

ANNEX A

REGULATION 28: REPORT TO PREVENT FUTURE DEATHS (1)

	<p>REGULATION 28 REPORT TO PREVENT FUTURE DEATHS</p> <p>THIS REPORT IS BEING SENT TO:</p> <ol style="list-style-type: none">1. Philips Respironics2. The Rt Hon Sajid Javid MP, Secretary of State for Health and Social Care3. Mid Yorkshire Hospitals NHS Trust
1	<p>CORONER</p> <p>I am Kevin McLoughlin, Senior Coroner for the Coroner area of West Yorkshire (East).</p>
2	<p>CORONER'S LEGAL POWERS</p> <p>I make this report under paragraph 7, Schedule 5, of the Coroners and Justice Act 2009 and regulations 28 and 29 of the Coroners (Investigations) Regulations 2013.</p>
3	<p>INVESTIGATION and INQUEST</p> <p>On 22 February 2021 I commenced an investigation into the death of Mary Land, aged 76. The investigation concluded at the end of the Inquest on 27 September 2021. The conclusion of the Inquest was a narrative conclusion that Mrs Land died from:</p> <ol style="list-style-type: none">1a Respiratory Failure2 Obesity hypoventilation, atrial fibrillation, ischaemic heart disease <p>on 5 February 2021, after the tubes connecting her BIPAP ventilator became detached from her facemask.</p>
4	<p>CIRCUMSTANCES OF THE DEATH</p> <p>On 5 February 2021, Mary Land, aged 76, was a patient on an Acute Respiratory care unit 'surge' ward at Pinderfields Hospital, Wakefield. She was being treated for covid pneumonia against a background of comorbidities, including COPD. At 5am that morning, she was discovered in an unresponsive condition, with the tube connecting her facemask to a BIPAP ventilator detached at the connection point to the mask. The Inquest was unable to conclude, on the balance of probability, whether this malfunction contributed to her death, but it remains a possibility, and has the potential to do so in other cases unless a design solution is found.</p>
5	<p><u>CORONER'S CONCERNS</u></p> <p>During the course of the Inquest the evidence revealed matters giving rise to concern. In my opinion there is a risk that future deaths will occur unless action is taken. In the circumstances it is my statutory duty to report to you.</p> <p>The MATTER OF CONCERN is as follows. –</p> <p>The Philips Respironics AF 541 mask connects to the tubing, linking it to the BIPAP ventilator by means of a 'push on' connection (rather than a fitting involving positive engagement). Evidence taken at the Inquest indicates this connection has come undone on other occasions as well. The introduction of a filter at the site of this union increases the potential for the joint to come apart. Consideration should be given to installing a more robust docking mechanism which is less vulnerable to working loose, or being inadvertently pulled apart, for example, by a patient suffering from delirium.</p>

6	<p>ACTION SHOULD BE TAKEN</p> <p>In my opinion action should be taken to prevent future deaths and I believe you or your organisation have the power to take such action.</p>
7	<p>YOUR RESPONSE</p> <p>You are under a duty to respond to this report within 56 days of the date of this report, namely by Monday 22nd November 2021. I, the Coroner, may extend the period.</p> <p>Your response must contain details of action taken or proposed to be taken, setting out the timetable for action. Otherwise you must explain why no action is proposed.</p>
8	<p>COPIES and PUBLICATION</p> <p>I have sent a copy of my report to the Chief Coroner and to the following Interested Persons:</p> <p>The family of Mary Land, deceased.</p> <p>I have also sent this report to the Medicines and Healthcare Products Regulatory Agency.</p> <p>I am also under a duty to send the Chief Coroner a copy of your response.</p> <p>The Chief Coroner may publish either or both in a complete or redacted or summary form. He may send a copy of this report to any person who he believes may find it useful or of interest.</p> <p>You may make representations to me, the coroner, at the time of your response, about the release or the publication of your response by the Chief Coroner.</p>
9	<p>29th September 2021</p> <p><i>Kerri McLaughlin</i> Senior Coroner.</p>