HYPOTENSION DECISION ASSIST (HDA)

User Manual

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Foreword

This manual and the equipment it describes are for use only by Board Certified medical professionals who have been trained in the use of Hypotension Decision Assist, referred to as HDA in the rest of this manual.

Equipment covered in this manual:

HDA, comprising:

Item	Part Number
Touch screen computer	Advantech AIM-58 or TM-5040-16-i5*
Power Cord and DC Adapter Pack for touch screen computer	Advantech 96PSA-A65W19V1-M1, 1700029083-01 or Teguar AC/DC Medical Adaptor Model No: GSM20A19
Serial Connection Cable for Philips Patient Monitors supporting the MIB Protocol	Connector-Philips
Serial Connection Cable for GE Patient Monitors supporting the S/5 Protocol	Connector-GE
VESA monitor mount	VESA 75 Mount

***** Model supplied as per order

Manufacturer
Directed Systems Limited
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Cambridge
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For information, call 1-855-912-0663

Terms Used in this Manual

Warning
Indicates a situation which, if not avoided, could result in death or serious injury.

Caution
Indicates a situation which, if not avoided, may result in minor or moderate injury.

Be aware
Indicates that the operator should be aware of a hazard that may damage the product.

Advice
Indicates advice to the operator to optimise performance of the system.

Statement on Electromagnetic Compatibility

Electromagnetic and radiofrequency interference may cause loss of measurements provided by HDA. Please refer to EMC and RF Safety section of this user manual and the touch screen computer User Manual, supplied with HDA.

HDA system warning

No modification of this equipment is allowed.

Warranty

Please consult term and conditions of sale for details of the warranty offered with the HDA system and accessories.

Labelling

Labelling on or within the package from which the device is to be dispensed bears information for use, including indications, effects, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the device can use the device safely and for the purpose for which it is intended, including all purposes for which it is advertised or represented:

All labelling, except labels and cartons, bearing information for use of the device also bears the date of the issuance or the date of the latest revision of such labelling.

Caution
Federal law restricts this device to sale by or on the order of a physician.

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LIST OF ABBREVIATIONS

BP	Blood Pressure
C	Celsius
CO	Cardiac Output
CVP	Central Venous Pressure
DBP	Diastolic Blood Pressure
DC	Direct Current
HDA	Hypotension Decision Assist
HR	Heart Rate
IABP	Intra Aortic Balloon Pump
ICU	Intensive Care Unit
IEC	International Electrotechnical Commission
kPa	kiloPascal
m	Meter
MAP	Mean Arterial Pressure
MR	Magnetic Resonance
nCO	Nominal Cardiac Output
OR	Operating Room
SBP	Systolic Blood Pressure
SVR	Systemic Vascular Resistance
SVRi	Systemic Vascular Resistance index
TSVR	Total Systemic Vascular Resistance
TSVRi	Total Systemic Vascular Resistance index
USA	United States of America
V	Volt
W	Watt

PART 1: HDA
Overview and general features

This section describes the indications for use for HDA and its features.

Caution
Read all warnings, cautions and instructions provided with the HDA system before using it.

Indications for use

HDA is indicated to acquire, process and display arterial pressure and other key cardiovascular characteristics of adult patients who are at least eighteen years of age that are undergoing surgery where their arterial pressure is being continuously monitored by a vital-signs monitor. It is indicated for use to assist anesthesia healthcare professionals manage the blood pressure, hemodynamic stability and the cardiovascular system during such surgery.

Warning
HDA is for use only by Licensed and Credentialed medical professionals who have been trained in its use.

Warning
HDA must not be used on any patient who is less than 18 years of age.

Warning

HDA is MR unsafe and is not intended for use in a MR environment.

Warning
Arterial transducers providing blood pressure data must be placed in the radial artery. Other locations are not supported.

Caution
The output from HDA should not solely be used to determine the use of vasopressors. Other treatments including fluids are an option in blood pressure management.

Contraindications for use

HDA is contraindicated in the following situations:

1. Patients under 18 years of age;
2. Patients with aortic regurgitation;
3. Patients fitted with an intra-aortic balloon pump (IABP);

Parts shipped with HDA

All items required for HDA to function are shipped with the HDA system.

Before use, confirm that the shipping carton contains the following items:

1. Touch Screen Computer*
2. Post card providing QR link to User Manual for HDA and for Touch Screen Computer
3. Power cord and DC Adapter Pack for Touch Screen Computer
4. User Manual for HDA
5. Serial connection cable for use in connecting HDA to the operating room (OR) multiparameter patient vital signs monitor. Connection cables for both monitor types (Philips or GE) that HDA connects to are supplied.

Warning
HDA can only be used with Philips multiparameter patient vital signs monitors supporting the MIB or LAN data export protocol and GE multiparameter patient vital signs monitors supporting the S/5 protocol.
The same cable cannot be used for Philips and GE multiparameter patient vital signs monitors.
Connection cables supplied for use with Philips multiparameter patient vital signs must not be used for GE multiparameter patient vital signs.

6. Additional cable (customer specified) for connection to Philips multiparameter patient vital signs monitor
7. Additional cable (customer specified) for connection to GE multiparameter patient vital signs monitor
8. VESA mount (optional and if not specified by customer will not be supplied)

* Advantech or Teguar as per order.

If any of the items listed above are not in the shipping carton, please contact Directed Systems Limited before attempting to use the system.

Prior to use, inspect all items listed supplied for any damage. Please contact Directed Systems Limited if you have any concerns.

HDA – Principle of Operation

HDA consists of software, user interface and hardware. The hardware platform is a medically-rated touch-screen computer, Teguar TM-5040-16 or Advantech AIM-58, as per order.

HDA can be connected to Philips and GE multiparameter patient vital signs monitors that are routinely used in the operating room. This is achieved via a serial connection cable to the digital output port of the vital signs monitor. Connection over wired or wireless LAN[1] is also possible when connecting to Philips IntelliVue patient monitors. The vital signs monitor will also provide continuous arterial blood pressure waveform data and cardiovascular-related numeric parameters.

The medical user, an anesthesiologist, has the option to set up a patient in HDA by entering patient-specific information (height, weight, age) and define a target range for mean arterial blood pressure (MAP). The user will confirm that HDA is correctly communicating with the vital signs monitor that is connected to the patient.

In routine operation, HDA will track the vital signs of the patient. It will check that data are being acquired correctly and that the signals are of adequate quality and consistent, alerting the user with an appropriate action if not. The system will compute additional derived variables to help with its function and algorithms. For example, changes in cardiac output will be derived from the blood pressure waveform.

HDA will continually process and display, in graphical charts and numerical format, the data and derived variables in comparison with the user defined targets. It will detect and indicate to the user when blood pressure shown as MAP is below or is trending to fall below the target range. HDA will allow the user to add labels to the graphic display chart to show the administration of vasopressors, as bolus or infused, and volume challenges.

Similarly, HDA will indicate when MAP is above or trending above the target range.

The intent of HDA is that with this information, the anesthesiologist will make faster and more accurate assessment and treatment decisions regarding cardiovascular management. The anesthesiologist may then implement these decisions manually with syringe boluses or vasopressors, or by changing the infusion rate of vasopressors, by volume challenges, or other means. The user may then optionally record these events using markers on HDA.

The following items, supplied with the HDA system, are required for it to function.

1. **Display**
   According to model ordered either a:
   Teguar 15.6" Medical Computer, Model Number TM-5040-16 (Teguar Corp, NC, USA). LVD, CE/FCC Class A Certification, IEC 60601-1 4th Edition.

[1] In order to connect on a hospital or other vendors network please first check with the hospital IT department and/or the respective vendor if specific network compliance requirements apply.

OR

Advantech Medical Computer, Model Number AIM-58 (ADVANTECH CO., LTD, Taiwan). LVD, CE/FCC Class A Certification, UL 60601-1 4th Edition, IEC 60601-1-2.

2. Connection cable (to connect HDA to OR monitor)

Serial cable, 3m in length.

Connection cables are customer specified.

Different cables are required for use with Philips and GE multiparameter patient vital signs monitors in the OR.

The cables are labelled at both ends (see Figure 1). The labels indicate what device each end should be connected to ("To HDA" or "To Monitor") and include a part number that indicates the monitors supported by that cable. Table 1 can be used to look up this part number.

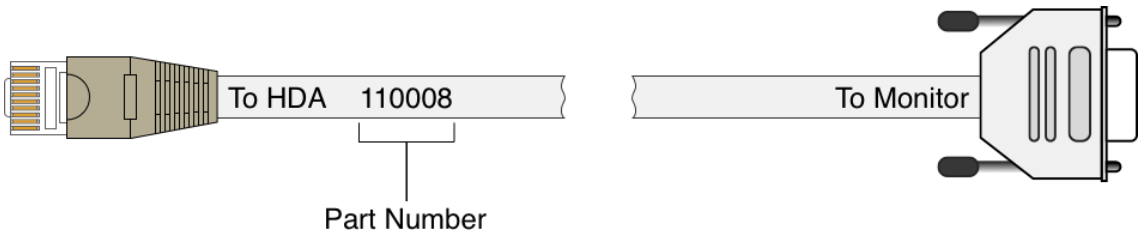
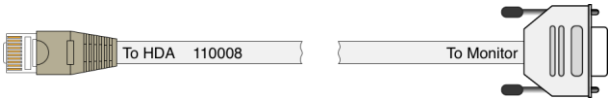
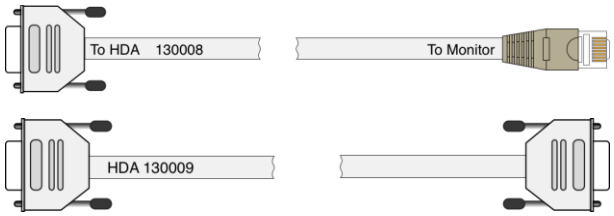


Figure 1: *HDA data cable labelling*

Cable	Supported Monitors
	Teguar all-in-one to: GE Monitors supporting the S/5 Computer Interface
	Teguar all-in-one to: Philips Intellivue MX600-800 Philips Intellivue MX400-550 (with dual MIB/RS232 ports) Philips Intellivue MP20-90
	Teguar all-in-one to: Philips Intellivue MX400-550 (with single MIB/RS232 port Advantech tablet to: Philips Intellivue MX600-800 Philips Intellivue MX400-550 (with dual MIB/RS232 ports) Philips Intellivue MP20-90
	



Advantech tablet to:
Philips Intellivue MX400-550 (with single MIB/RS232 port
Advantech tablet to:
GE Monitors supporting the S/5 Computer Interface

Table 1: *Connection cables and supported monitors*

Warning
HDA can only be used with Philips multiparameter vital signs patient monitors supporting the MIB or LAN Data Export Protocol and GE multiparameter vital signs patient monitors supporting the S/5 Protocol.

Warning
Different cables are required for Philips and GE monitors.

The same cable cannot be used for both types of OR monitors.

Connection cables supplied for use with Philips multiparameter vital signs patient monitors supporting the MIB Protocol must not be used for GE multiparameter vital signs patient monitors supporting the S/5 Protocol.

Connection cables supplied for use with GE multiparameter vital signs patient monitors supporting the S/5 Protocol must not be used for Philips multiparameter vital signs patient monitors supporting the MIB Protocol.

3. DC Power Adaptor and Mains cord for Touch Screen Computer
Either Teguar or Advantech Adaptor A/D 100 ~ 240V, 120W, 19V, C6 DC jack (for medical devices) depending on model ordered.

4. Additional serial cables
Serial cable, 3m in length. Customer specified.

Warning
See warning above related to connection cables.

5. VESA mount
A VESA mounting options are available for the Touch Screen Computer. This is an optional part of the HDA system and if not specified by a customer will not be supplied.

Operating Parameters

- For operating and transport and storage conditions refer to Part 8 and the user manual for the Touch Screen Computer model ordered.

Patient, Operating Room and General Use Safety

Warning
Only attending and resident anesthesiologists who have received specific user training from, or approved by, Directed Systems Limited may use HDA.

During initial set-up and before each use, the HDA system and connection cables should be inspected for any damage. If damage is identified, do not use or attempt to repair HDA. Please call Directed Systems Limited for assistance.

The touch screen computer is IEC/ES60601-1 certified, protecting the unit from electrical interference and preventing interference with other electrical equipment.

HDA should not be positioned in such a way that makes it difficult to disconnect the power cord from the mains supply.

Do not drop or mechanically shock the display unit. This may cause damage.

Do not hold or suspend the display unit by its cable. This may cause damage.

Plug the power cord directly into the power outlet socket. Do not use any extension power cords or adaptor plugs.

Periodically check the power cord for damage to the insulation or plug. Do not use a damaged power cord.

Do not connect a wet power cord to a power outlet socket.

Caution
Read all warnings, cautions and instructions provided with the HDA system.

Be aware of trip hazards presented by the mains cord and the cable used to connect HDA to the operating room vital signs monitor.

Maintenance

Warning
Inspect HDA and its connection cables before each use. If there is evidence of damage, do not use. In such circumstance, please call Directed Systems Limited for assistance.

Always turn off HDA and unplug the mains cord from the power supply socket before cleaning.

Be Aware

Use only those detergents and/or agents that are already in routine use within the hospital to clean HDA.

Do not apply abrasive, corrosive, caustic or alcohol-based cleaning or disinfectant compounds, solvents or materials that could cause damage.

Software Updating

Updates to the HDA software are provided by Directed Systems Ltd periodically. These updates are distributed as installers pre-loaded on USB drives or over the internet.

Procedure to install a software update

If updating from USB, then connect the provided USB drive to any USB port on HDA. If updating over the internet, the update will automatically be downloaded when HDA is online.

When an update is available, "Update Available" will display on the launch screen (figure 2). Tap this button to launch the HDA software updater (figure 3).

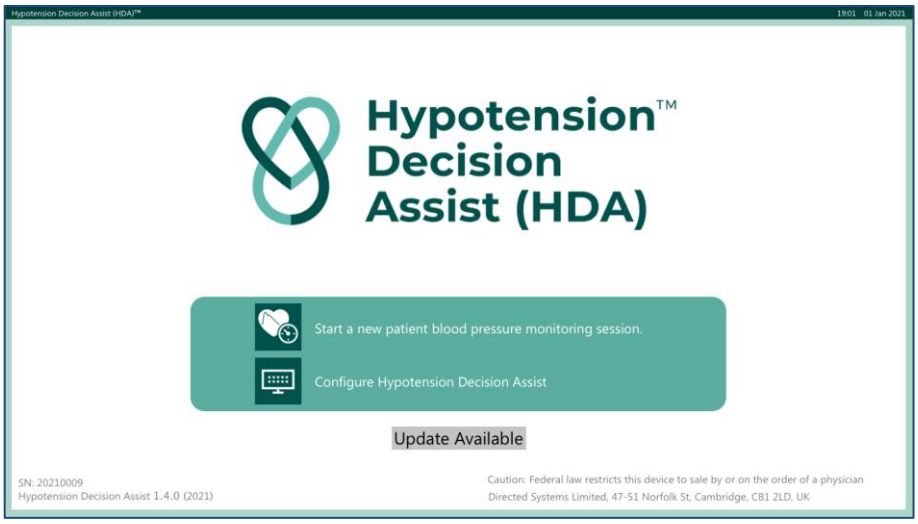


Figure 2: *HDA screen when new version is available*

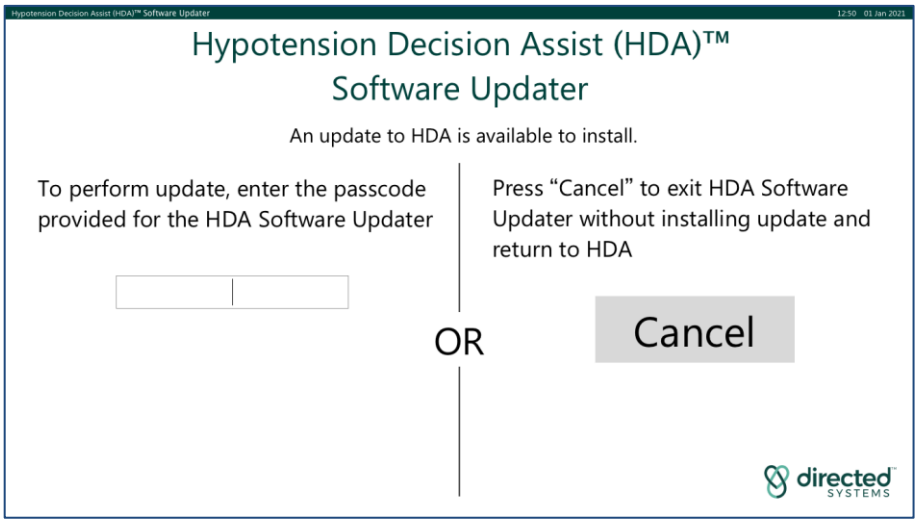


Figure 3: *HDA Software Updater screen*

Enter passcode provided by Directed Systems Ltd. HDA will display a screen (see Figure 4) showing the current version of HDA installed and the version you are updating to.

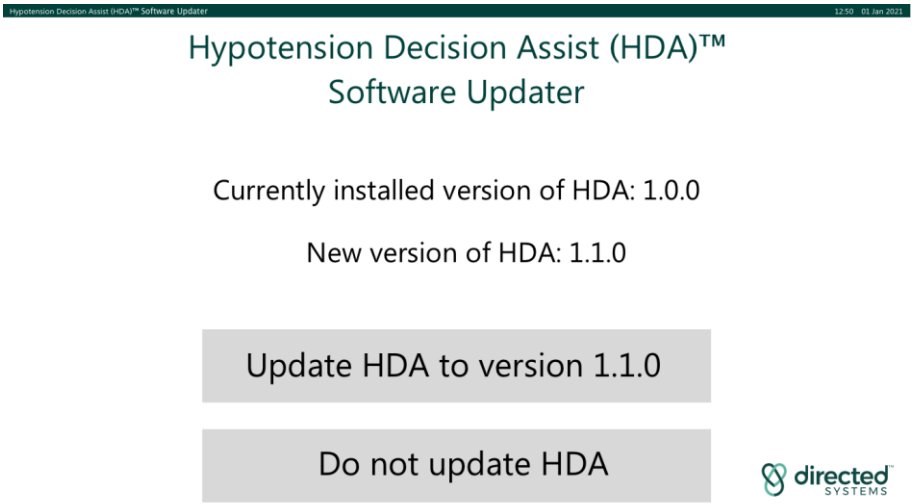


Figure 4: *HDA Software Updater command screen*

To perform the update, press the update button, which will show the version that HDA will be updated to (in this example "Update HDA to version 1.1.0"). HDA will then launch the installer for this update.

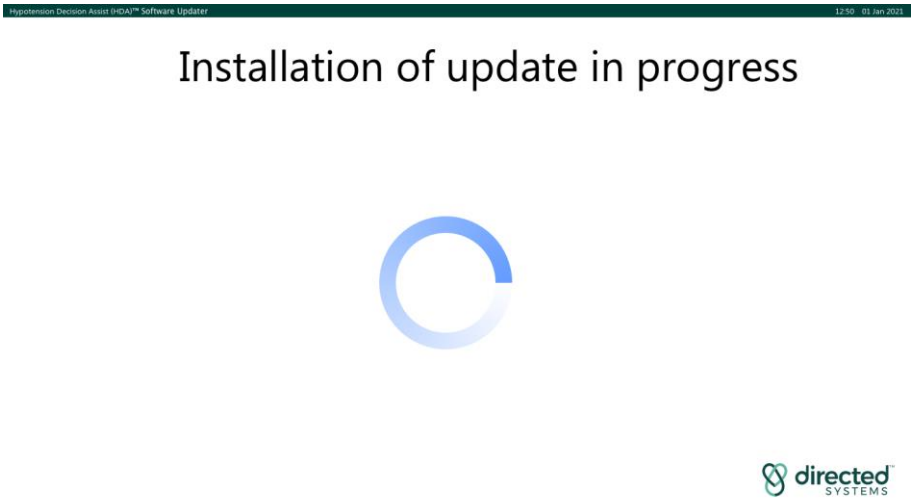


Figure 5: *HDA Software Updater install command*

After the installer completes installation, HDA will display the result of the install. If successful, the following screen (see Figure 6) is shown and the version that HDA has been updated to is visible. If updating from a USB drive, remove the USB drive from HDA to return to Running Mode.

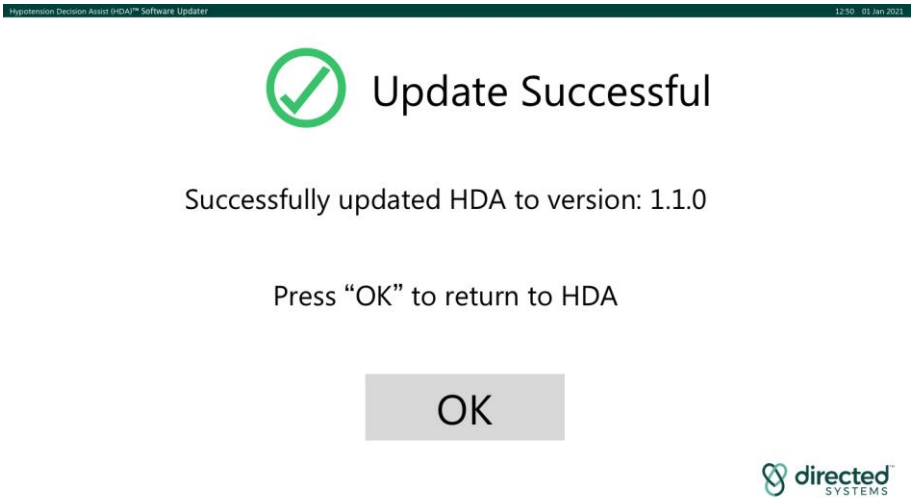


Figure 6: *Update successfully installed screen*

If the installation fails, all changes will be rolled back and the following screen (see Figure 7) will be displayed. You have the option to re-try the installation or to restart HDA into Running Mode without installing the update or to re-try the installation. If the installation cannot be completed contact Directed Systems Ltd for support.

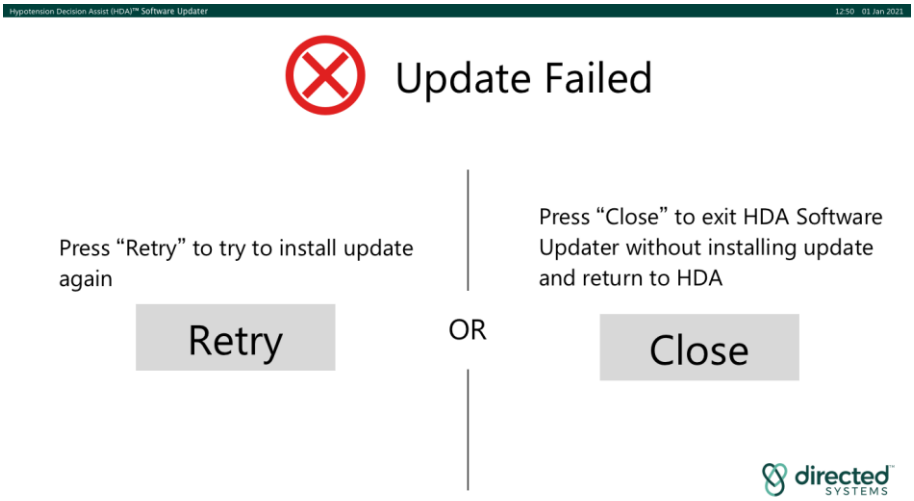


Figure 7: *Update failed screen*

EMC and RF Safety

Warning

Electromagnetic Interference (including RF) may impact the performance of HDA. This does not affect patient safety or the safety of HDA.

Warning

Use of accessories other than the supplied cables or modification of the HDA hardware could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Warning

Portable RF communications equipment should be used no closer than 30 cm (12 inches) to any part of HDA, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Warning
Use of this equipment adjacent to, or stacked with, other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

The following wireless technology is included in HDA

- WLAN IEEE 802.11 a/b/n/ac
- Bluetooth v4.1 (not used)
- NFC 13.56 MHz, compatible with ISO15693, ISO14443A, ISO 14443B, FeliCa (not used)

Quality of Service: Wireless connectivity is not required for HDA to maintain safety. Wireless QoS can impact performance if receiving data from Philips IntelliVue patient monitors using the Philips LAN protocol over a wireless network. If bandwidth is insufficient, then HDA will be unable to receive data from the patient monitor. In this case HDA will display a "Disconnected" alert and show gaps in the trended signals.

Wireless Security: Suggested wireless security measures are securing connection using WPA2 security.

Electromagnetic interference could result in HDA being unable to receive data from patient monitors. In this case HDA will display a "Disconnected" alert and show gaps in the trended signals. If the interference stops, HDA will reconnect and resume display of signals. This does not impact patient monitor operation.

PART 2: SOCKETS AND INDICATORS

This section describes the sockets and indicators on the front, side and rear panels of the HDA system display monitor.

> **Warning**
> Read all instructions before operating HDA.

Inputs and Outputs

Inputs and outputs on the Touch Screen Computer are detailed in Figure 8 and 9 depending on the model ordered.

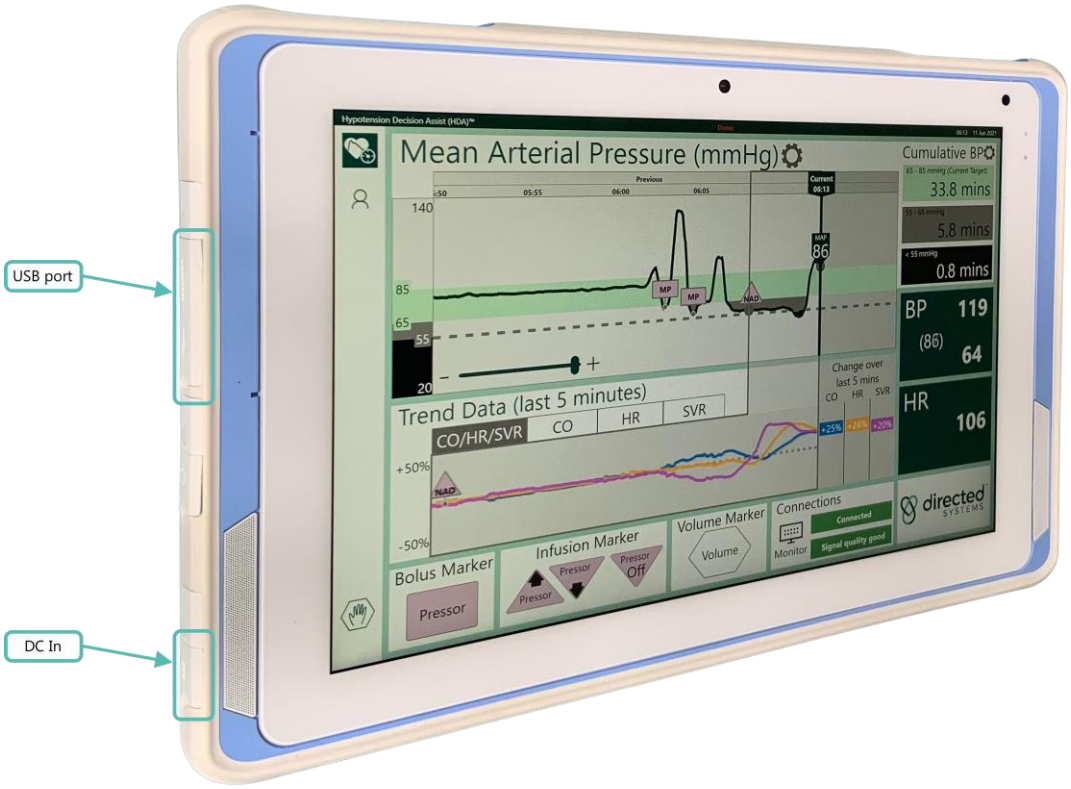


Figure 8: *Inputs and Outputs on Advantech Medical Computer*

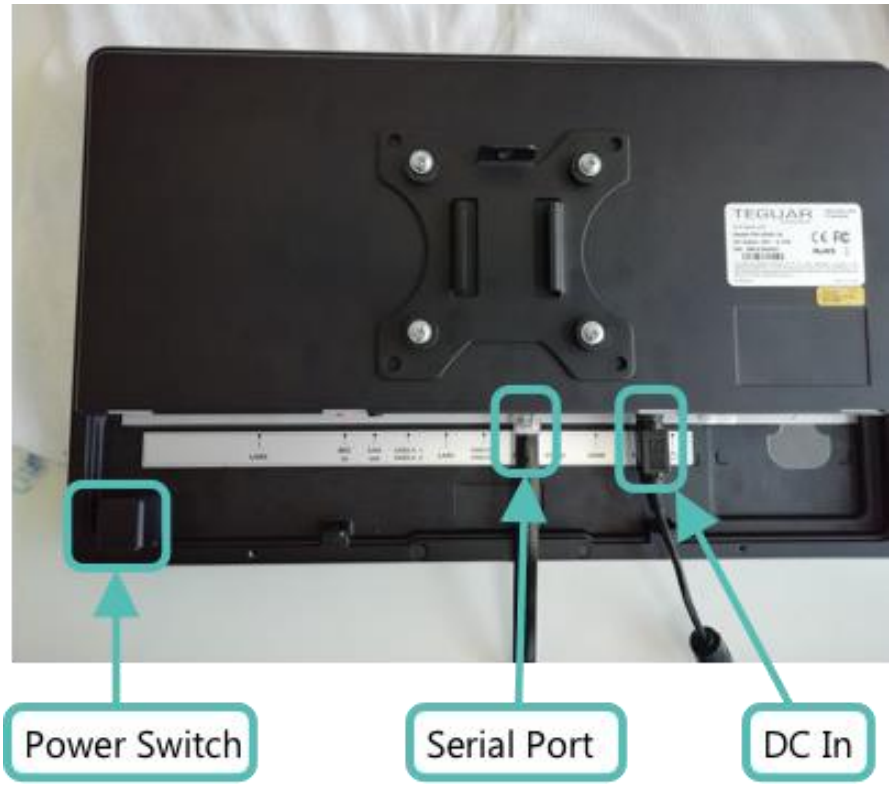


Figure 9: *Inputs and Outputs on Teguar Medical Computer*

PART 3: ICONS DISPLAYED BY HDA

Icons displayed by HDA are listed in Table 2 with their meaning.

Icon	Meaning
	Warning
	Check
	Bolus marker
	Infusion decrease marker
	Infusion increase marker
	Infusion stopped marker
	Volume marker
	Show main screen
	Show patient info & settings screen
	Configure marker formulary
	Configure date and time
	Export log files to USB
	Configure element
	Monitor connection
	Stop monitoring session

Table 2: *Icons displayed by HDA*

PART 4: PREPARING HDA FOR USE

This section describes how to prepare the HDA system for use.

Warning
HDA is intended for use exclusively in the operating room.

Warning
Before using the HDA system, read all warnings, cautions and instructions provided.

Warning

Do not set up HDA in a MR environment.

Periodic Inspection

As a minimum, the HDA system and its connection cables should be visually inspected annually, irrespective of use. The inspection should check for:

- Damage to the display monitor.
- Damage to the power cord.
- Damage to the cable connecting HDA to operating room multiparameter patient vital signs monitors.
- Damage to sockets that interferes with the correct positioning and mating of connection cables.

Warning
Do not use the HDA system if it, or the supplied connection cables, are damaged. Please contact Directed Systems Limited for assistance.

Initial Setup by OR Technician (HDA installed on Teguar all-in-one)

1. The relevant VESA mount should be attached to the Touch Screen Computer).
2. An arm and pole clamp should be attached to the VESA adapter (see Figure 8).
3. The power block should be connected to a mains socket using the supplied cord, and to the DC In socket on the Touch Screen Computer.
4. Philips Monitors
    a. Connecting via serial cable: the Philips serial cable should be connected to the COM1 serial port socket on the Touch Screen

Computer and to the RS232 port socket on the Philips Monitor (see Figure 8).

b. Connecting via a wired network: connect HDA to the network using an ethernet.

5. GE Monitors– the GE serial cable should be connected to the COM1 serial port on the Touch Screen Computer and to the USB port socket on the GE Monitor (see Figure 8).

Initial Setup by OR Technician (HDA installed on Advantech tablet)

1. An arm and pole clamp should be attached to the tablet.
2. The power block should be connected to a mains socket using the supplied cord, and to the DC In socket on the Tablet's dock.
3. Philips Monitors
    a. Connecting via serial cable: the Philips serial cable should be connected via the serial cable to the serial port on the Tablet's dock and to the RS232 port socket on the Philips Monitor (see Figure 8).
    b. Connecting via wireless network[2]: from the Windows login screen, tap the network icon and select the network that the IntelliVue monitor is connected to and enter the password.
    c. Connecting via a wired network: connect HDA to the network using an ethernet cable and Ethernet-USB adapter.
4. GE Monitors– the GE serial cable should be connected via a USB-serial adapter and serial cable to the serial port on the Tablet's dock and to the USB port socket on the GE Monitor (see Figure 8).

Powering up HDA

Once setup and connected to the OR multiparameter patient vital signs monitor, HDA can be switched on and configured for use.

The Advantech Medical Computer can be turned on using the switch located in the bottom right corner on the back of the monitor.

The ON/OFF switch is located on the rear of the Teguar model (see Figure 9).

[2] In order to connect on a hospital or other vendors network please first check with the hospital IT department and/or the respective vendor if specific network compliance requirements apply.

PART 5: CONFIGURING HDA

On power up, the "Launch Screen" (see Figure 10) will be displayed.

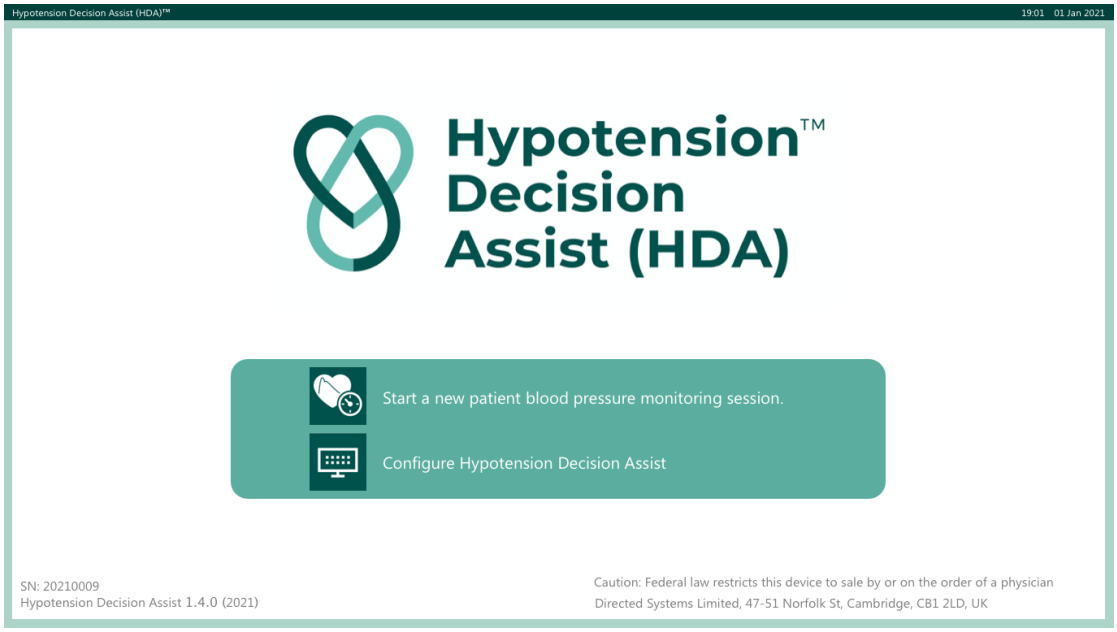


Figure 10: *"Launch Screen" display*

The "Launch Screen" presents the user with two options:

1. "Start a new blood pressure monitoring session"
2. "Configure Hypotension Decision Assist"

The Configure Hypotension Decision Assist option allows selection of the patient monitor, changing the brightness of the display screen, setting the display time and configuring the medication markers.

Selecting the Patient Monitor

To select the patient monitor, press the monitor connection button. 

The "Configuration Screen" will be displayed (see Figure 11)

Advice
Enter the passcode provided by Directed Systems when prompted.

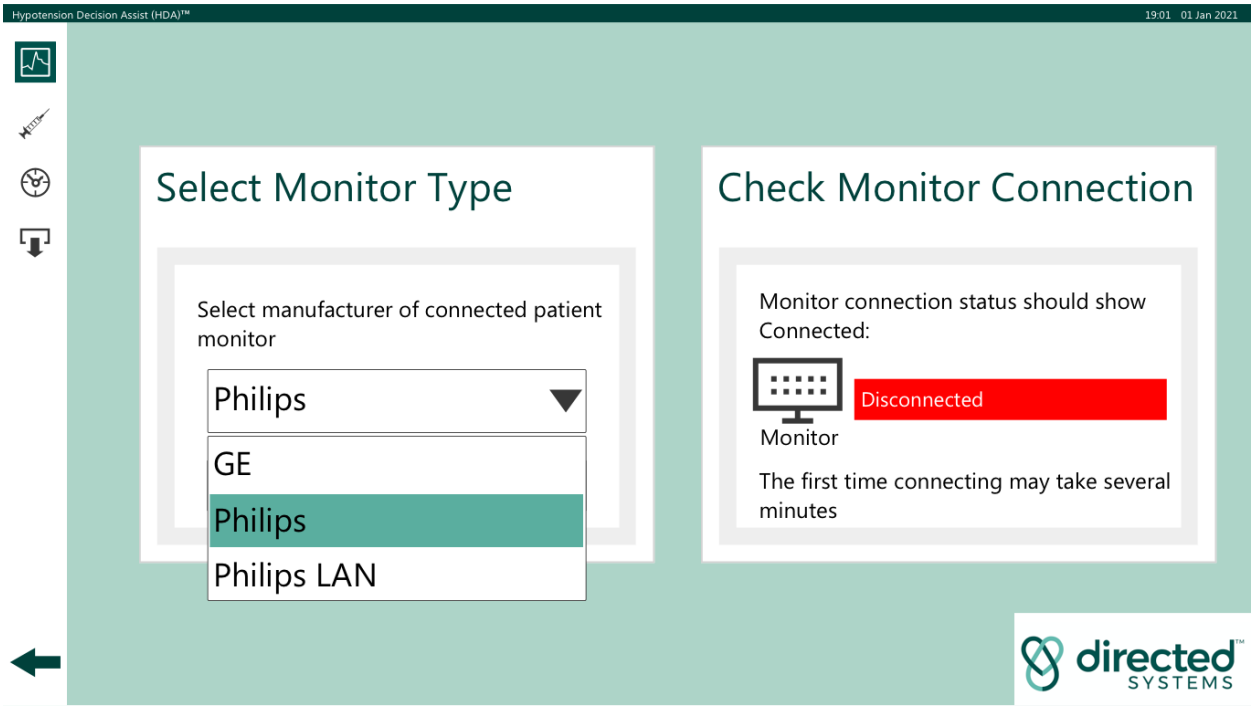


Figure 11: *"Configuration Screen" display*

Using the drop-down menu in the window marked "Configuration", select the type of multiparameter patient vital signs monitor to which HDA is connected (see Figure 12).

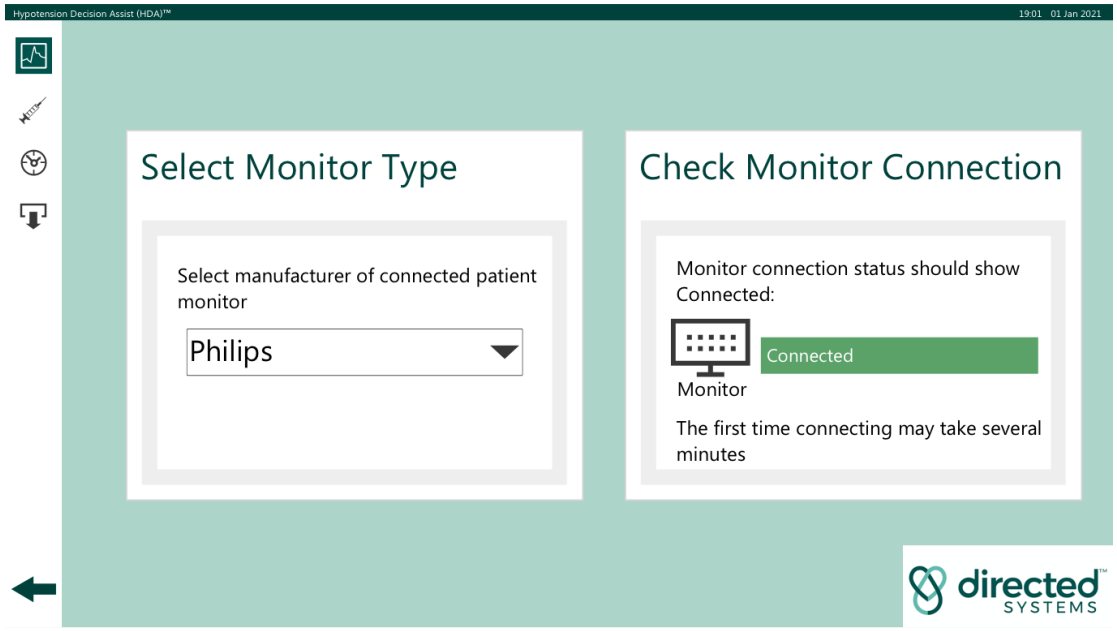


Figure 12: *"Configuration Screen" with GE vital signs monitor selected*

The window marked "Check Monitor Connection" will display a green "Connected" message when a successful connection has been detected.

A red "Connecting" message will be displayed when establishing a connection and "No Connection" will be displayed in red if no connection to the patient monitor is detected.

Pressing "SAVE AND EXIT" selects the chosen monitor and returns to the "Launch Screen".

Screen Brightness

The brightness of the display screen can be adjusted (increased or decreased) by using the slider at the bottom of the "Patient Information and Settings" screen (see part 6). Touching and moving the slider to the right increases the screen brightness. Touching and moving the slider to the left decreases the screen brightness. The default setting for screen brightness is with the slider at the mid-point.

Setting the Display Time

The time and date displayed by HDA can be configured to match the local time. Touching the  icon in the menu side bar will open the Configure Date and Time screen (see Figure 13) where the date, time and time zone can be set using the touch screen.

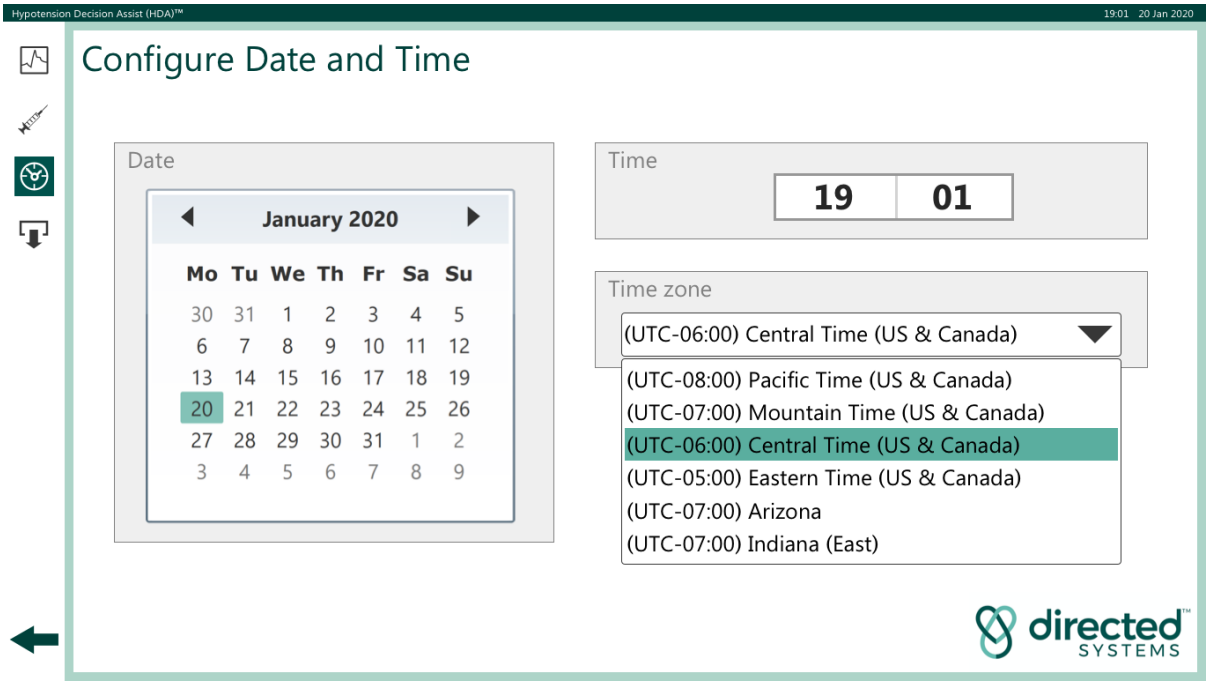


Figure 13: *Configuring the display time*

Configuring the Markers

The bolus and infusion markers can be configured to match the local formulary. Touching the icon  in the menu side bar will open the Configure Marker Formulary screen (see Figure 14).

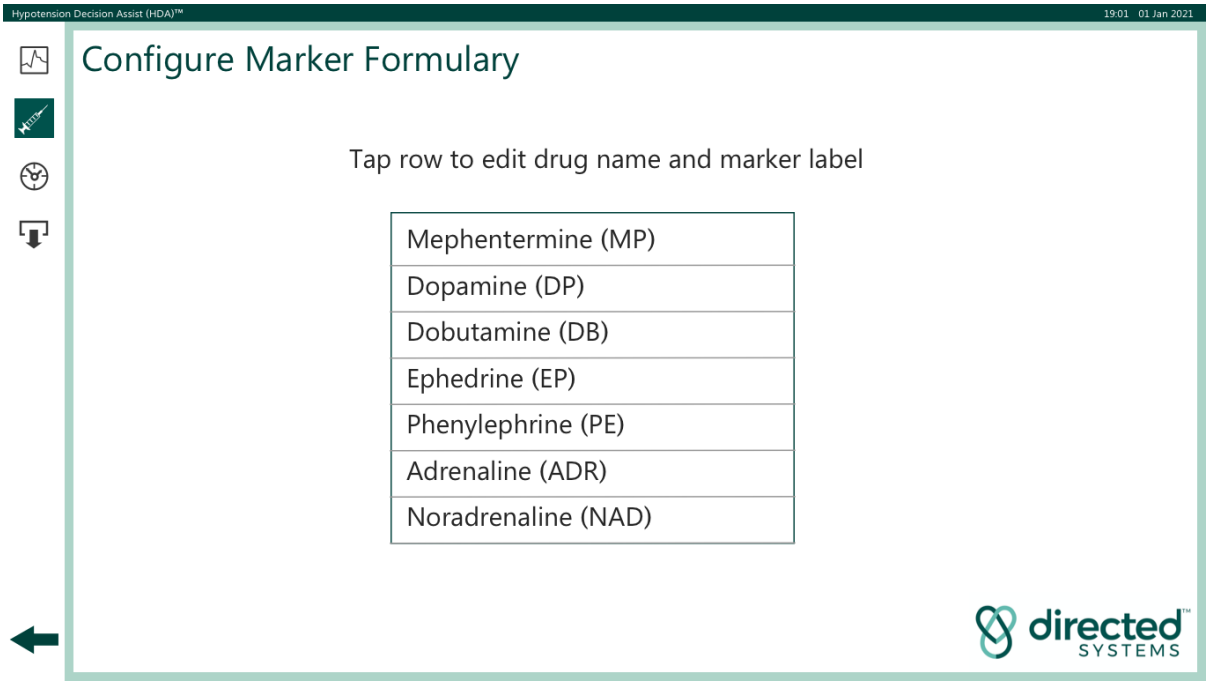


Figure 14: *Configure Marker Formulary Screen*

Touching any row transitions the screen to an editing mode (see Figure 15) where the keyboard can be used to change a drug name and add an associated marker label. Touching "Discard Changes" will close the screen without changing the existing formulary configuration. Touching "Save changes" will close the screen and add the new drug name and associated marker to the formulary.

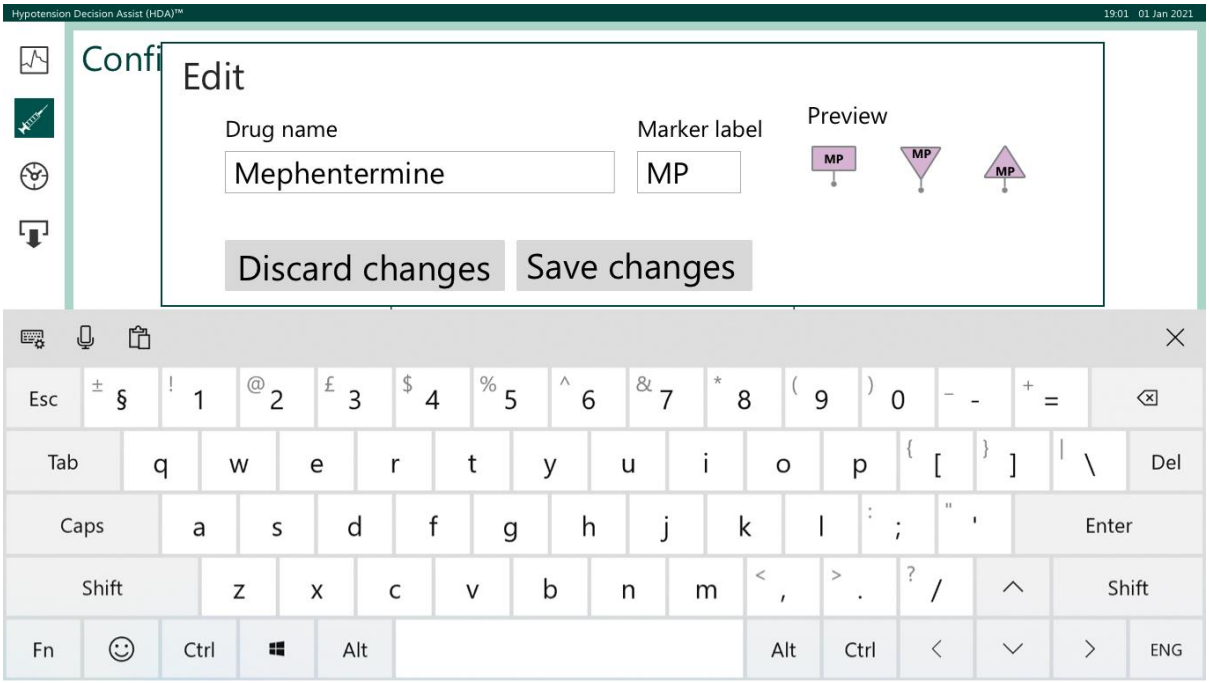


Figure 15: *Editing the Formulary*

Advice

The marker label must be unique. The system will not allow the addition of a marker label that is a duplicate

Exporting log files to USB drive

The data generated by and input to HDA is saved to internal storage as log files. Touching the icon in the menu side bar will open the Export Log Files screen (see Figure 16).

Use the list on the left to select the log files you would like to export. Logs files already exported to the attached USB drive are not shown.

If you select the check box "Delete logs from HDA", then HDA will delete the log files from its internal storage after the logs are exported.

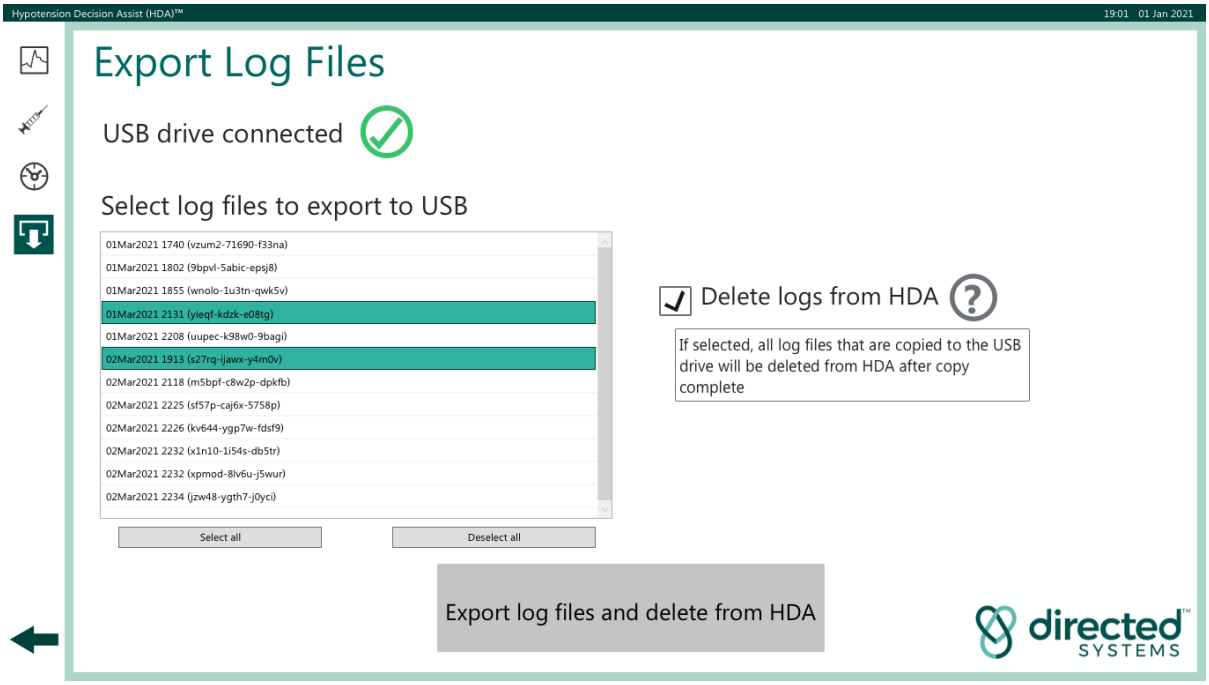


Figure 16: *Exporting (and deleting) log files*

After exporting log files, the exported log files are listed (see Figure 17). If any log files failed to export, these are listed separately (see Figure 18).

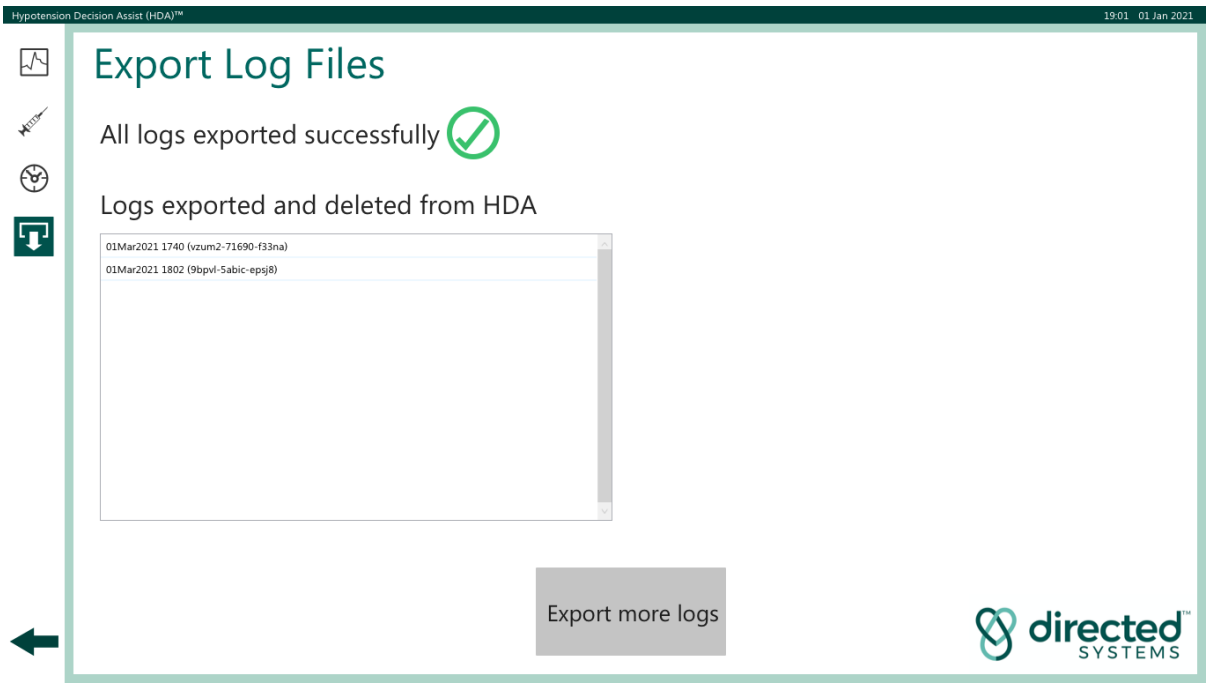


Figure 17: *Exporting (and deleting) log files, successful export*

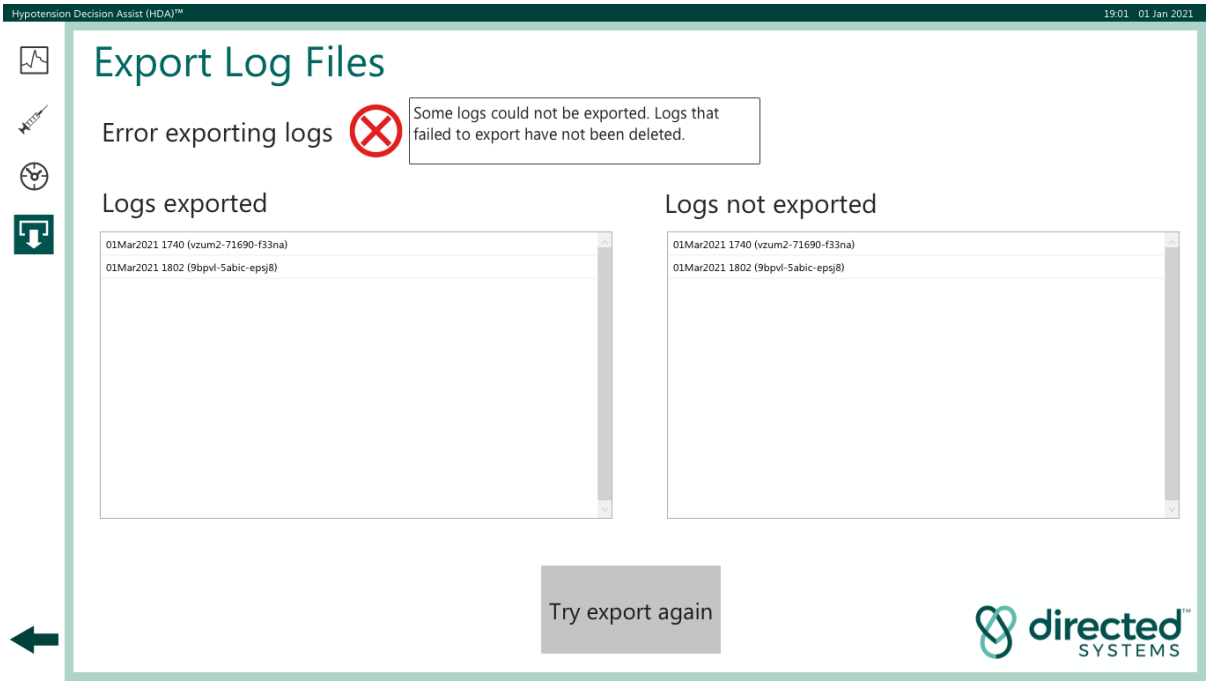


Figure 18: *Exporting (and deleting) log files, export with error*

PART 6: USING HDA

Warning
If using the Teguar model, it does not have an internal battery. Disconnecting from the mains power will end the patient session

Starting a new blood pressure monitoring session

To start a new blood pressure monitoring session, select "Start a new BP monitoring session" on the "Launch Screen". Either the text or the icon may be touched. The main screen will then appear, (see Figure19). Initially, this shows the numeric values computed from the incoming data.

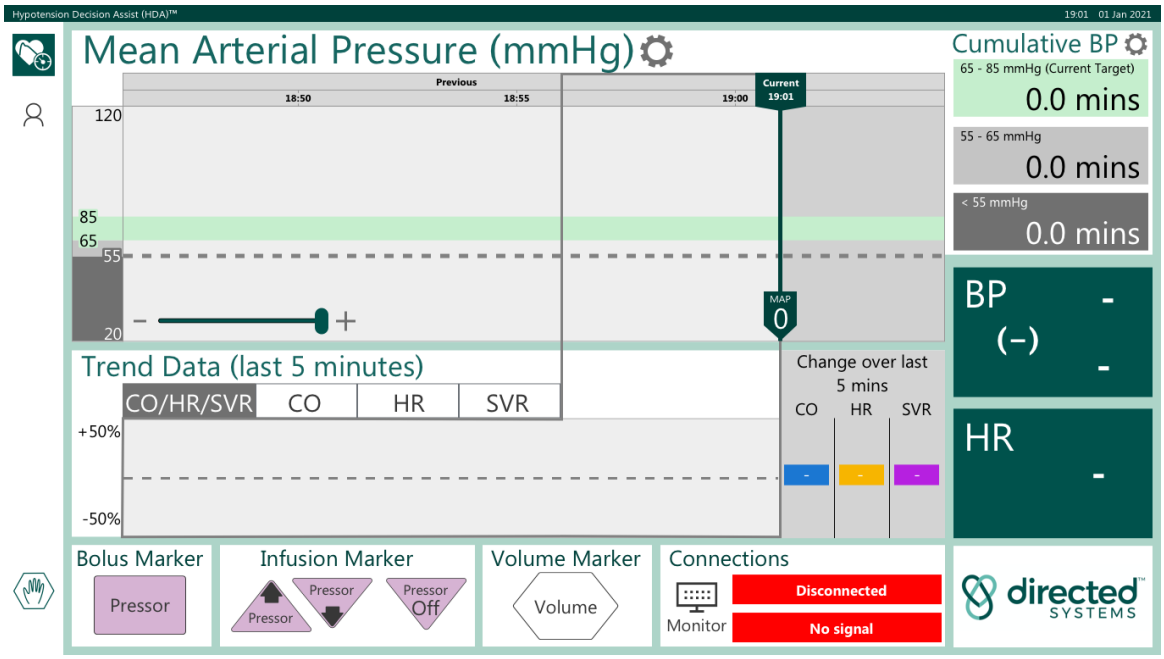


Figure 19: *"Running Mode" display screen initially*

Figure 20 shows the main screen after 90 minutes of the patient session.

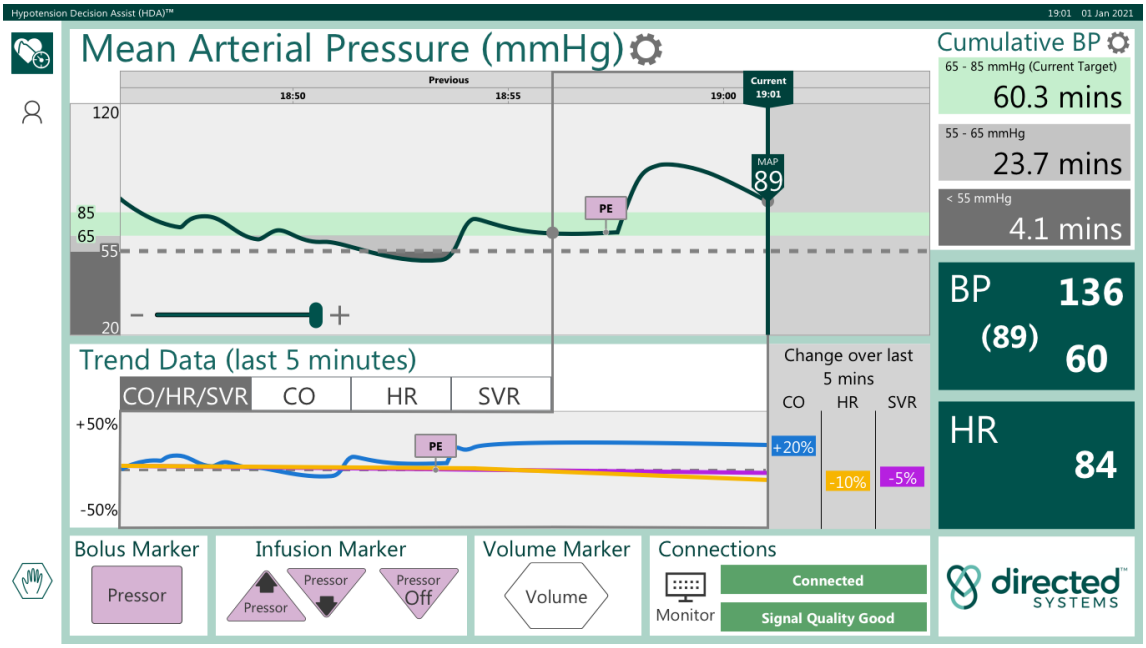


Figure 20: *"Running Mode" display screen after the session has been running for 30 minutes*

The "Running Mode" screen displays MAP in the upper panel. Trend data (previous five minutes) for percentage changes in the selected parameter (CO/HR/SVR) are displayed in the lower panel. The percentage change over the last 5 minutes of the selected parameter(s) is displayed immediately adjacent to the right of the trend display panel.

The default parameter displayed in the trend window is a combined view of CO, HR, and SVR, individual trends can be viewed by tapping each of the tabs, labelled "CO", "HR", and "SVR" in the Trend Data panel. The information in the other windows in this screen are described in subsequent sections of this user manual.

Patient Information

To enter details of the patient being monitored, including adjusting the target blood pressure range, touch the patient set-up icon on the toolbar on the left-hand side of the display screen.

The "Patient Information and Settings" screen will appear. The icon will change to . Figures 21 & 22 show the screen before and after input of patient data.

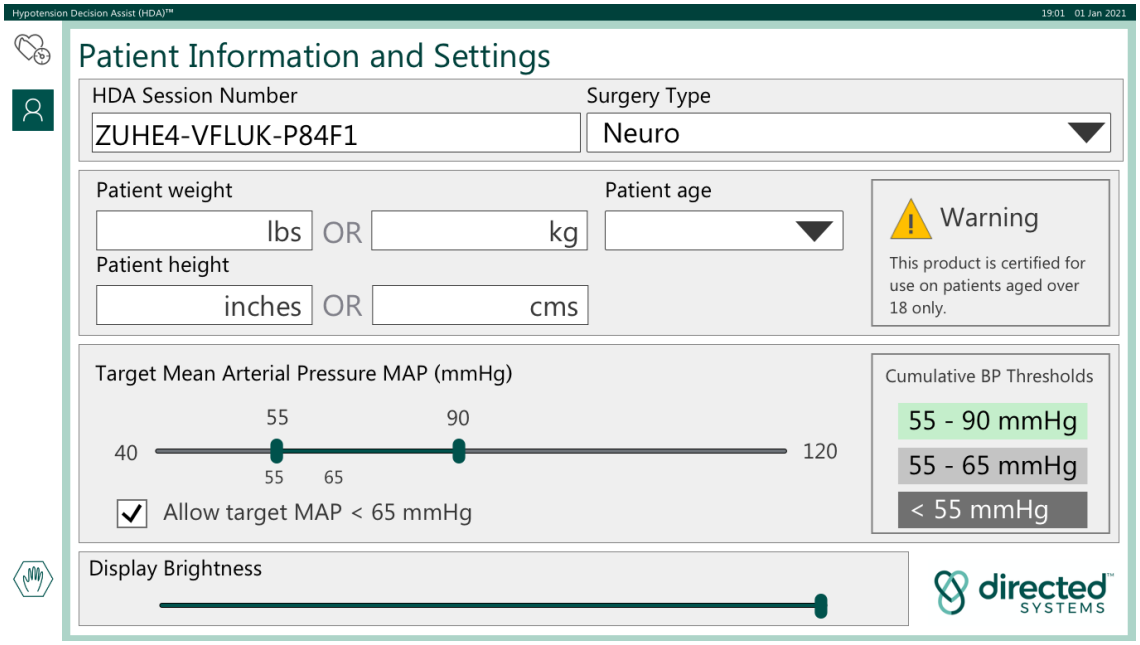


Figure 21: *Patient Information and Settings screen*

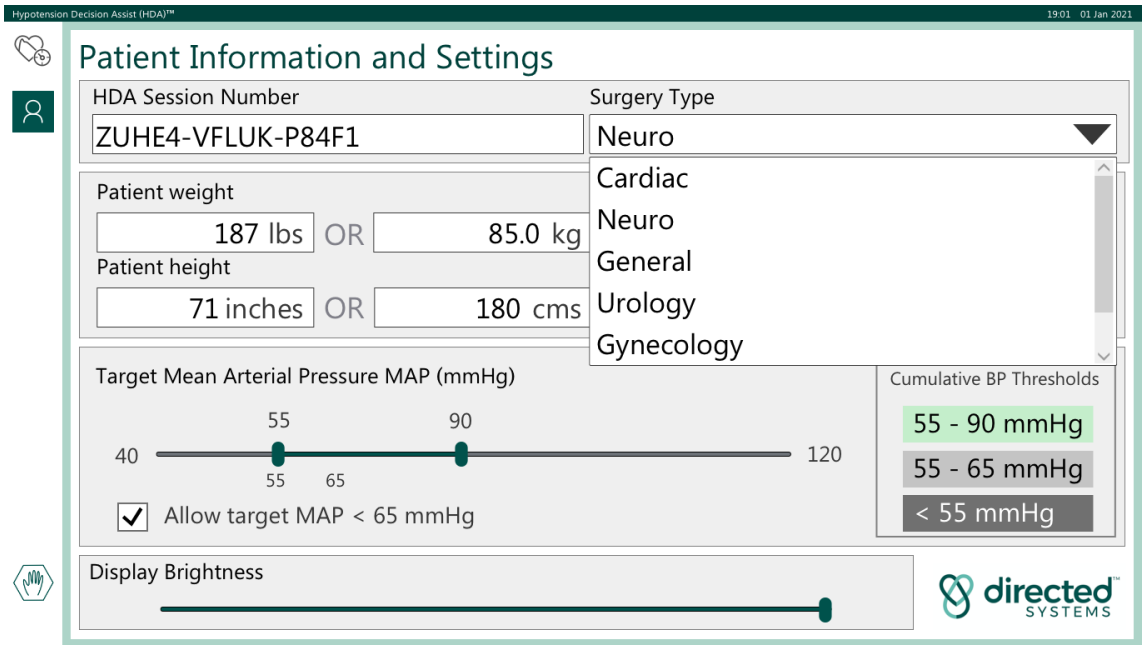


Figure 22: *Patient Information and Setting Screen populated*

Warning

HDA system is certified for use on patients aged 18 years or older only.

Warning

Use of the HDA system is contraindicated in the following groups:

- Patients with aortic regurgitation;
- Patients fitted with an intra-aortic balloon pump (IABP);

The "Patient Information and Settings" screen enables patient demographics to be entered and/or edited at any time throughout the monitoring session. Patient

weight can be entered in either pounds or kgs. Patient height can be entered in inches or centimeters.

Valid range values for each of the patient demographic entry fields are listed in Table 3.

Parameter	Units and Valid Ranges	
Patient Weight	20 to 300 pounds	9 to 136 kg
Patient Height	24 inches to 72 inches	61 cm to 183 cm
Patient Age	18-90 years	

Table 3: *Units and Valid Ranges for Patient demographic information*

Surgery type can be selected from a drop-down list of common surgical categories.

Ages are binned into the following ranges: 18-19, 20-24, 25-29, …80-84, 85-89, >=90.

Setting Target Blood Pressure Ranges

Target ranges for blood pressure can be set from the "Patient Information and Settings" window. Upper and lower target levels for blood pressure can be set using the range slider located in the display window entitled "Patient Target Blood Pressure Range".

The target range can be varied between 40mmHg and 120mmHg by touching the slider and moving it horizontally to the value required. Moving the slider to the right increases the value. Moving the slider to the left decreases the value. The value selected will be indicated above the slider thumb.

By default, when you start a Patient Session, the MAP target range is limited to >65 mmHg. To over-ride this and enable setting a MAP target range lower than 65 mmHg, tick the check box "Allow target MAP < 65 mmHg".

The HDA default setting for severe hypotension is <55mmHg.

Advice
The warning level of 55mmHg on the main screen is fixed and cannot be changed.

Press the icon to save the patient information and return to the main screen.

Configuring Mean Arterial Pressure (MAP) Plot Y-Limits

Press the icon next to "Mean Arterial Pressure (MAP)" to configure the y-limits of the MAP plot by dragging the Max and Min sliders (see Figure 23).

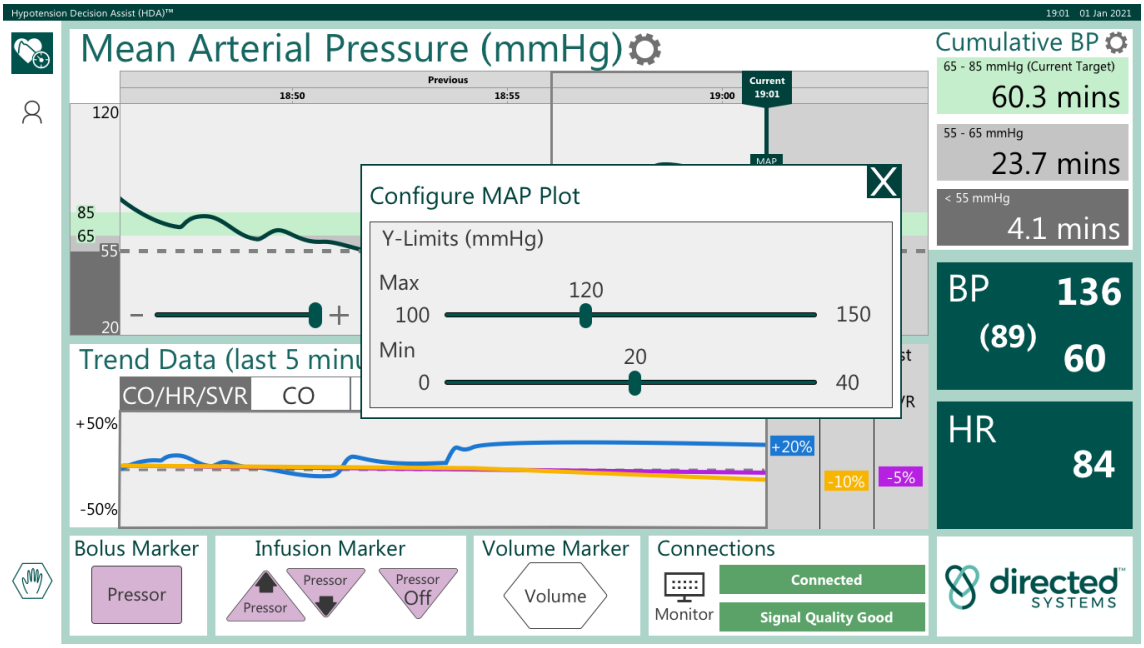


Figure 23: *MAP plot y-limits configuration dialog*

Configuring Hypotension Highlights Contrast

Press the ⚙ icon next to "Cumulative BP" to select a low or high contrast color scheme for the highlighting of hypotensive MAP values (see Figure 24).

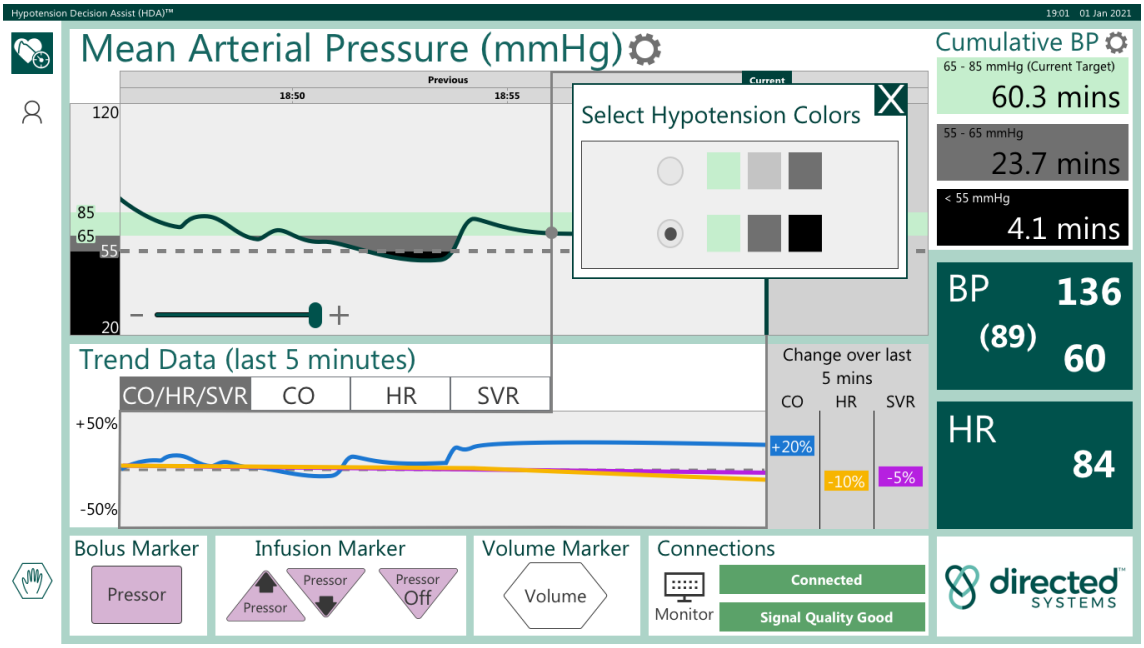


Figure 24: *Hypotension highlights configuration dialog, showing the high contrast color scheme selected*

PARAMETERS DISPLAYED BY HDA

HDA determines systolic blood pressure (SBP), diastolic blood pressure (DBP), MAP and heart rate (HR) from the arterial wave signal obtained from the vital signs monitor.

Artefacts, such as those due to line flushing and transducer zeroing, are removed from the signal and the results passed through a 30 second smoothing filter. The current values of these parameters are displayed in the right-hand panel. See below for more information on artefact handling by HDA.

A chart of MAP is displayed in the upper panel (as described above).

SBP, MAP, DBP and HR should be interpreted in the usual clinical way. Their accuracy is:

- SBP, MAP, DBP ± 4 mmHg
- HR ± 1 bpm

Cumulative BP Thresholds

The "Cumulative BP Thresholds" panel located in the upper right of the main "Running Mode" screen contains three icons that show the current target range and thresholds for moderate and severe hypotension. These are highlighted on the main MAP trace by color.

Recent Changes in Cardiac Output (ΔnCO)

The Liljestrand and Zander[3] algorithm is used by HDA to compute an estimate of nominal cardiac output (nCO) from the arterial pressure waveform. The values of nCO over the last five minutes are compared with a baseline value at the start of the latest five-minute period (ΔCO) and expressed as a percentage change which is plotted on the HDA trend display.

The percentage difference between the current and baseline values is also displayed numerically. This percentage difference is approximately the same percentage difference that would be calculated if a calibrated CO value had been used, as the calibration coefficient approximately cancels out in the percentage difference formula between baseline and current values. If there are periods where the arterial pressure signal quality is too low to compute ΔCO, the ΔCO trend chart will include gaps.

The accuracy of the Liljestrand and Zander formula in estimating cardiac output and its trend changes has been evaluated by Sun *et al*., (2009)[4], Monge Garcia *et al*., (2013)[5], Zhang *et al*., (2015)[6] and Caillard *et al*., (2015)[7].

Caillard *et al*., (2015)[6] concluded: '*Liljestrand-Zander showed the best*

[3] Caillard A, Gayat E, Tantot A, Dubreuil G, M'Bakulu E, Madadaki C, Bart F, Bresson D, Froelich S, Mebazaa A, Vallée F. Comparison of cardiac output measured by oesophageal Doppler ultrasonography or pulse pressure contour wave analysis. Br J Anaesth 2015; 114: 893-900
[4] Sun JX, Reisner AT, Saeed M, Heldt T, Mark RG. The cardiac output from blood pressure algorithms trial. *Crit Care Med* 2009; **37**: 72-80
[5] Monge García MI, Romero MG, Cano AG, Rhodes A, Grounds RM, Cecconi M. Impact of arterial load on the agreement between pulse pressure analysis and esophageal Doppler. *Crit Care* 2013; **17(3)**: R113
[6] Zhang J, Critchley LA, Huang L. Five algorithms that calculate cardiac output from the arterial waveform: a comparison with Doppler ultrasound. *Br J Anaesth* 2015;**115**: 392-402
[7] Caillard A, Gayat E, Tantot A, Dubreuil G, M'Bakulu E, Madadaki C, Bart F, Bresson D, Froelich S, Mebazaa A, Vallée F. Comparison of cardiac output measured by oesophageal Doppler ultrasonography or pulse pressure contour wave analysis. *Br J Anaesth* 2015; **114**: 893-900

performance, namely the lowest error rate and greater concordance with DCO value for static value and after therapeutic intervention, especially after use of vasopressors'.

Warning

In patients with cardiac arrhythmias, use of the Liljestrand and Zander algorithm for the calculation of CO may result in inaccurate values.

Therefore, in situations involving a patient with diagnosed or suspected cardiac arrhythmia it is essential that an appropriately qualified physician determines the clinical value and reliability of the CO values displayed by HDA.

Recent Changes in Systemic Vascular Resistance (ΔSVR)

HDA uses a measure of total systemic vascular resistance (TSVR) to compute the recent changes in systemic vascular resistance (SVR). TSVR is defined as:

$$TSVR = 80 * \frac{MAP}{CO}$$

The conventional definition is:

$$SVR = 80 * \frac{MAP - CVP}{CO}$$

Atlas *et al*., (2010)[8] showed mathematically that changes in TSVR are approximately equal to changes in SVR (ΔTSVR ≈ ΔSVR). They also showed that in a series of ICU patients, "*there was also a high degree of correlation (ranging from 94 to 100%) noted between the hour-to-hour change in SVRi with the hour-to- hour change in TSVRi (P<0.0001). The results, of this pilot study, support the premise that the use of CVP may not always be necessary for afterload evaluation in the clinical setting*."

The values of nSVR over the last five minutes are compared with a baseline value at the start of the latest minute period (ΔnSVR) and expressed as a percentage change which is plotted on the HDA trend display.

The percentage difference between the current and baseline values is also displayed numerically.

The changes in CO and SVR, combined with the values and trends in MAP, HR and other clinical factors may be used to help assess the patient's cardiovascular state and select appropriate cardiovascular treatments.

See the information on the accuracy of the Liljestrand and Zander formula in the previous section on recent changes in cardiac output which is incorporated in the computation of SVR.

[8]Atlas G, Berger J, Dhar S. Afterload assessment with or without central venous pressure: A preliminary clinical comparison. *Cardiovasc Eng* 2010; **10(4)**: 246–252

Artefacts Detected by HDA

Prior to applying 30 seconds smoothing, HDA tests for a range of artefacts in the incoming arterial waveform and removes them if present prior to smoothing. The complete list of artefacts detected by HDA is shown in Table 4.

Artefact	Potential Impact on HDA Performance
Systolic pressure >300 mmHg	Maximum physiological range.
Diastolic pressure <20 mmHg	Minimum physiological range. This may also indicate a damped arterial transducer.
Pulse pressure <20 mmHg	Minimum physiological range. This may also indicate a damped arterial transducer.
Mean arterial pressure <30 mmHg	Minimum physiological range. This may also indicate a damped arterial transducer.
Mean arterial pressure >200 mmHg	Maximum physiological range.
Heart rate < 20 bpm	Minimum physiological range.
Heart rate > 200 bpm	Maximum physiological range.
High frequency noise $\eta < -40\ mmHg/100ms$	High frequency noise may correspond to arterial transducer under-damping.
$\Delta P_{sys} > 20\ mmHg$	Change of systolic pressure between any 2 successive beats >20 mmHg. Such events may be caused by intermittent arrythmias. Inclusion of the features of such beats may result in an inaccurate measurement of the parameters displayed by HDA.
$\Delta P_{dia} > 20\ mmHg$	Change of diastolic pressure between any 2 successive beats >20 mmHg. Such events may be caused by intermittent arrythmias. Inclusion of the features of such beats may result in an inaccurate measurement of the parameters displayed by HDA.
$\Delta T > \frac{2}{3} sec$	Change of heart period between any 2 successive beats >0.667 seconds. Such events may be caused by intermittent arrythmias. Inclusion of the features of such beats may result in an inaccurate measurement of the parameters displayed by HDA.
Zeroing Arterial pressure <10 mmHg for >=10 s	The number of non-abnormal beats in the 30 second filter reduces as the artefact continues. When there are less than 6 non-abnormal beats in the last 30 seconds, HDA indicates a signal quality error, and parameters are not displayed. A very low constant blood pressure will occur during zeroing of the transducer.
Flushing Arterial pressure >180 mmHg for >=10 s	The number of non-abnormal beats in the 30 second filter reduces as the artefact continues. When there are less than 6 non-abnormal beats in the last 30 seconds, HDA indicates a signal quality error, and parameters are not displayed. A very high constant blood pressure will occur during line flushing or clamping.

Table 4: *Artefacts Detected by HDA and Potential Impact on HDA Performance*

During flushing or zeroing of the arterial line (and other long artefact events), HDA will not compute parameters and a warning message will be shown (see Section on Low Signal Quality for more information). The numerics will display the symbol "-". When the event is over, and there is a good quality signal, calculation and display of these parameters will resume automatically.

The screen will show a gap in the MAP and 5-minute recent trend charts for CO, HR and SVR corresponding to the duration of the event, as shown in Figure 25 and Figure 26.

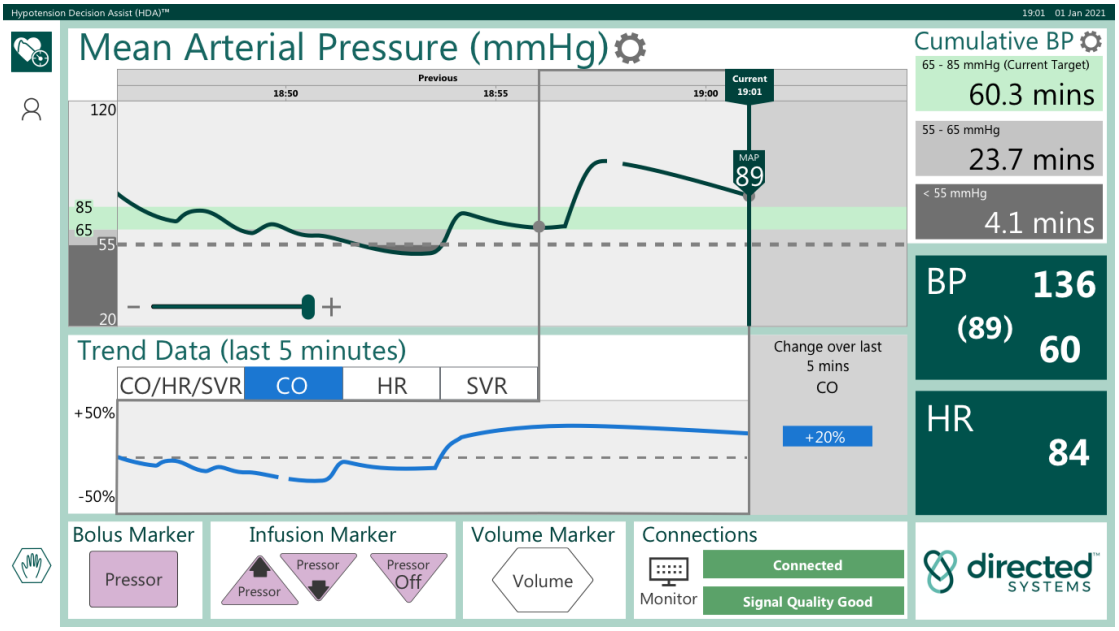


Figure 25: *Gap in the recent 5-minute trend chart for CO*

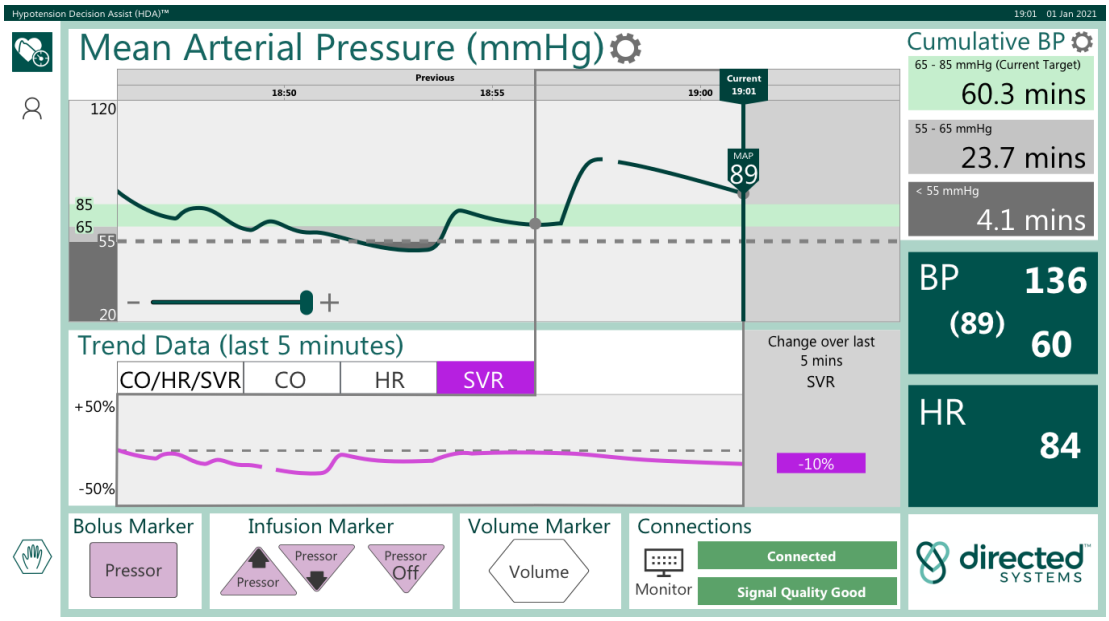


Figure 26: *Gap in the recent 5-minute trend chart for SVR*

Warning

Following flushing or zeroing there may be re-scaling of blood pressure parameters. This may affect the accuracy of the CO and SVR changes. Under these circumstances, the value of CO and SVR immediately after the flushing or zeroing should be taken as the baseline value, until such time as the gap reaches the left-hand side of the 5-minute trend window.

Setting Marker Labels

Marker labels can be entered on the screen display and data record to record/annotate specific events such as the bolus delivery of a drug. Instructions for configuring the marker labels to match the local formulary are provided in Part 5.

Activation buttons for "Bolus Marker", "Infusion Marker" (up or down) and "Volume Marker" are located at the bottom left of the main display screen when in "Running Mode" (see Figure 27).

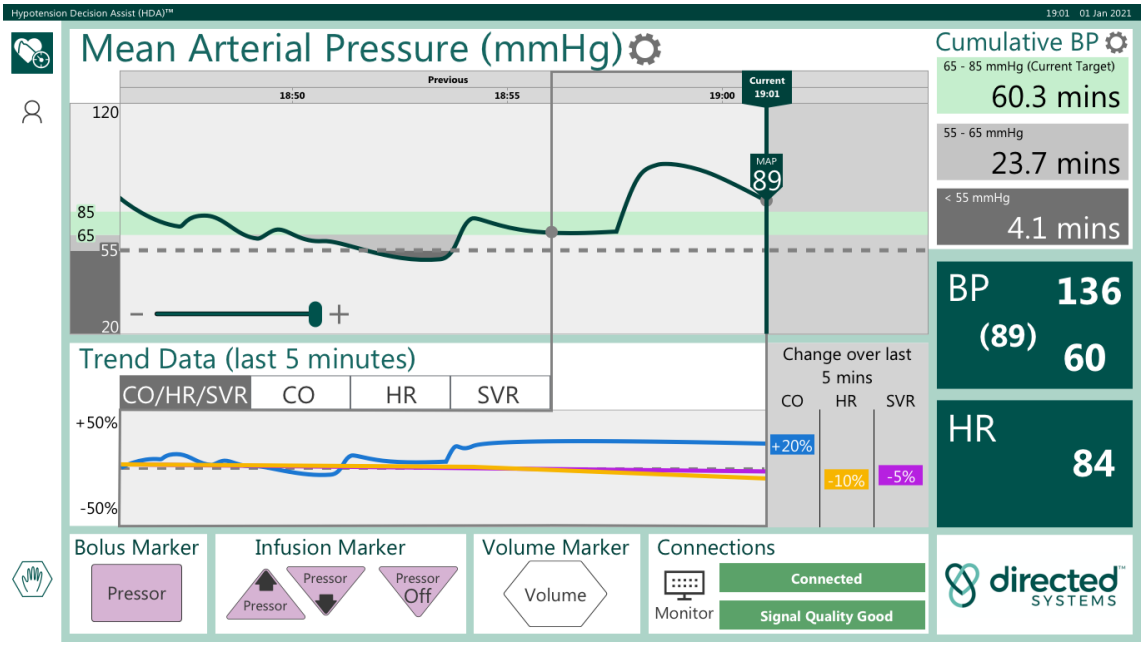


Figure 27: *Marker Label activation buttons*

Bolus Marker

To add a bolus marker to the display and data record, touch the "Bolus Marker" button. A pop-up screen will appear in the left of the main display (see Figure 28) which includes a list of routinely used vasopressors (which will be pre-configured for your site).

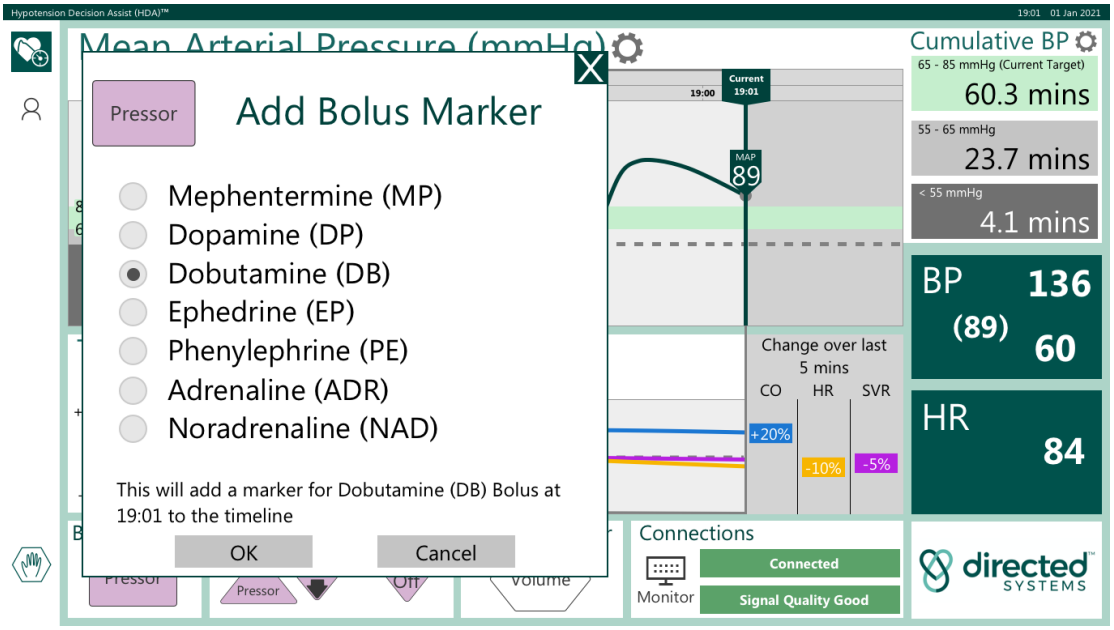


Figure 28: *Bolus Marker screen*

The list specifies the formal name of the vasopressor, the standard color of vials containing the drug and the abbreviated name that will be displayed on the drug label added to the timeline when the bolus marker is activated. The vasopressor administered can be selected from the menu displayed. Touching the "OK" button adds a bolus marker, Pressor , with the 3-letter drug abbreviation, to the display screen as well as recording the event and time in the data record. The command can be cleared by touching the "Cancel" button.

Advice
Only one vasopressor can be selected at a time.

Infusion Marker

To add an infusion marker to the display and data record, touch the "Infusion Marker" button (up or down). A pop-up screen will appear in the left of the main display. As with the bolus marker, a list of routinely used vasopressors is presented on the screen.

Markers can be added to the screen display and data record for both increases and decreases in the infusion rate of drugs delivered to the patient during the blood pressure monitoring session. A marker for an increase in the rate of drug infusion can be added using the Pressor icon (see Figure 29).

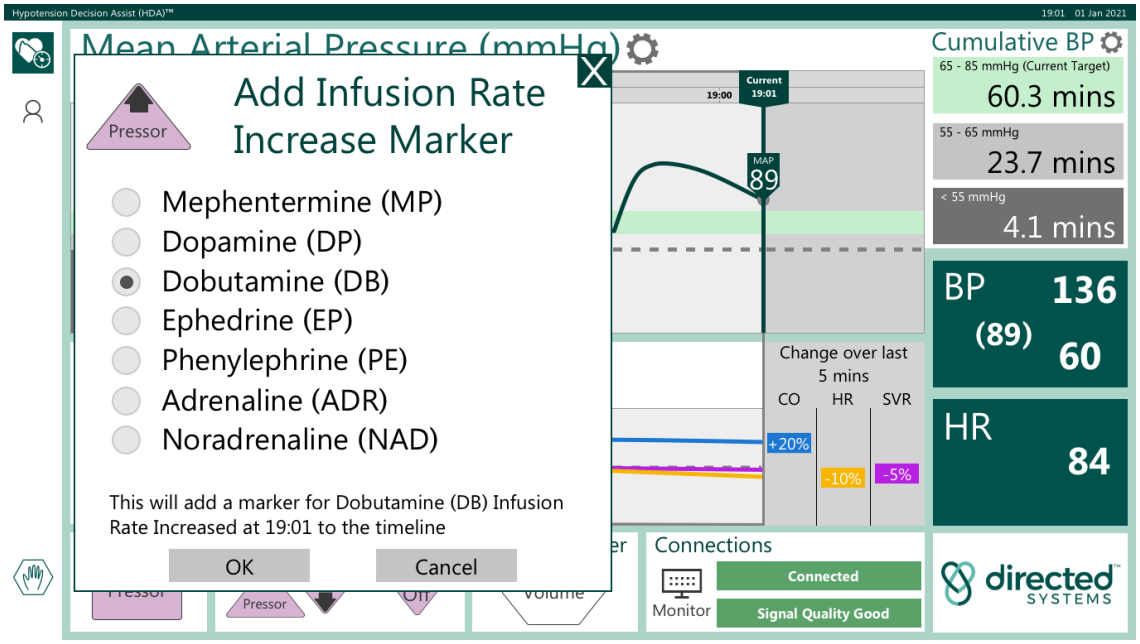


Figure 29: *Infusion rate increase marker screen*

Conversely, a decrease in the rate of drug infusion can be marked by using the Pressor icon (see Figure 30).

Advice

Only one vasopressor can be selected at a time.

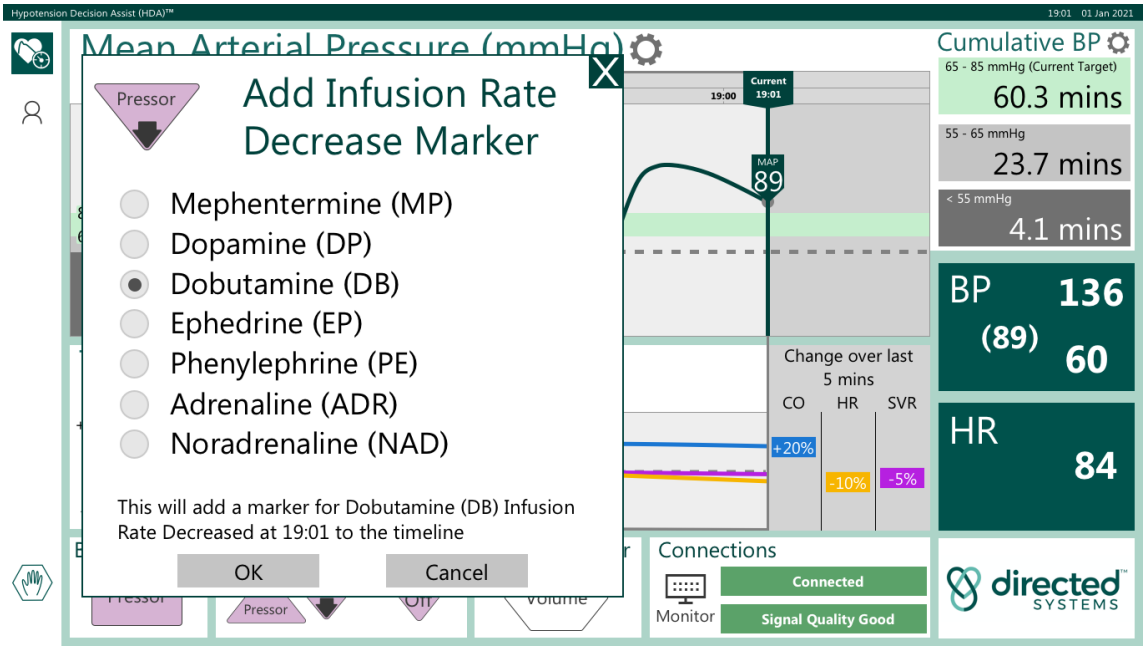


Figure 30: *Infusion rate decrease marker screen*

Finally, a drug infusion that has been stopped can be marked by using the Pressor Off icon (see Figure 31).

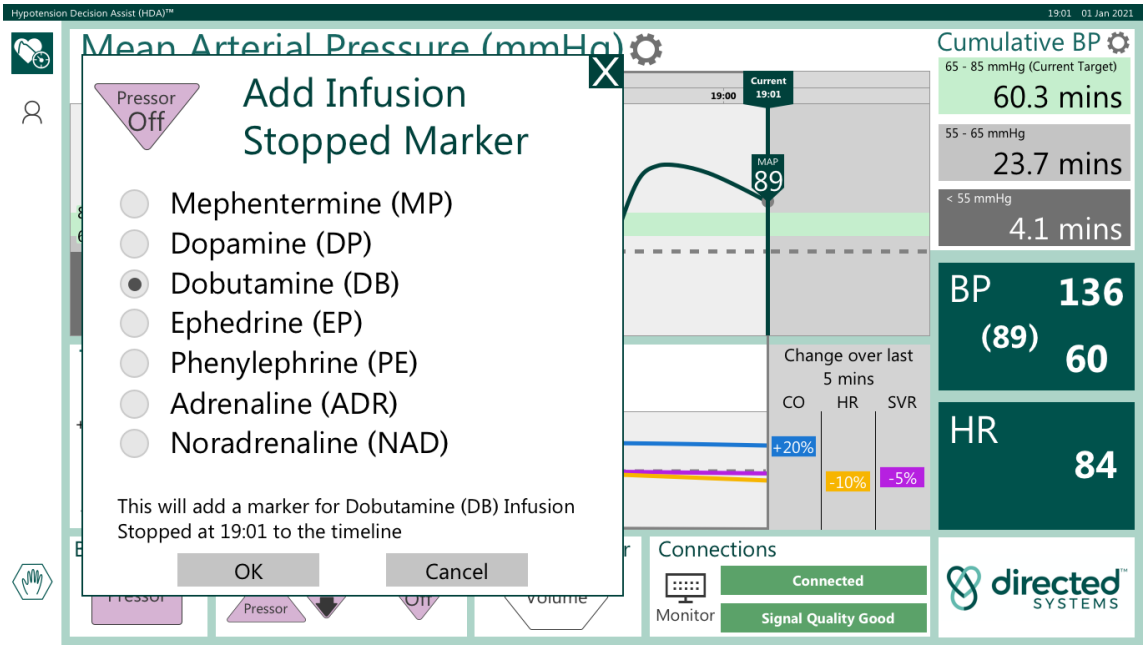


Figure 31: *Infusion stopped marker screen*

The list specifies the formal name of the vasopressor, the standard color of vials containing the drug and the abbreviated name that will be displayed on the drug label added to the timeline when the marker is activated. Touching the "OK" button adds a marker to the display screen and records the event and time in the data record. The command can be cleared by touching the "Cancel" button.

Volume Marker

To add a marker signifying a volume challenge has been initiated, touch the "Volume Marker" Volume icon. A pop-up screen will appear in the top left quadrant of the main display (see Figure 32).

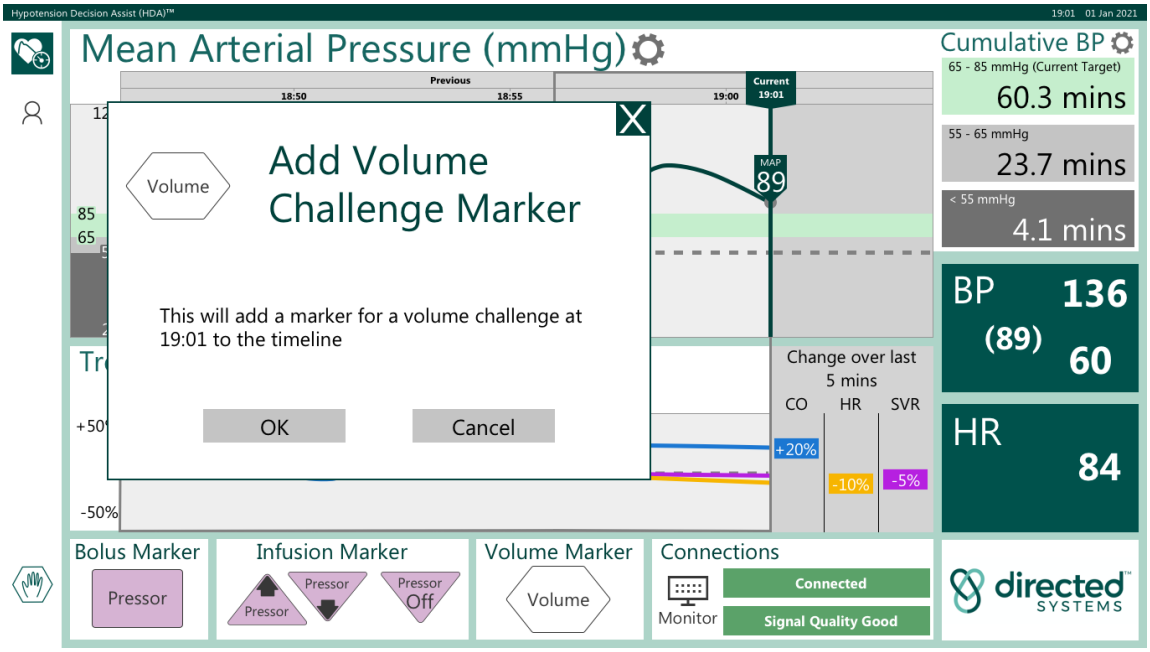


Figure 32: *Volume Marker screen*

Touching "OK" adds a marker to the display screen and records the event and time in the data record. Touching "Cancel" clears the command.

Examples of Marker Use

Examples of Bolus, Infusion Rate changes and Volume markers are illustrated in Figure 33.

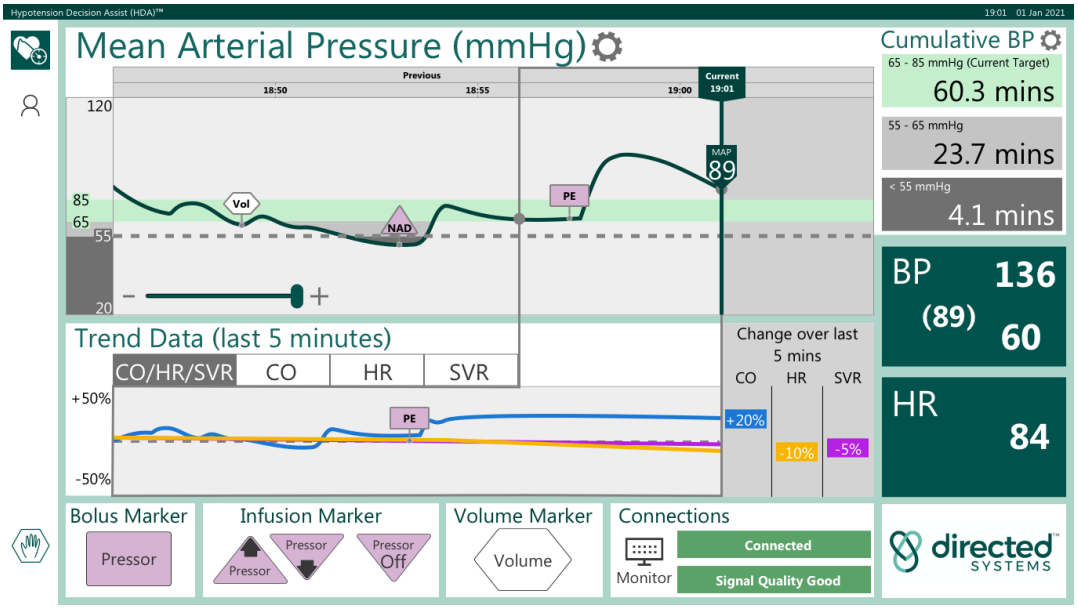


Figure 33: *Examples of Markers on Main Display Screen*

Ending a monitoring session

A monitoring session can be terminated by touching the "Stop" hand icon on the bottom left of the main display screen .

A pop-up window will appear in the center of the main display screen as illustrated in Figure 34.

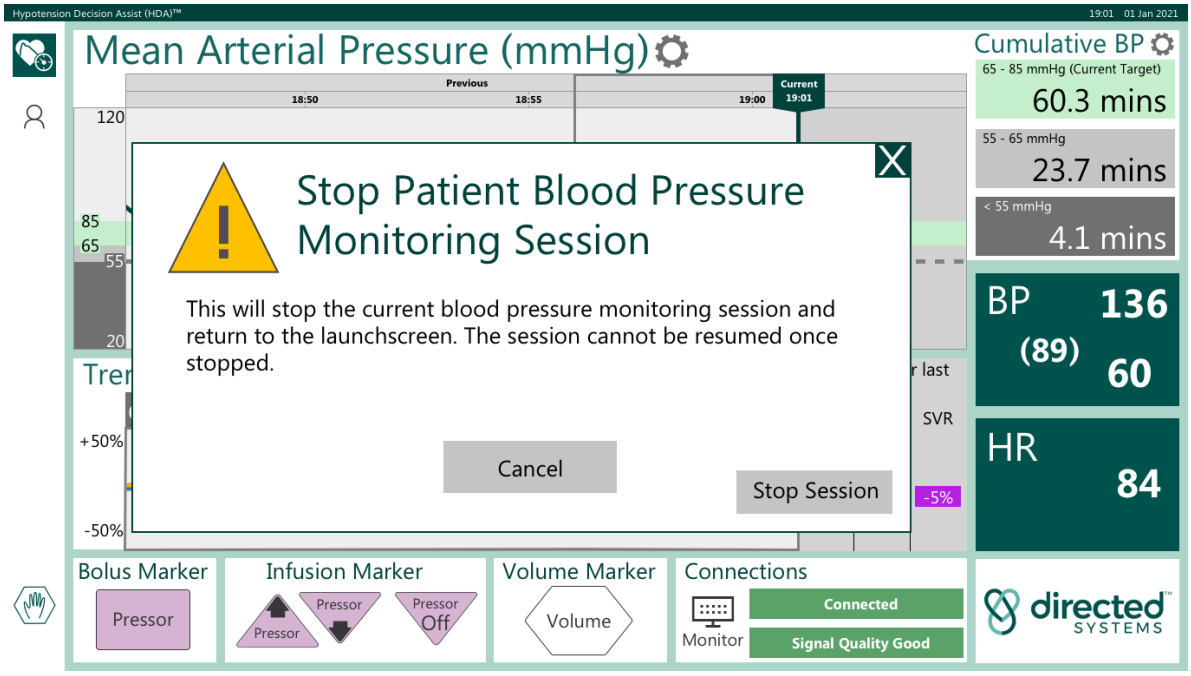


Figure 34: *End Monitoring Session display window*

Touching the "Stop Session" button will close the monitoring session, terminate data recording and present you with the Case Review screen (see Case Review).

All data displayed on HDA are stored to log files. These files can only be accessed from "Service Mode".

Advice

When a recording session is stopped by touching the "Stop Session" button, it cannot be restarted.

Data will be stored to log files that are only accessible via use of the "Service Mode" facility.

Case Review

Upon stopping a patient monitoring session, you will be presented with the Case Review (CR). See Figure 35.

Caution

The Case Review is provided to allow you review data after a case and is not provided for any other clinical use.

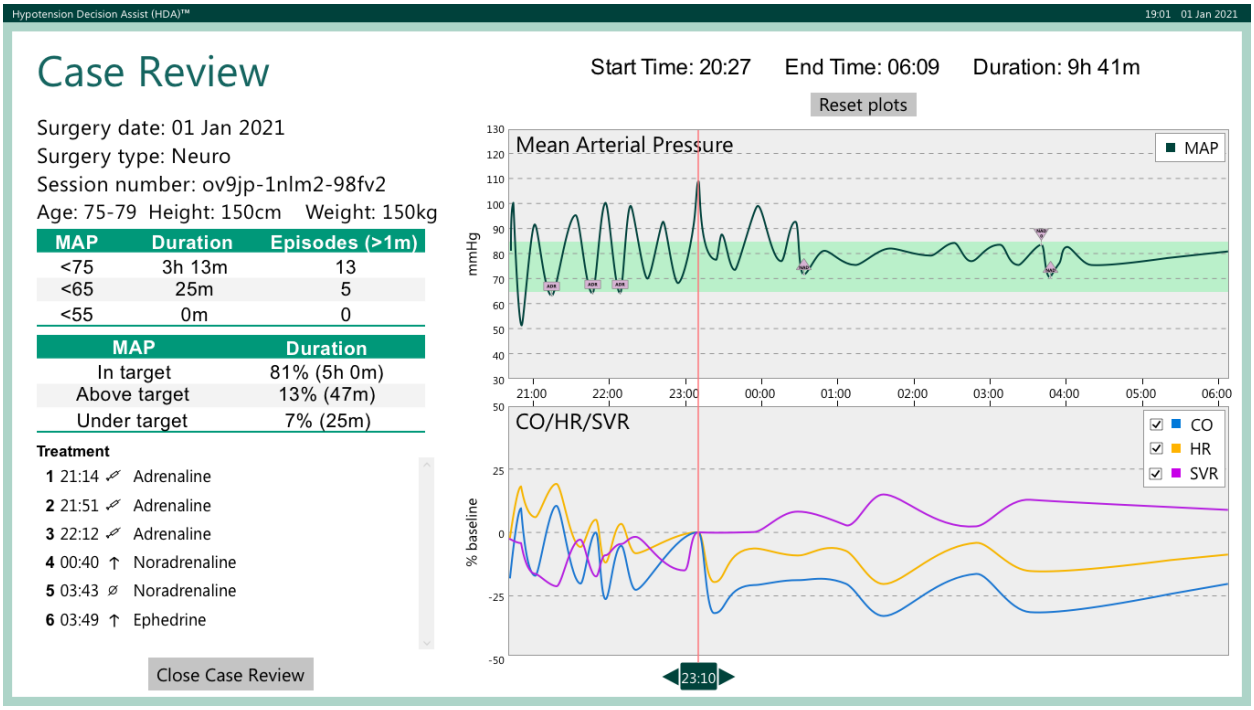


Figure 35: *Hypotension Case Review (HCR)*

Case Review will display the surgery date, type, session number (unique to each case and will be shown in the log file name), age, height, weight of patient (age, height, weight are optional).

On the upper left side of the screen, a table with the breakdown of MAP by episodes that occurred for greater than 1 minute is shown. These episodes are classified according to a MAP <75, <65 AND <55 mmHg.

Below this table the MAP time spent in target, above target and under target is shown as a percentage of time of the procedure.

The bottom left of the Case Review provides a list of the treatment markers recorded and the time they were added. This list can be scrolled using the scroll bar down the right-hand side of the list.

On the right-hand side of the screen, you will see the HDA session start, end and duration (shown in hours and minutes).

There is a graph of the MAP trend for the duration of the procedure which has a scrollable and pinch zoom feature using the touch screen. Below that graph, the trend for CO/HR/SVR are shown. There is an option using tick boxes in the graph's legend, to select and filter each particular trend. This graph has a scrollable and pinch zoom feature using the touch screen.

At the bottom of the trend data there is a green cursor attached to a red line. The position of this line determines the time at which the CO, HR, and SVR signals are baselined. These signals are shown as percentage changes and the baseline is the value from which the percentage change in the signal is calculated. The baseline time is displayed in the green cursor (in Figure 35 this time is 23:10). You can drag this cursor to set the baseline to any time in the case, for example, the time a treatment was administered.

To reset all plots to the default position, press the 'reset plots' button at the top of the trend graphs.

To close the Case Review, press the 'close case review' button at the bottom left of the screen. This will close the case review and return you to the launch screen.

Alerts displayed on screen during use of HDA.

If there has been a period of more than 30 minutes with no signal being received, when a new blood pressure signal is detected by HDA, a large pop-up window will appear cross the whole of the main display screen (see Figure 36).

The window presents the user with the option to either create a new blood pressure monitoring session or to continue with the existing blood pressure monitoring session.

A new session can be created by pressing "NEW".

Pressing "CONTINUE" will resume the current monitoring session.

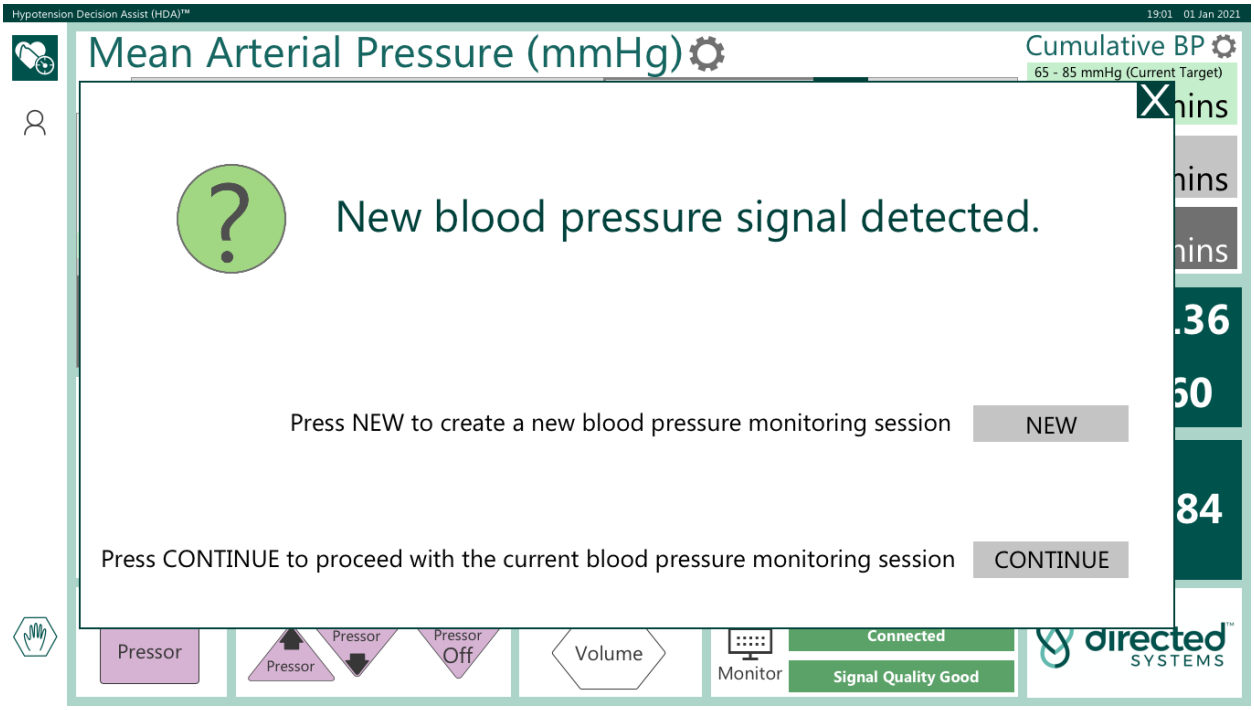


Figure 36: *HDA display screen when a new BP is detected*

Connection Alerts

HDA will display one of two alerts to indicate the status of the connection between it and the OR vital signs monitor. These are illustrated in Figures 37 and 38.

Figure 37 illustrates the red "Disconnected" alert displayed when HDA cannot detect a connection to the OR vital signs monitor.

Figure 38 illustrates the green "Connected" alert displayed when HDA has established a connection to the OR vital signs monitor.

Figure 37: *Alert displayed when no signal from blood pressure monitor is detected*

Figure 38: *Alert displayed when good connection to blood pressure monitor is achieved*

Loss of connection to monitor

The quality of the connection between HDA and the vital signs monitor to which it is connected is displayed in the "Connections" window in the lower right of the main display screen.

If the connection between HDA and the vital signs monitor is interrupted, a pop-up alert will be displayed in the Connections window (see Figure 39).

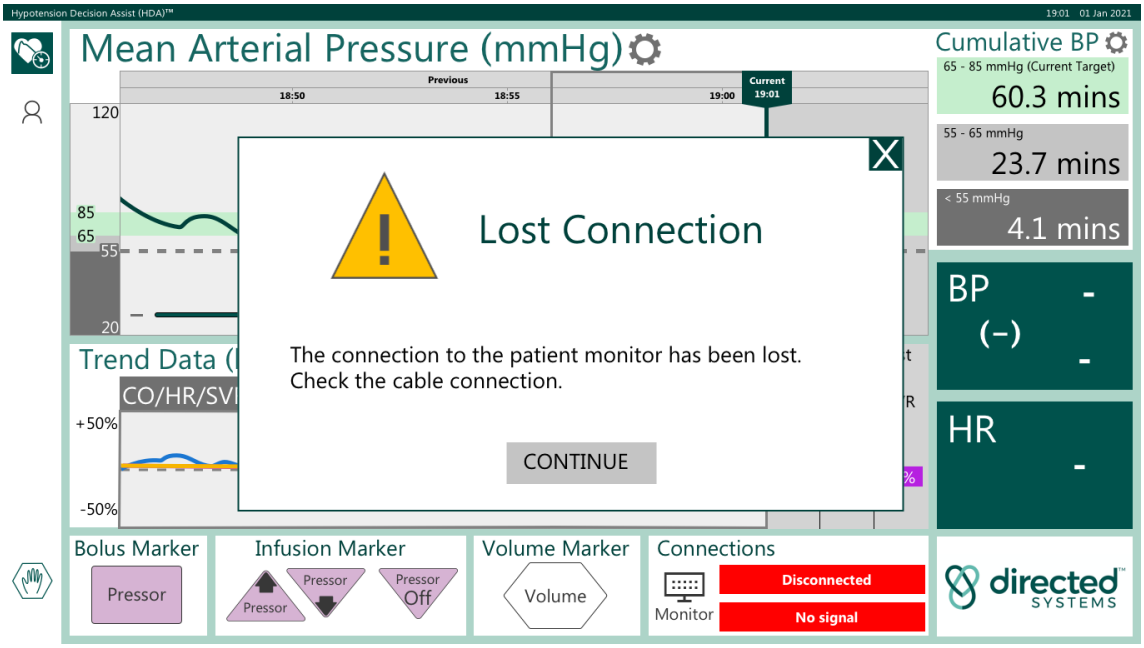


Figure 39: *Loss of signal display screen*

Low signal quality

An alert will be displayed on the main screen if the quality of the blood pressure signal being received from the multiparameter vital signs monitor is such that HDA cannot compute accurate parameter values. "Poor Signal Quality" will be displayed as illustrated in Figure 40.

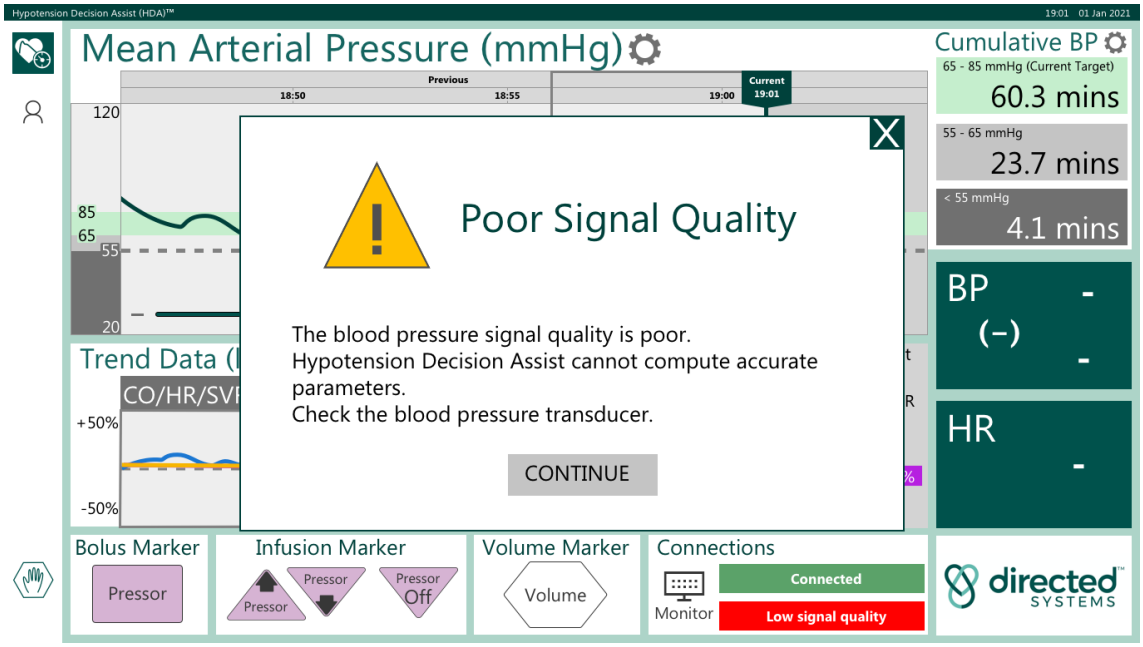


Figure 40: *Alert for low signal quality from blood pressure monitor*

When this warning is showing, the plots of MAP, ΔCO, ΔHR, and ΔSVR will show gaps in the trace and the numerics will display the symbol "-" as the arterial pressure signal is of insufficient quality to compute these parameters at the current time. When signal quality improves, calculation and display of these parameters will resume automatically. The warning alert can be cleared by pressing "OK".

No blood pressure signal detected

An alert will be displayed on the main screen when a valid blood pressure signal has not been detected by HDA for a duration of one hour (see Figure 41).

When this alert is displayed, HDA will automatically terminate the monitoring session after 60 seconds have elapsed. The display will count down from 60 to zero.

The monitoring session can be continued by pressing "Continue Session".

Advice

The "Time Remaining" display in the alert will countdown from 60s to 0s before the monitoring session is automatically terminated.

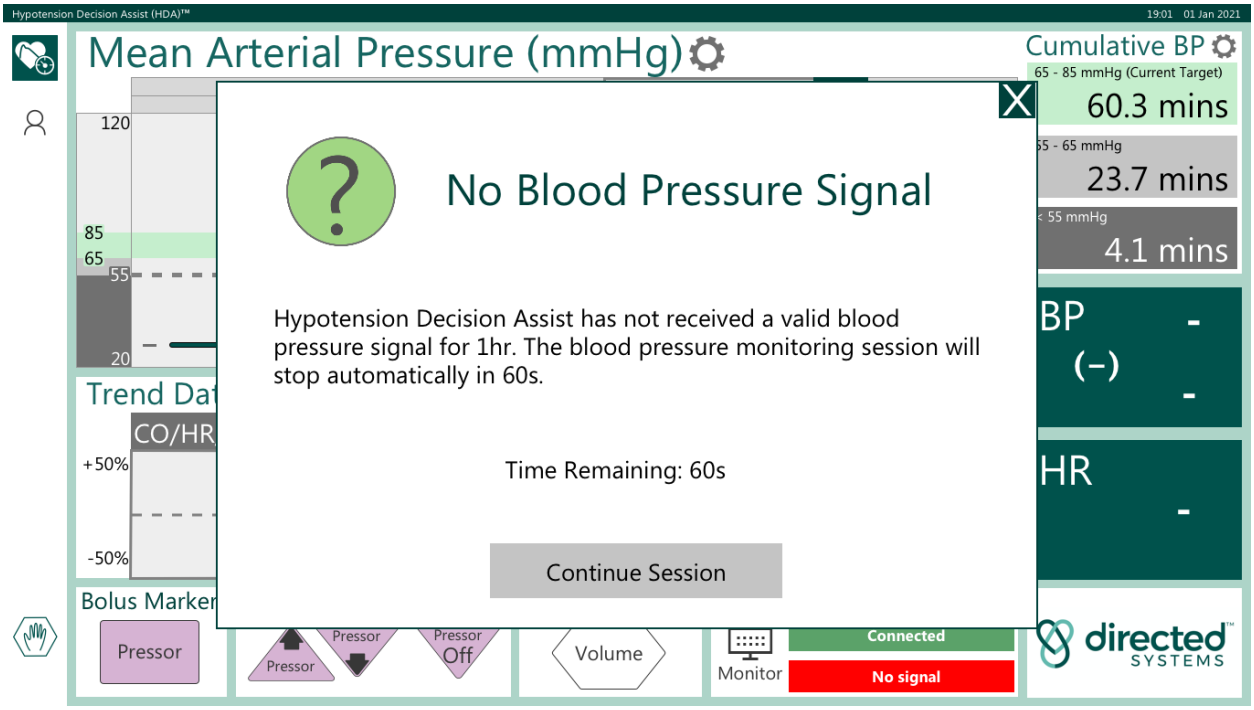


Figure 41: *Alert displayed when no blood pressure signal is detected*

PART 7: CYBER SECURITY

HDA incorporates a range of features to address cyber security concerns.

Access Control and Least Privilege

HDA provides access to the main clinical decision support application and configuration for clinical users. Access to the core operating system features/sub-systems is restricted. Local or domain user accounts can be added to HDA to facilitate IT access (for example, to setup network security policies or similar customer specific controls).

Firewall

Windows Firewall is enabled and denies all unsolicited incoming network connections.

Operating System Updates

Windows security updates are configured to auto download. Feature updates are disabled to increase system stability.

HDA Updates

When connected to the internet, updates to HDA are automatically delivered to the unit.

Data Security

HDA log data is not identifiable. De-identification has been established by a statistical analysis.

Cloud log upload, if enabled, is secured via a mutual TLS connection.

Additional Security Layers

App Locker is used to prevent the clinical user account executing any programs outside Program Files or System directories unless they are signed by Directed Systems Limited. This filtering also applies to removable media.

Auto-run is disabled for removable media.

PART 7: TROUBLESHOOTING

This section details situations that may arise during use of the HDA system. Possible causes and recommended actions are listed in Table 5.

Situation	Possible cause(s)	Recommended Action(s)
HDA display does not power up when connected to mains supply and turned on.	Faulty monitor.	Contact Directed Systems Limited.
Connection loss.	The serial cable between HDA and the patient monitor has come loose or been pulled out.	Check that the serial cable is still plugged firmly into HDA and the patient monitor.
Poor signal quality.	Problems with the arterial line or the blood pressure transducer, such as under or overdamping.	Follow your local arterial line and blood pressure management protocols to ensure the reliability of the arterial waveform
Poor signal quality while monitor shows good quality signal.	Electromagnetic interference (e.g. RF interference) causing data loss in the connection to the monitor.	The situation should resolve once the source of interference is removed. While interference is present the signal from the monitor may be interrupted, as the signal is digital the values that are received should be accurate.
HDA intermittently shows Disconnected when connecting to IntelliVue monitors over wireless network	Wireless quality of service is insufficient.	Connect HDA via wired network connection or serial if available. Improve wireless infrastructure (e.g. install wireless access point in operating room) Reduce load on wireless access point (e.g. where possible connect devices to network via ethernet)

Table 5: *Troubleshooting the HDA System*

PART 8: SUMMARY SYSTEM SPECIFICATIONS

Summary specifications of the HDA System are detailed in Table 6 or Table 7 depending on the model of Touch Screen Computer ordered.

Full specifications for the Touch Screen Computer are contained within the User Manual for the model ordered, which is supplied with the HDA System.

Item	Specification
Storage and Transport Requirements	-20°C to 60°C (-4°F to 140°F) at maximum 98% relative humidity. Altitude below or equal to 3000m (above 70KPa)
Operating Requirements	0°C to 35°C (32°F to 95°F) at 12-85% relative humidity. Altitude below or equal to 3048m (above 70KPa)
Mains Power Supply input voltage range	12 -48V
Electrical Safety standards	IEC 60601-1 4th Edition ANSI/AAMI ES60601-1 (2005/®2012 + A1:2012, C1:2009/(R)2012+ A2:2010/(R)2012) - Amendment 1 - Revision Date 2012/08/21
EMC compliance standards	IEC 60601-1-2: 2014
Deviations from standards	IEC 60601-1-2: 2014 ELECTROSTATIC DISCHARGE IMMUNITY TEST (ESD) The standard only requires contact discharge to be performed at ± 8 kV, the tests were performed at ± 2 kV, ± 4 kV, ± 6 kV, ±8 kV .
Weight	4.5kg
Dimensions	396mm x 48 mm x 245mm
Dust & Water Proof	IPX0 (IP54 for front panel only)

Table 6: *System Specifications for Teguar Models*

Item	Specification
Storage and Transport Requirements	-20°C to 60°C (-4°F to 140°F) At 5% - 95% relative humidity. Altitude below or equal to 3000m
Operating Requirements	0°C to 35°C (32°F to 95°F) At 10-90% relative humidity. Altitude below or equal to 3000m
Mains Power Supply input voltage range	12V/2A or 19V/3.42A
Electrical Safety standards	IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012 ANSI/AAMI ES60601-1 (2005/®2012 + A1:2012, C1:2009/(R)2012+ A2:2010/(R)2012) - Amendment 1 - Revision Date 2012/08/21
EMC compliance standards	IEC 60601-1-2: 2014
Weight	980g
Dimensions	280mm x 18.3 mm x 180.1mm
Dust & Water Proof	IPX0

Table 7: *System Specifications for Advantech Models*

Part 9: DISPLAYED PARAMETER DEFAULT VALUES

Default values for displayed parameters are detailed in Table 8.

Parameter	Default value	Unit
Blood pressure target range Upper target, lower limit	50	mmHg
Blood pressure target range Upper target, upper limit	120	mmHg
Blood pressure target range Lower target, lower limit	40	mmHg
Blood pressure target range Lower target, upper limit	110	mmHg
Warning blood pressure threshold	55	mmHg

Table 8: *Displayed Parameter Default Values*

Part 10: PARAMETER PERFORMANCE SPECIFICATIONS

Parameters performance specifications are detailed in Table 9.

Parameter	Range	Unit	Accuracy
Mean Arterial Pressure (MAP)	50-125	mmHg	±4 mmHg
Systolic Pressure (Sys)	65-150	mmHg	±4 mmHg
Diastolic Pressure (Dia)	35-100	mmHg	±4 mmHg
Heart Rate (HR)	50-110	bpm	±1 bpm

Table 9: *Parameter Performance Specifications*

Please see part 6 of this User Manual for information on the accuracy of Liljestrand and Zander formula used for computation of ΔCO and in the computation of ΔSVR.