RENASYS GO: Service and maintenance competency

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Negative Pressure Wound Therapy

Service and maintenance sample checklist

Note: In the event a device fails any test, has sustained obvious damage, has a missing or illegible specification badge, or has any indication it may not be fit for intended use, return unit to Smith & Nephew global repair center.

UNIT SERIAL #				
	Steps	**Yes**	**No**	**Comments**
Device cleaning and single-use component removal (performed after each patient use)				
1	Device cleaning record is present and/or cleaned according to this procedure.			
2	Inlet port and air exhaust port are free from obstructions, dust or foreign materials.			
3	Existing O-ring and odor filters are removed.			
4	Inlet port and air exhaust port cleaned.			
5	All external surfaces of the device, power cord and power supply are cleaned with recommended antimicrobial disposable wipes.			
Single-use component replacement (performed after each patient use)				
6	New O-ring correctly fitted on inlet port.			Date (mm/dd/yyyy):
7	Two (2) odor filters placed within odor filter door.			Date (mm/dd/yyyy):
Device physical appearance check (performed after each patient use)				
8	Device is unplugged and placed on flat surface.			
9	Device is free of damage, cracks or missing pieces.			
10	Buttons and indicator lights below display screen and display itself are undamaged.			
11	Inlet port is undamaged.			
12	AC mains power inlet is undamaged.			
13	Carry strap pins are present and secure.			
14	Power cord is not fraying, missing insulation, and has no bent, loose or missing plug blades or earth/ground.			
15	Power supply cord is not fraying, missing insulation, and DC plug is not bent, loose or missing.			
16	Device is free from rattles indicating loose components.			
17	The device specification badge is present and REF and SN numbers are clearly visible.			REF: SN:
18	The power supply labels are present and clearly visible.			REF: SN:
Functionality check - Operations check (performed after each patient use)				
19	All indicator lights and status/alarm indicator flash briefly as AC mains power is connected.			
20	When AC mains power is connected the battery indicator light flashes green or illuminates solid green if battery is fully charged.			
21	Screen display shows “Welcome, Starting”, current software version, and changes to “Standby” and therapy set-point after powering on. Record the software version under comments.			Version:

	Steps	Yes	No	Comments
Functionality check - Language check (performed after each patient use)				
22	Record set language. (If language is changed during functionality check, set to original language once checks are complete).			Language:
Functionality check - Modes of operation check (performed after each patient use)				
23	Device starts operating, status/alarm indicator illuminates solid green, and the screen displays “Continuous” and therapy set-point.			
24	Device stops operating, status/alarm indicator is no longer illuminated and the screen displays “Standby” and therapy set-point.			
25	Intermittent operation selected.			
26	Device starts operating, status/alarm indicator illuminates solid green, and the screen displays “Intermittent” and therapy set-point.			
27	Device operates for 5 minutes ± 30 seconds and then stops operating.			
28	Device does not operate for 2 minutes ± 30 seconds, status/alarm indicator remains illuminated and the screen displays “Intermittent” and therapy set-point.			
Functionality check - Keypad lock check (performed after each patient use)				
29	Device starts operating, status/alarm indicator illuminates solid green, and the screen displays “Continuous” and the therapy set-point.			
30	The blue indicator light above the KEYPAD LOCK button illuminates solid blue and the screen displays “Keypad Locked”, then changes to “Continuous” and the therapy set-point.			
31	Verify device does not stop operating when the SELECT button is pressed and the screen displays “Keypad Locked”.			
32	The indicator light above the KEYPAD LOCK button is no longer illuminated and the screen displays “Keypad Active”.			
Functionality check - Homecare lock check				
33	Verify indicator above KEYPAD LOCK button illuminates solid blue, screen displays “Keypad Locked”, “Continuous” and the therapy set-point on upperline, followed by ”***” on lower line.			
34	Verify device does not stop operating when the SELECT, UP and DOWN buttons are pressed and the screen displays “Keypad Locked”.			
35	Verify indicator light above KEYPAD LOCK button is no longer illuminated and screen displays “Keypad Active”.			

	Steps	Yes	No	Comments
Functionality check - Battery function check (performed after each patient use)				
36	During the 2 seconds the POWER button is pressed, status/alarm indicator illuminates solid yellow and all indicator lights illuminate.			
37	Display shows “Welcome, Starting”, current software version (e.g. V 1.06), and changes to show “Standby” and therapy set-point.			
38	Device starts operating, status/alarm indicator illuminates solid green, and screen displays “Continuous” and therapy set-point.			
Alarm indicator check – Complete blockage / canister over capacity alarm and audio pause button check (performed after each patient use)				
39	Within 5 minutes the screen displays “!! WARNING !! BLOCKAGE/FULL”, status/alarm indicator illuminates solid yellow, audible alarm beeps 2 times every 20 seconds.			
40	The audible alarm is temporarily paused, audio pause indicator illuminates solid yellow, and screen displays “!! AUDIO PAUSED !! BLOCKAGE/FULL”.			
Alarm indicator check – Low vacuum, leak and audio pause button check (performed after each patient use)				
41	Within 30 ± 5 seconds the screen displays “ !! WARNING !! LOW VACUUM”, status/alarm indicator illuminates solid yellow, and audible alarm beeps 2 times every 20 seconds.			
42	The audible alarm is temporarily paused, audio pause indicator illuminates solid yellow, and the screen displays “!! AUDIO PAUSED !! LOW VACUUM”.			
43	**Devices with software V 1.06 or later** Within 1 minute ± 5 seconds the audible alarm resets and beeps 2 times every 20 seconds and the screen displays “!! WARNING !! LEAK” alternating with “!! WARNING !! LOW VACUUM”.			
Alarm indicator check – Over vacuum check (performed after each patient use)				
44	Device stops, screen displays “!! THERAPY STOP !! OVER VACUUM” alternating with “!! THERAPY STOP !! Restart Device”, status/alarm indicator illuminates solid yellow, audible alarm beeps 2 times every 20 seconds and the keypad lock indicator illuminates solid blue.			
45	The audible alarm does not pause, and the screen displays “!! Press !! POWER Key” while the AUDIO PAUSE button is pressed.			
46	Device does not restart, audible alarm does not pause, and the screen displays “!! Press !! POWER Key” while the SELECT button is pressed.			

	Steps	Yes	No	Comments
Electrical safety check (performed annually)				
47	Equipment leakage current check (normal polarity): Acceptance criteria (class II power supply REF 66801558 paired with appropriate power cord): Max: 100 µA IN ACCORDANCE WITH IEC 62353			Class: µA
48	Equipment leakage current check (reversed polarity) Acceptance criteria (class II power supply REF 66801558 paired with appropriate power cord): Max: 100 µA IN ACCORDANCE WITH IEC 62353			Class: µA
Device pressure check (performed annually)				
49	Pressure measured on the calibrated pressure gauge controls to 40 mmHg ± 10 mmHg.			mmHg
50	Pressure measured on the calibrated pressure gauge controls to 180 mmHg ± 10 mmHg.			mmHg
Battery charge: Charge level check (preparation for return to clinical use)				
51	Battery charge level is above 50%.			
Clearing therapy time (preparation for return to clinical use)				
52	Therapy time cleared.			
Total time of operation (preparation for return to clinical use)				
53	Total time of operation recorded.			
Cleaning and packing				
54	Device cleaned and re-packaged with all necessary items for customer use.			

Performed by:

Print Name:		Date:
Signature:		Day Month Year
Location (Address):		

Advanced Wound Management

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