Rear of prosthesis

“On / Off” switch

Front of prosthesis

Prosthesis status LED

“On / Off” switch

Prosthesis status LED

Rear of prosthesis

Lock tab

Battery

Prosthesis status LED

Prosthesis status LED

Battery charger status LED

Battery charger status LED

Power supply

Battery charger

Battery charger

Power inlet

Wall outlet

Power supply

Battery charger

Battery

Fan

Status LED

Rear

Front

Charging

Charge completed

Problem

Battery charger status LED

Prosthesis Status LED

OK

Vibr

Problem
INTRODUCTION

FOREWORD
This manual is for certified prosthetists-orthotists who will be preparing and maintaining POWER KNEE™ systems for users with transfemoral amputations. A copy of the “POWER KNEE™ Instructions for Use”, which contains more general information for POWER KNEE™ users, should also be enclosed with this manual.

The instructions contained in this manual should be sufficient to enable you to prepare and maintain the POWER KNEE™. We welcome any corrections or comments you may have to improve this guide.

INTENDED USE
POWER KNEE is designed for transfemoral and knee disarticulation amputees with moderate to high activity level. In addition, POWER KNEE can be used for an extended user population, namely bilateral transfemoral amputees and unilateral hip disarticulation amputees. For these extended user profiles, please contact your Össur representative for further information.

SYMBOLS USED IN THIS MANUAL
The symbols below are used in this manual to identify safety warnings, product precautions and other relevant information. It is very important that you read and understand them completely before using your prosthesis for the first time.

User Safety

⚠️ Refers to a potential personal hazard. Failure to comply with this warning may result in bodily harm or injury.

Product Precaution

Caution: Refers to a potential product hazard. Failure to comply with this caution may result in damage to the product.

Note

ℹ️ Refers to any information regarding the operation or handling of the product which should not be overlooked.
SYMBOLS USED IN THE EQUIPMENT
Symbols used in the POWER KNEE system (prosthesis and accessories) include the following:

⚠️ Caution: Indicates the need for the user to consult the instructions for use for important cautionary information

 RestClient with Notified Body identification number

Direct Current

On/Off

Non-ionizing radiation

Battery status

This marking on the product, packaging, accessories or literature indicates that the product contains electronic components and/or batteries that should not be disposed of in regular waste at the end of its usable life. To prevent possible harm to the environment or human health from uncontrolled waste disposal users are requested to separate these items from other types of waste and recycle them responsibly to support sustainable reuse of material resources. Users should contact their local government office for information on how these items can be recycled or disposed of in an environmentally sound manner.

To protect natural resources and to promote material reuse, please separate batteries and electronic components from other types of waste and recycle them through your local, free electronic parts return system.

PRODUCT LABELS (Figure 1)

GENERAL WARNINGS (Figure 2)
You are expected to train the user to operate the POWER KNEE intensively enough before letting him use it in a daily-living environment.

Always exercise good judgment and common sense when using the prosthesis and accessories (battery, battery charger and power supply), limit their utilization to the use they were designed for, and follow the instructions provided in this manual.

Never attempt to open or modify any component of the prosthesis or accessories. No modifications or adjustments except those described in this manual are authorized.

Instruct the user to stop walking immediately whenever an alarm signal is felt (prosthesis vibrates) and/or heard (prosthesis beeps) and to proceed to walk with caution.

When making adjustments to the prosthesis, make sure that the user is seated or in a stable standing position.

High-impact activity and sports, excessive loading, and heavy-duty use should be avoided.
POWER KNEE is suitable for use in any environment except where spillage or immersion in water or any other fluid is possible, or where exposure to highly electrical and/or magnetic fields can occur (e.g., electrical transformers, high-power radio/TV transmitters, RF surgical equipment, CT and MRI scanners). The battery charger and power supply are for indoor use only.

Make sure that no component of the prosthesis or accessories has been altered or tampered with.

Keep fingers away from the back side of the prosthesis joint to prevent the risk of pinching in the event of flexion. Keep fingers away from the front side bumpers to prevent the risk of pinching during extension.

Visually inspect the prosthesis before each use.

The prosthesis has been designed for users between 50 kg (110 lb) and 165 kg (363 lb).

Power on the prosthesis only when the user is wearing it.

Improper handling or adjustment of the prosthesis may cause the system to malfunction, subjecting the user to the risk of falling.

If you experience any problems with a component of the prosthesis or accessories that are not documented in this manual, contact your authorized supplier. Never attempt to make any technical repairs yourself.

Caution: Avoid exposure to rain, snow, ice, or salt. Maintain and store in a clean and dry condition.

Caution: Avoid exposure to intense dust or smoke or to excessive mechanical shocks or vibrations. Avoid impact to the battery.

Caution: Not suitable for use in the presence of flammable anesthetic mixture with air oxygen or nitrous oxide.

Caution: Operate the prosthesis at temperatures between –10°C and +40°C.

Caution: Have the prosthesis serviced by your authorized supplier at recommended maintenance intervals (every 20 months).

INDICATIONS FOR USE
The POWER KNEE is designed for patients with transfemoral and knee disarticulation amputation. The healthcare practitioner must provide each patient with training for appropriate use and proper application of the system. Limited to community and workplace ambulators with the ability or potential to traverse through most environmental barriers such as curbs, stairs or uneven surfaces. Low to moderate impact only.

CONTRAINDICATIONS FOR USE
N/A

SYSTEM OVERVIEW

The POWER KNEE system comes with the following accessories:
- “POWER KNEE Instructions for Use”;
- “POWER KNEE Quick Reference Card”;
- This manual (“POWER KNEE Technical Manual”);
- Battery charger;
- Two battery packs;
- Power supply & power cord;
- PowerLogicII™ software on CD-ROM.
PROSTHESIS & BATTERY (Figure 3)

BATTERY CHARGER & POWER SUPPLY (Figure 4)

SET-UP

MECHANICAL ASSEMBLY (Figure 5)

BENCH ALIGNMENT

Sagittal plane: Perform a basic static assembly of the prosthetic components starting with the foot and gradually working your way up.

1. Make sure that the middle wedge is correctly inserted into the prosthetic foot for first assembly (read the selected foot module Instructions for Use for information).
2. Place the prosthetic foot into the foot cover cosmetics and into the shoe.
3. Assemble the tube adapter which will connect the prosthetic foot to the POWER KNEE: Verify that the proximal end of the tube adapter is positioned horizontally.
4. Assemble the knee on top of the foot and tube adapter, using the screws to modify alignment: Verify that the proximal adapter of the knee is horizontally aligned; Verify that the load-line through the center of the knee divides the posterior and the middle 1/3 of the foot; If required, consider an offset adapter to achieve appropriate alignment.
5. Assemble the socket onto the proximal part of the knee: Verify that the load-line dividing the socket into two equal parts also goes through the center of the knee and the posterior and middle ⅓ of the foot.

Frontal/Transverse Plane: For the static alignment of the base in the frontal plane, work from the back of the prosthesis to ensure that the center of the knee is vertically aligned with the center of the socket and the center of the prosthetic foot.

Caution: Excessive abduction-adduction can lead to incorrect behavior of the prosthesis control system and should be avoided.

Caution: Excessive exo-rotation of the prosthetic knee can lead to incorrect behavior of the prosthesis control system and should be avoided.

STATIC ALIGNMENT

When activated, the prosthetic knee will provide a five-degree flexion. This might affect the flexion angle in which the prosthesis adapter is aligned. Verify whether the flexion in standing is not excessive once the POWER KNEE is donned and activated.

SOCKET INSTALLATION (Figure 6)

Caution: Care should be taken when configuring the socket so that there is no contact between the socket and the posterior/proximal part of the prosthesis when in maximal flexion.

PREPARATION FOR USE

CHECKING THE BATTERY STATUS (Figure 7)

Check the battery status on the battery at the front of the prosthesis. To check the battery status, press the battery status button:

1. If five LEDs go on, the battery is fully charged.
2. If only the bottom LED goes on, the battery is nearly depleted and needs to be charged.
3. If no LED goes on, the battery is totally depleted and needs to be charged.
4. If five LEDs flash, the battery needs to undergo a “self-maintenance” process and needs to be charged.
5. If five LEDs go on in a wave-like pattern this indicates that self maintenance process will take place the next time the battery is inserted into the charger. The LEDs will then indicate the battery status.

You can check the battery status at any time (whether or not the battery is inserted into the prosthesis or charger, and whether or not these are “ON”).

**BATTERY “SELF-MAINTENANCE”**

To optimize battery operation, a battery “self-maintenance” feature is included in the charging procedure and is automatically repeated every three months. The “self-maintenance” process may take up to 12 hours.

To start a “self-maintenance” process, simply insert the battery into the battery charger as explained in CHARGING THE BATTERY section.

The “self-maintenance” process starts automatically. The five LEDs on the battery flash simultaneously at the beginning of the “self-maintenance” process.

**Caution:** Never interrupt a charging or “self-maintenance” process.

In normal operation, the five LEDs will first go on in a wave-like pattern when you press the battery status button in order to indicate that a “self-maintenance” process will take place the next time the battery is inserted into the charger. The LEDs will then indicate the battery status.

**REMOVING THE BATTERY** (Figure 8)

1. First make sure that the prosthesis is powered off. The prosthesis status LED at the rear of the prosthesis is off when the prosthesis is powered off. (A)
2. If the prosthesis is still powered on, power it off by pressing the “On/Off” switch until a three-tone descending beep is heard and the prosthesis status LED goes off. (A)

**Caution:** Never remove the battery if the prosthesis is not powered off as data could be lost.

3. Push down the lock tab as shown in (B) below.
4. Release the battery in the direction of the arrow (C).

**Caution:** Remove the battery in a dirtfree environment.

**CHARGING THE BATTERY** (Figure 9)

1. Connect the power supply to the battery charger power inlet. (A)
2. Connect the power supply to a wall outlet using the power cord provided. (B)
3. Insert the battery into the battery charger as shown until a click is heard. The charging process starts automatically. The battery charger status LED flashes green during the charging process. (C)
4. Wait until the charging process is completed. The fan, located at the rear of the battery charger, will go on during the charging process. The normal charging time for a fully depleted battery is approximately 3.5 hours. Once the battery is fully charged, the battery charger status LED stays “ON” green steady.

**Caution:** Do not block the opening of the fan while charging. (C)

5. If a problem occurs during the charging process, the battery charger status LED will flash orange. Remove the battery by releasing the lock tab and repeat the charging process. If the problem persists, contact your Össur representative. (D)

**Caution:** Operate the charger between 0°C and +40°C.
Whenever you suspect a defective battery, let it fully charge (this may take a couple of hours). An insufficient charge is the most probable cause of a problem with a battery.
BATTERY TIPS

For optimum system performance, the battery should ideally be charged at the end of each day so it is fully charged the next day. If a battery is not used for an extended period of time, it may have to be recharged prior to use. Short battery charging/discharging cycles will indicate that the battery is approaching end of life or is defective. At the end of battery life, only the bottom LED will flash when you press the battery status button.

RE-PLACING THE BATTERY (Figure 10)

Push the newly charged battery into place (bottom first) until a click is heard. The prosthesis is now ready for use.

POWERING ON OR OFF THE PROSTHESIS

1. To power on the prosthesis, press the “On/Off” switch at the rear of the prosthesis. The prosthesis vibrates shortly, a three-tone ascending beep is heard, then the prosthesis status LED flashes slowly.

A flashing green LED indicates that the prosthesis is ready for use or operating. An abnormal condition will be indicated by a beep sound, an orange LED and/or a vibration (the prosthesis will vibrate shortly at power-up, however, which is normal). See additional information on warnings and errors in TROUBLESHOOTING section.

2. To power off the prosthesis, press the “On/Off” switch again. A three-tone descending beep is heard and the prosthesis status LED goes off. (Figure 11)

TROUBLESHOOTING

<table>
<thead>
<tr>
<th>PROBLEM</th>
<th>CAUSE</th>
<th>ACTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Battery Charger</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Battery charger status LED flashes orange.</td>
<td>Temporary malfunction</td>
<td>Remove battery and repeat the charging process. If problem persists, contact your authorized supplier.</td>
</tr>
</tbody>
</table>

POWER KNEE

<table>
<thead>
<tr>
<th>PROBLEM</th>
<th>CAUSE</th>
<th>ACTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prosthesis will not power up.</td>
<td>Possible temporary problem with the battery</td>
<td>Fully charge battery until the battery charger status LED stays “ON” green steady (this may take a couple of hours). If problem persists, contact your authorized supplier.</td>
</tr>
<tr>
<td>Prosthetic knee behaves abnormally.</td>
<td>Incorrect step detection or temporary malfunction</td>
<td>User must stop his current activity and determine whether stance support is present. Prosthetic foot must be held in contact with the ground for approx. 3 seconds. If problem persists, prosthesis should be reset. If problem still persists, contact your authorized supplier.</td>
</tr>
<tr>
<td>Prosthesis vibrates/beeps and LED flashes orange slowly.</td>
<td>“Low-battery warning”: battery is nearly depleted.</td>
<td>Check battery status. If battery charge is low, replace/charge the battery. During an “energy demanding” activity like ascending stairs or standing up, a “low-battery warning” may occur temporarily although the battery charge is still good.</td>
</tr>
<tr>
<td></td>
<td>“Overheat warning”: prosthesis temperature is increasing.</td>
<td>User must stop his current activity, feel the prosthesis temperature and let the prosthesis cool. The risk of an “overheat warning” may increase due to high ambient temperature, especially during an “energy demanding” activity like ascending stairs or standing up.</td>
</tr>
<tr>
<td>Prosthesis vibrates/beeps repeatedly and LED flashes orange quickly.</td>
<td>“Low-battery fatal error”: battery charge has dropped below a critical level.</td>
<td>User must stop his current activity and determine whether stance support is present. Prosthetic motor will shut down soon (prosthetic knee will no longer be functional and will provide limited support). Check battery status. If battery charge is low, replace/charge the battery.</td>
</tr>
<tr>
<td></td>
<td>“Overheat fatal error”: prosthesis temperature has reached a critical level.</td>
<td>User must stop his current activity, feel the prosthesis temperature and let the prosthesis cool. If problem persists, prosthesis should be reset. If problem still persists, contact your authorized supplier.</td>
</tr>
</tbody>
</table>

Any other warning signals (see table below) Technical failure User must stop his current activity and determine whether stance support is present. Prosthetic motor will shut down soon (prosthetic knee will no longer be functional and will provide limited support). Prosthesis should be reset. If problem persists, contact your authorized supplier.

Any other problems Contact your authorized supplier
The feedback provided by the POWER KNEE system in various operating situations is as follows:

<table>
<thead>
<tr>
<th>BATTERY CHARGER</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>State</strong></td>
</tr>
<tr>
<td>Charge in progress</td>
</tr>
<tr>
<td>Charge completed</td>
</tr>
<tr>
<td>Problem during the charging process</td>
</tr>
<tr>
<td><strong>Battery</strong></td>
</tr>
<tr>
<td>Battery fully charged</td>
</tr>
<tr>
<td>Battery nearly depleted</td>
</tr>
<tr>
<td>Battery totally depleted</td>
</tr>
<tr>
<td>“Self-maintenance” required</td>
</tr>
<tr>
<td>“Self-maintenance” to take place next charge cycle.</td>
</tr>
<tr>
<td>End of battery life</td>
</tr>
<tr>
<td><strong>Battery (During Charge)</strong></td>
</tr>
<tr>
<td>“Self-maintenance” in progress</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PROSTHESIS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>State</strong></td>
</tr>
<tr>
<td>Initialization</td>
</tr>
<tr>
<td>Normal</td>
</tr>
<tr>
<td>Shutdown</td>
</tr>
<tr>
<td>Warning</td>
</tr>
<tr>
<td>Battery/temperature error</td>
</tr>
<tr>
<td>“No Actuator” error</td>
</tr>
<tr>
<td>Other error</td>
</tr>
</tbody>
</table>

TECHNICAL DATA

<table>
<thead>
<tr>
<th>PROSTHESIS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Class of user</strong></td>
</tr>
<tr>
<td><strong>Operating autonomy</strong></td>
</tr>
<tr>
<td><strong>Operating conditions</strong></td>
</tr>
<tr>
<td><strong>Dimensions</strong></td>
</tr>
<tr>
<td><strong>Weight</strong></td>
</tr>
<tr>
<td><strong>Rating</strong></td>
</tr>
<tr>
<td><strong>Angle of knee flexion</strong></td>
</tr>
<tr>
<td><strong>Expected lifetime</strong></td>
</tr>
<tr>
<td><strong>Foot Module</strong></td>
</tr>
<tr>
<td><strong>Level walking cadence</strong></td>
</tr>
</tbody>
</table>

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</tr>
<tr>
<td><strong>Rating</strong></td>
</tr>
<tr>
<td><strong>Expected lifetime</strong></td>
</tr>
</tbody>
</table>
DAILY MAINTENANCE
There are no user-serviceable components in the POWER KNEE. Just make sure that it remains in good outward condition. Clean the surface of the prosthesis with a soft damp cloth regularly and if necessary with a mild disinfectant.

The battery charger and power supply are maintenance-free. Make sure that they remain in good outward condition and clean their surface with a soft damp cloth regularly.

VISUAL INSPECTION
Thorough visual inspection of the prosthesis is required every six months. See the POWER KNEE Warranty Card with regard to the maintenance of the motorized prosthesis.

Caution: Do not remove dirt or dust from the battery compartment using compressed air. Instead, try using a computer vacuum cleaner.

SCHEDULED MAINTENANCE
The Power Knee is to be serviced by your authorized supplier at recommended maintenance intervals (every 20 months). See the Power Knee Warranty Card with regard to the maintenance of the motorized prosthesis.

STORAGE & TRANSPORT CONDITIONS
- Prosthesis and accessories should be stored and transported at temperatures between 0°C and +45°C at a humidity level of 10% to 90% RH, non-condensing, and atmospheric pressure of 700 hPa to 1060 hPa.
- To extend battery life, avoid storing batteries at full charge for extended periods of time.
- Handle with care.
- Do not transport in harsh or marine environments.

PARTS ORDERING
Contact your Össur representative to order any replacement items (including the battery charger and power supply).
WARRANTY

For warranty information, see the POWER KNEE Warranty Card.

DISPOSAL OF EQUIPMENT

Dispose of the POWER KNEE accessories in an environmentally responsible manner. Never incinerate a battery as it may explode. Contact your Össur representative for further information.

PRODUCT CERTIFICATION INFORMATION

The POWER KNEE system has been tested by an independent, accredited laboratory and found to comply with the IEC 60601-1 standard (Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance) and its collateral standard IEC 60601-1-2 (Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests) and national deviations. The equipment complies with the MDD 93/42/EEC European directive and ISO 10328 standard. The POWER KNEE system carries the CE mark. The POWER KNEE meets IEC type BF leakage current requirements ( ). The Össur hf. company fulfills the requirements of ISO 13485.

LIABILITY

The manufacturer recommends using the device only under the specified conditions and for the intended purposes. The device must be maintained according to the instructions for use. The manufacturer is not liable for damage caused by component combinations that were not authorized by the manufacturer.

COMPLIANCE

This component has been tested according to ISO 10328 standard to three million load cycles. Depending on the amputee’s activity this corresponds to a duration of use of three to five years. We recommend carrying out regular yearly safety checks

ISO 10328 - P6 - 165 kg *)

*) Body mass limit not to be exceed!
For specific conditions and limitations of use see manufacturer’s written instructions on intended use!
EN – Caution: Ossur products and components are designed and tested according to the applicable official standards or an in-house defined standard when no official standard applies. Compatibility and compliance with these standard is achieved only when Ossur products are used with other recommended Ossur components. If unusual movement or product wear is detected in a structural part of a device at any time, the patient should be instructed to immediately discontinue use of the device and consult his/her clinical specialist. This product has been designed and tested based on single patient usage. This device should NOT be used by multiple patients. If any problems occur with the use of this product, immediately contact your medical professional.