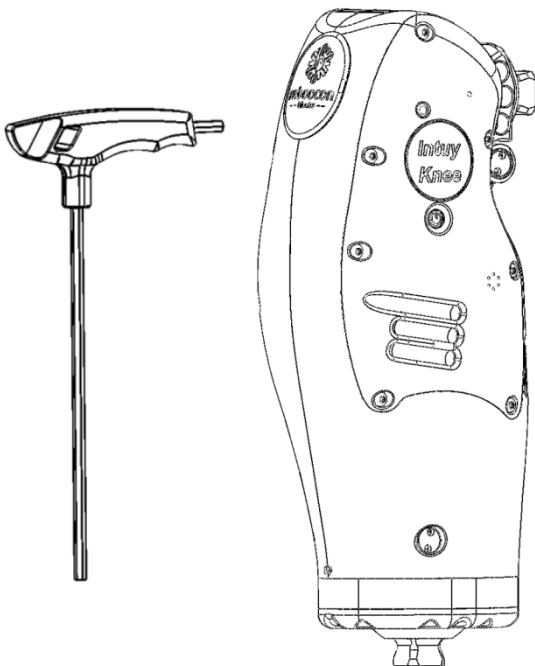



Intuy Knee

Instructions for Use (Practitioner) (EN) [Original Instructions]

**CE**₁₉₁₂

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Intuy Knee

Instructions for Use (Practitioner) **(EN)**

[Original Instructions]

Electronic Instructions for Use in different languages are available on the Manufacturer's website and can be downloaded using the QR code or the link below.



<https://www.rbionics.com/documentation>

Instructions for Use in paper format can be requested using the Manufacturer's helpdesk at no additional cost and shall be delivered within 7 calendar days.



Helpdesk



<https://www.rbionics.com/helpdesk>

This document is subject to change, please contact the local Representative of the Manufacturer or visit the Manufacturer's website to obtain the latest version.

Translations were performed by a certified translation service provider given below.



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United Kingdom




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TERMS AND ABBREVIATIONS

EU	The European Union
UI	User Interface

GENERAL WARNINGS AND RESIDUAL RISKS

WARNING SYMBOLS USED IN THIS DOCUMENT

WARNING: Statement regarding possible risks of death or serious injury.

CAUTION: Statement regarding possible risks of minor or moderate injury.

NOTICE: Statement regarding possible damages to the product or other property.

GENERAL WARNINGS

WARNING: Read and understand DOC-66 Instructions for Use (Wearer) and get an adequate understanding of the device before reading this document.


WARNING: Only qualified practitioners are allowed to fit the device and train the patients.

WARNING: The practitioner must provide adequate training to the Patient before the patient can start using the device independently.

WARNING: Patient training must be performed in a safe environment and according to the physical condition of the patient.

WARNING: The practitioner must provide instructions and training regarding common safety concerns:


- Always use handrails during stair/ramp ascent or descent.
- The patient must power off the device when driving a car.
- Place 1/3 of the foot on the stair during stair descent.
- If the stair ascent function is triggered after stepping onto a higher platform (e.g. pavement), flex the hip, put the foot down, and continue to walk.
- Turning in place will trigger a walking step if the forefoot is loaded; the user has to get accustomed to this.
- Power on the device before standing up.
- Ensure the device is activated by leaning on the prosthetic side before taking a step.

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- Power off the device when doffing the prosthesis.

WARNING: When using modular prosthetic components to fabricate a prosthetic limb, the following aspects have to be considered:

- Use components only according to their intended purpose.
- If components with different weight limits are combined, the weight limit of the weakest component applies to the whole prosthesis.
- If components for different activity levels are combined, the activity level of the component with the lowest activity level applies to the whole prosthesis.
- Using individual, certified components with the CE-marking does not release prosthetists from their duty to check component combinations within their means for fitness for purpose, proper assembly, and safety.
- Should there be evidence that a certain combination of components is not as safe as required, the components must not be combined.
- The prosthesis has to be configured and assembled according to the recognized technical rules.
- The locking torque specifications given for the modular components have to be met. A suitable tool (i.e. a torque wrench) has to be used to set the locking torque accordingly.
- Before the prosthesis is handed over to the user, all modular components have to be secured against accidental loosening or twisting.
- Safety-related regulations for individual components (e.g. specific combination possibilities, maintenance intervals, etc.) must be followed.
- Only use components that meet the requirements of EN ISO 10328:2016 and the Regulation (EU) 2017/745 (MDR) (for the users in the EU).
- In the event of damage to a prosthesis that combines components from different manufacturers, every manufacturer can only be held liable for the failure of those components produced by them. Beyond that, manufacturers can only be held liable if their components are proven to have caused damage to

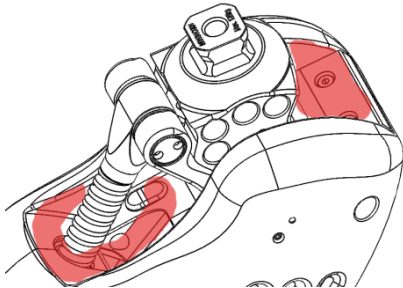
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or failure of components that were produced by other manufacturers.

RESIDUAL RISKS

The following residual risks remain for the practitioner.

CAUTION: Keep fingers away from the back of the knee joint and the extension bumper to prevent the risk of pinching.



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1. INTRODUCTION

The Intuy Knee (hereafter referred to as the Device, or the Knee) is a motorized external knee prosthesis designed to actively assist leg amputees in performing daily activities. It is an active-power electromechanical device, which is a component of a lower limb prosthesis designed to functionally replace, in part or total, an absent knee.

This document is intended for a practitioner in the relevant field such as a prosthetist. The practitioner must always first read DOC-66 Instructions for Use (Wearer) to be able to gain knowledge of the device and then follow this document for proper installation, alignment, component selection, and device setup.

Besides this document, training videos on the use of the device are provided on the manufacturer's website; both the patient and the practitioner have to watch the videos carefully.

2. INSTALLATION REQUIREMENTS AND VERIFICATION

2.1. QUALIFIED PERSONNEL

The prosthesis must be installed by qualified personnel and qualified personnel means:

- certified prosthetic practitioners who attended the Intuy Knee training and obtained the certificate or
- qualified personnel from the Manufacturer.


Information regarding training and certification is available on the Manufacturer's website.

2.2. COMPONENT SELECTION

CAUTION: Consult the Manufacturer before applying articulated prosthetic feet such as microprocessor-controlled feet.

NOTICE: Connecting adapters with a big diameter to the knee might jam the knee cover and cause damage to the cover. Stainless steel or titanium adapters with small diameters are recommended.

The Intuy Knee may be fitted with the majority of CE-approved adapters and prosthetic feet. It is recommended to use components with the same or higher body weight rating. Non-articulated prosthetic feet for moderate to high activities are recommended.

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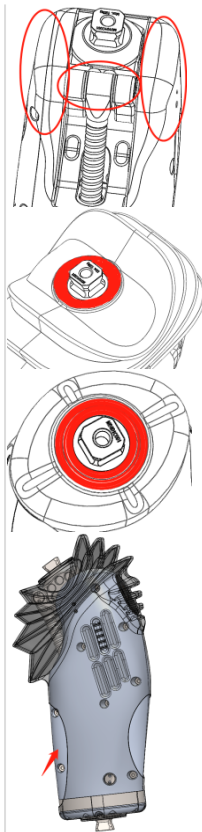
2.3. KNEE COVER INSTALLATION

NOTICE: Lubricate the Knee Cover sufficiently and push it out of the way when connecting the prosthetic adapters. Don't jam the Knee Cover.

The device comes with a protective cover designed to protect the user from pinching and the device from dust and debris. The cover is preinstalled out of the factory, in case of a replacement, please follow the instructions below:

1. Make sure the knee is not connected to any other modular prosthetic component.
2. Power off the knee.
3. Apply food-grade silicone oil (CAS no. 63148-52-7) to the encircled area on the knee and the highlighted rims on the knee cover.
4. Insert the knee into the cover from the back hole (the largest hole) and push through.
5. Adjust the top bellows to fit the top pyramid. Align the cover with the device.
6. Lift the bottom of the cover over the bottom pyramid of the device until it fully covers the bottom of the device. The bottom pyramid should be in the middle of the hole of the cover.


To remove the cover, reverse the sequence above.



2.4. CONNECT THE FOOT TO THE KNEE

WARNING: All four setscrews of the tube adapter must be tightened with a torque wrench to the specified torque of the tube adapter or clamp adapter. Not doing so can lead to incorrect sensor reading.

1. Determine and shorten the tube to the required length. Deburr to smoothen the surface.

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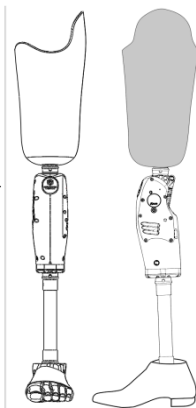
2. Connect the prosthetic foot with the tube.
3. Connect the subassembly to the bottom of the knee.
4. Push the knee cover out of the way, and tighten the setscrews of the tube adapter according to the specifications of the tube adapter. Make sure the knee cover is not jammed by the tube adapter.

2.5. CONNECT TO THE SOCKET

The socket should have the pyramid adapter/lamination anchor placed in a neutral position, which permits more dynamic and not overly-stable construction.

Adjust the setscrews in the pyramid adapter to reach a neutral orientation and tighten the screws according to the specifications of the pyramid adapter. Make sure that the knee Cover is not jammed by the adapter.

NOTE: the knee Cover is omitted in the illustration to allow the sight of the adapter, but it is necessary to install the knee cover.




⚠ WARNING: Incorrectly secured screws may cause screw connections to come loose and could lead to a fall. Apply thread-locking fluid (e.g. Loctite) to screws if the manufacturer of the adapters has specified to do so.

3. ALIGNMENT

3.1. PREPARE THE KNEE

1. Power on the Knee (in case the knee is in Hibernation Mode, plug in the charger and wait for the amber LED to turn on, disconnect the charger, and then power on the device).
2. Connect to the knee using the phone app (see next chapter).
3. Search and connect to the device using the app.
4. Click the "LOCK KNEE" button from the app dashboard to straighten the prosthetic leg.

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- The device is ready for Bench Alignment. Use the picture below as a reference.

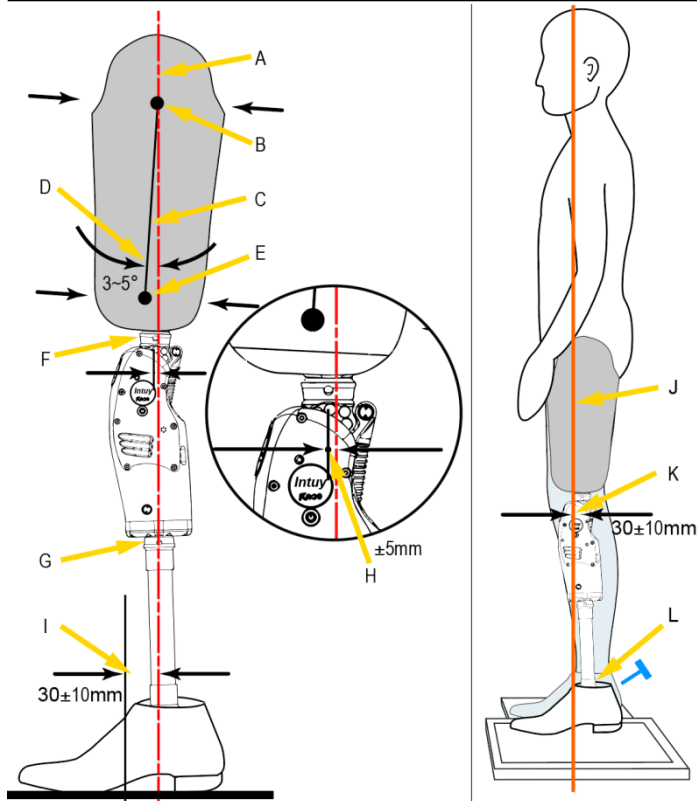
3.2. BENCH ALIGNMENT

CAUTION: Excessive ab/adduction, knee rotation, knee preflexion, and/or foot dorsiflexion, can lead to incorrect behavior of the prosthesis and should be avoided.

Perform the alignment using a laser plumb, a plumb line, or a similar instrument.

- Reference Line: Create a vertical Reference Line using a plumb.
- Foot placement: Keep the shoe on. Keep Mid-foot approximately 30±10mm anterior to the Reference Line. Place the foot with a 5-7° toe-out angle.
- Knee Placement: Place the knee with approximately 5° external rotation. Adjust the fore-aft setscrews of the foot to move the Knee Axis within ±5mm w.r.t. the Reference Line.
- Mark the socket: Mark the Proximal Center, Distal Center, and the Socket Centerline.
- Socket Alignment: Let the Reference Line pass the Proximal Center, and set the Socket Flexion Angle to 3-5°. Take individual conditions into account, e.g. hip flexion contractures.
- Socket Connection: Align and fixate the Socket Adapter to the socket, and connect the knee to the socket via the socket adapter.
- Proceed to Static Alignment.


NOTE: Check out the assistive tools provided by the Intuy app (SETUP tab → Alignment)



A. Reference line, B. Proximal Center, C. Socket Centerline, D. Socket Flexion Angle, E. Distal Center, F. Socket Adapter, G. Tube Adapter, H. Knee Axis, I. Distance between the reference line and mid-foot, J. Loading Line, K. Distance between the Knee Axis and Loading Line, L. Adapter for the Foot.

3.3. STATIC ALIGNMENT OPTIMIZATION

Perform the static alignment using L.A.S.A.R Posture or a similar instrument. If such an instrument is not available, let the patient put on the prosthesis, stand straight, and feel the pressure around the socket. Adjust

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the setscrews of the foot, until the user feels comfortable and stable. You can skip the steps below.

1. Load Line: Instruction the user to step onto the force plate of the L.A.S.A.R with the prosthetic foot and place the other foot on a height compensation panel. Instruct the user to distribute weight evenly on both feet. The Load Line will be visible on the side.
2. Foot Adjustment: Adjust solely the plantar- and dorsiflexion of the foot so that the Knee Axis is about $30\pm 10\text{mm}$ posterior to the Load Line.

NOTE: Check out the assistive tools provided by the Intuy app (SETUP tab → Alignment)

3.4. DYNAMIC ALIGNMENT OPTIMIZATION


Click the "START" button on the phone app and instruct the patient to perform a trial walking between parallel bars. Observe and check the following aspects:

1. Sagittal Plane: Check stride symmetry and stance stability, and adjust knee flexion or foot flexion when necessary.
2. Frontal Plane: Observe the lateral motion and stability of the trunk. Check the pressure on the medial-lateral side of the socket with the user. Adjust ab/adduction and position of the socket adapter when necessary. Adjust ankle inverse of eversion when necessary.
3. Transversal Plane: Adjust knee rotation when excessive leg rotation is observed during swing. Adjust foot rotation when leg rotation is observed e.s.p. during stance.

4. MOBILE APP FOR THE KNEE

4.1. SYSTEM REQUIREMENTS ON MOBILE DEVICES

- Operating system: Android 10.0 or above, iOS 13.6 or higher
- RAM: 2 GB or more
- Internal Storage: 100 MB for app installation/ 1024 MB for diagnostic data storage
- Bluetooth: Bluetooth 4.0 or higher
- Screen: touch screen, 4 inches or bigger
- Network: WiFi or mobile network enabled

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4.2. HOW TO OBTAIN THE APP

Search for "Intuy by Reboocon" in the Play Store on an Android device or App Store on an Apple device and install it. The app will be made available to more app stores. Alternatively, use this link:

<https://www.rbionics.com/app/>

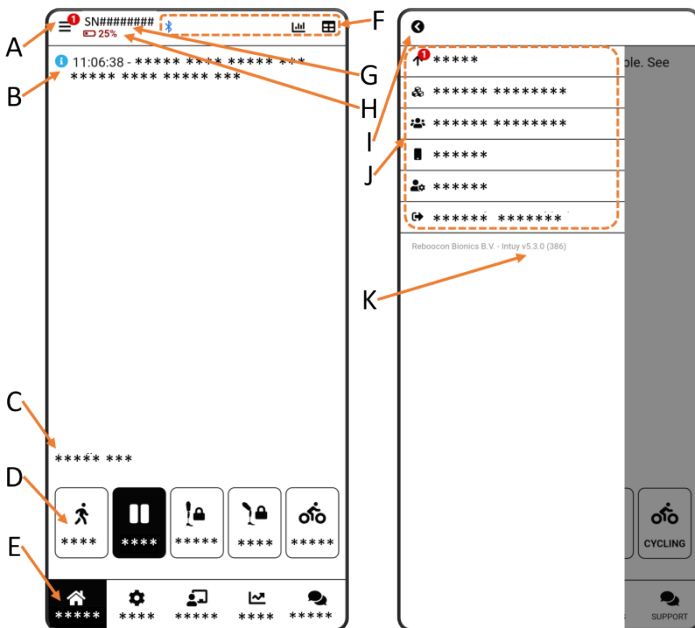
4.3. PERSONAL ACCOUNT FOR THE APP

It is required to have a personal account to use the app. The account is invitation based. The Manufacturer or the local Representative of the Manufacturer should send an invitation to the potential users (both professional and end users).

Instructions about logging in are given in the (email) invitation. After logging in, the app can be used.


Different user accounts have different authorization levels. The higher the authorization level, the more app features the user can access. With a personal account, the user can connect to a Knee authorized to him/her and store personalized settings on the app server.















4.4. THE USER INTERFACE (UI) OF THE APP






The **🏠 DASHBOARD** tab (the main UI) is shown in the left picture above. The key elements:

- A. **☰ Menu button**: when clicked, the picture on the right shows up. It has a return button **⬅️ (I)** and you can see the app version **(K)**. When clicking the individual Menu Items **(J)**, diverse pages for different purposes pop up:
 - **⬆️ Update**: manage Knee firmware update and app update;
 - **⚙️ Device management ***: manage all the devices authorized to you, e.g., authorizing others to use the device in the list;
 - **👤 User management ***: manage all the users under your authorization;

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-  **App settings:** e.g., change the server settings or other settings of the app;
 -  **My account:** manage your own account information, e.g., change password or email;
 -  **Log out** button;
 - **App version (K)** is shown at the bottom of the menu.
- B. **Notification Center:** it shows error messages or notifications such as software updates or periodic maintenance deadlines.
- C. **Device Status:** It indicates the current mode/state of the device, such as cycling or sitting.
- D. **Mode Switching Buttons ****, from left to right:
-  **START:** switch the Knee to operational mode, the user can walk with the Knee;
 -  **SLEEP:** switch the Knee to sleep mode, the motor of the Knee is shut down, and no support is given;
 -  **STRAIGHT:** fully extend the Knee and lock it.
 -  **LOCK:** lock the knee at the current angle
 -  **CYCLING:** enable cycling mode.
- E. **Function tabs:** each tab has its own function, with its contextual buttons and fields. From left to right:
-  **DASHBOARD:** this shows the dashboard, as shown in the picture on the left;
 -  **SETUP:** This tab provides a step-by-step guide for setting up the knee, e.g., alignment, user data, calibrations, options, extra and advanced parameter configurations;
 -  **TRAINING:** this tab includes some training related features such as training feedback settings;
 -  **GRAPH *:** it shows the knee torque, knee angle, etc. in real-time;
 -  **SUPPORT:** data from the Knee and app use are collected and can be sent to the Manufacturer's server for troubleshooting purposes.
- F. **Contextual Buttons:** these buttons change according to the tab or page, on the DASHBOARD tab, these buttons are shown,
-  **Bluetooth:** a new page will pop up when clicked to allow the user to connect or disconnect to a Knee.

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-  **Activity Report**: check the step counts, activity intensity, stair ascent counts, etc.;
-  **Statistics**: check the daily and total steps, stair count, etc.;

G. **SN#####**: it shows the serial number of the device.



H.  **Battery**: battery level in percentage.

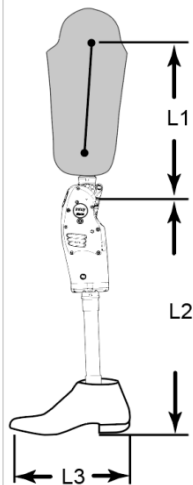
* Not available for the patient.


** If enabled in the app settings, more buttons can be shown, such as Intuy Mode buttons.

5. QUICKSTART FOR THE APP

To quickly start using the Knee, follow the steps below:

1. Input User Data: Click the following 
SETUP tab → **User Data**, and input the patient data, such as
 - Body weight
 - Height
 - L1: Thigh length: the distance from the hip joint to the Knee Axis
 - L2: Shank length: the distance from the Knee Axis to the ground including the shoe
 - L3: Shoe size (in cm): convert the shoe size to centimeters using the in-app information table. Don't rely on measurement.
 - Activity Level: the more active, the bigger the value. We recommend 3 and 4 for most users.
2. Perform **Calibrations**
 - Force Sensor Calibration:
 - Lift and keep the prosthetic foot in the air, click the buttons 
SETUP tab



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→ **Calibrations** → **Force Sensors**

- Follow the in-app instructions and wait until it completes
 - Standing Position Calibration:
 - Instruct the user to stand straight and stand still, click the buttons ⚙️
- SETUP** tab
- **Calibrations** → **Standing Position**
- Follow the in-app instructions and wait until it completes.

3. The user can start using the prosthesis.

6. OTHER FEATURES OF THE APP


6.1. ↑ SOFTWARE UPDATE

WARNING: Possibility of falling

- Sit down or doff the prosthesis when performing the Knee firmware update. Don't use the Knee.
- After the firmware update, the Knee is in sleep mode, and the user is required to load the prosthesis sufficiently (>50% bodyweight) before making the first step.
- Make sure that the phone has more than 20% charge and that the Knee has more than 40% charge.
- Keep the Knee and the phone close to each other during the update process.





















The app checks whether the app itself or the firmware in the Knee is up to date.

To update, click the item **↑ Update** in the **≡ Menu**. On the update page, click the update button if an update is available. An app update is straightforward and relatively quick. A firmware update typically takes 5 to 20 minutes. Don't perform any other activities on the phone. If the firmware update fails, retry according to the app's instructions.

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6.2. 👤 USER MANAGEMENT

The table below lists 4 types of user accounts, with their authorization level from high to low (top-down). The table also defines the user management capability and accessible app features for each type of user account.

Account authorization levels	Create and manage	Accessible app features
Distributor Administrator	CPO Administrator, CPO, Clinician, Wearer	Basic features,  GRAPHS,  SETUP,  User Management,  Device Management
CPO Administrator	CPO, Clinician, Wearer	Basic features,  GRAPHS,  SETUP,  User Management,  Device Management
CPO	Clinician, Wearer	Basic features,  GRAPHS,  SETUP,  User Management,  Device Management
Clinician	Wearer	Basic features,  GRAPHS,  SETUP (incomplete access),  User Management,  Device Management
Wearer	nobody else	Basic features (such as  DASHBOARD,  SETUP (incomplete access),  SUPPORT, and some  Menu items)


By going to  User Management from the  Menu, a user can

- see a list of users under his/her management,
- invite or delete a user, or update the details of a user, e.g. authorizing (linking) a new device to the user.

6.3. DEVICE MANAGEMENT

By going to  Device management from the  Menu, a user can

- see a list of devices linked to him/herself,
- authorizing (linking) a device to another user under his management.

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In the near future, a user can also upload the device settings to the cloud and download the settings from the cloud to the currently connected device. This will facilitate switching devices during periodic maintenance and repair.

6.4. OPTIONS IN THE SETUP TAB

Some modes or features can be toggled on and off, such as

- Cycling
- Holding
- Stairs
- Wheelchair
- E-Stairs
- Power Saving

NOTE: the exact list can change due to software update. Follow the instructions of the app.

6.5. EXTRA PARAMETERS IN THE SETUP TAB

WARNING: when adjusting these parameters, make sure the user is aware of the change. Perform the change in a safe condition, e.g. on level ground not on a staircase, while standing not while walking.


CAUTION: Always remember to save the settings to the Knee by clicking the ✓ button on the top right.

CAUTION: Normally Extension speed, Force sensor sensitivity, and Flexion amplitude are adjusted simultaneously to achieve a higher walking speed.

CAUTION: Stance resistance affects multiple activities.

To customize extra parameters to fit the personal need of the end user, go to the ⚙️ **SETUP** → **Extra Parameters**.

1. Reset Defaults: if the Knee is not new, such as a loaner Knee, use this button to reset the extra parameter to their factory value.
2. Walking parameters:
 - Extension speed: the bigger the value, the earlier the Knee switches to swing extension during the swing phase.
 - Force sensor sensitivity: the bigger the value, the easier it is to trigger a swing.

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- Flexion amplitude: the bigger the value, the higher the maximal flexion angle during the swing phase.
 - Pre-flex angle: the bigger the value, the bigger the pre-flexion angle before heel strike, and the more bent the leg is.
3. Standing parameters:
- Stance resistance: the higher value, the higher resistance when sitting down or performing similar activities.
 - Sit-to-stand power level: the bigger the value, the more assistance when standing up
4. Stair and Ramp parameters
- Stair ascent power level: the bigger the value, the more assistance when climbing stairs.
 - Stair ascent sensitivity: the bigger the value, the easier to trigger stair ascent.
 - Descent resistance level: the bigger the value, the higher resistance during stair or ramp descent.

6.6. ADVANCED (SETTINGS) IN THE SETUP TAB

Certain features require configuration before putting to use. This can be done from the **Advanced** accordion of the **SETUP** tab, for example,


- Intuy Modes
- AI-Gait Optimization

NOTE: the exact list can change due to software update. Follow the instructions of the app.

6.7. TRAINING FEEDBACK CONFIGURATION IN THE TRAINING TAB

During rehabilitation phase, it is useful to obtain feedback such as beeps or vibrations when the user has performed the movement correctly. The feedback options, such as heel load, toe load, or swing, can be toggled on and off.

The feedback can be transmitted from the knee (beeps) or the phone (sound or vibrations), this can be selected via the app as well.

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6.8. REHAB MODES CONFIGURATION IN THE TRAINING TAB

Rehab modes are progressive modes made for rehabilitation purpose.

Four modes are given, READY, SET, GO, and a CUSTOM mode.

- **READY:** this mode has very limited feature turned on. User can stand and train for stability and sit down.
- **SET:** this mode additional allows yielding and swing. User can walk with it.
- **GO:** this mode enables all the essential features except Kneeling and Cycling. User can go up and down stairs.
- **CUSTOM:** professional users can turn on and off certain feature and configure a personalized mode for the user.

NOTE: Rehab modes are not accessible to the end user. Professional users must ensure a proper mode is set and the end user is sufficiently informed.

6.9. INTERACTIVE TRAINING IN THE TRAINING TAB

To improve the efficacy of training, we are making some training videos and instructions available in the app. Both professional and end users can follow the instructions given by the app and learn how to use the device.


7. TRANSPORTATION, STORAGE, AND DISPOSAL

7.1. TRANSPORTATION AND STORAGE


- The device including its accessories should be stored and transported using its original packaging, in a cool and dry environment. The temperatures should be between 0°C and 40°C. The humidity level should be between 10% to 90% RH, non-condensing.
- Do not transport in a harsh environment. Do not expose to extreme coldness, heat, or humidity.
- Handle with care during transportation.
- Avoid storing a fully charged device for extended periods.

7.2. DISPOSAL

- Do not dispose of the device as regular garbage, since the Li-ion battery is integrated inside.

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- For device disposal, please contact the Manufacturer's local Representative or the Manufacturer (if the local Representative is not designated).

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8. CONTACT INFORMATION

8.1. MANUFACTURER



Reboocon Bionics B.V.
Ambachtsweg 4,
2641 KS, Pijnacker,
the Netherlands
www.rbionics.com

8.2. DISTRIBUTOR OR RETAILER

The Distributors or Retailers of the Product shall place their contact information sticker below. The user should always contact them first before contacting the Manufacturer.

