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<http://www.merwis.hu/merwis-en>

1 Introduction

However, there are several tools and solutions for aiding the melanoma detection (variable dermatoscopes, full-body mapping tools and Applications), they were not able to achieve breakthrough in the early diagnosis phase. It comes from the wrong methodologies.

There are two types of available tools: 1) diagnostic tools, with the aim of diagnosing skin-cancer without human intervention, and 2) medical equipment, which help the work of dermatologist during the examination in a doctor's office. The problem with first methodology (artificial based skin-cancer diagnosis) is that these do not work reliable or do not work at all.

The main problem of the second methodology is the very rare examination frequency. An average health conscious European adult visits skin-cancer screening in every 3-7 years. In contrast with these, MERWIS offers a solution that focuses on increasing the examination frequency, where the system does not need to establish a full diagnosis. MERWIS only looks for evolution (change) of every single monitored mole, but with high or very high frequency.

The validated and demonstrated MERWIS prototype is based on the fact that most clinical signs of melanoma are all visible. Through using the combination of a special body-mapping cabin, a mobile application based "self dermoscopy", and a computer assisted qualitative data analysis software we can detect all the visible changes of melanoma ABCDE.

Furthermore our system uses a custom made distributed ledger technology-based network cloud solution. Based on this framework it is possible to build the MERWIS decentralized database on a maximum security level and ensure scalability.

The aim of the Phase 1 project was to carry out an extended feasibility study consisting of market assessment, business model validation, risk and IP strategy assessment, up-date and advancement of the business plan, and international pilot location selection to support the global commercialisation of our technology.

1.1 Objectives

During the project we aimed to demonstrate the economic, technological and social advantages of our solution compared with current technologies.



Figure 1 - Naevus Photocapsule advanced prototype

Comprehensive assessment of our potential European and global markets.	
1	NEXCON is a relatively new player on the medical equipment market. That is the reason why we have built research and commercial partner network at the beginning of our development. Our core partners (Zeiss, Wolf and Resdevco) have been in this industry for many years. Throughout their support this objective will enable us to select and prioritise the most attractive markets on EU and on a global level for MERWIS. Additionally, this objective will also help revalidate the main assumptions in our business plan.

	Validation of our business models and product specification with relevant stakeholders.
2	Potential customers of MERWIS will continue to be identified and will be surveyed to validate our business models consisting of our B2G and B2B business lines.
	Determining pilot locations for the Phase 2 project and engage the relevant partners.
3	Selection of pilots based on the results of our market assessment and the medical requirements of potential sites. Correspondingly, we will identify, assess, and start negotiations with potential partners to be involved in the pilots (testing the system at their own locations and processes).
	Technology watch assessment and examination of external system integration possibilities.
4	Based on the potential customer feed-back it will be a big advantage if the MERWIS system is able to directly connect with the most common digital dermatoscopes. We will carry out an elaborated technological watch to examine the integration possibilities and the necessary technological steps.
	Complete risk analysis, contingency planning, and revised IPR strategy
5	We will perform a risk analysis from technological and commercial points of view, and develop the required mitigation and follow-up actions in order to minimise the likelihood and effect of these risks. In parallel we will reiterate on our freedom to operate analysis in light of the project outcomes and align our IPR strategy with the market entry plan taking into consideration the targeted countries.



Figure 2 - Naevus pre-production prototype

2 Market research

2.1 Task 1.1 Market assessment

The aim of this task was to further study the relevant market and a deep analysis of the market characteristics, trends, drivers and restrains to increase the business potential and minimise market entry risks of our new product.

Work done during task implementation

1. Update the MERWIS market analysis

2.1.1 Melanoma overview

Melanoma, the most dangerous type of skin cancer

According to WHO statistics, around 2-3 million people worldwide suffer from skin cancer, and this figure is growing by about 130,000 a year. In their lifetime, about 20 percent of European people develop this disease. Skin cancer is the most common cancer, with one in three cancers linked to skin cancer. The three most common types of skin cancer are basalioma, spinalioma and melanoma. The most common varieties are basalioma and spinalioma; melanoma is considered to be the most serious type of skin cancer, accounting for 75 percent of deaths from skin cancer.¹ Melanoma can be cured with appropriate diagnostics, after early detection, in more than 90 percent of cases.²

Cancer of the skin can be examined in four stages, parts of it; skin lesion, diagnosis of lesions, treatment of the disease and effectiveness of treatment. In the market analysis, of the four stages associated with the disease, while assessing the frequency of occurrence, we only deal with the market for diagnostics.

Thanks to new technologies, diagnostic efficiency increases, treatment times are reduced, lesions become filterable at an earlier stage, and it is easier for doctors to monitor and monitor changes. The challenge of the present age is to diagnose data analytics and Artificial Intelligence, not in the work of the specialist, but to minimize the time requirements for diagnostics.

Causes of skin cancer

There are several causes and risk factors for the development of skin cancer. One of the most important of these is the increasing UV radiation, as well as the disregard for it, the inadequate protection. In addition, frequent repetition of skin colour, location, age, working environment, genetic conditions, and highly risky activities such as improper sun exposure and regular tanning use are decisive.

Residence

In the geographical location study of the diseases, care shall be taken of the colour of the skin of the people living in that area, the amount of UV radiation in the area and the thickness of the layer of the ozone providing protection.

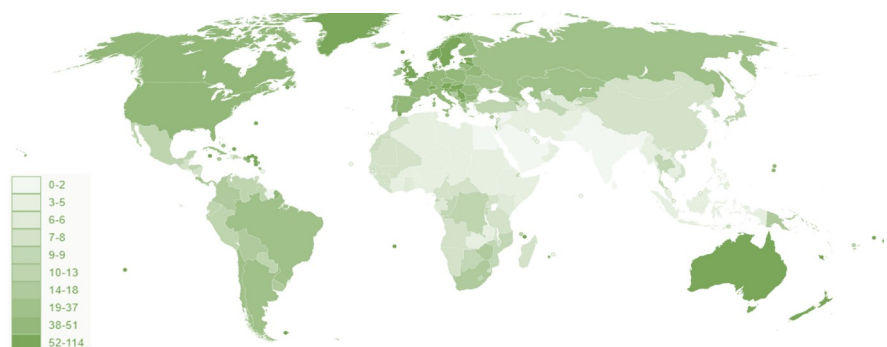


Figure 3 - Skin cancer and melanoma deaths per 1 million people per region in 2012

On this basis, the areas most exposed are:

- Australia and New Zealand
- Scandinavian countries
- Caribbean
- Caribbean
- Switzerland
- United States
- Hungary and other European countries are among the most dangerous areas.

¹ World Health Organization - Skin cancers – How common is skin cancer?

² American Cancer Society - Key Statistics for Melanoma Skin Cancer

Age

The development of melanoma is strongly related to age, most at risk for the elderly, looking at the UK as a living pad, where around 50% of new diseases have been diagnosed among those over 60. Unlike most cancers, melanoma also poses³a relatively high risk for minors.

The risk factor starts to rise significantly from the age of 20-24, while in men over the age of 90 it reaches its maximum, in women 85-89 years of age. In men, the incidence of occurrence over the age of 55 begins to increase intensely. Between the ages of 19 and 59, the number of patients among women is higher, after which malignant skin cancer occurs more frequently among men.

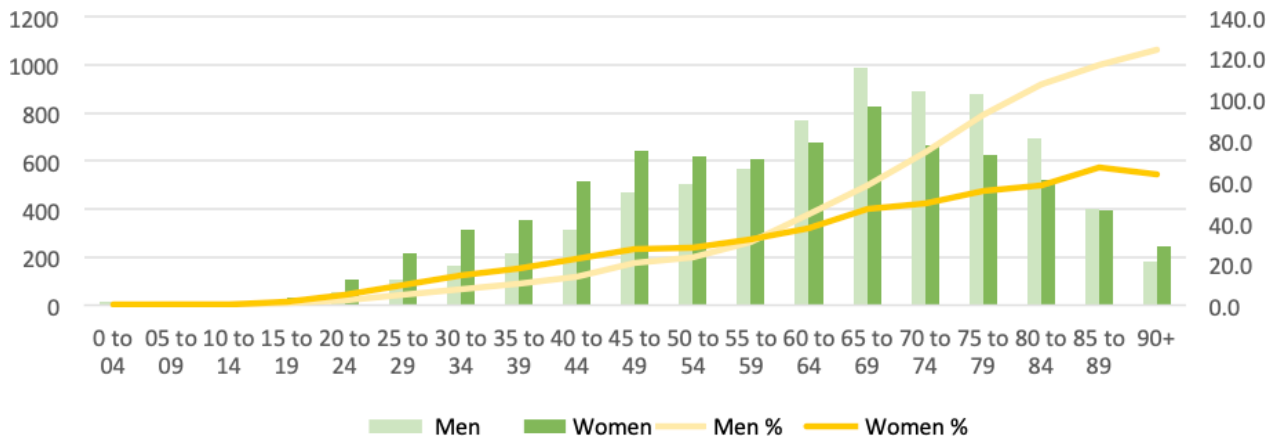


Figure 4 - Breakdown of new diseases per 100,000 inhabitants by age and gender (UK)

Affected skin surface

In men and women, the disease develops at different places on the body. The highest proportion of men were on the torso (41%), to a lesser extent on the head and neck (23%), in the smallest rotation on the limbs (19%, leg 13%) melanoma occurs. For women, the most niga proportion on the legs (38%) melanoma occurs at a lower rate on the hands and trunk⁴(25%, 20%).

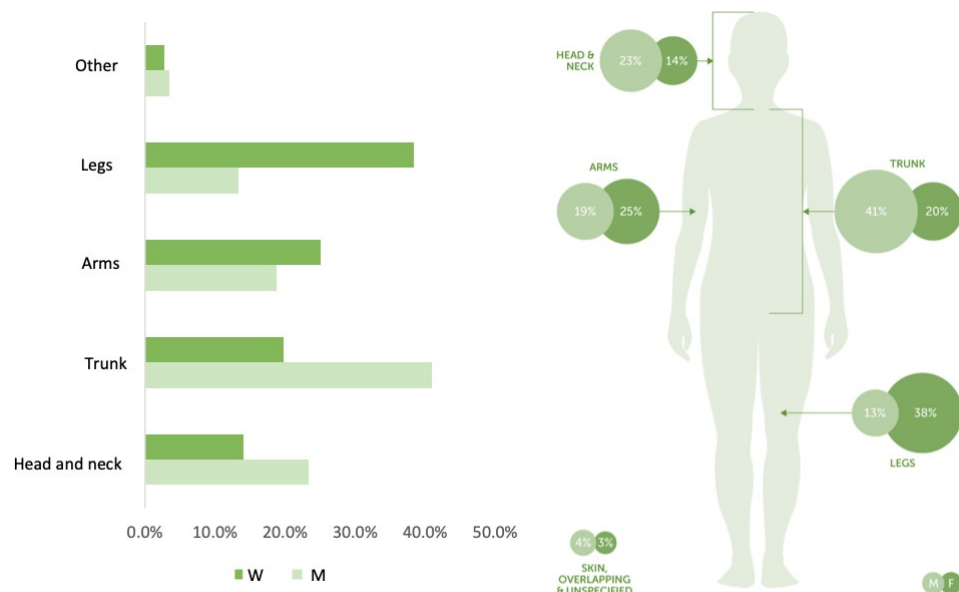


Figure 5 - The location of melanoma on the body surface by frequency

Source: Cancer Research UK 2017

In addition to the sex,

the development of the disease is also affected by the extent to which the person is exposed to regular, strong sunlight in the areas of his body.

Skin type, skin tone, race

Skin cancer is significantly more likely to develop in people with higher exposure to sunlight than people with more resistant, darker skin. You can group skin types into 6 groups, which groups are best identified in the table below.

³ Cancer Research UK - Skin Cancer incidence by Age 2017

⁴ Cancer Registration Statistics, England 2010-2012

Skin type risk classification	Sunburn on day during stay	Day stay frequency	Von Luschan Scale
I	Always	Rarely	1 - 6
II	Usually	Sometimes	7 - 13
III	Sometimes	Usually	14 - 20
IV	Rarely	Always	21 - 27
A	Natural brown skin		28 - 34
Ip	Natural black skin		35 - 36

Figure 6 - Skin types by risk classification
(Source: Thomas B. Fitzpatrick and VonLuschan scale)

One of the determinants of skin colour is the race, so you can also test the risk of skin cancer based on a race. By eliminating the effects of age, research by Cancer Research UK found that 13.1 to 13.6 cases of melanoma develop in 100,000 white males. This figure is significantly lower for Asian men, with between 0.6 and 2.6/100,000 for both men and black men. For women, the pattern is similar; Looking at 100,000 people of the same ethnicity, the expected number of cases is expected to be between 14.7 and 15.2 for white⁵women, between 0.2 and 1.1 for Asian women and between 1 and 3.6 for black women.

1	10			19	28
2	11			20	29
3	12			21	30
4	13			22	31
5	14			23	32
6	15			24	33
7	16			25	34
8	17			26	35
9	18			27	36

Figure 7 - Von Luschan scale values by skin color

The Figure 7 summarises data from surveys conducted in the United States between 1999 and 2014. On this basis, the risk is clearly visible to people with white skin and the intensity at which they increase compared to other ethnicities.

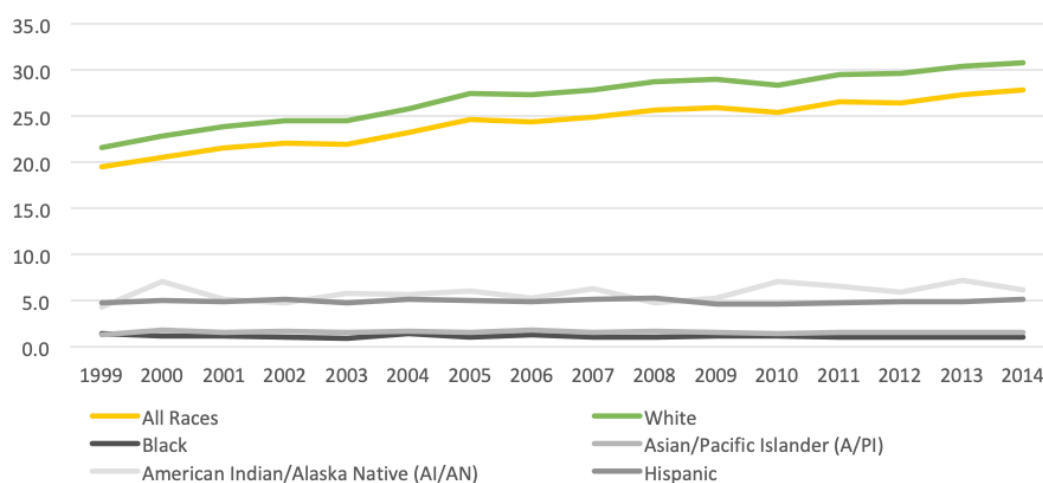


Figure 8 - Chances of developing melanoma by race and ethnicity
(Source: Centres for Disease Control and Prevention Skin Cancer by Ethnicity 2016)

Based on this, it can be concluded that the risk for white American men is 20 times higher than that of African Americans. Thus, 2.5% (1-to-40) the chance of developing melanoma in a white American, 0.1% for a black person (1 in 1000) and 0.5% for a Latin American (1 for 200).

Environment

The working environment should be examined primarily by place of work. The risk to indoor workers at work is minimal (filtering radiation), and for outdoor workers it is worth analysing exposure and risk factor. A German analysis, published in 2009 and based on data from 2001 to 2005, looked at the development of three types of skin cancer, basalioma (BCC), spinalioma (SCC) and melanoma (CMM) and the relationship between the place of work. The analysis monitored all registered skin cancer patients in 11 Bavarian districts, based on a total of 2,156,336 measurement events over 5 years. The subjects included indoor, mixed indoor and outdoor workers, as well as outdoor workers. As a result of the survey, the development

⁵ Cancer Research UK Skin Cancer incidence statistics 2016, Centers for Disease Control and Prevention - Skin Cancer Rates by Race and Ethnicity

of basalioma and spinalioma is at increased risk for outdoor workers (2.9% for men;⁶95%; for women the same is 2.7; 95%), but the development of melanoma is slightly affected by the working environment. On this basis, screening and continuous monitoring of outdoor workers is of paramount importance, in which case frequent testing and diagnostics are inevitable. It is the responsibility of public and health institutions to inform people that they also undergo dermatological screening more frequently in case of exposure at work, focusing primarily on skin sediments directly exposed to high UV radiation.

Prevention and training - international programme

The main means of preventing cancers is education, which is primarily the responsibility of health and public institutions. The aim of the training is to teach the most effective methods of defence and to raise awareness of the importance of regular screening and diagnostics as early as childhood. The aim is to ensure that all concerned are aware of the sensitivity of their own skin, their endangered moles, and to protect and walk to their doctor accordingly. Australia, New Zealand and the United States are at the forefront of the risk of skin cancer, with a large-budget training programme across the country in recent years.

2.1.2 Analysis of the market for melanoma treatment and diagnostics

Thanks to the growing awareness associated with skin cancer, both public and private sector actors are increasingly devoting money to disease-related research, diagnostics and treatment. These trends have led to a more intense increase in the size of the melanoma market than the turnover of submarkets related to total cancer research and other cancers. The purpose of the market analysis is to examine the turnover associated with melanoma, including the amount spent on diagnostics, and to present the relevant submarkets such as dermatology and dermatology aids.

Melanoma diagnostics and treatment

In 2016, the global market for general cancer diagnostics had a turnover of USD 125, which is projected to reach USD7232.7 billion by 2025 at an average annual growth rate of 7.2%. The market for the diagnosis and treatment of melanoma had a turnover of USD 2.7 billion in 2015, reaching USD86.3 billion by 2021 at an intense average annual growth rate of 15.4%. The factors driving the growth of the market are the increasing number of cases, the widening of the portfolio of available therapies and medicines, effective treatment procedures, opportunities for new technologies, and public initiatives and support programmes. In addition, growth continues to be significantly hampered by people's irresponsibility (increased in developing regions), high costs of therapies, low rates of subsidies and a regulatory environment.

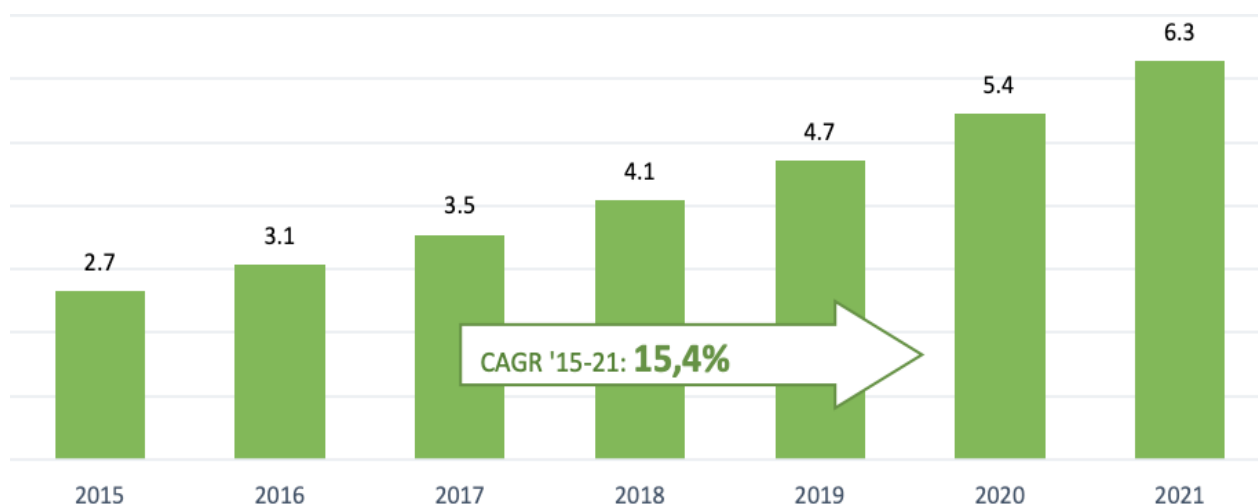


Figure 9 - Turnover for Melanoma Diagnosis and Treatment (Market Billion USD)

⁶ NCBI 2009 - Outdoor work and skin Cancer incidence: (a) registry-based study in Bavaria.

⁷ Grand View Research 2017 - Cancer Diagnostics Market

⁸ Global Melanoma Diagnostics & Therapeutics Market 2016

The United States has the largest share of the melanoma market, followed by Europe. Due to the higher relative growth rate of the European market⁹, its share will increase to more than 36 % by 2023. The distribution of market shares and the slow development of other regions (Asia) can be explained by a lower exposure of the populations living there.

Market for dermatological aids

The most important tool for melanoma diagnostics is the dermatoscope. A dermatoscope is a special medical aid similar to a microscope, which can be used to examine lesions on the skin surface. In addition to traditional devices, innovative digital dermatoscopic statoscopes for imaging and capture are becoming more prevalent in the market, and a growing number of research and development projects are focusing on combined hardware and software solutions with automated change tracking and intelligent intelligence throughout the world - a move that has been criticised by some as well as a number of research and development projects. Generally speaking, the aids and dermatoscopes available on the market can be divided into the four groups listed below: (1) traditional dermatoscope, (2) digital dermatoscope for imaging, (3) full-bodied diagnostic imaging equipment, (4) automatic imaging, processing, and analytics software and hardware solutions. The global dermatology and diagnostics market reached USD 18.5 billion in 2015, rising to USD 21 billion by 2024. Most of the market (95%) traffic related to the treatments. The remaining 3% are linked to diagnostic tools, whose market value could grow from USD 595.6 million to USD 1.1 billion in 2016-2024, with an annual growth of 7.1%. The largest share of the total dermatology market (USD 18.5 billion in 2015) is complemented by activities related to medical dermatology (80%), complemented by activities related to cosmetic activities (20%).

App appearance

The latest area of diagnosis and treatment of melanoma, which is growing extremely intensely thanks to smart devices, is a segment of dermatological applications that can be useful to both doctors and patients in preventing, testing and treating melanoma. Research by Transparency Market

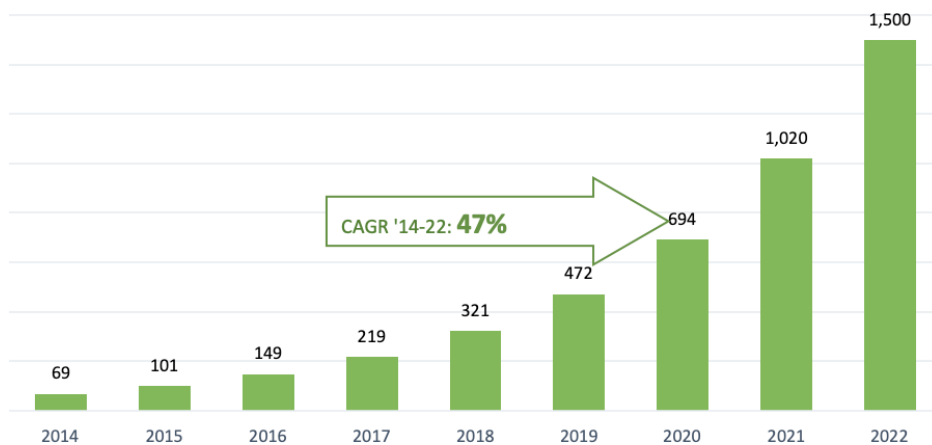


Figure 10 - European Dermatological Mobile Applications Market Turnover 2014-2022 (USD Million)

(Source: Transparency Market Research - Mobile Apps for Melanoma Detection 2015)

Research shows that the turnover of the European dermatological mobile app market in 2014 was still below USD 70 million, which could reach USD 220 million by the end of 2017. In the coming years, with an average annual growth rate of nearly 47 percent, according to market forecasts, the value of the European mobile app market is expected to be USD 1.5 billion in 2022. His research also shows that applications for this purpose are the fastest in the UK, Switzerland, the Netherlands and the Scandinavian states, both for the cause and among patients.¹⁰ Smart device cameras are getting more advanced, but they typically can't capture the right quality, so most medical mobile apps have small optics that can be attached to a phone to ensure the right quality imaging.

⁹ Global Data Pharma Point: Melanoma – global Drug forecast and market analysis To 2023

¹⁰ Transparency Market Research 2015 - Mobile Applications for Melanoma Detection Market

2.1.3 Examination of target markets

The target markets for the MERWIS project could be based on the number of illnesses and the attention and amount of attention and amount of attention and amount to the prevention and treatment of the disease, the specific countries of Australia, the United States, New Zealand and Europe. But taking into account the project's capabilities, the cost of market management and the limitations of organic market expansion, the target countries of the project are: (1) Hungary, (2) Czech republic, (3) Switzerland, (4) United Kingdom, (5) Scandinavian countries.

Melanoma in Europe

Over the past 30 years, Europe has seen a consistent trend in melanoma diseases. The increase in the number of melanoma screening tests and diagnoses is due to the fact that more people go for screening tests, and the technology is constantly evolving in medical diagnostics, which allows doctors to perform dermatoscopic examinations with greater efficiency. More than 102,000 new melanoma cases were recorded in Europe in 2012 and 22,000 people died from skin cancer. The rate of disease and death varies considerably from country to country. Based on the WHO report, it can be seen that Switzerland, the Scandinavian countries, Slovenia and Great Britain¹¹ recorded the highest proportion of the new diseases in Europe.

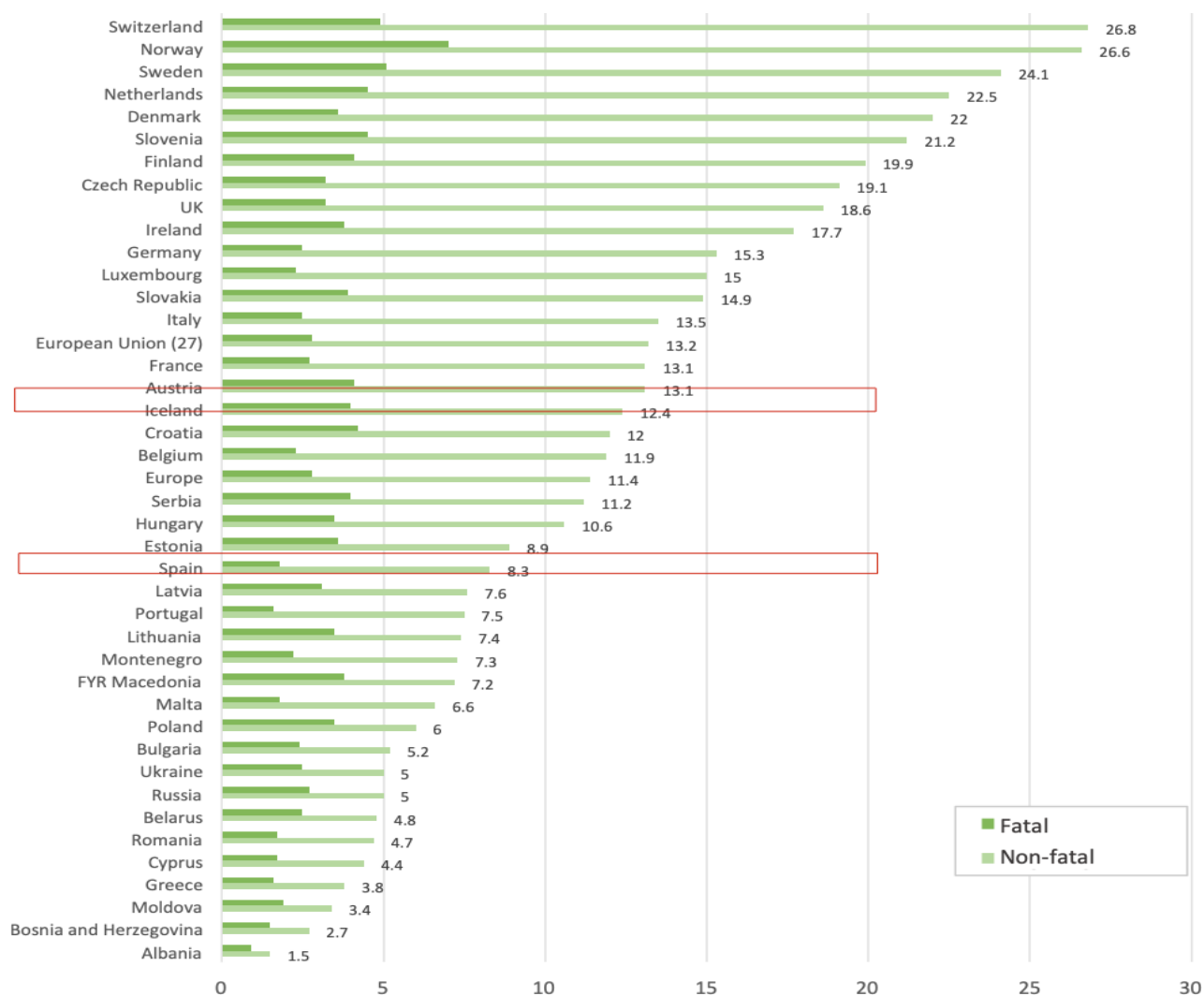


Figure 11 - Number of new melanoma cases and deaths per 100,000 populations in Europe in a given year (thousands)
(Source: WHO International Agency for Research on Cancer 2012)

¹¹WHO International Agency for Research On Cancer – Malignant Melanoma of skin 2012



Figure 12 - European countries with the highest exposure, categorized by new diseases (Disease per 100,000 inhabitants 2012)

(Source: WHO International Agency for Research on Cancer 2012)

Hungary

According to WHO statistics, Hungary is below the EU27 average (13.2 per 100,000 inhabitants) for new diseases, according to which 10.6 new diseases per 100,000 inhabitants in Hungary are awarded per year. By contrast, in terms of deaths, Hungary is in the top 1/3, with 3.5 deaths per 100,000 inhabitants in Hungary (EU 27 average 2.8). On this basis, melanoma is registered in about 1 040 inhabitants per year in Hungary.

State-sponsored screening test

The preventive purpose is carried out by comprehensive skin cancer screening, which is not funded by NHS insurance. NHS only finances a targeted dermatoscopic examination of the surface considered suspicious, not a full-body examination. As defined on the website of the National Health Fund Manager (NEAK), dermacopy is a test of dermacopy with an upper-lit magnifying glass of skin.¹² According to NEAK regulations, a doctor can report a maximum of 8 dermatoscopic diagnostic activities on a patient at one test time, and the tests beyond it should be carried out at the next test time in the context of public funding. In the early 2000s, a few hundred thousand were accounted for, a number that increased by several fold in 2016, reaching 3.67 million. In terms of the pace of growth, the recognised studies could reach 4 million by 2020. According to the studies recorded in 2016, at least 458,000 dermatoscopic studies were conducted at a state health institute in Hungary. In view of the number of dermatoscopic studies, it is possible to estimate the value of the annual turnover associated with the state segment of the Hungarian market. According to 2017 NEAK data, 56 OENO funding points¹³ are awarded- one point is 310.08 HUF, with a total of HUF 17,365 on average for one study. Based on these and the number of studies, the funding paid for the dermatoscopic study in 2016 was HUF 1.136 billion.

¹² <http://finanszirozaskozas.oep.hu/szabalykonyv/index.asp?strInput=16990>

¹³ NEAK Healing Preventive Benefits OENO Points

Health budget in Hungary

The total budget for the 2018 government health budget adopted by the Parliament is HUF 1 660 billion, which is HUF 102 billion higher than the previous year's budget. In addition to government spending, the total health budget includes voluntary health and funding subsystems and household health expenditure, which account for 32-33% of the total amount (KSH).

About 10% of the total annual budget is allocated to medical aids, durable medical devices and ancillary services. In addition, health investment, which includes both real estate developments and large asset purchases, includes health investment, is part of the budget. This has increased sharply since 2013, reaching HUF 163 billion in 2015. On this basis, the market size of the purchase of domestic healthcare equipment, aids and raw materials reached HUF 409 billion in 2015, which includes the target market for the state sale of the MERWIS Naevus cabin.

Data MRD HUF	Government ethno. expenditure (public expenditure)	Full health budget	Health investments
2013	1 464	2 196	58
2014	1 553	2 314	89
2015	1 642	2 460	163
2016	1 659	n.a.	n.a.
2017	1 558	n.a.	n.a.
2018	1 660	n.a.	n.a.

Figure 13 - Health spending evolution (2013-2017)

(Source: KSH)

2.2 Task 1.2. Business model validation

The aim of this task was to validate core and alternative business models.

Work done during task implementation

1. Define business model
2. Define Sales strategy
3. Validate model

2.2.1 Business model definition

With our project we are initially entering the Hungarian healthcare market as a medical technology diagnostic aids sales and collaborative medical service provider (Government Decree 96/2003. (VII. 15.)).

Our business model is based on selling and deploying MERWIS framework units to potential partners, as well as maintaining and operating the system in the form of service delivery.

Our customers will be public (hospitals, research institutes, military), private institutions and organizations (hospitals, clinics, private practices, medical hotels) that purchase equipment and use the service, as well as residential users who download and buy application optics.

Products and services

- For state and business entities:
 - Sales of Assets: Sales of Assets by Naevus Kabin
 - System operation (service): Cloud based server access, IT system operation and medical interface in the form of monthly fee service
- For the general public:
 - Device sales: Smartphone accessory optics (Naevus appliance)
 - Provision of services: Mobile application based on freemium business model

Sales to public and private actors are directly addressed by the management and sales team, while the expansion of the application's user base is indirectly based on the marketing strategy.

Pricing was determined by the cost of assets from below and by competitors from above. Our goal is not to excel in price competition, but to offer a more comprehensive and efficient service portfolio than the solutions currently available. With these in mind, we have developed our high value-for-money product portfolio for both our products and services.

Targeted groups

The target group of our project is the state and market players who purchase the equipment and services, as well as the individuals who use the system, on the basis of which we distinguish B2B (B2G) and B2C clientele.

Potential state partners

The main target group of our sales strategy is the state health institutions, in particular the institutions with specialized dermatological outpatient care. There are currently 522 such institutes in Hungary, most of which are in Budapest. On the NEAK website, there were 7.5 million interventions in general dermatology and paediatric surgeries in 2019 for a total of 1.5 million patients, of which approximately 49% (3.67 million) were conventional dermatoscopic examinations.

Research centres and university clinics:

In addition to hospitals and clinics, university research laboratories are a secondary public target group. There are 33 research laboratories and clinics in Hungary, 5 of which may be relevant for the introduction of the MERWIS Naevus Cabin (<http://korhazakaneten.hu>). Sales to university clinics were not considered in the preparation of the financial plans, as the focus will be on reaching public hospitals and institutions, but contact and communication with research institutes are needed only for the further development of the project and the prestige of such institutes.

Hungarian Defence Forces:

The project leader, Dr. Gyula Kóródi, pointed out that military troops stationed abroad are exposed to UV radiation, which poses an extraordinary risk to European soldiers due to unusual geographical conditions. In 2016, the Hungarian Defence Forces consisted of 19,871 personnel, of which 13,647 are sold, excluding the staff of the General Staff. Adjusting this figure with the technical and administrative staff, we can count 8-10 thousand actual armed service soldiers. Of these, around 850 are permanently serving overseas, most of whom are based in the Middle East. The Defence Forces budget for 2017 was HUF 312.9 billion, which according to the government's target is to increase by 0.1% of GDP annually by 2026, by about HUF 35-40 billion. Most of the total budget will be spent on maintaining the organization and financing the service, but the government plans to increase military and medical supplies. Based on these, and thanks to their direct contact, the Hungarian Defence Forces Hospital and the Hungarian Defence Forces can be a privileged partner in their project. In addition to the Defence Forces, we are preparing for the international sale of MERWIS by screening soldiers from other NATO member states serving with Hungarian soldiers.

Potential Market Customers

Among the business sector, private health care institutions, private hospitals and clinics are primarily focused on sales, targeting a narrow segment of the spa and wellness hotels.

Private institutions:

Our target group, which is relevant to our potential clientele, includes outpatient, day care and inpatient care institutions, private hospitals and private clinics. In Hungary, the above group includes 66 private hospitals and a total of 334 private outpatient care institutions. Similarly to state institutions, their location is Budapest-centric, while in the case of rural institutions the concentration is western, Transdanubian. A special group of potential clients in private institutions will be dermatologists with private practice who

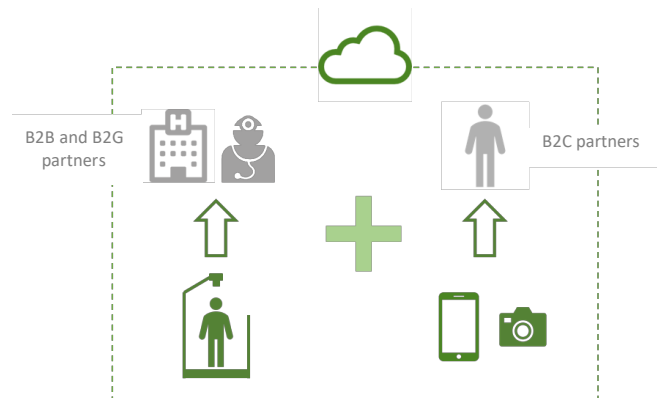


Figure 14 - Target groups and their relationship with MERWIS framework units

work in a trust, often operating a common surgery. Estimating them is difficult because their operation is less transparent, their acquisition of patients and their acquisition activity are primarily related to their activities in public hospitals.

Spa and wellness hotels:

The target group of our project is the players of the hotel market who provide health care, beauty care or cosmetic services as an integral or integral part of their activities, or possibly operate their own health care services. In 2019, there will be 40 spa hotels and nearly 70 wellness hotels in Hungary that focus on health services in addition to 4-5 * quality levels. Hotels can be an important sales tool for raising brand awareness. The spa hotels are mainly visited by foreign visitors (65.7% of the turnover), while the wellness hotels are preferred by the domestic audience (69.1% of the turnover). The number of guests reached by the spa hotels in 2015 was 663 thousand, which in the wellness hotels was close to 1.4 million (KSH).

Potential app users

Users of the MERWIS application are expected to be primarily exposed to high risk factors for skin cancer risk. Our aim is to determine the profile of the people who will be photographed in the booth, rather than the profile of those who will be actively using the application in the future. In the market analysis, risk factors and risk factors were specified and exposure was determined by gender, age, age group, skin color, place of residence and work environment. According to WHO data, Hungary is one of the high-risk countries for malignant skin cancer, which is supported by the high malignancy rate (10.6 cases per 100,000 people).

In terms of potential user characteristics, based on market analysis and project specifics:

- Skin type: Risk classification I-III, Von Luschan scale 1-20 points
- Gender: Mostly women. Increased self-use of female users for preventive purposes. Female users use health-related applications to a greater extent. For men, this is primarily on medical advice to treat the actual illness.
- Age:
 - Age group 35-59: They have the highest risk of disease - taking into account and weighting the penetration of smart devices related to age groups. This is expected to be the highest proportion recommended by specialists.
 - 20-34 year-olds: The age group is open to novelties, uses more health-related applications (at least 1 out of 7 installed apps is related to health promotion), and the need for self-care and self-monitoring based on fear of illness is growing. Enhanced for female users.
- Location:
 - The use of the application is higher in the urban population as it is more common to use the application as part of everyday life (active app users -> urban inhabitants use 3.6 applications actively while a rural person uses only 1.8).
 - The rural population is also expected to use the application for medical advice.

Potential international partner institutes (public hospitals)

According to WHO statistics, in 2018 there were about 20,904 public hospitals in operation in Europe. Most public hospitals are located in Russia, Germany, France and in the United Kingdom. Given the specificities of European health systems and relying on WHO research, there are nearly the same number of private institutions in the countries of the region. The number of private institutions and clinics commonly found in the indicated countries is 0.8 to 1.7 times the number of public institutions and clinics, which is increasing in the west. On the basis of domestic ratios, about 15% of institutions in a given country are considered relevant partners.

2.2.2 Sales strategy

Our sales strategy is primarily aimed at expanding our partner network of public and private institutions and raising awareness of the brand among potential retail users. For public and private operators, the task is to sell the entire Cabin and the use of the Cabin in the form of a monthly fee, while the general public is to sell the premium services of the application and additional optics.

Market launch and sales start in Hungary, with the majority of sales expected to come from state buyers. International sales are included in the project schedule, but sales are not included in this business plan and are planned to be deployed from the next investment round. Sales are done by the owners, management, and their own sales team, and external sales partners assist in expanding the partner network in exchange for a different commission per transaction from the proceeds of the acquisition.

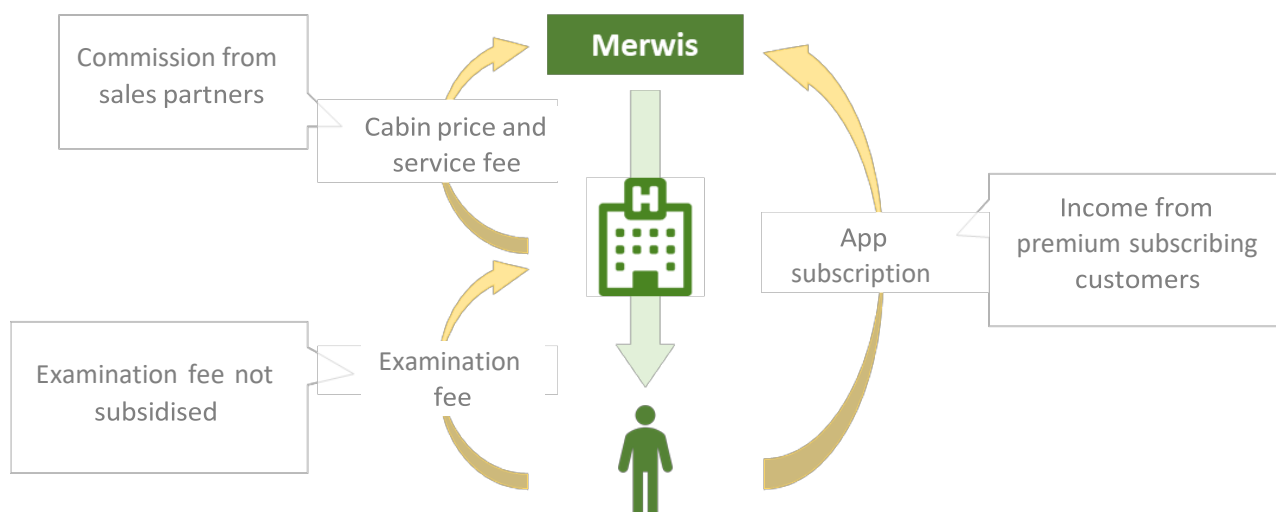


Figure 15 - Cash flow and Service direction

Potential retail users (B2C) will be reached only indirectly through the use of appropriate marketing tools and no direct sales activity will be associated with this target group. B2C sales are detailed in the marketing strategy and action plan.

Local Sales

Market launch in Hungary is scheduled to begin in August 2022 with a 5-month pre-sales cycle, during which we will begin negotiations with public organizations and hospitals, as well as private hospitals. Sales of Naevus Cabin differ greatly in both volume and cyclicity between public and private players, thus separating B2G and B2B acquisition activities.

Sales to State Actors (B2G)

Government sales are bidirectional. On the one hand, the sales team is tasked with reaching out to management decision-makers in targeted government institutions and presenting the benefits of the MERWIS Framework and Naevus Cabin, and on the Central Healthcare Centre for Centralized Procurement, and presenting MERWIS assets. If the CPU recognizes Naevus Cabin as a medical diagnostic tool and adds it to its portfolio, intense sales by state institutions can begin. Negotiations with the GEA are conducted by the owners and have direct access to the decision-making level of the organization through their network of contacts. Public hospitals are visited by the sales team and external distributors, processing the built-in partner database. The acquisition centre is Budapest, followed by the country's largest cities and county seats. The sale of state assets can be linked to the annual asset purchase cycles, which are preceded by significant acquisition preparations each year, and deals are expected to fall into the fourth quarter of the year. We plan to sell 90 cabins to the target group in Hungary between 2022 and 2025. The Digital Wellbeing Program (DJP) Digital Health Industry Development Strategy (DEFS) is helping to establish a market position for state sales. DEFS receives significant state support for the introduction of devices that

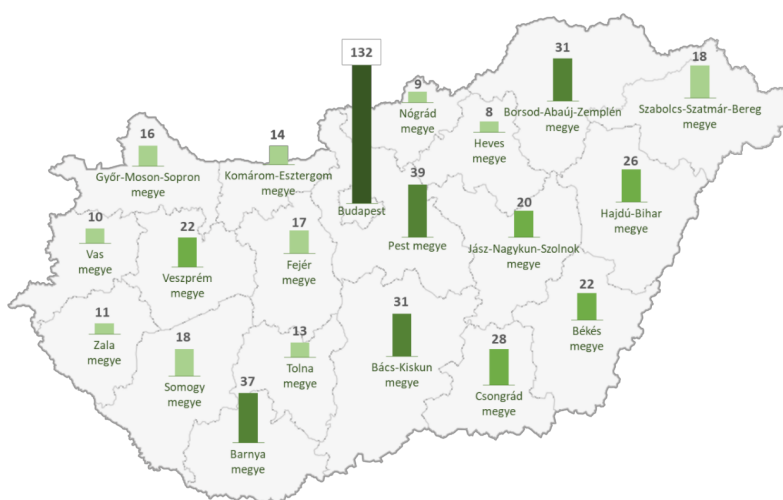


Figure 16 - Location of State Dermatology Specialists in Hungary by counties

digitally address health, diagnosis and disease management, and provide innovative solutions to health problems. The MERWIS project fits perfectly into the program.

Sales to Private Actors (B2B)

For private actors, a traditional B2B sales strategy will be developed and implemented. The sales team implements the acquisition of the relevant 66 private hospitals and 334 clinics and outpatient institutes by processing the built-in database and direct sales. Sales targets are conservative, and we plan to sell a total of 35 cabs over 4 years.

International sales

International sales, according to the sales strategy, begin in the second year after launch, the fourth year of the project, focusing on the most relevant countries identified in the analysis of target markets:

- United Kingdom
- Scandinavian countries
- France
- Germany
- Switzerland
- Netherlands
- As well as the surrounding countries (Slovakia, Austria, Czech Republic)

B2G and B2B sales can be achieved through the establishment of local offices that oversee a regional distribution partner network coordinated from a home-based headquarters. We provide products and services to foreign market agents and partners from Hungary and provide them with education, integration and system operation services. A separate team will focus on the acquisition of public and private institutions, similar to domestic sales activity.

Planned Representations and Related Regions:

- Budapest: Hungary, V4 countries
- London Headquarters: UK, Ireland
- Paris: France, Germany, Switzerland
- Stockholm: Scandinavian countries

2.3 Technology watch and investigate of external system integration possibilities

The aim of this task was to carry out a technology watch and to examine the integration possibilities of the most common digital dermatoscopes and the necessary technological steps.

Work done during task implementation

1. Technology watch of competitors
2. Identify common dermatoscopes and select the most suitable ones for integration

2.4.1 Technology watch

The purpose of the analysis was to uncover market leading and innovative players in the global market, grouped primarily by developed solutions, technologies and services, and to identify local providers and operators that are part of our immediate competitive environment. According to Markets and Research market research, the top five players in the global market for dermatoscopy-related devices, led by the number of devices sold, revenue and R&D spending, are: Canfield Scientific, 3Gen – DermLite, Fotofinder Systems, Heine Optotechnik and Optilia instruments AB. The market is dominated by German, American and Swedish manufacturers. In addition to traditional products (Heine Optotechnik NC1, DermLite DL4 or DL200), all of our product portfolios now include data management and processing software and digital dermatoscopes, and all five leading companies have in-house optional optics and applications, for doctors (B2B) and secondly for patients (B2C).

Company	Product name	Method	Price	Country	Evaluation software	Info
Local imaging						
HEINE Optotechnik	Heine IC1	Manual	N/a	But	iOS app	Link
Optilia Instruments	Optilia Digital Dermatoscope	Manual	N/a	Se	OptiPix	Link
DermaSensor	DermaSensor	Manual	N/a	Usa	Spectroscopy and AI automated system	Link
MedX Health	MedX SIAScope	Manual	N/a	Can	MoleMate	Link
Full body image						
Fotofinder Systems	FotoFinder Bodystudio ATBM	Manual	29 600	But	Dynamole, follows changes	Link
Derma Medical Systems	DermaMedical MoleMax	Manual	13 100	A	6 different assist software, does not evaluate	Link
Canfield Scientific	Vectra WB 360	Automatic	96 700	Usa	DermaGraphix, no software diagnosis	Link
Canfield Scientific	Vectra XT	Manual	N/a	Usa	Vectra Capture Module	Link
Derm Spectra	DermSpectra	Automatic	N/a	Usa	N/a	Link

2.4.2 Selected dermatoscopes for integration

Selected dermatoscope		Price	Selected dermatoscope		Price
	Pxience / C Cube 2	950 EUR		Firefly WPD	315 EUR
	DermLiteDL3	1.053 EUR		DermLite Foto II Pro	1.650 EUR

2.4 Task 1.5 Risk assessment and IPR strategy

The aim of this task was firstly to identify probable risks and evaluate them in order to assess a range of possible outcomes and their potential impact. Also to develop plans to reduce the impact of the most probable risks. Secondly the aim was to carry out an elaborated investigation into current technologies with

respect to intellectual property and to prepare a freedom to operate study ensuring that our development does not harm any rights.

Work done during task implementation

1. Identify and prioritise possible risks
2. Develop a mitigation and contingency plan for each
3. IPR strategy
4. Patent watch

2.5.1 Risk Assessment

We have identified the following risks for the project development and collected the corresponding mitigation and contingency plans.

Event identification	Probability (A)	Impact (B)	Risk (AxB)	Mitigation Plan/ Contingency Plan
Overall system cost is above the originally planned	Low	Medium	Low	Careful product and industrialization will be performed in order to remain within the acceptable range.
Low or slow acceptance of the technology by end users / the market - Because of the conservative character of the target market	Medium	Medium	Medium	Extensive dissemination, communication and marketing actions will be performed to put through our main messages to the key stakeholders.
After the introduction of the MERWIS technology to the global markets, competitors will adapt our main innovations and our product will lose the competitive advantages.	Low	Medium	Low	We are strongly committed in the continuous development of the MERWIS. This attitude will provide the competitive advantages of the product.
The clinical validation of the new diagnostic tool gives negative results	Low	High	Medium	During the clinical validation process we will permanently monitor the operation of the system and we will collect all of the feed backs. It will guarantee that we will know as soon as possible if there are any problem.
The new technology used by MERWIS will face difficulty to enter the market due to being and unknown player at present.	High	Low	Medium	We have already got signed agreements with large well-known players on the market who can support our market entry and penetration
The technology relies on trust and user acceptance that might limit the market penetration.	Low	Low	Low	Through our pilot studies we will demonstrate both the precision (high quality end results) and cost of our system coupled with patience satisfaction.
After the introduction of MERWIS to the global markets, competitors will also change for it, which weakens the global development potential	Low	Low	Low	The technology will be patented to ensure an advantage over our competitors.




IPR strategy

The main exploitable result of the MERWIS system is the technology of using in the Photocapsule, mainly the optical solutions (special lenses) and lighting elements (custom-made LEDs), which are the main drivers of our low market price (very low costs of the cameras, which is a significant competitive advantage) and our technological advantage. During the project, we plan to up-scale our national patent to an international level and apply for the Unitary European Patent system is expected due to start in 2020. Subsequently we will consider extension to other regions such as US and Asia. We have started to prepared a “Freedom to operate” analysis with the help of a [professional IPR consultancy](#), which is presented below, and will continue it during the project phase. The results have been positive, stating that MERWIS technology can be accessed without restrictions. During the project, we plan to involve our expert to monitor potentially concurring and conflicting patents and licences in more depth. All results of the MERWIS development and patents will be registered and owned by NEXCON Ltd.

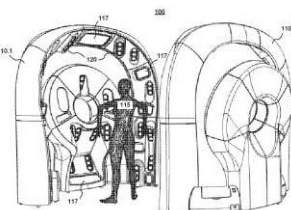
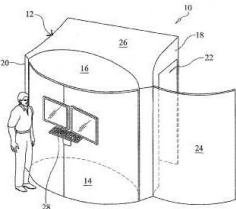
Patent watch

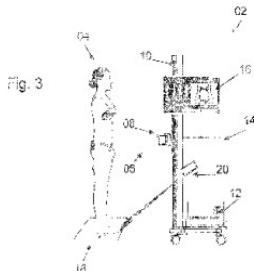
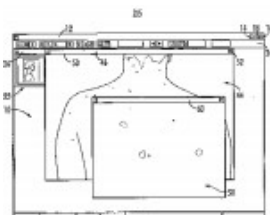
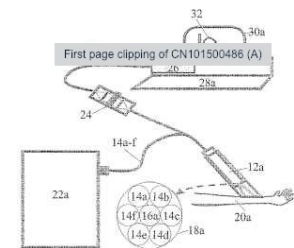
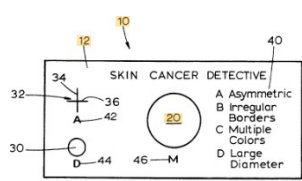
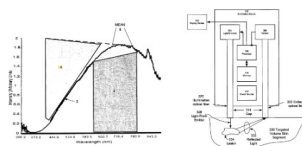
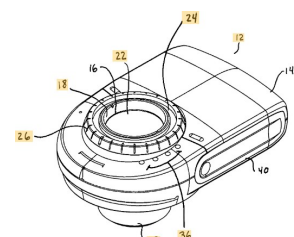
The methodology of patent search was to investigate national and international patent database through the Hungarian Patent Office system and double-checked the results through on-line available databases, such as EPO, USPTO and Google Patent. During the process we searched for keyword (e.g. “melanoma” plus “detect” or “melanoma” plus “image”, etc.), and we checked all of the patents of the whole body imaging solution suppliers (e.g. Canfield Scient Inc, Fotofinder Systems GmbH, Derspectra LLC, etc.) A number of existing patents have been reviewed, which concluded the following findings:

Summary:

Existing solutions			MERWIS solution
All the relevant patents found (detailed below) target a better solution for digital dermatoscopy (1), 3D whole body image capturing with ultra high-resolution image quality (2), and the malignant melanoma diagnosis based on a single image of the naevus (3).			MERWIS targets only naevus evolution monitoring and is not dealing with cancerous moles. The malignisation process and the signs of the starting of this process are in focus of our examination methodology. Furthermore, own developed digital dermatoscope is not a part of MERWIS system currently. Finally our full-body mapping solution does not target to real 3D and/or ultra high quality image capture, because we do not use this pictures for diagnosis.
			

Most relevant patents

Patent number	Schematics	Comment
2018255292		Apparatuses and methods are disclosed for capturing three-dimensional images, particularly of all or parts of human subjects and employing polarization. In disclosed implementations, cross-polarized, whole-body images of human subjects can be captured
2018125370		An imaging station/booth for automated total body imaging having a small footprint and capable of quickly, efficiently, effectively, and consistently capturing multiple body images of a user or patient over time with minimal assistance from medical staff.

2017150064		The invention relates to a full-body image capturing and image processing system and to a method for operating a system of this kind. Within the scope of treating psoriasis, it is known to create what is known as a Psoriasis Area and Severity Index (PASI) and to document the course of the disease and the course of treatment using said index.
20090010555	N/A	A diagnosis system for malignant melanoma with image analysis is provided to detect characteristics of malignant melanoma by using an image of pigmentosa skin disease obtained from dermoscopy.
2005060466		A software-based image management system for use in dermatological examination of a patient's skin for cutaneous melanoma is carried on a compact disk together with images of all portions of the skin.
101500486		A device and method to non-invasively identify pathological skin lesions. The method and device detect and identify of different kinds of skin nevi, tumours, lesions and cancers (namely, melanoma) by combined analyses of visible and infra-red optical signals based on integral and spectral regimes for detection and imaging leading earlier warning and treatment of potentially dangerous conditions.
5369527A		An apparatus and method for detecting indications of skin cancer, includes a magnifying glass for magnifying a lesion on an area of skin to be tested and indicia for determining the presence or absence of skin disease indications.
9788730		A non-invasive, optical method and device for the detection of melanoma in skin lesions. The detection of the presence of melanoma is accomplished optically by looking for specific changes (signatures) in the spectrum of optical light elastically scattered off melanoma molecules. Elastic scattering spectroscopy (ESS) converts subcellular morphological changes into scattering spectrum signatures.
20040201846		The present invention provides a hand held dermoscopy epiluminescence device having a generally circular optical magnification lens incorporated into the housing of the device. A lighting array provides the light necessary for medical examination of the skin.

