



Thermal Stress and Point-of-Care Testing Performance: Suitability of Glucose Test Strips and Blood Gas Cartridges for Disaster Response

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ABSTRACT

Objective. Point-of-Care Testing (POCT) devices are deployed in the field for emergency on-site testing under a wide range of environmental conditions. Our objective was to evaluate the performance of glucose meter test strips and handheld blood gas analyzer cartridges following thermal stresses that simulate field conditions.

Methods. We evaluated electrochemical and spectrophotometric glucose meter systems and a handheld blood gas analyzer. Glucose test strips were cold stressed (-21°C) and heat stressed (40°C) for up to four weeks. Blood gas cartridges were stressed at -21°C, 2°C, and 40°C for up to 72 hours. Test strip and cartridge performance was evaluated using aqueous quality control solutions. Results were compared to those obtained with unstressed test strips and cartridges.

Results. Heated glucose test strips and blood gas cartridges yielded elevated results. Frozen test strips and cooled cartridges yielded depressed glucose and blood gas results, respectively. Frozen cartridges failed.

Conclusions. The performance of glucose test strips and blood gas cartridges were affected adversely by thermal stresses. Heating generated elevated, and cooling, depressed results. Disaster medical assistance teams (DMATs) should be aware of these risks. Field POCT must be robust to withstand adverse conditions. We recommend that industry produce POCT devices and reagents suitable for DMATs.

INTRODUCTION

Point-of-Care devices are used under many different circumstances including emergencies in the field or disaster situations as in Hurricane Katrina and the Southeast Asia Tsunami.

Reagent test strips and cartridges of commonly used devices like glucose monitoring devices and handheld blood gas (HHBG) analyzers may be subjected to extreme storage and transport conditions, such as high and low temperature.

OBJECTIVES

To assess whether glucose meter test strips and handheld blood gas analyzer cartridges can provide accurate results after exposure to high and low temperature that may be encountered at disaster sites.

MATERIALS AND METHODS

Three glucose meter systems (GMS) were tested:

- Two electrochemical-based glucose meter systems (GMS 1-EC and GMS 2-EC)
- One spectrophotometric glucose meter system (GMS 2-S)

One handheld blood gas (HHBG) analyzer was tested.

One lot of test strips and cartridges were used for the respective GMS and HHBG.

Test strips were tested using one level of aqueous quality control (QC) solution supplied by the manufacturer. The mean glucose level of the QC test solution was 60.0 mg/dL for GMS 1-EC, 111.4 for GMS 2-EC, and 137.3 for GMS 2-S.

Blood gas cartridges were tested using Level 1 RapidQC Complete QC solution (Bayer HealthCare). The mean PO₂ and PCO₂ levels were 162.5 and 52.7 mmHg.

GMS and HHBG were operated at room temperature (21°C)

Five replicate measurements with control and each exposed group were performed at each time point for high and low temperature exposed glucose test strips, and HHBG cartridges

Table 1. Storage and Operating Temperature (°C) Specifications.

Device	Meter & Analyzer		Test Strip & Cartridge	
	Storage	Operating	Storage	Operating
GMS 1-EC	-25 – 70	14 – 40	2 – 32	14 – 40
GMS 2-EC	ND	6 – 44	< 30 ^a	6 – 44
GMS 2-S	ND	10 – 35	< 30 ^b	10 – 35
HHBG	-10 – 46	16 – 30	2 – 8	16 – 30

^aNot to be refrigerated, ^bNot to be refrigerated or frozen. ND, not defined.

High Temperature & Glucose Test Strip Measurements

Three trials were conducted. Each trial consisted of testing strips exposed to 40°C for 15, 30, 60 minutes; 12, 24, 72 hours; and 1, 2, 4 weeks. Test strips in original containers were placed in waterproof bags and submerged into 40°C waterbath. Results from exposed strips were compared to results from control (room temperature) strips at the respective time points.

Low Temperature & Glucose Test Strip Measurements

Three trials were conducted. Each trial consisted of testing strips exposed to -21°C for 12, 24, 72 hours; and 1, 2, 4 weeks. We tested strips directly from the freezer and strips that were allowed to thaw for 30 minutes to room temperature. Results were compared to glucose measurements from control strips at the respective time points.

Heating & Cooling of Cartridges on Blood Gas Measurements

Three trials were conducted. Each trial consisted of testing five sets of blood gas cartridges that have been exposed to high (40°C), freezing (-21°C), and refrigerated (2°C) temperature conditions for 12, 24, and 72 hours. Each set consisted of testing a cartridge from each condition plus a control. The cartridges were tested in parallel and the order randomized for each set. PO₂, PCO₂, and pH were measured. Each set was conducted with the same blood gas control solution.

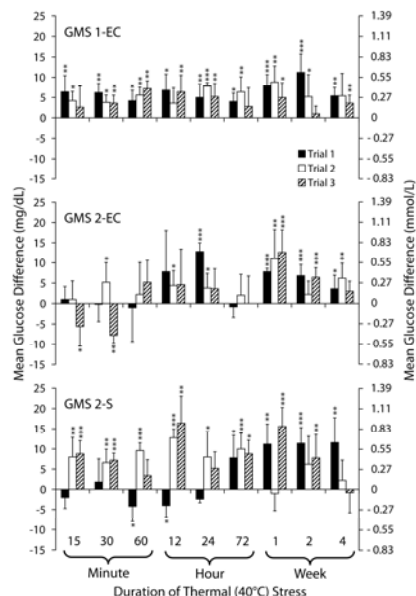
Statistics. Student's t-test for means was applied to compare the results obtained with thermally stressed test strips relative to controls, which were serialized and compared in the same order. Student's t-test for paired-differences was applied to compare the differences in PO₂ and PCO₂ measurements between thermally stressed and control cartridges. We reported the mean and standard deviation of the glucose differences and HHBG cartridge paired differences.

RESULTS

Heated glucose test strips generated elevated glucose results, which varied and were inconsistent, especially GMS 2-EC and GMS 2-S.

Mean glucose differences between heat-stressed and control test strips were as high as **11.2 mg/dL** (4.5, SD) on GMS 1-EC, Trial 1; **12.8** (2.2) on GMS 2-EC, Trial 1; and **16.4** (6.6) on GMS 2-S, Trial 3.

Figure 1. Effects of thermal stress on glucose test strips. This figure shows the mean differences in glucose results obtained with heat-stressed test strips relative to control for the three GMSs. Test strips were stressed at 40°C. Controls were stored and measured at room temperature (21°C). The asterisk denotes statistical significance: *, P<0.05; **, P<0.01; and ***, P<0.001.



Heated blood gas test cartridges generated significantly higher PO₂ and PCO₂ results. The mean of the PO₂ differences was as high as 13.7 mmHg (5.4, SD).

Cooled cartridges generated significantly lower PO₂ and PCO₂ results. The mean of the PO₂ differences was as low as -29.7 mmHg (10.0, SD).

Figure 3. Effects of heating and cooling of test cartridges on PO₂ obtained with a handheld blood gas analyzer. This figure shows the mean PO₂ paired-differences between heated (40°C) or cooled (2°C) test cartridges and control (21°C).

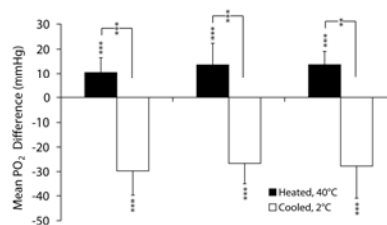
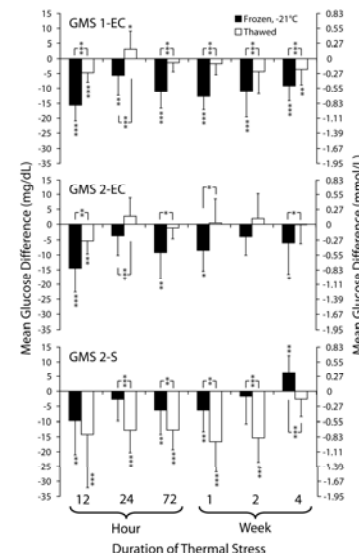


Figure 2. Effects of freezing and thawing on glucose test strip results. This figure shows mean glucose difference between frozen or thawed test strips relative to control. Test strips were cold stressed at -21°C. Controls were stored and measured at room temperature (21°C). The asterisk denotes statistical significance.



Glucose results obtained from frozen test strips were significantly lower than control.

Mean glucose differences between frozen and control test strips were as low as **-15.6 mg/dL** (5.3, SD) on GMS 1-EC; **-14.5** (8.1) on GMS 2-EC; and **-9.8** (11.3) on GMS 2-S.

GMS 1-EC and 2-EC had partial recovery in performance when thawed to room temperature.

CONCLUSIONS

The performance of glucose meter test strips and blood gas analyzer cartridge was affected adversely by thermal stresses.

Heating generated falsely elevated, and cooling falsely depressed, test results.

DMATs and emergency medical responders should be aware of the potential risks of inaccurate results from POCT when operated in adverse conditions.

Industry must produce POCT devices and reagents suitable for DMATs working under these conditions. POC technologies should be designed for environmental challenges encountered at disaster and emergency response sites.

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