Ventilation-Warnings

This section reviews warnings related to Mechanical Ventilation.

During position changes, transfer, and initiation of rotation, ensure that ETT and all critical lines are secure and visible.

Patients who are mechanically ventilated should be rotated Prone toward the ventilator. This provides the most "slack" for the ventilator tubing. Adjust settings accordingly in Prone Therapy or Rest at Angle tabs.

Ventilator tubing should be secured in the opening that is opposite of ventilator to prevent tube dislodgement when turning the patient Prone.

During position changes (Prone to Supine, Supine to Prone), always monitor all critical lines including ventilation tubing and ETT.

When initiating rotation therapy, monitor two full rotation cycles to ensure line securement.

If Intubation Lever is used, ensure it is re-engaged after use by lifting up on panel to secure.

Section B
Tracheostomy

Some patients requiring the Prone Position may have a tracheostomy. Considerations include:

- Adjust Chest Wedge to avoid compression of the tracheostomy.
- Consider using a swivel connector to extend the length and reduce the torque at the tracheostomy tube. The use of the tracheal tube extension enables an increase in working space in the area in front of the tracheal tube, thus allowing for the convenient and rapid access to the various connectors that may be coupled to the patient.
- Ensure the securement device for the tracheostomy is intact and secure.

Section B
Tracheostomy-Warnings

This section reviews warnings related to Mechanical Ventilation for patients with a tracheostomy.

Patients who are mechanically ventilated should be rotated Prone toward the ventilator. This provides the most "slack" for the ventilator tubing. Adjust settings accordingly in Prone Therapy or Rest at Angle tabs.

Ventilator tubing should be secured in the opening that is opposite of ventilator to prevent tube dislodgement when turning the patient Prone.

Ensure that Mechanical Ventilation tubing and all critical lines are secure and visible during transfer.

During position changes (Prone to Supine, Supine to Prone), always monitor ventilation tubing.

When initiating rotation therapy, monitor two full rotation cycles to ensure line securement.

Section C
Extracorporeal Membrane Oxygenation (ECMO)

Some patients may require the Prone Position in addition to ECMO. Some additional considerations for these patients include:

- Consider the size of the room with the Pronova-O_2™, ventilator, ECMO machine, and any other devices, and adjust the location of the devices as appropriate to allow for proper assessment and access to patient. Keep in mind that all critical lines must be routed through the top or bottom hoop and stowed in appropriate critical line management areas.
- Consider the location of the ECMO cannula and ventilator tubing to determine the safest direction to turn to the Prone Position. The desired direction is toward these critical invasive lines to allow for optimal slack. Adjust the direction of Prone rotation in the Prone Therapy or Rest at Angle tabs.

Section C
ECMO-Warnings

Exercise extreme caution to prevent dislodgement of ECMO cannula. It is strongly recommended to have an additional clinician in the room during any position change, whose sole purpose is to manage the ECMO cannula.

Confirm proper support of the cannula to ensure patency and flow.

During rotation and position changes (Prone to Supine, Supine to Prone), always monitor ECMO tubing and circuit during maneuver.

When initiating rotation therapy, monitor two full rotation cycles to ensure line securement.

Section D
Dialysis

Dialysis is a common adjunctive therapy with patients requiring the Prone Position. Some considerations include:

- Assess length of dialysis tubing and add extensions if required.
- The Prone Position is not a contraindication to continue dialysis treatment. Ensure proper treatment and assessment of the line, insertion site, and appropriate personnel to monitor equipment.
- Consider the size of the room with the Pronova-O_2™, ventilator, dialysis machine, and any other devices, and adjust the location of the equipment as appropriate to allow for proper assessment and access to patient. Keep in mind that all critical lines must be routed through the top or bottom hoop.

Section D
Dialysis - Warnings

Consider placement of dialysis catheter. To ensure patency of this line, adjust or add padding to any site that can affect patency. (i.e., femoral line-knee bending may alter patency)

Ensure that dialysis tubing and all critical lines are secure and visible during transfer.

During rotation and position changes (Prone to Supine, Supine to Prone), always monitor dialysis tubing during maneuver.

When initiating rotation therapy, monitor two full rotation cycles to ensure line securement.

Section E

Other Critical Lines (i.e., Arterial Line, Gastric Tube, Chest Tube, Central Lines, among others)

This section reviews the management and considerations of invasive lines while in the Pronova-O₂™.

- Consider length of invasive lines and need for extensions, if necessary. Note: extension of arterial lines may dampen the waveform – amplitude may need to be adjusted.
- Ensure securement of lines with proper tape, dressings etc, prior to placement Prone.
- Consider need for additional padding, if necessary, to ensure patency and reduce risk for skin breakdown.
- Route all lines mid chest and above through top hoop, and lines below mid chest through Foot Opening at foot of surface.

Section E

Other Critical Lines - Warnings

Ensure that dialysis tubing and all critical lines are secure and visible during transfer.

During rotation and position changes (Prone to Supine, Supine to Prone), always monitor critical line tubing during maneuver.

When initiating rotation therapy, monitor two full rotation cycles to ensure line securement.

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Patient Care and Procedures

This section reviews considerations related to patient care and procedures on the Pronova-O₂™ device. Most patient procedures are possible while on the Pronova-O₂™ device. Follow applicable hospital and facility protocols and procedures.

Patient Care and Procedures

Most patient procedures are possible while on the Pronova-O₂™ device. Follow applicable hospital and facility protocols and procedures.

- Bathing
- Skin Care
- Extended Supine Position
- Intubation
- X-Ray
- C-Arm

Bathing

Bathing

- Consider the use of fluids on the Pronova-O₂™ surface and avoid excessive fluids to reduce risk for moisture impacting the motor and circuits.
- Consider bathing in the Prone or Supine position based on patient status.
- Bathe patient according to facility protocols, ensure that patient's skin and patient surface is clean and dry.
- Consider doing skin assessment when bathing and ensure skin is clean, dry and intact. Place appropriate dressings to areas of breakdown or potential for breakdown.

Skin Care

Special considerations should be taken for any patient placed in the Prone Position. Follow all facility protocols related to skin assessment while the patient is in Pronova-O₂™. Consider the following and refer to the picture at the end of this section when considering pressure points in the Prone Position to reduce risk of skin complications while the patient is in Pronova-O₂™:

Face

- Consult facility Wound Care Registered Nurse (WOCN) to discuss risk for breakdown and potential ways to mitigate this risk.
- The InteliDerm™ Face Pack utilizes Microclimate Management technology to reduce risk for breakdown while in the Prone Position. Ensure the Face Pack is secured, connected and turned **on** on the User Interface. The InteliDerm™ Face Pack is a one-time patient use system. Discard after use.

Avoid excessive pressure when applying the InteliDerm™ Face Pack. Make sure the Face Pack does not touch the eyes.

Open the Occipital Panel when patient is in the Prone Position to reduce pressure to the face and occiput.

- Consider the type of device that is securing the ETT. Commercially available ETT securement devices can cause increased risk for skin breakdown.
- Soft, hydrophylic, multilayered prophylactic dressings should be applied to known areas at risk for breakdown such as the cheeks and forehead.
- Manage excessive moisture on the face by assessing oral secretions and following facility protocol during the Prone Position when appropriate.
- Maintain and perform eye care to reduce risk for corneal abrasion.
- Apply ophthalmic lubricant if appropriate. Due to excessive facial and ocular edema, taping eyes shut is not recommended.
- Utilize Reverse Trendelenburg when possible to reduce risk for edema.
- Consider submerging soft cloths in ice water or properly insulated ice packs while in the Supine Position with InteliDerm™ Face Pack off to reduce edema. **NOTE: Never place ice packs directly onto patient's skin.**

Skin Care
continued

Chest/Torso

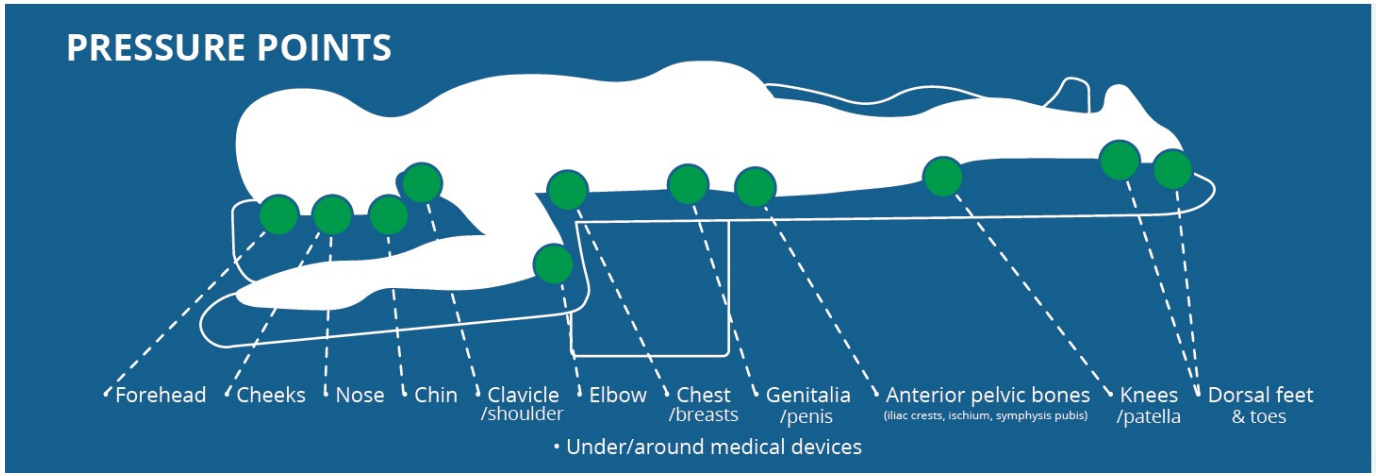
- The **InteliDerm™ Chest Wedge** utilizes Microclimate Management technology to reduce risk for breakdown while in the Prone Position. Ensure the Chest Cushion is secured, connected and turned **on**. This system is a single patient use system. Discard after use.
- Ensure proper securement of Side Supports against the Torso to reduce risk for friction and shearing during position changes and rotation.
- When Prone, open as many panels on Pronova-O_2™ as possible to help minimize the risk of skin breakdown and provide maximal lung expansion.
- Ensure all panels are closed and secure prior to turning Supine.
- Ensure proper adjustment of Side Supports of 2-4 finger breadths (approximately 2 inches) between the side support and axilla to reduce risk for soft tissue nerve injury.
- Place EKG leads on back when appropriate.
- Soft, hydrophylic, multilayered, prophylactic dressings should be applied to known areas at risk for breakdown such as the shoulders and pelvic bone.
- Consider external devices such as invasive lines, chest drains, surgical drains, among others, and the need for additional securement and/or prophylactic dressings to reduce risk for breakdown near these sites.
- Only breathable pads should be used to manage moisture and minimize soiling of the therapeutic surface. **Do not use any plastic backed pads.**
- To reduce risk for breakdown, ensure the patient does not have any additional linens such as gown, towel, sheet, etc.

Skin Care
continued

Lower Body

- Soft, hydrophylic, multilayered prophylactic dressings should be applied to known areas at risk for breakdown such as the knees, shins and/or toes, among others.
- Consider external devices such as invasive lines, urinary/fecal drains, surgical drains, SCDs, among others, and the need for additional securement or adjustment and prophylactic dressings to reduce risk for breakdown near these sites.
- Ensure that foot is placed directly on the foot support so that the entire foot from ball to heel is making contact with the padding; assess for foot drop or pressure per hospital protocol.
- Avoid direct pressure over the **knees** and **toes** when possible.
- When Supine, elevate heels off of patient therapy surface.

NPIAP Prone Position Pressure Points



Pressure Injury Prevention: PIP Tips for Prone Positioning. (2020) National Pressure Injury Advisory Panel. https://npiap.com/store/ViewProduct.aspx?id=16156674.

Extended Supine Position

An intubation lever is located on the head panel to assist in placing the patient in an appropriate position for intubation. If it is required, please consider the following:

- Elevate heels off surface
- Initiate Supine Rotational Therapy when possible
- Assess skin at regular intervals
- InteliDerm™ Face Pack is not required for Supine Position

InteliDerm™ Face Pack does not have a sensor.

- Place patient in Reverse Trendelenburg when possible
- Consider removing EKG leads from back and placing anteriorly to reduce skin breakdown risk

Intubation Procedures

Intubation on Pronova-O₂™

For assistance with intubation, a lever is located on the head panel. If intubation is required while the patient is in Pronova-O₂™, squeeze purple handle to lower head panel and allow for visibility of patient airway.

Follow all hospital/facility protocols during procedure.

Re-engage panel after use by lifting and locking panel in place, in line with surface.

Monitor all critical lines while lowering head panel.

Intubation lever does not have a sensor. Ensure securement by lifting after lowering for use.

X-Ray Procedures

The following instructions review the procedures for taking an X-Ray on Pronova-O₂™. For detailed information regarding stowing and securing a patient, refer to ***Preparation of Pronova-O₂™ for Placement*** *(pages 21-28)and* ***Patient Transfer and Securement*** *sections (pages 29-37) to review these procedures in depth. The below steps should be used as a reference in conjunction with the detailed steps provided in the proper section.*

Supine

1. Press Rest at Angle to place patient at 0° Supine.
2. Once 0° Supine reached, fully insert Lock Pin to locked position.
3. Remove InteliDerm™ Face Pack.
4. Release and stow Prone Support buckles.
5. Consider need for removing the least amount of items required to rotate patient to side to place X-Ray Cassette: Inner Leg Supports, Shin Slings, Side Supports, etc.

Ensure two clinicians remain at bedside when side supports are stowed.

6. Remove invasive lines from Critical Care Management System to provide slack for turn.
7. Turn patient to side to slide X-Ray Cassette to appropriate position.

Monitor patient and invasive lines during rotation.

8. Once X-Ray is complete, re–secure patient in Pronova-O₂™ and follow procedures to Prone patient and open panels and Center Chest Panel to remove X-ray Cassette OR turn patient to side to remove X-ray Cassette.
9. Use either the Prone Therapy or Rest at Angle tabs on User Interface to place patient back in Prone Position at 0° Prone.
10. Once patient is stable, open Thoracic Panels.
11. Pull black knob above Center Chest Panel to release and remove X-Ray Cassette.
12. Continue with Prone Therapy orders as prescribed by physician.

X-Ray Procedures

The following instructions review procedures for taking an X-Ray on Pronova-O₂™ in the Prone Position. For detailed information regarding stowing and securing a patient, refer to the sections reviewing these procedures in depth. These steps should be used as a reference in conjunction with the detailed steps provided in the proper section.

Prone

1. Once X-Ray tech is in room, press stop to access Rest at Angle tab to rest at 0° Prone.
2. Open Thoracic Panels, if not already open.
3. Pull knob on Center Chest Panel to allow X-Ray tech to place cassette.

Center Chest Panel does not have a sensor. Ensure it is secured prior to going Supine.

4. Close panels.
5. Refer to Step 1: Supine X-Ray Procedures to continue X-Ray Process. (page 84)

C-Arm Imaging

- The surface of the Pronova-O_2™ has radiolucent panels to allow for C-Arm Imaging if required.
- Raise the height of the surface to allow for proper placement of the imaging device under the surface.
- Follow all hospital protocols and policies during procedure.
- Prone Support Arms are not radiolucent. In the Supine Position, unbuckle Prone support surfaces and rest surface against the Prone Support Arm to allow for imaging visibility.
- If it is anticipated that the patient will remain in the Supine Position for an extended period of time, refer to section **"Extended Supine Position"** (page 83) for additional considerations.

Monitor all critical lines during surface position changes.

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Therapy Considerations

This section reviews settings considerations for the Pronova-O₂™ device.

Prone Therapy Considerations

Initiating Prone Therapy

A landmark trial implemented Prone Positioning with the following criteria and found improved outcomes[2]:

- FiO_2 requirement Supine ≥ 60%
- PEEP requirement Supine ≥ 5 cm H_20
- P/F Ratio ≤150

International guidelines for the management of patients requiring the Prone Position include that patients should be Prone a minimum of 16 hours per day[1]. The total time in the Prone Position does not need to be continuous, unless patient condition requires continuous Prone Positioning. Pronova-O_2™ allows the time desired in the Prone Position to be for incremental time to reach 16+ hours per day (i.e., 8 hour sessions) or to provide the Prone duration for 16+ hours concurrently*.

Rotational Therapy Settings

Rotational Therapy has been shown to decrease the risk for ventilator-associated events[3], reduce ventilator length of stay[4], ICU length of stay[4], and reduce the risk for pressure injury[3] and is recommended to be implemented when patient condition allows. Rotation can be set from 0-65° bilaterally.

Reverse Trendelenburg

Reverse Trendelenburg is recommended to be implemented when possible to allow for lung expansion and increase in oxygenation[5].

1. Papazian, L., Aubron, C., Brochard, L. et al. Formal guidelines: management of acute respiratory distress syndrome. Ann. Intensive Care 9, 69 (2019). https://doi.org/10.1186/s13613-019 0540-9
2. Guérin C, Reignier J, Richard JC, Beuret P, Gacouin A, Boulain T, Mercier E, Badet M, Mercat A, Baudin O, et al. Prone Positioning in severe acute respiratory distress syndrome. N Engl J Med. 2013;368:2159–2168
3. Simonis, G., Steiding, K., Schaefer, K. et al. A prospective, randomized trial of continuous lateral rotation ("kinetic therapy") in patients with cardiogenic shock. Clin Res Cardiol 101, 955 962 (2012). https://doi.org/10.1007/s00392-012-0484-7
4. Staudinger, T., Bojic, A., Holzinger, U., Meyer, B., Rohwer, M., Mallner, F., Schellongowski, P., Robak, O., Laczika, K., Frass, M., & Locker, G. J. (2010). Continuous lateral rotation therapy to prevent ventilator-associated pneumonia. Critical care medicine, 38(2), 486–490. https://doi.org/10.1097/CCM.0b013e3181bc8218
5. Robak, O., Schellongowski, P., Bojic, A., Laczika, K., Locker, G. J., & Staudinger, T. (2011). Short-term effects of combining upright and Prone Positions in patients with ARDS: a prospective randomized study. Critical care (London, England), 15(5), R230. https://doi.org/10.1186/cc10471

*** If the Prone Position is applied for 16 hours concurrently, it is recommended to also provide rotational therapy to reduce risk for skin breakdown. Follow all hospital policy and protocols during Prone Positioning.**

Prone Therapy Considerations
Discontinue Therapy

Discontinue Prone Therapy

It is recommended to monitor oxygenation and ventilatory requirements and trends while in the Prone Position and the Supine Position. The landmark trial related to the treatment of patients with the Prone Position utilized the following criteria[2] for discontinuing of Prone Positioning[2]:

- FiO_2 requirement Supine ≤ 60%
- PEEP requirement Supine ≤ 10 cm H_20
- P/F Ratio ≥ 150

In the study[2], all of these requirements were met and remained consistent for 4 hours before discontinuing Prone Positioning.

Once the decision has been made to discontinue Prone Therapy, it is also recommended to continue with Supine rotational therapy for 24 hours post Prone positioning discontinuance to follow early mobility protocols.
Follow all hospital protocols and policies when utilizing the Pronova-O_2™ device.

1. Papazian, L., Aubron, C., Brochard, L. et al. Formal guidelines: management of acute respiratory distress syndrome. Ann. Intensive Care 9, 69 (2019). https://doi.org/10.1186/s13613-019 0540-9
2. Guérin C, Reignier J, Richard JC, Beuret P, Gacouin A, Boulain T, Mercier E, Badet M, Mercat A, Baudin O, et al. Prone Positioning in severe acute respiratory distress syndrome. N Engl J Med. 2013;368:2159–2168

Cleaning and Disinfection Procedures

General Recommendations:

It is recommended that Pronova-O_2™ is cleaned daily to remove any solids or bodily fluids from the surface. Refer to your facility protocols and procedures for cleaning and disinfecting policies while following the guidelines below.

Cautions:

- Do not use harsh or abrasive cleaners, solvents, or scouring pads.
- Do not use jet stream cleaning or automated bed washing machines.
- Do not allow the mains power cord to get wet.
- Do not expose the bed to excessive moisture.

Cleaning:

- Use a disposable soft cloth moistened with warm to hot water and a facility approved cleaning detergent. Ensure the cloth is not so wet as to cause pooling of fluid on the mattress or other bed components or allow the fluid to flow over the mattress, paying special attention to the zipper closures.
- A soft brush can be used to remove resistant stains and soil. Do not use a scouring pad.
- Wipe with a new cloth moistened with clean water, then wipe dry.

Disinfecting:

- Wipe down the cleaned surfaces with facility approved disinfectants.
    - Pronova-O_2™ materials are compatible with alcohol, phenol, and quaternary ammonium based disinfectants. Chlorine based disinfectants can be used up to a concentration of 5000 ppm. Always wipe off the patient surfaces extensively with a new cloth moistened with pure water after using chlorine.
- Wipe the patient surfaces dry before allowing mattress sections to contact patient skin.

Daily Device Check

It is recommended to check the device daily for proper functionality and safety. The following is recommended:

- Inspect all packs, padding, buckles, handles, etc to ensure all are in good condition and functional.
- Inspect InteliDerm™ Face Pack and Chest Wedge for soiling and excessive moisture.
- If any items are not in good condition, contact Turn Medical for additional support at 1.855.ASK.TURN (1-855-275-8876)

Operating Instructions

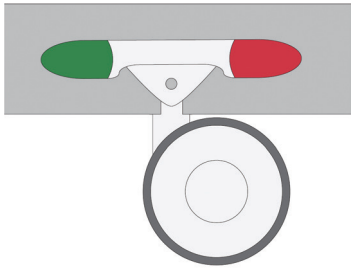
This section provides instructions for setting and adjusting components of the product which are intended to be used by the caregiver. Adjustments intended to be made by technicians are not included in this section. It is highly recommended to review all sections of this manual prior to operating the product. Contact your Turn Medical representative for further information on device inservicing and education.

Brakes and Steering

Foot pedals to engage the Brake and Steer Lock functions are provided on all four corners of the product. Adjusting any of the pedals will cause the other pedals to adjust at the same time.

Neutral

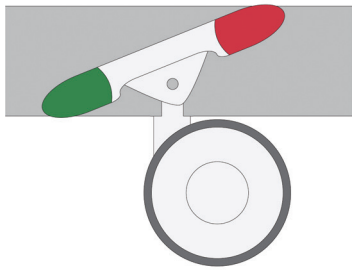
All casters are free to rotate and swivel. Use this position when moving short distances or in crowded spaces where lateral movement is required.



Neutral Position

Steer Lock

All casters are free to rotate, but the head casters are locked from swiveling. Use this position when moving the product long distances where movement in a straight line is desired.

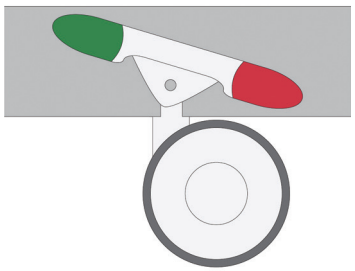


Steer Lock

Brake

All casters are locked from rotating and swiveling. Use this position any time the product is not being actively moved.

Always ensure brakes are set when Pronova-O₂™ is not being transported.



Brake Position

Head Hoop

The Head Hoop opening is designed to allow for safe stowage of critical lines.

To open Head Hoop:

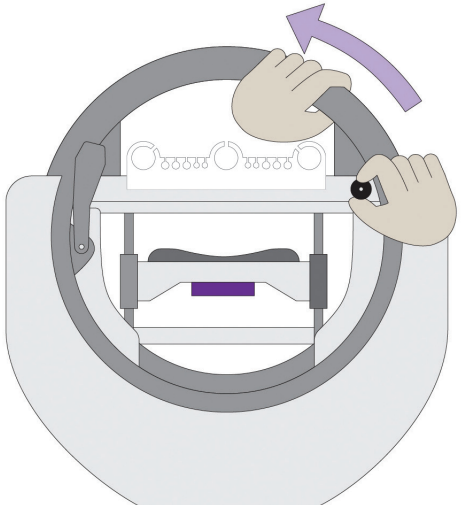
- Pull knob located on right side of head end of the device.
- Lift top of hoop opening to fully open.

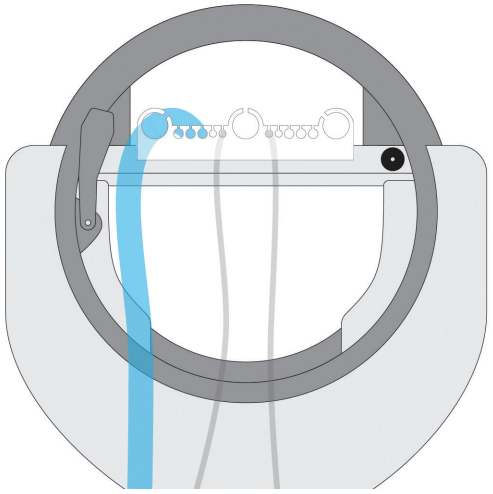
Do not stow any lines outside of the head or foot opening to reduce risk for dislodgement.

Ensure proper slack in all critical lines and tubing to allow for safe rotation.

To close Head Hoop:

- Rotate top of hoop opening towards the hoop.
- Press down until you hear a click to fully lock the hoop in the closed position.





Head Support

The head support is adjustable to create a customized support for the patient in any position.

To adjust the Head Side Support width:

Press down on the lever on the front edge of the head support and slide the Head Side Support in or out as desired.

To stow the Head Side Supports:

Pull knob on back edge of head support and rotate the Head Side Supports downward.

To raise the Head Side Supports:

Rotate the Head Side Support upward until you hear a click.

To secure the InteliDerm™ Face Pack:

- Ensure that all four black clips are in the open position. To open the levers, push upward on the recessed area of the clip below the label **lift to release**.
- Hold the InteliDerm™ Face Pack above the patient's face and guide each of the four straps into the holes on the top edge of the head side supports.
- When the InteliDerm™ Face Pack is in the correct position, gently pull the slack out of each strap and push each lever labeled **press to lock** inward until you hear a click.

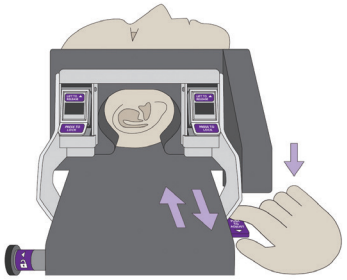
To remove InteliDerm™ Face Pack:

- Open all four clips by pushing upward on the recessed area of each clip.
- Pull upward on the InteliDerm™ Face Pack until all four straps are completely removed from the Head Side Supports.

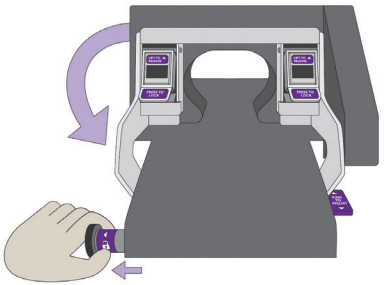
Do not secure Head Side Supports too tightly against face, causing undue pressure.

The Face Pack does not have a sensor to ensure securement prior to Prone rotation.

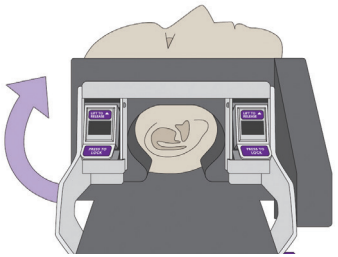
Adjust



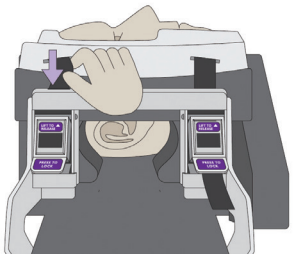
Stow



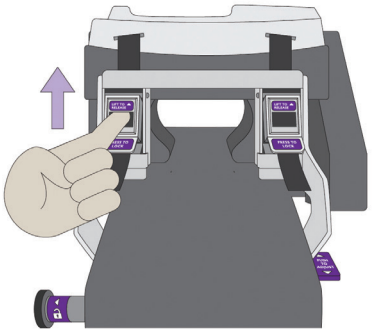
Raise



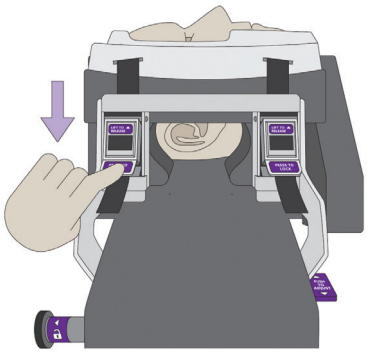
Secure



Remove



Secure



Head Support
continued

Intubation Release

The bottom of the head support can be lowered 15° to accommodate intubation on the device.

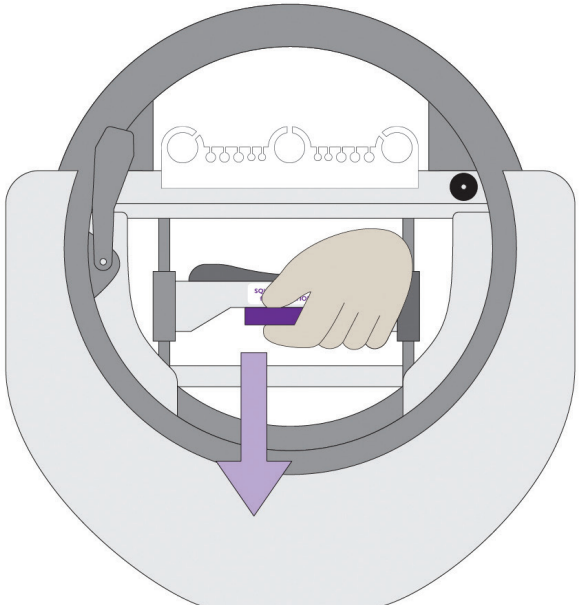
To engage intubation position:

Pull purple handle beneath head support and gently lower the head support platform.

To disengage intubation position:

Lift panel upward until you hear a click.

Ensure Intubation lever is engaged and secured after use.



Prone Head Support

The Prone Occipital Panel allows access to the patient's head and can reduce facial pressure in the Prone Position. The Prone Head Alignment adjuster provides the ability to align the head with the body as needed after the patient reaches the Prone position.

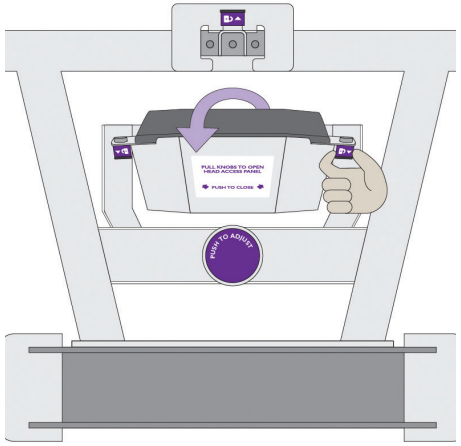
Prone Occipital Panel:

To Open:

- When in the Prone Position, pull back on both knobs on the back of the Prone Head Panel and lift upwards to rotate the panel open.

To Close:

- Press panel downward until you hear a click.
- Lift upward on the panel to ensure both knobs are fully secured.

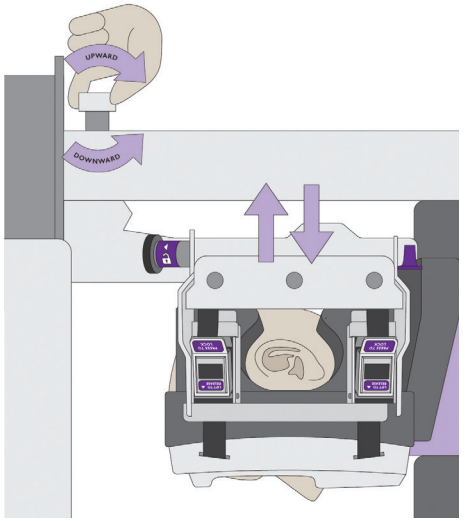


Prone Head Alignment Adjuster:

The Head Alignment Adjuster can be used to adjust the vertical position of the head support platform by up to 2 inches when the bed is in the Prone Position.

To Adjust Head Alignment:

- When in the Prone Position, rotate knob clockwise to lower the head support platform.
- When in the Prone Position, rotate knob counterclockwise to raise the head support platform.



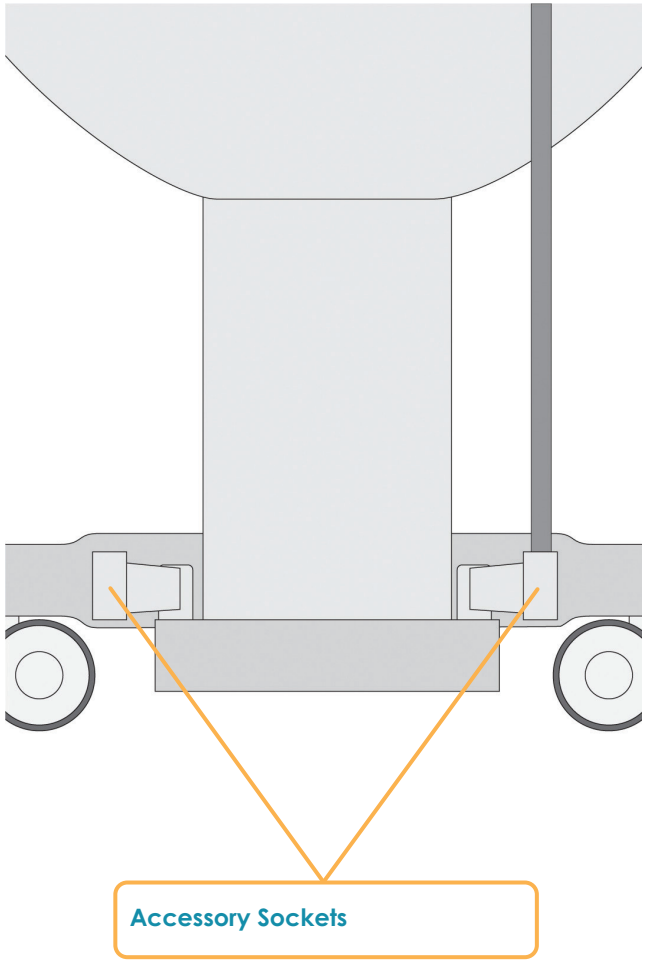
Accessory Sockets

Two 3/4-inch Accessory Sockets are provided at the head end of the product to secure accessories weighing up to 35lb (15.9kg). Each socket is mounted on a swivel which can be rotated inward for storage or outward for use. If IV poles are mounted in the Accessory Sockets, they shall not exceed 54 inches in height and 20 lb (9.07kg) including items on IV pole.

Accessory Sockets are on the weighing portion of the frame, so anything added or subtracted from the sockets will affect scale readings.

When placing accessories in the Accessory Sockets, always ensure that there is clearance for the patient surface and head pack to rotate without interference.

Do not use accessories mounted in the Accessory Sockets to push or pull the product.



Side Support Panels

Side Support Panels are permanently mounted to both sides of the patient support surface and can be stowed under the patient support surface to allow for patient transfer. The Side Support Panels can be adjusted in and out to accommodate patients of varying widths and are adjustable in length and angle to accommodate patients of different heights and shapes.

To slide the Side Support Panels inward:

- Press the button located in the side of the patient frame and push inward on the Side Support Panel until the desired position is reached.
- Release the button.

To slide the Side Support Panels outward:

- Press the button located in the side of the patient frame and pull outward on the Side Support Panel until the desired position is reached.
- Release the button.

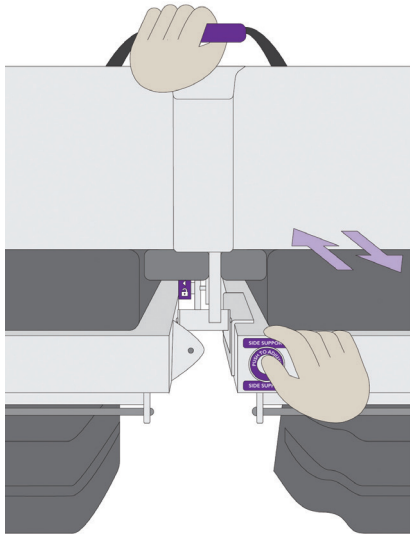
Ensure snug placement against patient's body to reduce friction and shearing during position change and rotation.

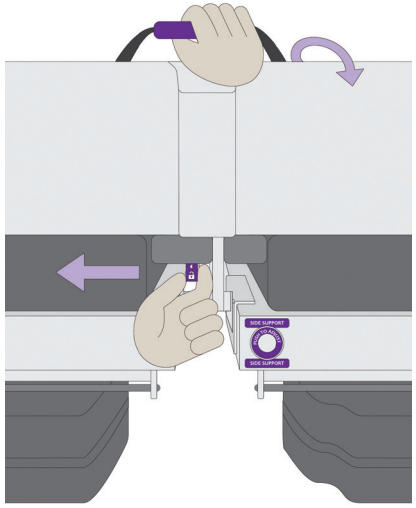
To stow the Side Support Panels:

- Slide the Side Support Panels outward to the edge of the patient surface.
- Pull knob below side support panel out with left hand and lift and rotate the Side Support Panel outward with right hand.

To raise the Side Support Panels:

- Hold handle in middle of side support and lift and rotate the Side Support Panel upward until you hear it lock into position on the patient support surface.





Side Support Panels
continued

To increase length of the Side Support Panels:

- Pull the end of the Side Support Panel toward head of surface until the desired position is reached.

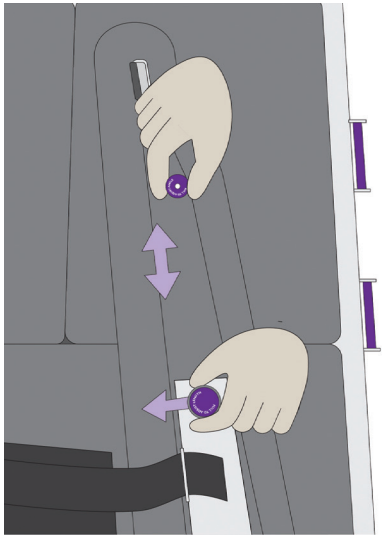
To decrease the length of the Side Support Panels:

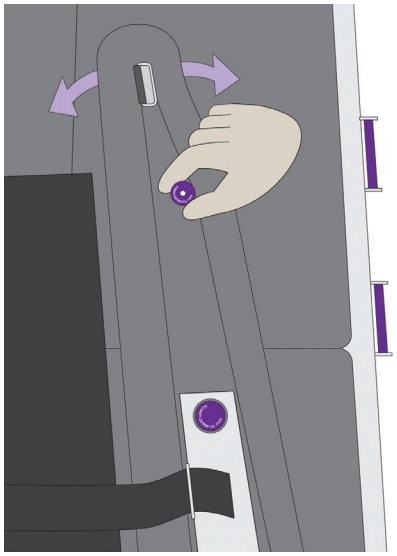
- Pull up on the knob located on top of the main body of the Side Support Panel.
- Push inward on the Side Support Panel extension until the desired position is reached.

Always ensure a minimum of 2 inches of clearance from patient axilla to Side Support Panel to reduce risk for nerve damage and undue pressure.

To adjust angle of the Side Support Panel extension:

- Pull up on the knob located on top of the Side Support Panel extension.
- Rotate the Side Support Panel extension until the desired position is reached. There are three positions:
    - **5° Out** use this position for patients with a wide chest where additional space is required.
    - **Neutral** use this position for patients with a chest that is in line with their abdomen.
    - **5° In** use this position for patients with a narrow chest where less space is required.



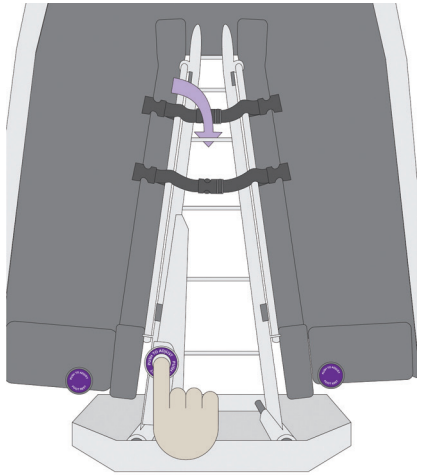


Inner Leg Support

The Inner Leg Support is permanently mounted to the center of the patient support surface and can be adjusted vertically and locked into position once the desired position is reached. When fully lowered, the Inner Leg Support rests flush with the top of the surface to allow for patient transfer.

To adjust the Inner Leg Support down:

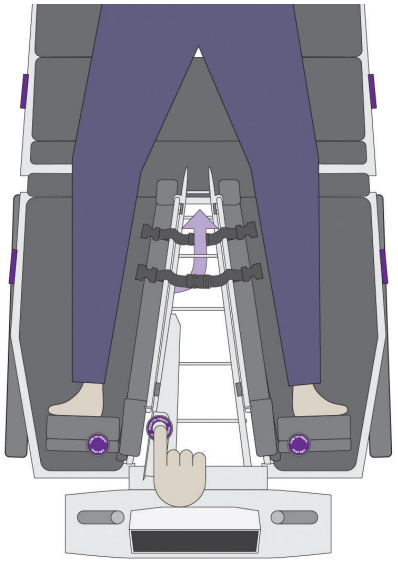
- Press down on the button located on top of the Inner Leg Support.
- Push downward until the desired position is reached



To adjust the Inner Leg Support up:

- Press down on the button located on top of the Inner Leg Support.
- Pull upward until the desired position is reached.

Always ensure Inner Leg Support is raised before rotating the patient.



The Inner Leg Support has two buckles which may be used to secure patient lines and tubes during rotation.

To secure lines and tubes in the Inner Leg Support:

- Buckle both Inner Leg Securement Straps.

Always monitor lines and tubes through one full rotation cycle to ensure they do not get pulled or caught during rotation.
WARNING: Do not route critical lines or tubes outside of the top or bottom hoop to reduce risk for dislodgement.

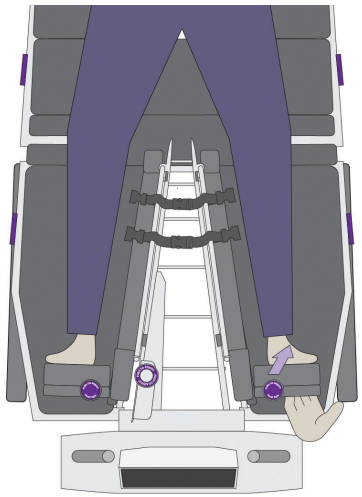
Foot Rests

The Foot Rests are permanently mounted to both sides of the patient support surface and are adjustable utilizing a ratcheting lock mechanism so they can be easily repositioned and lock in place once the desired position is reached. The Foot Rest will adjust to support patients ranging from 4'6" to 6'6".

To adjust the Foot Rest inward:

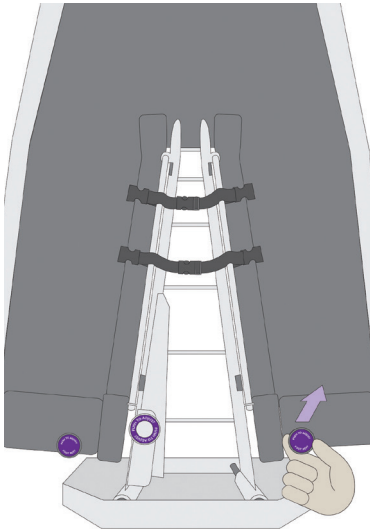
- Place your hand on the back side of the foot pack and push inward until the desired position is reached.

Do not secure the Foot Rest too tightly against the feet, causing undue pressure and risk for hyperextension of leg.



To adjust the Foot Rest outward:

- Pull up on the knob located on top of the Foot Pack.
- Place your hand on the inside of the Foot Pack and push outward until the desired position is reached.

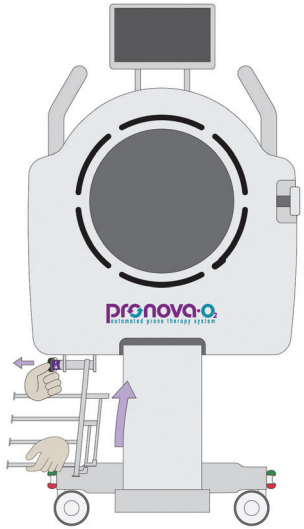


Accessory Rack

The Accessory Rack is located at the foot end of the surface and is delivered in the stowed position. The safe working load for this rack is 30 lb, 5 pounds per arm (13.6 kg).

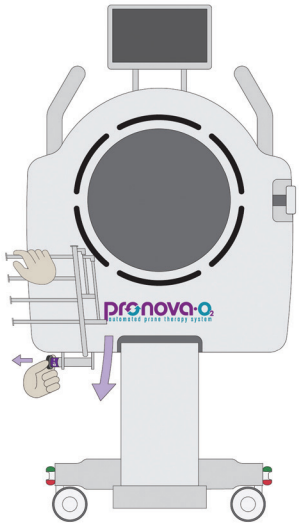
Engage Accessory Rack

- Pull black knob located under foot opening to release system.
- Lift system upward to lock in place.
- If required, pull two additional arms outward for additional storage for critical lines.



Disengage Accessory Rack

- If additional rungs are lowered, rotate them upward until they clip into the locked position.
- Pull black knob located under foot opening to release system.
- Lower system downward to stow in place.



Always monitor lines and tubes through one full rotation cycle to ensure they do not get pulled or caught during rotation.

Always ensure there is enough slack in lines before placing through foot opening. Add line extension as needed.

Do not stow any lines outside of the head or foot opening to reduce risk for dislodgement.

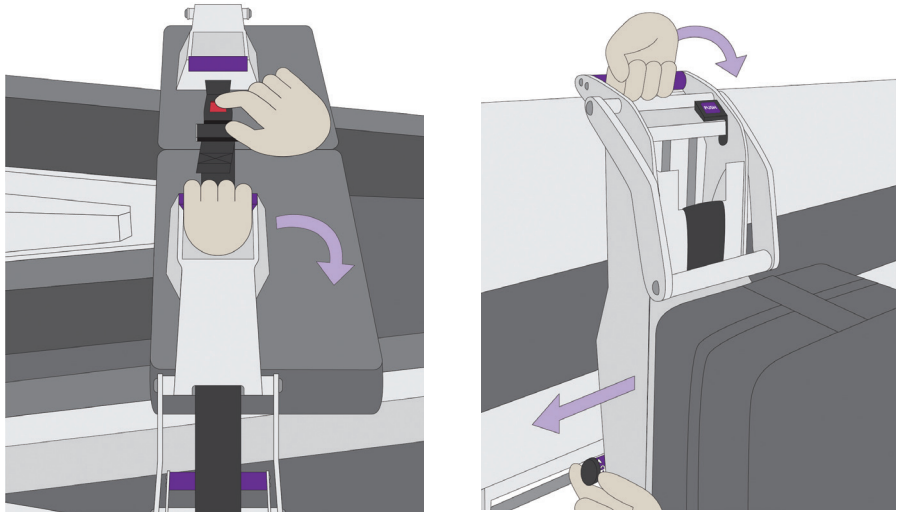
Accessory Rack is on the weighing portion of the frame, so anything added or subtracted from it will affect scale readings.

Prone Support Surface and Buckles

There are three Prone Support Surface sections and buckles permanently mounted on each side the product. Each Prone Support Surface can be stowed under the patient surface to allow for patient transfer and can be adjusted laterally to accommodate patients of different heights and shapes when in the secured position. The Prone Support Surface Sections on the patient left side of the product contain the male side of a buckle and a quick release safety mechanism. The Side Pack Arms on the patient right side of the product contain the female side of a buckle.

To stow each Prone Support Surface:

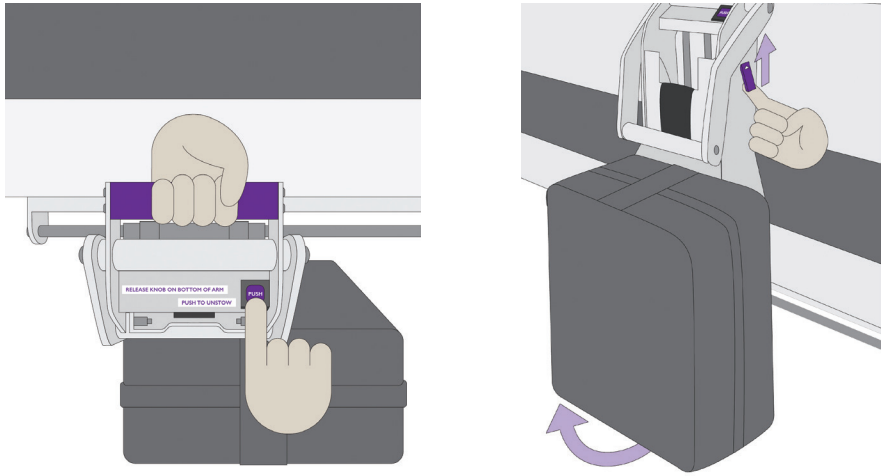
- Unbuckle the buckles on the Prone Surface Support.
- Fold the Prone Support Surface back onto the lower Side Pack Arm. Arms should lock into each other.
- With right hand, grab the purple handle on top of Side Pack Arm.
- Pull the black knob located on the left side of the Prone Support Arm, just below the frame, to allow the Side Pack Arm to release.
- Rotate the arm downward and then slide inward until it is stowed completely under the surface.



Stow

To unstow each Prone Support Surface:

- Press the lever on the front face of the Side Pack Arm.
- Pull outward on the purple handle and slide it fully outward (like a drawer).
- Once fully slid out, pull upwards towards the patient frame until you hear a click to lock the Side Pack Arm in place against the frame.
- Pull purple lever on right side of each Prone support to disengage Prone pack padding and rotate the padding in place over patient's body.
- Buckle each Prone pack with the opposite side, considering landmarks for each area.



Unstow

Prone Support Surface and Buckles
continued

Chest Prone Support

Place surface in alignment with top of shoulders, usually the highest possible position for this Surface Support.

Avoid compression of Endotracheal Tube with placement of Chest Prone Support.

Pelvic Prone Support

Place surface over pelvic bone, typically over the pelvic pad. Avoid compression of the abdomen.

Thigh Prone Support

This Surface is placed depending on patient height, to avoid direct compression over knees. If possible, place over the thigh. It is also possible to be placed over the shins.

Line Retention Straps

Line retention straps are located on the Inner Leg Support to secure lines and tubes routed through the foot opening of the device. Buckle Line Retention Straps after routing lines and tubes to prevent them from dangling during Prone Position.

Always monitor lines and tubes through one full rotation cycle to ensure they do not get pulled or caught during rotation.

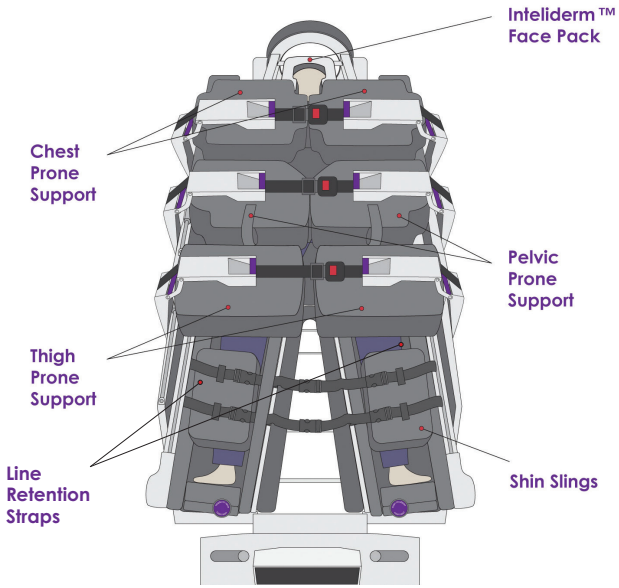
Always ensure there is enough slack in lines before placing through foot opening. Add line extension as needed.

Do not stow any lines outside of the head or foot opening to reduce risk for dislodgement.

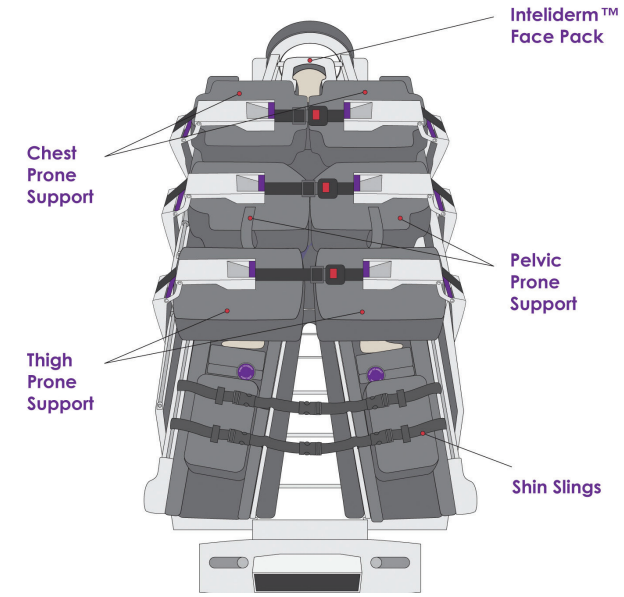
Shin Slings

This surface is placed depending on patient height, either over the shins if the Thigh Prone Support is over the thighs, or below the Foot Rest if the Thigh Prone Support rests over the shins. This surface is attached the Side Supports and does not have a sensor.

Proper Prone Support Placement with Shin Slings (tall patients)



Proper Prone Support Placement without Shin Slings (shorter patients)

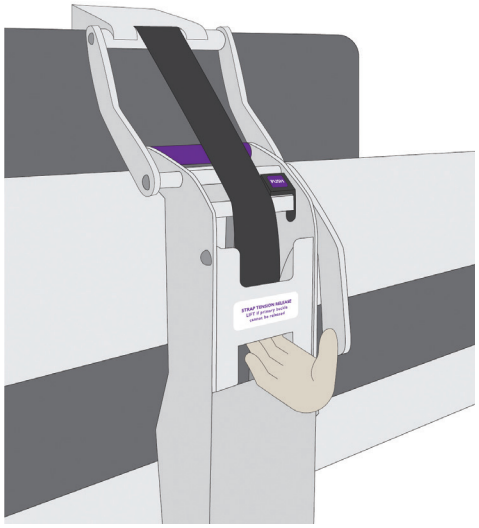


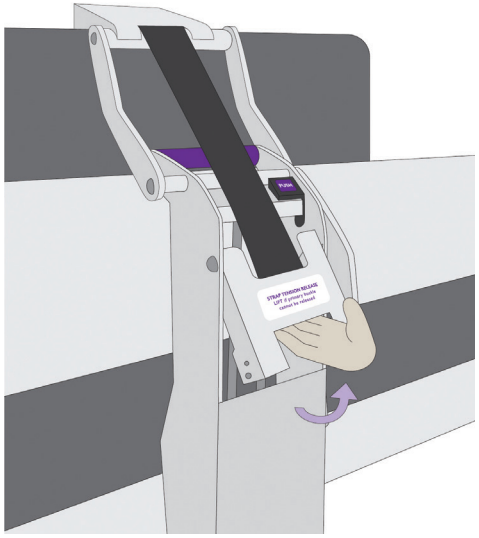
Strap Tension Release

If required, an emergency strap tension release is available on the patient left Side Pack Arms to allow for reduction of tension on straps to release buckles. If unable to depress and release buckles in the Supine Position, follow the below instructions:

To Engage Strap Tension Release:

- On the outside of arm of each patient left Side Pack Arm, a lever is located on the top of the arm.
- Lift this lever to release tension on the buckle that cannot be released.
- Once buckle is released, re-engage the emergency buckle release lever by pressing it downward to engage into place.





Prone Panels

There are five separate panels that can be opened in the Prone Position to assess the patient and relieve pressure. All panels are monitored with sensors to ensure securement before automated rotation can begin.

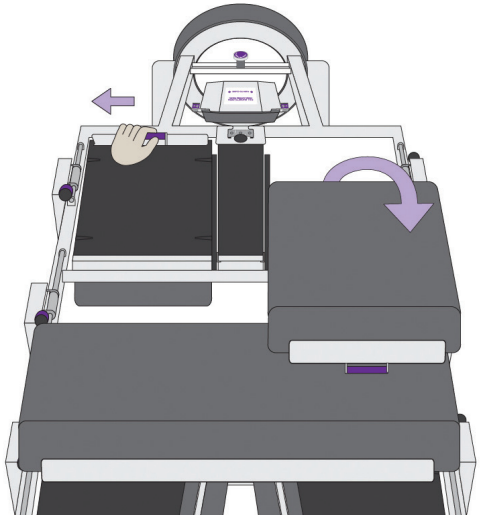
To Open a Prone Panel:

- Slide the purple handle in the direction indicated.
- Lift upward and rotate the panel open.

To Close a Prone Panel:

- Grab the purple handle and rotate the panel towards the patient frame.
- Push downward to ensure that the latch is fully secured.

The Center Center Chest Panel can be temporarily opened to allow for further access to the patient or for placement of equipment, such as X-ray cassettes. The center panel only partially opens.



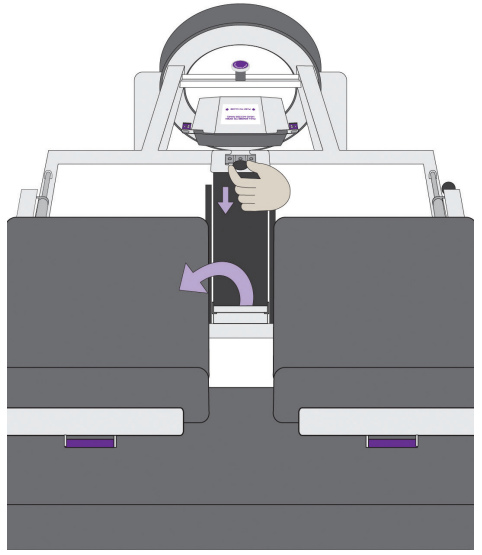
To Open the Center Center Chest Panel:

- Pull the knob on the center Center Chest Panel.
- Lift upward and rotate the panel open.

To Close Center Center Chest Panel:

- Push downward to ensure that the latch is fully secured.

Center Center Chest Panel does not have a sensor indicating securement prior to rotation into the Supine Position. Ensure Center Center Chest Panel is closed and locked prior to Supine rotation.

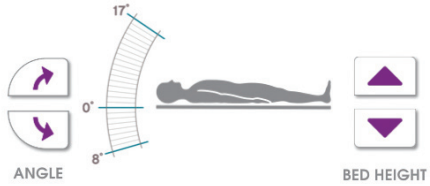


Patient Surface Adjustment

To adjust the surface height of the device, there are three options. The maximum degree of Reverse Trendelenburg is 16°, the maximum degree of Trendelenburg is -8°. The ***lowest*** *surface height is 33.5 inches and can be raised to 45.5 inches.*

User Interface:

- Press home at top of screen.
- The surface adjustment is located on the right side of the screen.
- Press and hold the arrows to adjust to desired position.



Hand Control:

- Locate Hand Control at head end of device.
- Press and hold the arrows to adjust to desired position.

Manual Switches:

The manual switches are available to lower the surface of Pronova-O_2™ in the event that the Hand Control or User Interface are not available. The switches are located on the head end of the bed on the caster frame, with designated labels for functions of each switch.

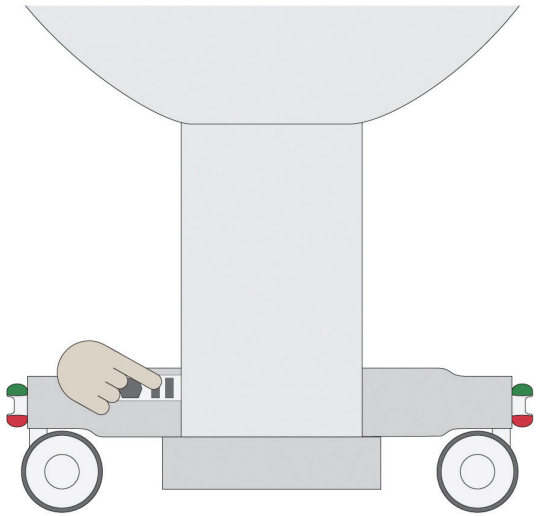
Monitor all critical lines and tubes during surface position change.

System Reset Switch

A system reset switch is available to reset the device in the event that the system and/or User Interface becomes unresponsive. The reset switch is located on the caster frame just inside the head lift actuator.

EMR Connection

An EMR connection port is provided to send device information to Electronic Medical Record systems. This DB-9 connection port should only be connected to approved devices providing isolation (IEC60601-1, IEC62360-1, IEC60950-1). To facilitate communication with a particular device or EMR system, contact Turn Medical.



Do not touch EMR port/connections and patient at the same time.

Troubleshooting

Symptom	Potential Cause	Potential Resolution
Device will not provide Prone Therapy or Supine Therapy	Device is not plugged into AC mains power. Prone Therapy, Supine Therapy, and InteliDerm™ Microclimate functions are disabled when the device is operating on battery power.	Plug device into AC mains power outlet.
Device will not rotate, device stall occurs.	Manual CPR lever is engaged in the outward position.	Ensure that the Manual CPR lever is rotated fully inward.
	Patient weight may not be centered on the patient surface.	Use the Manual CPR lever to place the patient at 0° Supine. Ensure that the patient is centered on the patient surface and that the side panels are tight against the patient.
	Device may be stuck on an external object.	Ensure that there are no external objects (furniture, other devices, etc.) in the rotation path of the patient frame.
Device will not power on.	Product is not plugged into a powered AC mains power outlet.	Plug device into AC mains power outlet. Device will automatically power on once it is plugged into AC mains power.
Scale displays unrealistic weight reading	Scale was not properly zeroed before placing the patient on the device.	Use the Manual Adjust function to set the displayed weight to the last known patient weight.
Stuck button on Hand Control error	One or more buttons on the Hand Control have been depressed for more than 70 seconds.	Discontinue pressing all buttons on the hand control. If not intentionally pressing a button, look for situations where a button on the hand control may inadvertently be pressed, such as being wedged between cushions or having another object placed on top of it.
Product will not move up/down or Trendelenburg/ Reverse-Trendelenburg	User Interface may be frozen.	Use the Hand Control and/or emergency column down switches to ensure the patient is in a safe position. Press the reset button located on the head end of the caster frame to reset the device.
User Interface not responsive	User Interface may be frozen.	Use the Hand Control and/or emergency column down switches to ensure the patient is in a safe position. Press the reset button located on the head end of the caster frame to reset the device.
Lock Pin is difficult to insert or pull out	Rotation angle calibration may be out of calibration.	First, lift up slightly on patient frame to loosen the Lock Pin. If unable to resolve, contact Turn Medical at 1.855.ASK.TURN (1-855-275-8876).

Expected Service Life

The expected service life of this product is ten years when preventative maintenance is performed as required by a qualified technician. Certain components may have a shorter life expectancy and have been designed to be replaceable to ensure that the product performs as intended for the duration of its expected service life.

Upon request, Turn Medical will make available circuit diagrams, component part lists, descriptions, calibration instructions, or other information that will assist qualified technicians to repair the device. Do not modify the device or replace components without contacting Turn Medical for the approriate components and replacement instructions.

Mattress Replacement

The mattress sections on the Prone Support Surfaces, Supine Support Surfaces, Side Supports, Foot Rests, and Head Support are unique to the Pronova-O2™ device and can only to be replaced with patient support surfaces from Turn Medical. Replacement with incompatible mattresses can create hazards.

Battery Replacement

Batteries should be replaced every two years or sooner if battery life is significantly degraded. To test battery capacity, charge batteries for 24 hours, unplug the bed and let it sit idle. The batteries should support the device without a low battery alarm for at least three hours. If a low battery alarm occurs in less than three hours, batteries should be replaced.

Batteries should also be replaced if Low Battery or Battery Disconnected errors occur when the device is plugged in for at least 12 hours.

Batteries should only be replaced by a qualified technician when the device is not in use.

Fuse Replacement

The device should be shut down and remain unplugged from AC mains prior to any fuse replacement. Fuses should be replaced according to the table below:

Symptom	Potential Cause
AC Mains Inlet (both fuses)	250VAC, 10A, fast acting, cartridge fuse, UL recognized
In-line fuse in cables 100607, 100612 (near power supply	32VDC, 25A, ATO blade type fuse, UL listed
In-line fuse in cable 100609 (near batteries)	32VDC, 25A, ATO blade type fuse, UL listed
Fuses on FCUIO board 100574 (in caster frame) (values labeled on board)	32VDC, 20A, ATO blade type fuse, UL listed 32VDC, 7.5A, ATO blade type fuse, UL listed
Fuses on RMCUIO board 100343 (in foot end pillar) (values labeled on board)	32VDC, 15A, ATO blade type fuse, UL listed 65V, 1A, TE5 fast acting fuse, UL recognized

Fuses should only be replaced by a qualified technician when the device is not in use.

Preventative Maintenance

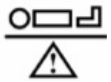
In order to ensure performance continues as expected, the product should be inspected periodically. Functional checks should be conducted regularly according to the table below. If any issues are found during these inspections, contact Turn Medical for guidance on proper repair procedures.

All fabric covers are intact with no rips or cuts.	All Prone straps are not frayed or damaged.	Inner leg support moves up and down smoothly and locks in position when button is released.
All pack arms rotate smoothly and lock in the up and down positions.	All buckles are undamaged and lock securely.	Side panels move in and out smoothly and lock in position when buttons are released.
Manual CPR release allows the patient frame to rotate smoothly in both directions.	Brake and directional lock functions work on all casters and from all pedals.	Head support components move freely and are undamaged.

A more comprehensive list of checks should be performed annually by qualified technicians who are familiar with the product. Product should be removed from service and should not have a patient on it while preventative maintenance checks are performed. The following is a minimum list of what shall be checked annually:

All welds are intact and free of cracking.	All Prone straps are not frayed or damaged.	Drive belt is intact and does not show excessive signs of wear.
Paint is intact and no rust or corrosion is present.	All buckles are undamaged and lock securely.	InteliDerm™ pumps turn on when commanded and air is felt coming out of the connection ports.
All hardware is in place and secure.	All fabric covers are intact with no rips or cuts.	All sensors are secure, undamaged, and respond to device movement appropriately.
All casters roll and swivel freely.	All labels are legible and fully adhered.	Manual CPR release allows the patient frame to rotate smoothly in both directions.
Brake and directional lock functions work on all casters and from all pedals.	User Interface is free of damage and responds to touch appropriately.	Lock Pin is easily inserted when patient surface is moved to 0° Supine.
Actuators move the device up and down smoothly and quietly.	Hand Control is free of damage and responds to button presses appropriately.	Power Cord is not frayed or damaged.
Actuators move the device into Trendelenburg and reverse Trendelenburg smoothly and quietly.	All electrical connections (including ground cables) are present and secure.	Batteries are within acceptable date range and hold a full charge.
All plastic covers are intact and free of cracking or sharp edges.	Inner leg support moves up and down smoothly and locks in position when button is released.	Ground Impedance is within acceptable limits.
Patient surface rotates smoothly and quietly in both directions.	Side panels move in and out smoothly and lock in position when buttons are released.	Scale is within acceptable limits.
Head support components move freely and are undamaged.	All pack arms rotate smoothly and lock in the up and down positions.	

Reference Symbols

	General Warning		UL Classification Mark
	Operation Information		Cardiopulmonary Resuscitation
	Consult Instructions for Use		Storage Temperature Limits
	Manufacturer		Settings
	Date of Manufacture		Unit provides terminal for connection of a potential equalization conductor. The potential equalization conductor provides direct connection between the unit and potential equalization busbar of the electrical installation.
	Safe Working Load		Type B Applied Part
	Max Patient Weight		Made in USA
	Refer to Instruction Manual/Booklet		Keep Dry
	Single Patient Use		Do Not Use if Damaged
	Non Sterile		

Specifications

General Specifications	
Safe Working Load - includes patient weight and all accessories	500 lb (226.8 kg)
Safe Working Load - Accessory Sockets (head end)	35 lb (15.9 kg) each with IV poles, do not exceed 54 inches in height and 20 lb (9.1 kg).
Safe Working Load - Accessory Rack (foot end)	Per Arm: 5 lb (2.3 kg) Total: 30 lb (13.6 kg)
Minimum Patient Weight	88 lb (40 kg)
Maximum Patient Weight	400 lb (181.4 kg)
Minimum Patient Height	54 in (137 cm)
Maximum Patient Height	78 in (198 cm)
Audible Acoustic Energy	79dBA with powered rotation, lift actuators, and both Microclimate pumps on

Environmental Specifications	
Operating Temperature	50°F to 95°F (10°C to 35°C)
Operating Relative Humidity	30% to 75% non-condensing
Transport Temperature	4°F to 140°F (-15.5°C to 60°C)
Transport Relative Humidity	15% to 85% non-condensing

Electrical Specifications	
Power Input	6A max at 120 VAC, 60Hz
Duty Cycle (Lift Actuators)	10% (2 minutes on, 18 minutes off)
Duty Cycle (Rotation Motor)	Continuous
Safety Standards	ANSI/AAMI ES 60601-1 (2005) + AMD (2012) IEC 60601-2-52 Ed 1.1 (2015-03)
Equipment Classification per UL60601-1	Class 1, Internally Powered Equipment
Degree of Electrical Shock Protection	Type B Applied Part
EMC	Complies with IEC60601-1-2:2014
Fluid Ingress Protection	IPX4
Battery Information	Two 12V, 9Ah sealed lead acid batteries connected in series

Mechanical Specifications - subject to manufacturing tolerances	
Product Weight (approximate)	800 lbs (363 kg)
Product Width (arms up)	44 7/8 in (114 cm)
Product Width (arms down)	41 7/8 in (106.4 cm)
Product Length (w/ Accessory Rack stowed)	93 15/16 in (238.6 cm)
Product Length (w/ Accessory Rack raised)	97 1/4 in (247 cm)
Height to Top of Supine Mattress (highest position)	45.5 in (115.6 cm)
Height to Top of Supine Mattress (lowest position)	33.5 in (85.1 cm)
Maximum Trendelenburg Angle	8°
Maximum Reverse-Trendelenburg Angle	16°
Caster Size (Diameter)	6 in (152 mm)
Underbed Clearance	6.1 in (155 mm)
Scale System Accuracy	± 2% for weight greater than 100 lb ± 2 lb for weight less than 100 lb

Applied Parts	
Supine Mattress Sections	Side Supports
Head Support Cushions	Inner Leg Supports
Prone Support Surfaces	Foot Rest Cushions
Proximity Sensors	Shin Slings
InteliDerm™ Face Pack	Abdominal Sling
InteliDerm™ Chest Wedge	Hip Positioning Pads
Detachable Parts	
InteliDerm™ Face Pack	Abdominal Sling
InteliDerm™ Chest Wedge	Hip Positioning Pads
Critical Line Management System	

The product information label containing the serial number and the power specifications for the device is labeled on the head end of the patient frame, above where the AC mains power inlet is located.

California Proposition 65 Warning –

This product contains chemicals known to the State of California to cause cancer and birth defects or other reproductive harm.
For more information: www.P65Warnings.ca.gov

Disposal

At the end of their usable service life, dispose of components and the Pronova-O_2™ device in accordance with local requirements.

Electromagnetic Emissions Guidance

Product Environment

The Pronova-O₂™ is intended for use in the electromagnetic environment specified in the table below. The customer or the user of the Pronova-O₂™ should assure that it is used in such an environment.

Essential Performance

Essential performance is identified as the bed being able to rotate. For the purposes of electromagnetic immunity testing, essential performance was confirmed by either utilizing rotation therapy or the CPR function, as appropriate. "Being able to rotate" refers to the physical ability to rotate the bed under mains power, battery power, or no power. If, during a normal rotation operation (Rest at Angle, Rotation Therapy, or CPR), the bed stops rotating due to an electromagnetic disturbance, attempt the operation again. In case of emergency, pull the Manual CPR Lever to rotate the bed manually.

Replaceable Accessories That Affect EMC Compliance of Pronova-O₂™

Hand Control, Turn Medical Part Number P200286

Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Portable RF Communications Equipment Compatibility

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Pronova-O₂™, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Requirements for ME Equipment Classified Class A According to CISPR 11

NOTE: The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Manufacturer's declaration – electromagnetic emission and immunity		
Emissions		
Test	**Compliance**	**Test Level**
Conducted Emissions CISPR 11:2009 +A1:2010	Group 1, Class A	Low Voltage AC Mains 120 VAC, 60 Hz
Radiated Emissions CISPR 11:2009 +A1:2010	Group 1, Class A	Enclosure Port 30 MHz to 1 GHz 120 VAC, 60 Hz
Harmonic emissions IEC 61000-3-2:2014	Class A	AC Power Harmonic Emissions 120 VAC, 60 Hz
Voltage Flicker IEC 61000-3-3:2013	Not applicable	Voltage Flicker 120 VAC, 60 Hz
Immunity		
Electrostatic Discharge IEC 61000-4-2:2008	Basic Safety & Essential Performance	Air: ±2 kV, ±4 kV, ±8 kV, ±15 kV Contact: ±8 kV
Radiated RF Electromagnetic Field IEC 61000-4-3:2006 +A1:2007 +A2:2010	Basic Safety & Essential Performance	3 V/m: (80 MHz to 2.7 GHz) Wireless Frequencies
Electrical Fast Transient/Burst IEC 61000-4-4:2012	Basic Safety & Essential Performance	AC Mains: ±2 kV
Surge Immunity IEC 61000-4-5:2005	Basic Safety & Essential Performance	Line-to-Ground: ±2 kV Line-to-Line: ±1 kV
Conducted Disturbances Induced by RF Fields IEC 61000-4-6:2013	Basic Safety & Essential Performance	AC: 3 Vrms /6 Vrms
Power Frequency Magnetic Field IEC 61000-4-8:2009	Basic Safety & Essential Performance	30 A/m
Voltage Dips, Short Interruptions and Voltage Variations IEC 61000-4-11:2004	Basic Safety & Essential Performance	Dips: 100% for 0.5 and 1 Cycles, 30% for 30 Cycles
	Basic Safety & Essential Performance	Interruptions: 100% for 300 Cycles

EMC Deviations From Standard and Allowances Used

None

Instructions For Maintaining Basic Safety And Essential Performance With Regard To Electromagnetic Disturbances For The Expected Service Life

The Pronova-O_2™ device should not be used adjacent to or stacked with other electrical equipment. If adjacent or stacked use is necessary, observe Pronova-O_2™ and the other electrical equipment to make sure they operate as intended.

Make sure Pronova-O_2™ operates correctly when it is used near other electronic devices. Portable and mobile radio frequency (RF) communications equipment can affect electrical equipment.

Instructions for Use

Contact Information

For questions regarding the Pronova-O₂™ device, training, maintenance, single patient use items, service offerings or any additional information, please contact Turn Medical.

Website: www.turnmedical.com

Phone: 1.855.ASK.TURN (1-855-275-8876)

Email: info@turnmedical.com

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