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Al at the bedside: First ever Extubation Decision Support Product Approved in Canada

Canadian medical technology company Therapeutic Monitoring Systems Inc. (TMS) announces Health Canada approval of their first clinical decision support tool - *Extubation Advisor (EA)*, a Class III Medical Device, via its commercial software manufacturing partner OBS Medical Ltd.

What is innovative about Extubation Advisor? EA is a Canadian global triple-first innovation. (1) It is world's first tool to provide doctors with extubation decision support, helping them to safely liberate critically ill patients from a breathing machine. (2) EA is the first clinical decision support tool using patient's own monitored data to generate artificial intelligence (AI) predictive modelling, implemented at the bedside. (3) EA is the first medical tool that utilizes innovative analysis of breathing rhythms (i.e., respiratory rate variability analysis) to generate predictive models. With these clinical, technological and physiological advances, TMS aims to improve care, save lives and reduce health care costs for critically ill adult patients requiring mechanical ventilation.

What problem does Extubation Advisor help? EA is a clinical decision support software tool that addresses an international critical care challenge: when to safely remove the airway tube from recovering ventilated patients. This is a high-stakes decision, as prolonged ventilation is harmful and costly; and yet in addition, if patients fail extubation requiring emergency re-intubation, it is profoundly harmful, increasing their chance of dying, lengthening their hospital time and recovery, all costing hospitals approximately \$50,000 CDN each time it occurs. Currently, doctors make the decision regarding extubation based on their considerable training, skills, experience, and judgment. With variability-based AI prediction along with standardized assessment and individualized risk mitigation, EA can assist critical care physicians to better determine timing and safety of liberating patients from mechanical ventilation.

How can Extubation Advisor help Canadian healthcare? In a health economic modelling study published in the *International Journal of Technology Assessment in Healthcare* (2022), the return-on-investment analysis revealed the following: "A large center seeing 2,500 intubated ICU patients per year could save US\$532,295 or C\$723,124/year/percent reduction in failed extubation." By reducing extubation failure by several percent, EA has the potential to help hospitals avoid millions of critical care costs per year.

Who is TMS? Therapeutic Monitoring Systems (TMS) is a Canadian medical technology company that develops innovative critical care technology utilizing the combined value of bedside waveform collection, variability analysis and AI predictive modeling, all embedded into clinical decision software support tools. These tools are intended to be utilized by care providers at the bedside to assist them in making the best possible decisions about vital transitions in care. EA and other TMS products are supported by issued patents. TMS is commercializing technology developed at The Ottawa Hospital's Dynamical Analysis Laboratory (https://www.ohri.ca/dal/) along with its commercial software manufacturing partner OBS Medical.

What do doctors say about EA? (1) "Extubation decision-making is vital for recovery of critically ill patients, as both prolonged ventilation and extubation failure are harmful to patients and costly to hospitals. I believe EA can help expedite safe liberation from the ventilator, and I am grateful to all those who have helped us achieve this milestone." Dr. Andrew JE Seely, MD PhD FRCSC; CEO and Founder, Therapeutic Monitoring Systems. (2) "What Dr. Seely and TMS are doing is revolutionary. It's the future of medicine. This kind of technology will allow us to make more informed decisions that are precise and patient centered. This will allow for better outcomes and improved resource use. Honestly, this is groundbreaking research." Dr. Kwadwo Kyeremanteng MD FRSPC; Chair, Department of Critical Care, Ottawa Hospital; Founder of Research Optimization Network; Founder of Solving Healthcare podcast.

What are TMS' next steps? TMS is actively involved in rigorously evaluating EA in prospective real-world studies and a clinical trial. TMS is partnering with hospitals, monitoring companies, and researchers to help transform routine bedside monitoring into valuable actionable information that improves patient care.

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