Medicines & Healthcare products Regulatory Agency

MHRA

Coroner ME Hassell
Senior Coroner
Inner North London
St Pancras Coroner's Court
Camley Street
London N1C 4PP

17 September 2021

Medicines & Healthcare products Regulatory Agency

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

+44 (0) 20 3080 6000

gov.uk/mhra

Dear Ms Hassell

Reference Mr Chimezie DANIELS

I write with reference to your Regulation 28 letter following the inquest into the sad death of Mr Chimezie Daniels. You requested that we take action to prevent similar events of this kind occurring in the future.

I have taken the opportunity to provide supporting information below before providing a response to your matters of concern.

Introduction and regulation of medical devices in the UK

The Medicines and Healthcare products Regulatory Agency (MHRA) is an executive agency of the Department of Health and Social Care and is responsible for the regulation of medical devices, blood components for transfusion and medicinal products in the UK.

The aim of the MHRA Devices Division is to take all reasonable steps to protect the public's health and safeguard the interests of patients, public and users. We ensure manufacturers of medical devices comply with the UK Medical Devices Regulations 2002 to show they meet appropriate standards of safety, quality, and performance for as long as a device is in use. Where possible, we work with a range of stakeholders including patients and the public to work towards the promotion of safer medical devices and their safe use.

Manufacturers must demonstrate compliance with the Regulations before a medical device can be UKCA or CE marked and placed on the UK market. Although not mandatory, device manufacturers can use designated standards to demonstrate that they are compliant with relevant requirements of the Regulations.

One major area of the MHRA's responsibilities is to collect, analyse, monitor, and act on information relating to safety concerns from a range of data sources including reports of adverse incidents. An adverse incident is an event involving a medical device, which produces, or has the potential to produce, unwanted effects involving the safety of patients, users, and other persons. These effects may arise from shortcomings in the device, its operating instructions, user practice or conditions of

use. Adverse incidents may also occur due to patient factors, as not all interventions are suitable for all patients and their condition may change over time, requiring a different approach.

Patient safety is our highest priority and we encourage everyone to report safety concerns to MHRA through our Yellow Card scheme. However, it is mandatory for manufacturers of medical devices to report certain incidents to MHRA.

In general, where an adverse incident occurs the manufacturer of a medical device is responsible for carrying out any investigation required and informing MHRA of their findings. We review their findings and actions and will advise on whether additional action is required. Where necessary we will issue safety messages to health and care organisations, patients, and the public. These types of actions help to reduce the risk of similar incidents happening again.

Incident summary

The MHRA was informed of the death of Mr Daniels on 26 July 2021 by your Regulation 28 report. We had not previously been notified of the adverse event by the manufacturer, healthcare professionals or any other parties involved.

From the details within your report, Mr Daniels was receiving CPAP therapy when there was a 20-25 minute interruption to the oxygen supply to the CPAP device. Although the device alarmed, there was some delay in identifying and resolving the cause of the alarm.

The situation was exacerbated by a number of factors. There were four other alarms sounding simultaneously for four other patients in the bay where Mr Daniels was being nursed, all of which were alarming with the same type of alarm. In addition, the pressure on beds during the pandemic had resulted in patients being treated in medical wards.

Additional information from the minutes of the NHS Homerton University Hospital Board of Directors Meeting, 28 July 2021 (published by the Trust on their website) indicates that initially the breathing mask was placed on Mr Daniels' face without the oxygen connection having been plugged into the wall. Although the alarm sounded to alert clinicians to the situation, clinicians were wearing full PPE, the environment was loud, and the alarms on the CPAP devices in the ward had been "standardised", so until they looked at the machine it was not possible to identify the reason for the alarm. The clinicians did attempt to reconnect the oxygen tubing but unfortunately did not make a secure connection.

MHRA were advised on 09 August 2021 by [redacted], Head of Legal Services at Homerton University Hospital that the device in question was a Trilogy 202 ventilator manufactured by Philips Respironics. This model is a ventilator for use within a facility which is capable of delivering ventilation in a variety of different modes, one of which is CPAP.

Matters of Concern:
You have expressed as a matter of concern that the alarms on the device implicated were the same regardless of the severity of the alarm scenario (alarm for small leak from mask no different to total cessation of oxygen supply), and this is the case for the wider range of CPAP devices used the UK.

We have considered your request as one to cover ventilators as a whole rather, than limited to models which only provide a CPAP function. To provide a full response to this request, we contacted Philips Respironics on 10 August 2021 and asked them to investigate, provide clarification on the reported problem and report their findings back to us. We also asked for a summary of the alarms on the Trilogy 202 for all alarm scenarios, how each one sounds, and what message is displayed when they are activated.

Investigation by Philips Respironics

On 19 August 2021, Philips Respironics provided MHRA with their findings.

The device was not returned to Philips Respironics for examination, but a copy of the device log was received from [redacted] and passed to Philips Respironics for review. To investigate, Philips Respironics requested additional information from the healthcare professionals involved.

According to the report from Philips Respironics, Mr Daniels "had been temporarily been taken off the Trilogy 202 device to be fed. When reconnected, the staff forgot to connect the O2 hose to the wall outlet. The machine did alarm that insufficient O2 was been delivered to the patient but the staff took no note, thinking that the hose had been properly connected."

Philips Respironics state that the device alarmed as designed for insufficient oxygen flow and low oxygen inlet pressure. This would include an audible alarm, a warning light and an alarm message showing a description of the alarm condition. No faults were identified with the way the device performed.

Alarms on the Trilogy 202

Philips Respironics state in the clinical manual provided with the Trilogy 202 that when an alarm condition occurs:
• The alarm LED indicator on the Alarm Indicator/Audio Pause button lights
• The audible alarm sounds
• A message appears on the screen describing the type of alarm
• The remote alarm (if applicable) is activated.

They have confirmed that there are three levels of alarm on the Trilogy 202. These are:

High Priority	Requires immediate response by the operator. The Alarm Indicator/Audio Pause button flashes red. A series of beeps sound in the following pattern, which is repeated twice: 3 beeps, a pause, and then 2 more beeps. This indicator continues until the cause of the alarm is corrected or the audible alarm is paused. The alarm pattern is • • • • • • • • • • An alarm message is displayed showing a description of the alarm condition highlighted in red.
Medium Priority	Requires prompt response by the operator. The Alarm Indicator/Audio Pause button flashes yellow. A series of beeps sound in a 3-beep pattern. This pattern repeats until the cause of the alarm is corrected or the audible alarm is paused. The alarm pattern is • • • An alarm message is displayed showing a description of the alarm condition highlighted in yellow.
Low Priority	Requires operator awareness. A solid yellow light appears on the Alarm Indicator/Audio Pause button. A series of beeps sound in a 2-beep pattern. This pattern repeats until the cause of the alarm is corrected or the audible alarm is paused. The alarm pattern is • • An alarm message is displayed showing a description of the alarm condition highlighted in yellow.

If an alarm is manually reset by the user, the Alarms and Messages screen is removed and the Monitoring Screen is re-displayed. If the alarm self-cancels, the Alarms and Messages screen remains displayed, but the highlight for the active alarm is removed, the LED is unlit, and the audible alarm stops.

According to the device log provided by [redacted], over the period in question (09.11-09.38) the device alarmed for 'low oxygen inlet pressure' (alarm activated 4 separate times), 'low oxygen flow' (alarm activated 3 separate times), 'apnea' (alarm activated 4 separate times), and 'circuit disconnect' (alarm activated once). The alarm reset button was pressed but the alarm condition remained and the alarms were re-activated by the device.

The following relevant alarms are taken from the clinician's manual for the Trilogy 202:

"Low Oxygen Inlet Pressure
This is a high priority alarm. It occurs when the oxygen source inlet pressure measures less than 40 psi. This could be caused by the oxygen source being disconnected from the device, an occlusion in the tubing from the oxygen source to the device, or a problem with the oxygen source supply system."

"Low Oxygen Flow
This is a high priority alarm. It occurs when the concentration of oxygen from the device is 10% below the FiO2 set point for more than 30 seconds. This could be caused by the oxygen source being disconnected from the device, an occlusion in the tubing from the oxygen source to the device, or a problem with the output of the oxygen source."

"Apnea Alarm
This is a high priority alarm. It occurs when the patient has not triggered a breath within the time specified in the apnea alarm setting. The device continues to operate. The alarm will automatically terminate when two consecutive patient breaths are detected that meet the apnea alarm time setting."

"Circuit Disconnect Alarm
This is a high priority alarm. It occurs when the breathing circuit is disconnected or has a large leak. The device continues to operate. The alarm will automatically terminate when the circuit is reconnected or the leak is fixed."

The MHRA have asked Philips to comment specifically on the concerns raised around the alarms which activate when a face mask is removed being of the same priority level as the alarm for low oxygen inlet pressure. Philips have confirmed this is by design; their rationale is the situation when one of these alarms becomes active "would constitute a possible loss of therapy to the patient and should be addressed by the clinician with the utmost importance."

Philips have confirmed there are a number of alarms which can be set by the user, as well as some which are always on. The 'always-on' alarms which would activate if a patient removed their mask are: Check Circuit Alarm, Low Inspiratory Pressure Alarm, and Low Expiratory Pressure Alarm.

There are however also a number of user settable alarms which would also sound if set by the clinician if a patient removed their mask (Circuit Disconnect Alarm, Apnea Alarm, Low Vte Alarm, Low Vti Alarm, and Low Minute Ventilation Alarm). To avoid excessive alarms, it is possible for the clinician to deactivate these in specific ventilation modes. Information on how to do this is provided by Philips in their clinical manual. However, it should be noted that deactivating alarms has the potential to introduce additional risk as clinicians will not be notified of changes in the patient's condition.

Philips have confirmed that the volume of the alarms can be changed by the clinician from loud (92dB) to soft (47 dB). However, they have no evidence to indicate this was done on the device in use at the time of the event.

In light of this unfortunate event, Philips have offered additional support and training to the site involved to increase confidence in the correct setup and use of these devices.

Review of other incidents

This model was first CE marked to be placed on the market in the UK in November 2010. Around 88,000 have been sold worldwide in the past 3 years alone.

Information supplied by Philips Respironics states they are aware of 11 reports worldwide of events involving alarms which were not acknowledged or addressed during the last 3 years. Of these, 8 involved alarms which were not acknowledged by the caregiver, one concerned a device which alarmed but was not acted upon as the family were on another floor, one involved a patient who went into cardiac arrest before the caregiver acknowledged the alarm, and one involved a patient who desaturated before the caregiver acknowledged the alarm. None of these occurred in the UK and none involved failure of the device.

A search of the MHRA database of reported adverse incidents and corrective actions relating to all types of ventilators over the past 5 years has not identified any similar reports where an inability to identify the device fault from the audible alarm tone has been reported.

We are not currently aware of any significant information from other data sources to suggest a wider safety concern.

Actions taken by the MHRA in response to the Matters of Concern

1. We reviewed the designated standard available relating to alarms on medical equipment, 'EN 60601-1-8:2007+A11:2017 Medical electrical equipment, Part 1-8: General requirements for basic safety and essential performance — Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems'. This standard provides guidance to medical device manufacturers on requirements for alarm systems, including how the alarms should sound to allow users to prioritise action by level of risk involved. Philips have confirmed that they used the international (ISO) version of this standard during the design of their product. The text is the same in both standards.

2. Alarm systems on medical electrical equipment have been designed in this internationally recognised format across devices for a number of years, with user training and usability taken into account. It has been developed with contributions from clinicians, engineers, and applied psychologists. Devices designed in line with the standard are considered state of the art in this respect.

3. Following a review of all available information, a change in design of all audible alarm severity levels would likely introduce new risks and/or increase the risk of confusion on prioritisation. Use of the designated standard in the design of alarm systems is an acceptable method of minimising the risk associated with alarm conditions. User training and manufacturer guidance in the instructions for use are used to mitigate residual risks.

4. We are engaging with the Association of Respiratory Nurse Specialists to explore how the current training programme addresses the issue of audible alarm prioritisation, and whether there may be more actions for the health care system to take to mitigate the risk. We are also engaging with the Royal College of Anaesthetists and Association of Anaesthetists for their input into how this issue can be addressed.

5. The MHRA has also requested information from NHS Improvement's database of patient safety incidents in England; the Learn from Patient Safety Events Service (LPSE)

https://www.england.nhs.uk/patient-safety/patient-safety-incident-management-system, to identify whether they are aware of any pattern in similar reported events. We expect a response shortly.

This information will inform whether any further action is required.

Conclusion

The audible alarm system in the Philips Trilogy 202 device is based on an internationally recognised and well-established standard. There is currently no evidence to indicate a wider safety concern. Therefore, based on the information currently available to us, MHRA do not intend to take further action beyond that detailed above. However, we will review our position should evidence obtained during our ongoing engagement with stakeholders and monitoring of safety concerns suggest that further action is required.

Yours sincerely

Dr [redacted]
Chief Safety Officer, MHRA

[redacted]
[redacted]