

**Medisafe**

[www.medisafe.uk.com](http://www.medisafe.uk.com)

*Welcome !*

Medisafe Research

# **Validation of the Ultrasonic Process**

world leaders in decontamination of complex instruments...

# Standards

**Medisafe**

[www.medisafe.uk.com](http://www.medisafe.uk.com)

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

**Both call for Validation!**



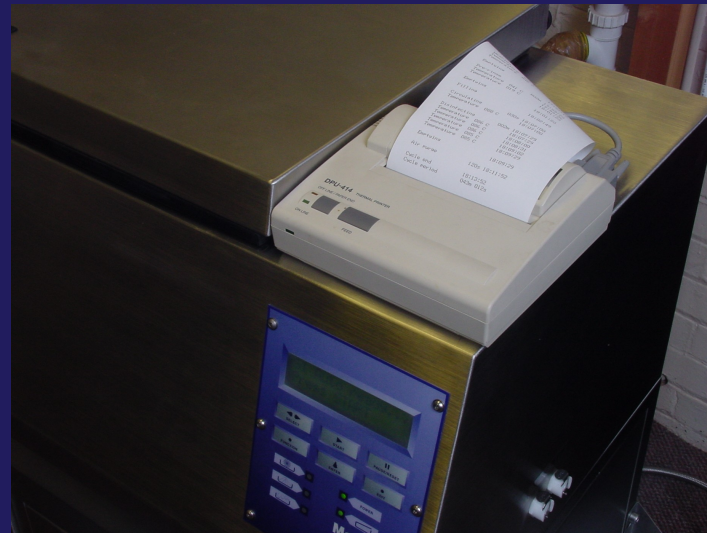
The link between BSE and vCJD  
was established in 1996...

# Validation & Routine Testing

- **Manufacturers Validation**
- **Installation & Commissioning**
- **Daily Tests<sup>1</sup>**
- **Weekly Tests<sup>1</sup>**
- **Quarterly Tests and Validation<sup>1</sup>**
- **Annual Validation<sup>1</sup>**

# 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<sup>1</sup>

- To be carried out by the user
  - Automatic Control Test
  - Remove & Clean Strainers and Filters

# Weekly Tests<sup>1</sup>

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





# Yearly & Revalidation Tests<sup>1</sup>

- 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<sup>1</sup>**

**(Continued From Previous Page)**

- 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

**Medisafe**

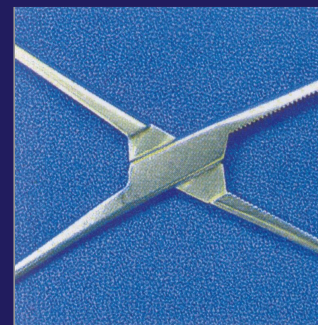
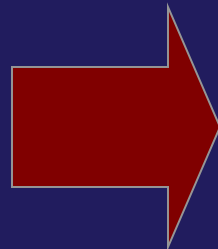
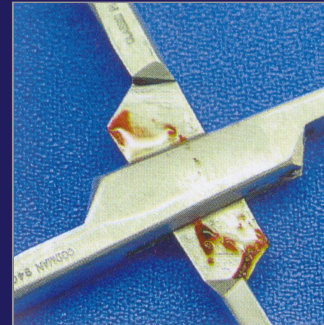
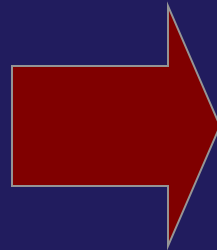
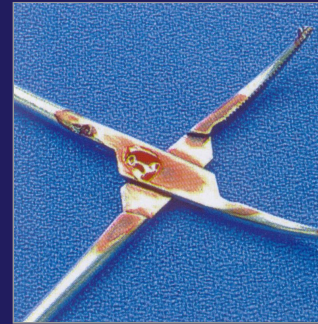
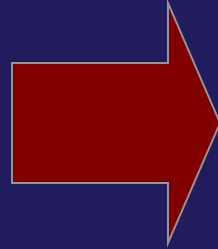
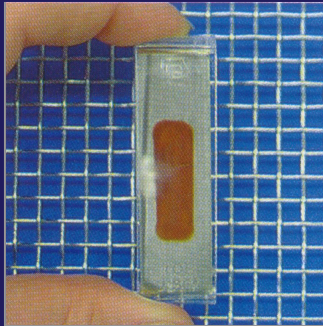
[www.medisafe.uk.com](http://www.medisafe.uk.com)

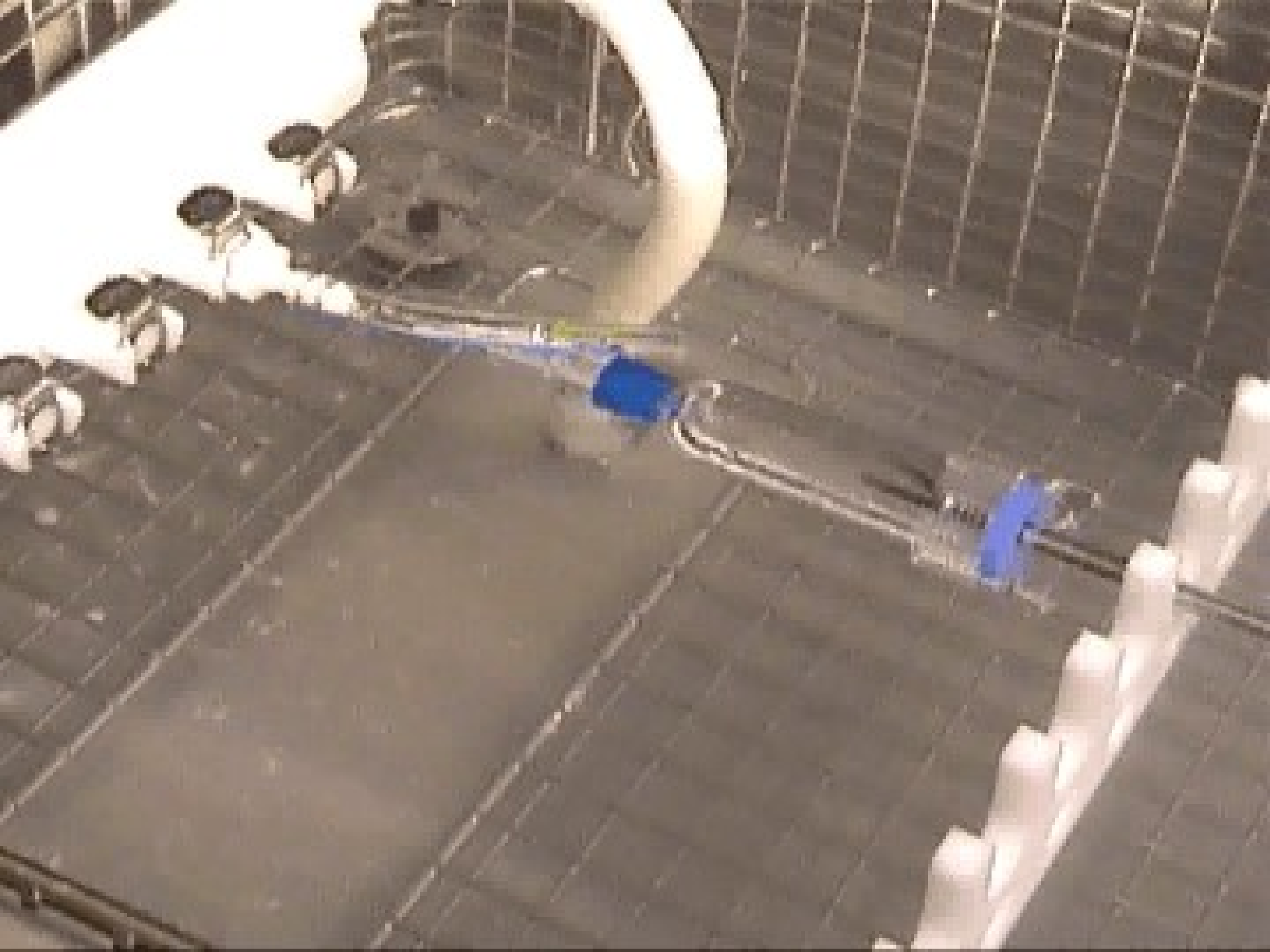
- **Clearly defined Test Load of Instruments**
- **Tests Correlate to Blood**
- **Simulates Protein Removal**
- **Simulates Blood Coagulation**
- **Quantifiable Test Results**
- **Convenient and Easy to use**

# Soil Residue Testing

**Medisafe**

[www.medisafe.uk.com](http://www.medisafe.uk.com)





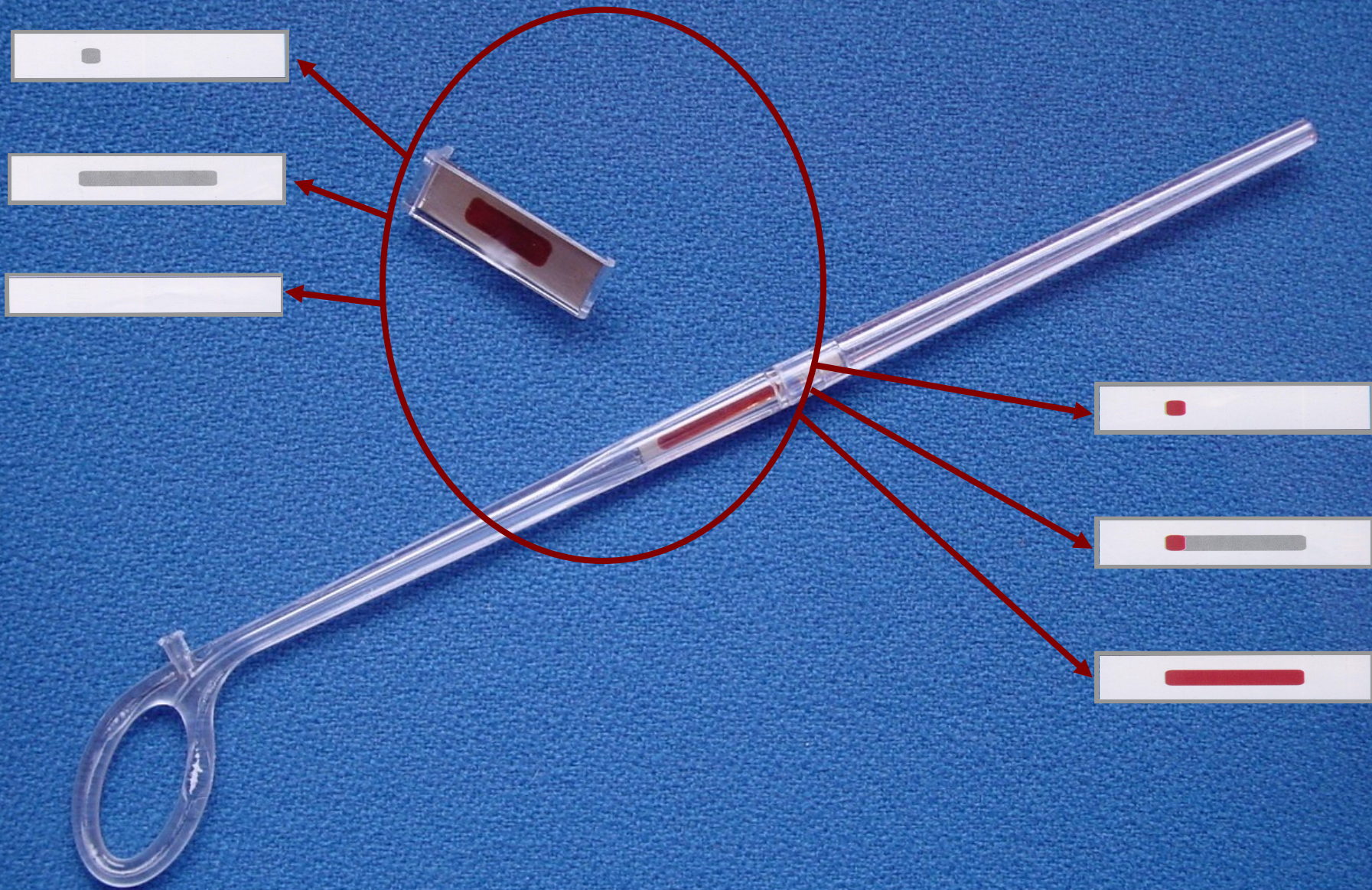


**A Regular Laparoscopic instrument**

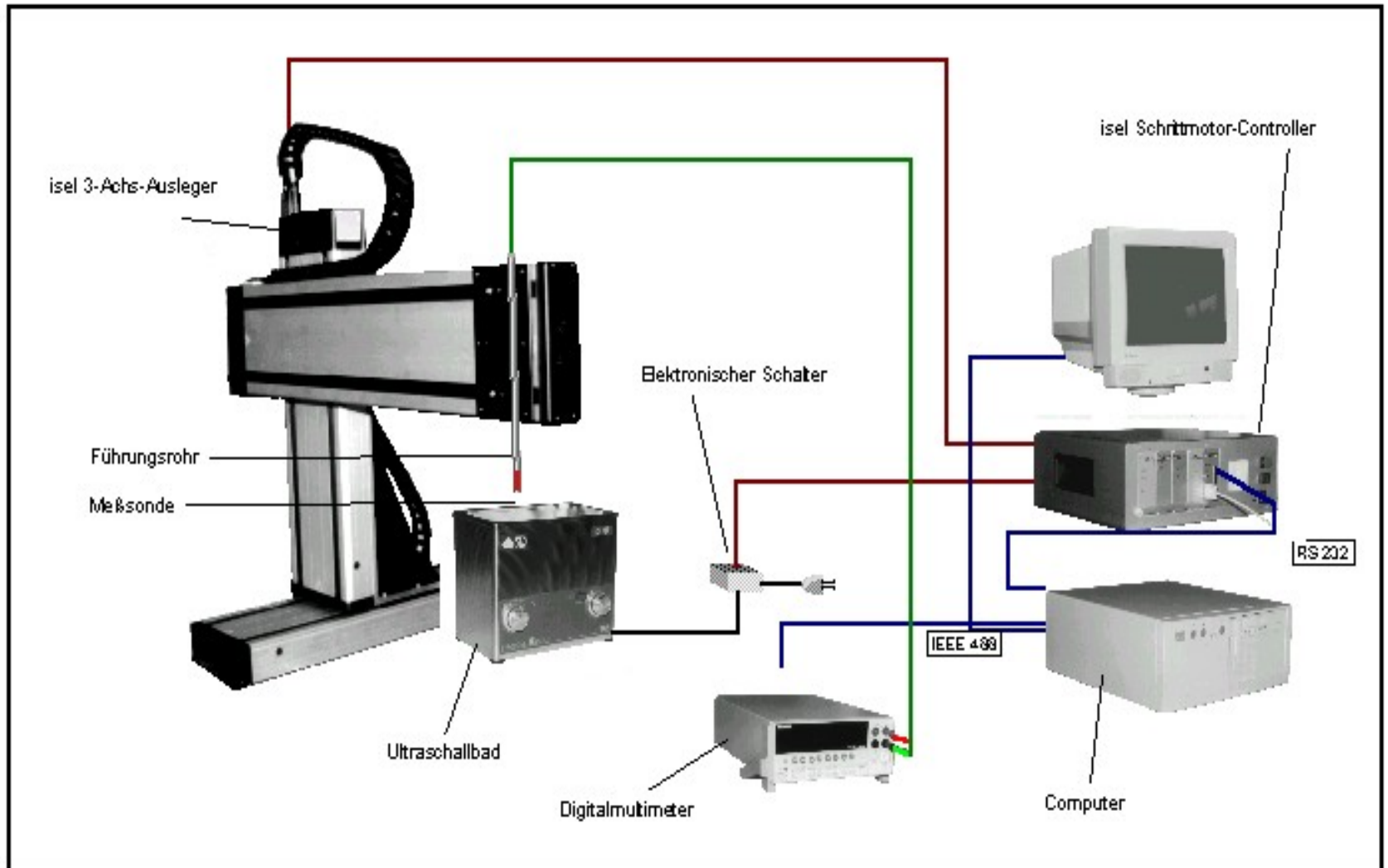


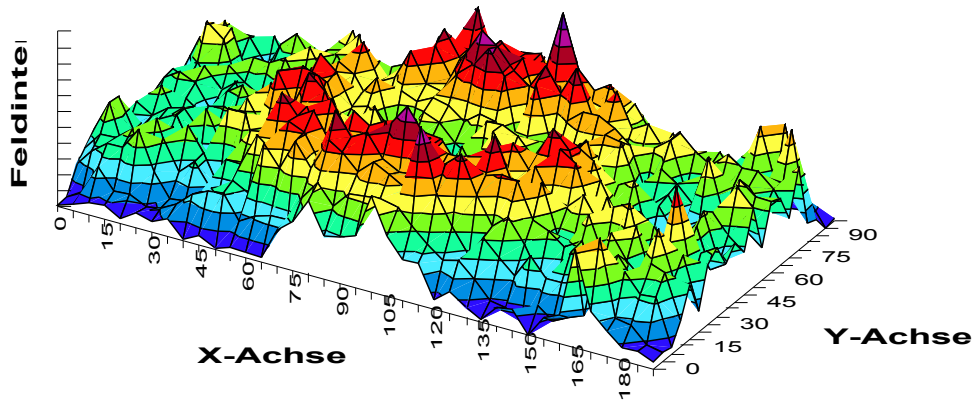
**Medisafe's "See Thru" indicator  
Laparoscopic instrument**



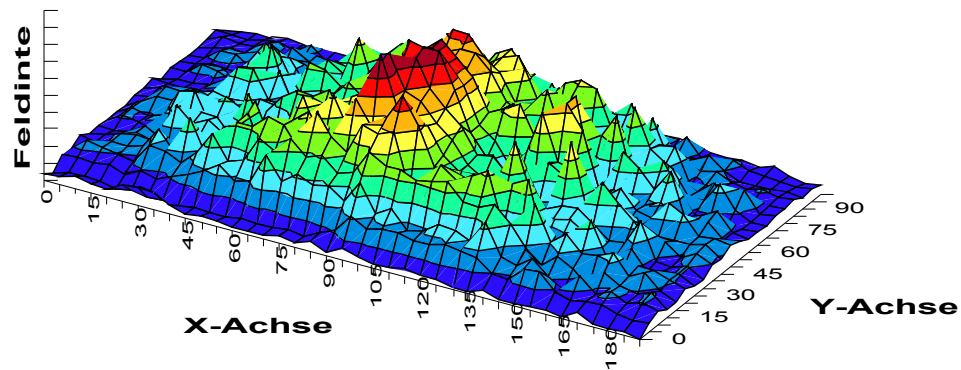


**Lumen Test**





Ultrasonic  
Cleaner #1  
at  $Z=65\text{mm}$



Ultrasonic  
Cleaner #2  
at  $Z=65\text{mm}$

**Medisafe**

[www.medisafe.uk.com](http://www.medisafe.uk.com)



**Medisafe**

[www.medisafe.uk.com](http://www.medisafe.uk.com)

# Foil Testing in Action!



# Alternative methods... [www.medisafe.uk.com](http://www.medisafe.uk.com)

- **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” !**



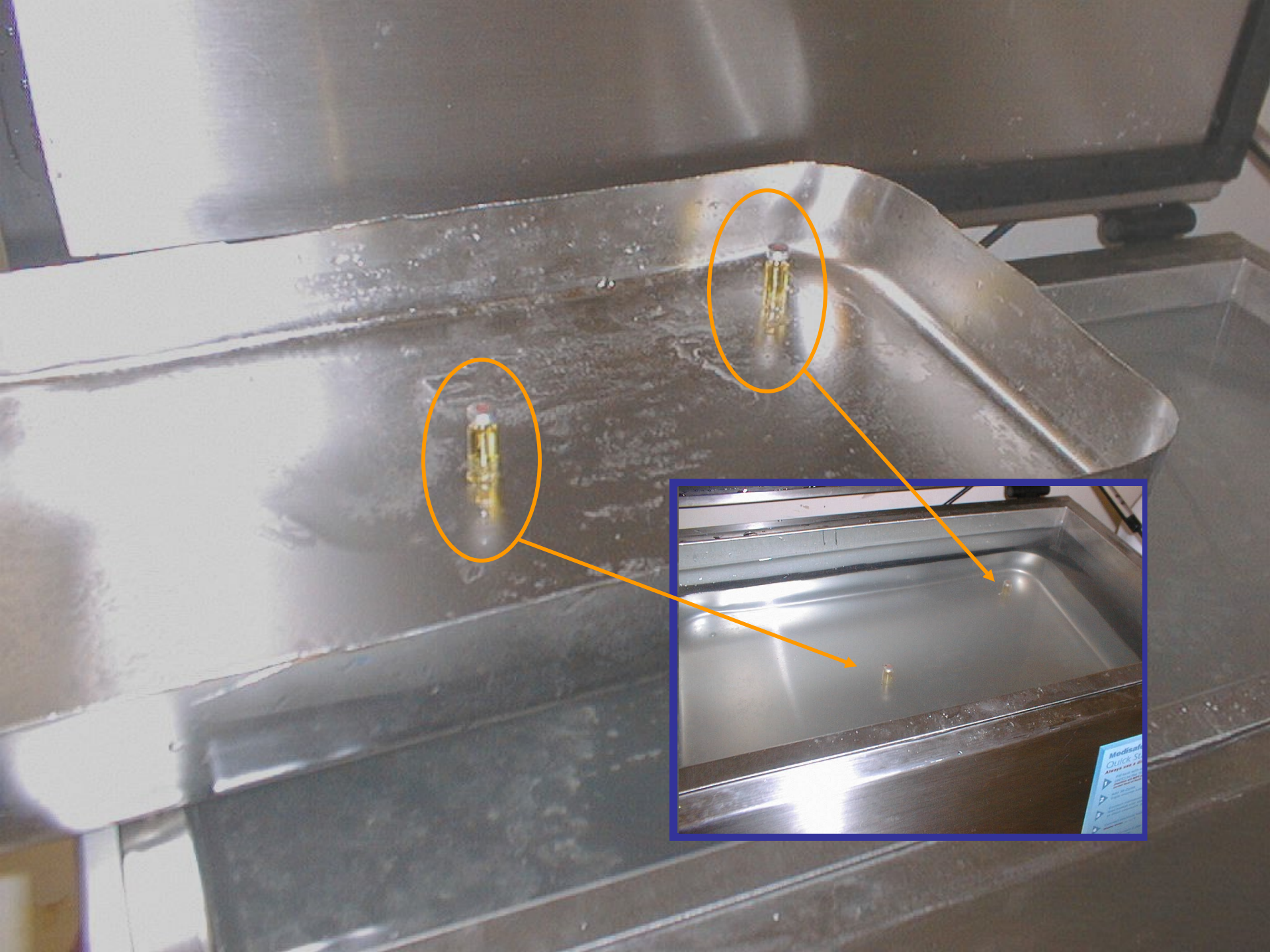
# More alternatives.....

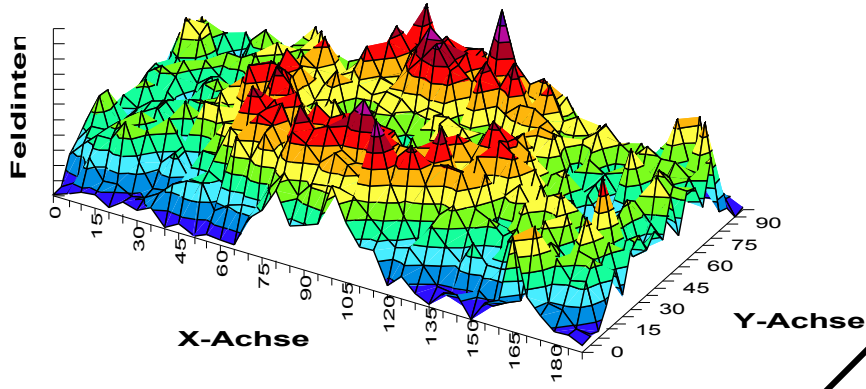
- **Measures ultrasonic activity**
- **Quantifies the results**
- **Manual process**



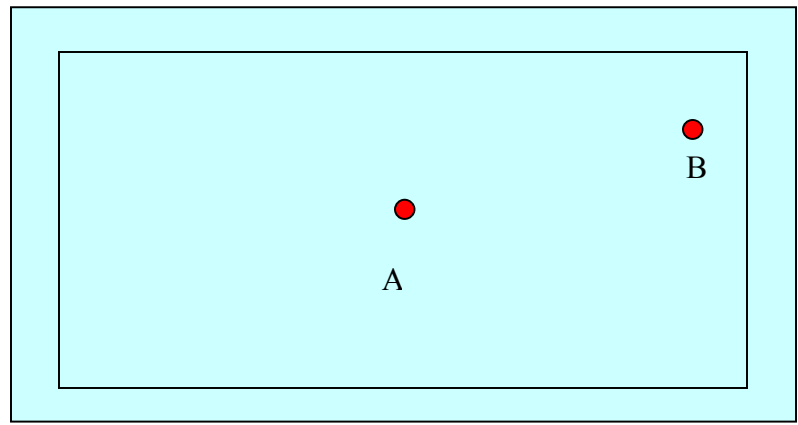








Front



Front

**Standard SI Digital**

**Wire Basket:**

10mm of ofice 1mm wire

**Flat Plate:**

0.6mm guage stainless steel

**Temp:**

28 Degrees Celcius

Test Method

Pereg – Sonoc Check

Position	Wire Basket	Plate
A	2.10	1.28
B	3.18	1.50

Time Taken for Colour Change – (Mins:sec's)

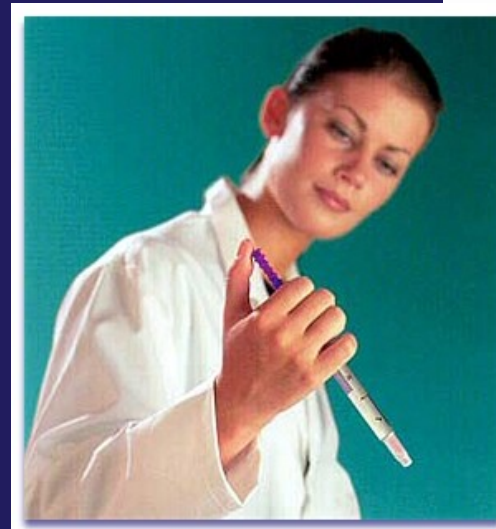
# What about....???

.....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.....

<sup>1</sup> HTM 2030, Validation & Verification, p52,  
NHS Estates, 1997

**Medisafe**

[www.medisafe.uk.com](http://www.medisafe.uk.com)

*Thank you !*

*Questions are Welcome...*

world leaders in decontamination of complex instruments...