The *Future* of Device Therapy for Monitoring and Treating Heart Failure

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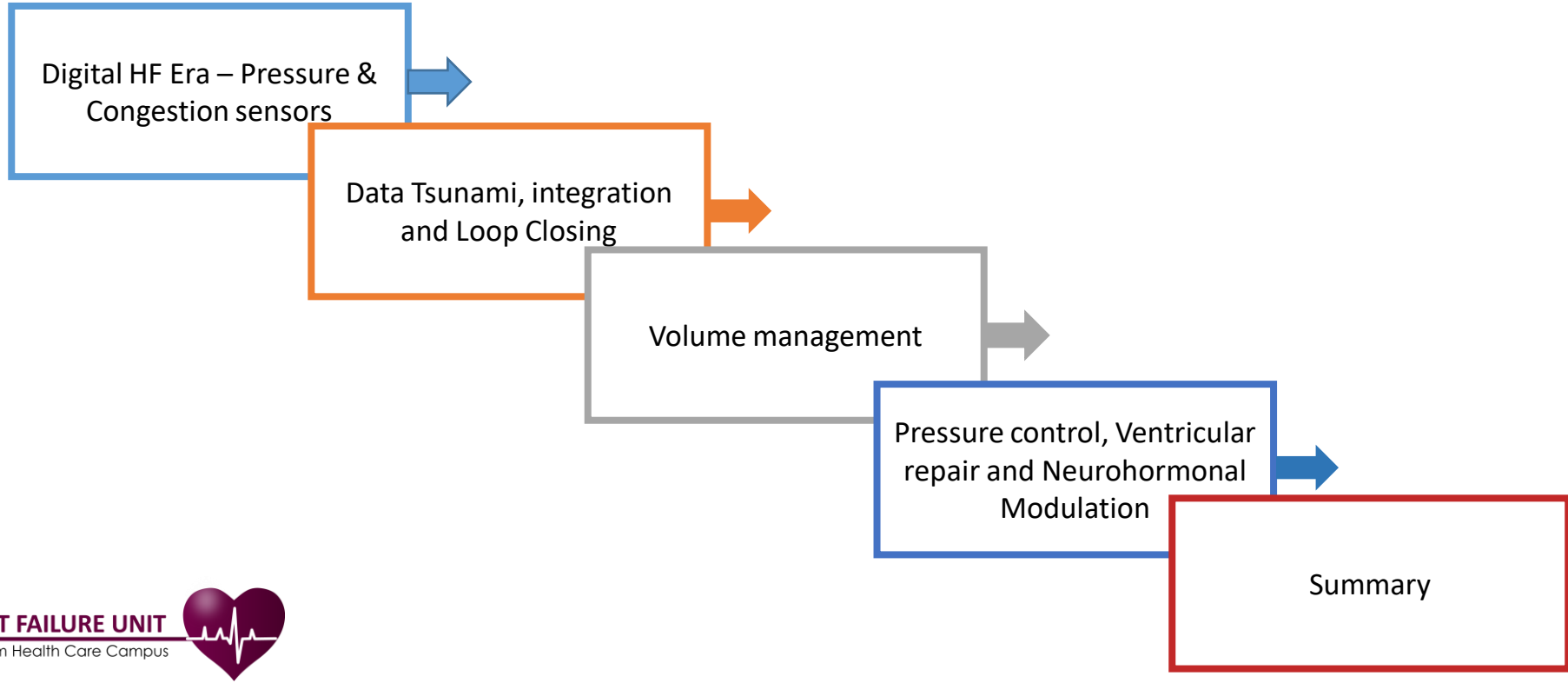
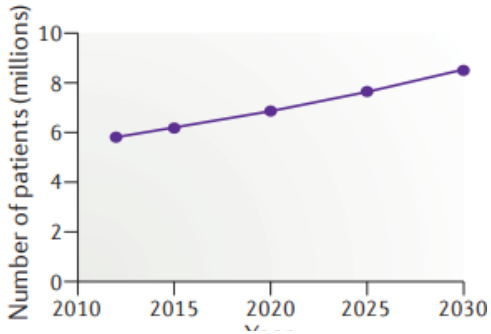
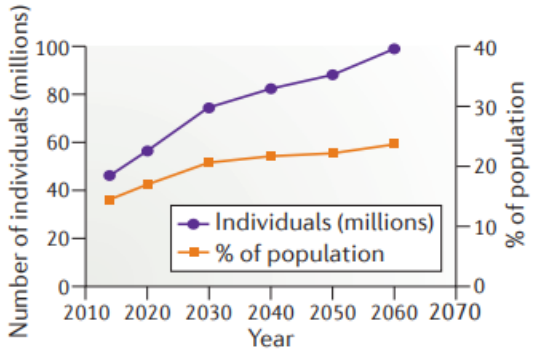
Outline


Digital HF Era – Pressure & Congestion sensors
Data Tsunami, integration and Loop Closing
Volume management
Pressure control, Ventricular repair and Neurohormonal Modulation
Summary

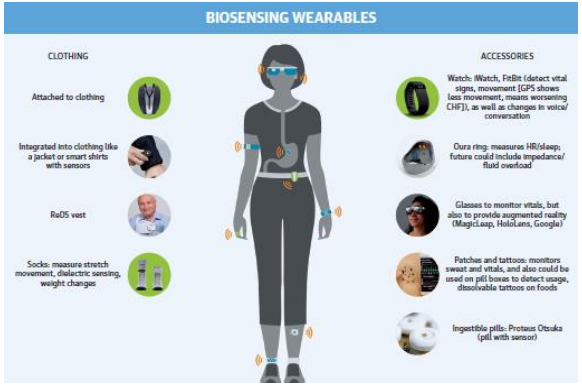
Monitoring Heart Failure
The Digital Era





Prevention

Digital Remote Care



Dunaly et al. Nature Rev Cardiol 2017, Devore et al. JACC HF 2019

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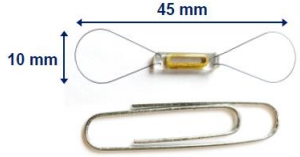
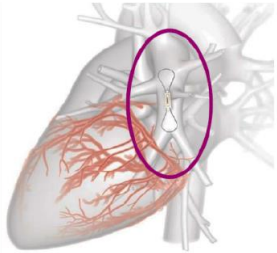
Digital Heart Failure – Monitoring Pressures

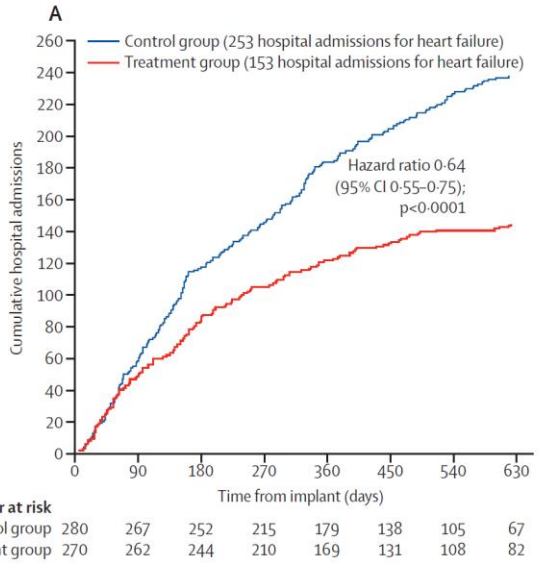
Pulmonary Artery pressure Sensors

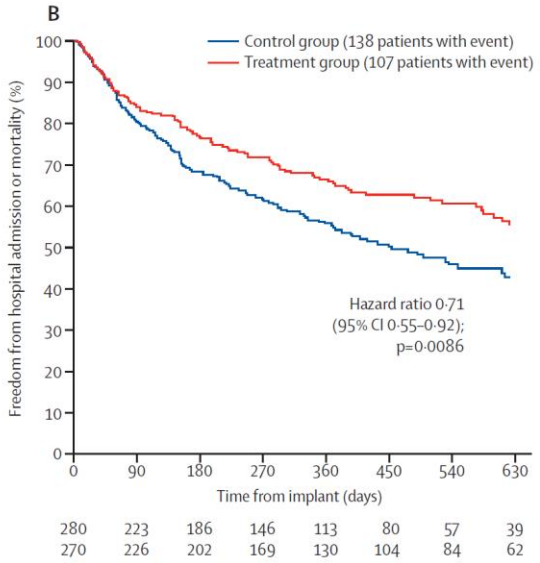




Study population
NYHA III /w recent HF hospitalization

CHAMPION trial (CardioMEMs)





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Abraham et al. Lancet 2011

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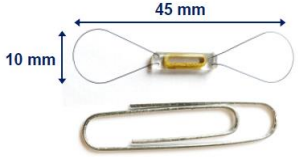
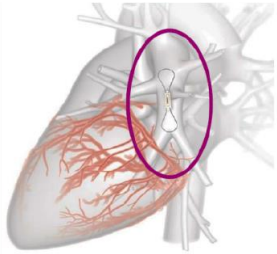
Digital Heart Failure – Monitoring Pressures

Pulmonary Artery pressure Sensors



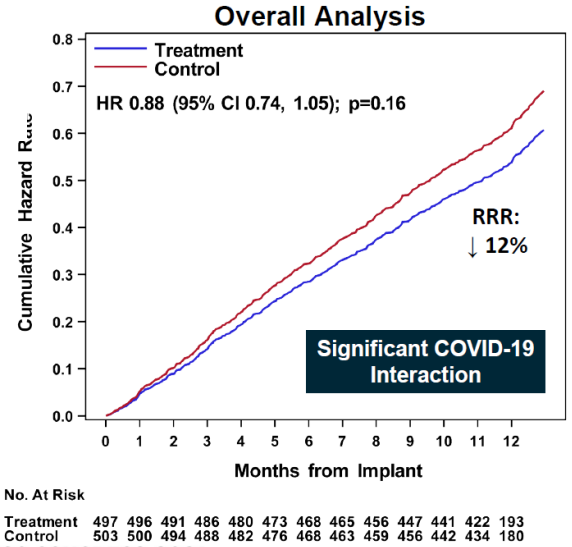


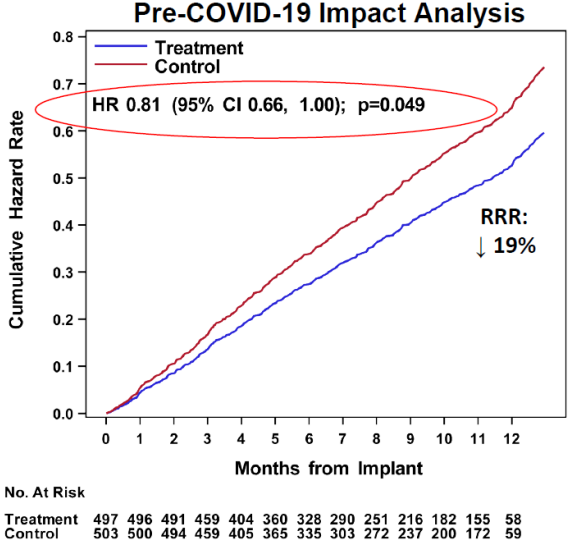
Study population
NYHA II-IV /w recent (12mo)
HF hospitalization or ↑BNP

Primary Endpoint

GUIDE-HF | CardioMEMS HF System IDE Clinical Trial

(All-Cause Mortality, HF Hospitalizations, Urgent HF Visits)





ESC CONGRESS 2021
THE DIGITAL EXPERIENCE

Lindenfeld et al. Lancet 2022

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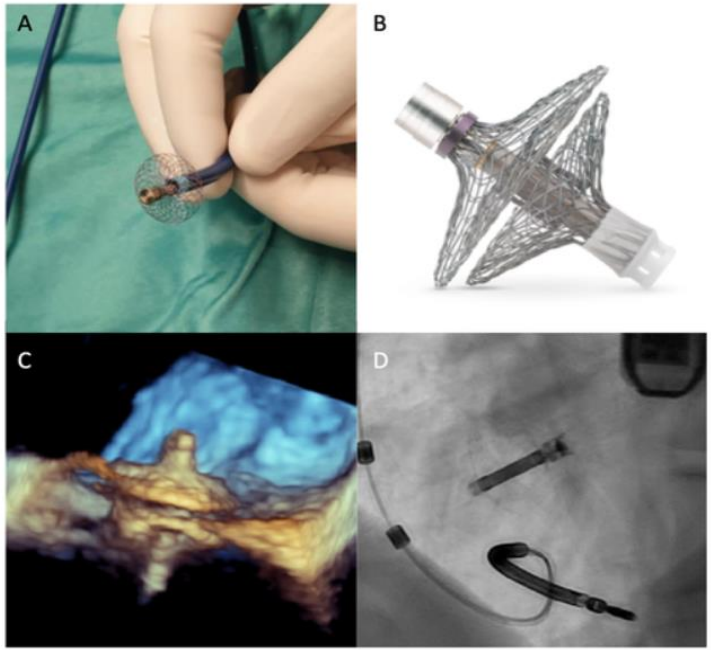
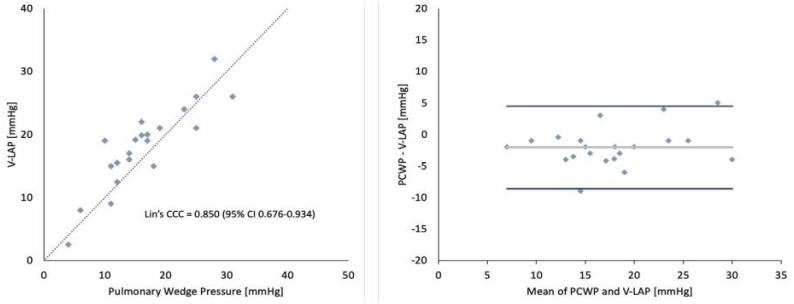
Digital Heart Failure – Monitoring Pressures

Left Atrial pressure sensors





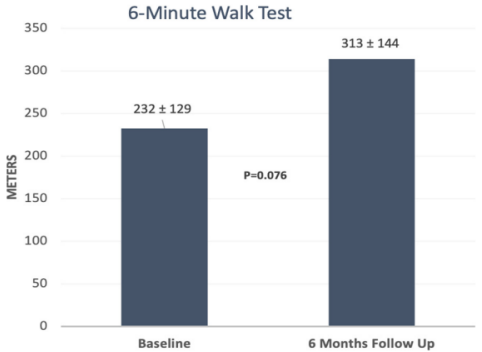


Fig. 4. Comparison of 6-minute walk test at baseline and 6 months after device implantation.

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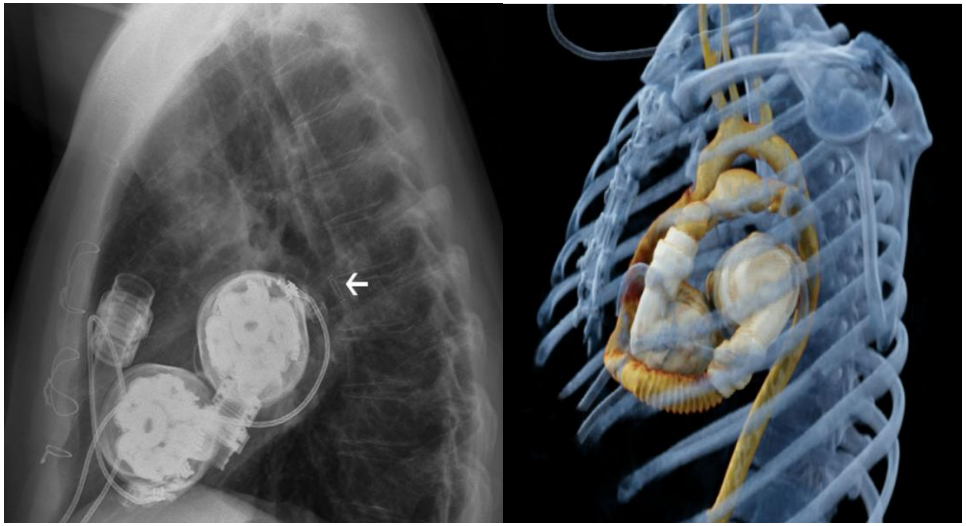
Perl et al. J Card Failure 2022

Digital Heart Failure – Monitoring Pressures

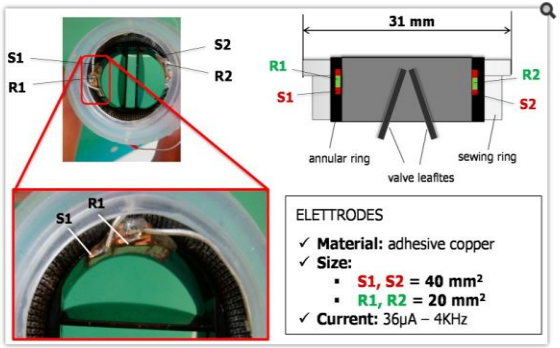
Left Atrial pressure sensors

Implanted Pressure monitor for biventricular VADs

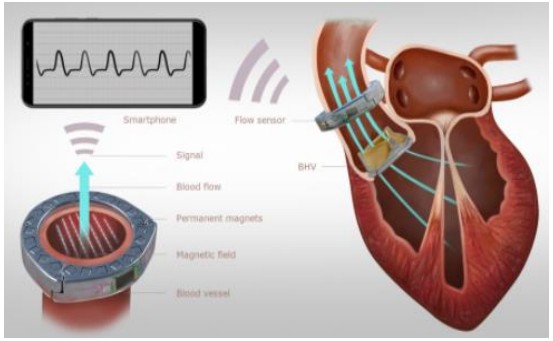


Angleitener et al. ASAIO 2022

Pressure and Flow Sensorized Valves



Marcelli et al. Sensors 2018

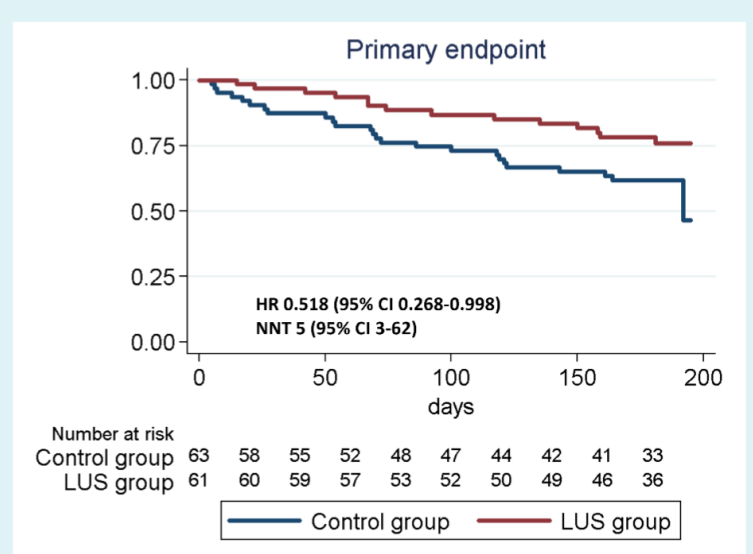


Vennemann et al. Plos One 2020

Digital Heart Failure –Assessing Congestion

Lung ultrasound

Single center, single-blind, randomized clinical trial

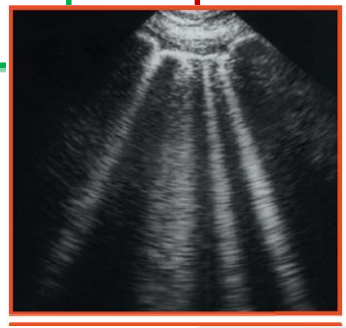


INCLUSION CRITERIA

- ✓ >18 years old
- ✓ Hospitalization for HF
  - shortness of breath
  - pulmonary congestion in X-ray
- ✓ High NT-proBNP levels:
  - < 50 years: > 450 ng/L
  - 50-75 years: >900 ng/L
  - >75 years: >1800 ng/L

EXCLUSION CRITERIA

- ✓ Severe lung disease that prevents interpretation of the LUS
- ✓ Life expectancy of less than 6 months



Rivas-Lasarte et al. EHJ-HF 2019

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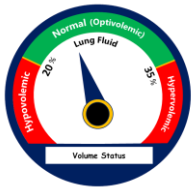
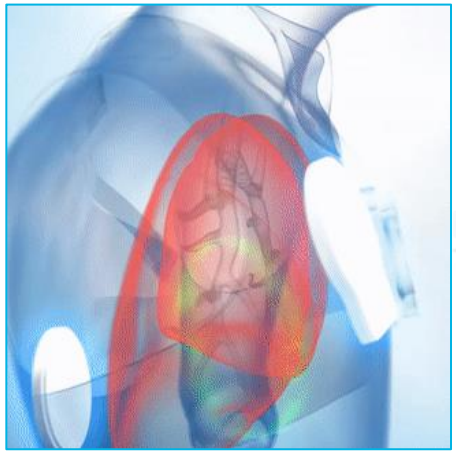
LUS-HF trial

Digital Heart Failure –Assessing Congestion

Electromagnetic radar beams

- Focused electromagnetic radar beam through the right lung
- Normal lung measures 20-35% lung fluid content
- ≥36% is considered congestion
- Continuous score
- The device range is 15-60%
- 45 sec. measurement
- On top of clothes - no skin contact





ReDS™ Medical Radar Technology

ReDS™ System

FDA CE

משרד הבריאות

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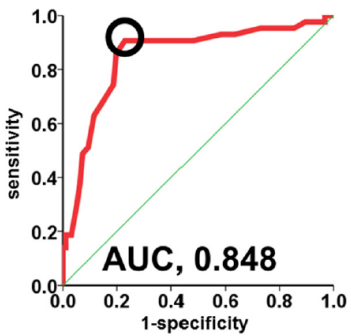
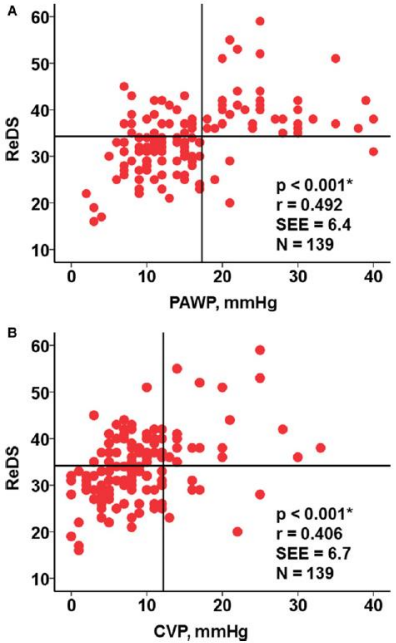
Digital Heart Failure –Assessing Congestion

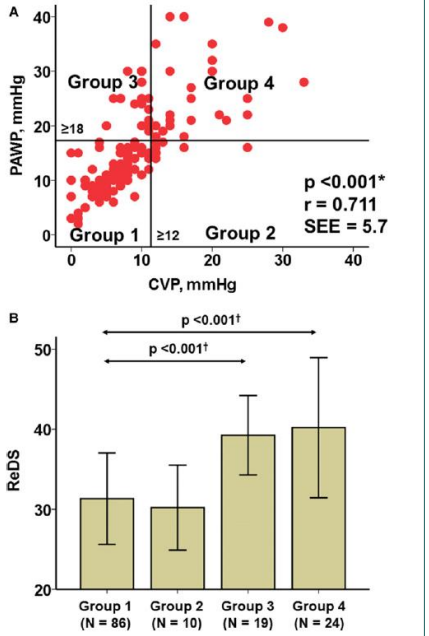
Electromagnetic radar beams

ReDS™ vs. RHC (N=139)



	N = 139
Endpoint	PAWP ≥18
Cutoff	ReDS >34
Sensitivity	90.7%
Specificity	77.1%
Positive predictive value	63.9%
Negative predictive value	94.9%





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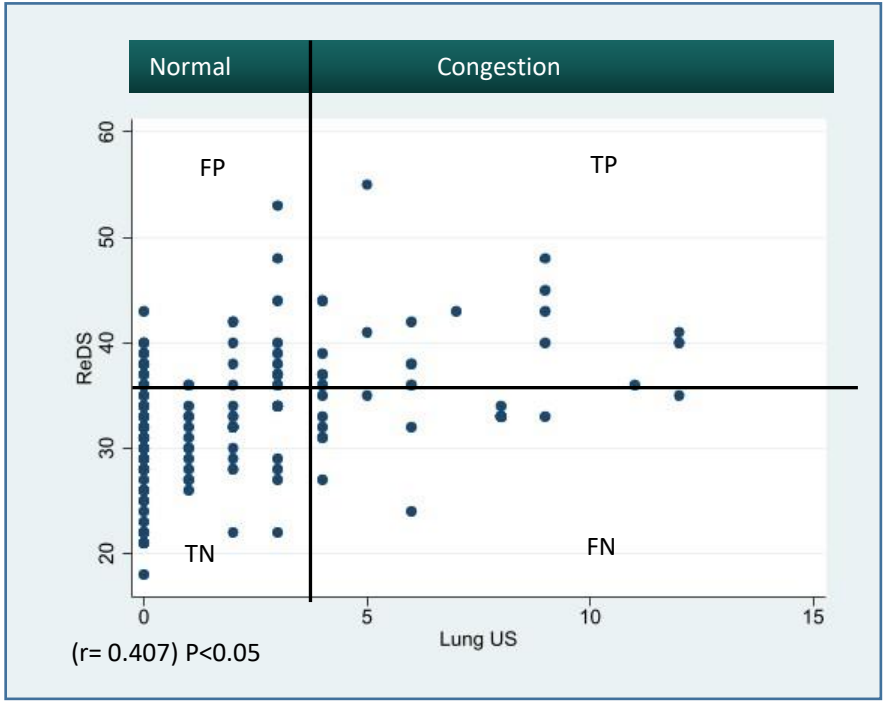
Uriel et al. JACC (Journal of the American College of Cardiology), 2017-03-21

Digital Heart Failure –Assessing Congestion

REDS – LUS correlation

Roni Abbo

- The Correlation between continuous variables for LUS and ReDS using the Pearson correlation coefficient was ***moderate (r= 0.407) P<0.05***
- Correlation kept with different EF or BMI categories:
  - HFpEF(>50%) 0.42, HFrEF: 0.44
  - BMI<25 0.49, BMI<30 0.45
    - Sensitivity 55%
    - Specificity 70%
    - PPV 27%
    - NPV 88%



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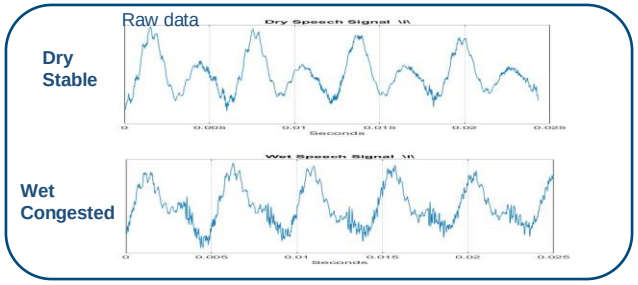
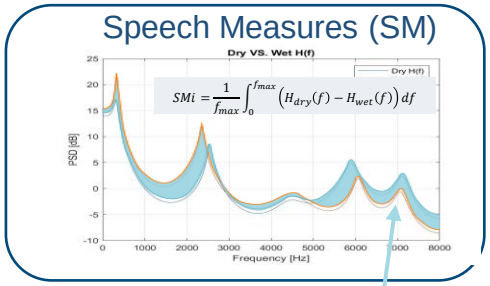
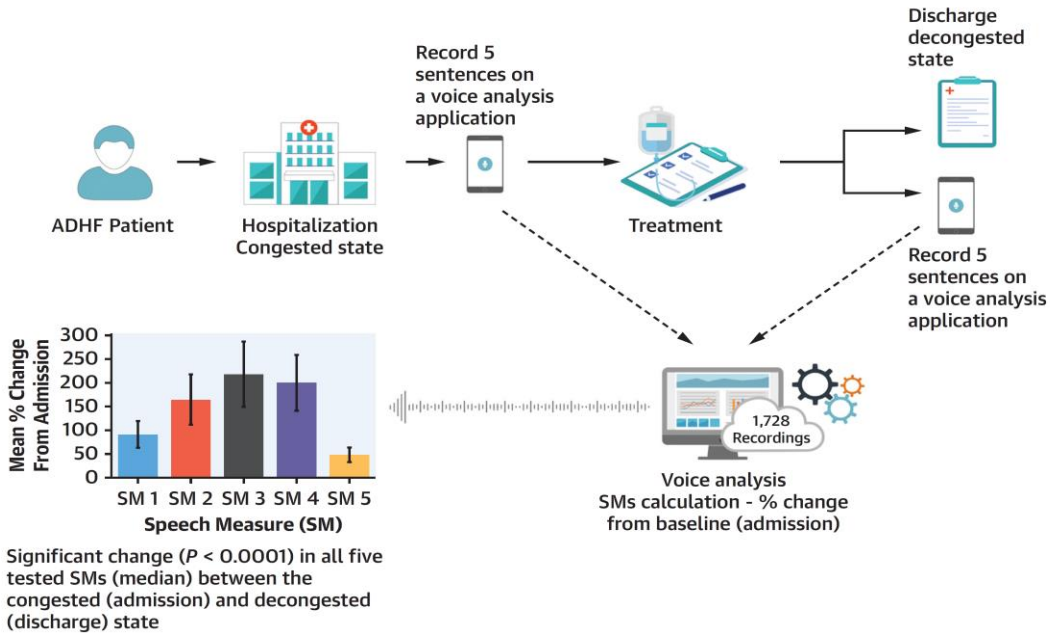
Digital Heart Failure –Assessing Congestion

Speech Analysis





Speech measures Area between curves



Significant change ($P < 0.0001$) in all five tested SMs (median) between the congested (admission) and decongested (discharge) state

Amir eal. JACC HF 2022

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Digital Heart Failure –Assessing Congestion

Speech Analysis

Study Goal : Detect impending HF decompensation (HF hospitalization or diuretic escalation)
Retrospective analysis, 180 patients ,460K recordings, 49 events.

System preliminary group results:

	True Positive (TP)	False Negative (FN)
Sensitivity	**82% (32)**	18% (7)

False positive (false priority) rate: One priority every ~4.72 months (average) per patient (2.54 per year)

# of False positives (FPs)	FP rate [months]	Total analysis days
744	4.72	106,747

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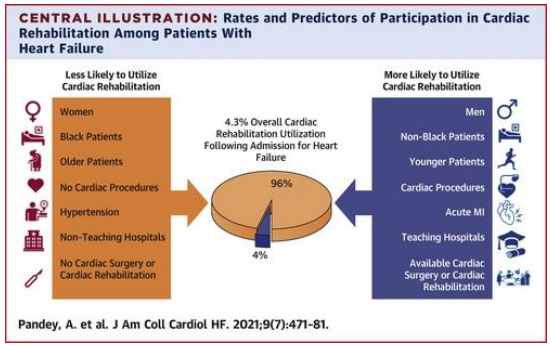
Abraham et al. Cordio HearO community stude – ESC –HF madrid 2022

Digital Heart Failure

Patient activity and Rehabilitation

- Cardiac Rehabilitation is Class IA recommendation for heart failure patients.
- Only **4.3%** of heart failure patients are participating in an active program.
- **Multiple reasons:** bureaucracy, financial, time consuming, motivation, fear.



Recommendations for exercise and participation in sport in individuals with heart failure with preserved ejection fraction

Recommendations	Class[a]	Level[b]
Moderate endurance and dynamic resistance exercise, together with lifestyle intervention and optimal treatment of cardiovascular risk factors (i.e. arterial hypertension and type 2 diabetes) are recommended.[287,289 – 292,299]	I	C
Competitive sports may be considered in selected stable patients without abnormalities on maximal exercise testing.	IIb	C

Recommendations for exercise prescription in heart failure with reduced or mid-range ejection fraction

Recommendations	Class[a]	Level[b]
Regular discussion about exercise participation and provision of an individualized exercise prescription is recommended in all individuals with heart failure.[260,261,285]	I	A
Exercise-based cardiac rehabilitation is recommended in all stable individuals to improve exercise capacity, quality of life, and to reduce the frequency of hospital readmission.[260,261,285]	I	A

Beatty et al (2018). Geographic Variation in Cardiac Rehabilitation Participation in Medicare and Veterans Affairs Populations. *Circulation*
Pandey et al (2021). Temporal Trends and Factors Associated With Cardiac Rehabilitation Participation Among Medicare Beneficiaries With Heart Failure. *JACC: Heart Failure*

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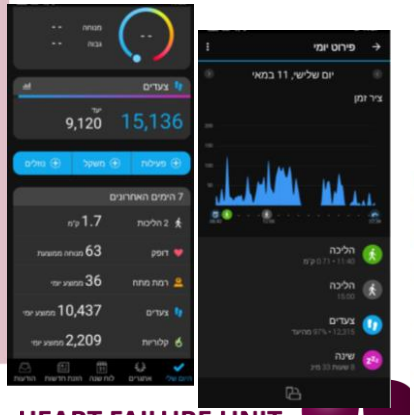
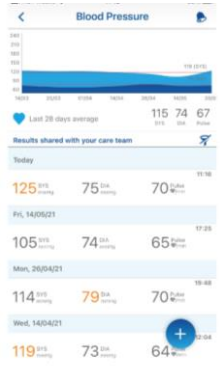
Patient View





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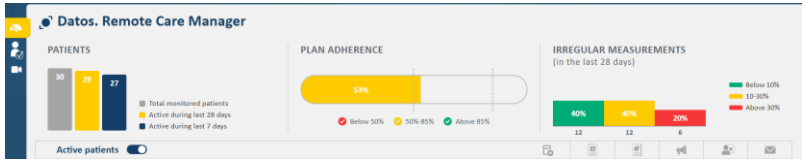
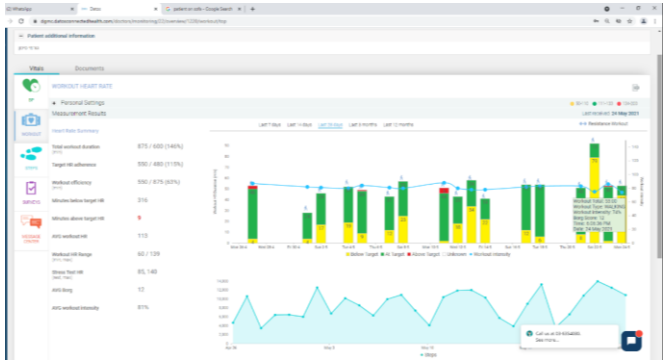
CRx Team View





Cardiac Rehab - RHCC

Digital CRx and COVID

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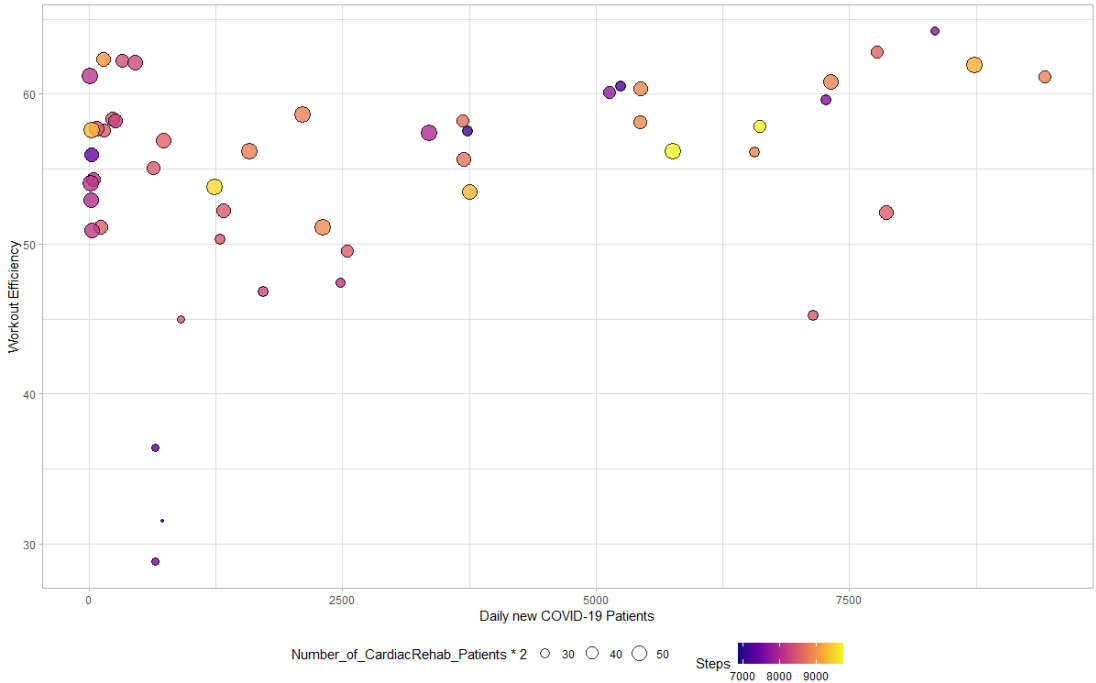
Boaz Elad



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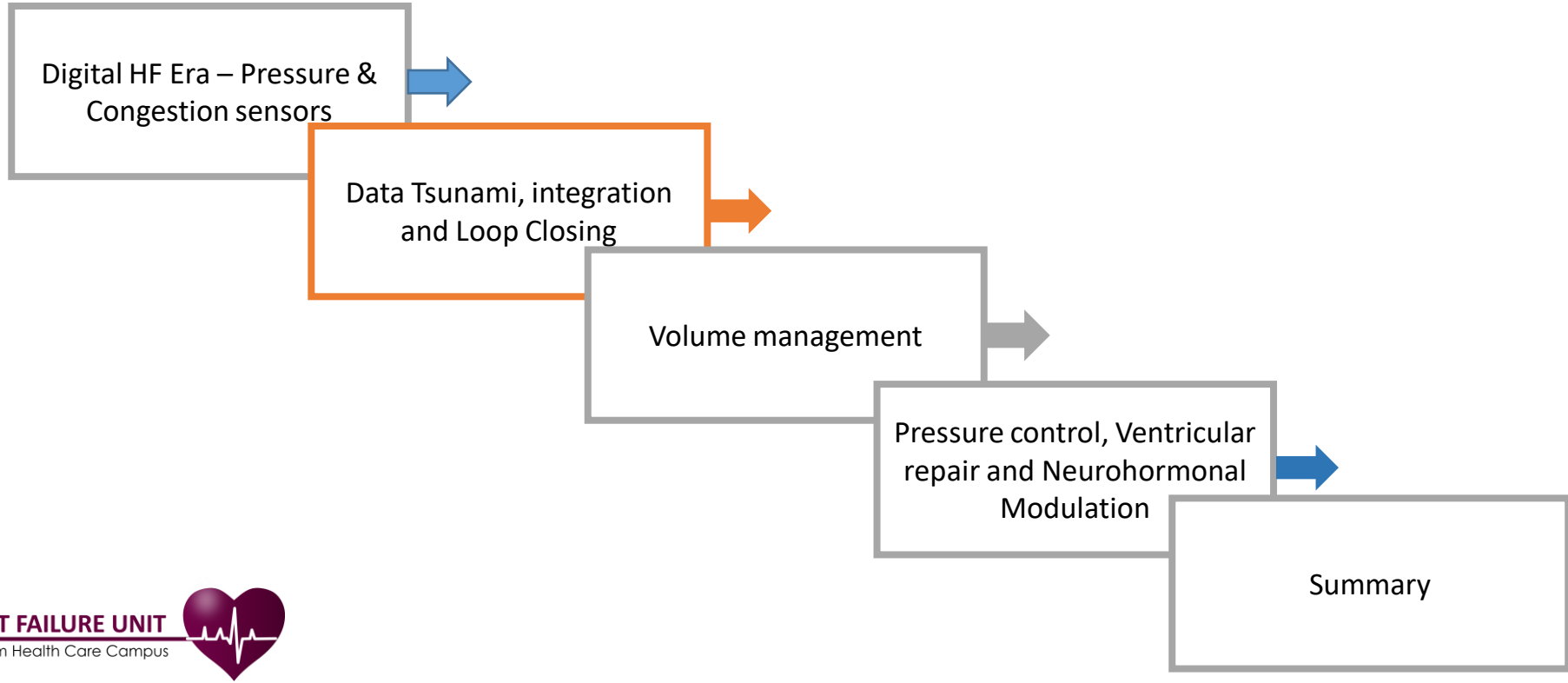

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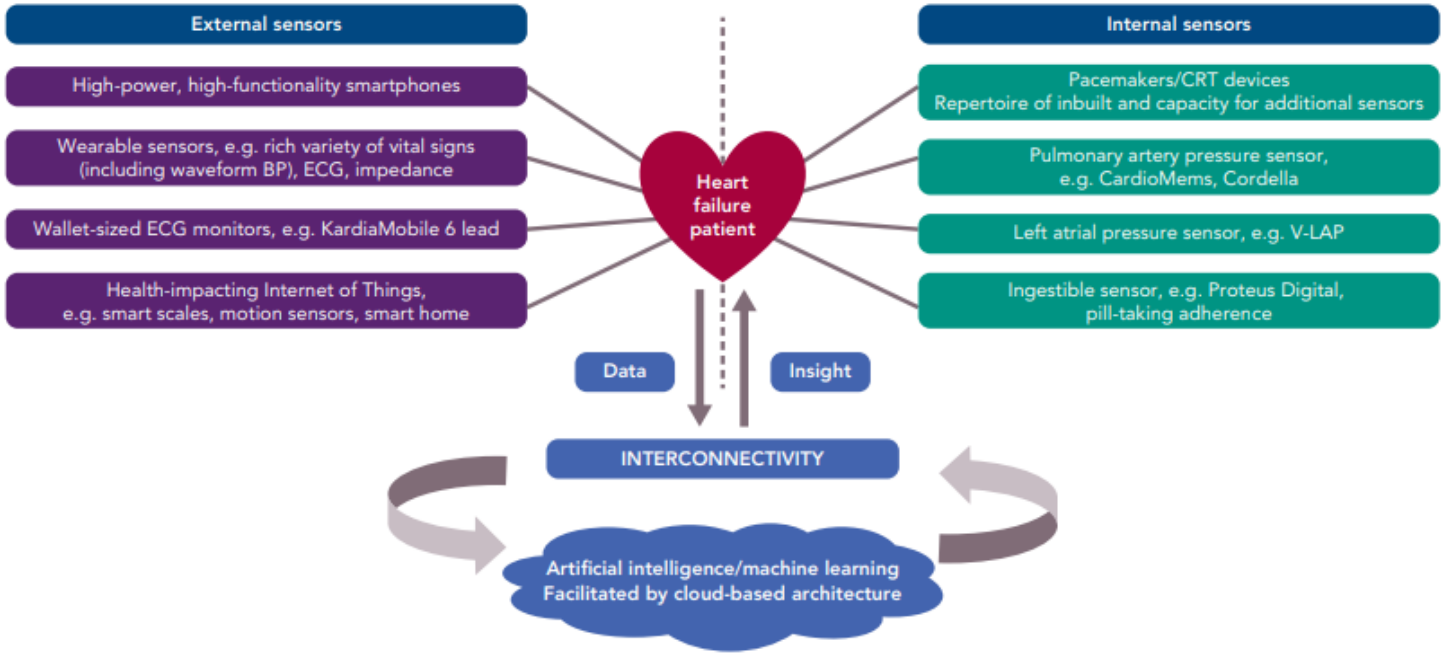
Digital Heart Failure – AI decision support



The interconnected nature of these devices facilitates the collection of data, which can be stored and processed in the cloud back end, facilitating machine learning or other analytic techniques to generate predictions, visualisations or decision support. These insights can then be fed back to the patient and clinical teams. BP = blood pressure.

J Card Failure 2020

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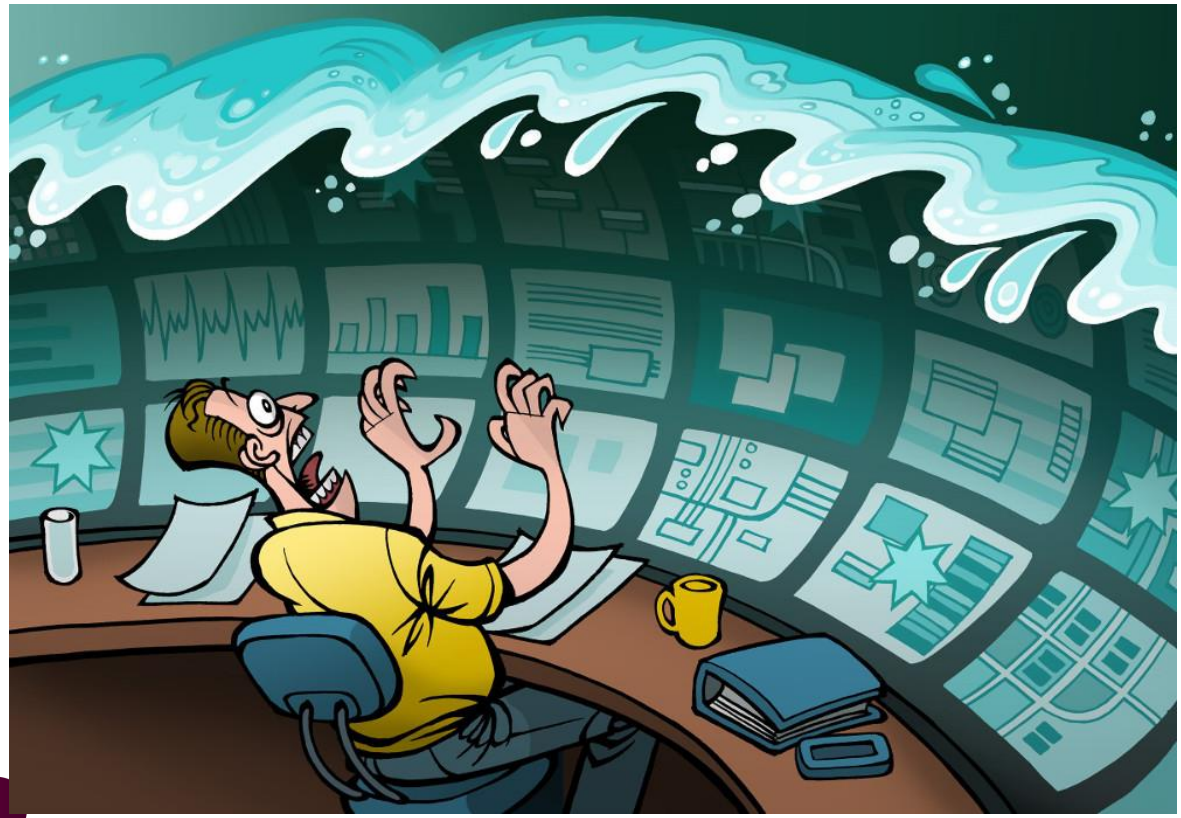
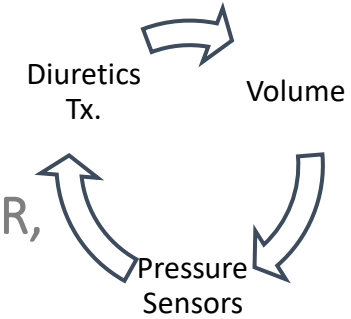
Data Tsunami



EPRI journal

Digital Heart Failure – Data Integration and Loop Closing



- Data Security
- Data Integration from multiple platforms (patient's input, EMR, wearables, IOT devices)
- Data Sensemaking
- Smart, Selective and Personalized Alarms.
- Overlay of decision support tools based on Data (Machine Learning and Artificial intelligence).

Heart Failure Data Integration System

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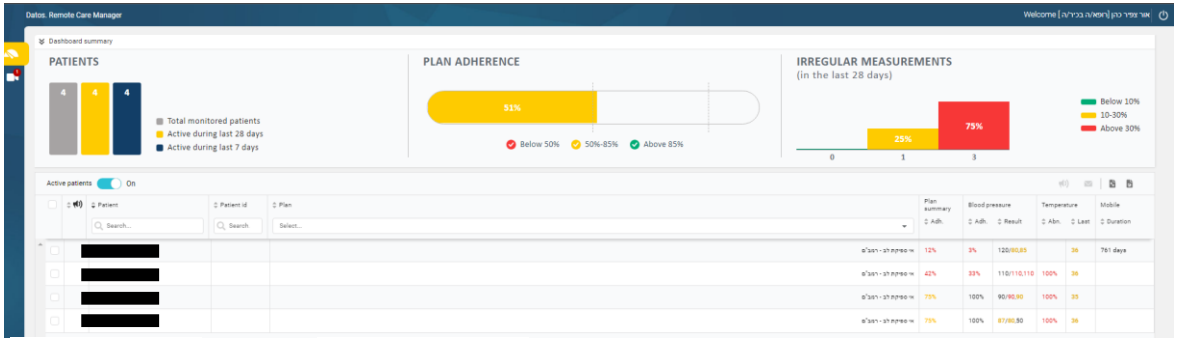
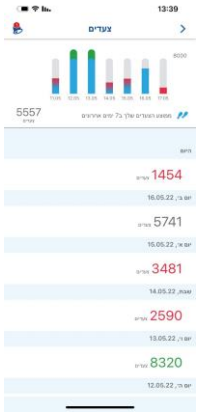
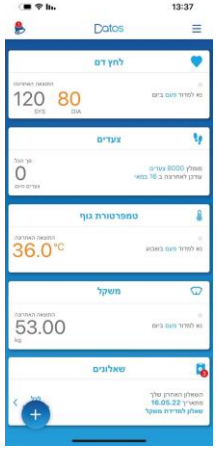
- Patient - Self Management Alerts
  - Tailored pre-defined set of actions
- RN, HF specialist alerts
  - **Tailored pre-defined set of actions**







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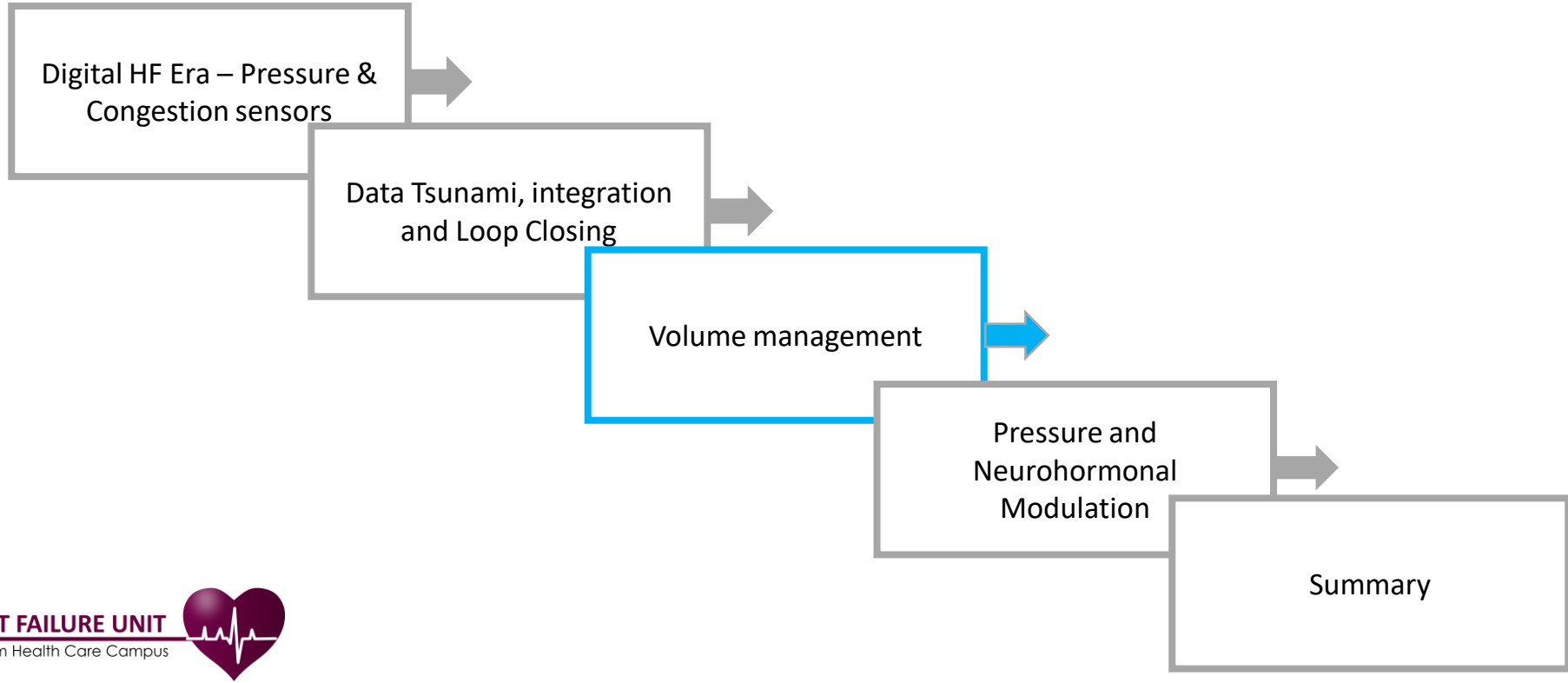

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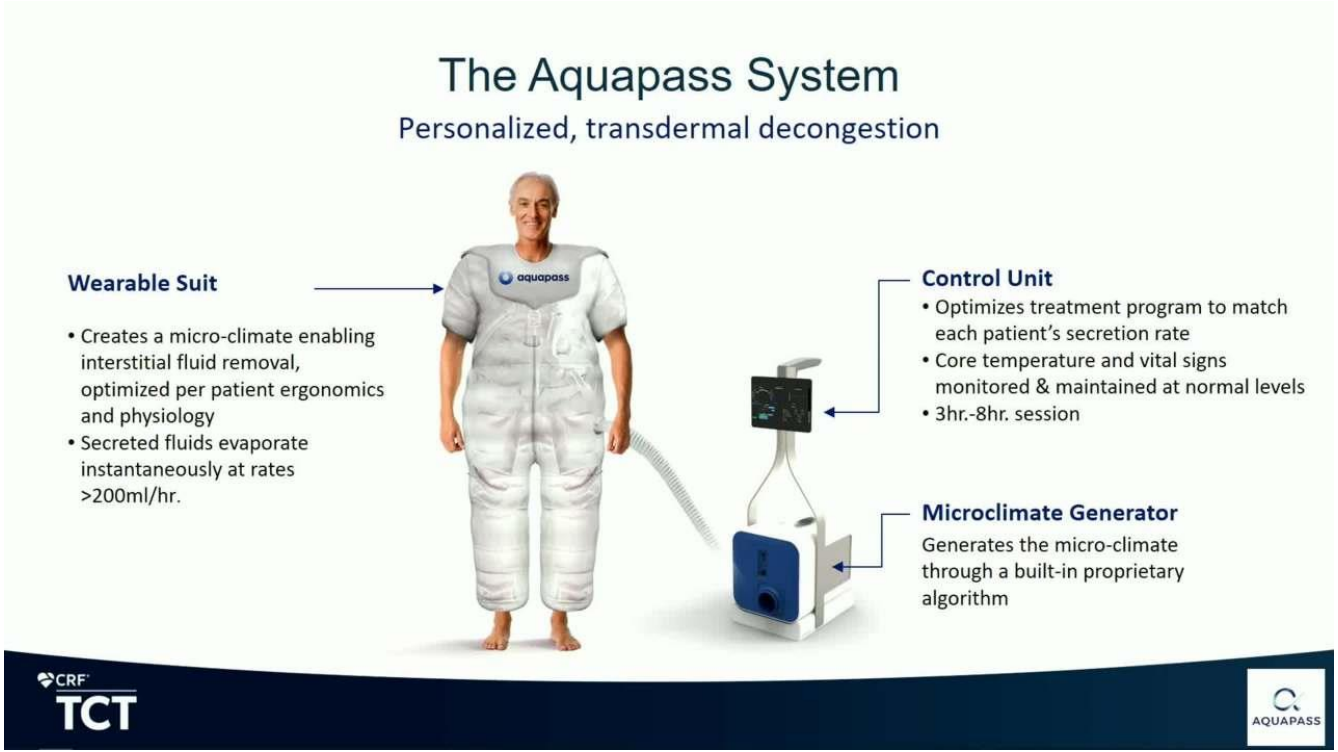
Volume Management
Transdermal Decongestion



Volume Management
Transdermal Decongestion

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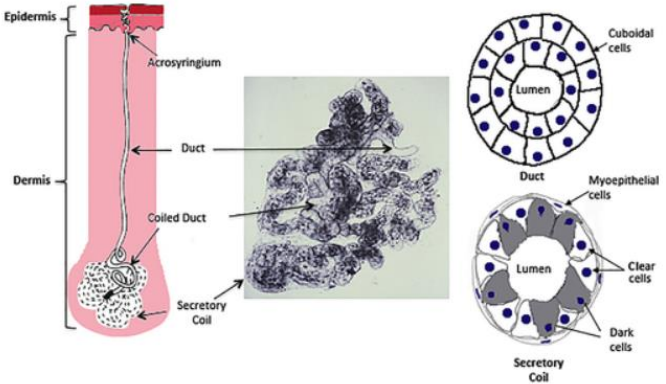
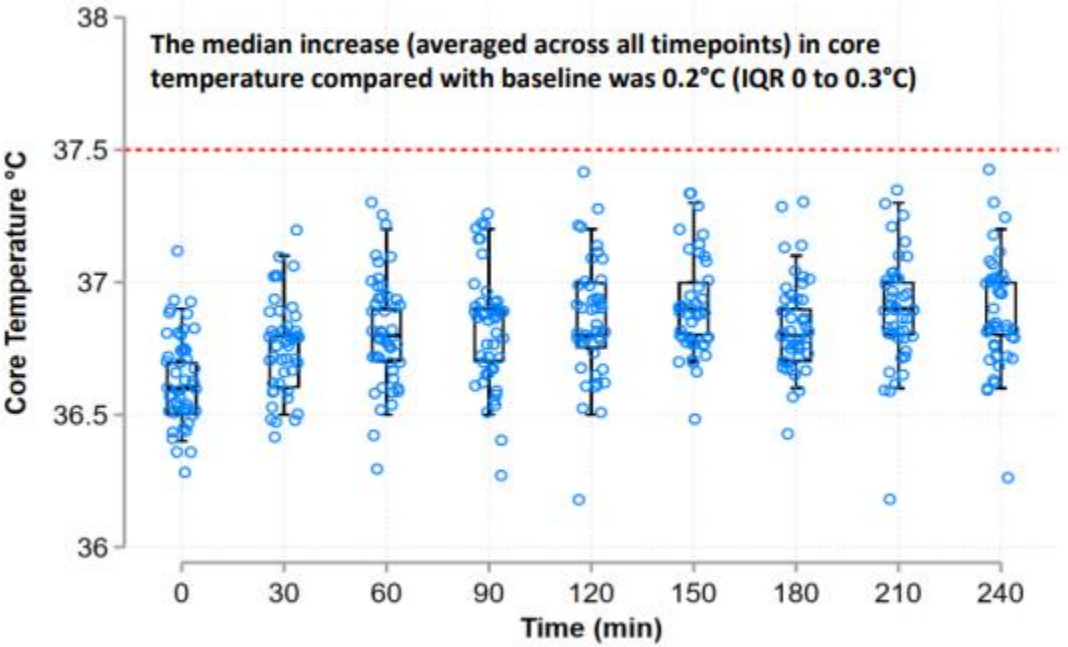
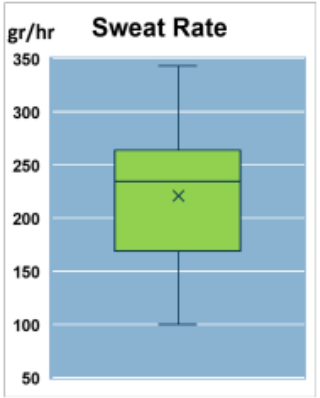
- Eccrine glands – “mini-nephrons”, interstitial fluid & electrolytes
- Direct **interstitial** decongestion
- Can excrete **>200ml/hr**.
- Facilitated perspiration – a natural process, kidney independent.
- Can be conducted **on top of other medical therapy**.

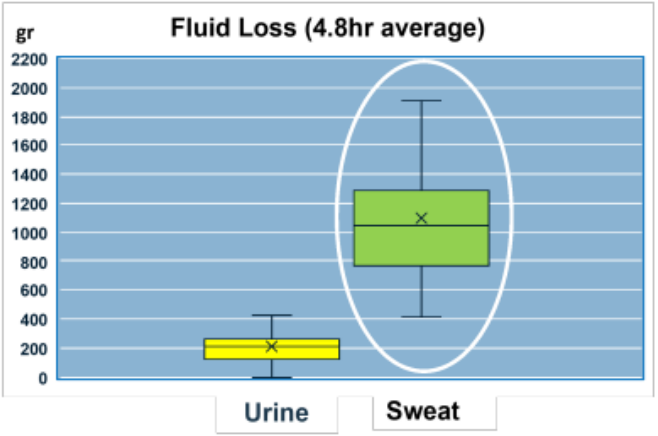


Volume Management
Transdermal Decongestion



Volume Management
Transdermal Decongestion

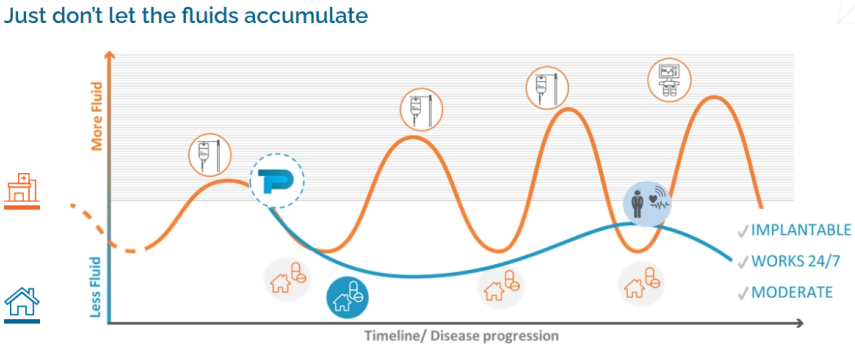




- No significant changes in hemodynamic variables or renal function
- No procedure-related adverse events

Volume Management

Peritoneal ultrafiltration device - Paragate

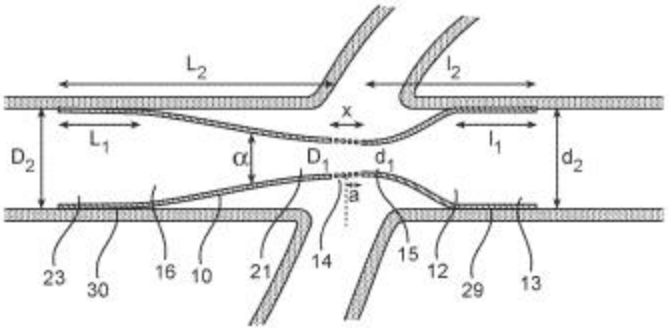


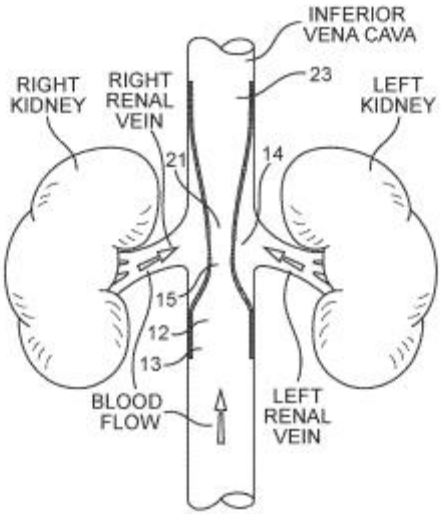
→negative hydrostatic pressure pump

→Peritoneal fluid ultrafiltration using Polytetrafluoroethylene (PTFE) disk-shaped absorption chamber.

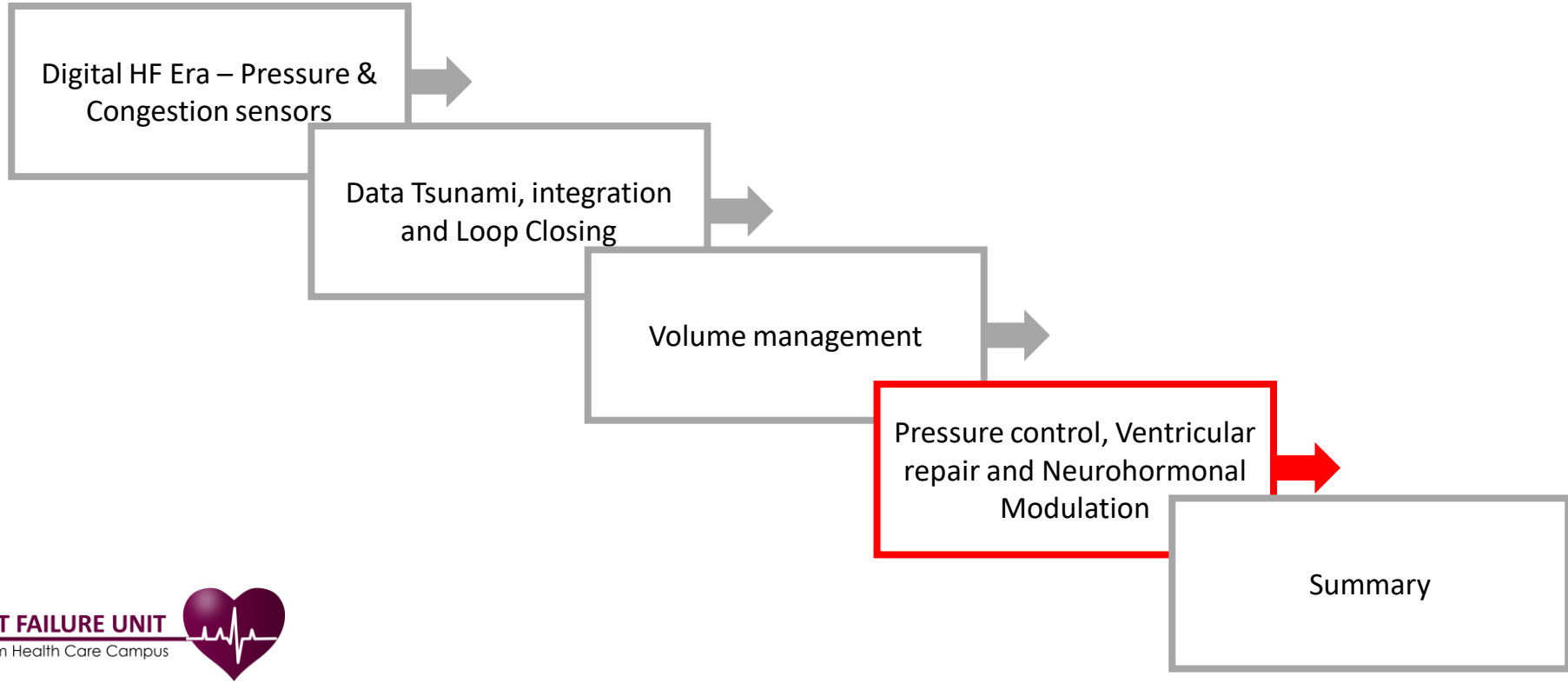
Volume Management

Facilitating Renal Decongestion - Nephronyx



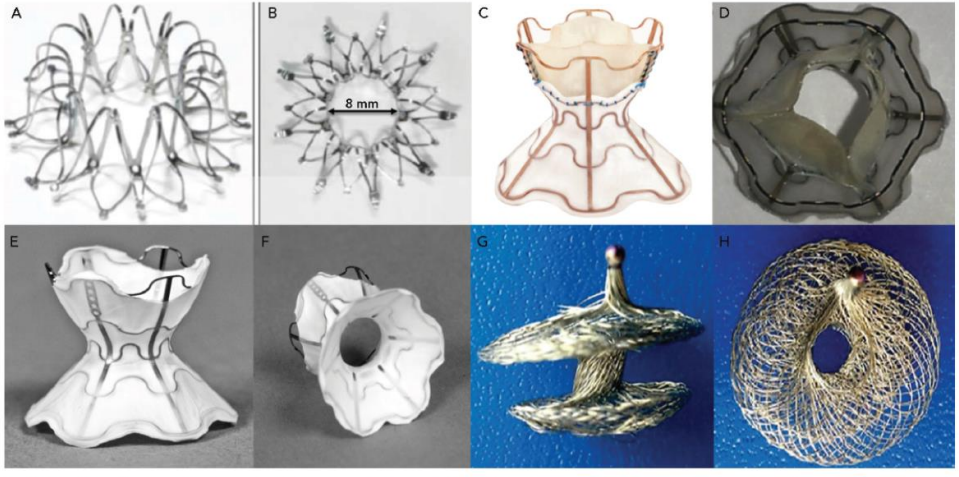


Outline

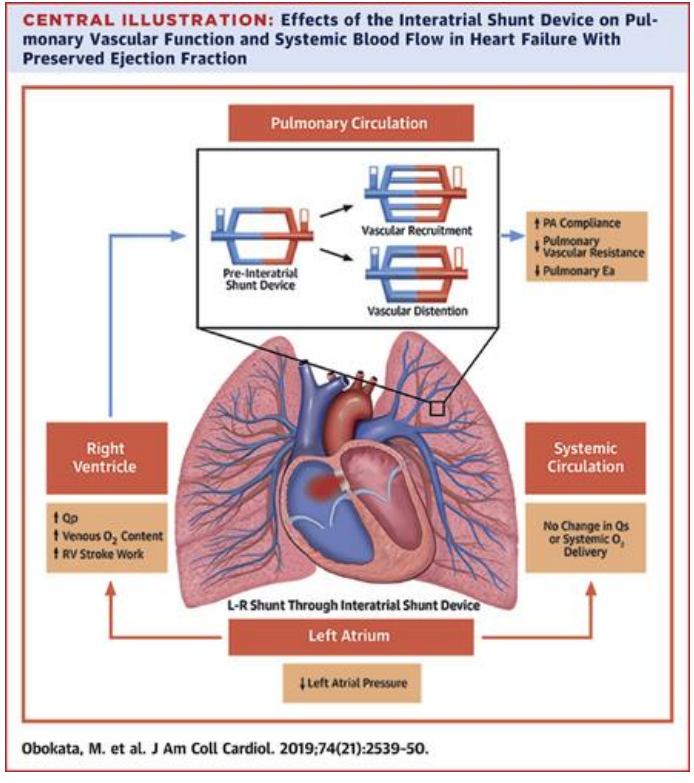

Digital HF Era – Pressure & Congestion sensors
Data Tsunami, integration and Loop Closing
Volume management
Pressure control, Ventricular repair and Neurohormonal Modulation
Summary

LA Pressure control

Inter-atrial shunting



A and B: InterAtrial Shunt Device. C and D: V-Wave device. E and F: Second-generation (valveless) V-Wave device. G,H: Atrial Flow Regulator. Source: A and B: Reproduced with permission from Corvia Medical Inc. C–F: Reproduced with permission from V-Wave. G and H: Reproduced with permission from Occlutech International AB.



Obokata, M. et al. J Am Coll Cardiol. 2019;74(21):2539-50.

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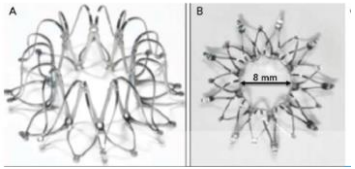
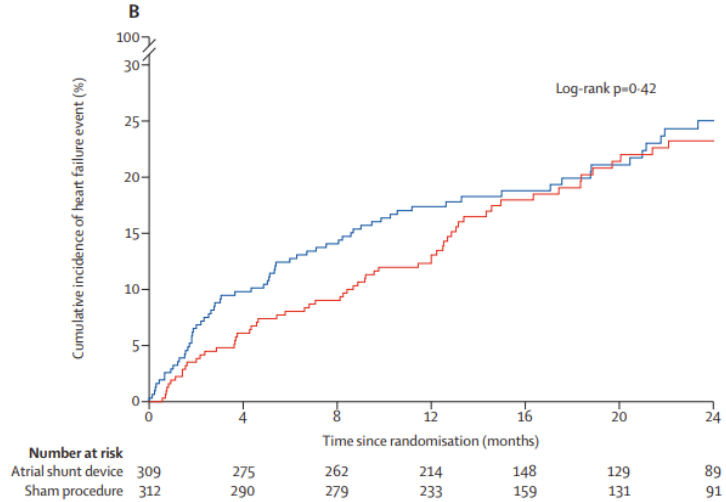
LA Pressure control

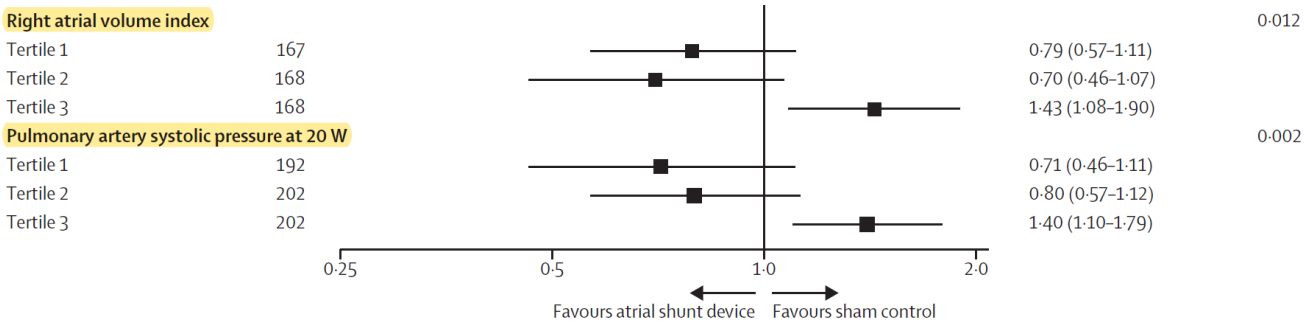
Inter-atrial shunting – Reduce LAP-HF2

Study population:
HFpEF patients /w exercise
PCWP≥25mmHg
NYHAII (21%), NYHA III (77%)
Shunt inner diameter 8mm



Shah et al. Lancet Feb. 2022





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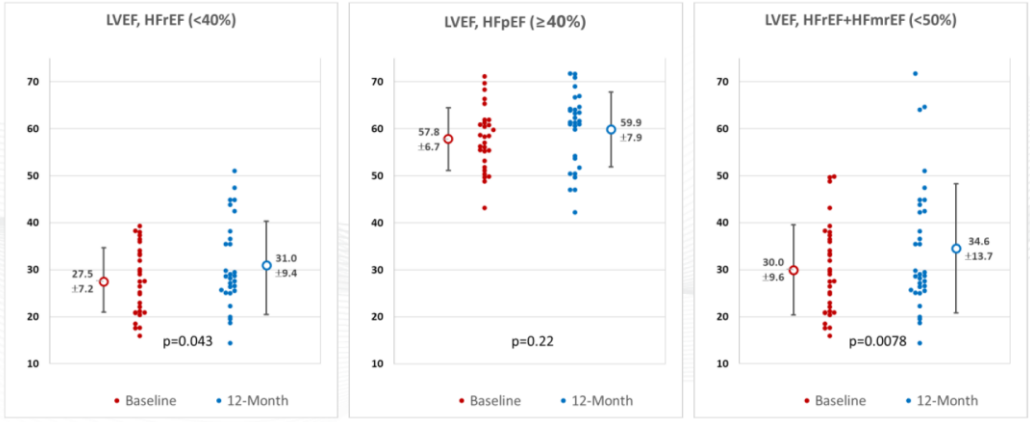
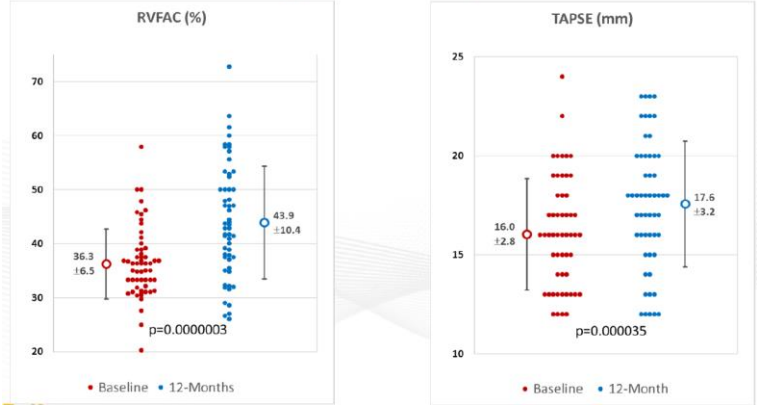
LA Pressure control

Inter-atrial shunting – Relive HF Trial (V-wave) –Roll in cohort

Study population:
HFrEF and HFpEF, NYHA III or IV and PASP<70mmHg
Shunt inner diameter
5.1mm





Nunez-Villota et al. ESC-HF Madrid 2022

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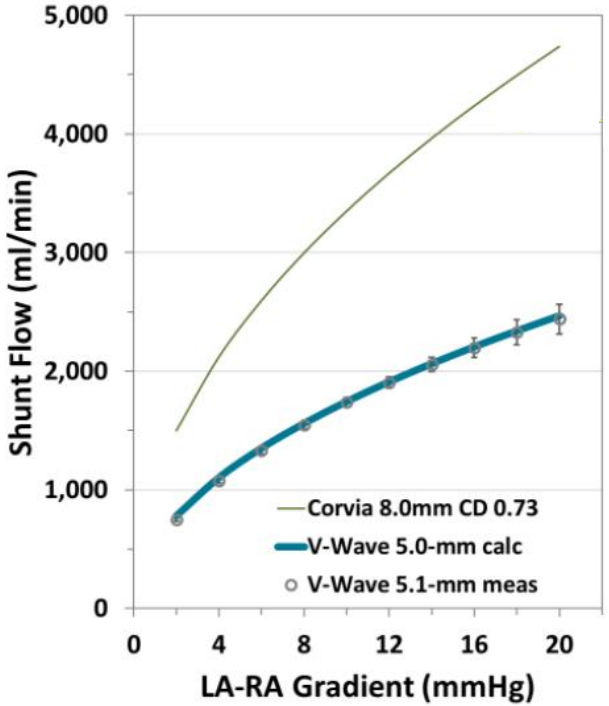
LA Pressure control

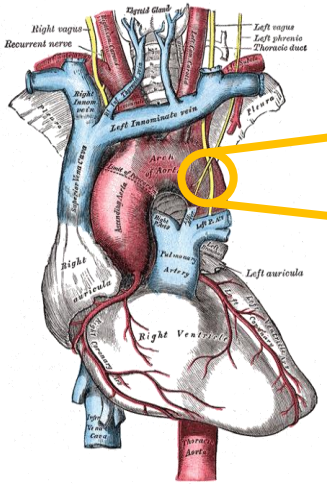
Does Size Matter?

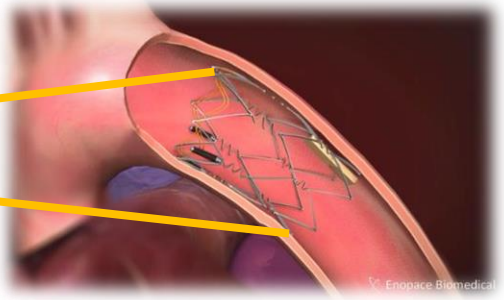


Nunez-Villota et al. ESC-HF Madrid 2022

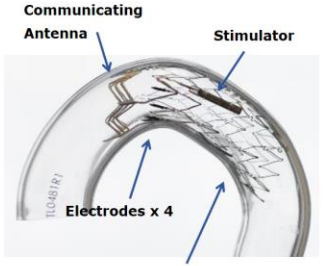
Neuro-hormonal modulation

Aortic pacing based autonomic modulation

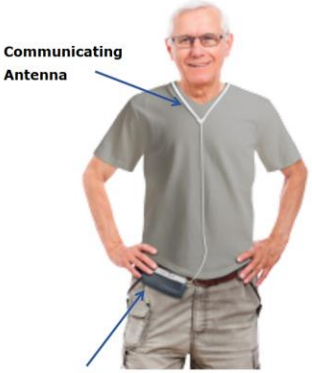




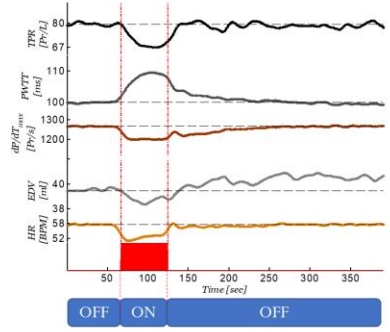
An Implant Unit



A Wearable, Patient Unit

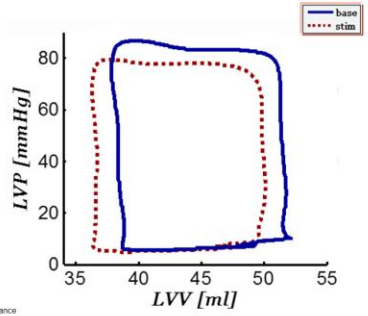


Reduced vascular resistance
Increased vascular compliance



TPR: Total Peripheral Resistance
PWTT: Pulse Wave Travel Time
EDV: End Diastolic Volume

Leftward shift in PV area



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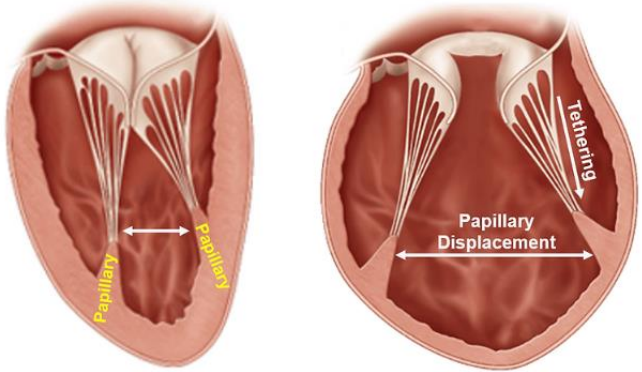
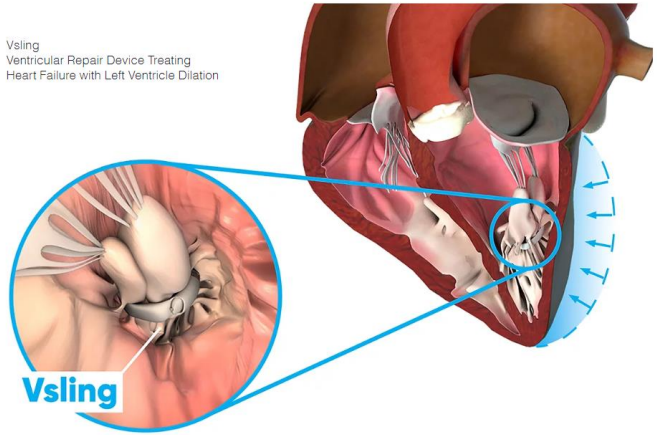
Ventricular Repair

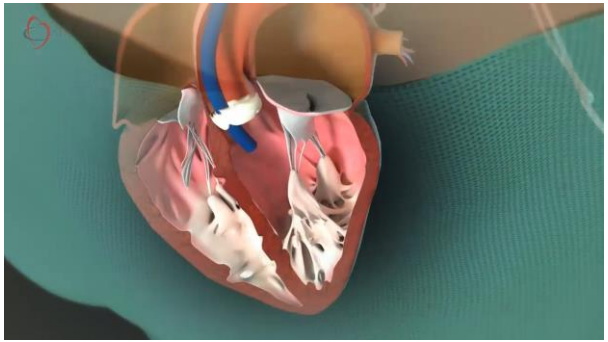
V-Sling – Ventricular Repair



Normal
Left Ventricle

Heart Failure
Dilated Left Ventricle





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Summary

- Heart failure epidemic → **PPM** Patient-(HF)Physician Mismatch→ **Digital and remote management**
- **Data Tsunami → Data integration platforms: sense-making algorithms, and tailored alerts.**
- **Renaissance of heart failure devices (mainly from )**

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Thank You

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