# THORAGUARD SURGICAL DRAINAGE SYSTEM



# **RESOURCE GUIDE**

IFU-2128 Ver 8 11-04-2024

### Scope of Resource Guide

The Thoraguard Resource Guide is a supplement to the Thoraguard Operator's Manual and not to be used in place of the Operator's Manual. The information and figures contained within the Resource Guide are an abbreviated version of those found in the Operator's Manual. For a complete description of Thoraguard's operation or a comprehensive list of instructions, please refer to the Thoraguard Operator's Manual.

#### **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.

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

Thoraguard is a registered trademark of Centese, Inc. Patent: www.centese.com/patents © 2024 Centese, Inc. All rights reserved. Printed in the USA.

Centese, Inc. 4156 S 52<sup>nd</sup> St Omaha, NE 68117 402-300-3150 www.centese.com

# **Table of Contents**

Thoraguard Home Screen Navigation	4
4" x 6" Reference Cards	5
Thoraguard Chest Tube OR Tips	6
Clog Clearance Settings	7
Example Clog Clearance Incomplete Workflow	8
Clamping Chest Tubes with Thoraguard	9
Air Leak Assessment with Thoraguard	10
Thoraguard Canister Replacement Sequence	11
Thoraguard System Check Sequence	12
System Check Fail Troubleshooting	13
Thoraguard Fluid Sample Guide	14
Thoraguard SmartCheck Guide	15
Multi-Step Alarm Troubleshooting	17
Using the Drainage Tubing Clamp	18
Frequently Asked Questions (FAQs)	19
Thoraguard After Use Processing	21
Thoraguard Cleaning Instructions	22
Thoraguard Instructional Videos	23
Suggested Competencies Training Form: Bio-Engineering Team	24
Suggested Competencies Training Form: OR Team	25
Suggested Competencies Training Form: Patient Care Location Team(s)	26
Suggested Competencies Training Form: Materials Management / Supply Team	27



### **Thoraguard Home Screen Navigation**

4" x 6" Reference Cards





# **Thoraguard Chest Tube OR Tips**





The Thoraguard Chest Tube is a proprietary chest tube for use only with the Thoraguard Drainage System. Due to the unique design and to ensure proper functionality of the Clog Clearance feature, the following tips may help optimize results:



Submerge Thoraguard Chest Tube in saline or sterile water for at least 10 seconds prior to use



Position drainage holes for optimal access to draining fluid



Ensure all chest tubes and connectors are free from blood / fluid build-up or other surgical materials prior to connecting to Thoraguard Drainage System



Do not cut or create additional holes in the chest tube



Surgical Sealants and Hemostatic Agents should not come in contact with chest tubes



Do not over-tighten sutures on chest tubes during securement



Do not apply direct suction to the relief (small) lumen of the chest tube

## **Clog Clearance Settings**

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

When clog clearance is enabled and dynamic mode is selected, Thoraguard automatically monitors for the completeness of the clog clearance cycle. If the system cannot detect the completion of the clog clearance cycle, Thoraguard will alarm.

Although the clog clearance incomplete alarm is not necessarily an indicator of an obstructed chest tube, always check the chest tube and SmartValve for potential obstructions when the alarm activates. During this time, the system will continue to provide suction at the pre-determined setting, including ongoing activation of the clog clearance functionality.

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 again monitor for completeness of the clog clearance cycle. Clog clearance may also be turned off.



### 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.

### Continuous Clog Clearance

Continuous clog clearance maintains suction at -100 cmH<sub>2</sub>O to clear the tube continuously. To enable this mode, press "CONTINUOUS" —the user must then 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.

[!] Continuous clog clearance maintains suction at -100 cmH<sub>2</sub>O. Clog clearance incomplete alarms are unavailable in this mode.

# **Example Clog Clearance Incomplete Workflow**



Timing (Post-Op)	0 - 24 hours	24 - 72 hours	72 hours +	
Alarm 1	Check for chest tube kinks and visible build-up. Correct and press NO			
2nd Alarm (within 60 minutes of Alarm 1)	YES Continuous Mode 1-hour	Continuous Mode 1-hour	Continuous Mode 1-hour (2x with each additional alarm) or Disable Clog Clearance if clinically appropriate	
Alarm 3+	Continuous Mode 2-hour (2x with each additional alarm)	Continuous Mode 2-hour (2x with each additional alarm) or Disable Clog Clearance if clinically appropriate		

### **Clamping Chest Tubes with Thoraguard**

In certain clinician directed scenarios, it may be desirable to purposely seal off a patient's chest tube(s). To properly clamp a Thoraguard Chest Tube, the clamp should span both the drainage lumen and relief lumen as shown in Figure 1. To clamp a non-Thoraguard chest tube, the clamp should be placed on the chest tube as shown in Figure 2. The drainage tube should not be clamped (Figure 3). Thoraguard does not need to be powered down.



Figure 1: Clamped Thoraguard Chest Tube



Figure 2: Clamped Traditional Chest Tube



Figure 3: Incorrect Clamp location

# Air Leak Assessment with Thoraguard

Thoraguard's digital air leak displays current and historical data to assess patient air leak and to inform clinical decisions. The information supports a comprehensive clinical assessment.

### CURRENT:

A real-time measurement patient air leak. Measured as the volume of air removed in mL/min.

### AVERAGE AIR LEAK

The average air leak measured over the specified time period. Default display is PAST HOUR (prior 60-minutes). Touch to display PAST 6 HOURS, PAST 12 HOURS, or PAST 24 HOURS.



### AIR LEAK TRENDS GRAPHS

Displays patient air leak rate over 6-hour, 12-hour, and 24-hour time periods. This may be used to identify trends in a patient's air leak over time and the incidence of recent air leak fluctuations.



Air leak graphs update with incremental bars that represent the average air leak value over a 5-minute period. Note that the "Air Leak Rate" axis of the graph automatically adjusts.



### PLEURAL ASSESSMENT:

# Note: this functionality only works with a chest tube in the intrapleural space.

A digital surrogate for patient tidaling. Pleural Assessment provides a real-time measurement of pressure at the drainage tubing barb as a proxy for pleural pressure.

The pleural assessment can be accessed at any point in therapy and may be useful if the clinician desires to monitor for tidal oscillations or pressure fluctuations generated by patient maneuvers such as a Cough or Valsalva, or to check that the chest tube is not occluded.

### **Thoraguard Canister Replacement Sequence**



**PROCEED: Complete System Check Sequence**\* (next page) \*Failure to complete System Check Sequence after Canister Replacement will result in inaccurate data readings

# **Thoraguard System Check Sequence**

- 1. Confirm the canister is firmly attached and check off on screen. [A]
- 2. Confirm all tubing is properly connected and check off on screen. [B]
- 3. Properly clamp drainage tube and check off on screen. [C]
- 4. Press "BEGIN SYSTEM CHECK" to continue. [D]









### SYSTEM CHECK FAILED Warning:

- 1. Check canister connection.
- 2. Confirm tubing connection.
- 3. Unclamp tubing and re-clamp ensuring clamp is <u>fully engaged and tubing is fully sealed</u>.
- 4. Press RESUME.
- 5. Re-try System Check Sequence.

# System Check Fail Troubleshooting



### Troubleshooting Stage 1:

- A. Ensure canister is properly connected.
- B. Confirm canister latch is fully engaged
- C. Confirm drainage lines are securely attached.
- D. Clamp tubing prior to system check
  - 1. Consider using additional clamp (double clamp)
- E. Re-try system check sequence

#### IF SYSTEM CHECK FAILED Move to Troubleshooting Stage 2







#### Troubleshooting Stage 2:

- A. Canister may be damaged
  - 1. Replace canister (retain drainage line)

#### IF SYSTEM CHECK FAILED

Move to Troubleshooting Stage 3

#### Troubleshooting Stage 3:

A. Drainage line may be damaged1. Replace drainage line

#### IF SYSTEM CHECK FAILED Move to Troubleshooting Stage 4

### Troubleshooting Stage 4:

- A. Control Module may be damaged
  - 1. Replace Control Module
    - 2. Tag Control Module for service inspection





# **Thoraguard Fluid Sample Guide**



## **Thoraguard SmartCheck Guide**

#### SmartCheck Functionality

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 5-95mL/min
- Average air leak 5-95mL/min
- Maximum air leak 5-95mL/min
- Drainage output 50-500mL

N/A Past 2HR, 4HR, 6HR, and 12HR Past 2HR, 4HR, 6HR, and 12HR Last 6HR, 8HR, 12HR, and 24HR



### SmartCheck Setup

#### SmartCheck Settings

The threshold values for each SmartCheck criterion can be accessed from the SmartCheck settings screen. From this screen, each criterion can be turned ON or OFF, a status indicator for each criterion is displayed, and each criterion threshold can be viewed and adjusted as needed. Criteria may be turned ON or OFF at any time.



SmartCheck Settings Screen

SmartCheck Criterion #2 Settings Screen

#### SmartCheck In Use

On the main screen, in the bottom center area, the SmartCheck button allows access to the SmartCheck settings screen.

In addition, the button appearance changes to indicate the real-time status of SmartCheck.



#### SmartCheck Complete Notification

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.



## **Multi-Step Alarm Troubleshooting**

A selected list of alarms and troubleshooting steps is provided below. "What to Do" with multiple troubleshooting steps should be followed sequentially. Should a step yield a resolved alarm condition further progression is not necessary.

Displayed Message	Description	Alarm Level	What to Do
	Use Warnings	;	
CANISTER DISCONNECTED 0035	The canister has become disconnected.	High	<ol> <li>Re-connect canister.</li> <li>Ensure canister latches properly.</li> <li>Replace canister.</li> <li>If alarm persists despite canister firmly attached and no visible damage, consider replacing Control Module.</li> </ol>
DRAINAGE LINE OBSTRUCTED 0040	A clog has been detected in the drainage tubing.	High	<ol> <li>Check tubing for clogs.</li> <li>Confirm clamp is unclamped.</li> <li>Inspect chest tube connector for build-up.</li> <li>Replace drainage line.</li> </ol>
CANISTER FILTER CLOGGED 0050	The filter in the drainage canister is clogged.	High	1) Replace canister. 2) Replace Control Module.
EXCESSIVE AIR LEAK 0055	A large air leak (over 5000 ml/min) has been detected.	High	<ol> <li>Check all connections for leaks.</li> <li>Inspect all tubing for damage.</li> <li>Ensure canister is securely attached to Control Module.</li> <li>Replace canister and drainage line.</li> </ol>
Control Module System Faults			
CONTROL MODULE FAULT 0210	Internal error with Control Module during startup.	Medium	<ol> <li>Restart Control Module</li> <li>Replace Control Module and return unit to Centese for repair</li> </ol>
CONTROL MODULE FAULT 0215	Internal error with Control Module during use.	High	<ol> <li>Restart Control Module</li> <li>Replace Control Module and return unit to Centese for repair</li> </ol>

# 24/7 Tech Support: 402-300-3150

### Using the Drainage Tubing Clamp

When clamping the drainage tubing, clamp perpendicularly across the tubing with the large tube facing the inside hinge. Position the tube near the inside hinge and clamp without overlapping the tubing as shown below:



## **Frequently Asked Questions (FAQs)**

#### 1. Canister drainage reading displays "NOT LEVEL"

Thoraguard has integrated leveling sensors in the control module which improve the accuracy of digital measurements. When in use, if the control module is not held upright or placed on a level surface the words "NOT LEVEL" appear under "CANISTER" drainage measurement section of the Home Screen. To resolve this, place the control module on a level surface and wait for the system to stabilize-this may take a few moments.

Note, if Thoraguard has less than 200 mL of drainage, the control module must be level within  $\pm 5^{\circ}$ . If greater than 200 mL of drainage has accumulated, the control module must be level within  $\pm 10^{\circ}$ . This notification is different than the "Device Tipped Over" Alarm.

#### 2. Canister drainage reading is higher than actual amount of fluid in canister

When Thoraguard has been calibrated properly, the accuracy of the drainage volume measurement is  $\pm 5\%$  of the total volume of fluid in the canister. This applies to volumes greater than 100 mL. If the digital display of Canister exceeds the actual volume amount by more than approximately 5%, this may be a caused by specific scenarios:

- a) Excessive fluid sloshing or foaming during movement or ambulation this can cause digital readings to skew high due to fluid movement in the canister. Once increased, the digital readings do not return lower. If no further sloshing occurs, normal fluid accumulation will cause the total amount of fluid to match the digital reading, at which point the measurements will once again begin to correlate accurately. Alternatively, the canister may be replaced with a new canister and completion of the Canister Replacement sequence.
- b) If the canister is tipped over this may result in the fluid measurement sensors incorrectly detecting an increase in fluid volume. This can result in a discrepancy between the digitally displayed fluid drainage levels and actual fluid levels. If this occurs, Thoraguard should be kept in a stable and upright position until normal fluid accumulation will cause the total amount of fluid to match the digital reading, at which point the measurements will once again begin to correlate accurately. Alternatively, the canister may be replaced with a new canister and completion of the Canister Replacement sequence.
- c) The canister was replaced, but system check was not completed correctly. When the Canister Replacement sequence is performed completely, the drainage reading under canister resets to -- mL. If this scenario occurred, the Canister Replacement sequence can be re-run with the existing canister if less than 50 mL of fluid is in the canister. If there is greater than 50 mL of fluid in the canister a new replacement canister should be connected and Cannister Replacement with System Check should be completed correctly.

#### 3. Canister Full Alarm continues despite canister being recently replaced

If the canister is replaced, but system check is not completed correctly, the Canister Full Alarm may continue to trigger. If the Canister Replacement sequence is performed correctly, the canister drainage reading displayed resets to -- mL. If this occurred and there is <50 mL of fluid is in the canister, the Canister Replacement sequence can be re-run with the existing canister. If there is >50 mL of fluid in the canister a new replacement canister should be connected and the full Canister Replacement sequence performed.

#### 4. The Control Module is not charging despite being plugged in

Troubleshooting steps:

- a) Confirm that the correct power supply is being used. The words "Centese Thoraguard" should be prevalent on the black power transformer.
- b) Ensure that the connection between the gray power cord and black transformer is secure and the green light on the black transformer is illuminated when the power cord is plugged.

c) The power plug is fully inserted into the power port on the side of the Control Module. In some cases, the connection may feel snug, but the system requires additional force to engage the final 1/8". Rotating the plug while pushing into the power port may help.

The charging battery icon will appear when the control module and power supply are properly connected.

#### 5. Can the Clog Clearance feature be used with any chest tube?

No. The Clog Clearance feature is for use with the Thoraguard Chest Tube Kit only. The Thoraguard Control Module and Drainage Kit can be used with any standard chest tube. However, activating the Clog Clearance feature with a chest tube other than a Thoraguard Chest Tube will not provide active clearance and may trigger a Clogged Chest Tube alarm.

#### 6. If a Control Module needs to be replaced while on a patient, can I use the same canister?

No. If a Control Module needs to be replaced while providing therapy to a patient, a new canister should be used and the New Patient set-up sequence should be followed. Re-use of an existing canister will cause errors in the drainage readings. If the drainage tubing connected to the chest tube is intact, this may be reused.

#### 7. The System will not pass system check, what do I do now?

For Thoraguard to pass system check, the Control Module must have 3 core steps in place during the entire system check process:

- A. The canister must be firmly attached to the Control Module with both feet (located at the base of the system) engaged and the canister securely latched.
- B. Both drainage lines must be securely connected. Note, over-tightening of the connectors may result in damage to the canister.
- C. The drainage line must be entirely clamped so that no airflow can occur during the entire system check sequence.

The first step of troubleshooting should be to re-try the system check sequence confirming A–C above. Additional troubleshooting steps can be found on Page 13 of this Resource Guide.

#### 8. Does Centese have Technical Support?

Yes. Technical Support via phone is available 24/7. Call: 402-300-3150.

### **Thoraguard After Use Processing**

Thoraguard Control Module and Power Supply should be cleaned and reused following standard hospital wipe down protocols.



Storage location for cleaned units: \_\_\_\_\_

Contact for storage cleaned units: \_\_\_\_\_

Note: 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.** 

### **Thoraguard Cleaning Instructions**



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.

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

Acceptable Common Cleaning Wipes:



### **Thoraguard** Instructional Videos



Thoraguard Instructional Video – Full Length (19:39)



Thoraguard – Set-up in the OR Guide (3:29)



Thoraguard – System Operation Overview (1:32)



Thoraguard – Data Trends Overview (1:54)



Thoraguard – Canister Replacement Guide (2:16)



Thoraguard – Taking a Fluid Sample Guide (0:46)



Thoraguard – Pleural Assessment Overview (0:36)



Thoraguard – Settings Menu Overview (1:12)



Thoraguard – Power Down & Disconnection Guide (1:21)



Thoraguard – Chest Tube Set-up Guide (3:06)



Thoraguard – Set-up Outside of the OR Guide (2:07)



Thoraguard – Clog Clearance Incomplete Guide (1:03)

### Suggested Competencies Training Form: Bio-Engineering Team

THORAGUARD COMPETENCY			YES	NO	N/A
Opening shipment packaging and removin	ng com	ponents			
Identification of serial number location					
Location and storage of IFU / Operator's N	<i>l</i> anual				
Review of product specifications					
Attaching power cord and charging					
Powering on and off					
Setting date and time for user location					
Confirming set-up / calibration					
Cleaning instructions					
Location of spare power cords					
Transfer to charging / use locations					
Location of Centese service / repair inform	nation				
Location of Centese main contact informat	tion				
Name:	Date:				
Print Name:	-				
Location:	Shift				
	_ Or in t				
Confirmed by:		Date:			

### Suggested Competencies Training Form: OR Team

THORAGUARD COMPETENCY	YES	NO	N/A
Location of disposables and Control Modules			
Control module power cord and charging / status			
Opening Drainage and Chest Tube Kits while maintaining sterility			
Presentation of Kits to the Sterile Field			
Location of Thoraguard Drainage Kit Set-up Instructions			
Location of Thoraguard Chest Tube Kit Set-up Instructions			
Correct removal and hydration of Thoraguard Chest Tube			
Maintenance of SmartValve in a dry location			
Flush Thoraguard Chest Tube with sterile water / saline			
Attaching SmartValve to Thoraguard Chest Tube			
Correct attachment of the canister and drainage tube set			
Correct placement and use of set up clamp			
Turning Control Module power on / off			
Set-up positioning of Control Module outside of sterile field			
Performing System Check set up			
Connection to Thoraguard SmartValve and Chest Tube			
Connection to a standard chest tube			
Changing suction level setting			
Setting to SmartSeal - Zero Suction Mode			
Set-up of Clog Clearance feature			
Use of Clog Clearance Incomplete workflow			
Configuring Drainage Alarm			
Disable Air Leak Display			
Pleural Assessment feature			
Assessing initial drainage and air leak			
Understanding and managing Alarms and Notifications			
Transport from OR with power charging cord			
Control Module handle / hook adjustment			
Location of Centese contact information			
Review of Thoraguard Warnings and Precautions in Operator's Manual			
SmartCheck configuration and setup		ļ	
		ļ	

Name:	Date:
Print Name:	-
Location:	_Shift:
Confirmed by:	Date:

Thoraguard Competency Training - Sample for reference purpose only

### Suggested Competencies Training Form: Patient Care Location Team(s)

THORAGUARD COMPETENCY	YES	NO	N/A
Location of Thoraguard Operator's Manual			
Location of replacement Thoraguard Disposables and Control Modules			
How to ambulate or transport patients with Thoraguard			
Control Module handle / hook adjustment			
Control Module Power Supply connection and charging status			
Maintaining aseptic technique during canister replacement			
Correct replacing a canister			
Replacement of drainage tube			
Correct performance of system check			
Changing suction setting			
Setting to SmartSeal - Zero Suction Mode			
Understanding and resolving Alarms and Notifications			
How to check for air leak			
Monitoring fluid drainage			
Using Pleural Assessment feature			
Identifying necessary patient data for documentation			
Historical data review (ex. Last Hour, Past Hour, Trends, etc.)			
How to draw a fluid sample			
When to use Clog Clearance feature			
Activating Clog Clearance			
Use of Clog Clearance Incomplete Workflow			
Disposal of single-use materials			
Power down / turning off			
Restart after unintentional power down			
Thoraguard Control Module and power cord cleaning			
Destination of Control Module and power cord after removal			
Location of Centese contact information			
Review of Thoraguard Warnings and Precautions in Operator's Manual			
SmartCheck settings, status indication, usage and notification			
Name: Date:			

Print Name: \_\_\_\_\_

Location: \_\_\_\_\_ Shift: \_\_\_\_\_

Confirmed by: \_\_\_\_\_

Date: \_\_\_\_\_

Thoraguard Competency Training - Sample for reference purpose only

### Suggested Competencies Training Form: Materials Management / Supply Team

THORAGUARD COMPETENCY	YES	NO	NA
Centese part numbers loaded			
Centese shipment / case and order quantities confirmed			
Centese warranty and return policies reviewed			
Cleaning instructions reviewed			
Return Control Module and Power Cord to storage location			
Location of spare power cords			
Location of Centese service / repair information			
Location of Centese main contact information			

Name:	Date:
Print Name:	
Location:	Shift:
Confirmed by:	Date: