Non-invasive continuous arterial pressure and cardiac index monitoring with Nexfin after cardiac surgery

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Editor’s key points

- Nexfin is a non-invasive photoplethysmographic monitor for continuous arterial pressure and cardiac index (CI) measurements.
- The performance of Nexfin was compared with invasive measurements of arterial pressure and transpulmonary thermodilution CI in 50 consecutive cardiac surgical patients admitted to the intensive care unit.
- Nexfin was a safe and accurate device for continuous measurements of arterial pressure, but showed high percentage error in measuring CI in critical care patients.

Background. This observational study was designed to evaluate the reliability and precision of a new digital photoplethysmographic device (Nexfin, BMEYE B.V., Amsterdam, The Netherlands) for continuous and non-invasive assessment of arterial pressure and cardiac output.

Methods. Fifty consecutive adult subjects were prospectively enrolled at admission to the intensive care unit after conventional cardiac surgery and investigated hourly from T0 to T4. Simultaneous comparative systolic, diastolic, and mean arterial pressures and cardiac index (CI) data points were collected from an invasive radial artery catheter, transpulmonary thermodilution catheter, and the Nexfin device. Correlations were determined by linear regression. The Bland–Altman analysis was used to compare bias, precision, and limits of agreement.

Results. Six (12%) subjects were excluded from the analysis because of the inability to obtain a reliable photoplethysmographic signal. No complications were observed. A significant relationship was found between absolute values of photoplethysmographic and radial systolic ($r^2 = 0.56$, $P < 0.001$), diastolic ($r^2 = 0.61$, $P < 0.001$), and mean ($r^2 = 0.77$, $P < 0.001$) arterial pressures. A significant relationship was also found between transpulmonary thermodilution and Nexfin CI absolute values ($r^2 = 0.33$, $P < 0.001$). Bias, precision, and limits of agreement between the mean photoplethysmographic and radial arterial pressures were 4.6 (95% confidence interval: 3.7–5.5), 6.5, and –17.3 to 8.1 mm Hg, respectively. The percentage error between transpulmonary thermodilution and the Nexfin for CI measurement was 50%.

Conclusions. The Nexfin device is safe, convenient, and reliable in measuring continuous non-invasive arterial pressure but not interchangeable with transpulmonary thermodilution to monitor CI.

Keywords: arterial pressure determination; diagnostic techniques and procedures; haemodynamics; photoplethysmography

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The utility of advanced haemodynamic monitoring in conducting goal-directed therapy is increasingly acknowledged in critically ill patients and during major surgery.¹ ² However, a recent survey showed a considerable gap between the accumulating evidence about the benefits of perioperative haemodynamic optimization and the available technologies that might facilitate its clinical implementation.³ Reference methods to determine continuous arterial pressure and cardiac index (CI) at the bedside are invasive, leading to potential clinical complications,⁴ ⁵ and the lack of convenience, accuracy of minimally invasive measurement of cardiac output, or both could contribute to disappointing results.⁶ ⁷ ⁸ Based on the volume-clamp method, continuous non-invasive measurement of finger arterial pressure has been used for a long time, and recent developments could improve its routine applicability.⁹ ¹⁰ The Nexfin device (BMEYE B.V., Amsterdam, The Netherlands) is the current photoplethysmographic technology that offers the ability to non-invasively and continuously monitor arterial pressure and cardiac output. Initial studies conducted in the setting of anaesthesia or intensive care included small samples of patients and reported contrasting results.¹¹ ¹² Before considering a wider use of this new device for daily practice, its accuracy must be further validated in
independent studies, including different subgroups of unselected critically ill patients.

The objectives of the present study conducted in patients undergoing conventional cardiac surgery with cardiopulmonary bypass were two-fold: (i) to compare continuous non-invasive finger arterial pressure measured with the Nexfin device with invasive radial pressure used as the reference method; and (ii) to compare continuous non-invasive CI measured by the Nexfin with transpulmonary thermodilution used as the reference method. We tested the hypothesis that the Nexfin device is a convenient and reliable tool for both arterial pressure and CI measurements in this setting.

**Methods**

**Patient population**

The study was conducted in accordance with the Statements for Reporting Studies of Diagnostic Accuracy (the STARD initiative).18 Fifty consecutive adult subjects admitted to the cardiac surgical intensive care unit (ICU) after conventional cardiac surgery with cardiopulmonary bypass were investigated at the Teaching University Hospital of Caen (Caen, France) from March to July 2011. Institutional approval was obtained from the Ethical Committee (Comité de Protection des Personnes Nord Ouest III, CHU de Caen, Caen Cedex 9, France). Because data were collected during routine care that conformed to standard procedures currently used in our institution, authorization was granted to waive written informed consent (Ref. CPP: A11-D03-VOL.11). Verbal consent was however obtained from all study participants. Patients undergoing conventional cardiac surgery with cardiopulmonary bypass (coronary artery bypass grafting, aortic and/or mitral valve replacement or repair, and combined cardiac surgery) and requiring advanced haemodynamic monitoring (transpulmonary thermodilution) were included in the study. Patients undergoing emergency surgery (<24 h), redo surgery, off-pump coronary artery bypass grafting, and complex, unusual procedures or not requiring advanced haemodynamic monitoring were not included in the study. Patients with abnormalities in postoperative cardiac rhythm were excluded from the study.

**Perioperative cardiac rhythm**

General anaesthesia and postoperative management followed institutional standards. Intraoperative and postoperative haemodynamic management were left entirely to the discretion of the attending anaesthesiologist, who was not involved in the study protocol. All subjects were admitted after operation to the ICU intubated, ventilated (volume-controlled regimen), and sedated with propofol and remifentanil to maintain a Ramsay score above 5. Extubation was performed after completion of the institutional weaning protocol. For each enrolled subject, a radial artery catheter (Leadercath 20 G, Vygon, Ecouen, France), a femoral 5 F thermistor-tipped arterial catheter (Pulsicath thermodilution catheter PV2015L20N, Pulsion France SARL, La Montagne, France), and a jugular central venous catheter were inserted in the operating theatre after induction of general anaesthesia. The invasive radial arterial pressure was recorded at a frequency of 14 Hz using the standard equipment (Marquette Solar 8000, GE Healthcare, Bucks, UK). The signal quality of intra-arterial pressure was checked by both visual inspection of the waveform and a square wave test.15 The Pulsiocath thermodilution catheter was connected to the standalone PiCCO2 computer PC8500 version 2.0 (Pulsion Medical Systems, Munich, Germany). All pressure monitors were zeroed at the midaxillary line. CI measurement was performed by a triplicate 15 ml ice-cold normal saline injection through the central venous catheter (transpulmonary thermodilution).20

Continuous non-invasive arterial pressure was measured on the same arm with the Nexfin device. An appropriate finger cuff was applied to the middle phalanx of the second or third finger, according to the manufacturer’s recommendations. The heart reference system (HRS) measured and corrected the hydrostatic pressure difference between the finger and the heart. HRS was reinitialized before the finger side of the HRS was fixated next to the measurement finger and the heart side of the HRS at arterial pressure transducer level according to the manufacturer’s recommendations. The sensor was then connected to the monitor, enabling the registration of the arterial curve at a 200 Hz sampling rate. The calibration procedure was performed automatically and frequently activated at the start of the measurement. The frequency progressively declined when a more stable signal was detected. Signals derived from the cuff were analysed and presented in real time on the Nexfin device. Continuous beat-to-beat measurement of stroke volume was derived from the arterial signal by dividing the area under the systolic portion of the arterial pressure curve by the aortic input impedance, determined from a three-element Windkessel model in which the non-linear effect of mean arterial pressure and the influence of age, height, weight, and sex on aortic mechanical properties are incorporated.21 CI was calculated using the formula CI = (stroke volume × heart rate)/body surface area.

**Study protocol**

Five consecutive sets of measurements were recorded for each subject during a 4 h period: at the arrival in the ICU (T0), and at 50–70 min (T1), 110–130 min (T2), 170–190 min (T3), and 230–240 min (T4) after arrival in the ICU. Simultaneous comparative systolic, diastolic, and mean blood pressures were collected from the invasive radial catheter and the Nexfin. All measurements were performed over a 5 s time interval and then averaged. Bolus transpulmonary thermodilution CI (CI_{TD}) was averaged on three consecutive measurements performed at any time during the respiratory cycle. The total time for obtaining CI_{TD} values was recorded, and the corresponding Nexfin CI (CI_{NF}) values were averaged to report the mean CI_{NF} at the same data collection point.

**Statistical analysis**

According to our primary objective and to the recommendations of the Association for the Advancement of Medical
Instrumentation,\textsuperscript{22} we considered that a mean difference of 5 mm Hg in intra-arterial and digital mean arterial pressure would be acceptable. The power analysis showed that 190 comparative data points of mean arterial pressure (38 subjects) were necessary to detect a difference between sample means of 5 mm Hg [5% type I error rate, 10% type II error rate, expected standard deviation (so) at 15 mm Hg for both methods]. On the basis of a previous report conducted in the setting of cardiac surgery,\textsuperscript{17} we postulated that the overall success rate of finger arterial pressure monitoring would be nearly 75%. Thus, we decided to include 50 subjects in the study.

Data are expressed as mean (so) or median (range) for non-normally distributed variables (Kolmogorov–Smirnov test) or number and percentage as appropriate. Arterial pressure and CI values obtained from the reference methods and the Nexfin device were compared using the unpaired t-test or the Welch test, according to equal or unequal variances. Absolute values and changes in haemodynamic parameters were compared using one-way analysis of variance (ANOVA) for repeated measurements completed in the case of statistical significance by the paired Wilcoxon’s test with the Bonferroni correction. Correlations between absolute values of intra-arterial and photoplethysmographic arterial pressure and between per cent maximum difference vs first value of systolic, diastolic, and mean arterial pressures were determined by linear regression. Correlations between absolute values of CI\textsubscript{TD} and CI\textsubscript{NF} and between per cent maximum difference vs first value of CI were also determined by linear regression. The Bland–Altman analysis was used to compare the bias, precision (so of bias), and limits of agreement.

Trending analysis was performed with polar plotting of CI changes among consecutive time points as described.\textsuperscript{26} The acceptable bias and precision for arterial pressure measurements were fixed \textit{a priori} at <5 and 8 mm Hg, respectively.\textsuperscript{22} The percentage error to determine acceptable limits of agreement between both techniques of CI measurement was calculated using the formula given by Critchley and Critchley.\textsuperscript{25} The acceptable bias and precision for arterial pressure measurements were fixed \textit{a priori} at <5 and 8 mm Hg, respectively.\textsuperscript{22} The percentage error to determine acceptable limits of agreement between both techniques of CI measurement was calculated using the formula given by Critchley and Critchley.\textsuperscript{25}

A P-value of <0.05 was considered as statistically significant and all P-values were two-tailed. Statistical analyses were performed using MedCalc\textsuperscript{26} Software bvba version 12.1.4 (Mariakerke, Belgium) and Deltagraph\textsuperscript{26} version 5.6 (RockWare, Golden, CO, USA).

**Results**

Six (12%) subjects were excluded from the analysis because of the inability to obtain a reliable photoplethysmographic signal, despite multiple attempts with different sized cuffs on different fingers. The overall success rate of finger arterial pressure monitoring was 88%. Baseline characteristics for the remaining 44 subjects are indicated in Table 1. No complications related to the use of the Nexfin device were observed over the study period. A complete data set was available for all subjects for arterial pressure analysis and in the last 24 studied subjects for CI analysis. Fifteen (34%) subjects received norepinephrine infusion and three (7%) required inotropic support with dobutamine. The median mediastinal bleeding and fluid loading over the study period were 50 (0–280) and 500 (0–1000) ml, respectively. The median duration of volume-controlled mechanical ventilation was 5 (3–19) h.

Comparisons of arterial pressure and CI between the Nexfin and the reference methods are given in Table 2. While photoplethysmographic systolic arterial pressure was significantly underestimated by 5 mm Hg on average

<table>
<thead>
<tr>
<th>Type of surgery</th>
<th>Number (%)</th>
<th>CI (litre min\textsuperscript{-1} m\textsuperscript{-2})</th>
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<tbody>
<tr>
<td>Coronary artery bypass grafting</td>
<td>19 (43)</td>
<td>2.5 (0.6) (1.5–4.5)</td>
</tr>
<tr>
<td>Valve surgery</td>
<td>19 (43)</td>
<td>2.5 (0.7) (1.1–4.7)</td>
</tr>
<tr>
<td>Combined surgery</td>
<td>6 (14)</td>
<td></td>
</tr>
<tr>
<td>Inotropic and vasoactive drug requirement</td>
<td></td>
<td></td>
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<tr>
<td>Dobutamine\textsuperscript{a}</td>
<td>3 (7)</td>
<td></td>
</tr>
<tr>
<td>Norepinephrine\textsuperscript{b}</td>
<td>15 (34)</td>
<td></td>
</tr>
<tr>
<td>Central core temperature (°C)</td>
<td>36.1 (33.9–38.3)</td>
<td></td>
</tr>
<tr>
<td>Haemoglobin at arrival in ICU (g dl\textsuperscript{-1})</td>
<td>11.2 (8.3–14)</td>
<td></td>
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<tr>
<th>Reference method</th>
<th>Nexfin</th>
<th>P-value</th>
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<tr>
<td>SAP (mm Hg)</td>
<td>113 (20) (56–176)</td>
<td>108 (20) (55–166)</td>
</tr>
<tr>
<td>DAP (mm Hg)</td>
<td>57 (11) (29–87)</td>
<td>67 (10) (44–94)</td>
</tr>
<tr>
<td>MAP (mm Hg)</td>
<td>76 (13) (36–115)</td>
<td>81 (12) (48–117)</td>
</tr>
<tr>
<td>CI (litre min\textsuperscript{-1} m\textsuperscript{-2})</td>
<td>2.5 (0.6) (1.5–4.5)</td>
<td>2.5 (0.7) (1.1–4.7)</td>
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Table 1 Subjects baseline characteristics (n=44). Values are median (range) or number (%). *Dose from 2 to 5 \mu g kg\textsuperscript{-1} min\textsuperscript{-1}. †Dose from 0.01 to 0.1 \mu g kg\textsuperscript{-1} min\textsuperscript{-1}
compared with radial pressure over a large range of arterial pressure values, both diastolic and mean arterial pressures were significantly overestimated by 10 and 5 mm Hg on average, respectively. No difference was found between absolute values of CI TD and CI NF (Table 2). Haemodynamic data at different postoperative time points are reported in Table 3. No significant variation in arterial pressure was observed over the study period. Conversely, CI globally increased over time (Table 3). The relationships between absolute values of photoplethysmographic and radial arterial pressures are reported in Figure 1A–C, and the relationship between absolute values of CI TD and CI NF is reported in Figure 1D. Correlations and linear regressions between the per cent maximum difference vs first value of arterial pressure and CI given by the Nexfin device and invasive reference methods are reported in Table 4. The bias and limits of agreement between photoplethysmographic and radial arterial pressure are depicted in Figure 2A–C. The bias, precision, and limits of agreement between the mean photoplethysmographic and mean invasive radial arterial pressures were 4.6 (95% confidence interval: 3.7–5.5), 6.5, and −17.3 to 8.1 mm Hg, respectively. The bias and limits of agreement between CI TD and CI NF are depicted in Figure 2D. The percentage error between transpulmonary thermodilution and the Nexfin for CI measurement was 50%, meaning that the methods were not interchangeable. Polar plot analysis showed that 99% of CI changes by Nexfin and bolus transpulmonary thermodilution among data points T0, T1, T2, T3, and T4 (n=96) were within 0.4 litre min$^{-1}$m$^{-2}$ limits of agreement (20%) (Fig. 3).

**Discussion**

The main findings of the present observational study conducted in unselected postoperative cardiac surgery patients are that: (i) the Nexfin device is convenient, safe, and reliable in measuring continuous non-invasive arterial pressure; and (ii) the Nexfin device, although not interchangeable with transpulmonary thermodilution, provides consistent continuous non-invasive measurements of CI and seems able to track in real time the direction and changes over the time.

Initial validation studies in humans only included small samples of patients and reported contrasting results concerning the ability of photoplethysmography to reliably measure both arterial pressure and CI in the setting of anaesthesia, critical care, or both.15 16 27 In the current study, we report a large range of arterial pressure and CI values in unselected cardiac surgical patients. Many subjects had a history of hypertension, peripheral vascular disease, or both and up to 34% received i.v. norepinephrine. Nevertheless, we found an acceptable relationship and agreement between the Nexfin system and invasive radial pressure. The accuracy and precision for measurement of mean arterial pressure were in accordance with the standards of the Association for the Advancement of Medical Instrumentation that allow for a maximum bias of 5 mm Hg and a maximal precision of 8 mm Hg.22

The Nexfin uses a built-in proprietary software algorithm that converts in real time the measured finger arterial pressure to a reconstructed brachial artery pressure waveform.28 This could partially explain why we observed a significant overestimation in mean and diastolic arterial pressures and a significant underestimation in systolic arterial pressure. Because of the physical characteristics of the vascular tree, well-known differences exist between central and peripheral arterial pressures.29 30 This pulse amplification phenomenon is explained by the progressive proximal-to-distal stiffening of the arterial tree29 and results in an increase in systolic and a decrease in diastolic arterial pressures. As radial arterial pressure has been found to poorly correlate with central

![Table 3](https://academic.oup.com/bja/article/109/4/514/237201)

<table>
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<th>Postoperative time points</th>
<th>P-value</th>
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<tr>
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<tr>
<td>Heart rate (beats min$^{-1}$)</td>
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</tr>
<tr>
<td>SAP (mm Hg)</td>
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<tr>
<td>Radial catheter</td>
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<tr>
<td>Nexfin</td>
<td>0.371</td>
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<tr>
<td>DAP (mm Hg)</td>
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<tr>
<td>Radial catheter</td>
<td>0.572</td>
</tr>
<tr>
<td>Nexfin</td>
<td>0.383</td>
</tr>
<tr>
<td>MAP (mm Hg)</td>
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<tr>
<td>Radial catheter</td>
<td>0.701</td>
</tr>
<tr>
<td>Nexfin</td>
<td>0.362</td>
</tr>
<tr>
<td>CI (litre min$^{-1}$m$^{-2}$)*</td>
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<td>Thermodilution</td>
<td></td>
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<tr>
<td>Nexfin</td>
<td>0.010</td>
</tr>
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</table>

Table 3 Haemodynamic data at different postoperative time points (n=44 except for CI). Values are mean (SD). P-value refers to one-way ANOVA for repeated measurements. CI significantly increased over time (*P<0.05 vs T0, paired Wilcoxon's test with the Bonferroni correction). CI, cardiac index; DAP, diastolic arterial pressure; MAP, mean arterial pressure; SAP, systolic arterial pressure. *n=24 patients
aortic pressure after cardiac surgery, the reconstructed brachial artery pressure given by the Nexfin device could better reflect the aortic arterial pressure than invasive radial pressure in this setting. This last point remains however to be validated. Furthermore, it was our decision to place the sensor on the same arm as the radial catheter, preferably on the non-dominant hand. This could have potentially decreased the amplitude of the finger arterial pressure signal. While we did not calculate the damping coefficient, a square wave test was conducted for each patient, ensuring that the signal was interpretable.

In the current study, the Nexfin device was not interchangeable with transpulmonary thermodilution to measure CI. Even if a negligible bias was evidenced, the limits of agreement were large and the percentage error was as high as 50%. In their recent meta-analysis, Peyton and Chong showed however none of the four alternative tested methods (i.e. pulse contour analysis, oesophageal Doppler, 

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**Fig 1** The relationship between absolute values of (a) arterial invasive and photoplethysmographic systolic arterial pressure (220 paired data points); (b) arterial invasive and photoplethysmographic diastolic arterial pressure (220 paired data points); (c) arterial invasive and photoplethysmographic mean arterial pressure (220 paired data points); and (d) transpulmonary thermodilution and photoplethysmographic CI (120 paired data points). AI, arterial invasive; CI, cardiac index; DAP, diastolic arterial pressure; MAP, mean arterial pressure; NF, Nexfin; SAP, systolic arterial pressure; TD, transpulmonary thermodilution.
partial \( pO_2 \) rebreathing, and thoracic electrical bioimpedance) achieved agreement with bolus thermodilution, which meets the expected 30% limits. They raise questions about the appropriateness of imposing arbitrary limits on the acceptability of accuracy and precision of CI measurement, suggesting that the percentage error of agreement was only one marker of acceptability of a method. Thus, a more dynamic approach could be more interesting for clinical practice, and the efficacy of a clinical cardiac output monitor involves many factors other than its absolute accuracy and includes safety, convenience, and adaptability, which are characteristics that could be attributed to the Nexfin system. Finally, real-time tracking of the direction of changes in CI could be more important than the ability of the monitor to deliver a highly accurate single measurement under stable conditions.

Some comments are necessary concerning the limitations of the current study. First, we only investigated a subgroup of postoperative cardiac surgery ICU patients. Other studies conducted in other groups of critically ill patients or during general anaesthesia are mandatory to further demonstrate the clinical usefulness of the Nexfin device before recommending a spread use at the bedside. In particular, ICU patients with spontaneous breathing or arrhythmia should

| Table 4 | Correlations and linear regressions between the per cent maximum difference vs first value of arterial pressure and CI given by the Nexfin device and invasive reference methods. Reference methods were invasive radial pressure and transpulmonary bolus thermodilution. CI, cardiac index; DAP, diastolic arterial pressure; MAP, mean arterial pressure; SAP, systolic arterial pressure |
|----------|-------------------------------------------------|-----------------|-----------------|-----------------|-----------------|-----------------|
|          | \( n \) | \( r^2 \) | \( r \) | \( Y \) | \( P \)-value |
| SAP (mm Hg) | 44 | 0.53 | 0.73 | 6.36+0.79x | <0.001 |
| DAP (mm Hg) | 44 | 0.40 | 0.63 | 1.45+0.55x | <0.001 |
| MAP (mm Hg) | 44 | 0.55 | 0.74 | 2.32+0.70x | <0.001 |
| CI (litre \( min^{-1} m^{-2} \)) | 24 | 0.27 | 0.52 | 4.44+0.47x | <0.001 |

Fig 2 Bland–Altman analysis between (A) arterial invasive and photoplethysmographic systolic arterial pressure (220 paired data points); (B) arterial invasive and photoplethysmographic diastolic arterial pressure (220 paired data points); (C) arterial invasive and photoplethysmographic mean arterial pressure (220 paired data points); and (D) transpulmonary thermodilution and photoplethysmographic CI (120 paired data points). Symbols and colours refer to each patient (five observations per individual). AI, arterial invasive; CI, cardiac index; DAP, diastolic arterial pressure; MAP, mean arterial pressure; NF, Nexfin; SAP, systolic arterial pressure; TD, transpulmonary thermodilution.
be included. Secondly, we were unable to perform finger arterial pressure in 12% of subjects. Similar difficulties have been reported with a higher incidence in children undergoing cardiac surgery, and clearly represent a limit of the technique. Other well-known limits have been suggested with photoplethysmography, such as electrical cautery or intense surrounding light, and must be kept in mind when using the Nexfin device. Thirdly, the present study was not designed to compare arterial pressure or CI variations induced by significant changes in heart loading conditions, as in fluid challenge or passive leg raising. Further studies should address this important issue and evaluate the ability of the Nexfin to predict fluid responsiveness. Lastly, clinical utility/outcome (phase 3) studies are mandatory to fully evaluate the Nexfin device and validate its clinical interest for goal-directed haemodynamic therapy. In conclusion, the Nexfin device is safe and seems reliable to continuously and non-invasively monitor arterial pressure after cardiac surgery. While not interchangeable with transpulmonary thermodilution, the monitor also seems convenient and consistent to continuously monitor CI, and could track the direction of changes under dynamic conditions.

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**Declaration of interest**

None declared.

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**References**


