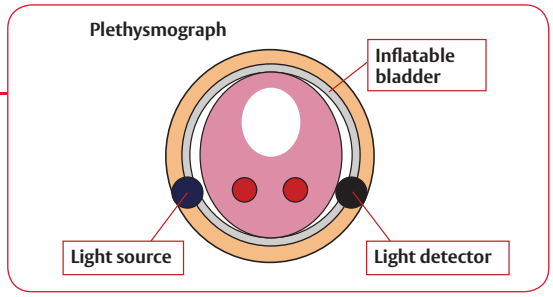
ClearSight System Technology Overview

How does it work?

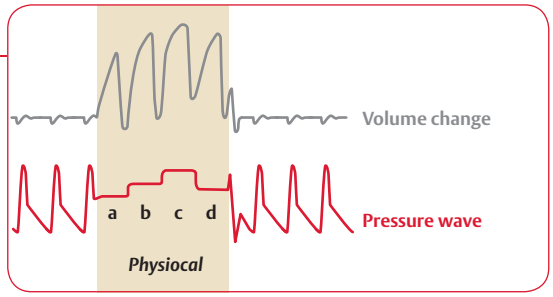
Volume clamp method

- The essence is to dynamically provide equal pressures on either side of the wall of the artery by clamping the artery to a certain constant volume
- 1000 times each second the cuff pressure is adjusted to keep the diameter of the finger arteries constant
- Continuous recording of the cuff pressure results in a real-time finger pressure waveform[1]



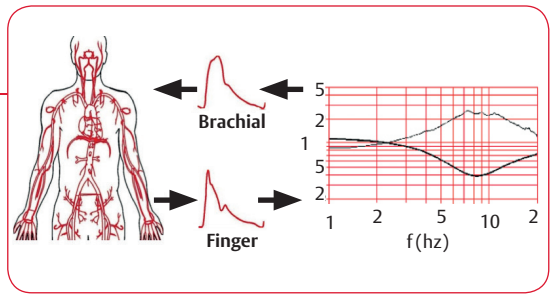
The Physiocal method – Physiological Calibration

- The Physiocal method is the real-time expert system that determines the proper arterial 'unloaded' volume, i.e. no pressure gradient across the arterial wall
- Automatic, periodic adjustments are essential to track the unloaded volume clamp setpoint when smooth muscle tone changes (e.g. during vasoconstriction)
- Calibration interval starts at 10 beats, but it increases to every 70 beats as stability increases
- Physiocal interval >30 beats is considered reliable[2]



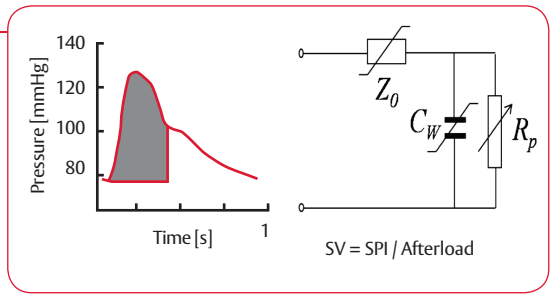
Brachial pressure reconstruction

- Clinical standard for noninvasive BP is brachial level
- The ClearSight system reconstructs the brachial arterial pressure waveform from the finger arterial pressure waveform
- The reconstruction algorithm is based on a vast clinical database[3]



Cardiac output calculation

- Stroke volume is calculated by an algorithm based on an improved pulse contour method using:
  - The area under systolic portion of blood pressure curve (Systolic Pressure-time Integral - SPI)
  - A physiological model to calculate afterload individualized by age, gender, height and weight
- Cardiac output results from stroke volume times heart rate and is updated every beat[4]



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Edwards

Validation of monitoring blood pressure and cardiac output with non-invasive finger cuff technology versus traditional methods

Blood pressure validation studies

BP can be measured reliably according to AAMI standard, bias <5 and SD < 8 mmHg

Vs. Noninvasive upper arm cuff		Bias ± SD
Akkermans et al. – Hypertension in Pregnancy 2009[5]	33 pregnant patients	SYS 2.3±6.8 / DIA 0.8±6.3
Eeftinck Schattenkerk et al. – Am J Hypertension 2009[6]	104 volunteers	SYS 4.3±9.3 / DIA -2.5±8.1
Vs. Invasive radial line		
Martina et al. – Anesthesiology 2012[7]	50 cardiac surgery patients	MAP 2.2±6.4 mmHg
Fischer et al. – Brit J Anesthesia 2012[8]	44 cardiac surgery patients	MAP 4.6±6.5 mmHg
Martina et al. – ASAIO J 2010[9]	18 patients during CPB	MAP -1.3±6.5 mmHg
Vos et al. – Brit J Anesthesia 2014[10]	112 OR patients	MAP 2.0±9.0 mmHg
Balzer et al. - J Inter Med Res 2016[18]	20 mod ortho patients	MAP -1±13 mmHg
De Wilde et al . - Anaesthesia 2016[19]	19 GI patients	MAP 3.5±5.2 mmHg
Heusdens et al. - Brit J Anesthesia 2016[20]	25 vascular patients	MAP 1.1±7.4 mmHg
Berkelmans et al. - J Clin Monit Comput 2017[21]	31 AF patients in ICU/MCU	MAP 0±8 mmHg
Rogge et al. - Anesthesia & analgesia 2018[22]	35 obese patients	MAP 0.82±5.03 mmHg
Noto et al. - EU J of Anaesthesia 2018[23]	30 awake vascular patients	MAP -6.8±6.7 mmHg

Cardiac output validation studies

Measurement of relative changes in CO performs comparably with invasive measurements

Vs. Pulmonary thermodilution		Percentage error
Bubenek-Turconi et al – Anesthesia-Analgesia 2013[11]	28 cardiac surgery patients	38%
Bogert et al – Anaesthesia 2010[12]	25 post CABG patients	30%
Stover et al – BMC Anesthesiology 2009[13]	10 severely ill ICU patients	29%
Vs. Transpulmonary thermodilution		
Broch et al – Anaesthesia 2012[14]	40 cardiac surgery patients	23% / 26%
Hofhuizen et al. – J of Critical Care 2014[15]	20 post-cardiac patients	38.9%
Vs. Trans-thoracic echo-Doppler		
van der Spoel et al. – J Clin Anesth 2012[16]	40 ASA 1-2 patients	39%
Vs. Esophageal echo-Doppler		
Chen et al. J Clin Anesth 2012[17]	25 ASA 1-3 patients	37%

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