

The Future of Dialysis

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Who am I?

Fresenius Medical Care Since 1994.

- Reuse Technician
- Equipment Technician
- Area Chief Technician
- Central Technical Program Manager
- Corporate Technical Support Manager
- Corporate Director of Biomedical Support Services
 - Member FMC Patient Safety Organization
 - Member FMC Disaster Response Team
 - Member FMC Biomedical Advisory Board
 - NNCO Board Member

Disclaimer

The following represents what I believe the future holds for the industry. Some of the items I will discuss are not 510k approved by the FDA or approved for use by regulatory agencies.

I am a Techy Geek

I am a Red Sox and New England Patriots Fan



Dialysis...the final frontier.

**These are the voyages of the starship
Hemodialysis.**

**A five year mission to explore strange new
treatment options.**

**To seek out improvements in dialysate quality
and patient outcomes.**

**And to bundle like no others have bundled
before.**

www.free-background-wallpaper.com

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Time Travel!



Yours may look like this?



We have come a long way in 70 years!



Kolff and Berk Haemodialysis Machine. Circa 1943. Photo courtesy of Renal Unit of the Royal Infirmary of Edinburgh.

Time Travel to 2002

Dialysis Times, News and Views From RRI. What Industry Experts Said in 2002:

Peter Crooks MD, Optimal Renal Healthcare

Hector Rodriguez MD, Gambro Healthcare

Charles McAllister MD, CMO Davita

Michael Lazarus MD, Fresenius Medical Care

Industry Experts Said in 2002:

- Wide adoption of improved kinetic measures –equilibrated (double-pool) and standardized (weekly) Kt/V.
- Participation of the dialysis industry in pre-ESRD care to deliver healthier, self-empowered dialysis patients.
- Increased hemodialysis frequency for patients with persistent fluid overload, CHF and/or uncontrollable hypertension.
- More flexible scheduling with staggering of on times for hemodialysis patients.
- Increased corporate commitment to dialysis facility employees, i.e. provide a clear career ladder, profit sharing.

Industry Experts Said in 2002:



capitation for ESRD care (since can transfer hospital savings into dialysis care)

Dialysis Times, News and Views From RRI. August 2002. Vol. 9, No.3. Renal Research Institute. Image courtesy of VGo Communications, Inc

BACK
TO
THE FUTURE

What does the future of dialysis look like?

ESRD Prevalence and Meeting the Demand

- Patients
- Modalities

Improving Patient Care Through Technology

- Advances in Technology
- Sodium Control
- Ultrapure Dialysate
- Automation

ESRD Prevalence

Population continues to grow.

Diabetes population continues to rise. American Diabetes Association (2012) reports the following:

- **Total prevalence of diabetes**
- 25.8 million children and adults in the United States—8.3% of the population—have diabetes.
- **Diagnosed:** 18.8 million people
- **Undiagnosed:** 7.0 million people
- **Prediabetes:** 79 million people*
- **New Cases:** 1.9 million new cases of diabetes are diagnosed in people aged 20 years and older in 2010.
- Diabetes is the leading cause of kidney failure, accounting for 44% of new cases in 2008.

ESRD Prevalence

Dialysis Industry will need to meet prevalence rates.

- Home Dialysis
 - Peritoneal Dialysis
 - NxStage®
 - Fresenius (2008K@Home®, Sorbent)
 - Home Monitoring Systems (Weight, Glucose, BP)
 - Other systems to be introduced.
- Nocturnal Dialysis (more frequent and longer dialysis)
 - Home
 - Incenter
- Incenter Dialysis
 - Increasing the number of beds available.
 - Better facility design = Treatment Modalities, Improve Staff Efficiency (Lean)
- Inpatient
 - New and existing patient needs
 - Newer technology = Dialysis Machines, Water Treatment

Sorbent Technology



Redy Image courtesy of Advanced Renal Education.

<http://www.advancedrenaleducation.com/SorbentTechnology/HistoryofSorbentTechnology/tabid/587/Default.aspx>

What do sorbents bring to the future?

Mobility (Small)

- No RO attached
- No special hook ups or drains

Portability (Smaller)

- Low water volume
 - No structural modifications needed
 - Uses 6 liters of ordinary tap water
- Light weight for transportation

Wearability (Smallest)

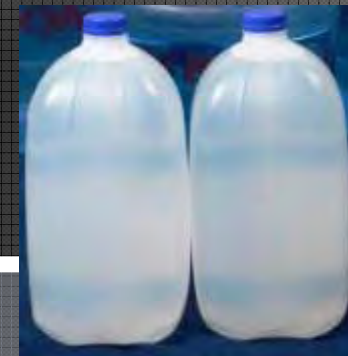
- Belt/Vest/Purse concepts

Conservation?

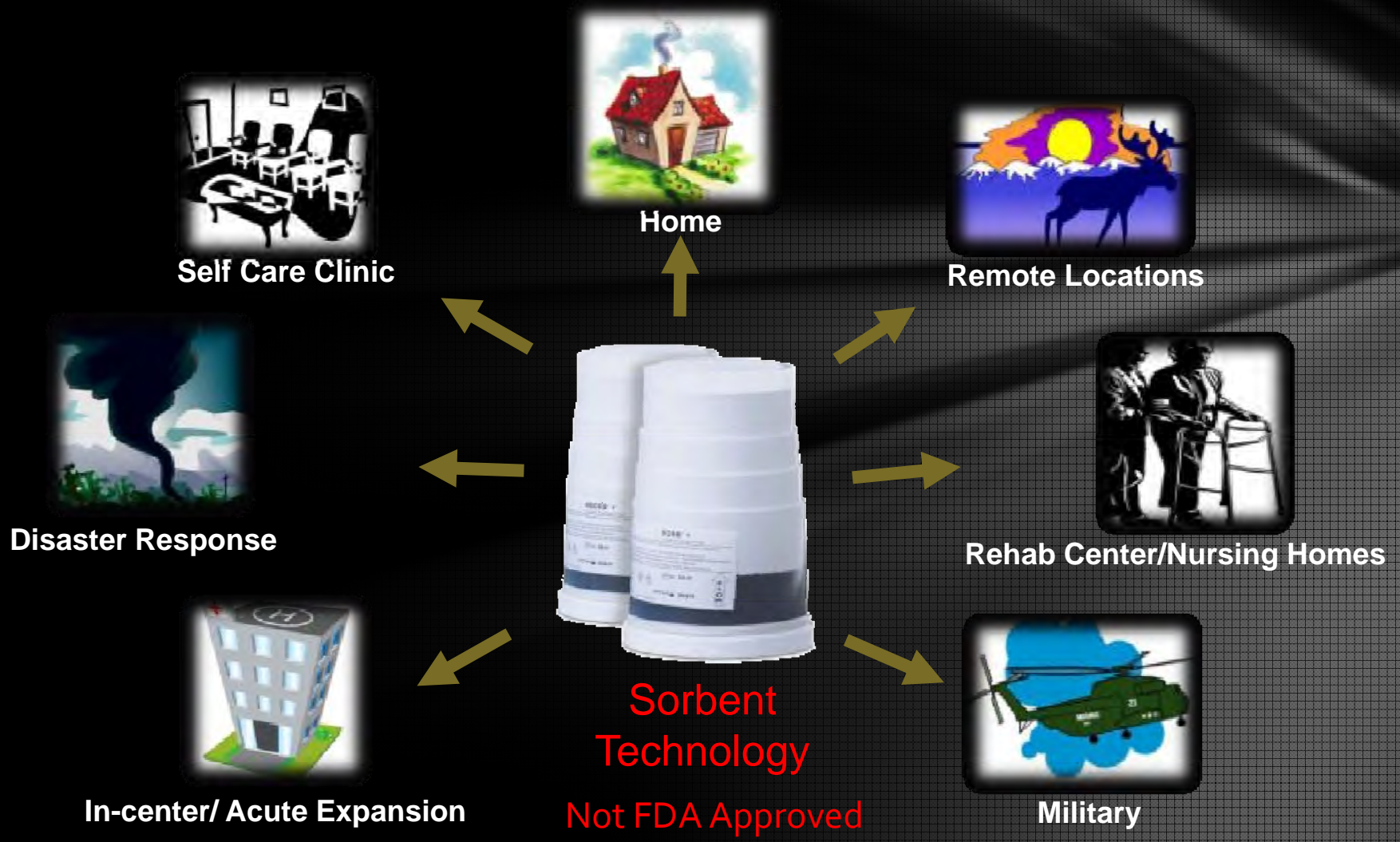
Is there another use for our water? The typical single pass dialysis machine running at 500cc/min for 4 hours uses enough potable water to take a bath



Sorbent Dialysis uses as little as 2 gallons of water and requires no special water processing for the same treatment parameters



The Range of Future Possibilities

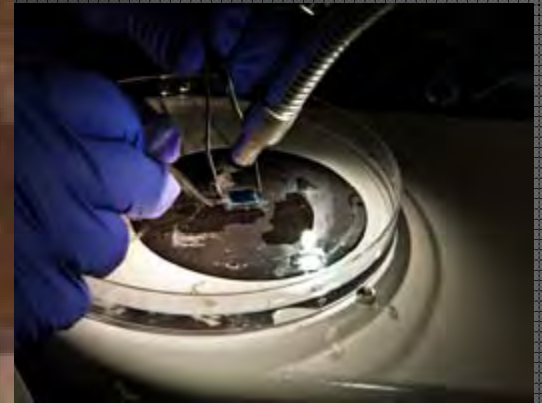


Advancing Technology - Implantability

Scientist C. Edward Jennings of Houston Texas

Shuvo Roy, PhD - UCSF

Implantable Artificial Kidney



Not FDA Approved

Improving Patient Care Through Technology

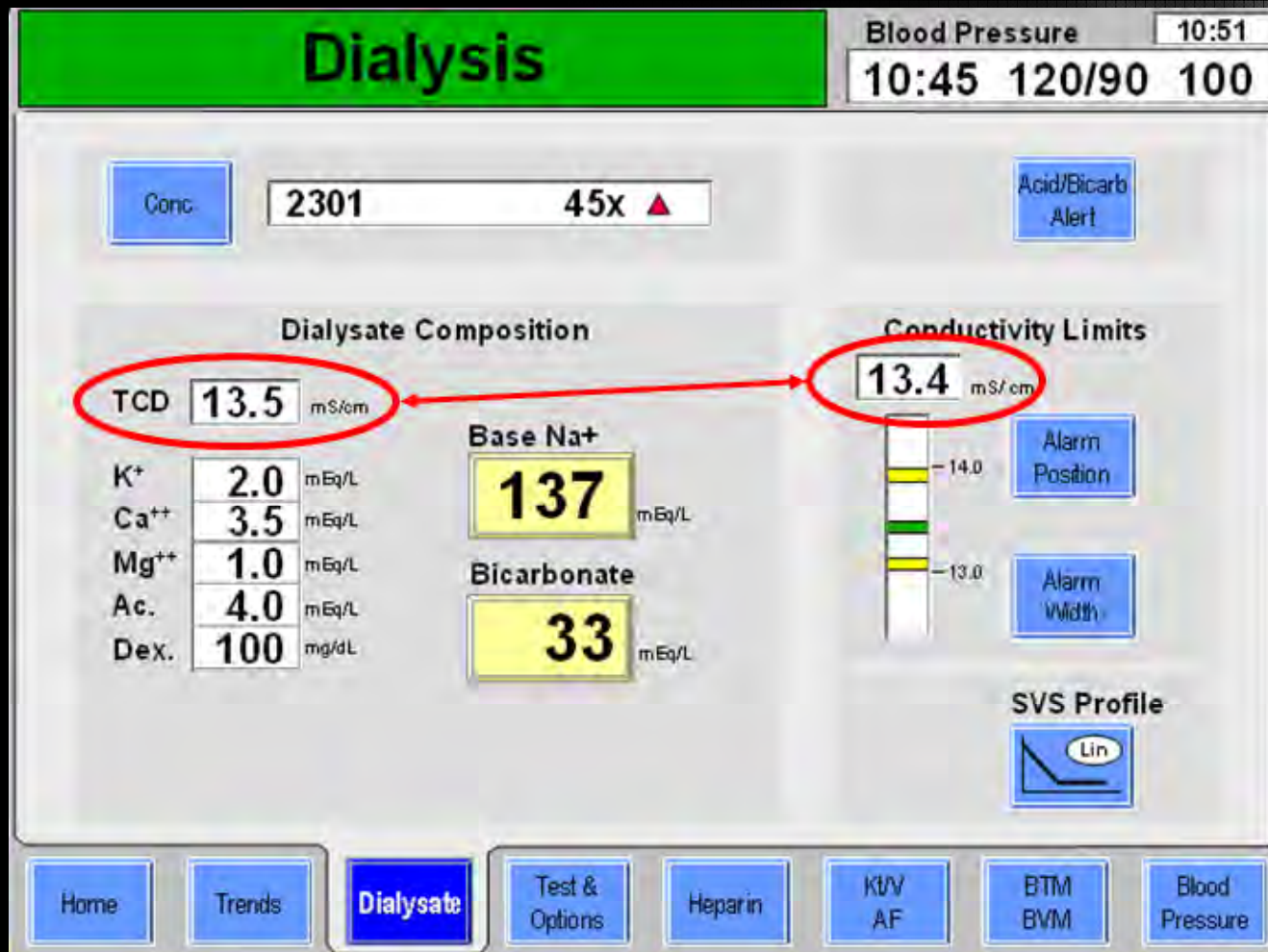


Improving Patient Care Through Technology

Controlling Sodium

- Accurate delivery of sodium to hemodialysis patients.
 - Dialysis machine setting = actual vs. nominal conductivity

Target(theoretical) vs. Actual Conductivity

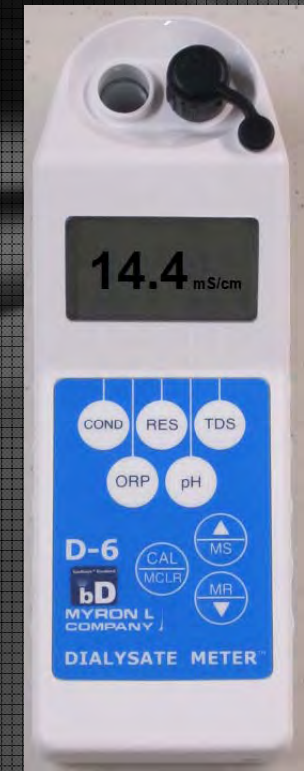
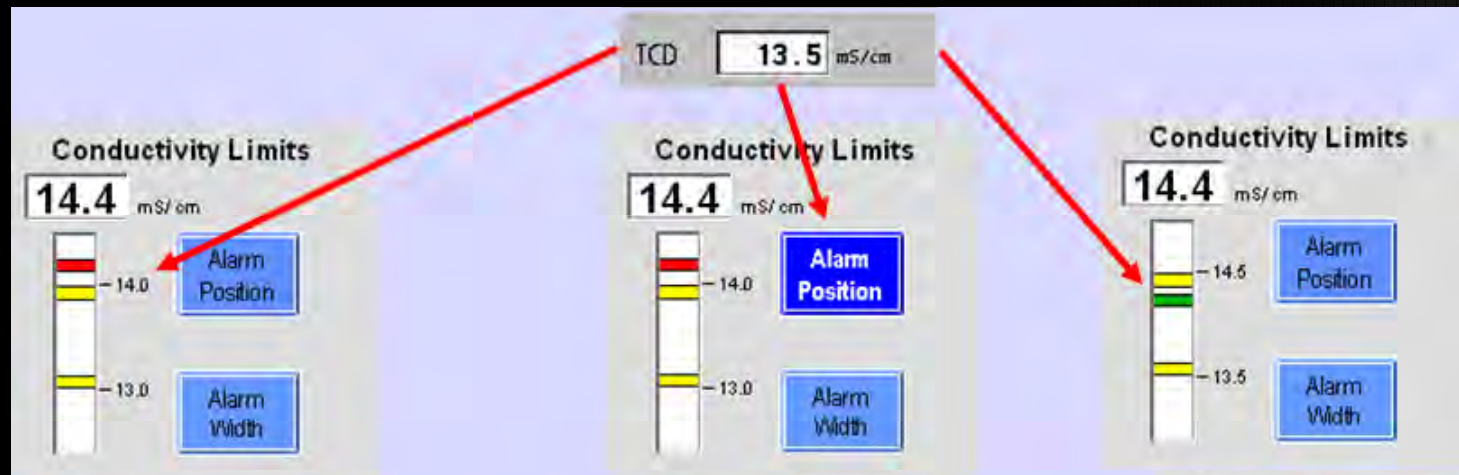


Improving Patient Care Through Technology

Improving the delivery of sodium

- Accurate delivery of sodium to hemodialysis patients.
 - Dialysis machine setting & actual vs nominal conductivity
 - Calibrations = Dialysis Machine, concentrate mixing equipment, concentrate delivery equipment, meters = (process validation)

Target(theoretical) vs. Actual Conductivity



Improving Patient Care Through Technology

Improving the delivery of sodium

- Accurate delivery of sodium to hemodialysis patients.
 - Dialysis machine setting & actual vs nominal conductivity
 - Calibrations = Dialysis Machine, concentrate mixing equipment, concentrate delivery equipment, meters = (process validation)
 - What if we had fixed conductivity limits?

Improving Patient Care Through Technology

Total Buffer – What if the machine displayed total buffer rather than bicarb.

Increase use of individualized treatments rather than clinic wide machine settings.

Ultrapure Dialysate – Quality & Regulatory

- Studies demonstrate improved patient outcomes.
- Right thing to do for our patients.
- Could it become a regulatory requirement?

Improving Patient Care Through Technology

Increase use of automation

- Dialysis Machines
- Concentrate Equipment
- Water Purification

Improving Patient Care Through Technology

Dialysis Machines

- Requirements for machines knowledge has and will continue to change.
 - Less knowledge of advance electronics = Basic Electronics
 - More knowledge in dialysis physiology

Improving Patient Care Through Technology

Concentrate Equipment Design Changes

- Reduction of mixing errors:
 - Timed mixing = loss of bicarbonate
 - Temperature control = assure full dissolution
 - Correct volumes = Powder to water ratios.
- On demand – reduce staff time mixing and handling.
 - BiCart®
 - Bibag®



Improving Patient Care Through Technology

Water Purification

- Reduced bioburden – Reduced CIS
- Automation:
 - Disinfection – Heat, Ozone
 - Online Quality Monitors - Chemical

Process Validation (AAMI/ISO)

- Process Design
- Process Qualification
- Continued Process Verification

Risk Analysis/Mitigation – FMEA (Lean, 6 Sigma)

Improving Patient Care Through Technology

Increased use of IT systems (automation) to improve:

- Patient Safety
- Regulatory Compliance
 - Water Testing
 - Equipment Maintenance
- Efficiency
 - Staff
 - Financial
- Reporting and Trending

Regulatory Affect on Technology/Future

AAMI → ISO

CMS

- Adoption of RD52 & RD62
- When will they incorporate ISO?

TJC - Inpatient

- Adoption of AAMI / ISO documents

FDA

How involved are you in this process?

- Your company involved?
- Do you review and comment on CMS Policy development?
- Voice your concerns

What can you do to prepare for the future?

- Develop a greater understanding of the various modalities and how you can support them.
- Physiology of Dialysis (How does what we do affect our patient both positively and adversely?)
- Process Validation
- Risk Analysis & Mitigation = How can you find ways to help keep our patient safe.
- Lean and 6 sigma Training

“Everyone here has the sense that right now is one of those moments when we are influencing the future.”

Steve Jobs (1955 – 2011)

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