Study Guide — BI Problem 3: Medical Innovation (End-of-Unit Cumulative Test)

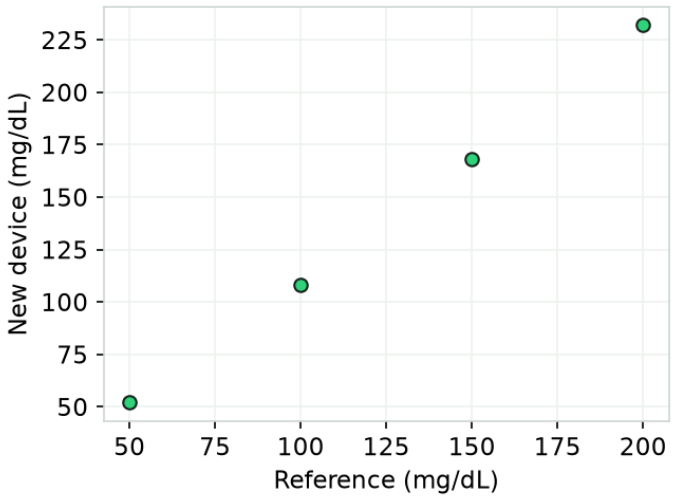
Biomedical Innovations · Problem 3 — Medical Innovation · Modeled on the PLTW Guided Review format

Vocabulary to know cold

Term	Definition
Iterative design loop	Define need, prototype, test, analyze data, refine — repeated until requirements are met.
Criteria	Measurable performance targets a successful design must meet.
Constraints	Limits on a design such as cost, size, or materials.
Calibration / standard curve	Using known standards to relate a device's signal to concentration so unknowns read accurately.
Accuracy	Closeness of a measurement to the true value.
Precision (reliability)	Consistency of repeated measurements of the same sample.
Proportional (concentration-dependent) error	A bias that grows larger as the measured value increases.
Replication	Repeating trials to confirm results are real and not due to chance.
Positive control	A sample known to contain the target; if it fails to react, the test is malfunctioning.
Negative control	A sample known to lack the target; a signal here means contamination or false positives.
Pre-analytical error	An error before testing (mislabeling, wrong storage temp, hemolysis) that ruins results.
Hemolysis	Rupture of red blood cells that can invalidate certain test results.
Sharps vs. biohazard waste	Sharps (needles, broken glass) go in rigid containers; soft contaminated items go in biohazard bags.
SDS storage requirements	Conditions (e.g., 2 to 8 degrees C) a Safety Data Sheet specifies to keep reagents stable and safe.

Worked examples (follow the reasoning)

Example 1. A new device is tested against a reference at 50, 100, 150, and 200 mg/dL and reads 52, 108, 168, and 232. Describe the type of error and what it means for the design.



- Compare device to reference at each point: +2, +8, +18, +32 — the gap GROWS as values rise.
- A constant offset would be a fixed error; a growing offset is a proportional, concentration-dependent error.
- The device is acceptable at low values but reads increasingly too high at high values.
- Design implication: recalibrate the slope or adjust the sensor so high-range accuracy improves before release.

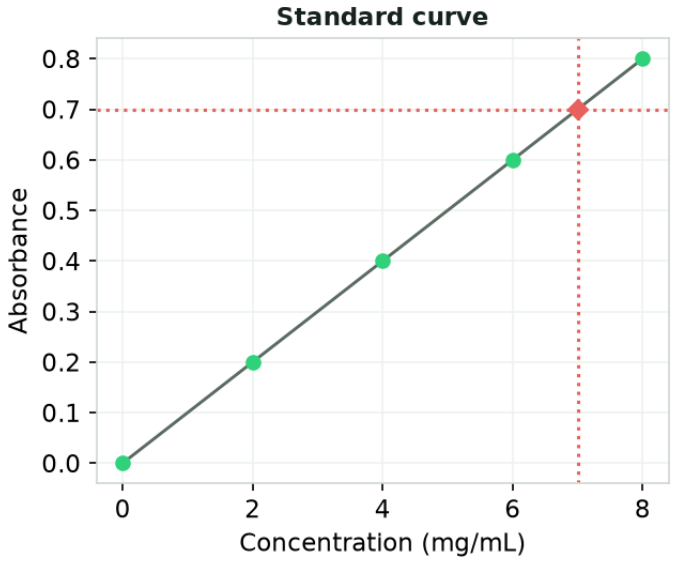
Answer: It is a proportional (concentration-dependent) positive bias; the device needs slope recalibration for high values.

Example 2. A validation run reports: positive control = NO signal, negative control = correct (no signal), patient sample = no signal. Can the team report the patient as negative? Explain.

- The positive control should produce a signal; here it did not.
- A failed positive control means the assay/device did not function for that run.
- Because the test itself is unreliable, the patient's 'no signal' cannot be interpreted.
- The team must invalidate the run, troubleshoot (reagents, calibration, device), and repeat with working controls.

Answer: No — a failed positive control invalidates the whole run, so the patient result cannot be reported.

Example 3. Using a standard curve where 0.10 absorbance = 1 mg/mL (line through origin), find the concentration of an unknown reading 0.70.



- Slope = 0.10 absorbance per 1 mg/mL, intercept at origin.
- Concentration = absorbance / slope = 0.70 / 0.10.
- 0.70 / 0.10 = 7 mg/mL.
- Check: 7 mg/mL lies between the 6 mg/mL (0.60) and 8 mg/mL (0.80) standards — consistent.

Answer: The unknown is 7 mg/mL.

Practice questions (with reasoning)

1. Repeated readings of one control (true value 100) are 100, 60, 140. The device is:

A. accurate and precise
B. accurate on average but not precise
C. precise but not accurate
D. neither accurate nor measurable

Answer: B. The average is 100 (accurate) but the spread is wide (not precise).

2. A broken, blood-contaminated glass slide is discarded into the:

A. biohazard bag
B. rigid sharps container
C. regular trash
D. recycling

Answer: B. Contaminated broken glass is a sharp and goes in a rigid sharps container.

3. SPIRAL: Which adult resting vital sign set is within normal limits?

A. HR 72, BP 118/76, temp 37.0 C
B. HR 160, BP 90/60, temp 41 C
C. HR 28, BP 210/130, temp 33 C
D. HR 200, BP 70/40, temp 39 C

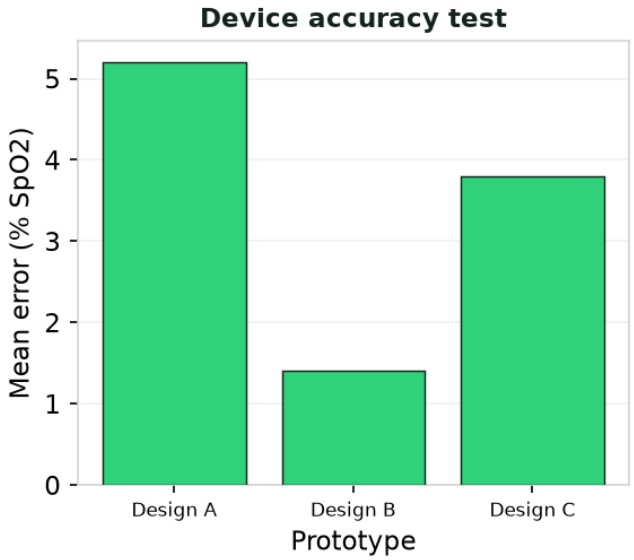
Answer: A. HR ~72, BP ~118/76, and temp 37 C are normal adult resting values.

4. SPIRAL: A physiology study testing a new exercise protocol must include a control group in order to:

A. increase costs
B. attribute observed changes to the protocol rather than other factors
C. shorten the study
D. avoid taking baseline measurements

Answer: B. A control group isolates the protocol's effect from confounding variables.

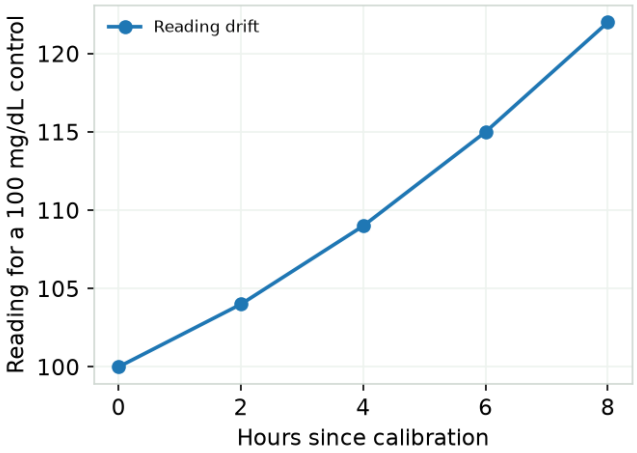
5. The bar graph shows the average measurement error of three prototype pulse-oximeter designs tested against a gold-standard monitor. Which design performs best?



A. Design A, because its bar is tallest
B. Design B, because it has the lowest error
C. Design C, because it is in the middle
D. All three perform equally

Answer: B. Lower measurement error means closer agreement with the gold standard, so Design B (1.4%) is the most accurate.

6. The graph plots one prototype glucose meter's reading for a fixed 100 mg/dL control over a work shift. What does the trend say about the device's reliability?



A. The device is stable and needs no recalibration
B. The device drifts upward over time and should be recalibrated during the shift
C. The device drifts downward over time
D. The data show random noise with no trend

Answer: B. The reading for a fixed 100 mg/dL control climbs steadily to 122, an upward drift that signals the device must be recalibrated within the shift.