

Hypotension Decision Assist - HDA-OR2™

- * New lightweight tablet computer
- * Hypotension Case Review – HCR™
- * Networked
- * HDA Analytics and Reporting – HDA-AR™

Contents

| | |
|---|----|
| The problem of intra-operative hypotension | 1 |
| Benefits of preventing intra-operative hypotension | 2 |
| Cumulative total time of IOH matters | 3 |
| The Hypotension Decision Assist - HDA-OR2™ solution | 5 |
| HDA-AR™ secure cloud based Analytics and Reporting | 6 |
| Expected benefits | 7 |
| References | 10 |
| Who we are | 11 |



The problem of intra-operative hypotension

Intra-operative hypotension (IOH) is a common and frequent occurrence in patients undergoing general anesthesia for non-cardiac surgery.

A 2014 study of almost 17,000 anesthetic records revealed that 26% of the surgical patients involved had a peri-operative systolic blood pressure of <80 mmHg for >5 minutes¹.

Intra-operative hypotension has long been associated with post-operative mortality². Acute kidney injury (AKI) and myocardial injury (MI) has been conclusively demonstrated as adverse outcomes associated with intra-operative hypotension^{3,4,5}. Even brief periods of hypotension may be harmful to patients⁶. Of concern is the fact that the threshold for harm may reside below blood pressure levels that are currently accepted as standard of care⁷.

Even brief periods of hypotension may be harmful to patients

In a study of 104,000 non-cardiac surgery patients, 30-day mortality was strongly related to time-weighted average intra-operative MAP⁸.

The threshold for myocardial injury is a MAP ≤ 65 mmHg. The threshold for renal injury may be higher, possibly nearer 75 mmHg. A few minutes of a MAP <55 mmHg is associated with AKI and MI and has been demonstrated to increase markedly with prolonged intra-operative hypotension⁹.

AKI and MI increase markedly with prolonged intra-operative hypotension

It was found that in a retrospective study of 42,000 cases of non-cardiac surgery, 5% of patients developed post-operative acute kidney injury. It has also been found that acute kidney injury occurs in 10.9-16.4% of patients undergoing major abdominal surgery and found that this is associated with a 12.6-fold increase in the risk of death¹⁰.



Benefits of preventing intra-operative hypotension

The prevention of IOH by tailoring management of blood pressure to individual patient physiology, may improve post-operative outcomes.

In a randomized clinical trial of patients undergoing major abdominal surgery, those in the individualized blood pressure management arm demonstrated significantly lower rates of post-operative organ dysfunction than those managed with standard practice (38.1% vs. 51.7% respectively)¹¹.

Individualized blood pressure management equates to lower rates of postoperative organ dysfunction

Intra-operative hypotension, if not optimally controlled, may contribute to poor outcomes, even death in post-operative high-risk patients. Even short periods of hypotension can increase the risk of organ injury¹².



Cumulative total time of IOH matters...

- MAP below 60–70 mmHg among adults is associated with increased risk of acute kidney injury (AKI), myocardial injury (MI), and mortality, and the risk is a function of both hypotension severity and duration¹⁵.
- Patients are at increased risk of AKI when their cumulative time below a MAP of 65 mmHg reaches or exceeds 13 minutes¹⁸.
- When patients fall even further below this threshold (for example, MAP below 55 mmHg), even short durations are associated with increased risk of AKI. A MAP of 50 mmHg can significantly increase the risk of AKI and MI even after just 1 minute¹⁶.

“There does not appear to be any safe duration of a MAP less than 55 mmHg”

Walsh, 2013⁵.



Cumulative total time of IOH matters... (continued)

In 2020, the Anesthesia Quality Institute (AQI) published a quality metric for hypotension¹⁸. This measure (IIM025: ePreop 31) evaluates the proportion of cases in which the patient's MAP is below 65 mmHg for 15 minutes or more, cumulatively over the course of the surgery.

Evidence of the harmful effects continues to grow. Intra-operative hypotension

“is common and associated with increased 30-day major adverse cardiac or cerebrovascular events. ...The potentially avoidable nature of the hazard, and the extent of the exposed population, makes hypotension in the operating room a serious public health issue that should not be ignored for any age group”

Gregory et al 2021¹³.

And is associated with increased health resource usage (HRU) and cost,

“We report a significant association of perioperative hypotension with an increase in HRU, including additional LOS and readmissions, both important contributors to overall medical costs”

Stapelfeldt et al 2021¹⁷.

The Hypotension Decision Assist - HDA-OR2™ solution

Hypotension Decision Assist HDA-OR2™ has been designed with and for anesthesiologists - to assist anesthesia healthcare professionals manage blood pressure, hemodynamic stability and the cardiovascular system during surgery where an arterial line is present and arterial pressure is being continuously monitored.

There are no additional disposable or re-usable sensor costs when using HDA-OR2™.

HDA-OR2™ provides an intuitive visualization via a single at-a-glance screen. You just connect HDA-OR2™ to your existing multiparameter patient monitor, with no additional calibration required and are ready to use HDA-OR2™.

Now with Hypotension Case Review - HCR™, HDA-OR2™ gives you an end of surgery complete case summary that visualizes hypotensive episodes and cardiovascular parameters over the entire operation. It includes key metrics such as cumulative time MAP < 65 mmHg.

HDA-OR2™ is supplied pre-installed on a lightweight medical grade 10" tablet computer with a low glare, wide angle, crisp high-definition display. This enables rapid

at-a-glance awareness of hypotension and its depth and duration through novel accumulator displays.

HDA-OR2™ can be installed on existing pole or VESA mounts in order to consume minimal or no additional footprint in the OR.

HDA-OR2™ can be connected to your hospital network by Wi-Fi or Ethernet connection, enabling remote software updates, cloud data storage, and HDA Analytics and Reporting – HDA-AR™.



HDA-AR™ secure cloud based Analytics and Reporting

HDA-AR™ is a secure cloud based app that provides access to all the data collected by all HDA-OR2s installed at your facility.

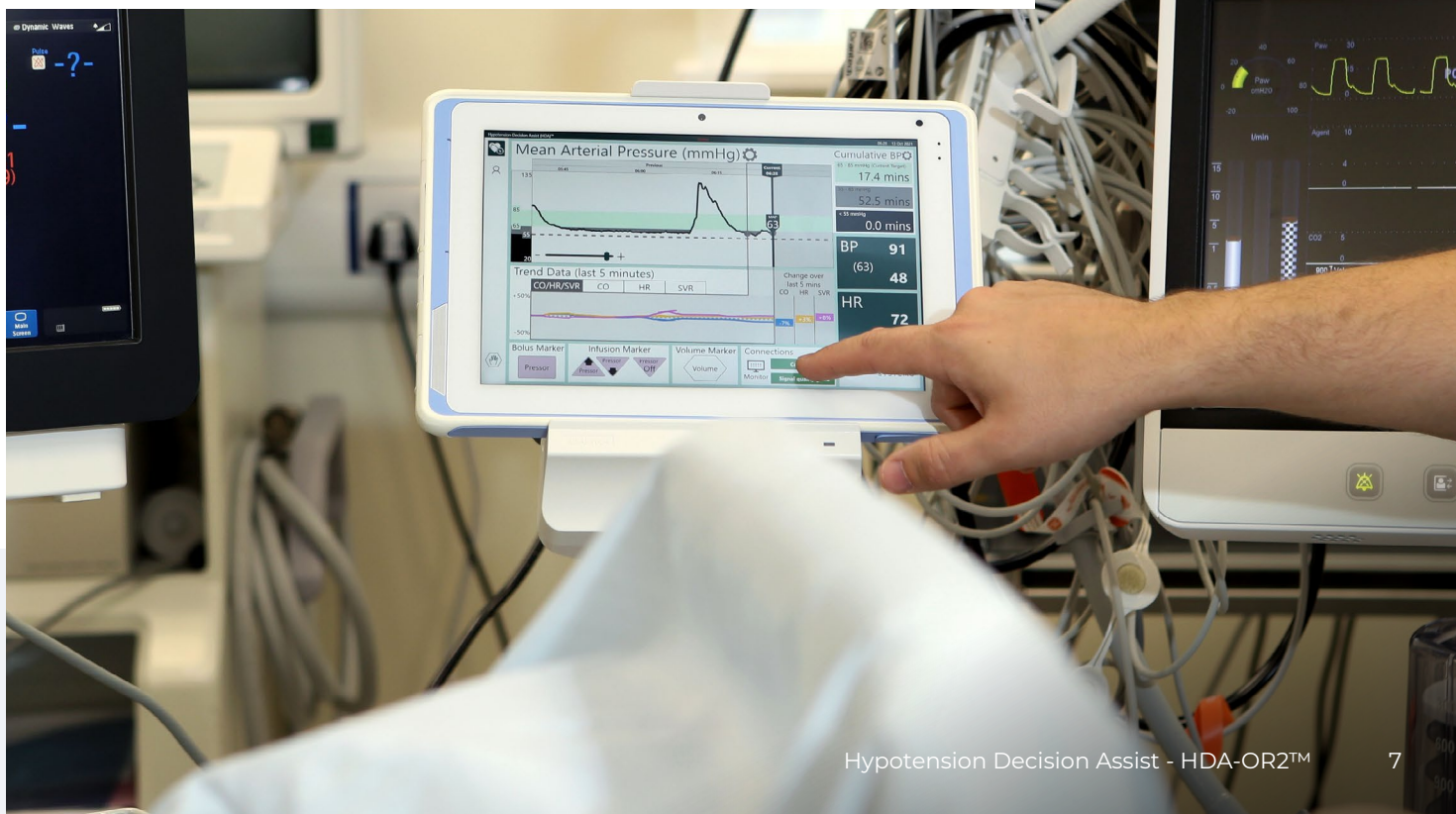
HDA-AR™ allows you to see how IOH rates are changing over time, see how IOH rates vary by type of surgery, patient age, and other demographic parameters, and to zoom in and view all the detailed high-resolution data HDA-OR2™ generates from every surgery it is used on when required.

HDA-OR2™

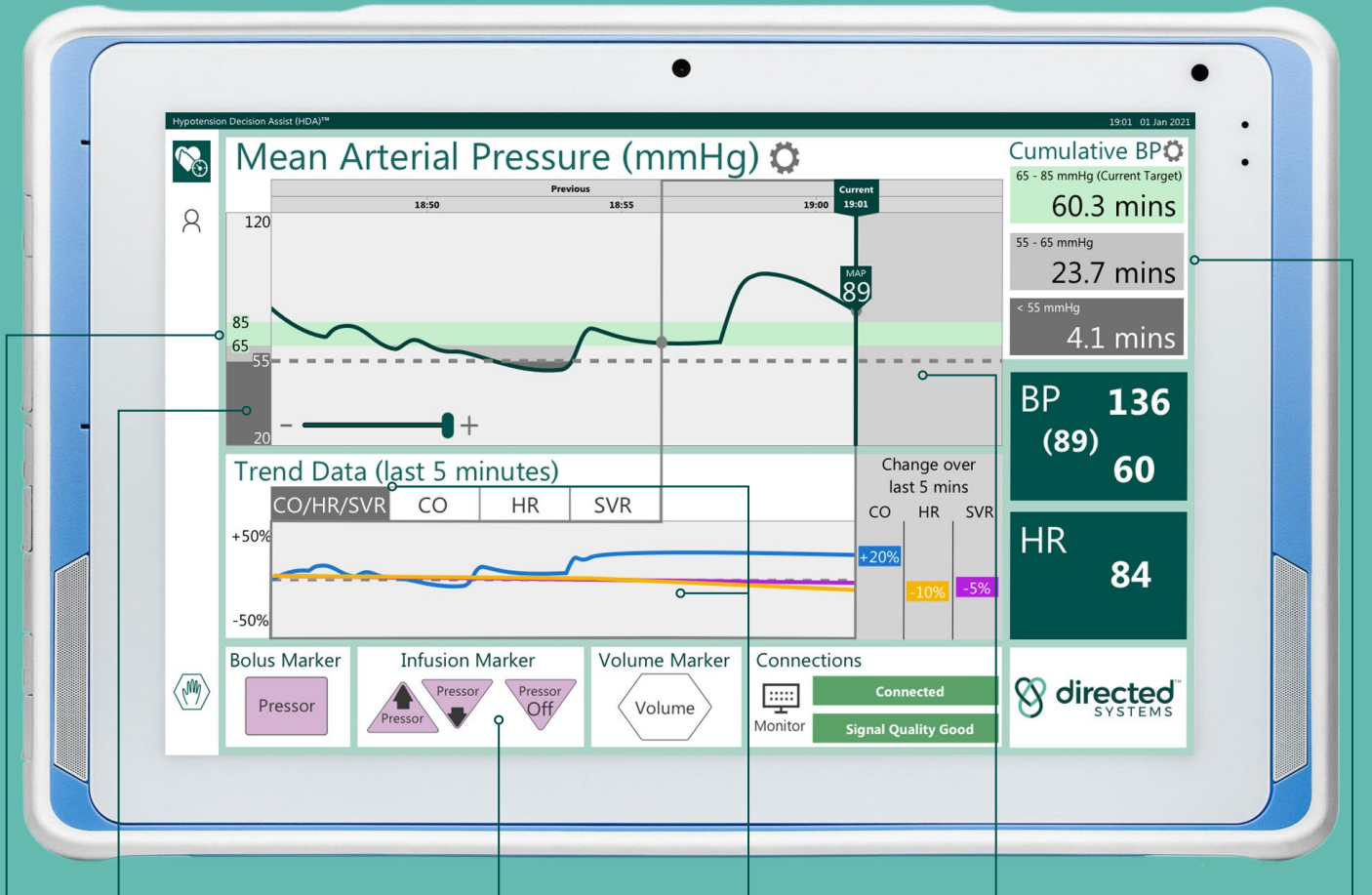
- Analyzes continuous high-fidelity arterial blood pressure waveform data from the existing standard multiparameter patient monitor that is utilizing an existing standard arterial line and transducer.
- Cumulative totals of IOH given to inform not only length but depth of IOH experienced during the surgical procedure
- Provides at-a-glance time- critical information of current and emerging cardiovascular situations.
- Enables post-surgery HCR™ for full case visualization at-a-glance
- Networked data export capabilities for further statistical analysis and review.
- Uses proprietary patent pending Blood Pressure and Cardiac output Insight (BCI)™ algorithms to provide insight into the determinants of cardiovascular function (e.g. CO and SVR).
- No additional costly medical disposables, reusable sensors or calibration is required keeping ongoing Total Cost of Ownership (TCO) low.
- Simple to install – interfaces easily with existing patient monitors
- Very intuitive to use, as developed together with anesthesiologists and extensively tested.
- Fits in with current clinical workflow.
- Delivered installed on a medical grade high resolution, compact and lightweight touchscreen tablet with required patient monitor interface cable.

Expected benefits of HDA-OR2™

- Help anesthesiologists to better manage blood pressure and the cardiovascular system including the detection and control of IOH episodes and cumulative IOH during surgery within user defined limits.
- Contribute to reducing hospital resource usage and costs: an independent study by Keuffel et al (2019) showed that controlling IOH more effectively could save between \$119-\$458 per non-cardiac surgical patient¹⁴.



Main screen



Slider allows MAP timescale to be zoomed in and out so that changes over time can be seen macroscopically and in detail.

Cardiovascular treatments can be indicated by pressing these "marker" buttons.

A marker will appear on the main MAP chart and on the CO, HR and SVR trends.

These allow the patient's responsiveness to different treatments to be assessed.

They can also act as an aide-memoire for recording on the main medication chart.

Main chart shows mean arterial pressure (MAP) trend and its current numeric value. With user defined hypotension warning limits and defined severe hypotension range. To assist the user to maintain MAP within acceptable limits.

Trend data for cardiac output (CO), heart rate (HR) and systemic vascular resistance (SVR).

Values are calibrated using their values 5 minutes ago as baseline and expressed as % change.

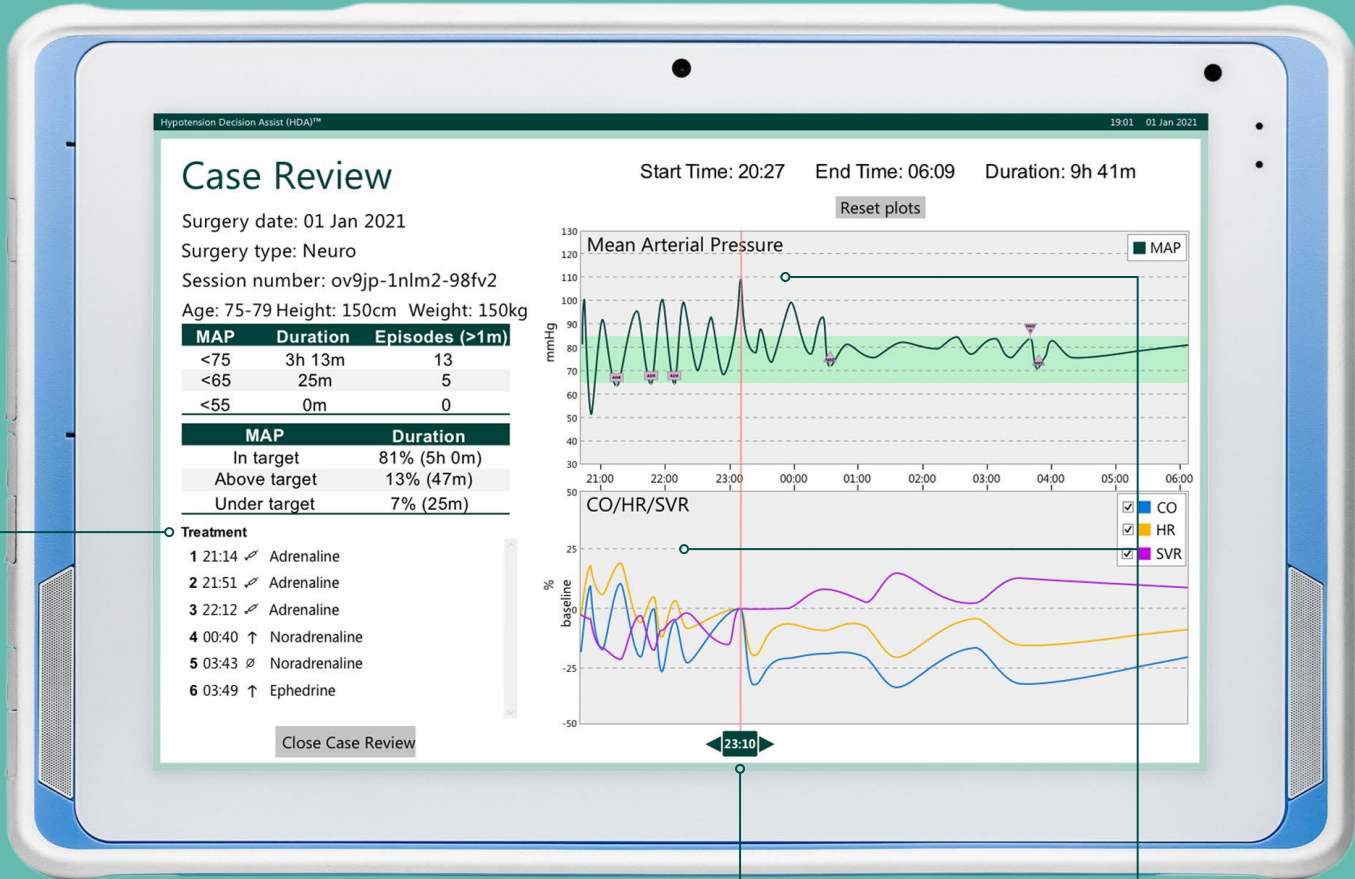
The pattern of changes allows the user to assess cardiovascular status and helps them decide appropriate treatment.

Amount of time in target MAP range and in user defined and severe hypotension ranges.

The "green zone" shows the target range for mean arterial pressure (MAP) set by the user for the patient.

This allows rapid visualization of how the MAP is changing and enables the user to decide whether intervention is needed.

Hypotension Case Review - HCR™



Treatment marker record showing time and type of marker placement.

Baseline slider.

MAP & CO/HR/SVR trend data screen

The charts can be zoomed with a pinch-zoom and scrolled.

Data Extraction via USB and networking

All case files can now be extracted via USB memory stick or automatically uploaded to HDA analytics and reporting - HDA-AR™ (see 'HDA analytics and reporting' technical application note) via networking, to enable further off line analysis of patient cases postoperatively.

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Who we are

Directed Systems is a fast-moving medical software and data analytics company based in Cambridge, UK and Austin, USA. Our target customers for HDA are the anesthesiologists and hospitals who are concerned about the incidence and cost of post-operative complications of intra-operative hypotension. We develop software that incorporates smart proprietary algorithms to analyze, visualize, predict and interpret real-time physiological signals.

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