



**Water Quality
Criteria Control (WQCC)
of Dialysate:
:Meeting the ISO Standard**

Tadaaki IGOSHI

June 2, 2012, Charlotte, NC



History of ISO Standards related with Dialysis Water & Fluid



TC150 / SC2 / WG5

- TC150 → Implants for surgery
- / SC2 → Cardiovascular Implants
and extracorporeal systems
- / WG5 → Renal replacement,
detoxification and apheresis

Steps for ISO standardization





Development of International Standards (1)

- Jan. 2004: USA proposed draft based on ANSI/AAMI RD52 about control of dialysis fluid
- Sept. 2004: Accepted as draft at ISO meeting
- Oct. 2005: Started to discuss **23500** regarding dialysis fluid and its control

Besides **13958**: concentration,
13959: dialysis water,
26722: water treatment system



Development of International Standards (2)

**13958, 13959, 26722, 11663
were established and published on
Apr. 15, 2009**

**23500 was established and published
on May 15, 2011**



Japanese quality standard for dialysis water and dialysis fluid

(Microbiological contaminants)

Maximum allowable level for TVC

	Dialysis Water	Standard Dialysis Fluid	Ultra-pure Dialysis Fluid	On-Line Prepared Substitution Fluid
I S O 2 3 5 0 0	< 1 0 0 (CFU/mL)	< 1 0 0 (CFU/mL)	< 0.1 (CFU/mL)	Sterile
J S D T 2 0 0 8	< 1 0 0 (CFU/mL)	< 1 0 0 (CFU/mL)	< 0.1 (CFU/mL)	< 1 0⁻⁶ (CFU/mL)

Maximum allowable level for ET

	Dialysis Water	Standard Dialysis Fluid	Ultra-pure Dialysis Fluid	On-Line Prepared Substitution Fluid
I S O 2 3 5 0 0	< 0. 2 5 0 (EU/mL)	< 0. 5 0 0 (EU/mL)	< 0. 0 3 0 (EU/mL)	Non-pyrogenic
J S D T 2 0 0 8	< 0. 0 5 0 (EU/mL)	< 0. 0 5 0 (EU/mL)	< 0. 0 0 1 (EU/mL)	< 0. 0 0 1 (EU/mL)



RO System and Heat Disinfection



RO membrane

- Reverse Osmosis Membrane
(RO membrane)
 - Membrane to have characteristic that water can permeate, but ions or electrolytes are trapped.
 - Pore size is around less than 2 nm or equal.



LRO membrane

- Loose Reverse Osmosis Membrane (LRO membrane)
- Membrane to have characteristic that less than 60% of ions or electrolytes are trapped.
- Water permeability per unit area is larger than that of RO membrane.



Feature of Double-stage treatment I

I : Water Quality Improved Further

- **Double-stage treatment with LRO and RO module**

LRO module is laid before RO module and the treated water with LRO module is re-treated with RO module.



Feature of Double-stage treatment II

II : Work & Energy Saved

- No Softener

- Decrease contaminated source and labor to operate
- No tank or stock area for sodium chloride



Central Dialysis fluid Delivery System

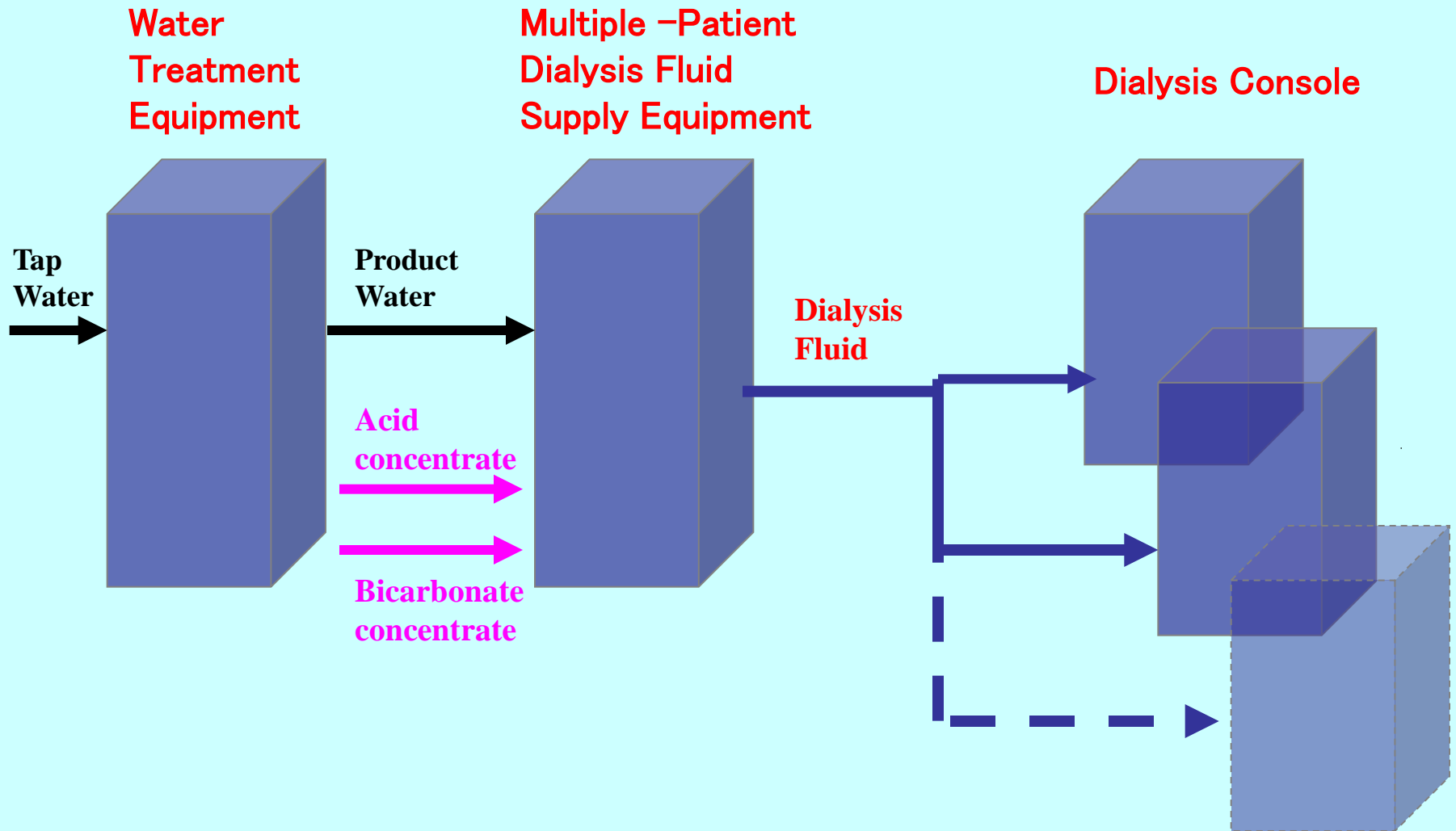


New Term and Definition

- **Central Dialysis fluid Delivery System (CDDS)**

system that produces dialysis fluid from dialysis water and concentrate or powder at a central point and distributes the dialysis fluid from the central point to individual dialysis machines

Central Dialysis Fluid Delivery System (CDDS)



Outline of CDDS

