

Appendix 2

Details of 7 excluded datasets from 5 patients.

Below are further details of the 5 patients with 7 datasets excluded from the study. Patients are presented in a random order and were from either participating centre.

Patient A – Protocol deviation due to patient improvement during the study, therefore no longer fitted the inclusion criteria. The patient was found to not require supplemental oxygen after measurements started. None of this patient data was included in the analysis.

Patient B1 – Protocol deviation and incomplete dataset due to insufficient memory available in the device that ended the recording at 12h20min into the 1st arm of the study and did not record any data for the 2nd arm of the study. No written records from either patient charts or CRFs noted any issues with device performance when not recording the data. None of this patient data was included in the analysis.

Patient B2 – Repeated study in patient B1. Protocol deviation due to less than 12 FiO₂ adjustments in the manual arm. None of this patient data was included in analysis

Patient C1 and C2 (episode occurred twice in same patient) – Protocol deviation due to equipment failure (heater element) of the Precision Flow unit. This happened twice on two different Precision Flow units. None of this patient's data for either attempt was included in the analysis.

Patient D – Protocol deviation due to user setup-error causing data recording/collection failure. The auto arm did not record due to adjustment of year/date/time after the study recording started. The study was repeated with this patient and a complete dataset was included. None of the 1st (incomplete) dataset was included in subsequent analyses.

Patient E – Protocol deviation with an incomplete dataset. The patient was removed from the study at the attending Consultant discretion and placed on bilevel CPAP for respiratory support. This was not felt to be related to the study. None of this patient data was included in the analysis.

Details of incomplete data / data issues included in study for analysis

Patient F – Protocol deviation. The manual arm completed 23h40min of data. This was noted on the Case Report Form (CRF) as human error recording the start time of 2nd arm. This patient data was included in the analysis.

Patient G – Protocol deviation. The manual arm was ended 18h25min47sec into the study arm. Auto arm completed 24-hours. This patient data was included in the analysis.

Patient H – Protocol deviation due to target saturation being set to 94% instead of 93% - noticed quickly. The study was subsequently restarted and completed with correct target saturation value. This patient data was included in the analysis.

Patient I – Protocol deviation. The Precision Flow unit had equipment failure – noted on CRF as “blank screen.” Within 10-20sec it was noted that the patient was switched to their original Precision Flow unit. Manual arm completed 24-hours. Auto arm completed 23h05min of data. This patient data was included in the analysis.

Patient J – Protocol deviation. SpO₂ connector cable was faulty. The patient was placed on manual control for 21 minutes and the SpO₂ cable was replaced & functioned again. This patient data was included in the analysis.

Patient K – Protocol deviation. The manual arm completed 23h10min of data. Auto arm completed 24-hours. This patient data was included in the analysis.

