Review report of MTG37: Thopaz+ portable digital system for managing chest drains

This medical technology guidance was published in March 2018.

All medical technology guidance is usually reviewed 3 years after publication, unless NICE become aware of significant new information before the expected review date.

This review report summarises new evidence and information that has become available since this medical technology guidance was published, and that has been identified as relevant for the purposes of this report. This report will be used to inform NICE's decision on whether this guidance will be updated, amended, remain unchanged (static list) or withdrawn.

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1. Original objective of guidance

To assess the clinical and cost effectiveness of Thopaz+ portable digital system for managing chest drains.

2. Current guidance recommendations

The current recommendations as outlined in NICE MTG37 (NICE 2018) are:

1. The case for adopting Thopaz+ for managing chest drains is supported by the evidence. Thopaz+ can reduce drainage time and length of stay in hospital, and improves safety for people with chest drains. Its use may also improve clinical decision-making through continuous, objective monitoring of air leaks and fluid loss.
2. Thopaz+ should be considered for people who need chest drainage after pulmonary resection or because of a pneumothorax. The system can increase patient mobility because it is portable. Staff find it more convenient and easier to use than conventional chest drains.
3. Cost modelling indicates that Thopaz+ is cost saving compared with conventional chest drains in people after pulmonary resection. The estimated saving is £111 per patient per hospital stay, with savings mainly achieved through reduced length of stay. The NICE resource impact assessment shows that, at a national level, adopting Thopaz+ is expected to save around £8.5 million per year in England.

3. Methods of review

Update searches, based on the original EAC searches for this guidance, were conducted by information specialists at NICE on 27th July 2021 and covered the period June 2017 to July 2021. Details are provided in Appendix D.

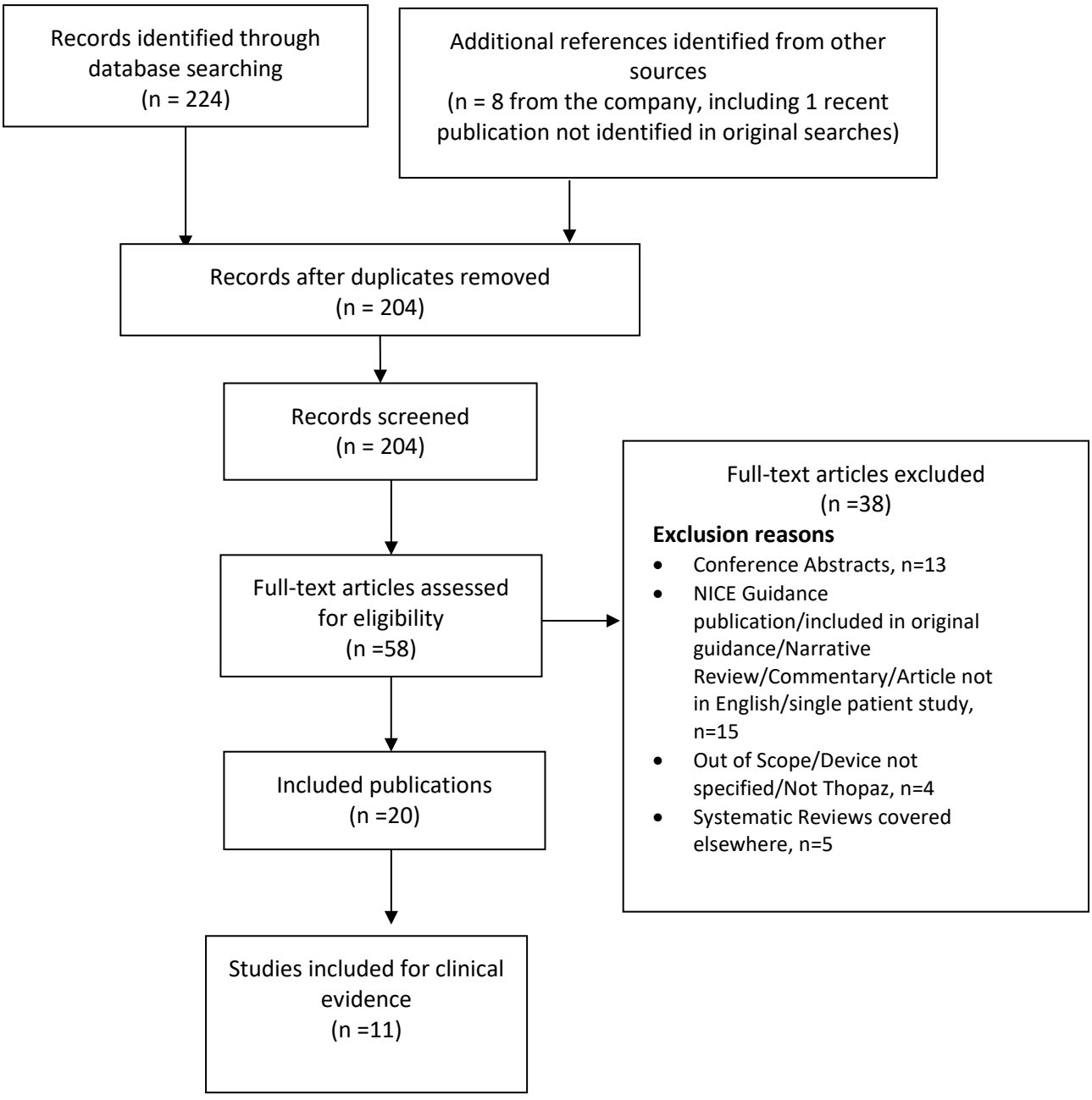
Search results provided to Cedar were imported into Endnote and duplicate records were removed. The company additionally submitted a list of 38 potentially relevant studies which were crossed checked against the results of the searches. The company results included 7 references which had not been identified by the literature searches. Following de-duplication, a total of 203 publications were included for title and abstract sift. The company later provided details of an additional, newly published study which would not have been identified by the searches, bringing the total number of publications for title and abstract sift to 204.

Following review of records by two researchers, 58 were selected as being relevant for full text review.

Following full text review 21 publications covering 20 studies were considered relevant for inclusion a selection of 12 studies considered to provide a representative indication of the new evidence, identified and discussed further

(Section 4.4). A number of conference abstracts were identified however these have been excluded due to the fact that for a number of the abstracts, a full publication was available or because the abstracts did not state that Thopaz was the digital device used. One abstract (Hofmann 2018) compared 3 types of drainage, including Thopaz, but did not report results by drainage system used and has therefore also been excluded. Details of all possibly relevant studies are summarised in Appendix C.

Figure 1: PRISMA Flow Chart



Searches were also conducted for ongoing and/or unpublished trials in ClinicalTrials.gov, ISRCTN and WHO International Clinical Trial Registry Platform (ICTRP).

4. New evidence

4.1 Changes in technology

There have been no changes to the technology since publication of the original guidance however it should be noted that there are currently two versions of the Thopaz device in use – Thopaz and Thopaz+. Information from the manufacturer indicates that the difference between Thopaz and Thopaz+ is that Thopaz+ measures both air leak and fluid leak whereas Thopaz only measures air leak. Consumables required are the same for both devices. While both Thopaz and Thopaz+ were available during original guidance development, there has been a move towards use of Thopaz+ with information from the company indicating that only 14% of devices in use are the older Thopaz devices. The company indicated that reasons for not moving over to the newer Thopaz+ device are usually financial as many units rent the devices and there is a small increase in rental costs to make the change to Thopaz+. The company are working with users to make the move to Thopaz+. One clinical expert noted that cost was likely the main barrier to introducing and using Thopaz or Thopaz+ digital drainage devices in the NHS.

4.2 Changes in care pathways

Chest drains are used after all types of thoracic surgery to assist with the drainage of air and fluid from the pleural cavity and encourage re-inflation of the lung (NICE MTG37 Scope 2017). Thopaz+ is indicated for all people who receive a chest drain, such as those requiring thoracic drainage from the pleural and mediastinal cavities in circumstances such as pneumothorax, recovery after cardiac or thoracic surgery (post-operative), thorax injury, pleural effusion, pleural empyema or other related conditions.

No changes have been identified in the current care pathway however one clinical expert noted that adoption of the Thopaz+ drains has increased over the past few years and in their own Trust they are now used in respiratory medicine, upper GI surgery, trauma and general ICU in addition to thoracic surgery. One clinical expert noted that Thopaz+ is used in cardiac surgery for patients requiring pleural drains once the mediastinal drains are removed but not for mediastinal drainage.

Information provided by the company indicate that approximately 50 hospitals in England are currently using Thopaz or Thopaz+. There are 33 hospitals using it in thoracic departments (including a small number of private hospitals) and 20 using it in respiratory departments. Additionally, 3 hospitals are using it in cardiac departments. A national survey carried out in the UK (Asghar 2019)

reported on approaches to pneumothorax surgery and included a question on preferred drainage approach and whether conventional underwater seal or digital drainage systems were used. A total of 56 consultants responded to the survey (70% response rate) and 35 of the respondents (60%) reported using a digital drainage system but the specific system used was not stated.

4.3 Results from the MTEP research commissioning workstream

Not Applicable. No research was commissioned.

4.4 New studies

In total, 20 new publications were identified as potentially relevant to the topic (Aldaghlawi 2020, Alam 2020, Arai 2018, Barozzi 2020, de Waele 2017, Eriguchi 2021, Jacobsen 2019, Lee 2019, Lijkendijk 2019, Lijkendijk 2018, Mori 2017, Mitsui 2021, Perez-Egido 2018, Pompili 2016, Pfeuty 2020, Ruigrok 2021, Saha 2020, Takamochi 2018, Tamura 2021, van Linden 2019). It should be noted that Lijkendijk 2019 and Lijkendijk 2017 are separate publications reporting different outcomes from the same study and for the purposes of this review, are considered as one study.

Only one of the studies potentially included UK patients, the study was a multicentre study with UK centre included however the proportion of data which is from UK is not reported (Pompili 2016). There was a mix of study types including:

- 1 systematic review (Aldaghlawi 2020)
- 7 randomised trials from 8 publications (Alam 2020, Barozzi 2020, de Waele 2017, Lijkendijk 2019, Lijkendijk 2017, Ruigrok 2021, Takamochi 2018, van Linden 2019),
- 3 prospective case series (Mori 2017, Perez-Egido 2018, Pompili 2016) and
- 8 retrospective studies (Arai 2018, Eriguchi 2021, Jacobsen 2019, Lee 2019, Mitsui 2021, Pfeuty 2020, Saha 2020, Tamura 2021).

Broadly the evidence falls into two settings, a respiratory setting and a cardiac setting. One clinical expert noted that these classifications were appropriate while one suggested splitting the respiratory group according to surgery and medical, indicating that the initial take-up of Thopaz was within thoracic surgery. The majority of the studies are in a respiratory setting (n=15) within which the most reported population was patients undergoing lung surgery for a range of indications (n=14). One additional study in the respiratory setting included patients treated for pneumothorax. There were fewer studies in a cardiac setting (n=4) and the population was predominantly patients undergoing cardiac surgery such as coronary artery bypass (table 1). There were 2 studies in paediatric populations (Alam 2020, Perez-Egido 2018). All studies included the use of the Thopaz or Thopaz+ digital drainage systems

although in one study it is not clearly reported that the digital system used was Thopaz (Jacobsen 2019). One randomised trial (Lijkendijk 2019, Lijkendijk 2018) compared the use of Thopaz at different suction settings.

In the original assessment report, the majority of the evidence was also in patients undergoing lung surgery and there was only one study reporting in patients with pneumothorax and none in a cardiac setting. This may therefore be seen as indicative of the expanded use of Thopaz/Thopaz+ into more clinical settings.

Table 1: Distribution of studies by setting

Setting	**Studies**
Respiratory – Lung Resection	• Alam 2020 • Arai 2018 • deWaele 2017 • Eriguchi 2021 • Jacobsen 2019 • Lee 2019 • Lijkendijk 2019/Lijkendijk 2017 • Mitsui 2021 • Mori 2017 • Perez-Egido 2018 • Pfeuty 2020 • Pompili 2016 • Takamochi 2018
Respiratory - Pneumothorax	• Ruigrok 2021
Cardiac	• Barozzi 2020 • Saha 2020 • van Linden 2019 • Tamura 2021

A selection of the representative studies in the respiratory setting (Alam 2020, Arai 2018, de Waele 2017, Perez-Egido 2018, Ruigrok 2021, Takamochi 2018) and, due to the limited numbers, all 4 studies in the cardiac setting (Barozzi 2020, Saha 2020, van Linden 2019, Tamura 2021) are reported in some detail in this section. Additional potentially relevant studies in the respiratory setting were identified but are not reported in the main text due to reasons such as a lack of reporting of p values (Eriguchi 2021), unclear if Thopaz is the digital device used (Jacobsen 2019), patient management unclear (Mori 2017), outcomes or comparisons potentially not relevant to scope (Lee 2019, Lijkendijk 2019, Lijkendijk 2017, Matsui 2021, Pfeuty 2020, Pompili 2016). A summary of all studies published since the original guidance is reported in Appendix C.

Systematic Reviews and Meta-Analyses

Five potentially relevant systematic reviews (Aldaghlawi 2020, Wang 2019, Zhou 2018, Deng 2017 and Gao 2017) were identified in the searches however all included digital drainage devices other than Thopaz. Therefore, they are not directly relevant to the scope. The most recent systematic review (Aldaghlawi 2020), summarised below, was used to check that all relevant studies were identified by the searches.

Aldaghlawi 2020 The most recent systematic review (Aldaghlawi 2020) included a total of 23 studies of which 15 used the Thopaz/Thopaz+ device. Of these 15 included studies, 10 (Gilbert 2015, Jablonski 2014, Lijkendijk 2015, Marjanski 2013, Mier 2010, Miller 2016, Pompili 2011, Pompili 2014, Shoji 2016, and, Tunnicliffe & Draper 2014) were appraised as part of the original guidance; 4 were identified by the update searches (Arai 2017, De Waele 2017, Pompili 2016 and Takamochi 2018). One study was not accounted for. Chiappetta 2018 was not identified by the searches and the EAC cannot electronically access the full text to verify whether this study uses Thopaz/Thopaz+. Outcomes reported include mean chest tube duration and mean length of hospital stay for post-operative air leak and mean chest tube duration and hospital stay for air leak secondary to spontaneous pneumothorax. There is no meta-analysis included due to heterogeneity of the individual studies and therefore no results are discussed here. Instead the relevant individual studies are summarised below and in Appendix C.

Respiratory Setting

Randomised Trials

Alam 2020 is a randomised controlled trial based in India. The study randomised a total of 100 patients with empyema thoracis undergoing open decortications (50 to Thopaz and 50 to conventional chest drainage system). Patients of all ages were eligible for inclusion but most were children and young people; mean age in the standard care arm was 21.78±15.8 years (range 2 to 61 years) and was 19.87±14.6 (range 1.8 to 58) in the Thopaz group. Outcomes for the study included duration of air leak, duration of post-decortication chest tube placement, post-operative length of hospital stay, pre and post-operative lung function (FEV1, FVC) and post-operative complications. Results indicated FEV1 and FVC increased significantly in both groups post-operatively ($p<0.05$) compared with pre-operative measurements. Patients managed with Thopaz had a significantly shorter duration of air leak (5.34 days vs. 7.16 days; $p=0.001$), shorter duration of post-decortication chest tube placement (7.44 days vs. 10.44 days; $p=0.001$) and shorter length of hospital stay (10.16 vs. 14.76 days; $p=0.001$) compared with standard care. There was a statistically significant difference in post-operative complications between the two groups with fewer in the Thopaz group ($p<0.05$). No

pneumothorax or subcutaneous emphysema was reported in the Thopaz group postoperatively compared with 6 each in the standard care arm.

DeWaele 2017 is a randomised controlled trial based in Canada. The study randomised a total of 112 adult patients undergoing lung resection of primary or secondary lung malignancies (56 allocated to conventional analogue drainage and 56 randomised to digital drainage using Thopaz). Nine patients were excluded peri-operatively leaving a total of 103 patients in the final analysis (50 in the conventional analogue drainage arm and 53 in the digital arm). The primary outcome was total quantity of pleural drainage and secondary outcomes included chest tube duration, length of hospital stays, 90-day mortality and postoperative morbidity, rate of re-intervention, 30-day hospital readmission and pleural inflammatory markers. Results indicated no significant difference in mean volume of total pleural drainage between the groups (conventional analogue 944.0ml vs. Digital 1,001.4ml; p=0.467). Chest tube duration was shorter in the Thopaz arm but the difference was not statistically significant (2.3 versus 2.5 days; p=0.055). Incidence of prolonged post-operative air leak was significantly higher when using the conventional analogue system compared with Thopaz (p=0.025). No significant difference in length of hospital stay was observed between the groups (4.9 vs. 4.8 days, p=0.403). Analysis of pleural inflammatory mediators indicated elevated IL-8 (908.12 vs. 575.67pg/ml; p=0.009) and TNF-α (3.1 vs. 1.21 pg/ml, p=0.001) on the first day post-operatively with the use of conventional analogue drainage systems compared to Thopaz. On post-operative day 2 and 3 there was a significant increase in pleural fluid IL-8 concentration in the Thopaz group (790.20pg/mL) however while pleural IL-8 levels decreased in the analogue arm (to 588.58pg/mL) in the same time period (p=0.034).

The study also reported significant differences in outcomes when comparing open vs. video-assisted thoracoscopic surgery (VATS) procedures and lobar vs. sub-lobar procedures regardless of the drainage system used (details reported in Appendix C).

Ruigrok 2021 is a randomised trial based in the Netherlands. The study randomised 102 adult patients with a primary spontaneous pneumothorax (PSP) to conventional analogue or digital drainage (Thopaz). Outcomes of the trial included length of hospital stay and recurrence of pneumothorax within 12 weeks. Cross-over to another drainage system was allowed and there were 4 cross-overs from conventional analogue to digital and 1 cross-over from digital to conventional analogue during the study. Study results indicate no significant difference in duration of chest tube drainage (median 3 vs. 2 days; p=0.488) or hospital length of stay (median 3 vs. 2.5 days; p=0.640). In total, 19 patients underwent surgery due to prolonged air leak (6

in the conventional analogue group and 13 in the digital group (p=0.127)) and after excluding these patients, duration of chest tube drainage (median 1 vs. 3 days; p=0.024) and length of stay (median 1 vs. 3 days p=0.014) were significantly shorter in patients in the digital drainage arm compared with conventional analogue drainage. Three patients in each group had a clinically relevant pneumothorax within 1 week of discharge. Excluding patients with recurrence within one week, 7 patients in the conventional analogue group and 4 patients in the digital group had a recurrence (clinically relevant pneumothorax within 12 weeks).

Takamochi 2018 is a randomised trial based in Japan. The study randomised 320 patients undergoing anatomic lung resections to either digital chest drainage with Thopaz or conventional thoracic drainage. Outcomes for the study included duration of drain placement, duration of post-operative leak, frequency of post-operative leak, frequency of postoperative pleurodesis, days of hospitalization and postoperative adverse events. Results of the study reported no significant difference in duration of chest tube placement (median 2 days with Thopaz and 3 days with conventional analogue; p=0.149), length of hospital stay (6 days with Thopaz vs. 7 days with conventional analogue, p=0.548), incidence of post-operative air leaks (0.867) or frequency of post-operative adverse events (p=0.361) between the two groups. Frequency of chest tube clamping trial before removal was significantly lower with Thopaz (0.7% vs. 35.3%; p<0.001).

Non-Randomised Studies

Arai 2018 is a retrospective case-control study based in Japan. The study included a review of 540 lung surgeries performed in a single hospital between April 2014 and March 2015 (265 treated with a conventional 3 bottle drainage system and 275 treated with Thopaz). Outcomes included operative blood loss, operation time, duration of chest tube placement, chest tube reinsertions, clamping test and re-operation rates. Results indicated no significant difference between the groups for blood loss (Thopaz 34ml±96.5 vs. conventional 45.2mls±122.6; p=0.237), duration of chest tube placement (Thopaz 2.4days vs conventional 2.3 days; p=0.678), rate of chest tube reinsertion (8 reinsertions in Thopaz group reinsertions vs 6 in conventional group p=0.637), clamping test (9 in Thopaz group vs 15 in conventional group; p=0.178) or reoperation (4 reoperations in Thopaz group vs. 3 in conventional group; p=0.520). There were 5 incidences of minor complications in patients treated with the Thopaz system including increased air flow (n=1), marked subcutaneous emphysema (n=1), device malfunction (n=1) and canister displacement (n=2).

Perez-Egido 2018 is a prospective, observational study based in Spain. The study included 13 paediatric patients undergoing pulmonary resection and the

Thopaz digital drainage was used. The group was compared with a historical cohort of patients in whom conventional drainage was used. Outcomes included duration of chest tube placement, number of postoperative radiographs, length of hospital stay and complications. The median number of days with the chest tube was 2 in the Thopaz group compared with 4 in the analogue group ($p<0.05$). Median number of postoperative radiographs was 3 in the Thopaz group vs. 4 in the analogue group ($p<0.05$). Median length of hospital stay in the Thopaz group was 4 days versus 7 days in the analogue group ($p>0.05$). No complications related to use of the Thopaz system were reported. It should be noted that the results section in the main text of the paper reports median values but the abstract reports mean values but it is not clear why this is the case. The results reported in the abstract are included in the data tables in Appendix C for reference.

Cardiac Setting

Randomised Trials

Van Linden 2019 is a randomised controlled trial based in Germany. The study randomised 354 adult patients (340 included in analysis) undergoing cardiac surgery. There were 16 cross-overs giving 152 patients in the Thopaz+ arm and 188 in the analogue arm. Outcomes included number of drains, amount of evacuated fluid, chest tube duration, length of ICU stay and length of hospital stay. The mean number of drains per patients was 2±0.8 and the median amount of fluid evacuates was 705ml with analogue drain and 686ml with Thopaz+ ($p=0.83$). Total chest tube duration was significantly shorter with Thopaz+ compared with analogue drainage (median 49 hours vs. 65 hours; $p\leq0.01$) but the length of ICU stay (median 1 day for both arms, $p=0.57$) and length of hospital stay (median 9 days for both arms, $p=0.65$) were not significantly different between the arms. Incidence of chest x-rays with clamped drains to detect air leaks was significantly lower with Thopaz+ compared with analogue drainage (8.6% vs 20.2%; $p<0.01$).

Barozzi 2020 is a randomised trial conducted in Italy and Switzerland. The study randomised 120 adult cardiac patients undergoing elective coronary artery bypass graft and/or valve surgery. There were 7 cross-overs from Thopaz+ to conventional analogue drainage, 2 for massive air leak due to incorrectly connected reservoir, 2 after reoperation for bleeding and 3 for surgeon preference. There was no significant difference in size and number of tubes between the two groups. There was significantly higher drainage in the Thopaz+ group at the end of operation before transport and on arrival in ICU ($p<0.01$), after which no difference in drainage was reported between the groups. Mean duration of chest drainage was not significantly different with 29.8 hours with Thopaz+ and 38.4 hours with analogue drains ($p=0.19$).

Halfway through the study, a web-based Satisfaction Assessment Questionnaire was completed by 52 healthcare professionals (12 ICU nurses, 10 operating room nurses, 16 ward nurses, 8 surgeons and 6 cardiac anaesthetists). Satisfaction with Thopaz+ was overall reported as “high” although nurses reported slightly lower satisfaction for ease of use and use for data collection. All staff scored Thopaz+ highly for noise reduction and for mobility.

Non-randomised studies

Tamura 2021 is a retrospective study based in Japan which included 80 consecutive adult patients (n=42 analogue drainage and n=38 digital drainage with Thopaz) who underwent cardiac surgery (excluding coronary artery bypass grafting only, with or only aortic surgery, emergency operation, and patients with haemolysis). Outcomes included duration of chest drainage, rate of drainage related complications and length of hospital stay. The study reported a significantly shorter duration of drainage in the Thopaz group (Analogue: 94.8± 31.5 vs. Digital: 81.1 ± 20.6 h, p = 0.036) and the length of hospitalisation was significantly shorter in the Thopaz group compared with analogue drainage (Analogue: 22.7 ± 7.9 vs. Digital: 19.5 ± 7.2 days, p = 0.041, although it should be noted that elsewhere in the paper length of hospitalisation is reported to be Analogue: 21.9±5.3 vs. Digital: 18.8±7.2 days, p = 0.031). No significant difference in duration of ICU stay was reported between both groups (p = 0.134) .

Saha 2020 is a retrospective study based in Germany which included 265 consecutive adult patients who underwent cardiac surgery. There were 65 patients with analogue conventional drainage systems and 200 patients with digital systems (Thopaz+) and the majority of patients had undergone coronary artery bypass grafting (72.5%). The amount of fluid collected during the first 6 hours post-operatively was significantly higher with Thopaz+ (250ml vs. 200ml with analogue systems; p=0.043) but the total amount of fluid collected did not differ between the groups (p=0.741). Length of stay on ICU (median 2 days for both Thopaz+ and analogue drainage; p=0.107) and total hospital stay (median 14 days for both groups; p=0.714) were similar in both groups. Clotting of connectors in the tubing system was observed in 13 patients with a digital drainage system (p=0.042) which were managed by a change of tubing system without any further negative implications for the patients. The authors noted that as analogue display units do not provide any alarms, there may have been undetected clotting events in the analogue group.

A questionnaire about user experience was completed by 11 doctors and 59 nurses. ICU staff did not report any difference in ease of set-up, connection of tubes, ease of obtaining probes, positioning of CDUs or reading of

displays/scales however on the regular wards, the Thopaz+ system was significantly more favoured ($p<0.001$).

4.5 Adverse Events

Searches of MHRA identified no adverse events related to Thopaz/Thopaz+. Searches of the FDA MAUDE database identified one device related adverse event, reported as 'Increase in Pressure', which resulted in a patient sustaining life threatening tension of mediastinum due to the drain being set to an incorrect suction level. This appeared to be a result of user error rather than device malfunction.

4.6 Ongoing trials

Searches by NICE information specialists identified a total of 6 ongoing studies and 10 completed studies (3 with associated publications). These publications (Gilbert 2015, Linder 2012 and Pompili 2014) were all appraised as part of the original guidance and will not be discussed further here.

An additional 2 studies (Trial ISRCTN10408356, Trial ISRCTN14884587) that were identified have related publications (Barozzi 2018; Lijkendijk 2019, Lijkendijk 2017) that were identified in the literature searches.

In total, 9 ongoing studies were identified as being possibly relevant however it should be noted that 4 of these have either stopped or been withdrawn at this time. Details of these ongoing studies considered potentially relevant are reported in Appendix C.

4.7 Changes in cost case

A recent review of the cost of the Thopaz+ technology was conducted in November 2021 the results of which indicated that Thopaz+ remains cost saving compared to standard care (appendix B). The estimated saving per patient arising from Thopaz+ (£107.99) is attenuated by a very small amount compared to that of NICE MTG37 (£111.34) (NICE, 2018).

Table 1: Updated Thopaz+ Cost Modelling

	NICE MTG37 (NICE, 2018)		**Cost update, 2021**	
	Thopaz+	**Conventional**	**Thopaz+**	**Conventional**
Device cost per patient	£26.47	£0.00	£26.47	£0.00
Training cost	£5.29	£0.00	£6.01	£0.00
Time using device	£0.00	£0.00	£0.00	£0.00

Consumables per patient	£30.85	£35.45	£32.96	£24.00
Cost of Bed Days	£1,829.20	£1,964.69	£1,976.02	£2,122.39
Complications	£0.00	£3.00	£0.00	£3.06
Total	£1,891.80	£2,003.14	£2,041.46	£2,149.45
Incremental	**-£111.33**		**-£107.99**	

The updated sensitivity analysis also has similar results to that undertaken for NICE MTG37 (NICE, 2018), with the model being most sensitive to changes in the length of hospital stay for Thopaz+ and for conventional chest drainage. Full details of the cost update are reported in Appendix B.

4.8 Other relevant information

None

5. Conclusion

Since the publication of the guidance and recommendations in 2018, a large number of new, relevant studies have been completed and results published. Although, as was the case for the original assessment report, the majority of the studies are in the respiratory setting, there are also a small number of studies in a cardiac setting which were not available previously. The use of Thopaz/Thopaz+ in other settings is covered by the original scope and the availability of these studies lends support to the clinical expert opinions that the use of Thopaz and/or Thopaz+ had expanded into settings other than pulmonary/respiratory settings within the NHS.

Although a number of the new studies are randomised trials, none are UK based (although one may include UK patients), which may limit the generalisability of the results to the NHS setting and in one study (Jacobsen 2019) it is not clear that the digital drainage device being used is Thopaz/Thopaz+. The most reported outcomes for both respiratory and cardiac studies were duration of chest tube and length of hospital stay as well as outcomes such as duration of air leak, volume of fluid collected, post-operative lung function, chest tube reinsertions, adverse events and user satisfaction.

The evidence broadly suggests that outcomes for patients are more favourable with digital drainage using Thopaz/Thopaz+ when compared with analogue drainage systems.

From key studies in the respiratory setting, patients undergoing lung resections had a shorter duration of chest tube placement and duration of

hospital stay in all 3 randomised trials (Alam 2020, DeWaele 2017, Takamochi 2018), although the differences were only statistically significant in one study (Alam 2020).

In one randomised trial in patients with primary spontaneous pneumothorax, the duration of tube drainage and length of hospital stay were also shorter in the Thopaz group but the difference was again not statistically significant. The EAC consider that as all randomised trials continue to show a reduced length of hospital stay with Thopaz/Thopaz+ and as the economic model is most sensitive to changes in length of hospital stay, Thopaz/Thopaz+ is likely to remain cost saving.

No evidence for the use of Thopaz/Thopaz+ in a cardiac setting was available at the time of the original guidance and therefore no recommendation could be made for its use in this setting. The EAC consider that the costs associated with use of Thopaz/Thopaz+ and analogue comparators are likely to be similar to those in the original cost model for respiratory settings. The current evidence from 4 studies in the cardiac setting indicates that although the duration of chest drainage in 3 studies was shorter with Thopaz than with analogue drainage (Tamura 2021, van Linden 2019, Barozzi 2020), there is uncertainty around the impact on duration of hospital stay with one study reporting significantly shorter duration (Tamura 2021) and 2 studies reporting that the duration of hospital stay was the same for both groups (van Linden 2019, Saha 2020). One clinical expert considered that 0.5-day reduction in drain removal or hospital length of stay would be clinically significant but noted that many factors can affect this. As the original cost saving was due to a reduced length of hospital stay, it is possible, based on the currently available evidence that Thopaz/Thopaz+ may not be cost saving in a cardiac setting. This however cannot be stated with certainty without a full review of the economic model cost and resource inputs to ensure that they are appropriate to the cardiac setting, as well as discussion around the most appropriate choice of hospital stay data.

Table 2: Potential Impact on Recommendations

MT37 Recommendation	**Potential Impact on Recommendation**
The case for adopting Thopaz+ for managing chest drains is supported by the evidence. Thopaz+ can reduce drainage time and length of stay in hospital, and improves safety for people with chest drains. Its use may also improve clinical decision-making through continuous, objective monitoring of air leaks and fluid loss.	The EAC suggests that this recommendation may need to be updated to reflect the fact that there is now evidence available for the use of Thopaz in a cardiac setting. The new studies indicate a shorter duration of drainage with Thopaz in both the respiratory and cardiac settings. For length of hospital stay however the evidence is less certain in the cardiac setting.

Thopaz+ should be considered for people who need chest drainage after pulmonary resection or because of a pneumothorax. The system can increase patient mobility because it is portable. Staff find it more convenient and easier to use than conventional chest drains.	The EAC suggests that this recommendation does not need to be changed Limited new evidence was identified relating to pneumothorax specifically however the results from a single randomised trial suggest a shorter duration of chest tube drainage and a shorter length of hospital stay. There was no new evidence around patient mobility or staff preferences but neither was there anything to contradict the statements in the recommendation. Updated cost modelling (Appendix B, scenario analysis) indicates that use of Thopaz in this setting is cost saving.
Cost modelling indicates that Thopaz+ is cost saving compared with conventional chest drains in people after pulmonary resection. The estimated saving is £111 per patient per hospital stay, with savings mainly achieved through reduced length of stay. The NICE resource impact assessment shows that, at a national level, adopting Thopaz+ is expected to save around £8.5 million per year in England.	The EAC suggests that this recommendation should be updated to include the cardiac setting. A review of costs in the economic model suggest that Thopaz remains cost saving in a respiratory setting and also when considering pneumothorax specifically. New evidence in the cardiac setting suggests uncertainty around the impact of Thopaz compared with conventional drainage on duration of hospital stay. As the original cost saving was due to a reduced length of hospital stay, it is possible, based on the currently available evidence that Thopaz/Thopaz+ may not be cost saving in a cardiac setting.

Appendix A – Relevant guidance

To be supplied by the NICE gIS team

NICE guidance – published

NICE guidelines (clinical, public health, social care, medicine practice guidelines, safe staffing)

Major trauma: assessment and initial management (2016) NICE guideline 39

All other NICE guidance and advice products

PleuraFlow Active Clearance Technology for maintaining chest tube patency (2017) NICE medtech innovation briefing 125

Insertion of pleuro–amniotic shunt for fetal pleural effusion (2006) NICE interventional procedures guidance 190

NICE pathways

None found

NICE guidance – in development

NICE guidelines (clinical, public health, social care, medicine practice guidelines, safe staffing)

None found

All other NICE guidance and advice products

None found

Suspended or terminated

None found

In topic selection

None found

Guidance from other professional bodies

British Thoracic Society.(2020) Guidance to support the implementation of Local Safety Standards for Invasive Procedures (LocSSIPs) - Bronchoscopy and Pleural Procedures

Appendix B - Costing update report of MTG37: The Thopaz+ portable digital system for the management of chest drains

This medical technology guidance was published in March 2018.

All medical technology guidance is reviewed 3 years after publication according to the process described in the MTEP Interim addendum on guidance reviews.

This report is part of the information considered in the guidance review. It describes an update of the cost model so that it reflects any new relevant information including revising the cost and resource parameters to current values. The results from the updated cost model are used to estimate the current savings associated with the use of the technology.

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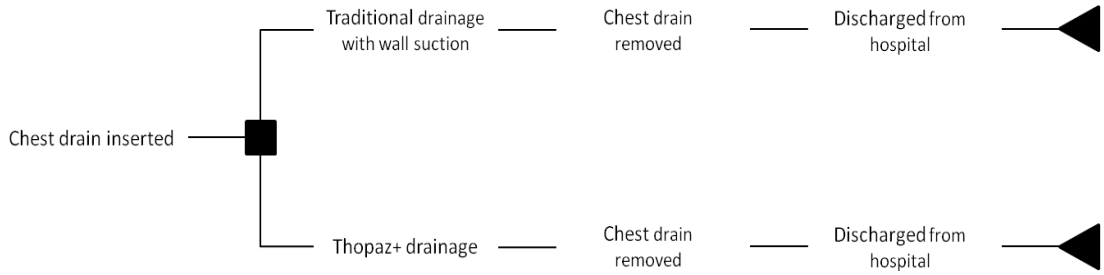
1. Background

In 2018 NICE published medical technologies guidance MTG37 on the Thopaz+ chest drainage system (NICE, 2018). In development of NICE MTG37 the EAC undertook a critique of the company's submission of evidence. The company did not provide any published economic evidence in its economic submission but included a simple cost comparison of Thopaz+ versus conventional drainage using wall suction. This estimated that Thopaz+ was cost saving compared to traditional drainage at £35.55 per patient. The company's cost comparison lacked sufficient detail; it did not consider complications of chest drainage and it did not explore uncertainty concerning

model inputs. The EAC considered that the cost comparison had potential to underestimate the benefits of Thopaz+. Therefore the EAC constructed its own model to inform NICE MTG37 (NICE, 2018). The model structure, as shown in Figure 1, was a decision tree with two executable arms comparing Thopaz+ chest drainage with conventional drainage using wall suction. Time to removal of the chest drain in either arm was based on published evidence, as was length of hospital stay and rates of complications.

Figure 1. Decision tree economic model



Key parameters in the model

All parameters in the model were constructed to estimate the following elements:

- The cost incurred by renting the Thopaz+ device (versus zero cost for conventional wall suction which is standard hospital infrastructure)
- The cost of training clinical staff to use the Thopaz+ system (versus zero training cost for conventional drainage)
- The cost of consumables for Thopaz+ and for conventional drainage
- Length of hospital stay for patients treated with Thopaz+ and for patients treated with conventional drainage and the cost of each included as cost per bed-day
- Rate of a specific, single complication only: that of needing to reinsert the chest drain.

Sources of cost data in the EAC model included Personal Social Services Research Unit (PSSRU) for staff time, National Schedule of NHS Costs for reinsertion of chest drains, NHS supply chain for consumables for drainage,

and the company for Thopaz+ device rental and consumable items. Prices were up to date at the time of NICE MTG37 (NICE, 2018).

The time horizon of the model was the duration of hospital stay (5.4 days per Thopaz+ and 5.8 days for conventional drainage) and no discount rate was applied to costs. The base case assumed that the Thopaz+ reusable device is rented.

The EAC model's base case found Thopaz+ to be cost saving at £111.33 per patient compared to standard care. This saving originated because while Thopaz+ incurred a small additional rental cost, this was more than offset by avoidance of the need to reinsert chest drains and shorter hospital stay compared to standard care.

One way sensitivity analysis revealed that the model was most influenced by variation in length of hospital stay, followed by rate of device utilisation and the cost of hospital beds. Other parameters had little effect in the sensitivity analysis. Larger savings were estimated when the Thopaz+ device is purchased rather than leased, or when Thopaz+ is used to treat patients with pneumothorax.

2. Current validity of model

The EAC model did not include probabilistic sensitivity analysis. The model explores sufficient parameters to address the simple decision problem and one-way sensitivity analysis explores uncertainty of model inputs adequately.

Responses provided to NICE from three clinical experts suggest that there have been no significant changes to the care pathway for chest drainage, except that use of Thopaz+ is expanding in volume and to the cardiothoracic surgery speciality.

The Thopaz+ device has retained its CE mark and there have been no changes to the device.

Two clinical experts have confirmed that there have been no changes made to Thopaz+ since NICE MTG37 (NICE, 2018) and that the current decision tree model design remains fit for purpose.

Therefore the EAC considers that no structural changes are required to the economic model. Clinical experts did not suggest that structural changes or new scenarios were needed.

Clinical evidence

The company has reported that a volume of evidence has emerged since the production of NICE MTG37 (NICE, 2018), including two new randomised controlled trials related to the use of Thopaz+ in cardiac surgery. The company cites this as the beginning of the evidence for this new indication for Thopaz+.

NHS use

The company also reports increased use of Thopaz+ in NHS hospitals performing cardiac surgery, including coronary artery bypass graft (CABG) and aortic valve replacement/repair procedures. The company reports that Thopaz+ has potential to support the aims of enhanced recovery after surgery (ERAS) protocols.

One clinical expert noted that in their trust, Thopaz+ is used in Thoracic surgery, by respiratory medicine, trauma, adult intensive care and occasionally cardiac surgery. Other than in the thoracic surgery setting it is mainly used for pneumothorax and haemothorax. A second expert stated that their thoracic surgeons used Thopaz+ in post-operative patients and a third expert noted it was used in other cardiothoracic units. When asked specifically about the use in cardiac surgery, one expert noted that they couldn't comment on use in cardiac surgery as Thopaz+ hasn't been implemented for their standard post-operative pathways and there were no plans to do so.

3. Updated input parameters

Table 1 presents the unit costs that were used in the original EAC model for NICE MTG37 (NICE, 2018), with a column for revision for the 2021 update. Every unit cost was considered for revision. For unit costs that did not require a stepwise change (e.g. based on new information) then as a minimum, costs were inflated to 2021 values using a citable method. Table 1 presents the values and sources of the model's input parameters, for the original EAC model for NICE MTG37 (NICE, 2018), and for the 2021 cost update. In Table 1, the cost of reinserting a chest drain is an aggregated procedure cost calculated by the EAC and including consumables, staff time and a chest X-ray. The calculation of this cost is shown in full in Table 2.

Table 1. Changes to unit costs

Costs in original guidance NICE MTG37 (NICE, 2018)			**Cost in 2021 update**	
	Unit cost	**Source**	**Unit cost**	**Source**
Thopaz+ Equipment costs				
Device capital cost	£3,400.00	Company statement	£3,570.00	Company's updated value
Lifespan (years)	5	From company	5	
Calculated daily cost for purchase	£1.86	EAC calculation. Maintenance costs included in price. Warranty for 2 years and then an extended warranty can be purchased.	£1.96	Daily cost based on £3570 device capital cost spread over 5 years i.e. £3570/365/5 = £1.96 per day

Monthly rental	£115.00	Company statement, Price for <25 units, includes any repairs	£115.00	Company's update confirms no change
Thopaz+ Consumable items				
Disposable canister	£14.10	From company's economic submission. Different sizes and types are available	£15.18	Updated list price provided by the company.
Disposable tubing	£9.70	From company's submitted list prices. Different sizes and types are available.	£10.19	Updated list price provided by the company.
Conventional equipment costs				
Rocket drain	[redacted]	NHS Supply chain - no tubing	[redacted]	Cost of Rocket Medical chest drain [redacted]. NHS Supply chain 2021 price

Wall suction unit	£0.00	EAC. This is already in place for other procedures	£0	Wall suction units remain as standard bedside equipment
Sterilisation cost for bottles	£0.00	EAC	£0	
Disposable tubing	[redacted]	NHS Supply chain	[redacted]	This is the mean of the single tube cost and the double tube cost, assuming a 50/50 split. Cost of Rocket Medical single tube [redacted], cost of Rocket Medical double tube [redacted], NHS Supply Chain 2021.
Staff costs				
Consultant (surgical)	£137.00	PSSRU 2016	£148.77	Consultant (surgical) cost per working hour. PSSRU 2020 costs. Page 159. https://www.pssru.ac.uk/project-pages/unit-costs/unit-costs-2020/ provides £114 (Curtis and Burns, 2020). Unlike the 2016 PSSRU the hourly rate no longer includes the cost of training. Based on 2016 values the training inflates the cost by a factor of 137/105=1.305. So 114*1.305=148.77, which includes training costs.

Registrar	£59.00	PSSRU 2016	£73.75	Registrar cost per working hour. PSSRU 2020 costs. Page 159. https://www.pssru.ac.uk/project-pages/unit-costs/unit-costs-2020/ provides £50 (Curtis and Burns, 2020). Unlike the 2016 PSSRU the hourly rate no longer includes the cost of training. Based on 2016 values the training inflates the cost by a factor of 59/40=1.475. So 50*1.475=£73.75, which includes training costs.
FY2	£42.00	PSSRU 2016	£50.68	FY2 cost per working hour. PSSRU 2020 costs. Page 159 https://www.pssru.ac.uk/project-pages/unit-costs/unit-costs-2020/ provides £35 (Curtis and Burns, 2020). Unlike the 2016 PSSRU the hourly rate no longer includes the cost of training. Based on 2016 values the training inflates the cost by a factor of 42/29=1.448. So £35*1.448 = £50.68 which includes training costs.
Nurse, band 9	£122.00	PSSRU 2016	£136.00	Hospital-based nurse Band 9 cost per working hour. PSSRU costs 2020 page 155.

				https://www.pssru.ac.uk/project-pages/unit-costs/unit-costs-2020/ (Curtis and Burns, 2020)
Nurse, band 8a	£62.00	PSSRU 2016	£69.00	Hospital-based nurse Band 8a cost per working hour. PSSRU costs 2020 page 155. https://www.pssru.ac.uk/project-pages/unit-costs/unit-costs-2020/ (Curtis and Burns, 2020)
Nurse, band 7	£53.00	PSSRU 2016	£60.00	Hospital-based nurse Band 7 cost per working hour. PSSRU costs 2020 page 155. https://www.pssru.ac.uk/project-pages/unit-costs/unit-costs-2020/ (Curtis and Burns, 2020)
Nurse, band 6	£44.00	PSSRU 2016	£50.00	Hospital-based nurse Band 6 cost per working hour. PSSRU costs 2020 page 155. https://www.pssru.ac.uk/project-pages/unit-costs/unit-costs-2020/ (Curtis and Burns, 2020)

Bed days cost				
Bed day	£338.74	Company mean calculation	£365.93	The model structure utilises a cost per bed-day to include the impact of a differential in hospital stay between Thopaz+ and Standard care. In NICE MTG37 (NICE, 2018) the cost per bed day was derived from year 2015/6 costs per excess bed days that were specific to complex thoracic procedure codes DZ02H, DZ02J and DZ02K in the National Schedule of NHS costs. A weighted average was applied using the costs of each of the three procedures and also for elective and non-elective patients. The 2019/20 costs for DZ02H, DZ02J and DZ02K (NHS England, 2021) are no longer presented in the same format and they do not include excess bed days. They include the national average unit cost for the thoracic procedures but these are far in excess of a single hospital bed day. This does not permit

				a bottom upwards reconstruction of the weighted mean average. A solution may be to derive a generic, modern hospital bed-day cost, but neither PSSRU nor the national schedule of NHS costs provide a generic bed-day cost. Therefore the value of £338.74 used in MTG37 has been inflated using the PSSRU inflation rate (Curtis and Burns, 2020), giving a value of £365.93.
Cost of complications				
Chest drain re-insertion	£176.37	EAC estimate based on information from a clinical expert	£180.00	This is an aggregated cost with several components. For the current update the cost has been reconstructed from the bottom upwards using the same structure and procedure time as the 2017 model, and with up-to-date staff salary hourly rates and with disposables identified and costed from NHS Supply Chain, 2021. The component cost of a chest X-ray has been inflated from the 2015/16 value to a 2019/20 value using the

				PSSRU inflation rate (Curtis and Burns, 2020). Details are shown in Table 2.

Table 2. Calculation of updated cost for reinsertion of chest drain

Item	Number required	Value	Cost incurred	Notes
Procedure time (hours)		0.5		Unchanged from 2017 model
Consultant hourly rate		£148.77		Based on 2019/20 PSSRU (Curtis and Burns, 2020) and multiplied by a factor to incorporate training (medical school) cost
Registrar hourly rate		£73.75		Based on 2019/20 PSSRU (Curtis and Burns, 2020) and multiplied by a factor to incorporate training (medical school) cost
Mean hourly rate		£111.26		This is the mean of the consultant hourly rate and the registrar hourly rate, assuming a 50/50 split.
Total staff cost		£55.63	£55.63	

Cost of Rocket Medical Insertion set FSW1607	1	[redacted]	[redacted]	NHS Supply chain 2021 price
Cost of Rocket Medical single tube FSW077		[redacted]		NHS Supply chain 2021 price
Cost of Rocket Medical double tube FSW559		[redacted]		NHS Supply chain 2021 price
Mean tube cost	1	[redacted]	[redacted]	This is the mean of the single tube cost and the double tube cost, assuming a 50/50 split
Cost of Rocket Medical bottle FSW076	1	[redacted]	[redacted]	NHS Supply chain 2021 price
Cost of Rocket Medical chest drain FSU384	3	[redacted]	[redacted]	NHS Supply chain 2021 price
Cost of chest X-ray (inflated)	1	£33.72	£33.72	Value is based on the 2016 cost (£31.21) inflated to 2019/20 value using PSSRU inflation rates (Curtis and Burns, 2020).
Total updated cost			**£180.00**	

4. Results from updated model

Updated base case

Keeping the model structure and all clinical parameters the same as for MTG37, the updated costs listed in Table 1 revise the model's base case as shown in Table 3. In the updated base case Thopaz+ remains cost saving compared to standard care. The estimated saving per patient arising from Thopaz+ (£107.99) is attenuated by a very small amount compared to that of NICE MTG37 (NICE, 2018) (£111.34).

Table 3 Original versus updated EAC base case

	NICE MTG37 (NICE, 2018)		**Cost update, 2021**	
	Thopaz+	**Conventional**	**Thopaz+**	**Conventional**
Device cost per patient	£26.47	£0.00	£26.47	£0.00
Training cost	£5.29	£0.00	£6.01	£0.00
Time using device	£0.00	£0.00	£0.00	£0.00
Consumables per patient	£30.85	£35.45	£32.96	£24.00
Cost of Bed Days	£1,829.20	£1,964.69	£1,976.02	£2,122.39
Complications	£0.00	£3.00	£0.00	£3.06
Total	£1,891.80	£2,003.14	£2,041.46	£2,149.45
Incremental	**-£111.33**		**-£107.99**	

Sensitivity analysis

Table 4 presents the parameters explored in one-way sensitivity analysis in the original EAC model, and the 2021 cost update. In the cost update sensitivity analysis, each base case parameter was decreased by 20% to give a low input value and increased by 20% to give a high input value. The EAC has not added or removed parameters as no new information was received from clinical experts. Where no specific change was indicated to a given cost, the value was inflated to 2021 prices using the PSSRU inflation rate (Curtis and Burns, 2020). Table 4 also shows the effects of the variation of each parameter on the model's result i.e. the incremental cost difference per patient between Thopaz+ and conventional chest drainage. Negative values indicate a cost saving as a result of using Thopaz+. Most inputs have little effect on

the result when varied. The model is sensitive to changes in the length of hospital stay (for Thopaz+ and for conventional drainage) and to a lesser extent, changes in hospital bed-day cost. Hospital stay is the only variable which when varied, could change the model's result such that Thopaz+ becomes cost-incurring (Table 4 and Table 5). The base case values for length of hospital stay are 5.4 days (Thopaz+) and 5.8 days (conventional drainage). Table 5 presents a two-way sensitivity analysis in which length of hospital stay in each group is varied in the range 5.3 days to 5.8 days. If length of stay for Thopaz+ is held constant at 5.4 days, Thopaz+ becomes cost-incurring if length of stay for conventional drainage reduces by 0.3 days to 5.5 days. If length of stay for conventional drainage is held constant at 5.8 days, Thopaz+ becomes cost-incurring if length of stay for Thopaz+ increases by 0.3 days to 5.7 days. Table 5 shows that if hospital stay is assumed to be equal in both arms of the model, Thopaz+ retains its cost saving. One clinical expert reported that use of Thopaz+ has resulted in shortened hospital stays compared to conventional drainage, which supports the economic case for Thopaz+.

Table 4. Revised unit costs for one-way sensitivity analysis

	Costs in original guidance NICE MTG37 (NICE, 2018)			Cost in 2021 update			Effect on 2021 updated model: incremental cost per patient	
Thopaz+ Equipment costs	**Base case**	**Low Cost**	**High Cost**	**Base case**	**Low Cost**	**High Cost**	**Low value**	**High value**
Daily cost	£3.78	£3.45	£4.53	£3.78	£3.02	£4.54	-£113.28	-£102.70
Disposable canister	£14.1	£13.6	£28.09	£15.18	£12.14	£18.22	-£112.54	-£103.44
Disposable tubing (Thopaz+)	£9.70	£9.20	£19.66	£10.19	£8.15	£12.23	-£110.03	-£105.95
Rocket drain	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	-£102.28	-£109.62
Sterilisation cost for bottles	£0.00	£0.00	£0.00	£0.00	£0.00	£0.00	NA	NA
Disposable tubing (Rocket)	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	-£106.86	-£109.12

Training cost	£5.292	£4.02	£8.10	£6.01	£4.81	£7.21	-£109.19	-£106.79
Bed days cost	£338.74	£301.69	£423.70	£365.93	£292.74	£439.12	-£78.72	-£137.26
Chest drain re-insertion cost	£176.37	£114.24	£258	£180.00	£144.00	£216.00	-£107.38	-£108.60
Device utilization (proportion)	0.5	0.2	0.8	0.5	0.4	0.6	-£101.37	-£112.40
Average canisters per patient Thopaz+	1.5	1	2	1.5	1.2	1.8	-£112.54	-£103.44
Average Rocket drain canisters per patient	3	2	4	3	2.4	3.6	-£104.93	-£111.66
Additional set up for Thopaz+ (hours)	0	0	0	0	0	0	NA	NA
Additional drain management/staff time for Thopaz+ (hours)	0	0	0	0	0	0	NA	NA

Duration of tube placement, Thopaz+ (days)	3.5	2.4	4.9	3.5	2.8	4.2	-£113.28	-£102.70
Length of stay (days) Thopaz+	5.4	4.5	7.7	5.4	4.32	6.48	-£503.19	£287.21 (cost incurring)
Length of stay (days) Conventional	5.8	5.5	6	5.8	4.64	6.96	£316.49 (cost incurring)	-£532.47
Reinsertion rate of chest drains Thopaz+	0	0	0	0	0	0	NA	NA
Reinsertion rate of chest drains Conventional	0.017	0	0.02	0.017	0.014	0.020	-£107.38	-£108.60

Table 5. Two-way sensitivity analysis: effect upon incremental cost per patient of varying length of hospital stay for patients receiving Thopaz+ versus patients receiving conventional drainage

		Length of stay (days) conventional drainage					
		5.3	**5.4**	**5.5**	**5.6**	**5.7**	**5.8***
Length of stay (days) Thopaz+	**5.3**	£38.38	£1.79	-£34.80	-£71.40	-£107.99	-£144.58
	5.4*	£74.98	£38.38	£1.79	-£34.80	-£71.40	-£107.99
	5.5	£111.57	£74.98	£38.38	£1.79	-£34.80	-£71.40
	5.6	£148.16	£111.57	£74.98	£38.38	£1.79	-£34.80
	5.7	£184.75	£148.16	£111.57	£74.98	£38.38	£1.79
	5.8	£221.35	£184.75	£148.16	£111.57	£74.98	£38.38

Negative values highlighted in green represent a cost saving for Thopaz+. Positive values highlighted in red represent a cost incurred for Thopaz+.

* denotes the base case input values.

Update of additional scenarios

The three additional scenarios modelled by the EAC for the original MTG37 guidance (NICE, 2018) have been reproduced with updated input costs. These are presented in Table 6. Table 6 shows that, like in MTG37 (NICE, 2018), the additional scenarios result in stronger savings resulting from the use of Thopaz+.

Table 6. Additional scenarios

Scenario	Incremental cost saving	Changes to the model in this scenario
Base case: Thopaz+ device is rented. Patients undergo pulmonary resection.	-£107.99	None
Thopaz+ device is purchased. Patients undergo pulmonary resection	-£120.74	The updated purchase cost of £3570 is incurred over five years, resulting in a daily purchase cost of £3570/365/5 = £1.96 i.e. cheaper than renting.
Thopaz+ device is rented. Patients treated for pneumothorax	-£653.82	Length of hospital stay values are based on Jablonski et al. (2014): Thopaz+: 5.1 days

		versus Conventional drainage: 7 days. The rate of chest drain reinsertion was changed to zero in the conventional drainage arm because this was not an outcome in the study by Jablonski et al. (2014).
Thopaz+ device is purchased. Patients treated for pneumothorax	-£666.57	The updated purchase cost of £3570 is incurred over five years, resulting in a daily purchase cost of £3570/365/5 = £1.96 i.e. cheaper than renting. Length of hospital stay values are based on Jablonski et al. (2014): Thopaz+: 5.1 days versus Conventional drainage: 7 days. The rate of chest drain reinsertion was changed to zero in the conventional drainage arm because this was not an outcome in the study by Jablonski et al. (2014).

5. Conclusion

The cost update has had very little impact on the results of the EAC decision tree's base case result, which suggests that Thopaz+ remains cost saving compared to standard care. The estimated saving per patient arising from Thopaz+ (£107.99) is attenuated by a very small amount compared to that of NICE MTG37 (£111.34) (NICE, 2018). The updated sensitivity analysis also has similar results to that undertaken for NICE MTG37 (NICE, 2018), with the model being most sensitive to changes in the length of hospital stay for Thopaz+ and for conventional chest drainage. Three additional scenarios included in the EAC model explored the effect of buying (versus renting) the Thopaz+ device and also when patients are treated for pneumothorax. Once updated, all three scenarios have similar results to those in the original EAC model: in each scenario Thopaz+ results in larger savings than in the updated base case. The cost case on which the recommendations of NICE MTG37 (NICE, 2018) were made appear to be still valid.

6. References

Curtis, L. & Burns, A. (2020) Unit Costs of Health and Social Care 2020, Personal Social Services Research Unit, University of Kent, Canterbury. DOI: 10.22024/UniKent/01.02.84818 Available at: https://www.pssru.ac.uk/project-pages/unit-costs/unit-costs-2020/

Jablonski, S., Brocki, M., Wawrzycki, M., Smigielski, J. A. & Kozakiewicz, M. (2014) Efficacy assessment of the drainage with permanent airflow measurement in the treatment of pneumothorax with air leak. Thoracic & Cardiovascular Surgeon, 62(6), 509-515.

NHS England (2021) National Cost Collection for the NHS. 2019/20 National Cost Collection data. Available at: https://www.england.nhs.uk/national-cost-collection/

NICE (2018) Thopaz+ portable digital system for managing chest drains. Medical technologies guidance [MTG37] Published: 21 March 2018. Available at: Overview | Thopaz+ portable digital system for managing chest drains | Guidance | NICE

Appendix 2. Background documents for this review

Hyperlinks for the background documents for this review report:

1. Medical technologies guidance document
2. Assessment report
3. Scope of assessment
4. A copy of the company information request regarding the technology
5. A list of expert advisers and their completed questionnaires on the MTG review
6. Executable cost model which aligns with the base case described in the MTG documents
7. If there is new evidence which is relevant to any of the clinical parameters in the model, the analyst should send the updated values.
8. Any relevant other documents which are not available on the NICE website.

Appendix C – Details of studies and ongoing trials

New Studies Identified

Study	Population	Intervention/Comparator	Outcomes	Results	EAC Comments
Aldaghlawi (2020) Study Type: Systematic Review Location: Various	Studies evaluating the use of digital drainage devices in adult patients with • air leak after thoracic surgery • air leak after spontaneous pneumothorax	Intervention: Digital drainage devices including Thopaz Comparator: traditional analogue drainage, other digital devices, no comparator	*Post-operative Air Leak* • Chest tube duration • Length of Hospital stay *Air Leak after Spontaneous Pneumothorax* • Chest tube duration • Length of Hospital stay	*Post-operative Air Leak* Mean chest tube duration was ranged from 1.7-5.5 days with a digital system and 1.9-6.1 days with an analogue system Mean length of hospital stay ranged from 3.3 – 6.5 days with a digital system and 3.9-9.0 days with an analogue system *Air Leak after Spontaneous Pneumothorax* Mean chest tube duration was ranged from 47-96 hours with a digital system and 74-94 hours with an analogue system	Mixed study types (comparative and non-comparative) Mixed interventions (different digital systems) No meta-analysis Limited generalisability

Study	Population	Intervention/Comparator	Outcomes	Results	EAC Comments
				Mean length of hospital stay ranged from 3.5 – 5.1 days with a digital system and 4.0-7.0 days with an analogue system	
Alam 2020 Study Type: Randomised Trial Location: India Study Period: December 2016 to December 2018	N=100 patients of empyema thoracis who underwent decortications, primarily children and young people Setting: Respiratory	Intervention: Digital drainage using Thopaz (-20cmH_2O) Removal when patient had radiological and clinical expansion with output of ≤50ml serous fluid and air leak of <50ml/min for 8 consecutive hours. Comparator: water seal chest drainage system without external expansion. Removal when patient had radiological and clinical expansion with output of	• Duration of air leak (days) • Duration of chest tube placement (days) • Pre and post-operative lung function • Postoperative complications	Air leak duration was significantly shorter with Thopaz: 5.34 days vs. 7.16 days Duration of postdecortication chest tube placement was significantly shorter with Thopaz: 7.44 days vs. 10.44 days. Postoperative length of stay was shorter with Thopaz: 10.16 days vs. 14.76 days	Not UK based Population may be out of scope

Study	Population	Intervention/Comparator	Outcomes	Results	EAC Comments
		≤50ml serous fluid and no air leak on coughing.			
Arai 2018 Study Type: Retrospective Case Series Location: Japan Study Period: April 2014 to March 2015	N=540 adult patients undergoing thoracic surgery Setting: Respiratory	Intervention: Thopaz digital drainage system (average intrathoracic pressure set at -8cmH_2O). Chest tube removed when air flow was <20ml/min for 24 hours consecutively. Comparator: Standard 3 bottle drainage system (-15cmH_2O suction after surgery followed by water seal management). Chest tube removed when air bubble could not be recognised.	• Operative blood loss • Operation time • Duration of chest tube placement • Rate of chest tube reinsertion • Rate of re-operation	• No significant difference between the groups for blood loss, duration of chest tube placement, rate of chest tube reinsertion or reoperation. • There were 5 incidences of minor complications in patients treated with the Thopaz system including increased air flow (n=1), marked subcutaneous emphysema (n=1), device malfunction (n=1) and canister displacement (n=2).	Not a randomised study Not UK based
Barozzi 2020 Study Type: Randomised Trial	N=120 adult patients undergoing elective, first-time coronary artery bypass graft and/or valve surgery.	Intervention: Thopaz+ digital drainage system set at -20cmH_2O	• Chest drainage • Chest drain related events	• There was no significant difference in size and number of tubes between the two groups.	Not UK based

Study	Population	Intervention/Comparator	Outcomes	Results	EAC Comments
Location: Italy Study Period: Not reported	Setting: Cardiac	Comparator: Conventional wall suction chest drainage system set at -20cmH_2O	• Device related adverse events • Intra-operative and post-operative events (e.g. excess bleeding, transfusions, pneumothorax, drainage of pleural/pericardial effusions) • User Satisfaction	• There was significantly higher drainage in the Thopaz+ group at the end of operation before transport and on arrival in ICU ($p<0.01$), after which no difference in drainage was reported between the groups. • Mean duration of chest drainage was 29.8 hours with Thopaz+ and 38.4 hours with analogue drains ($p=0.19$). • User satisfaction for Thopaz+ digital drain system was higher when compared to conventional chest drainage system	
De Waele 2017 Study Type: Randomised Trial Location: Canada	N=112 adult patients undergoing lung resection via thoracotomy or VATS for primary or secondary lung malignancies at a tertiary thoracic surgery centre.	Intervention: Thopaz pleural drainage system set to intermittent negative suction to maintain a pleural negative pressure of -20cm H_2O	• Total quantity of pleural drainage • Chest tube duration • Length of hospital stay • 90-day mortality • Post-operative mortality • Rate of re-intervention	• No significant difference in mean volume of total pleural drainage between the groups (analogue 944.0ml vs. Digital 1,001.4ml; $p=0.467$). • Chest tube duration was shorter in the Thopaz arm	Not UK based

Study	Population	Intervention/Comparator	Outcomes	Results	EAC Comments
Study Duration: April 2013 to November 2013	Setting: Respiratory	Comparator: Analogue, underwater pleural drainage system connected to -20cm H_2O of negative pressure wall suction	• 30-day hospital readmission • Pleural inflammatory marker levels	but the difference was not statistically significant (2.3 versus 2.5 days; p=0.055). • Incidence of prolonged post-operative air leak was significantly higher when using the analogue system compared with Thopaz (p=0.025). • No significant difference in length of hospital stay was observed between the groups (4.9 vs. 4.8 days, p=0.403). • Analysis of pleural inflammatory mediators indicated elevated IL-8 (908.12 vs. 575.67pg/ml; p=0.009) and TNF-α (3.1 vs. 1.21 pg/ml, p=0.001) on the first day post-operatively with the use of analogue drainage systems compared to Thopaz. • On post-operative day 2 and 3 there was a significant increase in	

Study	Population	Intervention/Comparator	Outcomes	Results	EAC Comments
				pleural fluid IL-8 in the Thopaz group however while pleural IL-8 levels decreased in the analogue arm in the same period (p=0.034). • Significantly larger amounts of chest tube drainage when compared to VATS (1,201.2 vs. 712.7 ml, p<0.001). • Similarly, lobar resections were associated with greater quantity of postoperative pleural fluid when compared to sub-lobar resections (1,138.2 vs. 613.8 ml, p<0.001) Secondary analysis indicated significant difference in chest tube duration • open vs. VATS resections (2.6 vs. 2.1 days, p=0.001) • lobar versus sub-lobar procedures (2.5 vs. 2.1 days, p=0.001)	

Study	Population	Intervention/Comparator	Outcomes	Results	EAC Comments
Eriguchi 2021 Study Type: Retrospective single centre study Location: Japan Study Duration: January 2018 to March 2020	N=714 adult patients who underwent lung resection with chest tube Setting: Respiratory	Thopaz+. Patients were divided into two groups: • N = air leakage did not exist consistently (n=412). Pressure set to -8 or -10 cmH_2O • A= air leakage existed (n=272). Pressure changed to -1cmH_2O if the air leak flow was >100ml/min fir n=more than 24hours (occurred in 58 cases)	• Operative time • Intraoperative bleeding • Duration of chest drainage • Chest tube re-insertion	Significant differences were observed in baseline characteristics such as age, sex, body mass index, smoking history, the ratio of forced expiratory volume in the first 1 s to the forced expiratory capacity of the lungs, types of lung resection and surgical approach between both groups. Group A had significantly • longer operation time • more intraoperative bleeding • higher intraoperative air leakage Duration of chest drainage was 28,326 hours in group N and 21,227 hours in group A Median chest tube duration was 2 days in group N and 4	Not compared with standard analogue drainage Not UK based Limited applicability to the scope Reporting of outcomes and results not clear

Study	Population	Intervention/Comparator	Outcomes	Results	EAC Comments
				days in group A (p values not reported) Incidence of used pleurodesis substance and atelectasis for air leakage was significantly higher in group A.	
Jacobsen 2019 Study Type: Retrospective correlation study Location: USA Study Duration: January 2014 to December 2017	N=182 adult patients with lung cancer undergoing RATS pulmonary lobectomy, lobectomy with wedge resection or bilobectomy due to incomplete fissure Setting: Respiratory	Intervention: Digital chest drainage system set to -20cmH_2O suction. Presumed to be Thopaz although this is not explicitly stated. Comparator: traditional chest drainage system	• Postoperative chest tube days • Length of hospital stay • Chest tube reinsertion during hospitalisation • 30-day readmission for pneumothorax	• Mean chest tube duration was 2.07 days with the digital system compared with 2.73 days for the traditional system (p=0.003) • Mean length of hospital stay was 4.02 days with digital system compared with 5.06 days with traditional drainage (p=0.01) • Chest tube reinsertions occurred 4 times with digital drainage compared with 1 reinsertion with traditional drainage (p=0.059)	Not a randomised trial Unclear if actually Thopaz although reference made to Thopaz in the paper it is only in relation to the NICE guidance. Lack of detail for both intervention and comparator

Study	Population	Intervention/Comparator	Outcomes	Results	EAC Comments
				• 1 patient in each group was readmitted for pneumothorax	
Lee 2019 Study Type: Retrospective Review Location: Taiwan Study Duration: Not reported	N=497 adult patients receiving chest drainage with a digital system following thoracic surgery Setting: Respiratory	Intervention: Thopaz digital thoracic drainage system under continuous negative pressure of -5 to -20 cmH_2O	Incidence of air leak-related complications after drainage tube removal including: • Subcutaneous emphysema • Pneumothorax Reintervention in patients monitored with digital drainage systems including: • Shift from digital to traditional chest bottles • Reinsertion of chest drainage tubes due to progression of subcutaneous emphysema and/or pneumothorax	• 175 patients had air-leak related complications after drain tube removal including ○ Progressive subcutaneous emphysema (n=109) ○ Pneumothorax (n=81) ○ Both (n=15) Factors associated with air leak complications included male sex, smoking history, previous chest surgery, poor FEV1, multi-port VATS or thoracotomy, lobectomy, larger size of drainage tubes, lower suction pressure (≤-10cmH_2O), presence of initial air leaks, longer duration of chest drainage and, primary lung cancer diagnosis.	Not randomised Non-comparative Not UK based Limited applicability of outcomes to scope

Study	Population	Intervention/Comparator	Outcomes	Results	EAC Comments
				• Of these patients, 25 required re-interventions (23 needed chest drainage tube reinsertion, 1 moved to traditional drainage on post-op day 5 and 1 patient had both) Factors associated with reinterventions included smoking history, lobectomy, lower suction pressure (≤-10cmH_2O), presence of initial air leaks and longer chest drainage	
Lijkendijk 2019 Lijkendijk 2018 Study Type: Prospective, open label randomised trial	N=106 adult patients admitted for standard lobectomy Setting: Respiratory	Low variable suction (-5 cm H_2O) or high variable suction (-20 cm H_2O) on a Thopaz digital drainage device. N=53 in each group	2017 outcomes • Fluid output 2019 outcomes • Air leak • Duration of chest drain • Length of stay (days)	2017 Outcomes • Increased suction resulted in significantly more drainage output on day 1 ($p<0.001$) but the difference was not significant on day 2 ($p=0.08$)	Randomised trial Not UK based Comparison may have limited applicability to the scope as compares low and high suction with digital drainage.

Study	Population	Intervention/Comparator	Outcomes	Results	EAC Comments
Location: Denmark Study Duration: March 2015 to April 2016				2019 Outcomes • Perioperative air leak occurred in 15 patients in the low suction group and 26 patients in the high suction group. • Median chest drain duration was 25 hours [IQR 21-55 hours] in the low suction group and 28 hours [IQR 23-77 hours] in the high suction group (p=0.97). • Median length of hospital stay was 5 days (3-6) in the low suction group and 5 93-7) in the high suction group (=0.75).	
Mitsui 2021 Study Type: Retrospective case series Location: Japan	N=217 adult patients who were monitored with Thopaz digital drainage system after pulmonary resection Setting: Respiratory	3 groups A (n=49), low pressure suction: -5cm H_2O (Oct 2019 to June 2020) B (n=100), intermediate pressure suction: -	• Duration of air leak • Duration of chest tube replacement • Postoperative air leak • Postoperative 1st day air leak • Postoperative 2nd day air leak	Duration of air leak A: 0.57 ± 1.60 B: 0.78 ± 1.65 C: 1.13 ± 1.70 Duration of chest tube replacement A: 2.12 ± 1.78	Not randomised Historical comparators Comparison may have limited applicability to the scope as compares low,

Study	Population	Intervention/Comparator	Outcomes	Results	EAC Comments
Study Duration: December 2017 to June 2020		10cmH_2O (May 2018 to Oct 2019) C (n=68), high pressure suction: -20cmH_2O (Dec 2017 to May 2018)	• Maximum air leaks • Fluid volume	B: 2.17 ± 1.66 C: 2.35 ± 1.67 Postoperative air leak A: 15.71 ± 48.18 B: 6.00 ± 12.87 C: 22.50 ± 78.92 Postoperative 1st day air leak A: 7.76 ± 28.00 B: 3.40 ± 8.31 C: 8.53 ± 16.41 Postoperative 2nd day air leak A: 7.59 ± 23.55 B: 3.12 ± 8.15 C: 8.40 ± 29.51 Maximum air leaks A: 16.94 ± 49.04 B: 7.20 ± 16.09 C: 27.06 ± 81.77 Fluid volume: A: 304.5 ± 356.6 B: 289.7 ± 295.0 C: 289.0 ± 280.1	intermediate and high suction with digital drainage.

Study	Population	Intervention/Comparator	Outcomes	Results	EAC Comments
Mori 2017 Study Type: Prospective Case Series Location: China Study Duration: August 2013 to September 2013	N=25 adult patients who underwent lung resection All patients appear to have had both analogue and digital drainage systems Setting: Respiratory	Intervention: Thopaz digital drainage system Comparator: Analogue water seal chest drainage device Note: The analogue system was used for PAL management with the digital system used for data collection	• Postoperative pleural air leakage (PAL)	• PAL occurred in 5 patients (4 with lung cancer, 1 with spontaneous pneumothorax) • 4 patients who underwent lobectomies and 1 patient who underwent wedge resection had post-op PAL on day 1. • Chest drainage tubes were removed on post-op day 1 in 17 patients with no PAL. 4 patients had tube removed on day 2, 1 on day 3, 1 on day 4 and 1 on day 8. • 1 patient with persistent level 3 PAL underwent a re-operation on post-op day 6. • No patients had a re-operation	Not a randomised study Small sample size Not UK based Unclear whether all patients were managed using both analogue and digital systems at the same time.

Study	Population	Intervention/Comparator	Outcomes	Results	EAC Comments
				• There was a statistically significant positive correlation between the PAL classification (Level 0±4) and actual value using the DCS (ml/min) (R = 0.8477, p < 0.001).	
Perez-Egido 2018 Study Type: Prospective Observational Study Location: Spain Study Duration: June 2015 to September 2017	N=26 paediatric patients undergoing pulmonary resection in whom Thopaz digital drainage system was used Setting: Respiratory	Intervention: Thopaz Chest drain system (n=13) Comparator: water seal chest drain (n=13)	• Chest tube duration • Length of hospital stay • Number of postoperative radiographs • Complications	Results from main text results section: • Median number of days with the chest tube was 2 in the Thopaz group compared with 4 in the analogue group (p<0.05). • Median number of postoperative radiographs was 3 in the Thopaz group vs. 4 in the analogue group (p<0.05). • Median length of hospital stay in the Thopaz group was 4 days versus 7 days in the analogue group (p>0.05).	Unclear why mean values are reported in the abstract and median values are reported in the main text results section.

Study	Population	Intervention/Comparator	Outcomes	Results	EAC Comments
				• No complications related to use of the Thopaz system were reported. Results from abstract: • Mean number of days with chest tube was 1.69±0.6 with Thopaz and 5.38±4 days with conventional drainage ($p<0.05$) • Mean number of post-operative radiographs was 2.8±1.1 with Thopaz and 6.23±5.2 with conventional drainage ($p<0.05$) • Mean duration of hospital stay was 5.69±2.7 days with Thopaz and 7±4.7 days with conventional drainage ($p<0.05$)	
Pfeuty 2020 Study Type: Retrospective Cohort Study	N=100 consecutive adult patients undergoing major pulmonary resection Setting: Respiratory	Intervention: Digital drainage protocol using Thopaz digital drainage system to facilitate early chest tube removal.	• Duration of chest tube • Pleural Complications • Length of stay	• Chest tube was removed on Day 0 in 45 patients • Median length of drainage was 2 days (IQR 1-3) in the remaining 55 patients	Not randomised Non-comparative Outcome may have limited applicability in the sense that all

Study	Population	Intervention/Comparator	Outcomes	Results	EAC Comments
Location: France Study Duration: December 2016 to December 2018		Comparator: patients who could not have chest tube removed on day 0. Note: It is not clear whether the intention was for all patients to have their chest tube removed on day 0 and those who couldn't formed the comparator group or whether there was a pre-assigned comparator group but appears to be the former.		• Reasons for protocol failure included air leak >20ml/min (n=46), haemorrhagic fluid production (n=5) and surgery in third position (n=4). • No significant difference between the two groups in relation to pleural complications such as pneumothorax requiring tube reinsertion, readmission or reoperation due to pleural complications • Length of stay was significantly shorter for patients with tube removal on day 0 compared with day 1+ (median 1 (1-2) vs 2 (1-4) days; p<0.001)	patients were managed using digital drainage and the comparison is between patients who had tubes removed on day 0 or later. It cannot necessarily be ascertained whether early removal of tubes is facilitated by the digital system more effectively than an analogue system.

Study	Population	Intervention/Comparator	Outcomes	Results	EAC Comments
Pompili 2016 Study Type: Prospective observational analysis Location: UK and Italy Study Duration: 12 months (2012-2013)	N=129 patients undergoing pulmonary lobectomy for non-small cell lung cancer Setting: Respiratory	All patients managed post-operatively with Thopaz digital drainage Results compared for patients with and without an air leak	Not clearly stated. Appears to be occurrence/duration of post-operative air leak identification of risk factors for intermittent or recurrent air leak (RAL).	• Air leak was stopped in 95/129 (68%) of patients within 24 hours of operation • 12 patients had at least one recurrence of air leak after the first stop • Patients with a RAL had a lower FEV1 (p=0.04) and lower FEV1/FVC ratio (p=0.06). • The proportion of patients with moderate to severe COPD was higher in patients with RAL (p=0.03) • Air leak recurrence was higher after VATS compared with thoracotomy but not significantly (p=0.11) • Incidence of prolonged air leak was 46% in patients	Not randomised Not comparative Not clear if UK based patients Outcomes and comparisons may have limited applicability to the scope

Study	Population	Intervention/Comparator	Outcomes	Results	EAC Comments
				who had their air leak stopped after the first 24 hours compared with 3% in patients who had their air leak stopped within the first 24 hours (p<0.0001)	
Ruigrok 2021 Study Type: Randomised Controlled Trial Location: The Netherlands Study Duration: October 2012 to September 2017	N=102 patients with spontaneous pneumothorax Setting: Respiratory	Intervention: Thopaz digital drainage (n=52) Comparator: Analogue drainage (n=50) Cross-over to another drainage system was allowed and there were 4 cross-overs from analogue to digital and 1 cross-over from digital to analogue during the study.	• Duration of chest drainage • Hospital length of stay • Clinically relevant pneumothorax	• no significant difference in duration of chest tube drainage (median 3 vs. 2 days; p=0.488) or • hospital length of stay (median 3 vs. 2.5 days; p=0.640). 19 patients underwent surgery due to prolonged air leak (6 in the analogue group and 13 in the digital group (p=0.127)) and after excluding these patients • duration of chest tube drainage (median 1 vs. 3 days; p=0.024) • length of stay (median 1 vs. 3 days p=0.014) were significantly	

Study	Population	Intervention/Comparator	Outcomes	Results	EAC Comments
				shorter in patients in the digital drainage arm compared with analogue drainage. • Three patients in each group had a clinically relevant pneumothorax within 1 week of discharge. • Excluding patients with recurrence within one week, 7 patients in the analogue group and 4 patients in the digital group had a recurrence (clinically relevant pneumothorax within 12 weeks).	
Saha 2020 Study Type: Retrospective Review Location: Germany	N=265 consecutive patients who underwent cardiac surgery Setting: Cardiac	Intervention: Thopaz Digital system (n=200) Comparator: Analogue drainage (n=65)	• Amount of fluid • Length of stay (ICU and hospital) • Complications • User experience	• The amount of fluid collected during the first 6 hours post-operatively was significantly higher with Thopaz+ (250ml vs. 200ml with analogue systems; p=0.043) but the total amount of fluid collected	Not randomised Retrospective

Study	Population	Intervention/Comparator	Outcomes	Results	EAC Comments
Study Duration: June 2017 to October 2017				did not differ between the groups (p=0.741). • Length of stay on ICU (median 2 days for both Thopaz+ and analogue drainage; p=0.107) and total hospital stay (median 14 days for both groups; p=0.714) were similar in both groups. • Clotting of connectors in the tubing system was observed in 13 patients with a digital drainage system (p=0.042). A questionnaire about user experience was completed by 11 doctors and 59 nurses. ICU staff did not report any difference in ease of set-up, connection of tubes, ease of obtaining probes, positioning of CDUs or reading of displays/scales however on the regular wards, the Thopaz+ system was	

Study	Population	Intervention/Comparator	Outcomes	Results	EAC Comments
				significantly more favoured (p<0.001).	
Takamochi 2018 Study Type: Prospective, randomised trial Location: Japan Study Duration: February 2015 to January 2016	N=320 patients undergoing anatomic lung resection Setting; Respiratory	Intervention: Digital chest drain system (Thopaz) Comparator: traditional thoracic drainage system	• Duration of drain placement • Duration of post-operative leak • Frequency of post-operative leak • frequency of postoperative pleurodesis • days of hospitalization • postoperative adverse events	Median duration of chest tube placement was 2 days in the digital group vs 3 days in the traditional group (p=0.149). Incidence of post-operative air leak ≥5 days was 7.4% with Thopaz vs. 7.9% with traditional drainage (p=0.867) Median duration of hospital stay was 6 days with Thopaz vs. 7 days with traditional drainage (p=0.548) Frequency of post-operative adverse events was no significantly different between the groups (p=0.361) Frequency of chest tube clamping trial before removal was significantly lower with	Not UK based

Study	Population	Intervention/Comparator	Outcomes	Results	EAC Comments
				Thopaz (0.7% vs. 35.3%; p<0.001) Incidence of post-operative air leak after surgery was significantly higher with traditional drainage (26.8% vs. 14.8%, p=0.012). In patients with a post-op air leak (n=64), duration of chest tube placement, duration of post-op air leak and duration of hospital stay did not differ significantly.	
Tamura 2021 Study Type: Retrospective comparative study Location: Japan Study Duration: August 2016 to November 2018	N=80 adult patients undergoing cardiac surgery Setting: Cardiac	Intervention: DCS, Thopaz digital drainage system (n=38) Comparator: ACS, Analogue chest drainage (n=42)	• Duration of chest drainage • Rate of drainage related complications • Duration of hospitalisation	• Duration of drainage: ACS vs. DCS = 94.8 ± 31.5 vs. 81.1 ± 20.6 h,p = 0.036 • Duration needed for rehabilitation: ACS vs. DCS = 10.7 ± 1.2 vs. 9.6 ± 1.5 days, p = 0.047 • Duration of hospitalisation: ACS vs. DCS = 22.7 ± 7.9	Not randomised Not UK based Length of hospital stay results are reported different in the main text and tables/abstract.

Study	Population	Intervention/Comparator	Outcomes	Results	EAC Comments
				vs. 19.5 ± 7.2 days, p = 0.041 (reported in abstract and table 3 as: ACS vs. DCS = 21.9 ± 5.3 vs. 18.8 ± 7.2 days, p = 0.031)	
Van Linden 2019 Study Type: Randomised Controlled Trial Location: Germany Study Duration: September 2016 to September 2017	N=340 adult patients undergoing cardiac surgery Setting: Cardiac	Intervention: Thopaz+ digital system (n=152) Comparator: Analogue drainage (n=188)	• number of drains • amount of evacuated fluid • chest tube duration • length of ICU stay and length of hospital stay	• mean number of drains per patients was 2±0.8 • median amount of fluid evacuates was 705ml with analogue drain and 686ml with Thopaz+ (p=0.83). • Total chest tube duration was significantly shorter with Thopaz+ compared with analogue drainage (median 49 hours vs. 65 hours; p≤0.01) • length of ICU stay (median 1 day for both arms) and length of hospital stay (median 9 days for both arms) were not significantly different between the arms.	

Study	Population	Intervention/Comparator	Outcomes	Results	EAC Comments
				• Incidence of chest x-rays with clamped drains to detect air leaks was significantly lower with Thopaz+ compared with analogue drainage (8.6% vs 20.2%; p<0.01).	

Abbreviations

ACS, analogue chest drain dystem; CDU, computer display unit; DCS, digital chest drain system; FEV, forced expiratory volume, FVC, forced vital capacity, ICU, intensive care unit; IQR, interquartile range; PAL, pleural air leak; RAL, recurrent air leak RATS, Robotically assisted thoracoscopic surgery; VATS, Video-assisted thoracoscopic surgery

Ongoing Studies

Title	Population	Intervention and Comparator	Inclusion Criteria	Outcomes	Comment
Trial: JPRN-jRCT1032180388: Ideal regulated pressure level on the digital thoracic drainage system for earlier resolution for postoperative air leak after pulmonary resection: A prospective multicentre randomized trial	Patients with primary lung cancer, metastatic lung tumour, benign lung tumour undergoing pulmonary resection, postoperative air leak, thoracic drainage	Thoracic drainage is performed after pulmonary resection under the setting of pleural pressure at -8cmH2O or -15cmH2O on the Thopaz or the Thopaz plus	Inclusion criteria: Patients who underwent lobectomy or segmentectomy and developed postoperative air leak (100-1000mL/min on Thopaz or Thopaz plus) on POD1 Exclusion criteria: Patients who developed severe subcutaneous emphysema or collapse of the lung on POD1	• Frequency of prolonged air leak • Treatment completion rate • Duration of post-operative leak • Duration of drain placement • Duration of hospitalisation • Frequency of postoperative pleurodesis • Adverse events	Study compares two different pressure setting for the Thopaz drain. Not UK based (Japan) Respiratory Setting
Trial JPRN-UMIN000016715: Prospective Randomized Trial of the Effectiveness of Managing Postoperative Air Leak	Patients with lung cancer	Intervention: Thopaz Comparator: Conventional drainage	Inclusion criteria: Patients who have no history of ipsilateral lung surgery, scheduled to undergo pulmonary resection associated with more	• Duration of drain placement • Occurrence of air leak • Frequency of intraoperative sealant use	Not UK based (Japan) Respiratory setting

Title	Population	Intervention and Comparator	Inclusion Criteria	Outcomes	Comment
between Electronic Versus Traditional Chest Drainage System in Pulmonary Resection			than segmentectomy excluding pneumonectomy	• Occurrence of post-operative air leak • Duration of air leak • Frequency of post-operative pleurodesis • Duration of hospitalisation • Adverse events	
Trial ACTRN12613000931774: A Randomized, one-center, Phase 2 Study to Compare the efficacy of the treatment of patients with spontaneous pneumothorax (SP) with air leak (AL) using digital versus traditional suction drainage systems.	Patients with pneumothorax with air leak	Group A: digital drainage system (DDS) with electronic portable pump that supports a constant negative pressure which can be regulated from -15 cm H2O was applied in the patients. Group B: traditional suction drainage system (TSDS) connected to the wall suction port with a constant negative pressure which can be regulated from -15 cm	Inclusion criteria: Symptomatic Spontaneous Pneumothorax The treatment using chest tube drainage Air leak observed after insertion of the drain into the pleura Exclusion criteria Non-Symptomatic Spontaneous Pneumothorax	• Mean duration of drainage	Not UK based (Poland) Respiratory setting

Title	Population	Intervention and Comparator	Inclusion Criteria	Outcomes	Comment
		H2O was used. AL was subjectively assessed by bubbling in the water-seal column.	Pneumothorax treated conservatively or using simple aspiration. Chest tube drainage without air leak		
Trial ISRCTN46137912: Manual Aspiration Versus Digital drainage system in spontaneous primary pneumothorax: open blinded two parallel group randomised controlled trial	People with spontaneous primary pneumothorax, respiratory, other spontaneous pneumothorax	Intervention: Thopaz Comparator: traditional analogue drainage	Inclusion criteria: Patients with first episode of primary spontaneous pneumothorax	• Pneumothorax resolution • Risk of hospital admission • Relapse of pneumothorax • Resolution after 1 week • Percentage of patients that need surgery • Percentage of smoking cessation	Not UK based (Spain) Respiratory setting
Trial NCT03021369: Comparison of Two Different Pleural Drainage Systems	Adults undergoing cardiac surgery	Intervention: Pleural drainage with Thopaz Comparator: Pleural drainage with analogue	Inclusion Criteria: • adult patients undergoing cardiac surgery • capability to give informed consent	• Detection of air leak • Duration of chest drain • Fluid volume • Pericardial tamponade treated	Not UK based (Germany) Cardiac Setting

Title	Population	Intervention and Comparator	Inclusion Criteria	Outcomes	Comment
				by puncture or surgery • Pleural effusion at discharge echo	
Trial NCT02282462: A Randomized Comparison of Active Suction vs. Passive Chest Tube Drainage and Regulated and Unregulated Pleural Pressure After Anatomic Lung Resection Primary comparator: analogue system Atrium OCEAN	Patients undergoing segmentectomy, lobectomy, or bilobectomy (including sleeve resection). Both open and minimally invasive (thoracoscopic or robotic)	A: Regulated pressure with active suction using Thopaz B: Regulated pressure with passive drainage C: Unregulated pressure with active suction using Thopaz D: Unregulated pressure with passive drainage	Inclusion Criteria: Able and willing to read, understand, and provide written consent Age 18-90 Undergoing a segmentectomy, lobectomy, or bilobectomy (including sleeve resection). Both open and minimally invasive (thoracoscopic or robotic) resections are acceptable	• Duration of air leak • Duration of chest tube • Duration of hospital stay • Fluid Volume	The company confirmed that this study is not continuing.
Trial NCT02002273: Effect of Regulated Pleural Pressure on The Duration of Air Leak and Fluid Drainage Following Pulmonary Anatomic	Patients with lung cancer	A: Regulated suction using Thopaz	Inclusion Criteria: Able and willing to read, understand, and	• Duration of air leak • Differences in airflow detected after pressure levels are switched	Trial registration details state that this study has been withdrawn.

Title	Population	Intervention and Comparator	Inclusion Criteria	Outcomes	Comment
Resections: A Multicenter Randomized Trial Primary comparator: Atrium Express Dry Seal Chest Drain		B: Regulated seal using Thopaz	provide written Informed Consent; Age range of 18-90 years; Patients submitted to lobectomy, segmentectomy and bilobectomy due to lung cancer or other intrathoracic lesions. Both open and minimally invasive (thoracoscopic) resections are acceptable.	• Duration of chest tube • Duration of hospital stay	No participants were recruited.
Trial NCT01776372: Effect of the Use of a Digital Pleural Drainage System on Reducing Pleural Effusion Formation Following Lung Resection	Patients with lung neoplasms or pleural effusions	Intervention: Thopaz thoracic drainage Comparator: Dry seal chest drain	Inclusion Criteria: Participants must be between 18 and 90 years of age Diagnosed with suspected lung cancer or metastatic cancer to the lungs	• Volume of pleural effusion • Duration of chest tube • Duration of hospital stay • Mortality and morbidity • Occurrence of dyspnea	Not UK based (Canada) Respiratory setting

Title	Population	Intervention and Comparator	Inclusion Criteria	Outcomes	Comment
			Surgery must include lung resection (Wedge; single or multiple, lobectomy or bi-lobectomy) and mediastinal lymph nodes sampling or dissection Demonstrate an ability for understanding the study procedures Demonstrate willingness to remain on-study for the complete duration Must be able to give informed consent to participate at this study.	• Clinically significant reintervention • Readmission	
Trial NCT01566032: Digital Versus Analog Pleural Drainage in Patients With Pulmonary Air Leak (DiVA)	Patients experiencing pulmonary air leak following pulmonary resection	Intervention: digital drainage using Thopaz	Inclusion Criteria: 18 years of age or over Male and Female.	Inter-rater variability of air leak measurements	Trial registration details note that this study was terminated as interim analysis showed the test

Title	Population	Intervention and Comparator	Inclusion Criteria	Outcomes	Comment
		Comparator: Analogue drainage	Air leak occurring after any pulmonary resection Air leak persisting on or after the first post-op day of pleural drainage Air leak not entirely secondary to poor air seal at the pleural drainage incision site Pulmonary resection for benign or neoplastic diagnosis		protocol did not improve treatment.

Appendix D – Literature search strategy

Conducted by NICE gIS who amended the original EAC assessment report searches.

Database:
Database: Ovid MEDLINE(R) <1946 to July 28, 2021> Search Strategy: --- 1 ((digital* or electronic* or portab*) adj5 (chest adj3 drain*)).tw. (44) 2 ((digital* or electronic* or portab*) adj5 CDU*).tw. (13) 3 (((digital* or electronic* or portab*) adj5 (air leak* or suction* or drain*)) and (lung* or pleural or thora*)).tw. (97) 4 Drainage/is, mt (16070) 5 exp Thorax/ (37942) 6 4 and 5 (218) 7 thopaz*.af. (9) 8 Drainage/is, mt and ((chest or thora*) and (digital* or electronic* or portab*)).tw. (78) 9 1 or 2 or 3 or 6 or 7 or 8 (355) 10 animals/ not humans/ (4833033) 11 9 not 10 (347) 12 limit 11 to english language (283) 13 limit 12 to ed=20170601-20210729 (72) Database: Ovid MEDLINE(R) In-Process & In-Data-Review Citations <1946 to July 28, 2021> Search Strategy: --- 1 ((digital* or electronic* or portab*) adj5 (chest adj3 drain*)).tw. (2) 2 ((digital* or electronic* or portab*) adj5 CDU*).tw. (0) 3 (((digital* or electronic* or portab*) adj5 (air leak* or suction* or drain*)) and (lung* or pleural or thora*)).tw. (2) 4 Drainage/is, mt (0) 5 exp Thorax/ (0) 6 4 and 5 (0) 7 thopaz*.af. (1) 8 Drainage/is, mt and ((chest or thora*) and (digital* or electronic* or portab*)).tw. (0) 9 1 or 2 or 3 or 6 or 7 or 8 (2) 10 animals/ not humans/ (0) 11 9 not 10 (2) 12 limit 11 to english language (2) Database: Ovid MEDLINE(R) Epub Ahead of Print <July 28, 2021> Search Strategy: --- 1 ((digital* or electronic* or portab*) adj5 (chest adj3 drain*)).tw. (2) 2 ((digital* or electronic* or portab*) adj5 CDU*).tw. (1)

3 (((digital* or electronic* or portab*) adj5 (air leak* or suction* or drain*)) and (lung* or pleural or thora*)).tw. (3)
4 Drainage/is, mt (0)
5 exp Thorax/ (0)
6 4 and 5 (0)
7 thopaz*.af. (0)
8 Drainage/is, mt and ((chest or thora*) and (digital* or electronic* or portab*)).tw. (0)
9 1 or 2 or 3 or 6 or 7 or 8 (4)
10 animals/ not humans/ (0)
11 9 not 10 (4)
12 limit 11 to english language (3)

Database: Embase <1974 to 2021 July 28>
Search Strategy:
---
1 ((digital* or electronic* or portab*) adj5 (chest adj3 drain*)).tw. (109)
2 ((digital* or electronic* or portab*) adj5 CDU*).tw. (28)
3 (((digital* or electronic* or portab*) adj5 (air leak* or suction* or drain*)) and (lung* or pleural or thora*)).tw. (243)
4 thorax drainage/ (9946)
5 devices/ (107426)
6 4 and 5 (54)
7 thopaz*.af. (105)
8 Medela*.dm. (71)
9 thorax drainage/ and (digital* or electronic* or portab*).tw. (234)
10 1 or 2 or 3 or 6 or 7 or 8 or 9 (532)
11 nonhuman/ not human/ (4829194)
12 10 not 11 (527)
13 limit 12 to english language (499)
14 limit 13 to dc=20170601-20210729 (182)
15 limit 14 to (conference abstract or conference paper or "conference review") (43)
16 14 not 15 (139)

Database: Econlit <1886 to July 22, 2021>
Search Strategy:
---
1 ((digital* or electronic* or portab*) adj5 (chest adj3 drain*)).tw. (1)
2 ((digital* or electronic* or portab*) adj5 CDU*).tw. (0)
3 (((digital* or electronic* or portab*) adj5 (air leak* or suction* or drain*)) and (lung* or pleural or thora*)).tw. (0)
4 [Drainage/is, mt] (0)
5 [exp Thorax/] (0)
6 4 and 5 (0)
7 thopaz*.af. (1)
8 [Drainage/is, mt and ((chest or thora*) and (digital* or electronic* or portab*)).tw.] (0)
9 1 or 2 or 3 or 6 or 7 or 8 (1)

Cochrane Library

#1 ((digital* or electronic* or portab*) near/5 (chest near/3 drain*)):ti,ab,kw 41
#2 ((digital* or electronic* or portab*) near/5 CDU*):ti,ab,kw 4
#3 (((digital* or electronic* or portab*) near/5 (air leak* or suction* or drain*)) and (lung* or pleural or thora*)):ti,ab,kw 93
#4 MeSH descriptor: [Drainage] this term only and with qualifier(s): [instrumentation - IS, methods - MT] 812
#5 MeSH descriptor: [Thorax] explode all trees 562
#6 #4 and #5 11
#7 thopaz* 21
#8 (chest or thora*):ti,ab,kw and (digital* or electronic* or portab*):ti,ab,kw 1301
#9 #4 and #8 11
#10 #1 or #2 or #3 or #6 or #7 or #9 115
#11 "conference":pt or (clinicaltrials or trialsearch):so 553775
#12 #10 not #11 with Publication Year from 2017 to 2021, with Cochrane Library publication date Between Jun 2017 and Jul 2021, in Trials 23

CRD

1	(((digital* or electronic* or portab*) near5 (chest near3 drain*)))	0
2	(((digital* or electronic* or portab*) near5 CDU*))	0
3	((((digital* or electronic* or portab*) near5 (air leak* or suction* or drain*)) and (lung* or pleural or thora*)))	2
4	MeSH DESCRIPTOR drainage WITH QUALIFIERS IS, MT	90
5	MeSH DESCRIPTOR thorax EXPLODE ALL TREES	48
6	#4 AND #5	0
7	(thopaz*)	0
8	((chest or thora*) and (digital* or electronic* or portab*))	186
9	#4 AND #8	2
10	(#1 OR #2 OR #6 OR #7 OR #9) FROM 2017 TO 2021	0

INAHTA

thopaz* 0
(digital* or electronic* or portab*) and (chest and drain*) 0
(digital* or electronic* or portab*) and CDU* 0

(digital* or electronic* or portab*) and (air leak* or suction* or drain*) and (lung* or pleural or thora*) 0 "Thorax"[mhe] and "Drainage"[mh] 0 "Drainage"[mh] and (chest or thora*) and (digital* or electronic* or portab*) 0

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