



Extracorporeal Interstitial Fluid Removal

Non-invasive, Kidney Independent

ICD-10 Coordination and Maintenance
Committee Update
Fall 2026



The AQUAPASS System Provides Controlled, Non-invasive, High-volume Fluid Removal Through The Skin

Wearable Garment

Activates the eccrine glands
Integrated patient monitoring sensors



Console

Heat & Air sources
Enables controlled fluid removal
Flow Sensors and Safety controllers



Granted 2 FDA Breakthrough Designations

Chronic Heart failure; Chronic Kidney Disease



December 9, 2022

AquaPass Medical
Gali Vino
Regulatory and Clinical Affairs
P.O. Box 35
Kibbutz Shefayim, 6099000
Israel

Re: Q220327/S001
Trade/Device Name: AquaPass System
Received: October 11, 2022

Heart Failure or CKD Intended Use: *Reducing fluid overload in patient with Chronic Heart Failure or with CKD stages 2-3*

and have been granted designation as a Breakthrough Device. Please refer to the FDA guidance document entitled "Breakthrough Devices Program", for more information regarding the program, available at <https://www.fda.gov/media/108135/download>.

End stage kidney disease



February 7, 2024

AquaPass Medical
Marybeth Gamber
Consultant
P.O. Box 35
Kibbutz Shefayim, 6099000
Israel

Re: Q240141
Trade/Device Name: AquaPass System
Received: January 19, 2024

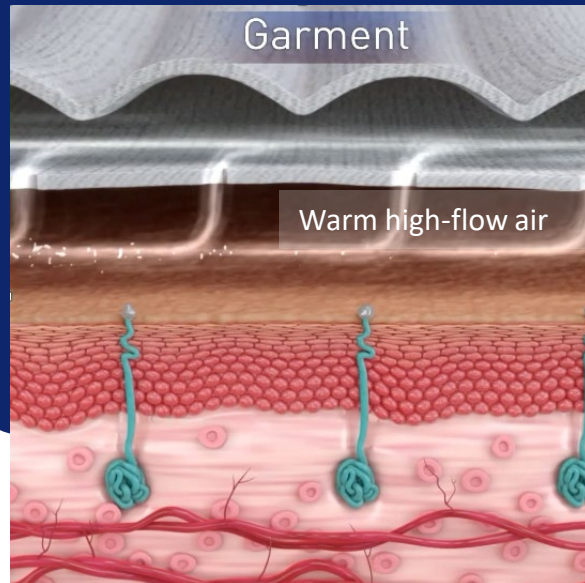
ESKD Intended Use: *remove fluids in end stage renal disease patients*

information regarding the program, available at <https://www.fda.gov/media/108135/download>.

AQUAPASS System Enables Skin-Based Decongestion

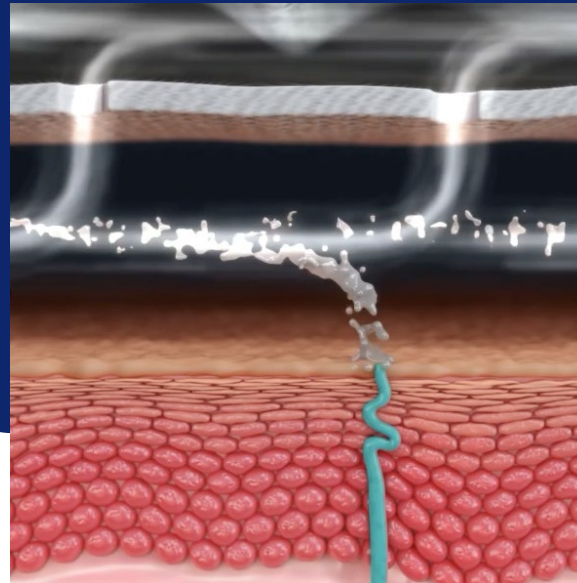
Eccrine Gland Activation

The System creates a controlled warm environment around the patient's skin



Fluid Removal

Sweat is evaporated continuously, keeping the patient **dry and comfortable**



Decongestion

1 - 2 L removed per treatment with meaningful net fluid loss & decongestion



Fluid Overload Drives Patient Outcomes

HEART FAILURE

6.2M Patients with Stage C/D heart failure

1.2M Admissions annually

80% Admissions are due to fluid overload

**Worsens heart failure symptoms,
pulmonary congestion,
increases mortality**

END STAGE KIDNEY DISEASE

515K Patients receiving maintenance dialysis

1.1M Admissions annually (>2 per patient)

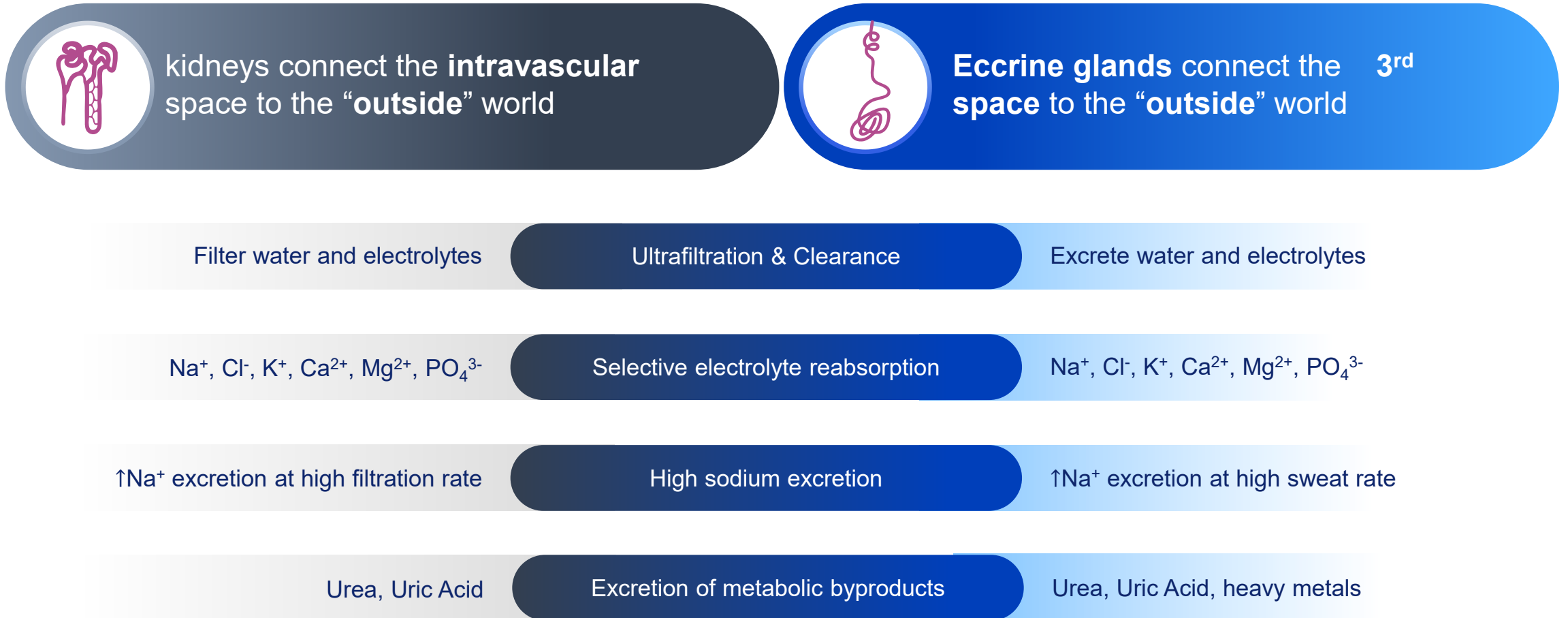
30% Of patients struggle with fluid balance

**Worsens hypertension, pulmonary congestion
higher rates of dialysis complications,
increases mortality**

- 2024 heart disease and stroke statistics: Circulation. 2024;149:e347–913
- Heidenreich PA, Bozkurt B, Aguilar D, et al. Circulation. 2022;145(18):e895–e1032
- American Kidney Fund. Quick kidney disease facts and stats. February 11, 2025
- Flythe JE, Watnick S. JAMA. 2024;332(18):1559–1573
- Weinhandl ED, Ray D, Kubisiak KM, Collins AJ. American Journal of Nephrology. 2019;50(1):63–71

The Skin Can Act As A “Third Kidney”

Analogous Morphologies. Comparable Functionalities



How To Use The Skin As A “Third Kidney”

Our skin has 2-4 million eccrine glands that release interstitial fluid containing water, electrolytes, toxins, heavy metals, and urea.

Activation of Perspiration

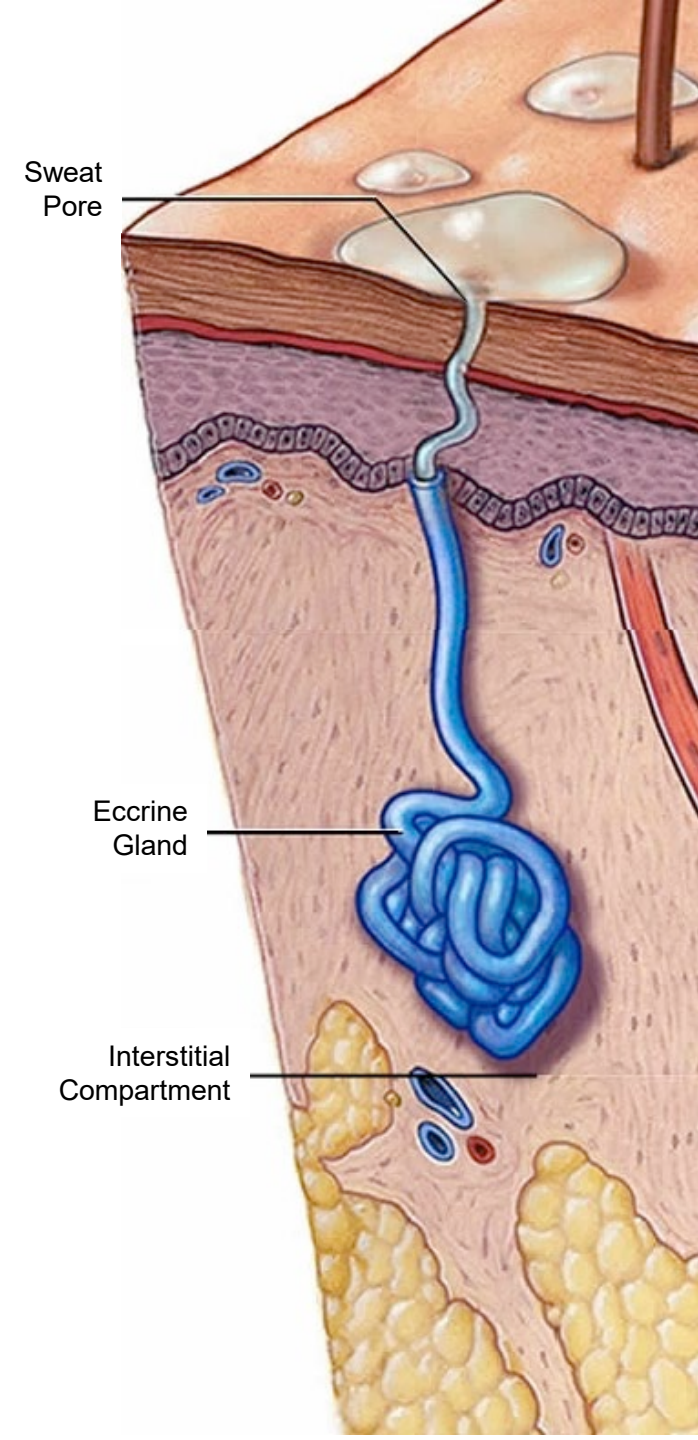
Warming the skin activates the eccrine glands, alleviating fluid overload at clinically meaningful rates

A Renal-Independent Solution

First technology to remove fluid without relying upon or negatively affecting renal function

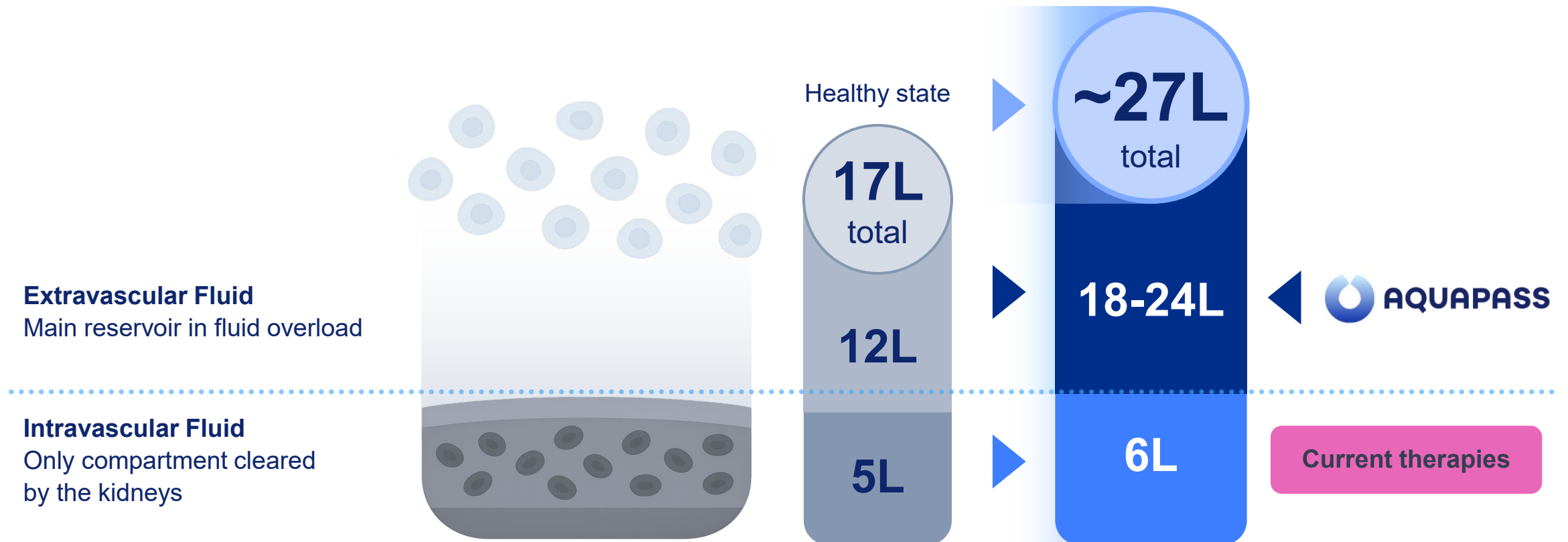
Staying Cool and Comfortable

Evaporation of fluid during treatment cools the skin, keeping the body temperature normal and the patient dry and comfortable

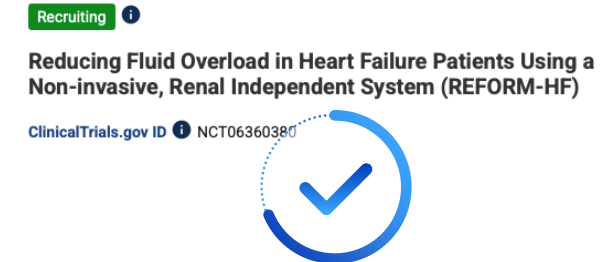
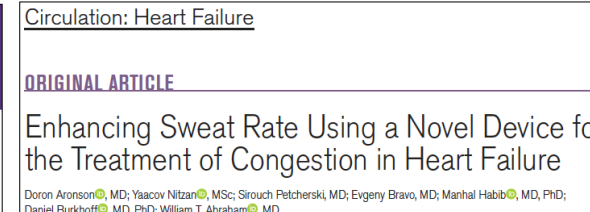
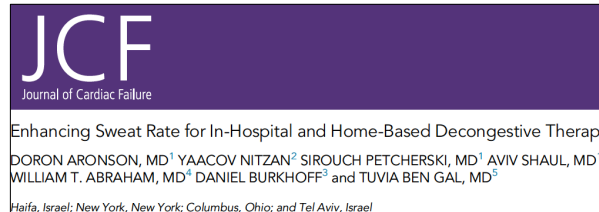
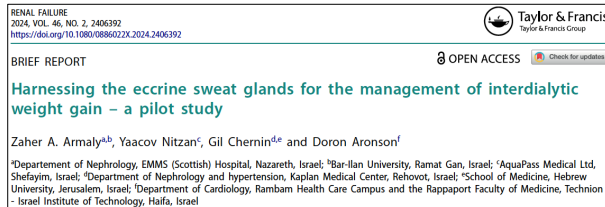


AQUAPASS Is The Only Technology Removing Fluid **Directly** From The **Interstitial / Extravascular Space**

Fluid overload



Substantial Experience In Chronic Heart Failure & End Stage Kidney Disease



Completed

First-in-human
ESKD patients

5 patients /
40 procedures

Single center (Israel)



Completed

First-in-human
Heart failure patients

18 patients /
54 procedures

Single center (Israel)



Completed

Acute to Chronic study
ADHF patients

15 patients /
219 procedures

2 centers (Israel)

ADHF: Acutely Decompensated
Heart Failure

Currently Enrolling

US Market Clearance study
Heart Failure patients

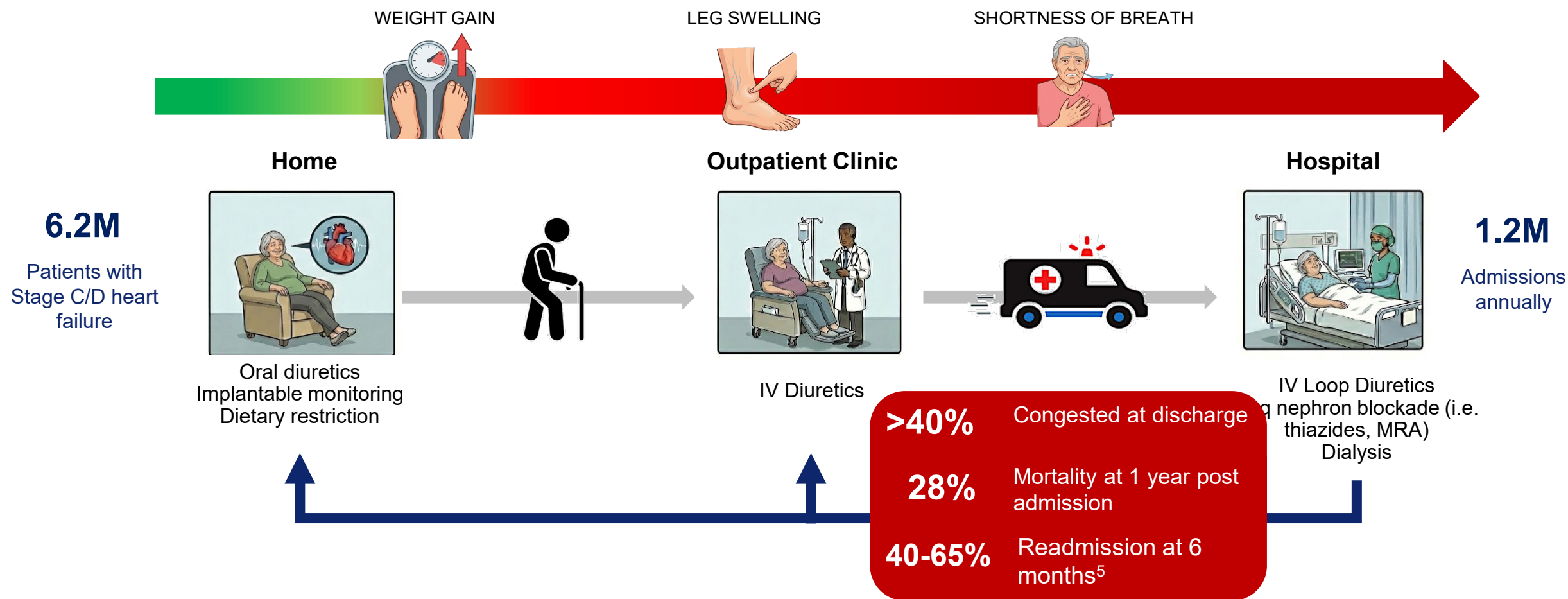
40 patients /
120 procedures



ESKD: End Stage Kidney Disease

AQUAPASS is set to transform the entire patient journey

Current patient care results in suboptimal outcomes



1. Ceelen DCH, et al. **Clinical profiles and prognostic impact of residual intravascular and tissue congestion in acute heart failure.** *Eur J Heart Fail.* 2025 Nov 11
2. Hollenberg, S, Warner Stevenson, L, Ahmad, T. et al. **2019 ACC Expert Consensus Decision Pathway on Risk Assessment, Management, and Clinical Trajectory of Patients Hospitalized With Heart Failure: A Report of the American College of Cardiology Solution Set Oversight Committee.** *JACC.* 2019 Oct, 74 (15) 1966–2011
3. Hajduczuk AG, Sauer AJ, Wettersten N. **Do I really need to be admitted? A case for more outpatient therapies for acute decompensated heart failure.** *Heart Fail Rev.* 2025 Dec 2;31(1):5
4. Chioncel O et al. **Acute heart failure congestion and perfusion status - impact of the clinical classification on in-hospital and long-term outcomes; insights from the ESC-EORP-HFA Heart Failure Long-Term Registry.** *Eur J Heart Fail.* 2019 Nov;21(11):1338-1352
5. Rogers et al, JACC 2007 (ESCAPE); Fudim et al, Am Heart J 2018 (ESCAPE); Lala et al, Circ Heart Fail 2015; Hollenberg et al, JACC 2019; Costanzo et al, JACC Heart Failure 2015

Procedural Steps



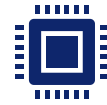
Physician Setup

Physician determines the fluid removal target and prescribes treatment parameters.



Patient Preparation

Patient is sized for the wearable garment.
Clinician secures the garment against the patient's skin and records baseline weight.



System Connection & Programming

Garment is connected to the control station via the air tube.
Clinician programs patient-specific temperature and treatment duration.



Treatment Session (≈4 hours)

Patient may sit, recline, or walk short distances.
Controlled warming raises skin temperature to induce sweating and fluid removal.
Sensors monitor temperature and humidity, enabling real-time sweat-rate calculation and maintaining prescribed limits.
Continuous evaporation cools the skin and supports comfort.



Clinical Oversight

Staff monitor vital signs per standard practice (AQUAPASS does not measure them).



Completion

Treatment ends after the prescribed duration, and the garment is removed.

The AQUAPASS System is indicated as a standalone extracorporeal hyperthermia procedure using external thermal application.
No vascular access or organ-specific body part coding is required.

Clinical Documentation



1. Physician Orders

Physician Orders section (or Treatment Orders, Therapy Orders)

What is recorded:

Fluid removal target

Prescribed treatment parameters (temperature limits, session duration, safety thresholds)



2. Pre-Treatment Assessment

Nursing Assessment or Pre-Procedure Assessment
Vital Signs flowsheet

What is recorded:

Baseline weight

Skin assessment at garment placement site

Patient condition prior to therapy



3. System Setup & Preparation

Garment sizing and placement
Connection to the control station

Programmed treatment parameters (as verified by the clinician)



4. Treatment Session

Procedure / Therapy Notes
Nursing Flowsheets (if time-based documenting is used)

What is recorded:

Start and stop times
Patient tolerance and comfort
Observational data about the system functioning normally
Patient activity (sitting, reclining, ambulating)



5. Vital Signs Monitoring

Vital Signs flowsheet in the EHR

What is recorded:

Periodic vital signs obtained by staff during the session
Any clinically significant changes



6. Post-Treatment Documentation

Procedure / Therapy Notes
Nursing Assessment

What is recorded:

End-of-treatment summary
Patient response/tolerance
Post-treatment weight
Any adverse events or interventions

- Sensor data such as sweat rate, temperature, and humidity remain within the AQUAPASS system and are not typically charted manually unless clinically relevant
- As with all extracorporeal hyperthermia procedures, theoretical risks include skin irritation or discomfort, which are mitigated through continuous monitoring.

Common Naming Conventions in the Medical Record

Coders should expect the procedure to appear under one of the following standardized naming forms:

- **AQUAPASS Therapy**
- **AQUAPASS Fluid Removal Therapy**
- **AQUAPASS Thermal Treatment**
- **Transdermal Fluid Removal Using AQUAPASS**
- **Wearable Hyperthermic Fluid Removal Therapy**
- **AQUAPASS ECCON Therapy**

Coders should be aware that clinicians may also chart using descriptive language, such as:

- *Regional hyperthermia fluid removal*
- *Noninvasive thermal fluid removal*
- *Wearable garment-induced sweating therapy*
- *Therapeutic hyperthermia session*
- *AQUAPASS session / AQUAPASS treatment*
- *Controlled skin warming for fluid removal*
- *Wearable garment applied to torso/flanks*
- *4-hour treatment session with evaporation-based fluid removal*

Thank you.