

AccelHeal Solo

INSTRUCTIONS FOR USE

Each Accel-Heal Solo treatment pack includes:

- 1 Accel-Heal Solo device with removable clip
- 12 electrode pads
- 6 alcohol wipes
- 1 fastening strap
- Instructions for use

Description

Accel-Heal Solo is a single use, automated electrical stimulation wound therapy device designed to stimulate healing, reduce inflammation and help to alleviate pain in hard to heal wounds. The device is easily operated, wearable and is to be used alongside topical wound treatments such as dressings and compression bandages. Once applied and started it automatically delivers a pre-set programme of sub-sensory electrical stimulation over a continuous 12 day treatment period.

Indications

Wounds that are not healing as expected or where pain is restricting a patient's mobility or tolerance of other wound care treatments such as compression therapy. Appropriate wounds include chronic wounds such as venous leg ulcers, diabetic foot ulcers, pressure ulcers and arterial insufficiency ulcers as well as delayed healing acute wounds such as burns and dehisced post-surgical wounds.

General advice



The Accel-Heal Solo device has been designed to be applied by either the healthcare professional or, following a consultation, the patient or a carer. Users should have a minimum of 8 years of education.



Accel-Heal Solo is a single-use device and must not be reused. The device is to be applied to an individual patient for 12 days and then discarded. During the 12-day treatment period, it is not to be detached from one patient and applied to another patient. Attempting to repurpose the device may lead to potentially serious consequences for patients such as cross infection and contamination.

Application and use

1. Before attaching the electrode pads, clean the skin with the alcohol wipes included in the pack. Attach two electrode pads to healthy unbroken skin either side of, and in close proximity to, the wound or dressing area. Figure 1.
2. Attach the device to the electrode pads by pushing the device cable connectors into the electrode pad cable receptors. Figure 2.
3. Press and hold the start/pause button for two seconds to activate the device. Figure 2.
4. Once activated the device will automatically run the 12-day sequence of electrical stimulation treatment. When the treatment is completed the LED will stop flashing and the device will turn itself off. The device and the electrode pads should be removed and disposed of.

It is important to note that the device cannot be switched on and off. Once activated, the device is programmed to run for the 12-day treatment cycle. It is therefore advised not to activate the device until the electrodes pads are securely attached to the patient and the cables connected (Figures 1 and 2). If the device is inadvertently activated before it is connected to the patient, it will not be possible to establish an electrical circuit and the LED will indicate a fault (rapidly flashing orange). The fault will only be corrected by connecting the activated device to the patient and establishing the required electrical circuit which will be indicated with a slow green flashing LED.

Securing the device

The device is provided with a removable clip and a strap that can be fed through the clip to secure the device. Figure 3. Wrap the strap around the thigh or shin and use the Velcro tabs to secure the strap in the desired position. Figure 4. If the strap is applied directly to the skin, ensure the silicone line is in contact with the skin and, once secured, ensure the device does not cause the

patient discomfort while moving or put pressure on the skin while resting.

Alternatively, the device can be popped out of the clip mechanism and can be secured using a bandage or inserted into the top of a stocking. The electrode wires can also be taped down if required.

Pausing the treatment

The treatment can be paused at any time and the electrode pads removed. Press the start/pause button for 2 seconds and the LED will flash orange every 2 seconds to show the device has been paused. To restart the treatment, follow steps 1 to 3 opposite. If the treatment is not restarted within 2 hours of being paused, the device will automatically turn itself back on. At that time, the patient should be ready to resume the treatment; the device should be attached to the electrode pads and the electrode pads should be in place either side of the wound or dressing area.

The device is programmed to deliver a set number of active treatment sessions, interspersed by rest periods of a set duration, over a continuous treatment period of 12 days. Depending on how many times the treatment is paused, the treatment period may differ from 12 days by plus or minus half a day. Once the prescribed number of active sessions has been delivered, the device will turn itself off and the LED will stop flashing.

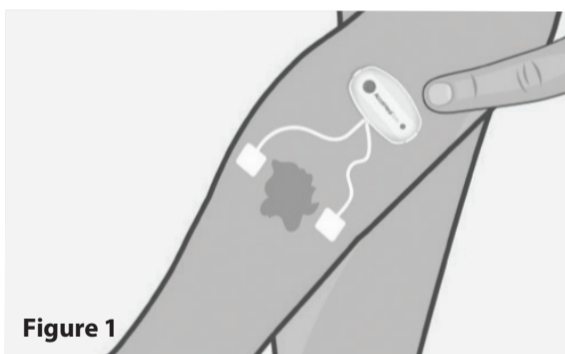


Figure 1



Figure 2

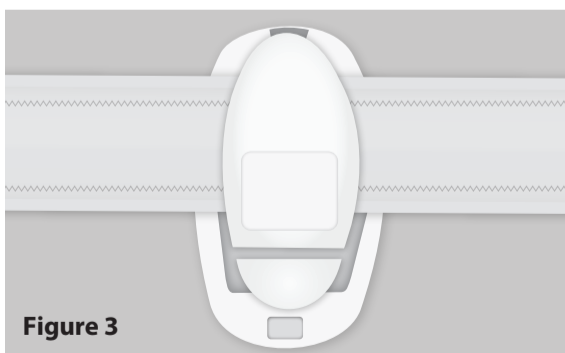


Figure 3



Figure 4

LED indicator - post successful application	
Flashing green every 2 seconds	Operating normally
Flashing orange every 2 seconds	Device in pause mode
Flashing orange rapidly - twice every second	Fault - action required - see Troubleshooting
No LED displayed before 12 day treatment period completed	Fault - consult healthcare professional
No LED displayed	12 day treatment period completed

Changing the electrode pads

The treatment pack includes 12 electrode pads and 6 alcohol wipes. If required, the electrode pads can be replaced during the treatment period by following steps 1 and 2 opposite. The device does not need to be paused to replace an electrode pad and the LED will flash green every 2 seconds to indicate the device is operating normally once the new electrode pad is in place and attached to the device.

Skin irritation

Ensure skin is clean and dry before the electrode pads are applied, avoiding the use of emollients. In the presence of high exudate, if possible, place the pads horizontally, to avoid gravitational moisture. If skin irritation develops under or around the electrode pads, reposition the electrode pads on healthy unaffected skin away from the wound edge.

Treatment discomfort

Electrical stimulation therapy with Accel-Heal Solo should be sub-sensory (without feeling). However, a tingling sensation may occasionally be felt by some patients, particularly if not well hydrated, and is normal. Sometimes increased sensation/pain is experienced in neuropathic wounds as neural regeneration is initiated. If the treatment causes significant additional pain or discomfort, detach the device immediately and review therapy with the prescribing healthcare professional.

Electrode pads

Only the electrode pads provided should be used with Accel-Heal Solo. No unauthorised extension leads, cables or attachments should be used.

WARNING: Use of accessories, transducers and cables other than those included in the treatment pack could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation, such as the device turning off. However, it is unlikely that an adverse event will occur.

Disposing of the used Accel-Heal Solo Device

The Accel-Heal Solo device is a medical electrical device which should be disposed of in accordance with local clinical protocol and not with general waste. Patients should return used items to their visiting healthcare professional for disposal. The used Accel-Heal Solo device should be decontaminated by wiping it with 70% isopropyl alcohol and disposed of in a Waste Electrical and Electronic Equipment (WEEE) disposal facility. Reprocessing the device or exposing the device to chemicals may lead to a failure of the device.

Troubleshooting

Problem: The LED is flashing orange rapidly at a rate of twice per second.

Remedy: There is poor contact between the electrode pads and the skin or one or both electrodes have become detached from the device preventing treatment current being delivered. Clean the skin and reapply the electrode pads, or use new electrode pads and / or reattach the electrodes to the device. Note this fault message will only occur during an active treatment session and not during a resting phase.

Problem: The LED is flashing orange every two seconds.

Remedy: The device has been paused. Press the start/pause button again to commence the treatment.

Problem: The treatment commenced successfully and now no LED lights are flashing.

Remedy: The device has completed its treatment course and can be disconnected.

Problem: No LED lights are displayed when turning the device on or before the 12 day treatment period has been completed.

Remedy: Consult your healthcare professional. Under rare circumstances a software failure could occur resulting in the device not being able to be used and should be changed.

For further assistance or to report unexpected operations or adverse events please contact Accel-Heal Technologies Limited.

Contraindications of Accel-Heal Solo

Heart conditions

Do not apply Accel-Heal Solo to the chest in patients with cardiac arrhythmias or cardiac failure.

Implanted electronic devices

Do not apply Accel-Heal Solo to the chest where electrical stimulation may cause malfunction of implanted cardiac pacemakers, or shocks from implanted cardiac defibrillators.

Pregnancy

Do not apply to the lower back or abdomen of pregnant women.

Patients with cancer in the wound

Do not apply to regions of known or suspected malignancy in the wound or adjacent tissue.

Epilepsy

Do not apply to the neck or head region of persons known to have seizures.

Active deep vein thrombosis


Do not apply to persons with active deep vein thrombosis or thrombophlebitis. (Accel-Heal Solo can be applied to persons with a history of DVT treated with anticoagulant therapy.)

Warnings

Strangulation Hazard

The wires could pose a strangulation hazard if misused.

Water

 Accel-Heal Solo is an electrical device and should be kept dry at all times.






Children

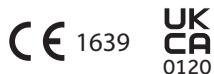
Accel-Heal Solo is not for use on patients under 18. Keep the device and accessories out of reach of children.

Pets

Keep the device and accessories out of reach of pets.

Environmental conditions for transport, storage and operation

-  Please ensure Accel-Heal Solo and its accessories are stored, and transported within the temperature range of 5°C-40°C.
-  Please ensure Accel-Heal Solo is operated within the temperature range of 10°C-40°C.
-  Please ensure Accel-Heal Solo and its accessories are stored, transported and operated within the humidity range of 20-80%.
-  Please ensure Accel-Heal Solo is stored and transported between 50 - 106 kPa (atmospheric pressure).
-  Please ensure Accel-Heal Solo is operated between 70 - 106 kPa (atmospheric pressure).



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Guidance and manufacturer's declaration Electromagnetic Immunity for Accel-Heal Solo

Immunity Test	Immunity Test Levels: Patient Coupling Port		Compliance Level: Patient Coupling Port		Electromagnetic Environment Guidance
	Professional healthcare Facility Environment	Home Healthcare Environment	Professional healthcare Facility Environment	Home Healthcare Environment	
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV contact ± 2kV, ±4 kV, ±8 kV, ±15 kV air		±8 kV contact ± 2kV, ±4 kV, ±8 kV, ±15 kV air		Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material the relative humidity should be at least 30%.
Conducted disturbances induced by RF fields IEC61000-4-6	3 V 0.15 MHz - 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz	3 V 0.15 MHz - 80 MHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz	3 V 0.15 MHz - 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz	3 V 0.15 MHz - 80 MHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer than 0.3m to any part of the device, including cables. The recommended separation distance calculated from the equation application to the frequency of the transmitter. Recommended separation distance: $E = \frac{6 \sqrt{P}}{d}$ Where P is the maximum power in W, d is the minimum separation distance in m, and E is the immunity test level in V/m.
If abnormal performance is observed, such as the device turning off, additional separation distance or screening may be necessary.					

Recommended separation distances

Between portable and mobile RF communications equipment and Accel-Heal Solo.

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The healthcare professional or the user of the device can help prevent electromagnetic interference by maintaining a minimum 0.3m distance between portable and mobile RF communications equipment (transmitters) and the device.

Essential performance

When used in accordance with these instructions for use there are no aspects of device performance that are considered Essential Performance.

Guidance and manufacturer's declaration

Electromagnetic immunity IEC 60601-1-2 for Accel-Heal Solo

Accel-Heal Solo is intended for use in the electromagnetic environment specified below. The customer and / or the user of the device should assure that it is used in such an environment.

Immunity Test	Immunity Test Levels: Enclosure Port		Compliance Level: Enclosure Port		Electromagnetic Environment Guidance
	Professional healthcare Facility Environment	Home Healthcare Environment	Professional healthcare Facility Environment	Home Healthcare Environment	
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV contact ± 2kV, ±4 kV, ±8 kV, ±15 kV air		±8 kV contact ± 2kV, ±4 kV, ±8 kV, ±15 kV air		Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material the relative humidity should be at least 30%.
Radiated RF EM fields IEC61000-4-3	3 V/m 80 MHz - 2.7 GHz 80% AM at 1 kHz	10 V/m 80 MHz - 2.7 GHz 80% AM at 1 kHz	3 V/m 80 MHz - 2.7 GHz 80% AM at 1 kHz	10 V/m 80 MHz - 2.7 GHz 80% AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer than 0.3m to any part of the device, including cables.
Proximity fields from RF wireless communications equipment IEC 61000-1-3					
Radiated power frequent magnetic fields IEC 61000-4-8	30 A/m 50 Hz or 60 Hz		30 A/m 50 Hz or 60 Hz		Power frequency magnetic fields should be at levels characteristic of a typical location in a professional healthcare facility or home healthcare environment.
If electromagnetic disturbances are observed, such as the device turning off, additional separation distance or screening may be necessary.					

Interference

When the Accel-Heal Solo treatment is in use the devices may interfere with ECG and EEG monitors and alarms. There may also be interference from other electronic devices that affect the performance of the Accel-Heal Solo device. If there are problems increase the separation distance between the devices.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 0.3m to any part of the Accel-Heal Solo device, including the cables provided by the manufacturer. Otherwise, degradation of the performance of the device could result, such as the device turning off. However, the degradation will not cause an adverse event.

WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation, such as the device turning off. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

WARNING: No modification of this device is allowed.

Guidance and manufacturer's declaration Electromagnetic emissions IEC 60601-1-2 for Accel-Heal Solo

Accel-Heal Solo is suitable for use in the specified electromagnetic environments described below. To prevent the risk of adverse events, healthcare professionals and/or users should ensure it is used in accordance with the following tables to avoid electromagnetic disturbances.

Emission Test	Professional healthcare Facility Environment	Home Healthcare Environment	Electromagnetic Environment Guidance
Conducted and radiated RF Emissions: CISPR 11	Group 1 Class B	Group 1 Class B	The device does not use RF for its function. Therefore its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Harmonic distortion IEC	Not applicable	Not applicable	The device is suitable for use in professional healthcare facility environments and home healthcare environments.
Voltage fluctuations and flicker	Not applicable	Not applicable	Exclusions: Professional Healthcare Facility: device is not intended for use in areas of the hospital where there is sensitive equipment or sources of intense electromagnetic disturbances, such as the RF shielded room of an ME system for magnetic resonance imaging, in operating rooms near active HF Surgical equipment, electrophysiology laboratories, shielded rooms, or areas where short wave therapy equipment is used. Home Healthcare Environment: device is not intended for use in helicopters, spacecraft, or submarines. Special Environments: device is not intended for use in Military or heavy industrial areas.













Test Specifications for Accel-Heal Solo Immunity to RF wireless communications equipment

Test Frequency (MHz)	Band (MHz)	Modulation	Immunity Test Level (V/m)
385	380-390	Pulse modulation 18 Hz	27
450	430-470	FM ±5 kHz deviation 1 kHz sine	28
710	704-787	Pulse modulation 217 Hz	9
745			
780			
810	800-960	Pulse modulation 18 Hz	28
870			
930			
1720	1700 - 1990	Pulse modulation 217 Hz	28
1845			
1970			
2450	2400 - 2570	Pulse modulation 217 Hz	28
5240	5100 - 5800	Pulse modulation 217 Hz	9
5500			
5785			

If abnormal performance is observed, such as the device turning off, additional separation distance or screening may be necessary.

For transmitters rated at a maximum output power not listed above, the recommended separation distance in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Glossary of symbols used

Symbol Used	Meaning
	Caution
	Keep Dry
	Keep Out of Direct Sunlight
	Temperature Limitation
	Single Use Only - Do NOT Reuse
	WEEE Directive 2002/96/EC Compliant
	Atmospheric Pressure Limitation
	Humidity Limitation
	Accel-Heal Solo is a Type BF Applied Part
	Start/Pause
	Accel-Heal Solo is a Medical Device
	Importer



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