Appendix 1

Information about the PRICO algorithm

The PRICO algorithm of the Fabian® ventilator is a rule-based control scheme with proportionintegral-derivative characteristics that uses both the current SpO₂ and the trend in the SpO₂ measurement as input. The SpO₂ target range is set by the caregiver. A FiO₂-adjustment takes place every 30s. The adjustment is based on the current SpO₂ and its position in one of the four SpO₂ regions: above target range, below target range, in upper half of target range or in lower half of target range. When the SpO₂ is outside the SpO₂ target range, the size of the FiO₂ adjustment (0.01-0.1) is determined by current SpO₂, trend of SpO₂ data and an extrapolation of SpO₂ data to limit over- and undershoot. When the SpO₂ is in the lower half of the target range, no adjustment in FiO₂ takes place. When SpO₂ is in upper half of the target range, FiO₂ is decreased by 0.01. A number of safety checks are performed before an automated FiO2 adjustment takes place: reliable connections between all devices and an assessment of the correctness of all measured parameters. FiO₂ limits are set by the staff to define a range wherein the algorithm can operate. If these FiO₂ limits are reached PRICO will alarm and will not increase or decrease outside the predefined range. If the algorithm gets no signal or is disconnected, it will alarm and FiO₂ returns to a pre-set (backup) level. The algorithm uses input from a separate Masimo pulse oximeter, therefore a second pulse oximeter is attached to the patient.

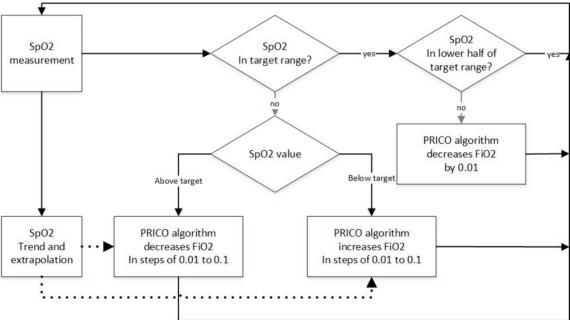


Figure: Scheme of PRICO algorithm: The algorithm uses both current SpO₂ and trend in SpO₂ measurements in order to adjust FiO₂. An adjustment is made which is based on the current SpO₂ and its position in one of the four SpO₂ regions: above target range, below target range, in upper half of target range or in lower half of target range. When the SpO₂ is outside the SpO₂ target range, the FiO₂ adjustment (0.01-0.1) is determined by current SpO₂, trend of SpO₂ data and an extrapolation of SpO₂ data. When the SpO₂ is in the lower half of the target range, no adjustment in FiO₂ takes place. When SpO₂ is in upper half of the target range, FiO₂ is decreased by 0.01.