



The Impact of Time and Environmental Conditions on Contaminated Instrumentation

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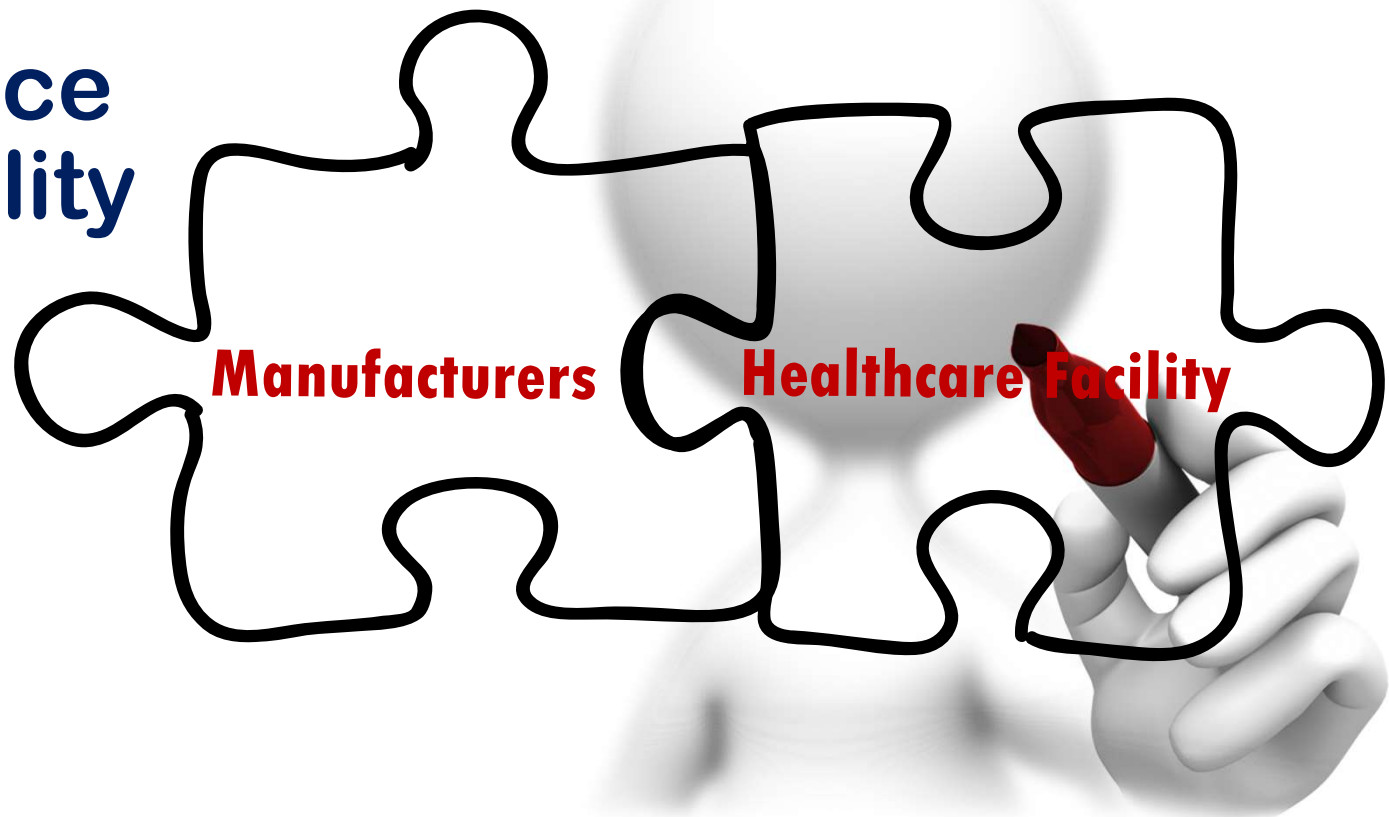
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Device Performance Responsibility



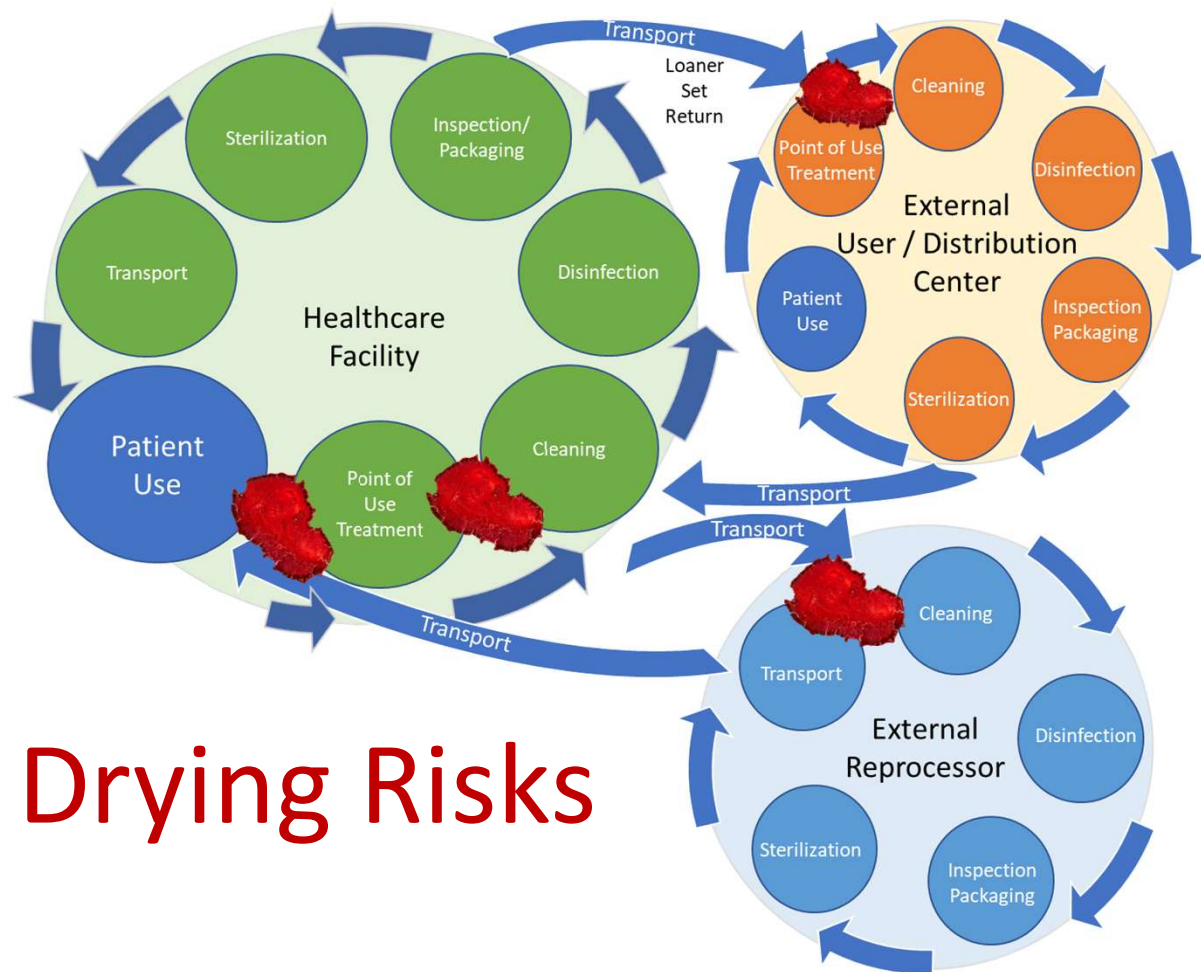


Don't let the soil dry!

IFU Example Wording – Point of Use Cleaning

- Remove visual blood and/or debris from device following the surgical procedure by wiping and/or immersion with water or a detergent solution labelled and prepared for use for devices
- Flush all lumens with water or a detergent solution labelled and prepared for use for devices
- **Prevent residual soil from drying on surfaces** by either removing at the point of use, covering with a towel dampened with purified water, or equivalent procedure (e.g., immersion in water or a detergent-based product). Reprocessing should be initiated as soon as possible following use.

End-to-End Device Processing Cycle



Drying Risks



Soil Drying Risk

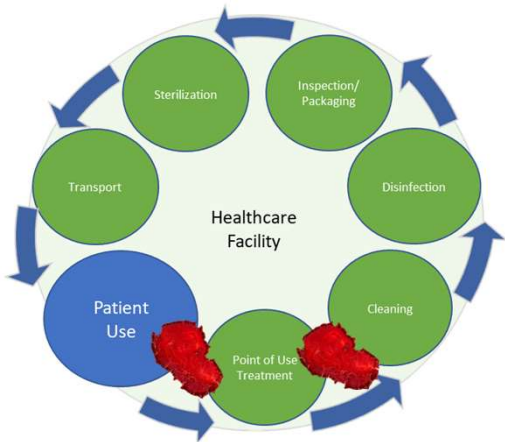
- Lack of Point of Use Treatment



- Delays in Transport to Decontamination

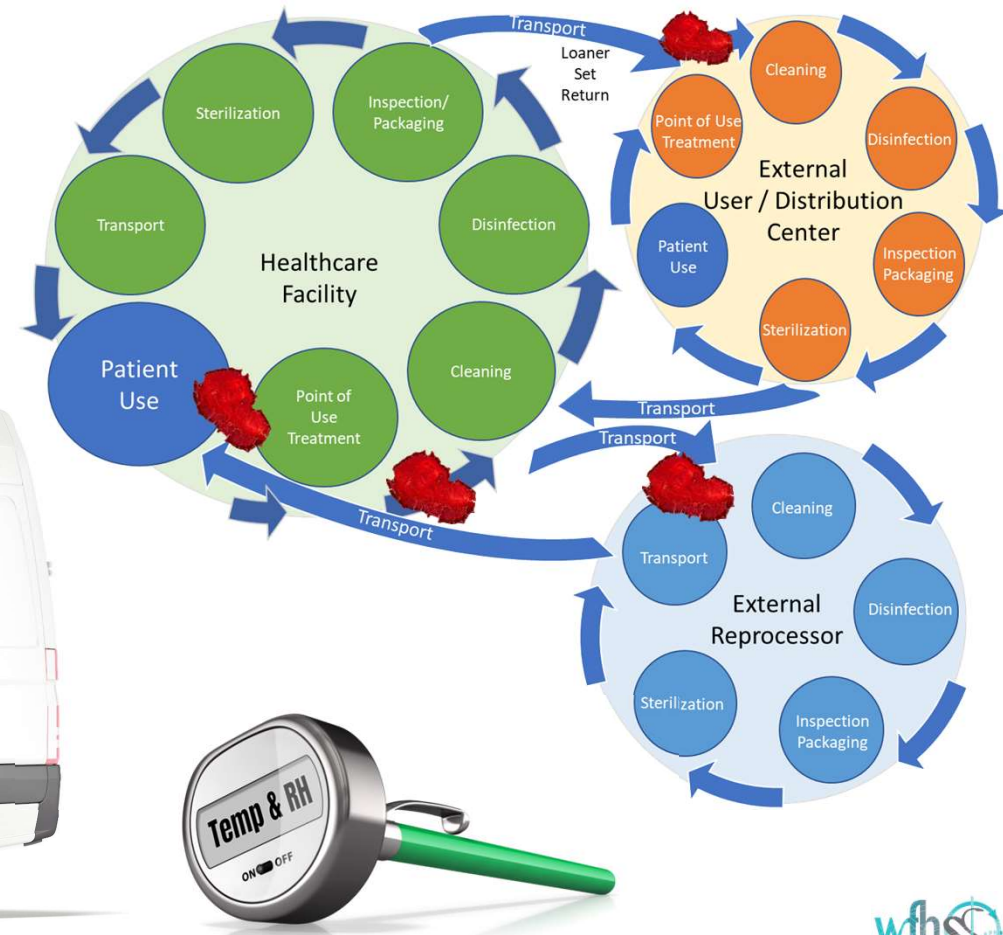


- Delays in Processing

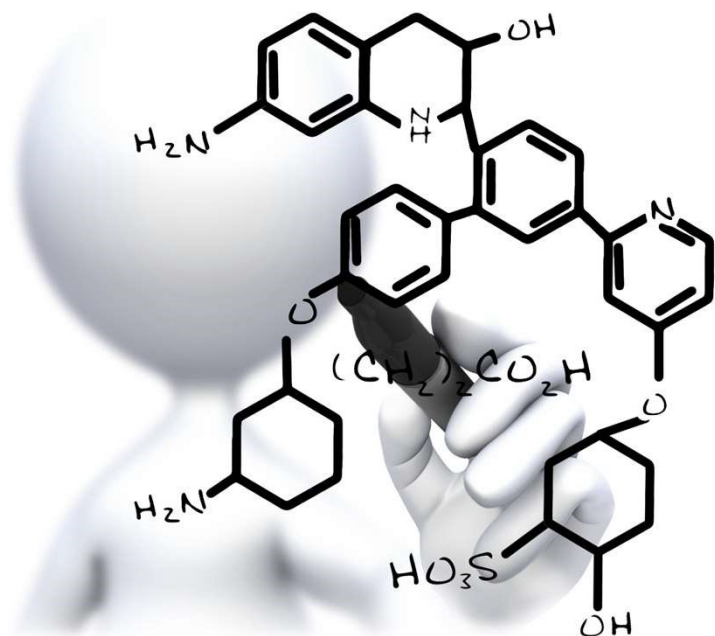


Soil Drying Risk

External Transport



CLEANING IS CHEMISTRY



- Soil Composition
- Water
- Cleaning Agents

Universal Solvent

Solubility: The ability to be dissolved, especially in water.

EXPERIMENTAL QUESTIONS

1. Do environmental conditions (e.g., time, temperature & humidity) effect drying?
2. What is happening chemically to the soil during drying?
3. Is it possible to reverse the chemical changes with a pre-cleaning treatment?



Problem Questions:



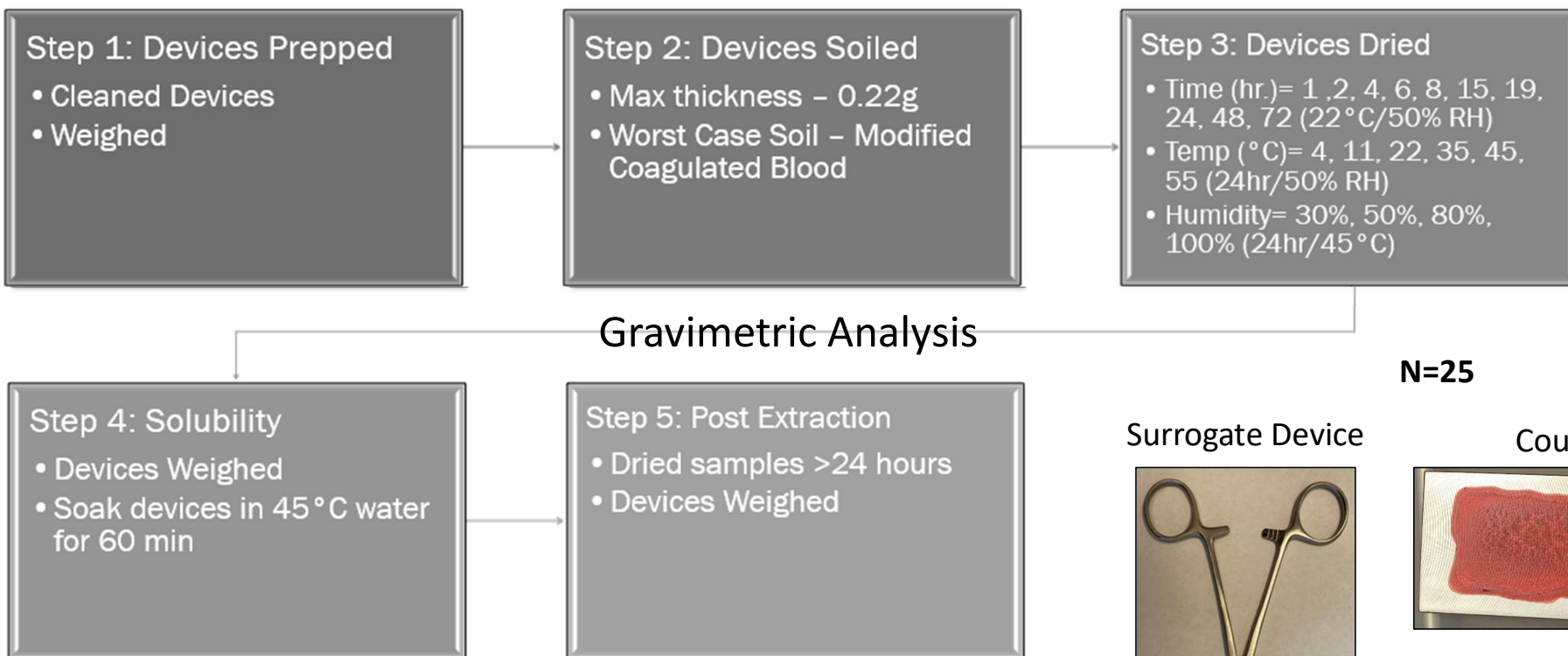
1. What effect does time have on the solubility of dry soil?



2. What effect does temperature have on the solubility of dry soil?

3. What effect does humidity have on the solubility of dry soil?

EXPERIMENTAL DESIGN



N=25

Surrogate Device



Coupon



Drying Conditions

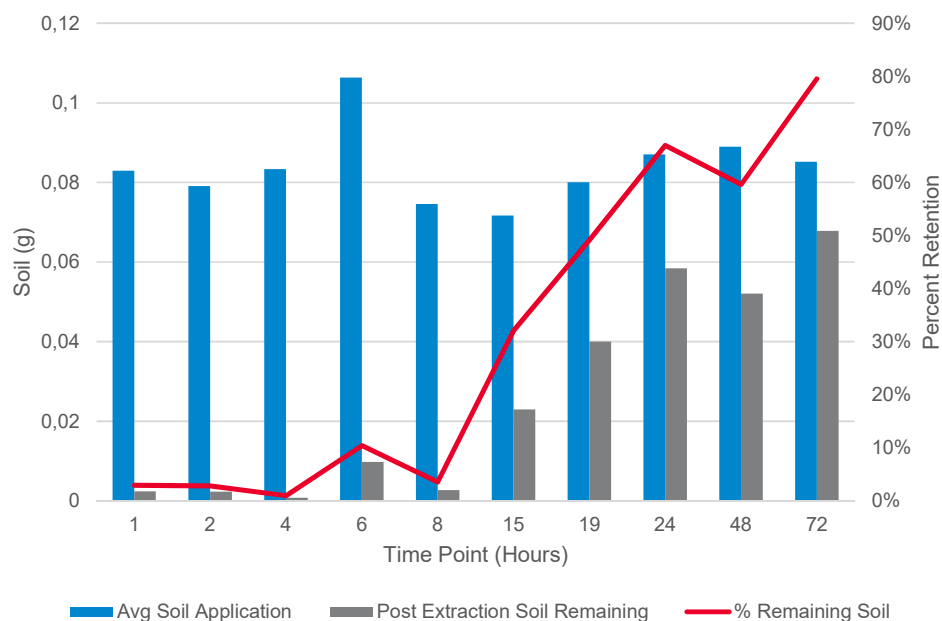
IMPACT OF TIME

Dry is dry for the first 8 hours, and then the solubility of soil changes.

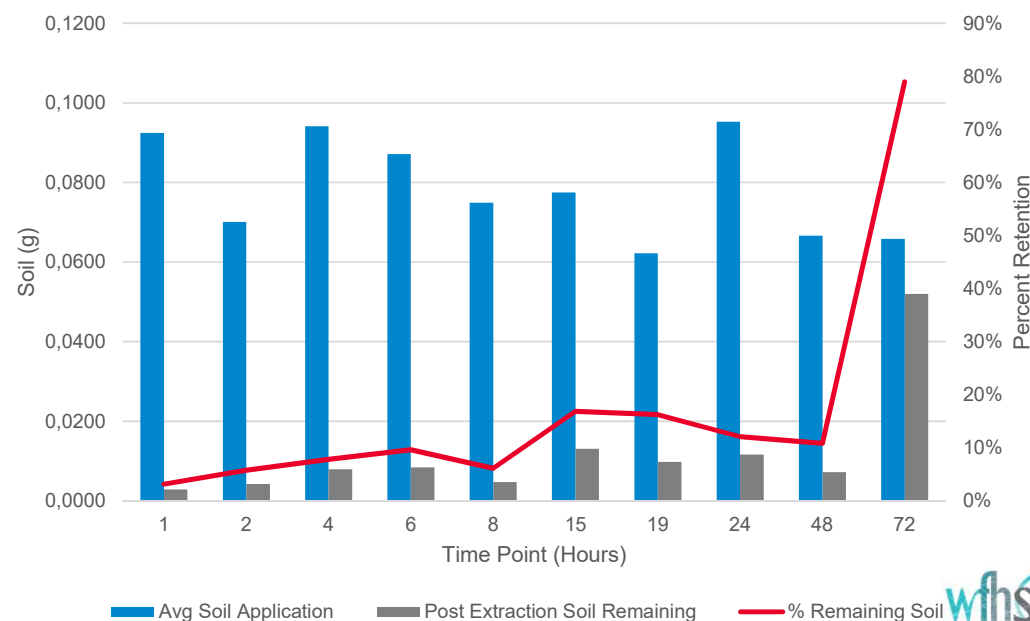


Experiment Conclusion: No statistical difference for change in solubility between 1 and 8 hours of dry ($p_{\text{value}} = 0.041$ for surrogate). A statistical difference was demonstrated between 8 and 15 hours. The most retention of the soil was observed at 72 hours.

Coupon Soil Retention Vs Dry Time



Surrogate Soil Retention Vs Dry Time



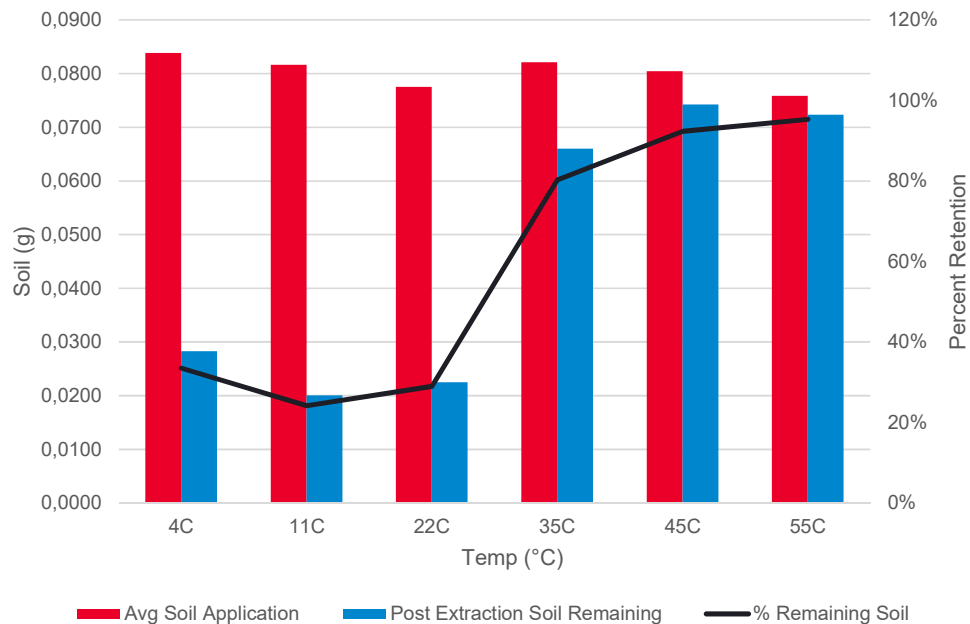
IMPACT OF TEMPERATURE

Yes - As the temperature rises after 22°C/71.2°F the solubility decreases.

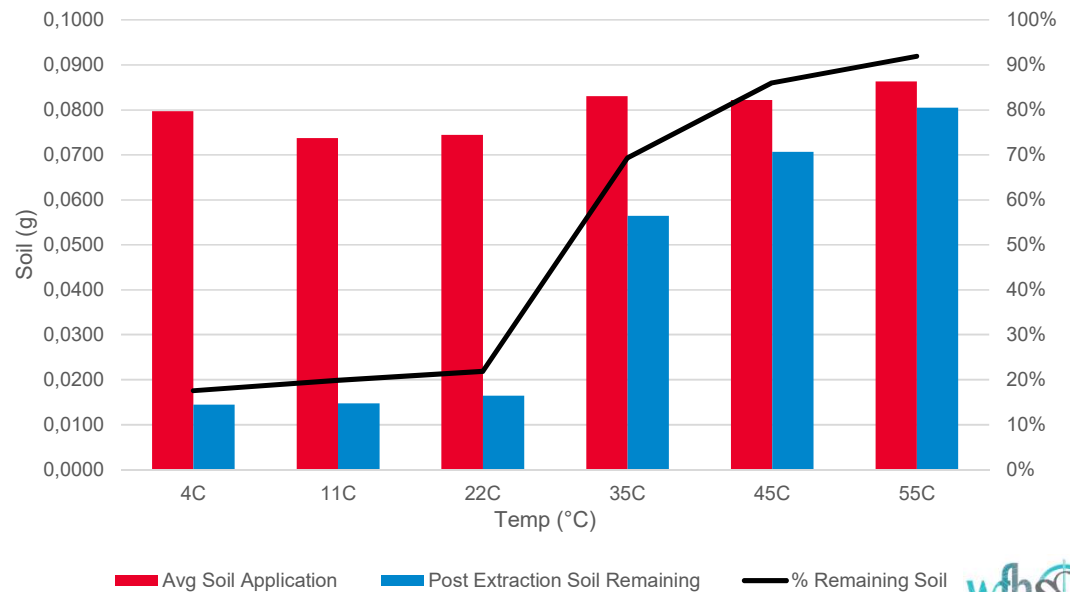


Experiment Conclusion: No statistical difference for change in solubility between 4°C and 22°C ($p_{\text{value}} = 0.214$ for surrogate). After 22°C soil retention increased from 21.9% to 69.3% (surrogate) at the 35°C mark and continued to increase at higher temperatures.

Coupon Soil Retention Vs Dry Temp



Surrogate Soil Retention Vs Dry Temp



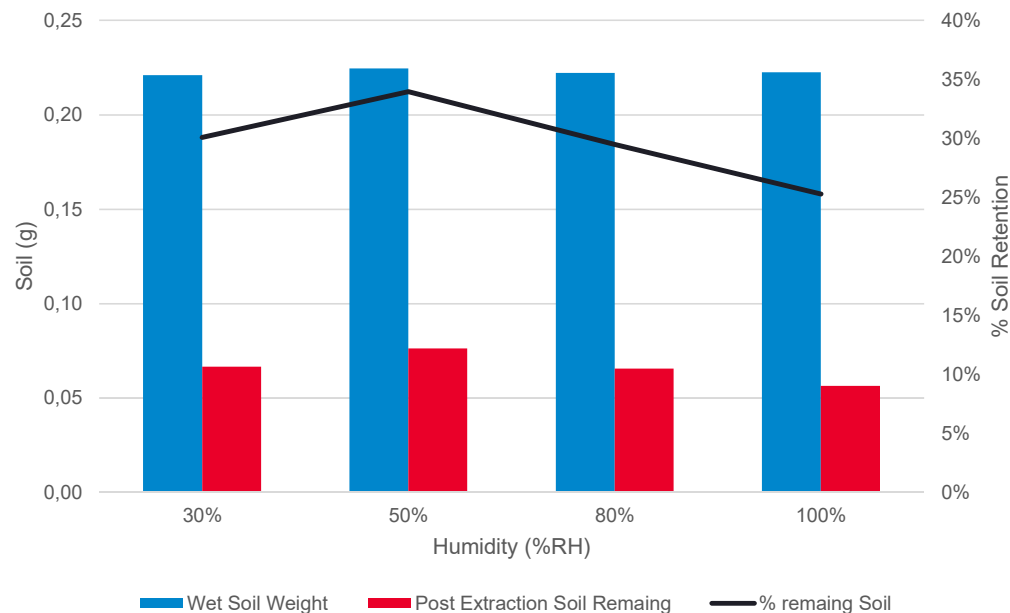
IMPACT OF HUMIDITY



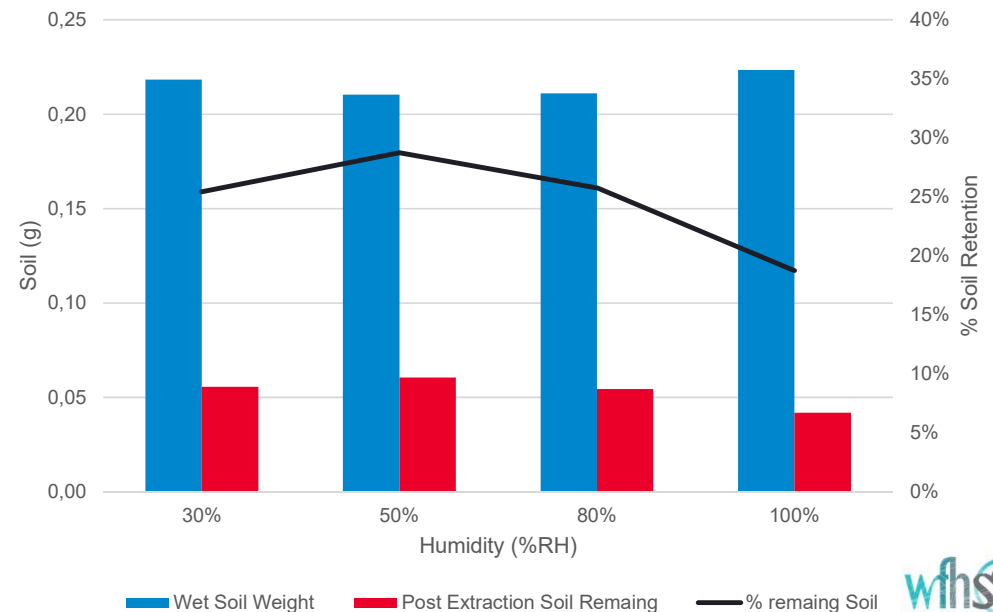
Yes - As the humidity increases after 50% RH the solubility increases.

Experiment Conclusion: After 50% RH the soil retention decreases with a negative correlation to increase in humidity. At 100% humidity the soil did not dry.

Wet Soil Coupon Retention Vs Humidity

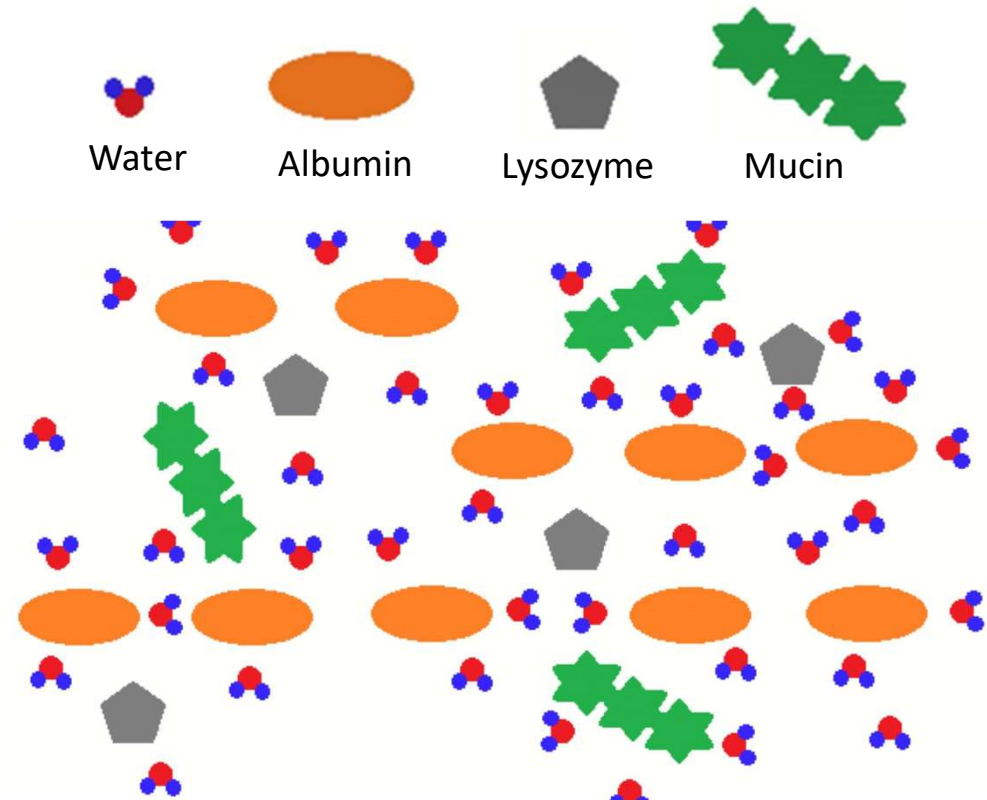
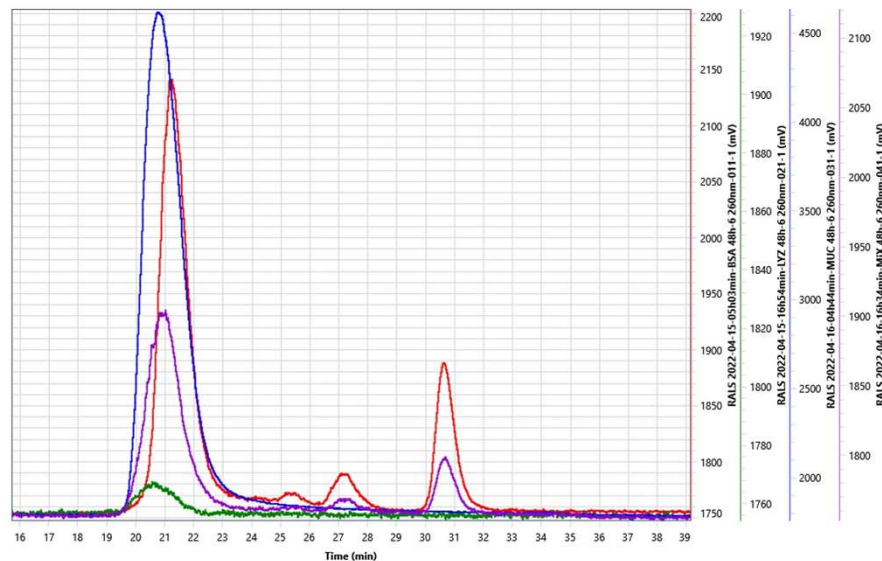


Wet Soil Surrogate Retention Vs Humidity



SOIL CHEMISTRY CHANGES

Overlay chromatogram of 48-h dried samples obtained from 90° angle light scattering detector



The drying process is a combination of degradation, polymerization and aggregation as water is removed and protein-protein interactions are enabled. The molecular weight distribution changes over time affecting the solubility.

EXTENDED DRY IMPACT

Does adding a soak to the processing steps reverse the chemistry changes after an extended dry as measured by solubility?

N=33

Pre-Treatment Chemistry

Water

Enzymatic Detergent:
8mL/L

Alkaline Detergent
10mL/L

Enzymatic Humectant
Foam Spray

pH Neutral Detergent
4mL/L

Step 1: Devices Prepped

- Cleaned Devices
- Weighed

Step 2: Devices Soiled

- Max thickness – 0.22g
- Worst Case Soil – Modified Coagulated Blood

Step 3: Devices Dried

- Time (hr.)= 72 (22° C/50% RH)

Gravimetric Analysis

Step 4: Pre-treatment Step

- Highest recommended concentration soak for 60min at ambient temperature

Step 5: Solubility

- Devices Weighed
- Soak devices in 45° C water for 60 min

Step 6: Post Extraction

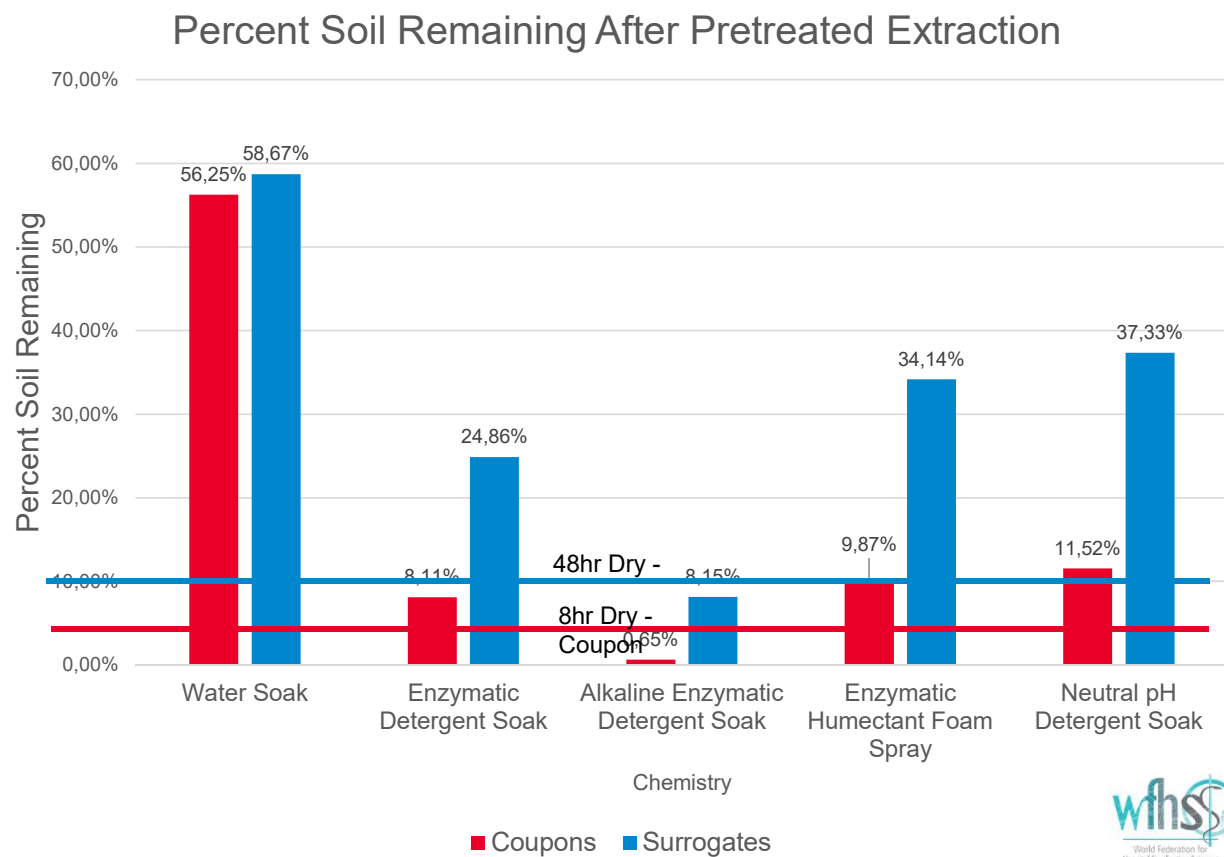
- Dried samples >24 hours
- Devices Weighed

Extended Dry

EXPERIMENTAL CONCLUSION

An alkaline detergent soak at 60 minutes reverses the chemistry changes from extended dry.

Pre-Treatment Chemistry	Coupons	Surrogates
Water	Least Effective	Least Effective
Alkaline Detergent: 10mL/L	Most Effective	Most Effective
Enzymatic Detergent: 8mL/L	Statistically similar (p-value of 0.683)	Statistically similar (p-value of 0.054)
Enzymatic Humectant Foam Spray		
pH Neutral Detergent: 4mL/L		Statistically similar to Enzymatic Humectant Foam Spray (p-value of 0.433)





DISRUPTIVE DATA

Soil Drying
Matters

Effects are
Reversible

Manufacturers must be aware of the realities of device processing at the Healthcare facility.

Healthcare facilities must understand the impact of decisions made during device processing.

Caution: Not all devices are compatible with Cleaning Chemistries so all chemistries used must be in accordance with the device IFU. (e.g., ophthalmic devices often state in the IFU to not expose to enzymatic cleaning agents)

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Extended Dry

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