Instructions for Use

GTIFU01 Version H, August 2025

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1 Introduction

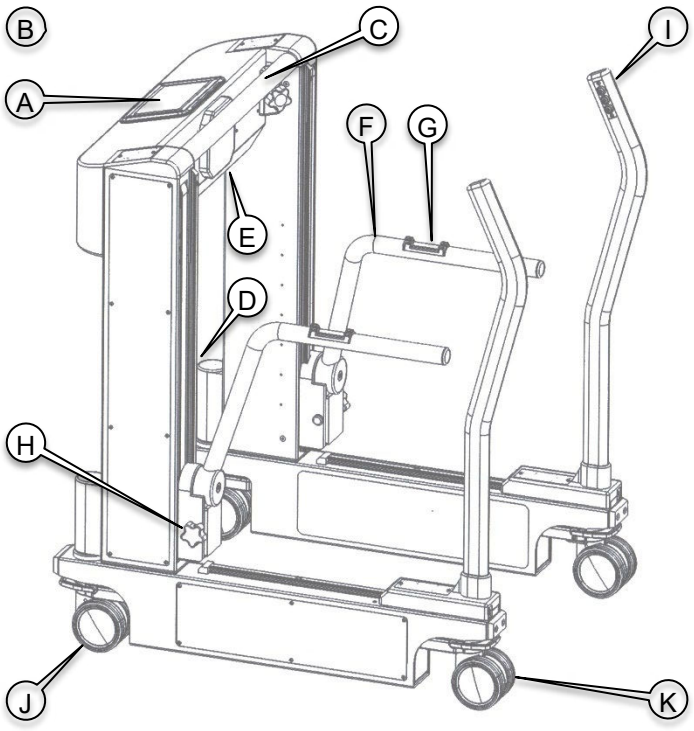
The Lite Run Gait Training System is a Class I, internally powered device, intended to be used by a trained medical professional as a gait training tool. The innovative system uses differential air pressure and space suit technology to dynamically unweight (or lift) a patient during gait training therapy.

The Lite Run Gait Training System has two components: a battery powered gait trainer (GT01) and a soft lower exosuit (Exosuit or pants) The Exosuit latches into the GT01 and connects to an air compressor via an air hose. The compressor delivers air pressure to the Exosuit and as air pressure builds, the differential air pressure causes an upward force, unweighting the patient.

This guide will explain how to set-up and use the GT01 during gait training and physical therapy.

2 System Features

2.1 Key GT01 Features



A. Touch Screen
B. Power switch & emergency stop (front, not visible)
C. Handle bar
D. Pressure hose connect
E. Charging port
F. Lift arms
G. Lift arm latches
H. Lift arm width adjustment
I. Rear push bar
J. Front casters
K. Rear casters

2.2 GT01 Specifications

- Maximum device weight with all accessories: 200lbs (90.9 kg)
- Maximum patient weight: 350lbs (159 kg);

- Environmental operating conditions: 10-30°C, 10-80% humidity and atmospheric pressures of 72-100 kPa.
- Battery charger: 100-240 VAC, 50/60 Hz, (see Appendix E).
- Maximum rated life: 5 years.

2.3 Key Exosuit Features

- Color: gray-green
- A safety strap support for the patient's upper torso.
- All Velcro™ latches (no buckles).
- Knee straps for PT assistance in gait therapy.
- The legs zip open to facilitate donning and doffing.
- Machine washable.

2.4 Exosuit Specifications

- Waist Sizes: 30, 32, 34, 36, 38, 40, 42, 44, 46, 48, 50 & 52.

3 Warnings

Sources of harm or injury include:

- Unintentional brake lockup may result in a sudden stop.
- Walking into an obstruction causing a sudden stop.
- Operating the system too fast to avoid an obstruction.
- Tipping the system over.
- Patient fainting while in the system.
- Fingers being pinched during operation.
- Sudden pneumatic failure leading to unexpected unweighting.
- Not removing or adjusting for wheelchair arm rests when connecting, raising or lowering a patient

Attention:

- The GT01 must not be used on inclined surfaces.
- When transferring a patient from the GT01 to a wheelchair, if wheelchair features interfere with the descending lift bar, raise the patient and reposition the wheelchair before continuing.
- The GT01 battery must be charged before use.
- The power switch must be turned OFF during charging.

- Only use the specified battery charger, plugged into the indicated GT01 receptacle and a standard 120V outlet.
- The charger should be connected anytime the device is not being used for therapy.
- The batteries should be removed if the GT01 is to be unused for longer than 3 months.
- A qualified technician may contact Lite Run technical support for battery removal instructions.
- Modification of this equipment is not allowed.

4 Indications for Use

The product is an “unweighting walker” with attendant balance stabilization. It is intended for use in a clinical environment by trained medical professionals. In addition, the system is intended for facilitating ambulation for patients with an impaired ability to stand or walk.

5 Contraindications

This system is contraindicated for patients that are ineligible for ambulation therapy.

6 Instructions for Use

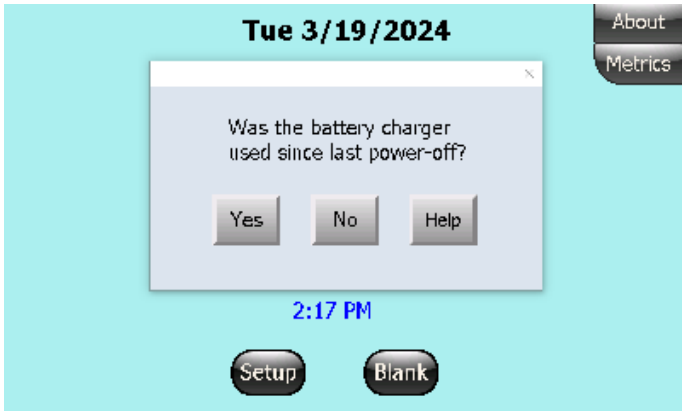
6.1 Turning on the GT01

A black switch on the front of the GT01 turns the system on and off. Flip the switch to **ON** to power up the system. The GT01 runs on a battery and should be fully charged at the start of each therapy session. See Section 6.14 for a guide to charging the GT01.

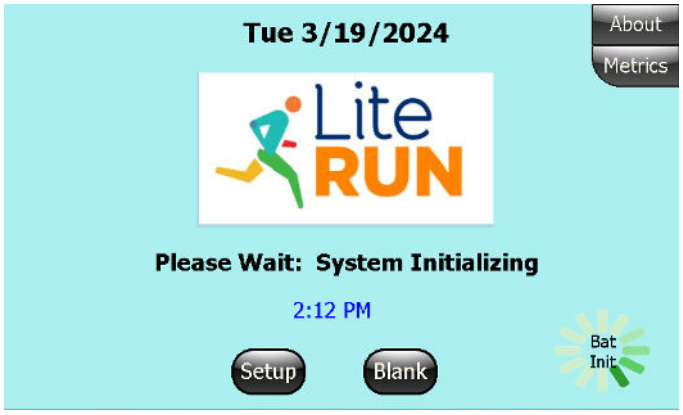
6.2 Using the Touch Screen Interface

A touch screen on the front of the Lite Run system allows you to control and interact with the GT01. The touch screen is pressure sensitive and requires a firm touch or tap when pressing a button or selecting a value.

6.3 The “New” Screen



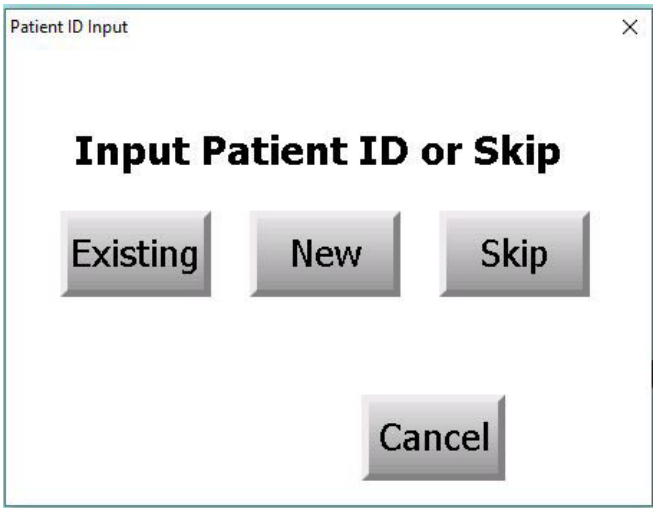
When the GT01 is first turned on, this dialog box will appear. Typically, if the charger was used during the off time, you should tap ‘Yes’. If it was not, or you are unsure, tap ‘No’.



A rotating 'busy wheel' will show over the battery gauge for a few seconds while the system is calculating the battery charge level.

***Note**: if the system has just powered up, the message "Please Wait: System Initializing" will show in blue. When ready, the "Press Setup to Begin" message will show. Pressing the **Setup** button brings up the Input Patient ID Selector.*

6.4 Input Patient ID Selector



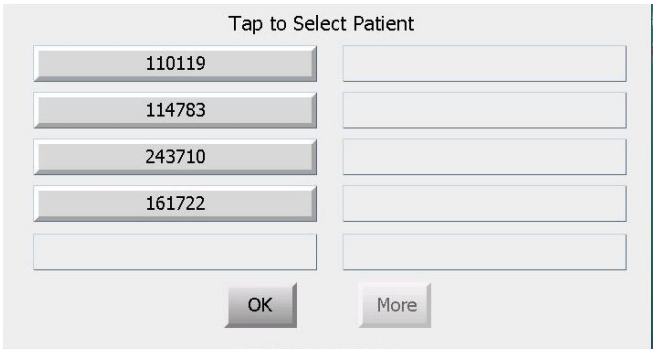
If your site has chosen to use the Patient ID option (and thus the ability to store patient metrics), the "Input Patient ID" selector will appear.

Tap **Existing** to bring up a listing of patient IDs in the database.

Tap **New** to set up a new patient.

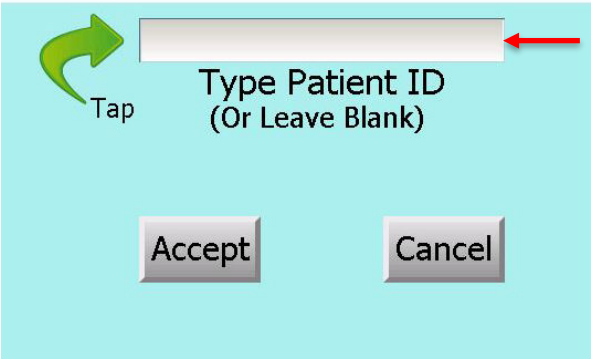
Tap **Skip** to move forward without entering a patient ID.

Tap **Cancel** to return to the previous screen.



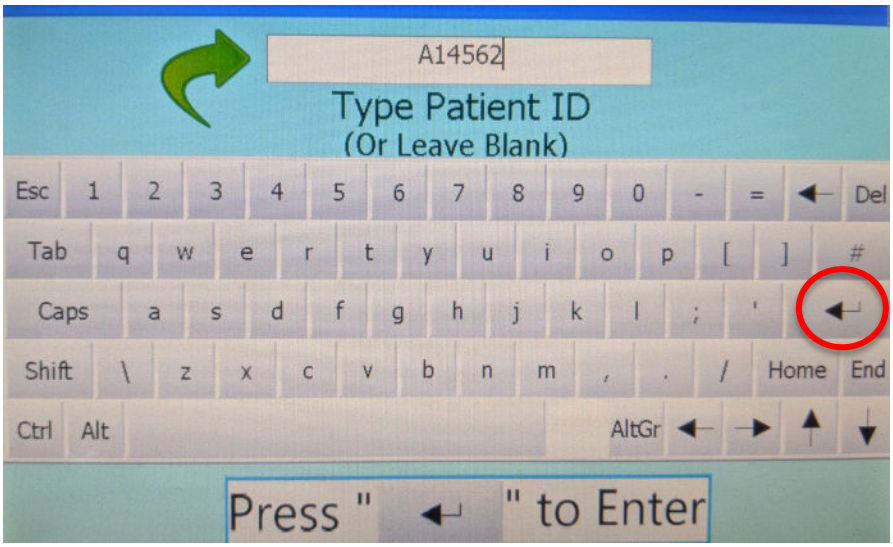
If **Existing** is selected, tap the current patient's ID in the list to select it. The selection will turn green, then tap **OK**.

Tapping the **New** button on the “Input Patient ID” selector brings the following menu up.

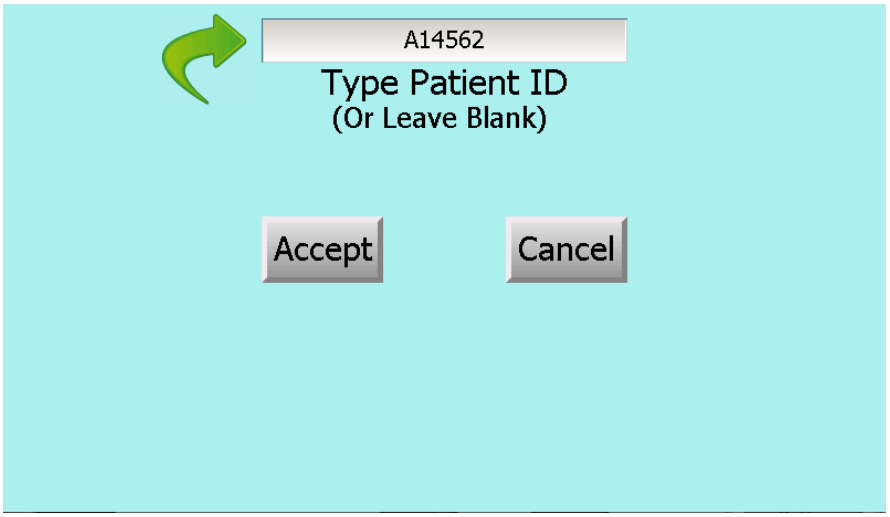


Tap the “Type Patient ID” box to enable the alphanumeric keypad

Once the alphanumeric keypad appears, the patient ID may be keyed in by tapping the letters and numbers. When complete, tap the “Return” key as indicated below.



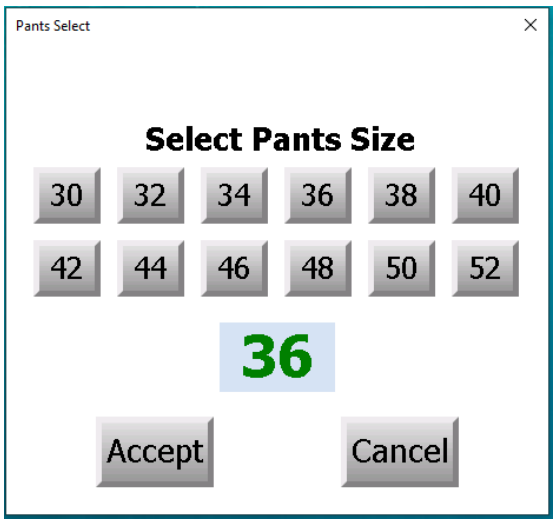
Tap the “Return” key to complete patient ID entry.



Tap **Accept** to proceed.

Tap **Cancel** to go back to the previous screen.

6.5 Exosuit Size Selector



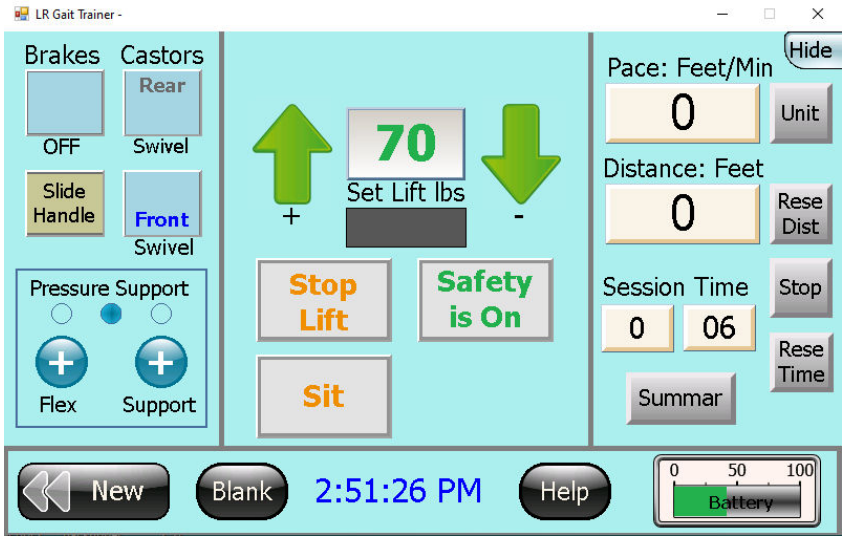
Tap the Exosuit size that the subject is wearing.

The selected value will appear in green text in the window adjacent to the **Accept** button.

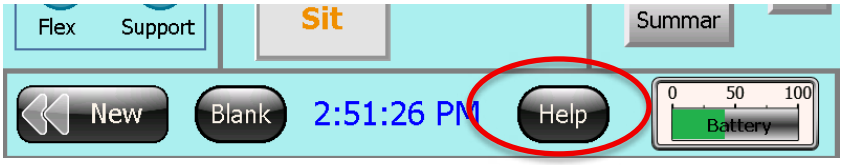
Tap **Accept** when the value shown is correct and the Setup Screen will appear.

6.6 The "Setup" Screen

The Setup Screen will appear following the **Accept** button from the Exosuit Selector popup. This is the primary screen that is operative for system use. It will allow you to start the unweighting (or "lift"), vary the amount of lift, control brakes and steering, access the Safety button and use the **Boost** function to add extra lift for sit-to-stand or other maneuvers. In addition, the study parameters may be viewed.



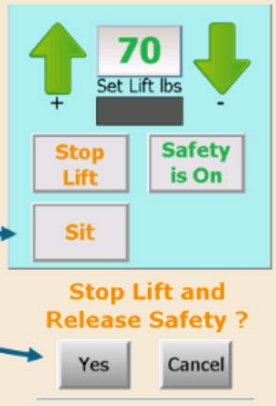
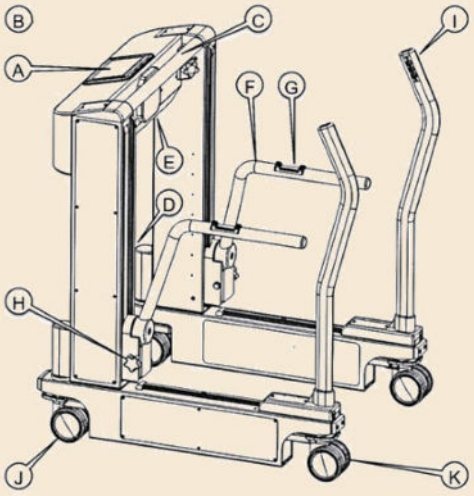
6.6.1 The Help Button on Setup Screen

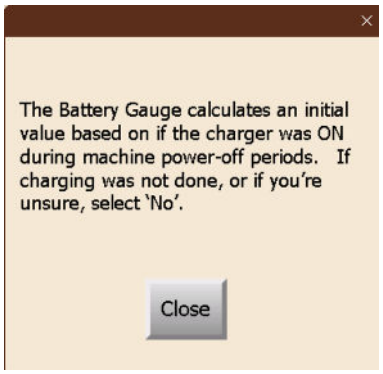


Tapping the Help button at the bottom of the Setup screen brings up a 7-option drop-down menu of topics that may be selected for additional information according to the following table.

Table 1. Help Menu Options.

Button	Response
Video QR	Setup Video: Point Cell Phone Camera or QR Reader at Code The "Video QR" button provides a QR code to an online video that may be especially useful to new users.
Sit-> Stand	**Operator: Sit-to-Stand from Wheelchair Instructions** 1) Press the black buttons on the Push Bars (**A**) to release the bases, and swing then swing them open. 2) Seat subject near front of wheelchair (this will help with latch-in). 3) Adjust the lift bars width by turning knobs (**B**) to accommodate the wheelchair. 4) Wheel the subject forward to align the pants latch pins and latches (**C**). 5) Insert each pin into the latch with the green side of strap facing up. 6) Lock the wheelchair and release the **GT** brakes. 7) Connect the air hose to the exosuit quick connect nozzle. 8) Ensure that the arm rests are up and out of the way (not shown). 9) Have the subject place hands on padded crossbar (**D**). 10) On the **Setup** screen, set **Lift** to a generous amount up to ½ of subject's body weight. 11) Explain to subject that they will soon feel the air pressure and tap **Start Lift.** 12) The **Boost** will appear after the exosuit inflates. Allow the progress bar on **Boost** display to reach near near completion before asking the subject to stand. 13) As the subject begins to stand, pull the **GT** forward slowly about 1 foot to aid the transition. 14) Once the subject stands, tap **Cancel** on **Boost**, lower the arm rests and engage the subject's arms. Boost Lift Active % Lift Cancel Boost Sit Boost A B C D

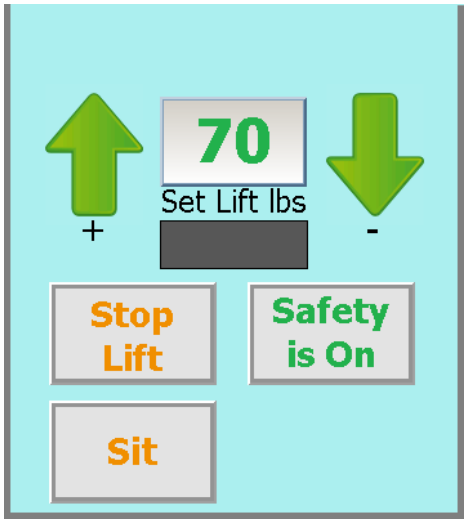
Button	Response
Stand-> Sit	**Operator: Stand-to-Sit Instructions** 1) Position the wheelchair immediately behind the subject and lock the brakes 2) Position yourself in front of the **GT**, facing the subject 3) Move the armrests to the upright position 4) Release the **GT** Brakes 5) Tap the **Sit** Button a. Tell the subject that in a moment they will be asked to sit down b. Tap '**Yes**' Button to confirm pop-up 6) Ask the subject to sit, and as they descend, slowly push GT towards them about 1 foot so that they sit directly onto the wheelchair 
Sit->Stand Bench / Bed	**Operator: Sit-to-Stand from Bench or Bed Instructions** 1) Check that the bench or bed has 7" clearance for the **GT** bases (**A**) to slide beneath 2) Proceed to the Setup screen by entering patient ID and exosuit size 3) Press the black buttons on the Push Bars (**B**) to release the bases, and swing then swing them open. 4) Tap the Slide Handles button on the Touchscreen, and slide the handles (**C**) forward 5) Seat subject near edge of bench or bed (this will help with latch-in. 6) Adjust the lift bars width by turning knobs (**D**) to accommodate the subject. 7) Wheel the **GT** toward the subject, and lift bars as needed to align exosuit latch pins and latches (**E**). 8) Insert each pin into the latch with the green side of strap facing up. 9) Connect the air hose to the exosuit quick connect nozzle. 10) Release the **GT** brakes. 11) Ensure that the arm rests are up and out of the way (not shown). 12) Have the subject place hands on padded crossbar (**F**). 
Diagram	 A. Touch Screen B. Power switch & emergency stop (front, not visible) C. Handle bar D. Pressure hose connect E. Charging port F. Lift arms G. Lift arm latches H. Lift arm width adjustment I. Rear push bar J. Front casters K. Rear casters

Button	Response
Battery	
Close	Returns to the Setup Menu.

6.6.2 The Safety Stop Feature.

The GT01 has a physical "Safety" stop that prevents a subject from lowering more than a few inches once they are standing, regardless of the status of the unweighting air pressure. When starting with a new subject, the Safety is ON by default. Thus, once a subject stands up, the Safety will prevent them from lowering or falling below the physical stop. This also means that for a patient to return to a sitting position, the Safety must be turned OFF by pressing the button shown below, OR by using the Sit button.

Important: Once a patient sits down during a session, the Safety will normally have been turned OFF, and if it is desired to stand the patient up again, the Safety should manually be re-enabled. This can be done at any time, as having the Safety ON will not impede the standing motion.

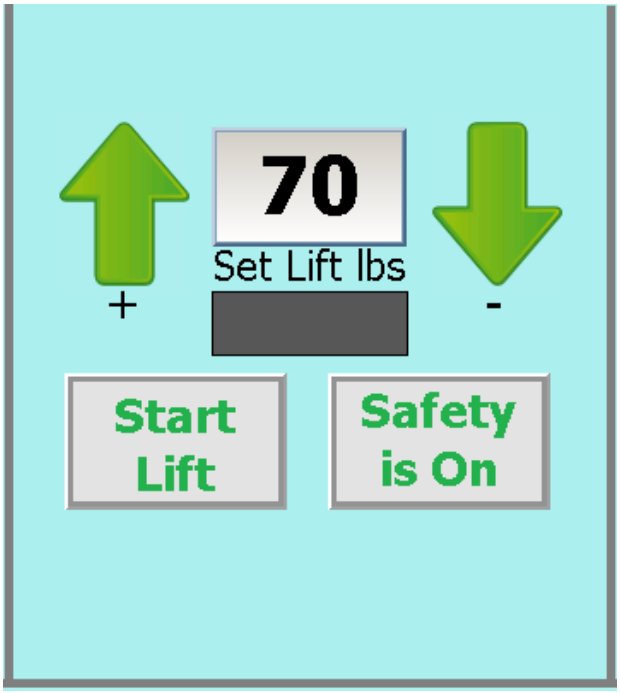


Tapping "Sit" will bring up a dialog (below) that will allow you to turn off, or release the Safety, as well as Stop the unweighting, with one button press.

Alternatively, tapping the button labeled "**Safety is ON"** in green text will cause the label to switch to state "**Safety OFF"** in red text. In this case, Stop Lift will also be need to be pressed to stop unweighting which is necessary for the patient to sit down

6.6.3 How to set the desired lift

The amount of desired lift in pounds is selectable using the large green arrows. The range is from 10 pounds to up to 150 pounds (the latter available for the larger Exosuit sizes). The maximum unweighting that is available will depend on the Exosuit size which correlates to the patient's weight. The upper limit is lower for smaller Exosuit sizes. (See Appendix A for a table showing the maximum lift for each size.)



Tap green arrows to increase or decrease lift

Press **Start Lift** when ready to unweight the subject. This will bring up a Safety Checklist.

6.6.4 Start Lift and Checklist Popup

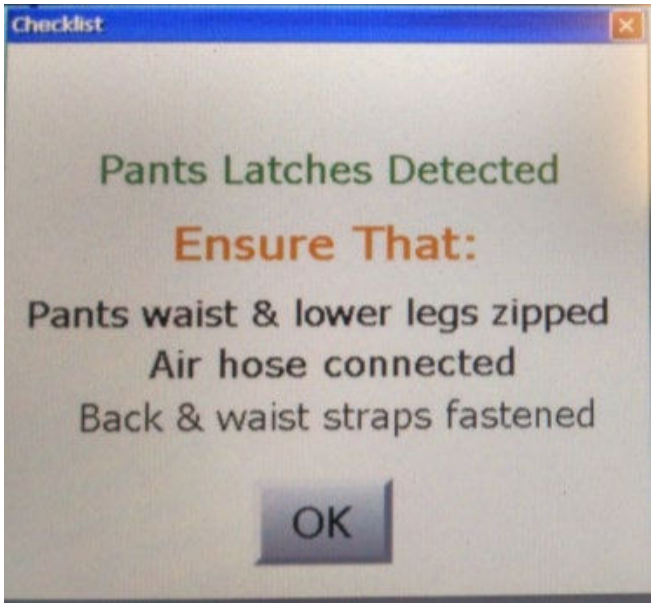
The Checklist popup shown below appears after selecting **Start Lift** from the Setup screen. If correct Exosuit latching is detected, pressing **OK** initiates unweighting.

The Exosuit latch sensors (right and left) detect latch state.

If they are not correctly latched it will indicate this in a red message.

The latching must be corrected to begin unweighting.

Pressing **OK** will remove the popup without starting unweighting.

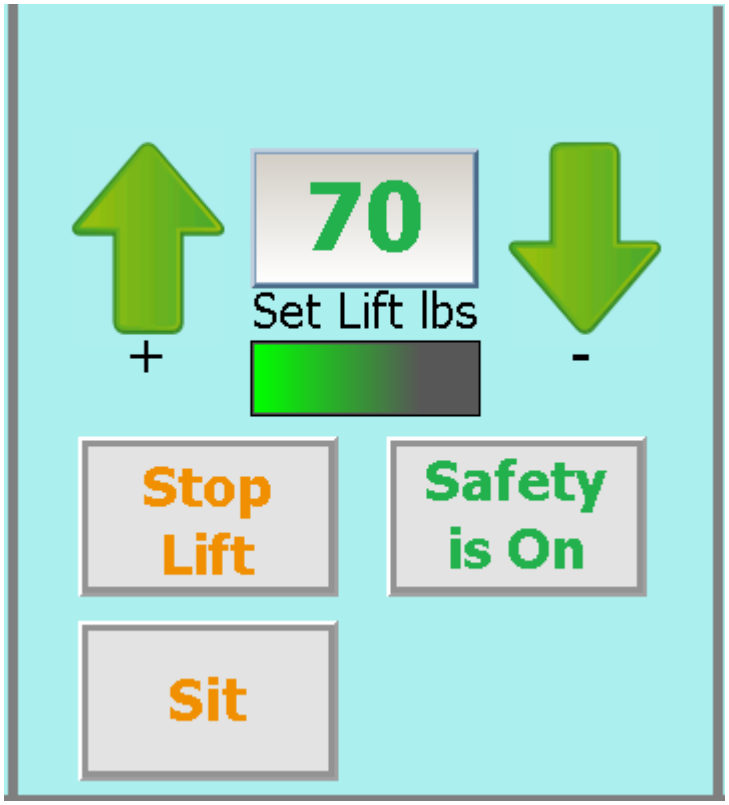


This message will appear in green when the correct Exosuit latch state is detected.

Verify the other checklist items before pressing **OK**, which will begin unweighting.

6.6.5 Progress Bar

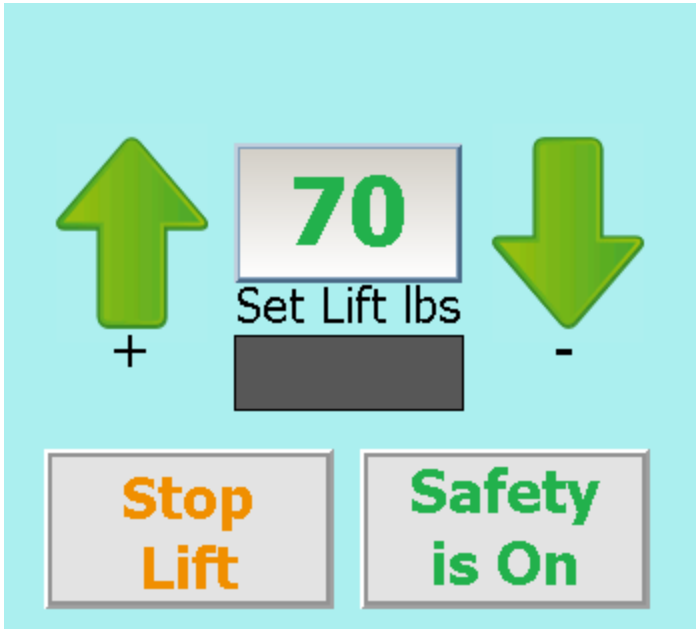
The Progress Bar indicates the progress of air pressure building up in the Exosuit. When the bar reaches 100%, the desired amount of lift, or unweighting has been reached.



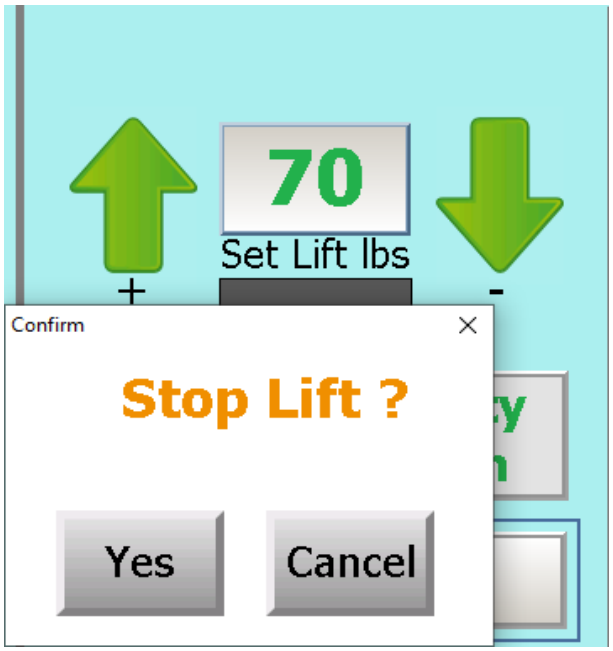
The unweighting requires air pressure to build and can take from 10 to 60 seconds.

This bar shows progress (the example here is at about 75%) with respect to the target lift of 70 lbs.

6.6.6 Adjusting or Stopping Lift

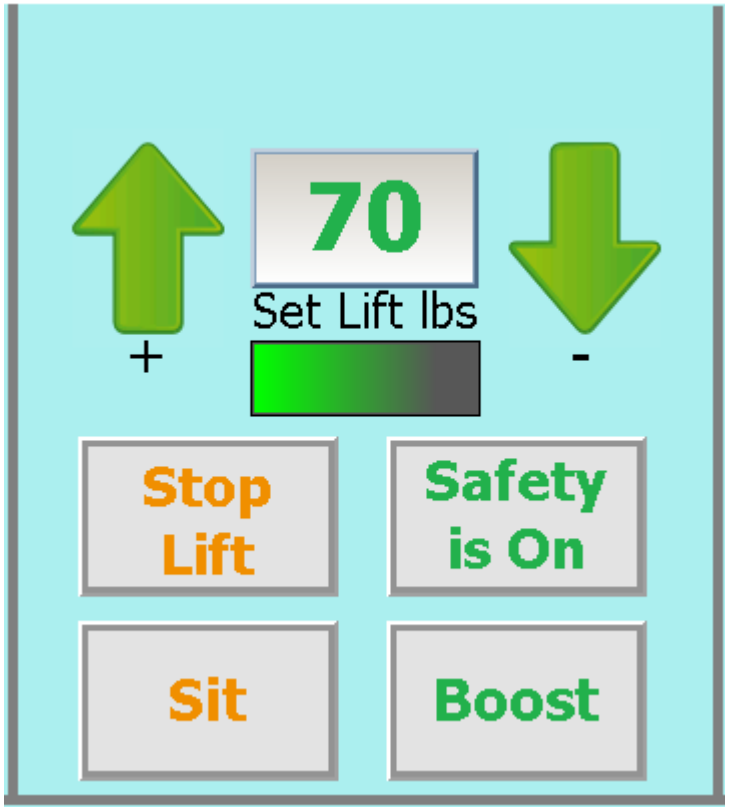


The lift value may be adjusted higher or lower using the green Up/Down arrows at any time while the subject is being unweighted


70
Set Lift lbs
+
-
Confirm
Stop Lift ?
Yes
Cancel

6.6.7 The Boost Function

The Boost function adds temporary extra lift to assist patients with sit-to-stand transitions.



Boost is setup to automatically engage upon first use with a patient, once Exosuit pressure reaches 80%. For use in subsequent sit-to-stand transitions with the same patient, tap this key.

Boost can be engaged manually at anytime (once Exosuit pressure is at least 80%) by pressing the manual Boost button

Note: The boost value will not exceed the upper unweighting level of the Exosuit size in use.

When Boost is activated, a pop-up will appear to indicate this.

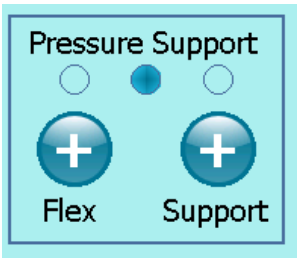
The progress bar indicates the percent of maximum boost. Thus during sit-to-stand transitions it may be useful to wait a few seconds until bar is fully green, or nearly so.

Boost automatically cancels after about 30 seconds. It may be cancelled at any time prior to that by tapping the **Cancel Boost** key.

6.6.8 Pressure Support Adjustment (Optional)

The Lite Run Exosuits provide patient lift using differential air pressure in conjunction with a counter-balancing system. Due to differences in patient morphology and/or patient condition, it is sometimes useful to adjust the Exosuit pressure independently of the lift setting. This capability is provided in the Pressure Support panel. There are 3 settings: **Flex**, **Nominal** and **Support**. It will take a few seconds once a setting is changed for Exosuit pressure to adjust. **Note:** Adjustment of the Pressure Support is not routinely required.

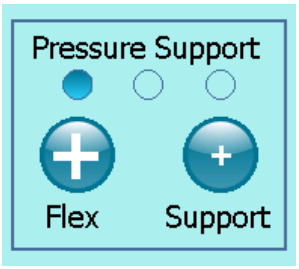
Nominal: most comfortable for most patients.



The **Nominal** (default) setting is indicated by the indicator dot between **Flex** and **Support** setting.

Tapping the **+** key above **Flex** moves toward the **Flex** setting shown below.

Flex: for patients requiring either less lift or relief from “snuggy” type discomfort.

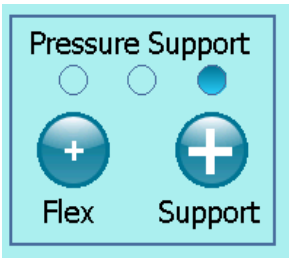


The **Flex** setting indicated.

Tapping the **+** key above **Support** moves toward the **Support** setting.

In this example, one tap will bring to **Nominal** (the center indicator dot), and the second tap will move to **Support**.

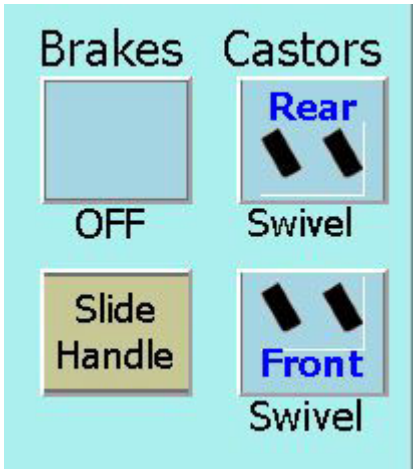
Support: for patients requiring additional lift.



Support setting indicated.

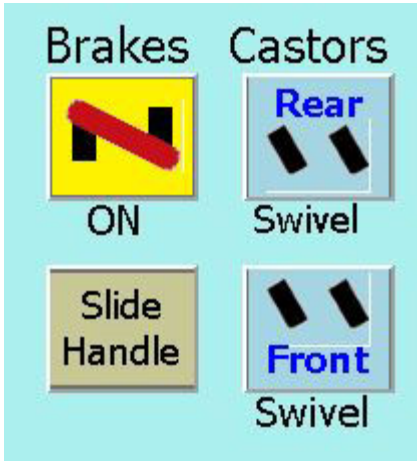
6.6.9 Brake Settings

The Brakes and Castors may be controlled from either the touchscreen, or the push handles.



Brakes are indicated as OFF

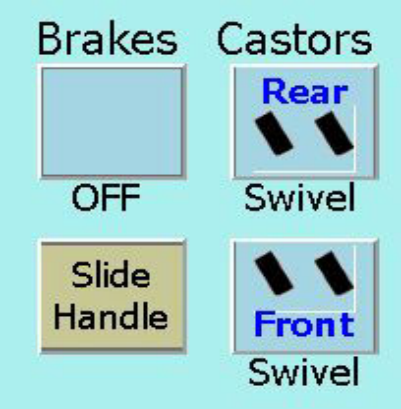
Tap to turn ON. After a short (less than 2 seconds) wait the brakes will be indicated as ON.



Brakes are indicated as ON.

Tap to turn OFF

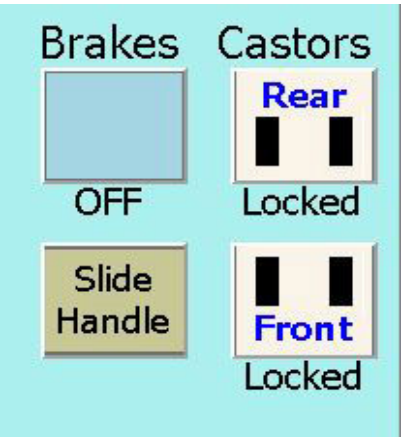
6.6.10 Castor Settings



The modes for the Rear & Front castor pairs are independent of each other.

Either pair may be set to Swivel mode (shown) or Lock mode by pressing their respective buttons.

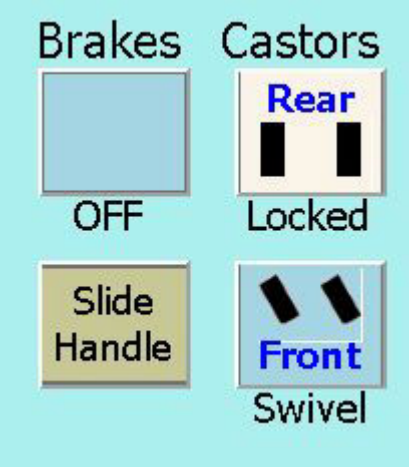
The mode selection buttons turn blue when in Swivel mode.



Both Front and Rear castor pairs are in lock mode.

This mode may be useful to keep a subject walking in a straight line for a given distance.

The mode selection buttons turn white when in Lock mode.



Front and Rear castors are set independently.

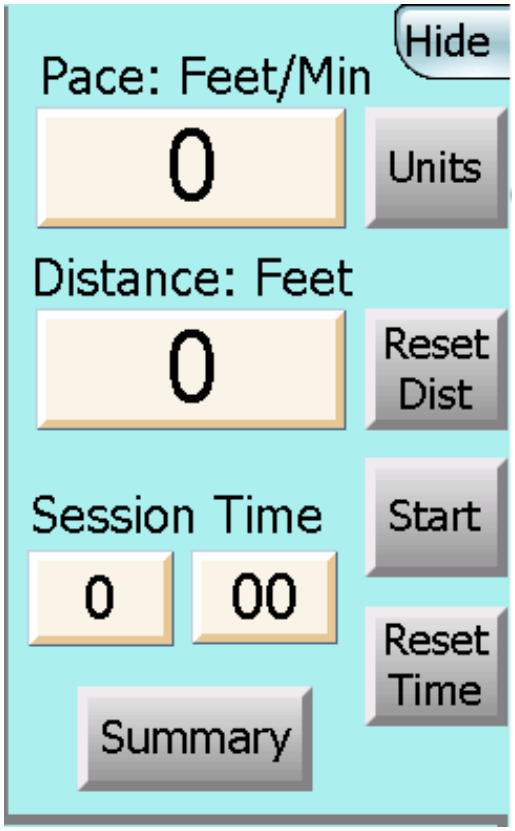
Front **Swivel** / Rear **Locked** (shown here) may be useful when guiding the patient from the front.

Alternately, Front **Locked** / Rear **Swivel** may be useful in guiding the patient from the rear push handles.

Note: Rear Lock is not allowed when bases are spread. The button will not actuate the castors to lock in that case.

6.6.11 Pace and Distance Display

The pace and distance display appears on the left of the screen automatically once unweighting is begun.



The **Units** button toggles the units displayed between feet and meters.

Pace displays the patient's walking speed per "Units" setting.

Distance displays the patient's walking distance per "Units" setting and,

- can be zeroed by pressing the **Reset** button and,
- can be suspended (along with timer) by pressing the **Start/Stop** button.

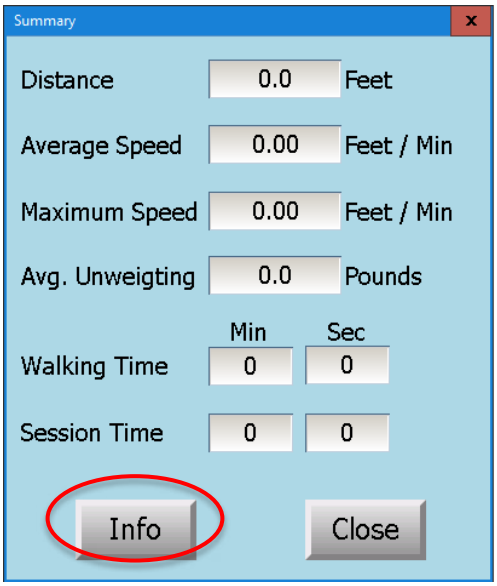
Session Time starts automatically when unweighting begins;

- may also be started manually (along with the distance tracker) by pressing the **Start** button; and,
- may be reset to zero by pressing the **Reset Time** button.

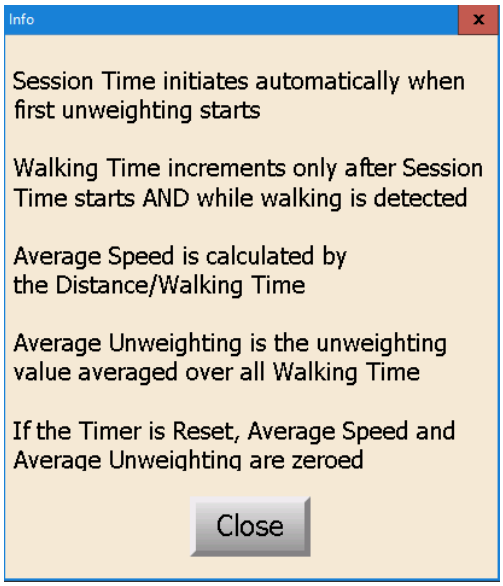
While the timer is on, the **Start** button changes to **Stop** which may be pressed to stop the timer and distance tracker.

6.6.12 Summary of Session Statistics

Clicking the **Summary** button beneath the Session Time display brings up the Session Statistics Summary as below.

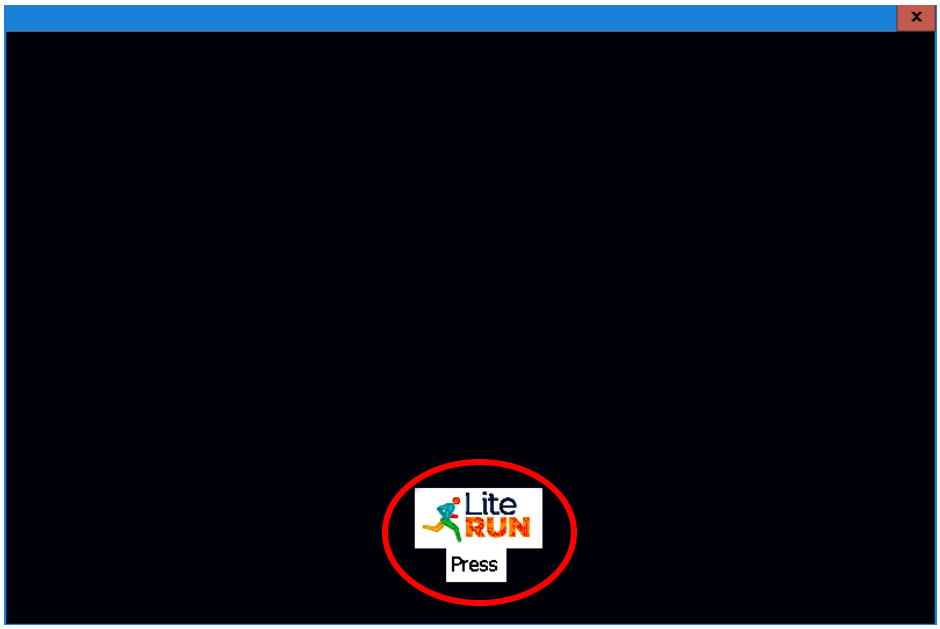


Pressing the **Info** button on this screen provides an explanation of these metrics as shown below.



6.6.13 Hiding & un-hiding the Setup display

For patients who find the screen distracting or to prevent patients from pressing buttons, tap **Blank** to turn off display. To restore the screen, tap the Lite Run icon on the blanked screen.



6.6.14 Battery Gauge

The battery gauge bar at the bottom of the Setup Screen indicates the amount of charge remaining. The gauge below shows 25% charge remaining in the battery. Remember to turn the GT01 off and plug the charger in whenever not in use to keep the battery charged.

6.6.15 Exiting the Setup screen (returning to New screen)

Pressing the **New** button in the lower left corner returns to the New Screen. This ends the current session and returns to the New Screen ready to begin a new session. This step must be done to prepare the system for a new patient, with new data logging and a possibly a different exosuit size selection.

6.7 Starting a New Therapy Session

The Lite Run system has a variety of features that make it easy to transfer patients to the GT01 from a standing position, wheelchair, platform or bed. Each patient must be wearing a correctly fitting Exosuit to use the GT01. See Appendix A for a fit guide.

6.7.1 Turn on the system and tap Setup

Ensure that for a new patient, you begin from the Start Screen. Tap **Setup** and follow the steps in sections 6.3 – 6.5 to bring you to the Setup Screen.

6.7.2 Adjust the height and width of the Patient Lift Bars

The Patient Lift Bars adjust to accommodate small to extra-large body widths.

Turn the knobs at the base of the patient lift bars clockwise to narrow and counterclockwise to widen. You can raise or lower the lift bars manually to adjust the height needed to position them for attachment to a seated or standing patient.

The Support Arms should be positioned approximately one inch wider than the patient on either side. Support Arm height will vary whether the patient is sitting or standing and should be low enough so that the Exosuit can be latched into the GT01.

6.7.3 Engaging the patient to the GT01

6.7.3.1 Entering the system from a standing position

Patients who are able to stand on their own may walk into the system. Instruct patients to walk up to the GT01 from the rear. The support arms should be adjusted so the latch pins on the webbing of the Exosuit align with the latches on the Patient Support Arms.

6.7.3.2 Transferring a patient from a wheelchair

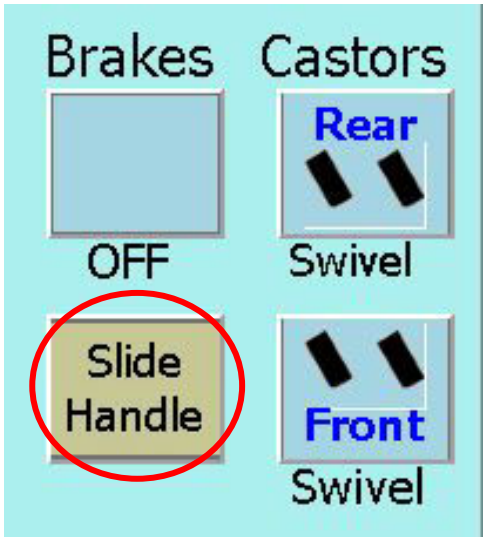
The right and left bases of the Lite Run GT01 can be spread in order to accommodate manual or power wheelchairs up to extra-large size. The bottom buttons on the push bars allow the bases to spread. Press and hold the lower button labeled **SPREAD** (see section 6.9.3 Base Spread for more details on the Base Spread function). Wait a moment to disengage the bases, then push out laterally as far as possible until you hear a click.

Note: Each base can spread independently of the other.

To position a patient in a wheelchair for latching you may either brake the wheelchair and move the Lite Run GT so the patient is positioned between the lift bars, or brake the Lite Run GT and move the wheelchair to position. Position the patient so that the latch pins on the Exosuit align with the latches on the Patient Support Arms.

Note: It is necessary to remove armrests from the wheelchair prior to moving it into position.

6.7.3.3 Transferring a patient from a bed or therapy platform



To engage a patient seated on a platform or bed the push bars should be moved forward after the bases are spread so the bases can slide under the platform (or bed).

To do this, first use the Base Spread function (see section 6.9.3) to open both bases.

Next press the **Slide Handle** button on the touch screen to allow the handles to be moved forward while the bases are spread. The base of the system can now slide partially underneath a bed or therapy platform as the System is positioned for attaching the patient.

With the patient sitting on the edge of the bed or platform, position the System so that that latch pins of the Exosuit align with the Patient Support Arms.

6.7.4 Connect the Exosuit to the Patient Support Arms

The webbing of the Exosuit latches must be positioned with either:

- the green side facing up for green side/black side color coded latch straps, or

- the black pull strap facing up for black only latch straps.

Pins on either side of the Exosuit connect to latch receptacles in the Patient Support Arms. With one hand, pull the latch receptacle tabs toward the patient to open. With the other hand, grab the latch pin and pull it into the receptacle.

If the pin does not reach the latch receptacle, you may need to adjust the width or height of the Patient Support Arm as in Step 6.7.2.

Release the latch tabs to finish latching the pins. Tug up on the webbing to ensure the latch has set correctly. Repeat on the other side of the system.

6.7.5 Connect the air hose to the Exosuit

An air hose hangs down on the front left side of the system. To connect the air hose to the Exosuit press the metal tab on the connector of the hose and firmly push in the nozzle on the Exosuit.

6.7.6 Attach Safety Straps

Latch the Exosuit Safety Straps to the Lift Arm Safety Strap Posts.

6.7.7 Proceed to unweighting

Patients seated in a wheelchair or platform remain seated until the Exosuit is inflated as shown on the progress bar of the touch screen.

6.8 Unweighting

To begin unweighting, select the desired amount of lift from the Setup Screen.

6.8.1 Brakes during Sit-to-Stand

When starting a new therapy session, the brakes will automatically be set to ON. Once the patient is latched in and ready to stand, turning the Brakes OFF will allow the GT01 to roll forward a few inches during the transition, as the patient's center of gravity comes forward. It is useful if the therapist, standing in the front of the GT01 and facing the patient, helps the sit-to-stand transition by pulling the GT01 forward during the sit-to-stand transition.

6.8.2 Select the amount of lift and tap *Start Lift*

Set the desired lift per 6.6.3 and tap **Start Lift** to bring up the Checklist per 6.6.4. Pressing **OK** on the Checklist pop-up initiates lift.

Tip: Lift may be adjusted at any time during therapy by returning to the Setup Screen. Simply select a new lift value, which may be done even when Lift is active. The system will adjust lift automatically.

6.9 Setting Brakes and Steering

The GT01 power castors may be controlled from the Setup Screen, or buttons on the rear push bars.

Brakes and steering may be adjusted at any time throughout the therapy session.

6.9.1 Brakes

The brakes may be set to ON or OFF from the front touch screen. If ON the **ON** button will be highlighted in yellow.

On the right rear push bar, the upper button labeled **BRAKES** can toggle the brakes ON and OFF. A yellow LED light embedded in the button lights up to indicate that the brakes are on.*

*(**Note**: Pushing the **BRAKES** button will cause the system to suddenly stop. Only set the brakes to ON when the system has come to a complete stop.)

You may set the brake on each individual castor by pushing the blue foot pedal switch down toward the floor. If the system is powered down, this is the only way to set or release the brakes on each castor.

6.9.2 Castor Swivel

The GT01 front and rear castor pairs may be independently locked in the forward direction or allowed to swivel. These may be selected from the touch screen (see 6.6.9), or via the two buttons on the rear left handle. The upper button on the rear left handle toggles the front castor pair to either swivel (LED lights blue), or lock (LED off). Similarly, the middle button on the rear handle toggles the rear castor pair to either swivel (LED lights blue), or lock (LED off).

*(**Note**: When changing between castor states, you may have to move the GT01 forward until the casters align to move into the selected state.)

You may also set each caster's state manually. Push the pedal switch on the caster all the way up to lock in a fixed direction. Set the pedal switch parallel to the floor to set the caster to free swivel. Set the pedal switch all the way down to set the brake on a castor.

6.9.3 Base Spread

The lower button on each handle may be pressed to allow the base on that side to be spread open by pushing out laterally on the handle. The base should be latched into one of two available locking positions. The farthest open position is intended to allow space for a wheelchair to be rolled into position to engage a patient into the GT01 while seated in the wheelchair. The intermediate locking position is to allow walking for subjects who may need more lateral “swing” movement with their gait, such as subjects with foot drop. To return the base to its normal “closed” position, the respective lower buttons on each handle must be pressed and the handles pulled together until the bases close and latch into the normal position.

Right handle, inside view

Right handle, outside view

Open the base. Press the **Spread** button and manually spread the base.

Note: the brake light can be either on or off and when the base spread button is pushed the brakes will go off.

6.9.4 Manual Caster Actuation

There are blue foot pedals just above each castor wheel. They act on each individual wheel. There are three positions. The down position will set the brake for that wheel. The middle position is full swivel, and the upper position is swivel lock. If a castor is not in the desired state, or if power is OFF it may be useful to manually set the castors as desired. In normal system operation, the castors should be set with either the pushbuttons on the handles, or via the touchscreen.

6.9.5 Brake Actuation when System is Powered OFF

When powered down there are two options to enable or disable the brakes or to change the state of the castors. One is to simply power ON the GT01. The push buttons on the rear push bars that control the castors will be operational in less than 5 seconds. You do not need to wait for the touchscreen to boot up. The second option is to set them manually (see 6.9.4).

6.10 Sit-to-Stand Transitions

The GT01 has several features to aid patients with the transition from sitting to standing. Always wait for the system to achieve at least 80% of full lift as indicated on the progress bar before instructing a patient to stand.

Turning the brakes off and setting the casters to **Lock** during sit-to-stand transitions will allow the system to shift forward, matching the patient's natural movement forward as he or she stands.

Tip: Patients may find it useful to grab the handlebar at the front of the system before attempting to stand.

Note: While the system will support and stabilize the patient during sit-to-stand transitions, additional therapist support may still be necessary.

6.11 Pulling Back Rear Push Bars and Closing the Base

If you used Push Bar forward function, you will need to return them,to their original back position before beginning therapy.

6.11.1 Pulling back the rear push bars

Instruct the patient to walk forward until they are clear of the wheelchair or bed. Pull each handle backward (towards the rear castors) until you hear a click.

6.11.2 Closing the Base

Instruct the patient to walk forward until they are clear of the wheelchair or bed. Press and hold the lower button on each rear push bar labeled **SPREAD** while pulling the handles inward until they stop and are parallel to each other. You may leave one or both wheel bases open if desired, depending on the needs of the patient and the walking area available. It is recommended that they be latched in one of the 3 positions of 'normal closed', 'intermediate open' or 'fully open'.

6.12 Ending a Therapy Session

At the end of each therapy session, you will need to set the brakes to ON and use the Base Spread and Push Bar Retract functions to return patients to a bed or wheelchair.

6.12.1 Set brakes to *ON*

You may set the brakes from the touch screen, the button labeled **BRAKE** on the right rear push bar, or manually on the casters themselves.

6.12.2 Use Base Spread and Push Bar Retract to transfer patient from system

As in initially entering the system, use the Base Spread and Push Bar Retract features to open the base to accommodate a wheelchair or slide under a bed or therapy platform. (see 6.7.3.2 and 6.7.3.3)

6.12.2.1 Transferring to a wheelchair

Open the base and position the wheelchair so that the patient can easily sit down. Instruct the patient to sit down.

6.12.2.2 Transferring to a bed or therapy platform

Open the base and retract the handles. Assist the patient in backing up toward the bed so he or she can easily sit down. Instruct the patient to sit down.

6.12.3 Press Stop Lift or Sit

Stop Lift brings up the Stop Lift confirmation popup. Sit brings up the Sit confirmation popup.

CAUTION: Once either **Stop Lift or Sit** is selected, the system will depressurize and return the patient to full weight quickly. In the case of Sit, the Safety is also released. Patients who cannot support their full weight on their own may need manual support or before **Stop Lift or Sit** is selected. Note that before sitting, Stop Lift does not release the Safety so this must be done by tapping the Safety button. The Sit button does this as well as depressurizes when the confirmation is accepted.

6.12.4 Release latches on the Exosuit and disconnect the air hose

To release the latches, simply pull the latch toward the patient to open and lift the pin out of the latch. Repeat on the other side.

To disconnect the air hose, press the grey button on the air hose and pull apart.

6.12.5 Unlock brakes and slide the GT01 away from the patient

For maneuvering the GT01 in tight spaces, it may be helpful to set all the casters to swivel.

6.12.6 Close the base, pull back the rear push bars, and power down

For easy maneuvering and storage between therapy sessions, close the base and pull the rear push bars back to a locked position. Flip the power switch on the front of the GT01 to **OFF**. The GT01 should be charged between therapy sessions. See 6.15 for a guide to charging the GT01.

6.13 Emergency Stops

A red emergency stop button is located on the front of the GT01 above the power switch. The emergency stop will automatically set the brakes and disable unweighting.

CAUTION: The system will depressurize quickly when the emergency stop is pressed. If possible, ensure that patients who cannot support their own body weight are supported or sitting before pressing the emergency stop.

The only way to proceed with therapy from an emergency stop is to power down the system. Power the system down and pull the emergency stop button out and clockwise to reset. Ensure that you have correctly identified and resolved the cause of the emergency. If the cause of the emergency is unknown or you are not able to resolve it, contact Lite Run Technical Support. Only reboot the system once the conditions that led to the emergency have been resolved.

Additionally, the GT01 self-monitors and may detect and declare a system emergency. See Appendix B for more information on system emergencies.

6.14 Charging

The GT01 battery should be connected to the supplied Lite Run charger between therapy sessions and after hours.

- Do **not** connect the charger to the GT01 when a patient is in the system.
- The GT01 **must be powered down** or it will not charge
- When charging, position the GT01 so the plug can be reached to disconnect it from the wall receptacle.

Attach the charging cord to charger receptacle (see 2.1 item D) and plug the supplied Lite Run charger into a standard 110-120 VAC outlet. An amberlight on the charger indicates that effective charging is occurring. A green light indicates that the battery is fully charged.

6.15 Battery Replacement

The batteries must be replaced by qualified technical personnel. Do not attempt to replace the batteries unless you are authorized to do so.

6.16 Fuse Replacement.

The fuses must be replaced by qualified technical personnel. Do not attempt to replace the batteries unless you are authorized to do so.

7 Electrical Input Ratings: 100-240VAC, 50/60 Hz, 1.5A Contact Information

The GT01 and Accessories e are manufactured by:

Lite Run, Inc.
1000 Westgate Drive, Suite 30-16
St. Paul, MN, 55114

Contact Lite Run Technical Support for additional support and service.

CustomerService@LiteRun.com

8 Appendices

Appendix A: Fitting the Lite Run Exosuit

Appendix B: Messages, Attention, and Warnings

Appendix C: Symbol Definitions

Appendix D: Regulatory Classifications

Appendix E: Accessories

Appendix F: Misuse Scenarios

Appendix G:

Appendix H:

Appendix A: Fitting the Lite Run Exosuit

All patients must wear a correctly fitting Exosuit in order to use the GT01.

Defined by the patient's waist, there are twelve sizes of Exosuits available as shown in table below. The size determines maximum unweighting, which should not exceed the full body weight of the patient.

Waist Size	Unweighting limit
30	90 lbs
32	100 lbs
34	110 lbs
36	120 lbs
38	140 lbs
40	150 lbs
42	150 lbs
44	150 lbs
46	150 lbs
48	150 lbs
50	150 lbs
52	150 lbs

Before putting the Exosuit on the patient, unzip the zippers at the waist and at each leg.

Close the zippers at the waist and ankles, then close the Velcro waist belt and ankle straps. The fit should be snug but not tight. If the patient complains that the fit is too tight, loosen the Velcro belt or try a larger Exosuit.

Appendix B: Messages, Attention, and Warnings

There are three categories of information that is presented to the user:

1) Message,
2) Attention, and
3) Warning.

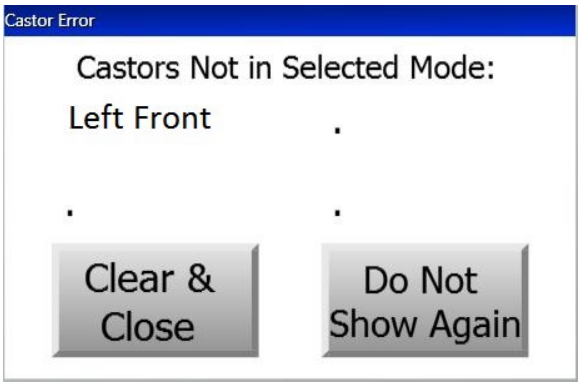
For a **Message**, information appears on the touch screen, but it is not accompanied by an audible indicator.

An **Attention** message is accompanied by a steady audible indicator (beep).

A **Warning** is accompanied by engaging the brakes, disabling unweighting, and an audible indicator (beep).

1. **Messages**

Casters not in selected mode.



An error message will appear if the casters are not in the selected or correct mode. This may occur when switching between steering states if the casters have not aligned. The example to the left shows this error indicated for the Left Front castor. Move the GT01 forward in a straight direction until the casters align. If the error persists, retry selecting the brake or steering setting or manually switch the caster indicated to the desired mode.

2. **Attention notifications**

Attention notifications are accompanied by a steady audible indicator (beep). They require operator attention. The Lift (unweighting) is maintained if engaged. The following table shows conditions that will trigger the Attention notification.

Message	Cause
Pants Air Hose May Be Disconnected	Air hose not connected and Lift is started
Battery is Low Finish Soon and Recharge	Battery is getting low of charge
Pants Latch Disconnect Please Stop Lift and Check	One or both Exosuit latches are disconnected while Lift is ON

Air hose disconnected

If you attempt to start lift without connecting the air hose, the following warning will appear on the screen:

Reconnect the air hose to the Exosuit, then tap **Clear & Close**

Battery low

When approximately five minutes of battery power remain, a warning will appear instructing you to end the session and recharge.

Press **Clear & Close,** then follow procedure to end the therapy session. Power the system down, plug in, and fully charge the battery before the next session.

Exosuit Latches Disconnected

This attention notification will be shown if an Exosuit latch is not connected while Lift is active.

Stop Lift and ensure both latches are secure before starting Lift again. Press **Clear & Close** to resume.

3. **System Warnings**

The GT01 self-monitors. If the system detects a problem, a steady audible indicator will sound and the system will automatically disable unweighting and set the brakes. A pop-up like the one shown below will appear on the touch screen.

Message	Cause
User E-Stop	User declared emergency by pressing emergency Stop
Battery Low: Can't Sustain System	Battery too low for operation
System Error #Number An internal error has occurred. Please report the System Error Number to Lite Run Technical Support.	System Error

This example shows the **Battery Low: Can't Sustain System** warning.

The other warnings in the table above will each have their respective Message text. All Warnings will declare the **Lift is Now Off** message, and the **System Must be Powered Down** instruction.

The only way to proceed with therapy from one of the above System Warnings is to restart the system by powering OFF then ON. Before doing so make a note of the message on the screen. Contact Lite Run Technical Support in the event of system declared warning, unless you are certain that you have identified the reason (such as running the battery completely down).

Note: If the user Emergency Stop button has been pressed, remember to rotate the button clockwise to reset it before powering up the GT01.

CAUTION: The system will depressurize quickly when a system warning is declared. Ensure that patients who cannot support their own weight are supported manually in the event of discontinuation of lift.

Appendix C: Symbol Definitions

Symbol	Description
	Consult accompanying documents.
	Used by the IFU as a risk control measure for a specific risk.
	Type B applied part.
	General warning.
	General prohibition.
	General mandatory action.
	Lite Run trademark.

Appendix D: Regulatory Classifications

- FDA Class I, internally powered device.
- IEC 60601-1 Type B Applied Part (GT01, Exosuit, and arm rest).
- IEC 529 Class IPX0
- FCC 15.247:2024
- FCC 22.913:2024
- FCC 24.232:2024
- FCC 27.50:2024
- FCC 90

Appendix E: Accessories

Appendix E.1, Arm Rest

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- One, two or no arm rests (Figure A, left side arm rest shown) may be used as appropriate.
- Insert the arm rest post into the Accessory Receptacle of the GT01 (Figures B & C, circled in red).
- Loosen the retaining knob for arm rest insertion to the desired height and hand tighten.

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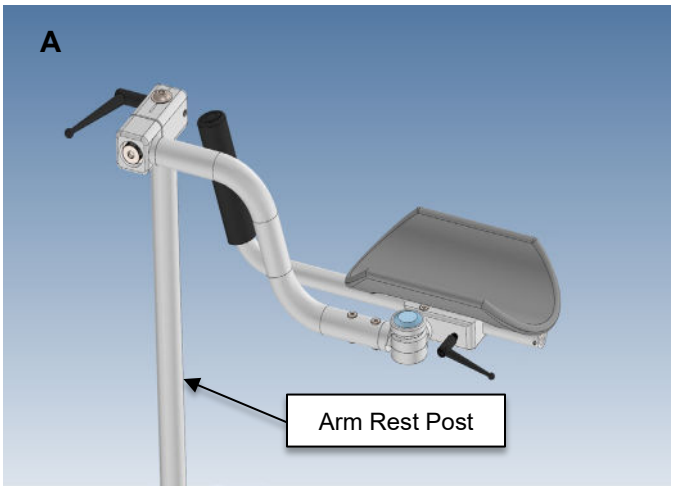

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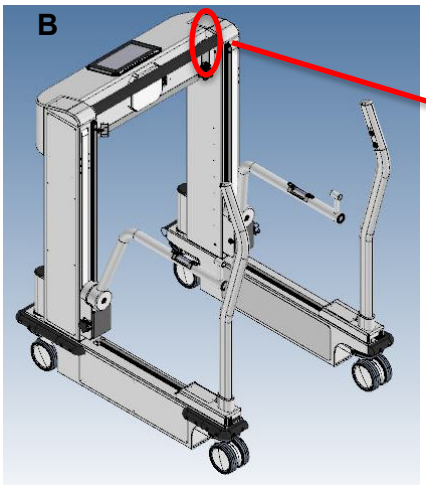

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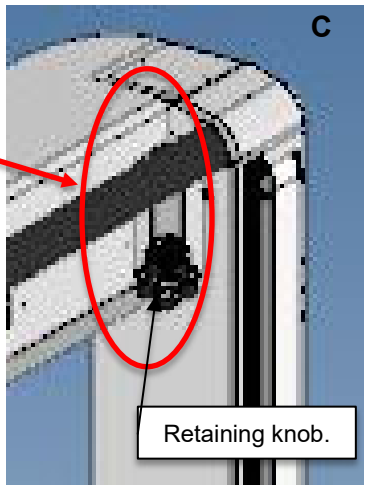

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Appendix E.2, Battery Charger Specifications

- DC Output
  - Rated Voltage: 14V x 2 outputs
  - Max Voltage: 14,6V x 2 outputs
  - Current : 4A x 2 outputs
- AC Input
  - Voltage : 100 – 240 V
  - Current: 3.2A max
  - Frequency : 50-60 Hz
- Mechanical
  - Dimensions: 188.0mm x 110.0mm x 100.0mm (7.402”x4.33” x3.94”)
  - Weight: 0.78 kg
  - DC Output Connector: 1.5 meter cord with custom Lite Run 5 pin connector
  - AC Input Connector: standard 2-pin IEC60320 C7 inlet mating 2.0metesr AC cord.
- Safety Protection: short circuit, reverse polarity, over voltage and many more
- Approvals: UL, TUV, CE, GS, RoHS, EMC, EVD

Appendix E: Software Updates

Occasionally it may be beneficial for the Lite Run Gait Trainer to receive a software update. Software updates may be instigated due to a bug, or to provide new features and enhancements. The update method may be performed in person, by a Lite Run representative during a visit to the site where the device is located, or by a remote method using cellular (LTE) or WiFi technology.

Appendix F: Exosuit Cleaning and Disinfecting

Because Lite Run Exosuits only contact a user's skin, are non-sterile, and are shared across patients with cleaning in between uses, they are classified as "Non-Critical Patient Care Equipment" per CDC Disinfection and Sterilization Guidance, Dec. 7, 2023.

See: *https://www.cdc.gov/infection-control/hcp/disinfection-and-sterilization/index.html*

Based upon CDS guidance cited above, Lite Run recommends the following:

- When visible dirt or organic matter is present (e.g., blood, mucus, etc.) launder the Exosuit using a certified hospital laundering process.
- For use between cases where laundering is not required, use a disinfectant specifically designed for LLD (low-level disinfection), such as EPA-registered wipes, and ensure the entire surface of the device is covered.
- Follow the recommended LLD contact time. Refer to the disinfectant product label for the necessary contact time (duration the surface must remain wet). This is crucial for the disinfectant to work effectively.
- Allow the device to air dry completely, or if the product label advises rinsing, use a clean cloth with plain water and dry thoroughly.

Important considerations

- Always carefully read and adhere to the manufacturer's instructions for the specific low-level disinfectant being used, including safety precautions like wearing gloves, ensuring proper ventilation, and appropriate dilution ratios (if applicable).
- Ensure the chosen disinfectant is compatible with the device's material to prevent damage.
- Pre-cleaning is crucial because organic matter can hinder the disinfectant's effectiveness.
- If spore-forming organisms are a concern, a higher level of disinfection or sterilization may be necessary.
- When Exosuits are shared, disinfect between each patient use.
- Store cleaned and disinfected devices in a manner that prevents recontamination.