From the Lord Prior of Brampton
Parliamentary Under Secretary of State for NHS Productivity (Lords)

Department of Health

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[redacted]

Ms Angela Hodes, Assistant Coroner
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04 MAY 2016

Dear Ms Hodes,

Thank you for your letter of 17 March 2016, following the inquest into the death of Jacqueline Scott. I was sorry to hear of her death and wish to extend my condolences to her family.

You raise four main concerns in this case regarding:

- the BIPAP Trilogy 202 machine and it's visual display symbols and alert alarms;
- staff training on use of the BIPAP machine;
- the provision of electrical power to the ward; and
- notification to and response from the hospital's estates management concerning a failed emergency call bell

Many of these issues need to be addressed by Phillips Healthcare and the NHS Foundation Trust. However, I do acknowledge your concerns about the design of the BiPAP machine and the safe provision of power supply which I will address.

My officials contacted colleagues at NHS England who have advised that the design of some non-invasive ventilation (NIV) systems and other critical devices could be improved by having safety features which warn staff of delivery problems, such as disconnection and power failure. NHS England has a close working relationship with the Medicines and Healthcare Regulatory Agency (MHRA) and is able to share such concerns with them. Their collective power to improve the design of medical devices is often limited however, as manufacturers are not required to make changes to a product if it

meets the relevant regulatory requirements (the Trilogy 202 ventilator is CE marked to show compliance with the Medical Devices Directive). In order to impose manufacturers to make such improvements would require a change to the UK and EU requirements.

NHS England has been able to raise awareness of unintentional interruption of this type of therapy however, and on 13 February 2015, it issued a Patient Safety Alert concerning the risk of severe harm and death from unintentional interruption of non-invasive ventilation. This publication was a joint effort with the Medicines and Healthcare Regulatory Agency (MHRA) and served as a reminder of the correct procedures and the importance of familiarity with the ventilators and disposables used.

A copy of the alert can be found at:

https://www.england.nhs.uk/2015/02/psa-niv/psa-niv/

MHRA was made aware of the events outlined in your letter in April 2015 and submitted a report to the coroner which confirmed the manufacturer had examined the device and found no faults.

The Phillips model of ventilator has features to alert users to the status of the power supply. There is an LED that lights up on the unit when on mains power, and icons on the display to show whether the device is currently drawing from mains or battery power. There are also multiple visual and audible alarms to alert users to the depletion of battery power. On inspection by the manufacturer, the alarms were seen and heard to function correctly. The device log showed that on the day of the event, the ventilator had alarmed as expected to alert users to the depleting battery power.

MHRA has conducted a search of its adverse incident database which has not revealed any similar reported incidents (involving the ventilator being used on battery power until it fully depleted) for this model of ventilator. Philips has reported that it is aware of one similar event reported to them in 2011, which occurred in the USA. This involved a device which "was being used on DC power and an AC source was unavailable when the batteries depleted", but MHRA is not aware of the detailed circumstances.

MHRA has confirmed that this model of ventilator was first placed on the UK market in July 2010. At the time of its report to the coroner, the manufacturer had advised that a total of 501 Trilogy 202 ventilators have been sold in the UK, with a further 1,582 sold in the

rest of Europe and 5,799 in the rest of the world. Given the number of ventilators of this model that have been sold, the available evidence indicates that battery power depletion with no corrective action taken by the user is not currently a widespread problem with this model of ventilator.

I am aware that Phillips Electronics has already provided you with a detailed response to your Regulation 28 letter and has concluded that no changes to the design of the Device, including the alarm system, visual and audible alerts, and the instructions for use are required to prevent future deaths. However, MHRA is planning to ask Philips Electronics to consider the visibility of alarms and battery icons in terms of usability in the next design review as part of their ongoing post market surveillance.

With regard to issues around the provision of power to the ward, you quote from our Department's Hospital Technical Memoranda (HTM) 06-01and consider that there is a conflict of advice in Part A between clauses 4.22 and 6.62.

HTM 06-01 ***Electrical services supply and distribution - Part A: design considerations***, provides best practice guidance and should be read in conjunction with the Institution of Engineering and Technology (IET) Wiring Regulations, British Standard 7671. The HTM sets out the application of BS7671 in the specific, unique context of healthcare.

Moreover, the text at paragraph 4.22 relating to *Category 4 – Patients in special medical locations* should be read in a holistic manner in conjunction with the guidance provided within other sections of the HTM and BS7671. If this task is undertaken, there is no conflict of advice between 4.22 and 6.62 of the HTM.

By way of illustration, the HTM contains the following guidance which it is imperative to follow:

2.6 It is recommended that designers and stakeholders review Chapter 4 as well as Chapter 6 for all projects.

4.17 While it is not intended to be absolute, this section should be sufficient to prompt the necessary discussion at all stages of the design process. The categories given are intended to demonstrate a range of patient risk from an electrical fault or loss of electrical supply
4.18 Consideration of the categories in Figure 6 should establish a minimum acceptable risk option at the point of treatment or care. For the purpose of this guidance, the patient levels described are not intended to be exhaustive, but rather an aid to consider the issues.

The definition relating to Medical Location (Chapter 1) (*location intended for the purpose of diagnostic treatment (including cosmetic) or monitoring a patient under medical supervision),* identifies those locations where discontinuity of the electrical supply can cause danger to life.

- *Group 0 Medical locations where no applied parts are intended to be used.*
- *Group 1 Medical locations where discontinuity of the electrical supply is not a risk to human life (unless the location is part of a Group 2 location).*
- *Group 2 Medical locations where discontinuity of the electrical supply can cause danger to life.*

Should a patient's life be endangered by a discontinuity of supply, then a Group 2 definition may be required to be applied to the Category 4 patient clinical risk.

The HTM contains the following guidance with respect to Group 2 areas:

16.37 IEC 60364-7-710 and BS 7671 require Group 2 areas to have at least two separate socket-outlet sub circuits at each patient treatment location (for example bedhead or theatre pendant). This applies to Group 1 areas also. This can be achieved from a single IPS unit with an integral single-phase distribution board. The resilience would be further enhanced if the IPS had dual 100%-rated isolation transformers serving different integral distribution boards. Such arrangements would provide an N+1 resilient IPS isolation transformer as defined in paragraphs 6.8–6.14.

The HTM also provides guidance on the provision of audible and visual alarms in relation to interruptions to power supply failures and the need to provide indication at the nurse's station for the relevant medical area.

Department of Health

For the reasons set out above, the Department does not consider that there is a conflict of advice in the HTM. However, the concerns you raise are noted and the relevant sections of the HTM will be considered and reviewed, as part of the wider technical guidance programme, to determine if there is a need for greater clarity. Similarly, the issue of alerts will be considered, although the HTM is considered to provide adequate guidance on this issue.

I hope that this reply is helpful and I am grateful to you for bringing the circumstances of Mrs Scott's death to my attention.

Yours sincerely

DAVID PRIOR