Welcome!

Medisafe Research

Validation of the Ultrasonic Process

world leaders in decontamination of complex instruments...
Standards

• HTM 2030 - Guidance being used as a standard.
• EN ISO 15883 - Washer-disinfectors

Both call for Validation!
The link between BSE and vCJD was established in 1996...
Validation & Routine Testing

- Manufacturers Validation
- Installation & Commissioning
- Daily Tests¹
- Weekly Tests¹
- Quarterly Tests and Validation¹
- Annual Validation¹
Manufacturers Validation

- Manufacturers are obliged to test machines prior to delivery.
- Test results are to be available to the customer.
Installation & Commissioning

• Installation checks and tests to ensure safe and effective operation of the machine
Daily Tests

• To be carried out by the user
  – Automatic Control Test
  – Remove & Clean Strainers and Filters
Weekly Tests

• Weekly Safety Checks
• Carry Out Daily Tests
• Cleaning Efficacy Test By Soil Residue Detection
Quarterly Tests

• Weekly Safety Checks
• Automatic Control Test (Verification of Calibration of WD Instruments)
• Test For Ultrasonic Activity
• Cleaning Efficacy Test

– Test Soil
– Reference Load
Yearly & Revalidation Tests

• In addition to Quarterly Tests:
  – Water System
  – Drainage
  – Doors & Interlocks
  – Fault Interlock
  – Aerosol Discharge Test
  – Chemical Additive Dosing Tests
  – Cleaning Efficacy Test
Yearly & Revalidation Tests

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- Chamber Wall Temperature Test
- Load Carrier Temperature Test
- Over Temperature Cut-Out Test
- Thermometric Test For Disinfection
- Load Dryness Test
- Test for Ultrasonic Activity
- Sound Pressure
Soil Residue Testing

- Clearly defined Test Load of Instruments
- Tests Correlate to Blood
- Simulates Protein Removal
- Simulates Blood Coagulation
- Quantifiable Test Results
- Convenient and Easy to use
Soil Residue Testing
A Regular Laparoscopic instrument

Medisafe`s “See Thru” indicator
Laparoscopic instrument
Field distribution in two different Ultrasonic bathes

Ultrasonic Cleaner #1 at Z= 65mm

Ultrasonic Cleaner #2 at Z= 65mm
Foil Testing in Action!

www.medisafe.uk.com
Alternative methods...

• Gives Indication of:
  • Ultrasonic Cleaning Performance.
  • Energy Levels throughout the tank.
  • Potential wash “over” load.
  • Required time for “de-gas”

• Used for optimisation “fine tuning”!
More alternatives......

• Measures ultrasonic activity
• Quantifies the results
• Manual process
Field distribution in two different Ultrasonic bathes

Standard SI Digital

Wire Basket:
10mm ofoffice 1mm wire

Flat Plate:
0.6mm guage stainless steel

Temp:
28 Degrees Celcius

Test Method
Pereg – Sonoc Check

<table>
<thead>
<tr>
<th>Position</th>
<th>Wire Basket</th>
<th>Plate</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>2.10</td>
<td>1.28</td>
</tr>
<tr>
<td>B</td>
<td>3.18</td>
<td>1.50</td>
</tr>
</tbody>
</table>

Time Taken for Colour Change – (Mins:sec’s)
What about.....???

.....ultrasonic units that incorporate a disinfection phase???
A combination of tests!

- Classified as a Washer/Disinfector
- Further design considerations
- Protein residue testing
- Thermometric testing
With thanks......

• Klaus Roth/SMP

References.....

¹ HTM 2030, Validation & Verification, p52, NHS Estates, 1997
Thank you!

Questions are Welcome...

world leaders in decontamination of complex instruments...