directed® SYSTEMS

Blood pressure and cardiovascular management for anesthesia professionals

Hypotension Decision Assist HDA™ point of care clinical decision support software with integrated cloud-based DS Aware™ analytics for quality improvement & research

The Hypotension Decision Assist - HDA™ solution

Hypotension Decision Assist HDA™ 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.

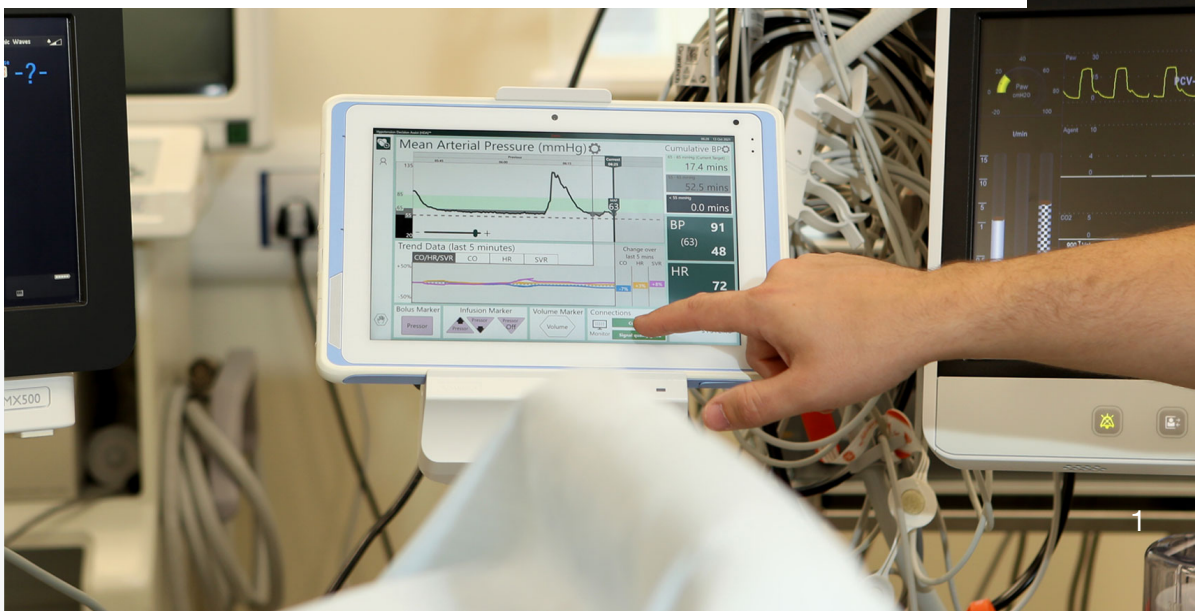
Features

- Intuitive visualization
- No additional calibration required
- Pre-installed on a lightweight medical grade 10” tablet computer
- Connects digitally to the patient monitor through serial or network connections
- Streams the invasive arterial blood pressure (ABP) waveform through our patented algorithms providing:
  - Trends in cardiac output (CO) and systemic vascular resistance (SVR)
  - Cumulative time at different mean arterial pressure (MAP) thresholds, including hypotension
- Hypotension Case Review
  - End of surgery complete case summary
  - Visualizes hypotensive episodes and cardiovascular parameters over the entire operation.
  - Includes key metrics such as cumulative
- Network & cloud connected enabling:
  - Remote software updates & maintenance.
  - Cloud data storage.
  - Access to secure DS Aware™ analytics & reporting.

Expected benefits of HDA™

- No additional disposable or re-usable sensor required - on-going total cost of ownership low
- 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 defined limits.
- Contribute to reducing hospital resource usage and costs by approximately $119-$458 per non-cardiac surgical patient[14].

AKI and MI increase markedly with prolonged intra-operative hypotension



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 minutes[1].

Intra-operative hypotension has long been associated with:

- Post-operative mortality[2].
- Acute kidney injury (AKI)
- myocardial injury (MI)[3,4,5]

In 2020, the Anesthesia Quality Institute (AQI) published a quality metric for hypotension[9]. 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.

Benefits of preventing intra-operative hypotension

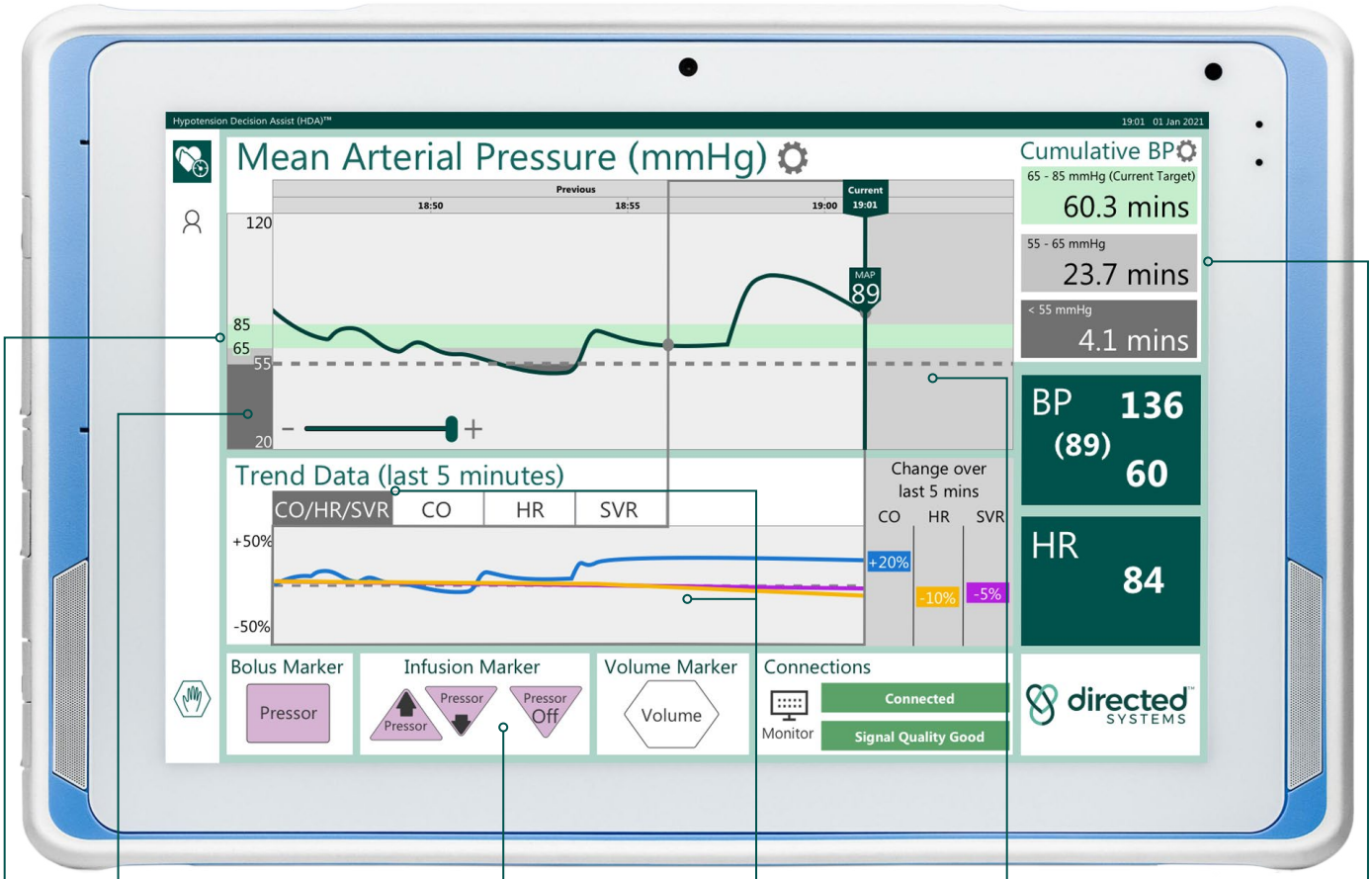
The prevention of IOH by tailoring management of blood pressure to individual patient physiology, may improve post-operative outcomes[6].

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[7]

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 duration[8].
- Patients are at increased risk of AKI when their cumulative time below a MAP of 65 mmHg reaches or exceeds 13 minutes[9].
- 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 minute[10].

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.

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.

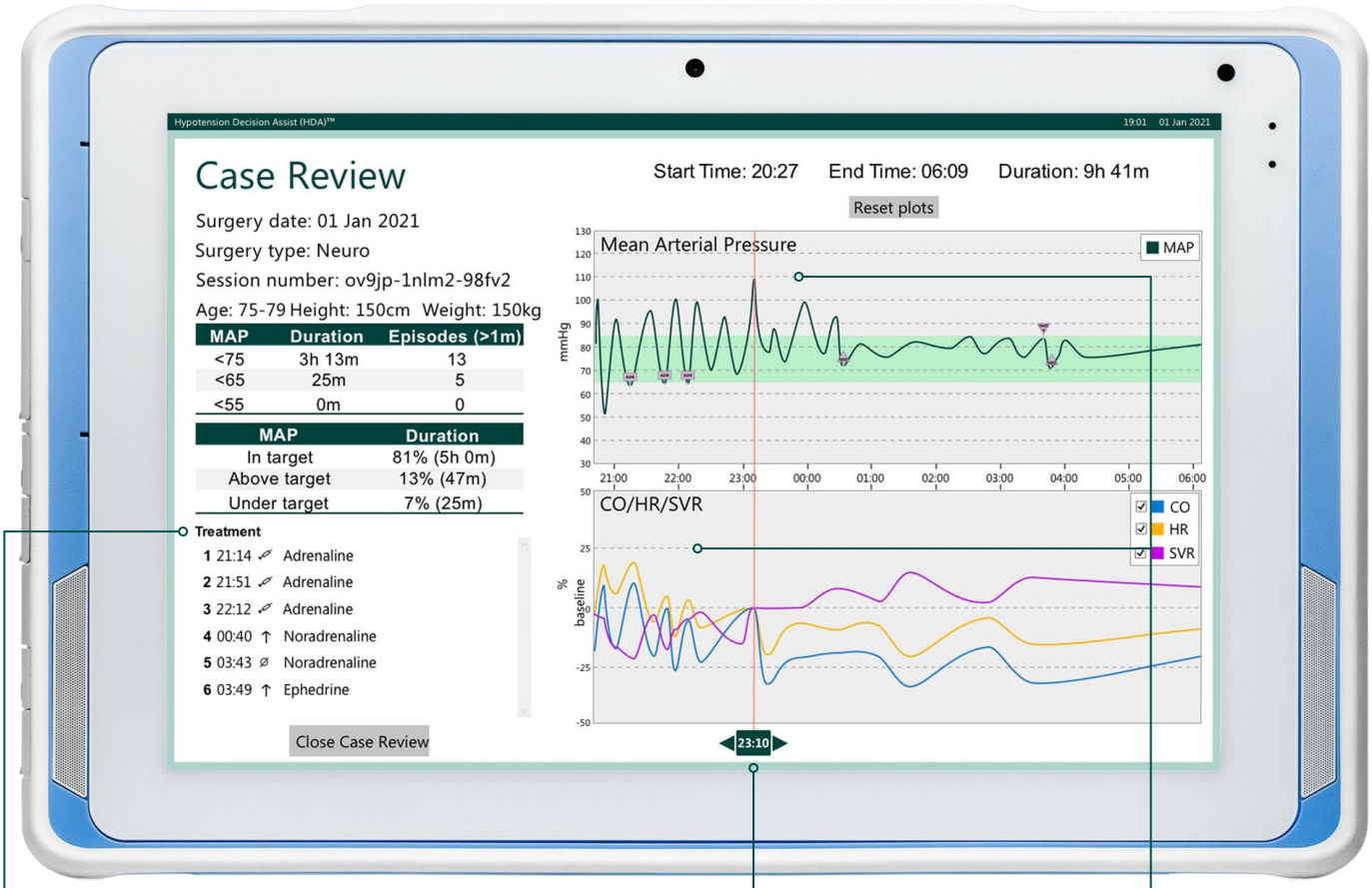
Trend data for cardiac output (CO), heart rate (HR) and systemic vascular resistance (SVR).

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 stet 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.

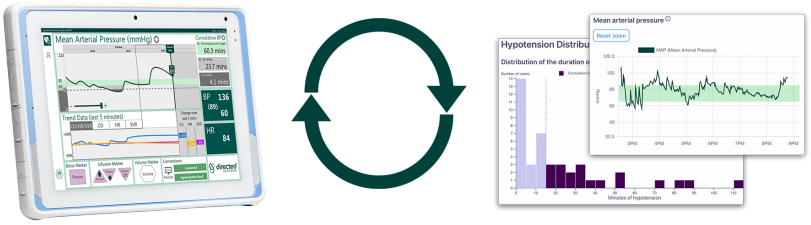
Data Extraction via USB and networking

All case files can now be automatically uploaded to DS Aware™ analytics and reporting (see DS Aware™ brochure) via networking, to enable further off line analysis of patient cases postoperatively.

DS Aware™ secure cloud based integration for analytics and reporting

DS Aware™ is a secure cloud based app that provides access to all the data collected by all HDAs installed at your facility.

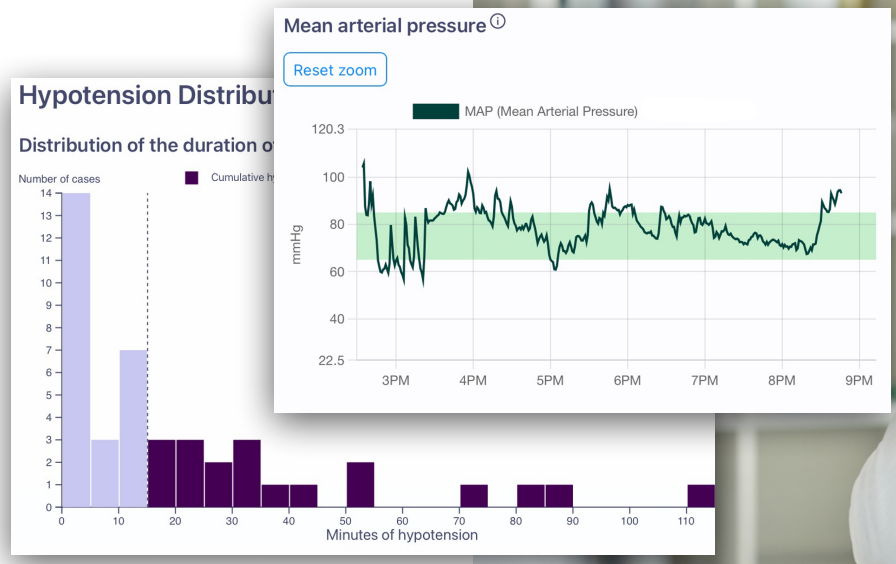
DS Aware™ allows you to see how IOH rates are changing over time, see how IOH rates vary by type of surgery, patient age, and other demographic parameters, and to zoom in and view all the detailed high- resolution data DS Aware™ generates from every surgery it is used on when required.



Fully integrated solution

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

Walsh, 2013



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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.

For further information

Email: info@directedsystems.com Website: www.directedsystems.com

Customer Support & Sales:

Tel: 1-855-912-0663

UK address:

47-51 Norfolk Street, Cambridge, CB1 2LD

US address:

Texas Health CoLab,
1601 Trinity Street Bldg B, Austin, TX78712

BPA-MCM-006 Issue 6
April 2023