

THE INQUEST TOUCHING THE DEATH OF PATRICK NEIL WOODS

Ref: 39895-2016

RESPONSE TO REGULATION 28

REPORTS TO PREVENT FUTURE DEATHS

1. This document is filed on behalf of Draeger Medical UK Limited (“Draeger”), pursuant to regulation 29 of the Coroners (Investigations) Regulations 2013, in response to the reports dated 19 June 2017 served by Acting H.M. Senior Coroner for Bedfordshire and Luton following the inquest touching the death of Patrick Neil Woods.
2. The concerns expressed by the HM Coroner are:
 - a. The evidence of some clinicians at the Inquest would suggest that the training was not effective;
 - b. There is a risk that busy clinicians:
 - i. Do not identify that the Tiro is a machine that they have not been trained on;
 - ii. Do not identify that the Tiro is any different to other machines that they have been trained on;
 - iii. Forget the relevance of the COSY switch;
 - iv. Are not alert, in the absence of sufficient emphasis on the same, to the risk of delivering a hypoxic mix;
 - v. Are not aware, in the absence of a reminder/alert, that the Tiro is not functioning how the clinicians think it should be functioning.

3. Whilst the concerns are expressed in two separate documents, they are inter-related, since the desired result of addressing the concerns is that, in the future, all clinicians using a workstation such as the Tiro will know how to select the correct fresh gas path for the intended ventilation mode. Draeger therefore responds to both PFD reports within this one document.
4. Draeger recognises as a crucial priority the importance of optimising patient safety through optimising clinician competence regards the functionality of the machine. With those objectives in mind, Draeger has decided to take the following steps:
 - a. The updating of its training documentation, which has already taken place, including:
 - i. The Basic Skills Checklist, which is and has been used in basic user training, and which the trainer and user must both specifically sign when completed. In addition to listing the skill for the selection of the external ACGO outlet, the Checklist now includes the demonstration of the correct/incorrect procedure for switching between external ACGO and manual/controlled ventilation, paying attention to monitored parameters and gas flow direction.
 - ii. The Workbook, which is and has been provided for self-guided use to be completed by the user, although a Draeger trainer can be on hand to offer advice. Pages 30-32 test the awareness of how the machine can operate and include several boxes with yellow triangle warnings, which refer to the selection of the correct circuit and appropriate routing of the fresh gas, as well as the context for measurement of O₂, pressure and volume.
 - iii. The Quick Guide, which is and has been given to users who have training on the devices. Page 8 shows the operation of

- the ACGO switch and now includes a box with a yellow triangle warning, which refers to the risk of a hypoxic gas mixture;
- iv. The Practical Exercises, which have been intended for the user to do as part of the training package, now include five questions (out of a total of 23) intended to concentrate on the functionality of COSY and ACGO ventilation modes.
 - v. The powerpoint presentation which had been intended for use by trainers now includes four slides devoted to the use of the COSY switch and the relevant ventilation modes.
 - vi. The Training Needs Analysis includes reference specifically to "*Ventilation Modes*" and "*Operation of Auxiliary Common Gas Outlet.*"
- b. The circulation worldwide of a Field Safety Notice ("FSN") to hospitals for circulation amongst their anaesthetic departments drawing attention to the principles applicable to re-breathing circuit systems. Draeger will also send a copy of the FSN to electrical and biomedical engineering (EBME) bodies within each hospital within the UK to whom the FSN is sent. Draeger anticipates that the distribution of the FSN will begin from October 2017. Draeger will follow up the circulation of its FSN within the UK by seeking confirmation of receipt.
- c. Having identified from its database all customers within the UK to whom a Fabius machine has been supplied, Draeger will take steps to contact all such customers for the purposes of arranging a site visit from Draeger representatives within a 16 week period after the FSN to address any concerns raised and discuss any further training needs.

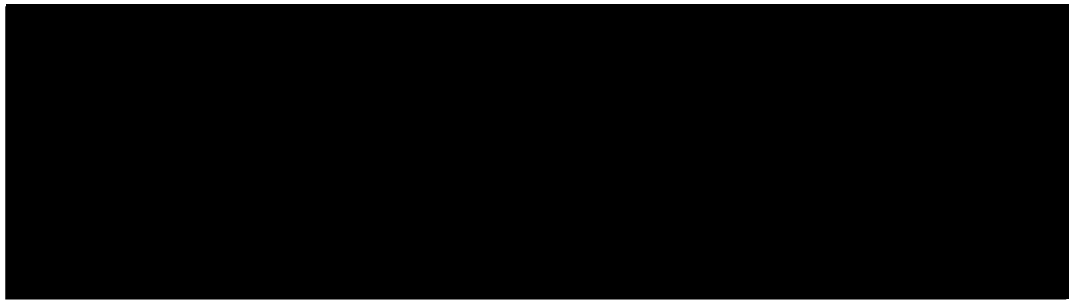
5. In further pursuit of achieving the objectives identified above, Draeger intends also to take the following steps:

a. Making a training video specifically to address use of the ACGO switch, for use in both introductory basic training and in refresher training sessions.

b. Continuous review of performance data and of all feedback from hospital and individual user information;

c. Regular review at Competence Board level of such information; and

d.



6. Draeger would respectfully ask HM Coroner and HM Chief Coroner not to publish paragraph 5(d) above and / or to redact paragraph 5(d) above when publishing this document. The particular design, technical and commercial considerations are, it is submitted, confidential.

DAC Beachcroft LLP
Solicitors for Draeger
29 September 2017