

# Sanity™ G6 NPWT System

## User's Manual



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# 1. INTRODUCTION

This user manual contains important information regarding the safe and effective operation of the Sanity™ G6 NPWT System. This manual is intended to aid training of personnel and to provide a reference for experienced users.

## 1.1 INDICATIONS

The Sanity™ G6 NPWT System may promote healing, through the drainage and removal of infectious material and other fluids from the wound site using continuous and/or intermittent negative pressure.

The Sanity™ G6 NPWT System is indicated for patients who would benefit from a suction device (negative pressure to help promote wound healing by removing fluids including irrigation and body fluids wound exudates and infectious materials. Examples of appropriate wound types include: Diabetic/Neuropathic ulcers, Pressure ulcers, Chronic wounds, Acute wounds, Dehisced wound, Partial-thickness burns, and Flaps and Grafts.

## 1.2 CONTRAINDICATIONS

The Sanity™ G6 NPWT System is contraindicated in the presence of:

- Malignancy in the wound
- Untreated osteomyelitis
- Non-enteric and unexplored fistulas
- Necrotic tissue with eschar
- Exposed nerves
- Anastomotic sites

**The Sanity™ G6 NPWT System is MR Unsafe. Do not take the system into the MRI environment.**

## 1.3 WARNINGS

- Patients must be closely monitored for bleeding. If sudden or increased bleeding is observed, immediately discontinue therapy, take appropriate measures to stop bleeding and contact the treating clinician.
- Patients suffering from difficult hemostasis or who are receiving anticoagulant therapy have an increased risk of bleeding. During therapy, avoid using hemostatic products that may increase the risk of bleeding.
- Sharp edges or bone fragments in a wound must be covered or removed prior to using the system, due to risk of puncturing organs or blood vessels while under negative pressure.
- Do not use the system on exposed blood vessels, organs or nerves.
- In the event defibrillation is required, disconnect the device from the wound dressing prior to defibrillation. Remove the wound dressing if the location will interfere with defibrillation.

- **The system is not MRI or CT compatible. Do not bring the device into the MRI suite or scanner range.**
- When operating, transporting, repairing or disposing of the system and its accessories, the risk of infectious liquids being aspirated or contamination of the device through incorrect use cannot be eliminated. Universal precaution should be observed whenever working with potentially contaminated parts or equipment.
- Sanity™ G6 NPWT System has not been studied on pediatric patients. Patient size and weight should be considered when prescribing this device.
- Sanity™ G6 NPWT System is not suitable for use in areas where there is danger of explosion (e.g., hyperbaric oxygen unit).
- Sanity™ G6 NPWT System is not suitable for use in the presence of a flammable anesthetics.
- The device and canister kits are provided non- sterile and should not be used in a sterile field.

## 1.4 PRECAUTIONS

**Federal law restricts this device to sale by or on the order of a physician.**

**As with any prescription medical device, failure to follow product instructions or changing settings and performing therapy applications without the express direction and/or supervision of a trained clinical caregiver may lead to improper product performance and the potential for serious or fatal injury.**

Precautions should be taken for patients who are or may be:

- Receiving anticoagulant therapy or platelet aggregation inhibitors, actively bleeding or have weakened blood vessels or organs;
- Suffering from difficult wound homeostasis;
- Untreated for malnutrition;
- Noncompliant or combative;
- Suffering from wounds in close proximity to blood vessels or delicate fascia.
- Infected wounds may require more frequent dressing changes. Regular monitoring of the wound must be maintained to check for signs of infection.
- To avoid false alarms during initial wound dressing application, no alarms are activated during the first 5 minutes of treatment.
- Therapy should remain ON in the CONTINUOUS mode for the duration of the treatment. There may be situations when the patient needs to be disconnected from the Negative Pressure Wound Therapy (NPWT) device, for example for activities of daily living and diagnostic testing. If the patient needs to be disconnected, the tubing should be clamped/capped and the ends of the tubing capped. How long patients may be disconnected from the NPWT device is a clinical decision based on individual characteristics of the patient

and the wound. Factors to be considered would include, amount of drainage, location of the wound, integrity of the dressing seal, assessment of bacterial burden in the wound and patient's risk of infection.

- This device should only be used by qualified and authorized personnel. The user must have the necessary knowledge of the specific medical application for which Sanity™ G6 NPWT System is being used.
- If the device has been at temperatures below freezing, the device must be brought to room temperature prior to use or the pumping unit may be damaged.
- Ensure that tubing is connected correctly and without kinks to avoid leaks or blockages in the vacuum circuit.
- Position the device and tubing appropriately to avoid the risk of causing a trip hazard and so the patient does not lie on the tubing.
- When bathing/showering, the patient must be disconnected from the device.
- DO NOT IMMERSE Sanity™ G6 unit. If so, discontinue use and return to your authorized provider for service.
- Do not apply NO-STING SKIN PREP wipes directly onto open wounds.
- Underlying structures, such as bone and tendon, must be covered by the non-adherent dressing layer.
- Inspect the dressing site as appropriate based on therapeutic need.
- The vacuum level should never be painful. If the patient reports discomfort with the vacuum level, consider reducing the vacuum level.
- Sanity™ G6 NPWT System should only be used with Progressive Wound Care authorized components.
- Sanity™ G6 NPWT System is to be used in the upright or flat positions.
- Sanity™ G6 NPWT System is to be used only with canisters designed specifically for use with the Sanity™G6 300 cc/ml canister. (part #15-300)
- Ensure the tubing clamp is closed prior to switching off the device. When re-connecting to the device, ensure clamp is open before activating unit.

## **Monitoring NPWT**

Carefully monitor the patient, device, and dressing frequently to determine if there are any signs of bleeding, exudate accumulation (pooling), infection, maceration, or loss of Negative Pressure Wound Therapy (NPWT). The frequency should be determined by the clinician based on individual characteristics of the patient and wound. NPWT devices are not designed to detect or issue an alarm condition based on the presence of bleeding or pooling. These conditions may only be detected by frequent monitoring.

NPWT may be impacted by various conditions related to system configuration, set-up and individual characteristics of the patient and wound (e.g. exudate characteristics, patient anatomy). Special attention to the risks of bleeding or loss of NPWT should be considered when prescribing for use in the home environment.

Alignment of the port to the opening in the drape, use of a bridging technique and choice of dressing configuration based on wound characteristics may impact NPWT vacuum delivery over the course of therapy. Exudate volume, viscosity and consistency may influence fluid removal or occlusion formation. A full canister or incorrect canister orientation can contribute to loss of NPWT and exudate accumulation within the wound, which could lead to maceration, infection, or unrecognized bleeding. Monitor the wound for infection and ensure that all wound filler is removed at each dressing change to reduce the risk of infection. Skin grafts should be closely monitored to ensure NPWT is being delivered.

## **Caution – Partial Blockage**

Full or near full blockages will activate blockage alarm; however, if a partial blockage occurs, the change in pressure status detected by the device may not be significant enough to activate the blockage alarm.

Therefore, appropriately frequent monitoring of wound dressing is recommended to confirm adequate delivery of therapy for NPWT systems. In the event of heavy or viscous drainage, drainage with sediment or when blood is present, regular monitoring and more frequent dressing changes may be required. If a complete blockage is present in the system, but an air leak occurs between blockage and device, the alarm may not activate. Ensure all connections are secure and no air leaks are present in system.

## **1.5 DEVICE DESCRIPTION**

The Sanity™ G6 NPWT System features a powered unit (Sanity™ G6) that utilizes a pump drive to generate low negative pressure. The pump drive incorporates a maintenance free stepper motor and is powered by a rechargeable battery. Optionally, the unit can be operated by connecting to AC power using the included power supply converter.

Sanity™ G6 NPWT System has a negative pressure setting range of -50 mmHg to -175 mmHg which is electronically monitored and controlled. The system includes user touch keypad controls as well as audible and visual alarm indicators. The system is supplied with a single detachable 300cc disposable canister. The system can be set on a countertop (secure surface), carried using the carry pouch, or mounted to an IV pole or bedside rail with use of SANITY™ G6's specialty pole mount.

The Sanity™ Advanced NPWT System includes the following four components:

- The Sanity™ G6 power unit.
- A/C power adapter/charger
- The disposable canister with integrated suction tubing
- Compatible FDA- cleared NPWT dressings – (GelTex® Wound Care Set /SanTex™ Wound Care Set. See product listing section 7, page 30 )

The Sanity™ G6 power unit is non-disposable and contains the motor, pump drive, battery, and controls. The drive has a piston which partially protrudes from the unit, reciprocating to activate the suction pump, which is located within the canister. The user interface includes a vacuum level monitor which displays the vacuum at all times and maintains the required set therapy.

The waste canister attaches to the Sanity™ G6 and has an integral pump which is activated by the drive. The pump creates vacuum within the waste canister for the purpose of suctioning exudates from the wound and collecting them in the canister. The canister also has a hydrophobic filter which protects the environment from contamination by filtering the air exhausted from the canister directly to the atmosphere, as well as prevents exudates from draining out of the waste canister. The canister also has a disinfectant and deodorizer as well as a desiccant, which gels the collected exudates. Graduations on the side of the waste canister allow the user to observe the content of exudates within the canister. A latch on the top of the canister releases it from the unit when pressed. The canister has an internal snorkel which allows it to operate equally effective when lying on the side with the four feet. The hydrophobic filter prevents canister over-flow, by blocking off the canister outlet when wet.

Accordingly, liquid and exudates are prevented from leaking out of the canister during or after use. The waste canister is intended for single patient use and is disposable.

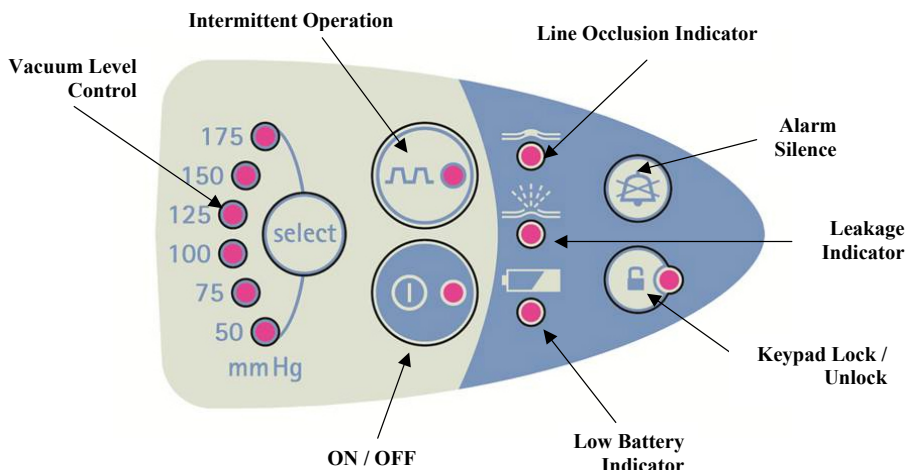
The suction tube connects the waste canister to the wound dressing applying the vacuum generated within the waste canister to the wound site. The tube also transfers the exudates from the wound to the waste canister by maintaining flow from the wound site toward the waste canister at all times. A bleed hole at the connection of the suction tube to the wound dressing allows the entry of ambient air when the vacuum is applied to the wound. This flow of air in the direction of the canister results in the following benefits:

The exudates are moved to the waste canister continuously, rather than stagnate in the suction tube.

The tube being cleared of exudates maintains the same vacuum level at the wound site as in the waste canister, and thus the monitoring of the pressure in the canister provides an accurate reading of the pressure at the wound site.

No exudates drain back into the wound when the vacuum level at the waste canister is reduced, since the reduction in vacuum is a result of ambient air entering the tube at its end from the bleed hole.

## **SANITY™ G6 User keypad controls and indicators**



### **User interface instructions:**

The Sanity™ G6 unit has 5 keys by which the user controls all functions.

**ON/OFF Key:** Pressing it for 2 seconds will either turn the Sanity™ G6 on or off. An audible BEEP will sound with each key activation, together with a green indicator light within the key pad.

**Intermittent Operation Key:** Pressing this key for 2 seconds will result in changing from continuous operation to intermittent operation – 5 minutes on and 2 minutes off. An indicator light will be lit in green when in intermittent mode. If the SANITY™ G6 is operating in intermittent mode and the intermittent key is pressed, the Sanity™ G6 will revert to continuous mode.

**Select mmHg Key:** Each press of the SELECT key will result in raising the set vacuum level by one step, always starting at -50 mmHg. After reaching -175 mmHg, pressing the SELECT key will loop back to -50 mmHg. Each press of the SELECT key will result in turning on one of the green lights indicating the desired set vacuum level. When increasing the vacuum level, the indicator will blink green until that level is reached.

**Alarm Silence Key:** When pressed, will stop the audible alarm for a period of 30 seconds.

**Keypad Lock Key:** When pressed, will de-activate the keypad with exception of the Lock key. Pressing the Lock Key again will activate the keypad. The keypad will lock automatically when no key is pressed for 5 minutes. When an alarm condition exists the keypad will become inactive.



### **Visual indicators**

There are 11 light indicators on the keypad panel and an additional light indicator on the wall power supply, providing the following indications:

**ON /OFF** green indicator light turns on when the SANITY™ G6 is operating.

One of the 6 **Vacuum Level** green indicators lights when the SANITY™ G6 is operating, indicating the set vacuum level.

**Intermittent Mode** green indicator light is on when the Sanity™ G6 is operating in the intermittent mode.

The orange **Leakage Indicator** light is on when a leakage condition exists and the unit alarms.

The orange **Occlusion Indicator** light is on when an occlusion condition exists and the unit alarms.

The orange **Battery Charge** indicator light is on when the battery is being charged. It will blink when the battery charge level is low.

The battery power supply has a blue color indicator light. It illuminates when the power supply is plugged into a working 110v outlet..

The keypad lock is indicated by an orange light, turning green when unlocked.

### **Audible Alarm**

An audible alarm will sound to alert on a situation which requires patient or caregiver's attention and handling. It will also sound to provide indications as follows:

- Turning the Sanity™ G6 ON or OFF.
- Changing the VACUUM LEVEL SETTING.
- Changing the Sanity™ G6 operational MODE.
- Locking or Unlocking the Keypad
- If a LEAKAGE alarm condition exists.
- If an OCCLUSION alarm condition exists.
- If the BATTERY IS LOW.
- If the WASTE CANISTER is full.
- If the WASTE CANISTER is not in place.
- A single BEEP sounds when connecting the power supply and charging starts, or when power supply is disconnected.
- A double BEEP sounds when the vacuum set level is attained.

**Notes:** The leakage alarm will not sound during the first 5 minutes of operation, giving the caregiver enough time to dress the treated the wound without interruption. Should a leak occur after the silent 5 minutes, the alarm will sound after 20 seconds.

If the tube is blocked or kinked an alarm will sound after 60 seconds.

### **Power connection**

The power supply provided for the Sanity™ G6 is the only power supply allowed for charging. The power supply plug is to be inserted into the socket on the lower end of the Sanity™ G6 for charging. Please observe the battery charging indicator light to assure the Sanity™ G6 is being charged. It is preferable to keep the Sanity™ G6 charging when not in use to assure a full charge when needed.

## 1.6 SAFETY RECOMMENDATIONS

### KEEP THERAPY ON

The Sanity™ G6 NPWT System should be operated at least 22 hours out of every 24 hour period. Remove the dressing if therapy is terminated or is off for more than 2 hours in a 24 hour period.

### DRESSING CHANGES

Clean the wound per physician order prior to dressing application. Routine dressing changes should occur every 48 to 72 hours. Dressing changes for infected wounds should be performed more frequently than 48-72 hours. Always replace with sterile disposables from unopened packages. Follow established institution protocols regarding clean versus sterile technique.

### MONITORING THE WOUND

Inspect the dressing frequently to ensure that therapy is being delivered in a consistent manner. Monitor periwound tissue and exudates for signs of infection\* or other complications. Extra care and attention should be given if there are any signs of possible infection or related complications. Infection can be serious. With or without the Sanity™ G6 NPWT System, infection can lead to many adverse complications including pain, discomfort, fever, gangrene, toxic shock, septic shock, and various other complications. With signs of more serious complications of infection, discontinue use of the Sanity™ G6 NPWT System until the serious infection is diagnosed and properly treated.

*\* Signs of possible infection may include fever, tenderness, redness, swelling, itching, rash, increased warmth in the wound area, purulent discharge or a strong odor. Nausea, vomiting, diarrhea, headache, dizziness, fainting, sore throat with swelling of the mucous membrane, disorientation, high fever (>102°F, 38.8°C), refractory hypotension, orthostatic hypotension, or erythroderma (a sunburn-like rash) may be added signs of more serious complications of infection.*

### DISCOMFORT / ADHERENCE

If patient complains of discomfort during dressing change, consider pre-medication, use of a non-adherent (such as LipoGel™ or other barrier layer) prior to foam placement or irrigation of a topical anesthetic agent such as 1% Lidocaine prior to dressing removal.

### UNSTABLE STRUCTURES

Over unstable body structures such as unstable chest wall or non-intact fascia, use the lowest pressure setting on the Sanity™ G6.

### SPINAL CORD INJURY

In the event a patient experiences sudden elevation in blood pressure or heart rate in response to stimulation of the sympathetic nervous system) discontinue use of the Sanity™ G6 NPWT System to help minimize sensory stimulation.

## BODY CAVITY WOUNDS

Underlying structures must be covered by natural tissues or synthetic materials that form a complete barrier between the underlying structures and the Dressing.

## DRESSING USE

The Sanity™ G6 NPWT System should be only used with the NPWT Dressing Sets (a.k.a. “NPWT Kits”) provided by Progressive Wound Care. A complete listing of dressings available from Progressive Wound Care is shown in Section 7 on page 30.

**NOTE:** *All dressing components are packaged sterile. The decision to use clean versus sterile/aseptic technique is dependent upon wound physiology and physician/clinician preference.*

Be sure to comply with all other CONTRAINDICATIONS, WARNINGS and PRECAUTIONS for the Sanity™ G6 NPWT System.

## WARNING!

**Do not pack the dressings into any areas of the wound. Forcing dressings in a compressed manner into any wound is contrary to approved protocols.**

## 1.7 FEATURES

**Easy-to-use “One Touch” Operation** - Therapy can be activated simply by pressing the ON-OFF key for two seconds, and setting the desired vacuum level by pressing the SELECT key, scrolling through the vacuum level options of -50 mmHg, -75mmHg, -100 mmHg, -125 mmHg, -150 mmHg and -175 mmHg and stopping when the desired therapy vacuum level is indicated by the light indicator. Keypad keys may be locked by the caregiver (see “*Therapy Selection Lock/Unlock*” Section), or will lock automatically 5 minutes after setting is complete.

**Intermittent Mode** - The Sanity™ G6 NPWT System can be set to operate intermittently (5 minute/2 minute cycle).

**Noise Guard** - Unit is virtually silent during operation, increasing patient comfort and compliance.

**Power Guard** - An internal battery provides at least 30 hours of operation from a single full-charge. Battery will charge while unit is activated using the AC power supply. While running on battery, a low-battery alarm will sound and the low battery indicator light will flash when remaining capacity of the battery is less than 20%.

**Therapy Guard** - Automated alarms for leakage/low pressure occluded tube or full canister. Alarms provide both visual and audible indication. Alarms will self-reset once the alarm condition is removed or may be reset by turning the unit off and back on.

**Blockage Guard** - A bleed hole at the connection of the suction tube to the wound dressing allows the entry of ambient air when the vacuum is applied to the wound. This flow of air in the direction of the canister provides the following benefits:

- The exudates are moved to the waste canister continuously, rather than stagnate in the suction tube.
- The tube being cleared of exudates maintains the same vacuum level at the wound site as in the waste canister.
- No exudates drain back into the wound when the vacuum level at the waste canister is reduced, since the reduction in vacuum is a result of ambient air entering the tube at its end from the bleed hole.

**Single Patient Use Canister** - Canister can contain 300 cc of exudates.

**Light Weight** - The therapy unit weighs only 1.8 lbs (820 g) and allows patient mobility while using the carry pouch.

**Long-life Pump** - Diaphragm-type pump with stepper motor increases life expectancy of the unit which is maintenance free.

**Infection Control** -Canister exudate containment- An important feature unique to the Sanity™ Wound Therapy System is that the actual vacuum pump is located within the canister rather than inside the drive unit. Unlike other systems, there is no air flow from the canister to the unit, thus eliminating any chance of fluid aspiration and internal contamination. Likewise, during removal and disposal, the sealed canister ensures no contact with exudate by patient or caregiver.

## 2. CARE & CLEANING

### 2.1 INTRODUCTION

Daily and weekly cleaning is recommended along with infection control procedures for the Sanity™ G6. The Caregiver should review this manual in its entirety before attempting product use. Carefully read the **PRECAUTIONS** and **SAFETY TIPS** in the **INTRODUCTION** section before cleaning the Sanity™ G6.

### 2.2 PROTECTIVE EQUIPMENT

Universal Safety Precautions should be used to minimize the risk of infection and contact with contaminated blood or bodily fluids during the dressing changes or disposal, it is important to protect all exposed skin and mucous membranes. The protective equipment includes:

- Disposable gloves (latex or latex-free).
- Protective eyewear to help prevent splashing of cleaning solutions and/or blood or bodily fluids.
- Protective mask (to protect the nose and mouth from inadvertent fluid ingress). Disposable impervious gown (if splashing of blood or bodily fluids is possible).

### 2.3 DISPOSAL

After patient use, all disposable components of the system should be treated as contaminated. These include:

- The Dressing, drape, tubing, and connectors.
- The exudates collection canister.
- Dispose of all disposable components in accordance with local code.

**NOTE: Cleaning procedures should not be performed when unit is connected to a patient. Disconnect the unit from the patient and power source before cleaning or servicing.**

### 2.4 DAILY CARE AND CLEANING

Perform a visual inspection of the unit. Check for any sign of contamination and ensure that the unit is functioning properly. If the unit is not operating properly, refer to the Alarm Troubleshooting guide in the **OPERATING INSTRUCTIONS** section of this manual or contact Progressive Wound Care to have the unit serviced. If there are visible signs of contamination or the unit appears dirty, follow the **WEEKLY CARE AND CLEANING** instructions below.

## 2.5 WEEKLY CARE AND CLEANING

To help reduce the risk of infection and contact with contaminated blood and bodily fluids use the protective equipment identified above when cleaning the Sanity™ G6.

**NOTE: Always follow Universal Safety Precautions. Follow established institution protocols regarding clean versus sterile technique.**

The following cleaning procedure must be performed at least once a week and must be completed between patients. The Sanity™ G6 should be wiped with either a diluted solution of 5 milliliters bleach in 1 liter of warm water (approximately 1 teaspoon bleach in 1 quart water), alcohol, or mild disinfectant. Use a coarse cloth and wring out any excess solution until the cloth is damp and not dripping. Other cleaning fluids are not recommended as they may damage the finish of the enclosure.

**DO NOT IMMERSE THE SANITY™ G6 UNIT.**

### POWER SUPPLY INSPECTION

The Power supply housing and cord should be inspected regularly and replaced if damaged. (Available from Progressive Wound Care).

### WARNING!

**The Sanity™ G6 should only be used with the supplied power supply. Use of an incorrectly rated power supply could create a shock hazard for the patient or caregiver, or cause irreparable damage to the unit.**

### WARNING!

**Avoid spilling liquids on any part of the Sanity™ G6. Liquids can cause corrosion when left on electronic controls which can lead to failure. Component failure may cause the therapy unit to operate erratically, possibly causing a potential hazard to the patient or Caregiver.**



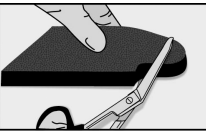
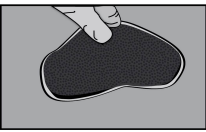

**Do not immerse the Sanity™ G6 unit.**

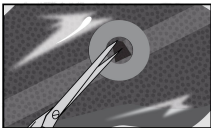
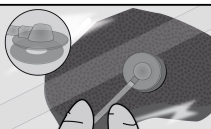
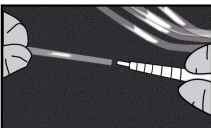
## 3. PATIENT CARE

### 3.1 APPLYING THE DRESSING

It is recommended that all sections of this manual be reviewed prior to using the product. Carefully read the **INDICATIONS, WARNINGS, CONTRAINDICATIONS, PRECAUTIONS** and **SAFETY TIPS** in the **INTRODUCTION** section before attempting to perform patient care for a patient with the Sanity™ G6 NPWT System.

The Sanity™ G6 NPWT System is used with compatible FDA cleared NPWT dressings – (GelTex® Wound Care Set /SanTex™ Wound Care Set). See listing page 30.

|  |   |
|--|---|
| <p><b>Step 1</b> Debride any necrotic/ eschar tissue if necessary. Cleanse and dry wound bed.</p> <ul style="list-style-type: none"> <li>• Thorough wound cleansing should occur with each dressing change</li> </ul>  |    |
| <p><b>Step 2</b></p> <p>If desired, apply skin sealant to periwound area.(skin sealant not included as part of kit)</p> <ul style="list-style-type: none"> <li>• Protect the periwound from exposure to moisture and adhesive</li> </ul>   |    |
| <p><b>Step 3</b></p> <p>Cut the foam dressing to fit the size and shape of the wound and place into wound cavity. Foam should fill the wound cavity and may be necessary to stack pieces of foam in deep wounds.</p> <p><b>Warnings:</b></p> <ul style="list-style-type: none"> <li>• Foam should be cut to fit loosely into wound bed.</li> <li>• Do not cut the foam directly over the wound bed to avoid foam fragments from falling into the wound.</li> <li>• If multiply pieces of foam are needed to cover the wound bed, count and record how many foam pieces are present.</li> <li>• If a tunnel exists, ensure that contact is made with foam in the primary wound cavity.</li> </ul> | <br> |
| <p><b>Step 4</b></p> <p>Cover foam with transparent film, which should extend 2 in (5cm) beyond wound margin to facilitate adequate seal.</p> <ul style="list-style-type: none"> <li>• Film should be securely anchored to periwound area to maintain a good seal.</li> </ul>  |    |

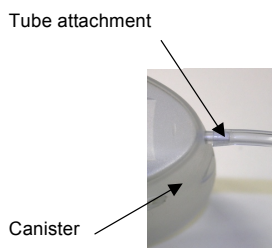
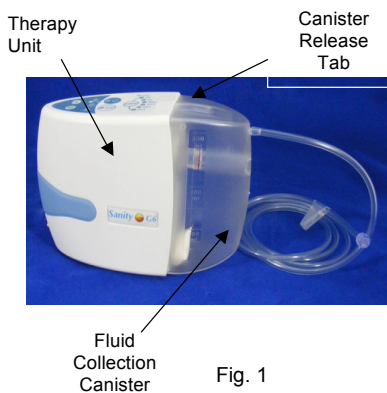
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| <p><b>Step 5</b></p> <p>Remove the plastic cover on one side of the adhesive disc and press firmly to the film over the center of the foam. Cut a small hole .25in (0.6 cm) in the film, in the center of the adhesive disc over the foam. Remove excess trimmed film. The center opening of the suction head will be aligned over the hole to deliver negative pressure.</p> |  |
| <p><b>Step 6</b></p> <p>Remove the cover from the upper side of the adhesive disc and position the suction head over the disc. Use Gentle pressure to press the suction head to the adhesive disc.</p>  |  |
| <p><b>Step 7</b></p> <p>Attach the port tubing to the canister tubing and activate the device.</p> <p>Finished and leak-free dressing should be firm to the touch. Secure tubing with tape to minimize tension on the port and position to avoid patient lying on tubing</p>  |  |



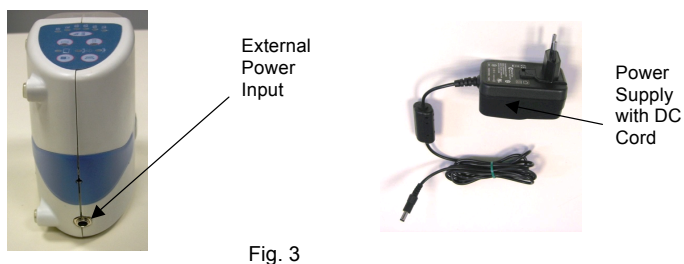
### 3.2 CANISTER INSTALLATION

1. Ensure that a Sanity™ canister is properly inserted in the receptacle located on the side of the unit (see Fig 1). Insert lower edge of canister into notch on bottom of Sanity™ G6. Raise top corner into place and the canister should “snap” into place and lock. The canister release tab may need to be depressed to permit canister insertion.

**NOTE: Always use a new canister for a new patient.**



2. Inspect the Tube connector to ensure that it is properly connected (Fig.2)



3. Plug the therapy unit's Power supply into a suitable 110-220 VAC, 50-60 Hz, outlet. Insert the power plug into the Power Input on the side of the therapy unit (see Fig.3).

4. Verify the dressing application is correct; the tubing is connected and secured.
5. Begin therapy (see **OPERATING INSTRUCTIONS**).

### 3.3 CANISTER REMOVAL

1. Press the OFF button to turn the therapy off.
4. Press canister release tab and pull canister from top of unit (see Fig. 4).
5. Dispose of canister according to local institutional protocols.

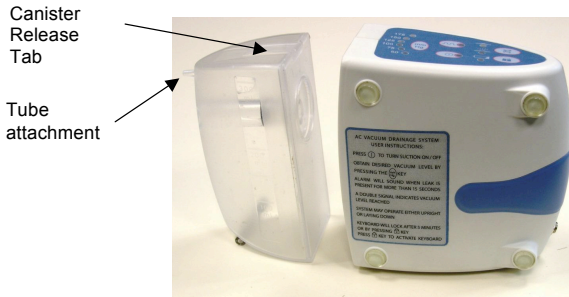


Fig. 4

### **3.4 DISPOSAL OF DRESSINGS, CANISTER AND OTHER DISPOSABLES**

To minimize the risk of infection and contact with contaminated blood or bodily fluids during the dressing changes or disposal, it is important to protect all exposed skin and mucous membranes.

The protective equipment includes:

- Disposable gloves (latex or latex-free).
- Protective eyewear to help prevent splashing of cleaning solutions and/or blood or bodily fluids.
- Protective mask (to protect the nose and mouth from inadvertent fluid ingress).
- Disposable impervious gown (if splashing of blood or bodily fluids is possible).

After patient use, all disposable components of the system should be treated as contaminated. These include:

- The Dressing and drape.
- The exudates collection canister.

Dispose of all disposable components in accordance with local regulations and institution protocols.

## 4. OPERATING INSTRUCTIONS

This section contains instructions for setting and adjusting functions of the Sanity™ G6. The section details the procedure for providing therapy and explains the major functions which are keypad controlled.

Carefully read the **PRECAUTIONS** and **SAFETY TIPS** in the **INTRODUCTION** section before attempting to operate and adjust the Sanity™ G6.

The Sanity™ G6 should only be used with the supplied Power supply. Use of an incorrectly rated power supply could create a shock hazard for the patient or caregiver, or cause irreparable damage to the unit. The part number for the power supply can be found in the **REPLACEMENT PARTS** section of this manual.

The Sanity™ G6 may work in two positions, as shown in Fig. 5. Side with 4 feet is placed down.

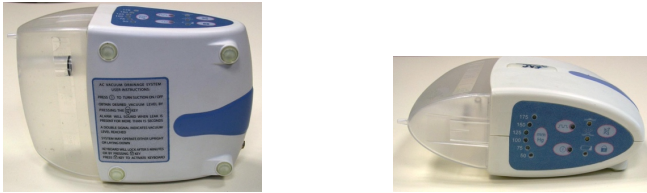


Fig. 5

## 4.1 POWER ON/OFF

The ON/OFF button is located on the front top of the control panel. The ON/OFF button controls the application of power to the therapy unit.

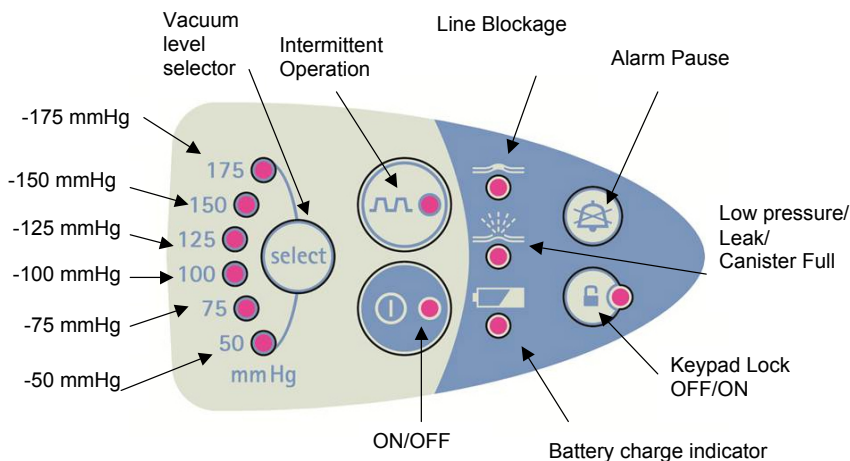


Fig. 6

## 4.2 POWER-UP PROCEDURE

1. Verify that the dressing application is correct and the tubing is connected.
2. Place the Sanitary™ G6 in an upright position. The unit can be placed on a table or attached to a bedrail or IV pole using the Sanitary™ G6 clamp, or hung within the carry pouch.
3. Press the ON/OFF key. The ON/OFF light indicator will turn on green.
4. Dressing should collapse indicating the presence of vacuum.
5. Carefully check dressing for vacuum or fluid leaks and repair with additional material as needed.
6. The Sanitary™ G6 NPWT System should be operated for at least 22 hours out of every 24 hour period. Remove the Dressing if therapy is terminated or is off for longer than 2 hours within a 24 hour time period.

## 4.3 THERAPY SETTING ADJUSTMENT

### **CAUTION!**

**Only a physician can prescribe the proper settings for the therapy unit. Failure to follow product instructions or adjusting settings and performing therapy application without the express direction and/or supervision of your trained caregiver may lead to improper product performance and the potential for serious or fatal injury.**

### **Negative Pressure Level Adjustment**

There are six selectable settings for the negative pressure: -50 mmHg, -75 mmHg, -100 mmHg, -125mmHg, -150 mmHg and -175 mmHg. The negative pressure level SELECT key is located on the keypad. Use this key to select the therapy setting that is appropriate for the patient.

1. Once the unit is powered-up, the default setting of -50 mmHg is automatically selected.
2. To change the setting, simply press the **SELECT** Key; each press of the key will result in raising the desired vacuum level from its present level by one step, always starting at -50 mmHg. After reaching -175 mmHg, pressing the key will cycle back to - 50 mmHg.
3. Each press of the SELECT key will result in turning on the green indicator light for the set vacuum level.
4. As vacuum level rises after turning the pump on, the flickering indicator light will indicate the pressure level attained.

### **Intermittent Operation ON/OFF**

The Sanity™ G6 can operate in an intermittent suction mode with a 5 minute “On” and 2 minute “Off” cycle. To turn the intermittent operation on, press and hold the intermittent operation key for 2 seconds. A green LED indicator will light up when in intermittent mode.

During intermittent operation, the Sanity™ G6 will provide selected therapy pressure throughout the “on” part of the cycle and approximately ambient pressure throughout the “Off” part of the cycle.

To return to Continuous mode, press and hold the Intermittent Operation key for 2 seconds until the unit beeps and the illuminated light goes off.

Keypad settings are not maintained after unit is turned off. This is a safety feature protecting the patient from being exposed to excessive pressure settings when first connected to the Sanity™ G6.

## **4.4 BATTERY OPERATION**

**NOTE:** *The Sanity™ G6 NPWT System is designed to permit use of the product while the internal battery is charging. The therapy unit will continue to operate properly while charging is taking place.*

### **Average Battery Life**

The specified battery life of the Sanity™ G6 with a fully-charged battery is more than 30 hours. The actual life is dependent on the therapy settings.

### **Average Time for Recharging**

To ensure that the battery has been fully charged, the unit should be charged for approximately 4 hours. After approximately 3 hours of charging, the unit will achieve 80% of total battery charge. For best results in maintaining battery charge and life, leave unit connected to an outlet whenever conveniently located during operation.

### **Low Battery Alarm**

While running on battery, a low-battery alarm will “sound” every 10 seconds and the orange indicator light will turn on when remaining capacity of the battery is less than 20%. Typically, the unit will continue to operate for approximately 1 hour after the low-battery alarm is activated.

### **Low Battery Shutoff**

If the battery charge falls below a critical level, the unit wills shutoff automatically and therapy will be discontinued. At this point, the unit must be plugged into a power source for therapy to resume. Once the Power supply is plugged in, pressing the ON/OFF button will restart the unit, and therapy pressure level would need to be selected again.

### **Recharging the Battery**

Plug the power cord from the Power supply into the power receptacle on the side of the therapy unit. Plug the Power supply into a suitable 110 -220 VAC, 50-60 Hz wall outlet.

When the unit is connected to an AC power source, the orange LED will indicate charging, and green LED will indicate when the battery is fully charged.

When the Sanity™ G6 Power supply is disconnected it will continue to operate without interruption.

## 4.5 ALARM OPERATION

### Clearing an Alarm Condition

To silence an alarm, press the Alarm Silence Key. The Low Pressure/Dressing Leak alarm will clear if the alarm condition stops. Other Alarms will not clear automatically and must be manually addressed.

### Alarm Troubleshooting

| ALARM TYPE                      | INDICATION  | CORRECTIVE ACTION  |
|---------------------------------|---|--|
| CANISTER IS FULL                | Leakage/Canister Full Indicator light turns on accompanied by an intermittent audible alarm.<br>Unit will continue to alarm until the canister is replaced.   | Press Unlock key, then turn unit off by pressing the ON/OFF button.<br>Remove canister and replace as necessary.<br>Press the ON/OFF button to resume therapy.   |
| LOW PRESSURE/<br>DRESSING LEAKS | Leak Indicator light turns on accompanied by an intermittent audible alarm. Unit will continue to alarm until the low pressure / leak condition is corrected or the alarm is silenced.  | Check all tubing connections between the therapy unit and Dressing.<br>Check to ensure the canister is fully seated and locked.<br>Press drape around wound to check for leaks. If leak is found, patch with extra drape material. |
| LOW BATTERY                     | Low Battery Indicator will flash orange accompanied by an intermittent audible "alarm" every 10 sec. Alarm will continue until unit connected to AC outlet. When the charge falls below a critical level, the therapy will be discontinued. | Utilizing an approved Power supply, connect unit to a power source to provide operating power and to recharge the internal battery.  |
| TUBING OCCLUSION/<br>BLOCKAGE   | Tubing Occlusion Indicator will flash orange accompanied by audible alarm every 10 seconds.   | Press Alarm Mute, Press Unlock Key, Press ON/OFF key. Locate occlusion (closed clamp, tubing kink, blockage in tubing or dressing). Change tubing or dressing if necessary.<br>Press ON/OFF to restart unit, reset vacuum level.   |

**NOTE:** In the event of an emergency, please contact your physician, caregiver, or your local emergency responders.

**NOTE:** If an Alarm Condition persists and cannot be resolved, please contact Progressive Wound Care for further assistance.



## **4.6 THERAPY SETTING SELECTION LOCK/UNLOCK**

The Sanity™ G6 is equipped with a keypad locking feature designed to prevent unauthorized individuals from changing the therapeutic settings inadvertently.

### **Locking**

After making the desired keypad selections, the keypad may be locked by pressing the Lock key. Locking will also occur automatically after 5 minutes from setting the therapy parameters to prevent accidental change in the settings.

At this point, the unit is locked and the indicator light turns from green to orange.

### **Unlocking**

To unlock the unit, press Lock Key - audible beeps are heard. At this point the unit is unlocked and therapy settings can be changed. Indicator light turns from orange to green. Additionally, when the unit is powered OFF / ON, the unit will remain unlocked and will automatically revert to the default setting of -50 mmHg.

## 5. ELECTROMAGNETIC COMPATIBILITY

Electromagnetic Interference – Although this equipment conforms to the intent of the directive 89/336/EEC in relation to Electromagnetic Compatibility (EMC), all electrical equipment may produce interference. If interference is suspected, move equipment away from sensitive devices or contact the manufacturer.

The Essential Performance requirements of the Sanity™ G6 NPWT System are to maintain 175 mmHg +/- 15 mmHg (30 seconds average) vacuum pressure with no false alarms.

Portable and mobile RF communications equipment can effect medical electrical equipment.

Radios, cell phones and similar devices may affect this equipment and should be kept at least 6.5 feet (2 meters) away from the equipment.

Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information in the following tables.

The following tables document compliance levels and guidance from the IEC 60601-1-2 2007 Standard, for the electromagnetic environment in which the Sanity™ G6 NPWT System should be used in a clinical environment. The Sanity™ G6 NPWT System also meets the intent of the draft guidance for Electromagnetic Compatibility related to use in the home care environment (IEC 60601-1-11 2007-11-30 draft).

### Electromagnetic Emission

| Guidance and manufacturer's declaration – Electromagnetic Emissions   |            |   |
|---|------------|---|
| The Sanity™ G6 NPWT System is intended for use in electromagnetic environment specified below. The user of the Sanity™ G6 NPWT System should assure that it is used in such an environment. |            |   |
| Emission test   | Compliance | Electromagnetic environment - guidance  |
| RF emissions,<br>CISPR 11   | Group 1    | The Sanity™ G6 NPWT System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. |
|   |            |   |
| Harmonic emissions,<br>IEC 61000-3-2  | Class B    |   |
| Voltage fluctuations/<br>flicker emissions<br>IES 61000-3-3   | Complies   |   |

**Table 1 - Sanity™ G6 NPWT System Electromagnetic Emission.**

## Electromagnetic Immunity

| Guidance and manufacturer's declaration – electromagnetic immunity  |  |  |  |
|---|--|--|--|
| The Sanity™ G6 NPWT System is intended for use in the electromagnetic environment specified below. The user of the Sanity™ G6 NPWT System should assure that it is used in such an environment. |  |  |  |
| Immunity test   | IEC 60601<br>Test level  | Compliance level   | Electromagnetic environment - guidance   |
| Electrostatic discharge (ESD)<br>IEC 61000-4-2  | ±8 kV contact<br>±15 kV air  | ±8 kV contact<br>±15 kV air  | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be least 30%  |
| Electrical fast transfer/burst<br>IEC 61000-4-4   | ±2 kV for power supply lines<br>±1 kV for input/output lines   | ±2 kV for power supply lines<br>±1 kV for input/output lines   | Mains power quality should be that of typical commercial or hospital environment.  |
| Surge<br>IEC 61000-4-5  | ±1 kV differential mode<br>±2 kV common mode   | ±1 kV differential mode<br>±2 kV common mode   | Mains power quality should be that of typical commercial or hospital environment.  |
| Voltage dips, short interruptions and voltage variations on power supply input lines<br>IEC 61000-4-11  | <5 % $U_T$<br>(>95% dip in $U_T$ ) for 0.5 cycle<br>40 % $U_T$<br>(60% dip in $U_T$ ) for 5 cycles<br><5 % $U_T$<br>(>95% dip in $U_T$ ) for 5 sec | <5 % $U_T$<br>(>95% dip in $U_T$ ) for 0.5 cycle<br>40 % $U_T$<br>(60% dip in $U_T$ ) for 5 cycles<br><5 % $U_T$<br>(>95% dip in $U_T$ ) for 5 sec | Mains power quality commercial or hospital environment. The user of the Sanity™ G6 NPWT System during continued operation not depend from power mains interruptions, because Sanity™ G6 NPWT System powered from a batteries. During system charging is recommended that the Sanity™ G6 NPWT System be powered from an uninterruptible power supply. |
| Power frequency (50/60 Hz) magnetic field<br>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.  |
| NOTE $U_T$ is the a. c. mains voltage prior to application of the test level.   |  |  |  |















**Table 2 – Sanity™ G6 NPWT System Electromagnetic Immunity**

## 6. SPECIFICATIONS

### 6.1 DEVICE SPECIFICATIONS

|                            |  |
|----------------------------|--|
| Weight:                    | 1.8 lbs (0.82 kg.) with an empty canister  |
| Dimensions:                | 7.4"W x 5.5"H x 2.7"D (19 x 14 x 7 cm)   |
| Battery Type:              | Lithium ion rechargeable battery   |
| Battery Life:              | Up to 30 hour average  |
| Recharging Time:           | 4 hours to reach full charge from a completely discharged state  |
| Canister Capacity:         | 300 ml   |
| Therapy Delivery Modes:    | Continuous or Intermittent   |
| Options: Negative Pressure | 50mm,75mm,100mm,125mm. 150mm, 175mm  |
| Electrical Data:           | External power supply input voltage: 100-240 VAC<br>Input current: < 0.6 A RMS max<br>Input frequency: 47 - 63 Hz<br>External power supply output voltage : 12 VDC, 2.08A<br>Output power: 5 W max,  |
| IEC Classification:        | Type B, Applied Part Class II IPX0<br>Equipment not suitable for use in presence of flammable anesthetic mixture with air, oxygen or nitrous oxide.  |
| Environmental Conditions:  | Storage Conditions<br>Temperature Range: -4° F (-20° C) to 140° F (60° C)<br>Relative Humidity Range: 0-95% non-condensing<br>Operating Conditions<br>Temperature Range: 41° F (5° C) to 104° F (40° C)<br>Relative Humidity Range: 0-95% non-condensing<br>Altitude Range: 0 to 14,000 feet (0 to 4267 m)<br>Optimum Performance: 0 to 8,000 feet (0 to 2438 m) |
| Expected useful life       | 3 years  |

## 6.2 EXPLANATION OF SYMBOLS

|   |   |   |   |
|---|---|---|---|
|    | Class BF applied part                   |  | CE mark   |
|    | Do not reuse                            | SN  | Serial number   |
|    | Caution, consult accompanying documents |  | Batch Code  |
|    | Manufacturer                            |  | Keep upright  |
|    | EU: Not for general waste               |  | Authorized representative in the European Community   |
|    | Use by (YYYY-MM)                        |  | Date of manufacture (YYYY-MM)   |
|    | Patient number                          |  | Keep dry  |
|  | Catalogue number                        | <b>Rx only</b>  | Federal (USA) law restricts this device to sale or rental by or on the order of a physician |

## 7. System Components and Accessories:

### Therapy Unit

Sanity™ G6 Part # 15-101  
User's Manual Part #SG6UM001Ver.2

### Power supply. Part #15-102

### Dressings . Dressing Packaging (100 per case, 12 per box)

Sanity™ Wound Care Sets  
STX100S Small Foam Kit  
STX100M Medium Foam Kit  
STX100L Large Foam Kit  
STX100XL Extra Large Foam Kit

GelTex Wound Care Sets  
GTX101S Small Foam Kit w/LipoGel  
GTX101M Medium Foam Kit w/LipoGel  
GTX101L Large Foam Kit w/LipoGel

### Canisters. Part # 15-300 (300ml, 100 per case, 8 per box.)

### Accessories

Power supply plug for EU or US Part # 15-102-2  
Carry Bag part # 15-103  
Polyurethane Drape (10 per pkg.) part #15-201  
IV pole hanger attachment part #15-225

## 8. LIMITED WARRANTY

Progressive Wound Care (PWC) warrants that the Sanity™ G6 shall be free of defects for one year starting the date of product shipment. The liability of PWC under this limited warranty is limited to the repair by PWC or replacement (at PWC's option) of any parts under warranty at its expense. Defective devices shall be returned to PWC, accompanied by notice describing the nature of the problem. Please contact PWC for a Return Authorization Number.

This warranty does not apply to product which was abused, subjected to any conditions not authorized in the user manual, disassembled or otherwise tampered with.

Disposable components such as canisters or dressings are warranted for a single use.

## **9. CUSTOMER ASSISTANCE**

For service and replacement parts please contact:

Progressive Wound Care  
1212 E. Montgomery Cross Rd., Unit C  
Savannah, Georgia USA 31406

Phone: 912-401-3234  
Email: [info@progressivewoundcare.com](mailto:info@progressivewoundcare.com)  
Website: [www.progressivewoundcare.com](http://www.progressivewoundcare.com)