
THORAGUARD

SURGICAL DRAINAGE SYSTEM



OPERATOR'S MANUAL

Introduction

NOTE: Refer to Drainage Kit and Chest Tube Kit for additional information regarding disposable kits.



Please read carefully.

This manual covers the function and proper use of the Thoraguard Surgical Drainage System. The Thoraguard System refers to the combined use of the Thoraguard Control Module, Thoraguard Drainage Kit, and optionally the Thoraguard Chest Tube Kit. **NOTE: These kits have their own accompanying package inserts and labels.** All instructions and labels must be referenced for proper usage of the Thoraguard System. Refer to the separate instructions and labels for additional warnings, precautions, and contraindications.














Do not use or operate the Thoraguard System until you have read and understood this manual and the separate instructions included with the disposable kits.

CAUTION: The Thoraguard System is only intended for use by or on the order of a physician.

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Symbols Glossary

Symbol	Description
	Power on / off Press this button to turn the Control Module on and off.
	General warning sign Follow on-screen instructions and / or consult operator's manual.
	Catalogue number Indicates the model number of the kit or the Control Module.
	Serial number Indicates the serial number of the Thoraguard Control Module.
	Date of manufacture Indicates the date the Control Module was manufactured.
	Positive polarity Indicates that the center (tip) of the output plug is positive (+) and the barrel (ring) of the output plug is negative (-).
	Do not dispose Indicates this product contains materials which, if disposed with general waste, could be damaging to the environment. Return unit to manufacturer for disposal.
	Lithium-ion battery inside Indicates not to dispose of lithium-ion battery. Return unit to manufacturer for disposal.
	Refer to instruction manual / booklet Indicates a requirement to read and understand the Operator's Manual and other accompanying instructions before use of the device.
	MR unsafe Indicates the device is known to pose hazards in all MRI environments.
	Defibrillation-proof type CF applied part Indicates the device complies with the highest degree of protection against electrical shock and is defibrillation-proof.
IP22	Protection against solid particles and ingress of liquid Indicates device is protected against ingress of solid foreign objects ≥ 12.5 mm diameter and against vertically falling water drops when equipment is tilted up to 15°.
Rx Only	Prescription-use only Indicates that federal law restricts this device to sale by or on the order of a physician.
	Manufacturer Indicates the manufacturer of the device.
	Expiration date Indicates the use-by date.






	<p>Batch code Indicates lot number of the Thoraguard Drainage and Chest Tube Kits.</p>
	<p>Sterilized using ethylene oxide Indicates the kit was sterilized using ethylene oxide.</p>
	<p>Do not use if package is damaged Indicates that the device must not be used if the package is damaged.</p>
	<p>Do not re-use Indicates that the Thoraguard Drainage and Chest Tube Kits are for single use.</p>
	<p>Do not re-sterilize Indicates that the Thoraguard Drainage and Chest Tube Kits cannot be re-sterilized.</p>

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Background

Scope of Operator's Manual

This manual covers the function and proper use of the Thoraguard Surgical Drainage System. The Thoraguard System refers to the combined use of the Thoraguard Control Module, Thoraguard Drainage Kit, and optionally the Thoraguard Chest Tube Kit. **NOTE: These kits have their own accompanying instructions for use, which are found inside the kit packages.** All IFUs must be referenced for proper usage of the Thoraguard System. Refer to the separate IFUs for additional warnings, precautions, and contraindications.

Definitions

Thoraguard System	Complete system for providing post-operative surgical drainage, including suction management, chest tube and drainage tubing clearance, and measurement of drainage volume and air leak. Includes the Thoraguard Control Module, Thoraguard Drainage Kit, and optionally the Thoraguard Chest Tube Kit.
Thoraguard Control Module	Reusable electronic monitor that provides the core functionality of the Thoraguard System. Includes integrated pump and sensors for suction management and output measurements.
Thoraguard Drainage Kit [STERILE EO]	Disposable kit for draining and collecting fluid output from patient. Includes drainage canister and drainage tubing.
Thoraguard Drainage Canister	Disposable canister with 1200 ml capacity for fluid collection.
Thoraguard Drainage Tubing	Disposable tubing that connects drainage canister to chest tube.
Thoraguard Chest Tube Kit [STERILE EO]	Disposable kit that includes chest tube for insertion into patient and SmartValve for automated clog clearance.
Thoraguard Chest Tube	Disposable dual-lumen drainage catheter with one lumen for drainage and one for venting during clog clearance. The catheter (applied part) comes into physical contact with the patient and must be used with the SmartValve, Drainage Kit, and Control Module to perform its function.
Thoraguard SmartValve	Disposable valve that provides automated clearance of clogs from chest tube when used with the rest of the Thoraguard System.

Overview

Intended Use

The Thoraguard System is intended to be used for aspiration and removal of surgical fluids, tissue, gases, bodily fluids or infectious materials. The Thoraguard System is indicated for all situations where chest drains are applied – especially for thoracic drainage in the pleural and mediastinal cavity in situations such as pneumothorax, after cardiac or thoracic surgery (post-operative), thorax injury, pleural effusion, pleural empyema or other related conditions. The Thoraguard System is intended for use on patients in appropriate care settings.

Warnings

WARNING: The Thoraguard System should only be used by licensed medical professionals who have been trained on proper use of the device and read this Operator's Manual along with kit-specific instructions for use.

WARNING: Do not attempt to open, repair, or modify the unit or replace broken parts. Attempting to do so could result in bodily injury or harm. If the unit or any parts are not working, please contact Centese Customer Service at 402-300-3150 or customerservice@centese.com. Repairs should only be made by Centese-trained personnel. The Thoraguard System has no serviceable parts.

WARNING: Keep the Control Module away from water and other liquids. Do not immerse or submerge the Control Module in water or other liquids.

WARNING: To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

WARNING: A hazard may exist if different alarm presets are used for the same or similar equipment in any single clinical area (e.g. in the intensive care unit (ICU) or a cardiac operating theatre).

WARNING: Do not connect the USB cord to the Control Module during use. The USB port should only be used by Centese-trained personnel when the Control Module is not in use.

WARNING: Do not steam autoclave, EO sterilize, immerse the Control Module, or allow liquids to enter the housing. Do not spray liquids directly into the Control Module, especially into any connector.

WARNING: The Thoraguard Control Module and SmartValve are MR unsafe. Do not take the Control Module or SmartValve into an MRI unit.

WARNING: Use the cables and accessories provided with the Thoraguard System to provide protection against the effect of the discharge of a cardiac defibrillator.

WARNING: Do not use blood collected into the Thoraguard Drainage Canister for autotransfusion.

Precautions

[!] The Thoraguard Control Module requires special precautions regarding electromagnetic compatibility. The use of accessories, transducers and cables other than those specified, except for transducers and cables sold by Centese as replacement parts for internal components, may result in increased emissions or decreased immunity of the Thoraguard Control Module or the Thoraguard System.

[!] The Thoraguard Control Module or the Thoraguard System should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the Thoraguard Control Module or the Thoraguard System should be observed to verify normal operation in the configuration in which it will be used.

[!] Handle the Thoraguard Control Module carefully. Do not drop.

[!] Only plug cables provided with the Control Module into the power port. Only connect the Thoraguard Drainage Canister to the Thoraguard Control Module. Attempting to plug in non-approved cables or devices may compromise the function of the Control Module or the external device.

[!] Do not excessively tilt the Control Module during use.

[!] Unplug the power cord before moving the Control Module. Failure to do so could damage the cord or the Control Module.

[!] During cleaning, do not use strong solvents such as acetone or trichloroethylene and do not use abrasive materials (such as steel wool or silver polish).

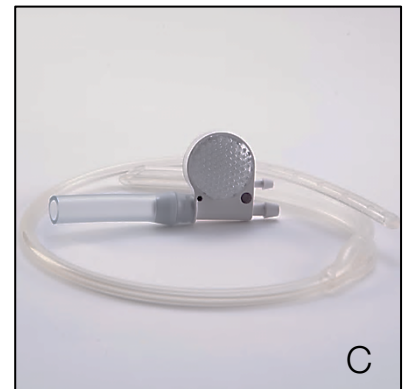
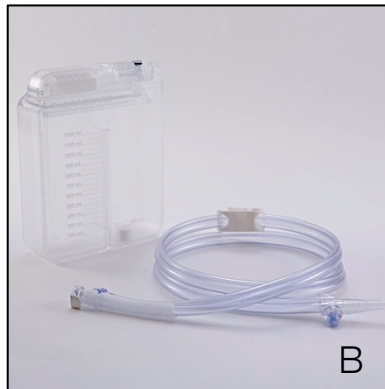
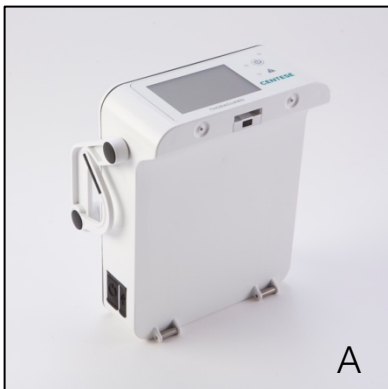
[!] Do not position the Control Module so that it is difficult to disconnect the power supply from the Control Module.

[!] The Thoraguard Control Module is a reusable device and should not be discarded.

[!] The Thoraguard Control Module should only be used with the Thoraguard Drainage Kit, including the drainage tubing and drainage canister as defined above.

Functional Description

The Thoraguard System provides chest drainage following cardiothoracic surgery. The Thoraguard System consists of the three sub-systems: the Thoraguard Control Module [A], a reusable electronic device for generating and regulating suction; the Thoraguard Drainage Kit [B], a disposable collection canister and dual lumen drainage tubing set; and the optional Thoraguard Chest Tube Kit [C], a dual lumen chest tube with a passive valve and sterile filter. The Control Module and Drainage Kit are used together to transmit proper suction to the chest tube and collect drained fluid, and may be used with any chest tube. When used with the Thoraguard Chest Tube, the system provides automated clearance of clogs within the chest tube itself.



Package Contents

Each Thoraguard Control Module package contains:

- 1 TGCM1000 Thoraguard Control Module
- 1 TGPS0100 Thoraguard Power Supply
- 1 IFU-1286 Thoraguard Operator's Manual

[!] Do not use the Thoraguard Control Module with power supply other than the one listed above.

System Components

The Thoraguard System is composed of the following individual components:

Reusable

TGCM1000 Thoraguard Control Module

Disposable

TGDK110012 Thoraguard Drainage Kit
TGCT120020 Thoraguard Chest Tube Kit, 20 Fr
TGCT120028 Thoraguard Chest Tube Kit, 28 Fr

System Functionality

The Thoraguard System is an intelligent system for maintaining proper post-operative surgical drainage. Thoraguard provides reliable drainage while delivering useful quantitative information about patient recovery. The system automatically maintains chest tube and drainage tubing patency by monitoring pressure levels and clearing the lines of pooled liquid and clogs. This provides consistent drainage without the need for milking, stripping, or other interventions. Because suction is integrated into the device, wall suction is not necessary, making patient transport and ambulation possible under applied suction. The touchscreen display provides useful system and patient status, including digital measurements of drainage volume and air leak over time.

Suction Regulation

With the Thoraguard System, suction level is actively monitored by the system. Thoraguard automatically adjusts the suction level to ensure the prescribed pressure is transmitted to the chest.

Fluid Output Measurement

The Thoraguard System accurately quantifies the fluid collected in the canister. Also, by automating the clearance of the drainage tubing (and the chest tube when used with the Thoraguard Chest Tube Kit), Thoraguard provides a more reliable reading of real-time fluid output levels. Historical fluid output levels are also recorded, allowing the system to create an accurate display of trends so the clinician can easily monitor the patient's fluid output levels over time.

Air Leak Measurement

The Thoraguard System also accurately quantifies the rate of air leak for thoracic surgery patients. Air leak is quantified in output levels of ml/min. By actively recording data points over time, the system creates an accurate display of trends so the clinician can easily monitor the extent of the patient's air leak over time. The integrated software filters out irregular measurements that may otherwise lead to false readings.

SmartCheck

SmartCheck monitors historical air leak and drainage data from the control module over the course of the patient's recovery against user-specified criteria and provides real-time status and notification on the screen. SmartCheck is capable of monitoring the following user-specified criteria:

- Current Air Leak 5 – 95 ml/min N/A
- Average Air Leak 5 – 95 ml/min Past 2HR, 4HR, 6HR, or 12HR
- Maximum Air Leak 5 – 95 ml/min Past 2HR, 4HR, 6HR, or 12HR
- Drainage Output 50 – 500 ml Last 6HR, 8HR, 12HR, or 24HR

Chest Tube and Drainage Tubing Clearance

To ensure proper drainage, the Thoraguard System automatically clears the drainage tubing every five minutes to prevent build-up from occurring and to maintain the prescribed suction at the patient's chest. The Thoraguard drainage tubing is cleared by temporarily allowing air to enter and sweep accumulated fluid into the drainage canister. When used in combination with the Thoraguard Chest Tube Kit, clog clearance mode can be enabled, which extends this functionality to the tip of the chest tube. If enabled, "Clog Clearance" mode activates the Thoraguard System to automatically sweep the chest tube clear by pulling additional suction, either intermittently or continuously for a set period of time, depending on the user setting.

Importantly, at no time is pressurized air introduced into the drainage system or thoracic cavity, as the sweeping of the drainage tubing and chest tube are activated only in the presence of suction. The entire drainage tubing and chest tube clearance sequences take approximately 15 seconds and up to 5 minutes to complete, respectively, and require no activation by the user or awareness of the patient. During these clearance activations, the Thoraguard Control Module actively monitors pressure levels in the drainage tubing and chest tube to ensure that suction is maintained.

Surgical sealants and hemostatic agents are commonly administered in cardiac and thoracic surgery to achieve adjunctive hemostasis by mechanically sealing areas of leakage. These agents are specifically designed to restrict fluid flow and as a result may contribute to limitation/loss of clog clearance functionality or chest tube clogging when brought into contact with the Thoraguard Chest Tube.

Safety Alarms

The Thoraguard System is equipped with safety alarms to protect the patient from system malfunction, and to alert the physician to dangerous physiologic conditions. For example, safety alarms will sound in the presence of suction loss, system leaks, drainage tubing obstructions, and irregular output levels. Descriptions of all alarms and the actions to be taken are described in detail in Appendix A.

Power Loss Safety Valve

The Thoraguard System is a self-contained, closed system. In the event that the Control Module loses power (e.g. facility power loss, inadvertent power down), the system will no longer be able to apply regulated suction. However, the Control Module contains an integrated one-way mechanical safety valve for patient protection. The mechanical safety valve is designed to prevent exposure to atmospheric pressure while still allowing fluid and air to drain.

Disconnecting the chest tube, drainage tubing, or canister from the Control Module may allow exposure to atmospheric pressure and is not recommended unless clinically desired. If possible, restoring power to the Control Module is recommended.

Carrying Handle and Mounting Hooks

The Thoraguard System is equipped with a handle and hooks built into the Control Module for carrying the device by hand or attaching to a bed, walker, or IV pole mount hole during transport or patient ambulation. The hooks can collapse into the handle supports when not in use and the handle can be stored on the backside of the Control Module, out of the way and easily accessible.

[!] Digital volume measurement is most accurate when the Thoraguard System is placed on a stable and level surface, so it is recommended that the device be placed on the ground during normal operation.



Setup and Operation

Setup

The Thoraguard System should be initialized in the operating room toward the end of the surgical procedure and connected to the patient's chest tube(s), then transferred with the patient to recovery. At that time, the Thoraguard Control Module should either be placed bedside on the floor or hung on the patient's bed using the integrated hooks.

The disposable Chest Tube Kit and Drainage Kit are supplied sterile by means of EO. Inspect each package for damage, and if found, discard and replace with an undamaged kit.

Chest Tube Placement

Place all chest tube(s) using standard surgical technique prior to connection to the Thoraguard Control Module. For additional details on the Thoraguard Chest Tube Kit regarding instructions, warnings, and precautions, see the included instructions for use.

Thoraguard Chest Tube Placement and Connection

Prior to opening the packaging, check for damage and replace if necessary. Open the package and pass the contents into the sterile field using sterile technique.

1. Remove the chest tube and SmartValve from the tray and place in a dry area until ready for use.
2. Immediately prior to use, soak chest tube(s) with sterile water or saline solution for at least ten seconds by submersion and/or flushing the inside of the tubing [A].

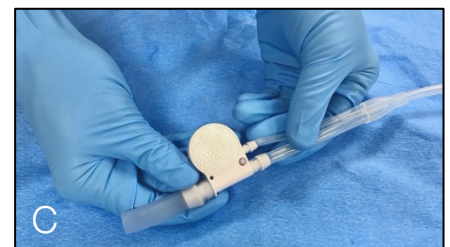
[!] Do not allow fluid to come in contact with the filter of the SmartValve. Doing so may adversely impact the functionality of the Clog Clearance feature, if enabled.

3. Place the chest tube and secure using standard surgical technique.

[!] Do not cut or puncture the chest tube for any reason, including the addition or expansion of drainage holes. Doing so may adversely impact the functionality of the Clog Clearance feature, if enabled.

[!] Do not overtighten sutures used to secure chest tube. Overtightening can limit flow through the chest tube and adversely impact the functionality of the Clog Clearance feature, if enabled.

4. Make a perpendicular cut across the double tube portion of the chest tube. Cut both tubes at the same location to achieve the desired chest tube length. [B]
5. Connect the chest tube to the SmartValve by connecting the individual tubes to the associated barbs on the SmartValve [C]



Use of Surgical Sealants and Hemostatic Agents

When using surgical sealants and hemostatic agents in conjunction with the Thoraguard Chest Tube Kit, the Instructions for Use (IFU) from the manufacturer should be followed thoroughly. This may include agent specific cure or stabilization times, removal or irrigation and aspiration of unnecessary or excess agent, and avoidance of direct contact with chest tubes. Please refer to the manufacturer's IFU for appropriate use guidelines.

Should surgical sealant or hemostatic agent come in contact with the Thoraguard chest tube or enter the drainage lumen of the Thoraguard chest tube, remove the agent itself from the chest tube along with any material or fluid that may have come in contact with the agent by wiping the chest tube clean and flushing the drainage lumen with sterile saline. If it is not possible to remove the material, replace with a new Thoraguard Chest Tube Kit.

Drainage Kit Assembly

For additional details on the Thoraguard Drainage Kit regarding instructions, warnings, and precautions, see the included instructions for use.

Connect Canister to Control Module

Prior to opening the packaging, check for damage and replace if necessary. Open the package and pass the contents into the sterile field using sterile technique.

1. Remove the drainage canister from its sterile wrap.
2. Connect both tubes to the drainage canister [A].
3. Pass the canister, with tubes securely connected, out of the sterile field for setup with the Thoraguard Control Module [B].

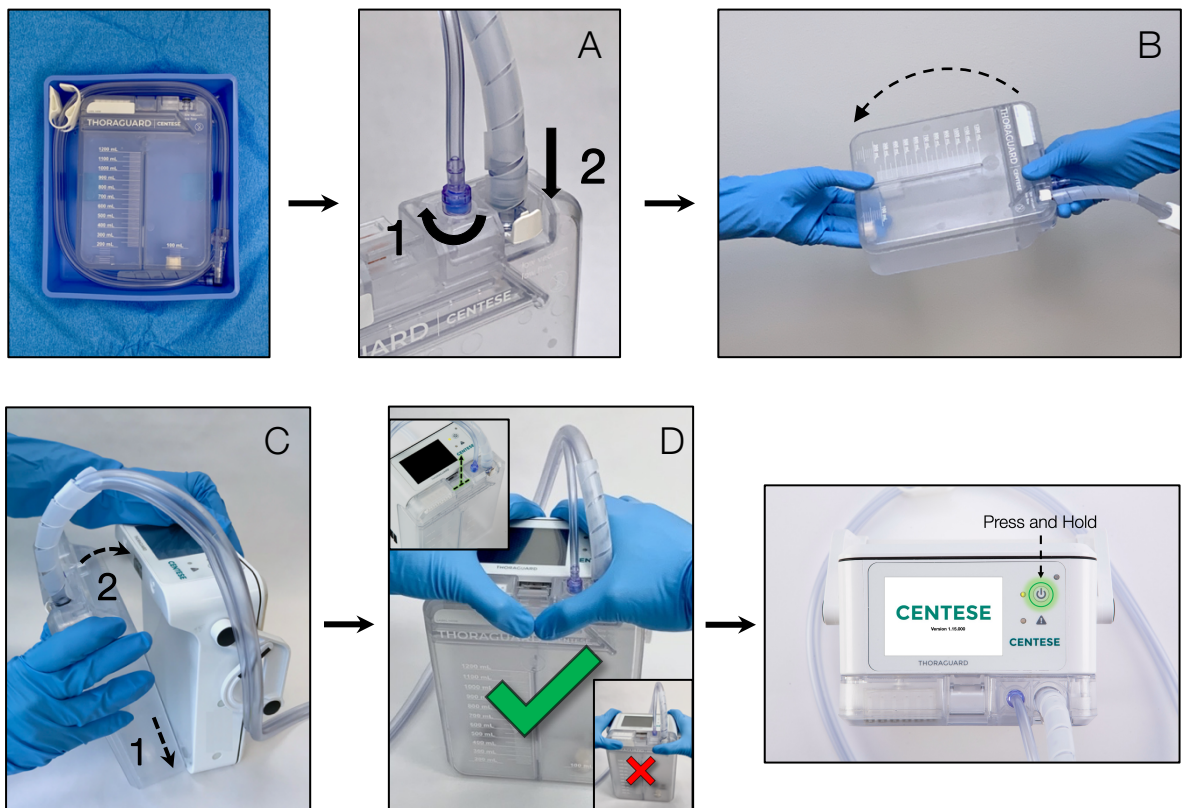
[!] Retain drainage tubing barb in sterile field for connection to chest tube when setup is complete.

4. Use one hand to hold the drainage canister at the top, while slightly tilting the Control Module backwards with the other hand. Place the bottom of the drainage canister onto the metal pins at the bottom of the Control Module [C].
5. Slowly rotate the top of the drainage canister into position, while maintaining a gentle downward pressure. To connect, firmly squeeze the drainage canister into the Control Module. If necessary, lift latch to connect. [D].

[!] Squeeze in the middle of the drainage canister and Control Module, not on the sides [D].

[!] An audible click should be heard when the drainage canister is properly in place.

6. Turn on Control Module and follow on-screen prompts to set up system for New Patient (see below).

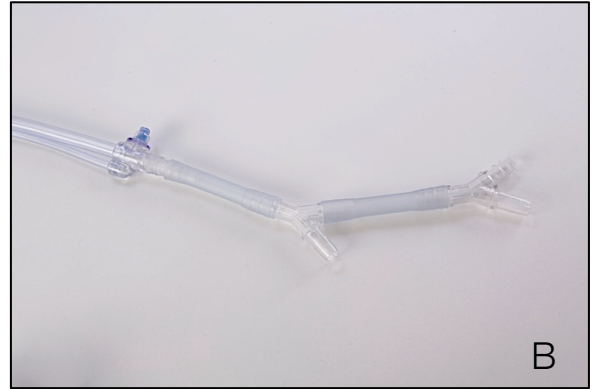
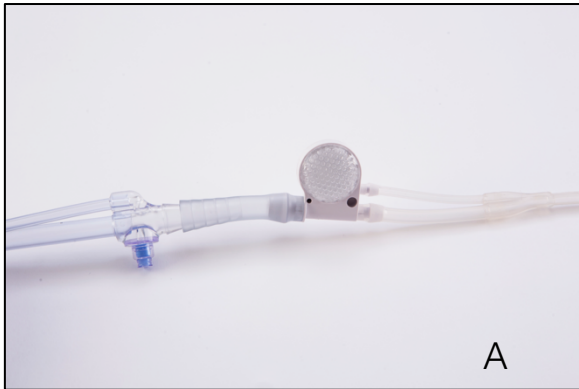


Confirm that all connections are secure before continuing.

Connect Drainage Tubing to Chest Tube

Note that the Control Module should be set up prior to connecting the drainage tubing to the chest tube. See next section for instructions on how to properly set up the Control Module.

1. Firmly attach the drainage tubing barb to the chest tube [A].
2. If multiple chest tubes are to be used, connect using the included adapters [B].



Control Module

Turn On the Thoraguard Control Module

To start the Thoraguard Control Module, press and hold the power button until the screen and green LED turn on.



Select Patient Type

Select whether the patient is a New Patient or Existing Patient (device turned off and back on with same patient connected).



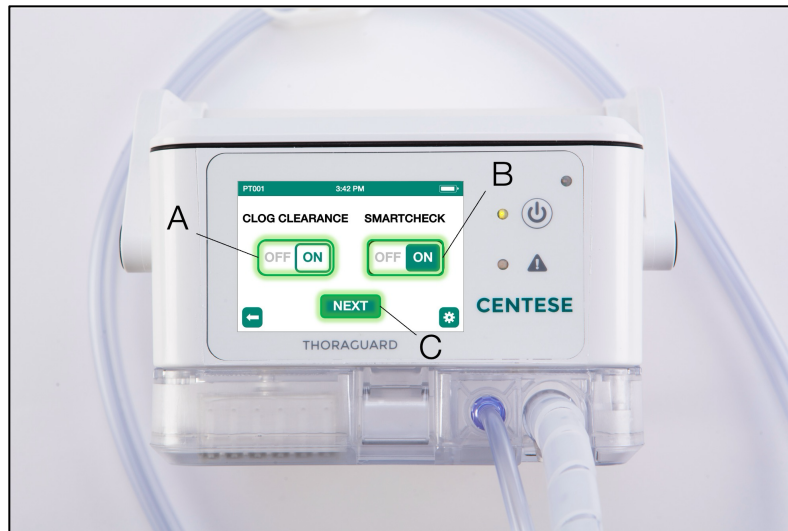
Choose Initial Feature Settings

1. Select whether Clog Clearance mode should be enabled [A]. See Clog Clearance section for details on selection of options that appear.

[!] Clog Clearance mode should only be used in combination with the Thoraguard Chest Tube Kit.

[!] Clog Clearance mode pulls additional suction to help keep the chest tube patent and is not recommended in the presence of an active air leak.

2. Select whether SmartCheck should be enabled [B]. See SmartCheck section for details on selection of options that appear.
3. Press “NEXT” to proceed to suction settings [C].



Choose Initial Suction Settings

Set the initial suction level with the up and down arrows [D]. If Clog Clearance mode is activated, initial suction cannot be set above 40 cmH₂O. If suction is set in excess of 70 cmH₂O, the following warning appears on the display: “Suction in excess of 70 cmH₂O may cause pain and / or serious injuries to the patient.” This warning must be acknowledged with “CONFIRM” before the suction can be increased further.

[!] Increasing suction in excess of 70 cmH₂O may cause pain and / or serious injuries to the patient.

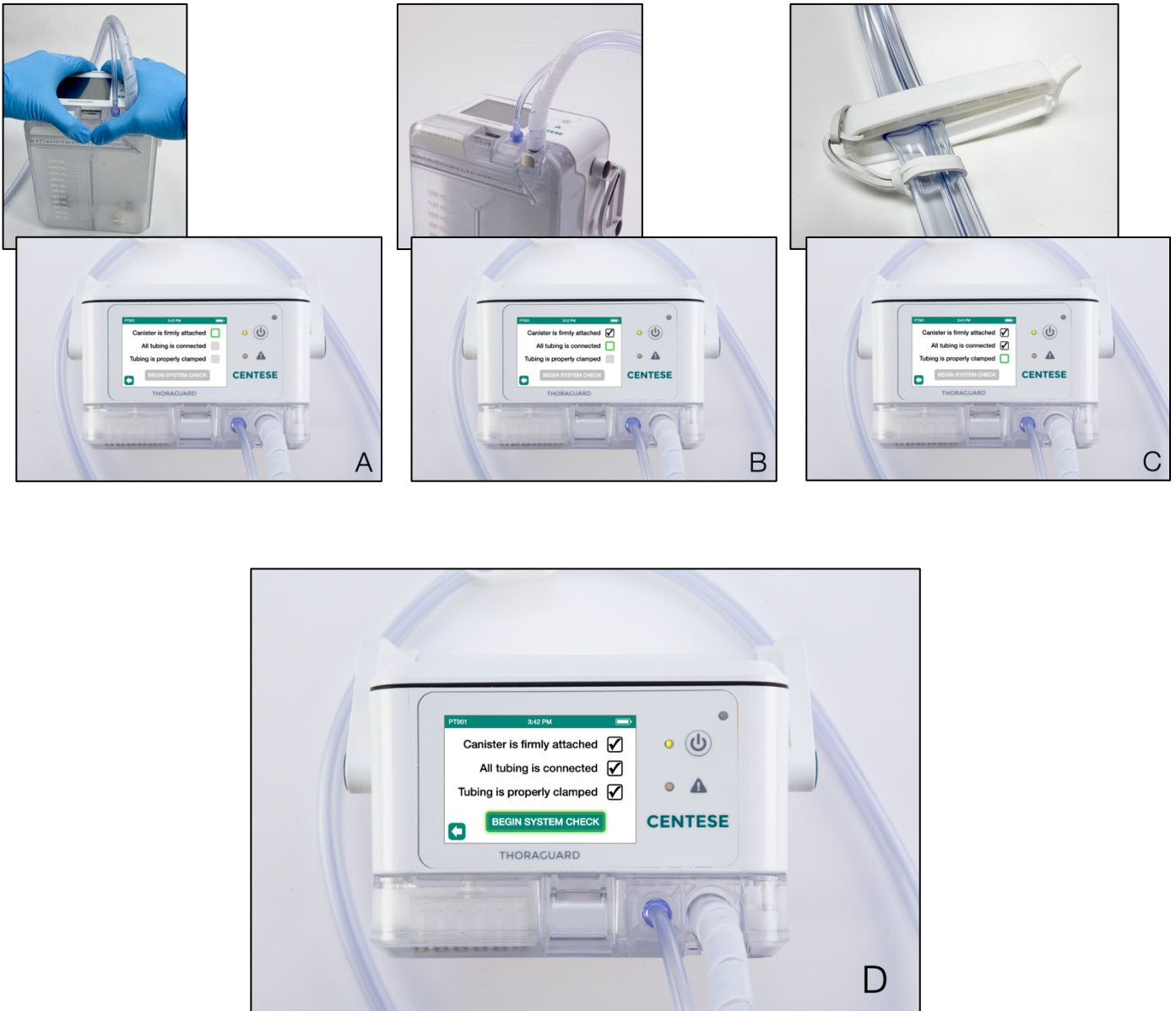
Press “NEXT” to proceed to system check [E].



Perform System Check

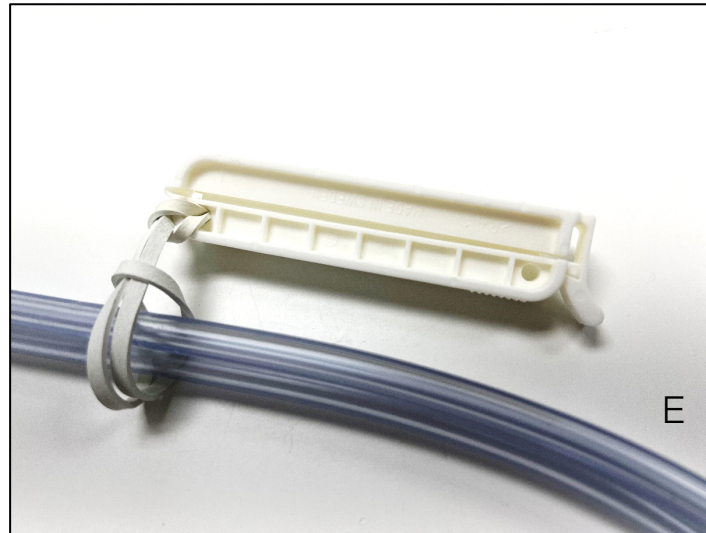
To begin the system check, complete the following steps.

1. Confirm the canister is firmly attached and press checkbox on screen [A].
2. Confirm all tubing is properly connected and press checkbox on screen [B].
3. Clamp the drainage tubing with the included clamp and press checkbox on screen [C]. Once this check is completed, the “BEGIN SYSTEM CHECK” button should turn from gray to green.
4. Press “BEGIN SYSTEM CHECK” to continue [D].



The Thoraguard Control Module will perform a system check to ensure the system is airtight and the device is functioning properly.

[4] Once the system check is complete, be sure to unclamp tubing before continuing [E].



Once complete, connect the drainage barb to the chest tube and press “BEGIN” to start operation [A]. At this point, the system is fully operational and the home screen will be displayed [B].

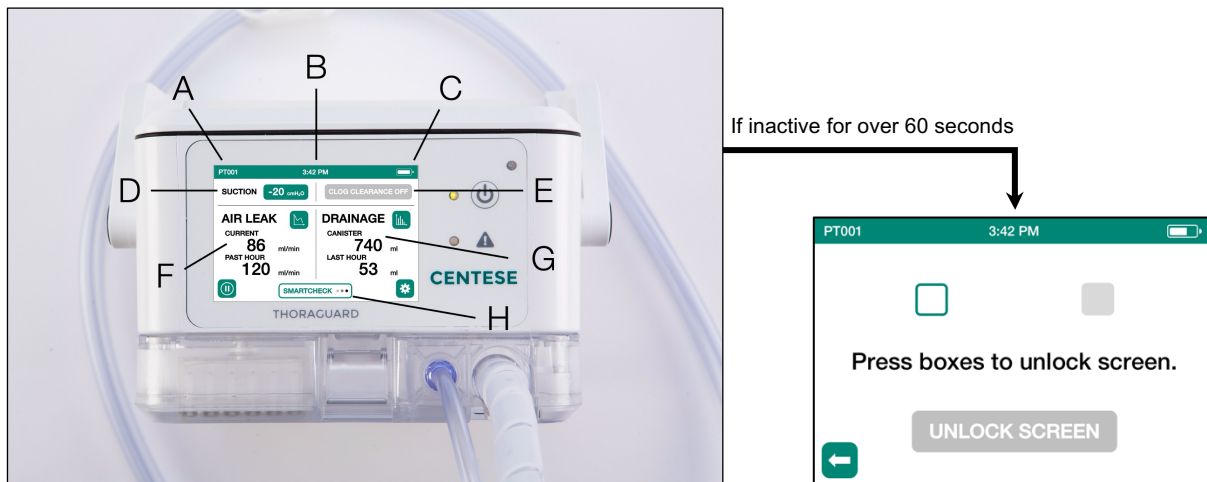


Operation

Information Displayed

During normal operation, the Thoraguard intuitive user interface displays relevant information visible on the main screen at all times. These include the patient ID (unique identifier specific to the Control Module) [A], time [B], battery status [C], level of applied suction [D], whether clog clearance mode is activated [E], current and past / last hour air leak and drainage volume values [F and G], and whether SmartCheck is active and current status [H]. Navigation to additional screens is achieved by pressing the buttons indicated with green icons. These buttons include suction adjustment, clog clearance activation, air leak and drainage data trends, standby, and settings.

In order to prevent accidental input to the user interface, Thoraguard has a lockout feature requiring user acknowledgement to proceed before adjusting any device functionality any time the touchscreen has not been used for over 60 seconds. To proceed, simply press the two checkboxes and then “UNLOCK SCREEN.”



Thoraguard only displays fluid output information while the measurement is stable. In the event of a rapid input of fluid Thoraguard will display the last measurement in gray text until it becomes stable again. If the device is not sufficiently level to provide readings, Thoraguard will display “NOT LEVEL” until it becomes level again.

For fluid volumes between 100 ml and 200 ml, the fluid level on the right side must be at the 100 ml mark to obtain an accurate reading using the graduations on the drainage canister. In the event that fluid spills over to the left side prematurely, Thoraguard may be angled to move fluid from the left side back into the right side. In the event that the fluid level is above the 100 ml mark on the right side, Thoraguard may be tipped slightly forward to allow fluid to spill over into the left side, until the level on the right is at 100 ml.

When Thoraguard is performing a clearance cycle of either the drainage tubing, the current air leak value will temporarily cease to update and will be displayed in gray text. Additionally, if clog clearance is enabled, a 30-second measurement of air leak is taken every 20 minutes, and the last reading is displayed in place of current and historical air leak data. To restore air leak readings for current and past hour simply disable clog clearance.

The historical data for air leak and drainage volume can also be toggled back in time beyond the past / last hour. For air leak, the display can be toggled to the past 1, 6, 12, and 24 hours (this is not available when clog clearance is enabled). For drainage volume, the display can be toggled to the last 1, 4, 12, and 24 hours, as well as to the total volume since the device was turned on.

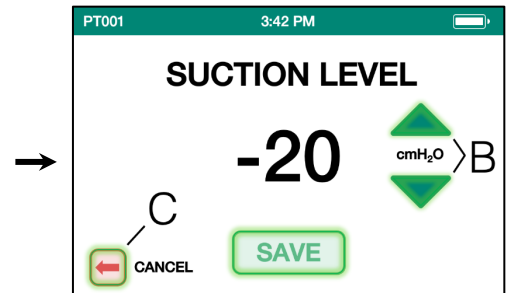
The information displayed in the “PAST HOUR” section of the screen for air leak rate and “LAST HOUR” for drainage volume output will be gray during the first hour of use, indicating that the values displayed are tentative until Thoraguard has collected data for an entire hour.

Suction Adjustment

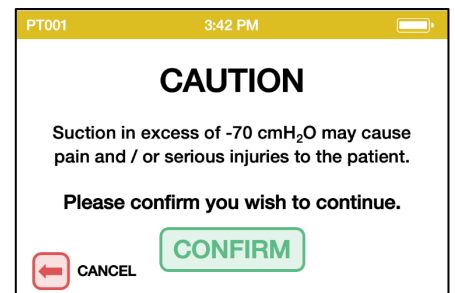
During operation, the level of applied suction can be adjusted from the main screen. To do so, follow these steps:

1. To bring up the suction adjustment screen, press the suction value in the top-left section of the screen [A].
2. Press the up button to increase or the down button to decrease suction [B]. Once the suction is at the desired level, press “SAVE” to complete the change. If the user decides not to adjust the suction, press the cancel button [C]. If suction is set in excess of 70 cmH₂O, the following warning appears on the display: “Suction in excess of 70 cmH₂O may cause pain and / or serious injuries to the patient.” This warning must be acknowledged with “CONFIRM” before the suction can be increased further.

[!] Increasing suction in excess of 70 cmH₂O may cause pain and / or serious injuries to the patient.



If suction is set in excess of 70 cmH₂O ↓

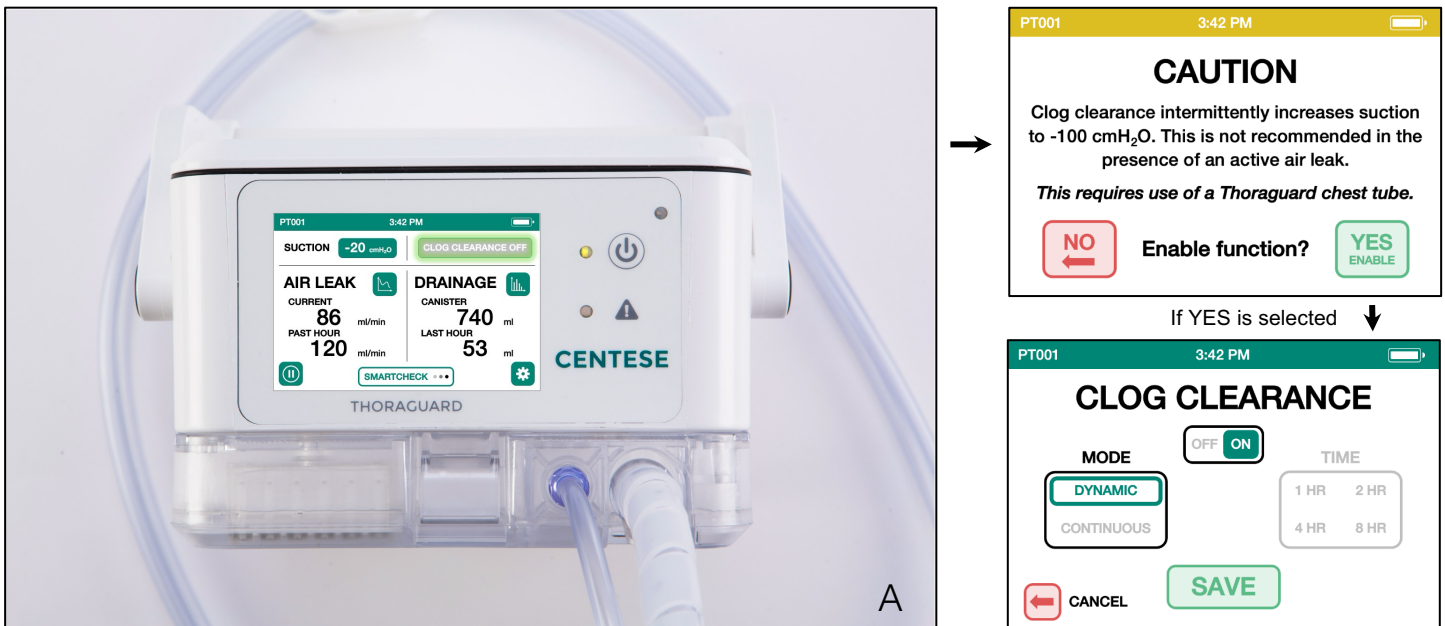


Clog Clearance

When used with the Thoraguard Chest Tube Kit, the Thoraguard Control Module can be enabled to provide automated chest tube clearance. This functionality is accomplished by intermittently increasing the applied suction to as high as 100 cmH₂O, which activates the incorporated SmartValve and allows sterile air to sweep any clogs that may have formed into the collection canister. To turn Clog Clearance on or off, press the toggle button in the top-right section of the screen [A]. When enabling the clog clearance feature, the user will be asked for confirmation before progressing to the mode selection screen.

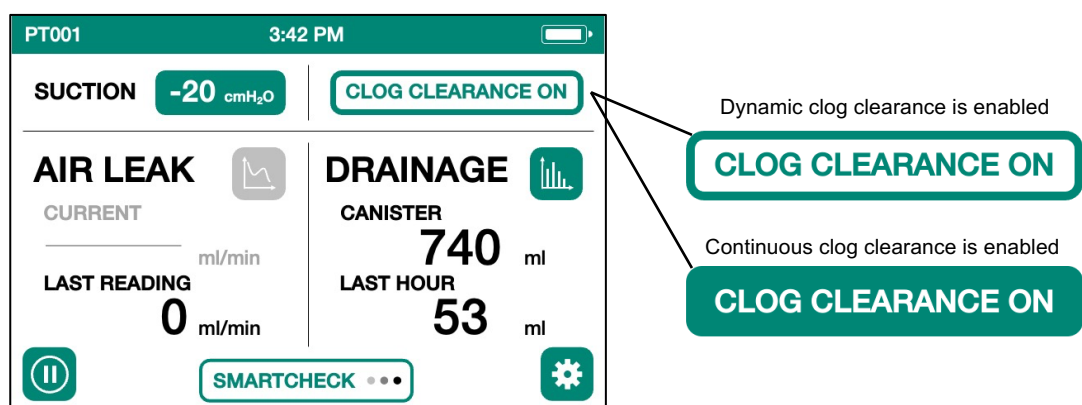
[!] Clog Clearance mode should only be used in combination with the Thoraguard Chest Tube Kit.

[!] Clog clearance intermittently pulls suction up to 100 cmH₂O. Clog clearance is not recommended in the presence of an active air leak.



Once the user enables clog clearance, either dynamic or continuous mode must be selected. Each of these modes is described in further detail on the next page. Once the selection is made, press “SAVE” to enable clog clearance.

The clog clearance mode that has been enabled is indicated on the main screen as shown below. When clog clearance is enabled, the last air leak reading (taken every 20 minutes) is displayed instead of current and historical air leak data, and access to the air leak data trends is disabled.

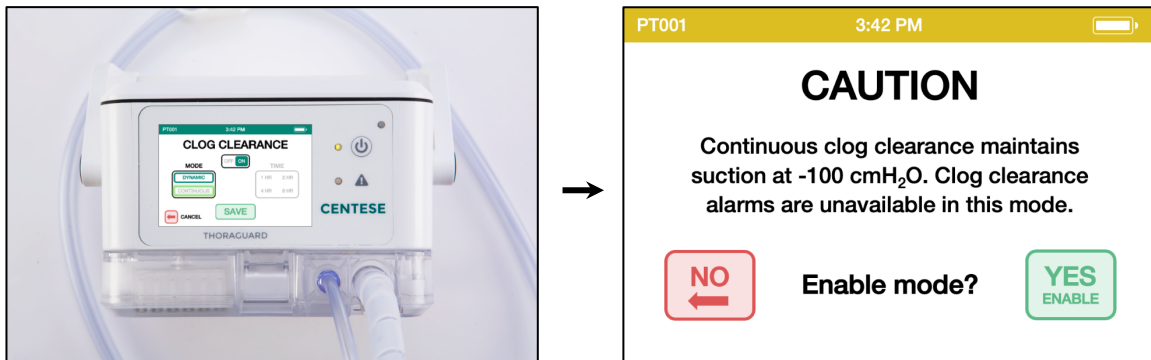


Dynamic Clog Clearance

Dynamic clog clearance is the standard clog clearance mode, whereby cycles will intermittently run and last from 30 seconds to 5 minutes, with time between cycles ranging from 5 seconds to 1 minute, based on the pressure response of the system during the last cycle. To enable this mode, leave the mode selection on DYNAMIC and press “SAVE”.

Continuous Clog Clearance

In addition to the standard dynamic clog clearance mode, Thoraguard can be set to continuous clog clearance, which maintains suction at $-100\text{ cmH}_2\text{O}$ to clear the tube continuously. To enable this mode, press “CONTINUOUS” – the user will be asked for confirmation before progressing to time selection.



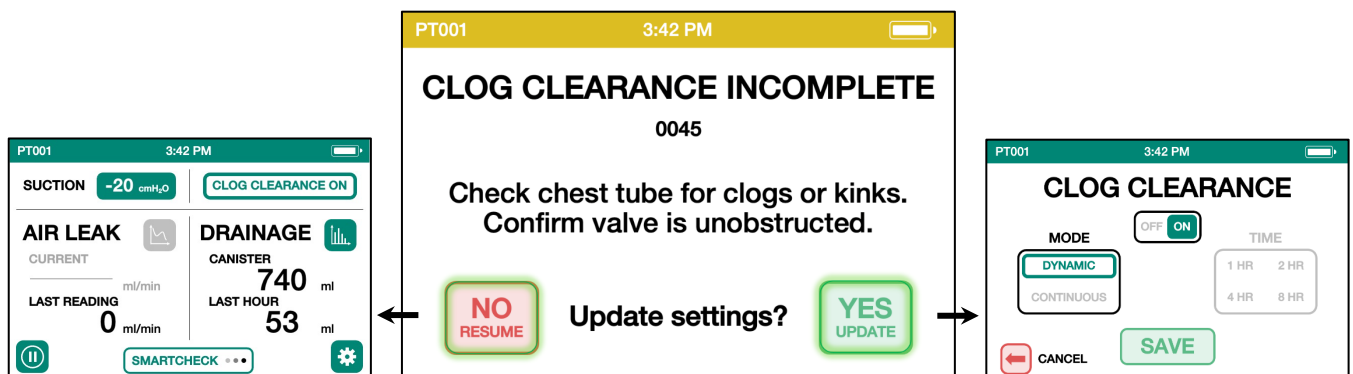
[!] Continuous clog clearance maintains suction at $-100\text{ cmH}_2\text{O}$. Clog clearance alarms are unavailable in this mode.

When continuous clog clearance is selected, the user must also select whether to enable this mode for 1 hour, 2 hours, 4 hours, or 8 hours. Once the selected period of time has passed, Thoraguard will automatically resume operation in dynamic mode.

Clog Clearance Alarm

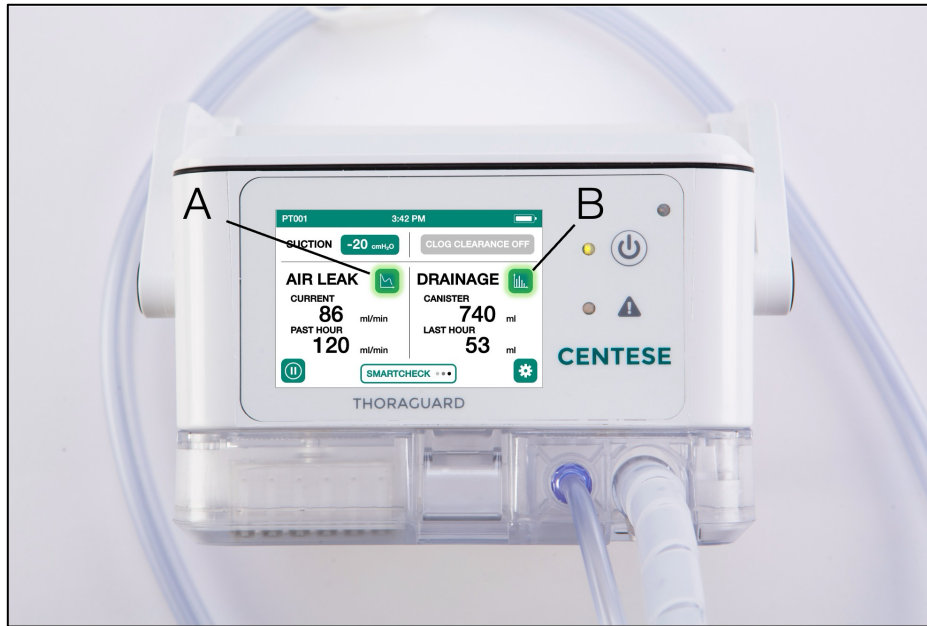
When clog clearance is enabled and dynamic mode is selected, Thoraguard automatically monitors for the completeness of the clog clearance cycle based on the pressure response of the system. If the pressure response meets pre-determined criteria that indicate the SmartValve may not have been opened during the last cycle, Thoraguard will alarm for an incomplete clog clearance cycle. If this occurs, check the chest tube for clogs or kinks and confirm the valve is unobstructed.

The alarm also prompts the user to consider updating the clog clearance settings. Selecting “YES” takes the user to the clog clearance setting screen, where continuous clog clearance may be selected for a set period of time, after which dynamic clog clearance will resume and Thoraguard will alarm again if another incomplete clog clearance cycle is detected. Clog clearance may also be turned off.



Data Trends

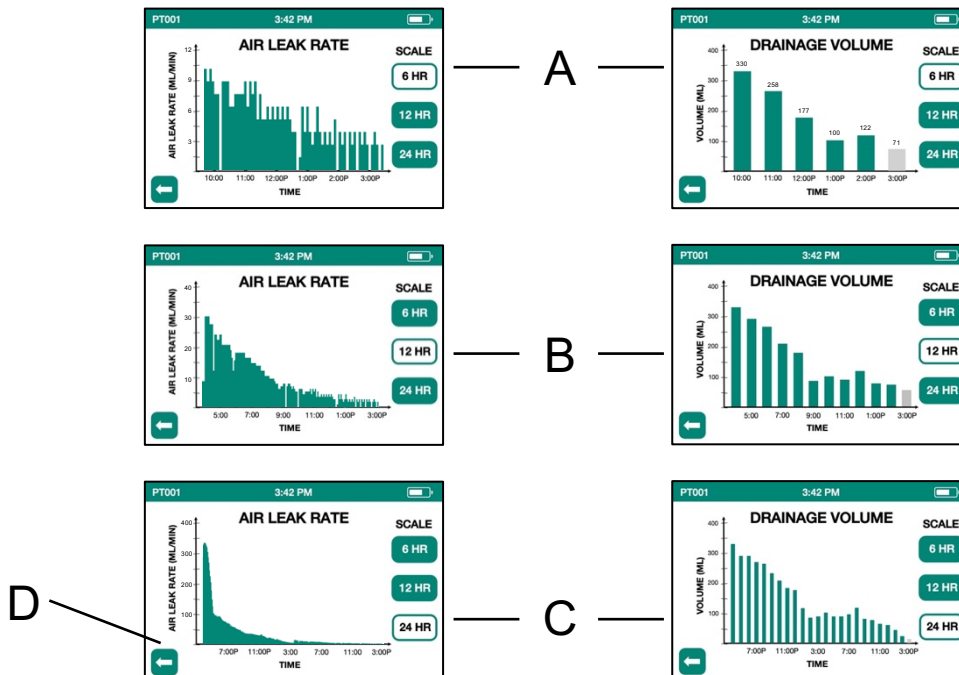
To see historical trends for Air Leak or Drainage, press the corresponding button next to the text on that section of the screen [A] and [B].



Air Leak trends are shown as a bar graph in ml/min and drainage trends are shown as a bar graph in ml. Both can be displayed over the past 6, 12, or 24 hours. To change the time scale for either plot, click the corresponding button [A], [B], or [C].

The vertical axis for both plots will scale automatically depending on the values being displayed over the chosen time period. The horizontal axis shows the time, in hours, with the most recent hour on the right side of the screen.

To go back to the main screen, press the back button [D].



SmartCheck

On the main screen, the “SMARTCHECK” button displays the real-time status of SmartCheck. To access the SmartCheck settings, press “SMARTCHECK”.



SMARTCHECK OFF

→ SmartCheck Disabled

SMARTCHECK ●●●

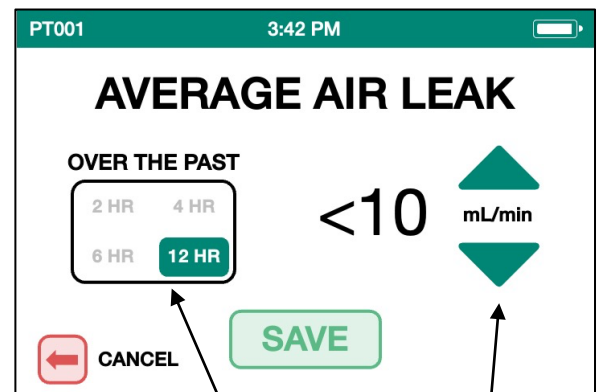
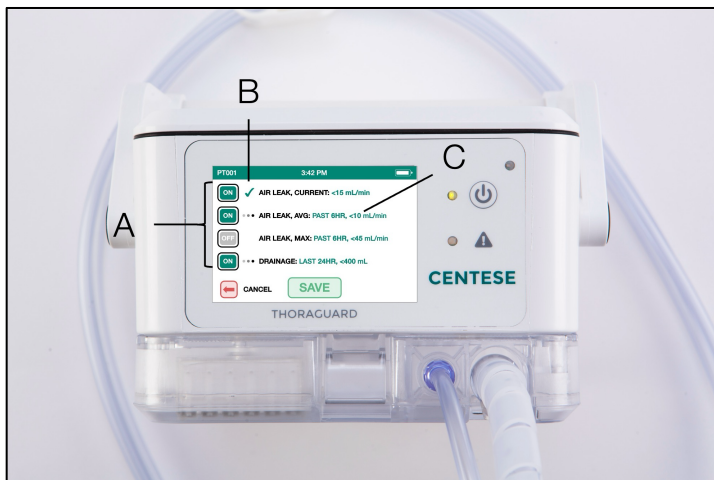
→ SmartCheck Enabled, In Use

SMARTCHECK ✓

→ SmartCheck Enabled, Complete

SmartCheck Settings Adjustment

Pressing “SMARTCHECK” on the main screen navigates to the SmartCheck settings adjustment screen. The threshold values for all SmartCheck criteria can be accessed from the SmartCheck settings screen. From this screen, all criteria can be turned ON or OFF [A], a status indicator for each criterion is displayed [B], and each criterion threshold can be viewed and adjusted as needed by pressing the green text for the desired criterion [C]. Criteria may be turned ON or OFF at any time.



Time Window Selection

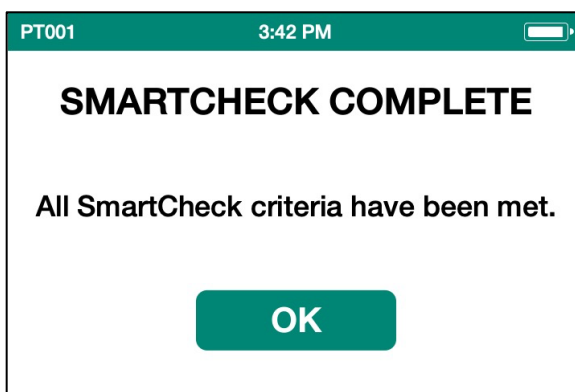
Value Selection

SmartCheck Complete Notification

SmartCheck analysis monitors the entire period of time Thoraguard is used for a patient, from the most recent completing of the New Patient System Check sequence to the present moment.

When all enabled SmartCheck criteria have met their respective threshold values for 15 minutes continuously, the Control Module will provide an on-screen notification with auditory information signal to indicate SmartCheck is complete.

This auditory information signal will repeat every 5 minutes until the notification is acknowledged by selecting “OK” on the screen. After pressing “OK”, the notification screen and auditory information signal will not recur, unless the status of SmartCheck changes from complete to incomplete. If this occurs, the Control Module will provide the on-screen notification and auditory information signal as before when the status of SmartCheck changes from incomplete to complete.

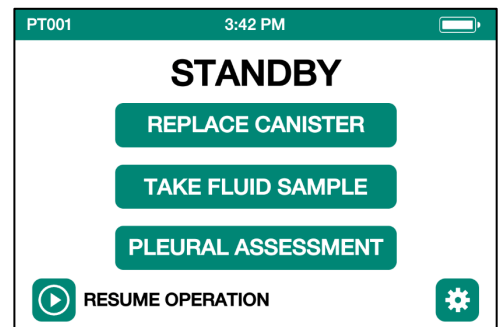


Parameter	Specification
Auditory Information Signal Sound Level	58 to 68 dB
Auditory Information Signal Details	A sequence of two short beeps (0.3 seconds each with a 0.15 second interval) repeated every 5 minutes after SmartCheck is complete. Volume: 80 dB at 10cm Frequency: 795 Hz \pm 24 Hz Voltage Range: 5.0 \pm 0.5 V DC Max Current: <250 mA

Please note that this auditory information signal is distinct from the device’s auditory alarm signals. The alarm signals are designed to alert users about potential issues or malfunctions with the device, while the information signal is intended to provide information about the device’s normal operational status pertaining to SmartCheck.

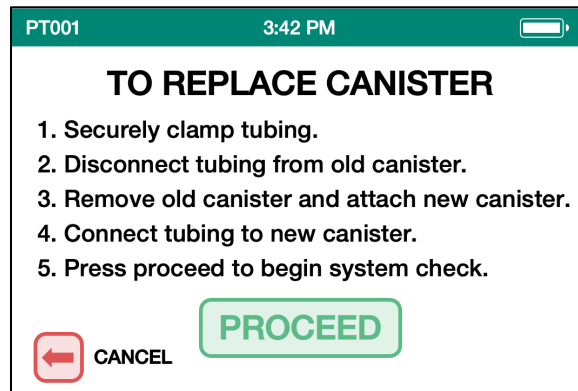
Standby

To place the device in Standby, press the button in the bottom-left corner of the screen [A]. Placing the device in standby disables the pump but does not relieve the existing suction applied to the patient. It is required to enter standby mode to replace the canister, take a fluid sample, or perform a pleural assessment.

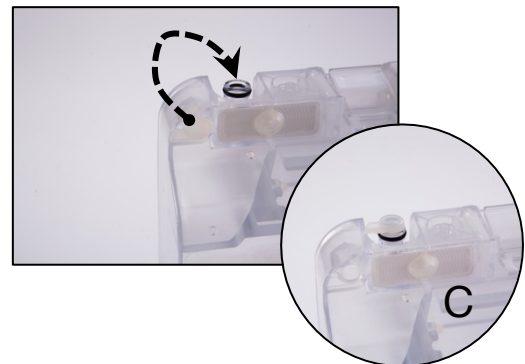
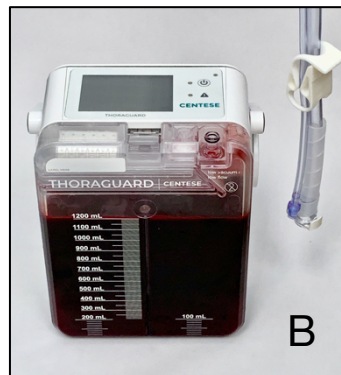
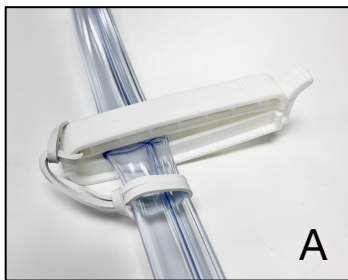


Canister Replacement

If the canister reaches 1200 ml in drainage volume, a replacement canister will be required. To replace the canister, press “REPLACE CANISTER” and follow the on-screen instructions:



1. Clamp tubing in appropriate location [A].
2. Disconnect tubing from canister [B].
3. Remove old canister and plug opening [C].
4. Connect new canister to Control Module [D].
5. Connect tubing to new canister [E].

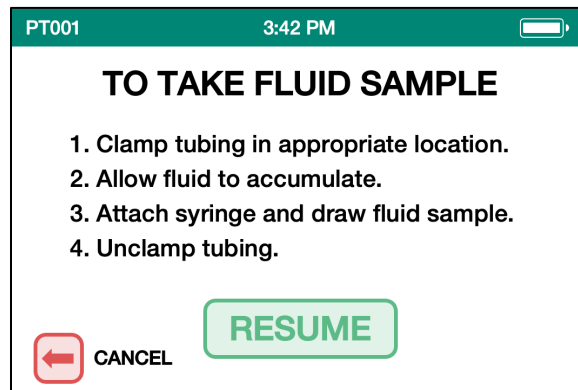


Once these steps are complete, press “PROCEED” to continue to system check (see Perform System Check on Page 17). The original canister should be plugged and discarded in compliance with standard hospital procedures.

When Thoraguard detects that the drainage canister is full, it sounds an alarm informing the user that the drainage canister needs to be replaced. This alarm occurs immediately when full (1200 ml) and will recur after every user acknowledgement in sequential increments of 5 minutes, 15 minutes, 1 hour, and 2 hours indefinitely, until the drainage canister is replaced.

Fluid Sample Collection

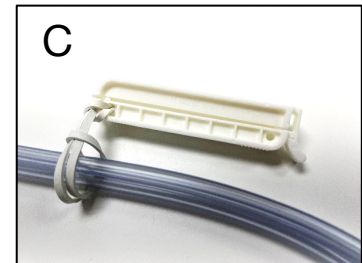
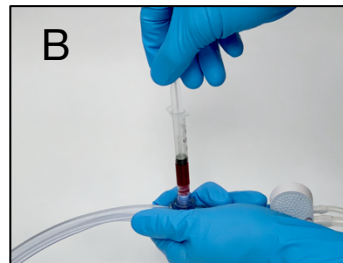
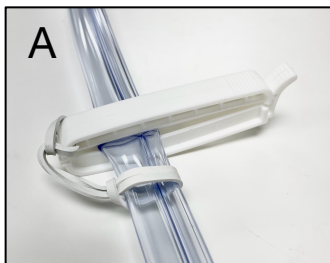
With Thoraguard, it is possible to take a fluid sample from the patient without the use of a needle or the need to break sterility. To take a fluid sample, press “TAKE FLUID SAMPLE” and follow the on-screen instructions:



1. Clamp tubing in appropriate location [A].
2. Allow fluid to accumulate.
3. Attach syringe and draw fluid sample [B].
4. Unclamp tubing [C].

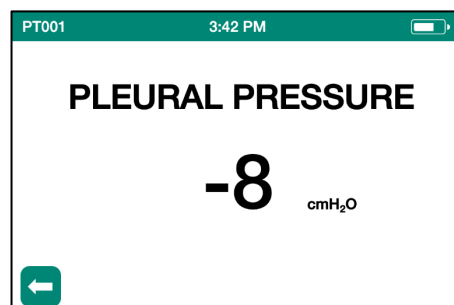
[!] Be sure to unclamp tubing before continuing.

Once these steps are complete, press “RESUME” to restore active suction.



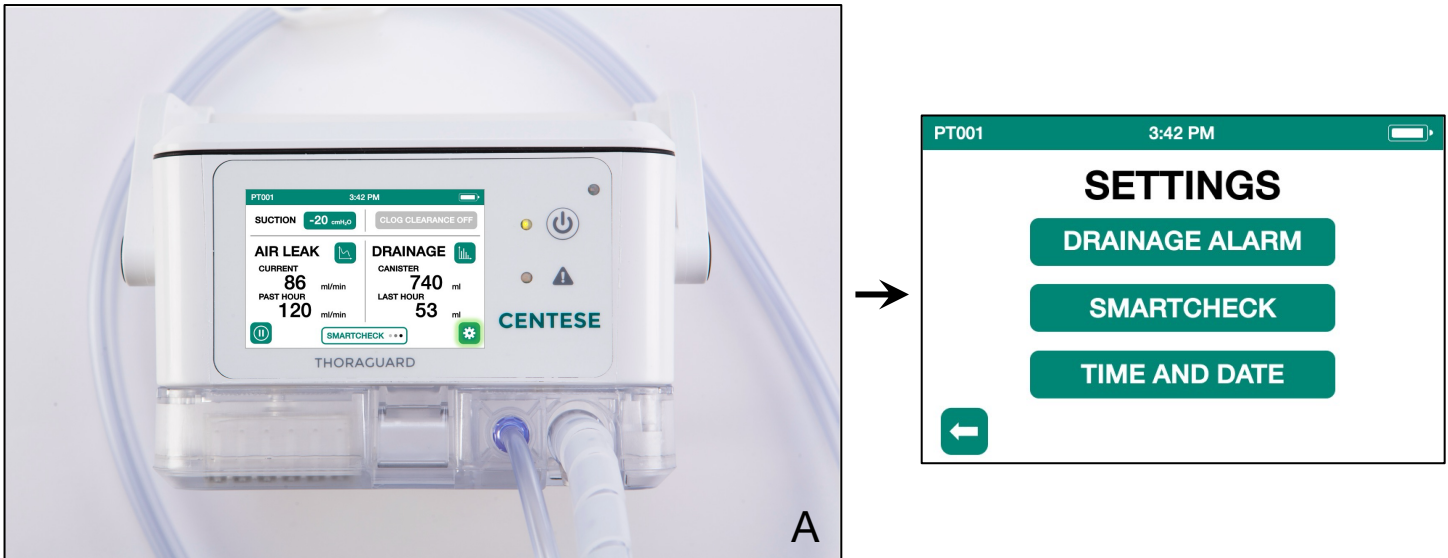
Pleural Assessment

Thoraguard’s pleural assessment screen provides a digital means to monitor for patient tidaling to help confirm that the drainage tubing and chest tube are not occluded. **Note: this functionality only works with the chest tube in the intrapleural space.** This screen provides a real-time display of the pressure measured at the drainage tubing barb (proxy for patient’s pleural pressure). The pleural assessment may also be useful in situations where the clinician desires to monitor for tidal oscillations or pressure fluctuations generated by patient maneuvers, such as a Valsalva.



Settings

Thoraguard has certain settings that are adjustable by the user, including a drainage alarm, SmartCheck defaults, and time and date. To access the settings screen, press the button in the bottom-right of the screen [A].

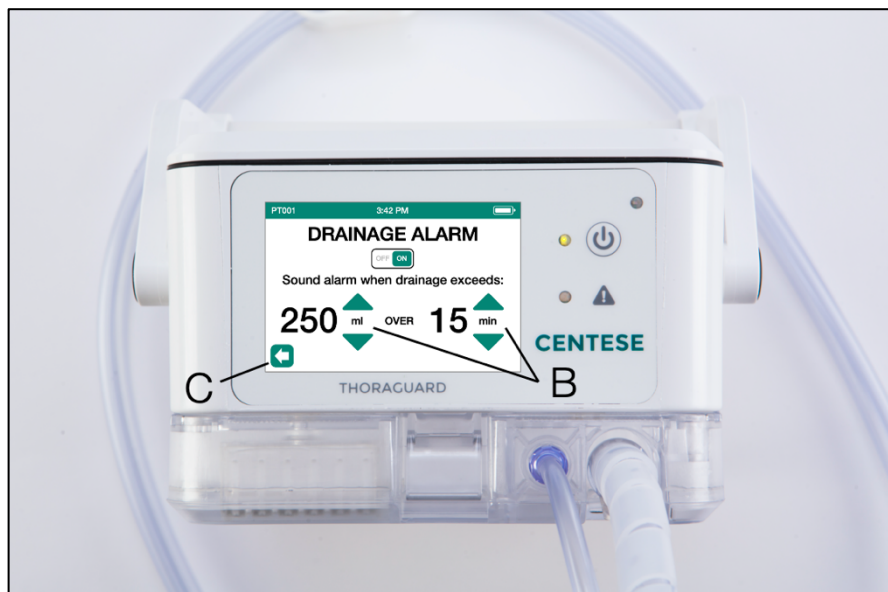


Drainage Alarm

As a safety precaution, Thoraguard can be configured to alarm when the rate of fluid output exceeds a user-defined threshold. The default setting for this alarm is to activate when fluid output increases by 250 ml in 30 minutes. To adjust this setting, press “DRAINAGE ALARM”.

Once in the setting screen, press the arrows to adjust the alarm to the desired level [B].

When complete, press the back button to enter the settings screen, and the back button again to resume operation [C].



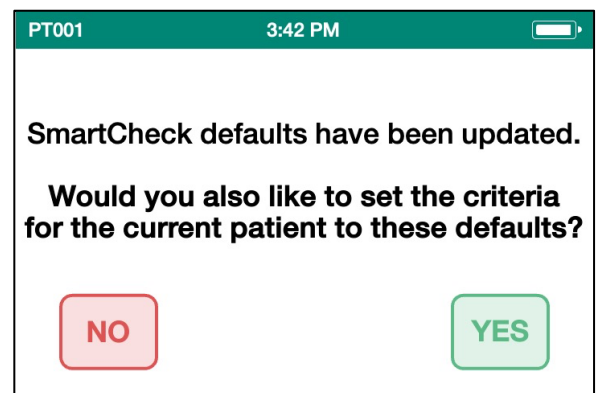
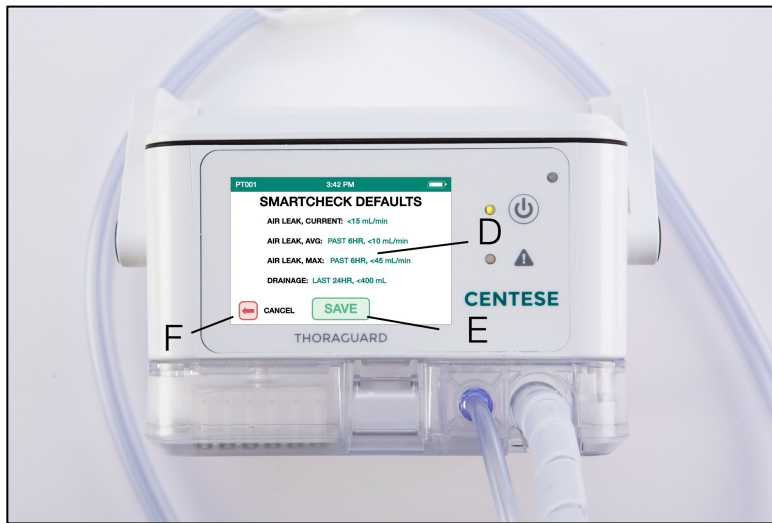
SmartCheck

Every time Thoraguard is turned on for use, SmartCheck criteria will automatically populate a pre-defined set of default values. These values are user adjustable to accommodate unique and / or preferred use cases.

To adjust the default criteria, press “SMARTCHECK”.

Once in the SmartCheck default settings screen, select the desired criteria and adjust to the desired values [D].

When complete, press “SAVE” to save the adjustments [E]. Otherwise, press the cancel button to return to the settings screen [F].



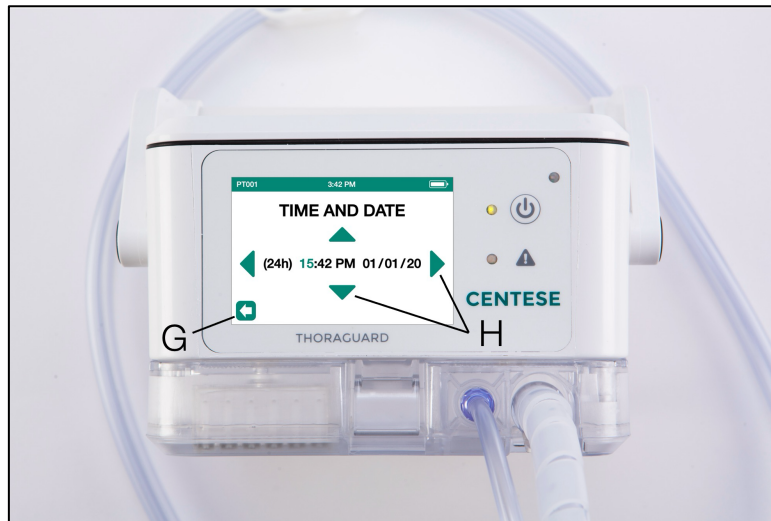
After pressing “SAVE”, a confirmation screen shown above will appear asking if you would like to adjust the current patient SmartCheck settings to match the default settings that were just adjusted. Selecting “NO” will save the default settings but not adjust the current use settings. Selecting “YES” will save the default settings and adjust the current use settings to match.

Time and Date

Thoraguard has a built-in real time clock to enable syncing of data timestamps with the rest of the patient's medical record. To adjust this clock, press "TIME AND DATE".

Once in the setting screen, press the right and left arrows to change the value being adjusted and the up and down arrows to adjust the value [H].

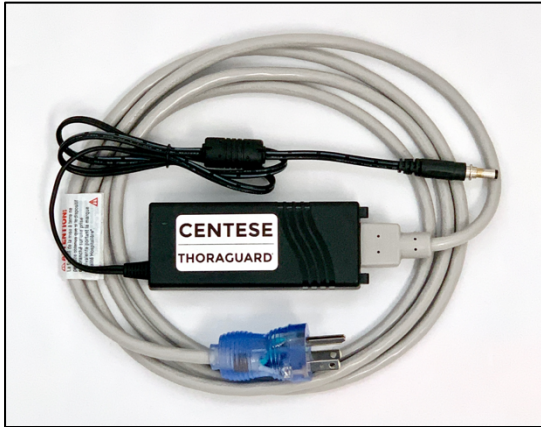
When complete, press the back button to enter the settings screen, and the back button again to resume operation [G].



Battery Charging

Thoraguard is built with a rechargeable battery that, when fully charged, will last for at least four hours in normal use. It is recommended to keep Thoraguard plugged in when possible and to fully re-charge the unit between uses. During use, the battery icon at the top-right of the screen will indicate the battery charge status, as well as whether the device is running from battery or wall power.

[!] Ensure the power plug is fully inserted into the charging port of the Control Module by applying gentle, but firm pressure until the plug bottoms out. It is possible for the power plug to be incompletely inserted, preventing the device from charging.



Overfill Protection

The Thoraguard System is equipped with overfill protection to prevent liquid from being drawn into the Control Module when the canister becomes full. This protection is activated based on a sensed obstruction of the in-line filter, which activates an alarm when the canister becomes excessively full. Once overfill protection is activated, suction will cease. To restore suction, follow the on-screen prompts to replace the canister as instructed above. If liquid or solid is drawn into pump, the device should be serviced by Centese-trained personnel only.

Shutting Down

To discontinue use with Thoraguard, it is recommended to first place the device in Standby mode (see section above). However, in any mode or on any screen, Thoraguard can be shut down by pressing and holding the power button for five seconds [A]. During the power down cycle, Thoraguard places the unit into a safe state before fully turning off.

Once disconnected from the Control Module, the drainage canister and drainage tubing should be clamped and discarded in compliance with standard hospital procedures.

USB Connection

[!] Do not connect the USB cord to the Control Module during use. The USB port should only be used by Centese-trained personnel when the Control Module is not in use.

Environment and Cleaning

Use and Storage Environment

The Thoraguard Control Module is intended to be used and stored in a hospital environment between 50°F and 104°F (10°C to 40°C), relative humidity of 10-90%, non-condensing, altitude within 0 to 2,000 meters (6,560 feet), and pressure of 101 kPa to 81 kPa. **Do not use Thoraguard near active HF Surgical Equipment or MRI.** Please refer to Appendix D for guidance on conditions impacting electromagnetic performance of the device.

Cleaning and Disinfecting

Turn off the Control Module and unplug the power cord from AC power before cleaning. The exterior surfaces of the Control Module may be cleaned with a soft, non-abrasive cloth dampened with warm water / mild detergent, alcohol, or a non-staining chemical disinfectant.

Always dilute cleaning agents according to manufacturer’s instructions, or lowest possible concentration.

Clean by spraying cleanser directly onto a soft lint-free cloth and then wiping surfaces dry.

Take extra care when cleaning the screen of the Control Module because it may be damaged by aggressive cleaning methods. Wipe around, not over, connector sockets when possible. Clean around the barbs where the drainage canister connects, but pay special attention not to leave dirt or lint inside the barbs.

Recommended cleaning and disinfecting agents are listed below. In addition, follow your institution’s guidelines for cleaning and disinfecting of devices.

Recommended Cleaning Agents	Mild soaps
	Common bleach 10% solution diluted with water
	Mild detergent mixed with water
	Isopropyl alcohol 70% solution ¹
Recommended Disinfecting Agents	Alcohol based (E.g. Ethanol 70% ¹ , Isopropyl 70% ¹ , Cutasept®, Hospisept®, Kodan® Tinktur Forte, Sagrosept®, Spitacid®, Sterilium®)
	Aldehyde based (E.g. Dilution of formaldehyde (3-5%), Cidex®, Gigasept®)
	Bleach (E.g. Dilution of sodium hypochlorite (laundry bleach): concentration ranging from 500 ppm (1:100 dilution of household bleach), Hydrogen peroxide 3% ¹ , Clorox (1:10 dilution), Dakin’s Solution)
	Phenol based (E.g. Wofasept®, Sporicidin®)

¹Agents have been tested and qualified.

Servicing, Troubleshooting, and Technical Support

Servicing

All servicing and/or repairs are to be completed by Centese-trained personnel only. Daily basis or scheduled basis activity to be performed by a clinical operator to test visual and auditory alarm signals is not required.

Preventive Maintenance

Centese recommends performing basic preventative maintenance on the Thoraguard Control Module every six months. The Control Module should be visually inspected and thoroughly cleaned. To inspect, visually review all surfaces for signs of wear, cracks, damage, or missing components. Minor damage may impact system functionality. Contact Centese if any damage is identified during inspection.

Cleaning should be performed per the cleaning instructions in the Operator's Manual. Special attention should be paid to the face of the control module and canister mounting locations, including the two circular ports near the top. Harder to clean areas include the handle, feet, and power port. Ensure all surfaces are clean, dry, and free from residue, build-up, or debris.

The Thoraguard Control Module should not be disassembled by anyone other than a Centese representative. The Thoraguard Control Module has no annual system calibration requirement.

For a more comprehensive annual maintenance inspection, please contact Centese directly.

Troubleshooting

A list of common problems and possible solutions is below. Please consult Centese Customer Service at 402-300-3150 if the problem cannot be resolved after referring to the list below.

Problem	Potential Solution
Unable to complete system check	<ol style="list-style-type: none">1) Check connections and re-test.2) Replace canister if error persists.
Canister Disconnected Alarm (0035) will not resolve	<ol style="list-style-type: none">1) Re-connect canister.2) Ensure canister latches properly.3) Replace canister.4) If alarm persists despite canister firmly attached and no visible damage, consider replacing Control Module.
Drainage Line Obstructed Alarm (0040) will not resolve	<ol style="list-style-type: none">1) Check tubing for clogs.2) Confirm clamp is unclamped.3) Inspect chest tube connector for build-up.4) Replace drainage line.
Canister Filter Clogged Alarm (0050) will not resolve	<ol style="list-style-type: none">1) Replace canister.2) Replace Control Module.
Excessive Air Leak Alarm (0055) will not resolve	<ol style="list-style-type: none">1) Check all connections for leaks.2) Inspect all tubing for damage.3) Ensure canister is securely attached to Control Module.4) Replace canister and drainage line.

Technical Support

For technical support, please contact Centese Customer Service by phone at 402-300-3150 or by email at customerservice@centese.com.

Additional Resources

Additional troubleshooting resources and supplemental educational materials can be found in the Thoraguard Resource Guide (IFU-2128) or by visiting: <https://www.centese.com/resources/>.

Appendix A: Alarms and Alerts

Visual Alarms / Alerts – Technical and Physiological Alarm Conditions

When an alarm is activated, the LED next to the warning sign on the Control Module will illuminate and the screen will provide a description of the alarm and instructions to resolve the issue.



**Potential device malfunction and / or hazardous patient situation.
Follow on-screen instructions and / or consult Operator's Manual.**

Displayed Message	Description	Alarm Level	What to Do
Use Warnings			
SYSTEM CHECK FAILED 0010	The system check has failed to maintain seal.	Medium	Check connections and re-test. Replace canister if error persists.
CANISTER FULL 0015	The canister is full (over 1200 ml).	Medium	Replace canister.
BATTERY LOW 0020	The battery is low (<20%).	Medium	Connect Control Module to wall power.
PROLONGED STANDBY 0025	The device has been in standby for over 5 minutes.	Medium	Exit standby if no longer desired.
USB NOT PERMITTED 0030	The USB cable has been detected during use.	Medium	Disconnect USB cable.
CLOG CLEARANCE INCOMPLETE 0045	An incomplete clearance cycle has been detected.	Medium	Check chest tube for clogs or kinks.
CANISTER DISCONNECTED 0035	The canister has become disconnected.	High	Re-connect canister.
DRAINAGE LINE OBSTRUCTED 0040	A clog has been detected in the drainage tubing.	High	Check tubing for clogs. Confirm clamp is unclamped.
CANISTER FILTER CLOGGED 0050	The filter in the drainage canister is clogged.	High	Replace canister.
EXCESSIVE AIR LEAK 0055	A large air leak (over 5000 ml/min) has been detected.	High	Check all connections for leaks.
BATTERY DEPLETED 0060	The battery is depleted. Device shutoff is imminent.	High	Connect Control Module to wall power.
DEVICE TIPPED OVER 0065	The device is tipped and at risk of losing suction.	High	Place Control Module upright.
Alarms Based on Alert Settings			
EXCESSIVE DRAINAGE 0110	Drainage has surpassed the alarm threshold rate.	High	Check patient for signs of hemorrhage.
Control Module System Faults			
CONTROL MODULE FAULT 0210	Internal error with Control Module during startup.	Medium	Record error number and contact Centese (402-300-3150).
CONTROL MODULE FAULT 0215	Internal error with Control Module during use.	High	Record error number and contact Centese (402-300-3150).

Appendix B: Technical Specifications

Performance Specifications

Characteristic	Specification
Power Supply	15V \pm 1.8V, DC, 2A EN55011, Class B FCC Part 15, Class B EN61000
Battery Capacity	4 hours
Suction Regulation Capacity	Range: 0 to 100 cmH ₂ O vacuum Accuracy: \pm 10%
Flow Capacity	Range: 0 to 5000 ml/min
Drainage Canister Capacity	1200 ml in all planes 10° from horizontal
Drainage Volume Measurement	Range: 100 to 1200 ml Accuracy: \pm 5%
Air Leak Measurement	Range: 0 to 5000 ml/min Accuracy: \pm 10%

General Characteristics

Parameter	Specification
Dimensions	8 ⁵ / ₈ in (21.9 cm) H x 6 ¹ / ₂ in (16.5 cm) W x 4 ¹ / ₂ in (11.4 cm) D (Control Module and drainage canister connected)
Weight	4.5 lbs (2.0 kgs)
Mobility	Portable
Ingress Protection	IP22
Use / Storage Conditions	Ambient temperature: 50–104°F (10–40°C) Relative humidity: 10–90%, non-condensing Altitude: 0– 2,000 meters (0–6,560 feet) Pressure: 101 kPa to 81 kPa
Electrical Utility Requirements	100–240 V 50–60 Hz 0.5A (0.5–0.3A)
Electromagnetic Compatibility	See Appendix D
Patient Connected Circuits	Type BF (IEC 60601-1) classification Defibrillator-proof NOT ESU compatible (electro-surgical / electro-cautery)
Electrical Safety Designations	Class II Medical Equipment Type CF defibrillator-proof applied parts

Mains of Isolation	Disconnect power supply
Alarms, Alerts	See Appendix A
Alarm Sound Level	58 to 68 dB
Alarm Details	Meets IEC 60601-1-8 requirements Volume: 80 dB at 10cm Frequency: 795 Hz \pm 24 Hz Voltage Range: 5.0 \pm 0.5 V DC Max Current: <250 mA
Data Recording	Data written to internal SD card
Sampling	Pressure: 1x every 10ms Drainage volume: 1x every 10ms
Calculation	Air leak: 1x every 10 seconds
Screen Update	Drainage volume: 1x every second Air leak: 1x every 10 seconds

Appendix C: Patient Risks

There are potential risks associated with using the Thoraguard System:

- bleeding
- malposition
- chest tube dislodgement organ injury
- infection
- skin irritation
- retained blood
- cardiac tamponade
- pneumothorax
- hemothorax
- fibrothorax
- empyema
- fluid overload
- allergic reaction

Appendix D: Guidance and Manufacturer's Declaration

Essential Performance

The Thoraguard Surgical System has been tested to verify ability to provide essential performance in the presence of electromagnetic disturbances as outlined in the summary of tests below. These essential functions include:

- Providing and regulating applied suction
- Displaying applied suction, air leak rate, and drainage volume on the screen
- Alarming when dangerous situations arise

If any of these functions are impacted due to electromagnetic disturbances, suction may cease and the screen may freeze or go dark. The red warning LED will illuminate and the alarm will provide a continuous warning tone. Should this occur, please restart the device. If functionality does not resume upon reboot, please replace the Control Module with another unit and contact Centese at 402-300-3150.

Electromagnetic Emissions


The Thoraguard Control Module is intended for use in the electromagnetic environment specified below. The customer or the user of the Thoraguard Control Module should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF Emissions CISPR 11	Group 1	The Thoraguard Control Module uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations / Flicker Emissions IEC 61000-3-3	Complies	

Electromagnetic Immunity

The Thoraguard Control Module is intended for use in the electromagnetic environment specified below. The customer or the user of the Thoraguard Control Module should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV contact discharge ±15 kV air discharge	±8 kV contact discharge ±15 kV air discharge	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	AC power ports: ±2 kV	AC power ports: ±2 kV	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	AC power ports: ±2 kV (line to ground) ±1 kV (line to line)	AC power ports: ±2 kV (line to ground) ±1 kV (line to line)	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	AC power lines: Reduction 30%, 25 periods; Reduction 60%, 5 periods; Reduction 100%, .5 periods; Reduction 100%, 5 seconds	AC power lines: Reduction 30%, 25 periods; Reduction 60%, 5 periods; Reduction 100%, .5 periods; Reduction 100%, 5 seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Thoraguard Control Module requires continued operation during power mains interruptions, it is recommended that the Thoraguard Control Module be powered from an uninterruptible power supply or battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
<p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p>	<p>AC power ports, 0.15-80 MHz, 3 V_{rms}, 80% AM at 1 kHz</p>	<p>AC power ports, 0.15-80 MHz, 3 V_{rms}, 80% AM at 1 kHz</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of the FGN-1387, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance $d = (1.2)\sqrt{P}$ $d = (1.2)\sqrt{P}$ 80 MHz to 800 MHz $d = (2.3)\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>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</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
<p>NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.</p>			
<p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			
<p>^aField strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur 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 FGN-1387 is used exceeds the applicable RF.</p>			
<p>^bOver the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			

Separation Distance

The Thoraguard Control Module is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Thoraguard Control Module can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Thoraguard Control Module as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = (3.5/v_1)\sqrt{P}$	80 MHz to 800 MHz $d = (3.5/E_1)\sqrt{P}$	800 MHz to 2.5 GHz $d = (7/E_1)\sqrt{P}$
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 1 At 80 MHz and 800 MHz, the separation distance for 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.
