Paraglide<sup>®</sup> Automated Repositioning System

# Operator's Manual



010055 Rev C

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# Must Read Prior to Use

Improper use of the Paraglide<sup>®</sup> Repositioning System or the wheelchair to which it is attached can present a potential for injury and/or damage to the wheelchair or Paraglide<sup>®</sup> system. The Paraglide<sup>®</sup> Repositioning System should only be operated under the following conditions:

- The occupant and/or caregiver is both physically and mentally capable of operating the Paraglide<sup>®</sup> Repositioning System.
- Proper instructions on the use and operation of the device has been received by reading and understanding this Operator's Manual in its entirety.
- No technical modifications have been made to the device.

If any issues or malfunctions exist, cease the use of the Paraglide repositioning system immediately and contact MacKenzie Healthcare Technologies for service or further instruction.

Any use contrary to the directions of this Operator's Manual, contrary to the recommendations of one's mobility equipment dealer, or contrary to the technical limitations defined by either MacKenzie Healthcare Technologies or one's wheelchair manufacturer is considered misuse of the Paraglide<sup>®</sup> Repositioning System. MacKenzie Healthcare Technologies is not responsible or liable for any injuries or damage caused by this type of misuse.

# **1** Notices

# **Contact Information**

For all inquiries, including servicing and purchasing, contact:

| ⊠ Address | MacKenzie Healthcare Technologies<br>P.O. Box 121<br>Unit #3 – 6 Rowlings Avenue<br>Musquodoboit Harbour, Nova Scotia<br>Canada B0J 2L0 |
|-----------|---|
| Thone 2   | 1 (902) 889-2044  |
| 🖀 Fax     | 1 (902) 889-3673  |
| 🖂 Email   | support@mackenziehealthcaretech.com   |
| 💻 Website | www.mackenziehealthcaretech.com   |

### Manual Part Number

The part number for the Paraglide® Operator's Manual is 010055.

An electronic version of this Operator's Manual along with informational videos are available on our website (<u>www.mackenziehealthcaretech.com</u>) for people with visual, reading, or cognitive disabilities.

# **Device Serial Number**

The serial number of your Paraglide<sup>®</sup> Repositioning Device is located both on the Main Device's label as well as on the shipping box. It is recommended that you save this Operator's Manual and record the serial number below for reference.

Serial Number: \_\_\_\_\_

# **Copyright Notice**

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All brand and product names mentioned herein are used for identification purposes only and are the trademarks or registered trademarks of their respective holders. Paraglide<sup>®</sup> is a trademark of MacKenzie Healthcare Technologies.

# **Technical Support**

For technical support, please contact MacKenzie Healthcare Technologies directly.

### **Disposal Instructions**

Paraglide<sup>®</sup> and its components are not suitable for regular trash disposal. Follow local guidelines for proper disposal of medical devices and electronics including for lithium containing batteries.

# Paraglide<sup>®</sup> Intended Use

The Paraglide<sup>®</sup> device is a wheelchair accessory intended to reposition an occupant from a slouch to a proper upright seated position, operated by a wheelchair occupant or their caregiver after being properly trained in its use.

### Paraglide<sup>®</sup> Intended Environments

The Paraglide<sup>®</sup> device is intended to be used in all healthcare and home settings.



Use of this equipment adjacent to or stacked with other electrical equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

# Paraglide<sup>®</sup> Intended Operator

The Paraglide<sup>®</sup> system can be operated by the wheelchair occupant themselves, or by a caregiver not seated in the wheelchair.

# Paraglide<sup>®</sup> Intended Use Population

The intended patient population is adult wheelchair occupants weighing up to 550lb (250kg) who are otherwise unable to reposition themselves in their wheelchairs.

# Paraglide<sup>®</sup> Contraindications

There are no known contraindications to the user of the Paraglide® system.

The Paraglide device has not been tested or approved for use in conjunction with any other types of repositioning or restrictive equipment including slings or positioning wedges. Use of Paraglide in conjunction with any medical or assistive equipment is at the sole discretion of the user or certified medical staff providing care.
 MacKenzie Healthcare Technologies Ltd. makes no representation and assumes no responsibility for any negative outcomes, including personal injury, accident or illness (including death), associated with the use of Paraglide in conjunction with any slings, or other wheelchair or positioning devices, accessories, fabrics or positioning methods.

# 2 Labeling

The following labels are applied to the Remote and Device.





# 3 Symbols, Cautions, and Warnings

Paraglide<sup>®</sup> is wheelchair accessory in the United States, a Class I device under FDA jurisdiction. In Canada, Health Canada classifies such wheelchair accessories as Class I.

All warnings and safety precautions issued by one's wheelchair manufacturer must be heeded in addition to those stated in this manual. Failure to do so could result in serious injury.

Handling or use of the Paraglide<sup>®</sup> repositioning system by anyone who has not received proper instruction from this manual could result in serious injury.

In addition to the Warnings and Cautions in the following sections, statements throughout the product manual with special significance are indicated by symbols as explained in the following table.

| SYMBOL   | DESCRIPTION  |  |  |
|----------|--|--|--|
| NOTE     | Notes are used to call attention to statements pertaining to more efficient or convenient operation or service of the equipment. |  |  |
|          | A caution indicates that there is a possibility of damage to the product or equipment attached to it.                            |  |  |
| WARNING! | A warning means that there is a possibility of personal injury to the operator or patient.                                       |  |  |

# **Product Labels Symbols**

The following symbols appear on product labelling:

| SYMBOL | DESCRIPTION                  |  |
|--------|------------------------------|--|
|        | Follow instructions for use  |  |
| IP67   | Degree of ingress protection |  |
|        | Manufacturer                 |  |
| REF    | Reference or Model Number    |  |
| SN     | Serial Number                |  |

# 4 The Paraglide<sup>®</sup> Device

MacKenzie Healthcare Technologies' Paraglide<sup>®</sup> Repositioning System is exclusively intended to reposition occupants of powered and non-powered wheelchairs from a forward/slouched position to a proper seated position with a maximum user weight of 550lbs (270kg). It is intended to be operated by either wheelchair occupants capable of using the wireless remote control or by caregivers assisting the occupant.

It is strongly recommended that the Paraglide<sup>®</sup> Repositioning System only be used on wheelchairs that meet the wheelchair specifications listed below. If a wheelchair is outside these noted specifications, the Paraglide<sup>®</sup> system may still be attached with wheelchair modifications, however these modifications should only be made by a professional wheelchair service technician.

### Wheelchair Specifications

MacKenzie Healthcare Technologies has designed a repositioning system for easy attachment to most wheelchairs. Below are the required specifications of the wheelchair for each of the five Paraglide<sup>®</sup> models.



Do not attempt to attach the Paraglide<sup>®</sup> Repositioning System to a wheelchair that does not meet the dimensions outlined in this section.



| Down Cane/Arm Rest<br>Tube Diameter        | The wheelchair must have down canes or arm rest tubes 1.0" or less in diameter. Spacers (provided) must be used for down canes with a diameter less than 1.0".  |  |  |
|--|---|--|--|
| <i>Down Cane/Arm Rest<br/>Tube Spacing</i> | t The Paraglide <sup>™</sup> System supports down canes or arm rest<br>tubes spaced between 14.25" and 25.25". Five sizes of<br>the Paraglide <sup>®</sup> Device exist to accommodate these<br>spacings. |  |  |
| Wheelchair back                            | There must be a gap between the backrest of the wheelchair and the chair cushion to allow for the Paraglide <sup>®</sup> Sheet to pass freely through.  |  |  |

### List of Included Components

The Paraglide® System comes packaged with the following items:

Paraglide<sup>®</sup> Remote (with lanyard)

Paraglide<sup>®</sup> Device (with x2 clamps, x6 screws, x2 down cane spacers, and x1 hex key)

Paraglide® Power Adapter/Power Cord

Paraglide® Sheet

Operator's Manual



Figures and diagrams of the Paraglide<sup>®</sup> Repositioning System in this manual may vary slightly from your device.

An electronic version of this Operator's Manual along with informational videos are available on our website (<u>www.mackenziehealthcaretech.com</u>) for people with visual, reading, or cognitive disabilities.

For a list of replaceable parts, see Servicing & Maintenance.

# Paraglide<sup>®</sup> Device

The Device is a large metal cylinder that houses a motor, gearbox, lithium-ion battery, and control electronics. It is responsible for pulling the occupant into an upright position. This is accomplished by rotating itself in place, which wraps the Sheet around its cylinder and thus pulls the wheelchair occupant toward the back of the seat.



**Velcro for Sheet** 

The Device comes with clips for attachment to the wheelchair down canes, see *Installing the Device*.



At one end of the Device, a Charge Port and multi-function Pinhole button with status light is found. For charging, see *Batteries & Charging*. The Pinhole button and light are described in the table below.



| Pinhole Button                | Light Status  | Function  |
|-------------------------------|---|---|
| Not pressed                   | OFF   | Normal operation  |
| -                             | Solid ON  | AC Adaptor is plugged into Device,<br>and Device's battery is fully charged<br>(see <i>Batteries &amp; Charging</i> )                         |
| -                             | Blinking  | AC Adaptor is plugged into Device,<br>and Device's battery is charging<br>(see <i>Batteries &amp; Charging</i> )                              |
| Hold for 1-3<br>seconds       | Blinking, slow  | Sends a signal to the Remote to<br>start beeping so the user can locate<br>a potentially lost Remote (see<br><i>"Find-My-Remote"</i> Feature) |
| Hold for 3-10<br>seconds      | Blinking, fast  | Enters the pairing mode, where the<br>Remote and Device can pair<br>through Bluetooth to each other<br>(see <i>Pairing the Remote &amp;</i> ) |
| Hold for more than 10 seconds | Blinks twice, OFF for 2<br>seconds; repeats until<br>button is released | Resets the Device electronics, see <i>System Reset</i>  |

The Device houses a lithium ion battery, which cannot be replaced by the user. The Device is always ON, there is no explicit OFF button. To reset the Device, see *System Reset*. For additional information, see the Troubleshooting or *Servicing* & Maintenance sections.

# Paraglide® Sheet



Always check the Sheet and Velcro Straps for signs of wear or damage before installation and use.

The occupant sits on the Paraglide<sup>®</sup> Sheet. The Sheet is attached to the Device, which pulls it to reposition the occupant in the wheelchair. The Sheet is made of a machine-washable organic material and has Velcro straps to connect with the Device cylinder.

Since the occupant is in constant contact with the Paraglide<sup>®</sup> Sheet, over a long period of time, the Sheet is considered an Applied Part of Type BF as per IEC 60601-1:2015.





# Paraglide<sup>®</sup> Remote

The Paraglide<sup>®</sup> Remote is a wireless Bluetooth controller for the Device. The Remote allows the user to initiate a Glide (see *Gliding (Performing a "Reposition")*), view usage statistics (see *Usage Statistics*), and adjust user settings (see *Configuring the Device*).

The Remote uses two (2) AA batteries (batteries not included) which must be replaced when depleted (see *Batteries & Charging*). See the Troubleshooting or *Servicing &* Maintenance *s*ections for further information.



| ON      | Wakes the remote from sleep.   |  |  |  |
|---------|--|--|--|--|
| GLIDE   | Repositions the user<br>when pressed and<br>held ("Glides").   |  |  |  |
| PAUSE   | Stops the Device<br>from rotating while it<br>is Homing (different<br>from Gliding).   |  |  |  |
| RESET   | When pressed from<br>the Home Screen, it<br>resets the 60-minute<br>timer for monitoring<br>reposition. When a<br>notification pops-up<br>on the Remote, it can<br>be pressed to<br>acknowledge the<br>notification. |  |  |  |
| DATA    | Displays the daily,<br>weekly, and monthly<br>usage statistics.  |  |  |  |
| NOTE In | addition to the  |  |  |  |

IOTE In addition to the functions described above, all buttons help navigate the Settings Menu, as described further in the manual. The Paraglide<sup>®</sup> Remote has a Home Screen with basic information, as described below.



The Remote allows the user to modify settings for the system. This is accomplished by pressing both the RESET and DATA buttons for 3 seconds. Three (3) settings pages will appear.

| PAGE 1 |   |  |                  |             |  |
|--------|---|--|------------------|-------------|--|
| MENU:  | Reconnect<br>Record Force   |  | RECONNE          | СТ          | Reconnects the<br>Remote to the Device                     |
|        | Sound: ON<br>Set Name<br>Next Page  |  | RECORD<br>FORCE  |             | Records a new force<br>limit used to monitor<br>the system |
|        |   |  | SOUND: Of        | N           | Turns the notification sounds ON or OFF                    |
|        |   |  | SET NAME         |             | Set the name to<br>appear on the Home<br>Screen            |
|        |   |  | NEXT PAG         | E           | Goes to Page 2 of the<br>Settings Menu                     |
| PAGE 2 |   |  |                  |             |  |
| MENU:  | SOUND: OI<br>SET NAME<br>NEXT PAG<br>SET Date<br>Forget Device<br>Next Page<br>FORGET<br>DEVICE<br>NEXT<br>PAGE | Set the time that appears on the Home Screen |                  |             |  |
|        | Forget Device   |  | SET DATE         | Set<br>on t | the date that appears<br>the Home Screen                   |
|        | Next Page   |  | FORGET<br>DEVICE | Bre<br>the  | aks the pair between<br>Remote and Device                  |
|        |   |  | NEXT<br>PAGE     | Goe<br>Set  | es to Page 3 of the<br>tings Menu                          |
| PAGE 3 |   |  |                  |             |  |
| MENU:  | RV 1.9.0<br>DV 1.8.1  |  | RV               | Ver<br>inst | sion of software<br>alled on the Remote                    |
|        | ▷First Page<br>Exit   |  | DV               | Ver<br>inst | sion of software<br>alled on the Device                    |
|        |   |  | FIRST<br>PAGE    | Ret<br>Set  | urns to Page 1 of the<br>tings Menu                        |
|        |   |  | EXIT             | Exit        | ts to the Home Screen                                      |

# **5** Installing the Device

The Paraglide<sup>®</sup> Repositioning System is designed to be easily and quickly attached to many types of manual and powered wheelchairs, both rigid and folding. Refer to the *Wheelchair Specifications* section to verify the compatibility of the wheelchair.





### Device Attachment

The Paraglide<sup>®</sup> device is supplied with a simple clamping system that is adjustable to accommodate different sizes and styles of wheelchair.

- 1. Remove the Tightening Screws to open each Clamp into two parts.
- 2. Test-fit the clamp on the down cane without a spacer. If the clamp closes tightly without the need for a spacer, continue to the next step. If not, add a spacer on the down cane to take-up the gap between clamp and down cane.



There are two sizes of spacers, only use 1 size of spacer, not both. If neither spacer is enough then stop installation and contact the manufacturer as your wheelchair down cane diameter is likely too small. 3. Attach both clamps to the down cane and screw together. Pay careful attention to the orientation of the clamps on the down canes.



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4. Insert the Adjustment Block in both Clamps. This socket can slide within the Clamp. It screws into place with one screw.





5. Line up the Device attachment pegs with spring-loaded clips of the Clamps.

- 6. Push in until you hear the audible click of both pegs
- 7. Firmly pull on the Device to ensure it is properly secured.
- 8. Ensure the top of the Device lines up with the top of the wheelchair seat cushion. If not, adjust clamps by repeating above instructions for installing clamps.

If the Device attachment pegs do not line-up with the spring-loaded clips of the Clamps, remove the Adjustment Blocks on both Clamps. Re-attach the Adjustment Blocks to the opposite Clamps. This will provide the minimum spacing and will allow the Device attachment pegs to line-up with the spring-loaded clips of the Clamps. Complete steps 6-8.



Click



Device must be level — if needed, loosen the Tightening Screws on the Clamp and slide Clamp (with Spacer) up or down as needed to ensure level installation.

If there is any difficulty in releasing or reattaching the Device, simply repeat above instructions.



The Device adds roughly 10lbs to the back of the wheelchair and may cause unbalance, instability or tipping. Wheelchair stability should be checked prior to use with the Paraglide<sup>™</sup> Repositioning System. In all cases anti-tip bars should be installed to minimize the risk of tipping, especially when going up an incline.





### **Remote Batteries and Attachment**

The Paraglide<sup>®</sup> Remote <u>does not</u> come with two AA batteries which must be installed prior to use. Follow the instructions in *Batteries & Charging* for instructions to install.

The Remote comes with a lanyard that can be attached for ease of carrying.

The Remote's clip can easily be used for attachment to other fixture points, such as the wheelchair or user.

# 6 Configuring the Device

### Pairing the Remote & Device

The Remote must be paired to a Device before operation can start. The following steps apply for a new Remote or in the event the connection is lost.

- 1. On the Device, press-and-hold the pinhole button for 3–10 seconds. Its LED will start flashing indicating Pairing Mode is active.
- 2. If the Remote is not awake, press the ON button.
- 3. On the Remote, press-and-hold the DATA and RESET buttons simultaneously for 3 seconds to enter the Settings Menu.
- 4. Navigate to the option "Forget Device" and press DATA to select. You should see the screen:



5. Navigate to the option "Reconnect" and press DATA to select. You should see the screen:



When the Remote has connected to the Device, the Remote will display the Home Screen and show the Device's battery icon and charge level.

### Setting Time

- 1. If the Remote is not awake, press ON.
- 2. Press the DATA and RESET buttons simultaneously and hold until the Settings Menu screen appears (approximately 3 seconds).
- 3. Navigate to the Set Time option and select.



- Scroll up (GLIDE) or down (PAUSE) while hours are selected (indicated with an underline). You may scroll through 12AM to 12PM — AM/PM is automatically updated as the hour increases. Press DATA when finished to select the minutes.
- 5. Scroll up (GLIDE) or down (PAUSE) while minutes are selected (indicated with an underline). You may scroll through 00 to 59. Press DATA when finished to return to the Settings Menu.

# Setting Date

- 1. If the Remote is not at the Settings Menu, navigate there now.
- 2. Press the DATA and RESET buttons simultaneously and hold until the Settings Menu screen appears (approximately 3 seconds).
- 3. Navigate to the Set Date option and select.



- 4. Scroll up (GLIDE) or down (PAUSE) while the month is selected (indicated with an underline). You may scroll from JAN to DEC. Press DATA to when finished to select the day.
- 5. Repeat for the day and year values.

### Setting Name

- 1. If the Remote is not awake, press ON.
- 2. Press the DATA and RESET buttons simultaneously and hold until the Settings Menu screen appears (approximately 3 seconds).
- 3. Navigate to the Set Name option and select.



- 4. Change the first letter by pressing GLIDE (move up in alphabet) or PAUSE (move down in alphabet). The numbers 0 9 can also be added which appear after the alphabet; a space can be added which is represented as an underscore. The first letter in a word is automatically capitalized, e.g. Mr Jones99.
- 5. To select a character, press DATA; to delete a character press RESET; when finished selecting all characters press ON.



# Setting the Pull Force



Setting and testing the force limit is an important safety feature that needs to be done properly to minimize the risk of a user being over pulled in their chair.

The Paraglide<sup>®</sup> Repositioning System monitors and notifies the user if too much force is required to reposition an occupant. The amount of "normal" force required to reposition an occupant is dependent on their weight and must therefore be configured for each new occupant in the wheelchair.

The steps below should be performed anytime a new wheelchair occupant uses the Paraglide<sup>®</sup> Repositioning System, or a Device has been replaced. If the Remote is not awake, press ON.

- 1. Press the DATA and RESET buttons simultaneously and hold until the Settings Menu screen appears (approximately 3 seconds).
- 2. Navigate to the Record Force option and select. The following screen will appear:



- 3. Exit the Settings Menu.
- 4. Perform a Glide and release the GLIDE button when the occupant is seated upright, comfortably. The force will not be recorded until the Device returns to home and will save the recorded force until a new pull force is recorded.

# 7 Device Operation

# **Typical Operation**

The Paraglide<sup>®</sup> Repositioning System is designed to reposition (Glide) a wheelchair occupant. It is recommended to perform a reposition at minimum once per hour. A typical Glide is:

- 1. Turn the remote ON
- 2. Press-and-hold the Glide button
- 3. Continue to press the Glide button while the Device repositions the wheelchair user
- 4. When the user is seated comfortably upright, release the Glide button.
- 5. The Device will stop rotating for 3 seconds. After that it will rotate in the opposite direction to provide slack in the Sheet so the sheet can move freely with the user.

If the system detects you are seated for 60 minutes without a reposition, it will automatically notify you to recommend a reposition.

MHT recommends repositioning yourself at minimum every 60 minutes (1 hour).

# Gliding (Performing a "Reposition")

The Paraglide<sup>®</sup> Repositioning System is designed to reposition (or Glide) a wheelchair occupant. Ensure the system is properly setup and configured as described in Installing and Using the Paraglide<sup>®</sup> Device.

To initiate a Glide:

- 1. If the Remote is not awake, press the ON button.
- 2. Press-and-hold the GLIDE button. The following screen will appear:



3. Continue to hold the GLIDE button while the occupant is being repositioned.

4. When the occupant is properly repositioned, release the GLIDE button. The following screen will appear:



5. The Device will stop rotating for 3 seconds, then it will start to rotate in reverse to provide slack to the Sheet (known as "homing").



This slack is necessary for the occupant to slide forward and carry the Sheet with them, so the next reposition can occur.

- 6. During this 3 second pause, you may press GLIDE again to continue repositioning.
- 7. If nothing is pressed, the following screen will appear, and Homing will start.



While the Device is "homing," the user may press the PAUSE button to pause this rotation, followed by RESET to continue homing. The following screen will appear:

> Paused, Press Reset to Return

### **Exclusions to Gliding**

As a Glide is initiated by the user, the system will check the following conditions before allowing the Glide to start. A notification will be displayed on the Remote for 3 seconds, accompanied by beeps from the Remote, unless the Sound option in the Settings Menu is set to OFF.

#### Device Battery Too Low

If the Device has insufficient charge to complete a full reposition, the Remote will not allow the user to initiate the reposition and will display the following notification. Charge the Device battery before performing a Glide.



#### Charging

If the Device is charging, the Remote will not allow the user to perform a reposition and the following notification will be displayed. Remove the charger from the Device to perform a Glide. Unplug Charger

#### Notifications during Rotation

While the Device is rotating, either for a Glide or Homing, the system will monitor for abnormal conditions and display notifications on the remote. These notifications will be accompanied by beeps from the Remote, unless the Sound option in the Settings Menu is set to OFF. To exit these notifications, press RESET.

#### Force Limit Exceeded

If high torque is observed while rotating the Device, the following message will appear. Check surroundings to ensure nothing is snagged in the Sheet.



#### Glide Limit Reached

The Device will only rotate 2.5 revolutions before automatically stopping



### Automatic Reposition Notification

The Paraglide<sup>®</sup> Repositioning System automatically monitors whether an occupant is seated in the wheelchair, and if they have been repositioned within the past 60 minutes. If they have not repositioned within this time period, the Remote will display the following notification:



When this notification is displayed, it is recommended to perform a Glide. If the user wishes to dismiss the notification, they can press RESET. If no action is taken, the notification will remain on the Remote screen for 15 minutes, with beeps every 2 minutes.



### "Find-My-Remote" Feature

If the user is having trouble locating the Remote, a signal can be sent from the Device to the Remote to start beeping, if the Remote is within Bluetooth range. To activate this feature, press the pinhole button on the Device for 1 to 3 seconds then let-go. The light will start blinking. It may be required to wait up to 30 seconds for the Remote to receive the signal from the Device and to start beeping.

When the Remote receives the signal from the Device to beep, the following screen will be displayed:



The Remote will continue to display this notification and beep continuously for 2 minutes, or until the user presses RESET.

### **Usage Statistics**

| Missed<br>Alarms              | Increments if the user ignores the automatic Reposition Notification   |
|-------------------------------|--|
| Resets                        | Increments if the user presses<br>RESET when an automatic<br>Reposition Notification is displayed<br>on the Remote |
| Repositions                   | Increments each time the user performs a reposition  |
| Time since<br>last Reposition | The amount of time (in minutes,<br>hours, days) since the last reposition<br>occurred.                             |

The Paraglide<sup>®</sup> Repositioning System tracks the following usage statistics, which can be reviewed daily, weekly, or monthly, for up to six months:

To view the first three statistics listed above, press the DATA button while on the Home screen. The "time since last reposition" is always displayed on the Home screen. For example, the image below shows that Mr Jones99 was repositioned 4 minutes ago; Mr Jones99 repositioned 3 times today, but reset one 60-minute automatic notification, and missed none.

Use the PAUSE and GLIDE buttons while on the data page to scroll through the previous days, weeks, and months of data.



### Sound: On/Off

When the Remote displays notifications it also beeps. This can be disabled if the sound is not desired, or re-enabled if it was previously turned off.

To turn sounds ON/OFF:

- 1. If the Remote is not awake, press the ON button.
- 2. Press-and-hold the DATA and RESET buttons for 3 seconds to enter the *Settings Menu*.
- 3. Navigate to the *Sound: ON/OFF* item. Selecting this item will toggle the sound either ON or OFF, depending on its current state. The Remote will display a screen with the new setting once selected, as shown below:



### System Reset

In the event it is necessary to reset the Remote, remove the batteries for 10 seconds before returning them.



The Remote may lose its Name and Sound: ON/OFF settings when removing the batteries. It may be necessary to update those once the batteries are inserted again.

In the event it is necessary to reset the Device, press-and-hold the pinhole button for more than 10 seconds. The light will quickly blink twice followed by a 2 second pause, and then blink quickly twice again. It will repeat this until you release the pinhole button. Once you release the button, the Device will reset itself.



No information is lost when the Device is reset.

# 8 Batteries & Charging

# Paraglide<sup>®</sup> Device



Although the battery in the Paraglide<sup>®</sup> Device is very small and compact, it can store a large amount of power. Faulty handling or storage can damage the equipment, and in some cases result in electric shock, burns, or fire. Please handle with care.

The Device houses a rechargeable lithium-ion battery used to power its motor. From a full charge, the battery should provide 3 days of service before requiring a new charge (depending on daily usage and users weight). The Device can stay attached or be removed for charging; in either situation, repositioning will not be allowed while charging. It is recommended to charge the Device battery every night. If necessary, a reposition can be performed after approximately 20 minutes of charging from a state of complete battery depletion.



Charge the Device battery every night to avoid running out of charge during daily use. The life of the battery will not be deteriorated by charging when it is partially drained.



You will be unable to Glide while the Paraglide<sup>™</sup> device is charging.

To view the current charge level of the Device's battery, the Remote displays a battery icon with the level of charge remaining in the Device's battery. If this level falls below 15%, the Remote will display the following message when attempting to perform a Glide:

Device Battery Is Too Low To charge the Device battery:

- 1. Plug the Power Adaptor into a wall outlet.
- 2. Open the Cap covering the charge port on the Device



- 3. Connect the Power Adaptor receptacle into the charge port. The LED will now start to blinking to indicate the battery is actively charging.
- 4. Confirm the charger is connected by: 1) looking at the Device's light, it should be blinking, and 2) pressing-and-hold the GLIDE button to initiate a reposition. The following message should appear, indicating it is charging.



5. When charging has completed, the LED will stop blinking but remain ON. Also, the Remote should display the following message:





Charging should take 4-5 hours.

6. When charging is complete, unplug the Power Adaptor and close the charge port with the Cap. It is important to keep this charge port clean and free of any debris.



Only use the provided charger and cable to recharge the Paraglide<sup>®</sup> Device. Other chargers may damage your unit or cause a fire.



Make sure the charging receptacles are completely dry and free of debris before plugging in the charger.



The battery charger should be used indoors and in dry locations only.



Do not use or attempt to repair a damaged/defective charger. Contact MacKenzie Healthcare Technologies if the charger is damaged or defective.

# Paraglide<sup>®</sup> Remote

The Remote houses two (2) AA batteries that are user replaceable. New batteries should provide roughly 2 months of service before replacement.

The amount of charge remaining in the Remote batteries cannot be viewed. However, when the charge falls to 5%, the Remote will display the following notification, indicating they should be replaced:

Remote Battery Is Too Low REPLACE BATTERY

To replace the Remote batteries:

- 1. Remove the battery cover. This does not require a tool but does require the Remote clip to be pulled-up while accessing the battery cover latch.
- 2. Remove the depleted AA batteries and replace with new AA batteries.
- 3. Re-attach the battery cover to the Remote.
- 4. It may be necessary re-configure the Remote's name and re-pair with the Device, see *Configuring the Device*.





# 9 Travelling, Shipping, Storage

# Travel

Since the Paraglide<sup>®</sup> Repositioning System houses a lithium-ion battery, special considerations must be taken when travelling with it on an airplane. The Paraglide<sup>®</sup> Device must be "carry-on" to your flight and should be stored in the overhead bin. It is recommended that advance arrangements be made with the airline and approval received prior to your departure date.

It is recommended during any travel (plane, vehicle, etc.) that the Paraglide<sup>®</sup> Repositioning System be protected against vibration, shock, and jostling to minimize the risk of damage.

# Shipping

If shipping the Paraglide<sup>™</sup> Repositioning System (specifically the Device), special considerations must be taken due to the lithium-ion battery. Contact your shipping company for instructions on how to correctly package and label prior to shipping.

# Storage

When storing the device for a prolonged period, please ensure the Remote's AA batteries are removed from the Remote prior to storage.



Long-term storage of the battery (more than 3 months) reduces its capacity. Charge the Device battery to at least 30% before long-term storage.



Avoid storing the unit where the temperature or humidity is too high.

# **10 Troubleshooting**

Prior to contacting the manufacturer, refer to this troubleshooting guide. If the steps fail to resolve the problem, contact the manufacturer.

| lssue  | Possible Causes and Solutions   |
|--|---|
| Remote screen stays  | The batteries are likely out of charge. Replace the batteries.  |
|  | Ensure you are pressing the ON button, and don't let go.  |
| Remote does not<br>connect to the Device                   | Ensure the Remote and Device are within 6 feet (2m) of each other.  |
|  | Go to Settings Menu on page 2 and select option to Reconnect. If this does not work, proceed to the next step.  |
|  | Re-pair the Remote and Device, see <i>Pairing the Remote</i> & . If this does not work, proceed to the next step.   |
|  | Reset the Device then restart the above troubleshooting steps.  |
| Device does not glide                                      | Ensure the Remote and Device are within 6 feet (2m) of each other.  |
|  | Ensure the Device battery is sufficiently charged. This can be verified on the Remote's Home screen where the Device battery level is displayed. If battery is low, charge the Device                                   |
|  | Ensure the Remote is paired to the Device. This can be done by pressing the Device's pinhole button to activate the "Find My Remote" feature. If no sound is heard on the Remote, attempt to pair the Remote and Device |
| Remote continuously<br>says "Force Limit<br>Exceeded" when | Ensure the wheelchair is free of any obstructions that could prevent smooth pulling of the occupant by the Device. Inspect the front and back of the wheelchair.  |
| Gliding  | With the occupant OFF the wheelchair, attempt to Glide. If notification still occurs, contact manufacturer. If not, proceed to next troubleshooting step.   |
|  | Record a new force limit.   |

| Remote Batteries                      | AA non-rechargeable, user-replaceable<br>~2 months of normal use before changing   |
|---------------------------------------|--|
| Device Battery                        | Lithium lon, rechargeable, not user-replaceable ~3 days of normal use per charge   |
| Device Battery<br>Charging            | Wall power required: AC 100-240V; 50-60Hz; 75W 4-5 hours to full charge  |
| Operating<br>Conditions               | 5-40°C<br>15-90% (relative humidity)<br>70-106kPa  |
| Storage and<br>Shipping<br>Conditions | -25 to 70°C<br>up to 90% (relative humidity)<br>70-106kPa  |
| Wireless                              | Bluetooth Low Energy (BLE), 5.0<br>ISM Band 2.402 to 2.480 GHz Operation<br>Max. 1mW radiated power from Paraglide™ Device<br>Max. 1mW radiated power from Paraglide™ Remote |
| Weight, packaged                      | 12 lbs   |
| Dimensions,<br>packaged               | 29" x 10" x 6"   |
| Weight,<br>unpackaged                 | Device: 8.5 lbs  |
| Dimensions,<br>unpackaged             | Device: Min  |

# **11 Specifications**

# Standards Compliance

| IEC 60601-1:2005<br>A1:2012                       | Medical electrical equipment - Part 1: General requirements for basic safety and essential performance  |
|---|---|
| IEC 60601-1-2<br>(4th edition)                    | Medical electrical equipment - Part 1-2: General requirements<br>for basic safety and essential performance - Collateral<br>Standard: Electromagnetic disturbances - Requirements and<br>tests  |
| IEC 60601-1-11:2015                               | Medical electrical equipment — Part 1-11: General<br>requirements for basic safety and essential performance —<br>Collateral standard: Requirements for medical electrical<br>equipment and medical electrical systems used in the home<br>healthcare environment |
| ISO 14971:2007                                    | Medical devices - Application of risk management to medical devices   |
| IEC 60601-1-6:2010<br>A1:2013<br>IEC 62366-1:2015 | Medical electrical equipment - Part 1-6: General requirements<br>for basic safety and essential performance - Collateral<br>standard: Usability   |

# EMC (Electromagnetic Compatibility) Statements

The Paraglide<sup>®</sup> system passes the requirements in IEC 60601-1-2:2014 (4th Edition) for Electromagnetic Disturbances in medical equipment, specifically for the Home Healthcare environment (as guided by IEC 60601-1-11:2015).



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



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

The Paraglide<sup>®</sup> system is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.

| Emissions Test  | Compliance | Electromagnetic Environment   |  |
|---|------------|---|--|
| RF Emissions<br>CISPR 11                                    | Group 1    | The Paraglide <sup>®</sup> system uses radiofrequency (RF)<br>energy only for its internal function. Therefore, its<br>RF emissions are very low and are not likely to<br>cause any interference in nearby electronic<br>equipment. |  |
| RF Emissions<br>CISPR 11                                    | Class B    | The Paradide <sup>®</sup> system is suitable for use in all   |  |
| Harmonic Emissions<br>IEC 61000-3-2                         | Class A    | establishments including domestic establishments<br>and those directly connected to the public low-   |  |
| Voltage Fluctuations/<br>Flicker Emissions<br>IEC 61000-3-3 | Complies   | buildings used for domestic purposes  |  |

The Paraglide<sup>®</sup> system is intended for use in the electromagnetic environment specified below. The customer or the user of the Paraglide<sup>®</sup> system should assure that it is used in such an environment.

| Immunity Test   | IEC 60601<br>Test Level   | Compliance<br>Level  | Electromagnetic<br>Environment  |
|---|---|--|---|
| Electrostatic<br>Discharge (ESD)<br>IEC 61000-4-2   | ±8 kV Contact<br>±15 kV Air   | ±8 kV Contact<br>±15 kV Air  | Floors should be wood, concrete<br>or ceramic tile. If floors are<br>covered with synthetic material,<br>the relative humidity should be at<br>least 30%.   |
| Electrical Fast<br>Transient/Burst<br>IEC 61000-4-4   | ±2 kV for power supply lines  | ±2 kV for power supply lines   | Mains power quality should be that of a typical residential or hospital environment.  |
| Surge<br>IEC 61000-4-5  | ±0.5 kV, ±1 kV<br>line to line  | ±0.5 kV, ±1 kV<br>line to line   | Mains power quality should be that of a typical residential or hospital environment.  |
| Voltage Dips,<br>short interruptions<br>and voltage<br>variations on<br>power supply<br>input lines<br>IEC 61000-4-11 | 0% <i>U</i> <sub>T</sub><br>(100% dip in <i>U</i> <sub>T</sub> )<br>for 0,5 cycle<br>0% <i>U</i> <sub>T</sub><br>(100% dip in <i>U</i> <sub>T</sub> )<br>for 1 cycles<br>70% <i>U</i> <sub>T</sub><br>(30% dip in <i>U</i> <sub>T</sub> )<br>for 25 cycles<br>0% <i>U</i> <sub>T</sub><br>(100% dip in <i>U</i> <sub>T</sub> )<br>for 5 sec | $\begin{array}{c} 0\% \ U_{\rm T} \\ (100\% \ {\rm dip} \ {\rm in} \ U_{\rm T}) \\ {\rm for} \ 0,5 \ {\rm cycle} \\ 0\% \ U_{\rm T} \\ (100\% \ {\rm dip} \ {\rm in} \ U_{\rm T}) \\ {\rm for} \ 1 \ {\rm cycles} \\ \hline 70\% \ U_{\rm T} \\ (30\% \ {\rm dip} \ {\rm in} \ U_{\rm T}) \\ {\rm for} \ 25 \ {\rm cycles} \\ \hline 0\% \ U_{\rm T} \\ (100\% \ {\rm dip} \ {\rm in} \ U_{\rm T}) \\ {\rm for} \ 5 \ {\rm sec} \end{array}$ | Mains power quality should be<br>that of a typical residential or<br>hospital environment. If the user<br>of the Paraglide <sup>®</sup> system<br>requires continued charging<br>during power mains<br>interruptions, it is recommended<br>that the Paraglide <sup>®</sup> system be<br>powered from an uninterruptible<br>power supply or a battery. |
| Power Frequency<br>Magnetic Field<br>(50/60 Hz)<br>IEC 61000-4-8  | 30 A/m  | 30 A/m   | Power frequency magnetic fields<br>should be at levels characteristic<br>of a typical location in a typical<br>residential or hospital<br>environment.  |

NOTE  $U_T$  is the AC mains voltage prior to application of the test level.

The Paraglide<sup>®</sup> system is intended for use in the electromagnetic environment specified below. The customer or the user of the Paraglide<sup>®</sup> system should assure that it is used in such an environment.

| Immunity Test | IEC 60601<br>Test Level                                 | Compliance Level  | Electromagnetic Environment –<br>Guidance                             |
|---------------|---|---|---|
| Conducted RF  | 3 Vrms  | 3 Vrms  |   |
| IEC 61000-4-6 | 150 kHz to 80 MHz                                       | 150 kHz to 80 MHz                                       |   |
|               | 6 Vrms  | 6 Vrms  | Portable and mobile RF  |
|               | ISM/Amateur   | ISM/Amateur   | communications equipment should                                       |
|               | Radio bands inside                                      | Radio bands inside                                      | be used no closer to any part of the                                  |
|               | 150 kHz to 80 MHz                                       | 150 kHz to 80 MHz                                       | Paraglide <sup>®</sup> Device, Remote, Charger                        |
| Radiated RF   | 10 V/m  | 10 V/m  | (including cables), than the recommended separation distance of 7 cm. |
| IEC 61000-4-3 | 80 MHz to 2,7 GHz                                       | 80 MHz to 2,7 GHz                                       |   |
|               | RF communication<br>equipment inside<br>80 MHz to 6 GHz | RF communication<br>equipment inside<br>80 MHz to 6 GHz |   |

# 12 Servicing & Maintenance



Never attempt to operate the Paraglide<sup>®</sup> system if it shows damage or is malfunctioning — doing so may result in unintended harm.

#### IMPORTANT There are no user-serviceable parts in the system.

Always inspect the Paraglide<sup>®</sup> Device, clamps, Sheet, and Remote for any missing parts or damage prior to use. For servicing or technical support please contact the manufacturer.

The Paraglide<sup>®</sup> Device contains a fuse however, it cannot be replaced or reset by the user. Contact the manufacturer for support.

Cease use and contact the manufacturer if you notice any of the following:

- Broken or cracked plastic, clamp buttons
- Rips or tearing in the Paraglide® Sheet or Velcro straps
- Missing or loose screws, charging port plug
- Abnormal motor activity, degraded performance (e.g. Device pulling slowly)
- Broken or damaged outside endcaps, charging plug, etc.

To replace main components, call the manufacturer and reference the following appropriate part number based on your needs. Never replace an item while the Paraglide<sup>®</sup> system is in use.

| Component    | Part Number |
|--------------|-------------|
| Device       | 010054-1XX  |
| Remote       | 010000-100  |
| Sheet        | 010040-XX   |
| Charger      | 100027      |
| Charger Cord | 100028      |
| User Manual  | 010055      |

# **13 Cleaning**



Never use bleach or chemical cleaners for Paraglide<sup>®</sup> components.

# Paraglide<sup>®</sup> Remote

The Paraglide<sup>®</sup> Remote should be cleaned using a damp rag, cleaning wipe, or generalpurpose soap and warm water. Do not use harsh bleaches or chemical cleaners. Water intrusion may cause failure of the Remote, do not submerge in liquid.



Never submerge the Paraglide<sup>®</sup> Remote in water.

# Paraglide<sup>®</sup> Device

The Paraglide<sup>®</sup> Device can be cleaned using general purpose soap and warm water or any other standard cleaning method. Before cleaning, it is important to ensure the Cap over the Charge Port is closed. Neglecting to close the Cap may allow water to enter the Device, causing permanent failure of the internal electronics.



Never submerge the Paraglide<sup>®</sup> Device in water.

# Paraglide<sup>®</sup> Sheet

The Paraglide<sup>®</sup> Sheet can be washed with personal laundry using typical household or industrial detergents. Extreme heat or chemical dryers should be avoided as it can cause the premature breakdown of the fabric.

# 14 Warranty

This device is warranted to be free from defects in materials and workmanship appearing within 12 months from the date of purchase, when used in accordance with the instructions provided with the device. MacKenzie Healthcare Technologies' (MHT) obligation under this warranty shall be limited to repairing or providing replacement of parts that are found to be defective.

To make a claim under warranty, please contact our servicing department using the information provided in the contact information on page 5 at the beginning of this manual.

#### Warranty may be voided if:

- the product has not been used or installed in accordance with the instructions and guidelines herein;
- defects were caused by improper use or installation, as determined by MacKenzie Healthcare Technologies.
- modification or alteration of any nature has been made in the electrical circuitry or physical construction;
- defects are due to causes beyond the control of the user or MacKenzie Healthcare Technologies, such as lightning, abnormal voltage, or as may have occurred during transit after purchase.

# **15 Revisions**

| Revision | Description  | Approved By |
|----------|--|-------------|
| Rev A    | Initial release  | M.M         |
| Rev B    | Addition of TUV logo on title page   | M.M         |
| Rev C    | <ul> <li>Warning on the use of Paraglide in conjunction with a sling</li> <li>Updated information on cleaning the Paraglide Sheet</li> <li>Grammatical and descriptive improvements/updates</li> </ul> | M.M         |