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A Go-to-Market Strategy for Vertebral Metrics

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Abstract

“A Go-to Market Strategy for Vertebral Metrics” is a project for commercialization of a technology capable of measuring the spatial coordinates of previously marked points. The device has been initially developed for spine assessment even though it can be applied in different fields. The strategy for market penetration followed outlines some of these applications but will focus on the original purpose for which the device has been created. Market research analysis has resulted in different target segments ranging from small and medium sized healthcare providers to health club and wellness facilities.

The project's timeline proposed for the next 6 years will be the following: Product development by NGNS, Innovative Solutions (Developer of Vertebral Metrics current prototype) to be finished in 2012. Sales initiation in Portugal (2013) followed by the product's entrance in Spain (2014) and Italy (2015).

Commercialization will depend upon the creation of a new company called IHS – Innovative Healthcare Solutions which will manage sales, marketing and financial activities. Product assembly and early technical support will be performed by NGNS. Technical assistance will be, with time, incorporated in IHS and production outsourced, with NGNS maintaining its activity as an R&D partner.

Marketing objectives will focus on attracting new customers and establishing partnership with both suppliers and distributors. IHS will have its own sales force in Portugal and depend upon partners for local distribution in other countries.

The project depends upon an initial investment of 500 000€ with a payback period of 4 years and 3 months. The return is expected to be 6 times higher than the initial investment after 6 years.

Resumo

“*A Go-to-Market Strategy for Vertebral Metrics*” é um projecto para comercialização de uma tecnologia de medição de coordenadas espaciais de pontos previamente marcados. O aparelho foi inicialmente desenvolvido para avaliação da coluna vertebral, apesar de poder ser aplicado em diferentes áreas. A estratégia de penetração no mercado seguida considera algumas destas aplicações, mas focar-se-á no propósito original para o qual o equipamento foi desenvolvido. A análise de mercado resultou em diferentes segmentos-chave, desde entidades de saúde de pequena e média escala a *Health Clubs* e centros *Wellness*.

A cronologia proposta para o projecto nos próximos 6 anos será a seguinte: Desenvolvimento do produto pela empresa NGNS, Innovative Solutions (Responsável pelo protótipo actual) em 2012. Comercialização em Portugal a partir de 2013, seguida de Espanha (2014) e Itália (2015).

A comercialização dependerá de uma *start-up* a ser criada, IHS – Innovative Healthcare Solutions, que será responsável por gerir as actividades de vendas, marketing e financeiras. A produção, bem como o suporte técnico inicial, estará a cargo da NGNS. Com o tempo, os serviços de suporte serão integrados na empresa IHS e a produção terceirizada, sendo que a NGNS se manterá como parceira para pesquisa e desenvolvimento.

Os objectivos de marketing focar-se-ão em atrair novos clientes e em estabelecer parcerias com distribuidores e fornecedores. A IHS terá a sua própria equipa de vendas em Portugal e dependerá de parceiros para distribuição local noutros países.

O projecto requer um investimento inicial de 500 000€, com um período de reembolso de 4 anos e 3 meses. O retorno esperado é 6 vezes superior ao investimento inicial, após 6 anos de actividade.

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Chapter 1 Executive Summary

“A Go-to-Market Strategy for Vertebral Metrics” is a thesis project aiming at studying and elaborating a strategy for the transfer of Vertebral Metrics (VM), a technology developed in the Physics Department of Universidade Nova de Lisboa, from the academic environment to the market. The following paragraphs will explain the structure followed and briefly resume each chapter’s contents and some conclusions. It is structured in eleven chapters which describe environmental analysis of the market and the strategy followed according to external and internal factors.

The first step is to describe the technology itself. Even if the purpose of this project is not in any way to technically improve the technology, knowing what is Vertebral Metrics, how the project started, it’s evolution in time and an explanation of the latest prototype’s main features is important to understand, not only its capacities, but also where it stands in terms of development. Some focus is given to the description of the algorithm responsible for controlling the measurement process and the current graphic user interface. (Chapter 2)

The third chapter studies the external environment in order to determine the best applications for the technology and the preferred markets. It starts with a *brainstorming* exercise on the possible applications for the technology and choosing the most appealing (market funnel).

It is followed by an outlook on market potential for the chosen solutions (spine assessment) and its division in different segments (segmentation) and subsequent choice of each one to target and positioning.

Another important aspect of the market research is competitor analysis. Here are presented the technologies offering similar solutions to Vertebral Metrics in the targeted markets, each one’s strengths and weaknesses and possible market leaders. This analysis has resulted in the identification of a major competitor, Idiag’s SpinalMouse which, however, lacks accuracy in the measurement process.

This is followed by a description of the main characteristics of the supply chain in healthcare and a brief overview of suppliers and distributor chains and the importance of a coordinated effort in the healthcare sector.

The next step in market analysis is to understand which aspects need to be regarded in terms of intellectual property, namely patent concerns and copyright issues, as well as regulation exigencies of the market in terms of certification marks and quality control. Certification for Vertebral Metrics in Europe is a relatively easy process since it’s a non-invasive device. The same doesn’t apply for the US due to the necessity for legal representation.

The environmental analysis ends-up with an evaluation of the market's potential value, which includes a six year sales projection in some European countries, an overview of growth rate of the concerned industries and who the key stakeholders are.

External analysis is followed by a short internal analysis, which is the aim of chapter four, focusing on available resources and the negative or positive aspects offered by some possible strategies. This analysis results in the decision of creating a new company, IHS – Innovative Healthcare Solutions, to commercialize the device.

Chapter Five is the business model where the product's value proposition, value creation and capture are stated. This is followed by the Marketing Plan (Chapter Six).

The Marketing Plan starts by summarizing the company's vision, mission and objectives for the first period in the market. Internal and external factors are analyzed in a TOWS matrix, followed by the Marketing Mix where Product (quality and personalized support), Price (Leasing Option and focus on selling the device), Place (Sales force in Portugal and distributor's abroad) and Promotion (Trade Shows, new platforms, distributors) strategy is discussed.

Chapter seven highlights operational concerns related to Vertebral Metrics commercialization. It focuses on the needs for product development, team's formation and equipment requirements for the tasks ahead. It ends up concluding that a group of technicians is necessary to conclude product development (NGNS) and suggests the creation of a commercialization team.

The Financial Plan is the subject of chapter eight where a six year projection is performed based on previously detailed assumptions on costs, sales revenue and necessary investment. The plan follows the "Discounted Cash Flow Model" to predict the financial outcome for the first six years with a positive cash flow in the fourth year, a payback period on investment (ROI) of 5 years and an Internal Return Rate (IRR) of 31%

Chapter 9 is dedicated to critical risks in the venture (overspending, competitor's price strategy, wrong sales projection).

Finally, a page is dedicated to discuss the introduction of a lower limbs assessment option (Chapter 10) and another to conclusions (Chapter 11).

All the research and decisions taken will be synthesized in the *Business Plan* (Appendix A) and Appendix B contains the results of a short online survey on the technology.

Chapter 2 Description of Vertebral Metrics and it's technology

2.1 What is VM and why?

Vertebral Metrics (VM) came up as an innovative solution to measure the spatial coordinates of the vertebral column's apophysis. It identifies the X, Y and Z positions of each spinous process from the first cervical to the first sacral vertebra in a standing position. (Quaresma, Secca, & Santos, Dispositivo de Avaliação da Coluna Vertebral, 2009)

It has been initially developed by PhD. Claudia Quaresma (CEFITEC - FCTUNL) and PhD Mário Secca as a result of her close work with pregnant women at *Maternidade Alfredo da Costa* and *Centro de Saúde de Sete Rios* in Lisbon. They've realized that back pain is a common symptom amongst pregnant women, mainly due to the extra weight the column has to support during the late gestational period. As a consequence, they've decided to team up with PhD MD João Goyri O'neill (FCMUNL), in order to achieve an efficient and simple method of diagnosing the problem.

The partnership was responsible for VM's first prototype (Quaresma, Secca, & Santos, A Mechanical Instrument to Evaluate Posture of the Spinal Column in Pregnant Women, 2008) (Quaresma, Secca, Branco, & O'Neill, 2009), which is a purely mechanical solution and, it's formed by two main components, called "body" and "support".



Image 2-1 - Vertebral Metrics first prototype with body, support and positioners.

The first comprises the actual measuring section with 18 horizontal pieces mounted on a column, the “2D positioners”. The “support”, as the name indicates, is a structure where the patient stands while the measure is performed. The measurement starts by marking the patient’s skin above the spinous processes from the first cervical to the first sacral vertebra with a washable pen. The “2D positioners”, all identical and adjustable, can be moved until they touch the marks and allow the identification of each vertebrae position.

Despite this simple setup, the initial version has provided encouraging results and has been validated through comparison with measurements obtained through a known and reliable technique (Quaresma, Secca, Veloso, Fonseca, O’neill, & Branco, 2009). However, due to the mechanical nature of the process, it takes a considerable long time (approximately 7 minutes) to obtain all the measures necessary. Since the patient can’t be maintained in a complete static position for such a period, the actual measuring process is prone to errors. Moreover, as the coordinates are measured by the examiner, there is always the possibility of human error in the process.

From the previously stated, it became apparent the necessity to accelerate the measuring process and increase accuracy.

In order to answer to the previous requirements, a new prototype has been developed. More than automating the measurement process, it constitutes a completely new approach to the problem. This has been achieved through a partnership with Prof. Pedro Vieira and his company [NGNS, Ingenious Solutions](#).



(I)



(II)



(III)



(IV)

Image 2-2 Photos of the second prototype: I – Device and spine model; II – Spine model with marking; III – Device's detail of horizontal *positioned* and measuring apparatus; IV – Detail of spine model with laser mark (green dot).

The setup is fairly different, using a camera and a laser to find the vertebral apophysis. The recognition is achieved with software capable of distinguishing prominent marks in the skin. The measurement of the apophysis coordinates are, thus, obtained through previous marking with a dark blue washable pen. The new prototype has, as expected, drastically reduced measurement time and increased accuracy. However, patient marking is still a necessity.

In the next section, a more thorough description of the actual prototype is made

2.2 Prototype description

The development of the new prototype was made in three fronts:

- Projecting the mechanical apparatus and electronic controls needed to automate the process. (Duque, 2010) (Eng. Pedro Duque)
- Writing the software responsible to recognize the marks above the apophysis. (Jordão, 2010) (Eng. António Jordão)
- Building a reconstruction algorithm and 3D representation of the vertebral bodies. (França, 2010) (Eng. Carla França)

2.2.1 Mechanical apparatus and electronic controls

The new prototype has been designed considering the measuring process automation. The laser/camera bundle had to be controlled in two dimensions, being the third coordinate determined by the distance to the object.

In order to obtain a bi-dimensional displacement, two *positioners*, name X and Z positioned were developed.

The X *positioner* is responsible for the horizontal displacements. It is composed by a lead screw module ([SHTS – Fast by Ingus DryLin](#)) powered by a step motor ([Lin Engineering](#)).

The *Z positioner* coordinates the vertical displacements. It uses a toothed belt axis also powered by a step motor. To limit the *positioner's* displacement, photomicrosensors were placed in the belt's ends.

The following table indicates the main characteristics of both *positioners*:

	X positioner	Z positioner
Maximum displacement	2m	0,1m
Step Motor	Lin Engineering's Model 4209L-01P	Lin Engineering's Model 5709L-01P + 7:1 gearbox
Motor's Maximum Torque	0,44Nm	1,86Nm (improved by gearbox)
Resolution	0,125mm	0,025mm
Material	Lead screw module in anodized duraluminum (no lubrication needed)	Toothed belt axis in anodized duraluminum (no lubrication needed)
Maximum velocity	1 m/s	5 m/s

Table 2-1 *Positioner's main characteristics.*

The *X positioner*, other than being responsible for horizontal displacements, supports the camera, laser and illumination. This module constitutes the core of the technology itself as it's the one responsible for performing the measurements needed to determine the desired coordinates.

The actual prototype uses An USB 2.0 RGB Camera from uEye (Model UI-1440C) with a resolution of 1280x1024 pixels and a CMOS sensor (every pixel is treated individually). Its lightweight characteristics make it ideal to reduce inertia and thus, avoid compromising the *positioners* performance. The USB interface facilitates communication with computers.

The laser diode is placed above the camera with a determined angle. The reason for this has to do with the measuring technique and it's briefly explained in the next section. The illumination is done through halogen lamps, both with 20W of power (12V DC). The use of halogen lamps, thus not being purely white light, alters the camera color pattern making it necessary to consider this when developing the acquisition algorithm.

The electronic coordination of both *positioners* and all the necessary modules is achieved with an 8-bit microcontroller (Microchip Model PIC16F877A), as shown in the following scheme.

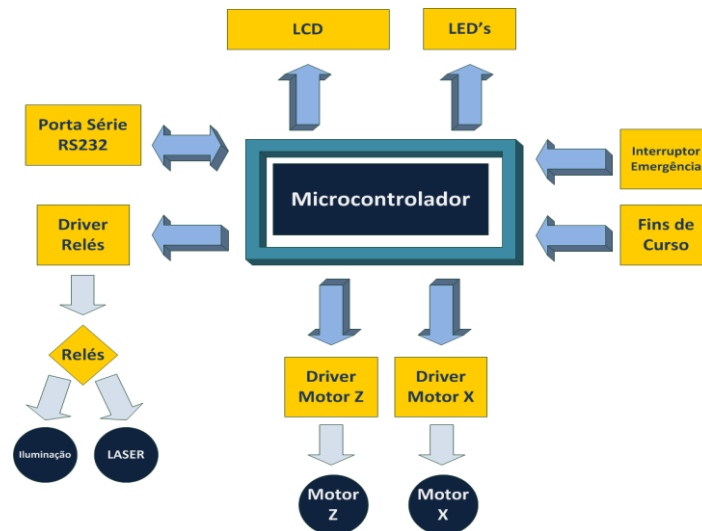


Image 2-3 Electronic coordination diagram (Duque, 2010) (Page 34)

Other than the *positioners*, the microcontroller is also responsible for:

- Controlling Laser and Illumination
- Communication with computer through RS232 (serial port)
- Coordinating LEDs, LCD and switches in the control tower
- Interpret information sent by photomicrosensor delimiters of the Z positioner.

The software programmed in the microchip has been written in order to fulfill all the previous functions.

2.2.2 Measurement principles and image resolution

The laser diode angle and the distance between the camera sensor and the plane of measurement are obtained from geometric optics principles and some trigonometric relations, experimentally.

Some parameters which influence the laser positioning are the distance between the plane of measurement and the camera sensor, the camera's vertical angle of vision, the height of the laser in relation to the camera and its fixation angle.

The distance between object and equipment has also to observe some security limits since its motion can cause physical damage. However, the farthest from the sensor the object is, the less detailed the obtained image will be, because the number of pixels attributed to a certain region will be inferior.

Another aspect which has to be taken into account is the maximum distance between the apophysis in the antero-posterior axis (y). In this case, the studies performed by PhD. Cláudia Quaresma on pregnant women constitute a good reference, since the column's curvature is usually higher, thus providing a safe interval.

From the previous considerations, and admitting an object-equipment distance of 33,2cm (distance to the reference plane, where the laser intersects the camera central axis) and that the vertical vision angle of the camera is 10°, the laser diode was put 9cm above the camera with an angle of 72°.

Adopted configuration details	
Depth interval allowed	Between 26,2 and 45,2cm (reference plane at 33,2cm)
Pixel dimensions	Between 0,044 and 0,077mm (0,057mm in the reference plane)
Adopted interval (to avoid losing image resolution)	7cm before and after the reference plane (33,2cm)
Maximum resolution achieved	0,2mm

Table 2-2 Adopted configuration intervals and achieved resolution

2.2.3 Image processing algorithms

The program developed to compute de spatial coordinates of the apophysis is based in 3 algorithms. The programming language used was MATLAB due to its simplicity. However, adapting the code to another language such as C, may improve acquisition.

Each of the 3 algorithms is responsible for one of the following functions: **Determine the laser diode mark coordinates, detect the vertebral apophysis coordinates and data acquisition.**

The marking of the vertebral apophysis is done with a blue permanent pen. The type and color of the pen has been chosen after several trials, which took into account several factors, such as the camera sensor and color response and paint's spreading on skin.

The algorithm developed to determine the laser diode mark follows the same pattern as the one responsible for detecting the blue marks put above the apophysis. Image processing is similar in both cases differing only in some steps. The following paragraphs briefly explain both algorithms and the existing differences.

1st Algorithm: Laser Diode mark coordinates – “Laser” function (See algorithm's flowchart on (Jordão, 2010) - Page 32)

The algorithm loads the image captured by the camera, executes binarization and some cropping to speed up the process. In the gray scale image obtained, the laser mark is found because of its elliptic shape (caused by laser inclination) which enables the calculation of the centroid's coordinates.

2nd Algorithm: Blue mark (apophysis) coordinates – “pontos” function (See flowchart on (Jordão, 2010) – Page 35)

This algorithm used to find the marks is very similar to the previous one. It starts by loading the image from the camera and determining whether there are previous coordinates and the laser position (1st algorithm). It then binarizes the image above the laser mark, having in mind that the camera illumination changes the color pattern. If there are previous coordinates stored, it crops the image and applies a mask to reduce possible artifacts introduced by binarization.

The marks identification follows the same pattern of the 1st algorithm though it introduces a 250px restriction for the horizontal distance between two objects - based on previous studies (Quaresma, Secca, Veloso, Fonseca, O'neill, & Branco, 2009). In the end, it returns the centroid's position.

3rd Algorithm – Data acquisition Algorithm (See flowchart on (Jordão, 2010) – Page 40)

This is the most important part of the acquisition software. It coordinates the previous algorithms in order to superimpose the laser mark and the point's found.

It starts by capturing the image and running the *laser* and *pontos* functions. The 1st algorithm returns the laser coordinates (I) and the second, a list with the marks found (P). In case any of the algorithms returns a null variable, the program is terminated. Otherwise, vertical displacement is initialized and a cycle is started.

The horizontal distance between I and the first point in P is calculated and the laser is aligned with the mark found. Vertical distance is determined by measuring time and velocity. Both x and z coordinates are stored. All distances are converted to millimeters so that hardware can perform displacements and alignments and the values are then reconverted to pixels.

A new image is captured and the process is repeated until the z coordinate of the first point and that from the laser mark are overlapped (15px interval around the laser z coordinate). The distance from object to camera (y) is then calculated and stored with the (x,z). The point is erased from P and kept as *last point*. The number of marks is incremented (*n_vert*) until it reaches the maximum value of 25 which terminates the program.

Otherwise, the search for new points goes on. If the P list is empty, the *points* function is called based in the “last point” and its results stored in a variable called *p*. In case P isn't empty, the z coordinates are updated and the *points* function called using as a reference the top point in the P list.

The cycle is repeated until P is empty and the search for new points reaches 65. This value results from experimental studies and avoids missing point detection. Once the value is reached, the program terminates, returning the number of points detected (n_{vert}) and the coordinates in pixels ($coord$).

Graphic User Interface (GUI)

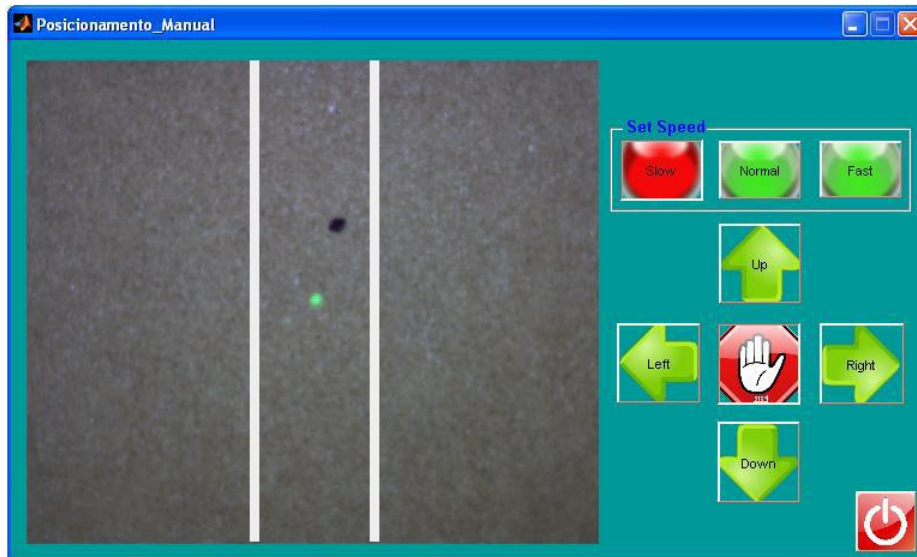


Image 2-4 GUI for coordinates' measurement (Jordão, 2010)

A program has been developed to work as a graphic interface for the user to communicate with the instrument. It's very simple to use and intuitive.

When loaded, it starts by checking if the hardware-software communication (RS232) is established. It then asks for the number of marked points to make sure the measurement process finds all the coordinates.

The user can use the directional arrows to displace the camera and should guarantee that the laser mark stays under the first mark and between the white lines, as shown in image 2-3. There's a home position option which can be used to automatically place the camera in its initial position.

There are 3 different speed options for manually displacing the camera to ensure a better precision.

Running the program calls the 3rd algorithm, proceeds with measurements and prompts the user where to store the results.

The results are stored in three columns which represent the x, y and z coordinates. Different acquisitions are separated by a row of zeros. The program can be used independently or

coordinated with an interface especially developed to mathematically reconstruct the vertebral column.

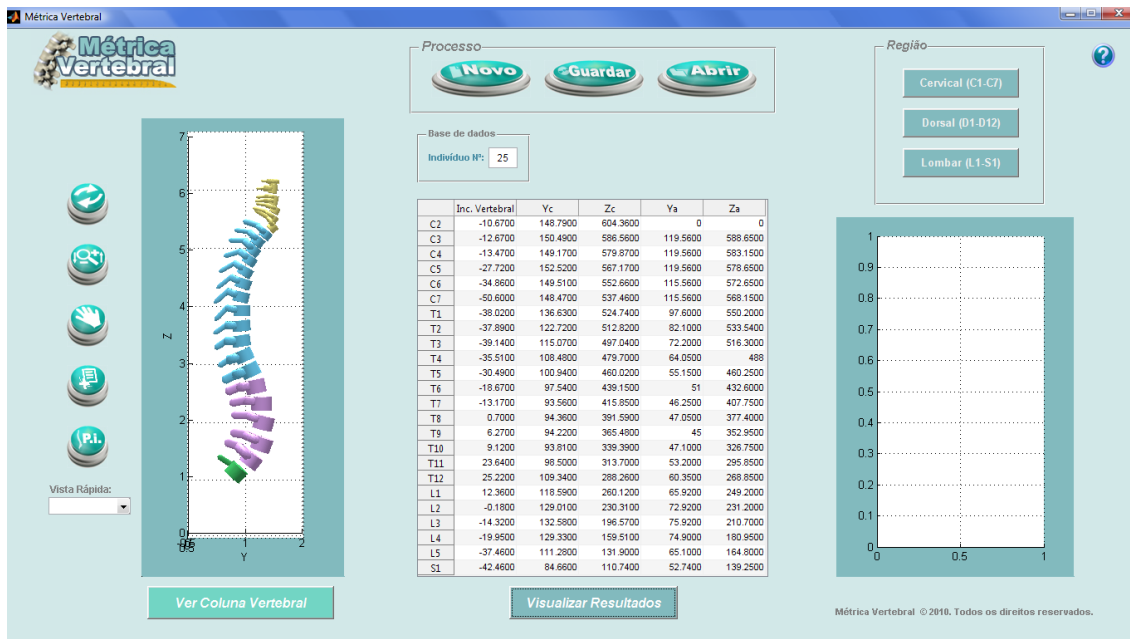


Image 2-5 Vertebral Metrics GUI developed by Carla França. (França, 2010)

This interface creates a better environment to interpret the collected data and shows a model which represents accurately the patient's column. The model uses MATLAB and considers that the column can be reconstructed as a system of masses and springs interconnected. It follows the basic principle that the real position of the column in the sagittal plane, i.e. its geometric centres, can be determined by minimizing the total elastic energy of the system and knowing the apophysis position.

The model has been validated in a patient without any associated pathology. The results confirmed that the coordinates for the vertebral centres were very close to reality if fixing the *sacrum* inclination with an angle close to that of a healthy person (42.46°). Overall, even in patients with associated pathology, the *sacrum*'s fixation resulted better.

Other than the column's model, the GUI shows the measured coordinates' values. In the end, this interface already provides a useful tool for the healthcare professional due to its simplicity. Its improvement is one of the important steps in the Vertebral Metrics development for commercialization and will be referred in later chapters.

Chapter 3 Market Analysis

3.1 Possible Applications

The base technology of Vertebral Metrics has several fields of application. Fast and accurate measurement of three-dimensional coordinates is essential in many industries and creates numerous opportunities for innovative solutions. The applications here presented result from a free thinking exercise. Only the capacity for measuring 3D coordinates and its speed were considered. Technical adaptations and limitations, as well as market potential, are considered in the next sub-chapter.

3.1.1 Healthcare Solutions: Using VM as a non invasive and radiation free method for human body diagnostics

Determine vertebral apophysis coordinates and global assessment of the column

Rachialgia, commonly known as back pain, is recurrent symptom in modern societies. It affects the overall population, with special impact on specific groups, such as, pregnant women and adolescents.

Productivity is considerably affected, since back pain is one of the main causes of work absenteeism. Preventive population screening might help defining strategies to reduce its negative impact.

An accurate diagnose could potentiate rehabilitation and improve life quality.

Measure lower limb articulations and posture

Biomechanical imbalances causing postural alterations in lower limb may impose excessive tensions in muscles and articulations.

Ankle, knee and hip lesions are life impairing pathologies and regeneration if often complex. Identifying asymmetries is essential to improve the success of rehabilitation programs.

Design models of body surfaces as a pre-surgery tool

Some surgeries involve more careful planning than others. Mapping the body area to intervene, not only potentiates the surgeon's performance, as it might help both professional and patient to predict the outcome. This becomes especially interesting when considering reconstructive surgery in areas of high contrast such as the face.

3.1.2 Civil Engineering applications: Monitoring displacements and calculate distances in structures under stress

Structures are usually submitted to different kinds of stress (compression, shear and traction). Assessing how they respond to these tensions is important, mainly for security reasons.

Bridges

Since bridges have different designs, they also have different monitoring requirements. Simpler structures such as viaducts are very common and are often less complicated to monitor.

Water bridges on the other hand, might be complex structures when compared to the previous example. Such is the case of suspension bridges like “Ponte 25 de Abril” in Lisbon. The measurement requirements in these cases are usually much higher.

Dam Walls

Dams are massive infrastructures and, as a result, their wall is constantly under high stress forces. These forces cause erosion and displacements which need to be controlled. Constant monitoring of the wall overtime might be an interesting approach.

Road Pavement

Pavement quality control is essential to guarantee financially efficient repair plans. Road surface faults can be identified through laser scanning. 3D scanning machines are often too expensive to be considered an option.

Control seismic structural damages

Anti-seismic architectures are a recent concern and which is often limited to areas of high seismic activity. Older and more fragile infrastructures are always at risk of collapsing due to medium/high intensity earthquakes.

Being able to measure displacements resulting from seismic activity on building foundations may help preventing its collapse.

3.1.3 Industry: Analyzing product quality through distance measurement

Mass production requires inspection of materials to guarantee quality standards. Identifying if an object abides by the projected dimensions is very important. Control must be quick and inexpensive.

3.2 Market Funnel

Looking at the applications presented, how promising is the market and which obstacles each one faces?

3.2.1 Healthcare

The solutions found in the healthcare field provide a quick method for examination of both column and the lower limbs. Back pain is one of the most common pathologies existent and is often the result of an incorrect spine posture. According to Deyo et al., 26% of the US population had suffered at least one episode of back pain (Deyo, Mirza, & Brook, 2006). Mechanical disorders in the lower limbs can also be responsible for back related problems as well as foot, hip or knee pain. It's non-invasive, radiation free and potentially cheaper than other technologies used for the same purposes. It represents an innovation in the field of prevention since it can be applied several times without harmful effects to the patient. Furthermore, a study has been conducted with pregnant women for the column application, which proved its effectiveness. (Quaresma, Secca, Veloso, Fonseca, O'Neill, & Branco, 2009)

The market size may not be the most promising if only considering VM as a diagnostic tool for hospitals and clinics. Population screening, however, widens opportunities and might be used to develop work medicine policies.

The solution for lower limb measurement is especially interesting for professional sport academies and health clubs.

The main drawback in using VM as a medical solution is the possibility for demanding certification requirements. Furthermore, using Vertebral Metrics as a pre-surgery tool has some limits, especially because it would have to recognize several markers in high contrast areas such as the face in order to give an accurate topography of the area to intervene. Even if they're considerably more expensive, the outcome of body surface exam with 3D laser and white light scanning devices will always be far more detailed than that achieved with Vertebral Metrics.

3.2.2 Civil Engineering

Civil engineering appears as an interesting solution since the market is potentially wider in terms of units sold and solutions. For example, there are 10 new projects for hydroelectric centrals in Portugal. Other than that, devices in this market are subjected to far less regulation requirements than those used in healthcare, which makes their commercialization easier.

Monitoring displacements still highly depends on equipment such as theodolites. The main reason is the high price of more recent scanning technologies.

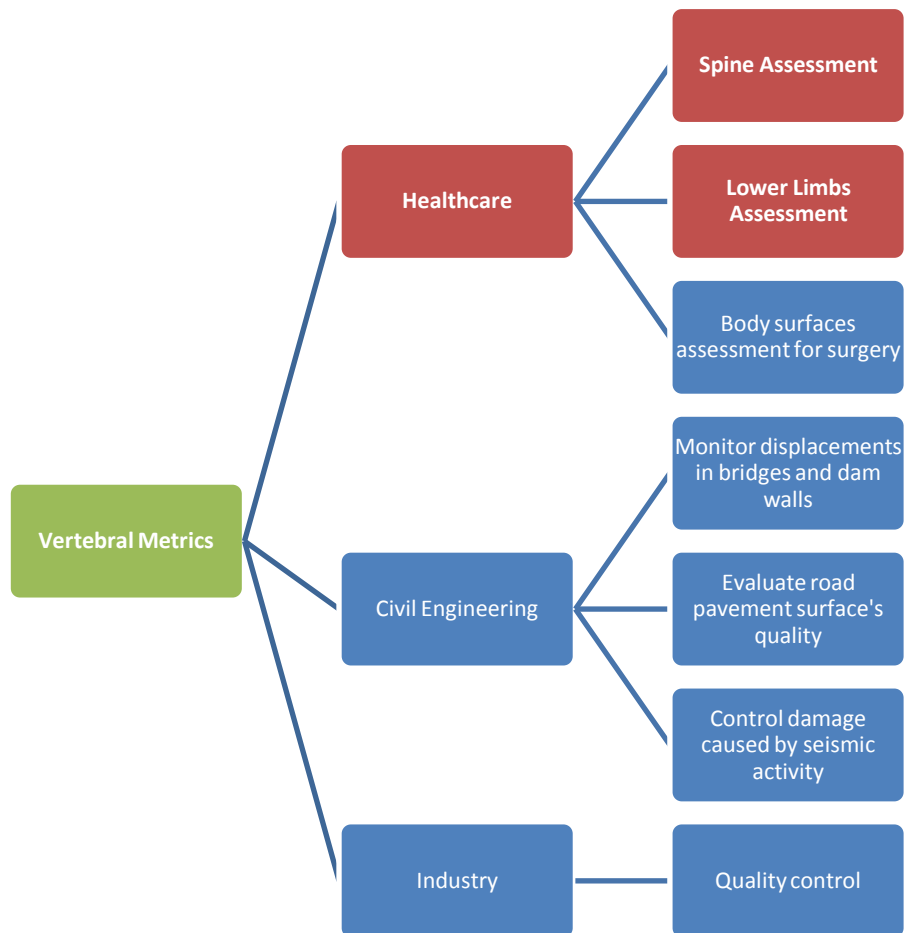
Distances in civil engineering are rather different than those for which VM has been designed. Rather than centimetres, the equipment would have to be adapted to monitor displacements at distances reaching several meters. Changing the order of magnitude, maintaining the same resolution, would be difficult. These changes would require new tests to verify its applicability in the sector, thus making this solution less attractive for an early introduction in the market. The design of VM will need to change and new tests will be required in a different setting. Thus, this market segment less interesting as a first approach to the market.

3.2.3 Industry

Quality control is necessary in several industries, thus providing a relatively big market. However, there are many current scanning technologies at use. For VM to be a solution, it would have to be efficient, both in performance and costs. Considerable adaptations would be required according to each industry standards and its capacity to offer a better and cheaper service than currently available solutions would vary greatly, thus making it difficult to predict how the device can add value to customers. The design of VM will need to change according to each industry characteristics and it is not clear that will solve a market pain that has not yet been addressed by current equipments available in the market.

3.2.4 Choosing application

Looking at the pros and cons provided for each application, using VM as a healthcare solution stands out as the most logic. Both vertebral column and lower limb applications seem the most interesting options. The prototype is currently adapted for the column and will have to be adapted to the lower limbs. However, any adaptations are far easier than those required in civil engineering. The possibility of using VM to perform population screenings is interesting in widening the market potential. More details on possible markets for these solutions are presented in the next chapter.



Scheme 3-1 – Market funnel for Vertebral Metrics Applications

3.3 Potential Market Dimension

An estimate on the potential market for Vertebral Metrics as a diagnostic tool for the spine and lower limbs has to take into account epidemiologic data as well as the size of markets dealing with postural disorders.

3.3.1 Back pain prevalence

Several studies have tried to look upon the problem of back pain in the society and its prevalence. Though there are differences between the results found, mainly due to the different methods and questions used, some consistent percentages have been found.

Most international studies on low back pain show **point prevalence rates of about 15% to 30%, a 1-month prevalence between 19% and 43%, and a lifetime prevalence varying from 60% to 80%.** (Nachemson, 2004)

Richard Deyo et al. (Deyo, Mirza, & Brook, 2006) have analyzed a 2002 survey from the National Health Interview Survey (NHIS) which returned a 26.4% prevalence of low back pain amongst U.S. citizens, making it the most common cause of pain.

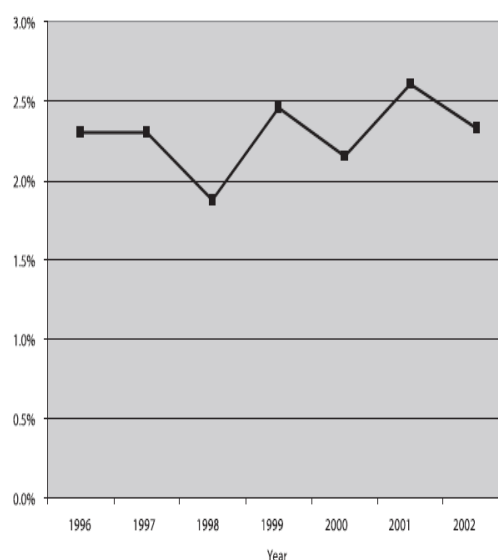
	Age-Adjusted % (SE)
Low back pain	26.4 (0.32)
Migraine or severe headache	15.0 (0.25)
Neck pain	13.8 (0.25)
Face or jaw pain	4.6 (0.15)

Table 3-1 Prevalence of low back pain amongst U.S. citizens in comparison with other pathologies (Deyo, Mirza, & Brook, 2006)

This study also reveals no significant differences between age groups and a slight decrease of prevalence with higher education levels as well as greater family income. Another study by Burton, however, has indicated a somewhat higher incidence of back pain amongst adolescents. (Burton, Clarke, McClune, & KM, 1996)

Selected Characteristic	Age-Adjusted % With Back Pain (SE)
Respondent age	
18-44 yr	23.7 (0.43)
45-64 yr	29.8 (0.58)
65-74 yr	28.8 (0.97)
75 yr or more	28.7 (1.03)
Sex	
Male	24.3 (0.45)
Female	28.3 (0.43)
Race/ethnicity	
White (non-Hispanic)	27.4 (0.39)
Black	23.9 (0.85)
Hispanic	24.3 (0.81)
American Indian/Alaska Native	35.0 (4.46)
Asian	19.0 (1.59)
Native Hawaiian/Pacific Islander	26.8 (10.76)*
2 or more races	
Black and white	20.0 (5.25)
American Indian/Alaska Native and white	45.5 (4.24)
Education	
≤High school diploma	31.8 (0.81)
High school diploma or GED	28.6 (0.59)
Some college	28.9 (0.64)
Bachelor's degree or higher	22.2 (0.59)
Family income	
≤\$20,000	31.8 (0.79)
\$20,000-\$34,999	29.9 (3.21)
\$35,000-\$54,999	26.4 (0.83)
\$55,000-\$74,999	25.0 (0.77)
\$75,000 or more	23.3 (1.81)

Table 3-2 Back pain prevalence according to different socio-economic groups. (Deyo, Mirza, & Brook, 2006)



Graphic 3-1 Visit rates to physicians due to back pain from 1996 to 2002. (Deyo, Mirza, & Brook, 2006)

This information has been cross-referenced with data from the National Ambulatory Medical Care Survey (NAMCS) on visit rates to physician offices due to lumbar spine problems. The percentage of respondents visiting a physician was 2.3% in 2002. Results have shown no changes in visit rates to physicians between 1996 and 2002.

Another fact resulting from these studies is that back pain is the most common cause for work absenteeism in adults under the age of 45 and the fourth most frequent in those between 45 and 64 according to (Andersson, 1997). It represents **7 to 14% of U.S. adults with some disability due to back pain for at least a day in each year and about 1% of Americans permanently disabled.**

3.3.2 Lower limb postural disorders

Finding epidemiologic data on lower limb disorders and its impact on the population is somewhat more difficult. Some studies have been conducted but rarely on its impact. Foot disorders seem to be the most studied, mainly flat feet.

A North-American survey indicates a **19% prevalence of flat feet amongst** the respondents and **5.2% for High Arch.** (Dunn, 2004). (Garrow AP, 2004) tried to relate self-reported foot disorders with disabling and no disabling foot pain.

Associations between disabling foot pain and self-reported foot problems			
Superficial foot conditions	Disabling foot pain, <i>n</i> = 298 (%)	No disabling foot pain, <i>n</i> = 2746 (%) ^a	Odds ratio ^b (95% CI) DFP vs. no DFP
<i>Foot deformities</i>			
Flat feet/pes planus	28 (9.4)	161 (5.9)	1.8 (1.2, 2.7)
High-arched feet/pes cavus	55 (18.4)	349 (12.7)	1.8 (1.3, 2.5)
Any toe deformity	98 (32.9)	357 (13.0)	3.5 (2.6, 4.7)

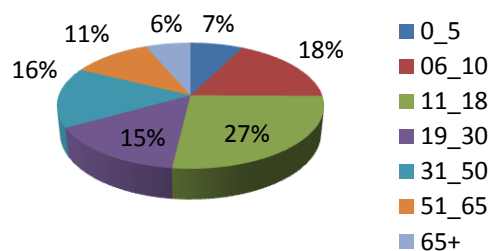
Table 3-3 Relation between self-reported foot problems and disabling foot pain. (Garrow AP, 2004)

It is however acknowledged by healthcare professionals that some of these imbalances, mainly when excessive, might have considerable impact on people's quality of life and should be monitored in early stages.

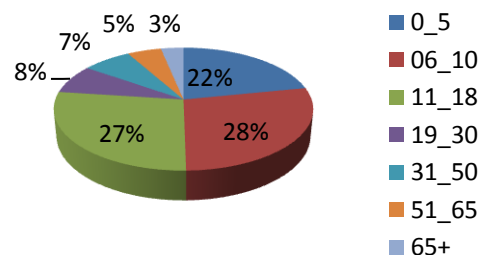
Pain symptoms and disability resulting from biomechanical disorders become more evident in athletes because of the significantly higher efforts exerted. This explains the efforts made by healthcare professionals and the sports industry to come up with compensation mechanisms.

3.3.3 Vertebral Metrics: Spine or lower limbs evaluation?

Data collected from interviews and a questionnaire (Appendix B) performed to professionals dealing with postural changes, have revealed some common perceptions in terms of Vertebral Metrics's applicability. (The questionnaire was conducted online to healthcare and sports professionals. There were a total of 68 participants from which 33 were healthcare professionals from orthopaedics, physical medicine and rehabilitation, physiotherapy, osteopathy and chiropraxy) and to 35 fitness sports professionals – Fitness instructors, managers and teachers.)



Graphic 3-2 - Age groups (in years) in which monitoring the column is more important (See Appendix B for details)



Graphic 3-3 Age groups (in years) in which monitoring the lower limbs is more important (See Appendix B for details)

Age

Healthcare and sports professionals seem to consider adolescence (11 to 18 years old) as the period in which it's more important to monitor postural alterations, both in the column and the lower limbs. In the lower limbs it is also considered important to monitor the 6 to 10 years age group. The same results state that, while the relevance of spine monitoring during adulthood is pertinent, the importance for lower limbs is more centred in early development stages.

Professional activities, routines and conditions

Differences can also be found when considering routines, some conditions and activities. Once again, children in school age appear as an important group, sustaining the results found by age groups. Many of the inquired said that monitoring the lower limbs of athletics' practisers is important due to the higher stresses imposed, while most have chosen sport practisers in general in the case of the column. Pregnancy had also some expression in terms of column monitoring, especially amongst interviewed physicians, thus meeting the initial goal for which the device was developed. The extra weight during the later gestational period often results in changes on the column's natural position and the appearance of back pain. At the same time, sports professionals have given priority to gym frequenters in the case of lower limb monitoring.

Although survey and interviews ended up recognizing the pertinence of measuring both spine and the lower limbs, from now on, only the spine application will be considered. The reasons for this choice will be explained in a later chapter called "The Lower Limbs Assessment Solution" and are mostly technical. In the end, the market is pretty much the same for both solutions.

3.3.4 Market Size

Healthcare is one of the biggest and fast growing industries worldwide, employing large segments of the population and providing high revenues. The focus here is on VM used for postural assessment.

Evaluation of postural disorders constitutes a considerable percentage of this market and employs a rather large number of professionals, spanning from conventional to alternative medical practices.

In Portugal, the biggest healthcare provider is the National Healthcare System run by the State. According to DGS (Direcção Geral da Saúde), there are 69 public hospital centres and a network of 346 primary care units (2008) with 1930 extensions. The same study says there are approximately 937 orthopaedists and 500 psychiatrists inscribed at OM (Ordem dos Médicos). (Estatísticas da Saúde, 2005, 2006)

Though smaller in size, the private market is present and growing. ERS (Entidade Reguladora da Saúde) has in its registry, amongst private and public entities, a total of 863 orthopaedic providers, 748 for rehabilitation and 102 for sports medicine.

Alternative medicine is starting to play a major role in diagnosing and treating postural disorders with osteopaths and chiropractors being the most solicited by patients. In 1992, from 39% of the people seeking care for back pain, 13% went to a chiropractor. (Carey, et al., 1996)

Healthcare is today less confined to conventional providers. Adopting a healthy lifestyle is becoming, each day, more common and the fast growing health club and fitness industry is a result of that.

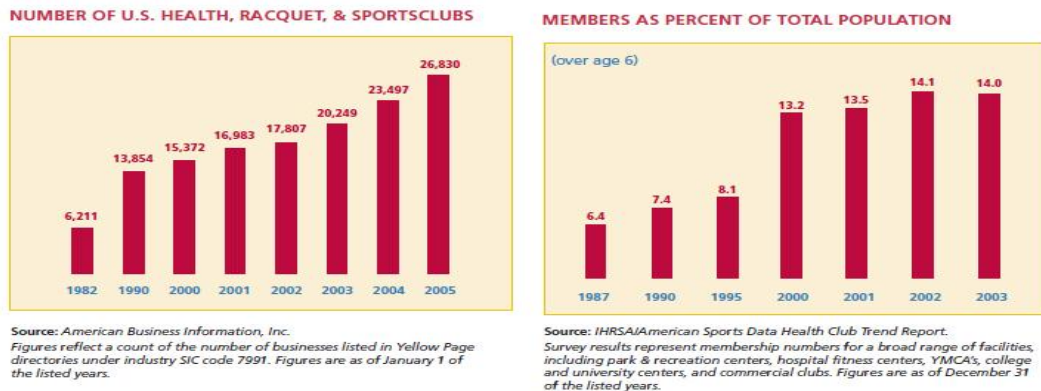
In recent years, health clubs have become more than a place where people go to exercise. New services are emerging with doctors, trainers and nutritionists working together to improve results and diagnose some pathologies affecting society. (Health Club Industry Review, 2007)

According to IHRSA's (International Health, Racquet & Sportsclub Association) 2005 global report (IHRSA, 2005), there were a total of 82000 clubs registered worldwide, with the U.S. and Europe leading in customer number and revenues. The total number of members and corresponding percentage of the population is presented in the next table for the U.S. and some European markets.

Country	Total number of clubs	Percentage of the population
United States	26830	14%
Spain	3800	7%
Germany	5650	5,5%
United Kingdom	4380	5%
Portugal	1100	4,8%
Italy	6200	4,5%

Table 3-4 - Market size information and differences amongst different countries. (IHRSA, 2005)

Plus, in the U.S., the number of clubs is rising as a result of an increased search for these services, as the following graphics show:



Graphic 3-4 Health club industry evolution in the USA (IHRSA, 2005)

According to the data provided, the Health club and fitness industry seems to be a promising market for the implementation of VM.

Healthcare is a vast market. The information necessary to segment, target and position the selected markets was gathered through qualitative interviews, a questionnaire and market research reports on behaviour, perceived necessity for the equipment, as well as, demographic and geographic factors.

3.3.5 Segmentation

When looking at the big picture, healthcare can't be seen as a "traditional" *business to business* (B2B) market. The profile of the customer (i.e. hospitals, clinics, health clubs, etc.) is not the only factor influencing the buying decision. The perceived necessity for the equipment is also strongly influenced by the number of patients whose care would benefit from it. Devices aimed at solving problems which have a high incidence in the population are seen as more cost effective by purchasers.

The organizational nature of healthcare systems worldwide might indicate location as a possible variable. While in the U.S., healthcare is run by private initiative, in Europe the State often is the main provider. It isn't possible, however, to label to market according to this private/public dichotomy since most of the time, decision processes are similar and the autonomy conferred to each unit is the same in both sectors. A stronger segmentation variable in terms of organization is the **level at which the decision to acquire the equipment is made.**

Decision level to acquire the equipment

There's no reason to treat private and public hospitals differently since in most cases, they've the same kind of autonomy to acquire equipment. Such is the case of Portugal and most European countries with universal healthcare.

Primary care units, on the other hand, usually don't have this kind of autonomy. Buying decisions are taken at a central level by the country's health authorities

This kind of differentiation is utterly important when considering the main interlocutors in any acquisition. The first opinion belongs to the healthcare professionals who will use the equipment. Their perceived utility for the product will greatly influence the process. A less centralized decision will cut down intermediaries between this first opinion and the final administrative decision.

Market size

When considering a diagnostic approach to Vertebral Metrics we think of hospitals, clinics and private physicians as the logic customers. However, each of these units would acquire from 1-3 units of the equipment according to the number of patients, and only if they're specialized in orthopaedics and rehabilitation.

As previously stated, ERS has in its database approximately 1600 entities providing this kind of services in Portugal. Almost all entities provide both specialties so, the real number is lower. Hospitals represent only a small percentage of the total number of providers.

Primary care units become interesting when considering a population screening instead. They're the closest link with the population, they're evenly spread in the country and their size varies according to a country's population. The same happens with pharmacies. In July 2006, there were approximately 3000 pharmacies in Portugal. (Estatísticas da Saúde, 2005, 2006)

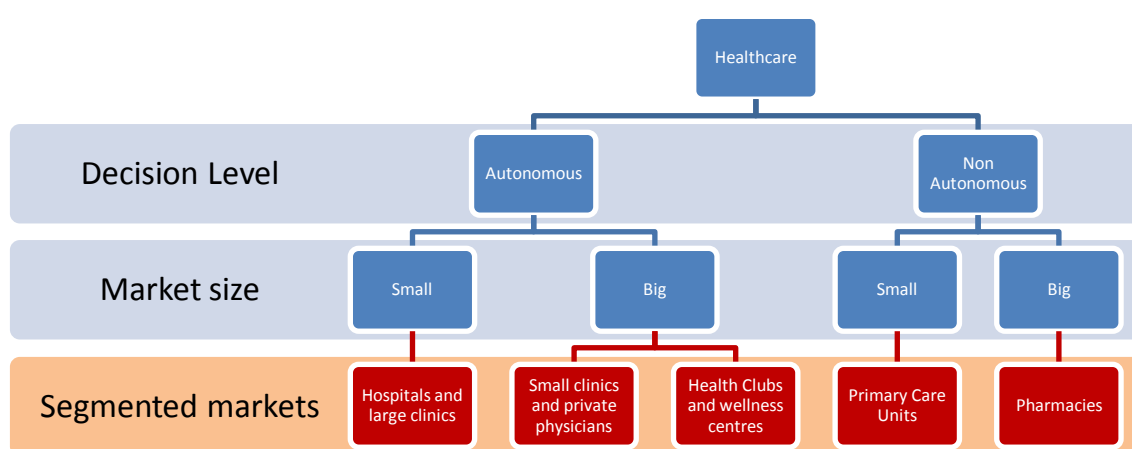
Equally promising in terms of customer size is the health club industry. As seen before, the market is growing and, at the moment, covers from 5 to 10% of most western countries population. The total number of clubs (See table 3.4) makes it a very interesting market to introduce the technology.

Applying segmentation variables

Applying the first variable allows a differentiation based on the autonomy level of each unit. Public initiative doesn't necessarily mean a centralized decision since there are differences in each country. For example, while in Portugal primary care units are managed directly by the health ministry (through ARS), in Spain, some units are managed by private initiative and thus, can take their own decisions. Nowadays, hospitals are almost all autonomous in managing and

acquiring resources. The context in which VM is applied also influences the decision level. For instance, a population screening would greatly benefit from policies defined at a central level. Pharmacies have the power to acquire any equipment they want but, in order to introduce them on a screening project one would depend on the pharmacies association and the health authorities. Even if VM was introduced in pharmacies as a diagnostic tool and not as part of an official screening campaign, it would greatly benefit from the approval of the entity overseeing pharmacies. This is the reason for them to be considered as non-autonomous.

Using the market size variable is important to identify which customers provide a more interesting opportunity in terms potential number of units to sell.



Characterization of segmented markets

Hospitals and larger clinics

Hospitals offer a wide variety of medical specialties where the diagnostic capabilities of Vertebral Metrics can be applied. The traditional branches dealing with postural changes are orthopaedics and physical medicine and rehabilitation (PM&R). But VM may also be interesting in other areas. The results from the conducted survey and interviews indicate the importance of following specific age groups, such as children and adolescents (paediatrics), as well as some conditions like pregnancy (obstetrics).

In most developed countries, hospitals function as autonomous entities (even if publicly owned) so they can decide on what to buy. The process of acquisition of any technology is highly dependent on the perceived necessity by each department's professionals and follows a well defined acquisition process.

Larger clinics function on the same basis as autonomous hospitals but offering fewer services.

Small clinics and private physicians

Small clinics and private physicians usually offer more specific services to their patients. They form a much vaster market than hospitals but also have less bargaining power since they're smaller units. Rehabilitation clinics, physiotherapist and orthopaedic offices are the main clients. Paediatric services may also be interesting to explore.

Acquisition is somewhat easier since the negotiation process is usually more direct comparing to hospitals.

Clinics and physician offices become especially important when they're the first contact with the patient. This often occurs in markets without a public primary care unit network, such as the US.

The offer widens when considering alternative medicine solutions such as those offered by chiropractors and osteopaths. Providing more accurate diagnose solutions is seen as very important by practisers. Patient search for alternative therapies related to postural issues is rising and already significant in North America and some European Countries. Further recognition is, however, still hampered by lack of official approval, mainly in Europe.

Health Clubs and wellness centres

As previously stated, the Health Club industry is growing fast and becoming increasingly interesting as a healthcare market. Health Clubs are including medical care in they offer, in order to provide a more complete service. Physiatrists, osteopaths, physiotherapists, orthopaedists are working together with fitness instructors to potentiate customer's performance and health.

According to healthcare and sports professionals (**Appendix B**), monitoring postural changes in the spine is important for athletes and weight trainers. Health Clubs aren't, however, the ideal place for monitoring the core age groups identified by the same professionals since children and teenagers rarely frequent these facilities.

Pharmacies and Primary Care Units: The population screening market

Pharmacies and primary care units are the best approach for the purpose of posture evaluation, since they're closer to the population. As already stated, population screening is highly dependent on the adoption of governmental programs so, their capacity to influence the acquisition of VM is important. European healthcare markets are thus preferable to less regulated ones, such as the US.

In both cases, and according to professionals, the focus should be on children and adolescents to accompany the growing phase. Monitoring the column during pregnancy has also been referred

as important. Using primary care units instead of pharmacies makes it easier to focus on specific age groups or conditions and allows for a more controlled monitoring over time.

Including pharmacies in an official screening campaign isn't as easier as with primary care units since there isn't a direct link to doctors. An alternative approach in this case would be to have VM as a simple diagnostic tool for the population.

3.3.6 Targeting

Customer and environmental characteristics are important to decide which markets are preferable as a point of entry to VM. In order to measure attractiveness, each segment will be rated according to the following factors: **Market size, Growth Potential, Bargaining power, competitor threat and easiness of introduction**¹

Market Size has been important to segment the market according to the potential number of customers. It's also important to evaluate the relative attractiveness of each segment. Hospitals and primary care units are the less interesting according to this factor since the potential number of units sold isn't as promising.

Growth potential isn't the same for each segment. While there are good perspectives in terms of market growth for the health club industry (also in the importance given to healthcare), primary care units and pharmacies are highly dependent on a country's demographic figures and health policies. The number of clinics and private practisers offering rehabilitation services has also been growing. Here, osteopaths and chiropractors, will have an increasingly importance with time. The number of hospitals has been rising in some European countries due to private initiative.

Bargaining power is also important since each customer's perception of the product's value is different. Here, hospitals and larger clinics have more financial power than smaller units so they might be keen to pay more for the product. Primary care units, private physicians and smaller clinics have less bargaining power and cover a smaller range of clients, so they would require lower prices to justify the investment.

In some segments, **competition** is bigger than in others. Hospitals and larger clinics already possess conventional imaging devices (X-Ray) capable of assessing the spine. Private physicians and smaller clinics usually depend on medical imaging centres to perform this kind

¹ Though both factors make possible a distinction between segmented markets, only market size has been used as a segmentation variable. Growth potential, bargaining power, competitor threat and easiness of introduction are good comparison factors between segments but they don't enable a distinction of the potential markets for Vertebral Metrics as clearly as market size and decision level do. Using them to find segments would result in a somewhat less robust segmentation.

of analysis, mainly because imaging devices are too expensive. However, they're the preferred target of simpler radiation free technologies as it will be discussed in the competitor analysis chapter. Health clubs can be considered a competition free market since it seems there aren't any technologies targeting this segment. The same happens applies to pharmacies and primary care units. **Easiness of introduction** is especially important because of the population screening option. It is much more difficult to negotiate with health authorities, so that a screening campaign is adopted, than addressing the customer directly. This factor makes primary care units the less attractive segment, followed by pharmacies. Furthermore, not all health clubs are yet focused on a consonance between sports practising and healthcare follow-ups, though future trends indicate that possibility in the near future.

	Market Size	Growth potential	Bargaining power	Competition threats	Introduction easiness	Total score
Hospitals and larger clinics	2	3	4	2	4	15
Small Clinics and private physicians	5	4	3	4	5	21
Health Clubs and Wellness centres	5	5	3	5	3	21
Primary care units	3	2	2	4	2	13
Pharmacies	4	3	3	5	3	18

Table 3-5 – Segment evaluation

According to the overall scores achieved in the previous table, the most promising segments to introduce Vertebral Metrics are Small Clinics and Private Physicians, as well as Health Clubs and Wellness Centres. It's however important to have in mind that, if a screening policy was to be adopted, Pharmacies and Primary Care Units would become considerably more attractive.

3.3.7 Positioning

How to position Vertebral Metrics in the chosen segments? In order to answer to this question, it's important to make another one: What attributes are most valued by customers?

Current diagnostic methods for postural changes observation are mainly based on one of the following options: Visual examination by healthcare professionals and X-Ray imaging.

Both methods have their own issues, visual analysis introduces a substantial error in the diagnostic and, submitting the patient to considerable doses of ionizing radiation, is something no doctor wants to do.

During interviews, there were some aspects that have always aroused interest about the product: Improved accuracy, the possibility of three dimensional analysis, being fast and radiation free.

Price, of course, has also been mentioned by almost everyone, especially in the targeted segments. Cost-effectiveness is valued by most professionals.

Customers also value products that are easy to use so, a user-friendly interface is important.

Current competitors (See competitor analysis for details) are positioning their products precisely according to some of the previously referred attributes: Accuracy, radiation free, user friendly and cost-effective are common advantages presented by every manufacturer.

It isn't enough for VM to be more accurate than other products and more user-friendly and present it as such. More important is to find ways to differentiate the product in respect to competitors.

According to what has been stated and to the competitor attributes (See Performance Map in the competitor analysis chapter), VM will be positioned as a medical device that **adds value to the customer's services**:

1. It provides **fast measurement without contact**, for improved accuracy.
2. It **radiation free**: Can be used repeatedly without compromising the patient's health.
3. Is **user-friendly** and **focused on customer needs**: Provides a simple interface for analysis and offers software with personalized solutions for healthcare and sports professionals. **Different customers, different needs**.
4. **Compatible and versatile**: Software is compatible with different platforms and data can be edited and saved in widely used file formats so that it can be easily shared.

Positioning statement

For healthcare and sports professionals who value simplicity and care about patient's well-being. Vertebral Metrics is an innovative solution for contact-free postural assessment providing better accuracy and offering personalized data analysis software, always based on a strong commitment to invest in ways of simplifying and bring value to customer's activities.

3.4 Competitor Analysis

X-Ray imaging is common in hospitals and large clinics but rarely found in smaller units due to its price, size and the security measures involved. According to this, companies producing X-Ray systems won't be considered as potential competitors in the selected markets. However, they'll be included in the performance maps further ahead for comparison purposes.

More direct competitors of VM in the chosen segments are recent technologies based on non-invasive methods such as the devices developed by the following companies:

Diers International GmbH

Dier is a German biomedical company which has a bodyline product family with 3 different solutions for clinical analysis of posture and spine: Formetric 4D, Statico 3D and 2scan.

According to Diers website, product development values interdisciplinary utilization by various professional groups such as orthopaedists, orthopaedic technicians, physical therapists, dentists, orthodontists and sports medicine specialists. The company identifies itself as a worldwide market leader in the field of optical 3D / 4D postural and locomotion analysis.

Formetric 4D analysis system permits rapid static and dynamic (functional) optical measurement of the human back and spine. The following clinical applications are indicated for the product: Scoliosis, pelvic positions, kyphosis and lordosis, back pain patients, differences in leg length, foot malpositions, and functional analyses.

Statico 3D uses the same base technology as Formetric 4D though not permitting dynamic measurements.

2scan is a static measurement system for postural analysis using manually positioned marker points. The 2-camera-system allows a three dimensional caption of specific markers, which are set on the patient's back prior to the measurement, making it very similar to Vertebral Metrics.



Image 3-1 – Diers 2scan device and spine mark-up.

Idiag AG

Idiag is a Swiss based company offering colleges, universities and other research facilities an effective conduit to recognize and commercialize their product potential.

One of the products developed by Idiag is SpinalMouse, a compact measuring device allowing assisted analysis and display of the spinal cord shape and mobility in the sagittal and frontal planes. The SpinalMouse measuring head is guided along the spinal column, automatically adjusting itself to the contours of the back. The relevant clinical data is then wirelessly transferred to a personal computer or laptop.



Image 3-2 – SpinalMouse: Device, 3D column reconstruction and measurement mechanism.

According to the company, it is both practitioner and patient friendly, non invasive, and completely free from radiation.

Idiag is selling SpinalMouse worldwide, mainly through local distributors. According to their website, it's currently being distributed in the following countries:

Europe: Hungary, Norway, Spain, Greece, Austria, Germany, Finland, Italy, Ukraine, United Kingdom, Netherlands, France and Romania.

Asia: Iran, Japan, South Korea and China.

Central America: Mexico

SpinalMouse is promoted in the North American market through **SpinalMouse Solutions**.

Orthoscan Technologies, Inc

Orthoscan is North-American Company with production and R&D facilities in Israel. Their mission statement is “To become a premier supplier for radiation-free diagnostic products for the orthopaedic field”. They commercialize two products for spinal assessment: **Spine Scan** and **Ortelius800**.

Spine Scan operates much in the same way as Idiag's SpinalMouse. According to the manufacturer it can be used to: Follow-up kyphosis and lordosis angles, quantitative assessment of posture asymmetries (Including head, shoulders and hip) and motion analysis in the spine.

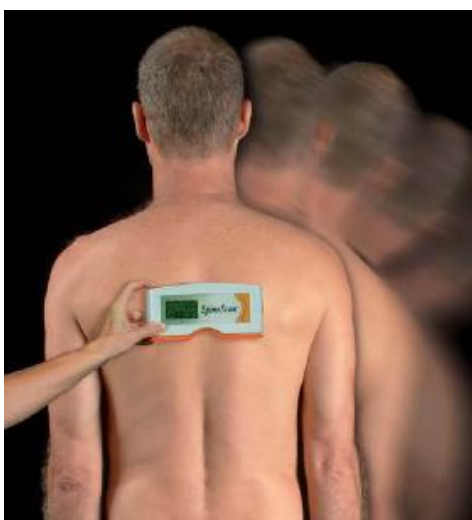


Image 3-3 – Spine Scan measuring a patient's vertebral column deviations.

Ortelius800 is a radiation-free system capable of monitoring spinal deformities (focusing on scoliosis and kyphosis) in less than a minute, providing an accurate graphical image of the spine and calculating the Cobb angle in both coronal and sagittal views.



Image 3-4 – Ortelius 800 device, measurement procedure and spine model.

3.4.1 Competitors' Analysis using a Performance Map

The following map compares the performance of the described technologies according to some attributes. DIERS 2scan isn't considered here since there's little or virtually no information about it. Again, X-Rays will be included as the most used method of diagnose, for comparison purposes.

Attribute/Product	Vertebral Metrics	SpinalMouse	Ortelius800	Spine Scan	X-Ray Equipment
Accuracy	Green	Yellow	Yellow	Yellow	Red
Health Risks	Green	Green	Green	Green	Red
Portability	Yellow	Green	Yellow	Green	Red
Price	Green	Green	Yellow	Green	Red
Speed	Green	Yellow	Green	Yellow	Green
Easy to use	Yellow	Red	Yellow	Red	Yellow
3D Data	Green	Green	Green	Green	Yellow

Table 3-6 – Performance Map: Attributes VS Competitors – Green: High performance; Yellow: Medium performance; Red: Low performance.

Accuracy: VM provides measurement without contact. Contact between equipment and patient, even if only for a brief moment (Ortelius800), influences the results and compromises accuracy. Both SpinalMouse and Spine Scan depend upon constant contact with the body.

Health Risks: Both products are radiation free and provide a safer solution than X-Ray.

Portability: It's probably VM's Achilles'Heel. SpinalMouse and Spine Scan are very easily transported. The same cannot be said about VM, Ortelius800 and much less of X-Ray machines.

Price: VM price is estimated to be around 5000 to 10000€ which is in the same range of SpinalMouse (~9000€). It won't be possible though to compete on price with Spine Scan (~2000€). Even if it's cheaper than most X-Ray systems, Ortelius800 (~30000€) can hardly be sold to the targeted markets with its current price.

Speed: Both products provide fast measurement. However, user's technique can seriously bias the exam's duration, especially with Spine Scan and SpinalMouse.

Easy to use: Ortelius800 and VM both depend upon the marking/recognition of the patient's spinous process, which is relatively easy for an healthcare professional. As already said, both SpinalMouse and Spine Scan require a good measurement technique to avoid errors so they can become difficult to use.

3D Data: Both products provide direct tridimensional analysis. The same doesn't happen with radiographies.

In conclusion, SpinalMouse seems to be the strongest competitor due two main reasons:

- i) Customer focus is directed exactly to the same markets as Vertebral Metrics (Typical fields of usage referred in Idiag's website are: Physiotherapy and rehabilitation training, manual therapy and chiropractics, Orthopaedics, Osteopathy, Health, fitness and wellness centres).
- ii) Idiag's distribution channel evidences good global penetration for a recent product, especially in Europe.

However, none of the VM competitors seems to have yet become a standard for radiation-free postural assessment, mainly because they're all recent products and still trying to build a reputation and convince customers. The case would be more difficult if targeting hospitals and larger clinics, since X-Ray systems are usually manufactured and distributed by very large corporations with a strong market implementation and have been the standard method for decades.

3.5 Supply Chain

Healthcare supply chains are often very complex and thus, choosing the best approach is essential for the success of the business. This chapter will be focused on identifying the key figures, exploit the best strategic options and highlighting differences in the chosen markets. Since any decision regarding the supply chain is extremely dependent on the adopted business and marketing models, further considerations will be held in later chapters

Traditional supply chains for medical devices usually follow this overall sequence:

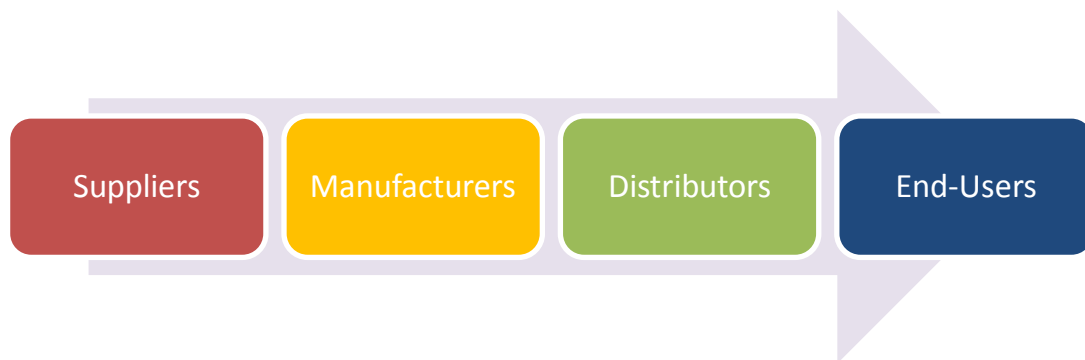


Image 3-5 – Supply chain traditional sequence

However, when using this sequence, each element tends to consider only its immediate neighbours in the chain instead of looking at the entire picture. This usually results in the absence of a global strategy, which implies less efficiency and higher costs for everyone. Furthermore, smaller manufacturing companies often have difficulties in choosing the most competitive position in the supply chain.

Optimizing value for Vertebral Metrics should always focus in building trust with every element in the supply chain since information sharing is important to all intermediaries.

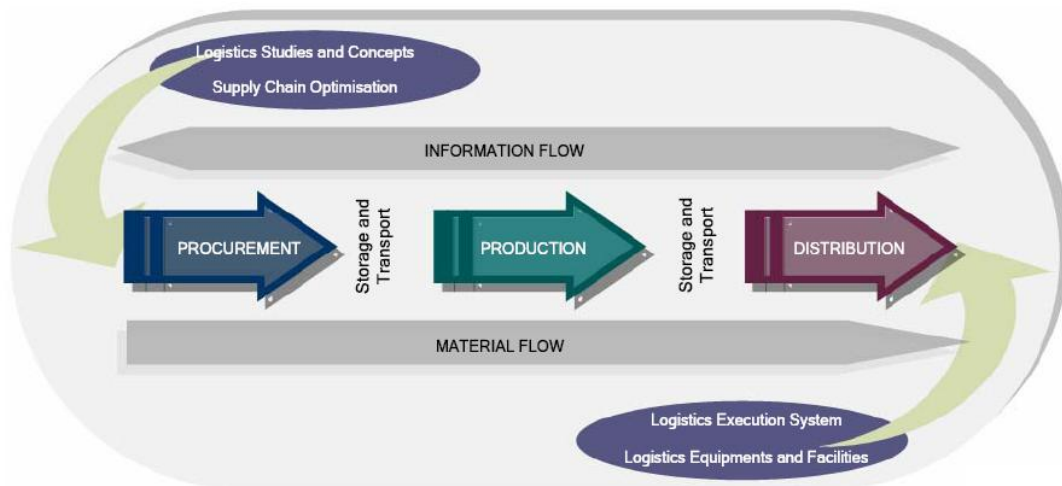


Image 3-6 - Supply chain optimization: Information sharing is essential in both directions. Source: Frost & Sullivan (An overview of medical device supply chain and trends in Europe, 2010)

3.5.1 Potential Suppliers

The raw materials necessary to produce VM are easily obtained. Most materials can be purchased at lower prices in the Asian market for electric and mechanical components. However, the choice is also vast in Europe and the US. Some potential suppliers are: Igus® (Plastic structures, worldwide coverage), Ever Elettronica Srl., Lin Engineering and Toshiba (Stepper motors, worldwide coverage), Microchip Technology Inc. (microcontrollers, worldwide coverage).

There are some important things a manufacturer should consider regarding supplier relationship:

- Investing on supplier diversity. Being dependant on larger suppliers may not be the best option for smaller manufacturers. Having local smaller companies as potential suppliers, may help gaining competitive advantage.
- Avoid purchasing big volumes of raw materials. It's usually better to make smaller purchases to lessen inventory concerns.

3.5.2 Raw Materials and inventory concerns

As previously referred, the materials needed to produce VM are easily obtained through many suppliers who distribute their products on a global scale. External dependence is unavoidable but not necessarily a problem. Locating production facilities near local suppliers is also important, not only to avoid significant costs with transportation, but also to reduce the need for large inventory concerns.

3.5.3 Distributors

Distribution channels are essential to bring the product to healthcare providers, especially because most small manufacturers can't afford to (or don't want to) take their devices directly to customers. They take responsibility for all the necessary transportation and inventory concerns.

Marketing for new products in a small firm might be difficult and "building" a reputation in the market is essential to gain competitive advantage in distribution channels. Sometimes is important to gain visibility, not only amongst distributors, but also with healthcare providers.

Finding the correct distributors for each target market might prove a difficult task to achieve since they form a very complex network. Trade associations focused on medical devices are usually a good starting point and provide important advice when choosing local distributors. In Europe, two examples are The European Medical Device Distributors Alliance - EMDDA and The European Confederation of Medical Devices Associations - EUCOMED.

3.6 Market Barriers to Entry

3.6.1 Intellectual Property

Patenting process chronology and current situation

The following table describes the main steps taken in the process of patenting Vertebral Metrics:

Filing for a National Patent with Instituto Nacional de Propriedade Intelectual - INPI	07.03.2008
Filing for an international patent under the Patent Cooperation Treaty of the World Intellectual Property Organization (PCT)	06.03.2009
Publication of the National Patent PT 103990 (Quaresma, Secca, & Santos, Dispositivo de Avaliação da Coluna Vertebral, 2009)	07.09.2009
AFTER AN INTERNATIONAL SEARCH PERFORMED BY THE EUROPEAN PATENT OFFICE (EPO)	
Publication of the International Patent WO 2009109859 (Quaresma, Secca, & Santos, Device for assessing the spinal column, 2009)	11.09.2009
Publication of the European Patent EP 2263531 (Quaresma, Secca, & Filipe, Device for assessing the spinal column, 2010)	22.12.2010
Publication of the US Patent US 20111004125 (Quaresma, Secca, & Santos, Device for assessing the spinal column, 2011)	06.01.2011

Table 3-7 Chronology for patent submission and publication.

This patent refers to VM's first prototype. Adaptation is necessary in order to guarantee protection to the current device's prototype, namely in the following sections:

- State of the Art description with introduction of some devices aiming at performing similar measurements.
- Description of drawings needs to be completely reformulated since the new prototype's geometry and functioning are rather different.
- Only the first claim could be maintained since the other three make references to the device's functioning.

Though amendments are allowed, the necessary updates to the current patent can't be performed under the US Code of Federal Regulations – CFR – and the European Patent Convention – EPC:

US 37 CFR 1.121 (37 CFR 1.121) states under f): *«No new matter. No amendment may introduce new matter into the disclosure of an application»*

EPC Article 123 (EPC's Article 123) reads in paragraph 2: *«The European patent application or European patent may not be amended in such a way that it contains subject matter which extends beyond the content of the application as filed. »*

As a result, in order to protect the new prototype, a new patent would have to be filed.

Considerations on filling for a new patent

Filing for a patent is expensive and not always necessary. Though current protection for VM doesn't fulfill the role of describing the new prototype, it clearly states the purpose of the device. Protection for the product's design and elements might not be as important as, for example, protecting the software controlling how the device operates.

However, this might prove to be difficult, especially under Europe regulation. Making claims on computer-implemented inventions is forbidden under article 52 2 c) of the EPC (EPC's Article 52):

«The following in particular shall not be regarded as inventions within the meaning of paragraph 1: (...) (c) schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers; »

However, prohibitions on paragraph 2 are subjected to the condition on paragraph 3:

«Paragraph 2 shall exclude the patentability of the subject-matter or activities referred to therein only to the extent to which a European patent application or European patent relates to such subject-matter or activities as such. »

This means that, under EPC's article 52, software is not patentable as a standalone invention. EPC examination board has been changing their view on claims which include software used for controlling technical processes. This is the case of the software used for controlling VM.

Revision of EPC's Guidelines now state that if *«the subject matter as claimed makes a technical contribution to the known art, patentability should not be denied merely on the ground that a computer program is involved in its implementation. »*

The inclusion of a claim describing the software used for managing the equipment is something to have in mind if the decision of writing a new patent is made.

Copyright concerns

The brand name and logo for the device or any software for data analysis in the product line should be registered (Further details on brand to be discussed in the Marketing Plan). The best approach is filing for international registration under WIPO's Madrid System.

International registration has several advantages:

1. After registering in the office of origin – INPI – the applicant has to file only one application, in one language and pay a single fee instead of registering individually at each country's trademark offices.
2. It speeds up the process of granting the trademark since, if no refusal is notified by each country's office, the mark is protected, thus avoiding individual evaluation.
3. There is only one expiry date and changes subsequent to registration are simpler because they're subjected to a single simple procedural step and fee.

3.6.2 Regulatory concerns related to market/consumers

Product certification prior to its introduction in the market is an important issue to consider. Certification of medical devices may be complex and is something to bear in mind since in the early stages of development of any equipment. Though some efforts are in progress by the Global Harmonization Task Force (GHTF) to standardize medical device regulation across the world, there are still many differences according to each region.

There are two main concerns when trying to certificate a product: To ensure **product's conformity with each country or regional directives** and a **quality certificate**.

Quality certificates

Usually, the process of ensuring a product's conformity includes quality assessment so, quality certificates are rarely mandatory. However, they may be used in order to facilitate the process of product recognition. The ISO 13485:2003 standard, for example, is used by most manufacturers as quality management system necessary to obtain a CE mark. ISO 13485 can be obtained with the help of a quality certification company, such as APCER in Portugal.

The following paragraphs will briefly explain the steps necessary for VM to obtain European - CE mark and US - FDA certification.

CE Marking

Obtaining certification for medical devices in Europe is regulated by the Directive 93/42/EEC - MDD. (MDD 93/42/EEC) According to the directive, in order for any product to be recognized as a medical device, it must verify conformity with Article 1, paragraph 2a):

«'medical device' means any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:

- 1. diagnosis, prevention, monitoring, treatment or alleviation of disease;*
- 2. diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;*
- 3. investigation, replacement or modification of the anatomy or of a physiological process;*
- 4. control of conception;*

And which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;»

If the device is in accordance with the previously stated, the next step is to find which class it belongs to – Annex IX of the MDD. There are 4 classes: Class I, Class IIa, Class IIb and Class III based on the risk level and 'invasiveness' of the product. Class specification is achieved by following specific rules. There are two rules which determine the class of Vertebral Metrics:

Rule 1 – Non invasive devices: Either does not touch patient or contact only intact skin - Class I device.

Rule 12 – All other active devices. (Example: Active diagnostic devices intended to illuminate the patient’s body in the visible spectrum, such as illumination lights, or optically view the body, such as surgical lamps) - Class I device.

The product is thus a Class I medical device and the next steps are necessary to guarantee certification:

1. All requirements in Annex I must be followed as well as all provisions related to clinical validation data in Annex X.
2. The best way of ensuring the necessary quality evaluation for the product is to apply for an ISO13485 quality certificate.
3. Though Class I devices do not require a notified body to perform external evaluation of the product, VM has a measuring function and thus, according to Annex VII: 5 of the MDD, a notified body is necessary to audit all aspects related to product’s conformity with the metrological requirements.
4. Prepare a technical file with all the information required by the MDD and keep a copy for at least 5 years.
5. Prepare a legally binding Declaration of Conformity stating that the device is in accordance with the MDD.

The declaration of conformity and other documents must be submitted to an official body such as INFARMED I.P., in Portugal. The product can then receive CE marking and be introduced in the European market.

Food and Drug Administration certification

Getting certification for medical devices in the US is somewhat different to the European process of CE marking.

The following steps must be followed:

1. Determine the class for the product in the FDA’s website. There are 3 classes based on the level of control necessary to assure the safety and effectiveness of the device. Finding whether VM is a Class I, Class II or Class III device must be done in one of two ways:
 - a. Search for similar technologies in FDA’s database and see attributed class.
 - b. In case there are no technologies with the same characteristics, make a 513(g) request for product’s evaluation and counseling on necessary steps to be follow. The request must contain device description and body interaction, a concise

indication for use statement, proposed labeling for the product or similar product's labeling. A fee must be paid.

2. Vertebral Metrics falls in the example of 1b) so class is uncertain. Class definition is extremely important to determine the following steps of certification. Every device, independently from its class, must be subjected to a Quality Management system. ISO 13485 is not recognized by the FDA so, quality system regulation (QSR) must be done according to directive 21CFR820. (21CFR820)
3. Since VM probably falls in the Class I or Class II device type, there is a major difference in terms of fee payment. Class I devices aren't subjected to any other kind of regulation than complying with QSR standards and paying an annual fee. Class II devices must prepare and submit a 510(k) application, pay the 510(k) submission fee and wait for FDA review within a period of 90 days. After that, the annual fee is paid and the product is certified.
4. FDA does not issue a certificate on QSR compliance but every company will be subjected to random inspections. Any company outside the US must appoint an agent to be able to ask for certification.

3.7 Market Size, trend and Growth Potential

3.7.1 Potential Value of market

The market potential value is predominantly based on the number of entities offering services in rehabilitation and fitness. These figures will be further used to estimate sales projection according to the percentage of the market which is accessible considering some environmental factors.

Some values have been extrapolated since there is no information available; others result from information given by associations and regulation entities or found through online databases. The source will always be indicated next to the value.

The evolution in the number of providers is considered to be negligible for three main reasons: No significant demographic evolution is expected in the studied countries and the period of economic recession makes it less probable for a considerable market expansion. The most likely expansion would be on the number of entities providing Osteopathy and Chiropraxy services but, even in this cases, the lack of recognition in some countries like Portugal makes this growth potential hard to predict.

Sales Projections: Portugal and Europe (2012-2017)

In 2012 all the technology refinements will be made in VM in order for it to be ready for commercialization. Sales will start in 2013 in Portugal, 2014 in Spain and 2015 in Italy.

This commercialization strategy will help in negotiations with potential medical equipment distributors: it will be easier if VM is tested successfully in Portugal and, only after that to introduce it in other markets.

Portugal sales projection (2012 – 2017)

Health clubs

A 5% share of accessible market will be applied based in the fact that the expected healthcare follow-up trend in the health club industry will take its time to be adopted by most providers.

Number of Health Clubs (1)	1100
Potentially accessible market (5%)	55

Table 3-8 –Potentially accessible market for health clubs in Portugal (1) Source: HIRSA’s Health Club Global Report 2005 (Values are approximately the same in 2011)

The 6-year projection for the Health Clubs market and corresponding market share is shown in the following table

Year (Market share)	2012 (0%)	2013 (5%)	2014 (10%)	2015 (20%)	2016 (30%)	2017 (30%)
Sales Projection (units)	0	3	6	11	17	17

Table 3-9 – 6-year projection for the number of units sold to Health Clubs in Portugal

Healthcare providers

The percentage for the potentially accessible market (10%) accounts for the fact that, at first, not every professional is interested in adopting new technologies as well as the need to establish the product in the market.

Number of entities providing services in:	
Physical and Medicine Rehabilitation (1)	745
Orthopaedics (1)	863
Osteopathy (2)	80
Chiropraxy (2)	40
Total (3)	983
Potentially accessible market (10%)	98

Table 3-10 – Potentially accessible market for healthcare providers in Portugal (1) Source: ERS – Entidade reguladora da Saúde; (2) Value extrapolated from the Spanish Value (see below); (3) This sum considers a 100% superposition of the P&MR and the Orthopaedics entities and thus, only considers the highest value

The 6-year projection for the Healthcare Providers market and corresponding market share is shown in the following table:

	2012	2013	2014	2015	2016	2017
Year (Market share)	(0%)	(5%)	(10%)	(20%)	(30%)	(30%)
Sales Projection (units)	0	5	10	20	29	29

Table 3-11 – 6-year projection for the number of units sold to healthcare providers in Portugal.

Projection for other European countries (2012-2017)

Country	Number of entities providing services in:						
	Popul.	Orthopaed.	P&RM	Chiropr.	Osteop.	H. Club	Total
	(1)	(2)	(3)	(4)	(5)	(6)	(7)
Portugal	10	863	745	80	40	1100	-
Spain	46	4300	3427	224	393	3800	8717
Italy	60	5178	4470	395	1419	6200	13192
Germany	82	7077	6109	540	1939	5650	15206
UK	62	5351	4619	1036	1466	4380	12233

Table 3-12 – Number of entities existent in some European markets. (1) Estimated Population In millions; (2) All values extrapolated from the Portuguese one, except for Spain (Source: SECOT); (3) All values extrapolated from the Portuguese one; (4) Sources: Italy – AIC , Associazione Italiana Chiropratici, Spain – AEQ, Asociación Española de Quiroprática, UK – BCA, British Chiropractic Association. German value extrapolated from the Italian; (5) Sources: Spain – ROE, Registro de los Osteopatas en España, Italy – ROI, Registro degli Osteopati d'Italia. German and UK values extrapolated from the Italian. (6) IHRSA 2005 (7) Total is the sum of all entities considering only Orthopaedics or P&RM (100% superposition, highest number)

An overall 10% percentage is considered for the potentially accessible market, following the assumption made in the previous projections that not every professional is interested in adopting new technologies, but also the difficulty inherent to placing a product in international markets.

Potentially accessible Market (10%)	
Portugal	-
Spain	872
Italy	1319
Germany	1521
UK	1223

Table 3-13 – Potentially accessible market in some European Countries

The 6-year projection and corresponding market share is shown in the following table:

Sales	Projection	2012	2013	2014	2015	2016	2017
(potential share)	market						
Spain		0	0	87 (10%)	131 (15%)	174 (20%)	218 (25%)

Italy	0	0	0	132 (10%)	198 (15%)	264 (20%)
Germany (If entering in 2014)	0	0	152 (10%)	228 (15%)	304 (20%)	380 (25%)
UK (If entering in 2014)	0	0	122 (10%)	183 (15%)	245 (20%)	306 (25%)

Table 3-14 – Sales projection for the first 6 years of activity in each country.

3.7.2 Growth Rate of Industry

Medical Devices Industry

The Medical devices industry is expected to continue to grow in the US and Europe, mainly due to an aging population and an increasing incidence of chronic diseases. In the United States, Frost & Sullivan has estimated a compound annual growth rate in medical devices industry of 9% for the period 2006-2013.

Orthopaedic devices are amongst the most promising areas, both in the US and Europe, even though recent figures have shown a drawback in revenues in the US spine market. In Europe, according to a Frost & Sullivan report on growth opportunities for medical devices, the only areas where a rise in profits is expected in the 2008-2012 timeframe is orthopaedic and cardiovascular solutions.

On a global scale, most future investments will be done on new developing markets such as new EU members and, in a later stage, the BRIC countries: Brazil, Russia, India and China. Though still facing serious organizational problems in terms of providing healthcare services for its population, China is starting to attract many investors.

Health Club industry

Health Club membership has been rising in the past decade, both in Europe and the US. The rise on customer spending in wellness centres and gyms is usually dependent on income per capita growth. However, the industry has been able to adapt and differentiate their offer to meet customer's needs. Recent trends have focused on a closer relationship between healthcare and sports professionals, providing a more holistic approach on exercise and healthcare and giving rise to an increased commitment to a healthier lifestyle and customer loyalty.

3.8 Key Stakeholders

This chapter resumes all the external stakeholders who influence product delivery from production to consumers.

On the demand and supply side:

Government and regulatory authorities: Even though targeted segments aren't under direct public jurisdiction, government policies, namely fiscal or healthcare related, can influence the market environment. Moreover, regulatory authorities such as INFARMED in Portugal are crucial in the process of certification.

On the supply side:

Supply chain partners: Suppliers and distributors are crucial in delivering product to client. The effectiveness of inbound and outbound logistics greatly depends on them so, it's important to maintain constant communication.

On the demand side:

It's important to know who may influence the buying decision:

Small clinics and private physician offices: The opinion of the healthcare professionals is extremely important because it's them who can better ascertain product's utility and how it brings benefit to their activity. In the case of private physician offices, the healthcare professional is also the person making the purchasing decision so, he or she are the only stakeholders. When talking about clinics, the situation is different. Here, even if the user's opinion is crucial, the ultimate decision is taken by the administration board. Their weight on the decision may vary substantially from one clinic to the other but in general, they only contradict the healthcare professional's opinion due to budget reasons.

Health clubs and wellness centres: The situation is almost the same as in clinics, with healthcare and sports professionals' opinion being essential. In this case, however, the purchasing decision might also depend on how their clients view the product and if they're interested in having this service at disposal.

Professional associations: Professionals in the segmented markets are usually represented in societies or federations according to their area of intervention. They often play a major role in divulging new techniques and innovative solutions for their members. Almost every country has its own Orthopaedics, PM&R, Osteopaths, Chiropractors or Health Club association. The following table shows these entities in some European countries:

Portugal

SPOT – Sociedade Portuguesa de Ortopedia e Traumatologia

SPMFR – Sociedade Portuguesa de Medicina Física e de Reabilitação

FPO – Federação Portuguesa de Osteopatas

APO - Associação de Profissionais de Osteopatia

APQ – Associação Portuguesa dos Quiropráticos

AGAP – Associação de Empresas de Ginásios e Academias de Portugal

Spain

SECOT - Sociedad Española de Cirugía Ortopédica y Traumatología

SERMEF - Sociedad De Medicina Física Y Rehabilitación

ROE – Registro de los Osteopatas de España

AEQ - Asociación Española de Quiropráctica

CEGIP - Confederación Española de Gimnasios Privados

FNEID – Federacìon Nacional de Empresários de Instalaciones Deportivas

Italy

SIOT – Società Italiana di Ortopedia de Traumatologia

SIMFER – Società Italiana di Medicina Fisica e Riabilitativa

ROI – Registro degli Osteopati d'Italia

AIC – Associazione Italiana Chiropratici

FIF – Federazione Italiana Fitness

Germany

DGOU – Deutsche Gesellschaft für Orthopädie und Unfallchirurgie

DGPMR - Deutsche Gesellschaft für Physikalische Medizin und Rehabilitation e.V.

VOD – Verband der Osteopathen Deutschland e.V.

DCG – Deutsche Chiropraktoren Gesellschaft e.V.

DIFG - Deutscher Industriesverband für Fitness und Gesundheit e.V.

United Kingdom

BOA – British Orthopaedic Association

BSRM – British Society of Rehabilitation Medicine

BOA – British Osteopathic Association

BCA – British Chiropractic Association

FIA– Fitness Industry Association

Table 3-15 – Main professional and regulatory entities in Portugal, Spain, Italy, Germany and the UK.

Chapter 4 Internal Analysis and Strategy

Vertebral Metrics is being currently developed through a partnership between Universidade Nova de Lisboa (CEFITEC) and NGNS, a start-up company focused on R&D for new technologies. But what should be the role of NGNS in the process of delivering VM to customers? Is it better to trust development and commercialization to a company already settled in the healthcare market or to follow another solution? These answers imply a closer analysis of current resources, the pros and cons of each option as well as the investment needed.

There are 3 important steps to consider in taking the product to market:

Product development: NGNS focus on R&D makes it the best option to continue Vertebral Metrics optimization before entering the market.

Manufacture: Assembly requirements for Vertebral Metrics depend on the number of orders. While the production volume is low, the device can be assembled by few technicians and won't require full time dedication. Outsourcing can be cheaper, especially when the number of orders rises significantly.

Commercialization: Distribution can be managed by the company or rely on specialized distributors. Which solution is the best approach depends on each market characteristics.

Trusting the device's manufacture and commercialization to a company already established in the market would bring some benefits:

1. Better access to suppliers
2. Using the company's own distribution channels, thus guaranteeing an efficient flow of materials and information along the supply chain.
3. Better brand recognition, attracting new customers would be easier.

This option also has its drawbacks. Even if it would generate revenues faster, the share percentage would be shorter in the long term since the company would retain most profits. However, the main issue is not future profits but independency. Trusting all the responsibilities to a third party would limit the developer's participation in the decision process and lose control of product's evolution overtime.

Manufacture: Outsourcing VS In-house production

Manufacture implies production capabilities and, for a start-up to be able to comply with the necessary requirements, it needs investment on equipment, human resources and logistics.

The following table compares some of the advantages of trusting production to another company or maintain it in-house:

	Outsourcing	In-house production
Advantages	Avoid production costs: Equipment and Human Resources	Sell the product under own brand
	Avoid inbound and outbound logistics	Bigger share on revenues
	Allows greater focus on R&D	More independency on how to market and develop the product line and control the value chain

Table 4-1 – Main advantages for manufacture: Outsourcing and In-house assembly.

The In-house production approach requires more costs but can also bring increased revenues, since they wouldn't have to be shared with the other company. It's also a more flexible option because it allows the commercialization of the product line under an independent brand and gives more control on future decisions.

Distribution concerns

It's usually difficult for a start-up to compel with the exigencies of distributing a product because distributors can often offer a better service at cheaper price. Creating a dedicated distribution channel is something companies usually only think about when the volume of sales is high enough to justify the choice.

However, this also depends on factors such as market size and the knowledge of how it works. For example, when a company decides to distribute its product in a relatively small market, hiring its own sales team may be more advantageous than trusting this task to a distributor.

Distribution must then be analysed according to the characteristics of the market to enter and what is best in one place, might not be in another.

4.1 The strategy for commercialization to follow

While recurring to an established company may have its advantages, the start-up approach comes up as more rewarding despite being more challenging.

The logistic requirements during the early period of market introduction will be relatively low since the expected sales number is quite low. The main concerns during these first years are:

Product improvement, reaching customers by direct contact and promotional activities and guaranteeing a high quality technical support.

While sales volume is low, the development team can focus both on improving the product and deliver all the technical support required. The same happens with product's assembly which is best to maintain in-house since it's highly probable that first customer's feedback will result in some changes. Moreover, while customer number increases, product development requirements will be lower and technicians will have more time to focus on assembling the device. There will, of course, be a moment when it will become impossible to answer to all incoming orders without outsourcing production or investing on creating an assembly line.

In order to best answer to these tasks, the following strategy is proposed:

Creation of a start-up called "IHS - Innovative Healthcare Solutions" to perform all the tasks related to marketing, accountancy and sales (this one only at a national level). It will also be the company's role to guarantee technical support when sales volume rises and to coordinate the assembly strategy when it becomes impossible to be maintained by the development team.

NGNS, due to its *knowhow* on the technology, will guarantee product development until it is market-ready, as well as initial technical support and assembly. NGNS will be one of IHS's owners and the one with the largest share.

IHS - Innovative Healthcare Solutions will perform the distributor's role in Portugal by having its own sales force. Finding distributors will be important when introducing VM in other European and markets to guarantee contact with customers and transportation. Further details on the channel strategy will be outlined in the Marketing Plan.

Chapter 5 Business Model

The Business Model stands for businesses as a script for movies. It's about writing the story for a new venture, or re-writing an existing one, where the following aspects are outlined: **Value Proposition, targeted customers, value creation, network and capture.**

5.1 Value Proposition: How does Vertebral Metrics answers to the customer's problem?

Pain caused by an incorrect posture is very common especially if considering certain body areas. Back pain caused by postural changes in the spine is the main reason for work absenteeism in the world and constitutes a serious epidemic risk in most societies.

Healthcare professionals dealing with postural problems recognize the necessity of finding ways of answering to this situation, especially during childhood and adolescence, as well as with specific risk groups. Nowadays, monitoring postural changes is mainly achieved through visual observation or X-Ray imaging with doctors emphasizing the importance of developing new simpler, more accurate and safer methods of diagnostic.

Vertebral Metrics aims at solving this problem. It provides a quick and precise method for examining postural deviations in the column. Furthermore, it's a much safer diagnostic method than X-Ray, since it only uses light sources instead of ionizing radiation.

Targeted Customers: Different segments, different needs.

Product introduction in the market will be focused on two segments: **Small clinics/private physicians** and **Health Clubs/Wellness Centres**. The main difference in targeting healthcare and sports professionals is not on the distribution channels but on the marketing approach that needs to be made, since both have the same diagnostic interest but may use the information provided by VM differently.

5.2 Creating Value

According to what has been stated in the value proposition, VM's simplicity and higher accuracy in respect to other devices in the market can greatly improve healthcare and sports professional's work. By enabling safe long term examination it increases the chances of finding posture related pathologies at an earlier stage when treatment is still possible or it's easier to control its effects. By introducing a new level of accuracy in posture evaluation and providing a set of tools capable of taking the most out of those results, it helps in determining the best therapy approach.

Vertebral Metrics introduction in the market will be achieved through the creation of a new start-up venture called “IHS - Innovative Healthcare Solutions”. Product development, assembly and technical support will be conducted by NGNS who has the *knowhow* and capacity to perform these tasks during the first years. NGNS will also have an important role on R&D, especially through its privileged relationship with Universidade Nova de Lisboa .IHS’s team knowledge in the rehabilitation field and its commitment with providing the best diagnostic tools guarantees a continued search for product improvement and other innovative solutions. Moreover, the company believes this can only be achieved by working together with healthcare and sports professionals in order to update the device according to their needs.

5.3 Capturing value

Being an innovative solution isn’t enough to guarantee success in the market. IHS proposes the following measures to increase value capture from VM:

1. High quality and fast technical support guaranteed by the developing team.
2. Provide solutions other than purchasing the product which can result more appealing to customers in terms of the cost-benefit provided (See price strategy in the Marketing Plan chapter).
3. Adapt channel strategy according to each country/region characteristics (See channel strategy in the Marketing Plan chapter).

Further information on value capture will be explained in the marketing plan chapter.

Chapter 6 Marketing Plan

6.1 Vision, Mission and Objectives

Vision

IHS team is committed to build a bridge between the academic environment and the market, in order to provide innovative and useful healthcare solutions.

Mission

It's our purpose to establish a position in the rehabilitation market by developing products and services which fit our customers' needs and help providing a healthier lifestyle to their clients.

Objectives

Careful planning of marketing objectives is essential to guarantee they're realistic but challenging and go along with the mission statement. As a start-up, focus must be on building solid relationships with partners and finding potential buyers for products, with a growth perspective in mind. The company currently accounts for a single product, Vertebral Metrics, whose commercialization marks the company's introduction in the market. As a result, the following objectives are proposed:

1. **Acquiring new customers:** Finding potential buyers for Vertebral Metrics should be the baseline for the marketing approach. With this in mind, the company sets as its top priority to add at least 100 potential customers to its database in the first year.
2. **Establish supply chain partners:** Choose a limited set of suppliers and distributors to focus on building trust among partners.
3. **Customer satisfaction:** Work with supply chain partners to build an effective communication platform, capable of providing an efficient delivery service.

6.2 TOWS Analysis

		EXTERNAL	
		Opportunities	Threats
		<ol style="list-style-type: none"> 1. Good network of distributors in the healthcare market (global scale). 2. New and unsaturated market for radiation free diagnostics. Absence of established market leader. 3. Fast growing market (Private Healthcare and Health Club industry). 4. Customer interest in differentiated solutions and flexibility. 5. Increased customer usage of versatile low-cost marketing platforms (Websites, social networks, etc...) 	<ol style="list-style-type: none"> 1. Direct competitors already selling their products. 2. Economic crisis: More difficult to SMEs to gain competitive advantage (Higher taxes and customer less eager to buy). 3. Patent may not be strong enough. 4. Customer failure to see the product as cost-efficient.
INTERNAL	Strengths <ol style="list-style-type: none"> 1. Close partnership with university (skilled collaborators in the biomedical field). 2. Good knowledge of digital image processing (NGNS) and knowledge of the rehabilitation field. 3. Innovation driven and strong R&D investment. 4. Company with access to privileged services (business incubator). 	<p>Take advantage of the easy access to skilled technicians to provide a good range of support tools for products, capable of meeting customer's interest in flexibility and targeted solutions.</p> <p>Offer high quality and fast technical support to customers.</p> <p>Take advantage of services at disposal in the business incubator to establish a solid base of external distributors.</p>	<p>Use knowledge in the rehabilitation field to target customer needs and improve customer's perception value of product and services.</p>
	Weaknesses <ol style="list-style-type: none"> 1. Short product catalogue. 2. Poor relationship with distributors in the healthcare environment. 3. Needs financial support for initial investment. 4. No direct market experience 5. New product: Low customer awareness. 	<p>Widespread access to internet and membership on social networks makes it a good solution for cheaper and easier marketing solutions and also facilitates communication with other business partners.</p>	<p>Focus on service innovation and widening the product line to differentiate from competitors.</p>

Table 6-1 – TOWS Analysis

6.3 Marketing Mix

Vertebral Metrics is at an early stage in the product cycle. The marketing-mix should focus on building customer awareness and increase product's availability in the market to incentive sales growth. As a result, focus will be on product and place (channel) strategy.

6.3.1 Product Strategy

Vertebral Metrics is an innovative medical device for postural assessment of the spine designed for healthcare and sports professionals in small clinics, health clubs and wellness centers.

The product's **main features** are:

Three dimensional assessments of previously marked points – 3D Analysis makes it simpler to diagnose several postural changes, by enabling multiple plan observation, including rotation.

High resolution and contact-free measurement – The use of an HD camera, in combination with an efficient measuring algorithm, guarantees excellent resolution and speed. Moreover, since there's no contact with the patient during the examination period, is less prone to errors than competitors.

There is no harmful radiation involved – VM only functions in the visible spectrum, therefore making it the perfect solution for multiple examinations and to accompany the evolution of the patient's posture during therapy.

Simple interface – VM is simple to use. It has a user-friendly interface with a touch screen panel and intuitive menu. Plus, it uses no cables to connect with other devices, such as computers. All communication is done via wireless.

Core product characteristics, alone, aren't sufficient to meet customer's needs. Additional services are essential to complement the offer and improve customer's perceived value of the product. Some of these services are expected by customers in the segmented markets such as product warranty for a determined period and pre-sale and post-sale technical support.

Some other solutions may be included to further enhance the product, such as:

1. Training programs on how to correctly market the patient.
2. Data analysis software capable of using the calculated coordinates to build realistic models of the measured area, as well as, tools to quickly measure specific curvature angles and distances.

3. Establish protocols with healthcare and sports institutions to provide customers with resources capable of improving their service to patients/clients. These could be therapy information or customized exercises based on the exam result.

Product design

Product design mainly concerns three aspects:

Quality – Since a new product’s main concern is to attract customers and build trust, the quality of the used materials is essential to avoid post-sale problems.

Size – Size is important because customers often have little space to accommodate devices in their offices.

Appearance – As an innovative medical device, it must look modern and have a friendly appearance. Neutrality is important so that it can adapt to different scenarios. This comes as especially important for private physician offices, which tend to vary a lot in appearance.

Packaging and labeling

Packaging and labeling concerns are focused on guaranteeing products protection during transportation. Communication through package labeling is irrelevant since it won’t affect the customer’s choice. However, the product’s brand must be placed in the device itself. Package labels should be limited to certification marks and other mandatory signs.

Branding

Product brand: Brand plays an important role on product’s identification. It can both work negatively or positively in promoting customer awareness depending on the values they associate to it. One crucial aspect of brand is the logo and its impact on customers. Brand’s influence on customers has been increasing in all markets and the continued growth in competitiveness in healthcare drives the need for building the right image.

The following attributes were taken into account when designing a logo for Vertebral Metrics:

1. Communicate its main features.
2. Simple and easily readable lettering, which transmits the sobriety and professionalism often seen as the image of the healthcare market. Red gives impact without having to use several colors.
3. Have some element that reflects product’s functionality and which is understood by customers.

As a result, the following proposal is done:



Image 6-1 – Vertebral Metrics: 1st logo suggestion.

The lettering is simple and easily readable. The *motto* goes straight to the point and numbers the main advantages of the device. Furthermore, *italic* gives the sense of movement, which was lacking. The visual element is inspired in the measuring process and represents the marking of the apophysis.

6.3.2 Price Strategy

Determining how much a customer is willing to pay for Vertebral Metrics isn't easy.

Production costs and distributor's share make it hard to sell the product under 5000€. At the same time, the price depends, not only on the perceived value by customer, but also on its financial capacities. For example, while a hospital might be willing to invest 15000€ to 20000€ in such a product, this value is unthinkable for a private physician which wants to install it in its office, even if the product is perceived as valuable.

Since the main concern in this initial stage of market entry is to attract new customers, a possible strategy would be to offer lower prices at the beginning. However, this might prove to be a dangerous approach because it would be hard to raise prices later. Offering early discounts could also be perceived as lack of quality. Since competition in the market isn't too much fierce, there is also no pressure to follow competitor's prices.

Looking at the segmented markets, a plausible price range seems to go from 5000€ to 10000€. Going much higher than 5000€ starts to become difficult for a private physician to pay. In order to guarantee that price isn't a limitation in these cases, a good strategy is to consider leasing. With this option, the client would have the chance to determine which way will better serve its interests. The offer however, would have limited services in comparison with acquisition. For

example, if the customer chooses to lease the equipment, he/she would have to buy the software for data analysis separately and have no access to some extra resources, in comparison with those acquiring the product. Another possibility is to impose a minimum leasing period.

6.3.3 Place/Channel Strategy

Lack of careful channel planning seriously reduces the chances of a new product succeeding in the market. This chapter focuses on defining a strategy to better deliver Vertebral Metrics to end-users. This involves the recognition of customers needs for product information, installation and post-sales services such as technical assistance.

The process involves three main channels: Sales, product delivery and service. The different tasks involved in each can be performed directly by the producer or through specialized intermediaries, with the possibility of both being responsible for more than one function.

The sales channel involves the sales team responsible to present the device to customers, as well as negotiating purchase conditions. This requires sales professionals with a good knowledge of the environment, which is extremely important in the healthcare sector. Trusting this task to an intermediary usually guarantees easier access to customers and, at the same time, avoids the necessity of training a new sales force. However, it also limits the producers control over the product's final price and reduces profit margins due to the distributors' commission.

The product channel refers to the logistic concerns over product's transportation from producer to customers. Transportation can hardly be met by the producer because it requires an enormous logistic effort. Only big companies with a large market penetration and high sales volume opt for this approach. During product introduction in the market, and while the number of units sold is low, it's best to leave this responsibility to others. These can be specialized distributors (the same responsible for the sales effort) or transportation companies.

Service channel involves all the activities related to training, installing and providing post-sales technical support. While outsourcing these tasks reduces producer's investment on human resources, it implies providing training to the external team. Furthermore, by providing direct technical support, the producer benefits from all the superior knowledge of its developing team. This fact is important to provide a quick and efficient solution to eventual product-related problems and guarantee customer satisfaction.

According to the company's available resources and what has been stated above, different regional strategies will be followed.

Portugal

Portugal is relatively small, both in customer size and area, which means that many of the processes related to product delivery to customers are simple. This fact, allied to an expected low sales volume in an early stage of introduction, makes it easier for the producer to assume most of the placement strategy without significant efforts.

Gathering a sales team is then relatively simple because it can be small and still cover the entire country. In addition to that, the developing team has a fairly good knowledge of the local healthcare environment thus facilitating the access to customers.

For the same reasons, technical support (pre and post sales) can also be provided by the company's technicians without considerable human resources efforts. Moreover, there are no language barriers and it's relatively easy to provide assistance *in loco* in the entire country.

Product transportation must be managed through an intermediary because the initially expected sales volume doesn't justify the investment needed to support the effort.

Conclusion: In a relatively small country like Portugal, both in customer size and area, the company should focus on gathering an experienced sales team to reach customers directly, thus having more control over the final price and avoid paying commission to intermediaries. Technical support performed by technicians familiarized with the technology helps in delivering a good assistance to customers and in gaining their trust.

External markets

Even if the regulations to commercialize a medical device are the same inside the EU, the team's knowledge about the healthcare sector in other countries isn't the same as in Portugal. In addition, due to some countries dimensions, it's difficult to reach all segments without engaging in considerable efforts, both in human resources and logistics.

Having a distributor, or different distributors (if the country is big enough), to represent the product in those markets is important because they already have a sales force with experience in the market and knowledge about how to deliver the product to customers in time.

The service channel is perhaps the only one where the inclusion on intermediaries must be better evaluated. While it's difficult to use a team based in Portugal to provide local assistance abroad, their knowledge of the equipment is invaluable to maintain high quality support standards. Since product's installation isn't bound to be a difficult task, training can be delivered fairly easy to local distributors. Post-sales technical support however should be guaranteed by those who know the product well. Even if it can be a more challenging approach it isn't impossible to achieve, especially during product's introduction in the market when sales volume is low. A compromise solution between distributors and producers is essential to

provide the best service possible, thus giving the customer the possibility of contacting directly with its local distributor for support and this working as a link between the first and the producer.

Conclusion: Having distributors to manage contact with customers and product delivery abroad is more advantageous, especially due to lack of knowledge about the market environment. Technical support must be provided through a compromise between distributors (first contact) and producers who have the knowledge to perform a high quality service.

Power-Trust Balance between producers and channel partners: Negotiating with distributors for better conditions and defining specific goals may prove difficult at first, especially because the producer's capacity to persuade distributors is limited by lack of demand. When using distributors to perform any of the channel tasks it's important to monitor their performance and interest in selling Vertebral Metrics. Only through increased demand for the device will leverage the producer's position and give him more power to decide over channel strategy.

6.3.4 Promotion Strategy

When launching a new product in the market, publicity and public relations assume a prominent role in the process of increasing customer awareness. Though the approaches tend to vary with the targeted markets, in the B2B environment and especially in healthcare, direct sales is the most used strategy. According to this, knowing customers' behaviour and building trust with them is important to improve their perception of the product's value.

The promotion strategy for Vertebral Metrics shall include two different approaches to fulfil the above mentioned objectives. They involve both direct and indirect methods in an effort to increase potential buyers' knowledge of the product and its benefits.

Direct contact

Having a sales force that knows how to best engage potential customers is important. They are specialized in promoting company's products through direct contact with healthcare and sport's professionals as well as others key elements in the buying decision. This kind of internal *lobbying* is essential to establish the product in an environment that still fairly ignores the existence of technologies with VM's characteristics and capabilities.

Other than personalized contact with customers, it's also important to negotiate with eventual external distributors for regular promotional actions to increase product's visibility.

Indirect promotional actions

The developing team also has an important role in promoting the product. The weight of digital marketing tactics is rising substantially due to increased internet accessibility and the growth of mobile digital readers' usage. This can be used as a cheap and effective way of spreading knowledge about the product's features and benefits.

Examples of currently available platforms are:

Websites – Highly versatile, relatively cheap to create and an excellent way of presenting a new product to customers.

Social Networks – These platforms can be used to interact with healthcare and sports professionals who are starting to use them to share knowledge. A quick share for groups and discussion forums will reveal a considerable network of people discussing themes related to rehabilitation. The usage of these platforms is especially recurrent among students and young professionals, which are generally more open to new diagnosing techniques. Social networks are an excellent vehicle for cheap advertising and an easy method of teaching customers how to better interact with the product and take full advantage of its capacities. YouTube style videos can be used for such purpose.

Email – It has never been easier to contact professionals in the healthcare field, especially due to the existence of online registry databases. This resource may constitute one of the most direct methods of letting customers know about Vertebral Metrics. However, using email to reach customers may also have its inconveniences, especially if they start receiving too many messages. A good solution might be to create a newsletter and invite potential clients to subscribe if they're interested in following product updates.

The impact of using such digital platforms isn't the same everywhere and may vary considerably depending on the region/country to enter. The importance given to such methods must be carefully evaluated to ascertain its benefits.

More traditional promotional tactics in the B2B environment include trade shows, which can be considerably expensive but also very rewarding, namely to introduce the product in international markets. They're an excellent place to find new customers and even potential distributors. Due to their influence on the promotion of medical devices, Vertebral Metrics will be present in, at least, one major trade show each year.

Chapter 7 Development and operations plan

7.1 Prototype to finish product

There are still important steps to be taken before Vertebral Metrics can be considered as market ready.

Product design: As previously referred in product strategy (under the marketing plan), the device's design is extremely important, not only to make it attractive, but also because it's essential to reduce its size as much as possible. Current prototype's size may still be a problem; especially due to the fact healthcare offices usually have space limitations. Studying product's architecture to reduce size must be a priority. Sizes reduction must affect not only the measuring structure but also the control apparatus.

In terms of attractiveness, VM is still very "raw" and no appearance concerns were addressed. However, this will greatly depend on the architectural adaptations referred in the previous paragraphs.

Testing: Currently, only the first prototype has been tested for accuracy with a significant patient sample but this was only composed by pregnant women. It's important that these accuracy tests are performed in a wider segment of the population and using the current prototype. This is essential to support the accuracy claims with customers.

Software and algorithm development: The development of software for data analysis is still under an early stage. Software has been developed to use the measured coordinates to generate a mathematic model of the spine but in order to turn VM into a versatile diagnostic tool other functionalities must be added.

The same applies for the algorithm responsible for the measurement. Current programming language limits the device's velocity so it has to be re-written using a more efficient solution.

Obtain certification: The device is still missing all the certification requirements described in chapter 3.

7.2 Team

The group responsible for taking VM to the market is an important asset since a good team will improve the chances of success. Teamwork and empowerment must be the key factors to ensure a good coordination and the motivation necessary for the tough task of bringing a new device to customers. Initially, the team will be small and with special focus on product development and all tasks involved in raising customer's knowledge of VM. As the number of sales rises,

technical support and sales weight will increase. The starting team should be composed of collaborators which can answer to the following aspects:

Product development and production: Technicians with skills in electronics, instrumentation and computer programming to improve the current prototype and fulfil the objectives cited in the previous section. This team should also be responsible to assemble the devices requested by customers. Product assembly may be initially the responsibility of few people since the volume of sales expected is considerably low and the process won't involve complex procedures. Outsourcing manufacture should only be an option when the sales volume justifies the need for continued allocation of human resources. To start, the number of team members responsible for this task should be about three to five people.

Research and Development: Focusing on research for new projects, at this time, might seem disproportionate according to the limited resources available. However, this is one of the most important tasks to perform from the first minute since it is what better reflects the company's vision. Moreover, new solutions are what will guarantee continued success in the future and enriching the company's portfolio of healthcare solutions, especially in the rehabilitation field. Partnership with Universidade Nova de Lisboa plays a strategic role in providing these team members which, to start should be no more than one or two.

Marketing and communication: Letting customers know about VM and its capabilities is the first goal to have in mind. Communication, other than direct contact (sales force) plays a significant role as evidenced in the marketing plan. The team should count at least with one or two people with marketing and design skills.

Technical support: Personalized and efficient customer support is one of the differentiating features to invest when selling VM. These functions must be the responsibility of someone who is well acquainted with the device. Probably the best approach is to give this responsibility to team members working in product development. The need for support will depend on the number of units sold and, even if sales volume for early stages of introduction is expected to be low, the company must be prepared to answer any abnormal flow of assistance requests. The development team should be able to address support issues for the first units sold.

Sales: The sales force will be the company's frontline in contacting with potential and current customers. They'll be responsible to advertise the device but also provide assistance during purchase and installation. Furthermore, they'll work as a link between the company and customers during the post-sale period, at least during the first years and while support is maintained by the development team. As explained before, the sales team should be able to cover the national territory. Initially, one sales professional is enough.

Finances: Managing financial resources is very important during this initial period, characterized by high spending and low revenues. Accountancy should be strict and all eventual loans and funds carefully allocated to current needs. One person with the necessary skills may be enough for the first period.

Coordinators: The constant necessity to work as much as possible with the available resources makes it important to require the team's flexibility in terms of task performing. Coordinators must function as a link between all team members and work to take the most out of them. Their main concern should be to include all team members in the decision process and take note of their ideas about the strategies to follow. This is important, not only to motivate everyone, but also because it widens their point of view. There should be at least two coordinators, one to oversee the development tasks and other to focus in the remaining functions and to perform all external contacts with channel partners.

Advisors: Probably as important as the operational team are some key people that have been involved in VM's project since its early stages. Their knowledge about the product and the market environment is invaluable for its market success. PhD Claudia Quaresma, who invented VM with Prof. Mário Secca are such examples. MD João Goyri O'neill who has participated in its development is another example, as well as MD João Gamelas and all the healthcare professionals who can play an important role in bringing Vertebral Metrics into the healthcare sector.

7.3 Workspace and necessary equipment

Other than the supply parts necessary for product assembly, the technicians working on prototype development will require computers and licensed software for programming purposes. NGNS has the capability to perform these tasks during an early stage, however, when the sales number increases assembly needs to be guaranteed by a third party or through the creation of a manufacture facility. "IHS" will need to have its own workspace, capable of accommodating the remaining team members and activities. The office will need to be furnished with the following equipment: Computers with internet access and printing devices; Software: operating systems, security, office suits, accountancy managers, web and graphics design; Office furniture; Telephones.

Moreover, some team members will require communication tools such as cell phones and portable computers, especially in the case of external activities like those performed by the sales person. In addition to that, the sales professional will need a car to cover the entire country.

Workspace's location: The Company's office should be located not far from the development team, at least during this early period of introduction when most support activities will be

guaranteed by NGNS. Business incubators are a good option but cost-benefit must be carefully weighted.

Note: Software licenses can represent a considerable weight on the Company's budget. Opting for licensed software should only be adopted when there aren't open source solutions or when this option limits performance. This may happen with some software used by designers.

Chapter 8 Financial Plan

The financial plan presented is a projection for the first 6 years of activity. The Vertebral Metric's project will be evaluated according to a Discounted Free Cash Flow Model.

Assumptions

Period of activity: Product development in 2012 and commercialization from 2013 to 2017.

Investment: Total investment of 510 000 € (As of December 2011)

1. Cash contributions from owners: 10 000€.
2. Others (VC's, BA): 500 000 €

Sales Projection: The sales forecast will be based on the assumptions made on chapter three's six-year-model. Sales will initiate in Portugal in 2013, in Spain in 2014 and in Italy in 2015

	2012	2013	2014	2015	2016	2017
Sales in Portugal	0	8	15	31	46	46
Sales in Spain	0	0	87	131	174	218
Sales in Italy	0	0	0	132	198	264
International Sales	0	0	87	263	372	482
Total Sales	0	8	102	294	418	528

Table 8-1 – Unit Sales projection for financial plan.

Product's Price: The final price for Vertebral Metric's commercialization considered in this model will be of 8500€. International sales assume a 35% share on the final price to distributor's, turning revenue to 5525€ per unit sold.

Expenses and capital expenditures

Certification and IP cost are based on the cost of obtaining a CE Mark and patent costs for country designation and translation (to be held in 2011). CE Marking price was estimated in approximately 7000€. Country designation will be based on the five European countries for which a sales projection was made and has a unique fee of 500-600€. Translation is necessary for Spain and Italy and will cost approximately 1000€ each. A new patent submission is considered in 2015 to improve the prototype's protection (as referred in a previous chapter). 10000€ will account for the submission of a new international patent (PCT) and to pay for search and supplementary fees.

General expenses (€)	2012	2013	2014	2015	2016	2017
Office Rent			18000 each year			

Telecommunications	2000	2000	2000	2000	5000	5000
Development	20000	0	0	0	0	0
Certification/I.P.	10000	1000	1000	10000	1000	1000
Utilities, travel	5000	5000	5000	10000	15000	20000

Table 8-2 – Generic costs

Marketing expenses (€)	2012	2013	2014	2015	2016	2017
Website design	0	5000	1000	1000	1000	5000
Brand design	0	5000	0	0	2500	0
Trade shows	0	20000	20000	20000	30000	30000
Other costs	1000	5000	10000	20000	20000	25000
Total Marketing Costs	1000	35000	31000	41000	53500	60000

Salaries (annual income - €)	2012	2013	2014	2015	2016	2017
Team coordinator	21000	21000	22400	23800	26600	29400
Financial manager	-	21000	22400	23800	26600	28000
Marketing manager	-	21000	22400	23800	26600	28000
Sales manager	-	25200	26600	28000	30800	32200
Support Technician 1	15400	15400	16800	18200	21000	22400
Support Technician 2	15400	15400	16800	18200	21000	22400
Total expenditure:	51800	119000	127400	135800	152600	162400

Social Security and Worker's rights: 34,75% of annual income

Table 8-3 – Salary expenses.

Capital Expenditures and depreciation (Straight-Line method)

Asset	Value (€)	Life-expectancy (yr)	Depreciation (€/yr)			
Office furniture	3000	10	300			
Computers	10000	5	2000			
Car 1	20000	5	4000			
Car 2 (In 2016)	20000	5	4000			
Year	2012	2013	2014	2015	2016	2017
Depreciation (€)	6300	6300	6300	6300	6300	6300

Table 8-4 – Depreciation calculus on capital expenditures

Variable Costs (Depend upon the number of units sold)

As one of the patent owners for Vertebral Metrics, Universidade Nova de Lisboa will be paid royalties on the device's commercialization. Royalties in the field usually range from 2% to 10% for each unit sold. The financial plan will consider a 10% fee even though this must be negotiated before starting sales.

The Cost of Goods Sold is dependent on the number of units to sell. The production price is estimated on 3500€ for the first year of commercialization. As the number of units produce

rises, the costs decrease and the financial plan will consider a 2500€ cost per unit. In the fifth and sixth years, the sales projection recommends outsourcing assembly. The production cost considered is 20% of the final price.

Variable costs (€)	2012	2013	2014	2015	2016	2017
Royalties (Universidade Nova de Lisboa)		10% of sales revenue each year				
Supplies (cost per unit sold)	0	3500	2500	2500	20% of final unit price	

Table 8-5 Variable costs.

The detailed financial plan spreadsheet, since it is shared with the Business Plan is available at the end (Appendix C).

The financial plan for the first six years of activity has a payback period of approximately 4 years and 3 months after the loan and 3 years and 3 months after initiating Vertebral Metrics' commercialization. The Internal Return Rate is 34%, which is an acceptable value. The company's estimated value with the rule of thumb in 2017 is 7 600 000€ and the Return 6 times higher than the investment (ROI).

Chapter 9 Critical Risks

This chapter will highlight some of the risk factors associated with Vertebral Metrics commercialization. It tries to identify which assumptions are more likely to fail, the reasons for failure and which measures will be taken to avoid or mitigate the impact.

Negative Cash Balance: Even if this is unlikely to happen, especially if a strict control over spending is maintained, unexpected costs can always appear, especially with the device's internationalization and its promotion. The eventuality for such negative results is higher in the 3rd and 4th years of activity when cash balance is lower and spending is higher (See Financial Plan on chapter 8). Rather than trying to solve the problem if it happens, it's better to include a comfortable margin for these costs in the investment capital.

Competitor's price changes: High price variations aren't expected, especially because such devices aren't sold to the same client in large quantities, thus not being subjected to high discounts. However, as part of its strategy, one or more competitors may cut down their product's price. Vertebral Metrics strategy has taken into consideration the purchasing power of its target customers and, with that in mind will always compete on quality rather than price. Thus, instead of following a price cut tendency, the strategy will focus on promoting the device's benefits to customers over its competitors.

Failure to achieve projected sales: This is probably the most difficult problem to overcome even though sales projection is conservative (See assumptions in chapter 3.7). The timeline for entering the Spanish and Italian markets depends upon reaching the projected sales in Portugal in 2013.

Delays in product development and higher costs: Even though product development will be finished before starting its commercialization, some changes may be needed after. This is more likely to happen as a result of customer feedback from the first sales. The eventuality of some serious problem with the device functioning that would require both time and money to overcome needs to be considered in the investment capital.

Delays in the procurement of raw materials: This possibility, along with fact that a supplier may run out of the required materials for Vertebral Metrics assembly is something to worry about. The best solution to overcome this scenario is to have more suppliers at disposal in case one fails to fulfill its duty.

Chapter 10 The Lower Limbs Assessment Solution

Vertebral Metrics has been developed with spine measurement in mind. Limb measurement came up as a possibility to take advantage of the more recent prototype capabilities and in order to provide a more complete solution. However, the technical issues for its implementation weren't, as of this moment, properly discussed. Thus, it becomes difficult to ascertain whether it is possible or not to incorporate this application in the same device responsible for measuring the spine. While Vertebral Metric's capacity for spine assessment is a certainty, having pursued also the lower limbs solution throughout the rest of this work would be an exercise based purely on assumptions.

The market for the lower limbs solution and its relevance

As seen on chapter 3, pain caused by lower limb pathologies also has some prevalence in the society (Garrow AP, 2004), though not as high as for back pain. What is interesting is that, in general, the segmented markets found for the spine solution are the same for the lower limbs application. The online survey on Appendix B has evidenced little difference in the importance given to both solutions, thus confirming the idea that healthcare and sports professionals are equally interested in monitoring spine and lower limbs.

		Average result
Healthcare professionals (n=33)		4.08
Sports professionals (n=35)		4.47

Table 10-1 – Relevance given to spine assessment (From 1 (Not Relevant) to 5 (Highly Relevant))

		Average result
Healthcare professionals (n=33)		4.04
Sports professionals (n=35)		4.8

Table 10-2 - Relevance given to lower limbs assessment (From 1 (Not Relevant) to 5 (Highly Relevant))

Technical challenges

According to the development team, it's relatively easy to achieve lower limb measurement through device's adaptation because the algorithm used measures marks, independently from where they're placed. However, other than having to pass all the validation tests to confirm accuracy, there are two main obstacles to overcome and which may require some time and even not be possible in the end:

1. Recreate a virtual model of the lower limbs based on the collected coordinates as it was developed for the spine.

2. According to Prof. Pedro Vieira, the lower limbs measurement apparatus would have to rotate around the limb. Adapting this architecture to be compatible with that for spine measurement isn't easy and may not even be possible. If that is the case, the only solution would be for two separate devices.

Moreover, even if it's possible to put everything in the same device, the production costs would rise significantly and the product's price strategy would have to be re-thought. The same would happen, for example with the products brand.

Products branding for device with both applications

Maintaining the products previous name would focus excessively on its spine application. This could be fought with proper communication of its versatility without letting go a name, which stays in the air. The original name also reflects the device's initial purpose and tells a bit about its evolution. However, since brand can seriously influence customers' perception another solution is hereby presented which maintains the spine allusion but changes product's name to something more abstract.



Image 10-1 – Vertebral Metrics: 2nd logo suggestion.

Conclusion

The lower limbs solution still needs to travel a long path in terms of development and validation of its feasibility. Furthermore, the results of this development can seriously influence the commercialization strategy, even if the potential costumers are the same as for spine assessment.

Chapter 11 Conclusion

Vertebral Metrics is a device capable of assessing the tridimensional coordinates of previously marked points. It has been initially developed for spine assessment though it can be adapted for usage in different areas, from other healthcare applications to civil engineering. Due to technical limitations, the existence of other technologies and the size of the target markets, spine and lower limbs evaluation have been chosen as preferred applications for the device. Though both solutions are aimed at the same markets, only spine assessment was considered for commercialization, mainly due to current technical limitations.

According to the potential size of the market for the chosen application and, using **customer's autonomy** and **market size** as segmentation variables, the following segments have been identified: **Hospitals and Large Clinics, Small Clinics and private practitioners, Health Clubs and Wellness Centres, Primary Care Units and, finally, Pharmacies.**

Amongst these, it was decided to target two segments: **Small Clinics and private practitioners AND Health Clubs and Wellness Centres.** This decision was taken having in mind factors such as **Market Size, Growth Potential, Bargaining Power, Competition Threats and Introduction Easiness.** For these segments, Vertebral Metrics has been defined as a device for healthcare and sports professionals who value simplicity, as well as, safe and innovative solutions.

Some competitors in the market target the same segments as Vertebral Metrics, though none stands as an obvious market leader. From the collected information, Idiag's Spinal Mouse appears to be the most successful one.

Vertebral Metrics is the only radiation free solution which, at the same time, provides contact free measurement for better accuracy. Vertebral Metrics is also superior to some competitors in terms of speed and simplicity. It lacks some device's portability, though.

Though the technology is patented, the first prototype's description may prove insufficient to protect the device at its current stage of development. However, protecting the device algorithm is more important than patenting the design.

Certification is relatively easy in Europe since Vertebral Metrics can apply as a Class I medical device for CE Marking. Rules for US Patenting are more demanding.

Sales projections have been based on a conservative perspective, mainly due to the uncertainty inherent to customer's receptivity to innovative solutions and the fact that the investment in such solutions by the Health Club Industry is still a recent trend.

Vertebral Metrics commercialization strategy will be based in the creation of a start-up company – IHS: Innovative Healthcare Solutions – which will be responsible for the device’s commercialization. Product development and early assembly and support will be guaranteed by NGNS (current developer). As the number of sales rises, manufacture will be outsourced and the technical support performed by IHS. Distribution will follow different strategies: IHS will have its own sales team for Portugal and negotiate with local distributors for international sales.

The Marketing Strategy for Vertebral Metrics will have as **main objectives customer acquisition and satisfaction, as well defining its supply chain partners**. In order to reach such goals, the marketing mix will take advantage from the access to skilled technicians and the capacity to provide high quality technical support. The widespread usage of new platforms to promote the device will also be an excellent opportunity to explore.

Product Mix

Product strategy will focus on the products main features: Simplicity, accuracy and safety, as well as some additional services such as training programs, data analysis software and providing customers with the most recent literature on therapy. Product design will have in mind the quality of the materials, the device’s size and appearance.

Price Mix

The final price will consider competitors. However, pricing strategy won’t be much dependent on competitor’s price changes but more on what customer’s are willing to pay. A final price of 8500€ is accessible for most targeted segments but may be a problem for private practitioners. For that reason, a leasing option will be made available though the priority will always stay on selling the device.

Place Mix

As previously referred channel strategy will depend on the creation of a sales force for device’s distribution in a small size country like Portugal and having local distributors for external markets. Distributors will be responsible for establishing contact with customers but any support will always be performed by NGNS, and later, IHS.

Promotion Mix

The promotion strategy will be based mostly on direct contact by IHS’s salespeople or distributor’s commercials. Trade Shows will play an important role in promoting Vertebral Metrics in new markets. Some indirect promotional strategies will complement direct contact

actions and will be mainly based on online platforms whose impact is growing in the healthcare environment.

Missing stages of product development will focus on design, testing and software and algorithm upgrades as well as certification. The IHS's team will count with a coordinator, a financier, a marketer, a salesperson and one or two technicians. NGNS's development team will need a coordinator and at least three technicians. The project will benefit from having some key advisors and promoters.

The financial plan depend upon an initial investment of 510 000€. A 6-years projection has resulted in a positive cash flow after 4 years and ROI period of 5 years. The Internal Return Rate (IRR) is 31% and the ration between the last year's EBITDA and the Net Present Value (NPV) is 64%.

The main risks associated with the project are the possibility of overspending resulting in a negative cash balance, mainly in the 3rd and 4th years and failure in achieving the projected sales, especially those of 2013 in Portugal.

The lower limbs application still lacks much of the technical development already done for spine assessment. The eventual incorporation of this option in the device is something to be discussed and studied but should not be considered for product's immediate commercialization.

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APPENDIXES



Appendix A: Business Plan

1 Executive Summary

1.1 Why VM?

Back pain is one of the most prevalent pathologies in modern societies. Most international studies on low back pain show point prevalence rates of about 15% to 30%, a 1-month prevalence between 19% and 43%, and a lifetime prevalence varying from 60% to 80%. Moreover, it is one of the main causes for work absenteeism in adults under the age of 45. It represents 7 to 14% of U.S. adults with some disability due to back pain for at least a day in each year and about 1% of Americans permanently disabled.

Vertebral Metrics provides simple, accurate and fast measurement of the postural changes responsible for some of the most common pain causing pathologies affecting the society. Healthcare professionals have acknowledged that such a device can improve their diagnostic methods and, at the same time, minimize the use of radiation based technologies.

1.2 Company and concept

Vertebral Metrics current prototype was developed in partnership with NGNS, a start-up company specialized in R&D for different sectors, including healthcare. For the purpose of its introduction in the market, a new company called “IHS - Innovative Healthcare Solutions” will be created. The company’s focus will be on technology transfer of healthcare solutions from the academic environment to the market, including those developed by NGNS. For now, Vertebral Metrics is the only product in the company’s portfolio and will mark its debut in the market.

1.3 Target Markets

Vertebral Metrics commercialization strategy will focus on specific segments in Healthcare and the Health Club Industry. Its target customers will be medium and small sized healthcare units, private practitioners, health clubs and wellness centres.

1.4 Team

The team will be composed by a team coordinator, a financier, a marketer, a salesperson and highly skilled technicians. The project’s key members are acquainted with the technology and highly motivated to proceed with it.

1.5 Investment

IHS will require an initial investment of 500 000€. The project has a payback period of approximately 4 years and a return on investment ratio (ROI) of 6.

2 Description of the technology

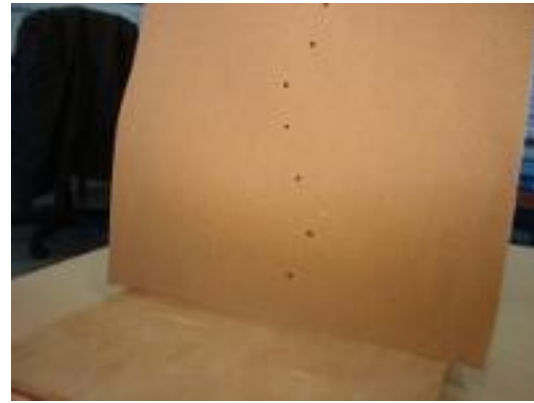
Vertebral Metrics has been initially developed by PhD. Claudia Quaresma ([CEFITEC - FCTUNL](#)) and PhD Mário Secca as a result of their work with pregnant women at *Maternidade Alfredo da Costa* and *Centro de Saúde de Sete Rios* in Lisbon. They've realized that back pain is a common symptom amongst pregnant women, mainly due to the extra weight the column has to support during the late gestational period. As a consequence, they've decided to team up with PhD MD João Goyri O'neill (FCMUNL), in order to achieve an efficient and simple method of diagnosing the problem.

The partnership was responsible for VM's first prototype (Quaresma, Secca, & Santos, A Mechanical Instrument to Evaluate Posture of the Spinal Column in Pregnant Women, 2008) (Quaresma, Secca, Branco, & O'Neill, 2009), which is a purely mechanical solution.

Despite the simple setup, the initial version has provided encouraging results and has been validated through comparison with measurements obtained through a known and reliable technique (Quaresma, Secca, Veloso, Fonseca, O'Neill, & Branco, 2009). However, due to the mechanical nature of the process, it takes a considerable long time (approximately 7 minutes) to obtain all the measures necessary.

In order to improve the device's capabilities, a new prototype has been developed. More than automating the measurement process, it constitutes a completely new approach to the problem. This has been achieved through a partnership with Prof. Pedro Vieira and his company [NGNS, Ingenious Solutions](#).





Photos of the second prototype: I – Device and spine model; II – Spine model with marking; III – Device's detail of horizontal *positioned* and measuring apparatus; IV – Detail of spine model with laser mark (green dot).

The setup is fairly different, using a camera and a laser to find the vertebral apophysis. The recognition is achieved with software capable of distinguishing prominent marks in the skin. The measurement of the apophysis coordinates are, thus, obtained through previous marking with a dark blue washable pen. The new prototype has, as expected, drastically reduced measurement time and increased accuracy. However, patient marking is still a necessity.

3 Market Research Analysis

3.1 The industry

The Healthcare industry, more specifically the medical devices industry, is one of the most dynamic and fast growing markets. It is currently worth around \$209 billion US dollars with the US holding the largest share (circa 40%), followed by Japan and Germany. The rest of the world accounts for only 35% of the market share, with some countries importing more than 90% of their medical supplies. Such trend is expected to continue due to the industry's requirement for high level technical skills.

The offer in orthopaedics and rehabilitation has grown in the past decades, being one of the most promising in the future. Most of the available devices are for surgical appliance, with medical imaging devices playing a major role in diagnostics. Some recent products, however, are trying to overcome the need for radiation dependent assessment of the inner body.

In the healthcare industry, distributors with market knowledge are usually responsible for engaging customers, especially because some healthcare providers group in order to buy equipment so that they can gain some bargaining power. This is, however, more common when large quantities are involved. Whether the producer decides to build its own distribution channels (usually only big companies opt for this method or market size is relatively small and known) or find regional distributors (preferable when there is little knowledge of the market),

maintaining a constant flow of information along the chain is extremely important to optimize efficiency. Raw materials are widely available but not all locally. Vertebral Metrics assembly will always depend on some international suppliers, which reinforces the need for constant communication and building trust with supply chain partners.

Vertebral Metrics is directed to the healthcare market, more specifically to markets related with rehabilitation and postural changes assessment. Possible customers for the device range from healthcare professionals in orthopaedics and physical and rehabilitation medicine to osteopaths and chiropractors. It may also have some interest in paediatrics and obstetrics. Moreover, Vertebral Metrics is also useful to professionals working in the sports market, namely the Health Club industry, due to the growing influence of healthcare in this area.

According to this, the main purchasers for the device are hospitals, clinics and private practitioners working in the fields above, as well as health clubs and wellness centres. Primary regions of interest are the European market, particularly Union countries, and the United States. This has mainly to do with the maturity of the healthcare and sports industries in these regions, which make them more receptive to such solutions.

As previously stated, the supply chain in these markets greatly depends upon intermediaries who bring the product from developers to the client. The smaller sized the customer is, the easier it is to reach him since the acquisition process usually becomes more straightforward. Several other factors influence purchase decisions and their complexity, ranging from each customer's internal organization mechanisms to knowing the level of public intervention in the process.

In the end, and independently from these factors, the opinion of the professionals who will be using the device is extremely important, with administration boards only interceding for budget reasons.

Healthcare and sports professionals' feedback on Vertebral Metrics has been assessed through an online survey and a few interviews. When asked about the importance given to a device capable of measuring postural deviations in a simple and objective manner, with a success rate above 80%, the result was the following (On a scale of 1 to 5 with 1 meaning *Not Relevant* and 5 meaning *Highly Relevant*).

		Average result
Healthcare professionals (n=33)		4.30
Sports professionals (n=35)		4.65

Both survey (Appendix B) and interviews confirmed how VM is seen by potential users as a tool which can add substantial value to their practise. Nonetheless, product’s introduction in the market may not be as straightforward. The market for innovative solutions usually represents only a small percentage of the potential market. Nonetheless, it tends to grow with customer awareness of product and the recognition of its effectiveness. Moreover, the recent trend in the health club industry to combine healthcare services with exercise also limits the currently available market. The following table is a 6-year projection of unit sales in some European countries and considers a potentially accessible market that currently ranges from 5 to 10% of the currently available market.

Sales Projection	2012	2013	2014	2015	2016	2017
Number of units (potential market share attained each year)						
Portugal	0	8 (5%)	15 (10%)	31 (20%)	46 (30%)	46 (30%)
Spain	0	0	87 (10%)	131 (15%)	174 (20%)	218 (25%)
Italy	0	0	0	132 (10%)	198 (15%)	264 (20%)
Germany (If entering in 2014)	0	0	152 (10%)	228 (15%)	304 (20%)	380 (25%)
UK (If entering in 2014)	0	0	122 (10%)	183 (15%)	245 (20%)	306 (25%)

Healthcare industry growth in the US and Western European countries is expected to grow, mainly due to an ageing population and increased incidence of chronic diseases and despite the relative stagnation in demographic evolution. Both in Europe and the US, the orthopaedics field is one of the few where a consistent rise in profits is expected in the following years.




































Emerging countries, especially newer members of the EU and the BRIC block will become a very interesting market for healthcare devices. However, most of these countries still face concerns in terms of providing basic healthcare services to the population.

The expected growth in the recent trend of combining sport and healthcare services makes the industry one of the most promising for Vertebral Metrics.

Healthcare and health club industries evolution can, however, be severely affected by the recent socioeconomic crisis. The government healthcare policies have been changing at a fast pace in Europe because of it. The effects of these reforms may significantly change current assumptions of the sector’s behaviour, namely the relative weight of public and private initiatives.

Despite its innovative nature, Vertebral Metrics already has some competition in the market. The following table outlines some of these competitors and its main strengths and weaknesses:

3.2 Performance Map: Competitors' Analysis

	V. Metrics (5000-1000€)	SpinalMouse (~9000€)	Ortelius800 (~30000€)	Spine Scan (~2000€)	X-Ray (> 20000€)
Accuracy					
Health Risks					
Portability					
Price					
Speed					
Easy to use					
3D Data					

Though it isn't clear whether any of these products detains a significantly higher share of the market, Idiag's SpinalMouse seems to be the most widely recognized. Idiag AG has a robust distribution chain for the device, with global level coverage. SpinalMouse is also the most published device, being used in several academic studies. X-Ray continues to be the most widely available solution, even if it is usually only present at larger healthcare units due to its price, dimension and safety requirements.

Vertebral Metrics provides contact-free measurement, thus being more accurate than any of the solutions presented above, without compromising the price. Though existing competitors may be a concern, it's apparent they don't detain high market shares. Recognition of Vertebral Metrics higher accuracy by customers is essential to establish a competitive advantage over other devices. Comparison studies by credited institutions in the sector play an important role here. Furthermore, the presence of competition is higher in some countries than others, for example, SpinalMouse has a higher penetration rate in the Swiss and German markets where Idiag is established.

Continued evaluation of the market is essential, especially in the targeted segments, to predict sales evolution as well as price strategy. Product improvement during the first years of

commercialization will be crucial as well as the research of new devices, so that the company has a robust portfolio.

4 Economics of the Business

Vertebral Metrics brings innovation into spine's diagnostics. The device has the capacity to revolutionize how healthcare professional detect, treat and accompany the posture of a patient, without having to worry about the harmful effects of radiation and turning it into a simple procedure. As a result, both healthcare and sports professionals will gain with Vertebral Metrics introduction in their practice since they'll be able to perform more accurate decisions which will benefit their patients/customers.

With patient's satisfaction and awareness becoming increasingly more important in relation to healthcare providers, such a device can attract new patients and enable the healthcare professionals to raise the price of its services. This becomes even more obvious for health clubs and wellness centres which try constantly to innovate in their offer to attract new customers. For these reasons, the investment made in Vertebral Metrics can easily be justified. The following to examples show how short can be the payback period with a final price of 8500€:

Healthcare practitioners: Assuming that each physician charges an additional 10€ fee for each visit and that each professional receives 40 patients each month this means that it would take 1 year and 3 months approximately to pay for the device.

Health Clubs and Wellness Centres: Assuming a 5€ rise in the monthly fee paid for a 150 members facility, would result in a payback period of 1 year.

In the end, Vertebral Metrics has the potential to attract new customers, improve healthcare and sports professionals' services and pay itself without those having to significantly raise their fees.

5 Marketing Plan

The marketing plan will have in mind the following objectives: **Acquire new customers, establish supply chain partner and customer satisfaction.**

In order to accomplish this , the company will focus on establishing direct contact with potential customers, be it through the establishment of a sales force (national market) or using distributors (international markets).

5.1 TOWS Analysis

		EXTERNAL	
		Opportunities	Threats
		<p>6. Good network of distributors in the healthcare market (global scale).</p> <p>7. New and unsaturated market for radiation free diagnostics. Absence of established market leader.</p> <p>8. Fast growing market (Private Healthcare and Health Club industry).</p> <p>9. Customer interest in differentiated solutions and flexibility.</p> <p>10. Increased customer usage of versatile low-cost marketing platforms (Websites, social networks, etc...)</p>	<p>5. Direct competitors already selling their products.</p> <p>6. Economic crisis: More difficult to SMEs to gain competitive advantage (Higher taxes and customer less eager to buy).</p> <p>7. Patent may not be strong enough.</p> <p>8. Customer failure to see the product as cost-efficient.</p>
INTERNAL	Strengths	<p>Take advantage of the easy access to skilled technicians to provide a good range of support tools for products, capable of meeting customer's interest in flexibility and targeted solutions.</p> <p>Offer high quality and fast technical support to customers.</p> <p>Take advantage of services at disposal in the business incubator to establish a solid base of external distributors.</p>	<p>Use knowledge in the rehabilitation field to target customer needs and improve customer's perception value of product and services.</p>
	Weaknesses	<p>Widespread access to internet and membership on social networks makes it a good solution for cheaper and easier marketing solutions and also facilitates communication with other business partners.</p>	<p>Focus on service innovation and widening the product line to differentiate from competitors.</p>

Product advertisement will be based on its superior accuracy in respect to competitors, in the flexibility of the data analysis software and the quality and speed of the support given to customers. Moreover, it is IHS's intention to make full use of digital advertising tools, still uncommon in the sector. Price flexibility is something the company cares about so, it pretends to introduce a leasing solution as an alternative to purchasing the device.

5.2 Product Mix

The device's main features are: **3D Assessment of previously marked points, high resolution and contact-free measurement for improved accuracy, being radiation free and having a simple interface.**

Some extra features will be included to improve the customer's experience such as: Training programs on skin marking, flexible yet simple data analysis software, protocols with sports and healthcare institutions to provide resources capable of helping customers with the diagnose and treatment of their patients.

Product design will focus on superior quality, reducing its size for better portability and sober but professional appearance.

Vertebral Metrics logo will reflect its main features and directly state its purpose of measuring the spine.



Service and Warranty

It's important to provide customers with all the necessary training to a correct usage of the device. Even if operating Vertebral Metrics is pretty much straightforward, providing some training on how to better mark the spinous processes is essential. The sales personnel will give this simple training during product's installation. Furthermore, the company will provide training videos on its website on how to best operate the device.

Post sales technical support will be the company's top priority on its relation with customers. For that reason, all support will be directly provided by experienced technicians. In the beginning, the development team will guarantee the support since they're more experienced and can incorporate any necessary changes to the device. When the sales volume rises, the company will have technicians solely to provide technical assistance. Assistance will also be provided directly to international customers. This way, the company controls quality and avoids training distributors, thus not being dependent on the quality of their service.

Product warranty should follow the standards for all medical devices. In Europe, a minimum two years warranty is required and expected by customers. IHS will offer a 2 years extended warranty for all sales during the first 3 years in each market as a guarantee of the device's quality, after which all support provided will be paid by customers. The leasing option, however, will follow different rules.

5.3 Pricing Mix

Vertebral Metrics price will be around 8000 to 9000€, which falls in the range of most competitors price. The value is acceptable for most of the segmented markets, even though some customers may find it excessive. For this reason, the leasing option previously stated will provide an alternative solution. The client avoids paying a price he/she can't afford and the company receives a continuous flow of income from the rent, which should last for a pre-determined period. However, product advertising should focus on selling the device rather than leasing it.

5.4 Sales tactics and distribution (Channel Mix)

Contact with customers will be done in two different ways. In Portugal, the sales strategy will depend upon establishing a sales force responsible for direct contact with customers in clinics, offices and health clubs. According to the expected sales volume for the first years and the small size of the Portuguese market, one sales professional may be enough. It will be his/her responsibility to inform potential customers about Vertebral Metrics features, benefits to their practice, establish purchasing conditions and follow device installation. Moreover, he/she shall carefully accompany the post-sales period for the first customers and establish a bridge with the support team.

International sales, on the contrary, will depend on regional distributors to conduct these tasks. Distributors know the market better and can provide a cheaper method to reach customers. Furthermore, markets like Spain or Italy are much bigger than Portugal and may require more than one regional distributor. The activity in Portugal during the first two years will be extremely important because it will function as a baseline for convincing external distributors to

sell Vertebral Metrics in their own markets. The company's bargaining power with distributors will be proportional to the product's success, as will happen with the effort put in selling it. The distributors' share will depend on their competences. In order to manage sales, transportation, direct marketing and, since they won't be responsible for the device's technical support, a 35% share on the final price is a good reference and will be used in the financial plan.

5.5 Advertising and promotion (Promotion Mix)

The promotion strategy will be based on direct contact with customers by the sales professionals and indirect promotional actions by IHS.

In the segmented markets, the sales personnel activity is crucial to advertise the device, thus the importance of hiring good commercials or guaranteeing the quality of the distributor's sales team. The sales team work will be reinforced with products prospects and product's presentations resuming its benefits to customers. This support material is important since the device's size makes it difficult to perform live demonstrations everywhere.

Indirect promotional actions will depend upon more traditional approaches and through increased usage of digital platforms. Tradeshows are extremely important in the targeted markets for Vertebral Metrics. As a result, the product's marketing budget will include the participation in a major tradeshow for medical devices each year with the possibility of an extra one when entering new regional markets.

Digital platforms provide a low cost vehicle for promotional actions with increasing impact in the sector. Websites are common in advertising a company's healthcare solutions but few take advantage of other platforms such as social networks and video-sharing websites. Nowadays it's already possible to find several discussion forums on rehabilitation where different professionals share their knowledge on the subject.

Using email to promote the product may not be a clever approach. A newsletter option, however, is a viable solution. Website visitors may subscribe to receive the latest news on the rehabilitation field and the impact the product is having on customer's practice. This is an excellent method to divulge any studies revealing the device's effectiveness.

Marketing expenses will have considerable impact on the company's budget, especially in the first years.

6 Development Plan

Some steps need to be taken before putting Vertebral Metrics in the market. The following paragraphs will briefly describe all the issues which still need to be addressed as well as how much time it will take so that the device can be considered a finished product.

Technically the device needs some improvements such as: Redefine its design to make it more compact, attractive and simple to use, upgrade the coordinate detection algorithm's language to make it faster.

The data analysis software must also be adapted to add more functions and improve the graphic user's interface.

The technology's accuracy was, until now, only tested for the 1st prototype. The results of the improvements made in the 2nd prototype must be validated so that customer's have some data on its reliability. As a result, it's important that some studies are performed with different population segments.

Last but not least, the product must get certification and obey the quality standards imposed by the regional laws of each market.

According to the NGNS, the company currently developing Vertebral Metrics, it will take at least an year to address all this concerns and a team of three to five technicians working on product's development.

7 Manufacturing and Operations Plan

Manufacture during the first years will be guaranteed by NGNS since the expected number of units sold is relatively low. Furthermore, customer feedback from first purchases will be crucial to eventual improvements made to the device. For this reason, it's important that product assembly is performed by the development team. Once customer number rises, it will be impossible for NGNS's development team do keep up with the assembly rate thus becoming necessary to outsource manufacture. According to the projection for unit sales number used as an assumption for the financial plan, outsourcing manufacture would become necessary in the fifth year of activity.

IHS will require an office for all the marketing, sales, financial and customer's support activities which should be located close to the development team. A business incubator facility may be useful for most of the company's tasks during the first years but the service's price must be carefully weighted.

8 Team

Teamwork and empowerment must be the key factors to ensure a good coordination and the motivation necessary for the tough task of bringing a new device to customers. Initially, the team will be small and with special focus on product development and all tasks involved in raising customer's knowledge of VM. As the number of sales rises, technical support and sales weight will increase.

NGNS will perform all the tasks related to product development and manufacture (until reaching a certain number of customers). These tasks require technicians with skills in electronics, instrumentation and computer programming to improve the current prototype and assemble the product. To start, the number of team members responsible for this task should be **about three to five technicians**.

IHS will manage all the team members responsible for delivering Vertebral Metrics to the market. This involves complying with the following tasks:

Marketing and Communication: Letting customers know about VM and its features is very important. Communication, other than direct contact (sales force) plays a significant role in marketing. Initially, the team will count with a **marketing manager** responsible for implementing the marketing strategy.

Technical support: Personalized and efficient customer support must be executed by someone who is well acquainted with the device. To start, the best approach is to give the responsibility to team members working in product development. Later, when the volume of sales rises, IHS will have to guarantee full support to customers and hire **one or two technicians** to perform this task.

Sales: The sales force will be the company's frontline in contacting with potential and current customers, as well as providing any assistance during purchase and installation. It will also work as the company's link for post-sales support during the first years. Since it will only work at a national level and according to the expected sales volume in this initial period, **one sales manager** is sufficient.

Finances: Managing financial resources is very important during this initial period, characterized by more spending than sales revenues. Carefully overseeing every investment fund, and how it's being spent, while controlling that everything is going according to the financial plan's projections, are the tasks of the **financial manager**.

Coordinators: Coordinators must function as a link between all team members and work to take the most out of them. Their main concern should be to include all team members in the

decision process and take note of their ideas about the strategies to follow. IHS should have a **team coordinator** which oversees all the company’s tasks while maintaining constant communication with NGNS’s development team.

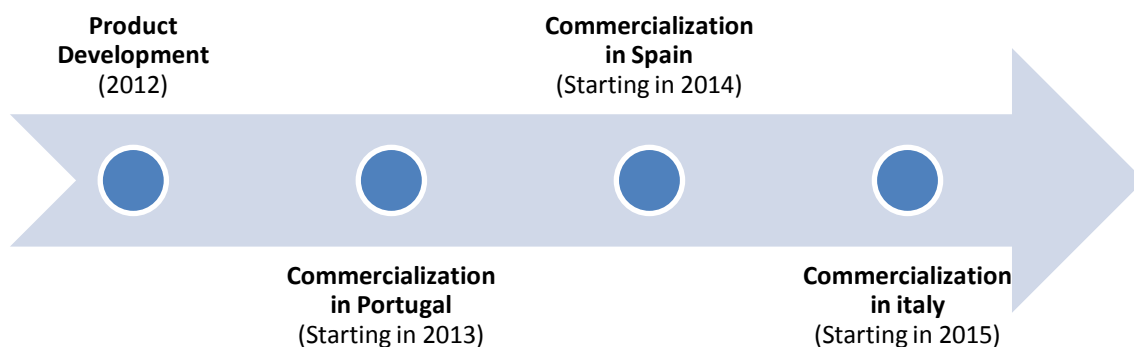
Advisors: They’re a group of professionals who are in some way connected to product’s development or that can positively influence its commercialization. Some will have a more direct degree of participation like PhD. Cláudia Quaresma and Prof. Mário Secca, as well as Prof. Pedro Vieira who has overseen the technology’s development through NGNS. On a different level, healthcare professionals like MD PhD. João O’neill and MD João Gamelas can help endorsing the product in the healthcare sector.

9 Sustainability and Impact

As previously stated, Vertebral Metrics will mark a new era in diagnosing one of the most common problems worldwide: Back pain. An accurate and safe diagnose of the pathologies causing this symptom will greatly improve the patients health and, at the same time, reduce work absenteeism numbers which severely affect a country’s economy.

10 Overall Schedule

The planed schedule for Vertebral Metrics commercialization will have two main phases: **Product development and introduction in the market.**



If the device accomplishes good sales results in both markets, its introduction in other countries should be considered. In Europe, the UK and Germany are two such examples, as are the US

(although the investment is significantly higher) and the BRIC countries (though only in a later period).

11 Critical Risks

There are some risk factors associated with Vertebral Metrics commercialization. Some assumptions on what is more likely to fail, why and what would be the measures taken to avoid or mitigate their impact are hereby presented.

Negative Cash Balance: This may become an issue due to unexpected costs during internationalization years. Promotional actions are keen to become the most obvious reason for overspending, especially because trade shows are expensive but highly necessary. Considering the eventuality of extra costs in the financial plan, applying for governmental funds may be a solution to pay for tradeshows, for example.

Failure to achieve projected sales: This is probably the most difficult problem to overcome even though the sales projection presented on the market research analysis is conservative. The timeline for entering the Spanish and Italian markets depends upon reaching the projected sales in Portugal in 2013.

Delays in product development and higher costs: It is possible to complete product development in one year prior to commercialization. However, customer feedback from the first sales and the eventuality of some serious problem with the device functioning would require both time and money to overcome. Investment capital must also have this in mind.

12 The Financial Plan

The financial plan is available as an Appendix to this Business Plan.

Months to reach a positive cash flow

According to the free cash flow of operations, it will take 3 years to reach a positive cash flow.

(€)	2012	2013	2014	2015	2016	2017
Cash flow of operations	-132101	-189328	114183	586211	965606	1202910

The payback period is of approximately 4 years and 3 months after the investment and 3 years and 3 months after commercialization begins. The Internal Return Rate for the 6-year plan is 34%.

13 Proposed Company Offering

This 6-year plan will require an initial investment of 500 000€ to guarantee a positive cash balance during the first years while sales are unable to cover up the expenses. According to the financial plan, IHS – Innovative Healthcare Solutions expects to obtain a Return on Investment four years after the loan (3rd year of commercial activity). The remaining shareholders intend to offer a 15% share on the venture in return for the necessary funding. Furthermore drag-along rights will be conceded to the investor. If it wants to sell its participation after a 6 years period it must be accepted by the remaining shareholders. Otherwise, the investor has the right to sell the company's entire capital for a price equal or higher to the value of venture's evaluated capital.

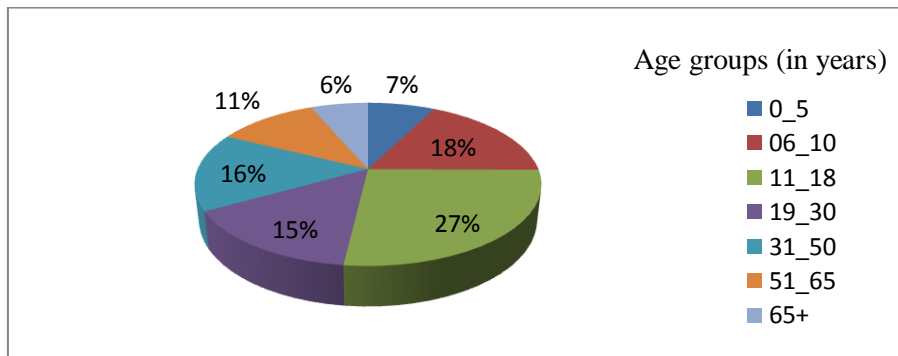
Appendix B: Questionnaire performed to healthcare and sports professionals about techniques for diagnosing and preventing pathologies related to postural asymmetries.

The questionnaire has been performed online through the platform “Google Docs”. There were 74 answers, from which 6 have been discarded because the respondents didn’t match the targeted public. The valid sample is then of 68 participants (n=68).

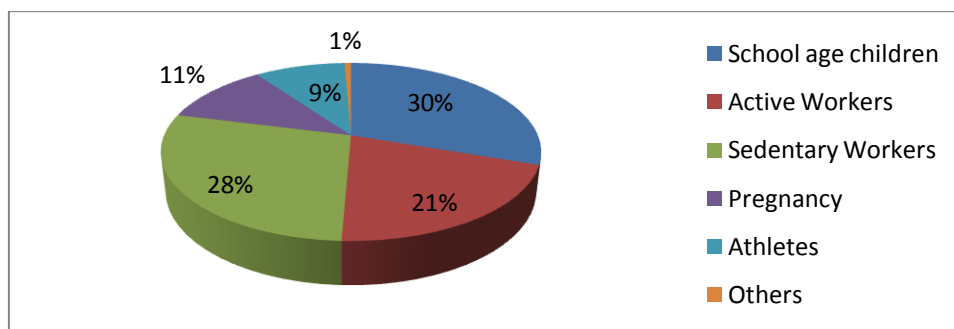
Question 1: How relevant do you consider performing a preemptive diagnose of postural deviations in the spine? (Answer from 1 (Not relevant) to 5 (Highly Relevant))

	Average result
Healthcare professionals (n=33)	4.08
Sports professionals (n=35)	4.47

Question 2: Choose between the following age groups the ones in which is more important to monitor those deviations. (Three at maximum)



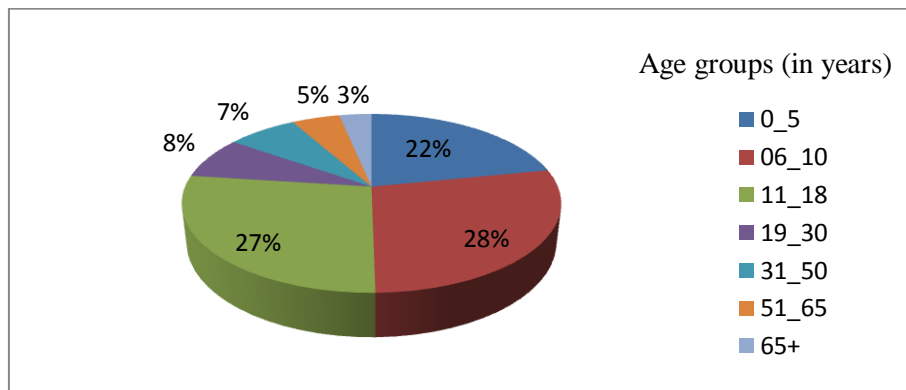
Question 3: Please indicate in which of the following conditions there is a special interest in monitoring the spine’s posture. (Two at maximum)



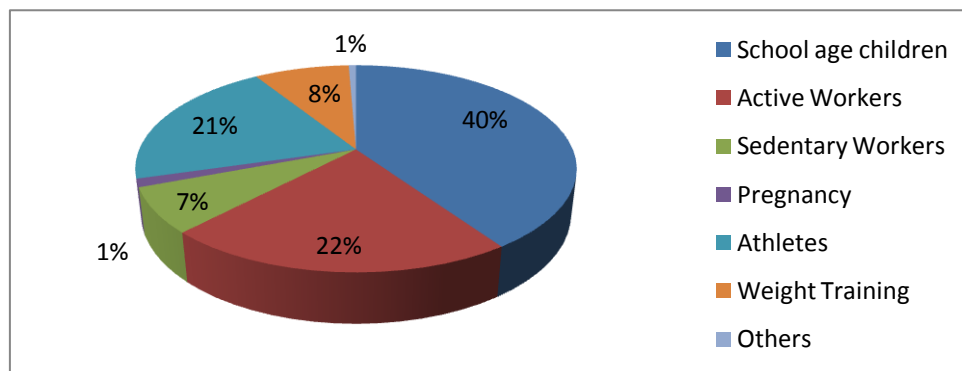
Question 4: What is the relevance you give to a similar approach related to postural deviations in the lower limbs? (Answer from 1 (Not relevant) to 5 (Highly Relevant))

		Average result
Healthcare professionals (n=33)		4.04
Sports professionals (n=35)		4.8

Question 5: Choose between the following age groups the ones in which is more important to monitor those deviations. (Three at maximum)



Question 6: Please indicate in which of the following conditions there is a special interest in monitoring the lower limbs posture. (Two at maximum)



Question 7: Please rate the importance you give to equipment capable of measuring postural deviations in a simple and objective manner? (Considering a preemptive diagnose/population screening perspective with a success rate above 80% - Answer from 1 (Not relevant) to 5 (Highly Relevant).)

		Average result
Healthcare professionals (n=33)		4.30
Sports professionals (n=35)		4.65

Appendix C: Financial Plan

Financial Plan for Vertebral Metrics							
Sales Projection (€)							
	2011	2012	2013	2014	2015	2016	2017
Units (Portugal)		0	8	15	31	46	46
Units (Abroad)		0	0	87	263	372	482
Price (National)		8500	8500	8500	8500	8500	8500
Price (International)		5525	5525	5525	5525	5525	5525
Sales Revenue		0	65153	611919	1711889	2447431	3052667
Cost Projection (€)							
	2012	2013	2014	2015	2016	2017	
University royalties (10%)		0	6515	61192	171189	244743	305267
Marketing		1000	35000	31000	41000	53500	60000
Office Rent		18000	18000	18000	18000	18000	18000
Telecommunications		2000	2000	2000	2000	5000	5000
Development		20000	0	0	0	0	0
Salaries		51800	119000	127400	135800	152600	162400
S. Security and W. Rights (34,75%)		18001	41353	44272	47191	53029	56434
Certification/PI		10000	1000	1000	10000	1000	1000
Utilities and travel		5000	5000	5000	10000	15000	20000
Depreciation		6300	6300	6300	6300	6300	6300
The discounted Free Cash Flow (€)							
	2012	2013	2014	2015	2016	2017	
Total Revenue		0	65153	611919	1711889	2447431	3052667
Cost of goods sold		0	26828	256250	733338	710957	897184
Gross Profit		0	38325	355669	978552	1736474	2155483
Selling, general and admin. expenses		132101	234168	296163	441479	549172	634401
EBITDA		-132101	-195843	59506	537072	1187302	1521082
Depreciation		6300	6300	6300	6300	6300	6300
EBIT		-138401	-202143	53206	530772	1181002	1514782
Interest		0	0	0	0	0	0
Earnings before tax		-138401	-202143	53206	530772	1181002	1514782
Available Tax Loss Carryforwards		0	-138401	-340543	-287337	0	0
Net taxable earnings		0	0	0	243435	1181002	1514782
IRC		0	0	0	60859	295250	378696
Net profit after tax		-138401	-202143	53206	469914	885751	1136087
Add back depreciation		6300	6300	6300	6300	6300	6300
Add increase in royalties payable		0	6515,25	54676,7	109997	73554,1	60523,61
Cash flow from operations		-132101	-189328	114183	586211	965606	1202910
<i>Investing Activities</i>							
Capital Expenditures		-33000	0	0	0	-20000	0
<i>Financing Activities</i>							
Venture capital	500000	0	0	0	0	0	0
Owner's Participation	10000	0	0	0	0	0	0
Increase/Decrease in Cash	510000	-165101	-189328	114183	586211	945606	1202910
Beginning Cash Balance	0	510000	344900	155572	269755	855965	1801571
Ending Cash Balance	510000	344900	155572	269755	855965	1801571	3004481

Present Value of Free Cash Flow (20%)	2670465			57%	OK?		1	
Payback period	268635	241365	98942	Approximately 4 years and 3 months				
IRR (EBITDA)	-510000	-132101	-195843	59506	537072	1187302	1521082	34%
IRR (Net Profit After Tax)	-510000	-138401	-202143	53206	469914	885751	1136087	27%
Company Value in 2017 (rule of thumb)	7605412	15%	1140812					
ROI	6							