convatec

ConvaVAC™
Negative Pressure Wound Therapy System (NPWT)

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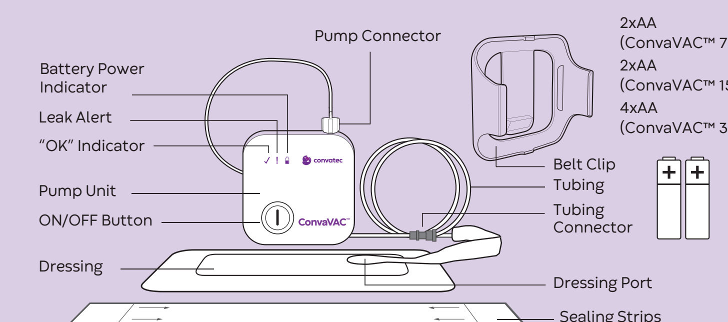

1 PRODUCT DESCRIPTION

ConvaVAC™ is a Negative Pressure Wound Therapy (NPWT) system which consists of:

- A non-sterile (7, 15 or 30 day) pump
- Tubing set
- A sterile Hydrofiber Technology wound dressing
- Sealing strips
- Batteries
- A belt clip

The ConvaVAC™ NPWT Pump maintains a nominal negative pressure of 80mmHg at the wound surface.
The ConvaVAC™ dressing manages exudate via the absorption and gelling capability of Hydrofiber® Technology and via moisture evaporation at the dressing outer surface.
The sealing strips are intended for application around the perimeter of the dressing to maintain a seal throughout wear time **(see Section A)**.
The pump is a battery operated, single use, disposable unit designed to operate for 7 days (ConvaVAC™ 7), 15 days (ConvaVAC™ 15), or 30 days (ConvaVAC™ 30).
The ConvaVAC™ dressings and pump can only be used together.

2 INTENDED PURPOSE

The ConvaVAC™ NPWT system is intended for patients who would benefit from negative pressure wound therapy, as it may promote wound healing via removal of low to moderate levels of exudate.

3 INDICATIONS

The ConvaVAC™ NPWT System is indicated for use on patients that would benefit from a NPWT device and with a low to moderately exuding wound, such as:

- Closed surgical incisions
- Venous Leg Ulcers
- Dehisced wounds
- Flaps and grafts
- Traumatic wounds
- Diabetic Ulcers
- Pressure Ulcers.

4 INTENDED USERS

Healthcare Professionals and Patients and Carers under the supervision of a Healthcare Professional. The ConvaVAC™ NPWT System is suitable for use both in a hospital and homecare setting.

5 INTENDED PATIENT POPULATION

ConvaVAC™ is intended for adult patients who are indicated for negative pressure wound therapy (NPWT).
Healthcare professionals (HCPs) trained in the use of the ConvaVAC™ NPWT System should assess patient suitability for in home use.
Patient selection for home use should be based upon:

- Wound location
- Patient/carer understanding of the device and its use
- Physical ability of the patient/carer to operate the System on a daily basis

Selection should take into account the indications, contraindications, observations and warnings.
The HCP should ensure that users are educated in the use of the ConvaVAC™ NPWT System, alerting them to **Sections B** and **C** of this information leaflet.

6 CLINICAL BENEFIT

To provide negative pressure wound therapy to promote wound healing via removal of low to moderate level of exudate.

7 CONTRAINDICATIONS

The ConvaVAC™ NPWT System should NOT be used in the following situations:

- Patients who are sensitive to, or have known allergies to, silicone acrylic adhesives, sodium carboxymethylcellulose, polyurethane
- Malignant wounds (wound bed and/or wound margins), except in palliative care to enhance quality of life
- Wounds with confirmed and untreated osteomyelitis
- Non-enteric and unexplored fistulas
- Necrotic wounds or wounds with eschar present
- Wounds with exposed arteries, veins, nerves or organs
- Anastomosis sites
- For emergency airway aspiration
- Pleural, mediastinal or chest tube drainage
- Surgical suction

8 PRECAUTIONS/WARNINGS FOR USE UNDER THE DIRECTION OF A HEALTHCARE PROFESSIONAL

- **Do not** use if the product or the packaging is damaged. Dressing sterility is guaranteed unless the dressing pouch is damaged or opened prior to use. Do not re-sterilise.
- The ConvaVAC™ NPWT System is single use and should not be re-used. Re-use may lead to increased risk of infection or cross contamination.
- The ConvaVAC™ NPWT System has not been demonstrated for use in paediatrics. Patient size and weight should be considered when prescribing NPWT.
- If during the use of this device or as a result of its use a serious incident has occurred, please report it to the manufacturer and to the competent authority of the Member State in which the user and/or patient is established.

8.1.Dressing application

- The ConvaVAC™ NPWT Dressing is single use and should not be re-used.
- **Do not** cut the dressing pad.
- The dressing change frequency must be determined and performed by a suitably qualified HCP.
- **Do not** place occlusive dressings over the ConvaVAC™ NPWT Dressing as this may prevent inspection and moisture evaporation.
- Protruding sharp bones or fragments in wounds must be protected by a suitable dressing, or removed prior to using the ConvaVAC™ NPWT System, due to a risk of puncturing organs or blood vessels while under negative pressure.
- Exposed sensitive structures (e.g. blood vessels, nerves, organs and tendons) should be protected from direct contact with the NPWT dressing.
- Hot and humid environments may affect the adherence of the dressing.
- Care should be taken that circulation is not lost through use of a circumferential dressing or NPWT on ischaemic limbs.
- **Do not** use with creams/oil-based products, such as petrolatum, as the dressing and strips may not form an effective seal.

8.2. Use with Surgical Drains

- The ConvaVAC™ NPWT System may be used with surgical drains, but the dressing must not be placed over the tubing as this may compromise the dressing seal and performance of the drain. Surgical drains should operate independently of the ConvaVAC™ NPWT System and be positioned away from the dressing edge.

8.3. Use with Other Electrical Equipment

- The ConvaVAC™ NPWT System should be considered a fire hazard in oxygen rich environments. ConvaVAC™ NPWT System is unsuitable for use in areas where there is danger of explosion (e.g. hyperbaric oxygen chamber).
- The ConvaVAC™ NPWT System is **MR Unsafe;** the system must be removed prior to entry into the MRI suite.
- The ConvaVAC™ NPWT Pump could affect or be affected by CT scanning/X-ray equipment.
- The ConvaVAC™ pump must be removed prior to entry into the scanner/x-ray suite. The dressing may remain in place.

8.4. Bleeding

- Patients must be closely monitored for bleeding as some patients are at a high risk of bleeding complications. If left unmanaged, this could be fatal. If increased or sudden bleeding is observed, the pump should be turned off and disconnected instantly, the dressing left in place and suitable measures taken to stem the bleeding; medical assistance should be sought if necessary.
- Precautions should be taken in the following situations due to a high risk of bleeding complications:
  - Patients actively bleeding, receiving anticoagulants or platelet-aggregation inhibitors.
  - Patients with wounds in close proximity to delicate fascia or blood vessels.
  - Patients having weakened or friable blood vessels, or organs in or around the wound.
- The ConvaVAC™ NPWT System can be used on patients receiving anticoagulants; however, haemostasis must be achieved prior to application. Ensure haemostasis is maintained throughout NPWT. Assess frequently throughout therapy as patients receiving anticoagulants have an increased risk of bleeding during therapy,
- Care should be taken where wounds are near an anastomosis site, near weakened or friable blood vessels or organs, or in the presence of wound infection, trauma or radiation.

9 PRECAUTIONS/WARNINGS FOR THE PUMP DURING HCP APPLICATION OR DAILY USE WITH PATIENT

- **Do not** cut the tubing or pull on the tubing.
- Ensure the tubing and the connections to the pump are not kinked, trapped, or placed where they could be a trip or strangulation hazard.
- Ensure the pump, tubing and the connections are not in a position where they could cause pressure damage to the patient.
- The ConvaVAC™ NPWT System should be used with caution when in the vicinity of electronic equipment such as metal detectors, Radio Frequency Identification Readers or anti-theft equipment, as the potential of EMC interference in all settings cannot be eliminated. When in close proximity to other electrical equipment, check to ensure the pump is functioning correctly as explained in **Section C**.
- **Do not** disassemble or modify the pump. The pump unit does not contain any serviceable parts and does not require calibration prior to use.
- **Do not** use pump if battery compartment cover is missing.
- The system contains small parts which could be a choking hazard. Keep out of reach of children.
- Avoid exposure of the ConvaVAC™ NPWT Pump to sources of liquid. If fluid ingress is observed, discontinue use of the device.
- ConvaVAC™ NPWT System is not intended for use on aircraft; batteries must be removed prior to boarding.

10 OBSERVATIONS

During the body's normal healing process, non-viable tissue is removed from the wound (autolytic debridement), which could initially make the wound appear larger.
If the wound becomes infected, dressings should be checked more frequently and may require changing more often. NPWT is not intended to treat infection; if there are any signs of systemic or advancing infection at the wound area the HCP should be contacted.
When the ConvaVAC™ NPWT Dressing is repeatedly used or used on friable skin, a skin protector, such as ESENTA™ Barrier, should be used prior to the application of the sealing strips to avoid skin stripping.
If the ConvaVAC™ NPWT System is used to bolster skin grafts, inspect the wound regularly, to ensure negative pressure is continually applied and a seal is maintained.
If the dressing's wound contact pad is adhered to the wound, lift the adhesive border, then soak with sterile saline or sterile water prior to removal of the dressing. Careful patient selection is essential; the stated contraindications and precautions should be taken into account.

The HCP must advise the patient of the following:

- To inform their HCP should they experience symptoms of irritation, increased pain, leakage of wound exudate, or evidence of bleeding.
- If bleeding is evident, patients should be instructed to disconnect the pump, leave the dressing in place and seek medical assistance.
- Not to change the ConvaVAC™ NPWT Dressing.
- When showering, disconnect the ConvaVAC™ NPWT Pump from the dressing and avoid exposing the pump to liquid. Do not directly spray the dressing or submerge in water.
- The ConvaVAC™ NPWT Pump does not emit an audible alarm and that the Pump should be accessible so that status can be monitored regularly.
- Check that the system is functioning correctly immediately prior to sleeping and on awakening.
- Check the pump and tubing placement during use based on the guidance in Section B2 and as directed by the HCP.

11 ADVERSE REACTIONS

A serious risk linked to the use of negative pressure on wounds is excessive bleeding which may lead to serious injury or death.
The wound and wound dressings should be regularly inspected for any sign of a change in the patient's blood loss status or spontaneous changes in colour and volume of exudate.

D1 CAUTIONS

These instructions for use are not intended as a guarantee or warranty. They are only intended as a guide. For medical questions, please consult a physician.
This product must be used in accordance with these instructions for use and related labelling.

D2 ELECTROMAGNETIC COMPATIBILITY

The ConvaVAC™ Negative Pressure Wound Therapy (NPWT) System complies with Essential Performance requirements of IEC 60601-1:2005+AMD1:2012 Clause 4.3. Essential Performance of the ConvaVAC™ NPWT System, to achieve its intended use, is to maintain a nominal Negative Pressure of 80 mmHg.
Having been tested, this device is compliant with the limits for medical devices in accordance with IEC 60601-1-2:2014 + A1:2021.

These limits are designed to provide reasonable protection to assure the safety of medical devices from interference from other electrical equipment and devices. The equipment can be affected by radio frequency energy and, if not installed and used in accordance with the instructions, may cause interference to other devices in the vicinity. There is no guarantee that interference will not occur in a particular installation. If further information or guidance on electromagnetic immunity and emissions is needed, please contact Convatec or visit us online at www.convatec.com.

D3 REQUIRED COMPONENTS TO OPERATE THE ConvaVAC™ NPWT SYSTEM EFFECTIVELY

- ConvaVAC™ NPWT sterile dressing (sterilisation via Ethylene Oxide)
- Adhesive sealing sterile strips (supplied with dressing, sterilisation via Ethylene Oxide)
- ConvaVAC™ NPWT pump unit
- ConvaVAC™ 7 / 15: 2x AA Energizer L91 Ultimate Lithium batteries (supplied with pump unit and recommended)
- ConvaVAC™ 30: 4x AA Energizer L91 Ultimate Lithium batteries (supplied with pump unit and recommended)
- Extension tubing with connectors (supplied with pump unit)
- Instructions for use (supplied with dressing and pump unit)

SECTION D | ELECTROMAGNETIC COMPATIBILITY / PUMP SPECIFICATION

Guidance and Manufacturer Declaration - Electromagnetic Immunity

The ConvaVAC™ NPWT System is intended for use in the electromagnetic environment specified below. The customer or the user of the ConvaVAC™ NPWT System should assure that it is used in such an environment.

Immunity Test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8kV contact ± 15 kV air	± 8kV contact ± 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%.
Electrical fast transient/burst IEC 61000-4-4	± 2kV for power supply lines ± 1 kV input/output lines	Not Applicable	Not Applicable
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2kV line(s) to earth	Not Applicable	Not Applicable
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (95% dip in UT) for 0.5 cycles 40% UT (60% dip in UT) for 5 cycles 70 % UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 cycles	Not Applicable	Not Applicable
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	**30 A/m**	**30 A/m**	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6	**10Vrms, 150kHz to 80 MHz**	Not Applicable	Not Applicable
Radiated RF IEC 61000-4-3	**10V/m, 80 MHz to 2,7 GHz 9V/m to 28 V/m, 385 MHz to 5785 MHz**	**10V/m, 80 MHz to 2,7 GHz 9V/m to 28 V/m, 385 MHz to 5785 MHz**	Field strength from fixed RF transmitters, as determined by an electromagnetic site survey a, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:

Note 1 UT is the a.c. mains voltage prior to application of the test level.
Note 2 At 800 MHz, the separation distance for the higher frequency range applies.
Note 3 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ConvaVAC™ NPWT System is used exceeds the applicable RF compliance level above, the ConvaVAC™ NPWT System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the ConvaVAC™ NPWT System

Guidance and Manufacturer Declaration - Electromagnetic Emissions

The ConvaVAC™ NPWT System is intended for use in the electromagnetic environment specified below. The customer or the user of the ConvaVAC™ NPWT System should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The ConvaVAC™ NPWT System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The RF emissions characteristics of ConvaVAC™ NPWT System make it suitable for use in hospitals, transport and home use environments.
Harmonic emissions IEC 61000- 3-2	Not Applicable	
Voltage fluctuation/flicker Emissions IEC 61000-3-3	Not Applicable	

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

Recommended separation distances between portable and mobile RF communications equipment and ConvaVAC™

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz	80 MHz to 800 MHz d=0.35√p	800 MHz to 2,5GHz d=0.7√p
0.01	Not Applicable	0.04	0.07
0.1	Not Applicable	0.11	0.22
1	Not Applicable	0.35	0.70
10	Not Applicable	1.11	2.21
100	Not Applicable	3.50	7.00

For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where is the maximum power rating of the transmitter in watts (W) according to the transmitter manufacturer.
Note 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
Note 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

CE UKCA 2797 0086

Symbol	Meaning	Symbol	Meaning
EC REP	Authorized representative in the European Community		Keep dry
	Risk of explosion		Use-by date
	EU: Not for general waste		Follow instructions for use
	Do not re-use	LOT	Batch code
IP22	Enclosure Rating	US UK	Country of manufactur
	Equipment Classification: Isolation Type BF		Date of manufacture
1060 mbar 700 mbar	Atmospheric pressure limitation		Do not use if package is damaged and consult instructions for use
	Manufacturer		Keep away from sunlight
	Consult instructions for use or consult electronic instructions for use	3V	Voltage
MD	Medical Device		Opening End / Tear
85% 15%	Humidity limitation	MR	MR Unsafe - keep away from magnetic resonance imaging (MRI) equipment
	Fragile, handle with care		Caution
	Non-ionising electromagnetic radiation		Caution
UDI	Unique Device Identifier		Importer
	Single sterile barrier system	STERILE EO	Sterilized using ethylene oxide
	Single sterile barrier system with protective packaging outside	Rx ONLY	Federal (U.S.A.) law restricts this device to sale by or on the order of a physician
2 x 1.5V AA FR6	Battery Type and Quantity	REF	Catalogue number
RECICLA Al Azul Cartón / Al Amarillo Plástico / Metal	Sorting symbol for Spain.	SN	Serial number
FR	Sorting symbol for France.		Do not resterilize
		NON STERILE	Non-sterile
		5°C 41°F 25°C 77°F	Temperature limit

ConvaVAC™ Pump unit Specifications

Dimensions (maximum)	70mm x 70mm x 30mm 2.8in.x2.8in.x1.2 in.
Weight (excluding batteries)	<80g
Lifespan (pump unit) once batteries installed	**ConvaVAC™ 7:** 7 days **ConvaVAC™ 15:** 15 days **ConvaVAC™ 30:** 30 days
Battery type/ Quantity	**ConvaVAC™ 7**: 2 xAA Energizer L91 Ultimate Lithium **ConvaVAC™ 15**: 2 xAA Energizer L91 Ultimate Lithium **ConvaVAC™ 30**: 4 x AA Energizer L91 Ultimate Lithium
Mode of Operation	Continuous
Operating range	-80 ±20mmHg at the wound bed
Vacuum level cut off	<=-200mmHg
Equipment Classification	Internally Powered
Degree of Protection Against Electric Shock	Type BF, Applied Parts include ConvaVAC™ pump, extension tubing and ConvaVAC™ dressing
Ingress protection	IP 22
Storage/ Transport	5-25°C (41-77°F) 15-85%RH 700 to 1060 mbar atmospheric pressure
Operation environment	5-40°C (41-104°F) 700 to 1060 mbar atmospheric pressure
Compliance	IEC EN60601-1 IEC EN60601-1-2 IEC EN60601-1-11
Sterility	non-sterile
Materials of Construction (patient contact)	Pump (moulded parts): Polycarbonate/ABS Tubing: Polyurethane Connectors: Polypropylene

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SECTION A | DIRECTION FOR USE - For the Healthcare Professional Only

A1 DEVICE STORAGE AND PREPARATION

The device should be used in a temperature range of 5-40°C. If the NPWT device has been stored outside of this range, allow the pump to warm up or cool down to room temperature before use.

A2 DRESSING SELECTION

- The wound should fit comfortably within the pad area, allowing for the port to be positioned over intact skin.
- For moderately exuding wounds, the wound area should be no more than 25% of the pad area of the dressing.
- Ensure there is at least a 1cm/0.39 inch overlap of the pad onto the peri-wound skin.
- For shallow wounds (up to 0.5cm/0.2 inch depth) the ConvaVAC™ NPWT System does not need to be used with a filler dressing.
- Wounds greater than 0.5cm/0.2 inch up to 4.5cm/1.8 inch in depth may need to be used in conjunction with filler dressings such as AQUACEL™ Extra, AQUACEL™ Ag+ Extra (Canada only) or AQUACEL™ Ag Advantage (US only) and AQUACEL™ WSF Ribbon dressings. AQUACEL™ filler dressings can be used to bolster exudate management within the System. Consult the specific filler dressing's IFU for more information. If unavailable, standard gauze may be used.

A3 WOUND PREPARATION

- Remove any excess hair from around the wound to ensure good adhesion.
- Irrigate the wound with sterile saline and ensure the peri-wound skin is dry prior to dressing application.

A4 DRESSING APPLICATION

- The application and setup of the System is to be performed by an HCP trained in the application of NPWT devices.
- Whilst the following dressing application steps are recommended, in certain circumstances it may be advantageous to apply the sealing strips after applying negative pressure.

- Use an aseptic technique to apply the dressing to the wound.
- Remove the release liners from the dressing.

A4 - 1

- Apply the dressing centrally to the wound with the port positioned uppermost over intact skin to minimise the risk of fluid collecting around the port and potentially reducing the application of negative pressure, as shown in Diagram A4-1.
- Ensure dressing is not stretched during application.

- Cutting of the silicone adhesive border is permittable, provided a seal is maintained.
- **Do not** cut the pad to reduce risk of leaks.
- Gently smooth down the dressing adhesive border, taking care to avoid creasing, to secure it in place.
- Reposition if required to avoid creasing.
- If ESENTA™ Barrier is used to protect surrounding skin from use of sealing strips, use in accordance with its Instruction For Use (IFU) and allow skin to completely dry.
- The ConvaVAC™ NPWT System can be used in conjunction with compression therapy and offloading devices (e.g., shoes) if required. Care should be taken to ensure that the tubing is routed outside the bandage or the offloading device.

A5 APPLYING SEALING STRIPS

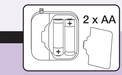
A5 - 1

- Apply sealing strips using 1/2/3 method
- There should be a 1cm/0.39 inch overlap to all sides of the dressing in order to maintain a seal during the wear time of the dressing.

- **Do not** trap the tubing.
- Ensure all release liners are removed.
- Sealing strips and dressing should be replaced simultaneously if either one is removed or lifted.
- **Do not** stretch sealing strips during application.

A6 PUMP APPLICATION

A6 - 1



- Insert the 2 x AA batteries supplied with the pump by removing the battery compartment cover at the back of the pump and inserting them as indicated in the compartment and Diagram A6-1.

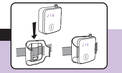
A6 - 2

- All indicator lights will immediately flash simultaneously to indicate the batteries have been inserted correctly.
- Replace the battery compartment cover.

A6 - 3

- Connect the dressing to the pump by twisting the pump tube connector clockwise and the dressing tube connector counter-clockwise. See Diagram A6-3.
- Connect tubing to pump by twisting counter-clockwise. Do not over-tighten. See Diagram A6-3.

A6 - 4



- During use, the pump should either be clipped to the belt using the belt clip or placed in the patient's outer garments such as a pocket or handbag.
- Ensure all tubing is free from kinks and is not trapped to restrict the flow of negative pressure.
- Affix the pump to the belt clip with the display facing outwards and connector tube at the top. Slide the clip onto the patient's belt to secure the clip in place as shown in Diagram A6-4.

A6 - 5

- To apply negative pressure, press the ON/OFF button on the front of the pump for 1.5 seconds to start. **The Green '✓' indicator light will start to flash to confirm the pump is working.**

- It will take up to 60 seconds to establish negative pressure. If negative pressure is not established, the Amber '!' indicator will illuminate. If this happens refer to **Section C** for troubleshooting.
- Contact Convatec if you require assistance in setting up, using or maintaining the ConvaVAC™ NPWT System, or if any unexpected alerts, faults or events are noted with the System.

A7 DRESSING CHANGE/REMOVAL

- Check the dressing regularly.
- The dressing should be changed in accordance with these instructions, or change dressing:
  - If clinically indicated
  - If saturated (See Diagram A7-1)
  - If there are signs of leakage
  - If there is pooling around the port
  - If there is a loss of adhesion
- A typical wear time is 3-4 days, up to a maximum wear of 7 days. The need for silver dressings should be re-assessed after 14 days and alternative wound management considered where appropriate.
- Please refer to Diagram A7-1 for further guidance on when to change the dressing.
- These images should be used as a guide for the HCP to estimate dressing saturation and does not replace clinical judgement.

A7- 1

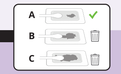


Image A - Dressing is positioned correctly and can remain in place.
Image B - Dressing needs to be changed as port may become blocked with exudate.
Image C - Dressing needs to be changed as dressing has reached its absorption capacity and port may become blocked with exudate.

A7 - 2

- Before changing the dressing:
  - Turn off the pump by pressing the ON/OFF button for 3 seconds.
  - Disconnect the tubing to separate the pump from the dressing as shown in Diagram A7-2.

- To remove the dressing, carefully stretch the sealing strips away from the skin and lift and remove the dressing. Use an adhesive releaser to help with removal, e.g., ESENTA™ Adhesive Releaser.
- If on removal, the dressing is dry, hydrate with sterile saline prior to removal to reduce risk of trauma.
- Fillers should be changed at the same time as the Dressing.
- If NPWT is to be continued, apply a new ConvaVAC™ NPWT dressing repeating the steps in **Section A4**.
- Reconnect the dressing to the ConvaVAC™ NPWT pump.
- Press the ON/OFF button for 1.5 seconds to restart NPWT. The Green '✓' indicator light will flash to show the System is working correctly.

A8 PUMP CHANGE

A8 - 1

- The pump is designed to operate for 7days (ConvaVAC™ 7), 15 days (ConvaVAC™ 15) or 30 days (ConvaVAC™ 30) from start of negative pressure therapy.

- The Amber '🔒' indicator light will flash when battery power is low.
- At the end of the pumps life all indicator lights will stop illuminating (7days, 15days, or 30days).
- To change the pump, first turn off the pump. Then disconnect the tubing from the dressing by untwisting the connectors.
- To connect the new pump, refer to instructions in **Section A6**.

A9 DISPOSAL

- Used dressings and tubing should be disposed of as clinical waste in accordance with local clinical protocols.
- Used pump units should have batteries removed and recycled in accordance with local regulations.
- Where possible, pump units should be decontaminated and recycled.
- For additional guidance on disposal and recycling the patient or carer should visit www.convatec.com or contact Convatec.

SECTION B GENERAL/DAILY USE

Users of the ConvaVAC™ NPWT system are Healthcare Professionals and Patients or carers at home or in care facilities. The ConvaVAC™ NPWT system must be used under the directions of a Healthcare Professional.

B1 ON/OFF

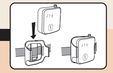
B1 - 1

- The ConvaVAC™ pump unit is fitted with a single button. Press the ON/OFF button for 1.5 seconds to turn the pump on or 3 seconds to turn off.

B2 ROUTINE USE

- The ConvaVAC™ NPWT Pump unit is fitted with lights to show the pump is functioning correctly. The Pump unit is not fitted with audible alarms.
- During use, users should regularly check the pump is functioning correctly. See **Section C** on **Pump Indicators**.
- If therapy cannot be established for any reason, the patient or carer should contact their Healthcare Professional or Convatec.

B2 - 1



- During use, the pump should be attached to the user's belt using the belt clip or placed in a pocket.
- **Do not** trap tubing. Ensure all tubing is free from kinks and is not trapped to restrict the flow of negative pressure.

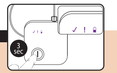
B3 SHOWERING AND BATHING

- A light shower is possible, but the dressing should not be directly sprayed or submerged in water.

B3 - 1

- Separate the pump from the dressing by twisting the pump tube connector counter-clockwise and the dressing tube connector clockwise and place the pump and tubing in a safe, dry place.

B3 - 2



- Before showering, turn off the pump by pressing the ON/OFF button for 3 seconds.

B3 - 3

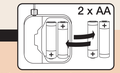
- The dressing will maintain vacuum for approximately 60 minutes after disconnection from the pump.
- After showering reconnect the dressing to the pump by twisting the pump tube connector clockwise and the dressing tube connector counter-clockwise.

- Press the ON/OFF button for 1.5 seconds to re-instate therapy.
- The Green '✓' light will start to flash to confirm the pump is working.
- It will take up to 60 seconds to reach negative pressure and if this fails the Amber '!' light will light up. If this happens see **Section C** for troubleshooting.

B4 BATTERY REPLACEMENT

- If the Amber '🔒' light flashes the batteries are low and will need to be changed.
- If the batteries become low enough that they are nearly drained, the pump will automatically stop therapy and the green '✓' indicator light will no longer be flashing.
- Turn the pump OFF by pressing the ON/OFF button for 3 seconds.

B4 - 1



- Insert the replacement batteries supplied with the pump by removing the battery compartment cover at the back of the pump, lifting out the used batteries and inserting the new batteries as indicated in the compartment and Diagram B4-1.

- All indicator lights will immediately flash simultaneously to indicate the batteries have been inserted correctly.
- Replace the battery compartment cover.
- Press the ON/OFF button for 1.5 seconds to re-instate therapy.

B5 CLEANING

- To clean the pump unit's outer surfaces, wipe with a soft, lint free cloth dampened with mild soapy water.
- If the pump has been splashed with blood or wound fluid, wipe with a soft lint free cloth dampened with a non-flammable anti-bacterial wash.
- Do not immerse in fluids.

⚠ B6 GENERAL ADVICE

Patients should be advised of the following:

- **Do not** perform any maintenance while the pump is in use, i.e. cleaning or changing of batteries.
- Keep out of reach of children and animals.
- Routinely inspect the pump unit and tubing for damage. If there is evidence of damage, contact the Healthcare Professional.
- For any queries relating to the specifications of the ConvaVAC™ device refer to **Section D**.

SECTION C PUMP INDICATORS, OPERATIONS AND TROUBLESHOOTING GUIDE

	Possible Cause(s)	Corrective Action/Comments
No lights illuminated C-1 	The pump is turned OFF. The batteries are depleted. The pump has exceeded its lifespan.	Therapy is not being applied. Press the ON/OFF button for 1.5 seconds to initiate therapy. The Green '✓' light will flash as negative pressure is established. Change batteries as per **Section B4** "Battery Replacement". When the 7/15/30 day lifespan has expired, the pump will stop operating and therapy will cease. If the ON/OFF button is depressed, the Amber '🔒' and '✓' lights will flash alternately. If the fault persists after changing batteries, please contact Convatec customer services or visit the Convatec website.
All lights flash once C-2 	The batteries have been inserted and fitted correctly.	The pump is ready for use. Press the ON/OFF button for 1.5 seconds to initiate therapy. The Green '✓' light will flash as negative pressure is established. Note: If the Amber '🔒' light illuminates after pressing the ON/OFF button, the battery power is too low to start the pump.
Flashing Green '✓' light C-3 	When attached to an affixed dressing and turned ON, the pump is operating correctly.	During regular use, the pump should run intermittently ensuring negative pressure within the System is maintained. Creases in the dressing's adhesive border may cause the pump to run more frequently; smoothing creases out may reduce pump run frequency.
Flashing Green '✓' light & Flashing Amber '🔒' light C-4 	The batteries are low.	Change batteries as per **Section B4** "Battery Replacement". Note: If the batteries become low enough that they are nearly depleted, the pump will automatically cease therapy and the Green ' ✓ light will no longer be flashing.
Flashing Amber '!' light C-5 	Negative pressure therapy is not being delivered due to an air leak in the System.	Check dressing/tubing/pump connections are secure. Check for possible air leaks and smooth out any creases in the dressing's adhesive border. Press the ON/OFF button for 1.5 seconds. The Green '✓' light will flash as negative pressure is established. If the air leak persists, the Amber '!' light will flash and the pump will again turn OFF. Continue checking the dressing for creases and all connectors for leaks and press the ON/OFF button for 1.5 seconds to re-instate therapy. If therapy cannot be established, please contact the Healthcare Professional.
Steady Amber '!' light & Amber '🔒' light C-6 	Negative pressure therapy is unable to be maintained due to a fault in the pump.	**Please contact Convatec customer services or visit the Convatec website.** **Contact the Healthcare Professional to replace the pump.**