WHITE PAPER

Solsius SelfCare Medical Device

Our mission : Prevent diabetic foot complications on a daily basis

Solsius

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1. Who are we ?

Solsius: A MedTech Company Based in Lille

Founded in 2023, Solsius is a French startup that designs, develops, and markets an innovative medical device dedicated to preventing diabetic foot complications.

1.1. Our story

Solsius was born from a simple yet alarming observation: each year in France, **80,000** diabetic patients develop a foot ulcer, a complication that is preventable in most cases if detected early [1]. However, available tools remain insufficient: daily visual inspection is poorly suited and often impossible for patients with visual impairment, and podiatry consultations do not allow for continuous monitoring.

It was in this context that Solsius' ambition emerged: to design a simple medical device enabling at-risk patients to monitor their foot health daily, independently and without constraints.

1.2. Our mission

Solsius' mission is to provide diabetic patients with a solution capable of detecting early signs of ulceration before they become visible and enabling healthcare professionals to intervene in time to prevent complications and improve daily care.

2. Context and challenges

Diabetes and its complications : a major public health issues

Diabetes is a major global public health issue. In 2024, the global prevalence reached 589 million adults and could rise to 853 million by 2030 [2].

Beyond chronic hyperglycemia, long-term complications represent the primary threat :

> **Peripheral Neuropathy** **(up to 50%)**
> Nerve damage disrupting signal transmission between the central nervous system and the rest of the body. Causes loss of sensation, tingling, pain, numbness, or muscle weakness, often affecting hands and feet.

Retinopathy (30%)
Damage to small blood vessels in the eye, potentially leading to visual impairment or blindness.

Nephropathy (over 30%)
Kidney damage reduces blood filtration capacity, potentially leading to kidney failure and dialysis.

Peripheral Arterial Disease (PAD) (up to 30%)
Narrowing or obstruction of leg arteries. Causes pain, cramps, poor wound healing, and in severe cases, ulcers or gangrene due to reduced blood supply.

Diabetic Foot (up to 50%)
Tissue deterioration that may become infected and progress to ulceration, potentially leading to minor or major lower-limb amputation.

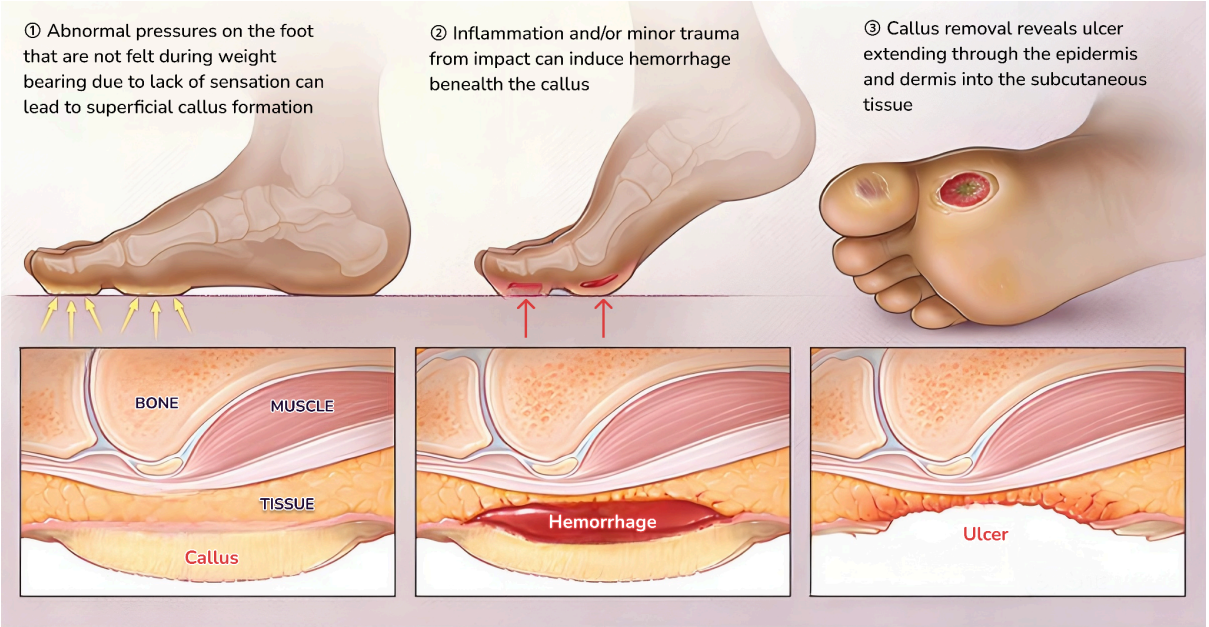
Among these complications, the **diabetic foot ulcer (DFU)** is one of the most feared due to its frequency, severity, and cost.

3. Diabetic Foot Ulcer

A high amputation-risk complication

3.1. Description

A diabetic foot ulcer (DFU) is a chronic skin lesion resulting from the combined effects of peripheral neuropathy, peripheral arterial disease (PAD), and repeated mechanical microtrauma. It typically develops on pressure points: forefoot, toes, and heels. Without early and appropriate care, DFU may progress to severe infection, tissue ischemia, and amputation.



The International Working Group on the Diabetic Foot (IWGDF) has established an international reference classification for assessing the risk of ulceration in diabetic patients. This classification is based on the evaluation of four fundamental clinical parameters and determines the recommended frequency of podiatric monitoring and preventive interventions appropriate to each level of risk.

Grading of podiatric risks according to the IWGDF and the HAS [1, 3]

Grade	Risk of ulceration	Characteristics	Screening frequency
0	Very low risk	**No sensory neuropathy**	Podiatric risk screening at least once a year
1	Low risk	**Isolated sensory neuropathy** *a)*	Screening every 6 to 12 months
2	Moderate risk	**Sensory neuropathy** and **une artériopathie des membres inférieurs** *b)* et/ou à une **déformation du pied** *c)*	Screening every 3 to 6 months
3	High risk	History of foot ulceration lasting more than 4 weeks and/or lower limb amputation (including part of a toe)	Consultation every 1 to 3 months

a) Defined by an abnormal Semmes-Weinstein monofilament test (10g)

b) *Defined by the absence of at least one of the two foot pulses or an ABI < 0.9*

c) *Hallux valgus, hammer or claw toe, metatarsal head prominence, post-surgical or Charcot foot deformities*

3.2. Main causes

Diabetic foot ulcers (DFUs) primarily result from the combination of peripheral neuropathy and peripheral arterial disease (PAD).

Peripheral neuropathy

Neuropathy causes a progressive loss of sensation, reducing the patient's ability to perceive pain, excessive pressure, or minor trauma; these injuries go unnoticed and may progress to ulceration.

Peripheral Arterial Disease (PAD)

PAD is a condition affecting the leg arteries, often asymptomatic. PAD is the second pathophysiological mechanism involved in the onset of foot wounds: it is associated with delayed healing and a significantly increased risk of amputation [4, 5].

Aggravating factors

In these vulnerable patients, any foot deformity, even minor, becomes an additional risk factor by creating areas of excess pressure. Apparently minor trauma can trigger a wound: inappropriate footwear (the most common cause), iatrogenic acts such as burns or inappropriate care, lack of podiatric care (long nails or hyperkeratosis), or poor hygiene [6].

3.3. Consequences

The onset of a diabetic foot wound is a serious complication. It is estimated that 20% to 25% of people living with diabetes will develop a foot wound at some point in their lives. The presence of infection or PAD are aggravating factors, increasing healing time, the risk of non-healing, and the risk of minor and major amputation [7].

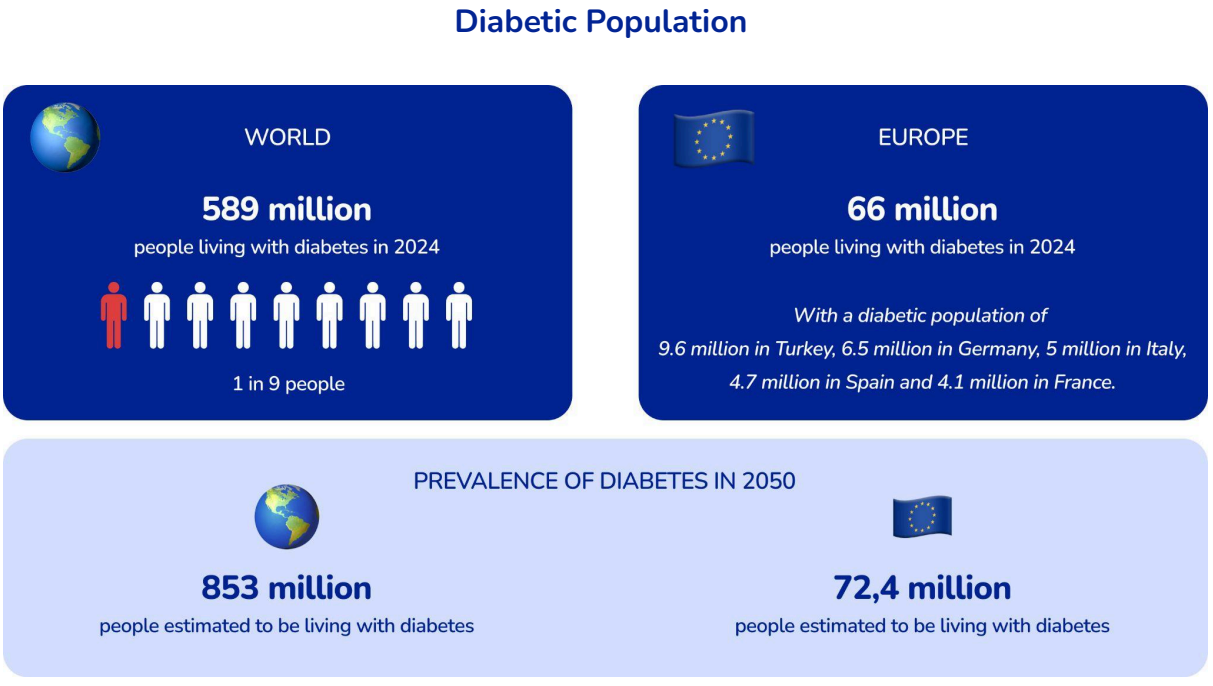
Approximately 20% of infected wounds result in lower limb amputation [5]. Diabetic foot wounds precede 80% of lower limb amputations in people diagnosed with diabetes and are associated with an increased risk of death.

Ulcer recurrence is frequent: approximately 40% of patients experience a new ulcer within one year of healing, 60% within 3 years, and up to 65% within 5 years [8–13].
The severity is also reflected in long-term outcomes after amputation, with a 5-year mortality risk reaching up to 69% [14].

From an economic standpoint, treating a foot ulcer is very costly. The cost of treating a wound is estimated at between €4,000 and €8,000, and the cost of amputation varies between €20,000 and €50,000 depending on the type of amputation (minor or major). These costs cover all costs related to these events: consultations with diabetologists/nurses/specialists, nursing costs, hospitalisation costs, travel costs, wound and ulcer treatment costs, surgical costs, dressing costs and other care costs.

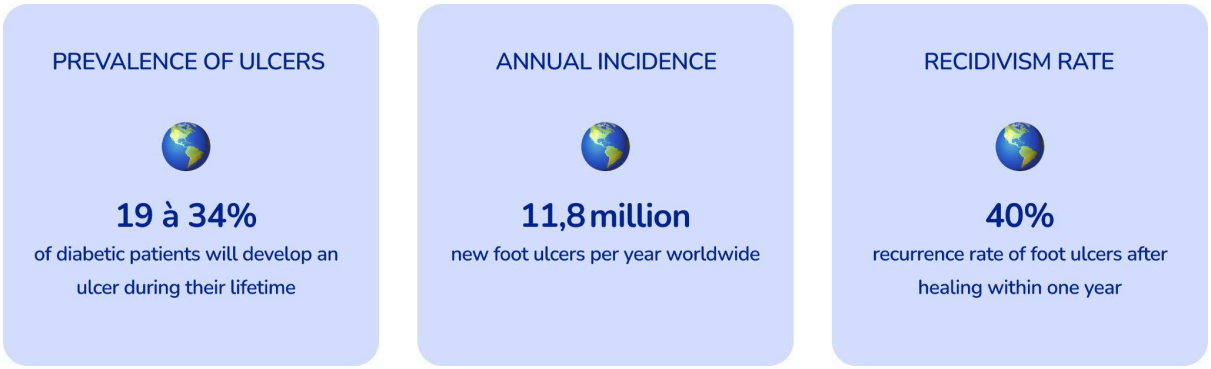
Ultimately, the total cost in France (amputation or hospitalised foot wound) is estimated at €660 million per year, of which €350 million is related to patients with amputations and €310 million is related to those who have been hospitalised in acute care for foot wounds [15].

3.4. Epidemiology



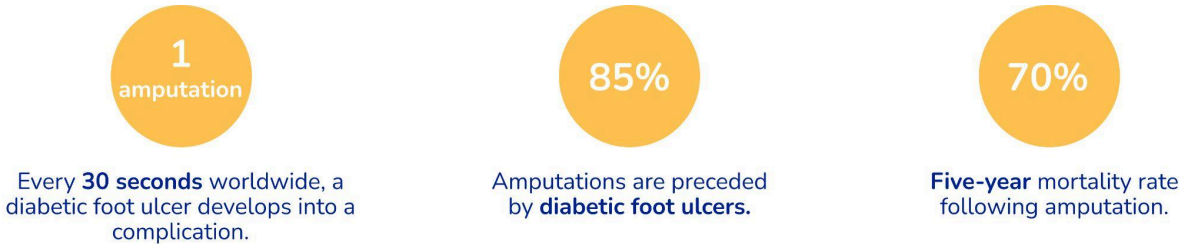
Source : Diabetes Atlas

Diabetic foot ulcers



Source : IWGDF 2023

Diabetes related-amputations



3.5. Limitations of traditional prevention

Despite guidelines from learned societies, traditional prevention of the diabetic foot relies on practices that are often insufficient, irregular, or poorly adapted, limiting early detection of lesions and reducing the effectiveness of preventive intervention :

✖ **DAILY VISUAL INSPECTION**

Recommended by all learned societies, it is nonetheless impractical for many patients: mobility difficulties, obesity, visual deficits, or lack of training make this exercise insufficient.

✖ **NEUROPATHY MASKS WARNING SIGNALS**

In high-risk patients, the loss of pain sensitivity prevents the perception of

microtrauma, friction areas, and local heat. The injury can progress without any perceived symptoms.

✖ **ANATOMICAL DEFORMITIES**
Areas of excess pressure, often under the forefoot or toes, are difficult to visualize without appropriate equipment, creating blind spots during inspection.

✖ **DISCONTINUITY OF FOLLOW-UP**
Monthly or quarterly podiatric consultations do not allow monitoring of foot lesion onset between visits. Moreover, the majority of diabetic patients do not comply with the recommended consultation frequency for their risk level.

✖ **ABSENCE OF EARLY ALERT**
Without a dedicated tool, the diagnosis of ulceration is made once the lesion is already established, closing the preventive intervention window.

4. Plantar temperature monitoring

A predictive marker of ulceration

4.1. Pathophysiological basis

The onset of a diabetic foot ulcer is generally preceded by local inflammation, detectable through an elevation of plantar skin temperature before any visible lesion. Monitoring this temperature, and in particular identifying 'hot spots' — defined as areas where the temperature of one foot is significantly higher than that of the corresponding site on the opposite foot — makes it possible to identify repetitive mechanical trauma before an ulcer occurs.

These thermal abnormalities, considered early markers of inflammation, can be predictive of ulceration and should lead to a reduction in ambulatory activity and/or adaptation of footwear to offload the affected area [16].

1 **Repetitive microtrauma**
Ambulatory activity generates mechanical stress on pressure areas. In neuropathic patients, these traumas go unnoticed.

2	**Local inflammatory reaction (preclinical stage)** In response to trauma, local inflammation develops: vasodilation, leukocyte influx, enzymatic autolysis. This generates a measurable rise in skin temperature, with no visible symptom.
3	**Detectable thermal asymmetry (intervention window)** A temperature difference > 2.2°C between symmetrical sites on both feet becomes measurable. This early marker is the clinical data retained by Solsius to prevent ulcers. This window precedes the ulcer by an average of 37 days (Rothenberg 2020).
4	**Skin breakdown: onset of the ulcer** Without intervention, uncontrolled inflammation leads to tissue necrosis and skin breakdown. The ulcer is now visible but the preventive window is closed.

4.2. Clinical evidence

Several studies evaluating remote plantar thermometry devices have confirmed the clinical value of this approach. They have notably shown that contralateral thermal asymmetries greater than 2.2°C (4.0°F) constitute a relevant threshold for predicting the onset of plantar ulcers.

Multiple studies and meta-analyses show that plantar temperature monitoring significantly reduces the risk of ulcers in people with diabetes. Clinical trials report a reduction in plantar ulcer onset ranging from 61% [17] to more than 70% [18], while meta-analyses show a risk reduction of between 49% and 63% compared to standard care [16, 19, 20].

Beyond primary prevention, thermal monitoring has also proven beneficial in preventing recurrence. In one study, only 15% of patients monitored using thermal monitoring developed a new plantar ulcer, compared to 35% in the group without monitoring. Another study also observed fewer recurrences and better outcomes when patients adjusted their physical activity after receiving an alert [12, 21].

Furthermore, thermal monitoring can detect foot lesions before they become clinically apparent. One device was able to predict 91% of ulcers, on average 41 days before they became visible, in an initial study [22], and 97% of lesions approximately 37 days before their clinical diagnosis in another study [23]. Thermal monitoring devices are also associated with an 83% reduction in amputations and a 63% reduction in hospitalisations [24].

All of these results position thermal monitoring as an effective and clinically relevant preventive measure in the management of diabetic foot.

4.3. International guidelines

According to the recommendations of the International Working Group on the Diabetic Foot (IWGDF), diabetic patients at moderate to high risk of ulceration (grade 2-3) should monitor the temperature of their feet daily. A difference of > 2.2 °C on two consecutive days should lead to limiting ambulatory activity and promptly consulting a healthcare professional [1].

> **Recommendation n°7 - IWGDF 2023**
>
> Consider coaching a person with diabetes who is at moderate or high risk of foot ulceration (IWGDF risk 2-3) to self-monitor foot skin temperatures once per day to identify any early signs of foot inflammation and help prevent a first or recurrent plantar foot ulcer. If the temperature difference between corresponding regions of the left and right foot is above a temperature threshold of 2.2 °C (or 4.0 °F) on two consecutive days, coach the person to reduce ambulatory activity and consult an adequately trained healthcare professional for further diagnosis and treatment.

5. The Solsius SelfCare solution

An innovative medical device for diabetic foot complications

In this context, the Solsius SelfCare medical device is designed to detect abnormal foot temperature variations > 2.2°C, providing patients and healthcare professionals with a prevention tool based on a clinical biomarker validated in scientific literature.

5.1. Description

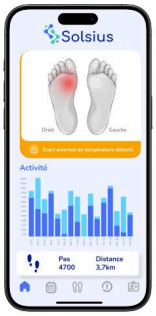
The Solsius SelfCare self-monitoring medical device is a CE-marked Class I medical device that detects abnormal variations in foot temperature that may be an early sign of diabetic foot ulcers, a common complication in diabetic patients.

The Solsius SelfCare medical device consists of a pair of connected insoles (which may or may not be combined with a foot orthosis or orthopaedic shoe) and a Solsius SelfCare mobile application installed on the patient's smartphone.

Connected insoles for patient use

- **Lightweight, flexible,** and **thin,** designed from biocompatible materials.
- Easily **integrated** into an orthopedic insole or shoe.
- Transparent temperature **data collection** for the patient, offering 12 months of autonomy.

Mobile application for the patient



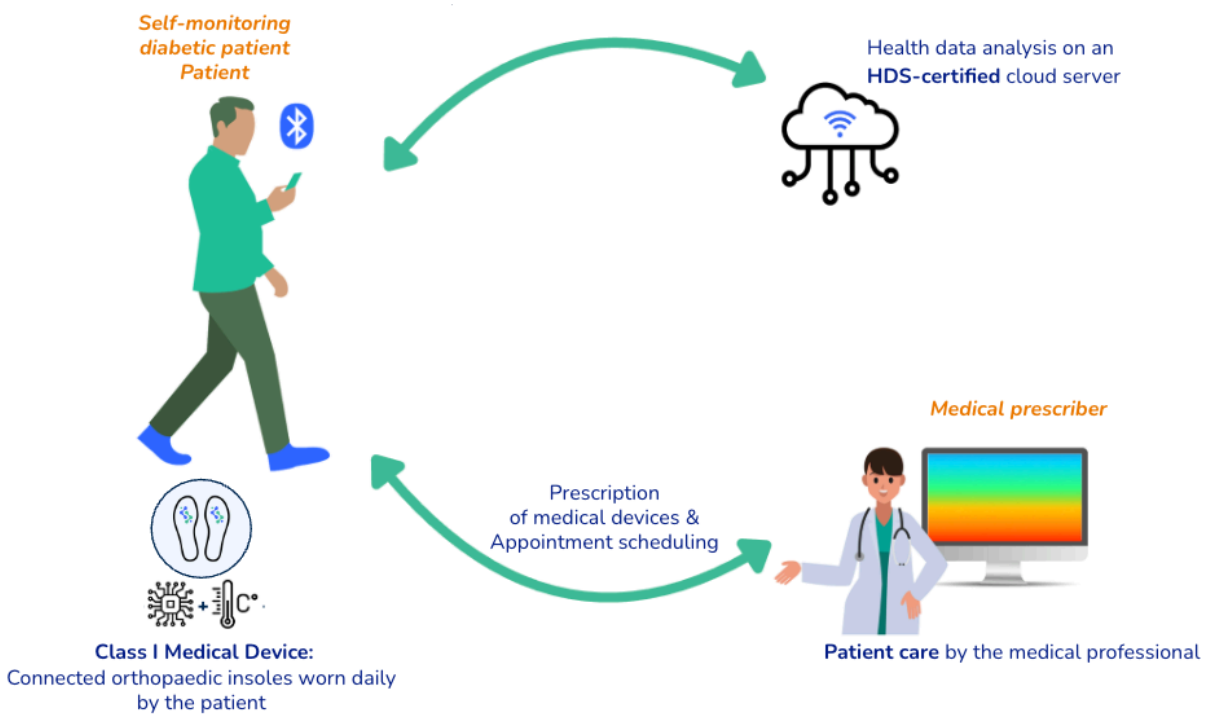
- Synchronization of temperature data enabling **continuous monitoring.**
- Notification in case of need to **anticipate** the podiatry follow-up appointment.
- **Patient support** and therapeutic education.

Solsius SelfCare insoles collect and transmit foot temperature data (as well as the number of steps taken by the patient) at regular intervals via Bluetooth (BLE) technology to the dedicated mobile application, which is pre-installed on the patient's smartphone.

The data received by the mobile application is then stored on secure HDS (Health Data Host) certified servers for processing.

As soon as an abnormal temperature variation is detected between the two feet for two consecutive days, the Solsius algorithm generates a push notification on the patient's smartphone. This push notification invites the patient to reduce their physical activity, fill out a questionnaire directly on their mobile application, and make an appointment with their healthcare professional.

5.2. Operating principle



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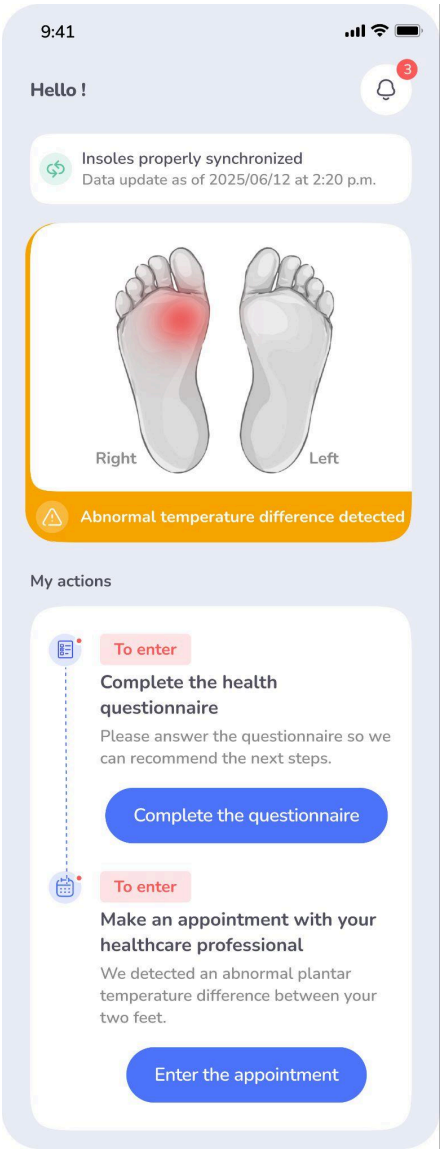
The patient wears their Solsius SelfCare insoles

The insoles are inserted into the patient's regular shoes, just like any other insole. No manipulation is required: monitoring is automatic from the very first step.

2	**Continuous collection of thermal data** The 16 sensors distributed across the entire sole of the foot continuously measure the temperature: forefoot, midfoot and rearfoot. Step count data is also collected.
3	**BLE Bluetooth transmission to the application** At regular intervals, the data is transmitted via Bluetooth technology to the Solsius SelfCare application installed on the patient's smartphone.
4	**Analysis and detection of abnormal temperature variations** If a temperature variation greater than 2.2°C is detected on the same area of the foot for two consecutive days, a notification is sent to the patient recommending that they reduce their physical activity, complete a self-monitoring questionnaire, and consult a healthcare professional. They can also view the affected area of the foot on their mobile app.
6	**Consultation with a healthcare professional** Thanks to the Solsius SelfCare medical device, patients can consult their healthcare professional at the most appropriate time, before the lesion progresses and develops into a foot ulcer, thus promoting early and appropriate treatment.

The questionnaire to be completed in the event of an abnormal temperature variation being detected is designed to help patients monitor themselves. It encourages them to carefully examine their feet, as well as the condition of their shoes and socks, in order to improve their compliance and independence in managing their condition.



Main screen in case of abnormal temperature variation detected

5.3. Technical specifications

Solsius SelfCare insoles are self-powered (no recharging required) and incorporate patented technology (registered with the INPI) that makes them lightweight, flexible and thin.

Thanks to their thickness of less than 5 mm, Solsius SelfCare insoles fit perfectly into a foot orthosis or orthopaedic shoe (CHUT/CHUP), depending on the patient's needs.

The main technical characteristics of the soles are as follows :

Characteristic	Description
Power source	CR2025 button cell battery
Battery life	Minimum 12 months without recharging
Connectivity	Bluetooth® Low Energy 4.1
Sensors and electronic components	16 temperature sensors (accuracy ±0.1°C) accelerometer pedometer
Thickness	5 mm
Weight	250 g
Sizes	Size 1: 36/37/38 Size 2: 39/40 Size 3: 41/42 Size 4: 43/44/45/46
Solsius SelfCare mobile application	Available on the App Store (iOS) and Google Play (Android) iOS 15+ and Android 9+

Conclusion

Diabetic foot remains one of the most severe complications of diabetes today, although it is often preventable. However, due to a lack of suitable tools for daily foot monitoring, thousands of patients develop foot ulcers every year, which can lead to amputations or even death, when the lesion could have been detected early on as a preventive measure.

Plantar thermomonitoring addresses this challenge: clinically validated by multiple clinical trials and included in the IWGDF's international recommendations, it detects signs of ulceration before any visible lesions appear, opening up a window of opportunity for intervention that traditional practices do not allow.

Solsius SelfCare translates this approach into a concrete solution: a CE-marked medical device, designed to be easily integrated into the patient's daily life, and capable of continuously measuring abnormal variations in plantar temperature, which can be an early sign of the onset of ulcers.

The use of the Solsius SelfCare medical device therefore enables daily foot temperature monitoring, allowing patients to better protect themselves against diabetic foot complications.

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