

Relieve Cardiovascular, Inc.

Computer-aided Monitoring of Urine Output with Diuretic and Saline Administration

Clinical Presentation

Relieve Therapy For Treatment of Acute Decompensated Heart Failure (ADHF)

CAUTION – Investigational Device. Limited by United States Law to Investigational Use Only.

The Clinical & Economic Burden of ADHF

Hospitalization Outcomes & Readmission Challenges

6.8M

Americans
affected by HF

1M+

Annual HF
hospital discharges

>50%

Die within 5 yrs
of HF diagnosis

80% of HF hospitalizations and **90%** of HF deaths
occur in patients aged 65+

Hospitalization Burden

- HF is the #1 cause of hospital admission in patients over 65
- ~80% of HF hospitalizations admitted from the ED
- Prevalence expected to rise to 8.5M by 2030
- More than 90% of patients have reduced renal function (GFR < 90) at admission

Readmission & Discharge

- ~50% of 30-day readmissions occur within first 2 weeks
- >50% of patients have congestion at discharge
- Up to 20% of patients fail to lose any weight during hospitalization
- Lower rehospitalization & mortality when congestion-free at discharge

Key Insight: Premature discharge, inefficient transition to oral diuretics, and lack of comprehensive post-discharge care plans all contribute to 30-day readmission and mortality. Sodium excretion is strongly associated with 6-month mortality, whereas traditional fluid-based metrics are not.

Diuretic Resistance & Treatment Challenges

Current Standard of Care in Diuretic Management

20-50%

Poor diuretic
response rate

>90%

ADHF patients
given diuretics

~24hr

Typical dosing
re-evaluation cycle

Loop diuretics remain the **cornerstone** of decongestive therapy. Multiple randomized control trials (RCTs) have failed to show clinical improvement over loop diuretics.

The ADHF Paradox

- Patients may have excess total body fluid yet be intravascularly dehydrated
- Extra fluid resides in cells and “third space” — diuretics deplete the already low intravascular volume
- Kidneys attempt to retain lost fluid, leading to diuretic resistance and urine output can drop to zero
- Unchecked fluid retention can cause pulmonary edema — a life-threatening complication

Treatment Limitations

- “Usual care” decongestion is slow, inefficient, and often results in persistent congestion at discharge
- Diuretic dosing is unique to each patient’s cardio-renal physiology; too low fails to decongest, too high risks excess exposure
- Aggressive strategies improve diuresis but may increase electrolyte abnormalities and/or worsening kidney function
- Poor diuretic response is associated with higher risk of rehospitalization and death

Critical Gap: Sodium retention drives volume overload, yet standard monitoring (urine output, body weight) tracks fluid rather than sodium balance. Current tools to diagnose diuretic resistance rapidly and reliably are limited in fidelity. Poor sodium excretion — even with fluid loss — portends worse 6-month mortality.

Technology Overview & FDA Status

Reprise Intelligent Decongestion Management

Designed to personalize decongestion management



- 1 • **Find the right dose, fast** : Real-time, continuous urine output informs the dose finding algorithm to **personalize and optimize the diuretic dose in first hour.**
- 2 • **Maintain the right dosing** : Real-time monitoring **automatically recommends when to escalate/end therapy** to limit inefficient time on diuretics.
- 3 • **Keep the kidney happy (and diuretic resistance under control)** : When needed, saline replacement is continuously titrated to maximize urine output and maintain renal function. Both urine sodium and urine output used to inform algorithm. **Enabling faster, safer, more complete fluid loss.**

FDA Status - Breakthrough Device and Investigational Device Exemption (G210258 – US FDA)

The Reprieve Console Components



Procedure Summary

Max therapy: 72 hours

Phase	Step	Action
Phase 1 — SETUP	1	Power on system and enter physician-estimated excess fluid remaining
	2	Load Saline Infusion Set, Diuretic Infusion Set (with anti-siphon valve), and Urine Collection Set
	3	Load 50 mL BD Plastipak syringe (10 mg/mL furosemide) and connect Y-site
	4	Run Auto Prime & Self-Test sequence (~4.5 min); verify no air in lines before connecting patient
Phase 2 — CONNECT PATIENT	1	Ensure patient has peripheral IV access (≥20 gauge) and urinary Foley catheter in place
	2	Remove priming adapter; connect Y-site to patient IV and urine collection set to Foley catheter
	3	Drain priming fluid; confirm all final checklist items; press Start Therapy to begin
Phase 3 — THERAPY	1	Dose Finding Phase (~60 min): system ramps furosemide exponentially to find optimal dose targeting urine rate ≥525 mL/h
	2	Continuous Infusion Phase: system delivers personalized diuretic dose; saline infused per urine output and lab-measured urine sodium
	3	Each time urine bag is drained: collect urine sample for sodium analysis; enter lab result into touchscreen
	4	Replace saline bag at 'Saline Bag Empty' alarm; replace diuretic syringe when empty or when system notifies <2hr diuretic remaining
Phase 4 — COMPLETION	1	System alerts when stopping criteria met; urine output low, near-maximum diuretic dose, most excess fluid removed
	2	Therapy ends when urine output is low at maximum diuretic infusion rate and majority of excess fluid removed
	3	Press Pause System → End Case → power down; disconnect and remove Y-site and Foley per standard procedure
	4	Discard all single-use sets (Saline, Diuretic, Urine Collection) as biohazard per facility protocol

Medical Record

Documentation of the use of Reprise Therapy will be included in the progress notes in the medical record:

- Reprise System
- Reprise Therapy
- Reprise Fluid Management System
- Fluid Management System