INSTRUCTIONS FOR USE

EN

ProStride

PSMPK

This manual is intended for use by a certified professional prosthetist

1 - DESCRIPTION

ProStride is a microprocessor-controlled and polycentric prosthetic knee.

The upper joint section ① and lower joint section ② are connected by two anterior links ③ and a posterior link ④ to form a four-bar linkage.

In extension, the instantaneous center of rotation ⑤ is located above the joint and behind the weight bearing line, thus providing knee stability in the stance phase (Fig.1).

This prosthetic knee joint features a large flexion angle of up to 142° (Fig.2). The integrated extension assist spring (located inside the knee body) ⑥ is part of the swing phase control mechanism and ensures adequate extension of the prosthetic knee (Fig.3).

The "Adjustment Screw for Initial Head Angle" ⑦ function provides additional possibility to adjust the alignment of the knee and increase safety for the patient (Fig.4).

The pneumatic system ⑧ is part of the swing phase control mechanism and provides flexion/extension resistance adjustment. It is controlled by a microprocessor and sensors. The resistance of the knee, depending on the user's walking speed and gait, will be automatically adjusted (Fig.1).

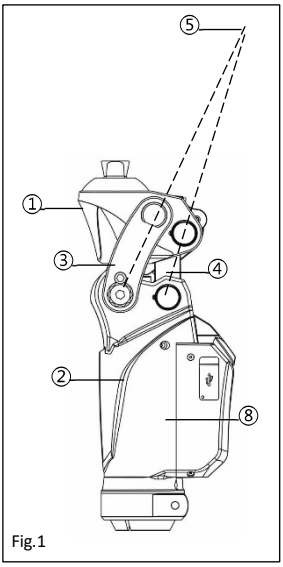


Fig.1

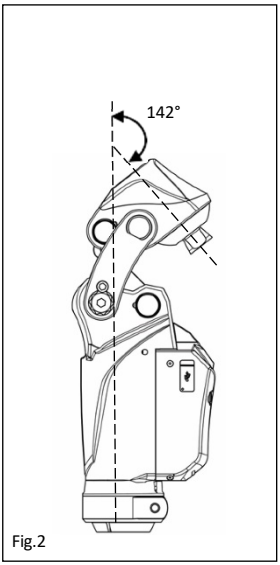


Fig.2

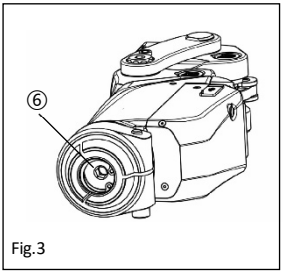


Fig.3

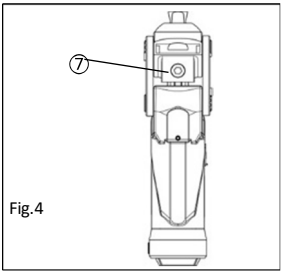


Fig.4

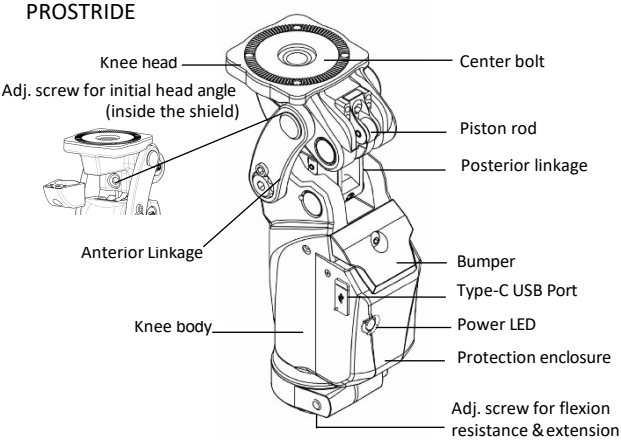
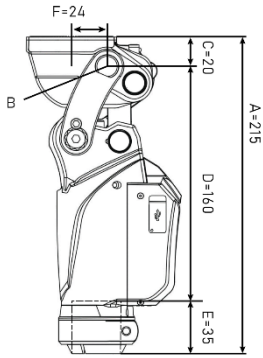


Fig.5

PROSTRIDE DIMENSIONS



A System Height
B Alignment Reference Point
C Proximal build height up to the alignment reference point
D Distal build height up to the alignment reference point
E Tube insertion length
F Centro-Bolt to Alignment Reference
All measurements in mm

Fig. 6

Intended use

The device is intended to be used as a part of a lower limb prosthetic. The device replaces knee function of the missing lower limb for patients with above knee amputation.

⚠ **The device must be fitted and adjusted by a certified professional**.

2 – SPECIFICATIONS

Material	Aluminum alloy (mainly), Stainless steel
System height	214 mm / 8.46 inches
Proximal built height	20 mm / 0.79 inches
System weight	1.260 gr / 2.78 Lbs
Maximum flexion angle	142 °
Maximum body weight	125 Kg / 275 Lbs
Proximal connection	For connection with standard 4-hole adaptor
Pylon diameter	30 mm / 1.18 inches
Activity Level	K2 – K3
Compatible software	Mobile App compatible with Android 9 or later version (App is not guaranteed adaptable to all Android devices)

Electrical Equipment Classification

Protection against electrical shock	Internally powered
Applied part	Type BF 
Degrees of protection	IP 22
Mode of operation	Continuous operation

Wireless Transmission and Power Specifications

Wireless technology	Bluetooth v5.0
Operation voltage	3.7 – 4.2 V d.c.
Power	Brand：RPC Co., Ltd Rechargeable lithium battery
Charger specifications	Brand：ELJINTEK Inc. Model No.：GMPU12EI-1-USB / GMPU12UI-1-USB Input：100 – 240 V a.c. , 50/60 Hz, 0.4 – 0.2A Output：5 – 6 V d.c. 2.4 – 2.0 A

Features

The ProStride microprocessor knee can be set up and adjusted through a mobile phone. It can automatically detect the walking speed and gait and adjust the resistance to give appropriate feedback to meet the user's gait needs.

In auto mode, the knee resistance can be selected to suit the patient's level of mobility through the mobile phone App.

In manual mode, the resistance can be selected through the App in three ways: 1. Self-adjusting; 2. Scenarios; 3. Self-definition.

The App displays the status of the current mobile-knee Bluetooth connection, the power status of the knee, and the value of the knee control resistance.

The ProStride has a four-bar mechanical design. The Instant Center of Rotation trajectory mimics a normal gait pattern. The trajectory of the instant center of rotation (ICR) of the knee ensures stability in stance phase and sufficient toe clearance during swing.

3- PATIENT POPULATION, ACTIVITY LEVEL, WEIGHT LIMITATIONS

Target patient population

Lower limb transfemoral amputees, both unilateral and bilateral.
Indicated for users having different walking speed requirements.
The device is designed for single patient use.

The device is indicated for limited to medium activity level (K2 and K3 activity levels).

- Activity Level K2: single speed cadence, with the ability to traverse low level environmental barriers, typical of the limited community ambulator.
- Activity Level K3: variable cadence, with the ability to traverse most environmental barriers. Patient may have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion.

Maximum patient weight

The ProStride is indicated for users with a maximum cumulative weight (patient + loads) of 125 Kgs.
Lifting and carrying loads. Verify that the cumulative weight does not exceed the maximum weight limit.
Do not exceed the weight limit. Risk of device failure. ⚠

4 – LIMITATIONS AND CONTRAINDICATIONS

Weight limit, activity level, carrying loads

Do not exceed the weight limit. Risk of device failure.

Intended Life

This device has been tested according to ISO 10328 standard to two million load cycles. Depending on the amputee's activity this corresponds to two to three years of use.

The service life of the rechargeable battery is about 2 years.
For an extended use beyond this time frame, periodic safety checks are recommended, taking into consideration the level and the type of activities performed with the prosthetic leg, the user's weight, and the effective operating time of the product. Inspect the device and discontinue use in case of signs of wear or deterioration.

Environment

Allowable operating conditions
From -10°C (14°F) to +40°C (104°F), 2% ~ 95% relative humidity, non-condensing, 700-1060hPa
IP Rating: 22

Inadmissible operating conditions
Mechanical vibrations or impacts
Perspiration, urine, fresh water, salt water, acids
Dust, sand, highly hygroscopic particles (e.g. talcum)
Highly electrical and/or magnetic environments.

Storage conditions
Store in original packaging. From -20°C (-4°F) to +40°C (104°F), 45% ~ 85% relative humidity, non-condensing, 700-1060hPa, no mechanical vibrations or impacts.

Transport conditions
Transport in original packaging. From -20°C (-4°F) to +50°C (122°F), 2% ~ 95% relative humidity, non-condensing, 700-1060hPa, no mechanical vibrations or impacts.

Battery charging conditions
The battery must be charged normally within the ambient temperature range of 0°C (32°F) to 45°C (113°F).
Do not charge if the ambient temperature is lower than 0°C (32°F).

5 - SAFETY INFORMATION AND WARNINGS

The certified prosthetist must inform the patient about all pertinent details in this document relative to the safe use of this device.

Warnings for the professional user ⚠

⚠ ▪ **Incorrect assembly may lead to injury.**

- Insufficient or improper tightening force applied to the pylon clamp screw may cause the tube to loosen. After fully tightening the screw, a torque wrench is needed to confirm that the correct torque has been applied.
- Incorrect mounting of the tube may lead to risk of breakage. Slide the tube all the way up until the stopping point in the distal part of the knee is reached.
- Connection with the prosthetic leg. Before delivering the prosthetic leg to the patient, make sure Loctite has been applied to the screws of the connecting adaptors and that the appropriate torque has been applied, as per the manufacturer's indications.

⚠ ▪ **Incorrect alignment of a polycentric knee can make the knee less stable, increasing patient's risk of falling.**

- Static alignment. We recommend keeping the upper plane of the knee head horizontal during static standing.
- Dynamic alignment. Proceed gradually by making only slight adjustments and explain the effects of the adjustment to the patient. Check the results by having the patient use the prosthetic leg in different situations, such as sitting, walking at different speeds, negotiating slopes and stairs.
- For the safety of the patient, use a suitable support device (as parallel bars or handrail) during initial standing and dynamic alignment.

⚠ ▪ **Maximum patient weight. Do not exceed the weight limit. Risk of device failure.**

⚠ ▪ **Lifting and carrying loads. The cumulative weight (patient + loads) must not exceed the maximum weight limit. Risk of device failure.**

⚠ ▪ **No high impact activities – risk of device failure.** The device was developed for low to medium impact use and must not be used for unusual and high-level activities. These unusual/high level activities include sports such as free climbing, skating, dancing, etc.

- **Installation and maintenance of the device.** Installation and maintenance must be carried out only by a certified professional.
- **Do not modify this equipment without authorization of the manufacturer.**
- **Danger! Placing fingers in the mechanism as shown in Fig. 7 will result in injury!**
- **Incorrect product operation – risk of injury due to the knee flexion/extension resistance settings.**
  - Teach patients to use the manual mode correctly and inform them how scenario selection affects the knee's resistance.
  - Do not provide the patient with the mobile app if in doubt of the patient's ability to use it safely.
- **Explain the section "Warning for the patient" to your patient before delivering the device.**

<u>Warnings for the patient</u>

Please explain this section carefully to the patient before delivering the device.

- **Environmental conditions. Use only in the specified permitted environments to prevent the risk of device failure or to prevent the device not responding correctly.**
  - The product is not resistant to infiltration from water jets or steam.
  - This product may not be used in underwater activities.
  - Avoid exposing the device to corrosive elements such as fresh water, salt water, acids or any other liquids.
- **Do not use in proximity to sources of strong magnetic or electrical interference.** Risk of falling due to device failure or device non responding correctly. Do not operate this product near other electronic equipment or near objects having a strong magnetic field (such as theft prevention systems, metal detectors, auto induction gates). Take off the device before entering a room or area with strong magnetic fields and store it outside this room or area
- **Use of charging equipment**
  - Use of charging equipment may result in electric shock and injury.
  - For charging the knee, do not use any device other than the charger provided. An unsuitable charger may use abnormal voltage and result in a failure to charge the device. The charging equipment provided with this

product complies with safety requirements, ensuring optimum performance of the device and safety of the user.

- **Charging and battery warnings**
  - The knee should be charged daily for optimal performance.
  - During charging, it is advisable to remove the charging adapter as soon as the LED turns green to prolong the battery service life.
  - If the LED is blinking purple, it indicates an abnormal state of the device. Please reset. If the device cannot be restored to its normal setting, contact a certified prosthetist as soon as possible.
  - When the battery power is less than 20% (LED flashes green), please charge it as soon as possible.
  - When the battery of the knee runs out of power, it will not provide the resistance level change in auto mode. You can still walk with your prosthetic knee, but the resistance will be fixed at “3” (low resistance level).
- **Bluetooth Connection**
  - Make sure the LED of the knee unit is green. Bending the knee head can activate/wake up the unit.
  - It will not be possible to connect via bluetooth when charging or if the unit has low battery.
  - If the mobile app is disconnected during the setup process and needs to be reconnected, please place the mobile phone close to the prosthesis
- **Danger! Placing fingers in the mechanism as shown in Fig. 7 will result in injury!**
- Improper product care.

  Improper cleaning agents can damage the product’s internal components.
  - Do not use acid or alkali solvents to clean the product.
  - Do not use compressed air for cleaning.
- **Any change in the performance of the knee, in the level or type of activity performed with the prosthetic leg or any significant increase in body weight or activity must be immediately reported to a certified professional. Risk of device failure.**

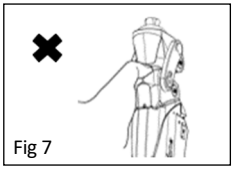


Fig 7

5- FITTING AND ALIGNMENT INSTRUCTIONS

Static alignment

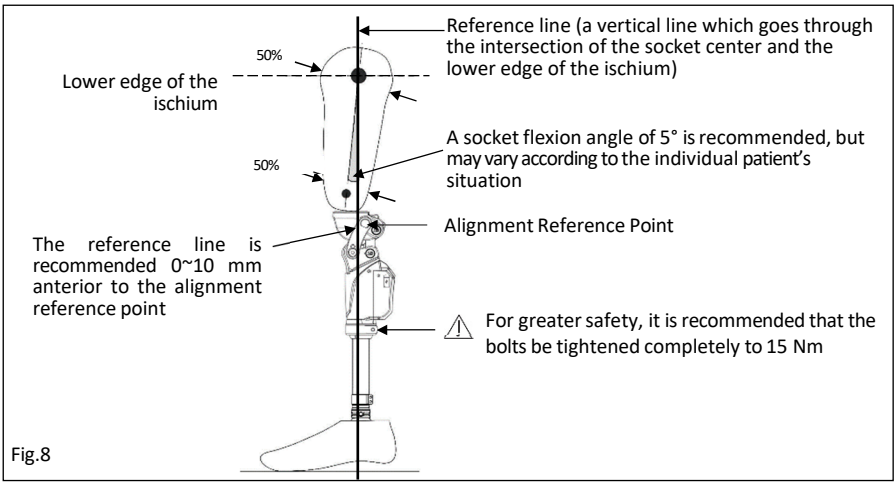


Fig.8

Adjustment of stance phase stability

Use a 3mm Allen wrench to remove the screw of the Knee Shield before adjusting. Axial alignment can be changed using the 6 mm Allen wrench (Fig.9)

- Turn the adjustment screw clockwise for a more dynamic alignment.
- Turning the adjustment screw counter-clockwise for a safer alignment.

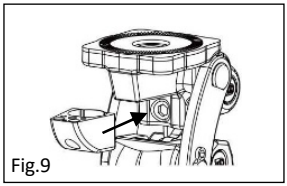


Fig.9

Adjustment of mechanical swing phase control

Adjusting the extension spring

The knee flexion resistance and extension assistance force can be adjusted by an adjusting screw. Use a 6mm Allen wrench to adjust the screw at the distal end of the unit (Fig.10).

- Turn the adjustment screw clockwise to increase the flexion resistance and the extension assistance force.

- Turn the adjustment screw counter-clockwise to decrease the flexion resistance and the extension assistance force.

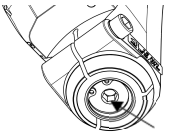


Fig.10 Adj. screw

6- APP INSTALLATION AND BLUETOOTH CONNECTION

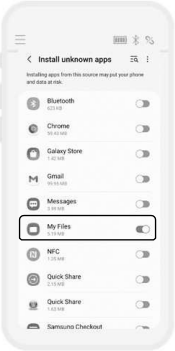
App installation

- Install the App on your phone.
- Scan the QR code inside the product packaging to download the app.
- Save the APK file into the Download folder of the mobile phone.
- Set permissions for security and Bluetooth connection
- After performing the above step, return to the mobile phone home screen for installation. Go to my file – downloads, select the APK file and install.

!Notice!

Before installing the APK file, some Android system phones may need to set permissions for security and Bluetooth connection. Please refer to “App Permission Setting”. Without this setting, the App may not work.

App Permission Setting



Step 1. Permission Setting for App installation

- Go to your mobile phone setting
- Go to Biomimetics and Security
- Tap on “Install Unknown App”
- Move “My Files” to on

Step 2. Permission Setting for Bluetooth connection

- Go to your mobile phone setting
- Go to App
- Select the ProStride App
- Then go to Permission – Nearby devices
- Click on Allow

Connection instructions

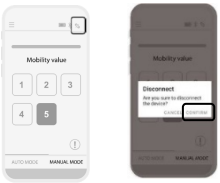
- The Bluetooth effective connection distance is about 5-7 meters (16-23 feet).
- Before using the App for the first time, please ensure Bluetooth pairing between the mobile phone and the knee (Please see "Pairing the knee for Initial use").
- Activate/wake up the knee. The knee can only be paired with the mobile App when it is in the active state (the LED light is Green and constant). Bending the knee head can activate/wake up the knee.

Pairing the knee for initial use

- Turn on "Settings" and tap "Connections" to turn Bluetooth on.
- Then tap “Scan” to find the available devices “MPK- RX_XXXXXXX” and tap it to pair and connect
- Open the App, enter the control panel, tap the Bluetooth connection symbol in the upper right corner, then tap the designated "MPK- RX_XXXXXXX" device.
- The knee power symbol and the Bluetooth symbol will change from gray to green/aqua when the connection is successful.
- If connection is lost, bend the knee joint from flexion to full extension to wake up the knee prosthesis, then tap the gray Bluetooth symbol

Unpairing the knee

To unpair and then pair with other knee unit, tap the connection symbol and then tap CONFIRM to unpair.



Auto sleep

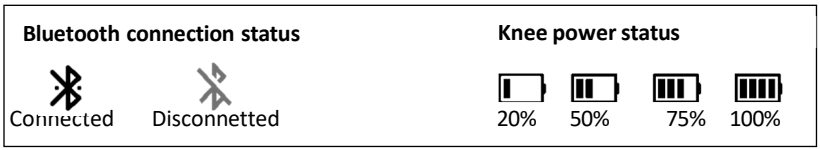
If the knee has no walk action (30 seconds), the system will enter the power-saving(sleep) mode, the Bluetooth will be disconnected, the mobile phone cannot be connected, and the App will be unable to operate.

Icon description

Icons with an all white background ( ) will be displayed in reverse color after clicking and selecting ( ), indicating that the manual mode is being executed.
Scenarios. Icons with an all white background ( ) will be displayed in reverse color after clicking and selecting ( ), indicating that the scenario mode is being executed.
Level of resistance. Icons with an all white background ( ) will be displayed in reverse color after clicking and selecting ( ), indicating that the set resistance is being executed.
This icon ( ) indicates that the resistance level is not set.

This icon () indicates that the resistance level has been set.

Status indication description



Troubleshooting

Should you encounter any issues in the use of your product, please check the following list. If you are encountering an issue not listed below, please contact your prosthetist or distributor.

Issue	Check item	Solution
App can't be installed	Check that the mobile phone's operating system is appropriate	Android system should be updated to Android 9 or later.
	Check that the mobile phone has storage space	Free up mobile phone storage space
	Check whether the permission for security has already been set.	Refer to App Permission Setting
Bluetooth can't connect	Verify that the knee is on the list of available Bluetooth devices of the mobile phone	Verify that the Bluetooth device is connected to the knee on the mobile phone's settings page
	Verify that the knee is not connected to other devices	Check whether there are other nearby devices connected to the knee
	Check that your mobile phone's Bluetooth is turned on	Turn on your mobile phone's Bluetooth
	Check whether the permission for security has already been set.	Refer to App Permission Setting
Knee and mobile phone get disconnected	Check if the knee or mobile phone is low on power	Charge your knee or mobile phone
	Check whether the knee is connected or being used in a specific environment, such as railways, electric tower, and radio station	Avoid using the device in environments with frequent trains or other vehicles, or in environments with multiple wireless connections.
	Check if there is radio wave signal interference in the surroundings	Remove the radio wave object or leave the environment.

7- PROGRAMMING THE KNEE RESISTANCE

There are two options for setting the knee resistance: manual or auto.
In auto mode, after selecting an appropriate mobility value, the knee will set an appropriate level of resistance according to the user's walking speed.
The manual mode includes the following options: self-adjusting, scenarios, and self-definition. Users can manually adjust to the required resistance level intuitively.

Auto mode setting

- After entering the setting page, tap "AUTO MODE" to enter the auto mode setting.
- Select the appropriate mobility value according to the user's level of activity. The higher the mobility value, the higher the resistance provided by the knee.
- The mobility values 1 to 5 are calculated based on the stride cadence and vibration magnitude in combination with the algorithm program built into the knee, corresponding to the resistance level suitable for the user. The faster the walking speed, the greater the resistance required. Therefore, a higher mobility value should be selected.

- Tap the number on the screen. The mobility value 1 is suitable for low activity, and 5 is suitable for high activity. It is recommended that resistance levels be increased gradually. The user should practice for a period of time to establish the appropriate resistance level.

Manual mode setting

After entering the setting page, first tap "MANUAL MODE" to enter the manual mode setting.

Self-adjusting: tap the icon and then open the adjustment window.
Resistance can be adjusted through the button .
The higher the number, the greater the resistance. The adjustment window will display the number and enlarge the color scale block for the selected level of resistance. Tap "Close" to return to the settings page, and the icon will be changed to , confirming that the resistance level has been successfully set.

Scenarios: One of six default scenarios can be selected; the resistance level corresponding to the scenarios is shown in the table below. Tap the desired icon after sliding left/right according to the users' needs, and tap "Confirm" to return to the setting page. At this time, the icon will change to the selected resistance level.

Scenarios	Bicycle	Hiking	Brisk walking	Cross-legged	Sitting	Fishing
Default resistance level	0	5	7	0	0	9
Icon						

Users can change the default resistance level for a specific scenario according to their needs. Please note, this option is available only for certain scenarios and the resistance level can be adjusted only within a limited range. After tapping and holding the scenario icon for two seconds, the adjustment window will open. Adjust the resistance

level through the button and tap "Confirm" to complete the change of the default resistance level.

Self-definition: 6 additional self-defined scenarios can be created. After tapping and holding the icon for two seconds, the adjustment window will open. Adjust the resistance level and enter the description and tap "Confirm" to complete the setting.
Tap the icon required and confirm to select the self-defined scenario.

8- CHARGING AND POWER

The internal battery of the knee should be charged exclusively with the specific charger included in the package.
Use of any other charging device than the designated charger. may lead to abnormal use of voltage and failure to charge.
Before using the knee, charge it until the light turns green to ensure sufficient power supply.

Charging process

- Connect the Type-C interface to the side of the knee prosthesis to the Type-C USB connector of the charging cable, and then insert the USB on the other end of the charging cable into the USB charger for charging. The battery LED of the knee will show a blue light during charging.
- Charge the product through the USB charger provided with the device. The charging time depends on the remaining battery capacity. Generally, the charging can be completed within about 2 hours.
- When charging is completed, the battery LED of the knee will show a green light
- It is recommended that the unit be charged every day so that the battery is never completely drained, so as to ensure product performance and extend lithium battery life.
- To ensure safety, the knee prosthesis will not be able to connect with the mobile phone Bluetooth during charging.

Battery capacity

Lithium battery (2040 mAh): When fully charged, the battery can operate

continuously for 9 hours, depending on the level of patient's activity and how much it is actually being used.

Battery warnings

- When the battery capacity drops below 20%, both the knee and the mobile phone App will simultaneously display warnings. The Battery LED will blink green, and the mobile phone App will show a low power warning message, the user should charge the battery.
- When the battery goes below 5%, the battery protection mode will be activated and the resistance will be automatically set to level 3. Please charge the battery as soon as possible to ensure safety.
- When the battery is completely drained, the knee will shut down automatically. After shutdown, the resistance will remain at level 3. At this resistance level, you can still use the knee prosthesis to walk normally. It is strongly recommended to charge it as soon as possible to restore optimum device performance.

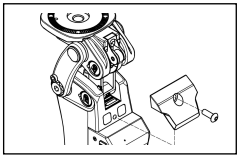
Power status display

LED Color	Status
Green	20%~100% / Charging complete
Blinking green	<20%
Off	0% / Sleep
Blue	Charging
Blinking purple	Knee malfunction

Notice!

- The knee should be charged before it shut down.
- The knee should be charged daily for optimal performance.
- When charging, when the LED turns green, it is recommended to disconnect the charger as soon as possible, to maintain the battery service life.
- If the LED is blinking purple, it indicates that something is wrong with the knee. Please try to reset. If it cannot be restored to normal, contact a certified prosthetist as soon as possible.

Reset



Use a 3mm Allen wrench to remove the screw of the rubber block, then use a paperclip to press the reset button inside the prosthetic knee. The knee will restart and the failure can be ruled out.

9- CLEANING

Clean the product if it gets dirty.

Use a only damp cloth to clean the product and then wipe it dry.

If dirt cannot be removed, the product must be sent to the manufacturer or to a local distributor.

Do not use compressed air for cleaning. Compressed air can force dirt into the seals and bushings. This can damage the device and lead to premature wear

Do not use acid or alkali solvents to clean the product. This can damage the device and lead to premature wear.

10 - MAINTENANCE

The device and the overall prosthesis must be examined periodically by a certified professional. Intervals should be determined based on patient activity and amount of usage of the device.

We recommend carrying out regular safety checks every 12 months in order to maintain operational safety.

Should any malfunctioning be found, e.g. abnormal noise, screw loosening, control and stability problems, please contact the official distributor.

11 – WARRANTY AND LIABILITY

Warranty terms

ALPS ProStride knee is covered by a 24-month warranty against manufacturing defects.

Specific exclusions from this warranty are: devices used without respecting the recommended use conditions, in adverse environmental conditions or without respecting weight bearing limits; devices not fitted properly according to the instructions for use; devices not maintained as directed. The user should be aware that any changes or modifications carried out on the device which have not been expressly approved by the manufacturer will void the warranty.

Return authorization

To obtain an ALPS Return Authorization Number (RA#) for a warranty call ALPS Customer Service and provide an ALPS representative with the following information:

Customer ID # – Invoice # – Date of Invoice – Nature of Return

The RA# must be displayed on the exterior of the box of the returned item or it will be refused at the dock

Symbol Legend		
Manufacturer	Medical device	Single patient multiple use
		

Disposal

The device and packaging must be disposed of in accordance with local or national environmental regulations.

Electronic components (battery, charger, cables) must be disposed of in accordance with local or national environmental regulations.

Please verify your local and national environmental regulations and dispose accordingly.

CE Conformity

This product meets the requirements of the European Regulation EU2017/745 for medical devices.

This product has been classified as a class I device according to the classification rules outlined in Annex VIII of the regulation.

MD CE

Reporting serious incidents

In the unlikely event of a serious incident occurring in relation to this device, it should be reported to the manufacturer and to your national competent authority.

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