NICE National Institute for Health and Care Excellence

Medical Technologies Evaluation Programme

MT325 – The Thopaz system for the portable digital management of chest drains

Expert Adviser questionnaire responses

Name of Expert Adviser	Job title	Organisation
Dr Kamlesh Mohan	Respiratory Consultant	Liverpool Heart and Chest Hospital NHS Foundation Trust
Mr Kostas Papagiannopoulos	Consultant Thoracic Surgeon	Leeds NHS Foundation Trust
Mrs Catherine Plowright	Consultant Nurse Critical Care	Medway NHS Foundation Trust
Mrs Jenny Mitchell	Senior Advanced Nurse Practitioner	Oxford University Hospital NHS Trust

Comments on specific sections of the draft Topic Briefing

Dr Kamlesh Mohan **Respiratory Consultant**	**Page/section**	**Blank**
Mr Kostas Papagiannopoulos **Consultant Thoracic Surgeon**	**Page/section**	**Blank**
Mrs Catherine Plowright **Consultant Nurse Critical care**	**Page12**	**Has the study due to finish Dec 16 finished yet** **If so any results**
Mrs Jenny Mitchell **Senior Advanced Nurse Practitioner**	**Page 2, Summary - final bullet point** **Page 3, Innovations**	**It is possible to discharge patients home with a number of ambulatory chest drains with a dry seal / flutter valve system (Rocket, Atrium and Pleurex all make such systems). I am only aware of one centre discharging patient's home with the Thopaz drain. The advantage of Thopaz in our unit is that patients are able to mobilise much quicker after surgery, stop requiring suction earlier and are ready for discharge earlier than those with underwater seal drains attached to wall suction.** **It is possible to download data from the Thopaz pump once therapy has finished. This can be very useful for clinical review of patients. It can also be used for research purposes.**

Your opinion on how this technology would be used in practice

Question 1: How do you rate this technology's level of innovation? Is it a minor variation on existing technologies or does it represent a novel concept/design?

Dr Kamlesh Mohan **Respiratory Consultant**	**It is a novel concept which is portable and helps in the accurate measurement of fluid and air leakage.**
Mr Kostas Papagiannopoulos **Consultant Thoracic Surgeon**	**This is a novel concept and design for the following reasons: yhe device actively reads the intrapleural pressure and provides a regulated suction with no large variations. The device is not subject to variations of filter, patient position, chest wall suctioning accuracy and has important safety mechanisms with alarms detecting blockage or sudden changes in air leak or readings which do not exist in the traditional systems.** **It also eliminates interobserver variations as readings of air leak are not visual but digital with appropriate recorded data. This has an additional legal benefit as measurements are objective and recorded allowing retrospective evaluation in case of incidences or complaints.**
Mrs Catherine Plowright **Consultant Nurse Critical Care**	**Represents a new design as it detects air leak, intrapleural pressures and fluid drainage**
Mrs Jenny Mitchell **Senior Advanced Nurse Practitioner**	**This is innovative technology.** **The use of regulated suction in the pleural space allows an accurate amount of pressure to be used when managing the pleural space. A traditional underwater seal system attached to wall suction cannot provide regulated pressure to the pleural space.** **With traditional underwater seal chest drain systems air leak is measured by the visual assessment of bubbles exiting the drainage tube. There is no standardised measuring or grading system for the recording of visually assessed air leaks. The introduction of an accurate measure of air leak in mls/minute of air is innovative and extremely helpful in clinical assessment of patients with air leaks.**

Question 2: Would users of this technology require any special training?

Dr Kamlesh Mohan **Respiratory Consultant**	**Yes, both doctors and nurses would require education and training. This system is simple to use and therefore the education and training can be easily delivered and adopted in daily practice**
Mr Kostas Papagiannopoulos **Consultant Thoracic Surgeon**	**They are required to have an elementary knowledge of peural physiology and understand the basic principles of chest tube drainage.** **The device allows safe monitoring of patients with no interference and a simple to follow guide in case of problems which are available on a 'in device' mini manual.** **Training though will be required for safe connection and assembly of canister and tubing to the pump, safe cleaning and a period of assesment by an experienced user or medical representative.**
Mrs Catherine Plowright **Consultant Nurse Critical Care**	**Yes**
Mrs Jenny Mitchell **Senior Advanced Nurse Practitioner**	**Users require training on the set-up of the drainage system, on the day to day management of the system and on trouble shooting if there are issues when using they system. The training required is different but no more onerous than for underwater seal chest drains.**

Your experience with this technology

Question 3: Are you familiar with the technology?

Dr Kamlesh Mohan **Respiratory Consultant**	**Yes**
Mr Kostas Papagiannopoulos **Consultant Thoracic Surgeon**	**I have used this technology since march 2008 and have been involved in providing evidence for improving the software and hardware.** **Our Department is the largest global user so far with over 8000 uses over the last 9 years**
Mrs Catherine Plowright **Consultant Nurse Critical Care**	**No**
Mrs Jenny Mitchell **Senior Advanced Nurse Practitioner**	**Yes**

Question 4: Have you used this technology before? Do you use it currently?

Dr Kamlesh Mohan **Respiratory Consultant**	**Yes**
Mr Kostas Papagiannopoulos **Consultant Thoracic Surgeon**	**Please refer to previous question. The department has 20 pumps utilised on every patient who has a chest tube inserted in his chest**
Mrs Catherine Plowright **Consultant Nurse Critical Care**	**No**
Mrs Jenny Mitchell **Senior Advanced Nurse Practitioner**	**Thopaz has been in use on our unit since 2012, I have lead clinically on the introduction and on-going management of the drains.**

Question 5: If so how regularly and how many times?

Dr Kamlesh Mohan **Respiratory Consultant**	**It depends on the practice /Hospital. I don't see as many pneumothoraces. In my role, I use it on 1 patient a month. However I can see it being used regularly in other trusts. Our Surgical colleagues use it on all their patients.**
Mr Kostas Papagiannopoulos **Consultant Thoracic Surgeon**	**Approximate use of 1000 times per annum**
Mrs Catherine Plowright **Consultant Nurse Critical Care**	**N/A**
Mrs Jenny Mitchell **Senior Advanced Nurse Practitioner**	**Daily involvement with the clinical care of patients with Thopaz chest drains since 2012.**

Question 6: Were you involved in the development/testing of this technology?

Dr Kamlesh Mohan **Respiratory Consultant**	**No**
Mr Kostas Papagiannopoulos **Consultant Thoracic Surgeon**	**Yes**
Mrs Catherine Plowright **Consultant Nurse Critical Care**	**N/A**
Mrs Jenny Mitchell **Senior Advanced Nurse Practitioner**	**No**

Question 7: Has this technology been superseded or replaced already?

Dr Kamlesh Mohan **Respiratory Consultant**	**To my knowledge , no**
Mr Kostas Papagiannopoulos **Consultant Thoracic Surgeon**	**No as there is no other similar technology available in the market at present**
Mrs Catherine Plowright **Consultant Nurse Critical Care**	**N/A**
Mrs Jenny Mitchell **Senior Advanced Nurse Practitioner**	**No, the original Thopaz is still current; Thopaz+ will supersede it at some point.**

Patient impact

Question 8: How could this technology improve patient health outcomes? Are there any groups of people who would particularly benefit?

Dr Kamlesh Mohan **Respiratory Consultant**	**I think all patients (patients with pneumothorax or patients undergoing lung surgery) with benefit from this technology**
Mr Kostas Papagiannopoulos **Consultant Thoracic Surgeon**	**There is evidence that the digital systems are not simply and passively drain air and fluid from the chest but rather treat 'gently' the pleural space.** **Patients with lungs with low or high compliance can be treated more accurately than traditional systems.** **Digital systems are safer as they have an internal alarm mechanism allowing 24/7 monitoring of patients even in Wards with limited nursing resources and junior doctor cover after hours.** **The regulated pressure can allow faster lung healing and safe and accurate system readings prevent uncertainty from Junior doctors leading often to unnecessary imaging studies with cost, patient and staff destruction.** **They offer mobility as suction can be provided with no connection to power or the wall suction, they are light and allow early mobilisation of patients with faster discharge and offer a more civilised and dignified medical environment while patients are hospitalised. They are also considered by patients and relatives as treatment medical devices rather than drainage bottles.**
Mrs Catherine Plowright **Consultant Nurse Critical Care**	**If patient can be sent home with it, it will save acute hospital bed days**

Mrs Jenny Mitchell **Senior Advanced Nurse Practitioner**	**Thopaz is of benefit to patients who require thoracic suction or who need monitoring of pleural air leaks. In addition it provides safer thoracic drainage for all patients who require chest drainage.** **Thoracic suction via a wall suction unit requires a system with a spacer unit and a permanent connection to a wall suction unit. Connection tubing should be of the shortest length possible to minimise vacuum loss between the wall unit and the patient. This limits patient mobility to the immediate bed space. Most of these patients would actually benefit greatly from mobilising while they have a chest drain in situ. Mobilisation promotes lung expansion so aiding resolution of pneumothorax and pleural effusion. Use of a battery powered thoracic drainage system such as Thopaz enables patients to mobilise without restriction.** **Thoracic suction via a traditional wall unit system is unregulated and unmonitored. A dial is used to set the suction level on the wall unit; there is no way of monitoring the pressure either in the drain bottle or in the pleural space. Thopaz measures thoracic pressure at the point of connection to the chest drain, this is usually no more than 20 cm from the pleural cavity, giving an accurate measure of pressure in the pleural space. The Thopaz pump only applies negative pressure where required, e.g. if the pump is set to -1 kPa and the pressure at the measuring point is -1.2 kPa no extra suction will be applied. This prevents excessive pressure being applied to the pleural cavity, minimizing the risk of damage to structures in the pleural cavity. Conversely where extra pressure is required, e.g. to aid the drainage of air and fluid after thoracic surgery, the correct negative pressure is applied to the pleural cavity.** **With traditional chest drainage systems the air leaking from the pleural cavity is seen as bubbles passing through the underwater seal. This visual representation of the air leak can be useful but it is not quantifiable or measurable, leading to variations in the recording of air leaks. Thopaz measures the amount of air draining from the pleural cavity and gives a reading in mls per minute. The change from a visual representation of the air to a measurable figure can be difficult for some clinicians to adjust to but is more accurate and removes the variability associated with observing bubbles in fluid. This new way of measuring air leaks has improved our understanding of the mechanics of air leaking from the pleural cavity. Accurate information about an air leak aids the decision to remove a chest drain, this decision making process can be delegated to nurses and junior doctors working to set criteria. This promotes the timely and safe removal of chest drains.** **The Thopaz system has alarms for a number of issues that may arise such as the canister reaching capacity, a disconnection in the system or the battery power is low. These alarms aid patient safety. For example if the drain is accidently disconnected from the tubing an alarm will sound alerting staff to the problem. Traditional drainage systems have no safety features, relying on patients and staff to observe issues with the system. This is of particular benefit where patients are nursed in single rooms.** **The easy transportation of the Thopaz drain and the inclusion of alarms has led to a change in the patient transportation criteria on our unit. Patients can be sent to Radiology without a nurse escort if they have a Thopaz drain; a nurse escort is required for patients with an underwater seal drain.**

Question 9: How could it change patient experience? Would it lead to fewer hospital visits, less invasive treatment or other benefits for patients?

Dr Kamlesh Mohan **Respiratory Consultant**	**1. Patients can be mobile with this technology. They don't need to be connected to the wall suction. Therefore theoretically, it can reduce DVT, prevent xrays on the wards and help patients with mobility which can indirectly help with discharge.** **2. It can accurately measure both fluid and air leakage** **3. It also helps in identifying air leak during endobronchial valve insertion in patients with persistent pneumothorax.**
Mr Kostas Papagiannopoulos **Consultant Thoracic Surgeon**	**Please refer to previous question.** **Additionally:** **1. patients can potentially get discharged home with such devices allowing domiciliary monitoring and reduction of unnecessary hospital visits.** **2. Alarms can alert for possible issues with chest tube drainage with safer communication with the treating team** **3. Such benefits are magnified in specialist Units and Regional centres in which patients might becoming from remote geographical areas or long distances.**
Mrs Catherine Plowright **Consultant Nurse Critical Care**	**Less inpatient days in hospitals**
Mrs Jenny Mitchell **Senior Advanced Nurse Practitioner**	**Improved patient experience, the ability to mobilise freely while on thoracic suction enables patients to leave their bed space and mobilise around the ward. This increases their social interaction and can improve their psychological wellbeing.** **The ability to transport patients to Radiology with the Thopaz drain reduces the risk of exposure to ionising radiation from portable x-rays on the ward and produces better imaging.**

Question 10: Are you aware of any safety alerts for this technology?

Dr Kamlesh Mohan **Respiratory Consultant**	**No**
Mr Kostas Papagiannopoulos **Consultant Thoracic Surgeon**	**None so far. We have experienced a small number of issues with the initial experience which lead into a modification and improvement of the software but no patient related untoward incidences.**
Mrs Catherine Plowright **Consultant Nurse Critical Care**	**Aware of none**
Mrs Jenny Mitchell **Senior Advanced Nurse Practitioner**	**No**

System impact

Question 11: How would use of this technology impact on NHS services?

Dr Kamlesh Mohan **Respiratory Consultant**	**The impact will be positive - Good for patients and NHS staff**
Mr Kostas Papagiannopoulos **Consultant Thoracic Surgeon**	**1. cost effectiveness** **2. faster discharge with potential improvement of efficiency by cycling larger number of patients through the same allocatyed bed space** **3. innovation and modernisation of health care by providing a recordable treatment for all patients leading to standardisation of care across the country regarding chest tube management** **4. legal benefits by having data available in case of legal cases**
Mrs Catherine Plowright **Consultant Nurse Critical Care**	**Potential money saving**
Mrs Jenny Mitchell **Senior Advanced Nurse Practitioner**	**The data obtainable from the Thopaz drain has not been available in normal clinical practice in the past. Use of this technology improves clinicians understanding of the management of the pleural space and over time this knowledge will contribute to improvements in care.**

Question 12: Would any changes in facilities or infrastructure be needed for this technology to be used?

Dr Kamlesh Mohan **Respiratory Consultant**	**No.** **Doctors and Nurses will need some education and training which the company usually provides free of charge. The system is simple to use and the training can be easily delivered in a matter of minutes to hours.**
Mr Kostas Papagiannopoulos **Consultant Thoracic Surgeon**	**Not at all**
Mrs Catherine Plowright **Consultant Nurse Critical Care**	**Probably not**
Mrs Jenny Mitchell **Senior Advanced Nurse Practitioner**	**No**

Question 13: Do you think that use of this technology could lead to cost savings for the NHS?

Dr Kamlesh Mohan **Respiratory Consultant**	**I am aware two trials (1 Multicentre and 1 Poland study) have suggested cost savings. The difference in price between underwater seal and thopaz is not huge (20 pounds). Furthermore, water seal bottles need changing several times. So overall, I don't think there will be any difference in cost to the NHS**
Mr Kostas Papagiannopoulos **Consultant Thoracic Surgeon**	**Yes indeed. The model has already been published and although not applicable to all practices it will lead to cost effectiveness as soon as national standardisation of chest tube management becomes more evident**
Mrs Catherine Plowright **Consultant Nurse Critical Care**	**Overall yes**
Mrs Jenny Mitchell **Senior Advanced Nurse Practitioner**	**Safe and effective thoracic suction via a Thopaz drain allows improved management of patients who require this treatment. Improving access to this equipment will allow patients who require this therapy quick and easy access, this will reduce length of stay and lead to improved clinical outcomes.**

Any other comments or opinions on this technology (optional)

Dr Kamlesh Mohan **Respiratory Consultant**	None
Mr Kostas Papagiannopoulos **Consultant Thoracic Surgeon**	**Nursing Staff benefit:** 1. easier to record data as they are captured electronically 2. available alarms to warn of chest tube occlusion or disconnection especially when staffing capacity is an issue 3. better handling of patients fluids and infection control 4. improve teaching on chest tube management at junior nursing level **medical staff benefit:** 1. abolishes inter observer variability and allows safe and comfortable decisions to be made during ward rounds 2. provision of a standardised check list in case of problems 3. teaching tool for juniors 4. allows retrospective assessment of tube drainage without reliance on medical records future benefits 5. wireless assessment of chest tube drainage 6. data recording and capture on hospital electronic patient records 7. wireless change of settings through out treatment 8. enhance domiciliary/primary health care
Mrs Catherine Plowright **Consultant Nurse Critical Care**	Blank
Mrs Jenny Mitchell **Senior Advanced Nurse Practitioner**	Blank

CONFLICTS OF INTEREST

PERSONAL FINANCIAL INTERESTS

Expert Advisers	Consultancies or directorships	Clinicians receiving payment for a procedure	Fee-paid work	Shareholdings	Financial interest in a company's product	Expenses and hospitality	Funds	Personal non-pecuniary interest
Dr Kamlesh Mohan **Respiratory Consultant**	No	No	No	No	No	No	No	No
Mr Kostas Papagiannopoulos **Consultant Thoracic Surgeon**	No	No	No	No	No	No	No	No
Mrs Catherine Plowright **Consultant Nurse Critical Care**	No	No	No	No	No	No	No	No
Mrs Jenny Mitchell **Senior Advanced Nurse Practitioner**	**Yes**	No	No	No	No	No	No	No
Conflict(s) declared								
Mrs Jenny Mitchell **Senior Advanced Nurse Practitioner**	**I taught on a 'Nurse Master Class' run by Medela in September 2016 and was paid for my time in teaching and writing the educational material. This teaching event aimed to educate nurse to be specialist in caring for electronic chest drains. It was organised by Medela and run as a free event for nurses in units who either already use Thopaz or are thinking of implementing its use. The teaching material was generic and would be applicable to any electronic chest drain; the practical sessions used the Thopaz pump.**							

CONFLICTS OF INTEREST (cont.)

PERSONAL NON-FINANCIAL INTERESTS

Expert Advisers	Expressed a clear opinion reached as a conclusion of a research project or in a published statement	Been an author on a document submitted as an evidence publication to a NICE advisory committee	Hold office in a professional organisation, charity or advocacy group with a direct interest in the topic	Have any other reputational risks in relation to the topic
Dr Kamlesh Mohan **Respiratory Consultant**	No	No	No	No
Mr Kostas Papagiannopoulos **Consultant Thoracic Surgeon**	No	No	No	No
Mrs Catherine Plowright **Consultant Nurse Critical Care**	No	No	No	No
Mrs Jenny Mitchell **Senior Advanced Nurse Practitioner**	No	No	No	No

CONFLICTS OF INTEREST (cont.)

NON-PERSONAL INTERESTS

Expert Advisers	Grant for the running of a unit	Grant or fellowship for a post or member of staff	Commissioning of research	Contracts with or grants from NICE
Dr Kamlesh Mohan **Respiratory Consultant**	No	No	No	No
Mr Kostas Papagiannopoulos **Consultant Thoracic Surgeon**	No	No	No	No
Mrs Catherine Plowright **Consultant Nurse Critical Care**	No	No	No	No
Mrs Jenny Mitchell **Senior Advanced Nurse Practitioner**	No	No	No	No

LINKS/FUNDING FROM THE TOBACCO INDUSTRY

Expert Advisers	Yes or No?	*Conflict(s) declared*
Dr Kamlesh Mohan **Respiratory Consultant**	No	N/A
Mr Kostas Papagiannopoulos **Consultant Thoracic Surgeon**	No	Blank
Mrs Catherine Plowright **Consultant Nurse Critical Care**	No	N/A
Mrs Jenny Mitchell **Senior Advanced Nurse Practitioner**	No	N/A

OTHER COMPETING INTERESTS BELIEVED TO BE RELEVANT BUT NOT LISTED ABOVE

Expert Advisers	Yes or No?	*Conflict(s) declared*
Dr Kamlesh Mohan **Respiratory Consultant**	No	N/A
Mr Kostas Papagiannopoulos **Consultant Thoracic Surgeon**	No	Blank
Mrs Catherine Plowright **Consultant Nurse Critical Care**	No	N/A
Mrs Jenny Mitchell **Senior Advanced Nurse Practitioner**	No	N/A

National Institute for Health and Care Excellence

External Assessment Centre correspondence

The Thopaz+ portable digital system for the management of chest drains

The purpose of this table is to show where the External Assessment Centre relied in their assessment of the topic on information or evidence not included in the sponsors' original submission. This is normally where the External Assessment Centre:

a) become aware of additional relevant evidence not submitted by the sponsor
b) need to check "real world" assumptions with NICE's expert advisers, or
c) need to ask the sponsor for additional information or data not included in the original submission, or
d) need to correspond with an organisation or individual outside of NICE

These events are recorded in the table to ensure that all information relevant to the assessment of the topic is made available to MTAC. The table is presented to MTAC in the Assessment Report Overview, and is made available at public consultation.

Submission Document Section/Sub-section number	Question / Request	Response	Action / Impact / Other comments
General.	The EAC requested CE marking information which was not included by the company in its submission.	The company sent through CE marking certification to the EAC.	Used by the EAC to determine whether or not Thopaz+ was CE marked and to determine its intended use.
General.	The EAC requested an Annex II certificate for Thopaz+ from the company as this was required to assess the CE mark status of Thopaz+.	The company sent through the Annex II certificate to the EAC.	Used by the EAC to determine whether or not Thopaz+ was CE marked.
Clinical evidence.	The EAC requested citations for three studies excluded by the company due to a “publisher paywall”.	The company sent the requested citations to the EAC.	The studies were excluded by the EAC as they were conference abstracts with little information.
Economic model.	The EAC contacted Mr Papagiannopoulos (clinical expert) with the following questions: 1. Have you had any experience with Thopaz+? (If yes would you be able to answer the sub-questions below?) a. What consumables are used with Thopaz+?	Mr Papagiannopoulos gave the following responses: 1. The department in Leeds has the largest experience in the world with over 9000 patients in whom the pump has been applied so far a. Tubing single or wuth y connector if 2 chest drains are used at surgery. 300ml canister or 800ml canister	Used by the EAC in the development of its economic model.

Submission Document Section/Sub-section number	Question / Request	Response	Action / Impact / Other comments
	b. Does your department buy or rent the device(s)? c. To your knowledge does staff time differ between Thopaz+, an analogue system and glass bottle drainage? d. How much is Thopaz+ used? E.g. is there down-time where the device isn't used between patients, is Thopaz+ always used over an analogue system or is it only used in a specific sub-group of patients). e. Does the chest tube inserted following surgery get connected to Thopaz+, or is this replaced with tubing that comes with Thopaz+? f. How often do patients require more than 1 drainage canister for Thopaz+? 2. What is the most common chest drainage analogue system used in your department	depending on drainage postoperatively b. we had them rent but recently purchased as the purchase deal gave us different pricing on consumables (obviously we are a high volume centre) c. yes it does. with Thopaz all readings are recorded in the sytem (air leak and fluid drainage) and therefore are easy to put on nursing charts. on analogue systems air leak cannot be quantified but a rudimentary score is used and fluid drainage means nurses have to fall on their knees to check fluid level and drainage as well as mark with pen on the bottle the last reading d. The vast majority of departements use it routinely except special	

Submission Document Section/Sub-section number	Question / Request	Response	Action / Impact / Other comments
	(e.g. glass bottle drainage, a system such as Pleur-Evac)? 3. What consumables are required for analogue chest drainage? 4. Does the same patient tubing stay in place for the duration of drainage?	cases i.e. pneumonectomies and lvrs e. original chest drain remains in situ and this is connected with special tubing from Thopaz+ f. 1. for minor cases one canister 300 or 800cc is enough 2. for major cases usally 2 800cc cannisters In Leeds we have always used a large canister to minimize changes and cost 2. we use the Rocket drains. single bottle system and this is used throughout the Trust 3. Bottle, tubing, sterile saline, 1L bottle 4. yes it does	

Submission Document Section/Sub-section number	Question / Request	Response	Action / Impact / Other comments
Economic model.	The EAC contacted Mrs Mitchell (clinical expert) with the following questions: 1. Have you had any experience with Thopaz+? (If yes would you be able to answer the sub-questions below?) a. What consumables are used with Thopaz+? b. Does your department buy or rent the device(s)? c. To your knowledge does staff time differ between Thopaz+, an analogue system and glass bottle drainage? d. How much is Thopaz+ used? E.g. is there down-time where the device isn't used between patients, is Thopaz+ always used over an analogue system or is it only used in a specific sub-group of patients).	1. We don't have Thopaz+ in use clinically here (we use the original Thopaz machines) but I have been able to test a demonstration model. Most of the questions below have the same answer for both versions of Thopaz. a. The same consumables are used with both Thopaz and Thopaz+. Every machine needs tubing (either single or double connector) and a canister, there are different sizes of canisters. We mainly use 800ml canisters after surgery but sometimes use 350ml canisters when a patient has a drain for an extended period of time with low levels of fluid drainage. We also have sealing caps available for use with double connector tubing when one drain is removed. b. We currently rent machines but I am looking for funding to purchase. c. Once staff have experience with Thopaz+ taking readings will be quicker, otherwise the differences are negligible.	Used by the EAC in the development of its economic model.

Submission Document Section/Sub-section number	Question / Request	Response	Action / Impact / Other comments
	e. Does the chest tube inserted following surgery get connected to Thopaz+, or is this replaced with tubing that comes with Thopaz+? f. How often do patients require more than 1 drainage canister for Thopaz+? 2. What is the most common chest drainage analogue system used in your department (e.g. glass bottle drainage, a system such as Pleur-Evac)? 3. What consumables are required for analogue chest drainage? 4. Does the same patient tubing stay in place for the duration of drainage?	d. Practice varies between centres. We use Thopaz on all thoracic surgery patients, there will be time between uses where the machines are in the equipment room but this is short as we only have a limited number of machines. We always use Thopaz except for patients having pneumonectomy. Another department in our Trust only uses Thopaz for patients who need suction (mostly those with a pneumothorax) but this is mainly due to a limited supply of machines. e. All drainage systems connect to a chest drainage tube which is inserted into the pleural cavity at the time of surgery. Every system has its own tubing, usually with a barbed connector. There are two types of Thopaz tubing – single or double connector – the correct one is selected in theatre depending on if there are one or two chest	

Submission Document Section/Sub-section number	Question / Request	Response	Action / Impact / Other comments
		drains inserted at the end of the operation. f. Approximately 20% of patients will require a canister change. 2. We have Rocket pleural drains available but rarely use them. Approximately 10% of patients will be discharged with a chest drain and in these cases we use Atrium Mini 500. 3. The whole drainage system (tubing and collection canister) is a consumable in this case as they are single patient use. Rocket drains come as separately packaged tubing and bottles. The tubing will stay in place until the drain is removed. The bottles are changed every 48 hours or sooner if the drainage is more than 300mls. Atrium Mini 500 drains are packaged with tubing and canister together. They can be emptied with a syringe and last on average 1-2 weeks. About half of the patients discharged with one will require a drain change (mainly due to the needleless emptying port becoming blocked). 4. Yes, in all drainage system in use here the tubing stays in place unless there	

Submission Document Section/Sub-section number	Question / Request	Response	Action / Impact / Other comments
		are doubts about patency). Even though the Atrium Mini 500 comes with tubing the canister can be changed while retaining the original tubing. We do this and discard the new tubing in the package as this causes less discomfort for the patient. Tubing does need to be changed when moving to a different drainage system (for example changing from Thopaz to Atrium Mini 500 for discharge home with a chest drain).	
Economic model.	The EAC contacted Mrs Catherine Plowright (clinical expert) with the following questions: 1. Have you had any experience with Thopaz+? (If yes would you be able to answer the sub-questions below?) a. What consumables are used with Thopaz+? b. Does your department buy or rent the device(s)?	Mrs Plowright replied with the following answers: 1. I have had no personal experience with Thopaz+ 2. We use Thora-Seal (Covidien) 3. We need the drainage unit, the chest drain trochar, dressing pack and cleaning fluid. Gowns and Gloves. H2O for the drainage bottle. Needles, syringes and sutures ?? forceps and access to cut down set at times 4. Usually I think	Used by the EAC in the development of its economic model.

Submission Document Section/Sub-section number	Question / Request	Response	Action / Impact / Other comments
	c. To your knowledge does staff time differ between Thopaz+, an analogue system and glass bottle drainage? d. How much is Thopaz+ used? E.g. is there down-time where the device isn't used between patients, is Thopaz+ always used over an analogue system or is it only used in a specific sub-group of patients). e. Does the chest tube inserted following surgery get connected to Thopaz+, or is this replaced with tubing that comes with Thopaz+? f. How often do patients require more than 1 drainage canister for Thopaz+? 2. What is the most common chest drainage analogue system used in your department (e.g. glass bottle drainage, a system such as Pleur-Evac)?		

Submission Document Section/Sub-section number	Question / Request	Response	Action / Impact / Other comments
	3. What consumables are required for analogue chest drainage? 4. Does the same patient tubing stay in place for the duration of drainage?		
Economic model.	The EAC asked Mr Papagiannopoulos the following question: Question 1d asked how much Thopaz is used, and your answer was helpful for this. But I'd like to ask what happens to the device between patients. Is the device used straight away on another patient or is it "rested" for a time? The manufacturer has estimated that a single device is only in use 50% of the time. Does this seem reasonable to you or is there no "rest" for the device between patients?	Mr Papagiannopoulos gave the following response: In Leeds pumps hardly rest because they are used from one patient to another. it certainly depends on number of pumps available, practice locally and activity. In Leeds we use the pumps almost 1000 times annually and we have 20 although some might be out of action for maintenance or repair.	Noted by the EAC.
Economic model.	The EAC requested the following information from the company: 1. Firstly, would it be possible to send us list prices for the following: • The tubing used to connect Thopaz+ to a chest drain. • Canisters (both sizes)	The company replied with the following responses: 1. • 0.3 litre - 11.50 per piece • 0.8 litre - 13.30 per piece • 0.3 litre with solidifier - 13.00 per piece • 0.8 litre with solidifier - 15.00 per piece • Tubing single 9.20 per piece	Used by the EAC in the development of its economic model.

Submission Document Section/Sub-section number	Question / Request	Response	Action / Impact / Other comments
	• Canisters with and without a solidifying agent (if these are available for Thopaz+ and for each size if so) 2. We also wanted to ask whether you had any information on the life-time of the device? This is important if a centre decides to buy the device outright instead of renting the device. 3. I can see that maintenance costs are covered during rental. If someone buys the device are there any maintenance costs that need to be considered? 4. Finally, in your model you assume that there are no costs associated with treatment, consumables, maintenance and training for comparator devices. Have Medela at any point collected information on how much treatment with a comparator device costs? If so would it be possible to share this information with us?	• Tubing double 10.20 per piece • Thopaz tubing single, small connector - 10.50 price per piece • Thopaz tubing double, small connector, sterile - 12.60 price per piece • Thopaz tubing, single, large connector, sterile - 9.20 price per piece • Thopaz tubing, double, large connector, sterile 10.20 price per piece 2. Medela quotes a device life of 5 years 3. An extended warranty can be purchased but there are no routine maintenance costs 4. We have analysed costs for a number of hospitals but we have not had the results verified by health economists but you are welcome to look at those attached. You will have to check he dates and prices at the time but they were produced in good faith and accepted as such by the accounts. They may well help and if they do please feel free to use them. The company also attached list prices for Thopaz+ and its consumables in addition to business cases.	

Submission Document Section/Sub-section number	Question / Request	Response	Action / Impact / Other comments
Economic model.	The EAC emailed NHS supply chain to ask why there was a discrepancy between the company's list prices and its prices for Thopaz+ and consumables: We have received list prices from the manufacturer for Thopaz+ consumables (eg containers and tubing), however they appear to be considerably cheaper than the prices quoted on NHS Supply Chain. The prices from the manufacturer are where there is a monthly rental paid for the device. Possibly those on NHS Supply chain are related to device purchase or a free device loan?	The query was passed onto various addresses at NHS supply chain but ultimately was not answered.	No response to consider.
Economic model.	The EAC contacted Mrs Catherine Plowright (clinical expert) with the following questions: 1. Do you have any experience with HRG/cost codes (NHS reference costs)? (If yes would you be able to answer the sub-questions below?) a. What HRG codes for bed days are relevant for patients undergoing pulmonary resection? We have identified the HRG codes below (from NHS reference costs 2015-2016), are these sensible or have	Mrs Plowright replied with the following answers: 1. I am sorry but I have no experience of HRG or cost codes 2. If anything it is blockages and accidental removal 3. It is used in our medical HDU 4. Extra training is required initially I am sorry but I have no access to any info re numbers of devices used per patient	Considered by the EAC in its economic model.

<table>
<tr><th>Submission Document Section/Sub-section number</th><th>Question / Request</th><th>Response</th><th>Action / Impact / Other comments</th></tr>
<tr><td></td><td>we missed any (e.g. codes for very complex and intermediate)?

<table><tr><td>DZ02 H</td><td>Complex Thoracic Procedures, 19 years and over, with CC Score 6+</td></tr><tr><td>DZ02 J</td><td>Complex Thoracic Procedures, 19 years and over, with CC Score 3-5</td></tr><tr><td>DZ02 K</td><td>Complex Thoracic Procedures, 19 years and over, with CC Score 0-2</td></tr><tr><td>DZ02 H</td><td>Complex Thoracic Procedures, 19 years and over, with CC Score 6+</td></tr><tr><td>DZ02 J</td><td>Complex Thoracic Procedures, 19 years and over, with CC Score 3-5</td></tr><tr><td>DZ02 K</td><td>Complex Thoracic Procedures, 19 years and over, with CC Score 0-2</td></tr></table>
b. Is there a HRG/cost code for chest drain re-insertion?
c. Is there a HRG/cost code(s) for pneumothorax?</td><td></td><td></td></tr>
</table>

Submission Document Section/Sub-section number	Question / Request	Response	Action / Impact / Other comments
	2. What complications, if any, could be associated with chest tube drainage (specifically to the drainage device)? 3. Is Thopaz+ used at all in your department? **4.** How many Thora-Seal devices do you estimate are required per patient during chest drainage and is extra training required to use the Thora-Seal device?		
Economic model.	The EAC contacted Mr Papagiannopoulos (clinical expert) with the following questions: 1. Do you have any experience with HRG/cost codes (NHS reference costs)? (If yes would you be able to answer the sub-questions below?) a. What HRG codes for bed days are relevant for patients undergoing pulmonary resection? We have identified the HRG codes below (from NHS reference costs 2015-2016), are these sensible, have we missed any (e.g. codes for very complex and intermediate) or are there codes which would be better suited to pulmonary resection?	No response received.	No information for the EAC to consider.

Submission Document Section/Sub-section number	Question / Request	Response	Action / Impact / Other comments
	<table><tr><td>DZ02H</td><td>Complex Thoracic Procedures, 19 years and over, with CC Score 6+</td></tr><tr><td>DZ02J</td><td>Complex Thoracic Procedures, 19 years and over, with CC Score 3-5</td></tr><tr><td>DZ02K</td><td>Complex Thoracic Procedures, 19 years and over, with CC Score 0-2</td></tr><tr><td>DZ02H</td><td>Complex Thoracic Procedures, 19 years and over, with CC Score 6+</td></tr><tr><td>DZ02J</td><td>Complex Thoracic Procedures, 19 years and over, with CC Score 3-5</td></tr><tr><td>DZ02K</td><td>Complex Thoracic Procedures, 19 years and over, with CC Score 0-2</td></tr></table> b. Is there a HRG/cost code for chest drain re-insertion? c. Is there a HRG/cost code(s) for pneumothorax? 2. What complications, if any, could be associated with chest tube drainage (specifically to the drainage device)? 3. How many doctors/nurses carry out chest drainage with Thopaz+ in your department and can you give an estimate of the band level they are on? (We want to obtain this information for use in our calculation of training costs).		

Submission Document Section/Sub-section number	Question / Request	Response	Action / Impact / Other comments
	4. Can you estimate how long it takes to train a nurse/doctor to use Thopaz+? 5. How many Rocket drains do you estimate are required per patient during chest drainage and is extra training required to use a Rocket drain? 6. Thank you for letting me know how many Thopaz+ machines you have at your site. You said that you use the pumps almost 1,000 times annually, would you be able to give a more specific number for the number of time the pumps are used annually?		
Economic model.	The EAC emailed the company with the following questions: 1. We have noticed that the prices you sent through to us are noticeably cheaper than those quoted on the NHS supply chain (http://my.supplychain.nhs.uk/catalogue/search?query=thopaz). The prices in the table are inclusive of VAT whilst the list prices you provided are not, but that still doesn't account for the discrepancy. Could it be that the prices you sent through to us are based on centres renting Thopaz+ units whilst the	The company sent the following answers: Hospitals get a better price if they deal directly with us. NHS supplies state they must make a margin on the product and we insisted it did not come from our prices which we believe are very fair hence they have added their costs to our prices. As most accounts already used Thopaz when they approached us this seemed and seems reasonable to us. In answer to questions 2; a. the Thopaz+ battery has to be changed by Medela if it is faulty. Very few faults	Used and considered by the EAC in the development of its economic model.

Submission Document Section/Sub-section number	Question / Request	Response	Action / Impact / Other comments
	NHS supply chain prices are based on centres purchasing a device or have the device on a free loan? We have emailed NHS supply chain but have not received an answer yet. Do you know why there is a difference in prices? 2. How long does the Thopaz+ battery last? a. Is it easily swapped or does the device have to be changed? b. Is this covered under "maintenance" when renting the device? c. What happens if you have bought a device and the battery needs changing?	have been experienced, we have no record of any in the UK. b. it is covered by the warranty and for the entire rental period c. it will be covered by warranty for first 2 years if bought. Send back to Medela and we will repair/replace. Once outside warranty we would still change a battery as it is such an unusual fault.	
Economic model.	The EAC contacted Mrs Jenny Mitchell (clinical expert) with the following questions: 1. Do you have any experience with HRG/cost codes (NHS reference costs)? (If yes would you be able to answer the sub-questions below?) a. What HRG codes for bed days are relevant for patients undergoing pulmonary resection? We have identified the HRG codes below	Mrs Mitchell replied with the following answers: 1. Sorry, I don't have experience with HRG codes. 2. Device specific complications would be: • Failure of the machine, occasionally they alarm internal error, in which case the machine will need to be changes. • The tubing could potentially become blocked, I have only ever seen this at the connection	Used and considered by the EAC in the development of its economic model.

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b. Is there a HRG/cost code for chest drain re-insertion?
c. Is there a HRG/cost code(s) for pneumothorax?

2. What complications, if any, could be associated with chest tube drainage (specifically to the drainage device)?</td><td>point where the barbed connector joins the chest tube.
• Disconnection of one of the disposable parts is possible, the canister can come off the machine I it is dropped from height. Disconnection at the barbed connector is rare and a potential complication of all drainage system.

3. Every member of the team in our department is involved in care of patients with Thopaz drains. The ward has an establishment of 39 nurses spread over band 2-7, all are trained and competent in managing Thopaz. There are approximately 15 scrub nurses in theatres (we have a specific theatre team) plus approximately another 30 nurses who work in recovery. Critical care nurses tend to train on the device as needed rather than train the whole department, due to large staff numbers and turn over. All medical staff from FY2 to consultant also need training. We have 3 surgeons, 3 fellows / SpRs and 6 SHO / FY2s</td><td></td></tr>
</table>

Submission Document Section/Sub-section number	Question / Request	Response	Action / Impact / Other comments
	3. How many doctors/nurses carry out chest drainage with Thopaz in your department and can you give an estimate of the band level they are on? (We want to obtain this information for use in our calculation of training costs). 4. Can you estimate how long it takes to train a nurse/doctor to use Thopaz? 5. Thank you for letting me know how often a Rocket drain is changed. Could you give an estimate of how many Rocket drains are required per patient during chest drainage? Is extra training required to use a Rocket drain? 6. Thank you for letting me know that the time between use for your Thopaz machines is short as you only have a few. How many Thopaz machines do you have in your department and can you give an estimate of the number of patients require chest drainage annually with these devices? (We	4. When we introduced Thopaz we had two weeks of intensive training with everyone receiving a specific classroom type session then hands on support on the ward. New staff now will have a 30 minute session on Thopaz then be supported clinically until competent. 5. Nursing staff will require training on Rocket drains similar to Thopaz, medical staff are usually trained on this type of drain as medical students. We used to use 2-4 drains per patient stay when we used Rocket on everyone. 6. We currently have 10 machines and undertake about 500 cases per year.	

Submission Document Section/Sub-section number	Question / Request	Response	Action / Impact / Other comments
	want to obtain this information to calculate device utilisation, which will be used in our economic model).		
Economic model.	The EAC contacted the company with the following question: 1. Do you know how long a Thopaz+ battery would last? All rechargeable batteries have a limited number of charge/drain cycles and we may need to take that into account.	Response from the company: Technical support at Medela tells me that the battery has at least 500 charge / drain cycles although I have no data for this.	Considered by the EAC but not used in its economic model.
Economic model.	The EAC contacted the company with the following questions: 1. How much does an extended warranty cost? 2. How many years of the 5 year lifespan of a Thopaz+ machine does the extended warranty cover?	Response from the company: 1. Warranty covers faults and accidental damage and we repair/replace and can offer a temp replacement if necessary if the repair takes a long time. 2. Cost for warranty extension is £165 per year per device to a maximum of 3 years (5 years total).	Considered and used by the EAC in its economic model.
Economic model.	The EAC contacted Mrs Jenny Mitchell (clinical expert) with the following question: You kindly let me know that your department undertakes around 500 cases per year. Does this include patients who require chest drainage following	Response from Mrs Mitchell: This is all cases so includes those having surgery for pneumothorax and empyema.	Considered and used by the EAC in its economic model.

Submission Document Section/Sub-section number	Question / Request	Response	Action / Impact / Other comments
	pulmonary resection **only** or does this figure also include treatment of patients with pneumothorax?		
Economic model.	The EAC contacted Mrs Plowright (clinical expert) with the following questions: 1. Are chest drain reinsertions carried out in theatre or are these done on a ward by a nurse, consultant nurse or a doctor? 2. What is needed to carry out the chest drain reinsertion (e.g. chest drain trocar, chest drain, dressings etc.)? 3. How much staff time do you estimate is required to carry out a chest drain re-insertion? 4. Is another chest radiograph required to confirm correct placement and position after chest drain reinsertion?	Mrs Plowright replied with the following answers: 1. Generally NOT done in theatres and usually inserted by a doctor. There are other healthcare professionals starting to insert these but not that many as yet 2. I am sure I have answered this before Roughly Sterile field, Sterile dressing pack and gloves & Chlorhexadine swab Local Analgesia Lidocaine & Needles and syringes Chest drain kit Chest drain tubing and bottle Sterile water/saline Suture kit Sterile dressing 3. Not sure but in competent hands not long – may be 10 minutes from start to finish 4. Yes	Considered and used by the EAC in its economic model.

Submission Document Section/Sub-section number	Question / Request	Response	Action / Impact / Other comments
Economic model.	The EAC contacted Mrs Jenny Mitchell (clinical expert) with the following questions: 1. Are chest drain reinsertions carried out in theatre or are these done on a ward by a nurse, consultant nurse or a doctor? 2. What is needed to carry out the chest drain reinsertion (e.g. chest drain trochar, chest drain tubing, dressings etc.)? 3. How much staff time do you estimate is required to carry out a chest drain re-insertion? 4. Is another chest radiograph required to confirm correct placement and position after chest drain reinsertion?	Mrs Mitchell replied with the following answers: 1. Chest drain reinsertion is normally carried out on the ward by an SpR or consultant with one other assisting, usually a nurse. A reasonable number of patients go to radiology for image guided reinsertion of the drain, usually in cases where it isn't straightforward. Very occasionally patient go to theatre but this is rare. It would be feasible for a nurse practitioner to carry out drain insertion with appropriate specific training, I haven't taken this forward in my role but it may happen in other centres. 2. We have a chest drain insertion pack which contains all the appropriate equipment apart from: 3. Drain with trochar (need to select appropriate size) Local anaesthetic Gloves (need to select appropriate size) Obviously you also need an appropriate drainage system to connect to as well. I'll	Considered and used by the EAC in its economic model.

Submission Document Section/Sub-section number	Question / Request	Response	Action / Impact / Other comments
		see if I have a list of the contents of the pack. 4. It takes about 30 minutes to carry out a drain reinsertion on average. Yes the patient needs a chest x-ray to check the drain position and lung inflation.	

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical Technologies Evaluation Programme

Sponsor submission of evidence:

Evaluation title: The Thopaz+ portable digital system for the management of chest drains

Sponsor: **Medela UK**

Date sections A and B submitted: 30th June 2017

Date section C submitted: 28th July 2017

August 2011 (Version 1.1)

Contents

Instructions for sponsors

This is the template for submission of evidence to the National Institute for Health and Care Excellence (NICE) as part of the Medical Technologies Evaluation Programme process for developing NICE medical technologies guidance. Use of the submission template is mandatory.

The purpose of the submission is for the sponsor to collate, analyse and present all relevant evidence that supports the case for adoption of the technology into the NHS in England, within the scope defined by NICE. Failure to comply with the submission template and instructions could mean that the NICE cannot issue recommendations on use of the technology.

The submission should be completed after reading the 'Medical Technologies Evaluation Programme Methods guide' and the 'Medical Technologies Evaluation Programme Process guide' available at www.nice.org.uk/mt. After submission to, and acceptance by, NICE, the submission will be critically appraised by an External Assessment Centre appointed by NICE.

Under exceptional circumstances, unpublished evidence is accepted under agreement of confidentiality. Such evidence includes 'commercial in confidence' information and data that are awaiting publication ('academic in confidence'). When data are 'commercial in confidence' or 'academic in confidence', it is the sponsor's responsibility to highlight such data clearly. For further information on disclosure of information, submitting cost models and equality issues, users should see section 11 of this document 'Related procedures for evidence submission'.

The submission should be concise and informative. The main body of the submission should not exceed 100 pages (excluding the pages covered by the template and appendices). The submission should be sent to NICE electronically in Word or a compatible format, not as a PDF file.

The submission must be a stand-alone document. Additional appendices may only be used for supplementary explanatory information that exceeds the level

of detail requested, but that is considered to be relevant to the case for adoption. Appendices will not normally be presented to the Medical Technologies Advisory Committee when developing its recommendations. Any additional appendices should be clearly referenced in the body of the submission. Appendices should not be used for core information that has been requested in the specification. For example, it is not acceptable to attach a key study as an appendix and to complete the economic evidence section with 'see appendix X'.

All studies and data included in the submission must be referenced. Identify studies by the first author or trial ID, rather than by relying on numerical referencing alone (for example, 'Trial 123/Jones et al.[126], rather than 'one trial[126]').Please use a recognised referencing style, such as Harvard or Vancouver.

The sponsor should provide a PDF copy of full journal articles or reports – in electronic or hard copy form – included in the submission, if the sponsor is either the copyright owner or has adequate copyright clearance to permit the intended use by NICE. This clearance must be wide enough to allow NICE to make further copies, store the article electronically for a limited period of time on a shared drive to be accessed by a limited number of staff. Additionally, any full article obtained and submitted in electronic format must be done so in a manner compliant with the relevant contractual terms of use permitting the sponsor electronic access to the article. If the sponsor does not have sufficient copyright clearance, they are asked to submit references or links only, or details of contacts for unpublished research. NICE will then itself obtain full copies of all relevant papers or reports, paying a copyright fee where necessary. For unpublished studies for which a manuscript is not available, provide a structured abstract about future journal publication. If a structured abstract is not available, the sponsor must provide a statement from the authors to verify the data provided.

If a submission is based on preliminary regulatory recommendations, the sponsor must advise NICE immediately of any variation between the preliminary and final approval.

Document key

Boxed text with a grey background provides specific and/or important guidance for that section. This should not be removed.

Information in highlighted black italic is to help the user complete the submission and may be deleted.

The user should enter text at the point marked ‘Response’ or in the tables as appropriate. ‘Response’ text may be deleted.

List of tables and figures

Glossary of terms

Section A – Decision problem

Section A describes the decision problem, the technology and its clinical context. There is also information about ongoing studies, regulatory information and equality issues.

Sponsors should submit section A before the full submission (for details on timelines, see the NICE document 'Guide to the Medical Technologies Evaluation Programme process', available from www.nice.org.uk/mt

1 Statement of the decision problem

The decision problem is specified in the final scope issued by NICE. The decision problem states the key parameters that should be addressed by the information in the evidence submission. All statements should be evidence based and directly relevant to the decision problem.

Table A1 Statement of the decision problem

	Scope issued by NICE	Variation from scope	Rationale for variation
Population	All people requiring a chest drain.		
Intervention	Thopaz+		
Comparator(s)	Underwater seal drain, chest drains involving a flutter valve and any other recognised mechanism or valve.		
Outcomes	Duration of chest drain placement. Incidence of chest drain re-insertion. Fluid loss measurement. Length of hospital stay. Rate of complications and device related adverse events. Staff time. Patient satisfaction (including measures of patient discomfort).		
Cost analysis	The intervention and comparators for the cost analysis are described above. Costs will be considered from an NHS and personal social services perspective. The time horizon for the cost analysis will be sufficiently long to reflect any differences in costs and consequences between the technologies being compared. Sensitivity analysis will be undertaken to address uncertainties in the model parameters.		

	Scope issued by NICE	Variation from scope	Rationale for variation
Subgroups to be considered	Use in adults: any clinical situation in which a chest drain is indicated. Use in children. Specific indications: • pneumothorax (differentiating spontaneous and other air leaks) • post-operative use after cardiac or thoracic surgery • patients with pleural disease, thoracic trauma or injury		
Special considerations, including issues related to equality	No equality issues were identified. People undergoing thoracic surgery as a result of a long-term condition may be classed as disabled under the Equality Act 2010. Use of Thopaz^{+} will not impact on any of the protected characteristics under the Equality Act 2010.		

If the sponsor considers that additional parameters should be included in the submission, which are not stated in the decision problem, this variation from the scope and the rationale for it must be clearly described in the relevant columns in table A1.

2 Description of technology under assessment

2.1 Give the brand name, approved name and details of any different versions of the same device.

The Thopaz system first received a CE mark in 2008 (Thopaz) and 2014 (Thopaz+) as a class IIb medical device (classification from IIa to IIb due to Indication Extension, addition of mediastinal indication, in November 2012). Thopaz+, the upgraded device with both digital fluid and air leak management, was launched in to the UK in 2014[1].

2.2 What is the principal mechanism of action of the technology?

Thopaz+ (Medela UK) is a portable digital chest drain system that provides regulated negative pressure close to the patient's chest and continuously monitors the air leak. Thopaz+ maintains negative pressure at a level prescribed and set by the managing physician. The digital display provides objective air leak data in real time as well as in historical graphs, which allows tracking of the therapy progress. Thopaz+ also monitors fluid drainage and therefore measures fluid loss as well.

Thopaz+ consists of an in-built, regulated suction pump with digital display, rechargeable battery, tubing to connect to any standard chest drain catheter and a Thopaz+ disposable fluid collection canister. Thopaz+ is compact and lightweight (223 x 255 x 95 mm and 1 kg) and has an early warning alarm to alert users if safety issues arise, such as a full canister, blocked tubing or a low battery.

Thopaz+ is intended for use by suitably trained healthcare professionals in hospital operating theatres, intensive care and high dependency units as well as recovery wards.

[1] From 2017 only the Thopaz+ system will be available to new users, although the manufacturer will continue to support both systems.

3 Clinical context

3.1 Provide a brief overview of the disease or condition for which the technology is being considered in the scope issued by NICE.

Thopaz+ is indicated for all patients undergoing chest drainage. It is not condition-specific and is designed to monitor air leakage and fluid drainage in every circumstance of chest drain insertion.

In England in 2014-15, there were 31,710 episodes of insertions of tube drains into the pleural cavity, 10,853 drainages of the pleural cavity and 6,633 episodes requiring attention to tube drains into the pleural cavity[2].

Tube drain insertion was undertaken in these instances to treat patients requiring thoracic drainage from the pleural and mediastinal cavities in circumstances including pneumothorax, recovery post-cardiac or post-thoracic surgery, thoracic injury, pleural effusion, pleural empyema or other related conditions.

3.2 Give details of any relevant NICE or other national guidance or expert guidelines for the condition for which the technology is being used. Specify whether the guidance identifies specific subgroups and make any recommendations for their treatment. If available, these should be UK based guidelines.

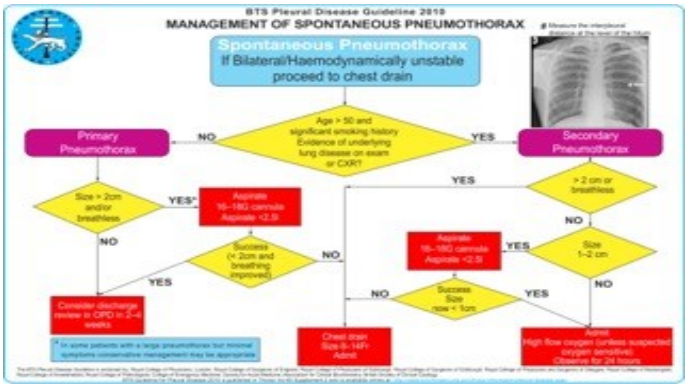
Tube drains are routinely used in the treatment of a number of conditions affecting the thoracic cavity. The British Thoracic Society (BTS) has issued guidelines on the treatment of pneumothorax[3], pleural infection in children[4] and general guidelines on the insertion of chest drains[5]. Individual health boards throughout the UK are likely to have their own, in-house, guidelines on chest drain insertion and maintenance based on the overarching BTS guidelines. Balfour-Lynn et al make recommendations specifically related to the use of chest drains in the paediatric population, which

[2] Hospital Episode Statistics, available at http://www.content.digital.nhs.uk/catalogue/PUB22378
[3] BTS Pleural Disease Guideline: management of spontaneous pneumothorax available at www.brit-thoracic.org.uk/clinical-information/pleural-disease.aspx
[4] Balfour-Lynn et al, *Thorax* 2005; 60 (suppl. 1): i1-i21
[5] Daws et al., Daws et al., *Thorax* 2003; 58 (suppl. II): ii53-ii59

specify that *"[a]ll chest drains should be connected to a unidirectional flow drainage system (such as underwater seal bottle) which must be kept below the level of the patient's chest at all times"*[6], that the use of paediatric chest drains should be supervised by appropriately trained staff, that drains should be checked for blockage or kinking if there is a sudden cessation of drainage, and that *"[a] clamped drain should be immediately unclamped and medical advice sought if a patient complains of breathlessness or chest pain"*[7]. This is in line with guidelines for the insertion and monitoring of chest drains in the adult population. None of the guidelines make any recommendation about the specific brand of drain, other than to stress the need for careful monitoring by adequately trained staff.

3.3 Describe the clinical pathway of care that includes the proposed use of the technology.

Tube drains are routinely inserted to treat a number of conditions where air and / or fluid need to be removed from the thoracic cavity. These include, but are not limited to, cardiac or thoracic surgery, pleural effusion and thoracic trauma; consequently, the relevant pathway of care for each individual patient will depend heavily on the circumstances surrounding their admission to hospital. The pathway of care described here is the standard BTS guidance[8] on the management of pneumothorax and represents the approach which would be taken in the management of chest drains.



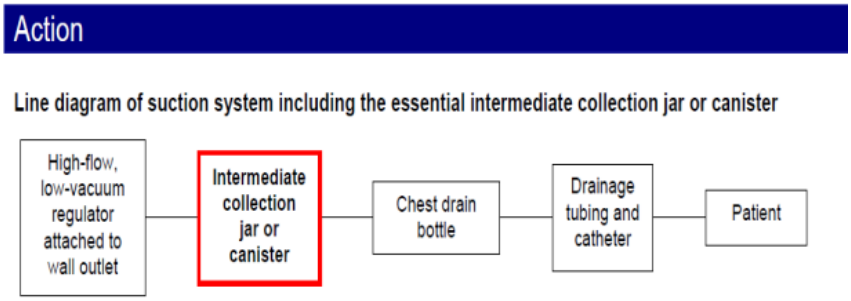
[6] Balfour-Lynn et al, *Thorax* 2005; 60 (suppl. 1): i1-i21, pi4
[7] ibid
[8] BTS Pleural Disease Guideline: management of spontaneous pneumothorax available at www.brit-thoracic.org.uk/clinical-information/pleural-disease.aspx

3.4 Describe any issues relating to current clinical practice, including any uncertainty about best practice.

The management of chest drainage has evolved from common practice, largely based on Level D evidence. There are two principal issues which Thopaz$^+$ can address:

i. The technology can minimise variation in clinical practice by promoting standardisation and adherence to protocols, a key principal of enhanced recovery programmes. The Thopaz$^+$ system in particular lends itself well to protocolised care.

ii. An issue with current practice which Thopaz$^+$ addresses is compliance with MRHA Medical Device Alert Ref: MDA/2010/040 Issued on 13 May 2010. This requires two canisters to be connected in series between the patient and the wall mounted thoracic suction. This has not been achieved in our department. The purpose of the second canister is to prevent fluid up the suction tubing to the wall suction resulting in contamination of the suction system and loss of suction placing the patient at risk. The current Rocket Chest Drain System means that the patient`s recovery is hindered due to restricted mobility and the requirement of the system to be attached to wall suction. There is also an impact on patient dignity and privacy as a result.



/Describe the new pathway of care incorporating the new technology that would exist if the technology was adopted by the NHS in England.

The incorporation of Thopaz$^+$ will not result in any alteration to the pathway of care for patients who undergo chest drain insertion. The improved automation of the technology will make monitoring more

consistent and assist trained staff in chest drain care and management by promoting adherence to a standardised protocol.

3.5 Describe any changes to the way current services are organised or delivered as a result of introducing the technology.

As a result of introducing the Thopaz$^+$ system, there will be an improvement in the adherence to protocol-driven standardisation of care. Other benefits will be:

- Reduced chest tube duration
- Reduced length of stay
- Reduced length of patient complications
- Higher patient satisfaction
- Reduced hospital costs
- Enhanced recovery
- Increased convenience for Doctors & Nurses
- Improved chest drain management and standardisation
- Better prediction of patient outcomes

These are likely to result in improvements to the patient pathway, and consequently the patient experience, with some patients able to return directly to the ward post-operatively, bypassing the need for a critical care bed.

3.6 Describe any additional tests or investigations needed for selecting or monitoring patients, or particular administration requirements, associated with using this technology that are over and above usual clinical practice.

No additional tests or investigations are required for the selection and monitoring of patients; Thopaz$^+$ is indicated for use in all circumstances of chest drain insertion and is appropriate to use in all categories of patient. Monitoring is easier due to the historical data collected by Thopaz$^+$, which collates graphs of fluid loss and air leak for up to 72 hours. Ordering of

consumables is simple and easy via NHSSC, NHS Scotland procurement lists and direct ordering from Medela.

3.7 Describe any additional facilities, technologies or infrastructure that need to be used alongside the technology under evaluation for the claimed benefits to be realised.

Thopaz^{+} is designed for use as an adjunct to current models of tube drain. It does not require any additional facilities, technologies or infrastructure over and above those which would be utilised in the normal course of chest drain insertion and management.

3.8 Describe any tests, investigations, interventions, facilities or technologies that would no longer be needed with using this technology.

Use of Thopaz^{+} results in a reduction in the number of chest radiographs required. The technology saves money by reducing waste as fewer consumables are used and improves patient safety and experience by reducing exposure to radiation. Mobilisation of patients is far easier with Thopaz^{+} than with conventional underwater seal drains,

3.9 Describe how the NHS in England can disinvest from tests, investigations, interventions, facilities or technologies described in section 3.9 that would no longer be needed with using this technology.

Although Thopaz^{+} will reduce costs by reducing the need for chest radiographs and consumables, there is currently no opportunity to disinvest completely from existing treatments and technologies. Work is currently being undertaken to evaluate the potential to

reduce numbers of physiotherapy staff due to the easier mobilisation of patients using Thopaz+.

4 Regulatory information

4.1 Provide PDF copies of the following documents:

- instructions for use
- CE mark certificate or equivalent UK regulatory approval such as EC declaration of conformity
- Quality systems (ISO 13485) certificate (if required).

4.2 Does the technology have CE mark for the indication(s) specified in the scope issued by NICE? If so, give the date that authorisation was received. If not, state current UK regulatory status, with relevant dates (for example, date of application and/or expected approval dates).

PDF copies of all relevant regulatory documentation are appended.

4.3 Does the technology have regulatory approval outside the UK? If so, please provide details.

Thopaz+ is a global product and is licensed for use in the UK, USA, Japan and Europe

4.4 If the technology has not been launched in the UK provide the anticipated date of availability in the UK.

Thopaz was launched in the UK in 2008, and Thopaz+ in 2014.

4.5 If the technology has been launched in the UK provide information on the use in England.

Currently, twenty-seven thoracic units in the UK are using Thopaz and Thopaz$^+$. Three units use a mix of both technologies; seventeen units use Thopaz, ten of which are keen to upgrade to sole use of Thopaz$^+$; seven units are using Thopaz$^+$ and five centres have evaluated Thopaz$^+$ and are awaiting a decision on whether to take it forward.

5 Ongoing studies

5.1 Provide details of all completed and ongoing studies on the technology from which additional evidence relevant to the decision problem is likely to be available in the next 12 months.

Please see below the list of ongoing studies. They should be published in the next year.
All studies are Investigator Initiated Studies. Which means we are not legal sponsor of the studies.

Thoracic

1. A randomized comparison of Active suction vs Passive chest tube drainage and Regulated and Unregulated pleural pressure after anatomic lung resection (APRU). Multicentre randomized clinical trial. Principal investigator: Dr Frank Detterbeck, Yale University, New Haven US
2. We also starting one study this Year in China, however, this will not be published until 2018. The role of digital drainage in general thoracic surgery: a prospective Chinese multicentre database. Principal investigator: Dr Alan Sihoe; Hong Kong University, Shenzhen, China

Pulmonology

1. Multicentre Trial Randomised Ambulatory Management of Primary Pneumothorax (RAMPP). Principal investigator: Dr Robert Hallifax; Royal Brompton Hospital, London, UK

Cardiac

1. Comparison of two chest drainage systems. Single centre randomized clinical trial. Principal Investigator: Dr Arnaud Van Linden; Kerckhoff Klinik, Bad Nauheim, DE
2. Assessment of a New Continuous Chest Drainage System for Post-Operative Cardiac Surgery: A Prospective Randomized Control Trial. Single centre randomized clinical trial. Principal Investigator: Dr Barozzi; Verona University hospital, Verona

5.2 If the technology is, or is planned to be, subject to any other form of assessment in the UK, please give details of the assessment, organisation and expected timescale.

Thopaz^{+} is not currently subject to any other assessment in the UK.

6 Equality

NICE is committed to promoting equality of opportunity and eliminating unlawful discrimination on the grounds of age, disability, gender reassignment, race, religion or belief, sex, and sexual orientation, and to comply fully with legal obligations on equality and human rights.

Equality issues require special attention because of NICE's duties to have due regard to the need to eliminate unlawful discrimination, promote equality and foster good relations between people with a characteristic protected by the equalities legislation and others.

Any issues relating to equality that are relevant to the technology under assessment should be described. This section should identify issues described in the scope and also any equality issues not captured in the final scope.

Further details on equality may be found in section 11.3 of this document.

6.1 Describe any equality issues relating to the patient population and condition for which the technology is being used.

No equality issues have been identified. Thopaz and Thopaz^{+} are suitable for use in all patients, regardless of age, disability, gender, race, religion or sexual orientation.

6.1.1 Describe any equality issues relating to the assessment of the technology that may require special attention.

No equality issues were identified relating the assessment of the technology.

6.2 How will the submission address these issues and any equality issues raised in the scope?

N/A

Section B – Clinical evidence

7 Published and unpublished clinical evidence

Section B requires sponsors to present published and unpublished clinical evidence for their technology.

Sponsors should read section 6 of the Medical Technologies Evaluation Programme methods guide on published and unpublished evidence, available from www.nice.org.uk/mt

All statements should be evidence-based and directly relevant to the scope. Reasons for deviating from the scope should be clearly stated and explained in table A1.

Sponsors are required to submit section B in advance of the full submission (for details on timelines, see the NICE document 'Guide to the Medical Technologies Evaluation Programme process', available from www.nice.org.uk/mt

7.1 Identification of studies

Please note: sections 7.1 and 7.2 of the submission are divided into published and unpublished data. Responses must be split accordingly.

The sponsor's review of the clinical evidence should be systematic and transparent, and a suitable instrument for reporting such as the PRISMA statement (http://www.prisma-statement.org/statement.htm) should be used and CRD should be referred to (www.york.ac.uk/inst/crd).

The strategies used to retrieve relevant clinical data from the published literature and unpublished sources should be clearly described. The methods used should be justified with reference to the scope. Sufficient detail should be provided to enable the methods to be reproduced (the External Assessment Centre must be able to reproduce the search), and the rationale for any inclusion and exclusion criteria regarding search terms should be given.

Published studies

7.1.1 Describe the strategies used to retrieve relevant clinical data from the published literature. Exact details of the search strategy used should be provided in section 10, appendix 1.

Using OVID, searches were undertaken of Medline, Medline(R) In-process and EMBASE using the search terms (“Thopaz” OR “Thopaz+” OR “digital drainage device”) in Title OR Abstract OR Text. A search was also made of the Cochrane database, using the same search terms. Papers were included if they were written in English and published between 2008 (when Thopaz was first licensed for use in the UK) and 2017.

Unpublished studies

7.1.2 Describe the strategies used to retrieve relevant clinical data from unpublished sources.

The OVID search described above included an option to search unpublished and in-press papers. No unpublished studies were returned in this search.

7.2 Study selection

Published studies

7.2.1 Complete table B1 to describe the inclusion and exclusion criteria used to select studies from the published literature. Suggested headings are listed in the table below. Other headings should be used if necessary.

Table B2 Selection criteria used for published studies

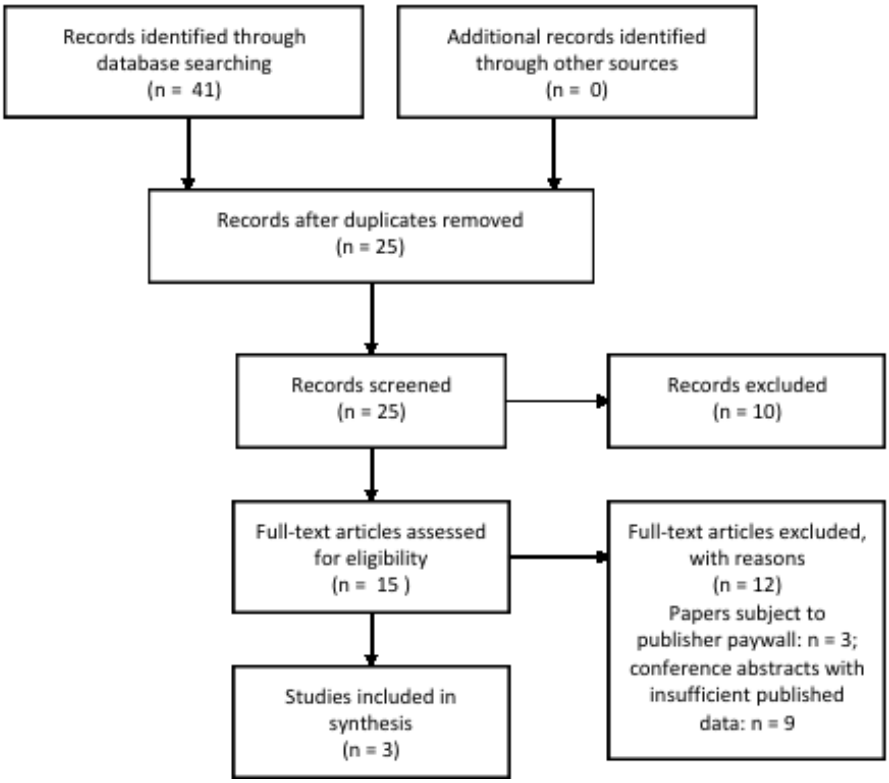
Inclusion criteria	
Population	Patients with significant lung disease and / or undergoing thoracic surgery.
Interventions	Thoracic surgery, VATS, chest drain insertion.
Outcomes	Requirement for chest drain placement or insertion.
Study design	Comparative studies of Thopaz or Thopaz$^+$ with conventional technologies; evaluation; assessment; individual case studies with no comparator.
Language restrictions	Paper must be published in English and freely available online.
Search dates	2008 – 2017
Exclusion criteria	
Population	All other patient cohorts
Interventions	Any other surgical procedure
Outcomes	Any other outcome
Study design	Studies where there was no element of comparison, evaluation or assessment.
Language restrictions	Papers not published in English; papers subject to a publisher's paywall.
Search dates	Outwith 2008 – 2017

7.2.2 Report the numbers of published studies included and excluded at each stage in an appropriate format.

The OVID search returned 36 papers; 5 papers were returned from the Cochrane Database search giving a total of 41 papers. No systematic reviews of either Thopaz or Thopaz$^+$ were found.

Removal of duplicates from the search results resulted in a total of 25 papers. Based on information contained in the abstract, studies were further excluded where they referred to the use of Thopaz or Thopaz$^+$ in non-thoracic surgeries, and where the study design offered no comparison with traditional, analogue technologies or was not an evaluation or assessment of the technology (10 papers). Studies were also excluded at this stage if the full text article was subject to a publisher's paywall (3 papers) or a conference abstract containing insufficient data for review (9 papers). This left a total of 3 papers for full text review.

The PRISMA diagram (below) illustrates the literature search process and results.



It is recommended that the number of published studies included and excluded at each stage is reported using the PRISMA statement flow diagram (available from *www.prisma-statement.org/statement.htm*)

Unpublished studies

7.2.3 Complete table B2 to describe the inclusion and exclusion criteria used to select studies from the unpublished literature. Suggested headings are listed in the table below. Other headings should be used if necessary.

Table B2 Selection criteria used for unpublished studies

Inclusion criteria	
Population	Patients with significant lung disease and / or undergoing thoracic surgery.
Interventions	Thoracic surgery, VATS, chest drain insertion.
Outcomes	Requirement for chest drain placement or insertion.
Study design	Comparative studies of Thopaz or Thopaz^{+} with conventional technologies; evaluation; assessment; individual case studies with no comparator.
Language restrictions	Paper must be published in English and freely available online.
Search dates	2008 – 2017
Exclusion criteria	
Population	All other patient cohorts
Interventions	Any other surgical procedure
Outcomes	Any other outcome
Study design	Studies where there was no element of comparison, evaluation or assessment.
Language restrictions	Papers not published in English; papers subject to a publisher's paywall.
Search dates	Outwith 2008 – 2017

7.2.4 Report the numbers of unpublished studies included and excluded at each stage in an appropriate format.

No unpublished studies were found.

It is recommended that the number of unpublished studies included and excluded at each stage is reported using the PRISMA statement flow diagram (available from *www.prisma-statement.org/statement.htm*)

7.3 Complete list of relevant studies

The sponsor should provide a PDF copy of all studies included in the submission if the sponsor is either the copyright owner or has adequate copyright clearance to permit the intended use by NICE. If the sponsor does not have sufficient copyright clearance, they are asked to submit references or links only, or details of contacts for unpublished studies. For unpublished studies for which a manuscript is not available, provide a structured abstract

about future journal publication. If a structured abstract is not available, the sponsor must provide a statement from the authors to verify the data provided.

7.3.1 Provide details of all published and unpublished studies identified using the selection criteria described in tables B1 and B2.

The details of all published and unpublished studies that compare the technology with other treatments for the relevant group of patients should be presented using tables B3 and B4 respectively. The studies that compare the intervention directly with the appropriate comparator(s) referred to in the decision problem should be clearly highlighted. If there are none, please state this. All types of studies should be considered, including observational studies such as cohort, case series and case-control studies, and single case reports and qualitative studies when relevant to the scope.

The list of relevant studies must be complete and will be validated by independent searches conducted by the External Assessment Centre.

Published studies should be referenced by first author name and year of publication. Unpublished studies should be referenced by first author and date of report. Full details of each reference should be provided in the reference list after section 9. In addition, list any trial short names if useful.

Table B3 List of relevant published studies

Primary study reference	Population	Intervention	Comparator	Included / excluded
Rathinam S; Bradley A; Cantlin T; Rajesh PB 'Thopaz Portable Suction Systems in Thoracic Surgery: an end user assessment and feedback in a tertiary unit.' *Journal Of Cardiothoracic Surgery. 6:59, 2011 Apr 21.*	120 thoracic surgical patients.	Bullectomy / pleurectomy; VATS lung biopsy; VATS metastatectomy; lung resection.	Evaluation: no comparator.	Included

Primary study reference	Population	Intervention	Comparator	Included / excluded
Tunnicliffe G; Draper A 'A pilot study of a digital drainage system in pneumothorax' *BMJ open respiratory research. 1(1):e000033, 2014.*	13 patients with pneumothorax requiring a chest drain.	Chest drain insertion.	Evaluation: no comparator	Included
Pompili C, Detterbeck, F, Papagiannopoulos K, Sihoe A, Vachlas K, Maxfield M W, Lim H C, Brunelli A "Multicenter international randomized comparison of objective and subjective outcoems between electronic and traditional chest drainage systems" *Annals of Thoracic Surgery 2014; 98:90-97*	381 thoracic surgical patients.	Chest drain placement.	Traditional water seal chest drainage.	Included
Araujo P., Vega A.D., Lauricella L., Bibas B., Pego-Fernandes P., Terra R 'Digital drainage system reduces chest tube duration and hospitalization after anatomic pulmonary resections for malignancies.' *Journal of Thoracic Oncology. Conference: 17th World Conference of the International Association for the Study of Lung Cancer, IASLC 2016. Austria. 12 (1 Supplement 1) (pp S1403-S1404), 2017.*	110 patients	Chest drain placement	Conventional chest drainage	Excluded

Primary study reference	Population	Intervention	Comparator	Included / excluded
Tsakiridis K., Marinos T., Arikas S., Tzamtzis S 'Digital thoracic drainage: Our initial experience in hundred patients' *Interactive Cardiovascular and Thoracic Surgery. Conference: 19th European Conference on General Thoracic Surgery. Marseille France. Conference Publication: (var.pagings). 13 (pp S17), 2011.*	200 thoracic surgical patients	Chest drain placement	Traditional water seal chest drain	Excluded
Costa A.S., Leao L.E.V., Miotto A 'Initial evaluation of digital drainage system in pediatric postoperative thoracic surgery' *American Journal of Respiratory and Critical Care Medicine. Conference: American Thoracic Society International Conference, ATS 2015. Denver, CO United States. Conference Publication: (var.pagings). 191 (no pagination), 2015.*	11 patients	Chest drain placement	No comparator.	Excluded
Sakai E., Kohno T., Fujimori S., Ikeda T., Harano T., Suzuki S., Iida T 'Clinical evaluation of thopaz portable digitalized suction systems in thoracic surgery' *Interactive Cardiovascular and*	226 thoracic surgical patients	Chest drain placement	Traditional water seal chest drain.	Excluded

Primary study reference	Population	Intervention	Comparator	Included / excluded
Thoracic Surgery. Conference: 23rd European Conference on General Thoracic Surgery. Lisbon Portugal. Conference Publication: (var.pagings). 21 (no pagination), 2015.				
Hallifax R.J., Corcoran J.P., Rahman N.M 'Post-thoracoscopy lung re-expansion: Pilot data using digital suction device' *American Journal of Respiratory and Critical Care Medicine. Conference: American Thoracic Society International Conference, ATS 2014. San Diego, CA United States. Conference Publication: (var.pagings). 189 (no pagination), 2014.*	32 thoracoscopy patients	Chest drain placement	No comparator	Excluded
Addy C., Bateman K., Bell N.J 'Management of pneumothoraces in cystic fibrosis (CF): A novel approach using an ambulatory suction device (ThopazTM system, Medela Ltd)' *Journal of Cystic Fibrosis. Conference: 37th European Cystic Fibrosis Conference. Gothenburg Sweden.*	3 cyctic fibrosis patients with pneumothorax.	Chest drian insertion	No comparator	Excluded

Primary study reference	Population	Intervention	Comparator	Included / excluded
Conference Publication: (var.pagings). 13 (pp S89), 2014. Date of Publication: June 2014.				
Morcos K., Kirk A.J.B 'Experience with a digital chest drainage suction system (Thopaz) in the management of patients with malignant chest disease.' *Lung Cancer. Conference: 11th Annual British Thoracic Oncology Group Conference, BTOG 2013. Dublin Ireland. Conference Publication: (var.pagings). 79 (pp S69), 2013. January 2013.*	642 thoracic surgical patients	Chest drain placement	Tradtional water seal chest drain (historical comparison group)	Excluded
Marjanski T., Sternau A., Pawlak K., Gasiorowski L., Rzyman W 'Conservative drain removal protocol does not favor digital chest drainage after lobectomy: Multicenter randomized trial' *Interactive Cardiovascular and Thoracic Surgery. Conference: 19th European Conference on General Thoracic Surgery. Marseille France. Conference Publication: (var.pagings). 13 (pp S27), 2011.*	126 thoracic surgical patients	Chest drain placement	Traditional water seal chest drain	Excluded

Primary study reference	Population	Intervention	Comparator	Included / excluded
Arts C.H., Van Geffen E.H., Olsman J.G., Bolhuis R.J 'Thopaz compared with conventional postoperative thorax drainage' *Interactive Cardiovascular and Thoracic Surgery. Conference: 18th European Conference on General Thoracic Surgery. Valladolid Spain. Conference Publication: (var.pagings). 11 (pp S34), 2010.*	75 patients	Chest drain placement	Traditional water seal chest drain	Excluded
Papagiannopoulos K., Kuppusami M., Kefaloyanis M 'The use of Thopaz Pump in the management of air leaks. A transition from analogue to standardised digital scoring. Experience of first 100 cases from a single institution' *Interactive Cardiovascular and Thoracic Surgery. Conference: 17th European Conference on General Thoracic Surgery. Krakow Poland. Conference Publication: (var.pagings). 9 (pp S31), 2009.*	100 surgical patients.	Chest drain placement.	No comparator	Excluded

Table B4 List of relevant unpublished studies

Data source	Study name (acronym)	Population	Intervention	Comparator
N/A				

7.3.2 State the rationale behind excluding any of the published studies listed in tables B3 and B4.

Studies marked as “excluded” in table B3 were conference abstracts which contained insufficient data to contribute meaningfully to the overall synthesis.

7.4 Summary of methodology of relevant studies

7.4.1 Describe the study design and methodology for each of the published and unpublished studies using tables B5 and B6 as appropriate. A separate table should be completed for each study.

Table B5 Summary of methodology for randomised controlled trials

Study name	Multicentre international randomized comparison of objective and subjective outcomes between electronic and traditional chest drainage.
Objectives	To compare objective (duration of chest tube placement) and subjective (patient satisfaction) outcomes with a novel portable electronic chest drainage system (Thopaz, Medela Healthcare) with a traditional one in patients who underwent pulmonary lobectomy or segmentectomy.
Location	UK, Europe, Asia, United States
Design	Multicentre prospective randomised trial
Duration of study	January 2013 – January 2014
Sample size	381
Inclusion criteria	Patients undergoing pulmonary lobectomy or segmentectomy
Exclusion criteria	Patients requiring mechanical ventilation at any time during the post-operative course and those undergoing re-do thoracotomies – both are confounding factors influencing the duration of chest drainage.
Method of randomisation	Simple unrestricted randomisation using a computer-generated randomisation list in sequentially numbered envelopes. These were opened by a nurse at the end of each operation to allocate the patient to the traditional or digital arm of the study.

Method of blinding	Study was unblinded.
Intervention(s) (n =) and comparator(s) (n =)	Digital arm: 191 patients Traditional arm: 190 patients
Baseline differences	Patients were well matched for baseline surgical characteristics.
Duration of follow-up, lost to follow-up information	N/A
Statistical tests	Normal distribution was assessed by the Shapiro-Wilks normality test. Numerical variables were compared using Student's *t* test (normal distribution) or by the Wilcoxon signed rank test. Categorical variables were compared by the χ^2 test or Fisher's exact test as appropriate. All tests were 2-tailed, with a significance level of 0.05.
Primary outcomes (including scoring methods and timings of assessments)	
Secondary outcomes (including scoring methods and timings of assessments)	

Table B6 Summary of methodology for observational studies

Study name	Thopaz portable suction systems in thoracic surgery: and end user assessment and feedback in a tertiary unit.
Objective	To evaluate the utility of the device, and staff and patient feedback.
Location	Tertiary thoracic centre
Design	Clinical evaluation, staff and patient feedback forms
Duration of study	Two months
Patient population	Patients undergoing bullectomy / pleurectomy, VATS lung biopsy, VATS metastatectomy or lung resection.
Sample size	120
Inclusion criteria	Patients undergoing video-assisted thoracic surgical procedures and elective lung resections.
Exclusion criteria	Patients undergoing pneumonectomy or decortication
Intervention(s) (n =) and comparator(s) (n =)	No comparator: study focused on evaluation of the Thopaz system.
Baseline differences	Not stated.
How were participants followed-up (for example, through pro-active follow-up or passively). Duration of	N/A

follow-up, participants lost to follow-up	
Statistical tests	No statistical tests stated.
Primary outcomes (including scoring methods and timings of assessments)	
Secondary outcomes (including scoring methods and timings of assessments)	

Study name	A pilot study of a digital drainage system in pneumothorax
Objective	To evaluate the feasibility of using Thopaz for patients admitted with pneumothorax; to subjectively evaluate patient, nurse and physician satisfaction with the device; to gather observational data about the recorded air leak and analyse whether this appeared to be related to patient outcome.
Location	UK
Design	Gatekeeper approached potential participants to discuss and obtain consent. Consented patients had their underwater seal chest drains changed for a digital device.
Duration of study	September 2012 – April 2013
Patient population	Patients admitted under the medical team with pneumothorax.
Sample size	13
Inclusion criteria	Medical admission with pneumothorax.
Exclusion criteria	Not stated.
Intervention(s) (n =) and comparator(s) (n =)	13
Baseline differences	Not stated.
How were participants followed-up (for example, through pro-active follow-up or passively). Duration of follow-up, participants lost to follow-up	Standard care.
Statistical tests	N/A
Primary outcomes (including scoring methods and timings of assessments)	

Secondary outcomes (including scoring methods and timings of assessments)

7.4.2 Provide details on data from any single study that have been drawn from more than one source (for example a poster and unpublished report) and/or when trials are linked this should be made clear (for example, an open-label extension to randomised controlled trial).

N/A

7.4.3 Highlight any differences between patient populations and methodology in all included studies.

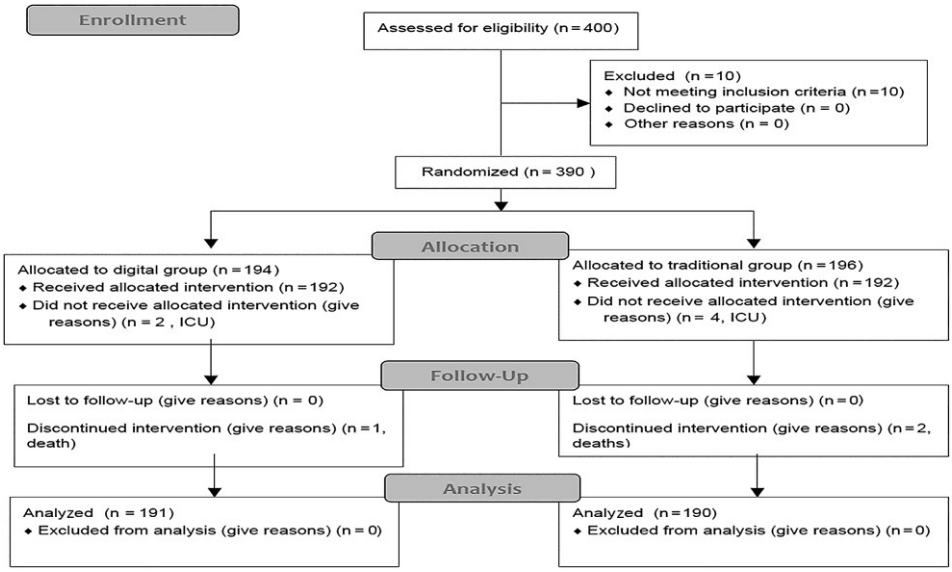
The evidence included in this analysis are heterogeneous in nature; each of the three studies used a different methodology to reach their overall conclusions. Pompili et al used the rigorous methodology of a randomized control trial, with a large sample, comparator and complex statistical analysis. This was a multi-center, international study, with a baseline patient population of thoracic surgical patients. Rathinam et al also used a large sample, but patients were not randomised; there was no comparator, and analysis was of a simple, arithmetical nature. The study took place in one tertiary centre, with a baseline population of thoracic surgical patients. Tunnicliffe and Draper used qualitative methods to complete their study, which sought to observe and document end-user experience from both the patient and the clinician perspective.

The study took place in one respiratory unit, with a baseline population of medical respiratory patients.

7.4.4 Provide details of any subgroup analyses that were undertaken in the studies included in section 7.4.1. Specify the rationale and state whether these analyses were pre-planned or post-hoc.

None of the studies noted above undertook any sub-group analyses.

7.4.5 If applicable, provide details of the numbers of patients who were eligible to enter the study(s), randomised, and allocated to each treatment in an appropriate format.



Source: Pompili C, Detterbeck, F, Papagiannopoulos K, Sihoe A, Vachlas K, Maxfield M W, Lim H C, Brunelli A "Multicenter international randomized comparison of objective and subjective outcomes between electronic and traditional chest drainage systems" *Annals of Thoracic Surgery 2014; 98:90-97.* This was the only RCT included in the synthesis.

It is recommended that details of the numbers of patients that were eligible to enter the study(s), randomised and allocated to each treatment are presented as CONSORT flow charts if possible (see www.consort-statement.org/consort-statement/).

7.4.6 If applicable provide details of and the rationale for, patients that were lost to follow-up or withdrew from the studies.

None of the studies included data on patients who were lost to follow up, or withdrew from the study.

7.5 Critical appraisal of relevant studies

The validity of the results of an individual study will depend on the robustness of its overall design and execution, and its relevance to the scope. Each study that meets the criteria for inclusion should therefore be critically appraised. Whenever possible, the criteria for assessing published studies should also be used to assess the validity of unpublished and part-published studies.

For the quality assessments use an appropriate and validated quality assessment instrument. Key aspects of quality to be considered can be found in 'Systematic reviews: CRD's guidance for undertaking reviews in health care' (www.york.ac.uk/inst/crd).

The critical appraisal will be validated by the External Assessment Centre.

7.5.1 Complete a separate quality assessment table for each study. A suggested format for the quality assessment results is shown in tables B7 and B8.

Table B7 Critical appraisal of randomised control trials

Study name	Multicentre international randomized comparison of objective and subjective outcomes between electronic and traditional chest drainage systems.	
Study question	**Response (yes/no/not clear/N/A)**	**How is the question addressed in the study?**
Was randomisation carried out appropriately?	Yes	The process of randomisation is explained in detail: "[s]imple unrestricted randomisation was performed in each center according to a computer-generated randomization list concealed in sequentially numbered envelopes" (p492).
Was the concealment of treatment allocation adequate?	Yes	Yes. Sufficient steps were taken to ensure that neither patients nor clinicians were aware of allocation until the immediate post-operative period.

Were the groups similar at the outset of the study in terms of prognostic factors, for example, severity of disease?	Yes	The authors detail that patients were "well matched for baseline and surgical characteristics. There were 325 lobectomies / bilobectomies and 56 segmentectomies…" (p490).
Were the care providers, participants and outcome assessors blind to treatment allocation? If any of these people were not blinded, what might be the likely impact on the risk of bias (for each outcome)?	Yes.	Care providers, participants and outcome assessors were blind to initial allocation; however, post-placement it would not have been possible for blinding to be continued. The Thopaz system is an external chest drain, with characteristics very obviously different from a traditional analogue system. There is always a small risk of bias; however, the authors provide significant detail of the monitoring criteria used to determine the utility of Thopaz, and also undertook a patient satisfaction survey which is likely to have funcitoned as an alert system had the results been significnatly different from those of the main study.
Were there any unexpected imbalances in drop-outs between groups? If so, were they explained or adjusted for?	N/A	No drop-outs were reported in either group.
Is there any evidence to suggest that the authors measured more outcomes than they reported?	No.	
Did the analysis include an intention-to-treat analysis? If so, was this appropriate and were appropriate methods used to account for missing data?	N/A	Thopaz is not a treatment; it is a digital device which forms part of the post-operative moitoring process.
Adapted from Centre for Reviews and Dissemination (2008) Systematic reviews. CRD's guidance for undertaking reviews in health care. York: Centre for Reviews and Dissemination		

Table B8 Critical appraisal of observational studies

Study name Thopaz portable suction systems in thoracic surgery: an end user assessment and feedback in a tertiary unit.

Study question	Response yes/no/not clear/N/A)	How is the question addressed in the study?
Was the cohort recruited in an acceptable way?	Not clear.	Question is not addressed; authors simply state that 120 patients were evaluated.
Was the exposure accurately measured to minimise bias?	N/A	
Was the outcome accurately measured to minimise bias?	Yes	The authors are explicit about the number of staff involved in the evaluation of the device (15) and clearly state the proportion of responses for each stage of the Likert scale used for measuring satisfaction.
Have the authors identified all important confounding factors?	N/A	
Have the authors taken account of the confounding factors in the design and/or analysis?	N/A	
Was the follow-up of patients complete?	N/A	The purpose of the study was to evaluate staff satisfaction with the device.
How precise (for example, in terms of confidence interval and p values) are the results?	N/A	This was not a statistical analysis.
Adapted from Critical Appraisal Skills Programme (CASP): Making sense of evidence 12 questions to help you make sense of a cohort study		

Study name A pilot study of a digital drainage system in pneumothorax.		
Study question	**Response yes/no/not clear/N/A)**	**How is the question addressed in the study?**
Was the cohort recruited in an acceptable way?	Yes	Authors are clear that patients within a given age range with a chest drain in situ for the purpose of treating pneumothorax were invited to participate and adequately consented if they agreed.
Was the exposure accurately	N/A	

measured to minimise bias?		
Was the outcome accurately measured to minimise bias?	N/A	
Have the authors identified all important confounding factors?	N/A	
Have the authors taken account of the confounding factors in the design and/or analysis?	N/A	
Was the follow-up of patients complete?	Yes	Patient records were checked at 120 days post-discharge to determine recurernce rates of pneumothorax.
How precise (for example, in terms of confidence interval and p values) are the results?	N/A	This was a qualitative evaluation of patient and clinician experiences of using the device.
Adapted from Critical Appraisal Skills Programme (CASP): Making sense of evidence 12 questions to help you make sense of a cohort study		

7.6 Results of the relevant studies

7.6.1 Complete a results table for each study with all relevant outcome measures pertinent to the decision problem. A suggested format is given in table B9.

A separate table for each study must be completed. State N/A or unknown if appropriate. Any outcomes not tested statistically can be included in the comments section.

For each outcome for each included study, provide the following information:

- *The primary hypothesis under consideration and the statistical analysis used for testing hypotheses. Provide details of the power of the study and a description of sample size calculation, including rationale and assumptions.*

- *The outcome name and unit of measurement. Indicate the outcomes that were specified in the study protocol as primary or secondary, and whether they are relevant with reference to the decision problem.*
- *The size of the effect. For dichotomous outcomes, the results ideally should be expressed as both relative risks (or odds ratios) and risk (or rate) differences. For time-to-event analysis, the hazard ratio is an equivalent statistic. Both absolute and relative measures should be presented.*
- *A 95% confidence interval.*
- *The number of participants in each group included in each analysis and whether the analysis was by 'intention to treat'. State the results in absolute numbers if feasible.*
- *Details of how the analysis took account of patients who withdrew and if patients were excluded from the analysis, give the rationale for this.*
- *Data from pre-specified outcomes rather than post-hoc analysis. If appropriate, provide evidence of reliability or validity, and current status of the measure (such as use in current clinical practice).*
- *Clear statements of when interim study data are quoted, along with the point at which data were taken and the time remaining until completion of that study. Analytical adjustments should be described to cater for the interim nature of the data.*
- *Other relevant data that may assist in interpretation of the results, such as adherence to medication and/or study protocol.*
- *Discussion and justification of definitions of any clinically important differences.*
- *Reports of any other analyses performed, including subgroup analysis and adjusted analyses, indicating whether they are pre-specified or exploratory.*
- *Graphs or figures to supplement text and tabulated data if available.*

Table B9 Outcomes from published and unpublished studies

Study name		Multicenter international randomized comparison of objective and subjective outcomes between electronic and traditional chest drainage systems.
Size of study groups	**Treatment**	Placement of digital chest drainage system.
	Control	Placement of traditional chest drainage system.
Study duration	**Time unit**	One year
Type of analysis	**Intention-to-treat/per protocol**	Per protocol
Outcome	**Name**	Shorter air leak duration
	Unit	Days
Effect size	**Value**	1.0 for digital drainage arm versus 2.2 for traditional drainage arm.
	95% CI	
Statistical test	**Type**	Student's *t* test (normal distribution) or Wilcoxon signed rank test.
	p value	0.001
Other outcome	**Name**	Duration of chest tube placement
	Unit	Days
Effect size	**Value**	3.6 versus 4.7 days
	95% CI	
Statistical test	**Type**	Student's *t* test (normal distribution) or Wilcoxon signed rank test.
	p value	0.0001
Comments		Other outcomes considered were: Postoperative length of stay (4.6 vs 5.6 days, $p<0.0001$); lower incidences of prolonged air leak (10 vs 22 cases, $p=0.03$).

Study name		Thopaz portable suction systems in thoracic surgery: an end user assessment and feedback in a tertiary unit
Size of study groups	**Treatment**	Placement of Thopaz digital chest drainage system.
	Control	No control.
Study duration	**Time unit**	2.5 months
Type of analysis	**Intention-to-treat/per protocol**	Per protocol
Outcome	**Name**	Staff feedback evaluation of the device.
	Unit	N/A
Effect size	**Value**	N/A
	95% CI	N/A
Statistical test	**Type**	N/A
	p value	N/A
Other outcome	**Name**	N/A
	Unit	N/A
Effect size	**Value**	N/A
	95% CI	N/A
Statistical test	**Type**	N/A
	p value	N/A
Comments		Staff were asked to evaluate the device under four categories – set up, instructions, characteristics andoverall performance. Evaluation was by means of a standard Likert scale, with choices of excellent, very good, good, satisfactory, could be improved and poor. Overall, staff were satisfied with the device; although there were some initial concerns, these were dealt with during the initial learning period and by moving to a newer version of the device.

Study name		A pilot study of a digital drainage system in pneumothorax.
Size of study groups	**Treatment**	Replacement of analogue chest drain with digital version.
	Control	No control
Study duration	**Time unit**	Eight months
Type of analysis	**Intention-to-treat/per protocol**	Per protocol
Outcome	**Name**	Safety of Thopaz as a tool for the medical management of pneumothorax.
	Unit	N/A
Effect size	**Value**	N/A
	95% CI	N/A
Statistical test	**Type**	N/A
	p value	N/A
Other outcome	**Name**	N/A
	Unit	N/A
Effect size	**Value**	N/A
	95% CI	N/A
Statistical test	**Type**	N/A
	p value	N/A
Comments		Qualitative study to evaluate patient, clinician and nursing perspectives of the efficacy of the device, and it's potential safety and utility in the medical management of pneumothorax. Patient and nurse satisfaction with the device was high, particularly in relation to its portability. Clinician satisfaction was also high, with good clinical agreement on the management of each case; issues raised around the time to drain removal for one patient who suffered an intermittent leak, although there were no surgical findings to explain this. Clinicians also raised a concern that it was only possible to review 24' worth of data – this has been taken forward with the company concerned who, at the time of the study, planned to extend the time period for historical data to 72'.

7.6.2 Justify the inclusion of outcomes in table B9 from any analyses other than intention-to-treat.

Thopaz / Thopaz^{+} is not a treatment. All patients included in the studies mentioned above were admitted with an intention to treat

their underlying condition; digital chest drainage formed a part of that treatment but was not a treatment in and of itself.

7.7 Adverse events

In section 7.7 the sponsor is required to provide information on the adverse events experienced with the technology being evaluated in relation to the scope.

For example, post-marketing surveillance data may demonstrate that the technology shows a relative lack of adverse events commonly associated with the comparator.

7.7.1 Using the previous instructions in sections 7.1 to 7.6, provide details of the identification of studies on adverse events, study selection, study methodologies, critical appraisal and results.

A search of the databases outlined in previous sections was conducted, using the search terms ((“Thopaz” OR “Thopaz+”) AND (“MHRA” OR “adverse event”)) in TITLE OR ABSTRACT OR TEXT WORD. No studies were identified.

For studies that have already been identified as relevant and appraised in sections 7.1 to 7.6 of the submission that were designed primarily to assess safety outcomes (for example, they are powered to detect significant differences between treatments with respect to the incidence of an adverse event), should be presented as a list of studies with the relevant study reference used in the submission.

Examples of search strategies for specific adverse effects and/or generic adverse-effect terms and key aspects of quality criteria for adverse-effects data can found in ‘Systematic reviews: CRD’s guidance for undertaking reviews in health care’ (available from www.york.ac.uk/inst/crd).

Exact details of the search strategy used should be provided in section 10 appendix 2.

The sponsor's search strategy will be replicated by the External Assessment Centre.

7.7.2 Provide details of all important adverse events reported for each study. A suggested format is shown in table B10.

N/A: no studies were identified.

When providing details of important adverse events reported for each study, for each group, give the number of people with the adverse event, the total number of people in the group and the percentage with the event. Present the relative risk and risk difference and associated 95% confidence intervals for each adverse event.

Table B10 Adverse events across patient groups

	Time period 1			***Time period 2 etc.***		
	***Intervention* % of patients (n = *x*)**	***Comparator* % of patients (n = *x*)**	**Relative risk (95% CI)**	***Intervention* % of patients (n = *x*)**	***Comparator* % of patients (n = *x*)**	**Relative risk (95% CI)**
Class 1 (for example, nervous system disorders)						
Adverse event 1						
Adverse event 2						
Class 2 (for example, vascular disorders)						
Adverse event 3						
Adverse event 4						

CI, confidence interval
Adapted from European Public Assessment Reports published by the European Medicines Agency

7.7.3 Describe all adverse events and outcomes associated with the technology in national regulatory databases such as those maintained by the MHRA and FDA (Maude).

Medela had 1 official MHRA cases in UK where Thopaz system was affected. Both cases have been closed.

1. Docking Station from 2013, where we exchanged the Docking station in the hospitals
   We at Medela has a complaint, a vigilance and as well a post market surveillance process according to the regulation.

7.7.4 Provide a brief overview of the safety of the technology in relation to the scope.

The technology appears to be both safe and effective relative to the scope, with the caveat that users should follow manufacturer guidance with regard to cleaning at all times.

7.8 Evidence synthesis and meta-analysis

When more than one study is available and the methodology is comparable, a meta-analysis should be considered.

Section 7.8 should be read in conjunction with the 'Medical Technologies Evaluation Programme Methods Guide', available from www.nice.org.uk/mt

When direct comparative evidence about two key treatments is not available, indirect treatment comparison methods can be used to derive comparative estimates of the effectiveness of these two treatments. For example, if there is evidence comparing A with B, and B with C, indirect treatment comparison techniques could be used to help compare A with C. This option should be considered even though it may be less suitable for the evaluation of many new medical technologies, either because of lack of multiple comparators in the evidence base, or limitations in the evidence base/study designs.

7.8.1 Describe the technique used for evidence synthesis and/or meta-analysis. Include a rationale for the studies selected, details of the methodology used and the results of the analysis.

Due to the small number of studies included, and their heterogeneity, a traditional, meta-analytic review is not appropriate here. Consequently, a short qualitative review is presented in the next section.

Details should include the selection and quality assessment of the studies, the methodology used for combining the outcomes from the studies, including any tests for heterogeneity, and the results of the analysis including an assessment of the uncertainty associated with these results.

7.8.2 If evidence synthesis is not considered appropriate, give a rationale and provide a qualitative review. The review should summarise the overall results of the individual studies with reference to their critical appraisal.

As outlined above, evidence synthesis was not considered appropriate due to the small number of studies and their heterogeneous nature. The following is a qualitative review of study findings, paying particular attention to the robustness and reliability of the study technique.

Pompili et al randomised 381 patients to receive either a traditional chest drain or a Thopaz digital system. The study was undertaken over the course of one calendar year, and involved thoracic surgical units on four continents. Patient baseline and surgical characteristics were well matched between the two arms of the study. Findings demonstrated that patients who received the Thopaz chest drainage system had a shorter chest drain placement, shorter hospital stay and greater satisfaction with the device than those randomised to the analogue control arm. The theme of patient satisfaction was also foregrounded in Rathinam et al and Tunnicliffe and Draper, with patients and staff overall proving very satisfied with the use of the device.

Tunnicliffe and Draper, in contrast, use a broadly qualitative approach to their observational study of patient and clinician perspectives on the utility of the Thopaz system in the non-surgical treatment of pneumothorax. Their sample was small but this is

acknowledged and there is clarity that the purpose of the study was to run a small pilot to test the subjective potential of the product, rather than a large-scale statistical analysis. While there is limited detail around how the questionnaires given to patients and staff were analysed, the authors are explicit in their description of patient recruitment and go into some detail in the discussion of the potential utility of the device in the non-surgical management of pneumothorax, finding that there is potential for Thopaz to be used effectively and safely in this regard.

The methodology utilised by Rathinam et al is not clear, necessitating a caveat about the reliability of their findings. Staff who participated in the end-user assessment were, overall, happy with the device and felt it was an improvement on analogue chest drainage; however, no detail is given about how the 120 patients were recruited to the study and no detail is given about how the Likert scale satisfaction form given to staff was analysed. There is some discussion about the perceptions of patients, but no detail on how these opinions were sought and analysed. While this study is broadly supportive of the use of Thopaz, there is a lack of detail about data collection and analysis methods.

Overall, the three studies (two of which are rigorous and robust in their description of selection, recruitment and analysis, and one slightly less so) indicate that Thopaz is safe and effective. Compared with traditional analogue chest drainage systems, it reduces the length of time patients need a chest drain, reduces length of stay, improves clinician agreement on the best time for drain removal and is popular with patients and staff due to its ease of use and the facility it gives to patients to enable them to mobilise while on chest drainage without having to disconnect any equipment.

7.9 Interpretation of clinical evidence

7.9.1 Provide a statement of principal findings from the clinical evidence highlighting the clinical benefit and any risks relating to adverse events from the technology.

The principal findings are that Thopaz / Thopaz^{+} is safe, effective and liked by patients, clinicians and nursing staff. It increases

patient mobility during the recovery period, and increases clinician agreement on the optimum time to remove chest drainage.

The only risk identified is that the base unit should not be immersed in water during cleaning, as it is an electrical item. A single incidence of this was reported to the MHRA and appropriate steps taken by Medela to reinforce this information during staff training.

7.9.2 Provide a summary of the strengths and limitations of the clinical-evidence base of the technology.

The clinical evidence base for the technology is limited. While absence of evidence is not evidence of absence, it has proven difficult to find robust studies relating to the technology. Several authors have published conference abstracts, but these are insufficiently detailed to contribute to a robust synthesis of the evidence.

Two of the three studies included in the above review are robust and conducted within the parameters of the research paradigms they represent. The results of the remaining study should be treated with caution; while there is no suggestion that the study was not conducted with rigour, it is not well written up and key elements of the data collection and analysis processes are not referenced.

7.9.3 Provide a brief statement on the relevance of the evidence base to the scope. This should focus on the claimed patient- and system-benefits described in the scope.

The evidence base is relevant to the scope. All studies reviewed contained an element of patient satisfaction in addition to their focus on clinical efficacy, and it is clear that, although limited, the evidence base supports the use of the Thopaz system as increasing clinician agreement on time to remove chest drains, is safer for patients due to its portability and reduced opportunities for

infection, and is likely to save health boards money given the reduction in consumables.

7.9.4 Identify any factors that may influence the external validity of study results to patients in routine clinical practice.

No factors were found which would influence the external validity of study results to patients in routine clinical practice.

7.9.5 Based on external validity factors identified in 7.9.4 describe any criteria that would be used in clinical practice to select patients for whom the technology would be suitable.

Criteria used to select patients for whom the technology would be suitable would be unchanged from the status quo. The technology is currently suitable for any patient requiring chest drain placement or insertion.

Section C – Economic evidence

Section C requires sponsors to present economic evidence for their technology.

All statements should be evidence-based and directly relevant to the decision problem.

The approach to the de novo cost analysis expected to be appropriate for most technologies is cost-consequence analysis. Sponsors should read section 7 of the Medical Technologies Evaluation Programme Methods guide on cost-consequences analysis, available from www.nice.org.uk/mt

Sponsors are requested to submit section C with the full submission. For details on timelines, see the NICE document 'Guide to the Medical

Technologies Evaluation Programme process', available from www.nice.org.uk/mt

8 Existing economic evaluations

8.1 Identification of studies

The review of the economic evidence should be systematic and transparent and a suitable instrument for reporting such as the PRISMA statement (www.prisma-statement.org/statement.htm).

A PDF copy of all included studies should be provided by the sponsor.

8.1.1 Describe the strategies used to retrieve relevant health economics studies from the published literature and to identify all unpublished data. The search strategy used should be provided as in section 10, appendix 3.

Response

Health economics studies should include all types of economic evaluation and cost studies, including cost analyses and cost-effectiveness and budget-impact analyses. The methods used should be justified with reference to the decision problem.

Sufficient detail should be provided to enable the methods to be reproduced (the External Assessment Centre must be able to reproduce the search), and the rationale for any inclusion and exclusion criteria regarding search terms should be used.

8.1.2 Describe the inclusion and exclusion criteria used to select studies from the published and unpublished literature. Suggested headings

are listed in the table below. Other headings should be used if necessary.

Table C1 Selection criteria used for health economic studies

Inclusion criteria
Population
Interventions
Outcomes
Study design
Language restrictions
Search dates
Exclusion criteria
Population
Interventions
Outcomes
Study design
Language restrictions
Search dates

8.1.3 Report the numbers of published studies included and excluded at each stage in an appropriate format.

Response

It is recommended that the number of published studies included and excluded at each stage is reported using the PRISMA statement flow diagram (available from *www.prisma-statement.org/statement.htm*)

8.2 Description of identified studies

8.2.1 Provide a brief review of each study, stating the methods, results and relevance to the scope. A suggested format is provided in table C2.

Outcome measures should be included if applicable. Patient outcomes could include gains in life expectancy, improved quality of life, longer time to recurrence, and comparative costs.

Table C2 Summary list of all evaluations involving costs

Study name (year)	**Location of study**	**Summary of model and comparators**	**Patient population *(key characteristics, average age)***	**Costs *(intervention and comparator)***	***Patient outcomes (clinical outcomes, utilities, life expectancy, time to recurrence for intervention and comparator)***	***Results (annual cost savings, annual savings per patient, incremental cost per QALY)***
Study 1 (20xx)						
Study 2 (20xx)						
Study 3 (20xx)						

8.2.2 Provide a complete quality assessment for each health economic study identified. A suggested format is shown in table C3.

Table C3 Quality assessment of health economic studies

Study name		
Study design		
Study question	**Response (yes/no/not clear/N/A)**	**Comments**
1. Was the research question stated?		
2. Was the economic importance of the research question stated?		
3. Was/were the viewpoint(s) of the analysis clearly stated and justified?		
4. Was a rationale reported for the choice of the alternative programmes or interventions compared?		
5. Were the alternatives being compared clearly described?		
6. Was the form of economic evaluation stated?		
7. Was the choice of form of economic evaluation justified in relation to the questions addressed?		
8. Was/were the source(s) of effectiveness estimates used stated?		
9. Were details of the design and results of the effectiveness study given (if based on a single study)?		
10. Were details of the methods of synthesis or meta-analysis of estimates given (if based on an overview of a number of effectiveness studies)?		
11. Were the primary outcome measure(s) for the economic evaluation clearly stated?		
12. Were the methods used to value health states and other benefits stated?		
13. Were the details of the subjects from whom valuations were obtained given?		

14. Were productivity changes (if included) reported separately?		
15. Was the relevance of productivity changes to the study question discussed?		
16. Were quantities of resources reported separately from their unit cost?		
17. Were the methods for the estimation of quantities and unit costs described?		
18. Were currency and price data recorded?		
19. Were details of price adjustments for inflation or currency conversion given?		
20. Were details of any model used given?		
21. Was there a justification for the choice of model used and the key parameters on which it was based?		
22. Was the time horizon of cost and benefits stated?		
23. Was the discount rate stated?		
24. Was the choice of rate justified?		
25. Was an explanation given if cost or benefits were not discounted?		
26. Were the details of statistical test(s) and confidence intervals given for stochastic data?		
27. Was the approach to sensitivity analysis described?		
28. Was the choice of variables for sensitivity analysis justified?		
29. Were the ranges over which the parameters were varied stated?		

30. Were relevant alternatives compared? (That is, were appropriate comparisons made when conducting the incremental analysis?)		
31. Was an incremental analysis reported?		
32. Were major outcomes presented in a disaggregated as well as aggregated form?		
33. Was the answer to the study question given?		
34. Did conclusions follow from the data reported?		
35. Were conclusions accompanied by the appropriate caveats?		
36. Were generalisability issues addressed?		
Adapted from Drummond MF, Jefferson TO (1996) Guidelines for authors and peer reviewers of economic submissions to the BMJ. The BMJ Economic Evaluation Working Party. British Medical Journal 313 (7052): 275–83. Cited in Centre for Reviews and Dissemination (2008) Systematic reviews. CRD's guidance for undertaking reviews in health care. York: Centre for Reviews and Dissemination		

9 De novo cost analysis

Section 9 requires the sponsor to provide information on the de novo cost analysis.

The de novo cost analysis developed should be relevant to the scope.

All costs resulting from or associated with the use of the technology should be estimated using processes relevant to the NHS and personal social services.

Note that NICE cites the price of the product used in the model in the Medical Technology guidance.

9.1 Description of the de novo cost analysis

9.1.1 Provide the rationale for undertaking further cost analysis in relation to the scope.

As no cost-effectiveness studies could be identified in the literature search, a de novo analysis was undertaken to estimate the potential cost implications of introducing Thopaz+ into thoracic units in the UK for patients for whom chest drainage is required.

Patients

9.1.2 What patient group(s) is (are) included in the cost analysis?

The analysis focusses on adult patients undergoing thoracic surgery who require chest drainage. This is because the economic analysis is based around the Pompili study which only considered this patient group.

Technology and comparator

9.1.3 Provide a justification if the comparator used in the cost analysis is different from the scope.

The comparator was traditional devices with wall suction in line with the scope.

Model structure

9.1.4 Provide a diagram of the model structure you have chosen.

There is no model as such. The calculation can be seen however as a simple single node decision tree where patients requiring chest drainage following thoracic surgery receive Thopaz+ or traditional drainage with no difference in patient outcomes and with cost difference being driven by the costs of the different drainage systems and the overall length of stay post surgery.

9.1.5 Justify the chosen structure in line with the clinical pathway of care identified in response to question 3.3.

Thopaz+ does not change the pathway of care (although it may if a reduction in the requirement for physiotherapists or number of chest radiographs per patient). As only the costs of drainage and a reduction in length of stay with Thopaz+ compared to traditional drainage was considered in the calculation no formal model was required.

9.1.6 Provide a list of all assumptions in the cost model and a justification for each assumption.

It is assumed that the cost of traditional drainage with wall suction is zero (the machine, consumables and any training). This is a simplifying assumption that produces conservative estimates of any potential cost avings for Thopaz+.

Costs of staff time dedicated to drainage are assumed to be equal for Thopaz+ and traditional drainage. Again this is a conservative assumption as the Pompili study reported that time on drainage was 1.1 days shorter with Thopaz+ compared to traditional drainage. Training costs for Thopaz+ were

included in the analysis but excluded for traditional drainage – again a conservative assumption.

The calculation assumes that the only difference in outcome between Thopaz+ and traditional wall suction devices is length of stay. This is based upon the findings from the Pompili study.

Utilization rates of each machine are unknown so assumed to be 50%. This was varied in sensitivity analysis.

9.1.7 Define what the model's health states are intended to capture.

Not relevant

9.1.8 Describe any key features of the cost model not previously reported. A suggested format is presented below.

As patient outcomes postoperatively are assumed to be identical with Thopaz+ and traditional drainage, the time horizon for the analysis was the time from drainage commencement until postoperative discharge.

9.2 Clinical parameters and variables

9.2.1 Describe how the data from the clinical evidence were used in the cost analysis.

The cost analysis took data from the Pompili study and where possible only from the UK centre in the study. The values from the study required for the cost calculation were the length of time drainage was required (3.6 days from

all centres in the study) and the reduction in length of stay (0,3 days for the UK centre only).

9.2.2 Are costs and clinical outcomes extrapolated beyond the study follow-up period(s)? If so, what are the assumptions that underpin this extrapolation and how are they justified?

Outside of training costs, costs and outcomes over the patient hospital stay only are considered in the analysis. No extrapolation of costs or benefits was required or performed.

9.2.3 Were intermediate outcome measures linked to final outcomes (for example, was a change in a surrogate outcome linked to a final clinical outcome)? If so, how was this relationship estimated, what sources of evidence were used and what other evidence is there to support it?

No linkage between outcomes was performed as patient outcomes outside of length of stay were assumed to be equal for both Thopaz+ and traditional drainage.

9.2.4 Were adverse events such as those described in section 7.7 included in the cost analysis? If appropriate, provide a rationale for the calculation of the risk of each adverse event.

The literature review did not identify any adverse events from either Thopaz+ or standard drainage. Due to the design of Thopaz+ any adverse events that could occur with chest drainage should be reduced with Thopaz+.

9.2.5 Provide details of the process used when the sponsor's clinical advisers assessed the applicability of available or estimated clinical model parameter and inputs used in the analysis.

Due to the simplicity of the cost analysis and the limited nature of the assumptions a formal check of the values was not undertaken. However, the elements of the calculation were approved by….

9.2.6 Summarise all the variables included in the cost analysis. Provide cross-references to other parts of the submission. A suggested format is provided in table C5 below.

Table C5 Summary of variables applied in the cost model

Variable	Value	Range or 95% CI (distribution)	Source
Machine cost per month (Thopaz+)	£115	£105-£115	9.3.5
Machine cost per month (traditional drainage)	£0	-	9.3.5
Cost of consumables (Thopaz+)	£30.05	-	9.3.5
Cost of consumables (traditional drainage)	£0	-	9.3.5
Cost of staff time training per thoracic unit (Thopaz+)	£6710	-	9.3.10
Cost of staff time training per thoracic unit (traditional drainage)	£0	-	9.3.10
Costs of a bed day thoracic procedures requiring drainage	£338.74	£302-£424	9.3.8
Postoperative length of stay (Thopaz+)	4.6	-	9.3.8
Postoperative length of stay (traditional drainage)	4.9	-	9.3.8

9.3 Resource identification, measurement and valuation

NHS costs

9.3.1 Describe how the clinical management of the condition is currently costed in the NHS in terms of reference costs and the payment by results (PbR) tariff.

There is no reference cost specifically for chest drainage for thoracic surgery. Reference costs do exist for complex thoracic procedures (DZ02H-DZ02K) and for pleural effusion with interventions (DZ16H-DZ16N).

9.3.2 State the Office of Population, Censuses and Surveys Classification of Surgical Operations and Procedures (OPCS) codes for the operations, procedures and interventions relevant to the use of the technology for the clinical management of the condition.

Response

Resource identification, measurement and valuation studies

9.3.3 Provide a systematic search of relevant resource data for the NHS in England. Include a search strategy and inclusion criteria, and consider published and unpublished studies.

The only resources considered were the cost of Thopaz+ (including training) and the costs of the hospital stay. The costs of Thopaz+ are provided by Medela. Time required for training was provided by Medela and costed using unit costs from the PSSRU Unit Costs of Health and Social Care 2016. The costs of the hospital stay were taken from NHS Reference Costs.

The costs of standard drainage with wall suction were assumed to be zero which resulted in the analysis being conservative for Thopaz+ and negates the need to identify costs for standard drainage.

Given the simplicity of the calculation and the evidence for costs either being directly from Medela or from recognised and routinely used sources (NHS Reference Costs and the PSSRU) no systematic search was required.

9.3.4 Provide details of the process used when clinical advisers assessed the applicability of the resources used in the model[9].

As was stated in 9.2.5, no formal process of validation was required due to the simplicity of the calculation. However, the costs involved were verified by ,,,

Technology and comparators' costs

9.3.5 Provide the list price for the technology.

Thopaz+ can be purchased at a unit price of £3,400 with a reduction in price for volume orders. Alternatively, the rental price of Thopaz+ is £105 per month for over 25 units and £115 per month for under 25 units. In the cost analysis we have assumed a rental agreement at a price of £115 per month. This rental cost includes the cost of any machine repairs.

To estimate a machine cost per patient, the following variables were required:

- The average duration of drainage (Dd) (3.6 days from Pompili)
- The utilization rate of machines (Um) (ie. How long the machine is likely to stand idle). This was assumed to be 50% in the base case

This gave the following calculation for the machine cost per patient (Mc):

Mc = ((£115*12)/Um)*(Dd/365) = £27.22 per patient.

Consumable costs are £23.70 per patient with the single tubing costing £9.60 and the 0.8l canister costing £14.10. Whilst one 0.8l canister should be sufficient for each patient, in the analysis it was assumed that half of patients

[9] Adapted from Pharmaceutical Benefits Advisory Committee (2008) Guidelines for preparing submissions to the Pharmaceutical Benefits Advisory Committee (Version 4.3). Canberra: Pharmaceutical Benefits Advisory Committee.

would require two canisters raising the average consumable costs to £30.75 per patient.

Costs of the comparator were assumed to be zero which was a conservative assumption underestimating the potential cost savings of Thopaz+

9.3.6 If the list price is not used in the de novo cost model, provide the alternative price and a justification.

Not relevant.

9.3.7 Summarise the annual costs associated with the technology and the comparator technology (if applicable) applied in the cost model. A suggested format is provided in tables C6 and C7. Table C7 should only be completed when the most relevant UK comparator for the cost analysis refers to another technology.

Table C6 Costs per treatment/patient associated with the technology in

the cost model

Items	Value	Source
Price of the technology per treatment/patient	£27.22 per patient	9.3.5
Consumables (if applicable)	£30.75 per patient	9.3.5
Maintenance cost	£0	Medela
Training cost	£8.10	9.3.10
Total cost per treatment/patient	£66.07	

Table C7 Costs per treatment/patient associated with the comparator technology in the cost model

Items	Value	Source
Cost of the comparator per treatment/patient	£0	Assumption
Consumables (if applicable)	£0	Assumption
Maintenance cost	£0	Assumption
Training cost	£0	Assumption
Total cost per treatment/patient	£0	Assumption

Health-state costs

9.3.8 If the cost model presents health states, the costs related to each health state should be presented in table C8. The health states should refer to the states in section 9.1.7. Provide a rationale for the choice of values used in the cost model.

The calculation did not require health states modelling but rather the cost of a bed day following thoracic surgery to be estimated. To estimate this, the weighted average reference cost (NHS Reference Costs 2015/16) for elective and non-elective excess bed days for complex thoracic procedures was calculated. This is summarised in Table C8 where the weighted average cost is estimated to be £338.74 per day. From the Pompili study, the length of stay

for Thopaz+ was found to be 0.3 days lower than with traditional drainage (4.6 vs 4.9) which would result in a saving of £101.62 per patient.

Table C8 Estimate of unit costs of a bed day following thoracic surgery

HRG	Description	Excess bed days	National average unit costs
Non-elective inpatient			
DZ02H	**Complex Thoracic Procedures, 19 years and over, with CC Score 6+**	1,018	£306
DZ02J	**Complex Thoracic Procedures, 19 years and over, with CC Score 3-5**	226	£424
DZ02K	**Complex Thoracic Procedures, 19 years and over, with CC Score 0-2**	189	£373
Elective inpatient			
DZ02H	**Complex Thoracic Procedures, 19 years and over, with CC Score 6+**	1,224	£302
DZ02J	**Complex Thoracic Procedures, 19 years and over, with CC Score 3-5**	777	£378
DZ02K	**Complex Thoracic Procedures, 19 years and over, with CC Score 0-2**	393	£395
Weighted average			£338.74

Adverse-event costs

9.3.9 Complete table C9 with details of the costs associated with each adverse event referred to in 9.2.4 included in the cost model. Include all adverse events and complication costs, both during and after longer-term use of the technology.

No adverse events are included in the model although it is anticipated that adverse events would be lower with Thopaz+ due to its design features compared to traditional drainage.

Miscellaneous costs

9.3.10 Describe any additional costs and cost savings that have not been covered anywhere else (for example, PSS costs, and patient and carer costs). If none, please state.

All members of a clinical team involved in chest drainage should be trained in the use of Thopaz+. This would include everyone from Theatre Nurses,

Surgeons, Physicians, Specialist Nurses, Practice Educators, Recovery Nurses, HDU / CCU Nurses to finally the ward based nurses who include the Ward Manager, Staff Nurses, physiotherapists and Health Care Assistants.

The basic training to go through the Thopaz+ for an end user is around ten minutes for someone to understand the basic interface and make changes if they are instructed to do so by the Surgeon or Physician. This would be a practical session with a demonstration of Thopaz(+)

All training is provided free of charge by Medela, but the time costs of staff needs to be accounted for. To produce a conservative estimate on the costs of training it was assumed that a full 30 minutes was required to demonstrate the system. This is to allow for any time for questions or delays in starting whilst all staff arrive. In reality training will occur over multiple sessions with different staff or individual 'champions' will be trained who then cascade the training to their colleagues.

Based on Medela's experience of training in thoracic units, the maximum staff numbers each unit will have would that would require training would be 12 physicians/surgeons and 110 nurses/other health care staff. Again, to keep the analysis conservative, it was assumed that this maximum staffing level was the same for all units, that all physicians/surgeons were at consultant level (at a cost of £137 per hour (PSSRU 2016)) and all health care staff were the equivalent of a Band 9 nurse (at a cost of £122 per hour (PSSRU 2016)).

Using the above assumptions, the total cost of training in terms of staff time for Thopaz+ was therefore estimated to be £6710. With an estimated 930 patients in each unit having thoracic surgery requiring drainage each year (need to reference this), the training costs would add a further £8.10 per patient onto the cost of Thopaz+. However, as training does not need to be repeated each year, over any time period over 12 months the training cost per

patient would be much lower even if the conservatively high cost assumptions for training above were accurate.

Thopaz+ has no regular maintenance or service costs and any repairs are covered as part of the lease agreement.

9.3.11 Are there any other opportunities for resource savings or redirection of resources that it has not been possible to quantify?

Experience in 80% of the thoracic units in the UK is that over time as clinicians gain confidence in Thopaz+ removal of drainage occurs even sooner than is seen in clinical trials. As Thopaz+ is not wall fixed and patients are free of drainage sooner than with traditional drainage physiotherapy costs would be lower with Thopaz+. Anecdotal evidence suggests that the requirement for chest radiographs is reduced with Thopaz+.

9.4 Approach to sensitivity analysis

Section 9.4 requires the sponsor to carry out sensitivity analyses to explore uncertainty around the structural assumptions and parameters used in the analysis. All inputs used in the analysis will be estimated with a degree of imprecision. For technologies whose final price/acquisition cost has not been confirmed, sensitivity analysis should be conducted over a plausible range of prices.

Analysis of a representative range of plausible scenarios should be presented and each alternative analysis should present separate results.

9.4.1 Has the uncertainty around structural assumptions been investigated? State the types of sensitivity analysis that have been carried out in the cost analysis.

As the calculation was effectively a simple one node decision-tree no structural assumptions were tested in sensitivity analysis.

9.4.2 Was a deterministic and/or probabilistic sensitivity analysis undertaken? If not, why not? How were variables varied and what was the rationale for this? If relevant, the distributions and their sources should be clearly stated.

Deterministic sensitivity analysis was carried out on all variables where there was uncertainty.

No distributions were provided in Pompili for the length of time of drainage with Thopaz+ or for the reduction in length of stay in the UK only with Thopaz+. These values were therefore varied by +- 50% from the base case values of 3.6 days and 0.3 days respectively.

The utilization rate was assumed to be 50%. This was varied by +-50% (25% to 75%).

Costs of length of stay were varied between the lowest unit cost in Table C8 (£302) and the highest (£424).

In the base case half the patients were assumed to require a second canister (an average of 1.5 canisters per patient). Whilst experience suggests this is an overestimate, the average number of canisters was varied between 1 and 2 per patient.

A “Best case” scenario used all parameter values considered in the sensitivity analysis that generated the most favourable cost saving for Thopaz+ and a “Worst case” scenario used parameter values least favourable for Thopaz+.

9.4.3 Complete table C10.1, C10.2 and/or C10.3 as appropriate to summarise the variables used in the sensitivity analysis.

Table C10.1 Variables used in one-way scenario-based deterministic sensitivity analysis

Variable	Base-case value	Range of values	Best-case value	Worst-care value
Days drainage required with Thopaz+	3.6	1.8-5.4	1.8	5.4
Reduction in LOS with Thopaz+	0.3	0.15-0.45	0.45	0.15
Utilization rate	50%	25%-75%	75%	25%
Average number of canisters required with Thopaz+	1.5	1.0-2.0	1.0	2.0
Cost of bed day	£338.74	£302-£424	£424	£302

9.4.4 If any parameters or variables listed in section 9.2.6 were omitted from the sensitivity analysis, provide the rationale.

Consumable costs were not varied. Consumables were assumed to be zero for the comparator which was already conservative and in addition in the base case a further conservative assumption was made that 50% of patients with Thopaz+ would require a second canister when our experience is that this is rarely the case. As such a scenario with even more pessimistic assumptions on consumables from a base case that was already unrealistically pessimistic was not considered informative. Similarly, due to the already unrealistically pessimistic per patient training costs higher training costs were not explored in sensitivity analysis.

9.5 Results of de novo cost analysis

Section 9.5 requires the sponsor to report the de novo cost analysis results. These should include the following:

- costs
- disaggregated results such as costs associated with treatment, costs associated with adverse events, and costs associated with follow-up/subsequent treatment
- a tabulation of the mean cost results
- results of the sensitivity analysis.

Base-case analysis

9.5.1 Report the total costs associated with use of the technology and the comparator(s) in the base-case analysis. A suggested format is presented in table C11.

Table C11 Base-case results

	Total per patient cost (£)
Thopaz+	£1624.27
Traditional drainage	£1659.83

9.5.2 Report the total difference in costs between the technology and comparator(s).

For each patient requiring drainage following thoracic surgery, Thopaz+ is estimated to cost £35.55 per patient less than traditional drainage.

9.5.3 Provide details of the costs for the technology and its comparator by category of cost. A suggested format is presented in table C12.

Table C12 Summary of costs by category of cost per patient

Item	Cost Thopaz+	Cost Traditional drainage	Increment	Absolute increment	% absolute increment
Technology cost	**£27.22**	**£0**	**£27.22**	**£27.22**	**77.0%**
Consumable costs	**£30.75**	**£0**	**£30.75**	**£30.75**	**87.0%**
Training costs	**£8.10**	**£0**	**£8.10**	**£8.10**	**22.9%**
Mean total treatment costs	**£66.07**	**£0**	**£66.07**	**£66.07**	**187.0%**
Postoperative length of stay costs	**£1558.20**	**£1659.83**	**-£101.62**	**£101.62**	**287.6%**
Total	**£1624.27**	**£1659.83**	**-£35.55**	**£35.33**	**100%**
Adapted from Pharmaceutical Benefits Advisory Committee (2008) Guidelines for preparing submissions to the Pharmaceutical Benefits Advisory Committee (Version 4.3). Canberra: Pharmaceutical Benefits Advisory Committee					

9.5.4 If appropriate, provide details of the costs for the technology and its comparator by health state. A suggested format is presented in table C13.

Not applicable

9.5.5 If appropriate, provide details of the costs for the technology and its comparator by adverse event. A suggested format is provided in table C14.

Not applicable

Sensitivity analysis results

9.5.6 Present results of deterministic one-way sensitivity analysis of the variables described in table C10.1.

Results of the deterministic sensitivity analysis are presented in table C13.

Table C13 Results of one-way scenario-based deterministic sensitivity analysis (base case incremental cost of Thopaz+ -£35.55)

Variable	Lower value	Upper value	Lower value incremental cost with Thopaz+	Upper value incremental cost with Thopaz+	Value at which Thopaz+ ceases to be cost saving
Days drainage required with Thopaz+	1.8	5.4	-£49.16	-£21.94	9.2
Reduction in LOS with Thopaz+	0.15	0.45	£15.26	-£86.36	0.17
Utilization rate	25%	75%	-£8.33	-£44.63	19%
Average number of canisters required with Thopaz+	1.0	2.0	-£42.80	-£28.50	4.0
Cost of bed day	£302	£424	-£31.58	-£68.18	£196.74

9.5.7 Present results of deterministic multi-way scenario sensitivity analysis described in table C10.2.

Results of the best and worst case scenarios are presented in table C14.

Table C14 Results of best and worst case scenarios (base case incremental cost of Thopaz+ -£35.55)

Variable	'Best case' value	'Worst case' value
Days drainage required with Thopaz+	1.8	5.4
Reduction in LOS with Thopaz+	0.45	0.15
Utilization rate	75%	25%
Average number of canisters required with Thopaz+	1.0	2.0
Cost of bed day	£424	£302
Incremental cost with Thopaz+	**-£149.93**	**£82.26**

9.5.8 Present results of the probabilistic sensitivity analysis described in table C10.3.

Not applicable

9.5.9 What were the main findings of each of the sensitivity analyses?

In the one way sensitivity analysis, the finding that Thopaz+ would be cost saving was robust against all values and all variables considered with the exception of the reduction in postoperative length of stay with Thopaz+. When the reduction falls below 0.17 days for Thopaz+ compared to traditional drainage than Thopaz+ is no longer cost saving. However, this is against a cost per patient for Thopaz+ that was already pessimistic and an assumed zero cost of traditional drainage.

In the best case analysis considered, Thopaz+ could save £149.53 per patient. In the worst case it could cost £82.26 per patient. The worst case scenario is based upon base case scenario parameters of training cost and zero cost of traditional drainage with parameter values – such as every patient requiring 2 canisters – that are in our experience implausible. In comparison, the best case scenario is not as implausible. It is also based around

pessimistic assumptions on training and traditional drainage costs, but, for example, our experience is that it is very rare for a patient to require more than one canister and utilization rates of the Thopaz+ machines in busy thoracic centres are likely to be closer to 100% than 50%.

9.5.10 What are the key drivers of the cost results?

The cost savings from Thopaz+ are driven by the reduction in length of stay postoperatively achieved by Thopaz+ over traditional drainage. It should be noted that this is based upon a zero cost for traditional drainage and if this cost was included the cost saving of Thopaz+ would likely be significantly greater.

Miscellaneous results

9.5.11 Describe any additional results that have not been specifically requested in this template. If none, please state.

None

9.6 Subgroup analysis

For many technologies, the capacity to benefit from treatment will differ for patients with differing characteristics. Sponsors are required to complete section 9.6 in accordance with the subgroups identified in the scope and for any additional subgroups considered relevant.

Types of subgroups that are not considered relevant are those based solely on the following factors.

- Subgroups based solely on differential treatment costs for individuals according to their social characteristics.
- Subgroups specified in relation to the costs of providing treatment in different geographical locations within the UK (for example, if the costs of facilities available for providing the technology vary according to location).

9.6.1 Specify whether analysis of subgroups was undertaken and how these subgroups were identified. Cross-reference the response to the decision problem in table A1 and sections 3.2 and 7.4.4.

No subgroup analysis was performed.

9.6.2 Define the characteristics of patients in the subgroup(s).

Not applicable

9.6.3 Describe how the subgroups were included in the cost analysis.

Not applicable

9.6.4 What were the results of the subgroup analysis/analyses, if conducted? The results should be presented in a table similar to that in section 9.5.1 (base-case analysis).

Not applicable

9.6.5 Were any subgroups not included in the submission? If so, which ones, and why were they not considered?

Not applicable

9.7 Validation

9.7.1 Describe the methods used to validate and cross-validate (for example with external evidence sources) and quality-assure the model. Provide references to the results produced and cross-reference to evidence identified in the clinical and resources sections.

As there was no model as such but a simple calculation, the calculation was quality assured internally by Medela and by an external economic advisor.

9.8 Interpretation of economic evidence

9.8.1 Are the results from this cost analysis consistent with the published economic literature? If not, why do the results from this evaluation differ, and why should the results in the submission be given more credence than those in the published literature?

There are no published economic evaluations of Thopaz+.

9.8.2 Is the cost analysis relevant to all groups of patients and NHS settings in England that could potentially use the technology as identified in the scope?

Whilst the analysis has focussed only on adult patients having thoracic surgery, the findings are driven by length of stay with Thopaz+ which in turn is linked with a reduction in time with drainage in situ. There is no reason to suppose that the reduction in time drainage would be required would be lower for the other patients within the submission scope. The savings with Thopaz+ for non-thoracic surgery patients in the scope are therefore likely to be commensurate with thoracic patients presented here.

9.8.3 What are the main strengths and weaknesses of the analysis? How might these affect the interpretation of the results?

The main strengths of the analysis are the simplicity and conservative nature of the calculation with a pessimistic set of assumptions for the potential cost saving with Thopaz+ - notably an assumption of zero cost for standard drainage. In addition, the finding of reduction in length of stay with Thopaz+ is based upon a robust and well conducted study with results from a UK centre.

The weaknesses of the analysis are that the effectiveness data was based upon patients undergoing thoracic surgery only, although similar findings would be expected for other patient groups within the submission scope. Potential benefits of Thopaz+ such as the reduction in need for chest radiography and increased reduction in the time drainage is required as clinicians gain confidence in the system could not be quantified and included in the analysis.

9.8.4 What further analyses could be undertaken to enhance the robustness/completeness of the results?

Further exploratory analyses to include the costs of traditional drainage or of the other unquantified benefits of Thopaz+ (eg. The reduction in the need for chest radiography or reduction in time drainage is required with Thopaz+) could be undertaken. However, as Thopaz+ was found to be cost saving with a zero cost of traditional drainage and with only a reduction in post operative length of stay considered, such analysis would only result in greater cost savings for Thopaz+ and do unlikely to be informative to decision makers.

References

Please use a recognised referencing style, such as Harvard or Vancouver.

Response

10 Appendices

10.1 Appendix 1: Search strategy for clinical evidence (section 7.1.1)

The following information should be provided:

10.1.1 The specific databases searched and the service provider used (for example, Dialog, DataStar, OVID, Silver Platter), including at least:

- Medline
- Embase
- Medline (R) In-Process
- The Cochrane Library.

Response

10.1.2 The date on which the search was conducted.

Response

10.1.3 The date span of the search.

Response

10.1.4 The complete search strategies used, including all the search terms: textwords (free text), subject index headings (for example, MeSH) and the relationship between the search terms (for example, Boolean).

Response

10.1.5 Details of any additional searches, such as searches of company or professional organisation databases (include a description of each database).

Response

10.1.6 The inclusion and exclusion criteria.

Response

10.1.7 The data abstraction strategy.

Response

10.2 Appendix 2: Search strategy for adverse events (section 7.7.1)

The following information should be provided.

10.2.1 The specific databases searched and the service provider used (for example, Dialog, DataStar, OVID, Silver Platter), including at least:

- Medline
- Embase
- Medline (R) In-Process
- The Cochrane Library.

Response

10.2.2 The date on which the search was conducted.

Response

10.2.3 The date span of the search.

Response

10.2.4 The complete search strategies used, including all the search terms: textwords (free text), subject index headings (for example, MeSH) and the relationship between the search terms (for example, Boolean).

Response

10.2.5 Details of any additional searches (for example, searches of company databases [include a description of each database]).

Response

10.2.6 The inclusion and exclusion criteria.

Response

10.2.7 The data abstraction strategy.

Response

10.3 Appendix 3: Search strategy for economic evidence (section 8.1.1)

The following information should be provided.

10.3.1 The specific databases searched and the service provider used (for example, Dialog, DataStar, OVID, Silver Platter), including at least:

- Medline
- Embase
- Medline (R) In-Process
- EconLIT
- NHS EED.

Response

10.3.2 The date on which the search was conducted.

Response

10.3.3 The date span of the search.

Response

10.3.4 The complete search strategies used, including all the search terms: textwords (free text), subject index headings (for example,

MeSH) and the relationship between the search terms (for example, Boolean).

Response

10.3.5 Details of any additional searches (for example, searches of company databases [include a description of each database]).

Response

10.4 Appendix 4: Resource identification, measurement and valuation (section 9.3.2)

The following information should be provided.

10.4.1 The specific databases searched and the service provider used (for example, Dialog, DataStar, OVID, Silver Platter), including at least:

- Medline
- Embase
- Medline (R) In-Process
- NHS EED
- EconLIT.

Response

10.4.2 The date on which the search was conducted.

Response

10.4.3 The date span of the search.

Response

10.4.4 The complete search strategies used, including all the search terms: textwords (free text), subject index headings (for example,

MeSH) and the relationship between the search terms (for example, Boolean).

Response

10.4.5 Details of any additional searches (for example, searches of company databases [include a description of each database]).

Response

10.4.6 The inclusion and exclusion criteria.

Response

10.4.7 The data abstraction strategy.

Response

11 Related procedures for evidence submission

11.1 Cost models

An electronic executable version of the cost model should be submitted to NICE with the full submission.

NICE accepts executable cost models using standard software – that is, Excel, TreeAge Pro, R or WinBUGs. If you plan to submit a model in a non-standard package, NICE should be informed in advance. NICE, in association with the External Assessment Centre, will investigate whether the requested software is acceptable, and establish if you need to provide NICE and the External Assessment Centre with temporary licences for the non-standard software for the duration of the assessment. NICE reserves the right to reject cost models in non-standard software. A fully executable electronic copy of the model must be submitted to NICE with full access to the programming code. Care should be taken to ensure that the submitted versions of the model programme and the written content of the evidence submission match.

NICE may distribute the executable version of the cost model to a consultee if they request it. If a request is received, NICE will release the model as long as it does not contain information that was designated confidential by the model owner, or the confidential material can be redacted by the model owner without producing severe limitations on the functionality of the model. The consultee will be advised that the model is protected by intellectual property rights, and can be used only for the purposes of commenting on the model's reliability and informing comments on the medical technology consultation document.

Sponsors must ensure that all relevant material pertinent to the decision problem has been disclosed to NICE at the time of submission. NICE may request additional information not submitted in the original submission of evidence. Any other information will be accepted at NICE's discretion.

When making a full submission, sponsors should check that:

- an electronic copy of the submission has been given to NICE with all confidential information highlighted and underlined
- a copy of the instructions for use, regulatory documentation and quality systems certificate have been submitted
- an executable electronic copy of the cost model has been submitted
- the checklist of confidential information provided by NICE has been completed and submitted.

- A PDF version of all studies (or other appropriate format for unpublished data, for example, a structured abstract) included in the submission have been submitted

11.2 Disclosure of information

To ensure that the assessment process is as transparent as possible, NICE considers it highly desirable that evidence pivotal to the Medical Technologies Advisory Committee's decisions should be publicly available at the point of issuing the medical technology consultation document and medical technology guidance.

Under exceptional circumstances, unpublished evidence is accepted under agreement of confidentiality. Such evidence includes 'commercial in confidence' information and data that are awaiting publication ('academic in confidence').

When data are 'commercial in confidence' or 'academic in confidence', it is the sponsor's responsibility to highlight such data clearly, and to provide reasons why they are confidential and the timescale within which they will remain confidential. The checklist of confidential information should be completed: if it is not provided, NICE will assume that there is no confidential information in the submission. It is the responsibility of the manufacturer or sponsor to ensure that the confidential information checklist is kept up to date.

It is the responsibility of the sponsor to ensure that any confidential information in their evidence submission is clearly underlined and highlighted

correctly. NICE is assured that information marked ‘academic in confidence’ can be presented and discussed during the public part of the Medical Technologies Advisory Committee meeting. NICE is confident that such public presentation does not affect the subsequent publication of the information, which is the prerequisite allowing for the marking of information as ‘academic in confidence’.

Please therefore underline all confidential information, and highlight information that is submitted under ‘commercial in confidence’ in blue and information submitted under ‘academic in confidence’ in yellow.

NICE will ask sponsors to reconsider restrictions on the release of data if there appears to be no obvious reason for the restrictions, or if such restrictions would make it difficult or impossible for NICE to show the evidential basis for its guidance. Information that has been put into the public domain, anywhere in the world, cannot be marked as confidential.

Confidential information submitted will be made available for review by the External Assessment Centre and the Medical Technologies Advisory Committee. NICE will at all times seek to protect the confidentiality of the information submitted, but nothing will restrict the disclosure of information by NICE that is required by law (including in particular, but without limitation, the Freedom of Information Act 2000).

The Freedom of Information Act 2000, which came into force on 1 January 2005, enables any person to obtain information from public authorities such as NICE. The Act obliges NICE to respond to requests about the recorded information it holds, and it gives people a right of access to that information. This obligation extends to submissions made to NICE. Information that is designated as ‘commercial in confidence’ may be exempt under the Act. On receipt of a request for information, the NICE secretariat will make every effort to contact the designated company representative to confirm the status of any information previously deemed ‘commercial in confidence’ before making any decision on disclosure.

11.3 Equality

NICE is committed to promoting equality and eliminating unlawful discrimination, including paying particular attention to groups protected by equalities legislation. The scoping process is designed to identify groups who are relevant to the evaluation of the technology, and to reflect the diversity of the population. NICE consults on whether there are any issues relevant to equalities within the scope of the evaluation, or if there is information that could be included in the evidence presented to the Medical Technologies Advisory Committee to enable them to take account of equalities issues when developing guidance.

Evidence submitters are asked to consider whether the chosen decision problem could be impacted by NICE's responsibility in this respect, including when considering subgroups and access to recommendations that use a clinical or biological criterion.

For further information, please see the NICE website (www.nice.org.uk/aboutnice/howwework/NICEEqualityScheme.jsp).

NICE National Institute for Health and Care Excellence

National Institute for Health and Care Excellence

Centre for Health Technology Evaluation

External assessment centre report factual check

MT325 The Thopaz+ portable digital system for the management of chest drains

The assessment report prepared for this assessment by the external assessment centre was sent to the company on 25th August 2017. The company was asked to check the assessment report to ensure there were no factual inaccuracies contained within it and to inform NICE by 12pm, Thursday 31st August 2017. No response was received. An email was sent on Monday 4th September stating that the report was being finalised to be sent to the committee and no response was received.

Medicines and Technologies Programme

Adoption Scoping Report

MT325 Thopaz systems for the portable digital management of chest drains

SUMMARY – for MTAC1 meeting

Adoption Levers

- Objective Assessment: more reliable process for the monitoring and measurement of air leaks therefore any trained member of the clinical team can monitor and record the measurements displayed on the device. No longer having to rely on the presence of bubbles as an indicator of air leaks.
- Accurate application of suction: amount of suction applied to patient's chest is more accurate using Thopaz.
- Potential reduced length of stay: opportunity to remove the drain earlier using objective digital measurements for clinical decision making.
- Earlier mobilisation: opportunity for patients to mobilise earlier and further as they are not restricted to the bed area. Thopaz does not require wall suction and is therefore portable.

Adoption Barriers

- Cost: initial and ongoing cost may act as a barrier but are believed by contributors to be outweighed by the potential benefits of using Thopaz.
- Process changes: major changes required to practice eg transition from a fully disposable system to one which has re-usable components.
- Training: reliance on the company for the support required during implementation which is considered as essential by the contributors.

1. Introduction

The Adoption team has collated information from healthcare professionals working within NHS organisations who have experience of using Thopaz.

This adoption scoping report includes some of the benefits and difficulties that may be faced by organisations when planning to adopt the technology into routine NHS use.

2. Contributing organisations

The company provided the Adoption team with contact details of 5 current users of the Thopaz system. Two NHS clinicians (consultant thoracic surgeon, advanced nurse practitioner) agreed to contribute to this adoption scope.

3. Use of Thopaz in practice

	Contributor 1	**Contributor 2**
Started using Thopaz	2010	2012
Current use	thoracic surgery patients	thoracic surgery patients
Patients/year	2000	500
Number of Thopaz units	25	15
Plans to upgrade to Thopaz+	May 2017	pending funding agreement

One contributor's trust is currently trialling an 'on the table removal' approach whereby the chest drain is removed immediately after surgery if Thopaz indicates that there is no air leak.

The MTEP analyst requested intelligence on whether patients are discharged to their own home with a Thopaz in place and if so what would be the criteria for this?

Both contributors confirmed that they do not allow patients to be discharged home with Thopaz in situ.

4. Reported benefits

The benefits of adopting Thopaz, as reported to the Adoption team by the healthcare professionals using the technology are that it:

- provides an objective and accurate measurement of air leaks which allows chest drains to be removed more quickly where appropriate. This may lead to decreased length of stay in hospital.
- removes the reliance on observing and counting air bubbles as an indication of air leaks.
- allows early mobilisation of the patient away from bed area as the device does not need to be connected to a wall suction unit and is therefore portable.
- Delivers more accurate suction than current methods.

5. Levers and barriers to adoption

The key considerations for adoption highlighted through discussions with expert contributors are:

Care pathway

One contributor reported that whilst using Thopaz was a major departure from using underwater seal drains, it was implemented quickly as a direct replacement for previously used chest drain systems. There was no requirement for changes to facilities or infrastructure, so this may serve as an adoption lever.

The other contributor reported that it took approximately 3 weeks to fully implement Thopaz within their care pathway. Throughout this time staff from the company were onsite 24 hours a day 7 days a week.

The transition to using Thopaz was described as a step change from the usual process of monitoring which involved counting bubbles in the chest drain. In addition to the transition from a subjective manual monitoring process to one which is objective and digital, there was the requirement to learn how to switch the device on, calibrate it, understand and respond to the alarms.

Patient Selection

Both contributors reported that Thopaz is used on all thoracic surgery patients in their respective trusts.

Clinician confidence / acceptance

One contributor reported that in order for hospitals to realise the potential to reduce patient length of stay, surgeons need to confidently transfer responsibility to nurses so they can make the decision to remove the chest drain, using the objective measurements provided by Thopaz.

Procurement

One contributor reported that a tender was developed in order to use Thopaz and the units were then procured via the Trust's purchasing and contracts department.

Another contributor reported that a business case was required. The trust currently rents Thopaz units as it was easier to obtain the funding for this within the organisation than to purchase them outright. The trust is now looking to obtain funding as it would like to upgrade to Thopaz+.

Resource Impact

Both contributors reported that cost (initial and ongoing) could be regarded as a barrier to the use of Thopaz but strongly believe that the benefits outweigh the cost implications. One contributor reported that a recent audit demonstrated decreased length of stay.

Training

Both contributors confirmed they had received training on how to use Thopaz from the company with one contributor receiving additional implementation support.

It was reported initial training takes approximately 30 minutes to 1 hour to deliver and once the training is complete it can take around 1-2 weeks of use to feel fully confident using Thopaz. The company will provide ongoing implementation support (in one trust this was 24/7 for three weeks).

Another contributor listed a number of areas for consideration including learning how to calibrate the device, understand and respond to alarms and reported that most clinicians were able to Thopaz after one training session.

Patient experience

Neither contributor had specifically requested feedback from patients although one contributor reported that some patients like to see the air leakage measurement displayed on Thopaz to monitor their progress.

Maintenance / Quality control

Previous practice included using single use chest drain devices which were disposed of when removed from the patient. Thopaz units are reusable (tubing and canisters are disposable) which introduces the requirement for a number of new processes for example appropriate cleaning of device.

One contributor highlighted the potential for the units to become lost as trusts are not used to returning chest drains for repeated use to a designated department.

Patient / Clinician safety

Neither contributor reported any patient/clinician safety concerns. One contributor reported that a recent audit demonstrated equivalent patient care / safety.

Further Considerations / Other

In the Notification document, the company states that Thopaz is attached to a chest drain catheter when a chest drain is put in, but is not inserted into the body itself.

This suggests that the trust would still need to buy the chest drain catheters for insertion in the patient which Thopaz is then connected to. The Adoption team would recommend that the cost of continuing to purchase chest drain catheters is included in any cost analysis / comparison.

Further exploration with additional contributors would have been preferred for example with regards to the potential benefit of ‘earlier mobilisation’.