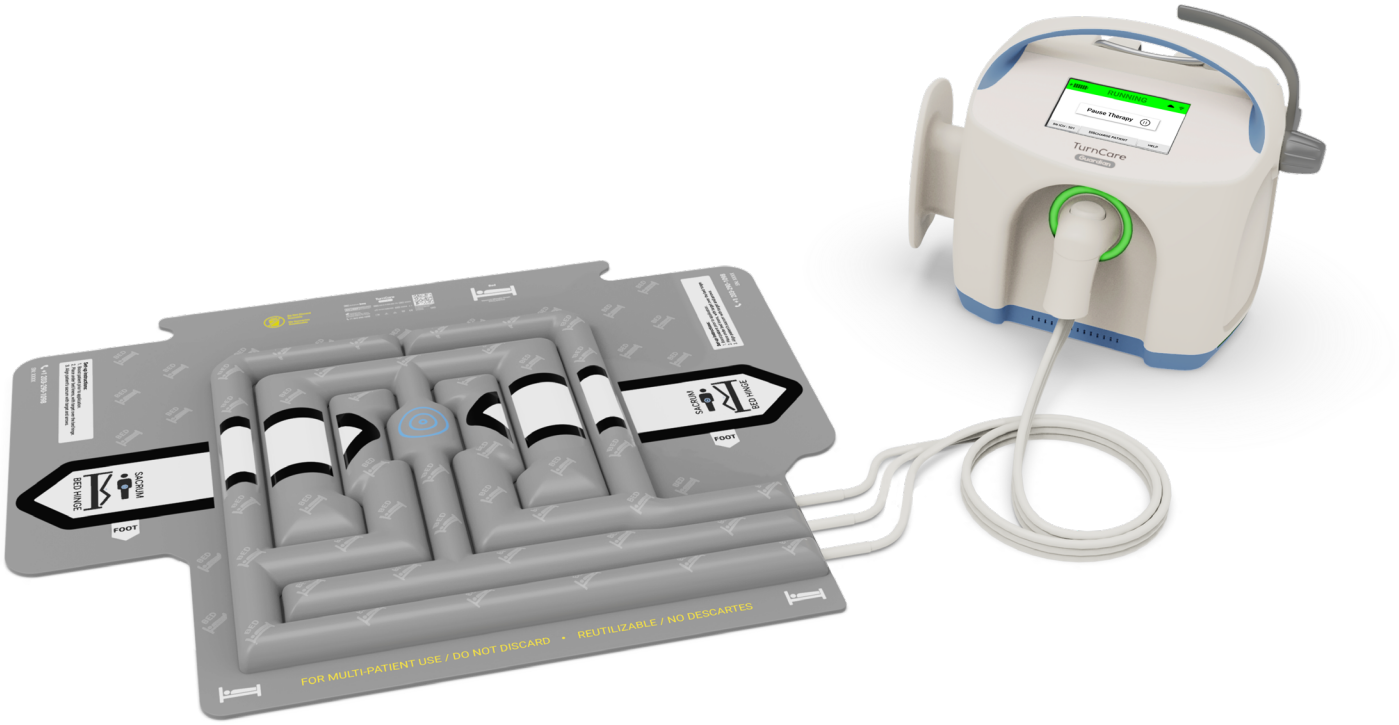
GUARDIAN

by TURNCARE.



Guardian System 2.8 User Manual

Version 02

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. It is the responsibility of the facility utilizing The Guardian System to ensure that user(s) are educated according to the provided materials and can operate this product safely in the use case setting. 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 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 support surface 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 is appropriate. The Guardian System 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 of the sacral, ischial, or trochanter areas, the patient should be evaluated for eligibility by the physician responsible for the procedure.

The Guardian System includes a sacral region patient support surface, which inflates and deflates during therapy and can result in movement of the patient. It is at the discretion of the user(s)/operator(s) to determine when the Guardian System can be used safely. TurnCare recommends pausing the system whenever elevation or patient motion could adversely impact a bedside procedure or patient care.

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

Convention

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.
- The Guardian System should not be brought into the MRI room.
- 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 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 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 with support surface inflated. For patient safety, support surface must be fully deflated prior to transfer.
- 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.
- Do not attempt to modify, disassemble, or otherwise alter the Guardian System.
- The Guardian System does not require maintenance. If an issue is encountered that appears to require maintenance, please contact TurnCare.
- Disconnect the controller from the power outlet before cleaning and inspecting.
- Keep the controller away from sources of liquids. Do not immerse controller in water.
- Do not insert objects into the fuse holder. Electrical shock may occur.
- The controller should not be operated if the power cord is damaged.
- Ensure the power cord and the support surface connector tubing placement does not create a tripping hazard or become entangled in equipment.
- 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 equipment.
- Keep the controller away from sources of liquids. Do not immerse the controller in water.
- Prior to transferring patient in or out of bed, the support surface must be fully deflated for patient and staff safety.

⚠ ATTENTION

- The Guardian System 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 Controller. 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 Controller on an IV pole, place the controller at the base of the pole to ensure stability.
- The Guardian System is not intended for use in the home healthcare environment.
- Ensure that all components are clean and dry prior to use.
- 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.
- If, for any reason, the Guardian Controller needs to be disconnected from the power supply, unplug the power cord from the power outlet.
- Prior to transferring a patient to or from the stretcher, the support surface must be fully deflated for patient and staff safety.
- Ensure all parts are clean and dry prior to transport. Transport the Guardian System support surfaces in a clear TurnCare Tote Bag. The Guardian 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.
- Ensure all parts are clean and dry prior to storage.
- When not in use, Guardian System support surfaces may be stored in an unused Guardian System Tote Bag. For safety reasons, the controller should be stored outside of the bag.
- If any support surface 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.
- If the controller is stored in conditions outside of “operating” range, it should be allowed to stabilize at normal operating conditions prior to use.

CONTENTS

INTRODUCTION

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

The TurnCare Guardian System 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 can include decreased adverse events, improved early mobility, and decreased pain and discomfort.

Guardian System 2.8

The Guardian System 2.8 consists of the following components:

1. Controller: Guardian 2.5 Controller (GS-2.5-C) running 2.8 software
2. Bed Support Surface:

   a. Loose Bed Support Surface (LBS): Guardian System Bed Support Surface - 76" Integrated Tube Connector (GS-EN-BD-76)

   OR

   b. Dual Clip Secured Bed Support Surface (SBS): Guardian System SBS (Dual Clip) - 76" Integrated Tube Connector (GS-SBS-76)

      i. Mounting Components: Determination is based on approved hospital frame and mattress configuration.

   OR

   c. Quad-Clip Secured Bed Support Surface (SBS): Guardian System SBS (Quad Clip) - 76" Integrated Tube Connector (GS-SBS-76-1) (Hercules Configuration)

      i. Mounting Components: Determination is based on approved hospital frame and mattress configuration.

3. Seat Support Surface: Guardian System Seat Support Surface - 70" Integrated Tube Connector (GS-EN-ST-70)
4. Information Services (iS)
5. A tote bag (GS-TB) is also available to aid in storage and transport of support surfaces.

⚠ ATTENTION

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

⚠ WARNING

- After set-up, ensure the support surface 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 equipment.
- The Guardian System should not be brought into the MRI room.

Controller

The Guardian System 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 in alert mode.

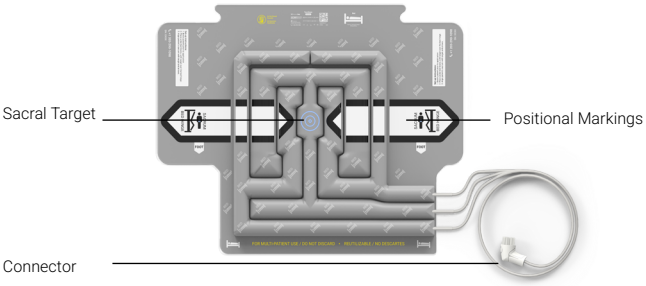
⚠ WARNING

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

Vasotactic Support Surface (Support Surface)

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

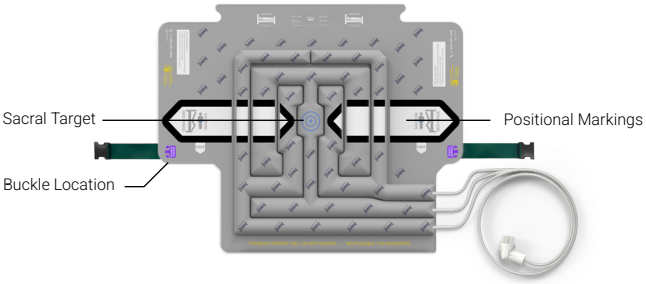
Loose Bed Support Surface



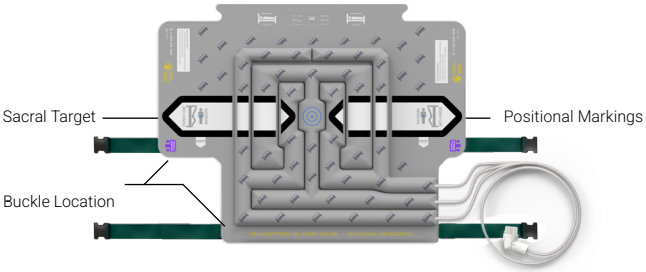
The loose bed support surface consists of anatomy-specific air chambers. The loose bed support surface is not intended for use on stretchers or procedure tables.

Secured Bed Support Surface

Dual Clip Secured Bed Surface (SBS)

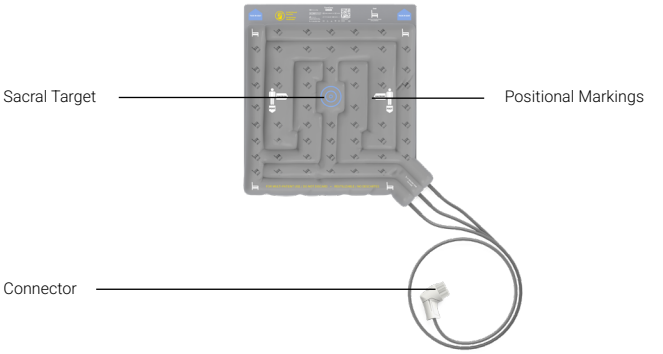


Quad-Clip Secured Bed Surface (SBS)



The secured bed support surface consists of anatomy-specific air chambers. The secured bed surface is anchored to the hospital bed using buckle and/or strap method, to increase consistent, correct positioning of surface. The secured bed surface is not intended for use on stretcher or procedure tables.

Seat Support Surface



The seat support surface consists of anatomy-specific air chambers. Positional markings on support surface promote correct and safe application. The seat support surface is typically utilized on recliners, but may also be used on other seating surfaces.

Tote Bag

The Guardian System comes equipped with an optional 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.

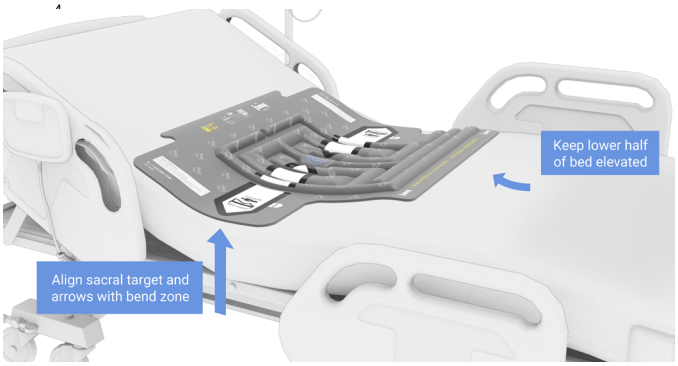
SETUP

Loose Bed Support Surface 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 support surface, ensure that the patient icon on the support surface is appropriately oriented in relation to the patient. Roll the bed support surface up halfway.
3. With the patient in the side lying position, place the support surface 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 support surface is centered horizontally on the bed.
4. Roll the patient to the opposite side of the bed and unroll the support surface.
5. It is recommended to elevate the knees to promote proper positioning on the support surface while the patient is in supine with the head of the bed elevated.

Loose Bed Support Surface Set-up without Patient in Bed

1. To assist with correctly placing the support surface ensure that the patient icon is appropriately oriented in relation to the bed.
2. Place the support surface 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 support surface is centered horizontally on the bed.



Secured Bed Support Surface 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. With the patient in side lying position, buckle one side of the surface to the securement strap.
3. Roll the support surface (toward the buckled end) half way.
4. With the patient in the side lying position, place the support surface 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 support surface is centered horizontally on the bed.
5. Roll the patient to the opposite side of the bed and unroll the support surface.
6. Secure the other side of the support surface by buckling the surface to the securement strap on the bed.

   Important: If any of the buckles or straps are damaged and unable to secure and latch appropriately, please remove secured bed support surface and replace with loose bed support surface. Contact your TurnCare representative for a replacement.

Secured Bed Support Surface Set-up without Patient in Bed

1. Securement straps for the secured bed support surface will be initially installed by a TurnCare Representative.
2. Ensure secured bed support surface is in correct position, 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 support surface is centered horizontally on the bed.
4. Check buckles on both left and right side of surface to ensure properly latched.
5. Apply linens on the bed, over secured bed support surface.

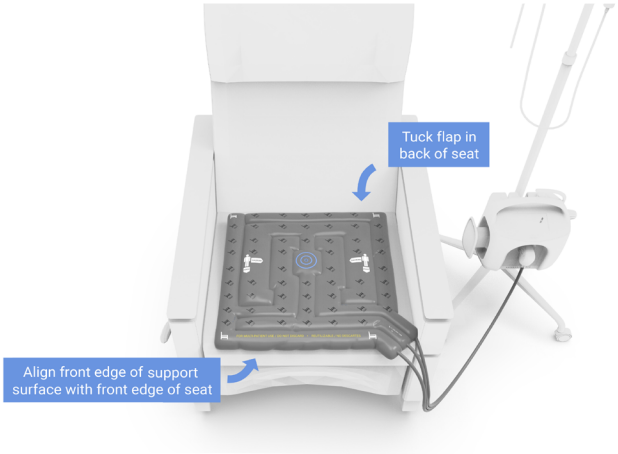
   Important: If any of the buckles or straps are damaged and unable to secure and latch appropriately, please remove secured bed support surface and replace with loose bed support surface. Contact your TurnCare representative for a replacement.

Secured Bed Support Surface Accessory Installation (if applicable)

If applicable to your facility, please refer to your facility's provided instructions on how to install straps and/or anchors properly. Contact your TurnCare representative with questions.

Seat Support Surface Set-up

1. To assist with correctly placing the support surface, 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 support surface on the seating surface. Tuck the rear flap into the back of the seat, so that the front edge of the support surface aligns with the front edge of the seat.
4. Place hospital linens over the support surface prior to seating the patient.



Controller Set-up

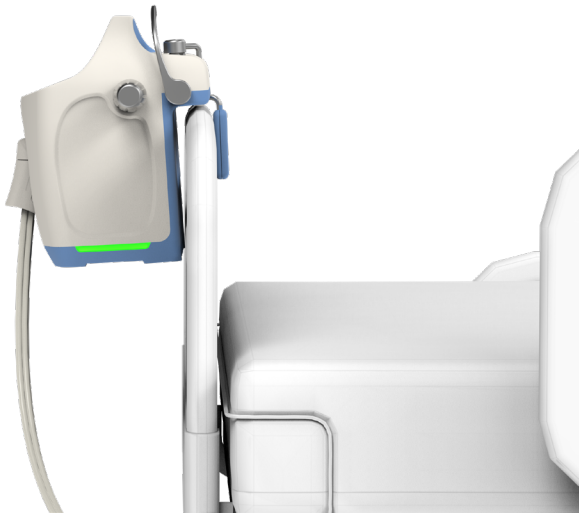
WARNING

- 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 and connector tubing placement does not create a tripping hazard or become entangled in equipment.

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. 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 right 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 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.

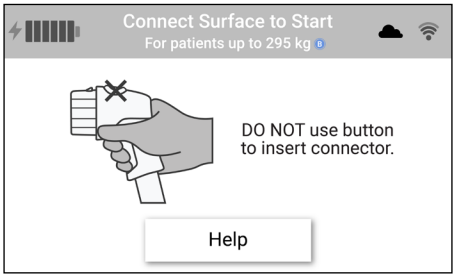


Figure 1. Set-up screen

Initiating Therapy

1. Connect a support surface to the controller. Do not use the button to insert the connector. Push in until there is a click.
2. Enter the patient's unique identifier (ID) and press continue. (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 medical record number (MRN).
3. Select the Facility unit and press continue. (Fig. 3)
4. Enter the patient's room number and press continue. (Fig. 4)
5. Therapy will begin with running screen visible. (Fig. 5)

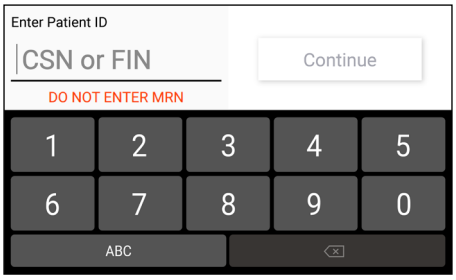


Figure 2. Patient ID entry screen

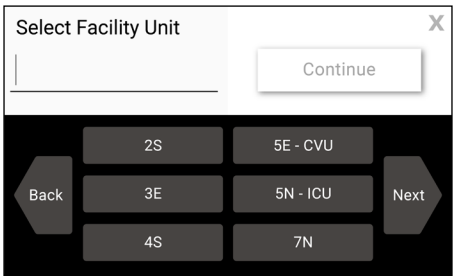


Figure 3. Facility unit selection screen

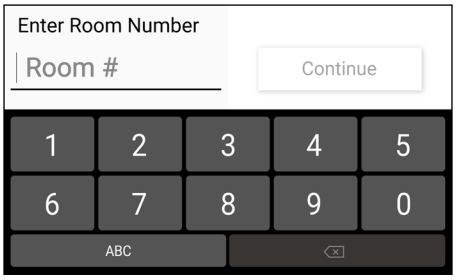


Figure 4. Patient room number entry screen

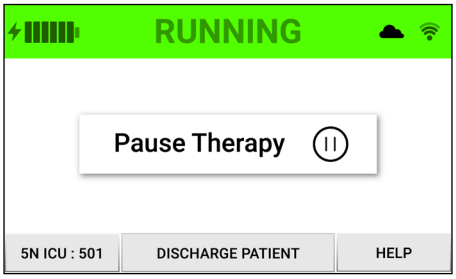


Figure 5. Running screen

Sacral Weight Adaption

1. Guardian System will automatically deploy pressure offsets for support surfaces.
2. Pressures and offsets applied are based on the interface load of the sacral weight on the support surface. They are dynamic and continue to adjust and adapt to the patient's position.
3. Parameters in place to ensure off-sets and pressures stay within optimal range.

Running Mode

When the controller is operating, a screen will display with a green status bar to indicate that the controller is running. (Fig. 5)

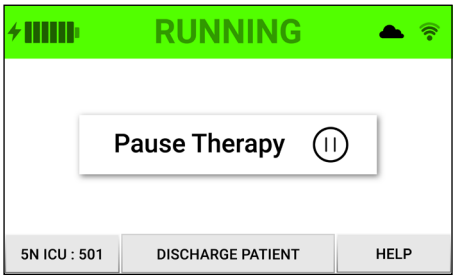


Figure 5 Running screen

Pausing Therapy

1. Therapy can be stopped by pressing "Pause Therapy" on the running screen. (Fig. 5)
2. A Paused screen will display with a yellow status bar and remaining pause time displayed on the right side of the screen. (Fig. 6)
3. Pause time may be extended if necessary when the patient is going off-unit by pressing "Off Unit" to display additional pause times. (Fig. 6)
4. Select the desired time frame based on when the patient is anticipated to return. (Fig. 7)
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. 8)
6. The controller operation will automatically resume after the selected time frame or press "Resume" to re-start therapy at any time.

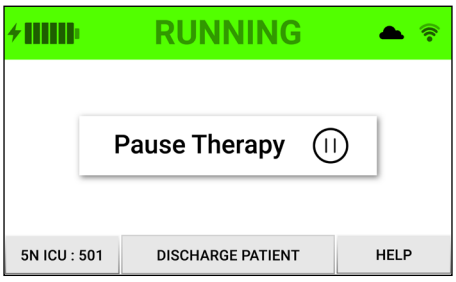


Figure 5. Running screen

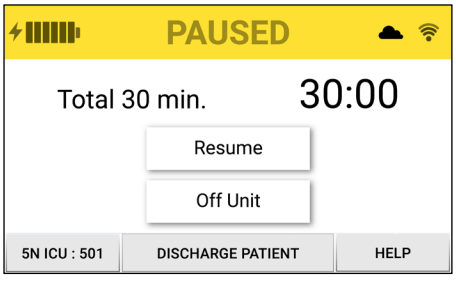


Figure 6. Paused screen

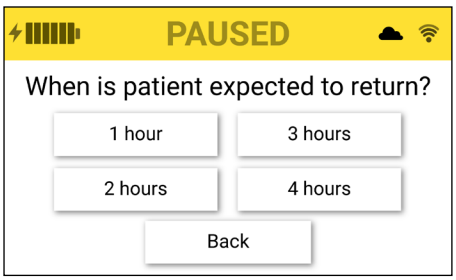


Figure 7. Off unit paused time selection screen

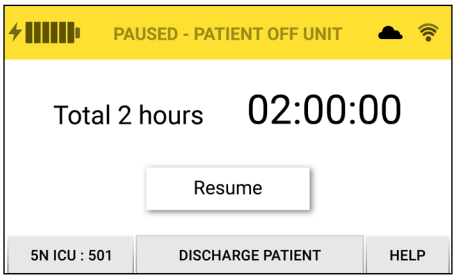


Figure 8. Paused - Patient off unit screen

Automatic Refresh

1. Under certain circumstances, the Guardian System 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 (Fig. 9) will appear for several seconds and then the device will re-start into the state it was in prior to the refresh. The status lights will turn red during the duration of the reboot.

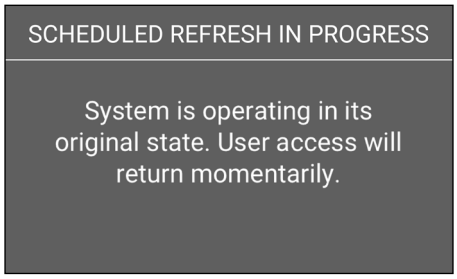


Figure 9. Scheduled refresh screen

Help

1. Press Help from the Set-up, Running, and Paused screens. Help screen will display. (Fig. 10 & 11)

2. Product demonstration videos can be accessed. Press any topic to view the corresponding tutorial video.

3. Clinical support number visible. Users can call with any questions or troubleshooting needs.

4. Unit Assignment will display at bottom of help screen. Controllers may be configured to have the unit assignment feature 'ON' (Fig. 10) or 'OFF'. (Fig. 11)

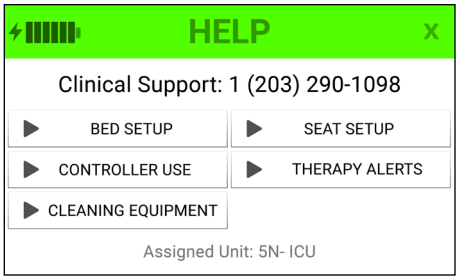


Figure 10. Help screen unit assignment on

Figure 11. Help screen unit assignment off

Status Lighting

The Guardian System 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

User Screen Functionality

When the Guardian System 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.

WIFI Connectivity

The TurnCare Guardian System is a WIFI connected system, enabling remote management services and support. The Guardian System 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 on last check-in

Discharging the Patient

1. To stop therapy at the end of patient use, press 'Discharge Patient'; at the bottom of the running (Fig. 5) or paused screens. (Fig. 6)
2. A confirmation screen will appear. Swipe to discharge the patient. (Fig. 12)
3. A Patient Discharged screen will appear for several seconds. (Fig. 13)
4. The controller will turn off following patient discharge, three (3) minutes after both the support surface is disconnected and the controller is unplugged from power.

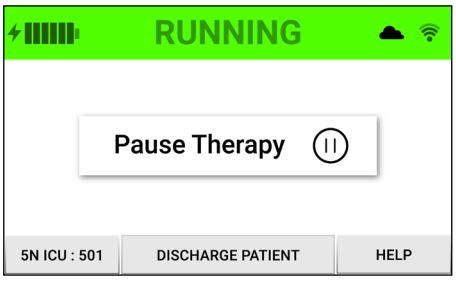


Figure 5. Running screen

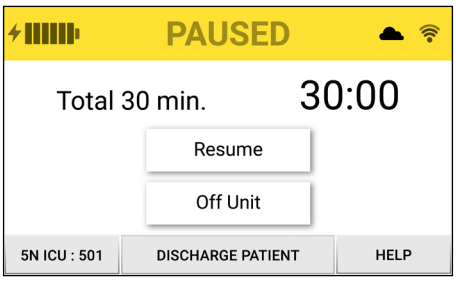


Figure 6. Paused screen

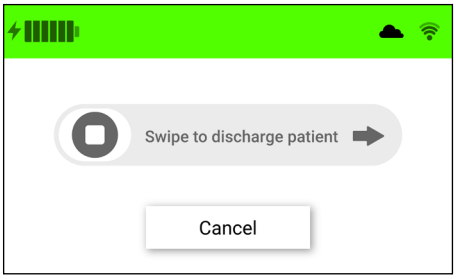


Figure 12. Confirm discharge screen

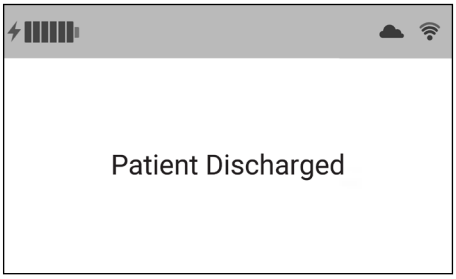


Figure 13. Patient discharge screen

Battery Operation

⚠ WARNING

- Keep the controller away from sources of liquids. 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 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 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. 14 & 15)

The 'Using Battery' visual shown below will blink in the upper left corner of the touch screen only when battery mode is in use. (Fig. 16) 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. 15) 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. 18) An auditory alert will sound for three (3) minutes 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. 19) the patient's information will be cleared from the system.

Figure 14. Battery level indicator

Figure 15 Battery level indicator while charging

Figure 16. Battery operation visual

Figure 17. 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

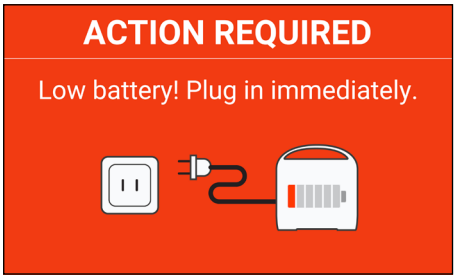


Figure 18. Low battery alert

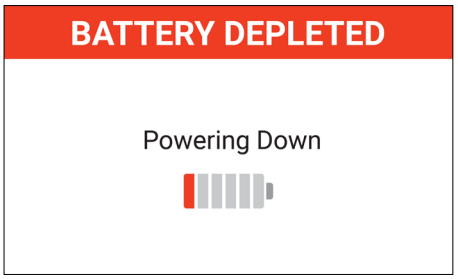


Figure 19. Terminal battery shutdown alert

AC Power Disconnected Alert

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. 20). 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.

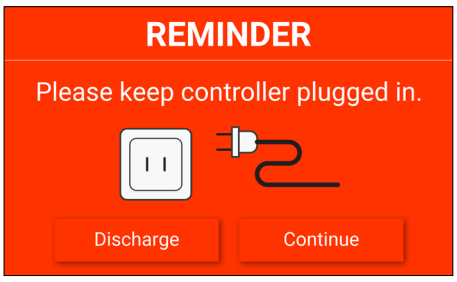


Figure 20. AC power disconnected alert

Action Required

Connect Support Surface to Controller

1. If the support surface is disconnected while running, a prompt will appear with a five (5) second auditory tone. Reconnect the support surface 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. 21)

2. If the Keep Support Surface Connected Prompt (Fig. 21) is not addressed within five (5) minutes, an auditory alert will occur and the support surface disconnected alert screen will for repeat every hour that the alert is active. (Fig. 22)

Figure 21. Keep Support Surface connected prompt screen

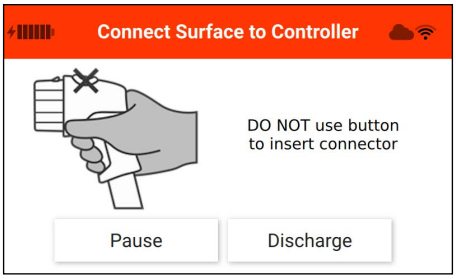


Figure 22. Support Surface disconnected alert screen

System Alert

No Patient Detected on Support Surface

1. The Guardian System will alert the user if after a period of time a patient is not detected on the support surface. An auditory alert will occur for three (3) minutes.

2. Follow the instructions on the screen to address the alert. (Fig. 23) Assess for proper placement of the support surface.

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

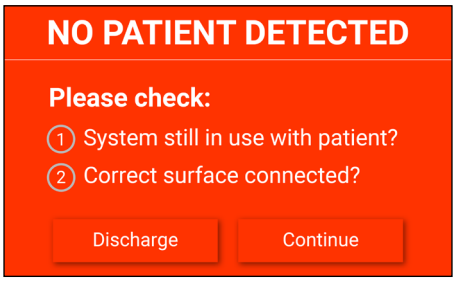


Figure 23. Patient not detected alert screen

Airflow Blocked

1. The Guardian System will alert the user if airflow to the support surface is blocked enough to interfere with therapy. (Fig. 24 & 25) If the system is being used on the bed or seat, the auditory alert will last for three (3) minutes.

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

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

4. Press Continue to dismiss the alert.

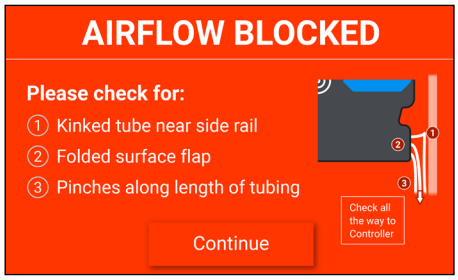


Figure 24. Airflow blocked alert screen: Bed Support Surface

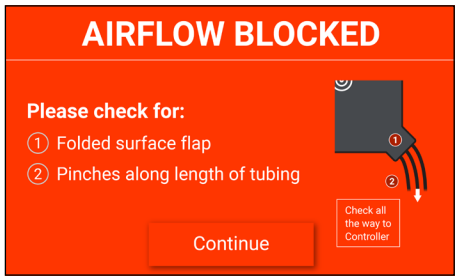


Figure 25. Airflow blocked alert screen: Seat Support Surface

Leak Detected

1. If the Guardian System 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. 26)

2. The Guardian System will first prompt the user to disconnect and reconnect the support surface 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. 26)

3. If the problem persists, a component failure is indicated. Replace the support surface as soon as possible. If the alert recurs after replacing the support surface, replace the controller immediately. (Fig. 27 & 28)

4. Please contact TurnCare.

Figure 26. First leak alert screen

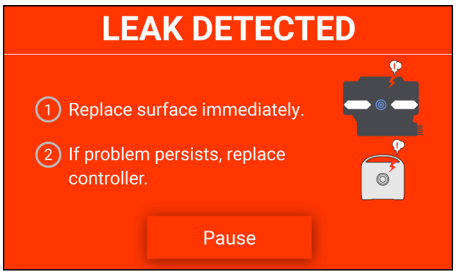


Figure 27. Recurring leak alert screen: Bed Support Surface

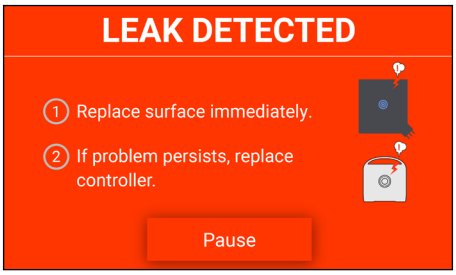


Figure 28. Recurring leak alert screen: Seat Support Surface

Broken Controller

1. If the Guardian System detects a controller malfunction that is interfering with therapy, it will alert the user. The controller must be removed from service, replaced immediately, and returned to TurnCare. (Fig. 29)
2. First, unplug the controller. The "Off" button will become active.
3. Press "Off" on the alert screen to initiate shutdown.
4. Please red tag per facility policy and contact TurnCare.

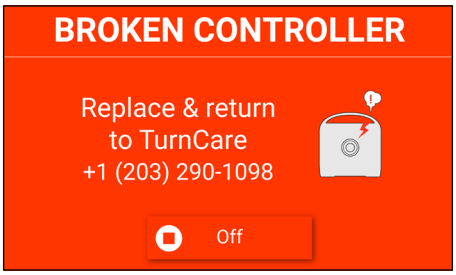


Figure 29. Broken Controller alert screen

Enter Room Number Alert

1. The Guardian Systems will alert the user if the user does not interact with the enter a room number screen for five (5) minutes. (Fig. 4)
2. It will continue to display the enter room number screen with red status lights and an auditory alert. The auditory alert will last for three (3) minutes.
3. Enter the patient's room number and select 'continue' to dismiss the alert and complete enrollment.

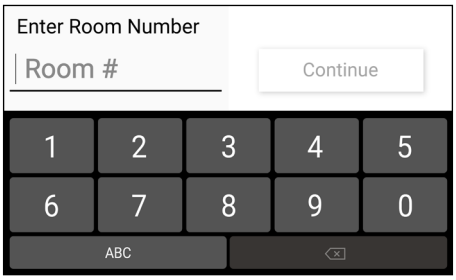


Figure 4. Enter room number screen

Prompts

Validate the Patient Unit & Room Number:

1. Whenever the Guardian System is unplugged and then plugged back into AC power during use, it will prompt the user to validate the current patient unit and room number. (Fig. 30)
2. If the patient's unit or room has not changed, press Yes to return to the previous screen. If the patient unit or room has changed, press No, enter the new information.

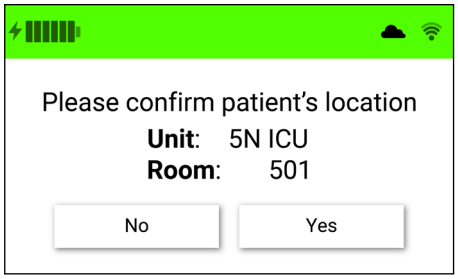


Figure 30. Validate patient unit and room number screen

CLINICAL USE

Patient Alignment on the Loose and Secured Support Surfaces in Supine and Upright Positions

1. Ensure that the patient is properly aligned on the support surface. The patient should be vertically and horizontally centered, with the sacrum over the center target of the support surface and aligned with the white arrows.
2. It is recommended to elevate the knees to promote proper positioning on the support surface while the patient is in the upright position, or supine with the head of the bed elevated.
3. Patient alignment on the bed support surface 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 in such a way that ensures ease of workflow with existing turn assist and repositioning devices existing within your organization.

Patient Alignment on the Loose and Secured Bed Support Surfaces in Side Lying Position

1. Once the patient is positioned in the side lying position, ensure that the patient is properly aligned on the support surface. The patient should be vertically and horizontally centered, with the trochanter over the center target of the support surface and aligned with the white arrows.
2. Patient alignment on the bed support surface can be quickly checked by viewing the graphics. The white arrows should point to the patient's sacrum when correctly positioned.

Prone Positioning on the Loose and Secured Bed Support Surface

1. Pause therapy.
2. Position the patient in prone position. Ensure that the patient is centered horizontally on the support surface 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 Support Surface

Orientation markings are located on the lateral portions of the support surface for checking patient position. Ensure that the patient is properly aligned on the support surface. 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 support surface must be fully deflated for patient and staff safety.

1. Press Pause on the touch screen. This will stop the support surface from inflating any further.
2. Once the support surface 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 support surface must be fully deflated for patient and staff safety.

1. Press Pause on the touch screen. This will stop the support surface from inflating any further.
2. Place the transfer assist device beneath the patient according to facility policy.
3. Transfer the patient according to facility policy.
4. To perform the transfer from the stretcher to the bed, follow the above instructions.

Transport of the Guardian System

ATTENTION

- Ensure all parts are clean and dry prior to transport. Transport the Guardian System support surfaces in a clear TurnCare Tote Bag. The Guardian 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 support surface, 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 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 Systems are manufactured free of material or functional defects. We agree to service the Guardian Controller if required due to malfunction and to replace or repair any controller or support surface 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 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.
- The Guardian System does not require maintenance. If an issue is encountered that appears to require maintenance, please contact TurnCare.

Replacement

The TurnCare Guardian System 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 is not active.

Storage

⚠ ATTENTION

- Ensure all parts are clean and dry prior to storage.
- When not in use, Guardian System support surfaces may be stored in an unused Guardian System 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 support surface 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 support surfaces may be cleaned using standard CDC guidelines for Healthcare facilities: Environmental Surfaces in Patient-Care Areas.

If the labeling on the support surface becomes illegible, replace the support surface.

Cleaning Instructions

1. Discontinue use according to Discontinuation of Use section.
2. Wipe down all surfaces of the controller and support surfaces using a dampened cloth or disinfectant wipe per facility protocol. Wipe both sides of the support surface, tubing, and connector. If cleaning a secured bed support surface, ensure the buckles are unclipped prior to cleaning, and are wiped down.
3. Avoid using overly saturated cloths on the controller surfaces.
4. Allow to air dry or use a clean cloth to dry the surfaces, before placing back on bed/seat.

Disposal

To ensure correct disposal, the Guardian System (controller and support surfaces) should be returned to TurnCare when no longer used. Components must be thoroughly cleaned prior to returning to TurnCare. If any support surface 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 support surface Do not use the button to insert the connector. Push in until there is a click.
	Airflow is blocked	Check the support surface flap, where the tubes are for folding or bunching. Check the tubing from the support surface to the controller for kinks or pinches.
	Patient is not on the support surface	Position the patient on the center target. Connect correct support surface being utilized.
	Component leak	Disconnect and reconnect the support surface. Replace the support surface if problem persists. Replace the controller if continues. Contact TurnCare support.
Controller does not function	Internal malfunction	Broken controller screen will appear. Unplug from AC power and Turn off. 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
Class	Class I Earthed
Voltage	100-120Vac
Frequency	50/60Hz
Power	110VA
Power Supply	Non-detachable power cord
Emergency Power Disconnection	Power cord unplug from power outlet, disconnect support surface
Battery	Lithium ion battery
Fuse	1.25 amp
Length	8.5” / 216mm
Width	13.75” / 349mm
Height	10.5” / 267mm
Weight	12.8 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.

Support Surface and Tubing Material (applied part):

- Front side support surface: TPU - Thermoplastic polyurethane elastomer (polyether)
- Back side support surface: Thermoplastic polyurethane coated onto knitted polyamide
- Tubing: TPU and polyvinyl chloride (PVC)

Secured Bed Support Surface Anchor:

- Webbing: Polyester webbing fully coated with low gloss TPU
- Buckle: 30% Glass-filled Nylon
- Threads: Polyethylene threads

Environmental

WARNING

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

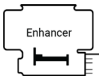
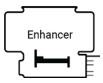
FDA Guidance – Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices

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 - 1:2021, reference no. 5.1.1)
	Non-sterile (ISO 15223 - 1:2021, reference no. 5.2.7)
	Not made with natural rubber latex (ISO 15223 - 1:2021, reference no. 5.4.5. with negation per IEC 80416-3:2002, Clause 7)
	Consult instructions for use (ISO 15223 - 1:2021, reference no. 5.4.3)
	Use by date (ISO 15223 - 1:2021, reference no. 5.1.4)
	Date of manufacture (ISO 15223 - 1:2021, reference no. 5.1.3)
	Medical Device (ISO 15223 - 1:2021, reference no. 5.7.7)
	Lot # (ISO 15223 - 1:2021, reference no. 5.1.5)
	Product code (ISO 15223 - 1:2021, reference no. 5.1.6)
	Serial # (ISO 15223 - 1:2021, reference no. 5.1.7)
	Unique Device Identifier (ISO 15223 - 1:2021, reference no. 5.7.10)
	Caution (ISO 15223 - 1:2021, 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)))
	Controller
	Loose bed support surface
	Secured bed support surface
	Seat support surface
	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)
	Single Patient Multiple Use (ISO 15223 – 1: 2021, reference no. 5.4.12)

LEGAL NOTICES

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GUARDIAN

by TURNCARE.