FREEDOM

QUATTRO

MICROPROCESSOR KNEE

by PROTEOR

Instructions *for* Use

PROTEOR

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01 | System Components

Part Description	Part Number	Included w/QUATTRO	Qty	Available/Sold Separately
QUATTRO Battery Wall Charger & Adapters	QNX0601	YES	1	YES
QUATTRO Instructions for Use (IFU)	IFU-03-014	YES	1	YES
QUATTRO Prosthetist Setup Guide	CG-03-011	YES	1	YES
QUATTRO Patient Setup Guide	CG-03-012	YES	1	YES
External Booster Battery Kit	ACC0010	NO	1	YES

02 | 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

SN — Serial number

Consult operating instructions

Key Pad Function

CEMark

Battery/Power Status Button

Change Mode Button

Wireless Button

CP — Certified Prosthetist

Quattro — MPC Knee System

03 | Warnings / Safety Precautions

- Please read this instruction manual thoroughly before using.
- Failure to comply with safety precautions can result in the QUATTRO malfunctioning and risk of injury to the user.
- Initial operation of the QUATTRO should take place in the presence of a trained care professional.
- Do not open or modify any component(s) and DO NOT make repairs on the QUATTRO unless otherwise directed in this IFU.
- If any issues or concerns with the QUATTRO arise, contact your Prosthetist for assistance.
- Improper and unsafe use of QUATTRO may result in injury.
- Do not use the QUATTRO while the battery is charging via the wall charger. Be sure to disconnect from the charger prior to putting on the prosthesis.
  - Do not submerge Quattro while charging using the Quattro Booster Battery Pack.
- If unusual movement or wear is detected in a structural part of the prosthesis at any time, immediately discontinue use of the device and consult your Prosthetist.
- The QUATTRO 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.
- If power is lost from the QUATTRO knee, it will default to the Power-Off Flexion resistance setting.
- When the battery is depleted, use extreme caution when descending ramps and stairs.
- The QUATTRO contains small parts and cords that can be potential choking hazards.
- If the QUATTRO has been stored outside its Operating Temperature Range, allow the knee to acclimate to the operating environment for a minimum of 30 minutes before use.
- Avoid running or other intense physical exercise above the specified operating temperature limit (45 °C [113 °F]). This can damage your QUATTRO.
- The proximal connection to the patient is the Applied Part of the device. All other external surfaces of the device, including the power supply and cord, are the Accessible Parts.
- Failure to comply with the instruction for use will void the warranty.

04 | Product Description

The QUATTRO is a microprocessor controlled, single axis prosthetic knee joint system with internal sensors to control knee flexion and extension resistance.

05 | Indications

The QUATTRO is indicated for use as a component in a prosthetic leg for individuals with unilateral or bilateral lower-limb amputations or limb deficiencies, including:

- Transfemoral amputation
- Knee disarticulation amputation
- Hip disarticulation amputation
- Congenital, lower-limb deficiencies

06 | Intended Use

The QUATTRO is intended for use by prosthesis wearers who would benefit from the safety, stability, and improved gait dynamics of a microprocessor controlled knee. Quattro should only be fit by a trained O&P professional.

- User Weight Limit: 136kg/300lbs
- Suitable for ambulatory level: K3/K4

07 | Contraindications

The QUATTRO is inappropriate for users with:

- Insufficient hip joint or pelvic voluntary muscle control
- Insufficient cognitive ability to charge the knee and care for the device

08 | Product Technical Specifications

The QUATTRO is tested and compliant with the following standards:

- ISO 10328-P7-136 kg [300 lbs.] (Body mass limit not to be exceeded for high activity users)
- IEC 60601-1
- Rating of IP67 under IEC 60529

09 | Physical Properties

- Product Weight: 1655 g [3.65 lbs.]
- Build Height: 216 mm [8.5 in]
- Maximum Flexion Angle: 135°

10 | Environmental

- Operating Temperature Range: 0 to 45 °C [32 to 113 °F]
- Storage Temperature Range: -25 to 60 °C [-13 to 140 °F]
- Altitude Range: 0-5,000 m [0 -16,400 ft.]
- Humidity Range: 0% to 100%, including condensation
- Water Resistance: Rated to IP67
  - QUATTRO is safe for occasional submersion in fresh water up to 1 m [3 ft.] for up to 30 minutes. The user should dry the knee with a towel once out of the water.
  - QUATTRO should not be used for showering or bathing.
  - QUATTRO should not be immersed in saltwater or chlorinated water as these may cause corrosion.
  - If the QUATTRO is sprayed by or accidentally submerged in salt water or chlorinated water, immediately rinse with fresh water and towel dry.

11 | Basic Operation

11.1. Battery Information

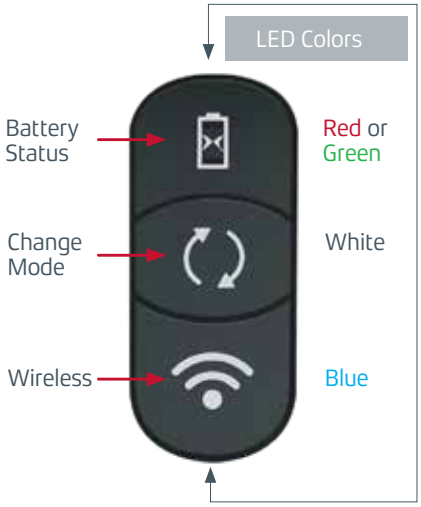
Operating voltage: 7.4 VDC
Charger input voltage: 12 VDC
AC power adapter input voltage: 100-240 VAC, 50/60 Hz
Battery life: Approximately 2 days of use based on the following user profile:

11.2. Battery Charge Port Access Location

11.3. Power-off Flexion Resistance Adjustment Screw Location

⚠ Use only the wall charger or the booster battery adaptor that are designed for QUATTRO to charge the device. Only use a 3mm hex wrench for making power off flexion resistance changes.

11.4. Keypad Location & Functionality



11.5. Charging Battery

Inserting Charge Connector

a. Pull the protective charging port cover open and insert charge connector with the cable oriented up. The connector is magnetic and will snap into place. Once inserted, the battery LED button will illuminate briefly, indicating that the knee is charging.

11.6. Keypad Operation

Power

11.6.1. Check Battery Status

Press and release button to show the current battery power status.

Normal mode

Indicator Light	Charge Level
Solid Green	51% - 100%
Flashing Green	21% - 50%
Solid Red	11% - 20%
Flashing Red	1% - 10%

When QUATTRO is plugged into a charger

Current battery charge is indicated by a flashing green light. The more the battery is charged, the longer time each flash will stay lit.

Rebooting The Knee

Hold button for six seconds until the green and blue lights flash. Only use this feature as directed by your prosthetist if you are having problems with your device.

Mode

11.6.2. Activity Mode

Press and release button to show current activity mode. Slow flashing white light means you are in Walking Mode. Fast flashing means you are using your currently selected Alternate Activity Mode.

Change Activity Mode

Hold button for three seconds to switch back and forth between Walking Mode and your currently selected Alternate Activity Mode. When changed, lights will indicate new mode (see above). White and red flashing means there is no Alternate to select, or it is unsafe to change modes right now.

Set or Release Flexion Lock

Double press button to set or release the flexion lock. When locked, the white light will be solid.

Wireless

11.6.3. Pair Knee with Mobile App

To pair your QUATTRO to the app the first time you connect, quickly press and release the button when prompted by app

Mode + Wireless

11.6.4. Putting the Knee into Storage Mode

Hold both the Mode button and the Wireless button at the same time for six seconds until all the lights flash, and then turn off. When in storage mode the QUATTRO will be completely powered off and unresponsive. Pressing the power button will not turn the device back on. To turn the knee back on, you must plug in the charger. The knee is shipped in Storage Mode from the factory (must be plugged into power source to turn on).

NOTE: The device will not enter storage mode if connected to the charger.

11.7. Keypad Button Reference

Feature	Action	Hold Time
Check battery status	Press Battery Button	
Flexion lock enable	Double Press Mode Button	
Flexion lock disable	Double Press Mode Button	
Check activity	Press Mode Button	
Toggle activity	Hold Mode Button	3 sec
Pair Press	Wireless Button	
Storage mode	Hold Mode + Wireless Buttons	6 sec
Reset	Hold Battery Button	6 sec

11.8. LED Reference

Condition	LED Behavior
Battery is charged	Battery LED solid green
Battery is charging	Battery LED flashing green
Battery is low	Battery LED solid red
Battery is very low	Battery LED flashing red
Knee is manually locked	LED solid white
Activity checked or change	LED flashing white: slow (walking) or fast (alternate)
Activity change failed Battery	LEDs alternate red / white
Entering storage mode	Flashing red / blue / white LEDs
System error Battery/Wireless	LEDs alternate red / blue
Booting	Flashing green / blue

11.9. Mode Button Reference

User Press	Current State	Product Behavior
Single Press to Check Status	Unlocked	White LED blinks to indicate current activity. Slow blink indicates “Walking”, and fast blink indicates the alternate.
	Locked	LEDs blink red/white to indicate error. No activity is active to check because the knee is in Locked Mode.
Double Press to Enable/Disable Lock	Unlocked	Flexion lock is engaged. White LED stays solid.
	Locked	Flexion lock is disengaged. White LED stays off. Previously selected activity is resumed.
Long Press to Toggle between Walking and Alternate Activity	Current activity is “Walking”, but an alternate has NOT been configured	LEDs blink red/white to indicate nothing has happened.
	Current activity is “Walking” and an alternate HAS been configured	Alternate activity is selected. White LED blinks fast to indicate alternate is now selected.
	Current activity is alternate	“Walking” activity is selected. White LED blinks slow to indicate “Walking” is now selected.

11.10. Modes

Sitting Mode:

The QUATTRO features two available behaviors when sitting, and the adjustment is found under the "Tools" tab along the bottom of the GaitLab and Freedom Innovations apps. With Sitting Mode turned on (default), when the knee is unweighted and the thigh reaches a 90 degree angle or greater, the knee flexes without resistance. With Sitting Mode off, the knee will continue to have hydraulic resistance to flexion independent of thigh flexion angle. Note: if Sitting mode is turned off, it will also disable Cycle Mode and Obstacle Assist.

Obstacle Assist:

Obstacle Assist can be turned off or on during full programming, and in the GaitLab App under "Setup" and "Adjust" after full programming is completed. With Obstacle Assist turned on (default), the knee will flex with no resistance when the thigh reaches 35 degrees of flexion or greater and is unweighted. This is helpful for stepping over tall objects or entering a high vehicle. When Obstacle Assist is turned off, the knee will flex slowly with hydraulic resistance when unweighted independent of thigh flexion angle. Note: if Sitting Mode is turned off, it will also disable Obstacle Assist.

Cycling Mode:

In Cycling Mode, the Knee will enter in low resistance when the user's thigh is near the horizontal plane (this position occurs when getting on the bike or during normal pedaling). The Knee will remain in low resistance until the user puts weight on the unit in full extension (triggering the QUATTRO to return to normal walking mode).
Note: if Sitting mode is turned off, it will also disable Cycle Mode.

Golf Mode:

Golf Mode allows you to limit the amount your knee flexes while playing golf. After selecting golf mode in the Freedom app as the alternate mode, navigate to the adjustment screen. On this screen you will have 3 choices for different degrees of flexion that will be allowed. Each of these can be customized by pressing the "+" or "-". This allows you to have 3 custom settings for the amount of flexion needed for a particular golf swing.

⚠ IN GOLF MODE THE KNEE WILL ONLY FLEX TO THE DEGREE THAT HAS BEEN CHOSEN IN THE APP. DESCENDING STAIRS AND SLOPES SHOULD BE AVOIDED WHEN IN GOLF MODE.

Stance Lock:

The QUATTRO features a Stance Lock for stability on a flexed knee. When the user stops the thigh at a flexion angle and weights the knee, it will automatically lock further flexion. The lock will automatically disengage when the thigh moves in an extension moment or the knee is unweighted.
Note: Stance Lock is available from 0-70° of flexion.

Engaging the Flexion Lock:

To engage flexion lock, in any Activity Mode, double click the mode button to engage the flexion lock. The button lights up with a solid white light to indicate that the Flexion Lock is engaged. When the lock is engaged, the knee can straighten but it cannot bend any further than the current angle. If the knee is straightened to a more upright position, the lock re-engages at the new angle. The knee will remain locked at this position until the knee is straightened or the flexion lock is disengaged. The solid white light remains on as long as the Flexion Lock is engaged.
Note: When the Flexion Lock is engaged and the knee is unweighted, it will be locked in both flexion and extension.

Disengaging the Flexion Lock:

With the lock engaged, double click the mode button to disengage the Flexion Lock. The solid white light now turns off, indicating that the Flexion Lock has disengaged. The knee returns to the currently selected Activity, i.e. Walking.
Note: Stance Lock is available from 0-70° of flexion.

11.11. Power-Off Behavior

When the battery is depleted or the knee has been put into storage mode, a Power-Off Flexion resistance is used. The power-off flexion resistance can be adjusted to accommodate different user preferences and weights.

⚠ PLEASE HAVE YOUR PROSTHETIST ADJUST THIS SETTING FOR YOU.

Making an Adjustment:
With the QUATTRO knee fully extended, insert a 3mm hex wrench into the power-off flexion resistance screw: CW adjustments provide more flexion resistance and CCW adjustments provide less flexion resistance.

⚠ DO NOT FLEX THE KNEE WITH THE HEX WRENCH INSERTED, THIS MAY CAUSE PERMANENT DAMAGE TO YOUR DEVICE.

Flexion resistance adjustment

Note: The knee ships with the flexion resistance at the middle of the range to allow for increased or decreased resistance based on patient preference.

12 | Knee Cap Replacement

Removing the Knee Cap
a. Use a 3/32" Hex Key to remove the two socket head cap screws from the Knee

3/32" Hex Key

Installing the Knee Cap
b. Install Knee Cap as indicated below. Tighten the 2 socket head cap screws using the 3/32"Hex Key.

NOTE: Tighten until flush plus 1/4 turn, do not over torque screws.

13 | Alignment and Setup

Follow the Clinician User Guide and the GaitLab smartphone app to properly align and setup the device. GaitLab is required to calibrate and optimize the microprocessor settings for each patient. Verify the smartphone requirements before app installation. Download Apps from the App Store or Google Play Store.

GaitLab App (*for Clinicians*)
Freedom Innovations (*for Patients*):

Available on the iPhone App Store

ANDROID APP ON Google play

14 | Cleaning

Use clean tap water to rinse off your QUATTRO knee. A soft-bristled brush (such as a toothbrush) is acceptable to dislodge stuck dirt on the outside of the knee only. Using any other chemicals or soaps on the QUATTRO may void the warranty. Dry the knee thoroughly with a towel after rinsing. Do not use a hairdryer, which may damage the electronics and void the warranty.

15 | Transferring Settings/Resetting to Factory Defaults

1. Connect to the knee you'd like to transfer the program from. Once connected, go to the "Tools" tab along the bottom of the app, then tap "Manage Settings". Tap "Copy settings" to save the settings to your device. You can now disconnect from the programmed knee.
2. Connect to the knee you'd like to transfer the program to. Go to the "Tools" tab along the bottom of the app, tap "Manage Settings", and tap "Paste settings". You will get a confirmation message "Are you sure you want to replace all settings?" Tap "OK" to transfer all settings, and "Cancel" to cancel the paste and keep the settings as is.

- Reset to factory defaults: this will reset all of the settings in the knee to factory settings.
- Recommendation: Have the patient sitting while transferring the program or resetting the knee for safety.

16 | Warranty and Service

Purchase of the QUATTRO includes a 36-month warranty covering all manufacturer defects effective only if the product is used according to manufacturer recommendations. The battery charger, and accessories are provided with a 12-month warranty. An exteded warranty and service recommendation is available. See company website for details.

For knee service or repair, please contact PROTEOR at 1.855.450.7300. A loaner knee will be provdied upon request. For loaner and shipping information please see technical support section.

17 | Technical Support

- For User Support, please contact your Certified Prosthetist
- For Prosthetist Technical Support, supplementary training material or to schedule service, please contact Proteor toll-free at 1.855.450.7300

- A loaner knee can be provided upon request. Knees requiring service from the US should be shipped in the provided case to the following address:

  PROTEOR USA
  3 Morgan
  Irvine, CA 92618

- In Europe, please ship to the following address:

  PROTEOR
  Rue du Cheffin
  21250 Seurre, France

18 | Electromagnetic Compatibility Precautions

- The QUATTRO 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:
- The QUATTRO may be susceptible to electromagnetic interference from portable and mobile RF communications devices such as mobile (cellular) telephones.
- The QUATTRO 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.

19 | Guidance and Manufacturer's Declaration – Electromagnetic Emissions

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

Emissions Test	Compliance	Electromagnetic Environment—Guidance
RF Emissions EN 55011/ CISPR	Group 1	QUATTRO 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	QUATTRO 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.

20 | CE Conformity

Freedom QUATTRO is tested and certified to comply with the MDR (EU) 2017/745 (EN 55011 Class B and IEC60601-1, STSI EN 300-328 under R&TTE Directive 1999/5/EC and ISO 10328). The device complies with Part 15 of the FCC Rules and carries the CE mark.

21 | Authorized Representative

EC REP

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France

QUATTRO Product Details
A. Key Pad Buttons
B. Charging Port
C. Flexion Resistance Adjustment
D. Replaceable Knee Cap

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