

SIGNATURES

Signature Meaning	Name	Title	Date	Signature
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CHANGELOG

Version	Change Date	Contributor	Change Description
0.0.1	2020/10/03	Shiqian Wang	Initial Draft
0.0.2	2020/12/21	Manav Penubaku	Added missing figures
1.0.0	2020/03/21	Shiqian Wang	remove "product description" section which is about ILK product, should not be repeated in ILapp IFU.

TERMS AND ABBREIVATIONS

BT	Bluetooth
IFU	Instructions for use
ILK	IntelLeg Knee
ILapp	IntelLeg app (the phone app for ILK)
MDR	REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices

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Instructions for Use (ILapp Wearer)

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1. INTRODUCTION

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

Please read this document thoroughly and discuss any questions you may have with your CPO (certified prosthetist and orthotist) before using this device. To ensure safe and proper operation of the device, you must follow the instructions provided in this document.

1.1. INTENDED USE

Practitioners can use ILapp to:

- Activate and register ILK when first being taken into use when sold by practitioner.
- Perform updates of the firmware on ILK.
- Calibrate ILK and verify ILK performance.

Wearers can use ILapp for:

- Adjusting of settings such as weight, length and shank length.
- Collecting diagnostic data from ILK when receiving support from practitioner or Reboococon.
- Being informed about the exact battery charge level as well as possible faults.

1.2. SAFETY WARNINGS IN THIS DOCUMENT



WARNING: Statement regarding possible risks of severe accident or injury.



CAUTION: Statement regarding possible risks of accident or injury.

PRECAUTION: Statement regarding possible damages to the device.

2. GENERAL WARNINGS

- Practice operating the prosthesis in the presence of a specially trained professional before using it in your daily environment. Start using the prosthesis in your daily environment only when authorized to do so.
- Stop walking immediately whenever an information signal is felt (prosthesis vibrates) and/or heard (prosthesis beeps).
- If you experience any problems with a component of the prosthesis or accessories that are not documented in this manual, contact your practitioner first. Never attempt to make any technical repairs yourself.



CAUTION: Power on the prosthesis only when you are wearing it.



CAUTION: Power off the prosthesis when sitting in a vehicle. Only power on the prosthesis when necessary.



CAUTION: Do not apply loads higher than the rating specified

3. SYSTEM REQUIREMENTS FOR MOBILE DEVICE

- Operating system: Android 9.0 or above, iOS 13 or higher
- RAM: 2 GB or more
- Internal Storage: 10 MB for app installation/ 1024 MB for diagnostic data storage
- Bluetooth: Bluetooth 4.0 or higher
- Screen: touch screen, 4 inch or bigger
- Network: WIFI or mobile network enabled

4. INSTALLING INTELLEG APP ON ANDROID DEVICES

1. Open a web browser and type in the download link provided by your practitioner. Download the latest IntelLeg app installation.
2. Locate and click the downloaded APK to start installation (your device might ask for installation permission to open the file, please allow the permission)
3. When the software start installing, please do not quit the installation screen or power off your device, wait for approximately 10 seconds to finish installation (sometimes it might take up to one minute, please wait patiently)
4. Wait until the app installation is finished.

5. INSTALLING INTELLEG APP ON APPLE DEVICES

1. Contact your practitioner and supply your e-mail address used for your Apple ID.
2. You will receive an e-mail from Apple with a TestFlight code.
3. Install the Apple TestFlight app from the App Store and press Redeem once in the app and logged in
4. The IntelLeg app should now show up in the list. Press Install to install the app.

6. INTELLEG APP DASHBOARD AND CONNECTION TO ILK

1. Power on ILK. Enable Bluetooth on your phone.
2. In the app gallery, locate and click this icon to start the app. The DASHBOARD of IntelLeg app is shown in Figure 6 (left).
3. Click on the Bluetooth icon on the top-right of the app if the device list is not automatically shown; IntelLeg app will scan ILK devices nearby and compatible devices will be listed, as illustrated in Figure 6 (right).
4. Click on the device you have to start the Bluetooth pairing process.
5. A device-specific activation code is required (supplied by Reboococon Bionics). This is illustrated by Figure 7 (left & mid).
6. For first-time connection, user registration is also required, as shown in Figure 7(right). Please fill in true data and click register to proceed.
7. A pairing request dialog might show up (depending on the mobile device's manufacturer). If not, check your android notification bar as shown in Figure 8(left). Tap on it to open the dialog as shown in Figure 8(right) and then click pair.
8. IntelLeg app will now be paired to your device.
9. The app now switches to the dashboard and will connect to the device.
10. After connection is setup, ILK battery percentage and serial number is displayed on the top ribbon. Under the DASHBOARD tab, the activity statistics of the device is also shown. The statistics record daily and long-term (since activation) activities of the device, such as step counts, number of stairs ascended, time of being active, and etc.

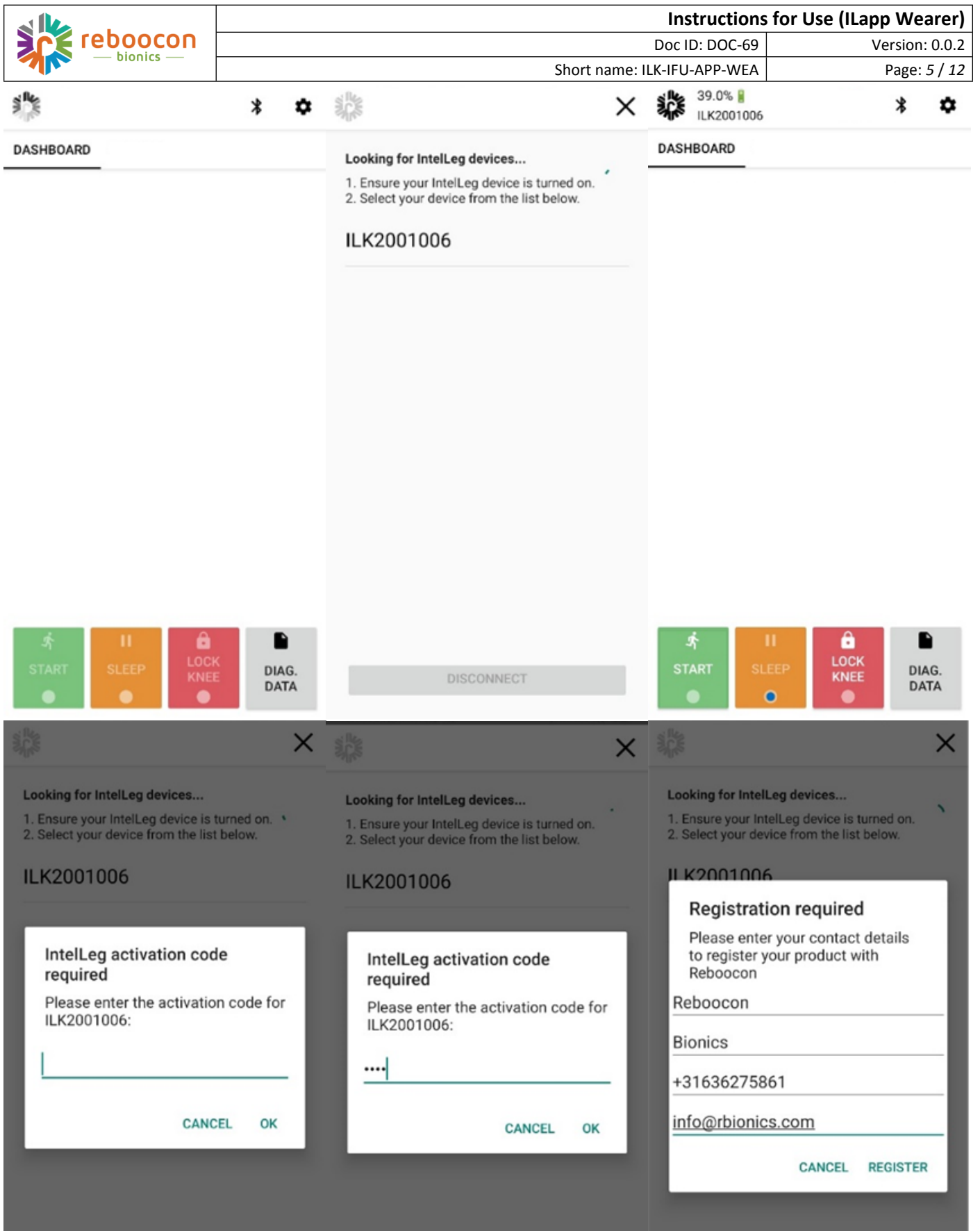


Figure 7: IntelLeg app (Wearer) activation code, entering activation code and user registration

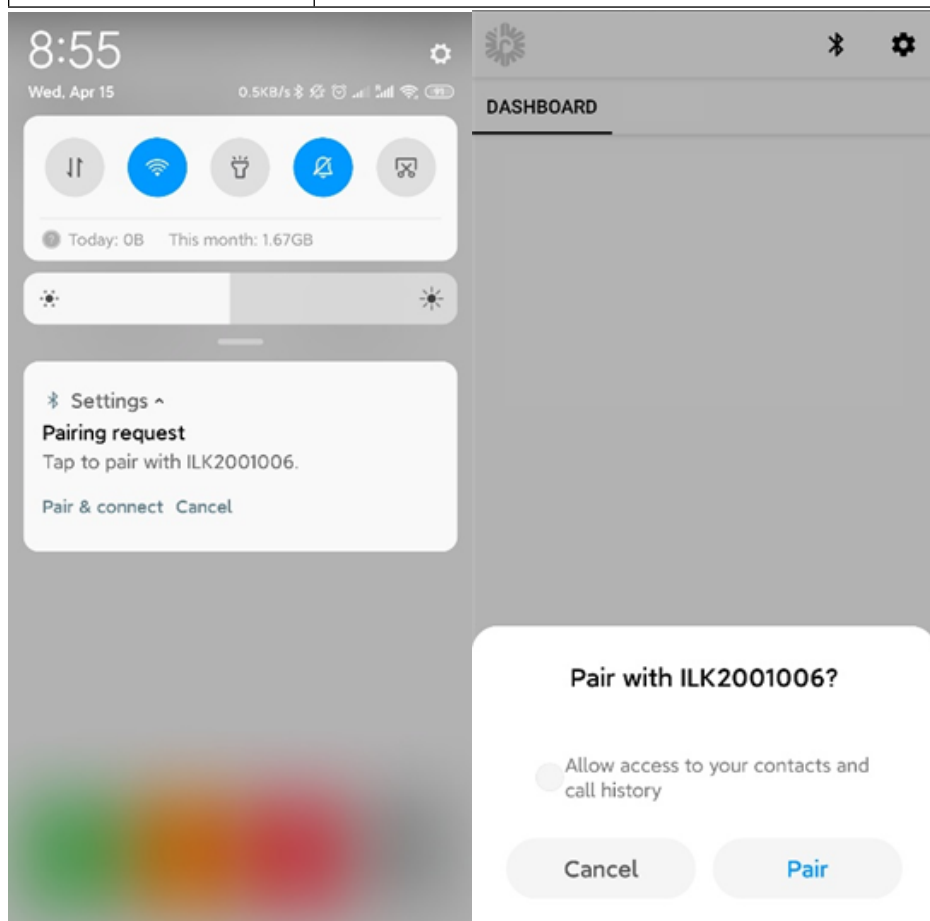
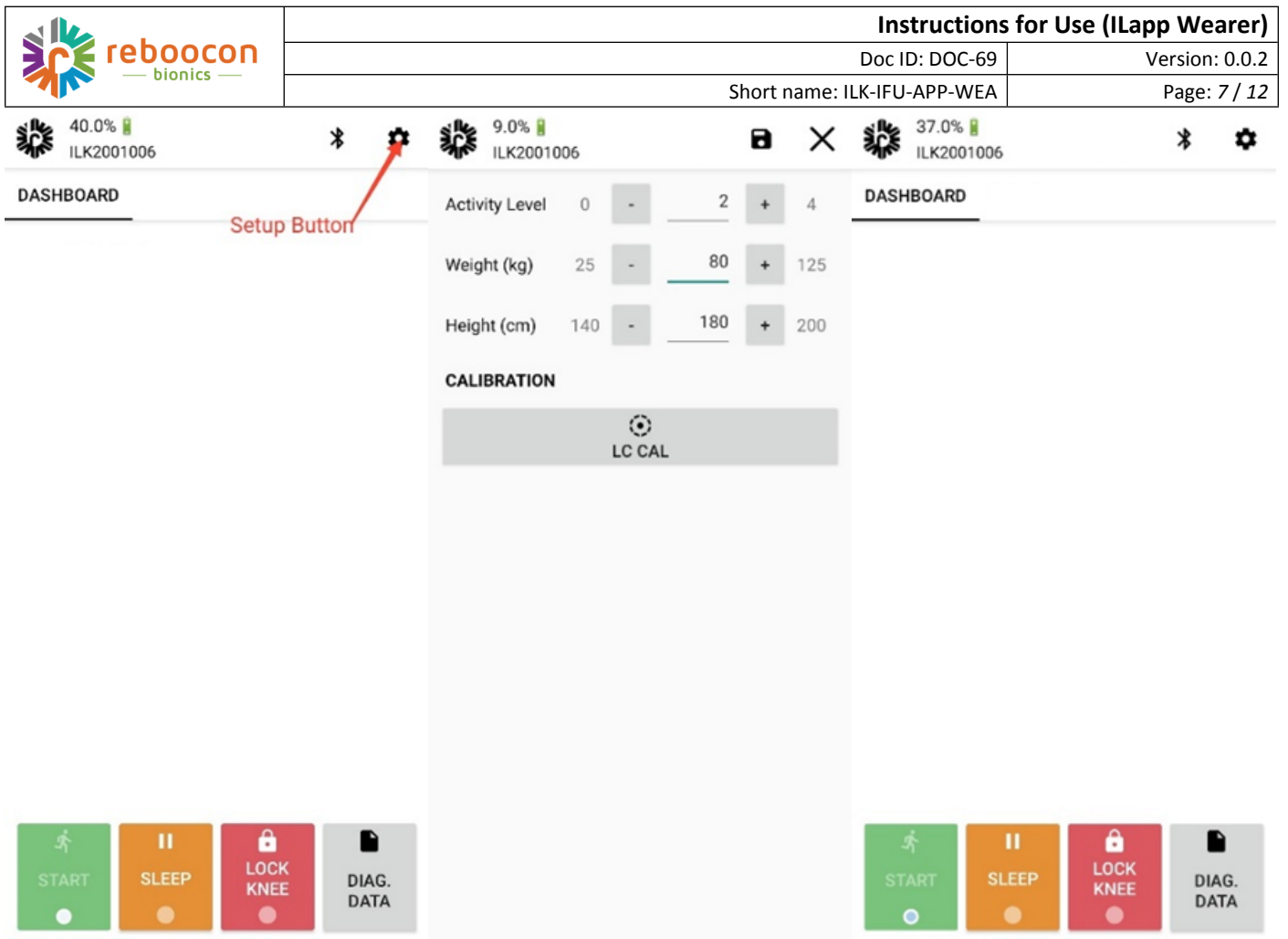


Figure 8 IntelLeg app (Wearer) Pairing Request

7. ILK DEVICE SETUP USING INTELLEG APP

This section provides guidance on the use of IntelLeg app.

1. Click **SETUP** button as shown in Figure 9(left) on DASHBOARD, the SETUP page pops up. Fill in your body height (in cm) and body weight (in kg), as shown in Figure 9(mid).
2. Adjust the activity level according to your preference, we recommend 2 to start with. High number meaning more active, lower number means less active.
3. Go back to dashboard and press START as shown in Figure 9(right) to start the device. You can now perform the activities described in Section 3.



8. INTELLEG APP MISCELLANEOUS

8.1. EMERGENCY STOP AND HIGH-RESISTANCE MODE

If something abnormal happens and you want to stop ILK from moving, please click on the emergency stop button on the IntelLeg app, as shown in Figure 10. Please make sure you are holding onto something or in a sitting posture. The knee will be in a high-resistance mode and resists both flexion and extension.

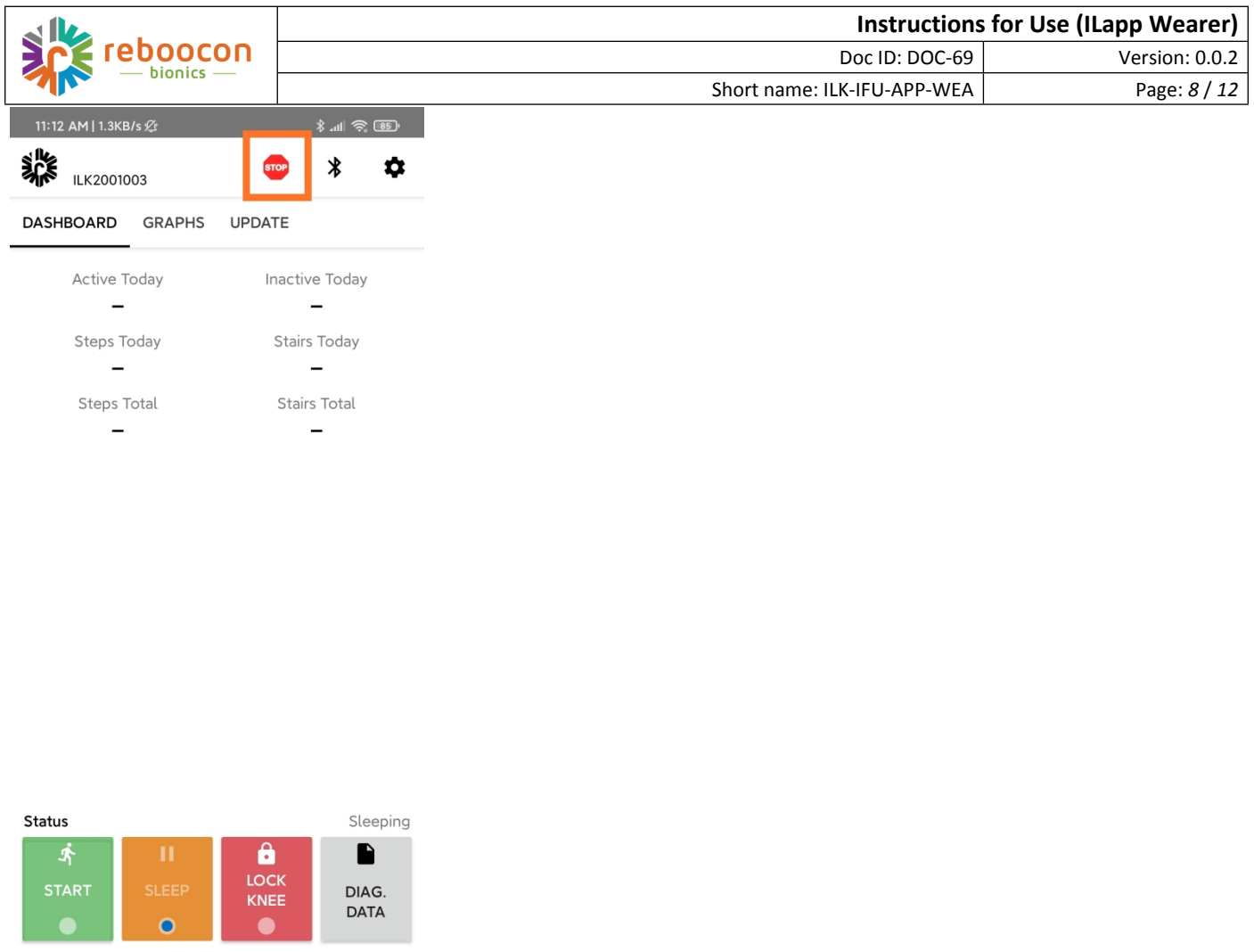


Figure 10 IntelLeg app (Wearer and Practitioner) Emergency Stop

In case of critically low battery or device error, the high-resistance mode will be activated automatically.

8.2. DIAGNOSTIC DATA

When you experience undesired behaviour from the IntelLeg Knee, it is possible to send a detailed data file to Rebocon Bionics with information about how the prosthesis was performing while it was being used.

IntelLeg app will continuously collect data if it is connected to ILK and ILK is in START mode.

The data will remain on your phone, up to 1GB, until you manually submit it to Rebocon Bionics.

To submit the data, open IntelLeg app, ensure the Dashboard page is showing and press the UPLOAD button, as shown in Figure 11. This opens a new page for the diagnostic data.

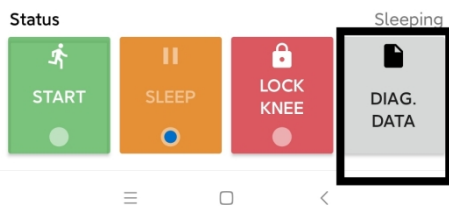
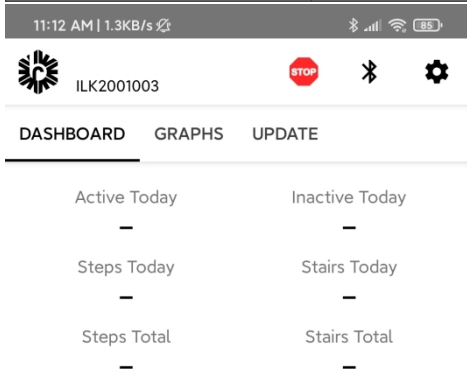


Figure 11 IntelLeg app (Wearer) Dashboard, UPLOAD diagnostic data.

You can enter an optional identification describing the issue. Agree to the privacy policy and press upload to proceed with uploading the data. Ensure your internet connection is active.

If any problem occurs during upload of the data, press UPLOAD again to restart the procedure. The files will remain on your phone until they are successfully submitted. Once they are successfully submitted, they will be removed from your phone. Once the amount of data reached 1GB, older diagnostic data will be removed to make room for new data.

8.3. STATISTICS

The user stats can be seen on the dashboard of the ILapp as shown in Figure 12. It gives the time spent in active activities like standing, walking, stair ascent, descent and the device inactive time indicating the time spent sitting, lying down. The number of steps and stairs on a given day and the total steps and stairs taken with the device can also be viewed. The user has the power to hide the statistics from other app users like the prosthetist, this can be done from the setup page.

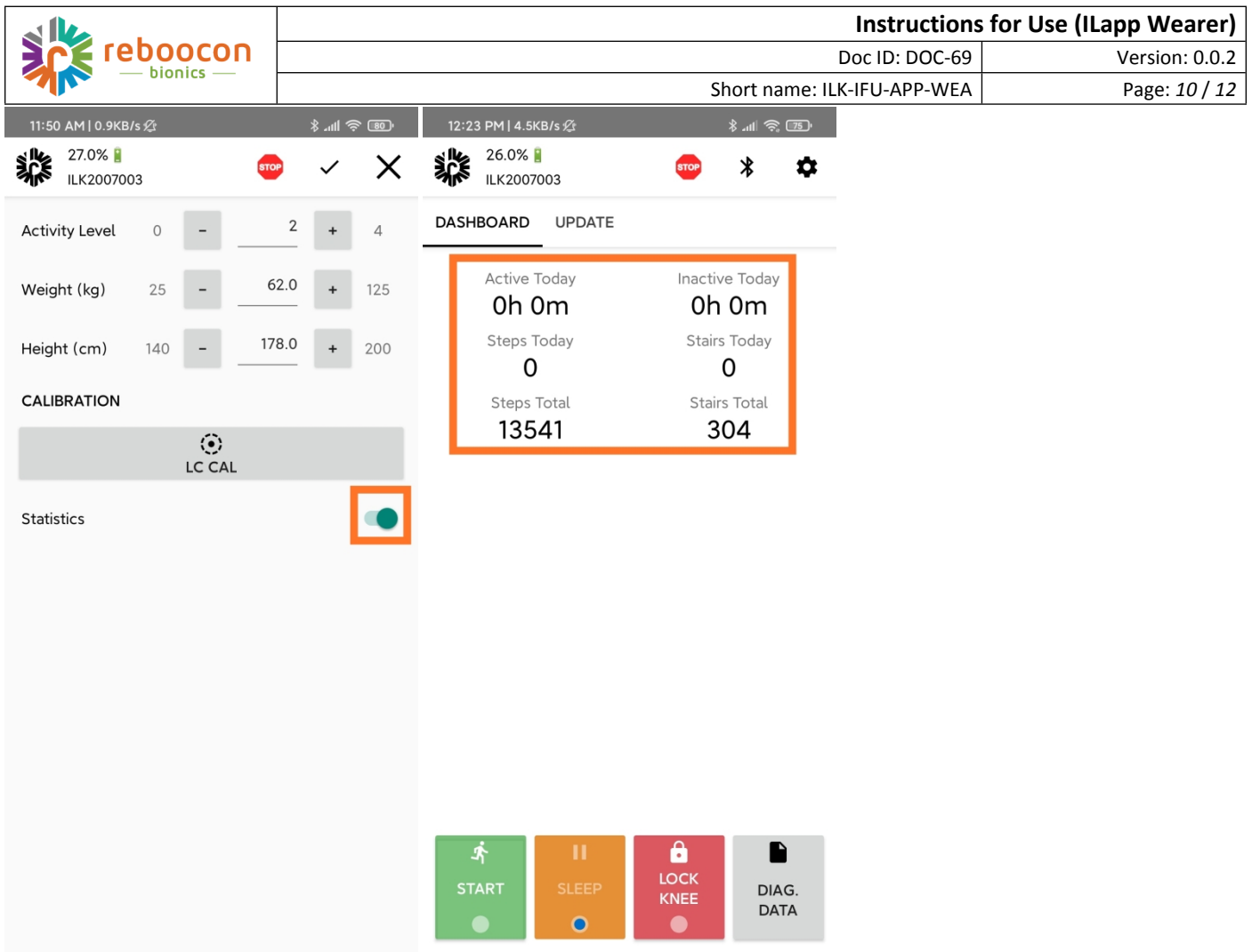


Figure 12: Statistics (Left), Statistics Switch (Right)

8.4. LOCK KNEE MODE

An additional lock-knee mode exists to keep the leg straight in a high stiffness state. If the user desires (e.g. when passing very challenging terrains), the lock knee mode can be manually activated by clicking on the LOCK KNEE button from the DASHBOARD, as shown in Figure 13. If the knee is not straight it will slowly extend to that position.

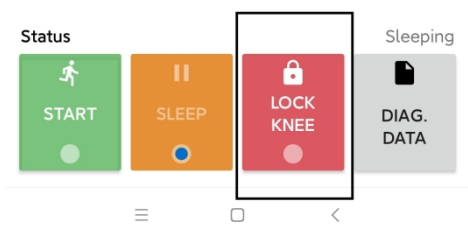
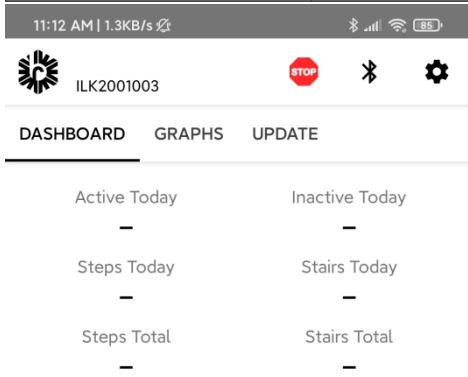


Figure 13 Lock ILK by clicking on LOCK KNEE button

9. TROUBLESHOOTING

LED signal	Beep signal	Vibration signal	Event	Potential Causes	Recommended action
N/A	N/A	N/A	Cannot connect to BT/ BT connection lost	BT antenna malfunction, communication error	- Disconnect from the ILK. Reconnect Attempt to upload diagnostic data from ILapp.

10. LIABILITY

- The manufacturer suggests using ILK for the intended purposes under the specified conditions.
- The device must be maintained according to the instructions for use.
- The manufacturer is not liable for damage caused by, improper use, unauthorized modification abuse or component combinations that were not authorized by the manufacturer.

11. PRODUCT CERTIFICATION INFORMATION

- ILK is going to be tested by accredited laboratories against the IEC 60601-1 standard (Medical Electrical Equipment, General Requirements for Safety) and its collateral standard IEC 60601-1-2 (Electromagnetic Compatibility, Requirements and Tests) and national deviations.
- ILK will comply with the MDR 2017/745/EU European directive and ISO 10328 standard.
- ILK will obtain the CE mark.
- Rebocon Bionics B.V. is to be certified according to ISO 13485.

12. CONTACT INFORMATION

For additional product information, sales and distribution locations:

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Web	www.rbionics.com
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