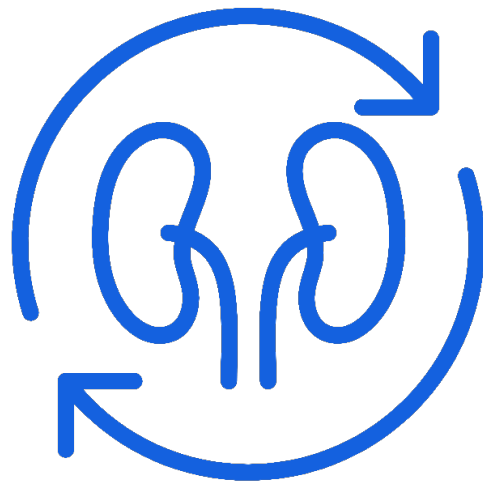


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# DialySafe

Making at-home dialysis easier,  
cleaner, and safer



## DialySafe

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# Executive Summary

**Problem:** Over 800,000 US patients are diagnosed with kidney failure annually, many relying on dialysis to survive. Peritoneal dialysis (PD) offers at-home flexibility and lower costs than hemodialysis but is underutilized due to infection risks and a tedious process. Patients must connect/disconnect the catheter transfer set multiple times daily under strict sterile conditions. This leads to fatigue, shortcuts, and increased infection risk—90% of peritonitis cases stem from touch contamination, affecting 25% of PD patients and costing \$2B annually. Pediatric patients face even greater risks, experiencing 53.3% higher peritonitis rates. There is a critical need for solutions that simplify PD, reduce infection risks, and improve outcomes.

**Solution:** DiallySafe is a two-part system designed to simplify PD and reduce infections:

- **Sterile Connection Apparatus:** Automates catheter connections, reducing touch contamination by 73%. Fully compatible with Baxter PD products.
- **Infection Monitoring Sensor:** Detects infection risks early, enabling timely intervention.

A digital health platform supports these devices, featuring:

- HIPAA-compliant database to store patient sensor data
- Web-based portal for providers to monitor patients and streamline billing
- Mobile app for patients/caregivers to track infection risk

This solution enhances safety, improves patient outcomes, and saves payers over \$1B annually.

**Target Market & Value Proposition:** Our beachhead market is the \$700M US PD market, with long-term expansion into the global PD market (200,000 patients) and eventually the wider total

global PD market. Pediatric PD (13,000 patients) and elderly patients with dexterity challenges are key segments.

DialySafe provides:

1. **Improved PD Outcomes:** Reduces manual steps by 90%, lowering peritonitis risk. This could prevent infections in 18,500 patients and save 1,300 catheters annually. Early detection reduces hospitalization rates by 80%.
2. **Expanded PD Adoption:** Only 12% of 467,500 US ESRD patients opt for PD due to infection fears and complexity. DialySafe removes these barriers, making PD a more viable option.

**Business Model:** DialySafe is provided at no upfront cost, generating revenue through insurance reimbursements under recurring billing codes. Our remote patient monitoring (RPM) model ensures continuous revenue for 3-5 years per patient. Clinics receive a revenue share, incentivizing adoption. PD costs \$86,976 per patient-year versus \$109,359 for HD. Increasing US PD adoption from 10% to 15% could save Medicare \$1.7B. We estimate that DialySafe can generate \$1.1B in direct cost savings. With a reimbursement model of \$1,061 per patient per month minimum, US market revenue potential is \$700M, and global revenue ranges from \$810M to \$3.2B.

## Introduction

DialySafe is an innovative medical device and digital health platform designed to improve the safety, accessibility, and efficiency of peritoneal dialysis (PD) for patients with kidney failure. Our solution integrates a sterile connection apparatus that automates catheter connections to

reduce touch contamination and an infection monitoring sensor that provides real-time detection of infections. These components are supported by a HIPAA-compliant digital platform that allows remote monitoring for healthcare providers and enhances patient engagement through a user-friendly mobile app.

Our business operates on a remote patient monitoring (RPM) reimbursement model, where patients receive the DiallySafe system at no upfront cost. Instead, revenue is generated through recurring insurance reimbursements using existing medical billing codes that directly apply to the DiallySafe technologies of connection hardware, sensor hardware, and the RPM software coming out to a minimum of \$1,061/patient in MRR. This model ensures continuous revenue streams while minimizing financial barriers for patients. Additionally, DiallySafe incentivizes adoption by sharing revenue with partner clinics, providing them with a new income stream for monitoring PD patients.

The dialysis industry is a critical sector of the healthcare market, serving over 550,000 patients annually in the US alone. Peritoneal dialysis, while clinically advantageous and cost-effective, remains underutilized due to concerns about infection risk and procedural complexity. DiallySafe addresses these barriers by automating critical steps, improving infection detection, and enhancing remote monitoring, ultimately making PD safer and more appealing. By increasing PD adoption, our solution has the potential to save the US healthcare system over \$1 billion annually while significantly improving patient outcomes, providing payers more than 60% return on their investment in DiallySafe.

## Market Analysis

Our beachhead market is the \$700M US peritoneal dialysis (PD) market, with future expansion into the global PD market of 200,000 patients. The pediatric PD segment, comprising 13,000 patients, is particularly vulnerable to infections due to weaker immune systems. Elderly patients with dexterity challenges also benefit from DialySafe's automation, increasing independence and reducing caregiver dependency.

DialySafe reduces manual steps by 90%, significantly lowering touch contamination risk, which accounts for 92% of peritonitis cases. This could prevent infections in 18,500 patients annually and lower PD catheter removal rates from 38% to 16%. Early infection detection reduces hospitalizations by 80% and shortens hospital stays by half.

**Expanding PD Adoption:** Only 12% of eligible ESRD patients in the US choose PD, mainly due to infection concerns and procedural complexity. By simplifying PD and enhancing safety, DialySafe makes PD a more viable option, expanding the market and capturing a portion of the \$21.6B total addressable dialysis market.

**Business Model & Economic Impact:** Patients receive DialySafe at no upfront cost, with recurring revenue generated through insurance reimbursements. Partner clinics receive a share, incentivizing adoption. Increasing PD adoption from 10% to 15% could save Medicare \$1.7B annually, with DialySafe alone delivering \$1.1B in estimated cost savings through reduced infections, hospitalizations, and PD failures.

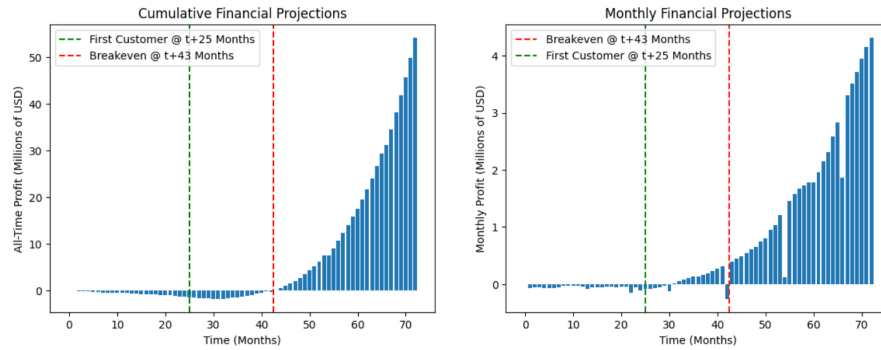
**Market Opportunity:** Unlike competitors that add manual steps or lack effective detection, DialySafe automates 90% of PD while maintaining portability and affordability. Our highly

sensitive sensor detects infections over 2,200 times earlier than clinical thresholds, making DialySafe the most comprehensive, cost-effective solution for safer PD. As the global population ages and lifespans extend, the prevalence of chronic diseases like kidney failure continues to rise, driving increased demand for peritoneal dialysis solutions and expanding the market for innovative, patient-centric technologies like DialySafe.

## Marketing and Financial Plan

The marketing and financial plan consists of 4 milestones: refining the prototype and conducting pre-clinical trials to submit for FDA premarket approval via the 510(k) substantial equivalence pathway (Year 1), manufacturing pilot batch of devices and nailing down processes (Year 2), pilot clinical launch to first batch of patients (Year 3), and then scaling to capture 8% of market share (Years 4-6). The financial model includes expenditures from regulatory costs (FDA 510(k) application + annual establishment fees, Legal + IP fees), prototyping and testing costs, labor costs (with scaling head counts according to each stage of development), utilities (rent, software costs, insurance, testing equipment), manufacturing and logistics costs, marketing and sales costs, and operating costs (the cut of the RPM revenue we share with clinics). According to the model, we estimate to receive the first revenue by month 25 and breakeven by month 43. The key to profitability comes in the innovative low-cost design of the technologies which are orders of magnitudes lower than any other competitor on the market.

| Year | Revenues     | Expenditures | Profits      | Gross Margin | Operating Margin |
|------|--------------|--------------|--------------|--------------|------------------|
| 1    | \$0          | \$609,150    | -\$609,150   | N/A          | N/A              |
| 2    | \$0          | \$774,184    | -\$774,184   | N/A          | N/A              |
| 3    | \$1,527,840  | \$1,474,840  | \$53,000     | 97.77%       | 3.47%            |
| 4    | \$6,779,790  | \$2,747,900  | \$4,031,890  | 98.50%       | 59.47%           |
| 5    | \$18,540,975 | \$3,698,650  | \$14,842,325 | 98.72%       | 80.05%           |
| 6    | \$41,219,850 | \$4,589,900  | \$36,629,950 | 98.68%       | 88.86%           |



DialySafe is a stable and growth-oriented venture, but the biggest risk factor is obtaining FDA approval. However, our competitors have already paved the way, providing a clear regulatory roadmap. By following established testing protocols and collecting the necessary data to demonstrate substantial equivalence, we can streamline the approval process and mitigate delays. Additionally, our team is proactively engaging with regulatory experts to ensure compliance, reducing risk and positioning DialySafe for a smooth market entry.

## Discussion

DialySafe embodies the Islamic principle of Ihsan (excellence) by striving to revolutionize peritoneal dialysis with automation and infection detection, ensuring the highest standard of patient care. This commitment to excellence directly aligns with this year's Showdown theme, Paving the Path to Greatness: A Commitment to Excellence, by addressing a critical medical need with innovation and precision. Beyond healthcare, the project's sensing technology is versatile and has the potential for broader applications, such as detecting diseases in other medical fields or monitoring material degradation in manufacturing, reinforcing the pursuit of excellence across industries. By pushing boundaries and forward-thinking innovation, DialySafe reflects the Islamic value of intentionality and leadership, serving both the Muslim community and society at large.