TurnCare

Guardian

TurnCare Guardian 2 System User Manual

Version 9

2021-04-02

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. 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 2 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 enhancer application and attachment, including but not limited to air fluidized beds
- Not for use with patients exceeding 250 kilograms or 550 pounds

Clinical Considerations

A healthcare professional should evaluate each patient to ensure that the decision to use the Guardian 2 System is appropriate. The Guardian 2 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 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 2 System 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 2 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 2 System 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 2 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 side pillows inflated. For patient safety, side pillows must be fully deflated prior to transfer.

⚠ ATTENTION

- The Guardian 2 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 2 System. 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 2 Controller on an IV pole, place the controller at the base of the pole to ensure stability.
- The Guardian 2 System is not intended for use in the home healthcare environment.

CONTENTS

INTRODUCTION

The TurnCare Guardian 2 System is a portable, therapeutic, multi-use patient support system designed to prevent sacral region vascular compromise. The Guardian 2 System protects high-risk patients in various positions across multiple surfaces, allowing clinicans flexibility while reducing risk.

The TurnCare Guardian 2 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 impaired 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 2 System can include improved pressure injury prevention and treatment, reduced length of stay in specific patient populations, and decreased pain and discomfort.

Guardian 2 System

The Guardian 2 System consists of the following components:

- Guardian 2 System, Controller (G2S-C, G2S-C-EU1)
- Guardian 2 System, Enhancer-Bed-70" integrated tube connector (G2S-EN-BD-70)
- Guardian 2 System, Enhancer-Seat-70" integrated tube connector (G2S-EN-ST-70)
- Guardian 2 System, Enhancer-Wheelchair-36" integrated tube connector (G2S-EN-WC-36)
- Guardian 2 System, Enhancer-Procedure Table-70" integrated tube connector (G2S-EN-PT-70)

A tote bag (G2S-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 2 System 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 2 System should not be brought into the MRI room.

Controller

The Guardian 2 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.

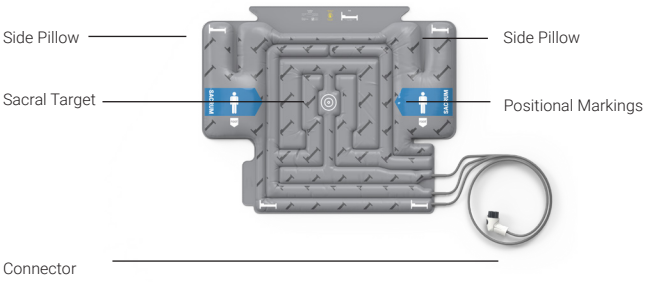
WARNING

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

Enhancers

The Guardian 2 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 2 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.

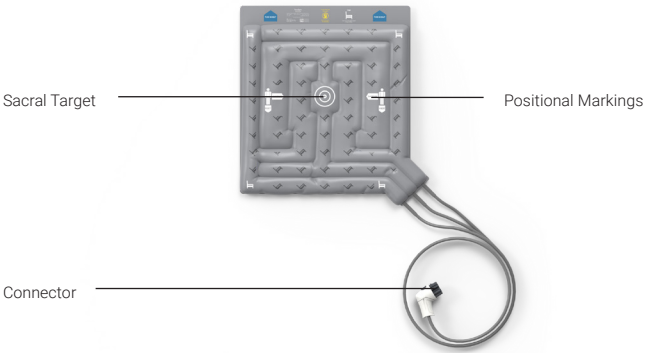
Bed Enhancer



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

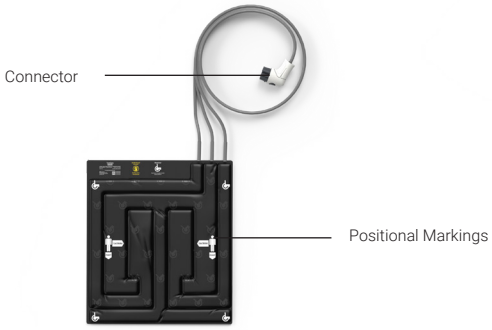
The bed enhancer consists of anatomy-specific air chambers and side pillows. The side pillows are an optional feature that will be pre-set to default to either an ON or OFF state at the start of therapy, per facility needs. They can be used to help maintain the patient in proper alignment on the bed enhancer. Both side pillows are marked with a blue arrow that points to the sacral target to assist with patient positioning. The bed enhancer is not intended for use on stretchers or procedure tables.

Seat Enhancer



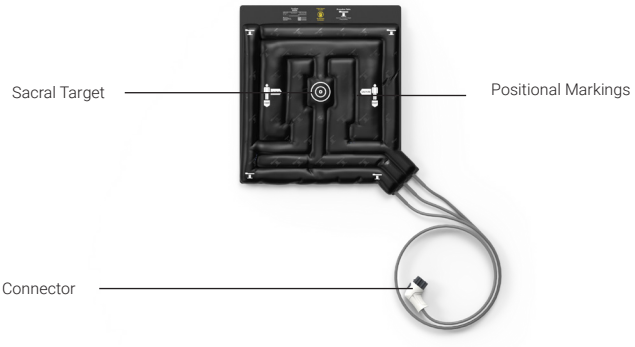
The seat enhancer also consists of anatomy-specific air chambers, but does not include side pillows in order to promote correct and safe application. The seat enhancer is typically utilized on recliners, but may also be used on other seating surfaces.

Wheelchair Enhancer



The wheelchair enhancer is similar to the seat enhancer in that it does not include side pillows. The Guardian 2 Wheelchair Enhancer is unique in that it is designed specifically for wheelchair seating, and therefore incorporates a smaller geometric design that is unique for an upright sitting position. If using the Guardian 2 System on a standard, open-sided chair, the wheelchair enhancer is recommended for use, based on its geometry.

Procedure Table Enhancer



The procedure table enhancer also consists of anatomy-specific air chambers, but does not include side pillows in order to promote correct and safe application to the procedure table.

Tote Bag

The Guardian 2 System 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 saftey reasons, the controller should be carried separately. Tote bags are for single patient use.

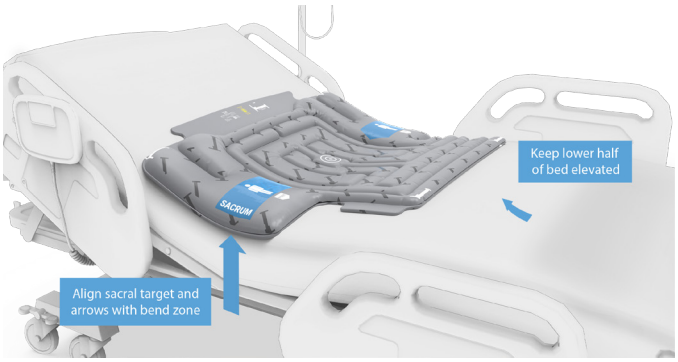
SETUP

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 side-lying 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.

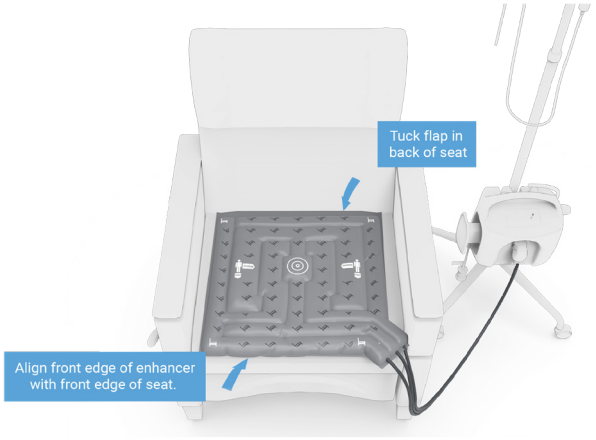
Bed Enhancer Set-up without Patient in Bed

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.



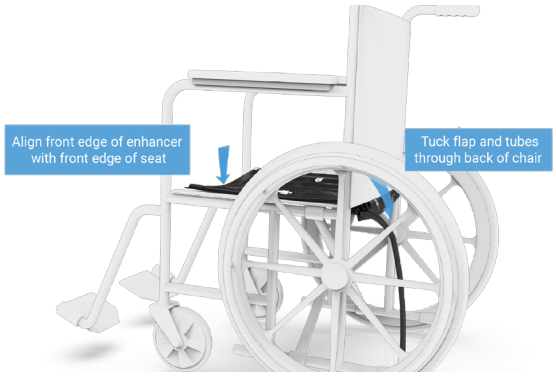
Seat Enhancer Set-up

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.



Wheelchair Enhancer Set-up

1. To assist with correctly placing the enhancer, ensure that the patient icon is appropriately oriented.
2. Orient the wheelchair enhancer so that the connector tubing is facing towards the back of the chair.
3. Center the enhancer on the chair with the connector tubing through the back of the chair. Tuck the rear flap into the back of the wheelchair, so that the front edge of the enhancer aligns with the front edge of the chair.
4. If the patient is not clothed, cover the wheelchair with the appropriate hospital linens.



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.

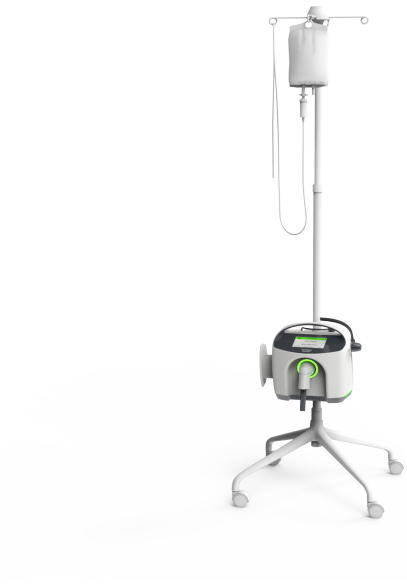
ATTENTION

- 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. 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

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.

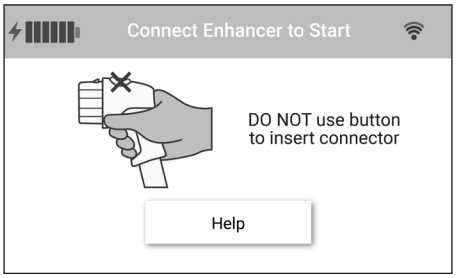


Figure 1. Set up screen

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. Enter the patient's room number. (Fig. 4)
5. Select the patient's weight range in kilograms. (Fig. 5)
6. Therapy will begin.

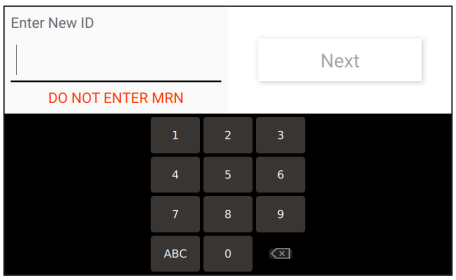


Figure 2. Patient ID entry screen

Figure 3. Patient ID re-entry screen

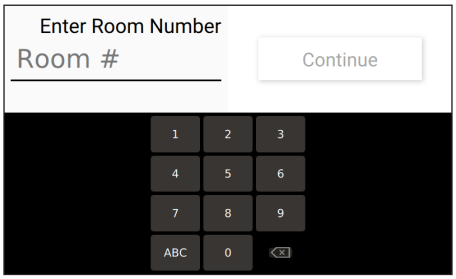


Figure 4. Patient room number entry screen

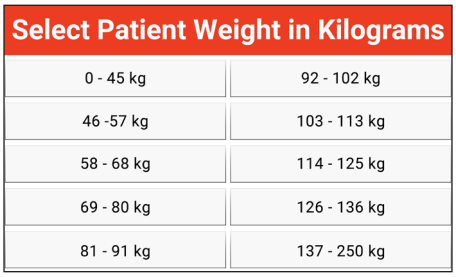


Figure 5. Patient weight screen

Running Mode

1. When the controller is operating, a screen will display with a green status bar to indicate that the controller is running. (Fig. 6)
2. The running screen will dim after 3 minutes. Touch at any time to return to full brightness.

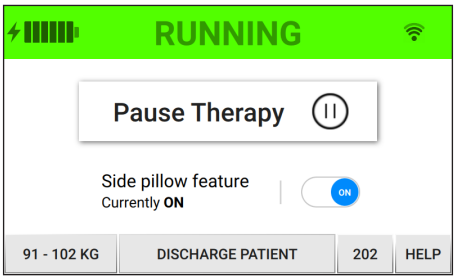


Figure 6. Running screen

Pausing Therapy

1. Therapy can be stopped by pressing "Pause" on the running screen. (Fig. 6)
2. A paused screen will display with a yellow status bar and remaining pause time displayed on the right side of the screen. (Fig. 7)
3. The controller operation will automatically resume after 1 hour, or press Resume to re-start therapy at any time.

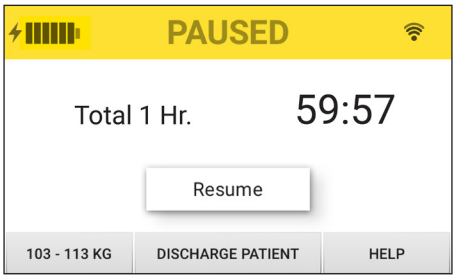


Figure 7. Paused screen

Automatic Refresh

1. When the Guardian 2 System is used long-term and approaches low memory, its memory will automatically refresh.
2. The Guardian 2 System will also refresh when a software update occurs.
3. 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. 8) Please note that this does not interrupt therapy being provided to the patient. The Guardian 2 System will remain active during the refresh process.

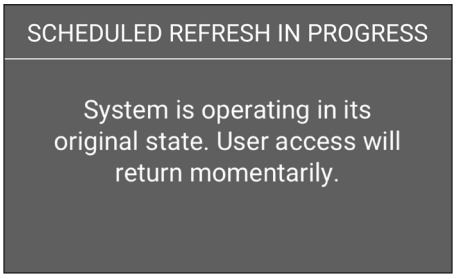


Figure 8. Scheduled refresh screen

Side Pillow Operation

1. The side pillows are an optional feature for use with the bed enhancer that will be pre-set to the default ON or OFF state at the start of therapy, per facility needs. They can be used to help maintain the patient in proper alignment on the bed enhancer.
2. Regardless of the device setting, the user may turn the side pillows on or off at any time while the bed enhancer is being used.
3. The running screen will display the current status of the side pillows at all times. (Figs. 9 and 10)
4. The side pillows may be turned on or off by pressing the button on the running screen. (Figs. 9 and 10)
5. If the Guardian 2 System is used with a procedure table, seat, or wheelchair enhancer, the side pillow button will not appear. These enhancers do not include side pillows. (Fig. 11)

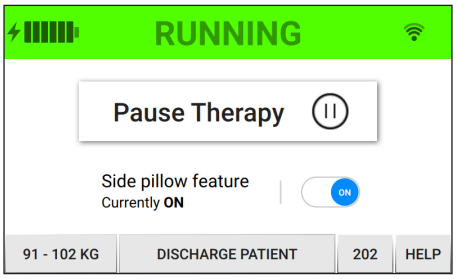


Figure 9. Running screen: side pillows on

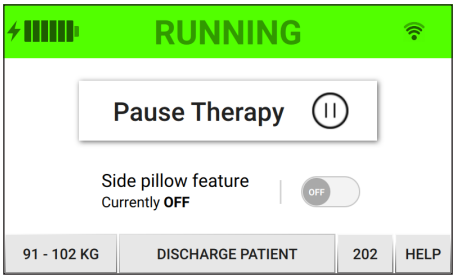


Figure 10. Running screen: side pillows off

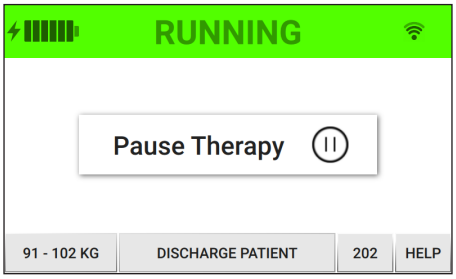


Figure 11. Running screen: no side pillows

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. (Figure 12)

Figure 12. Video menu screen

Status Lighting

The Guardian 2 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

Connectivity

The Guardian 2 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
- Cellular connected
- Cellular enabled but not connected

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. 13)
2. A confirmation screen will appear. Select Yes to discharge the patient. (Fig. 14)
3. A patient discharged screen will appear for several seconds. (Fig. 15)
4. The controller will turn off and patient data will be erased.

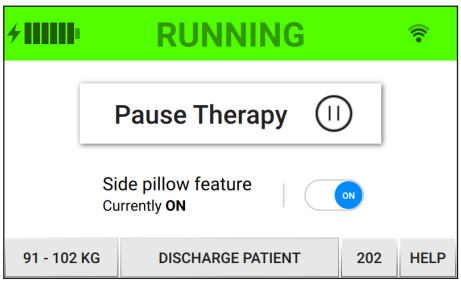


Figure 13. Discharge patient button

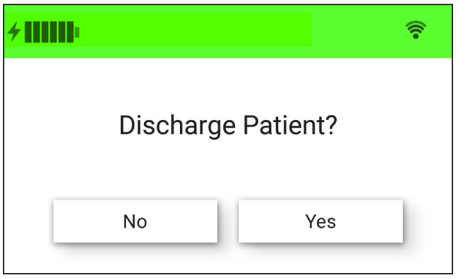


Figure 14. Confirm discharge screen

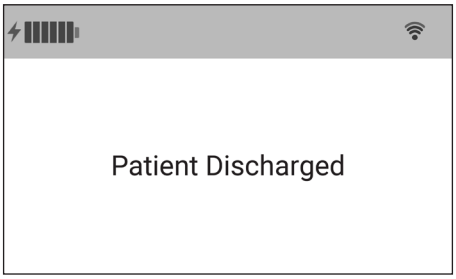


Figure 15. Patient discharge screen

WiFi Connection Alerts

1. If the Guardian System is unable to connect to WIFI when a new patient is enrolled in therapy the "No WiFi connection" alert will display. When this "No WIFI" alert occurs, an auditory alert will also sound for 3 minutes. This means that remote support is unavailable. Please contact TurnCare at (203) 290-1098. (Fig. 16)

2. If the Guardian System is unable to connect to WIFI after previously being connected to WIFI the "WIFI connection lost" alert will display. This means that the remote support is unavailable. Please contact TurnCare at (203) 290-1098. (Fig.17)

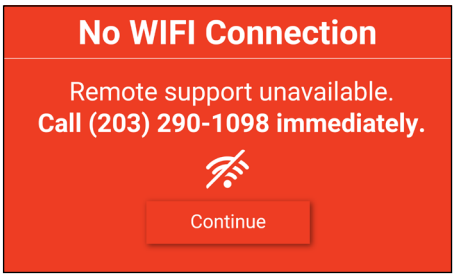


Figure. 16. No WIFI Connection

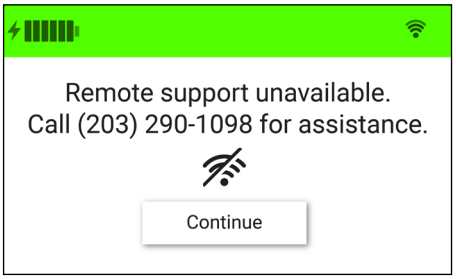


Figure 17. WIFI Connection Lost

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 2 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 2 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 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. 18 & 19)

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. 20 & 21) 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. 19)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. 22) 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 the patient's information will be cleared from the system.

Figure 18. Battery Level Indicator

Figure 19. Battery level indicator while charging

Figure 20. Battery operation visual

Figure 21. 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

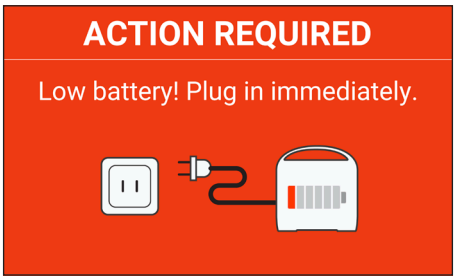


Figure 22. Low Battery Alert

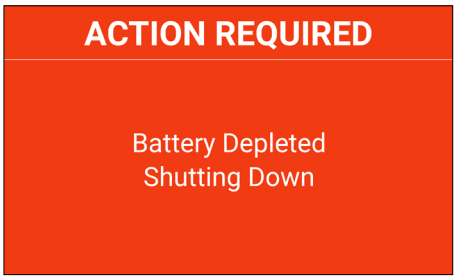


Figure 23. Terminal Battery Shutdown Alert

Action Required

Connect Enhancer to Controller

1. Insert the connecter 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. 24)

2. If the Connect Enhancer to Controller alert is not addressed for 5 minutes, an auditory alert will occur in addition to the screen.

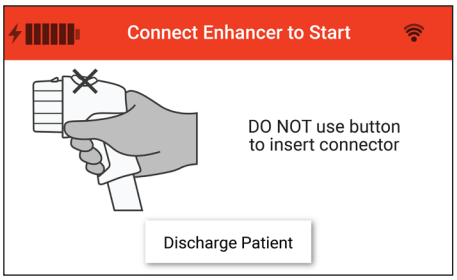


Figure 24. Connect enhancer to controller screen

Enter Patient Weight

1. The Guardian 2 System will alert the user if the user does not enter a patient weight within 5 minutes of accessing the weight selection screen. (Fig. 25)

2. The Guardian 2 System will continue to display the weight selection screen with red status lights and an auditory alert.

3. Enter the patient weight to dismiss the alert.

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

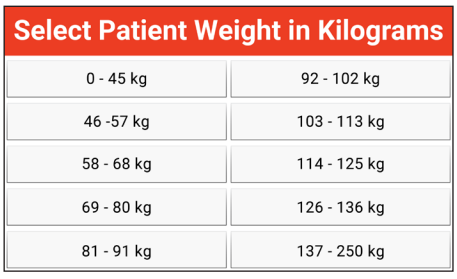


Figure 25. Patient Weight Screen

System Alert

Place Patient Properly on Enhancer

1. The Guardian 2 System will alert the user if after a period of time a patient is not detected on the enhancer. It may also alert if a patient is present but improperly positioned, with weight distributed significantly off-center from the target or if the enhancer is not completely underneath the patient.

2. For the bed enhancer, follow the visual pictured on the screen and ensure that the patient's sacrum is aligned with the blue arrows on the side pillows. (Fig. 26)

3. For the seat and wheelchair enhancers, ensure that the patient is positioned properly on the enhancer, with the sacrum centered over the target. It is important to ensure that the air chambers are entirely in contact with the underlying surface and not folded over the front of the seat. (Fig. 27)

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

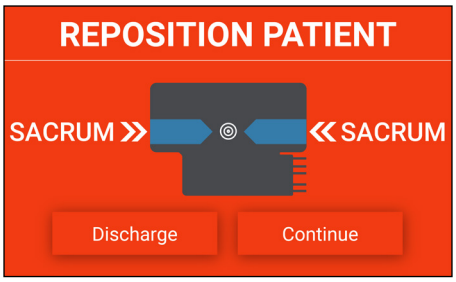


Figure 26. Patient not on bed enhancer alert screen

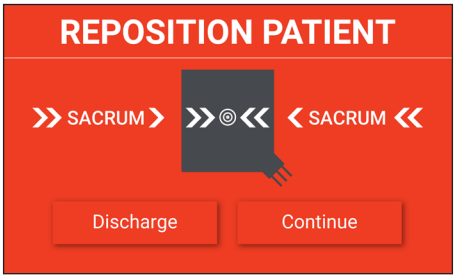


Figure 27. Patient not on seat, procedure table, or wheelchair enhancer screen

Pinched Tubing

1. The Guardian 2 System will alert the user if the connector tubing is pinched or otherwise occluded, causing an interruption in therapy. (Fig. 28)

2. Assess the connector tubing for a pinch, from the enhancer all the way to the controller, and correct any issue found.

3. Press Continue to dismiss the alert.

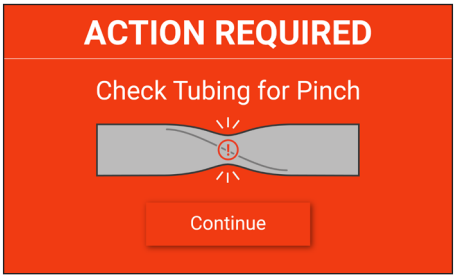


Figure 28. Pinched tubing alert screen

Problem Detected

1. If the Guardian 2 System detects a condition that is interfering with the ability to provide optimal therapy, it will alert the user. (Fig. 29)

2. The Guardian 2 System will first prompt the user to disconnect and reconnect the enhancer to ensure it is properly latched. Insert the connecter 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.

3. If the problem persists, a component failure is indicated. Follow the instructions on the screen, first replacing the controller. If the problem persists after replacing the controller, replace the enhancer. (Fig. 30)

4. Please contact TurnCare if needed for troubleshooting assistance.

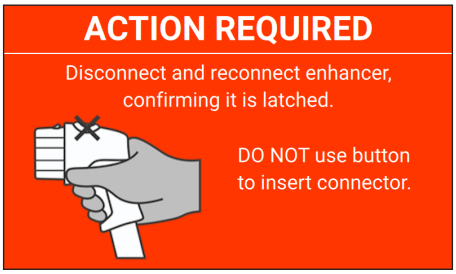


Figure 29. Initial problem detected alert screen

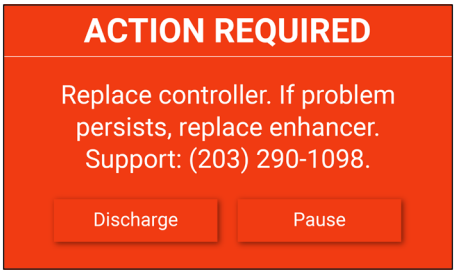


Figure 30. Persisting problem detected alert screen

Prompts

Validate Patient Room Number

1. Whenever the Guardian 2 System is plugged in, it will prompt the user to validate the current patient room number. (Fig. 31)

2. If the patient room has not changed, press Yes to return to the previous screen. If the patient room has changed, press No to access the patient room number entry screen and input a new room number.

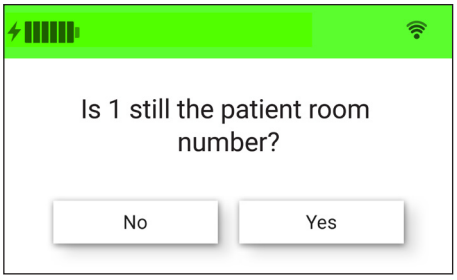


Figure 31. Validate patient room number screen

CLINICAL USE

Patient Alignment on the Bed Enhancer in Supine and Upright Positions

1. The bed enhancer's side pillows can be used to assist with keeping the patient properly positioned on the enhancer in supine position, with the head of the bed elevated to any degree, from flat to upright.

2. If the side pillow feature is set in the default on state, the two side pillows will inflate when therapy is initiated. Check to ensure that both side pillows are fully inflated. If the opposite side pillow does not fully inflate within 1-2 minutes, adjust the patient's position to facilitate airflow to the opposite side.

3. If the side pillow feature is set in the default off state, the two side pillows will not inflate when therapy is initiated. The side pillows can be turned on at any time by pressing the button on the touch screen.

4. 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 blue arrows on the side pillows.

5. 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.

6. Patient alignment on the bed enhancer can be quickly checked by viewing the graphics on the side pillows. The blue arrow on the side pillows should point to the patient's sacrum when correctly positioned.

Patient Alignment and Positioning with Turn Assist Devices

1. 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. In most of these circumstances, we recommend defaulting side pillows to off.

Patient Alignment on the Bed Enhancer in Sidelying

1. Depending on body habitus, the side pillows may or may not be used when the patient is positioned in the sidelying position. If the side pillows are inflated and it is desired to have them deflated, press the button on the touch screen.

2. 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 blue arrows on the side pillows.

3. Patient alignment on the bed enhancer can be quickly checked by viewing the graphics on the side pillows. The blue arrow on the side pillow should point to the patient's sacrum when correctly positioned.

Prone Positioning on the Bed Enhancer

1. If the Guardian System is being used with the side pillows on, be sure to first turn them off by pressing the button on the touch screen so that when therapy is resumed they do not inflate, causing a potential safety issue to the patient.

2. Pause therapy.

3. If side pillows were in use, wait for them to fully deflate. Moderate pressure can be applied to the side pillows to assist with deflation.

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

5. Resume therapy. Ensure that the side pillows are turned off to avoid improper upper extremity positioning.

6. When returning the patient to the supine position, be sure to Pause therapy prior to repositioning the patient.

Patient Alignment on the Seat, Wheelchair, 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.

Side Pillow Use

⚠ ATTENTION

- If being used, check to ensure that both side pillows inflate after initial set-up. If one or both are not inflated, shift the patient's weight to allow any air that may be potentially trapped to circulate to the opposite side.
- If the side pillows, once inflated, make unequal contact with the patient, or only make contact with one side of the patient, reposition the patient to be centered between the side pillows.
- Depending on body habitus, the patient's lateral trunk may or may not make contact with the side pillows when the patient is centered on the enhancer. If the patient is in firm contact with the side pillows, it is suggested to deflate the side pillows by pressing the Deflate Side Pillows button.
- If patient positioning wedges are being used, it is recommended to turn the side pillows off while the wedges are in use with the patient.

⚠ WARNING

- Ensure the side pillows are turned off at all times while being used with a patient in the prone position to avoid improper upper extremity positioning which may cause discomfort or injury to the patient.

Transferring the Patient In and Out of Bed

⚠ WARNING

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

1. Press Pause on the touch screen. Allow the pillows to fully deflate if being used.
2. Once the side pillows are 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 side pillows must be fully deflated for patient and staff safety.

1. Press Pause on the touch screen. Allow the pillows 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 2 System

⚠ ATTENTION

Ensure all parts are clean and dry prior to transport. Transport the Guardian 2 System using the Guardian 2 Tote Bag. The Guardian 2 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. Once the patient has been discharged from therapy, unplug the controller from AC power and remove the connecter.
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 2 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 labelling.

TurnCare warrants that all Guardian 2 Systems are manufactured free of material or functional defects. We agree to service the Guardian 2 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 2 System does not include user servicable parts. Return to the manufacturer for servicing.

MAINTENANCE

⚠ WARNING

Do not attempt to modify, disassemble, or otherwise alter the Guardian 2 System.

The Guardian 2 System does not require maintenance. If an issue is encountered that appears to require maintenance, please contact TurnCare.

Replacement

The TurnCare Guardian 2 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 2 System is not active.

Storage

⚠ ATTENTION

- Ensure all parts are clean and dry prior to storage.
- When not in use, Guardian 2 Enhancers may be stored in an unused Guardian 2 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 2 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	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	Attach the connector properly
	Air cannot flow through the connector tubing	Check the connector for kinks or occlusions. Check to ensure the connector is securely inserted.
	Patient is not on the enhancer	Position the patient on the center target.
	Enhancer leak	Replace the enhancer and 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.
Enhancer does not inflate sufficiently	Defective/leaking enhancer	Check the enhancer for leaks by pressing on it when it is inflated and listening for air flow. Check the connector for kinks or occlusions and ensure that it is securely inserted. If alarm persists, replace the enhancer and contact TurnCare support.
	Defective controller	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 problem persists, contact TurnCare support.
	Defective controller	Contact TurnCare support.

TECHNICAL SPECIFICATIONS

CONTROLLER	
Model	G2S-C, G2S-C-EU1
Class	Class I Earthed
Voltage	G2S-C: 100-120Vac G2S-C-EU1: 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 250 kg (550 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 & tubing: TPU - Thermoplastic polyurethane elastomer (Polyether)
- Back side enhancer: laminated nylon/TPU coated with clear, non-slip, matte-finished silicone rubber

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 2 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 C1SPR 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 his 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

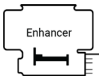
FDA Guidance – Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices

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)
	Medical device
	Lot # (ISO 15223 - 1:2016, reference no. 5.1.5)
	Product code (ISO 15223 - 1:2016, reference no. 5.1.6)
	Serial # (ISO 15223 - 1:2016, reference no. 5.1.7)
	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 marking (765/2008/EC 768/2008/EC MDD 93/42/ EEC Articles 4,11,12,17, Annex II)
	European Authorized Representative (ISO 15223 - 1:2016, reference no. 5.1.2)
	Controller
	Bed enhancer
	Procedure table enhancer
	Seat enhancer
	Wheelchair 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

TurnCare is a trademark belonging to the TurnCare, Inc. company. As our policy is one of continuous improvement, we reserve the right to modify designs without prior notice.

CONTACT

TurnCare Inc.

230 West Parkway

Unit 6, Pompton Plains

New Jersey 07444 US

(203) 290-1098

support@turncare.com

Emergo Europe

Prinsessegracht 20

2514 AP The Hague

The Netherlands

TurnCare

Guardian