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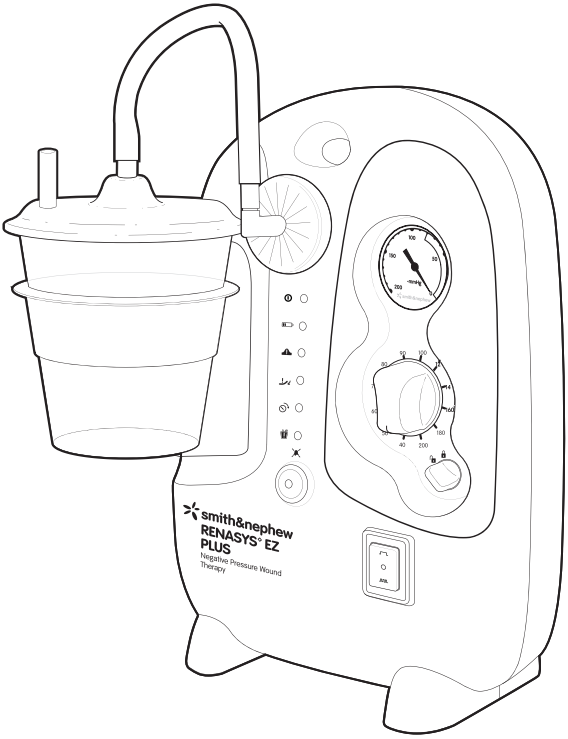
RENASYS® EZ PLUS

Service Manual for
REF 66800697



smith&nephew
RENASYS◇ EZ PLUS
Negative Pressure Wound Therapy

Service Manual for REF 66800697

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Purpose

This manual is intended for the use of biomedical engineers and service personnel responsible for the maintenance of the Smith & Nephew RENASYS® EZ PLUS Negative Pressure Wound Therapy (NPWT) device (REF 66800697).

This manual contains the information you need to maintain the Smith & Nephew RENASYS EZ PLUS NPWT device. It is essential that you read and understand all the information in this manual before conducting any of the test procedures described.

This manual must be used in conjunction with the RENASYS EZ PLUS User Guide which includes information on the operation of the device.

Warning

No modifications of this equipment are allowed. Repairs and adjustments are to be performed only by Smith & Nephew authorized service centers. If repair becomes necessary, contact your local Smith & Nephew customer care representative, sales representative, or call Smith & Nephew Technical Support.

Introduction

RENASYS EZ PLUS is a Negative Pressure Wound Therapy (NPWT) device. Smith & Nephew Wound Dressing Kits and Canisters are required for the proper and effective clinical use of the RENASYS EZ PLUS device.

NPWT involves the application of a wound filler, sealing drape, port or drain to a wound, and the connection of the port or drain to the canister of a RENASYS EZ PLUS device. The RENASYS EZ PLUS device can then be used to apply a controlled vacuum to the wound and fluid from the wound is drawn into the canister attached to the pump. The primary function of the RENASYS EZ PLUS device is to provide a controlled vacuum either continuously or intermittently (5 minutes ON followed by 2 minutes OFF).

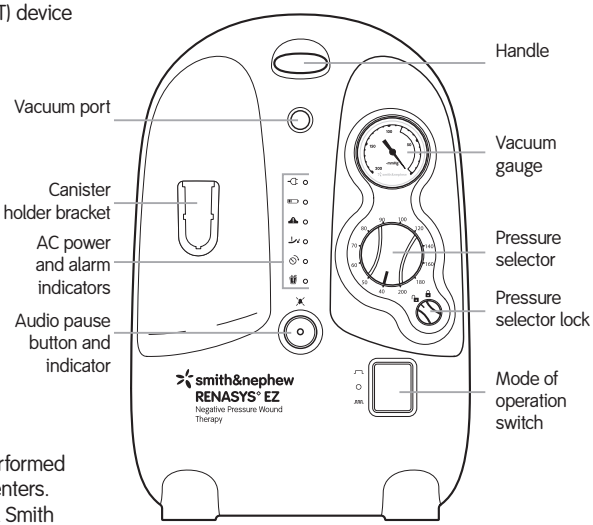
RENASYS EZ PLUS can be operated with or without mains power. In battery mode, the internal rechargeable lithium ion battery provides the necessary power source.

12 pre-set vacuum levels are provided: 40, 50, 60, 70, 80, 90, 100, 120, 140, 160, 180 and 200mmHg.

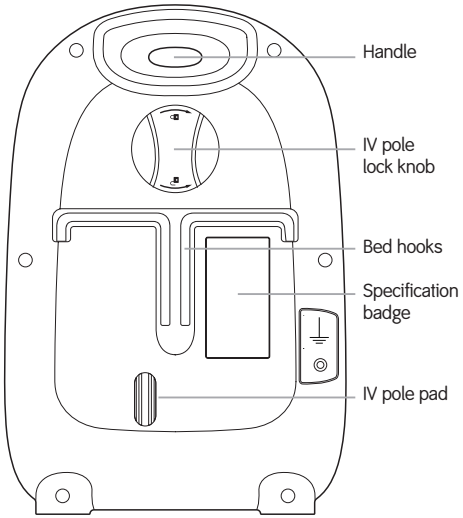
A number of alarms are provided on the RENASYS EZ PLUS device to alert the operator to situations which require user/operator interventions.

Device Controls and Features

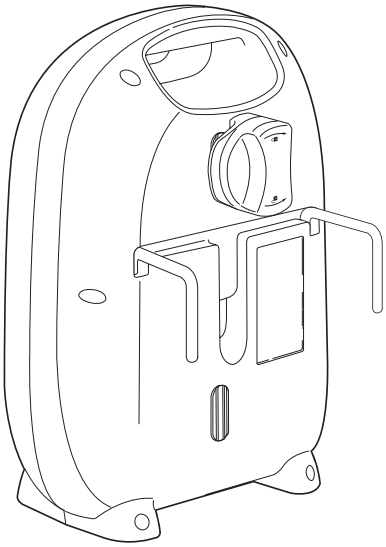
Front view of device



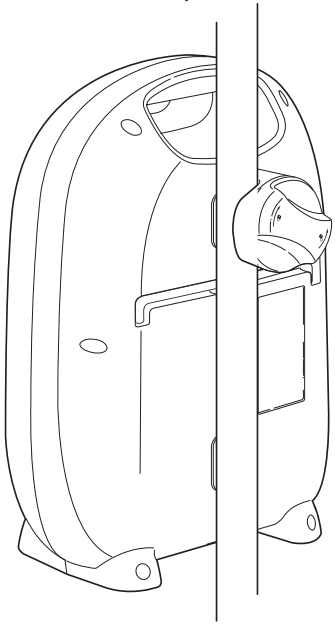
Rear view of device



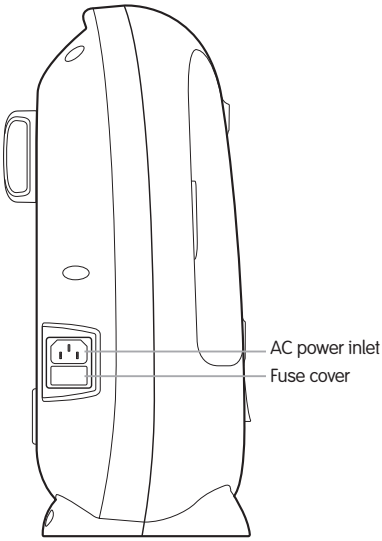
Rear view with bed hooks extended



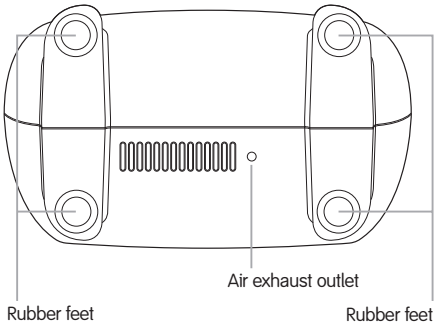
Rear view with IV pole mount in use



Left view of device



Underside of device



Exclusion of Liability

Smith & Nephew disclaims any responsibility if:

- The device is used in accordance with the User Guide (Instructions for Use),
- The electrical installation of the rooms in which RENASYS EZ PLUS is connected to a mains supply comply with the appropriate requirements,
- Testing and maintenance of the device is conducted at appropriate intervals as described in this document,
- Any repair or part replacement activity, other than the maintenance steps described in this document, is carried out by Smith and Nephew or by persons authorized by Smith and Nephew.
- The procedures described in this document are conducted by appropriately trained personnel.
- Please see the device warranty for full details.

Test Procedure

Schedule

The test procedures described in this section are essential in order to ensure that the RENASYS EZ PLUS device is within its service life. An optional checklist and record sheet is provided at the end of the Test Procedure section of this document to record the results of the checks described.

The recommended schedule is:

After each use:

- Cleaning
- Visual Inspection

Every 6 months:

- Functional Tests

Yearly:

- Electrical Safety Check

If there is suspicion of a malfunction of the RENASYS EZ PLUS device, the test procedures in this document will be used to ascertain whether the RENASYS EZ PLUS device is performing correctly.

If the RENASYS EZ PLUS device fails any of the tests described in this manual, has sustained obvious damage, has a missing or illegible label, or has any indication it may not be operating properly, the device should be returned to Smith & Nephew for repair (see the Repair section in this manual for further information).

If the RENASYS EZ PLUS device has been placed in long-term storage, then the tests described in this section must be conducted before returning the device back to service.

Equipment Required

- Electrical Safety Analyser capable of conducting testing in accordance with IEC 62353, e.g. Rigel 288 Safety Analyser, Fluke ESA 620.
- Vacuum measurement gauge with a minimum range of 0 to 250mmHg vacuum, e.g. Extech HD750, 406800 or 407910, Digitron 2000P series, Dwyer series 475, or equivalent.

  Note: All measurement/test equipment must be calibrated and be in acceptable condition prior to use.
- Digital Multimeter or continuity tester to test electrical continuity of fuses
- Disposable gloves
- Stopwatch
- Tube clamp
- Cotton swabs (e.g. Q-tip®)
- Cleaning materials: A range of cleaning materials have been shown to be suitable for use with RENASYS EZ PLUS. The following are recommended options:
  - Chlorine-containing cleaning agents providing up to 1,000ppm available chlorine (always wipe dry immediately after cleaning)
  - 70% Isopropyl alcohol wipes
  - High level disinfectant (e.g. Suprox®) wipes
  - Trionic (sporicidal/fungicidal) disinfectant wipes.

Note: If using Soft Port canisters (REF 66800912, 66800913, 66800937 or 66800938), in order to perform the vacuum test as part of the Functional Testing, you will need to acquire the 800ml canister kit REF 66800423 with T-connector. Please contact Smith & Nephew if you do not have this kit.

Cleaning Instructions (Recommended after each use)

Before conducting the Visual Inspection and subsequent Electrical and Functional Testing described below, ensure that the RENASYS® EZ PLUS device has been cleaned appropriately since its last use. If there is any doubt as to whether suitable cleaning has been conducted, undertake appropriate cleaning steps before proceeding further.

Note: The device should not be connected to AC mains power while being cleaned.

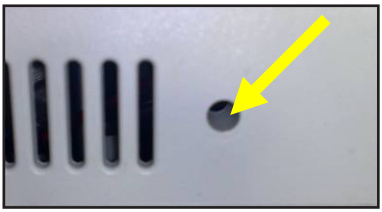
Adherence to facility directives concerning hygiene is of prime importance. Wear disposable gloves.

If there is a used canister, or other disposables present, dispose of these in accordance with your facility protocol and/or local ordinances for the disposal of potentially infected or bio-hazardous materials.

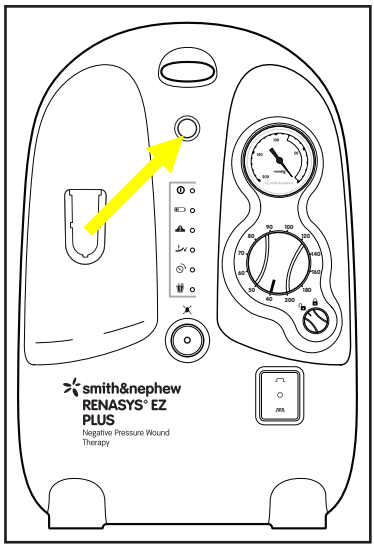
The following are guidelines for cleaning the RENASYS EZ PLUS device.

Cleaning of the RENASYS EZ PLUS outer casing:

- Wipe down the device surface with a damp soft cloth.
- Use a mild cleaning agent, disinfectant, or an antimicrobial agent and ensure its compatibility with plastics. Follow the cleaning/disinfectant agents manufacturer's guidelines for use of such products.
- For areas which are difficult to access with a wipe or cloth, e.g., the exhaust port on the case bottom or the vacuum port on the front of the device, use a cotton swab soaked in cleaning agent.



Exhaust Port (case bottom)



Vacuum Port (device front)

- Dampen another soft cloth with clean water and wipe down all surfaces to remove any excess solution.
- Dry with a separate soft cloth.
- Do not use solvents or abrasives.
- Do not immerse any part of RENASYS EZ PLUS in fluid or use an unnecessarily wet cloth. No fluids should be allowed to enter the device. If any liquids penetrate the device, contact your local distributor.

If a transit case is in use with the device this should be cleaned using the same steps as above on both the interior and exterior of the case. This includes the molded tray and pouch area of the interior and the handle and locks of the case.

Visual Inspection (Recommended after each use)

Following cleaning, conduct a visual Inspection as described below:

1. Make sure the device is unplugged from electrical power and placed on a flat surface.
2. Check the device for visible dents, cracks or missing pieces.
3. Visually assess and physically confirm that the vacuum port, vacuum selector, vacuum selector lock, rocker switch, labeling, case and indicator gauges have no external damage and can be actuated.
4. Visually confirm that the product fuse area is undamaged.
5. Physically confirm that the three position rocker switch moves to each position and remains in place.

6. Visually confirm that the switch printed symbols are legible.
7. Check the bed hook operation. Confirm the ease of opening and closing and the detent feel of the bed hooks when closed against the case. Verify the ability of bed hooks to support the weight of the device by holding the device by the bed hooks.
8. Confirm that the IV pole clamp knob can be freely rotated to the fully open position and then back to the fully closed position.
9. Confirm that the vacuum selector knob can be freely rotated in both directions from 40mmHg to 200mmHg with detents at each setting. NOTE: the vacuum selector knob should not be able to be moved directly between 40 and 200mmHg (clockwise or counter clockwise) nor when the patient lock is in the LOCKED position. Confirm that the patient lock inhibits movement when it is in the locked position.
10. Inspect the rear of the RENASYS EZ® PLUS device and confirm that the unit label is present and that the REF and SN number are clearly visible.

(Label information may vary from this example)

11. Inspect both ends of the AC power cord for any frayed or missing insulation, any bent, loose or missing plug blades.
12. Rotate the device through 360°. Confirm that the device does not have any rattles indicating loose internal or external components.

If any of the above checks are failed, the device is not suitable for use. Please follow the instructions in the Repair section to arrange repair.

Electrical Safety Checks (Recommended annually)

Perform the following electrical safety checks IN THE ORDER LISTED BELOW using the Electrical Safety Analyzer, in accordance with IEC 62353 for Class I Medical Electrical Equipment.

CAUTION: *Electrical safety testing should be performed by a biomedical engineer or other qualified person.*

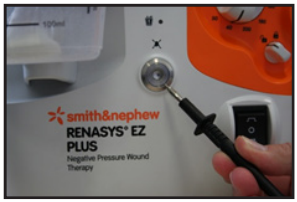
Protective Earth Resistance Tests

For measurement of protective earth resistance, the test equipment must be able to deliver at least 200mA into 500 mΩ. The open circuit voltage must not exceed 24 Volts.

First measure the protective earth resistance of the power cord alone. Acceptance criteria: <100mΩ.

Second measure the protective earth resistance with the power cord connected to the device. Measure the resistance between the earth pin on the power cord plug and two points on the device: (i) the metal screw adjacent to the AC power inlet, and (ii) the audio pause button on the front face of the device (see photographs below). Acceptance criteria: <300mΩ.

Test probe on the metal screw adjacent to the AC power inlet.



Test probe on the audio pause button

Equipment Leakage Current Tests

Equipment leakage current measurement shall only be performed after the protective earth testing has been passed.

For the Equipment Leakage Tests, use the probe of the Electrical Safety Analyzer to touch the metal screw adjacent to the AC power inlet (note: the probe must touch the metal).

Test 1: Normal polarity. Acceptance Criteria: Max: 500µA.

Test 2: Reversed polarity. Acceptance Criteria: Max: 500µA.

Precaution: Disconnect the Electrical Safety Analyzer before proceeding to the Functional Tests.

Functional Tests (Recommended every 6 months)

Mains Operation

Connect the power cord to the device and to an AC power supply.

Verify that the Alarm LEDs, the Audio Pause button indicator, and the audible alarm flash briefly as AC power is connected. An audible alert should chirp once. Note that the battery indicator has both a green LED and an amber LED. Both should be visible on close inspection.

The ON/OFF LED should remain off.

Connect an 800ml waste canister from kit REF 66800423 to the vacuum port.

Connect a tube set complete with T-piece (from kit with REF 66800423) in accordance with the instructions for use. It will be necessary to block flow within this tube for certain tests and to modify the terminal end of the tube to permit connection to your vacuum measurement equipment.

Move the three position rocker switch to the CONTINUOUS therapy position (up). Verify that the device starts suction and that the ON/OFF LED is illuminated solid green.

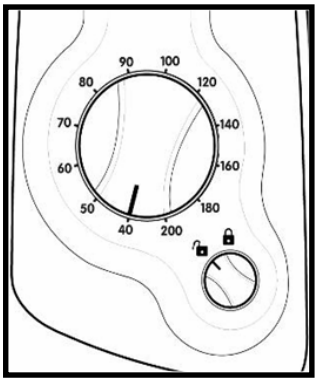
Move the three position rocker switch to the OFF position (center). Verify that the device stops and that the ON/OFF LED is no longer illuminated.

Move the three position rocker switch to the INTERMITTENT therapy position (down). Verify that the device starts suction and that the ON/OFF LED is illuminated solid green.

Move the three position rocker switch to the OFF position (center). Verify that the device stops and that the ON/OFF LED is no longer illuminated.

Connect the distal end of the canister tube to a calibrated vacuum gauge.

Set the vacuum selector to 40mmHg and position the rocker switch to CONTINUOUS mode (up). Verify that the vacuum measured on the calibrated vacuum gauge is 40mmHg ±10mmHg.



Confirm that the RENASYS EZ Plus analog gauge displays 40mmHg ±10mmHg.

Incrementally advance the vacuum selector to each set point up to 200mmHg confirming that the device controls to the target value ±10mmHg on both the analog gauge and the calibrated vacuum gauge.

Turn off the device. Disconnect the distal end of the canister tube from the calibrated vacuum gauge.

Battery Operation

The RENASYS EZ PLUS device should be within its operating temperature range for this test. If the battery is deeply depleted it should be charged for a minimum of 2 hours prior to this test. (A battery is assumed to be deeply depleted when the device will not turn on when not connected to AC mains power, but will operate on AC power without a charge fault indication (battery status LED solid amber)). When charging the battery, the battery status indicator LED will flash green. If the battery status indicator LED is solid amber, or if there is no indication of battery charging, the device requires repair.

Connect the power cord to the device. The battery status indicator LED should be flashing green or solid green [full charge]. Any variation should be noted as a failure [flashing amber, solid amber or no LED illumination are all failures]. Please note – this should be observed after 5 seconds to permit the startup sequence to conclude.

With the vacuum selector still set to 200mmHg press the rocker switch to Continuous.

Disconnect the device from AC power. Verify that the device continues to operate. Turn off the device.

Alarm Operation –
Low Vacuum, Leak and Audio Pause

Reconnect the power cord to the device and connect to an AC power supply.

Detach the canister from the device.

With the vacuum selection knob set to 200mmHg move the rocker switch to Continuous mode.

Verify that the Low Vacuum alarm LED flashes and an audible alarm asserts on and off. For reference, this should occur in less than 30 seconds.

Immediately press and release audible alert pause (large button below the LEDs). Verify that the Audio alarm is no longer active and that the Audio Pause LED and Low Vacuum LED both flash.

In less than 30 seconds, the High Flow alarm should assert. Verify that the High Flow alarm LED flashes and Audio alarm sounds on and off.

Press audible alert pause (mute). Verify that the audible alarm is no longer active and that the alert pause (mute) button LED, Low Vacuum LED and High Flow LED all flash. Start a timer when actuating the audible alert pause.

The audible alert pause (mute) should expire between two (2) and four (4) minutes. The audible alert should reassert.

Turn off the device.

Alarm Operation – Blockage/Canister Full

Reattach the canister and tube set to the device.

With the device set to 120mmHg, move the three position rocker switch to CONTINUOUS mode (up).

Clamp the canister tube between the T-piece and the canister. Allow the device to reach the set point; allow 1 minute. Start a timer and verify that within 3 minutes the blockage/full alarm asserts, with LED flashing and on/off sound.

Press audio pause. Verify that the audio alarm is no longer active, that the audio pause LED and the blockage/full alarm LED both flash.

Turn off the device.

Intermittent Vacuum

Loosen the pinch clamp on the canister tubing. Plug the end of canister tube and move the rocker switch to INTERMITTENT mode (down).

Verify that the device operates (pump runs) for 5 minutes ±30 seconds.

Next, verify that the device does not operate (pump does not run) for 2 minutes ±20 seconds. Note the ON/OFF indicator LED should remain illuminated throughout this test.

Turn off the device.

Battery charge

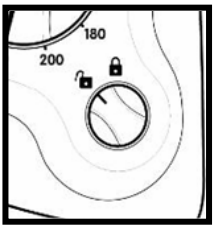
The battery should be prepared for shipment and/ or storage by charging to between 30% and 40% of its capacity. This may be achieved by first running the device until the battery alarm sounds and then recharging the unit for 1½ hours.

If the device is to be stored for an extended period, it should periodically (every 6 months) be re-charged to the 30 % – 40 % level as described above.

Cleaning and packing

After testing the device as described above, the device should be cleaned again as previously described.

Set the vacuum selector knob to 80mmHg and ensure the Patient Lock is in the unlocked position.



Confirm that the IV pole clamp is closed (screwed fully into the device).

Prior to returning the device for service, it should be packed in a polythene bag and if possible, either in the original packaging, or in a protective case (REF 66800587). The appropriate power cord and canister ring kit (REF 66800060) should be included.

Performance and Safety Check List		UNIT SERIAL #		
	Steps	**Yes**	**No**	**Comments**
Physical Appearance Check				
1	Device cleaning record present and/or cleaned according to this procedure			
2	Vacuum port and exhaust port on base of device are free from obstructions, dust or foreign materials			
3	Exhaust port and vacuum port cleaned			
4	Clean all external surfaces with germicidal/ antibacterial wipes and dry with disposable towel or cloth			
5	Device free of visible damage, cracks, missing pieces			
6	Vacuum port, vacuum selector, vacuum selector lock, rocker switch, labeling, case and indicator gauges have no exterior damage and can be actuated			
7	Fuse area has not been damaged and the two fuses are acceptable and are both T3.15A fuses			
8	Three position rocker switch moves to each position and remains in place			
9	Switch printing remain legible			
10	If present, both ends of the power cord are free from fraying, missing insulation, bent, loose or missing plug blades or missing earth/ground			
11	The device is free from rattles indicating loose components			
12	Bed hooks are secure and easy to operate			
13	IV pole clamp knob rotates freely across its range of operation			
14	Vacuum selector rotates 40mmHg to 200mmHg, clockwise and counterclockwise and selector knob lock functions			
15	The device label is present and that the REF and SN numbers are clearly visible			SN
Electrical Safey Check				
16	Protective Earth Resistance: Acceptance Criteria: Cord electrical resistance <100 mΩ IN ACCORDANCE WITH IEC 62353:			mΩ
17	Protective Earth Resistance: Acceptance Criteria: Cord + Device electrical resistance <300 mΩ IN ACCORDANCE WITH IEC 62353:			mΩ

	Steps	Yes	No	Comments
18	Equipment Leakage Current Test (Normal Polarity): Acceptance Criteria: Max: 500µA IN ACCORDANCE WITH IEC 62353:			µA
19	Equipment Leakage Current Test (Reversed Polarity): Acceptance Criteria: Max: 500µA IN ACCORDANCE WITH IEC 62353:			µA
Electrical Functionality				
20	Alarm LEDs, Audio Pause button LED, and the audible alarm flash and sound briefly as AC power is connected			
21	The ON/OFF indicator LED remains OFF			
22	When the rocker switch is set to CONTINUOUS, device starts suction and the ON/OFF LED is solid green			
23	When the rocker switch is set to off, the device stops suction and the ON/OFF LED is OFF			
24	When the rocker switch is set to INTERMITTENT, the device starts suction and the ON/OFF LED is solid green			
25	When the rocker switch is set to off, the device stops suction and the ON/OFF LED is OFF			
26	At all settings (40-200mmHg), the device controls and displays within ± 10mmHg			
Battery Operation				
27	The battery charging indicator LED remains flashing or steady green when AC power is connected			
Alarm Operation – Low Vacuum, Leak and Audio Pause				
28	The Low Vacuum LED flashes and an audible alarm asserts on and off within a period of 30 seconds (reference)			
29	Pressing audio pause interrupts the audible alert. The LED for the alert and the audible pause button LED flash			
30	Within 30 seconds (reference) after step 29 the high flow alarm LED flashes, the audible alert reasserts, and the Low Vacuum LED remains flashing			
31	Pressing audio pause interrupts the audible alert. The LED for the alert and the audible pause button LED flash			
32	Audible alert pause (mute) lasts between 2 and 4 minutes before sound reasserts			

	Steps	Yes	No	Comments
Alarm Operation – Blockage/Canister Full				
33	Blockage alert asserts within 3 minutes and can be muted			
Intermittent Vacuum				
34	Verify that the device runs for 5 minutes ±30 seconds			
35	Verify that the device remains stopped for 2 minutes ±20 seconds			
Battery Charge Level				
36	Battery charge level set per the procedure			
Cleaning and Packing				
37	Device cleaned			
38	Dial set to 80mmHg and patient Lock is OFF			
39	IV Pole Clamp is screwed fully in			
40	Device re-packaged			
Summary of Results				
41	Overall Physical Appearance showed no anomalies and device is clean			
42	Electrical Safety Testing readings meet the requirements (16-19)			
43	Functional evaluation successfully completed			
44	Battery charge level per the procedure			
45	Device re-packaged			

Performed by:

Print Name:		
Signature:		Date:
Location (Address):		

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Repair

There are no user-serviceable components inside the RENASYS® EZ PLUS NPWT device. Repairs and adjustments are to be performed only by Smith & Nephew authorized service centers. To arrange repair, please contact the Smith & Nephew Customer Care Center or your Smith & Nephew Sales Representative.

WARNING: No modification of this equipment is allowed.

Fuses

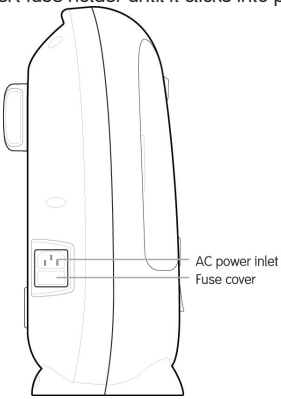
There are two replaceable fuses in the RENASYS EZ PLUS NPWT device. These are located in the fuse holder of the AC power inlet to the device. The fuses are T3.15Amp, 5.2 x 20 mm, time-lag T fuses with a glass body and a 250 Volt rating. (Schurter part number 0034.3122.)

WARNING: To prevent electric shock, unplug the unit from the electrical outlet before attempting to replace fuses.

WARNING: To avoid fire hazard, use only fuses of the correct type, voltage and current rating.

To Inspect and/or Replace Fuses

1. Unplug the power cord from the power outlet and from the RENASYS EZ PLUS device.
2. The fuse compartment can be found below the AC power inlet of the device.
3. Open the fuse compartment by depressing the catch and pulling outwards.
4. Replace fuses. See Technical Specification section of this document for replacement fuse types.
5. Reinsert fuse holder until it clicks into place.



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Spare Parts

The following replacement parts are available from Smith & Nephew:

Part Description	REF (product catalog number)
Fuse	Available from electrical suppliers. T3.15Amp, 5.2x20mm, 250v, time-lag T, glass body.
Canister Ring	66800060
Power Cords*	
North America Power Cord*	66800193
UK Power Cord*	66800213
Continental Europe Power Cord*	66800291
South African and India Power Cord*	66800302
Australia and New Zealand Power Cord*	66800303
Brazil Power Cord*	66801194
China Power Cord *	66801056

* WARNING: The use of replacement parts from any supplier other than Smith & Nephew may compromise safety as a result of increased electromagnetic emissions or decreased immunity to electromagnetic interference of RENASYS EZ PLUS device.

Technical Specification

Vacuum Set Points	40, 50, 60, 70, 80, 90, 100, 120, 140, 160, 180 and 200mmHg
Power Requirements	100-240VAC 50/60Hz 90VA
Fuse	T3.15Amp, 5.2x20mm, 250v, time-lag T, glass body
Dimensions	361x240x170mm (14.5x 9.5 x 7in)
Weight	3.7 kg (8.14 lbs)
Operating Time – Battery	~ 40 hours (therapy)
Battery Type	Lithium ion
Charging Time	~ 6 hours
Protection Against Electric Shock	Class I
Patient Protection	Type BF
Ingress Protection	IP2X
Mode of Operation	Continuous
Storage/ Transport	-10 to 55°C (14 to 131°F) 30 to 70% RH 700 to 1060mbar atmospheric pressure
Operating Environment	5-35°C (41-95°F) 30 to 70% RH 700 to 1060mbar atmospheric pressure
Compliance	UL 60601-1 IEC 60601-1 IEC 60601-1-2 CAN/CSA C22.2

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Glossary of symbols

Operation switch

Continuous therapy Device will maintain the preset vacuum level without stopping until switched off.

OFF Device is not delivering NPWT.

Intermittent therapy
Device cycles on and off in increments of approximately 5 minutes ON (active vacuum) and approximately 2 minutes OFF (no vacuum).

Indicators

On/off When the operation switch is in the continuous or intermittent mode, the indicator will illuminate green.

Battery indicator

- Battery full: Solid green indicator.
- Battery charging: Blinking green indicator.
- Battery low: Audible alarm and blinking yellow indicator.
- Battery fault: Solid yellow indicator.

Indicators

Over vacuum When the system encounters excessively high vacuum (of >235mmHg) the device will stop delivering NPWT. The audible alarm will sound and the alarm indicator will flash yellow.

Leak When the system detects a significant leak, the audible alarm will sound and the alarm indicator will flash yellow.

Low vacuum If the vacuum level is lower than set point of therapy by >15mmHg, the audible alarm will sound and the alarm indicator will flash yellow.

Blockage/Canister full When the system detects that the canister is full or that there is a blockage in the system, the audible alarm will sound and the alarm indicator will flash yellow.

Audio pause Pressing the audio pause button will silence the alarm for approximately 2–4 minutes.

Equipment Classification
Isolation type BF applied part

CSA International Classification

EU:
Not for general waste

Refer to instruction manual/booklet

Caution:
Follow operating instructions

Do not use if package is damaged

Biological risk

Single use
Do not reuse

Patient number

Patient

Keep dry

-10°C/14°F 55°C/131°F
Storage temperature

Date of manufacture

Place of manufacture

Earth
(ground)

Fuse

Alternating current

Lock position

Unlock position

EC REP European representative

LOT Batch code

SN Serial number

REF Product catalogue number

CE 0297 CE mark

Keep upright

Non-ionizing electromagnetic Radiation

℞ Only Caution: U.S. Federal law restricts this device to sale by or on the order of a physician

EN

Electromagnetic compatibility

This equipment has been tested and found to comply with the limits for medical devices to IEC 60601-1-2-2001. These limits are designed to provide reasonable protection against harmful interference in a typical medical 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 other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation.

Guidance and manufacturer's declaration - electromagnetic immunity

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

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidelines
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 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	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV line to line ±2 kV line to earth	Mains power quality should be that of a typical commercial or hospital environment
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 sec	>95% for 10ms 60% for 100ms 30% for 500ms >95% for 5000ms	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptable power supply or battery
NOTE *U_T is the a.c. mains voltage prior to application of the test level*			
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: d = 1.2 √*P* d = 1.2 √*P* (80 MHz to 800 MHz) d = 2.3 √*P* (800 MHz to 2.5 GHz) where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in yards/metres (yd./m). 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[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

NOTE 1: At 80 MHz, 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 device is used exceeds 3V/m, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Guidance and manufacturer's declaration – electromagnetic emissions

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

Emissions test	Compliance	Electromagnetic environment – guidelines
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The device is suitable for use in all establishments including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-2	Comply	

WARNING: The device should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the device should be observed to verify normal operation in the configuration in which it will be used.

Recommended separation distances between portable and mobile RF communications equipment and the device

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m):**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1.0	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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 *P* 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.

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10/2012

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