

Cardinal Health™ SVED®

Patient User Manual

Cat. **6701132**



About Your Cardinal Health SVED device

Your doctor has chosen the Cardinal Health SVED device to remove fluid from your wound by using carefully controlled suction. It is important, however, for you to carefully watch the wound and the Cardinal Health SVED device to make sure that the Cardinal Health SVED device is working properly. Below is some important information and questions that you should ask your Healthcare Professional.

Things you need to know about your Cardinal Health SVED device

- Do not allow the Cardinal Health SVED device to get wet. Clamp the tube and disconnect from the canister if you take a bath or shower.
- Keep the Cardinal Health SVED device plugged in whenever possible to keep the battery fully charged. Always take the power cord with you when you leave home.
- Keep the Cardinal Health SVED device upright to avoid a false canister full alarm.
- Keep the Cardinal Health SVED device turned on at all times unless there is bleeding from the wound or instructed by your Healthcare Professional.
- Do not change the settings on the Cardinal Health SVED device unless you are told to do so by your Healthcare Professional.

Things to ask your Healthcare Professional

- How to tell if there is a problem with your Cardinal Health SVED device or dressing.
- What to do if you have a problem or a leak with your dressing.
- What to do if you notice bleeding from the wound.
- What to do if you must take your dressing off.
- What activities you can do while using the Cardinal Health SVED device.
- Who to call if you need help.
- How to take care of your Cardinal Health SVED device.

CAUTION: This Cardinal Health™ SVED® PATIENT User Manual is not a guarantee or warranty. It is intended only as an operational guide. For additional information and questions, please contact the Cardinal Health Customer Service department at 1.866.484.6798.

In order for the Cardinal Health™ SVED® to provide safe, reliable, and proper performance, the following conditions must be met. Failure to comply with these conditions will void all pertinent warranties.

- There are no user serviceable components in the Cardinal Health™ SVED®. All assembly, operation, adjustment, modification, maintenance, and/or repair must be carried out only by qualified personnel authorized by Cardinal Health.
- The electrical installation of the room in which the device will be used complies with the appropriate national electrical standards.
- The product must be used in accordance with this manual and all associated labeling and the Instructions for Use.
- Any device that does not function as expected must be returned to Cardinal Health.

Notice to Users: CAUTION: 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.

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1. Important User Information

1.1 Indications

The Cardinal Health™ SVED® system is an integrated wound management system, indicated for the application of continual or intermittent negative pressure wound therapy to the wound as the device may promote wound healing by the removal of fluids, including wound exudates, irrigation fluids, body fluids and infectious materials.

The Cardinal Health™ SVED® system is intended for patients with chronic, acute, traumatic, subacute and dehiscent wounds, partial-thickness burns, ulcers (such as diabetic or pressure), flaps and grafts. The Cardinal Health™ SVED® system is intended for use in acute, extended and home care settings.

1.2 Contraindications

The Cardinal Health™ SVED® is contraindicated for patients with malignancy in the wound, untreated osteomyelitis, non-enteric and unexplored fistulas, or necrotic tissue with eschar present. Do not place the Cardinal Health™ NPWT Dressing over exposed blood vessels or organs. The Cardinal Health™ NPWT Dressings are also contraindicated for hydrogen peroxide and solutions which are alcohol based or contain alcohol. It is not recommended to deliver fluids to the thoracic cavity.

1.3 Precautions

Precautions should be taken for patients with infected wounds, active bleeding, difficult wound hemostasis, or who are on anticoagulants. When placing the Cardinal Health™ NPWT foam dressing in close proximity to blood vessels or organs, take care to ensure that they are adequately protected with overlying fascia, tissue or other protective barriers. Exposed tendon, nerves or blood vessels should be protected by moving available muscle or fascia over them or by a layer of synthetic material. Greater care should be taken with respect to weakened, irradiated or sutured blood vessels or organs. Bone fragments or sharp edges could puncture a dressing barrier, vessel or organ. Wounds with enteric fistula require special precautions in order to optimize therapy.

1.4 Additional Precautions

- **Defibrillation:** Remove the Cardinal Health™ NPWT Dressing if defibrillation is required in the area of dressing placement. Failure to remove the dressing may inhibit electrical current transmission and/or patient resuscitation.
- **Magnetic Resonance Imaging (MRI):** The Cardinal Health™ SVED® device is not MRI-compatible. Do not take the device into the MRI area.
- **Hyperbaric Oxygen Therapy (HBO):** NEVER allow a device—whether on or off—inside a hyperbaric chamber. The device must be disconnected from the patient prior to HBO treatment.
- **Large Canisters:** Use of Large Canisters (>500ml) may increase serious risks associated with excessive fluid loss. Monitor patient status continually.

- **DO NOT USE** for infants or other patients with low fluid volume, nor for patients at high risk of major hemorrhage.
- During Negative Pressure Wound Therapy, the Cardinal Health™ SVED® and Cardinal Health™ NPWT Dressing are a closed system and are NOT vented to atmosphere.
- During Negative Pressure Wound Therapy, when a canister fills with fluid, it should be replaced immediately as fluids such as wound exudate will not be removed from the dressing once the canister is full.

1.5 SAFETY TIPS

KEEP THERAPY ON

The Cardinal Health™ SVED® device should be operated at least 22 hours out of every 24 hour period. Contact your Healthcare Professional if therapy stops or if the device is OFF for more than 2 hours in a 24 hour period. Your Healthcare Professional will need to change your dressing.

MONITORING THE WOUND

Inspect the dressing frequently to ensure that the foam is collapsed and that therapy is being delivered in a consistent manner. Monitor wound exudates for signs of active bleeding. Monitor periwound tissue and exudate 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 Cardinal Health™ SVED® device, 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 the use of the Cardinal Health™ SVED® device until the serious infection is diagnosed and properly treated.

CARDINAL HEALTH™ NPWT DRESSING USE

Your Healthcare Professional will apply and change your dressings for you. The Cardinal Health™ NPWT Dressings distributed by Cardinal Health are to be used exclusively with the Cardinal Health™ SVED® device.

NOTE: All dressing components of the Cardinal Health™ NPWT Dressing kit are packaged sterile. The decision to use clean versus sterile/aseptic technique is dependent upon wound pathophysiology and physician/clinician preference. All components of the Cardinal Health™ NPWT disposable set are made without natural rubber latex.

Be sure to comply with all other **1.2 CONTRAINDICATIONS** and **1.3 PRECAUTIONS** for the Cardinal Health™ SVED® device.

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

2. Introduction to the Cardinal Health™ SVED® device

2.1 Getting to know the Cardinal Health™ SVED® device

You may not need to use many of the buttons on the device, but it is important that you are familiar with what they are and their location (see **Figure 1**).

NOTE: The Cardinal Health™ SVED® device will be virtually silent during normal operation with a well-sealed dressing.

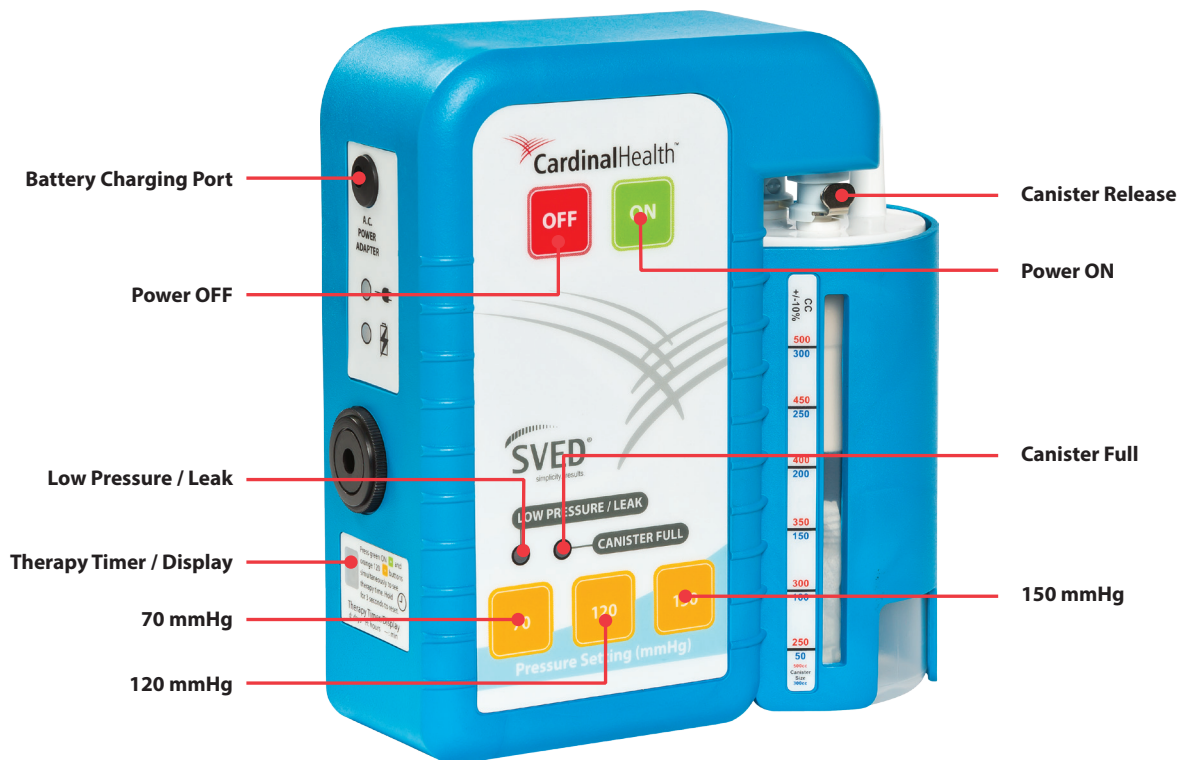


Figure 1

2.2 Charging the Battery

The Cardinal Health™ SVED® device has an internal battery that provides up to 18 hours of operation from a single full-charge. When the battery is running low, an alarm will sound to let you know you must plug in the device to charge the battery. See section **3.3 ALARM OPERATION** of this manual for Alarm Troubleshooting.

1. Plug the device's A.C. Adapter into a suitable wall outlet (100-240 VAC, 50-60Hz).
2. Insert the power plug into the Battery Charging Port on the side of the device (**Figure 2**).
3. The device will continue to work when charging.

The Cardinal Health™ SVED® device should only be used with the supplied A.C. Adapter. Use of an incorrectly rated adapter could create a shock hazard for the patient and caregiver.

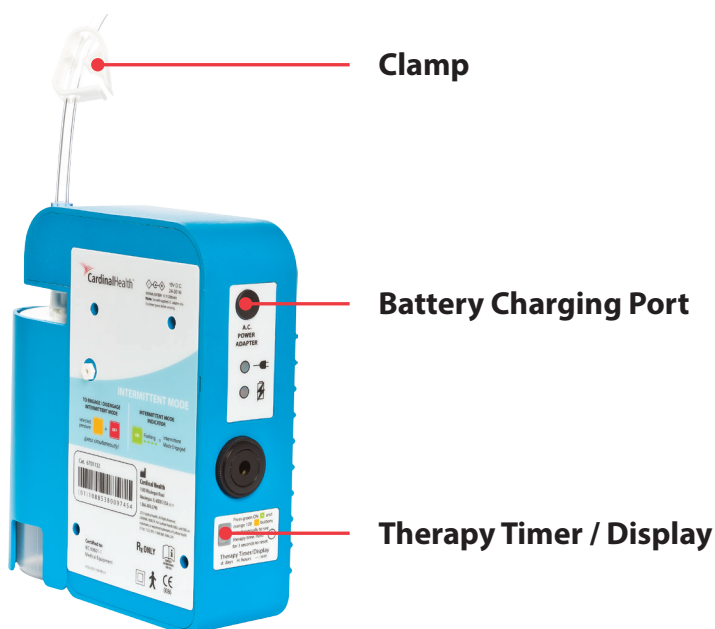


Figure 2

Additional Battery Information

NOTE: The Cardinal Health™ SVED® is designed to permit use of the product while the internal battery is charging. The device will continue to operate properly while charging is taking place.

Average Battery Life

The specified battery life of the Cardinal Health™ SVED® device with a fully-charged battery is approximately 18 hours. The actual life is dependent on the integrity of the dressing. A leak in the dressing can reduce overall battery longevity significantly.

Average Time for Recharging

To ensure the battery has been fully charged, the device should be connected to an A.C. supply for approximately 3 hours. After approximately 2 hours of charging, the device will have achieved 80% of total battery capacity.

Low Battery Alarm

While running on battery, a low-battery alarm will “chirp” every 10 seconds and the OFF  button will begin flashing when remaining capacity of the battery is less than 20%. Typically, the device 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 device will shutoff automatically and therapy will be discontinued. At this point, the device must be plugged into an A.C. power source for therapy to resume. Once the A.C. Adapter is plugged in, pressing the ON  button will restart the device.

Recharging the Battery

Plug the power cord from the A.C. Adapter into the power connector on the side of the device. Plug the A.C. Adapter into a suitable 120 VAC, 60 Hz wall outlet.

When the device is connected to an AC power source, the GREEN LED below the power connector will illuminate indicating AC power is present and the AMBER LED will illuminate when the battery is charging.

Once the battery is fully charged, the AMBER LED will extinguish indicating the charge cycle is complete.

When the Cardinal Health™ SVED® device is disconnected from the AC power source, the device will automatically switch over to the internal battery and continue to operate without interruption.

2.3 Changing the Canister

If the canister fills with fluid, an alarm will sound to let you know you must change the canister. Refer to the Alarm Troubleshooting guide found in the **3.3 ALARM OPERATION** section of this manual.

The canister full alarm begins when the canister is 90% full, but the device will continue to work until the canister completely fills.

1. Clamp the tubing closed (**Figure 3**).
2. Turn the device OFF by pressing the  button.
3. Remove the blue SpeedConnect™ tubing from the top of the canister (**Figure 3**). Twisting the tapered connector will make removing the Suction tube from the canister easier.

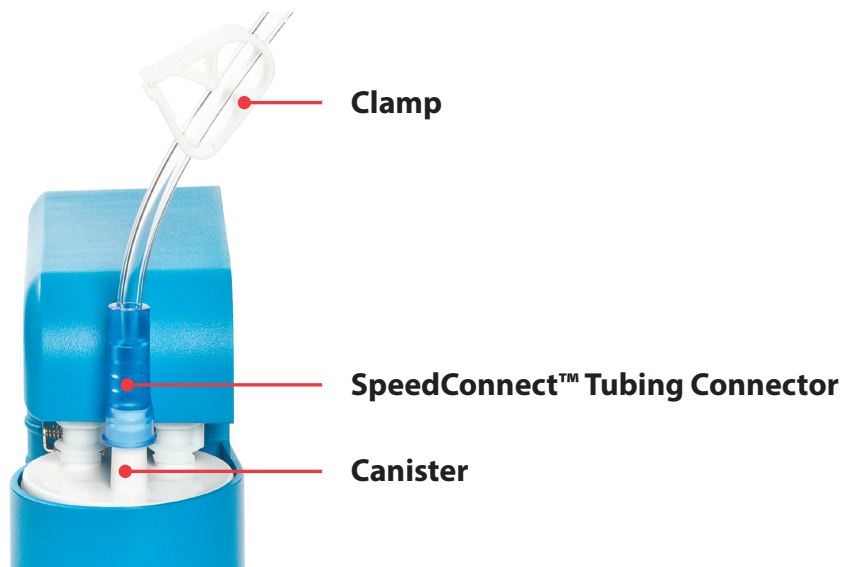


Figure 3

4. To remove the canister, press the silver canister release button located above the canister, grasp the canister at the bottom and pull downward (**Figure 4**).



Figure 4

5. Cap and dispose according to local, state and federal regulations. Ask your Healthcare Professional how to properly dispose of a used canister.
6. To install a new canister, hold the new unused canister at the bottom and slide upwards into the holder.
7. Align the two short ports and press upwards until it “clicks” into place.
8. Reconnect the SpeedConnect™ tubing to the canister. Gently twist and push the blue tapered connector on the open port of the canister just enough to secure and seal it.
9. Turn the device ON by pressing the  button to resume therapy.
10. Reopen the tubing clamp.

2.4 Disconnect from the Device

You may disconnect the device from your dressing for short amounts of time for activities such as bathing. Ask your Healthcare Professional about care of your dressing during bathing.

NOTE: The Cardinal Health™ SVED® device should be operated at least 22 hours out of every 24 hour period. Contact your Healthcare Professional immediately if therapy is terminated or is off for more than 2 hours in a 24 hour period. Your dressing may need to be changed.

1. Clamp the tubing closed (**Figure 5**).
2. Turn the device OFF by pressing the  button.
3. Remove the blue SpeedConnect™ tubing from the top of the canister (**Figure 5**). Twisting the tapered connector will make removing the Suction tube from the canister easier.

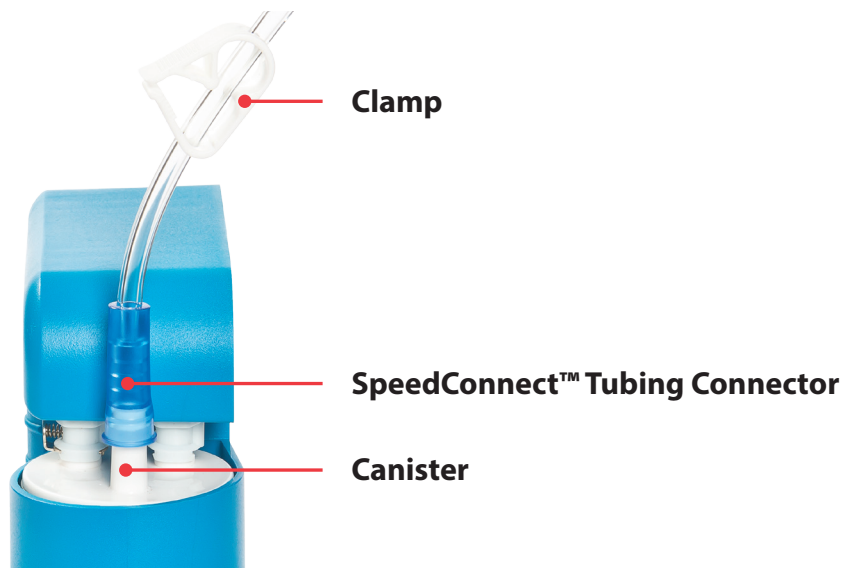


Figure 5

3. Operating Instructions

Carefully read the **1.3 PRECAUTIONS** and **1.5 SAFETY TIPS** in the **1. IMPORTANT USER INFORMATION** section before attempting to operate and adjust the Cardinal Health™ SVED® device.

WARNING: The Cardinal Health™ SVED® device should only be used with the supplied A.C. Adapter. Use of an incorrectly rated adapter could create a shock hazard for the patient or caregiver. The part number for the adapters can be found in the **6. REPLACEMENT PARTS** section of this manual.

3.1 Power ON/OFF

The ON  and OFF  buttons are located on the front top of the control panel and control the application of power to the therapy device.

3.2 Power-Up Procedure

When turning ON the Cardinal Health™ SVED® device, this is what you should expect to happen.

1. Press the ON  button. All LED indicators will illuminate for 1 second during the power-on self-test, after which, the ON  button will steadily light green.
2. Dressing should collapse indicating the presence of vacuum.
3. Carefully check dressing for vacuum or fluid leaks and repair with additional Polyurethane drape material as needed.
4. The Cardinal Health™ SVED® should be operated at least 22 hours out of every 24 hour period. Remove the Cardinal Health™ NPWT Dressing if therapy is terminated or is off for more than 2 hours in a 24 hour period.

3.3 Alarm Operation

Clearing an Alarm Condition

To clear an Alarm Type, remedy the condition using the Troubleshooting table below. Once the condition is corrected, the alarm will automatically reset. To manually reset an alarm, turn the therapy device OFF then ON. The alarm will clear when the power is cycled.

What you see or hear	Problem	What to do	More Information
OFF  button is flashing with audible chirp.	The battery is low.	Plug in the Cardinal Health™ SVED® device.	Green light on both the plug and the Cardinal Health™ SVED device indicates that the device is getting power. Amber light illuminates while battery is charging.
"LOW PRESSURE / LEAK" indicator is illuminated with an audible beep. Pressure Setting  button is flashing. Device is making more noise.	There is an air leak in either the dressing or the tubing connections.	- Clamp the tubing. - If Low Pressure/Leak LED and audible alarm resets, there is a leak below the clamp – often in the dressing. Reopen the clamp before addressing the leak. Gently press around drape to check for leaks. If leak is found, patch with extra drape material. - If Low Pressure/Leak LED and audible alarm continue, there is a leak above the clamp. Check tubing connection at the canister. Check to ensure the canister is fully seated and locked. Check for cracks in the canister or lid separation. If found, replace the canister. - Open the clamp.	The alarm will reset, the Pressure Setting button will stop flashing, and the device will become quiet after you find and seal the leak. Leaks often occur over areas of moist skin, creases or folds in skin, and wrinkles in the drape. They can occur if the drape snags on clothes or bed sheets.
"CANISTER FULL" indicator is illuminated with an audible beep.	The canister is full.	- Clamp the tubing. - Turn device off by pressing the OFF  button. - Press the canister release button above the canister and slide the full canister out. Cap and dispose of properly. Slide new canister in, align the short ports and click into place. - Open the clamp and press the ON  button to resume therapy.	The canister full alarm begins when the canister is 90% full, but the device will continue to work until the canister completely fills. If the Cardinal Health™ SVED® device is placed on its front, fluid entering the canister will cause a false canister full alarm and the canister must be changed.
Pressure Setting will not change.	Pressure lock-out is engaged.	Unlock the device.	Ask your Healthcare Professional how to unlock your device.
Device is quiet and fluid is not moving in the tube.	This is NOT a problem.	No action needed. If you want to move the fluid into the canister, ask your Healthcare Professional if you can use the intermittent mode.	When the dressing has a good seal, fluid may be removed from the wound and stay in the tubing. The foam will be compressed normally and the device will be quiet.
ON  button is flashing.	This is NOT a problem. The Cardinal Health™ SVED® is in intermittent mode.	No action needed.	Intermittent mode maintains target pressure for five minutes and decreases to 25 mmHg for two minutes.

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

NOTE: If an Alarm Condition persists and cannot be resolved, please contact Cardinal Health for further assistance.

4. Care & Cleaning

Your Healthcare Professional will handle much of the care and cleaning needed for your NPWT system. Please periodically check to make sure the device is working properly and look for signs that fluid has entered into the device. Also regularly inspect the AC adapter for any damage or unusual wear.

If the device is not working properly or is alarming, refer to the Alarm Troubleshooting guide in the **3.3 ALARM OPERATION** section of this manual or contact your Healthcare Professional for help. If the AC adapter is damaged, it must be replaced immediately. Contact your Healthcare Professional for help.

WARNING: Avoid spilling liquid on any part of the therapy device. Liquids can cause corrosion when left on electronic controls which can lead to failure. Component failure may cause the therapy device to operate erratically, possibly causing a potential hazard to the patient or Caregiver.

WARNING: The Cardinal Health™ SVED® device should only be used with the supplied A.C. Adapter. Use of an incorrectly rated adapter could create a shock hazard for the patient or caregiver and/or severely damage the device.

4.1 Disposal of Dressings, Canister and Other Disposables

Your Healthcare Professional should remove your dressings, tubings, clamps, used canisters and any other disposables. Ask your Healthcare Professional what to do with a used canister you have changed yourself.

Dispose of all disposable components in accordance with local, state, and federal regulations.

4.2 Cleaning the Device

The Cardinal Health™ SVED® device should need only light cleaning. Make sure to unplug the device before cleaning. The Battery will automatically provide power so therapy is not interrupted. Clean the device with a damp soft cloth and a mild soap and water solution.

Do not saturate the device with liquid or allow liquid to pool on the device. This can present a potential hazard for you and/or your Healthcare Professional.

4.3 A.C. Power Adapter Inspection

The A.C. Adapter should be inspected regularly for damage and/or unusual wear. Replace damaged or worn Power Supplies immediately. A.C. Adapters are available from Cardinal Health.

WARNING: The Cardinal Health™ SVED® device should only be used with the supplied A.C. Adapter. Use of an incorrectly rated adapter could create a shock hazard for the patient or caregiver and/or severely damage the device.

WARNING: Avoid spilling liquid on any part of the therapy device. Liquids can cause corrosion when left on electronic controls which can lead to failure. Component failure may cause the therapy device to operate erratically, possibly causing a potential hazard to the patient or Caregiver.

5. Specifications

Cardinal Health™ SVED® Device

Dimensions	7.5 x 2.5 x 6.8 in. (19.05 x 6.35 x 17.27 cm)
Weight	2.0 Lbs (910 g)
Therapy Settings	70, 120 & 150 mmHg
Canister Volume	300cc/500cc

Medical Equipment with respect to electric shock, fire, and mechanical hazards only in accordance with IEC60601-1.

IEC Classification

- Medical Equipment
- Equipment not suitable for use in presence of flammable anesthetic mixture with air, oxygen, or nitrous oxide.
- Continuous Operation
- Type B Applied Part
- Class II Internally Powered Equipment
- IPX0

Battery

Duration (Fully Charged)	up to 18 hours
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Electrical

External Power Supply Input	100-240 VAC, 50-60Hz, 700 mA
External Power Supply Output	15 VDC, 2 Amps
Patient & Enclosure leakage Current	< 100 Micro amps

Environmental Conditions

Storage Conditions

Temperature Range	10°F (-12°C) to 110°F (43°C)
Relative Humidity Range	20 – 95% Non-condensing
Atmospheric Pressure Range	50 kPa to 110 kPa

Operating Conditions

Temperature Range	40°F (4°C) to 90°F (32°C)
Relative Humidity Range	20 - 75% Non-condensing
Atmospheric Pressure Range	50 kPa to 110 kPa
Service life of Cardinal Health™ SVED®	3 years

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

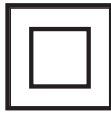
Specifications subject to change without notice

5.1 Explanation of Symbols

Device



Consult Instructions for Use



Class II, Internally
Powered Equipment



Type B, Applied Part



Alternating Current

IPXO

Not protected
against the harmful
effects of water

Dressings



Consult Instructions for Use



Method of Sterilization --
Ethylene Oxide



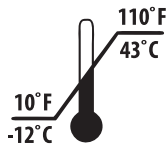
Expiry Date



Date of Manufacture



Lot/Batch Number



Storage Conditions



Fragile



Keep Dry



Single Use Only



Conforms with the
Medical Device
Directive (93/42/EEC)
and has been subject to
the conformity
procedures laid down in
the council directive

5.2 Electromagnetic Compatibility

The Cardinal Health™ SVED® therapy unit conforms to all pertinent requirements of IEC 60601-1-2.

The EMC summary tables are provided herein below for your reference.

Guidance and Manufacturer's Declaration: Electromagnetic Emissions (IEC 60601-1-2)		
Emissions Test	Compliance	Electromagnetic Environment
Harmonic emissions IEC 61000-3-2	Class A	The Cardinal Health™ SVED® device is suitable for use in all establishments, including medical facilities, 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	
RF emissions CISPR 14-1	Complies	The Cardinal Health™ SVED® device is not suitable for interconnection with other equipment.

Recommended separation distance between portable and mobile RF communications equipment and the Cardinal Health™ SVED® Device			
The Cardinal Health™ SVED® device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Cardinal Health™ SVED® device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Cardinal Health™ SVED® device as recommended below, according to the maximum output power of the communications equipment.			
Output Power of Transmitter in watt(s)	Separation distance according to frequency of transmitter in meter(s)		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5GHz
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 meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
Note: At 80MHz and 800MHz, the separation distance for the higher frequency range applies.			
Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

Guidance and Manufacturer's Declaration: Electromagnetic Immunity (IEC 60601-1-2)

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floor should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fasttransient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial and/or hospital environment.
Surge IEC 61000-4-5	±1 kV line to line ±2 kV line to earth	±1 kV line to line ±2 kV line to earth	Mains power quality should be that of a typical commercial and/or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0.5 cycle	<5 % U_T (>95 % dip in U_T) for 0.5 cycle	Mains power quality should be that of a typical commercial and/or hospital environment.
	40 % U_T (60 % dip in U_T) for 5 cycles	40 % U_T (60 % dip in U_T) for 5 cycles	
	70 % U_T (30 % dip in U_T) for 25 cycles	70 % U_T (30 % dip in U_T) for 25 cycles	
	<5 % U_T (95 % dip in U_T) for 5 sec.	<5 % U_T (95 % dip in U_T) for 5 sec.	
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.
Note: U_T is the A.C. mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration: Electromagnetic Immunity (IEC 60601-1-2)

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	3 V rms 150 kHz ~ 80 MHz	3 V rms	Portable and mobile RF communications equipment should be used no closer to any part of the Cardinal Health™ SVED® device including cables, than the recommended separation distance calculated from the equation appropriate to the frequency of the transmitter. Recommend separation distance $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P} \text{ 80 MHz to 800 MHz}$ $d = 2.3 \sqrt{P} \text{ 800 MHz to 2.5 GHz}$ 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 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: 
Radiated RF IEC 61000-4-3	3 V/m 800 MHz ~ 2.5 GHz	3 V/m	

Note1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note2: 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 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 Cardinal Health™ SVED® device is used exceeds the applicable RF compliance level above, the Cardinal Health™ SVED® device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Cardinal Health™ SVED® device.

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

6. Replacement Parts

Device

Cardinal Health™ SVED® device	6701132
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Power Supply

A.C. Power Adapter	47-9000
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Dressings

Cardinal Health™ NPWT Small Foam Dressing Kit (10 per case)	47-1702
Cardinal Health™ NPWT Medium Foam Dressing Kit (10 per case)	47-1701
Cardinal Health™ NPWT Large Foam Dressing Kit (10 per case)	47-1700
Cardinal Health™ NPWT X-Large Foam Dressing Kit (10 per case)	47-1703
Cardinal Health™ White Foam Dressing (10 per case)	47-1751

Canisters

Cardinal Health™ Disposable Canister with Gel, 300 cc (10 per case)	47-4000
Cardinal Health™ Disposable Canister with Gel, 500 cc (10 per case)	47-4500

Accessories

Cardinal Health™ SVED® I.V. Pole/Bed Hanger Adapter	47-5500
Cardinal Health™ SVED® Canvas Carry Bag	47-9500
Cardinal Health™ SpeedConnect™ Tubing	47-2000
Cardinal Health™ NPWT "Y" Connector	47-2500
Cardinal Health™ NPWT Polyurethane Drape (10 per pkg.)	47-7000
Cardinal Health™ NPWT SensiSkin™ Drape (10 per pkg.)	47-7100
Cardinal Health™ NPWT Irrigation Tubing with SpeedConnect™	47-6000

NOTE: Part numbers for Canisters, Dressings and Disposable Accessories may be obtained by visiting the Cardinal Health website (www.cardinalhealth.com).

NOTE: In order to assure the highest safety, quality and efficacy of the products, the Cardinal Health™ SVED® device should only be used with Cardinal Health™ NPWT components, and Cardinal Health™ NPWT components should only be used with the Cardinal Health™ NPWT Devices.

7. Questions & Information

For additional information pertaining to the Cardinal Health™ SVED® device, please contact your local Cardinal Health representative, or:

Call our customer support professionals at 1.866.484.6798

Cardinal Health
Waukegan, IL 60085
www.cardinalhealth.com
CustomerServiceNPWT@cardinalhealth.com

For questions or comments regarding the content of this User's Manual, please contact Cardinal Health at the above address. Please contact Cardinal Health Customer Service at 1.866.484.6798 for issues concerning the product and its use.

Always consult a physician and product instructions for use prior to application.

Caution: Federal law restricts these devices to sale by or on the order of a physician.



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US Pat. 7,532,953, 7,608,066, 8,066,243.



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