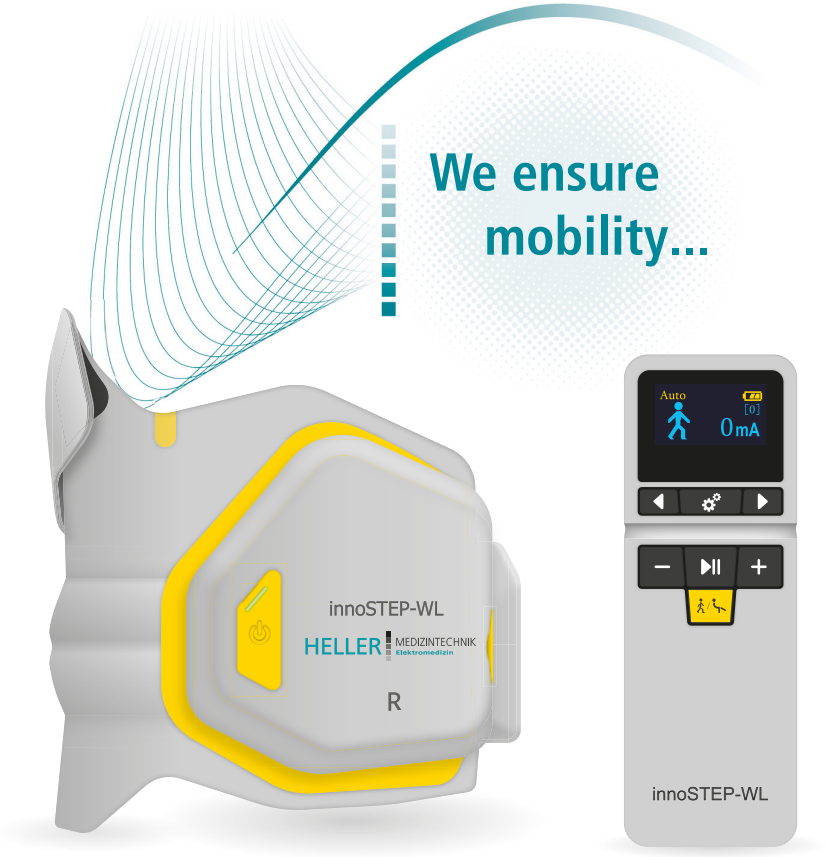
HELLER MEDIZINTECHNIK
Elektromedizin




# innoSTEP-WL
# The wireless foot drop system

## Instructions for use

HELLER MEDIZINTECHNIK
Elektromedizin

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**Please observe the instructions for use before starting the device and store them carefully!**

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# Contents



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## Scope of delivery

| Illustration | Description | Item number | Quantity |
|---|---|---|---|
|  | Stimulation unit | WL1001L (left) WL1001R (right) | 1 piece |
|  | Remote control | WL1002L (left) WL1002R (right) | 1 piece |
|  | Cuff with integrated electrodes | WL1003L (left) WL1003R (right) | 1 piece |
|  | Cuff for gel electrodes (not included in the standard delivery) | WL1004L (left) WL1004R (right) | 1 piece |
|  | Gel electrodes (not included in the standard delivery) | WL1005 | 1 pair |
|  | Charger including cable | WL1006 | 1 piece |
|  | Instructions for use | WL1007 | 1 piece |
|  | Equipment case | WL1008 | 1 piece |
|  | Water atomiser | WL1009 | 1 piece |



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# Information for your health and safety

## List of used symbols

| | |
|---|---|
|  | Contraindications |
|  | Warnings (please comply with these regulations!) |
|  | Type of protection BF (Body Floating) |
|  | Precautions |
|  | Instructions for use |
|   | Authorised EU representative |
|  | Non-ionising radiation |
|  | Manufacturer |
|  | Fragile - exercise caution when packing and transporting |
|  | Transport upright and pack upright |
|  | Protect from moisture and rain |
|  | Maximum stacking weight |
|  | Maximum stacking height |
|  | Do not dispose of in household waste |

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## Contraindications

- Patients with active implants (e.g. demand cardiac pacemaker, defibrillator or electronic metal implants) should not use the innoSTEP-WL.
- The device must not be used in sites where a tumour is present or where radiotherapy has been administered.
- The device should not be used if there are any signs of thrombosis.
- Patients suffering from epilepsy should not use the innoSTEP-WL.
- There is no information regarding the safe use of the innoSTEP-WL during pregnancy, so it should only be used after consulting the treating physician or gynaecologist.
- The innoSTEP-WL should not be used on a leg with a local injury, such as a fracture or dislocation, as the stimulated movement might be detrimental in such cases.
- The cuff must not be applied to swollen, infected or inflamed areas, skin rashes, venous inflammations, burns, thrombophlebitis or varicose veins.
- The device should not be used on a leg where other applications are taking place.
- Use of the device is contraindicated if the patient or the designated assistant is unable to recognise the risk, scope or principles of application and implementation.

## Warnings

- The use of the innoSTEP-WL may negatively impact on the faultless operation of electronic monitoring devices such as ECG devices.
- Please only use the original electrodes and cuffs supplied by the manufacturer; other electrodes may increase the risk of burns or discomfort. The cuffs and electrodes must not be used over open wounds, damaged skin or on skin covering metal parts such as surgical staples.
- Do not use the innoSTEP-WL within a radius of less than one metre from devices emitting radio waves, as some transmitter types can trigger unwanted stimulations.


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- Please do not use the device simultaneously with high-frequency medical devices (such as diathermy devices). This can cause burns around the electrodes and may damage the device.
- Improper or too frequent use of the electrodes may cause skin irritation and impair the effectiveness of the device. Rarely, allergic reactions to the adhesive or the gel of the electrodes may occur. Please do not attach the electrodes to already irritated or damaged skin. This increases the risk of discomfort or skin burns.
- The innoSTEP-WL should not be worn during an MRI examination or X-ray examinations.
- Like all devices used for functional electrical stimulation (FES), the innoSTEP-WL should only be used after consulting the treating physician.
- Using an external defibrillator with a patient wearing a FES device may result in damage to the device or injury to the patient even if the device is turned off. There is a potential risk of burns under the electrodes during defibrillation. To avoid this risk, the electrodes must be removed before defibrillation.
- Effects of long-term stimulation are unknown for this specific application.
- Any unauthorised repairs, conversions or modifications are not permitted for safety reasons and exclude any liability on the part of the manufacturer for any damages resulting thereof. Damage resulting from the use of replacement parts or accessories not approved by the manufacturer shall also exclude any further liability of the manufacturer.

## ⓘ Specific warnings

- Caution is advised for people with dizziness and balance problems. The innoSTEP-WL does not protect against a fall.
- The user should follow the instructions for positioning the electrodes inside the cuff. Please do not use the innoSTEP-WL without any electrodes, and only use it on the affected leg for which the device was prescribed.
- If the stimulation does not start when walking or if the sensation of the stimulation changes, stop using it.
- The innoSTEP-WL is not intended for use in flammable environments such as where oxygen or anaesthetics are used.
- The electrodes should be used only below the knee, on the leg for which the innoSTEP-WL has been prescribed.

## ⚠ Precautions

- Prior to using the innoSTEP-WL, a special approval should be obtained from the physician if a patient experiences any deviation of normal arterial or venous blood flow in the area of the cuff due to a local insufficiency, an occlusion, an arteriovenous fistula, or a primary vascular disease.
- Inflammation around the cuff can be aggravated by movement, muscular activity, or cuff pressure. The use of the innoSTEP-WL should be suspended until the inflammation has subsided.
- The cuff area may be subject to deterioration of skin problems.

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- In case of structural malformations of the leg, consult a physician before using the innoSTEP-WL.
- Please switch off the innoSTEP-WL before removing or replacing the electrodes.
- Protect all electronic parts to prevent contact with water.
- The recommended storage temperature for the innoSTEP-WL (-20 ° C to 60 ° C) must not be exceeded. Temperature extremes can damage the components.
- Please switch the power off before putting on the cuff. Do not turn on the unit until the cuff is properly fastened.
- In areas with reduced skin reaction to stimulation, care should be taken to avoid burns.
- The innoSTEP-WL should be kept out of the reach of children.
- Caution should be exercised in persons suspected of having epilepsy or heart disease. Due to a lack of extensive investigations on the subject, adverse reactions can not be ruled out. If necessary, please contact your treating physician.
- The innoSTEP-WL should not be used after surgery if muscular contractions might affect the healing process.
- Please do not apply lotion or oil to the skin around the electrodes; this may reduce stimulation.
- The safety and effectiveness of the innoSTEP-WL depend on the correct use of the device. Improper use of the device or electrodes may result in patient injury. Regularly inspect accessories for wear and tear and replace if necessary. The electrodes should be firmly attached to the skin.
- If you suspect a malfunction, please stop using the innoSTEP-WL. If there should be any changes in normal functioning (such as changes in perception, fluctuations in stimulation), please contact your doctor or HELLER MEDIZINTECHNIK GmbH & Co. KG immediately.
- The innoSTEP-WL must not be used while driving or operating machines, or when sleeping or bathing.
- The use of heat or cold generating equipment such as electric blankets, heat pads or cold pads may affect the patient's blood circulation and increase the risk of injury. Prior to simultaneous use with the innoSTEP-WL, a physician should be consulted.
- Electrical medical devices require special care with regard to their electromagnetic compatibility (EMC). This product complies with the standard ISO 60601-1-2 of the EMC.
- If you experience technical problems that are not described in the operating instructions, please do not try to repair the device yourself. Please contact HELLER MEDIZINTECHNIK GmbH & Co. KG.


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## Side effects

- In the unlikely event that any of the following reactions occur, the patient should discontinue treatment with the innoSTEP-WL immediately and contact the physician:
  - Signs of significant, painful skin irritation or pressure points on the areas of contact between the cuff and the skin
  - Significant increase in muscle spasms
  - Sensation of cardiac stress during stimulation
  - Swelling of the knee, leg, ankle or foot
  - Any other unexpected reaction
- Skin irritation may be caused by functional electrostimulation. Please observe the recommended application times (see page 27).
- After removing the cuff, it is normal for the skin under the electrodes to appear reddened and indented. The redness should disappear within about an hour. Persistent redness, injuries or blisters indicate skin irritation. The use of innoSTEP-WL should be suspended until all the inflammation has completely subsided. Please inform your doctor if the condition persists and discontinue use of the innoSTEP-WL until the problem is resolved.

## Beware

- Always use the innoSTEP-WL according to the specific instructions of your doctor.
- Do not use the innoSTEP-WL in situations where unexpected or unusual stimulations may occur, such as when driving a car or operating a motorised device.
- Do not use the innoSTEP-WL if any cables are damaged or broken.
- Please protect the remote control from excessive impact. This also includes the application of force by hard surfaces.
- Do not drop the device. This can lead to damages that affect the function of the device.
- The innoSTEP-WL contains no parts that can be serviced by the user or medical staff.
- Please switch the device off if you are going to be sitting down for a prolonged period of time.

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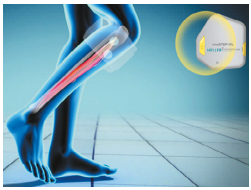
# Presentation of your innoSTEP-WL foot drop system

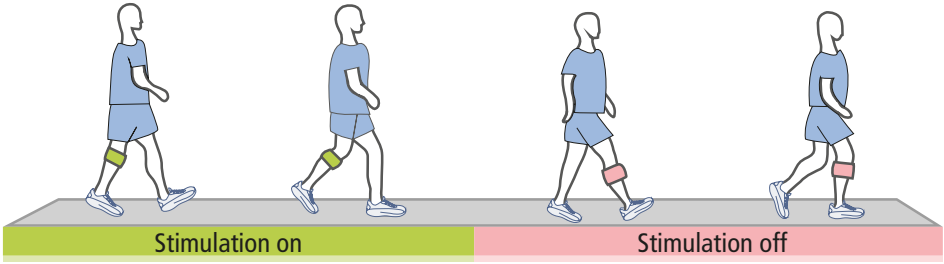
## 1. Introduction

The innoSTEP-WL is a state-of-the-art functional electrical stimulation (FES) device used in patients with drop foot and has a significantly positive impact assisted by technologies including gyroscopes, accelerometers and information transfer via Bluetooth. Affected patients with drop foot caused by central nervous system injuries, such as stroke, spinal cord injury, traumatic brain injury, cerebral palsy or multiple sclerosis, may benefit from the device.



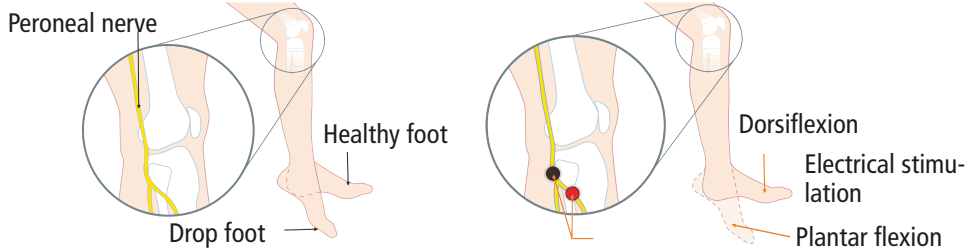
## How does the innoSTEP-WL foot drop system work?

The innoSTEP-WL uses advanced MEMS sensor technology and intelligent algorithms that precisely control the time and duration of electrical stimulation by measuring the flexion angle and pace speed using the built-in gyroscope (goniometer) and accelerometer.




When the leg is inclined backwards and reaches a certain angle, the stimulation is triggered.

Electrodes deliver impulses to the peroneal nerve, the tibialis anterior muscle, and other muscles involved in foot elevation (dorsiflexion and eversion). As a result, while walking the foot is raised during the swinging phase so that the patient can walk in a stable, natural and secure manner. The repeatedly transmitted impulses are perceived by nerve structures located in the brain and spinal cord (CNS) and are managed and processed as motor stimuli. This can result in improved gait and thereby greater mobility and better quality of life. In addition, it can also lead to a stable neuronal re-organisation and thereby an improvement in drop foot syndrome.



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## 2. Range of applications

- Foot drop/peroneal palsy
- Multiple sclerosis
- Apoplexy (stroke)
- Craniocerebral trauma (SHT)
- Spastic hemiparesis/cerebral palsy
- Peripheral and central nervous system damage
- Incomplete paralysis of the lower leg muscles
- Centrally-related paralysis of the leg muscles
- Peripherally-related paralysis as a result of accidents
- Herniated disc/spinal cord injuries
- Parkinson's syndrome

## 3. Functions and features

- Ergonomic and modern design of stimulation unit and cuff
- Easy handling
- Stable and reliable data transmission via Bluetooth 4.0
- Automatic adaptation to the gait pattern
- Cuff available with integrated electrodes or click gel electrodes
- Automatic switch-off at low voltage or after 30 minutes in standby mode
- Gait and training mode available
- The flat design offers great comfort - the device can be worn underneath clothing
- Without heel switch - can also be used barefoot

## 4. Application time

| Duration | Gait mode | Training mode |
|---|---|---|
| First week | 15 to 60 minutes daily | 20 minutes in the morning and evening |
| Second week | Walking 1 - 4 hours daily | 20 minutes in the morning and evening |
| Third and following weeks | Walking 4 - 9 hours daily | 20 minutes in the morning and evening |

**For details about the recommended application times, please refer to the table on page 27.**

**Please remove the cuff for 15 minutes after each use.**

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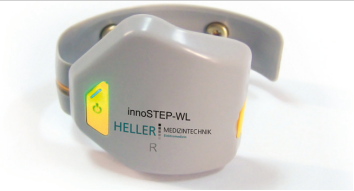
# Components of the innoSTEP-WL

## 1. Components

| | |
|---|---|
|   | Stimulation unit |
|  | Remote control |
|  | Cuff with integrated electrodes |
|  | (not included in the standard delivery)<br>Cuff for gel electrodes |
|  | (not included in the standard delivery)<br>Gel electrodes |
|  | Charger incl. USB charging cable |



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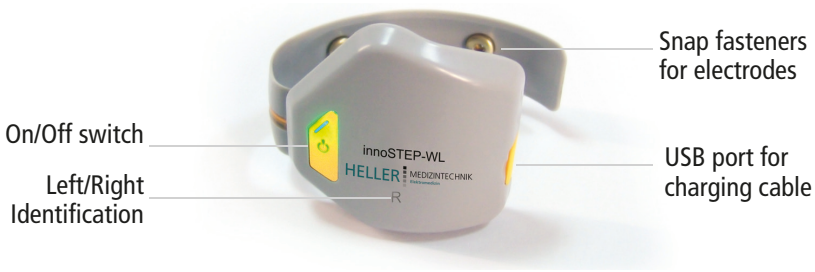
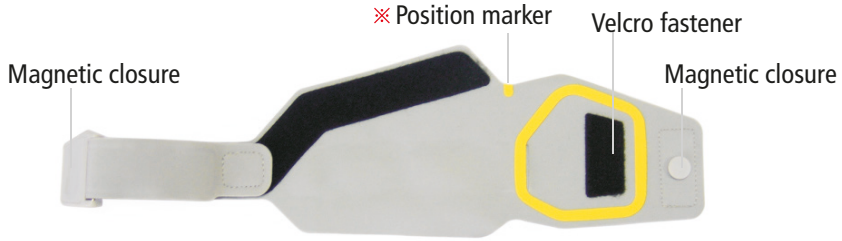
## 2. Stimulation unit and cuff

### Stimulation unit

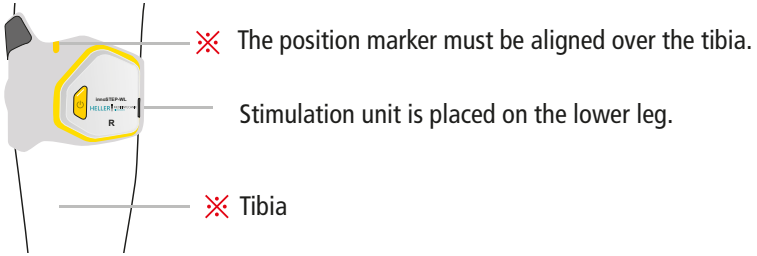



| | |
|---|---|
| On/Off switch: | Press and hold for one second to turn on the stimulation unit, the indicator turns green. To switch off, press again for one second. |
| Left/Right: | "L" for left leg, "R" for right leg. |
| USB port: | To charge the device. If the battery is completely drained, charging will take approx. 3 hours. The device is designed to run for 10 hours when fully charged. |
| Snap fasteners: | For connecting the cuff/gel electrodes to the stimulation unit. |

### Cuff




| | |
|---|---|
| Cuff: | The cuff serves to attach the stimulation unit to the leg. |
| Magnetic closure: | This allows attachment to the leg with only one hand. |
| Position marker: | Place the yellow position marker below the knee, aligned with the tibia. |
| Velcro fastener: | For attaching the stimulation unit to the cuff. |

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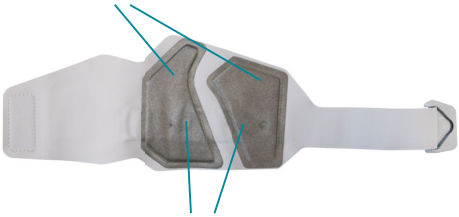
## 3. Electrodes

### Cuff with integrated electrodes

The cuff with integrated electrodes is an optimal solution for most patients: The placement of the flat tissue electrodes on the inside is optimised for stimulating the peroneal nerve, and the cuff can be attached to the leg easily, quickly and without the help of others. Please moisten the integrated tissue electrodes before every use, using the water atomiser.

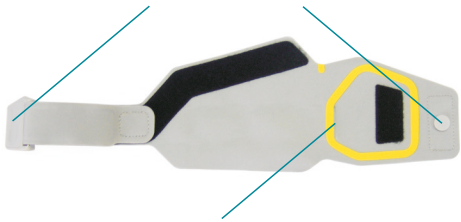
Tissue electrodes



Recessed
Snap fasteners

**Internal face**

Magnetic closure



Opening for introducing the
tongue of the stimulation unit

**External face**

### Gel electrodes

Gel electrodes are fixed in the inside of the cuff using the snap fasteners. Gel electrodes are placed on the leg according to the instructions (see page 18: Use of gel electrodes).

Gel electrodes

Cuff for
Gel electrodes



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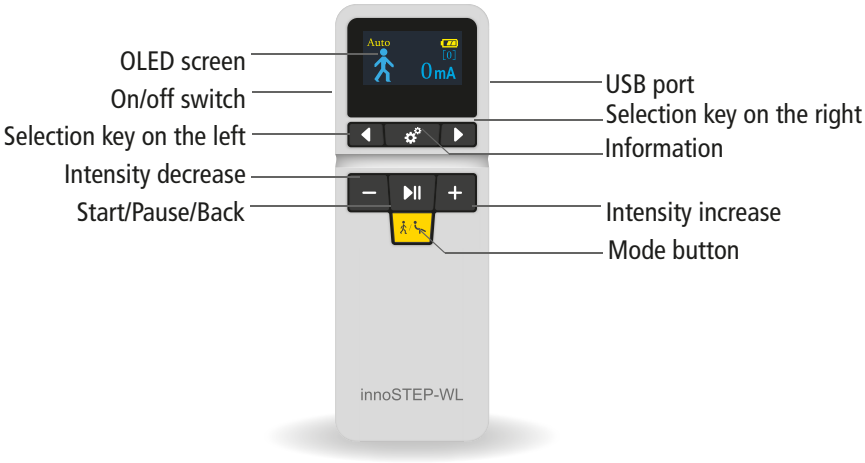
## 4. Remote control




### Buttons

| | |
|---|---|
| | On/off switch: Press for one second to turn the remote on. To switch off, press again for one second. |
| | Information: Press the button to view the battery charge levels of the remote control, the stimulation unit, and the pedometer. |
| | Start/Pause: Press the button to start or pause the stimulation. |
| | Mode button: Switch between gait mode and training mode. |
| | Right/Left: Switch between the different information panes. |
| | Intensity increase/decrease: Adjust intensity of stimulation. |
| | USB port: For charging the device and for software updates. |

### OLED screen

| | |
|---|---|
| | Charge indicator: In the upper right corner of the screen there is a dynamic charging indicator. When the battery icon is filled, the device is fully charged. |
| | Gait mode: This symbol appears in gait mode. |
| | Training mode: This symbol appears in training mode. |
| | Flash symbol: Appears on the display with every stimulation triggered. The flash symbol only disappears when the current stimulation has ended. |

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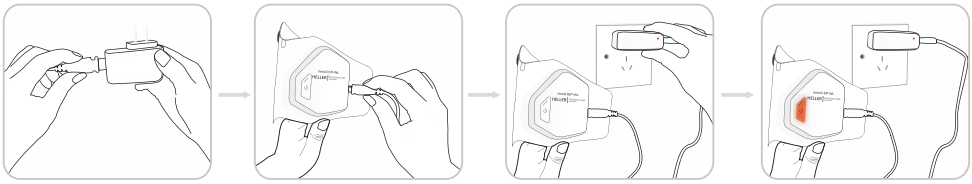
# Daily use of the innoSTEP-WL

## 1. Charging of the stimulation unit

If the stimulation unit indicates a low battery level, please connect it with the USB cable to the main adapter, and then connect the adapter to an electrical outlet. The stimulation unit display turns red when the device is charging and turns green when the device is charged.

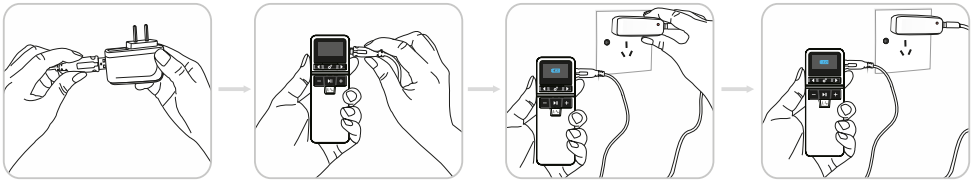
If the stimulation wears off during use or the "low battery" symbol appears on the screen, please charge the unit immediately. It takes about 3 hours to charge when completely drained. The unit is designed to run for 10 hours when fully charged. Please switch off the device when not in use. You can determine the battery charge level of the stimulation unit by pressing the information button.



**Note: Please do not use the device while it is being charged.**

## 2. Charging of the remote control

If the stimulation unit indicates a low battery level, please connect it with the USB cable to the main adapter, and then connect the adapter to an electrical outlet. The dynamic charging icon appears on the display while the device is charging. When the battery icon is filled, the device is fully charged. The operating time of the remote control is 2-3 days when fully charged. You can determine the battery charge level of the remote control by pressing the information button.



**Note: Please do not use the remote control while it is being charged.**



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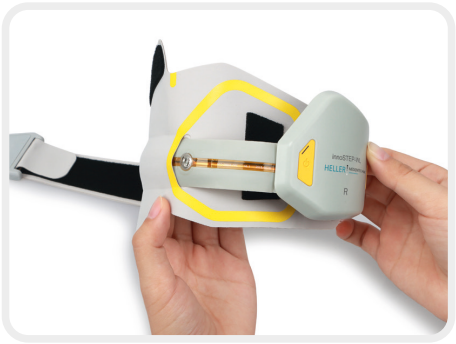
## 3. Using the cuff with integrated electrodes

To ensure a better functional electrical stimulation effect, carefully cleanse the skin of dirt, grease, creams, lotion, etc. before attaching the electrodes. Before attaching the cuff to the leg, moisten the tissue electrodes with water using the water atomiser.

### Attach the stimulation unit to the cuff with integrated electrodes

1. Grasp the cuff that matches the stimulation unit being used (right cuff for the right stimulator and vice versa).



2. Carefully guide the tongue of the stimulation unit with its snap fasteners into the opening on the outside of the cuff.

3. Seal the velcro fastener between the cuff and the stimulation unit.

4. Feel out and press the snap fasteners on the internal face of the cuff to connect it to the stimulation unit.

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## Wearing the cuff

1. Moisten tissue electrodes with water prior to use with the atomiser provided. This can be done after or before attaching the stimulation unit (see page 15).

2. The positive electrode (anode / +) is placed on the tibial muscle (m. tibialis anterior), while the negative electrode (cathode / -) is placed on the peroneal nerve at the fibular head.

3. Attach the cuff below the knee so that the yellow position marker is in line with the tibial bone. It is not absolutely necessary to remove the hair in this area.

3. Close the cuff. From time to time, remove the cuff so that the skin underneath can breath.

## Removal of the cuff

1) Make sure the stimulation unit is turned off.
2) Release the magnetic closure and carefully remove the cuff with the stimulation unit.
3) Air dry the cuff with the integrated electrodes after use.
4) Store the device, cuff and remote control safely in the supplied equipment case.



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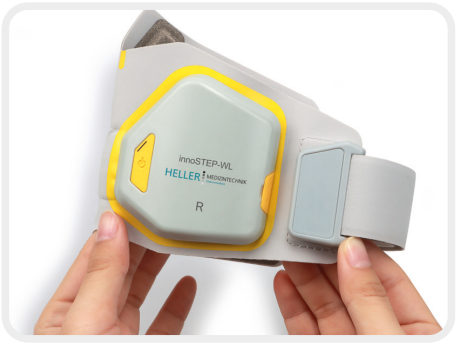
## Detach the stimulation unit from the cuff with integrated electrodes

After use, switch off the stimulation unit before removing it from the leg. Allow the cuff to dry before storing it securely in your equipment case, alsongside with the remote control and stimulation unit.

You must remove the cuff with integrated electrodes from the stimulation unit and attach the cuff intended for use with the gel electrodes if you want to use these gel electrodes.




1. To remove the cuff, turn off the stimulation unit and remove it from the leg.

2. Carefully feel out the snap fasteners with your fingers and then gently undo the fasteners with your fingernails.

3. Unfasten the velcro fastener to release the stimulation unit and cuff.

4. Gently pull the tongue of the stimulation unit out of the cuff.

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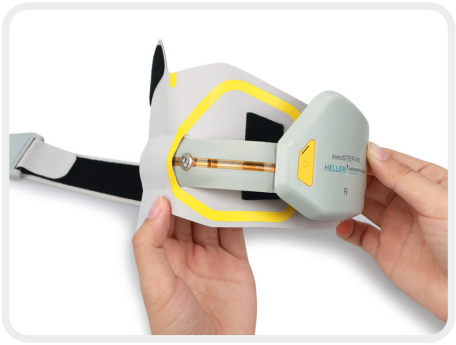
## 4. Using the gel electrodes

To use the gel electrodes, you must first connect the cuff intended for the use of the gel electrodes. The cuff can be recognised by the black and red marked openings on the inside of the cuff.

### Connecting the stimulation unit with the gel electrodes and placement on the leg

1. Grasp the cuff that matches the stimulation unit being used (right cuff for the right stimulator unit and vice versa).



2. Carefully guide the tongue of the stimulation unit with its snap fasteners into the opening provided on the outside of the cuff.

3. Seal the velcro fastener between the cuff and the stimulation unit.

4. Attach the gel electrodes to the skin and then connect the red electrode (anode / +) with the snap fastener marked red and the black electrode (cathode / -) with the black marked fastener.



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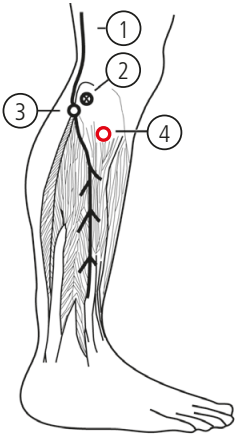
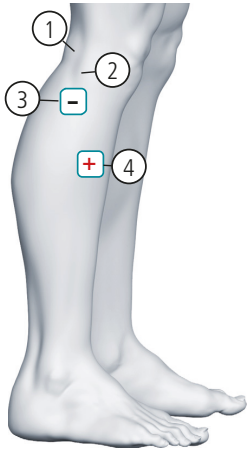
## Connecting the gel electrodes with the stimulation unit and placement on the leg

In the first step, the gel electrodes are attached to the lower leg of the affected limb. Before attaching the electrodes, carefully cleanse the skin of dirt, grease, creams, lotion, etc. This is how to locate the correct point for gel electrode placement:

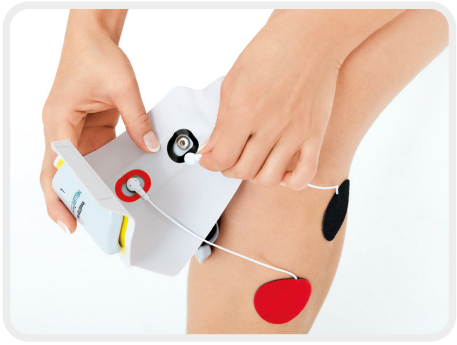



1. Peroneal nerve
2. Fibular head
3. "-" Cathode: black electrode
4. "+" Anode: red electrode




Example of fitting an electrode to the peroneal nerve

Feel for a bump on the outside of the knee of the affected leg. This is the fibula head (see picture). The peroneal nerve runs directly below the fibular head. This is where the black electrode should be placed. The red electrode is then placed on the tibialis anterior muscle. Attach the gel electrodes to the skin.



Then connect the snap fasteners to the stimulation unit. Note that the red electrode must be attached to the red snap fastener and that the black electrode must be attached to the black snap fastener.

Attach the cuff below the knee so that the yellow position marker is in line with the tibial bone and then close the cuff. Please remove the cuff from time to time to allow the skin to breath.

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## Gait mode

In gait mode, you can actively promote rehabilitation during walking by applying functional electrical stimulation (FES).

### Use of the stimulation unit as a walking aid/ for functional electrical stimulation

#### 1) Fitting

Place the cuff on the leg below the knee while seated
(see page 16).

#### 2) Select gait mode

Switch on the stimulation unit and the remote control and press it to select gait mode.

#### 3) Adjustment of the intensity

Press Start / Pause on the remote and set the desired level of intensity with + or −.

#### 4) Walk

Get up and take a first step with your healthy leg.
While walking, you can change the intensity level using + or −.



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## Training mode

The training mode is suitable for patients who have no opportunity to undergo active training while walking. The patient sits or lies down during the training.

### Use of the stimulation unit in training mode

**1) Fitting**

Place the cuff on the leg below the knee while seated
(see page 16).

**2) Select training mode**

Switch on the stimulation unit and the remote control and press on the remote to select training mode.

**3) Start training**

Press Play/Pause to start the training.

**4) Adjustment of the intensity**

You can press + or − to adjust the intensity.

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# Care and maintenance

## 1. Stimulation unit

The stimulation unit can be carefully cleaned using a damp cloth. However, the electrical components are not waterproof, so please refrain from immersing them in water.

## 2. Cuff for gel electrodes

The cuff can be washed using a gentle washing machine cycle.

## 3. Gel electrodes

When not in use, the gel electrodes should always be stuck to the round carrier foils and stored in a cool and dry place. This will allow the life of the gel electrodes to be extended. If it becomes necessary, the gel electrodes should be replaced.

## 4. Cuff with integrated tissue electrodes

- The cuff with integrated electrodes can be washed using a gentle washing machine cycle. Excessively frequent washing, folding or bending of the conductive material should nevertheless be avoided, as this might damage the adhesive layer connecting it to the cuff.
- The lifetime of the electrode integrated cuff varies depending on the user, and it should be replaced as required.
- For disinfection purposes, the cuff can be carefully cleaned under running water using a mild detergent. Please do not use laundry detergent or hot water.
- Please dry the skin before applying the electrode (e.g. after showering or exercising).
- Do not share electrodes with other users.
- Allow the electrode to air dry and store it safely in the equipment case when not in use.
- Moisten tissue electrodes with water prior to every use with the atomiser provided.

## 5. Storage:

If you do not need to use the innoSTEP-WL system, please place the components (cuff, remote control and stimulation unit) in the supplied equipment case for storage. The temperature during storage should be between 0 ° C and 40 ° C to prevent the electrodes from drying out. If the innoSTEP-WL is not used, the device should be switched off to save the battery.

**Disposal: Please observe the local and national regulations.**


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# Frequently Asked Questions

### 1. Weak stimulation

a. Increase the intensity level using the remote control.
b. If the battery charge is low, please recharge it.
c. Correct the position of the electrode or replace the electrode.
d. For better conductivity, moisten the tissue electrodes sufficiently with water.

### 2. The foot does not rise, and no stimulation is present.

a. Check if the electrode is properly connected to the cuff.
b. Change the position of the gel electrodes or the electrode integrated cuff.
c. Moisten the tissue electrodes on the cuff again.
d. Use gel electrodes instead of the electrode integrated cuff.

A non-occurrence of the desired dorsiflexion (upward flexion of the foot) may be indication-dependent and determined by the extent to which the peroneal nerve is damaged. The application should nevertheless be continued, since the stimuli are perceived by the central nervous system and a time-delayed improvement of the drop foot syndrome is still possible.

### 3. The skin under the electrode turns red.

A slight reddening of the skin may occur due to the circulation-stimulating effect of the electrical stimulation. In case of permanent and painful skin irritation, discontinue use until the skin recovers. Remove the cuff regularly to allow the skin to breathe and apply the recommended usage times (see page 27).

### 4. The display of the stimulation unit turns red and flashes,  battery charge appears on the display of the remote control.

Recharge both, the stimulation unit and the remote control.

### 5. The stimulation unit indicator turns red and flashes,  appears on the remote control display.

This indicates that the electrode is not connected properly. Press on the snap fasteners. Moisten the tissue electrodes if they have become too dry.

### 6. Inexplicably strong intensity.

a. The electrode is worn, so please replace it with a new electrode.
b. The electrode is too dry, so please moisten the tissue electrode again.
c. Please check if the skin under the electrode is severely reddened or injured.
d. Check that the electrode rests well on the skin, that the cuff is properly fastened, and that its position is correct.

### 7. Calibration - the stimulation unit light flashes red and green at the same time.

If the device flashes red and green at the same time, a calibration needs to be carried out. Switch off the stimulation unit and the remote control, remove the gel electrodes and fix the cuff with the stimulation unit vertically against a cylindrical object, such as a water bottle. Make sure the yellow marking is at the top. Press the power button for two to three seconds, so that the unit can automatically calibrate itself. After calibration, the stimulation unit will automatically turn off. The next time it is switched on, the device can then be used normally again.

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# Technical specs for innoSTEP-WL

## Stimulation unit

| | |
|---|---|
| MEMS | Micro-Electro-Mechanical-Systems |
| Data transfer | Bluetooth 4.0 |
| Angle measurement | Gyroscope |
| Speed measurement | Accelerometer |
| Frequency band | 2.4-2.4835 GHz |
| Power supply | DC3.7V, 480mAh, rechargeable lithium battery |
| Classification | Type BF device |
| Deactivation current | < 10 µA |
| Protection type | IP22 |
| Working current | < 110 mA |
| Waveform | Asymmetric, rectangular, biphasic pulse |
| Frequency | 16.7-33 Hz (± 10%) |
| Pulse width | 100-300 µs (± 10%) |
| Output current<br>Output voltage | 0 - 90 mA (resistance: 500 Ω)<br>90 V at maximum setting (resistance: 1000 Ω) |
| Dimensions | 73 × 70 × 10 mm |
| Weight: | 43 g |
| Risk category | IIa according to Directives 93/42 EEC |

## Cuff

| | |
|---|---|
| Dimensions | 495 × 117 × 2 mm |
| Weight | 40 g |

## Remote control

| | |
|---|---|
| Power source | DC 3.7 V, 480 mAh, rechargeable lithium battery |
| Deactivation current | < 10 µA |
| Working current | < 50 mA |
| Dimensions | 107 × 38 × 11 mm |
| Weight | 39 g |
| Range | 0-10 m |



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## Cuff with integrated electrodes

| | |
|---|---|
| Material | Lycra and conductive fabric |
| Storage | Temperature: - 5 °C to 40 °C<br>Humidity: < 80 %<br>Pressure: 70 - 106 kPa |

## Operating and storage conditions for the stimulation unit and the remaining parts:

| | |
|---|---|
| Operation | Temperature: - 5 °C to 40 °C<br>Humidity: < 80 %<br>Pressure: 86 - 106 kPa |
| Storage | Temperature: - 20 °C to 55 °C<br>Humidity: < 93 %<br>Pressure: 70 - 106 kPa |

## Glossary of Terms

## Foot anatomy: Terms/Explanations/Foot Contractions with Functional Electrical Stimulation (FES)

| | |
|---|---|
| Dorsiflexion | Contraction/movement of the foot upwards at the ankle joint towards the back of the foot |
| Plantar flexion | Contraction/movement of the foot downwards at the ankle towards the sole of the foot |
| Supination | "Bent back" position of the foot (outward rotation, rotation or elevation of the inner edge of the foot with simultaneous lowering of the outer edge or elevation of the medial edge) |
| Pronation | Rotation of the foot around its longitudinal axis, in which the outer edge of the foot is raised, the inner edge is lowered and the lateral edge is raised) |
| Eversion | Combined movement of abduction, dorsiflexion, pronation (foot tilts to the lateral side) |
| Inversion | Combined movement of adduction, plantar flexion and supination (foot tilts to the medial side) |

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## Glossary of terms (continuation)

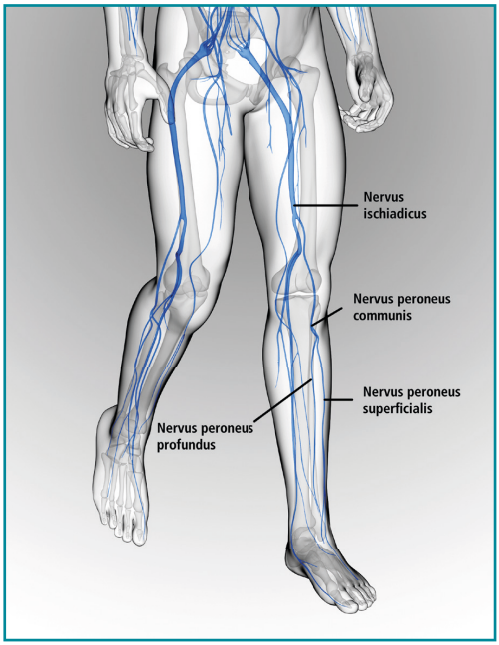
| | |
|---|---|
| Adduction | Lateral withdrawal (foot tilts in the medial direction) - counter-motion to abduction. Here, the leg or foot distant from the body is brought closer to the body. |
| Abduction | Lateral advance (foot tilts in the lateral direction) - countermotion to adduction. Here, the leg or foot distant from the body is guided further away from the body. |
| Lateral | Laterally away from the centre of the body. |
| Medial | Orientated towards the middle of the body. |

### Innervation:

Functional supply of a body part or tissue with nerve tissue, nerve cells and nerve fibres. Innervation serves to control body processes through exertion (stimulation) and stimulus perception. Motor innervation (control of movement processes by nerves).

### Tibialis anterior muscle:

The anterior tibial muscle (ankle/front tibial muscle) is innervated by the deep fibular nerve (deep peroneal nerve), which receives its fibres from the L4 and L5 nerve roots via the common peroneal nerve, the sciatic nerve and the lumbosacral plexus.





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## Recommended application times

**1. Week**

| Day | Walking with device | Training mode | |
|---|---|---|---|
| 1 | 15 min | 20 min | During the first week the cuff should only be worn for 1 - 2 hours during the whole week. It is recommended to schedule the wearing time of the innoSTEP-WL uniformly throughout the day (morning, midday or evening). |
| 2 | 20 min | | |
| 3 | 25 min | | |
| 4 | 30 min | | |
| 5 | 40 min | | |
| 6 | 50 min | | |
| 7 | 60 min | | |

**2. Week**

| Day | Walking with device | Training mode | |
|---|---|---|---|
| 1 | 1 hour | 20 min | During the second week the cuff should only be worn for 2 - 4 hours during the whole week. |
| 2 | 1.5 hours | | |
| 3 | 2 hours | | |
| 4 | 2.5 hours | | |
| 5 | 3 hours | | |
| 6 | 3.5 hours | | |
| 7 | 4 hours | | |

**3. Week**

| Day | Walking with device | Training mode | |
|---|---|---|---|
| 1 | 4 hours | 20 min | It is recommended to remove the cuff for at least 15 minutes after 4 hours of use to give the skin time to recover. |
| 2 | 5 hours | | |
| 3 | 6 hours | | |
| 4 | 7 hours | | |
| 5 | 8 hours | | |
| 6 | 9 hours | | |
| 7 | all-day | | |

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## Electromagnetic compatibility

Declaration of Conformity according to R & TTE Directive 1999/5 / EC

The Bluetooth module in the innoSTEP-WL complies with the essential requirements and other relevant provisions of Directive 1999/5 / EC.

The following standards were met during the assessment of the product for compliance with Directive 1999/5/EC:

Radio spectrum: ETSI EN 300 328 V1.8.1 (2012-06)
EMC: ETSI EN 301 489-1 V1.9.2 (2011-09) ETSI EN 301 489-17 V2.2.1 (2012-09)
Safety: EN 60950-1:2006 + A11:2009 + A1:2010 + A12:2011 + A2:2013
Health: EN 62479:2010

Number of the notified body 1313

## Manufacturer's Declaration - Electromagnetic Emissions

The device is intended for use in the electromagnetic surroundings specified below. The customer or the user of the device should ensure that it is used in such surroundings.

| Emission measurements | Compliance | Electromagnetic environment - guidelines |
|---|---|---|
| RF emissions according to CISPR 11 | Group 1 | The device uses RF energy only for internal functions. Therefore, the RF transmission is very low and it is unlikely that neighbouring electronic devices will be interfered with. |
| RF emissions according to CISPR 11 | Class B | The device is intended for use in all facilities, including residential areas and those directly connected to a public power supply network that also supplies buildings used for residential purposes. |
| Harmonics according to IEC 61000-3-2 | Class A | |
| Voltage fluctuations / flicker according to IEC 61000-3-3 | Compliant | |


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## Electromagnetic compatibility

| Immunity to electromagnetic interference tests | IEC 60601 test level | Compliance level | Electromagnetic environment - guidelines |
|---|---|---|---|
| Electrostatic discharge (ESD) according to IEC 61000-4-2 | ± 6 kV contact discharge<br>± 8 kV air discharge | ± 6 kV contact discharge<br>± 8 kV air discharge | Floors should be made of wood, concrete or ceramic tiles. If the floor is covered with synthetic material, the relative humidity must be at least 30%. |
| Electrical fast transient interference / bursts according to IEC 61000-4-4 | ± 2 kV for power cables<br>± 1 kV for input and output lines | ± 2 kV for power cables | The quality of the power supply voltage should be that of a typical business or hospital environment. |
| Surges according to IEC 61000-4-5 | ± 1 kV push-pull voltage<br>± 2 kV common mode voltage | ± 1 kV push-pull voltage<br>± 2 kV common mode voltage | The quality of the power supply voltage should be that of a typical business or hospital environment. |
| Voltage dips, short interruptions and voltage variations according to IEC 61000-4-11 | < 5% $U_T$<br>(> 95% dip of $U_T$)<br>for ½ period<br>40% $U_T$<br>(60% dip of $U_T$)<br>for 5 periods<br>70% $U_T$<br>(30% dip of $U_T$)<br>for 25 periods<br>< 5% $U_T$<br>(> 95% dip of $U_T$) for 5 s | < 5% $U_T$<br>(> 95% dip of $U_T$)<br>for ½ period<br>40% $U_T$<br>(60% dip of $U_T$)<br>for 5 periods<br>70% $U_T$<br>(30% dip of $U_T$)<br>for 25 periods<br>< 5% $U_T$<br>(> 95% dip of $U_T$) for 5 s | The quality of the power supply voltage should be that of a typical business or hospital environment. If the user of the device requires continuous function even in the event of power interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery. |
| Magnetic field at the power supply frequency (50/60 Hz) according to IEC 61000-4-8 | 3 A/m | 3 A/m | Mains frequency magnetic fields should correspond to those typical for those found in business and hospital environments. |
| Annotation: $U_T$ is the AC mains voltage before application of the test level. | | | |

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## Electromagnetic compatibility

| Immunity to electromagnetic interference tests | IEC 60601 test level | Compliance level | Electromagnetic environment - guidelines |
|---|---|---|---|
| Conducted RF disturbances according to IEC 61000-4-6 | 3 $V_{eff}$<br>150 kHz to 80 MHz | 3 $V_{eff}$ | Portable and mobile RF communications equipment should not be used closer to any part of the innoSTEP-WL or its cables than the recommended distance, which can be calculated using the equation used for the frequency of the transmitter.<br>$d = 1.2 \sqrt{P}$<br>$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz<br>$d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz<br>where P is the nominal power of the transmitter in watts (W) as specified by the transmitter manufacturer and d is the recommended safety distance in metres (m). The field strength of stationary radio transmitters (a) is lower than the compliance level (b) at all frequencies according to an on-site investigation. In the vicinity of devices bearing the following symbol, disturbances are possible:  |
| Radiated RF disturbance according to IEC 61000-4-3 | 3 V/m<br>80 MHz to 2.5 GHz | 3 V/m | |

Remark 1: At 80 MHz and 800 MHz, the higher value applies.
Note 2: These guidelines may not apply in all situations. The propagation of electromagnetic waves is influenced by their absorption by and reflection from buildings, objects and people.

a) The field strength of stationary transmitters such as base stations for radio or cellular telephony, amateur stations, AM and FM radio and television stations, can not be accurately predicted from a theoretical perspective. In order to assess the electromagnetic environment resulting from stationary RF transmissions, an examination of the location is recommended.
If the detected field strength at the location of the device exceeds the compliance level specified above, the device must be assessed for normal operation at each point that it is used. If any unusual performance characteristics are observed, it may be necessary to take additional measures, such as to reorient or reposition the device.

b) Over the frequency range from 150 kHz to 80 MHz, the field strength is less than 3 V/m.


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## Recommended safety distances between portable and mobile RF communications equipment and the innoSTEP-WL

The device is intended for use in electromagnetic environments in which radiated RF disturbances can be controlled. The customer or user of the device may help to prevent electromagnetic interference by complying with minimum safety distances between portable and mobile RF communications equipment (transmitters) and the equipment as recommended below according to the maximum output power of the communications equipment.

| Rated power of the transmitter (W) | Safety distance according to the transmission frequency (m) | | |
|---|---|---|---|
| | 150 kHz to 2 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 | 0.37 | 0.37 | 0.74 |
| 1 | 1.17 | 1.17 | 2.34 |
| 10 | 3.69 | 3.69 | 7.38 |
| 100 | 11.67 | 11.67 | 23.34 |

For transmitters whose rated power is not given in the above table, the spacing can be determined using the equation associated with each column, where P is the transmitter's rated power in watts (W) as specified by the transmitter manufacturer.

Note 1: Over the frequency range from 80 MHz to 800 MHz, the protective spacing applies to the respective higher transmission frequency.

Note 2: These guidelines may not apply in all situations. The propagation of electromagnetic waves is influenced by their absorption by and reflection from buildings, objects and people.

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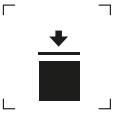
## Packaging and transport requirements

Exercise caution when packing and transporting
Fragile

Transport upright and pack upright
Stand upright

Protect from moisture and rain
No rain



Maximum stacking weight 80 kg
Maximum stacking weight

Stack at most SIX layers on top of each other
Maximum stacking height

Produced for:
HELLER MEDIZINTECHNIK GmbH & Co. KG
Europaplatz 2, D-35619 Braunfels, Germany
www.heller-medizintechnik.de



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## Nameplate

The nameplate on the rear panel contains important information about the unit, model, serial number, power supply, and precautions.

| | |
|---|---|
| Product Name: | Nerve and Muscle Stimulator (Foot Drop System) |
| Model: | XFT-2001D |
| Input Voltage: | DC 3.7V, rechargeable battery |
| Classification: | Type BF Equipment |
| Protection Grade: | IP22 |
| Max. Pulse Voltage: | 90V Frequency: 16.7~33Hz |

Shenzhen XFT Medical Limited
Room 203, Building 1, Biomedicine Innovations Industrial Park,
#14 Jinhui Road, Pingshan New District, Shenzhen, China

EC REP ShangHai International Holding Corp. GmbH (Europe)
Eiffestrasse 80 D-20537 Hamburg Germany

CE 0123 Please read the manual carefully before use.

Please do not remove the nameplate.

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## Manufacturer

Shenzhen XFT Electronics Co., Ltd.

Room 203, Building 1, Biomedicine Innovations Industrial Park, # 14 Jinhui Road, Pingshan New District, Shenzhen, China.

CE 0123

EC REP

## Representation in the EU

Shanghai International Holding Corp. GmbH (Europe)

Eiffelstrasse 80, 20537 Hamburg, Germany

## Distributed by

HELLER MEDIZINTECHNIK
Elektromedizin

HELLER MEDIZINTECHNIK GmbH & Co. KG

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nach § 126 SGB V
PRÄQUALIFIZIERT
durch die DGP®



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## Declaration of conformity

The innoSTEP-WL conforms to the following standards:

EN 60601-1-2: 2007 and
EN 60601-1: 2006 + A12: 2012 and
EN 60601-2-10: 2012

# Declaration of Conformity

**Manufacturer :**

**Shenzhen XFT Medical Limited.**

**Room 203, Building 1, Biomedicine Innovations Industrial Park, #14 Jinhui Road, Pingshan New District, Shenzhen, China.**

**EC- Representative:**

**Shanghai International Holding Corp. GmbH(Europe)**

**Eiffestraße 80, 20537 Hamburg Germany**

**Product Category(ies):**

**Nerve and Muscle Stimulator**

**Product Model:**

**XFT-2001、XFT-2001D**

**Classification (MDD, Annex IX-Rule9):**

**IIa**

We herewith declare that the above mentioned products meet the provisions of the EC Directive 93 / 42 / EEC which apply to them, as stated in Annex V of this directive. All supporting documentations are retained under the premises of the manufacturer. We are exclusively responsible for the DOC.

**Notify Body:**

Name: TÜV SÜD Product Service GmbH
ADD: Ridlerstrasse 65 80339 München

**Identification Number:0123**

**Certificate: G2 089777 0008 Rev.00**

**Valid until: 2024-05-26**

**Date of first CE-Marking:** 2012-12-21

Signature: _____ ( Tian Wei Song ) Subscription Date: 2020. 3. 6

Head Regulatory Place: Shenzhen, P.R.China

ENNE-2001-015 REV : 9

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## Warranty statement

1. You will receive a one year warranty from the date of purchase. Please keep the invoice.
2. In the following cases, repairs will not be carried out free of charge for functional errors:
   a) Disassembly, opening or modification of equipment without permission
   b) Damage or dropping during use or during transport
   c) Lack of care
   d) Improper use
   e) Repair by an unauthorised workshop
3. You will be invoiced for repairs not covered by the warranty.

## Guarantee

The innoSTEP-WL that you have purchased has been developed and manufactured with great care. The statutory guarantee period is 24 months from the date of purchase for material and manufacturing defects of the product. Please keep the proof of purchase as proof to assert any statutory guarantee claim.

Excluded from the statutory guarantee are:

- Damages due to improper use
- Defects that were already known to the customer at the time of purchase
- Consumable parts
- Damages due to unauthorised interventions and at the personal fault of the customer

**Note:**

If you have any technical problems, questions or statutory guarantee/warranty claims regarding this device, please contact the address below. Even after expiry of the statutory guarantee period, you will still have the opportunity to send us any defective device for repair. Repairs made after expiry of the statutory guarantee will be charged.

HELLER MEDIZINTECHNIK GmbH & Co. KG
Europaplatz 2
D-35619 Braunfels
Tel.: +49 (0)6442-9421-0
Fax: +49 (0)6442-9421-12
Mail: info@heller-medizintechnik.de
Web: www.heller-medizintechnik.de


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## HELLER MEDIZINTECHNIK GmbH & Co. KG

We have been active for over 20 years in providing medical technology and have accumulated many years of experience designing solutions for electrical nerve and muscle stimulation.

With our expertise, we hope to help patients in becoming more agile and having a better quality of life.

Our innovative company, with its headquarters in Germany, focuses in particular on customer-friendly service for both physicians and patients with technically high-quality and user-friendly devices for electrical stimulation in the following areas:

- Peroneal nerve stimulation
- Functional electrical stimulation (FES)
- Biofeedback therapy
- Incontinence therapy
- Muscle building
- Pain management

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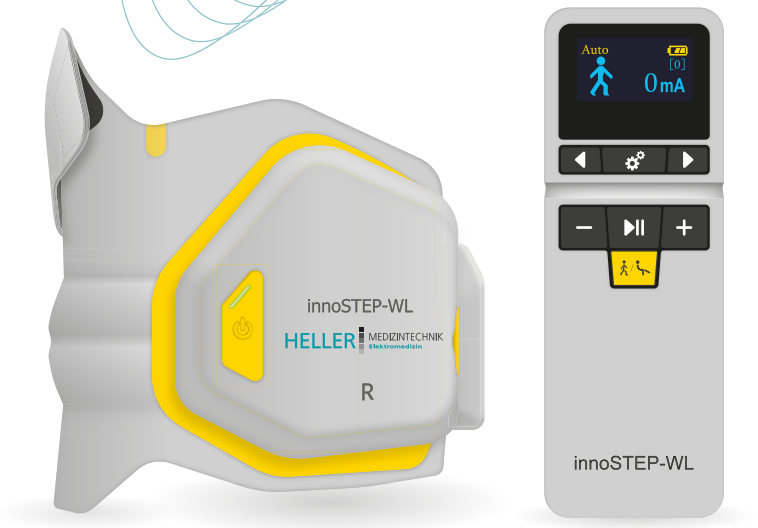
# The choice for better mobility and vitality




## InnoSTEP-WL foot drop system

HELLER MEDIZINTECHNIK GmbH & Co. KG
Your competent partner in the field of
Functional Electrical Stimulation (FES)

CE 0123

Current as of: August 2021

**www.heller-medizintechnik.de**