

Executive Summary

Disposable Phase B precision acceptance

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Report scope	core_judgement_business
Study ID	QH-PC-EXAMPLE-2026-0001
LSL / USL	9.985 / 10.015
Target	10.000

ENGINEERING RELEASE DECISION

Do not release

Decision confidence: High

Do not release. The process does not have sufficient inherent capability to meet the internal screening benchmark $Cpk \geq 1.33$. 6 observed measurements exceed the specification limits (3 above USL and 3 below LSL). Verify the nonconforming observation and measurement system, reduce sources of variation then confirm capability with a representative time-ordered study before release.

Why

- Cp 0.392 is below the internal screening benchmark 1.33.
- 6 observed out-of-spec measurements (3 above USL and 3 below LSL) in the supplied sample.
- Business Impact reliability: User-confirmed traceable production rate; dominant cost driver: Scrap.

Immediate priorities

- Contain or trace the affected output.
- Verify the observed upper-specification failure: repeat the measurement and confirm traceability before disposition.
- Record and verify measurement-system adequacy (MSA / Gage R&R) before a release decision.
- Reduce within-process variation.
- Collect a representative time-ordered confirmation study after corrective action and release only once the applicable requirement is demonstrated.

Core statistical assessment	critical
Business Impact	Calculated - see Business Impact section

This report is an engineering screening output. Confirm measurement-system adequacy, time order, sampling representativeness, specification authority, and customer-specific acceptance rules before release.

Study and Method

Study name	Disposable Phase B precision acceptance
Observation count	40
Minimum / maximum	9.978 / 10.022
Range	0.045
LSL	9.985
USL	10.015
Target	10.000
Method	Individuals / moving-range capability screening
Within estimate	Average moving range divided by d2 for individual data
Overall estimate	Sample standard deviation

Stability and normality screening

I-MR screening	No I-MR screening violation was detected in the supplied sequence. This does not prove statistical control.
Normality statistic	A-squared 0.038
Normality p-value	1.000
Normality interpretation	No strong screening signal detected. This does not prove normality.

Assumptions and limitations

- No I-MR screening violation was detected in the supplied sequence. This does not prove statistical control.
- No strong normality-screening signal was detected. This is not proof of normality.

Capability and Defect Performance

Capability metrics

Cp	0.392
Cpk	0.387
CPU / CPL	0.387 / 0.396
Pp	0.504
Ppk	0.499
PPU / PPL	0.499 / 0.510
Cpm	0.504
Mean	10.000
Within sigma	0.013
Overall sigma	0.010
Sample size	40

Defect performance

Observed defects	6 (15.0000%)
Observed below / above	3 / 3
Expected normal-model PPM	130420.3
Expected lower / upper PPM	63159.7 / 67260.6
Expected model yield	86.95797%

How to Read This Result

Cp and Cpk use the within estimate from successive moving ranges. **Pp and Ppk** use overall sample variation. A material Cpk-to-Ppk gap can indicate drift, shifts, mixing, or other time-related variation.

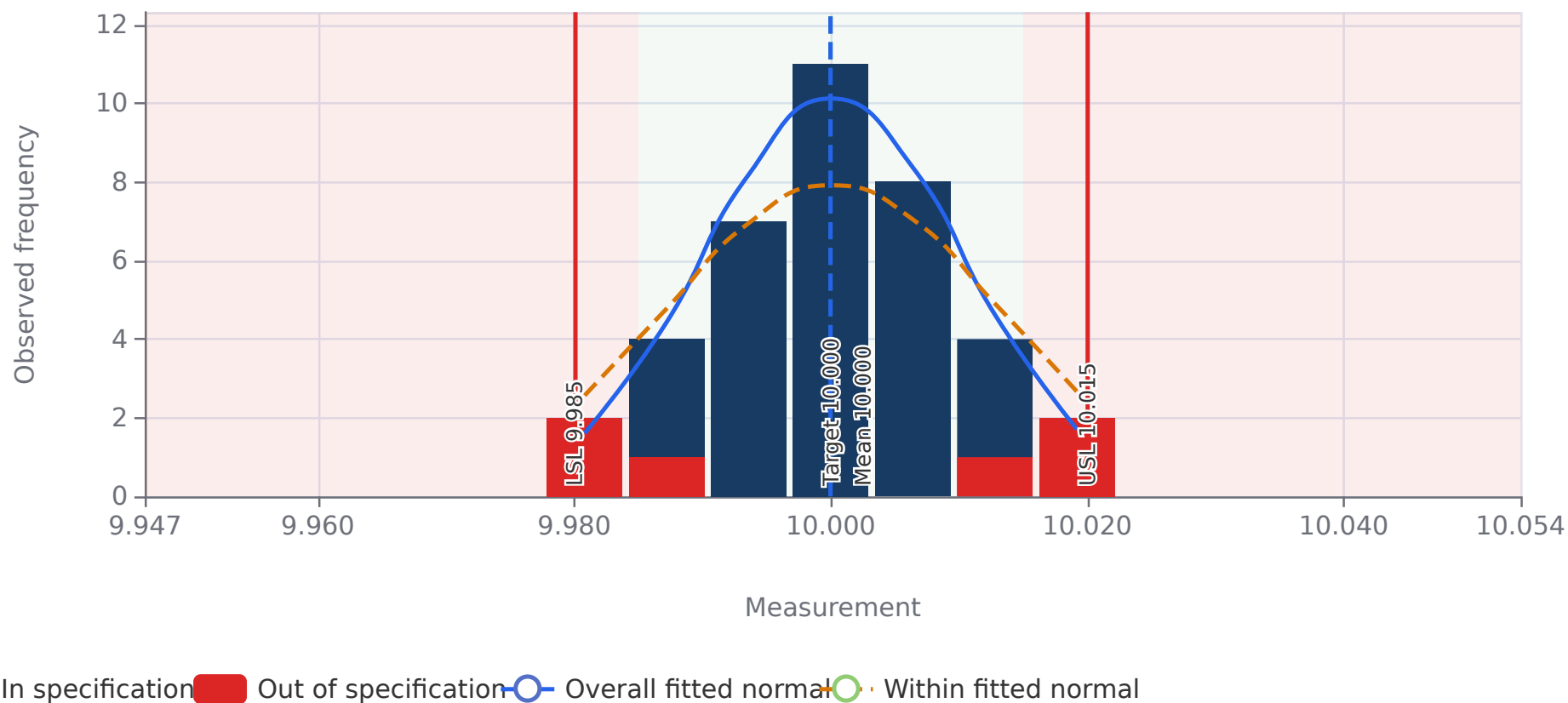
Observed defects describe this submitted sample. Expected PPM is a fitted normal-model tail estimate, not an observed production count and not proof of future performance.

Action Guidance

1. Address any stability signal before relying on capability for release.
2. Confirm the measurement system and specification authority.
3. Stratify by machine, cavity, tool, operator, lot, material, and time where relevant.
4. Collect a representative time-ordered confirmation sample after corrective action.

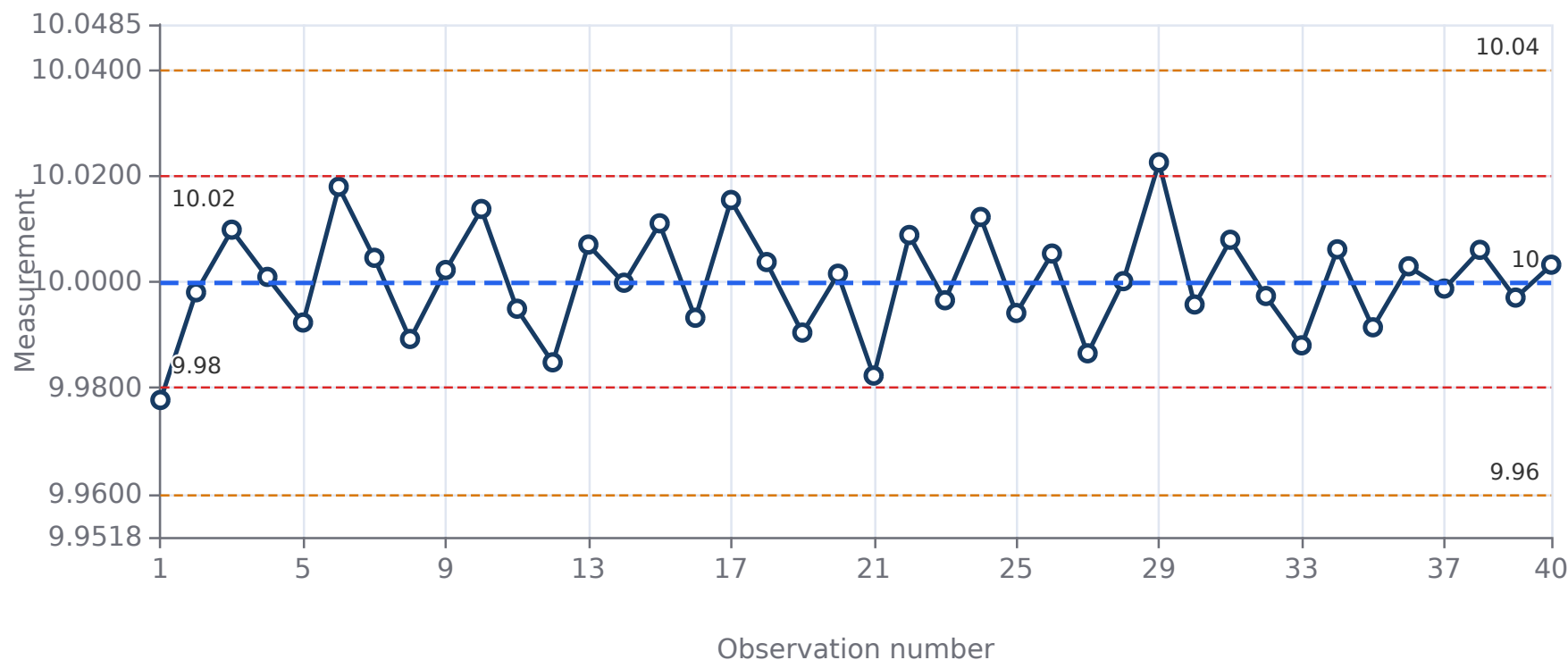
Process Distribution

Observed frequency and fitted normal-model frequency. The curve does not prove normality.



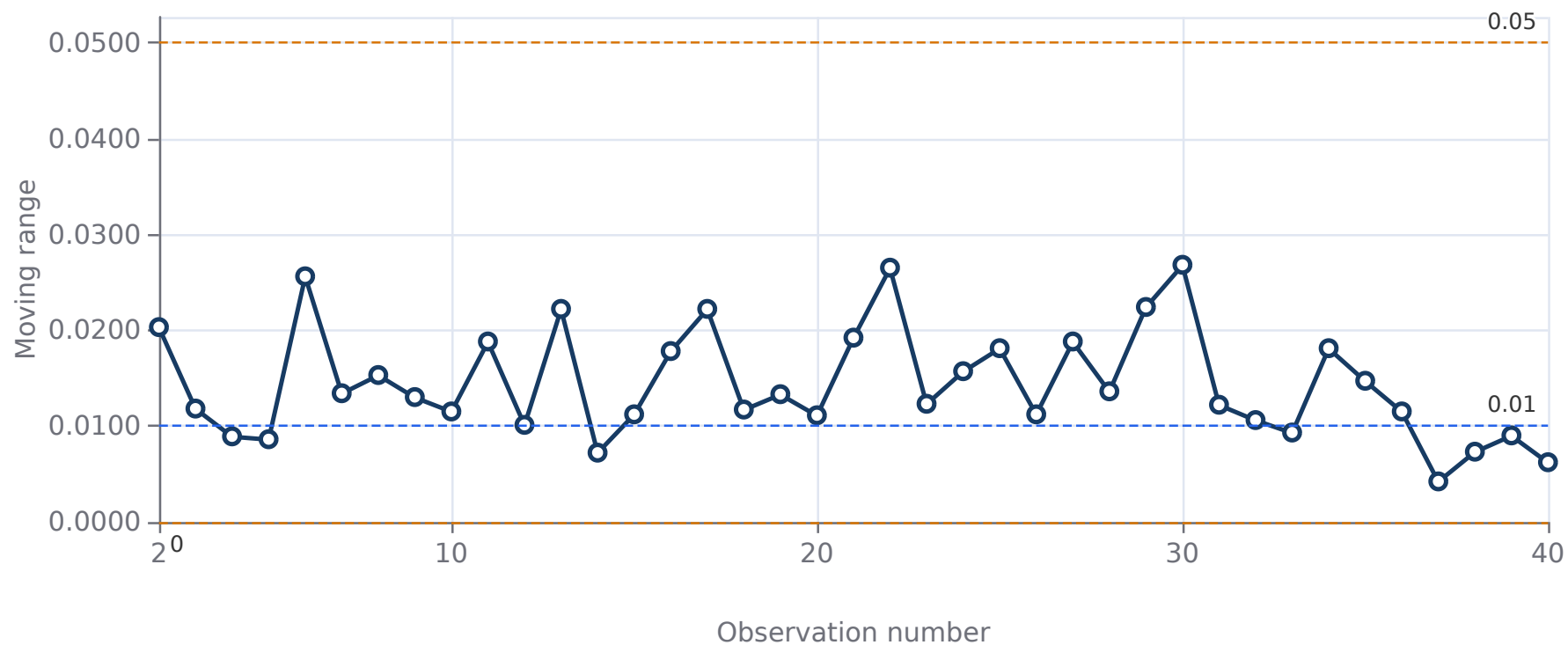
Individuals Chart

No I-MR screening violation was detected in the supplied sequence. This does not prove statistical control.



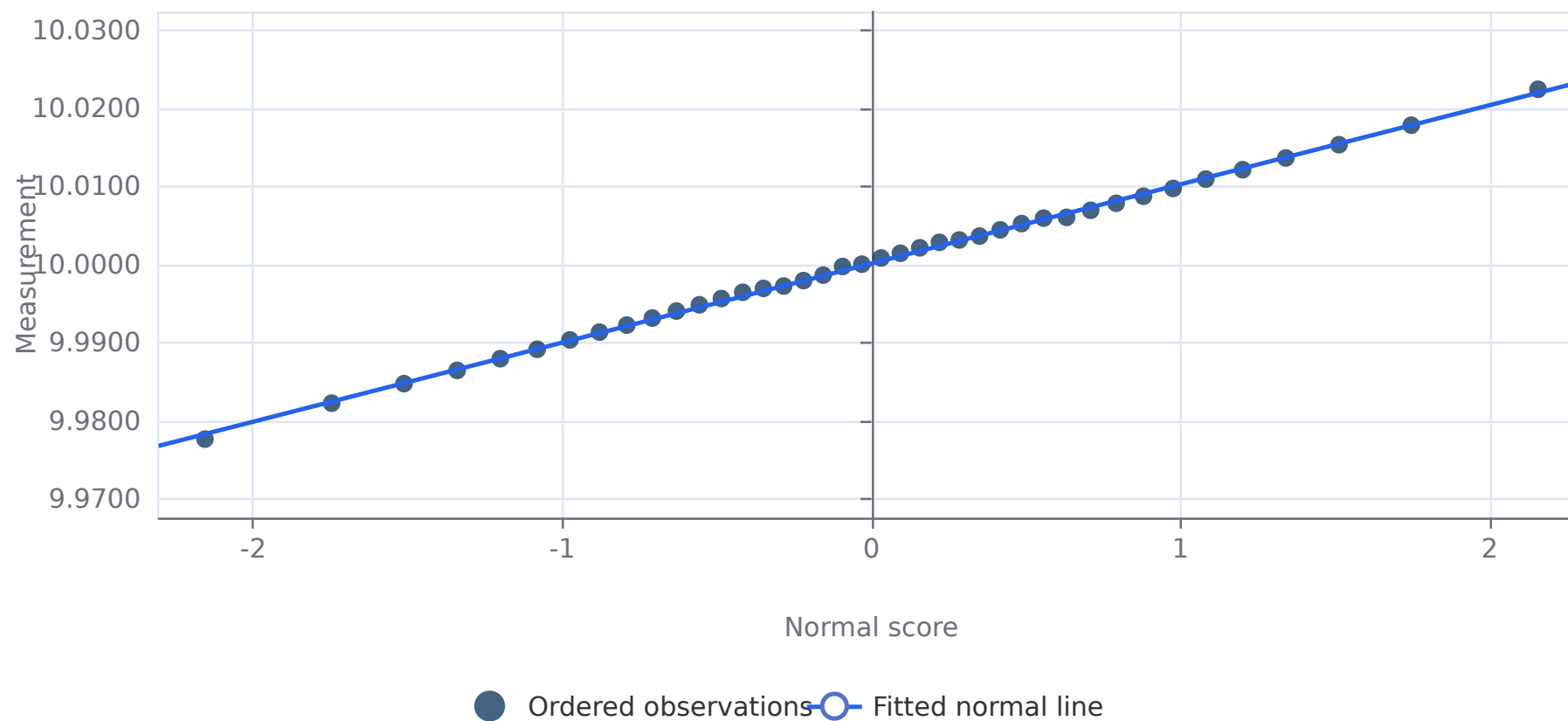
Moving Range Chart

Successive-measurement variation used by the within-process estimate.



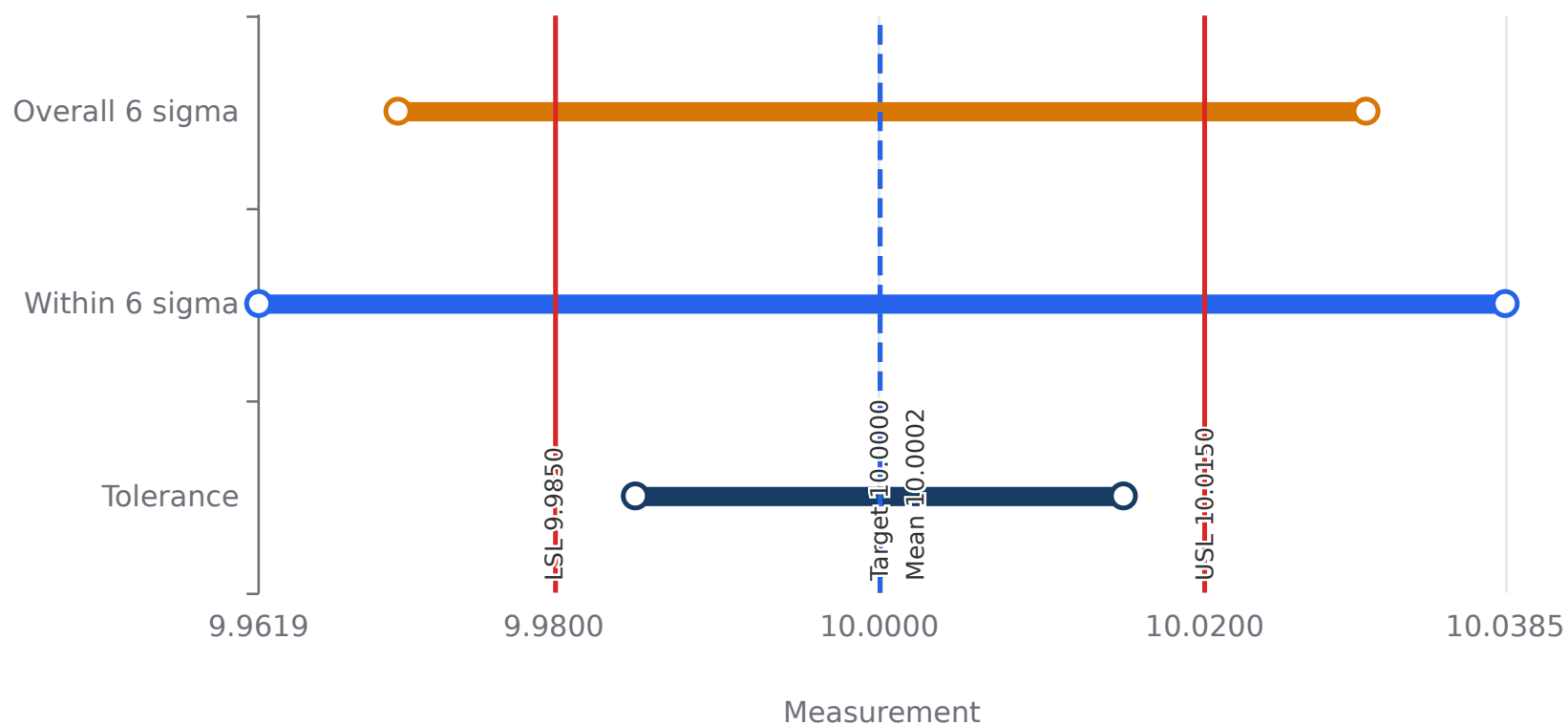
Normal Probability Plot

A-squared 0.038; p-value 1.000. No strong normality-screening signal was detected. This is not proof of normality.



Capability versus Performance

Tolerance compared with within 6 sigma and overall 6 sigma spread.



Engineering Context & Decision

Engineering Context

No traceability context recorded.

FROZEN JUDGEMENT

Do not release

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Decision confidence: High - 6 observed measurements are outside specification (3 above USL and 3 below LSL). These facts are direct measurements and do not rely on the fitted normal model.

Diagnostic confidence: Moderate - The statistical symptoms are well supported, but the exact physical cause, measurement-system adequacy, and sampling representativeness are not yet demonstrated.

Decision rationale

Do not release. The process does not have sufficient inherent capability to meet the internal screening benchmark $Cpk \geq 1.33$. 6 observed measurements exceed the specification limits (3 above USL and 3 below LSL). Verify the nonconforming observation and measurement system, reduce sources of variation then confirm capability with a representative time-ordered study before release.

Primary diagnosis

Excessive variation

Secondary factors

Measurement-system evidence gap

Engineering Evidence

Evidence hierarchy

Evidence	Result	Interpretation	Decision impact
Capability benchmark	Cpk $\geq$ 1.33 (internal screening benchmark)	No customer requirement was recorded for this study	Screening only - not a customer release gate
Cp	0.392	Potential short-term capability if centered; below the internal benchmark Cpk threshold 1.33, therefore perfect centering alone cannot satisfy it	Variation / corrective action
Cpk	0.387	Capability relative to nearest specification	Release decision
CPU / CPL	0.387 / 0.396	Two-sided capability contribution	Centering corrective action
Pp / Ppk	0.504 / 0.499	Overall performance evidence	Performance confirmation
Observed defects	3 above USL and 3 below LSL / 40 total	Observed nonconforming output in the supplied sample	Product / customer risk
Stability	No implemented I-MR signal detected	No screening signal detected; this does not prove statistical control	Diagnostic confidence
Normality	A ² 0.038 / p 1.000	No strong normality-screening signal detected; this does not prove normality	Model-assumption screening - no current blocking signal
Business Impact	User-confirmed traceable production rate	\$25,780.00; dominant driver Scrap	Improvement prioritization

Release risk

Release would accept a study that does not demonstrate the applicable capability requirement and contains 6 observed measurements outside specification (3 above USL and 3 below LSL).

Engineering Investigation Plan

Prioritized investigation

Priority	Action	Reason	Context source
Immediate	Contain or trace the affected output.	An observed measurement is outside specification (3 above USL and 3 below LSL) and the internal screening capability benchmark 1.33 is not demonstrated.	Statistical evidence
High	Verify the observed upper-specification failure: repeat the measurement and confirm traceability before disposition.	maximum 10.022 exceeds the USL 10.015. No measurement system is recorded for this study.	Statistical evidence
High	Record and verify measurement-system adequacy (MSA / Gage R&R) before a release decision.	No measurement system is recorded, so measurement error cannot be separated from process variation.	Statistical evidence
High	Reduce within-process variation.	Cp 0.392 is below the internal screening benchmark 1.33, so even perfect recentring is insufficient at the current within-process spread.	Statistical evidence
Normal	Collect a representative time-ordered confirmation study after corrective action and release only once the applicable requirement is demonstrated.	40 measurements were supplied. A confirmation study is required to demonstrate the corrected state.	Statistical evidence

Evidence Gaps, Context & Decision Criteria

Evidence gaps

- Measurement system not recorded; MSA / Gage R&R evidence is missing.
- Sampling representativeness is not independently proven by the supplied measurements.
- No customer capability requirement is recorded for this study.

Context used

What would change the decision

- Confirm and disposition the observed out-of-specification measurement and the affected material.
- Verify measurement-system adequacy appropriate to the characteristic.
- Reduce within-process variation sufficiently that a representative confirmation study meets the internal screening benchmark $Cpk \geq 1.33$.
- Demonstrate the applicable capability requirement on a representative time-ordered confirmation study with no unresolved stability-screening concern.

Business Impact

ANNUAL COPQ - USER-CONFIRMED TRACEABLE PRODUCTION RATE

\$25,780

Target scenario COPQ at Cpk 1.330: $\approx$ \$11,000

Potential scenario savings: $\approx$ \$14,700

Centered two-sided normal planning scenario. This is not a forecast and does not demonstrate that the target Cpk will be achieved.

Evidence and calculation assumptions

Evidence classification	Production estimate
Currency	USD
Reliability	User-confirmed traceable production rate
Defect-rate basis	Traceable production defect rate
Rate source	A rate from production, scrap, rework, inspection, warranty, complaint, return, or quality-system records.
Source category	quality system
Traceability reference	DISP-PHASE-B-20260815
Source validation	User-confirmed traceable production rate; Qhubio does not independently validate the production record.
Selected rate	2.00000% / 20,000 PPM
Annual production	100,000
Estimated annual defective units	2,000
Scrap disposition	60%
Scrap units	1,200
Scrap unit cost	8 USD
Rework disposition	30%
Rework units	600
Rework unit cost	3.5 USD
Residual defective units	200
Customer escape among residual defects	20%
Escaped units	40
Containment coverage / unit cost	50% / 2 USD

Sorting coverage / unit cost	25% / 0.2 USD
Inspection coverage / unit cost	10% / 0.1 USD
Complaint incidence / event cost	10% / 250 USD
Return incidence / event cost	5% / 40 USD
Downtime assumption	10 hours × 500 USD per hour
Target Cpk	1.330
Target scenario assumption	Centered two-sided normal planning scenario; not a forecast or evidence that target Cpk will be achieved.
Largest cost driver	Scrap
Scrap	\$9,600
Rework	\$2,100
Containment	\$2,000
Sorting	\$5,000
Inspection	\$1,000
Complaint	\$1,000
Return	\$80
Downtime	\$5,000
Annual COPQ	\$25,780
Target scenario COPQ	≈ \$11,000
Potential scenario savings	≈ \$14,700

Warnings and assumptions

- Evidence classification: production estimate.
- Defect-rate basis: manual.
- Scrap 60% and rework 30% are mutually exclusive defect dispositions.
- Containment applies to 50% of defective units; sorting and inspection apply to their stated annual production coverage.
- Rework disposition is the share successfully dispositioned internally; customer escape is 20% of residual defects after scrap and rework.
- Complaint and return rates apply only to escaped units and must contain distinct incremental costs to avoid double-counting.
- Target scenario COPQ uses a centered two-sided normal planning scenario; it is not a forecast and does not demonstrate that the target Cpk will be achieved. Sorting, inspection, and downtime remain fixed.
- Basis recommendation: The user confirmed a traceable production rate for the same product, process, period, and defect definition. Qhubio records the source and reference but does not independently validate the production record.
- Reliability: User-confirmed traceable production rate.
- The user confirmed a traceable production rate for the same product, process, period, and defect definition. Qhubio records the source and reference but does not independently validate the production record.
- Downtime equals annual downtime hours multiplied by USD per hour.

Measurement Data Appendix

Complete normalized measurement sequence used for this report. Specification limits are inclusive.

Observation	Value	Status
1	9.9776	Below LSL
2	9.9979	In specification
3	10.0097	In specification
4	10.0008	In specification
5	9.9922	In specification
6	10.0178	Above USL
7	10.0044	In specification
8	9.9891	In specification
9	10.0021	In specification
10	10.0136	In specification
11	9.9948	In specification
12	9.9847	Below LSL
13	10.0069	In specification
14	9.9997	In specification
15	10.0109	In specification
16	9.9931	In specification
17	10.0153	Above USL
18	10.0036	In specification
19	9.9903	In specification
20	10.0014	In specification
21	9.9822	Below LSL
22	10.0087	In specification
23	9.9964	In specification
24	10.0121	In specification
25	9.994	In specification
26	10.0052	In specification
27	9.9864	In specification
28	10.000	In specification
29	10.0224	Above USL
30	9.9956	In specification
31	10.0078	In specification
32	9.9972	In specification
33	9.9879	In specification
34	10.006	In specification
35	9.9913	In specification
36	10.0028	In specification
37	9.9986	In specification
38	10.0059	In specification
39	9.9969	In specification
40	10.0031	In specification