

PROTEOR

KINNEXTM 2.0

MICROPROCESSOR ANKLE/FOOT SYSTEM



EN Instruction for use

FR Notice d'Utilisation

DE Gebrauchsanweisung

IT Istruzioni per l'uso

ES Instrucciones de uso

PT Instruções de utilização

NL Gebruikershandleiding

DA Brugervejledning

NO Brukerveiledning

SV Bruksanvisning

FI Käyttöohjeet

PL Instrukcja użytkowania

CS Návod k použití

SK Návod na používanie

HR Upute za uporabu

RU Инструкция по использованию

UK Інструкція з використання

JA 取扱説明書

ZH 使用说明

AR تعليمات الاستخدام

PROTEOR

KINNEX TM **2.0**

MICROPROCESSOR ANKLE/FOOT SYSTEM

INSTRUCTIONS FOR USE

English



PROTEOR
KINNEX™ 2.0
MICROPROCESSOR ANKLE/FOOT SYSTEM

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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	IFU-03-009	YES	1	YES
Kinnex Microprocessor Foot/Ankle System	F14-N2-0XAYY-VV*	YES	1	YES
Foot shell	FTC-BK-1YYT4-CZ*	NO	1	YES
Booster Battery Pack	ACC0011	NO	1	YES
Heel Bumper Kit	KIT-00-1140U-00	YES	1	YES
Spectra Sock	S0-F14-000YY-00*	YES	1	YES

*X= category, YY= size, Z= side, T= skin tone, B= 2 sandal toe/3 regular toe, C= Regular or Sandal, VV= Regular Universal/Sandal Left/Sandal Right

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



CE Mark



Battery



Change footwear



Bluetooth



Single patient - multiple use



Authorized Representative in the European Union

Kinnex

Kinnex Ankle/Foot System



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 shell while in use to prevent foreign objects from being lodged in joints.
- Engage Kinnex Manual Lock when driving a vehicle. (see “Manual Lock”)

When the battery is completely depleted the Manual Lock feature is not available, and driving is NOT recommended

- Engage Kinnex Manual Lock when descending stairs step over step. This is highly recommended for transfemoral users.
- 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.
- In case of damaged packaging, check the integrity of the device
- Any serious incident that has occurred in relation to the device should be reported to the manufacturer and to the competent authority of the Member State in which the user is established

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, including increased step length, swing phase toe clearance, sitting comfort, comfort and safety on uneven terrain, comfort and control descending ramps, and knee stability.

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 amputations
- Persons or individuals with unilateral transfemoral amputations
- Persons or individuals with unilateral congenital limb loss

Product Technical Specs

Kinnex is tested and compliant with the following standards

- ISO 10328-P6-125 kg [275 lbs.]
- IEC 60601-1
- Rating of IP67 under IEC 60529

Physical Properties

Weight Limit for low activity users: 125kg/275lbs

Weight Limit for moderate activity users: 100kg/220lbs (Body mass limit not to be exceeded for moderate activity users)

Average Product Weight: 1.49kg/3.28lbs (without foot shell)

Build Height: 186mm / 7.32in

Heel height adjustability: 0-51mm / 0-2in

Suitable for ambulatory level: K3

Environmental

- Operating Temperature Range: 0 to 45 °C / 32 to 113 °F
- Storage Temperature Range: -20 to 80 °C / -4 to 176 °F
- Humidity Range: 0 – 100%
- Altitude Range: 0-5,000 m (0-16,400 ft)
- Water resistance: rated to IP67
 - Kinnex is safe for occasional submersion in fresh water up to 1 m (3 ft) for up to 30 minutes with the rubber plug in the charging port. 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.

Alignment

With the Kinnex connected to the GaitLab app, select “Bench Alignment”. This will lock the ankle at a neutral alignment position on a 3/8” heel height. The weight line should fall at or up to 1.5cm anterior to the anterior dome of the pyramid.

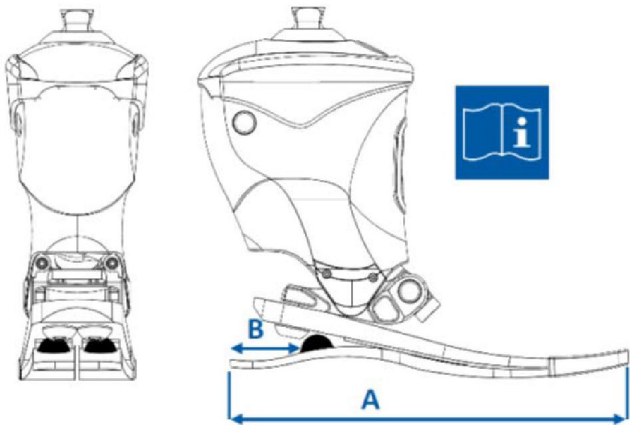


Compatibility

The Kinnex includes a male pyramid connection designed to be compatible with standard female pyramid connectors (see our catalog).

Heel Bumpers

The heel stiffness at heel strike can be adjusted using the stiffening bumpers. The bumpers may be temporarily attached using the pre-applied adhesive in the location indicated in the table to the right. The recommended location will stiffen the heel about 1 category. If necessary, move the bumpers anteriorly (stiffer) or posteriorly (softer) to get the desired stiffness. For permanent placement, clean off the pre-applied adhesive with acetone and adhere bumpers using cyanoacrylate glue.



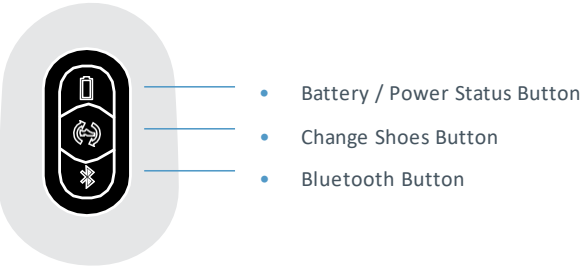
A	B
24-25 cm	33 mm
26-28 cm	40 mm
29-30 cm	41 mm

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 to wall 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.
- It is recommended to charge daily. The battery is rated for 24 hours on a full charge.



CAUTION: Use only the wall power supply provided with Kinnex or the optional booster battery pack 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

- Low battery notifications: When the battery charge level is at or below 20%, the ankle will periodically vibrate. While walking, the vibration feels like a grinding sensation as you take a step. While not walking, the vibration feels like a subtle buzzing. These notifications can be dismissed by quickly pressing and releasing the Battery Button on the front of the ankle, or by using the mobile app.
- 20% charge indicator: When the battery charge level falls to 20%, the ankle will notify every 15 seconds until dismissed. No indicator lights will flash.
- 10% charge indicator: When the battery charge level falls to 10%, the indicator light at the front of the ankle will flash red, and the ankle will notify every 5 seconds until dismissed.
- 2% charge indicator: When the battery charge level falls to 2%, the indicator light at the front of the ankle will flash red, and the ankle will notify every 2 seconds. Notifications cannot be dismissed when the battery charge is 2% or lower.
- 0% charge indicator: When the battery charge level falls to 0%, the ankle will power off and go into a low stiffness mode.

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. Unplugged (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 almost fully depleted. Once fully depleted, Kinnex is set to a constant resistance.	User will notice reduced resistance. Take caution performing normal activities.
	Solid white	Change shoes button	Manual Lock is engaged.	Kinnex is locked in desired position.
	Flashing white	Change shoes 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 shoes buttons	User: Attempt to change shoes failed. Prosthetist: Sensor calibration failed.	User: Repeat change shoes process. 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 Freedom Innovations App:

Follow these steps to manually change shoes.

1. Put on Kinnex with new shoes.
2. Press and hold the change shoes 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 shoes button is pressed and released.



Manual Lock

The Manual Lock feature is designed to assist with driving a car, putting on clothes or footwear, or any activity where a fixed ankle position is desired. When active, Kinnex will stay in the current position until a double-press of the change shoes button is used, or the manual lock is switched off in the app.

To manually engage the Manual Lock:

1. Move Kinnex to the desired orientation.
2. Quickly press and release the change shoes (middle) button 2 times.
3. The change shoes button white indicator light will turn on while Kinnex is in Manual Lock mode.
4. Perform the desired activity.
5. Quickly press and release the change shoe (middle) button 2 times to disengage the Manual Lock.
6. The white indicator light will turn off upon completion.



Caution: Engaging the Manual Lock feature for driving is required.

When the battery is completely depleted the Manual Lock feature is not available, and driving is NOT recommended

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:

- Press and hold both the Change Shoes and the Bluetooth Buttons simultaneously for 6 seconds.
- After 6 seconds, all three lights will flash on and off simultaneously as an indicator that the command was successful.
- 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:

- 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.
- The green indicator light at the front of the ankle will begin to flash indicating that the ankle is charging and powered on.

Freedom Innovations App for Patients

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

- Check battery charge level.
- Change shoes option.
- Engage Manual Lock.
- Make minor adjustment to the ankle settings based on established settings made by Prosthetist.
- NOTE: User will not be able to connect via the Freedom Innovations 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 Freedom Innovations App from the Apple App Store or the Google Play App Store.

Connecting and Pairing to Kinnex via App

- Once App is open, select “Kinnex”, then 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 App will instruct user to quickly press and release 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 App



Status

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

Change Shoes Option via App



Shoes

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

Making Minor Adjustment to Kinnex via App



Adjust

By utilizing the “Adjust” feature in the 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 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 App



Tools

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

- Manual Lock Mode
- Disconnecting from Kinnex
- Unpairing and disconnecting with Kinnex

Tools Utilization within App

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



Manual Lock

When activated, the Manual Lock 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 double-pressed.



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

Kinnex includes a 36-month warranty covering all manufacturer defects effective only if the product is used according to manufacturer recommendations. There is no required servicing during this time. Service and maintenance is required at 36-months if the optional 2-year extended warranty is purchased. The battery charger and accessories are provided with a 12-month warranty. See terms of Warranty for details. The lifetime of the Kinnex depends upon the patient’s level of activity.

Cleaning

Wipe with a damp soft cloth and dry.

Technical Support

- For User Support, please contact Prosthetist.
- For Prosthetist Technical Support, please contact PROTEOR.

Electromagnetic Compatibility Precautions

The PROTEOR Kinnex 2.0 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 RF communications 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 Kinnex is tested and certified to comply with the Medical Device Regulation (EU) 2017/745, EN 55011 Class B, EN 60601-1, EN 60601-1-2, ETSI EN 300-328 under R&TTE, Directive 2014/53/UE, ISO 10328. The device complies with Part 15 of the FCC Rules and carries the CE mark.

Kinnex 2.0 Product Detail



- A. Keypad buttons
B. Charging port
C. RapidResponse™ Valve Technology
D. Carbon fiber foot plate

Key Pad Button Functions

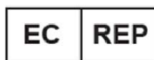
1	 Power Status Button <ul style="list-style-type: none">• Check battery power levels
2	 Change Footwear Button <ul style="list-style-type: none">• Change shoes and calibrate ankle to new shoes• Manual Lock Mode
3	 Bluetooth Button <ul style="list-style-type: none">• Pair ankle to smart device• Clinician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

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MICROPROCESSOR ANKLE/FOOT SYSTEM



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