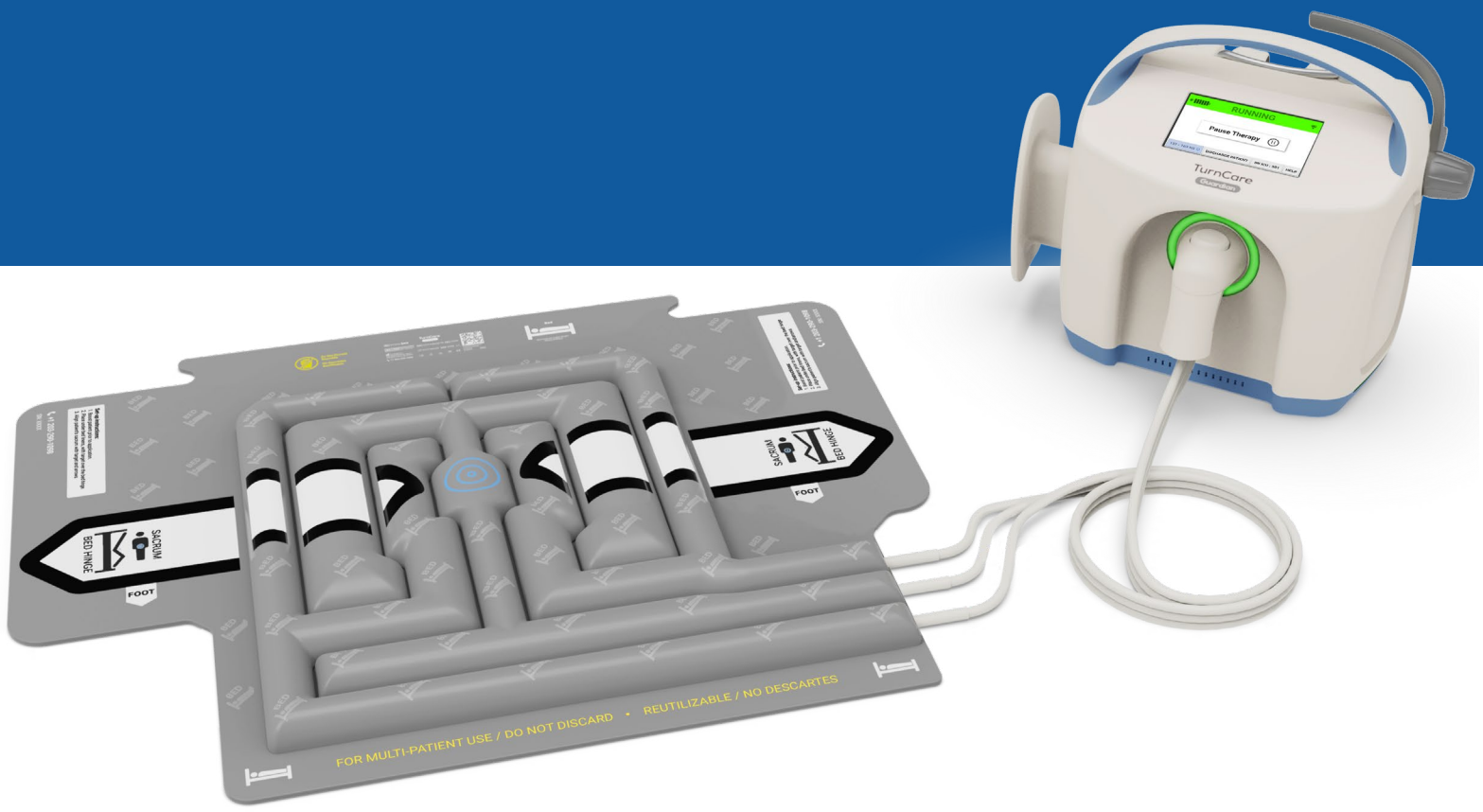
TurnCare Guardian



Guardian System 2.5 User Manual

Version 03

2023-06-16

SAFETY INFORMATION

As with any medical device, failure to carefully read and follow all instructions and safety information may lead to improper product performance and patient safety concerns. Furthermore, the information contained in this manual is not a substitute for clinical judgment. These guidelines are not intended as a guarantee of results, outcome, or performance. A healthcare professional should evaluate each patient to ensure use of the Guardian System 2.5 is appropriate. Any serious incident should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Indications For Use

- For use in the clinical setting
- For use with mobility-impaired patients
- For use with patients at risk for developing a sacral, ischial, or trochanter pressure injury
- For use with patients at risk for developing a pressure injury on the anterior superior iliac spine in prone position
- For use with patients who have a sacral, ischial, or trochanter pressure injury of any stage

Contraindications For Use

- Not for use with patients who have an unstable spinal or pelvic injury
- Not for use with any bed that limits proper enhancer application and attachment, including but not limited to air fluidized beds
- Not for use with patients exceeding 295 kg or 650 lbs

Clinical Considerations

A healthcare professional should evaluate each patient to ensure that the decision to use the Guardian System 2.5 is appropriate. The Guardian System 2.5 is not intended to replace any current standard care measure. If the patient's condition changes, the overall treatment plan should be reviewed by the Provider and Interdisciplinary Team.

Perfusion enhancement has varying clinical implications in cases related to central hypotension. Clinical judgment is required specific to each patient scenario. In cases where there is central hypotension, there is limited ability to enhance peripheral perfusion.

It is important to remember there are many considerations in the shared decision-making process for each patient.

Use with caution with patients at risk of harming themselves or others. The equipment, including a power cord, connector tubing, and controller, may create a hazard for at-risk patients and their caregivers.

For patients with a recent surgical skin graft or musculocutaneous flap to the sacral, ischial, or trochanter areas, the patient should be evaluated for eligibility by the physician responsible for the procedure.

No parts of the Guardian System 2.5 are intended to be in direct contact with the patient. Enhancers are intended to be set up beneath the appropriate hospital linens and not to come in direct contact with the patient's skin.

Conventions

To avoid physical and material damage, this document identifies safety instructions into two danger levels:

ATTENTION

- Hazardous situation which can cause material damage or lead to minor or moderate injury

WARNING

- Hazardous situation which can cause a serious or fatal injury

Important Safety Information Below

WARNING

- A healthcare professional should evaluate each patient to ensure that use is appropriate.
- Do not use damaged equipment. If you believe a component may be damaged, please contact TurnCare.
- Do not operate with a damaged power cord or plug. If the power cord or plug is damaged, contact TurnCare.
- To avoid risk of electrical shock, this equipment must only be connected to a supply main with protective earth.
- Do not bring into the MRI room.
- Keep the Guardian System 2.5 Controller away from sources of liquid. Do not immerse in water.
- Do not use in the presence of uncontained flammable liquids or gases. Do not expose the system to open flames.
- Avoid spilling on the Guardian System 2.5 Controller. If a spill occurs, unplug the controller immediately and clean the controller with an absorbent cloth. Plugging the controller in when wet can create a hazard. If the Guardian System 2.5 Controller is not working properly, call TurnCare.
- During set up and use, ensure the power cord placement does not create a tripping hazard or become entangled in the bed frame.
- Do not attempt to transfer the patient out of bed with enhancer inflated. For patient safety, enhancer must be fully deflated prior to transfer.

ATTENTION

- The Guardian System 2.5 should be set up such that the power outlet used for the controller is accessible at all times.
- Use with caution with patients at risk of harming themselves or others. The equipment, including a power cord, connector tubing, and controller unit, may create a hazard for at-risk patients and their caregivers.
- For patients with a recent surgical skin graft or musculocutaneous flap to the sacral, ischial, or trochanter areas, the patient should be evaluated for eligibility by the physician responsible for the procedure.
- Electrical equipment may be hazardous if misused. There are no serviceable parts in the Guardian System 2.5. Contact TurnCare if you believe your controller is not functioning properly. Do not remove the controller protective housing and attempt to troubleshoot.
- When hanging the Guardian System 2.5 Controller on an IV pole, place the controller at the base of the pole to ensure stability.
- The Guardian System 2.5 is not intended for use in the home healthcare environment.

CONTENTS

INTRODUCTION

The TurnCare Guardian System 2.5 is a portable, therapeutic, multi-use patient support system designed to prevent sacral region vascular compromise. The Guardian System 2.5 protects patients in various positions across multiple surfaces, allowing care flexibility in both the bed and the chair.

The TurnCare Guardian System 2.5 is uniquely designed to prevent vascular compromise in the sacral region. Vascular compromise involves the collapse of blood vessels from the external application of pressure, resulting in degraded blood flow. Vascular compromise can result in ischemia and reperfusion injury, which can lead to subsequent negative local and systemic health implications. TurnCare's unique Vasotactic technology involves the intelligent application of non-repeating, anatomy-aware, weight-specific pressure gradient therapy. The benefits of the Guardian System 2.5 can include decreased adverse events, improved early mobility, and decreased pain and discomfort.

Guardian System 2.5

The Guardian System 2.5 consists of the following components:

- Guardian System 2.5, Controller (GS-2.5-C, GS-2.5-C-EU)
- Guardian System 2.5, Enhancer-Bed-76" integrated tube connector (GS-2.5-EN-BD-76)
- Guardian System 2.5, Enhancer-Seat-70" integrated tube connector (GS-2.5-EN-ST-70)
- Guardian System 2.5, Enhancer-Procedure Table-70" integrated tube connector (GS-2.5-EN-PT-70)

A tote bag (GS-TB) is also available to aid in storage and transport of enhancers.

ATTENTION

- Ensure that all components are clean and dry prior to use.
- If, for any reason, the Guardian System 2.5 needs to be disconnected from the power supply, unplug the power cord from the power outlet.

WARNING

- After set-up, ensure the connector is properly secured to prevent a tripping hazard.
- Ensure the connector tubing placement does not create an entrapment for the patient.
- Ensure the power cord and connector tubing placement does not create a tripping hazard or become entangled in the bedframe.
- The Guardian System 2.5 should not be brought into the MRI room.

Controller

The Guardian System 2.5 Controller contains a Graphical User Interface (GUI) display on top of the controller for user interaction. The controller includes mechanisms for securing the controller to beds, stretchers, and IV poles. It includes a carrying handle and an actuating handle, which engages the securing mechanism for hanging the controller on beds and stretchers.

The connection port is located on the front of the controller. The permanently attached power cord is connected to the side of the controller, along with a built-in cord wrap mechanism. Status lights are located along the lateral edges of the controller and around the connection port to indicate whether the system is in running, paused, or alert mode.

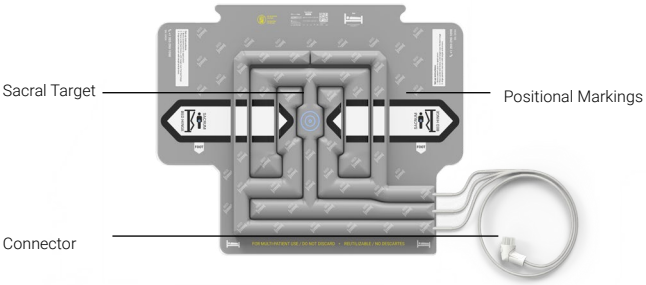
WARNING

- Do not insert objects into the fuse holder. Electrical shock may occur.

Enhancers

The Guardian System 2.5 Enhancer is an inflatable surface consisting of three, anatomy-specific air chambers, which are sequentially inflated and deflated to varying pressure levels by the Guardian System 2.5 Controller. The enhancer comes in versions for various support surfaces. All enhancers have a non-slip backing to promote proper placement on the underlying surface. All versions of the enhancer are for multi-patient use.

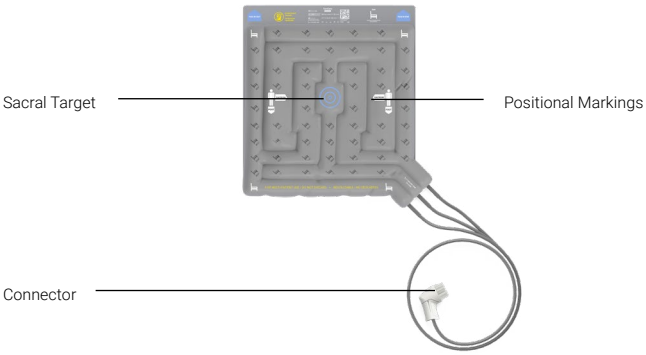
Bed Enhancer



*The image above does not represent the actual bed enhancer tubing configuration.

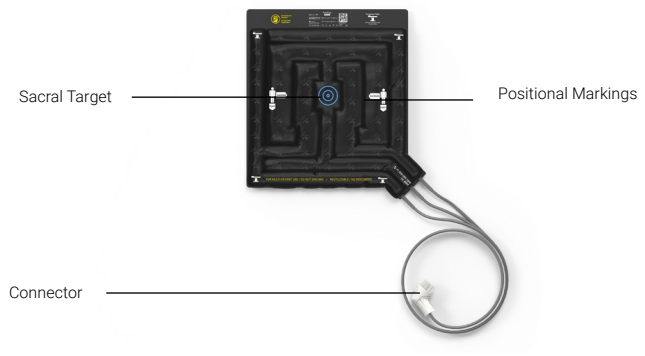
The bed enhancer consists of anatomy-specific air chambers. The bed enhancer is not intended for use on stretchers or procedure tables.

Seat Enhancer



The seat enhancer also consists of anatomy-specific air chambers in order to promote correct and safe application. The seat enhancer is typically utilized on recliners, but may also be used on other seating surfaces.

Procedure Table Enhancer



The procedure table enhancer also consists of anatomy-specific air chambers in order to promote correct and safe application to the procedure table.

Tote Bag

The Guardian System 2.5 comes equipped with a tote bag for storing and transporting the system components during patient use. The tote bag can be used to hold all components other than the controller. For safety reasons, the controller should be carried separately. Tote bags are for single patient use.

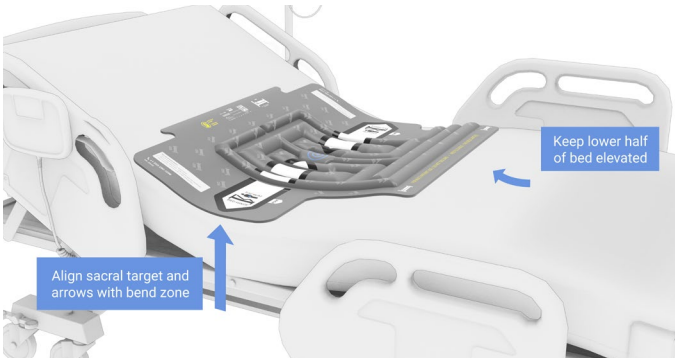
SETUP

Bed Enhancer Set-up with Patient in Bed

1. Prior to applying, ensure that the patient is not too low in the bed. Boost the patient to the appropriate position if needed.
2. To assist with correctly placing the enhancer, ensure that the patient icon on the enhancer is appropriately oriented in relation to the patient. Roll the bed enhancer up halfway.
3. With the patient in the sidelying position, place the enhancer beneath the fitted sheet and align the sacral target and arrow with the bend zone of the mattress, where the head of the bed meets the lower portion of the bed. Ensure that the enhancer is centered horizontally on the bed.
4. Position the patient to the opposite side and unroll the enhancer.
5. It is recommended to elevate the knees to promote proper positioning on the enhancer while the patient is in supine with the head of the bed elevated.

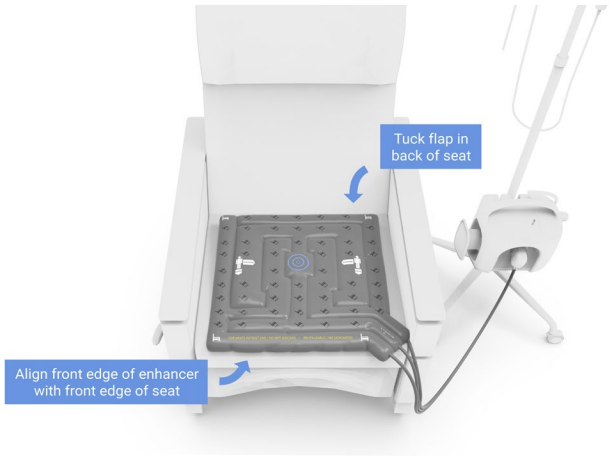
Bed Enhancer Set-up without Patient in Bed

1. To assist with correctly placing the enhancer, ensure that the patient icon is appropriately oriented in relation to the bed.
2. Place the enhancer underneath the bed linens, with the sacral target aligned with the bend zone of the mattress, where the head of the bed meets the lower portion of the bed.
3. Ensure that the enhancer is centered horizontally on the bed.



Seat Enhancer Set-up

1. To assist with correctly placing the enhancer, ensure that the patient icon is appropriately oriented.
2. Connector tubing should be oriented to the front of the seating surface.
3. Center the seat enhancer on the seating surface. Tuck the rear flap into the back of the seat, so that the front edge of the enhancer aligns with the front edge of the seat.
4. Place hospital linens over the enhancer prior to seating the patient.



Procedure Table Enhancer Set-up

1. To assist with correctly placing the enhancer, ensure that the patient icon is appropriately oriented in relation to the procedure table.
2. Layer the procedure table according to facility policy and procedure, placing the enhancer as close as possible to the patient and below the sheet.
3. Position the enhancer so that the center target is aligned with where the patient's sacrum will be.

Controller Set-up

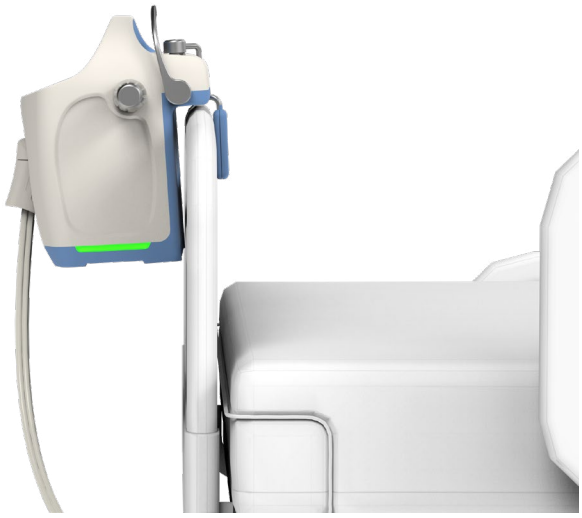
WARNING

- To avoid risk of electrical shock, this equipment must only be connected to a supply main with protective earth.
- The controller should not be operated if the power cord is damaged.
- Ensure the power cord placement does not create a tripping hazard or become entangled in the bedframe.

ATTENTION

- To prevent back injury, utilize proper body mechanics when lifting and carrying the controller. Avoid placing the controller on the floor, as this creates a tripping hazard for patients, families, and staff members. If securing the controller to an IV pole, be sure to hang the controller at the base of the pole in order to ensure stability.
- Electrical equipment may be hazardous if misused. There are no serviceable parts in the Guardian System 2.5. Contact TurnCare if you believe your controller is not functioning properly. Do not remove the controller protective housing and attempt to troubleshoot.

Controller Set-up on Footboard or Siderail



1. Engage the actuating handle in order to extend the securing mechanism.
2. Align the back of the controller with the footboard or siderail, ensuring that the controller support shelf located on the back of the controller rests on the top surface of the footboard or siderail.
3. Release the handle to secure the controller.
4. Plug the controller power cord into a properly grounded hospital grade receptacle.

Controller Set-up on IV Pole

1. Locate the knob on the left side of the controller.
2. Rotate the knob fully counter-clockwise to ensure that the clamp mechanism is open.
3. Align the groove on the back of the controller with the IV pole at the base of the pole.
4. Turn the knob fully clockwise to secure it.
5. Plug the controller power cord into a properly grounded hospital grade receptacle.

CONTROLLER OPERATION

The Guardian System 2.5 Controller must be plugged in to AC power to turn on. Touching the screen when AC power is disconnected will not turn the Controller on. The screen will become active after plugging into power.

Set-up Mode

1. Prior to patient use, the set-up screen will display. (Fig. 1)
2. Product demonstration videos can be accessed by pressing Help on the set up screen.

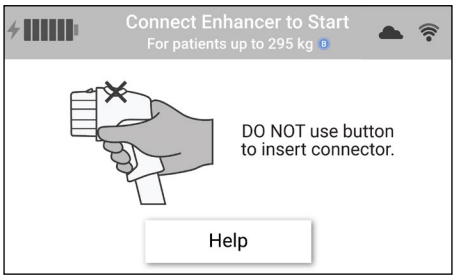


Figure 1. Set-up screen

Initiating Therapy

1. Connect an enhancer to the controller. Do not use the button to insert the connector. Push in until there is a click.
2. Enter the patient's Identifier (ID) and press Next. (Fig. 2) The patient ID refers to the patient's numeric or alphanumeric identifier associated with the patient-specific hospital encounter for that admission (i.e. CSN or FIN). This is not the patient's MRN number.
3. Re-enter the patient's ID on the second screen. (Fig. 3) Press Continue. Both entries must match to proceed.
4. Select the hospital unit and press Continue. (Fig. 4)
5. Enter the patient's room number (Fig. 5)
6. Select the patient's weight range in kilograms. (Fig. 6 & 7)
7. Therapy will begin.

Figure 2. Patient ID entry screen

Figure 3. Patient ID re-entry screen

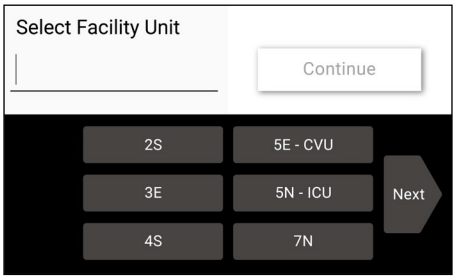


Figure 4. Hospital unit selection screen

Figure 5. Patient room number entry screen

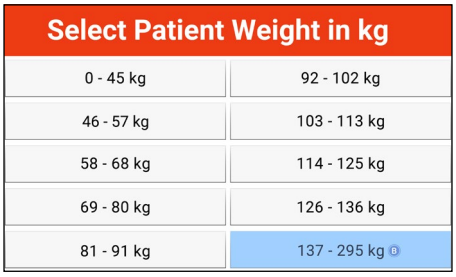


Figure 6. Patient weight screen

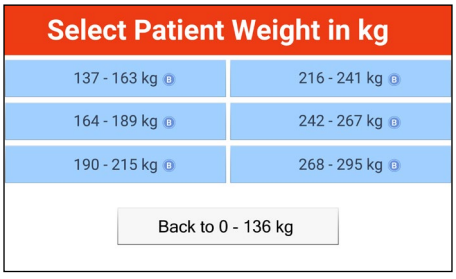


Figure 7. Patient weight screen - BariMode ranges

BariMode

The Guardian System 2.5 includes a BariMode feature for patients over 137 kg - 295 kg or 300 - 650 lbs, which is enabled when a BariMode weight range is selected (Fig. 7). BariMode ensures optimized therapeutic and comfort benefits for patients in these weight ranges.

User Screen Functionality

When the Guardian System 2.5 is in use with the patient, the user screen will dim and become inactive three (3) minutes after the last user interaction. Press anywhere on the screen to return to full brightness.

Running Mode

When the controller is operating, a screen will display with a green status bar to indicate that the controller is running. (Fig. 8 & 9)

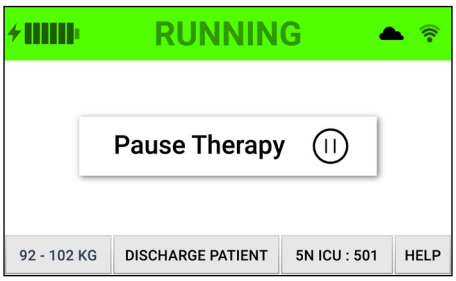


Figure 8. Running screen (standard)

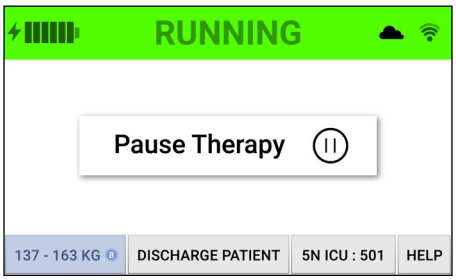


Figure 9. Running screen (BariMode)

Pausing Therapy: Bed & Seat Use

1. Therapy can be stopped by pressing “Pause” on the running screen. (Fig. 8 & 9)
2. A Paused screen will display with a yellow status bar and remaining pause time displayed on the right side of the screen. (Fig. 10 & 11)
3. Pause time may be extended if necessary for off-unit procedures by pressing “Off Unit” to display additional pause times.
4. Select the desired timeframe based on when the patient is anticipated to return from the off-unit procedure. (Fig. 12)
5. The Paused - Patient Off Unit screen will display the new remaining pause time and indicate that the patient is off unit for an extended period of time. (Fig. 13 & 14)
6. The controller operation will automatically resume after the selected timeframe or press “Resume” to re-start therapy at any time.

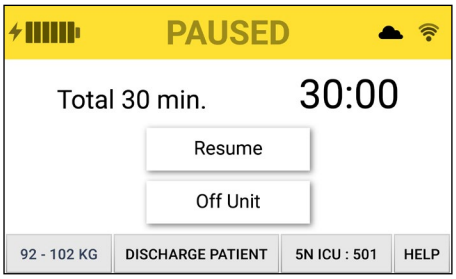


Figure 10. Paused screen (standard)

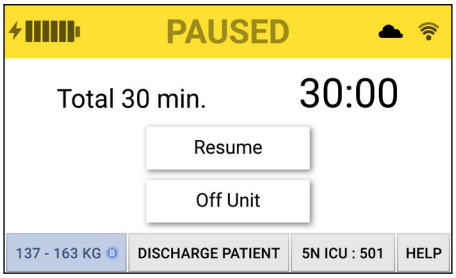


Figure 11. Paused screen (BariMode)

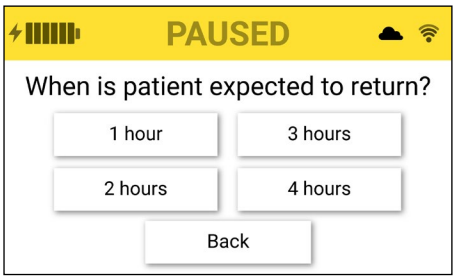


Figure 12. Off unit paused time selection screen

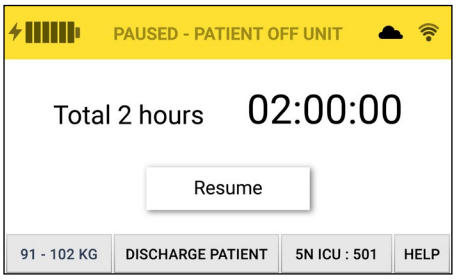


Figure 13. Paused - patient off unit screen (standard)

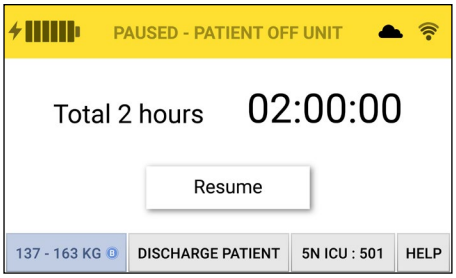


Figure 14. Paused - patient off unit screen (BariMode)

Pausing Therapy: Procedure Table Use

1. Therapy can be stopped by pressing “Pause Therapy” on the running screen. (Fig. 15)

2. A Paused screen (no timer) will display with a yellow status bar. (Fig. 16 & 17)

3. Controller operation will be Paused indefinitely until the user re-starts therapy. Press “Resume” to re-start therapy at any time. (Fig. 16 & 17)

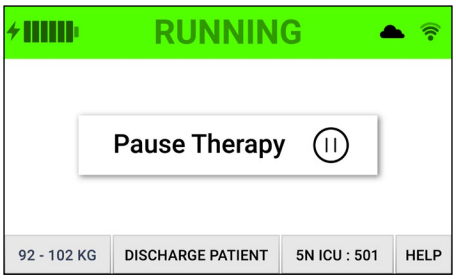


Figure 15. Running screen

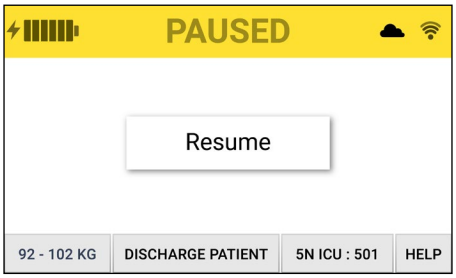


Figure 16. Paused - Procedure Table (standard)

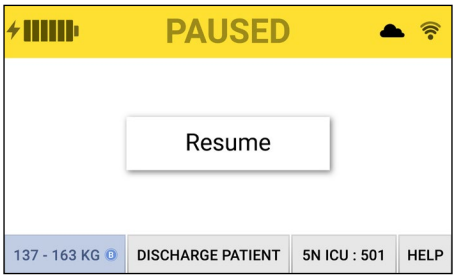


Figure 17. Paused - Procedure Table (BariMode)

Automatic Refresh

1. Under certain circumstances, the Guardian System 2.5 may reboot during use, including but not limited to when the system detects low memory, when the system is experiencing prolonged WIFI connectivity issues, and when an over-the-air software update occurs.

2. The refresh screen will appear for several seconds and then the device will re-start into the state it was in prior to the refresh. (Fig. 18). The status lights will turn red during the duration of the reboot.

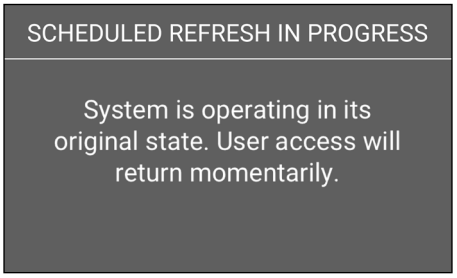


Figure 18. Scheduled refresh screen

Help

1. Product demonstration videos can be accessed from the Set-up, Running, and Paused screens.

2. Press Help to access the videos.

3. A menu will appear. Press any topic to view the corresponding tutorial video. (Fig.19)

Figure 19. Video menu screen

Status Lighting

The Guardian System 2.5 will illuminate along the lateral edges of the controller and around the connection port to indicate system status. The lighting colors and corresponding status are as follows:

- Green = running
- Yellow = paused
- Red = action required

WIFI Connectivity

The TurnCare Guardian System 2.5 is a WIFI connected system, enabling remote management services and support. The Guardian System 2.5 will display an icon in the upper right corner of the user screens to indicate current connectivity:

WIFI connected

WIFI enabled but not connected

Connected to server

Discharging the Patient

1. To stop therapy at the end of patient use, press Discharge Patient at the bottom of the running or paused screen. (Fig. 20)
2. A confirmation screen will appear. Swipe to discharge the patient. (Fig. 21)
3. A Patient Discharged screen will appear for several seconds. (Fig. 22)
4. The patient data will be erased after discharging the patient.
5. The controller will turn off following patient discharge, three (3) minutes after both the enhancer is disconnected and the controller is unplugged from power.

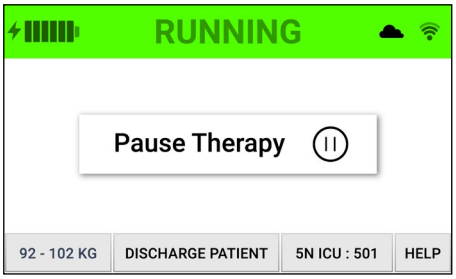


Figure 20. Discharge patient button

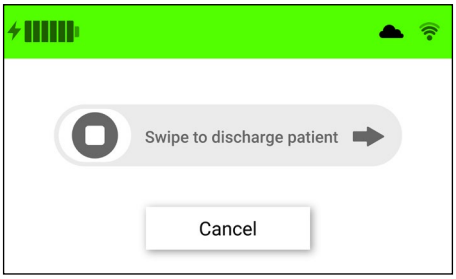


Figure 21. Confirm discharge screen

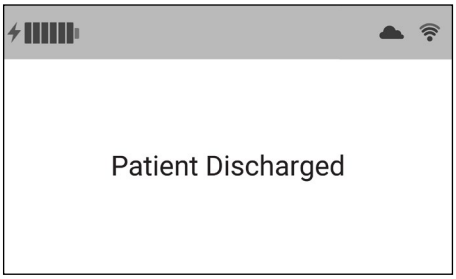


Figure 22. Patient discharge screen

Battery Operation

WARNING

- Do not immerse the controller in water.
- Do not touch or ingest any leaking electrolyte. If contact occurs, rinse skin and/or eyes immediately and seek medical attention. If ingested, contact local poison control center.
- If it is suspected that the battery is not working properly, please contact TurnCare. Do not attempt to remove the battery pack.

The Guardian System 2.5 is designed to operate on AC power or battery power without any interruption. The power supply cord/plug serves as the mains electrical supply disconnect. Ensure that the cord is not positioned where it is difficult to reach the plug.

The Guardian System 2.5 User Interface includes a battery level indicator to show the current charge level of the battery, as well as a blinking visual to indicate when the battery is being used and when the battery has reached a low level. The battery level indicators shown below are located in the upper left corner of the touch screen at all times. (Fig. 23 & 24)

The battery usage visuals shown below will blink in the upper left corner of the touch screen only when battery mode is in use. (Fig. 25 & 26) The battery begins charging when the controller is connected to AC power. When charging, the battery icon will display with a lightning bolt next to it. (Fig. 24) The amount of time to charge the battery will vary depending on the controller's state during charging. Always use the battery level indicator to determine the state of charge of the battery. A fully charged battery will typically provide 5 hours of operation, but this varies based on the conditions of use.

When the battery reaches approximately 2 hours of remaining run time, an alert will notify the user to plug in to AC power to avoid interruption in therapy. (Fig. 27) If being used on a bed or seat, an auditory alert will sound for three (3) minutes every hour while the alert is active. If being used on the procedure table, an auditory alert will sound for five (5) seconds every hour while the alert is active. The low battery alert screen will be dismissed by either plugging the controller into AC power or by pressing discharge on the screen. If a terminal shutdown occurs (Fig. 28) the patient's information will be cleared from the system.

Figure 23. Battery level indicator

Figure 24. Battery level indicator while charging

Figure 25. Battery operation visual

Figure 26. Low battery visual

Battery State	Bar 1	Bar 2	Bar 3	Bar 4	Bar 5	Bar 6
84-100%	Black	Black	Black	Black	Black	Black
67-83%	Black	Black	Black	Black	Black	Grey
50-66%	Black	Black	Black	Black	Grey	Grey
33-49%	Black	Black	Black	Grey	Grey	Grey
16-32%	Black	Black	Grey	Grey	Grey	Grey
< 16%	Red	Grey	Grey	Grey	Grey	Grey

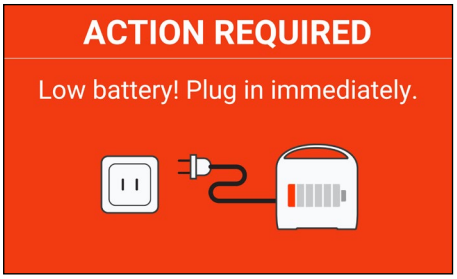


Figure 27. Low battery alert

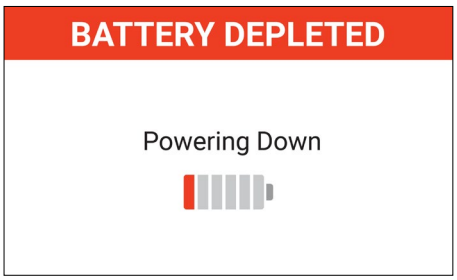


Figure 28. Terminal battery shutdown alert

AC Power Disconnected Alert

When being used on a bed or seat, if the user disconnects the controller from AC power while a patient is enrolled or if therapy is started using battery operation, an alert will notify the user to plug the controller into AC power. (Fig. 29). An audible alert will sound for three (3) minutes every hour while the alert is active. The alert can be dismissed by pressing Continue on the alert screen, plugging the controller into AC power, or by pressing discharge on the alert screen to end use. When being used on a procedure table, this alert will not occur.

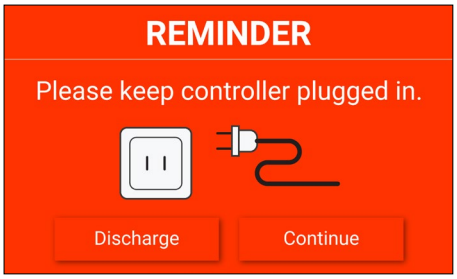


Figure 29. AC power disconnected alert

Action Required

Connect Enhancer to Controller: Bed & Seat Use

1. If the enhancer is disconnected while running, a prompt will appear with a five (5) second auditory tone. Reconnect the enhancer into the front of the controller or make a selection to dismiss the prompt. Do not use the button to insert the connector. Push until there is a click. (Fig. 30)

2. If the Keep Enhancer Connected Prompt is not addressed within five (5) minutes, an auditory alert will occur for three (3) minutes and repeat every hour that the alert is active. (Fig. 31)

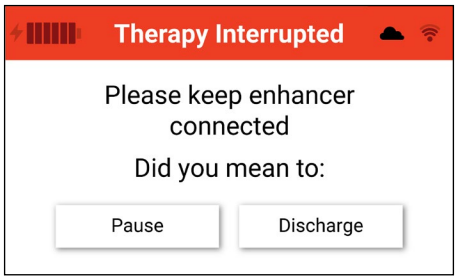


Figure 30. Keep Enhancer connected prompt screen

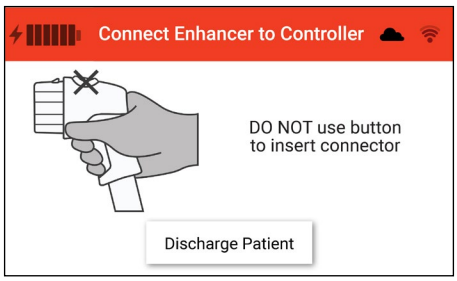


Figure 31. Enhancer disconnected alert screen

Connect Enhancer to Controller: Procedure Table Use

1. If the enhancer is disconnected while running, an auditory alert will sound for five (5) seconds and an alert screen will appear. Reconnect the enhancer into the front of the controller to dismiss the prompt. Do not use the button to insert the connector. Push until there is a click. (Fig. 31)

2. If the Connect Enhancer to Controller Alert is not addressed, an auditory alert will occur for five (5) seconds every hour that the alert is active. (Fig. 31)

Enter Patient Weight

1. The Guardian System 2.5 will alert the user if the user does not enter a patient weight within five (5) minutes of accessing the weight selection screen. (Fig. 32)

2. The Guardian System 2.5 will continue to display the weight selection screen with red status lights and an auditory alert. If the system is being used on the bed or seat, the auditory alert will last for three (3) minutes. If the system is being used on the procedure table, the auditory alert will last for five (5) seconds.

3. Enter the patient weight to dismiss the alert.

4. Please note that therapy will begin at a default, mid-range weight setting after five (5) minutes of accessing the weight selection screen. The patient's accurate weight must be entered to ensure the correct therapy is applied.

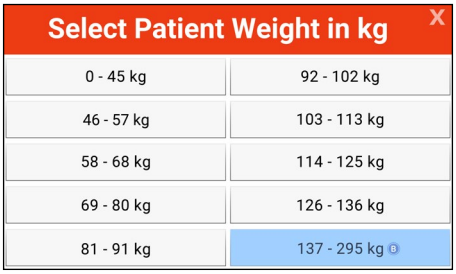


Figure 32. Patient weight screen

System Alert

No Patient Detected on Enhancer

1. The Guardian System 2.5 will alert the user if after a period of time a patient is not detected on the enhancer when being used on the bed or seat only. An auditory alert will occur for three (3) minutes.

2. Follow the instructions on the screen to address the alert. (Fig. 33)

3. Press Continue to dismiss the alert after repositioning the patient. If the Guardian System 2.5 is no longer in use with a patient, press Discharge to end therapy.

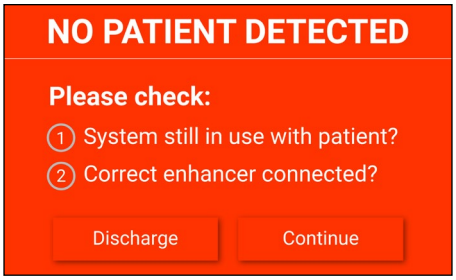


Figure 33. Patient not detected instruction

Airflow Blocked

1. The Guardian System 2.5 will alert the user if airflow to the enhancer is blocked enough to interfere with therapy.(Fig. 34 & 35) If the system is being used on the bed or seat, the auditory alert will last for three (3) minutes. If the system is being used on the procedure table, the auditory alert will last for five (5) seconds.

2. Assess the enhancer flap, where the tubes exit the enhancer, for folding or bunching.

3. Assess the tubing for a kink or pinch, from the enhancer all the way to the controller, and correct any issue found. Pay careful attention to the tubing position in the siderail and beneath the hospital bed.

4. Press Continue to dismiss the alert.

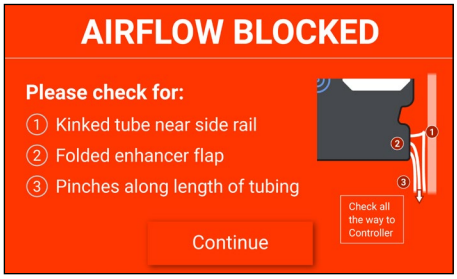


Figure 34. Airflow blocked: Bed Enhancer

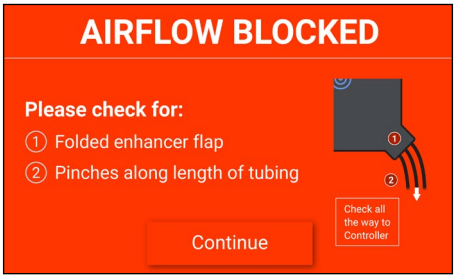


Figure 35. Airflow blocked: Seat and Procedure Table Enhancers

Leak Detected: Bed & Seat Use

1. If the Guardian System 2.5 detects a leak that is interfering with the ability to provide optimal therapy, it will alert the user with a red screen and three (3) minute auditory alert. (Fig. 36)

2. The Guardian System 2.5 will first prompt the user to disconnect and reconnect the enhancer to ensure it is properly latched. Insert the connector into the front of the controller to dismiss the alert. Do not use the button to insert the connector. Push in until there is a click. (Fig. 36)

3. If the problem persists, a component failure is indicated. Replace the enhancer as soon as possible. If the alert recurs after replacing the enhancer, replace the controller immediately. (Fig. 37 & 38)

4. Please contact TurnCare if needed for troubleshooting assistance.

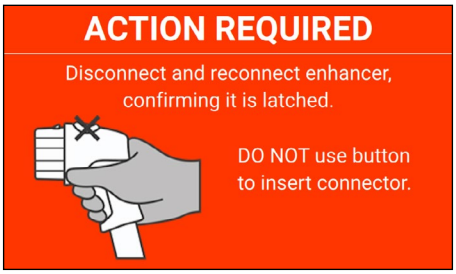


Figure 36. First leak alert screen

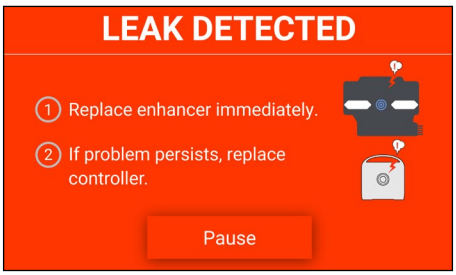


Figure 37. Recurring leak alert screen: Bed Enhancer

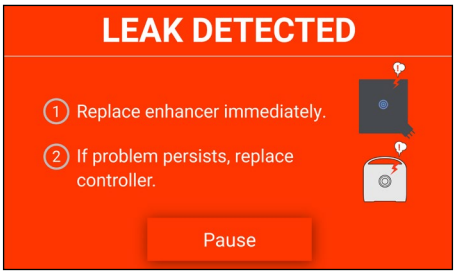


Figure 38. Recurring leak alert screen: Seat Enhancer

Leak Detected: Procedure Table Use

1. If the Guardian System 2.5 detects a leak that is interfering with the ability to provide optimal therapy, it will alert the user with a red screen and five (5) second auditory alert. (Fig. 36)

2. If the problem persists, a component failure is indicated. A subsequent alert will occur after the patient is discharged from the Guardian System. (Fig. 39)

3. Follow the directions on the screen and press 'Replaced' to confirm that the enhancer has been removed from service. If the alert recurs after replacing the enhancer, replace the controller immediately.

4. Please contact TurnCare if needed for troubleshooting assistance.

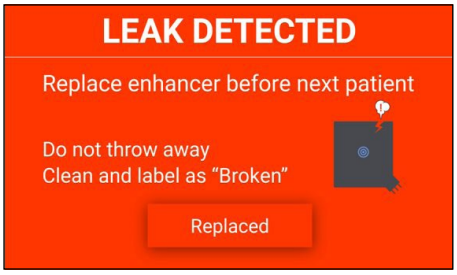


Figure 39. Recurring leak alert screen: Procedure Table Enhancer

Broken Controller

1. If the Guardian System 2.5 detects a controller malfunction that is interfering with therapy, it will alert the user. The controller must be replaced immediately and returned to TurnCare. (Fig. 40)

2. First, unplug the controller. The "Off" button will become active.

3. Press "Off" on the alert screen to initiate shutdown.

4. Please contact TurnCare if needed for troubleshooting assistance.

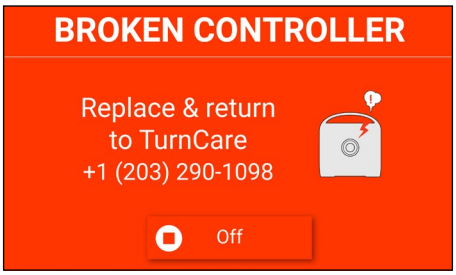


Figure 40. Broken Controller alert screen

Prompts

Validate the Patient Unit & Room Number

1. Whenever the Guardian System 2.5 is plugged in during use on the bed & seat, it will prompt the user to validate the current patient unit and room number. (Fig. 41)

2. If the patient room has not changed, press Yes to return to the previous screen. If the patient room has changed, press No, enter the new room number, and then select the patient unit.

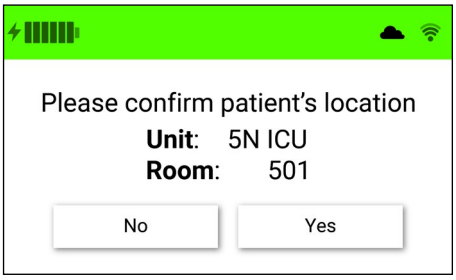


Figure 41. Validate patient unit and room number screen

Validate Patient's Weight

1. If user selects to change patient's weight by more than one weight range, a confirmation of weight selection will be required. (Fig. 42)

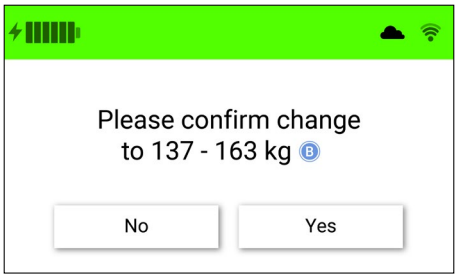


Figure 42. Weight change confirmation screen

CLINICAL USE

Patient Alignment on the Bed Enhancer in Supine and Upright Positions

1. Ensure that the patient is properly aligned on the enhancer. The patient should be vertically and horizontally centered, with the sacrum over the center target of the enhancer and aligned with the white arrows.

2. It is recommended to elevate the knees to promote proper positioning on the enhancer while the patient is in the upright position, or supine with the head of the bed elevated.

3. Patient alignment on the bed enhancer can be quickly checked by viewing the graphics. The white arrows should point to the patient's sacrum when correctly positioned.

Patient Alignment and Positioning with Turn Assist Devices

TurnCare will develop a plan to integrate the Guardian System 2.5 in such a way that ensures ease of workflow with existing turn assist and repositioning devices existing within your organization.

Patient Alignment on the Bed Enhancer in Sidelying Position

1. Once the patient is positioned in the sidelying position, ensure that the patient is properly aligned on the enhancer. The patient should be vertically and horizontally centered, with the trochanter over the center target of the enhancer and aligned with the white arrows.

2. Patient alignment on the bed enhancer can be quickly checked by viewing the graphics on the enhancer. The white arrows should point to the patient's sacrum when correctly positioned.

Prone Positioning on the Bed Enhancer

1. Pause therapy.

2. Position the patient in prone position. Ensure that the patient is centered horizontally on the enhancer with the sacrum aligned with the white arrows. This promotes proper positioning of the anterior superior iliac spines (ASIS) on the appropriate air chambers.

3. Resume therapy.

4. When returning the patient to the supine position, be sure to pause therapy prior to repositioning the patient.

Patient Alignment on the Seat and Procedure Table Enhancers

Orientation markings are located on the lateral portions of the enhancer for checking patient position. Ensure that the patient is properly aligned on the enhancer. The patient should be vertically and horizontally centered, with the sacrum over the center target.

Transferring the Patient In and Out of Bed

⚠ WARNING

Prior to transferring patient in or out of bed, the enhancer must be fully deflated for patient and staff safety.

1. Press Pause on the touch screen. Allow enhancer to fully deflate.
2. Once the enhancer is deflated, the patient may be transferred according to facility protocol.

Transferring the Patient to and from the Stretcher

⚠ ATTENTION

Prior to transferring a patient to or from the stretcher, the enhancer must be fully deflated for patient and staff safety.

1. Press Pause on the touch screen. Allow enhancer to fully deflate if being used.
2. Place the transfer assist device beneath the patient according to facility policy and procedure.
3. Transfer the patient according to facility policy and procedure.
4. To perform the transfer from the stretcher to the bed, follow the above instructions.

Transport of the Guardian System 2.5

⚠ ATTENTION

Ensure all parts are clean and dry prior to transport. Transport the Guardian System 2.5 using the Guardian System 2.5 Tote Bag. The Guardian System 2.5 Controller may be carried separately, hung on a bed or stretcher, or attached to an IV pole. For safety reasons, the controller should not be carried in the tote bag.

Discontinuation of Use

1. To discontinue therapy and power down, discharge the patient, disconnect the enhancer, and unplug from AC power. Once all three steps are completed, the system will shutdown after three (3) minutes.
2. If the controller is hung on the bed, engage the actuating handle to release the securing mechanism and remove the controller.
3. If the controller is hung on an IV pole, hold the carrying handle with one hand and rotate the knob fully counter clockwise to remove it.
4. Clean the Guardian System 2.5 re-usable components according to guidance in the Maintenance section. Discard tote bags after single patient use.

WARRANTY, USEFUL LIFE, AND SHELF LIFE

All controllers have manufacture dates located on the packaging and labeling.

TurnCare warrants that all Guardian System 2.5s are manufactured free of material or functional defects. We agree to service the Guardian System 2.5 Controller if required due to malfunction and to replace or repair any controller or enhancer which, following TurnCare examination, is deemed to have manufacturer defects. The warranty does not include or cover damage caused by misuse, tampering, or negligence.

The Guardian System 2.5 does not include user serviceable parts.

Return to the manufacturer for servicing.

MAINTENANCE

WARNING

Do not attempt to modify, disassemble, or otherwise alter the Guardian System 2.5.

The Guardian System 2.5 does not require maintenance. If an issue is encountered that appears to require maintenance, please contact TurnCare.

Replacement

The TurnCare Guardian System 2.5 components are interchangeable. If any component is damaged or for other reasons needs to be replaced, contact TurnCare. Replacement of components should only be performed when the Guardian System 2.5 is not active.

Storage

ATTENTION

- Ensure all parts are clean and dry prior to storage.
- When not in use, Guardian System 2.5 Enhancers may be stored in an unused Guardian System 2.5 Tote Bag. For safety reasons, the controller should be stored outside of the bag.

Cleaning

WARNING

- Disconnect the controller from the power outlet before cleaning and inspecting.

ATTENTION

- If any enhancer is too soiled to be cleaned by standard cleaning practices, discard and replace with a new one.
- If the controller is too soiled to be cleaned by standard practices, contact TurnCare for instructions.

The controller and enhancers may be cleaned using standard CDC guidelines for Healthcare facilities: Environmental Surfaces in Patient-Care Areas.

If the labeling on the enhancer becomes illegible, replace the enhancer.

Cleaning Instructions

1. Discontinue use according to Discontinuation of Use section.
2. Wipe down all surfaces of the controller and enhancers, including both sides of the enhancer, using a dampened cloth or disinfectant wipe per facility protocol.
3. Avoid using overly saturated cloths on the controller surfaces.
4. Allow to air dry or use a clean cloth to dry the surfaces.

Disposal

To ensure correct disposal, the Guardian System 2.5 Controller and Enhancers should be returned to TurnCare when no longer used. Components must be thoroughly cleaned prior to returning to TurnCare. If any enhancer is too soiled to be properly cleaned, it should be disposed of according to facility protocol. Tote bags are disposable and should be discarded after each patient use.

Electrical Safety Testing

An equipotential test point, located on the back of the device, is provided for electrical safety testing. This is the only exposed metal ground point. If the power cord resistance exceeds 0.2 ohms, the device should be returned to the manufacturer for repair.

TROUBLESHOOTING

SYMPTOM	POTENTIAL CAUSE	CORRECTIVE ACTION
Controller will not turn on	No power	Ensure the controller is fully plugged in. Check the wall outlet and ensure it is active.
	Power cord	Check the power cord visually for defects. If defective, contact TurnCare.
Controller runs and goes into alert	Connector not connected	Reconnect the enhancer. Do not use the button to insert the connector. Push in until there is a click.
	Airflow is blocked	Check the enhancer flap, where the tubes enter the enhancer, for folding or bunching. Check the tubing from the enhancer to the controller for kinks or pinches.
	Patient is not on the enhancer	Position the patient on the center target.
	Component leak	Replace the enhancer. If problem persists, replace the controller. Contact TurnCare support.
Controller does not function	Internal malfunction	Unplug the controller. Wait 30 seconds. Restart the controller by plugging it back in. If the controller still does not function properly, contact TurnCare support.
Excessive noise / vibration	Controller not on stable surface	Make sure the controller is standing on a solid surface or hanging on a solid footboard. If being used on an IV pole, ensure it is sufficiently secured on the pole using the knob to tighten. If problem persists, contact TurnCare support.
	Defective controller	Contact TurnCare support.

TECHNICAL SPECIFICATIONS

CONTROLLER	
Model	GS-2.5-C, GS-2.5-C-EU
Class	Class I Earthed
Voltage	GS-2.5-C: 100-120Vac GS-2.5-C-EU: 200-240Vac
Frequency	50/60Hz
Power	110VA
Power Supply	Non-detachable power cord
Emergency Power Disconnection	Power cord unplug from power outlet, disconnect enhancer
Battery	Lithium ion battery
Fuse	1.25 amp
Length	8.5" / 216mm
Width	13.75" / 349mm
Height	10.5" / 267mm
Weight	12.5 lbs / 5.7 kg
Case Material	Flame retardant ABS/PC plastic
Case Material Fire Rating	UL94 V0
Mode of Operation	Continuous
Patient Weight Range Limits	Less than 295 kg (650 lbs)
Therapy Pressure Range	0-100 mmHg

Materials of Construction

Case Material:

- Polycarbonate + ABS - biocompatible blend of polycarbonate (PC) and acrylonitrile butadiene styrene (ABS) for healthcare applications. Ignition resistance, halogen free.
- PUR - Thermoplastic polyurethane elastomer (polyether) Connector Material (applied part):
- Polycarbonate + ABS - biocompatible blend of polycarbonate (PC) and acrylonitrile butadiene styrene (ABS) for healthcare applications. Ignition resistance, halogen free.

Enhancer and Tubing Material (applied part):

- Front side enhancer: TPU - Thermoplastic polyurethane elastomer (polyether)
- Back side enhancer: laminated nylon/TPU coated with clear, non-slip, matte-finished silicone rubber
- Tubing: TPU and polyvinyl chloride (PVC)

Environmental

WARNING

- Keep the controller away from sources of liquids. Do not immerse in water.

ATTENTION

- If the controller is stored in conditions outside of "operating" range, it should be allowed to stabilize at normal operating conditions prior to use.
- The Guardian System 2.5 should be set up such that the power outlet used for the controller is accessible at all times.

ENVIRONMENTAL INFORMATION			
Condition	**Temperature Range**	**Relative Humidity**	**Atmospheric Pressure**
Operating	+10°C to +34°C (+50°F to 94°F)	45% to 75% (non-condensing)	860 hPa to 1060 hPa
Storage & Transport (Long Term)	+10°C to +40°C (+50°F to 105°F)	20% to 95% (non-condensing)	860 hPa to 1060 hPa
Storage & Transport (Short Term)	-20°C to +50°C (-4°F to 122°F)	20% to 95% (non-condensing)	860 hPa to 1060 hPa

ELECTROMAGNETIC COMPATIBILITY

Manufacturer's Guidance

This controller is intended for use in the electromagnetic environment specified below. The customer or the user should ensure that it is used in such an environment.

MANUFACTURER'S GUIDANCE		
Emissions Test	**Compliance**	**Electromagnetic Environment Guidance**
RF Emissions CISPR 11	Group 1	The controller uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	The controller is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

FCC SDoc Test Applicable Rules

Federal Register CFR 47, Part 15, subpart B:2017

Radiated Emissions, Part 15.109(g), Class A

Conducted Emissions, Part 15.107(b), Class A

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at their own expense.

Electromagnetic Compatibility (EMC) Testing Standards

IEC 60601-1-2:2014, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility – Requirements and tests

CISPR 11:2015+A1:2016 - Limits and methods of measurement of radio disturbance, Characteristics of industrial, scientific and medical radio frequency equipment

IEC 61000-4-2:2008 - Electromagnetic Compatibility-Part 4: Testing and measurement techniques – Section 2: Electrostatic discharge immunity test

IEC 61000-4-3:2010 - Electromagnetic Compatibility-Part 4: Testing and measurement techniques – Section 3: Radiated, radio-frequency, electromagnetic field immunity test

IEC 61000-4-4:2012 - Electromagnetic Compatibility-Part 4: Testing and measurement techniques – Section 4: Electrical fast transient/burst immunity test

IEC 61000-4-5:2005 - Electromagnetic Compatibility-Part 4: Testing and measurement techniques – Section 5: Surge immunity test

IEC 61000-4-6:2013 - Electromagnetic Compatibility-Part 4: Testing and measurement techniques – Section 6: Conducted immunity test

IEC 61000-4-8:2009 - Electromagnetic Compatibility-Part 4: Testing and measurement techniques – Section 8: Power frequency magnetic field immunity test

IEC 61000-4-11:2004 - Electromagnetic Compatibility-Part 4: Testing and measurement techniques – Section 11: Voltage dips and interruptions immunity test

AIM 7351731 – Medical Electrical Equipment and System Electromagnetic Immunity Test for Exposure to Radio Frequency Identification Readers

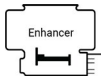
FDA Guidance – Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices

Co-Existence/Crosstalk Testing Standards

IEEE/ANSI C63.27-2017 – American National Standard for Evaluation of Wireless Coexistence

FDA Guidance Documents

SYMBOLS GLOSSARY

	Manufacturer (ISO 15223 - 1:2016, reference no. 5.1.1)
	Non-sterile (ISO 15223 - 1:2016, reference no. 5.2.7)
	Not made with natural rubber latex (ISO 15223 - 1:2016, reference no. 5.4.5. with negation per IEC 80416-3:2002, Clause 7)
	Consult instructions for use (ISO 15223 - 1:2016, reference no. 5.4.3)
	Use by date (ISO 15223 - 1:2016, reference no. 5.1.4)
	Date of manufacture (ISO 15223 - 1:2016, reference no. 5.1.3)
MD	Medical device
LOT	Lot # (ISO 15223 - 1:2016, reference no. 5.1.5)
REF	Product code (ISO 15223 - 1:2016, reference no. 5.1.6)
SN	Serial # (ISO 15223 - 1:2016, reference no. 5.1.7)
UDI	Unique Device Identifier
	Caution (ISO 15223 - 1:2016, reference no. 5.4.4)
	Do not throw in trash (ISO 50419 (Marking of Electrical and Electronic Equipment in accordance with Article 11(2) of Directive 2002/96/EC (WEEE)))
CE	CE marking (765/2008/EC 768/2008/EC MDD 93/42/ EEC Articles 4,11,12,17, Annex II)
EC REP	European Authorized Representative (ISO 15223 - 1:2016, reference no. 5.1.2)
	Controller
	Bed enhancer
	Procedure table enhancer
	Seat enhancer
	Equipotentiality (IEC60601 - 1:2005, reference no. D.1.8)

	Protective earth (ground) (IEC60601 - 1:2005, reference no. D.1.6)
	General warning sign (IEC60601 - 1:2005, reference no. D.2.2)
	Type B applied part (IEC60601 - 1:2005, reference no. D.1.19)

LEGAL NOTICES

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