Deltex

TrueVue SYSTEM

Advanced Haemodynamic Monitoring System

INSTRUCTIONS FOR USE (IFU) - OPERATING HANDBOOK

This operating handbook reflects the specification of the TrueVue haemodynamic monitoring system and its operation at the time of publication. Deltex Medical™ reserves the right to change the specification at any time, without notice

This operating handbook describes the operation of the TrueVue System using latest series application software.

Clinical benefit- Proven effective for haemodynamic optimisation using 10% SVO to reduce complications and shorten length of hospital stay. Any serious incident that occurs while using this product shall be reported to Deltex Medical Ltd and your member state competent authority.

Software upgrades will be carried out by your Deltex Medical representative as necessary

For further information, please contact your Deltex Medical sales representative or nearest sales office

Deltex Medical,
Terminus Road,
CHICHESTER,
West Sussex,
PO19 8TX.

Tel: (+44) 1243 774837
Fax: (+44) 1243 532534
Email: uksales@deltexmedical.com
internationalsales@deltexmedical.com

Website: www.deltexmedical.com

Operating handbook, English (UK). Part number 9052-5100.
Edition 5, March 2026.

CO1991

CE 2797

Acorn Regulatory
Consultancy Services Ltd.
Knockmorris,
Cahir, Co.
Tipperary,
E21 R766,
Ireland

EC REP

Contents

		Contents
Contents		3
1.	Indications, Precautions, Warnings and Contraindications	5
1.1	Acronyms and Symbols	5
1.2	Indications for Use	5
1.3	Intended Use	5
1.4	Precautions	5
1.5	Warnings	6
1.6	Contraindications	7
2.	Monitor Description	8
2.1	Front and Rear Panels	8
2.2	Patient Data Storage	8
3.	Deltex Medical Doppler Probes for the TrueVue System	9
3.1	General Information	9
3.2	Probe Storage	9
3.3	Probe Disposal	9
3.4	Probe Expiry	9
3.5	Adult Oral/Nasal Probes	9
3.6	Paediatric Probes	10
3.7	Usage Limits	10
3.8	Nomogram Limits	10
4.	Screen and icon description	11
4.1	Icons	11
4.2	Navigating the Run Screen	12
5.	Frequently Used Functions	17
5.1	Initial Assembly	17
5.2	Isolating from Mains Power and Shutting Down	17
5.3	Mounting the TrueVue System	18
5.4	Set Up	18
5.5	Connect the Probe	18
5.6	Localisation	19
5.7	System Settings	19
5.8	Usage Data	19
5.9	System Details	20
6.	Initial Screens	21
6.1	Remaining Probe Use Indicator	21
6.2	Patient Identification	21
6.3	Start Screen	21
6.4	Patient Data Screen	22
6.5	Monitoring a New Patient	22
6.6	Monitoring an Existing Patient With a New Probe	23
6.7	Deleting the Patient	23
7.	Obtaining the Correct Flow Signal	24
7.1	Positioning the Probe	24
7.2	Signal Scaling	26
7.3	Setting the Signal Filter	26
7.4	Setting the Signal Gain	26
7.5	Finding the Maximum Flow	27
7.6	Full Width Run Screen	27
7.7	Changing the Number of Cycles Averaged for Calculations	27
7.8	Pausing the Display	27
8.	Additional Calculations	28
8.1	Systemic Vascular Resistance (SVR) & Systemic Vascular Resistance Index (SVRI)	28
8.2	Additional Calculations Screen	28
8.3	SVR and SVRI Calculation Screen	29
8.4	DO_2 and DO_2I Calculation Screen	29
8.5	Time Elapsed or CO Drift	29
8.6	Display SVR Calculations	30
8.7	Delivered Oxygen (DO2) Delivered Oxygen Index (DO2I)	30
9.	Snapshots and Baseline	31
9.1	Taking a Snapshot	31
9.2	Gallery Screen	31
9.3	Setting a Baseline	32

10.	Trend and Information Screens	33
10.1	Trend Screen	33
10.2	Changing a Trend Parameter	34
10.3	Information Screen	34
11.	Pressure Monitoring	35
11.1	Uncalibrated Pressure Screen	36
11.2	Calibrated Pressure Screen	36
12.	Pop-up windows	37
12.1	Warning Pop-Up	37
12.2	Information Pop-Up	37
12.3	Confirmation Pop-Up	38
12.4	Form Pop-Up	38
12.5	Progress Pop-Up	38
12.6	Error Pop-Up	39
13.	Demonstration Mode	40
13.1	Running the Truevue system in Demonstration Mode	40
14.	Batteries	41
15.	System Specifications	42
15.1	Classification	42
15.2	Performance Characteristics	42
15.3	Physical Characteristics	42
15.4	Environmental Characteristics	42
15.5	Monitor and Accessories Disposal	42
15.6	System Characteristics	43
15.7	Acoustic Output	43
15.8	Acoustic Output Safety	44
15.9	Signal Scaling	44
15.10	Accuracy	44
15.11	Results	44
15.12	RS232 Protocols	45
15.13	Power Supply	45
15.14	Battery	45
15.15	Auxiliary Connections	45
15.16	Symbolic Markings	46
15.17	Accessories and Spares	47
15.18	Probes and Probe Accessories	47
15.19	ABP Cables & Modules	47
15.20	Other Associated Cables/Devices	48
15.21	Electromagnetic Compatibility	49
15.22	Manufacturers Declaration	49
16.	Software Update and USB offload	53
16.1	Updating Software	53
16.2	Exporting patient data	53
16.2	Patient Data Export Options	54
17.	Cleaning Maintenance and Warranty	55
17.1	Monitor Cleaning	55
17.2	Routine Maintenance	55
17.3	Repairs, Servicing and Calibration	55
17.4	Warranty	56

1. Indications, Precautions, Warnings and Contraindications

1.1 Acronyms and Symbols

The following symbol appears in the operating handbook:

Warning	

The following acronyms are used in the operating handbook

DPn	Doppler Probe	VESA	Video and Electronics Standards Agency
I2n	Awake Probe	MRI	Magnetic Resonance Imaging
KDP	Kinder Doppler Probe (paediatric)	CVP	Central Venous Pressure
EMR	Electronic Medical Records	ABP	Arterial Blood Pressure
IFU	Instructions For Use	SVO	Stroke Volume Optimisation
ODP	Oesphageal Doppler Probe	Dopplink	Doppler interface cable

1.2 Indications for Use

The TrueVue system's beat-to-beat data on cardiovascular status are used by the managing clinician to evaluate and optimise haemodynamic performance of patients who are; in surgery and are anaesthetised, sedated or conscious; in intensive care; in the emergency room; in the obstetrics department; in other wards or departments where haemodynamic measurements are required.

1.3 Intended Use

The purpose of the TrueVue system is to measure and calculate the haemodynamic parameters used to assess Preload, Afterload and Contractility of the heart on a beat-to-beat basis in real time. Parameters related to haemodynamics including Stroke Volume, Stroke Distance, Cardiac Output, Peak Velocity, Systemic Vascular Resistance, Mean Arterial Pressure, Pulse Pressure Variation, Stroke Volume Variation are examples of measurements and calculations to be made available to clinicians managing patient haemodynamics.

1.4 Precautions

The probes are only approved for oral or nasal placement into the oesophagus, depending on the type of probe. Depending on the method of placement and probe type, the patient may be fully sedated, or under general or local anaesthesia. Refer to the individual probe packaging for instructions for use.

The data will change as a result of cross-clamping of the aorta. However, during the cross-clamping period, the data are reliable and can be used to guide clinical practice. This data in the cross-clamping period should not be compared with data obtained in the periods when the aorta is not clamped.

The Doppler probes have a designated time limit and when that limit is exceeded, the probes will cease to function. Refer to the individual probe packaging for instructions for use.

No major oesophageal complications have been reported with probe use. As with any naso-gastric or naso-oesophageal tube/probe, some local inflammation can be seen on endoscopy after a number of days.

Interpretation of cardiac function should always be considered in conjunction with other clinical signs and symptoms. Users should review the manufacturer's clinical materials, as there is a learning curve that may affect the interpretation of results.

When using stroke volume variation (SVV), stroke distance variation (SDV), peak velocity variation

(PVV) or pulse pressure variation (PPV) to guide fluid management please note that the parameters sensitivity is optimal when tidal volume is ≥7-8 ml/kg and that higher tidal volumes elicit higher variations.

The TrueVue system excludes arrhythmic events based on heart rate variability (≥20%) and excessive variation in Stroke Volume. However the user should be aware that in periods of arrhythmia SVV, SDV, PVV or PPV should not be used to guide fluid management.

SVV, SDV, PVV or PPV parameters are only of clinical of use in patients which are fully mechanically ventilated with closed chest. Varying PEEP settings may affect haemodynamic measurements.
When using SVV, SDV, PVV or PPV parameters may be compromised during laparoscopic procedures or where the patient is in such a position that additional pressure is applied to the thorax e.g. prone or head down procedures.

1.5 Warnings

Do not use undue force upon insertion. Remove if difficulty arises and seek advice.

Coagulation status should be verified against the possibility of nasal bleeding when nasal placement is considered.

The Kinder Doppler probe (KDP) is for use in paediatrics and is only approved for oral placement in patients over 3 kg in weight.

TrueVue System is not a vital signs monitor, nor should it be used as a substitute for one.

This equipment is not suitable for use in the presence of flammable anaesthetics with air or oxygen or with nitrous oxide.

To avoid the risk of electric shock, this equipment must only be connected to a mains supply with protective earth.

No modification of this equipment is allowed.

Do not use if the pouch has been unintentionally opened, or if the probe or pouch show signs of damage. The probe shall be disposed of according to local procedures

Exercise caution when handling. The Probe contains an internal spring that will cause the probe to uncoil when released from the pouch.

Open the pouch at the chevron seal end and holding the Probe withdraw it from the pouch.

Allow the Probe to uncoil, keeping it free from contact with any object that may compromise its state of cleanliness.

Magnetic Resonance Imaging (MRI) unsafe, do not use this equipment in the MRI scan room.

1.6 Contraindications

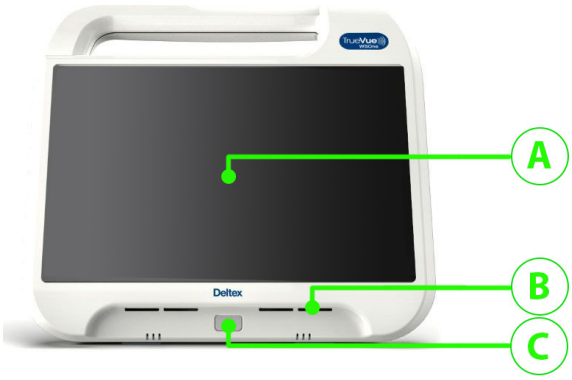
Doppler probes (DPn and I2n) should not be placed in patients under 16 years of age.
Do not use where nasal injuries are apparent or may have occurred.
Do not use where nasal polyps exist.
Do not use where there are circumstances of facial trauma.
Do not use where there is a risk of brain injury.
Do not use in patients undergoing intra-aortic balloon pumping.
Do not use with carcinoma of the pharynx, larynx or oesophagus.
Do not use with aneurysms of the thoracic aorta.
Do not use with tissue necrosis of the oesophagus or nasal passage.
Do not use in close proximity to laser surgery.
Do not use in patients with pharyngo-oesophago-gastric pathology and/or severe bleeding diatheses.

For detailed precautions and warnings on probe usage, refer to the individual probe packaging for instructions for use.

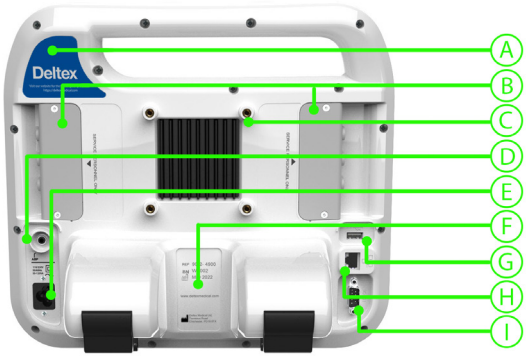
For further information including a Technical Report on how oesophageal Doppler monitoring works, summaries of randomised clinical trials and case histories, visit www.deltexmedical.com.

2. Monitor Description

2.1 Front and Rear Panels



A	Touch Screen
B	Speaker
C	Power, Standby and Battery Indicator button



A.	Label
B.	Covered Connections
C.	75mm VESA mounts
D.	Analogue to Digital Converter connector (ADC). Arterial Blood Pressure (ABP)
E.	Mains input
F.	Model and serial numbers
G.	USB port
H.	Network Port (UTP) for future use
I.	Serial (RS232) port

Any unauthorised connections to the auxiliary ports may compromise patient safety. Do not connect any equipment other than medical grade equipment (complying with BS EN 60601-1) to the TrueVue while the monitor is connected to a patient, unless a medical grade isolator meeting BS EN 60601-1 is used.

2.2 Patient Data Storage

The monitor has 32GB of storage available for storing patient data. The amount of data generated for each patient during monitoring will vary with the number of snapshots created and the number of measurement inputs in use (Flow and/or pressure). Patient data will be present until deleted by the user.

3. Deltex Medical Doppler Probes for the TrueVue System

3.1 General Information

Deltex Medical manufacture a range of Doppler probes designed for use with the TrueVue System. These probes are supplied in various multi-packs, with each probe in its own pouch.
Refer to the label on the probe packaging to ensure that a probe is suitable for the patient and placement type intended. Messages will appear on the screen if the patient data entered indicates that the connected probe is unsuitable, or a specific placement method must be used. All probe variants may not be available in certain countries. For more details on probe availability, contact your Deltex Medical representative.

Take care when removing the probe from the packaging, as the internal spring will cause the probe to uncoil and straighten on release from the packaging.

DPn, I2n and KDP probes are approved for use on a single patient only and must be disposed of as soon as use on that patient is no longer required. Under no circumstances should the probe be used in a different patient.

Warnings and mandatory limitations are available on the probe packaging.

3.2 Probe Storage

All probes should be stored in dry conditions and should not be exposed to direct U.V. light. The storage temperature is between **-20°C** and **60°C**. Probes may be stored at lower temperatures down to **-20°C**, but must be then allowed to recover for at least **30 minutes** at room temperature before use. The probe shaft may become inflexible if the temperature is too low.

3.3 Probe Disposal

Used probes should be disposed of in accordance with the appropriate guidelines for clinical waste.

The Doppler probes manufactured by Deltex Medical contain materials which are not completely destroyed by incineration.

3.4 Probe Expiry

When the usage time expires, the probe will cease to function immediately. Alerts are given during use and remaining usage is displayed using the icon in the bottom right-hand corner of the run screen in minutes. An alert is displayed before this occurs on screen, allowing a new probe to be prepared, when it is necessary to continue monitoring the patient. Access to all historical data on the TrueVue System monitor on which the old probe was started, will be transferred to the new probe. Data held on other TrueVue System monitors will not be transferred.

3.5 Adult Oral/Nasal Probes

The oesophageal Doppler probe (DPn and I2n series) are for oral and nasal insertion and have a maximum usage time, which is defined on the probe packaging. The probe usage time remaining is displayed on the screen. The probes are supplied sterile.

These probes are approximately 90cm long and only approved for oral or nasal placement into the oesophagus of a single patient 16 years or over in age.

If the patient's age, weight and height are such that the nomogram cannot be used to calculate volumetric output, then the message "Linear" is displayed, with the entered value(s) which are outside of the limits displayed in red. If use of the nomogram is precluded then a reduced set of variables (linear) is available for display.

The probe shaft has three depth markers visible through the transparent cover at 35cm from tip (marker 1), 40cm (marker 2) and 45 cm (marker 3) These markers facilitate correct probe placement. Although patient characteristics will vary between individuals, in an adult patient, signal acquisition is normally achieved at a depth of between 35cm (1) and 40 cm (2) using an orally placed probe, or at a depth of between 40cm (2) and 45 cm (3) for a nasally placed probe. For taller patients the insertion depth will be greater, and for shorter patients the insertion depth will be less.
If using the DPn series, the patient should be under full sedation or general anaesthesia.

If using the I2n series the patient may be awake or under full sedation or general anaesthesia. If the patient is not under full sedation or general anaesthesia, a local anaesthetic may be applied to the nasal passage and back of the throat. The probe must be placed nasally in 'awake' patients.

3.6 Paediatric Probes

The Deltex Medical Doppler probe for use in paediatrics is the Kinder Doppler Probe (KDP).

The KDP probe is 72 cm long and has maximum usage time which is defined on the probe packaging. The KDP probe is supplied sterile.

It is only approved for ORAL placement into the oesophagus of a single patient over 3 kg in weight. The patient should be under full sedation or general anaesthesia.

The probe shaft has six depth markers visible through the transparent cover starting at 15 (cm) through to 40 (cm) incrementing in steps of 5 (cm). These markers act as a guide to facilitate correct probe placement. Signals are normally acquired as shown in the following table.

Patient Height (cm)	50-60	61-80	81-100	101-120	121-140	Over 140
Acquisition depth (cm)	15-20	15-25	15-30	20-30	25-35	25-40

3.7 Usage Limits

Age	0-127yrs
Weight	3 - 450kg (5.5 to 992lb)
Height	45-300cm (17.7 to 118in)

3.8 Nomogram Limits

The adult nomogram:		**The paediatric nomogram:**	
Age	16-99yrs	Age	0-15yrs
Weight	30-150kg (66 to 330lb)	Weight	3-60kg (6.6 to 132lb)
Height	149-212cm (59 to 83in)	Height	50-170cm (20 to 67in)

The paediatric nomogram is only available with the KDP.

Nasal placement of any probes in paediatric patients is not approved, nor is usage of the TrueVue System for patients below 3 kg in weight.

If the patient's age, weight and height are such that the nomogram cannot be used to calculate volumetric output, then the message "Linear" is displayed, with the entered value(s) which are outside of the limits displayed in red. If use of the nomogram is precluded then a reduced set of variables (linear) is available for display.

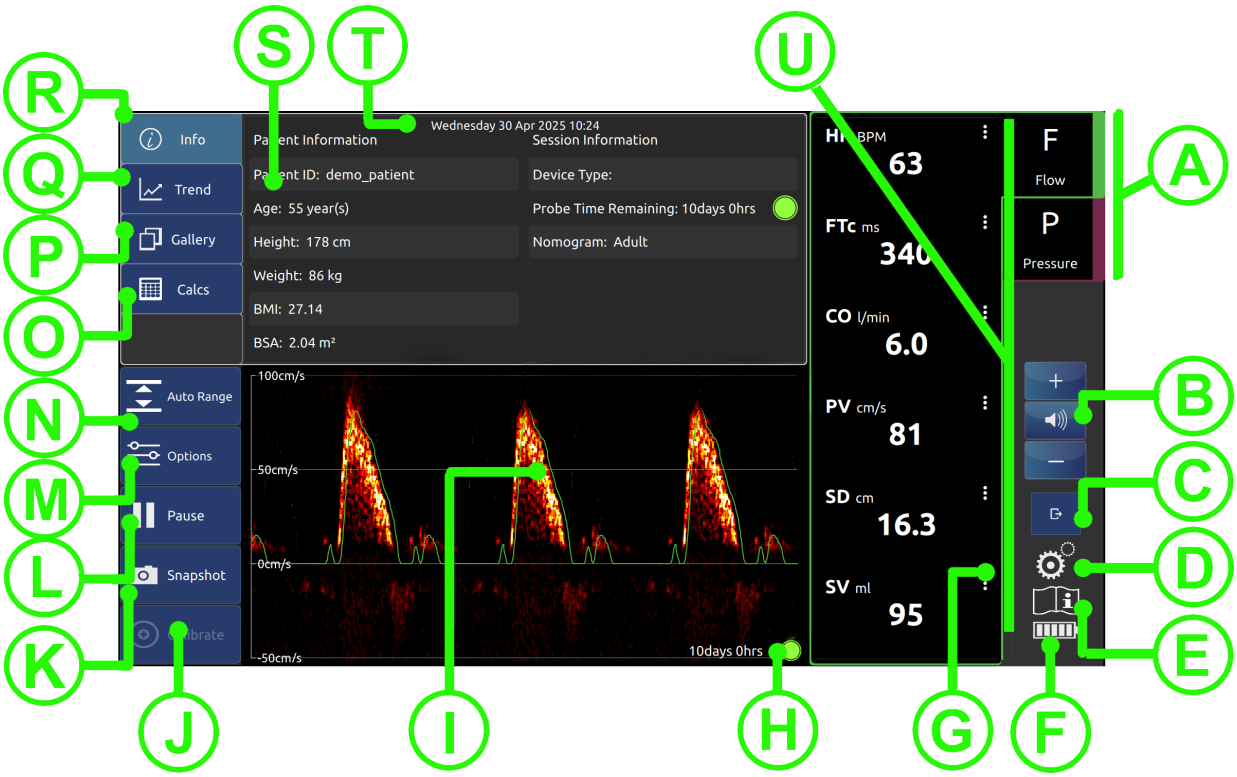
4. Screen and icon description

4.1 Icons

Icon	Description
	Indicates battery full
	Indicates battery charging
	Indicates battery fault
	Consult Instructions For Use (IFU)
	Settings
	Probe time remaining usage full
	Half Probe time remaining usage remaining
	Probe time almost expired

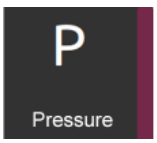
4.2 Navigating the Run Screen

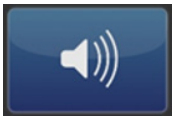
The TrueVue uses a high-resolution touch screen to display waveforms and parameters. A typical run screen is shown below.



A. Mode
B. Volume controls (Mute + -)
C. Exit
D. Settings
E. Instructions For Use
F. Battery status
G. Parameter adjustment
H. Probe time remaining
I. Run screen
J. Calibrate pressure
K. Snapshop function
L. Run button/Pause
M. Options button
N. Auto Range
O. Calculations screen
P. Gallery view
Q. Trend view
R. Info view
S Patient information
T. Date and time
U. Parameters

A - Mode - Change mode -
Flow mode - when selected the screen will change to Flow mode.
Pressure mode - when selected the screen will change to Pressure mode.

Flow Mode	Pressure Mode
	

B - Volume - Increase, decrease or mute the volume of live audio.		
Volume on	Volume muted	Volume adjust
		

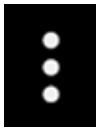
C - Exit - Return to start screen	
Exit	
	

D - Settings - Settings and Localisation	
Settings	
	

E - IFU - Open Instructions For Use	
IFU	
	

F - Battery Status - Onscreen battery icons indicate status

Battery level	**Icon**
0-20%	
21-40%	
41-60%	
61-80%	
>81%	
Faulty	
Charging	

G - Parameter Menu - Change or move the parameter selected	
Parameter menu	
	

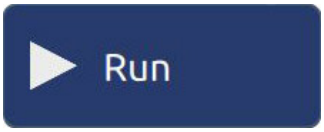
H - Probe Usage - On screen icons indicate time remaining

Time remaining	Icon
Start of monitoring	
<7/8 time remaining	
<3/4 time remaining	
<5/8 time remaining	
<1/2 time remaining	
<3/8 time remaining	
<1/4 time remaining	
<1/4 time remaining	
< 20 minutes remaining	
<5 minutes remaining	
Probe expired	

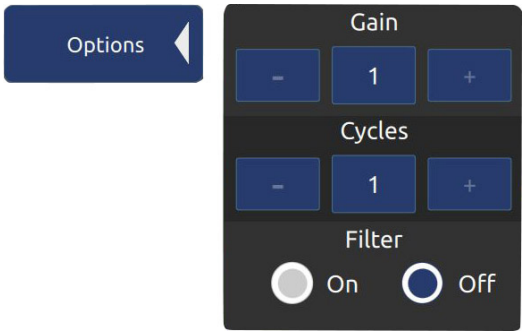
I - Run Screen - Displays patient waveform

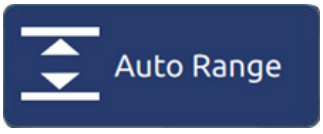
J - Calibrate Pressure - When both flow and pressure signals are available, the user can select calibrate to provide volumetric parameters		
Calibration Available	Calibration Not Available	
		

K - Snapshot - Captures snapshot for review, comparison or offload. See snapshot chapter for more information.	
Snapshot	
	

L - Run/Pause - Allows user to run or pause the waveform		
Run	Pause	
		

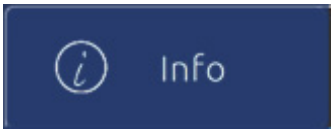
M - Options - Selecting options opens a new window allowing adjustment of other parameters.



N - Auto Range - Resets waveform	
Auto Range	
	

O - Calculations - For additional parameters	
Calculations	
	

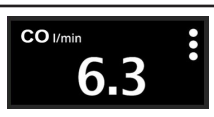
P - Gallery - For snapshots	
Gallery	
	

Q - Info - Allows user to access to patient and session info	
Info	
	

R - Trend - Allows user to access trend screen	
Trend	
	

S - Patient Identifier - Information related to patient	
Info	
	

T - Date and Time - Information related to Date and Time	
Info	
	

U - Parameters - Patient related parameters	
Parameter	
	

5. Frequently Used Functions

5.1 Initial Assembly

Before setting up the monitor for use, check the following items are present:

- TrueVue system
- Power Cord
- Appropriate pressure connection cable

On first power up, confirmation of date and time may be requested.

A suitable Deltex Medical oesophageal Doppler probe will also be required.

5.2 Isolating from Mains Power and Shutting Down

Unplug the monitor to isolate from mains

A. Power button, hold for 3 seconds to shutdown the monitor.

5.3 Mounting the TrueVue System

The TrueVue system can be placed on a shelf, roll stand or mounting arm. Roll stands and mounting arms are available as accessories.

For further details, contact your Deltex Medical representative.

5.4 Set Up

Insert the power cord into the appropriate socket.

If required, connect the invasive arterial blood pressure interface lead to the ABP input socket at the rear of the TrueVue system.

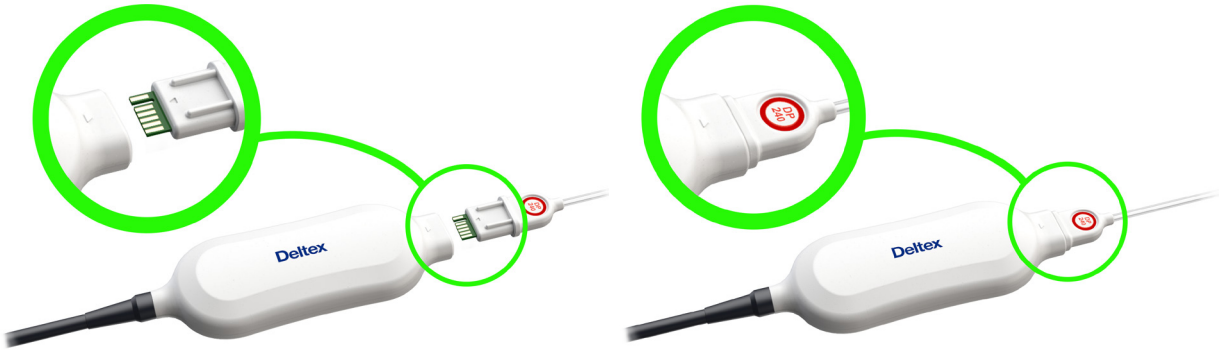
For further details, contact your Deltex Medical representative.

Turn on the TrueVue system using the ON/OFF switch on the front of the monitor. A screen will appear within about 5 seconds in the currently selected language. If the language, date or time is incorrect, the selection must be changed.

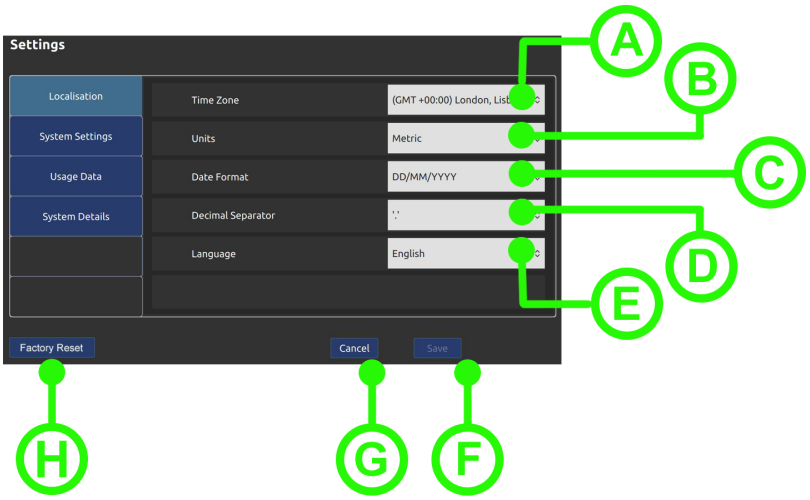
Monitors can be configured to available languages and units as required.

5.5 Connect the Probe

In order to monitor and collect data from a patient, a suitable probe must be connected to the monitor. The probe connector can only be inserted one way and must be firmly seated.

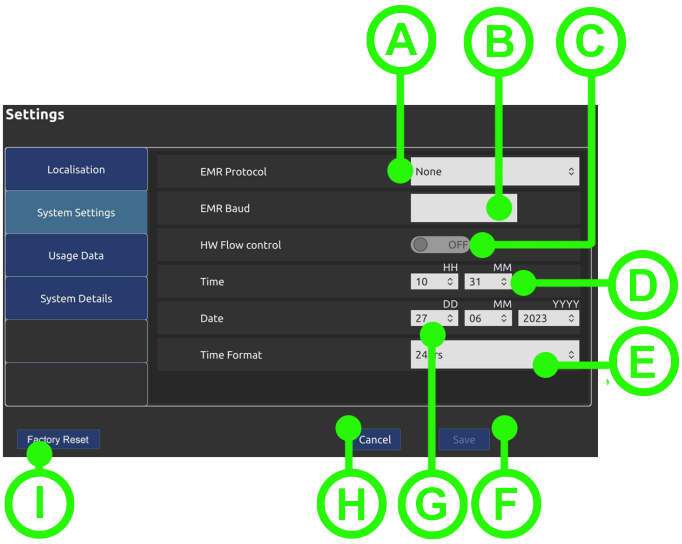


5.6 Localisation



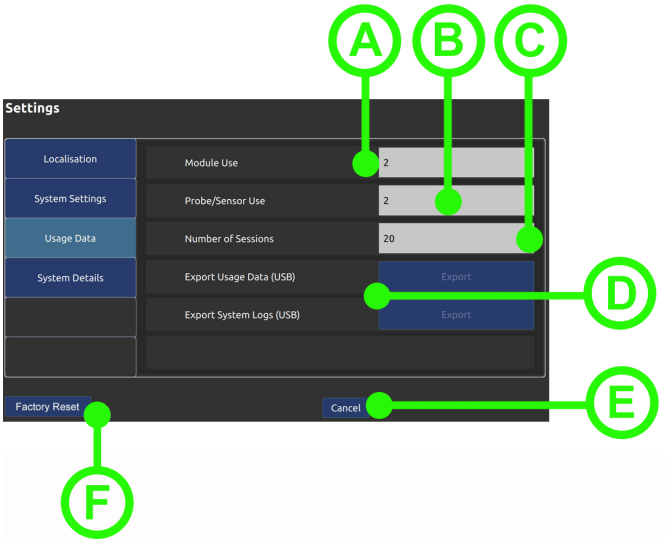
A. Time Zone - Selects local time
B. Units - Selection of preferred units
C. Date format - Change how the date is displayed
D. Decimal separator - Choose the decimal separator for displayed parameters
E. Language - Select what language the monitor displays
F. Save settings
G. Cancel selection
H. Factory Reset

5.7 System Settings



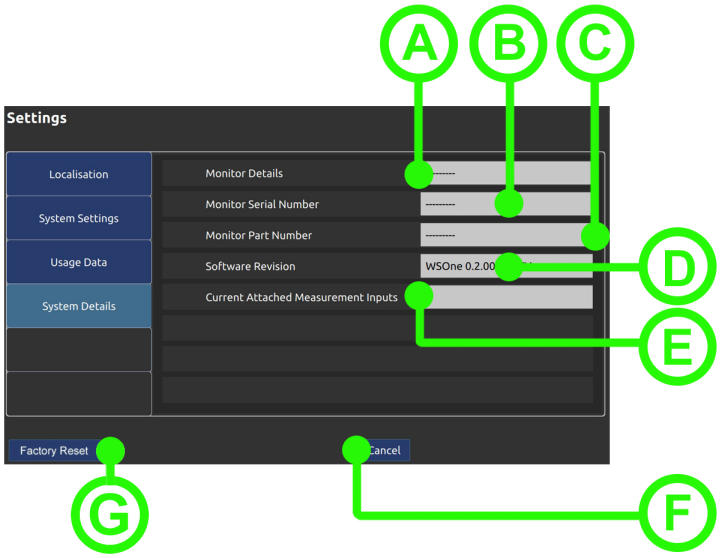
A - Serial/EMR protocol - Select which EMR protocol to use
B. Serial/EMR Baud Rate.
C. Hard Ware (HW) Flow control - Switch hardware flow control on or off
D. Time setting - Change the displayed time
E. Time format - Change between 12 and 24h clocks
F. Save - Saves settings
G. Date setting - Change the displayed date
H. Cancel - Cancel selection
I. Factory Reset

5.8 Usage Data



A. Module used - Number of measurement modules used on the monitor, automatically updated by the system
B. Number of probes used - Number of probes or sensors used on the monitor
C. Number of sessions - Number of patients monitor has been used on
D. Export Data - Export usage and logs
E. Cancel - Cancel selection
F. Factory Reset

5.9 System Details



A. Monitor details - Information about the monitor
B. Monitor serial number - Monitor unique serial number
C. Monitor part number - Part number of the monitor
D. Software revision - Software revision information
E. Attached measurement inputs - Details any attached measurement input devices
F. Cancels selection
G. Factory Reset

6. Initial Screens

When the TrueVue system is switched on, the first screen displayed varies depending on whether a probe is connected and the validity of the probe connected:

- If no probe is connected, the user may access the Demonstration Mode, view patient records, enter settings or Instructions for use.
- If an incompatible probe is connected a message will appear to that effect. Correct this situation by connecting a suitable Deltex Medical probe to the Dopplink
- If an invalid probe is connected, contact your Deltex Medical representative, or use a probe of a type for which the TrueVue system is enabled.
- If a time expired probe is connected a message will appear to that effect. If recorded data relating to the time-expired probe is available from the monitor, the user can view or offload the data.
- If an unused probe is connected, data can be copied from the list of patients to continue monitoring a specific patient, or a new patient's details can be entered.
- If a used probe is connected, commence or continue monitoring or offload data.

If space is needed for a patient when a probe is connected, the user will be prompted to delete an existing patient.

6.1 Remaining Probe Use Indicator

When a probe is connected to the TrueVue system, the remaining probe usage is displayed, both as a pie chart and as text, in the bottom right part of the screen.

As the remaining probe usage reduces, the pie chart changes from green to amber.

When the remaining probe usage reaches 5 minutes, the pie chart changes to red.

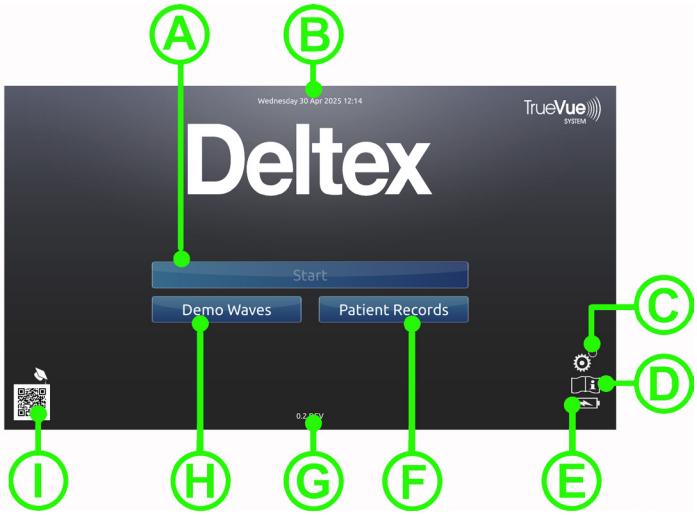
When the probe usage expires, "Probe expired" is displayed and monitoring (Doppler) will cease immediately. If valid pressure data are displayed, pressure monitoring will continue for up to 12 hours (6 hours only for DP6) If it is necessary to continue flow monitoring the patient, the probe should be changed as soon as possible.

6.2 Patient Identification

Patients will need an identification code added to their details. On the New Probe Screen an auto identification number can be used and will be allocated by the TrueVue system or the user can input a more suitable ID. The auto number is created from the date and time when the probe was connected.

6.3 Start Screen

The start screen is the initial screen to load after the monitor is switched on

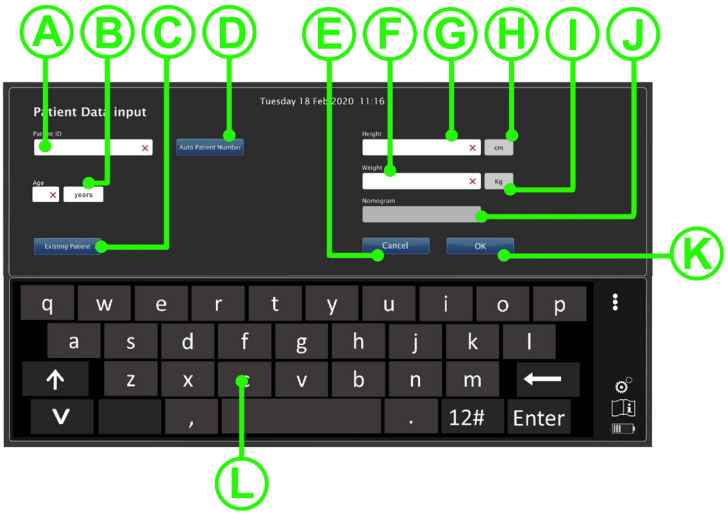


A. Start button - Access to patient data input screen
B. Time and date - Monitors time and date
C Settings - Access to monitor settings
D. IFU - Access to IFU
E. Battery - Indicates battery level
F. Patient Records - Access to patient records screen
G. Version of the software - Displays the current version of software
H. Demo waves - Access to demo screen. If button is greyed out demo is not available
I. Link to Deltex academy

6.4 Patient Data Screen

The Patient Data Screen is used to enter and display the patient's age, weight and height. This information is used to calculate the body surface area (BSA)

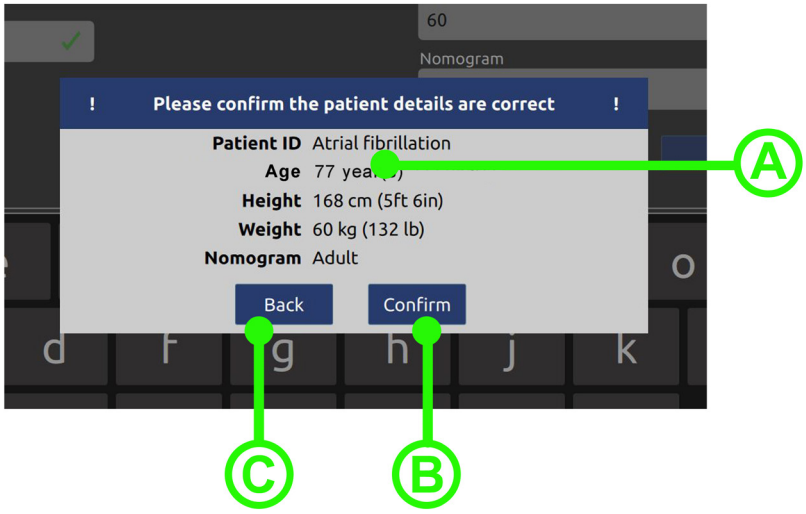
Follow the on-screen instructions to input patient data.



A. Patient ID - Used to select auto generated ID or a custom ID using the keyboard
B. Age - Used to add patients age
C. Existing Patient - Used to select an existing patient
D. Auto input - Automatically generates a Patient ID
E. Cancel - Cancel selection and return to the start screen
F. Weight - Used to enter patient weight
G. Height - Used to enter patient height
H. Height units - Used to change height units
I. Weight units - Used to change weight units
J. Nomogram - depending on information entered in weight, height and age this box displays the type of nomogram to be used
K. OK - Used to proceed to the confirmation page
L. Onscreen keyboard - Used to enter text

6.5 Monitoring a New Patient

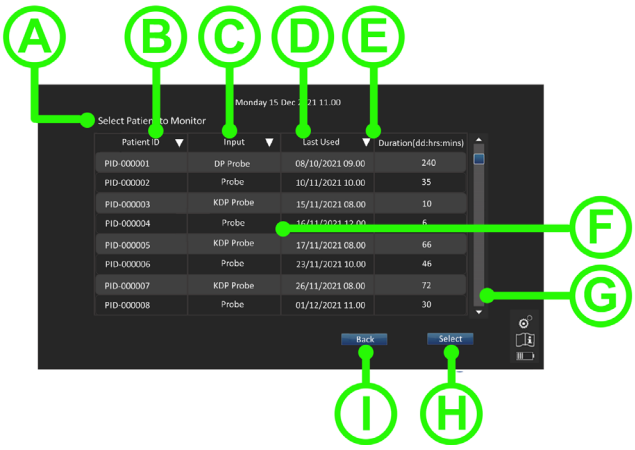
In order to start monitoring a new patient, the user must first add the patient in the patient input screen. Once OK has been pressed, the confirmation window will appear.



A. Patient information - Provides information about patient
B. Confirmation - Used to confirm information
C. Back - Return to previous screen

6.6 Monitoring an Existing Patient With a New Probe

In order to start monitoring an existing patient, the user must select the existing patient button on the patient input screen.



A. Select Patient to Monitor - Displays current mode
B. Patient ID - Patient ID Column, select arrow to change order high to low or low to high
C. Input - Input column - Used to sort column high to low or low to high
D. Last used - Last used column - Used to sort column high to low or low to high
E. Duration - Duration of use column - Allows user to sort column high to low or low to high
F. Patient list - List of all available patients
G. Scroll Bar - Used to scroll through off-screen patients
H. Select - User to select patient and continue
I. Back - Return back to patient input screen

The patient ID can be changed if an automatic ID number has not yet been altered before confirmation is pressed.

This action will associate all existing data for that patient with the new probe.

Once the user has confirmed patient selection the confirmation screen will be displayed

6.7 Deleting the Patient

The patient can be deleted manually if the data are no longer required

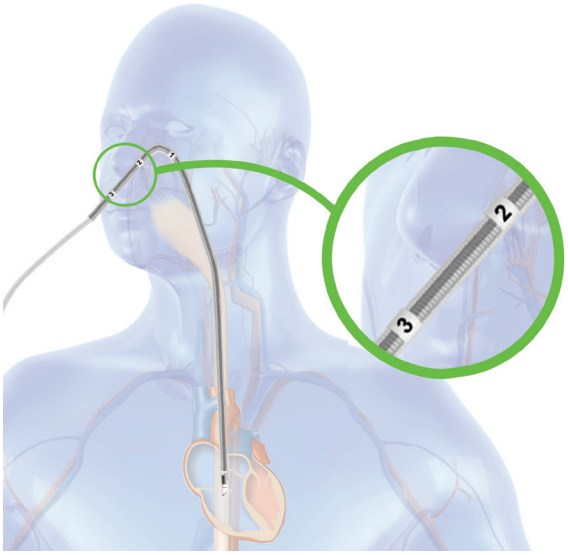
Select patient records from the start screen and then select the patient to be deleted followed by the Delete button.

If the TrueVue system has insufficient storage to start monitoring a new patient the user will be prompted to delete an existing patient.

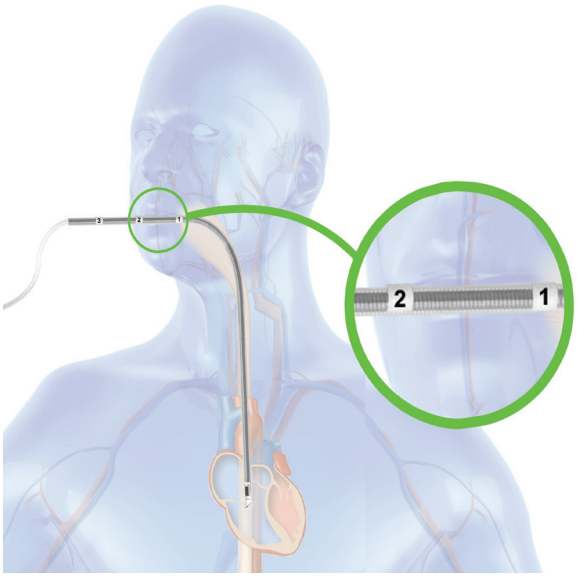
7. Obtaining the Correct Flow Signal

7.1 Positioning the Probe

The probe can be placed either orally or nasally.



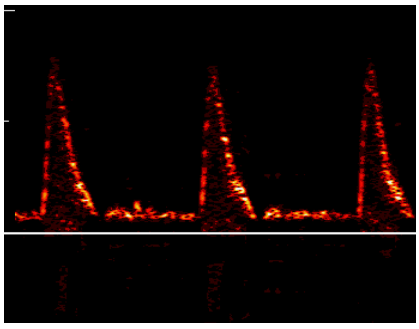
Nasal placement



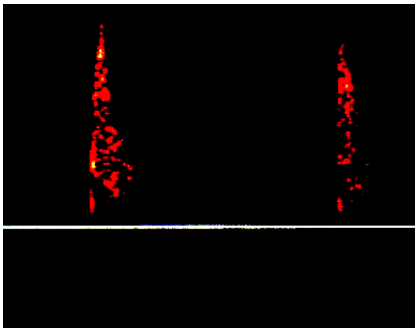
Oral placement

In the Run screen, the Doppler signal and accompanying audio are activated.

Probe positioning to achieve an optimal signal is essential. Incorrect probe placement will adversely affect the accuracy of data displayed on the screen.



Good signal quality.



Poorly defined waveform.

Probe movement can occur so it is essential to achieve the optimal signal during monitoring.

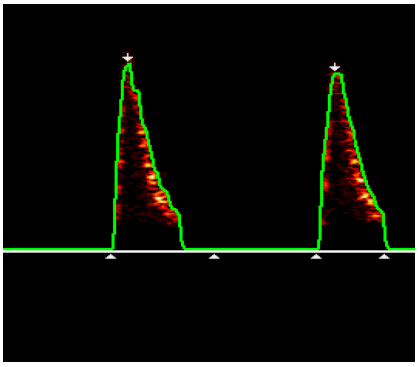
Identify the correct depth markers on the probe and insert to the appropriate proximal marker, and then rotate to locate the characteristic signal. If this is not obtained, withdraw slightly and rotate again. Repeat until the correct signal is obtained. The correct signal is also accompanied by the characteristic audible signal.

Adjust the position of the probe until the clearest and sharpest aortic waveform possible is obtained, in terms of both visual display and audible pitch. Typically, the aortic waveform with the highest peak velocity denotes the optimal signal.

An ‘ideal’ aortic waveform should have a sharp, well-defined outline, with a predominantly black centre, and a small amount of white in the trailing edge of the waveform.

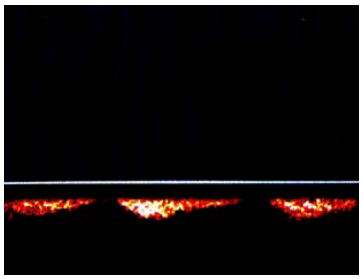
The green line, seen in the Run Screen, is the maximum velocity follower and should outline the waveform closely. There should be no ‘spikes’ in the maximum follower.

The three white arrows should be visible at the beginning and end of systolic flow as well as at peak velocity. Incorrect placement of the arrows will affect the data displayed. Refocus the probe.

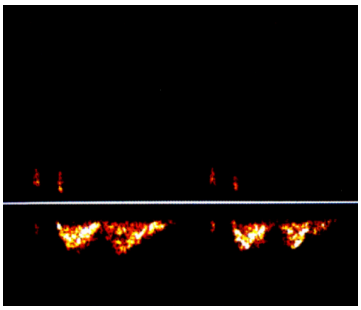


Misplacement of white arrows.

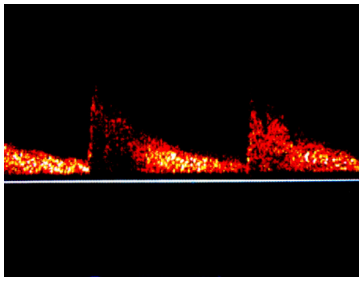
Signals from vessels other than the descending aorta will result in incorrect results.



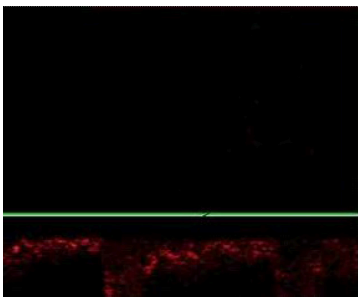
Venous signal.



Cardiac signal.



Coelic axis.



Pulmonary artery.

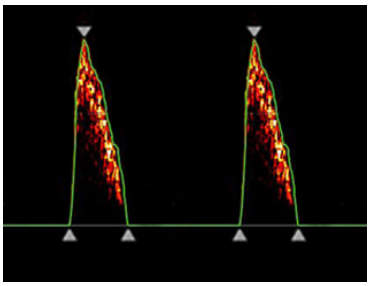
7.2 Signal Scaling

For optimal use, the TrueVue system auto scales the range of the waveform for the user. These scales may increase during monitoring. The scale will not decrease without a user intervention.

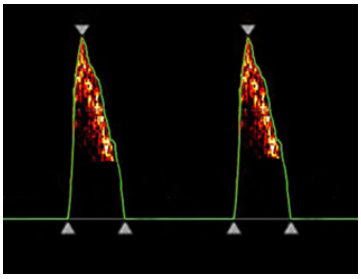
7.3 Setting the Signal Filter

The TrueVue system has a filter, which can be used to remove artifacts caused by low frequency signals due to excess heart valve or wall motion noise. This filter is off by default.

Wherever possible, the patient treatment should be carried out with the same filter settings. Changing the filter settings while monitoring is in progress or if the filter is used when not required, may cause inappropriate placement of the base arrows and may affect the reported results. This must be taken into account when interpreting trend or graphical data.



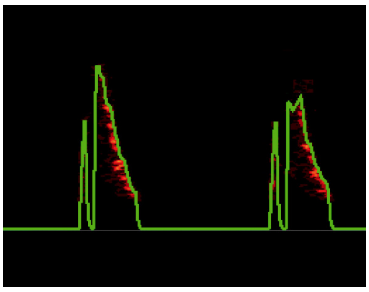
Filter not required.



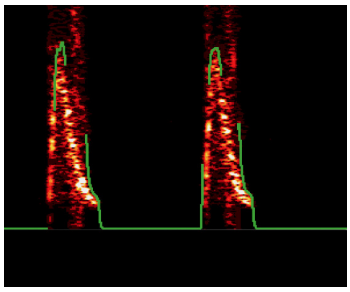
Inappropriate use of the filter.

7.4 Setting the Signal Gain

The amount of amplification applied to the signal in the TrueVue system is called the Gain. Insufficient or excessive gain will result in a poor-quality signal.



Insufficient gain.



Excessive gain.

The gain will increase or decrease on the numerical scale and will be seen by a corresponding increase or decrease of white within the trailing edge of the waveform.

The audio volume is not affected by the gain setting.

7.5 Finding the Maximum Flow

Rotate the probe as needed to obtain blood flow in the midstream of the descending thoracic aorta. This is denoted by a sharp, well defined outline indicating maximal velocity. This is accompanied by the sharpest audible pitch.

Blood flow at the aortic wall travels at a greater range of flow velocities producing more spectral dispersion and a less distinct sound indicating an inadequate signal.

7.6 Full Width Run Screen

The waveform is displayed on a Full Width Screen which scrolls from right to left. The waveform follower is shown on this display as a green line, with white arrows showing the position of the peak velocity and systole points on each heartbeat complex. The display window covers a period of 5 seconds.

The monitor will reject any heartbeat complexes which contain excess noise when performing systole-based calculations. It will also reject complete complexes for heart rate calculations if excess noise is detected between peaks. If the monitor is unable to calculate the heart rate, a triple dash (“---”) will be displayed for the values of the appropriate results.

The TrueVue system suppresses narrow-band noise of a constant frequency or interference from external sources. If noise is detected, it will be ignored. If the frequency is varying, the Truevue system will not be able to resolve the waveform.

If electrical noise is present, for example from an electro-surgery unit, then the TrueVue system will suppress the waveform follower when it encounters excess noise.

If continuous noise is detected, the waveform is removed and the white centre line changes to blue. A message will be displayed to indicate continuous noise and the results will remain visible for up to 1 minute or before if new results can be calculated.

7.7 Changing the Number of Cycles Averaged for Calculations

It may be helpful to adjust the cycles in some situations, for example 1-2 cycles during diathermy or 10-20 for irregular heart rhythms, such as atrial fibrillation, or a marked respiratory swing.

7.8 Pausing the Display

When the screen is paused, as well as examining the waveform, a snapshot can also be taken.

A scroll indicator bar will appear on the screen allowing the user to move back through previously captured waveforms.

Although the data displayed on the screen will not change when paused, the TrueVue system will continue to record trend information.

Press run to return to the normal real-time display.

8. Additional Calculations

SVR, SVRI, DO2 and DO2I calculations will only be displayed while the CO is within calibration. If CO drifts by >20% from the value talken when Hb or MAP are manually entered, the calculations will be replaced with “---” and will not be displayed again until a new calibration is performed or if CO returns within 20% of original value.

8.1 Systemic Vascular Resistance (SVR) & Systemic Vascular Resistance Index (SVRI)

These calculations are not available if the patient data are outside the nomogram limits since volumetric results will be required.

The most recent CVP entered will be used as the default.

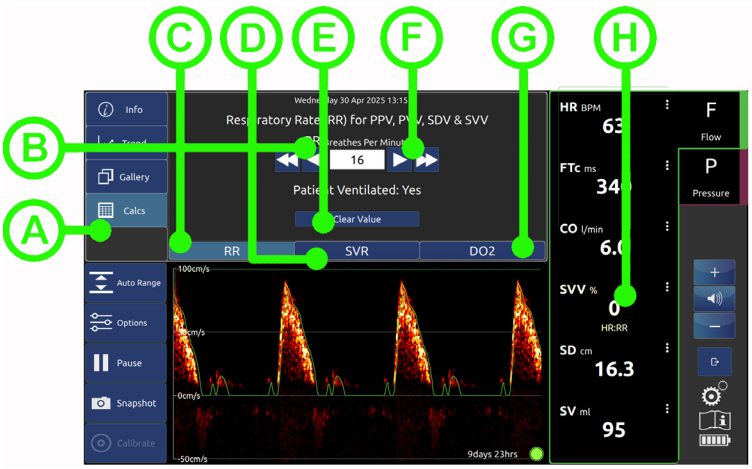
Continuous calculations:

If the pressure line is connected and valid data are being read, SVR and SVRI can be displayed on both Flow (Doppler) and Pressure Monitoring Modes by entering CVP and selecting SVR or SVRI as a displayed result in the 6 boxes.

CO is calculated from either flow (Doppler) or pressure according to the screen selected.

8.2 Additional Calculations Screen

The Additional Calculations page is used to enter information relating to parameters that require additional information.

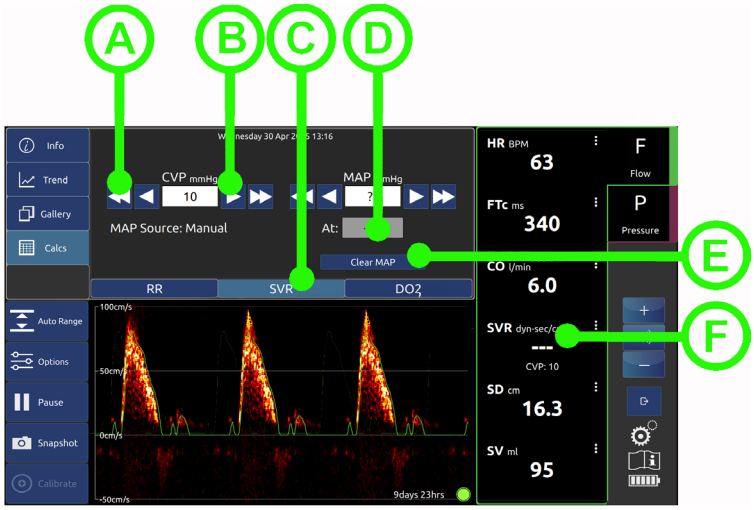


A. Calcs - Used to select the Calculation screen
B. Down button - Used to reduce the displayed number
C. Respiratory Rate - Used to enter the Respiratory Rate settings
D. SVR - Used to enter SVR settings
E. Clear Values - Clears the entered values
F. Up button - Used to increase the displayed number
G. DO2 - Used to enter DO2 settings
H. Displayed value - Entered value appears on display

Variance parameters cannot be calculated if ratio of Respiratory Rate (RR) to Heart Rate (HR) is more than 4 or Heart Rate Variation (HRV) is greater than 20%.

8.3 SVR and SVRI Calculation Screen

The SVR/SVRI Calculations page is used to enter information required to display the SVR parameter.



A. Down buttons - Used to decrease the displayed value
B. Up buttons - Used to increase the displayed value
C. SVR - Shows the selected parameter
D. Time Data entered - Records the time when the data was added
E. Clear MAP - Clears the entered MAP value
F. SVR parameter - Displayed SVR and associated values

MAP becomes invalid after 4 hours

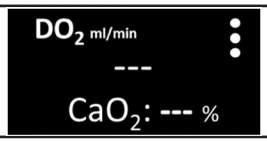
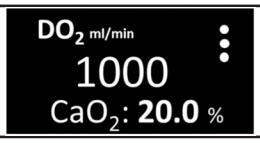
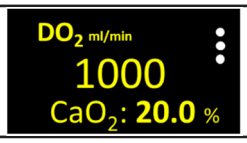
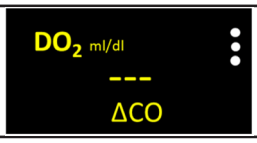
8.4 DO_2 and DO_2I Calculation Screen

The DO_2 screen allows the user to add values required to display the DO_2 parameter

A. Current CaO_2 - Displays the user entered CaO_2 value
B. Down buttons - Used to decrease the displayed value
C. Up buttons - Used to increase the displayed value
D. Clear Hb - Used to clear Hb values
E. Hb value - Used to enter Hb values
F. Time Hb entered- Displays the time Hb was calculated
G. DO_2 - Shows the selected parameter
H. DO_2 Display - Shows DO_2 value along with other required values

8.5 Time Elapsed or CO Drift

In order to display DO2, additional calculations are required. The text colour changes to yellow and if the CO drifts by more than 20%, the result will be replaced with "---'.

			
DO2 without required calculations	DO2 with required calculations	Time lapsed DO2	DO2 with drifted CO

8.6 Display SVR Calculations

SVR or SVRI can be displayed in the 6 results boxes providing these are a chosen parameter and will be displayed on a white background.

If the TrueVue system is turned off, or the probe is disconnected, then the data are retained. When monitoring recommences, the results of the last accepted SVR/SVRI are displayed within the 6 boxes, if already chosen as a default.

8.7 Delivered Oxygen (DO2) Delivered Oxygen Index (DO2I)

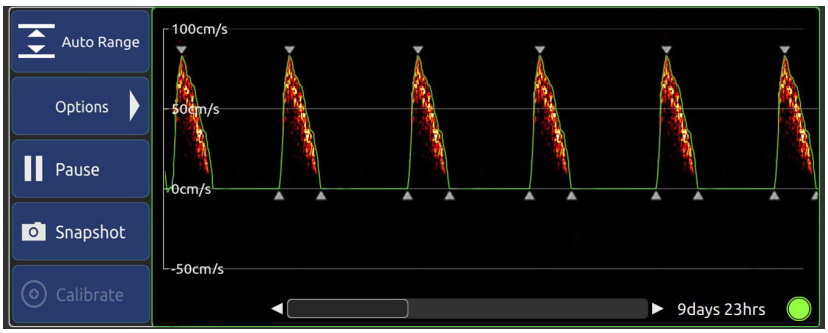
These calculations are not available if the patient data are outside the nomogram limits since volumetric results will be required.

9. Snapshots and Baseline

9.1 Taking a Snapshot

There are 2 methods of taking a snapshot.

- While in run mode
- While in pause mode



When in pause mode, the user can scroll the window to select which waveforms are captured.

Pressing the snapshot button brings up a confirmation window which when confirmed, the user is taken to the gallery view.

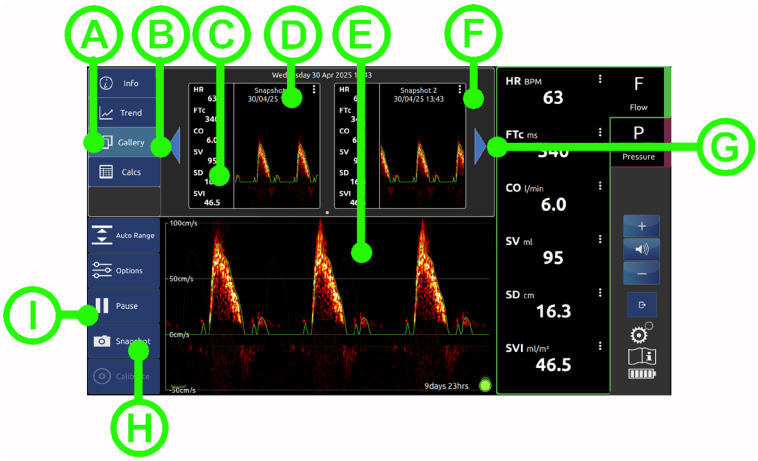
When the user presses the snapshot button a snapshot of all available waveforms and parameters are saved.

Snapshots are not limited, however, when storage is full the user will not be able to save any additional items.

Snapshot parameter values are displayed with the snapshot.

The parameter values are associated with first waveform displayed on the right of the snapshot.

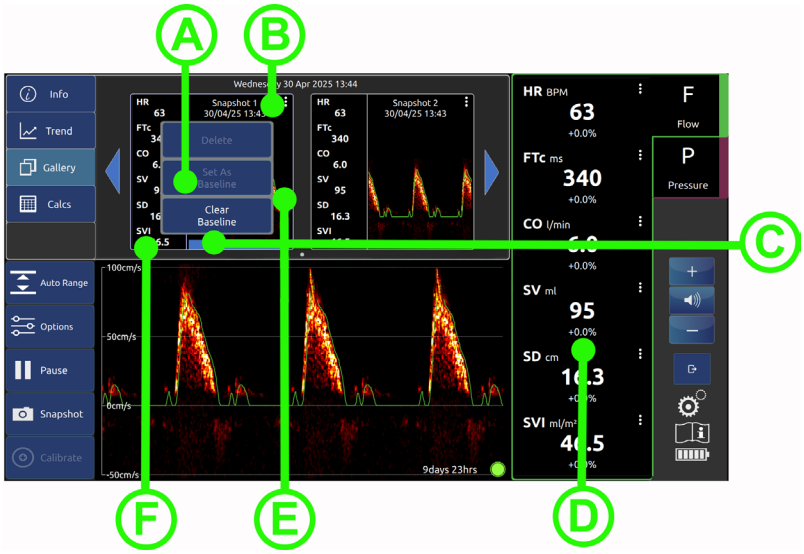
9.2 Gallery Screen



A. Gallery - Used to access all stored snapshots related to that patient
B. Scroll left - Used to scroll left through snapshots
C. Snapshot parameters - Parameters for pictured snapshot
D. Snapshot number and date - Automatically allocated number and time stamp
E. Slide indicator - Shows the number of snapshots saved
F. Snapshot options - Used to either set snapshot as baseline or delete
G. Scroll right - Scrolls through available snapshots
H. Snapshot button - Creates a new snapshot
I. Pause/Run Button - Pause or run flow screen

9.3 Setting a Baseline

In the snapshot gallery screen the user has the option of setting a snapshot as a baseline by pressing the option button in the top right corner of the snapshot.



A. Set Baseline - Used to set snapshot as baseline
B. Snapshots options - Used to open snapshot options
C. Baseline label
D. Parameters - Current parameters display percentage difference to baseline parameters
D. Remove baseline - Used to remove baseline
E. Baseline waveform - View of baseline waveform
F. Baseline parameters - Display of baseline parameters.

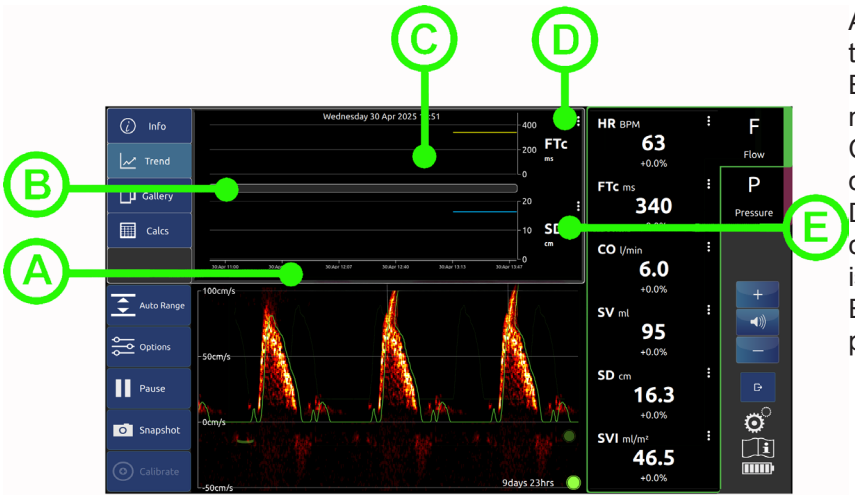
10. Trend and Information Screens

The TrueVue system records historical data for certain parameters, and can display the changes in these parameters graphically. This stored information can be used to monitor the patients trends and also to establish the effects of various interventions. While the average values for each of the results are stored every 30 seconds, trend data on up to two results can be graphically displayed.
Results for parameters such as SVR, SVRI, DO2 and DO2I calculations and any added events are also stored for later recall. Once the signal has been acquired, trend data will be recorded by the monitor even if the screen is frozen.

All trend and snapshot data are stored in the TrueVue system and not in the probe.
Displayed data is auto scaled in order to show all results and once collected trend information has exceeded the display area, the scroll bar will appear. Scrolling through historic trend data can be achieved by dragging the display. The selected mode controls which parameters are available for trending i.e. Flow based parameters in Flow Monitoring Mode and Pressure based parameters in Pressure Monitoring Mode.

10.1 Trend Screen

The selected mode will decide which parameters are available for trend i.e. when in Flow Monitoring Mode only parameters related to flow will be available.

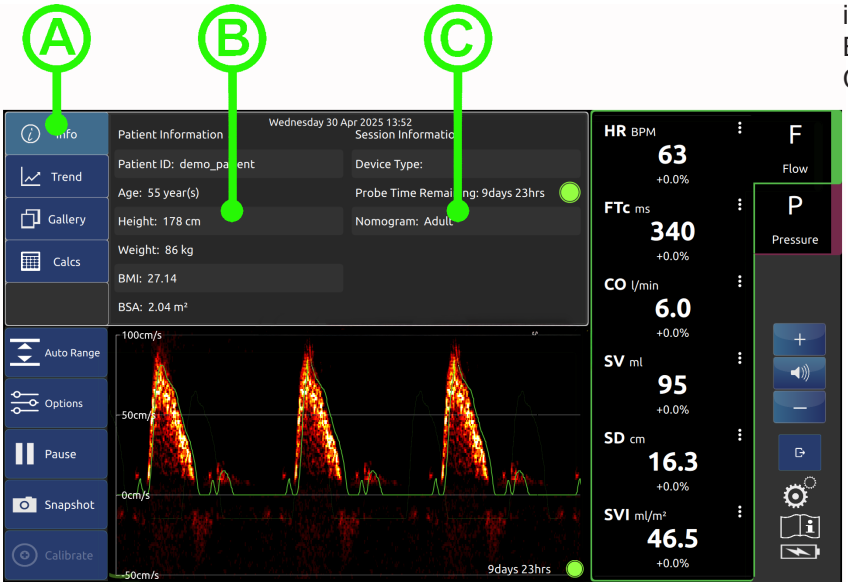


A Trend Time scale - Indicates time period of trend data
B. Trend Slide Bar - Used to move through collected data
C. Trend Data - Patient trend data
D. Trend Options - Used to choose which parameter trend is displayed
E. Parameter - Displayed parameter

10.2 Changing a Trend Parameter

A. Options - Selecting options brings up Parameter selection
B. Parameter Selection Table - Parameters available for trending

10.3 Information Screen

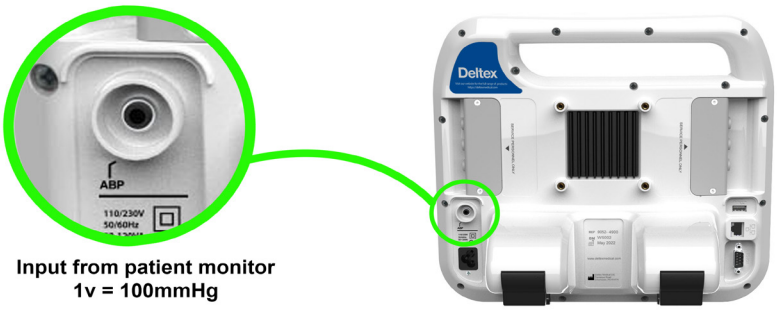


A. Info - Used to enter the information screen
B. Patient Information
C. Session Information

11. Pressure Monitoring

Any unauthorised connections to the auxiliary ports may compromise patient safety. Do not connect any equipment other than medical grade equipment (complying with BS EN 60601-1) to the TrueVue system while the monitor is connected to a patient, unless a medical grade isolator meeting BS EN 60601-1 is used.

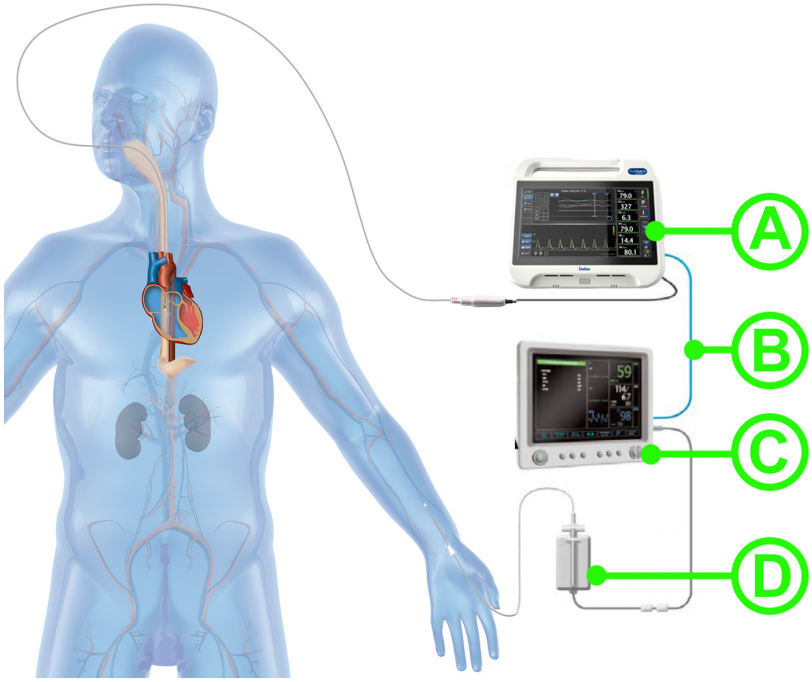
To enable Pressure Monitoring Mode, there must be an Invasive arterial blood pressure signal line connected and pressure data must be available.



ABP socket on the rear of the monitor

Connect a Deltex Arterial Blood Pressure (ABP) cable into the ABP socket. Please contact your Deltex Medical representative for details.

Before proceeding, ensure that the systolic, diastolic, and MAP pressure values displayed on both the TrueVue system and the Vital Signs Monitor are equivalent when connected via a Deltex ABP cable. If the pressure readings are not equivalent, do not use the pressure function of the TrueVue monitor and contact a Deltex representative for further assistance.



A. TrueVue System
B. ABP cable - Deltex cable that allows the transfer of invasive arterial pressure signal from vital signs monitor to TrueVue System
C. Vital signs monitor
D. Pressure transducer

Before cardiac output-based results can be displayed in Pressure Monitoring Mode, the pressure data must be calibrated using the flow waveform (Doppler).

A minimum of 10 heart beats or 10 seconds are required to calibrate.

The calibration status will be displayed as a progress bar within a pop-up window.

When the calibration time expires, all cardiac output-based parameters in Pressure Monitoring Mode will cease to function immediately. A calibration can be performed at any time providing a suitable flow signal can be obtained.

11.1 Uncalibrated Pressure Screen

A. Pressure parameters - Parameters relating to pressure
B. Pressure mode - Used to select pressure mode
C. Uncalibrated parameters - Results will be displayed once calibration has been performed
D. Pressure signal - Live pressure signal
E. Calibrate pressure - Used to calibrate pressure signal

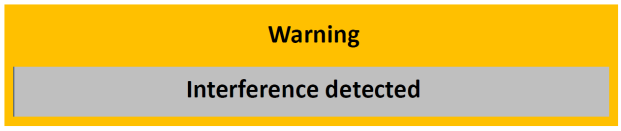
11.2 Calibrated Pressure Screen

A. Pressure parameters - Parameters relating to pressure
B. Pressure mode - Used to select pressure mode
C. Calibrated parameters - Standard and volumetric parameters
D. Pressure signal - Live pressure signal.
E. Calibrate pressure - Used to calibrate pressure signal

12. Pop-up windows

Pop-up windows are used to make the user aware of monitor events. Some windows require the user to perform an action, while others remove themselves automatically.

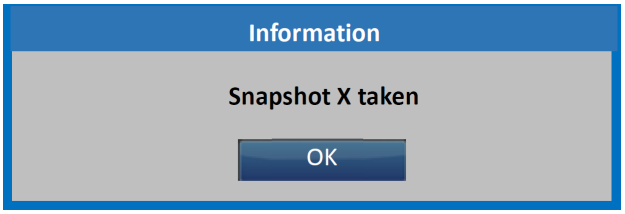
12.1 Warning Pop-Up



A warning pop-up is used to highlight an issue to the user without disrupting the use of the monitor. There is no user interaction on this pop-up, which will be removed by the application when it decides the event causing the warning has passed or a suitable time interval has elapsed.

Event	Message
Noise Detected	Interference detected
Battery Low	Battery level low. Connect to mains power

12.2 Information Pop-Up

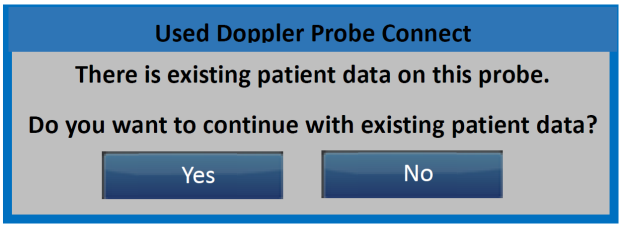


An information pop-up highlights an event to the user for the user to optionally acknowledge via an OK button. If the user does not acknowledge the event the pop-up will be dismissed after a defined time interval.

Informational pop ups are used for probe connections, snapshots and calibration events.

Event	Message
Invalid Probe Connected	An invalid probe has been connected.
Expired Probe Connected	An expired probe has been connected
Pressure Calibration Expired	Pressure calibration has expired
Doppler Probe Disconnected	Doppler probe disconnected
Doppler Probe Expired	Doppler probe has expired
Pressure Mode Selected for First Time	Check the arterial blood pressures displayed on the TrueVue and patient monitor align

12.3 Confirmation Pop-Up



A conformation pop-up is used when the user is required to perform an action before proceeding.

Confirmation pop-ups appear when used probes are connected, patients deleted and user deletions.

Event	Buttons	Message
Delete Patient Request	Yes, No	Delete Patient <patient id>?
Delete User Request	Yes, No	Delete User <user id>?

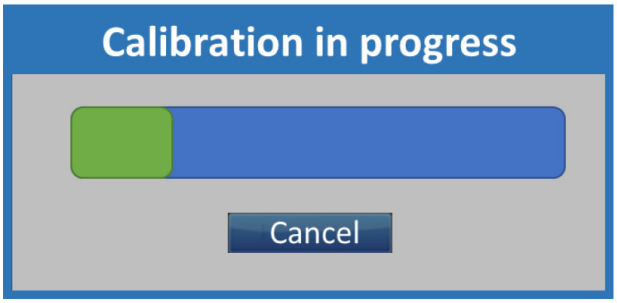
12.4 Form Pop-Up

A form pop-up is used to get the user to enter data.

Form pop-ups are used for adding licence requests and adding users

Event	Buttons	Message
Add Licence Request	Add, Cancel	Enter licence key
Add User	Add, Cancel	Enter user name

12.5 Progress Pop-Up



A progress pop-up is used to highlight to the user the progress of an action being performed with the possible ability to terminate the action before completion. The pop-up will be dismissed when progress is complete.

Progress pop-ups are used for pressure calibration and data export.

Event	Buttons	Message
Pressure Calibration Started	Cancel	Calibration in progress
Data Export in Progress	Cancel	Data export in progress

12.6 Error Pop-Up

An error pop-up is used to inform the user of an error condition on the monitor. The pop-up can only be dismissed by confirming the error via the OK button provided.

Error pop-ups are used for software and hardware errors

Event	Buttons	Message
Software Error	OK	Software Error <error id>
Hardware Error	OK	Hardware Error <error id>

13. Demonstration Mode

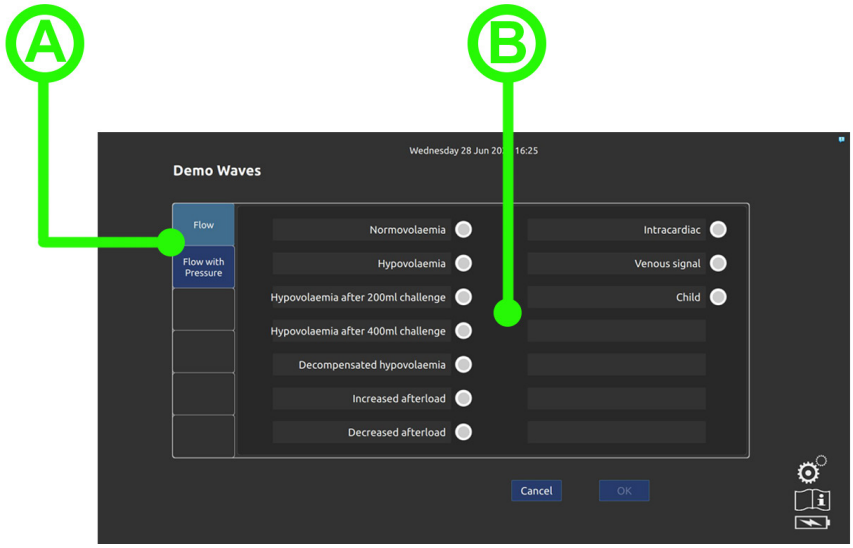
The monitor can also be operated using a set of pre-recorded waveform signals. This allows the TrueVue System to be demonstrated without the need for external signal sources. It also allows users to familiarise themselves with the operation of the TrueVue system and the various facilities available, without having a patient connected to the monitor.

The Demo Waves button is only active when a probe is not connected to the TrueVue system. If a probe is connected the Demo Waves button becomes inactive.

If a probe is connected to the TrueVue system while it is running in demonstration mode, the monitor will exit the demonstration mode.

13.1 Running the Truevue system in Demonstration Mode

Select Demo waves from the start screen

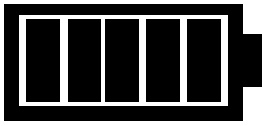
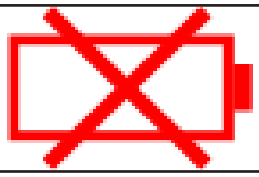


A - Demo type - Allows user to select type of demo, Flow or Flow with pressure.
B - Demo recordings - Allows user to select which demo to display

14. Batteries

The monitor has a battery intended to be used for short periods when mains power is not available. The battery is not a user serviceable component.

The table shows different battery icons displayed on-screen.

Battery level	Icon
0-20%	
21-40%	
41-60%	
61-80%	
>81%	
Faulty	
Charging	

At 5% battery charge the monitor will display a message requesting the user connects the monitor to a mains supply.

At 0% the monitor will shut-down

15. System Specifications

15.1 Classification

Protection Type	Class 2 (Functional Earth) equipment
Degree of Protection	Type BF applied part
Ingress Protection	IP2X
Mode of Operation	Continuously available (may need refocusing)
Medical Device Classification	IIb

The equipment is constructed and tested as defined in BS EN 60601-1 (Safety of Medical Equipment) Class 2 (Functional Earth) Type BF.
This equipment may be affected by the use of high-energy electro-surgical equipment (e.g. diathermy) in close proximity.

15.2 Performance Characteristics

This specification is valid after the monitor has warmed up for 60 minutes in an ambient temperature of 15°C to 30°C.

15.3 Physical Characteristics

Width	32cm (12.6”)
Depth	14cm (5.5”)
Height	29cm (11.4”)
Weight	3.4kg (5.7lb)

15.4 Environmental Characteristics

Ambient Temperature:	
Operating Transport and Storage	15 to 35°C (59°F to 95°F) -20 to 60°C (-4°F to 140°F)
Relative Humidity:	
Operating, Transport and Storage	5%-90% (non-condensing)
Atmospheric Pressure:	
Transport and Storage:	700hPa to 1060hPa (525mmHg to 795mmHg)

15.5 Monitor and Accessories Disposal

For the safe disposal of the TruVue System, please refer to the WEEE mark for additional details.

The Deltex Medical supplied power cords and leads contain no hazardous substances and apart from used probes no special disposal is required.

Used probes should be disposed of in accordance with the appropriate guidelines for clinical waste.

15.6 System Characteristics

Ultrasound

4.02MHz continuous wave Doppler ultrasound (Ispta < 250mW/cm2 at 5 mm in situ) 450Hz and 900Hz high pass filters.

Display

Touchscreeen 11.6” Full HD LCD display

Continuous Operation

15.7 Acoustic Output

The following table provides maximum acoustic output measurements from the 4.02 MHz oesophageal Doppler probe transmitting Continuous Wave ultrasound (in RUN mode) when connected to the True-Vue system monitor.

The measurement results presented in the table below were determined in accordance with the international standard IEC 61157 entitled ‘Requirements for the declaration of the acoustic output of medical diagnostic ultrasound equipment’.

The TrueVue system has one fixed acoustic output level which is fixed by the circuitry and cannot be adjusted by the user.

The monitor emits minimal ultrasound (acoustic) emissions that are classed as non-ionising radiation. The power and beam shape are specified in table below.

Ionising radiation is not emitted. Device emits safe controlled levels of diagnostic ultrasound via the ODP/TrueVue probe compatible with the intended device function in accordance with BS EN 61157:2007. Manufactured to meet the requirements of BS EN 60601-2-37:2008 +A1:2015.

Mode Parameter		Run mode
Peak-negative acoustic pressure	p_-	103 kPa (±16%)
Spatial-peak temporal average intensity	I_{spta}	362 mW.cm-2 (±33%)
System settings		not applicable
Distance from transducer output face to point of maximum pulse-pressure-squared integral	*lp*	0.5 mm (±0.2mm)
-6 dB beam width at lp	W_{b6} (||) (⊥)	1.9 mm (±21%) 1.3 mm (±20%)
Output beam dimensions*	(||) (⊥)	5.5 mm 2.1 mm
Arithmetic mean acoustic working frequency	f_{awf}	4.02 MHz
Initialisation and power-up modes		not applicable
Maximum power output		6 mW (± 14%)
Output beam intensity*	I_{ob}	42 mW.cm-2 (±14%)
Acoustic output freeze		No
Transducer stand-off distance	I_{TS}	contact

The values for the output beam dimensions, and the output beam intensity, are derived from the geometrical crystal dimensions provided by the manufacturer.

15.8 Acoustic Output Safety

The oesophageal Doppler probe transducer has a static continuous wave (CW) output. This output is fixed therefore TI and MI values cannot be changed by any system controls available to the user.

Testing to the requirements of IEC 62359 has determined the Thermal Indexes (TI) as follows:

Parameter	Value
Soft-tissue thermal index, TIS, for non-scanning modes	0.12 ± 16%
Bone thermal index, TIB, for non-scanning modes	0.94 ± 33%

The reported uncertainties are based on standard uncertainties multiplied by a coverage factor, k=2, providing a level of confidence of approximately 95%.

15.9 Signal Scaling

The TrueVue system automatically scales the displayed range for the user, if the velocity exceeds the displayed scale the system will automatically increase the range. The new range will remain until monitoring finishes.

15.10 Accuracy

Data acquisition is dependent upon probe positioning and patient anatomy and physiology, therefore interpretation depends less on absolute values than on comparative measurements.

For a correctly aligned probe the resolution of velocity measurement is 5% of the nominal full-scale value of the selected range. The timing resolution is 4ms, which is the interval at which FFTs are performed and the screen is updated.

Trend data is stored with fixed ranges and the accuracy of the displayed value will be better than ±1% of the displayed on-screen range marker value.

15.11 Results

Results based on flow

CO Cardiac Output
SV Stroke Volume
HR Heart Rate
CI Cardiac Index
FTc Flow Time Corrected
PV Peak Velocity
SVI Stroke Volume Index
SD Stroke Distance
SVV Stroke Volume Variation
SDV Stroke Distance Variation
PVV Peak Velocity Variation
FTp Flow Time to Peak
MA Mean Acceleration
MD Minute Distance
SVR Systemic Vascular Resistance
SVRI Systemic Vascular Resistance Index
DO2 Delivered Oxygen
DO2I Delivered Oxygen Index
SOI Stroke Output Index
InoI Inotropy Index

Results based on pressure

CO	Cardiac Output
SV	Stroke Volume
HR	Heart Rate
CI	Cardiac Index
SVI	Stroke Volume Index
SVV	Stroke Volume Variation
SVR	Systemic Vascular Resistance
SVRI	Systemic Vascular Resistance Index
PPV	Pulse Pressure Variation
BP	Blood Pressure
HRV	Heart Rate Variation
CPO	Cardiac Power Output
CPI	Cardiac Power Index
PP	Pulse Pressure
Ea	Arterial Elastance
Eadyn	Dynamic Arterial Elastance
DO2	Delivered Oxygen
DO2I	Delivered Oxygen Index

15.12 RS232 Protocols

Please contact your Deltex Medical Representative for more information

15.13 Power Supply

Power Requirements - 110/230 +/- 10% VAC (~)
50-120VA
50/60 Hz

15.14 Battery

Battery - 57-65Wh EN62133 UN38.3
Minimum 2 hour run time when new
Lithium ion type battery

15.15 Auxiliary Connections

Any unauthorised connections to the auxiliary ports may compromise patient safety. Do not connect any equipment other than medical grade equipment (complying with BS EN 60601-1) to the TrueVue system while the monitor is connected to a patient, unless a medical g–rade isolator meeting BS EN 60601-1 is used.

Serial Port -	For EMR
USB Port -	For software updates
ABP Port -	For connection to arterial blood pressure (ABP) signal, input scale must be 1volt per 100mmHg. For display of pressure parameters.
Patient Interfaces -	Connection to oesphageal doppler probe

15.16 Symbolic Markings

	Caution		Refer to instruction manual booklet
	Type BF		Latex-free product
	WEEE Mark (European Directive 2002/96/EC)*. Indicates separate treatment from general waste at end of life.		Conformité Européenne (CE) Marking of conformity to European Medical Device Directive
	Sterilised with ethylene oxide		Swiss authorised representatives
	Use by. YYYY-MM		EU authorised representatives
	Catalogue number		Batch code
	Serial number		Storage temperature range: -20° C to 60° C
	Degree of protection against harmful ingress of water	IP20	Degree of protection against solid foreign objects.
	USB port		Network port
IOIOI	RS232 port	ADC	Analogue to digital converter port
	Website symbol		Alternating current
	Probe connector orientation mark		AC power input
	Do not reuse. Single patient use		Date of manufacture
	Volume Control Knob		Not to be serviced by users
	Fragile. Do not get wet. This side up.		

* Within the European Union – EU-wide legislation, as implemented in each Member State requires that the waste electrical and electronic products carrying this mark must be disposed of separately from normal household waste. This includes the monitor and electrical accessories, such as the power cord. For UK customers contact Deltex Medical customer Services to arrange return.

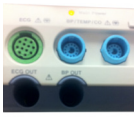
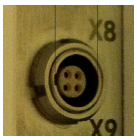
15.17 Accessories and Spares

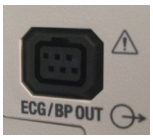
Operating handbook IFU (Electronic version is available on TrueVue system, a printed copy can be provided on request)
Roll stand
Power cord
RS232 null modem cable (Screened, 3m or less in length) – not provided by Deltex
ABP Cable

15.18 Probes and Probe Accessories

Deltex Medical probes DP12, DP240, I2C, KDP

15.19 ABP Cables & Modules

High end monitor (HEM) manufacturere	HEM Model & Number	DML Part Number	(HEM) Socket/ Module	(HEM) Plug Type required	Plug Images
Fukuda Denshi	DS7100 (must have IBP option) DS7200 & DS7300	**9051-3947**		**6.35mm Stereo Jack**	
GE Datex*	AS/3 & AS/5 Anesthesia monitors CS/3 & CS/5 Critical care monitors	**9051-3949**		**4 Way LEMO**	
Philips	IntelliVue MP40 and above. Cable used in conjunction with M1006B #C01 module	**9051-3950**		**3.5mm Stereo Jack**	
Draeger	Infinity Delta, Delta XL, Kappa XLT Infinity Acute Care System Infinity M540 Interface MS20662 required	**9051-3951**		**14 Way SCSI**	
GE PDM**	Solar 8000, Carescape 650, B850	**9051-3952**		**9 Way PDM (Special)**	
GE Marquette*	6000 series 7000 series using Tram 250/450 modules	**9051-3953**		**6 way LEMO**	
GE Datex & Marquette*	Some S/5 monitors, Carescape B650 & B850 (note: If PDM is being used port becomes inactive) TRAM 451 Dash 3000, 4000 & 5000	**9051-3957**		**Mini DIN 7**	

Spacelabs	90470 Pressure & ECG module, 90402 Pressure module, 90305 Mainframe	**9051-3958**		**4.4mm Bantam Stereo Jack**	
Fukuda Denshi	DS8500	**9051-3959**		**6 Way (Special)**	
Datascope	Spectrum & Passport 2	**9051-3960**		**Mini DIN 6**	
Mindray	***T5 & T8 Beneview monitors built after Nov 2009 are supported	**9051-3961**		**9 Way micro-D Plug**	
Mindray	T1 module, compatible with T5&T8 patient monitors	**9051-3962**		**Special**	
Mindray	N1 Module	**9051-3983**		**Special**	
GE Datex	Module FCU5(P)	**9051-3964**		**Mini DIN 8**	
GE Datex	Some AS/3&5 Anaesthesia monitors CS/3&5 Critical Care Monitors Cardiocap/5	**9051-3965**		**44 Way HDD**	
Nihon Kohden	Lifescope BSM 5100A, BSM 5100K, BSM 5105K, BSM 5106A	**9051-3966**		**Special**	

15.20 Other Associated Cables/Devices

Manufacturer	Manufacturer P/N	DML Part number	Image	Comments
Philips	M1006B #C01	**9051-3980**		Module compatible with Philips IntelliVue systems MP40 and above
Draeger	MS20662	**9051-3981**		Module required when using Draeger Infinity M540 Acute care systems
Draeger	MS22259	**9051-3951A**		Optional Draeger “Y” Splitter cable used with M540 device.

15.21 Electromagnetic Compatibility

The TrueVue system is designed for use in the professional health care environment except near the RF shielded room of an ME system for magnetic resonance imaging where the intensity of EM disturbances is high. Where the waveform is displayed correctly the calculated parameters will be within their stated accuracy. The system is sensitive to airborne interference especially in its band of operation. In flow mode the accuracy of the TrueVue system depends on the green line follower. If noise is observed on the spectral display, then the following steps can be used to eliminate or at least identify the source of the interference:

- If applicable Switch off and on equipment in the immediate vicinity in order to isolate the source of the noise.
- Relocate and/or re-orientate the offending equipment if possible.
- Increase the distance between the TrueVue system and the offending equipment as much as possible.
- Interference may be borne by the mains supply, so re-connect the TrueVue system to a different power outlet to see if this makes a difference.

If possible, the TrueVue system should not be used adjacent to or stacked with other equipment. However, if adjacent or stacked use is necessary, the TrueVue system should be observed to verify normal operation in the configuration in which it will be used.
To avoid increased emissions or decreased immunity of the TrueVue system, use only accessories and peripherals recommended by Deltex Medical.

Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the accompanying documents.

15.22 Manufacturers Declaration

The TrueVue System is intended for use in the electromagnetic environment described in Tables 1, 2, 3 & 4

Table 1: Guidance and manufacturer's declaration – electromagnetic emissions		
The TrueVue System is intended for use in the electromagnetic environment specified below. The customer or the user of the TrueVue System should assure that it is used in such an environment		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The TrueVue system(1 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
	Group 2	The TrueVue system(2 must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class A	NOTE: The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this Equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Table 2: Guidance and manufacturer's declaration – electromagnetic immunity			
The TrueVue System is intended for use in the electromagnetic environment specified below. The customer or the user of the TrueVue System should assure that it is used in such an environment.			
Immunity test	BS EN 60601 Test level	Compliance level	Electromagnetic environment - guidance.
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical transient/fast burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (95% dip in UT for 0.5 cycle) 40% UT (60% dip in UT for 5 cycles) 70% UT (30% dip in UT for 25 cycles) <5% UT (>95% dip in UT for 5 seconds)	<5% UT (95% dip in UT for 0.5 cycle) 40% UT (60% dip in UT for 5 cycles) 70% UT (30% dip in UT for 25 cycles) <5% UT (>95% dip in UT for 5 seconds)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the TrueVue System requires continued operation during power mains interruptions, it is recommended that the TrueVue System be powered from an uninterruptible power supply (UPS) or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: UT is the a.c. mains voltage prior to the application of the test level.			

Table 3: Guidance and manufacturer's declaration – electromagnetic immunity

The TrueVue System is intended for use in the electromagnetic environment specified below. The customer or the user of the TrueVue System should assure that it is used in such an environment.

Immunity test	BS EN 60601 Test level	Compliance Level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 V 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the TrueVue System system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance. $d = 1.2\sqrt{P}$. $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz. $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey a, should be less than the compliance level in each frequency range b. Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the TrueVue system is used exceeds the applicable RF compliance level above, the TrueVue System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as orientating or relocating the TrueVue system.
b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 4: Test communications specifications for ENCLOSURE equipment PORT IMMUNITY to RF wireless

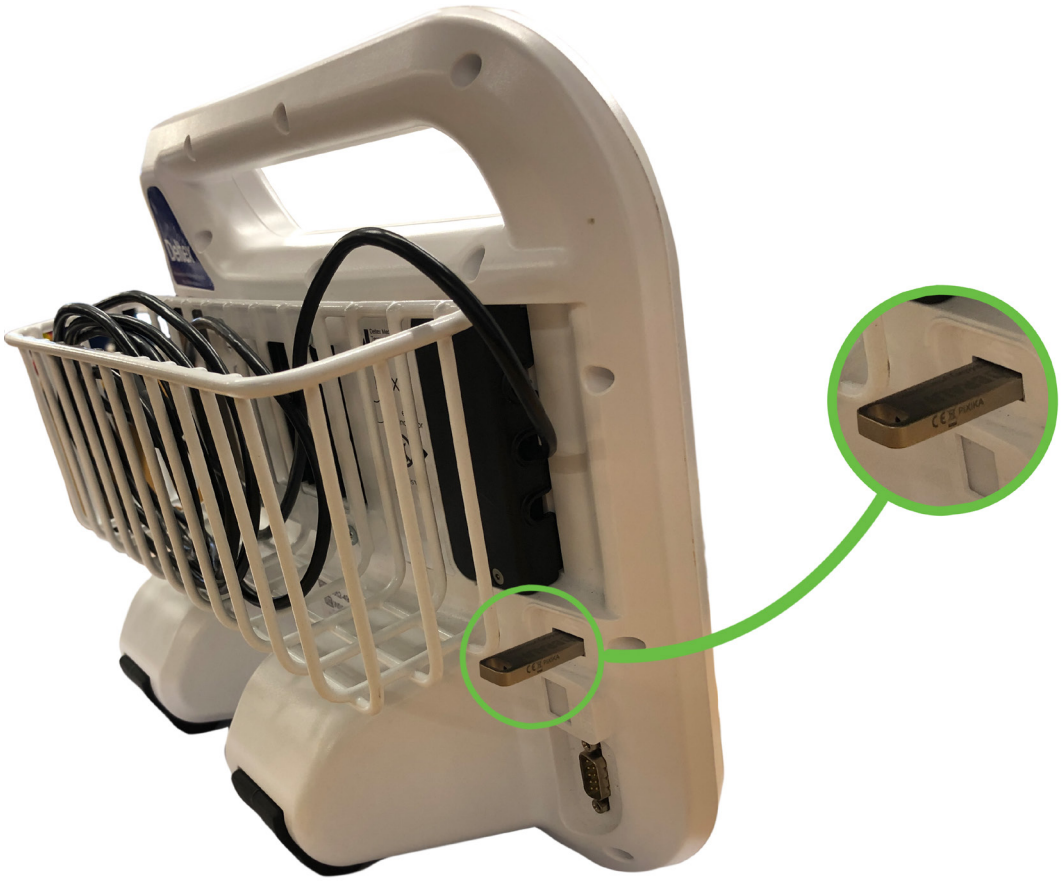
Test frequency (MHz)	Band (MHz)	Service	Immunity Test Level
385	380 - 390	TETRA 400	27
450	430 - 470	GMRS 460, FRS 460	28
710	704 - 787	LTE Band 13, 17	9
745			
780			
810	800 - 960	GSM 800/900, TETRA 800, IDEN 820, CDMA 850, LTE Band 5	28
870			
930			
1720	1700 - 1990	GSM 1800, CDMA 1900, GSM 1900; DEC LTE Band 1,3, 4, 25; UMTS	28
1845			
1970			
2450	2400 - 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	28
5240	5100 - 5800	WLAN 802.11 a/n	9
5500			
5785			

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the TrueVue system, Including cables specified by Deltex Medical. Otherwise, degradation of the performance of this equipment could result. Reviewed once EMC is complete

16. Software Update and USB offload

16.1 Updating Software

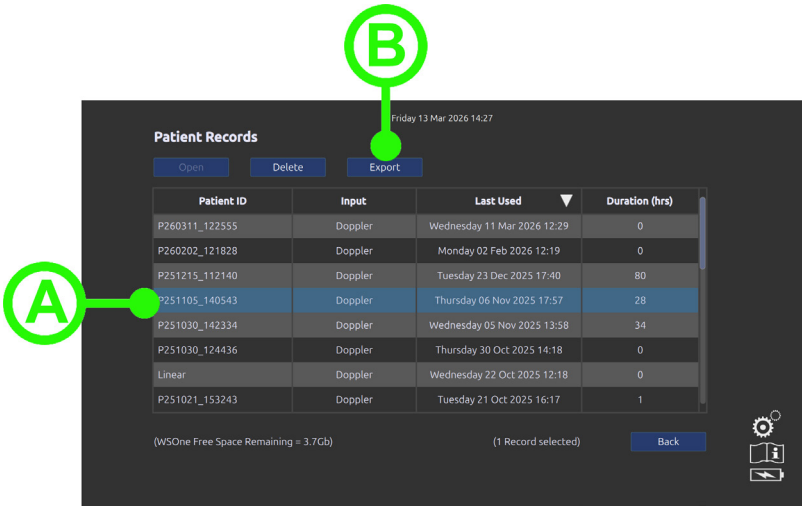
Plug USB in and switch the TrueVue system on. Follow on screen prompts in order to complete the software update process



16.2 Exporting patient data

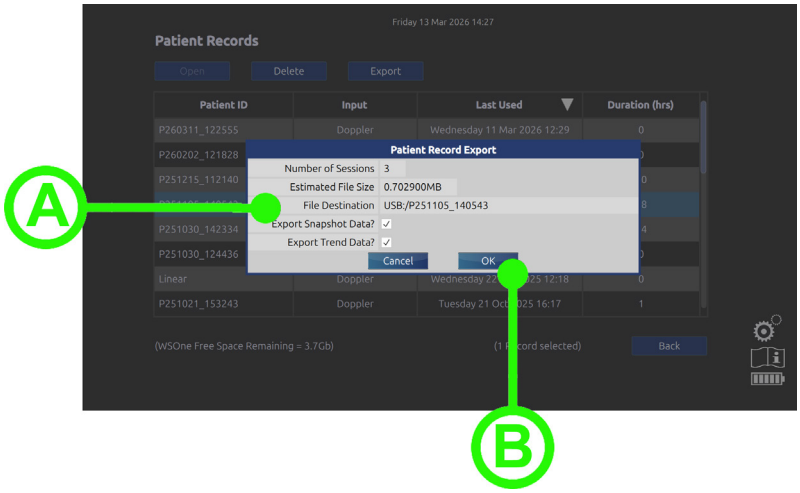
Navigate to the Start Screen (see Section 6.3). Select Patient Records to open the records list. Insert a USB drive. Wait for the Export button to activate.

Note: Use a formatted USB drive with a capacity less than 32 GB.



A. Selected Patient: The record chosen for export.
B. Export Button: Press to begin the data transfer.

16.2 Patient Data Export Options



A. Export Details: Displays the file size and destination.
B. OK Button: Select to begin the data transfer.

Note: Exported patient records can be viewed on a computer.

17. Cleaning Maintenance and Warranty

17.1 Monitor Cleaning

Deltex Medical recommends that the TrueVue system is cleaned at least once a month. It may be appropriate to clean the monitor more frequently depending on the environment in which it is used. The monitor must be switched off, and the power cord disconnected, before cleaning.

Deltex Medical recommends that the TrueVue system is cleaned with 1% Sodium Hypochlorite (Milton - 10,000ppm) solution. A damp soft cloth should be used.

The display should be cleaned with a soft cloth dampened with the solution to avoid scratching the screen. Do not use solvents, or cleaners containing solvents. Care must be taken to avoid liquid cleaning solution entering the monitor.

The monitor case, including the rear panel and button, may be cleaned with a soft cloth dampened with the solution. Solvents must not be used. Care must be taken when cleaning the speaker vents to prevent fluid entering the unit. Care must be taken to avoid liquid entering the connector sockets. As with any electronic equipment the monitor must not be immersed in liquid nor should any liquid be allowed to enter the unit.

The Dopplink may be cleaned using a soft cloth dampened with the cleaning solution. Under no circumstances should the end of the cable be immersed in the solution. Deltex Medical does not recommend sterilisation of the monitor or cable.

17.2 Routine Maintenance

TrueVue system routine maintenance is limited to cleaning as detailed above and inspection of cables and connectors for wear or damage. Deltex Medical recommends that the cables be inspected at least once a month. These cables and connectors should be replaced if any cracks are found that would allow ingress of conductive fluids.

17.3 Repairs, Servicing and Calibration

The monitor does not require regular servicing or calibration, however, Deltex Medical does recommend that the monitor has one planned preventative maintenance (PPM) check per year. This can either be arranged through Deltex Medical or one of its representatives. Deltex Medical has a return to manufacturer policy for repair and servicing. Please contact your Deltex Medical representative for details

Deltex Medical will be responsible for the safety, reliability and performance of this equipment only if:

- Adjustments, modifications or repairs are made only by persons authorised by Deltex Medical.
- The electrical supply at the point of use complies with appropriate local requirements and is within the specification of the monitor.
- The monitor is used in accordance with the instructions for use identified in this operating handbook.
- The monitor has an expected life of 7 years, the monitor’s battery life is approximately 3 years assuming the battery is stored and maintained correctly.

17.4 Warranty

The warranty gives a comprehensive level of repair and service and applies for two years from date of purchase. It will ensure that if the TrueVue system does develop a problem it will be rectified in the quickest possible time with the minimum inconvenience.

The agreement includes all parts and labour, packing and carriage. It excludes repairs due to loss or wilful damage.

Please call Deltex Medical Ltd and a loan TrueVue system will be dispatched for earliest possible delivery. The Maintenance Agreement can be extended after the one year warranty period. Contact your Deltex Medical representative for more details.