

# Thoracic Electrical Bioimpedance Measurement of Cardiac Output is Highly Reproducible in Heart Failure Patients

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## Introduction

The majority of care for heart failure is provided in ambulatory care settings. One of the greatest challenges to clinicians in these settings is to detect evidence of deterioration, disease progression and/or treatment efficacy in a timely and cost effective manner.

Data for assessment need to be:

- Objective and readily available
- Easy to obtain over time
- Sensitive to clinically significant events

Therefore, an important goal is to develop tools to obtain valid and reproducible data that are suitable for long term follow-up of patients in the outpatient setting. The BioZ® Thoracic Electrical Bioimpedance (TEB) device provides measurements of 12 hemodynamic parameters, including Stroke Volume, Cardiac Output, Systemic Vascular Resistance, Indices of Contractility, and Thoracic Fluid Status - important cardiac hemodynamic parameters for objective determination of changes in the status of heart failure patients.

## Purpose

- Establish the reproducibility of TEB hemodynamic measures obtained with the BioZ® on patients with clinically stable heart failure.
- Begin to establish "norms" for hemodynamic variability in a clinically-stable heart failure population when measurements are taken under the same or similar conditions within the same day and over a one-week interval.

## Clinical Stability

### Definition:

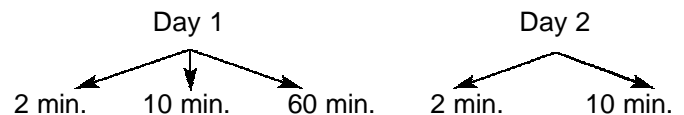
- Absence of clinically-significant changes in self-reported symptoms
- Absence of clinically-significant changes in physical signs of heart failure
- No changes in prescribed medical therapy

## Methods

**DESIGN:** Prospective evaluation of cardiac function with repeated measures over a 1 week interval.

**SAMPLE:** 58 heart failure patients followed in a university heart failure clinic.

**MEASUREMENTS:** BioZ® TEB measurements taken at rest:



### PARAMETERS:

- Heart Rate\*
- Diastolic, Systolic & Mean Arterial Pressure\*
- Thoracic Fluid Content
- Stroke Volume/Index\*
- Cardiac Output/Index\*
- Systemic Vascular Resistance/Index\*
- Acceleration Index
- Index of Contractility (Velocity Index)
- Systolic Time Ratio

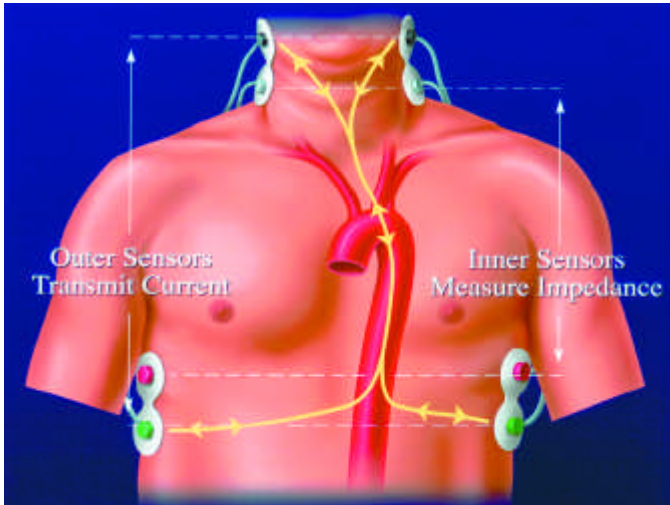
\* Included in this analysis

## Results

Table 1: Patient Characteristics

CHARACTERISTIC	GENDER	
	MALE (N = 38)	FEMALE (N=20)
AGE		
Range	33 - 78	25 - 86
Mean	58.55	57.75
EJECTION FRACTION		
Range	12 - 56	16 - 48
Mean	24.77	34.37
BODY SURFACE AREA		
Range	1.58-2.53	1.29-2.23
Mean	2.031	1.729
SD	±.188	±.220
P <0.001		
NYHA CLASS		
I	1	0
II	15	12
III	22	8
ETIOLOGY OF HF		
P <0.05		
Ischemic	18	3
Non-ischemic	20	17
MEDICATION THERAPY		
Digitalis, Diuretic, ACE Inhibitor	20	8
Digitalis, Diuretic, ACE Inhibitor & Beta Blocker	12	6
Other combinations	6	6

**Figure 1:**  
Thoracic Electrical Bioimpedance



- An alternating current is transmitted through the chest
- The current seeks the path of least resistance: the blood filled aorta
- The BioZ Systems measure the baseline impedance to this current
- With each heartbeat, blood volume and velocity in the aorta change
- The BioZ Systems measure the corresponding change in impedance
- The BioZ Systems use the baseline and changes in impedance to measure and calculate hemodynamic parameters

**Table 2:**  
Changes Between 2 Minutes & 60 Minutes At Week 1

	HR (bpm)	MAP (mm Hg)	CI (l/min/m <sup>2</sup> )	SI (cc/m <sup>2</sup> )	SVR (d/s/cm <sup>5</sup> )
2 Minutes	78.879	85.586	2.876	37.741	958.533
60 Minutes	76.172	86.276	2.705	36.741	1019.173
Difference	-2.707**	0.690	-0.171**	-1.000*	60.640*
95% Confidence Interval	-1.183 to -4.231	-1.873 to 0.494	-0.091 to -0.251	-1.985 to -0.015	103.524 to 17.756

\*p<0.05, \*\*p<0.001 Paired samples t-test

Abbreviations: HR = Heart Rate, MAP = Mean Arterial Pressure, CI = Cardiac Index, SI = Stroke Index, SVR = Systemic Vascular Resistance

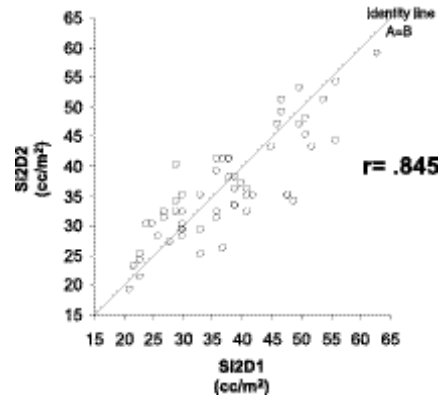
**Table 3:**  
Changes Between weeks 1 & 2 at 2 Minutes

	HR (bpm)	MAP (mm Hg)	CI (l/min/m <sup>2</sup> )	SI (cc/m <sup>2</sup> )	SVR (d/s/cm <sup>5</sup> )
Week 1	79.105	85.649	2.872	37.561	1217.449
Week 2	78.088	85.421	2.726	35.982	1258.388
Difference	-1.018	-0.228	-0.146**	-1.579*	40.940
95% Confidence Interval	0.925 to -2.960	-1.747 to 2.203	0.052 to -0.239	-0.130 to -3.038	97.079 to -15.200

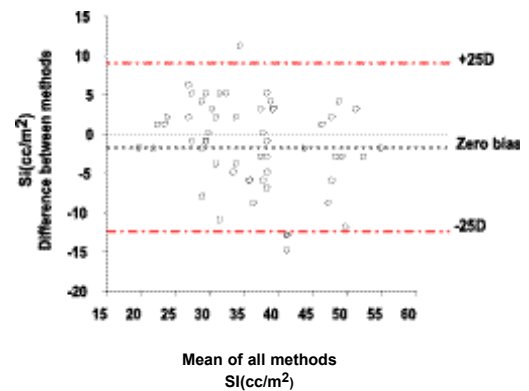
\*p<0.05, \*\*p=0.003 Paired samples t-test

Abbreviations: HR = Heart Rate, MAP = Mean Arterial Pressure, CI = Cardiac Index, SI = Stroke Index, SVR = Systemic Vascular Resistance

**Figure 2:**  
Scatterplot For Day 1 vs. Day 2 For Stroke Index



**Figure 3:**  
Bland Altman Confidence Interval Plot For Day 1 vs. Day 2



## Summary

- BioZ® measurements of cardiac performance are highly reproducible in heart failure patients followed in an outpatient setting.
- The reported confidence intervals provide useful guidelines for detecting clinically relevant changes over time.
- The changes in BioZ® measured CI over a 60 minute period are due largely to changes in HR.
- Measurement of SI is less variable than measurement of CI.
- BioZ® CI measurement variability can be reduced by evaluating patients at similar times after arrival in the clinic/office setting.

## Conclusions

BioZ® measurements of cardiac performance can be obtained rapidly and inexpensively in an outpatient setting. The results are highly reproducible. These findings suggest that BioZ® measurements are a sensitive way to detect changes in cardiac performance during follow-up of outpatients with heart failure and that they should help detect the effects of drugs or deterioration in cardiac function over time.