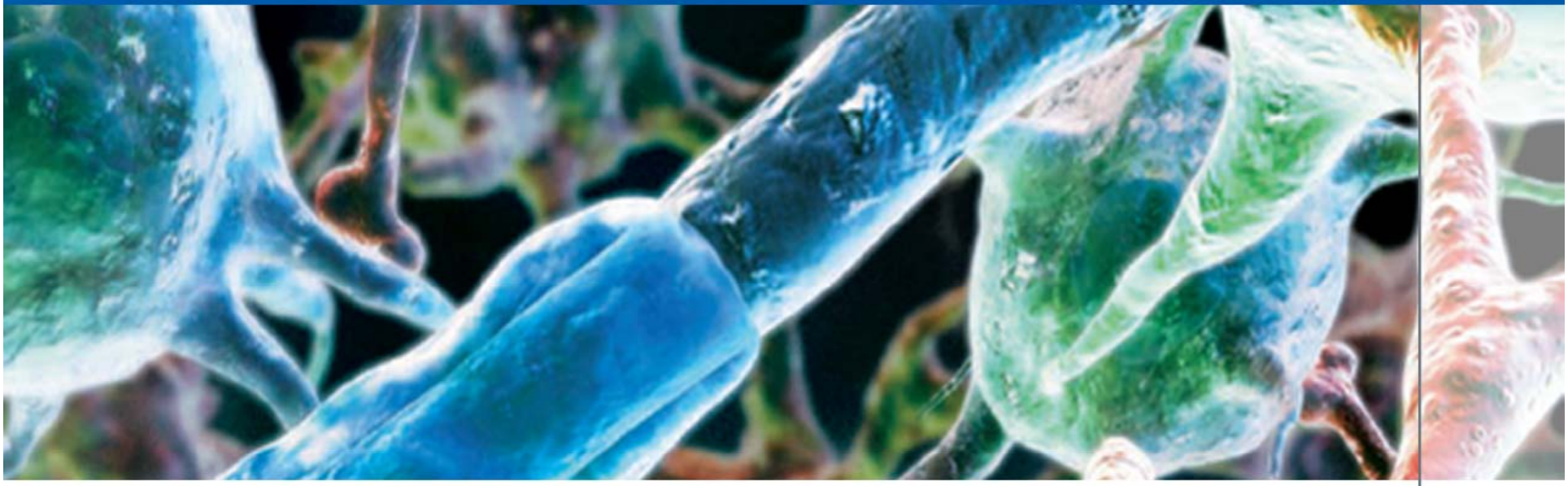

Performance, Characterization and Evaluation of a Disposable Bioreactor System

24Sep09

Kelly R. Wiltberger

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Future Improvements

Disposable Sensors

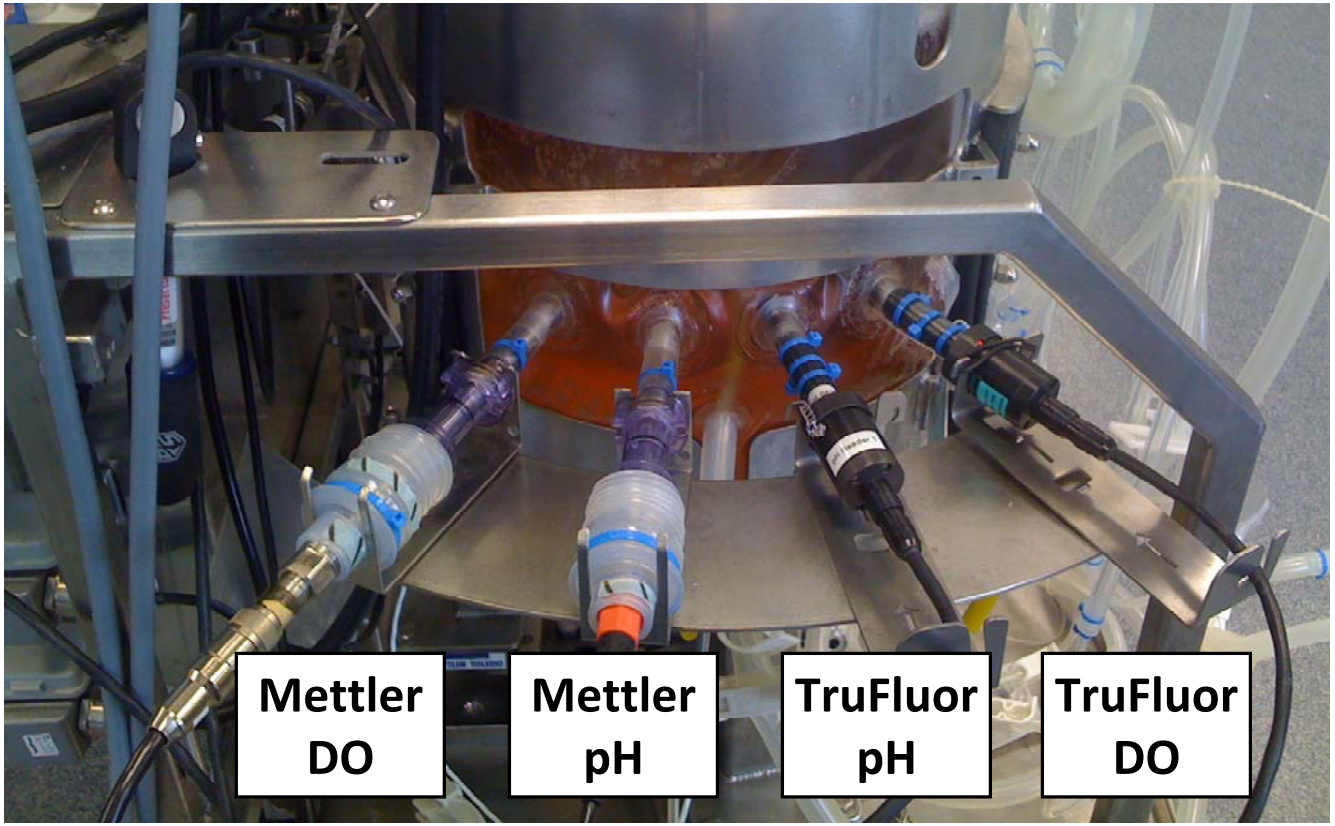
SUB Future Improvements

Initial working volume

- Reduce min. volume from 50% to 20%
- Adjustable height and angle mount
- 50L & 250L SUB
- Two passages in one vessel

- Disposable probes
  - Sensors made by Finesse for DO, pH, pressure
    - TruFluor DO, TruFluor pH, TruTorr
  - Sheath installed in bag with sensor
  - No probe insertion (reduce contamination risk)

Disposable Sensors
Finesse



-Sheath internal to bag
-Reader inserts into sheath

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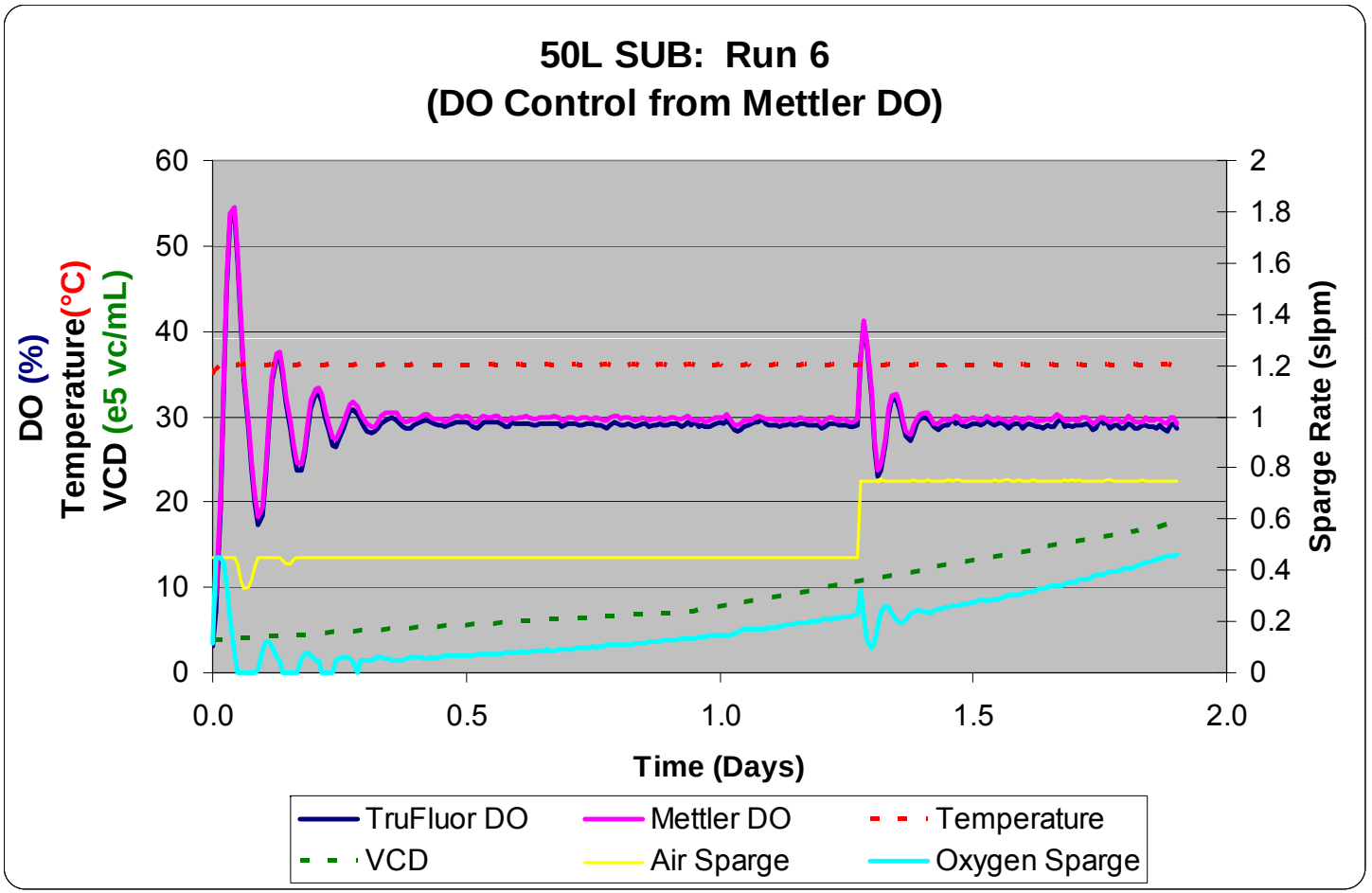
Dissolved Oxygen Sensors: Finesse TruFluor DO

50L Bioreactor



- DO controlled via Mettler probe
- Mettler and TruFluor DO agree & respond to air/oxygen flow rate changes

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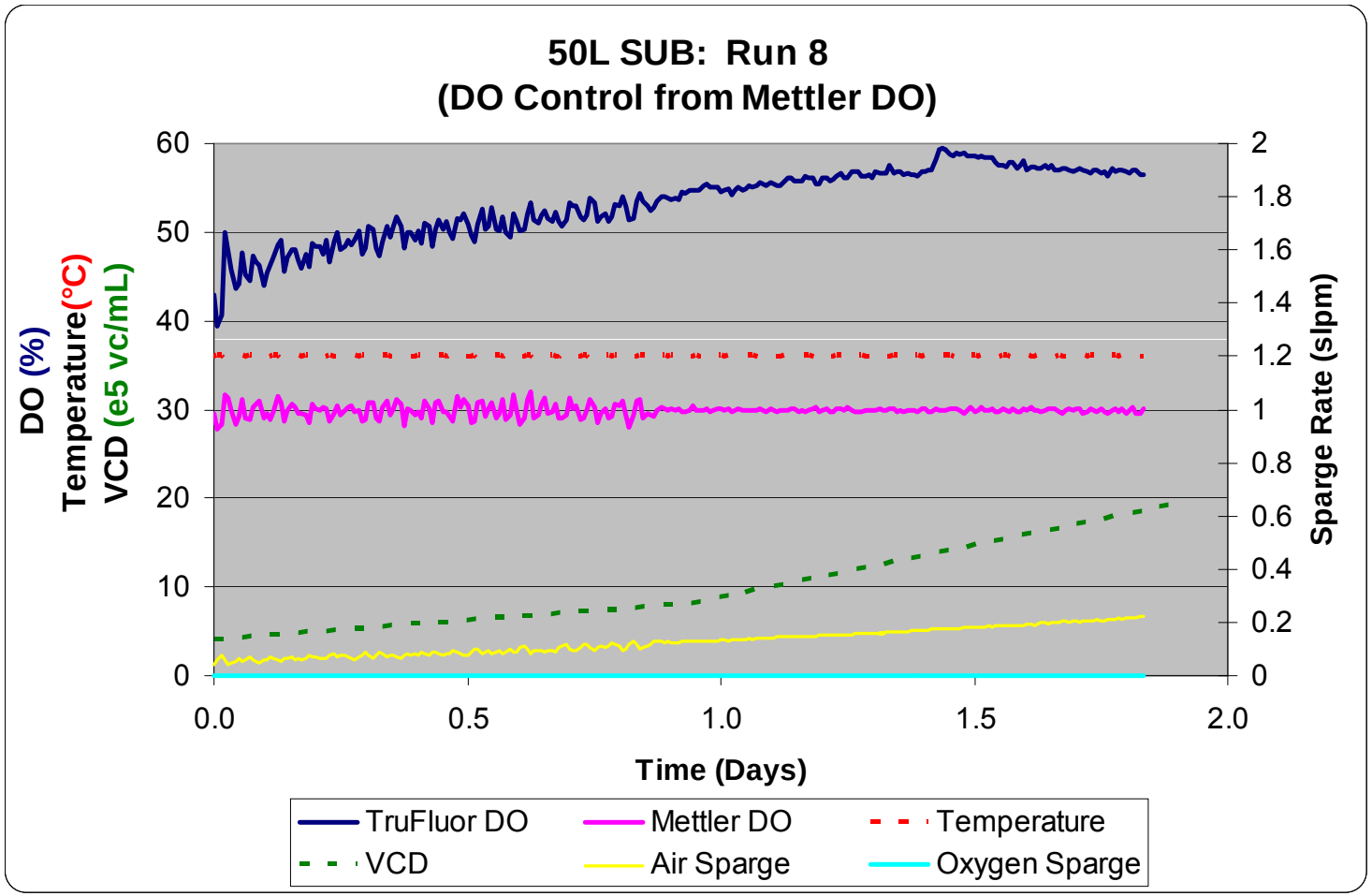
Dissolved Oxygen Sensors: Finesse TruFluor DO

50L Bioreactor



- DO controlled via Mettler probe
- Mettler probe was faulty based on its calibration slope

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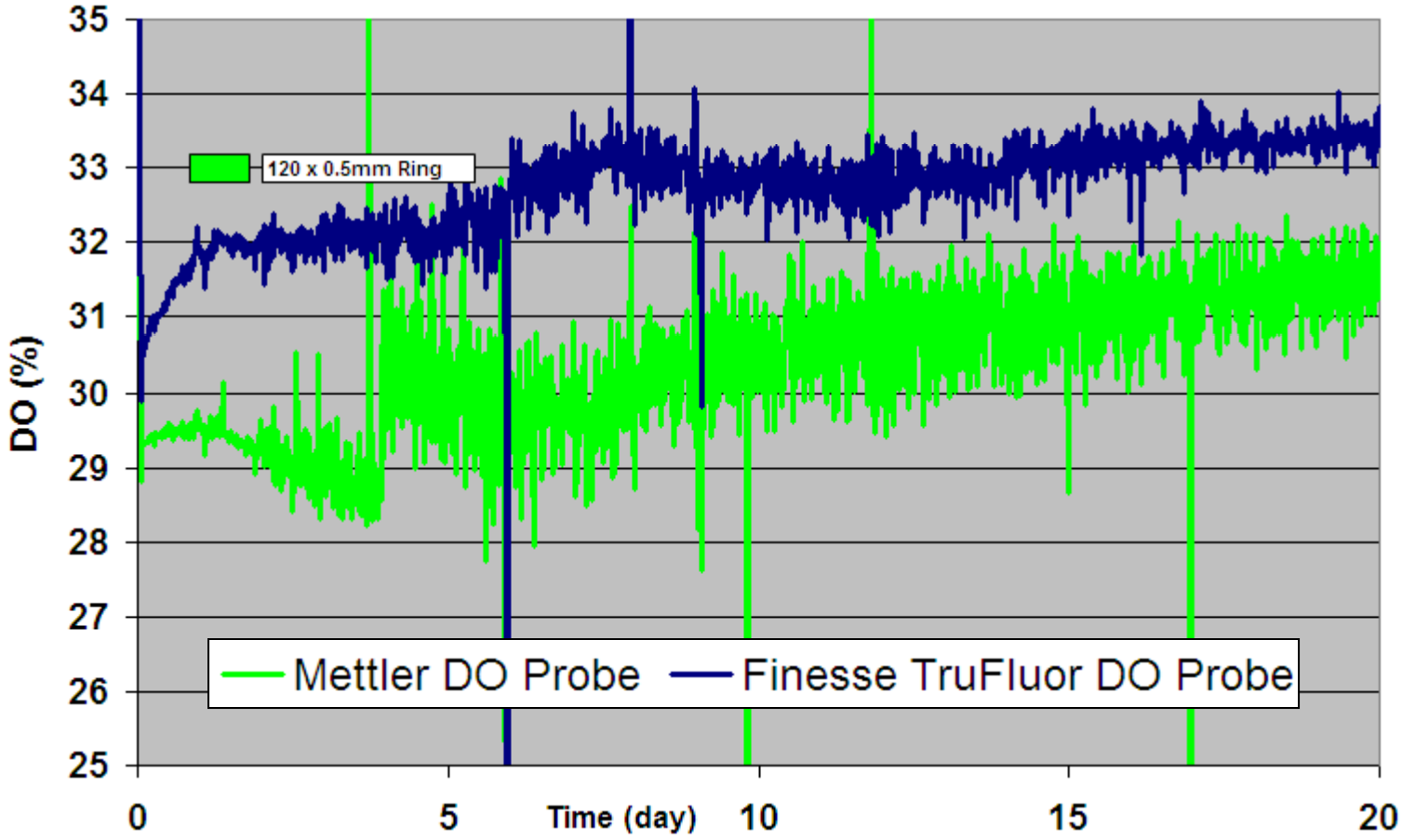
Dissolved Oxygen Sensors: Finesse TruFluor DO

1,000L Bioreactor



- DO controlled via Mettler probe
- 2-3% DO variation between two probes

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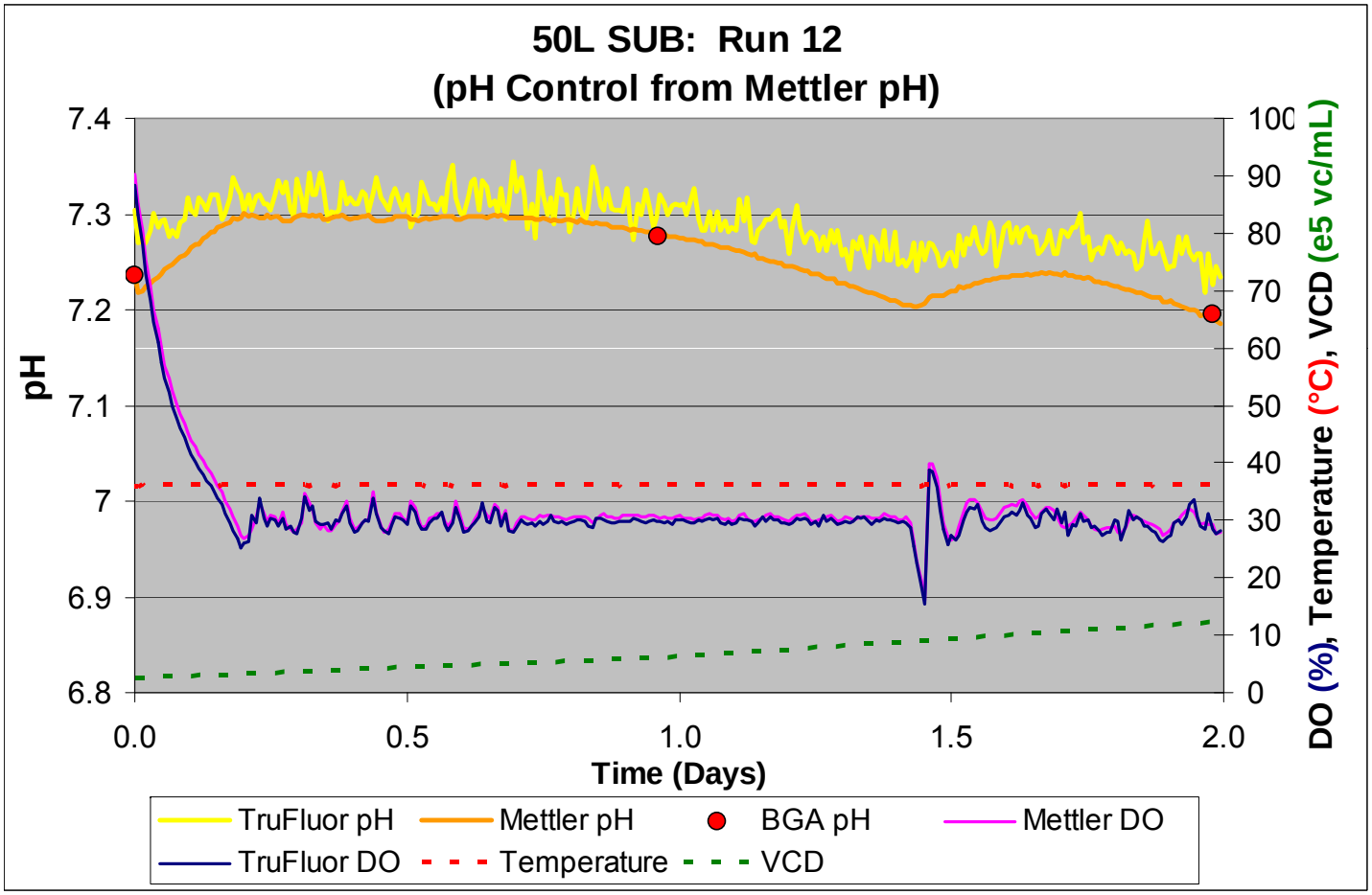
pH Sensors: Finesse TruFluor pH
50L Bioreactor



- pH controlled via Mettler probe
- pH noisy with Finesse TruFluor pH
  - First run with sensor
  - Prototype reader

TruFluor pH drift no greater than 0.05 pH units

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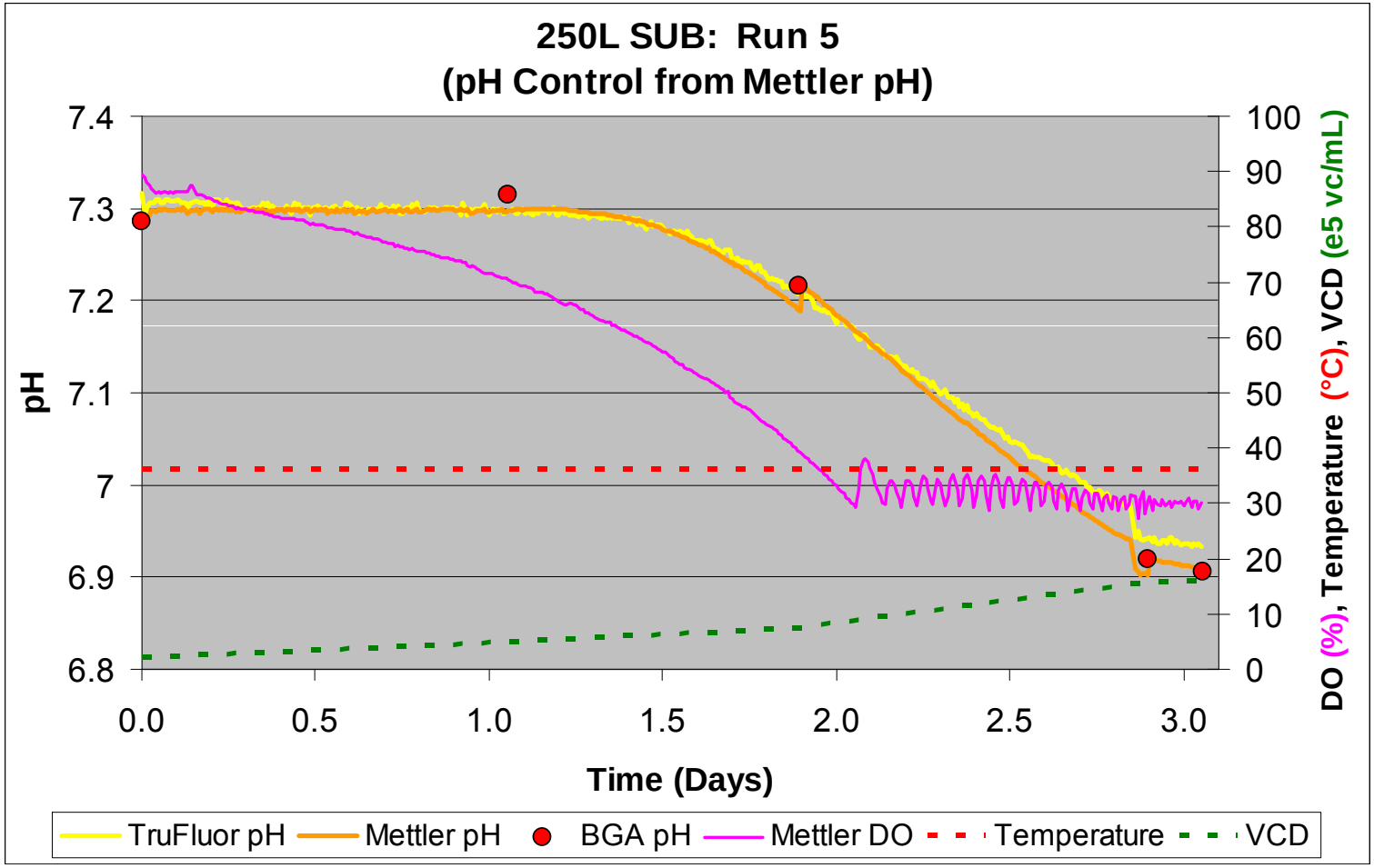
pH Sensors: Finesse TruFluor pH
250L Bioreactor



TruFluor pH in-line with Mettler pH

TruFluor pH drift no greater than 0.03 pH units

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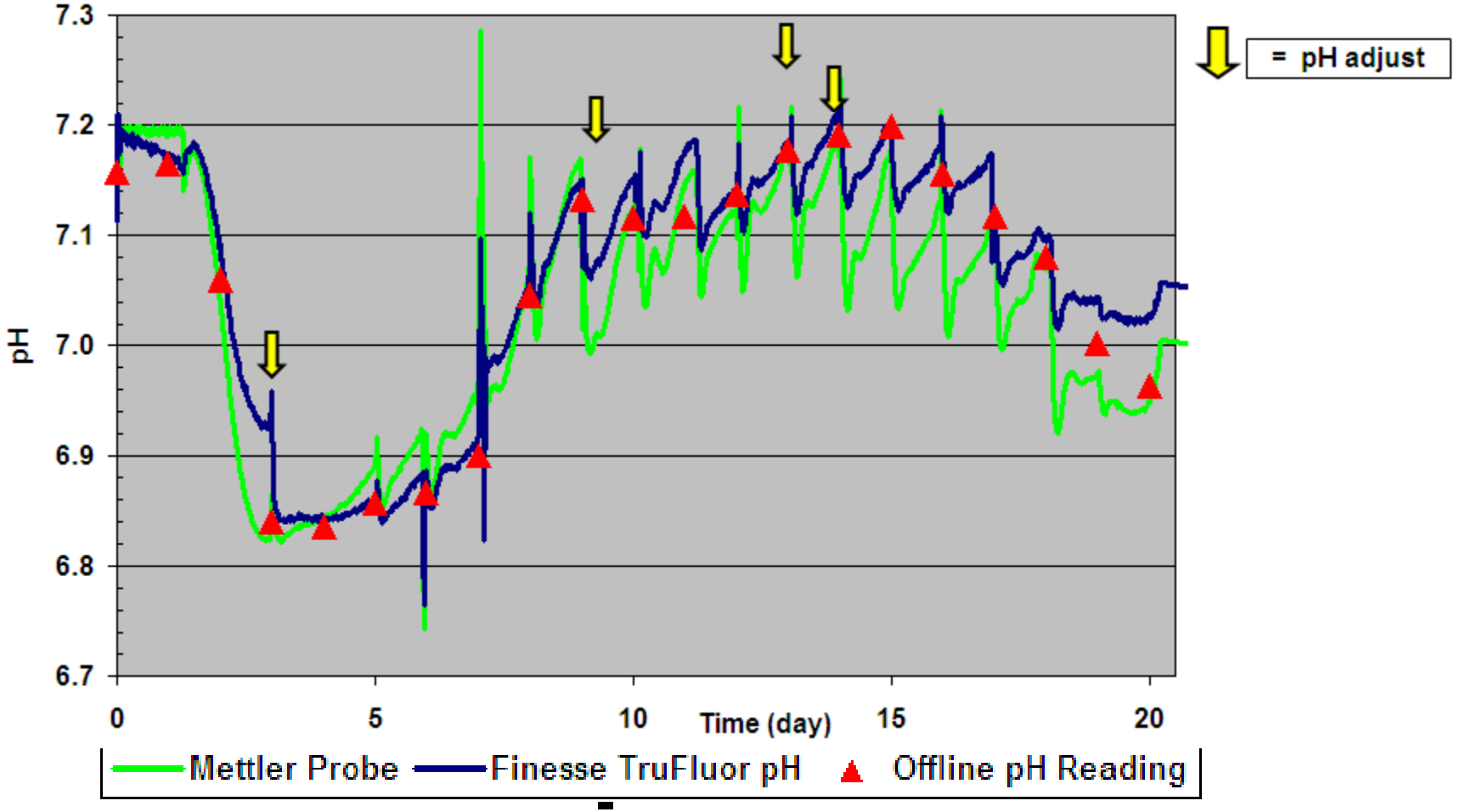
pH Sensors: Finesse TruFluor pH
1,000L Bioreactor



Variation between probes ≤ 0.08 pH units

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Disposable Sensor Summary

TruFluor DO sensors

- Commercial grade evaluated
- Robust comparable results vs std Mettler probes

TruFluor pH sensors

- Prototype units utilized, non-commercial grade
- Initial observations indicate positive results
- Robustness to improve with commercial grade sensor/reader

TruTorr pressure sensors

- To be evaluated with prototype in the near future

Conclusions

- Sufficient blend time and mass transfer
- Proof of concept cell culture runs successful
- High titer process supported
- Operating costs
  - Equivalent to stainless steel
  - Time savings
- Disposable sensors
  - Promising for the future

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