REF 68-1132

CardinalHealth™

Negative Pressure Wound Therapy

CATALYST™

Patient User Manual

About Your Cardinal Health™ CATALYST™

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

Things you need to know about your CATALYST™

- Do not allow the CATALYST™ to get wet. Clamp the tubing (if clamp is present) and disconnect from the canister if you take a bath or shower.
- Keep the CATALYST™ 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 CATALYST™ upright to avoid a false Canister Full/Blockage alert.
- Keep the CATALYST™ 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 CATALYST™ 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 CATALYST™ 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 CATALYST™.
- Who to call if you need help.
- How to take care of your CATALYST™.

This CATALYST™ 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 CATALYST™ to provide safe, reliable and proper performance, the following conditions must be met. Failure to comply with these conditions voids all pertinent warranties.

- All assembly, operation, adjustment, modification, maintenance and/or repair must be carried out only by qualified personnel authorized by Cardinal Health.
- The electrical outlets of the room in which the CATALYST™ is used complies with the appropriate national electrical standards.
- The CATALYST™ must be used in accordance with this Patient User Manual and all associated labeling.

CAUTION: Federal law restricts the CATALYST™ for 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 lay caregivers (lay responsible organizations): Be sure to include all of the warnings below when providing training to lay operators, especially in a home care environment. Lay users and caregivers should contact Customer Support if there is a change in the performance of the CATALYST™. Additionally, lay users and caregivers 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: The CATALYST™ 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 CATALYST™ 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 Occlusion Detection Dressing or Kendall™ NPWT Incision Management 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 CATALYST™ only as described in this User Manual. Do not interconnect the CATALYST™ with other devices not included in this user manual. Failure to comply could result in improper therapy and could result in damage to the CATALYST™.

CAUTION: This system is not intended to be used in MRI environments or in the presence of strong magnetic fields. Do not use the CATALYST™ 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 CATALYST™ system can be used outdoors for short periods of time (not more than 24 hours). Shelter from the rain.

Table of Contents

1. Introduction

1.1 Indications

The CATALYST™ 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 CATALYST™ may promote wound healing by the removal of fluids, including wound exudates, irrigation fluids, body fluids and infectious materials.

When used with the Cardinal Health™ Occlusion Detection Dressing, the CATALYST™ NPWT system is intended for patients with chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic or pressure), flaps and grafts. The CATALYST™ NPWT system is intended for use in acute, extended and home care settings.

The Kendall™ NPWT Incision Management Dressing Kit, when used with Cardinal Health™ NPWT CATALYST™, is intended to manage the environment of surgical incisions that continue to drain following sutured or stapled closure by maintaining a closed environment and removing exudate via the application of negative pressure wound therapy. The Cardinal Health™ NPWT CATALYST™ System is intended for use in acute, extended and home care settings.

1.2 Contraindications

The CATALYST™ 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 Occlusion Detection Dressing or Kendall™ NPWT Incision Management Dressing over exposed blood vessels or organs. The Cardinal Health™ NPWT Occlusion Detection Dressings and Kendall™ NPWT Incision Management 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 infected wounds, active bleeding, difficult wound hemostasis or if you are taking anticoagulants.

- **Defibrillation:** The NPWT Occlusion Detection Dressing or NPWT Incision Management Dressing 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 CATALYST™ is not MRI-compatible and cannot be used in the presence of strong magnetic fields. Do not take the CATALYST™ into the MRI area or any area of high magnetic fields. The CATALYST™ contains metal components that could cause unintended movement resulting in harm due to falling objects or collisions.
- **Hyperbaric Oxygen Therapy (HBO):** Do not take CATALYST™ — whether on or off — into a hyperbaric chamber. The CATALYST™ must be disconnected before HBO treatment.
- During negative pressure wound therapy, CATALYST™ and NPWT Occlusion Detection Dressing or NPWT Incision Management Dressing are a closed system and are NOT vented to atmosphere.
- During negative pressure wound therapy, when the canister fills with fluid, it should be replaced immediately. Fluids are not removed from the dressing once the canister is full.

1.4 Safety Tips

Keep Therapy On

The CATALYST™ should be operated at least 22 hours out of every 24-hour period.

Contact your healthcare professional if negative pressure wound therapy stops or if the CATALYST™ is off for more than 2 hours in a 24-hour period. Your dressing must be changed by your healthcare professional.

Troubleshooting

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

Monitoring the Wound

Inspect the dressing frequently to ensure that the foam is collapsed and that negative pressure wound therapy is being delivered in a consistent manner. Monitor your wound and the canister and tubing for signs of active bleeding. Monitor around your wound 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 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, refractory hypotension, orthostatic 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 CATALYST™, 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 CATALYST™ until the serious infection is diagnosed and properly treated by your healthcare professional.

NPWT Occlusion Detection Dressing or Kendall™ NPWT Incision Management 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 Dressing Kits are sterile. The decision to use clean versus sterile/aseptic technique is dependent upon your healthcare professional's preference. All components of the CATALYST™, the Dressing Kits, the canisters and other accessories are made without natural rubber latex.

NOTE: Lint, dust and light (including sunlight) has no effect on the performance of the system. Keep away from pets or children.

Be sure to comply with all **1.2 Contraindications** and **1.3 Precautions** for the CATALYST™.

2. Introduction to the CATALYST™

2.1 Getting to Know the CATALYST™

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

NOTE: The CATALYST™ is quiet during normal operation with a well-sealed dressing.

Figure 1

NPWT Incision Management Dressing

The Kendall™ Negative Pressure Wound Therapy Incision Management Dressing Kit is a wound dressing kit to be used with Cardinal Health™ Negative Pressure Wound Therapy (NPWT) CATALYST™, ALLY™ and ALLY TO GO™ systems (K171499). The disposable single-use sterile Kendall™ NPWT Incision Management Dressing Kit consists of five dressing configurations, tubing and drape strips. The dressing covers the closed surgical site and forms a seal over the sutured or stapled surgical site. The proximal end of the tubing is attached to the dressing while the distal end of the tubing attaches to an exudate canister. The powered suction pump delivers negative pressure to the dressing to aid in the removal of exudate from the wound into the exudate canister. The drape strips are used to patch any air leaks if necessary.

2.2 Charging the Battery

The CATALYST™ 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 sounds to let you know you must plug in the CATALYST™ to charge the battery. See **3.2 Troubleshooting**.

1. Plug the A.C. Power Adapter into a wall outlet.
2. Insert the A.C. Power Adapter into the Battery Charging Port on the left side of the CATALYST™ (**Figure 2**).

Figure 2

3. When the CATALYST™ is connected to an outlet, the green light next to the Plugged In symbol comes on (**Figure 3**). 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.

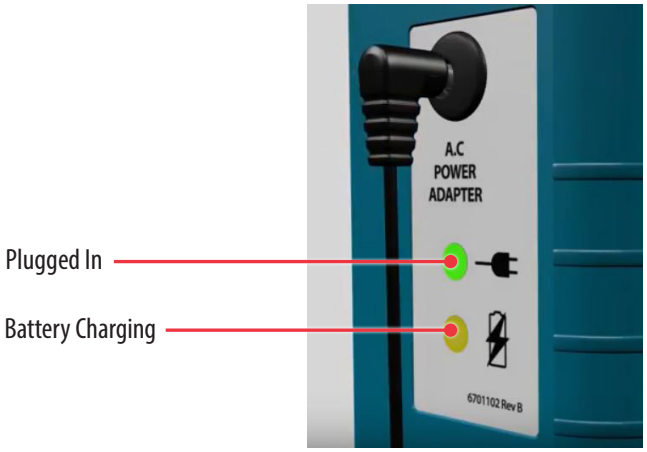


Figure 3

NOTE: If the CATALYST™ is plugged in and green light does not turn on, check to make sure outlet is working properly.

4. The CATALYST™ continues to work when charging.

CAUTION: The CATALYST™ must only be used with the supplied A.C. Power Adapter. Use of any other A.C. Power Adapter or charger could create a shock hazard, cause fire or severely damage the CATALYST™.

Average Battery Life

The battery life of the CATALYST™ 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 CATALYST™ should be connected to an outlet via the A.C. Power Adapter 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 (**3.2 Troubleshooting**). Typically, the CATALYST™ continues to operate for approximately 30 minutes after the Low Battery alert sounds.

If the battery charge gets too low, the CATALYST™ shuts off and the negative pressure wound therapy is stopped. At this point, the CATALYST™ 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 CATALYST™.

2.3 Changing the Canister

When the CATALYST™ detects that the canister needs to be changed, a Canister Full/Blockage alert sounds. The CATALYST™ continues to work until the canister completely fills. When the canister is completely full, the CATALYST™ turns off.

To change the canister:

1. Clamp the tubing closed (**Figure 4**).
   NOTE: Only applicable if clamp is present. If clamp is not present, skip to the next step.

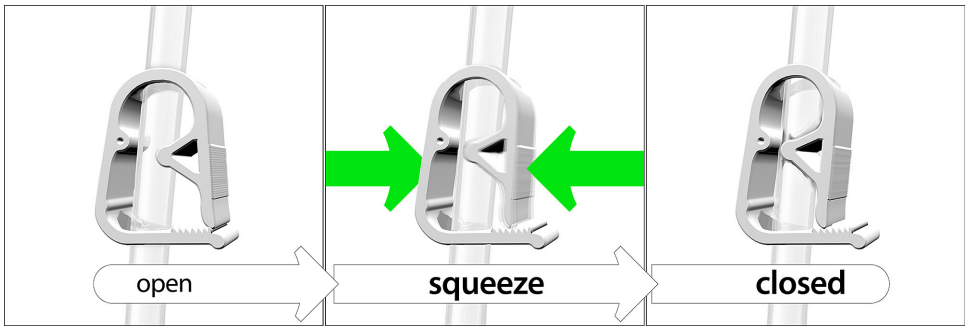


Figure 4

2. Turn the CATALYST™ off by pressing the OFF Button.
3. Grasp the blue Twist N' Connect™ end of the tubing attached to the canister. Gently twist counterclockwise and pull up to remove tubing from canister (**Figure 5**).

Figure 5

4. To remove the canister, press the Canister Release Button located above the canister (**Figure 6**), grasp the canister at the bottom and gently pull downward.

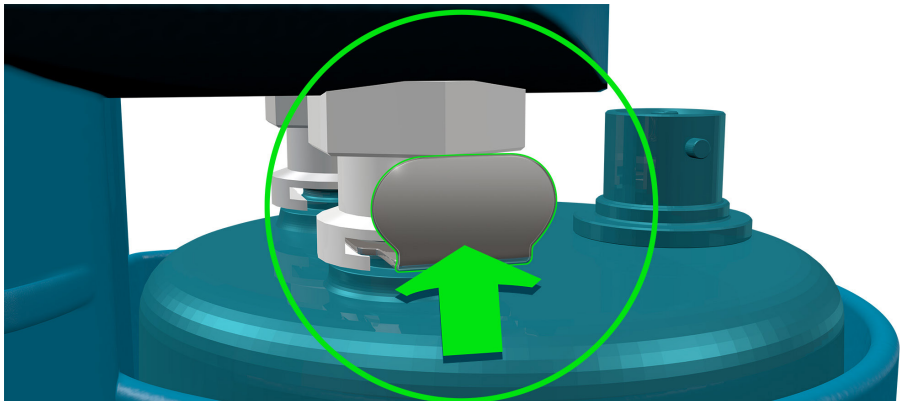


Figure 6

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 ports and press upwards until it "clicks" into place (**Figure 7**).

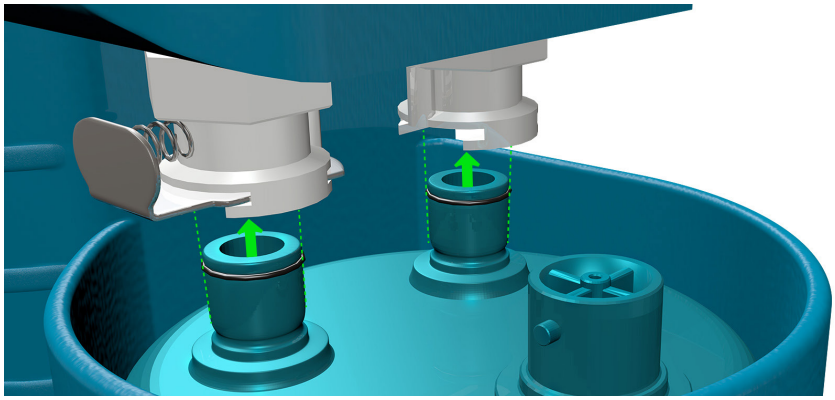


Figure 7

8. Gently line up the blue Twist N' Connect™ end of the tubing to the blue Twist N' Connect™ port on the canister, push down and twist clockwise to lock into place (**Figure 8**).

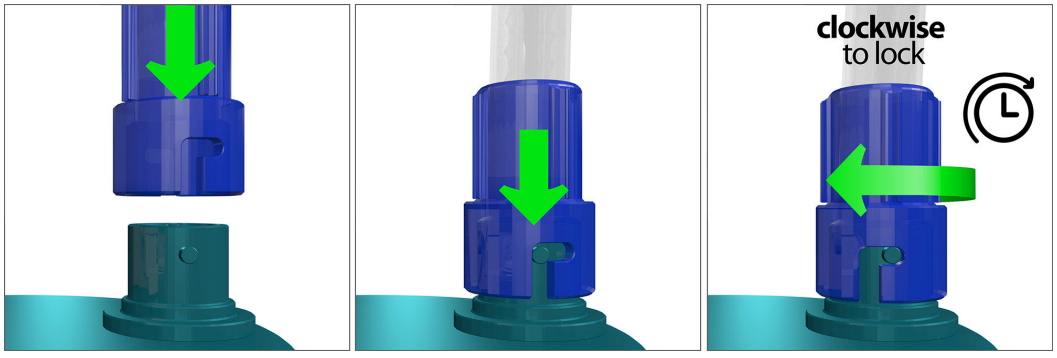


Figure 8

9. Reopen the tubing clamp by pushing down on the top of the clamp until it releases (**Figure 9**).
   NOTE: Only applicable if clamp is present. If clamp is not present, skip to the next step.

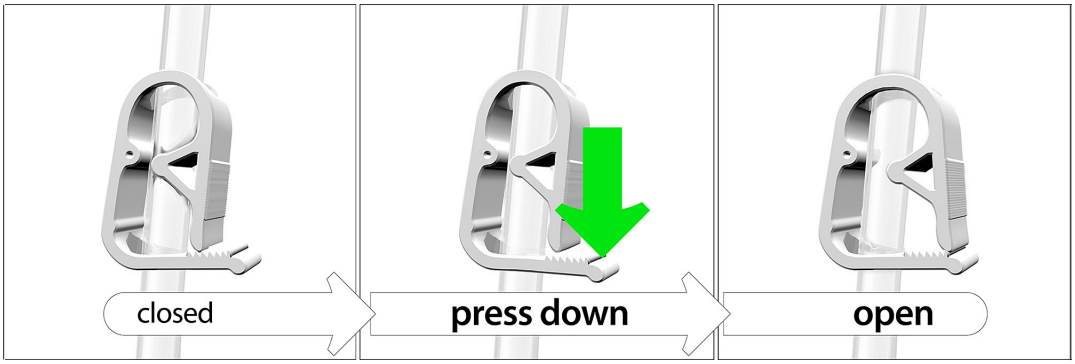


Figure 9

10. Turn the CATALYST™ on by pressing the ON Button to resume negative pressure wound therapy.

2.4 Disconnecting from the CATALYST™

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

NOTE: The CATALYST™ should be operated at least 22 hours out of every 24-hour period.

Contact your healthcare professional immediately if negative pressure wound therapy has stopped or is off for more than 2 hours in a 24-hour period. Your dressing may need to be changed.

To disconnect from the CATALYST™:

1. Clamp the tubing closed (**Figure 4**).
   NOTE: Only applicable if clamp is present. If clamp is not present, skip to the next step.
2. Turn the CATALYST™ off by pressing the OFF Button.
3. Grasp the blue Twist N' Connect™ end of the tubing attached to the canister. Gently twist counterclockwise and pull up to remove tubing from canister (**Figure 5**).
4. If canister is full, change the canister (**2.3 Changing the Canister**).

To reconnect to the CATALYST™:

1. Gently line up the blue Twist N' Connect™ end of the tubing to the blue Twist N' Connect™ port on the canister, push down and twist clockwise to lock into place (**Figure 8**).
2. Reopen the tubing clamp by pushing down on the top of the clamp until it releases (**Figure 9**).
   NOTE: Only applicable if clamp is present. If clamp is not present, skip to the next step.
3. Turn the CATALYST™ on by pressing the ON Button to resume negative pressure wound therapy.

3. Operating Instructions

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

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

3.1 ON/OFF

The ON and OFF Buttons are located on the front of the CATALYST™ (**Figure 10**).

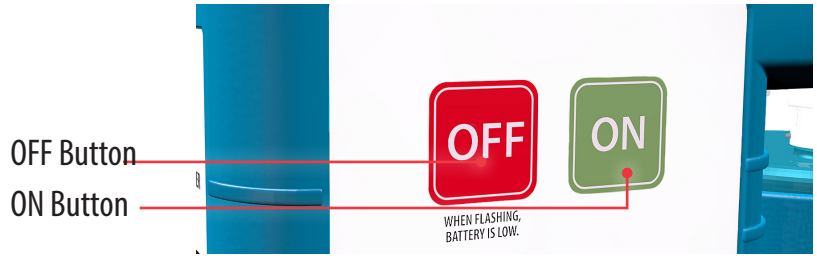


Figure 10

1. Press the ON Button. All lights show for 1 second during the power-on self-test. When finished, the ON Button stays green (**Figure 11**).

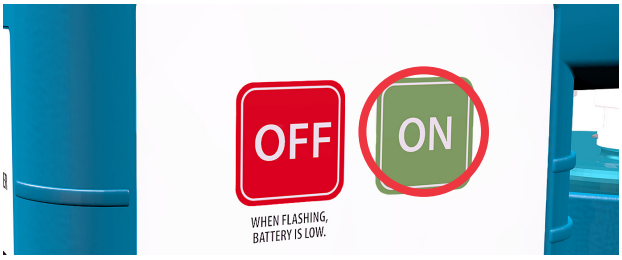


Figure 11

2. The dressing should collapse, indicating the presence of negative pressure. If there is a Low Pressure/Leak alert, there may be a problem (**3.2 Troubleshooting**).
3. The CATALYST™ should be operated at least 22 hours out of every 24-hour period. Contact your healthcare professional if the CATALYST™ 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.

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

3.2 Troubleshooting

Clearing an Alert

To clear an alert, use the **Troubleshooting** table below.

To manually reset an alert, turn the CATALYST™ OFF then back ON. The alert will clear when the power is cycled.

1. Low Pressure/Leak

WHAT YOU SEE/HEAR

Low Pressure/ Leak — *BLINK* + *BEEP* + *BLINK*

WHAT TO DO

1 **Push up on bottom of canister.**

Wait 30 seconds

2 **If you see:**

SOLID LIGHT

Low Pressure/Leak is fixed.

If you see/hear:

BLINK + *BEEP* + *BLINK*

! Call Cardinal Health at 1.866.484.6798

2. Canister Full/Blockage - With Clamp on Tubing

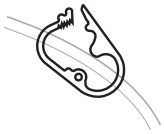
WHAT YOU SEE/HEAR

Canister Full/ Blockage — *BLINK* + *BEEP* + *BLINK*

WHAT TO DO

First, look at the canister to see if it is full. If the canister is full, change the canister . If the canister is not full, proceed with the steps below.

1 Make sure clamp is OPEN.



Wait 30 seconds

2 If alert continues, go to step 3.

3 Look for kinks in tubing. Unkink if found.

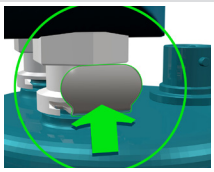
Wait 30 seconds

4 If alert stays on, go to step 5.

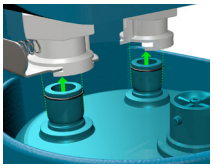
5 Turn OFF.

OFF

6 Clamp tubing and remove canister.



7 Replace with new canister, reattach tubing and open clamp .



8 Turn ON.

ON

Wait 1 minute

9 If you see:

SOLID LIGHT

Canister Full/Blockage is fixed.

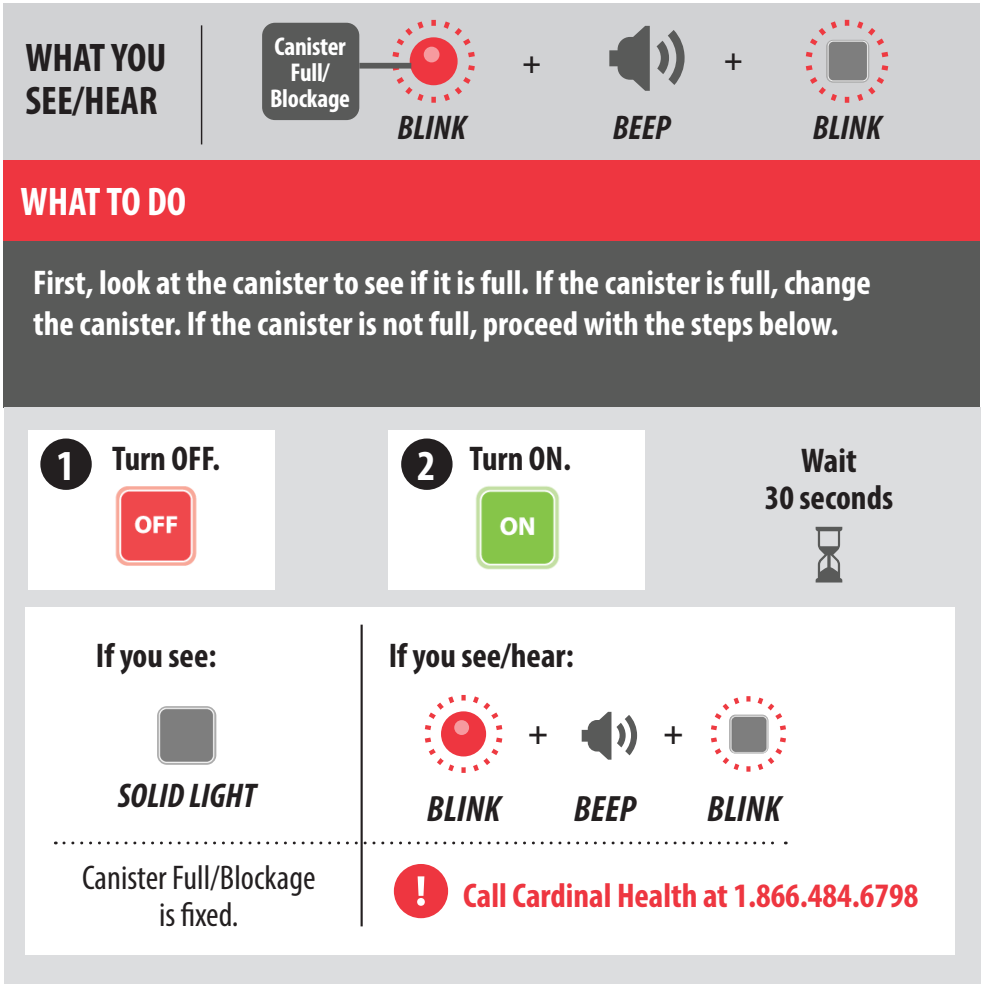
If you see/hear:

BLINK + *BEEP* + *BLINK*

! **Call Cardinal Health at 1.866.484.6798**

NOTE: A false Canister Full/Blockage alert can occur if drainage moves into the canister while the CATALYST™ is lying on its front (the button side) or if it is turned upside down. If this occurs, you must change the canister to resume device operation. Always keep the CATALYST™ upright.

3. Canister Full/Blockage - Without Clamp



NOTE: A false Canister Full/Blockage alert can occur if drainage moves into the canister while the CATALYST™ is lying on its front (the button side) or if it is turned upside down. If this occurs, you must change the canister to resume device operation. Always keep the CATALYST™ upright.

4. Battery Low

WHAT YOU SEE/HEAR		
	OFF BLINK +	CHIRP

WHAT TO DO

1 Plug A.C. Power Adapter into outlet.

Wait 30 seconds

2 If you see:

SOLID LIGHT

Low battery fixed.

If you see/hear:

OFF BLINK + CHIRP

! Call Cardinal Health at 1.866.484.6798

5. Intermittent Mode

WHAT YOU SEE/HEAR	
	BLINK

WHAT TO DO

CATALYST™ makes more noise every 5 minutes when in Intermittent Mode. No troubleshooting needed. For more information, contact your healthcare professional.

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

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

4. Care & Cleaning

Your healthcare professional will handle much of the care and cleaning needed for your CATALYST™. Periodically check to make sure the CATALYST™ is working properly and look for signs that fluid has entered into the CATALYST™.

If the CATALYST™ 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 CATALYST™ must only be used with the supplied A.C. Power Adapter. Use of another adapter/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, tubing and used canisters.

4.2. Care & Cleaning

Carefully read **1.3 Precautions** and **1.4 Safety Tips** before cleaning the CATALYST™ 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 CATALYST™ 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 CATALYST™. Check for any sign of contamination or fluid going into the canister ports. Ensure that the CATALYST™ is functioning properly. If the CATALYST™ 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 CATALYST™.

NOTE: Cleaning of the CATALYST™ must not be performed when the CATALYST™ is connected to a patient or power source. Disconnect the CATALYST™ 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 CATALYST™ 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 CATALYST™ and may void warranty.

Cleaning Frequency

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

Instructions for Cleaning CATALYST™ 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 CATALYST™ 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 CATALYST™ A.C. Power Adapter is not designed to be immersed, soaked, rinsed, or sprayed with water. Do not immerse, soak, rinse, or spray the CATALYST™ 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

CATALYST™ 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 CATALYST™ must not be performed when the CATALYST™ is connected to a patient or power source. Disconnect the CATALYST™ from the patient and power source before disinfecting.

Disinfection frequency

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

Instructions for Disinfecting CATALYST™ 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 CATALYST™ 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 CATALYST™ 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 CATALYST™.

CAUTION: Avoid spilling liquid on any part of the CATALYST™. Spilling liquid on the CATALYST™ may cause the CATALYST™ 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

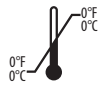
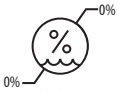
The A.C. Power Adapter should be inspected regularly for damage. If you notice any damage to the A.C. Power Adapter, call your healthcare professional for a replacement to avoid interruption of therapy.

CAUTION: The CATALYST™ must only be used with the supplied A.C. Power Adapter. Use of another adapter/power cord could result in physical hazards, including delayed therapy, electrocution and fire. These hazards could result in injury or death.

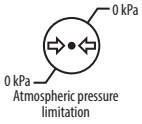
5. Symbols Glossary

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 Limitation	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		
	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 Limitation	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.
 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.

Symbol	Standard/Law Reference	Standard/Law Title	Symbol Title/ Text Reference	Explanatory Text
	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).
	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.
	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 or recycle this product in accordance with local laws or regulations that apply.
	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		
	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		

Symbol	Standard/Law Reference	Standard/Law Title	Symbol Title/ Text Reference	Explanatory Text
IPN1N2	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.
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		

Symbol	Standard/Law Reference	Standard/Law Title	Symbol Title/ Text Reference	Explanatory Text
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.
	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/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.
				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.

Symbol	Guidance	Guidance	Symbol Title	Explanatory Text
			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.
			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™ CATALYST™

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

IEC Classification

With respect to electric shock, fire, and mechanical hazards, conforms to IEC60601-1.

- 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

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

Environmental Conditions

CATALYST™ Storage Conditions

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

CATALYST™ 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 (IEC 60601-1-2)		
Emissions Test	**Compliance**	**Electromagnetic Environment**
Harmonic emissions IEC 61000-3-2	Class A	The CATALYST™ 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 CATALYST™ is not suitable for interconnection with other equipment.

Recommended separation distance between portable and mobile RF communications equipment and the CATALYST™.

The CATALYST™ is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the CATALYST™ can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the CATALYST™ 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 CATALYST™ 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 CATALYST™ is used exceeds the applicable RF compliance level above, the CATALYST™ should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the CATALYST™. [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™ CATALYST™, 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.

CardinalHealth™

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