The pleural manometry device has been designed as a simple but effective means of removing excess fluid from the chest whilst providing the attending clinician with key fluid pressure readings from within the patient's pleural space.

Rocket Medical is a family business based in the North East with a head office function in London. The main product focus area is cardio-thoracic devices with additional specialisms in in-vitro fertilisation, interventional radiology and obstetric/gynaecology products. The NHS is Rocket's main customer but around 35% of the company's turnover is from export sales.

Pleural effusion is a common condition. It is quite often experienced with malignancy, with lung and breast cancer accounting for 50-65% of these effusions.

Patients often present with dyspnoea caused by an effusion and undergo a thoracentesis for symptomatic relief. Current guidelines recommend that only up to 1 litre of fluid can be removed from the lung at any one time, and there are risks of Re-expansion Pulmonary Oedema.

The monitoring of the pleural pressure may also indicate that the patient has entrapped lung and therefore may have some sort of malignancy involvement.

The Case for Change

Current guidelines recommend only 1 litre of fluid can be removed from the chest at any one time or 1.5 litres over 24 hours. This due to the life-threatening risk of Re-expansion Pulmonary Oedema. Pulmonary oedema is an excess accumulation of fluid in the tissues and air spaces of the lungs due to an increase in pressure, or damage, in the blood vessels. This often occurs with heart failure and can restrict gaseous exchange to potentially life threatening levels.

Currently there is no way to establish if the patient has a trapped lung or reoccurrence of pleural effusion. By monitoring the pressure within the pleural space research has shown that so long as the pressure remains above -20cmH2O, the lung can be fully drained in one drainage session rather than multiple 1 litre sessions.

Maintaining the pressure above -20cm H2O prevents the occurrence of Re-expansion Pulmonary Oedema. In addition, pressure dropping below this level can also indicate a trapped lung and the patient could experience a reoccurrence of their pleural effusion which may indicate the involvement of a malignancy.

Overview of Innovation

The pleural manometry device will measure changes of pressure within the pleural space in real time, with a graph of pressure versus time and a series of alarms to warn of low pressures.

The monitoring information available from the device may indicate if a different choice of long term treatment may be required, such as the insertion of an indwelling pleural catheter. In addition, if a trapped lung is experienced this may be an indication of malignant involvement.

Pleural manometry pressure display unit
The pressure information provided by the device can also, therefore, be used as a diagnostic tool to inform the best course of treatment for the patient. The pressure reading information can be downloaded from the unit for inclusion in the patient’s notes.

**Progress to Date**

Activities undertaken to develop the device include the following:

- Implementation of the Social Accountability Standard which is a pre-requisite for entry onto the NHS Supply Chain Framework agreement;
- Design, prototyping and software development;
- Design verification and integration;
- Documentation and electromagnetic compatibility (EMC) testing;
- IP protection – patent application.

In addition to the support received from NHS Innovations North the company has committed around £90K of internal resources to this project.

Support has been secured for research at the Queen Elizabeth University Hospital, Glasgow - see next steps and plans for the future for more information about how this funding is being used.

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**Impact**

The removal of all pleural fluid in one session is likely to contribute towards improved outcomes, with implications for clinical time saved.

If the device can predict a trapped lung, it means interventions, such as insertion of an Indwelling Pleural Catheter, can be carried out in a more timely manner, rather than the patient having to wait to see if the effusion will return before having more intervention.

The device, with other measurements, may contribute towards early identification of malignancy and the need for a biopsy.

However, at this time it is too early to say what the full health economic impact could be.

It is anticipated that this product will:

- comprise 8% of company sales within 2 years including significant export sales (to the US in particular), and
- create 2-4 permanent jobs in the North East.

**Next Steps and Plans for the Future**

Research will be performed at the Queen Elizabeth University Hospital, Glasgow to investigate Pleural Elastance as a Predictor of Trapped Lung in Patients with Suspected Pleural Malignancy.

After the device has been proven in the UK it will be released to EU, US, Canadian and Australian markets.

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**Pleural manometry catheter**

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