Instruction for Use

POWER KNEE®
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INTRODUCTION

FOREWORD
Thank you for your decision to use the POWER KNEE motorized prosthesis! This next generation of Bionic prosthesis for above-knee amputees will offer you unprecedented performance and flexibility in your activities of daily-living after due training and adaptation.

Please read this manual thoroughly and discuss any questions you may have with your CPO (certified prosthetist-orthotist) before using your prosthesis. To ensure safe and proper operation of the equipment, you must follow the instructions provided in this manual. Please note that the POWER KNEE has been fitted to your personal specifications and is not interchangeable with any other motorized prosthesis.

Using your prosthesis safely depends upon your diligence in following the instructions contained in this manual and upon your good judgment and common sense.

We hope that you will find the POWER KNEE to your complete satisfaction!

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.

The POWER KNEE is designed to support a variety of functions including stairs ascent. Training will be required to master the system and expectations should be discussed with your CPO prior to the fitting.

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
- **IEC type BF leakage current requirements**
- **Direct Current**
- **On/Off**
- **CE label with Notified Body identification number**
- **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
Practise 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.

Power off the prosthesis when performing tasks which may be critical to your safety, such as driving a motor vehicle or operating a power tool or other potentially dangerous machinery.

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.

Stop walking immediately whenever an alarm signal is felt (prosthesis vibrates) and/or heard (prosthesis beeps) Proceed to walk with caution.

Avoid high-impact activity and sports, excessive loading, and heavy-duty use.
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. (Figure 2)

Visually inspect the prosthesis before each use.

If you experience any problems with a component of the prosthesis or accessories that are not documented in this manual, contact your Össur representative. 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: Use the prosthesis at temperatures between –10°C and +40°C.

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

Caution: Follow recommended maintenance intervals.

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

PROSTHESIS & BATTERY (Figure 3)

BATTERY CHARGER & POWER SUPPLY (Figure 4)

PREPARATION FOR USE

CHECKING THE BATTERY STATUS (Figure 5)
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 6)
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 dirt-free environment.

CHARGING THE BATTERY (Figure 7)
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 8)
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 WARNINGS & ERRORS 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 9)

OPERATION
⚠️ Practise using your prosthesis until you are fully comfortable with each of the activities described below and have your CPO fine-tune all adjustments for maximum personal comfort and optimal system performance.

“STANDING STATE”
The prosthetic knee automatically adjusts its behavior to activities like walking, ascending or descending stairs/ramps, etc. When none of these activities are detected, it operates in “standing state”, allowing you to move effortlessly in confined spaces while performing common day-to-day tasks like cooking in the kitchen, and queuing at the bus station. The prosthetic knee locks and provides you full support whenever stance is detected, and unlocks and moves freely during swing phase. In “standing state”, the prosthetic knee allows you to take small steps more naturally without having a locked knee feeling.

WALKING ON A LEVEL SURFACE (Figure 10)
1. Take the first stride with whichever leg you decide and simply start walking at your normal pace. The behavior of the prosthetic knee adjusts automatically: the prosthetic knee provides support whenever ground contact is detected, releases as swing initiates and moves forward actively to support a dynamic swing pendulum motion.
2. If a problem occurs, stop walking, hold the prosthetic foot in contact with the ground for approx. 3 seconds then resume walking.

STANDING UP (Figure 11)
1. Place your weight on the prosthesis.
2. Lean forward slightly and initiate the standing-up movement by applying force on the prosthetic knee. Feel how the prosthetic knee assists your standing-up movement naturally.
3. If you stop the standing-up movement before completion, the prosthetic knee will lock at the same flexion angle to support your weight while you squat. To unlock the prosthetic knee, lift the prosthetic foot from the ground.

SITTING DOWN (Figure 12)
1. Allow the prosthetic knee to reach the “standing state”.
2. Place your weight on the prosthesis.
3. Force the prosthesis into flexion by leaning backwards. Feel how the prosthetic knee supports your sitting-down movement naturally.
4. If you stop the sitting-down movement before completion, the prosthetic knee will lock at the same flexion angle to support your weight while you squat. To unlock the prosthetic knee, lift the prosthetic foot from the ground.
5. Once you are in sitting position, you can lift the prosthetic foot from the ground and you will notice that the prosthetic knee will unlock and move freely.

EXERCISE MODE
1. Sit down.
2. Fully extend the prosthetic knee out.
3. Pull under the toe of the prosthetic foot for approx. 5 seconds while keeping the prosthetic knee extended out.
4. The knee will indicate that it is in exercise mode by giving one beep and a vibration.
5. To exit the exercise mode, turn the knee off. When you turn it back on the knee will be in normal mode. This prevents unwanted exercise mode exit during use.

Always use the banister or handrail when ascending or descending ramps and stairs.

DESCENDING STAIRS OR RAMPS (Figure 13)
1. Take the first stride with the prosthesis and transfer your weight onto the prosthesis. Feel how the prosthetic knee bends and supports you while you move the other foot to the next step. It is recommended to lean backwards slightly as this facilitates knee bending and, in case of loss of balance, prevents you from falling forward.
2. Continue descending the stairs or ramp at your normal pace. The behavior of the prosthetic knee will adjust automatically, supporting your descent naturally.
3. It is recommended to place half of the foot onto the lower step to ensure consistent support when walking down.
4. If a problem occurs, stop walking, hold the prosthetic foot in contact with the ground for approx. 3 seconds then resume descending the stairs or ramp, starting with the prosthesis.

Always use the banister or handrail when ascending or descending ramps and stairs.

KNEELING
1. Allow the prosthetic knee to reach the "standing state"
2. Place and maintain load onto the prosthesis.
3. Put your sound leg in front of the prosthesis.
4. Force the prosthesis into flexion by flexing your hip slightly. Feel how the prosthetic knee supports you while kneeling down.

ASCENDING RAMPs
1. When ascending ramps, simply walk at your normal pace.
2. The same knee function is used while ascending ramps as when walking on a level surface.
3. If a problem occurs, stop walking, hold the prosthetic foot in contact with the ground for approx. 3 seconds then resume walking.

Always use the banister or handrail when ascending or descending ramps and stairs.

ASCENDING STAIRS (Figure 14)
1. Come to a complete stop before the first step of the stairs.
2. Allow the prosthetic knee to reach the “standing state”. Keep the prosthesis still and avoid little steps or forward leaning on the prosthesis.
3. Gently lift the prosthesis off the ground by bending your hip. The knee will unlock and progress to slightly bent position. Place your foot onto the first step and transfer your weight onto the prosthesis. Now extend your hip and feel how the prosthetic knee lifts you and make sure to keep your balance.
4. Continue ascending the stairs at your normal pace. The behaviour of the prosthetic knee will adjust automatically, assisting your ascent naturally.
5. In order to avoid falls, make sure you verify your prosthetic foot placement on each step. At least half of the foot should be positioned onto the step to secure support when loading the prosthesis.
6. If a problem occurs, stop walking, hold the prosthetic foot in contact with the ground for approx. 3 seconds then resume ascending the stairs, starting with the prosthesis.
7. At the top of the stairs hold the prosthesis on the ground for approx. 3 seconds to interrupt the stair ascent function and avoid unwanted behaviour.

⚠ Always use the bannister or handrail when ascending or descending ramps and stairs.

**WARNINGS & ERRORS**

**The prosthetic knee behaves abnormally**

- **Action:** Stop walking and determine whether stance support is present.
- **Cause:** Steps are not properly detected.
- **Solution:** Hold the prosthetic foot in contact with the ground for approx. 3 seconds then resume your current activity. If the problem persists, reset the prosthesis by powering it off then on again and check if it returns to normal operation. If it does not, refrain from using the prosthesis and contact your Össur representative.

**The prosthesis vibrates/beeps and the LED flashes orange slowly**

- **Cause 1:** “Low-battery warning”: the battery is nearly depleted (battery charge reaches about 10%), leaving you approx. 10 min of walking autonomy.
- **Solution:** Check the battery status to confirm if this is the cause of the problem. If it is, only the bottom LED will go on when you press the battery status button. Replace the battery by a spare, fully charged.
- **Cause 2:** “Overheat warning”: the prosthesis temperature is increasing.
- **Solution:** Stop your current activity, feel the prosthesis temperature with your hand to confirm if this is the cause of the problem and let the prosthesis cool before resuming your current activity.

The risk of an “overheat warning” may increase due to high ambient temperature, especially if you are performing an “energy demanding” activity like ascending stairs or standing up.

**The prosthesis vibrates/beeps repeatedly and the LED flashes orange quickly**

- **Action:** Stop walking and determine whether stance support is present.

The prosthesis motor will shut down soon, meaning that the prosthetic knee will no longer be functional and will provide limited support.

- **Cause 1:** “Low-battery error”: the battery charge has dropped below a critical level.
- **Solution:** Check the battery status to confirm if this is the cause of the problem. If it is, only the bottom LED will go on when you press the battery status button. Replace the battery by a spare, fully charged.
- **Cause 2:** “Overheat error”: the prosthesis temperature has reached a critical level.
- **Solution:** Stop your current activity and feel the prosthesis temperature with your hand to confirm if this is the cause of the problem. Let the prosthesis cool. Reset the prosthesis by powering it off then on again and check if it returns to normal operation. If it does not, refrain from using the prosthesis and contact your Össur representative.

**Any other warning signals**

- **Action:** Stop walking and determine whether stance support is present.
The prosthesis motor will shut down soon, meaning that the prosthetic knee will no longer be functional and will provide limited support.

– **Cause:** Other type of “error”: technical failure.

– **Solution:** Reset the prosthesis by powering it off then on again and check if it returns to normal operation. If it does not, refrain from using the prosthesis and contact your Össur representative.

For any questions or problems that you cannot solve, contact your Össur representative.

**TECHNICAL DATA**

**PROSTHESIS**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class of user</td>
<td>Moderate to active amputees, 50kg (110 lb) to 165 kg (363 lb)</td>
</tr>
<tr>
<td>Operating autonomy</td>
<td>Approx. 12 hours depending on activity type and level</td>
</tr>
<tr>
<td>Operating conditions</td>
<td>-10°C to +40°C, 0% to 100% RH, N/C, 700 - 1060 hPa</td>
</tr>
<tr>
<td>Dimensions</td>
<td>27.5 cm x 10 cm x 10 cm (10 13/16” x 3 15/16” x 3 15/16”)</td>
</tr>
<tr>
<td>Weight</td>
<td>2.7 kg (6 lb) w/o battery</td>
</tr>
<tr>
<td>Rating</td>
<td>50.4 VDC, 25 A (max.)</td>
</tr>
<tr>
<td>Angle of knee flexion</td>
<td>Max. 120°</td>
</tr>
<tr>
<td>Expected lifetime</td>
<td>5 years</td>
</tr>
<tr>
<td>Foot Module</td>
<td>Variflex®, LP Variflex®, Talux®, Variflex® XC, Re-flex Shock™, Re-flex Rotate™</td>
</tr>
<tr>
<td>Level walking cadence</td>
<td>110 steps/min (actively supported), up to 125 steps/min with moderate muscle power support</td>
</tr>
</tbody>
</table>

**BATTERY**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operating conditions</td>
<td>-10°C to +40°C, 0% to 100% RH, N/C1</td>
</tr>
<tr>
<td>Charge time</td>
<td>Max. 3.5 hours (typically)</td>
</tr>
<tr>
<td>Dimensions</td>
<td>16.5 cm x 5 cm x 6 cm (6 1/2” x 2” x 2 3/8”)</td>
</tr>
<tr>
<td>Weight</td>
<td>0.49 kg (1.1 lb)</td>
</tr>
<tr>
<td>Rating</td>
<td>50.4 VDC, 25 A (max.)</td>
</tr>
<tr>
<td>Expected lifetime</td>
<td>1 year under typical use</td>
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</table>

**BATTERY CHARGER**

<table>
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<tr>
<th>Parameter</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operating conditions</td>
<td>0°C to +40°C, 30% to 95% RH, N/C1</td>
</tr>
<tr>
<td>Dimensions</td>
<td>24 cm x 8.5 cm x 7 cm (9 7/16” x 3 5/16” x 2 3/4”)</td>
</tr>
<tr>
<td>Weight</td>
<td>0.36 kg (0.8 lb)</td>
</tr>
<tr>
<td>Input</td>
<td>12 V, 2.4 A</td>
</tr>
<tr>
<td>Output</td>
<td>50.4 VDC, 450 mA (max.)</td>
</tr>
</tbody>
</table>

**POWER SUPPLY**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operating conditions</td>
<td>0°C to +40°C, 30% to 95% RH, N/C1</td>
</tr>
<tr>
<td>Dimensions</td>
<td>13 cm x 7.5 cm x 3.5 cm (5” x 3” x 1 5/16”)</td>
</tr>
<tr>
<td>Weight</td>
<td>0.39 kg (0.9 lb)</td>
</tr>
<tr>
<td>Input</td>
<td>100 - 240 VAC, 1 A</td>
</tr>
<tr>
<td>Output</td>
<td>12 VDC, 3.3 A</td>
</tr>
<tr>
<td>Manufacturer</td>
<td>Elpac Power systems</td>
</tr>
<tr>
<td>Model No.</td>
<td>MW 4012F</td>
</tr>
</tbody>
</table>

1 Relative humidity, non-condensing
MAINTENANCE

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.

SCHEDULED MAINTENANCE
Thorough visual inspection of the prosthesis is required every six months. See the POWER KNEE Warranty Card with regard to the maintenance of your 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 exceeded!
For specific conditions and limitations of use see manufacturer’s written instructions on intended use!

BLUETOOTH MODULES REGULATED INFORMATION

This device contains the following radio frequency transmitters:

<table>
<thead>
<tr>
<th>Model</th>
<th>Type and Frequency Characteristics</th>
<th>Effective Radiated Power</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bluetooth 2.1 Module:</td>
<td>FID 2402 MHz – 2480 MHz</td>
<td>0.0025 W</td>
</tr>
<tr>
<td>Model: KC22</td>
<td>(1 MHz Interval, 79 Channels)</td>
<td></td>
</tr>
</tbody>
</table>

USA-FEDERAL COMMUNICATIONS COMMISSION (FCC)
This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy. If not installed and used in accordance with the instructions, it may cause harmful interference to radio communications. However, there is no ensured specification that interference will not occur in a particular installation.

If this equipment does cause harmful interference to radio or television reception, which can be determined by tuning the equipment off and on, the user is encouraged to try and correct the interference by one or more of the following measures:
- Reorient or relocate the receiving antenna.
- Increase the distance between the equipment and the receiver.
- Connect the equipment to outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Any changes or modifications not expressly approved by the party responsible for compliance could void the user’s authority to operate the equipment.

Caution: Exposure to Radio Frequency Radiation.
This device must not be co-located or operating in conjunction with any other antenna or transmitter.

Canada – Industry Canada (IC)
This device complies with RSS 210 of Industry Canada. Operation is subject to the following two conditions:
1. this device may not cause interference, and
2. this device must accept any interference, including interference that may cause undesired operation of this device.”
**Caution: Exposure to Radio Frequency Radiation.**
The installer of this radio equipment must ensure that the antenna is located or pointed such that it does not emit RF field in excess of Health Canada limits for the general population; consult Safety Code 6, obtainable from Health Canada’s website www.hc-sc.gc.ca/rpb.

**ELECTROMAGNETIC COMPATIBILITY**

**Warnings**
Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

**Precaution**
The device may be susceptible to electromagnetic interference from portable and mobile RF communications devices such as mobile (cellular) telephones or other equipment, even if that other equipment complies with CISPR EMISSION requirements.

<table>
<thead>
<tr>
<th>Electromagnetic Emissions Compliance Information</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Emissions Test</strong></td>
</tr>
<tr>
<td>Conducted and Radiated RF Emissions</td>
</tr>
<tr>
<td>Harmonics Emissions</td>
</tr>
<tr>
<td>Voltage Fluctuations / Flicker Emissions</td>
</tr>
<tr>
<td>Immunity Test</td>
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<tr>
<td>Electrostatic Discharge</td>
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<tr>
<td>Electrical Fast Transient/Burst</td>
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<tr>
<td>Surge</td>
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<tr>
<td>Voltage Dips</td>
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<tr>
<td>Voltage Interruptions</td>
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<tr>
<td>Power Frequency (50/60 Hz) Magnetic Field</td>
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<tr>
<td>Conducted Disturbances Induced by RF Fields</td>
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<tr>
<td>Radiated RF EM Fields</td>
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<tr>
<td>Test frequency (MHz)</td>
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EN – Caution: Össur 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 Össur products are used with other recommended Össur components. If un-usual 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.