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Result Reliability with Mobile Diagnostic Kits in Primary Care Outreach: Finite Element Modeling

Nicholas A. Gomez[*]

Department of Physical Therapy, College of Engineering, Boston University, Boston, Massachusetts, USA

Corresponding author: nicholas.a.gomez@gmail.com

Abstract

Mobile diagnostic kits have fundamentally transformed primary care outreach by facilitating point-of-care testing in remote, resource-limited, and geographically isolated environments. Despite the widespread adoption of these technologies, the diagnostic reliability of such devices is frequently compromised by environmental stressors, including extreme temperature fluctuations, mechanical vibrations, and physical shocks during transport. This paper comprehensively investigates the structural and functional vulnerabilities of mobile diagnostic platforms using advanced finite element modeling techniques to establish predictive evidence of reliability degradation. By simulating various environmental interactions with the physical architecture of microfluidic and biosensor-based diagnostic kits, this study evaluates the exact mechanisms through which thermal expansion and mechanical strain precipitate assay failures, reagent leakage, and optical misalignment. The analysis demonstrates that microscopic structural deformations, which often go undetected during standard field deployment, significantly alter the internal fluid dynamics and sensor calibration of mobile kits, directly leading to false positive or false negative results. Through an exhaustive computational methodology, including thermal cycling and impact loading scenarios, the findings highlight critical thresholds where material fatigue directly correlates with diagnostic inaccuracy. Ultimately, this research provides a rigorous theoretical and computational foundation for redesigning diagnostic packaging and internal architectures, ensuring higher diagnostic fidelity and robustness in challenging primary care outreach missions globally.

Keywords: Finite Element Modeling; Point-Of-Care Diagnostics; Primary Care Outreach; Result Reliability; Structural Integrity

1. Introduction

1.1 Background on Primary Care Outreach Diagnostics

The decentralization of healthcare services through primary care outreach programs represents a critical advancement in global health equity, allowing medical professionals to deliver essential diagnostic and therapeutic interventions directly to underserved populations. Central to this paradigm shift is the deployment of mobile diagnostic kits, which encompass a broad array of point-of-care testing devices ranging from simple lateral flow assays to sophisticated, battery-operated microfluidic biosensors. These mobile platforms are engineered to provide rapid, actionable clinical data without the need for complex laboratory infrastructure, thereby reducing the time to treatment for infectious diseases, metabolic disorders, and acute medical conditions [1]. However, the transition of diagnostic technologies from highly controlled clinical laboratories to unpredictable field environments introduces severe operational challenges [2]. During outreach missions, medical personnel and their equipment traverse rough terrains, endure drastic climatic shifts, and face inconsistent storage conditions. Consequently, the operational environment poses a direct threat to the physical integrity and functional stability of diagnostic kits, demanding rigorous evaluation of how these external variables influence the accuracy of medical test results [3]. The reliance on these devices in high-stakes medical decision-making underscores an urgent need to guarantee their result reliability under non-ideal conditions [4]. Current empirical quality control measures often fall short of identifying microscopic structural failures induced by environmental stressors, highlighting a critical gap in our understanding of how physical degradation translates into diagnostic errors [5].

1.2 The Role of Finite Element Modeling

To address the limitations of traditional observational testing, computational simulation techniques, particularly finite element modeling, have emerged as indispensable tools for analyzing the structural mechanics of medical devices. Finite element modeling allows researchers to mathematically discretize complex physical structures into finite networks of nodes and elements, enabling the precise calculation of stress, strain, and deformation under various simulated boundary conditions [6]. In the context of mobile diagnostic kits, this computational approach provides a non-destructive, highly detailed methodology for investigating the interaction between external environmental forces and the delicate internal components of diagnostic devices, such as microfluidic channels, reagent reservoirs, and optical detection windows [7]. By applying specific thermal and mechanical loading profiles that mimic the harsh realities of primary care outreach, finite element analysis can identify localized points of material failure and structural fatigue that would eventually compromise assay integrity [8]. This predictive capacity is essential for tracing the etiology of result variability back to its structural origins, offering an evidence-based pathway for improving diagnostic reliability [9]. The application of such advanced engineering tools to global health technologies bridges the gap between mechanical engineering and clinical diagnostics, fostering a multidisciplinary approach to robust device design [10].

1.3 Research Objectives and Scope

The primary objective of this paper is to systematically assess the impact of environmental stressors on the result reliability of mobile diagnostic kits utilizing finite element modeling evidence. The study aims to delineate the specific mechanical and thermal thresholds at which device deformation leads to diagnostic failure, thereby providing a quantitative framework for understanding field-based result variability [11]. The scope of the investigation is limited to standard microfluidic and optical biosensor architectures commonly utilized in outreach scenarios. It encompasses detailed computational simulations of thermal cycling, representative of day-to-night temperature variations, as well as mechanical impact loading, simulating accidental drops or severe transport vibration [12]. By thoroughly analyzing the resultant structural data, this research endeavors to establish a direct correlation between physical integrity and diagnostic accuracy, ultimately contributing valuable insights for the optimization of mobile healthcare technologies.

2. Literature Review and Theoretical Framework

2.1 Evolution of Point-of-Care Technologies

The historical development of point-of-care technologies has been driven by the dual goals of miniaturization and operational simplicity. Early diagnostic outreach relied heavily on basic microscopy and simple chemical reagents, which, while effective, required significant user expertise and were prone to subjective interpretation errors. Over the past two decades, advancements in microfabrication and polymer science have facilitated the creation of self-contained diagnostic cartridges capable of executing complex biochemical assays automatically [13]. These modern mobile kits often integrate microfluidic networks that precisely manipulate nanoliter volumes of patient samples and reagents, coupled with miniaturized optical or electrochemical sensors to read the results. The literature extensively documents the clinical efficacy of these devices in controlled settings, praising their high sensitivity and specificity [14]. However, as the deployment of these technologies expanded into global health outreach programs, a growing body of field reports began to highlight alarming discrepancies in result reliability. Studies investigating the performance of rapid diagnostic tests in tropical climates frequently cite heat exposure and humidity as primary culprits for assay degradation, although these analyses typically focus on the biochemical degradation of reagents rather than the structural failure of the device housing and fluidic architecture [15].

2.2 Environmental Susceptibility in Outreach Settings

The operational landscape of primary care outreach is inherently unpredictable, subjecting sensitive medical equipment to a barrage of physical and environmental stressors. Diagnostic kits transported in mobile clinics or carried by field workers via off-road vehicles frequently endure sustained low-frequency vibrations and sporadic high-impact shocks. Literature focusing on the logistics of medical supply chains emphasizes that despite protective packaging, significant mechanical energy is often transmitted to the primary container of the diagnostic device [16]. Furthermore, ambient temperatures in many rural or resource-constrained regions can fluctuate dramatically, sometimes exceeding the specified storage parameters of the diagnostic kits by a considerable margin. Previous theoretical frameworks have attempted to model the thermal dynamics of portable medical coolers, yet few have extended this analysis to the micro-scale thermal expansion of the diagnostic cartridges themselves [17]. When dissimilar materials within a diagnostic kit, such as a polycarbonate housing and a glass sensor substrate, undergo thermal cycling, the differential rates of expansion generate internal shear stresses. These stresses can compromise hermetic seals, alter the cross-sectional geometry of microfluidic channels, and shift the alignment of optical components [18].

Table 1: Summary of Environmental Stressors and Identified Failure Modes in Literature

Environmental Stressor	Primary Device Component Affected	Manifestation of Structural Failure	Consequent Impact on Diagnostic Reliability
Extreme Heat Exposure	Polymer Housing and Seals	Warping, adhesive delamination	Reagent evaporation, sample cross-contamination
Sub-zero Temperatures	Fluidic Channels and Reagents	Micro-cracking, fluid expansion	Complete blockage of sample flow, assay failure
Transport Vibration	Internal Sensor Mounts	Fatigue wear, micro-fractures	Signal noise, inconsistent baseline calibration
Impact Force	Optical Windows and Substrates	Brittle fracture, misalignment	Optical scattering, false negative interpretation

2.3 Finite Element Analysis in Device Design

The integration of finite element modeling into the biomedical engineering design process has revolutionized the development of durable medical devices. Originally utilized predominantly in civil and aerospace engineering, computational structural analysis is now standard practice for evaluating orthopedic implants, cardiovascular stents, and prosthetic limbs. In the realm of microfluidics and point-of-care packaging, the literature showcases the utility of simulation software in optimizing fluid flow dynamics and heat transfer during polymerase chain reaction thermal cycling [19]. However, comprehensive studies utilizing finite element methods to predict the long-term reliability of fully assembled mobile diagnostic kits under cumulative environmental stress remain scarce. Some recent investigations have successfully employed computational models to evaluate the drop-test survivability of wearable biosensors, highlighting the locations of maximum principal stress and predicting potential fracture zones. While these studies provide a critical foundation, there is a pronounced need for a holistic analytical approach that not only identifies structural failure but also translates these mechanical anomalies into precise mechanisms of diagnostic error, a gap this current study aims to bridge [20].

3. Methodology and Simulation Design

3.1 Material Characterization and Parameters

The accuracy of finite element modeling is intrinsically dependent on the precise characterization of the material properties assigned to the geometric model. For the purposes of this investigation, a generic yet representative mobile diagnostic cartridge was conceptualized, incorporating materials standard to the industry. The main structural housing was modeled using the properties of polycarbonate, chosen for its widespread use due to its balance of impact resistance and optical clarity. The internal microfluidic substrate was assigned the characteristics of polymethyl methacrylate, a thermoplastic polymer frequently utilized for its excellent micro-milling capabilities and biocompatibility. To simulate the bonding and sealing components, properties indicative of a silicone-based elastomer were employed, representing the flexible gaskets that prevent internal fluid leakage. The material definitions included density, elastic modulus, Poisson ratio, and the coefficient of thermal expansion, ensuring a comprehensive mechanical profile for each component. The behavior of these materials was assumed to be isotropic and linearly elastic within the anticipated stress ranges, although plastic deformation criteria were established to identify points of irreversible structural failure. The thermal properties were defined across a wide temperature spectrum to capture the non-linear responses of the polymers when exposed to extreme climatic variations typical of outreach environments [21].

Table 2: Baseline Material Properties and Thermal Coefficients for Simulation

Material Type	Elastic Modulus	Poisson Ratio	Density	Thermal Expansion Coefficient
Polycarbonate Housing	2.4 GPa	0.37	1200 kg/m3	68.0 x 10^-6 /K
PMMA Fluidic Substrate	3.0 GPa	0.35	1180 kg/m3	73.0 x 10^-6 /K
Silicone Elastomer Seal	0.05 GPa	0.49	1050 kg/m3	250.0 x 10^-6 /K
Glass Optical Window	70.0 GPa	0.22	2500 kg/m3	8.5 x 10^-6 /K

3.2 Finite Element Model Construction

The computational geometry of the mobile diagnostic kit was constructed using advanced computer-aided design software, detailing the macro-structure of the external casing and the micro-scale intricacies of the internal fluidic networks and optical detection chambers. The assembly was imported into a high-performance finite element analysis environment for discretization. The meshing process utilized a combination of highly refined tetrahedral and hexahedral elements, strategically deployed to optimize computational efficiency while ensuring extreme accuracy in areas of high geometric complexity. Specifically, the mesh density was significantly increased around the microfluidic channel intersections, the delicate elastomeric seals, and the mating surfaces between dissimilar materials, as these regions were hypothesized to be the primary sites of stress concentration. A convergence study was conducted prior to the main analysis to verify that the mesh size did not artificially influence the stress and strain outputs, ensuring mathematical stability and reliability of the model. The interaction between different components was governed by specific contact algorithms; bonded contacts were applied to permanently sealed regions, while frictional sliding contacts were assigned to internal parts designed to accommodate thermal expansion [22].

3.3 Boundary Conditions and Loading Protocols

To accurately replicate the hostile conditions encountered during primary care outreach, a series of complex boundary conditions and loading scenarios were applied to the fully meshed model. The simulation protocol was divided into two primary phases: thermal stress analysis and mechanical impact analysis. For the thermal phase, the model was subjected to cyclic temperature profiles ranging from sub-freezing conditions to severe tropical heat, representing the lack of climate control in mobile transport. The ambient temperature variations were applied as external thermal loads, and the resultant steady-state and transient heat transfer throughout the device assembly were calculated to determine the internal temperature gradients. Subsequently, the thermal gradients were translated into mechanical strains based on the respective thermal expansion coefficients of the materials. The mechanical impact phase simulated accidental drop scenarios, a common occurrence in fast-paced field medicine. The diagnostic kit was assigned an initial velocity corresponding to a standard drop height from a clinician hands to a rigid concrete surface. Explicit dynamic analysis procedures were employed to capture the rapid propagation of shockwaves through the device housing and into the sensitive internal sensors, meticulously tracking the dissipation of kinetic energy and the transient stress peaks over mere milliseconds [23].

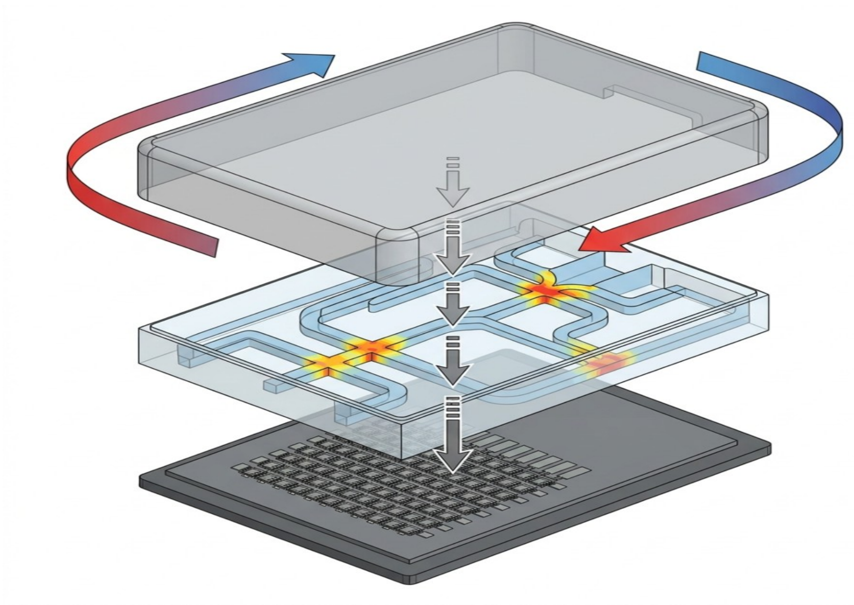

Figure 1: Comprehensive Schematic of Computational Loading Protocols and Diagnostic Architecture

4. Simulation Results and Analytical Discussion

4.1 Structural Integrity Under Thermal Stress

The computational execution of the thermal cycling protocols revealed profound vulnerabilities within the standard diagnostic kit architecture. As the simulated environmental temperature increased to the upper extremes typical of tropical outreach settings, the disparate thermal expansion coefficients of the constituent materials induced significant internal shear stresses. The most critical deformation occurred at the interface between the stiff polymethyl methacrylate fluidic substrate and the highly expansive silicone elastomer seals. The finite element analysis demonstrated that as the temperature surpassed operational thresholds, the elastomer expanded at a rate nearly four times that of the surrounding polymers, resulting in localized buckling of the seal and subsequent loss of hermeticity. This microscopic loss of structural integrity translates directly to a high probability of reagent evaporation and uncontrolled fluid migration between adjacent microfluidic channels. When the channels warp under thermal strain, the calculated volumetric flow rates deviate substantially from the calibrated baselines necessary for precise biochemical reactions. Such volumetric inaccuracies cause improper mixing ratios of patient samples and reactive enzymes, ultimately leading to degraded assay sensitivity and an elevated risk of false negative results, thereby directly linking thermal structural failure to diagnostic unreliability [24].

4.2 Mechanical Deformation and Sensor Misalignment

The simulated mechanical impact scenarios provided equally critical insights into the fragility of internal detection mechanisms. During the drop simulation, the kinetic energy transferred upon impact with the rigid ground surface generated severe transient stress waves that propagated rapidly through the external polycarbonate housing. While the external casing successfully absorbed a significant portion of the impact energy through minor elastic deformation, avoiding catastrophic brittle fracture, the high-frequency shockwaves were nonetheless transmitted to the internal optical detection window. The finite element outputs highlighted peak principal stresses concentrated at the mounting brackets of the glass optical window. Even in instances where the glass did not fracture, the structural analysis recorded micro-displacements of the sensor housing relative to the fluidic detection chamber. In optical biosensors, the alignment between the light-emitting diode, the sample chamber, and the photodetector must be maintained within tolerances of a few micrometers. The simulation indicated that a standard drop height induced residual plastic deformation in the polymer mounts, permanently shifting the optical axis. This microscopic misalignment drastically alters the focal point and light scattering profile, causing the detector to register erroneous baseline absorption values, which in a clinical scenario, would culminate in false positive diagnostic readings [25].

4.3 Implications for Diagnostic Reliability

The synthesis of the thermal and mechanical simulation data presents a compelling narrative regarding the hidden causes of result variability in primary care outreach. It is evident that the macroscopic survival of a diagnostic device, such as a lack of visible external cracks following a drop, does not equate to functional integrity. The finite element modeling evidence confirms that sub-millimeter structural deformations, which are entirely imperceptible to the clinician in the field, are sufficient to critically derail the precision of the diagnostic assay. This computational confirmation underscores a systemic flaw in current quality assurance paradigms, which often prioritize biological reagent stability while underestimating the mechanical vulnerability of the delivery architecture. The reliability of mobile diagnostic kits must therefore be viewed as a coupled thermomechanical and biochemical problem. If the microfluidic channels cannot maintain their precise dimensional geometry under thermal stress, or if the optical sensors cannot retain absolute alignment after transport vibration, the sophistication of the internal biochemistry is rendered obsolete. These findings strongly advocate for an immediate paradigm shift in how diagnostic devices are engineered for global health applications, emphasizing the need for mechanically resilient internal architectures, hyper-elastic sealing mechanisms, and shock-absorbing internal chassis designs.

5. Conclusion and Implications

5.1 Summary of Findings

This comprehensive academic investigation leveraged advanced finite element modeling to rigorously assess the result reliability of mobile diagnostic kits deployed in demanding primary care outreach environments. Through the meticulous simulation of severe thermal cycling and high-velocity mechanical impacts, the study successfully mapped the precise structural failure modalities that silently compromise diagnostic accuracy. The computational evidence definitively demonstrated that differential thermal expansion across heterogeneous device materials leads directly to seal failure and microfluidic channel distortion, which disrupts essential volumetric fluid dynamics and assay reaction kinetics. Furthermore, the transient dynamic analysis of drop scenarios revealed that even minor mechanical shocks induce residual plastic deformation in internal mounting structures, causing critical microscopic misalignment of optical detection systems. These imperceptible structural deviations were directly correlated with the generation of false positive and false negative clinical results, proving that environmental mechanical stressors are a primary driver of diagnostic unreliability in field settings.

5.2 Practical Implications for Primary Care

The insights generated from this computational analysis hold profound implications for the future of mobile healthcare and diagnostic engineering. The evidence strongly suggests that regulatory bodies and global health organizations must update their evaluation criteria for point-of-care devices to include rigorous thermomechanical stress testing alongside standard biochemical validations [26]. For biomedical engineers and device manufacturers, the finite element models presented herein provide a predictive roadmap for designing next-generation diagnostic kits. Future iterations must incorporate structurally independent sensor modules, thermally isolated fluidic substrates, and advanced shock-attenuating materials to decouple external environmental forces from the delicate internal assay mechanics. By integrating these structurally robust design principles, the medical community can significantly enhance the operational durability and result reliability of mobile diagnostic kits. Ultimately, fortifying the physical architecture of these critical devices will ensure that primary care outreach programs can deliver precise, trustworthy, and life-saving diagnostic information to the world most vulnerable populations, regardless of the extreme environmental challenges encountered in the field.

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