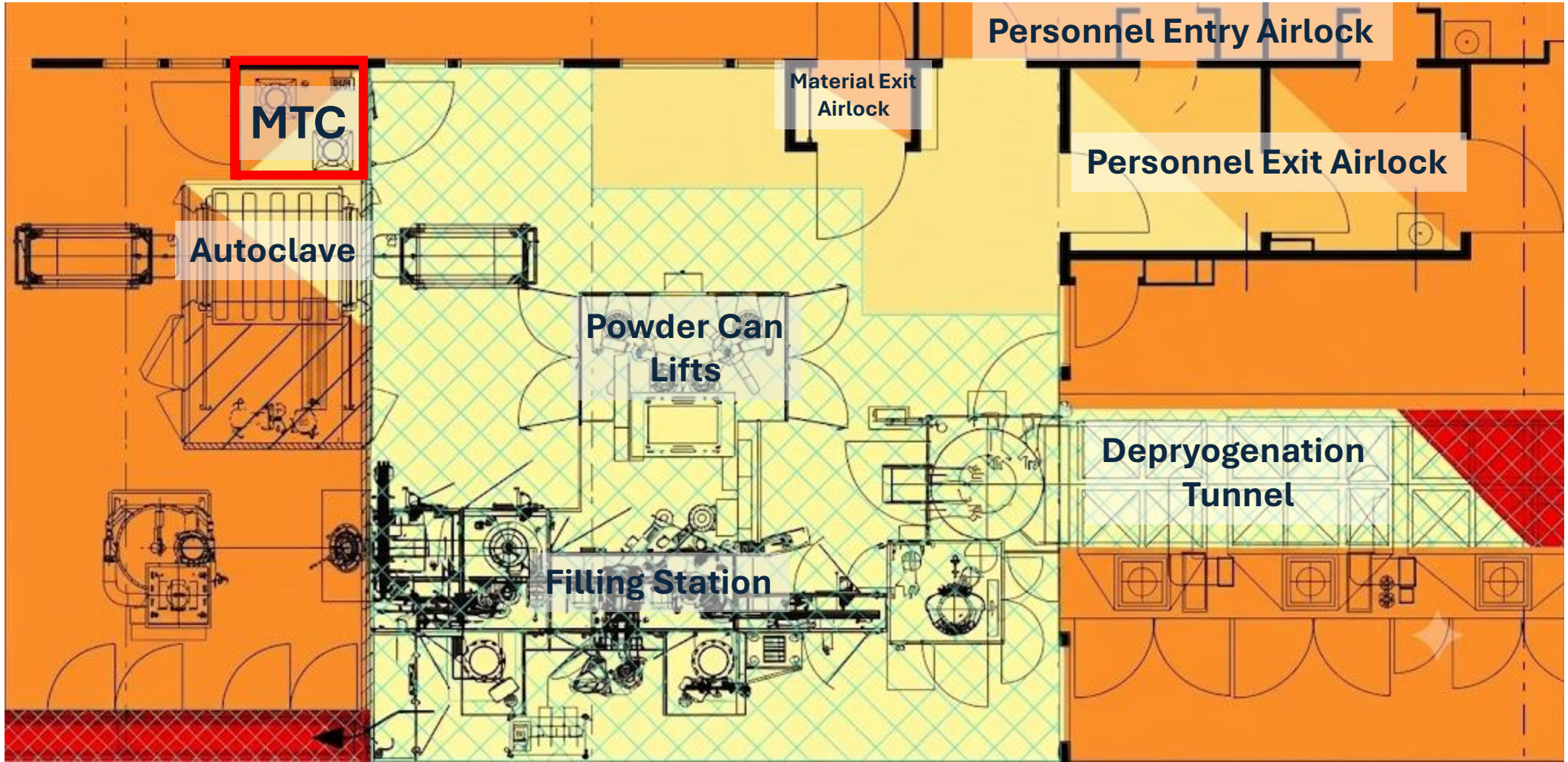
How can a homogeneous H_2O_2 Distribution enable time- and load-independent Decontamination in a Material Airlock

Comparative Analysis of Static vs. Active Distribution with Puro™ MagLev

Presenter: Dr. Simone Bläsi | Results of Case Study Nov 2025 & Jan 2026

Room Layout of Filling Line



A-Zone

B-Zone

D-Zone

Material Transfer Chambers (MTCs)

The Gateway to Grade A/B

- Material Transfer Chambers are critical for the safe transfer of tools, materials, and equipment between cleanliness zones.
- Prevents cross-contamination.
- “Sterilizes” surfaces via VHP (vaporized H_2O_2).
- Validated decontamination process ensures efficient surface decontamination of all validated loading patterns.

Load: Empty Cart

View on right side of cart

View on front side of cart

View from D-Zone

Load: Production (D)

View on right side of cart

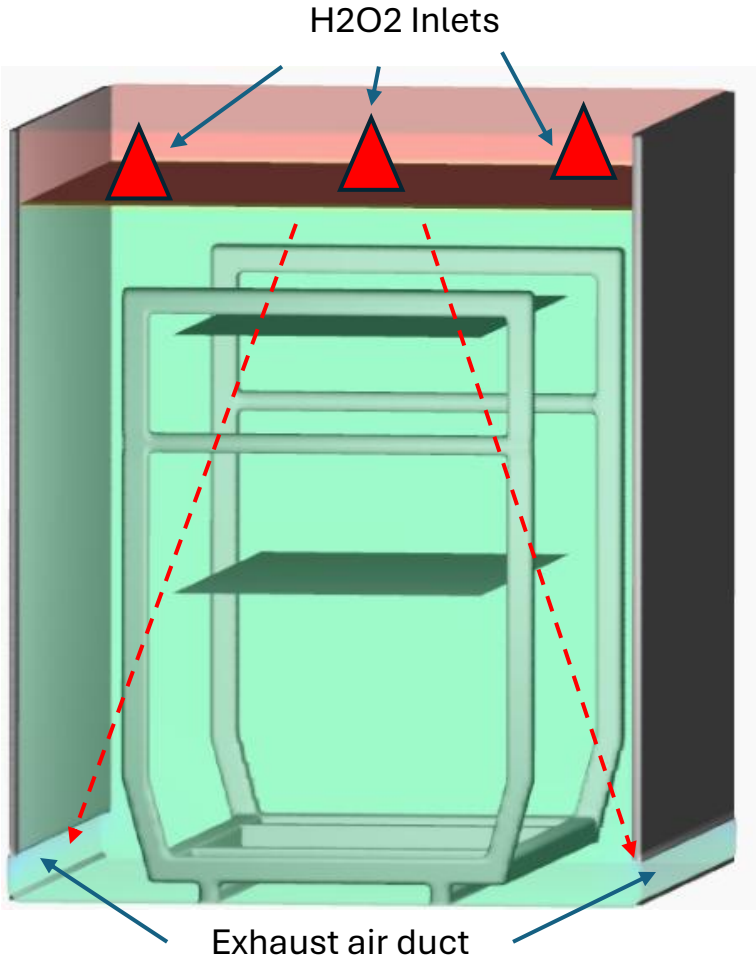
View on left side of cart

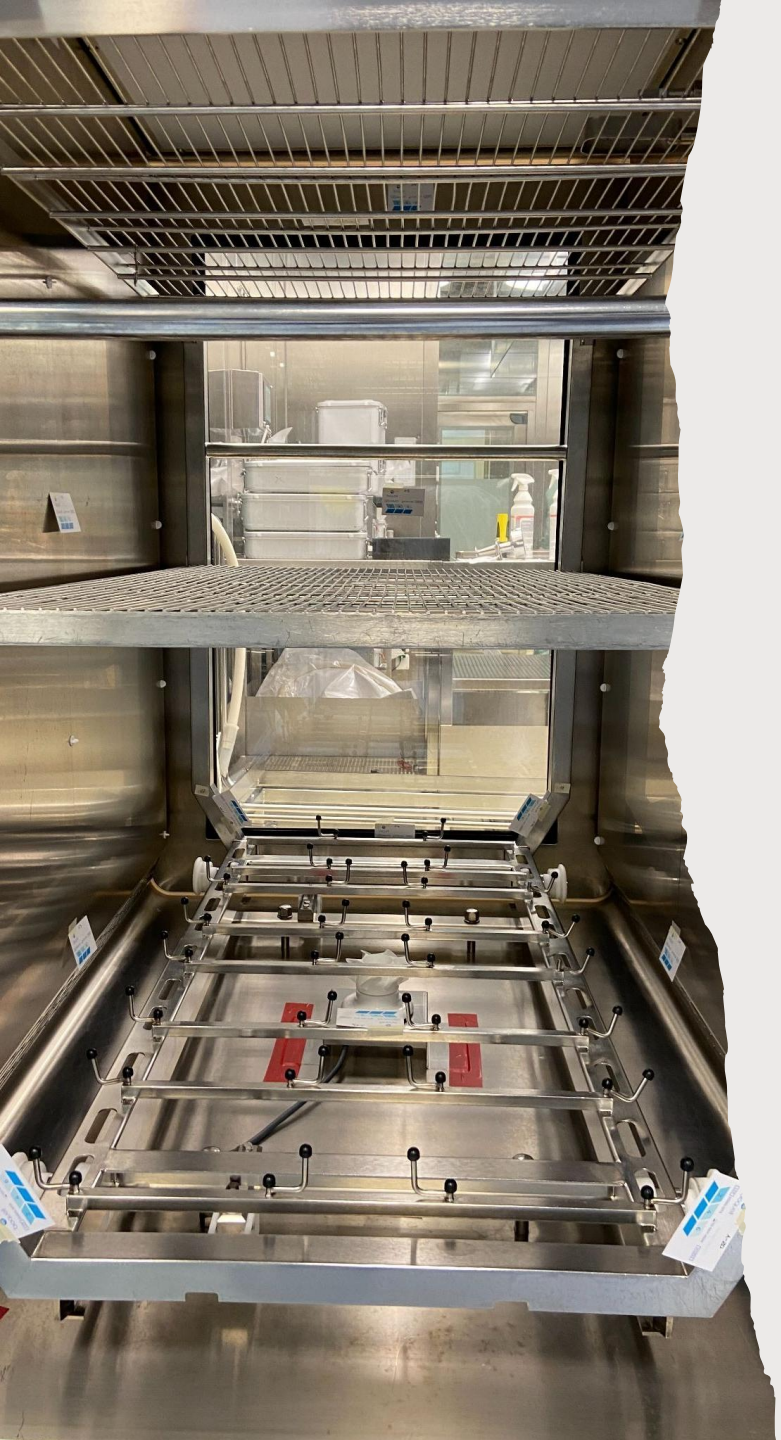
View from D-Zone

Material Transfer Chambers (MTCs)

The crucial Point – System Design

- Load-independent decontamination process depends on homogeneous H_2O_2 distribution, generated by turbulences.
- Distribution depends on design.
  - If given, the load is flexible.
    - Amount of items of validated loading patterns can be reduced
    - High flexibility
    - Adaptive to production need
  - If not given, the load is fixed and not variable.
    - Validated loading patterns are allowed to use, but
    - No flexibility in reducing amount of loading items.
    - Challenging for production, since loading can not reflect availability of items and need for production process.





How to improve H_2O_2 Distribution

Active Turbulence via Puro

Why Puro?

- does not require lubricants or sealings
- no mechanical bearing and thus no friction
- no mechanical contact between fan rotor and motor, therefore, no wear and no particle generation
- Maintenance-free
- non-absorbing high-performance plastic
- no other material in contact with H_2O_2
- can be operated at extremely high speeds

How to evaluate H_2O_2 Distribution

- Biological Indicators (BIs)
  => provide ≥1.0x10^6 spores
  => yes/no growth (≥ 6log-reduction)
  => no/growth (< 6log-reduction)

- Chemical Indicators (CIs)
  measure log-reduction
  => graduated result
  => spectrocolorimeter reader
- Calculation of Distribution (Range):
  Max log-reduction – Min log-reduction

Bioquell CI
Bericht

Benutzername: Klein, Leonie
Gerätekalibrierung gültig bis: 25.07.2025

Berichtsdatum: 16.01.2026
Gerät S/N: 2010007223

Bioquell Isolator CI
Chargennummer: 25261L1273

Verfallsdatum: 02.09.2026

Name	Datum	Zeit	dE	Log Reduzierung	Ergebnis
Sample 1	16.01.2026	11:06	16.11	4.95	FAIL
Sample 2	16.01.2026	11:06	13.01	5.52	FAIL
Sample 3	16.01.2026	11:06	17.02	4.78	FAIL
Sample 4	16.01.2026	11:06	16.85	4.81	FAIL
Sample 5	16.01.2026	11:07	13.99	5.34	FAIL
Sample 6	16.01.2026	11:07	18.54	4.50	FAIL
Sample 7	16.01.2026	11:07	16.78	4.82	FAIL
Sample 8	16.01.2026	11:07	13.97	5.34	FAIL
Sample 9	16.01.2026	11:07	18.13	4.57	FAIL
Sample 10	16.01.2026	11:07	15.56	5.05	FAIL
Sample 11	16.01.2026	11:07	16.46	4.88	FAIL
Sample 12	16.01.2026	11:08	16.29	4.91	FAIL
Sample 13	16.01.2026	11:08	17.73	4.65	FAIL
Sample 14	16.01.2026	11:08	19.01	4.41	FAIL
Sample 15	16.01.2026	11:08	16.18	4.93	FAIL
Sample 16	16.01.2026	11:08	15.46	5.06	FAIL
Sample 17	16.01.2026	11:08	18.51	4.50	FAIL
Sample 18	16.01.2026	11:09	16.95	4.79	FAIL
Sample 19	16.01.2026	11:09	15.84	4.99	FAIL
Sample 20	16.01.2026	11:09	19.42	4.33	FAIL
Sample 21	16.01.2026	11:10	16.51	4.87	FAIL
Sample 22	16.01.2026	11:10	17.85	4.62	FAIL
Sample 23	16.01.2026	11:10	15.89	4.99	FAIL
Sample 24	16.01.2026	11:11	15.82	5.00	FAIL
Sample 25	16.01.2026	11:11	14.38	5.26	FAIL

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Test Design

Jan 2026: Testruns with Puro

Nov 2025: Testruns without Puro
(N/A or Reference Runs)

2 loading patterns
empty cart / production load (D)

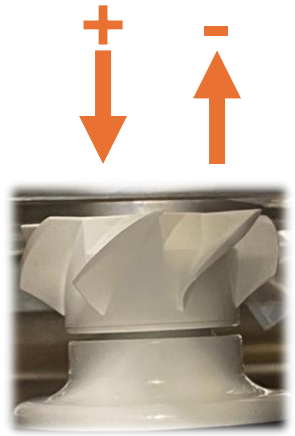
Number of tested locations (CIs)
26 empty cart
33 production load (D)

2 decontamination phase durations
7 min / 13 min

2 Puro positions
floor / side wall

Puro operating modes
continuous / iterative

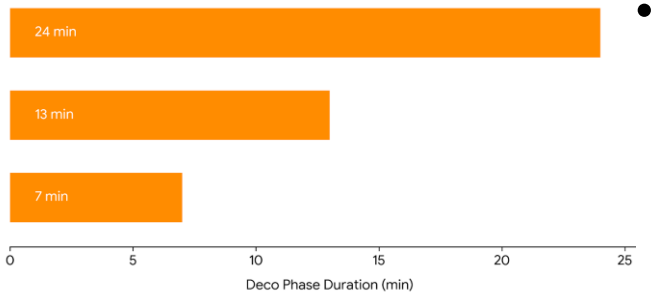
Puro programms
contin. -4000 rpm
contin. +4000 rpm
iterative 3 s -8000 rpm / 10 s pause
iterative 10 s -8000 rpm / 10 s pause
iterative 10 s +8000 rpm / 10 s -8000 rpm



Remarks

- Puro on side wall only tested in 3 runs (13 min) with production load.
  (contin. -4000 rpm ¦ iterative 3 s -8000 rpm / 10 s pause ¦ contin. +4000 rpm)

  For reasons of space, installation would not be feasible in the future.



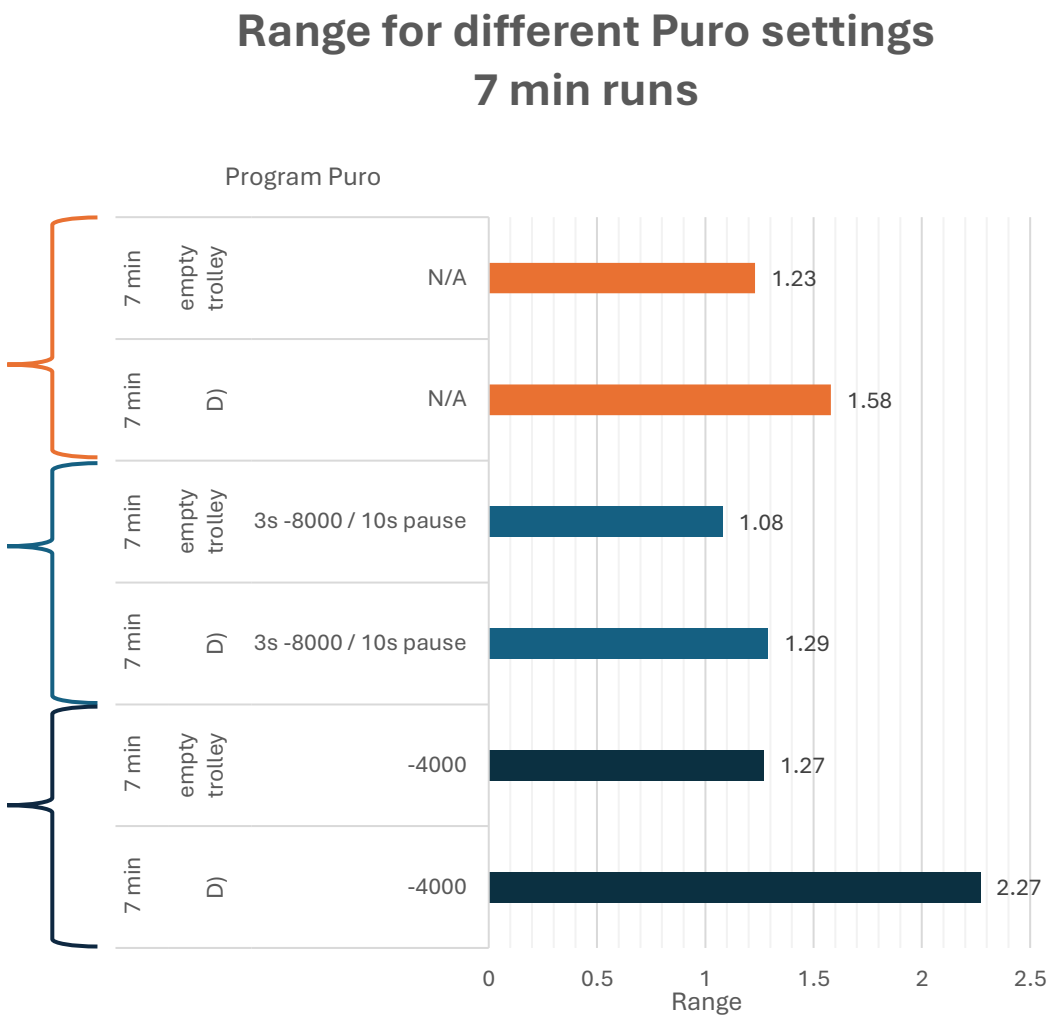
- Duration of production deco phase: 24 min

  Deco phase durations for testing (7 min / 13 min) were designed to not get a full kill to reveal differences.

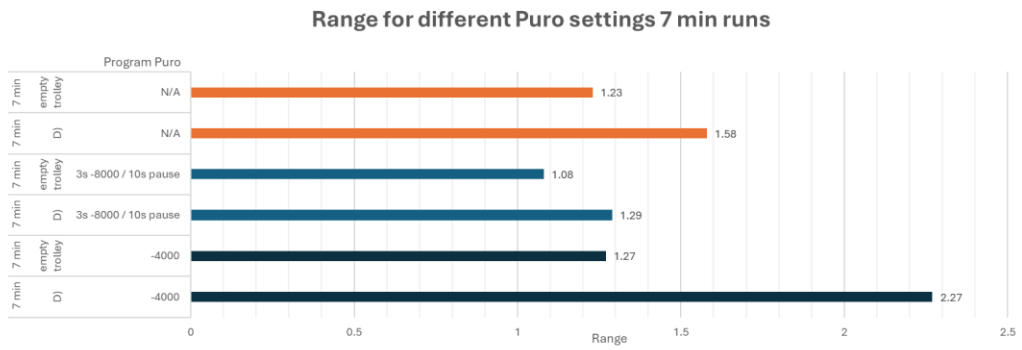
- The key learnings on the combination of Puro, load and deco phase duration will be summarized on the next 2 slides for a clear understanding.
- Further results from the tests can be found in the back-up slides.

Comparison of H_2O_2 distribution w/wo Puro (on the floor)

- In the absence of Puro, the distribution is proven to be dependent on the load.
- Best load independence shown for iterative operating mode.
- Cont. operating mode is load dependent.
- General: H_2O_2 distribution (range) is poorer with production load (D) than at minimum load (empty cart)



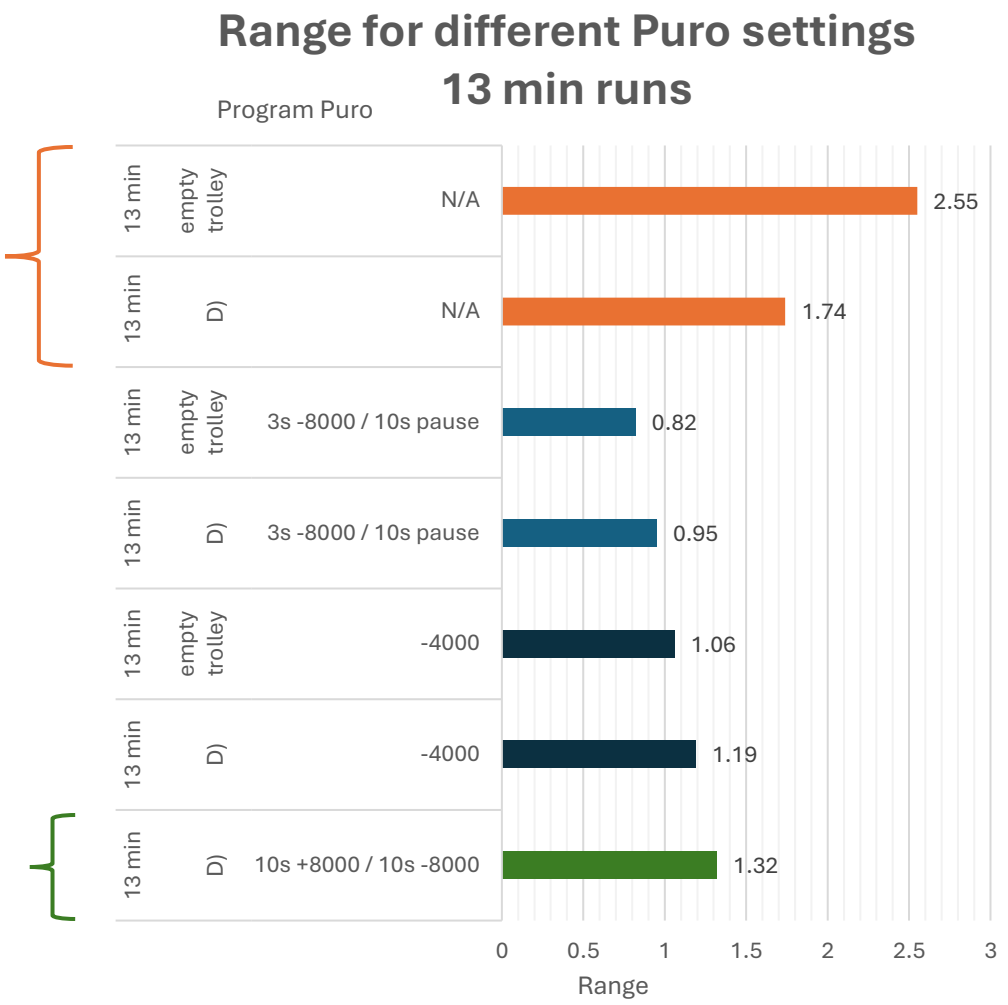
Comparison of H_2O_2 distribution w/wo Puro (on the floor)



- Impact of time: Distribution (range) is poorer at minimum load (empty cart) than at maximum load (D).
- Volume of load items causes turbulences (Best Case). Reason for need to stick to the defined loading pattern.

- With Puro, the distribution at minimum load is better for both settings than at maximum load (opposite of the reference)
- For both Puro settings tested, the differences in distribution between minimum and maximum load are closer to each other.

- Alternating mode of the Puro has the “worst“ distribution.



Summary

Reference Runs (N/A) without Puro

- As the duration increases, the difference in the distribution between minimum and maximum load is reversed.
- The minimum load represents the worst-case scenario due to the poor distribution.
- Conclusion: Distribution depends on both time and load

Puro Runs

- Iterative mode (3s -8000 rpm / 10 s pause) produced the most uniform distribution for both maximum and minimum loading, as well as for the two deco times.
- Slight differences in distribution (maximum vs. minimum loading) can be eliminated through cycle duration.
- Conclusion: Iterative operating mode of Puro offers load-independent distribution by means of an appropriate deco phase duration.

Conclusion

How can a homogeneous H_2O_2 Distribution enable time- and load-independent Decontamination in a Material Airlock?

- By using the Puro, this can be achieved.
- Based on the available results, the validation of a new process can take place.
- This makes it as flexible as possible to adapt the loading to the needs of production.
- The homogeneous distribution through the Puro with an iterative program enables a load-independent and largely time-independent process that meets the regulatory requirements for spore log-reduction.

Special Thanks to...

- the whole Levitronix team

  especially...
- Ivana Ferstera (online and site support)
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- Leonie Klein (executing tests in Jan 2026)

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Back-up Slides

Digging deeper into data….

Overview of Testruns

Execution Date	Run No. / Deco Dur.	Load	Position Puro	Programme Puro
29-Nov-2025	Lauf 8 / 13 min	D)	N/A	N/A
15-Jan-2026	Lauf 1 / 13 min	D)	Floor	-4000
15-Jan-2026	Lauf 2 / 13 min	D)	Floor	3s -8000 / 10s Pause
15-Jan-2026	Lauf 3 / 13 min	D)	Floor	+4000
16-Jan-2026	Lauf 4 / 13 min	D)	Wall	-4000
16-Jan-2026	Lauf 5 / 13 min	D)	Wall	3s -8000 / 10s Pause
16-Jan-2026	Lauf 6 / 13 min	D)	Wall	+4000
20-Jan-2026	Lauf 7 / 13 min	D)	Floor	10s -8000 / 10s Pause
20-Jan-2026	Lauf 8 / 13 min	D)	Floor	-8000
20-Jan-2026	Lauf 9 / 13 min	D)	Floor	10s +8000 / 10s -8000
29-Nov-2025	Lauf 7 / 7 min	D)	N/A	N/A
21-Jan-2026	Lauf 10 / 7 min	D)	Floor	3s -8000 / 10s Pause
21-Jan-2026	Lauf 11 / 7 min	D)	Floor	-4000
08-Nov-2025	Lauf 1 / 7 min	Empty Cart	N/A	N/A
22-Jan-2026	Lauf 12 / 7 min	Empty Cart	Floor	-4000
22-Jan-2026	Lauf 13 / 7 min	Empty Cart	Floor	3s -8000 / 10s Pause
08-Nov-2025	Lauf 2 / 13 min	Empty Cart	N/A	N/A
23-Jan-2026	Lauf 14 / 13 min	Empty Cart	Floor	-4000
23-Jan-2026	Lauf 15 / 13 min	Empty Cart	Floor	3s -8000 / 10s Pause

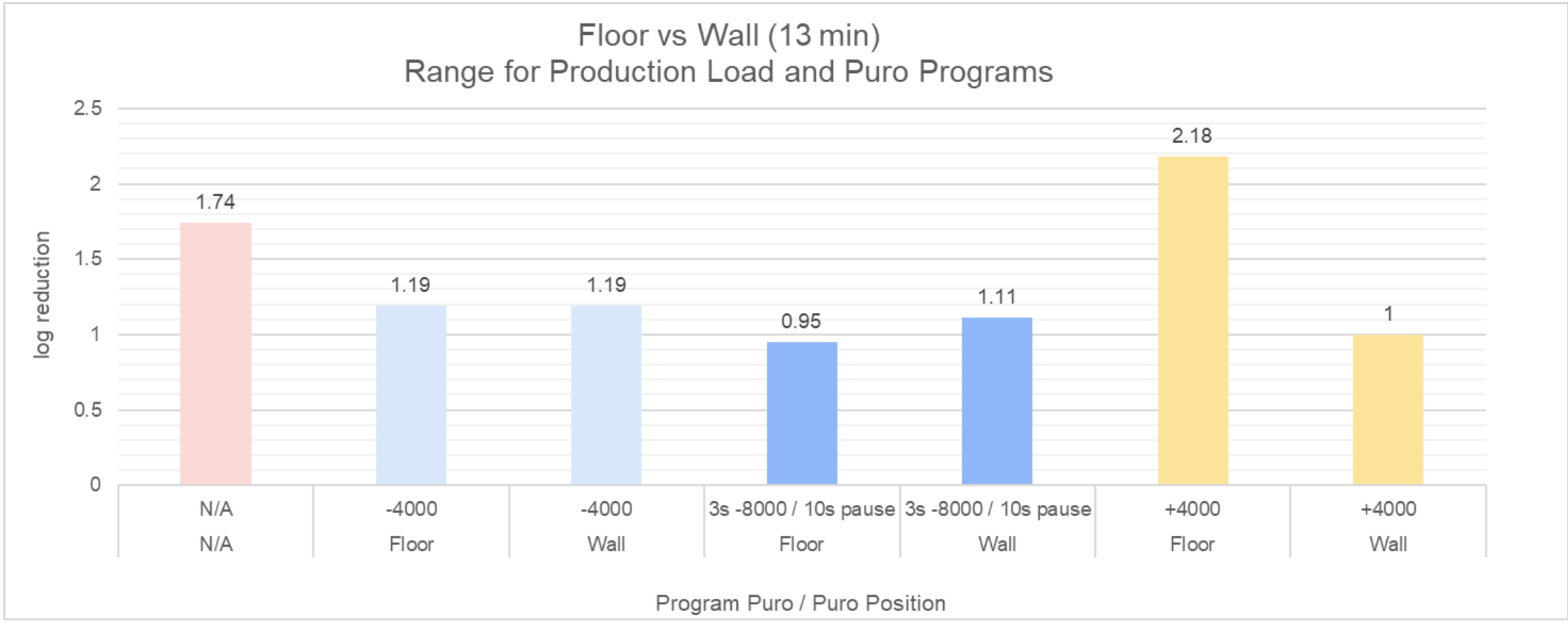
Overview
of the runs performed (Jan 2026)
and their corresponding reference runs
(Nov 2025)

Puro Position and Loading

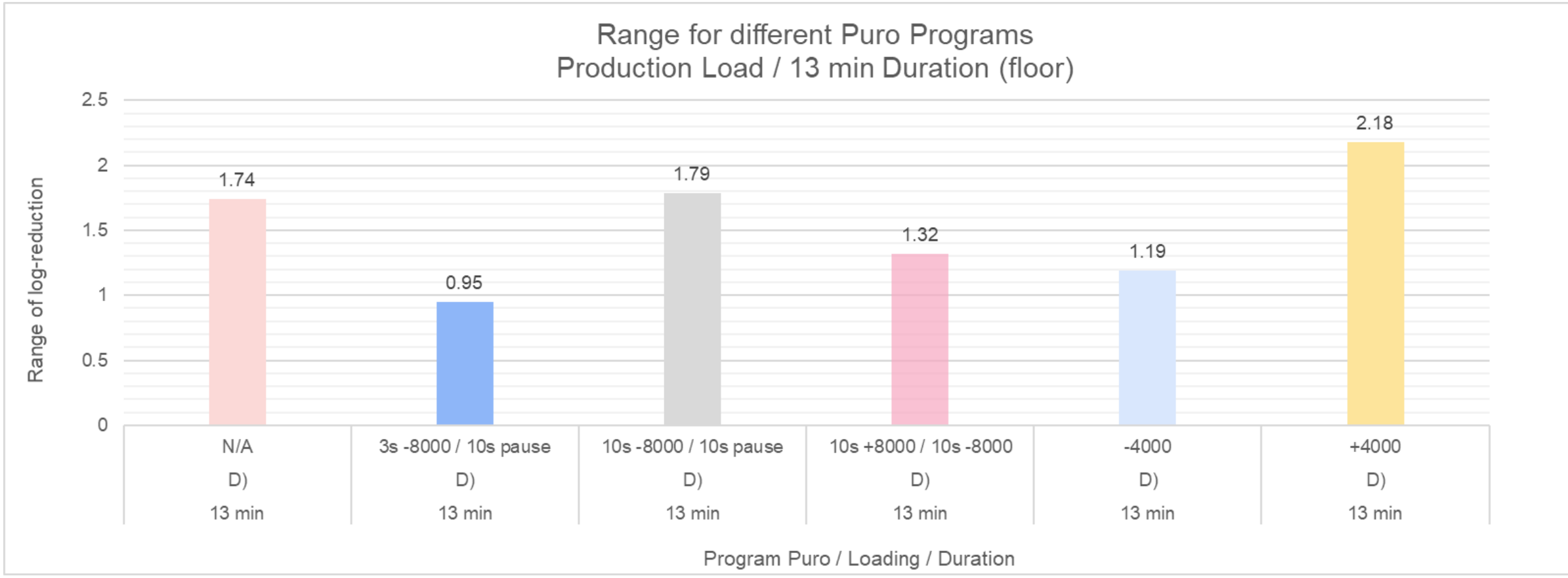
Puro on floor
empty cart

Puro on side wall
Production load (D)

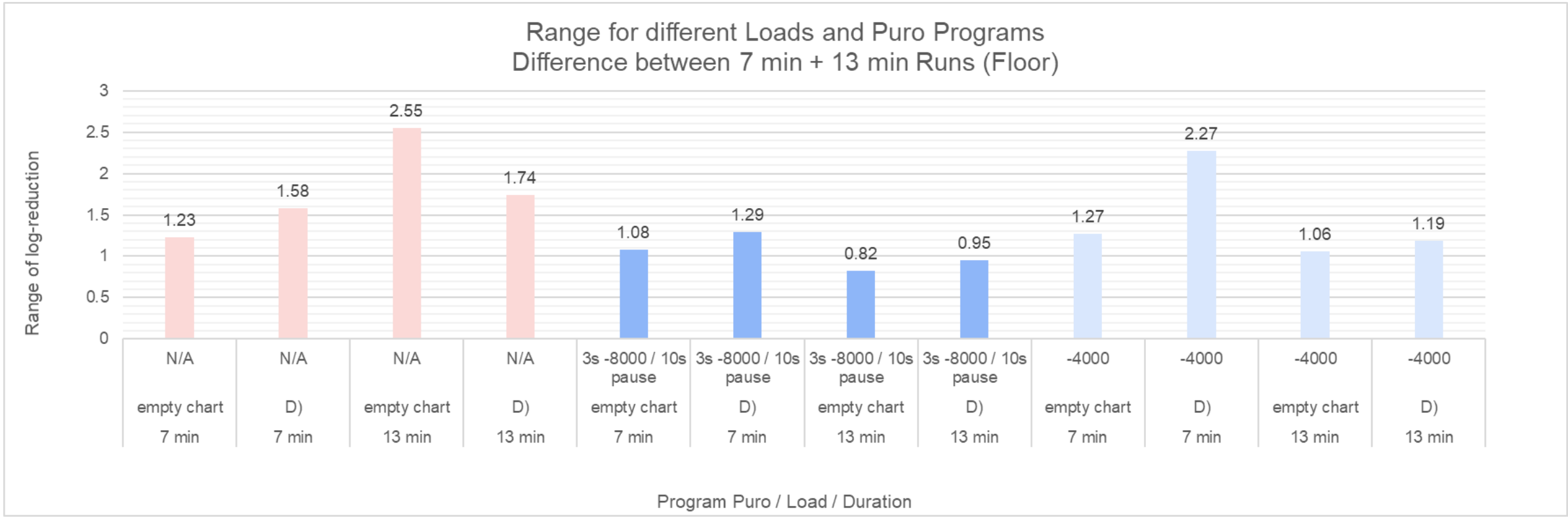
Comparison Puro Position



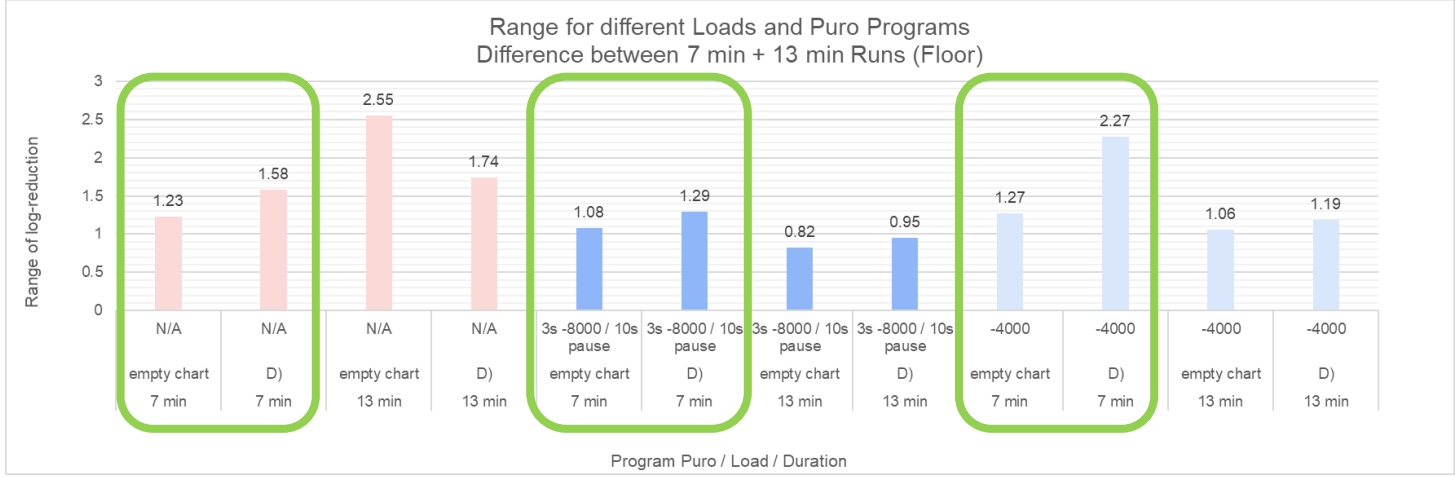
Comparision Puro Program



Load + Deco Time: Impact on Distribution



Conclusion for 7 min



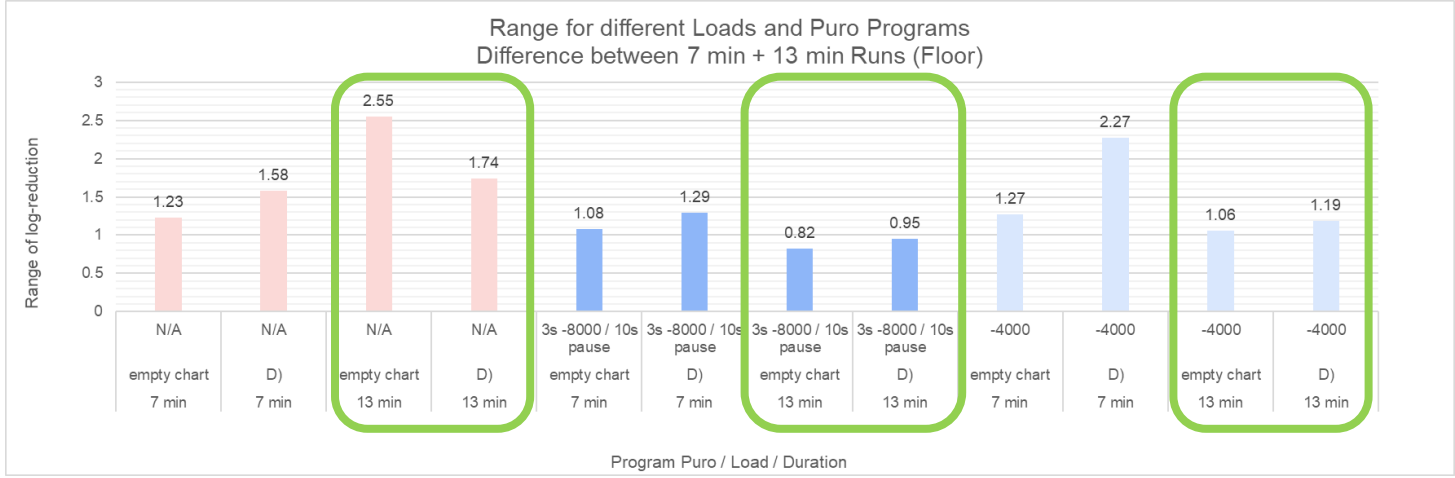
In general

- The distribution (range) is poorer at maximum load (D) than at minimum load (empty cart)

With Puro vs without Puro

- When set to 3 s at -8000 rpm / 10 s pause, the difference is smaller compared to the reference run.
- at -4000 rpm, the difference is more significant compared to the reference run

Conclusion for 13 min



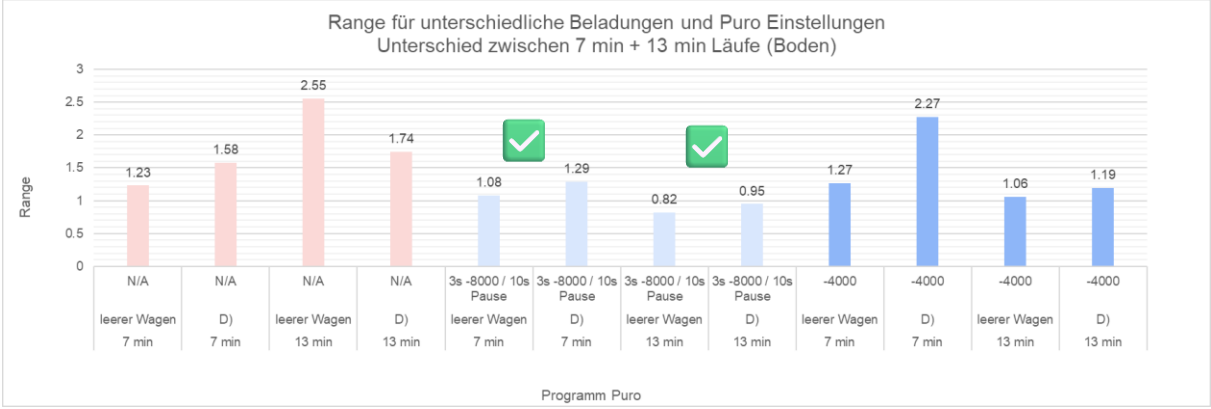
Reference Runs

- The distribution (range) is poorer at minimum load (empty cart) than at maximum load (D).

With Puro vs without Puro

- With Puro, the distribution at minimum load is better for both settings than at maximum load (the opposite of the reference)
- For both Puro settings tested, the differences in distribution between minimum and maximum load are closer to eaart other.

Summary
Load and Deco Duration



Reference Runs

As the duration increases, the difference in the distribution

between minimum and maximum load is reversed.

The minimum load represents the worst-case scenario due to the poor distribution.

Conclusion: the distribution depends on both time and load

Puro Programs

3s -8000 rpm / 10 s Pause produced the most uniform distribution for both

maximum and minimum loading, as well as for the two deco times.

Conclusion: the best setting for reaching a distribution independent of time and loading