

User Guide

Argo ReWalk™ P

Designed for Personal Use



Overcoming Mobility Impairment

Argo Medical
Technologies, Inc.

Important

The user of this product has sole responsibility for any malfunction that results from improper use, faulty maintenance, improper repair, unauthorized service, damage, or alteration by anyone other than Argo Medical Technologies.

The safety, reliability, and performance of this product can only be assured under the following conditions:

The product has been used according to the accompanying operating instructions.

All updates, extensions, readjustments, changes, or repairs have been carried out by Argo Medical Technologies' authorized representatives.

Document Information

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Patent pending

Notification Regarding Training



Warning: Training is mandatory. Use this document as a guide during training and as a reference after training.

This manual is not a substitute for training.



Caution: Before using the ReWalk, read this Guide carefully to attain a solid understanding of its functions and operations.

Keep this Guide handy so that it can be referred to whenever needed. Follow the operating procedures and usage described in this Guide.

Do not modify the device, replace parts (with the exception of the batteries), use non-specified parts, or remove protection devices, as these actions could result in a hazardous situation.

**PLEASE READ THIS USER GUIDE BEFORE
OPERATING THE SYSTEM**

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1. INTRODUCTION

1.1. ABOUT THIS USER GUIDE

This User Guide provides the information necessary to operate the Argo ReWalk™ P System. **PLEASE READ THIS USER GUIDE BEFORE OPERATING THE SYSTEM.** If any part of this User Guide is not clear, contact Customer Support for assistance.

1.2. GLOSSARY AND ABBREVIATIONS

BACKPACK	The shoulder-mounted carrying case for the ReWalk computer and other components
COMPANION	A specially-trained friend or caregiver who can help an independent ReWalk user in the day-to-day use of the device
COMMUNICATOR	The remote control device used to control the ReWalk
EXOSKELETON	The metal framework that is strapped to the user and which assists the user in sitting, standing and walking
MODE	The current method of operation of ReWalk. Examples of modes are SIT, STAND, and WALK.
THERAPIST	A specially-trained medical professional who adjusts the ReWalk to the individual user, and who helps the user to use the device
USER	The person wearing the ReWalk

2. SYSTEM DESCRIPTION

2.1. INTENDED USE

The Argo ReWalk™ orthotically fits to the lower limbs and part of the upper body and is intended to enable individuals with lower limb disabilities to perform routine ambulatory functions in an urban terrain (stand, walk on level surfaces and mild slopes) to increase their activity level. The ReWalk is not intended for sports, aggressive use, or stair climbing.

2.2. INDICATIONS

Before using the device, confirm that the following prerequisites are met by the user:

- Hands and shoulders can support crutches or a walker.
- Healthy bone density.
- Skeleton does not suffer from any fractures.
- Able to stand using a device such as EasyStand.
- In general good health.
- Height is between 160 cm and 190 cm (5' 3" - 6' 2").
- Weight does not exceed 100 kg (220 lbs).

2.3. CONTRAINDICATIONS

People with the following conditions should not use the ReWalk™- P:

- History of severe neurological injuries other than SCI (MS, CP, ALS, TBI etc).
- Severe concurrent medical diseases: infections, circulatory, heart or lung, pressure sores.
- Severe spasticity (Ashworth 4)
- Unstable spine or unhealed limbs or pelvic fractures.
- Heterotopic ossification.
- Significant contractures.
- Psychiatric or cognitive situations that may interfere with proper operation of the device
- Pregnant women.



Warning: Crutches are required when using ReWalk™- P.

3. SAFETY

3.1. TYPES OF WARNINGS, CAUTIONS AND NOTES

Three types of special message appear in this User Guide:



Warning: A **warning** indicates precautions to avoid the possibility of personal injury or death.




































Caution: A **caution** indicates a condition that may lead to damage to equipment, or a lower quality of treatment.







Note: A **note** provides other important information.

3.2. GENERAL SAFETY INSTRUCTIONS

 General Warnings	
	DO NOT USE BEFORE READING THIS OPERATION GUIDE.
	Changes or modifications not expressly approved by Argo Medical Technologies Ltd. can affect the safety and effectiveness of the device and will void the system's warranty.
	Users must be trained to use the ReWalk™ R. Use of the device without training can result in serious injury.
	The ReWalk™ R must be custom fitted to the User. Software settings must be customized per User. Use of the device without fitting and customizing can result in serious injury.
	Improper adjustment of device size to suit the user could cause skeletal fractures and injury to the patient.
	The System can collapse due to power cut-off such as a battery malfunction or a disconnected wire. To minimize the risk of injury, the unit is designed to execute a graceful collapse as the user has been trained to perform.
	Battery malfunctions—such as current leakage, electrical shock during charging, battery overheating, excessive charging current, etc.—can result in serious injury. To ensure that this does not occur, do not charge the battery while wearing the device.
	To ensure continuous power during use, always charge the battery at the end of the day.
	Charge the battery when the ReWalk™ R is turned off but do not charge batteries prior to air travel – batteries should be minimally charged prior to flight. An indication of medium charge is when the remote communicator's icon for the system battery displays in yellow.
	Changing the main and auxiliary batteries should only be done by a trained user or Companion, following the instructions given in 9.2.2. Inserting the Main Battery and the Auxiliary Battery . Battery replacement by inadequately trained personnel can result in a hazard, such as excessive temperatures, fire, or explosion.
	The batteries supplied by Argo are specially designed for the ReWalk system. Do not use other types of batteries.
	To avoid system malfunction during use, always test the system's functionality before using the device. See 5.3. Activating the ReWalk_P .
	Electromagnetic Emissions Interference (EMI) from other electronic devices may cause loss of system functionality.
	Do not attempt to use the device if a software malfunction has caused a total loss of functionality or if there is a general mechanical failure.
	Unintentional mode selection can cause loss of functionality and loss of user control. This may result in injury.
	Using the device on irregular surfaces could result in loss of balance and possible injury. Do not try to walk on sand, in stony areas, or on any surface that isn't appropriate for crutches. Do not use the device on a ramp.
	Do not use the device if you are distracted or not paying careful attention to your operation of the system.

 General Warnings	
	The device is designed for use with crutches.
	Use the device on paved surfaces or on dry, grassy surfaces.
	Do not use on an escalator, even with assistance. Escalator irregularities will cause a fall.
	Do not attempt to dismantle, open, service, or modify the device, accessories, or charger. Doing so could present the risk of electric shock or other hazard. Any evidence of any attempt to open and/or modify this device, including removal of any of the labels, will void the Limited Warranty.
	If a failure is detected while changing from a sitting position to a standing position, the system automatically returns the user to a sitting position.
	The device must be fitted over clothing to prevent skin abrasions. Where necessary, use the extra padding provided with the device.
	Ensure that the device does not put pressure on bony prominences or other bony-like protrusions.
	When removing the ReWalk after use, both the user and where appropriate, the therapist and Companion, should examine the user's skin, particularly in those areas where the device might have been pressing on the user's body. If there are signs of abrasions these should be reported to any or all of the following people: therapist, Companion, trainer, and/or the health care professional if the latter is involved.
	ByPass mode should be used with caution and only if the communicator has malfunctioned.
	Changes or modifications not expressly approved by Argo Medical Technologies Ltd. can affect the safety and effectiveness of the device and will void the system's warranty.
	Changes or modifications not expressly approved by Argo Medical Technologies Ltd. can affect the safety and effectiveness of the device and will void the system's warranty.
	The device contains no user-serviceable components.
	Electrical shock and flammability hazard – Cleaning the device should be limited to the simple procedure discussed in Section Error! Reference source not found. For any additional cleaning or servicing, always consult Argo Medical Technologies Ltd.
	Electrical shock hazard – Do not remove the cover from any components of the system. An operator may only perform maintenance procedures specifically described in this Operation Guide. Refer servicing to qualified service personnel trained in the repair of this equipment.

 General Cautions	
	Disposal of this device should be performed in accordance with local regulations.
	If the device is not working correctly, discontinue use and refer servicing to qualified service personnel.
	Do not disassemble any part of the system components. This system is not user-serviceable.

3.3. SAFETY STANDARDS

The device complies with the following standards for general requirements of medical electrical equipment safety:

IEC 60601-1 - Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance








IEC 60601-1-2 – Medical Electrical Equipment - Part 1: General Requirements for Safety 2. Collateral Standard: Electromagnetic Compatibility - Requirements and Tests

IEC 60601-1-11 – Medical Electrical Equipment -- Part 1-11: General Requirements for Basic Safety and Essential Performance -- Collateral Standard: Requirements for Medical Electrical Equipment and Medical Electrical Systems Used in the Home Healthcare Environment

IEC 61000-4 – Transient Immunity Standards

FCC 47 CFR Part 15 –Telecommunication/Radio Frequency Devices

3.4. SYMBOLS USED IN THIS GUIDE

Symbol	Symbol Meaning
	Caution , consult accompanying documents
	US federal law restricts this device for sale by or on the order of a physician
	Consult instructions for use
	Manufacturer
	Not for general waste
	Shock protection (B, BF, CF)
	RF radiation

4. SYSTEM COMPONENTS

WHAT ARE THE PARTS OF THE ARGO REWALK?

This section of the User Guide describes the various components of the system.

The Argo system consists of three main components:

- Communicator
- Exoskeleton
- Backpack.

In addition, the system includes a Charger for recharging the batteries when the system is not in use.

The Exoskeleton is the flexible supporting framework that helps you to sit, stand and walk.



The Backpack contains most of the system's electronic parts and batteries. It is worn like a conventional backpack.



The Communicator is a lightweight remote control that provides instructions and guidance in using the system. It is worn on the wrist.



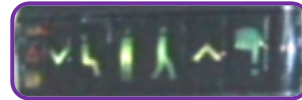
The Battery Charger is used to charge the system. It is typically used for overnight charging.



The following sections discuss each component in detail.

4.1. THE COMMUNICATOR

The Communicator is the wireless remote control for the ReWalk. It is worn on the wrist.



Details of front panel:

1. Mode icons
2. **Previous** button
3. **Select** button
4. **Next** button



Note: The Communicator enters Sleep mode when it is not used for a period of time. Press the large **Select** button to wake the Communicator. The icons will flash briefly.

4.1.1. COMMUNICATOR WARNINGS AND INDICATORS

The Communicator has several Warning signals that indicate a system requirement or a required action.

COMMUNICATION FAILURE/GENERAL WARNING



This signal indicates that the Communicator cannot communicate with the system. It is possible that the system battery is not charged, or there could be some other problem with the device. Try charging the system. If that does not clear up the problem, contact Argo support.

BATTERY INDICATORS

The system contains two sets of batteries: the Communicator batteries, located inside the Communicator, and the system batteries, located inside the backpack.

	Communicator battery indicator
	System battery indicator

BATTERY INDICATIONS

The following table explains the meaning of the various battery indicator values.

COMMUNICATOR BATTERY INDICATIONS			
Indicator Color	Communicator Battery	System Battery	Action
Green	Battery normal	Battery normal	None
Yellow	Battery medium	Battery medium	None
Red	Battery low	Battery low	10 minutes remaining. Exit system and charge batteries
Red flashing	Battery very low	Battery very low	Exit system immediately and charge batteries
Flashing red, or red and green or green with charger connected to communicator	Charging	NA	None



Note: A flashing RED Warning Icon indicates the loss of communication between the Communicator and the Onboard Computer (see **4.3.1. The Onboard Computer**).





A solid RED Warning Icon, displayed with any other icon, indicates a stuck leg that must be released by the therapist/user. If, after releasing the leg, the Red warning icon stays on, this could indicate a malfunction. You should contact technical support.

4.1.2. SELECTING A COMMUNICATOR MODE

The following table shows the icons that represent the various modes for the ReWalk™- P.



Note: Movement between modes is restricted. You can only move to a mode that the ReWalk™- P can accommodate. For example, you can move from **SIT** to **STAND**. However, you cannot move from **SIT** to **WALK**.

Communicator Icons and Components			
 SIT	 STAND	 WALK	 MANUAL
When in the above modes, you can <i>move to</i> the following modes:			
STAND or MANUAL	WALK or SIT	STAND mode only	MANUAL mode only available*
* With the system in Manual mode, to exit Manual mode, reselect the Manual icon. The system will exit Manual mode and the Communicator will display the Sitting mode.			

To select a mode:

Press any button to activate the Communicator. The icon of the current mode is colored green. Press the **Next/Previous** button. One icon flashes. This represents the mode that the ReWalk™- P will shift to and the mode that you most likely want to select. The icons of other available modes are solid yellow.

There are two possibilities:

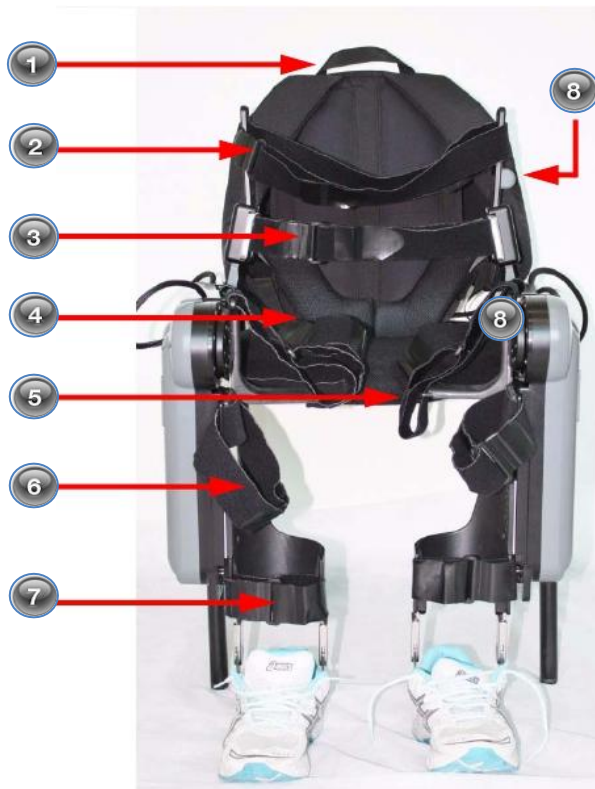
- If the flashing icon is the mode you want to move to, press **Select**.
- If the flashing icon is not the mode you want to move to, use the **Previous** and **Next** buttons.

When the icon of the mode you want to select is flashing, press **Select**.

The Onboard Computer emits a beep and a short vibration confirming that it has received the communication and enters the new mode, which is displayed in green.

4.2. THE EXOSKELETON

The exoskeleton is the flexible supporting structure that allows you to sit, stand and walk.



Components of the Exoskeleton	
Item	Description
1	Backpack
2	Chest Strap
3	Waist Strap
4	Thigh Straps
5	Upper Knee Straps
6	Lower Knee Straps
7	Ankle Straps
8	Tilt Sensor

4.3. THE BACKPACK

The backpack is worn like a regular backpack or knapsack and contains most of the ReWalk™- P electrical components.



Components of the Backpack	
Item	Description
1	Vibrator
2	Main Battery
3	Backup Battery
4	Onboard Computer

4.3.1. THE ONBOARD COMPUTER

The Onboard Computer provides audible alerts and vibrations to tell you what is happening in the system.

Audible Alerts and Vibrations Before Use		
Alert	Cause	Response
Long beep and vibration after turning on the ReWalk™- P	Internal test failed.	Wait a few seconds. If the beeper does not stop beeping, turn off and on the device. If the situation repeats itself, report it to a service center.
		Ensure that the system batteries are charged.



Warning: One of the batteries is disconnected or discharged.

Audible Alerts and Vibrations During Use		
Alert	Cause	Response
One short vibration and beep repeated every 5 seconds	Low battery	10 minutes remaining. Exit system and charge batteries.
One beep and vibration during use	-High power usage -High power usage could be caused by excessive friction between floor and the user's foot.	While standing up or sitting down, the unit switches to SIT mode and sits the user down.
		User notes that system relaxes pressure on the affected joints. User should reseat himself/herself firmly on chair to avoid falling.
		While in manual mode the system freezes. Select Manual mode on RC - the device exits Manual mode & transfers to SIT mode.
Long beep and vibration	Obstacle in path or limb is dragging. Overheating batteries.	Withdraw limb. If this does not help, seek help and contact technical support.
One short vibration and beep repeated every 1 or 5 seconds depending on whether the batteries are low or very low	Technical fault. Very low battery level.	Exit the system immediately and charge batteries.
Three repeating beeps while walking	High power usage	Tilt your body to release the immobilized leg.

NORMAL USE in STANDARD ORDER		
Alert	Indication	Response
One short vibration and beep	Device power ON	
One short vibration and beep	Received new mode and activated	
Three short vibration and beeps	Device is about to stand	Perform sit-to-stand procedure
One short vibration and beep during a walk	Ready for tilt	Perform a tilt as instructed
Three short vibration and beeps	Device is about to sit	Perform stand-to-sit procedure

4.3.2. CHARGING THE SYSTEM BATTERIES AND THE COMMUNICATOR

The ReWalk™- P uses three types of batteries: the Communicator batteries, the primary system battery, and the backup system battery. In order to prolong battery life and get the maximum use of the system, the batteries should be fully charged after use. A full battery charge takes about seven hours.



Warning: If any of the batteries is not functional (connection problem, low charge or other difficulty) the system will not operate. Do not attempt to proceed.



Warning: Charge the battery when the ReWalk™- P is turned off. Do not charge batteries before air travel - batteries should be minimally charged prior to flight. An indication of medium charge is when the remote communicator's icon for the system battery displays in yellow.



Warning: Use only the charging units provided with the Argo ReWalk P.

CHARGING THE SYSTEM BATTERIES



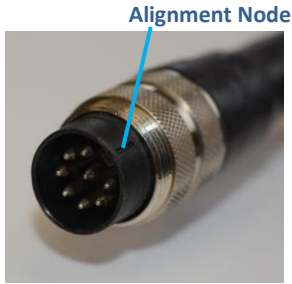
Warning: Do not charge the batteries when the ReWalk™ is on. Doing so will damage the ReWalk™- P.



Note: Both the main battery and the backup battery are charged via the single charging port on the Onboard Computer in the backpack.

To charge both system batteries:

1. Ensure that the ReWalk™- P is turned off.
2. Ensure that the charger is unplugged from the wall-socket.
3. Open the backpack's On/Off and Charging window.
4. Observe that the 8-pin connector has an alignment node.
5. Align the 8-pin connector with the charging port within the backpack.
6. Connect the charger to the Onboard Computer within the backpack.



Eight Pin Connector Attached to the Onboard Computer through the On/Off and Charging Window

7. Connect the charger to the wall socket. The charger can be plugged into either a 110V (United States) or a 220V outlet.

8. Continue charging procedure until the the green LED indicator displays (no damage can be caused if the onboard computer is still connected to the charger at this stage).

9. When charging is completed, first disconnect the charger from the wall socket and only then disconnect it from the Onboard Computer.

LED Behavior/ Color	Explanation
Off	Batteries are not connected to the charger or the charger is not plugged into the outlet.
Yellow, transition- ing to green	The batteries are charging. As the battery becomes more fully charged, the yellow shade gradually turns to a darker shade of green.
Green	Finished charging. The batteries are full.

CHARGING THE COMMUNICATOR

Charging the Communicator takes about five hours. The Communicator charger is a regular charging device, as shown below.



Warning: Use only wall-mounted 110V-240V mains.

To charge the Communicator:

1. Plug the charging unit into an outlet.

2. Plug the Communicator into the charging unit.



Communicator Charging Unit



Communicator Charging Port

The Communicator battery icon will flash green as the Communicator is charging. When it is fully charged, the icon will be solid green.

5. MOVING INTO THE REWALK

This section of the User Guide explains how to put on and secure the Argo Rewalk. It also explains how to activate the device, and how to remove it.

Your Companion will adjust the size of the ReWalk™- P to match your body and secure your designated ReWalk™- P shoes in the foot supports. The therapist will also configure the sensors and other software parameters.



Warning: The device must be fitted over clothing to prevent skin abrasions. Where necessary, use the extra padding provided with the device.



Warning: Ensure that the device does not put pressure on bony prominences or other bony-like protrusions.



Note: Remember to bring your specially fitted ReWalk™- P straps and shoes with you.

5.1. PREPARATION

Following the fitting and configuration process, you must learn how to get into, and out of, the unit.

1. Before beginning the move:

- Ensure that your crutches are within arms reach. Crutches are required when using ReWalk™- P.
- Ensure that your clothing is appropriate. Wear clothing that is neither tight nor loose. Do not wear dresses, skirts or other long clothing.
- Affix the Communicator to your wrist.



Communicator on Wrist

2. Ensure that the ReWalk™- P is placed on a chair with a width of at least 50 cm (24 inches).

The characteristics of an appropriate chair are:

- No arm-rests
- Does not tip forward
- Sturdy enough to support the user and the system which weighs 25 kg (55 lbs)

3. Ensure that the straps of the ReWalk™- P are open and that the thigh straps are dangling.



Thigh straps in preparation for move

4. Place the wheelchair alongside the ReWalk™- P.
5. Engage the wheelchair's brakes.
6. Test the stability of the chair.
7. While doing the following action, if necessary, request your Companion to stabilize the device: lift your body and move from the wheelchair to the ReWalk™- P.

You might need to rest on a segment of the ReWalk as you are moving: take care not to damage the ReWalk™- P.

8. Remove your shoes and place your feet into your ReWalk shoes.
9. Align your legs and make sure that both your feet are in firm contact with the floor prior to standing.



Your Position in the ReWalk™- P

5.2. SECURING THE REWALK™- P

Several straps secure the ReWalk™- P to your body. When securing the straps ensure that you use adequate padding (supplied) to prevent abrasions and skin injury that could occur if the padding is insufficient. The straps should be fastened snugly to your body.



Warning: Excessive tightening may cause discomfort, vascular occlusion, and edemas or pressure wounds. For catheter users, excessive tightening could cause blockage. Ensure there are no kinks in the tubing.

1. Close your shoes and secure the ankle straps.



2. Secure the straps below the knees.



3. Secure the straps above the knees.



4. Secure the thigh straps.



5. Secure the waist and chest straps.



6. Put on the backpack and secure the backpack straps.



5.3. ACTIVATING THE REWALK_P

Turn on the ReWalk™- P, as pictured below. The ReWalk™- P On/Off switch is located in the backpack.



Turning on the ReWalk-P



Warning: If a continuous beep is heard when activating the ReWalk , prepare yourself for sitting and switch off the device.



Warning: When you turn on the device, the system vibrates to indicate that it is functioning normally. If you do not feel this vibration, do not use the device. Contact Argo support for assistance.



Warning: If the On/Off switch cannot be moved freely to the ON or OFF position, do not use the device.

In the context of a continuous beep being heard, the RC will display an error message. Having switched off the device, attempt to restart the ReWalk. If the restart is not successful, contact Argo technical services.

If the system restarts, this is an indication that the error was caused by improper use.



Note The system passes through various pretests as it starts up. If there is a system failure a red triangle and the manual icon will display. If this happens, call your service center.



Warning: Do not charge the batteries when the ReWalk™- P is on. Doing so will damage the ReWalk™- P.

5.4. REMOVING THE REWALK



Warning: When removing the ReWalk after use, both the user and where appropriate, the therapist/Companion, should examine the user's skin particularly in those areas where the device might have been pressing on the user's body. If there are signs of abrasions, these should be reported to any or all of the following people: therapist, Companion, trainer, and/or the health care professional if the latter is involved.

To remove the ReWalk™- P:

1. Sit down. Do not try to remove the ReWalk™- P while standing.
2. Remove the backpack.
3. Remove the straps from chest to ankle, in this order:
 - a. Remove the chest strap.
 - b. Remove the waist strap.
 - c. Remove both thigh straps.
 - d. Remove both upper knee straps.
 - e. Remove both lower knee straps.
 - f. Remove the ankle straps.
4. Remove your feet from the shoes.

6. USING THE ARGO REWALK

This section of the User Guide shows you how to use the Argo ReWalk to sit, stand and walk.

Now that you are familiar with the Argo ReWalk, you can begin to operate the system.

6.1. TWO RULES OF THE COMMUNICATOR

The Communicator is very easy to use once you learn these two rules:

1. 100% of the time, you must press at least twice.

First, you press the Select button to activate the Communicator. Next, you must make a selection.

2. The flashing icon is the one that will be selected.

After you activate the Communicator:

- The icon of the current mode is colored solid green.
- One icon flashes yellow; it represents the mode that the ReWalk™- P will shift to—and the mode that you most likely want to select—if you push the Select button.
- The icons of other available modes are solid yellow.

There are two possibilities:

- If the flashing icon is the mode you want to move to, press the Select button right away.
- If the flashing icon is not the mode you want to move to, use the Previous and Next buttons. When the icon of the mode you want to select is flashing, press the Select button.

The Onboard Computer emits a beep confirming that it has received the communication. As the ReWalk™- P is entering the new mode, the icon flashes.

We recommend that you familiarize yourself with the mode icons and the operation buttons on the Communicator. These are explained in the table "Communicator Icons and Components" in **4.1.2.**

Selecting a Communicator Mode.



Note: Movement between modes is restricted. You can only move to a mode that the ReWalk™- P can accommodate. For example, you can move from **SIT** to **STAND**. However, you cannot move from **SIT** to **WALK**.

6.2. STANDING UP

To stand up:



1. Ensure that your feet touch the ground. If they do not, adjust the position of the legs using **MANUAL** Mode (see **7.1. Manual Mode**).

2. Ensure that you are in **SIT** mode. You can only stand up from **SIT** mode.

3. Take the crutches. The crutches need to be behind you as you stand up.

4. Set the Communicator to **STAND** mode:

a. Press any button to activate the Communicator.

b. Press the Next/Previous button, the **STAND** icon flashes yellow.

c. Press the Select button to confirm the choice.

5. Place the crutches behind you.

6. Ensure that there is adequate ROM (range of motion) for your shoulders. Before standing you up, the following occurs:

- The unit waits three seconds to allow you to position the crutches.
- After three seconds, the Onboard Computer emits three short beeps and vibrates.



Note: While the device stands you up, the **STAND** mode icon flashes green. Once it has entered **STAND** mode, the **STAND** icon changes to solid green.



Note: If the device does not perform as expected, a beep is sounded indicating a problem. This could be due to the position of your legs on the floor. Ensure that your knee alignment is within the 70-100 degree range. Restart the standing procedure.

7. The ReWalk™- P stands you up and enters **STAND** mode. Stabilize yourself.



Standing up

6.3. SITTING DOWN

To sit down:



1. Ensure that you are in **STAND** mode. You can only sit from **STAND** mode.
2. Set the crutches behind you. Ensure that there is adequate ROM (range of motion) for your shoulders.
3. Set the Communicator to **SIT** mode:
 - a. Press any button to activate the Communicator.
 - b. Use the Previous and Next buttons to shift focus to the **SIT** mode. When in focus, the **SIT** icon flashes yellow.
 - c. Press the Select button to confirm the choice.
4. Prepare to sit down. Before sitting you down the following occurs:
 - The unit waits three seconds to allow you to position the crutches.
 - After three seconds, the Onboard Computer emits three short beeps and vibrates.



Note: While the device is sitting you down, the **SIT** mode icon flashes green. Once it has entered **SIT** mode, the **SIT** icon changes to solid green

5. The ReWalk™- P sits you down and remains in **SIT** mode.



Note: While in **SIT** mode, if a beep is sounded this indicates that you are not sitting correctly. You should be seated well back on the chair so that there is no pressure on your knees. Ensure that your feet are together, firmly on the floor.



Sitting down

6.4. WALKING



Warning: Do not try to walk on sand, in stony areas, or on any surface that isn't appropriate for crutches. The device is designed for use with crutches. Use it on paved surfaces or on dry, grassy surfaces.

Do not try to get on an escalator, even with assistance. Escalator irregularities will cause a fall.

Do not use the ReWalk™- P in the rain. Water will cause significant damage to the system.

To walk:

1. Stand up (see **6.2. Standing Up**).
2. Set the Communicator to **WALK** mode:



- a. Press any button to activate the Communicator.
- b. Press Next/Previous button, the **WALK** mode icon flashes yellow.
- c. Press the Select button to confirm the choice. The **WALK** icon changes to green and stops flashing.

3. Activate **WALK** by moving both crutches forward. This action is called a "tilt". ReWalk™- P senses the tilt and moves the right leg first. Again, move both crutches forward. ReWalk™- P moves the left leg in front of the right leg.
4. Repeat step 3. Each movement of the crutches (tilt) results in a ReWalk™- P step.



Note: In the event you bump into something, the system reverts to **STAND** mode. Similarly, if you pause or if ReWalk™- P does not sense a tilt within the time specified on the user interface, the system will automatically revert to **STAND** mode.



7. MANUAL AND BYPASS MODE

Argo-ReWalk provides two special modes of operation for the user: **MANUAL** mode and **BYPASS** mode:

- **MANUAL** mode is only accessible from **SIT** mode and is used to control the joints manually without relying on the automated system.
- **BYPASS** mode is used if there is a problem with the Communicator but the user must still operate the system.



Warning: Manual mode should be used only for adjusting the leg position while sitting or in an emergency situation. Do not remain in manual mode longer than needed for the adjustment and when the adjustment is completed, change back to sit mode.



Warning: While in **SIT** mode, if a beep is sounded this indicates that the device has detected "high power" and the device will relax pressure on the affected joints.

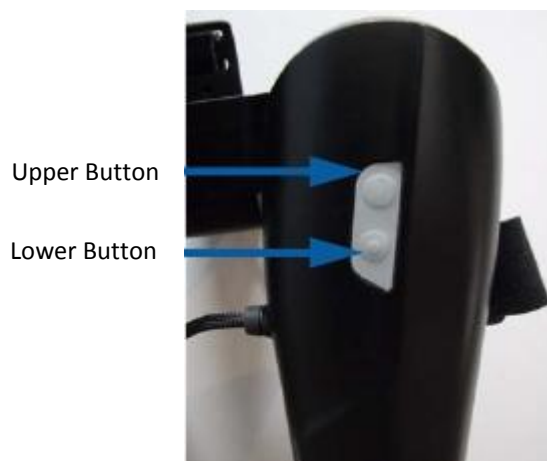
7.1. MANUAL MODE

1. Set the Communicator to **MANUAL**:

- Press any button to activate the Communicator.
- Use the Previous and Next buttons to shift focus to the **MANUAL** mode. When in focus, the **MANUAL** mode icon flashes yellow.
- Press the Select button to confirm the choice. The **MANUAL** mode icon changes to green and stops flashing.

2. Each of the four ReWalk™- P segments has two manual buttons. Press one of the buttons.

- The upper button moves the segment forward.
- The lower button moves the segment back.



Manual Mode buttons

3. To exit **MANUAL** mode, select the Manual icon (see step 1 above).



Note: If there is excessive friction between the floor and your foot while performing this procedure, a beep will sound and you will feel some vibration due to the device using high current. The device stops working. Proceed as follows: Change to **SIT** mode, ensure there is no friction with the floor and then revert to **MANUAL** mode.

7.2. BYPASS MODE

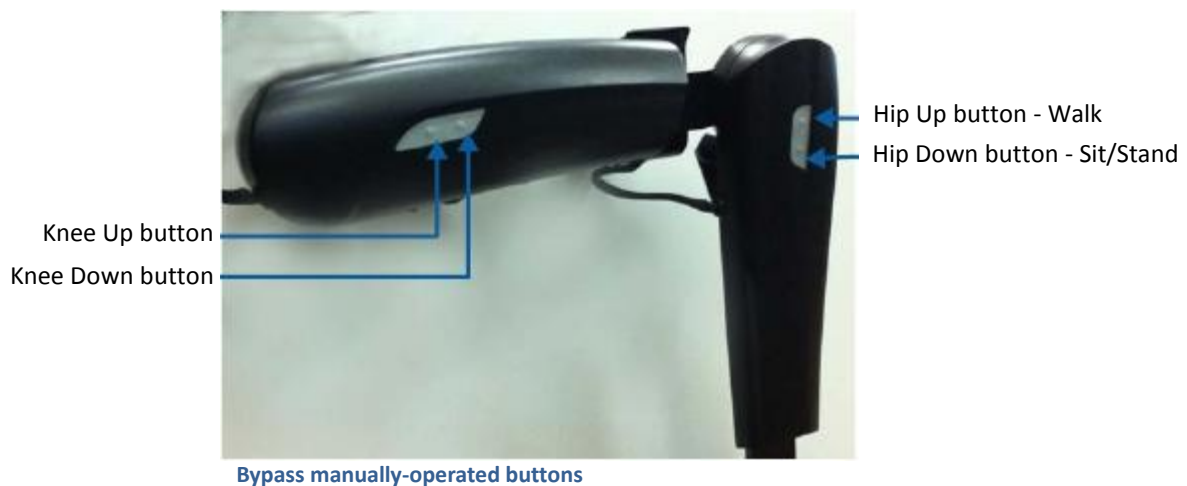
BYPASS mode is intended to handle situations when there is a loss of communication and the user realizes that he/she cannot operate the ReWalk.

Bypass enables the user to operate the system without using the Communicator. Bypass mode can only be activated when in a sitting/standing position or while in Manual mode.



Warning: **BYPASS** mode should be used with caution and **only** if the communicator has malfunctioned.

The Bypass buttons are located on the device's hip and knee segments, as shown below.



7.2.1. MODE SELECTION

Bypass Mode

- On the hip segment (either left or right), press both buttons simultaneously for two seconds; a long beep is sounded. The system enters Bypass mode.

Sitting/Standing Mode Selection

- Press lower hip button twice for two seconds to bring the system to a sitting\standing position depending on the system's current position i.e. if the system is in a standing position, the system enters a sitting position and visa versa.



Note: Complete activation of the hip buttons within 10 seconds.

Walking Mode

1. Proceed to walk mode from a standing position.
2. Press the upper hip button for two seconds. A beep is sounded.
3. Start walking.

Manual Mode

Manual mode enables you to operate each segment of the system individually and can only be invoked from a sitting position.

Press the upper knee button for two seconds. A beep is sounded and the system enters manual mode.

Exiting Manual Mode

- On the knee segment (either left or right), press both buttons simultaneously for two seconds; a long beep is sounded. The system exits Manual mode.

Exiting Bypass mode

- On the hip segment (either left or right), press both buttons simultaneously for two seconds; a long beep is sounded. The system exits Bypass mode and reestablishes communication with the Communicator.

7.3. GRACEFUL COLLAPSE



Warning: Graceful Collapse is a critical safety feature and requires careful execution. The User and/or Companion should be prepared to have a chair and appropriate padding on hand to protect the user if Graceful Collapse is invoked.

If the ReWalk encounters a fatal error, the device will power off and enter a "Graceful Collapse". Graceful Collapse will also occur if the power is switched off.

During Graceful Collapse, the device will support the user's weight while slowly lowering the user to a seat or the ground. The user's Companion can then assist the user by positioning a seat under the ReWalk. The user can then remove the ReWalk and transfer to a wheelchair.

See **8.3. The Companion's Role During a Graceful Collapse** for an explanation of the Companion's actions during a Graceful Collapse.

8. THE REWALK™ COMPANION

FOR THE COMPANION ...

This section of the User Manual explains how the user's Companion can help him to use the Argo ReWalk.

The ReWalk is designed for independent use, however we recommend that every ReWalk user, no matter how skilled, should have a trained ReWalk Companion such as a family member, friend or caregiver.

The first role of the Companion, after completing a basic training course at a trainer center, is to accompany and assist the user in practicing and using the ReWalk.

The Companion's second role is to assist the user in situations where the potential risk is high, e.g. walking on an uneven surface.

The user is responsible for deciding whether to use the ReWalk with or without a Companion, based on self-judgment of her/his ability and confidence.

In this section, specifically written for the Companion:

- The **Companion** is the person assisting the user
- The **friend** is the ReWalk user.



Warning: This section is intended for reference only. It does not constitute a Companion training course and cannot substitute for adequate Companion training. The Companion must undergo training in a formal Argo Companion Training course

8.1. PREPARATION

The user should wear appropriate clothing that is neither tight nor loose. Clothing that may interfere with wearing and using the ReWalk™ such as dresses, skirts or other long items should not be worn.

To secure the ReWalk™ device on the user, the device is supplied with customized straps specially prepared for the user. For more information about the straps, see **5.2. Securing the ReWalk™- P.**

8.1.1. THE SHOES

During training, specific shoes were approved for use with the ReWalk™. Make sure your friend is using only those specifically approved for use with the device. You will need to attach the shoes to the ReWalk™- P. Following is a summary of the procedure:

1. Remove the inner soles from the shoes.
2. Put the shoes on the unit's shoe-support bases.
3. Attach the shoes to the unit's shoe supports.
4. Return the inner soles to their position in the shoes.

8.1.2. DRESSING THE UNIT ON THE USER



Warning: Ensure that the device does not put pressure on bony prominences or other bony-like protrusions.

The ReWalk™ has previously been sized to fit your friend and so the next step is to move the user into the unit and fasten the unit on your friend.

Before you start:

1. Place the ReWalk™ on a sturdy chair that does not have arm supports and that cannot tip forward easily.
2. Arrange the ReWalk™ straps so that the user does not sit on them during the positioning process.

Your friend has already been trained to move from the wheelchair to the chair that the device is resting on. However, you need to know how your friend is going to make the move so that you can help if the need arises.

There are two ways of moving from the wheelchair into the supporting chair. Some users will be able to swing themselves over onto the chair. Other users will need your assistance.

DRESSING THE UNIT ON THE USER – FOR INDEPENDENT USERS

Briefly explain the transferring movement that your friend is now going to perform, which involves lifting oneself and swinging over to the supporting chair.

1. Place the wheelchair alongside the ReWalk™ and ensure that the wheelchair's brakes are now engaged.
2. Shoes should be removed so be ready to assist as needed.

3. If necessary, stabilize the chair during this maneuver.
4. Ensure that the user does not place his/her grip on a segment of the ReWalk™ that could be damaged.
5. Assist your friend placing their feet into their shoes and fasten the shoe laces.
6. Align legs on the ReWalk™.
7. Fasten your friend to the ReWalk™ using each of the eleven straps provided for this purpose ensuring that each of them is fastened snugly but comfortably.



Warning: Be very careful not to over-tighten the straps. Excessive tightening may cause discomfort, vein or artery occlusion, and edemas or pressure wounds.



Warning: For catheter users, ensure that the tubing is not kinked.

8. Finally, assist your friend putting on the backpack and secure it.

DRESSING THE UNIT ON THE USER – FOR USERS REQUIRING ASSISTANCE

Some ReWalk™ users are not able to transfer independently from their wheelchair to the chair supporting the ReWalk™. In this instance, you will need to assist your friend. You should review this procedure with your local ReWalk™ trainer.

Once your friend is positioned in the ReWalk™, proceed with Steps 5 through 8 above.

8.2. ACCOMPANYING THE USER

This section describes what you need to know when you are out on a ReWalk excursion.

8.2.1. THE COMMUNICATOR

From time to time, you may have to operate the Communicator. We strongly recommend that you familiarize yourself with the Communicator and its various operational modes. For a complete explanation of the Communicator, see **4.1. The Communicator** and see **6.1. Two Rules of the Communicator**. Following is a brief description of how to use the Communicator:

- Press any button to activate the Communicator.
 - The icon of the current mode is colored green.
- Press the **Next/Previous** button.
 - One icon flashes. This represents the mode that the ReWalk™- P will shift to and the mode that you most likely want to select.
 - The icons of other available modes are solid yellow.
- There are two possibilities:
 - If the flashing icon is the mode you want to move to, press **Select**
 - If the flashing icon is not the mode you want to move to, use the **Previous** and **Next** buttons. When the icon of the mode you want to select is flashing, press **Select**.
- The Onboard Computer emits a beep and a short vibration confirming that it has received the communication and enters the new mode, which is displayed in green.

COMMUNICATOR – MANUAL MODE

Your friend has been trained to use the RC. Manual Mode is additional functionality which can be activated only while in SIT mode. This controls the ReWalk segments independently of the device's software.

To set the Communicator to Manual mode:

1. Press the large Select button to activate the Communicator.
2. Use the Previous/Next buttons to scroll to the MANUAL mode. The MANUAL mode icon flashes yellow.
3. Press the Select button to confirm the choice. The MANUAL mode icon changes to green and stops flashing.

Each of the four ReWalk segments has two manual buttons. The upper button moves the segment forward. The lower button moves the segment back.

8.2.2. MECHANICAL AND MEDICAL ALERTNESS

As the Companion accompanying your friend, you should be in tune with your friend's general condition of health prior to beginning and should assess the surrounding area before setting out on a ReWalk™ outing.

When removing the ReWalk after use, both the user and the Companion, should examine the user's skin particularly in those areas where the device might have been pressing on the user's body. If there are signs of abrasions these should be reported to any or all of the following people: therapist, Companion, trainer, and/or the health care professional if the latter is involved.

In particular:

- When accompanying your friend, it is important to walk next to the individual and choose to walk with your dominant (stronger) hand adjacent to the ReWalk.
- Be aware of and alert your friend with regard to obstacles, rugs, doors, and ramps etc. that lie ahead. Give your friend ample time to adjust to changes in the pathway as you proceed.

ALERTS FOR MECHANICAL MALFUNCTION

In the unlikely event of a mechanical malfunction, first and foremost secure your friend offering physical support and give assurance to maintain your friend's confidence.

Do the following:

1. If the ReWalk™ device does not respond, power down the device and assist your friend to sit on a chair.
2. While assisting your friend, hold on to the pelvic belt section of the ReWalk™.
3. Assess the malfunction as per the user guide illustrations and determine how to get the unit operational.

8.3. THE COMPANION'S ROLE DURING A GRACEFUL COLLAPSE



Warning: Graceful Collapse is a critical safety feature and requires careful execution. The user and/or Companion should be prepared to have a chair and appropriate padding on hand to protect the user if Graceful Collapse is invoked.

If the ReWalk encounters a fatal error, the device will power off and enter a "Graceful Collapse". Graceful Collapse will also occur if the power is switched off.

During Graceful Collapse, the device will support the user's weight while slowly lowering the user to a seat or the ground. The Companion can then assist the user by positioning a seat under the ReWalk. The user can then remove the ReWalk and transfer to a wheelchair.

Graceful Collapse notes for the Companion

1. The user stands wearing the ReWalk with crutches providing support.
2. The user is accompanied by the Companion, who locates himself behind the user to ensure the user's safety.
3. The Companion provides a verbal cue to the user that the unit will be temporarily switched off.
4. The Companion switches off the ReWalk and allows the user to slowly descend until a sitting position is reached.
5. The Companion then assists the user to remove the device and transfer to a wheelchair.

9. CLEANING AND MAINTENANCE

9.1. CLEANING



Note: Do not use acetone-based products to clean the ReWalk™- P.

System surfaces that touch the body may be cleaned periodically using a dampened cloth with an alcohol-based disinfectant.



Warning: If the device is used by more than one user, it is essential to clean the device with disinfectant before use.

Straps that are torn, worn, or contaminated should be discarded and replaced with new ones.

9.2. BATTERY CARE

Correct battery care is essential for providing safe use of the ReWalk for the maximum useful battery life.

9.2.1. BATTERY CHARGING

Follow these guidelines for optimum battery charging:

- Charge batteries before each use.
 - The preferred method is to charge the battery overnight after each use.
- In the event that the ReWalk is not to be used for an extended period of time, the system should be charged overnight once a week. You may also leave the battery pack in the charger.



Warning: Battery malfunctions—such as current leakage, electrical shock during charging, battery overheating, excessive charging current, etc.—can result in serious injury. To ensure that this does not occur, do not charge the battery while wearing the device.



Warning: To ensure continuous power during use, always charge the battery at the end of the day.



Warning: Charge the battery when the ReWalk™ R is turned off but do not charge batteries prior to air travel – batteries should be minimally charged prior to flight. An indication of medium charge is when the remote communicator's icon for the system battery displays in yellow.



Changing the main and auxiliary batteries should only be done by a trained user or Companion, following the instructions given in **9.2.2. Inserting the Main Battery and the Auxiliary Battery**. Battery replacement by inadequately trained personnel can result in a hazard, such as excessive temperatures, fire, or explosion.



The batteries supplied by Argo are specially designed for the ReWalk system. Do not use other types of batteries.

9.2.2. INSERTING THE MAIN BATTERY AND THE AUXILIARY BATTERY

1. Locate the Main Battery you will be installing into the backpack.



2. Gently slide the Main Battery into the large pouch with the left side opening, taking care to ensure the battery cable is exiting at the bottom left corner of the pouch.



3. Close the Velcro flap to secure the Main Battery in its pouch and route the battery cable down towards the INF Computer.



Caution: Improper battery connections can result in device damage or failure. Please follow the next steps very carefully!

4. Locate the Main and Aux Battery connector terminals on the INF Computer.



5. Insert the connector for the Main Battery cable into the terminal labeled “Main” on the INF Computer. You will hear a “click” when the connector is fully seated.



6. Now locate the Aux Battery you will be installing into the backpack.



7. Gently slide the Aux Battery into the small pouch on top of the Main Battery pouch, taking care to guide the battery cable connector through the hole in the upper right corner at the back of the pouch.



8. Close the Velcro flap to secure the Aux Battery in its pouch and route the battery cable down to the INF Computer.



9. Insert the connector for the Aux Battery cable into the terminal labeled "Aux" on the INF Computer. You will hear a "click" when the connector is fully seated.



10. Once both Main and Aux Batteries are installed, double check your connections and the security of the battery packs in their pouches. The correct final install should look like this:



11. Close the backpack cover taking care not to pinch the cables in the zippers.

9.2.3. REMOVING THE MAIN BATTERY AND THE AUXILIARY BATTERY

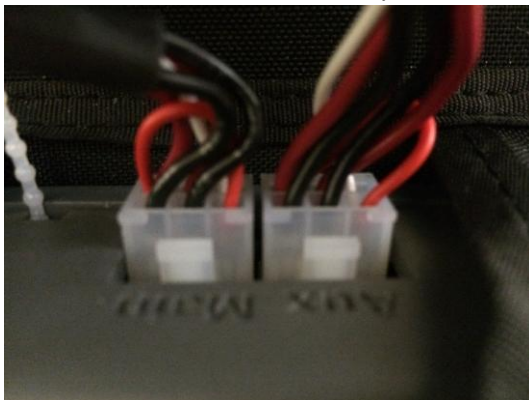


Note: The Main Battery and the Auxiliary Battery should be removed by the user when the device is being prepared for shipping, or if the device will be stored for a long period of time.

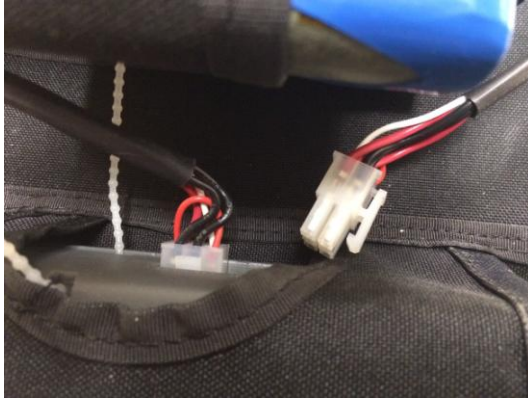
1. Open the Backpack to gain access to battery packs.



2. Locate Main and Aux battery connections on the INF Computer (grey box).



3. Disconnect the Aux Battery connector from the INF Computer by depressing the tab on the top of the connector while gently pulling the connector out.



4. Open the Velcro flap holding the Aux Battery in its pouch to allow for removal



5. Carefully guide the Aux Battery cable through the opening at the back of the pouch as you slowly pull the Aux Battery out of the pouch so as to avoid damaging the wiring or connector



6. Once the Aux Battery is completely removed, disconnect the Main Battery cable from the INF computer using the same procedure as with the Aux Battery



7. Once the Main Battery cable is disconnected, open the Velcro flap holding the Main Battery in and gently pull it out of its pouch.



10. TROUBLESHOOTING

This section includes a guide to troubleshooting various operational incidents, describes the symptoms, possible causes and gives an explanation how to fix them if these occur.

Symptom	Cause	Fix
Rewalk system battery does not charge	Onboard computer (INF)	Verify that system is off.
	Connection to charger	Verify charging connector is properly connected.
	Charger failure	Verify both charger LEDs are orange and green after 8 hours.
	Battery failure	If problem persists contact your distributor or technical support.
Remote Communicator battery does not charge	Connection to charger	Verify that plug is OK and properly inserted in unit.
	Charger failure	Swap chargers/RC if more than one unit is used.
System does not power up	Charger is connected to INF	Disconnect charger from INF and from mains.
	Batteries low	Charge batteries.
System does not stand	Knee alignment out of 70-100 degree range	Move knee to 90 degrees.
System does not walk	Communication error	See Communication error below.
	Tilt error	On user interface from Online data tab, click "Collect Data" to "On" and verify that the Tilt settings update. If the settings do not update, contact your distributor or technical support.
	Low current walk threshold	Increase current threshold in interface.
High frequency beeps every 5 seconds	Low batteries	Charge batteries

Symptom	Cause	Fix
Noisy system during operation	Loose screws	Check all system screws and tighten as needed.
	Noisy ankle joint	Lubricate ankle joint
Start Up self test failure - long beep after power up	Tilt failure, or one of the connectors not correctly inserted into the onboard computer	Check all connectors.
		On user interface from the Online data tab, click "Collect Data" to "On" and verify that the Tilt settings update.
Communicator does not power up	Communicator battery is not charged	Charge communicator unit. If problem persists, contact your distributor or technical support.
Communication error - flashing red triangle	Communicator unit	Verify that the correct paired Communicator unit is being used. If problem persists, contact your distributor or technical support.
	Communicator out of range	Test near unit
Communication error - constant red triangle with green walk mode icon	High current in one of the joints	User should manipulate his/her body to release weight on the leg. The leg will return to standing position. If problem recurs, increase the walk current threshold on interface.
Communication error - constant red triangle with green manual or stand mode icon	Global error	Verify user is in a safe position and restart the system. If problem persists, turn the system off and let the user safely sit on a chair. Contact your distributor or technical support.

Symptom	Cause	Fix
Continuous beep	Missing or discharged battery if this occurs during system power up. RC displays a flashing red battery icon.	Turn off system and replace the battery. Restart the device. If this fails, see technical fault below.
	User did not release leg	Restart system, if this fails see technical fault below.
	Technical fault	Connect the system to the GUI, an error message will display and a log file sent to Technical Support (given that there is Internet communication). System should not be used until it is certified for safe use by Technical Support.
Interface does not communicate with system	System needs to be restarted	Restart the system (turn off and on).
	USB cable	Verify cable is properly connected or replace cable.
	USB driver	Install USB driver from installation CD. 1. Insert the CD in the CD disk drive. 2. Open the "host_driver" directory and double click Install. 3. Follow the instructions on the screen.
System does not operate after connecting to interface	System needs restart	Disconnect USB cable from system and restart system (turn off and on).
RC prevents the user from selecting a new mode	The device is connected to the PC.	Disconnect the device from the PC.
	When powering up, the device was in an incorrect position.	Select "Sit" mode on the RC.

11. REPAIR POLICY

When under warranty, repair and service must be performed by Argo Medical Technologies Ltd. When the Argo Medical Technologies warranty is not applicable, repairs may be made by Argo Medical Technologies or an authorized representative.

For details, refer to the Warranty that is supplied with the Argo ReWalk system.



Warning: Do not remove the covers of the device components. Only perform maintenance procedures specifically described in this User Guide.

12. TECHNICAL SPECIFICATIONS

12.1. CAPACITIES

Capacities	
User weight	100 kg max.
User height	160 to 190 cm
Pelvic band width	29 to 37 in 2 cm increments
System weight	total: 25 kg (55 lbs)
Performance	
Walking	
Maximum Speed	2 km/Hr.
Joint movement	
Hip	34 degrees extension; 104 degrees flexion
Knee	110 degrees flexion; 2 degrees extension
Main & Auxiliary Batteries (Batteries have the same specifications except where noted)	
Materials	Li-Ion (Main) / Li-Polymer (Auxiliary)
Voltage	25.9 V DC
Capacity	10.4 AH (2 AH for Auxiliary battery)
Working time	Minimum 3 Hr. (15 min. for Auxiliary battery) of continuous walk
Charging temperature	0–45 degrees
Charging time	Minimum 4 hours
Power source	220 V or 110 V
Communicator	
Mode	Half duplex
RF signal	2.4 GHz (ISM band)
FCC	Complies with 47 CFR Part 15
ReWalk System Charger Specifications (Main and Auxiliary / Communicator)	
Input power	90-264 VAC @ 47-63 Hz / 100-240V AC @50-60Hz
Max. output power for 2 channels	60 W / 8 W
Temperature range	
Operating:	-25 to +40°C / -40 to +70°C
Storage:	-25 to +85°C / -40 to +70°C
Output connector	09-0571-00-08 (Output Male connector) / R-108 (Male match to PJ-041-SMT)
Output cable length	1.5–2 m / 1.83 m
Safety	EN60950-1, EN 60601-1, EN 60335-2-29 / IEC60601-1, ES60601-1
EMC standards	EMC med. EN 60601-1-2 /Emission EN 61000-6-3/ Immunity EN 61000-6-1

Environmental	
Water resistant	IP22- Per 60601-1-11, IEC:2010, EN 60529:1991, IEC 60529:1989
Broad band random vibration	6060068-2-64: 2008, IEC 60601-1-11 10.1.3c
Environmental shock to other than hand-held ME Equipment, parts and mounting accessories	6060068-2-27: 2008, 60601-1-11 10.1.3b
Operating range	-10 degrees C to 42 degrees C
Storage range	-20 degrees C to 60 degrees C


12.2. ELECTROMAGNETIC IMMUNITY

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

Argo ReWalk is intended for use in the electromagnetic environment specified below. The customer or the user of the device should make sure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment-Guidance
Electrostatic discharge(ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±8 kV contact ±15 kV air (<5% relative humidity)	The Argo ReWalk system should not be affected by electrostatic discharge that might occur under normal conditions of use.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Not applicable	Not applicable
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Not applicable	Not applicable

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
Argo ReWalk is intended for use in the electromagnetic environment specified below. The customer or the user of the device should make sure that it is used in such an environment.			
<p>Voltage dips, short interruptions and voltage variations on power supply lines</p> <p>IEC 61000-4-11</p> <p>For Charger only</p>	<p><5 % U_T (>95 % dip in U_T) for 0.5 cycle</p> <p>40 % U_T (60 % dip in U_T) for 5 cycles</p> <p><5 % U_T</p> <p>70 % U_T (30 % dip in U_T) for 25 cycles</p> <p><5 % U_T</p> <p><5 % U_T (>95 % dip in U_T) for 5 s</p>	<p>Not applicable</p>	<p>Not applicable</p>
<p>Power frequency (50/60 Hz) magnetic field</p> <p>IEC 61000-4-8</p>	<p>3 A/m</p>	<p>30 A/m</p>	<p>Power frequency magnetic fields should be at levels characteristic of a typical public low-voltage power supply network that supplies buildings used for domestic purposes, commercial or hospital, clinic environment. Was considered also other high levels until $H=30$ V/m</p> <p>Recommended separation distance</p> <p>$R = I/2\pi H = I/188$</p>
<p>NOTE: U_T is the AC mains voltage prior to application of the test level.</p>			

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
Argo ReWalk is intended for use in the electromagnetic environment specified below. The customer or the user of the device should make sure that it is used in such an environment.			
Conducted RF IEC 61000-4-6	3 Vrms 150kHz to 80MHz	Not applicable	<p>Portable and mobile RF communications equipment should be used no closer to any part of the Argo ReWalk, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = 1.17\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80MHz to 2.5GHz	10 V/m	<p>$d = 0.35\sqrt{P}$ 80 MHz to 800 MHz</p> <p>$d = 0.7\sqrt{P}$ 800 MHz to 2.5 GHz</p> <p>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation Distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey^a, should be less than the compliance level in each frequency range^b.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
<p>NOTE: At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption, and reflection from structures, objects and people.</p>			

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

Argo ReWalk is intended for use in the electromagnetic environment specified below. The customer or the user of the device should make sure that it is used in such an environment.

^aField strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcasts and TV broadcast cannot be predicted theoretically with accuracy. To access the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which Argo ReWalk is used exceeds the applicable RF compliance level above, the Argo ReWalk should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating Argo ReWalk.

^bOver the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.

12.3. RECOMMENDED SEPARATION DISTANCES

Recommended separation distances between portable and mobile RF communications equipment and the ReWalk system

This section provides information on the recommended separation distance between portable and mobile RF communications equipment and Argo ReWalk. Argo ReWalk is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. Argo ReWalk users can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Argo ReWalk as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to the frequency of transmitter (m)	
	80MHz to 800MHz $d = 0.35 \sqrt{P}$	800MHz to 2.5GHz $d = 0.70 \sqrt{P}$
0.01	0.035	0.07
0.1	0.11	0.22
1	0.35	0.7
10	1.1	2.2
100	3.5	7

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Recommended separation distances between Power bus or an appliance wire and the ReWalk system

Rated maximum current (I) in a power bus or an appliance wire Amperes [A]	Separation distance (in meters)	
	Meters [m]	
	$R = I/2\pi H = I/188$	
0.1	0.0005	
1	0.005	
10	0.05	
100	0.53	
1000	5.3	

NOTE 1 The power frequency magnetic field immunity of H=30 A/m is met.

12.4. ELECTROMAGNETIC EMISSIONS

Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
Argo ReWalk is intended for use in the electromagnetic environment specified below. The customer or the user of the Argo ReWalk system should make sure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions Test: CISPR 11	Group 1	Argo ReWalk uses RF energy only for system communication functions. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	Argo ReWalk is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. NOTE: The preceding statement is required by IEC 60601-1-2 for Group 1, Class B devices. However, since Argo ReWalk is battery powered, its emissions will not be affected by the establishment power supply and there is no evidence of any issues associated with the use of the system in domestic establishments.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

12.5. RADIO FREQUENCY (RF) COMMUNICATION SPECIFICATIONS

Radio frequency (RF) communication specifications
<ul style="list-style-type: none"> Communicator to INF frequency: 2.4 GHz; proprietary Argo protocol; range up to 6 feet (1.8 meters)

12.6. QUALITY OF SERVICE (QOS)

Quality of service

Common consumer electronic devices that transmit in the same frequency band used by the transmitter may prevent the INF from receiving the commands sent by the Communicator. Adherence to the following guidelines will result in a consistent and reliable quality of service:

- Cell phone 12 inches away from Communicator and INF
- Communicator and INF within 4 feet of each other

12.7. DATA SECURITY

Data security

Argo is designed to only accept radio frequency (RF) communications from recognized and linked devices (you must program your INF to accept information from a specific Communicator). Argo and system components (Communicator and INF) ensure data security via proprietary means, and ensure data integrity using error checking processes, such as cyclic redundancy checks.

12.8. COMMUNICATOR DISPLAY SIZE

Communicator display size

- Inches
 - Height approximately 2.0 inches
 - Width approximately 3.2 inches
 - Depth (thickness) approximately 0.77 inches
- Centimeters (cm)
 - Height approximately 5.1 cm
 - Width approximately 8.1 cm
 - Depth (thickness) approximately 2.0 cm

12.9. DAMAGE DUE TO RADIATION

Damage due to radiation

If you are going to have an X-ray, CT scan, MRI, or be exposed to other types of radiation, REMOVE YOUR COMMUNICATOR AND BACKPACK, and leave them outside the radiation area. The Argo ReWalk Communicator and INF are designed and tested to tolerate common electromagnetic interference, including microwave ovens.

12.10. FCC COMPLIANCE

12.10.1. COMPLIANCE WITH FCC AND INTERNATIONAL STANDARDS

FCC Compliance Statement

This device has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in residential installations. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio and television reception.

However, there is no guarantee that interference will not occur in a particular installation. If this device does cause such interference, which can be verified by turning the device off and on, the user is encouraged to eliminate the interference by one or more of the following measures:

- Re-orient or re-locate the receiving antenna.
- Increase the distance between the device and the receiver.
- Connect the device to an outlet on a circuit different from the one that supplies power to the receiver.
- Consult the dealer or an experienced radio/TV technician.

WARNING! Changes or modifications to this unit not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

This device complies with FCC Rules Part 15 and with Industry Canada licence-exempt RSS standard(s). Operation is subject to two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference that may be received or that may cause undesired operation.

Le present appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisee aux deux conditions suivantes :(1) l'appareil ne doit pas produire de brouillage, et (2) l'utilisateur de l'appareil doit accepter tout brouillage radioelectrique subi, meme si le brouillage est susceptible d'en compromettre le fonctionnement.

12.10.2. COMPLIANCE WITH FCC SECTION 1.1310

FCC Section 1.1310 Compliance Statement

To comply with FCC Section 1.1310 for human exposure to radio frequency electromagnetic fields, implement the following:

- A distance of at least 1 cm between the P Communicator and all persons should be maintained during the operation of the equipment.
- A distance of at least 5 cm between the P INF and all persons should be maintained during the operation of the equipment.

12.11. RF INTERFERENCE FROM OTHER DEVICES



Warning: Changes or modifications to this unit not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

RF interference from other devices

Common consumer electronic devices that transmit in the same frequency band used by the Communicator transmitter may prevent the INF from receiving the commands sent by the Communicator. Most cellular (mobile) phones and 900 MHz cordless phones, when transmitting or receiving, may cause significant interruption of Communicator – INF communication. It is likely that other devices operating in similar frequency ranges will have a similar effect. This interference, however, will not cause any incorrect data to be sent and will not cause any harm to your Communicator.

Argo ReWalk includes a programmable WEAK SIGNAL alert that notifies you when one or more expected transmissions were not received as expected by the INF. (The Communicator will also issue a LOST SENSOR alert if communication is interrupted.)

Communication problems can usually be resolved by:

- Ensuring that there is less than 6 feet (1.8 meters) between the Communicator and INF;
- Turning off or moving away from other RF transmitting devices; or
- Reorienting or relocating the Communicator and INF, or both.

Communications problems may also occur due to cellular telephone interference. Testing conducted with several different cellular telephones indicates that, while a command is being transmitted, using a cell phone within 12 inches (31 cm) of receiving devices, transmitters can interfere with reception of the transmitted values. In the event of such interference, normal communication can be re-established by:

- Turning the cell phone off; or
- Keeping the cell phone at least 12 inches away from the Communicator or INF when an instruction is being transmitted.

If you have questions, please contact your local representative for assistance.

This device complies with FCC Rules Part 15 and with Industry Canada licence-exempt RSS standard(s). Operation is subject to two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference that may be received or that may cause undesired operation.

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes : (1) l'appareil ne doit pas produire de brouillage, et (2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

13. CLINICAL STUDIES

Clinical Study Overview

Clinical testing consisted of a pilot study and multi-center open, non-comparative, non-randomized studies evaluating the safety and performance of the ReWalk device. All subjects were diagnosed with complete spinal cord injury per the American Spinal Injury Association (ASIA) guidelines. The level of injuries ranged for T2 to L1. A total of 39 subjects were enrolled and 30 completed the study and were considered performance-evaluable. All of the performance-evaluable subjects were able to complete the performance outcome measures. There were no serious device related adverse events during the course of the two studies. The adverse events reported were all skin related, such as abrasions, which occurred in approximately 4% of the training sessions and were all resolved with adjustments to the fit of the device.

Pilot Study Summary

<p>Title of Study: Performance Evaluation of ReWalk™ Reciprocating Gait Orthosis</p>
<p>Objectives: <i>Primary Objective:</i> Establish the safety and performance of the ReWalk™ device to enable people with lower limb disabilities to carry out routine ambulatory functions. <i>Secondary Objectives:</i> Extend the safety assessment to establish the performance of the ReWalk™ device by examining device functionality, such as device ergonomics, user friendliness, and satisfaction.</p>
<p>Methodology: An open, non-comparative, non-randomized study of the safety and performance of the ReWalk™ device.</p>
<p>Number of Subjects: <i>Enrolled:</i> 7 <i>Completed:</i> 6</p>
<p>Diagnosis and Main Criteria of Inclusion: Male/Female subjects of any race, ages 18-55, with chronic (at least 6 months after the injury) complete cervical (C7-8) or thoracic (T1-T12) spinal cord injury according to American Spinal Injury Association (ASIA) guidelines.</p>
<p>Duration of Treatment/Exposure: Approximately 24, 60 – 90 minute sessions over the course of approximately 8 weeks.</p>
<p>Criteria for Evaluation: <i>“Intent-to-Evaluate” (ITE)</i> subjects were defined as those who provided written informed consent (i.e., those who “enrolled”). <i>Performance: “Performance-Evaluable”</i> subjects were defined as those who used the ReWalk™ device during user training and completed the performance testing. <i>Safety: “Safety-Evaluable”</i> subjects were defined as those who had any exposure to the ReWalk™ device.</p>

<p>Statistical Methods: <i>Investigational Product Primary Performance Endpoints:</i> Ability of a trained subject to, at final visit, complete:</p> <ul style="list-style-type: none"> • Six minute walk; and • Ten meter walk. <p><i>Secondary Performance Endpoint:</i></p> <ul style="list-style-type: none"> • Spasticity (Ashworth Scale); and • The device’s ability to carry a load. <p><i>Primary Safety Endpoints:</i></p> <ul style="list-style-type: none"> • No expected or unexpected adverse events. <i>Secondary Safety Endpoints:</i> <ul style="list-style-type: none"> • Frequency of autonomic dysreflexia; and • Multiple systems complications (e.g., skin abrasions and joint integrity).
<p>Summary Conclusions: PERFORMANCE RESULTS: <i>Primary Performance Endpoints:</i></p> <ul style="list-style-type: none"> • 100% of performance-evaluable subjects, who completed training, were able to complete the six minutewalk. • 100% of performance-evaluable subjects, who completed training, were able to complete the ten meter walk. <p><i>Secondary Performance Endpoints:</i></p> <ul style="list-style-type: none"> • Sixty-seven percent of performance-evaluable subjects (4/6) demonstrated no change in Ashworth value; thirty-three percent (2/6) demonstrated a decrease in Ashworth value. • No device failures or malfunctions were reported in association with a subject whose weight approached the device’s upper limit of load specification. <p>SAFETY RESULTS: <i>Primary Safety Endpoints:</i></p> <ul style="list-style-type: none"> • There were no expected or unexpected adverse events reported for this study. There were no serious adverse events reported for this study. <p><i>Secondary Safety Endpoints:</i></p> <ul style="list-style-type: none"> • No incidents of autonomic dysreflexia were reported for any subject during this study. Further, no incidents of autonomic dysreflexia were suggested by the complications reported. • No incidents of multi-system complications were reported for any subject during this study. <p>CONCLUSIONS: This study demonstrates that the ReWalk™ device is safe and well-tolerated in enabling people with lower limb disabilities to carry out routine ambulatory functions (e.g., stand and walk).</p>

Multi-Center Study Summary

<p>Title of Study: Performance Evaluation of ReWalk™ Reciprocating Gait Orthosis</p>
<p>Objectives: <i>Primary Objective:</i> Establish the safety and performance of the ReWalk device to enable people with lower limb disabilities to carry out routine ambulatory functions. <i>Secondary Objectives:</i> Extend the safety assessment to establish the performance of the ReWalk device by examining device functionality, such as device ergonomics, user friendliness, and satisfaction.</p>
<p>Methodology: An open, non-comparative, non-randomized study of the safety and performance of the ReWalk device.</p>
<p>Number of Subjects: <i>Enrolled:</i> 32 <i>Completed:</i> 24</p>
<p>Diagnosis and Main Criteria of Inclusion: Male/Female subjects of any race, ages 18-55, with chronic (at least 6 months after the injury) complete cervical (C7-8) or thoracic (T1-T12) spinal cord injury according to American Spinal Injury Association (ASIA) guidelines.</p>
<p>Duration of Treatment/Exposure: Approximately 16 - 24, 60 – 90 minute sessions over the course of approximately 8 weeks.</p>
<p>Criteria for Evaluation: <i>“Intent-to-Evaluate” (ITE)</i> subjects were defined as those who provided written informed consent (i.e., those who “enrolled”). <i>Performance: “Performance-Evaluable”</i> subjects were defined as those who used the ReWalk device during user training and completed the performance testing. <i>Safety: “Safety-Evaluable”</i> subjects were defined as those who had any exposure to the ReWalk device.</p>
<p>Statistical Methods: <i>Investigational Product Primary Performance Endpoints:</i> Ability of a trained subject at the final visit to complete: <ul style="list-style-type: none"> • Six minute walk; and • Ten meter walk. <i>Secondary Performance Endpoint:</i> <ul style="list-style-type: none"> • Spasticity (Ashworth Scale); and • The device’s ability to carry a load. <i>Primary Safety Endpoints:</i> <ul style="list-style-type: none"> • The incidence of adverse events. <i>Secondary Safety Endpoints:</i> <ul style="list-style-type: none"> • The incidence of autonomic dysreflexia; and • The incidence of multi-system complications (e.g., skin abrasions and joint integrity). </p>

Summary Conclusions:

PERFORMANCE RESULTS:

Primary Performance Endpoints:

- 100% of performance-evaluable subjects for the six minute walk (20/20), who completed training, were able to complete the six minute walk.
- 100% of performance-evaluable subjects for the ten meter walk (22/22), who completed training, were able to complete the ten meter walk.

Secondary Performance Endpoints:

- In the performance-evaluable (for spasticity) population, as measured with average Ashworth Scale: 8/13 demonstrated no change; 1/13 demonstrated an increase; and 4/13 demonstrated a decrease in spasticity after use of the device.
- The device is able to carry a patient load near the upper limit of the device's load specification.

SAFETY RESULTS:

Primary Safety Endpoints:

- The most frequent adverse events involved skin.
- All adverse events resolved uneventfully.
- No device-related or study-related serious adverse events were reported during this study.

Secondary Safety Endpoints:

- No incidents of autonomic dysreflexia were reported for any subject during this study.
- No incidents of autonomic dysreflexia were suggested by the complications reported.
- Skin abrasions and related skin complications were reported in approximately 4% of all training sessions.

CONCLUSIONS:

This study demonstrates that the ReWalk™ device is safe and well-tolerated in enabling people with lower limb disabilities to carry out routine ambulatory functions (e.g., stand and walk).

Conclusions:

The Pilot and Multi-center studies both support the conclusion that the ReWalk™ device is safe and well-tolerated in enabling people with lower limb disabilities to carry out routine ambulatory functions (e.g., stand and walk).

14. WARRANTY AND DISCLAIMER

Service Support

Repairs of the ARGO REWALK P System under warranty must be made by authorized repair centers. If the device needs repair, contact Argo Medical Technologies Ltd. service department or your local distributor for Warranty details.

If you need to ship the device, pack the device and its accessories carefully to prevent shipping damage.



Caution: Always transport the system in the original shipping container.



Caution: Always ship the system with the batteries removed.