dioxide is monitored in the patient's airway between the cuff and the vocal cords. Based on the monitoring, the inflation of the cuff is adjusted so as to prevent the leakage of carbon dioxide past the cuff. The inflation of the cuff is adjusted to provide a minimum inflation pressure, which prevents leakage of carbon dioxide past the cuff.

Additional prior arts of relevance include U.S. Pat. Nos. 3,504,676, 3,794,036, 4,305,392, 4,770,170, 4,825,862, 5,067,497, 5,579,762, 5,582,166, 5,582,167, 5,752,921, 5,819,723, 5,937,861 and 6,062,223.

The present invention provides solutions to the problems associated with prior art endotracheal intubation techniques.

SUMMARY ~~OF THE INVENTION~~

The background art does not teach the optimization of endotracheal tube cuff filling by measuring a measure indicative of secretion leakage past the cuff to the lungs and comparing the indicative measure with an optimal level of the measure. The background art does not teach the optimal value of carbon dioxide concentration nor does it teach any measure other than carbon dioxide concentration. Furthermore, the background art does not teach the use of additives to identify formation of leakage duct near the cuff for the purpose of cuff adjustment.

The present ~~invention~~disclosure provides a method and system which can be efficiently used in intubation procedures in which an endotracheal tube is introduced into the tracheal airway and a cuff is inflated within the airway below the vocal cords.

In various exemplary embodiments of the ~~invention~~disclosure the method and system of the present ~~invention~~disclosure perform measurement of one or more measures being indicative of secretion leakage past the cuff, compare the measure(s) to one or more optimal values of the measure(s) and adjust cuff filling based on the comparison. The measure(s) according to preferred embodiments of the present ~~invention~~disclosure can be carbon dioxide concentration, a proxy measure from which such concentration can be inferred, or the level of one or more additives delivered to a subject during intubation so as to identify formation of leakage duct near the cuff.

When one or more additives are delivered to the subject, they can be delivered either to the lungs, through the main lumen of the endotracheal tube (*e.g.*, by mixing the breathing gas with the additive), or to a location above the cuff between the

internal wall of the subject's airway and the external wall of the endotracheal tube. The level of the additive is monitored at a monitoring location which is selected according to the delivery technique. For example, when the delivery is through the main lumen of the endotracheal tube, the monitoring location can be above the cuff between the internal wall of the subject's airway and the external wall of the endotracheal tube; and when the delivery is to a location above the cuff between the airway and the endotracheal tube, the monitoring location can be below the cuff or within the main lumen of the endotracheal tube.

Thus, according to one ~~aspect~~embodiment of the present ~~invention~~disclosure there is provided a method of intubating a subject having a tracheal airway ending with lungs. The method comprises: inserting an endotracheal tube into the airway; inflating a cuff associated with the endotracheal tube within the airway below the vocal cords; measuring a level of at least one measure being indicative of leakage of secretion past the cuff to the lungs; comparing the level of the measure(s) with an optimal level of the measure(s); and adjusting inflation of the cuff based on the comparison so as to generally minimize leakage of secretion from above the cuff to the lungs, while minimizing pressure associated damages to the airway.

According to further features in preferred embodiments of the ~~invention~~disclosure described below, the measure is other than carbon dioxide concentration between the cuff and the vocal cords

According to still further features in the described preferred embodiments the method further comprises performing at least one measurement of ambient carbon dioxide partial pressure, and utilizing the ambient carbon dioxide partial pressure for setting the value of the optimal level.

According to still further features in the described preferred embodiments the measurement of ambient carbon dioxide partial pressure is performed continuously, so as to provide a series of real-time values of the ambient carbon dioxide partial pressure.

According to still further features in the described preferred embodiments the ambient carbon dioxide partial pressure is used as a reference partial pressure, whereby the optimal level corresponds to a carbon dioxide partial pressure being larger than the reference partial pressure by about 4 mm Hg.

According to still further features in the described preferred embodiments the optimal level corresponds to a partial carbon dioxide pressure of from about 0.32 mm Hg to about 4 mm Hg.

According to another ~~aspect~~embodiment of the present ~~invention~~disclosure there is provided a method of intubating a subject having an airway ending with lungs and vocal cords. The method comprises: inserting an endotracheal tube into the airway; inflating a cuff associated with the endotracheal tube within the airway below the vocal cords; delivering a breathing gas and at least one identifiable additive through the endotracheal tube; monitoring a level of the at least one identifiable additive at a monitoring location in the body of the subject; and adjusting inflation of the cuff based on the monitoring so as to generally minimize leakage of secretion from above the cuff to the lungs, while minimizing pressure associated damages to the airway.

According to further features in preferred embodiments of the ~~invention~~disclosure described below, the method further comprises signaling when a level of the at least one identifiable additive exceeds an optimal level of the at least one identifiable additive.

According to still further features in the described preferred embodiments the monitoring location is at a nostril of the subject, oropharynx, above the cuff between the endotracheal tube and walls of the airway and/or below the cuff and adjacent thereto.

According to still further features in the described preferred embodiments the method further comprises suctioning secretions at a suctioning location in the airway above the cuff.

According to still further features in the described preferred embodiments the insertion of the endotracheal tube comprises inserting at least one of a measuring conduit and a suctioning conduit.

According to still further features in the described preferred embodiments adjustment of the cuff inflation is performed manually.

According to still further features in the described preferred embodiments adjustment of the cuff inflation is performed automatically.

According to yet another ~~aspect~~embodiment of the present ~~invention~~disclosure there is provided a system for intubating a subject having an airway ending with lungs, comprising: an endotracheal tube, adapted to be inserted into the airway and being associated with a

cuff capable of being inflated below the vocal cords; and a measuring device for measuring at least one measure being indicative of leakage of secretion from above the cuff to the lungs.

According to further features in preferred embodiments of the ~~invention~~disclosure described below, the measuring device is designed and configured to signal when a level of the at least one measure exceeds the optimal level.

According to still further features in the described preferred embodiments the system further comprises the optimal level is a predetermined optimal level.

According to still further features in the described preferred embodiments the measuring device is designed and configured to signal when a level of the measure(s) exceeds an optimal level corresponding to a partial carbon dioxide pressure of from about 0.32 mm Hg to about 4 mm Hg.

According to still further features in the described preferred embodiments the measuring device is designed an configured to perform at least one measurement of ambient carbon dioxide partial pressure, whereby the ambient carbon dioxide partial pressure is utilized for setting the value of the optimal level.

According to ~~an additional~~one aspect of the present ~~invention~~disclosure there is provided a system for intubating a subject having an airway ending with lungs, ~~The system~~ comprise~~s~~ing: an endotracheal tube, adapted to be inserted into the airway and being associated with a cuff capable of being inflated below the vocal cords; an additive delivering unit operatively associated with ~~the~~said endotracheal tube and configured to deliver at least one identifiable additive through ~~the~~said endotracheal tube; and a measuring device for measuring a level of ~~the~~said at least one identifiable additive.

According to further features in preferred embodiments of the ~~invention~~disclosure described below, the measuring device is designed and configured to signal when a level of the at least one identifiable additive exceeds an optimal level of the at least one identifiable additive.

According to still further features in the described preferred embodiments the endotracheal tube comprises an additive delivery conduit configured to deliver the at least one identifiable additive.

According to still further features in the described preferred embodiments the additive delivery conduit is disposed within a lumen of the endotracheal tube.

selected from the group consisting of a technetium radioisotope, a xenon radioisotope and a krypton radioisotope.

The present ~~invention~~disclosure successfully addresses the shortcomings of the presently known configurations by providing a system and method for performing endotracheal intubation and optimizing endotracheal tube cuff filling.

Unless otherwise defined, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this ~~invention~~disclosure belongs. Although methods and materials similar or equivalent to those described herein can be used in the practice or testing of the present ~~invention~~disclosure, suitable methods and materials are described below. In case of conflict, the patent specification, including definitions, will control. In addition, the materials, methods, and examples are illustrative only and not intended to be limiting.

Implementation of the method and system of the present ~~invention~~disclosure involves performing or completing selected tasks or steps manually, automatically, or a combination thereof. Moreover, according to actual instrumentation and equipment of preferred embodiments of the method and system of the present ~~invention~~disclosure, several selected steps could be implemented by hardware or by software on any operating system of any firmware or a combination thereof. For example, as hardware, selected steps of the ~~invention~~disclosure could be implemented as a chip or a circuit. As software, selected steps of the ~~invention~~disclosure could be implemented as a plurality of software instructions being executed by a computer using any suitable operating system. In any case, selected steps of the method and system of the ~~invention~~disclosure could be described as being performed by a data processor, such as a computing platform for executing a plurality of instructions.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention is herein described, by way of example only, with reference to the accompanying drawings. With specific reference now to the drawings in detail, it is stressed that the particulars shown are by way of example and for purposes of illustrative discussion of the preferred embodiments of the present invention only, and are presented in the cause of providing what is believed to be the most useful and readily understood description of the principles and conceptual aspects of the invention. In this regard, no attempt is made to show structural details of the invention