

PROTEOR
QUATTRO™
MICROPROCESSOR KNEE



Instructions *for Use*


















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01 | System Components

Part Description	Part Number	Qty.	Sold Separately
Battery Wall Charger & Adapters	QNX0601	1	NO
Instructions for Use (IFU)	IFU-03-014	1	NO
Flexion Angle Limiter Kit	ACC0007	1	NO
External Booster Battery Kit	ACC0010	1	YES

02 | Terms / Symbols Used In This Guide

	Type BF applied part		CE Mark
	WEEE Directive on waste electrical and electronic equipment, which should not be disposed of in regular wastes at the end of its usable life		Battery/Power Status Button
	FCC Declaration of Conformity		Change Mode Button
	Manufacturer		Wireless Button
	Serial number		Certified Prosthetist
	Consult operating instructions		EU Authorized Representative
	Keypad Function		Single patient, multiple use
			MPC Knee System



##QUATTROMPK
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 us.proteor.com
 shop.proteorusa.com

03 | Warnings / Safety Precautions



- Please read this instruction manual thoroughly before using.
- Failure to comply with safety precautions can result in QUATTRO malfunctioning and risk of injury to the user.
- Initial operation of 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.
- 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.
- In case of damaged packaging, check there is no damage to the QUATTRO.
- If any issues or concerns with 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 with 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.
- 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, it will default to Power-Off Flexion resistance.
- When the battery is depleted, use extreme caution when descending ramps and stairs.
- 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

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

05 | Indications

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

QUATTRO is for SINGLE PATIENT use and 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 Certified Prosthetist.

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

07 | Contraindications

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

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 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 2-3 days, plus an available Booster Pack with additional days of battery based on the following user profile:



11.2. Battery Charge Port Access Location

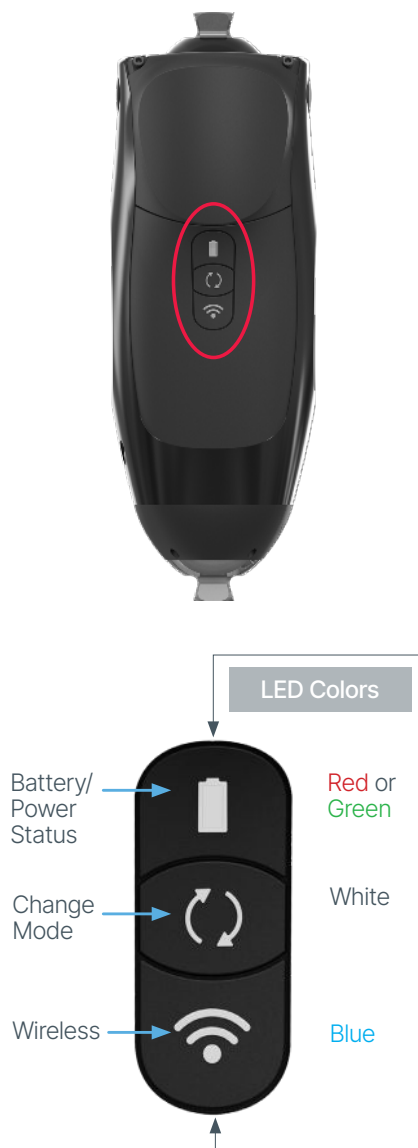


11.3. Power-off Flexion Resistance Adjustment Screw Location



! 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

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

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 Plugged Into A Charger

Current battery charge is indicated by a flashing green light. The more the battery is charged, the longer 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.

Battery/
Power



11.6.2. Activity Mode

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

Change Activity


Hold button for three seconds to switch back and forth between Walking and your currently selected Alternate Activity. 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.




11.6. Keypad Operation



Wireless

11.6.3. Pair Knee with Mobile App

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



Mode
+
Wireless

11.6.4. Put Knee Into Storage Mode

Hold both the Mode and Wireless buttons 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 Battery/Power button will not turn the device back on. To turn the Knee back on, you must plug it into the charger or Booster Pack. 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	Solid green
Battery is Charging	Flashing green
Battery is Low	Solid red
Battery is Very Low	Flashing red
Knee is Manually Locked	Solid white
Activity Checked or Change	Flashing white: slow (Walking); fast (Alternate)
Activity Did Not Change	Alternate red / white
Entering Storage Mode	Flashing red / blue / white
System Error	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" fast blink indicates Alternate.
	Locked	LEDs blink red/white to indicate error. No Activity is active to check because the Knee is Locked.
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.	LED blinks red/white to indicate nothing has happened.
	Current activity is "Walking" and an Alternate has been configured.	"Walking" activity is selected. White LED blinks slow to indicate "Walking" is now selected.
	Current Activity is Alternate	Alternate activity is selected. White LED blinks quickly to indicate alternate is now selected.

11.10. Modes

Sitting Mode:



QUATTRO features two available behaviors when sitting, and the adjustment is found under the “Tools” tab along the bottom toolbar in both the Clinician and Patient apps.

Sitting Mode On (default): When the Knee is unweighted and thigh is near the horizontal plane, the Knee flexes without resistance.

Sitting Mode Off: 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 Cycling and Obstacle Assist.

Obstacle Assist:



QUATTRO's Obstacle Assist feature is helpful for stepping over tall objects or when entering a high vehicle.

Obstacle Assist On (default): The Knee will flex with no resistance when the thigh reaches 35 degrees of flexion or greater and is extended and unweighted.

Obstacle Assist Off: The Knee will flex slowly with hydraulic resistance when unweighted independent of thigh flexion angle.

The Clinician can turn this feature off/on for different Activities for the patient under “Setup” and “Adjust” along the bottom toolbar in the GaitLab app after full programming is completed. Patient is unable to turn this on/off, it can only be done by the Clinician in the GaitLab app.

Note: If Sitting Mode is turned off, it will also disable Obstacle Assist.

Cycling:



In Cycling, the Knee will enter a user-defined low resistance setting when the user's thigh is near the horizontal plane which occurs when getting on the bike or during normal pedaling. The Knee will remain in low resistance until the user puts weight on the Knee in full extension, triggering the QUATTRO to return to normal walking function. When the Knee is in Cycling, it will disable Obstacle Assist, Sitting Mode, and Stance Lock.

***It is not recommended to keep Knee in Cycling for extended periods of time after patient has finished the Activity. Use app or Keypad to switch Activity back to Walking to avoid triggering Cycling unintentionally.**

Note: If Sitting Mode is turned off, it will also disable Cycling.

Golfing:



Golfing allows you to limit the amount your Knee flexes while playing golf.

After selecting Golfing as the Alternate Activity on the Activities screen via the Patient app, 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 “-“. The patient can program up to 3 different custom resistance settings for the amount of flexion needed for either a particular golf swing or other activities requiring custom resistance settings.

***It is not recommended to keep Knee in Golfing for extended periods of time after patient has finished the Activity. Use app or Keypad to switch Activity back to Walking to avoid triggering Golfing unintentionally.**

! WHEN GOLFING IS ENABLED, THE KNEE WILL ONLY FLEX TO THE DEGREE THAT HAS BEEN CHOSEN IN THE APP. DESCENDING STAIRS AND SLOPES SHOULD BE AVOIDED WHEN GOLFING IS ENABLED AS ALTERNATE ACTIVITY.

Stance Lock:

QUATTRO includes a Stance Lock feature for stability that will automatically lock when patient is on a flexed Knee.

Stance Lock On (default): When the patient stops the thigh at a flexion angle and weights the Knee, it will automatically lock the Knee from further flexion. The lock will automatically disengage when the thigh moves in an extension moment, or the Knee is unweighted.

Stance Lock Off: When the patient stops the thigh at a flexion angle and weights the Knee, the Knee will not lock and it will allow the Knee to continue to flex.

The Clinician must give a patient permission to turn this feature on/off and it can be found under “Setup” and then “Permissions” along the bottom toolbar of the GaitLab app.

If patient has permission to turn this feature on/off it can be found under “Tools” and then “Settings” along the bottom toolbar of the patient app.

Note: Stance Lock is available from 5-70° of flexion. If the Knee is in Cycling, it will disable Stance Lock.


Engage Flexion Lock:

To engage Flexion Lock while in any Activity, double click the Mode button. The button will light up with a solid white light to indicate that 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 Flexion Lock is engaged and the Knee is unweighted, it will be locked in both flexion and extension.

Disengage the Flexion Lock:

With Flexion Lock engaged, double click the Mode button to disengage. The solid white light now turns off, indicating that the Flexion Lock has been disengaged. The Knee returns to the currently selected Activity, e.g., Walking.

 SOCKETS AND COMPONENTS MUST NOT CONTACT THE FRAME OR CYLINDER. THIS WILL CAUSE DAMAGE TO THE UNIT. CONTACT BETWEEN THE SOCKET AND QUATTRO'S REAR BRACE (RED ARROW) IN FULL FLEXION IS RECOMMENDED AND WILL NOT CAUSE DAMAGE.




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.



Note: The Knee ships with the flexion resistance at the middle of the range, plus two turns, to allow for increased or decreased resistance based on patient preference.

12 | Knee Cap Replacement

Removing the Knee Cap

Use a $\frac{3}{32}$ " Hex Key to remove the two socket head cap screws from the Knee



Installing the Knee Cap

Install Knee Cap. Tighten the 2 socket head cap screws using the $\frac{3}{32}$ " Hex Key.

Note: Tighten until flush plus $\frac{1}{4}$ turn, do not over torque screws.



13 | Flexion Angle Limiter Kit

1. Ensure the Knee is in full extension.
2. Use a 3/32" Hex Key or Driver to remove the two socket head cap screws from the rear of the Knee.
3. Maneuver Flexion Angle Limiter around the Cylinder Shaft to remove.

Note: This may require orienting the back of the Knee downward.



4. Ensure the Knee is in full extension.
5. Maneuver the replacement Flexion Angle Limiter into position to install.
6. Tighten the two socket head cap screws using a 3/32" Hex Key or Driver.
7. The inscribed text on the Flexion Angle Limiter should be visible.



Note: Tighten until flush plus 1/2 turn (equivalent to 80oz-in torque).

14 | Compatibility

QUATTRO is available with a male pyramid connection or threaded top connection designed to be compatible with standard connectors (see our catalog).

Use only the wall power supply provided with QUATTRO or the optional Battery Booster pack for battery charging.

15 | Alignment and Setup

Download the Clinician GaitLab smartphone app to properly align and setup the device. GaitLab is required to calibrate and optimize the microprocessor settings for each patient. Patients can change Modes and adjust settings with the Freedom Innovations App. Verify the smartphone requirements before app installation. Download Apps from the App Store or Google Play Store.

App		
GaitLab		
Freedom Innovations		

16 | 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.

17 | Transferring Settings/Resetting to Factory Defaults

Transferring Settings:

1. Connect to the Knee you'd like to transfer the program from.
2. Once connected, go to the "Tools" tab along the bottom toolbar of the app, then tap "Manage Settings".
3. Tap "Copy settings" to save the settings to your device.
4. You can now disconnect from the programmed Knee.
5. Connect to the Knee you'd like to transfer the program to.
6. Go to the "Tools" tab along the bottom toolbar of the app, tap "Manage Settings", and tap "Paste settings".
7. You will get a confirmation message "Are you sure you want to replace all settings?" Tap "OK" to transfer all settings, or "Cancel" to cancel the paste and keep the settings unchanged.
8. Calibration does not transfer over and will need to be recalibrated.

17 | Transferring Settings or Resetting to Factory Defaults (cont.)

Reset to Factory Defaults: This will reset all the settings in the Knee back to factory settings. This action cannot be undone.

1. Connect to the Knee you'd like to reset the settings for.
2. Once connected, go to the "Tools" tab along the bottom toolbar of the app, then tap "Reset to Factory Defaults."
3. You will get a confirmation message "Are you sure you want to reset all settings on your QUATTRO to factory defaults..."
4. Tap "OK" to reset the Knee, or "Cancel" to exit.

Recommendation: Have the patient sitting while transferring the program or resetting the Knee for safety.

18 | Warranty and Service

QUATTRO includes a 36-month warranty covering all manufacturer defects effective only if the product is used according to manufacturer recommendations. QUATTRO does not need to be serviced during this time. Service and maintenance is required at 36-months if the optional 2-year extended warranty is purchased; and, at 36-months and 54-months if the optional 3-year extended warranty is purchased. The battery charger and accessories are provided with a 12-month warranty. The lifetime of QUATTRO depends upon the patient's level of activity. See company website for details.

For Knee service or repair, please contact PROTEOR. A loaner Knee will be provided upon request. For loaner and shipping information please see Technical Support section.

19 | Technical Support

- For User Support, please contact your Certified Prosthetist
- For Prosthetist Technical Support, supplementary training materials or to schedule service, please contact PROTEOR.
- A loaner Knee can be provided upon request. Knees requiring service should be shipped in the provided case to the following address (outside of Europe):
 PROTEOR
 3 Morgan
 Irvine, CA 92618, USA
- In Europe, please ship to the following address:
 PROTEOR
 Rue du Cheffin
 21250 Seurre, France

20 | Electromagnetic Compatibility Precautions

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:

- QUATTRO may be susceptible to electromagnetic interference from portable and mobile RF communications devices such as mobile (cellular) telephones.
- QUATTRO may be interfered with by other equipment, even if that other equipment complies with CISPR EMISSION requirements.
- QUATTRO complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:
 - (1) QUATTRO may not cause harmful interference, and
 - (2) QUATTRO must accept any interference received, including interference that may cause undesired operation.

21 | 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/	Group 1	QUATTRO uses RF energy only for its CISPR 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.
Harmonics IEC 61000-3-2	Complies	
Harmonics IEC 61000-3-2	Complies	

22 | Guidance and Manufacturer’s Declaration – Electromagnetic Immunity

QUATTRO is intended for use in both a professional and home healthcare environment. The customer or user of QUATTRO should ensure the electromagnetic compliance of the environment.

Immunity Test	IEC 60601 Test Level	Compliance Level
Electrostatic Discharge IEC 61000-4-2	±8kV Contact ±15kV Air	±8kV Contact ±15kV Air
Radiated radio frequency electromagnetic fields IEC 61000-4-3	10 V/m 80 MHz-2.7 Ghz 80% AM at 1 kHz	10 V/m 80 MHz-2.7 Ghz 80% AM at 1 kHz
Electrical fast burst transients IEC 61000-4-4	±2kV Mains ±1kV I/Os	±2kV Mains N/A
Surge IEC 61000-4-5	±1kV Differential ±2kV Common	±1kV Differential ±2kV Common
Conducted disturbances induced by RF fields IEC 61000-4-6	3 V 0.15 MHz-80 MHz 6 V ¹⁾ in 15M between 0.15 MNz and 80 MHz ²⁾	3 V 0.15 MHz-80 MHz 6 V ¹⁾ in 15M between 0.15 MNz and 80 MHz ²⁾
Magnetic field at network frequency IEC 61000-4-8	30 A/m	30 A/m
Voltage dips and interruptions IEC 61000-4-11	>95% dip for 0.5 cycle >95% dip for 1 cycle 30% dip for 25/30 cycles >95% dip for 250/350 cycles	>95% dip for 0.5 cycle >95% dip for 1 cycle 30% dip for 25/30 cycles >95% dip for 250/350 cycles
<p>¹⁾ r.m.s. before modulation is applied.</p> <p>²⁾ The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0, 15MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4MHz, 7 MHz to 7,3MHz, 10,1MHz to 10,15MHz, 14MHz to 14,2MHz, 18,07MHz to 18,17 MHz, 21,0MHz to 21,4MHz, 24,89MHz to 24,99MHz to 29,7MHz and 50,0 MHz to 54,0MHz.</p>		

Test Frequency (MHz)	Band (MHz)	Modulation	Required Level	Compliance Level
385	380-390	18 Hz Pulse ¹⁾	27	27
450	430-470	18 Hz Pulse ¹⁾	18	28
710/745/780	704-787	217 Hz Pulse ¹⁾	9	9
810/870/930	800-960	18 Hz Pulse ¹⁾	28	28
1720/1845/1970	1700-1900	217 Hz Pulse ¹⁾	28	28
2450	2400-2570	217 Hz Pulse ¹⁾	28	28
5240/5500/5785	5100-5800	217 Hz Pulse ¹⁾	9	9
<p>¹⁾ Carrier shall be modulated using a 50% duty cycle square wave signal.</p>				

23 | CE Conformity 2021

QUATTRO is tested and certified to comply with the MDR (EU) 2017/745, EN 55011 Class B, IEC60601-1, ETSI EN 300-328 under Directive 2014/53/EU and ISO 10328. The device complies with Part 15 of the FCC Rules and carries the CE mark.

24 | QUATTRO Product Details

- A. Keypad Buttons
- B. Charging Port
- C. Flexion Resistance Adjustment
- D. Replaceable Knee Cap



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IFU-03-014, REV C



EC REP



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