Wearable Artificial Organs
The unmet needs…

WAO

Wearable Artificial Organs, Inc.
www.WearableOrgans.com

Artificial Kidney "WAK 2.0" Successful

DISCLOSURES

Patent holder
Stock holder Warable Artificial Organs Inc

UNMET NEEDS IN WEARABLE ORGANS

Do we have better answers to the following questions:

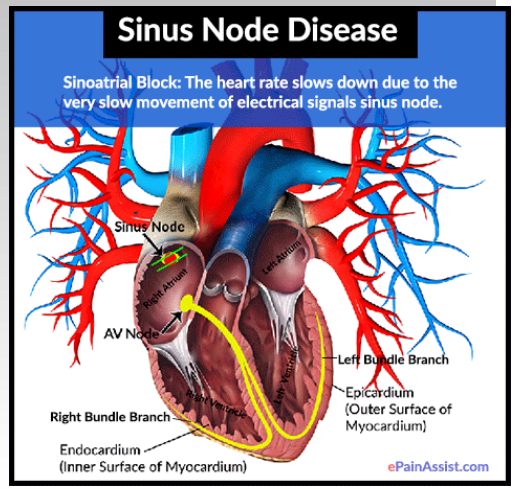
- What can I expect?
- How long do I have before I'm gone?
- Does it hurt?
- Can I work?
- Do I need help?
- How am I going to pay for this?

WEARABLE ORGANS, THE UNMET NEEDS

WHAT ARE THE GOALS

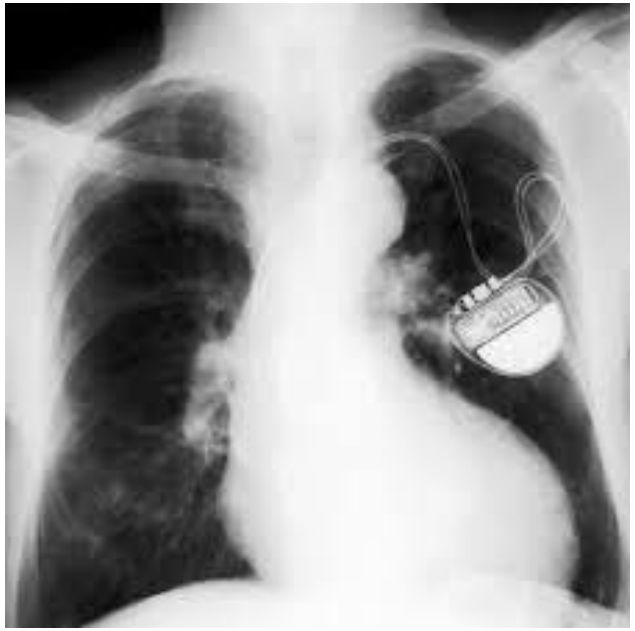
- Reduce mortality
- Improve quality of life
- Reduce cost
- Improve access
- Simplify care

UNMET NEEDS IN DIALYSIS: To improve quality of life


Sinus Node Disease
Sinoatrial Block: The heart rate slows down due to the very slow movement of electrical signals sinus node.
Sinus Node
AV Node
Left Bundle Branch
Epicardium (Outer Surface of Myocardium)
Right Bundle Branch
Endocardium (Inner Surface of Myocardium)
ePainAssist.com


epicardium
Sinus node

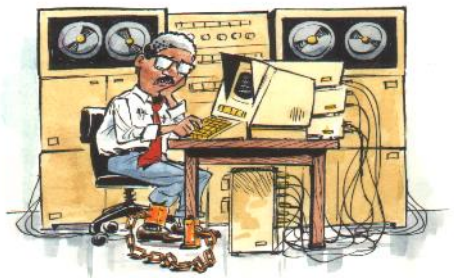

Medtronic



We can miniaturize anything and everything……

clock

computer



Why not a dialysis machine!!!?

Dialysis Today

The Lancet Dialysis with the WAK

WHY WE NEED THEM

Wearable Artificial Organs Will Disrupt They Way Medicine is Practiced Time After Time

Billions of Health Expenses Globally

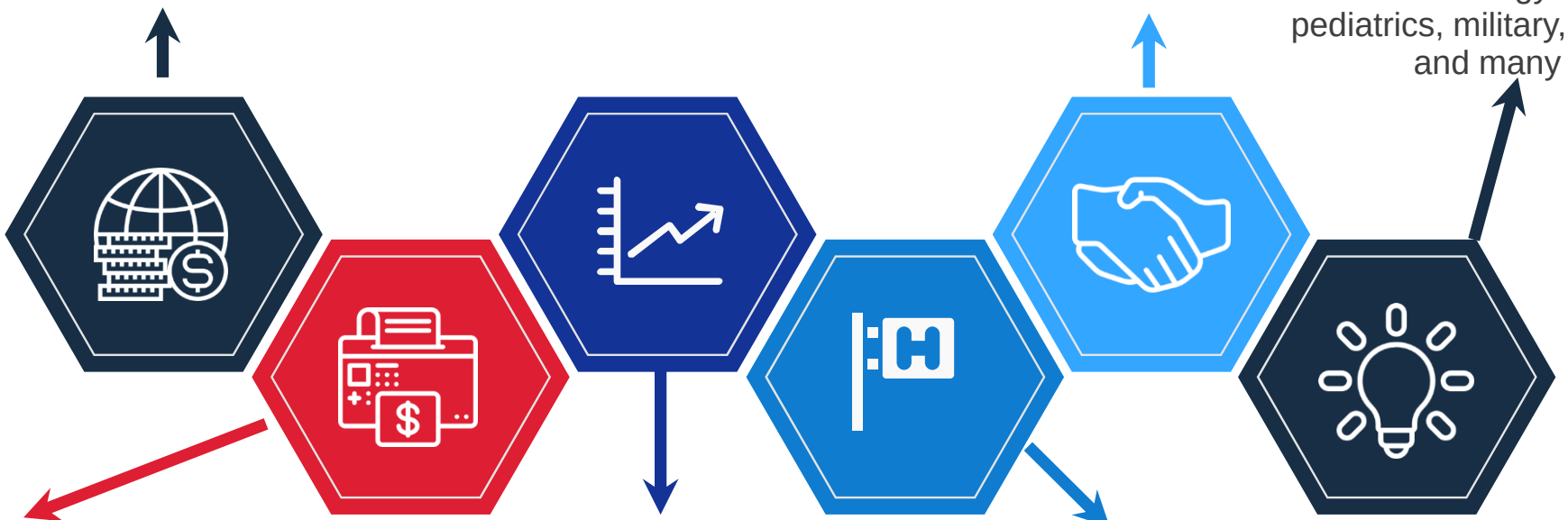
Worldwide there are millions of people with failing organs

Need for increased collaboration

Physicians, nurses engineers and.. patients.

We need IT, AI, Nano..

Better technology applications for pediatrics, military, disaster relief, and many other products



Dialysis alone $88,000+ Annual Cost

n the US, average cost per patient is $88,000…

In total $40B in for treatments and growing.

Improving life span and income

Older population, more western diets

Exorbitant Hospital Costs

Expensive technologies and drugs labor intensive, regulations

The World Cannot Afford ESRD

Eli Friedman M.D.

US CLINICAL TRIAL DATA

Peer Reviewed & Published Data

Clinical Trial Summary:

- WAK provided continuous solute clearance and volume removal capacity for patients with ESRD
- Acid-base and electrolyte homeostasis were maintained:
  - no restriction on patients' dietary choices,
  - no use of phosphorus-binding medications.
    - Hemodynamic parameters remained stable
    - Ultrafiltration was achieved as intended
  - No unexpected adverse treatment effects

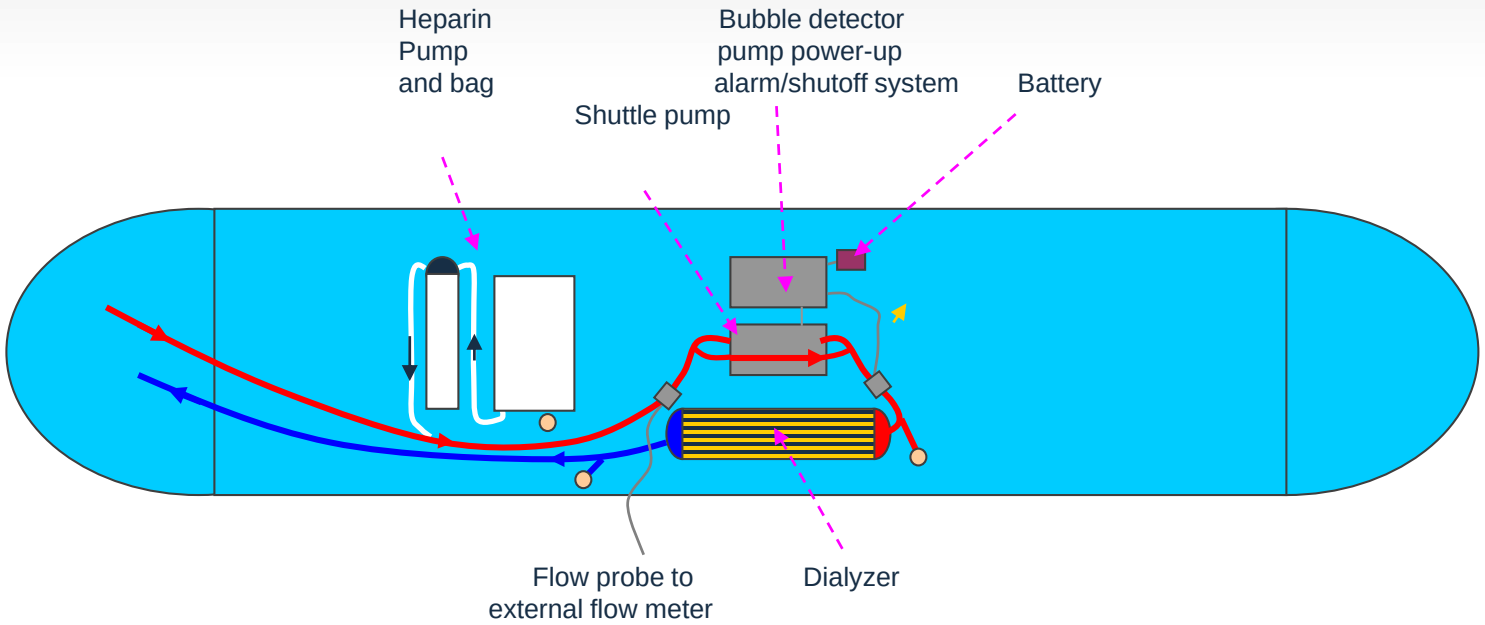
The Following 6 Slides Provide Key Data From The Study:

Table 1. Characteristics of the subjects at enrollment

Table 2. Mean plasma concentrations of blood urea nitrogen and β2-macroglobulin
Figure(A). Blood urea nitrogen (mg/dl).
Figure (B). Plasma β2-microglobulin (mg/l).

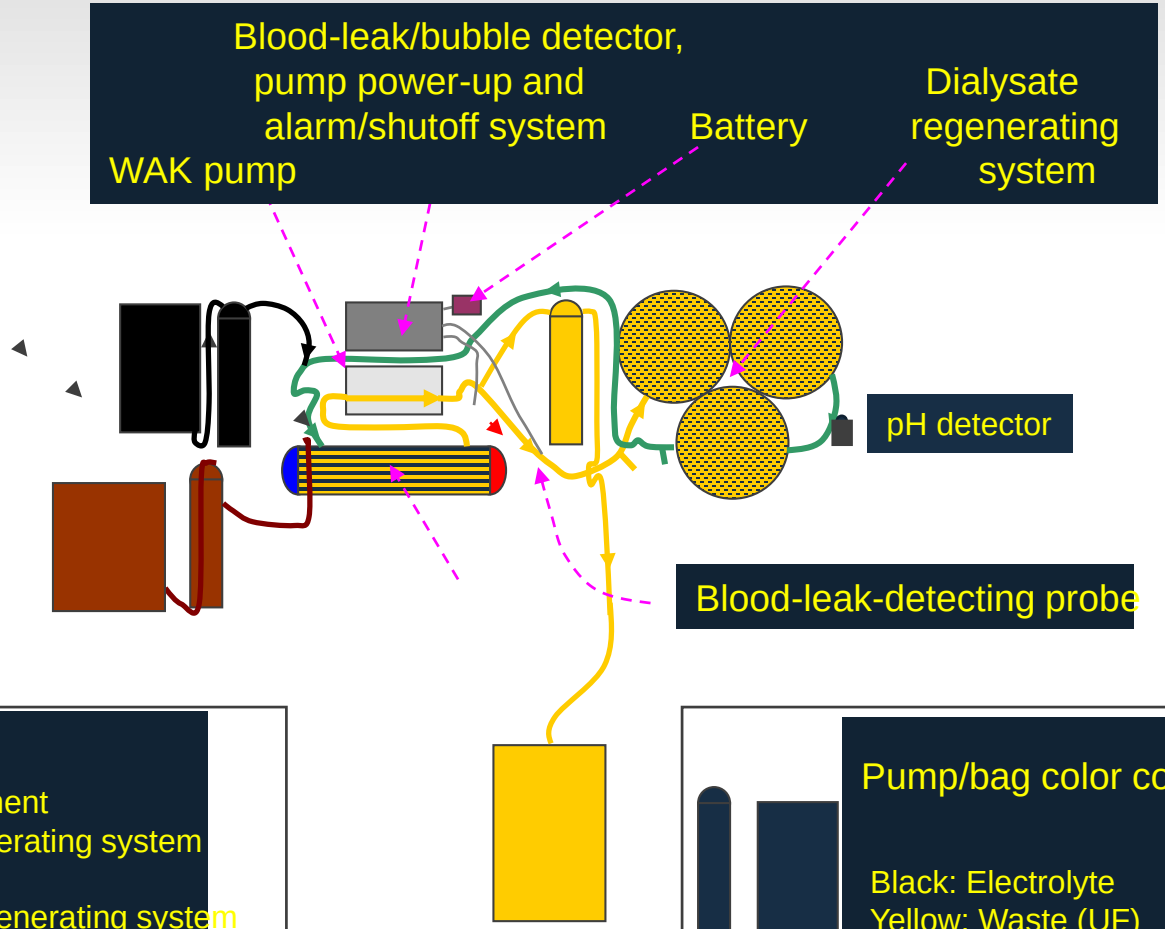
Figure 3. Summary small solute, middle molecule clearance, blood flow, dialysate flow
(A). Plasma urea, creatinine, phosphorus, β2-microglobulin clearances (ml/min)
(B). Blood and dialysate flow (ml/min).

The Wearable Artificial Kidney (WAK) Blood Circuit



Color Code
- Red: Blood from patient
- Blue: Blood to patient
- Gray: Electronics
- White: Heparin

Night Time Dialysate Circuit



Tubing color code:

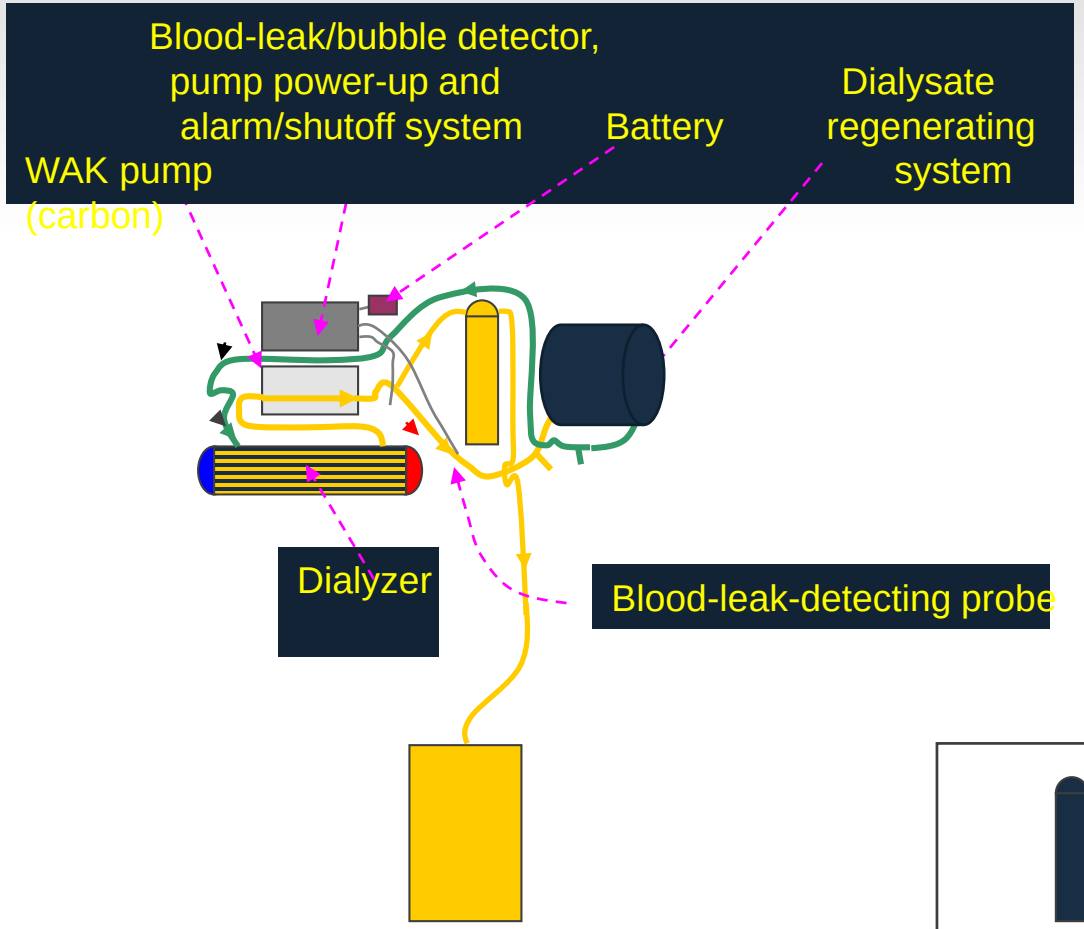
Black: Electrolyte supplement
Yellow: Dialysate to regenerating system
Brown: Bicarbonate
Green: Dialysate from regenerating system

Electronics/cables are shown in gray

Pump/bag color code:

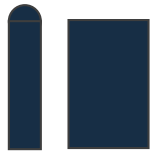
Black: Electrolyte
Yellow: Waste (UF)
Brown: Bicarbonate

Day Time Dialysate Circuit



Tubing color code:
Yellow: Dialysate to regenerating system
Brown: Bicarbonate
Green: Dialysate from regenerating system

Electronics/cables are shown in gray

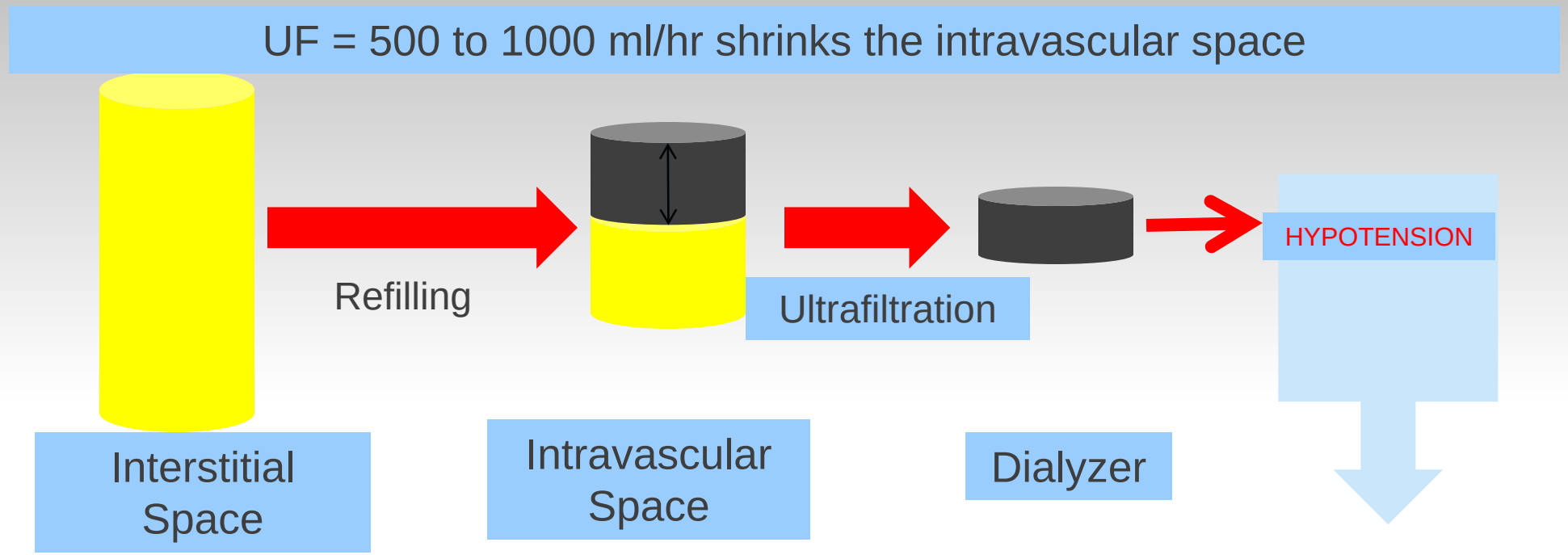


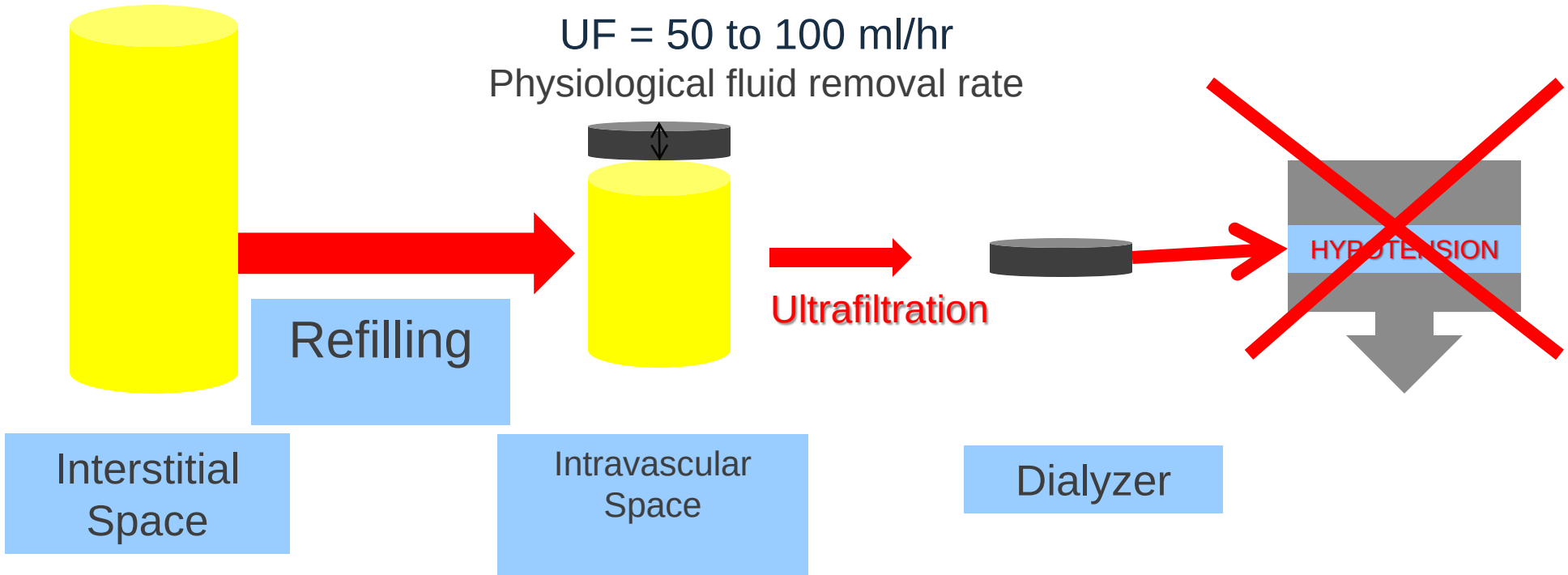
Pump/bag color code:

Yellow: Waste (UF)

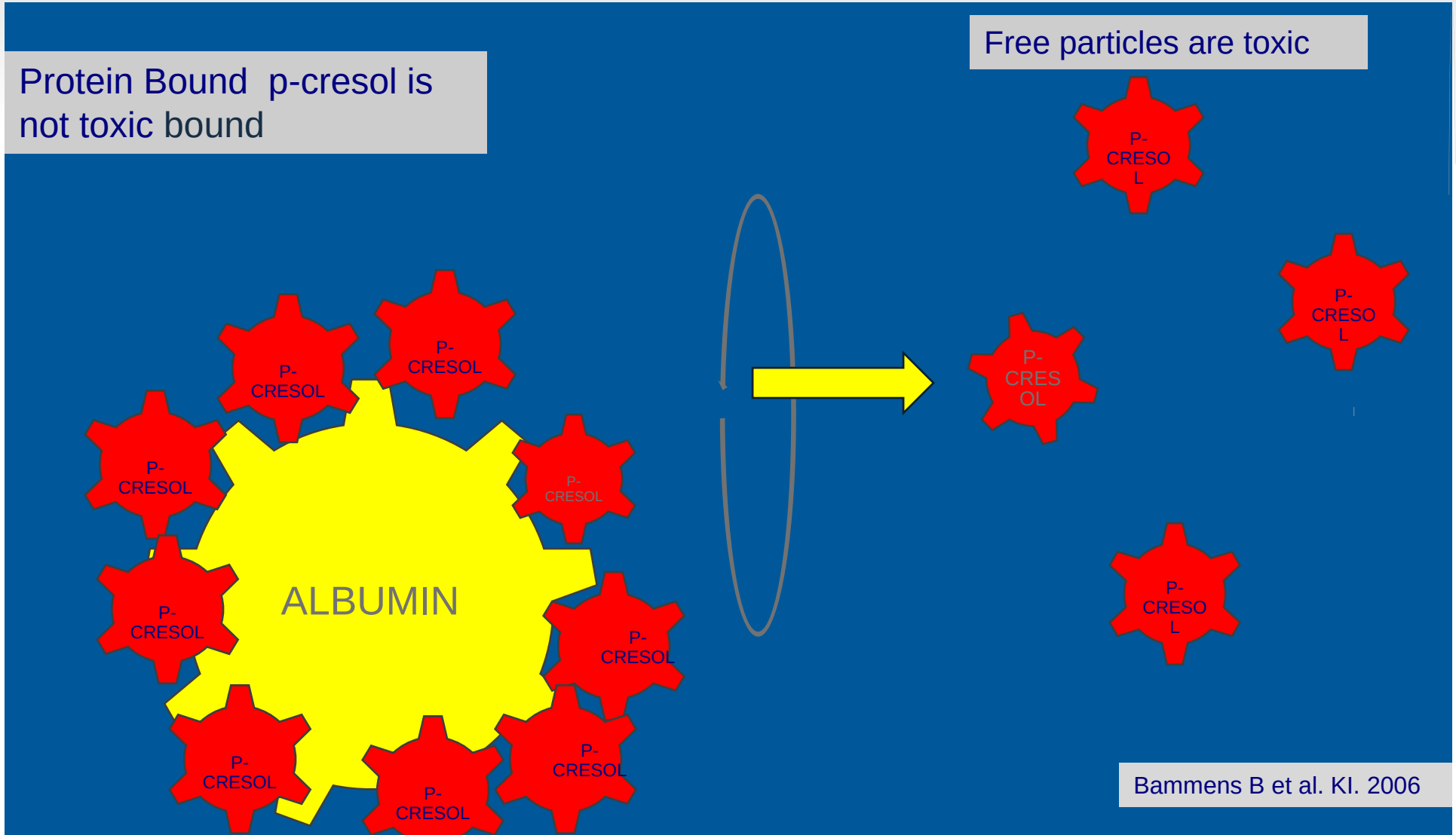
The Wearable Artificial Kidney V2.0

US Patent No. 6,960,179 and other patents


UF = 500 to 1000 ml/hr shrinks the intravascular space
Refilling
Ultrafiltration
HYPOTENSION
Interstitial Space
Intravascular Space
Dialyzer


UF = 50 to 100 ml/hr
Physiological fluid removal rate
Refilling
Ultrafiltration
HYPOTENSION
Interstitial Space
Intravascular Space
Dialyzer

Free serum concentrations of the protein-bound retention solute p-cresol predict mortality in hemodialysis patients



CLINICAL BENEFITS

Continuous (WAK) vs Intermittent (Stationary)

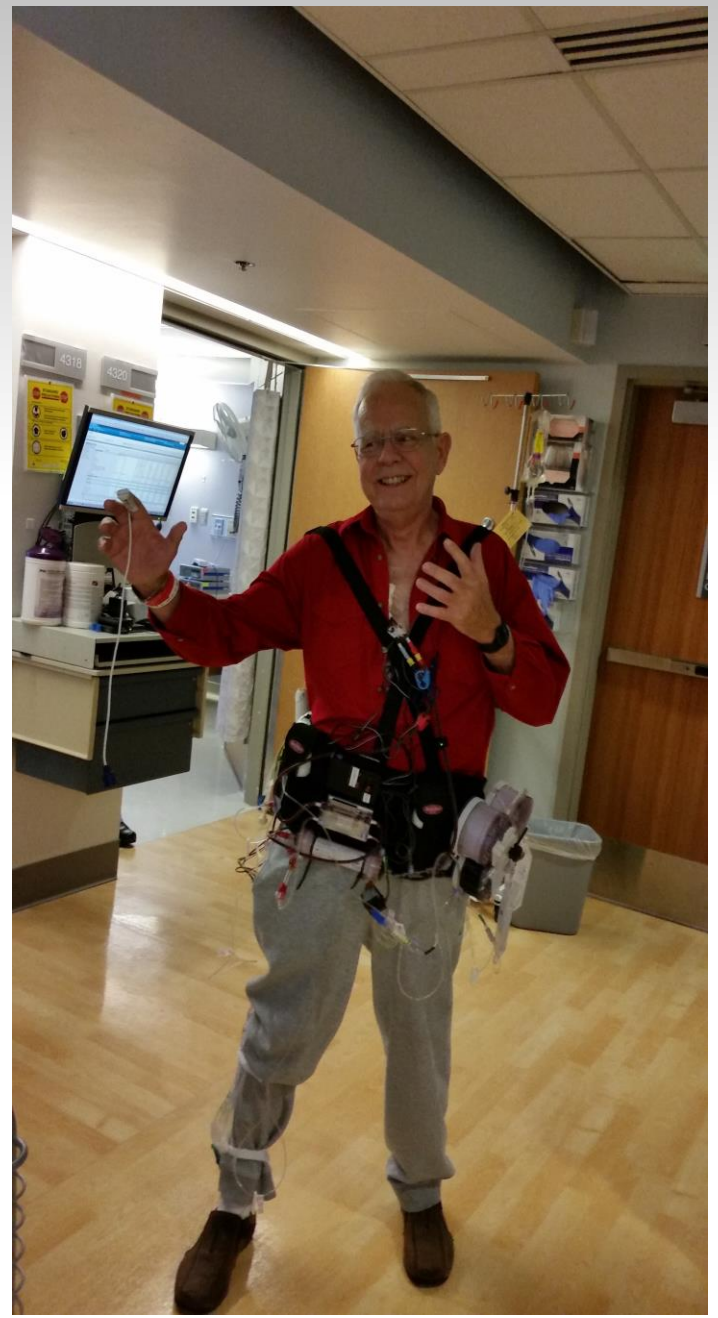
	Blood Filtration Time	Fluid Removal	Phosphorous Removal	Potassium Levels	Salt Overload	Arterio-Venous Connection	Hospitalizations
CONVENTIONAL HEMODIALYSIS (Intermittent)	9 to 12 hours per week	2 - 3+ liters in 3 - 4 hours	Insufficient: Must take many, expensive pills with stringent food restrictions	Fluctuating high & low levels can cause arrhythmia or sudden death.	Removal, requires severely limited intake	Shunt: 2 Large-bore needles; Multiple vascular surgeries	Frequent heart attacks, strokes, infections, and hypertension
WAK HEMODYALYSIS (Continuous)	Continuous 24 / 7 (168 hrs a week)	2 - 3 liters in a 24 hour period	Removes phosphorous similar to a healthy kidney, without pills	Normal levels	Removes like healthy kidney	Catheter: Tunneled under the skin	No fluid overload or salt retention
WAK ADVANTAGE	Continuously filters at **NATURAL** physiological rate	Continuous removal at **SAME RATE AS KIDNEYS**	Does NOT require food restrictions or pills. **$4B Savings a Year**	**LESS RISK OF SUDDEN DEATH** from abnormal potassium levels	Little salt. **NO HYPERTENSION, HEART DISEASE**; Patients eat normally.	**NO NEEDLE STICKS OR REPEATED SURGERIES**	Control blood pressure; **FEWER HEART ATTACKS AND STROKES**

PATIENT BENEFITS

Continuous (WAK) vs Intermittent (Stationary)

	Dietary Restrictions	Drinking Restrictions	Transportation Requirements
CONVENTIONAL HEMODIALYSIS (Intermittent)	Very little or no potatoes, dairy, citrus or juices.	No more than 800 ml/day since no water is excreted; no urine produced between sessions	Require an ambulance or van 3x per week round trip
WAK HEMODYALYSIS (Continuous)	NONE	NONE	Requires filter change 1x per week (Sterile environment)
WAK ADVANTAGE	**NO RESTRICTIONS**	**UNRESTRICTED WATER AND FLUIDS**	**MUCH FEWER** trips to doc office, hospitals, clinics

WAK 6 HOURS TRIAL



First US Human trial in progress

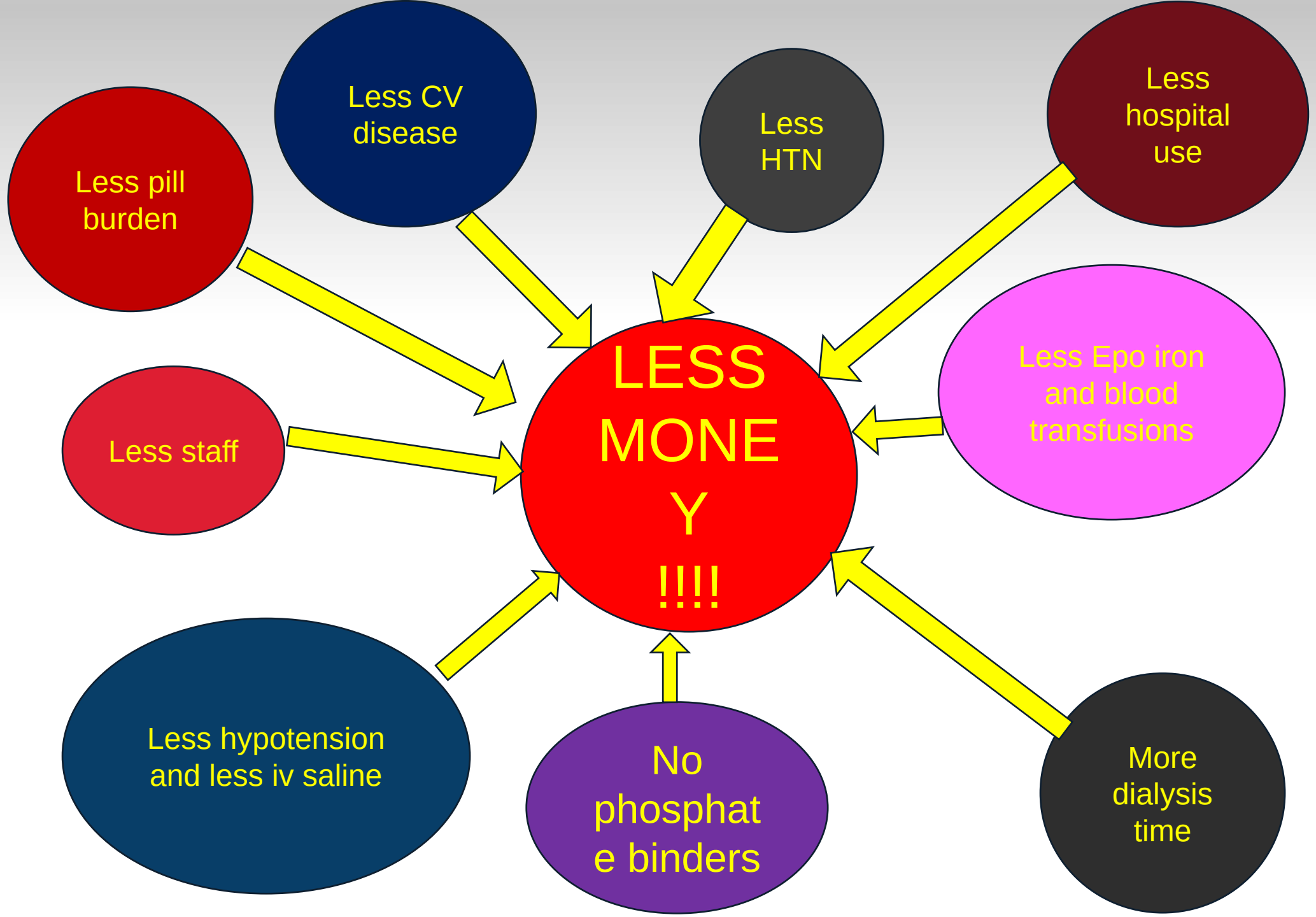

4SE8-4400
PHILIPS
m&m



CLINICAL BENEFITS: WAK VS STATIONARY

CLINICAL CRITERIA	CONVENTIONAL HEMODIALYSIS (HD)	WAK	BENEFITS: WAK vs HD
Blood Filtration Time	9 to 12 hours / week	Continuous 24 / 7 (168 hours / week)	**Continuously filters at natural physiological rate**
Fluid Removal	2 to 3+ liters in 3 to 4 hours	1.5 - 2.0 liters over 24 hour period	**Continuous removal at same rate as healthy kidneys**
Phosphorous Removal	Insufficient; patient must take numerous expensive pills, endure food restrictions	Removes like healthy kidney, no pills	**No food restrictions; no pills = $4B Savings / Year**
Potassium Levels	Fluctuating high / low levels can cause arrhythmias, sudden death.	Normal	**No food restrictions; no risk of sudden death from abnormal potassium levels**
Salt overload	Removal, requires severely limited intake	Removes like healthy kidney	**Patients eat normally, incl. salt; No hypertension, heart disease**
Arterio-venous connection	Shunt: 2 Large-bore needles; Multiple vascular surgeries	Catheter: Tunneled under the skin	**No needle sticks or repeated surgeries**
Hospitalizations	Frequent heart attacks, strokes infections, hypertension	No fluid overload or salt retention	**Control blood pressure; Fewer heart attacks, strokes**
KEY PATIENT ISSUES			
Restrictions: Dietary	Very little or no potatoes, dairy, citrus or juices.	None	**No restrictions, incl. salt**
Restrictions: Drinking	No more than 800 ml/day since no water is excreted; patients make no urine in between dialysis sessions	None	**Unrestricted salt, water and other fluid intake**
Transportation	Ambulance or van 3x / Wk round trip	Requires 1x / Wk filter change (Sterile environment)	**Fewer trips to doc office, hospitals, clinics**


Fresenius Medical Care
Anderson Dialysis
Pelzer
Rescue
Squad
AMBULANCE


Less pill burden
Less CV disease
Less HTN
Less hospital use
LESS MONEY !!!!
Less staff
Less Epo iron and blood transfusions
Less hypotension and less iv saline
No phosphate binders
More dialysis time


Inventions have long since reached and I see no hope for further developments….
Julius Sextus Frontinus (Roman Engineer 10 AD)
The Americans have need of the telephone but we do not. We have plenty of messenger boys…
Sir William Preece (Chief Engineer. British Post Office. 1878)
I think there is a world market for maybe five computers……
Thomas Watson. (Chairman. IBM. 1943

The WAO Team Thanks You!

WAO

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Blood access via outpatient catheter placement