

9. AVELLE™ NPWT PUMP UNIT SPECIFICATIONS (MODEL CR4395)

Pump Unit Specifications	
Dimensions (maximum)	72mm x 78mm x 25mm / 3 in. x 3 in. x 1 in.
Weight (excluding batteries)	78g
Lifespan (pump unit) once batteries installed	30 days
Supply Voltage	4.5V DC/Battery (1.5V DC/Battery)
Battery type/Quantity	3x AAA Philips™ Lithium Ultra FR03 batteries
Mode of Operation	Continuous
Nominal vacuum	80mmHg
Maximum vacuum	144mmHg
Equipment Classification	Internally Powered
Degree of Protection Against Electrical Shock	Type BF. Applied parts include Avelle™ NPWT Dressing.
Ingress protection	IP22
Storage/Transport	-25 to +70°C (-13 - 158°F), 90% RH. 700 to 1060 mbar atmospheric pressure
Operation environment	5-40°C (41 - 104°F), 15-90% RH 700 to 1060 mbar atmospheric pressure
Compliance	21 CFR 807, subpart E. Class II IEC 60601-1:2005+AMD1:2012, BS EN 60601-1:2006+A12:2014, ANSI/AAMI ES60601-1:2005/(R)2012, CAN/CSA-C22.2 No. 60601-1:14 IEC 60601-1-2:2014 IEC 60601-1-11:2015
Sterility	non sterile
Programmable Electronic Medical Systems (PEMS) identifier	SNPC1
Materials of Construction (patient contact)	Pump (moulded parts) - Polycarbonate/ABS Tubing – PVC (DEHP free)

10. ELECTROMAGNETIC COMPATIBILITY

Having been tested, this device is compliant with the limits for medical devices in accordance with IEC 60601-1-2:2014 (4th Ed). These limits are designed to provide reasonable protection to assure the safety of medical devices from interference from other electrical equipment and devices. This 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.

The Avelle 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 Avelle NPWT System, to achieve its intended use, is to maintain a nominal Negative Pressure of 80 mmHg.

If damage to the Avelle Negative Pressure Wound Therapy System occurs, please contact your Health Care Professional as soon as possible.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The Avelle™ NPWT System is intended for use in the electromagnetic environment specified below. The customer or the user of the Avelle™ 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 Avelle™ 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 Avelle™ NPWT System make it suitable for use in hospitals, transport and home use environments.
Harmonic emissions IEC 61000-3-2	Not Applicable	
Voltage fluctuations/flicker Emissions IEC 61000-3-3	Not Applicable	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The Avelle™ NPWT System is intended for use in the electromagnetic environment specified below. The customer or the user of the Avelle™ 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	± 8 kV contact ± 15 kV air	± 8 kV 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	± 2 kV for power supply lines ± 1 kV for input/output lines	Not Applicable	Not Applicable
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV 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% U_T (>95% dip in U_T) for 0.5 cycles 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) 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.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The Avelle™ NPWT System is intended for use in the electromagnetic environment specified below. The customer or the user of the Avelle™ NPWT System should assure that it is used in such an environment.			
IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	10 Vrms 150kHz to 80MHz	Not Applicable	Not Applicable
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2,7 GHz 9 V/m to 28 V/m 385 MHz to 5785 MHz	10 V/m 80 MHz to 2,7 GHz 9 V/m to 28 V/m 385 MHz to 5785 MHz	Field strengths 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 At 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.			
^a 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 Avelle™ NPWT System is used exceeds the applicable RF compliance level above, the Avelle™ 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 Avelle™ NPWT System			

Portable RF communications equipment should be used no closer than 30cm (12 in.) to the Avelle™ NPWT Pump unit.












































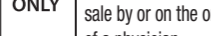
11. CAUTIONS

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 labeling.

12. REQUIRED COMPONENTS TO OPERATE THE AVELLE™ NPWT SYSTEM EFFECTIVELY

- Avelle™ NPWT sterile dressing (sterilisation via Ethylene Oxide)
- Adhesive fixation sterile strips (supplied with dressing and sterilisation via Ethylene Oxide)
- Avelle™ NPWT pump unit (CR4395)
- 3x AAA Philips™ Lithium Ultra FR03 Lithium batteries (six batteries supplied with pump unit and three to be in use at any one time)
- Extension tubing with luer connectors (supplied with pump unit)
- Instructions for use (supplied with dressing and pump unit)

13. DEFINITION OF SYMBOLS

Symbol	Definition	Symbol	Definition
	Batch Code		Temperature limit 5°C /41°F - 25°C /77°F
	Sterilized Using Ethylene Oxide		Atmospheric Pressure Limits
	Humidity Limits		Follow Instructions for Use
	Non Sterile		ON/OFF
	Serial Number		Low Power Indicator
	Catalogue Number		Device is Operating Correctly
	Manufacturer (EU)		Device is Not Operating Correctly
	Date of Manufacture		Pump Unit Battery Type/Quantity
	CE Mark (EU)		Keep Away from Sunlight
	Do Not Reuse		Opening End
	Keep Dry		
	EU: Not for General Waste		Consult Instructions for Use
	Equipment Classification Isolation Type BF		Do Not Re-sterilise
	Latex Free		4.5V Voltage
	Caution		Fragile - Handle with Care
	Do Not Use if Pack is Damaged		Expiry Date
	Risk of Explosion		IP22 Protection of fingers against access to hazardous parts, and protection of equipment against objects larger than 12.5mm (0.5 in.). Protection against drops of water falling vertically when the object is tilted up to 15 degrees from its normal position (in any direction).
	MR Unsafe - keep away from magnetic resonance imaging (MRI) equipment		
	Federal (U.S.A.) law restricts this device to sale by or on the order of a physician		
	Do Not Charge		Do Not Mix Different Types of Brands
	Do Not Deform or Damage		Do Not Mix New and Used
	Do Not Dispose of in Fire		Do Not Open or Dismantle
	Do Not Insert Incorrectly		Do Not Short Circuit
		Keep Out of Reach of Children	

The Avelle™ NPWT System is manufactured and packaged in the UK; origin of batteries is as labelled.

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