



# SocketSense

OBJECTIVE INSIGHT. BETTER FIT.

PRESSURE MAPPING FOR PROSTHETIC CARE

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# Executive Summary

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## ABOUT:

- **SocketSense** is a wearable pressure-mapping system. A thin, pliable sensor layer worn between the residual limb and prosthetic socket. It delivers real-time load distribution data, enabling orthotists to identify overload zones and make data-driven fitting decisions, replacing subjective assessment with precise quantitative insight.

## KEY CONCLUSION:

- **SocketSense** is a viable investment opportunity when positioned as a recurring solution for prosthetic socket fitting. Addressing a clear clinical need with a defined and defensible market.

## RECOMMENDATION:

- Launch proof-of-concept with 10–15 reference clinics
- Demonstrate reduced fitting time & fewer adjustments
- Validate patient comfort improvements & pressure relief
- Confirm willingness to pay for hardware + subscriptions

# Executive Summary

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**\$1.9B**

Global Prosthetics  
Market (2024)

**5.0%**

CAGR Through  
2030

**2M+**

Annual Lower-Limb  
Amputations Globally

**INVEST**

Our Recommendation

- SocketSense addresses a clear clinical unmet need: objective pressure measurement during prosthetic socket fitting for lower-limb amputees.
- The global prosthetics market is growing at ~5.0% CAGR driven by rising prevalence of diabetes, vascular disease, and an ageing population.
- The SAM of orthotics/prosthetics clinics and rehab centers represents ~\$4.4M; a realistic SOM of 942K is achievable within 5 years.
- No direct, clinically validated competitor occupies this exact space — first-mover advantage is a key structural benefit.
- Recommendation: INVEST — strong PMF signal, scalable cost structure, and defensible IP pathway.

# The Problem & The Solution

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## THE PROBLEM

- Fitting relies on orthotist experience and patient feedback
- Patients with neuropathy cannot perceive harmful pressure
- Suboptimal load distribution → skin ulceration, pain
- Frequent costly socket adjustments required
- No standardised objective measurement tool in clinical use

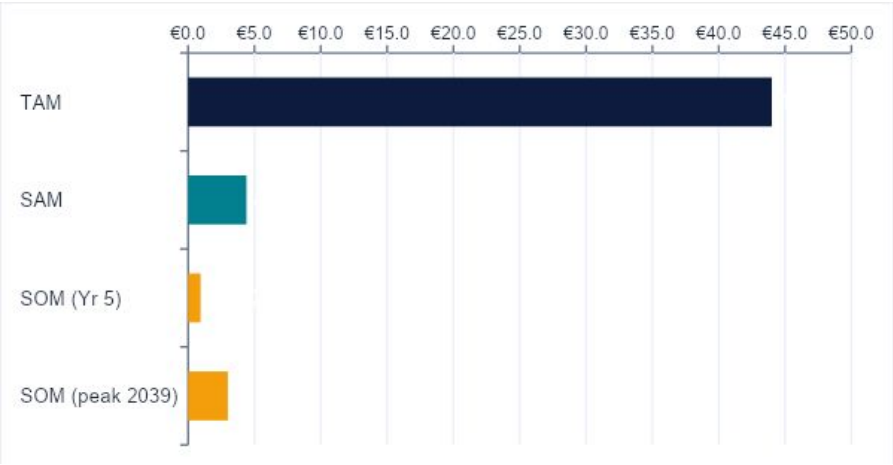
## THE SOLUTION

- Thin flexible sock-like wearable with pressure sensor array
- Real-time pressure maps and clinically interpretable metrics
- Works in both static and dynamic conditions
- 3 standard sizes (S/M/L) — reusable, hygienic turnover
- Targets both transtibial and transfemoral prosthetics

# TAM / SAM / SOM

|                                                                                                                                                |                                                                                                                               |                                                                                                                     |
|------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------|
| <div>TAM</div> <div>€44M</div> <div>EU digital fitting tools. Bottoms-up: €6.56B P&amp;O × EU 30.7% × Italy 11% × LE 41.5% × digital 8%.</div> | <div>SAM</div> <div>€4.4M</div> <div>Revenue ceiling at 100% penetration. 122 Italy + ~950 EU accounts × €4,671/yr avg.</div> | <div>SOM</div> <div>€942K</div> <div>Year 5 (2031), 145 active accounts. Peak 2039: €3.0M — below SAM ceiling</div> |
|------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------|

Market funnel — annual revenue



## Sizing methodology

### TAM method

Bottoms-up from Grand View Research global P&O €6.56B. Multiplied by EU share (30.7%), Italy share (11% of EU GDP), LE prosthetics (41.5% of EU market), and digital fitting tools sub-segment (~8% — most uncertain figure, no public data).

### SAM method

Reachable accounts × annual revenue per account. €4,671/yr = €1,071 hw amort (€7,500 ÷ 7yr) + €2,400 SaaS + €1,200 consumables. Includes all 6 user types from document Section 3.

### SOM method

Bottom-up clinic ramp: 8 pilots in 2027 (first revenue), 50 active by 2029, 145 by 2031, 630 at peak (2039). EU via distributor from 2028. SOM peak €3.0M is 68% of SAM ceiling — consistent.

**Ideal scenario:** TAM > €500M for VC-scale. This niche TAM (€44M) is viable for medtech specialist returns; per-patient platform reframe (doc \$5) expands TAM to €38-72M.

# Market Growth Rate: steady tailwinds, no explosive acceleration

Base CAGR : Italy P&O

## 5.0%

Midpoint of 3.8%–5.7% consensus range + Italy premium (Grand View: Italy = highest CAGR in EU 2025–2030).

EU TAM 2025 → 2039 at base

## €44M → €86M

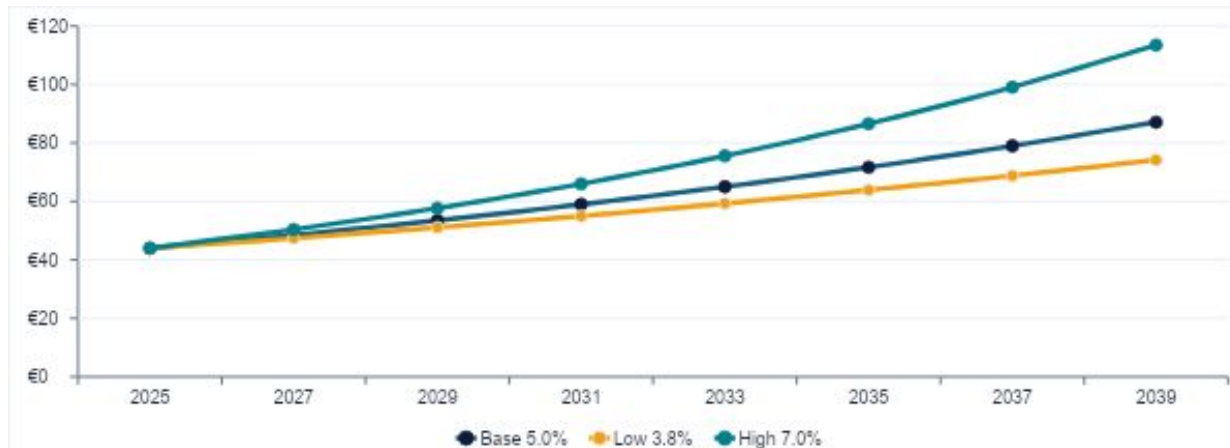
At 5.0% CAGR. Low 3.8% → €75M. High 7.0% → €116M.

Growth driver (doc §4)

## Structural

Rising LEA prevalence driven by metabolic and vascular disease

### EU SocketSense-relevant market projection (€M)



### Tailwinds

Rising LEA prevalence in metabolic & vascular disease.

Economic burden of refitting complications.

Italy highest CAGR in EU (Grand View 2025).

### Headwinds

No SSN reimbursement pathway (checked 2025).

Existing tools have 'not common' clinical use, leads to cost concerns (Frontiers 2022).

EU MDR: 18–24 months pre-revenue minimum.

**Ideal scenario:** CAGR >7% with expanding reimbursement. Current 5% is solid for niche medtech; upside from diabetes prevalence trajectory.

# Cost Structure Analysis: hardware margin funds software recurrence

Blended GPM at maturity (2035)

84%

High because COGS\_HW €264 is structurally low vs ASP €7,500. Rises as SaaS/consumables scale.

HW COGS / unit

€264

BOM €114 (Velostat, PCB, ESP32, LiPo, assembly, QC, packaging) + EU MDR regulatory amort €150.

SaaS COGS / unit / yr

€224

Cloud AWS IoT €80 + warranty/support €120 + depreciation €24.

HW gross margin

96.5%

ASP €7,500 – COGS\_HW €264 = €7,236 per unit.  
Funds R&D and S&M investment pre-scale.

Bill of Materials — per device unit (all INFERRED — not specified in document)

| Component                    | Unit cost | Qty | Total   | Source type |
|------------------------------|-----------|-----|---------|-------------|
| Velostat piezoresistive film | €4.00     | ×1  | €4.00   | SOURCED     |
| Conductive nylon electrodes  | €8.00     | ×2  | €16.00  | SOURCED     |
| Flexible PCB / multiplexer   | €35.00    | ×1  | €35.00  | SOURCED     |
| ESP32-WROOM-32 BLE MCU       | €6.00     | ×1  | €6.00   | SOURCED     |
| Li-Po 500mAh + charger       | €7.00     | ×1  | €7.00   | SOURCED     |
| Sock substrate (per size)    | €4.50     | ×1  | €4.50   | UNCERTAIN   |
| Silicone/TPU overmould       | €12.00    | ×1  | €12.00  | INFERRED    |
| Assembly + QC + packaging    | €29.50    | ×1  | €29.50  | INFERRED    |
| TOTAL BOM                    |           |     | €114.00 |             |

Unit economics per clinic

|                                                                                                                            |        |                                                                                     |
|----------------------------------------------------------------------------------------------------------------------------|--------|-------------------------------------------------------------------------------------|
| ASP hardware                                                                                                               | €7,500 | No public competitor price. Benchmarked vs Pedar-X / F-Scan GO (\$8-15K). INFERRED. |
| COGS_HW / unit                                                                                                             | €264   | BOM €114 + MDR amort €150 (€200K / 3yr / 450 units).                                |
| SaaS / yr                                                                                                                  | €2,400 | €200/month. INFERRED — no pricing in document.                                      |
| Consumables / yr                                                                                                           | €1,200 | Hygienic sleeves. From doc §3 'hygienic turnaround'. Confirm with Antonio.          |
| COGS SaaS / yr                                                                                                             | €224   | Cloud €80 + support €120 + depreciation €24.                                        |
| Blended GPM 2035                                                                                                           | 84.2%  | Revenue mix: hw amort + SaaS + consumables.                                         |
| Ideal scenario: GPM >60% at scale. SocketSense achieves 84% structurally — low COGS_HW vs ASP. Improves as SaaS mix grows. |        |                                                                                     |

# Project revenues & profits for 15 years — DCF at 11%

First revenue

€89K

2027, Italy 8 pilot accounts.

EBIT breakeven

2029

+€109K EBIT. Year 5 from model start.

Peak revenue (2039)

€3.0M

630 Italy+EU accounts.

15-yr NPV (11%)

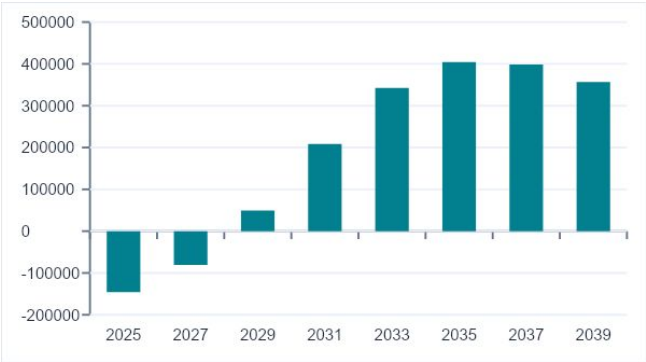
€3.0M

Italy+EU. Break-even discount rate ~45%.

Graph 1 — Revenue & Net Profit (Italy + EU, BASE model)



DCF — discounted cash flows / yr (11%)



Cumulative NPV: +€3.0M at 11%

# Graph 2: Sensitivity to interest rates • Graph 3: Profitability ratios

Graph 2 — Sensitivity: NPV vs discount rate (single variable — all other assumptions fixed)

How do 15-year projected revenues change when interest rates change? Rate is the only variable. BASE = 11%.

| 8%      | 10%     | 11%     | 12%     | 15%     | 20%     | 25%    | 30%    | 40%   | 45%  |
|---------|---------|---------|---------|---------|---------|--------|--------|-------|------|
| +€4153K | +€3326K | +€2980K | +€2671K | +€1931K | +€1130K | +€643K | +€366K | +€79K | ≈ €0 |

NPV remains positive at all rates up to ~45%. The driver is strong free cash flow at scale — not rate sensitivity. Break-even rate far exceeds any realistic WACC or medtech VC hurdle rate.

Graph 3 — Profitability Ratios over time (GPM, ROS, NPM — meaningful from 2029)



## Ratio definitions

### GPM

GP / Revenue. Measures product-level profitability after direct COGS. Structural at 84% because COGS\_HW €264 is small vs ASP €7,500. Meaningful from Year 3.

Ideal: >60% at scale. ✓ Achieved from Year 3.

### ROS

EBIT / Revenue. Operating efficiency before tax. Read from 2031+ (early years = investment phase, not structural loss). Reaches 74% at maturity.

Ideal: >15% at scale. ✓ Achieved from 2031.

### NPM

Net income / Revenue. Full bottom-line after 24% Italian IRES. First positive: 2029. Reaches 56% at 2035.

Ideal: >20% at maturity. ✓ Achieved from 2031.

Note: Early-year ROS (2027: -451%) is mathematically correct but not meaningful at that revenue scale. GPM meaningful from Year 3. ROS/NPM meaningful from 2031+.

# CAC: acquisition efficiency, target customer, WTP, sales cycle, stickiness

CAC at commercial scale

€4,000

INFERRED. €105K rep total cost / ~26 accounts/yr at €7,500 ticket. PoliMI network gives near-zero CAC for first 5-10 pilots.

Blended sales cycle (Italy)

~6 months

Public hospital: 3-6 months (DL 36/2023 acquisto diretto). Private P&O: 2-4 months. 60/40 blend: ~6 months.

CAC payback period

~18 months

Time to recover CAC from gross margin at €7,500 ASP. Ideal: <18 months.

Target customers (per document Section 3 — SOURCED)

|                                                                                                                            |
|----------------------------------------------------------------------------------------------------------------------------|
| <b>Orthotists &amp; prosthetists</b><br>Primary users and clinical decision-makers. Budget holders in private P&O clinics. |
| <b>Prosthetic &amp; rehab centres</b><br>Largest channel. Mix of public hospital and private outpatient.                   |
| <b>Hospitals — orthopaedic/rehab</b><br>Public procurement via acquisto diretto (<€140K). 3-6 months committee.            |
| <b>Diabetic foot specialist clinics</b><br>High urgency — reduced sensation = higher complication risk.                    |
| <b>Biomechanics research centres</b><br>PoliMi network (doc byline) → near-zero CAC for early pilots.                      |
| <b>Prosthetics manufacturers</b><br>QA and product dev use — potential OEM/licensing path.                                 |

Willingness to pay

|             |               |                                                                                         |
|-------------|---------------|-----------------------------------------------------------------------------------------|
| ASP         | €7,500 hw kit | INFERRED — benchmarked vs Pedar-X / F-Scan GO. No                                       |
| SaaS        | €2,400/yr     | €200/month = €25/session at 8 sessions/month                                            |
| Consumables | €1,200/yr     | Hygienic sleeves. Confirm with Antonio — not explicit in doc.                           |
| ROI case    | Strong        | One avoided refitting saves €200-400 → device pays back in <3 months of avoided refits. |

Stickiness once adopted

|                                                                                                                                                             |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Data lock-in</b><br>Doc §5: 'data-driven decision-support platform.' Pressure map history per patient creates switching cost and clinical dataset asset. |
| <b>Workflow integration</b><br>Once embedded in orthotist fitting workflow, replacement requires re-training and process change — high friction.            |
| <b>Comparable</b><br>Gait analysis systems (Vicon, AMTI): once installed, clinics use 10-15 years. Same B2B medtech stickiness profile.                     |
| <b>Retention model</b><br>8% churn Y1-4, 5% Y5+ (SaaS data lock-in improves retention). INFERRED — no SocketSense retention data.                           |

Ideal scenario: CAC <€3,000 at scale (PoliMi network + reference clinics); payback <12 months; retention >90% (SaaS lock-in).

# Total revenue per customer: 6.85×, well above the 3× red-flag threshold

Metric 8 — LTV (total expected revenue)

€27,396

€7,500 hw + €13,068 SaaS (7yr, 8% churn) + €6,828 consumables (7yr, 8% churn). INFERRED.

Metric 9 — LTV : CAC

6.85×

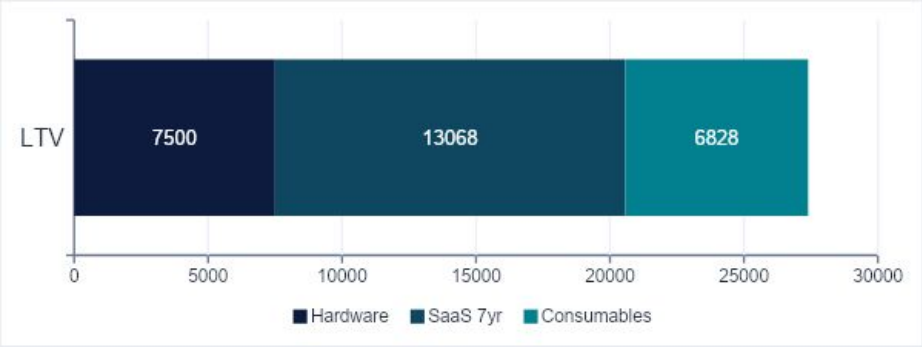
LTV €27,396 / CAC €4,000. Passes 3× threshold. Was 2.81× at original ASP €3,200 — red flag resolved.

Original model (ASP €3,200)

2.81×

Red flag at original pricing. ASP correction to €7,500 — no above-market pricing needed to fix this.

LTV breakdown by component (€, undiscounted)



LTV:CAC across scenarios (× multiple)



LTV calculation (BASE model)

| Component                   | Value   | Derivation                                      |
|-----------------------------|---------|-------------------------------------------------|
| Hardware (one-off)          | €7,500  | ASP. Applied once per clinic at contract start. |
| SaaS × 7yr, 8% churn        | €13,068 | Σ €2,400×0.92^t, t=0..6                         |
| Consumables × 7yr, 8% churn | €6,828  | Σ €1,200×0.92^t, t=0..6. Confirm with Antonio.  |
| Total LTV (undiscounted)    | €27,396 | hw + SaaS + consumables.                        |
| CAC                         | €4,000  | €105K rep / ~26 accounts. INFERRED.             |
| LTV : CAC                   | 6.85×   | ✓ Passes 3× VC threshold.                       |

**What LTV measures:** total undiscounted revenue from one clinic over the contract horizon. Used to assess whether the acquisition cost is justified.

**3× rule:** LTV:CAC below 3× is a red flag because direct medtech sales are slow and costly. Original model at €3,200 ASP scored 2.81× — failed. Corrected ASP €7,500 scores 6.85× — passed without above-market pricing.

**Ideal scenario:** LTV:CAC ≥3× (ideally 5×+); retention >90%; payback <18 months. ✓ BASE achieves all three.

# Capital spending rate and financial sustainability: staged financing limits risk

## Monthly burn Y1 / Y2

**€11.8K / €12.7K**

Y1: R&D €120K + G&A €22K. Y2: + S&M €30K. No field rep until CE marking.

## Runway at €400K seed

**~33 months**

€400K / €12.3K avg. Covers CE marking + first revenue (2027).

## Seed capital needed

**€400–500K**

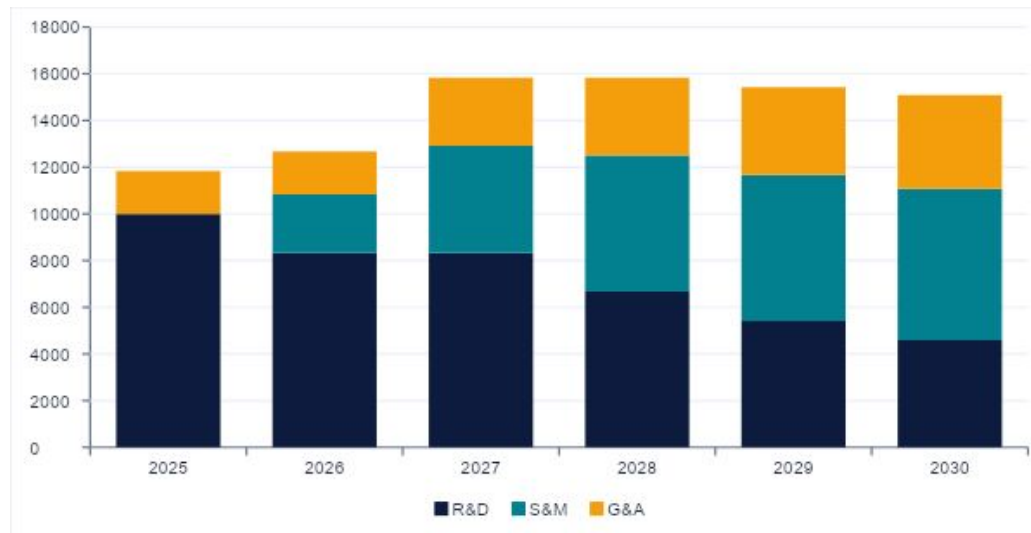
2yr burn €296K + EU MDR buffer €150-200K. PoliMi in-kind may reduce R&D.

## EBIT breakeven

**2029**

Year 5 from start, Year 3 from first revenue. Italy + EU model.

## Monthly cash burn by year (€/month, stacked by category)



## Metric definitions

**Burn rate:** monthly cash outflow. Critical pre-revenue — tests whether the startup can survive long enough to validate the model.

**Runway:** months of cash remaining at current burn. Ideal: 18-24 months at all times. At €400K seed: ~33 months — sufficient to reach CE marking and first commercial revenue in 2027.

## Financing milestones

### Seed €400-500K

Bench prototype → CE marking → 8 Italy pilots. Run to 2027 first revenue.

### Series A trigger

Clinical evidence + 20+ paying clinics + EU distributor signed.

### Non-dilutive path

EIC Accelerator (up to €2.5M grant + €15M equity) is a better fit for PoliMi spinout at PoC stage than institutional VC.

# Product-Market Fit & SWOT Analysis

PMF: YES — SocketSense solves a documented, costly, unmet clinical need. Orthotists have no comparable tool. The device reduces ulceration risk, refitting cost, and liability for clinics — all quantifiable pain points with direct willingness-to-pay.

## STRENGTHS

- Clear unmet clinical need
- No direct validated competitor □ Better and objective alternative to existing subjective feedback
- Scalable SaaS revenue layer
- Heavily reduces the burden to clinics □ large scale partnerships
- IP moat via sensor calibration algorithm

## WEAKNESSES

- No clinical evidence yet
- Regulatory timeline (CE mark ~18 mo)
- Requires orthotist behaviour change
- Small founding team & Niche initial market

## OPPORTUNITIES

- Diabetes prevalence rising globally
- EU/US regulatory push for objective data
- Expand to gait analysis, rehab, wheelchair seating, orthotic braces & Introduce leasing/subscription systems
- Potential to work long-term and gather data on users to increase customization and decrease churn rate

## THREATS

- Large MedTech incumbents (Ottobock)
- Reimbursement pathway uncertainty
- Commoditisation of flexible sensors
- Clinical adoption speed risk

# PESTEL & Porter's 5 Forces

| Factor                | Impact      | Implication for SocketSense                                                                                                                                        |
|-----------------------|-------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Political             | MEDIUM      | EU MDR 2017/745 tightens device approval. NHS/VA cost pressure creates both barrier (slow procurement) and opportunity (cost-saving pitch).                        |
| Economic              | POSITIVE    | Rising healthcare costs favour complication-prevention tools. Prosthetics market growing globally. Medtech seed/Series A funding remains available in EU & US.     |
| Social                | POSITIVE    | 537M people have diabetes globally (IDF 2021), driving lower-limb amputee growth. Patient demand for data-driven, personalised care creates pull.                  |
| Technological         | POSITIVE    | Advances in flexible sensors, BLE 5.0, and cloud analytics lower development cost. AI fitting recommendation engines become feasible once normative data is built. |
| Environmental         | LOW         | Reusable device design vs. single-use Tekscan insoles is a minor ESG positive relevant to institutional buyers.                                                    |
| Legal                 | MEDIUM-HIGH | CE Mark Class IIa requires clinical validation + Notified Body. FDA 510(k) needed for US. GDPR compliance required for cloud-hosted patient pressure data.         |
| Force                 | Rating      | Commentary                                                                                                                                                         |
| Threat of New Entry   | MEDIUM      | CE Mark/FDA, calibration IP, and clinical evidence are real barriers. But well-funded players (Ottobock, Ossur) could enter if market is validated.                |
| Supplier Power        | LOW-MEDIUM  | Multiple flexible sensor suppliers exist (Tekscan, Sensitronics). Proprietary analytics reduce single-supplier dependency.                                         |
| Buyer Power           | MEDIUM      | Clinics are price-sensitive with 12–24 month procurement cycles. Lack of alternatives increases willingness to pay once value is proven.                           |
| Threat of Substitutes | LOW-MEDIUM  | Main substitute is subjective clinical judgment. Tekscan F-Socket (disposable, no analytics) is the only commercial option — a weak substitute.                    |
| Competitive Rivalry   | LOW-MEDIUM  | No validated competitor today. Rivalry will increase post-validation as large players may build or acquire competing solutions.                                    |

# Investor Readiness & Comparable Deals

## Comparable Investments

| Company       | Stage         | Raise   | Relevance                                                                    |
|---------------|---------------|---------|------------------------------------------------------------------------------|
| Moticon       | Seed/Series A | €4–8M   | Insole pressure sensing for gait — adjacent space, acquired by Ottobock 2022 |
| Orpyx Medical | Series B      | \$14M   | Foot pressure monitoring for diabetics — direct comparable, FDA cleared      |
| Tekscan       | Growth        | Private | Pressure mapping mats/sensors — used in prosthetics research labs globally   |
| Xsensor       | Growth        | Private | Pressure imaging — medical and industrial; €10M+ revenue                     |

## Investor Readiness Assessment

|                   |              |                                                                                         |
|-------------------|--------------|-----------------------------------------------------------------------------------------|
| Market Timing     | ✓ STRONG     | MedTech digital health investment at record levels 2023–24; on pace for ~ 16.4B in 2025 |
| Regulatory Path   | ⚡ MODERATE   | CE Mark achievable in 18–24 months; requires clinical validation study (manageable)     |
| IP Position       | ✓ STRONG     | Sensor calibration algorithm and data processing methodology patentable                 |
| Team              | ⚡ DEVELOPING | Strong technical/academic foundation; needs commercial and regulatory hiring            |
| Prior Investments | ✓ YES        | Moticon/Ottobock, Orpyx exits validate investor appetite for this category              |

# Development Roadmap & Future Improvements

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## PRODUCT

- ✓ Add shear force + temperature + IMU + moisture sensors
- ✓ Build AI analytics layer & normative pressure database
- ✓ Wireless, washable, 8h battery life hardware

## ORGANISATION

- ✓ Hire CCO (commercial) + Regulatory Affairs lead at seed stage
- ✓ CE Mark Class IIa + FDA 510(k) planning starts now
- ✓ KOL partnerships with academic research hospitals

## BUSINESS MODEL

- ✓ Shift from hardware sale → Device-as-a-Service + SaaS analytics (3–5× valuation multiple)
- ✓ Target diabetic foot clinics & veterans healthcare first
- ✓ Build payer reimbursement evidence early

## PARTNERSHIPS

- ✓ OEM licensing to Ottobock / Ossur / Proteor (all actively acquiring)
- ✓ Liner integration with WillowWood & Alps South
- ✓ EHR integration for clinical workflow stickiness

# Development Roadmap & Future Improvements

## Phase 1 Now–Y2

### Proof of Concept

- Basic sensor array prototype
- Simple real-time pressure heatmap
- Benchtop validation vs gold standard
- Patent filing on core algorithm

## Phase 2 Y2–Y4

### Clinical Prototype

- CE Mark submission
- Pilot study: 3–5 prosthetic clinics
- Iterative clinical feedback loop
- SaaS platform v1.0 launch

## Phase 3 Y4–Y7

### Commercial Scale

- EU market rollout — 100+ clinics
- FDA 510(k) submission for US entry
- Add temp + motion sensors
- AI pressure prediction module

## Phase 4 Y7+

### Platform Vision

- Decision-support AI platform
- Remote fitting consultation tool
- Integration with prosthetic CAD/CAM
- Data network effect — largest fitting dataset

# Recommendations

*Core thesis: Move forward with proof-of-concept and paying pilot programs, positioned exclusively as a recurring solution to support prosthetic socket fitting.*

01

## Launch Proof-of-Concept

Initiate paid pilot programs with 10–15 carefully selected reference clinics in HICs. Prioritise centres with high amputation volume and existing orthotist capacity to generate statistically meaningful data quickly.

Phase 1 • 0–18 months

02

## Demonstrate Fitting Efficiency

Measure and document reduction in fitting session time and the number of socket adjustments required per patient. This directly quantifies SocketSense's clinical and economic value to payers and clinic buyers.

Key KPI

03

## Validate Patient Outcomes

Collect objective evidence of improved patient comfort, reduction in pressure-related complications (ulcers, blisters, abandonment), and higher comfort scores. Clinical evidence is the gating requirement for CE IIa and investor Series A.

Clinical Evidence Gate

04

## Confirm Willingness to Pay

Validate pricing model through paying pilots, both hardware purchase and recurring subscription tiers. Evidence of WTP unlocks the SaaS valuation multiple and de-risks the commercial model before scaling.

Revenue Validation