

Specification (cont.)

Power Requirements	
Power input voltage	12 V
Pump input power	25 W
Mains Adapter	Input: 100-240 V~, 50-60Hz, 1.2 A(1.2 A-0.5 A) Output: +12V  , 3.4 A
Physical	
Dimensions	150W x 150H x 110D with 300 ml canister
Weight	1kg
Sound Level	
Normal operations	45 dBA @ 1 m maximum
Battery	
Operating time	~ 10–16 hours (therapy) when operating from 25 mmHg to 120 mmHg ~ 8 hours (therapy) at 200 mmHg
Type	Lithium ion
Compliance	UL 2054/IEC62133
Safety Protection	
Protection against electric shock	Device internally powered; external power supply. Class II.
Patient protection	Defibrillation proof type BF
Ingress protection	IP34 Enclosure protected ingress of small objects (>2.5 mm in width) and light water spray.
Compliance	
Certified to: CSA STD C22.2 No 60601-1	
Conforms to: ANSI/AAMI STD ES60601-1 IEC STD 60601-1-6, IEC STD 60601-1-8, IEC STD 60601-1-11	
Evaluated to: IEC STD 60601-1, IEC STD 60601-1-2	
Maximum Pump Temperature (°C)	
LCD screen	TBD
Underside near exhaust	TBD
Attachment knobs	TBD
Carry case exhaust	TBD
Waming and Cooling time	
The pump will require TBD minutes to warm from -25 °C at 20 °C	
The pump will require TBD minutes to cool from 70 °C at 20 °C	
Wireless interfaces	
Bluetooth 5 Class 2 interface	
Type 2 NFC-A tag interface	

Replacement Parts and Accessories

The following products are available from Smith+Nephew. Contact Smith+Nephew customer assistance for availability and ordering information.

New Item Description	SKU number
RENASYS° EDGE PUMP	66803126
RENASYS° EDGE 300 ml Canister with Solidifier	66803139
RENASYS° EDGE 800 ml Canister with Solidifier	66803140
RENASYS° EDGE 300 ml Canister without Solidifier	66803141
RENASYS° EDGE 800 ml Canister without Solidifier	66803142
RENASYS° EDGE Carry Straps	66803137
RENASYS° EDGE Carry Bag	66803136
RENASYS° EDGE Transit Case	66803138
RENASYS° EDGE Plug-in Main Adapter Type A (North America, Japan)	66803146
RENASYS° EDGE Plug-in Main Adapter Type G (UK)	66803147
RENASYS° EDGE Plug-in Main Adapter Type I (Australia, NewZealand, China)	66803149
RENASYS° EDGE Plug-in Main Adapter Type C (Europe, South America, Asia)	66803150
RENASYS° EDGE Clinician Manual	66803143
RENASYS° EDGE Home Healthcare Manual	66803144
RENASYS° EDGE Repair Manual	66803145
RENASYS° Y-Connector	66020971

Storage Conditions

The system and all components should be stored in the following environmental conditions:

Temperature	Between 5 °C and 40 °C (41 °F to 104 °F)
Relative Humidity	15% to 93%
Atmospheric Pressure	700 mbar to 1,060 mbar

Wireless Quality of Services

The RENASYS° EDGE pump overall wireless Quality of Services is implemented accordingly with three wireless communication functions. The RENASYS° EDGE pump has two types of wireless communications interfaces: One Bluetooth Low Energy (BLE) and two NFC.

The Bluetooth interface uses the legal manufacturer UUID and follows the Bluetooth 5 specification utilizing frequency hopping, latency and error correction. It also employs encryption to keep the data secure. The maximum communication range is around 20m. If BLE errors are detected, the RENASYS° EDGE pump may respond in one or two ways:

- The pump could regard the error as fatal and abandon the communication, or
- Request or hint that the transmitter should send the data again in the hope that a subsequent attempt is successful.

The two NFC communication interfaces are ensured by using close range communications less than 50mm, reducing the likelihood of interference. The NFC in the top of the RENASYS° EDGE pump communicates in close proximity to the external smart device and to transfer URL. The internal NFC located in the bottom communicates with the Canister to transfer canister configuration and status information.

- Bluetooth 5 Class 2 interface
- Type 2 NFC-A tag interface

Wireless Coexistence

RENASYS° EDGE was tested for wireless coexistence for Tier 3 indicating a high likelihood of coexistence following the guidelines and test results from ANSI C63.27:2017.

IC (Industry Canada) Statement (IC ID 26135-EDGE)

Antenna Statement

Under Industry Canada regulations, this radio transmitter may only operate using an antenna of a type and maximum (or lesser) gain approved for the transmitter by Industry Canada. To reduce potential radio interference to other users, the antenna type and its gain should be so chosen that the equivalent isotropically radiated power (e.i.r.p.) is not more than that necessary for successful communication.

Conformément à la réglementation d'Industrie Canada, le présent émetteur radio peut fonctionner avec une antenne d'un type et d'un gain maximal (ou inférieur) approuvé pour l'émetteur par Industrie Canada. Dans le but de réduire les risques de brouillage radioélectrique à l'intention des autres utilisateurs, il faut choisir le type d'antenne et son gain de sorte que la puissance isotrope ayonnée équivalente (p.i.r.e.) ne dépasse pas l'intensité nécessaire à l'établissement d'une communication satisfaisante.

Canadian Department of Communications Compliance Statement CAN ICES-3(B)/NMB-3(B)

FCC Compliance (FCC ID 2AWH9-EDGE)

Modifications not expressly approved by Smith+Nephew could void the user's authority to operate the equipment. Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 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

Radio frequency radiation exposure information

For body worn operation, this device has been tested and meets the FCC RF exposure guidelines when used with the Smith+Nephew accessories supplied or designated for this product. Use of other accessories may not ensure compliance with FCC RF exposure guidelines.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Warranties

LIMITED WARRANTY

LIMITATION OF REMEDIES/LIABILITY:

The Smith+Nephew negative pressure wound care electro-mechanical pump (“Pump”) is warranted against defects in workmanship and materials for the warranty period specified below (“Warranty Period”). Smith+Nephew reserves the right to discontinue any Pump or change any Pump’s specifications or designs from time to time. For any Pump that fails to meet the foregoing warranty, this warranty provides and is restricted to replacement or repair (onsite service not included) as elected by Smith+Nephew in its sole discretion. If Smith+Nephew replaces a Pump under this warranty and requests Customer to return the Pump that was replaced, Customer will be invoiced, at Smith+Nephew’s then current list price, for the replacement Pump if Customer does not return the replaced Pump within thirty (30) days after Smith+Nephew’s shipment of the replacement Pump. This warranty does not cover and is voided by any of the following: (i) a warranty claim not made within the first to occur of expiration of the Warranty Period or thirty (30) days following the failure of the Pump to perform as warranted; (ii) a Pump packaged or labeled by someone other than Smith+Nephew or its authorized agents; (iii) a Pump not used in compliance with the specifications, instructions or claims for use of the Pump; (iv) a Pump used in conjunction with disposables, accessories or any other products not specified for use with the Pump; (v) a Pump used in conjunction with expired or reprocessed disposables, accessories or other products specified for use with the Pump; (vi) modification of the Pump; (vii) damage due to misuse, reprocessing, alteration, unauthorized repair or negligent handling or damage due to lack of care by the owner, user, or handler of the Pump including but not limited to storage, handling or cleaning; and (viii) any other damage inflicted to a Pump by the owner, user or handler. This warranty applies only to the original buyer from Smith+Nephew or its authorized distributor and is not transferable.

THIS WARRANTY IS THE SOLE WARRANTY OF SMITH+NEPHEW. ALL OTHER WARRANTIES OF ANY KIND OR DESCRIPTION WHATSOEVER, INCLUDING WARRANTIES OF MERCHANTABILITY, SATISFACTORY QUALITY AND FITNESS FOR A PARTICULAR PURPOSE, EXPRESSED OR IMPLIED, ARE EXCLUDED TO THE FULLEST EXTENT PERMITTED BY LAW.

Pump	Warranty Period
RENASYS [®] NPWT electro- mechanical devices (inclusive of the power cord and power supply)	Two (2) years from date of delivery to original buyer.

CUSTOMER’S SOLE REMEDY, AND SMITH+NEPHEW’S SOLE LIABILITY, FOR ANY CLAIM WILL BE THE REPAIR OR REPLACEMENT BY SMITH+NEPHEW AS PROVIDED FOR IN THIS WARRANTY. EXCEPT FOR THIS LIMITED LIABILITY OF SMITH+NEPHEW, SMITH+NEPHEW UNDER NO CIRCUMSTANCES WILL BE LIABLE FOR ANY (A) CLAIM, FOR DAMAGES OR OTHERWISE, WHETHER ARISING FROM BREACH OF CONTRACT, TORT (INCLUDING NEGLIGENCE) OR OTHERWISE, AND WHETHER OR NOT BASED ON OR FLOWING DIRECTLY, INDIRECTLY OR AS A CONSEQUENCE OF A WARRANTY CLAIM, BREACH OF CONTRACT, A TORT, BREACH OF LAW, OR ANY OTHER CAUSE OR LEGAL THEORY, OR (B) DIRECT, INCIDENTAL, CONSEQUENTIAL OR SPECIAL DAMAGES, LOSSES OR EXPENSES ARISING FROM THIS AGREEMENT OR ITS PERFORMANCE OR LACK THEREOF, OR IN CONNECTION WITH THE SALE OR USE OF, OR INABILITY TO USE, THE PUMP, INCLUDING BUT NOT LIMITED TO, LOSS OF PROFIT OR ANTICIPATED SAVINGS, LOSS OF ANTICIPATED PROFIT, COST OF COVER FOR REPLACEMENT OR ALTERNATIVE PRODUCT, ECONOMIC LOSS, LOSS OF DATA, WASTED EXPENDITURE OR LOSS OF REPUTATION OR GOODWILL.

Icon and Symbol Glossary

Pump buttons

	Play/Pause button
	Mute Button
	Canister Release Button
	Recessed Lock/Unlock Button
	Three Multifunction Buttons

Pump lights

	System OK Light
	Battery Warning Light
	Alarm/Alert Light
	External Power Indicator

Therapy screen icons

	Y-Connector Mode
	Intermittent Mode
	Continuous Mode

Battery icons

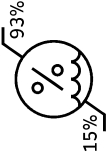
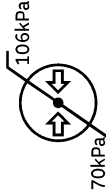
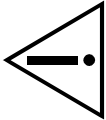
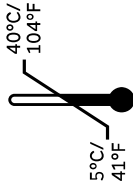
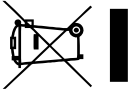
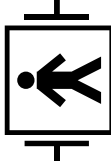
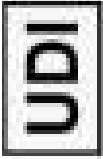
	Full Charge Battery
	Low Battery
	Critical Low Battery
	Charging
	Fully Charged

Status bar icons

	Paused
	System OK
	Alarm/Alert
	Critical Air Leak
	Moderate Air Leak
	Blockage
	Canister Missing
	System Failure
	Pump Too Hot Alert
	Pump Too Hot Alarm
	Paused Too Long
	Canister Full
	Locked
	Bluetooth On
	Muted

Icon and Symbol Glossary

Additional symbols

	Direct current		Relative humidity limitation
	ETL listing mark		
	Manufacturer		Atmospheric pressure
	Refer to instruction manual/ booklet		Serial number
	Caution refer to instruction		Authorized European representative
	Do not use if package is damaged		Single use: do not reuse
IP34	Enclosure protected against ingress of small objects (>2.5 mm in width) and light water spray		Batch code
	Keep dry		MRI Unsafe keep away from magnetic resonance imaging (MRI) equipment
	Storage limit temperature		Product catalogue number
	Date of manufacture		EU: WEEE 2012/19/EU symbol not for general waste
	Caution: U.S Federal law restricts this device to sale by or on order of a physician		Federal Communications Commission Identifier
	Defibrillation proof type BF applied part		Near-field communication (NFC)
	Intentional Radiator		Biological waste symbol
	Medical Device		
	Unique Device Identifier		

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