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Passive Thermal Protection of In-Use Insulin During Summer Travel: Device Description and Single-Patient Case Report with a Simple Cost Perspective

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Abstract

Insulin and other injectable biologics can lose potency when exposed to temperatures above labelled in-use storage limits, potentially contributing to hyperglycemia and treatment instability. VIVICap is a passive, pen-cap replacement device designed to reduce heat transfer to in-use insulin cartridges using space-grade vacuum insulation and a phase-change material (PCM) heat sink, maintaining the insulin cartridge temperature below ~29°C for prolonged periods under hot ambient exposure. We report a single case of a 32-year-old woman with type 1 diabetes on multiple daily injections and Dexcom G7 continuous glucose monitoring (CGM), comparing July (Germany, no VIVICap) with August vacation travel in hot weather (Greece, with VIVICap). Mealtime insulin requirements were similar across months. Glycemic outcomes were modestly improved during the hot-weather month with VIVICap (time in range 86% vs 82%; time >250 mg/dL 3% vs 5%) with a slightly lower basal dose (20 U/day vs 22 U/day). No emergency care was required. A simple basal-insulin cost comparison (0.0346 €/unit) showed a minor difference (~€2.15 lower basal insulin cost in August), while the main economic rationale for thermal protection remains prevention of insulin wastage and avoidance of heat-related glycemic deterioration and downstream resource utilization.

Keywords: Passive Thermal Protection, Single-Patient, Insulin, injectable biologics, hyperglycemia.

Introduction

Insulin is a temperature-sensitive biologic and must be handled in accordance with manufacturer storage recommendations to preserve potency. After first opening or when carried as a spare, commonly used insulins have labelled upper temperature limits (e.g., insulin degludec [Tresiba] not above 30°C for up to 8 weeks [1]; insulin aspart [NovoRapid] during use generally stored below 30°C with a defined in-use time window [2]). Despite these instructions, many people with diabetes carry insulin for prolonged periods during daily activities, commuting, work, and travel where ambient temperatures can exceed these thresholds, especially in summer climates and during heat waves. A contemporary review highlights that real-world insulin storage conditions often deviate from recommendations and that users may face uncertainty about potency after temperature excursions [3].

At the molecular level, insulin degradation under thermal stress involves both chemical and physical pathways. Chemically, insulin undergoes hydrolytic reactions, most prominently deamidation (e.g., at AsnA21 in acidic environments and at AsnB3 in near-neutral formulations), generating desamido/isoAsp derivatives that can alter conformation and biological activity; the rate of these reactions increases with temperature and depends on formulation context [4]. In addition to hydrolysis, elevated temperatures promote intermolecular transformation reactions with formation of covalent higher–molecular-weight products, including covalent insulin dimers and, at temperatures ≥25°C, increasing amounts of oligomers and polymers, a process that may compromise potency and stability [5].

Thermal exposure also facilitates conformational destabilization and physical degradation, including aggregation, precipitation, and amyloid-like fibrillation. These processes are accelerated not only by heat but also by agitation and contact with hydrophobic interfaces-conditions that can occur during everyday carrying and (particularly) in pump systems [6]. In pump therapy, such physical instability is clinically relevant because precipitation/fibrillation can contribute to catheter occlusions and erratic delivery, while in any insulin delivery modality, partial loss of potency may manifest as unexplained hyperglycemia and increased correction requirements [7]. Clinically, heat exposure has been associated with a higher burden of diabetes-related complications and healthcare utilization; reviews emphasize that heat can affect glucose homeostasis, insulin kinetics, and insulin stability, increasing the complexity of diabetes management in hot environments [8]. In extreme cases, impaired insulin effectiveness due to heat exposure has been linked to diabetic ketoacidosis (DKA), as illustrated by a published case report of DKA following exposure of an insulin pump to heat and sunlight [9].

Device description

The thermal protection concept of VIVICap (Figure 1) is based on a synergistic pairing of an ultra-high–performance “space-grade” vacuum insulator with a high latent-heat (phase-change) thermal buffer with a phase transition point at 30°C/98°F. The insulating element is characterized as a thin layer of ultrahigh vacuum encapsulated between thin stainless-steel layers, which markedly reduces heat transfer from the environment into the pen by suppressing conduction and convection (and by limiting radiative heat gain through reflective metallic surfaces [10]. This “deep vacuum” approach is particularly effective for a small form factor because it provides very high thermal resistance without requiring a bulky insulation thickness.

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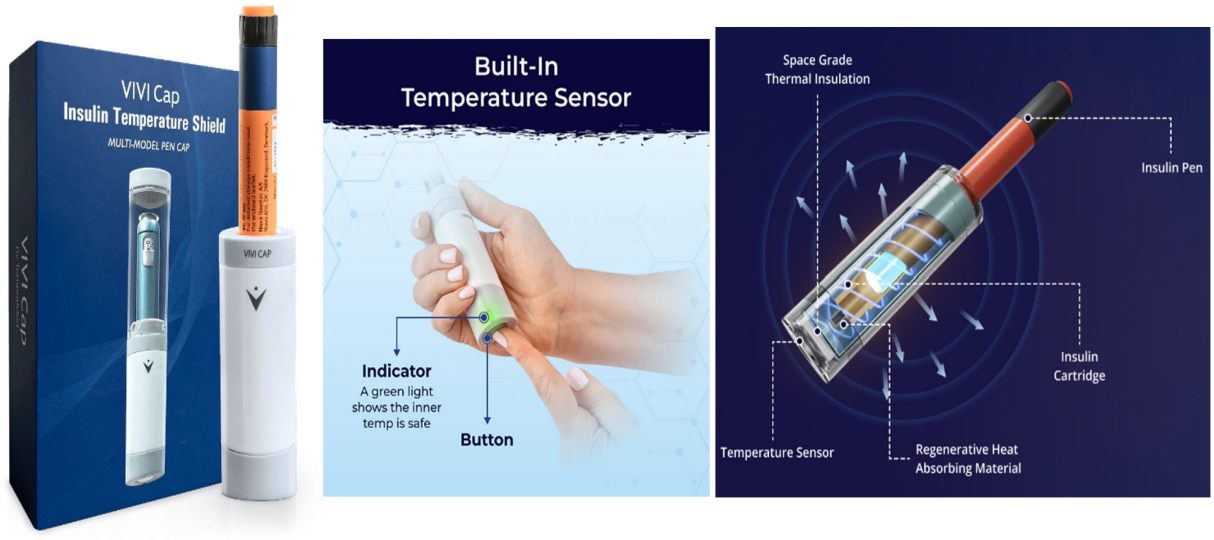
Figure 1: *VIVICap can be used with all available insulin pen devices*



However, even excellent insulation does not fully prevent heat ingress-especially during prolonged exposure to hot ambient temperatures. VIVICap therefore adds a second mechanism: an internal phase-change material (PCM) placed between the insulated barrier and the pen adaptor [10]. During exposure to temperatures above the PCM's phase-transition point, the PCM melts and absorbs a large amount of thermal energy as latent heat, keeping the internal temperature relatively stable near the melting temperature until the PCM's phase transition progresses substantially [11]. In VIVICap-1, the PCM melting temperature was selected to be below the commonly cited "upper safe" temperature range for insulin in use, thereby creating a thermal "ceiling" effect during typical daytime carrying. The process is reversible: when ambient temperature falls below the PCM transition range, the PCM resolidifies and releases heat outward, effectively "recharging" the thermal buffer for subsequent exposures [10, 12]. The device includes a built-in temperature sensor which is positioned next to the medication section of the pen. The temperature sensor measures that internal temperature by pressing a button positioned at the bottom end of the device. The result is compared to a limit temperature of 30°c (86°F) and a GREEN/RED indicator provides the user a simple reading of the current internal temperature status.

This combination-high thermal resistance (vacuum insulation) plus high thermal capacity at a targeted temperature (PCM latent heat)-increases the system's overall thermal time constant and extends the duration for which the protected item remains within a desired temperature range. Consistent with this principle, the VIVICap-1 report describes maintaining the insulin cartridge environment below ~29°C for at least 12 hours even under continuous 37.8°C ambient exposure, without external power [10, 12]. More broadly, the engineering literature in other harsh-environment applications likewise reports that integrating a vacuum insulation panel (VIP) with PCM can produce a measurable synergistic effect, significantly extending "safe operational time" compared with insulation or PCM alone, supporting the general rationale for combining these two passive thermal-management elements [13].

Case presentation

We report a single case of a 32-year-old woman with type 1 diabetes treated with multiple daily injections (MDI) and Dexcom G7 continuous glucose monitoring (CGM), observed over two consecutive summer months with and without VIVICap. The patient specifically sought a reliable, low-burden method to protect insulin in hot weather because, in prior years, she had experienced marked glycemic instability during heat exposure and was never satisfied with water-evaporation–based cooling pouches (perceived as inconvenient and insufficiently reassuring). Notably, she reported a diabetic ketoacidosis (DKA) episode during travel in Egypt in the preceding year, which she associated with severe heat exposure and heightened concern about insulin effectiveness (patient narrative; no direct insulin temperature measurements were available).

In July (1-31 July), the patient stayed in Germany with daytime temperatures reported at approximately 25–32°C and did not use VIVICap. Basal insulin was insulin degludec (Tresiba) at 22 units once daily. Mealtime insulin was insulin aspart (NovoRapid) with carbohydrate factors 1.5/1.0/1.0 (breakfast/lunch/dinner). Prandial insulin requirements were reported as stable and comparable to the subsequent month. CGM metrics during July showed a time in range (70-180 mg/dL) of 82% and time >250 mg/dL of 5%. No emergency department (ED) or urgent care visits were reported.

In August (1-31 August), the patient travelled on vacation to Greece with daytime temperatures reported at approximately 35-38°C and used VIVICap for in-use insulin storage during daily carrying. Basal insulin degludec (Tresiba) was 20 units once daily. Mealtime insulin remained insulin aspart (NovoRapid) with the same carbohydrate factors (1.5/1.0/1.0), and the patient reported similar mealtime insulin requirements compared with July. CGM metrics during August showed a time in range of 86% and time >250 mg/dL of 3%. She reported one hypoglycemic episode that did not require emergency assistance. No ED/urgent care encounters or acute metabolic events were reported. The patient emphasized a substantial subjective benefit: with VIVICap she felt notably more comfortable and safer regarding insulin effectiveness during heat exposure, contrasting with her prior dissatisfaction and anxiety when relying on evaporative cooling pouches.

Discussion

This single-patient, two-period observation suggests that VIVICap use during a month of sustained high ambient temperatures (35-38°C) was associated with stable-to-improved CGM outcomes compared with a milder month without VIVICap, while mealtime insulin requirements (NovoRapid) were reported as similar across both months. The patient's prior history is clinically relevant: she

described repeated difficulties managing diabetes in hot weather, dissatisfaction with evaporative cooling pouches, and a DKA episode during travel in Egypt the year before. In the current observation, she reported a marked improvement in perceived safety and comfort when carrying insulin in hot conditions while using VIVICap. Although subjective, this patient-centred outcome is important because uncertainty about insulin potency after heat exposure can drive risk-avoidant behaviours (e.g., discarding pens) and additional healthcare contacts, and can undermine confidence in diabetes self-management.

Mechanistically, these findings are consistent with VIVICap's intended function: a passive, battery-free approach that reduces heat gain through vacuum insulation while buffering residual heat via phase-change material. The clinical plausibility is strengthened by published bench/climate-chamber work describing maintenance of internal temperatures below approximately 29°C for extended periods even under constant hot ambient exposure, and by reports of reduced temperature-induced insulin degradation when insulin pens are protected by a reusable cap-based thermal shield [10,12]. While the present case cannot establish causality, the direction of effect (no deterioration despite extreme heat; modest improvement in hyperglycemia metrics) is compatible with preserved insulin effectiveness during heat exposure, potentially reducing the need for corrective dosing and mitigating risk of severe hyperglycemic events in vulnerable situations.

From a health-economic perspective, the direct medication-acquisition cost difference observed here (driven by a small basal dose change) is unlikely to capture the full value proposition of thermal protection. Instead, the main savings pathways are expected to come from (i) reduced medication wastage (discarded pens after suspected temperature excursions), (ii) fewer avoidable clinical interactions related to concerns about insulin effectiveness, and (iii) prevention of rare but high-cost acute deterioration such as severe hyperglycemia with ketosis/DKA. In this context, it is noteworthy that TempraMed's payer return-on-investment (ROI) model for VIVI Cap has received independent third-party validation for "Savings and Metrics" by the Validation Institute, with validation reported as effective through January 2027 and accompanied by a formal credibility guarantee. The validated model, as summarized publicly, attributes potential net savings for payors to reduced medication waste, fewer adverse clinical events, improved adherence, and lower anxiety-related healthcare utilization [14]. Validation Institute's own materials describe its Credibility Guarantee program intended to increase accountability and confidence in validated economic claims [15].

Two points are important. First, the Validation Institute validation pertains to the economic credibility of the ROI model (assumptions, methodology, arithmetic, and use of supporting evidence) rather than constituting direct proof of clinical effectiveness in all settings [14, 15]. Second, this case provides an illustrative "micro-level" example aligned with several drivers emphasized in the validated ROI narrative—particularly reduced anxiety and increased confidence during heat exposure, and the potential to avert severe outcomes in patients with prior heat-related instability and a history of DKA. Nevertheless, single-patient evidence is inherently limited, and future work should prospectively combine (a) direct device/insulin temperature logging, (b) standardized CGM endpoints, (c) glycemic variability, (d) objective capture of pen discard/wastage, and (e) payer-relevant utilization outcomes to quantify the real-world magnitude of savings in specific healthcare systems and climates.

In conclusion, this case describes a patient with type 1 diabetes on MDI who historically struggled with diabetes management in hot climates and did not feel adequately protected by evaporative cooling pouches. During a very hot summer vacation month in Greece, use of VIVI Cap coincided with stable to improved CGM outcomes compared with the preceding month in Germany, without increased mealtime insulin requirements, and with a strong improvement in perceived safety and comfort. Prospective studies incorporating direct insulin temperature logging, standardized behavioral covariates, and payer-relevant endpoints (wastage, resource utilization) are warranted to quantify clinical and economic impact beyond single-case observations.

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