ISO Compliance With Advanced Water Purification Technology

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Mar Cor Purification
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Topics for Discussion

- AAMI Adoption of ISO Standards
- ISO Standards
- Sensitivity Studies
- Keys to Consistent ISO Compliance
- Hot Water Disinfection Systems
- High Purity Water Distribution Systems
- Posiclear Capsule Filter
Adoption Process


- United States adopted five standards related to fluids for dialysis developed by International Organization for Standardization (ISO).

- United States in line with other areas of the world, Europe and Japan.
New ISO Standards for Fluids and Fluid Handling in Dialysis (Published April 15, 2009)

- **ISO 13958:2009** Concentrates for hemodialysis and related therapies. ANSI/AAMI RD61
- **ISO 13959:2009** Water for hemodialysis and related therapies. ANSI/AAMI RD62
- **ISO 26722:2009** Water treatment equipment for hemodialysis applications and related therapies. ANSI/AAMI RD62
- **ISO 11663:2009** Quality of Dialysis fluid for hemodialysis and related therapies. ANSI/AAMI RD52
- **ISO 23500:2011** Guidance for the preparation and quality management of fluids for hemodialysis and related therapies. ANSI/AAMI RD52
AAMI/ISO Standards

• **Microbial Standards**
  • **Current AAMI RD52:2004 Standard**
    • Bacteria <200 CFU/ml and <2 EU/ml
    • Action Level <100 CFU/ml and <1 EU/ml
  • **New ISO Standard ISO/FDIS 13959:2009**
    • Bacteria <100 CFU/ml and <0.25 EU/ml
    • Action Level <50 CFU/ml and <0.125 EU/ml

• **Testing Methods**
  • **Current AAMI RD52:2004 Standard**
    • 2004, TSA Agar, 35 C, 48 hours
  • **New ISO Standard ISO/FDIS 13959:2009**
    • 2009, TGEA, R2A Agar, 17-23 C, 168 hours
### CULTIVATION

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**INCUBATION TIME (Days)**

1 2 3 4 5 6 7

**Temperature** 17 – 23°C
DIALYSIS UNIT 050601

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Incubation: 3 days at 35° C
Keys to Consistent ISO Compliance

- Frequent, complete disinfection of the RO and distribution system.
  - Proactive
  - Wetted surfaces

- Distribution system materials designed for high purity fluid delivery.
  - Smooth internal lumen, minimal surface area, low complexity.
  - Materials should not contribute impurities.

- Point of use bacteria/endotoxin filtration.
  - Absolute filtration of pyrogen/endotoxin.
Advanced Water Purification Technology

- Automated, Hot Water Disinfection Systems
  - Central RO Systems
  - Portable RO Systems

- High Purity Water Distribution Systems
  - Medical Grade CleanPEX
  - Microfree Teflon

- Point of Use Endotoxin Filters
  - Posiclear Capsule Filter
Mar Cor CWP H

- Manufactured in Plymouth, Minnesota beginning March 2011.
- Over 700 systems installed
- Closed loop, direct feed purified water production.
- Automated, nightly hot water disinfection of the distribution system.
- End to end hot water provides cleaning of inlet water line and kidney machines.
Mar Cor 4400HX

- Multiple skid design
- Hot water disinfection of RO & Loop
- Pretreatment off skid
- Design is available in several configurations
  - Cold RO/Hot loop
  - Hot RO/Hot Loop
  - Direct/Indirect feed
Mar Cor WRO 300 H

- Weekly hot water disinfection of complete RO.
- Alternative heat programs.
  - Manual
  - Automatic
Mar Cor Millenium HX (MHX)

- Newest portable RO product.
- Designed with the home and acute environment in mind.
- Hot water disinfection while disconnected from water.
- Remote data collection and view.
- Early stages of product launch.
CleanPEX Distribution Loop Piping

- CleanPEX comes in 100 meter rolls and can bend around corners.
- The joints are polished stainless steel barbs with no glue or other chemical solvents.
- Smooth inner surface for the entire distribution loop.
- Ranked 2nd lowest microbial attachment in study.
- Tolerates hot water for disinfection – 90 C.
Microfree Teflon Loop

• Proven performance attributes
  • Smooth wall – Biofilm resistant, low friction, high flow velocity.
  • Fast rinse of chemical sanitizers.
  • Few and clean fittings/couplings.
  • Compatible with wide array of disinfection options.
  • Regulatory recognition, approval for use
  • Ease of installation
  • Ranked #1 in attachment study.
Posiclear Capsule Filter

- FDA 510(k) cleared.
- Positively charged, pleated membrane.
- Filters through size exclusion and adsorption.
- 0.2 micron absolute filter.
- Hot water (90 C) and peracetic acid compatible for disinfection.
- High flow rate up to 2 GPM.
- Replace every 6 months or with significant decrease in flow rate.
Thank You