




**Hypotension<sup>TM</sup>  
Decision  
Assist (HDA)**

Now with Hypotension Case Review (HCR)

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## The problem of intra-operative hypotension

Intra-operative hypotension 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 <80mmHg for >5minutes<sup>1</sup>.

Intra-operative hypotension has long been associated with post-operative mortality<sup>2</sup>. Acute kidney injury (AKI) and myocardial injury (MI) has been conclusively demonstrated as adverse outcomes associated with intra-operative hypotension<sup>3,4,5</sup>. Even brief periods of hypotension may be harmful to patients<sup>6</sup>. Of concern is the fact that the threshold for harm may reside below blood pressure levels that are currently accepted as standard of care<sup>7</sup>.

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**Even brief periods**  
of hypotension  
may be harmful  
to patients

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In a study of 104,000 non-cardiac surgery patients, 30-day mortality was strongly related to time-weighted average intra-operative MAP<sup>8</sup>.

The threshold for myocardial injury is a MAP  $\leq 65$ mmHg. The threshold for renal injury may be higher, possibly nearer 75mmHg. A few minutes of a MAP <55mmHg is associated with AKI and MI and have been demonstrated to increase markedly with prolonged intra-operative hypotension<sup>9</sup>.

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**AKI and MI**  
**increase markedly**  
with prolonged  
intra-operative  
hypotension

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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 this associated with a 12.6-fold, increase in the risk of death<sup>10</sup>.



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## Benefits of preventing intra-operative hypotension

The prevention of intra-operative hypotension, 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)<sup>11</sup>.

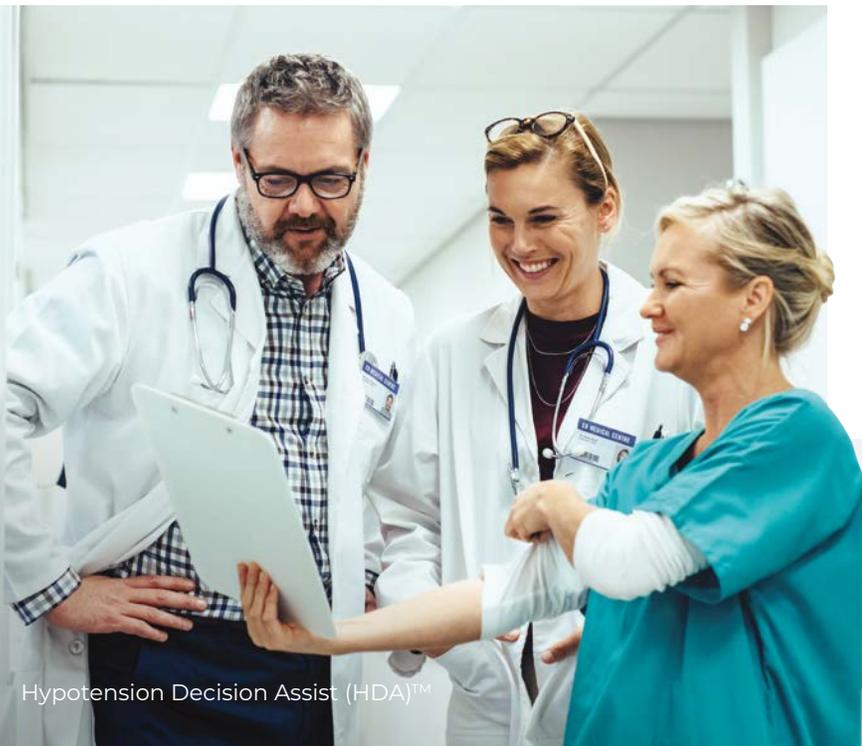
“there does not appear to be any safe duration of a MAP less than 55 mmHg”

(Walsh, 2013).

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

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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 injury<sup>12</sup>.

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”<sup>13</sup>.



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## The Hypotension Decision Assist (HDA)<sup>™</sup> solution

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

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no additional  
disposable costs  
when using HDA

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

**Now with Hypotension Case Review (HCR)<sup>™</sup>**, you get an end of surgery complete case summary that visualizes hypotensive episodes and parameters over the entire operation.



## HDA ...

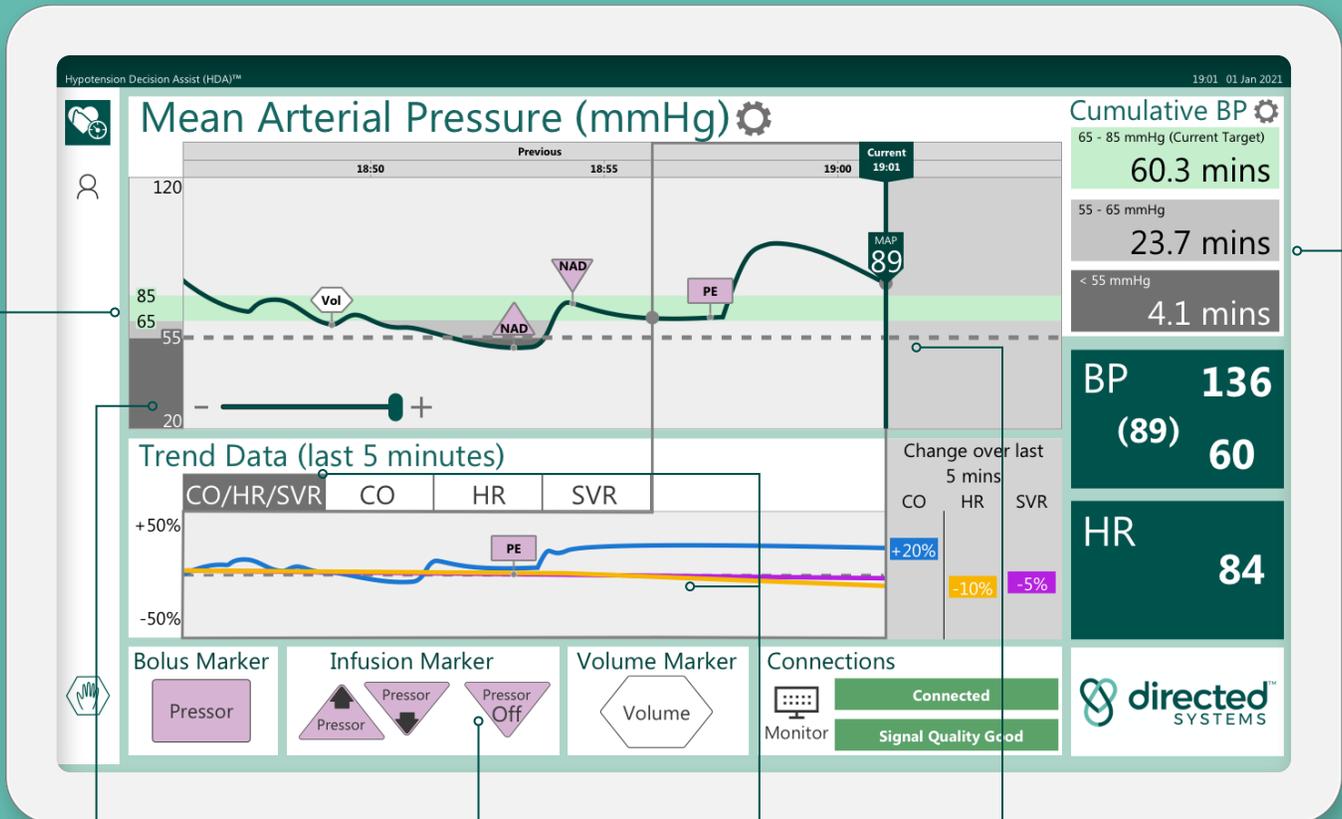
- Analyzes continuous high-fidelity arterial blood pressure waveform data from the existing standard multiparameter patient monitor that is utilizing an existing standard arterial line and transducer.
- Provides at-a-glance time-critical information of emerging cardiovascular situations.
- Enables Post-surgery HCR™ for full case visualization at-a-glance
- USB data export for further statistical review.
- Uses our patent pending Blood Pressure and Cardiac output Insight (BCI)™ algorithms to provide insight into the determinants of cardiovascular function.
- No need for additional costly medical disposables, reusable sensors or calibration keeping ongoing Total Cost of Ownership low.

- Simple to install — integrates 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 touchscreen PC with interfacing cable.

## Expected benefits of HDA

- Assists anesthesiologists to manage blood pressure and the cardiovascular system including the detection and control of IOH within user defined limits.
- Contribute to reducing hospital costs: an independent study by Keuffel et al (2019) showed that controlling IOH more effectively could save between \$119-\$458 per non-cardiac surgical patient<sup>14</sup>.

## Main screen



Slider allows MAP timescale to be zoomed 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.

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.

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.

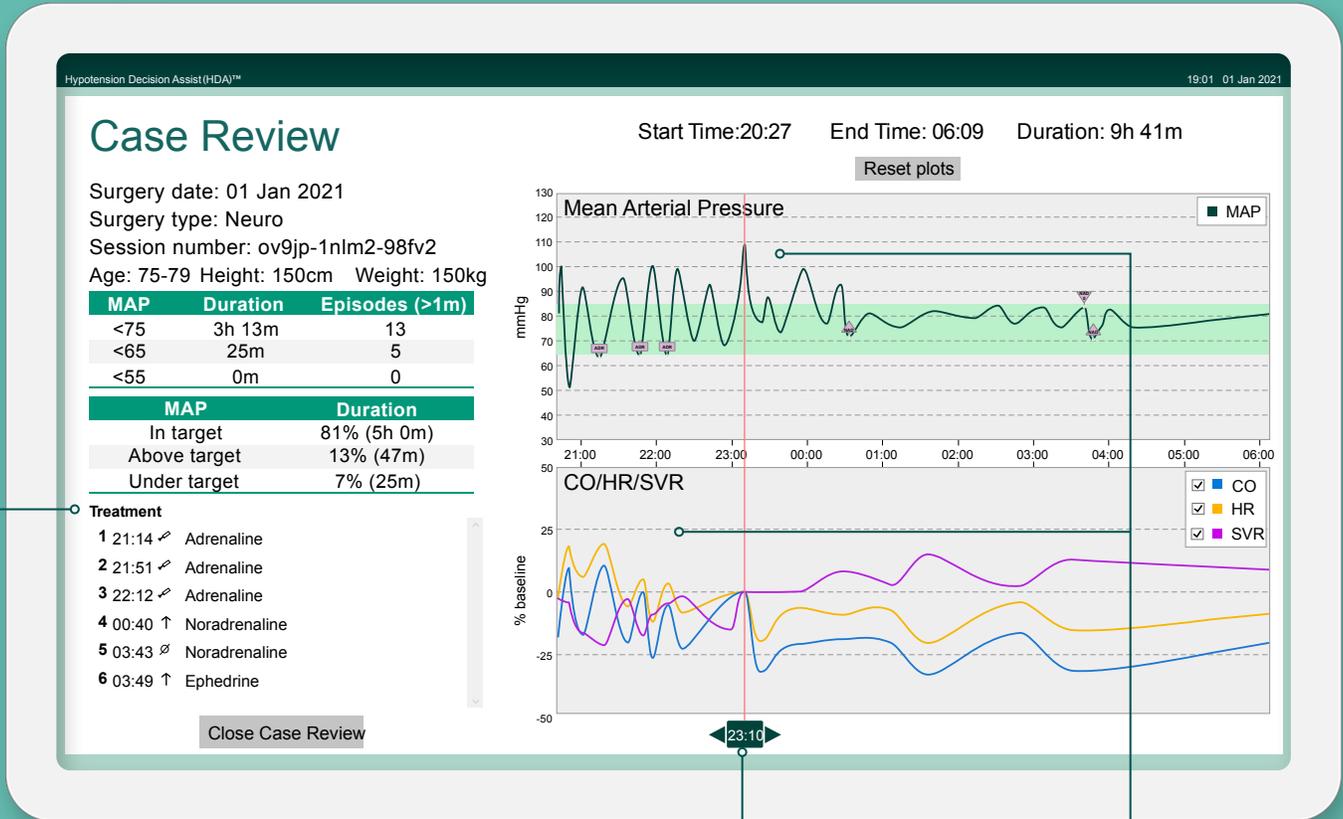
Trend data for cardiac output (CO), heart rate (HR) and systemic vascular resistance (SVR).

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.

# 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

All case files can now be extracted via USB memory stick 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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