IMTEK

ALBERT-LUDWIGS-
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MST Design Lab I

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Virtual design project

„Energy-autonomous embedded systems“

Homework

Prediflex insoles

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1. Product idea and product functions

Prediflex is an innovative foot insole designed specifically for children, aiming to aid in the early detection and monitoring of orthopaedic conditions. It is embedded with advanced sensors to monitor and analyse a child's foot movement and pressure distribution in real-time. Prediflex's primary objective is to identify abnormalities or irregularities in a child’s walking pattern, indicative of various orthopaedic conditions.

A standout feature of Prediflex is its dynamic size adjustment capability. The insoles incorporate a unique, flexible material that expands when immersed in hot water which responses to the growing size of the child's foot when stepped on it. This material stretches gently, ensuring a comfortable fit over a range of shoe sizes. This insole is designed to intelligently respond to hot water treatment by expanding, ensuring a customized fit that adapts to the unique contours and growth patterns of a child's foot. The Ethylene Vinyl Acetate provides the structural integrity and thermoplastic responsive expansion properties.

It is also equipped with pressure sensors that map the distribution of force across the foot, highlighting areas of excessive pressure or abnormal gait patterns. These sensors relay data to a microcontroller embedded in the insole, which then sends it to a parent-controlled smartphone app via Bluetooth. The app uses a machine learning model to interpret the data, providing insights into the child’s walking patterns and identifying potential issues such as flat feet, toe walking, or other gait abnormalities. It also tracks the child's overall physical activity levels, encouraging healthy exercise habits.

The functionality of the pressure sensors is linked to the expansion of the insole and the data analysis performed by the accompanying app. As the insole expands in response to the child's foot growth, the placement and distribution of the pressure sensors shift. The app, equipped with AI algorithms, then interprets these changes in sensor placement to predict and adjust the pressure values accordingly. This intelligent system ensures that despite physical changes in the insole's size, the pressure mapping remains accurate and reliable.

Additionally, the pressure sensors and cushioning features adapt as the insole expands, maintaining accurate pressure mapping, gait analysis, and providing continuous comfort and orthopaedic support. Prediflex also boasts a self-adjusting mechanism that detects when the child's foot has grown and expands accordingly. This is complemented by a scalable software algorithm in the app, which adjusts its analysis based on the insole size and the child’s age. Visual indicators on the insole inform parents when it has expanded and when a larger size might be needed.

The Prediflex smart insoles are designed to be energy-autonomous, leveraging the convenience and eco-friendliness of kinetic energy harvesting to offer users a maintenance-free experience and align with environmentally conscious values. While this innovative approach eliminates the need for regular charging or battery replacements, thus ensuring uninterrupted health monitoring and data collection, it also presents challenges such as limited power generation, potential inconsistency in power supply during sedentary periods, and increased design complexity and costs. Moreover, the reliance on movement-generated power necessitates a robust energy storage solution to maintain functionality during inactive periods, and the mechanical components involved might be prone to wear and tear. Balancing these factors is crucial; the design of Prediflex must adeptly manage energy efficiency and storage while maintaining user comfort and device durability, ensuring that the benefits of energy autonomy effectively support the product's core health monitoring functions without compromising practical usability or market competitiveness.

Made with eco-friendly, skin-safe materials, Prediflex insoles are comfortable, safe for children, and highly durable, withstanding the stress of expansion over time. By providing early detection and ongoing monitoring of orthopaedic conditions, Prediflex aims to aid in timely intervention and treatment, ensuring better long-term outcomes for children's foot health. This product is ideal for parents who wish to proactively manage their child's physical development and for orthopaedic specialists seeking a non-invasive monitoring tool.

The expandable insole sets itself apart from competitor products with its innovative, user-driven expansion mechanism. This process involves immersing the insole in hot water, then placing it in a specially designed mould that has been shaped to the child's foot. The insole, responsive to the heat, expands within the mould, conforming precisely to the contours and size of the child's foot impression. This method ensures an accurate and comfortable fit, tailored to each individual child, distinguishing the product in its ability to provide customised support and comfort. This allows for precise, tailored fitting to a child's changing foot size. This innovation mitigates the need for frequent size replacements, delivering a cost-effective and sustainable solution. Unlike traditional insoles, this product's ability to adapt and conform to the child's foot provides both immediate comfort and long-term developmental benefits, making it a standout choice in the market for children's footwear.

2. Market situation and market chances

2.1 Product Competitors:

PrediFlex differentiates itself from other products on the market by focusing on children as its target audience. The justification for this focus is that using a smart insole from a young age greatly simplifies the detection and prevention of orthopaedic disorders. This prompt action and regular monitoring is a major backbone of PrediFlex.

Distinctive Features of PrediFlex in the Competitive Market:

- PrediFlex helps to slow the progression of illnesses. When orthopaedic disorders are recognized early, they can be treated better before they progress to more severe states. This not only reduces the chance of advancement but also improves the overall treatment of the disease.
- Early detection of an orthopaedic disease usually results in a greater range of therapy alternatives. These alternatives are usually simpler than those necessary for more severe problems, making early management with PrediFlex a wise decision.
- PrediFlex has the potential to improve long-term outcomes. For disorders such as scoliosis, early intervention can significantly reduce the need for procedures such as surgery, resulting in a simpler and more manageable treatment plan.
- PrediFlex can also help prevent issues that can arise from the advancement of an orthopaedic condition, such as joint deformities, typically seen in arthritis.
- PrediFlex can be used to manage an orthopaedic issue from the beginning, which can significantly minimize symptoms like pain and discomfort and help to better regulate these symptoms from the start.
- Early management with PrediFlex often leads to an improved quality of life. Individuals are likely to experience very less restrictions in their activities and maintain a higher standard of living at the same time,

Furthermore, PrediFlex with its pioneering extensible design, immediately addresses the critical demand for sustainable products, positioning itself as a market leader. This one-of-a-kind innovation allows the insole to adapt and expand in parallel with a child's foot growth, a game-changing technique in the world of footwear. This adaptability not only extends the product's life cycle, decreasing the need for frequent replacements, but it also demonstrates a commitment to sustainable consumption. PrediFlex distinguishes itself by appealing to consumers' increased environmental consciousness while also providing a practical, long-term solution. PrediFlex's revolutionary technique blends environmental sustainability with cutting-edge technology to continuously monitor foot mobility and pressure distribution, representing a significant leap in orthopaedic therapy. This makes it an appealing alternative for green-conscious customers, establishing it as a potential leader in the rapidly developing smart insole market.

PRODUCT	FEATURES	COST	REFERENCE
Pandere	• Lymphedema, Lipedema - provide compression on feet that can help a person with swelling to feel better. • Diabetes- designed to expand in the toe box, midfoot and ankle areas. Pandere's closed-toe styles all have a removable insole and are orthotic friendly.	128 €	[1]
Aretto	• Designed to accommodate the rapid growth of children's feet • Fewer SKUs mean less material waste and potentially more efficient manufacturing processes	29 €	[2]
Dr. Scholl's	• Helps stabilise the feet and absorb the impact of your feet hitting the ground • Prevent lower body pains caused by being on your feet	53 €	[3]
Moticon	• Biomechanical analysis • Gait analysis • Motion tracking	600 €	[4]
NURVV Run	• Running biomechanics data • Performance metrics Running performance optimization, injury prevention	300 €	[5]

Table 1: Product Competitors for Prediflex

2.2 Market chances and statistics

The smart insole market, a subcategory of the broader wearable health technology sector, is showing promising growth. Prediflex smart insoles, designed for early detection of orthopaedic conditions in children, are entering a market that is ripe for innovative health solutions.

Fig. 1: Smart Shoes Market Share and Growth

Source : Fact.MR [1]

According to a market analysis by Fact.MR as shown in the figure, the smart insole segment is projected to reach $2.11 billion by 2033, growing at a CAGR of 22.8% [6] . The increasing focus on pediatric health, coupled with the rise of connected devices, is a key driver of this growth. In particular, the market for children's shoes market is estimated to grow at an even faster rate, with a CAGR of 8.21% [9] in the same period, as parents and healthcare providers seek out preventative and monitoring solutions using footwears.

The European market, with Germany at the forefront, presents a strong growth opportunity for the Prediflex smart insoles. The wearable technology sector in Europe has seen a robust expansion, with the smart insole segment carving out a significant niche. The Europe Smart Shoes Market would witness market growth of 10.1% CAGR during the forecast period (2019 - 2025) [8].This is fuelled by Germany's well-established healthcare system, high disposable incomes, and a cultural propensity towards health and wellness.

The Europe Shoe Insoles Market would witness market growth of 4.5% CAGR during the forecast period (2023-2030). In the year 2020, the Europe market's volume surged to 54,495.9 thousand units, showcasing a growth of 4.7% (2019-2022) [4]. However, the market is not without its challenges. The cost of advanced sensor technology and the necessity of ongoing software updates and support can contribute to higher retail prices for end-users. There is also the consideration of insurance coverage for such devices, which can greatly influence market penetration.

Prediflex stands out with its unique features, such as kinetic energy harvesting, which addresses the concern of battery life and sustainability. Furthermore, its adaptability to growing children's feet not only provides convenience but also cost-effectiveness for parents, who would otherwise need to replace devices frequently. To capitalize on these market trends, Prediflex will need to focus on strategic partnerships with pediatric clinics and shoe retailers, invest in targeted marketing campaigns that highlight the long-term health benefits for children, and navigate the competitive landscape with a clear value proposition.

3. Fabrication costs and sales numbers

In the landscape of children's smart wearable technology, Prediflex insoles and Aretto shoes represent the cutting edge of innovation and practical design. While Aretto has made a notable entry with their patented growing shoes, leveraging key technologies such as SuperGrooves™, InfiKnit™, and Squishy Foam™ to accommodate the rapid growth of children's feet [5]. Prediflex smart insoles offer a complementary technology that focuses on the health and development of children's feet through advanced monitoring features. Much like Aretto's commitment to comfort and growth, Prediflex ensures that the health of the child's foot is continuously monitored, providing a data-driven approach to foot care.

Aretto's products, priced competitively between $29.32 and $38.65, reflect an understanding of market demand for high-quality, durable children's footwear that can keep up with the pace of growth. Similarly, Prediflex must strategically price its smart insoles to align with market expectations and consumer willingness to invest in health-oriented technology for their children. As mentioned below in the report the fabrication cost for making Prediflex is around $90. The average price that a buyer is willing to pay for a child's shoe, according to a 2018 study, is $50 [6]. Based on this research, we have determined that 200 euros would be an appropriate price for a smart feature-rich athletic shoe, which consumers are willing to spend.

The projected $2.11 billion market value for smart insoles by 2033, with a CAGR of 22.8% [6], indicates not only a growing interest in health and fitness technology but also suggests a significant increase in sales volume over the forecast period. This robust growth can be attributed to a combination of factors:

There is a heightened awareness and demand for health-monitoring devices that can provide early detection of potential health issues, particularly in children. The surge in sales is also driven by the integration of smart technology into everyday items, making it easier for consumers to monitor health metrics. The emphasis on preventive healthcare means parents are more inclined to purchase devices that can track their child's development and catch potential issues early, which translates to increased sales in the smart insole market. Regarding the children's shoes market, with an estimated CAGR of 8.21% [1], the sales growth in this sector is spurred by similar health and wellness trends. However, the slower growth rate compared to the smart insole segment could be due to the broader nature of the market that includes a wide range of products not solely focused on health monitoring.

In Europe, and specifically Germany, the noted CAGRs of 10.1% [3] for smart shoes and 4.5% [7] for shoe insoles indicate a strong but more moderate growth trajectory in sales. This can be linked to: Europe's established healthcare system and higher disposable incomes contribute to a steady demand for health-related products. A cultural focus on health and wellness in Germany, in particular, supports sustained sales in this segment.

The pricing strategy for Aretto shoes, positioned between $29.32 and $38.65, aligns with the market demand for quality and durable children's footwear that accommodates growth, indicating a sales strategy that balances affordability with value-added features. For Prediflex, the proposed price point of 200 euros, despite being higher than the average children's shoe, is justified by the added value of health monitoring and potential orthopaedic benefits. The higher price reflects the advanced technology and added benefits of the smart insoles, which are likely to resonate with a segment of consumers who prioritize health and are willing to pay a premium for products that offer these benefits. This price point would need to be supported by a strong value proposition and clear communication of the health benefits to drive sales in a competitive market. The approximate fabrication cost for Prediflex insoles could be in the range of 80 euros to 100 euros.

In conclusion, the sales potential for both Aretto shoes and Prediflex smart insoles seems to be supported by market trends towards health monitoring and preventive care. The provided statistics suggest that there is a growing consumer base that is receptive to innovative health-focused products for children, which can be tapped into with the right marketing and sales strategies.

Literature to the preamble and specification sheet

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Specification sheet

Uni Freiburg/IMTEK ***Lab course „MST Design Lab I“*** **Semester: WS2023/2034** **Group No.: 3**	**Project name:** **PrediFlex Insoles**	**Version : 04** **Pages total: 10** **Delivery date:05/02/24**

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RWO	Change date	Description	Respons.
		1. **Insole**	
		1.1. **Dimensions of the insole:**	
R		- Length: 19.7cm	
R		- Width of the ball of foot:7.3cm	
R		- Width of the heel: 4.5cm	
R		- Width of the arch: 6.1cm	
R		- Height at the Arch: 3cm	
R		- Heel height: 1cm	
R		- Toe box height: 0.5cm	
R		- Shape of edges: square	
R		- Slit length: 14.8cm	
R		- Slit width: 0.1cm	

		1.2. **Dimensions of the Electronic box inside Insole:**	
R		- Length: 19.7cm	
R		- Height at the Arch: 2cm	
R		- Heel height: 0.5cm	
R		- Toe height: 0.3cm	
R		- Shape of the edges: Square	
R		- Projection Length to close the slit: 14.8cm	
		- Projection Width to close the Lid: 0.1cm	
		Use: Possibility for the user to open the insole to get the electronic box (filled with insole material) out and replace it by a solid box with the same dimensions as the electronic box and a slit to prevent the opening from closing when the insole is sunk in hot water.	
		1.3. **Insole Weight:**	
R		- Without electronics: 110g ± 10g	
R		- With Electronics: 150g ± 10g	
		1.4. **Mechanical Properties of the insole and the electronic box material:**	
R		- Poisson's ratio range: 0 to 1	
R		- Hardness shore A: 55±15 (Measurement acc. to ASTM D2240)	
R		- Stress-strain test: test procedure according to ISO 37-2017 *Parameters : Elongation at 50 kPa±1000Pa and at 100°C in a thermostatically controlled chamber following ISO 23529 guidelines.* *Expected outcomes: tensile and yield strengths above 50kPa at 40°C and even expansion of the melt from 0 to 4cm*	
R		- Stiffness: test procedure according to ISO 458-1:1985 at temperatures 40± 2°C and 100°C	

R		- Abrasion Resistance: 0 to 0.1% volume loss test procedure according to ISO 4649:2017	
R		- Fatigue resistance: (test procedure according to ISO 10768:2010 at 110% extension)	
R		- Tear resistance: 250g ± 50g (measurements according to Elmendorf Tear Strength MD)	
R		- Dimensions stability: test procedure according to ISO 22651:2002	
		1.5. **Thermal properties of the insole and the electronic box material:**	
R		- Operating and storage temperature range: -10°C to 50°C	
R		- Melting temperature range: between 50°C and 100°C (Measurement acc. to DSC)	
R		- Ring and Ball softening point : above 100°C (Measurement acc. to ASTM E28)	
R		- Thermoplastic properties	
R		- Thermal conductivity : 0.02 ± 0.01W/mK (Measurement acc. to DIN 52612)	
		1.6. **Packaging: adjustable mold for the insole and solid box (for substitution purposes):**	
R		- Geometry: Dimensions of the insole as per manufactured, with possibility to expand its length and width by respectively 1x0.2cm at the heel, 0.7x0.2cm at the arch, 1.5x0.2cm around the ball of feet	
R		- Use: Thermoforming of the insole using a insole-shaped packaging with adequate surface finish and good thermal fatigue resistance. *Test procedure:* *Dipping the insole in hot water (80°C±10°C) for 20 to 30 seconds, and then stepping on the insole (50kPa±1000Pa) placed in the mould previously adjusted to the feet size (19.7 to 23.2cm, +0.35cm added/ test) until it solidifies. The electronic box will have been removed and replaced by*	

		the solid box. Repeat the experience 10 times until the max expansion allowed by the mould is reached.	
R R R R R R		*Expected outcomes: surface roughness below 5 microns (measurement according to ISO 4287), no surface defects (bubbles, pits, wrinkles), foreign materials or thermal fatigue induced defects (cracks, deformations or delamination)* - Material: Metal (Suggestions : aluminium, steel, cast iron) 1.7. **Mechanical properties of the mold material and the solid box:** - Hardness (Vicker's Hardness number) : 25± 10HV - Corrosion resistant: test procedure according to ISO 7539-7:2005 1.8. **Thermal properties of the mold material and the solid box:** - Thermal conductivity: 150W/mK ±100 (Measurement acc. to DIN 52612) - Melting point range: greater than 150°C (test procedure according to ASTM E1952-17) - Thermal fatigue: 0±0.002m change of length (test procedure following ISO 12111:2011 at 50kPa±1000Pa and temperature range from -20°C to 100°C)	

RWO	Change date	Description	Respons.
		2. **Electronics Module**	
		2.1. **Piezoelectric force sensor:**	
		2.1.1 **Geometry:**	
R		- Maximal Geometry: 40 mm × 45 mm × 3 mm, each ±1 mm	
		2.1.2 **Signal:**	
R		- Full Range: 100g to ~5000g (0.98N to 49N)	
R		- Life Cycle : >10 Million	
R		- Response time : <1ms	
R		- Connector options : Female contacts , Solder tabs or Bare tail	
W		- Supports I2C/SPI/UART communication	
O		- Low power sensing mode	
		2.1.3 **Energy:**	
R		- Operating Voltage: 2.5V to 5V at 20°C ±5°C	
R		- Supply current : Minimum 3mA in normal mode	
R		- Operating temperature : -30°C to +80°C with ± 5°C	
R		- Packing: Surface mounted technology	
		2.1.4 **Performance:**	
		- Test procedure according to Nemko	

		2.2. **Microcontroller:**	
		2.2.1 **Geometry:**	
R		- Maximal Geometry: 50mm × 60mm × 5mm ± 1mm	
		2.2.2 **Signal:**	
R		- Low power mode compatible	
R		- Should have low power bluetooth transmission	
R		- Response time : 50µs ± 1µs.	
R		- Storage and updation of values	
R		- Connectors compatible	
W		- Communication protocol : I2C/UART/SPI supported	
		2.2.3 **Energy:**	
R		- Supply voltage: 2V - 5V at 20°C ±5°C	
R		- Operating temperature : -30°C to +80°C with ± 5°C	
R		- Supply current : Minimum 3mAh in normal mode	

RWO	Change date	Description	Respons.
		3. **Bluetooth Signal Transmission:**	
R		- Bluetooth Version: Bluetooth 5.0	
R		- Range: Up to 10 meters (33 feet) in open space.	
R		- Transmission Speed: 1 Mbps	
R		- Protocol: Low Energy (LE)	
R		- Transmission Frequency: 2.4 GHz ISM Band	
R		- Enhanced Interference Management: Frequency Hopping (FH)	
R		- Security: AES with 128-bit key length.	
R		- Compatible Devices: Compatible with Bluetooth Smart Ready devices.	
R		- Latency: Less than 50 ms.	
R			

RWO	Change date	Description	Respons.
		4. **Energy harvesting and storage:**	
		4.1. **Type:**	
R		- A power cell that is preferably self charging with bio electric piezo separator is expected.	
O		- The design should be similar to stainless-steel 2016-coin-type cell.	
		4.2. **Energy (per module):**	
R		- The expected output voltage: 10 V	
R		- The expected Power capacity range : 0.02 mWh.	
		4.3. **Geometry:**	
R		- Expected outer diameter: 20 - 25 mm.	
R		- Expected overall height: 1.6 - 2.0 mm.	
R		- Expected overall weight : 1.74 - 1.9 g	
		4.4. **Number of Cells:**	
R		- The product must consist of one self charging power cells (SCPC).	
		4.5. **Temperature:**	
R		- Usable temperature range: -20 ~ 65 deg °C.	
R		- Storage temperature range : -20 ~65 deg °C.	
		4.6. **Control:**	
R		- The designed battery should be in compliance with the European Battery Regulation EU 2023/1542 that satisfies the performance and durability, reduced carbon print, and recycled content.	
R		- The battery should be properly designed such that it doesn't catch fire according to IEC 62133 testing regulations.	
R			

RWO	Change date	Description	Respons.
R R R		- The battery must withstand the heat test where it is stored for 24hrs at 80+/-2 deg °C and a humidity of 70% RH or less. Expected outcome: No abnormal appearance and no substandard dimensions are to be observed. - The battery must withstand the mechanical stability test where the fully charged battery is dropped from 1.2m height 6 times. - The battery must withstand the short circuit test where the battery is short circuited for 48 hours. Expected outcome : No burst, No fire.	
R R R R R		5. **General:** 5.1. **Delamination resistance:** - ISO 20866:2018 is a test method for the determination of the delamination resistance of insoles, irrespective of the material. 5.2. **Perspiration resistance:** - ISO 22652:2002 a method for the determination of the ageing of insoles, linings, or insocks, caused by human sweat 5.3. **Water and dust protection:** - ISO 20535:2019 specifies a method for determining the dimensional change of footwear insoles and insocks after cycle wetting and drying, regardless of the material. - Another test is ISO 22649:2016 which specifies two test methods for determining the water absorption and desorption of insoles and insocks, irrespective of the material. - These methods are as follows. Method A: determination of the static water absorption and desorption of insoles and insocks. Method B: Determination of the dynamic water absorption and desorption of insoles and insocks.	

RWO	Change date	Description	Respons.
		5.4. **Maintenance:**	
R		- Washing the sole at temperatures ranging from 0 to 40 degrees Celsius	
		5.5. **Use:**	
R		- Not intended for kids over 14 years old.	
R		- Recommended Weight: Not over 55 Kgs.	
		5.6. **Product Size:**	
R		- EU Size Range: 32 - 36	

Legend to RWO:

R = Requirement	must be fulfilled
W = Wish (Priority 1-2-3 can be set)	should be fulfilled, if possible
O = Option	„nice to have“, must NOT be fulfilled

Signature (customer)

Signature company

Abbreviation

N……………newton

°C …………... Celsius

K…………... Kelvin

SCPC ………...Self Charging Power Cell

V ……………Voltage

mm ……………. Millimeter

ms………………. Milliseconds

IEC ……………. International Electrotechnical Commission

EU ……………. European Union

R ………………. Requirement

W ……………… Wish

O ………………. Option

g ………………… Gram

mWh……………. Milli-watt-hour

mAh ……………. Milli Ampere-hour

W/mK…………… Watt per meter Kelvin

HV………………. Vickers Pyramid Number

Pa………………. Pascal

ISO………………. International Organization for Standardization

ASTM………………. American Society for Testing and Materials

DIN………………. German Institute for Standardization

MD………………. Machine direction

Mbps………………. Megabits per Second

AES………………. Advanced Encryption Standard

I2C………………. Interconnected Circuit

SPI………………. Serial Peripheral Interface

UART………………. Universal Asynchronous Receiver Transmitter

4. Abstraction of the specification sheet

Step 2: Essential statements for the described functions

1. General **1.1 Insole and electronic box** - Non-auxetic material with thermoplastic properties - Limited size and limited weight: 32EU size - Dedicated space and its slit for electronic components - Poisson's ratio range: 0 to 1 - Hardness shore A: 55±15 - Abrasion Resistance: 0 to 0.1% volume loss - Fatigue resistant - Tear resistance: 250g ± 50g - Dimensions stability - Melting temperature range: between 50°C and 100°C - Thermal conductivity: 0.02 ± 0.01W/mK **1.2 Packaging: adjustable mold** - Limited dimensions to fit the insole inside - Adjustable length and width at the different section of the feet (1x0.2cm at the heel, 0.7x0.2cm at the arch, max 1.5x0.2cm around the ball of feet) - Suitable for thermoforming of thermoplastic material - Vicker's Hardness number: 25±10HV	**2.2 Microcontroller** - Low power mode compatible - Should have low power Bluetooth transmission - Response time: 50μs ± 1μs. - Storage and updating of values - Connectors compatible - Communication protocol: I2C/UART/SPI supported **3. Bluetooth Signal Transmission:** - Bluetooth Version: Bluetooth 5.0 - Range: up to 10 meters in open space. - Transmission Speed: 2 Mbps - Protocol: Low Energy (LE) - Pairing Method: Secure Simple Pairing (SSP) - Transmission Frequency: 2.4 GHz ISM Band - Security: AES with 128-bit key length. - Compatible Devices: Compatible with Bluetooth Smart Ready devices. - Latency: Less than 50ms. **4. Energy harvesting and storage:** - Self-charging power cell with bio electric piezo separator. - Output voltage range: 10 V

- Corrosion resistant: - Thermal conductivity: 150W/mK ±100 - Melting point range: greater than 150°C - Thermal fatigue: 0±0.002m **2. Electronics Module** **2.1 Piezoelectric force sensor:** - Full Range: 100g to ~5000g (0.98N to 49N) - Life Cycle: >10 million - Response time: <1ms - Connector options: Female contacts, Solder tabs or Bare tail - Supports I2C/SPI/UART communication - Low power sensing mode - Operating Voltage: 2.5V to 5V - Supply current: >3mA - Operating temperature: -30°C to +80°C ± 5°C	- Power capacity range: 0.02 mWh. - Dimensions and weight (outer diameter x height x weight): 22.5mm x 1.8mm x 1.81g - One self-charging power cell (SCPC) per sole. - Usable temperature range: -20 ~ 65 deg °C. - Storage temperature range: -20 ~65 deg °C.

Step 3: Qualitative statements

1. General **1.1 Insole and electronic box** - Non-auxetic material with thermoplastic properties - Limited kid's insole size range and limited weight - Provide a space and a slit to insert and remove the electronic components	- Supports I2C/SPI/UART communication - Power consumption in range with battery supplied power **2.2 Microcontroller** - Limited size to fit in the insole - Low power mode compatible - Low power Bluetooth transmission - Quick response time for data accuracy - Storage and updating of values

- Withstand scratching, abrasion, delamination and plastic deformation at low stress and ambient temperature

- Provide support and cushion for the feet with elastic deformation

- Stable dimensions when exposed to ambient water and low stress

- High perspiration resistance to slow the ageing process

- Melt at a temperature above the ambient temperature and under the boiling water temperature

- Low thermal conductivity to retain heat to keep the feet warm

1.2 Packaging: adjustable mold

- Limited dimensions to fit the insole inside with adjustable length and width at the different section of the feet (heel, arch, ball of feet)

- Suitable for thermoforming of thermoplastic material

- Corrosion resistant

- Dimension stability during low stress and hot water exposure cycles

- Conduct thermal energy well to cool down wafer

- Don’t melt when exposed to hot water

2. Electronics Module

2.1 Piezoelectric force sensor:

- Limited size to fit in the insole

- Detect low pressures as well as higher pressures

- Withstand many pressures cycles

- Connectors compatible with battery and sensors

- Communication protocols: I2C/UART/SPI supported

- Power consumption in range with battery supplied power

3. Bluetooth Signal Transmission:

- Power effective and low energy Bluetooth generation

- Signal range sufficient to reach a phone

- Quick transmission time of small data packets to be power effective

- Transmission Frequency with longer range

- Adjusted frequency with range

- Standard Security Protocol

- Compatible with Bluetooth Smart Ready devices.

- Low latency for data reliability

4. Energy harvesting and storage:

- Energy harvesting and storage autonomous cell

- Small, light, compact and flat to fit in the insole

- Power generated should be sufficient to power the sensor and the microcontroller

- High device stability with low charge transfer resistance for energy efficiency

- Quick response time for accurate data - Compatible connector with microcontroller	

Step 4: Reduced statements

1. General **1.1 Insole and electronic box** - non-auxetic material with thermoplastic properties - Limited kid's insole size range and limited weight - Provide a space and a slit to insert and the electronic components - Withstand scratching, abrasion, delamination and plastic deformation in daily use conditions - Comfortable - Durable - High perspiration resistance - Expandable below boiling water temperature - Thermal insulator **1.2 Packaging: adjustable mold** - Limited dimensions to fit the insole inside - Adjustable length and width at the different sections of the feet (heel, arch, ball of feet) - Suitable for thermoforming of thermoplastic material	- Monitor the applied pressure - High fatigue resistance - Compatible connector with microcontroller - Power consumption in range with battery supplied power **2.2 Microcontroller** - Limited size to fit in the insole - Low power mode compatible - Low power Bluetooth transmission - Accuracy - Storage and updating of values - Connectors compatible with battery and sensors - Power consumption in range with battery supplied power **3. Bluetooth Signal Transmission:** - Power effective and low energy Bluetooth generation - Broad range of transmission - Frequency modulation with range

- Corrosion resistant - Durability - Thermal conductor - High melting temperature **2. Electronics Module** **2.1 Piezoelectric force sensor:** - Limited size to fit in the insole - High resolution and accuracy	- Compatible with Bluetooth Smart Ready devices. - Reliability **4. Energy harvesting and storage:** - Energy harvesting and storage autonomous cell - Convert mechanical energy into electrical energy - Small, light, compact and flat to fit in the insole - High device stability and low discharging loss

Step 5: Qualitative formulation of the problem statements

Energy autonomous adjustable-size insole with a removable and accurate pressure monitoring electronic system inserted inside is used to predict children's orthopedic conditions. Small, light, compact, energy-efficient, and isolated electronic components are used. The updated data are regularly sent to the customer. The insole should be durable, comfortable, and withstand plastic deformations in daily use conditions, but plastically expand under boiling water temperature when low stress is being applied. The initial properties of the insole, other than the dimensions, shouldn't be altered after undergoing the deformation process.

5. Functional analysis

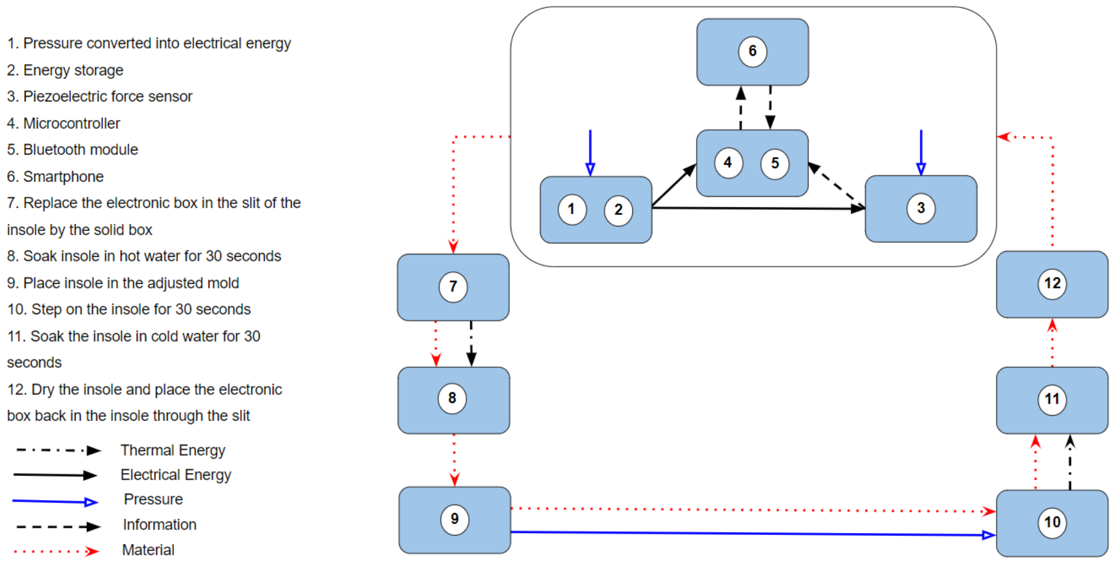

Fig. 2: Functional Analysis of Prediflex Insoles

6. Creativity

Various Creativity techniques were employed to productize our idea. Here are the following techniques and there outcomes to developed our idea into a product:

Other Applications: This method involves looking at different uses for an idea. The concept of a smart shoe sole might have originated from a different application, such as sports performance tracking or general activity monitoring. Realizing that the mechanics of walking can reveal a lot about a person's health, the idea could have been adapted to focus on medical diagnostics, particularly for conditions that affect gait and balance.

Adaptation: This involves finding similarities between different things. The developers might have looked at existing medical devices like ECG monitors, which track heart health, and thought about adapting a similar monitoring concept to a shoe sole. They could have considered how gait analysis is used in physiotherapy and neurology, leading to the idea of integrating piezoelectric sensors to analyze walking patterns for health predictions.

Modification: This method asks what can be changed in an existing idea. Initially, the shoe sole might have been a standard, non-interactive component. Through modification, it became expandable to accommodate electronics. Changes in materials (e.g., using flexible, conductive polymers) and design (e.g., integrating cavities for sensors and electronics) would have been essential.

Miniaturization: In developing this idea, aspects of the technology would have needed to be reduced in size. Miniaturizing the electronic components, such as sensors and processors, to fit comfortably and unobtrusively within a shoe sole would have been a critical step. This would involve reducing the size of the piezoelectric sensors and any associated circuitry.

Combination: This involves merging different ideas or technologies. Combining piezoelectric sensors (for capturing walking data) with advanced data analysis algorithms (for predicting medical conditions) in a single shoe sole is a prime example. Additionally, combining comfort (expandable sole) with utility (medical diagnostics) would have been key.

Replacement: This method asks what can be replaced in an idea. In developing this smart sole, traditional shoe sole materials could have been replaced with new, more flexible materials that can house electronics without compromising comfort. Also, instead of using conventional pressure sensors, piezoelectric materials, which are more sensitive and can generate their own electrical charge in response to pressure, would have been chosen.

After this a powerful technique called brain storming was used to cultivate the final idea from all the above techniques.

Based on the brainstorming structure represented in the image, here is an explanation of how the ideas were refined and finalized for each component of the expandable shoe with smart technology:

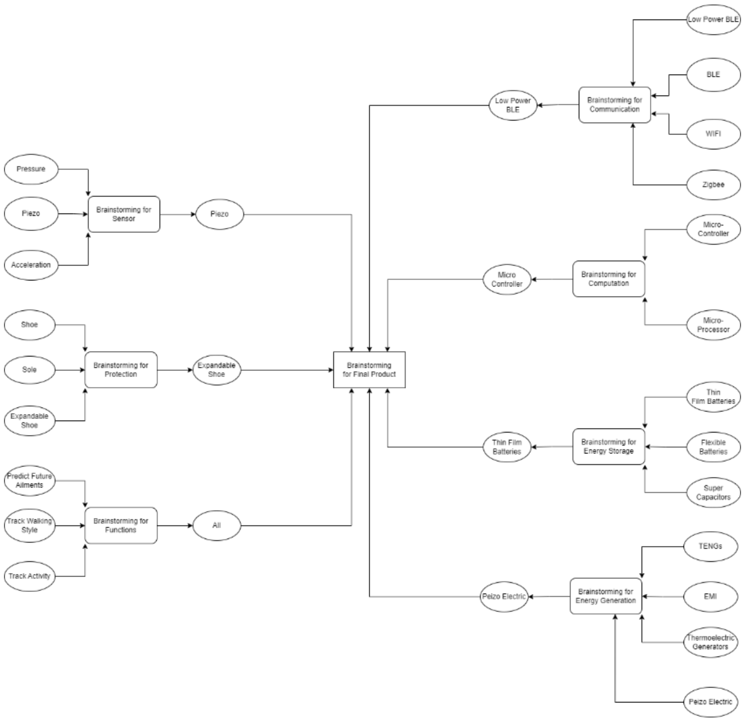

Fig. 3: Brainstorming Map for Creative Thinking

Sensors: Brainstorming for sensors likely included a discussion on various types of sensors that could track movement and provide data on walking style. The decision to use piezoelectric sensors was made because they can generate electrical energy from pressure, which is plentiful when walking. This choice not only provides the necessary data but also contributes to the power supply.

Protection: For the protection of the shoe and its embedded technology, the brainstorming might have focused on materials and designs that could safeguard the electronics from environmental factors such as water, dirt, and impact. The expandable shoe concept itself may have been a result of the need for protection, ensuring that the electronics have enough space and are shielded by the shoe's structure.

Functions: The team would have brainstormed the various functions that the shoe needed to perform, which include tracking walking style and predicting future ailments. These functions drive the selection of sensors and other components, ensuring that the shoe can collect the appropriate data to fulfill its intended health-monitoring role.

Communication: Different communication protocols such as Bluetooth Low Energy (BLE), Wi-Fi, and Zigbee would have been considered. BLE was likely chosen for its low power consumption and sufficient data transfer rate, which is ideal for a wearable device that requires long battery life and isn't dependent on high-speed data transmission.

Computation: For data processing, brainstorming would have focused on finding the most efficient and compact computing solutions. Microcontrollers were selected for their ability to process sensor data, control power management, and interface with communication modules, all while maintaining a small footprint suitable for integration into a shoe.

Energy Storage: Brainstorming for energy storage would have included discussions on various ways to store the energy generated by the piezoelectric materials. Options such as thin-film batteries, flexible batteries, supercapacitors, and TENGs were considered. The final choice would balance storage capacity, flexibility, size, and weight to ensure the shoe remains comfortable and functional.

Energy Generation: Besides piezoelectric materials, other energy generation methods like TENGs and electromagnetic induction (EMI) would have been on the table. These methods would be evaluated based on their efficiency, the complexity of integration into the shoe's sole, and the amount of energy they can reliably generate from walking.

Final Product: The brainstorming for the final product would synthesize all the above discussions to design a shoe that is expandable to accommodate the necessary electronics, durable to protect them, and comfortable for the user. It would integrate the chosen sensors, communication protocols, computation hardware, and energy storage and generation methods into a cohesive and marketable smart shoe.

This structured brainstorming approach allows the team to address each component of the product in detail, ensuring that all aspects are carefully considered and the best options are selected to create a functional and innovative final product.

7. Evaluation, demonstration of feasibility

7.1 Calculations on the power consumption of the embedded system part

Component	Operating Voltage (V)	Average Current Consumption (mA)	Power Consumption (mW)	Time Powered On (s)	Energy (mWh)	Reference
Microcontroller (Active)	3	3.3	9.9	80	**0.22**	[11]
Microcontroller (Sleep)	3	$0.97x10^{-3}$	2.85x10-3	86300	**0.0683**	[11]
Bluetooth Tx @ 8 dBm	3	16.4	49.2	20	**0.273**	[11]
Piezo Pressure Sensor	3	$3x10^{-3}$	$9x10^{-3}$	80	**0.0002**	[12]
Total Power (mW)	59.1					
Total Energy (mWh)	0.561					

Table 2: Power Consumption Calculations for embedded system of Prediflex

Microcontroller (CPU Running for Data Measurement): The microcontroller is active for 80 seconds each day to measure pressure data from the piezo sensor. This period, constituting about 0.07% of the day, is critical for capturing accurate pressure readings essential for the monitoring function. During these moments, the microcontroller operates at full capacity, resulting in an average power consumption of 9.9 mW.

Microcontroller (CPU Running with Bluetooth Transmission): For an additional 20 seconds daily, amounting to approximately 0.03% of the day, the microcontroller is active with the Bluetooth transmitter enabled. This phase is dedicated to transmitting the collected data, consuming an average power of 49.2 mW. This brief yet efficient transmission period ensures rapid data transfer while managing power consumption effectively.

Microcontroller (Sleep Mode): Occupying the vast majority of the day, for 86,310 seconds (99.90%), the microcontroller remains in sleep mode. In this low-power state, it maintains minimal functions, drastically reducing power usage to about 0.00285 mW. This mode is pivotal in extending the device's battery life, as it minimizes energy consumption when active monitoring or data transmission is not required.

Piezo Sensor Triggered Wake-Up: The microcontroller is programmed to wake up for 80 seconds when the piezo sensor detects pressure, indicating activity like walking. These micro-moments of activity, triggered by sensor interrupts, allow for real-time data capture without significantly impacting overall power consumption. The system thus ensures continuous monitoring capability while maintaining efficient energy usage.

The insole monitoring system, with its total power consumption of 59.1 mW and total energy use of 0.561 mWh, exemplifies high efficiency in wearable technology. This optimized power management significantly extends battery life, reducing the need for frequent recharges and allowing for a smaller, lighter battery design. It also ensures user safety through minimal heat generation. Overall, the system skillfully balances energy efficiency with robust functionality, making it a prime example of innovative wearable technology.

7.2 Calculations on the power supply of the generator part

Piezoelectric materails generate electrical voltage when subjected to mechanical stress or deformation. Using an SCPC is differnet from the typical set up of extracting power from a bunch of piezoelectric sensors at the bottom of the sole, as the SCPC consumes less space and weight but produces equivalennt or greater mW output. In the self-charging mechanism, the role played by the piezoelectric polymer separators is similar to the DC power supply used in the conventional charging process of a Li ion battery. Both of them can be deemed as charge pumps, but the specific mechanisms are different. In the self-charging system, the perforated fish swim bladder that is used as a bio-piezoelectric separator material moves the ions, not electrons, from the positive to the negative side, which charges the device.[13]

GENERATOR MODEL	COUNT	OUTPUT VOLTAGE RANGE (V)	OUTPUT CURRENT RANGE (A)	STANDARD POWER RANGE (mW)
Bio Piezo Electric Seperator SCPC [14]	1	10	2×10^{-6}	0.02

Table 3: Power Supply Specifications for embedded system of Prediflex

When a compressive force of 12 N or is applied onto the SCPC at the frequency of 1 Hz, the voltage of the SCPC as mentioned in the table above is obtained. With just one SCPC, a power capacity of 0.02 mW is obtained, which is more than sufficient for the required application.

7.3 Calculations on the design of a battery

BATTERY MODEL	INPUT VOLTAGE (V)	CAPACITY (mAh)	MAX ENERGY (mWh)
Panasonic BR-2032/HEN [15]	3.3	200	660

Table 4: Battery Specifications for embedded system of Prediflex

Battery Capacity and Energy Storage

The energy storage capacity of the battery is a fundamental aspect of any portable electrical system. For the device in question, a battery with a capacity of 200 mAh is employed. The total energy (E_bat) stored by this battery can be calculated using the formula:

E_bat = V x C_bat

where V is the battery voltage in volts, and C_bat is the battery capacity in ampere-hours (Ah). Using a voltage of 3.3V, the energy storage comes out to:

E_bat = 3.3V x 0.2Ah = 660 mWh

This value indicates the total usable energy stored in the battery under ideal conditions.

Buck Converter Efficiency

The buck converter's role is to step down the voltage from the battery to a level suitable for the device. The converter takes an input voltage of 10V and an input current of 2 µA and steps it down to an output voltage of 3.3V and a current of 100 µA at an efficiency of 85%. To assess the efficiency of the buck converter, one would typically compare the input power to the output power.

Energy Generation and Duration

The duration of energy generation is crucial in determining the battery's life span. For the device, the energy generation over a period of 9000 seconds (2.5 hours) can be calculated as follows:

E = P x t

where P is the power in watts, and t is the time in seconds. With a power requirement of 9.9 mW, the energy consumption over the duration is:

E = 3.3 mW x 9000s / 3600 = 0.825 mWh

This represents the energy production of the device for the specified operational period.

Requirements	Energy Generated in 24 Hours	Energy Consumed in 24 Hours
Energy	0.825 mWh	0.561 mWh

Table 5: Generated and Consumed Energy for our Embedded System respectively

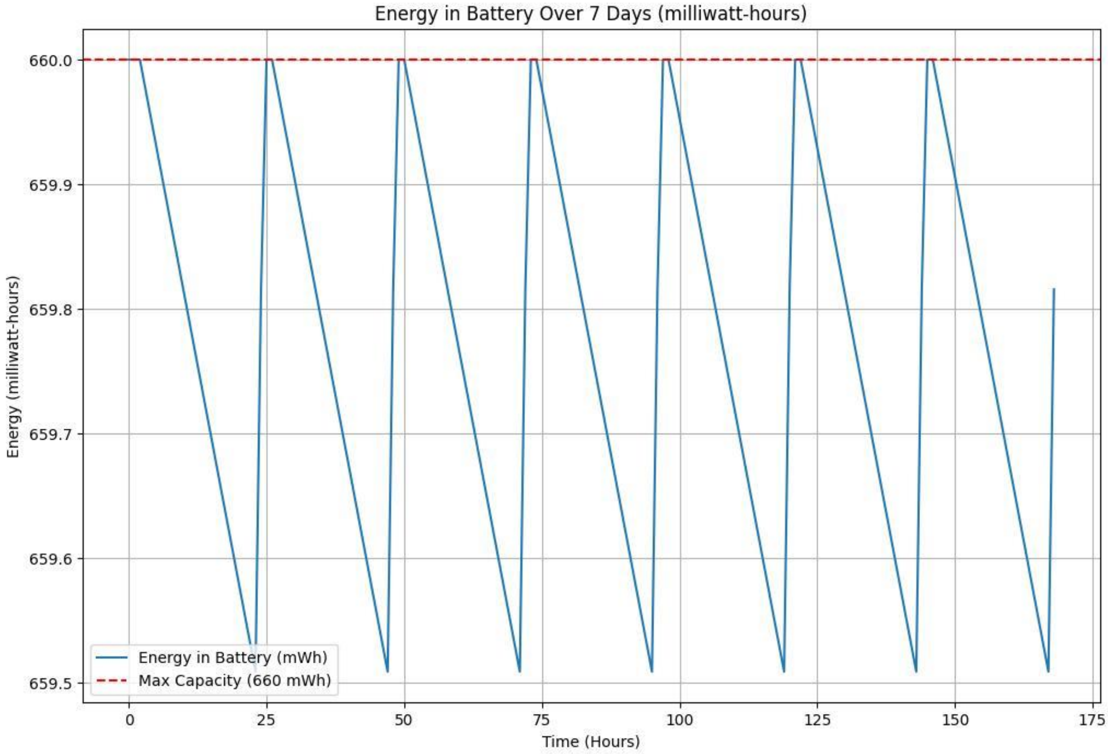

Fig. 4: Fluctuation in energy consumption over a period of 2 days

This graph shows how the energy level fluctuates daily within the confines of the battery's capacity, increasing during the generation periods each day and decreasing due to consumption.

From Fig 4 and Table 5 it is clear that we could meet the energy requirements of our circuit powered by SCPC and a battery.

7.4 Calculation of bill of materials and fabrication costs

Serial No	Name	Quantity required for both Soles	Volume required for both soles (cc)	Cost (€)	Total Cost (€)
1	Microcontroller nRF52840	2	NA	7.5	15
2	Piezo Pressure Sensor	2	NA	6	12
3	Arkema EVATANE® 33-25 Copolymer Ethylene - Vinyl Acetate	NA	100	0.2	20
4	Aluminum Box	NA	30	0.433	13
5	TPS62745 Buck Converter	2	NA	1	2
6	3.3v 200mAh Battery	2	NA	1	2
7	SCPC	2	NA	10*	20
Total					84

Table 6: Material Cost Calculation for Prediflex

The initial production expense, primarily attributed to the pre-fabricated nature of numerous components, stands at 16€, requiring a careful assessment for the assembly process of the housing unit. Coupled with the material expenditure totalling 84€ bring the total production cost to 100€, the comprehensive financial evaluation suggests a proposed retail price for the product at 200€. This pricing strategy has been meticulously formulated to ensure a balance between cost-effectiveness and maintaining the quality standards our customers expect.

* Price approximiated based on ongoing research

7.5 Still existing deficits, solution concepts

Prediflex faces several distinct challenges, each requiring targeted solutions to optimize its functionality and marketability.

Firstly, the inconsistency of kinetic energy harvesting poses a significant problem, potentially leading to power issues during periods of low activity. A practical solution is the integration of a backup battery, ensuring consistent operation regardless of activity levels.

Secondly, the durability of the mechanical components used for size adjustment and energy harvesting is a concern, as they are prone to wear and tear. To mitigate this, using high-grade, durable materials and adopting simpler mechanical designs can enhance the overall longevity of the product.

Thirdly, maintaining accurate gait analysis as the insole expands to accommodate the child's growing foot presents a challenge. Implementing a dynamic calibration system within the app, which adjusts to the changing size of the insole, would be an effective way to ensure continued accuracy.

Lastly, the selling cost is at 200€, which is very high compared to our competitors. To address this, we aim to reduce the cost by manufacturing our own ethylene-vinyl acetate (EVA) foam, which is a significant component of the insoles. By controlling the production of EVA, we can not only cut down on material costs but also customize the formulation to our specific needs, potentially enhancing the product's energy-harvesting efficiency. Furthermore, by streamlining our fabrication process and seeking economies of scale, we can further drive down manufacturing costs. This, combined with potential automation of certain production steps, could lead to significant savings that we can pass on to our customers, making our product more competitive in the market. Implementing these measures will help us to reduce the final retail price while maintaining, or even improving, the quality and functionality that Prediflex is known for.

The advanced features of Prediflex, while innovative, increase production costs, potentially impacting its market competitiveness. Offering a basic version at a lower cost and exploring partnerships to subsidize the advanced model could make the product more accessible and appealing to a broader market.

Literature on product design and elaboration

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