Water, It’s Quality and Decontamination of Medical Devices

• John Harrison  MBE. MIDSc
• Sterile Services Manager
ROYAL WELSH SHOWGROUND
BUILTH WELLS
31st October 2007
Water, It’s Quality and Decontamination of Medical Devices

WATER IS VITAL TO THE CLEANING PROCESS

UNIVERSAL SOLVENT

- carrier of the detergent to the surface of a device
- carrier of the soil/contaminants from the surface

The unique properties of water are related to its structure
Water, It’s Quality and Decontamination of Medical Devices

Polarity of the water molecule lends itself to the unique properties of water:

- Hydrogen atoms (the positive charge) from one water molecule can bond (hydrogen bond) with the oxygen atom (negative charge) from another water molecule.

- Combined total forces of the bonds give water surface tension.
water, It’s Quality and Decontamination of Medical Devices Problems
Water, It’s Quality and Decontamination of Medical Devices

**WHY IS CLEANING NECESSARY?**

- Ensure that adherent infectious agents are removed together with the organic matter that protects them.

- Ensure better contact between the disinfectant and any remaining infectious agents that may be present on surfaces of devices being processed.
Why is cleaning necessary?

- Ensure instrument function
- Heat and some disinfectants (alcohols and aldehydes) are tissue fixatives and may cause moving parts of a device to stiffen if surfaces are not thoroughly cleaned before sterilisation/disinfection
Water, It’s Quality and Decontamination of Medical Devices

WHY IS CLEANING NECESSARY?

Clinically Relevant Soils

Problem occurs when:

- **blood is allowed to dry on the instruments**
- **when heated, blood becomes insoluble (heat causes blood to denature**

Dried blood on the surface
with fibrins tightly attached to the surface

Magnified surface of metal device

Surface of metal device
Water, It’s Quality and Decontamination of Medical Devices

**WHY IS CLEANING NECESSARY?**

- Ensure that adherent infectious agents are removed together with the organic matter that protects them.
MICRO ORGANISMS

Definition: Living entity (organism) of microscopic or sub-microscopic size

- HIV virus
- Mycobacterium tuberculosis
- Cryptosporidium
- Malaria parasite
- Yeast
- Flu-virus
- SARS virus
Water, Its Quality and Decontamination of Medical Devices

WHY IS CLEANING NECESSARY?
Water, It’s Quality and Decontamination of Medical Devices

WHY IS CLEANING NECESSARY?

• Source of all life forms.
  - Potable Water Not sterile.
  - Cause of infections
    • Legionella
    • Pseudomonas
    • Tuberculosis ++

  - NEED TO ESTABLISH AND MAINTAIN SYSTEMS THAT WILL PERMIT SAFE PRODUCTS TO BE PRODUCED FROM THE DECONTAMINATION FACILITY
NATURAL CONTAMINANTS OF WATER

Minerals:
- Calcium
- Magnesium
- Iron
- Sulfates
- Chlorides
- Silica

Organics
- Humic acid
- Tannin
- Pyrogens

Solid –organic:
- Algae
- Fungi
- Bacteria

Organics
- Silt
- Rust
- Floc
- Clays

Solid inorganic
Water, It’s Quality and Decontamination of Medical Devices

WHY IS CLEANING NECESSARY?

FACTORS AFFECTING CLEANING

- PRE-TREATMENT
- CLEANER (CHEMISTRY) (DETERGENT)
- WATER - QUALITY
- WASHER/DISINFECTOR
Water, It’s Quality and Decontamination of Medical Devices

WHY IS CLEANING NECESSARY?

FACTORS AFFECTING CLEANING TYPE

Clinically Relevant Soils

3 SOIL TYPES

- Organic: fat, grease, proteins, carbohydrates and micro organisms
- Inorganic: rust, scale (hard water deposits), residues from cleaners
- Combination: organic + inorganic example - bone
Water, It’s Quality and Decontamination of Medical Devices

WHY IS CLEANING NECESSARY?

FACTORS AFFECTING CLEANING
Water, It’s Quality and Decontamination of Medical Devices

**FACTORS EFFECTING CLEANING**

- **WHAT IS A SURFACTANT?**

- **SURFACTANT = SURFACE ACTIVE AGENT**

- Agents which change the properties of water by lowering the surface tension of water, allowing the cleaner to penetrate soil and surface irregularities.

- Emulsify oily soils keeping them dispersed and in suspension.
Surfactant molecule

1) A hydrophilic or ‘water loving’ head
   
   (Hydrophile)

2) A hydrophobic or ‘water hating’ tail

Amphi ‘double’

Philos ‘affinity’
Water, It’s Quality and Decontamination of Medical Devices

BASIC WATER CYCLE

CONDENSATION

PRECIPITATION

SURFACE WATER

ROCK DEEP PERCOLATION

GROUND WATER

EVAPORATION
Therefore:
There is a need to know the quality of the raw water

And:
There may be a need to improve quality

And:
There will be a need to continually monitor the quality of the purification system
Water, It’s Quality and Decontamination of Medical Devices

Important factors

- pH
- Water Hardness
- Conductivity/metal ion content
- Alkalinity
Water, It’s Quality and Decontamination of Medical Devices
Factors affecting water

pH

French term ‘pouvoir hydrogene’ or
Hydrogen Power
Water, It’s Quality and Decontamination of Medical Devices

Important factors

- Ca$^{2+}$ and Mg$^{2+}$ ions make up the hardness
- CO$_2^-$ creates the alkaline environment
- Alkalinity lowers cleaning efficacy and results in the formation of lime scale
Water: Decontamination of Medical Devices

**Hardness:**

- Affects efficiency of disinfectant
- May leave deposits on devices
Water: Decontamination of Medical Devices

**Hardness:**
For cleaning, hardness should be less than 50ppm

**But:**
As softening does not improve quality, excessive softening will lead to deposits on devices

**So:**
Additional purification may be required
Treatment:

Water softening removes molecules involved in hardness of water.

- It does not reduce the OVERALL salt content.
- It does not remove chlorides or silicates.

Important factors:

- Water hardness
- Sodium
- Softener resin
Water, It’s Quality and Decontamination of Medical Devices

Water: Softening Plant
Water: Decontamination of Medical Devices

Ionic contamination:

- Create cosmetic changes to flexible endoscopes
- May lead to more serious damage
- May provide a habitat for microorganisms
Water: Decontamination of Medical Devices

Ionic contamination:

If this is high then purification will be required:

Limits are given in HTM 2030
Water: Decontamination of Medical Devices

**Microbiological contamination:**

Contravenes the purpose of decontamination
Water: Decontamination of Medical Devices

Microbiological contamination:

This will be removed by purification

Weekly TVC limits of post-disinfection rinse water for AERs is, 0 cfu/100ml
Water, It’s Quality and Decontamination of Medical Devices

**Important factors**

**What is Conductivity**

**FACTORS EFFECTING CLEANING – WATER QUALITY**

Conductivity is the ability of a water solution to conduct electricity

(measure of how much (not what) material is dissolved in water)

Parameter used to measure relative purity of water (µS/cm)

(2µS/cm is classed as high purity)
Water: Decontamination of Medical Devices

_Bacterial endotoxins:_

- Can create toxic shock
- Serious patient reaction
- Patient deaths?
What Are Endotoxins?

- **Endotoxins** are part of the outer membrane of the cell wall of Gram-negative bacteria. Endotoxins are invariably associated with Gram-negative bacteria whether the organisms are pathogens or not. Although the term "endotoxin" is occasionally used to refer to any cell-associated bacterial toxin, it is properly reserved to refer to the **lipopolysaccharide** complex associated with the outer membrane of Gram-negative bacteria such as *E. coli*, *Salmonella*, *Shigella*, *Pseudomonas*.
Water: Decontamination of Medical Devices

*Bacterial endotoxin contamination:*
This may be removed by purification or may need additional endotoxin filtration

Limits in HTM 2030 are $\leq 0.25$ EU/ml

Does this apply to non-invasive (?) endoscopy procedures?
Water: Decontamination of Medical Devices

**Purification methods:**

- Softening – may not be sufficient
- Demineralisation – may lead to microbe pass-through
- Reverse Osmosis – preferred method but may require prior softening
- Distillation – unnecessary
Water, It’s Quality and Decontamination of Medical Devices

Water is removed from the impurities
- create water vapour
- passed down a column (condenser)
- vapour changes back to liquid and collects as distillate

Distillation Removes:
- most inorganic solids
- all organics with a BP > than water (>100ºC)
- all bacteria
Water Filtration
Water: Filtration

- 5um
- 1um
- 0.22um
Water flows from less concentrated solution, through a semi-permeable membrane, to a concentrated saline solution.
REVERSE OSMOSIS (RO)

External pressure is applied to reverse the natural osmotic flow
Resulting in removal of particles from the solution

Less corrosive to steel and copper

Pressure > Osmotic Pressure

RO removes
- bacteria/pyrogens
- salts
- sugars
- proteins
- particles
- dyes

Membrane

Flow
Water: Decontamination of Medical Devices

Normal Osmosis

Higher Contaminant Concentration

Semipermeable Membrane

Lower Contaminant Concentration

Direction of Water Flow
Water Decontamination of Medical Devices

Reverse Osmosis

Applied Pressure

Pure Water

Semipermeable Membrane

Direction of Water Flow
Water: Decontamination of medical Devices

Testing AERs:

Weekly:
- hardness
- conductivity
- TVC

Annually:
- chemical purity (10 parameters)
- bacterial endotoxins
- TVC
- Environmental mycobacteria
Water: Decontamination of medical Devices

10 parameters for annual testing

- Appearance
- pH
- Total dissolved solids
- Hardness
- Chloride
- Conductivity
- Heavy metals
- Iron
- Phosphate
- Silicate
Water, It’s Quality and Decontamination of Medical Devices

Factors affecting cleaning

**AGITATION:**

- Physical agitation from water spray brings fresh cleaning solutions to the soiled instruments, washes away used-up detergents (spray loosens blood with physical impact)

- Spray from different angles helps prevent blocking from piled up instruments
What Quality of Water is Required for Washing and Rinsing?

Bacteria Free Water
&
Endotoxin Free Water

Are required for both Surgical Instrument Washers and Automated Endoscope Re-Processors
Water: Decontamination of Medical Devices

- **Qualities required:**
  
  - **Manual cleaning:** Softened Potable Water
  - **AWD Pre Wash with chemistries:** Softened Potable water
  - **Main wash with chemistries:** Softened Potable Water
  - **Rinse:** RO water
  - **Rinse and thermal disinfection:** RO water

Maintaining RO quality: filtered, heated (min 60C), re circulated, UV- disinfection (AEWD)

Disinfection of RO with Chlorine if more than 6ppm chlorine potential for damage of membrane unit cuts out once 30 (µS/cm) reached.
Where/How Do We Generate This Quality of Water

- Buy in as “Sterile Water for irrigation” – No Endotoxins
- Buy in as “Sterile Water for Injection” – No Endotoxins
- Basic micro filtration – *Endotoxins Present*
- Ultrafiltration – No endotoxins
- Nano filtration – No Endotoxins
- Reverse osmosis – No Endotoxins
Water RO Maintenance Costs:

• Cost to company for call outs and set visits £23,130.00pa

• In House Maintenance costs £7000.00pa

• Water testing costs @£13.00 per test x 4 machines in Endoscopy = £3000.00pa

• Totals = minimum £33,000.00pa
THANK YOU FOR YOUR TIME