

Instructions *for Use*





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System Components

| Part Description | Part Number | Included w/Kinnex | Qty | Available/Sold Separately |
|---|-----------------|-------------------|-----|---------------------------|
| Kinnex Battery Wall Charger | F14-00-CHRG1-00 | YES | 1 | YES |
| Universal wall adapters | F14-00-ADAPT-00 | YES | 1 | YES |
| Kinnex IFU | R-720-239 | YES | 1 | YES |
| Kinnex User Guide | R-720-241 | YES | 1 | YES |
| Kinnex Certified Prosthetist Set up Guide | R-720-240 | YES | 1 | YES |
| Footshell | Varies | YES | 1 | YES |

Terms/Symbols Used In This Guide



Type BF applied part



WEEE Directive on waste electrical and electronic equipment, which should not be disposed of in regular wastes at the end of its usable life



FCC Declaration of Conformity



Manufacturer



Serial number



Consult operating instructions



Key Pad Function



CEMark



Battery



Change footwear



Bluetooth

CP

Certified Prosthetist

Kinnex

Kinnex Ankle/Foot System

Don

Put on

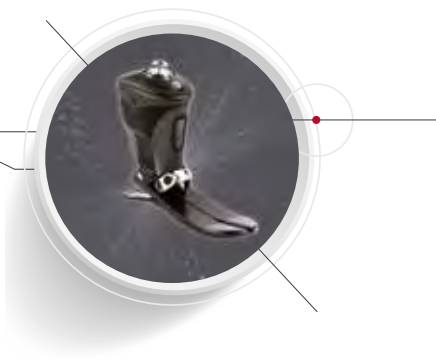
Doff

Take off



Warnings/Safety Precautions

- Failure to comply with safety precautions can result in Kinnex malfunctioning and risk of injury to the user.
- Always exercise good judgment and common sense when using Kinnex.
- Initial operating of Kinnex should be done in the presence of a trained care professional.
- Do not attempt to open or modify any component of Kinnex.
- If any issues or concerns with the Kinnex arise, contact Prosthetist for assistance. DO NOT attempt to make technical repairs.
- Cover Kinnex with a foot cover while in use to prevent foreign objects from being lodged in joints.
- Engage Kinnex Manual Lock when driving a vehicle. (see “Manual Lock”)
- Improper and unsafe use of Kinnex may result in injury. Please read the instruction manual thoroughly before using.
- Do not use Kinnex while the battery is charging. Be sure to disconnect it from the charger prior to putting on the prosthesis.
- If it becomes necessary to isolate Kinnex from the mains while charging, unplug the battery charger.
- If unusual movement or product wear is detected in a structural part of a prosthesis at any time, immediately discontinue use of the device and consult a clinical specialist.
- Do not use if Kinnex enclosure or covers are broken.
- Kinnex contains a Lithium-ion battery that is not field replaceable and requires factory service for repair. Lithium-ion batteries contain hazardous metals and should never be disposed of in residential or commercial garbage. They should never be incinerated because they may explode. Reference local regulations for proper disposal of product.
- Kinnex contains small parts and cords that can be a potential choking hazard.
- Kinnex is not for running, jumping or high activity usage.



Product Description

Kinnex is a microprocessor controlled hydraulic ankle/foot that monitors sensors to control plantar and dorsiflexion resistance.

Intended Use

Kinnex is intended for use by individuals with lower limb amputations who would benefit from improved gait dynamics.

Indications

Kinnex is indicated for use as a component in a prosthetic leg for individuals with lower limb deficiency including:

- Persons or Individuals with unilateral or bilateral transtibial and transfemoral amputations
- Individuals with congenital limb loss below the knee

Product Technical Specs

Kinnex is tested and compliant with the following standards

- IEC/EN 60601-1
- MDD 93/42/EEC
- ISO 10328
- ISO 13485

Physical Properties

Weight Limit for low activity users: 125 kg

Weight Limit for moderate activity users: 100kg

Average Product Weight: 1.49kg (without footshell)

Build Height: 186 mm

Heel height adjustability: 0–51 mm

Suitable for ambulatory level: K3

Environmental

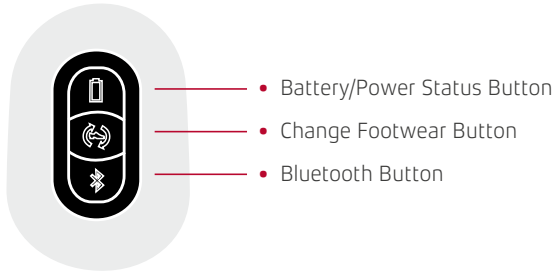
- Operating Temperature Range: 0 to 45 °C
 - Storage Temperature Range: -20 to 80 °C
 - Humidity Range: 0–100%
 - Altitude Range: 0–5,000 m
 - Weather resistance: rated to IP67
- Kinnex is safe for occasional contact with fresh water (up to 1 m for up to 30 minutes). If Kinnex was in contact with water, the user should dry the ankle with a towel once out of the water.
 - Kinnex should not be used for bathing.
 - Kinnex should not be immersed in saltwater or chlorinated water as these may cause corrosion. Failure to comply will void the warranty.
 - If Kinnex is sprayed by or accidentally submerged in salt water or chlorinated water, immediately rinse with fresh water and allow to dry.

Basic Operations

Manual Adjustments

To manually adjust Kinnex, utilize the three buttons on the front of Kinnex. The buttons are used to control and interact with Kinnex when a mobile device is not available or desired.

Button Symbols and Functions



Battery Function

Charging Battery

- To charge the battery:
 - Remove the rubber plug from the port at the top front of the ankle.
 - Connect either to wall or car power supply provided with Kinnex.
 - The green battery indicator light at the front of the ankle will begin to flash indicating that the ankle is charging. After a short period of time, the indicator light will turn off but charging will continue. While charging, the indicator light can be turned back on by pressing and releasing the battery button on the front of the ankle. The duration of the flash indicates the amount of charge in the battery. The longer the flash, the closer the battery is to being charged.
 - Once the ankle is completely charged, the indicator light will be solid green when the button is pressed and released.
 - A full charge requires three hours or less using the wall power supply.

Caution: Use only the wall power supply provided with Kinnex for battery charging.

Battery Charge Level

- To manually check the charge level of Kinnex when unplugged (discharging) using the button located on the front of the ankle:
 - Press and release the battery button on the front of the ankle.
 - Indicator lights will illuminate briefly giving the charge level as shown in table below:

| Indicator Light | Charge Level |
|-----------------|--------------|
| Solid green | 51% – 100% |
| Flashing green | 31% – 50% |
| Solid red | 11% – 30% |
| Flashing red | 1% – 10% |

- To manually check the charge level of Kinnex while charging (plugged in):
 - Press and release the battery button on the front of the ankle.
 - The green indicator light will flash briefly. The longer the flash, the closer the battery is to being charged.











A solid light indicates the battery is fully charged.

Battery Low Indicators

- 10% charge indicator: When the battery charge level reaches 10%, the indicator light at the front of the ankle will flash red, and the ankle will go into a low battery mode in order to provide an alert that the battery is about to be fully depleted.
- 2% charge indicator: When the battery charge level reaches 2%, the ankle will power off and go into a low stiffness mode.
- Note: If the ankle goes into the low battery mode or powers off and the battery cannot be charged at that time, the prosthetic wearer can change shoes to those with the same heel height as the shoes used during the initial dynamic alignment (typically 10 mm) and engage the Manual Lock.

LED Button Quick Reference Sheet

Each button on Kinnex incorporates one or more indicator lights to indicate the status of Kinnex. The table below lists what the indicator lights mean.

| | Indicator Light | Location | Meaning | Action |
|--|---------------------------|-------------------------------------|--|---|
|  | Solid green | Battery button | Battery is fully charged | Kinnex is fully charged and ready to use |
|  | Flashing green | Battery button | Charging (plugged in): Battery is charging Plugged in (discharging): Battery charge level has dropped below 50% | Charging (plugged in): Continue charging battery until solid green light for full charge Unplugged (discharging): Charge the battery in the next few hours |
|  | Solid red | Battery button | Battery charge level is low | Charge battery as soon as possible |
|  | Flashing red | Battery button | Battery is depleted; Kinnex is set to a constant resistance | Engage manual lock, change footwear if necessary and charge battery as soon as possible |
|  | Solid white | Change footwear button | Apparel Assist is engaged | Kinnex is ready to do apparel |
|  | Flashing white | Change footwear button | Manually adjusting footwear | Stand evenly weighted and wait 5 seconds |
|  | Solid blue | Bluetooth button | Connected in clinician mode | Clinician can configure Kinnex; to exit, press Bluetooth button for 3 seconds until the Blue indicator light turns off |
|  | Flashing blue | Bluetooth button | Ready for clinician mode connection | Clinician can connect to Kinnex; to exit, press Bluetooth button for 3 seconds until the Blue indicator light turns off |
|  | Alternating red and white | Battery and change footwear buttons | User: Attempt to change footwear failed Prosthetist: Sensor calibration failed | User: Repeat change Prosthetist: Repeat sensor calibration process |
|  | Alternating red and blue | Battery and Bluetooth buttons | Kinnex system error | Contact Prosthetist |



Changing Footwear/Shoe Selection

The change footwear button will allow you to manually change your footwear without use of the Kinnex App:

- Follow these steps to manually change footwear.
 1. Don Kinnex with new footwear.
 2. Press and hold the change footwear button until the indicator light in the button begins to flash white.
 3. Once the white indicator light begins to flash, stand with toes even and with feet shoulder width apart.
 4. Remain still until the white indicator light stops flashing. (Usually takes <5 seconds.)
 5. If Kinnex ankle cannot adjust within 10 seconds it will indicate an error condition by alternating flashing of the white and red indicator lights. The error light indicator will flash for 15 seconds or until the change footwear button is pressed and released.



Apparel Assist Mode

Apparel Assist is designed to help in putting on clothes or footwear. When active Kinnex will stay in the current position until the change footwear button is pressed or until weight is put on it.

- To manually use Apparel Assist:
 1. Move Kinnex to the desired orientation.
 2. Quickly press and release the change footwear (middle) button 2 times.
 3. The change footwear white indicator light will turn on while Kinnex is in Apparel Assist mode.
 4. Don apparel as needed.
 5. Press and release the change footwear (middle) button 1 time to release Kinnex.
 6. The white indicator light will turn off upon completion.



Manual Lock Feature *(See Kinnex Product Detail page 18)*

The Manual Lock pull ring located on the rear of the Kinnex allows for manual locking of Kinnex without use of the Kinnex App. This feature will lock the ankle at the “neutral position” (90° angle with 10mm heel).

To engage Manual Lock:

1. Fully unweight Kinnex.
2. Remove the pull ring from the housing at the back of the ankle.
3. Pull upward on the ring until a click is heard.
4. Rotate the ankle to a neutral position (90° angle with 10 mm heel) until another click is heard and the ankle no longer moves.
5. Snap the pull ring back into the housing.

To disengage Manual Lock:

1. Fully unweight Kinnex.
2. Remove the pull ring from the housing at the back of the ankle.
3. Pull upward on the ring until a click is heard. The ankle should now move freely.
4. Snap the pull ring back into the housing.

Caution:

Engaging the Manual Lock feature for driving and when battery level is low or completely depleted is required.

Long-Term Storage Mode

If Kinnex needs to be stored for more than 60 days, it should be put into long-term storage mode to avoid over discharge of the battery pack.

- To put Kinnex into long-term storage mode:
 1. Press and hold both the Change Footwear and the Bluetooth Buttons simultaneously for 6 seconds.
 2. After 6 seconds, all three lights will flash on and off simultaneously as an indicator that the command was successful.
 3. After the lights turn off Kinnex will enter into longer term storage mode and power off.
- To bring the ankle out of long-term storage mode:
 1. Charge the battery as you normally would by removing the rubber plug from the port at the top front of the ankle and connect the wall power supply provided with Kinnex.
 2. The green indicator light at the front of the ankle will begin to flash indicating that the ankle is charging and powered on.

Kinnex App for Patients

The Kinnex App for patients will allow patient to change the following settings of the product via app:

- Check battery charge level.
- Change footwear options.
- Make minor adjustment to the ankle settings based on established settings made by Prosthetist.
- NOTE: User will not be able to connect via the Kinnex App when Kinnex is in wireless “Clinician Mode”. (A blinking blue light on the ankle will indicate that Kinnex is in “Clinician Mode.” To exit “Clinician Mode,” press and hold the Bluetooth button until the blue light turns off.)

Downloading and Launching App

- Download the Kinnex App from the Apple App Store or the Google Play App Store.

Connecting and Pairing to Kinnex via Kinnex App

- Once App is open, tap the “Connect” button.
- Tap the serial number (or custom name) of the ankle to connect.
- Note: When connecting to Kinnex with mobile device for the first time, the Kinnex App will instruct to press the Bluetooth button to acknowledge the pairing request. If the pairing request is not acknowledged within 30 seconds, the connection attempt will fail.

Check Battery Charge Level via Kinnex App



Status

Check the battery charge level of Kinnex by selecting the “Status” button in the Kinnex App.

Change Footwear Option via Kinnex App



Shoes

Change footwear option by selecting the “Footwear” button in the Kinnex App. Once inside the “Shoes” Window, simply click on shoe of choice.

Making Minor Adjustment to Kinnex via Kinnex App



Adjust

By utilizing the “Adjust” feature in the Kinnex App, minor adjustments to the ankle setting can be made based on established settings made by the Prosthetist. To do this, select the “Adjust” button in the Kinnex App.

- From here the user will be able to increase or decrease the adjustments to the Heel, Ankle, and Toe based on parameters established by the Prosthetist.

Connecting/Tools via Kinnex App



Tools

Selecting the “Tools” Button in the App will allow access to the following:

- Apparel Assist Mode
- Disconnecting from Kinnex
- Unpairing and disconnecting with Kinnex

Tools Utilization within Kinnex App

The following features are available within the Tools Section of the Kinnex App.

Apparel Assist Mode



When activated, the Apparel Assist Mode will maintain Kinnex in its current position until one of the following occurs:

- The button is deactivated in the App.
- The change footwear button is pressed.
- Weight is put on the Kinnex.

Disconnect



The Disconnecting feature will disconnect the app from Kinnex. However it will not unpair Kinnex from the App. This will allow connection without repairing at a later time.

Unpair and Disconnect



The unpair and disconnect feature will unpair and disconnect the App from Kinnex. A window will pop up requesting to confirm unpairing prior to proceeding. If Kinnex is unpaired from the App and assistance is required, please contact Prosthetist.

Warranty

See terms of Warranty for details.

Technical Support

- For User Support, please contact Prosthetist.
- For Prosthetist Technical Support, please contact Freedom Innovations toll-free at **+31 53 20 30 300**.

Electromagnetic Compatibility Precautions

The Freedom Kinnex™ microprocessor ankle/foot system needs special precautions regarding electromagnetic compatibility (EMC).

Specifically it needs to be installed and put into service according to the EMC information provided as follows:

- Kinnex may be susceptible to electromagnetic interference from portable and mobile RFcommunications devices such as mobile (cellular) telephones.
- Kinnex may be interfered with by other equipment, even if that other equipment complies with CISPR EMISSION requirements.
- 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.

Guidance and Manufacturer's Declaration

– Electromagnetic Emissions

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

| Emissions Test | Compliance | Electromagnetic Environment – Guidance |
|--------------------------------|------------|---|
| RF Emissions EN 55011/CISPR | Group 1 | Kinnex uses RF energy only for its internal function. Therefore, its RF emissions are low and are not likely to cause any interference in nearby electronic equipment. |
| RF Emissions EN 55011/CISPR | Class B | Kinnex 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. |

CE Conformity

The Freedom Kinnex is tested and certified to comply with the MDD 93/42/EEC (EN 55011 Class B and EN60601-1 and EN60601-1-2), STSI EN 300-328 under R&TTE Directive 1999/5/EC and, ISO10328. The device complies with Part 15 of the FCC Rules and carries the CE mark.

Authorized Representative

Advena Ltd.
Pure Offices
Plato Close, Warwick, CV 34 6 WE
United Kingdom






Kinnex Product Detail



- A. Key Pad buttons
- B. Charging port
- C. RapidResponse™ Valve Technology
- D. Carbon fiber foot plate
- E. Manual Lock



Key Pad Button Functions

| | | |
|---|---|--|
| 1 |  | Power Status Button <ul style="list-style-type: none"> • Check battery power levels |
| 2 |  | Change Footwear Button <ul style="list-style-type: none"> • Change shoes and calibrate ankle to new shoes • Apparel Assist Mode |
| 3 |  | Bluetooth Button <ul style="list-style-type: none"> • Pair ankle to smart device • Clinician Mode |

FREEDOM
KINNEX
 MICROPROCESSOR ANKLE/FOOT SYSTEM



Connect with us



#freedomeveryday

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