



# Measurement Validation: Terminology and Concepts

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# MEASUREMENT VALIDATION

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- The process of characterizing aspects associated with device measurement
  - » Precision
  - » Bias
  - » Accuracy
  - » Agreement

# Precision of Measurement

- Closeness of agreement between replicate measurements on the same object (eye) under *specified testing conditions*
  - » Sources of variability include device, operator, physiologic, settings, patient alignment, time, etc.
  - » “Specified testing conditions”:
  - » repeatability: test-retest within a short period of time, same device, same operator
  - » reproducibility: test-retest with greatly changed conditions including different time, measuring device, operators, etc.
- Expressed as standard deviation (SD) and % coefficient of variation (%CV)

# Bias of Measurement

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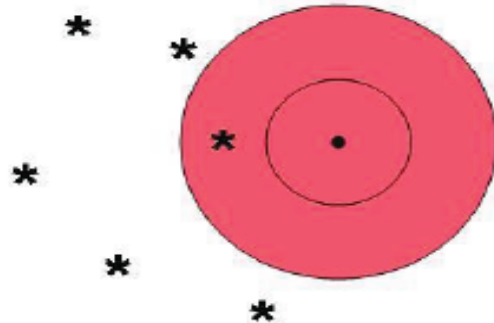
- An estimate of *systematic* measurement error
- Mean difference between the measured value and the true (or reference) value
- Expressed as difference (units of measurement), or percent difference

# “Accuracy” of measurement

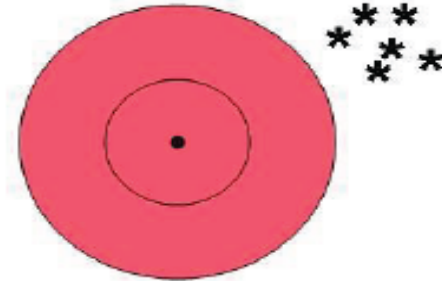
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- How measurements from one device model compares to “true value” and/or the “reference method” (“gold standard”)
- Incorporates both measurement bias and precision

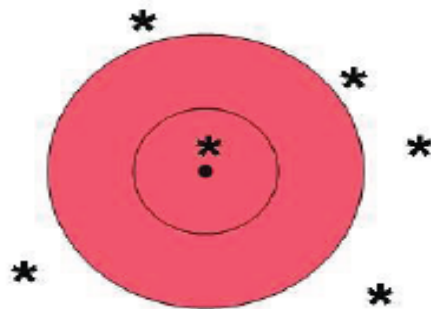
# Bias and imprecision



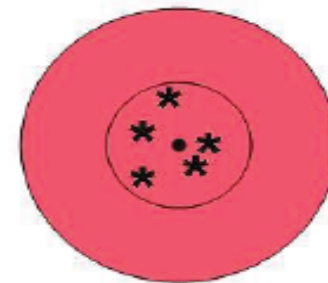
High Bias-High Imprecision



High Bias-Low Imprecision



Low Bias-High Imprecision



Low Bias-Low Imprecision

# Agreement of Measurements

- How measurements from one device model compares to another device model (“comparator”)
  - » Not the same as “accuracy” unless comparing to established reference (“gold standard”) method
- Often characterized by:
  - » Mean and SD of the paired differences (or percent or absolute value of differences)
  - » Plot of “Differences vs. Predicate measurements,” with “limits of agreement”



# Measurement Performance

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## Precision, bias and agreement measures

- » Can be constant or vary across the measurement range of the device
  - e.g., thin to thick RNFL measurements
- » May be different for apparently healthy subjects versus subjects with pathology
- » May depend on image quality

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- The terminology defined here will be used in the FDA presentations that follow
  - *Thank you for your attention*