

Letter to the Editor

ADAPTIVE SUPPORT VENTILATION IS A PATENTED VENTILATORY MODE

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Tehrani FT, Roum JH. Adaptive support ventilation is a patented ventilatory mode.

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Dear Editor

This is in reply to a Letter to the editor by Drs. Josef X. Brunner and Giorgio A. Iotti that was recently published on line [1]. In their letter, they contest several comparisons we made between a patented ventilatory mode known as adaptive support ventilation (ASV), and a new computerized system for ventilation, FLEX, which incorporates the features of ASV mode in addition to many other features for improvement of oxygenation and weaning [2]. Furthermore, in their letter, they provide an erroneous and misleading outline of how ASV was invented, commercialized, and later licensed under a patent covering the technology.

ASV is a closed-loop ventilatory mode in which tidal volume and respiratory rate of a patient on mechanical ventilation are automatically adjusted based on patient's requirements. The ASV algorithm uses respiratory mechanics data to compute the optimum frequency and tidal volume of patient's breaths to minimize the work rate of respiration [3]. The rationale is to provide a natural respiration pattern to the patient and thereby reduce the work load of breathing on the respiratory muscles and stimulate spontaneous breathing. The principles of operation of this mode as provided by the manufacturer of the technology can be found in the operating manuals and product literature for ASV by Hamilton Medical [4, 5].

This technology was invented by Dr. Fleur Tehrani, a university professor in the US, in 1980s. She developed her algorithm to minimize the work rate of respiration for the reasons mentioned above, and used a modified version of a physiological equation derived in 1950 [6] to calculate the optimum frequency of mechanical ventilation. She built a prototype of her invention in late 1980s and obtained a patent on the technology that was issued in January 1991 [7]. A brief look at ASV features shows that this commercial mode is described as one of the embodiments of Dr. Tehrani's patent. In fact, not only does her patent embody the ASV technology, but the ASV and her patent algorithms use the exact same equations as a mainstay to calculate optimal rate and depth of breathing.

Shortly after Dr. Tehrani's patent was issued in 1991, Dr. Josef Brunner, who was Director of Scientific Research at Hamilton Medical at that time, wrote to Dr. Tehrani and expressed interest in learning more about her invention that he referred to as "fascinating work" in his written communications to her. Dr. Brunner flew to California in May 1992 to meet with Dr. Tehrani for

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several days regarding her patented technology. He asked her numerous questions about her invention while going through the patent document virtually line by line, and Dr. Tehrani answered his questions in detail. Then Dr. Brunner returned to Switzerland, and after not communicating for several months, he eventually wrote to Dr. Tehrani and informed her that his company was not ready to manufacture the technology. Copies of correspondence between Drs. Brunner and Tehrani are included in the third volume of an appendix filed with the United States Court of Appeals for the Federal Circuit, Case # 00-CV-428 that was filed in later years in the course of a patent litigation on ASV as will be described briefly below [8].

In 1994, however, Dr. Brunner and several coauthors published an article describing the results of evaluation of a system called adaptive lung ventilation or ALV [9]. The technique evaluated in that article was based on the same principles that were described in Dr. Tehrani's patent [7, 10]. Despite that, they did not credit Dr. Tehrani and made no references to her patented invention or publications linked to it. At this point, Dr. Tehrani could not do anything to defend her patent rights unless a commercial product embodying her invention was marketed in the US. This indeed eventually happened, when in 1997, Hamilton Medical (spear-headed by Dr. Brunner) started marketing a variation of ALV that was called ASV in the US without obtaining a license on her patent. Dr. Tehrani had to take legal action against this practice and filed a complaint on May 4, 2000 [11]. This case represented such a clear act of infringement to the district court of California that the court ruled in favor of Dr. Tehrani on patent infringement on July 5, 2001, based on a motion for summary judgment; which is not a usual practice in patent cases. Shortly afterwards, a jury panel decided in the court that the patent infringement by US based Hamilton Medical Inc., was willful, and subsequently the district court determined the case as exceptional and awarded Dr. Tehrani enhanced damages and attorneys' fees. Hamilton Medical appealed the district court's rulings and the appeal court in June 2003 determined that patent infringement should not have been summarily decided by the judge and needed to be retried. Therefore, the case was sent back to the district court for trial. Hamilton Medical then filed more claims and motions that were defeated in the court for about another year. Eventually, on the eve of the second jury trial, Hamilton Medical decided to settle the case and licensed Dr. Tehrani's patent in 2004 [12]. Although the terms of the settlement agreement are confidential, but Hamilton Medical that had undergone several years of litigation under the leadership of Dr. Brunner, had to accept the terms of the agreement and license the ASV mode under

Dr. Tehrani's patent that originally described the technology.

Drs. Brunner and Iotti also make several comparisons between FLEX and ASV. The following is our response to those comments.

They criticize FLEX for being "lacking" compared to ASV because FLEX is designed for a wide range of ventilatory modes, and state that ASV is a pressure-controlled SIMV mode. Clearly because FLEX is designed to be more flexible than ASV, it cannot be criticized to be "lacking" in comparison.

They go on to claim that FLEX is lacking compared to ASV because it pushes for weaning by reducing the level of controlled ventilation in the weaning phase and ASV does not. Indeed FLEX does push for weaning but this is done at the discretion of clinician and only when it carefully analyses the patient's conditions and finds them favorable for weaning. This does not mean that FLEX is "lacking" compared to ASV. Rather, as stated by Drs. Tehrani and Roum in their article FLEX "incorporates the features of the patented ventilatory mode known as Adaptive-Support Ventilation (ASV) along with other features for control of weaning, and patient's oxygenation" [2].

Drs. Brunner and Iotti further criticize FLEX for requiring airway resistance and dynamic compliance. First, there is no reason why airway resistance should not reflect added expiratory resistance as they contend, and second, dynamic compliance is measured and used by ASV [3–5], as well as FLEX, and it is quite appropriate to use this data in equation 1 by FLEX [2].

They further claim that FLEX requires calculation of the expected peak pressure (P_{peak}) as input. This is incorrect. FLEX takes the measured value of P_{peak} as input if it is available, but the FLEX algorithm calculates the required P_{peak} by dividing computed tidal volume by dynamic compliance and adding the result by positive end-expiratory pressure (PEEP) in equation 12 [2]. As stated in [2], " P_{peak} is then compared to a minimum pressure which is $PEEP + 5 \text{ cmH}_2\text{O}$ and a maximum value which is $8 \text{ cmH}_2\text{O}$ below the maximum pressure alarm limit set on the ventilator. If P_{peak} is not in the safe range, its value is adjusted." In ASV, P_{peak} is also calculated from tidal volume, dynamic compliance, and PEEP, and adjusted to remain in the safe range [3–5]. Therefore, despite what Drs. Brunner and Iotti claim, FLEX incorporates the features of ASV and augments those by automatic adjustment of fraction of inspired oxygen F_{IO_2} [13, 14], PEEP, and control of weaning as correctly stated by Drs. Tehrani and Roum in their article [2].

In summary, ASV is based on a previously patented technology developed by Dr. Tehrani. Drs. Brunner and Iotti present an incorrect, incomplete, and misleading

account of the development of this technique, which we correct by reference to public domain documentation. Indeed neither in their letter, nor during the above-mentioned litigation, was there any evidence presented that could prove ASV was invented by anyone other than Dr. Tehrani. The fact is that ASV is a patented technology which has been marketed by Hamilton Medical under license of Dr. Tehrani's US Patent No. 4,986,268. FLEX, as mentioned above and in our article, is based on ASV, and, as its name implies, has features which provide enhanced flexibility to computerized mechanical ventilation.

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