DYNAMIC COMPARTMENTALISED HEAT TRANSFER MODELLING FOR SYSTEMS WITH BIOLOGICAL APPLICATIONS

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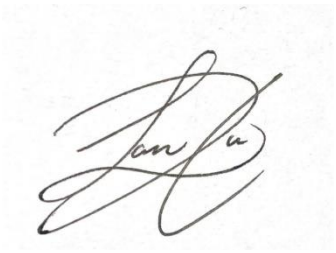
Declaration

I declare that this dissertation is my own unaided work without any collaboration with other students, staff or third parties aside from those acknowledged. It is being submitted to the Degree of Master of Science in Chemical Engineering to the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination to any other University.



_____ 20th of April 2023

Signature of Candidate Date

Contributions

Chapter 2 of this work has been published as Chapter 5 in the textbook *"Medical Devices Innovation for Africa: Enabling Industrialisation"*:

Xu, L., Stacey, N., Rubin, D., & Hildebrandt, D. Low-Cost Load Shedding-Resilient Medicine Storage with Phase-Change Material: Theoretical Heat Transfer Evaluation Of A Design Concept. In Medical Devices Innovation for Africa: enabling industrialization. S. Sivarasu, Ed. Cape Town: University of Cape Town Libraries. 30–39. DOI: https://doi.org/10.15641/UCTLib40

Minor modifications have been made to make the chapter compatible for a dissertation format.

The work has also been accepted as part of the merSETA (manufacturing, engineering, and related services SETA) Mediventors' Integrated Skills Development conference for oral presentation and has won the prize for the Western Cape Medical Devices Cluster (WCMDC) most promising medical device award.

It has also won 2nd prize for the University of the Witwatersrand's 13th Cross-Faculty Postgraduate Symposium.

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Abstract

Proper thermal management is crucial to controlling the temperature of biological systems within an optimized operating range. A biological system is comprised of a multitude of interacting facets, where a system is often disrupted as a consequence of random events such as the change in ambient temperature. In contrast the design of most human engineered chemical systems or processes may assume steady state operation and as a result is relatively straightforward to design and optimise. Yet, often steady temperature ranges are required in unsteady conditions. This sort of unsteady state system requires consideration of the dynamic changes to the conditions and are often required to be within many applications.

A narrow temperature band is essential for controlling the outcomes of how biological systems' function—thermal denaturation of biological components depend on precise control of the transport of heat. Insulin—a hormone peptide drug—is temperature sensitive and undergoes thermal fibrillation when exposed to temperatures above manufacturers' recommendations. To maintain such medication within specific temperature bands is a challenge in the face of energy intermittency from the energy crisis that South Africa is currently facing. Within this dissertation, a medical device to contain thermosensitive biological compounds is designed and modelled as a system undergoing dynamic thermal conditions. This heat transfer modelling is used as a prototyping process for designing the medical device to protect temperature sensitive medication during power outages. The simulated device, when used correctly, is able to keep medication thermally stable under 8°C during Stage 4 load shedding (7.5 hours of power outages within a 24-hour period).

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Chapter 1

INTRODUCTION AND LITERATURE SURVEY

1. Introduction

Within the scope of chemical engineering, there are a plethora of systems that have optimal temperature ranges. In most chemical applications, steady state optimization can be achieved more easily when a specific set of reactions operating at specific temperatures or temperature ranges is used in manufacturing a product. Artificial chemical systems tend to be designed with one objective in mind, such as maximizing selectivity or minimizing capital costs, while the physical phenomena at play may be exceedingly complex, their design tends to be straightforward.

In contrast, biological systems evolve naturally over time and interact on many levels with an ever-changing environment. As a consequence, such systems tend to be comprised of a multitude of subtle interactions intended to maintain homeostasis in the face of unpredictable conditions. Thus, systems containing biological components/factors have a number of interacting facets, often with randomly occurring events causing disruptions to the ideal temperature margin. One such unpredictable factor is human behaviour. This means that systems involving individual behaviour must be modelled with that unpredictability in mind and optimized in ways that can tolerate it.

As such, ideal temperatures are difficult to achieve, but heat transfer modelling can be used as a tool to generate solutions by predicting the behaviour and outcomes by accounting the energy inputs and outputs to temperature sensitive systems. However, the frequent power outages resulting from the energy crisis is an impediment to achieving precisely controlled parameters. Worldwide, issues of electrical intermittency are becoming more commonplace; therefore, having solutions involving energy storage for temperature control is vital.

Within this dissertation, a system containing a biological compound that is subjected to thermal instability is modelled. Frequent power outage in developing nations and rising global extreme temperature events present a challenge in cold storage of thermosensitive medicines—especially in a domestic setting where individuals generally do not have the resources to

maintain constant energy supply. Furthermore, it is an unfortunate coincidence (with the exception of Australia) that a number of countries between the tropics of Cancer and Capricorn have the hottest average temperature and tend to be developing nations. Moreover, climate change has led to hotter temperatures and unpredictable weather affects electricity delivery in countries with weaker infrastructure. Thus, a cheap and ergonomic medical device is needed where there is a higher probability of thermal denaturation of medicine. A design of a medical device solving this problem is explained and developed via heat transfer modelling. Using heat transfer modelling reduces the cost in initial product development.

1.1. Motivation

The intersection of the increasing diabetic cases, the lack of awareness around storing insulin formulations, and the energy crisis leading to frequent power outages in South Africa creates a need for a device that is able to protect the efficacy of insulin in a domestic setting. With the reliability of electrical supply called into question, the storage of temperature sensitive drugs has become an overlooked problem. According to manufacturers' recommendations insulin must be stored at 2°C–8°C to maintain its potency and keep it within the expiry date (International Diabetes Federation, 2020). Most insulin formulations expire after a year when unopened; this means that there may be patients that are storing their insulin in their fridge for several months in advance for convenience, unaware that temperature instability will cause loss of potency. Since domestic refrigerators do not always operate within the recommended temperatures (0°C –4°C), it is likely that the recommended temperatures cannot be maintained during load shedding (James, et al., 2016).

This research is focused specifically on the South African context, but most developing countries has similar foundational issues. The energy landscape for most Sub-Saharan countries is even bleaker than South Africa's declining electricity stability; the average accessibility in the Sub-Saharan region to electricity is only 43%, compared to South Africa's 86% (Hafner, et al., 2018). Most developing countries will have some degree of power supply instability and a higher rate of increase in diabetes cases. Therefore, this research is applicable to other developing nations where socioeconomic conditions lead to higher likelihood of temperature failure in domestic refrigerators. Management of chronic diseases requires an integrated approach where a number of preventable issues have to be tackled. In a region where insulin availability is a limited resource and represents a financial burden to both individuals and healthcare systems (Beran & Yudkin, 2006; Mbanya & Mba, 2021), having an affordable

device to protect thermosensitive medications means that diabetic insulin users have one less variable in glucose level management. Moreover, with emerging energy crises in European countries and the shift towards renewables, energy intermittency is likely to be a problem that requires urgent solutions that guarantee temperature stability for a number of products—including the subject of this thesis: temperature sensitive medications.

As a part of the recent merSETA Mediventors' Integrated Skills Development Programme for medical device industrialization, a medical device for preventing temperature failure was presented. The need for a device that stores insulin is explained and foundational development for the device is explored in Chapter 2 and, Chapter 3 presents a design that is able to withstand stage 4 load shedding—three power outages lasting two and a half hours in a 24-hour period, during peak times.

1.2. Overview of thesis

Chapter	*Title*	*Purpose or Objective*
1	Introduction and Literature Review	Gives the background and purpose of the research presented in this dissertation. Present a literature review that explains the need for a device that prevents temperature failure, the gap in market arising from temperature failure/incorrect drug storage in domestic settings, and a review of relevant patents/other device on the market. This section also describes the South African energy landscape and the implication on diabetic insulin users.
2	Concept development and initial solution	Creates a potential solution by developing a medical device and explains the concept and how the device is used. Applies heat transfer modelling to the proposed device to test the design, thereby presenting a potential solution to the problem.

3	Heat transfer modelling for preventing temperature failure for insulin and other temperature sensitive medication	Refines the design of a medical device so that it provides temperature stability in a domestic setting. Simulates steady state and dynamic external conditions and its effect on the presented design.
4	Conclusion	Offers recommendations for future research and discusses limitations of the work. Lastly, concluding remarks are made.

1.3. Objectives

The objectives are as follows:

1. To design a device that can store thermosensitive medication in a refrigerator in a domestic setting where the refrigerator experiences periodic power outages.
   1.1. Define the usability criteria that will make the device effective and simple to use.
   1.2. Propose a design and the materials of construction that will make the device cheap to manufacture—cost of manufacturing the device will affect the affordability to users.
   1.3. Devise a visual indicator to show the user that medication has been stored at temperatures above 8°C in order to alert users that medication may not be effective.
2. To model the heat transfer behaviour of proposed device and test the performance of the proposed device in a simulated environment.
   2.1. Predict the performance of the device in steady state condition—when no random temperature changes occur.
   2.2. Predict the performance of the device under dynamic conditions such as load shedding or a user opening a fridge and interacting with the device. These activities will influence ambient temperature around the device.
3. To use the model to refine the proposed design to reduce or eliminate uncertainties during future physical prototyping.
   3.1. Give recommendations for the approximate size, physical geometry and quantity of materials needed for prototyping for further development and testing in

experimental conditions of temperature failure from load shedding and fridge opening.

2. Literature Review

The following two sections describes parts of the South African energy landscape that are relevant to the dissertation and gives background information on diabetic insulin users and the storage of their medication to contextualise the problem definition (Section 2.3).

2.1. Insulin Storage

Most systems with biological components consist of multiple interconnected systems—the modelling of such systems; therefore, is seldom simple. In medical applications, medication based on biological components must be stored at recommended temperature ranges. Insulin, a hormone peptide drug, must be stored at 2°C–8°C when unopened to maintain its potency and to keep insulin within manufacturers' suggested expiry date (Krämer, et al., 2019). However, one of the unforeseen consequences of frequent power outages in South Africa—and many other developing nations—is thermal denaturation of insulin within household refrigerators caused by temperature excursions due to frequent power outages. Along the supply chain, strict quality systems are in place to ensure there is a cold chain, but this is not the case at users' homes.

The focus on thermal denaturation of insulin is usually on storing insulin at approximately "room temperature" once opened; numerous short-term storage devices exist on the market to keep insulin under 30°C. However, these devices are mainly designed around the periodic need to transport insulin, not around long-term disruption of refrigeration, and frequently depend on reliable refrigeration for their operation. Hence, disruptions to reliable refrigeration are an under-researched problem. Studies have found that 11.3% of the time insulin is stored out of the temperature bounds even without frequent power outages (Braune, et al., 2018; Heinemann, et al., 2020). Users cannot tell if insulin has reduced pharmacological action from thermal degradation; only when the quality is extremely compromised will the medication show visual signs of spoilage, otherwise, users may unwittingly inject insulin that will not control their glycaemic index to the expected degree.

If diabetics use insulin that has undergone thermal degradation, in the best-case scenario patients experience dysglycaemia—an imbalance of glucose in the bloodstream that includes hyperglycaemia and hypoglycaemia—and in the worst case, they suffer from ketoacidosis,

which can result in death (Sun & Joffe, 2007). Premature mortality and diabetes related disability is higher in developing countries (International Diabetes Federation, 2020), where 80% of diabetics live, yet only 1% of the global diabetes-related expenditures are in these countries (Mbanya & Mba, 2021).

To contextualise the extent of the problem, there are 4.5 million (12.8% of the adult population) diabetics in South Africa (International Diabetes Foundation, 2020) and approximately 0.72 million require insulin treatment (16% of diabetics). This includes all type 1 diabetics and a portion of type 2 diabetics—a recent meta-analysis has found that the prevalence of type 1 diabetes is 9.5% (Mobasseri, et al., 2020; Gregory, et al., 2022) and of the adult population about 15.5% of type 2 diabetics require insulin treatment (Basu, et al., 2018).

2.2. Energy landscape

With over a thousand hours of power outages annually in South Africa, preventing temperature failure is a crucial aspect of diabetic healthcare. Therefore, it is reasonable to question the reliability of domestically stored insulin in a country that has shown increasing power outage frequency and duration.

The energy crisis has undoubtedly affected every economic sector. In South Africa, frequent power outages, referred to as "load shedding," are becoming more commonplace (Figure 1); a trend unlikely to change in the near future. Load shedding is implemented in stages where each successive stage allows for 1000MW of energy to the national load to shed—for customers, this is realised in two-and-a-half-hour power outages throughout the day, usually during peak electricity usage hours (morning, midday, and evening). Each stage increases the number of outages (e.g., one power outage lasting two-and-a-half-hours during stage 1, two power outages lasting two-and-a-half-hours during stage 2, etc.). With long and frequent hours of power outages, people have to make contingency plans to accommodate for the hours without electricity.

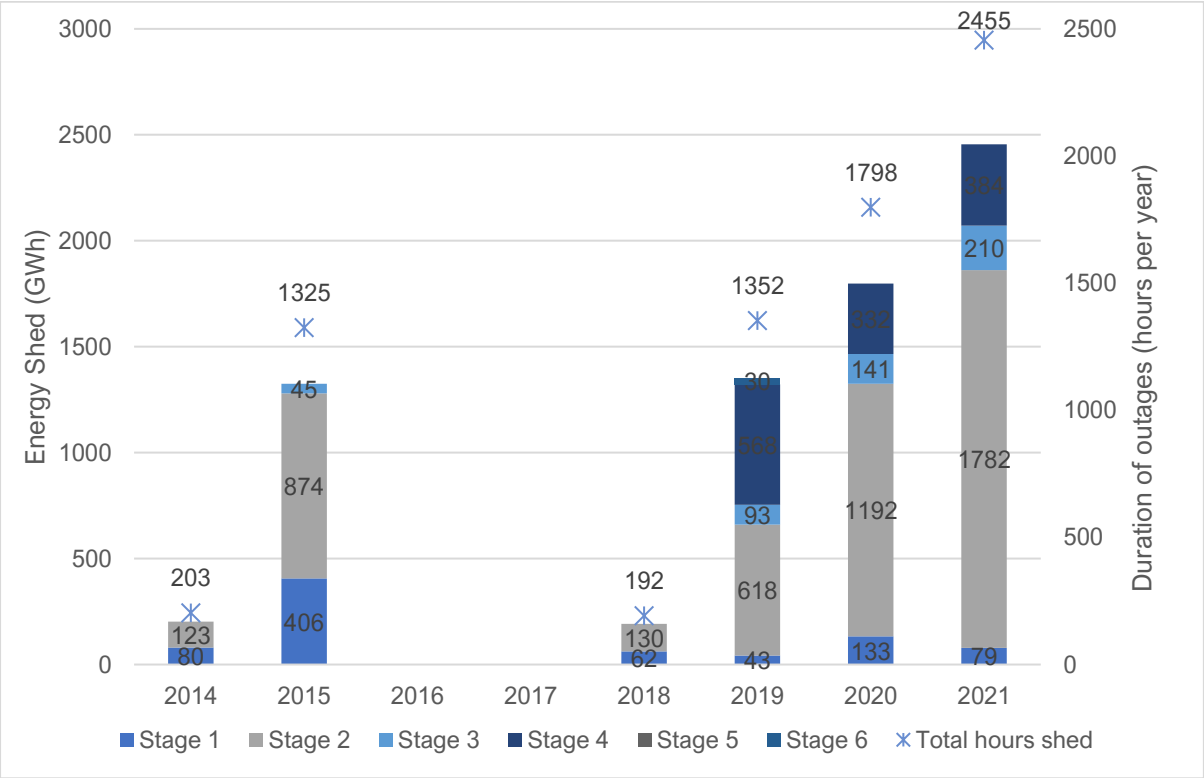

Figure 1 South Africa Power Outage Trends (CSIR, 2022)

South Africa's electricity infrastructure has been on the decline for more than two decades, with load shedding starting since 2007 (Yelland, 2022). The hours lost to load shedding have been increasing yearly since 2017. Additionally, escalating energy prices have put pressure on the population. South Africa's primary electricity supplier is Eskom, the national utility generates approximately 90% of the electricity used in the country (Department of Energy, 2019). Eskom tariffs have increased drastically beyond normal inflation—increasing by 753%, compared to 134% in the same period (Moolman, 2021). Since intermittent electricity has become the status quo, alternate solutions including shifting to renewables and energy storage have become more popular. This means that dealing with an intermittent energy supply is essential in both South African and international contexts.

The detriment of load shedding to many economic sectors is an obvious problem, but issues of intermittency affect beyond the obvious; the wellbeing of diabetic insulin users is at stake when temperature failure occurs in domestic refrigerators. However, there is limited literature on domestic storage of unopened insulin—no quantitative studies have been conducted on diabetes deaths stemming from denatured insulin for poor storage in a domestic setting because this issue is most likely overlooked by developed nations. However, given that:

1. Studies conducted in the US and EU (regions with reliable electricity) have confirmed that insulin is stored out of temperature range 11.3% of the time (Braune, et al., 2018; Heinemann, et al., 2020).
2. There is evidence that there is an increased risk of developing diabetes after contracting COVID-19, even after a mild infection (Barrett, et al., 2022; Xie & Al-Aly, 2022; Wander, et al., 2022). As of September 2022, more than 600 million cases of recovered patients have been reported—for every 1,000 people studied, about 13 more individuals in the COVID-19 group were diagnosed with diabetes (Watson, 2022)—this translates to a massive diabetic burden worldwide.
3. Insulin is known to undergo thermal denaturation when stored out of manufacturers' recommended temperature range.
4. The second most common cause of death in South Africans is diabetes (Statistics South Africa, 2017)
5. Diabetic ketoacidosis deaths are more common in developing countries (Hamdy, 2021; Lotter, 2020)
6. Climate change is resulting in rising temperatures, unpredictable and/or extreme weather events, potentially disrupting refrigeration and cold transport.

One can thus conclude that the likelihood of using spoiled insulin is high in South Africa; therefore, the health of insulin users is compromised by the aggregation of factors listed previously. Thus, the solution to the problem is to ensure that there is increased temperature stability in domestic refrigerators during power outages to decrease the likelihood of using spoiled insulin.

2.3. Problem definition and Area of Need

The prevalence of diabetes in low- and middle-income countries has increased drastically over the past few decades and increasing urbanization leads to physical inactivity and poor diet choices (Cullen, 2020). The UN estimates that by 2045 the number of diabetics in Africa is expected to increase by 129% to 55 million people (Moeti, 2022). Moreover, this issue is likely to worsen in the near future, as infection with COVID-19 has been found to be a risk factor for subsequent diabetes diagnosis (Barrett, et al., 2022; Xie & Al-Aly, 2022; Wander, et al., 2022). Consequently, the number of new diabetes diagnoses is likely to increase above normal baseline. The public health needs of developing nations are not the focus of research and development (World Health Organisation, 2021), where there is a greater burden from increasing rate of diabetes cases and a lack of thermostable insulins. Moreover, limited access

to reliable medication is exacerbated by insulin's cold chain requirements and frequent power outages. Currently, it is assumed that domestic refrigeration is reliable enough to store insulin, because developed nations generally have reliable power supplies.

Insulin potency and quality are compromised by storing the insulin at non-ideal temperatures; when unopened, vials must be stored at 2°C–8°C, once opened they must be stored under 25°C–30°C (depending on manufacturer) and discarded shortly thereafter. Using insulin that has undergone thermal denaturation causes unstable blood glucose. In the case where insulin has undergone partial denaturation, glucose levels do not decrease to the desired level, which can lead the user to increase their dose—leading to reactive hypoglycaemia (commonly known as "sugar crash"). Other niche markets include temperature sensitive medications such as Humira (antirheumatic drug), VePesid (lung cancer medication), Leukeran (lymphoma and leukaemia chemotherapy medication (scisafe.com, 2019; Hatchett, 2017). Along the supply chain for insulin distribution, stakeholders such as manufacturers, distributors, and pharmacies have quality systems to maintain ideal storage conditions. Yet, when diabetics purchase insulin, the cold chain stops at the pharmacy door because the same standard is not maintained domestically (Braune, et al., 2018; Heinemann, et al., 2020).

Coincidentally, many of the developing regions that experience frequent power outages have hot climates, compounding the issues caused by socioeconomic equality and access to reliable diabetes care. Regions with this burden in descending order are: Sub-Saharan Africa, South Asia, the Middle East, and some South American countries. With long and frequent hours of power outages, it is likely diabetics will either waste money on more insulin to replace spoiled insulin, or accidentally use insulin with decreased potency—which is potentially life-threatening. Albeit the situation is not as dire in developed nations, recent global political changes have also threatened the electrical stability of developed countries (Hall, 2022). Europe faces an energy crisis that has led to some countries planning controlled outages to avoid rolling blackouts (Bloomberg, 2022; Sillars, 2022). This may expedite transition to renewables, but electrical intermittency may still be an issue while renewable energy infrastructure is developed and strengthened (Gross, et al., 2007).

In 2021, South Africa experienced 1136 hours of load shedding (see Figure 1). Most household refrigerators should operate between 0°C - 8°C for food safety, but may vary depending on position, air circulation, time, and age of the fridge. Therefore, temperatures within a household fridge are almost never ideal for medication storage (especially when load shedding occurs)

even when the mean temperature (6.1°C) is within insulin manufacturers' recommendation; the typical range (1.5°C - 16.1°C (James, et al., 2016)) is unsuitable. Ambient temperatures in the South Africa can reach up to temperatures well over 30°C on the hottest days and the major cities have temperatures over 25°C for 28%–55% of the year, depending on the climate zone (Table 1).

Table 1 Maximum temperatures and number of days above 25°C in major cities for past three years

	Johannesburg			*Durban*			*Cape Town*		
	Number of days and Percentage of year >25°C		Maximum temperature (°C)	Number of days and Percentage of year >25°C		Maximum temperature (°C)	Number of days and Percentage of year >25°C		Maximum temperature (°C)
2021	129	35%	31.9	163	45%	37.0	105	29%	36.0
2020	144	39%	33.0	194	53%	35.0	104	28%	36.0
2019	200	55%	34.8	186	51%	35.0	104	28%	37.4

This compromised storage situation creates two urgent needs for insulin users in this context. The first of these is better thermal stability of storage and the second is a visual indicator when a given batch of medication has been exposed to out-of-range temperatures, alerting a user to potential thermal degradation. These needs are also subject to several constraints imposed by the South African context. South Africa has a median per-capita household income in the region of R1200 per month and 55.5% of the population—30.3 million people live in poverty at the national upper poverty line (World Bank Group, 2020)—severely constraining the acceptable cost of any accessories to treatment.

Moreover, there are also limitations on access to healthcare services, meaning that a solution must be ergonomic and low maintenance (i.e., not frequently require specialised replacement parts). This means that common solutions to cold-chain management are unsuitable. Thermochromic stickers that detect out-of-temperature warming events are unsuitable because they would require replacement after each such event and would also require a cold chain for their distribution and delivery. Accurate digital temperature tracking, while potentially feasible, is comparatively costly and requires externalities including either battery replacement or charging, as well as either their own interface, or connectivity with outside electronic devices. Neither of these approaches to indicating out-of-temperature events address the core issue of thermal stability.

Ideally, the product should be available to end-users in clinics and pharmacies, but the key area of concern stems from the lack of solutions to the problem: end-users are unaware that they should protect their medication if they live in areas with frequent power outages, or old/unreliable household refrigerators. This can be mitigated by sufficient marketing and advertising, to both end-users (diabetics) and health practitioners—who may suggest users protect their medication by purchasing the device.

2.4. Current Solutions and Patent Search

The current solutions do not have the same *indications for use*[1] as described above, for protecting against temperature failure in the 2°C–8°C range. If temperature excursions occur the user may unaware of loss of potency of the insulin. Most advice for storing insulin emphasises the importance of discarding insulin if it has been stored above 25°C –30°C after it has been opened. Users may stock up on their insulin supply from the pharmacy and use the medication over a period of time and may lack awareness that thermal degradation during storage (unopened) is more likely than after opening a vial. Many insulin storage solutions address keeping insulin under 30°C, because it is wrongly assumed that insulin is stored correctly for the entire duration when unopened (when required to be kept between 2°C–8°C) but protecting medication from thermal degradation before opening the vial is crucial for reliable blood glucose control.

No other device on the market currently can give the user an indication that the insulin has been stored at the wrong temperature without the use of electronics or giving an indication of temperature failure. The proposed device must keep the temperature of the drugs stable, as well as have visual indications to the user that there is a possibility that the drugs be compromised as the temperature in the device has exceeded the 2ºC-8ºC range that the medication should be stored at. It is proposed that the device insulates the drugs within a fridge and ensures that storage temperature is stable and adheres to the drug manufacturers' instructions.

There are some devices on the market that protect from temperature-related insulin degradation, but these are all for opened insulin and do not have the same indications for use. Most of these products fall under the description for "Autoinjector insulation case". Table 2 summarises most of the commercial products for storing insulin.

[1] Indications for use cover the reasons or situations in which someone would use the device.

Table 2 Current medical devices on the market for insulin thermal protection

Device on market	*Advantages*	*Disadvantages*	*Action Principle*
Basic insulation case/pouch	Affordable (R180–R300) Lightweight, portable for everyday use Versatile, stores all types of medication *Stores 1–5 autoinjector pens	Does not indicate when medication is likely degraded Decreased protection when temperatures are very high—inaccurate/unreliable protection time	Uses an insulating material to keep medication under 30ºC
Cooling wallet/bag *e.g., Frio wallet (Frio, 2021)*	Has indication of how long protection action lasts (45 hours) Lightweight, portable for everyday use Versatile, stores all types of medication *Stores 1–5 autoinjector pens	Expensive** (R500–R1200) Does not indicate when medication is likely degraded User interaction: user must submerge product in cool water	Water evaporation from gel beads
Cooling flask *e.g., Disoncare*	Portable, but large and unwieldy Versatile, stores all types of medication *Stores 2–8 autoinjector pens *Has indication of how long protection action lasts (25-72 hours)	Expensive** (R700–R1800) Might include batteries or electronics (charging needed) Protection time depends on external temperature and temperature of medication when placed in device	Vacuum-sealed flask

Device on market	*Advantages*	*Disadvantages*	*Action Principle*
Insulin pen cap *e.g., Vivi Cap (TempraMed, 2021)*	Lightweight, portable for everyday use No user interaction needed (no charging, water, or ice for product to function) Has visual indication if insulin is in range (green light)	Very expensive (R3000) Stores 1 insulin pen, only compatible with popular manufacturers' insulin pens with specific dimensions. Needs battery replacement	"Space-grade" thermal insulation Phase change material
Refrigeration case *e.g., 4AllFamily medicine cooler; LifeinaBox; QIRDLP mini drug refrigerator; AIJUN portable insulin refrigerator (Oerum, 2022)*	Reliable cool environment with electricity *Stores 2–8 autoinjector pens *Indicates temperature from built in thermometer *Connected to phone/application	Very expensive* (R2000–R4000) Most brands are not intended to be portable or may be unwieldy during use if portability is incorporated into design Electronic and/or battery (power source needed, some brands offer USB for charging in cars)	Refrigeration *Combined with cooling packs or insulation for travelling

**Depending on brand/manufacturer*

***Depending on holding capacity*

In addition to the marketed devices that can be found by users seeking medical devices for temperature failure in the search engines, a patent search was conducted to find similar devices, or inventions with similar components. The results of the patent search are presented in Table 3.

Table 3 Patents of devices that protect thermal sensitive medication

Patent identification	*Patent*	*Date filed*	*Reason/Similar Claim*
US195947A	Improvement in hypodermic-syringe bottles	1877-10-09	Box/storage device for insulin with hinge
US4848587A	Container for storing materials for use by diabetics	1987-05-07	Compartmented insulin storage
US5850917A	Syringe dosage tracking device with cooling feature	1996-12-23	Insulin storage with cooling feature
US9429350B2	Shipping box system with multiple insulation layers	2012-05-03	Insulating layer Maintain medicine between 2°C–8°C for at least about 72 hours when the container system is subjected to 22° C Phase change material: deuterium oxide (heavy water)
GB2534908A	A cool pack	2015-02-05	Cool pack with coolant is phase change material (not specified) Material of construction is formed from polypropylene or polyethylene
CA3023684C	A thermally insulated container	2016-05-31	Thermally insulated shipping container Phase change material: tetradecane

2.5. Regulatory Classification

All medical devices have legal requirements and quality control attached to their production and sales. Product registration and certification requires product and system compliance. Depending on the different markets, regulatory compliance pathways will differ. For sales

within a South African context, the device must be registered under the South African Health Products Regulatory Authority (SAHPRA); in the United States the device should be approved by the Food and Drug Administration; in the European Union (CE marking) it must be approved by the relevant Competent Authority of member State[2]. Other regulatory bodies are discussed in APPENDICES

Appendix A: Regulatory Pathways Information, as the product will be useful beyond the South African context, since there are many countries facing energy crises which may led to poor medicine storage during power outages.

In general, registering a device requires a classification according to the risk impact the device will have on the user. Defining the product in terms of its *intended use*[3] and *indications for use*[4] is necessary for classification (Class A, B, C or D). A manufacturer, importer, distributor or exporter of Class B, C or D medical devices must apply for a license through SAHPRA and implement a quality management system. Classification is divided into the following classes:

- Class A Low Risk
- Class B Low to Moderate Risk
- Class C Moderate to High risk
- Class D High Risk

The proposed device is a class A (low risk) device because its function is to protect medication and maintain its efficacy within the recommended storage temperature range within a refrigerator, with special attention to protect from power outages and visually indicate to the user that insulin might have degraded. The patient population is most likely people with diabetes (using insulin), cancer patients (using Etoposide or Chlorambucil), or people with rheumatoid arthritis (using Adalimumab) using temperature sensitive medication. The device is intended to assist with achieving the correct storage temperature range—it is not life supporting, but it will assist diabetics or other patients with maintaining the quality of their temperature sensitive medication.

[2] For example, the Austrian Agency for Health and Food Safety (AGES) for Austria, or Agencia Española de Medicamentos y Productos Sanitarios (AEMPS) for Spain; or the Medicines and Healthcare products Regulatory Agency (MHRA) for the UK.

[3] The general purpose of the device or its function. This includes the indications for use.

[4] Describes the disease or condition the device will diagnose, treat, prevent, cure, or mitigate, including a description of the patient population for which the device is intended.

2.6. Business Consideration and Product Lifecycle/Development

Since the problem of temperature failure for storing insulin during power outages in domestic settings is often overlooked in multiple developing countries, it is likely that this product will improve the reliability of medication in countries other than South Africa. There is no other product that addresses this pertinent issue. Internationally, developed countries have near constant electrical supply and have not addressed this issue, but that is not the case in developing countries. Since energy intermittency is not a problem for these countries, a solution has not been developed to address this issue. Therefore, this device does not exist because this is overlooked problem by overseas developers—this means there is a gap in the medical device market that addresses a legitimate problem; furthermore, is a means of deriving profit. The regulatory compliance pathway may be more complicated for other countries, requiring different approval—Appendix A includes a summary of information for FDA and EU approval (Snyman, 2021), which will likely encompass similar contents for medical device approval in most countries.

In addition to insulin users that would like to have better storage of their medication, other stakeholders on the consumers side would benefit from such a product. Healthcare workers, diabetes organisations, rural pharmacies or clinics prefer better glucose stability and control of patients. Furthermore, other organizations (such as insurance companies that cover for chronic medication) would prefer less wasted medication.

Ideally, the product should be purchasable off-the-shelf at pharmacies or clinics. The product should be priced economically, since the device is filling a gap in the market of countries with unreliable power supply; people in developing countries have less expendable income and are more likely to experience power outages and issues of electrical intermittency. The device's price is highly dependent on the design and the materials of construction; thus, these criteria will be factored into the design of the device and discussed further in Chapter 2.

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Chapter 2

CONCEPT DEVELOPMENT AND INITIAL SOLUTION

This chapter is included as a chapter in the textbook *"Medical Devices Innovation for Africa: Enabling Industrialisation"*:

Xu, L., Stacey,N., Rubin, D., & Hildebrandt, D. Low-Cost Load Shedding-Resilient Medicine Storage With Phase-Change Material: Theoretical Heat Transfer Evaluation Of A Design Concept. In Medical Devices Innovation for Africa: enabling industrialization. S. Sivarasu, Ed. Cape Town: University of Cape Town Libraries. 30–39. DOI: https://doi.org/10.15641/UCTLib40

Abstract

Diabetes mellitus is one of the most common non-communicable diseases; approximately 0.72 million people in South Africa require insulin treatment. Insulin—a hormone peptide drug—is temperature sensitive and undergoes thermal fibrillation when exposed to temperature above manufacturers' recommendations. Most insulin formations must be stored at 2°C - 8°C in a refrigerator when unopened to maintain its potency and to keep insulin within manufacturers' suggested expiry date. However, one of the unforeseen consequences of frequent power outages in South Africa—and many other developing nations—is thermal denaturation of insulin within household refrigerators caused by frequent power outages. Users cannot tell if insulin has reduced pharmacological action. This publication presents a preliminary design for an in-refrigerator medicine storage container utilizing phase-change material to stabilize the temperature of insulin or other medications during power outages, and to provide a visual indicator if a melting event has occurred, even if refrigeration has subsequently been restored, to alert the user that their insulin may have expired. It is found that the principal variables of interest to determine the time to melting are the thickness of the layer of phase-change material in the unit's walls, and the degree of insulation of the outer shell surrounding the phase-change material. It Is also determined that asymmetric insulation parameters for the inner and outer surfaces of the container's walls are a crucial design feature for usability, permitting an initial freezing time that is more rapid than the melting time. The current design has been found to be

unable to meet all usability criteria, primarily due to an unacceptably long freezing time, regardless of the values of the available parameters. It is therefore concluded that design revisions are required in order to meet all usability criteria.

Keywords: Diabetes, medicine storage, phase-change material, public health

Nomenclature

Q	Rate of heat transfer
A	Area for heat transfer
ΔH	Change in enthalpy
M	Mass
t	Time
T	Temperature
U	Overall heat transfer coefficient
d	Thickness
k	Thermal conductivity
h	Film heat transfer coefficient
d	Thickness of material of construction
δ	Thickness of PCM layer

3.1. Introduction

The prevalence of diabetes in low- and middle-income countries has increased drastically over the past few decades—increasing urbanization leads to physical inactivity and poor diet choices (Cullen, 2020). Within South Africa, 4 581 200 (12.8%) (International Diabetes Foundation, 2020)of the adult population has diabetes and about 15.5% of people with type 2 diabetes need insulin (Basu, et al., 2018). This issue is likely to worsen in the near future, as infection with COVID-19 has been found to be a risk factor for subsequent diabetes diagnosis (Barrett, et al., 2022). Consequently, the number of new diabetes diagnoses is likely to increase above normal baseline for the duration of the pandemic. The public health needs of developing nations are

not the focus of research and development (World Health Organisation, 2021), where there is a greater burden from increasing rate of diabetes cases and a lack of thermostable insulins. Moreover, limited access to reliable medication is exacerbated by insulin's cold chain requirements and frequent power outages.

Along the supply chain for insulin distribution, stakeholders such as manufacturers, distributors, and pharmacies have quality systems to maintain ideal storage conditions. Yet, when diabetics purchase insulin the same standard is not maintained for several reasons (Braune, et al., 2018; Heinemann, et al., 2020). Currently, it is assumed that domestic refrigeration is reliable enough to store insulin, because developed nations have reliable power supplies. However, studies have shown that even during normal daily domestic refrigerator usage (without power outages) 11.3% of the time insulin degradation is an underestimated risk (Braune, et al., 2018). Insulin potency and quality is compromised from storing the insulin at non-ideal temperatures. Most household refrigerators should operate between 0°C - 8°C for food safety, but may vary depending on position, air circulation, time, and age of the fridge. Therefore, temperatures within a household fridge are almost never ideal for medication storage, even when the mean temperature (6.1°C) is within insulin manufacturers' recommendation; the typical range (1.5°C - 16.1°C (James, et al., 2016)) is unsuitable.

Coincidentally, many of the developing regions that experience frequent power outages have hot climates, compounding the issues caused by socioeconomic equality and access to reliable diabetes care. Regions with this burden in descending order are: Sub-Saharan Africa, South Asia, the Middle East, and some South American countries. In South Africa, frequent power outages, referred to as "load shedding," are becoming more commonplace (Table 4) —a trend unlikely to change quickly. Therefore, with long and frequent hours of power outages, it is likely diabetics will either waste money on more insulin to replace spoiled insulin, or accidentally use insulin with decreased potency—which is potentially life-threatening.

Table 4 Power outage trends in South Africa (CSIR, 2020)

Year	*Duration of power outages (hours)*	*Energy shed (GWh)*
2007	-	176
2008	-	476
-	-	-
2014	121	203
2015	852	1325
-	-	-
2018	127	192
2019	530	1352
2020	859	1798
2021	1136	2455

This compromised storage situation creates two urgent needs for insulin users in this context. The first of these is better thermal stability of storage and the second is a visual indicator when a given batch of medication has been exposed to out-of-range temperatures, alerting a user to potential thermal degradation. This solution is also subject to several constraints imposed by the South African context. South Africa has a median per-capita household income in the region of R1200 per month, severely constraining the acceptable cost of any accessories to treatment. There are also limitations on access to healthcare services, meaning that a solution must be low-maintenance and not frequently require replacement parts. This means that common solutions to cold-chain management are unsuitable. Thermochromic stickers that detect out-of-temperature warming events are unsuitable because they would require replacement after each such event and would also require a cold chain for their distribution and delivery. Accurate digital temperature tracking, while potentially feasible, is comparatively costly and requires externalities including either battery replacement or charging, as well as either their own interface, or connectivity with outside electronic devices. Neither of these approaches to indicating out-of-temperature events address the core issue of thermal stability.

3.2. Initial development considerations

3.2.1. Solution to Thermal Stability

The proposed solution to meet the usability criteria is the use of a phase-change material (PCM) as a thermal stabilizer within the device. The thermostable medical container's construction is simple; it consists of a moulded thermoplastic shell containing a layer of PCM that melts at a temperature within the recommended temperature band (2°C–8°C)—this will ensure that medication stored within will stay within range during the power outage because the temperature stays constant during melting and freezing. Subsequently, when the power returns and the fridge cools, the PCM will refreeze and may be reused.

At this stage of the project, the objective is identifying the key design parameters and experimental targets for prototyping. This will be done on a theoretical basis by using a heat transfer model to identify which parameters affect the main usability requirements, and to determine whether the current design concept will be able to meet the criteria for usability, namely; a sufficiently long melting time to last through typical power outages, a sufficiently rapid freezing time for user convenience, and sufficient excess thermal capacity to repeatedly re-normalize temperature after the container has been opened to retrieve medications as needed[5].

The proposed PCM is C-14 paraffin, which has a melting/freezing temperature of 6°C (Khan, et al., 2016). The benefit of using a PCM is that it is a cheap material of construction, is readily available from chemical suppliers, and using it will occlude the use of electronics. A PCM is more reliable and accurate in temperature control than electronic controls as long as the purity of the paraffin is correct.

The main usability requirements for this device are that it must have a sufficiently long time-to-melting, and once solidified, to maintain thermal stability over the course of a sustained power outage. It must also have a sufficiently short time-to-freezing to allow users to freeze the phase-change material within a convenient amount of time. Ideally, the device should also hold enough excess thermal capacity to restore its internal temperature through multiple occasions of it being opened to retrieve insulin.

[5] This usability criteria are explained in more detail in the following chapter.

It is important that there is an indicator in the device to warn that user that the temperature in the device exceeded 6°C—this will alert the user that the effectiveness of the insulin in the container may be reduced. Figure 2 shows how the visual indicator functions.

Figures 3, 4 and 5 show the proposed device and how it is reused before, during and after a power outage. The steps for using the device are:

1. Place the device with the top open within a fridge
2. Allow the device to cool for 1-2 hours
3. Place medication within to keep temperature sensitive medication within the range of 2°C -8° for the duration of load shedding.
4. If temperature failure occurs the PCM will melt, and the visual indicator will have a different appearance. This will alert the user hat their insulin has been stored at a temperature higher than the manufacturer's instructions. The user should discard insulin[6].
5. The device may be reused and reset from step 1.

However, as discussed in Chapter 1, insulin users often do not know when temperature failure has occurred, which is why a visual indicator is necessary. Figure 2 shows a visual indicator that will show a change in the positioning of the beads if temperature failure has occurred. The beads are locked in one position during the freezing process. When temperature failure has occurred, the PCM will melt and the beads will sink—i.e., the user will observe that the change in positioning of the beads from their original state and this is an indication that temperature failure has occurred.

3.2.2. The Visual Indicator: Temperature Failure Warning System

Because of the gravimetric and buoyancy properties of C-14, designing a visual indicator that relies on its melting point will indicate to the user when temperature failure has occurred in the entire device. Coloured beads of a slightly greater density of the PCM will sink in the liquid PCM when the temperature exceeds 6°C, which will alert the user to temperature failure. Such beads can be locked into one position base on the container's orientation during the freezing process and then, with the container's orientation altered for storage, only sink to an alternate position if the phase change material melts.

[6] Though some diabetics may still choose to use the medication, the device would serve its purpose in alerting the user and they would use the medication with more caution

This design will ensure that if there is a warming event there will be an irreversible positional change giving a visual indication. Afterward, re-freezing the material in the appropriate orientation will reset the beads' position for reuse. Figure 2 shows the simplified version of how the visual indicator works. Between stage 2 and 3, the user anticipates load shedding and closes the device to protect medication. From state 3 to 4, the device will keep the medication cool for several hours, but beyond this period the device’s thermal capacity runs out (the PCM melts) and the beads fall from their locked position. From state 4 to 1, the user knows their medication has been stored above 8°C and should use their medication with caution, or preferably discard the insulin for safety reasons. They may reset the device and place new insulin within

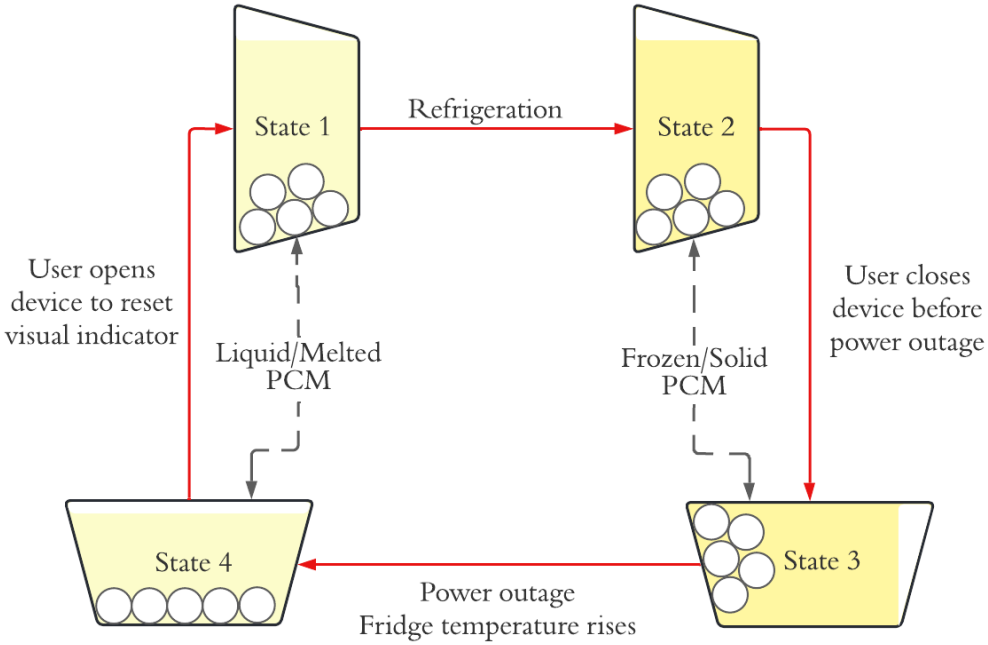

Figure 2 An explanatory picture showing the simplified version of the visual indicator

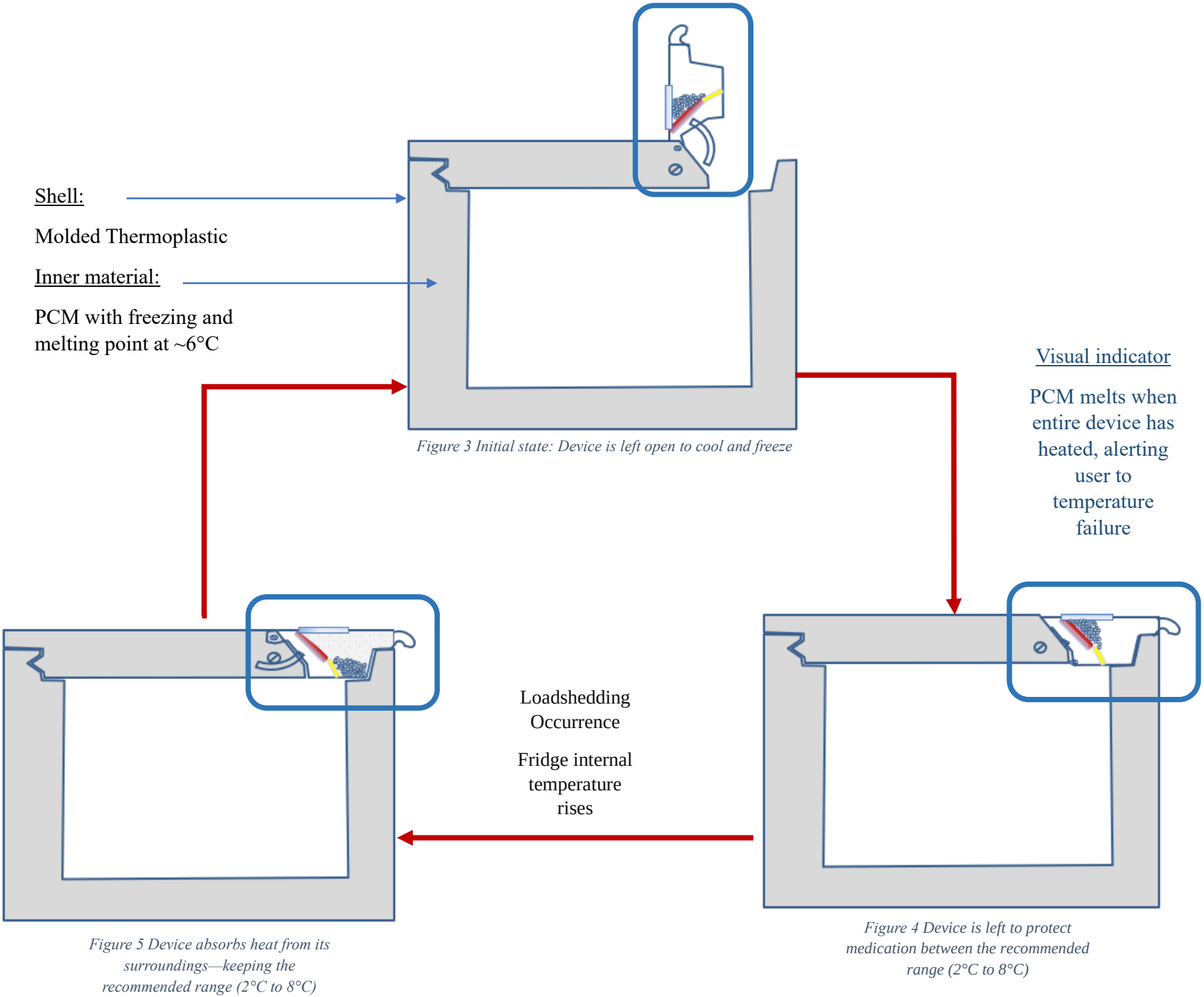

Figure 3 Initial state: Device is left open to cool and freeze

Figure 4 Device is left to protect medication between the recommended range (2°C to 8°C)

Figure 5 Device absorbs heat from its surroundings—keeping the recommended range (2°C to 8°C)

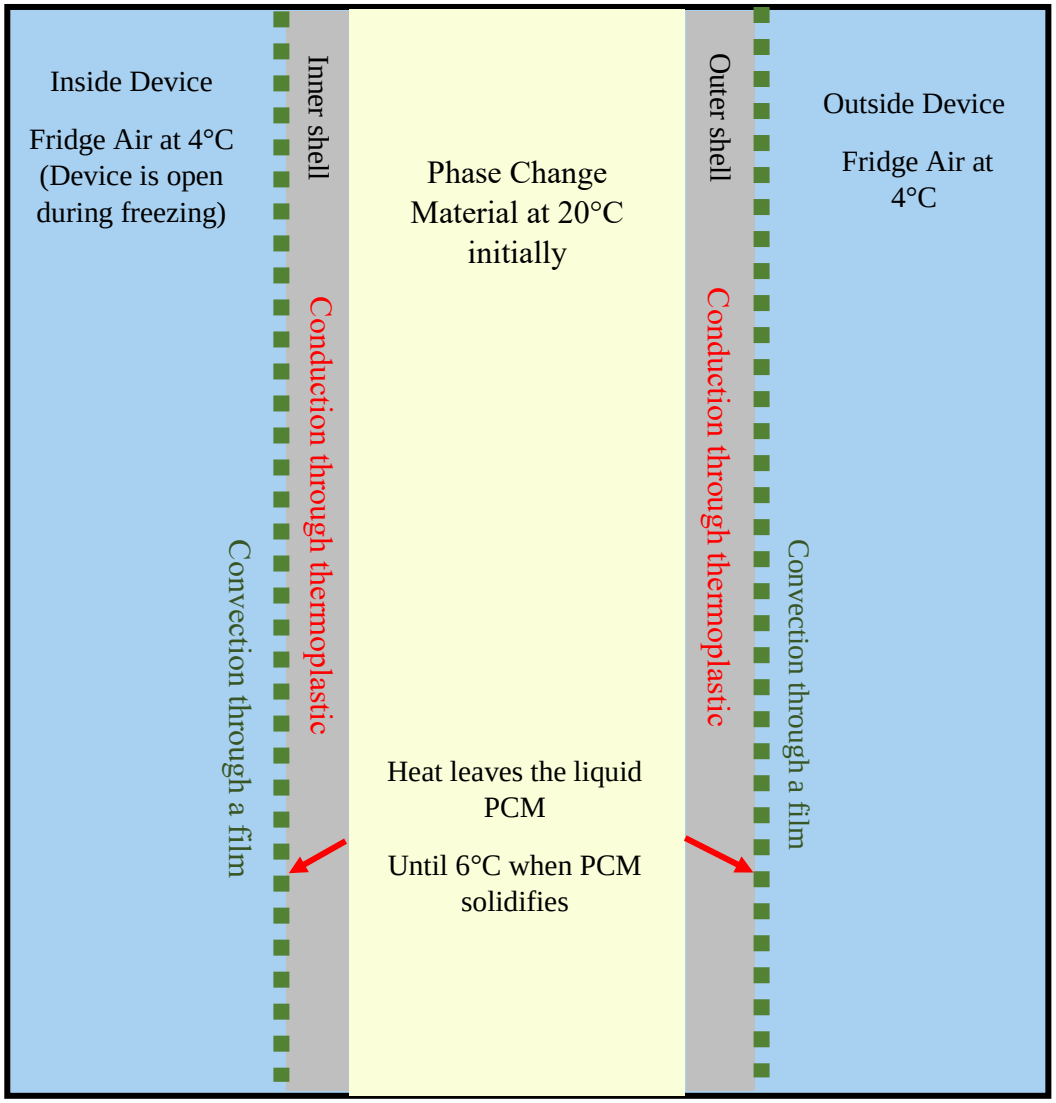

Figure 6 Cross section showing heat transfer out of PCM when device is cooling.

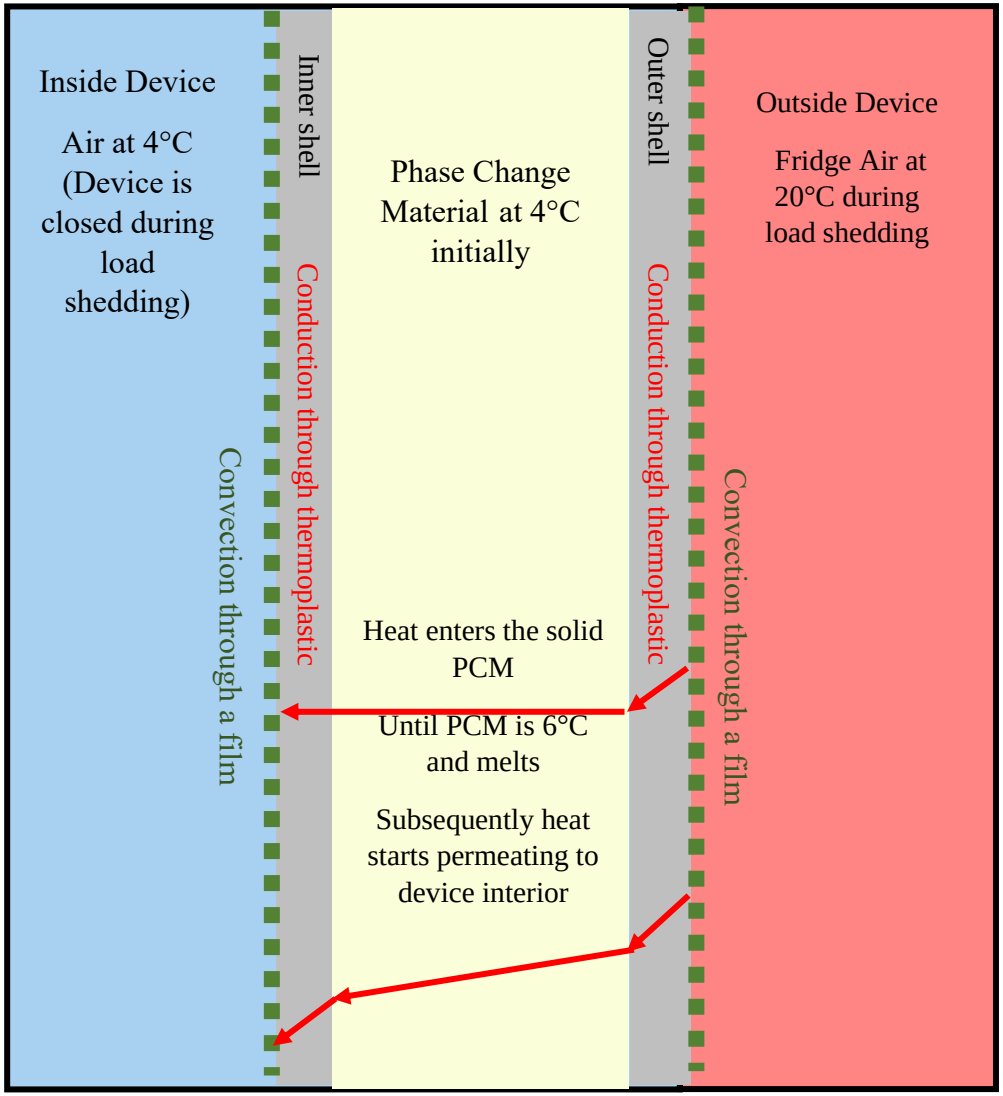

Figure 7 Cross section showing heat transfer during load shedding.

3.3. Physical properties and modelling assumptions

The device is conceived to be a rectangular prism, with outer walls comprised of polypropylene, which will enclose a volume of C-14 paraffin as a phase-change material. For simplicity, the device can be envisioned as a cube, but the actual dimensions may vary. All 6 walls of the device are assumed to have the same dimensions and enclose an equal thickness of PCM. Final design may deviate from this approach, as it may turn out that different properties of convection from vertical and horizontal surfaces may require that the respective wall thicknesses of those surfaces differ. The physical properties of the material are listed in Table 5.

Table 5 Table of properties

Property	***Material***	***Value***
Thermal Conductivity	Polypropylene	0.11 W/m·K
	Air	0.025W/m·K
	C-14 Paraffin	0.14 W/m·K
Heat capacity	Air	1.00 kJ/kg·K
Density	C-14 Paraffin (liquid)	763 kg/m^3
	Air	1.2 kg/m^3
	Polypropylene	946 kg/m^3
Convective heat transfer coefficient	Air	10W/m^2·K

For purposes of modelling, the following simplifying assumptions are made:

- The phase-change material has uniform temperature of 6°C during melting.
- The air temperature within the refrigerator is uniform.
- A plausible worst-case scenario is considered for simplicity, where the fridge interior has rapidly reached 20°C to determine the time to melting during strenuous conditions. During the warm season, average air temperature is above 24°C (NASA Global Modeling and Assimilation Office (GMAO), 2022), but fridges will have thermal capacity from stored food and the polyurethane insulation. Hence, a worst-case uniform air temperature of 20°C is assumed for

the refrigerator. In practice, the temperature will initially be lower, and follow a profile of gradually increasing profile. However, energy incursion into refrigerators is highly inconsistent, being driven more by opening/closing than by continuous heat loss and so, a refrigerator reaching a high internal temperature early on in the course of a power outage is a scenario that will occur at times. Therefore, any device intended to thermally stabilize medicine must be able to handle the worst-case scenario. Hence, the performance benchmark that is considered is the time to melting under those conditions.

- For the freezing process, the internal temperature of the refrigerator is assumed to be uniform at 4°C.
- The difference between inner and outer skin surface areas is neglected as being minor.
- In order to fit inside a refrigerator and so the device is ergonomic, the device's dimensions are within the bounds of 10cm to 20cm on each side

3.4. Governing Equations

The device will be closed for storage, which means that heat transfer will occur through the outer skin only. The rate of heat transfer during melting is therefore given by:

$$Q = A_{outer} U_{outer\ skin} \Delta T$$

Equation 1

During freezing, the device will be open, so the inner surfaces will also interact with the interior air of the refrigerator, so the rate of heat transfer is given by:

$$Q = A_{outer} U_{outer\ skin} \Delta T + A_{inner} U_{inner\ skin} \Delta T$$

Equation 2

The energy balances governing freezing and melting are as follows:

$$\Delta H_{total} = \Delta H_{phase\ change} \Delta M_{solid}$$

Equation 3

$$\Delta H = \int_{t0}^{tfinal} Q dt$$

Equation 4

$$U_{outer\ skin} = \frac{1}{\left(\frac{d_{outer\ skin}}{k_{outer\ skin}} + \frac{1}{h_{air}}\right)}$$

Equation 5

$$U_{inner\ skin} = \frac{1}{\left(\frac{d_{inner\ skin}}{k_{inner\ skin}} + \frac{1}{h_{air}}\right)}$$

Equation 6

Conveniently, because the PCM is at a fixed temperature during freezing or melting, when a constant internal air temperature is assumed for the refrigerator, both processes take place at a constant rate, and the freezing and melting times can be estimated as follows:

$$t_{melt} = \frac{M_{PCM} \cdot \Delta H_{phase\ change}}{U_{outer\ skin} \cdot A_{exterior} \cdot (20°C - 6°C)}$$

Equation 7

$$t_{freeze} = \frac{M_{PCM} . \Delta H_{phase\ change}}{U_{outer\ skin} \cdot A_{exterior} \cdot (6°C - 4°C) + U_{inner\ skin} \cdot A_{interior} \cdot (6°C - 4°C)}$$

Equation 8

The total mass of the PCM is given by the total surface area of the container walls multiplied by the thickness, δ, of the PCM volume, multiplied by its density—or contained within the interior and exterior surfaces of the device, the difference between the volumes of

$$M_{PCM} = \delta \cdot A \cdot \rho_{PCM} = (V_{exterior} - V_{interior}) \cdot \rho_{PCM}$$

Equation 9

Consequently, the above equations can be summarized as the following:

$$t_{melt} = \frac{\rho_{PCM} \cdot V_{PCM} \cdot \Delta H_{phase\ change}}{(20°C - 6°C) \cdot A_{exterior}} \Big/ \left(\frac{d_{outer\ skin}}{k_{outer\ skin}} + \frac{1}{h_{air}}\right)$$

Equation 10

$$t_{freeze} = \frac{\rho_{PCM}.V_{PCM} \cdot \Delta H_{phase\ change}}{(6°C - 4°C) \cdot A_{exterior}} \Big/ \left(\frac{d_{outer\ skin}}{k_{outer\ skin}} + \frac{1}{h_{air}}\right) + (6°C - 4°C) \cdot A_{interior} \Big/ \left(\frac{L_{inner\ skin}}{k_{inner\ skin}} + \frac{1}{h_{air}}\right)$$

Equation 11

Equation 10 and

Equation 11 only have the thicknesses of the inner and outer skins, and the thickness of the PCM volume as independent variables, which makes it possible to assess two major usability criteria just in terms of those independent variables.

The other critical usability criterion is tolerance to opening and closing of the unit for retrieval of medicines. Now, there will be considerable user-variability in how much additional heat exchange takes place with each such event. However, it can be reasonably assumed that most users will open the container only briefly during a power outage, to conserve the cold environment inside. Therefore, the worst-case scenario among the likely use cases is that when the container is opened, all of its air contents are replaced with interior air from inside the refrigerator and then the container will be closed with air at the refrigerator temperature now inside. Now, it can be fairly assumed that heat transfer between the storage container and now-enclosed air will be rapid enough to prevent medicines warming above the desirable range and that the temperature inside the container will re-stabilize at 6°C in a reasonable timeframe. Hence, the area of concern is that the excess energy of the enclosed air will be added to the PCM each time the container is opened and closed.

This performance characteristic can be expressed as a fraction of the PCM volume that will be melted in order to re-stabilize temperature after a single opening event, and can be estimated using the following equation:

$$fractional\ melt = \frac{V_{container} \cdot \rho_{air} \cdot Cp_{air} \cdot \Delta T}{V_{PCM} \cdot \rho_{PCM} \cdot \Delta H_{Phase\ change}}$$

Equation 12

The only variables remaining in this equation are the volumes of the container interior and that of the PCM; the other parameters are physical constants. Hence, by substituting the known physical constants, the fraction of phase-change material required to melt to normalize temperature after an opening event can be expressed as the following linear relationship to the ratio of interior container volume to PCM volume.

$$fractional\ melt = 0.0001 \cdot V_{ratio}$$

Equation 13

3.5. Results and discussion

3.5.1. Fractional melting during opening and closing of storage container

The fractional melting per usage, as defined by *Equation 13* is 0.0001·Vratio. To test the fractional melting, multiple ratios of the container volume to PCM volume can tested to understand how the performance of the device is during opening and closing. The device has to fit within the fridge, so it cannot be too large. Assuming the device's exterior dimensions ranges from 10cm to 20cm on each side and varying amounts of PCM is used from 1cm to 0.4cm beneath the exterior to maintain the temperature, the resulting fractional melt for the device can be estimated.

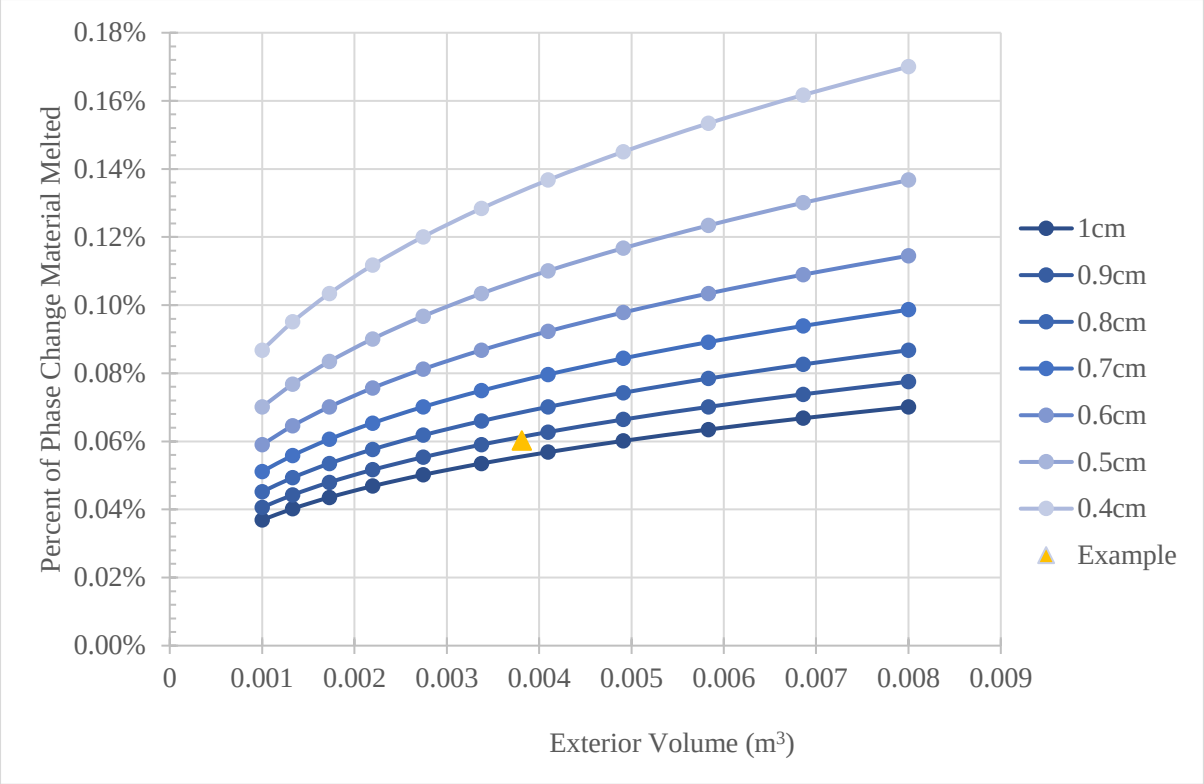

Figure 6 PCM melt percent during opening and closing device

The figure above demonstrates that in the most extreme case when the container is at its largest (20cm×20cm×20cm), with a layer of PCM with thickness of 0.4cm will only have a fractional melt of 0.0017, equivalent to 0.17%. Any other rectangular prism with the dimensions within the bounds of 10cm to 20cm will have fractional melt values between 0.000369 to 0.0017 (Figure 6). This means that the overall excess thermal capacity available to compensate for opening or closing of the box will be far in excess of what is required.

For example, a container of square base measuring 18cm on each axis, a height of 12cm, PCM thickness of 1cm, and plastic thickness of 1mm: the interior volume will be 3813 cm^3, and the PCM volume will be 634cm^3 (Figure 6 and Figure 7), and thus the fractional melting per opening and closing event will be only 0.0006, or roughly 0.06%.

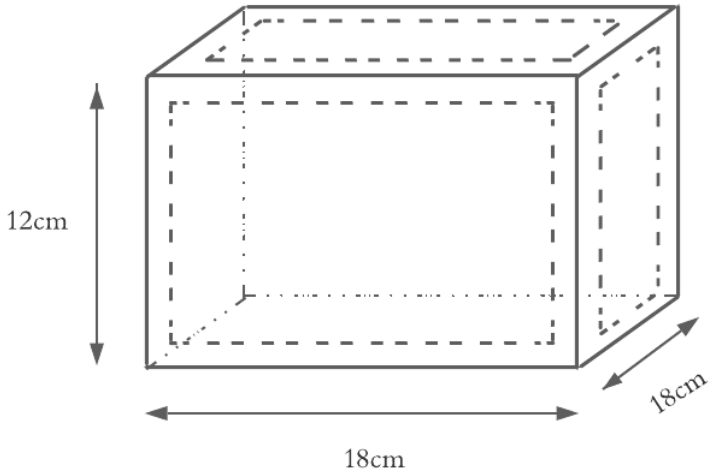

Figure 7 A figure depicting the dimensions of a simplified version of device with a layer of PCM under each surface of the prism

This implies that the main consideration for opening or closing is in fact just ensuring that the interior skin's heat transfer is rapid enough that warmer interior air is cooled quickly enough to prevent temperature rise in the medicines themselves. The low heat capacity of the air volume inside the container suggests that this will not be a problem if a user is careful to not keep the container open for extended periods during a power outage, the opening and closing of the container will not significantly affect its performance.

Because of this, heat incursion of this type is not a severe design constraint, leaving the volume of PCM relative to the interior volume of the container as a free variable, subject to other constraints.

3.5.2. Melting and freezing times

The simplest conceptualization of the device is a container with a layer of PCM of equal thickness enclosed between two layers of thermoplastic. To determine the approximate thickness of PCM needed (commensurately, PCM volume can be determined) to protect the medication, comparing the melting and freezing time by the varying amounts between the largest and smallest possible volumes for the device will give an indication of the required PCM volume.

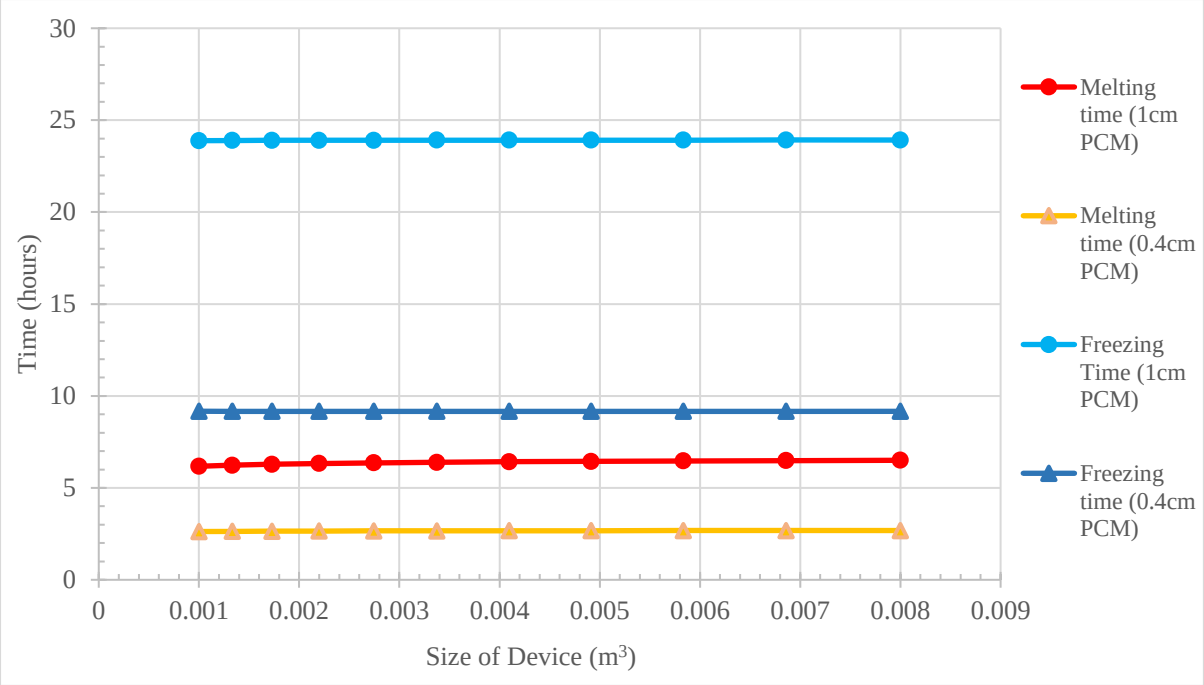

Figure 8 Comparison of melting and freezing times for a phase-change material container with 0.4cm thickness or 1cm of phase-change material, 1mm thickness of inner skin and outer skin surface, assuming refrigerator temperature of 4°C during freezing, and 20°C during melting.

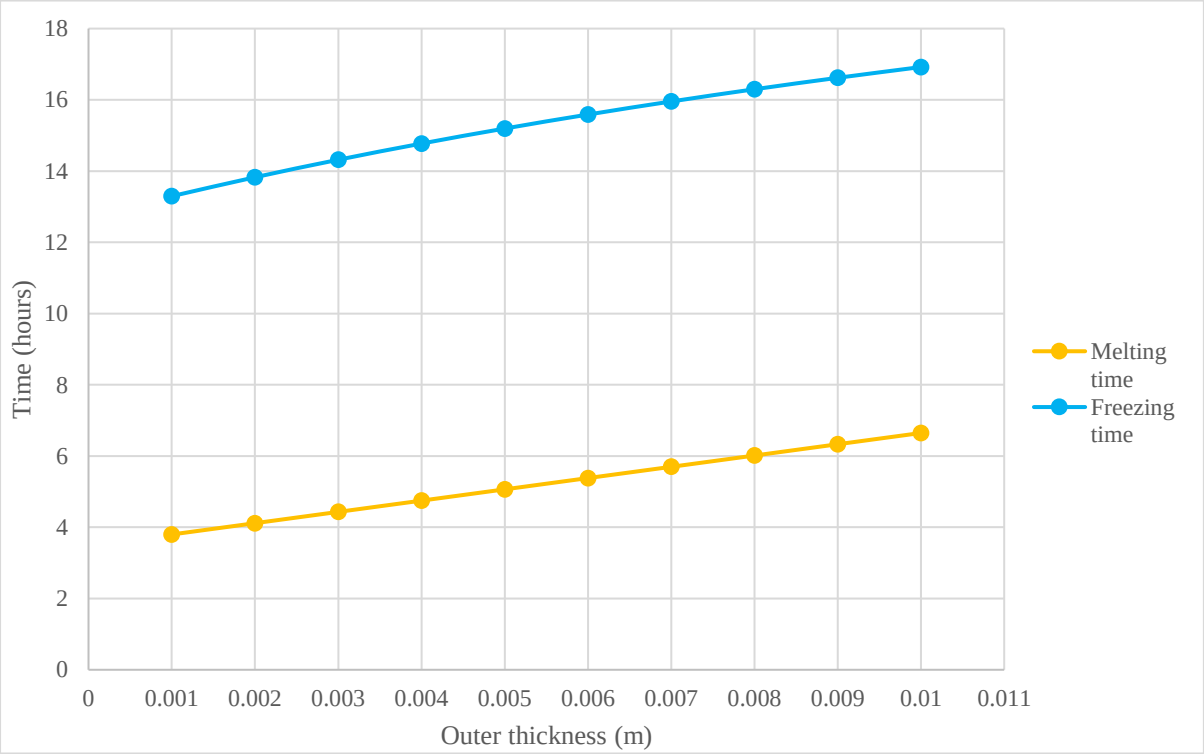

Figure 9 Melting and freezing times for a phase-change material container with 1cm thickness of phase-change material, 1mm thickness of inner skin surface, assuming refrigerator temperature of 4°C during freezing, and 20°C during melting.

Figure 8 demonstrates that the design, as currently conceptualised, is not able to meet all usability requirements. While a suitable melting time is of 6.5 hours is achievable, for the

largest possible device (volume of 0.008m^3) with a layer PCM of 1cm to prevent temperature failure, the associated freezing time is unacceptably high—almost 24 hours is needed to freeze the device (Appendix B). The freezing to melting ratio for the device ranging from a 10cm–20cm is 3.7 to 3.9 (Appendix B), but this ratio needs to be lower. The freezing time must be at least shorter than 5.5 hours, since during load shedding the shortest periods with power will only provide cooling for this period. During stage 6 load shedding (currently, this is the most extreme stage that has been implemented) the planned power outage could be implemented three times—for example, at 2:00 to 4:30, 10:00 to 12:30, and 18:00 to 22:30. The exact times of the power outage may change, but the pattern of having one 4.5-hour power outage and two 2.5-hour outages around morning, midday and evening is applied nationally.

Figure 9 shows that even with a comparatively thick outer skin, the freezing time is still unacceptably high—even when the thickness of the exterior surface is increased, the device still takes 2.5 times longer to freeze. Freezing time is directly proportional to thickness of PCM volume but lowering freezing time by reducing δ will also commensurately reduce melting time, adversely affecting another key usability criterion.

From Figure 8 and Figure 12, it can be observed that the volume changes (i.e., scaling) of the device do not change the melting and freezing time significantly—this applies for any rectangular prism or cube with equal thickness of PCM. The variable that changes the melting and freezing time is the volume of PCM; for the simplest conceptualization of the device, the thickness of PCM between the interior and exterior surfaces (Figure 10) affects these criteria.

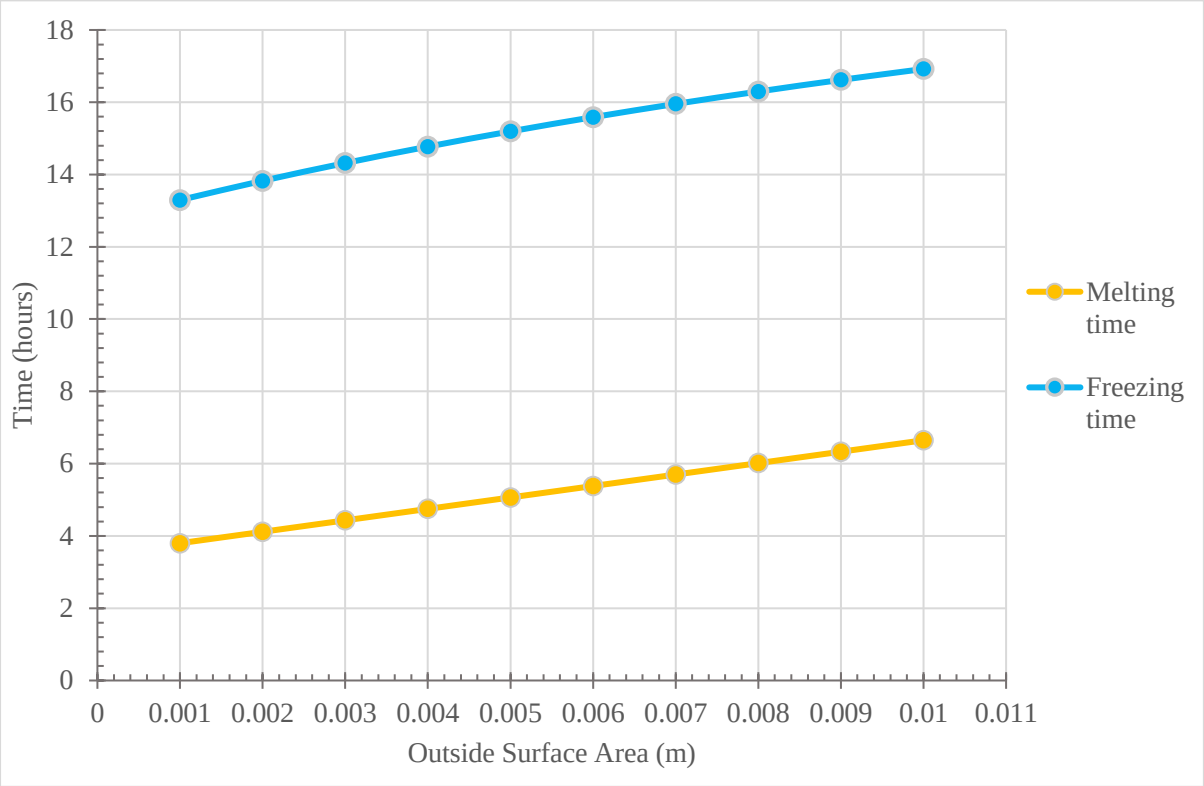

Figure 10 Melting and freezing times of varied PCM, assuming 1mm thickness of plastic surfaces

Reducing inner skin thickness would also reduce freezing time, but not by a significant enough amount to yield a viable design, because the limitations of convective heat transfer will still apply and so, the heat transfer through the inner skin cannot be increased by that large a factor through that modification. Moreover, decreasing the inner skin thickness to less than the 1mm thickness currently envisioned risks compromising its structural strength. Increasing the outer skin thickness much beyond the 1cm thickness that is the maximum value in Figure 9 is also not viable because it will drive up the cost of the unit and make it excessively bulky.

The fundamental reason for the difficulty in achieving both of these usability criteria resides in the respective driving forces for heat transfer during melting and freezing. During freezing, the temperature difference between the refrigerator interior and phase-change material at its freezing point is very small, as low as 2°C, resulting in a very small driving force for removing heat from the PCM. During melting, the temperature difference, and therefore the resulting driving force, is considerably larger.

Consequently, fundamental design revisions are required to meet all usability criteria. Modifications that would potentially improve the relationship between the melting time and freezing time are as follows:

1. Insulation on the outer skin to reduce the rate of energy loss and allow for a reduction in PCM volume to reduce freezing time without compromising on melting time. The limitation on this approach is the requirement for excess thermal capacity to withstand the heat incursions when opening and closing the container, but it has been found that it would be possible to decrease thermal capacity very significantly before that constraint becomes onerous. Consequently, this is a highly promising modification.
2. Higher surface area for the inner skin than for the outer. This would require the inclusion of heat transfer features such as fins to increase surface area. There are limitations to how many such heat exchange features can be included without occluding an unreasonable amount of the storage volume, so this modification must be considered in conjunction with others.
3. More conductive material for the inner skin. This modification unfortunately has only small scope for increasing overall conduction, because of the additional role of the convective barrier to heat transfer. Moreover, conductive materials tend to be more expensive than the proposed material of construction, so this has to be considered a modification with little promise.

3.6. Conclusion

It has been shown that a storage container utilizing C-14 paraffin as phase-change material is potentially feasible as a means of thermally stabilizing medications stored in a household refrigerator during power disruptions, as a sufficiently long melting time is achievable with reasonable design parameters. However, it has been found that an unreasonably long freezing time affects the usability of the proposed design and, consequently, design revisions are needed in order to meet the required usability criteria. It has also been shown that the main parameters of interest for usability are the thickness of the PCM layer and the heat transfer coefficients for the inner and outer skins respectively. It has been found that the inner skin heat transfer coefficient must be considerably higher than that of the outer skin in order to meet the usability criterion of freezing time being shorter than melting time. Once a revised design that meets the usability requirements is developed, prototyping and laboratory testing should be focused on determining those heat transfer coefficients and achieving values for those parameters that meet the specified usability criteria.

3.7. Acknowledgements

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Chapter 3

PRODUCT MODIFICATIONS AND SIMULATIONS OF DYNAMIC ENVIRONMENT

The problems of the initial design is mainly due to the difference in the driving force of heat transfer; for melting the temperature difference is for greater than for freezing, namely 14°C and 4°C, respectively (Figure 13).

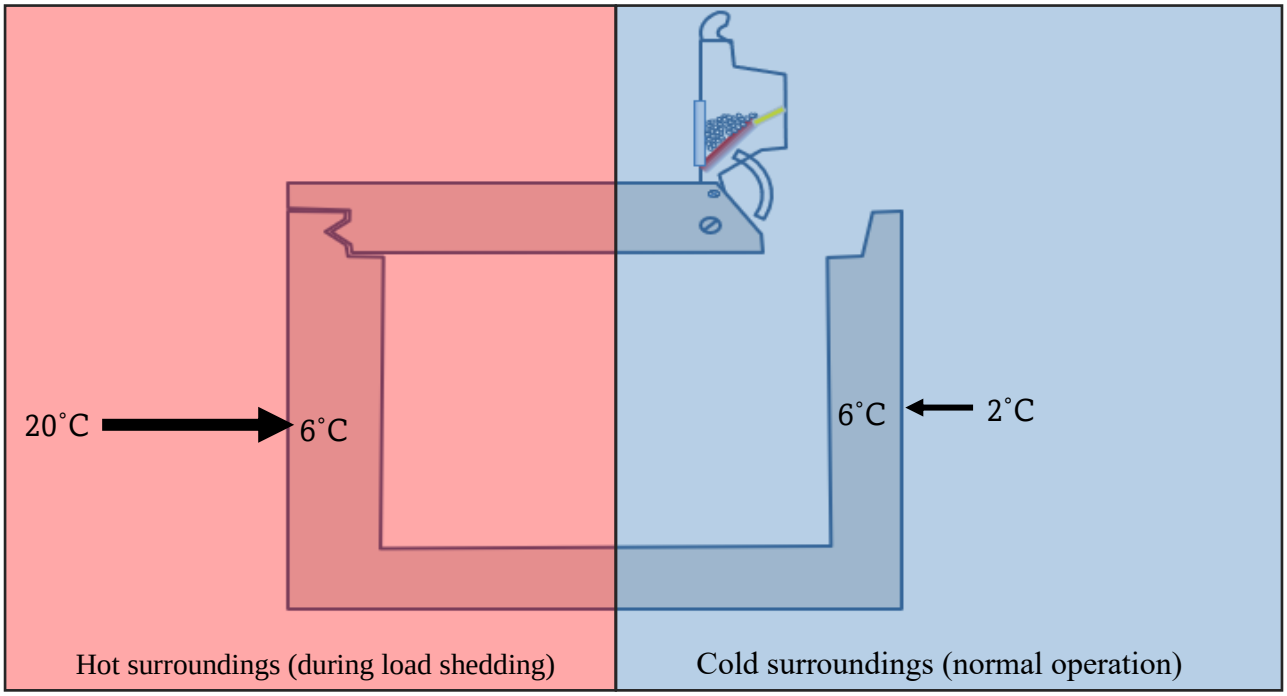

Figure 11 Driving force affecting device performance

As a consequence, it was found that the device's freezing time was unacceptably long, requiring patients to wait an inordinate amount of time before using their device, likely leading to poor patient compliance with intended usage. Moreover, in periods of frequent load shedding, a long freezing time might not permit the device to freeze properly during the periods in which electricity is available.

Hence, this chapter is devoted to redesigning the proposed device to better achieve its aim. To do this, a set of usability criteria must be defined and met in order for the design proposal to be considered successful. Design shortcomings could lead to use errors, from being non-intuitive

or difficult to learn and could result in the device failing. The three most important criteria for the device to be functional were identified:

1. Thermal capacity

Temperature control can be achieved using a material that absorbs or releases heat; this is to ensure that the device is not complicated nor requires electronics; therefore, is affordable to insulin users. An alternative to achieving the tight temperature range is via latent heat storage (LHS)—the heat transfer material maintains constant temperature as it undergoes phase change at a specific temperature. LHS by solid-liquid phase transition is particularly suitable because it provides a high storage density and will maintain steady temperatures during melting (charging) and solidification (discharging) (Sarbu & Dorca, 2018). Analogous to a battery, the device must have sufficient thermal capacity to last through a typical load shedding period. The most common load shedding scheduled is stage 2—which means that the most common power outage within a 24-hour period lasts two and a half hours, twice daily (Eskom Distribution, 2022). However, recently stage 4 load shedding—three power outages lasting two and a half hours daily—has been implemented more frequently.

2. Melting time

The storage device must have adequate thermal inertia to resist temperature increase during load shedding. The load shedding data presented in Figure 1 shows stage 2 load shedding is most common. The load shedding stages are cumulative—each successive stage adds a two-and-a-half-hour slot within the 24-hour period. This means that the device must at least withstand over two hours of temperature increase within the refrigerator.

3. Freezing Time

Assuming the phase change material melts over the duration of the load shedding slot, the device needs to be able to refreeze in order to meet the thermal constraints for the following load shedding period. Once the temperature failure has occurred, the device should be able cool quickly thereafter when electrical supply returns—the device should not trap insulin at a heat beyond 8°C for an extended period. A material used for its properties in latent heat transfer while the environment is heating up will also require time to cool down.

4. Modifications

4.1. Strategy 1: Exterior insulation

Implementing insulation on the exterior of the device is the most promising modification—this can be achieved in two different ways:

1. Use a material with low thermal conductivity on the exterior of the device
2. Enclose a layer of air (which has low thermal conductivity) between the two layers of exterior plastic.

The latter modification has the benefit of being easier to implement during the manufacturing process, since it uses the same material of construction and is only a modification to the moulding process. The former requires more design modifications to adhere an insulating material to the exterior surface and requires another source of material—which will increase the cost of manufacturing.

This modification changes *Equation 5* to *Equation 14*

$$U_{inner\ skin} = \frac{1}{\left(\frac{d_{inner\ skin}}{k_{inner\ skin}} + \frac{1}{h_{air}}\right)}$$

$$U_{outer\ skin} = \frac{1}{\left(\frac{d_{outer\ skin}}{k_{outer\ skin}} + \frac{1}{h_{air}}\right)}$$

Equation *5*

$$U_{outer\ skin} = \frac{1}{\left(\frac{d_{mid\ skin}}{k_{mid\ skin}} + \frac{1}{h_{air}} + \frac{d_{insulating\ air}}{k_{air}} + \frac{1}{h_{air}} + \frac{d_{outer\ skin}}{k_{outer\ skin}} + \frac{1}{h_{air}}\right)}$$

Equation 14

Compared to the design with no exterior insulation the device performs more in line with the desired usability requirements. Table 6 compares the performance of the original (uninsulated) design with the modified (insulated with a layer of air between an additional layer of plastic on the exterior). The device's melting time is improved considerably—an insulated device takes approximately four times as long to melt. Although the freezing time is also increased (Figure 12) because heat is not as readily transferred out the exterior surface through the insulation, the ratio of freezing to melting time is improved.

Table 6 Performance comparison of insulated versus uninsulated device

Averaged values for devices	Insulated	Uninsulated
Freeze to melt ratio	1.4	3.5
Melting time (hours)	14.2	3.6
Freezing time (hours)	20.1	12.5

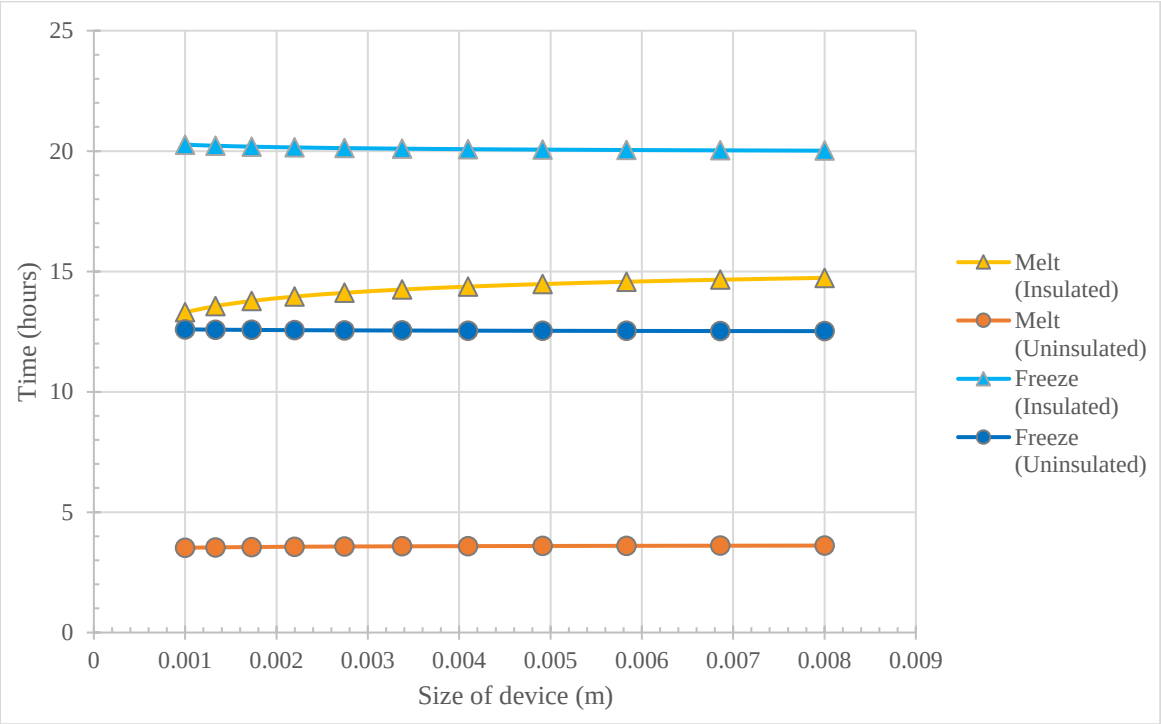

Figure 12 Comparison of an insulated devices and uninsulated devices assuming 0.005m of PCM, 0.001m of plastic between each layer

The thickness of the insulating air will affect the melting time; within the model, it is assumed that no convection occurs within the insulating air. However, in reality, an insulating layer that is too thick will decrease the melting time. This is because convection can occur within the insulating air and should be a design consideration.

4.2. Strategy 2: Increased Interior Surface Area

Increasing the surface area permits faster heat exchange during freezing, when the device is open (**Error! Reference source not found.**: Figure 3). Changes in the ratio of surface area can b e achieved with geometric modifications such as extended heat transfer surfaces. Ideally, the freezing time should be shorter than the melting time—this means the ratio of freezing to melting should be lowered. However, changes to the internal surface area changes the PCM

volume. Additionally, there are limitations to how much the surface area can be increased without affecting the functionality of the device.

Although a thicker PCM layer permits a longer melting time, Figure 10 shows that the rate of freezing is greater than the rate of melting, so for a thicker layer PCM, more heat transfer features need to be included since the ratio of total surface area to volume of PCM is smaller. Thus, the appropriate thickness of PCM should be approximated. Refining the design requires the device to protect the medication for periods of load shedding. Since stage 4 load shedding has been implemented more frequently the model must show that the device can keep the medication cool during load shedding times. During stage 4 load shedding, power outages last 2.5 hours (Eskom Distribution, 2022), so the device must have a melting time that at least matches or exceeds the duration. To allow for contingencies, around 4 hours melting time is chosen; this corresponds with 0.6 cm of PCM.

Table 7 shows the freezing and melting ratios and the respective surface area needed to achieve the desired freezing time. In order to achieve a freezing to melting ratio of 1 (i.e., the device takes equally long to melt and freeze) the internal surface area must be sixfold the surface area of the exterior. However, there is a limit to the geometric changes that can achieve the required ratio and correct PCM volume. A larger PCM volume has a higher thermal capacity but requires a greater surface area to achieve a low melting time. Thus, combining the modifications should produce a feasible design.

Table 7 Required surface area ratio for different freeze-to-melt ratios

Average Freezing time (hours)	***Average Melting time (hours)***	***Freeze to Melt Ratio***	***Required Surface Area Ratio***
3.9	3.9	1.0	6.0
2.0	3.9	0.5	13.0
1.2	3.9	0.3	22.3
0.8	3.9	0.2	33.8
0.4	3.9	0.1	68.4

4.3. Strategy 3: Combined modifications

To find a reasonable design that combines both modifications, firstly, an adequate melting time must be found—this depends on the exterior insulation and PCM volume. Then, in order decrease the freezing time, increasing the interior surface area decreases the freeze-to-melt ratio.

Previously, it was noted that the insulating layer of air cannot be too thick; this would allow for convection to occur within the layers of plastic—increasing heat transfer from the fridge interior during loadshedding and decreasing the melting time. However, the air gap thickness must be of a reasonable value so as not to make manufacturing challenging. A practical insulation thickness is approximately 0.005m—this insulation thickness is chosen because manufacturing a thinner layer of insulation is more difficult. The approximate PCM thickness to achieve a reasonable melting time is between 0.001m and 0.002m.

Table 8 Determining the PCM thickness and air/insulation thickness to protect through stage 4 load shedding

PCM Thickness (m)	***0.001***	***0.0015***	***0.002***	***0.003***
Insulating Air Thickness (m)	Average Melting Time (hours)			
0.001	3.09	4.62	6.14	9.14
0.002	3.05	4.55	6.05	9.01
0.003	3.00	4.49	5.96	8.88
0.004	2.96	4.42	5.88	8.75
0.005	2.92	4.36	5.79	8.62
0.006	2.87	4.29	5.71	8.49
0.007	2.83	4.23	5.62	8.37

We can then assume that the inner surface area can be increased by some geometric manipulation for increased heat transfer. The inner area of the possible box dimensions between 0.1m–0.2cm is multiplied by a constant to achieve a desirable freezing time and yields the results listed in Table 9:

Table 9 Averaged surface area and freezing time for a cubic device with dimensions between 10cm–20cm

Multiple	***Averaged Surface Area Ratio***	***Average Melting Time (hours)***	***Average Freezing Time (hours)***	***Freeze to Melt Ratio***
1	0.87	4.36	5.93	1.36
2	1.74	4.36	3.29	0.75
3	2.62	4.36	2.27	0.52
4	3.49	4.36	1.74	0.40
5	4.36	4.36	1.41	0.32
6	5.23	4.36	1.18	0.27
7	6.10	4.36	1.02	0.23
8	6.97	4.36	0.89	0.21
9	7.85	4.36	0.80	0.18
10	8.72	4.36	0.72	0.17

The following trend emerges (see Figure 15):

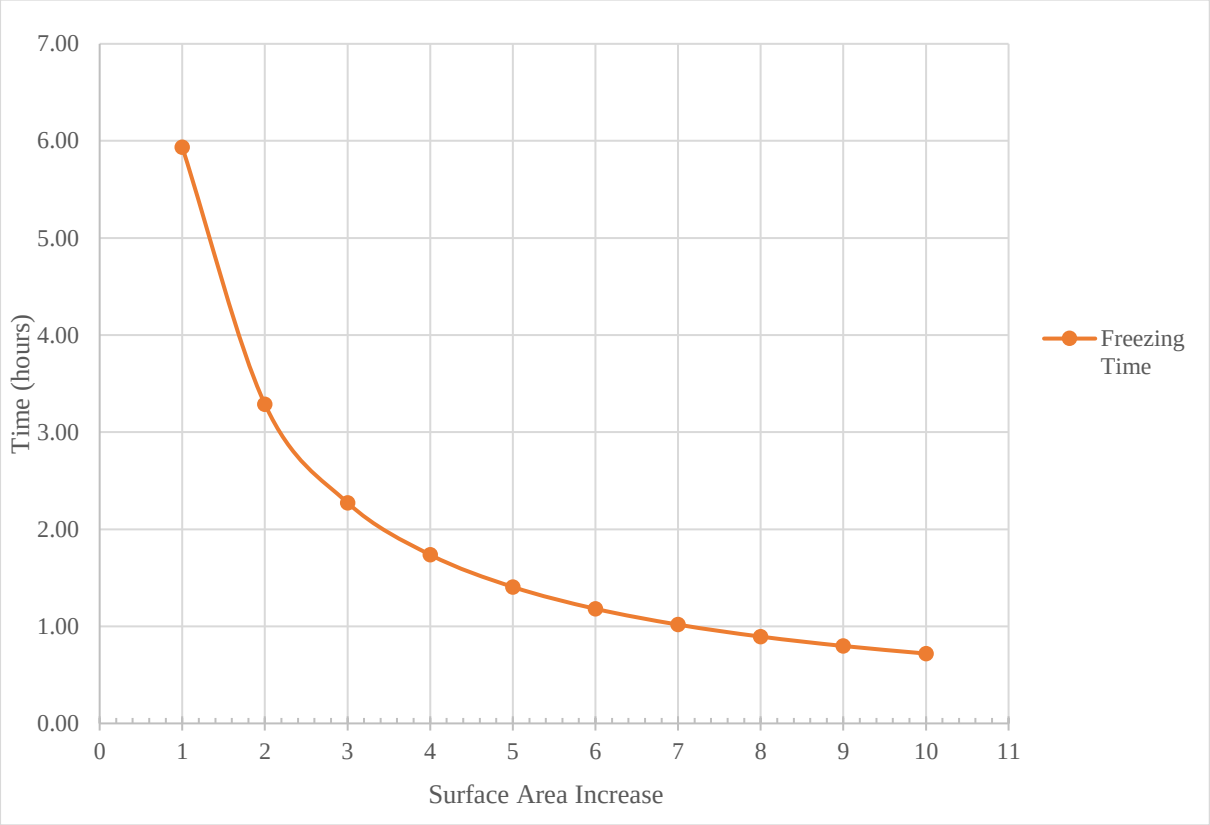

Figure 13 Relationship between surface area and freezing time

This exponential decrease shows that it is unnecessary to increase the inner surface beyond sevenfold of the outer surface area; the benefit of increasing the surface area decreases beyond this point and hour and 10 minutes (1.18 hours) of freezing time is a reasonable freezing time for the device to reach the desired temperature. Furthermore, the device would be more difficult and expensive to manufacture with a larger surface area.

To achieve this surface area ratio the interior of the device needs to have modifications that extend the inner surface area—akin to fins—for better heat transfer during freezing. The design can be achieved by creating a grid-like compartments extending the interior surface area in the device that hold insulin vials. This grid-like configuration must enclose a layer of PCM for heat transfer—Figures 15 and 16 show this modification.

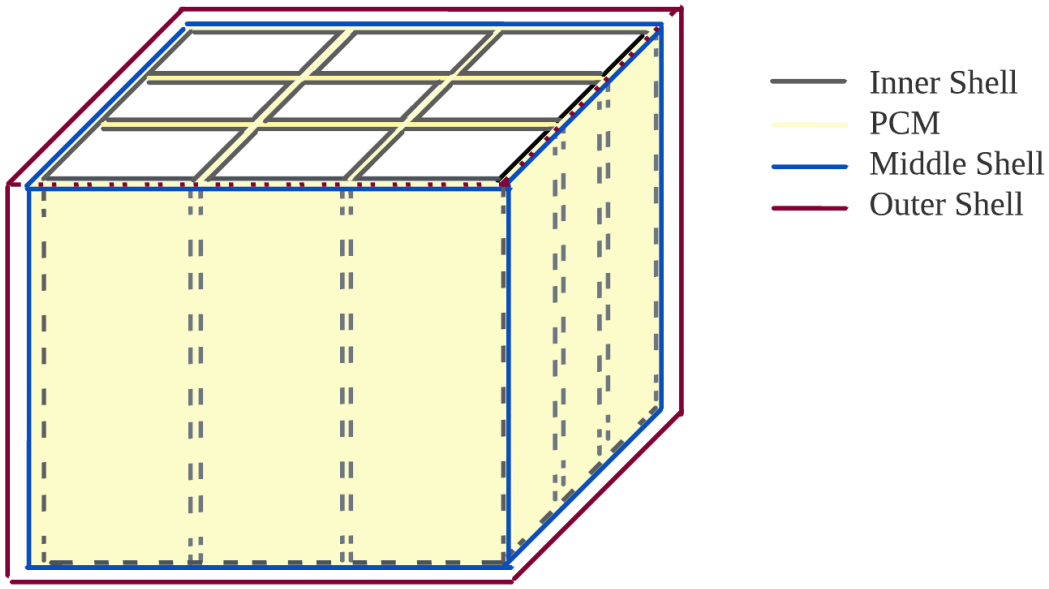

Figure 14 Simplified diagram of device with increased inner surface area

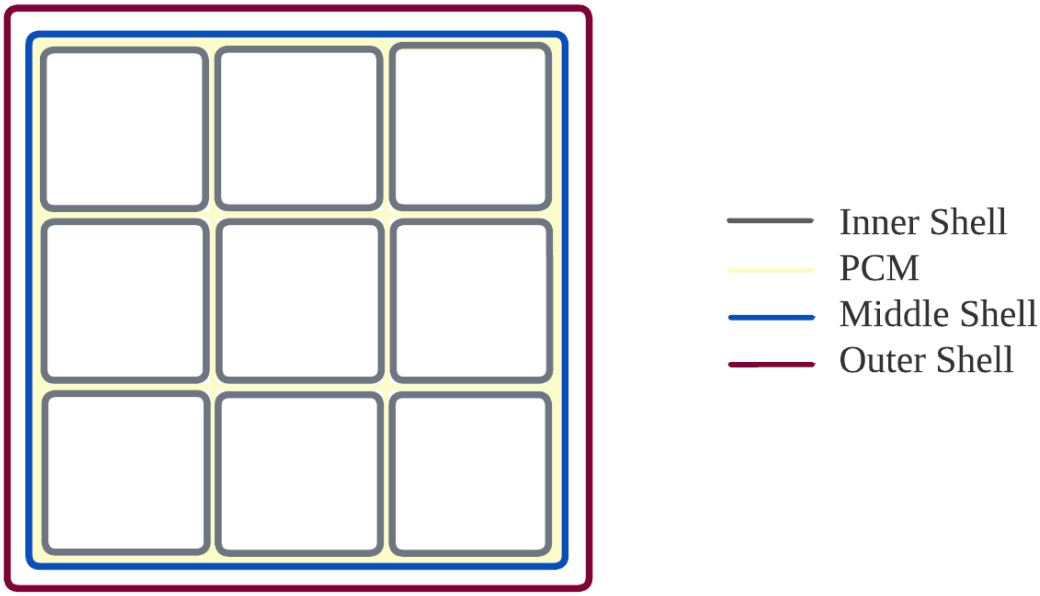

Figure 15 Simplified top view of device

The following table shows the calculation for the surface area ratio that is achieved by inserting a grid like structure containing PMC within the device. The surface area ratio between the inner and outer area can be approximated.

- Assume the device is a cube with inner dimensions of *x* cm (ranging from 15cm to 20cm).
- Assume the device outer shell consists of 6 square panels forming a cube and the inner shell is formed with 6 slightly smaller panels (because the thickness of the insulating air and middle shell is negligible compared to the dimensions of the device).
- The grid is formed by 4 panels containing PCM with the same dimensions as the inner shell.

Table 10 Calculation for increased surface area for inserting a grid within the device

Dimension of cube (cm)	x
External surface area of device (cm^2)	$6x^2$
Number of fins	*4*
Number of exposed inner surfaces = Inner surface of cube + (Number of fins × Number of exposed surfaces of 1 fin)	$6+(4\times2) = 14$
Internal surface area (cm^2) = Number of internal surfaces exposed × Area of inner surface	$[6+(4\times2)] \times x^2 = 14x^2$
Inner: Outer Surface Area Grid Ratio	$14x^2 / 6x^2 = 2.333$

This grid-like configuration achieves an approximate surface ratio of 2.33, but a ratio of 6 has been targeted to facilitate heat transfer for the device's PCM to freeze in approximately an hour.

Thus, to further increase the surface area, the interior must have a modified surface to further increase the surface area ratio. The geometry of the surface of the "fins" can be modified to achieve this—instead of flat "fins" the surface can be moulded (the shells are made of thermoplastic) in a corrugated shape to increase the area of each fin (see Figure 18). In order to achieve a model this "corrugated" surface, equation 15 is used. A corrugated surface can be approximated by a sinusoid, where A is amplitude and B is the period.

$$y = A\sin(Bx)$$

Equation 15

However, there are limitations in implementing this design; the pattern cannot be too small and tightly packed (see Figure 16) since this will impede airflow and heat transfer out of the PMC during freezing. This means the amplitude (i.e., the height of corrugations) cannot be too big and the period (i.e., length of corrugations) cannot be too small—even if this yields a higher inner surface area.

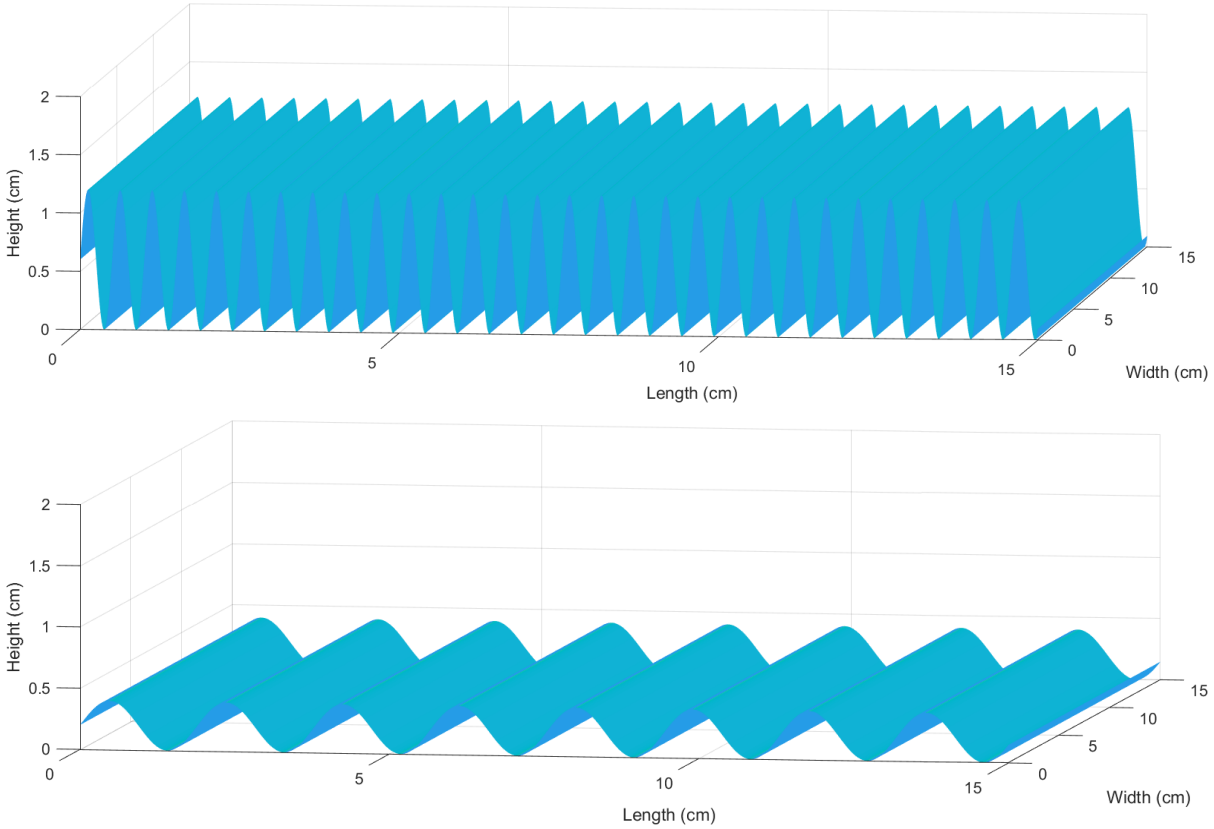

Figure 16 Corrugated modified inner surface with a large amplitude relative and small period (top) vs inner surface with small amplitude and large period (bottom)

The area of one exposed interior surface can be found by finding the arclength multiplied by the width of a dimension on the inner shell:

Equation 16

$$r = \int_0^{inner\ length} \sqrt{1 + \left(\frac{dy}{dx}\right)^2}\, dx$$

Equation 17

$$Area\ of\ one\ exposed\ inner\ surface = Inner\ width \times r$$

The overall interior surface area can be calculated by multiplying the width of the inner shell of the device and the number of exposed inner surfaces. This inner surface area is compared to the external surface area; to achieve a freezing time of approximately one hour, the inner area must be sixfold the outer area.

The proposed device's dimensions range from within 10cm×10cm×10cm to 20cm×20cm×20cm. The final form and dimensions of the final product will depend on customer preference, which can be found by marketing teams once it determined that the device can sufficiently meet the usability criteria. Geometrically complex designs may also result in manufacturing challenges, particularly in detaching finished boxes from manufacturing moulds. However, corrugation on a single axis is unlikely to pose stringent manufacturing constraints. If additional surface area increase is needed, it would be possible to corrugate on another axis as well, resulting in an "egg-carton" type dimpled shape—an example of this surface and its equation is attached in Appendix C. This would, however, make moulding more difficult and might necessitate 3D printing, a more costly method of manufacture.

At this stage, the approximate design features that facilitate adequate heat transfer must be found. The amplitude and period that achieve a surface area of 6.03 are 0.825cm and 1.25cm, respectively. The steps for finding the values are attached in Appendix C. Figure 17 and Figure 18 show how the surface looks and the scale of the surface in a 15cm × 15cm × 15cm space. The following table shows the inner to outer surface area ratios when the corrugation with these values is applied:

Inner dimensions (cm)	*Inner: Outer Surface Area Ratios*
10	5.712
11	5.803
12	5.881
13	5.948
14	6.006
15	6.058
16	6.103
17	6.144

18	6.180
19	6.213
20	6.242
Average:	6.027

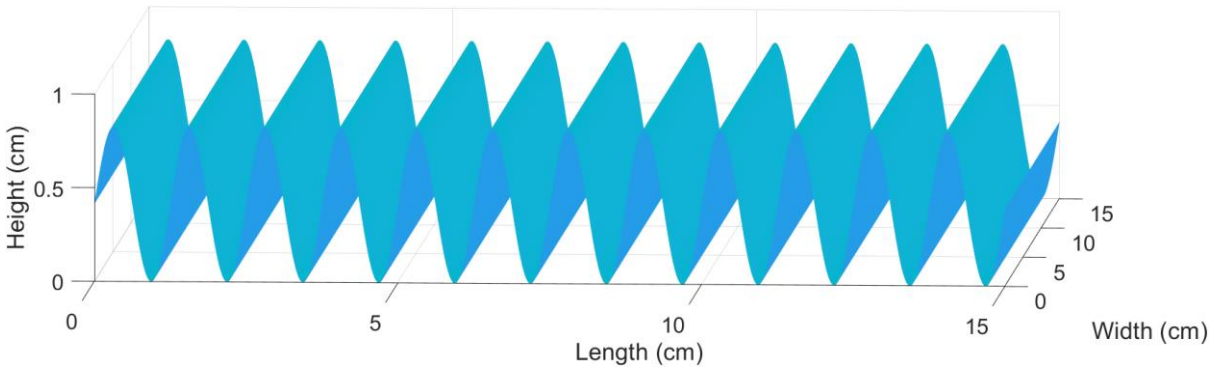

Figure 17 Example of the corrugated surface with amplitude of 0.825cm and period of 1.25cm in a 15cm device

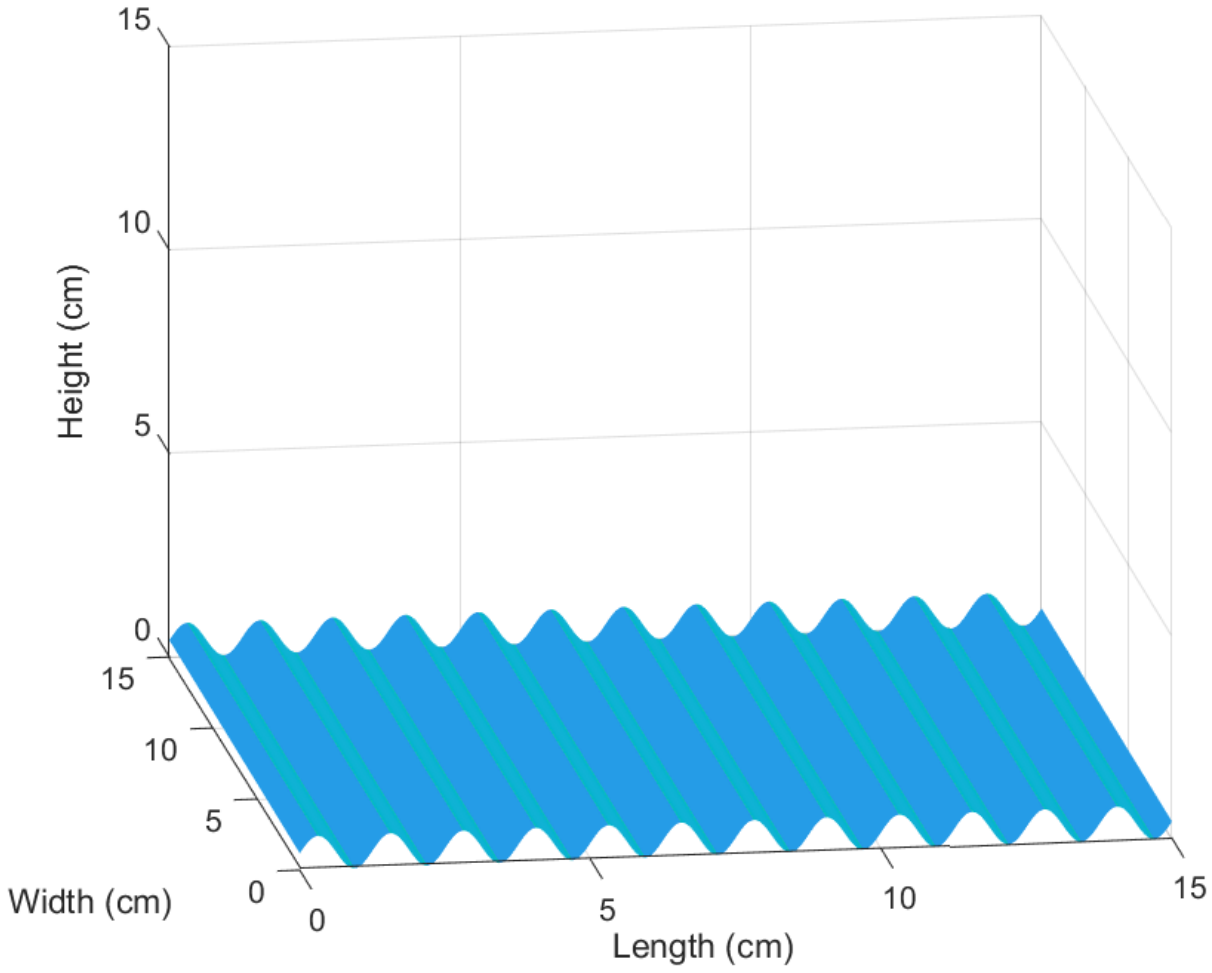

Figure 18 Scaled example of inner surface area in a 15cm × 15cm × 15cm space

Thus, the device has met the usability criteria for the most onerous conditions—all the air is exchanged with ambient temperature air once a user has opened the fridge and has reached a steady state temperature of 20°C. The design and its respective performance are summarised as follows:

Table 11 Summary of design parameters

Performance summary	***Value***	***Units***
Melting time	4.36	hours
Freezing time	1.18	hours
PCM Thickness	0.0015	m
Insulating Air Thickness	0.005	m
Outer Plastic Shell Thickness	0.001	m
Middle Plastic Shell Thickness	0.001	m
Inner Plastic Shell Thickness	0.001	m
Averaged Surface Area Ratio (Inner:Outer)	6.00	-

5. Dynamic model

For this section, one of the simplifying assumptions applied to the model will be removed to simulate realistic conditions. Previously, the assumption that the interior space of the fridge has rapidly reached 20°C after the user has opened the fridge was applied. The ambient temperature is needed for when the user opens the fridge. A simple temperature profile model that generates daily temperatures from 2 inputs—the midnight temperature and daily temperature difference—is introduced as a tool for determining the temperature of the air that enters the fridge when a user opens the fridge during load shedding.

During a power outage, the interior temperature of the fridge decreases. However, this system is also highly unpredictable and influenced by multiple aspects. For example, if a person has many food items in the fridge the temperature will decrease slowly, because the fridge space will have greater thermal inertia; food will have a higher heat capacity than air from high water content and acts as a temperature ballast. As discussed in the assumptions section, opening the fridge will have the greatest effect on fridge temperature—however, when a user decides to open the fridge is a highly unpredictable event. the devices' performance under steady state is reliable, however, the behaviour of the device under somewhat random and the most onerous circumstances must be tested to ensure the device functions under more realistic conditions.

The correct and intended usage of the device are summarised in the steps below:

1. Place the device within the fridge with the top open.

2. Place temperature sensitive medication/insulin inside the device, when the visual indicator is set with the beads locked by solid PCM (this shows that the device has cooled and will keep the medication within range for several hours).
3. Close the device. The device should keep temperatures more stable and within the medication manufacturers recommendations if a power outage occurs
4. If temperature failure has occurred (beyond load shedding or expected power outage hours), the visual indicator will show beads in a different position, in this case, user should remove medication, use with caution, or preferably, discard for health and safety reasons.
5. The user may reuse the device by repeating the steps.

The following scenarios will include the temperature profiles within the fridge, the behaviour of the device when used correctly, and when user error has occurred. User error will likely occur in two ways:

- Case 1:

  The user does not place the device in the fridge with the top open (error in step 1). The inner surface area is not exposed to facilitate heat transfer out of the ambient temperature PCM. This means the device will take very long to freeze/reach the ideal temperature range for medication protection because the device is designed specifically to insulate from temperatures on the outside surface area, whilst the inner surface area is increased to facilitate PCM freezing.
- Case 2:

  The user forgets to close the device (error step 3). The inside of device is simply exposed to the temperature within the fridge, so if the fridge heats up via power outage or opening and closing, the inside of the device will be at a similar temperature. In this case there is not much difference between storing the medication within the device and storing it in the fridge.

Four scenarios will be examined; each scenario presents more onerous conditions than the previous case (Appendix D contains the MatLab code used to generate the graphs in the following sections).

5.1. Scenario 1: Refrigerator operating without power outages

A household refrigerator's thermostat should be set at 4°C for food safety and will fluctuate around the setpoint—the temperature is normally distributed around the setpoint (James & Evans, 1992; Krämer, et al., 2019). For example, a fridge that is not opened might exhibit the following random behaviour within 24 hours:

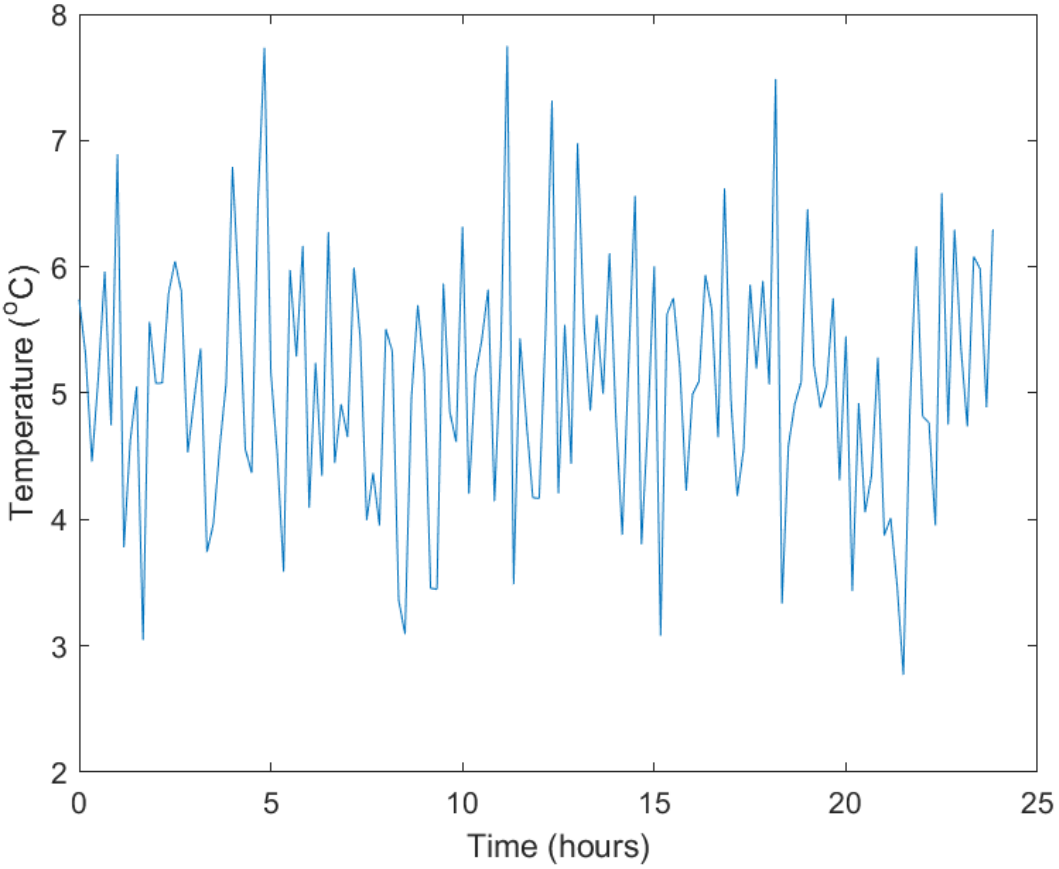

Figure 19 Simulated temperatures for a fridge with setpoint of 5°C, with 10-minute intervals, in a 24-hour period

The distribution of temperatures of this temperature profile is as follows:

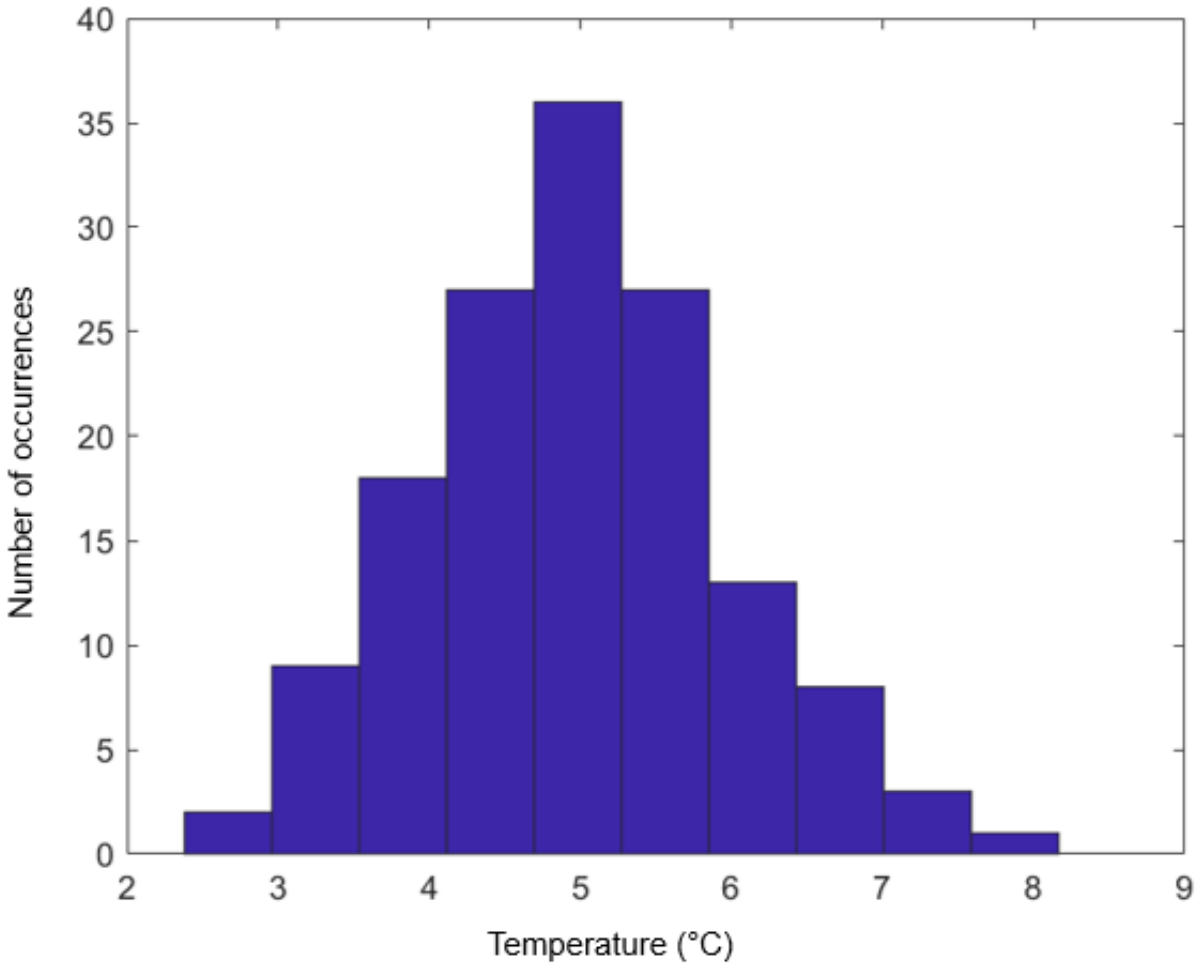

Figure 20 Distribution of temperatures in a fridge with no power outages

The device, if used correctly, should be placed with the top open within the fridge to cool and set. The usability criteria require that the device cool down within 1 to 2 hours. The actual time it will take for the device to set will vary in different fridges, but the maximum time for a usable design should be less than 2 to 3 hours. In different scenarios, the freezing time will vary between simulations since the fridge temperatures numbers are generated randomly but still fall within a bandwidth around the setpoint. The proposed device responds in the following manner for this simulated environment:

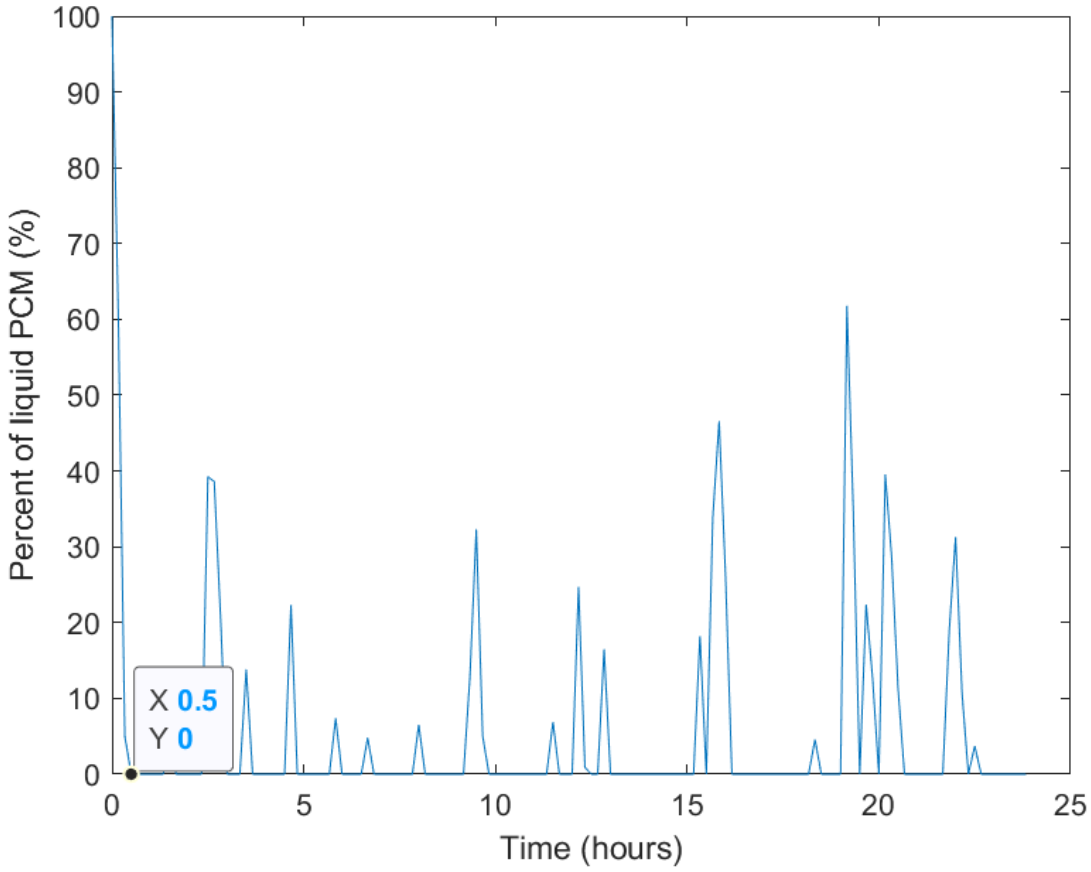

Figure 21 User error case 1: Device is left open in fridge

However, this shows only that the user has put the device into the fridge to freeze, without closing, which is why there are peaks indicating that the device is partially melting.

It is important to note that each of the following graphs analysing the scenarios will start with the PCM in liquid form and is placed in at time 0:00. This does not necessarily mean that the user places the device in at midnight, but it is included to indicate how long the device takes to set. This means the user could have placed the device to set the day before, and the PCM would be cooled and solid at 0:00, but have the same behaviour when temperatures increase in the fridge, the following day.

Assuming the user closes the device after it is frozen, the device responds accordingly:

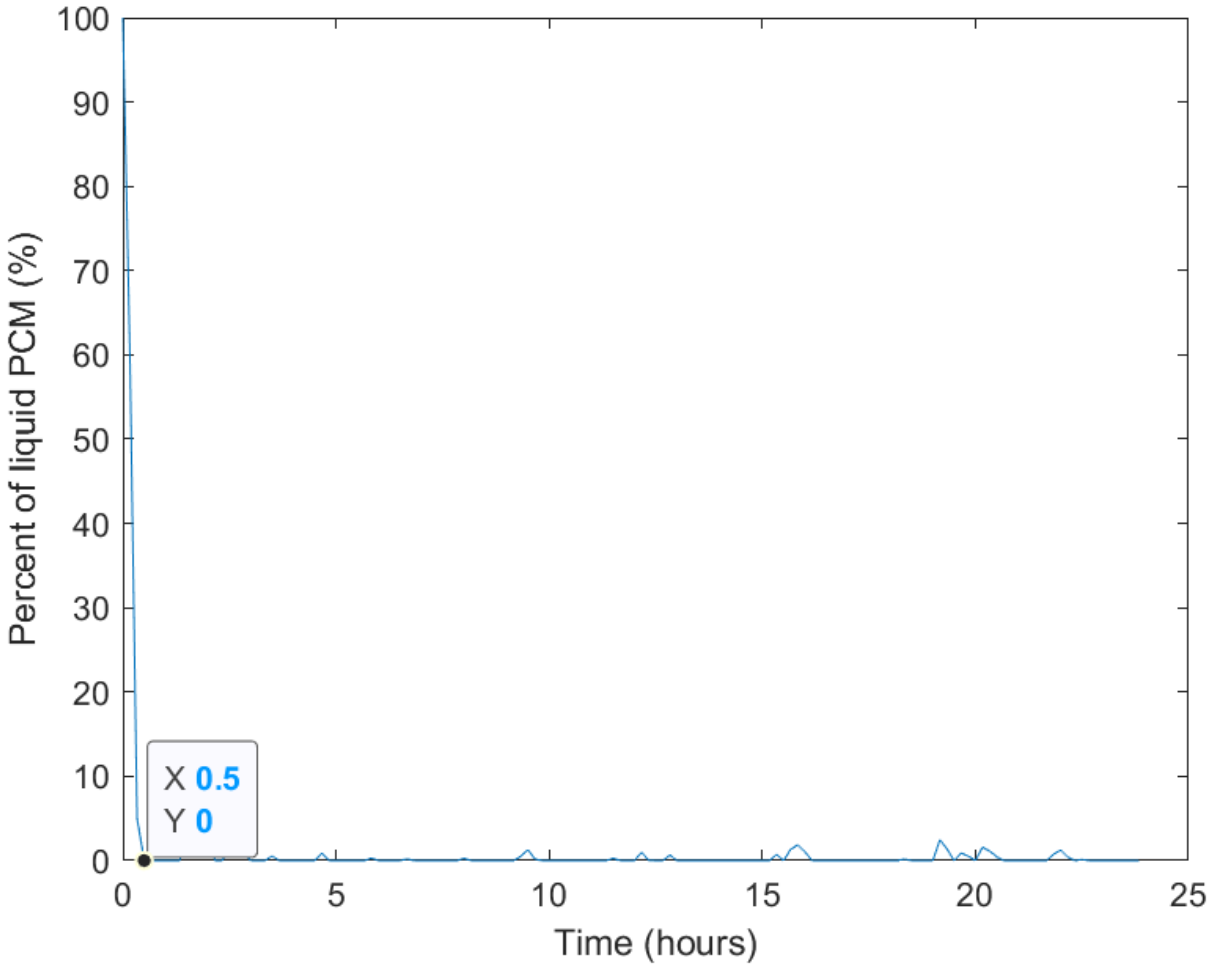

Figure 22 Simulation of correct device usage

Figure 22 shows that the device barely melts once closed, thus keeping the temperature stable once the device has been closed.

However, to compare the scenario where user error has occurred and they have placed the box in the closed position while the PCM still needs to cool and set, the rate of heat transfer is drastically reduced, and the device takes much longer to set to the required temperature:

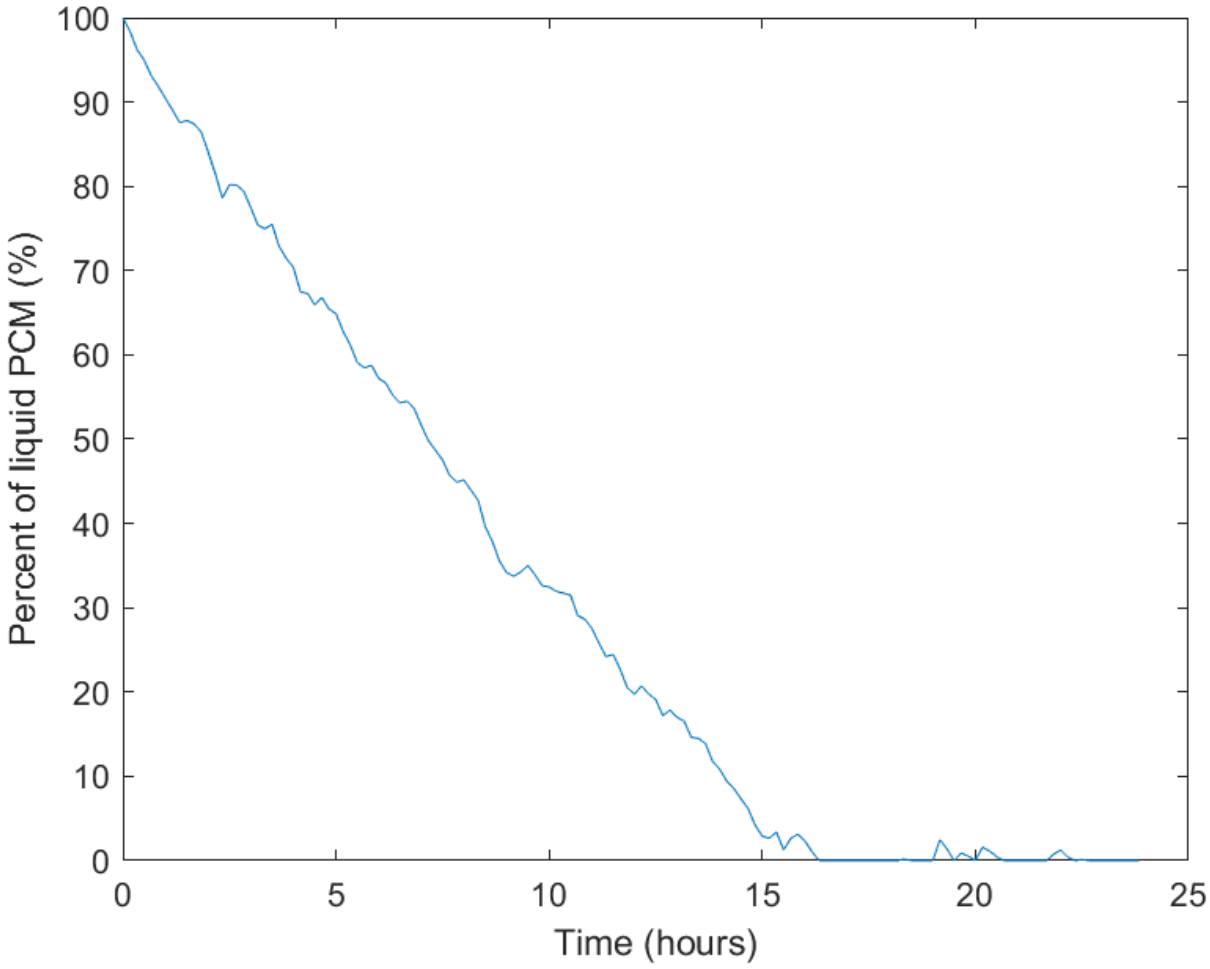

Figure 23 User error case 2: Simulated behaviour of the closed device placed within the refrigerator

Whilst generating random temperatures in certain cases temperature spikes can occur before closing the device (Appendix D, Scenario 1: Figure 49). This causes a portion of the PCM to melt when the device is closed, the remaining fraction liquid PCM takes long to freeze when the device is closed (Figure 24). This indicative of a potential shortcoming. This behaviour is also likely to occur during usage because users opening the fridge will cause temperature spike and the scenarios 3 and 4 intentionally simulate this temperature spike. As such, more PCM in the body of the device may be needed for testing other scenarios or to rectify circumstances where the PCM melts fully during temperature spikes. However, as long as a the PCM is not completely melted temperature failure will not occur inside the device—for this scenario the device is able prevent temperature failures when tested in number of random temperature simulations.

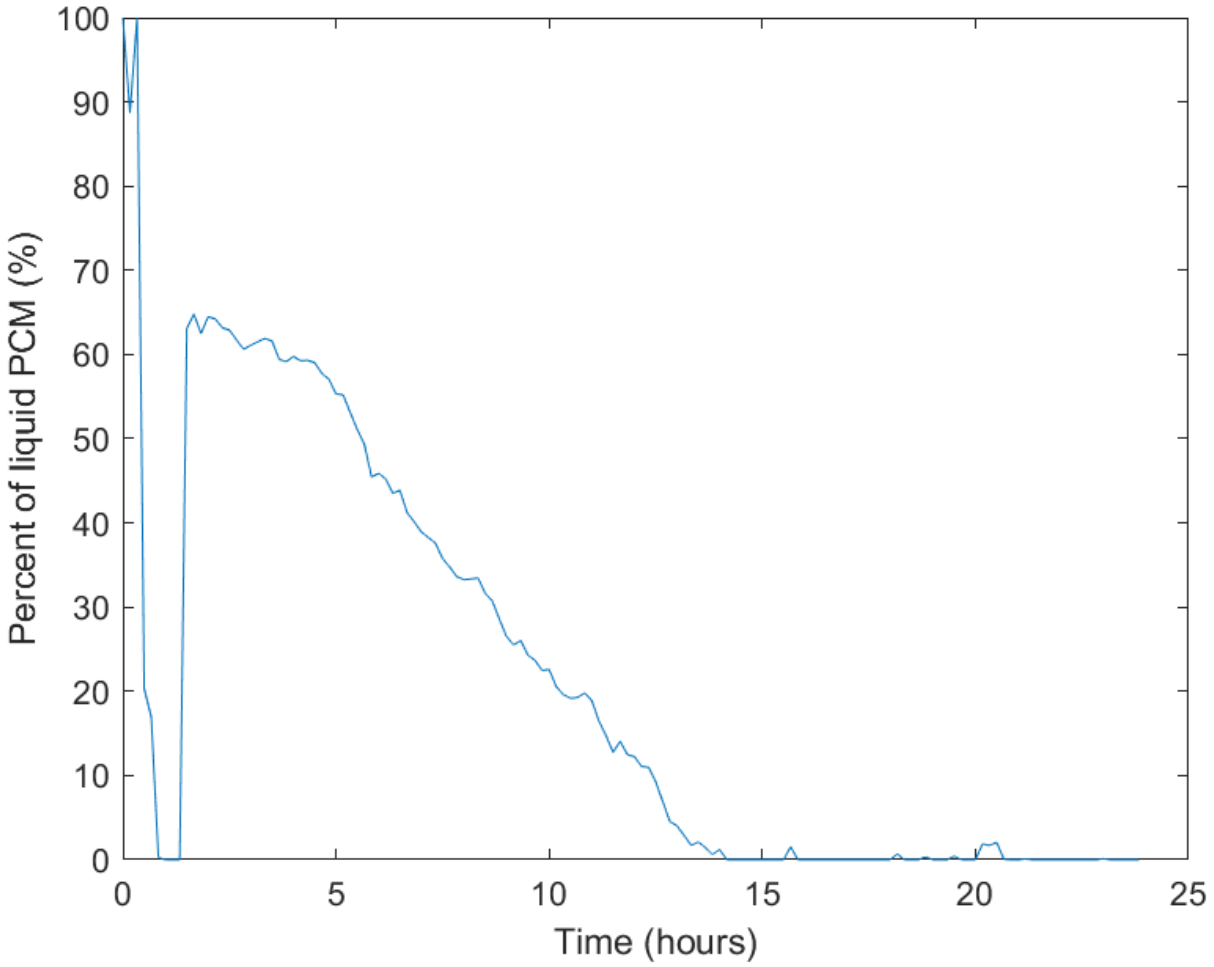

Figure 24 Example of the device melting from a random temperature spike before closing the device—related temperature condition graphs attached in Appendix D

5.2. Scenario 2: Normal operation with opening and closing events

However, scenario 1 does not include the temperature spike that would occur during opening and closing the fridge. When a user opens the fridge, air is exchanged and the temperature rises quickly to the ambient temperature, then returns slowly down (Laguerre, et al., 2002)—controls within the fridge bring the new air down to the setpoint—additionally, heat from the new exchanged air interacts with fridge contents. This behaviour is similar to a triangular pulse with left skewedness. The gradient of the temperature profile as temperature returns down is unpredictable, since this depends on the stored food content, type, and age of the fridge.

A daily temperature profile is simulated and used in this chapter to generate the daily ambient temperature profile so that temperatures during the different temperatures of the day can be used for opening and closing events.

Daily Temperature Profile:

The daily ambient temperature can be created using a function to generate a temperature profile; a 6th order polynomial was fit with historical climate data. Historical climate data shows the shape of the temperature profile does not change much throughout the year—daily average temperatures only shift the profile vertically from season to season.

The parameters were fitted in a climate (around Johannesburg) with a day-night variance of 12 (i.e., the day-night temperature difference for the fitted data was 12°C), hence 12 being the baseline for amplitude (de Visser & Dijkxhoorn, 2012; Meteoblue, 2022). Thus, the amplitude (T_{max} - T_{min}) between the highest and lowest temperature is a required input to scale the temperature profile. The model creates a temperature profile starting from midnight (t=0), at a certain temperature ($T_{midnight}$)—these are the additional inputs required for generating the daily temperature profile.

Using fitted parameters, the shape of the day-night temperature can be represented by the following equation, where *a'*, *b'*, *c'*, *d'*, *e'*, *f'* are coefficients of the polynomial, with values attached within Appendix C.

$$\boldsymbol{T_{Profile} = \frac{T_{max} - T_{min}}{12}\left(a'x^6 + b'x^5 + c'x^4 + d'x^3 + e'x^2 + f'x\right) + T_{midnight}}$$

Equation 18

Figure 25 shows a comparison of the simulated day and averaged hourly temperatures in January.

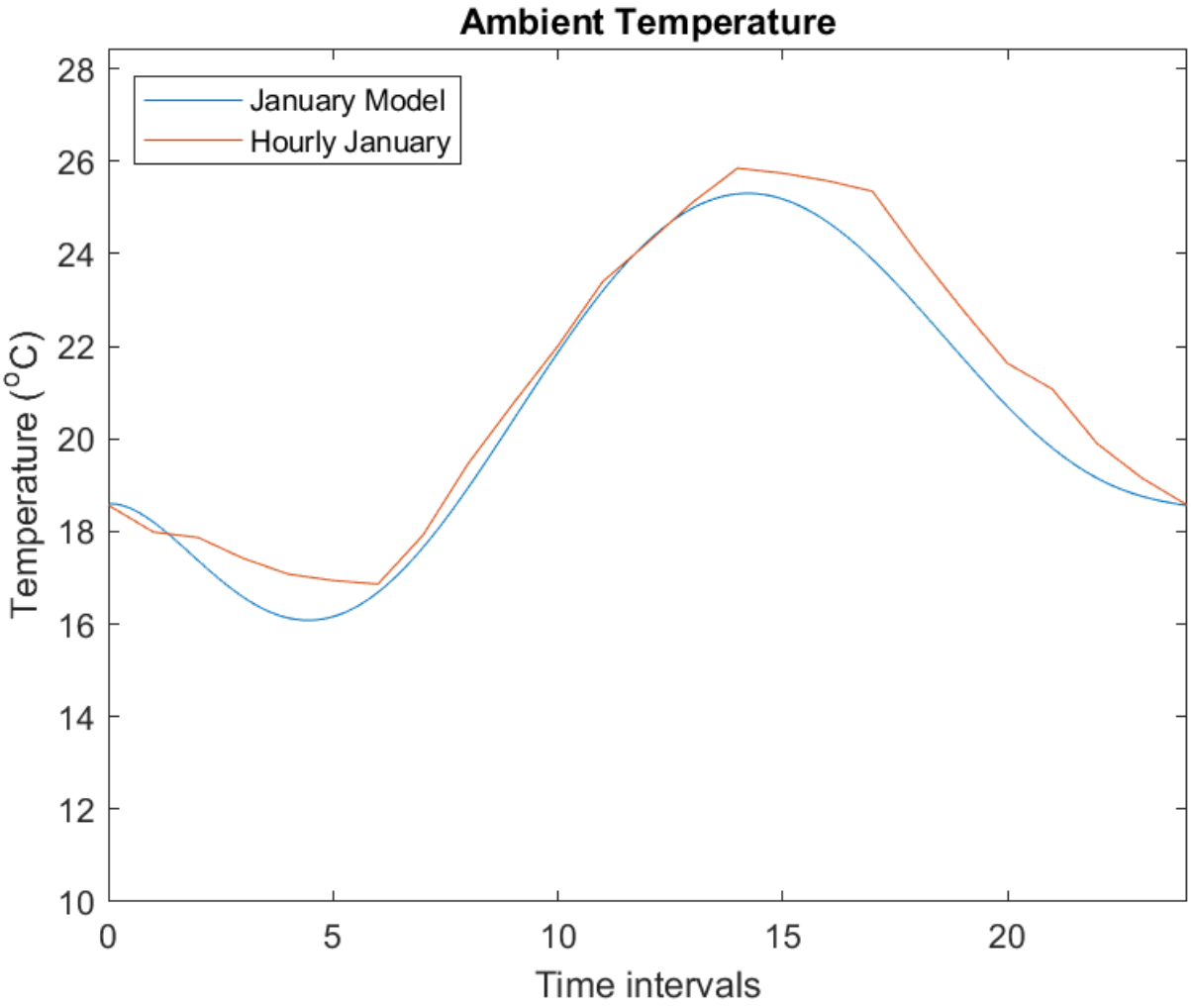

Figure 25 Daily temperature profile for a summer day

Several simplifying assumptions are made:

- The user opens the fridge in the morning (6:00), midday (12:00) and in the evening (17:00)
- The fridge takes 1 hour to equilibrate back to the set point temperature after opening—typical values for a partially loaded fridge that has been opened for 5 minutes takes approximately 60 minutes return down to the setpoint (James, et al., 2016). This assumption will be used for other scenarios—for mealtime fridge opening, a person may open the fridge for a longer time to retrieve food.
- All the contents of the fridge heat to ambient temperature during the opening. This assumption is made because it is impossible to determine the amount of food a given user will store at a particular time nor the heat capacity of the various foods within a fridge. However, most perishable foods stored in a fridge will have at least 50% water (Popkin, et al., 2010), which means it will have a higher heat capacity than what is

assumed and will not heat to ambient temperatures immediately. To account for uncertainty around the different food items are stored, the worst-case scenario where all the food is heated quickly to ambient temperature and gradually brought down is used to test the device. Compensating for these uncertainties is necessary because device must be able to withstand the most onerous conditions—standards for storing medication should be stringent—and the user's consumer and food storage patterns cannot be influenced, so if a user were to have a relatively empty and old fridge, the device must withstand similar conditions. Although this assumption seems unrealistic, this process also guarantees that the device will work in more average/normal fridge conditions.

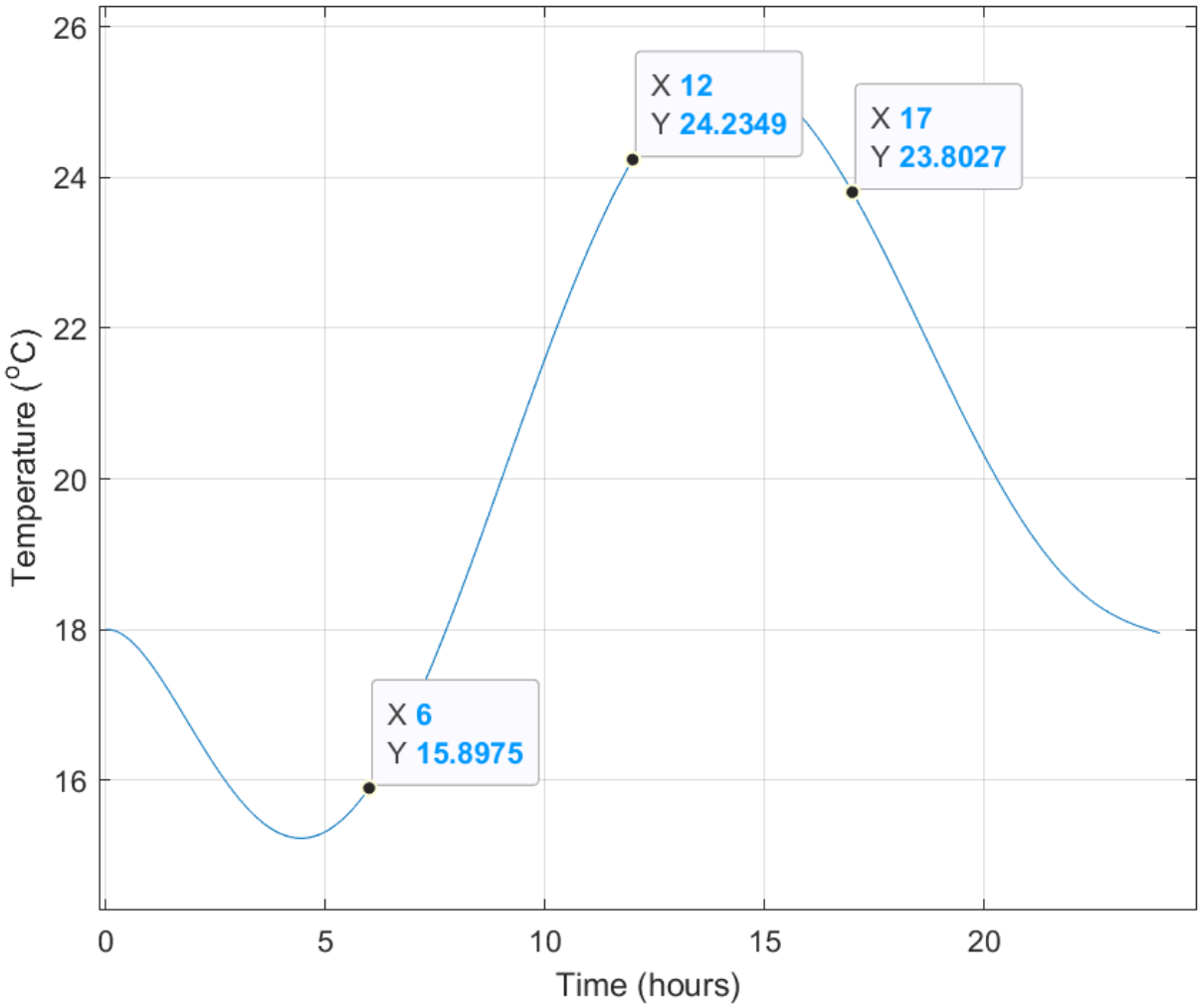

Figure 26 Simulated temperatures of a hot day in 24 hours

Using these temperatures, the temperature of the air entering the fridge can be used to find the following temperature profile:

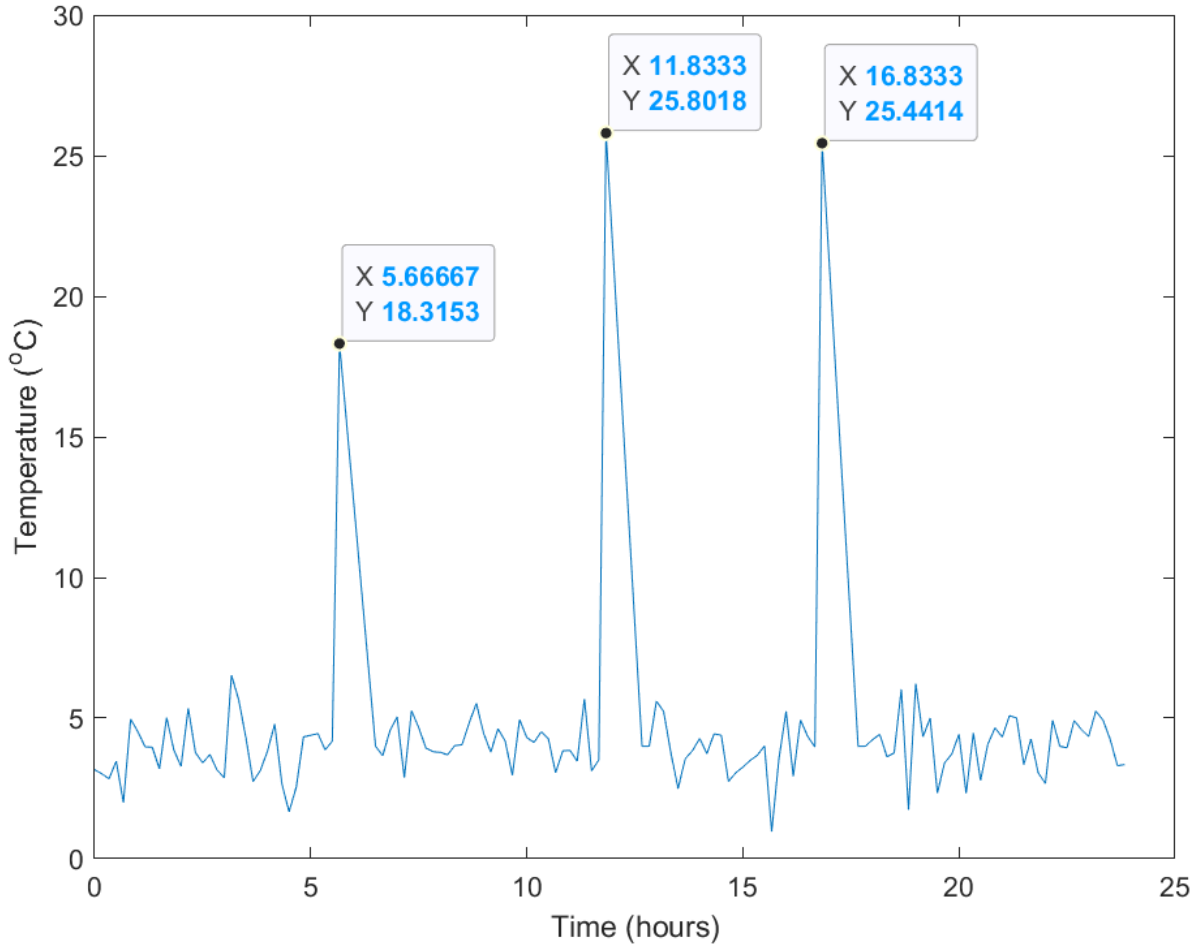

Figure 27 Temperature profile for a fridge opened three times throughout the day

The triangular pulses have left skewedness of 85%, since it is assumed that ambient air enters the refrigerator quickly, but not immediately when the user opens the fridge door. These higher temperature spikes also may account for opening and closing the fridge several times during mealtimes. The temperature distribution of this temperature profile is as follows:

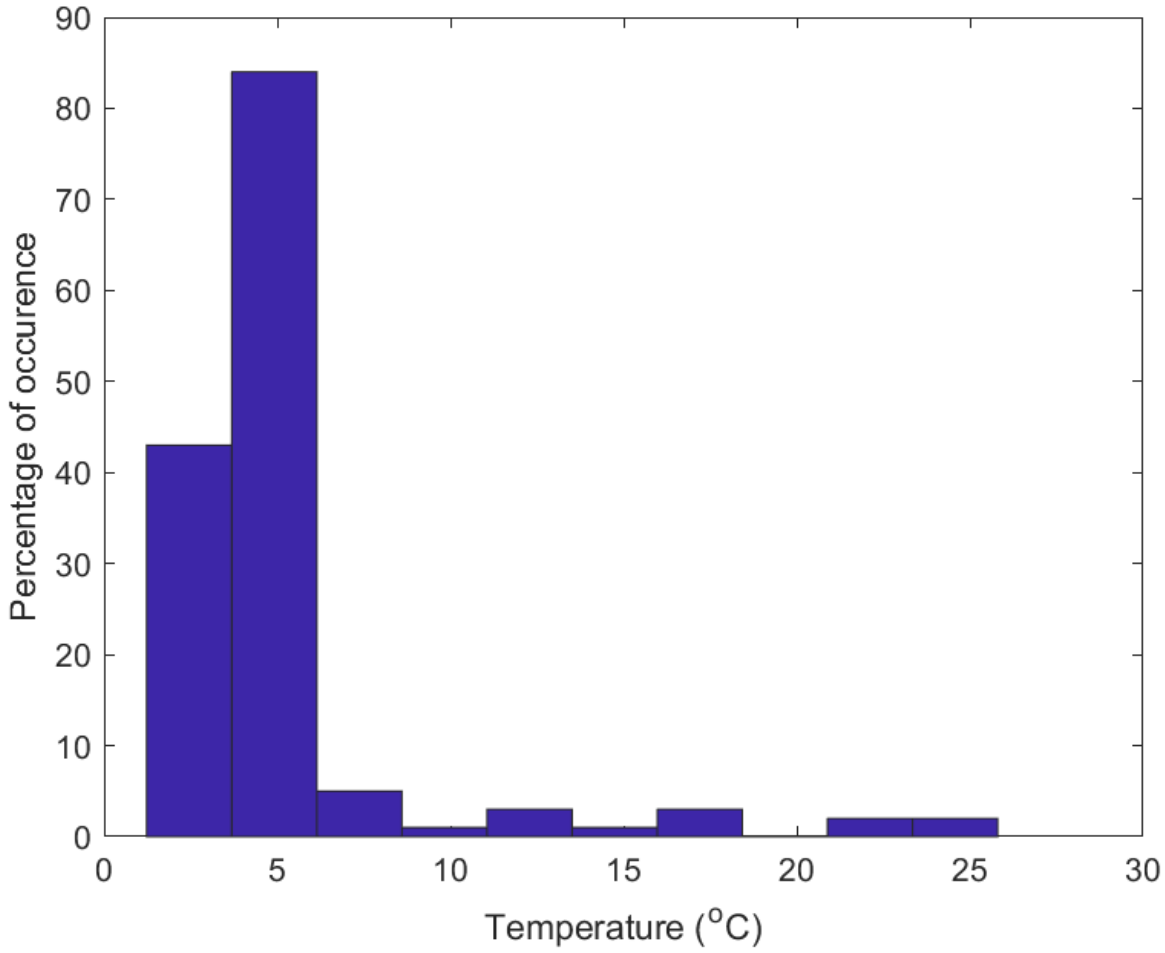

Figure 28 Distribution of temperature for a fridge opened throughot the day

When used correctly, the device is able to keep the temperature of the medication stable. The figure below shows that when the temperature spikes to 25°C occurs at 12:00 and 17:00, about half of the PCM melts, but because the latent heat of C-14 paraffin is 6°C the medication within the device will not heat beyond the recommended range unless the entire PCM layer melts.

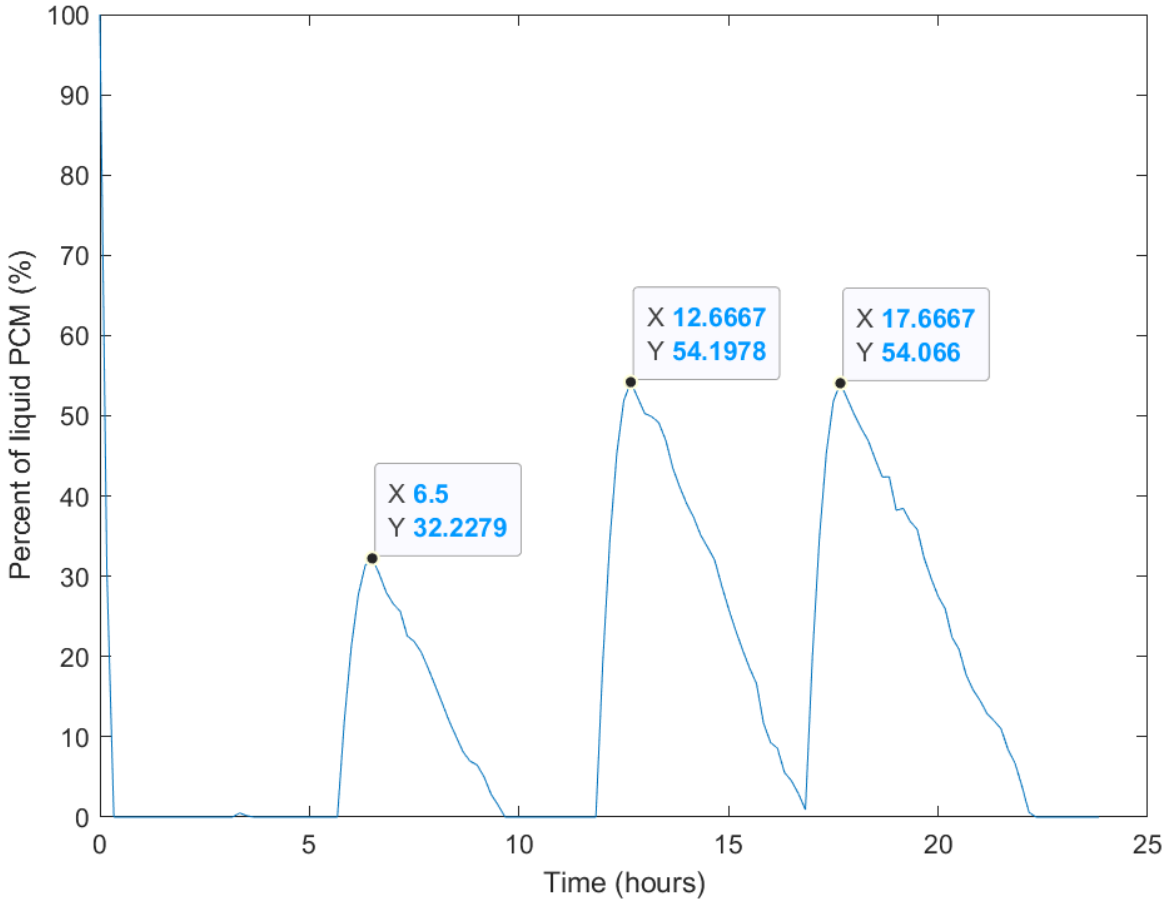

Figure 29 Device performance when fridge is opened without power outages

However, user error could occur in 2 main ways: the user could leave the box open after freezing, so the inner area and volume of the box will be exposed; thus, the box interior (and medication) will be exposed and simply reach the fridge internal temperature when the fridge is opened (Figure 30). Alternatively, the user could misunderstand how to use the device correctly and put the box in without leaving it open, so the inner area is not exposed to facilitate faster heat transfer out of the PCM, hence the device will not cool correctly (Figure 31).

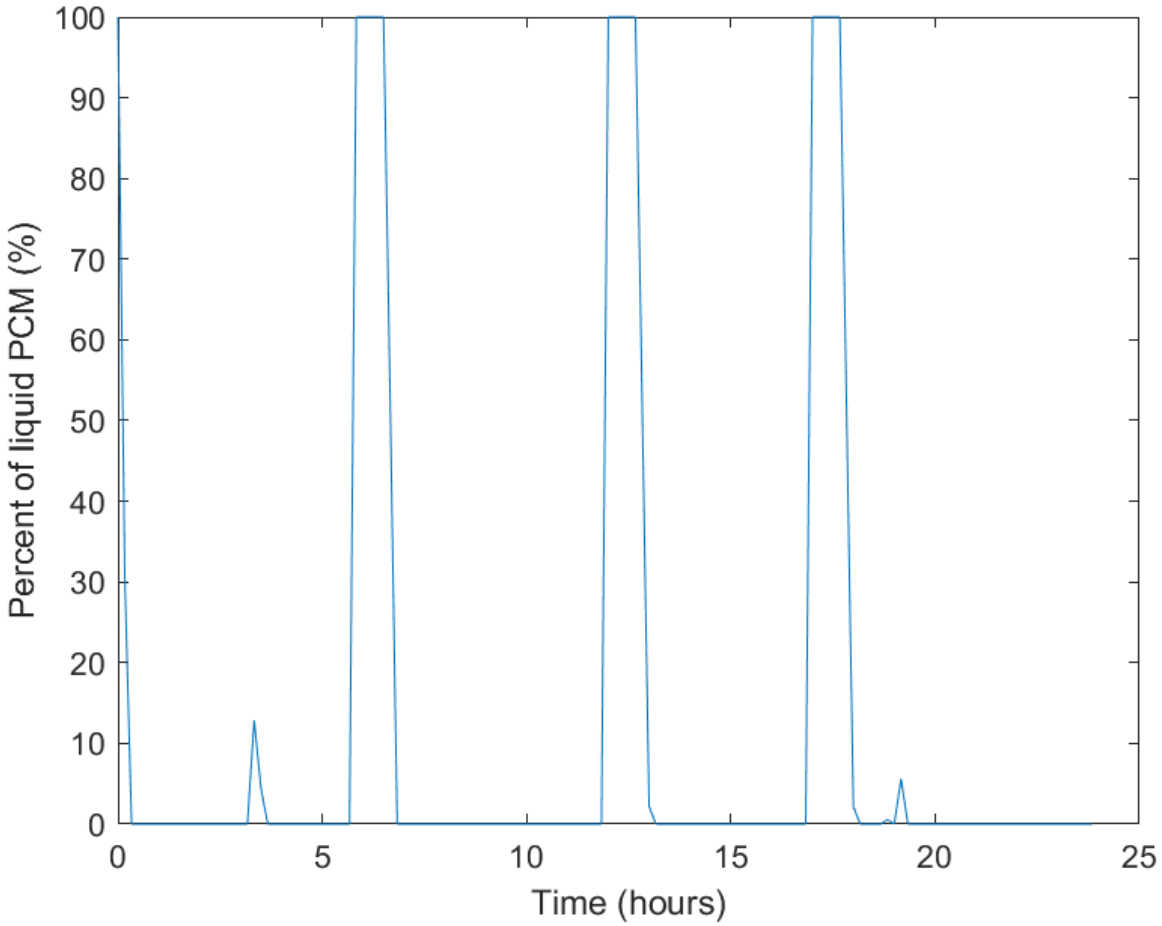

Figure 30 User error case 1: Device left open to freeze, but user neglected to close the device

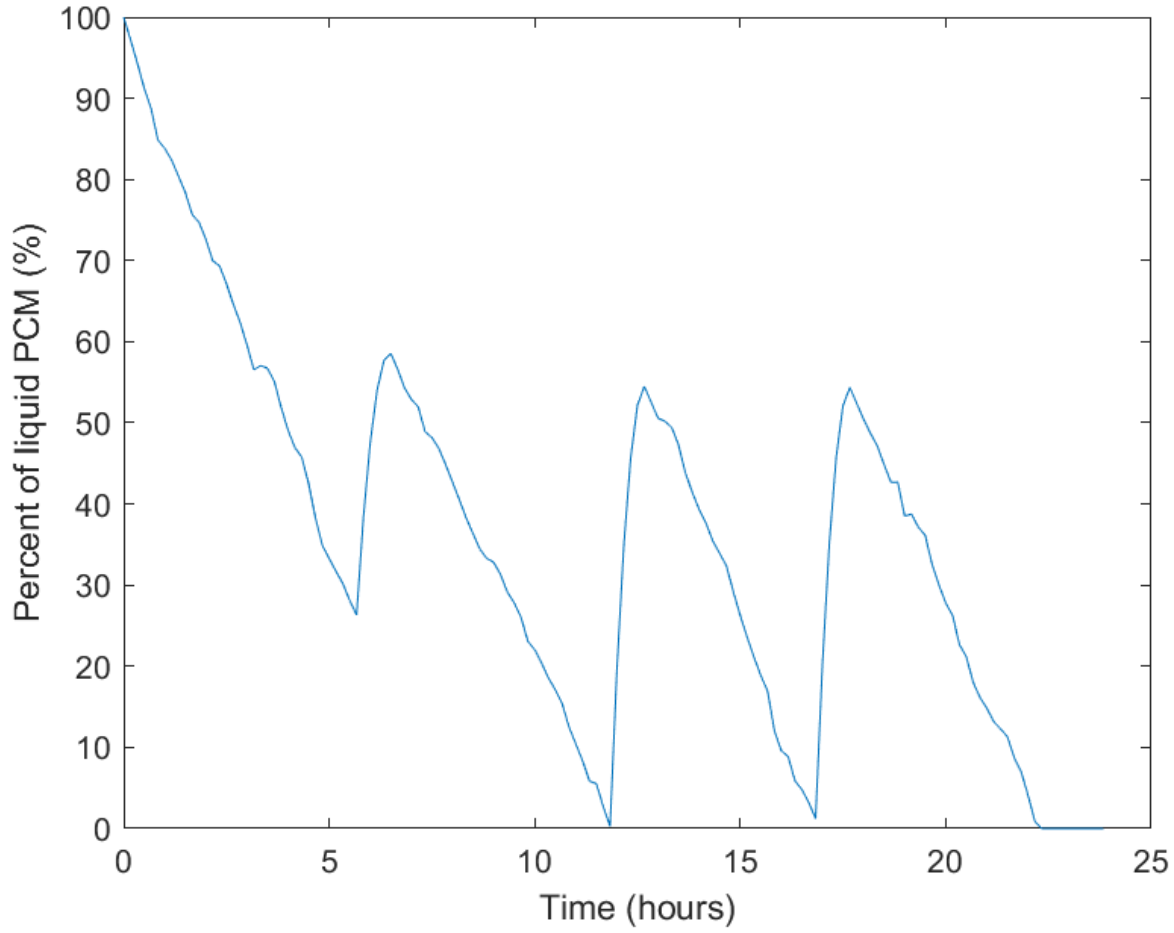

Figure 31 User error case 2

Figure 32 shows that if the user does not remember to close the device, temperature failure occurs each time the fridge is opened—this would expose medication to temperatures above 8°C each time the fridge is opened. Figure 33 shows the delayed time to freeze the medical device's contents—if used incorrectly, the time delay in cooling the contents of the device could be longer, since if the device is placed in at room temperature, the heat within the contents of the device still undergoes heat exchange from sensible heat before latent heat exchange occurs. This is why it is vital that the instructions for how to the device the device must be made very clear to the user. The *instructions for use*[7] must be produced by the manufacturer and distributed within the packaging of the device. From the developers' side, these instructions

[7] "refers to the information provided by the manufacturer to inform the user of a device's intended purpose and proper use and of any precautions to be taken" (Regulation(EU) 2017/745, 2017)

are important to communicate and related to the *intended use*[8], which is part of the regulatory process.

However, so far, the assumption is that all the air and the contents of the fridge have rapidly been heated to ambient temperature and the user has opened the fridge for more than 5 minutes (which is why the fridge takes an hour to return to temperature). This is necessary to test the device rigorously for people who have older fridges, obsessive fridge opening habits, and/or mostly empty fridges. A more accurate and realistic representation may be to have the temperature increase, but to a lower temperature—to account for the cooled fridge body material and the food.

Moreover, this assumption means that opening the fridge to close the device after it has set will be disadvantageous. The following temperature profile and device response will be used in cases Temperatures in the fridge will likely not reach the exact same value at the end of each power outage, but the approximation gives a way of evaluating how the device will behave during the power outages. In response to this temperature profile, the device is able to refreeze (albeit gradually if the device is not manually opened) down after each load shedding period. The response of the device when user error has occurred is attached in Appendix D since the melting and freezing patterns is similar to scenario 2, with the only difference being that temperature failure will result in the device being melted for longer when it is open (case 1) and the device is unable to freeze within 24 hours if left in the fridge without allowing the PCM to cool and set (case 2).

[8] "use for which the device is intended according to the data supplied by the manufacturer on the labelling, in the instructions and/or promotional materials" (EC Directive 93/42/EEC, 1993)

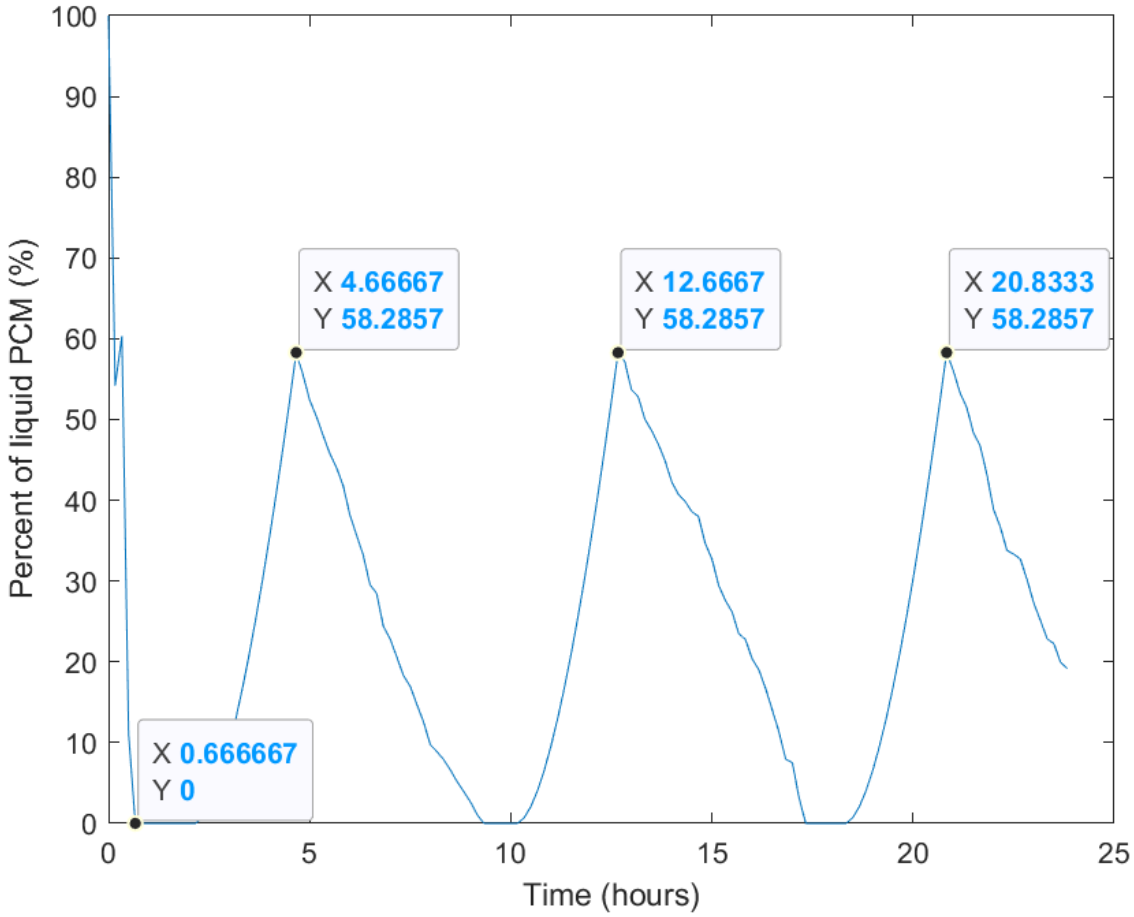

Figure 35 Device performance during stage 4 load shedding

Since the device does not melt to 100% liquid, the medication within will be protected during load shedding. The device, with these design parameters, do meet the requirements of protecting insulin during stage 4 load shedding. Currently, stage 4 load shedding is most common 'worst' stage that occurs, but if the energy crisis worsens in South Africa, stage 6 could be implemented more often.

For stage 6 load shedding (does not occur often), power will also be out three times daily, with two power outages lasting 4.5 hours (270 minutes) and one 2.5-hour period. Stage 6 load shedding conditions were also applied to the device. Unsurprisingly, the PCM within the device would melt since the device is designed to protect medication with Stage 4 load shedding.

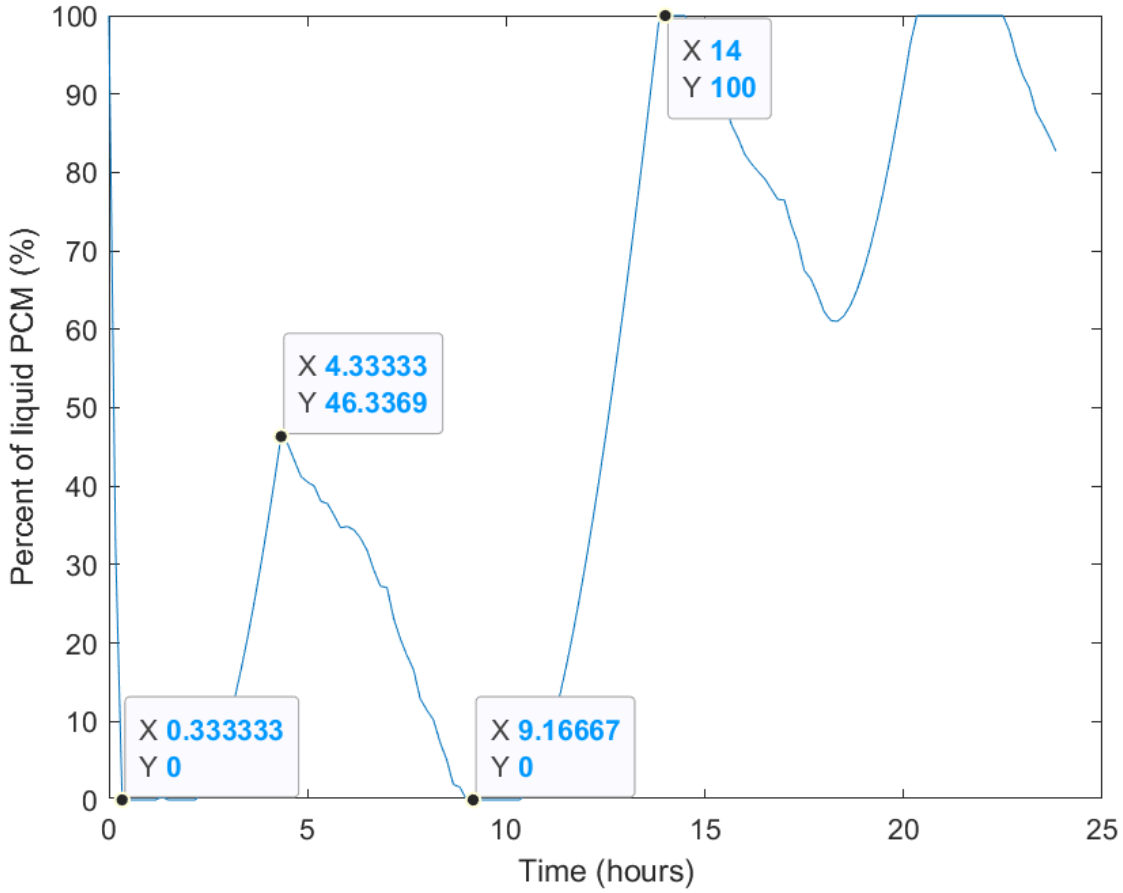

Figure 36 Stage 6 load shedding applied to device with 0.0015m PCM thickness and sixfold inner to outer surface area

Within the model, it has also been assumed that the user does not interact with the device after it has been successfully set. However, it is important for users to check daily if their medication is subjected to temperature failure—as the use of denatured insulin will be detrimental to their health and should be treated as an important factor in their diabetes management.

The position of the beads in visual indicator is designed to alert the user that the temperature in the device has exceeded the safe storage specifications; thus, the insulin may no longer be safe to use. The user should be instructed with instructions within a user manual included in the product packaging to check the visual indicator and to reset the device an hour or so after load shedding has ended. This is so that the device will cool and refreeze before the following load shedding event.

In addition to the user checking the device, a slightly larger volume of PCM material could be used to increase the thermal capacity of the device to extend the time that the medication is protected (Figure 37). This is helpful for the user who is not home during the day (in Figure 36 the device is melted by 14:00) but returns home during the afternoon or evening. However, this design change incurs the disadvantage of a longer setting/ freezing time, which means a larger

inner surface area may be needed. As can be seen in Figure 37 (simulating a larger surface area), it takes longer to freeze the large container than that shown in Figure 36.

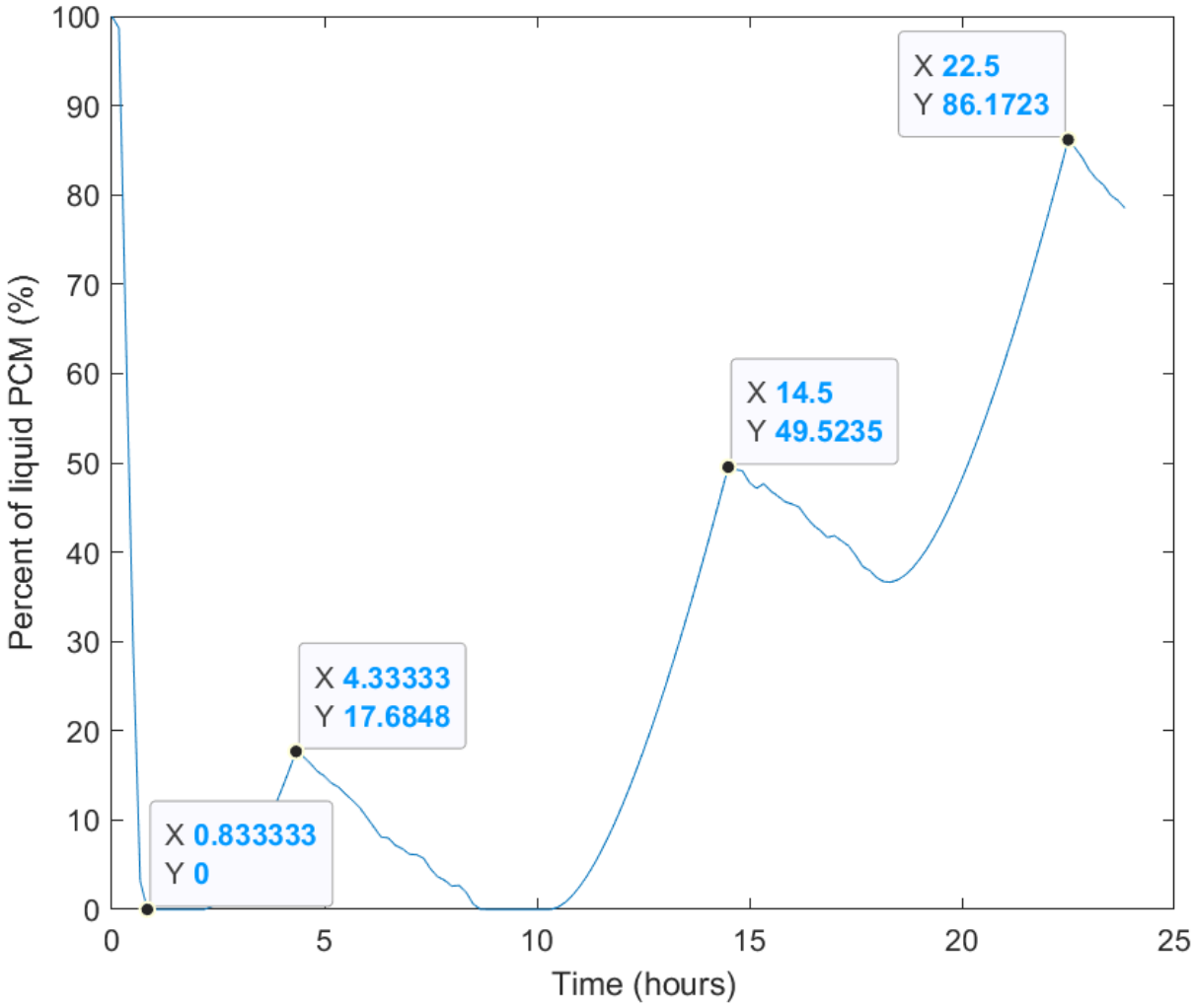

Figure 37 PCM thickness 0.004m with sixfold inner area to outer surface area

Combining a slightly larger PCM layer and user interaction, may have the most promising results. Figure 38 shows a PCM thickness of 0.0025m, the same inner surface area multiplier (inner area is sixfold outer surface area) and the user opens the top of the device at 17:00 to let the device cool, then closes it at 17:30 to protect it for the 18:30 to 22:30 planned power outage. In this way, the user does not have to worry about the medication during working hours but does have to be mindful of protecting their medication for longer load shedding hours.

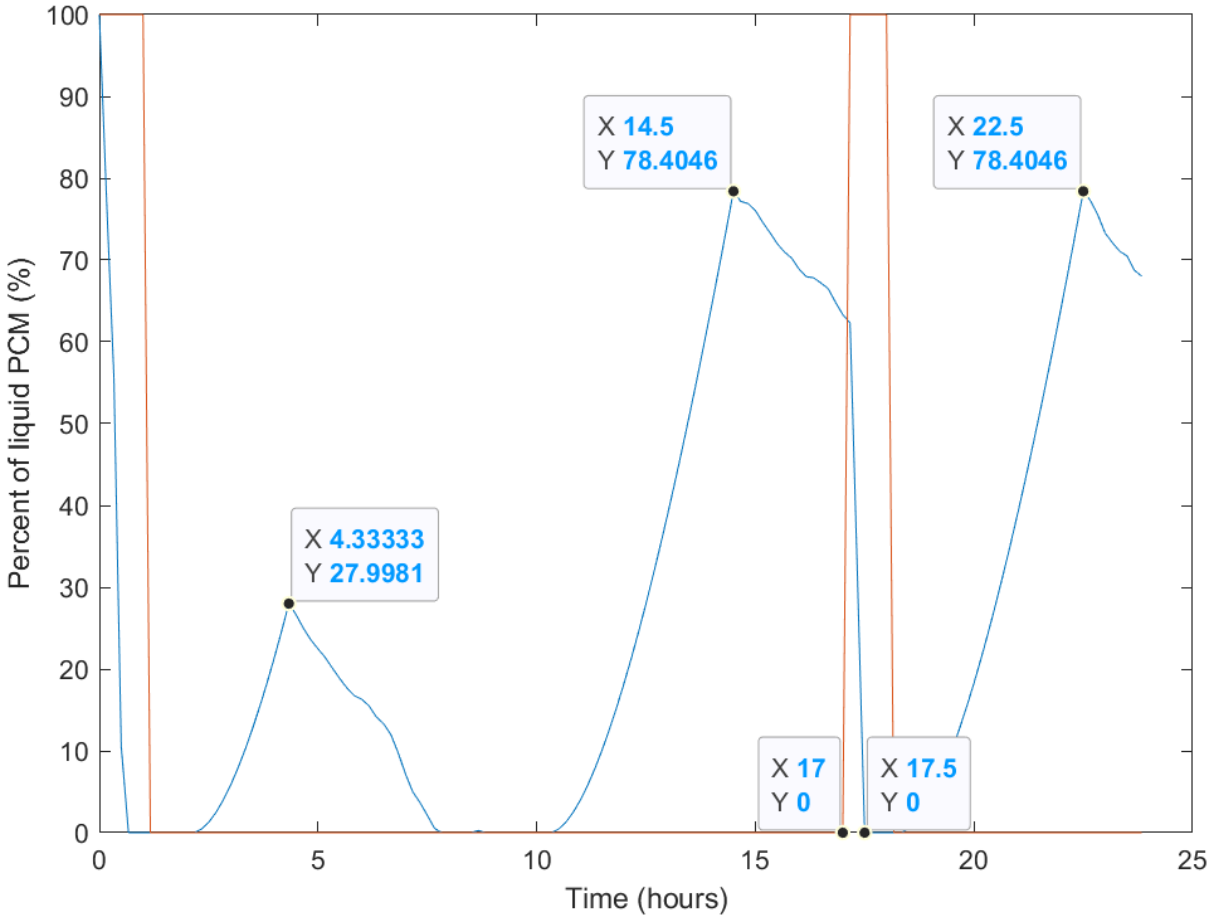

Figure 38 Device performance with user interention

Figure 38 shows that if the device can cool, even for longer load shedding periods as long as the user opens the device when the power is on to cool before the following load shedding period. However, this graph is not completely accurate because it shows how the device would respond if the user opened and closed the device but does not include the temperature increase that would occur during setting the device. As discussed before, it is also not necessary for the entire PCM volume to be frozen for the device to protect the medication; the following section will include fridge opening and load shedding and consider the balance between a thickness that is likely to keep user interaction to a minimum.

Scenario 4: Power outage with opening and closing, for simulating the person opening the fridge for a shorter period of time, simply to open or close the device to reset it between load shedding. A more reasonable temperature will be between the set point and ambient temperature—this more realistic representation of the temperature change during opening a fridge will be used in Temperatures in the fridge will likely not reach the exact same value at the end of each power outage, but the approximation gives a way of evaluating how the device will behave during the power outages. In response to this temperature profile, the device is able

to refreeze (albeit gradually if the device is not manually opened) down after each load shedding period. The response of the device when user error has occurred is attached in Appendix D since the melting and freezing patterns is similar to scenario 2, with the only difference being that temperature failure will result in the device being melted for longer when it is open (case 1) and the device is unable to freeze within 24 hours if left in the fridge without allowing the PCM to cool and set (case 2).

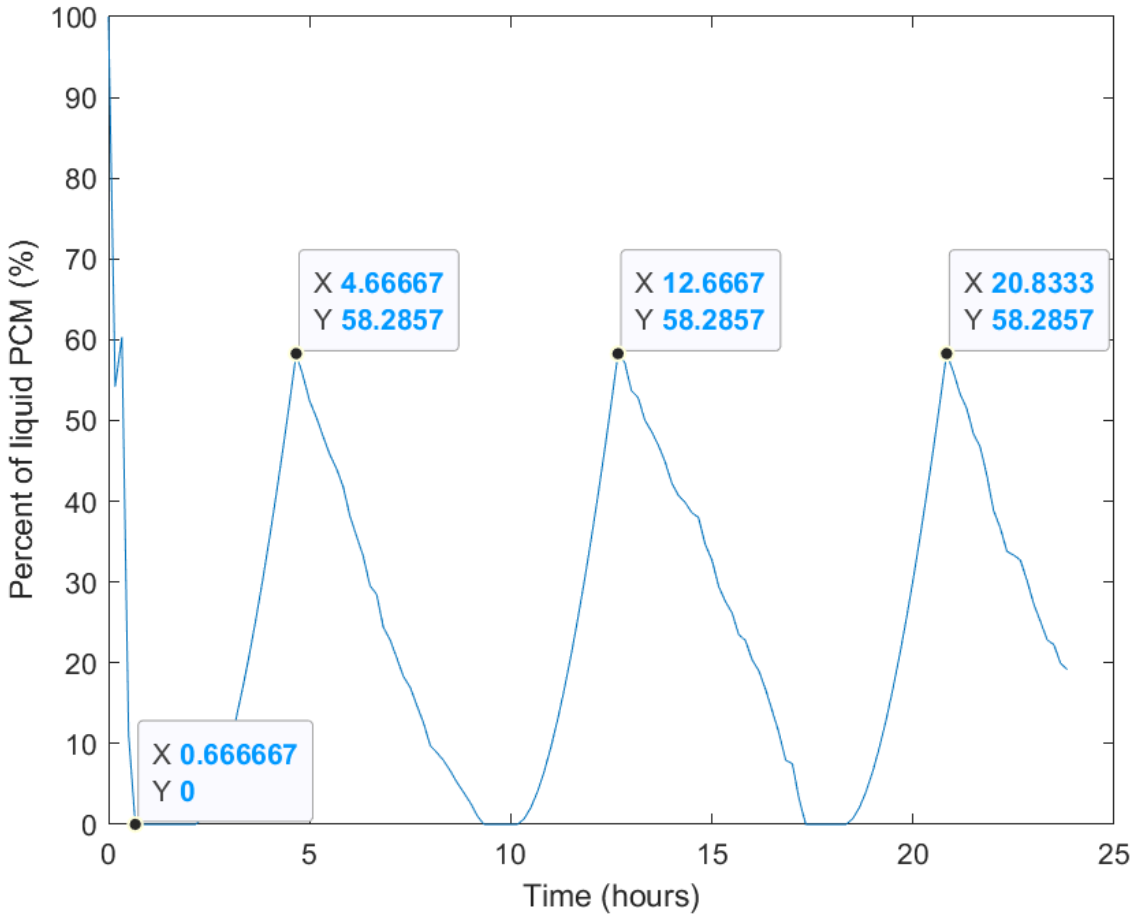

Figure 35 Device performance during stage 4 load shedding

Since the device does not melt to 100% liquid, the medication within will be protected during load shedding. The device, with these design parameters, do meet the requirements of protecting insulin during stage 4 load shedding. Currently, stage 4 load shedding is most common ‘worst’ stage that occurs, but if the energy crisis worsens in South Africa, stage 6 could be implemented more often.

For stage 6 load shedding (does not occur often), power will also be out three times daily, with two power outages lasting 4.5 hours (270 minutes) and one 2.5-hour period. Stage 6 load shedding conditions were also applied to the device. Unsurprisingly, the PCM within the device would melt since the device is designed to protect medication with Stage 4 load shedding.

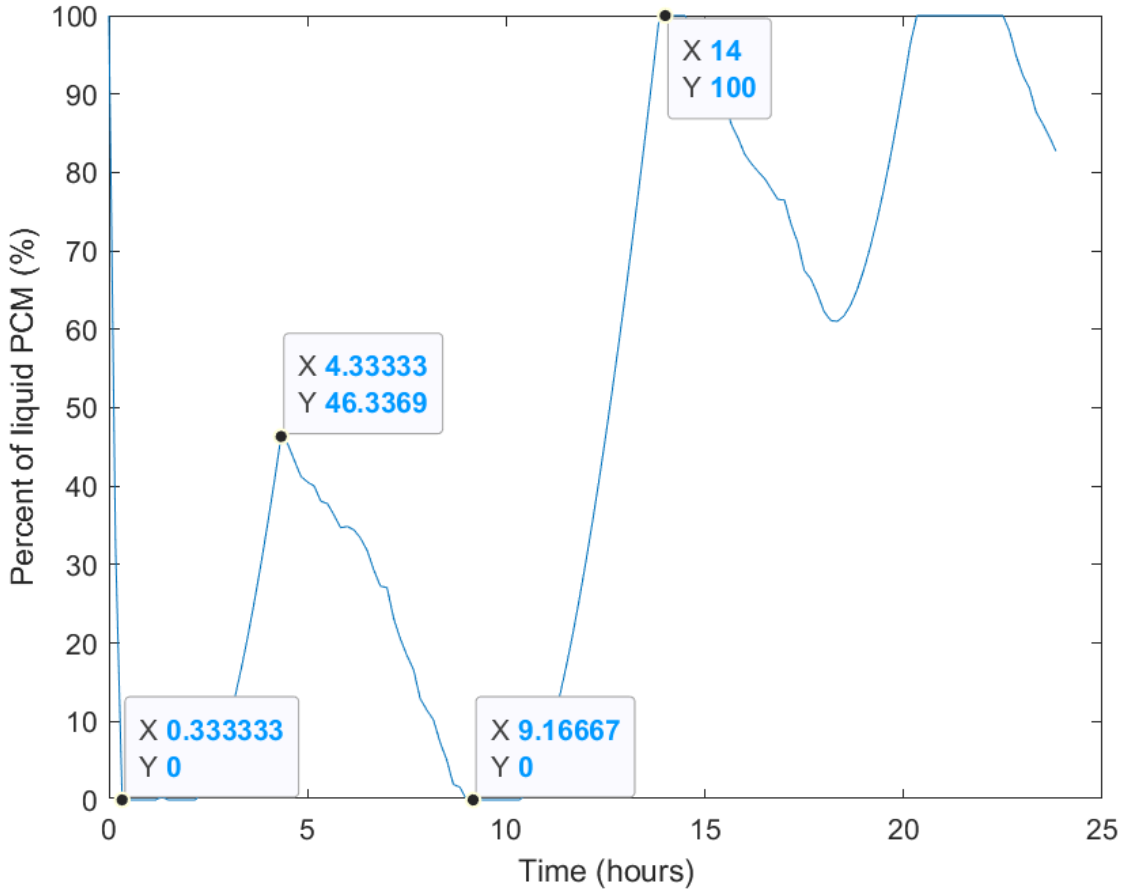

Figure 36 Stage 6 load shedding applied to device with 0.0015m PCM thickness and sixfold inner to outer surface area

Within the model, it has also been assumed that the user does not interact with the device after it has been successfully set. However, it is important for users to check daily if their medication is subjected to temperature failure—as the use of denatured insulin will be detrimental to their health and should be treated as an important factor in their diabetes management.

The position of the beads in visual indicator is designed to alert the user that the temperature in the device has exceeded the safe storage specifications; thus, the insulin may no longer be safe to use. The user should be instructed with instructions within a user manual included in the product packaging to check the visual indicator and to reset the device an hour or so after load shedding has ended. This is so that the device will cool and refreeze before the following load shedding event.

In addition to the user checking the device, a slightly larger volume of PCM material could be used to increase the thermal capacity of the device to extend the time that the medication is protected (Figure 37). This is helpful for the user who is not home during the day (in Figure 36 the device is melted by 14:00) but returns home during the afternoon or evening. However, this design change incurs the disadvantage of a longer setting/ freezing time, which means a larger

inner surface area may be needed. As can be seen in Figure 37 (simulating a larger surface area), it takes longer to freeze the large container than that shown in Figure 36.

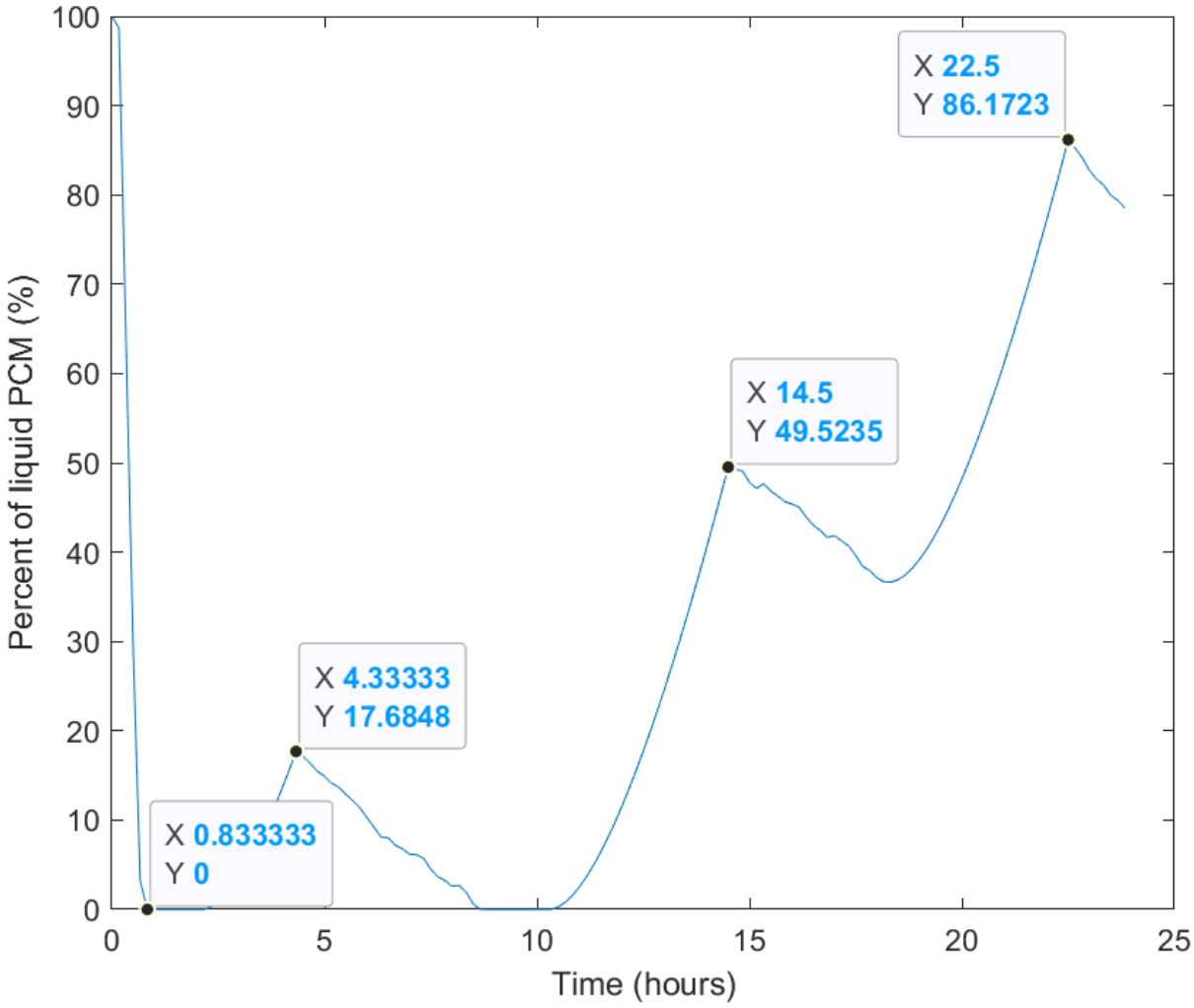

Figure 37 PCM thickness 0.004m with sixfold inner area to outer surface area

Combining a slightly larger PCM layer and user interaction, may have the most promising results. Figure 38 shows a PCM thickness of 0.0025m, the same inner surface area multiplier (inner area is sixfold outer surface area) and the user opens the top of the device at 17:00 to let the device cool, then closes it at 17:30 to protect it for the 18:30 to 22:30 planned power outage. In this way, the user does not have to worry about the medication during working hours but does have to be mindful of protecting their medication for longer load shedding hours.

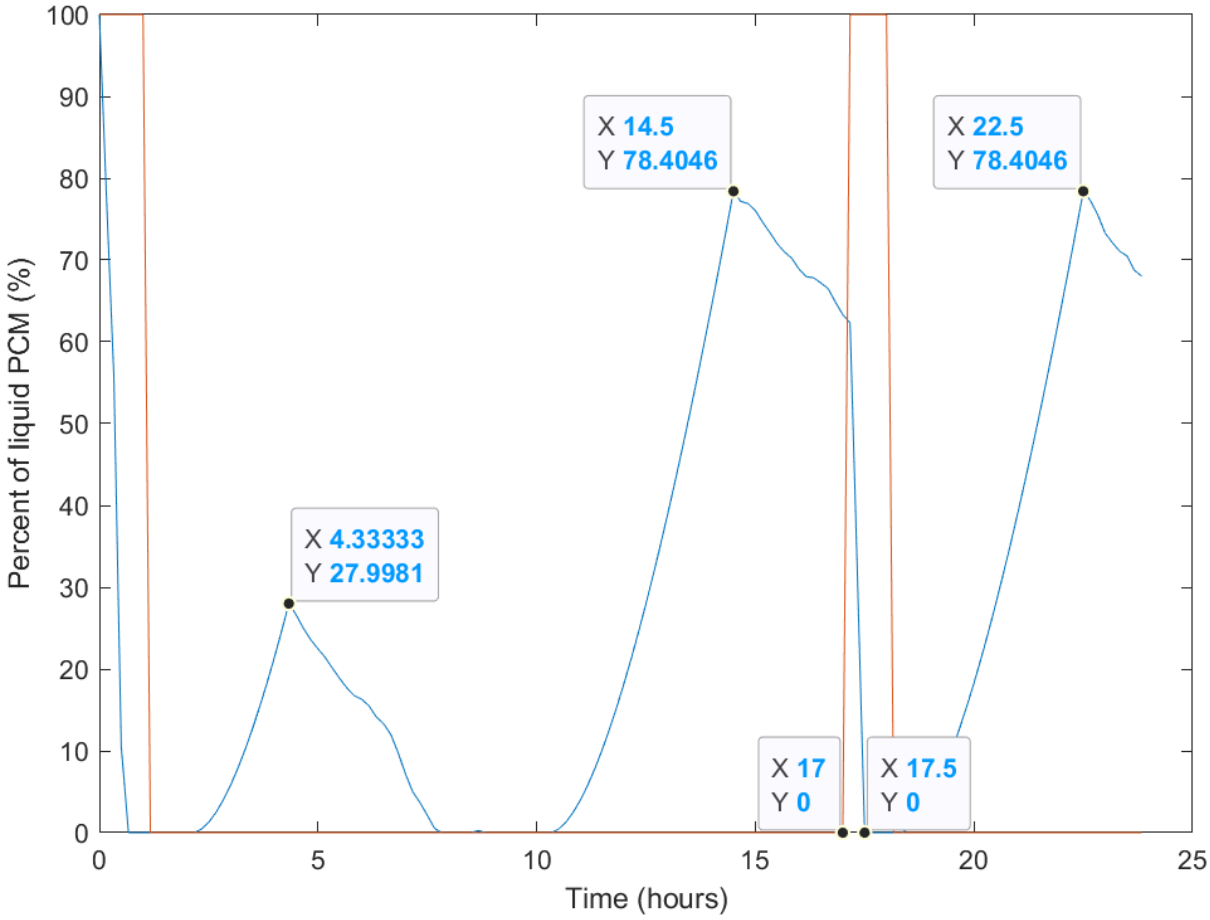

Figure 38 Device performance with user interention

Figure 38 shows that if the device can cool, even for longer load shedding periods as long as the user opens the device when the power is on to cool before the following load shedding period. However, this graph is not completely accurate because it shows how the device would respond if the user opened and closed the device but does not include the temperature increase that would occur during setting the device. As discussed before, it is also not necessary for the entire PCM volume to be frozen for the device to protect the medication; the following section will include fridge opening and load shedding and consider the balance between a thickness that is likely to keep user interaction to a minimum.

Scenario 4: Power outage with opening and closing. Appendix C shows the temperature data, the corresponding melt percentage of the PCM, and the user error cases for a fridge that does not have an exaggerated temperature spike. This section shows that the device will be able to maintain thermal stability even when temperatures in the fridge reach ambient temperatures.

5.3. Scenario 3: Power outage

During a power outage, the air within the fridge rises rapidly then temperature increase slows down (Chojcnacky, et al., 2009) —this can be approximated by following a logistic curve:

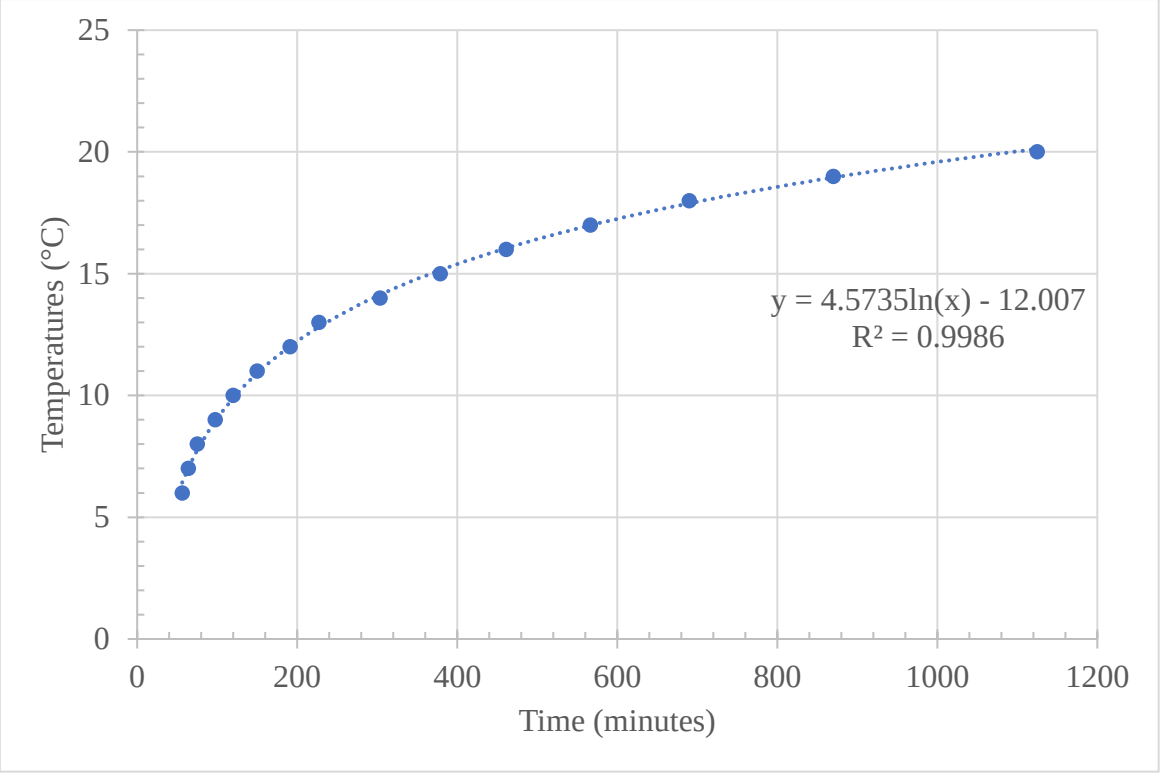

Figure 32 Approximation of temperatures within a fridge during a power outage. Data points source: (Chojcnacky, et al., 2009)

The equation on Figure 32 is an approximation that can be applied within the model. Load shedding occurs on a schedule; for stage 4 load shedding, power will be out three times daily with each power outage slot lasting 2.5 hours (150 minutes). Temperatures will peak at the end of each 2.5-hour period. Assuming the fridge is well insulated, the temperature within an unopened fridge will reach the same maximum value if each load shedding period is the dame amount of time. An approximation temperature profile for such an event will be as follows:

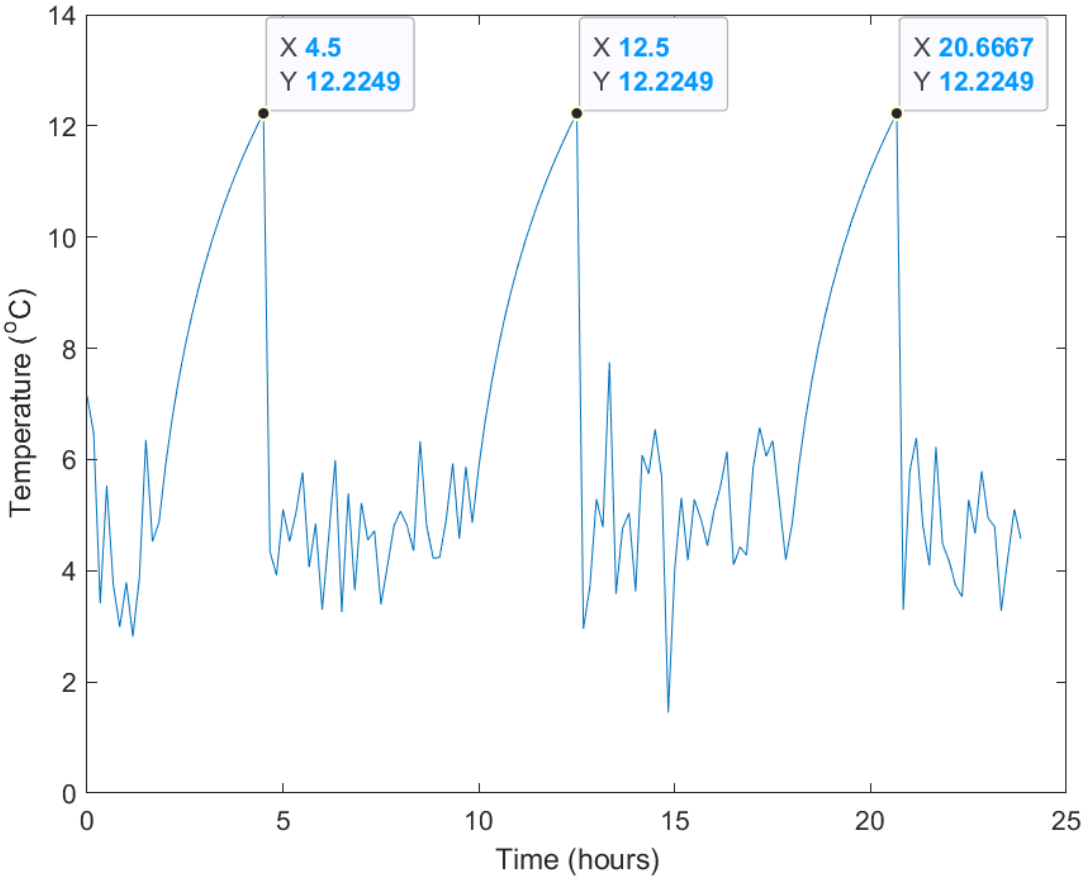

Figure 33 Simulated tempertures for a closed fridge with Stage 4 load shedding

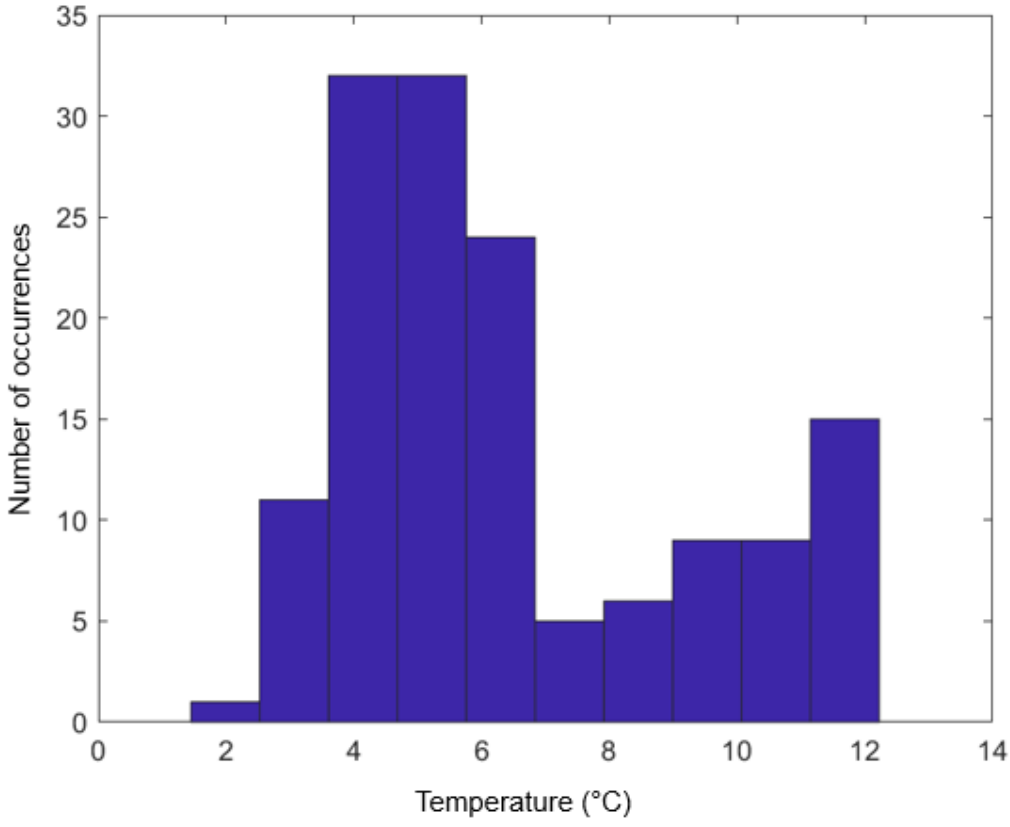

Figure 34 Temperature distribtion for a fridge with power outage without user opening fridge

Temperatures in the fridge will likely not reach the exact same value at the end of each power outage, but the approximation gives a way of evaluating how the device will behave during the power outages. In response to this temperature profile, the device is able to refreeze (albeit gradually if the device is not manually opened) down after each load shedding period. The response of the device when user error has occurred is attached in Appendix D since the melting and freezing patterns is similar to scenario 2, with the only difference being that temperature failure will result in the device being melted for longer when it is open (case 1) and the device is unable to freeze within 24 hours if left in the fridge without allowing the PCM to cool and set (case 2).

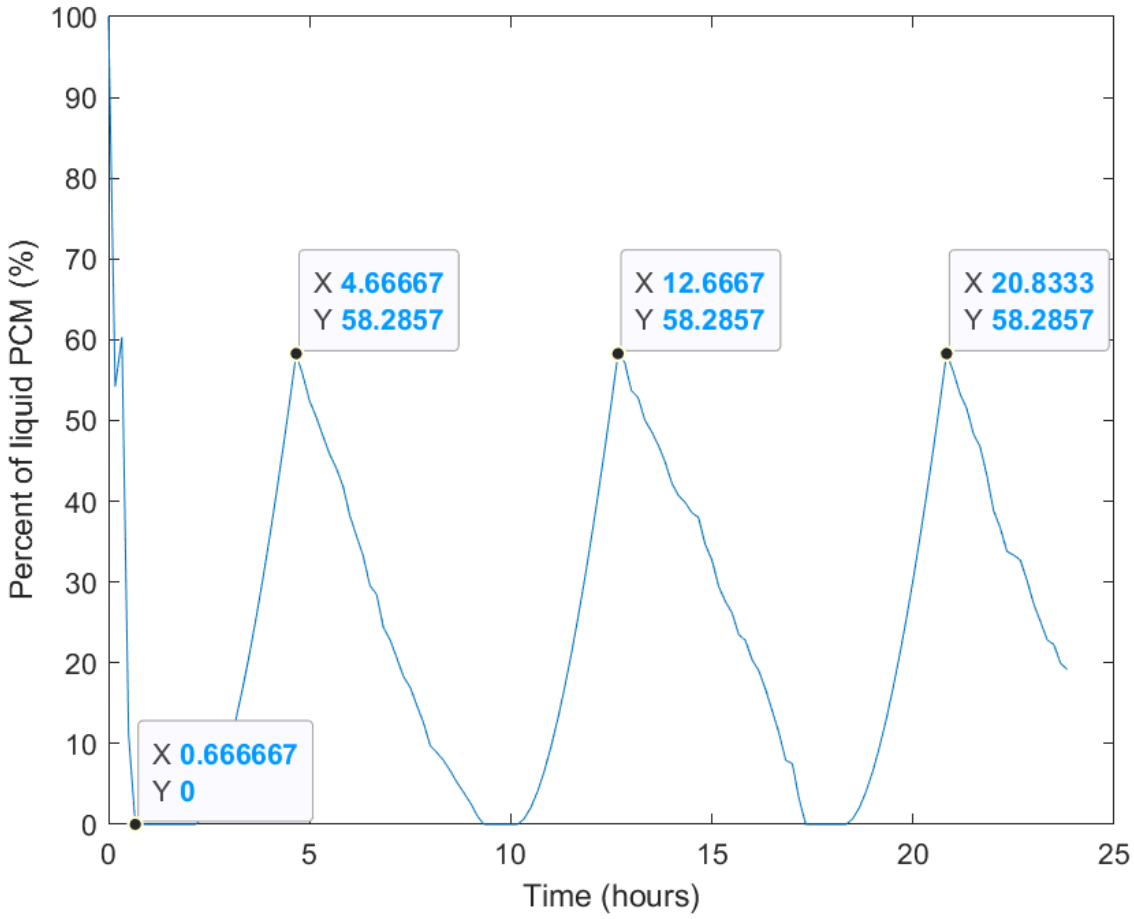

Figure 35 Device performance during stage 4 load shedding

Since the device does not melt to 100% liquid, the medication within will be protected during load shedding. The device, with these design parameters, do meet the requirements of protecting insulin during stage 4 load shedding. Currently, stage 4 load shedding is most common ‘worst’ stage that occurs, but if the energy crisis worsens in South Africa, stage 6 could be implemented more often.

For stage 6 load shedding (does not occur often), power will also be out three times daily, with two power outages lasting 4.5 hours (270 minutes) and one 2.5-hour period. Stage 6 load shedding conditions were also applied to the device. Unsurprisingly, the PCM within the device would melt since the device is designed to protect medication with Stage 4 load shedding.

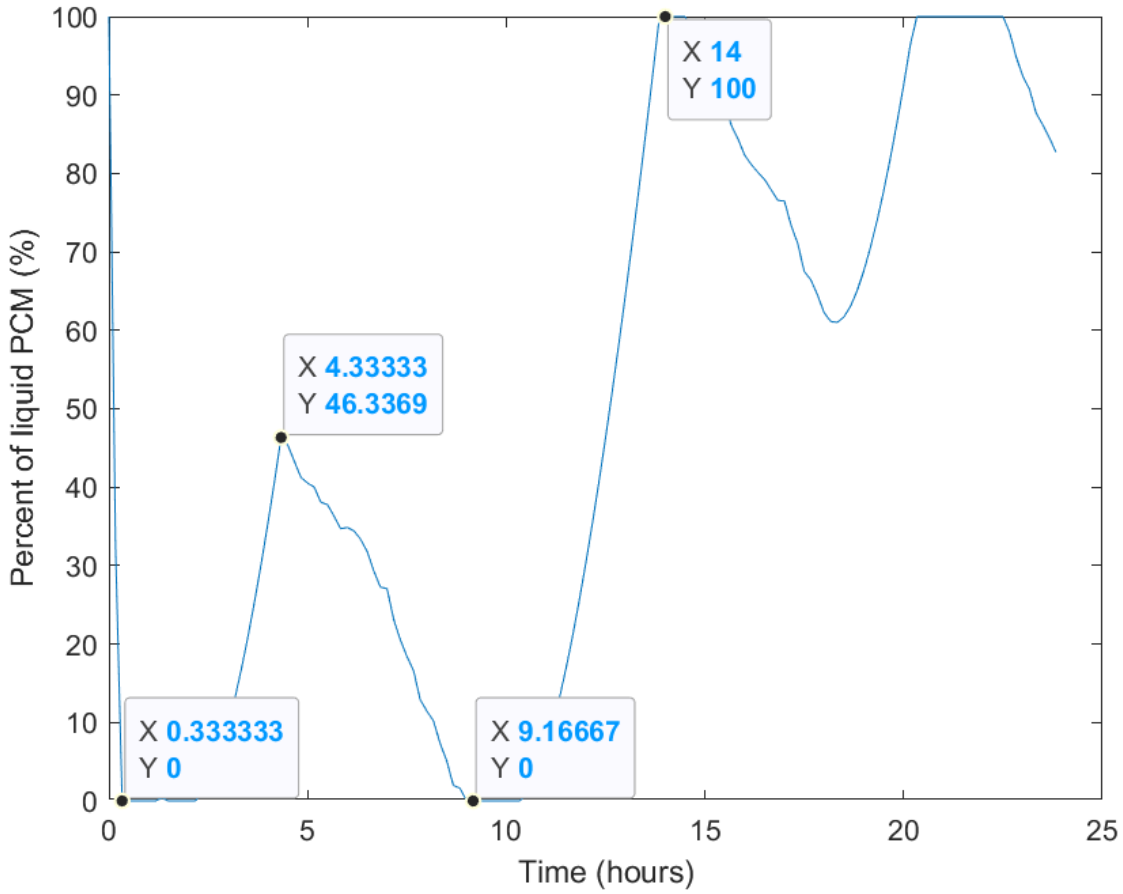

Figure 36 Stage 6 load shedding applied to device with 0.0015m PCM thickness and sixfold inner to outer surface area

Within the model, it has also been assumed that the user does not interact with the device after it has been successfully set. However, it is important for users to check daily if their medication is subjected to temperature failure—as the use of denatured insulin will be detrimental to their health and should be treated as an important factor in their diabetes management.

The position of the beads in visual indicator is designed to alert the user that the temperature in the device has exceeded the safe storage specifications; thus, the insulin may no longer be safe to use. The user should be instructed with instructions within a user manual included in the product packaging to check the visual indicator and to reset the device an hour or so after load shedding has ended. This is so that the device will cool and refreeze before the following load shedding event.

In addition to the user checking the device, a slightly larger volume of PCM material could be used to increase the thermal capacity of the device to extend the time that the medication is protected (Figure 37). This is helpful for the user who is not home during the day (in Figure 36 the device is melted by 14:00) but returns home during the afternoon or evening. However, this design change incurs the disadvantage of a longer setting/ freezing time, which means a larger inner surface area may be needed. As can be seen in Figure 37 (simulating a larger surface area), it takes longer to freeze the large container than that shown in Figure 36.

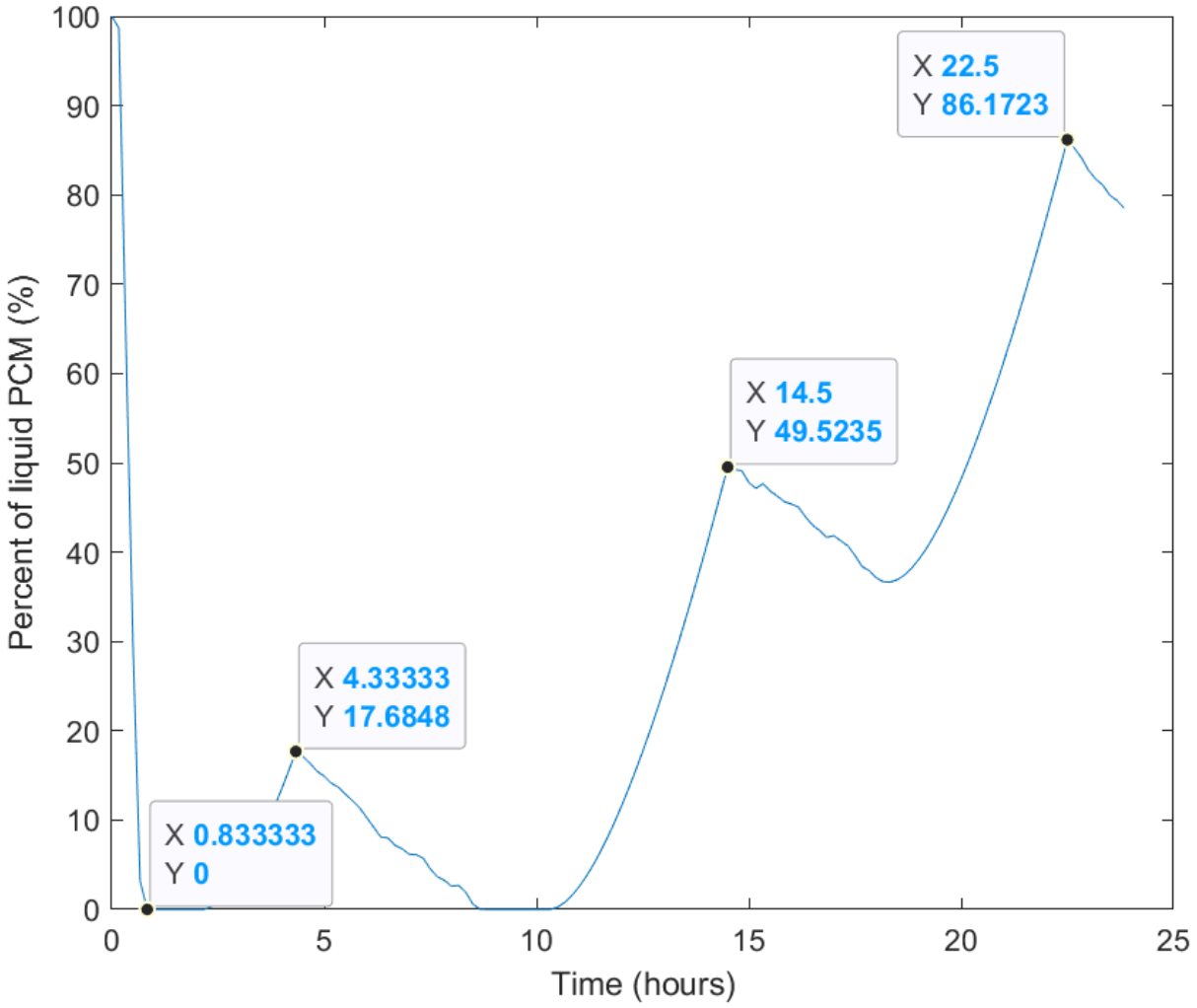

Figure 37 PCM thickness 0.004m with sixfold inner area to outer surface area

Combining a slightly larger PCM layer and user interaction, may have the most promising results. Figure 38 shows a PCM thickness of 0.0025m, the same inner surface area multiplier (inner area is sixfold outer surface area) and the user opens the top of the device at 17:00 to let the device cool, then closes it at 17:30 to protect it for the 18:30 to 22:30 planned power outage. In this way, the user does not have to worry about the medication during working hours but does have to be mindful of protecting their medication for longer load shedding hours.

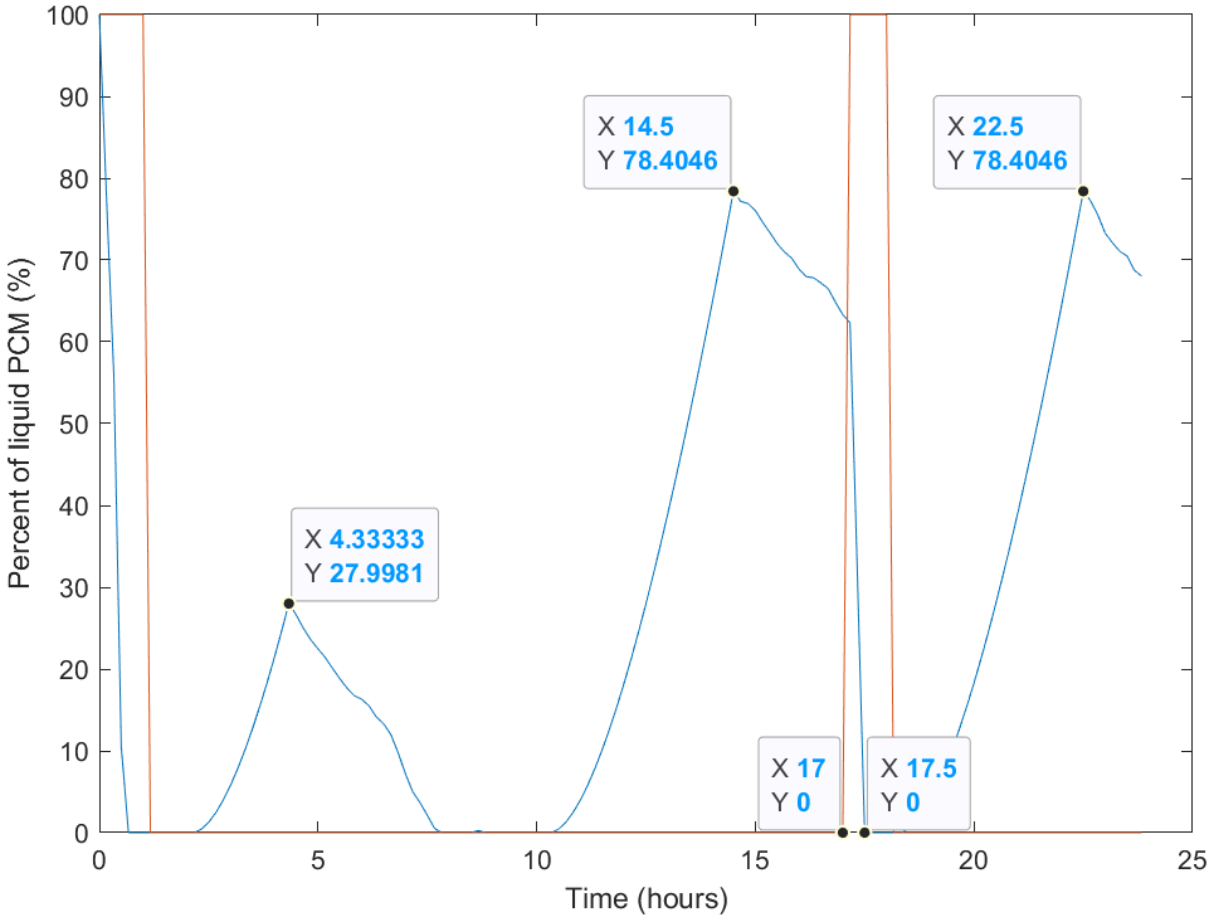

Figure 38 Device performance with user interention

Figure 38 shows that if the device can cool, even for longer load shedding periods as long as the user opens the device when the power is on to cool before the following load shedding period. However, this graph is not completely accurate because it shows how the device would respond if the user opened and closed the device but does not include the temperature increase that would occur during setting the device. As discussed before, it is also not necessary for the entire PCM volume to be frozen for the device to protect the medication; the following section will include fridge opening and load shedding and consider the balance between a thickness that is likely to keep user interaction to a minimum.

5.4. Scenario 4: Power outage with opening and closing events

This is a combination of the prior work to emulate how people may interact with their fridge.

- To test the device under the most taxing conditions, the highest temperature that the fridge could reach is used that is it is assumed that once opened, the fridge interior reaches ambient temperature. As there are many unknown factors that impact the fridge internal temperature, for example the more food the user has in their fridge, the less likely it will rapidly reach room temperature, this assumption is quite conservative.

Despite the fact that this assumption does not simulate the actual temperatures, because the device must be able to withstand more onerous conditions, even if they are unlikely. It is unlikely that temperatures within a house are the same as ambient outside temperatures— depending on building insulation. Although it is likely that diabetics with access to insulin may be in a better socio-economic position, temperatures in low-cost residences with poor insulation, flat or corrugated metal roofs can reach temperatures 4°C above ambient temperatures and have larger temperature fluctuations (Naicker, et al., 2017).

- Stage 4 load shedding is implemented. Power outages start at 2:00, 10:00 and 18:00, lasting 2 and a half hours each. Load shedding schedules for different areas within South Africa vary, but the general pattern of stage 4 load shedding is that there are three power outages: during the morning, around midday, and in the evening.
- User opens fridge at inopportune times (before, during or as load shedding ends)—further increasing the temperature of the fridge during load shedding. Unfortunately, load shedding coincides with mealtimes often. Additionally, if a user is negligent or unaware about safe insulin storage, they may not consider the impact of fridge opening on temperature stability for medication.
- It is assumed that the user opens the fridge for a longer time during mealtimes, but for a shorter time for setting the device.

The three temperature peaks will simulate different opening times throughout load shedding and forms a complex temperature profile (Figure 39).

1. In the first peak, the user will open the fridge to close the device[9].
2. The second temperature spike towards the end of the load shedding period at 4:30—in this case the temperature in the fridge temperature increases, and then spikes up to the ambient temperature. The return down to the setpoint will be approximately 90 minutes (4:30 to 6:00), to replicate a longer time for the fridge to return to setpoint from food heating during the power outage.
3. To test the device under the most disadvantageous conditions, the user will open the fridge as load shedding starts at 10:00, then the fridge will continue to heat up to

[9] Recall that this period does not indicate that the user sets the device at midnight but is included at the beginning of the 24-hour period to show the time taken to set the device.

ambient temperature during the load shedding period, then return slowly down to the set point after the power outage (12:30 to 14:00).

4. The user must reset the device before the afternoon/evening load shedding period. In scenario 3 it was established that longer periods of heightened temperature require a thicker PCM and user intervention.
5. The afternoon/evening power outage will simulate a case where the user opens the fridge 30 minutes before load shedding (17:30) and the fridge controls lower the temperature for 30 minutes, but temperatures do not return to the setpoint before load shedding commences, which results in a gradual increase in temperature from a higher initial temperature (18:00 to 20:30) and a gradual decrease to the setpoint.

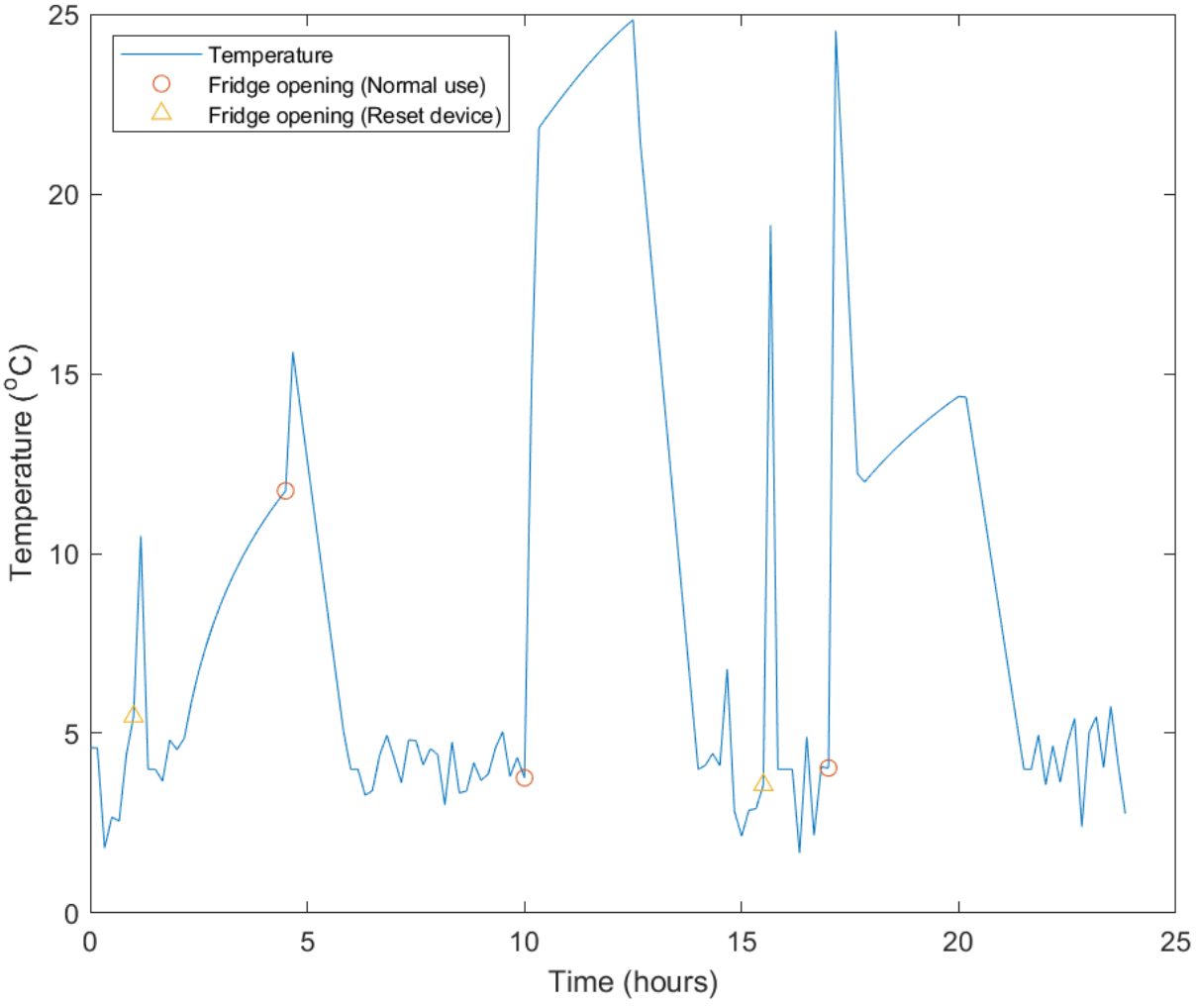

Figure 39 Temperature profile of load shedding and fridge opening during Stage 4 load shedding

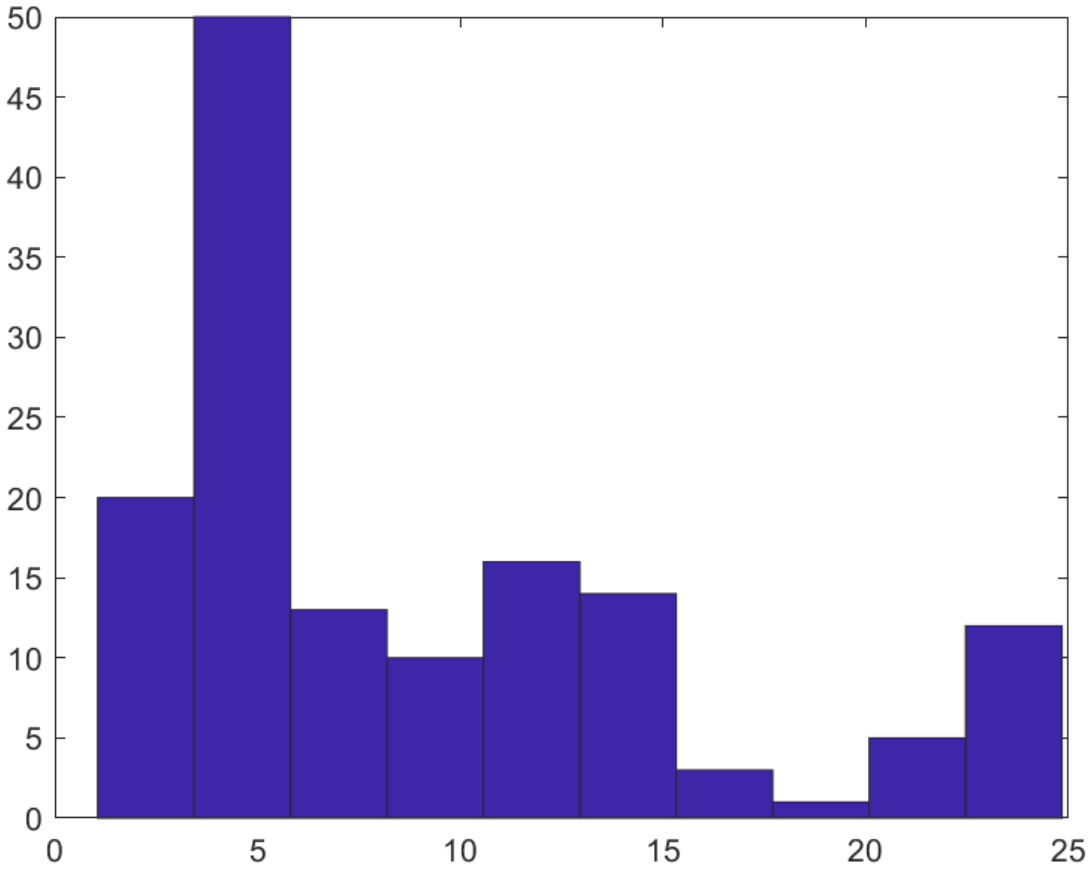

Figure 40 Distrubution of tempertures with power outages and fridge opening

The peaks of this temperature profile are likely possibly an overestimation of the actual temperatures within a domestic refrigerator. Therefore, the device as initially conceptualized (Table 11) will be able to function with more realistic lower temperatures. Nevertheless, if experimental data of fridge temperatures are high, the design parameters can be adjusted by increasing the PCM and inner surface area. Comparing Figure 41 and Figure 42, the difference between changing the PCM volume to match the temperature demands is clear.

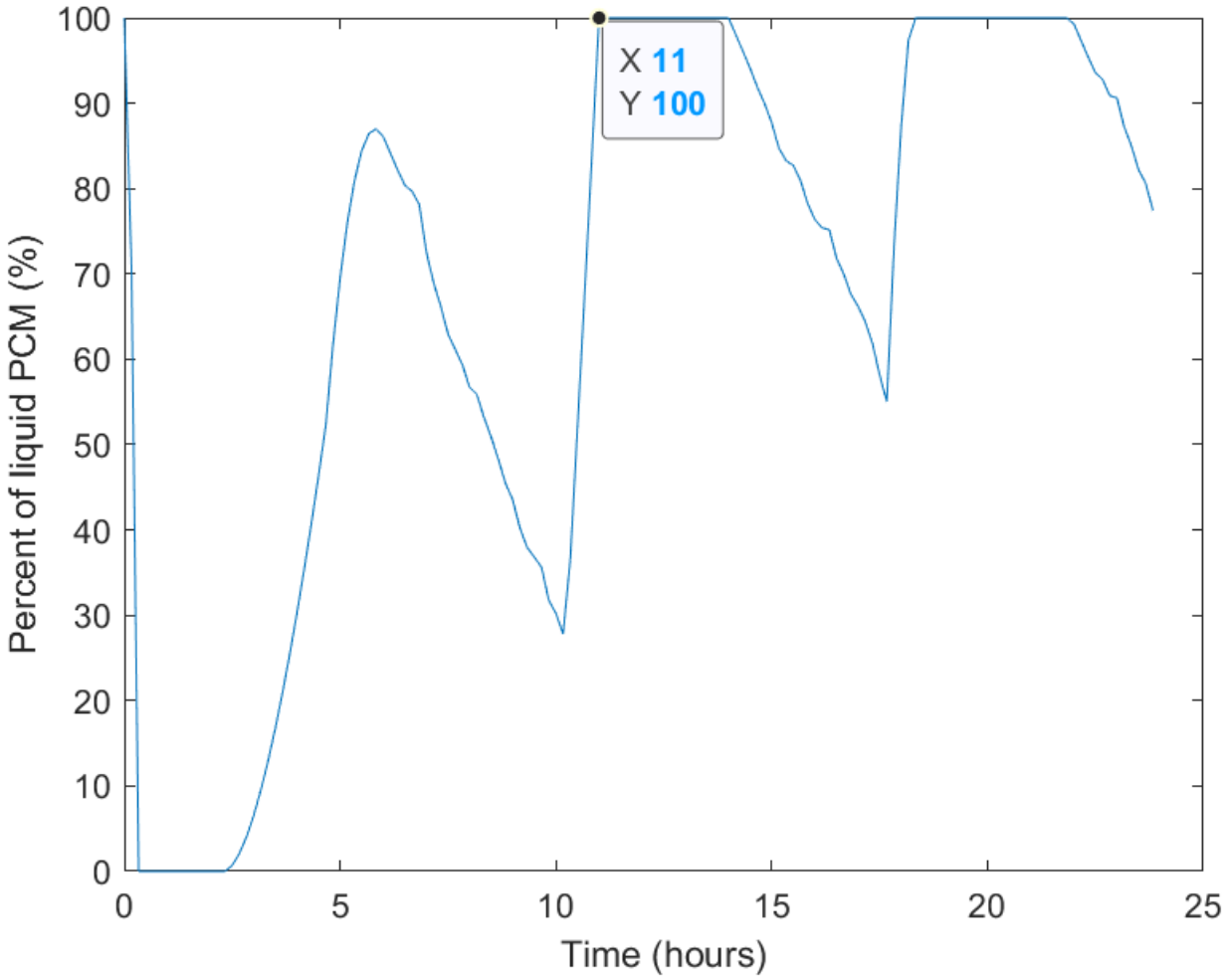

Figure 41 Device with 0.0015m layer of PCM and inner surface to outer surface ratio 6

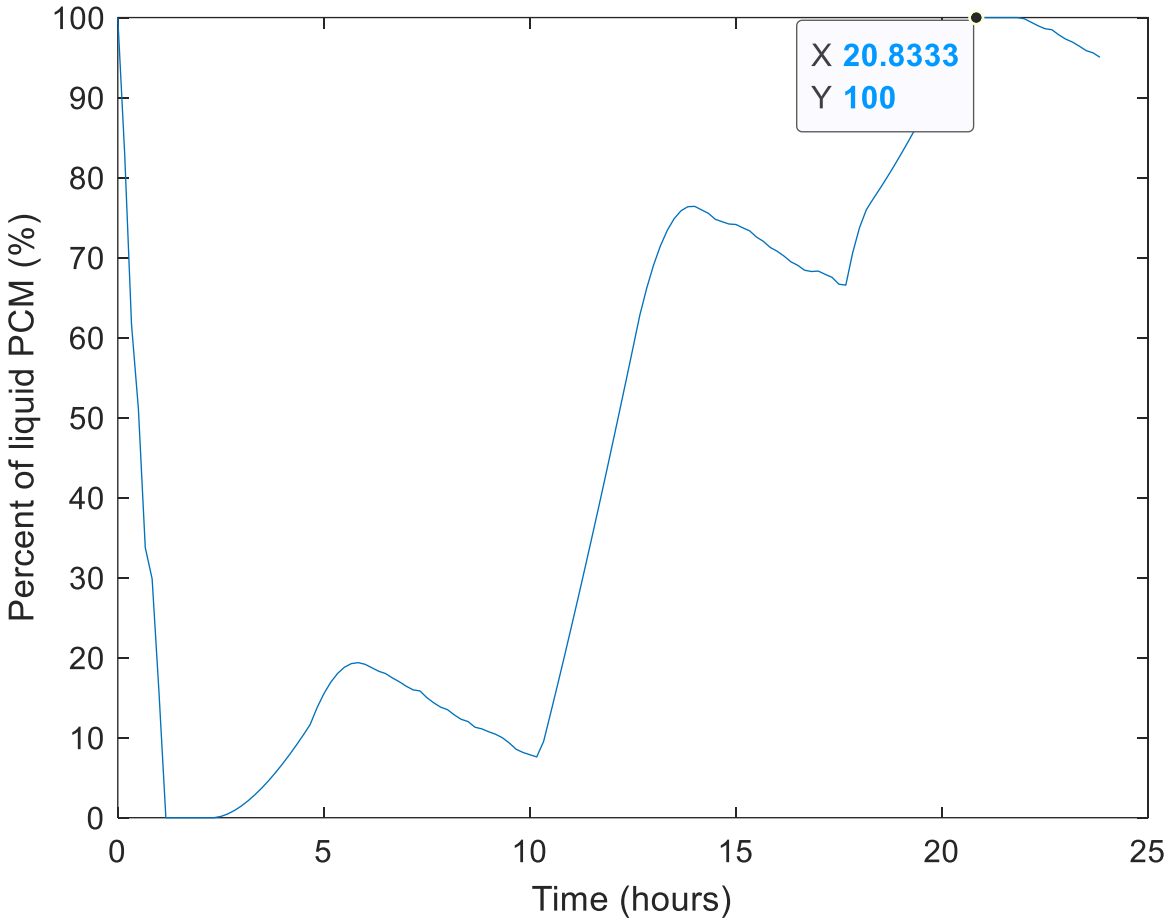

Figure 42 Device with 0.007m layer of PCM and inner surface to outer surface ratio 6

A PCM layer of 0.0015m (Figure 41) melts completely at 11:00 during the second temperature peak (and has a shorter initial freezing time), but a PCM layer of 0.007m (Figure 42) only melts completely at 20:50, which gives the user time to intervene during the period between the midday and evening load shedding period. People may be working away from home during working hours, so the device must be able to protect the medication for this time. However, this compromises the freezing time to 1.5 hours for the PCM to completely solidify (with the inner-to-outer surface area ratio of 6). The user must open the device during the time when the fridge is cool to allow the medication to set for the evening load shedding period. The following figure shows the response of the device when parameters have been adjusted for the temperature changes displayed in Figure 39, where load shedding has occurred, and the user interacts with the device and opens and closes the fridge to retrieve food:

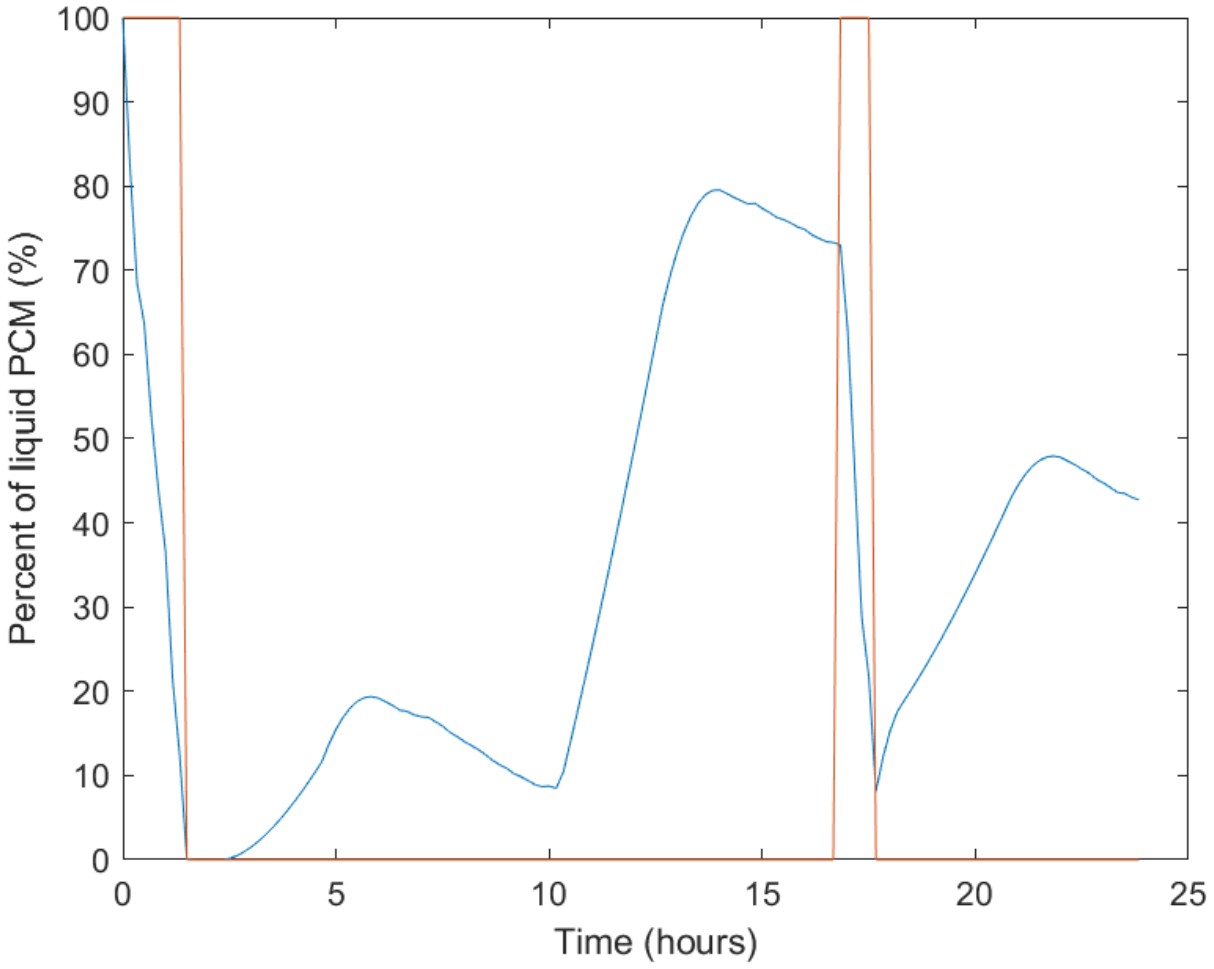

Figure 43 Simulation of device (PCM thickness 0.006m and surface area ratio 6) response during Stage 4 load shedding with user interaction

After initial freezing, which takes approximately 1.5 hours, the device melts to 19% and 79% for the morning and midday load shedding periods respectively. The user must reset the device if they would like the device to last during the afternoon load shedding period. In this simulation, the user opens the fridge and the device while the fridge has power, but because it is assumed the air the within the fridge is exchanged with ambient air and there is not much thermal inertia from an empty fridge, the temperature rises rapidly. Because the inner surface area is exposed and heat exchange occurs rapidly, the device melts rapidly when in contact with warmer air. However, the power is on, and the device sets in one hour—before the following load shedding period (18:00). Appendix D, Figure 57, includes a version of this figure with data points included.

To summarise:

Table 12 Summary of simulated fridge temperature changes for scenario 4

Time of fridge opening	*Reason*	*Effect on temperature profile*
1:00	To simulate that the temperature has risen when user has followed instructions to close device after being set To indicate the approximate time for the device to set and effect it may have on device performance	Small/rapid temperature spike
4:30	To simulate the extended time that the fridge may take to cool down To simulate a user opening in the morning for normal use/to retrieve food after load shedding	Temperature spike at the end of load shedding Longer period to cool down
10:00	To simulate a user opening the fridge for normal use/to retrieve food during load shedding	Temperature rises rapidly and continues to rise during load shedding
15:30	To simulate the user opening the device to let it cool to keep medication cool during the afternoon load shedding period (18:00)	Small/rapid temperature spike
17:00	To simulate closing the device and/or normal refrigerator use in the afternoon	Temperature rises before load shedding, but may not return to setpoint if allows more air to be exchanged during food retrieval

6. Discussion

Each subsequent section has subjected the device to different nonideal temperature conditions with increasing severity. Scenarios 1 to 3 are used as building blocks towards developing a model that simulates conditions that may occur in households in South Africa (Scenario 4)—

incorporating random temperature fluctuations in a fridge, users opening and closing fridges, and power outages. From scenario 1, it was found that the design of the device would prevent temperature failure during normal fridge operation. This is not the objective for designing the device but from the study conducted by (Braune, et al., 2018) and (Heinemann, et al., 2020), insulin is often stored at incorrect temperature ranges even when the refrigerator does not turn off during power outages. Another key finding from Scenario 1 was that the thin layer of PCM was highly sensitive to temperature spikes. Despite having enough PCM to meet the usability criteria, a thin layer of PCM may still pose problems because the device during temperature spikes; a thicker layer of PCM would provide more thermal inertia.

From the simulation of the device behaviour during fridge opening and closing without a power outage (Scenario 2) it was evident that the user behaviour will impact the effectiveness of the device and its ability to meet the usability requirements. As shown in the Figure 30 and Figure 31 depicting the user error cases, instructions for how the device is to be used is crucial to communicate with the intended user. When the final product is developed, a statement of intended purpose/use (which will include the indications for use) is the basis for the instructions for use. Usually, the statement of intended use is prepared by the manufacturer, where a process of usability engineering will define:

- Operating principle
- Use environment
- The intended medical indication
- The intended patient population
- The intended user profiles

This will ensure that the device is up to the relevant standards, such as ISO 14971:2007 (Medical devices – Application of risk management to medical devices); IEC 62366-2:2016 (Medical devices – Part 2: Guidance on the application of usability engineering to medical devices); IEC 62366-1:2015 (Medical devices – Part 1: Application of usability engineering to medical devices). If these standards are applied, the relevant information is supplied to the user, and usability testing is conducted, the information shown in Figure 29 demonstrates that the device certainly will protect medication that must be stored below 8°C since the assumptions applied exaggerated the temperature conditions that the device were subjected to.

Scenario 3 was similar to Scenario 2 but incorporated the change in temperatures over a period of time due to loadshedding. This section utilises literature on developing the temperature profile in a fridge during a power outage (Chojcnacky, et al., 2009). A device with a 0.0015m PCM layer and sixfold inner surface area was able to maintain thermal stability without user intervention during stage 4 load shedding. However, it was observed that the device fails during stage 6 loadshedding with a 0.0015m PCM layer without correct user behaviour. Furthermore, a design with a thicker layer of PCM (0.004m) was tested because the following scenario would present a temperature profile with higher temperatures for longer periods. Testing in this section was used to develop the simulation for correct user behaviour; the user opens the fridge at some point in the day when there is power to open the device to facilitate heat transfer out for the following power outage.

However, it is unrealistic to assume that people do not open their fridge throughout the day (during a power outage or otherwise). The behaviour of people is unpredictable, but the simulation in scenario 4 incorporated several possible behaviours. The behaviour that would most likely exacerbate temperature failure within the device were simulated to ensure the design would work under extreme and unpredictable conditions. Mainly, this simulation included the user opening the fridge after, during, and before a power outage. Air is insulated within the fridge during a power outage as long as the user does not open the fridge; however, opening the fridge towards the end of this period lengthened the period of time to return to the fridge setpoint—leading to an extended period when temperatures within the fridge were elevated. When the user opens the fridge during a power outage, this leads to a high temperature spike that is maintained through the power outage. This situation is when temperature failure is most likely to occur. When the user opens the fridge right before a power outage, the fridge does not have enough time to return down to the setpoint temperature; thus, temperatures increase from an (initial) temperature that is higher than the setpoint temperature until power returns.

As observed in Scenario 3, the device with a 0.0015m of PCM is not able to ensure temperature stability, but a thickness of 0.007m does. The freezing time is compromised from 0.5 hours to 1.5 hours, but this is still an acceptable timeframe for the device to set because the device does not need to completely solidify to keep its contents under 6°C and periods between power outages are 5.5 hours during stage 4 loadshedding. Alternatively, the inner surface area ratio could be increased to further facilitate heat transfer out during cooling periods. In this case, the amplitude and/or the period of the corrugations on the inner surface can be increased slightly.

In summary, the device design that works in protecting medication with stage 4 loadshedding and correct user behaviour is summarised in Table 13:

Table 13 Thicknesses for producing a cubic shaped medical device prototype with dimensions ranging from 10cm to 20cm.

	Value	***Units***
PCM Thickness	0.007	m
Insulating Air Thickness	0.005	m
Outer Plastic Shell Thickness	0.001	m
Middle Plastic Shell Thickness	0.001	m
Inner Plastic Shell Thickness	0.001	m
Averaged Surface Area Ratio (Inner:Outer)	6.00	-

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Chapter 4

CONCLUDING REMARKS AND FUTURE WORK

Feasible design parameters have been found for a storage container utilising C-14 paraffin as phase-change material as a means of thermally stabilising medication stored in a household refrigerator during power disruptions. A simulated prototyping process was conducted using heat transfer modelling.

The initial conceptualisation of the device as a simple box with a layer of PCM between two layers of thermoplastic was not able to satisfy the constraints imposed by the identified problem. The simulated prototyping process showed that the time taken for the initial concept device to freeze would significantly exceed the time it would take to melt once exposed to warmer air. This would not just pose an inconvenience to the user; it would also result in overall thermal failure if the device was subjected to an ongoing cycle of daily power outages, as is the case in South Africa with load shedding. In this scenario, the device must be able to refreeze during windows of time between power outages, and those timeframes will be further limited by limitations on user access, such as being away from home or being asleep. Thermal modelling has been a critical step in the design process and if the initial design was prototyped without the modelling being done, the device would have failed. It has been identified that the root cause of this particular failure is that the temperature difference which drives the freezing process is smaller than that which drives the melting process. The former is constrained to the difference between the fridge temperature and the temperature of phase change, and a natural consequence of the desired operation is that those two temperatures will be close together. The temperature difference that drives the melting process, on the other hand, is not tightly constrained, as it depends instead on the ambient temperature, which is considerably more variable.

This disparity in driving forces could in principle be reduced by selecting a phase change material with a slightly higher melting point, or by modifying the chosen phase change material to raise its melting point slightly. Bringing the melting point as close to the 8°C limit as possible would yield the best theoretical performance, because the temperature difference for freezing would be maximized and the temperature difference for melting would be minimized.

However, this is inadvisable, because heat transfer requires there be at least a slight temperature difference between the interior of the device and the phase change material, which in turn means that during melting, the device interior will be at a slightly higher temperature than the phase change material. Temperature polarization may also occur, resulting in warmer areas within the device interior. Consequently, retaining a safety margin of 2°C is sensible.

It is evident that the device is able to protect temperature sensitive medication during the simulations of the performance of device under fairly hot fridge temperatures. The assumptions in this case exaggerated the fridge temperature profile and these fridge temperatures were rather unlikely to occur except under extreme conditions. An example of this situation occurring is if the user has a relatively empty fridge and lives in a house with inside temperatures similar to the outside which might arise if they leave windows open or have poor insulation. The device must be able to withstand fridge opening and closing under these conditions. In this situation, the design modifications discussed in the simulations must be applied. It was found that the device was able to work if design modifications are intensified and user behaviour/awareness is encouraged.

Since the device is targeted to users in underdeveloped countries that may experience unstable power supply, the target market is likely to have less disposable income and the price should be affordable. Additional marketing research should be conducted to understand the economic situation of the possible stakeholders. Understanding customers such as diabetic insulin users or parents/guardians of diabetics; their knowledge and awareness of storage conditions; the number of affected people, the likeliness and severity of thermal failure in the fridge is part of the commercialization process. Beyond the obvious incentive to the producers/manufacturers of the device to make a profit by commercializing the device, other stakeholders on the consumer side (such as rural clinics, medical practitioners, diabetes awareness organizations or insurance companies that cover medication for chronic diseases such as diabetes) also have an incentive to keep stored medication from degrading.

Experimental values of fridge temperatures during load shedding will help confirm the ideal PCM volume and inner surface ratio and also enable the testing of effectiveness of the visual indicator. However, these simulations show that protecting medications with the device is plausible. it is important to note that the model simulates more extreme external temperature conditions compared to what may occur in a common household fridge to prove that the device can function under the most onerous conditions that may possibly occur. In developing this

device, heat transfer modelling has been a crucial tool as a part of the prototyping process to test the design of the proposed medical device. Many parameters in the design have been tested by modelling rather than experimentally testing a physical prototype. In this way, the number of times the product may need to be iteratively tested and the cost associated with such prototyping and testing is reduced. Initially, if the original design of the device (presented in chapter two) was 3D printed and tested, the product would have failed. This process of simulating the possible temperature changes has significantly reduced the cost of developing the device.

For potentially unstable and high fridge temperatures (simulated in Scenario 4) a thicker PCM and a larger surface area is required. A higher surface area ratio is more difficult to manufacture than a lower surface area ratio and it would be better if the user did not have to interact with the device for ease of usability. This feature cannot be included at this stage of the design without including a temperature sensitive switch, which may include the use of electronics. This would significantly increase the cost of manufacturing, as well as increase manufacturing complexity. For example, electronics must be robust to withstand fridge temperatures. For users, the device needs to either have batteries replaced, or charged—which is inconsistent with the requirement for easy usage during frequent load shedding, since changing an extra device is often inconvenient. Additionally, at the end of the products' life cycle, electronics complicates the disposal of the device.

A revised design was developed, incorporating new heat transfer features to better address the usability criteria for the device by improving heat transfer during the freezing period, when the device is open. These features are an arrangement of internal partition fins, to increase interior surface area, sinusoidal corrugation of those fins to further increase the surface area available for heat transfer, an insulation layer on the exterior surface, and differing skin thickness for the inner and outer surfaces. Through the combination of these features, the heat transfer model indicates that the revised device design has an overall heat transfer coefficient that is 6 times higher when the device is open than when it is closed, which enables it to freeze more rapidly than it melts, even under unusually strenuous conditions.

To understand user awareness and response, I would recommend collecting data from the target market, as well as conducting usability engineering methods such as FMEAs suggested from ISO 62366-1 (Medical devices - Part 1: Application of usability engineering to medical devices). Alternatively, a solution that may warrant further development is the use of a

bimetallic strip to open the lid of the device when the temperature is cold within the fridge and close the device when hot. The challenge with this solution is that the switch could wear out over time and lose tension over multiple uses, reducing the reusability of the device. Another limitation is that the switch would only provide partial airflow during cooling and cannot replace correct user behaviour, since the lid will open but airflow will be limited through a small opening. Additionally, implementing and designing this change could increase the unit cost of the device.

It is important to note that more work is needed to develop and fine tune the visual indicator, since if the visual indicator is not sensitive enough and the beads set before the entire PCM volume has cooled then the user may be under the impression that they may close the box. This is problematic since if the device is partially frozen the device will take longer to freeze the remaining PCM volume. Thus, the protection time is compromised because the PCM is partially melted at the beginning of the power outage. For example, the behaviour of a device that has been closed when partially melted as a result of a random temperature spike is shown in Appendix D, Figure 49 to Figure 52. However, the temperature in device is not an issue, in this situation because, even if the device is partially frozen, the temperature will still be held at the latent heat of fusion. Additional prototyping with non-simulated environments will increase the reliability of the understanding of the behaviour of the device. Thus, during further development, it is important that the visual indicator's PCM melting is contiguous with the melting in the main body of the device.

An added feature that should be incorporated for temperature control is a component preventing temperature failure below 2°C. This component would essentially act as a "thermal ballast" against freezing and could be achieved by incorporating a layer of water into the design. This dissertation primarily deals with temperature failure above 8°C because the issue of power outages is emphasized, but certain storage spaces within a domestic fridge will reach 0°C. If medicine is frozen or partially frozen, the effectiveness may also decrease which could also be problematic. This would not significantly increase the cost per unit since this change would entail one additional thermoplastic shell and water—both of which are not expensive to test and produce. To test this feature, a layer of plastic and water could be incorporated into the heat transfer model and temperatures below 0°C applied to test the performance (internal temperature stability) of the device.

The proposed design of the device has however achieved the desired melting and freezing performance with design parameters within reasonable limits and thus physical prototyping should be the next step.

APPENDICES

Appendix A: Regulatory Pathways Information

Regulatory Compliance Pathway for United States of America (FDA)
(Adapted from: (Snyman, 2021))

Device Classification

1.1.Definition:

- The FDA considers a product to be a device, and subject to FDA regulation, if it meets the definition of a medical device per Section 201(h) of the Food, Drug, and Cosmetic Act.
- Define the product's intended use (the general purpose of the device or its Function—this includes the indications for use) and indication for use (describes the disease or condition the device will diagnose, treat, prevent, cure, or mitigate, including a description of the patient population for which the device is intended) and match it with the definition of your medical device

1.2.Classes:

Federal Food, Drug, and Cosmetic Act, section 513, established the risk-based device classification system for medical devices:

- Class I medical device (low to moderate risk) > General Controls (Device listing, Vigilance etc.
- Class II medical device (moderate to high risk) > General Controls and Special Controls (Performance standards, PMS, Guidelines, etc.)
- Class III medical device (high risk) > General Controls and Premarket Approval (PMA)

2. Establishment Registration and Device Listing

Owners or operators of establishments involved in the production and distribution of medical devices intended for use in the U.S.:

- Required to register and maintain annual fee with the FDA Establishment registration (Title 21 CFR Part 807)
- Fee 2021 ≈ $5550
- Establishments also required to list the devices and activities performed devices.
- If a device requires a premarket submission owner/operator must go through FDA premarket submission process first (510(k), De Novo, PMA, etc.)

3. Device Approval Pathways:

   510(k) notification

   - Based on predicate devices (SE)
   - Class I and II devices (mostly Class II)

   The 510(k) submission includes in summary:

   - Classification of your device
   - Predicate device(s)
   - Final draft labelling
   - Specifications including engineering drawings, photos, etc.
   - Performance data such as bench, animal, or clinical testing (if applicable)
   - Sterilization information (if applicable)
   - Guidance document(s) specific to your device type (if applicable)

   Submit documentation pack with the following headings:

   1) Group A General Information
      - Medical Device User Fee Cover Sheet (Form FDA 3601)
      - CDRH Premarket Review Submission Cover Sheet
      - Cover Letter
   2) Group B Table of Contents
   3) Group C 510(k) Acceptance Checklist
   4) Group D Statement of Indications for Use
   5) Group E Proposed Labelling
   6) Group F 510(k) Summary or Statement
      - A 510(k) Summary is a summary of information upon which you based your claim of substantial equivalence.
   7) The 510(k) Statement is a certification to provide safety and effectiveness information supporting the FDA finding of substantial equivalence within 30 days of a written request.
   8) Group G Truthful and Accurate Statement
   9) Group H Specifications
      - Narrative Description
      - Physical / Technical Description

10) Group I Substantial Equivalence (SE) Comparison

SE can be proven if the device

- has the same intended use as the predicate; and
- has the same technological characteristics as the predicate;

Or

- has the same intended use as the predicate; and
- has different technological characteristics and does not raise different questions of safety and effectiveness; and
- the information submitted to FDA demonstrates that the device is as safe and effective as the legally marketed device.

The following equivalence areas should be considered:

- human factors
- design
- performance
- standards met
- materials
- biocompatibility
- intended use
- indications for use
- target population
- anatomical site where used (hospital, home, ambulance,
- energy used and/or delivered
- sterility
- electrical safety
- mechanical safety
- chemical safety
- thermal safety
- radiation safety

11) Group J Performance

- Performance data to demonstrate SE of your device to one or more legally marketed devices (predicate device).

- Test results from engineering, bench, design verification, human factors, and animal testing, and clinical studies and clinical trials

De Novo

- Novel medical devices
- No legally marketed predicate device
- Risk based classification process

PMA

- Class III medical devices (devices supporting or sustaining human life or preventing impairment of human health, or that may present a potential unreasonable risk of illness or injury)

4. Quality System (QS) Regulation

- FDA uses 21 CFR 820 as quality system guidance.

5. Labelling Requirements

- Labelling regulations pertaining to medical devices are found in the Parts of Title 21 of the Code of Federal Regulations (CFR):
  - General Device Labelling - 21 CFR Part 801
    - Use of Symbols - 21 CFR Part 801.15
- Labelling includes labels on the device as well as descriptive and informational literature that accompanies the device.

6. Medical Device Reporting

- Medical Device Reporting according to 21 CFR Part 803

Regulatory Compliance Pathway for European Union (CE)

Device Classification

- Medical Device Regulation (MDR 2017/745) or
- In Vitro Diagnostics Regulation (IVD 2017/746)
- Definition and classification of your medical device.
  Annex VIII of the Medical Device Regulation (MDR) to classify your medical device according to its risk profile.
- Classification criteria are based on:
  - the duration of contact with the patient,

    - the degree of invasiveness of the device, and
    - the parts of the body affected by use of the device, among other items.

1. The Quality Management System
    - Use ISO 13485 Part A
2. Technical File

   To satisfy MDR Safety and Performance Requirements

- Review Medical Device Regulation (MDR 2017/745) Annex I General safety and performance requirements to ensure that your device meet all requirements relating to its:
    - intended use,
    - safety,
    - labelling and packaging,
    - effects of transportation and storage,
    - and risk versus benefit for the end user.
- The technical file should include (Annex II and III):
    - Product Description and Specifications
    - Manufacturing Information
    - Risk Management File
    - Design Verification and Validation Test Reports
    - Clinical Evaluation
    - Labelling & IFU
    - Post Market Surveillance Information

3. External Audit by Notified Body
    - Notified Body third party company accredited by European competent authorities to conduct audits of medical device companies, and their products and systems.
    - QMS and Technical File audited by Notified Body (SGS, BSI, TUV etc.)
    - Class I devices is self-certified and do not require an audit by a Notified Body (Unless sterile, metrology, re-usable).
    - Fees could range from R80k-R300k depending on size and if technical audits are included.
4. Declaration of Conformity
    - Upon QMS and Technical Files certifications final step is to create a Declaration of Conformity

- Legally binding document declares that your device meets all General Safety and Performance Requirements.
- Affix the CE marking to your product, having established compliance with European regulations.

Appendix B: Calculation for Steady Temperatures

Calculations for device with 1cm of PCM

Constants

Table 14 Table of constants used for calculating heat transfer

polypropylene k (W/m·K)	0.11
air h ($W/m^{2}·K$)	10
Latent heat (kJ/kg)	230
density PCM (kg/m^{3})	763
outer skin (m)	0.001
inner skin (m)	0.001

Table 15.1 Calculations for initial design

		Out		In		
PCM thickness (cm)	PCM volume (V_{out}-V_{in}) m^3	edge (m)	SA	edge (m)	SA	SA ratio
1.00	2.71E-04	0.10	0.06	0.09	0.05	0.81
1.00	3.31E-04	0.11	0.07	0.10	0.06	0.83
1.00	3.97E-04	0.12	0.09	0.11	0.07	0.84
1.00	4.69E-04	0.13	0.10	0.12	0.09	0.85

1.00	5.47E-04	0.14	0.12	0.13	0.10	0.86
1.00	6.31E-04	0.15	0.14	0.14	0.12	0.87
1.00	7.21E-04	0.16	0.15	0.15	0.14	0.88
1.00	8.17E-04	0.17	0.17	0.16	0.15	0.89
1.00	9.19E-04	0.18	0.19	0.17	0.17	0.89
1.00	1.03E-03	0.19	0.22	0.18	0.19	0.90
1.00	1.14E-03	0.20	0.24	0.19	0.22	0.90

Table 15.2 Calculations for initial design (continued)

UoutA	UinA	tmelt (numerator)	tmelt (denominator)	time to melt (hours)	tfreeze (numerator)	tfreeze denominator	time to freeze (hours)	freeze/melt ratio
0.55	0.45	47.56	7.70	6.18	47.56	1.99	23.89	3.87
0.67	0.55	58.09	9.32	6.23	58.09	2.43	23.89	3.83
0.79	0.67	69.67	11.09	6.28	69.67	2.92	23.90	3.80
0.93	0.79	82.30	13.01	6.32	82.30	3.44	23.90	3.78
1.08	0.93	95.99	15.09	6.36	95.99	4.02	23.91	3.76
1.24	1.08	110.73	17.33	6.39	110.73	4.63	23.91	3.74
1.41	1.24	126.53	19.71	6.42	126.53	5.29	23.91	3.73
1.59	1.41	143.38	22.25	6.44	143.38	6.00	23.92	3.71
1.78	1.59	161.28	24.95	6.46	161.28	6.74	23.92	3.70

1.99	1.78	180.23	27.80	6.48	180.23	7.54	23.92	3.69
2.20	1.99	200.23	30.80	6.50	200.23	8.37	23.92	3.68

Appendix C: Supplementary material

This appendix contains material that was used in developing parts of the device or the model

Temperature peaks of fridge opening with food, device response and error cases

The fridge has greater thermal inertia and air temperatures do not rise to ambient temperatures

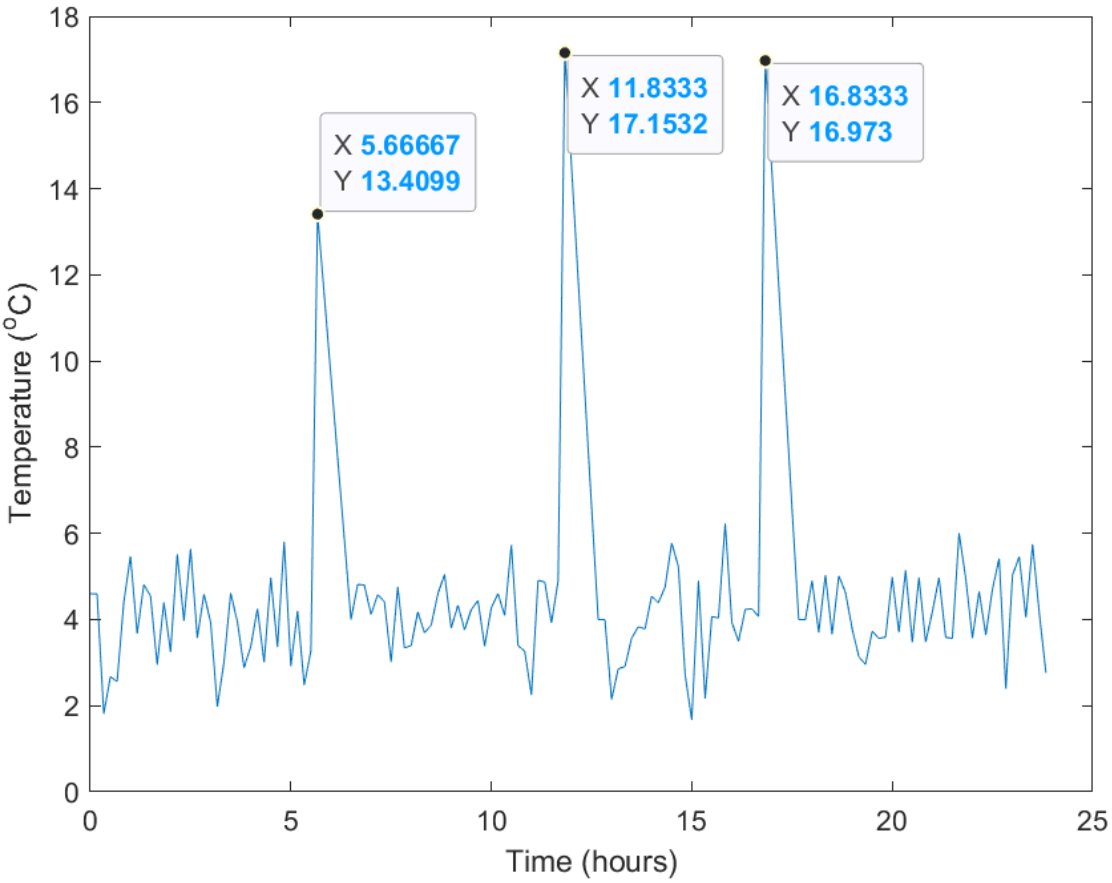

Figure 44 Temperture spikes due to fridge opening/closing with food

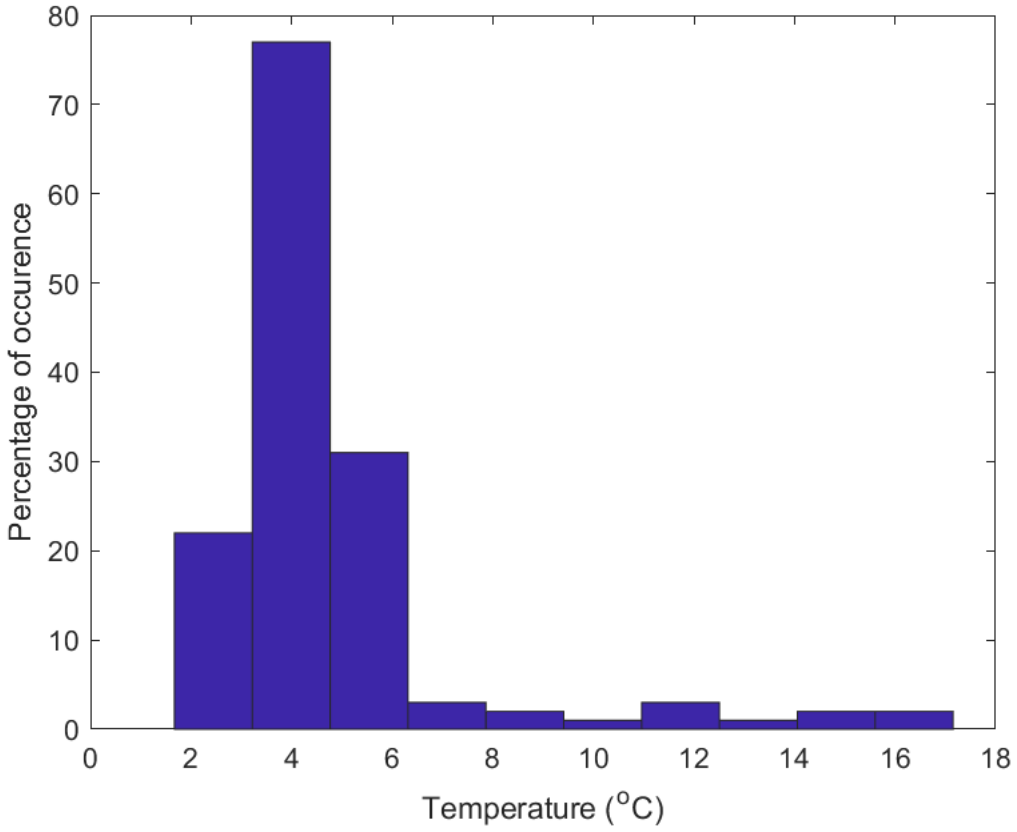

Figure 45 Distribution of tempertures for fridge with thermal ineria from foods

Since the device was tested under hotter conditions, the percentage of melted PCM is less than when the assumption applied (Figure 46). The user error cases are attached in **Error! Reference source not found.**, since they show the same behaviour, but with smaller peaks, than in the hotter fridge temperature.

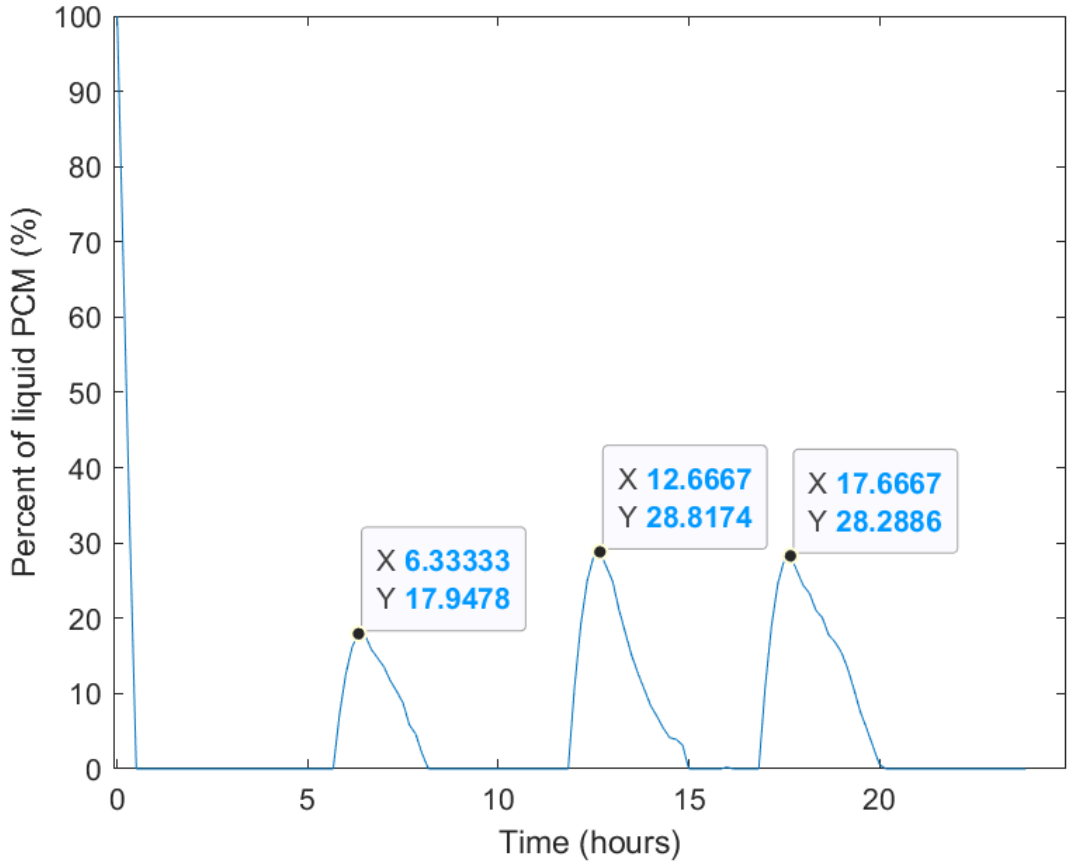

Figure 46 Behaviour of device with smaller temperature spikes

Steps for finding dimensions of corrugations of inner surface

Table 16 Steps for finding dimensions of corrugations of inner surface

Step		Example
1	Choose a value for the cube dimension between 10cm to 20cm as a basis to work from to find the corresponding arclength	I chose 15cm as the dimension of the cube will vary from 10cm to 20cm. This value will let me adjust parameters for the device and see how a smaller device or larger device will behave.
2	Choose a reasonable amplitude that will not impede airflow or restrict the volume within the device (i.e., a small value)	I chose 0.3cm as amplitude for now. If the device is 15cm with a 3 by 3 grid, this means that each compartment in the device is 5cm by 5cm, and from each side 0.3cm is removed from the storage space. Insulin vial diameter is likely not greater than 3cm, so if 0.3cm is used from each side of the inner surface area

		for increased heat transfer, 4.4cm is still available for storage.
3	Divide the dimension chosen by an integer to find a reasonable period that will not impede airflow and is reasonable for molding manufacturing (i.e., a value that is not too small)	I divide the dimension by 10, giving me a period of 15cm/10=1.5cm
4	Use the values in for finding the equation of the sinusoid that will describe the corrugated surface	$y = A\sin(Bx)$ The equation for the sinusoid is $y = 0.3\sin\left(\frac{2pi}{1.5}x\right)$
5	Apply the relevant steps to find the arclength	Find the derivative, apply formula: $r = \int_0^{inner\ length} \sqrt{1 + \left(\frac{dy}{dx}\right)^2}\, dx$ The result is 20.05cm
6	Take the arclength and divide by the inner length to find the ratio of the corrugated surface vs flat surface	20.05cm/15cm=1.33
7	Multiply this ratio by 14/6 to find an estimated of the surface area ratio	1.33*14/6=3.11
8	Restart at step 2 and adjust period and amplitude until step 7 yields approximately 6. Preferably, more than 6 since this is an approximation and the actual device outer surface area will be larger because the insulation and layers of plastic will increase the outer dimension	In this case the ratio is too low, so I increase the amplitude and decrease the period. I eventually settle on an amplitude of 0.825cm and a period of 1.25cm (15cm/12) that gives me an approximate inner to outer surface ratio of 6.849
9	Find the precise inner to outer surface area ratio using these steps: **9.1.** Find the area of one interior side (arclength*width)	**9.1.** 44.03216974cm * 15cm = 660.4825461cm^2 **9.2.**

	9.2. Multiply by the number of exposed interior sides (6 sides inside a cube + 4 fins to form grid*2) **9.3.** Find the area of one exterior surface (inner length + thickness of inner shell + thickness of PCM + thickness of middle shell + thickness of insulating air + thickness of outer shell)^2 **9.4.** Find the total exterior area (one exterior area*6) **9.5.** Divide total inner surface area by total outer surface area	660.4825461cm^2 * 14 = 9246.755646cm^2 **9.3.** [15cm +0.1cm +0.015cm +0.1cm +0.5cm +0.1cm]^2 = [15.95cm]^2 = 254.4025 cm^2 **9.4.** 6*254.4025 cm^2 = 1526.415 cm^2 **9.5.** 9246.755646cm^2/1526.415 cm^2 = 6.0578
10.	The surface area ratio has been achieved for a 15cm cubic device, but to generalize for the device from 10cm to 20cm, use the values found to create a relationship between the amplitude and the period, and the period and the length.	I have settled on an amplitude of 0.825cm and period of 1.25cm. I do not want these dimensions to scale with the cube, because if the box is 10cm less airflow will occur—airflow does not scale with the box. Thus, I can determine that the amplitude should be about 0.66 of the period. I have settled on a period of 1.25, which is 12 repeated sine waves with 15cm. Therefore, I can determine that the number of periods within a given length of the device is 0.8 (12/15) of the inner length. I apply these rules to the worksheet and see this heuristic does keep the inner to outer surface area ratio around 6 (the average value is 6.02)

Cartesian equation, code, and graphs for "egg carton" surface

An "egg carton" surface is formed by superimposing 2 corrugated surfaces at 90° on the same plane—i.e., the surface that is obtained by translating a sinusoid along another isometric sinusoid, perpendicularly (Ferreol & Mandonnet, 2017).

Equation 19

$$z = A\,[sin(\frac{x}{b})) + sin\,(\frac{y}{b})]$$

```
clear
clc
x=[0:0.01:15];
y=[0:0.01:15];
[wx,wy]=meshgrid(x,y);
a=.825/2;
b=(2*pi/1.25)^-1;
a= .5 %.6
b = .1
z=a*(sin(wx/b)+sin(wy/b)) % for a "egg carton" surface, formed by
superimposing 2 corrugated surfaces at 90° on the same plane—i.e., the surface
that is obtained by translating a sinusoid along another isometric sinusoid,
perpendicularly.
% a*(sin(wx/b))+ a for single axis corrugation
fig=surfl(wx,wy,abs(z))
axis([0 2 0 2 0 2]);
xlabel('Length (cm)')
ylabel('Width (cm)')
zlabel('Height (cm)')
shading interp;
colormap default;
```

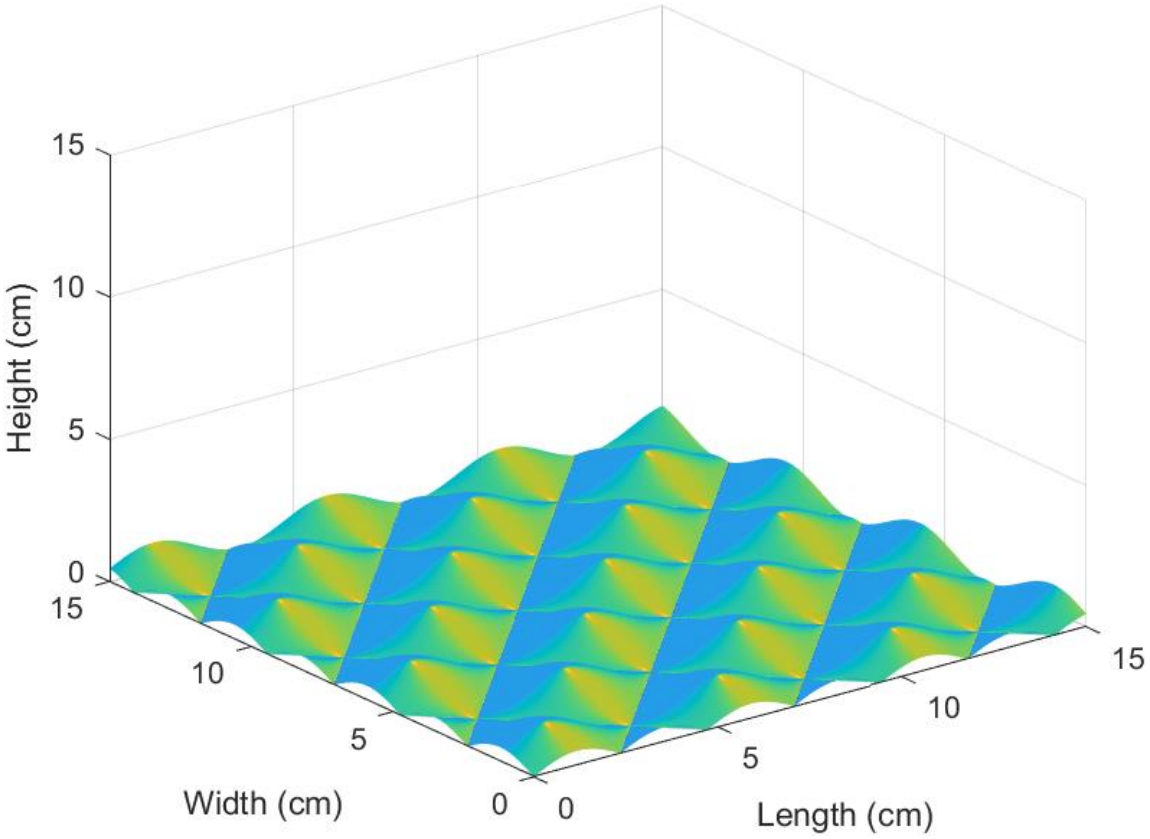

Figure 47 Example of dimpled "egg carton" surface applied to one surface

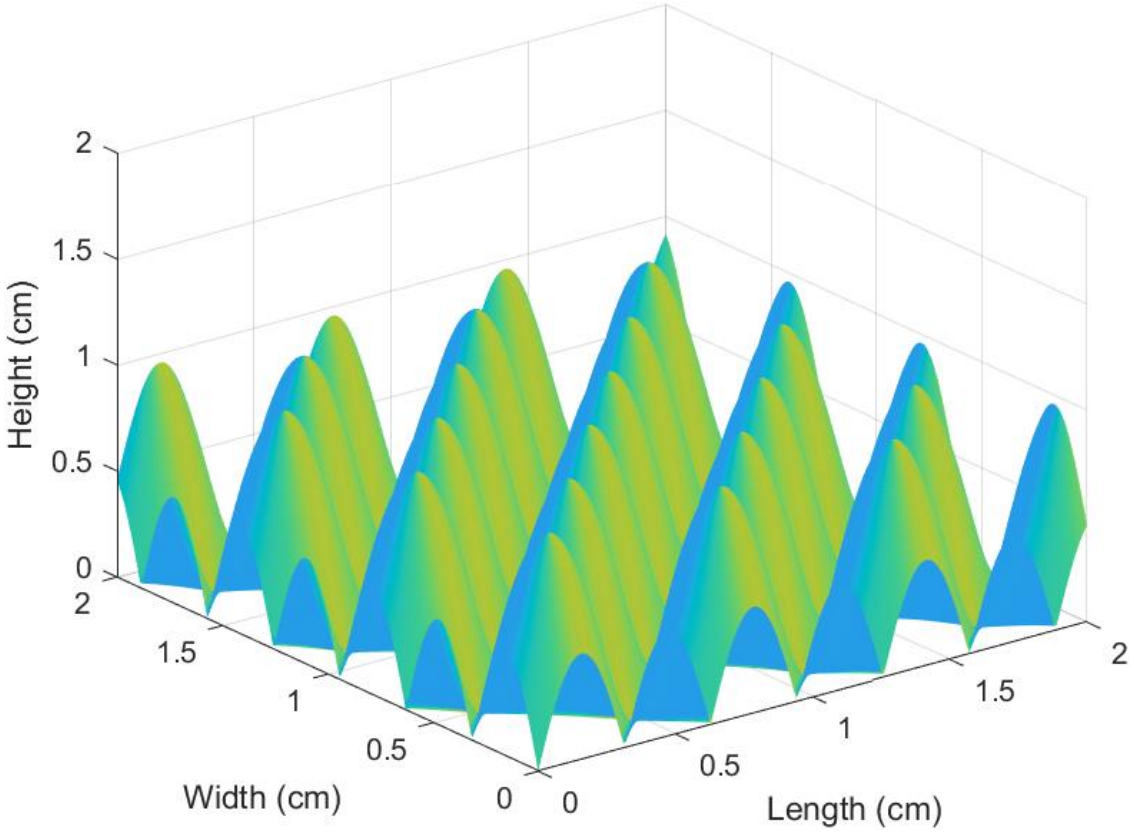

Figure 48 Dimpled surface geometry (not to scale)

Code for generating an ambient temperature profile

```
function [TProfile] = TProfile(midnight,amplitude,timeIn)
%This function generates an ambient temperature profile given the midnight
temperature and the temperature difference in a 24 hour period starting at
midnight
time=timeIn'.*(288/size(timeIn,2));
a= -0.000000000000198971255;
b= 0.000000001919784925O8;
c= -0.000000666959861091S1;
d= 0.000096454303741389O0;
e= -0.004645394676018100O0;
f= 0.004420415762979250O0;

TProfile=amplitude/12*(a*(time.^6)+b*(time.^5)+c*(time.^4)+d*(time.^3)+e*t
ime.^2+f.*time)+midnight;%The parameters were initially fitted to a
day/night temperature swing of 12

End
```

Appendix D: Code for Dynamic Tempertures

Scenario 1: Power on and no opening/closing

```
clear;

clc;

polyprop_k=0.00011; %(kW/mK)

air_h=.01; %(kW/m^2K)

air_k=.000025; %(kW/mK)

Latent_heat=230; %(kJ/kg)

rho_PCM=763;  %(kg/m^3)

d_out=0.001; %m

d_air=0.005; %m

d_mid=0.001; %m

PCM_thickness=0.0015; %m

d_in=0.001; %m

c=6; %Inner surface area multiplier

L_out = .15; %m

L_mid = L_out-(d_out+d_air);

L_in = L_out-(d_out+d_air+d_mid+PCM_thickness);

PCM_Volume = (L_mid-d_mid)^3-L_in^3;%total volume


intervals=144;


step=600;%seconds
time = 0:step:step*intervals-1


mean_temp = 5;
T_fridge = T_fridge_sim(intervals,step,mean_temp)

plot(time/3600,T_fridge)

xlabel('Time (hours)')

ylabel("Temperature (^oC)")

hist(T_fridge)

xlabel('Time (hours)')

ylabel("Temperature (^oC)")

T_phasechange=6; %degC
```

```
delT= T_fridge-T_phasechange;


%SolidPCM = PCM_Volume


SA_out = 6*L_out^2;
SA_in = 6*(L_in-d_in)^2*c;

UoutA =
SA_out/(d_mid/polyprop_k+1/air_h+d_air/air_k+1/air_h+d_out/polyprop_k+1/air_h)
;

UinA = SA_in/(d_in/polyprop_k+1/air_h);



dQm = UoutA*delT;
dQf = UinA*delT;



Qm = dQm*step;
Qf = dQf*step;



mPCM_melt = Qm/Latent_heat;
mPCM_freeze = Qf/Latent_heat;
```

Open device

```
%Device is open and PCM starts melted, this is the base for user error 1

Open=ones(1,intervals+1);

SolidPCM = 0

for i=1:intervals-1

V_PCM_c = mPCM_melt/rho_PCM;

V_PCM_o = -mPCM_freeze/rho_PCM;

    if (Open(i)==1) %it's open so we use 'freeze' quantity even if melting is
occurring. If melting is happening, freeze volume will be negative and so
solid volume will decrease.

    SolidPCM(i+1)=SolidPCM(i)+V_PCM_o(i);

        if SolidPCM(i+1)>PCM_Volume;

        SolidPCM(i+1)=PCM_Volume;

        end

        if SolidPCM(i+1)<=0

        SolidPCM(i+1)=0;

        end
```

```
    end
    if (Open(i)==0) %it's closed so we use 'melt' quantity even if freezing is
occurring. We subtract the volume that melts so if it's surprisingly cold then
the solid volume will increase.
    SolidPCM(i+1)=SolidPCM(i)-V_PCM_c(i);
        if SolidPCM(i+1)<=0
        SolidPCM(i+1)=0;
        end
        if SolidPCM(i+1)>PCM_Volume
        SolidPCM(i+1)=PCM_Volume;
        end
    end
end


%disp(SolidPCM)
percent_change = ((PCM_Volume-SolidPCM)/PCM_Volume)*100;
xaxistime = seconds(time);
xaxistime = time/3600
plot(xaxistime,percent_change);
xlabel("Time (hours)")
ylabel("Percent of liquid PCM (%)")
```

Device closed after freezing

```
%This represents closing after PCM is frozen
Open = [ones(1,9) zeros(1,144-9)]
for i=1:intervals-1
V_PCM_c = mPCM_melt/rho_PCM;
V_PCM_o = -mPCM_freeze/rho_PCM;
    if (Open(i)==1) %it's open so we use 'freeze' quantity even if melting is
occurring. If melting is happening, freeze volume will be negative and so
solid volume will decrease.
    SolidPCM(i+1)=SolidPCM(i)+V_PCM_o(i);
        if SolidPCM(i+1)>PCM_Volume;
        SolidPCM(i+1)=PCM_Volume;
        end
        if SolidPCM(i+1)<=0
```

```
        SolidPCM(i+1)=0;
        end
    end
    if (Open(i)==0) %it's closed so we use 'melt' quantity even if freezing is
occurring. We subtract the volume that melts so if it's surprisingly cold then
the solid volume will increase.
    SolidPCM(i+1)=SolidPCM(i)-V_PCM_c(i);
        if SolidPCM(i+1)<=0
        SolidPCM(i+1)=0;
        end
        if SolidPCM(i+1)>PCM_Volume
        SolidPCM(i+1)=PCM_Volume;
        end
    end
end


%disp(SolidPCM)
percent_change = ((PCM_Volume-SolidPCM)/PCM_Volume)*100;
xaxistime = seconds(time);
xaxistime = time/3600
plot(xaxistime,percent_change);
xlabel("Time (hours)")
ylabel("Percent of liquid PCM (%)")
```

Device closed and liquid PCM

```
%This is the base for user error 2
Open = zeros(1,intervals+1);
for i=1:intervals-1
V_PCM_c = mPCM_melt/rho_PCM;
V_PCM_o = -mPCM_freeze/rho_PCM;
    if (Open(i)==1) %it's open so we use 'freeze' quantity even if melting is
occurring. If melting is happening, freeze volume will be negative and so
solid volume will decrease.
    SolidPCM(i+1)=SolidPCM(i)+V_PCM_o(i);
        if SolidPCM(i+1)>PCM_Volume;
        SolidPCM(i+1)=PCM_Volume;
```

```
        end
        if SolidPCM(i+1)<=0
        SolidPCM(i+1)=0;
        end
    end
    if (Open(i)==0) %it's closed so we use 'melt' quantity even if freezing is
occurring. We subtract the volume that melts so if it's surprisingly cold then
the solid volume will increase.
    SolidPCM(i+1)=SolidPCM(i)-V_PCM_c(i);
        if SolidPCM(i+1)<=0
        SolidPCM(i+1)=0;
        end
        if SolidPCM(i+1)>PCM_Volume
        SolidPCM(i+1)=PCM_Volume;
        end
    end
end


%disp(SolidPCM)
percent_change = ((PCM_Volume-SolidPCM)/PCM_Volume)*100;
xaxistime = seconds(time);
xaxistime = time/3600
plot(xaxistime,percent_change);
xlabel("Time (hours)")
ylabel("Percent of liquid PCM (%)")
```

Random temperature spike has caused the device's PCM to partially melt

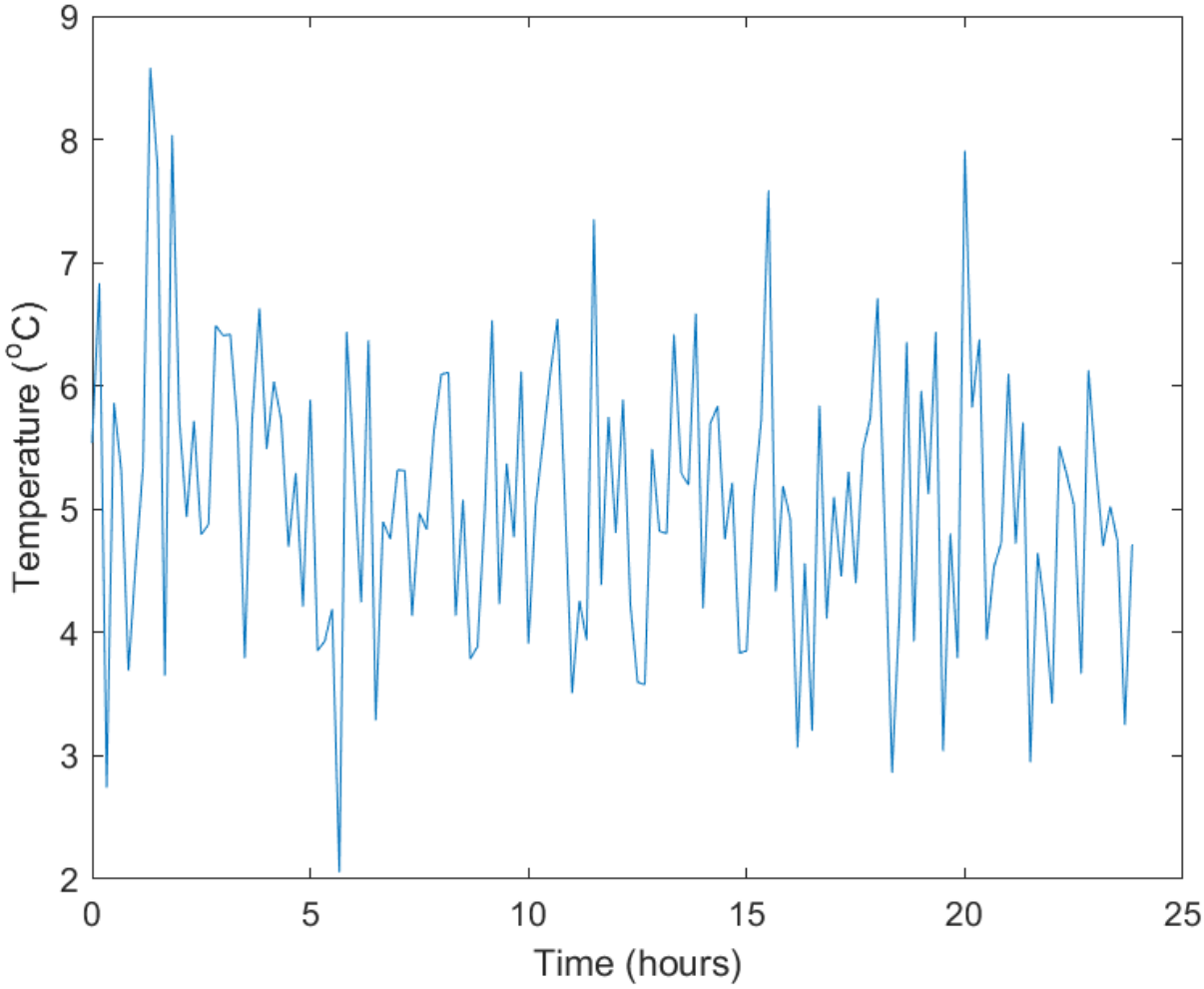

Figure 49 Fridge internal temperature: Simulated temperature profile that causes the PCM to partially melt before closing

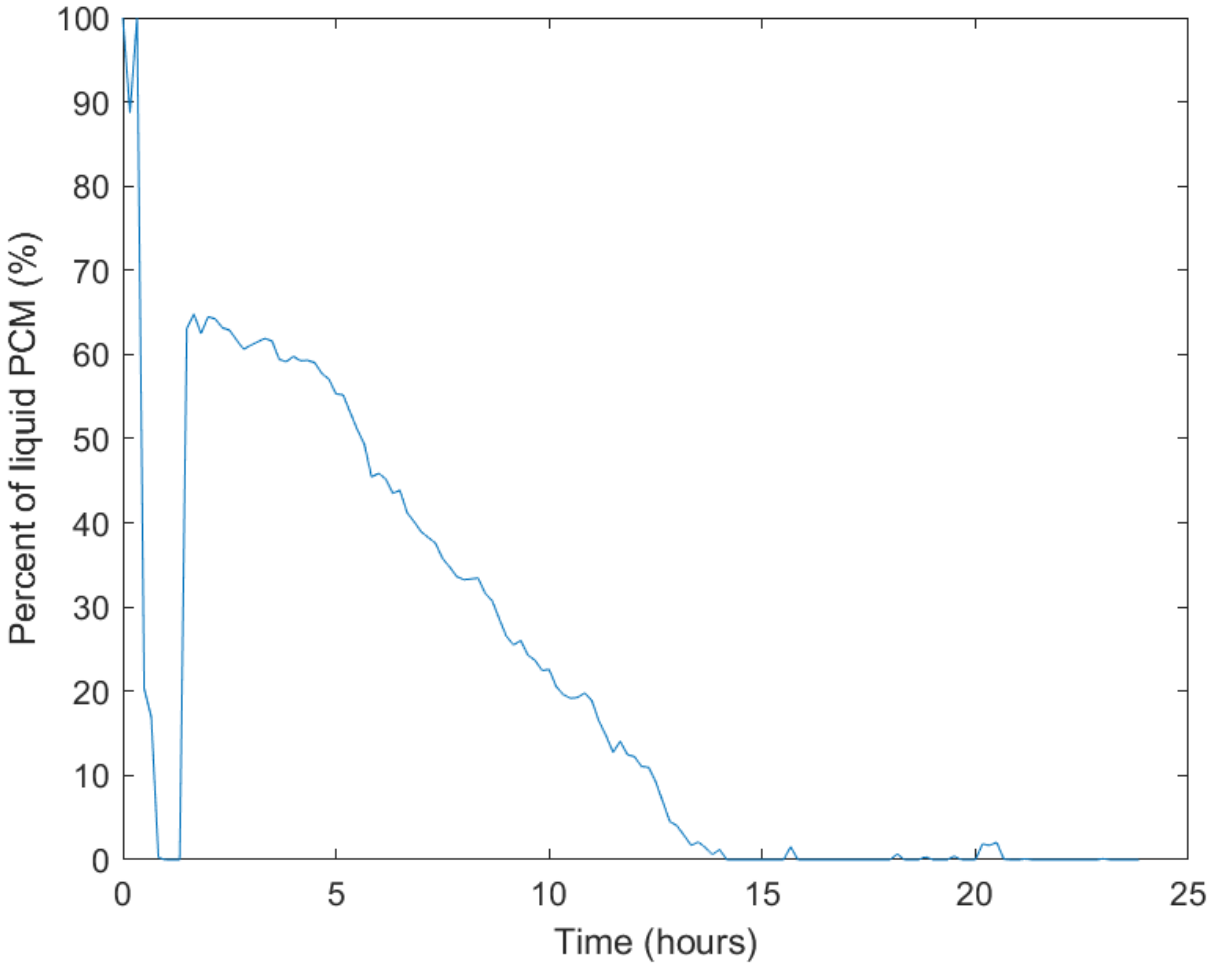

Figure 50 Device response when closed during freezing

User error theoretical behaviour

Theoretical behaviour of device if user incorrectly places device with liquid PCM and closed, so only outer surface area heat exchange occurs, or the device is left open so that the internal temperate of the device is essentially the same as the internal temperature of the fridge. The related code is used in other scenarios to simulate user interaction during opening and closing.

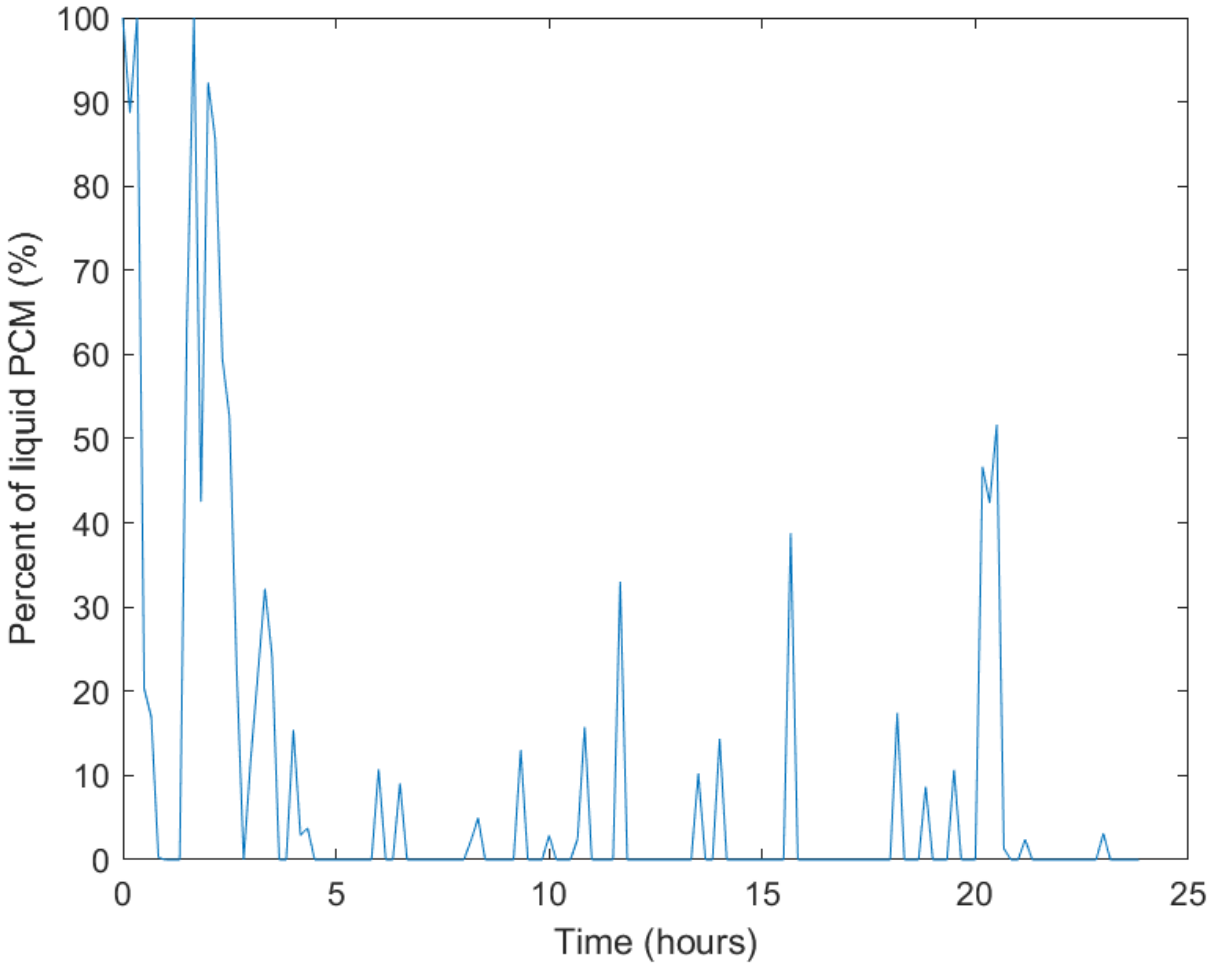

Figure 51 User error case 1: Device response when open

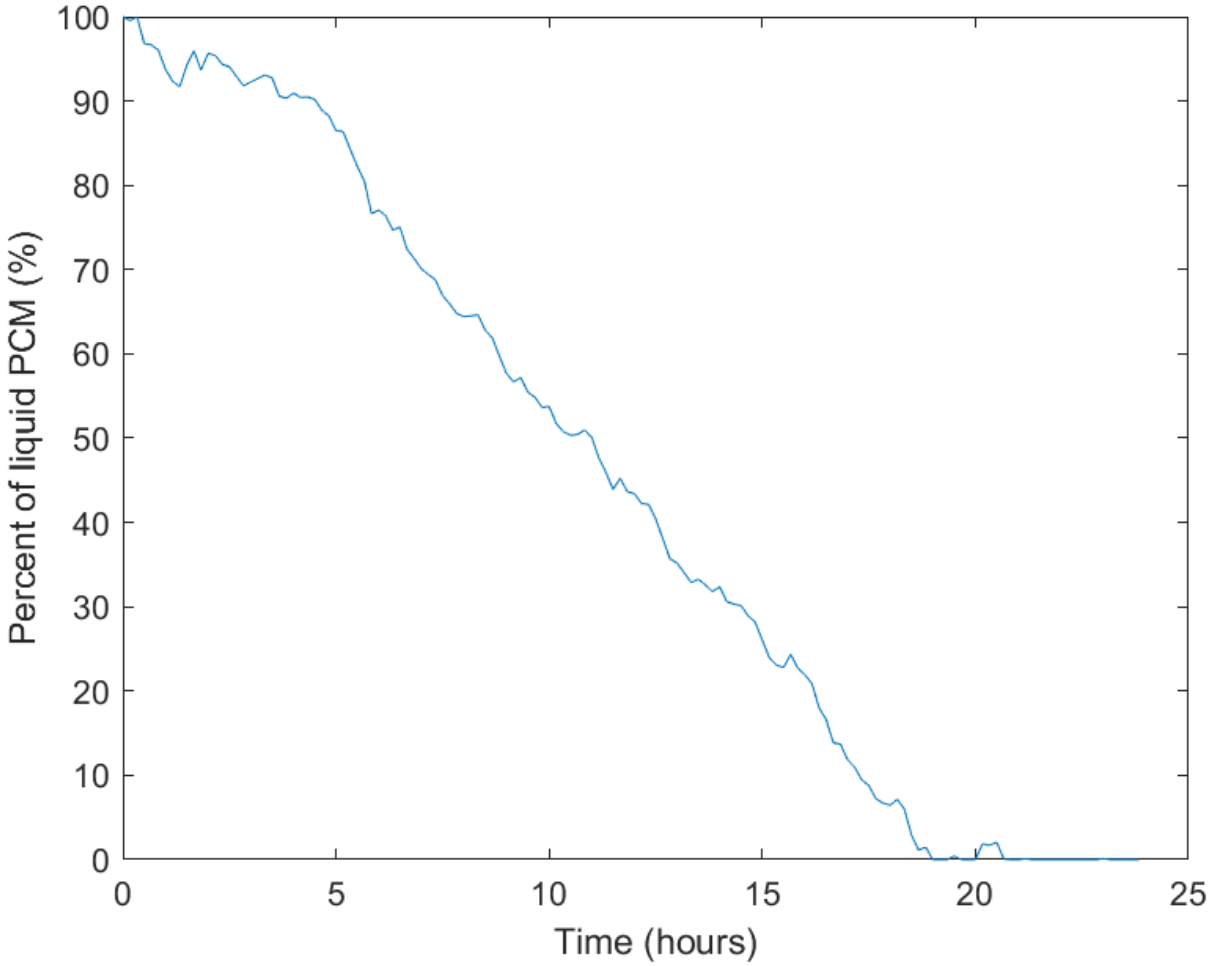

Figure 52 User error case 2: Device response when closed

Scenario 2: Power on with opening/closing

```
clear;
clc;
polyprop_k=0.00011; %(kW/mK)
air_h=.01; %(kW/m^2K)
air_k=.000025; %(kW/mK)
Latent_heat=230; %(kJ/kg)
rho_PCM=763;  %(kg/m^3)
d_out=0.001; %m
d_air=0.005; %m
d_mid=0.001; %m
PCM_thickness=0.0015; %m
d_in=0.001; %m
```

```
c=6; %Inner surface area multiplier

L_out = .15; %m

L_mid = L_out-(d_out+d_air);

L_in = L_out-(d_out+d_air+d_mid+PCM_thickness);

PCM_Volume = (L_mid-d_mid)^3-L_in^3;%total volume
```

Fridge temperature during loadshedding

This section creates the temperature profiles

```
intervals=144;
step=600;

time = 0:step:step*intervals-1;

w = 3600;

s = -.85;

t_morning = 3600*6;

t_midday = 12*3600;

t_evening = 17*3600;

x1 = 15.89*tripuls(time-t_morning,w,s)+4;

x2 = 24.2*tripuls(time-t_midday,w,s)+4;

x3 = 23.8*tripuls(time-t_evening,w,s)+4;

plot(time/3600,x1);

hold on

plot(time/3600,x2);

plot(time/3600,x3);

hold off


T_fridge_norm = T_fridge_sim(144,1,4);
n0 = T_fridge_norm(1:34);

p1 = x1(35:34+6);

n1 = T_fridge_norm(40:70);

p2 = x2(71:71+6);

n2 = T_fridge_norm(78:100);

p3 = x3(101:101+6);

n3 = T_fridge_norm(109:144);
```

```
T_sim_O_C = [n0 p1 n1 p2 n2 p3 n3]
plot(time/3600,T_sim_O_C)

xlabel('Time (hours)')

ylabel("Temperature (^oC)")

hist(T_sim_O_C)

xlabel('Temperature (^oC)')

ylabel('Percentage of occurence')
```

This section sets up the device behaviour

```
T_phasechange=6; %degC


T_fridge = T_sim_O_C;
delT= T_fridge-T_phasechange;


%SolidPCM = PCM_Volume


SA_out = 6*L_out^2;
SA_in = 6*(L_in-d_in)^2*c;

UoutA =
SA_out/(d_mid/polyprop_k+1/air_h+d_air/air_k+1/air_h+d_out/polyprop_k+1/air_h)
;

UinA = SA_in/(d_in/polyprop_k+1/air_h);


dQm = UoutA*delT;
dQf = UinA*delT;


Qm = dQm*step;
Qf = dQf*step;


mPCM_melt = Qm/Latent_heat;
mPCM_freeze = Qf/Latent_heat;
```

Open device

```
Open=ones(1,intervals+1);

SolidPCM = 0

for i=1:intervals-1
```

```
V_PCM_c = mPCM_melt/rho_PCM;

V_PCM_o = -mPCM_freeze/rho_PCM;

    if (Open(i)==1) %it's open so we use 'freeze' quantity even if melting is
occurring. If melting is happening, freeze volume will be negative and so
solid volume will decrease.

    SolidPCM(i+1)=SolidPCM(i)+V_PCM_o(i);

        if SolidPCM(i+1)>PCM_Volume;

        SolidPCM(i+1)=PCM_Volume;

        end

        if SolidPCM(i+1)<=0

        SolidPCM(i+1)=0;

        end

    end

    if (Open(i)==0) %it's closed so we use 'melt' quantity even if freezing is
occurring. We subtract the volume that melts so if it's surprisingly cold then
the solid volume will increase.

    SolidPCM(i+1)=SolidPCM(i)-V_PCM_c(i);

        if SolidPCM(i+1)<=0

        SolidPCM(i+1)=0;

        end

        if SolidPCM(i+1)>PCM_Volume

        SolidPCM(i+1)=PCM_Volume;

        end

    end

end


%disp(SolidPCM)
percent_change = ((PCM_Volume-SolidPCM)/PCM_Volume)*100;

xaxistime = seconds(time);

xaxistime = time/3600;

plot(xaxistime,percent_change);

xlabel("Time (hours)")

ylabel("Percent of liquid PCM (%)")
```

Device closed after freezing

```
Open = [ones(1,9) zeros(1,144-9)]
for i=1:intervals-1
```

```
V_PCM_c = mPCM_melt/rho_PCM;

V_PCM_o = -mPCM_freeze/rho_PCM;

    if (Open(i)==1) %it's open so we use 'freeze' quantity even if melting is
occurring. If melting is happening, freeze volume will be negative and so
solid volume will decrease.

    SolidPCM(i+1)=SolidPCM(i)+V_PCM_o(i);

        if SolidPCM(i+1)>PCM_Volume;

        SolidPCM(i+1)=PCM_Volume;

        end

        if SolidPCM(i+1)<=0

        SolidPCM(i+1)=0;

        end

    end

    if (Open(i)==0) %it's closed so we use 'melt' quantity even if freezing is
occurring. We subtract the volume that melts so if it's surprisingly cold then
the solid volume will increase.

    SolidPCM(i+1)=SolidPCM(i)-V_PCM_c(i);

        if SolidPCM(i+1)<=0

        SolidPCM(i+1)=0;

        end

        if SolidPCM(i+1)>PCM_Volume

        SolidPCM(i+1)=PCM_Volume;

        end

    end

end


%disp(SolidPCM)
percent_change = ((PCM_Volume-SolidPCM)/PCM_Volume)*100;

xaxistime = seconds(time);

xaxistime = time/3600;

plot(xaxistime,percent_change);

xlabel("Time (hours)")

ylabel("Percent of liquid PCM (%)")
```

Device closed and liquid PCM

```
Open = zeros(1,intervals+1);
for i=1:intervals-1
```

```
V_PCM_c = mPCM_melt/rho_PCM;

V_PCM_o = -mPCM_freeze/rho_PCM;

    if (Open(i)==1) %it's open so we use 'freeze' quantity even if melting is
occurring. If melting is happening, freeze volume will be negative and so
solid volume will decrease.

    SolidPCM(i+1)=SolidPCM(i)+V_PCM_o(i);

        if SolidPCM(i+1)>PCM_Volume;

        SolidPCM(i+1)=PCM_Volume;

        end

        if SolidPCM(i+1)<=0

        SolidPCM(i+1)=0;

        end

    end

    if (Open(i)==0) %it's closed so we use 'melt' quantity even if freezing is
occurring. We subtract the volume that melts so if it's surprisingly cold then
the solid volume will increase.

    SolidPCM(i+1)=SolidPCM(i)-V_PCM_c(i);

        if SolidPCM(i+1)<=0

        SolidPCM(i+1)=0;

        end

        if SolidPCM(i+1)>PCM_Volume

        SolidPCM(i+1)=PCM_Volume;

        end

    end

end


%disp(SolidPCM)
percent_change = ((PCM_Volume-SolidPCM)/PCM_Volume)*100;

xaxistime = seconds(time);

xaxistime = time/3600;

plot(xaxistime,percent_change);

xlabel("Time (hours)")

ylabel("Percent of liquid PCM (%)")
```

Scenario 2: User error during fridge opening and closing with lower temperatures

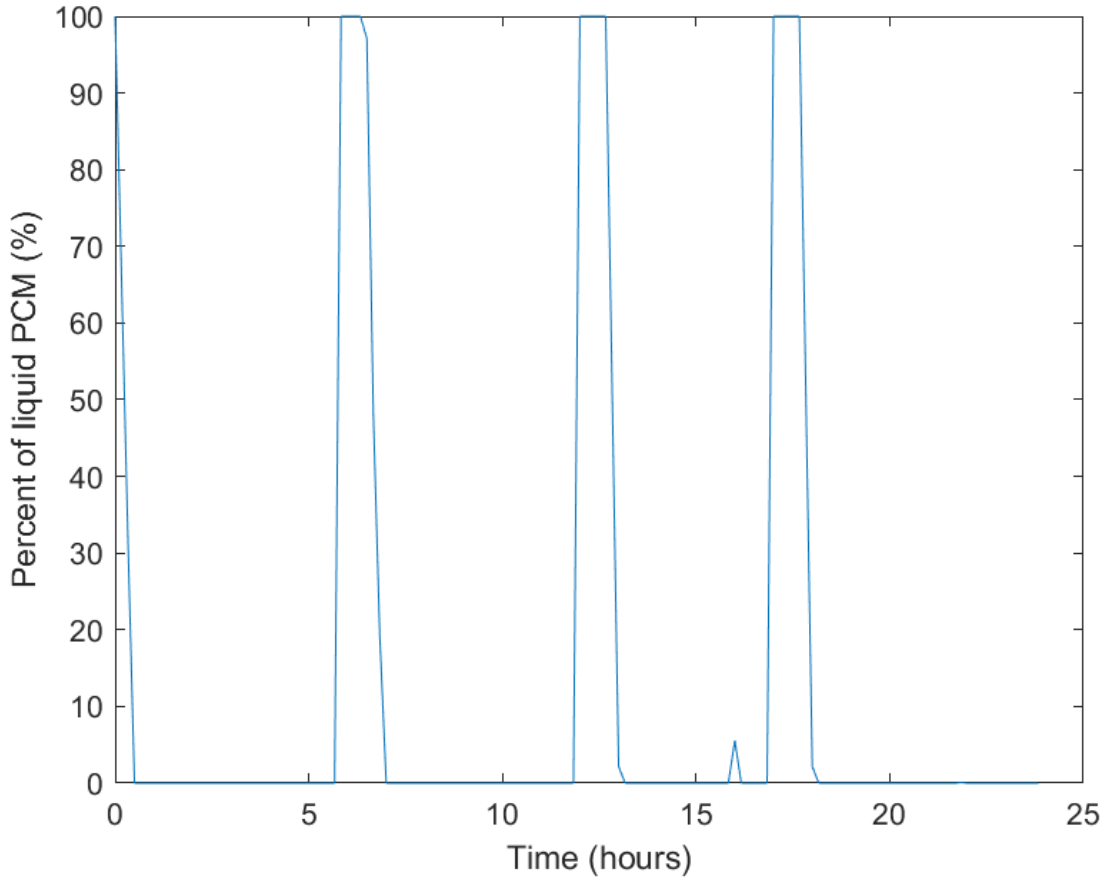

Figure 53 User error case 1

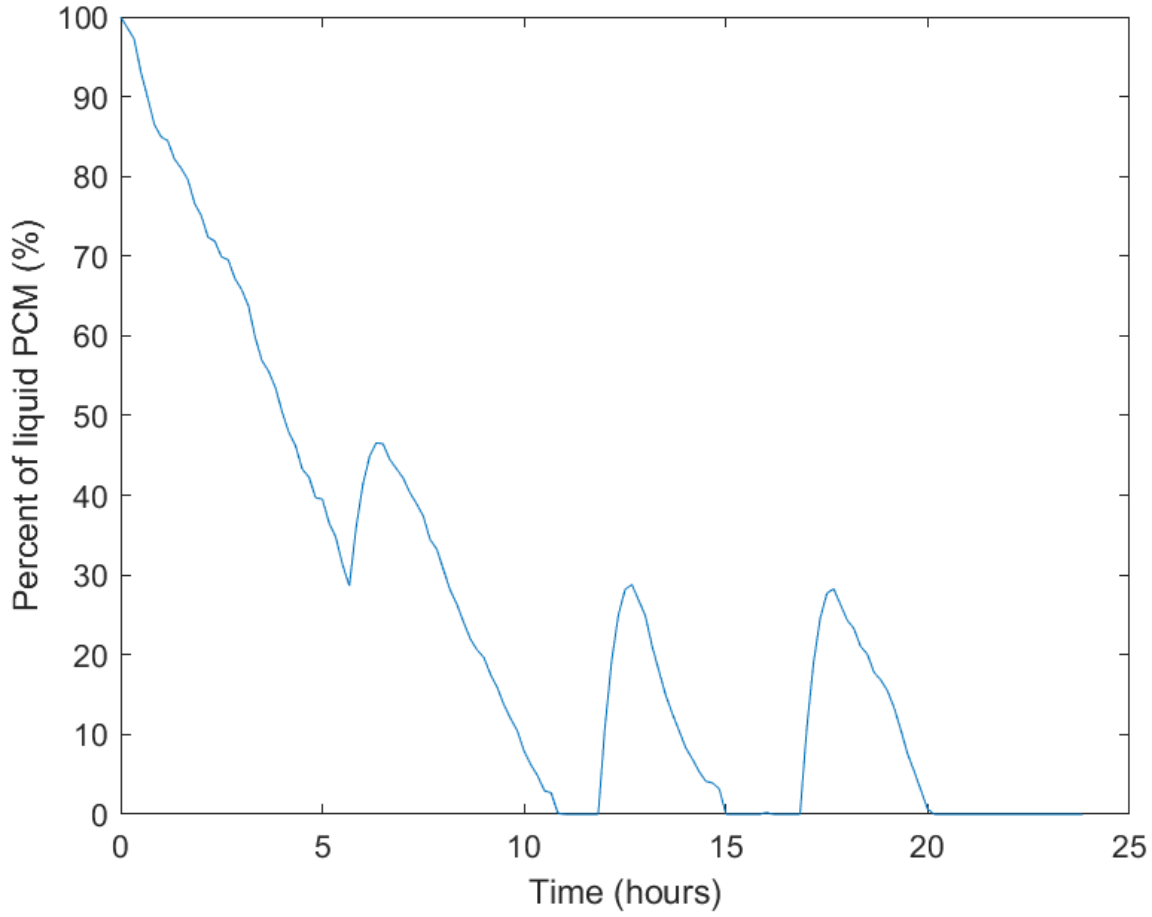

Figure 54 User error case 2

Scenario 3: Power off without opening/closing

```
clear;

clc;

polyprop_k=0.00011; %(kW/mK)

air_h=.01; %(kW/m^2K)

air_k=.000025; %(kW/mK)

Latent_heat=230; %(kJ/kg)

rho_PCM=763;  %(kg/m^3)

d_out=0.001; %m

d_air=0.005; %m

d_mid=0.001; %m

PCM_thickness=0.0015; %m

d_in=0.001; %m

c=6; %Inner surface area multiplier
```

```
L_out = .15; %m

L_mid = L_out-(d_out+d_air);

L_in = L_out-(d_out+d_air+d_mid+PCM_thickness);

PCM_Volume = (L_mid-d_mid)^3-L_in^3;%total volume
```

Fridge Temperature with opening/closing events

This section creates the temperature profiles

```
intervals=144;

step=10;

time = 0:step:step*intervals-1;

y = 4.5735*log(time)-12.007;

plot(time/60,y)


T_fridge_norm = T_fridge_sim(144,1,4);
plot(time/60,T_fridge_norm)


%Stage 4
n0 = T_fridge_norm(1:11);

loadshedding1 =  y(5:5+16); %2am-4:30am

n1 = T_fridge_norm(27:57);

loadshedding2 = y(5:5+16); %10am-12:30pm

n2 = T_fridge_norm(73:104);

loadshedding3 = y(5:5+15); %18-20:30pm

n3 = T_fridge_norm(126:144);


T_sim_loadshedding_S4 = [n0 loadshedding1 n1 loadshedding1 n2 loadshedding1
n3]
plot(time/60,T_sim_loadshedding_S4)

xlabel('Time (hours)')

ylabel("Temperature (^oC)")

hist(T_sim_loadshedding_S4)


%Stage 6
n0 = T_fridge_norm(1:11); %0-2

loadshedding4 =  y(5:5+16); %2am-4:30am

n1 = T_fridge_norm(28:28+31); %4:30-10
```

```
loadshedding5 = y(5:5+16+11); %10am-14:30pm

n2 = T_fridge_norm(88:88+18) ;

loadshedding6 = y(5:5+16+11); %18-22:30pm

n3 = T_fridge_norm(136:144);


T_sim_loadshedding_S6 = [n0 loadshedding4 n1 loadshedding5 n2 loadshedding6
n3]
plot(time/60,T_sim_loadshedding_S6)

xlabel('Time (hours)')

ylabel("Temperature (^oC)")

hist(T_sim_loadshedding_S6)
```

This section sets up the device behaviour

```
intervals=144;

step=600;

time = 0:step:step*intervals-1;


T_phasechange=6; %degC


T_fridge = T_sim_loadshedding_S4;
delT= T_fridge-T_phasechange;


%SolidPCM = PCM_Volume


SA_out = 6*L_out^2;
SA_in = 6*(L_in-d_in)^2*c;

UoutA =
SA_out/(d_mid/polyprop_k+1/air_h+d_air/air_k+1/air_h+d_out/polyprop_k+1/air_h)
;

UinA = SA_in/(d_in/polyprop_k+1/air_h);


dQm = UoutA*delT;
dQf = UinA*delT;


Qm = dQm*step;
Qf = dQf*step;
```

```
mPCM_melt = Qm/Latent_heat;
mPCM_freeze = Qf/Latent_heat;

Device Open
Open=ones(1,intervals+1);

SolidPCM = 0

for i=1:intervals-1

V_PCM_c = mPCM_melt/rho_PCM;

V_PCM_o = -mPCM_freeze/rho_PCM;

    if (Open(i)==1) %it's open so we use 'freeze' quantity even if melting is
occurring. If melting is happening, freeze volume will be negative and so
solid volume will decrease.

    SolidPCM(i+1)=SolidPCM(i)+V_PCM_o(i);

        if SolidPCM(i+1)>PCM_Volume;

        SolidPCM(i+1)=PCM_Volume;

        end

        if SolidPCM(i+1)<=0

        SolidPCM(i+1)=0;

        end

    end

    if (Open(i)==0) %it's closed so we use 'melt' quantity even if freezing is
occurring. We subtract the volume that melts so if it's surprisingly cold then
the solid volume will increase.

    SolidPCM(i+1)=SolidPCM(i)-V_PCM_c(i);

        if SolidPCM(i+1)<=0

        SolidPCM(i+1)=0;

        end

        if SolidPCM(i+1)>PCM_Volume

        SolidPCM(i+1)=PCM_Volume;

        end

    end

end


%disp(SolidPCM)
percent_change = ((PCM_Volume-SolidPCM)/PCM_Volume)*100;
```

```
xaxistime = seconds(time);

xaxistime = time/3600;

plot(xaxistime,percent_change);

xlabel("Time (hours)")

ylabel("Percent of liquid PCM (%)")
```

Device closed after freezing

```
Open = [ones(1,7) zeros(1,144-7)]
for i=1:intervals-1

V_PCM_c = mPCM_melt/rho_PCM;

V_PCM_o = -mPCM_freeze/rho_PCM;

    if (Open(i)==1) %it's open so we use 'freeze' quantity even if melting is
occurring. If melting is happening, freeze volume will be negative and so
solid volume will decrease.

    SolidPCM(i+1)=SolidPCM(i)+V_PCM_o(i);

        if SolidPCM(i+1)>PCM_Volume;

        SolidPCM(i+1)=PCM_Volume;

        end

        if SolidPCM(i+1)<=0

        SolidPCM(i+1)=0;

        end

    end

    if (Open(i)==0) %it's closed so we use 'melt' quantity even if freezing is
occurring. We subtract the volume that melts so if it's surprisingly cold then
the solid volume will increase.

    SolidPCM(i+1)=SolidPCM(i)-V_PCM_c(i);

        if SolidPCM(i+1)<=0

        SolidPCM(i+1)=0;

        end

        if SolidPCM(i+1)>PCM_Volume

        SolidPCM(i+1)=PCM_Volume;

        end

    end

end
```

```
%disp(SolidPCM)
percent_change = ((PCM_Volume-SolidPCM)/PCM_Volume)*100;

xaxistime = seconds(time);

xaxistime = time/3600;

plot(xaxistime,percent_change);

xlabel("Time (hours)")

ylabel("Percent of liquid PCM (%)")


Open = zeros(1,intervals+1);
for i=1:intervals-1

V_PCM_c = mPCM_melt/rho_PCM;

V_PCM_o = -mPCM_freeze/rho_PCM;

    if (Open(i)==1) %it's open so we use 'freeze' quantity even if melting is
occurring. If melting is happening, freeze volume will be negative and so
solid volume will decrease.

    SolidPCM(i+1)=SolidPCM(i)+V_PCM_o(i);

        if SolidPCM(i+1)>PCM_Volume;

        SolidPCM(i+1)=PCM_Volume;

        end

        if SolidPCM(i+1)<=0

        SolidPCM(i+1)=0;

        end

    end

    if (Open(i)==0) %it's closed so we use 'melt' quantity even if freezing is
occurring. We subtract the volume that melts so if it's surprisingly cold then
the solid volume will increase.

    SolidPCM(i+1)=SolidPCM(i)-V_PCM_c(i);

        if SolidPCM(i+1)<=0

        SolidPCM(i+1)=0;

        end

        if SolidPCM(i+1)>PCM_Volume

        SolidPCM(i+1)=PCM_Volume;

        end

    end

end
```

```
%disp(SolidPCM)
percent_change = ((PCM_Volume-SolidPCM)/PCM_Volume)*100;

xaxistime = seconds(time);

xaxistime = time/3600;

plot(xaxistime,percent_change);

xlabel("Time (hours)")

ylabel("Percent of liquid PCM (%)")
```

Scenario 3: User error during load shedding

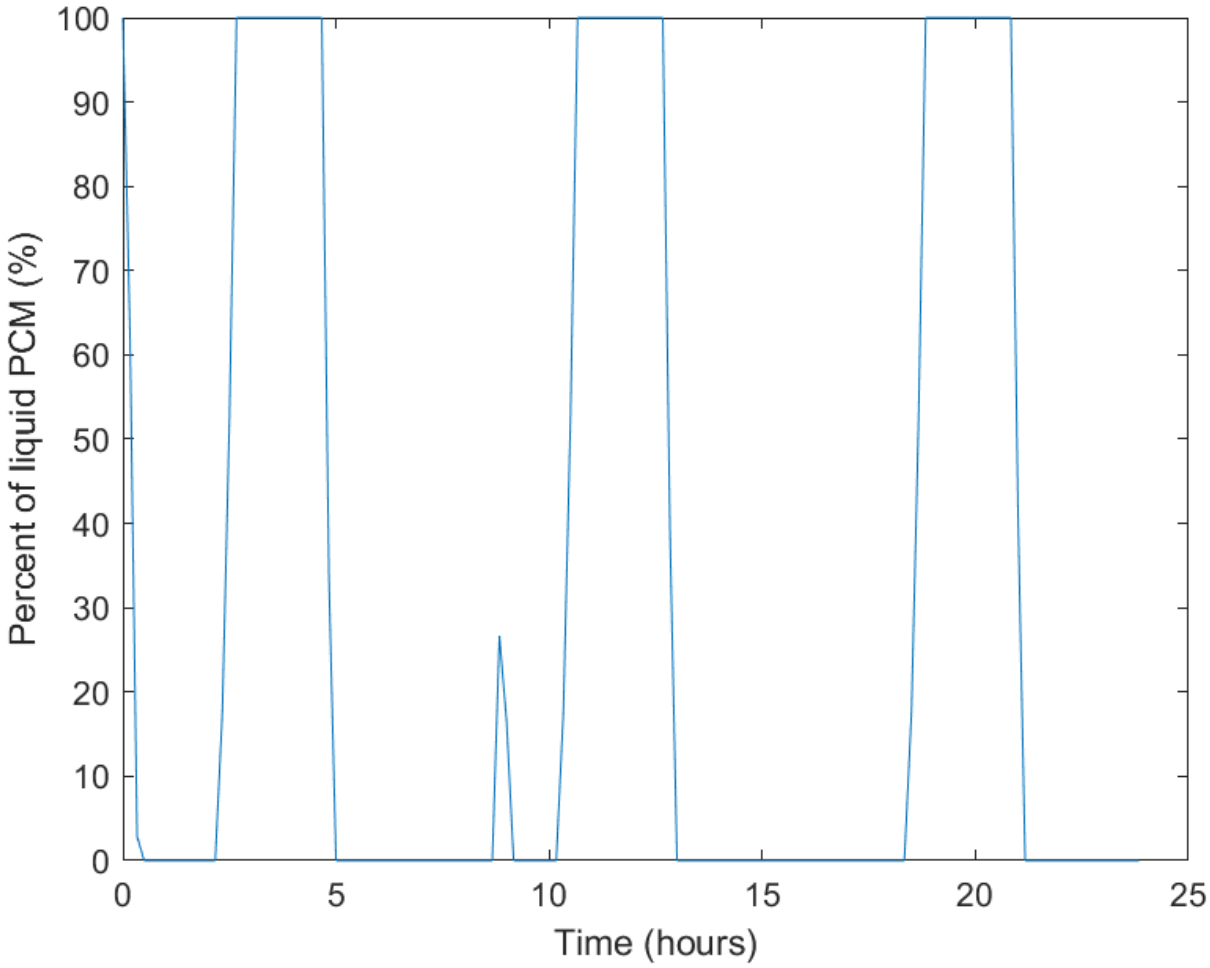

Figure 55 User error case 1

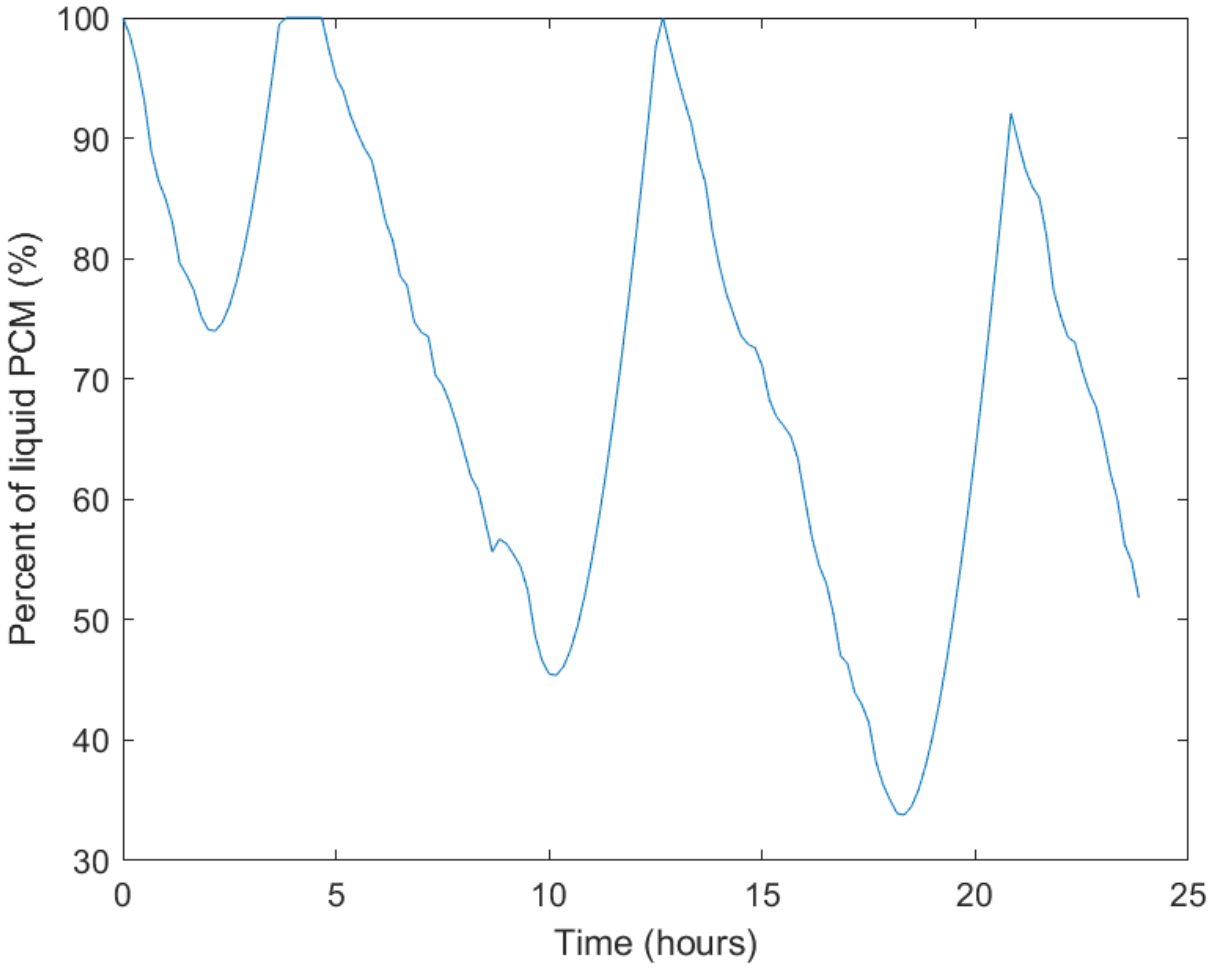

Figure 56 User error case 2

Scenario 4: Power off with opening/closing

```
clear;

clc;

polyprop_k=0.00011; %(kW/mK)

air_h=.01; %(kW/m^2K)

air_k=.000025; %(kW/mK)

Latent_heat=230; %(kJ/kg)

rho_PCM=763;  %(kg/m^3)

d_out=0.001; %m

d_air=0.005; %m

d_mid=0.001; %m

PCM_thickness=0.006; %m

d_in=0.001; %m

c=6; %Inner surface area multiplier
```

```
L_out = .15; %m

L_mid = L_out-(d_out+d_air);

L_in = L_out-(d_out+d_air+d_mid+PCM_thickness);

PCM_Volume = (L_mid-d_mid)^3-L_in^3;%total volume
```

Fridge Temperature with load shedding and opening/closing events

This section creates the temperature profiles

```
intervals=144;

step=600;

time = 0:step:step*intervals-1;

w = 3600;

s = -.85;

t_06 = 3600*6;

t_10 = 10*3600;

t_12 = 12.5*3600;

t_17 = 17.5*3600;

x1 = 15.89*tripuls(time-t_06,w*1.9,s)+4;

x4 = 20.14*tripuls(time-t_10,w*2,s)+4;

x2 = 24.21*tripuls(time-t_12,w*2,s)+4;

x3 = 22.8*tripuls(time-t_17,w,s)+4;

x5 = 14.35*tripuls(time-t_12,w*2,s)+4

plot(time/3600,x1);

hold on

plot(time/3600,x2);

plot(time/3600,x3);

plot(time/3600,x4)

plot(time/3600,x5)

hold off


time = 1:1:144;
TAmb=transpose(TProfile(18,12,time))

plot (time/6,TAmb);

xlabel('Time (hours)')

ylabel('Temperature (^oC)')

grid on
```

```
intervals=144;
step=10;

time = 0:step:step*intervals-1;

y = 4.5735*log(time)-12.007;

y2 = 4.5735*log(time)-12.007+22;

%plot(time/60,y2)


T_fridge_norm = T_fridge_sim(144,1,4);
%plot(time/60,T_fridge_norm)


%Stage 4
n0 = T_fridge_norm(1:12);

loadshedding1 =  y(5:5+15); %2am-4:30am

fridgeopen1 = x1(35:34+10); %temp increase + more gradual decrease

n1 = T_fridge_norm(34:34+26-4);

fridgeopen2= x4(61); %person opens fridge just before loadshedding, temp spike

loadshedding2 = TAmb(60:12.5*6-2); %10am-12:30pm power off fridge continues to
heat

cool1 = x2(74:74+9); %fridge cools slower

n2 = T_fridge_norm(73:104-10-2); %

fridgeopen3 = x3(104:107); %open at 17:30, temp spike, but power is still on
so fridge brings temp down briefly before temp increase starts again

loadshedding3 = y(20:20+13); %18-20:30pm

cool2= x5(74:74+9);

n3 = T_fridge_norm(126:144-9);


T_sim_loadshedding_S4_Open = [n0 loadshedding1 fridgeopen1 n1 fridgeopen2
loadshedding2 cool1 n2 fridgeopen3 loadshedding3 cool2 n3]
plot(time/60,T_sim_loadshedding_S4_Open)

xlabel('Time (hours)')

ylabel("Temperature (^oC)")


hist(T_sim_loadshedding_S4_Open)
```

```
% %Stage 6
% n0 = T_fridge_norm(1:11); %0-2

% loadshedding4 =  y(5:5+16); %2am-4:30am

% n1 = T_fridge_norm(28:28+31); %4:30-10

% loadshedding5 = y(5:5+16+11); %10am-14:30pm

% n2 = T_fridge_norm(88:88+18) ;

% loadshedding6 = y(5:5+16+11); %18-22:30pm

% n3 = T_fridge_norm(136:144);

%

% T_sim_loadshedding_S6 = [n0 loadshedding4 n1 loadshedding5 n2 loadshedding6
n3];

% plot(time/60,T_sim_loadshedding_S6)

% xlabel('Time (hours)')

% ylabel("Temperature (^oC)")

% hist(T_sim_loadshedding_S6)
```

This section sets up the device behaviour

```
intervals=144;

step=600;

time = 0:step:step*intervals-1;


T_phasechange=6; %degC


T_fridge = T_sim_loadshedding_S4_Open;
delT= T_fridge-T_phasechange;


%SolidPCM = PCM_Volume


SA_out = 6*L_out^2;
SA_in = 6*(L_in-d_in)^2*c;

UoutA =
SA_out/(d_mid/polyprop_k+1/air_h+d_air/air_k+1/air_h+d_out/polyprop_k+1/air_h)
;

UinA = SA_in/(d_in/polyprop_k+1/air_h);
```

```
dQm = UoutA*delT;
dQf = UinA*delT;


Qm = dQm*step;
Qf = dQf*step;


mPCM_melt = Qm/Latent_heat;
mPCM_freeze = Qf/Latent_heat;
```

Device Open

```
Open=ones(1,intervals+1);

SolidPCM = 0

for i=1:intervals-1

V_PCM_c = mPCM_melt/rho_PCM;

V_PCM_o = -mPCM_freeze/rho_PCM;

    if (Open(i)==1) %it's open so we use 'freeze' quantity even if melting is
occurring. If melting is happening, freeze volume will be negative and so
solid volume will decrease.

    SolidPCM(i+1)=SolidPCM(i)+V_PCM_o(i);

        if SolidPCM(i+1)>PCM_Volume;

        SolidPCM(i+1)=PCM_Volume;

        end

        if SolidPCM(i+1)<=0

        SolidPCM(i+1)=0;

        end

    end

    if (Open(i)==0) %it's closed so we use 'melt' quantity even if freezing is
occurring. We subtract the volume that melts so if it's surprisingly cold then
the solid volume will increase.

    SolidPCM(i+1)=SolidPCM(i)-V_PCM_c(i);

        if SolidPCM(i+1)<=0

        SolidPCM(i+1)=0;

        end

        if SolidPCM(i+1)>PCM_Volume
```

```
        SolidPCM(i+1)=PCM_Volume;
        end
    end
end


%disp(SolidPCM)
percent_change = ((PCM_Volume-SolidPCM)/PCM_Volume)*100;
xaxistime = seconds(time);
xaxistime = time/3600;
plot(xaxistime,percent_change);
xlabel("Time (hours)")
ylabel("Percent of liquid PCM (%)")
title("Device open")
```

Device closed after freezing

```
Open = [ones(1,7) zeros(1,144-7)]
for i=1:intervals-1
V_PCM_c = mPCM_melt/rho_PCM;
V_PCM_o = -mPCM_freeze/rho_PCM;
    if (Open(i)==1) %it's open so we use 'freeze' quantity even if melting is
occurring. If melting is happening, freeze volume will be negative and so
solid volume will decrease.
    SolidPCM(i+1)=SolidPCM(i)+V_PCM_o(i);
        if SolidPCM(i+1)>PCM_Volume;
        SolidPCM(i+1)=PCM_Volume;
        end
        if SolidPCM(i+1)<=0
        SolidPCM(i+1)=0;
        end
    end
    if (Open(i)==0) %it's closed so we use 'melt' quantity even if freezing is
occurring. We subtract the volume that melts so if it's surprisingly cold then
the solid volume will increase.
    SolidPCM(i+1)=SolidPCM(i)-V_PCM_c(i);
        if SolidPCM(i+1)<=0
```

```
        SolidPCM(i+1)=0;
        end
        if SolidPCM(i+1)>PCM_Volume
        SolidPCM(i+1)=PCM_Volume;
        end
    end
end


%disp(SolidPCM)
percent_change = ((PCM_Volume-SolidPCM)/PCM_Volume)*100;
xaxistime = seconds(time);
xaxistime = time/3600;
plot(xaxistime,percent_change);
xlabel("Time (hours)")
ylabel("Percent of liquid PCM (%)")
grid on
title('Device closed')
```

User Interaction: Device open when power on and closed before loadshedding

```
Open = [ones(1,8) zeros(1,93) ones(1,5) zeros(1,144-96-6-5+1)]
for i=1:intervals-1
V_PCM_c = mPCM_melt/rho_PCM;
V_PCM_o = -mPCM_freeze/rho_PCM;
    if (Open(i)==1) %it's open so we use 'freeze' quantity even if melting is
occurring. If melting is happening, freeze volume will be negative and so
solid volume will decrease.
    SolidPCM(i+1)=SolidPCM(i)+V_PCM_o(i);
        if SolidPCM(i+1)>PCM_Volume;
        SolidPCM(i+1)=PCM_Volume;
        end
        if SolidPCM(i+1)<=0
        SolidPCM(i+1)=0;
        end
```

```
    end
    if (Open(i)==0) %it's closed so we use 'melt' quantity even if freezing is
occurring. We subtract the volume that melts so if it's surprisingly cold then
the solid volume will increase.
    SolidPCM(i+1)=SolidPCM(i)-V_PCM_c(i);
        if SolidPCM(i+1)<=0
        SolidPCM(i+1)=0;
        end
        if SolidPCM(i+1)>PCM_Volume
        SolidPCM(i+1)=PCM_Volume;
        end
    end
end


%disp(SolidPCM)
percent_change = ((PCM_Volume-SolidPCM)/PCM_Volume)*100;
xaxistime = seconds(time);
xaxistime = time/3600;
plot(xaxistime,percent_change);
hold on
plot(xaxistime,Open*100)
xlabel("Time (hours)")
ylabel("Percent of liquid PCM (%)")
hold off
title('Device with user intervention')
```

Device closed and liquid PCM

```
Open = zeros(1,intervals+1);
for i=1:intervals-1
V_PCM_c = mPCM_melt/rho_PCM;
V_PCM_o = -mPCM_freeze/rho_PCM;
    if (Open(i)==1) %it's open so we use 'freeze' quantity even if melting is
occurring. If melting is happening, freeze volume will be negative and so
solid volume will decrease.
    SolidPCM(i+1)=SolidPCM(i)+V_PCM_o(i);
```

```
        if SolidPCM(i+1)>PCM_Volume;
        SolidPCM(i+1)=PCM_Volume;
        end
        if SolidPCM(i+1)<=0
        SolidPCM(i+1)=0;
        end
    end
    if (Open(i)==0) %it's closed so we use 'melt' quantity even if freezing is
occurring. We subtract the volume that melts so if it's surprisingly cold then
the solid volume will increase.
    SolidPCM(i+1)=SolidPCM(i)-V_PCM_c(i);
        if SolidPCM(i+1)<=0
        SolidPCM(i+1)=0;
        end
        if SolidPCM(i+1)>PCM_Volume
        SolidPCM(i+1)=PCM_Volume;
        end
    end
end


%disp(SolidPCM)
percent_change = ((PCM_Volume-SolidPCM)/PCM_Volume)*100;
xaxistime = seconds(time);
xaxistime = time/3600;
plot(xaxistime,percent_change);
xlabel("Time (hours)")
ylabel("Percent of liquid PCM (%)")
title('Device left closed')
```

Temperature profile during load shedding

```
x6 = 12*tripuls(time,w*.015,s)+4; %temp spike for closing
x7 = 28*tripuls(time,w*.1,s)+4
```

```
%Stage 4
n0 = T_fridge_norm(1:7);

settingdevice1 = x6(1:3);

n1 = T_fridge_norm(8:10);

loadshedding1 =  y(5:5+14); %2am-4:30am

fridgeopen1 = x1(35:34+10); %temp increase + more gradual decrease

n2 = T_fridge_norm(34:34+9+8+5);

fridgeopen2= x4(61); %person opens fridge just before loadshedding, temp spike

loadshedding2 = TAmb(60:12.5*6-2); %10am-12:30pm power off fridge continues to
heat

cool1 = x2(74:74+8); %fridge cools slower

n3 = T_fridge_norm(73:86-5); %afternoon normal

settingdevice2 = x7(1:4); %15 open

n4 = T_fridge_norm(90:94);

fridgeopen3 = x3(104:107); %open at 17:00, temp spike, but power is still on
so fridge brings temp down briefly before temp increase starts again

loadshedding3 = y(20:20+13); %18-20:30pm

cool2= x5(74:74+9);

n5 = T_fridge_norm(132:144);


T_sim_loadshedding_S4_Open1 = [n0 settingdevice1 n1 loadshedding1 fridgeopen1
n2 fridgeopen2 loadshedding2 cool1 n3 settingdevice2 n4 fridgeopen3
loadshedding3 cool2 n5]
plot(time/3600,T_sim_loadshedding_S4_Open1)

%opening_events = 5*[zeros(1,6) ones(1,1) zeros(1,29) ones(1,1) zeros(1,17)
ones(1,1) zeros(1,39) ones(1,1) zeros(1,8) ones(1,1) zeros(1,144-10-39-1-17-1-
29-7)];

hold on

%plot(time/3600,opening_events)

xax2 = time/600

xopeningvalues_NormalUse = [ 4.5 xax2(11) xax2(18)]

yopeningvalues_NormalUse = [ T_sim_loadshedding_S4_Open1(28)
T_sim_loadshedding_S4_Open1(61) T_sim_loadshedding_S4_Open1(103)]

xopeningvalues_ResetDevice = [xax2(2) 15.5]

yopeningvalues_ResetDevice = [T_sim_loadshedding_S4_Open1(7)
T_sim_loadshedding_S4_Open1(94)]

plot(xopeningvalues_NormalUse,yopeningvalues_NormalUse,'o')
```

```
plot(xopeningvalues_ResetDevice,yopeningvalues_ResetDevice, '^')

legend ('Temperature', 'Fridge opening (Normal use)', 'Fridge opening (Reset
device)', 'location', 'northwest')

%text(1,23,'o User opens fridge')

xlabel('Time (hours)')

ylabel("Temperature (^oC)")

hold off


hist(T_sim_loadshedding_S4_Open1)


T_fridge = T_sim_loadshedding_S4_Open1;
delT= T_fridge-T_phasechange;



SA_out = 6*L_out^2;
SA_in = 6*(L_in-d_in)^2*c;

UoutA =
SA_out/(d_mid/polyprop_k+1/air_h+d_air/air_k+1/air_h+d_out/polyprop_k+1/air_h)
;

UinA = SA_in/(d_in/polyprop_k+1/air_h);



dQm = UoutA*delT;
dQf = UinA*delT;



Qm = dQm*step;
Qf = dQf*step;



mPCM_melt = Qm/Latent_heat;
mPCM_freeze = Qf/Latent_heat;
```

Proper use case

```
%Device open to freeze, closed during 2 loadshedding periods and opened in the
afternoon to refreeze
Open = [ones(1,7) zeros(1,87) ones(1,8) zeros(1,144-87-7-8)]

for i=1:intervals-1

V_PCM_c = mPCM_melt/rho_PCM;

V_PCM_o = -mPCM_freeze/rho_PCM;
```

```
    if (Open(i)==1) %it's open so we use 'freeze' quantity even if melting is
occurring. If melting is happening, freeze volume will be negative and so
solid volume will decrease.
    SolidPCM(i+1)=SolidPCM(i)+V_PCM_o(i);
        if SolidPCM(i+1)>PCM_Volume;
        SolidPCM(i+1)=PCM_Volume;
        end
        if SolidPCM(i+1)<=0
        SolidPCM(i+1)=0;
        end
    end
    if (Open(i)==0) %it's closed so we use 'melt' quantity even if freezing is
occurring. We subtract the volume that melts so if it's surprisingly cold then
the solid volume will increase.
    SolidPCM(i+1)=SolidPCM(i)-V_PCM_c(i);
        if SolidPCM(i+1)<=0
        SolidPCM(i+1)=0;
        end
        if SolidPCM(i+1)>PCM_Volume
        SolidPCM(i+1)=PCM_Volume;
        end
    end
end


%disp(SolidPCM)
percent_change = ((PCM_Volume-SolidPCM)/PCM_Volume)*100;
xaxistime = seconds(time);
xaxistime = time/3600;
plot(xaxistime,percent_change);
hold on
plot(xaxistime,Open*100)
xlabel("Time (hours)")
ylabel("Percent of liquid PCM (%)")
hold off
```

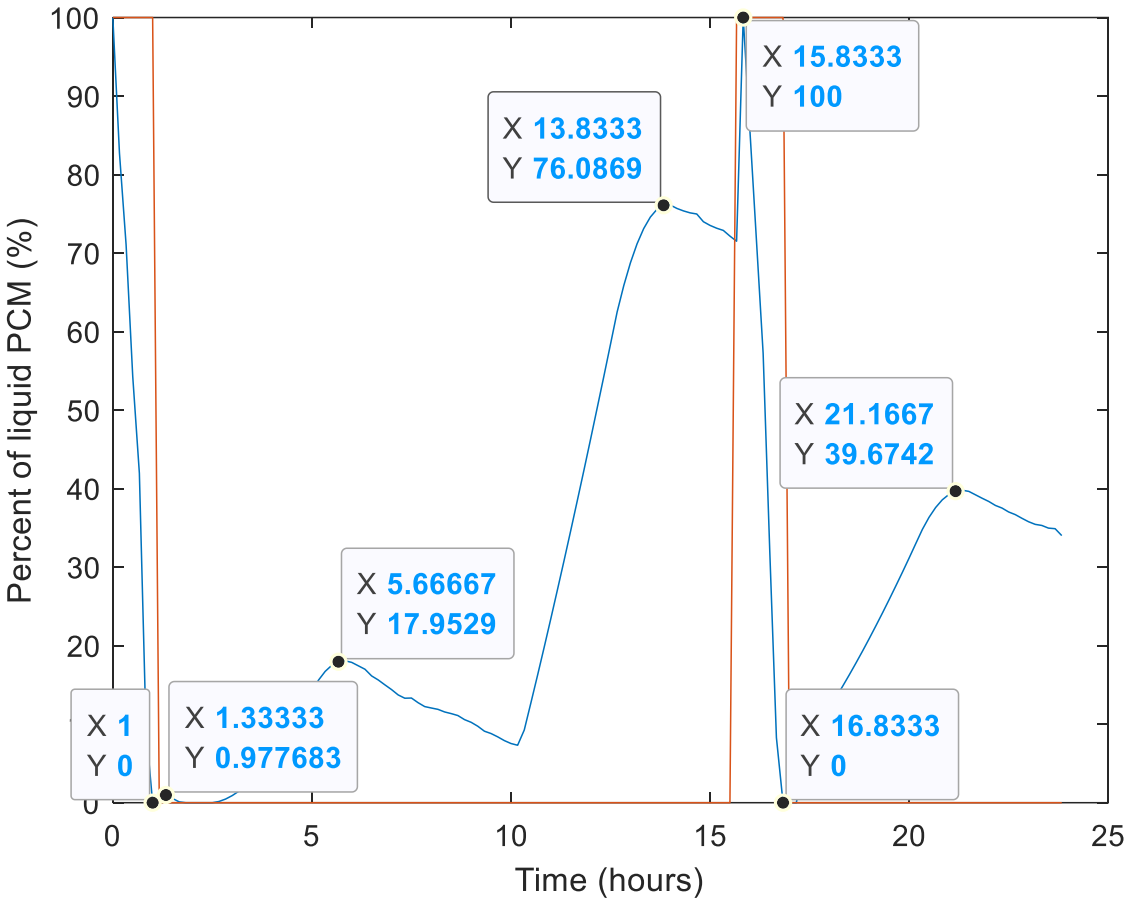

Figure 57 Device response with data tips