Acumen Hypotension Prediction Index (HPI) software Frequently asked questions

Acumen HPI software

What is Acumen HPI software?
Acumen HPI software is a decision support tool that detects the likelihood of a patient trending towards a hypotensive event* and provides you with insights to understand the root cause and inform a potential course of action for your patient. This software is effective in detecting hemodynamic instability and substantially reducing** the amount of intraoperative hypotension when used in surgical patients who require hemodynamic monitoring during noncardiac surgery.[1]

** Single arm, multicenter, prospective-to-historical control where patients received arterial line monitoring.

Which patient population is Acumen HPI software indicated?
Acumen HPI software is intended for use in surgical and non-surgical patients receiving advanced hemodynamic monitoring via the Acumen IQ sensor, and in surgical patients via the noninvasive Acumen IQ cuff. The Acumen HPI feature is considered to be additional quantitative information regarding the patient's physiological condition for reference only and no therapeutic decisions should be made based solely on the Acumen HPI parameter.

How is monitoring hypotension with Acumen HPI software different than monitoring with standard hemodynamic variables?
Davies,[2] et al sought to compare the accuracy in predicting impending hypotension with Acumen HPI software via arterial line sensor versus that of the commonly used hemodynamic parameters via ROC curve analysis. This study found that Acumen HPI software (at -5, -10, -15 min) was a superior predictor of hypotensive events.*

Additionally, clinical studies[3,4,5,6] suggest that the use of Acumen HPI software as an early indicator of hemodynamic instability may enable a longer reaction time to proactively evaluate the root cause of impending hypotension. These clinical studies also showed that Acumen HPI software in combination with a therapeutic protocol reduced the incidence, duration and severity of hypotensive events in noncardiac surgical patients monitored via an arterial line sensor.

Acumen HPI software algorithm

How was the Acumen HPI software algorithm developed?
Arterial waveform recordings from 130 million cardiac cycles were processed through machine learning techniques to identify 23 predictive features of impending hypotensive events. The algorithm includes these features and is proprietary to Edwards Lifesciences. At 10 minutes before an event, Acumen HPI software via arterial line sensor predicted hypotension with a sensitivity and specificity of 89% (87 to 91%) and 90% (87 to 92%) respectively, and with an AUC of 0.95 [0.95 to 0.96].[7]

How does the Acumen HPI algorithm work?
The algorithm evaluates the peripheral arterial waveform from the Acumen IQ sensor and cuff, and updates advanced hemodynamic parameters, including Acumen HPI parameter every 20 seconds. The HPI parameter displays a value ranging from 0 to 100 with higher values indicating a higher likelihood of a hypotensive event.* If the HPI parameter exceeds 85 for two consecutive 20-second updates or reaches 100 at any time, the Acumen HPI software high alert pop up window will appear, prompting you to review the patient hemodynamics using the Acumen HPI software secondary screen.

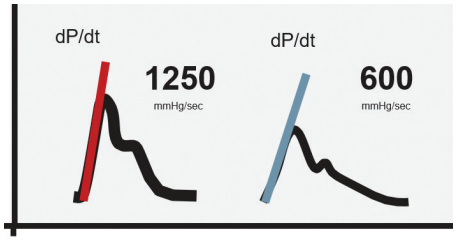
Systolic slope (dP/dt)

What is dP/dt?
Systolic slope (dP/dt) is calculated as the maximum upslope of the arterial pressure waveform measured from a peripheral line. It measures the maximum rate of the arterial pressure rise during left ventricular contraction.[8] Even though arterial dP/dt will have lower absolute values than isovolumic LV pressure dP/dt, their trends correlate strongly.[9,10] Changes from baseline or trend values of arterial dP/dt are more useful than absolute values, and may be an indicator of increasing or decreasing contractility.[11]

* A hypotensive event is defined as MAP <65 mmHg for a duration of at least one minute.

Edwards

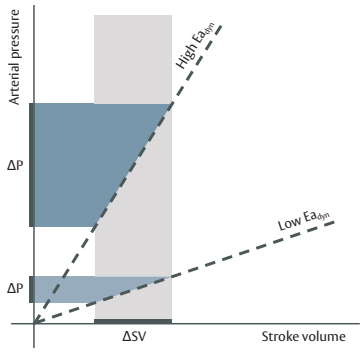
Although predominantly determined by LV contractility, dP/dt may be impacted by afterload during periods of vasoplegic states. Additionally, exercise caution when using dP/dt in patients with severe aortic stenosis, since the stenosis may reduce the coupling between the left ventricle and the afterload.



Dynamic arterial elastance (Ea_{dyn})

What is Ea_{dyn}?

Ea_{dyn} is the ratio of pulse pressure variation (PPV) to stroke volume variation (SVV). In the same way that we consider dynamic parameters like SVV to predict "fluid responsiveness," Ea_{dyn} has been shown to be an indicator of "pressure responsiveness" - predicting if blood pressure will increase in response to fluid administration in preload responsive patients.[12,13] In other words, it may be used as a predictor to determine when a preload responsive patient may also be pressure responsive. Ea_{dyn} greater than 1.0 may suggest that preload responsive patients will increase their mean arterial pressure in response to a fluid bolus. A gray zone exists between Ea_{dyn} values of 0.8 and 1.2.[14] An Ea_{dyn} value less than 1.0 (gray zone of 0.83 - 1.06) has been shown to predict whether blood pressure will remain stable when weaning Norepinephrine in vasoplegic states.[15,16]



Can Ea_{dyn} be used in spontaneously breathing patients?

Yes, Ea_{dyn} can be used with spontaneously breathing patients as the impact of irregular variations in intrathoracic pressure influences both PPV and SVV in the same magnitude, maintaining the validity of the ratio.[12]

Learn more about Acumen Hypotension Prediction Index

CAUTION: Federal (United States) law restricts this device to sale by or on the order of a physician. See instructions for use for full prescribing information, including indications, contraindications, warnings, precautions and adverse events.

References

1. Edwards Lifesciences LLC. 510(k) Summary: K203224; Acumen Hypotension Prediction Index. U.S. Food and Drug Administration; 2021. Accessed September 29, 2021. https://www.accessdata.fda.gov/ cdrh_docs/pdf20/K203224.pdf.
2. Davies, SJ. Ability of an arterial waveform analysis-derived hypotension prediction index to predict future hypotensive events in surgical patients. *Anesthesia & Analgesia* 2019; 130(2): 352-359.
3. Wijnberge, M. Effect of a machine learning-derived early warning system for intraoperative hypotension vs standard care on depth and duration of intraoperative hypotension during elective noncardiac surgery: The HYPE Randomized Clinical Trial. *JAMA* 2020.
4. Schneck,E. Hypotension prediction index based protocolized haemodynamic managementreduces the incidence and duration of intraoperative hypotension in primary total hip arthroplasty: a single center feasibility randomized blinded prospective interventional trial. *J Clin Monit Comput* 2020.Schneck
5. Grundmann CD. Hemodynamic monitoring with Hypotension Prediction Index versus arterial waveform analysis alone and incidence of perioperative hypotension. *Anesthesiologica Scandinavica*. 2021.
6. Tsoumpa M. The use of the Hypotension Prediction Index integrated in an algorithm of goal directed hemodynamic treatment during moderate and high-risk surgery. *Journal of Clinical Medicine*. 2021
7. Hatib, F. Machine-learning algorithm to predict hypotension based on high-fidelity arterial pressure waveform analysis. *Anesthesiology* 2018; 129: 663-674.
8. Ostadal, P. Continual measurement of arterial dP/dtmax enables minimally invasive monitoring of left ventricular contractility in patients with acute heart failure. *Crit Care* 2019; 23:364
9. De Hert et al, Evaluation of Left Ventricular Function in Anesthetized Patients Uding Femoral Artery dP/dtmax. Journal of Cardiothoracic and Vascular Anesthesia 2006; 20(3): 325-330.
10. Tartiere et al, Non-invasive radial pulse wave assessment for the evaluation of left ventricular systolic performance in heart failure. *Eur Journal of Heart Failure* 2007; 9: 477-483.
11. Garcia Monge et al. Performance comparison of ventricular and arterial dP/dtmax for assessing left ventricular systolic function during different experimental loading and contractile conditions. *Crit Care* 2018.
12. Garcia Monge et al. Dynamic arterial elastance as a predictor of arterial pressure response to fluid administration: a validation study. *Crit Care* 2014; 18: 626-637.
13. Cecconi et al. The use of Pulse Pressure Variation and Stroke Volume Variation in spontaneously breathing patients in spontaneously breathing patients to assess dynamic arterial elastance and to predict arterial pressure response to fluid administration. *Anest & Anealg* 2015; 120: 76-84.
14. Garcia Monge et al. Dynamic arterial elastance to predict arterial pressure response to volume loading in preload-dependent patients. *Crit Care* 2011; 15: R15
15. Garcia, M. Dynamic Arterial Elastance as a Ventriculo-Arterial Coupling Index: An Experimental Animal Study. *Front in Physiology* 2020.
16. Guinot, PG, Dynamic arterial elastance predicts mean arterial pressure decrease associated with decreasing norepinephrine dosage in septic shock. 2015.

Edwards Lifesciences • One Edwards Way, Irvine CA 92614 USA • edwards.com

Edwards