# Monitoring Outpatient Blood VolumE in Heart Failure (MOVE-HF)

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## INTRODUCTION

Over 6 million Americans suffer from heart failure (HF). High rates of rehospitalization and mortality and high treatment costs have persisted for decades despite advances in care. Clinical guidelines recommend assessment of blood volume and clinical management to euvolemia, but standard methods of diagnosing volume status are unreliable. FDA-cleared Blood Volume Analysis (BVA) [Daxor BVA-100™] is based on the gold standard indicator dilution technique. BVA quantifies otherwise undiagnosed volume derangements. Retrospective analyses have demonstrated that BVA-guided HF care reduces rehospitalization and mortality.[1]

## KEY ELIGIBILITY CRITERIA

**Inclusion:**

1. Age > 18 years.
2. Hospitalized male and female patients with primary or secondary admission diagnosis of acute HF exacerbation, inclusive of all ejection fraction.
3. Able and willing to provide informed written consent.

**Exclusion:**

1. Diagnosed with current acute strokes.
2. Pregnant women.
3. Severe hypotension requiring resuscitation, intubation or circulatory support.
4. Cardiogenic shock.
5. Patients with known cardiac amyloid and hypotension.
6. Known allergy to iodine or iodinated albumin.

## OBJECTIVES

This is the first prospective study of directly quantified volume change over a multi-month period immediately following hospital discharge, a clinical phase that is understood to be challenging due to high variability of patient status, physiology, and compliance. The primary objective is to quantify changes to Total Blood Volume (TBV), plasma volume (PV) and red blood cell volume (RBCV) over a 12-week period post-discharge for inpatient HF care.

## PROTOCOL

Hospitalized acute HF patients will be administered BVA tests prior to discharge, at first outpatient follow-up (7-10 days post-discharge), and after weeks 4, 8 and 12 post-discharge. BVA tests will be compared and analyzed over time to determine if, and quantify how much, subject TBV, PV, and RBCV change over time.

## PROCEDURES

| | Day 0 | Day 7-10 | Week 4 | Week 8 | Week 12 |
|---|---|---|---|---|---|
| **Informed Consent** | X | | | | |
| **Demographics** | X | | | | |
| **Medical History** | X | X | X | X | X |
| **Vital Signs** | X | X | X | X | X |
| **NYHA** | X | X | X | X | X |
| **BVA testing** | X | X | X | X | X |
| **Medications** | X | X | X | X | X |
| **Laboratory Values[1]** | X | X | X | X | X |
| **Imaging tests[2]** | X | X | X | X | X |

[1]NT-ProBNP, BMP, CBC, Galectin-3, ST2, Ferritin, Erythropoietin
[2]Echocardiogram, Electrocardiogram, Chest X-ray

## OUTCOME MEASURES

Primary: Quantify PV and RBCV changes over a 12-week period following discharge for acute HF care.

## STATISTICAL POWER

The sample size of fifteen patients is supported by a paired t-test power calculation, which gives an effect size of 0.90 with a significance level of .05 and a power of .90. The effect size corresponds to observing a minimum difference of means between discharge and post-discharge measurements of less than 2.25%, based on an observed standard deviation of 2.5% for BV measurements. This difference is significantly less than the observed difference of 4.5±3.9 in peripheral Hct during treatment of Hypervolemic patients, which translates to a change from baseline Hct of approximately 10%.

## STUDY INFORMATION

**Source of Support:** Daxor as a sub awardee to Center for Advancing Point of Care Technologies (CAPCaT) per NIH 5U54HL143541-03.

**Trial design:** Prospective, single-center, observational open-label study.

**Leadership:** Brendan Carry (Clinical & Site PI) & Jonathan Feldschuh (PI).

**Participating centers:** Geisinger Medical Center.

**Estimated study duration:** August 1, 2021 – October 30, 2022.

**Contact information:** For information about research opportunities with Daxor, contact Soren Thompson, Vice President, sthompson@daxor.com.

## REFERENCES

1. J. E. Strobeck, J. Feldschuh, and W. L. Miller, “Heart Failure Outcomes With Volume-Guided Management,” *JACC Hear. Fail.*, vol. 6, no. 11, pp. 940–948, 2018, doi: 10.1016/j.jchf.2018.06.017.