Examples of Sources of Error For Glucometers
CAPT_GLU_0700JA1

1. **Operator**. **Failure to follow procedure correctly, for example:**

   - Sample contamination
   - Incorrect specimen collection (e.g., poor lancing technique and incorrect volume)
   - Application of an insufficient amount of blood to the strip or incorrect application of blood to strip
   - Use of a sample from an alternate site not validated by the manufacturer
   - Application of the specimen to the strip more than once (for example, if the user believes not enough specimen was added the first time)
   - Incorrect insertion of strip into meter
   - Inaccurate timing
   - Use of contaminated, outdated, or damaged strips or reagents, including calibrators or quality control materials
   - Failure to understand or respond to meter output
   - Errors in meter maintenance or cleaning
   - Errors in calibration or failure to calibrate or otherwise adjust the meter or check performance with quality control materials, as directed by labeling
   - Incorrect saving or use of stored data
   - Improper storage or handling of the meter, calibrators, quality control materials or test strips, or maintenance of the meter
   - Inadvertent changes of parameters (such as units of measurement)
   - Incorrect incorporation of results into overall treatment plan (prescription-use)
   - Use of strips not validated for use on the meter

2. **Reagent**

- Expired strips or reagents
- Damaged or contaminated strip
- Failure of strips, calibrators, or quality control materials to perform adequately
- Incorrect manufacturing; product fails to conform with specifications
- Incorrect dimensions of reagent strip
- Interference with chemical reaction on strip (e.g., reducing substances
- Inadequate design of container for strips or other reagents; failure to prevent deterioration; failure of desiccant used to keep strips dry

3. Environmental

- DEVICE EFFECTS
  - Temperature
  - Humidity
  - Altitude; hyperbaric oxygen therapy conditions
  - Electromagnetic radiation
  - Visible light; sunlight
- HUMAN FACTORS
  - Lighting, glare off meter surfaces
  - Distractions, visual and auditory
  - Stressful conditions
  - Limited manual dexterity

4. Software

- Confusing or obscure user prompts and feedback
- Incorrect mathematical algorithm
- Undetected or unrecognized signal errors
- Timing failure
- Incorrect storage of test results in memory, including matching result with correct patient or time of test

- Other software failures

5. Hardware

- Electronic failure
- Physical trauma or vibration
- Damage to the device from incorrect strip dimensional tolerances (third party manufacturer)
- Electrostatic discharge
- Electromagnetic/radiofrequency interference
- Battery reliability, lifetime, and replacement
- Component(s) failure
- Incorrect manufacture

REFERENCE

U.S. Food and Drug Administration. Blood Glucose Monitoring Test Systems for Prescription Point of Care Use. October 11, 2016. Available from: https://www.fda.gov/downloads/ucm380325.pdf