A Validation of the Assisted Fluid Management Feature

CLINICAL STUDY PROTOCOL

Medical Device: EV1000 Platform with Acumen™ Assisted Fluid Management Feature

Date: October 25, 2018

NCT03469570

Title:	A Validation of the Acumen™ Assisted Fluid Management (AFM)
Short Title:	AFM Study
Purpose:	The primary objective of this study is to evaluate the performance of the Acumen™ Assisted Fluid Management (AFM) Feature in its ability to predict a subject's fluid responsiveness. The validity of the fluid bolus recommendation will be analyzed by reporting the number of recommendations followed by delivered boluses that did and did not have a stroke volume response meeting the set fluid strategy. Subjects enrolled in the validation study will have their fluid management decisions guided by the AFM Feature. The decision to provide fluid as recommended by the AFM Feature lies solely with the treating investigator. When a fluid recommendation is made by the AFM Feature, the investigator will assess the subject holistically prior to accepting or declining the system recommendation.
Device Name:	Edwards Lifesciences Acumen™ Assisted Fluid Management (AFM) software
Overall Design:	Pragmatic, multi-site, clinical study with subjects allocated to a single arm
Sample Size:	330 Subjects
Number of Sites:	Up to 20 sites
Subject Participation:	Subject participation will include: • Screening / consent • Placement of arterial line and use of Edwards FloTrac IQ • Undergo planned surgical procedure • Fluid management during surgical procedure • Data Collection • Device related adverse event/serious adverse event data collection, if applicable
Enrollment Period:	Anticipated to last 6 months

Clinical Study Population:	Inclusion Criteria: 1. Be ≥ 18 years of age 2. Non-cardiac/Non-thoracic surgery (e.g., abdominal surgery, combined abdominal/pelvic surgery, major peripheral vascular surgery) expected to last >2 hours post anesthesia induction 3. Procedure will require Mechanical ventilation 4. American Society of Anesthesiology (ASA) Score 3 or 4 5. Expected arterial line placement for surgical procedure and general anesthesia 6. Projected to receive hemodynamic monitoring during surgical procedure 7. Participate or have authorized representative participate in the Informed Consent process and sign/date the IRB approved informed consent form Exclusion Criteria 8. Are < 18 years of age 9. Have a body mass index ≥ 35 kg/m^2 10. Known acute congestive heart failure 11. Known aortic stenosis with valve area ≤ 1.5 cm^2 12. Known moderate to severe aortic regurgitation 13. Known moderate to severe mitral regurgitation 14. Known moderate to severe mitral stenosis 15. Current persistent atrial fibrillation 16. Liver resection procedure 17. Neurosurgery 18. Open chest procedures 19. Patient or surgical procedure type known as an SVV limitation[16] (e.g. tidal volume <8mL/kg of theoretical ideal weight, spontaneous ventilation, persistent cardiac arrhythmia, known atrial fibrillation, open chest surgery, Heart Rate/Respiratory Rate (HR/RR) ratio <3.6) 20. Emergent or cardiovascular surgical procedure 21. Patient who is confirmed to be pregnant 22. Participation in any other drug, device, or biologic study concomitantly, or within the last 30 days (which may clinically interfere with this Clinical Study) 23. Refusal of patient or authorized representative to sign consent
Endpoints:	Primary effectiveness endpoint: Evaluate the performance of the AFM feature in its ability to predict the fluid responsiveness of a subject. Primary safety endpoint: The primary safety endpoint is the assessment of serious adverse events which may be related to the Acumen™ Assisted Fluid Management Feature.