



PlumeSafe[®] X5TM Smoke Management System

▼ QUICK REFERENCE GUIDE



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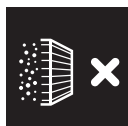
1. SYSTEM OVERVIEW

Figure 1. Explanation of Symbols

Touchscreen Display



Extended Evacuation
Time After Deactivation



Filter Empty



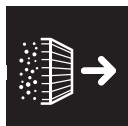
Decrease Suction /
Time Extension



Electrosurgical
Pencil Mode



Service Required



Filter Full



Active Continuous
Suction



Laparoscopic
Mode



Increase Suction /
Time Extension



Open Mode



Occlusion Detection

Front Panel and Sides



Power Button



Alignment Arrows for docking
and/or nesting the SEU and
future technology integration



Figure 2. PlumeSafe® X5™ Front Panel Overview

- A. CONMED PlumeSafe® X5™ Filter
- B. Accessory Connection with SafePort™ Technology
- C. Filter Handles to Remove Filter
- D. User Interface (UI)
- E. Power Button

1. SYSTEM OVERVIEW

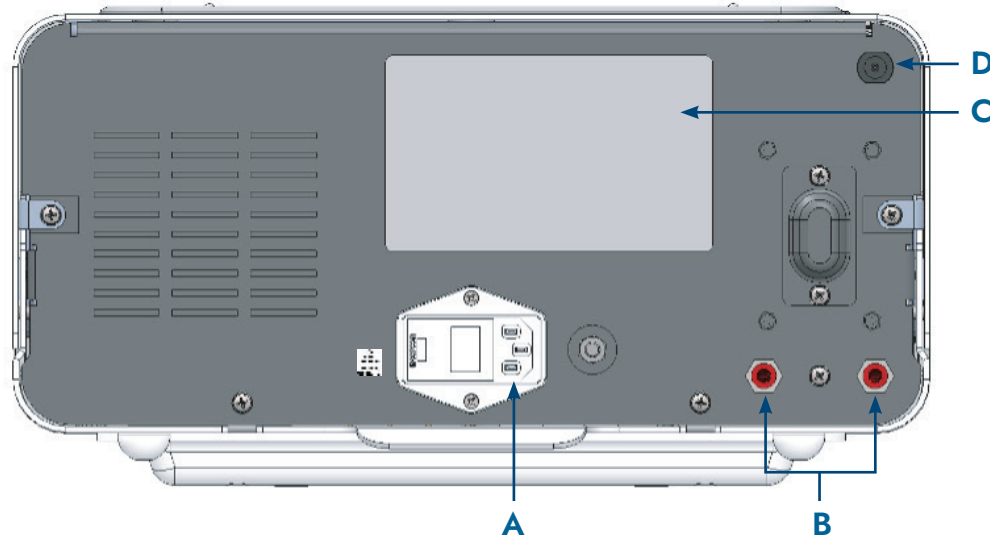


Figure 3. PlumeSafe® X5™ Rear Panel Overview

- A. Power Cord Receptacle
- B. Remote Switch Activation (RSA)
Device Ports
- C. Product Label
Specifies model number, serial number,
Unique Device Identification two-dimensional
barcode, nominal line voltages, frequency,
current, and CONMED contact information
- D. Footswitch

1. SYSTEM OVERVIEW

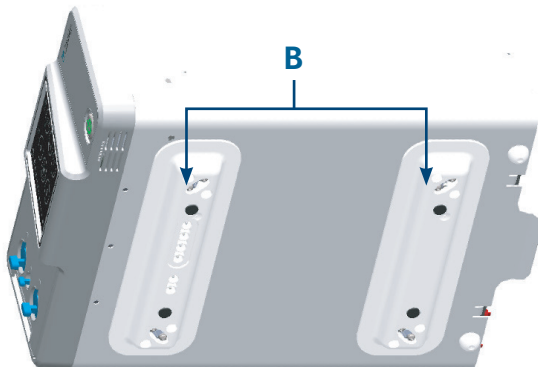
Figure 4. Top Panel



A. Docking Ports

These ports are designed for electrical docking between the PlumeSafe® X5™ and future technology integration. NOTE: All elements on these two ports are safe to touch and are not electrically active.

Figure 5. Bottom Panel



B. Docking Feet

These non-slip feet are designed to keep the unit body from sitting directly on a surface and from sliding around.

2. USER INTERFACE

The CONMED PlumeSafe® X5™ SEU features a fully integrated touchscreen display which allows selection of modes, changes to flow, extended evacuation time, and real time filter life monitoring. The SEU will store the most recent user settings.

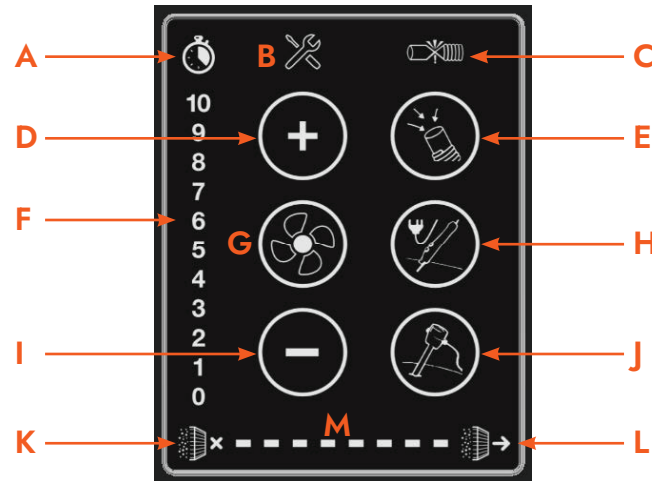


Figure 6. PlumeSafe® X5™ Front Panel Overview

- | | |
|---|------------------------------------|
| A. Time Extension After Deactivation | H. Electrosurgical Pencil Mode |
| B. Service Required | I. Suction/Time Extension Decrease |
| C. Occlusion Detection Mode | J. Laparoscopic Mode |
| D. Suction/Time Extension Increase | K. Filter Depleted Icon |
| E. Open Tubing Mode | L. Filter Full Icon |
| F. Flow Setting or Time Extension Setting | M. Filter Life Remaining |
| G. Continuous Use | |

3. SETUP FOR OPERATING ROOM USE

1. Plug the CONMED PlumeSafe® X5™ SEU into to a hospital grade power outlet.
2. Inspect and insert a CONMED PlumeSafe® X5™ Filter into the matching receptable of the PlumeSafe® X5™ SEU.
3. Inspect and insert the desired hand-held accessories in to the filter.
4. Turn on the smoke evacuator by pressing the ON button, which will illuminate green. (Image 1)
5. The smoke evacuator will conduct internal self-diagnostics during start up.
6. After the unit self-diagnostics are complete, the smoke evacuator will illuminate the screen and is ready for use.
7. Ensure filter life is adequate. (Image 2)
8. Connect appropriate accessory in the proper receptacle

NOTE: If the smoke evacuator illuminates the service light, or otherwise fails to respond during power-up, the generator has failed one of its internal tests. Power cycle the unit to see if it resolves the issue.



Image 1



Image 2

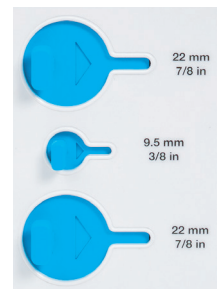


Image 3

3. SETUP FOR OPERATING ROOM USE

Mode Selection

The CONMED PlumeSafe® X5™ SEU touchscreen has three primary modes: Open, Electrosurgical Pencil, and Laparoscopic

1. Select the desired option for the specific procedure by touching the appropriate icon on the touchscreen. Only one mode may be active at a given time.
 - a. During a procedure in which smoke evacuation tubing will be utilized, please select the Open Tubing mode icon.
 - b. When using either an adapter to an electrosurgical pencil or an integrated smoke plume evacuation pencil such as CONMED's PlumePen™ product line, please select the Pencil mode icon.
 - c. When attaching to a surgical cannula during laparoscopic procedures, select the Laparoscopic mode icon.*
2. When the desired mode of operation is selected, the associated icon on the touch screen will illuminate.

Continuous Suction

Activation of continuous suction is achieved by pressing the Continuous Suction icon. If the continuous suction is activated, the Continuous Suction icon will brighten.

Strength of Suction

The strength of suction may be adjusted by pressing the plus and minus icons on the touch screen. The suction setting is shown by the numbers on the left side of the user.

* Laparoscopic mode may only be used with the PlumePort® SEO device. Failure to do so may result in a loss of pneumoperitoneum and may cause patient harm.

3. SETUP FOR OPERATING ROOM USE

5-Stage Filter Life

The filter life indicator on the touch screen control panel provides a visual indication of the status of the life of the filter ([Image 1](#)). As the filter is used, the filter life indicator will automatically adjust. Information about the amount of time each individual filter has been used is stored via the RFID tag of the filter. When a new or previously used filter is inserted, the smoke evacuator reads the stored information from the tag and updates the filter life indicator.

Laparoscopic Mode = 35 hours of filter life*

Electrosurgical/Diathermy (Pencil) Mode = 25 hours of filter life*

Open Tubing Mode = 18 hours of filter life*

When the maximum filter life is consumed, the filter expiration icon will flash, indicating that a filter replacement is needed. Replace the filter as indicated in this manual.

During operation, if a filter expires the system will not turn off suction; the unit will remain running until the system is powered down or one-hour passes, whichever comes first. After this point, the unit will no longer operate until a new filter is inserted into the system. It is always best practice to replace an expired filter immediately; however, a validated contingency life is built into the filter to ensure no interruption to the operative procedure.



Image 1

*Data on File.

3. SETUP FOR OPERATING ROOM USE

Filter Installation and Removal

1. Insert the CONMED PlumeSafe® X5™ Smoke Management Filter into filter receptacle. Be sure that the filter is seated completely against the bottom of the filter chamber.
2. After the CONMED PlumeSafe® X5™ Smoke Management Filter has been exhausted and requires changing, turn the smoke evacuation system off and disconnect any accessory tubing attached to the filter.
3. Grip the filter handles on each side and pull the CONMED PlumeSafe® X5™ Smoke Management Filter from the smoke evacuation system and dispose of in accordance with hospital policy.



3. SETUP FOR OPERATING ROOM USE

Extended Evacuation Time

The CONMED PlumeSafe® X5™ Smoke Management System also allows the user to increase or decrease the amount of time the CONMED PlumeSafe® X5™ Smoke Management System suction remains active after deactivation of the electrosurgical accessory. This evacuation extension is for the purpose of capturing residual smoke after the electrosurgical unit is deactivated. To adjust extension time, press the stopwatch icon (Image 1) in the top left corner of the user interface.

Extended Evacuation Time Adjustment

Upon pressing the stopwatch icon, select icons will illuminate green (Image 2). Depress the plus and minus icons to adjust the extended evacuation time from 0 to 10 seconds. The unit will return to normal operation after a few seconds. If the EZLink® Automatic Activation Device is used, additional suction time is programmed into that device. By default, the EZLink® is programmed with 3 seconds of extended suction time. The time extension on the smoke evacuator will be added to the time programmed into the EZLink®. If the EZLink® is programmed to 3 seconds of extension time, and the CONMED PlumeSafe® X5™ Smoke Management System extension time is set to 8, the actual total time the user experiences will be 11 seconds.



Image 1

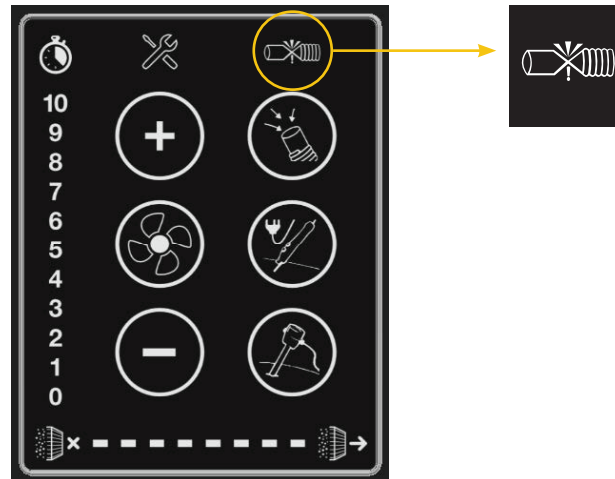


Image 2

3. SETUP FOR OPERATING ROOM USE

Occlusion Detection

The CONMED PlumeSafe® X5™ Smoke Management System is equipped with occlusion detection for use in Open Tubing mode. The default setup for the device has this option disabled. If the user preference is to utilize occlusion detection, select the Occlusion icon on the top right corner of the user interface. When activated, this icon will illuminate, and the smoke evacuator will actively monitor for occlusions. When an occlusion is detected, the occlusion icon will flash red and the motor will cycle on and off, monitoring to see if the obstruction has been cleared. If the obstruction is cleared, the motor will stop cycling, the occlusion icon will stop flashing, and the system will resume normal operation with occlusion detection still active. The user has the option of disabling detection at any time by pressing the occlusion icon.



4. SHUTDOWN PROCEDURE

At the end of use, turn off the unit and disconnect all accessories from the filter.

6. TROUBLESHOOTING SOLUTIONS

Noise

The higher the suction setting, the greater the noise. Minimize noise by using a lower suction setting. Effectiveness of a lower suction setting can be maximized by using a larger diameter tubing or positioning the tubing closer to the source of smoke, or both. Making sure all ports on the filter, other than the active one, are fully closed.

Suction

- Use of accessories with long tubing or tangled tubing with sharp bends will reduce flow.
- Unresolved occlusions will reduce flow.
- Use of a fluid trap will reduce flow.
- Use of the unit at higher altitudes will reduce flow.

Overheating

While every effort has been made to prevent overheating, it may still be possible with the right combination of events. Each unit/motor has a built-in thermal switch that protects the motor and unit from damage should the internal temperatures rise too high. When those temperatures are reached, the thermal switch disconnects power to the motor. If this happens, turn off the unit, remove the filter, and wait one hour for the thermal switch to reset. The outside of the unit may feel cool, but the internal motor temperature may still be high. In practice, if the motor turns off unexpectedly during use and cannot be activated by the touch screen or by an accessory, and everything on the touch screen still operates as normal, it is highly likely the unit has overheated. Items that can lead to overheating include:

- Running the unit continuously at maximum speed for an extended period
- Elevated mains voltage
- Unresolved occlusions
- Blocked or restricted exhaust
- Warm air environments



This Quick Reference Guide is not intended to replace the Instructions For Use (IFU) of the products mentioned in this guide. Please read all safety information provided in the CONMED PlumeSafe® X5™ Operator's Manual before using these products.

To access the digital library of CONMED IFUs, please refer to <http://eifu.conmed.com> or ask your local representative.