

Introducing TrueVue[™] LOOPS

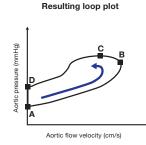
In collaboration with Lariboisiere Hospital Paris, Deltex Medical has developed a highly innovative method of simultaneously displaying aortic blood flow velocity and aortic blood pressure throughout every heartbeat. The system provides new biomarkers to predict cardiovascular risk.

Displaying the TrueVue™ LOOPS:

The system plots aortic blood flow velocity using TrueVue™ DOPPLER ultrasound, against aortic blood pressure from a standard arterial pressure transducer. It does this in real time, 180 times per second, to create a Velocity-Pressure Loop. Key to loop plot:

Synchronised raw aortic pressure and flow velocity waves Aortic flow velocity (cm/s

Time (s)



Point A.....is the diastolic pressure prior to heart contraction Point B..... is the plot at the point of maximum flow velocity

Point C.....is the plot at maximum pressure

Point D.....is the end point of the heart's ejection

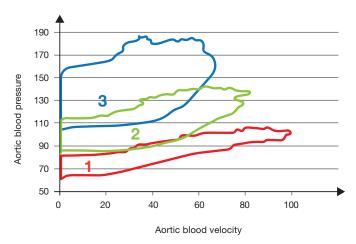
TrueVue™ LOOPS have various shapes depending on vascular resistance and patient characteristics.

Three TrueVue LOOPS showing visually three different blood flow and pressure states:

Loop 1a low blood pressure state (hypotension) with low vascular resistance, flow velocity is high due to low resistance to heart ejection; here there is risk of kidney injury or heart attack

Loop 2.....a more normal state with optimal flow and optimal pressure

Loop 3high blood pressure state (hypertension) where risks of stroke or heart failure are present.



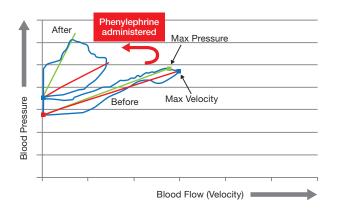
The system does not require calibration and provides a simple visual diagnostic display of the patient's current haemodynamic status. The display allows easy and rapid understanding of complex flow and pressure phenomena. In one display it provides immediate feedback, to better titrate vaso-active drugs, inotropes and fluids to optimise the patient's condition and keep them in the safe zone.

Why is TrueVue™ LOOPS distinct from all other haemodynamic systems:

The TrueVue™ LOOPS system is distinct from any prior approach. In real-time it shows the relationship of flow velocity and pressure throughout each heartbeat. The systems simplicity is entirely due to its ability to measure blood flow velocity and arterial pressure directly. TrueVue is the only available system combining two distinct technologies, Doppler ultrasound for flow velocity and a standard arterial line for arterial blood pressure. Vasopressors administered to improve blood pressure in hypotensive patients results in improved arterial pressure values, but what impact is there on flow? Devices using arterial pressure to derive flow (as Cardiac Output) will show that the rise in blood pressure also results in a rise in Cardiac Output (flow).

This would often be an erroneous result and an artefact of the measuring system. An example is the use of Phenylephrine as shown below.

Figure 3: TrueVue LOOPS display of flow velocity and blood arterial pressure, before and after Phenylephrine administration.



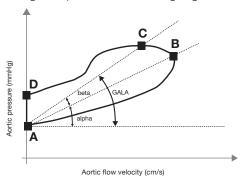
In the lower 'Before' loop the patient is in a hypotensive state with low blood pressure and high flow. The clinician administered Phenylephrine to increase blood pressure with the intention to improve blood flow to the patient's tissues and organs.

However the TrueVue™LOOPS 'After' shows that whilst blood pressure increased (the new loop moved up the display), blood flow velocity dramatically reduces (display moved markedly to the left). This risked lower tissue oxygen delivery and heart failure in a weak heart.

Using traditional pulse contour or pulse power based technologies the drop in flow would have been missed. The TrueVue™ LOOPS display provides the feedback to avoid this error and guides treatment correctly.

NEW Biomarkers:

TrueVue LOOPS also provides a new cardiovascular risk biomarker, the Global Afterload Angle (GALA). A GALA angle above 35° is associated with increased cardiovascular risks (Vallee, F et al. J Clin Monit Compt. 2017). Further research on the angles, Alpha and Beta, is on going.

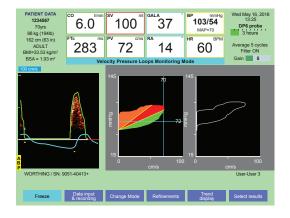


Definition of angles

- The Global Afterload Angle (GALA) value directly correlates to afterload parameters such as vascular resistance, aortic stiffness and wave reflections
- The Alpha angle (Ejection Angle) displays the immediate effect of afterload
- The Beta angle (Reflection Angle) displays the delayed effect of afterload.

TrueVue™ LOOPS immediate visual display of patient haemodynamics

- The **complete** haemodynamic picture in real time
- Unique biomarkers for early detection of hypo and hyper-volemia and hypo- and hyper-tension
- Immediate reliable feedback on response to fluids, inotropes and vaso-active drugs.



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