Acumen intelligent decision support suite



•



Proactive patient insights for smart recovery

Hemodynamic insights can help guide you with proactive decision support across care settings so you can maintain optimal patient perfusion.

Hypotension management



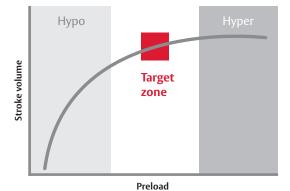
Intraoperative hypotension (IOH) is a common side effect of general anesthesia and is associated with unfavorable outcomes for the patient, such as acute kidney injury (AKI), myocardial injury (MI), and cardiac complications. Many studies demonstrate a link between hypotension and organ injury.

- **IOH is common** 88% of patients continuously monitored with an arterial line still experienced hypotension, defined as MAP <65 mmHg for 1 minute.⁹
- IOH has elevated risks prolonged exposures below mean arterial pressure (MAP) thresholds of 65 mmHg are associated with increased risk of mortality, myocardial injury and AKI after noncardiac surgery.^{1,3}
- **IOH is avoidable** maintaining intraoperative MAP greater than 65 mmHg may reduce the risk of AKI and myocardial injury.^{1,4}

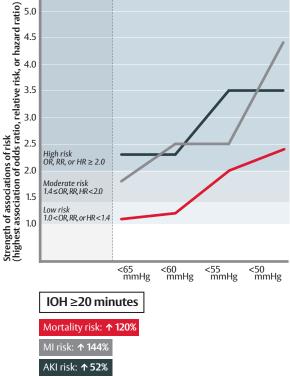
Hemodynamic instability

Continuous access to pressure and flow parameters allow you to evaluate hemodynamic instability and guide appropriate treatment. The patient's location on the Frank-Starling curve can be determined by measuring changes in SV in response to change in preload using a fluid challenge or passive leg raise (PLR). Dynamic and flow-based parameters are more informative than conventional parameters in determining fluid responsiveness and may help guide individualized volume administration in patients and avoid excessive or insufficient administration.⁵ When managing perfusion, stroke volume can be optimized using the patient's own Frank-Starling curve.

Frank-Starling relationship between preload and stroke volume (SV)



A systematic review of literature suggests that lower MAP thresholds and longer duration increases risk of AKI, MI and mortality. (Graphics created from Wesselink, 2018, table 4)



Cumulative duration MAP <65 mmHg vs MAP <50 mmHg

Acumen Hypotension Prediction Index (HPI) software

Acumen HPI software combined with a treatment protocol achieved statistically significant reduction in hypotension^{6,7}

Developed in partnership with clinicians across the world, the Acumen Hypotension Prediction Index software is the first in a new category of products. This first-of-its-kind predictive decision support software detects the likelihood of a patient trending towards a hypotensive event* before the event occurs, and provides you with insights to understand the root cause and inform a potential course of action for your patient management. Two randomized controlled trials have shown that using Acumen HPI software in combination with a hemodynamic treatment protocol significantly reduced the incidence and duration of hypotensive events in patients undergoing noncardiac surgery.^{6,7} Acumen HPI software had superior ability to predict hypotensive events than common hemodynamic parameters.⁸

Acumen HPI software is comprised of three key elements



HPI parameter: Index value ranging from 0 to 100 with higher values indicating a higher likelihood of a hypotensive event* to occur.



HPI high alert popup: Alert appears if HPI >85 for 2 consecutive 20-second readings or reaches 100, prompting you to review the secondary screen



HPI secondary screen

The advanced hemodynamic pressure and flow parameters provided on the HPI secondary screen allow you an opportunity to investigate and identify the root cause of potentially developing hypotensive events.



Preload: Stroke volume variation (SVV)** or pulse pressure variation (PPV) The percent difference between minimum and maximum stroke volume (SV) or pulse pressure (PP) during a respiratory cycle. Note: SVV serves as an accurate marker of position status on the Frank-Starling curve.

Contractility: Systolic slope dP/dt Maximum upslope of the arterial pressure waveform from a peripheral artery.

Afterload: Dynamic arterial elastance (Ea_{dyn}) The ratio of pulse pressure variation to stroke volume variation (PPV/SVV). It is an estimate of arterial elastance.

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

^{**} ΔSV can be used when appropriate

Innovation for proactive management of hypotensive events*

Acumen IQ cuff and Acumen IQ sensor each have the capability to unlock the Acumen Hypotension Prediction Index (HPI) software, enabling you to choose the right device for your patient and clinical needs.

Acumen IQ cuff**

Acumen IQ cuff unlocks Acumen HPI software and provides continuous blood pressure and advanced hemodynamic parameters from a noninvasive cuff. Acumen IQ cuff gives you noninvasive access to calculated beat-to-beat hemodynamic information for a broad patient population, including patients in whom an arterial line would not be typically placed.⁵

Easy-to-use cuff

Acumen IQ cuff design reduces variability in application. The easy-to-use self-coiling mechanism within the interior of the cuff wraps snugly around the patient's finger and offers improved cuff placement, consistent snugness, and usability.

Acumen IQ sensor***

Acumen IQ sensor unlocks the ability to predict hypotensive events* and provides insight into the root cause of hypotension (preload, afterload and/or contractility) with the Acumen Hypotension Prediction Index (HPI) software. The sensor was built on the foundation of the Edwards Lifesciences FloTrac sensor.

Acumen IQ sensor attaches to any existing radial arterial line and automatically calculates key parameters every 20 seconds, reflecting rapid physiologic changes in moderate- to high-risk surgery. Advanced hemodynamic parameters provided by Acumen IQ sensor offer you continuous insight to more accurately determine your patient's hemodynamic status.

Advanced hemodynamic parameters provided by Acumen IQ cuff and Acumen IQ sensor:

• Hypotension Prediction Index (HPI) • Cardiac output (CO)

- Systolic slope (dp/dt)
- Dynamic arterial elastance (Ea_{dyn})
- Stroke volume (SV)
- Stroke volume variation (SVV)
- Mean arterial pressure (MAP)
- Cardiac index (CI)

- Cardiac output (CO)
 Systemic vaccular registran
- Systemic vascular resistance (SVR)Pulse pressure variation (PPV)
- Systemic arterial systolic blood pressure (SYS.....)
- pressure (SYS_{ART})
 Systemic arterial diastolic blood pressure (DIA_{ART})



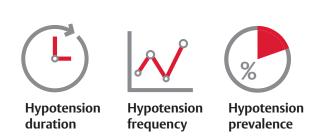


- * A hypotensive event is defined as MAP <65 mmHg for a duration of at least one minute
- ** Surgical patient use only
- *** Surgical and nonsurigical patient use

Acumen Analytics software

Acumen Analytics software allows you to retrospectively view and analyze previous hemodynamic parameter data from the HemoSphere advanced monitoring platform, highlighting events including:



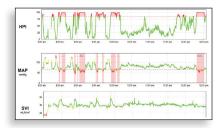


Key features of Acumen Analytics software



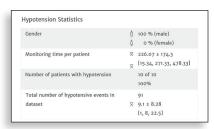
Customizable viewing pane

With a streamlined tile layout, the main viewing page organizes a list of all cases, cohort summaries, and cohort comparison for convenient overviews.



Trend parameters

At the core of Acumen Analytics software is advanced hemodynamic parameter data. You can review recorded data on a number of valuable pressure and flow parameters, as well as tissue oxygen saturation that are involved in clinical decision making.



Hypotension statistics

This case summary list provides statistics on key hypotensive calculations such as average number of hypotensive events,* duration of each event, number of patients in a cohort that experienced a hypotensive event.*

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

uman Analytica								- 0	×
			n Analyti						
The List 85 S	ammary 88 Comparison				O PGDT	@ 10H	L Custorni	. 0	POF
	Baseline Cehort Cohort 64 -			Cohort 02 -					
All Files	<u>A</u> ₹	12.0%	Time spo hypoten	Time spent in ypotension		*	16		ĺ
+ Add Calent Cohert on S : 0 lins Cohert 02 S : 1 lin Cohert 03 S : 1 lin Cohert 03 S : 1 lin Cohert 03 S : 1 lin Cohert 04 S : 2 lins	\odot	5	MAP events under 50 mmHG		12		\bigtriangledown		
	Description			Description					- 1
	Cohort Name	Callott as		Cahort Hame		Ca	hort eq.		- 1
	Number of Files	6		Number of File		3			- 1
	First Case Start Timestang	Aug. 5, 2015 (142.)	19 AM	Fini Cere Start	Timestanp	A1	E 5, 2115 F42.19 AM		- 1
	Last Cese Start Timestamp	Aug 1, 2018 8:000;	In AM.	Lest Cese Start	Timotany	A1	g 1, 2013 6:03 31 AM		
	Hypotension statistics		**	Hypotension	statistics			**	- 1
	Gender	2 100% (mile) § 0% (hanal		Gender		0	soo th (main) a th (female)		
	Age	7 77 33 1 15-09		Apr		3	77.33 1 15.99		
	Weight	2 80.58 1 10.55 2 175.67 1 20.5		Weight			00.58 1 10.55 k 171.47 1 2241 Ba		

Cohort comparison

The cohort comparison screen allows you to retrospectively compare data from two cohorts. When viewing intraoperative hypotension data, key callouts include duration of hypotension and MAP events under 65 mmHg. The customizable cohort summary screen displays a summary of the data collected for the chosen patient or patient group.

Acumen Intelligent Decision Support Suite

The Acumen intelligent decision support suite offers both predictive and retrospective decision support for the management of hypotensive events.*

Acumen Hypotension Prediction Index (HPI) software

Acumen Analytics software

Acumen			
Model	Description	Length (in)	Pack size
AIQCS	Acumen IQ cuff	Small	5
AIQCM	Acumen IQ cuff	Medium	5
AIQCL	Acumen IQ cuff	Large	5
AIQS8	Acumen IQ sensor	84 in / 213 cm	EA
AIQS85	Acumen IQ sensor	84 in / 213 cm	5
AIQS8C503	Acumen IQ sensor with TruWave disposable pressure transducer	84 in / 213 cm	5
AIQS6	Acumen IQ sensor	60 in / 152 cm	EA
AIQS65	Acumen IQ sensor	60 in / 152 cm	5
AIQS6AZ	Acumen IQ sensor with VAMP adult system	60 in / 152 cm	EA
AIQS6AZ5	Acumen IQ sensor with VAMP adult system	60 in / 152 cm	5
AIQS6C502	Acumen IQ sensor with TruWave disposable pressure transducer and VAMP adult system	60 in / 152 cm	5

Learn more on how you can stay ahead of hypotension at Edwards.com/Acumen

For more than 50 years, Edwards Lifesciences has been helping you make proactive clinical decisions and advance the care of surgical and acutely ill patients across the continuum of care.



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

References

- Salmasi, V., Maheshwari, K., Yang, G., Mascha, E.J., Singh, A., Sessler, D.I., & Kurz, A. (2017). Relationship between intraoperative hypotension, defined by either reduction from baseline or absolute thresholds, and acute kidney injury and myocardial injury. *Anesthesiology*, 126(1), 47-65.
- 2. Bijker JB, et al. Incidence of intraoperative hypotension as a function of the chosen definition: literature definitions applied to a retrospective cohort using automated data collection. *Anesthesiology*. 2007;107(2):213-220.
- 3. Wesselink EM, Kappen TH, Torn HM, Slooter AJC, van Klei WA. Intraoperative hypotension and the risk of postoperative adverse outcomes: a systematic review. Br J Anaesth. 2018;121(4):706-721.
- 4. Sun, L.Y., Wijeysundera, D.N., Tait, G.A., & Beattie, W.S. (2015). Association of Intraoperative Hypotension with Acute Kidney Injury after Elective non-cardiac Surgery. *Anesthesiology*, 123(3), 515-523.
- 5. Cannesson, M. (2010) Arterial pressure variation and goal-directed fluid therapy. Journal of Cardiothoracic and Vascular Anesthesia, 24(3), 487-97.
- 6. Wijnberge, M., Geerts, B., Hol, L., Lemmers, N., Mulder, M., Berge, P., Schenk, J., Terwindt, L., Hollman, M., Vlaar, A., Veelo, D. (2020) 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 Online, February 17, 2020.
- 7. Schneck, E., Schulte, D., Habig, L., Ruhrmann, S., Edinger, F., Markmann, M., Habicher, M., Rickert, M., Koch, C., Sander, M. (2019) Hypotension Prediction Index based protocolized haemodynamic management reduces the incidence and duration of intraoperative hypotension in primary total hip arthroplasty: a single centre feasibility randomized blinded prospective interventional trial. *Journal* of Clinical Monitoring and Computing online, November 29, 2019.
- 8. Davies SJ, Vistisen ST, Jian Z, et al. Ability of an arterial waveform analysis-derived hypotension prediction index to predict future hypotensive events in surgical patients. Anesth Analg 2019.
- 9. Shah, N., Mentz, G., Kheterpal, S. (2020). The incidence of intraoperative hypotension in moderate to high risk patients undergoing non-cardiac surgery: A retrospective multicenter observational analysis. *Journal of Clinical Anesthesia*. 2020; 66:1-12.

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.

Edwards, Edwards Lifesciences, the stylized E logo, Acumen, Acumen Analytics, Acumen IQ, FloTrac, HemoSphere, HPI, Hypotension Prediction Index, TruWave, and VAMP are trademarks of Edwards Lifesciences Corporation or its affiliates. All other trademarks are the property of their respective owners.

© 2021 Edwards Lifesciences Corporation. All rights reserved. PP--US-5984 v1.0

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

