Category

Best Startup

Product/Solution Name

JIMINI

Date of Approval

2022-05-25

Indications

JIMINI is an innovative In Vitro Diagnostic Medical Device (IVDMD) that combines ultra-miniaturized physical technologies with artificial intelligence. It is designed to revolutionize the aid to diagnosis and monitoring of various medical conditions by analyzing urine biomarkers.

Our cutting-edge medical device is intended for use in point-of-care settings, empowering healthcare professionals and patients with real-time, quantitative results for multiple urine biomarkers. We have carefully selected these biomarkers based on scientific literature and medical guidelines (1)(2), to ensure their clinical relevance in diagnosing and monitoring major health conditions such as liver function, kidney function, urinary tract health, and metabolism.

By accurately measuring these biomarkers within seconds, our device equips healthcare professionals with the information needed to make informed decisions, ultimately enhancing patient care, improving outcomes, and reducing healthcare costs. At Usense, we miniaturize the biological laboratory, making it easily available at the patient's bedside in collaboration with healthcare practitioners.

In addition to our biological approach, Usense is actively developing a digital diagnostic tool that leverages machine learning and utilizes the quality of the biological and clinical data we are generating. This tool will take our capabilities a step further by providing risk assessments for specific pathologies and suggesting complementary explorations to enable ongoing monitoring of treatment efficacy over time.

(1) Chair, R & Bartoletti, Riccardo & Johansen, Truls & Bonkat, Gernot & Bruyère, Franck & Cek, M & Grabe, Mpendulo & Tenke, Peter & Wagenlehner, Florian & Associates, B. & Cai, Tommaso & Köves, Béla & Pilatz, Adrian & Pradere, Benjamin & Veeratterapillay, Rajan. (2016). European Association of Urology Guidelines - Urological Infections.
(2) HAS - Cystite aiguë simple, à risque de complication ou récidivante, de la femme. (2021)

Therapeutic Categories

Our In Vitro Diagnostic Medical Device (IVDMD) has been developed as a versatile platform device, enabling its utilization across various medical settings such as emergency care, healthcare establishments, and patient self-monitoring. This flexibility enhances multiple care pathways and improves overall patient outcomes. Currently, Usense is actively focusing on three significant therapeutic categories associated with three medical environments.

JIMINI is designed to be utilized in the following ways:

1. In a general practice setting for the diagnosis of genetic diseases: Healthcare practitioners can utilize our device as an aid in diagnosing genetic diseases, specifically the screening of porphyrias (through Total Urinary Porphyrins detection) and the diagnosis of a specific pathology known as Acute Hepatic Porphyria (through Porphobilinogen detection). These genetic diseases, characterized by intense abdominal pain, pose significant diagnostic challenges without comprehensive biological examinations (3). The diagnostic process for these diseases can extend up to 15 years (4) due to non-specific symptoms often associated with more common conditions like UTIs. Our device streamlines the time-to-diagnosis and expedites the accurate identification of these complicated pathologies.
The validation of our first-use case in Q1 2023 marked a significant milestone for Usense for the following reasons:
- This use case was developed through a collaborative effort with Louis-Mourier Hospital (part of Paris Hospitals groupement), a leading center for rare diseases research, and Alnylam Pharmaceuticals, a major player in the field of rare disease treatments. This collaboration aimed to improve the detection and treatment of porphyrias, a group of rare diseases.
- Secondly, addressing a rare disease served as a critical validation for the scientific and technological robustness of our approach. Working in such an exigent environment allowed us to thoroughly demonstrate the effectiveness and reliability of our device.
The success achieved in this domain has paved the way for Usense to explore several new use cases with the same willingness to impact the care pathway by democratizing biological routine examination. Building upon the lessons learned from the first use case, we are actively pursuing opportunities in various areas described below, leveraging our expertise and technology to benefit a broader patient population.

2. In an emergency Setting with the detection of Urinary Tract Infections (UTIs): The incidence of UTIs linked to hospitalization has quadrupled between the 2000s and 2010s in the United States, affecting approximately 400,000 patients (5). Identifying UTIs poses a significant burden on primary healthcare structures, including emergency services and general practitioners, due to the large patient volume and non-specific symptoms such as abdominal pain. However, our device facilitates UTI identification by detecting urinary biomarkers like nitrites, leukocytes, hematuria, and bacteriuria. It serves as a rapid screening tool for early UTI detection, enabling healthcare professionals to achieve faster diagnoses and reduce the time-to-treatment for patients. This use case is currently under validation.

3. At the patient's bedside as a general healthcare monitoring tool: Our device also serves as a valuable tool for patients to monitor their general health on a day-to-day basis. It analyzes key biomarkers related to metabolism, nutrition, and hydration, providing crucial information to anticipate healthcare deterioration and prevent the onset of diseases (6). This use case is currently under validation.

While we currently focus on these initial use cases, the potential of our device extends far beyond. Ongoing scientific and medical research on urinary biomarkers, including those associated with oncology, fuels our commitment to continuous innovation and expanding the capabilities of our device.

(3) Puy H, Gouya L, Deybach JC. Porphyrias. Lancet Lond Engl. 13 mars 2010;375(9718):924-37.
(4) Wang B, Bonkovsky HL, Lim JK, Balwani M. AGA Clinical Practice Update on Diagnosis and

Management of Acute Hepatic Porphyrias: Expert Review. Gastroenterology. 1 mars 2023;164(3):484-91.
(5) Zilberberg MD, Nathanson BH, Sulham K, Shorr AF. Descriptive epidemiology and outcomes of emergency department visits with complicated urinary tract infections in the United States, 2016-2018. J Am Coll Emerg Physicians Open. 2022 Mar 17;3(2):e12694. doi: 10.1002/emp2.12694. PMID: 35342898; PMCID: PMC8931190.
(6) Authority (EFSA) EFS. Dietary Reference Values for nutrients Summary report. EFSA Support Publ. 2017;14(12):e15121E.

Attached Files:

- Prix Galien Therapeutic Categories.pdf
- Complementary information.pdf

Background information and need for solution/product

Usense exists because more than 1 billion people living today with a chronic disease have suffered a delayed diagnosis or even worse, missed diagnosis.
Some figures speak volumes to illustrate this issue:

- 90% of patients with chronic kidney disease receive their diagnosis only after symptoms become apparent, indicating severe impairment of kidney function that may be beyond treatment (1).
- 50% of patients with type 2 diabetes remain undiagnosed, enduring the detrimental effects of the disease on their bodies and overall well-being (2).

At Usense, we are committed to tackling this major unmet medical need by enabling early diagnosis of pathologies through advanced urinalysis and predicting the progression of health conditions, with a particular emphasis on chronic and silent diseases. At Usense, we are convinced that urinalysis deserves to be more utilized that it used to be in past years as it plays a pivotal role in early diagnosis due to its rich composition and accessibility:

- Urine is a non-invasive and easily obtainable biological fluid.
- It acts as a reservoir for over 3,000 molecules, including hormones, metabolites, and proteins, which can provide valuable insights into the presence of diseases and the body's metabolic state and overall health. (7)
- Urine is not subject to homeostasis, allowing the early detection of pathologic biomarkers that may emerge years before the onset of symptoms. (8)

To achieve our goal of early diagnosis, Usense has taken a groundbreaking approach to democratize the integration of biology in clinical practice. Currently, biological data informs around 70% of clinical decisions (9). However, obtaining these biological exams can be challenging due to lengthy waiting times, accessibility barriers, or sample degradation during transportation.
Usense's revolutionary device, JIMINI, aims to bridge this gap by bringing the power of biological knowledge directly to the patient's bedside, providing healthcare professionals with accurate and instantaneous results for informed medical decision-making. By leveraging the power of urine analysis, healthcare professionals can enhance early detection, enable timely intervention, and improve patient outcomes.

(1) Chair, R & Bartoletti, Riccardo & Johansen, Truls & Bonkat, Gernot & Bruyère, Franck & Cek, M & Grabe, Mpendulo & Tenke, Peter & Wagenlehner, Florian & Associates, B. & Cai, Tommaso & Köves, Béla

& Pilatz, Adrian & Pradere, Benjamin & Veeratterapillay, Rajan. (2016). European Association of Urology Guidelines - Urological Infections.
(2) HAS - Cystite aiguë simple, à risque de complication ou récidivante, de la femme. (2021)
(7) Sarigul N, Korkmaz F, Kurultak İ. A New Artificial Urine Protocol to Better Imitate Human Urine. Sci Rep. 2019 Dec 27;9(1):20159. doi: 10.1038/s41598-019-56693-4. PMID: 31882896; PMCID: PMC6934465.
(8) Jing J, Gao Y. Urine biomarkers in the early stages of diseases: current status and perspective. Discov Med. 2018 Feb;25(136):57-65. PMID: 29579412.a
(9) Beastall GH. Adding value to clinical biochemistry. Ann Clin Biochem 2010;47(Suppl 1):1

Attached Files:
- Prix Galien Background.pdf

History of the development of the solution/product

Usense's vision is to democratize early diagnosis by offering precise and regular healthcare assessments through urine analysis. To realize this vision, we have developed an innovative urinalysis device that is user-friendly and accessible anywhere. The creation of this device has been a collaborative effort, with trusted practitioners, biologists, and international key opinion leaders who have now joined Usense's scientific advisory board.

Our device incorporates two core technological units.

- Firstly, a state-of-the-art hardware "platform" device that integrates two types of technologies: optical and electro-analytical. These technologies, widely recognized as gold-standard methods in biology, are typically found in bulky and expensive machines. However, Usense has successfully miniaturized them to fit into a small and compact medical device. This device enables the generation of a unique "data imprint" from urine samples.
- Secondly, we have developed proprietary machine learning/artificial intelligence algorithms that process the data imprint to extract valuable medical information. Currently, we can measure biomarker concentrations, but our ultimate goal is to enable early diagnosis of pathologies and monitor overall health status.

To bring this product to life, we have secured over €8 million in funding and secured the support from major players in the biological field, including Eurobio Scientific (leader of in vitro medical devices in Europe) and Biogroup (leader in biological laboratories in France and Europe). Our vision has also attracted the support of the Praesens Foundation, dedicated to making healthcare accessible in developing countries.

In July 2020, we successfully achieved the first functional prototype, validating the proof-of-concept for using miniaturized technologies in biomarker detection in urine. As a result, in November 2020, we started to file three families of patents to protect our technology, product ecosystem, and overall approach. As of 2022, the JIMINI device has received CE marking, and Usense has implemented two quality management systems (ISO 27001 and ISO 13485). In June 2023, we officially launched the industrial production of the JIMINI, marking the market launch in France.

Attached Files:
- Prix Galien Background.pdf
- Prix Galien History of developement.pdf

Why this solution/product is innovative, the broad implications for future research, and/or how it will improve the human condition

Our patented device represents a significant innovation in the field of urinalysis, addressing the limitations of existing solutions, which can be categorized into two main types:

- Firstly, urine dipsticks are commonly used tools for qualitative or semi-quantitative analysis of specific biomarkers through biochemical reactions. While these dipsticks are convenient for rapid screening in biological laboratories and hospital services, their results are often deemed unreliable due to low accuracy and visual interpretation. Most urine dipsticks available on the market exhibit a specificity of only around 75% (10). Moreover, they are limited to a fixed number of analyzed biomarkers.
- Secondly, laboratory automates are predominantly found in centralized laboratory facilities. Although these machines enable precise and quantitative measurement of biomarkers, they are bulky and unsuitable for point-of-care settings. The logistical challenges associated with these automates lead to delayed results and potential errors.

In comparison, the JIMINI offers several advantages:
- Fast results: Each measurement takes only a few seconds.
- Light and compact device: It allows for mobility and brings urinalysis to the patient's bedside.
- Instant results: They are directly displayed on a secure tablet.
- Connected device: It facilitates real-time sharing of results with other data and patient platforms;
- Precise and accurate analysis: The JIMINI combines the precision of laboratory automates with the user-friendliness of urine dipsticks.

With our device, Usense will significantly improve the patient pathway of care, empowering healthcare practitioners to make informed and secure medical decisions through comprehensive biological analysis. In essence, the JIMINI aspires to become the new healthcare ‘thermometer’, providing patients with an easily accessible and user-friendly health check-up.

(10) Vuljanić D, Dojder A, Špoljarić V, Saračević A, Dukić L, Leniček-Krleža J, Vlašić-Tanasković J, Maradin I, Grzunov A, Vogrinc Ž, Šimundić AM. Analytical verification of 12 most commonly used urine dipsticks in Croatia: comparability, repeatability and accuracy. Biochem Med (Zagreb). 2019 Feb 15;29(1):010708. doi: 10.11613/BM.2019.010708. PMID: 30799977; PMCID: PMC6366948.

Attached Files:
- Prix Galien Innovation.pdf

Please provide appropriate references (ie Pubmed links)

[1] Chair, R & Bartoletti, Riccardo & Johansen, Truls & Bonkat, Gernot & Bruyère, Franck & Cek, M & Grabe, Mpendulo & Tenke, Peter & Wagenlehner, Florian & Associates, B. & Cai, Tommaso & Köves, Béla & Pilatz, Adrian & Pradere, Benjamin & Veeratterapillay, Rajan. (2016). European Association of Urology Guidelines - Urological Infections.

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[3] Zilberberg MD, Nathanson BH, Sulham K, Shorr AF. Descriptive epidemiology and outcomes of emergency department visits with complicated urinary tract infections in the United States, 2016-2018. J Am Coll Emerg Physicians Open. 2022 Mar 17;3(2):e12694. doi: 10.1002/emp2.12694. PMID: 35342898;

PMCID: PMC8931190.

[4] Puy H, Gouya L, Deybach JC. Porphyrias. Lancet Lond Engl. 13 mars 2010;375(9718):924-37.

[5] Wang B, Bonkovsky HL, Lim JK, Balwani M. AGA Clinical Practice Update on Diagnosis and Management of Acute Hepatic Porphyrias: Expert Review. Gastroenterology. 1 mars 2023;164(3):484-91.

[6] Authority (EFSA) EFS. Dietary Reference Values for nutrients Summary report. EFSA Support Publ. 2017;14(12):e15121E.

[7] Sarigul N, Korkmaz F, Kurultak İ. A New Artificial Urine Protocol to Better Imitate Human Urine. Sci Rep. 2019 Dec 27;9(1):20159. doi: 10.1038/s41598-019-56693-4. PMID: 31882896; PMCID: PMC6934465.

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Attached Files:

- 2_Use of an innovative in vitro medical device for the measuring of Porphobilinogen and Total Urinary Porphyrins in the detection of porphyrias and specifically Acute Hepatic Porphyria.pdf
- 1_Design and validation of a pointofcare device for the detection of multiple urinary biomarkers.pdf