## Troubleshooting

When an alarm sounds, the RENASYS® EDGE pump screen will display information about the alarm. The pump includes **Help** on how to resolve each alarm. If the alarm can not be resolved using the **Help** function, the table below provides further troubleshooting advice.

Do not switch the pump off and on during an alert or alarm this will reset the pump and the alarm/alert will continue once therapy is resumed.

### Blockage Alarm

| What has happened? | What to do next |
|---|---|
|  The pump has detected one or more of the following:<br>• A blockage within the canister<br>• A blockage within the tubing<br>• The internal canister filter is covered with exudate. This may occur even if canister does not appear visibly full. | 1. Press the **Help** button and follow the on screen instructions. If alarm persists continue with steps below.<br>2. If one dressing is connected to the pump, press the **Home** button icon to navigate to the home screen and ensure that the Y-Connect toggle icon is set to Y-Connect off .<br>3. If therapy is set to 25 mmHg consider reducing the height of the pump in relation to the wound.<br>4. Disconnect the canister tubing from the dressing tubing by applying pressure to the canister quick click connector and gently pulling the connectors apart. Leave open the tethered cap of the canister quick click connector and close the tethered cap of the dressing connector.<br>5. If the alarm continues, the blockage exists within the canister. Replace the canister. Refer to **Removing/changing canister** section of manual for more details. Ensure the Y-Connector mode is reset to on if appropriate.<br>6. If the alarm resolves, the blockage exists within tubing of the dressing. Reassess and replace as needed, and ensure the Y-Connector mode is reset to on if appropriate.<br>**7. If the alarm persists after troubleshooting, consider changing the pump. If failure still occurs contact Smith+Nephew Medical, Ltd.** |

### Canister Full Alarm

| What has happened? | What to do next |
|---|---|
|  The pump has detected that the canister is full. | 1. Press the **Help** button and follow on screen instructions. If alarm persists continue with steps below.<br>2. Ensure the pump is orientated correctly, in an upright position.<br>3. Pause therapy by pressing . See **Removing/changing canister** section for instructions.<br>**4. If the alarm persists after troubleshooting, consider changing the pump. If failure still occurs contact Smith+Nephew Medical, Ltd.** |

### Canister Missing Alarm

| What has happened? | What to do next |
|---|---|
|  The pump cannot detect a correctly connected canister. | 1. Press the **Help** button and follow on screen instructions. If alarm persists continue with steps below.<br>2. Pause therapy by pressing and reattach or replace canister. See **Removing/changing canister** section for instructions.<br>**3. If the alarm persists after troubleshooting, consider changing the pump. If failure still occurs contact Smith+Nephew Medical, Ltd.** |



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## Troubleshooting

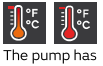
### Moderate Air Leak Alert and Critical Air Leak Alarm

| What has happened? | What to do next |
|---|---|
|  The pump has detected an air leak.<br>• The pump will provide an alert when a moderate leak is detected<br>• The pump will provide an alarm when a critical leak is detected. The pump will continue to operate but may not provide prescribed therapy.<br>• See **Alarms and Alerts** section for more information. | 1. Press the **Help** button and follow on screen instructions. If alarm persists continue with steps below.<br>2. In the event of an air leak, the flow meter will display on the therapy screen to assist in locating leaks in the pump, canister and tubing. Follow the instructions on screen to resolve the issue.  <br>3. Do not pause therapy or switch off the pump while resolving this alarm; the following steps will help identify the source of the leak.<br>4. Look for loose or decompressed dressing appearance, listen for air movement around the dressing and feel for areas less compressed.<br>5. Disconnect the canister tubing from the dressing tubing by holding the connectors above the level of the pump and patient's wound. Apply pressure to the canister tubing quick click connector and gently pull the connectors apart. Close the tethered caps of both connectors.<br>6. If the alarm continues, a leak exists within the canister or at the canister to pump connection. Replace the canister. Refer to **Removing/Changing Canister** sections of the manual for more details.<br>7. If the alarm resolves, a leak exists within the wound dressing or tubing. Reassess and replace as needed.<br>**8. If the alarm persists after troubleshooting, consider changing the pump. If failure still occurs contact Smith+Nephew Medical, Ltd.** |

### Low Battery Alert and Critical Low Battery Alarm

| What has happened? | What to do next |
|---|---|
|  The pump will provide an alert when there is less than 2½ hours remaining and an alarm when there is less than 20 minutes remaining. | 1. Press the **Help** button and follow on screen instructions. If alarm persists continue with steps below.<br>2. Plug the pump into an electrical (AC) outlet as soon as possible. The pump can be plugged into an electrical (AC) outlet to charge the battery without causing interruption to active therapy.<br>**3. If the alarm persists after troubleshooting, consider changing the pump. If failure still occurs contact Smith+Nephew Medical, Ltd.** |

### Pump Too Hot Alert or Alarm

| What has happened? | What to do next |
|---|---|
|  The pump has detected that the running temperature is too high. | Attempt to reduce the pump temperature.<br>1. Press the **Help** button and follow on screen instructions. If alarm persists continue with steps below.<br>2. Remove the pump from any covering or bag.<br>3. Move the pump out of direct sunlight.<br>4. Make sure there are no air leaks, see **Moderate and Critical Air Leak** for more information.<br>**5. If the alarm persists after troubleshooting, consider changing the pump. If failure still occurs contact Smith+Nephew Medical, Ltd.** |

Continued overleaf ››

## Troubleshooting

### High Vacuum / System or Battery Failure Alarm

| What has happened? | What to do next |
|---|---|
|  The pump has detected a pump, internal or battery failure. | 1. Press the Help button and follow on screen instructions. If alarm persists continue with steps below.<br>2. Switch off the pump and attempt a restart.<br>**3. If the alarm persists after troubleshooting, note the failure code and consider changing the pump. If failure still occurs contact Smith+Nephew Medical, Ltd.** |

### Therapy Paused Too Long Alert

| What has happened? | What to do next |
|---|---|
|  The pump has been paused for more than 30 minutes. | 1. Restart therapy by pressing ⏯ as soon as possible.<br>**2. If the alarm persists after troubleshooting, consider changing the pump. If failure still occurs contact Smith+Nephew Medical, Ltd.** |

### Unusual Noise

| What has happened? | What to do next |
|---|---|
| If the RENASYS® EDGE pump emits an unusual noise. | **Stop using the pump and consider changing the pump. If failure still occurs contact Smith+Nephew Medical, Ltd.** |

### Power Indicator Does Not Display

| What has happened? | What to do next |
|---|---|
| The power indicator does not light when the pump is plugged in to an external power source to charge. | **Stop using the pump and consider changing the pump. If failure still occurs contact Smith+Nephew Medical, Ltd.** |

### Pump does not switch on

| What has happened? | What to do next |
|---|---|
| The pump does not switch on. | 1. Plug the pump into mains power to charge the battery<br>**2. If the pump does not respond after charging, contact Smith+Nephew Medical, Ltd.** |

### Pump Starts or Runs Improperly

| What has happened? | What to do next |
|---|---|
| The pump appears to start improperly such as no start up animation or no sound or if the pump does not look as normal during run time. | **Stop using the pump and consider changing the pump. If failure still occurs contact Smith+Nephew Medical, Ltd.** |

### Pump Damaged

| What has happened? | What to do next |
|---|---|
| Any part of the pump is cracked or appears damaged. | **Stop using the pump and consider changing the pump. If failure still occurs contact Smith+Nephew Medical, Ltd.** |



## Electromagnetic Compatibility RENASYS® EDGE Pump

This equipment has been tested and found to comply with the limits for medical devices to IEC 60601-1-2. These limits and test levels are intended to provide reasonable safety with regard to electromagnetic disturbances when the pump is used 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 pump is intended for use in the electromagnetic environment specified below. The customer or the user of the pump 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- | ±8 kV contact<br>±2 kV, ±4 kV, ±8 kV, ±15 kV air | ±2 kV, ±4 kV, ±6 kV, ±8 kV contact<br>±2 kV, ±4 kV, ±6 kV, ±8 kV air<br>±15 kV air | Floors should be wood, concrete or ceramic tile. If floors are synthetic, the relative humidity should be at least 30% |
| Electrical fast transient/burst IEC 61000-4-4 | ±2 kV<br>For power supply lines 100 kHz Repetition frequency | ±0.5 kV, ±1 kV, ±2 kV, ±4 kV<br>For power supply lines 100 kHz repetition frequency | Mains power quality should be that of a typical commercial, home healthcare or hospital environment |
| Surge IEC 61000-4-5 | ±0.5 kV, ±1 kV Line-to-line<br>±0.5 kV, ±1 kV, ±2 kV Line-to-ground | ±0.5 kV, ±1 kV, ±2 kV, ±4 kV Line-to-line<br>±0.5 kV, ±1 kV, ±2 kV Line-to-ground | Mains power quality should be that of a typical commercial, home healthcare or hospital environment |
| Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 (NOTE UT is the a.c. mains voltage prior to application of the test level) | At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° phases<br>0% UT (100% dip in UT) for 0.5 cycle<br>At 00 single phase<br>0% UT (100% dip in UT) for 1 cycle<br>70% UT (30% dip in UT) for 25/30 cycles<br>5% UT (100% dip in UT) for 5 seconds<br>0% UT (100% dip in UT) for 250 cycles<br>0% UT (100% dip in UT) for 300 cycles | At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° phases<br>0% UT (100% dip in UT) for 0.5 cycle<br>At 00, 1800 phase<br>5% UT (100% dip in UT) for 0.5 cycle<br>40% UT (60% dip in UT) for 5 cycles<br>At 00 single phase<br>70% UT (30% dip in UT) for 25/30 cycles<br>0% UT (100% dip in UT) for 5 seconds | Mains power quality should be that of a typical commercial, home healthcare or hospital environment. If the user of the pump requires continued operation during power mains interruptions, it is recommended that the pump be powered from an uninterruptible power supply or battery |
| Power frequency (50/60Hz) magnetic field IEC 61000-4-8 | 30 A/m<br>50 or 60 Hz | 100 A/m 50 or 60 Hz<br>150 A/m 50 or 60 Hz<br>200 A/m 50 or 60 Hz<br>400 A/m 50 or 60 Hz | Power frequency magnetic fields should e at levels characteristic of a typical location in a typical commercial or hospital environment |
| Conducted RF IEC 61000-4-6 | 3 Vrms 150 kHz to 80 MHz<br>6 Vrms 150 kHz to 80 MHz<br>In ISM and amateur radio bands | 3 Vrms 150 kHz to 80 MHz<br>6 Vrms 150 kHz to 80 MHz<br>In ISM and amateur radio bands | Portable and mobile communications equipment should be separated from the pump by no less than distances calculated/listed below:<br>Recommended separation distance:<br>d = 0.58√P<br>d = 0.175√P (80 MHz to 800 MHz)<br>d = 0.35√P (800 MHz to 2.5 GHz))<br>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 meters (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 the pump is used exceeds 3V/m, the pump should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the pump.
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® EDGE Pump (REF 66803126)

Guidance and manufacturer's declaration – electromagnetic emissions for the RENASYS® EDGE pump (REF 66803126)

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

| Emissions test | Compliance | Electromagnetic environment - guidelines |
|---|---|---|
| RF emissions CISPR 11 | Group 1 | The pump uses RF energy only for its internal function.<br><br>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 pump 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 | Class A | |
| Voltage fluctuations/flicker emissions IEC 61000-3-3 | Comply | |

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

Do not use cables and accessories other than those specified or sold by Smith+Nephew as it may result in increased electromagnetic emissions or decreased electromagnetic immunity of the RENASYS® EDGE pump. Portable and mobile RF communication devices (mobile telephones) can affect the RENASYS® EDGE pump. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the RENASYS® EDGE pump (REF 66803126), including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

The user shall use the Class II power supply 66803146, 66803147, 66803148, 66803149 or 66803150 in a residential environment.

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

The pump is intended for use in an electromagnetic environment in which radiated RF disturbances are uncontrolled and Class II power supply 66801286 is used. The customer or the user of the pump can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the pump 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): | | |
|---|---|---|---|
| | 800 MHz to 2.7 GHz | 80 MHz to 800 MHz | 800 MHz to 2.7 GHz |
| | d = 0.58√P | d = 0.175√P | d = 0.35√P |
| 0.01 | 0.06 | 0.02 | 0.03 |
| 0.1 | 0.02 | 0.05 | 0.1 |
| 1.0 | 0.6 | 0.2 | 0.3 |
| 10 | 1.8 | 0.5 | 1.1 |
| 100 | 5.8 | 1.7 | 3.5 |

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (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.

## Example Table for EMS Use Environment

| Immunity Test | Test Level | Compliance Level | Electromagnetic environment - guidelines |
|---|---|---|---|
| IEC 60601-1-2 ed4.1 All Applicable Clauses | Home Healthcare Levels | Home Healthcare Levels | Emergency Medical Services Use – Road Ambulance |
| RTCA DO-160G | Section 21.4 (Category M)<br>Section 21.5 (Category M)<br>Section 20.5 (Category R)<br>Section 20.4 (Category Y)<br>Section 18 (Category R(CF))<br>Section 19 (Category AC) | Category M<br>Category M<br>Category R<br>Category Y<br>Category R(CF)<br>Category AC | Emergency Medical Services Use – Air Ambulance Commercial and private airborne |
| CISPR-25:2016 4th edition | Level 3 | Level 3 | Vehicles, boats and internal combustion engines |
| EN 50121-3-2 Part 3-2:2017 | Radiated emissions – 30 MHz to 40 GHz | 30 MHz to 40 GHz | Railway rolling stock |
| | AC Mains Conducted Emissions – 150 kHz to 30 MHz | 150 kHz to 30 MHz | |
| | ESD immunity – Contact +/-6 kV, Air +/-8 kV | Contact +/-6 kV, Air +/-8 kV | |
| | Radiated, radio-frequency, electromagnetic field immunity – 20V/m 80-1000 MHz<br>10V/m 1400-2000 MHz<br>5V/m 2000-2700 MHz<br>3V/m 5100-6000 MHz | 20V/m 80-1000 MHz<br>10V/m 1400-2000 MHz<br>5V/m 2000-2700 MHz<br>3V/m 5100-6000 MHz | |
| | EFT – +/-0.5 kV, +/-1 kV, +/-2 kV | +/-0.5 kV, +/-1 kV, +/-2 kV | |
| | Surge immunity - +/-0.5 kV, +/-1 kV | +/-0.5 kV, +/-1 kV | |
| | Conducted, radio-frequency, electromagnetic field immunity – 10Vrms | 10Vrms | |
| ISO 14708-4 Ed 1.0 (2008-11-15) | Section 27.103 – 50 mT<br>Section 27.104 – 10 Hz to 30 MHz<br>Section 27.105 – 30 MHz to 450 MHz<br>Section 27.106 – 450 MHz to 3 GHz | 50 mT<br>10 Hz – 30 MHz<br>30 MHz – 450 MHz<br>450 MHz – 3 GHz | Mains power quality should be that of a typical commercial, home healthcare or hospital environment |
| IEC 80601-2-49:2018 Ed.1.0 Medical Electrical Equipment - Part 2-49 | Section 202.8.102 | Section 202.8.102 | Mains power quality should be that of a typical commercial, home healthcare or hospital environment |
| IEC 61000-4-9*AEI issued: 03/01/2001 | Level 3 | Level 3 | Mains power quality should be that of a typical commercial, home healthcare or hospital environment |
| AIM 7351731 rev 2 (2017-02) | 134.2 kHz, 65 A/m<br>13.56 MHz, 7.5 A/m<br>13.56 MHz, 5 A/m<br>13.56 MHz, 12 A/m<br>433 MHz, 3V/m | 134.2 kHz, 65 A/m<br>13.56 MHz, 7.5 A/m<br>13.56 MHz, 5 A/m<br>13.56 MHz, 12 A/m<br>433 MHz, 3V/m | Mains power quality should be that of a typical commercial, home healthcare or hospital environment |

## Specification

| | | | |
|---|---|---|---|
| **Essential Performance** | | | |
| Essential performance of the RENASYS® EDGE, for safe operation, is to maintain the vacuum delivered by the pump within its specification for pressure selected, to provide Negative Pressure Wound Therapy (NPWT).<br>Contact your Smith+Nephew representative, distributor or authorized provider if service or additional guidance is required. | | | |
| **Vacuum** | | | |
| Continuous Therapy Levels | 25, 40, 60, 80, 100, 125, 150, 175, 200 mmHg | | |
| Intermittent Therapy Levels | High: 40, 60, 80, 100, 125, 150, 175, 200 mmHg<br>Low: 25, 40, 50 mmHg | | |
| Intermittent Therapy Cycles | High 5, 8, 10 mins | | |
| Times | Low: 2,3,5 mins | | |
| **Alarms** | | | |
| Frequency | 20 seconds | | |
| Priority | Low | | |
| Auditory Sound Level | Low: 55 dB<br>Medium: 65 dB<br>High: 75 dB | | |
| Indicator Color | Yellow | | |
| **Overall Alarm Delays** | | | |
| Over Temperature | 60 seconds | Canister Full | 120 seconds |
| High Vacuum | 360 seconds | Critical battery | 60 seconds |
| Leak/Low vacuum | 45 seconds | Battery failed | 60 seconds |
| Blockage | 300 seconds | Pump failed | 2 seconds |

All of RENASYS® EDGE components and dressings are considered applied parts. All of the applied parts are type BF (body floating) defibrilliation proof parts.