Accel Heal

INSTRUCTIONS FOR USE

Each Accel-Heal® treatment pack includes:

6 Accel-Heal® devices
12 electrode pads
6 alcohol wipes
Instructions for use

Description

Accel-Heal® 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 devices are easily operated, wearable and are to be used alongside topical wound treatments such as dressings and compression bandages. Once applied and started, each device automatically delivers a pre-set programme of sub-sensory electrical stimulation over a continuous 48-hour treatment period. The six individual 48-hour devices are applied consecutively to deliver the 12 day therapy.

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 devices have 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.

② The devices are single-use devices and must not be reused. The devices are to be applied consecutively to an individual patient for 12 days and then discarded. During the 12-day treatment period, the devices are not to be detached from one patient and applied to another patient. Attempting to repurpose the devices 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.
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.

⚠ Please note that once activated, the device cannot be switched off and will run for the 12-day therapy cycle. It is therefore advised not to start the device until the electrodes pads are securely in place on the patient and the cables connected (instructions 1. and 2. above). If this is done, or if the unit is inadvertently activated, it will trigger an error indicator light (rapidly flashing orange LED) which will only be corrected once the electrode pads are fully attached and the electrical circuit established, and which will be indicated with a slow green flashing LED.

LED indicator - post successful application	
Flashing green every 2 seconds	Operating normally - device delivering active treatment
Flashing every 5 seconds	Operating normally - device in rest period
Flashing rapidly - twice every second	Error - action required - see Troubleshooting
No LED displayed before the cycle of electrical stimulation is complete. On the basis the treatment is not paused, the cycle has a minimum time of 45.5 hours. 48-hour treatment period completed	Error - consult healthcare professional
No LED displayed	Cycle of electrical stimulation completed

Pausing the treatment

The treatment can be paused and the electrode pads removed. To ensure that the prescribed level of electrical stimulation is delivered, it is recommended that the treatment is only paused during a rest period.

To pause the device, press and hold the button for 2 seconds. The LED will stop flashing. To restart the device follow the Instructions opposite. On resumption of the treatment, the device will automatically start the next active session in the cycle. Depending on how often and how long the treatment is paused, the treatment period may differ from 48 hours. Once the prescribed number of active sessions has been delivered, the device will turn itself off and the LED will stop flashing.

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 every 2 seconds to indicate the device is operating normally once the new electrode pad is in place and attached to the device.

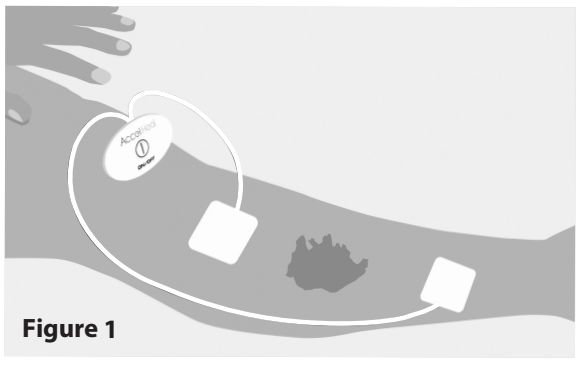

Figure 1

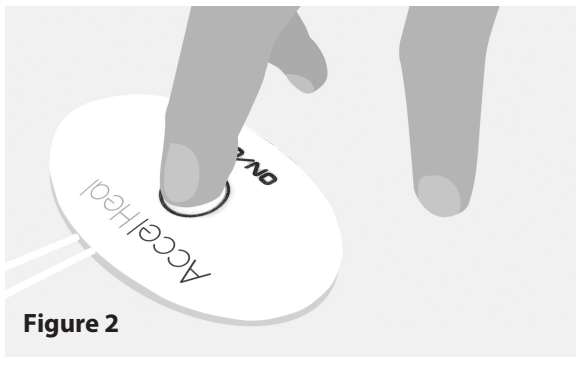

Figure 2

Electrode pads

Only the electrode pads provided should be used with the devices. 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.

Treatment discomfort

The treatment should not cause any additional pain to any wound pain and the electrical stimulation 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. If the treatment causes any additional pain or discomfort, detach the device immediately and contact your healthcare professional.

Skin irritation

Ensure skin is clean and dry before the electrode pads are applied. If skin irritation develops under or around the electrode pads, detach the device and contact your healthcare professional.

Disposing of the used Accel-Heal Devices

The Accel-Heal devices are medical electrical devices 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 devices should be decontaminated by wiping the devices with 70% isopropyl alcohol and disposed of in a Waste Electrical and Electronic Equipment (WEEE) disposal facility. Reprocessing the devices or exposing the devices to chemicals may lead to a failure of the devices.

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 error 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

Heart conditions

Patients with heart conditions or implanted pacemakers should consult their healthcare professional before using Accel-Heal.

Pregnancy

As a precaution, patients who are pregnant are advised to consult their healthcare professional before using Accel-Heal.

Serious diseases

Patients with serious diseases, such as cancer, are advised to consult their healthcare professional before using Accel-Heal.

Epilepsy

Patients with epilepsy should consult their healthcare professional before using Accel-Heal and are advised to refrain from using the devices near the head.

Varicose veins and main arteries

Do not place the electrode pads directly over broken capillaries, varicose veins or main arteries.

Warnings

Water

The Accel-Heal devices are electrical devices and should be kept dry at all times.

Children

Accel-Heal is not for use on patients under 18. To reduce the risk of strangulation or choking keep the devices and accessories out of reach of children.

Environmental conditions for transport, storage and operation

- Please ensure Accel-Heal is stored and transported within the temperature range of 0°C-40°C.
- Please ensure Accel-Heal is operated within the temperature range of 10°C-40°C.
- Please ensure Accel-Heal is stored, transported and operated at less than 95% humidity.
- Please ensure Accel-Heal is stored and transported between 50 - 106 kPa (atmospheric pressure).
- Please ensure Accel-Heal is operated between 70 - 106 kPa (atmospheric pressure).

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

Immunity Test	Immunity Test Levels: Patient Coupling Port		Compliance Level: Patient Coupling Port		
	Professional healthcare Facility Environment	Home Healthcare Environment	Professional healthcare Facility Environment	Home Healthcare Environment	Electromagnetic Environment Guidance
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: $E = \frac{6}{d}\sqrt{P}$ 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 the Accel-Heal devices.

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

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

The Accel-Heal devices are 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		
	Professional healthcare Facility Environment	Home Healthcare Environment	Professional healthcare Facility Environment	Home Healthcare Environment	Electromagnetic Environment Guidance
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 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 devices. 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 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 the devices is allowed.

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

Accel-Heal 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. The device is suitable for use in professional healthcare facility environments and home healthcare environments. 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.
Harmonic distortion IEC	Not applicable	Not applicable	
Voltage fluctuations and flicker	Not applicable	Not applicable	

Test Specifications for Accel-Heal 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 is a Type BF Applied Part
	On/Off

Manufactured by:
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NHSSC: ELZ752
PIP CODE: 373-0942

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