



1A1-2 Empower

EN Instructions for use (user)	2
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1 Product description

INFORMATION

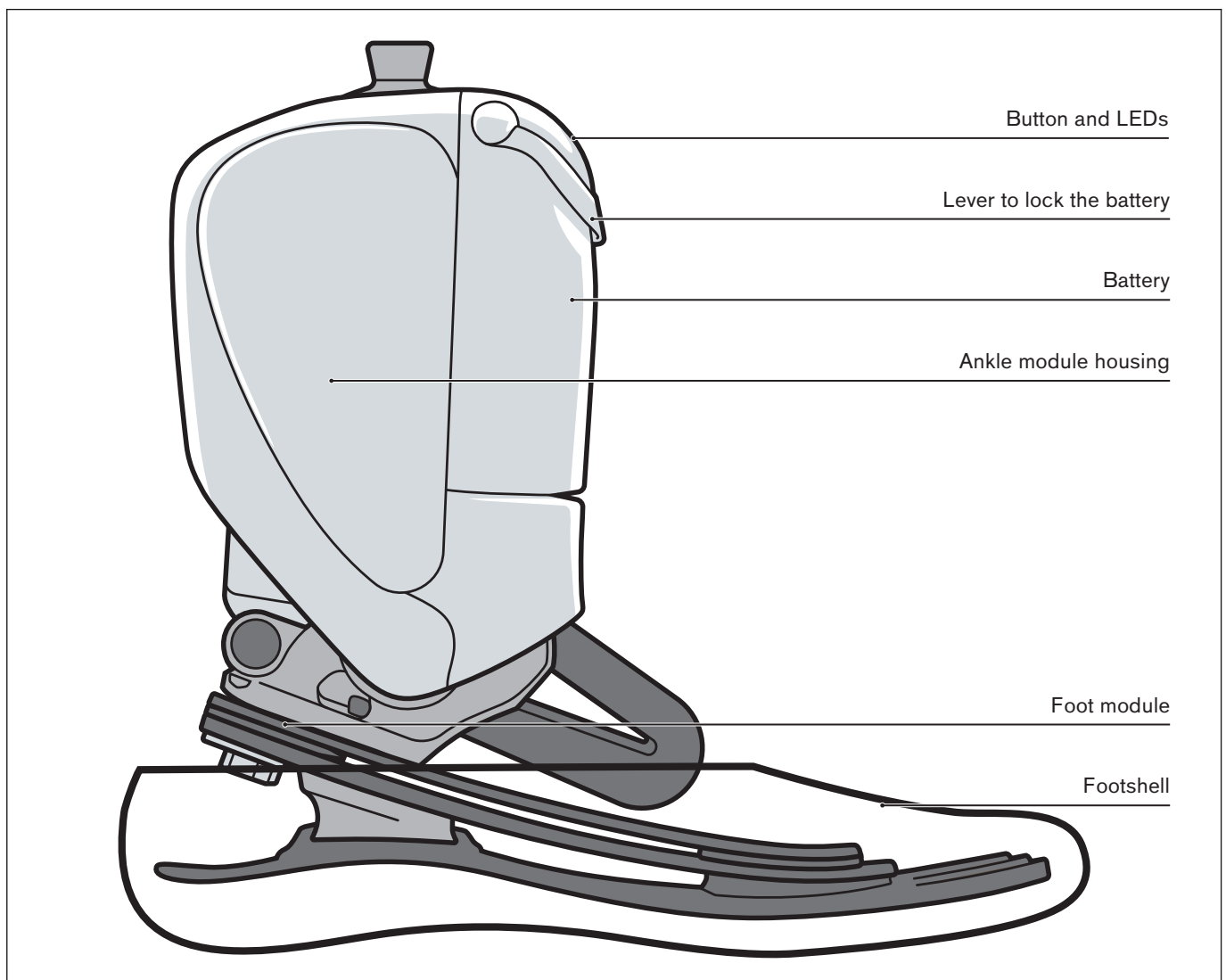
Date of last update: 2020-11-19

- ▶ Please read this document carefully before using the product and observe the safety notices.
- ▶ Obtain instruction from the qualified personnel in the safe use of the product.
- ▶ Please contact the qualified personnel if you have questions about the product or in case of problems.
- ▶ Report each serious incident related to the product to the manufacturer and to the relevant authority in your country. This is particularly important when there is a decline in the health state.
- ▶ Please keep this document for your records.

1.1 Construction and Function

The 1A1-2 Empower is an electronically controlled prosthetic foot with an actively driven ankle joint. The prosthetic foot simulates the function of the calf musculature and Achilles tendon for the toe-off at the end of each step. This toe-off supports the forward movement and is calculated in real time for every step. The force depends on the power supplied to the prosthetic foot while walking (due to the walking speed, stride length and terrain).

The prosthetic foot is lowered at heel strike to ensure rapid full-surface ground contact. This improves balance and stability, especially on uneven terrain or when going down ramps. The relief function makes a natural foot position possible while sitting.



2 Intended use

2.1 Area of application

- The product was developed for everyday use. In order to prevent injury or damage to the product, do not use it for sports or other high impact activities, i.e. jumping from a ladder.

2.2 Environmental conditions

Water:	<p>The prosthetic foot is protected against splash water (e.g. stepping into a shallow puddle or walking in the rain).</p> <ul style="list-style-type: none"> Do not submerge. Submersion can cause permanent damage. If water penetration is suspected, turn the prosthetic foot off and allow it to dry completely before turning it on again. <p>The battery and charger are not protected against water.</p>
Relative humidity:	10% to 90%, non-condensing
Sand/dust:	No contact with sand or dust. Sand and dust can get into the joint and damage the mechanics. Protect the product against sand and dust in situations where it may be exposed: walking on the beach, working on a building site, etc. .
Temperature:	<p>Operation: 0 °C to 45 °C (32 °F to 113 °F)</p> <p>Charging: 5 °C to 40 °C (41 °F to 104 °F)</p> <p>Storage: -30 °C to 60 °C (-22 °F to 140 °F)</p>
Impacts/vibrations:	Do not subject the product to mechanical vibrations or impacts.
Electric/magnetic power:	Do not use the product in environments with high levels of electric/magnetic power (e.g. electricity generators, transformers, high-performance radio transmitters, magnetic high-performance transmitters).

2.3 Service life

Prosthetic foot

Expected lifetime given compliance with maintenance intervals: **6 years**

Battery




The manufacturer has determined a maximal service life of one year for the product.

Footshell, protective sock



The product is a wear part, which means it is subject to normal wear and tear.

3 Safety

3.1 Explanation of warning symbols

 WARNING	Warning regarding possible serious risks of accident or injury.
 CAUTION	Warning regarding possible risks of accident or injury.
 NOTICE	Warning regarding possible technical damage.

3.2 General safety instructions

 WARNING Operation of motor vehicles Risk of accidents due to restricted body function ► Observe the applicable legal and insurance regulations for the operation of motor vehicles and have your driving ability examined and certified by an authorised agency.
 CAUTION Unintentional activation of the relief function Faulty operation of appliances/machines due to unintentional lowering of the prosthetic foot ► Turn the prosthetic foot off and bring it into a neutral position prior to operating control elements (e.g. vehicle pedals) in a sitting position.

⚠ CAUTION**Exceeding the service life**

Risk of injury due to change in or loss of functionality and damage to the product

- ▶ Ensure that the approved service life is not exceeded.

⚠ CAUTION**Use under restricted environmental conditions**

Risk of injury due to damage to the product

- ▶ Do not expose the product to restricted environmental conditions.
- ▶ If the product has been exposed to restricted environmental conditions, check it for damage.
- ▶ If damage is apparent or in case of doubt, do not continue using the product.
- ▶ Take suitable measures if required (e.g. cleaning, repair, replacement, inspection by the manufacturer or a specialist workshop etc.).

⚠ CAUTION**Mechanical damage to the product**

Risk of injury due to change in or loss of functionality

- ▶ Use caution when working with the product.
- ▶ If the product is damaged, check it for proper function and readiness for use.
- ▶ In case of changes in or loss of functionality, do not continue using the product (see "Signs of changes in or loss of functionality during use" in this section).
- ▶ Take any necessary measures (e.g. repair, replacement, inspection by the manufacturer's customer service, etc.).

⚠ CAUTION**Reaching into the area of the joint mechanism**

Pinching of limbs (e.g. fingers) and the skin due to uncontrolled joint movement

- ▶ Do not reach into the joint mechanism during daily use.
- ▶ Close attention is required during assembly and adjustment tasks.

NOTICE**Mechanical overload**

Impaired functionality due to mechanical damage

- ▶ Check the product for damage prior to each use.
- ▶ Do not use the product if its functionality has been impaired.
- ▶ Take any necessary measures (e.g. repair, replacement, inspection by the manufacturer's customer service, etc.).

Signs of changes in or loss of functionality during use

Reduced spring effect (e.g. decreased forefoot resistance or changed rollover behaviour) or delamination of the carbon spring are indications of loss of functionality. Unusual noises can indicate a loss of functionality.

4 Use

⚠ CAUTION**Malfunction of the prosthetic foot**

Risk of injury due to unfamiliar response of the prosthetic foot

- ▶ Turn the prosthetic foot off and contact your O&P professional.

NOTICE**Incorrect operation**

Functional limitations due to changed settings

- ▶ Check the product settings in case of changes.
- ▶ Take note of the warning signals.

4.1 Switching on/off

Switching on



- > **Prerequisite:** The prosthetic foot is not under load.
- 1) Press the button on the battery **for 3 seconds**.
 - The green LED on the battery lights up. The prosthetic foot performs a calibration. A single, high beep will sound and the prosthetic foot will vibrate briefly to signify that calibration is complete.
- 2) **If a number of soft beeps is emitted, the calibration has failed.** Flex the prosthetic foot down (plantar flexion) until the calibration is completed.

Switching off

- ▶ Press the button on the battery **for 6 seconds**.

4.2 Charging the battery

⚠ WARNING**Using an unapproved battery charger**

Risk of severe injuries due to electric shock

- ▶ Only use the supplied battery charger.

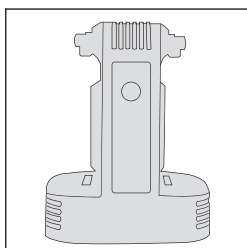
INFORMATION

If the battery is fully charged, the battery life during normal use is up to 8 h. Ottobock recommends charging the battery daily. Charging the battery before it is drained has a positive impact on its service life.

The charging process takes about 90 minutes. It can only be performed within the prescribed charging temperature range.

- ▶ Only charge the battery after it has warmed/cooled to room temperature.
- ▶ If you intend to store the battery for longer than 6 months: Fully charge the battery first in order to extend its service life.

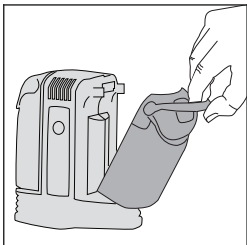
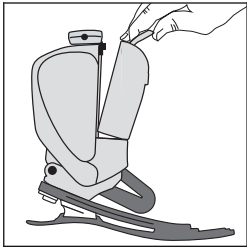
Putting the battery charger into operation



The battery charger can charge two batteries at the same time. There is an LED for each battery that indicates the status. An LED indicates whether the battery charger is being supplied with power. All LEDs can be turned off with a button on the front, for example so they are not bothersome in the dark.

- 1) Connect the cable of the power supply to the battery charger.
- 2) Connect the plug to an outlet. An LED lights up as soon as the battery charger is supplied with electricity.

Charging the battery



- 1) **If the prosthetic foot is on:** Turn the prosthetic foot off (see page 5).
 - 2) Flip up the lever on the battery and take the battery off the prosthetic foot.
 - 3) Insert the battery into the battery charger.
- **The LED to indicate the charge level slowly flashes green:** The battery is being charged.
- **The LED to indicate the charge level quickly flashes red:** An error has occurred. Take the battery out of the battery charger and check for the error (see page 6).
- **The LED no longer flashes:** The charging process is complete. Take the battery out of the battery charger. Disconnect the battery charger plug from the outlet when the battery charger is no longer needed.

4.2.1 Troubleshooting

The measures in this section help with systematic troubleshooting and error correction. They are carried out if errors occur in the battery or battery charger.

Problem	Solution
The battery or battery charger rattles when it is shaken	There may be loose parts inside due to product damage. <ul style="list-style-type: none"> • Do not use a possibly damaged product! • Contact your O&P professional.
LED to indicate the charging status on the battery charger quickly flashes red	<ul style="list-style-type: none"> • Remove the battery, disconnect the battery charger from the mains network, plug the battery charger back into the mains network and reinsert the battery. If the fast red flashing continues, contact your O&P professional.
LED to indicate the charging status on the battery charger flashes red, three times every five seconds	<ul style="list-style-type: none"> • Indicates a battery fault. Take the battery out of the battery charger and do not use it again. • Contact your O&P professional.
LED to indicate the charging status on the battery charger flashes red, five times every five seconds	<ul style="list-style-type: none"> • Indicates that the permissible temperature has been exceeded. Make sure the ventilation slots of the battery charger are not blocked and that the battery charger is in a cool location. Disconnect the battery charger from the mains network and allow it to cool before using it again.
No LEDs are lit on the battery charger	The battery charger is not connected to the mains network <ul style="list-style-type: none"> • Check whether the power supply is connected to the battery charger and the outlet is supplied with power.
Batteries are not being charged	<ul style="list-style-type: none"> • Check whether the battery charger is connected to the mains network. • Check whether the battery is properly inserted and is at the correct operating temperature. • Try the second slot on the battery charger. • If the error could not be corrected, contact your O&P professional.

4.3 Information on using the battery

INFORMATION




Lithium-ion batteries

The product is powered by a lithium-ion battery. Special requirements apply for this battery type.

- **Travel:** Before a trip, check the requirements of public authorities and transport companies (such as airlines). For example, a battery on its own may have to be transported in carry-on luggage.
- **Damaged batteries:** Contact your O&P professional for information on transporting a damaged battery.

Checking the charge level

- Briefly press the button on the battery. The charge level is displayed by a row of four LEDs.

	LEDs on the battery	Status
	LED shows green light	The prosthetic foot is switched on.
	LED is flashing red	There is an error. The prosthetic foot does not turn on.
	Four LEDs show continuous light	Charge level: 76% to 100%
	Three LEDs show continuous light	Charge level: 51% to 75%
	Two LEDs show continuous light	Charge level: 26% to 50%
	One LED shows continuous light	Charge level: 11% to 25%
	One LED is flashing	Charge level: <10%

Sleep mode

The battery of the prosthetic foot has a sleep mode. Sleep mode is activated to protect the battery, for example when:

- The temperature is too high (45 °C during charging, 65 °C during use)
- The temperature is too low (less than 5 °C during charging, no limit during use)
- The battery is drained (protection against deep discharge)

The prosthetic foot can still be used, but no longer has any active functions.

- 1) **If battery sleep mode has been activated:** Turn the prosthetic foot on.
 - **The LED on the battery flashes red:** There is a problem with the battery. Contact your O&P professional.
 - **The LEDs on the battery do not light up:** Charge the battery.
- 2) **If the temperature was too high:** Let the battery cool down.

4.4 Walking up/down stairs

⚠ CAUTION

Walking up/down stairs

Risk of injury due to slipping or stumbling

- Always use the handrail when walking on stairs.
- Note the product-specific information for walking on stairs.

Walking on stairs with the Empower should be practised. The toe-off provides support while walking up. When walking down, the toe-off must not be triggered since it could lead to falling. Therefore, it is important to position the forefoot of the Empower correctly with each step. The following instructions apply for one step of the stairs, respectively.

Walking up

- 1) Position the forefoot of the prosthetic foot (front third of the foot length) on the step.
- 2) Maintain slight flexion of the knee joint.
- 3) Shift the full weight to the prosthetic foot.

Walking down

- 1) **CAUTION! Risk of falling! Do not set the forefoot of the prosthetic foot onto the step. Otherwise, the toe-off could be triggered.**
Only position the heel and midfoot of the prosthetic foot on the step (rear two-thirds of the foot length).
- 2) Shift the full weight to the prosthetic foot.

5 Cleaning and Care

- 1) **CAUTION! Disconnect the battery charger from the mains network before cleaning it.**
Clean the product with a damp cloth and mild soap (e.g. Ottobock 453H10=1 Derma Clean) when needed. In doing so, make sure that no liquids can get into the product.
- 2) Dry the product with a lint-free cloth and allow it to air dry fully.

6 Maintenance

- Adhere to the maintenance appointments agreed with your O&P professional.

7 Disposal



In some jurisdictions it is not permissible to dispose of these products with unsorted household waste. Disposal that is not in accordance with the regulations of your country may have a detrimental impact on health and the environment. Please observe the instructions of your national authority pertaining to return and collection.

8 Legal information

All legal conditions are subject to the respective national laws of the country of use and may vary accordingly.

8.1 Liability

The manufacturer will only assume liability if the product is used in accordance with the descriptions and instructions provided in this document. The manufacturer will not assume liability for damage caused by disregarding the information in this document, particularly due to improper use or unauthorised modification of the product.

8.2 CE conformity

The product meets the requirements of Regulation (EU) 2017/745 on medical devices. The CE declaration of conformity can be downloaded from the manufacturer's website.

This product meets the requirements of the European Directive 1999/5/EC for radio equipment and telecommunications terminal equipment. The conformity assessment was drawn up by the manufacturer in accordance with Annex III of the directive.

The product meets the requirements of the RoHS Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic devices.

8.3 Warranty

The manufacturer warrants this device from the date of purchase. The warranty covers defects that can be proven to be a direct result of flaws in the material, production or construction and that are reported to the manufacturer within the warranty period.

Further information on the warranty terms and conditions can be obtained from the competent manufacturer distribution company.

8.4 Trademarks

All product names mentioned in this document are subject without restriction to the respective applicable trademark laws and are the property of the respective owners.

All brands, trade names or company names may be registered trademarks and are the property of the respective owners.

Should trademarks used in this document fail to be explicitly identified as such, this does not justify the conclusion that the denotation in question is free of third-party rights.

9 Symbols Used



Legal manufacturer



Declaration of conformity according to the applicable European directives



Serial number



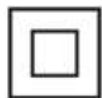
For indoor use only



Non-ionising radiation



Type BF applied part



Class II Electrical device



Please note the instructions for use



Polarity



Humidity limits for storage/transport



Temperature limits for storage/transport

IP##

Ingress protection classification



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This product, and the use thereof, may be covered by one or more of the following US patents:

7,313,463 8,376,971 8,551,029 8,734,528 8,900,325 9,345,592 9,351,856 9,693,883 9,737,419 10,335,292 10,406,002

Additional US and International patents may be pending.



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