REF 6701132

CardinalHealth™

Negative Pressure Wound Therapy

SVED®

Patient User Manual

About Your Cardinal Health™ SVED®

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

Things you need to know about your SVED®

- Do not allow the SVED® to get wet. Clamp the tubing and disconnect from the canister if you take a bath or shower.
- Keep the SVED® plugged in whenever possible to keep the battery fully charged. Always take the A.C.. Power Adapter with you when you leave home.
- Keep the SVED® upright to avoid a false Canister Full Alert.
- Keep the SVED® turned on at all times unless there is bleeding from the wound or instructed by your healthcare professional.
- Do not change the Pressure Settings on the SVED® 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 SVED® 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 SVED®.
- Who to call if you need help.
- How to take care of your SVED®.

This 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 Cardinal Health Customer Service at 1.866.484.6798.

In order for the 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.

- All assembly, operation, adjustment, modification, maintenance, and/or repair must be carried out only by qualified personnel authorized by Cardinal Health. Unauthorized modification of the SVED device may result in physical hazards, including delayed therapy, electrocution and fire that may lead to injury or death.
- The electrical outlets in the room in which the SVED® is used complies with the appropriate national electrical standards.
- The SVED® NPWT System must be used in accordance with this manual and all associated labeling and the Instructions for Use.
- Any SVED® that does not function as expected must be returned to Cardinal Health.

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 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.

Safety and Warnings

***Note to healthcare personnel providing training to lay users or caregivers (lay responsible organizations)*:**
Be sure to include all of the warnings below when providing training to lay operators, especially in a home care e nvironment. Lay users and caregivers should contact Customer Support if there is a change in the performance of the SVED®. Additionally, lay users should be instructed on proper cleaning procedures to avoid hazards such as electric shock. Lay users and caregivers should also be trained on inappropriate environments for use (e.g. bathtub).
For guidance on training, please contact Customer Support.

WARNING: Strangulation hazard. Do not leave A.C. Power Adapter cord, tubing or other choking hazards where infants or young children can become caught. If these objects get wrapped around the neck, strangulation and death can occur.

WARNING: Choking hazard. The SVED® contains small parts, which could become detached and pose a choking hazard. Some of these components could be inhaled or swallowed by a small child, toddler or infant, which could result in suffocation or death. Keep all parts of the SVED® system out of reach of small children.

WARNING: Do not modify this equipment without authorization from the manufacturer. Modification of this system could result in physical hazards, including delayed therapy, electrocution and fire. These hazards could result in injury or death.

WARNING: Use only the Cardinal Health™ NPWT Dressing and accessories listed in this manual. Use of other dressings and accessories can create hazardous situations, including improper therapy or delayed therapy. This could result in improper healing, damage to the wound area and infection.

CAUTION: Use the SVED® only as described in this user manual. Do not interconnect this SVED® with other devices not included in this user manual. Failure to comply could result in improper therapy and could result in damage to the SVED®.

CAUTION: This system is not intended to be used in MRI environments or in the presence of strong magnetic fields. Do not use this device in any areas with strong magnetic fields. The system contains metal components which could cause unintended movement. This unintended movement could cause clinician or patient harm due to falling objects or collisions.

CAUTION: If you are in an environment with pet hair, please use caution when adhering the wound dressing to the wound site. Pet hair could contaminate the wound site and prevent adhesion of the wound dressing. This could result in possible infection of the wound or reduced effectiveness of the system.

CAUTION: The SVED® can be used outdoors for short periods of time (not more than 24 hours). Shelter from rain.

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1. Introduction

1.1 Indications

The SVED® Negative Pressure Wound Therapy (NPWT) 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 SVED® NPWT System is intended for patients with chronic, acute, traumatic, subacute and dehisced wounds, surgical incisions following sutured or stapled closure, partial-thickness burns, ulcers (such as diabetic or pressure), flaps and grafts. The SVED® NPWT System is intended for use in acute, extended and home care settings.

1.2 Contraindications

The 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 dressings over exposed blood vessels or organs. The 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 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.

- **Defibrillation:** The dressings must be removed 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 SVED® is not MRI-compatible and cannot be used in the presence of strong magnetic fields. Do not take the SVED® into the MRI area or any area of high magnetic fields. The SVED® contains metal components that could cause unintended movement resulting in harm due to falling objects or collisions.
- **Hyperbaric Oxygen Therapy (HBO):** NEVER allow a SVED® inside a hyperbaric chamber. The SVED® must be disconnected from the patient prior to HBO treatment.
- **Changes in Performance:** If you notice unusual changes in the performance of the system, contact customer service at 1.866.484.6798.
- During negative pressure wound therapy, the SVED® and dressings 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. Fluid will not be removed from the dressing once the canister is full.

1.4 Safety Tips

Keep Therapy On

The SVED® 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.

Troubleshooting

If the SVED® alerts or does not seem to operate properly, see **3.2 Troubleshooting**.

Monitoring the Wound

Inspect the dressing frequently to ensure that the dressing is collapsed and that therapy is being delivered in a consistent manner. Monitor wound, canister and tubing for signs of active bleeding. Monitor around your wound or incision for signs of infection or other complications. Signs of possible infection may include fever, tenderness, redness, swelling, itching and rash, increased warmth in the wound area, sudden incerease in pain, purulent discharge or a strong odor. Nausea, vomiting, diarrhea, heacache, dizziness, fainting, sore throat with swelling of the mucous membrane, disorientation, high fever, refractory hypotension, orhtostatic hypotension, or periwound induration (a sunburn-like rash) may be added signs of more serious complications of infection. 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 SVED®, 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 SVED® until the serious infection is diagnosed and properly treated by your healthcare professional.

NPWT Dressing Use

Your healthcare professional will apply and change your dressings for you.

Monitoring the Tubing/A.C. Power Adapter Cord

Do not allow tubing or A.C. Power Adapter Cord around the neck area.

NOTE: All dressing components of the NPWT Dressing Kit are packaged sterile. The decision to use clean versus sterile/aseptic technique is dependent upon your healthcare professional's preference. SVED®, the NPWT Dressing Kits, the canisters and other accessories are made without natural rubber latex.

Be sure to comply with all other **1.2 Contraindications** and **1.3 Precautions** for the SVED®.

2. Introduction to the SVED®

2.1 Getting to Know the SVED®

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

NOTE: The SVED® will be quiet during normal operation with a well-sealed dressing.

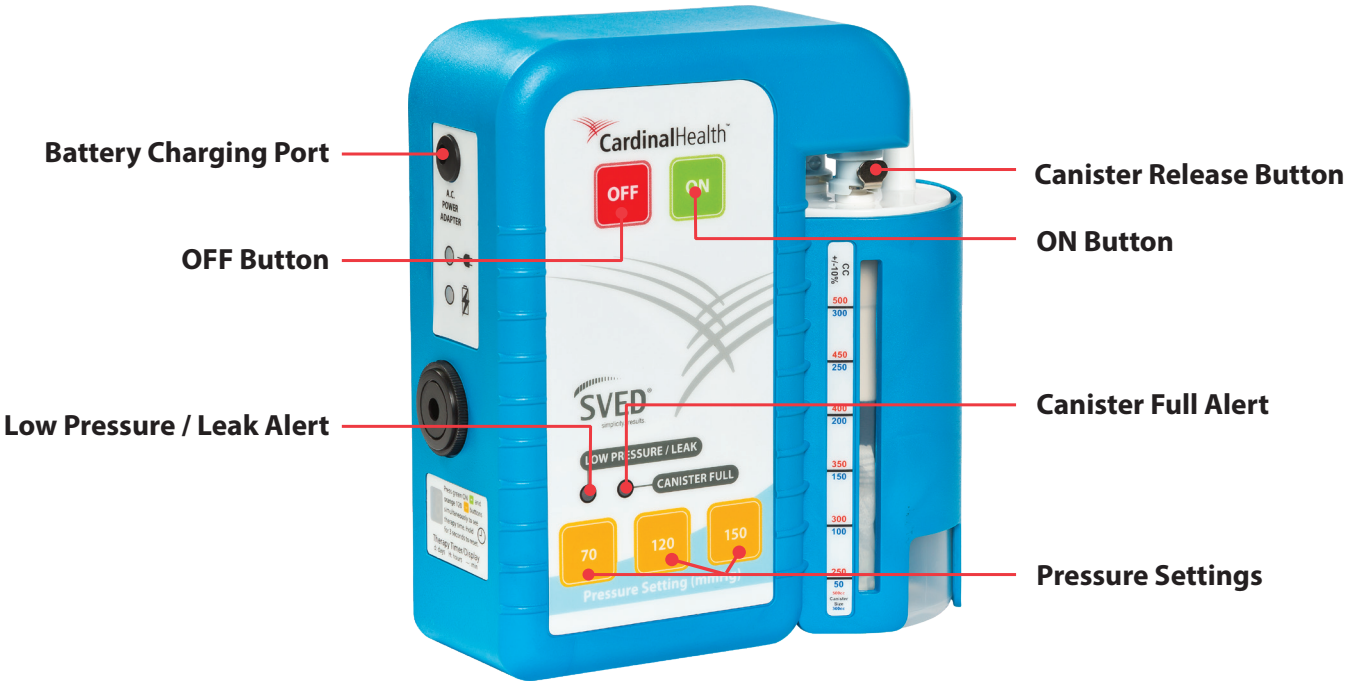


Figure 1

2.2 Charging the Battery

The SVED® has an internal battery that provides up to 10.5 hours of operation from a fully charged battery.
When the battery is running low, an alert will sound to let you know you must plug in the SVED® to charge the battery.
See **3.2 Troubleshooting**.

1. Plug the A.C. Power Adapter into a suitable wall outlet (100-240VAC, 50-60Hz).
2. Insert the A.C. Power Adapter into the Battery Charging Port on the left side of the SVED® (**Figure 2**).
3. When the SVED® is connected to an outlet, the green light next to the Plugged In symbol comes on. If the battery is charging, the yellow light next to the Battery Charging symbol comes on. Once the battery is fully charged, the light goes off.

   NOTE: If the SVED® is plugged in and green light does not turn on, check to make sure outlet is working properly.
4. The SVED® continues to work when charging.

WARNING: The SVED® must only be used with the supplied A.C. Power Adapter. Use of any other A.C. Power Adapter or charger could result in physical hazard, including delayed therapy, electrocution and fire. These hazards could result in injury or death.

Figure 2

Average Battery Life

The specified battery life of the SVED® with a fully-charged battery is up to 10.5 hours. The actual life is dependent on the integrity of the dressing. A leak in the dressing can significantly reduce overall battery longevity.

Average Time for Recharging

To ensure the battery has been fully charged, the SVED® should be connected to an A.C. Power Adaptor for approximately 3 hours.

Low Battery Alert

While running on battery, a Low Battery Alert "chirps" every 10 seconds and the OFF button flashes when remaining capacity of the battery is less than 20 percent (See **3.2 Troubleshooting**). Typically, the SVED® continues to operate for approximately 30 minutes after the Low Battery Alert sounds.

If the battery charge gets too low, the SVED® shuts off and the negative pressure wound therapy is stopped. At this point, the SVED® must be plugged into an outlet using the A.C. Power Adapter for negative pressure wound therapy to resume. Once the A.C. Power Adapter is plugged in, press the ON button to restart the SVED®.

2.3 Changing the Canister

When the SVED® detects that the canister needs to be changed, a Canister Full Alert sounds. The SVED® continues to work until the canister completely fills. When the canister is completely full, the SVED® turns off.

To change the canister:

1. Clamp the tubing closed **(Figure 3).**
2. Turn the SVED® OFF by pressing the OFF button.
3. Remove the blue SpeedConnect™ tubing connector from the top of the canister **(Figure 3)** by twisting off the tapered connector.

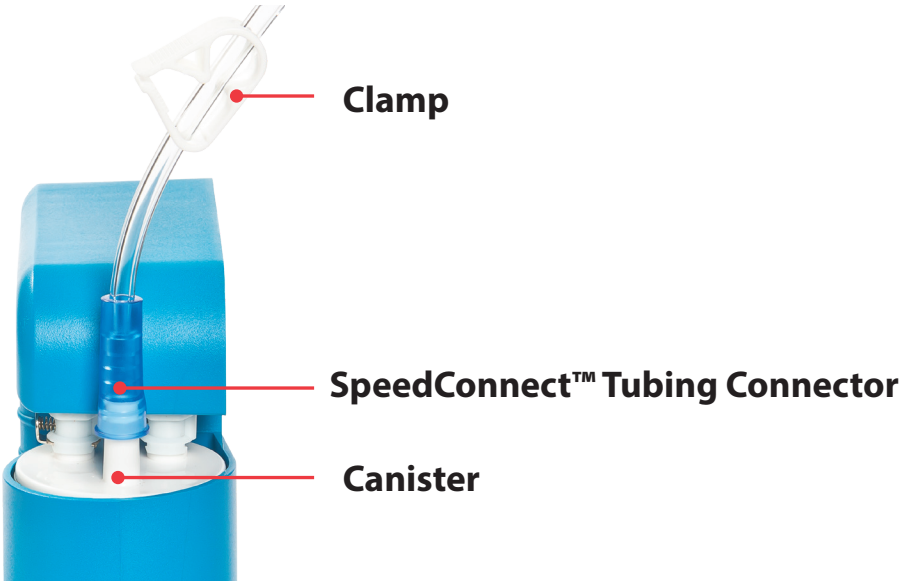


Figure 3

4. To remove the canister, press the Canister Release Button located above the canister, grasp the canister at the bottom and gently pull downward (**Figure 4**).

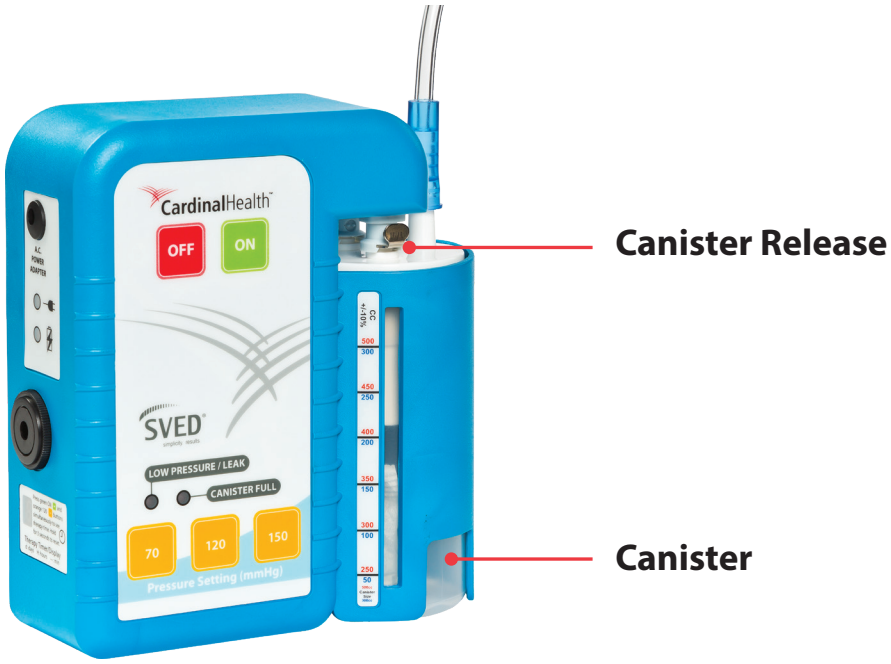


Figure 4

5. Cap the canister and 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 blue SpeedConnect™ tubing connector to the canister. Gently twist and push the connector on the open port of the canister just enough to secure and seal it.
9. Turn the SVED® ON by pressing the ON button to resume therapy.
10. Reopen the tubing clamp.

2.4 Disconnecting from the SVED®

You may disconnect the SVED® from your dressing for short amounts of time for activities such as bathing. Ask your healthcare professional about care of your dressing during bathing or showering.

NOTE: The SVED® 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.

To disconnect from the SVED®:

1. Clamp the tubing closed (**Figure 5**).
2. Turn the SVED® off by pressing the OFF button.
3. Remove the blue SpeedConnect™ tubing connector from the top of the canister (**Figure 5**) by twisting the tapered connector off the canister.

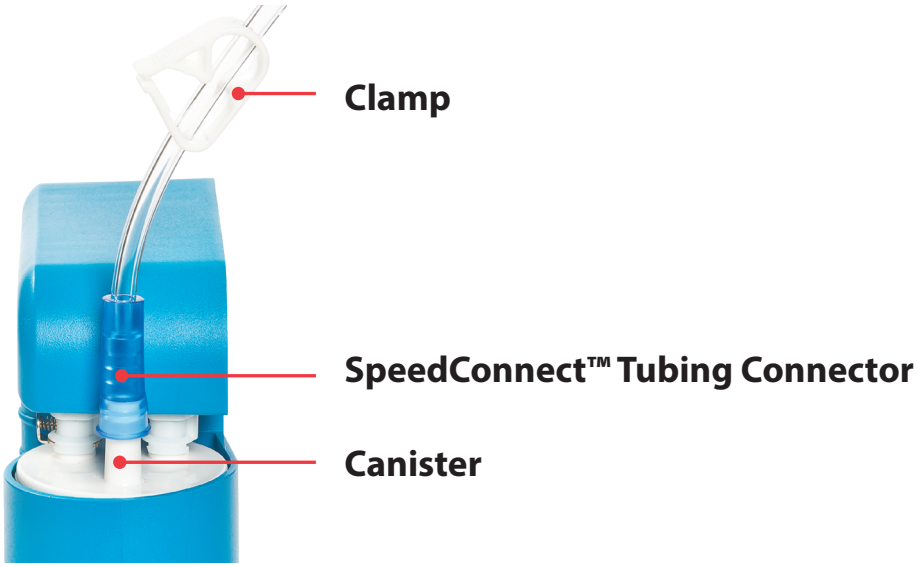


Figure 5

3. Operating Instructions

Carefully read the **1.3 Precautions** and **1.4 Safety Tips** in the **1. Introduction** section before attempting to operate the SVED®.

CAUTION: The SVED® should only be used with the supplied A.C. Power Adapter or Global Power Adapter. The Global Power Adapter must be purchased separately. Another A.C. Power Adapter or power cord could create a shock hazard for you or your caregiver, cause fire and/or severely damage the SVED®. If you need a replacement A.C. Power Adapter, call Cardinal Health Customer Service at 1.866.484.6798.

3.1 POWER ON/OFF

The ON and OFF buttons are located on the front of the SVED®.

1. Press the ON button. All lights show for 1 second during the power-on self-test. When finished, the ON button stays green.
2. Dressing should collapse indicating the presence of negative pressure. If there is a Low Pressure/Leak Alert, see **3.2 Troubleshooting**.
3. The SVED® should be operated at least 22 hours out of every 24-hour period. Contact your healthcare professional if the SVED® is off for more than 2 hours in a 24-hour period. Your dressing must be changed by your healthcare professional.

   NOTE: If an alert persists and cannot be resolved, please call Cardinal Health Customer Service at 1.866.484.6798.

3.2 Troubleshooting Guide

To clear an alert, use the **Troubleshooting** table below. To manually reset an alert, turn the SVED® OFF then ON. The alert will clear when the power is cycled.

What you see or hear	Problem	What to do	More information
OFF Button is flashing. Single beep.	The battery is low and has approximately 30 minutes before the battery will be too low to support continued operation of the SVED®.	Plug in the SVED. A green light shows next to Plugged In indicator and a yellow light next to Battery Charging indicates that power is going to the SVED®. The yellow light turns off after the battery is fully charged.	Use only the A.C. Power Adapter that came with the SVED. If the alert continues or a replacement A.C. Power Adapter is needed, call Cardinal Health at 1.866.484.6798 for more assistance.
LOW PRESSURE/LEAK indicator is lit. Single beep. Pressure Setting Button is flashing. SVED® is making noise.	There is an air leak in either the dressing or the tubing connections. Leaks often occur over areas of moist skin, creases or folds in skin and wrinkles in the dressing. They can occur if the dressing snags on clothing or bed sheets.	• Clamp the tubing. • If the Low Pressure/Leak light stops, there is a leak between the clamp and the dressing — 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 or drape strips. • If Low Pressure/Leak Alert continues, there is a leak between the clamp and the SVED®. Check the tubing connection at the canister. Check to ensure that the canister is fully seated and locked. Check for cracks in the canister or lid separation. If found, replace the canister. • Open the clamp.	Once the leak is found and sealed, the alert resets, the Pressure Setting Button quits flashing and the SVED® becomes quiet. If alert continues, call Cardinal Health at 1.866.484.6798 for more assistance.
CANISTER FULL indicator is lit. Single beep.	The canister is full.	• Visually assess the canister to see if full. If the canister is full, change the canister. • If the canister is not full, turn the SVED® off by pressing the OFF Button and then turn the SVED® back on to resume therapy.	The Canister Full alert begins when the canister is 90 percent full, but the SVED® continues to work until the canister completely fills. If the SVED® device is placed on its front, fluid entering the canister will cause a false Canister Full Alert and the canister must be changed. If alert continues, call Cardinal Health at 1.866.484.6798 for more assistance.
Pressure will not change.	Pressure Setting has been locked by the clinician.	No action needed.	Pressure Setting can only be changed per a healthcare professional's orders.
SVED® is quiet and fluid is not moving in the tubing.	This is NOT a problem. The dressing has a good seal and the SVED® is maintaining target pressure.	No action needed.	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 SVED® is quiet. Your healthcare professional will change the SVED® if required.
ON Button is flashing. The SVED® is making more noise every five minutes.	This is NOT a problem. The SVED® is in Intermittent Mode.	No action needed.	Intermittent Mode maintains target pressure for 5 minutes and decreases to -25mmHg for 2 minutes.

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

NOTE: If an alert persists and cannot be resolved, please contact Cardinal Health Customer Service at 1.866.484.6798 for further assistance.

4. Care & Cleaning

Your healthcare professional will handle much of the care and cleaning needed for your SVED®. Please periodically check to make sure the SVED® is working properly.

If the SVED® does not seem to work properly or is showing an alert, refer to **3.2 Troubleshooting** or contact your healthcare professional for help. If the A.C. Power Adapter is damaged, it must be replaced immediately. Contact your healthcare professional for help.

WARNING: The SVED® is rated IP22, but is not waterproof. Avoid spilling liquid on any part of the SVED®. Liquids can cause corrosion when left on electronic controls which can lead to failure. Component failure may cause the SVED® to operate erratically, possibly causing a potential hazard to the patient or caregiver. Avoid using the SVED® in or near the shower or bathtub, as electric shock could occur.

WARNING: The SVED® should only be used with the supplied A.C. Power Adapter. Use of an incorrectly rated adapter or power cord could result in physical hazards, including delayed therapy, electrocution and fire. These hazards could result in injury or death.

4.1 Disposal of Used Components

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

Carefully read **1.3 Precautions** and **1.4 Safety Tips** before cleaning the SVED® or A.C. Power Adapter.

Standard Precautions should be used to minimize the risk of infection and contact with contaminated blood or bodily fluids during the dressing changes and cleaning of the SVED® and A.C. Power Adapter. It is important to protect all exposed skin and mucous membranes by using Personal Protective Equipment (PPE). PPE includes:

- Disposable gloves
- Protective eyewear
- Protective mask
- Disposable impervious gown

Perform a visual inspection of the SVED®. Check for any sign of contamination or fluid going into the canister ports. Ensure that the SVED® is functioning properly. If the SVED® is not operating properly, refer to **3.2 Troubleshooting** or contact Cardinal Health at 1.866.484.6798.

To help reduce the risk of infection and contact with contaminated blood and bodily fluids, it is recommended to wear personal protective equipment (PPE) when cleaning the SVED®.

NOTE: Cleaning of the SVED® must not be performed when the SVED® is connected to a patient or power source. Disconnect the SVED® from the patient and power source before cleaning.

General Cleaning Instructions

A mild, common dish washing liquid detergent should be used for general cleaning. This detergent should be used with a 20:1 ratio water to detergent mixture.

Wipe down the SVED® with a paper towel moistened with the cleaning solution, removing all visible soil. Use a brush to remove soil from hard-to-reach crevices.

CAUTION: The use of cleaners and disinfectants other than a mild, common dish washing liquid detergent may cause significant damage to the SVED® and may void warranty.

Cleaning Frequency

It is recommended that SVED® be cleaned after each SVED® Canister use for a minimum duration of 30 seconds, to prevent bacterial contamination.

Instructions for Cleaning SVED® Housing

Refer to General Cleaning Instructions above before starting.
Clean outside surface with a disposable paper towel using a mild, common dish washing liquid detergent.
A clean cloth dampened with water may be used to remove any residual detergent.

Instructions for Cleaning SVED® A.C. Power Adapter

- Unless soiling is observed, the power adapter should not be cleaned.
- If cleaning of the power adapter is necessary, unplug and wipe the exterior surfaces with a cloth dampened with isopropyl alcohol.
- Allow excess moisture to evaporate prior to use.

CAUTION: The SVED A.C. Power Adapter is not designed to be immersed, soaked, rinsed, or sprayed with water. Do not immerse, soak, rinse, or spray the SVED A.C. Power Adapter in water or other cleaning solutions. Failure to follow the cleaning procedures described herein could result in hazards to users, patients, and clinicians. As with any medical electrical equipment, care must be taken to prevent liquid from entering the power adapter to avoid electrical shock hazard, fire hazard, or damage to the electrical components.

4.3 General Disinfection Instructions

SVED® can be disinfected by wetting its surfaces with a 10:1 water and chlorine bleach mixture. To wet the device, use at least two bleach mixture wetted, lint-free wipes and wipe as necessary to maintain visual wetness. Visual wetness should be maintained for a minimum duration of 10 minutes.

- Allow excess moisture to evaporate prior to use.
- Repeated disinfection with this solution can damage the plastic housing.

NOTE: Disinfecting of the SVED® must not be performed when the SVED® is connected to a patient or power source. Disconnect the SVED® from the patient and power source before disinfecting.

Disinfection frequency

It is necessary to clean and disinfect SVED® and A.C. Power Adapter after each use when used for multiple patients.

Instructions for Disinfecting SVED® Housing and A.C. Power Adapter

Refer to General Disinfecting Instructions above before starting. Clean outside surface with a damp cloth or sponge using the bleach mixture. A cloth dampened with 99% isopropyl alcohol may be used to remove any disinfectant residue. Use a brush to maintain wetness at hard-to-reach crevices.

CAUTION: The SVED® and A.C. Power Adapter is not designed to be immersed, soaked, rinsed, or sprayed with water. Do not immerse, soak, rinse, or spray the SVED A.C. Power Adapter in water or other cleaning solutions. Failure to follow the cleaning procedures described herein could result in hazards to users, patients, and clinicians. As with any medical electrical equipment, care must be taken to prevent liquid from entering the power adapter to avoid electrical shock hazard, fire hazard, or damage to the electrical components.

CAUTION: Care must be taken when handling undiluted chlorine bleach, including proper shielding of eyes. Always mix by adding chlorine bleach to the water. Do not spray liquids directly on to the SVED®.

CAUTION: Avoid spilling liquid on any part of the SVED®. Spilling liquid on the SVED® may cause the SVED® to operate erratically, possibly causing a potential hazard to the patient or clinical caregiver.

Carrying Case and IV Pole Adapter

Follow the same procedure as above.

4.4 A.C. Power Adapter Inspection

The A.C. Power Adapter should be inspected regularly for damage. If you notice any damage to the A.C. Power Adapter, call your healthcare professional for a replacement to avoid interruption of therapy.

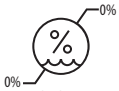
WARNING: The SVED® should only be used with the supplied A.C. Power Adapter. Use of an incorrectly rated adapter or power cord could result in physical hazards, including delayed therapy, electrocution and fire. These hazards could result in injury or death.

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

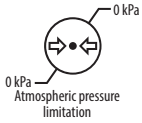
5. Symbols Glossary

Symbols Recognized by Standard/Law

Symbol	Standard/Law Reference	Standard/Law Title	Symbol Title/ Text Reference	Explanatory Text
	ISO 13225-1, Clause 5.1.1	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Manufacturer	Indicates the medical device manufacturer.
	ISO 7000-3082	Graphical symbols for use on equipment		
	ISO 15223-1, Clause 5.1.3	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Date of Manufacture	Indicates the date when the medical device was manufactured.
	ISO 7000-2497	Graphical symbols for use on equipment		
	EN 60417-6049	Graphical symbols for use on equipment	Country of Origin	To identify the country of manufacture of products. To identify country abbreviation, see https://www.iso.org/obp/ui/#search.
	ISO 3166-1	Codes for the representation of names of countries and their subdivisions - Part 1: Country Codes		
	ISO 15223-1, Clause 5.1.2	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Authorized European Representative	Indicates the Authorized Representative in the European Union.
	ISO 15223-1, Clause 5.1.6	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Catalogue or Model Number	Indicates the manufacturer's catalogue number so the device can be identified.
	ISO 7000-2493	Graphical symbols for use on equipment		
	ISO 15223-1, Clause 5.1.7	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Serial Number	Indicates the manufacturer's serial number so that a specific device can be identified.
	ISO 7000-2498	Graphical symbols for use on equipment		
	ISO 15223-1, Clause 5.1.5	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Batch/Lot Code	Indicates the manufacturer's batch/lot code so that the batch or lot can be identified.
	ISO 7000-2492	Graphical symbols for use on equipment		
 Use-by	ISO 15223-1, Clause 5.1.4	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Use by Date	Indicates the date after which the medical device is not to be used.
	ISO 7000-2607	Graphical symbols for use on equipment		

Symbol	Standard/Law Reference	Standard/Law Title	Symbol Title/ Text Reference	Explanatory Text
IVD	ISO 15223-1, Clause 5.5.1	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	*In Vitro* Diagnostic Medical Device	Indicates that a medical device is intended to be used as an *in vitro* diagnostic medical device.
 Caution	IEC 60601-1, Table D.1, Symbol 10	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	ISO 7000-0434	Graphical symbols for use on equipment		
 Temperature limit	ISO 15223-1, Clause 5.3.7	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Temperature Limit	Indicates the temperature limits to which the medical device can be safely exposed.
	ISO 7000-0632	Graphical symbols for use on equipment		
 Humidity limitation	ISO 15223-1, Clause 5.3.8	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Humidity Limitation	Indicates the range of humidity to which the medical device can be safely exposed.
	ISO 7000-2620	Graphical symbols for use on equipment		
 Keep dry	ISO 15223-1, Clause 5.3.4	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Keep Dry	Indicates a medical device that needs to be protected from moisture.
	ISO 7000-0626	Graphical symbols for use on equipment		
 Fragile, handle with care	ISO 15223-1, Clause 5.3.1	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Fragile, Handle with Care	Indicates a medical device that can be broken or damaged if not handled carefully.
	ISO 7000-0621	Graphical symbols for use on equipment		
 Do not re-use	ISO 15223-1, Clause 5.4.2	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Do Not Reuse	Indicates a medical device that is intended for one use or for use on a single patient during a single procedure.
	ISO 7000-1051	Graphical symbols for use on equipment		
 Do not resterilize	ISO 15223-1, Clause 5.2.6	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Do Not Resterilize	Indicates that a medical device should not be resterilized.
	ISO 7000-2608	Graphical symbols for use on equipment		

Symbol	Standard/Law Reference	Standard/Law Title	Symbol Title/ Text Reference	Explanatory Text
	ISO 15223-1, Clause 5.2.1	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Sterile	Indicates a medical device that has been subjected to a sterilization process.
	ISO 7000-2499	Graphical symbols for use on equipment		
	ISO 15223-1, Clause 5.2.2	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Sterile Using Aseptic Techniques	Indicates medical device that has been sterilized by using accepted aseptic technique.
	ISO 7000-2500	Graphical symbols for use on equipment		
	ISO 15223-1, Clause 5.2.3	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Sterilized by Ethylene Oxide	Sterilized by ethylene oxide
	ISO 7000-2501	Graphical symbols for use on equipment		
	ISO 15223-1, Clause 5.2.4	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Sterilized Using Irradiation	Indicates a medical device that has been sterilized using irradiation.
	ISO 7000-2502	Graphical symbols for use on equipment		
	ISO 15223-1, Clause 5.2.5	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Sterilized Using Steam or Dry Heat	Indicates a medical device that has been sterilized using steam or dry heat.
	ISO 7000-2503	Graphical symbols for use on equipment		
 Sterile fluid path	ISO 15223-1, Clause 5.2.9	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Sterile Fluid Path	To identify the presence of a sterile fluid path within the medical device when other parts of the medical device are not necessarily supplied sterile.
	ISO 7000-3084	Graphical symbols for use on equipment		
 Keep away from sunlight	ISO 15223-1, Clause 5.3.2	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Keep Away From Sunlight	Indicates a medical device that needs protection from light sources.
	ISO 7000-0624	Graphical symbols for use on equipment		
	ISO 15223-1, Clause 5.2.7	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process.
	ISO 7000-2609	Graphical symbols for use on equipment		

Symbol	Standard/Law Reference	Standard/Law Title	Symbol Title/ Text Reference	Explanatory Text
 Consult instructions for use	ISO 15223-1, Clause 5.4.3	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Consult Instructions for Use	Indicates user needs to consult instructions for use.
	ISO 7000-1641	Graphical symbols for use on equipment		
 Follow instructions for use	IEC 60601-1, Table D.2, Symbol 10	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	Refer to Instruction Manual/Booklet	Indicates user needs to consult instructions for use.
	IEC 60601-1-2:2007, Clause 5.1.1	Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic compatibility — Requirements and tests	Non-ionizing ElectroMagnetic Radiation	To indicate generally elevated, potentially hazardous, levels of nonionizing radiation, or to indicate equipment or systems e.g. in the medical electrical area that include RF transmitters or that intentionally apply RF electromagnetic energy for diagnosis or treatment.
	IEC 60417-5140	Graphical symbols for use on equipment		
	IEC 60878-5140	Graphical symbols for electrical equipment in medical practice		
	ISO 15223-1, Clause 5.3.9	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Atmospheric Pressure Limits	Indicates the range of atmospheric pressure to which the medical device can be safely exposed.
	ISO 7000-2621	Graphical symbols for use on equipment		
 Non-pyrogenic	ISO 15223-1, Clause 5.6.3	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Non-pyrogenic	Indicates that the medical device is non-pyrogenic.
	ISO 7000-2724	Graphical symbols for use on equipment		
 Do not use if package is opened or damaged	ISO 15223-1, Clause 5.2.8	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Do Not Use if Package is Damaged	Indicates that the medical device should not be used if the package holding device has been damaged or opened.
	ISO 7000-2606	Graphical symbols for use on equipment		
	ISO 7000-3079	Graphical symbols for use on equipment	Open Here	Indicates where the package can be opened and to indicate method of opening it.

Symbol	Standard/Law Reference	Standard/Law Title	Symbol Title/ Text Reference	Explanatory Text
 MR Unsafe	ASTM F2503	Standard practice for marking medical devices and other items for safety in the magnetic resonance environment	Magnetic Resonance (MR) Unsafe	Keep device away from magnetic resonance imaging (MRI) equipment.
	IS EN-15986:2011	Symbol for use in the labeling of medical devices. Requirements for labeling of medical devices containing phthalates.	Contains Presence of Phthalates	Indicates presence of Bis (2-ethylexyl) phthalate (DEHP).
 Not made with natural rubber latex	ISO 15223-1, Clause 5.4.5, Annex B.2	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Does Not Contain Natural Rubber Latex	The medical device or the packaging of the medical device does not contain natural rubber latex.
 Caution: This product contains natural rubber latex which may cause allergic reactions.	ISO 15223-1, Clause 5.4.5	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Contains or Presence of Natural Rubber Latex	Indicates the presence of natural rubber or dry natural rubber latex as a material of construction within the medical device or the packaging of a medical device.
	EN 50419	Marking of Electrical and Electronic Equipment in accordance with Article 11(2) of Directive 2002/96/EC (WEEE).	WEEE Wheeled Bin	This product contains electrical and electronic components that may contain materials which, if disposed with general waste, could be damaging to the environment. Residents of the European Union must follow specific disposal or recycling instructions for this product. Residents outside the European Union must dispose of or recycle this product in accordance with local laws or regulations that apply.
 Type BF applied part	IEC 60601-1, Table D.1, Symbol 20	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	Type BF Applied Part	Identifies a type BF applied part complying with IEC 60601-1-11.
	ISO 7000-5333	Graphical symbols for use on equipment		

Symbol	Standard/Law Reference	Standard/Law Title	Symbol Title/ Text Reference	Explanatory Text
	IEC 60601-1, Table D.1, Symbol 19	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	Type B Applied Part	Identifies a type B applied part complying with IEC 60601-1.
	ISO 7000-5840	Graphical symbols for use on equipment		
IPN$_1$N$_2$	IEC 60601-1, Table D.3, Symbol 2	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	Degrees of Ingress Protection Provided by Enclosure	Manufacturer-determined degree of particle and water ingress where N1= degree of protection from particles (scale of 0-6) and N2=degree of protection from water (scale of 0-8).
	IEC 60529	Degrees of protection provided by enclosures (IP Code)		NOTE: When a characteristic numeral is not required to be specified, it is replaced by the letter ÒXÓ.
IP28	IEC 60529	Degrees of protection provided by enclosures (IP Code)	Degrees of Ingress Protection Provided by Enclosure	Protected against solid foreign objects of 12.5mm and greater, and against the effects of continuous immersion in water.
IP48	IEC 60529	Degrees of protection provided by enclosures (IP Code)	Degrees of Ingress Protection Provided by Enclosure	Protected against solid foreign objects of 1.0mm and greater, and against the effects of continuous immersion in water.
IPX8	IEC 60529	Degrees of protection provided by enclosures (IP Code)	Degrees of Ingress Protection Provided by Enclosure	Protected against the effects of continuous immersion in water.
IPX7	IEC 60529	Degrees of protection provided by enclosures (IP Code)	Degrees of Ingress Protection Provided by Enclosure	Protected against the effects of temporary immersion in water.
IP22	IEC 60530	Degrees of protection provided by enclosures (IP Code)	Degrees of Ingress Protection Provided by Enclosure	Protection against the effects of insertion of fingers and will not be damaged or become unsafe when exposed to vertically or nearly vertical dripping water.

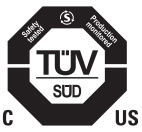
Symbol	Standard/Law Reference	Standard/Law Title	Symbol Title/ Text Reference	Explanatory Text
Rx ONLY For prescription use only	21 CFR Part 801.1(c)(1)(i)F	Labeling - Medical devices; prominence of required label statements	Prescription Use Only	Requires prescription for sale in the United States and is used in place of the statement below: **CAUTION**: Federal law restricts this device to sale by or on the order of a physician, dentist or licensed practitioner.
	21 CFR Part 801.109	Labeling - Prescription devices		
CE	Directive 93/42/ EEC Articles 4, 11, 12, 17 Annex 12	Council Directive 93/42/EEC of 14 June 1993 concerning medical devices	The requirements for accreditation and market surveillance relating to the marketing of products; Medical Device Directive.	Signifies European technical conformity.
	Directive 93/68/ EEC	CE Marking		
	IEC 60417-5172 Section 7.2.6	Class II equipment	Marking Requirements for Class II Equipment	Power adaptor meets the safety requirements specified for Class II equipment according to IEC 61140.
	ISO 7000-2616	External cord connected	External Cord Connected	Indicates that device is connected to an external power source.
	ISO 7000-5008	OFF (power)	OFF (Power)	To indicate disconnection from power.
	ISO 7000-5007	ON (power)	ON (Power)	To indicate connection to power.

Symbol	Standard/Law Reference	Standard/Law Title	Symbol Title/ Text Reference	Explanatory Text
	ISO 7000-5417	Programmable duration	Programmable Duration	To identify the control of a programmable timer to start an operation at a specific point in time and to stop the operation at a specific point in time or after a specific duration; or to identify a display of the programmed or to-be-programmed duration.
	ISO 7000-5546	Battery check	Battery Check	To identify the battery condition indicator.
 This way up	ISO 7000-0623	This way up	This Way Up	To indicate correct upright position of the transport package.

Symbols Not Recognized by Standard or Law

Symbol	Guidance	Guidance	Symbol Title	Explanatory Text
	INDA and EDANA Flushability Guidelines	INDA and EDANA Flushability Guidelines	Do Not Flush	Do not flush in toilet.
				This container can and should be recycled.
 Powder-free			Powder Free	Gloves are powder free.
			Synthetic	Indicates medical device contains synthetic latex.

Symbol	Guidance	Guidance	Symbol Title	Explanatory Text
				This glove has been tested for resistance to permeation of various chemotherapy drugs per ASTM D6978, "Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs."
				This glove has been tested for permeation of various chemicals per ASTM F739, "Standard Test Method for Permeation of Liquids and Gases through Protective Clothing Materials under Conditions of Continuous Contact."
 1 Pair of Gloves			1 Pair of Gloves	Contains a pair of gloves.
			Russian Registration Mark	Signifies technical conformity in Russia.
			Open Arrow	Open at arrow.
			Peel Here	Peel here to open package.
 Pouch Opening			Pouch Opening	Directions on how to open pouch.
 1 Single Glove			1 Single Glove	Contains a single glove.

Symbol	Guidance	Guidance	Symbol Title	Explanatory Text
			TUV Listed	Product is certified under TUV's Listing and Classification services and for TUV certifications for Canada and the USA.
			Device Plugged into an Outlet	Indicates that device is connected to an external power source.
 Battery charging			Battery Charging	Device is plugged into an outlet and the internal battery is charging.

6. Specifications

Cardinal Health SVED®

Dimensions ..... (7.6 x 2.8 x 7.1 in.)
Weight ..... 0.9kg (2.0 lb.)
Therapy Settings ..... -70, -120, -150mmHg

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 BF Applied Part
- Class II Internally Powered Equipment
- IP22 - ***Drip proof from rain falling at 15-degree angle***

Battery

Duration (Fully Charged) ..... up to 10.5 hours

Electrical

External Power Supply Input ..... 100-240VAC, 50-60Hz, 0.8Amp Max
External Power Supply Output 15VDC, 2Amp

SVED® Storage Conditions

Temperature Range ..... -12°C (10°F) to 43°C (110°F)
Relative Humidity Range ..... 20% to 95% RH
Atmospheric Pressure Range ..... 50kPa to 110kPa
Time to Warm from -12°C to 20°C Before Use ..... 120 minutes
Time to Cool from 43°C to 20°C Before Use ..... 120 minutes

SVED® Operating Conditions

Temperature Range ..... 4°C (40°F) to 32°C (90°F)
Relative Humidity Range ..... 20% to 75% RH
Atmospheric Pressure Range ..... 50kPa to 110kPa
Service Life ..... 3 years

Dressing Sets and Accessories

Expiration Date ..... 3 years from date of manufacture

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

6.1 Electromagnetic Compatibility

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
Emissions Test	**Compliance**	**Electromagnetic Environment**
Harmonic emissions IEC 6100-3-2	Class A	The SVED® 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	The SVED® is not suitable for interconnection with other equipment.
RF emissions CISPR 14-1	Complies	

Recommended separation distance between portable and mobile RF communications equipment and the SVED®

The SVED® is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the SVED® can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the SVED® 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)**		
	150kHz to 80MHz	**80MHz to 800MHz**	**800MHz 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	±6kV contact ±8kV air	±6kV contact ±8kV air	Floor should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 percent.
Electrical fast transient/burst	±2kV for power supply lines ±1kV for input/output	±2kV for power supply lines ±1kV for input/output	Mains power quality should be that of a typical commercial and/or hospital environment.
Surge IEC 61000-4-5	±1kV line to line ±2kV line to earth	±1kV line to line ±2kV 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 (50/60Hz) magnetic field IEC 61000-4-8	3A/m	3A/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.			
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3V rms 150kHz ~ 80MHz 3V/m 800MHz ~ 2.5GHz	3V rms 3V/m	Portable and mobile RF communications equipment should be used no closer to any part of the SVED® including cables, than the recommended separation distance calculated from the equation appropriate to the frequency of the transmitter. **Recommend separation distance** $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80MHz to 800MHz $d = 2.3\sqrt{P}$ 800MHz to 2.5GHz 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 80MHz and 800MHz, 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 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 SVED® is used exceeds the applicable RF compliance level above, the SVED® should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the SVED®. [b] Over the frequency range 150kHz to 80MHz, field strengths should be less than 3V/m.			

7. Questions & Information

For questions or additional information on the Cardinal Health™ SVED®, please contact your local Cardinal Health representative, or:

Call Customer Service at 1.866.484.6798

Cardinal Health
Waukegan, IL 60085
www.cardinalhealth.com

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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