

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

- AAMI Standards for hemodialysis major review 2009-2010. RD52:2004 and RD62:2006
- 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.

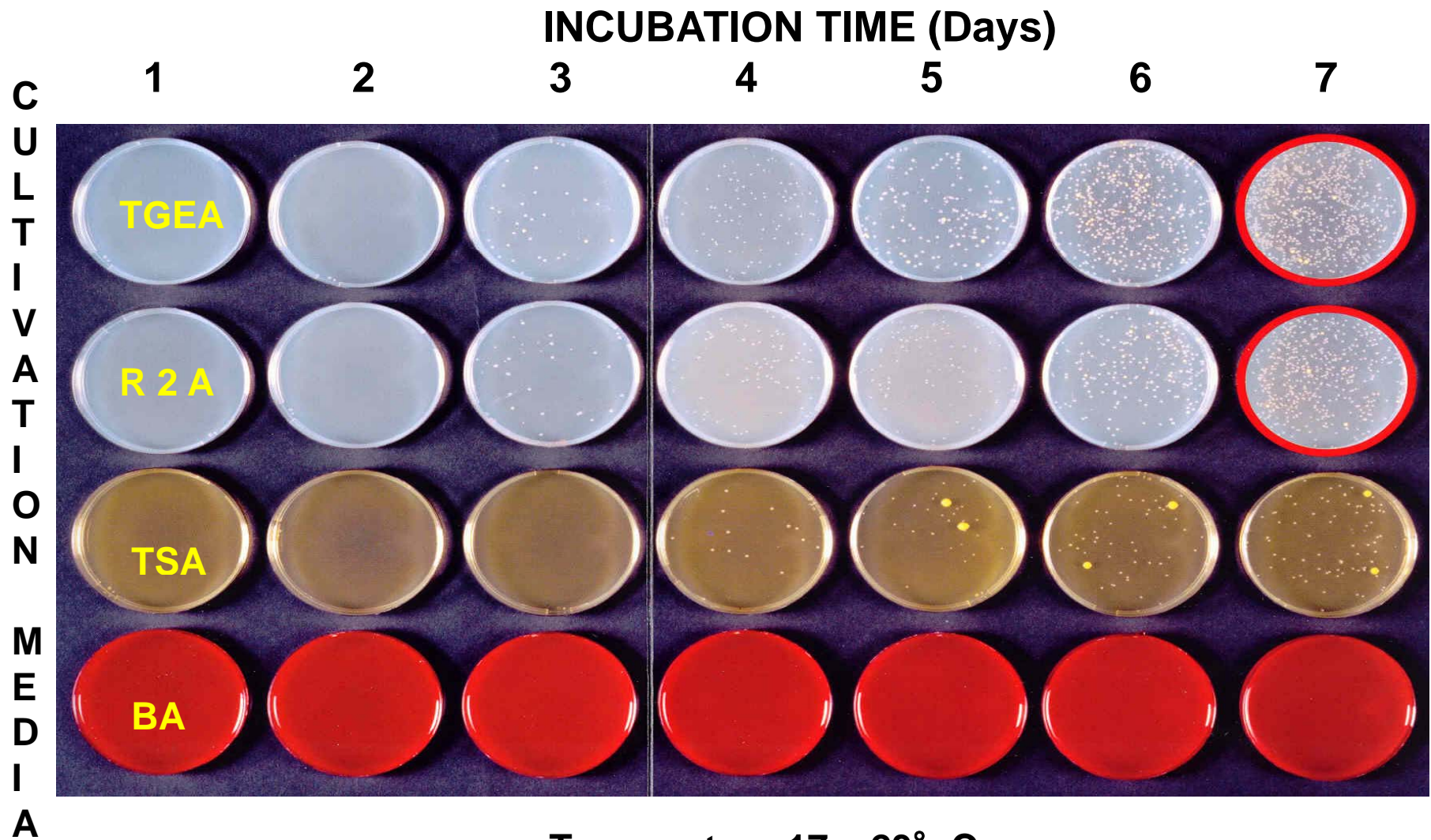
New ISO Standards for Fluids and Fluid Handling in Dialysis (Published April 15, 2009)

- **ISO 13958:2009** Concentrates for hemodialysis and related therapies. ANSI/AAMI RD61
- **ISO 13959:2009** Water for hemodialysis and related therapies. ANSI/AMMI 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 <.25 EU/ml
 - Action Level <50 CFU/ml and <.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



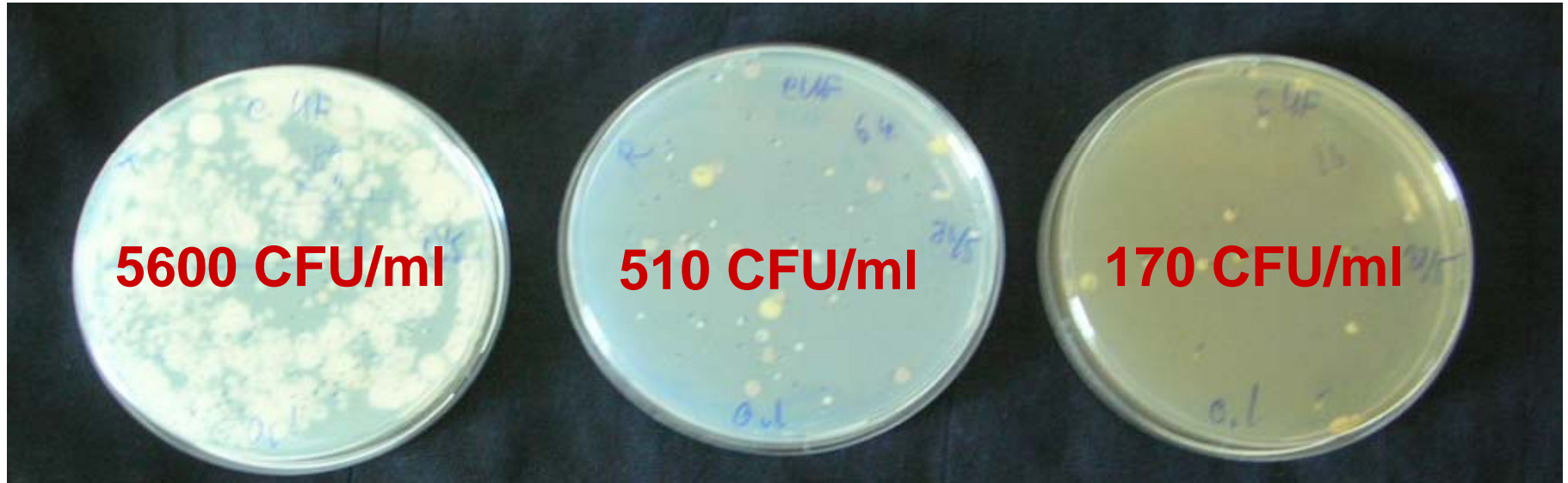
Temperature 17 – 23° C

DIALYSIS UNIT 050601

TGEA

R 2 A

TSA



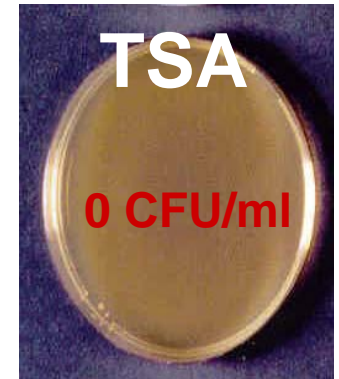
5600 CFU/ml

510 CFU/ml

170 CFU/ml

INCUBATION: 7 days at 17 – 23° C

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.

CWP 100 RO System
5,000 to 13,000 GPD



1998

Self contained design, hot water
loop disinfection

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



WRO 300
WRO 300 H

Efficient water purification
at your fingertips

- Two new water purification units from Gambrö
- Simple cleaning and disinfection procedures
- The WRO 300 H even offers hot water disinfection

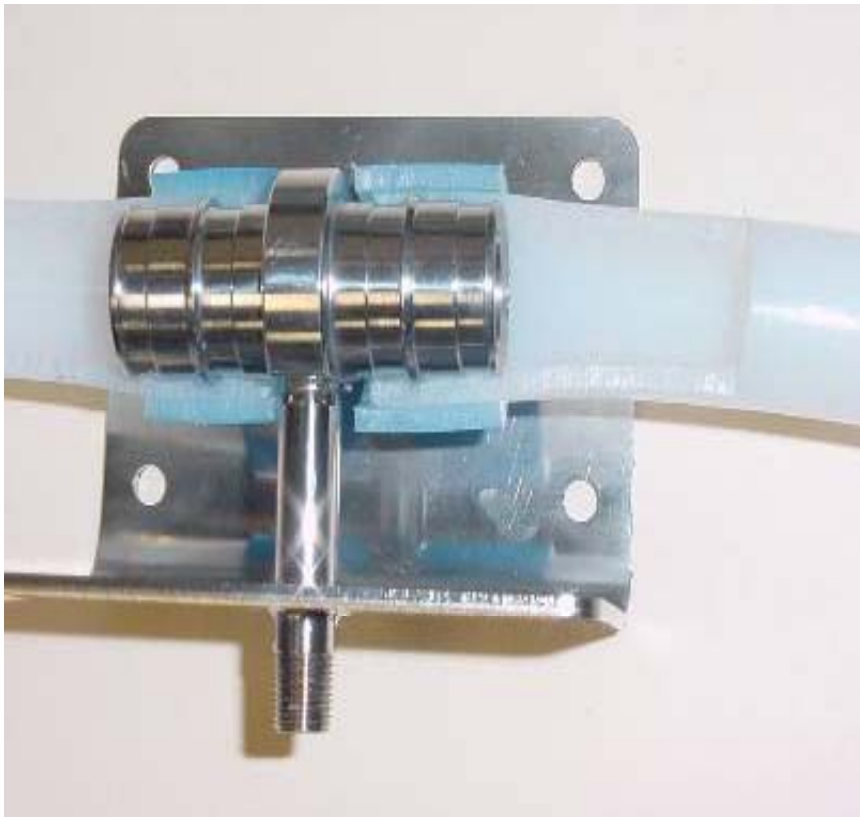


Mar Cor Millenium HX (MHX)

- 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