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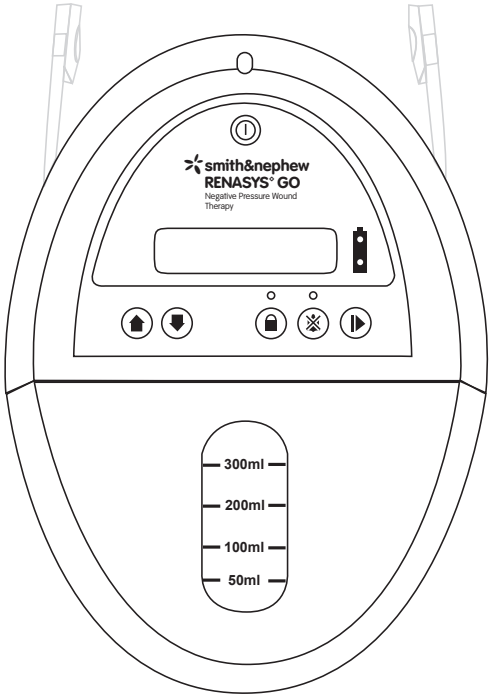
RENASYS GO

Service Manual for
REF 66800164



smith&nephew
RENASYS◇ GO
Negative Pressure Wound Therapy

Service Manual for REF 66800164

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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® GO Negative Pressure Wound Therapy (NPWT) device (REF 66800164) with software versions 0.64, 0.66 and 0.67.

Note: The software version can be viewed momentarily on the screen when the RENASYS GO device is first powered on.

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

This manual must be used in conjunction with the RENASYS GO 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 GO is a portable Negative Pressure Wound Therapy (NPWT) device. It is designed to be used with a Smith & Nephew Power Supply (REF 66800161 or 66800696). Smith & Nephew Wound Dressing Kits and canisters are required for the proper and effective clinical use of the RENASYS GO device.

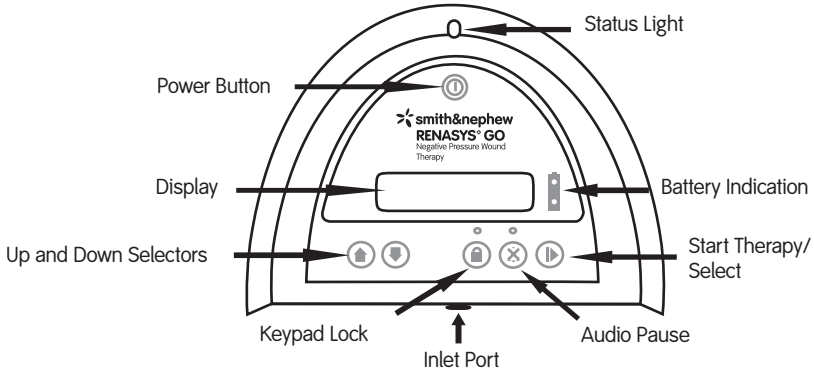
NPWT involves the application of a wound filler, sealing drape, port or drain to a wound, and the connection of the port or drain to the canister of a RENASYS GO device. The RENASYS GO device can then be used to apply a controlled vacuum to the wound and fluid from the wound is drawn into the canister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

RENASYS GO can be operated with or without mains power. An external power supply is used to provide a low voltage DC supply to the device when mains power is being used. 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 GO device to alert the operator to situations which require user/operator interventions.

Device Control Panel



Exclusion of Liability

Smith & Nephew disclaims any responsibility only if:

1. The device is used in accordance with the User Guide (Instructions for Use);
2. The electrical installation of the rooms in which RENASYS GO is connected to a mains supply comply with the appropriate requirements;
3. Testing and maintenance of the device is conducted at appropriate intervals as described in this document;
4. Any repair or part replacement activity, other than the maintenance steps describe in this document, is carried out by Smith & Nephew or by persons authorized by Smith & Nephew;
5. The proceedure describe in this document are conducted by appropriately trained personnel.

Plese 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 GO device is within its service life. An optional checklist and record sheet is provided at the end of the Test Proceedure 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 GO device, the test procedures in this document will be used to ascertain whether the RENASYS GO device is performing correctly.

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

Equipment Required

- Electrical Safety Analyzer capable of conducting testing in accordance with IEC 62353, e.g. Rigel® 288 Safety Analyzer, Fluke® ESA 620.
- Vacuum measurement gauge with minimum range 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.
- Disposable gloves
- Plastic O-ring removal tool, e.g. Golem Gear® GG Yellow Pick (or generic non-metallic or rubber tipped/coated forceps)
- Smith & Nephew O-ring (REF 66800603)
- Smith & Nephew odor filter (REF 66800061)
- #1 Posidriv® screwdriver
- Stopwatch
- Flexible tube with ~0.25 inch (6mm) internal diameter
- 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 GO.

  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 66800914, 66800916, 66800939 or 66800940), in order to perform the vacuum test as part of the performance check, you will need to acquire the 300ml waste container kit (REF 66800165) with T-connector. Please contact Smith & Nephew if you do not have this kit.

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Cleaning Instructions (Recommended after each use)

Before conducting the visual inspection and subsequent testing described below, ensure that the RENASYS® GO 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.

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

If there is a used canister, carry bag or strap, other single patient use accessories or 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 RENASYS GO device.

Cleaning of the RENASYS GO device outer casing:

1. Wipe down the device surface with a damp soft cloth.
2. 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.
3. For area which are difficult to access with a wipe or cloth, use a cotton swab soaked in cleaning agent.

4. Dampen another soft cloth with clean water and wipe down all surfaces to remove any excess solution.
5. Dry with a separate soft cloth.
6. Do not use solvents or abrasives.
7. Do not immerse any part of RENASYS GO 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. Confirm that the membrane LEDs, push buttons, and the LCD display are physically undamaged
4. Confirm that the inlet connector and O-ring are physically undamaged
5. Confirm that the DC inlet connector is physically undamaged
6. Confirm that strap pins on each side of the device are in place and secure
7. Inspect both ends of the AC power cord for any frayed or missing insulation, any bent, loose or missing plug blades
8. Inspect both ends of the power supply DC cord for any frayed or missing insulation, or bent, loose or missing DC plug
9. Inspect both AC and DC power cables for any signs of damage

10. 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 Repair section of this document 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 internally powered Medical Electrical Equipment with Class I or Class II Power Supply (depending upon the type of power supply provided for use with the device).

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

Note: If the device is fitted with the optional Class II power supply (REF 6800696), then step 1 below is not applicable and the acceptance values for Equipment Leakage are changed.

1. **Protective Earth Resistance Tests (Class I only)**

   For measurement of protective earth resistance the test equipment must be able to deliver at least 200 mA into 500 mΩ. The open circuit voltage must not exceed 24 Volts. The power cord acceptance criteria for electrical resistance is <100 mΩ.

2. **Equipment Leakage Current Tests**

   Note: For devices with Class I power supplied, the 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 securing the filter door on the base of the device.

   Test 1: Normal polarity.

   Acceptance Criteria (Class I): Max: 500µA.
   Acceptance Criteria (Class II): Max: 100µA.

   Test 2: Reversed polarity.

   Acceptance Criteria (Class I): Max: 500µA.
   Acceptance Criteria (Class II): Max: 100µA.

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

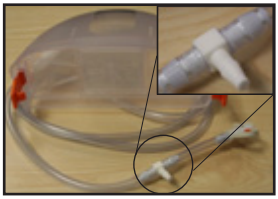
Functional Tests (Recommended every 6 months)

Mains Operation

1. Connect the DC cord from the power supply unit to the DC-in socket on the device. Connect the AC power cord to the power supply unit and to AC mains power.

2. Verify that all the membrane LEDs and the status light operate briefly as power is connected.
3. Verify that the green battery charging LED flashes slowly (or illuminates steadily if battery is fully charged).
4. Connect a RENASYS GO canister with REF 66800165 to the device.

   Note: This canister type must be used during Functional Testing. It has a white T-piece in the canister tubing close to the connector.



5. Connect a separate piece of tubing to the canister tubing connector, and a calibrated vacuum gauge to the other end of the tubing.

6. Press the POWER button for 2 seconds to switch on the device. Verify that the LCD display shows “Welcome Starting” screen and the current software version (e.g. V0.66), and then changes to “Standby” on the upper line and the set-point on the lower line.

7. Adjust the set-point to 40mmHg by use of the UP or DOWN button, and press the SELECT button to start the device. Verify that the device starts suction, that the status light is illuminated green, and that the LCD screen displays “Continuous” and the vacuum set-point.

8. Press the SELECT button to stop the device. Verify that the device stops suction, and the LCD screen displays “Standby” and the vacuum set-point.

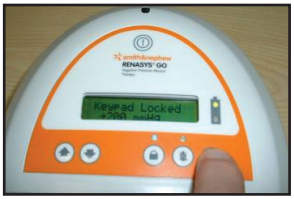
9. Press the SELECT button to start the device. Allow the vacuum level to stabilize (this may take up to 60 seconds), and verify that the pressure measured on the Test Vacuum Gauge is 40mmHg ±10mmHg.

10. Adjust the set-point to 180mmHg by use of the UP button and press the SELECT button to start the device. Allow the vacuum level to stabilize (this may take up to 60 seconds), and verify that the pressure measured on the Test Vacuum Gauge is 180mm ±10mmHg.

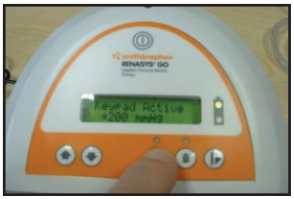
Keypad Lock

1. Press the KEYPAD LOCK button for 2 seconds. Verify that the blue LED above the button illuminates and that the LCD screen displays “Keypad Locked”, followed by “Continuous” on the upper line, with the set-point on the lower line.

2. Press the SELECT button to attempt to stop the device. Verify that the device does not stop and that the LCD screen displays “Keypad Locked”.



3. Press the KEYPAD LOCK button for 2 seconds. Verify that the blue LED above the button extinguishes and that the LCD screen displays “Keypad Active”.



4. Press the SELECT button to stop the device. Press the POWER button for 2 seconds to switch off the device.

Battery Operation

1. Switch off the AC mains supply. Disconnect the Power Supply DC lead from the device.

2. Press the POWER button for 2 seconds to switch on the device. Verify that during the POWER button press, the Status light illuminates amber, and the membrane LEDs all illuminate.

3. Verify that the LCD display shows “Welcome Starting” screen and the software version, and then changes to “Standby” on the upper line and the set-point on the lower line.

4. With the device still set to 180mmHg press the SELECT button. Verify that the device starts suction, that the Status light is illuminated green, and that the LCD screen displays “Continuous” and the vacuum set-point.

5. Press SELECT to stop the device. Press the POWER button for 2 seconds to switch off the device.

Alarms Operation
low vacuum, leak and audio pause

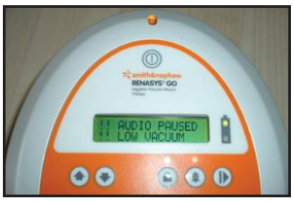
1. The alarms tests are done on either battery or mains operation. If battery operation is used, ensure that the battery charge is sufficient. See the RENASYS® GO User Guide for details.

2. Disconnect the test gauge; leave the canister connected to the device, with an open canister tubing connector.

3. Switch on the device. With the device set to 180mmHg press the SELECT button to start the device.

4. Verify that, after approximately 30 seconds, the LCD screen displays “!!WARNING !!LOW VACUUM”, the status light flashes amber, and the Audio Alarm pulses, 3 times every 10 seconds.

5. Press Audio Pause. Verify that the Audio alarm is no longer active, that the Audio Pause LED flashes, and that the LCD screen displays “!!AUDIO PAUSED !!LOW VACUUM”.



6. Wait for 2 minutes.

   • On devices with software V0.64, verify that, after 2 minutes the Audio alarm again pulses, 3 times every 10 seconds, and the LCD screen displays “!!WARNING !!LOW VACUUM”, alternating with “!!WARNING !!LEAK”.

   • On devices with software V0.66 or V0.67, verify that, within 2 minutes, “!!WARNING !!LEAK” is displayed, and the Audio alarm pulses, 3 times every 10 seconds, and the LCD screen displays “!!WARNING !!LOW VACUUM”, alternating with “!!WARNING !!LEAK”.

7. Press SELECT to stop the device.

Alarms Operation
blockage/canister full

1. Remove the canister from the pump and attach a ~0.25 inch (6mm) inner diameter section of tubing of about 3 inches (80mm) in length to the pump inlet.

2. Clamped this tubing to simulate a blockage/full canister.

3. Switch on the device. Select 100mmHg and press the SELECT button to start the device.

4. Verify that, after approximately 3 minutes, the LCD screen displays “!!WARNING !! BLOCKAGE/FULL”, the status light flashes amber, and the Audio Alarm pulses, 3 times every 10 seconds.

5. Press Audio Pause. Verify that the Audio alarm is no longer active, that the Audio Pause LED flashes amber, and that the LCD screen displays "!!AUDIO PAUSED !!BLOCKAGE/FULL".

6. Press SELECT to stop the device.

Alarms Operation
over-vacuum sensor/switch operation

1. Disconnect the tubing from the pump inlet, leaving the device inlet port open.

2. Switch on the device. With the device set to 200mmHg, press the SELECT button to start the device.

3. Wait 5-10 seconds, during which the pump will accelerate.

4. Quickly cover the open inlet port to the pump with a gloved thumb or finger. Verify that the pump stops, the Status light flashes amber, the LCD screen displays "!!THERAPY STOP !!OVER VACUUM" and the Audio Alarm pulses 3 times every 10 seconds.

5. Press the AUDIO PAUSE button to attempt to silence the Audio Alarm. Verify that the Audio Alarm does not silence, and that the LCD screen displays "!!Press !!POWER Key" while the AUDIO PAUSE button is pressed.

6. Press the SELECT button to attempt to restart the device. Verify that the device does not start, the Audio Alarm does not silence, and that the LCD screen displays "!!Press !!POWER Key" while the SELECT button is pressed.

   Note: The locked keyboard light should be lit as well.

7. Press the POWER button for 2 seconds to switch off the device.

Intermittent and Continuous Vacuum

Select INTERMITTENT operation via the Clinician Menu as follows:

1. Switch off the device by pressing the POWER button for 2 seconds.

2. Simultaneously press the DOWN, SELECT and POWER buttons for 2 seconds. The LCD screen will display "Continuous Intermittent" on 2 lines, with an arrow beside Continuous.

3. Use the DOWN button to move the arrow adjacent "Intermittent".

4. Confirm by pressing the SELECT button. The screen will show "Welcome Starting" and will then change to show "Standby" and the set-point.

5. Select a vacuum set point of 80mmHg using the UP or DOWN button as appropriate. Press the SELECT button. Verify that the device starts suction, that the Status light is illuminated green, and that the LCD screen displays "Intermittent" and the vacuum set-point.

6. Verify that the device remains ON for 5 minutes ±30 seconds and then stops pumping.

7. Verify that the device remains OFF (not pumping) for 2 minutes ±30 seconds and then restarts. During the OFF period the set-point display will show no value.

8. Press SELECT to stop the device.

9. Return the device to Continuous Mode as explained previously by using the Clinician Menu.

10. Press the SELECT button. Verify that the device starts suction, that the Status light is illuminated green, and that the LCD screen displays "Continuous" and the vacuum set-point.

11. Press SELECT to stop the device.

12. Press the POWER button for 2 seconds to switch off the device.

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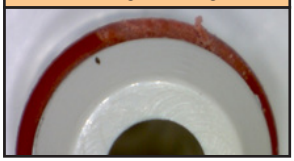
Device Replaceable Components

Inlet O-ring (REF 66800603)

To ensure the canister seal is secure, it is recommended that the inlet O-ring be replaced after each use.

Damaged O-ring



1. To replace the inlet O-ring, the existing ring must be carefully removed, using a plastic removal tool, ensuring that the inlet connector is not damaged during removal.
2. Clean the inlet connector, and carefully slide on the new O-ring; checking that any rolling of the O-ring is corrected once it is located in the groove.
   Precaution: DO NOT LUBRICATE THE O-RING!

Odor Filter (REF 66800061)

To minimize unpleasant odors from RENASYS GO devices, it is recommended that the odor filter be replaced per use of the device, depending on the type of exudates encountered or if an odor becomes apparent.

1. To change or verify the presence of the odor filter, turn the device over and lay it onto a soft surface, to avoid damage to the membrane.
2. Remove the Posidriv® screw holding the rear flap and open the flap to reveal the odor filter.
3. Remove the two odor filter elements and replace with 2 new odor filter elements.

4. Close the door flap and replace the screw tightening only until the door flap is flush with the case.
   Precaution: TAKE CARE NOT TO OVER-TIGHTEN!

Rubber Feet (REF 66800611)

If a rubber foot has become detached or is missing, it may be replaced. Use a small quantity of cyanoacrylate adhesive to reattach the rubber foot to the base of the device. Rubber feet can be obtained as replacement parts.

Prepare to Return into Use

Battery charge

If the device is to be returned into use within a short period, (up to 3 months), the battery should be re-charged to between 50% – 60% in order to provide maximum battery life. This can be achieved by re-charging from a low battery alarm condition for approximately 1 hour.

If the device is to be stored for a period over 3 months, then, for maximum battery life, the device should be periodically (every 3 months) re-charged to 50% to 60% level.

Alternatively, the battery may be re-charged to an almost fully charged state. While this may reduce the long-term life of the battery, it will enable the device to be stored for about 9 months, and still provide up to 4 hours of use at 80mmHg before re-charge is required. Re-charging from a low battery alarm condition for approximately 1.5 hours will achieve an almost fully charged state.

Checking the battery charge level after charging

Switch on the device in battery mode. If the upper green light on the battery symbol is steadily illuminated, the charge level is above 50%.

On devices with V0.66 and V0.67 software, the battery level may be checked in more detail by entering Clinician Menu, as follows:

1. Switch off the device (press the POWER button for 2 seconds).
2. Simultaneously press the DOWN, SELECT and POWER buttons for 2 seconds. The LCD screen will display “Continuous Intermittent” on 2 lines.
3. Use the DOWN button to scroll down the menu until the arrow is adjacent “Battery Charge”.
4. Confirm by pressing the SELECT button. The screen will show “Battery Charge” followed by the battery charge level in %.
5. The battery may be charged with this screen setting allowing the rise in battery charge level to be monitored.

Note: Storing the device connected to a live power supply is the least preferable storage arrangement as it will reduce the available battery capacity over time.

Total Time of Operation

On RENASYS® GO devices with V0.66 and V0.67 software and later, the total time the device has been used for delivering therapy may be noted, by entering Clinician Menu, as follows:

1. Switch off the device (press the POWER button for 2 seconds).
2. Simultaneously press the DOWN, SELECT and POWER buttons for 2 seconds. The LCD screen will display “Continuous Intermittent” on 2 lines.
3. Use the DOWN button to scroll down the menu until the arrow is adjacent to “Total Time”.
4. Press the SELECT button. The screen will show “Total Time” followed by a value indicating the number of hours the device has delivered therapy.
5. After 5 seconds this screen will clear and return to display “Continuous Intermittent” on 2 lines.
6. Press the POWER button for 2 seconds to switch off the device.

Cleaning and Packing for Service

Prior to returning the device for service, it should be packed in a polyethylene bag and if possible, either in the original packaging, or in the transit case (REF 66800586). The Instructions for Use, power cord and power supply should be included.

Performance and Safety Check List (optional)

Note: In the event that a device fails any test, has sustained obvious damage, has a missing or illegible label, or has any indication it may not be fit for intended use, please return the device to Smith and Nephew for repair.

	Steps	Yes	No	Comments
Cleaning and disinfection (recommended after each use)				
1	Confirm that the device has been cleaned and disinfected correctly with a Declaration of Cleaning and Disinfection.			
2	Clean and set aside transit case.			
3	Other Items packed for disposal.			
4	Check that the inlet port on the canister connection face of the pump and exhaust port on the side of the device are free from obstructions, dust or foreign materials.			
5	Clean both the inlet port and the exhaust port.			
6	Clean all external surfaces with suitable disinfectant and dry with disposable towel or cloth.			
Inspection of Device (recommended after each use)				
7	Device is unplugged and placed on flat surface.			
8	Check device for visible dents, cracks, or missing pieces.			
9	Confirm that the membrane LEDs and push buttons, and the LCD display are physically undamaged.			
10	Confirm that the inlet connector and O-ring are physically undamaged.			
11	Confirm that the DC inlet connector for the power supply is physically undamaged.			
12	Confirm that strap pins on each side of the device are in place.			
13	Inspect both ends of power cord for any frayed or missing insulation, bent, loose or missing plug blades or earth/ground.			
14	Inspect both ends of the power supply DC cord for any frayed or missing insulation, or bent, loose or missing DC plug.			
15	Rotate the device 360°. Confirm that the device does not have any rattles indicating loose components.			
16	RENASYS® GO pump: confirm the label is present and that the REF and SN numbers are clearly visible (record Serial Number SN).			SN_____
17	RENASYS GO Power Supply: confirm the Smith & Nephew label is on the front and the WK and SN numbers on the rear label are clearly visible. (record the serial number SN).			SN_____

	Steps	Yes	No	Comments
Electrical Safety Check (recommended annually)				
18	Protective Earth Resistance (Class I power supply only). Acceptance Criteria (in accordance with IEC 62353): Cord electrical resistance <100 mΩ			mΩ
19	Equipment Leakage Current Test (Normal Polarity): Acceptance Criteria (in accordance with IEC 62353): Class I power supply <500µA Class II power supply <100µA			µA
20	Equipment Leakage Current Test (Reversed Polarity): Acceptance Criteria (in accordance with IEC 62353): Class I power supply <500µA Class II power supply <100µA			µA
Functional Tests (recommended every 6 months) Mains Operation				
21	Verify that all the membrane LEDs and the status light flash briefly as AC power is connected.			
22	Verify that the green battery charging LED flashes slowly (or illuminates steadily if battery is fully charged) when power is connected.			
23	Verify that the LCD display shows the software version while displaying the "Welcome Starting" screen, and then changes to "Standby". Record the software version on the record sheet.			Version
24	Record set language.			
25	Adjust the set-point to 40mmHg by use of the DOWN button, and press the SELECT button. Verify that the device starts suction, the Status light is illuminated green, and the LCD screen displays "Continuous" and the vacuum set-point.			
26	Press the SELECT button. Verify that the device stops suction and LCD screen displays "Standby" and the vacuum set-point.			
27	Verify the test gauge vacuum measures 40mmHg ± 10mmHg.			mmHg
28	Verify the test gauge vacuum measures 180mmHg ±10mmHg.			mmHg
	Keypad Lock			
29	Press the KEYPAD LOCK button for 2 seconds. Verify that the blue LED above the button illuminates and that the LCD screen displays "Keypad Locked".			
30	Press the SELECT button to attempt to stop the device. Verify that the device does not stop and that the LCD screen displays "Keypad Locked".			
31	Press the KEYPAD LOCK button for 2 seconds. Verify that the blue LED above the button extinguishes and that the LCD screen displays "Keypad Active".			

	Steps	Yes	No	Comments
	Battery Operation			
32	Press the POWER button for 2 seconds to switch on the device. Verify that during the 2 seconds the POWER button is pressed, the Status light illuminates amber, and the membrane LEDs all illuminate.			
33	Verify that the LCD display shows “Welcome Starting” screen and the software version, and then changes to “Standby” on the upper line and the set-point on the lower line.			
34	With the device still set to 180mmHg press the SELECT button. Verify that the device starts suction, that the Status light is illuminated green, and that the LCD screen displays “Continuous” and the vacuum set-point.			
	Alarms Operation - Low Vacuum, Leak and Audio Pause			
35	Verify that, after approximately 30 seconds, the LCD screen displays “!!WARNING!!LOW VACUUM”, the status light flashes amber, and the Audio alarm pulses, 3 times every 10 seconds.			
36	Press Audio Pause. Verify that the alarm is no longer active, that the Audio Pause LED flashes, and that the LCD screen displays “!!AUDIO PAUSED!!LOW VACUUM”.			
37	On devices with software V0.64, verify that, after 2 minutes, the LCD screen again displays “!!WARNING !!LOW VACUUM”, alternating with “!!WARNING !!LEAK” and the Audio alarm again pulses, 3 times every 10 seconds.			
38	On devices with software V0.66 or later, verify that, within 2 minutes, “!!WARNING!!LEAK” is displayed alternating with “!!WARNING!!LOW VACUUM”, and that the Audio Pause resets, so that the Audio alarm pulses, 3 times every 10 seconds.			
	Alarms Operation - Blockage/Canister Full			
39	Place sealed tube directly onto pump inlet. Verify that, after approximately 3 minutes, the LCD screen displays “!!WARNING!!BLOCKAGE/FULL”, the status light flashes amber, and the Audio Alarm pulses, 3 times every 10 seconds.			
40	Press Audio Pause. Verify that the Audio alarm is no longer active, the Audio Pause LED flashes, and the LCD screen displays “!!AUDIO PAUSED!!BLOCKAGE/FULL”.			

	Steps	Yes	No	Comments
	Over-vacuum sensor/switch operation			
41	Quickly cover the open inlet port with a gloved thumb or finger. Verify that the pump stops, the Status light flashes amber, the LCD screen displays "!!THERAPY STOP!!OVER VACUUM", and the Audio Alarm pulses, 3 times every 10 seconds.			
42	Press the AUDIO PAUSE button to attempt to silence the Audio Alarm. Verify that the Audio Alarm does not silence, and that the LCD screen displays "!!Press!!POWER Key".			
43	Press the SELECT button to attempt to restart the device. Verify that the device does not start, the Audio Alarm does not silence, and that the LCD screen displays "!!Press!!POWER Key".			
	Intermittent and Continuous Vacuum			
44	Intermittent operation selected.			
45	Press the SELECT button. Verify that the device starts suction, and that the LCD screen displays "Intermittent" and the vacuum set-point.			
46	Verify that the device remains ON for 5 minutes ± 30 seconds and then turns off.			
47	Verify that the device remains OFF for 2 minutes ± 30 seconds and then restarts. During this period the set-point display will show no value.			
48	Device returned to Continuous Mode.			
49	Press the SELECT button. Verify that the device starts suction, that the Status light is illuminated green, and that the LCD.			
Replaceable Components				
50	New O-ring fitted?			DATE: month day year
51	New odor filter fitted?			DATE: month day year
Battery Charge Level				
52	Battery charge level above 50%?			%
Total Time of Operation (V0.66 software and above only)				
53	Total Time of Operation recorded.			Hours
Cleaning and Packing				
54	Device cleaned and re-packaged.			
	Steps	**Yes**	**No**	**Comments**

Summary of results				
57	Device is cleaned and disinfected.			
56	Device inspection showed no anomalies.			
59	Electrical safety testing verifies readings meet requirements.			
60	Mains operation verifies functions evaluated are operational.			
61	Battery operation is verified to be satisfactory.			
62	Alarms systems tested are operating correctly.			
63	Intermittent and continuous operation verified.			
64	Replaceable components recorded.			
65	Battery charge level above 50%.			%
66	Total Time of Operation recorded.			Hours
67	Device cleaned and re-packaged.			

Performed by:

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

Repair

There are no user-serviceable components inside the RENASYS GO® 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 Centre or your Smith & Nephew Sales Representative.

WARNING: No modification of this equipment is allowed.

Fuses

There are no replaceable fuses in the RENASYS GO NPWT device.

Spare Parts

The following replacement parts are available from Smith & Nephew:

Part Description	**REF**
O-ring	66800603
Odor Filter	66800061
Rubber Feet	66800611
Class I External Power Supply*	66800161
Power Cords for Class I External Power Supply*	
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
Class II External Power Supply with class II Continental Europe Power Cord*	66800696

* **WARNING:** The use of the 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 the RENASYS GO device.

Glossary of Symbols

Power Button
Turns the device on and off.

Battery Indication
Shows the status of battery life. Flashes when the battery life reaches levels that require user intervention.

Up Selector
Allows the pressure setting to be increased and scroll through menu options.

Down Selector
Allows the pressure setting to be decreased and scroll through menu options.

Keypad Lock
Locks the keypad to restrict accidental adjustment of therapy. When activated the light will illuminate.

Audio Pause
Silences the alarm for approximately 2-3 minutes. When activated the light will illuminate and flash.

If a new alarm occurs, the Audio Pause will cancel. (*This feature available with software version 0.66 and later).*

Start Therapy/Select
Allows therapy to be started or paused. It is also used to confirm settings within therapy.

Equipment Classification
Isolation type BF applied part

Single Use
do not reuse

EC REP **European Representative**

CSA International Classification

Keep Dry

LOT **Lot Number**

EU:
not for general waste

Storage Temperature

SN **Serial Number**

Follow instructions for use

Date of Manufacture

REF **Product Catalogue Number**

Follow instructions for use

Place of Manufacture

CE 0297 **CE Mark**

Do not use if package is damaged

Technical Specification

Vacuum Set Points	40, 50, 60, 70, 80, 90, 100, 120, 140, 160, 180 and 200mmHg
Power Requirements	Device 21VDC 36W Mains Adaptor Smith & Nephew REF 66800161 or 66800696 Input: 100-240VAC 50/60Hz 0.9A Output 21VDC 1.71A 36W
Fuse	Internal electronic fuse, not user changeable
Dimensions	175x210x85mm (7 x 8.3 x 3.5 in)
Weight	1.1 kg (2.4 lbs)
Operating Time – Battery	~ 20 hours (therapy)
Battery Type	Lithium ion
Charging Time	~ 3 hours
Protection Against Electric Shock	Device internally powered; external charger/power supply Class I or Class II (according to local supply). Class I when used with external power supply 66800161 and Class II when used with external power supply 66800696.
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 1060 mbar atmospheric pressure
Operating Environment	5-35°C (41-95°F) 30 to 70% RH 700 to 1060 mbar atmospheric pressure
Compliance	UL 60601-1 IEC 60601-1 IEC 60601-1-2CAN/CSA C22.2 No. 601.1

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 and home use environment. 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.

RENASYS® GO is intended for use in the electromagnetic environment specified below. The customer or the user of RENASYS GO 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 ±1 kV for input/output lines	±2 kV for power supply lines Not applicable	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 cycle 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 RENASYS GO requires continued operation during power mains interruptions, it is recommended that RENASYS GO be powered from an uninterruptible power supply or battery.
NOTE U_T is the AC mains voltage prior to application of the test level.			
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 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 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of RENASYS GO, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ (80 MHz to 800 MHz) $d = 2.3\sqrt{P}$ (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 metres (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: 

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 RENASYS GO is used exceeds 3V/m,
RENASYS GO should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating RENASYS GO.
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.

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

Emissions test	Compliance	Electromagnetic environment - guidelines
RF emissions CISPR 11	Group 1	RENASYS GO 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	
Harmonic emissions IEC 61000-3-2	Not Applicable	RENASYS GO is suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/flicker emissions. IEC 61000-3-3	Complies	

WARNING: RENASYS GO should not be used adjacent to or stacked with other electrical equipment and that if adjacent or stacked use is necessary, RENASYS GO 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 RENASYS GO.

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