



# 1A1-2 Empower

EN Instructions for use (qualified personnel) .....	2
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# 1 Product description

## INFORMATION

Date of last update: 2020-11-19

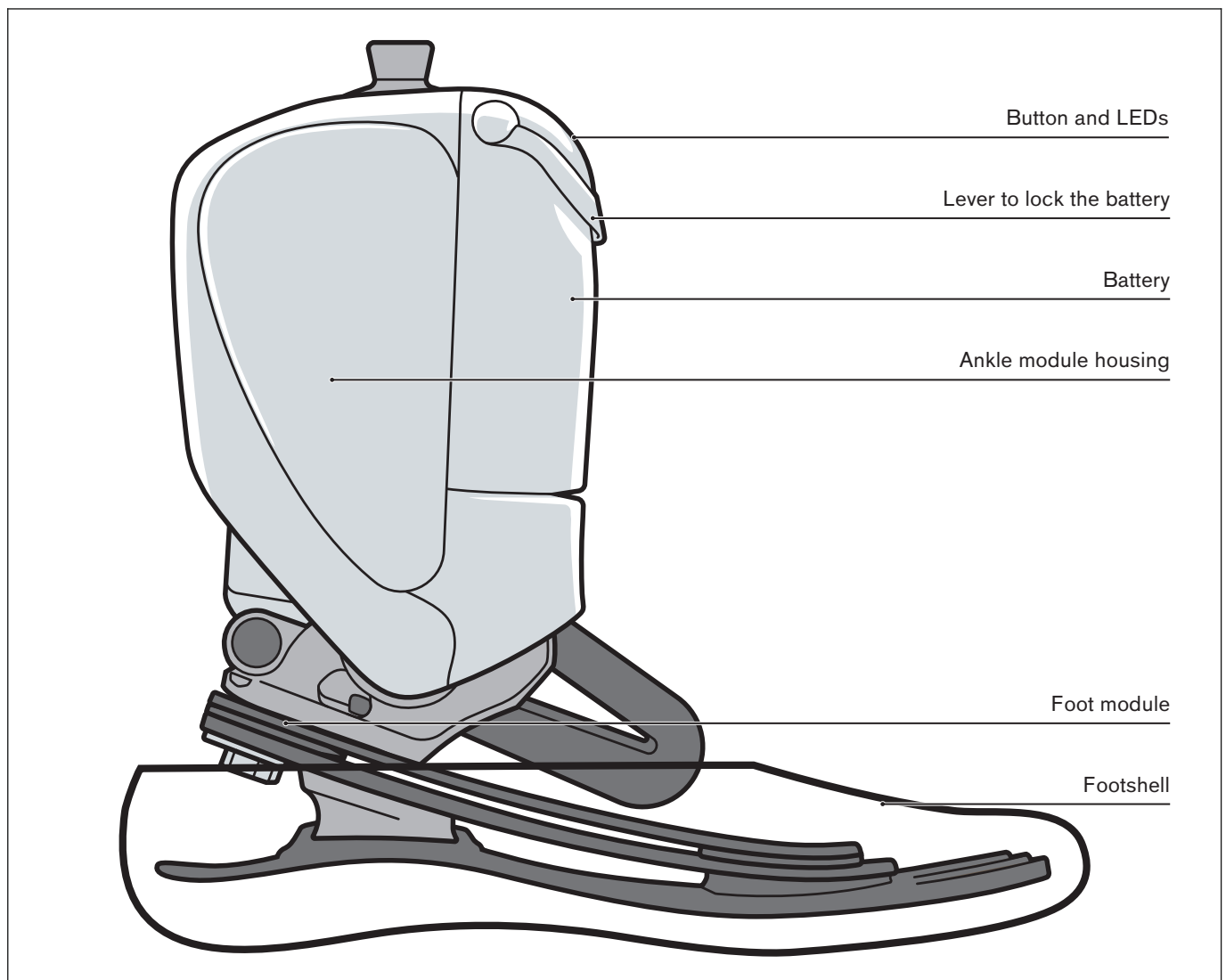
- ▶ Please read this document carefully before using the product and observe the safety notices.
- ▶ Instruct the user in the safe use of the product.
- ▶ Please contact the manufacturer if you have questions about the product or in case of problems.
- ▶ Report each serious incident related to the product 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 with the powered push-off at the end of the stance phase. This powered push-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).

Dampened plantar flexion of the prosthetic foot at heel strike ensures 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.

The parameters of the control can be adjusted with the Empower Setup app.



## 1.2 Combination possibilities

This prosthetic component is compatible with Ottobock's system of modular connectors. Functionality with components of other manufacturers that have compatible modular connectors has not been tested.

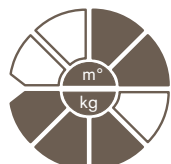
## 2 Intended use

### 2.1 Indications for use

The product is intended exclusively for lower limb exoprosthetic fittings.

### 2.2 Area of application

Our components perform optimally when paired with appropriate components based upon weight and mobility grades identifiable by our MOBIS classification information and which have appropriate modular connectors.



Recommended for mobility grades **3 and 4** (unrestricted outdoor walker and unrestricted outdoor walker with particularly high demands). Approved for a body weight of up to **130 kg (287 lbs)**.

- 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.
- **TT prostheses:** The product is designed for use by unilateral or bilateral amputees.
- **TF prostheses and knee disarticulation prostheses:** The product is designed only for use by unilateral amputees.

The following table shows the suitable spring stiffness of the prosthetic foot for the patient's body weight.

Body weight [kg]	Spring stiffness
<b>59 to 67</b>	3
<b>68 to 77</b>	4
<b>78 to 88</b>	5
<b>89 to 100</b>	6
<b>101 to 115</b>	7
<b>116 to 130</b>	8

### 2.3 Qualification

The fitting of a patient with the product may only be carried out by O&P professionals who have been authorised with the corresponding Ottobock training.

### 2.4 Environmental conditions

<b>Water:</b>	The prosthetic foot is protected against splash water (e.g. stepping into a shallow puddle or walking in the rain). <ul style="list-style-type: none"> <li>• Do not submerge. Submersion can cause permanent damage.</li> <li>• If water penetration is suspected, turn the prosthetic foot off and allow it to dry completely before turning it on again.</li> </ul> The battery and charger are not protected against water.
<b>Relative humidity:</b>	10% to 90%, non-condensing
<b>Sand/dust:</b>	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. .
<b>Temperature:</b>	Operation: 0 °C to 45 °C (32 °F to 113 °F) Charging: 5 °C to 40 °C (41 °F to 104 °F) Storage: -30 °C to 60 °C (-22 °F to 140 °F)
<b>Impacts/vibrations:</b>	Do not subject the product to mechanical vibrations or impacts.
<b>Electric/magnetic power:</b>	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).

## 2.5 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

 <b>WARNING</b>	Warning regarding possible serious risks of accident or injury.
 <b>CAUTION</b>	Warning regarding possible risks of accident or injury.
 <b>NOTICE</b>	Warning regarding possible technical damage.

### 3.2 General safety instructions

<p> <b>WARNING</b></p> <p><b>Operation of motor vehicles</b>                      Risk of accidents due to restricted body function</p> <ul style="list-style-type: none"> <li>▶ 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.</li> </ul>
<p> <b>CAUTION</b></p> <p><b>Unintentional activation of the relief function</b>                      Faulty operation of appliances/machines due to unintentional lowering of the prosthetic foot</p> <ul style="list-style-type: none"> <li>▶ 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.</li> </ul>
<p> <b>CAUTION</b></p> <p><b>Exceeding the service life and reuse on another patient</b>                      Risk of injury due to loss of functionality as well as damage to the product</p> <ul style="list-style-type: none"> <li>▶ Ensure that the approved service life is not exceeded.</li> <li>▶ Only use the product on a single patient.</li> </ul>
<p> <b>CAUTION</b></p> <p><b>Excessive strain on the product</b>                      Risk of injury due to breakage of load-bearing components</p> <ul style="list-style-type: none"> <li>▶ Use the product according to the specified area of application (see page 3).</li> </ul>
<p> <b>CAUTION</b></p> <p><b>Use under restricted environmental conditions</b>                      Risk of injury due to damage to the product</p> <ul style="list-style-type: none"> <li>▶ Do not expose the product to restricted environmental conditions.</li> <li>▶ If the product has been exposed to restricted environmental conditions, check it for damage.</li> <li>▶ If damage is apparent or in case of doubt, do not continue using the product.</li> <li>▶ Take suitable measures if required (e.g. cleaning, repair, replacement, inspection by the manufacturer or a specialist workshop etc.).</li> </ul>

**⚠ CAUTION****Improper combination of prosthetic components**

Risk of injury due to breakage or deformation of the product

- ▶ Only combine the product with prosthetic components that are approved for that purpose.
- ▶ Based on the instructions for use of the prosthetic components, verify that they may be combined with each other.

**⚠ 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 Scope of delivery**

1A1-2 Empower		
Quantity	Designation	Reference number
1	Instructions for use	–
1	Prosthetic foot	–
1	Heel wedge set	2F50=*
1	Footshell	2C16=*
1	Protective sock	SL=Spectra-Sock-7
1	Battery charger	757L38
1	Power supply	757L39
1	US power cord	BM-214-00005
2	Battery	757B38

**Empower**

Spare parts/accessories	
Designation	Reference number
EU power cord	BM-214-00007
GB power cord	BM-214-00008
AUS power cord	757S3=AUS

## Tablet

Spare parts/accessories	
Designation	Reference number
Empower Tablet	743Y840=V1
Travel charger	757L2
Adapter plug (EU)	757S7=EU
Adapter plug (GB)	757S7=GB
Adapter plug (AUS)	757S7=AUS

## 5 Preparing the product for use

### ⚠ CAUTION

#### Incorrect alignment, assembly or adjustment

Injury due to incorrectly installed or adjusted as well as damaged prosthetic components

- ▶ Observe the alignment, assembly and adjustment instructions.

### INFORMATION

The battery is not fully charged upon delivery. The battery must be charged before the product is used for the first time.

### INFORMATION

#### Only turn on the Empower when establishing the Bluetooth connection with the Empower Setup app.

The Empower can only be put into operation with the corresponding Setup app. The Empower Setup app guides you through the prosthetic alignment and adjustment of the prosthetic foot. This document only contains information that is not provided in the app:

- **Installing the Empower Setup app**
- **Installing the footshell**
- **Replacing the heel wedge**
- **Troubleshooting (batteries and charger)**

### 5.1 Installing the Empower Setup app

The Empower Setup app is to be installed on the tablet belonging to the prosthetic foot. The app can also be installed on your own, compatible Android device.

- 1) Download and install the Empower Setup app from the Google Play Store.
- 2) Start the Empower Setup app and register the user. The app can only be used by certified O&P professionals with a myOttobock account.

#### 5.1.1 Overview of the setting parameters

The Empower Setup app guides you through the alignment and adjustment of the Empower. The following setting parameters are available in the app:

Parameter	Description
Plantar flexion resistance	Affects the speed of plantar flexion during loading by adjusting the resistance.
Fast walking power	Sets the powered push-off for fast walking. This parameter also influences climbing stairs or walking up steep ramps.
Slow walking power	Sets the powered push-off for slow walking.
Power sensitivity	Increases the sensitivity for triggering the powered push-off.
Fast power timing	Influences the timing of the powered push-off for fast walking.
Slow power timing	Influences the timing of the powered push-off for slow walking.
Cadence range	Influences the increase in the power output based on the settings for slow walking and fast walking. Can be increased to obtain the maximum power output during fast walking.
Toe strike	Supports climbing stairs and walking up very steep ramps. The powered push-off for stair climbing is only triggered when the patient puts a considerable load on the toe region without first having put a load on the heel.

Parameter	Description
Virtual dorsi/plantar flexion	Virtual dorsi/plantar flexion has the same effect as flexing the prosthetic foot. Positive values mean virtual plantar flexion, negative values mean virtual dorsiflexion. Changing the value influences both the intensity of the powered push-off and the timing of its activation.

## 5.2 Applying/removing the footshell

### INFORMATION

- ▶ Pull the protective sock over the prosthetic foot to prevent noises in the footshell.
- ▶ Always use the prosthetic foot with the footshell.

### Putting on the footshell

> **Recommended tools:** 2C100 changing device

- 1) Slide the prosthetic foot into the footshell.
- 2) Press the heel of the prosthetic foot into the footshell until it engages.

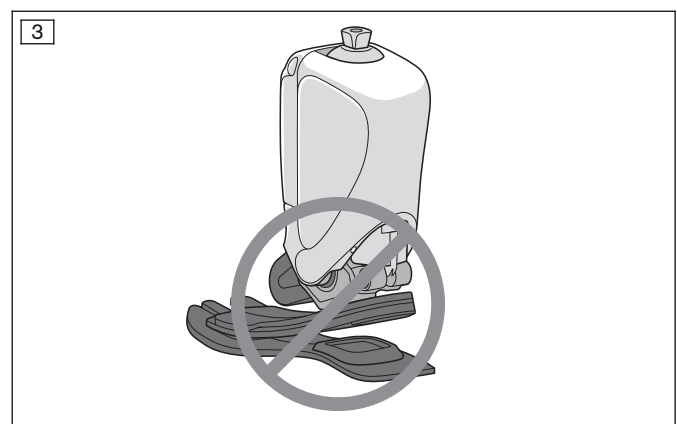
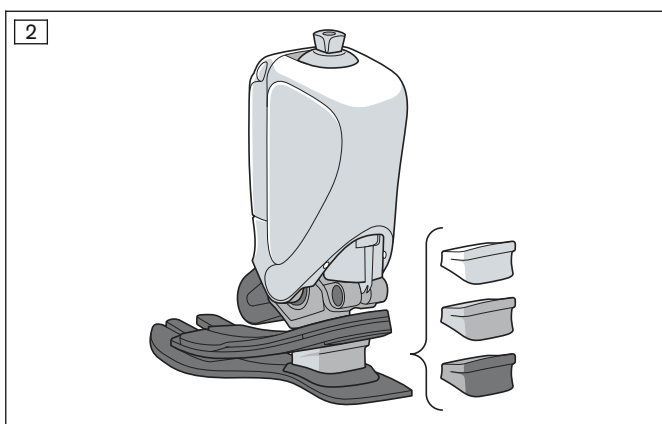
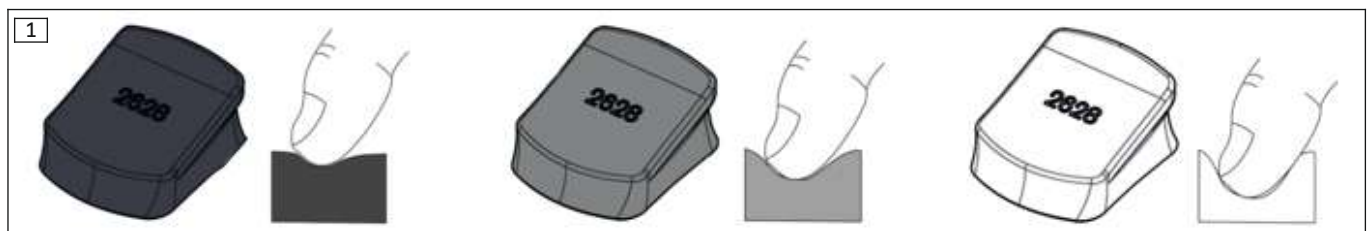
### Removing the footshell

- 1) Push the lock of the footshell to the rear and pull up the heel of the prosthetic foot.
- 2) Remove the prosthetic foot from the footshell.

## 5.3 Replacing the heel wedge

The behaviour of the prosthetic foot at heel strike and during heel contact in the mid-stance phase can be adapted by replacing the heel wedge. Heel wedges of various hardness are included in the scope of delivery.

**Heel wedge hardness:** The colour of the heel wedge indicates the hardness (see fig. 1). Ottobock recommends starting with the preinstalled heel wedge.



- 1) Pull the prosthetic foot apart slightly and remove the existing heel wedge.
- 2) Align the other heel wedge so the Ottobock lettering is right side up and the narrow edge points to anterior.
- 3) Insert the heel wedge into the prosthetic foot.

## 6 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.

### 6.1 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**.

### 6.2 Charging the battery

### ⚠ WARNING

#### Using an unapproved battery charger

Risk of severe injuries due to electric shock

- ▶ Only use the supplied battery charger.

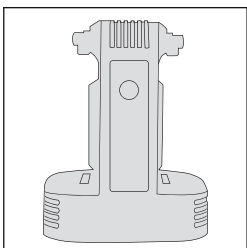
### INFORMATION

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

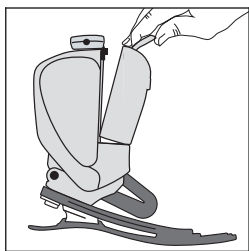


The battery charger can charge two batteries at the same time. There is an LED for each battery that indicates the status. An LED indicates whether the battery charger is being supplied with power. All LEDs can be turned off with a button on the front, for example so they are not bothersome in the dark.

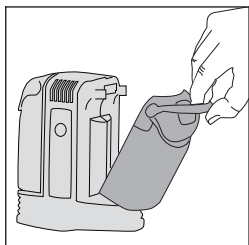
- 1) Connect the cable of the power supply to the battery charger.
- 2) Connect the plug to an outlet. An LED lights up as soon as the battery charger is supplied with electricity.



## Charging the battery



- 1) **If the prosthetic foot is on:** Turn the prosthetic foot off (see page 8).
- 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 9).
  - **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.



### 6.2.1 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 on the interior because the product is damaged. <ul style="list-style-type: none"> <li>• <b>Do not use a possibly damaged product!</b></li> <li>• Contact the manufacturer.</li> </ul>
LED to indicate the charging status on the battery charger quickly flashes red	<ul style="list-style-type: none"> <li>• Take out the battery, disconnect the battery charger from the mains network, connect the battery charger to the mains network again and reinsert the battery. If the quick red flashing continues, contact the manufacturer.</li> </ul>
LED to indicate the charging status on the battery charger flashes red, three times every five seconds	<ul style="list-style-type: none"> <li>• Indicates a battery fault. Take the battery out of the battery charger and do not use it again.</li> <li>• Contact the manufacturer.</li> </ul>
LED to indicate the charging status on the battery charger flashes red, five times every five seconds	<ul style="list-style-type: none"> <li>• 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.</li> </ul>
No LEDs are lit on the battery charger	The battery charger is not connected to the mains network <ul style="list-style-type: none"> <li>• Check whether the power supply is connected to the battery charger and the outlet is supplied with power.</li> </ul>
Batteries are not being charged	<ul style="list-style-type: none"> <li>• Check whether the battery charger is connected to the mains network.</li> <li>• Check whether the battery is properly inserted and is at the correct operating temperature.</li> <li>• Try the second slot on the battery charger.</li> <li>• If the error could not be corrected, contact the manufacturer.</li> </ul>

## 6.3 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 the manufacturer 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 the manufacturer.
  - **The LEDs on the battery do not light up:** Charge the battery.
- 2) **If the temperature was too high:** Let the battery cool down.

**6.4 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.

**7 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.

**8 Maintenance**

- Readjust the product 2 weeks and 6 weeks after first use. This ensures proper functioning of the product.

- Inspect the entire prosthetic foot for visible damage every six months or 500,000 steps. Make additional inspection appointments as needed (e.g. for highly active or heavy users).
- ▶ Inspect the entire prosthesis for wear during normal consultations.

### Maintenance intervals

The product requires regular maintenance by the manufacturer's service department to achieve the maximum lifetime. The scheduled maintenance intervals are as follows:

- USA, CAN: When problems occur, but no later than after **36 months**
- All other countries/regions: **24 months**

A cost estimate is prepared when a billable repair is required. The repair is carried out after the cost estimate is approved.

## 9 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.

## 10 Legal information

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

### 10.1 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.

### 10.2 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.

### 10.3 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.

### 10.4 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.

## 11 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


## 12 Technical data

Sizes [cm]	25	26	27	28	29	30
Heel height [mm]	10					
System height with footshell [mm]	198	203			208	
Structural height with footshell [mm]	216	221			226	
Range of motion, plantar flexion [°]	22					
Product weight [g]	Size 27: approx. 1950					
Product weight with footshell and protective sock [g]	Size 27: approx. 2145					
Max. body weight [kg]	130					
Mobility grade	3 and 4					
Battery and battery charger						
Battery type	Lithium-ion					
Battery charging temperature [°C]	5 to 45					
Battery capacity [Wh]	45					

Battery and battery charger	
Battery output voltage (nominal) [V]	18
Battery charger operating temperature [°C]	0 to 40
Battery charger supply voltage [V, Hz]	100 V to 240 V AC 50 Hz to 60 Hz
Battery charger input voltage [V]	23 to 26
Battery charger input current [A]	Max. 3.75
Charging current [A]	2.5

## 12.1 EMC information

Directive and manufacturer's declaration – electromagnetic emissions			
The prosthetic foot is intended for use in the electromagnetic environment described below. The customer or user must ensure that it is operated in such an environment.			
Emission test	Compliance	Electromagnetic environment – directive	
HR emissions CISPR 11	Group 2	The prosthetic foot emits electromagnetic power to carry out its intended function. This may affect electronic devices located nearby.	
HR emissions CISPR 11	Class B	The prosthetic foot is suitable for use in all buildings, including residential buildings.	
Harmonic wave emissions IEC 61000-3-2	Not applicable		
Voltage fluctuations and flicker IEC 61000-3-3	Not applicable		
Directive and manufacturer's declaration – electromagnetic interference immunity			
The prosthetic foot is intended for use in the electromagnetic environment described below. The customer or user must ensure that it is operated in such an environment.			
Interference immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – directive
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air±	± 8 kV contact ± 15 kV air±	Floors should be wood, concrete or ceramic tile. If the floor covering is made of synthetic material, the relative humidity must be at least 30%.
Electrical fast transients/bursts IEC 61000-4-4	± 2 kV for power lines ± 1 kV for input and output lines	Not applicable	Not applicable. The prosthetic foot is powered by a rechargeable battery.
Over voltage IEC 61000-4-5	± 1 kV line against line ± 2 kV line against earth	Not applicable	Not applicable. The prosthetic foot is powered by a rechargeable battery.
Voltage drops, brief interruptions and voltage fluctuations in power supply lines	<5 % $U_T$ (>95 % drop in $U_T$ ) for 0.5 cycles 40 % $U_T$ (60 % drop in $U_T$ ) for 5 cycles 70 % $U_T$ (30 % drop in $U_T$ ) for 25 cycles <5 % $U_T$ (>95 % drop in $U_T$ ) for 5 s	Not applicable	Not applicable. The prosthetic foot is powered by a rechargeable battery.
Mains frequency – (50/60 Hz) – magnetic field IEC 61000-4-8	30 A/m	30 A/m	Mains frequency magnetic fields must correspond to the values that are characteristic for commercial or hospital environments.
NOTICE: $U_T$ is the AC mains voltage before applying the test level.			
Line-conducted HR IEC 61000-4-6 Radiated HR IEC 61000-4-3	Not applicable 3 V/m 80 MHz to 2.5 GHz	Not applicable 10 V/m	Wearable and portable HR communication devices should not be operated closer to a component of the battery charger, including cables, than the recommended separating distance calculated using the equation applicable for the frequency of the transmitter. <b>Recommended separating distance:</b> Not applicable. The prosthetic foot is powered by a rechargeable battery. $d=1.2\sqrt{P}$ 80 MHz to 800 MHz $d=2.3\sqrt{P}$ 800 MHz to 2.5 GHz P stands for the maximum output power of the transmitter in watts (W) according to the transmitter manufacturer, and d is the recommended separating distance in metres (m).


Directive and manufacturer's declaration – electromagnetic interference immunity			
			Field strengths of HR transmitters determined according to an electromagnetic site survey <sup>a</sup> must be lower than the compliance level in every frequency range <sup>b</sup> . Interference may occur in the vicinity of devices that are marked with the following symbol: 
NOTICE 1: The higher frequency range applies at 80 MHz and 800 MHz. NOTICE 2: These directives may not apply in all situations. Electromagnetic propagation is influenced by absorption and reflection on buildings, objects and persons.			
<sup>a</sup> Field strengths of fixed transmitters, such as base stations for radio telephones (mobile radio/wireless) and land mobile radio, amateur radio, AM and FM radio, and television transmitters cannot be exactly determined theoretically. An electromagnetic site survey should be considered to evaluate the electromagnetic environment due to fixed HR transmitters. If the measured field strength at the location where the prosthetic foot is used exceeds the aforementioned applicable HR compliance level, the prosthetic foot must be observed during normal use. Should deviating performance be noted, additional measures may be required, for example realigning or repositioning the prosthetic foot.			
<sup>b</sup> Within the frequency range of 150 kHz to 80 MHz, the field strength must be less than 10V/m.			

Recommended separating distances between wearable and portable HR communication devices and the prosthetic foot			
The prosthetic foot is intended for use in an electromagnetic environment in which radiated HR interference can be controlled. The customer or user of the prosthetic foot can help avoid electromagnetic interference by maintaining a minimum distance between wearable and portable HR communication devices (transmitters) and the prosthetic foot, as recommended in the following, according to the maximum output power of the communication device.			
Maximum nominal output power of the transmitter (W)	Separating distance according to transmitter frequency (m)		
	150 kHz to 80 MHz d=1.2√P	80 MHz to 800 MHz d=1.2√P	800 MHz to 2.5 GHz d=2.3√P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters with a maximum nominal output power that is not listed above, the recommended separating distance (d) in metres can be calculated using the equation applicable for the frequency of the transmitter, where (P) is the maximum nominal output power of the transmitter in watts (W) according to the transmitter manufacturer. NOTICE 1: The higher frequency range applies at 80 MHz and 800 MHz. NOTICE 2: These directives may not apply in all situations. Electromagnetic propagation is influenced by absorption and reflection on buildings, objects and persons.			

The prosthetic foot uses a Bluetooth® wireless connection for the configuration of settings. Other devices can interfere with the wireless connection, including devices that meet the CISPR emission requirements. If a poor adjustment range or limited responsiveness is observed, the prosthetic foot may have to be adjusted in a location that is further away from the HR power sources. The Bluetooth® module receives and transmits the following electromagnetic HR power: frequency band: 2402 - 2480 MHz, modulation: FHSS/GFSK, effective radiant power: 12 dBm

Directive and manufacturer's declaration – electromagnetic emissions		
The battery charger is intended for use in the electromagnetic environment described below. The customer or user of the battery charger must ensure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment – directive
HF emissions CISPR 11	Group 1	The battery charger uses HF power only for its internal function. Therefore its HF emissions are very low, and it is unlikely to cause interference with electronic devices in the vicinity. The battery charger is suitable for use in all buildings, including residential buildings and buildings connected directly to the public low-voltage network that supplies residential buildings with electricity.
HF emissions CISPR 11	Class B	
Harmonic wave emissions IEC 61000-3-2	Class B	
Voltage fluctuations and flicker IEC 61000-3-3	Complies	

Directive and manufacturer's declaration – electromagnetic interference immunity			
The battery charger is intended for use in the electromagnetic environment described below. The customer or user of the battery charger must ensure that it is used in such an environment.			
Interference immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – directive
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air±	± 8 kV contact ± 15 kV air±	

Directive and manufacturer's declaration – electromagnetic interference immunity			
			Floors should be wood, concrete or ceramic tile. If the floor covering is made of synthetic material, the relative humidity must be at least 30%.
Electrical fast transients/bursts IEC 61000-4-4	± 2 kV for power lines ± 1 kV for input and output lines	± 2 kV for power lines ± 1 kV for input and output lines	The mains current quality must correspond to a typical commercial or hospital environment.
Over voltage IEC 61000-4-5	± 1 kV line against line ± 2 kV line against earth	± 1 kV line against line ± 2 kV line against earth	The mains current quality must correspond to a typical commercial or hospital environment.
Voltage drops, brief interruptions and voltage fluctuations in power supply lines IEC 61000-4-11	<5 % $U_T$ (>95 % drop in $U_T$ ) for 0.5 cycles 40 % $U_T$ (60 % drop in $U_T$ ) for 5 cycles 70 % $U_T$ (30 % drop in $U_T$ ) for 25 cycles <5 % $U_T$ (>95 % drop in $U_T$ ) for 5 s	<5 % $U_T$ (>95 % drop in $U_T$ ) for 0.5 cycles 40 % $U_T$ (60 % drop in $U_T$ ) for 5 cycles 70 % $U_T$ (30 % drop in $U_T$ ) for 25 cycles <5 % $U_T$ (>95 % drop in $U_T$ ) for 5 s	The mains current quality must correspond to a typical commercial or hospital environment. If the user wants to use the battery charger continuously during a power failure, operating the battery charger with an uninterruptible power supply or rechargeable battery is recommended.
Mains frequency – (50/60 Hz) – magnetic field IEC 61000-4-8	30 A/m	30 A/m	Mains frequency magnetic fields must correspond to the values that are characteristic for commercial or hospital environments.
NOTICE: $U_T$ is the AC mains voltage before applying the test level.			
Line-conducted HF IEC 61000-4-6 Radiated HF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 V 10 V/m	<p>Wearable and portable HF communication devices should not be operated closer to a component of the battery charger, including cables, than the recommended separating distance calculated using the equation applicable for the frequency of the transmitter.</p> <p><b>Recommended separating distance:</b>  <math>d=1.2\sqrt{P}</math>  <math>d=1.2\sqrt{P}</math> 80 MHz to 800 MHz  <math>d=2.3\sqrt{P}</math> 800 MHz to 2.5 GHz</p> <p>P stands for the maximum output power of the transmitter in watts (W) according to the transmitter manufacturer, and d is the recommended separating distance in metres (m).</p> <p>Field strengths of HF transmitters determined according to an electromagnetic site survey<sup>a</sup> must be lower than the compliance level in every frequency range<sup>b</sup>.</p> <p>Interference may occur in the vicinity of devices that are marked with the following symbol: </p>
NOTICE 1: The higher frequency range applies at 80 MHz and 800 MHz. NOTICE 2: These directives may not apply in all situations. Electromagnetic propagation is influenced by absorption and reflection on buildings, objects and persons.			
<sup>a</sup> Field strengths of fixed transmitters, such as base stations for radio telephones (mobile radio/wireless) and land mobile radio, amateur radio, AM and FM radio, and television transmitters cannot be exactly determined theoretically. An electromagnetic site survey should be considered to evaluate the electromagnetic environment due to fixed HF transmitters. If the measured field strength at the location where the prosthetic foot is used exceeds the aforementioned applicable HF compliance level, the prosthetic foot must be observed during normal use. Should deviating performance be noted, additional measures may be required, for example realigning or repositioning the prosthetic foot.			
<sup>b</sup> Within the frequency range of 150 kHz to 80 MHz, the field strength must be less than 10V/m.			

Recommended separating distances between wearable and portable HF communication devices and the battery charger			
The battery charger is intended for use in an electromagnetic environment in which radiated HF interference can be controlled. The customer or user of the battery charger can help avoid electromagnetic interference by maintaining a minimum distance between wearable and portable HF communication devices (transmitters) and the battery charger, as recommended in the following, according to the maximum output power of the communication device.			
Maximum nominal output power of the transmitter (W)	Separating distance according to transmitter frequency (m)		
	150 kHz to 80 MHz $d=1.2\sqrt{P}$	80 MHz to 800 MHz $d=1.2\sqrt{P}$	800 MHz to 2.5 GHz $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3

<b>Recommended separating distances between wearable and portable HF communication devices and the battery charger</b>			
100	12	12	23
<p>For transmitters with a maximum nominal output power that is not listed above, the recommended separating distance (d) in metres can be calculated using the equation applicable for the frequency of the transmitter, where (P) is the maximum nominal output power of the transmitter in watts (W) according to the transmitter manufacturer.</p> <p style="text-align: center;">NOTICE 1: The higher frequency range applies at 80 MHz and 800 MHz.</p> <p>NOTICE 2: These directives may not apply in all situations. Electromagnetic propagation is influenced by absorption and reflection on buildings, objects and persons.</p>			









**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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