

A non-invasive method for hemodynamic monitoring.

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Abstract

A non-invasive and cost-effective method to measure and analyze hemodynamics would present a cardiologist with very important diagnostic information for critical and continuous care of patients with hemodynamic disorders [1]. This report documents the construction and testing of a medical instrument to measure cardiac output, among other hemodynamic parameters, by measuring the changes in impedance across the thorax. An electrical equivalent model of the human thorax is developed, along with an algorithm for computing important hemodynamic parameters. The hardware required to implement the system is based on a signal generator to provide current and a microcontroller to measure the voltage changes across the thorax. Sample impedance data for a test subject are presented.

Introduction

Heart disease and stroke — the principal components of cardiovascular disease — are the first and third leading causes of death in the United States, accounting for more than 40% of all deaths. About 950,000 Americans die of cardiovascular disease each year, which amounts to one death every 33 seconds [6]. This problem is not unique to the United States – heart disease and stroke killed 17 million people worldwide in 1999, which is about 30 percent of all world deaths [6].

A consideration of deaths alone understates the burden of cardiovascular disease. About 61 million Americans (almost one-fourth of the population) live with this disease. Heart disease is a leading cause of disability among working adults. Stroke alone accounts for disability among more than 1 million Americans. Almost 6 million hospitalizations each year are due to cardiovascular disease [6].

The economic impact of cardiovascular disease on the U.S. health care system continues to grow as the population ages. The estimated cost of cardiovascular disease in the United States in 2001 is \$298 billion, including health care expenditures and lost productivity [6].

Once cardiovascular disease is diagnosed, treatment is often lifelong and thus very costly [2]. Successful treatment requires constant monitoring of cardiovascular status. A continuous monitor of hemodynamic status for patients being treated for

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cardiovascular disease would greatly improve care and decrease costs for the healthcare industry [2].

Currently in the clinical market, there is no good diagnostic tool for continuous hemodynamic monitoring. The most important of hemodynamic parameters is cardiac output (CO), the total volume of blood the heart pumps per minute. The three best available methods of measuring CO, direct Fick, indirect Fick, and thermodilution, all require right-heart catheterization [8]. This is a very expensive procedure that requires threading a catheter through the pulmonary artery into the heart. Numerous complications are possible, including artery perforation and secondary infection [9]. Because of these risks, this procedure is only done to critically-ill patients in the catheterization laboratory or intensive-care unit [2]. Echocardiography may be used to calculate CO, but this procedure is very expensive and time-consuming, requiring a highly-trained technician to carry out [9].

The market for ICG technology is very large. Currently there are several companies, such as CardioDynamics (<http://www.cdic.com>), CardioBeat (<http://www.cardiobeat.com>), and Medis (<http://www.medis-de.com>) that have developed or are in the process of developing non-invasive cardiac monitoring devices. CardioDynamics International Corporation is the only company on the market to have FDA-approval for their device. Yet, they only have 1% market penetration. The company foresees "The market potential for our proprietary technology is \$5 billion and \$800 million in recurring revenue" [7].

System Overview

"*Impedance plethysmography* is a method of determining changing tissue volumes in the body, based on the measurement of electric impedance at the body surface" [3]. Impedance cardiography is an application of this method to measuring hemodynamic variables by measuring the changes in impedance of the thorax [3]. The impedance of the thorax is directly related to the changes in blood volume in the aorta during the cardiac cycle, as well changes in tissue positions during respiration [1,3]. By using a mathematical model of a human subject, the following hemodynamic variables can be calculated from the impedance signal [4]:

- heart rate (HR)
- stroke volume/index (SV/SVI)
- cardiac output/index (CO/CI)
- Heather index (HI)
- systemic vascular resistance/index (SVR/SVRI)
- acceleration/velocity index (ACI/VI)
- thoracic fluid content (TFC)
- left cardiac work/index (LCW/LCWI)
- systolic time ratio (STR)
- left ventricular ejection time (LVET)
- pre-ejection period (PEP)

The basic idea behind ICG is to apply a current across the thorax in the frequency range 20 to 200 KHz, and to measure the resulting impedance change as a function of time. This requires two pairs of electrodes – one pair to apply the current, and a second pair to measure the impedance.

Figure 1 shows a diagram of where the electrodes should be placed on a human subject, as well as the path of the current flow through the subject's body. There are two pairs of electrodes -- the inner recording pair and the outer stimulating pair. It is not important precisely where the outer stimulating electrodes are placed, as long as there is at least a 5 cm distance between the stimulating and recording electrodes [12]. The upper stimulating electrode may be placed on the forehead, or back of the neck, and the lower stimulating electrode is usually placed at the waist. On the other hand, it is very crucial where the recording electrodes are placed, and the distance between them enters into the stroke volume expression, as will be discussed later. The upper recording electrode should be placed at the base of the neck. The lower recording electrode should be placed at the xiphoid process, that is the bottom of the sternum [12]. The ideal electrodes are band electrodes, although point electrodes would also work if several are wired together. Conducting duct tape also works as a replacement for special-purpose electrodes [2].

Figure 2 shows a simple block diagram of our system. An alternating-current generator is the current source; a series resistor limits the amount of current that passes through the subject. The frequency of the delivered current is between 20kHz and 200 kHz [1]. Because the skin's impedance increases at higher frequencies, a small amount of energy will be delivered to the patient, thus ensuring the safety of the system [5].

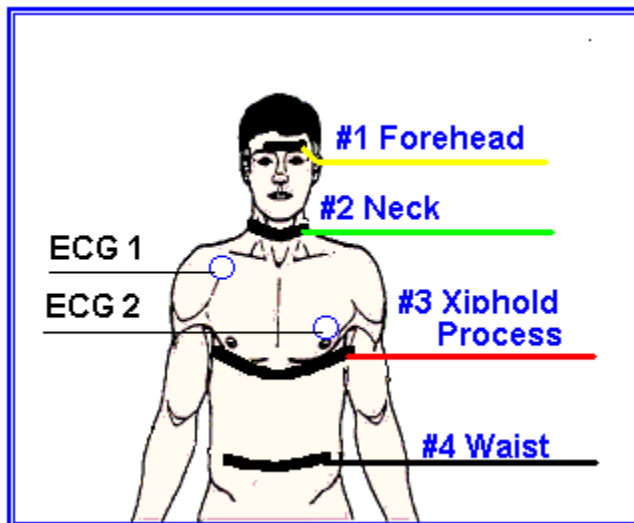


Figure 1. *Electrode placement in impedance cardiography [4].*

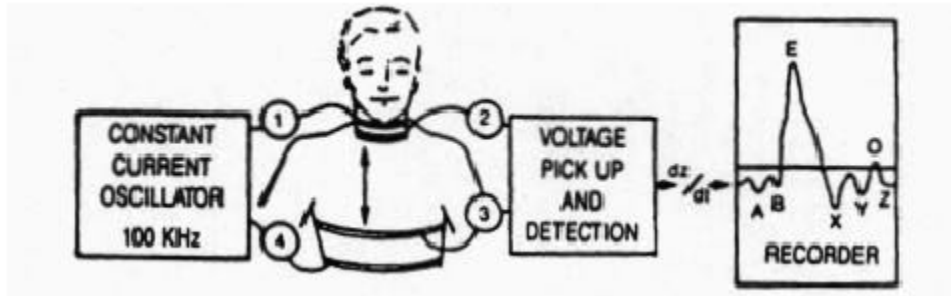


Figure 2. Block diagram of measuring system [1].

Figure 3 shows a typical output that we expect to see from the system. It includes the impedance, its first derivative, and the corresponding EKG. From this data, we will calculate the hemodynamic variables described above. The mathematical derivations for the variables comes from [3,4].

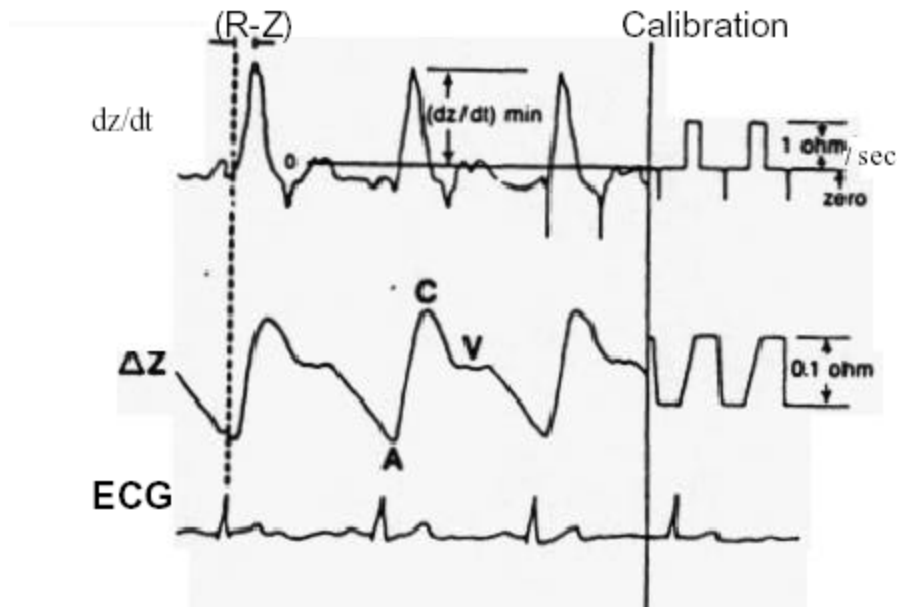


Figure 3. Example of raw impedance data, its first derivative, and the corresponding ECG signal in a typical setup [1].

The Design – Hardware

This system uses an external signal generator set to 80 kHz to power the oscillator, which creates a 20 kHz square wave. After passing through the Schmitt trigger, the wave is centered around 0V, and is 10V peak-to-peak. This signal is applied to the stimulating electrodes attached to the human subject. Figure 4 shows a block diagram of the system, and Appendix 2 shows the final schematic diagram. Figure 5 shows a schematic diagram of the oscillator. The oscillator reduces the 80 kHz square wave coming from the signal generator to a 20 kHz square wave.

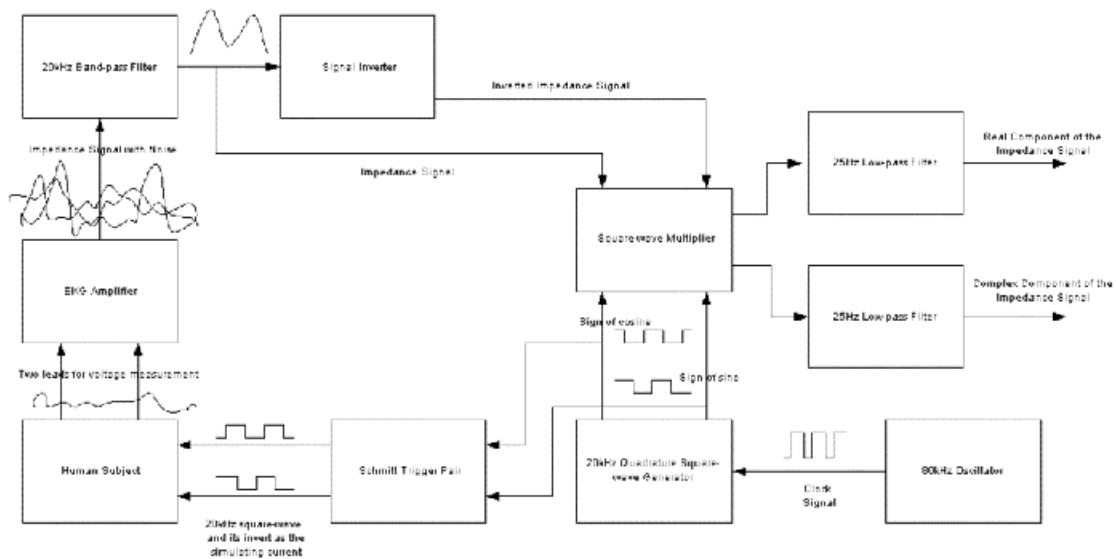


Figure 4. Block diagram of ICG system.

The output from the recording electrodes is input to the ECG amplifier, described elsewhere [14]. This signal has a lot of noise, including 60 Hz interference, and the ECG signal. A 20 kHz band-pass filter filters out the noise, and selects the 20 kHz impedance signal. The 20 kHz band-pass filter is implemented as a composition of a 19 kHz high-pass filter (multiple-feedback implementation), followed by a 21 kHz low-pass filter (based on the MAX292), followed by a second 19 kHz low-pass filter (multiple-feedback implementation).

Finally, the impedance signal is modulated by 20 kHz. The DS5000 can not sample at such a high rate, and there is no need to. This implementation uses a complex demodulator, the MAX353, to demodulate the signal. The output is fed through an attenuator to the ADC0848 interfaced to the DS5000.

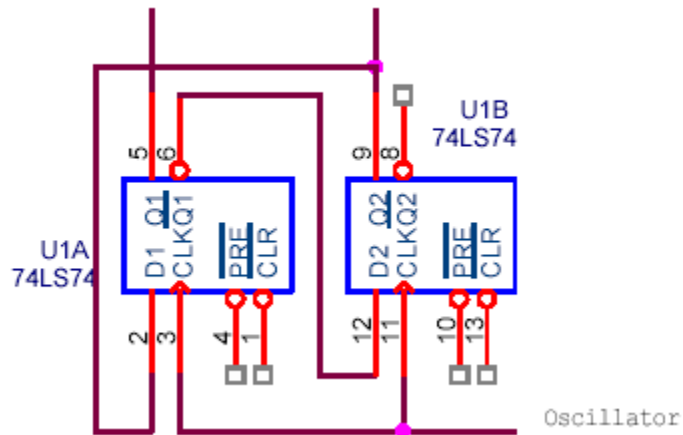


Figure 5. Schematic diagram of oscillator

A sample output from the entire system can be seen in Figure 6. Notice the noise in the impedance signal. Data analysis is presented in a later section.

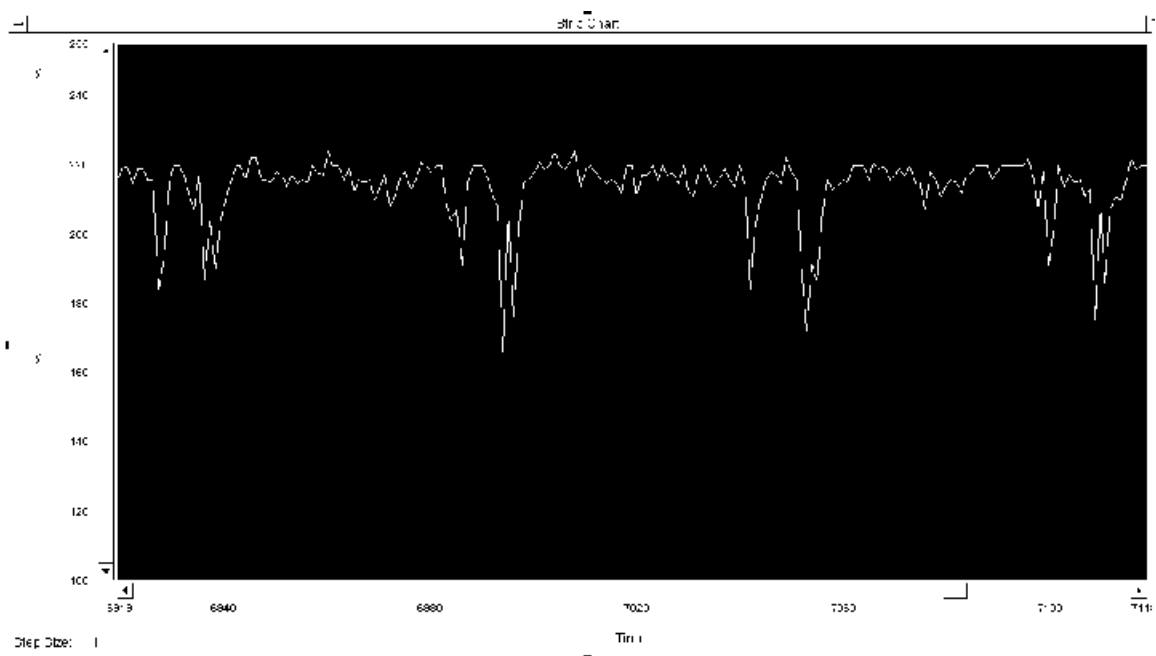


Figure 6. Sample preliminary output.

Design – Software

The algorithm for computing hemodynamic parameters all depend on Stroke Volume (SV) calculation. Figure 4 shows a flow-chart for the algorithm. The inputs are the impedance data as a function of time, the height and weight of the patient (for body surface area calculation), systolic and diastolic blood pressure, and (optionally) the hematocrit (%) reading. From the stroke volume, a whole collection of important hemodynamic parameters can be calculated. Table 1, adapted from *Cardiodynamics*

Corporation [13], summarizes the important hemodynamic variables, their definitions, the formulae used to compute them, and normal physiological ranges.

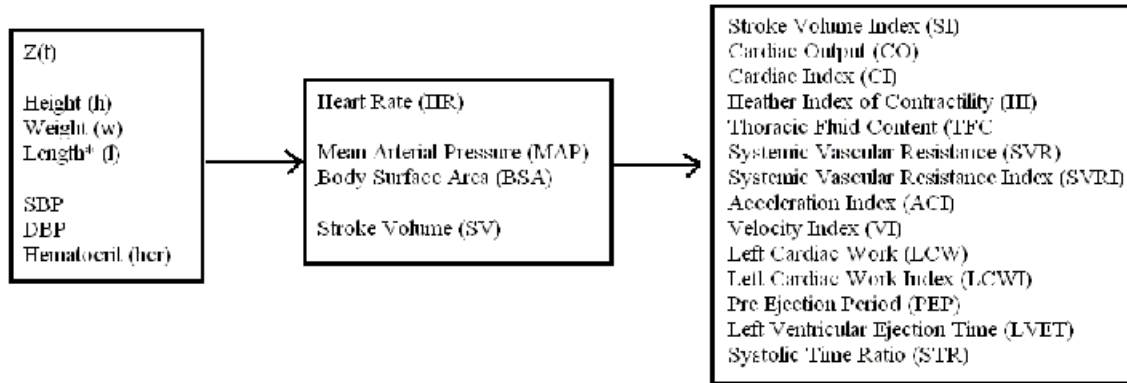


Figure 7. Flowchart of algorithm to compute hemodynamic parameters. *Length is the mean distance between inner recording electrodes.

Stroke Volume (SV) can be computed from the impedance function (Z(t)) using a simple formulae, Equation 1 [3].

$$SV = \rho_b \frac{l^2}{Z^2} \left| \frac{dZ}{dt} \right|_{\min} \cdot t_e \quad (1)$$

- where
- SV = stroke volume [mL]
 - ρ_b = resistivity of the blood [$\Omega \cdot \text{cm}$]
 - l = mean distance between the inner electrodes [cm]
 - Z = mean impedance of the thorax [Ω]
 - $\left| \frac{dZ}{dt} \right|_{\min}$ = absolute value of the maximum deviation of the first derivative signal during systole [Ω/s]
 - t_e = ejection time [s]

The resistivity of blood depends strongly on the hematocrit, Hct (which denotes the percent volume of the red blood cells in whole blood) [3]. This dependence has an exponential nature and is given in Equation 2:

$$\rho_b = 0.537 e^{0.025Hct} \quad (2)$$

The Body Surface Area (BSA) is computed using the Mosteller formula [10,11], given by Equation 3.

$$BSA \text{ (m}^2\text{)} = \left(\frac{[\text{Height(cm)} \times \text{Weight(kg)}]}{3600} \right)^{1/2} \quad (3)$$

Several assumptions must be made in order to simplify the calculation of stroke volume using Equation 1. The first major assumption that underpins the entire model is that the thorax can be modeled as a uniform cylinder with two uniform compartments – blood and tissue (Figure 5, left). The blood and tissue are assumed to form an equivalent electrical network in parallel combination (Figure 5, right). The second major assumption is that any impedance change comes from a change in the volume of blood flow in the thorax, primarily the aorta, which results in a change in Z_o . This means that the tissue impedance, Z_t , does not change during the measurement. This requirement means that the subject does not move or breathe during the measurement, as these may result in a change in Z_t , and thus give invalid readings. This is a very stringent requirement, and is a major limitation in the current mathematical formulation of the problem. Future iterations of this design would include these factors, and would automatically compensate for subject's breathing.

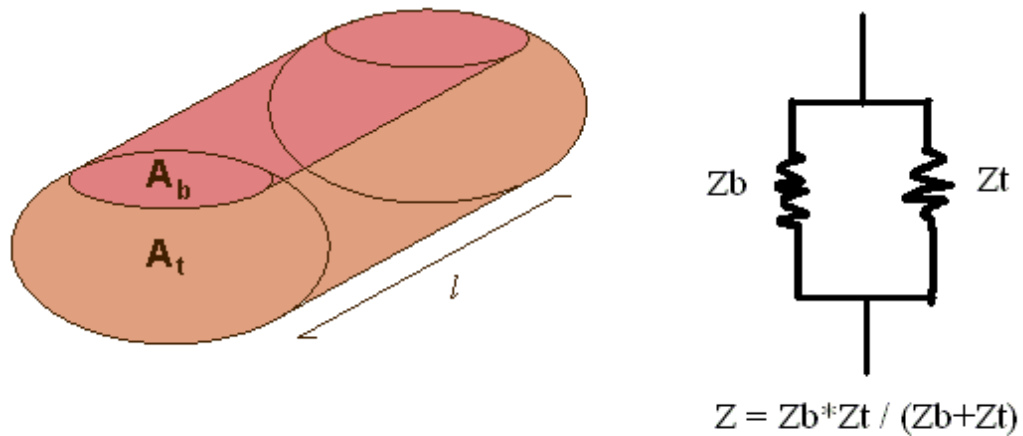


Figure 8. Cylindrical model of thorax (*left*), and the equivalent electrical circuit model (*right*).

The algorithm for calculating the hemodynamic variables was implemented in MATLAB. Appendix 3 is a program listing of the code. This was interfaced to HP-VEE through the built-in MATLAB Scripting control. MATLAB is a powerful mathematical modeling, signal processing, and graphics display tool. The majority of the data processing and analysis was done in MATLAB to simplify software development. Figures 9a and 9b show the HP-VEE user interface implementation. The system prompts for data inputs for the patient data listed in Figure 7, and then calculates hemodynamic parameters from the impedance signal. The physician is presented with the impedance waveform, as well as the hemodynamic parameters. A progress bar is used to display the parameters, and shows a warning red light whenever the parameter is outside the normal range (see Table 1) for immediate physician attention. It is the physician's task to perform further analysis of the patient's condition, diagnose the condition, prescribe medications, or seek further testing. This system is not designed to provide intelligent medical feedback.

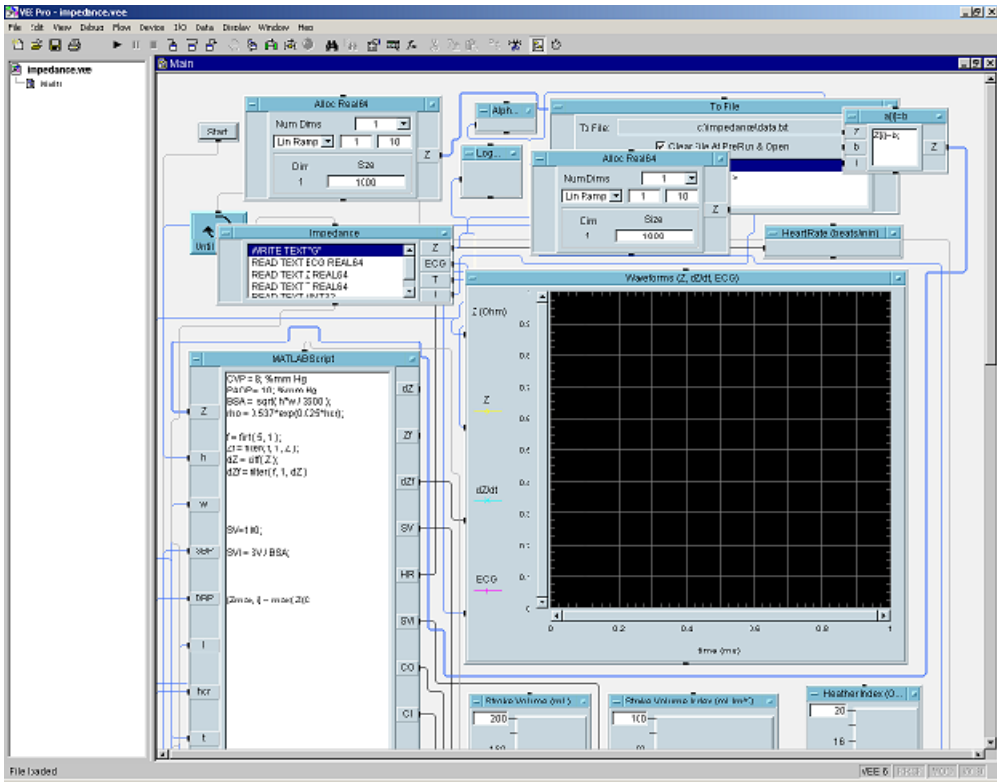


Figure 9a. HP-VEE user interface, top part.

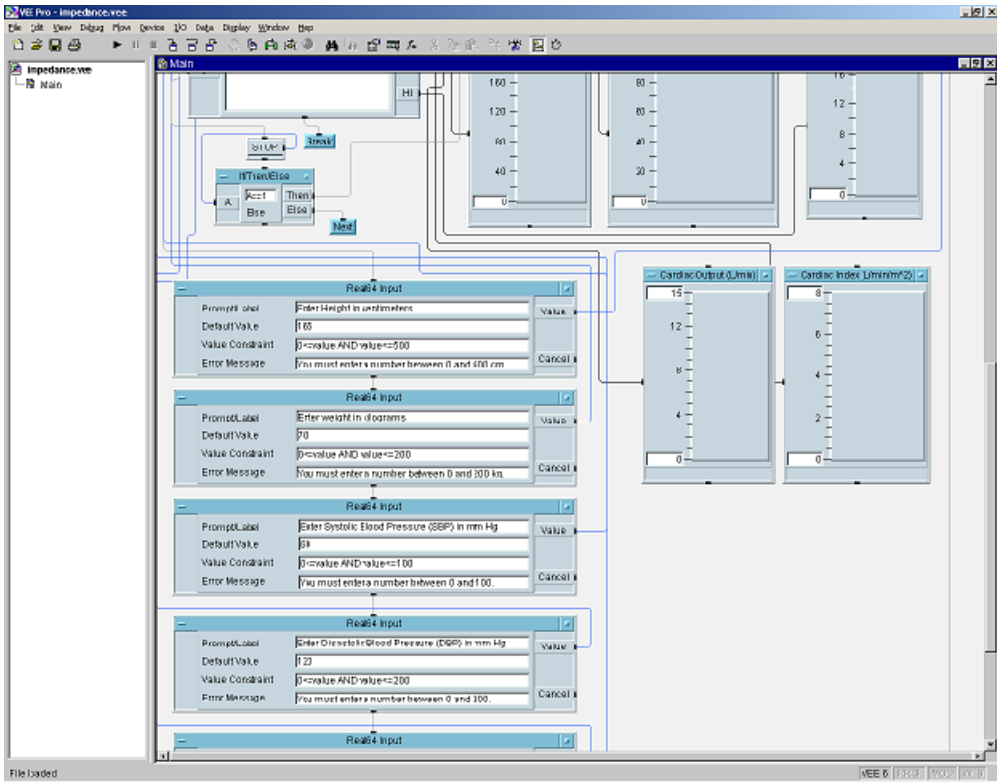


Figure 9b. HP-VEE user interface, bottom part.

Table 1. Hemodynamic parameters, definitions, formulae, and normal ranges.

Parameter	Abbrev.	Definition	Normal Range	Derivation/Formula
Heart Rate	HR	Number of heart beats each minute	58 - 86 bpm (beats per minute)	Measurement of the R-R interval on the ECG and extrapolation to bpm.
Mean Arterial Pressure (SBP & DBP)	MAP	Average pressure exerted by the blood on the arterial walls.	84 - 100 mmHg	<ol style="list-style-type: none"> 1. If SBP and DBP values manually entered, the formula for MAP = $(SBP+2*DBP)/3$ 2. If automatic BP (oscillometric method is used), MAP is measured directly and SBP and DBP are derived.
Cardiac Output	CO	Amount of blood pumped by the left ventricle each minute	4.5 - 8.5 l/min (liters per minute)	$CO = SV \times HR$
Cardiac Index	CI	Cardiac Output normalized for body surface area	2.5 - 4.7 l/min/m ² (liters per minute per meter squared)	$CI = CO / BSA$
Stroke Volume	SV	Amount of blood pumped by the left ventricle each heartbeat	60 - 130 ml (milliliters)	*See text for description of algorithm.
Stroke Index	SI	Stroke volume normalized for body surface area	35 - 65 ml/beat/m ² (milliliters per heart beat per meter squared)	$SI = \frac{SV}{BSA}$
Systemic Vascular Resistance	SVR	The resistance to the flow of blood in the arterial system (often referred to as "Afterload")	742 - 1378 dynes sec / cm ⁵ (dynes second per centimeter to the fifth power)	$SVR = 80 \cdot \frac{(MAP - CVP)}{CO}$
Systemic Vascular Resistance Index	SVRI	The resistance to the flow of blood in the arterial system normalized for body surface area	1337 - 2483 dynes sec m ² / cm ⁵ (dynes second meters squared per centimeter to the fifth power)	$SVRI = 80 \cdot \frac{(MAP - CVP)}{CI}$
Acceleration Index	ACI	Initial acceleration of blood flow in the aorta, which occurs within the first 10 - 20 milliseconds after the opening of the aortic valve	Males: 70 - 150 / 100 sec ² Females: 90 - 170 / 100 sec ² (per 100 seconds squared)	$ACI = \frac{d^2Z/dt^2_{MAX}}{TFI}$

Table 1, Continued. Hemodynamic parameters, definitions, formulae, and normal ranges.

Parameter	Abbrev.	Definition	Normal Range	Derivation/Formula
Velocity Index	VI	Peak velocity of blood flow in the aorta	33 - 65 / 1000 sec (per 1000 seconds)	$VI = \frac{dZ/dt_{MAX}}{TFI}$
Thoracic Fluid Content	TFC	The electrical conductivity of the chest cavity, which is primarily determined by the intravascular, intraalveolar, and interstitial fluids in the thorax	Males: 30 - 50 / kohm Females: 21 - 37 / kohm	$TFC = \frac{1}{TFI}$
Left Cardiac Work	LCW	An indicator of the amount of work the left ventricle must perform to pump blood each minute	5.4 - 10 kg m (kilogram meter)	$LCW = (MAP - PAOP) \cdot CO \cdot 0.0144$
Left Cardiac Work Index	LCWI	LCW normalized for body surface area	3.0 - 5.5 kg m / m ² (kilogram meter per meter squared)	$LCWI = (MAP - PAOP) \cdot CI \cdot 0.0144$
Systolic Time Ratio	STR	The ratio of the electrical and mechanical systole	0.3 - 0.5	$STR = \frac{PEP}{LVET}$
Pre Ejection Period	PEP	The time interval from the beginning of electrical stimulation of the ventricles to the opening of the aortic valve (electrical systole)	0.05-0.12 sec	Time interval from the beginning of the Q wave on the ECG to the B point on the dZ/dt waveform
Left Ventricular Ejection Time	LVET	The time interval from the opening to the closing of the aortic valve (mechanical systole)	0.25-0.35 sec	Time interval from the B point to the X point on the dZ/dt waveform
Heather Index	HI	A measure of contractility; index of left ventricular performance.	6 - 12 ohms ⁻²	Ratio of dZ/dt and the time interval from the R-wave of the ECG to the peak of dZ/dt

TFI Thoracic Fluid Index, which is the baseline thoracic impedance, Z_0
 SBP/DBP Systolic Blood Pressure/Diastolic Blood Pressure
 BSA Body Surface Area
 dZ/dt_{MAX} Maximum of the first time derivative of delta Z
 d^2Z/dt^2_{MAX} Maximum of the second derivative of delta Z
 CVP Central Venous Pressure, the BP in the thoracic vena cava and right atrium (default value of 6 mm Hg)
 PAOP Pulmonary Artery Occlusion Pressure or "wedge" pressure (default value of 10 mm Hg)

Sample Impedance Measurement

The system was deemed safe to connect to a human subject because the frequency range, 20 to 200 kHz, is deemed safe in the literature [1]. The entire system was first tested on a variable POT resistor to make sure the system was working as expected, and that no unnoticed short circuits existed. The system was connected to a human test, Tamara Yu, under free volition and informed consent. An active ground electrode attached to the right leg gave the design extra safety, as it protected the person from developing a high voltage above ground.

A portion of the impedance waveform is shown in Figure 11. This signal is quite noisy, and so it was first low-pass filtered with a 15th-order filter with cut-off frequency of 12 Hz. Figure 12 shows the filtered signal; it is much smoother, and more closely resembles the expected signal from Figure 3. The first-derivative of this filtered signal was computed, shown in Figure 13. Again, this signal was somewhat noisy, as taking derivatives tends to amplify noise. This signal was therefore low-pass filtered once again, with a 15th-order filter with cut-off frequency of 6 Hz. The result, shown in Figure 14, can be compared to the expected signal from Figure 3.

The system needs to be calibrated in order to be able to calculate meaningful hemodynamic parameters from this data. The y-axis on these graphs are just the digital output from the DAC, and do not represent any real voltage. In order to calibrate this system, a fixed resistor with a known impedance would be measured by the system. Further calibration and testing would involve hospital trials, by calculating the correlation coefficient between the impedance-measured cardiac output and the cardiac output measured by some other method, such as thermodilution.

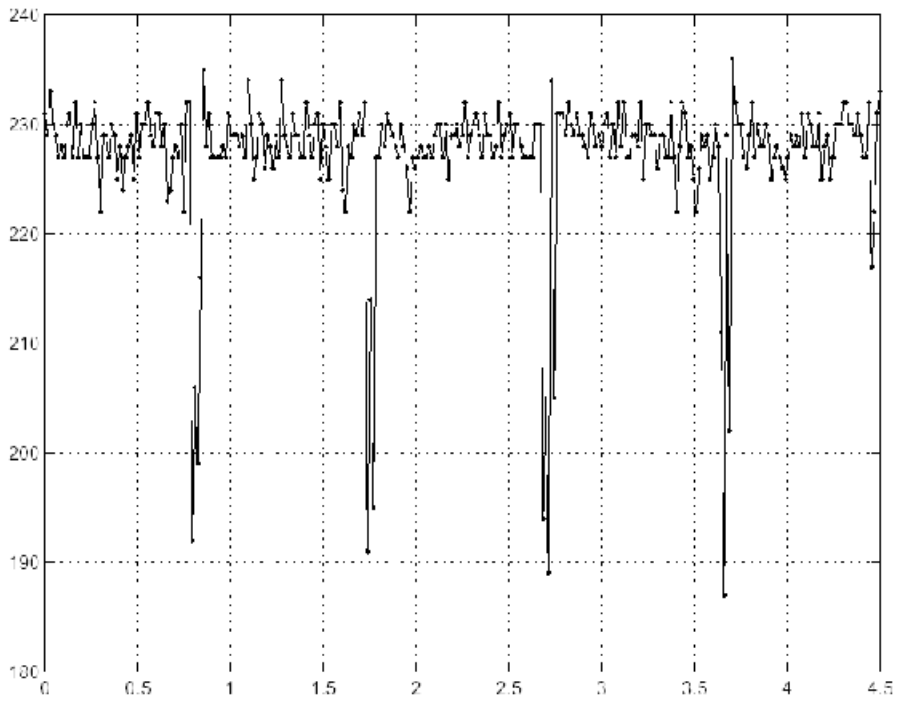


Figure 11. Original signal from ICG hardware.

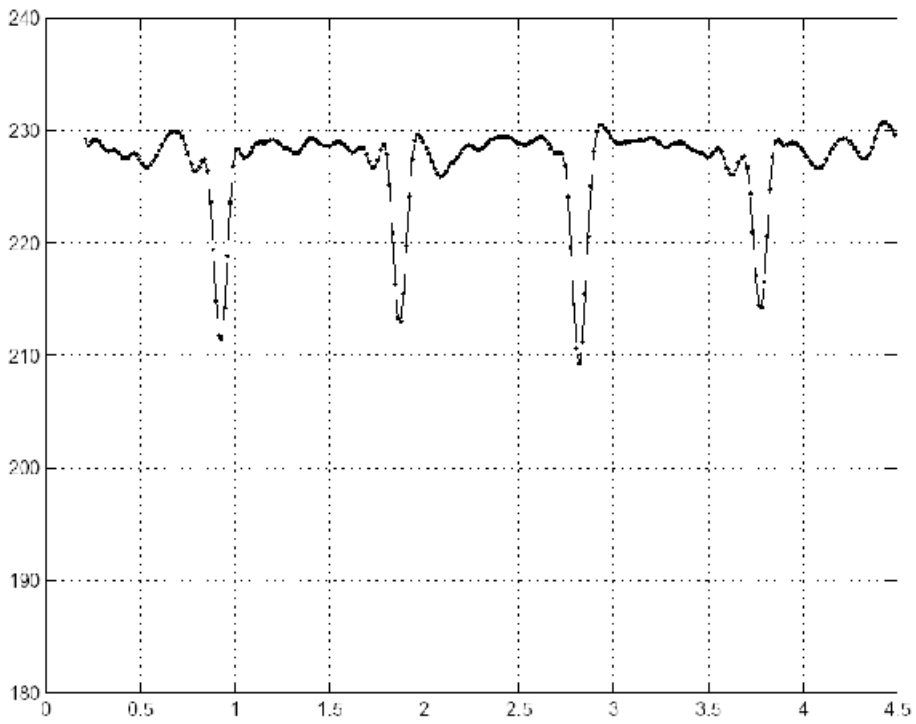


Figure 12. Filtered version of ICG signal from Figure 11.

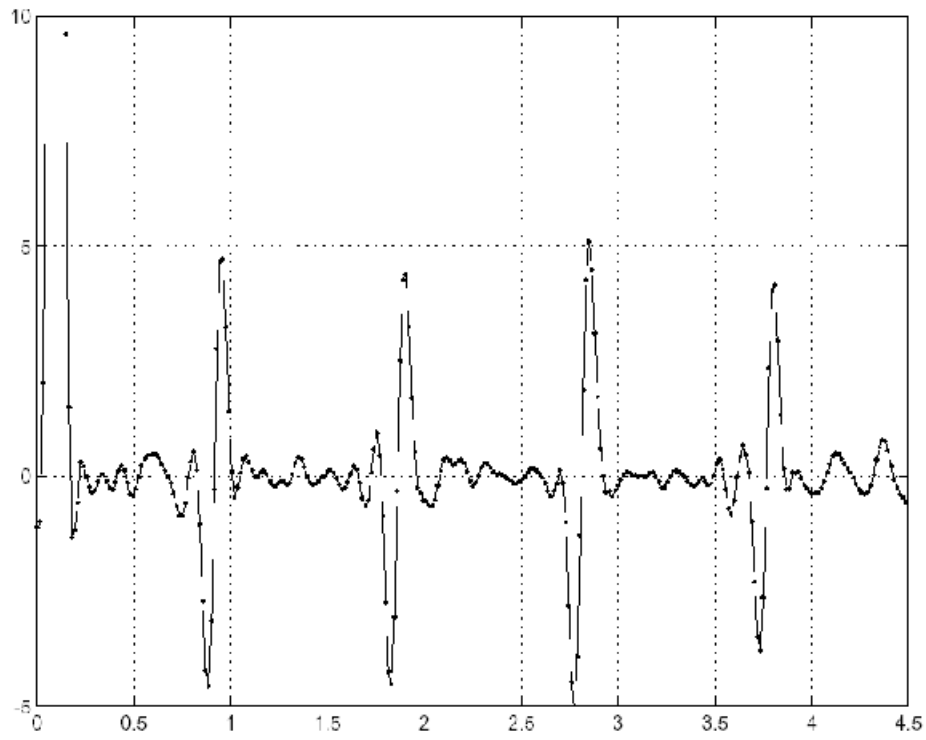


Figure 13. Derivative of filtered signal from Figure 12.

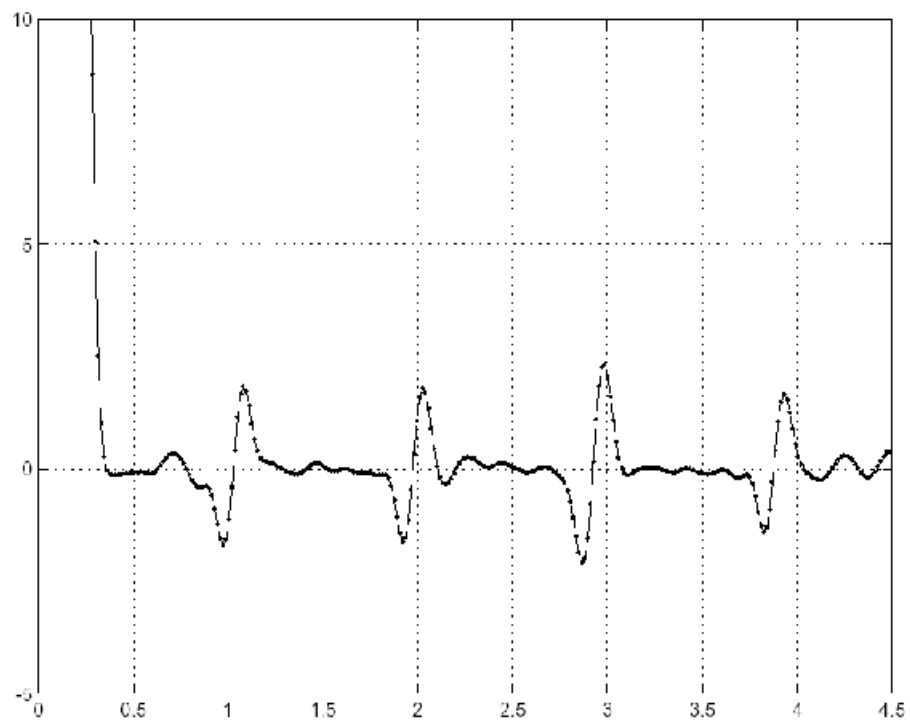


Figure 14. Filtered derivative from Figure 13.

Conclusions

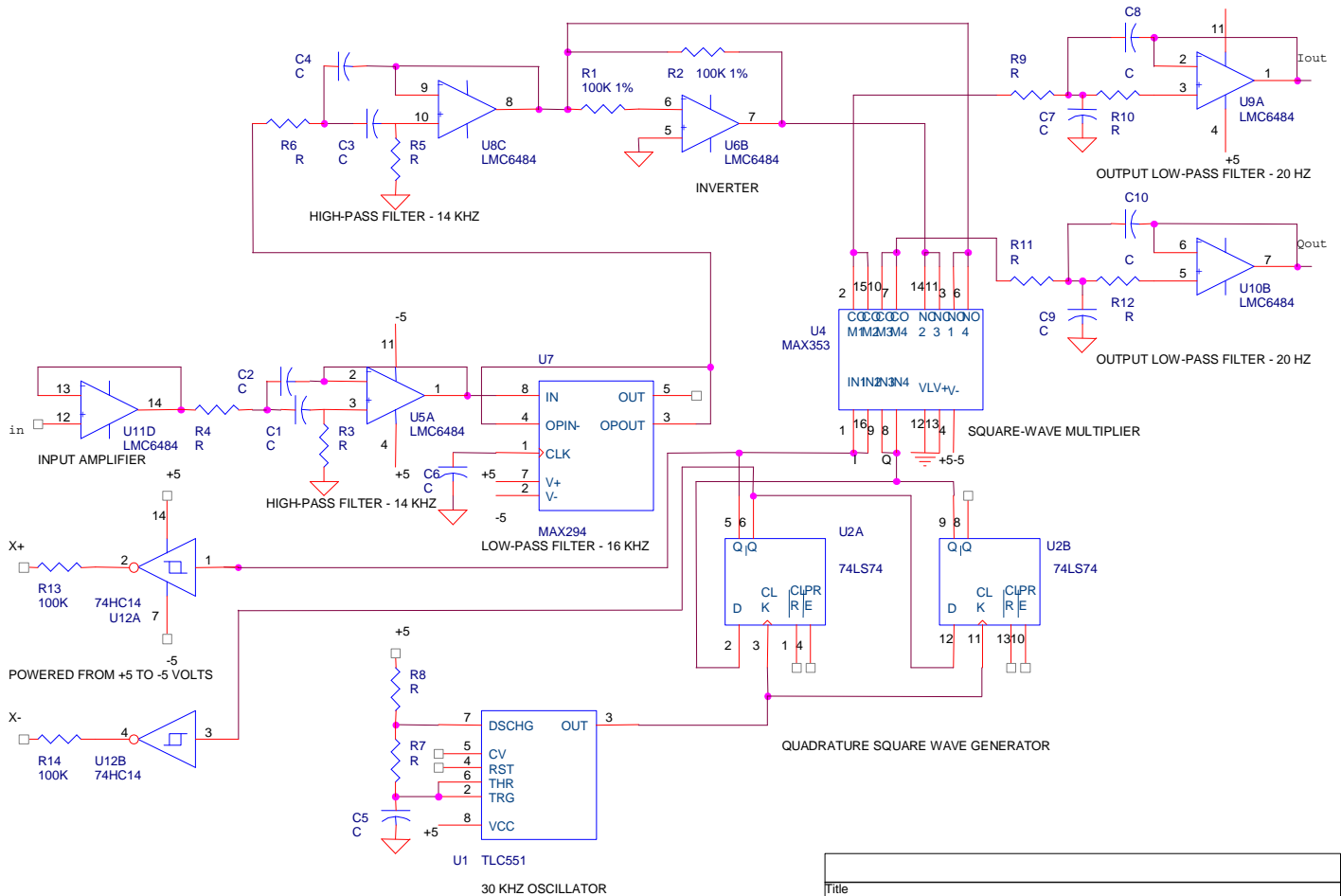
This report documents the design, construction, and testing of an Impedance Cardiogram instrument to measure the impedance changes across the thorax. These impedance changes can be used to derive important hemodynamic variables, such as stroke volume and cardiac output. While first researched by NASA for use on their astronauts on shuttle missions, this technology has evolved to provide important clinical data for earth-bound cardiologists. Only competing business interests in the health-care profession and a lack of education among physician-practitioners keeps this technology away from the patient's bedside. The company that succeeds in educating physicians and properly aligning business interests, will capture a significant market share in a very lucrative market. Only time will tell if this space-age technology will appear on our hospital bedsides when we eventually appear for cardiovascular treatment.

References

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Appendix I.

The system was not designed from scratch; Prof. Burns provided a sample circuit. This circuit measures the real and imaginary parts of a complex signal. It generates a 15 khz square wave (X+ and X-) which are used to excite the system. A differential amplifier provides an input. The input is high-pass filtered, low-pass filtered and then high-pass filtered to provide a 15 khz band-pass signal. The band-pass signal is inverted to provide both an inverted and non-inverted signal. This is multiplied by in-phase (I) and quadrature (Q) square waves and low-pass filtered to provide in-phase and



quadrature components.

Title		
COMPLEX SYNCHRONOUS DETECTOR		
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% Impedance
% This routine calculates several hemodynamic variables from impedance
% measured across the thorax.

function out = impedance( Z, t, SBP, DBP, height, weight, length, hct )
% INPUT:  Z - impedance measured across thorax (Ohm)
%         t - time points at which impedance is measured (s)
%         SBP - systolic blood pressure (mm Hg)
%         DBP - diastolic blood pressure (mm Hg)
%         height - patient's height (cm)
%         weight - patient's weight (kg)
%         length - mean distance between inner recording electrodes (cm)
%         hct - Hematocrit reading (%) used to compute blood resistivity
%              (default value of 44% assumed if none input)

% OUTPUT:
%         out(1) = HR, Heart Rate (beats/min)
%         out(2) = MAP, Mean Arterial Pressure (mm Hg)
%         out(3) = TFI, Thoracic Fluid Index (Ohm)
%         out(4) = BSA, Body Surface Area (m^2)

%         out(5) = SV, Stroke Volume (mL)
%         out(6) = SI, Stroke Volume Index (mL/m^2)

%         out(7) = CO, Cardiac Output (L/min)
%         out(8) = CI, Cardiac Index (L/min/m^2)

%         out(9) = HI, Heather Index of Contractility (Ohms^-2)
%         out(10) = TFC, Thoracic Fluid Content (1/kOhm)

%         out(11) = SVR, Systemic Vascular Resistance (dynes*sec/cm^5)
%         out(12) = SVRI, Systemic Vascular Resistance Index (dynes*sec*m^2/cm^5)

%         out(13) = ACI, Acceleration Index (per 100 sec^2)
%         out(14) = VI, Velocity Index (per 1000 sec)

%         out(15) = LCW, Left Cardiac Work (kg*m)
%         out(16) = LCWI, Left Cardiac Work Index (kg*m/m^2)

%         out(17) = PEP, Pre Ejection Period (sec)
%         out(18) = LVET, Left Ventricular Ejection Time (sec)
%         out(19) = STR, Systolic Time Ratio

%         out(20) = VR, Vascular Rigidity
%         out(21) = LZ, Length to Z0 Ratio

% ASSUMPTIONS:
%         CVP, Central Venous Pressure, the blood pressure in the thoracic vena cava and
right atrium is constant
CVP = 8; %mm Hg
%         PAOP, Pulmonary Artery Occlusion Pressure (or "wedge" pressure), is constant
PAOP = 10; %mm Hg

%         out(1) = HR, Heart Rate (beats/min)
f = fir1( 15, 0.001 ); % Low pass filter with cut-off frequency of 1
Zf = filter( f, 1, Z ); % Filter Z
dZ = diff( Zf ); % Differentiate Z
dZf = filter( f, 1, dZ ); % Filter derivative

t1 = find( t>1.3 );
t1 = t1(1);
[Zmax1, i1] = max( Zf(1:t1) );

t2 = find( t>1.6 );
t2 = t2(1);
[Zmax2, i2] = max( Zf(t1:t2) );

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Zmax = (Zmax1+Zmax2)/2;
P = t(t1+i2) - t(i1);
HR = 1/P*60;

% out(2) = MAP, Mean Arterial Pressure (mm Hg)
MAP = (SBP + 2*DBP)/3;

% out(3) = TFI, Thoracic Fluid Index (Ohm)
% Z0, Base (Mean) Impedance (Ohm)
Z0 = mean(Z);
TFI = Z0;

% out(4) = BSA, Body Surface Area (m^2)
BSA = sqrt( height*weight / 3600 );

% out(5) = SV, Stroke Volume (mL)
%Resistivity of blood (Ohm*cm)
rho = 0.537*exp(0.025*hcr);

SV = rho * length^2 / Z0^2 * (Zmax-Z0);

% out(6) = SI, Stroke Volume Index (mL/m^2)
SI = SV / BSA;

% out(7) = CO, Cardiac Output (L/min)
CO = SV * HR;
% out(8) = CI, Cardiac Index (L/min/m^2)
CI = CO / BSA;

% out(9) = HI, Heather Index of Contractility (Ohms^-2)

% out(10) = TFC, Thoracic Fluid Content (1/kOhm)
TFC = 1/( Z0/1000 );

% out(11) = SVR, Systemic Vascular Resistance (dynes*sec/cm^5)
SVR = 80*( MAP-CVP ) / CO;

% out(12) = SVRI, Systemic Vascular Resistance Index (dynes*sec*m^2/cm^5)
SVRI = 80*( MAP-CVP ) / CI;

% out(13) = ACI, Acceleration Index (per 100 sec^2)
ddZ = diff( dzf );
ddZmax = max( ddZ );
ACI = ddZmax / Z0;
% out(14) = VI, Velocity Index (per 1000 sec)
VI = dzmax / Z0;

% out(15) = LCW, Left Cardiac Work (kg*m)
LCW = 0.0144*(MAP-PAOP)*CO;
% out(16) = LCWI, Left Cardiac Work Index (kg*m/m^2)
LCWI = 0.0144*(MAP-PAOP)*CI;

% out(17) = PEP, Pre Ejection Period (sec)

% out(18) = LVET, Left Ventricular Ejection Time (sec)

% out(19) = STR, Systolic Time Ratio
STR = PEP / LVET;

% out(20) = VR, Vascular Rigidity

% out(21) = LZ, Length to Z0 Ratio

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