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Title: Performance assessment of a novel medical device for home monitoring of CPAP treatment in patients with obstructive sleep apnoea syndrome

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Body: Background: Home monitoring of Continuous Positive Airway Pressure (CPAP) is key to ensure on the long term patient compliance and normalisation of the apnoea-hypopnoea index (AHI). Those parameters are currently collected from CPAP devices but measured parameters differ and their algorithms may score differently respiratory events. The novel AL539 device allows remote control of treatment duration and of residual AHI in patients with obstructive sleep apnoea syndrome (OSAS), whatever the CPAP used. Objectives: To assess AL539 performance by comparing with respiratory polygraphy (Embletta GOLD®). Methods: OSAS patients requiring an in-lab control respiratory polygraphy with their usual CPAP and interface were included (82% males, mean age 61 yrs, BMI ranging 23-41 Kg/m^2). Descriptive analyses on 14 patients are presented. Results: Recordings were performed with 6 different CPAPs and nasal mask, face mask or nasal pillow. Minimum duration of the recordings was 6.75 hours. Overnight difference in CPAP treatment duration was of 2.4 minutes (95% confidence interval -0.2 to 5.1) between AL539 and the polygraph. Polygraphic AHI was 6.4±3.4/hr and mean difference with AHI estimated by AL539 was 2.5/hr (95% confidence interval 1.4 to 3.6). Conclusions: AL539 allows a precise measurement of CPAP treatment duration. As expected by the difference in the methods used to score respiratory events, AHI estimated by AL539 slightly differs from medical interpretation of polygraphic data. Interest of AL539 is homogeneity of the data collected and its compatibility with most of the currently available CPAPs, including those without internal monitoring systems.