FAQ

Thopaz™

Thopaz is the state-of-the-art mobile system in the market of digital thoracic drainages
## Glossar/Definitions

<table>
<thead>
<tr>
<th>Term</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Thoracic drainages</strong></td>
<td>Thoracic drainages are designed to remove air, liquids, and solids (fibrinous elements) from the pleural space or mediastinum, which collect there as a result of injury, disease, or surgical procedure (E. Munnell, 1997).</td>
</tr>
<tr>
<td><strong>Thoracotomy</strong></td>
<td>Thoracotomy is an incision into the chest. It is performed by a surgeon, and, rarely, by emergency physicians, to gain access to the thoracic organs.</td>
</tr>
<tr>
<td><strong>Lobectomy</strong></td>
<td>Surgical procedure to remove a lobe</td>
</tr>
<tr>
<td><strong>Pneumonectomy</strong></td>
<td>Surgical procedure to remove a lung</td>
</tr>
<tr>
<td><strong>Wedge resection</strong></td>
<td>Surgical procedure to remove a triangle-shaped slice of lung tissue</td>
</tr>
<tr>
<td><strong>Sleeve resection</strong></td>
<td>Surgical procedure to remove a lung tumor in a lobe of the lung and a part of the main bronchus (airway). The ends of the bronchus are rejoined and any remaining lobes are reattached to the bronchus. This surgery is done to save part of the lung.</td>
</tr>
<tr>
<td><strong>Lymphadenectomy</strong></td>
<td>Lymphadenectomy consists of the surgical removal of one or more (lymph node dissection) groups of lymph nodes. It is almost always performed as part of the surgical management of cancer.</td>
</tr>
<tr>
<td><strong>Pneumothorax</strong></td>
<td>Pneumothorax is a potential medical emergency wherein air or gas is present in the pleural cavity. A pneumothorax can occur spontaneously. It can also occur as the result of disease or injury to the lung, or due to a puncture to the chest wall. A pneumothorax can result in a collapsed lung, or can be created therapeutically to collapse a lung.</td>
</tr>
<tr>
<td><strong>Tension-Pneumothorax</strong></td>
<td>This condition occurs when air rapidly accumulates in the pleural cavity and cannot be evacuated. Pressure builds up, the lung collapses and the mediastinum can be shifted which severely block venous return and cardiac output. Especially at risk are patients receiving positive pressure ventilation.</td>
</tr>
<tr>
<td><strong>Haemo-Pneumothorax</strong></td>
<td>Air tends to collect at the top of the lung causing a condition called a “pneumothorax”. Blood and fluids will collect in the lower part of the lung; a condition known as a “haemothorax”. The combination of both conditions is called a “haemo-pneumothorax”.</td>
</tr>
</tbody>
</table>
Emphysema

Emphysema is a chronic obstructive pulmonary disease. Emphysema is commonly associated with bronchitis and chronic bronchitis. The walls between the air sacs in the lung (alveoli) lose their elasticity. This causes the alveoli to become fragile and over-inflated, leading to unnatural retention of air within the lungs and making breathing increasingly difficult. Lung volume reduction surgery (LVRS) can improve the quality of life for certain carefully selected patients. Parts of the lung that are particularly damaged by emphysema are removed, allowing the remaining, relatively good lung to expand and work better.

Empyema

Empyema is a collection of pus in the pleural space. In 50% of the cases the empyema is a consequence of pneumonia.

A surgical procedure with decortication might be required. This involves opening the chest, taking out the fluid, peeling the thick rind of infectious material off the lung, and then inserting chest tubes while the infection clears (usually with the help of antibiotics). Chest tubes in the setting of empyema have a tendency to become clogged. Chest tube clogging in the setting of an empyema can lead to re-accumulation of pus and infected material, a worsening clinical picture, organ failure and even death. Thus managing chest tube clogging is particularly important after the treatment of an empyema.

Pleural effusion

Pleural effusion is defined as an abnormal accumulation of fluid in the pleural space. It is an indicator of a pathologic process that may be of primary pulmonary origin or of an origin related to another organ system or to systemic disease. Congestive heart failure, pneumonia, malignancy, and pulmonary emboli account for most pleural effusions.

Treatment depends on the underlying cause of the pleural effusion. Therapeutic aspiration may be sufficient; larger effusions may require a thoracic drainage.

Repeated effusions may require chemical or surgical pleurodesis, in which the two pleural surfaces are scarred to each other so that no fluid can accumulate between them.

Pleurodesis

Pleurodesis is the artificial obliteration of the pleural space. It is done to prevent recurrence of pneumothorax or pleural effusion. It can be done chemically or surgically.

Chemicals such as bleomycin, tetracycline, or a slurry of talc can be instilled into the pleural space. The chemicals cause irritation between the parietal and the visceral layers of the pleura which closes off the space between them and prevents further fluid from accumulating.

Surgical pleurodesis is performed via thoracotomy or thoracoscopy. This involves mechanically irritating the parietal pleura, often with a rough pad. Moreover surgical removal of parietal pleura is an effective way of achieving stable pleurodesis.
Questions to Thopaz

How does the water seal function work?

Thopaz as a system is tight. Air cannot flow back to the pleural space if the pump does not run.

Additionally, a check valve inside Thopaz maintains the negative pressure on the patient side. It prevents air from re-entering the pleural space and potentially causing a pneumothorax:
- if the set vacuum value is reached
- if the battery is defective
- if the pump is defective

How do I change the pressure unit?

We refer to the IfU:
Adjust default settings from standby-mode

a) With the selection buttons choose the desired parameters and confirm with “OK”.
b) With the selection buttons choose the desired setting and confirm with “OK”.
c) With the “Back” button the setting mode is ended, and standby mode is activated.
How does the gravity mode work?

For patients who are to be treated by gravity drainage (= water seal), the gravity mode can be activated. This mode corresponds to the average pressure level in the pleural space of a healthy adult person (0.8 kPa / 8 cmH2O / 8 mbar / 6 mmHg).

Change Pressure while pump is running

- a) Press the «Standby» and «Graph» button at the same time. The pressure field will be highlighted.
- b) With the selection buttons, choose the desired pressure and confirm with «OK».
- c) To activate the gravity mode (=water seal), skip b) and press [ ] and confirm with «OK».

Does the flow number calculate fluids?

It does, but the fluid flow rate is minimal compared to the air flow rate:

**Example**

Patient fluid flow rate first day post-op 1000 ml/24h
(1000 ml/24h = 0.70 ml/min)
Average air flow rate first day post-op 500 ml/min
➡ Ratio fluid to air = 1:1400

Conclusion: The fluid flow rate accounts only for a very small fraction of the flow rate.

What is the ‘leakage’ warning?

In case of an unproblematic healing process the flow decreases over the course of therapy. The curve on the graph corresponds to this development. An increase in flow over a certain period of time can be an indicator of leakage in the system or an irregularity in the course of the therapy.

If following conditions are maintained for more than 5min, the warning ‘leakage’ is set off.
- Flow<300ml ➔ +300ml
- Flow<600ml ➔ +75%
- Flow>600ml ➔ +50%

The default settings are on OFF. The leakage warning can be set on ON in the pump settings if required.
<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>What is the difference between ‘Leakage’ and ‘Leak in system’?</td>
<td>In case of leakage, Thopaz can maintain the pressure by compensating the additional air leak. The pressure on the patient side is maintained. In case of leak in system, Thopaz cannot maintain the pressure. The pressure on the patient side is not maintained.</td>
</tr>
<tr>
<td>When will I see a graph on-screen?</td>
<td>Every 10 minutes the flow and pressure are averaged and then plotted on the graph. The flow is represented as a line and the pressure is shown as a solid area. The graph is generated after the patient has been on the system for 10 minutes but it is too small to see. After 4 hours of use, the graph is more prominent.</td>
</tr>
<tr>
<td>Is it possible to extract the digital data during the patient’s therapy?</td>
<td>No. While extracting the graph from the pump to the PC, the software also purges the information from the pump. After the information is purged, there is no way of resuming the previous therapy. By pressing ‘No’ to question – ‘New patient’, will not work. Note: Once the information is extracted the information is purged from the pump.</td>
</tr>
<tr>
<td>Does the data need to be extracted from the pump following each patient?</td>
<td>No, if the therapy number and pump’s serial number are recorded on the patient’s file.</td>
</tr>
<tr>
<td>How is the graph linked to the patient when extracted to the PC?</td>
<td>When the graph is extracted, it records on the graph the therapy and pump’s serial number. Note: Record the therapy number and pump’s serial number on patient’s record when the therapy begins.</td>
</tr>
<tr>
<td>What is the run-time of the battery if fully charged?</td>
<td>The charge on the battery is dependent upon the run-time of the pump. This is influenced by the extent of parenchymal leakage and the set pressure. It only runs when there is a difference between the set and current pressure. If Thopaz is running continuously, Medela guarantees a maximum of 4 hours of battery before it is necessary to re-charge (if Thopaz was initially fully charged). This case will not be encountered in practice; the real expectant charge of the battery exceeds 10 hours.</td>
</tr>
<tr>
<td>How long does the backup battery last?</td>
<td>The backup battery makes sure that the buzzer sounds for at least 3 minutes, in order to warn the user that the battery is completely empty and the pump is not running any more.</td>
</tr>
<tr>
<td>What happens if the battery of the pump is completely empty?</td>
<td>The pump keeps the settings and the data of previous patients but the record of the patient treated while the shutdown occurred will be lost. Charge the battery as quickly as possible.</td>
</tr>
</tbody>
</table>
**Does Thopaz have an internal clock?**

The internal clock of Thopaz is set on GMT. It is not displayed.

However, Thopaz’ internal clock will automatically synchronise with the PC as soon as ThopEasy is started.

**Are there spare parts for Thopaz?**

Yes. We refer to the spare parts concept.

**How can I clean Thopaz?**

We refer to the IfU and the Medela cleaning instructions (Art.No. 200.2391).

<table>
<thead>
<tr>
<th></th>
<th>Cleaning</th>
<th>Disinfection</th>
<th>Rinse cycle in washing machines</th>
<th>Sterilisation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thopaz / Docking station Accessory (e.g. docking station, carrying strap)</td>
<td>✔️</td>
<td>✔️</td>
<td>✗</td>
<td>✔️</td>
</tr>
<tr>
<td>Wipe off with a damp cloth.</td>
<td>Wipe off with a disinfecting agent, e.g., Mikrozid AF Liquid (supplier Schülke + Mayr).</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Classification according to RKI* guideline: non-critical**

**Disinfection**

Thopaz can be disinfected with the disinfecting agent group “alcohol”.

**Do not use** other cleaning agents (e.g. Terralin) as they can damage the plastic housing.

Immersion disinfection, thermal disinfection and ultrasound cleaning are not permitted.

**Sterilisation**

Thopaz and Thopaz accessories cannot be sterilised.

* Robert Koch Institute

---

Caution: This is a single use product not intended to be reprocessed. Reprocessing could cause loss of mechanical, chemical and / or biological characteristics. Reuse could cause cross contamination.
Questions as to the use of Thopaz

What are the main indications for the use of Thopaz?

The primary market for Thopaz is the drainage of the pleural space after surgery, injury or disease.

- Thoracic or general surgery departments (being the preferred intended use for Thopaz): lung surgery for the treatment of tumors, empyemas, emphysemas, traumas, etc.
- Pulmonology: treatment of lung diseases, pneumothoraces, pleural effusions, etc. can also lead to a surgery and/or a thoracic drainage
- ICU: traumas, intensive care medicine of respiratory systems
- Cardiac surgery: drainages being applied in the pleural space (please note that the drainage of the mediastinum does not require flow measurement). This application is not the primary market for Thopaz.
- Other surgeries, like operations on the oesophagus, the trachea, the diaphragm, etc. and when the pleural space is injured. These applications are not the primary markets for Medela, as we do not have a deep knowledge about them.

Note: We do not assume this information is complete.

Do you know particular conditions where Thopaz seems to reduce inpatient times?

The research performed with Thopaz demonstrates the medical, workload and financial benefits of the Thopaz system:

We refer to off-prints of Thopaz clinical studies, Thopaz Research Summary (pdf) and research presentations available on extranet.

Where are my bubbles gone?

Bubbles are difficult to quantify and only provide a snapshot of the situation. Changes in the air leak over time cannot be identified.

With Thopaz, for the first time users can objectively quantify the amount of air leak, in addition to the display of that data in trend format over a 24-hour period.

See-at-a-glance digital display of the parenchymal leakage in real-time (flow values) gives a precise picture of the healing process.

The digital flow display shows the flow and pressure over 24 hours.

The physician can detect any changes in the flow early and take appropriate measures quickly. In addition, with Thopaz, a reliable baseline is generated to make the decision to discontinue the drainage easier.
When do I pull the drain?

With traditional chest drains, the drains are pulled when there is no air leak (no bubbles in the water seal, even after the cough test) and the amount of secretion is below 200 - 450ml/day, depending on the country.

With Thopaz the users have to follow their own clinical protocols and try to correlate the data from Thopaz with their clinical assessment, and gain confidence that way to relate back the air leak value (or range of values) as to the best time for catheter removal.

Experience from the field

Primarily the user looks at the trend of the curve as well as the general condition of the patient. Generally x-ray photos are done for control purposes, especially at the start of the trial period. The amount of x-rays needed will decrease when more experience has been gathered with Thopaz.

Example of therapy progress

- High flow after connecting Thopaz to patient (1600 – 2500 ml/min)
- Reduction after patient moved onto back (500 – 1000 ml/min)
- Further reduction after extubation on value which remains stable during the first hours
- Continuous further reduction during following days
- Removal of drain when continuous air leak is graphed at no more than 50 ml/min without large variation for the prior 6 - 12 hours.

For the start of the evaluation we recommend to state „no bubbles“ equals 0 ml/min. To make a decision on when to pull the drain, follow the standard protocols to start with (e.g. no air leak for 24 hours and secretion loss of ≤ 250ml/24 hours). If unsure that the lung is expanded, perform X-rays. More aggressive treatment to optimize the therapy can be applied as the experience with the system increases.

Note: Chest tube management protocols elaborated by Dr K. Papagianopoulos and other KOLs are available from the extranet.
Other examples:
Questions as to the use of Thopaz

How do I manage a large pleural effusion with Thopaz?

In case of a pleural effusion, a canister can be connected between the patient and the patient tubing (not available from Medela).

Can I use Thopaz on patients after a pleurodesis procedure?

The experience shows that in case of a talc poudrage (insufflation of talc powder) with 4 to 8g talc, the use of Thopaz on pleurodesis patients is not a problem.

If talc slurry is used and the slurry comes through the Thopaz tube, the tube may get clogged. In this case the alarm „system clogged“ might sound and the tubing must be replaced.

How does Thopaz behave in case of ventilated patients?

During ventilation a positive pressure is imparted, thus generating an artificial positive pressure in the pleural space. Thopaz detects positive pressure and starts to run to restore the set pressure - which is negative - and consequently displays a flow rate triggered by the ventilator. All chest drainage systems, whether by wall suction or with Thopaz react the same to this positive pressure - the ventilator controls air flow and not the drainage device. Except for the alarms, Thopaz reacts no differently to these other chest drainage systems.

- If there is a small air leak (or no air leak) after chest closure, the patient can be put on the desired pressure level without any problem even when the patient is ventilated for a longer period.
- If the air leak is very important and Thopaz can not restore the set pressure, the alarm „leak in system“ might be triggered. The acoustic alarm can be suppressed for 60 sec by pressing on the two selection buttons simultaneously. These alarms indicate Thopaz is working according to specifications.

In order to minimise the risk of alarming, we recommend to set Thopaz on gravity mode (-0.8 kPa) or even less. This allows the fluids to be extracted from the pleural space and minimizes the probability of alarms. The pressure can be increased again as soon as the patient is off the ventilator.

Note: Be aware that the alarm „leak in system“ is inactivated during 5 minutes after starting Thopaz. After this lapse of time, Thopaz needs one more minute to identify the air leak.
Questions as to the use of Thopaz

How does Thopaz apply vacuum when 2 tubes and 1 unit are used on the same lung (unilateral) in case of a haemo-pneumothorax?

Thopaz measures the average pressure between the two tubes and creates a single pressure value.

Thopaz compensates the pressure difference until the patient pressure reaches the set pressure. Thopaz works harder to ensure that the fluids are removed in order to maintain the set pressure.

To find out which drain can be pulled first, they have to clamp one drain and then the other to find out which drain is still draining air and fluids.

What happens if I use 2 Thopaz on the same lung (unilateral)?

We do not recommend using 2 Thopaz unilaterally because the 2 devices might show slightly different flows, depending on the pressure regulation in the particular pleural cavity the drains are placed in. The assessment of this situation is difficult and has to be performed by the surgeon.

Important note: In this case it is imperative that both devices are set on the same pressure value. In case 2 different pressure levels are set on the two devices, there is a risk that the two pumps compete with each other and do not display the correct flow.

How to separate the liquid and air in the bottle?

Thopaz does measure the air and fluid rate. The fluid rate is a thousand times smaller than the air leak rate (see also example „Does Thopaz calculate fluids?”). Thus the fluid rate is negligible compared to the air leak rate. Thopaz does not quantify air and fluids separately.

If users want a separate quantification of the fluids from two drains, then they use two Thopaz, one for the apical and one for the basal drain. In this case it is imperative that both devices are set on the same pressure value. However we do not recommend using 2 Thopaz unilaterally, because the 2 devices might show slightly different flows, depending on the pressure regulation in the particular pleural cavity the drains are placed in. The assessment of this situation has to be performed by the surgeon.

Do we need to perform a “Cough Test”?

Reason for doing a cough test is to assess whether coughing provokes a spontaneous fistula, which could occur after drain removal due to a coughing action or other factors which may create a pneumothorax.

The Thopaz graph shows a snapshot of both the current status and a 24 hours history of the air leak. If no air leak is indicated in the 24 hours history, the decision to perform cough test would be based on patient assessment and facility guidelines.
In the case of a suspected spontaneous fistula which may lead to a subsequent cough related pneumothorax follow this pre-drain removal procedure:

Consider having the patient cough and watch the flow rate:
– If flow rate remains unchanged, consider assessment to determine no fistula. Wait 10 minutes for Thopaz to record this information in order to have it electronically documented that there was no air leak.
– If flow rate increases and stays higher than before, over the threshold of the surgeon’s “pull the drain criteria”, leave patient on treatment.

What happens if the pump stops working?

If Thopaz fails or the battery is empty, the corresponding alarm is sounded and the possible troubleshooting is displayed.

In this case the safety of the patient is still guaranteed (see FAQ: “How does the water seal function work?”)

When should I use the 300ml canister?

Normally the 800ml canister is used right after surgery, when more fluids are expected. The 300ml canister is useful in case of small fluid quantities and/or if the patient is mobilised.

Must I switch off the pump to change the canister?

When changing the canister we recommend first to clamp the patient tubing and then set Thopaz into standby mode.

What is the maximum flow rate of Thopaz?

5L/min is a general specification. Thopaz can actually manage a higher flow up to 6 L/min which depends on the set vacuum and the resistance in the tubing. Depending on these conditions the flow can temporarily exceed 5 L/min without triggering the alarm “leak in system”.
Troubleshooting

Battery does not charge.
1. Check if the docking station is connected to mains power
2. Check connections between docking station and Thopaz.
3. Use a different mains adapter
4. Contact Medela Customer Service

I cannot switch off the alarm.
Example:
The alarms can be acknowledged exclusively by pressing both selection buttons simultaneously. Then follow the troubleshooting tips on the display.

Tip: If the problem could not be resolved, the alarm will sound again after 60 seconds.

I cannot switch off Thopaz.
1. In order to turn off Thopaz correctly, press the Standby button for a minimum of 3 seconds (point 1) and then press the Power button quickly (point 2).

Note: If Thopaz is connected to mains power when turned off, the display shows the start picture (see illustration). The start picture switches off when the power cord is unplugged.
‘Internal fault’ is displayed repeatedly.

If ‘Internal fault’ is displayed, Thopaz must be turned off and on again using the Power button.

If the fault occurs repeatedly, contact your Medela Customer Service.

The self-test after switching on Thopaz takes more time than usual.

This mainly happens after connecting Thopaz to the patient in OR. Thopaz was most probably switched on when the patient was already connected.

For a proper calibration of the pressure sensors during the self-test, Thopaz must be switched on when the system is open to the atmosphere.

You can be faced with 2 situations.

– The self-test finally succeeds and you can start Thopaz. It can take several minutes.
– The calibration of the pressure sensors fails and alarm 311 (self-test failed) is triggered. Snap the canister out and in again and switch on Thopaz.

The alarm ‘leak in system’ is sounded although the flow is < 5000 ml/min.

The alarm ‘leak in system’ (301) is sounded when Thopaz cannot maintain the set pressure for a period longer than 60s, e.g. when there is a leak or a strong flow variation in the system.

Suppress the alarm by pressing the selection buttons once or twice to allow the system to stabilise. Check the system for air leaks and possible reasons why the set pressure cannot be maintained.

Note: The alarm ‘leak in system’ is inactivated during 5 minutes after starting Thopaz. After this lapse of time, Thopaz needs one more minute to identify the air leak before the alarm is triggered.

Thopaz displays flow whereas the patient is tight.

Possible reasons are:

– The canister is not clicked in properly
– The seal between canister and Thopaz is missing
– A hardware part is defective

Troubleshooting:

– Check if canister is clicked in
– Check seal
– If everything looks OK, send to ISS for repair

A positive Safety Test (only Firmware 1.20) confirms that flow measurement, the pressure regulation and the system tightness are according to specifications (see Instructions for Use).
A strong foam formation can be observed in the canister. Depending on the composition of the secretions and the height of the flow rate, it may occur that a foam formation can be noted in the canister. The foam can enter the filter chamber and close the filter prematurely. In this case the alarm 302 (System clogged) will sound and the canister must be changed immediately. Some users therefore add an anti-foam agent through the suction port of the canister (e.g. Infacol). Note: If the foam formation is combined with a high flow rate, the sudden obstruction of the filter might result in a pressure increase in the system. Then alarm 313 (Filter clogged) is triggered and Thopaz shuts down to protect the patient. Change the canister and switch on Thopaz.

The alarm ‘Canister full’ sounds, but the fluids have not reached the maximum level mark.

In case of condensate formation (dependent on temperature) or if secretions line the walls of the canister, the warning may be activated prematurely. This warning is triggered only once.

After deactivation (1), a symbol blinks in the run mode (2). From this moment the user is responsible for checking the canister filling level.

When Thopaz is switched on with open tubing, it takes some time until alarm 301 (leak in system) is triggered.

After switching on, there is a blank out of the alarm 301 (5 min). After this lapse of time, Thopaz needs one more minute to identify the air leak. This must be explained in case this alarm is demonstrated during trainings.

Furthermore Thopaz needs time for regulation and adjustment of the set pressure. Thopaz increases the pressure gradually in order to prevent strong pressure variations (like a pressure peak) inside the pleural space.