WillowWood®

LimbLogic® Patient Instructions

LimbLogic uses air pressure and a sealing system to suspend your prosthesis.

The system includes a fob that gives you remote control of the vacuum level.

Please read these instructions thoroughly. Contact your prosthetist if you have any questions.

The following information is required by law. If you are not familiar with these concepts, please discuss them with your prosthetist.

There are no field-serviceable parts inside the Vacuum Pump. Opening the Vacuum Pump or charger may result in injury or death and will void the warranty.

Unauthorized changes or modifications to the LimbLogic pump or accessories may; impair their function resulting in injury or death, will void the warranty, and may prevent their compliance with relevant standards.

This pump is only designed to move air; use of Vaseline® or similar lubricating creams inside the socket will clog the pump. Do not allow foreign substances to be pulled through the Vacuum Pump. This may impair function of your vacuum system.

Do not allow acetone to contact the Vacuum Pump or fob.

All LimbLogic components have passed safety testing for use as medical devices. Radio enabled devices comply with United States and international guidelines for low power transceivers. If LimbLogic components will be used around safety critical devices such as pacemakers or defibrillators, consult the manufacturer for appropriate usage instructions. Failure to do so may result in injury or death. Consult the section on Regulatory Information for more information on safety and compliance.

LimbLogic is designed for use by a single patient only. Use on more than one patient may result in cross-contamination potentially causing a serious infection.

Charge the Vacuum Pump in a well-ventilated area at a temperature between 5 °C (41 °F) and 33 °C (90 °F). Failure to do so may result in prolonged or incomplete charging of the Vacuum Pump and may damage the Vacuum Pump.

A Vacuum Pump enclosed by a cosmetic cover will retain heat, but in most cases should charge normally at temperatures below 27 °C (80 °F). The battery may not fully charge at higher temperatures.

Use of the LimbLogic at temperatures above 41 °C (106 °F) may heat the surface of the product to unsafe temperatures which could cause burns with extended contact. Use care when operating the LimbLogic at high temperatures.

LimbLogic has been constructed using polymer materials to create a durable, lightweight, water-tight, and radio-transparent design. These materials have all been certified to an inflammability rating of at least HB per UL 94. However, polymers can melt or burn if exposed to high temperatures or flame. Do not expose your LimbLogic product to these conditions. Doing so may result in ignition resulting in injury or death.

LimbLogic pumps cannot compensate for failures in the associated prosthetic socket or sealing system. Only use LimbLogic pumps with commercially proven socket and sealing systems. Use with other sealing systems may result in loss of suspension resulting in injury or death.

Electrical equipment can interact. Do not operate the fob, charger, or either LimbLogic pump design while they are stacked upon, or in close proximity to, other electrical equipment without monitoring performance. Doing so may result in equipment malfunction or failure.

Contact your prosthetist if you develop rashes or other reactions after contact with LimbLogic components.

The Side Mount LimbLogic Vacuum Pump has been designed and tested for mounting on transfemoral sockets. Use in other configurations may result in tripping or other hazards.

FCC NOTICE

Note:

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Changes or modifications not approved by The Ohio Willow Wood Company may degrade performance, possibly leading to injury or death and will void the user's authority to operate this equipment.

IC Notice

Note:

This device complies with Industry Canada RSS standards applicable to radio devices. Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) the user of the device must accept any interference, including interference that may cause undesired operation.

Remarque:

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio . 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.

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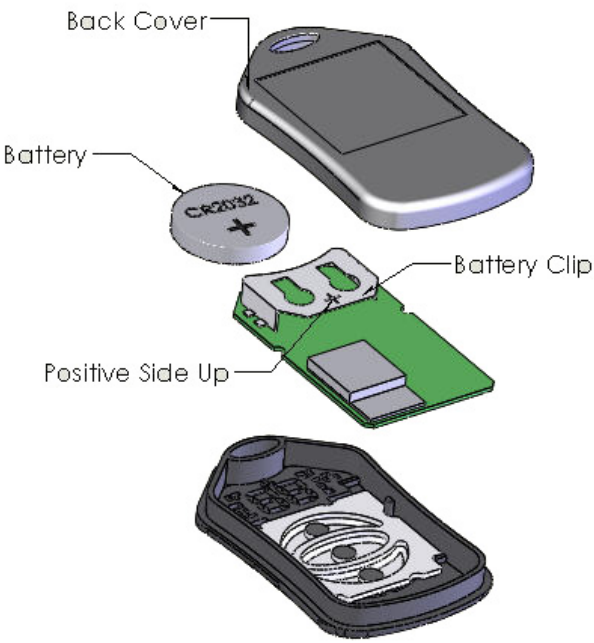
INSTALLING THE FOB BATTERY

The fob uses a coin cell battery. The type is CR2032. The battery that is shipped with the system must be installed prior to using the fob.

The battery will normally have to be replaced every 3 months.

Pry open the fob case with a small flat blade screwdriver. To snap it back together, start at the battery end and work back toward the opposite end.

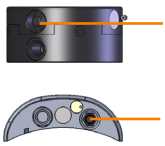


The fob battery could cause serious injury or death including choking. Keep coin cell type batteries away from children.

After you replace the battery, all of the LED indicators should light up. If they do not, the battery might be upside-down. Otherwise, either the battery or the LEDs are not working.

QUICK-START GUIDE

1. **Turn on the Vacuum Pump.**



Press one time.
Pump will beep once.
Wait 10 seconds.

2. **Turn on the fob.**

Press and hold the center button The yellow numbers will flash in a “chasing” pattern. Then they will display the current vacuum level. Release the button.
The pump is now Active. The pump will operate until the desired vacuum level is reached.

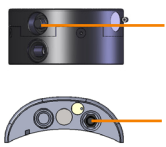
3. **To enter Standby Sate:**

Press for about 2 seconds.
The chasing pattern will be displayed, then the white Standby Indicator will light.

To resume vacuum regulation:

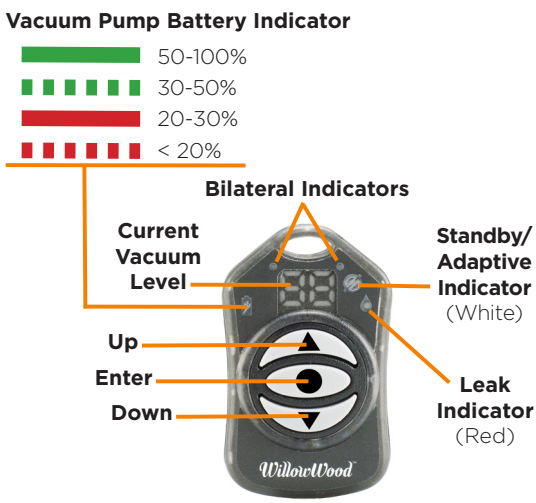
Press for about 2 seconds.
The chasing pattern will be displayed.
The pump returns to Active State.

6. **Turn off the Vacuum Pump.**



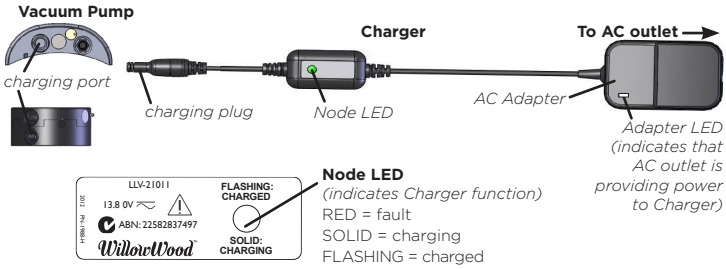
Press one time.
Pump will beep either two or four times to indicate its configuration. Talk to your prosthetist if you have questions.

FOB GUIDE



CHARGING THE VACUUM PUMP BATTERY

Charge the Vacuum Pump before it is used for the first time. Also charge it at the end of each day of use, and when the Battery Indicator on the fob is red.



Node LED
(indicates Charger function)
RED = fault
SOLID = charging
FLASHING = charged

1. Charge the Vacuum Pump in a well-ventilated area between 5 °C (41 °F) and 32 °C (90 °F). Charging outside of this range may damage your Vacuum Pump. It may also result in prolonged or incomplete charging.

   The following information is required by law. If you are not familiar with these concepts, please discuss them with your prosthetist.

Only charge the Vacuum Pump in a well ventilated area at a temperature between 5 °C (41 °F) and 32 °C (90 °F). Charging outside of these conditions may damage the Vacuum Pump.

A Vacuum Pump enclosed by a cosmetic cover will retain heat, but in most cases should charge normally at temperatures below 27 °C (80 °F). The battery may not fully charge at higher temperatures.

2. Insert the charging plug all the way into the charging port.

3. Plug the Charger into a power outlet. The Adapter LED will light. If the Node LED does not light, make sure you have inserted the charging plug all the way into the port.

   If the Node LED is red, reset the Charger by unplugging it from the wall and plugging it back in.

   While charging is in progress, the Node LED will be solid. The battery indicator on the fob will flash between red and green.

4. When charging is complete, the Node LED will flash. Disconnect the Charger from the Vacuum Pump and from the power outlet.

When you are ready for the pump to begin regulating the vacuum, either turn on the fob (refer to page 9) or press the **on/off button** on the Vacuum Pump. The pump will run until the preselected vacuum level is reached.

Note: Your pump can be used while charging. If the pump has just been unplugged from the Charger, it will be in Standby State (refer to page 10). To resume vacuum regulation, press the on/off button one time for Active State. Press again to turn the pump off.

Do NOT walk while charging your LimbLogic. You may trip and fall.

Use ONLY a WillowWood Charger. Use of any other charger may result in damage to the Vacuum Pump or the charger or both and may negatively affect EMC performance and/or compliance and may result in serious injury or death.

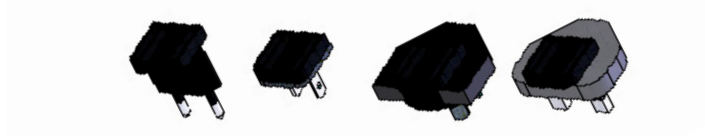
The charger may pose both a strangulation and/or electrocution hazard and should not be handled by children.

Do not use the Charger near water. The Charger is not waterproof. Use of the charger near water may result in serious injury or death.

The battery will power the pump for at least a full 18 hour day of normal usage. It will do so for the life of the product. (Refer to "Service Life" on page 13.) If it is unable to do so, please refer to page 14 or call your prosthetist.

CHARGING THE VACUUM PUMP BATTERY OUTSIDE THE UNITED STATES

Chargers sold for use outside the U.S. come with a set of prong adapters. These adapters allow you to use the Charger in many countries.



The following information is required by law. If you are not familiar with this concept, please discuss it with your prosthetist.

Plugging a prong set into an outlet without the Charger may expose you to dangerous voltages potentially leading to injury or death. Always plug the prong set into the Charger before plugging the Charger or the prong set into an outlet.

CHARGING THE VACUUM PUMP BATTERY IN A VEHICLE

To charge the Vacuum Pump in a vehicle, you need a Power Inverter. The Power Inverter must be rated at 75 Watts or less.

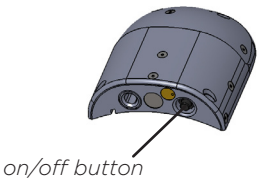
Example:

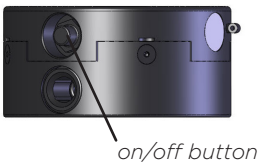
- Digital Concepts™ 75 Watt Portable Power Inverter (available from general retailers)

1. Plug the Power Inverter into the car's 12V DC socket.
2. Connect the Charger to the Vacuum Pump.
3. Plug the Charger into the Inverter.

Do not operate the Charger above 41 ˚C (105 ˚F). The battery may not fully charge at higher temperatures.

TURNING ON THE VACUUM PUMP





Press the **on/off button** on the Vacuum Pump one time. The Vacuum Pump will beep once.

Before turning on the fob wait 10 seconds for the pump to activate.

TURNING OFF THE VACUUM PUMP

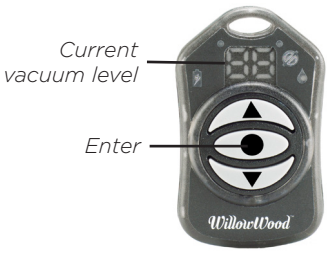
Press the **on/off button** on the Vacuum Pump and hold for 1 second. The pump will beep several times to indicate that it has been turned off. Refer to the Quick-Start Guide (page 6) for more information.

Note: if the pump has just been unplugged from the Charger, it will be in Standby State (refer to page 10). To resume vacuum regulation, press the on/off button one time for Active State. Press again to turn the pump off.

RESETTING THE VACUUM PUMP

The pump may stop working if it is exposed to static electricity. If this happens, press the on/off button on the pump and hold for at least 12 seconds until the unit beeps. You may also need to reset the pump when the fob displays certain error codes (see page 17).

TURNING ON THE FOB



Make sure the pump is on has been on for at least 10 seconds.

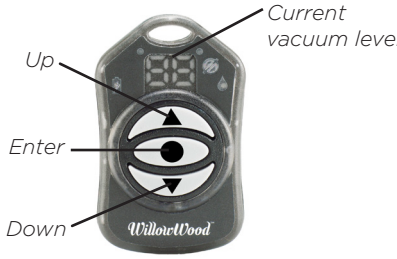
Press and hold the **Enter** (center) button. After about 2 seconds the yellow numbers will flash in a “chasing” pattern. The chasing pattern means that the fob is trying to communicate with the pump.

When the fob connects to the pump, the current vacuum level will be displayed in the center. A connected fob will shut off after one minute of non-use.

If the pump is off or does not connect to the fob, the chasing pattern will end after 6 seconds. All of the LEDs on the fob will turn off.

If you have a pump on each leg, the fob will try to communicate with the first pump, followed by the second pump. If the fob cannot communicate with either pump, the fob will shut down.

CHANGING VACUUM SET POINT



Make sure that the fob is on that the yellow numbers are showing the current vacuum level.

Press the **Up** or **Down** button for 1 second until the yellow numbers flash. The flashing numbers indicate that the **Vacuum Set Point** is being changed.

Adjust the **Vacuum Set Point** as follows:

- Press the **Up** or **Down** button again and again to change the Vacuum Set Point by one number at a time.

  or

- Press and hold the **Up** or **Down** button until the desired Vacuum Set Point is displayed.

Press the **Enter** button to apply the changes. The "chasing" pattern will be displayed while the setting is being applied. If the **Enter** button is not pressed, the settings will not be applied. The fob will shut off due to inactivity in 60 seconds.

CHANGING PUMP STATE

Make sure the fob is on and displaying the current vacuum level.

When the pump is on, it has two usage states.

Active: The pump turns on as needed to maintain the vacuum level.

Standby: This allows you to turn the pump off temporarily.

Press and hold the **Enter** button to toggle the vacuum pump between these two states. The "chasing" pattern will be displayed while the change is being applied.

The white **Standby indicator** will light up as follows.

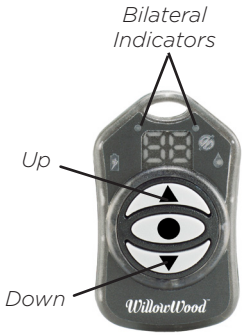
Not lit: **Active**

Lit: **Standby**

If the pump detects a leak, the red **Leak Indicator** lights up. Also, the pump enters **Standby State** and beeps 10 times rapidly. The beeps repeat every 30 seconds unless you press the **on/off** button on the pump. The beeps will stop after 6 minutes.

To return to **Active State**, press and hold the **Enter** button.

BILATERAL INDICATORS



If you have a pump on each leg, the white light on the top left of the fob lights up when the fob is controlling the left pump. The white light on the top right of the fob lights up when the fob is controlling the right pump.

To control the other pump, press and hold the **Up** and **Down** buttons together for about 1 second. While the fob tries to connect with the other pump, the “chasing” pattern lights up and the white lights alternate.

If the fob connects to the other pump, the fob functions like it would for a one-pump system.

If the fob does not connect to the other pump, the fob will return to controlling the first pump.

DETECTING A LEAK

If the pump detects a leak, the red **Leak Indicator** will light up. Also, the system will enter **Standby State**.

At this time, the pump will make 10 short beeps. The beeps repeat every 30 seconds unless you press the **on/off** button on the pump. The beeps will stop after 6 minutes.

If the **Leak Indicator** lights up just after you put on your prosthesis, restart the pump.

If the **Leak Indicator** lights up often while you are walking, call your prosthetist.

To start the pump again after a leak was detected, press the **on/off** button on the pump one time. Another option is to press the **Enter** button on the fob.

VACUUM PUMP BATTERY STATUS

When the pump battery is charging, this light flashes between red and green.

The level of charge is described below.

- Solid green: pump battery is charged more than 50% but less than 100%.
- Flashing green: pump battery is charged more than 30% but less than 50%.
- Solid red: pump battery is charged more than 20% but less than 30%.
- Flashing red: pump battery is less than 20% charged. The battery should be charged when possible. The pump will shut down when the battery level reaches 0%.
- At 10% the pump will start to beep 3 times every 30 seconds. This will repeat for 6 minutes unless you press the **on/off button** on the pump.

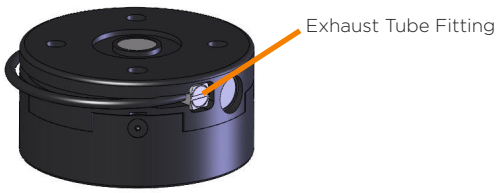
EXPOSURE TO WATER

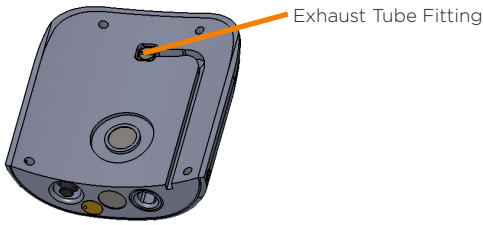
You may place the Vacuum Pump in 10 feet (or 3 meters) of fresh water for up to 12 hours. Do not submerse the Vacuum Pump in salt water. Do not submerse the Vacuum Pump in corrosive liquids. Be sure to dry off the Vacuum Pump if it is exposed to rain or other moisture.

The fob and Charger should not be exposed to water or other liquids. If your fob is damaged by water, call your prosthetist for a replacement. You can continue to use your LimbLogic by simply turning it on and off with the push button.

EXHAUST TUBE MUFFLER CLEANING

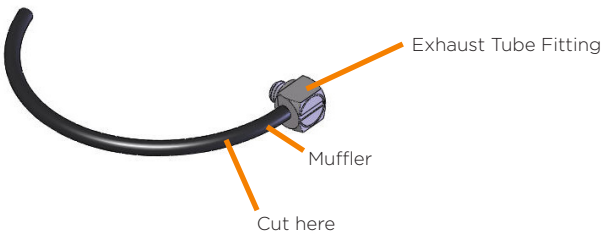
Using a flat blade screwdriver, remove the Exhaust Tube Fitting from the pump housing. Do not lose the o-ring from the fitting.





Clear the clog in the tube by running water or by gently blowing compressed air through the tube.

If you cannot clear the clog, ask your prosthetist for a replacement Exhaust Tube.



If the pump must be used before the replacement tube can be installed:

1. Remove the existing tube from the Exhaust Tube Fitting.
2. Cut the existing tube just past the Muffler.
3. Connect the Exhaust Tube Fitting to the section of tube that does not have the Muffler. The pump will function normally, but at a slightly higher noise level.

POTENTIAL HOME USE CHALLENGES

Your pump, fob, and charger are unlikely to be damaged by exposure to lint, dust, or light. However, it is best not to charge the pump while it is sitting in direct sunlight or near a furnace. This might heat the pump enough to prevent it from obtaining a full charge.

You can clean your pump by wiping it with a damp cloth. Use only water.

Do not allow children or pets to play with your LimbLogic or its accessories. They are designed to be durable, but they may be damaged if exposed to rough handling such as chewing.

SERVICE LIFE

The LimbLogic pumps are designed for a reliable service life of at least two years.

TROUBLESHOOTING GUIDE

Problem	Action
The pump does not beep when the on/off button is pressed and the Charger is not connected to the pump.	• The pump's internal battery may not be charged. Charge the pump with the Charger for at least 30 minutes and try again. • The on/off button could be damaged. Verify that the rubber boot is intact and hasn't been torn from impact. Contact your prosthetist if the switch needs to be replaced. • The pump may have been exposed to a large static charge. Press and hold the on/off button on the pump until you hear a beep (about 12 seconds).
Pressing the pump button does not start the pump.	• The pump's internal battery may not be charged. Charge the pump with the Charger for at least 30 minutes and try again. • The pump may have been exposed to a large static charge. Press and hold the on/off button on the pump until you hear a beep (about 12 seconds). • The pump may be partially stalled. Refer to the "Pump Stall" error code information on page 17.
Pump battery does not maintain charge for a full day.	• Ensure that the system is properly sealed. • Ensure that the battery has been charged for at least 4 hours. • The pump may have been exposed to a large static charge. Press and hold the on/off button on the pump until you hear a beep (about 12 seconds). • Ensure that your socket does not leak excessively. • Make sure that the charger plug stays fully inserted during charging. The rubber ring has been tested to last the life of your product. However, if the plug is too loose, replace the rubber ring.
The pump makes a "zip zip zip" sound as it controls the vacuum.	Call your prosthetist.
Pressing the center button of the fob does not cause the yellow LEDs to light in a "chasing" pattern.	The battery is likely dead and must be replaced per the instructions on page 5.

continued on next page

Problem	Action
When the vacuum level in your socket changes, the yellow numbers on the fob do not change.	Call your prosthetist.
The fob does not communicate with the pump. The “chasing” pattern of LEDs ends after 6 seconds, and the LEDs turn off.	• Wait one minute for the fob screen to turn off. Make sure the pump is on by pressing the on/off button and verify that the pump beeps once. Listen for about 30 seconds to make sure that the pump doesn’t quickly beep several times and turn off. (If it does, there is a battery problem.) Press the fob center button again. • The fob may be too close or too far from the pump. Place the fob about 2 feet away from the pump, and press the fob center button again. • The pump’s internal battery may not be charged. Charge the pump with the Charger for at least 30 minutes and try again. • The pump may have been exposed to a large static charge. Press and hold the on/off button on the pump until you hear a beep (about 12 seconds). • Do you have the correct fob-pump combination? The fob and pump are electronically matched. Ask your prosthetist to call WillowWood with the serial numbers of the fob and the pump. WillowWood will verify that the set is matched.
The Adapter LED on the Charger does not illuminate when plugged into the wall.	• The AC electricity to the wall outlet may not be turned on. Try plugging the Charger into a different wall outlet. • The prong may not be seated properly in the back of the Charger’s AC Adapter. Unplug the Charger from the AC outlet. Remove the Charger’s prong using the sliding latch on the back of the adapter. Make sure that the metal contacts are springy. Also make sure that the contacts are not completely flat against the adapter. Re-install the plug prongs. • If the problem persists, call your prosthetist.

continued on next page

Problem	Action
The Node LED on the Charger does not light or blink when the Charger is plugged into vacuum pump and AC outlet.	Call your prosthetist.
The Node LED is red.	Reset the Charger by unplugging it from the wall, waiting ten seconds, and then plugging it back in.
The pump runs repeatedly.	Using a flat blade screwdriver, remove the Exhaust Tube Fitting from the pump housing. Do not lose the o-ring from the fitting. Install the drain tube and flush the system with alcohol.
The pump beeps but does not run.	The Muffler on the Exhaust Tube may be clogged. Clean the Muffler as described on page 13.

SUPPORT

If you cannot fix a problem using this guide, call your prosthetist.

Under normal conditions, you should not need to rinse or sanitize your pump. If your pump starts to smell, or if you suspect contamination, call your prosthetist.

If you have other questions, call your prosthetist.

Error Codes

Sometimes the pump detects an error that it cannot fix on its own. When this happens, the fob display switches between “Er” and a two-digit error code. Refer to the chart below for a list of these codes and the action required for each code.

Problem	Description	Cause	Action
01	Pump stall	Possibly debris or lubricant stuck in pump	Call your prosthetist.
02	Temp out of range	Pump operation attempted at a temperature less than -20˚ C or greater than 50˚ C	Allow pump temperature to return to operating range. Then press and hold the pump’s on/off button for about 12 seconds until you hear a beep.
03	Motion fail	Motion sensor failure	Call your prosthetist.
04	ADC fail	Analog Digital Converter failure	Call your prosthetist.
05 or 09	Memory	Memory failure	Press and hold the pump’s on/off button for about 12 seconds until you hear a beep. If problem persists, call your prosthetist.
06	Radio	BLE Radio failure	Call your prosthetist.
07	Vacuum	Vacuum Sensor failure	Call your prosthetist.
08	Battery	Battery monitoring circuit failure	Call your prosthetist.

OPERATION AT HIGH ALTITUDE OR LOW PRESSURE

LimbLogic uses air pressure to hold on a prosthesis. There is less air pressure at higher altitudes. The system works normally at a height up to 1700 meters*. Above 1700 meters*, the system might act like it is leaking. If this happens, lower your vacuum setting. Try a setting of 17. This usually works up to a height of 3000 meters**.

*1700 meters = 5500 feet
**3000 meters = 10000 feet

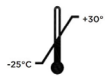
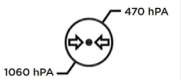
The following information is required by law. If you are not familiar with these concepts, please discuss them with your prosthetist.

REGULATORY INFORMATION

Return this product to the factory for proper disposal.

Essential performance:

The LimbLogic fob, charger, and side mounted pump perform no essential performance. The distally mounted pump is designed to provide structural support when assembled into a prosthesis and complies to ISO 10328 for this function.

Symbol	Definition
	Acceptable temperature range for long term storage.
	Acceptable humidity range for long term storage.
	Acceptable pressure range for long term storage.
	Consult instructions for use.
IP28	You may place the LimbLogic pump in 10 feet (or 3 meters) of fresh water for up to 12 hours. Your fob and charger are not resistant to water. The design is meant to keep fingers or similar objects outside of the pump, charger, and fob.
	Adjacent to Manufacturers name and address.
	This product complies with applicable standards for sale and use in EC countries.
7.0V 	This device operates on up to 7 volts of AC and DC current.
	Type BF applied part.
	On/Off button. Push-Push style.
	This product contains an RF transmitter.
POM	This device enclosure is manufactured with an acetal polymer.
	This product is compliant for sale in Australia and New Zealand.
2015	Year of manufacture.

LimbLogic Fob

This product contains a user replaceable lithium battery. Replace only with user replaceable CR2032 batteries. Discard of discharged batteries in accordance with local regulations. Observe polarity markings on the battery and the fob housing when replacing the battery.

This product complies with: EN 60601-1-2:2007, IEC 60601-1-11:2010, IEC 60601-1-6:2010, IEC 60601-1-2 ED. 3.0, and IEC 60601-1:2005 +CORR.1(2006) + CORR. 2 (2007).

IEC 60601-1 Classifications:

Internally powered

Degree of protection against electrical shock – Type BF Applied Part

In addition to the above compliances, this device complies with EN55022:1998/A1:2000/A2:2003 Class B ITE emissions requirements and all requirements for Low Interference Potential Devices (LIPD) and compliance with the requirements for a General User Licence (GUL).

LimbLogic Vacuum Pump

This product contains a rechargeable Lithium Ion Battery. Use ONLY a Willow Wood Charger. Use of other chargers may result in harm to the device, the user, or both and void the warranty.

Blocking or plugging the exhaust port of the vacuum control assembly will prevent proper operation of the vacuum pump.

The LimbLogic Vacuum Pump is intended for use on a single patient. Use of the system with multiple patients could lead to cross contamination between patients.

The LimbLogic vacuum system has been designed for and clinically tested as a suspension aid. It has not been clinically tested for wound healing or other uses. WillowWood does not currently support the use of the LimbLogic for uses other than suspension.

Use only the bolts supplied by WillowWood. All testing for the LimbLogic vacuum system has been tested with the bolts included with the system. Use of other bolts could result in mechanical failure.

LimbLogic has been constructed using polymer materials to create a durable, lightweight, watertight, and radio-transparent design. These materials have all been certified to an inflammability rating of at least HB per UL 94. However, polymers can melt or burn if exposed to high temperatures or flame. Do not expose your LimbLogic product to these conditions. Do not expose your LimbLogic product to these conditions. Doing so may result in ignition resulting in injury or death.

This product complies with: EN 60601-1-2:2007, IEC 60601-1-11:2010, IEC 60601-1-6:2010, IEC 60601-1-2 ED. 3.0, IEC 60601-1:2005 +CORR.1(2006) + CORR. 2 (2007), CEI/IEC 60529:1989+A1:1999 rating IP28, and ISO 10328:2005.

IEC 60601-1 Classifications:

Internally powered/Powered from Class II Power Supply

Degree of protection against electrical shock – Type BF Applied Part

This product complies with the requirements of ISO 10328.

In addition to the above compliances, this device complies with EN55022:1998/A1:2000/A2:2003 Class B ITE emissions requirements and all requirements for Low Interference Potential Devices (LIPD) and compliance with the requirements for a General User Licence (GUL).

LimbLogic Battery Charger

This product is designed to work with WillowWood products specifically designed for its use. Use WillowWood charger part number LLV-21011. Use with other products may result in harm to the device, the user, or both, may void the warranty, and may negatively affect EMC performance and/or compliance. Refer to product manuals to verify compatibility with this charger before attempting to use this charger with the product.

Electrical Ratings:
Rated input: 100 – 240 Vac, 0.6 A, 47 – 63 Hz
Rated output: 13.8 Vdc, 2.6 A

This product complies with: EN 60601-1-2:2007, IEC 60601-1-11:2010, IEC 60601-1-6:2010, IEC 60601-1-2 ED. 3.0, and IEC 60601-1:2005 +CORR.1(2006) + CORR. 2 (2007) and meets the "ICNIRP GUIDELINES FOR LIMITING EXPOSURE TO TIME-VARYING ELECTRIC AND MAGNETIC FIELDS (1 HZ – 100 kHZ):2010".

FCC AND IC COMPLIANCE INFORMATION

FOR THE SIDE MOUNT PUMP

This equipment contains:
FCC ID U3V-LLV21011
and module FCC ID XDULE40-S2
Module IC: 8456A-LE4S2

Cet équipement contient:
Module d'émission IC: 8456A-LE4S2

FOR THE DISTAL MOUNT PUMP

This equipment contains:
FCC ID U3V-LLV21011
and module FCC ID XDULE40-S2
Module IC: 8456A-LE4S2

Cet équipement contient:
Module d'émission IC: 8456A-LE4S2

FOR THE FOB

Module FCC ID XDULE40-S2
Module IC: 8456A-LE4S2

Cet équipement contient :
Module d'émission IC: 8456A-LE4S2

FOR THE CHARGER

This equipment contains:
FCC ID U3V-LLV21011
IC: 7475A-21011

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

1. This device may not cause harmful interference, and
2. This device must accept any interference received, including interference that may cause undesired operation.

Radio Frequency Interference Statement

This is a Class B product. In a domestic environment, this product may cause radio interference in which case the user may be required to take adequate measures.

Note:
This equipment 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 a residential installation. 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 communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

This digital apparatus does not exceed the Class B limits for radio noise emissions from digital apparatus set out in the Radio Interference Regulations of the Canadian Department of Communications.

REMARQUE:

Cet équipement a été testé et déclaré conforme aux les règles de ICES-001. Ces limites ont pour objectif de fournir une protection raisonnable contre les interférences nuisibles dans une installation résidentielle. Cet équipement génère, utilise et rayonne de l'énergie de fréquence radio et peut nuire aux communications radio s'il n'est pas installé et utilisé en accord avec le mode d'emploi. Cependant, il n'est pas garanti que des interférences surviennent dans une installation particulière. Si l'équipement cause des interférences nuisibles à la réception radio ou télévision, qui peuvent être localisées en allumant ou en éteignant l'équipement, l'utilisateur est encouragé à corriger les interférences en employant une ou plusieurs des mesures suivantes:

— Réorienter ou déplacer l'antenne de réception.

— Séparer davantage l'équipement et le récepteur.

— Connecter l'équipement à une prise de courant située sur un circuit différent de celui du récepteur.

— Demandez assistance à un revendeur ou un technicien expérimenté dans le domaine radio/TV.

ELECTROMAGNETIC COMPATIBILITY

Medical electrical equipment needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in this user manual. Portable and mobile radio frequency (RF) communications equipment can affect medical electrical equipment.

Guidance and Manufacturer's Declaration - Electromagnetic Emissions

LimbLogic is intended for use in the electromagnetic environments specified below. The customer or the user of the LimbLogic should assure it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 2	LimbLogic must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class B	LimbLogic is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Emissions from this device comply with the recommendations of the ICNIRP's "Guidelines for Limiting Exposure to Time-Varying Electric and Magnetic Fields (1 Hz - 100 kHz). Health Physics 99(6):818-836; 2010.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

LimbLogic is intended for use in the electromagnetic environment specified below. The customer or the user of the LimbLogic should assure 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	± 6 kV contact ± 8 kV Air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV on input/ output lines	± 2 kV on power supply lines ± 1 kV on Input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% U_T (>95 % dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (>95 % dip in U_T) for 5 sec	< 5 % U_T (>95 % dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T for 25 cycles < 5% U_T (>95 % dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the LimbLogic requires continued operation during mains interruptions, it is recommended that the LimbLogic be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE U_T is the a.c. mains voltage prior to application of the test level.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

LimbLogic is intended for use in the electromagnetic environment specified below. The customer or the user of the LimbLogic should assure it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance Level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the LimbLogic, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vms 150 kHz to 80 MHz	3 V	$d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz 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). 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] Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess 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 the LimbLogic is used exceeds the applicable RF compliance level above, the LimbLogic should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the LimbLogic.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the LimbLogic

LimbLogic is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of LimbLogic can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the LimbLogic as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

USER PROFILE

Prosthetist user

LimbLogic is intended to be used for assembly of prosthetic devices by a certified prosthetist or prosthetic technician.

Patient user

LimbLogic is intended for use by patients meeting the following conditions.

- Age: Any. Determined by clinician's evaluation of patient competence and health.
- Weight: (Body weight plus any loads normally or routinely carried cannot exceed these weight limits.)
  - <350 lb (160 kg) for U.S. Activity K Level 2 or 3
  - <300 lb (136 kg) for U.S. Activity K Level 4
- Health: Activity Level K2-K4
- Nationality: Any
- Mentally competent to operate system as judged by prosthetist.

PERFORMANCE CHARACTERISTICS

Capabilities:

- Vacuum setting up to 68 kPa. For ease of use, this range has been divided into twenty even steps between 1 and 20.
- Indoor & Outdoor usage
- Normal use
  - Temperature +5 °C to +50 °C.
  - Humidity 15% to 93% non condensing
  - Altitude -1250 to 10000 feet (-380 to +3000 meters)
  - Pressure 1060 to 700 hPA
- Transportation or short term storage between uses
  - Temperature -25 °C to +70 °C
  - Humidity 15% to 93% non condensing
  - Altitude -1250 to 20000 feet (-380 to +6000 meters)
  - Pressure 1060 to 470 hPA
- Long term storage
  - Temperature -25 °C to +25 °C to preserve battery life
  - Humidity 15% to 93% non condensing
  - Altitude -1250 to 20000 feet (-380 to +6000 meters)
  - Pressure 1060 to 470 hPA
- Charging
  - Temperature +5 °C to +33 °C
  - Humidity 15% to 93% non condensing
  - Altitude -1250 to 10000 feet (-380 to +3000 meters)
  - Pressure 1060 to 700 hPA

Restrictions:

- LimbLogic must not be used in salt water or any other corrosive environment.
- At temperatures below freezing, condensation will form and freeze in the pump preventing further operation until warmed.
- The hand-held fob, communicator, and charger should not be exposed to water.
- Frequency of use: Daily for 16 hours / day or as needed.

PHYSICAL MEASUREMENTS

Module	Dimensions (mm)	Weight (gms)
Fob with Battery	38L x 31W x 8H	17
Distal Mount Pump	105L x 92W x 37H	195
Side Mount Pump	101L x 99W x 36H	200
Charger Wall Transformer	86L x 56W x 37H	261

*Maximum vacuum drawn may be limited at altitudes significantly above sea level.

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