PHILIPS

Kevin McLoughlin
Senior Coroner, West Yorkshire (Eastern)
Coroner's Office and Court
71 Northgate
Wakefield, WF1 3BS

November 22, 2021

[redacted]

Dear Sir,

RESPONSE TO REGULATION 28 REPORT
Listed below is the concern described in the Regulation 28 report reference above, followed by the Philips response.

Concern: 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. The MATTER OF CONCERN is as follows. 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.

Philips Respironics response:
The AF541 mask elbow design is a 22mm non-latching conical connection compliant with ISO 5356-1. This design is not intended to prevent accidental disconnection. The AF541 mask is contraindicated for use with patients requiring life support ventilation.

During this incident, it is alleged that the AF541 mask was in use with a Trilogy EVO ventilator. The Trilogy EVO Clinical Manual states, "To prevent patient or ventilator contamination, you must use a Philips Respironics-approved main flow bacterial filter on the patient gas outlet port." An Intersurgical clear guard filter (part number unknown) is reported to have been fitted between the AF541 mask elbow and the tubing. This configuration is not approved by the manufacturer. The Intersurgical clear guard filter is not approved by Philips, and Philips is unable to verify the safety or performance of a device using an unapproved filter in an altered configuration.

The AF541 mask in use was not retained due to COVID-19 contamination. The manufacturer received the ventilator's event logs. On the day of the event, 5 February 2021, the below alarms occurred between 03:14:44 and 04:26:24.

Alarm	Duration
Low Inlet Oxygen Pressure	114 seconds
Circuit Disconnect	45 seconds
Low Inlet Oxygen Pressure	2 seconds
Circuit Disconnect	45 seconds
Low Inlet Oxygen Pressure	27 seconds
Circuit Disconnect	37 seconds
Low Inlet Oxygen Pressure	14 seconds
Circuit Disconnect	853 seconds
Circuit Disconnect	820 seconds

The last two circuit disconnect alarms logged were not acknowledged for a total of more than 27 minutes. Shortly after 5:00:00, the ventilator was turned off. Based on the information reviewed by the manufacturer – specifically the greater than 30 minutes of active alarming of the device, hospital verification that the circuit disconnect alarm sounded, incorrect connection of an inline filter, and use of an unapproved inline filter, Philips Respironics concludes that the AF541 mask and Trilogy EVO ventilator operated as designed. The facility apparently failed to follow the manufacturer's instructions and did not respond appropriately to ventilator alarms. In addition, the mask at issue meets the applicable standard for mask to circuit connection. Therefore, no action for the design of the AF541 22mm non-latching conical connection is proposed.

Notwithstanding the Coroner's duty to share a copy of this response with the Chief Coroner, Philips requests prior notification for the further release or publication of this response in a complete or redacted or summary form.

Philips wishes to formally record that it was not requested to provide evidence to the Coroner prior to, or at, the inquest in respect of the functionality or use of the AF541 mask or Trilogy EVO ventilator – either generally, or specifically in relation to their use on the patient at Pinderfields Hospital. Such evidence would have been provided as set out above which, we assert, may have provided the opportunity for clarification of the matter of concern during the inquest.

Best regards,

[redacted]

Quality System Manager, Post Market Surveillance
Philips Respironics - Sleep and Respiratory Care

[redacted]