

Systolic Pressure Variation

LIDCO^{Plus}

CONTINUOUS, REAL-TIME
CARDIOVASCULAR MONITORING

Pulse Pressure Variation



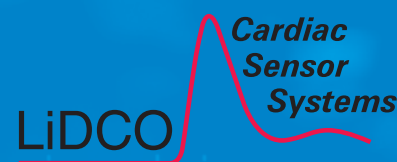
Absolute Output

Frequently Asked Questions & Features and Benefits

Continuous Stroke Volume Output

Beat to Beat

Stroke Volume Variation



Introducing the LiDCOplus Hemodynamic Monitor



1. What is the science underlying the LiDCOplus Hemodynamic Monitor?

The LiDCOplus Hemodynamic Monitor hosts the complementary LiDCO™ & PulseCO™ Systems and collectively provides a real time and comprehensive assessment of a patient's hemodynamic status.

The LiDCO™ System is a bolus indicator dilution method of measuring cardiac output and calibrating the PulseCO software. A small dose of lithium chloride is injected via a central or peripheral venous line; the resulting arterial lithium concentration-time curve is recorded by withdrawing blood past a lithium sensor attached to the patient's existing arterial line. In terms of accuracy, clinical studies have demonstrated that the LiDCO™ System method is at least as accurate as thermodilution over a wide range of cardiac outputs and in patients with varying cardiac outputs^{1,4-8}. The dose of lithium marker needed (0.15 – 0.3 mmol for an average adult) is very small and has no known pharmacological effects^{2,3}. An additional feature of the lithium measurement is its ability to estimate Intra thoracic blood volume (ITBV).

The PulseCO™ System software calculates continuous beat-to-beat stroke volume, stroke volume variation & cardiac output by analysis of the arterial blood pressure waveform following calibration with an indicator dilution cardiac output measurement. This system has been shown to be accurate and reliable in the peri operative and ICU settings. It has also been shown that a check on the calibration is required only every 8 to 24 hours and that the software can track changes in cardiac output even in the presence of moderately damped arterial lines^{10-14,44}.

2. What are the primary indications for use of the LiDCOplus Hemodynamic Monitor?

The LiDCOplus Hemodynamic Monitor is intended for monitoring continuous blood pressure and cardiac output in patients with pre-existing peripheral arterial line access. The system is safe, accurate and easy to use¹⁰⁻¹⁴. In acute care settings, where information on real time hemodynamic changes are required, the LiDCOplus Monitor can be set up in five to ten minutes by a trained nurse or doctor. It can be used on a conscious patient and used in pre, inter and post-operative situations.

The primary indications for use include: peri operative care of cardiac surgery and high risk surgical patients, acute heart failure, sepsis, drug intoxication, acute renal failure, severe hypovolemia, fluid shifts, complex circulatory situations & medical emergencies.

3. What are the common secondary indications for its use?

The LiDCOplus Hemodynamic Monitor provides a rapid response 'Early Warning' of a significant change in the hemodynamic status. Thus in patients who are conventionally indicated for invasive arterial blood pressure monitoring, the device is intended as a more sensitive way of displaying continuous hemodynamic data. In addition to arterial blood pressure parameters and cardiac output, the LiDCOplus Hemodynamic Monitor calculates a number of other parameters: Body Surface Area, Systolic Pressure Variation, Pulse Pressure Variation, Cardiac Index, Oxygen Delivery, Oxygen Delivery Index, Heart Rate, Heart Rate Variation, Stroke Volume, Stroke Volume Index, Stroke Volume Variation, Intra Thoracic Blood Volume, Systemic Vascular Resistance, Systemic Vascular Resistance Index. It has been shown that for fluid management the measurements of pulse pressure variation and stroke volume variation can be most useful in closed chest mechanically ventilated patients¹⁵⁻³⁷. These 'preload' measurements benefit from being dynamic, real time and available in a minimally invasive manner. One recent paper in Anaesthesia and Analgesia showed that "a SVV value of 9.5% or more, will predict an increase in the SV of at least 5% in response to a 100ml volume load, with a sensitivity of 79% and specificity of 93%."²²

4. What are the efficacy data to support its use?

The LiDCOplus Hemodynamic Monitor has been shown to be accurate and reliable in various clinical settings¹⁰⁻¹⁴. These studies include cardiac surgery patients undergoing bypass and off-pump procedures where cardiac output is rapidly changing and has ranged from 2.7-21.3 litres¹³. Data has also been presented validating its use in the medical intensive care unit with patients having a variety of diagnoses and the cath lab^{14,9}. It is clear that this system provides no incremental risk to the patient and could reduce the requirement for more invasive monitoring in many high-risk patients¹⁰⁻¹⁴.

5. What is the effect of lithium on patients?

There is no pharmacological effect from lithium chloride the dose is $\frac{1}{240th}$ of a therapeutic dose.

6. Are there any appropriate outcome data available?

Yes, in a recent study it was shown that optimising oxygen delivery index (DO₂) using the LiDCO_{plus} Monitor to a target of 600 ml/min/m² reduced morbidity by 50% and total length of stay by an average of 12 days⁴². There is a growing volume of evidence to suggest that optimising flow (cardiac output) and oxygen delivery (DO₂) can lead to improved outcomes in terms of mortality and morbidity in suitable patients³⁸⁻⁴¹. The LiDCO_{plus} Hemodynamic Monitor allows the patients hemodynamics to be 'optimised' in a safe, accurate and timely manner. In particular the ability to use the product in a non ventilated and conscious patient facilitates the implementation of peri operative optimisation protocols in high risk surgical patients.

7. What are the costs of using the technology?

In order to use the technology, a monitor (LiDCO_{plus}) and single patient use lithium dilution sensor and associated disposables are required. It is designed to work with any of the commonly used arterial catheter systems. The indicator dilution calibration method does not require the use of special catheters, introducer trays or a subsequent x-ray for catheter position verification. Savings can usually be realised against the costs associated with the use of more invasive continuous technologies.

8. Are there any contraindications for the use of this technology?

The LiDCO_{plus} Hemodynamic Monitor is suitable for patients who have arterial and venous catheters (peripheral or central) inserted and who require hemodynamic monitoring. Patients undergoing treatment with lithium salts, patients who are less than 40kg (88lb) in weight and patients in the first trimester of pregnancy are contraindicated for calibration with the lithium chloride indicator. Performance of the continuous waveform analysis PulseCO software may be compromised in patients with severe peripheral arterial vasoconstriction, those undergoing treatment with aortic balloon pumps and in the case of aortic valve regurgitation.

9. Do muscle relaxants prevent me from using the LiDCO_{plus}?

No you can use the LiDCO_{plus} as long as the calibration is performed prior to paralysis or after waiting a short time after their use. (e.g. Pancuronium (15min) Vecuronium (15-30min))

10. What is the current status of this technology?

The technology has FDA clearance and CE mark approval and has been actively marketed since July 2001 in the USA and UK. In continental Europe lithium approval (as an in vivo diagnostic) has been received in 11 markets including: Germany, Italy, Spain, Holland, Belgium and Austria. The use of minimally invasive hemodynamic monitoring is receiving widespread acceptance in the market place with many key institutions in the US, UK and EU now routinely using the LiDCO[™] technology.



Introducing the LiDCOplus Hemodynamic Monitor

LiDCOplus **FEATURE: Real Time**

Real time beat-to-beat display of key hemodynamic parameters including: cardiac output, stroke volume, blood pressure, peripheral resistance, and oxygen delivery

BENEFIT:

- Provides early warning of significant hemodynamic events
- Shows comprehensive hemodynamic status of patient
- Guides correct drug administration and shows hemodynamic response
- Indicates relationship between linked hemodynamic variables
- Facilitates the setting and achievement of patient specific hemodynamic targets.

LiDCOplus **FEATURE: Power Based Waveform Analysis**

The PulseCO™ Algorithm computes the heart beat period and stroke volume from the entire blood pressure waveform

BENEFIT:

- Uncalibrated, provides an indication of direction of changes in preload, cardiac output and oxygen delivery
- When calibrated, provides accurate measurement of both direction and magnitude of change in cardiac output and oxygen delivery
- Only requires a calibration check every 20 hours.

LiDCOplus **FEATURE: Minimally Invasive**

LiDCOplus uses existing arterial and peripheral/central venous access

BENEFIT:

- No incremental risk to the patient ¹⁻⁴
- Applicable to a wide arterial line patient population ¹⁻⁴
- Can be used on ventilated or non ventilated patients, in the peri-operative or ICU setting ¹⁻⁴
- Nurse or clinician applicability ¹⁻⁴.

LiDCOplus **FEATURE: Accurate and Reliable Lithium Indicator Dilution Calibration**

The LiDCO™ - Lithium Dilution Cardiac Output has been demonstrated to give an accurate and reliable measurement from a single injection

BENEFITS:

- Only one injection required - time consuming repeated determinations are unnecessary ^{5, 9-10, 12-15, 17}
- Accuracy even in the intra-operative situation - lithium is unaffected by thermal noise from respiration, cooling or fluid(s) infusion ^{5, 9-10, 12-15, 17}
- Results are consistent and reproducible between various users ^{5, 9-10, 12-15, 17}
- On-screen help
- Auto calibration of PulseCo™ via LiDCO.

LiDCOplus **FEATURE: Safe Lithium Chloride Indicator Dilution Technology**

The injectate is a solution of lithium chloride

BENEFIT:

- Uses existing central or peripheral venous and arterial catheters ^{5, 19}
- The dose of lithium chloride needed has no known pharmacological effect ¹¹.

LiDCOplus **FEATURE: Provides Beat-to-Beat Oxygen Delivery and Displayed SvO₂**

BENEFIT:

- Provides early and immediate indication of global oxygen delivery status, as actual or indexed value
- Allows for easy implementation of oxygen delivery based peri-operative and trauma optimisation protocols
- Allow for easy calculation of VO₂.

LiDCOplus **FEATURE: Data Communications**

BENEFIT:

- Link with Philips monitors via Vuelink™ module
- Ethernet TCP/IP Data Link for beat-to-beat output, real time
- RS-232 Link for Data output, real time.

LiDCOplus **FEATURE:** Continuous Pre Load, After Load and Cardiac Output Monitoring

BENEFIT:

- Optimises fluid administration through pre load parameters that indicate the likely response of the patient to volume ⁶⁻⁸
- Quantifies stroke volume response to increased pre load
- Indicates response in left ventricular contractility after inotrope administration.

LiDCOplus **FEATURE:** Provides Indexed Values

BENEFIT:

- Indexed values help normalise hemodynamic parameters to patient requirements.

LiDCOplus **FEATURE:** Novel User Interfaces

BENEFIT:

- The Chart Screen demonstrates the interrelationship between pressure, flow and resistance using indexed values and their variation from predetermined targeted normal values
- Demonstrates the patient's hemodynamic picture
- Visual (at a distance) displays
- Facilitates the interpretation of data to aid therapeutic intervention
- Facilitates appropriate action regarding the patient's hemodynamic status by nurses and doctors.

LiDCOplus **FEATURE:** Provides Volume Management Parameters

Volemia and preload management features of: Stroke Volume Variation, Pulse Pressure Variation, Systolic Pressure Variation, Heart Rate Variation and Intra Thoracic Blood Volume

BENEFIT:

- Measurements are available in realtime ⁶⁻⁸
- Available from pre-existing lines ⁶⁻⁸
- Allows for effective beat-to-beat volume management ⁶⁻⁸
- Guides volume based therapeutic intervention ⁶⁻⁸.

LiDCOplus **FEATURE:** Quick to Set Up and Use Typically takes between 5 and 10 minutes to set-up and establish cardiac output with the lithium indicator dilution method

BENEFIT:

- Quick, minimally invasive measure of cardiac output
- Ideal for nurse-led management practice
- Cost effective utilisation of resources.

LiDCOplus **FEATURE:** Records Patient Data

BENEFIT:

- Ability to mark and record interventions and events for later reference
- Ability to store data for each patient on an USB memory device for patient records and academic uses
- Ability to capture JPG images of History screen and LiDCO Calibration Curves.

LiDCOplus **FEATURE:** PC Based Monitor Platform

BENEFIT:

- Technology/software platform for future software measurements and displays
- Easy to maintain and repair
- Provides ability to upgrade software and remain current with new developments in hemodynamic monitoring and information management
- Can store data for up to 6 months.



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Systolic Pressure Variation

Pulse Pressure Variation

Lithium Calibration

Absolute Cardiac Output

Global Sales:

Email: info@lidco.com

Telephone: +44 (0) 1223 830 666

Fax: +44 (0) 1223 837 241

LiDCO Ltd, Unit M, South Cambridge Business Park
Babraham Road, Sawston, Cambridge, CB22 3JH, UK

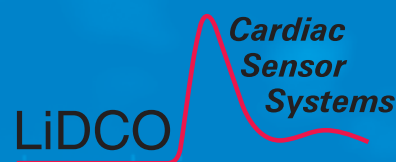
For USA Ordering:

Email: ussales@lidco.com

Tel: +1 877 LiDCO11 (877 543 2611)

Fax: +1 847 265 3737

LiDCO Ltd, 500 Park Ave., Suite 103
Lake Villa, IL 60046, USA



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