

# The ClearSight System

## Technology Overview

### Introduction

Edwards Lifesciences acquired BMEYE in October of 2012. Since then, Edwards has focused on integrating the ccNexfin technology into the scalable EV1000 clinical platform. The ccNexfin technology provides noninvasive continuous Blood Pressure (BP), Cardiac Output (CO) and other advanced hemodynamic parameters. The combination of the noninvasive ccNexfin technology with the decision support capabilities of the EV1000 clinical platform extends the benefits of hemodynamic optimization to a broader group of surgical patients.



Figure 1: EV1000 Clinical Platform

### History

The ccNexfin noninvasive technology was developed over the past 35 years and has been validated against gold-standard monitoring technologies. Beginning in the 1970s, finger arterial pressure was measured using finger cuff technology. This technology was based on two methods:

- The volume clamp method<sup>1</sup> to continuously measure Blood Pressure
- The Physiocal method<sup>2</sup> for initial and frequent calibration

The essence of the volume clamp method involves clamping the artery to a constant volume by dynamically providing equal pressure on either side of the arterial wall. The volume is measured by a photo-plethysmograph built into the cuff. The counter pressure is applied by an inflatable bladder inside the cuff and is adjusted 1000 times per second to keep the arterial volume constant. (see Figure 2)

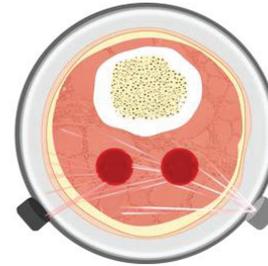


Figure 2: Cross-section of the finger (including bone and arteries) with the cuff (including photo-plethysmographic system and inflatable bladder)

Physiocal is the real-time method for determining the proper arterial 'unloaded' volume, i.e. the volume without a pressure gradient across the arterial wall. Physiocal analyzes the curvature and sharpness of the plethysmogram during short episodes of constant pressure levels. It then automatically and periodically recalibrates the system allowing accurate tracking of physiologic changes, e.g. in vasomotor tone.

The first device to use the finger cuff technology was the Finapres in the early 1980s.<sup>3</sup> During this time, dedicated systems were also developed for astronauts for use in space.<sup>4</sup> Further improvements continued to ensure the technology was ready for clinical use. In 2007, the Nexfin system was launched commercially, followed by the launch of the ccNexfin system three years later in early 2010. (see Figure 3)



Figure 3: The ccNexfin System

The ccNexfin system provided an intuitive user interface, touch screen controls and improvements for measuring Blood Pressure. These improvements include:

- Real-time reconstruction of the brachial Blood Pressure waveform (see Figure 4)
- Elimination of an upper arm cuff Blood Pressure measurement as a reference for calibration
- The Heart Reference Sensor (HRS) to compensate for potential errors due to differences in height between the finger and heart level

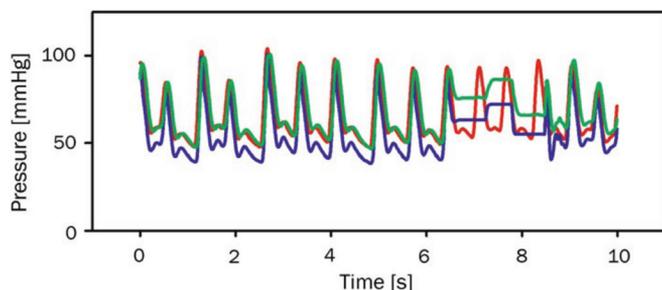


Figure 4: The differences in pressure levels and wave shape in the radial (red) and finger (blue) arteries; a physiological model reconstructs the brachial artery pressure (green) from the finger arterial pressure; the staircase is the result of an automatic calibration

The system also computes Stroke Volume (SV) and Cardiac Output using a pulse contour method based on a physiological model of the circulation. This allows the ccNexfin system to noninvasively provide additional advanced hemodynamic monitoring parameters.

## Validation

The ccNexfin technology has been validated extensively through the years. The Blood Pressure measurement has performed well against both intermittent noninvasive and continuous invasive methods.<sup>5,6</sup> Studies conclude that the ccNexfin technology measures Blood Pressure according to the AAMI criteria.<sup>7</sup> Moreover, the clinical data demonstrate that the Nexfin technology Blood Pressure is more accurate than a traditional upper arm Blood Pressure cuff when compared to invasive measurements in patients undergoing general surgery.<sup>20,21</sup>

Similarly, the ccNexfin technology Cardiac Output has been validated against several reference methods including pulmonary thermodilution,<sup>8</sup> transpulmonary thermodilution,<sup>9</sup> trans-esophageal/thoracic echo-Doppler<sup>10,11</sup> and inert gas rebreathing.<sup>12</sup> Percentage errors range from 23% to 39%, which is comparable to more invasive methods.<sup>9,13</sup> Larger errors have been reported, but these occurred in critically ill patients where compromised flow to the finger may affect the ccNexfin technology performance.<sup>15</sup> Beyond the ability to measure absolute Cardiac Output values, several

studies have shown that the ccNexfin technology is able to reliably track changes in Cardiac Output.<sup>9,10,16</sup> As a result, studies have concluded that the ccNexfin technology is a suitable monitor for the perioperative continuous measurement of Cardiac Output.<sup>9,16</sup>

## The ClearSight System

The ClearSight system (see Figure 5) is the fourth generation noninvasive platform to utilize the finger cuff technology. The system is comprised of the EV1000 clinical platform and the ClearSight finger cuff, leverages the core ccNexfin technology and provides several major benefits including:

- **Combination of noninvasive technology with decision support**

Clinicians are required to make quick decisions in a dynamic environment and need physiologic data presented in a meaningful and intuitive manner, i.e. more than just a number. The EV1000 clinical platform provides more visual and intuitive hemodynamic information through various displays such as the cockpit screen and provides visual clinical decision support.<sup>17</sup>

- **Fewer monitors in an already crowded OR**

Clinicians may have as many as six or seven different monitors to manage depending on the hospital and/or theater. This may distract clinicians from observing key changes in the patient. The EV1000 clinical platform provides a single monitor for use with both invasive and noninvasive technologies, offering continuous Blood Pressure and advanced hemodynamic parameters.

- **Features and flexibility**

The EV1000 clinical platform was purposefully designed to be scalable and adaptable for clinicians. The platform launched in 2010 with the FloTrac sensor, the VolumeView set, and the PreSep oximetry catheter. The addition of the ClearSight finger cuff provides a noninvasive option for advanced hemodynamic monitoring.



Figure 5: The ClearSight System includes the ClearSight Finger Cuff, the EV1000 Clinical Platform, the Heart Reference Sensor (HRS), and the Pump-Unit

The ccNexfin technology has been enhanced and is now the ClearSight system. Enhancements include:

- Trending screens tailored to support fluid management in OR with artifact filtering capabilities for easier interpretation
- Double-cuff pressure controller enabling alternation between finger cuffs allows for monitoring in longer surgical cases
- Computation of Stroke Volume Variation based on the noninvasive Blood Pressure waveform even in patients with multiple premature atrial or ventricular contractions (PACs and PVCs) allows for the ongoing use of Stroke Volume Variation as a reliable indicator of preload responsiveness
- IFM out serial port and HL7 connectivity for both minimally invasive and noninvasive technologies

The platform also takes advantage of critical features from the ccNexfin monitor:

- Real-time brachial Blood Pressure waveform on the trend screen
- Intuitive set-up and easily accessible help screens

## Solution

An increasing amount of clinical evidence demonstrates that patients at risk for post-surgical complications can benefit from perioperative goal-directed therapy (PGDT).<sup>18</sup> Hemodynamic needs vary as this risk may be related both to the procedure and the patient. Traditionally, only patients connected to an arterial line have benefited from hemodynamic optimization using flow-based parameters. However, only a fraction of all elective surgical patients at risk for post-surgical complications receive an arterial line.<sup>19</sup>

The EV1000 clinical platform with the ClearSight finger cuff provides a noninvasive solution to hemodynamically optimize patients without an arterial line and extends the benefit of PGDT to a broader group of surgical patients. The ClearSight system is noninvasive, easy to use, well validated and provides a complete set of hemodynamic parameters. Edwards Lifesciences provides a range of monitoring solutions for use in PGDT protocols to hemodynamically optimize your moderate to high-risk surgery patients.

**Edwards Lifesciences provides a choice of hemodynamic monitoring options to meet your clinical needs.**

Helping to advance the care of the acutely ill for 40 years,  
Edwards Lifesciences seeks to provide the valuable information you need,  
the moment you need it. Through continuing collaboration with you,  
ongoing education and our never-ending quest for advancement,  
our goal is to deliver clarity in every moment.

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