External Oscillatory Blood Pressure - EOBP™

Development of Novel Principle To Measure Blood Pressure

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Disclosures

- Authors are inventors of EOBP (patent pending) and cofounders of Pranevicius Biotech Inc. (Forest Hills, NY)
- Authors were awarded medical device development grant from National Instruments (Austin, Tx)

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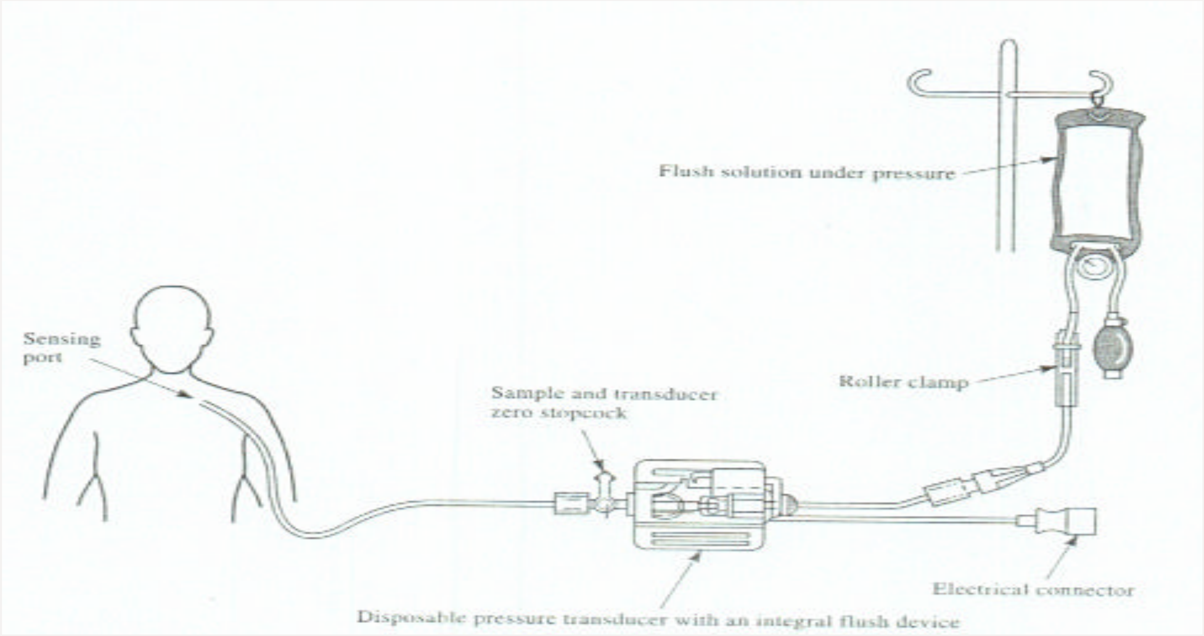
NATIONAL INSTRUMENTS™

History

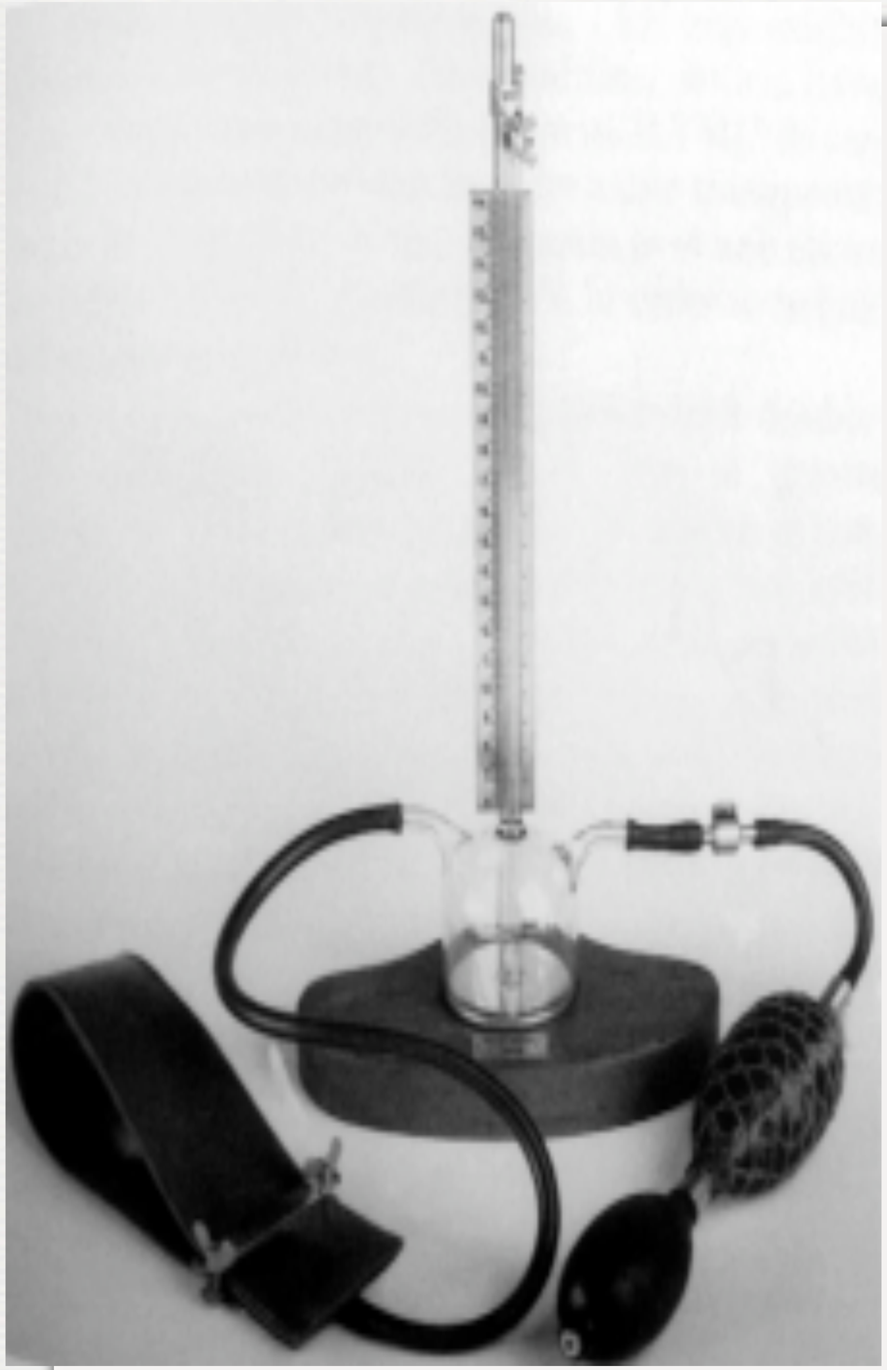
Direct blood pressure measurement
1714



Stephen Hales in 1714.

From Hall WD.
Stephen Hales: Theologian, botanist, physiologist, discoverer of hemodynamics. Clin Cardiol 1987;10:488

History



Indirect blood pressure measurement
1896

The Riva-Rocci sphygmomanometer.

Reprinted from Brown WC, O'Brien ET, Semple PF. The sphygmomanometer of Riva -Rocci 1896 –1996. J Hum Hypertens 1996;10:723–4.

History

Indirect blood pressure measurement
1905

Nicolai Korotkoff

Segall HN. N. C. Korotkoff—1874 –1920—Pioneer vascular surgeon. Am Heart J 1976;91:816–8.

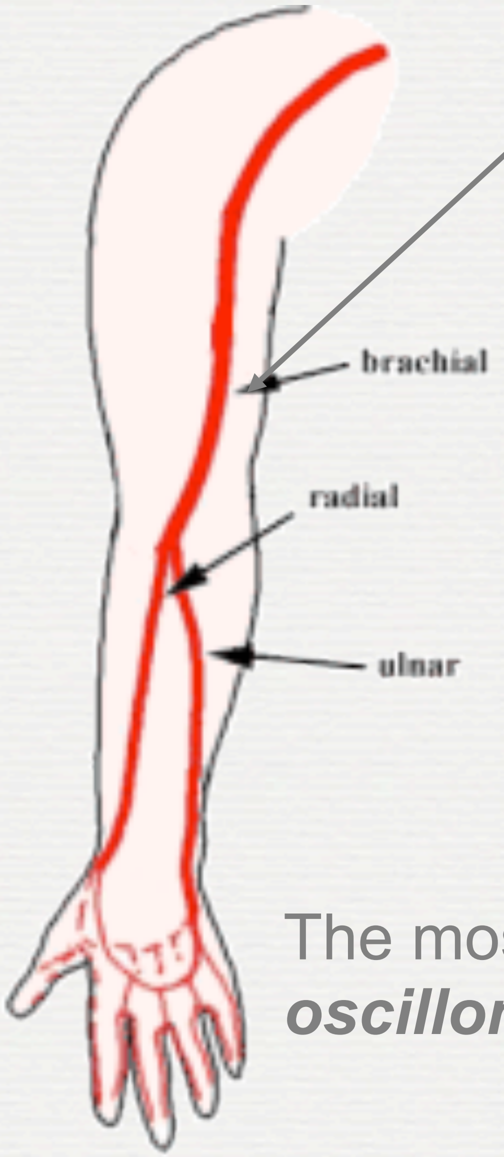
Current NIBP methods

- Auscultatory (golden standard)
- Oscillatory
- Volume clamp
- Tonometry

- All use counter-pressure and detect cardiac pulse dependant parameter

General Facts

Indirect measurement = non-invasive measurement



Brachial artery is the most common measurement site

Close to heart

Convenient measurement

Other sites are e.g.:

forearm / radial artery

wrist (tends to give much higher SP)

The most common indirect methods are ***auscultation*** and ***oscillometry***

General Facts (cont.)

An occlusive cuff is placed on arm and inflated to P_{cuff} > SP. Then the cuff is deflated gradually and the measurement of blood flow is done

The occlusive cuff should be of a correct size in order to transmit the pressure to the artery evenly and thus to obtain accurate results

A short cuff requires special attention in placement. Longer cuff reduces this problem.

The cuff should be placed at the heart level in order to minimize the hydrostatic effects

Palpatory Method (Riva-Rocci Method)

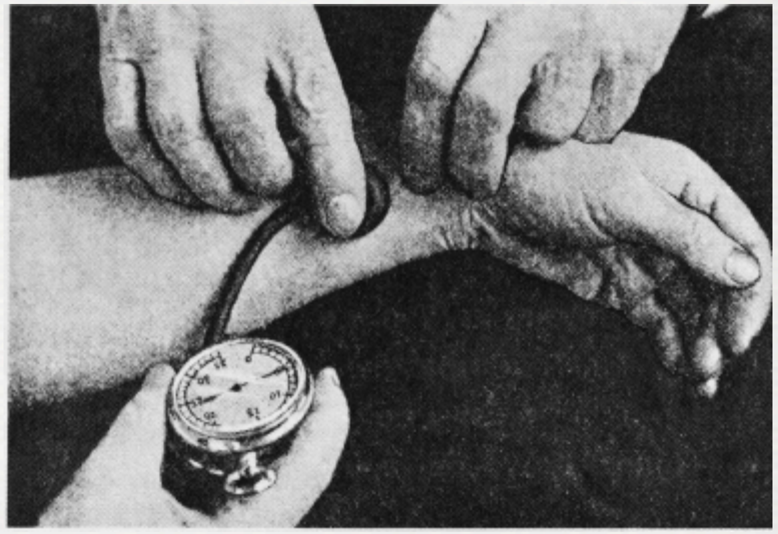
When the cuff is deflated, there is a palpable pulse in the wrist. P_{cuff} = BP

Several measurements should be done as the respiration and vasomotor waves modulate the blood pressure levels

ADVANTAGES

+) The blood pressure can be measured in noisy environment too

+) Technique does not require much equipment

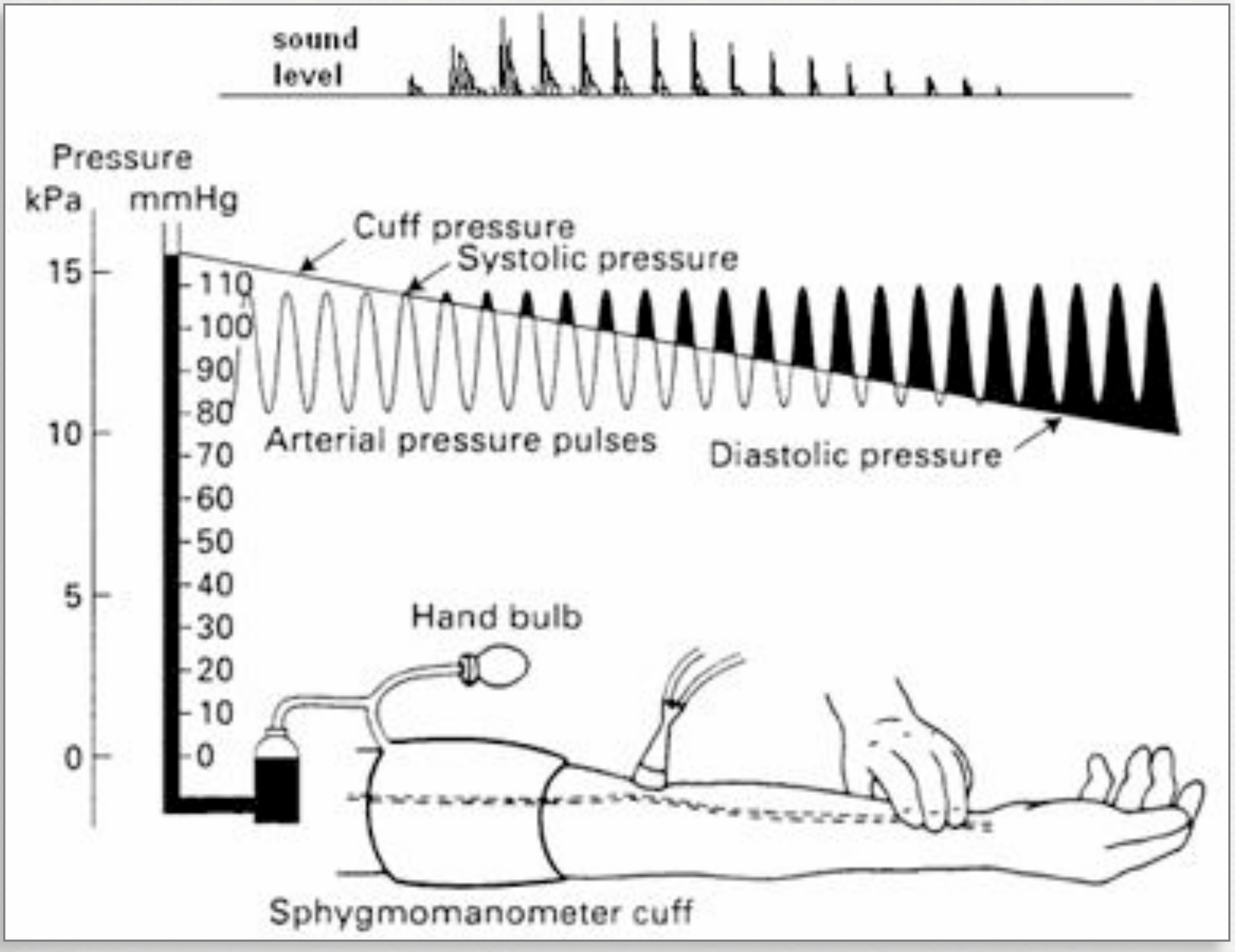


DISADVANTAGES

-) Only the systolic pressure can be measured (not DP)

-) The technique does not give accurate results for infants and hypotensive patients

Auscultatory Method



Pulse waves that propagate through the brachial artery, generate Korotkoff sounds.

There are 5 distinct phases in the Korotkoff sounds, which define SP and DP

The Korotkoff sounds are ausculted with a stethoscope or microphone (automatic measurement)

The frequency range is 20-300 Hz and the accuracy is +/- 2mmHg (SP) and +/- 4mmHg (DP)

Also with this method, several measurements should be done.

Auscultatory Method (cont.)

ADVANTAGES

+) Auscultatory technique is simple and does not require much equipment

DISADVANTAGES

-) Auscultatory tecnique cannot be used in noisy environment

-) The observations differ from observer to another

-) A mechanical error might be introduced into the system e.g. mercury leakage, air leakage, obstruction in the cuff etc.

-) The observations do not always correspond with intra-arterial pressure

-) The technique does not give accurate results for infants and hypotensive patients

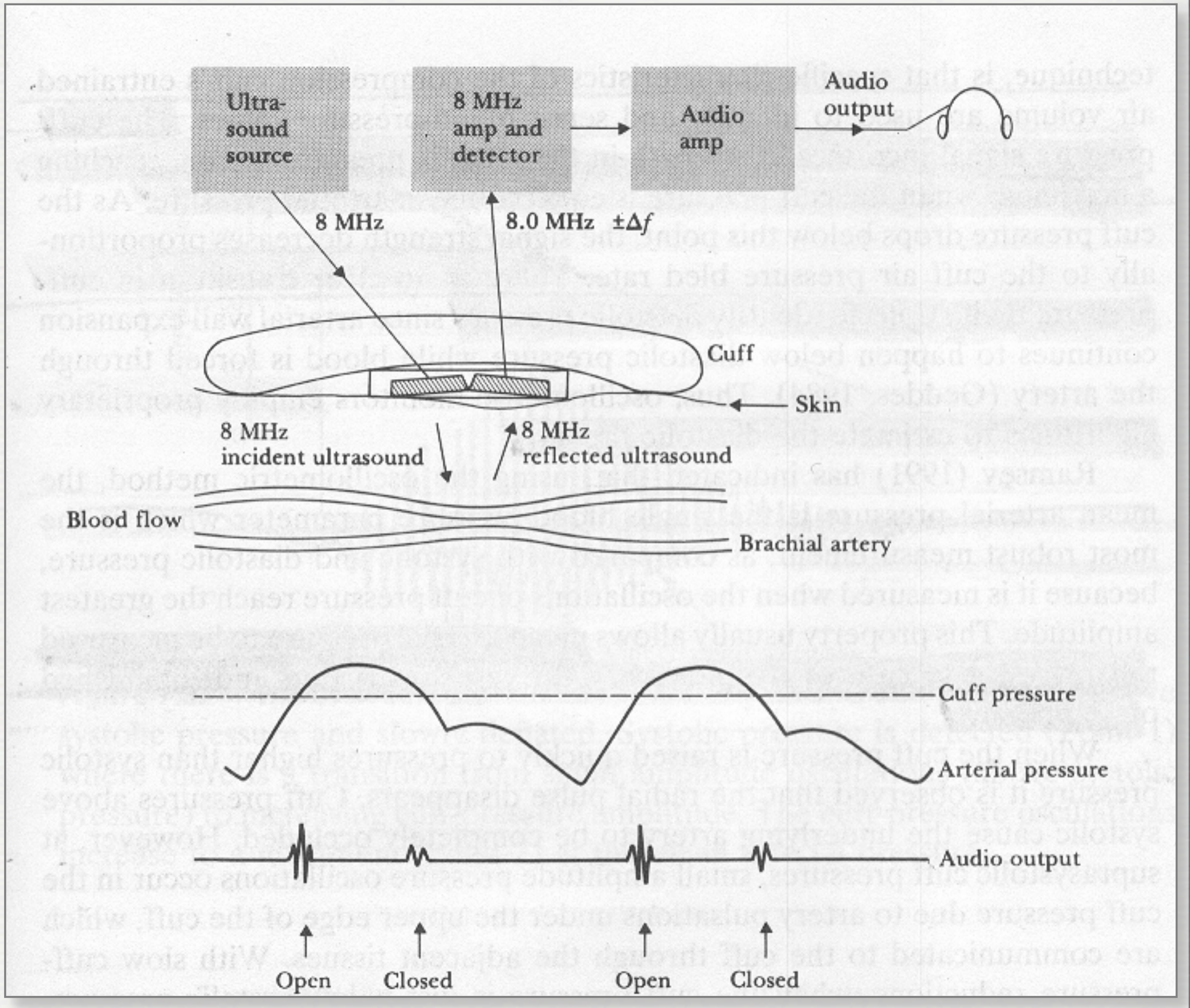
Ultrasonic Method

A transcutaneous (through the skin) Doppler sensor is applied here.

The motion of blood-vessel walls in various states of occlusion is measured.

The vessel opens and closes with each heartbeat when $DP < P_{cuff} < SP$

The frequency difference between transmitted (8 MHz) and received signal is 40-500 Hz and it is proportional to velocities of the wall motion and the blood.



Ultrasonic Method (cont.)

As the cuff pressure is increased, the time between opening and closing decreases until they coincide *Systolic pressure*

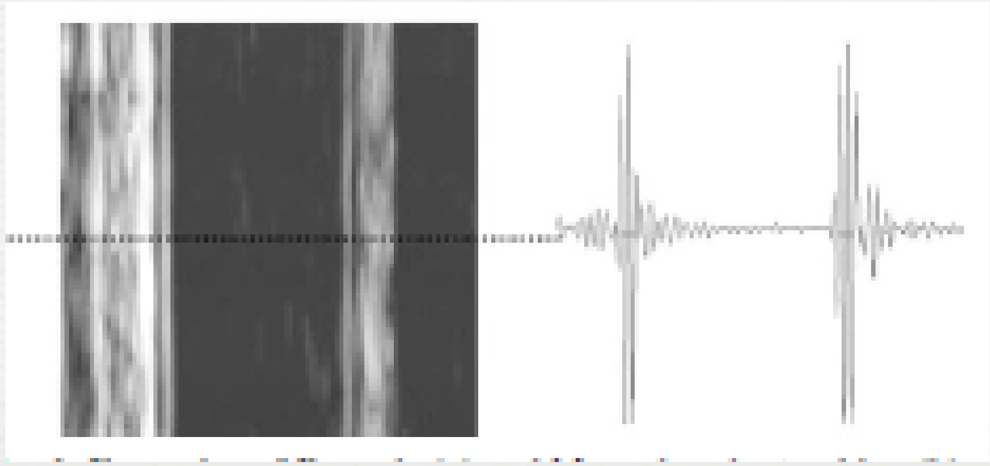
Again as the cuff pressure is decreased, the time between opening and closing increases until they coincide *Diastolic pressure*

ADVANTAGES & DISADVANTAGES

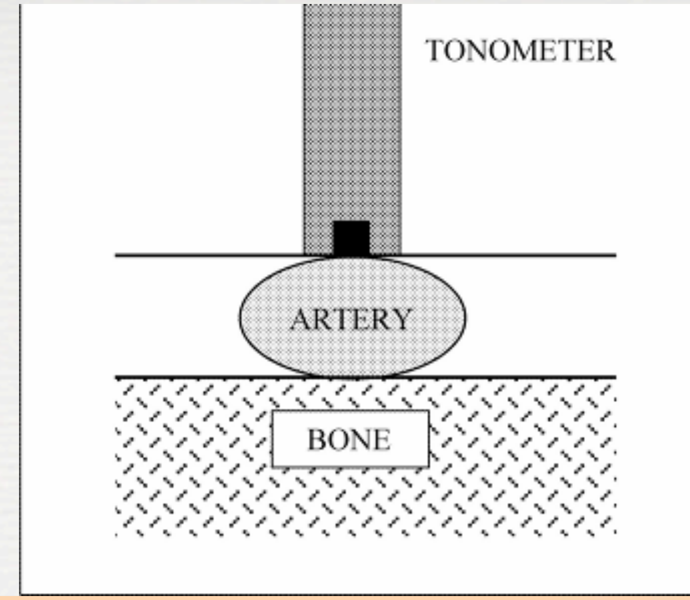
+) Can be also used in noisy environment

+) Can be used with infants and hypotensive individuals

-) Subject’s movements change the path from sensor to vessel

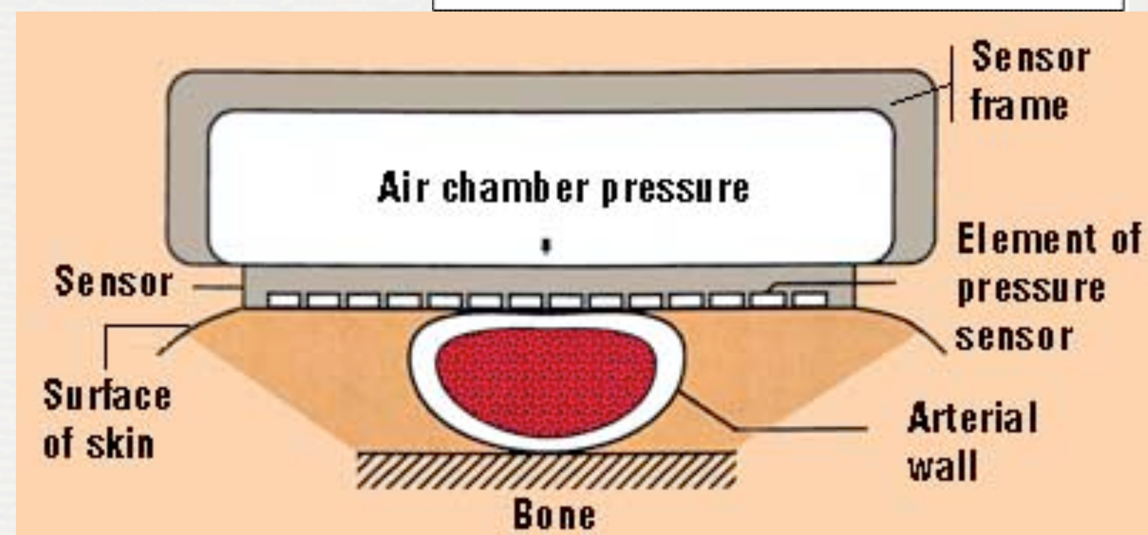


Tonometry

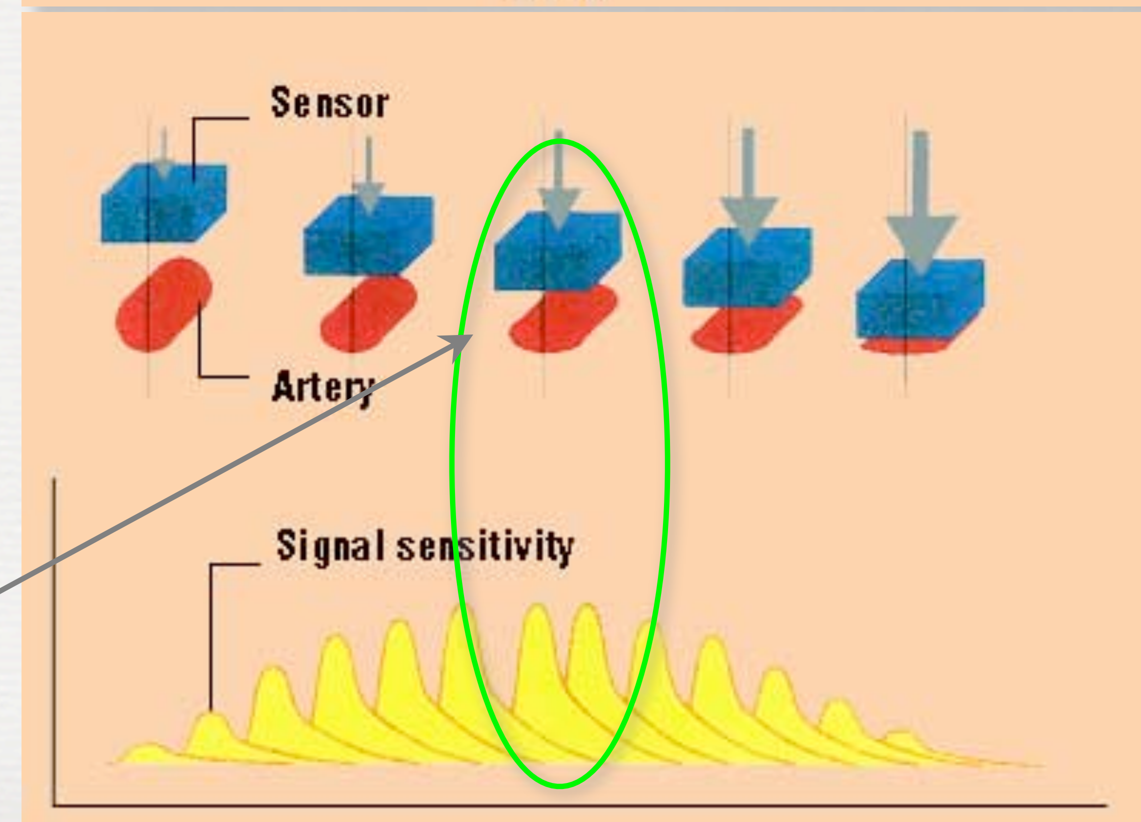


Linear array of pressure sensors is pressed against a superficial artery, which is supported from below by a bone (radial artery).

A sensor array is used here, because at least **one** of the pressure sensors must lay directly above the artery



When the blood vessel is partly collapsed, the surrounding pressure equals the artery pressure.



The pressure is increased continuously and the measurements are made when the artery is half collapsed

The hold-down pressure varies between individuals and therefore a ’calibration’ must be done

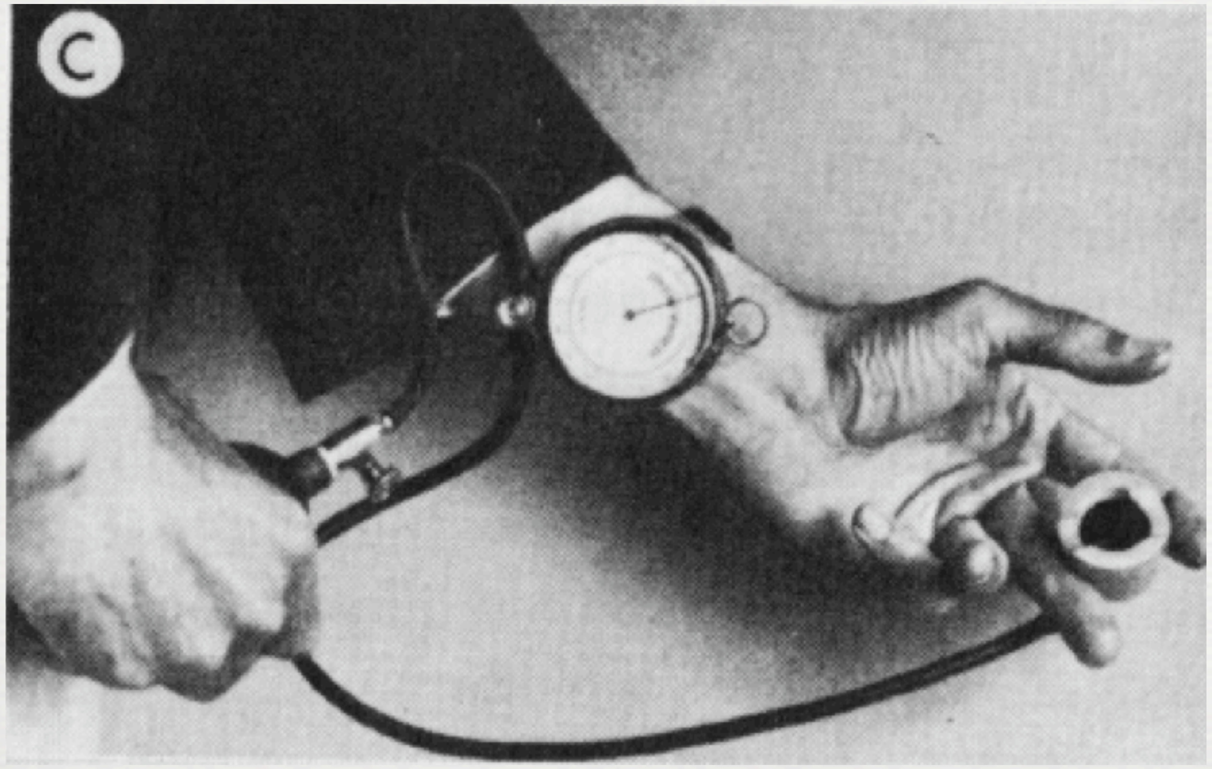
Tonometry (cont.)

ADVANTAGES

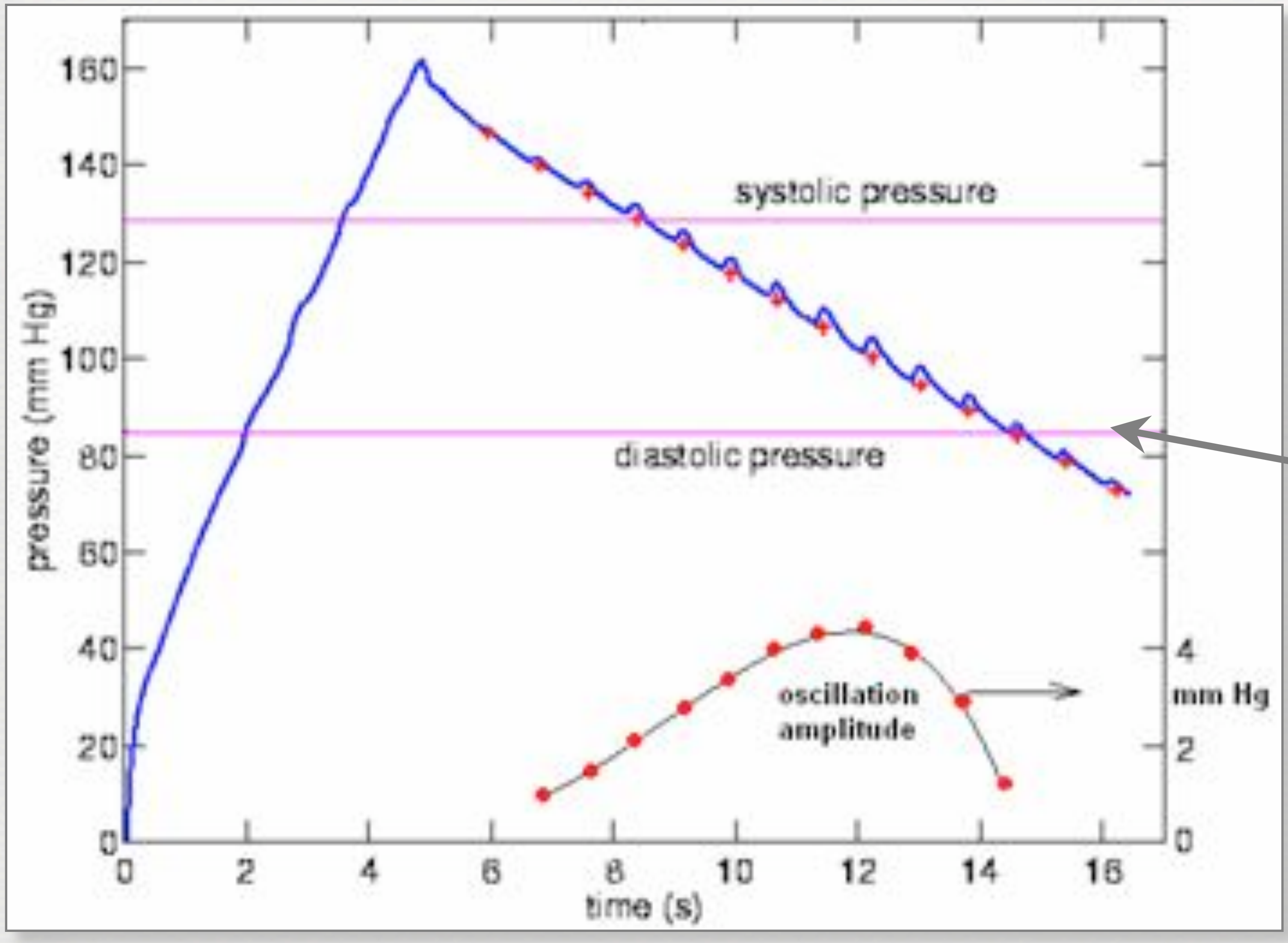
+) Can be used for *non-invasive, non-painful, continuous* measurement

DISADVANTAGES

-) Relatively high cost
-) The wrist movement and tendons result in measurement inaccuracies



Oscillometric Method



http://colin-europe.com/docpdfdemos/oscillo0104.wmv

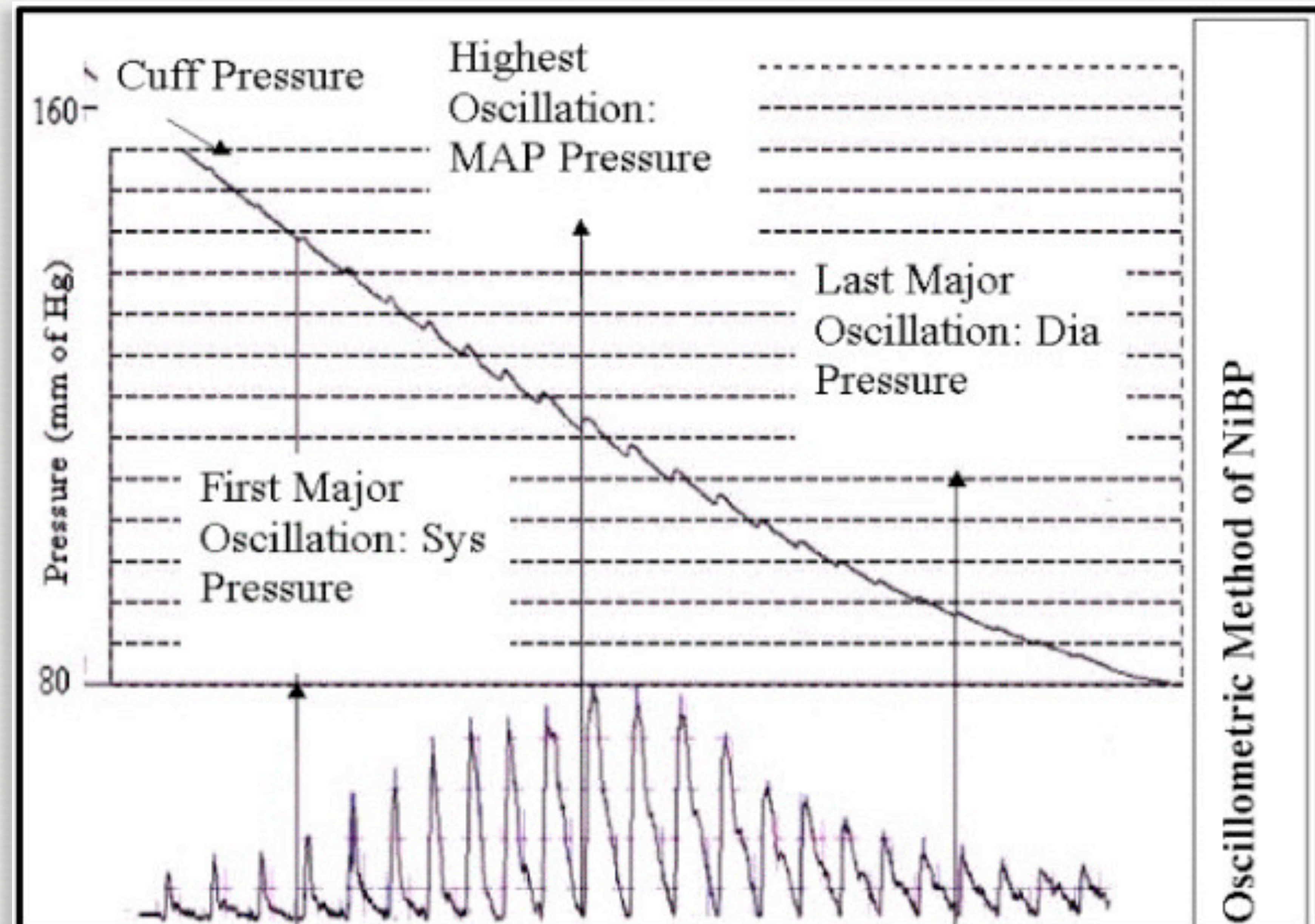
The intra-arterial pulsation is transmitted via cuff to transducer (e.g. piezo-electric)

The cuff pressure is deflated either linearly or stepwise

The arterial pressure oscillations (which can be detected throughout the measurement i.e. when P_{cuff} > SP and P_{cuff} < DP) are superimposed on the cuff pressure

SP and **DP** are estimated from the amplitudes of the oscillation by using a (proprietary) empirical algorithm.

Oscillometric Method (cont.)



ADVANTAGES

+) In the recent years, oscillometric methods have become popular for their simplicity of use and reliability.

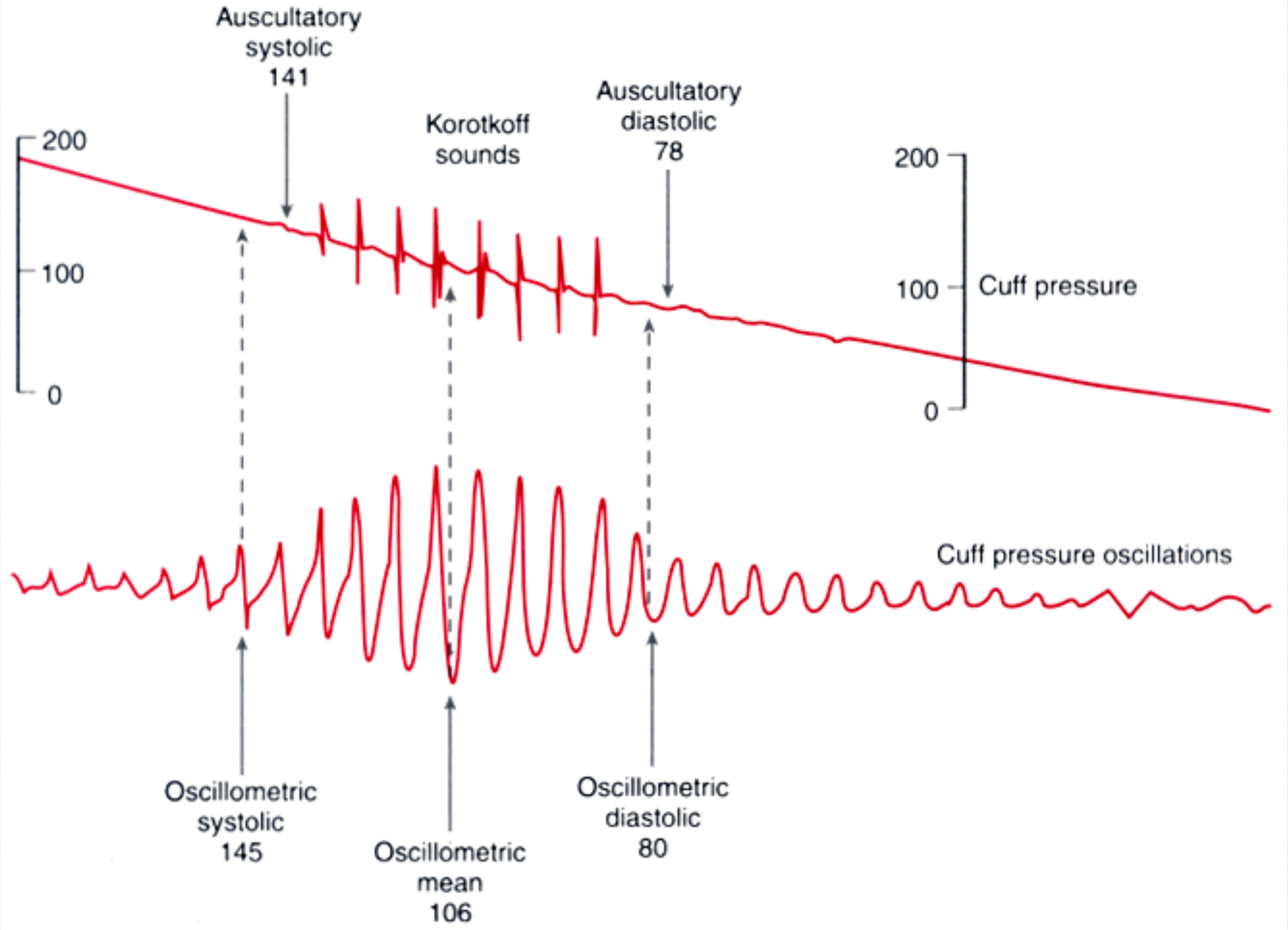
+) MP can be measured reliably even in the case of hypotension

DISADVANTAGE

-) Many devices use fixed algorithms leading to large variance in blood pressures

Principle of oscillometric NIBP

- Peak oscillation occurs when cuff pressure equals intraarterial (Ptm=0)



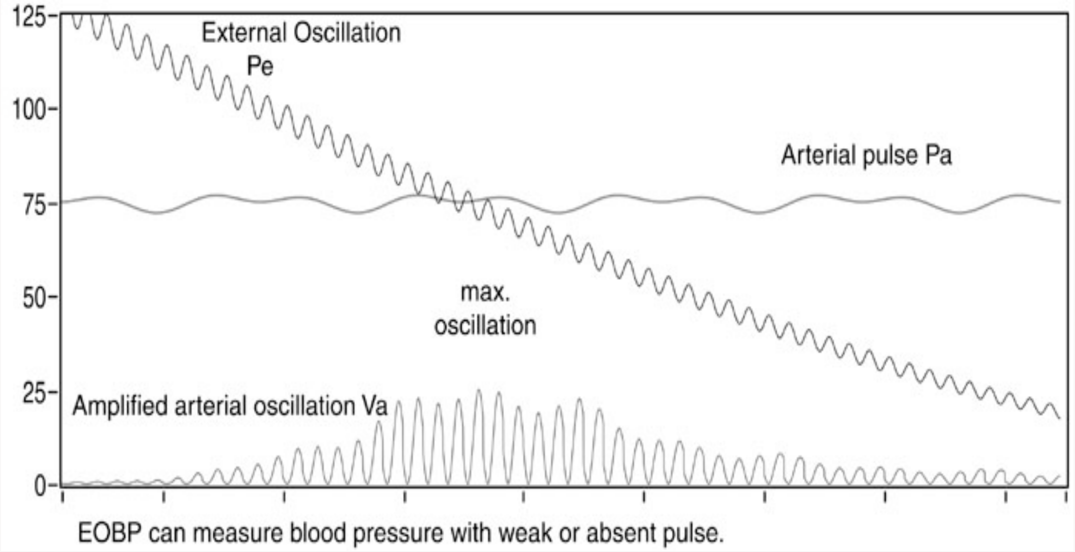
NIBP limitations

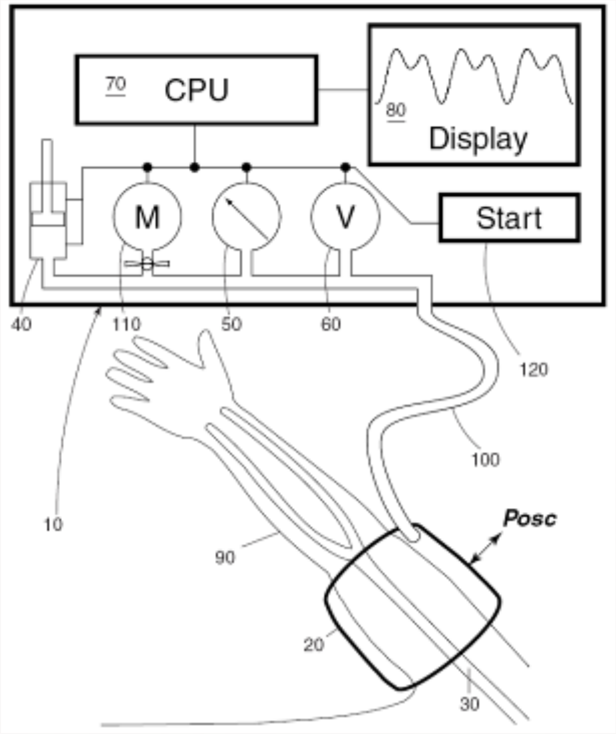
- Pulse weak (hypotension)
- Pulse irregular (arrhytmia)
- Pulse rare (bradycardia)
- Pulse absent (CPB)

- Does not work when we need to have reliable BP most

External oscillatory BP - EOBP™

- Variable counter pressure is applied
- External oscillation is introduced
- EOBP response is measured
- Response to external oscillation does not require regular cardiac pulse





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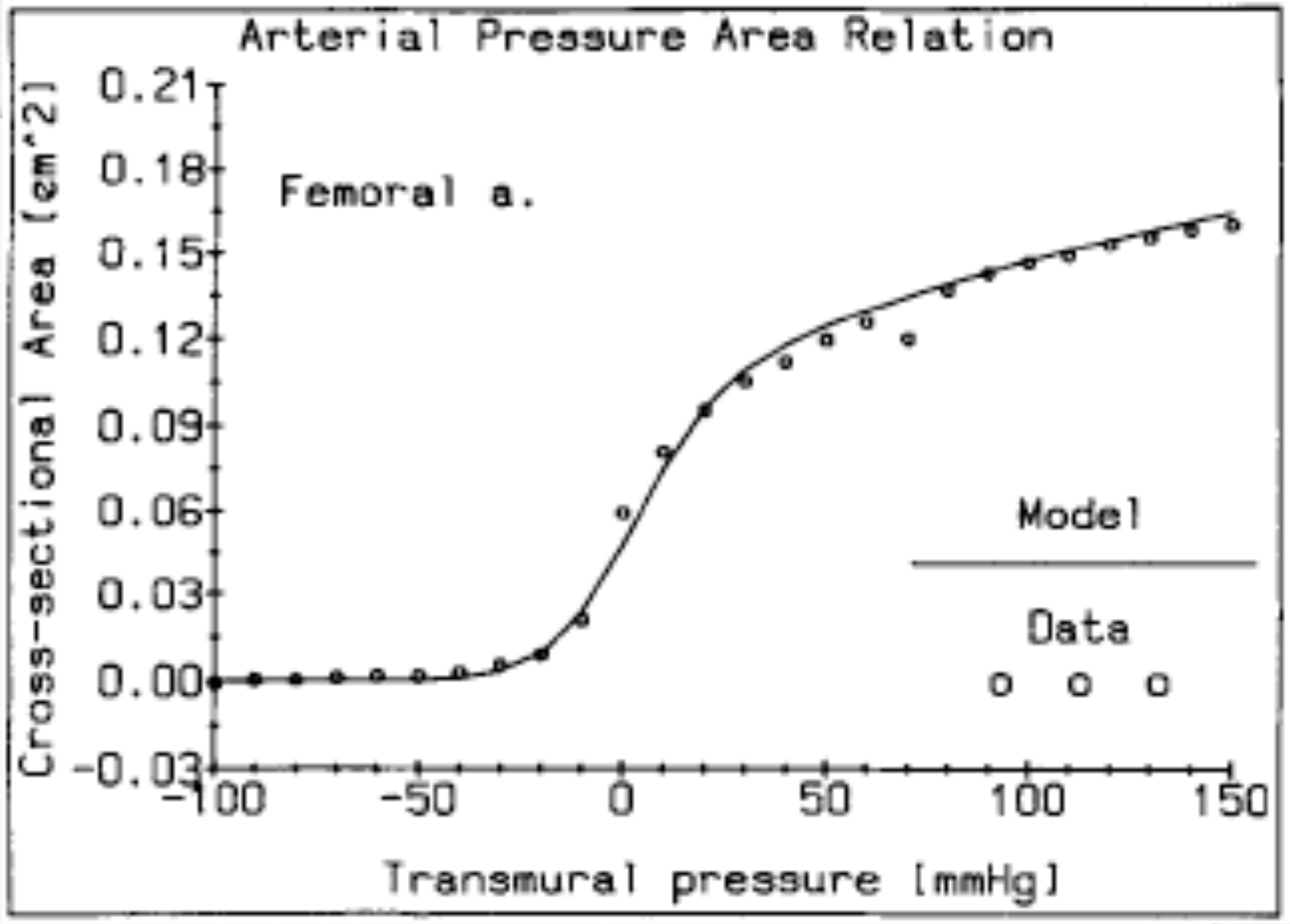
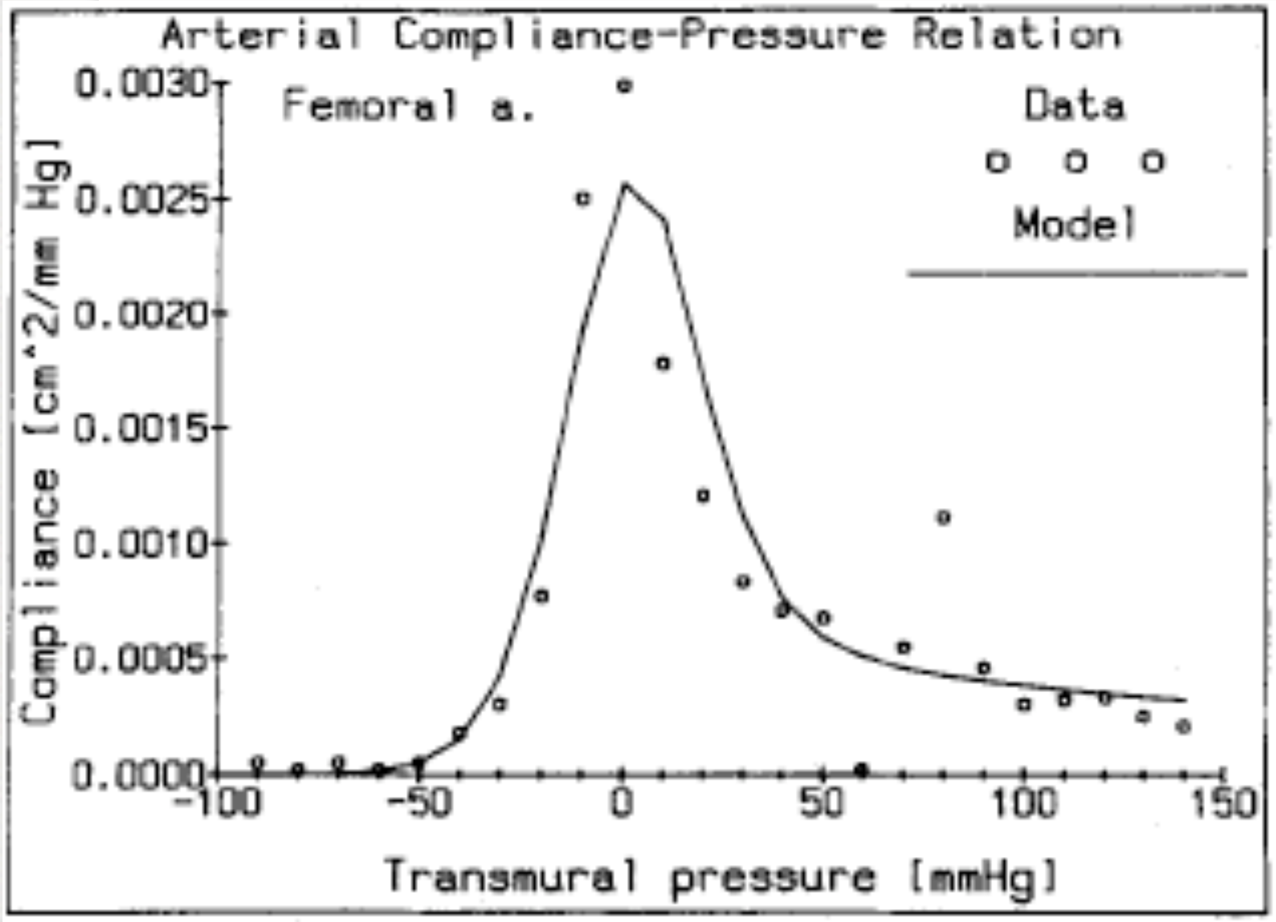
EOBP simulation study

- Based on P/V relationship for arterial segment

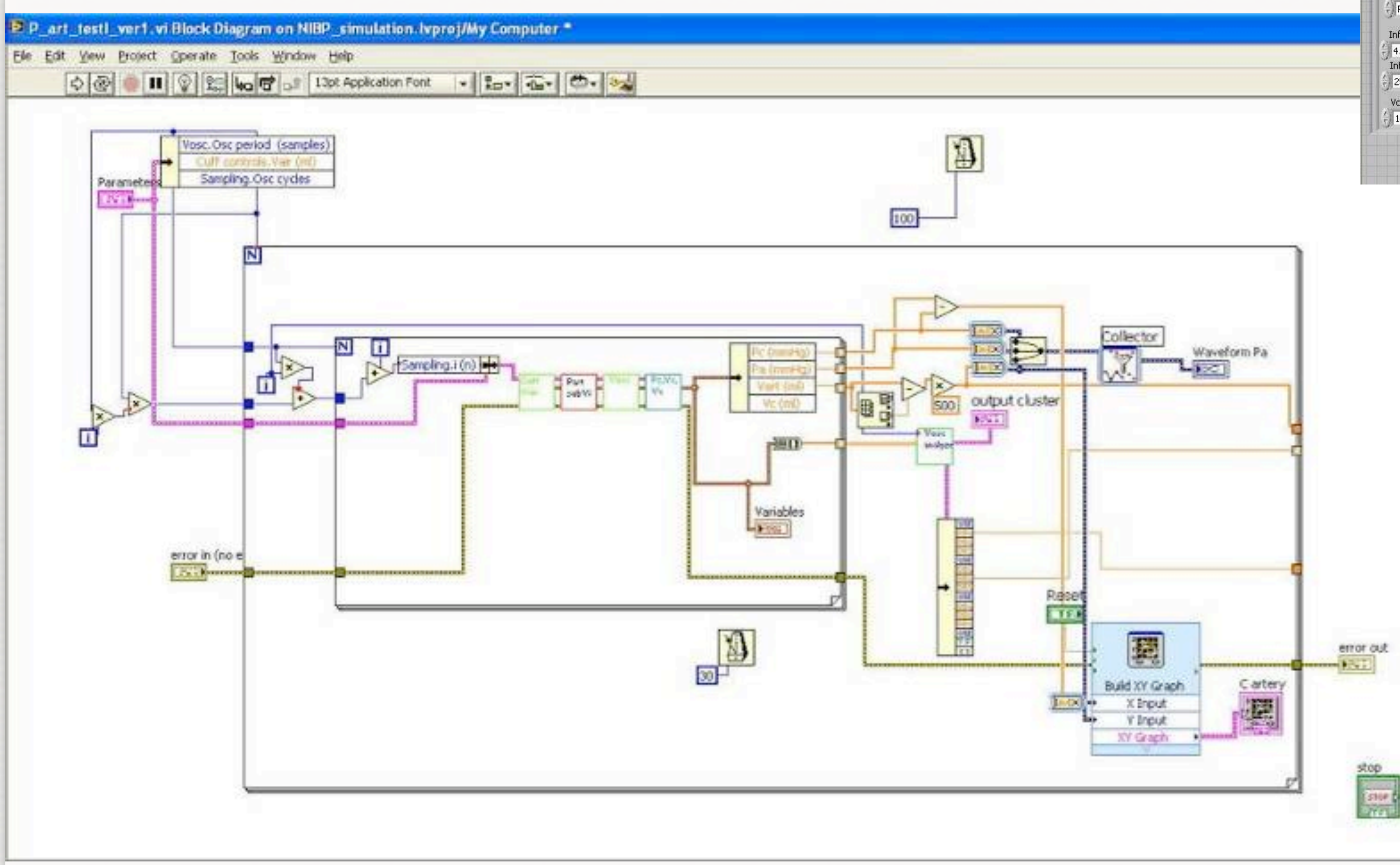


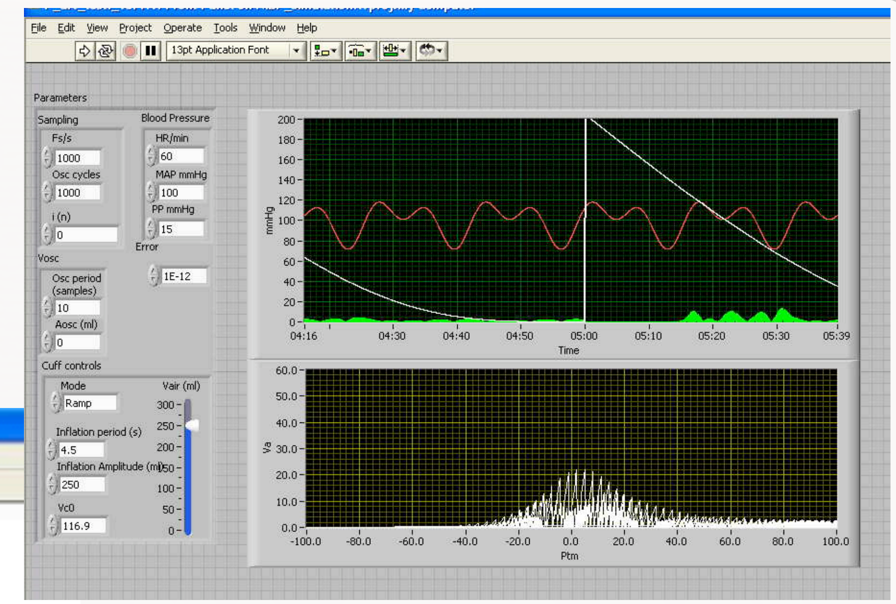


- (Drzewiecki, Annals of Biomedical Engineering, Vol. 22, pp. 88-96, 1994)

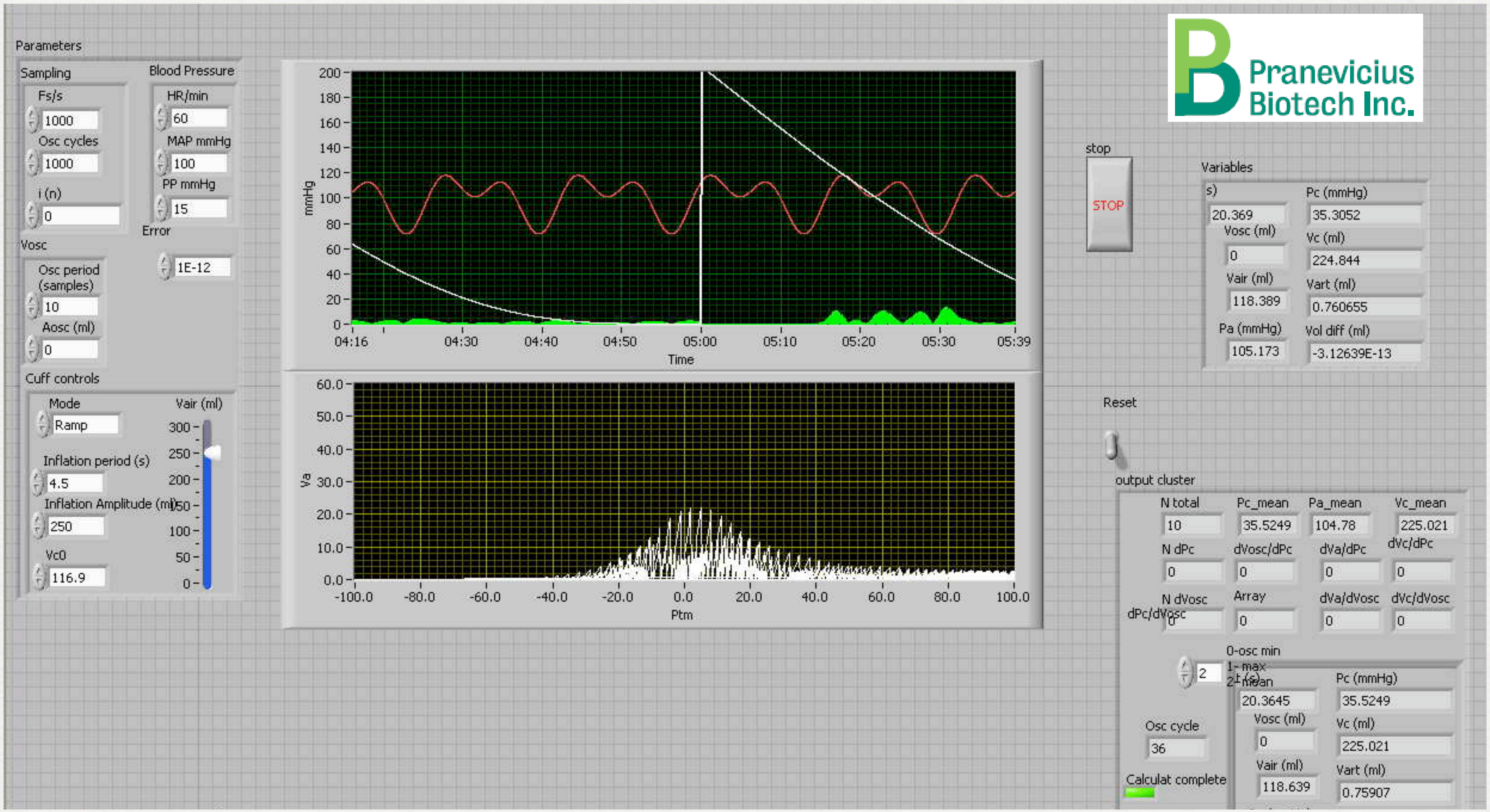
EOBP simulation study

- Simulation on Labview 8.6, NI, Austin, Tx

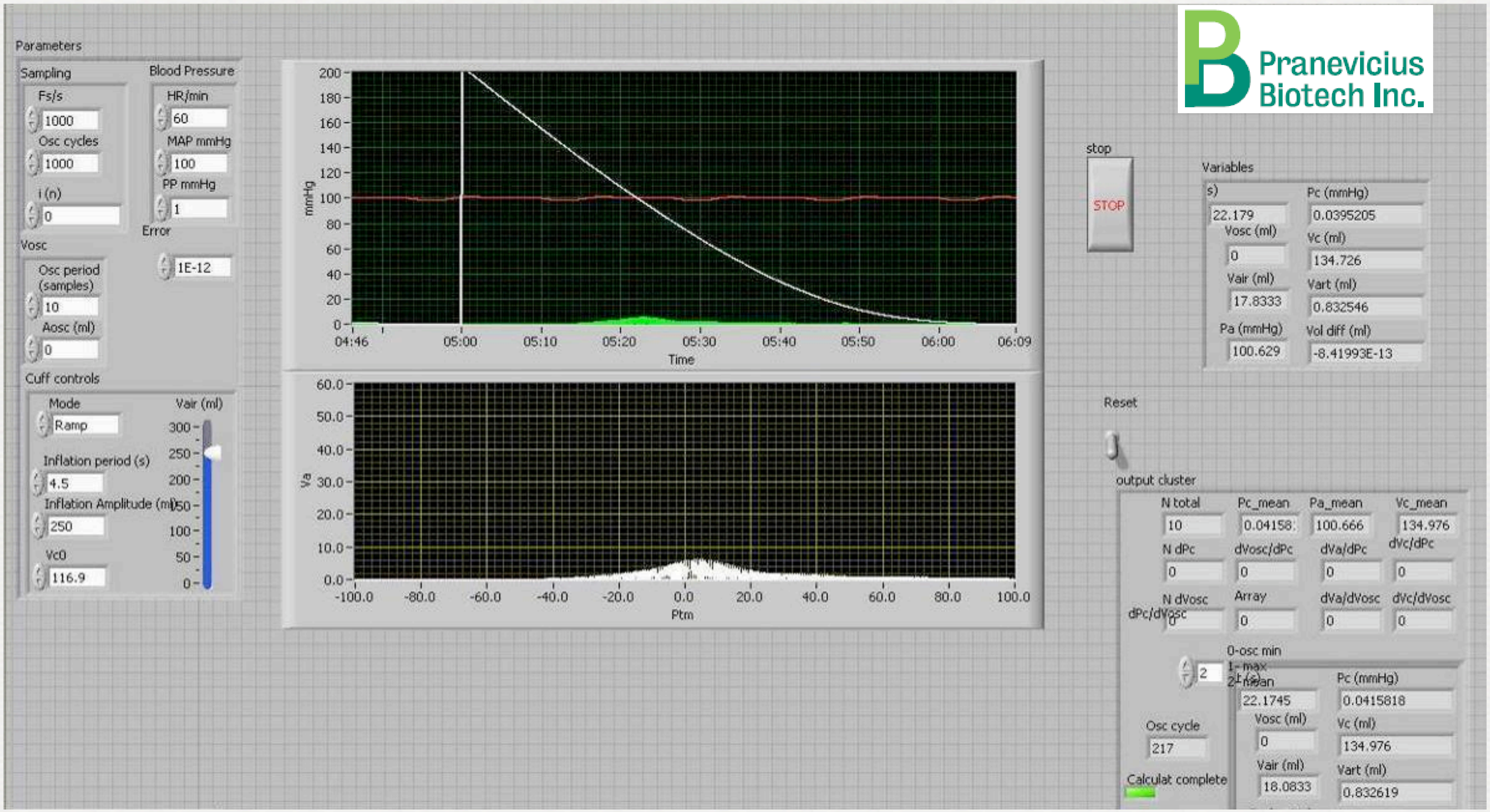




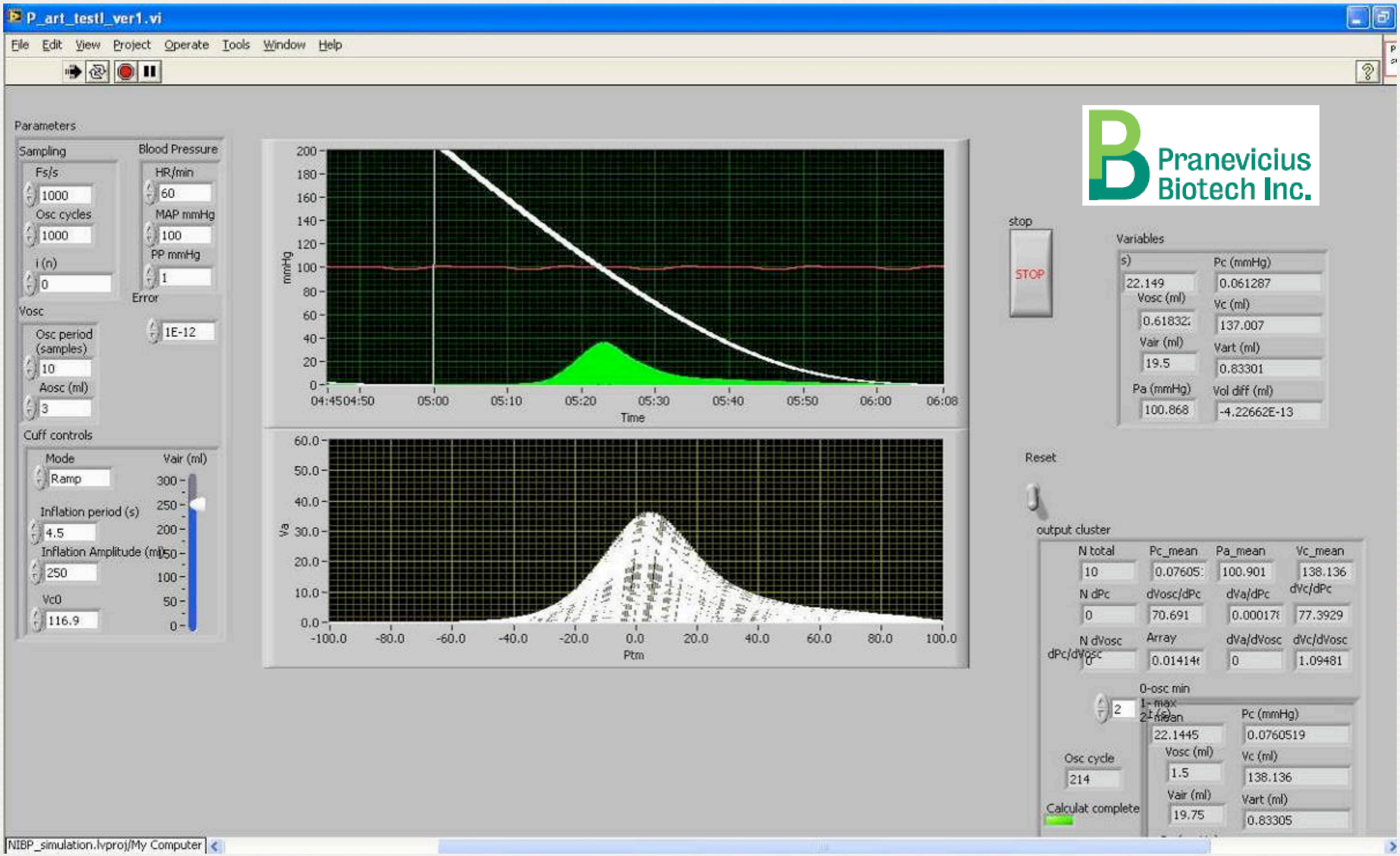
Pulsatile BP



Non-Pulsatile BP

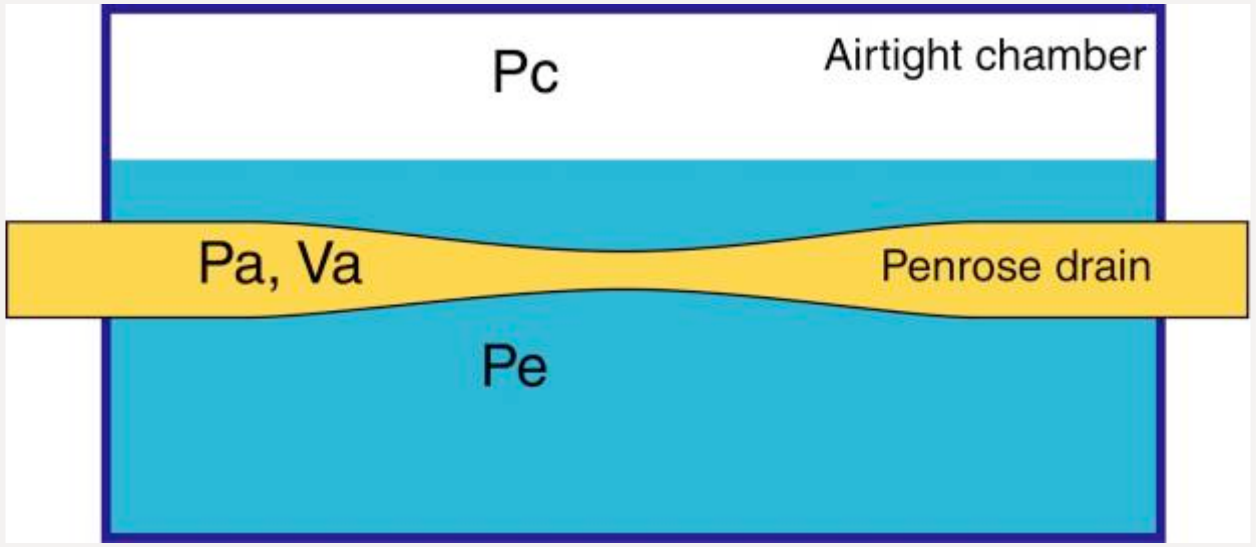


Non-Pulsatile EoBP™



Bench study

- Water filled airtight chamber with colapsible tube
- Oscillator
- DAQ (NI, Austin, TX)
- PC with Labview and Signal Express (NI)



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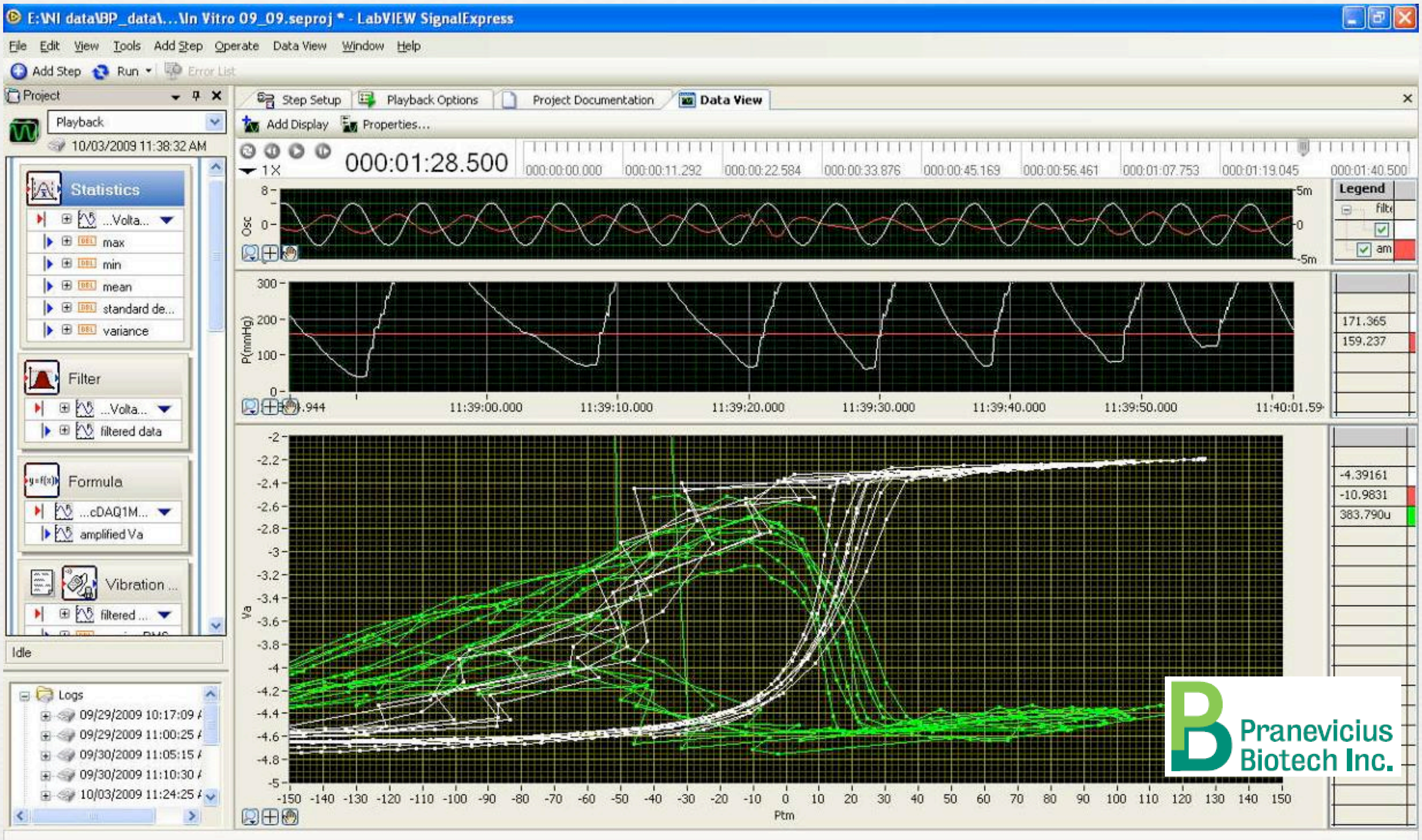
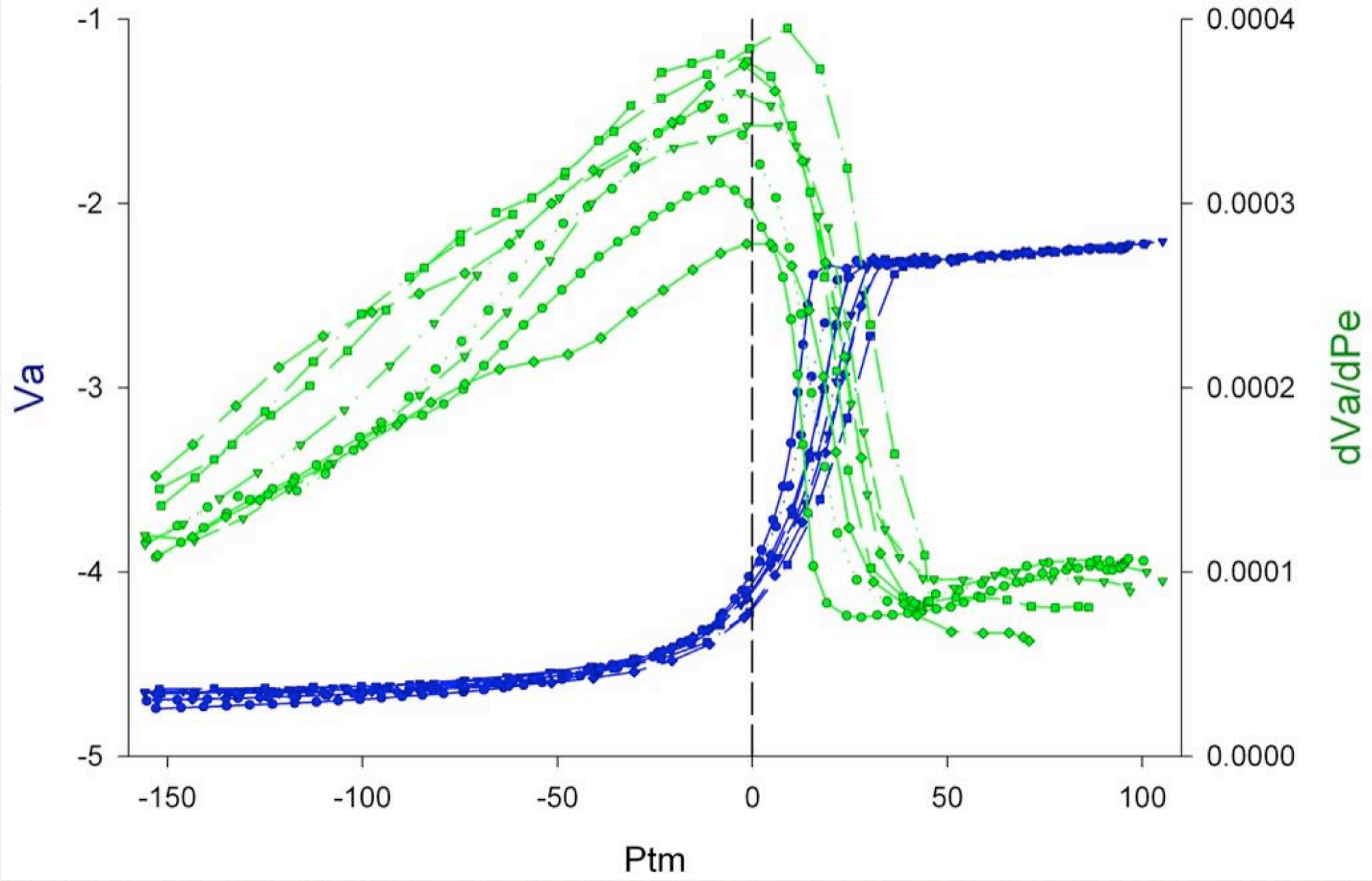
Bench study

Bench acquisition



Reproducibility of EOBP™



Target state:

- *Yes we can! We can accurately and reliably measure blood pressure*
- *in shock patients,*
- *in patients with arrhythmia,*
- *in the noisy environment like battlefield,*
- *in newborns,*
- *in patients with artificial cardiac assist devices without cardiac pulse,*
- *in obese patients,*
- *During periods of labile blood pressure (induction of anesthesia, "white coat" hypertension, trauma).*
- *when the limb where BP is being measured can not be kept motionless, and*
- *do that with the technique which is simple, automatic, based on inexpensive equipment, does not require any skills, and is totally operator independent*

EOBP advantages during atrial fibrillation and other irregular heart rhythms

- *irregular cardiac rhythms like in atrial fibrillation caused tremendous pulse to pulse pressure variations*
- *noninvasive blood pressure measurements are virtually impossible during atrial fibrillation and are extremely variable between the operators*
- *only EOBP can allow measurement of blood pressure during atrial fibrillation*

EOBP and White Coat Effect

- *in 15 - 20% of people with stage one hypertension blood-pressure might be persistently elevated in the presence of health care worker*
- *therefore elimination of health care worker by automatization of blood pressure measurement process and performing multiple measurements in short time would allow more precise estimation of hypertension in 15-20% of people*
- *the economic effect in the United States alone would be in tens of billions*

EOBP advantages in Obesity

- *the obesity in the United States increased up to 30% in the year 2000*
- *in 84% of the cases cuffs used in ambulatory setting were too small*
- *simple use of the larger cuff does not insure placement of the cuff over the brachial artery*
- *even using Doppler probe diastolic blood pressure is largely overestimated in the obese patients*
- *incorrect measurements can erroneously misclassify patient as hypertensive with the*

Dollars and Sense

- *blood pressure reduction by 5 mm Hg can reduce coronary artery disease by 16% and stroke by 38%*
- *5 mm Hg error at 90-95 mm Hg would miss 21 million of US hypertensives: treating this group would decrease death rate from coronary artery disease by 20%, saving 25,000 lives and prevent similar number of fatal strokes*
- *Measuring blood pressure 5 mm Hg too high, would falsely classify 27 million people as having hypertension: at the cost of $1000 per year to treat each patient, it would cost $27 billion a year*

Conclusions:

- Proof of concept study confirmed EOBP feasibility both in simulation and bench studies.
- EOBP can obtain indirect blood pressure reading when pulse or flow is absent.
- EOBP measurements are faster than NIBP.
- Clinical validation studies of refined EOBP system are necessary.

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