



PROPRIO FOOT[®] 

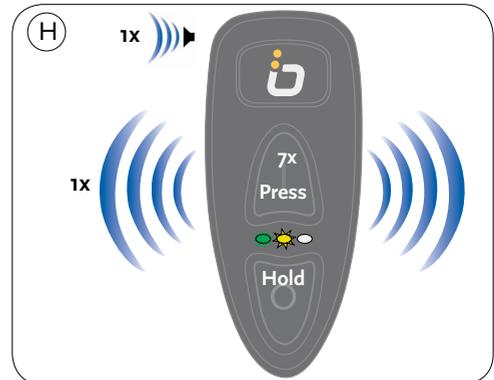
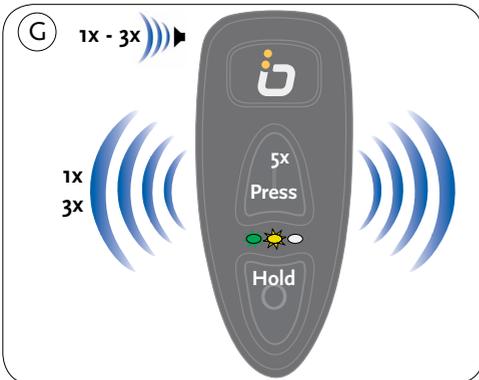
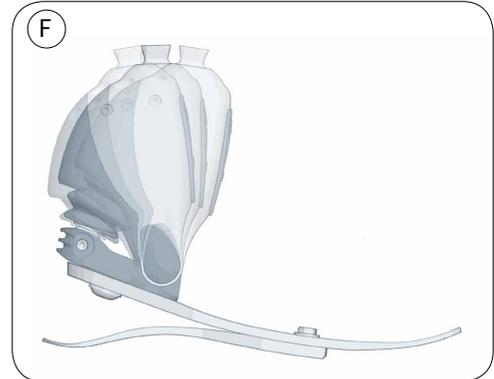
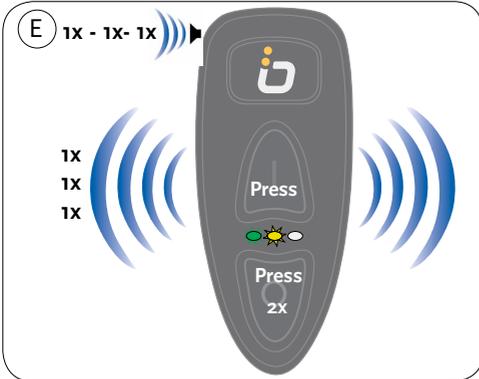
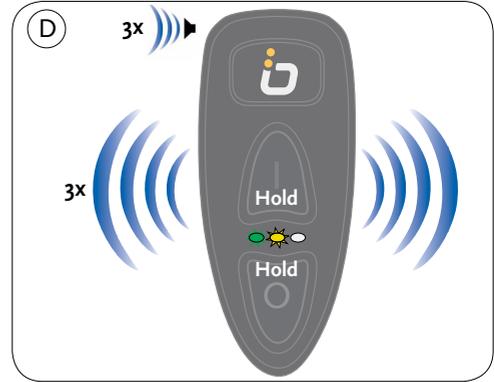
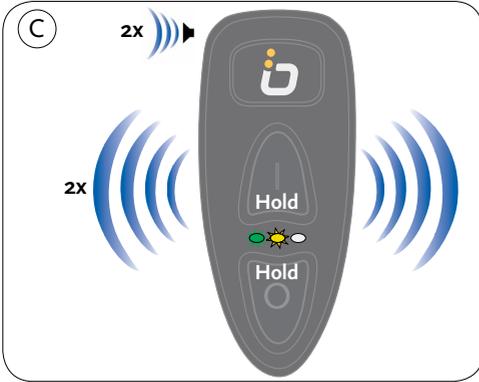




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Function	Hold	Press
Power NO/OFF	 	
Set heel height		 2x
Set relax mode		 5x
Sound NO/OFF		 7x

Warning	Indicates
2x BEEP	Approx 120 min left
3x BEEP	Approx 60 min left
4x BEEP	Approx 30 min left
5x BEEP	Foot will return to neutral prepare for immediate power loss



SAFETY PRECAUTIONS

- When the battery charge is low, PROPRIO FOOT® will return to the last preset heel height position. A warning signal will occur (**Figure B**).
- When making adjustments to PROPRIO FOOT® ensure the user is seated or in a stable standing position.
- The user should stop walking immediately if alarm signals are felt or heard. Proceed to walk with caution.
- Do not use PROPRIO FOOT® while the battery is charging. Be sure to disconnect it from the charger prior to putting on the prosthesis.
- When the power is off the ankle position might change resulting in misalignment.
- Improper handling or adjustment of PROPRIO FOOT® may cause malfunction that may subject the user to the risk of falling.
- High-impact activity and sports, excessive loading, and heavy-duty use should be avoided.
- Avoid impact to the battery.
- Ensure that the battery cable does not interfere with the actuator motion. Interference between the battery cable and the actuator can cause damage and interruption of function.
 - * Do not use power supplies other than those provided with the device.
 - * Ensure that the Flex-Foot sock, shoe or any external load does not interfere with the actuator motion, since this can cause restriction of the ankle motion.
- Lithium-ion batteries contain hazardous metals and should never be disposed of in residential or commercial garbage. They should never be incinerated because they may explode.
- Field service should be performed at the recommended intervals (**see chapter Service**). This will prevent malfunction or failure. Not following the instructions invalidates the warranty.
- Avoid spillage or immersion in water (or any other fluids), use in highly electrical and/or magnetic (i.e. electrical transformers, high-power radio/TV transmitters) and dirty environments.
- Avoid exposure to extreme heat and/or cold (**see chapter Technical Specifications**).
- Avoid exposure to intense dust, smoke or mechanical vibrations.
- Do not use if the product enclosure or covers are broken.
- Do not tamper with the keypad.
- Disable PROPRIO FOOT® when driving a vehicle (**see chapter Power OFF**).
- Steep inclines or declines (above 20°) may trigger the stair response resulting in unexpected foot alignment.
- PROPRIO FOOT® detects walking on uneven or level ground, walking on inclines and declines, climbing stairs and riding a bike. Non-identified movements may cause unexpected ankle alignments.
- Not suitable for use in the presence of flammable anesthetic mixture with air oxygen or nitrous oxide.
- Protect the foot and battery pack against water or rain, and ensure that no water enters the battery charge plug.
- Battery performance may be affected by very low or very high temperatures that may cause inconsistency in battery warnings.

EN - Caution: Össur products and components are designed and tested to ISO 10328. Compatibility and compliance with this standard is achieved only when Össur products and components are used with other recommended Össur or authorized components. If un-usual movement or product wear is detected in a structural part of a prosthesis 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.

INTRODUCTION

PROPRIO FOOT® from Össur is a Bionic foot and ankle system that is designed to facilitate walking on level ground and a variety of surfaces less stressful during activities of daily living.

FUNCTIONS

PROPRIO FOOT® adapts ankle position during swing phase as the user ascends or descends ramps and stairs making ambulation on these alternative surfaces easier, less stressful and more secure for the user. PROPRIO FOOT® is also designed to dorsi-flex during swing phase of level-ground walking to improve toe clearance for less stressful and more secure walking. When seated, PROPRIO FOOT® will plantarflex for a more natural appearance of the artificial leg. PROPRIO FOOT® is adjustable to a variety of heel heights to fit different types of shoes (i.e. tennis shoes, boots, and formal shoes). PROPRIO FOOT® has the ability to plantar-flex when kneeling and also when lying down.

INDICATIONS FOR USE

PROPRIO FOOT® is to be used exclusively for transtibial amputees engaging in low to moderate impact activities. It is not suitable for sport and high-impact activities like sprinting, jumping, free climbing, competitive athletic sports, etc. Suitable environmental conditions are described in the technical specifications. PROPRIO FOOT® is suitable for continuous use.

ABBREVIATIONS



Keypad: Upper button



Keypad: Lower button



Vibration feedback signal.



Auditory feedback signal "BEEP"

CALIBRATION

Level-Ground Calibration

SYMBOLS



Consult the accompanying documents.



Consult Instructions for use



Meets IEC type B leakage current requirements



CE label with Notified Body identification number



Must be disposed of or recycled properly

DC in

Connection for DC power supply

DC out

Connection for battery extension cable to PROPRIO FOOT®



Manufacturer



Date of manufacture

TECHNICAL SPECIFICATIONS

SAFETY STANDARDS AND CLASSIFICATION

PROPRIO FOOT® is tested and certified compliant with the IEC/EN60601-1, standard of electrical safety of medical devices and IEC/EN60601-1-2, electromagnetic compatibility for medical electrical devices and ISO 10328. The company fulfills the requirements of ISO13485, MDD 93/42/EEC, and the PROPRIO FOOT® carries the CE mark accordingly. It is in compliance with UL60601-1, CAN/CSA C22.2 No.601.1 - M90, US and Canadian Standards for medicaltechnical and electrical products.

The device has type B applied parts.

AUTHORIZED REPRESENTATIVE

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PHYSICAL PROPERTIES

Weight limit: 125kg (275lbs)
•Frame construction: Aluminum
•Net weight: 1220g (2.7lbs), (size 26, cat. 6)

BATTERY

Rechargeable lithium-ion battery (1800 mAh)
Output Voltage: 14,8 V
Charging time 3-4 hours at 90% discharge.

Fully charged battery is sufficient for 24-48 hours of use, dependent on activity.

POWER SUPPLY

An external power supply for medical use (Class 1)

Input voltage:	100-240 VAC
Input current:	600 mA
Input frequency:	50-60 Hz
Output current:	1.0 A
Input connector:	IEC 320 AC
Output connector:	Female 2,1x5,5x9,5
Output voltage:	24VDC

ENVIRONMENTAL

Operating temperature:	-10°C to 40°C (14°F to 104°F)
Operating humidity:	0% -90%
Shipping and storage humidity:	0%-90%
Shipping and storage temperature:	-40°C to 70°C (-40°F to 158°F)

BASIC OPERATION

POWER ON (Figure C)

- To turn on the PROPRIO FOOT, hold and press   (both buttons) for at least one second.
 - * The system confirms with two beeps and vibrations.
 - * LED will blink green and yellow

NOTE: The keypad will be disabled after 60 sec from use. To enable the keypad, hold and press   at least one second. When the PROPRIO FOOT® is activated for the first time, the default manufacturer settings will be enabled. Your prosthetist may alter the settings to adjust the response.

POWER OFF (Figure D)

- To enable the keypad, hold and press   for at least one second.
- To power OFF hold and press   (both buttons) for at least one second.

NOTE: Pay attention to the button audible feedback.

- * The system confirms with three beeps and three vibrations.
- * The LEDs turn off.

NOTE: The keypad will be disabled after 60 sec from use. To enable the keypad, press the upper and lower buttons at the same time.

HEEL HEIGHT ADJUSTMENT (Figure E+F)

The PROPRIO FOOT® can be adjusted for variable heel height. The heel height adjustment ensures correct alignment of the prosthesis which is essential for proper Terrain Logic™ function.

Heel height adjustment on the floor

- Wear suitable footwear and ensure free ankle motion.
- With power ON and the prosthesis standing on a level surface, initiate heel height adjustment by holding down the upper  button and pressing the lower button  twice .

NOTE: Pay attention to the audible feedback.

- * The system confirms with a beep and vibration.

- Heel height adjustment will start.

- * The system beeps and vibrates a second time.
- The actuator will move the prosthesis into a vertical position.
 - * The system confirms with a beep and vibration.
 - * The LED blinks **green** and **yellow**.
- Heel height adjustment is complete.

NOTE: If the heel height exceeds 50 mm (2") a signal will be heard and the unit will not adjust to the heel height. Change shoes for lower heel height and repeat the adjustment. Ensure free ankle motion.

Heel height adjustment when wearing the prosthesis.

If shoes are changed then the heel height may be adjusted while the user is wearing the prosthesis.

Advise the user to follow the instructions:

- Take a seat and ensure the prosthesis is positioned flat (heel and forefoot area) on the ground.
- Ensure power is ON and the keypad is enabled (**Figure C**).
- To initiate heel height adjustment, hold down the upper button  and press the lower button  twice.
 - * The system confirms with a beep and vibration
- Heel height adjustment will start.
 - * The system beeps and vibrates a second time.
- **Immediately** lift the prosthesis from the ground to allow for ankle adaptation!
- The actuator will move the prosthesis into a vertical position.
 - * The system confirms with a beep and vibration.
 - * The LED blinks **green** and **yellow**.
- Heel height adjustment is complete.

FUNCTIONS

LEVEL GROUND WALKING

- PROPRIO FOOT® is enabled.
- During level-ground walking at moderate speed PROPRIO FOOT® will raise the toe to provide more ground clearance.
- This is a result of the ankle motion.
- This will reduce the risk of stumbling and improve the gait symmetry.
- When the unit is turned on, this motion will be active during each step.
- You may feel enhanced shock absorption as the heel strikes the ground. This is a result of the ankle motion.

NOTE: Circumduction or any abnormal movement to the side may hinder the initiation of dorsiflexion in swing.

ASCENDING STAIRS

- During stair ascent, PROPRIO FOOT® will raise the toe of the prosthetic foot.
 - * This will facilitate stair ambulation and improve gait symmetry.

- Leading with the prosthetic side upstairs and leading with the prosthetic side when going down will provide stair adaptation after the second prosthetic step on the stairs.
- When finishing the stair ascent and stepping onto level ground, it will take one stride for PROPRIO FOOT® to adapt to the level ground position. You may also shift weight from sound limb to prosthetic limb to have the foot return to neutral.
- If you feel undue socket pressure with the stair response please consult your prosthetist, who may alter the stair response to decrease this socket pressure.

DESCENDING STAIRS

- During stair descent, PROPRIO FOOT® will raise the toe of the prosthetic foot.
 - * This will facilitate stair ambulation and improve gait symmetry.
- When descending stairs, it is important to understand that the toe of the prosthetic foot will be raised. Be prepared to PLACE THE ENTIRE FOOT ON THE STEP. This makes the descent much more stable when compared to using non-microprocessor controlled foot systems.
- Leading with the prosthetic side upstairs and leading with the prosthetic side when going down will provide stair adaptation after the second prosthetic step on the stairs.
- The dorsiflexed position allows you to position PROPRIO FOOT® completely into the step. There is no need to place the foot on the edge of the stair case.
- When reaching the bottom of the steps, it will take one stride for PROPRIO FOOT® to adapt to the neutral level ground. You may also shift weight from sound limb to prosthetic limb to have the foot return to neutral.
- If you feel undue socket pressure with the stair response, please consult your prosthetist, who may alter the stair response.

INCLINES

- On inclines, PROPRIO FOOT® gradually raises the toe of the prosthetic foot to the degree of the slope.
- During the swing phase, PROPRIO FOOT® will raise the toe to provide additional ground clearance,
 - * This will facilitate ramp ambulation, by reducing socket pressure and strain on ligaments, and lowers the risk of stumbling.
- It is not necessary to lead with a particular limb when ascending slopes.

DECLINES

- On declines, PROPRIO FOOT® lowers the toe of the prosthetic foot.
 - * This helps to increase safety and gives better support during roll over of the prosthetic side.

RELAX MODE/CHAIR EXIT MODE (FIGURE G)

RELAX MODE allows the ankle to move into full plantarflexion that will provide improved body symmetry to the natural limb when sitting.

RELAX MODE is OFF by default.

- To enable RELAX MODE hold down  and press  five times.
 - * The system confirms with two beeps and vibrations.
- To disable RELAX MODE and enable Chair Exit Mode ONLY, hold down  and press  five times.
 - * The system confirms with three beeps and vibrations.
- To disable RELAX MODE and disable CHAIR EXIT MODE hold down  and press  five times.
 - * The system confirms with a single beep and vibration.

- Initiate RELAX MODE in a sitting position by extending the knee for at least 2 seconds.
* This provides a more natural ankle position when sitting with the lower leg extended.

Following the Relax Mode the PROPRIO FOOT® will move into CHAIR EXIT MODE.

To initiate this use one of the following methods:

- 1) Tap the heel of the foot.
- 2) Flex the knee and place the foot beneath the chair. Lift the foot to allow the adjustment to take place.

The ankle will move to dorsiflexion that will enable the user to bring the leg further back, providing more controlled transition from sitting to standing. The ankle will move back to neutral after the first step.

Tapping on the heel will move PROPRIO FOOT® to the next mode, i.e. tapping the heel when in RELAX MODE will move PROPRIO FOOT® direct into CHAIR EXIT MODE. A second tap on the heel will move PROPRIO FOOT® further to neutral ready for walking.

If you feel uncomfortable with the RELAX MODE/CHAIR EXIT MODE please consult your prosthetist, who may alter the response to your comfort.

SOUND ON/OFF (Figure H)

To enable or disable the auditory feedback hold  down the lower button and press  down the upper button seven times.

* The system confirms with a beep and vibration when enabled.

- There is no confirmation when the audible feedback is disabled.

DRIVING (Figure D)

Caution should be taken with respect to use of PROPRIO FOOT® inside of a motor vehicle. Inadvertent movement of the ankle may interfere with automobile control functions of brake and/or accelerator. It is best to follow the recommendations below regarding use of the foot in a motor vehicle.

- When preparing to drive, turn the foot off (**see chapter Power OFF**).

OTHER ACTIVITIES

- When climbing ladders, adaptation will occur as if you are using the device while ascending a stair. It is generally best to lead with the prosthesis. This method allows for a more stable starting position and faster adaptation to the ladder.
- When kneeling PROPRIO FOOT® will enter RELAX MODE. The knee and shin will be allowed to rest in a less stressful position with less excessive knee flexion.

ERROR CONDITION:

If for any reason, PROPRIO FOOT® indicates an error

- it is confirmed by a beep and vibration
- the LED will blink **red**; the system returns to neutral position and acts like a standard prosthesis without ankle motion. To activate the system again proceed as indicated in chapter Maintenance.

CHARGING AND POWER

- Only use the power source, supplied for the PROPRIO FOOT®.
- Connect the power supply cable to DC.
- Connect the power source to the battery pack. Allow 3-4 hours to ensure a full charge.

Battery Charge – The LED lights indicate the charge state of PROPRIO FOOT®.

- Press the control button to check the charging level. When the battery is fully charged, all LED lights will turn green.

Guidelines Regarding Lithium-ion Battery:

- Avoid frequent full discharges. Recharging a partially charged lithium-ion battery does not cause harm. Recharging daily is the most efficient routine.

POWER SUPPLY:

Only use the charger supplied.

ATTENTION: Do not charge when prosthesis is being worn!

NOTE: The yellow LED light on the PROPRIO FOOT® will blink when charging. The green will be steady.

- Do not store the prosthesis/battery in hot places or close to heat-emitting devices like radiators.

WARNING SIGNALS FOR POWER LOSS: (Figure B)

Vibratory and/or auditory warning systems are provided by PROPRIO FOOT® to indicate to the user that power loss is forthcoming. The warning signals are provided in a series of intermittent pulses. Ensure that the user recognizes the warnings.

CAUTION: When the PROPRIO FOOT® battery charge is low and the warning pulses for power loss are delivered, the foot will return to the latest preset heel height position. The foot should not be used when the power is off.

MAINTENANCE

SERVICE

PROPRIO FOOT® is designed and manufactured to provide long and troublefree service intervals. It is warranted against defective materials and workmanship for a period of 24 months. To ensure proper function, it is recommended that PROPRIO FOOT® is inspected every six months by a qualified professional. Check for signs of unusual wear.

CLEANING

Follow these instructions:

- Remove PROPRIO FOOT® from the cosmetic cover
- Wipe the foot with a soft cloth moistened with a small amount of isopropanol alcohol.
- Remove debris or dust without the use of compressed air.

NOTE: Do not dip the whole foot or pour solvent over the foot. The bearings and seals will be damaged. Do NOT use compressed air to clean the foot. Air will force pollutants into the bearings which may cause malfunctions and early deterioration.

WARRANTY

Össur provides a warranty of 24 months on PROPRIO FOOT®. See Terms of Warranty for details.

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