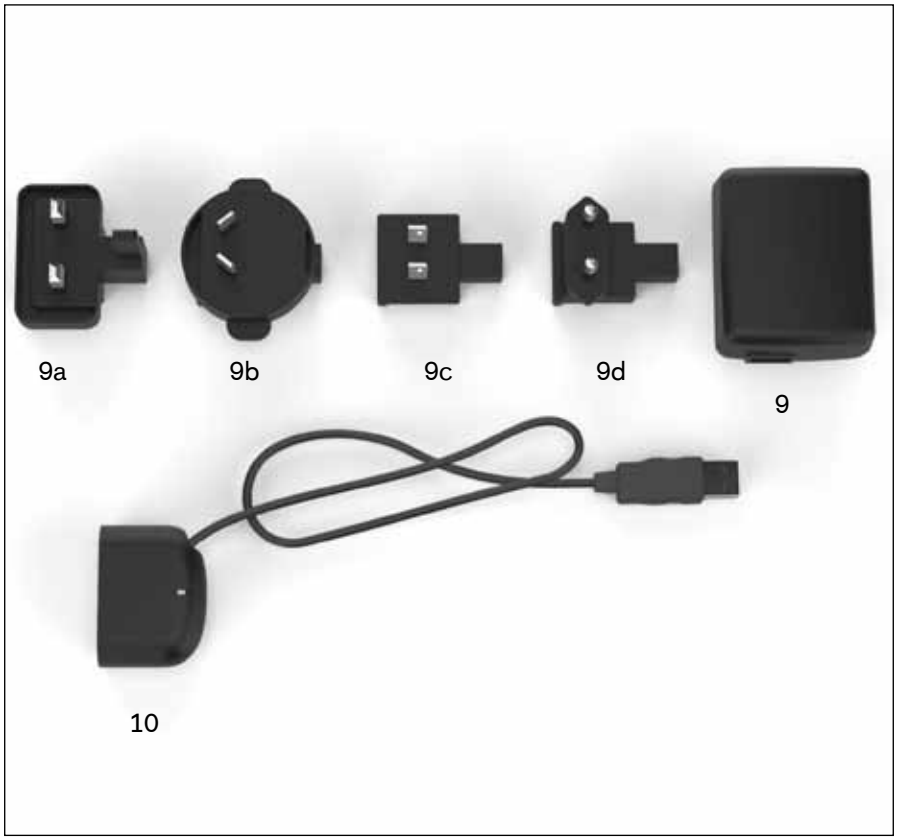

1: ActiGait® Heel Switch
2: ActiGait® Belt Loop
3: ActiGait® Body Clip
4: ActiGait® Belt Clip
5: ActiGait® Control Unit
6: ActiGait® Antenna
7: ActiGait® Heel Sock
8: ActiGait® Antenna Fixture

9: ActiGait® Charger (model FW7711/0.7) incl. plugs
10: ActiGait® Charger Cable

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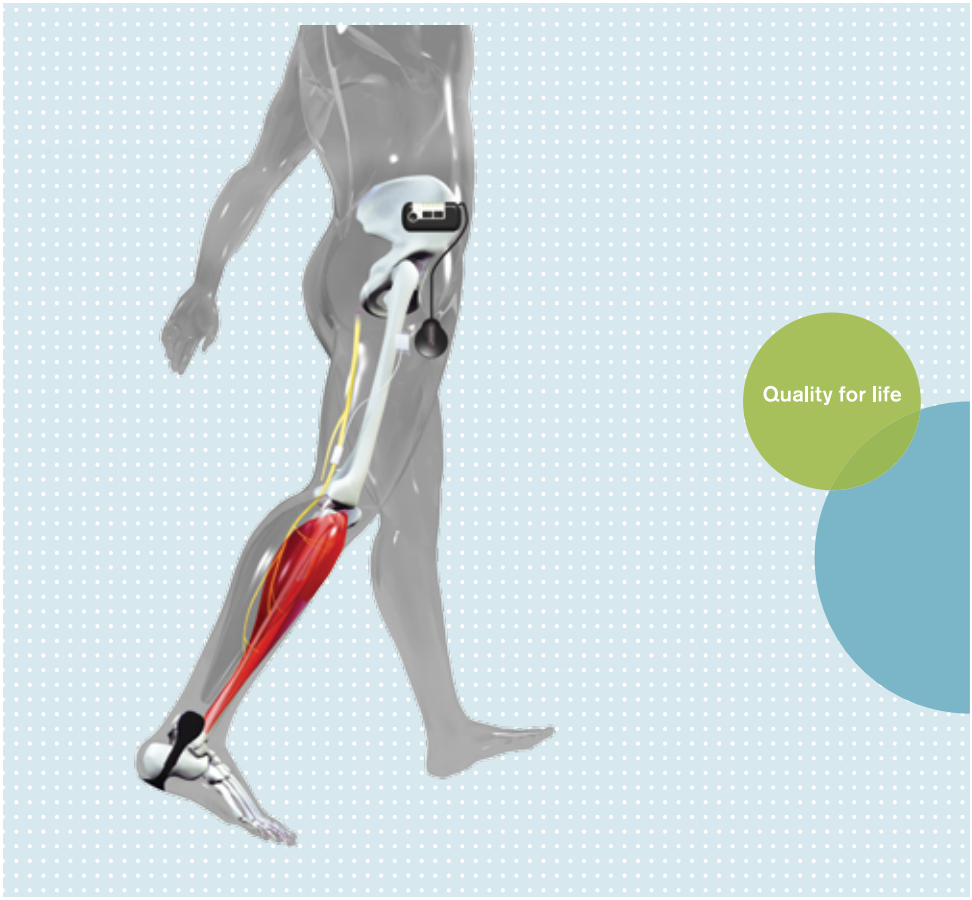
ActiGait® Implantable Drop Foot Stimulator
User Manual



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1. Introduction

This manual describes the use of the ActiGait® and is directed towards individuals with an ActiGait® Implant. The manual is to be used as an information resource and an instruction manual. The term “User” defines individuals who have an ActiGait® Implant and thereby are users of the ActiGait®.

For clinicians the Clinician Manual (647G805=GB) is available

2. Intended Use

2.1 Medical Purpose

The ActiGait® is solely to be used as treatment in patients having a drop foot following an upper motor neuron lesion.

2.2 Application

The ActiGait® system is a partially implantable medical device for treatment of drop foot which activates the muscles of the lower leg during walking. The system is intended for use by persons suffering from paralysis of the ankle dorsiflexor muscles caused by damage to the central nervous system. The largest group of potential users are persons with hemiplegia as a consequence of stroke. The system will not function for people with drop foot caused by peripheral nerve damage.

2.3 Qualification of Clinician

The selection of users for ActiGait®, setup and adjustment are done by clinicians such as medical doctors, physiotherapists or equivalent. To be able to program and adjust the ActiGait®, the clinician must have obtained a certificate on usage of the Clinical Station software following training by Otto Bock

2.4 Follow up Schedule

It is recommended that the ActiGait® is activated 1-3 weeks after implantation, as the wound healing must be finished first. The user should thereafter be followed closely with 2-3 follow-ups during the first 6 months for fine-tuning of the settings and general guidance. Subsequently, the user should be seen in the clinic on request.

3. Indications/Contraindications

Potential candidates for the ActiGait® are stroke patients with drop foot. The patients who may benefit from use of the ActiGait® are characterized by lacking the ability to obtain normal heel contact during gait. It must be possible to correct the heel contact by electrical stimulation of the peroneal nerve.

3.1 Indications

The individuals must:

- have a one-sided hemiparesis persisting for at least 6 months due to a cerebrovascular accident (CVA)
- be fully grown-up
- be able to walk 20 m in less than 2 minutes with or without a walking aid but without the help of another person
- have a reduced speed of walking
- be able to stand upright with both heels touching the floor while hip and knee are in neutral position
- have a passive range of movement of the affected ankle joint of at least 30 degrees
- have a positive response to surface electrical stimulation of the peroneal nerve – i.e. muscle contraction results in ankle dorsiflexion and improved gait

3.2 Contraindications

Individuals with:

- peripheral nerve damage in the affected leg
- severe or uncontrolled diabetes mellitus with peripheral nerve involvement
- poor skin condition on the affected leg
- a thickness of subcutaneous adipose layer on the thigh exceeding 40 mm.[1]
- inability to walk 100 m without stopping prior to CVA (with or without a walking aid, but without the help of another person)
- poorly controlled epilepsy
- need for Ankle Foot Orthosis (AFO) to maintain ankle stability
- concomitant medical and psychological conditions, which would limit the success of the ActiGait®, such as: active degenerative diseases of the back and legs, neglect or drug abuse

1 Individuals who by visual inspection seem to have an adipose layer of about 40 mm at the site where the stimulator should be placed must undergo a more precise examination to measure the exact thickness of the adipose layer (e.g. using ultrasonic measurement methods.)

- concomitant medical and psychological conditions, which would compromise the safety of the patient in connection with the implantation and use of the ActiGait®, such as: severe cardiac disease, uncontrolled hypertension or history of malignancy within the preceding five years
- other active implanted devices, such as demand pacemakers or implanted defibrillators, as mutual electromagnetic interference may distort the efficacy of both devices and expose the patient to dangerous situations

4. Warnings and Precautions

4.1 Safety precautions

Neurodan A/S is solely responsible for the safety, reliability, and function of the apparatus on the condition that repairs, adjustments, and alterations, incl. replacement of batteries, have been carried out by an individual appointed by Neurodan A/S and when the apparatus is used in accordance with the manual.

The ActiGait® and the ActiGait® Accessories contain radio circuits approved by the relevant authorities. Changes or modifications to any part of the ActiGait® or the ActiGait® Accessories could void your authority to operate the equipment.

Maintenance may only be carried out by trained personnel. It is the responsibility of the physician to inform the patient about all potential risks, warnings and precautions.

It is the responsibility of the clinician to instruct the patient in the correct use of the ActiGait® and to inform the patient to contact the clinician about any discomfort while using the ActiGait®.

4.2 Warnings

- The ActiGait® is a device for treatment of drop foot, and must be considered and used accordingly. Stimulation of other nerves besides the peroneal nerve with the ActiGait® involves a risk of potentially hazardous side effects. It is not meant as a device that eliminates or cures any condition.
- Implanting the ActiGait® Implant requires experience in peripheral nerve operations and handling of active implantable medical devices. Training is performed by self-study of the Surgeon Manual and the following steps:

  - Attending product training by OB personnel
  - Observing or assisting in the implantation of an ActiGait® Implant by an experienced surgeon
  - Performing the first surgery under supervision of a surgeon experienced in the procedure

- The clinicians, who select the patients and set up the ActiGait® stimulation, must be properly trained by someone experienced in patient selection and programming of the ActiGait®. The trainer must be authorized by Otto Bock. Improper selection of patients and programming of the ActiGait® may result in lack of effect of stimulation or lack of improvement of gait. Improper selection and programming may expose the patient to dangerous situations, discomfort or pain and the risk of falling during walking.
- ActiGait® patients should not engage in any activity which leaves them in a dangerous situation if the ActiGait® fails.
- The ActiGait® should not be exposed to therapeutic levels of ultrasound energy, as the device may inadvertently concentrate the ultrasound field and cause harm.
- Shortwave or microwave diathermy should not be used. Both the heating and non-heating modes of operation pose a risk of tissue destruction. If given any medical treatment in which an electrical current is passed through the body from an external source, care should be taken to monitor the functioning of the ActiGait® Implant during the initial stages of treatment.
- The electronic components of the ActiGait® Implant may be damaged by therapeutic ionizing radiation. This kind of damage may not be immediately detectable.
- Application of magnetic resonance imaging (MRI) or spectroscopy techniques to a patient with the ActiGait® Implant involves a risk of potentially hazardous side effects. Patients with an ActiGait® Implant should seek medical guidance before entering environments with strong magnetic or electromagnetic fields, such as magnetic resonance (MR) scanners or strong radio-transmitters or radars, including areas protected by a warning notice preventing entry by patients fitted with a pacemaker, as strong electromagnetic fields may heat the device excessively or result in uncontrolled pulses.
- Use of electrical stimulation in pregnancy involves a risk of potentially hazardous side effects. For use during pregnancy qualified medical guidance should be obtained.
- Extended periods of time with the legs in a fixed position, e.g. during travelling, should be avoided as this may cause fluid retention in the leg.

- The ActiGait® may not be used at an ambient temperature of more than 40° C due to risk of skin burn[2]. If the ambient temperature is above 40°C, the surface temperature of the ANT can exceed the intended maximum temperature of 42.5°C (the intended maximum temperature will not cause any harm to the skin). However, if any problems occur, please contact your local ActiGait® representative or your clinician.
- The ActiGait® may be interfered with by other equipment, even if that other equipment complies with CISPR emission requirements.

4.3 General cautions

- The ActiGait® should not be exposed to extreme pressure as this will damage the device.
- The external parts of the ActiGait® (e.g. the Control Unit, Antenna and Heel Switch) should not be immersed in water as this will damage the device. Proper maintenance instructions must be followed and the external parts should be shielded e.g. when walking in rain.
- The ActiGait® should not be used in areas where explosives are used or stored due to radio interference.
- This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 and part 18 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
    - Reorient or relocate the receiving antenna.
    - Increase the separation between the equipment and receiver.
    - Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
    - Consult the dealer or an experienced radio/TV technician for help

2 In warm weather you must be extra aware of skin irritation where the ActiGait® is in contact with your skin. In case of skin irritation you should remove the ActiGait®.

- The ActiGait® is radio controlled and may be disturbed by interfering devices; consequently, the effectiveness of the ActiGait® can be disturbed. In this situation you should move away from the source of the disturbance or turn off your ActiGait®.
- The external parts of the ActiGait® must be turned off on airplanes during a flight, as the radio transmission may interfere with other devices. Because the Heel Switch cannot be turned off it should be taken off and removed from the body during the flight to avoid activation of the switch.
- The ActiGait® may only be used at an atmospheric pressure between 700 hPa to 1060 hPa.
- Magnetic cards, such as bank or credit cards, should not be kept near the Control Unit, the Antenna plug, the Charger Cable, the Clinical Interface, the Body Clip, Belt Clip and Belt Loop at any time, as these devices contain magnets that may demagnetize a magnetic card.
- Magnetic cards, such as bank or credit cards, should not be kept near the Antenna while the ActiGait® is in use, as the card may become demagnetized.
- Wireless communication equipment such as wireless home network devices, mobile phones, DECT telephones and their base stations, Bluetooth devices etc. may disturb the ActiGait® during its use. These devices should be kept at a distance from the ActiGait® according to the table below.

Device type	**Distance**
Mobile phone	0.33 m
DECT telephones (incl. base stations)	0.12 m
Wlan	0.23 m
Bluetooth devices	0.075 m

- The Control Unit should be removed from the patient's body while charging the Control Unit or when the Control Unit is connected to a PC with the Clinical Interface to eliminate the risk of the patient being exposed to electrical shock.
- The ActiGait® should never be connected to other cables, e.g. extension cables, than the ones supplied with the ActiGait®. If another cable is used and this cable is defect there will be a risk of electrical shock or overheating of the equipment.
- Only the ActiGait® Charger and ActiGait® Charger Cable should be used for charging the ActiGait®. Further, the ActiGait® Charger and ActiGait® Charger Cable should not be used for charging other equipment than the ActiGait®. In such a case, the manufacturer will not be liable for any damages.

- The internal batteries in the Control Unit and Heel Switch are not replaceable. If you open the Control Unit or Heel Switch, the seals will be broken and you will compromise the ingress protection. The Control Unit battery has a life time of 5 years. When the capacity of the Control Unit battery is no longer sufficient to last for 1 day of use, the Control Unit should be discarded and replaced with a new one. When the Heel Switch battery runs out of power, the whole Heel Switch must be discarded and replaced with a new one.
- The ActiGait® should not be used while operating dangerous machines, which require foot or leg operation with the affected leg, such as motor vehicles, airplanes, industrial machinery etc., as failure of the ActiGait® may leave the patient in a dangerous situation.
- The ActiGait® fulfills all technical and legal requirements for use in the European Community. The ActiGait® has not yet been formally investigated for use outside this area. ActiGait® uses a wireless communication technology. Restrictions of its use may exist in some countries outside the area mentioned above. Please contact your local ActiGait® representative if in doubt whether the ActiGait® may be used in a specific area outside the European Community.
- There is a risk of rupture of the skin if the sutures are removed earlier than 14 days post surgery.
- Preoperative use of antibiotics is recommended to reduce the risk of infection. Infection is a potential hazard at any kind of surgery and the principle of preoperative use of antibiotics is therefore generally accepted.
- If the leg is not bandaged with elastic bandage or antithrombotic stocking up to the groin after surgery, fluid collections, such as oedema, may occur around the Implant.

4.4 Potential Risks/Side effects

As with all surgical procedures, the implantation of a stimulation system involves some risks. In addition to those normally associated with surgery, the implantation and use of the ActiGait® carries the following risks:

- Infection
- Accidental damage of the nerve during surgery
- Subjects undergoing anticoagulation therapies may be at greater risk for post operative complications such as hematomas
- Reoperation due to malfunction of the Implant

- Nerve damage in the case of the cuff electrode constricting the nerve
- Skin reactions to the material of the external components of the ActiGait® (Heel Switch and Antenna Fixture) in permanent contact with the body
- Device extrusion/migration
- In the presence of strong, environmental electromagnetic fields the device may heat excessively or send out uncontrolled pulses to the nerve
- If the ActiGait® malfunctions and the device does not stimulate, the patient may stumble
- Intolerable sensory stimulation during use (pain or paresthesia)
- Muscle pain may result from too high stimulation intensity or continuous stimulation
- Pain in the ankle joint or other joints of the affected and non-affected lower limbs may result from a change in movement pattern or improper programming of the ActiGait®
- The distance between the Implant and the Antenna of the external device may exceed 40 mm due to swelling around the Implant after operation, general oedema, or increase in the subcutaneous adipose layer
- Damage to the external parts of the ActiGait® due to improper cleaning methods
- Inability to produce an acceptable dorsiflexion movement due to 1) excessive spasticity, 2) improper programming of the ActiGait® or 3) movement or incorrect installation of the cuff-electrode

The safety of the ActiGait® has been documented by evaluating reports on Device Related Adverse Events and measurements of conduction velocity of the common peroneal nerve (branches for extensor digital muscles, anterior tibial muscle and peroneal muscles) before and three months after implantation.

5. Service Information

5.1 Scope of Delivery

The term “ActiGait®” is defined as the parts of the system that you have in or on your body. Besides this you will be given various “ActiGait® accessories” that you need for maintaining your ActiGait®. To be able to use the ActiGait® system you will need the following items:

Item	Part Number
ActiGait®	
1 ActiGait® Control Unit	9002=11
One of the following fixtures	
• 1 ActiGait® Belt Clip	9002M=11A
• 1 ActiGait® Body Clip	9002M=11B
• 1 ActiGait® Belt Loop	9002M=11C
1 ActiGait® Antenna	9002=13
1 package of ActiGait® Antenna Fixtures of 15 pieces	9002=M03
1 ActiGait® Heel Switch	9002=12
1 ActiGait® Heel Sock	9002M=12[3]
ActiGait® Accessories	
1 ActiGait® User Manual	647G808=country code
1 ActiGait® Charger	9002=14
1 ActiGait® Charger Cable	9002=15
1 ActiGait® User Suitcase	9002=17

5.2 Service

The ActiGait®must be set up and put into service in accordance with the information provided in this manual. Check ActiGait® for any visible damage before every use. In case of damage, malfunction or unexpected operation or events, contact your clinician or local ActiGait®representative.

3 The Heel Socks have the following number format: 9002M=12[Size-Color code]. Sizes: XS=Extra Small, S=Small, M=Medium, L=Large, XL=Extra Large, XXL= Extra Extra Large. Color code: 0=Beige, 6=White, 7=Black

Contact your local ActiGait®representative for assistance, if needed, in setting up, using or maintaining the ActiGait®.

Modification of the equipment is not allowed. If the equipment is modified by an unauthorized person or organization, the responsibility and liability for the equipment is transferred to the person/organization modifying it.

6. Description of the ActiGait®

The ActiGait® Implant and other main parts of the ActiGait® are illustrated in Figure 1.

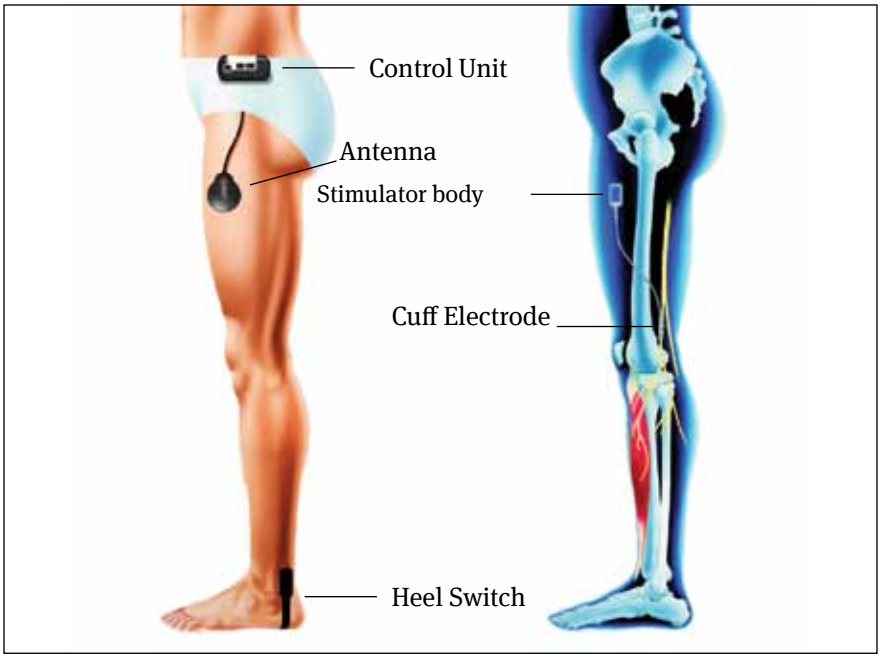


Figure 1: The Implant and other main parts of the ActiGait® and their locations during use.

The purpose of the ActiGait®is to lift your foot during the swing phase of walking. When you walk, the Heel Switch detects your heel strike and heel lift and transmits signals wirelessly to the Control Unit. If you have the Heel Switch on the affected foot, the Control Unit sends power and control signals to the Antenna on your thigh when it receives a heel lift signal. The Antenna then transmits power to the im-

planted stimulator through the skin via an inductive link and the Implant activates the muscles which produce a foot lift while you bring the affected leg forward in the swing phase. When you put your heel down again, the Control Unit receives a heel strike signal from the Heel Switch. The stimulation will continue shortly so that your foot will be set down in a well balanced way.

If you have the Heel Switch on the unaffected foot, the muscles on the affected leg will be activated by a heel strike instead of heel lift to produce the foot lift at the correct time. You can choose which foot you want to carry the Heel Switch on according to your preference and your clinician's advice. However, you can only switch from one foot to the other when you are at the clinic because your clinician must set up the stimulation timing accordingly.

Your clinician can connect the Control Unit to a PC and adjust the stimulation intensity and the timing with a dedicated ActiGait® software program so that it matches your gait pattern and walking speed. The clinician will set a range within which you can adjust the stimulation intensity with the Control Unit. Only trained clinicians can adjust the ActiGait®.

6.1 The ActiGait® Implant

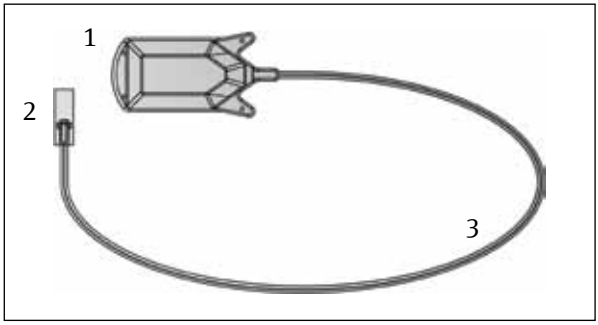


Figure 2: The Implant

The Implant consists of a stimulator body (1), a cuff electrode (2) and a cable (3). The Implant does not have an internal power source (such as a battery) and is activated through magnetic induction from an external power source. The Implant is as such passive, and it is necessary to have an ActiGait® Control Unit and ActiGait® Antenna to activate it.

The stimulator body (1) contains the receiver coil and electronics. The coil converts the signal from the external Antenna into an electrical current, which both powers and controls the Implant.

The cable (3) consists of eight individual metal wires, coiled in two bundles of four. The wires are individually coated with ETFE (Teflon), and the two bundles are inserted into a dual-lumen silicone tube. This design allows the cable to stretch slightly and makes it resistant to flexion and extension.
The cuff electrode (2) is a silicone cuff, 23 mm long with 12 platinum/iridium contact discs located on the inside. These discs form the electrical contact to the nerve. The electrode contacts are organized as four sets of three, each triplet making up one channel. The four channels are distributed evenly around the nerve, in order to allow selective stimulation of different fascicles inside the nerve.

6.2 The ActiGait®

Figure 3: The ActiGait®. 1: Heel Switch, 2: Belt Loop, 3: Body Clip, 4: Belt Clip, 5: Control Unit, 6: Antenna, 7: Heel Sock, 8: Antenna Fixture

Furthermore, you will be supplied with the accessories shown in Figure 4, i.e. the Travel Kit for the Charger consisting of 4 different plugs (9), the Charger (10) and the Charger Cable (11).

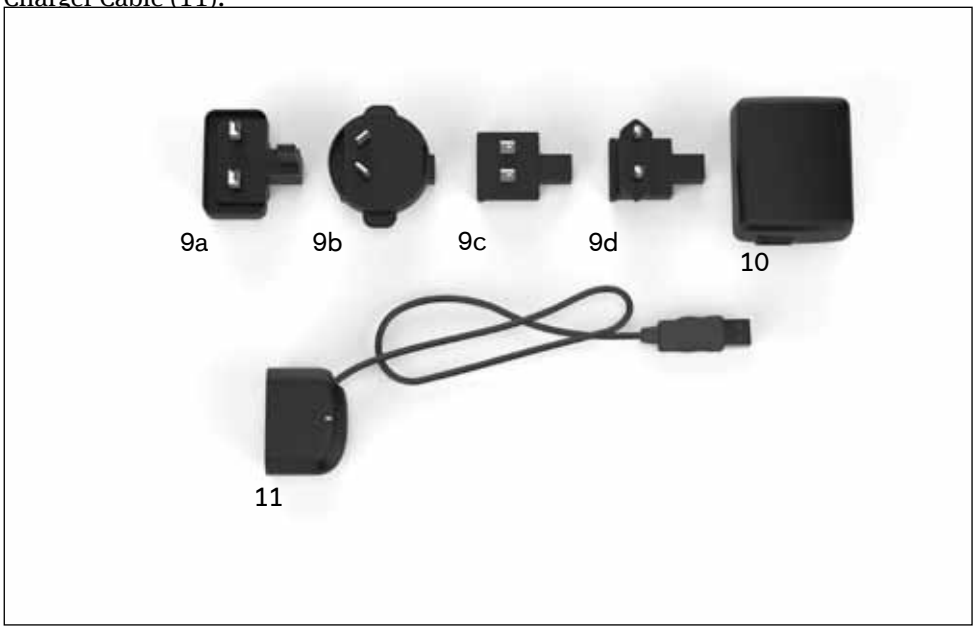


Figure 4: ActiGait® accessories. 9: Travel kit for Charger, 10: Charger, 11: Charger Cable

7. How ActiGait® works

When you receive your ActiGait®, the package will contain the items shown in Figure 3 and Figure 4. This chapter explains everything about the ActiGait®and its accessories.

7.1 The Control Unit

The Control Unit (Figure 5) controls the implanted stimulator via the Antenna, which must be located on the skin on top of the implanted stimulator. The Control Unit receives signals from the Heel Switch (see section 7.5 on page 35) about when to stimulate.

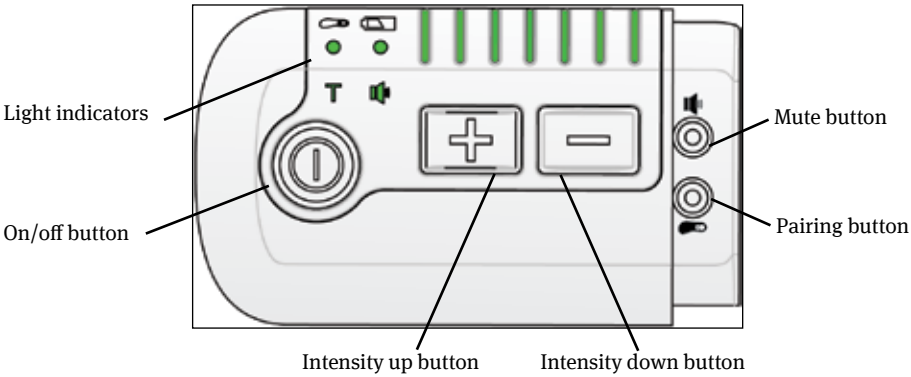


Figure 5: The control Unit

The various buttons are described in the following sections. The Control Unit should be carried at the waist but additional positions are also possible. On the back of the Control Unit there is a magnet that keeps the Control Unit fixed to the various fixtures used for carrying the Control Unit (see section 7.2 on page 27 about Control Unit fixation).

The Control Unit has a number of light indicators that show the status of the Control Unit (see Figure 6)

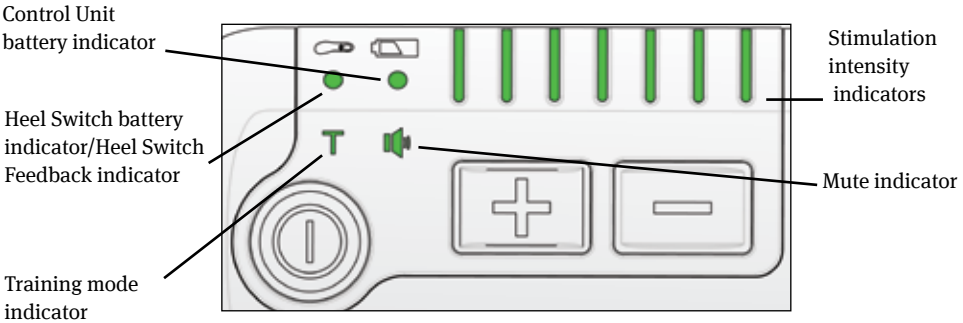


Figure 6: The light indicators on the Control Unit

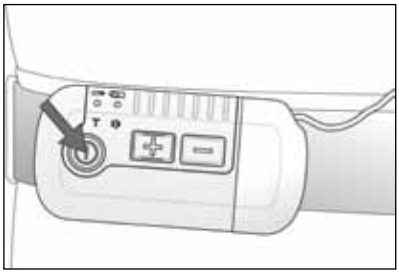
The light indicators are described in the following sections:

- Control Unit battery indicator: Section 7.1.5 on page 22.
- Heel Switch battery indicator/Heel Switch Feedback indicator: Section 7.1.6 on page 23, and section 7.5.2 on page 37
- Training mode indicator: Section 7.1.7 on page 25
- Stimulation intensity indicators: Section 7.1.2 on page 18
- Mute indicator: Section 7.1.8 on page 27, page 36

7.1.1 The On/Off Button

The on/off button is used for switching the ActiGait® Control Unit on and off. You must press the on/off button for at least 1.5 seconds to activate it.

Press the on/off button for at least 1.5 seconds to switch the Control Unit on or off.



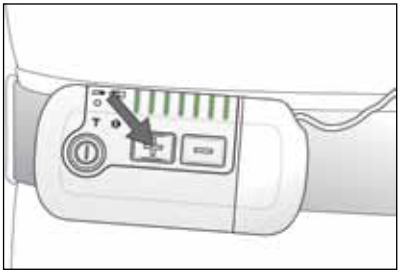
Every time the Control Unit is switched on it performs an indicator check. This means that all light indicators will flash once and a short beep is heard. This can be used for diagnostics because it shows if any of the light indicators or the buzzer is defect. If a light indicator is defect the function will most likely still be intact. When you switch off the Control Unit a long beep is heard. If the mute indicator (see section 7.1.8 on page 27) is red the beeps are not heard.

During use, the lights on the Control Unit will power down to save power. This means that the lights are turned off 30 seconds after the latest activation of a button but stimulation will continue as normal. When the lights of the Control Unit are powered down, a press on any button will switch the lights back on. The first press of a button when the lights of the Control Unit are powered down will therefore not activate this button's usual function.

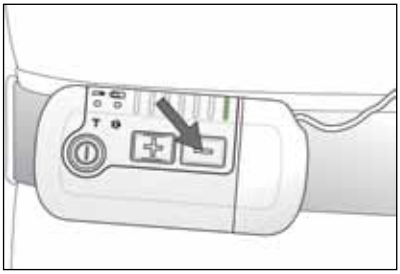
7.1.2 The Stimulation Intensity Buttons

When you walk you might experience that you sometimes need more stimulation than other times to get an adequate foot lift. This can depend on the kind of surface that you are walking on, your shoes, if you are tired or experience spasticity. You can turn the stimulation intensity up and down at any time with the intensity up (+) and intensity down buttons (–) on the Control Unit.

Turning the stimulation intensity up = increasing the foot lift...



...and down = decreasing the foot lift



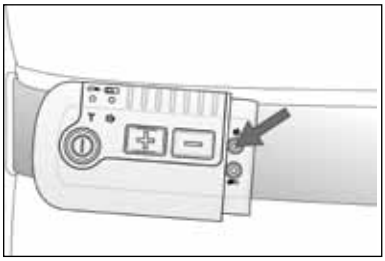
The row of light indicators on top of the Control Unit shows the current intensity level of the stimulation. There are 7 light indicators so the stimulation intensity can be adjusted in 7 steps. Your clinician will set the range within which you can adjust the stimulation intensity with the Control Unit.

If you press the intensity up button when the stimulation intensity is already at the highest level, you will hear a long beep to let you know that the stimulation intensity cannot be increased further. Likewise, if you press the intensity down button when the stimulation intensity is already at the lowest level, you will hear a short beep. If the mute indicator is red (see section 7.1.8 on page 27) these beeps are not heard.

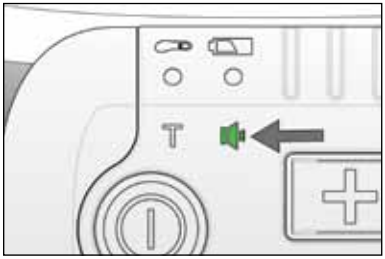
7.1.3 The Mute Button

The mute button is used for switching off the sounds from the Control Unit. The mute button is hidden under the Antenna plug, so you must disconnect the Antenna from the Control Unit to access it. The mute button is a pencil button, meaning that you must use a pencil or another pointy tool to press it. The mute button is marked with the same icon as the mute light indicator.

Press the mute button with a pencil or similar.



The current mute setting is shown by the mute light indicator.



The mute button has three settings:

	All sounds are on.
	All sounds are on, except for the Heel Switch feedback.
	All sounds are off, except for warnings.

As default, all sounds are activated and therefore the mute light indicator is green. If you press the mute button once, the light indicator turns yellow and if you press it once more, it turns red. The settings of the various audio signals are listed in Table 1.

	Stimulation Intensity maximum or minimum	**Heel Switch feedback**	**Indicator check**
	On	On	On
	On	Off	Off
	Off	Off	Off

Table 1: Mute settings

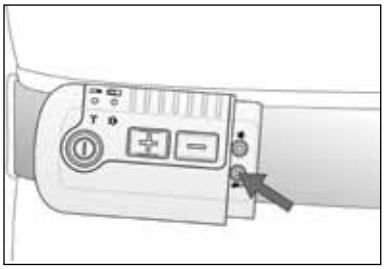
Warnings cannot be muted, only audio signals. See section 7.7.2 on page 43 for explanation of the audio signals

7.1.4 The Pairing Button

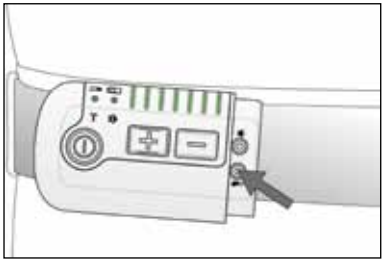
To avoid that another user's Heel Switch can communicate with your Control Unit, your Control Unit must be set up to only recognize your Heel Switch. This is called pairing. The pairing button is a pencil button hidden under the Antenna plug below the mute button. The pairing button is marked with the same icon as the heel switch light indicator.

Each Control Unit can be paired with up to 4 Heel Switches at the same time. If you pair a fifth Heel Switch, the first one will be erased from the Control Unit's memory. When you start using a new Heel Switch or Control Unit always remember to pair them.

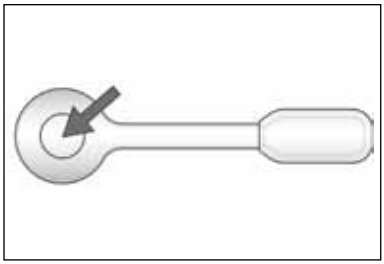
Press the pairing button with a pencil or similar...



...all indicators will light up...



...press the Heel Switch once. Your Control Unit and Heel Switch are now paired and the lights of the Control Unit are turned off.



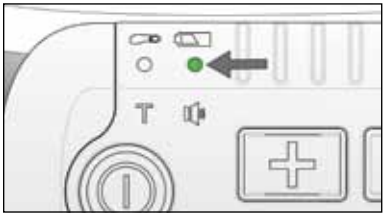
Note that if the Control Unit is powered down you must press the pairing button twice; first to activate the Control Unit and second to pair the Control Unit and Heel Switch.

Be aware that you will get a warning when you press the Heel Switch to indicate that the Antenna is not connected to the Control Unit. This is only the case if you usually wear the Heel Switch on the non-affected leg.

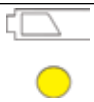
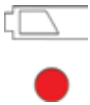
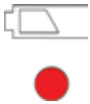
7.1.5 The Control Unit Battery Indicator

The Control Unit is powered by an internal rechargeable battery. You must charge the Control Unit with the ActiGait® Charger and it is recommended that you make a habit of charging the Control Unit regularly, e.g. every night (see section 7.6 on page 38 about the Charger and how to charge the Control Unit). The Control Unit battery is not exchangeable.

The Control Unit battery indicator.



The color of the Control Unit battery indicator can be green, yellow or red reflecting how much power you have left on the Control Unit.

	The battery level of the Control Unit is normal and you have power for at least one day of walking.
	The battery level of the Control Unit is medium and you have power for less than one day.
	Red and the Control Unit beeps once every 30 seconds: The battery level is low and you have power for less than 2 hours. Charge the Control Unit as soon as you can.
	Red and flashing while other light indicators are turned off and the Control Unit beeps for 8 seconds with an interval of 30 seconds: The Control Unit is out of power and stimulation has stopped. Turn off the Control Unit until you can charge it.

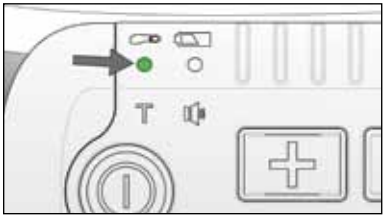
When the Control Unit battery is out of power, both this light indicator and the light indicator for the Heel Switch battery will flash and the Control Unit will beep for 8 seconds, while all other light indicators are switched off. You can tell which of the two batteries is low by checking which one of the two is red: the Control Unit battery indicator or the Heel Switch battery indicator.
It is recommended that you charge the Control Unit every night to avoid running out of power at an inconvenient time.

7.1.6 The Heel Switch Battery Indicator

The Heel Switch is powered by an internal battery. The Heel Switch battery cannot be recharged or exchanged so when the battery is empty you must discard the whole Heel Switch (see section 12.3 on page 53 about disposal). Remember to pair the new Heel Switch with the Control Unit when you replace it (see section 7.1.4 on page 21).

The battery indicator for the Heel Switch is shown by the top left light icon on the Control Unit.

The Heel Switch battery indicator.



The Heel Switch battery indicator can be green, yellow or red reflecting how much power you have left on the Heel Switch.

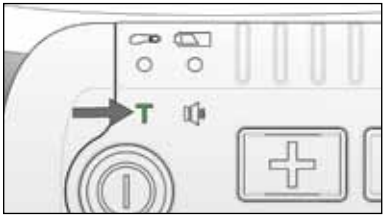
	The battery level of the Heel Switch is normal and you have power for at least 3 months.
	The battery level of the Heel Switch is medium and you have power for at least 1 week.
	Red and flashing while other light indicators are turned off and the Control Unit beeps for 8 seconds with an interval of 30 seconds: The battery level of the Heel Switch is low and you must discard the Heel Switch and replace it with a new one.

When the Heel Switch battery level is low both this light indicator and the light indicator for the Control Unit battery will flash for 8 seconds while all other light indicators are switched off. You can tell which of the two batteries is low by checking which one of the two is red: the Control Unit battery indicator or the Heel Switch battery indicator.
The Heel Switch battery indicator also serves as an indicator for the Heel Switch Feedback (see section 7.5.2 on page 37), i.e. the indicator flashes every time you step on the Heel Switch.

7.1.7 Training Mode Indicator

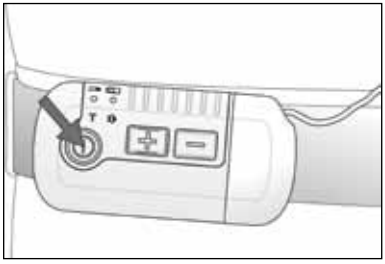
The Training Mode indicator flashes when the Control Unit is in Training Mode. The Training Mode is used to increase your muscle strength and endurance, and to inhibit spasticity. In Training Mode the ActiGait® Implant is cyclically activated without an input from the Heel Switch, e.g. during sitting or lying down. Training Mode will automatically be turned off if the Heel Switch is activated during training so Training Mode cannot be used for walking. The duration of each activation cycle is set by your clinician. Consult your clinician for advice about when and how to use training mode.

The Training Mode indicator.

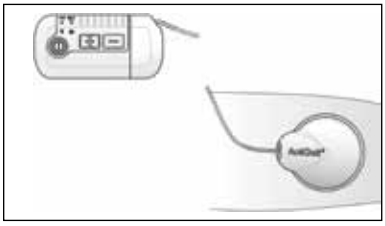


You must be sitting or lying down during training. You must wear the Antenna and Control Unit but you do not need the Heel Switch. Training Mode is switched off by pressing the on/off button on the Control Unit for 1.5 seconds.

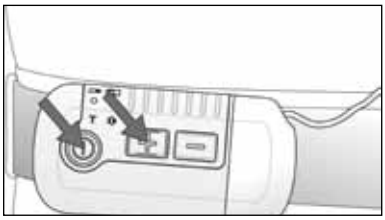
Switch off your Control Unit if it is on.



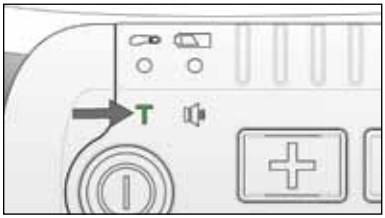
Sit or lie down in a comfortable position with the Antenna mounted on your leg and connected to the Control Unit. You do not need the Heel Switch.



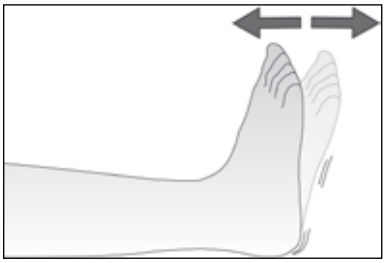
Press the on/off button and either of the intensity buttons at the same time for at least 1.5 seconds.



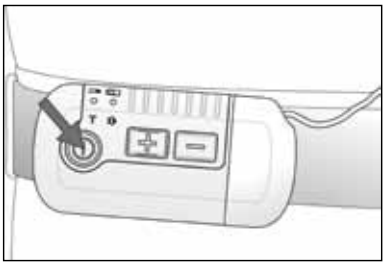
The Training Mode light indicator flashes as long as the Control Unit is in Training Mode.



Continue training for as long as recommended by your clinician.



Press the on/off button on the Control Unit for 1.5 seconds to stop Training Mode.



7.1.8 Mute Indicator

With the mute functionality you can switch the audio signals of the Control Unit on and off according to your preference. There are 3 different settings and the mute indicator shows the current setting.

	All sounds are on.
	All sounds are on, except for the Heel Switch feedback.
	All sounds are off, except for warnings.

See section 7.7 on page 42 for further information about the audio signals and section 7.1.3 on page 19 about how to operate the mute button.

7.1.9 Stimulation Intensity Indicators

The row of light indicators on top of the Control Unit shows the current intensity level of the stimulation. There are 7 light indicators so the stimulation intensity can be adjusted in 7 steps. Your clinician will set the range within which you can adjust the stimulation intensity with the Control Unit. See section 7.1.2 on page 18 about how to adjust the stimulation intensity.

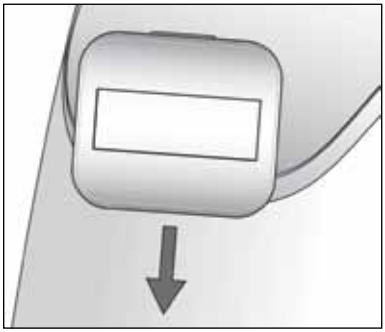
7.2 Putting On the Control Unit

You should wear the Control Unit on your waist so that you can easily access it while walking and sitting. You can use the three different Control Unit Fixtures to attach the Control Unit to your clothing, a belt or your skin or you can carry it in your pocket. The Antenna is available in two cable lengths so that you can choose to carry the Control Unit at the affected side or the non-affected side.

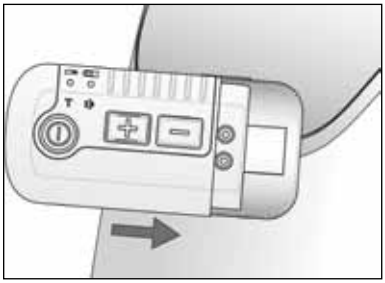
7.2.1 The Belt Clip

The Belt Clip is suitable if you want to attach the Control Unit to e.g. the waist line of a pair of trousers or a skirt or at the lining of your pocket.

Attach the Belt Clip to your clothing, e.g. your waistline or a pocket...



...orient the Control Unit as shown and slide it against the Belt Clip to fix the two together.

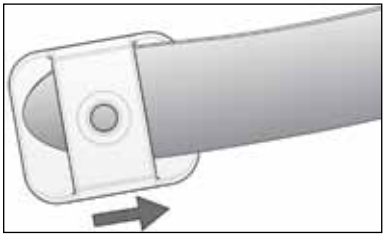


The Control Unit is held in place by magnets inside both the Control Unit and the Belt Clip.

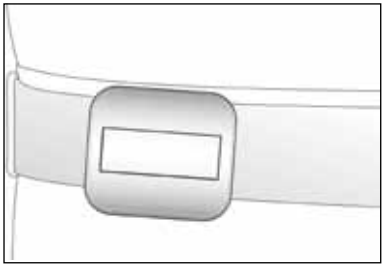
7.2.2 The Belt Loop

The Belt Loop is suitable if you want to carry the Control Unit on your waist and you are wearing a belt.

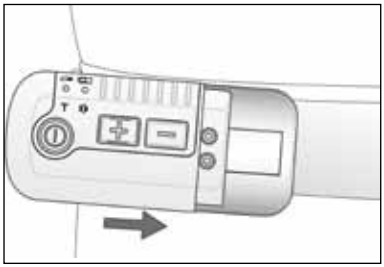
Slide the Belt Loop onto your belt as you are putting the belt on...



.
.put the belt on and slide the Belt Loop to the right position...



...orient the Control Unit as shown and slide it against the Belt Loop to fix the two together



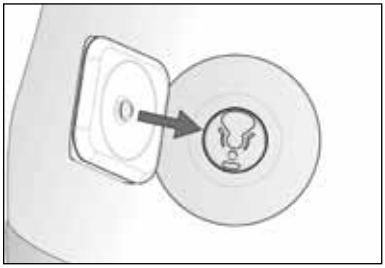
The Control Unit is held in place by magnets inside both the Control Unit and the Belt Loop.

7.2.3 The Body Clip

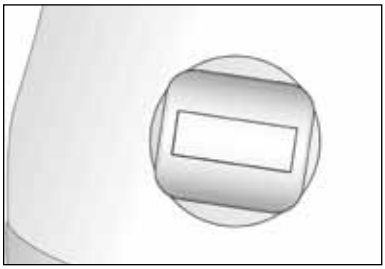
The Body Clip is suitable if you want to carry the Control Unit discretely underneath your clothing e.g. if you are wearing a dress. The Body Clip fits to the Antenna Fixture that is also used for attaching the Antenna to your thigh.

Put on an Antenna Fixture where you want the Control Unit to sit, e.g. on your stomach (see section 7.3 on page 30 about how to put on the Antenna Fixture).

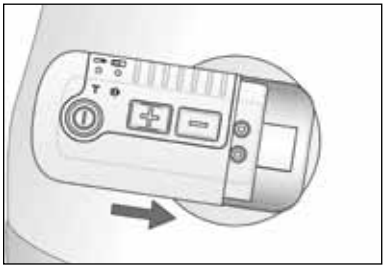
The knob in the middle of the Body Clip fits to the plastic part of the Antenna Fixture.



Insert the knob of the Body Clip into the opening in the plastic part of the fixture and push the Body Clip downwards until you hear a click.



Orient the Control Unit as shown and slide it against the Body Clip to fix the two together.



The Control Unit is held in place by magnets inside both the Control Unit and the Body Clip.

7.3 Putting On the Antenna Fixture

In order for the Antenna Fixture to sit securely on the skin, the following guidelines should be followed:

1. Wash and dry the skin thoroughly before positioning the Antenna Fixture.
2. Remove hair on the skin if the hair will prevent the Antenna Fixture from sitting securely
3. The adhesive side of the Antenna Fixture should not be touched as this will reduce its adhesiveness.
4. The use of moisturizer will reduce the adhesiveness of the Antenna Fixture.

Please note that the Antenna Fixture must not be placed on top of a wound.

The Antenna Fixture consists of 3 layers (Figure 7). On the backside, there is a bearing liner which protects the adhesive qualities of the Antenna Fixture. In the middle there is an adhesive patch with a round plastic disc onto which the Antenna is secured. On the front, there is a stiff applicator liner which makes it easier to place the Antenna Fixture.

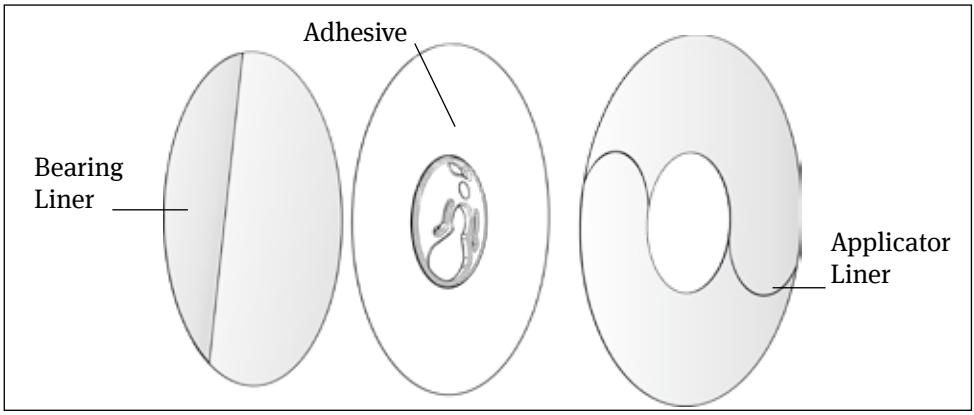
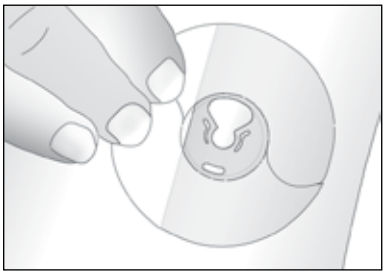


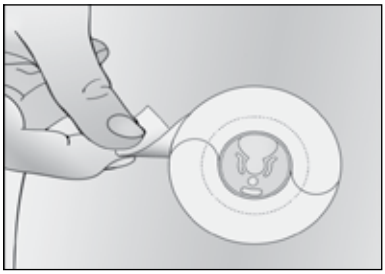
Figure 7: The 3 layers of the Antenna Fixture

Place the Antenna Fixture on a table with the bearing liner facing upwards. Peel off the first part of the bearing liner. Do not touch the adhesive side as this will decrease its adhesiveness.

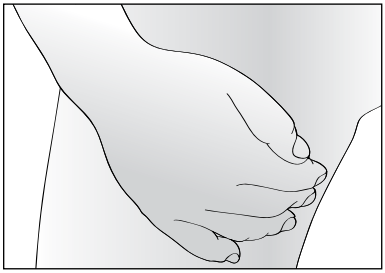
Attach the Antenna Fixture on the skin on top of the Implant by pressing the adhesive half of the fixture onto the bare skin. Orient the Antenna Fixture so the large opening points upward.



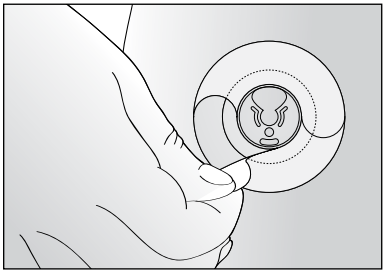
Peel off the remaining part of the bearing liner.



Press the entire Antenna Fixture firmly onto the skin to warm it up and ensure the adhesiveness of the fixture. Keep the pressure for 30 seconds.



Finally, remove the applicator liner on the front of the Antenna Fixture. This is done by carefully peeling off the two halves of the applicator liner.



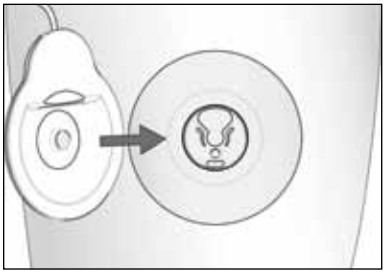
The Antenna Fixture is now ready for use.

If you experience any skin irritation where the Antenna Fixture is placed, you should stop using the fixture and your ActiGait® for a while. If the problem continues, contact your clinician.

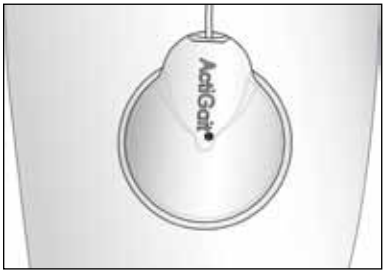
7.4 Putting On the Antenna

When you have attached the Antenna Fixture to your thigh above the Implant, you can click the Antenna into the Fixture.

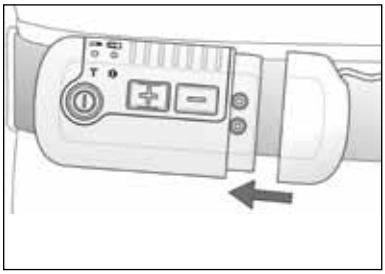
The knob in the middle of the Antenna fits into the plastic part of the Antenna Fixture.



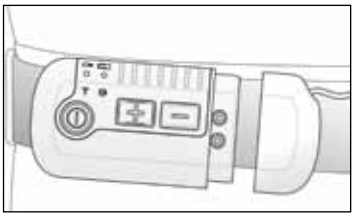
Insert the knob of the Antenna into the opening in the plastic part of the fixture and push the Antenna downwards until you hear a click.

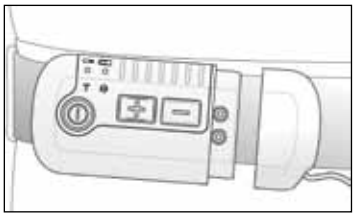


Connect the Antenna plug to the Control Unit.

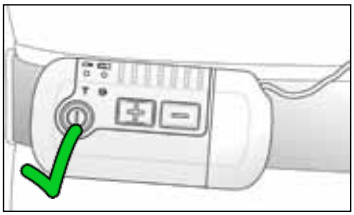


You can turn the Antenna plug both ways so that the Antenna Cable comes out at the top or at the bottom of the Control Unit.

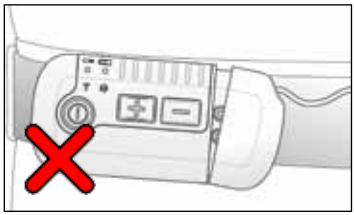




Make sure you attach the Antenna plug properly to ensure the connection to the Control Unit, otherwise you will get a warning when you start to walk, meaning that the Control Unit will beep and the stimulation intensity indicators will flash for 8 seconds.



Correct



Wrong

The Antenna plug is held in place by magnets inside both the plug and the Control Unit

You can disconnect the Antenna plug at any time, for example, when using a rest room. Never pull the cable to disconnect the Antenna from the Control Unit but take hold of the plug itself. Be careful not to make any sharp bends in the Antenna cable as this might damage the cable.

7.5 The Heel Switch

The ActiGait® Heel Switch (see Figure 8) is the device that sends information to the Control Unit about whether the foot is on the ground or lifted. It needs to be mounted on the foot, so that the sensor is placed under the heel, and the Heel Switch housing is placed along the ankle.

The sensor consists of a mechanical switch that activates when you put enough weight on it, i.e. when you place your heel on the ground. The radio transmitter transmits a radio code to the Control Unit for every heel lift and heel strike. The Control Unit reacts by activating the stimulation which makes the muscles lift the foot. The Control Unit and Heel Switch must be paired to communicate with each other (see section 7.1.4 on page 21).

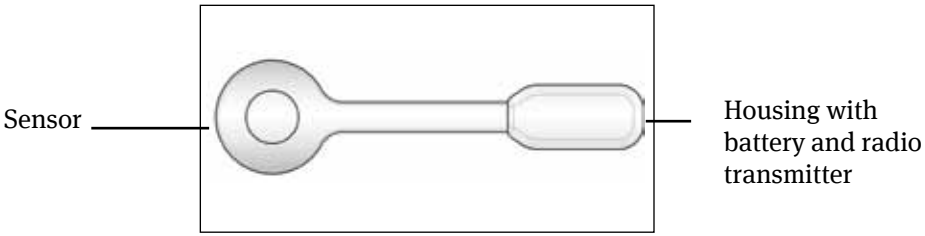


Figure 8: The Heel Switch

It is essential that the Heel Switch is kept in place when you walk so that the switch is activated and de-activated properly for every heel strike and heel lift, respectively.

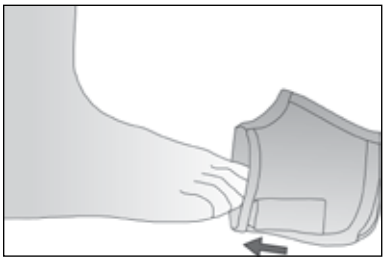
The Heel Switch can be placed under either foot; however, it can only be switched over in connection with reprogramming the Control Unit at the clinic. See section 7.5.1 on page 36 about how to place the Heel Switch and how to use the Heel Sock.

The Heel Switch battery is not exchangeable. If you open the Heel Switch to access the battery, you will break the sealing and thereby compromise the ingress protection against water and particles. When the battery of the Heel Switch is out of power, the whole Heel Switch must be discarded (see section 12.3 on page 53 about disposal).

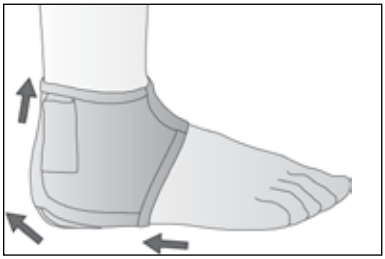
7.5.1 The Heel Sock

Your ActiGait® is delivered with a Heel Sock that keeps the Heel Switch in place. If you choose not to use the supplied sock but just put the Heel Switch into a normal sock, be aware that the Heel Switch could have a tendency to slide away from your heel when you walk.

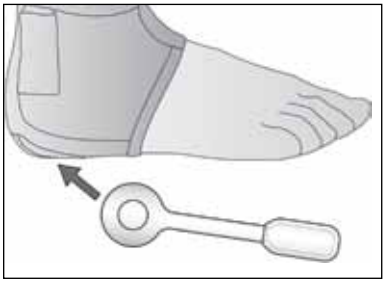
Pull the Heel Sock over your foot...



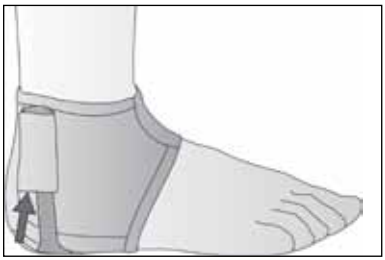
...pull it in position.



Put the round plate of the Heel Switch into the pocket under your heel...



...and put the house of the Heel Switch into the pocket at your ankle.



Be careful not to pull the pockets of the Heel Sock. The pockets are constructed only for holding the Heel Switch in place and not for being pulled.

7.5.2 Heel Switch Feedback

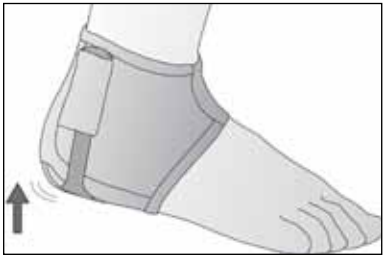
The Control Unit gives a short beep and the Heel Switch light indicator flashes for every signal from the Heel Switch; both at heel lift and heel strike. This is called Heel Switch feedback. It can be used to check if the Heel Switch is activated properly during walking. The Heel Switch feedback can be muted (see section 7.1.3 on page 19).

When you have put on the Heel Switch and before you start to walk, you should check that the Heel Switch is activated when you put your weight on it.

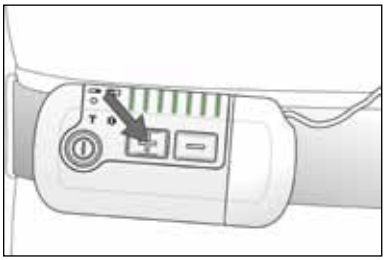
The Heel Switch light indicator.

Make sure that the Control Unit is switched on. If the Control Unit is switched on but no lights are on, the lights are powered down and you must press one of the buttons to turn them back on.

Stand up with your weight on the foot without the Heel Switch



...watch the Control Unit and press a button to make sure that the lights are not powered down...



...while you shift your weight to the Heel Switch.

Check that the Heel Switch indicator flashes when you put your weight on the Heel Switch.

If the Heel Switch indicator does not flash, it is probably because the Heel Switch is not placed properly under your heel. Adjust the position of the Heel Switch and check the connection again or go to section 9 on page 49 for troubleshooting.

If the mute indicator is green, you will hear a short beep for every time you step onto the Heel Switch and every time you step off it again, i.e. two beeps for every step.

7.6 The Charger

The Control Unit is charged with the supplied ActiGait® Charger and ActiGait® Charger Cable (see Figure 9). The Charger Cable has one light indicator that shows if the Charger is correctly connected to the wall outlet. For safety reasons the Charger Cable uses the same plug socket as the Antenna so you cannot use the ActiGait® for stimulation while charging the Control Unit. Do not keep the Control Unit on your body while charging.

The Control Unit battery is not replaceable. If you try to open the Control Unit to change the battery, you will compromise the sealing of the Control Unit.

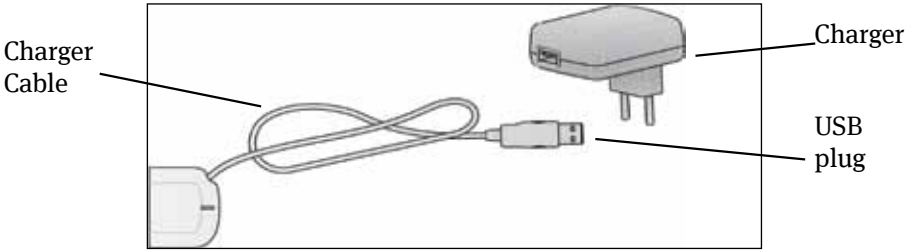


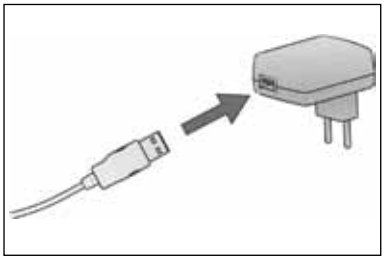
Figure 9: The Charger and Charger Cable

The Charger Cable is connected to the Charger with a USB plug. The Control Unit should only be charged with the supplied Charger and Charger Cable. If the Charger Cable is connected to some other equipment via the USB plug, e.g. a PC, the Control Unit might be harmed.

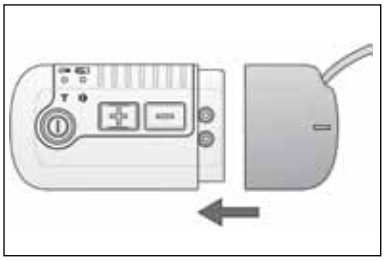
7.6.1 Charging the Control Unit

It is recommended that you charge the Control Unit regularly instead of waiting until the power level is low. Charging the battery will take a maximum of 5 hours depending on how much power is left on the battery.

Connect the Charger Cable to the Charger ...



...connect the Control Unit to the Charger Cable.
Put the Charger into a wall outlet and the Control Unit is charged.



When the Charger is connected correctly to the wall outlet, the light indicator on the Charger Cable will switch on. This means that the Charger is powered. If the Control Unit is switched off, the Charger will switch it on to show the charging status with the Control Unit battery indicator.

When the Control Unit is connected to the Charger, you can see the status of the power level on the light indicator for the Control Unit battery.

Control Unit battery indicator.

Charging status:

	The power level is low.
	You have enough power for a short walk.
	You have power for at least one day of normal use.
	Flashing: Control Unit is fully charged.

The light indicator will show a constant green light when the Control Unit is ready for one day of normal use. It is recommended that you charge the Control Unit battery fully, i.e. until the green light starts flashing, to ensure that you do not run out of power at an inconvenient time. However, do not hesitate to interrupt the charging if you want to use the Control Unit for walking, it will not shorten the lifetime of the battery to only charge it partly.

Charging stops when you disconnect the Charger Cable from the Control Unit or when the Control Unit is fully charged, i.e. the light indicator is green and flashing. It does not harm the Control Unit or the battery to leave it connected to the Charger Cable even though it is already fully charged.

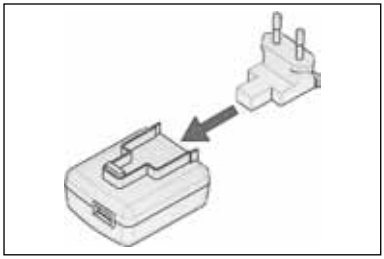
The lifetime of the Control Unit battery is 5 years as a minimum. The capacity of a rechargeable battery of this type becomes lower over time. When the battery is new, it can hold power for some days of use but after 5 years it can only hold power for one day

The Control Unit battery is not exchangeable. If you open the Control Unit to access the battery, you will break the sealing and thereby compromise the ingress protection against water and particles. When the battery of the Control Unit can no longer hold enough power to last for one day of use, the whole Control Unit should be discarded (see section 12.3 on page 53 about disposal).

7.6.2 Travel Kit for Charger

The Charger includes a travel kit with different wall plugs for different countries.

Slide the wall plug into the Charger to connect them.



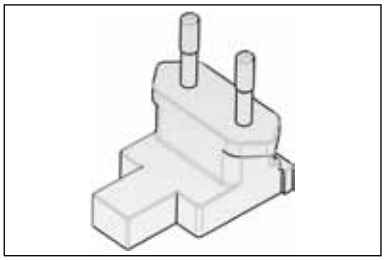


Figure 10: Wall plug Europe

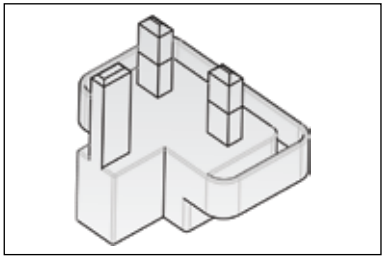


Figure 11: Wall plug UK

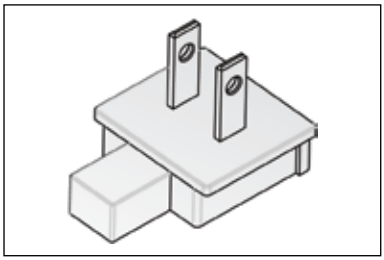


Figure 12: Wall plug US and Japan

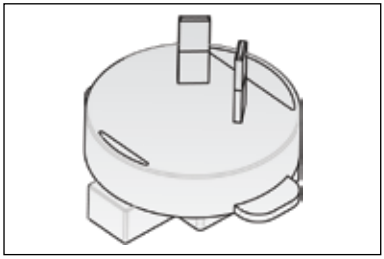


Figure 13: Wall plug Australia

7.7 Audio Signals and Warnings

The Control Unit has a number of audio signals and a warning signal. A warning consists of short beeps for 8 seconds while some or all of the light indicators flash depending on the reason for the warning. An audio signal is a single beep that can be either short or long.

7.7.1 Warnings

The Control Unit will always give a warning if it receives signals from the Heel Switch without being able to send a signal to the Antenna. This will typically be if the Antenna is disconnected but it can also be because there is not enough power on the Control Unit battery to send signals to the Antenna.

Reasons for warnings:

- The Control Unit is out of power. The Control Unit battery indicator is red and flashing and the Control Unit will beep for 8 seconds with an interval of 30 seconds until you charge it. The Heel Switch battery indicator is also flashing while all other indicators are turned off.
    - Response: Charge the Control Unit as soon as possible (see section 7.6.1 on page 39 about charging of the Control Unit).

- You start to walk while the Antenna is not properly connected to the Control Unit. The Control Unit will beep for 8 seconds while the stimulation intensity indicators flash.
    - Response: Make sure that the Antenna plug is properly connected to the Control Unit. (see section 7.4 on page 33 about the Antenna).

7.7.2 Audio Signals

The Control Unit has a number of audio signals to make it easier to adjust the settings. The audio signals mentioned in this section can all be muted but the warnings described above cannot.

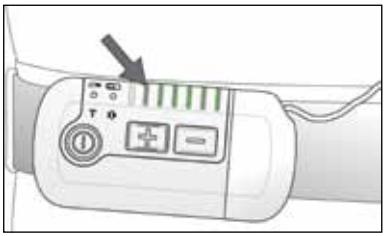
- Stimulation Intensity
    - Long beep: You have pressed the intensity up button when you are already at the maximum level
    - Short beep: You have pressed the intensity down button when you are already at the minimum level.
- Heel Switch feedback: The Control Unit gives a short beep for every signal from the Heel Switch; both at heel lift and heel strike. This can be used to check if the Heel Switch is activated properly during walking.
- Low battery level of the Control Unit: When the Control Unit battery indicator is red the Control Unit will give a short beep for every 30 seconds until you charge the battery.
- Indicator Check: Every time the Control Unit is switched on it performs an indicator check. This means that all light indicators flash once and a short beep is heard.

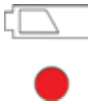
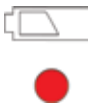
8. Lights and Audio Signals

The Control Unit has a number of light indicators and sounds that tell you different things about the settings or status of the Control Unit and the Heel Switch. This chapter contains a table of all the different light indicators and a table of the audio signals and what they mean.

The tables are meant to give an overview and therefore the explanations are very short. If you want more information please go to the chapters that are referred to in the tables.

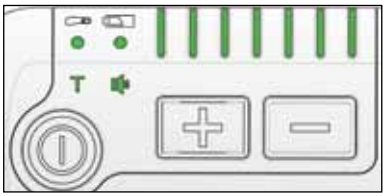
8.1 How to Interpret the Light Indicators

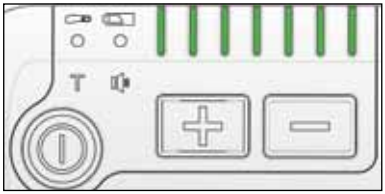
Stimulation intensity	
	The number of lights shows the current stimulation intensity.
See section 7.1.2 on page 18.	

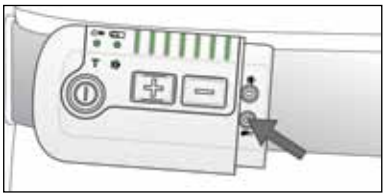
Battery status of the Control Unit	
	You have power for at least one day of walking.
	You have power for less than one day.
	Red and the Control Unit beeps once every 30 seconds: You have power for less than two hours. Charge the Control Unit as soon as you can.
	Red and flashing and the Control Unit beeps for 8 seconds with an interval of 30 seconds: The Control Unit is out of power and stimulation has stopped. Turn off the Control Unit until you can charge it.
See section 7.6.1 on page 39.	

Training Mode	
	Flashing: Training Mode is on.
See section 7.1.7 on page 25.	

Mute	
	All audio signals are on.
	All audio signals except the Heel Switch Feedback are on.
	All audio signals are off but warnings can still be heard.
See section 7.1.3 on page 19.	

Indicator check	
	All lights flash once when you switch on the Control Unit: This is the indicator check that is performed every time you switch on the Control Unit.
See section 7.1.1 on page 17.	

WARNING	
	The intensity level indicators flash and the Control Unit beeps for 8 seconds: WARNING: The Control Unit cannot send signals to the Implant. Check that the Antenna is connected correctly to the Control Unit.
See section 7.4 on page 33.	

Pairing the Control Unit and Heel Switch	
	All lights are switched on when you press the pairing button for the Heel Switch. When you press the Heel Switch they are switched off
See section 7.1.4 on page 21.	

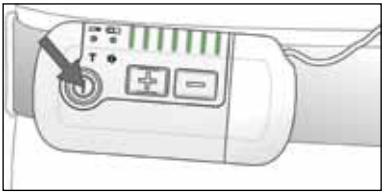
8.2 How to Interpret the Audio Signals

The Control Unit has audio signals and a warning signal. A warning means that the Control Unit will beep for 8 seconds whereas audio signals are single beeps. Warnings can never be muted. A warning means that stimulation has stopped and you must find out what the warning is about and respond accordingly.

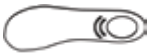
In this section you can see the different audio signals and warnings. The Control Unit only has one type of sound that can be short or long, single or continuous. Therefore, a short or long beep can mean different things depending on the situation. Most often the audio signals are used in combination with light signals making it possible to interpret what the audio signal tells you.

Short beep + 
A short beep when you press the intensity down button. Only one stimulation intensity light indicator is on: The stimulation intensity is already at the minimum level. See section 7.1.2 on page 18.

Short beep +



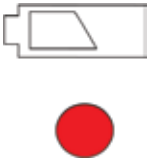
A short beep when you press the on/off button for 1.5 seconds. All lights flash once: Indicator Check. The Control Unit is now on.
See section 7.1.1 on page 17.

Short beep +   + flashing

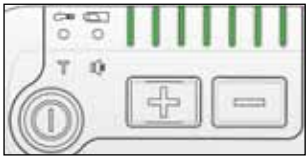
A short beep when you step onto the Heel Switch and when you step off it again. The Heel Switch battery light indicator flashes when the beeps are heard. The color of the light indicator can be green, yellow or red reflecting the Heel Switch Battery level: Heel Switch Feedback. See section 7.5.2 on page 37.

Short beep +  

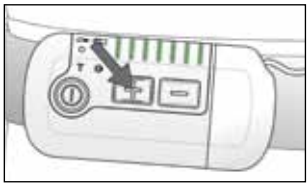
One short beep every 30 seconds. The Control Unit battery indicator is red: Charge the Control Unit, the power level is low.
See section 7.1.5 on page 22 for more information and section7.6.1 on page 39 for charging the Control Unit.

Short beeps 30 seconds Short beeps	+		+	flashing

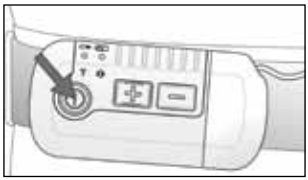
Short beeps for 8 seconds with a 30 seconds interval while the battery light indicators flash. All other light indicators are turned off.
WARNING: The Control Unit is out of power and stimulation has stopped. Turn off your Control Unit and charge it.
See section 7.1.5 on page 22 for more information and section 7.6.1 on page 39 for charging the Control Unit.

Short beeps	+		+	Flashing

Short beeps for 8 seconds while the stimulation intensity indicators flash.
WARNING: The Control Unit cannot send signals to the Implant. Check that the Antenna is connected correctly to the Control Unit.
See section 7.4 on page 33.

Long beep	+	

A long beep when you press the intensity up button. All stimulation intensity light indicators are on:
The stimulation intensity is already at the maximum level.
See section 7.1.2 on page 18.

Long beep + 	
A long beep when you press the on/off button for 1.5 seconds. The Control Unit is now turned off. See section 7.1.1 on page 17.	

9. Troubleshooting for ActiGait®

In this chapter you will find solutions to the most common problems that you might experience with your ActiGait®. If none of the described solutions works, or if you experience a problem that is not described, please contact your clinician.

Check regularly if all of the equipment is intact and has no visible damage. You should never pull the Antenna cable when you remove the Antenna from the Antenna Fixture or the Control Unit as this can damage the cable. Take hold of the Antenna or plug instead.

Problem	Solution
You do not get a foot lift when you are walking or You do not get a foot lift at every step	Make sure that the Control Unit is switched on (see section 7.1.1 on page 17).
	Make sure that the stimulation intensity is high enough (see section 7.1.2 on page 18). If it is already at the maximum, your need for stimulation may have changed since your last visit at the clinic. Contact your clinician for reprogramming of your ActiGait®.
	Make sure that the Antenna is placed correctly in the Antenna Fixture above the Implant. Check that the Antenna cable is intact and with no sharp bends.

Problem	Solution
	Check that the Heel Switch is placed correctly under your heel inside the Heel Sock (see section 7.5 on page 35).
	Check the connection between the Heel Switch and the Control Unit (see section 7.5.2 on page 37).
	Check that the Heel Switch works properly by pressing the switch with your fingers. If you cannot get a stable response when you are walking, contact your clinician or order a new Heel Switch.
	If the Control Unit does not respond with light signals and/or audio signals when you activate the Heel Switch: 1. Check the battery status of the Heel Switch (see section 7.1.6 on page 23) and the Control Unit (see section 7.1.5 on page 22). 2. Repeat pairing of the Heel Switch and Control Unit (see section 7.1.4 on page 21). 3. Replace the Heel Switch.
	If the Control Unit responds with light signals and/or audio signals when you activate the Heel Switch: Check that the Antenna plug is properly connected to the Control Unit.
You do not get a sufficient foot lift when you are walking	Make sure that the stimulation intensity is high enough (see section 7.1.2 on page 18). If it is already at the maximum, your need for stimulation may have changed since your last visit at the clinic. Contact your clinician for reprogramming of your ActiGait®.
Your foot is lifted too much when you are walking	Make sure that the stimulation intensity is low enough (see section 7.1.2 on page 18). If it is already at the minimum, your need for stimulation may have changed since your last visit at the clinic. Contact your clinician for reprogramming of your ActiGait®.

Problem	Solution
You get unwanted stimulation when you are not walking	Adjust the position of the Heel Switch so that it does not activate unless you stand on it
Your muscles hurt when you walk	You may be experiencing training induced muscle soreness, especially if you have been walking more than usual or if you have just started using your ActiGait®. Make sure to get enough rest so that your muscles have time to restitute
	Make sure that the stimulation intensity is low enough (see section 7.1.2 on page 18). If it is already at the minimum, your need for stimulation may have changed since your last visit at the clinic. Contact your clinician for reprogramming of your ActiGait®
Your muscles and/or joints hurt, also when you are not walking	Reduce the stimulation intensity (see section 7.1.2 on page 18) and/or walk less until the pain is reduced. Make sure to get enough rest so that your muscles have time to restitute. If the pain continues, contact your clinician.

10. Warranty

Safe and effective use of the ActiGait® requires that the product be transported, stored and used as intended, without modifications, following all the manufacturer's recommendations. The product must have been used and prescribed in accordance with the ActiGait® User Manual (647G808=GB), Clinician Manual (647G805=GB) and Surgeon Manual (647G806=GB).

The following parts of the ActiGait® are consumables with reduced warranty:

- ActiGait® Antenna Fixture
- ActiGait® Heel Sock
- ActiGait® Heel Switch

In accordance with European law, the following parts are covered by a 2 year warranty:

- ActiGait® Control Unit
- ActiGait® Belt Clip
- ActiGait® Body Clip
- ActiGait® Belt Loop
- ActiGait® Antenna
- ActiGait® Charger Cable
- ActiGait® Charger
- ActiGait® Implant

11. Expected lifetime

- ActiGait® Antenna Fixture: 7-14 days
- ActiGait® Heel Sock: 50 washes
- ActiGait® Heel Switch: 1 year (depending of the intensity of use the lifetime of the Heel Switch may vary)
- ActiGait® Control Unit: 5 years
- ActiGait® Control Unit Fixtures: 5 years
- ActiGait® Antenna: 2 years
- ActiGait® Charger Cable: 5 years
- ActiGait® Charger: 5 years
- ActiGait® Implant: 10 years

12. Cleaning, Storage and Disposal

12.1 Cleaning

The various parts of the ActiGait®should be cleaned when needed. To keep the Control Unit, Heel Switch, Antenna, Charger, Body Clip, Belt Clip and Belt Loop clean, they can be wiped down with a clean damp cloth. The electrical contacts in the Antenna plug and the Control Unit should not be cleaned.

Cleaning detergents or excessive amounts of water shall be avoided. ActiGait® is designed to withstand splashes of water and moisture, but not to be submerged in water. The Charger Cable should only be wiped with a clean, dry cloth.

12.2 Storage

When the equipment is not in use, the Antenna Fixtures should be stored at a temperature between +10˚C and +27˚C for up to 6 months. The rest of the equipment can be stored in a dry place at a temperature between +10˚C and +40˚C for up to 2 years.

In order to maintain the Control Unit battery's ability to become fully charged, the Control Unit must be charged with regular intervals during storage. If the Control Unit has been in use, it must be charged with 3 months intervals.
It is recommended that the equipment is stored in the original sales boxes or the User Suitcase to avoid accidental damage.

12.3 Disposal

The Antenna Fixtures, Heel Socks, Body Clip, Belt Clip and Belt Loop can be disposed of as household waste. The Control Unit, Antenna, Heel Switch, Charger and Charger Cable contain batteries or electronics and shall therefore be disposed of according to the national regulations for electronic and electrical waste. The parts can be returned to the clinician or your local ActiGait®representative.

13. Available Articles

Please contact your local ActiGait®representative to purchase any of the articles mentioned below.

Item	Part Number
ActiGait®	
ActiGait®Control Unit	9002=11
ActiGait®Belt Clip	9002M=11A
ActiGait®Body Clip	9002M=11B
ActiGait®Belt Loop	9002M=11C
ActiGait®Antenna 58 cm	9002=13A
ActiGait® Antenna 78 cm	9002=13B
ActiGait®Antenna Fixtures, package of 15 pieces	9002=M03
ActiGait®Heel Switch	9002=12

Item	Part Number
ActiGait®Heel Sock, extra small, black	9002M=12XS-7
ActiGait® Heel Sock, small, black	9002M=12S-7
ActiGait® Heel Sock, medium, black	9002M=12M-7
ActiGait® Heel Sock, large, black	9002M=12L-7
ActiGait® Heel Sock, extra large, black	9002M=12XL-7
ActiGait® Heel Sock, extra extra large, black	9002M=12XXL-7
ActiGait® Heel Sock, extra small, whit	9002M=12XS-6
ActiGait® Heel Sock, small, white	9002M=12S-6
ActiGait® Heel Sock, medium, white	9002M=12M-6
ActiGait® Heel Sock, large, white	9002M=12L-6
ActiGait® Heel Sock, extra large, white	9002M=12XL-6
ActiGait® Heel Sock, extra extra large, white	9002M=12XXL-6
ActiGait® Heel Sock, extra small, beige	9002M=12XS-0
ActiGait® Heel Sock, small, beige	9002M=12S-0
ActiGait® Heel Sock, medium, beige	9002M=12M-0
ActiGait® Heel Sock, large, beige	9002M=12L-0
ActiGait® Heel Sock, extra large, beige	9002M=12XL-0
ActiGait® Heel Sock, extra extra large, beige	9002M=12XXL-0
ActiGait® Accessories	
ActiGait® User Manual	647G808=country code
ActiGait® Charger	9002=14
ActiGait® Charger Cable	9002=15
ActiGait® User Suitcase	9002=17

14. Technical Data

14.1 ActiGait® Control Unit

Dimensions	9.5 cm x 4.8 cm x 1.8 cm
Mass	80 g (including battery)
Battery	Li-ion 1100mAh
Operating time	Minimum 16h after full 5 hour charging. Charging every night is recommended to ensure optimal performance of the ActiGait®
Charging time	5 hours
Ingress	IP 54
Operating temperature	Between +10 °C and +40 °C
Storage temperature	Between +10 °C and +40 °C
Humidity	30 – 75 % rel. H non-condensing
Short time storage and transportation temperature	Between -20 °C and +60 °C for max 2 months
Receiver frequency	2,401MHz
Transmitter	Frequency: 2,401 MHz Output power: 0.5 dBm Modulation: MSK

14.2 ActiGait® Belt Clip

Dimensions	5.3 cm x 4.6 cm x 1.3 cm
Mass	27 g
Operating temperature	Between +10 °C and +40 °C
Storage temperature	Between +10 °C and +40 °C
Humidity	30 – 75 % rel. H non-condensing
Short time storage and transportation temperature	Between -20 °C and +60 ° C for max 2 months

14.3 ActiGait® Belt Loop

Dimensions	5.3 cm x 4.6 cm x 1.3 cm
Mass	21 g
Operating temperature	Between +10 °C and +40 °C
Storage temperature	Between +10 °C and +40 °C
Humidity	30 – 75 % rel. H non-condensing
Short time storage and transportation temperature	Between -20 °C and +60° C for max 2 months

14.4 ActiGait® Body Clip

Dimensions	5.3 cm x 4.6 cm x 1 cm
Mass	20 g
Operating temperature	Between +10 °C and +40 °C
Storage temperature	Between +10 °C and +40 °C
Humidity	30 – 75 % rel. H non-condensing
Short time storage and transportation temperature	Between -20 °C and +60° C for max 2 months

14.5 ActiGait® Antenna

Dimensions	Ø 5.7 cm x 0.7 cm
Mass	10 g
Ingress	IP 54
Operating temperature	Between +10 °C and +40 °C
Storage temperature	Between +10 °C and +40 °C
Humidity	30 – 75 % rel. H non-condensing
Short time storage and transportation temperature	Between -20 °C and +60° C for max 2 months
Surface temperature	Max. 42.5 °C
Transmitter	Frequency: 6,772 MHz Modulation: CW Output power: 12.3 dBuA/m at 3 m

14.6 ActiGait® Antenna Fixture

Dimensions	Ø 6.2 cm x 0.4 cm
Mass	1.3 g
Storage temperature	Between +10 °C and +27 °C for max 6 months
Short time storage and transportation temperature	Between -20 °C and +60 °C for max 2 months

14.7 ActiGait® Heel Switch

Dimensions	17 cm × 2.5 cm x 0.8 cm
Mass	15.5 g
Battery	Lithium coin cell type CR2032
Operating time	Minimum 1 year
Transmitting range	Minimum 2 m
Ingress	IP 54
Operating temperature	Between +10 °C and +40 °C
Storage temperature	Between +10 °C and +40 °C
Humidity	30 – 75 % rel. H non-condensing
Short time storage and transportation temperature	Between -20 °C and +60 °C for max 2 months
Transmitter	Frequency: 2,401 MHz Modulation: MSK Output power: 2 dBm

14.8 ActiGait® Heel Sock

Sizes	XS, S, M, L, XL, XXL
Washing directions	1. Maximum 40 °C normal machine wash 2. Do not bleach 3. Do not iron 4. Do not dry-clean 5. Do not tumble-dry

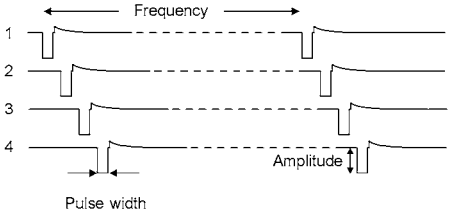
14.9 ActiGait® Charger Cable

Dimensions	3.5 cm x 4.7 cm x 1.8 cm
Mass	33 g
Input voltage	5 VDC
Input current	500 mA
Frequency	DC
Output voltage	5 VDC
Output current	Max 500 mA
Ingress	IP 4X
Operating temperature	Between +10 °C and +40 °C
Storage temperature	Between +10 °C and +40 °C
Humidity	30 – 75 % rel. H non-condensing
Short time storage and transportation temperature	Between -20 °C and +60 °C for max 2 months

14.10 ActiGait® Charger

Mass	50 g
Input voltage	100-240 VAC (±10 %)
Output voltage	5 VDC
Input current	75 mA
Output current	Max 500 mA
Frequency input	50-60 Hz
Efficiency	70 % typ. at full load
EMC	Conforms to EN 55022 + A1, CISPR 16-1, CISPR 16-2, AS/NZS CISPR 22
Output voltage tolerance	± 5 %
Operating temperature	Between 10 °C and +40 °C
Storage temperature	Between 10 °C and +40 °C
Humidity	5 % to 95 % non-condensing
Short time storage and transportation temperature	Between -20 °C and +60 °C for max 2 months
Standards	Fulfils Class II SELV for the following applications: EN 60950/IEC 60950, UL 60950, VDE, CE label
Plug connector	AC input: FRIWO exchangeable mains plug system: EURO, UK, USA/Japan, Australia DC output: USB socket type A

14.11 ActiGait® Implant

Implant length	365 mm
Implant weight	16 g
Stimulator body size	Length: 60 mm Width: 30 mm Thickness: 6.2 mm
Cuff length	23 mm
Cuff sizes	4.5 mm, 5.4 mm, 6.4 mm and 7.6 mm (inner diameter)
Pulse shape	Bipolar, charge-balanced. Active phase: Fixed 1.2 mA current, pulse width modulated 0-255 µs in steps of 0.25 µs. Passive phase: Exponential discharge (capacitive) 
Number of channels	4 bipolar, interleaved
Current	Amplitude of active phase = 1.2 mA
Repetition rate	5 Hz – 50 Hz, for each channel. Inter pulse interval 20-200 ms
Storage	Between +10 °C and +40 °C. Exposure to temperatures outside this range may result in Implant malfunction. Do not expose to sunlight or other heating sources. Store in a dry place, in original packaging, with seal unbroken
Humidity	Non-condensing
Short time storage and transportation temperature	Between -30 °C and +70 °C for max 2 months
Receiver frequency	6,772 MHz

14.11.1 X-Ray Identification

The Implant bears a tag that is identifiable by X-ray (see Figure 14). The X-ray tag makes it possible to identify the manufacturer and the year of manufacture as required by regulations.

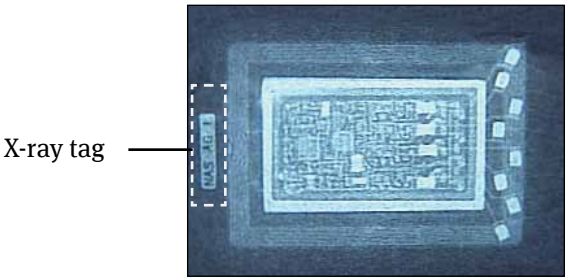


Figure 14: The X-ray tag of the Implant

The format of the information on the tag is “NAS 000 Y”, where:

- NAS is the manufacturer identification, short for Neurodan A/S
- 000 is an internal reference that identifies the Implant model. On Implants manufactured later than February 2009 it says AG, short for ActiGait.
- Y is the year of manufacture represented by a letter.
  - A is year 2001
  - B is year 2002
  - C is year 2003
  - etc.

15. Classification

The ActiGait®is classified as internally powered ME equipment according to IEC/EN 60601-1.

16. List of symbols

	Caution, see instruction
	Follow operating instructions, see instruction
SN	Serial number
	Lot number
PN	Part number
	Keep Dry
	Temperature limitation
	Type BF applied part
	Use by/expiry date
IP 54	Protection against ingress of water and particles
IP 4X	Protection against ingress of particles
	Date of manufacture

	Manufacturer
	Product contains battery, limitations on disposal of battery
	The device includes RF transmitter(s)
	Maximum 40 °C normal machine wash
	Do not bleach
	Do not iron
	Do not dry clean
	Do not tumble dry
	Recycle
CE 0197	In compliance with the applicable European directives
FCC	FCC ID number
	C-tick
IC	IC ID number

16.1 Ingress Protection

The IP (Ingress Protection) classification marked on the various parts of the Acti-Gait® defines the degree of protection against ingress of water and particles. The first number defines the protection against particles and the second number defines the protection against water.

Classification	Definition
IP 54	Particles: 5: Dust protected. Ingress of dust is not totally prevented, but dust shall not penetrate in a quantity to interfere with satisfactory operation of the apparatus or to impair safety.
	Water: 4: Protected against splashing water. Water splashed against the enclosure from any direction shall have no harmful effects.
IP 4X	Particles: 4: Protected against solid foreign objects of 1.0 mm Ø and greater. The object probe of 1.0 mm Ø, shall not penetrate at all.
	Water: X: Protection against ingress of water is not relevant.

17. Declaration of Conformity

This device complies with Part 15 of the FCC rules and RSS-210 IC rules. Operation is subject to the following two conditions:

1. This device may not cause harmful interference.
2. This device must accept any interference received, including interference that may cause undesired operation.

This ISM device complies with Canadian IES-001.

This device also complies with:
- 90/385/EEC for active implantable medical devices amended by 2007/47/EC
- 99/5/EC for R&TTE.

Manufacturer:

ActiGait® is a product made by the Danish manufacturer Neurodan A/S. Development and production is carried out with the highest possible diligence and in compliance with existing European directives and national medical devices laws and regulations. Warranties and other claims will be covered by the manufacturer if not explicitly stated otherwise.

Neurodan A/S is a Member of the Otto Bock Group and committed to “Quality for Life”. The Otto Bock Group logo will therefore be used in respective presentations.

Neurodan A/S

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Neurodan A/S has been certified by TÜV Rheinland LGA Products GmbH.

647G808=US Draft ver. 1.0 / 2012