



university of
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Assessing the risk of future falls in older adults without mobility limitations

Michael Chukudi

S4120744

UMCG/The Center for Human Movement Sciences

Master's Project

Supervisor: prof. dr. T. (Tibor) Hortobágyi

Mentor: prof. dr. ir. G.J. (Bart) Verkerke

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Confidentiality

This study is considered to be confidential. The device was designed using available techniques described in literature in combination with new concepts. The device is low-cost, portable and uses a single IR camera. The valuation of this device is on-going with the possibility to patent its application and/or technical design; therefore, secrecy is desired. Disclosure of the details of this study to the public domain could affect the commercialization of this device.

Abstract

Falling can lead to severe outcomes such as fractures, decreased mobility, and possibly death. Also, falls could have negative psychological effects and significantly increase the cost of healthcare. Statistically, the number of elderly people over age 65 who fall each year at least once is over 30% [1] [2]. Thus, there is a need for a system suitable to identify individuals predisposed to falling to aid fall prevention.

A device to assess the risk of future falls in older adults with mobility limitations is crucial. This system automatically detects while participants walk over the low-lying beam and compute desired outcomes. The main objective of this phase of the study was to investigate the performance of this device in measuring walking outcomes. Results show sensitivity of this system to detect steps is adequate for the low-lying beam walking test protocol. Accuracy of the system is yet to be fully validated and will continue in future phase of this project.

1. INTRODUCTION

As people advance in age (over 65), falling can lead to severe outcomes such as fractures, decreased mobility, and possibly death. Also, falls could have negative psychological effects and significantly increase the cost of healthcare. Statistically, the number of elderly people over age 65 who fall each year at least once is over 30% [1] [2]. Thus, there is a need for a system suitable to identify individuals predisposed to falling to aid fall prevention.

Currently, the Center for Human Movement Sciences of UMCG is evaluating balance impairment and the risk of falls in a clinical setting. Measuring postural sway involving standing on a force platform is regarded as the neuromechanical basis for measuring risks of falls and future falls. Older adults who are healthy show an increase in the magnitude of sway if standing with closed eyes while those with prior falls can modulate postural sway when performing visual-cognitive tasks. Therefore, it is difficult to correlate the risks of falls and future falls with the magnitude and velocity of postural sway as a result of inconsistencies across studies [3]. Furthermore, falls occur mostly in dynamic conditions and rarely while standing. Beam walking set up was designed to measure fall risks while walking. Vicon motion capture system is used to perform the test and it requires skilled operators and takes time.

A low-cost, portable device using a single infrared (IR) camera with IR markers has been designed using existing research protocols. It automatically detects while participants walk over the low-lying beam and compute desired outcomes. The main objective of this phase of the study is to investigate the performance of this device in measuring walking outcomes. These parameters include step length, step time, displacement, and velocity.

2. BACKGROUND

Unintended falls in old age are associated with decreased functionality, morbidity, and unplanned nursing home admissions. In 2014, a study from the Behavioral Risk Surveillance System Survey together with the Centers for Disease Control and Prevention indicate about 29 million falls and 7 million associated injuries in the United States [4]. Although the severity of injuries varied, 2.8 million required emergency treatments, and about 800,000 were hospitalized. Among those who fell, 37.5% reported medical treatment was needed for at least one fall for a day. An estimate of 27,000 older adults died as a result of falling within that period.

Economic implications due to the falling range from 11,4 billion to 24,6 billion euros annually. Although these figures are not restricted to the Netherlands, they give a good indication of how expensive healthcare costs are due to falling [5]. Currently, about 8% of the world's population is over 65 years of age and is expected to rise to about 16% in 2050 [6].

Falls are often caused by multiple but mostly correctible risk factors. These risk factors are categorized into intrinsic factors, extrinsic factors, and exposure to risk. Some intrinsic factors include a history of falls (increasing potential for recurrent falls), age, gender, lifestyle, race, drugs, and medical conditions. Extrinsic factors are usually associated with environmental influence. The magnitude of this influence is still uncertain. A survey showed that 30% - 50% of falls are caused by environmental factors such as poor lighting and wet floors. 20% of falls are also due to other external factors that could result in falls [7] [8]. About exposure to risk, a similar study indicated that more passive and more active people are predisposed to a higher risk of falls. The interaction between activity falls and risks are complex. For instance, studies show physical activity could reduce exposure to the risk of falls but equally increase the risk of serious injuries.

Gait and balance impairments are among the most prevalent causes of falls in elderly people and help to predict future falls more consistently than other factors [9] [10]. These disorders often require a concise assessment of gait and balance to determine what factors are responsible and possible interventions.

2.1 GAIT

Gait can be characterized by the gait cycle. The gait cycle is the total phase between two consecutive heel strikes of one foot (Figure 1). Phases involved are the stance and swing phase. The stance phase begins from heel strike (HS) to midstance (MS) and ends at toe-off (TO). Subsequently, the swing phase begins from toe-off to heel strike. What makes the bodyweight move forward is the acceleration caused by the swinging leg during the swing phase. If there is a controlled foot placement, acceleration is decreased [6].

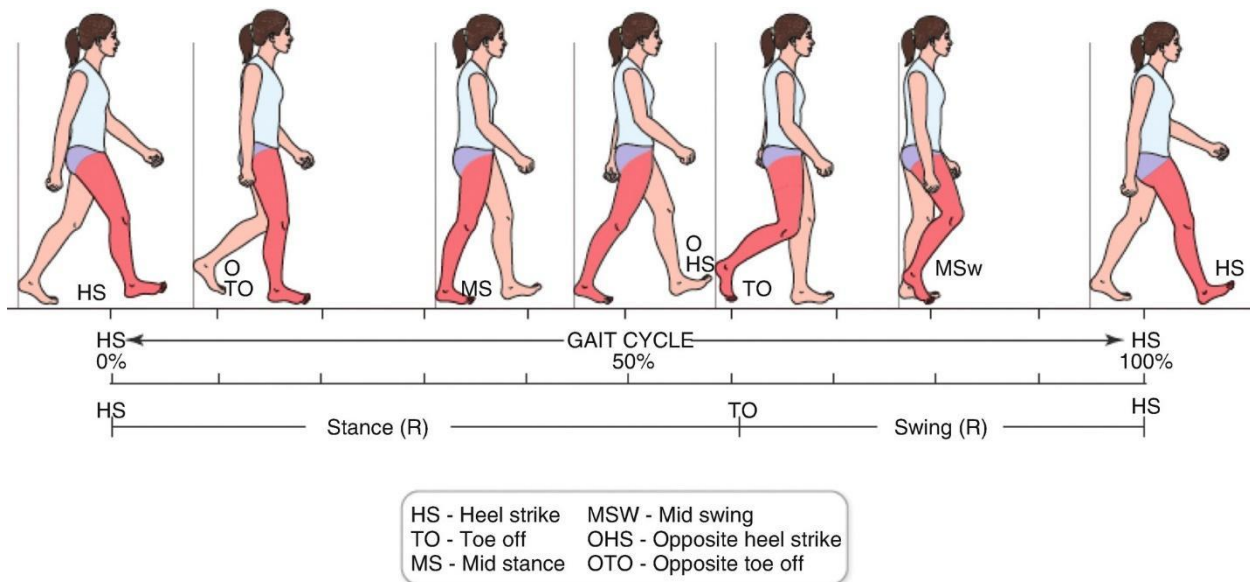


Figure 1 Gait Cycle [6]

Existing tests for assessing walking balance are not suitable. Some concerns are low sensitivity and specificity. Furthermore, results are quite subjective and as such, it is difficult to tell if treatments are working [14].

2.2 BALANCE

Static balance refers to balance in stationary objects while the dynamic balance is responsible for balance while in motion or changing positions. Some studies have been done to assess both static and dynamic balance. A few tests carried out are:

- **Time Up and Go (TUG)** – Subject rises from a chair, walks 3m to a marker, turns 180 degrees, and walks back to the chair as quickly as possible. Also, stand-to-sit and turns during transitions could be evaluated. Countdown dual tasks could be incorporated to vary the difficulty. The subject's performance is measured as the total time to complete the task [11] [12]
- **Berg Balance Scale (BBS)** – 14 tasks (static and dynamic) are carried out. Performance is measured on a scale of 0 – 4 with 4 being the highest [12]
- **Dynamic Gait Index (DGI)** – Subject completes 8 tasks which include: walking up the stairs, varying speeds, and making turns while walking. Performance is measured on a scale of 0 – 3 with 3 being the highest [13]

This project examines walking balance while walking on a low-lying balance board as part of an ongoing project by Hortobágyi et al at the Center for Human Movement Sciences. Healthy volunteers walk over low-lying beams of varying widths. Walking distance is the primary outcome as an indication of dynamic balance. Walking velocity is a secondary outcome. Age seems to affect beam walking performance measured in healthy younger ($n = 20$, 22 y) and older ($n = 16$, 71.2 y) adults. Older compared with younger adults tend to cover shorter distances at a slower pace using

higher step frequency. Levels of difficulty and ecological validity can be increased by incorporating cognitive tests simultaneously. Varying beam-width significantly affected both age groups however, dual-tasking only affected the performance of older subjects [15]. The implication is that walking becomes a more conscious task as people advance in age. Further tests are still needed to be able to validate the beam walking test as a good indicator for predicting future falls.

2.3 PROPOSED DEVICE

Currently, a manual video analysis is used to collect and analyze beam walking data and this process requires skilled operators and time. A low-cost portable device using a single infrared (IR) camera with IR markers was designed using existing research protocols. The cameras can automatically detect steps taken and computes desired outcomes. The camera was designed to meet some requirements and wishes:

The system should compute total length walked, time, average-gait speed, peak speed, step rate, step length, and variability. The resolution and accuracy of the system should be ≤ 5 mm.

SPACE REQUIREMENTS

The system should fit into a bag for easy mobility

The entire system should be no more than 1 meter when dismantled

SAFETY REQUIREMENTS

The system should cause no injury to the subject during use nor contribute to the risk of fall

The system should meet electrical standards

The system should be designed to ensure data of users are kept private and safe

USE REQUIREMENTS

The operator should not require advanced training to use the system

The system should not interfere with actual gait measurement

The system should be able to measure subjects with varying baseline characteristics

TIME REQUIREMENTS

System setup should take a maximum of 10 minutes

Switching between subjects after installation should not take more than 2 minutes

Readings should be obtained after a maximum of 2 minutes sequel to measurement

DESIGN WISHES

The system should use no disposable parts

The system should not require control of ambient conditions to function optimally

The system should be able to simultaneously track the position of both feet

Possibility to place the system in a hallway

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3. METHODOLOGY

3.1 DESCRIPTION OF THE SYSTEM

The IR range falls within 700nm and 1000nm and not within the visible light spectrum. Hence, it is not seen with the human eye. The markers used are illuminated with 940nm IR LED. By placing an IR pass filter in front of the camera lens, the markers can be detected differently from the regular image. However, if there are windows near the setup, IR illumination from the sun be introduced. In principle, measurement still works if the beam and marker are not placed directly in sunlight. Extremely high-intensity sunlight introduces artifacts into the experiment since the surrounding reflects the sun. Thus, making the markers difficult to be distinguished from the background. By adjusting the threshold and exposure parameters in the code, this can be compensated. Alternatively, using a narrow bandpass filter allows only the wavelength of the IR light. Also, using a room with no windows and curtains to limit sunlight can help reduce the artifacts.

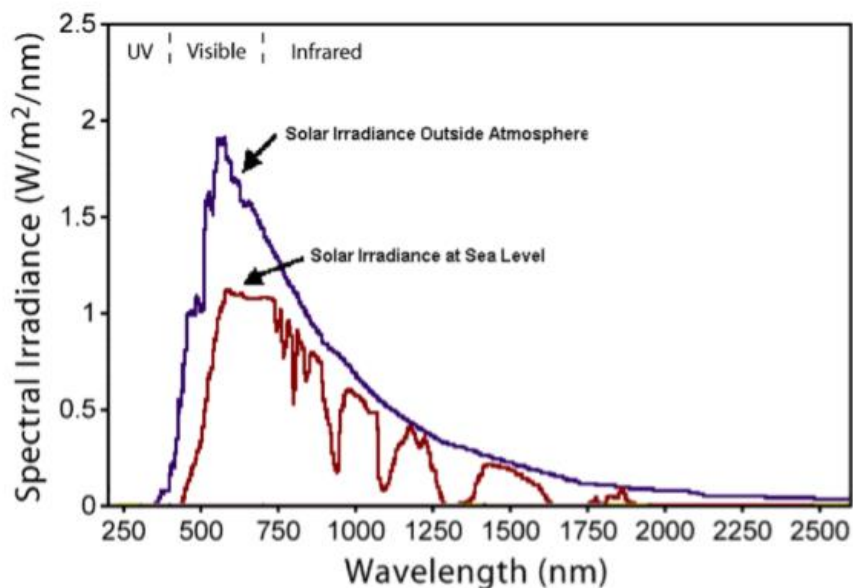


Figure 2 Irradiant sunlight

The intensity of the sun is low at wavelength 940 nm compared to 850 nm (since intensity is inversely proportional to wavelength). For this setup, the material used as a bandpass filter is an optical glass coating. With the previous test, it stopped 850 nm LED and visible light. Wavelengths above 940 nm were not tested.

The markers are composed of a retroreflective fabric used as a coat for a 3D printed sphere. The LED's are placed as close to the camera as possible, and a sphere ensures equal reflection of light in all directions with its center of mass in the middle.



Figure 3 Camera setup with IR markers

3.2 STUDY DESIGN

Device validation will include tests for accuracy and sensitivity. To test for accuracy, we will compare the readings obtained from the test camera against a reference camera (Vicon motion capture system). Acceptable errors should be within 1 – 3 cm. Furthermore, for sensitivity analysis, we will vary walking patterns (normal pace and tandem gait) to determine if the measurements with the test camera are sensitive to variations in step dimensions.

Young participants (age ≤ 30) will be signed up for this experiment. The assumption is if the measurements from the test camera are accurate with young and healthy participants, it will be valid for elderly participants.

- a. First, the workspace is calibrated using 4 spherical markers on a polished floor. The workspace is used to define the path for participants to walk. For this phase, it is set up to allow up to 5 steps. The Velleman DEM 700 laser meter will be used to minimize errors due to parallax. Markings placed on the polished floor at 400, 800, 1200, and 1300 mm with four calibration markers placed at the corners.



Figure 4 Workspace bound by 4 spherical markers

- b. Participant walks at a normal pace without any instruction along the workspace
- c. Participant walks in tandem gait (one foot directly in front of the other) along the workspace
- d. Participant walks backward in tandem gait along the workspace

3.3 EVALUATING SYSTEM PERFORMANCE

A measuring tape will be used to verify the distance between markers. Possible errors could be introduced due to parallax. However, a laser distance measuring device could be used to reduce the parallax to a minimum.

The horizontal resolution of the camera is 1920 pixels and the output image is 1600 pixels. This leaves 320 pixels lost in the perspective warp. With a 3-meter distance, the smallest change that can be measured is:

$$resolution = \frac{beam\ length}{output\ horizontal\ resolution} = \frac{3000\ mm}{1600\ pixels} = 1,875\ mm$$

Several factors could influence the measurement:

- Ambient light and exposure settings from the camera can have a crucial impact on disturbance in video making the light detected shift rapidly between neighboring pixels.
- The markers are not completely spherical because of the base attached to them. There is a slight shift from the center of the marker when viewed from the top compared to the side view.
- If illumination is insufficient, some dark regions could show since the markers are not perfectly covered with retroreflective material.

- The calibration markers must be in the same plane with the foot markers. If foot markers are raised above the calibration plane, there could be a deviation from the true value. However, this would be constant and can be calculated.

To validate the system performance at this phase, we will verify the sensitivity of the camera system at different walking patterns.

4. RESULTS

Four (4) tests were done to assess the camera performance. Parameters measured for both the left and right foot are the number of steps, position of the left and right foot, step length, and time taken for each step. Also, total time spent, step rate, mean steps, variance, and standard deviation were calculated.

Table 1 Subject walks at a normal pace

Steps (n)	1	5
Left foot (position)	563.22	1370.97
Right foot (position)	275.00	1703.29
Step length (mm)	288	332
Time (s)	1.43	3.06
Total time (s)	3.06	
Step rate (mm/sec)	38.7	
Mean steps (mm)	310	
Variance	484	
Standard deviation	22	

Table 2 Subject walks forward in tandem gait

Steps (n)	1	2	3	4
Left foot (position)	416.12	470.59	1112.64	1129.64
Right foot (position)	48.51	775.51	853.51	1432.37
Step length (mm)	368	305	259	303
Time (s)	1.23	2.06	2.97	3.57
Total time (s)	3.57			
Step rate (mm/sec)	66.7			
Mean steps (mm)	308.75			
Variance	1508.19			
Standard deviation	38.84			

Table 3 Subject walks backward in tandem gait

Steps (n)	1	3	4
Left foot (position)	1318.17	649.39	586.63
Right foot (position)	976.97	950.72	444.29
Step length (mm)	341	301	142
Time (s)	2.23	3.2	4.07
Total time (s)	4.07		
Step rate (mm/sec)	43.9		
Mean steps (mm)	261.33		
Variance	7386.89		
Standard deviation	85.95		

5. DISCUSSION

It is difficult to evaluate how accurate or precise the parameters measured are because this is only possible when comparing with a suitable system such as motion capture systems. Designing a suitable test with the Vicon system as the reference camera which uses the same principle of infrared light with markers for detection would validate the accuracy of the test camera. Although the sensitivity of the system to different walking patterns indicate some promising results, improvements are still necessary. The test camera can detect walking steps at a fixed frame rate of 30 fps. For each foot, the x-position is divided by time to give the speed of movement. The test camera measures the speed at which each foot moves to determine standstill (point each heel strikes the ground). Subsequently, the standstill is counted as a step. However, this is not a completely reliable way to detect variations in walking patterns.

In table 1, when the subject walks at a normal pace, only the first and fifth steps are detected. When participant walks at high speed, the test camera is unable to distinguish standing still moments for each foot and therefore is unable to record the steps correctly. The test camera used is Logitech C920 which supports OpenCV and streams at a fixed frame rate of 30 fps. For a walking beam test, this may be satisfactory as participants would have a controlled walking pace. However, to increase sensitivity a camera that streams at 60 fps and full HD is a better choice. The drawback is a higher cost and increases processing demand on the system.

In the second round of the test shown in Table 2, the subject walks in tandem gait along the workspace. The reason for this is to simulate the walking pattern that users make while walking on a low-lying beam. Although the camera detects 4 steps, the subject walked a total of 5 steps. A possible explanation for the fewer counts could be the calibration does not determine a starting

point ($x = 0$). An improved method to determine the reference point ($x = 0$) is needed to improve detection accuracy. In this phase of the test, a low-lying beam was not used because of limitations accessing one. With a beam, it would be possible to define a starting point with the spherical markers more accurately with reduced errors due to parallax.

For the final test, the subject walks backward and in tandem gait. Although the test camera only detects the first, third, and fourth steps, it can detect that the participant walks from the endpoint backward as shown in Table 3. The x-positions for both right and left foot have the maximum readings from the first step and reduce until the fourth step. This is an important feature as it shows that the calibration of the workspace clearly defines the boundaries and differentiates the start and endpoints.

With regards to the statistical analysis, the program automatically calculates mean, variance, and standard deviation of each test. The standard deviation for all tests is quite high, meaning the spread of values for step length is farther from the average step length calculated. To be able to validate the significance and accuracy, we will need to compare with a reference (e.g. Vicon motion capture system)

6. RECOMMENDATION

The future of this device depends largely on machine learning to better assess the dynamic stability of subjects. The idea is to train the system to distinguish between walking outcomes of healthy subjects and the target group to diagnose if performance was good or otherwise. First, a model would be generated as a standard and subsequent measurements can be compared to determine performance. The advantages of this approach include easier diagnosis, less skill required from

operators, and much more. However, to implement this approach, development time and access to subjects are required.

An alternative method is to take advantage of mobile phones. Smartphones today have increased processing power and sensors built into them. Also, with voice commands, it is easier to trigger controls like capture image, video, and run an analysis. The challenge, however, is how to bypass the IR filters already in-built in most smartphones.

Furthermore, using inertial sensors also present in smartphones is becoming more popular to measure the pose of an object that is attached to it. Inertial sensors describe the combination of an accelerometer and gyroscope generally referred to as inertial measurement units (IMUs). While the gyro meter measures angular velocity, the accelerometer measures force that acts on the sensor. These inertial sensors can be applied as motion capture systems for estimating the position and orientation of the subjects as they walk along the low-lying beam. The challenge with this method is the non-linear algorithms needed to improve the accuracy of measurements.

7. CONCLUSION

Test performed shows this system can distinguish walking patterns as required in walking beam test protocol. However, this may be true if the subject walks too fast or runs. The accuracy of the system is yet to be validated by choosing an appropriate reference system as a standard. Using spherical markers to track the position of the feet and step detection works as specified. Also, the automatic calculations of desired walking outcomes work and can be programmed to fit specific used cases. Thus, this system has shown the potential to be an improvement compared to the manual video analysis currently used.

Appendix I

ETHICAL PARAGRAPH

A few ethical issues are to be considered when introducing the test camera to be used for testing. First, this risk of falling during testing. Although, the test camera is non-invasive and falls under class 1 measuring devices, there are cables for connections to a computer. To address this risk, the camera must be placed about 2 meters away from the beam or workspace during testing.

Furthermore, the safety of participants is of utmost importance. This is zero risks from the use of a test camera. However, the operator is required to walk behind the subject while walking on the beam and also control the recording of the test camera. Wireless control of the system is therefore needed to guarantee the safety of older adults during testing. This has been implemented by using a mobile device to control the system.

A final consideration, if this system will be introduced in the market, is protecting data collected from subjects during testing. This phase of the test does not include the target groups of older adults at risk of falling. Furthermore, the camera focuses on tracking the feet position while walking a low-lying beam. The subject is not identifiable from video collected and the video is not needed after running analysis. For the data collected from walking parameters, secure cloud storage to the hospital server or local storage in a hard drive could help keep patient data private. The participant also must give consent for data storage and use if necessary, for further research.

IMPACT OF RESEARCH

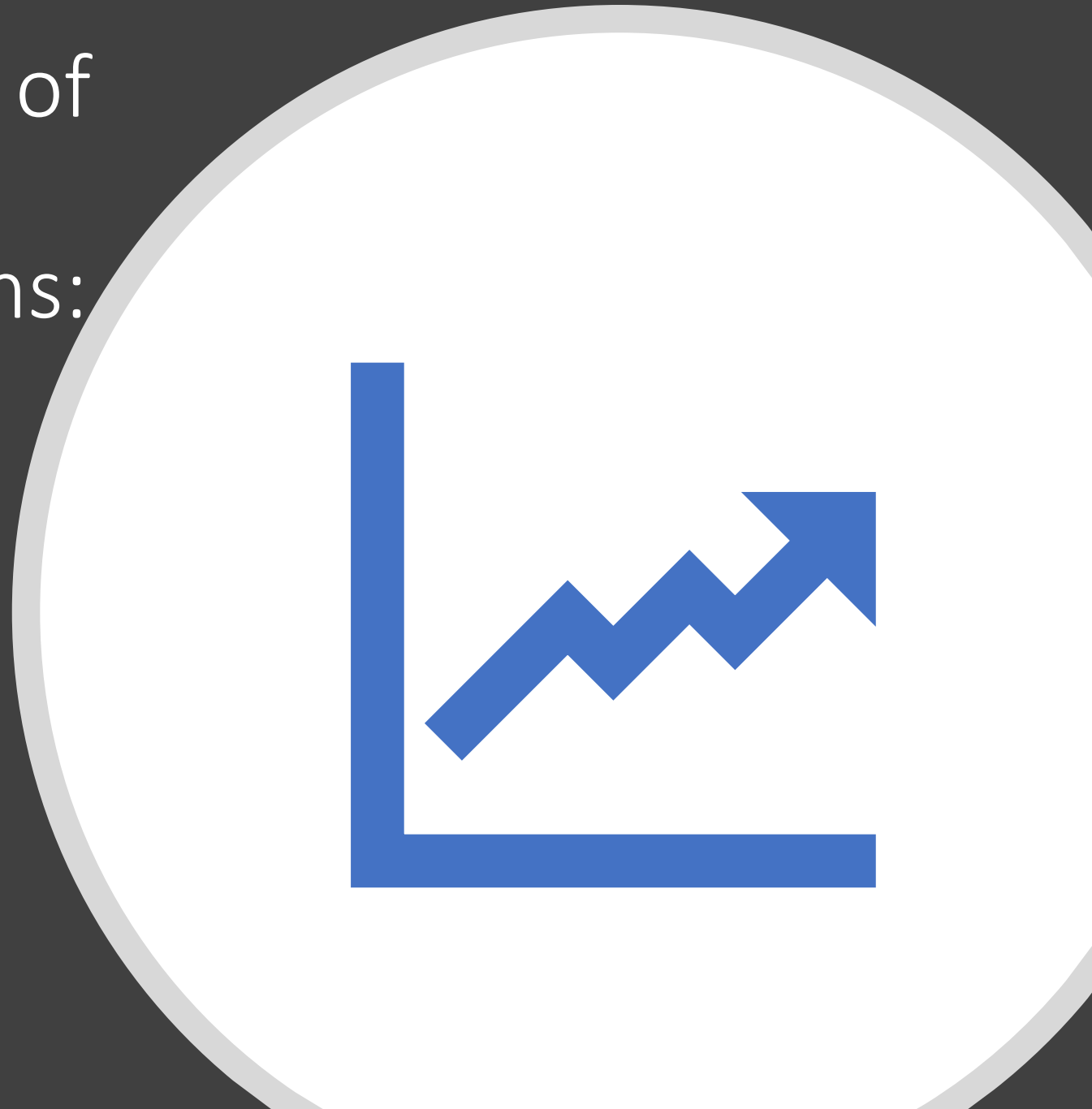
The impact of this study is to automate the process of assessing walking parameters in the beam walking test. This process could be a screening method to aid the diagnosis of older adults who are at risk of falling but without walking limitations. Also, this could shorten diagnosis time and

improve the timeliness of therapy, reducing the risk of falls, prevent further complications, and reduce healthcare costs.

PUBLICATION

More information about the Ethical perspectives on health technology assessment is further described in the article by (Henk ten Have, 2004)

A device for assessing risk of future falls in older adults without mobility limitations: Business Case Review



Michael Chukudi

Masters in Biomedical Engineering (MDD)

S4120744



INTRODUCTION

INTENDED USE:

This system is a measuring device intended to assist medical professionals in assessing the dynamic stability of individuals who are at risk of falling. It automatically tracks the position, displacement, and speed of motion using infrared markers attached to the feet while patients walk over a low-lying beam.

PROBLEM DESCRIPTION:

Several factors lead to a decrease in dynamic stability such as aging, or a previous fall. Even when a fall is not severe, it can increase mobility limitations and increase the risk of future falls. Assessing the dynamic stability of older adults can help to improve the accuracy of diagnosis and treatment targeting.

MODE OF OPERATION:

The system works based on infrared light detection. By using a retroreflective coating as markers attached to the feet, the infrared light emitted is captured by the camera and tracked while the patient walks on a low-lying beam.



MARKET ANALYSIS

CONSUMER ANALYSIS

Unintended falls in old age are associated with decreased functionality, morbidity and unplanned nursing home admissions. Currently, about 8% of the world's population are over 65 years of age and is expected to rise to about 16% in 2050.

In 2014, study from Behavioral Risk Surveillance System Survey together with the Centers for Disease Control and Prevention indicate about 29 million falls and 7 million associated injuries in the United States. Although, the severity of injuries varied, 2.8 million required emergency treatments and about 800,000 were hospitalized. Among those who fell, 37.5% reported medical treatment was needed for at least one fall for a day. An estimate of 27,000 older adults died as a result of falling within that period. Economic implications due to the falling range from 11,4 billion to 24,6 billion euros annually. Although these figures are not restricted to the Netherlands, they give a good indication of how expensive healthcare costs are due to falling.

COMPETITION IN THE MARKET

BRANDS	BUSINESS	TECHNOLOGY	PROS	CONS
VICON	<ul style="list-style-type: none"> 35 years in the market market reach in 70 countries Strong collaboration with other companies Diverse board membership: business, biomedical engineering, mechanical engineering, etc. Multiple business areas covering life sciences, entertainment, engineering, and virtual reality. 	<ul style="list-style-type: none"> Premium motion capture and analysis and application in sports and biomechanics. expertise in MoCap and inertial measurement develops both hardware and software 	<ul style="list-style-type: none"> High market influence Large customer base Specialist in multiple areas 	<ul style="list-style-type: none"> requires complex infrastructure: hardware and software requirements Cost requirements are high
OPTI Track	<ul style="list-style-type: none"> 24 years in tracking technology Application areas in movement science, virtual reality, animation and robotics Distributors in Asia, Europe, America and Oceania 	<ul style="list-style-type: none"> develops hardware and software High-speed tracking cameras 	<ul style="list-style-type: none"> Good distribution networks Contract engineering services Client base in several areas including universities, movie industry, games, etc. High-end consumer group 	<ul style="list-style-type: none"> Cost requirements are high Gaps in meeting the needs of low-end consumers
XSENS	<ul style="list-style-type: none"> 20 years in the market for motion capture systems, analysis, healthcare, sports, and industrial application Market locations include the Netherlands, America, and AsiaPacific regions The partnership includes Siemens and Autodesk 	<ul style="list-style-type: none"> Inertial Sensors Motion Capture 	<ul style="list-style-type: none"> A good partnership with thriving companies Expertise in the market 	<ul style="list-style-type: none"> High-end consumers. Complex infrastructure required (both hardware and software) High cost requirements

SWOT ANALYSIS

Strength	<ul style="list-style-type: none">• Low-cost requirements for materials or parts,• quick development time
Weakness	<ul style="list-style-type: none">• No IP (the software is open source)• no strong partnerships,• low-financial power,• First-time entry into the market
Opportunities	<ul style="list-style-type: none">• low-end focus group (could be covered with basic insurance) and in developing countries (out-of-pocket purchase)
Threats	<ul style="list-style-type: none">• Competition can buy out company easily,

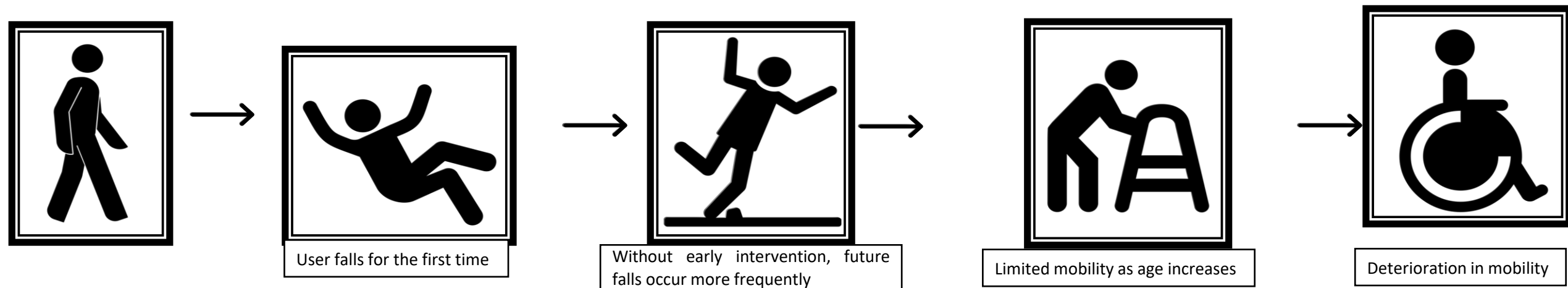
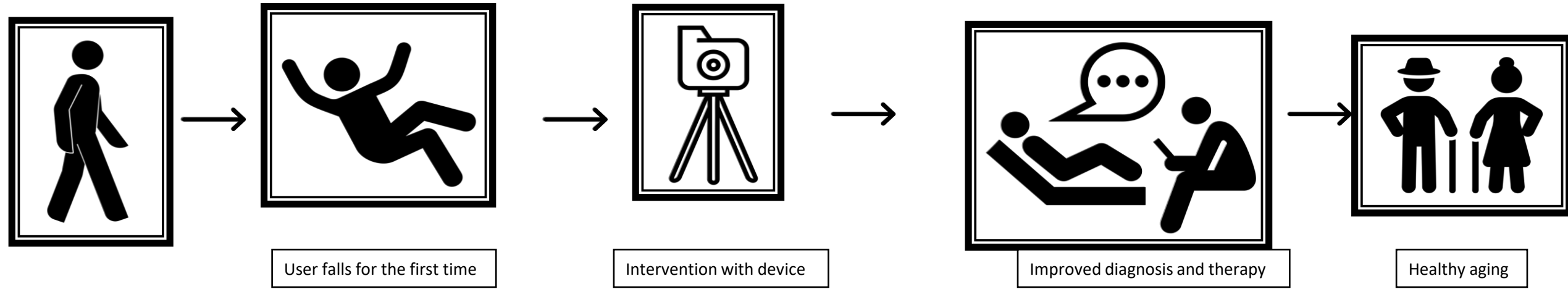
UNIQUE SELLING POINT

1. Direct sales to customers (out-of-pocket system)
2. Modular system for private use (operator designs what he wants)
3. Low-cost requirements (possible with basic insurance)
4. Focus on low-end consumers

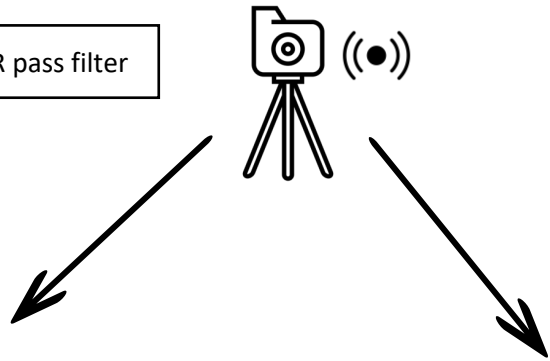


TECHNICAL SUMMARY

USER JOURNEY



Camera with IR pass filter



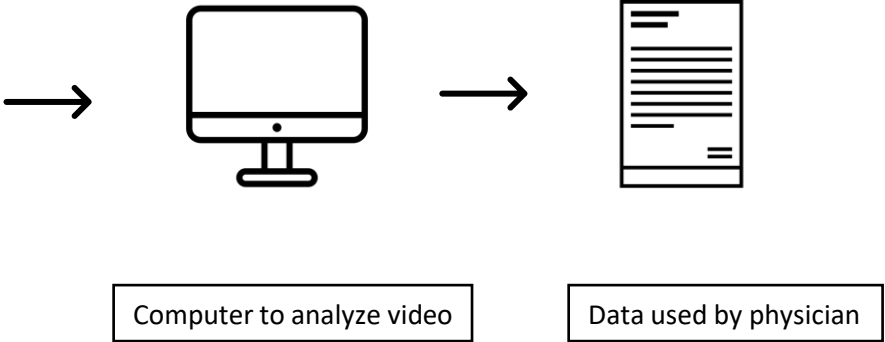
SKETCH FOR DEVICE

CLASSIFICATION: This device is intended to non-invasive and is intended to take measurement with no risk from use. It is a class 1 (m) device.



Patient walking over a low-lying beam

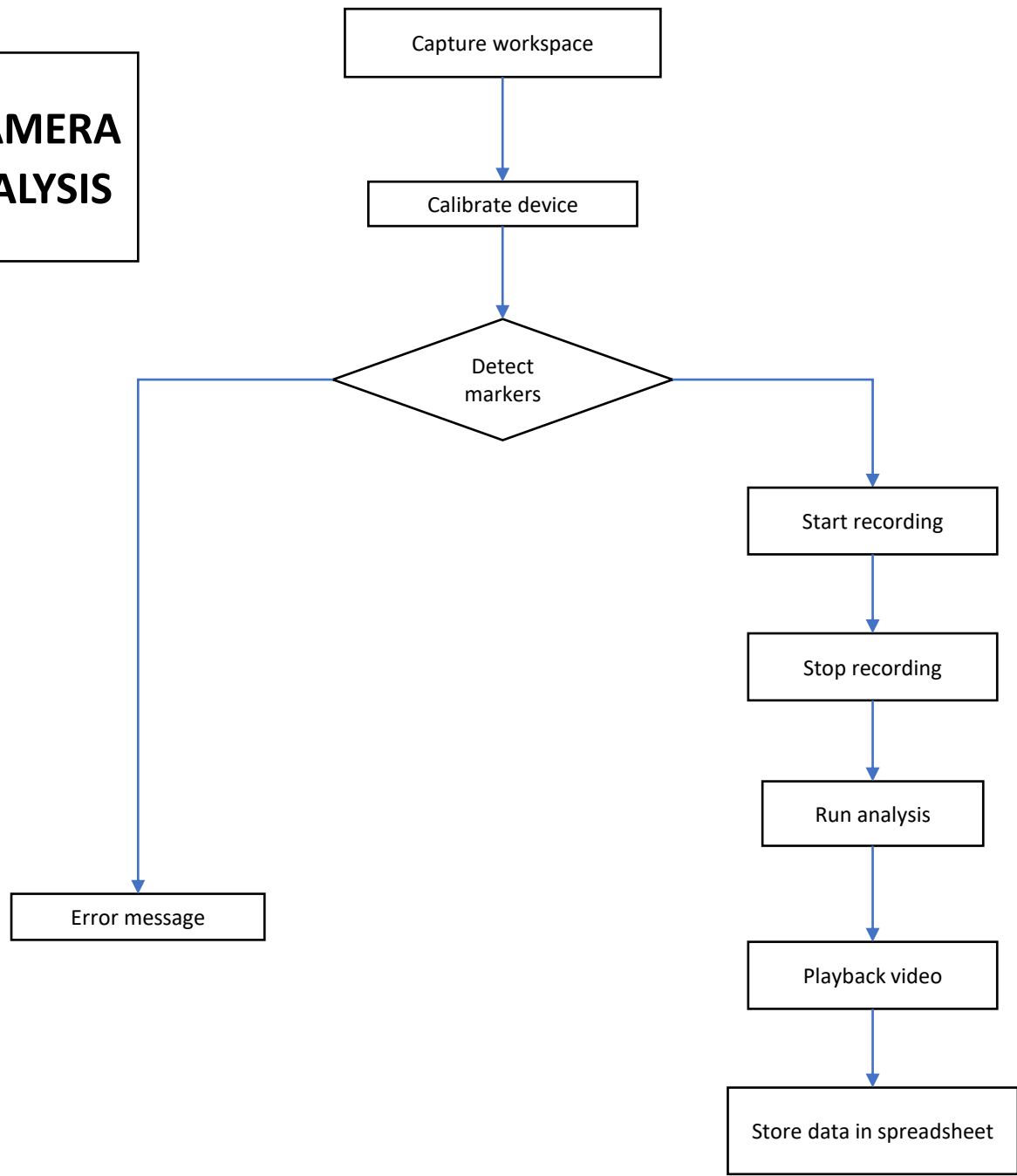
4 Spherical IR markers with retroreflective covering



Computer to analyze video

Data used by physician

FLOWCHART FOR CAMERA SETUP AND VIDEO ANALYSIS





BUSINESS MODEL

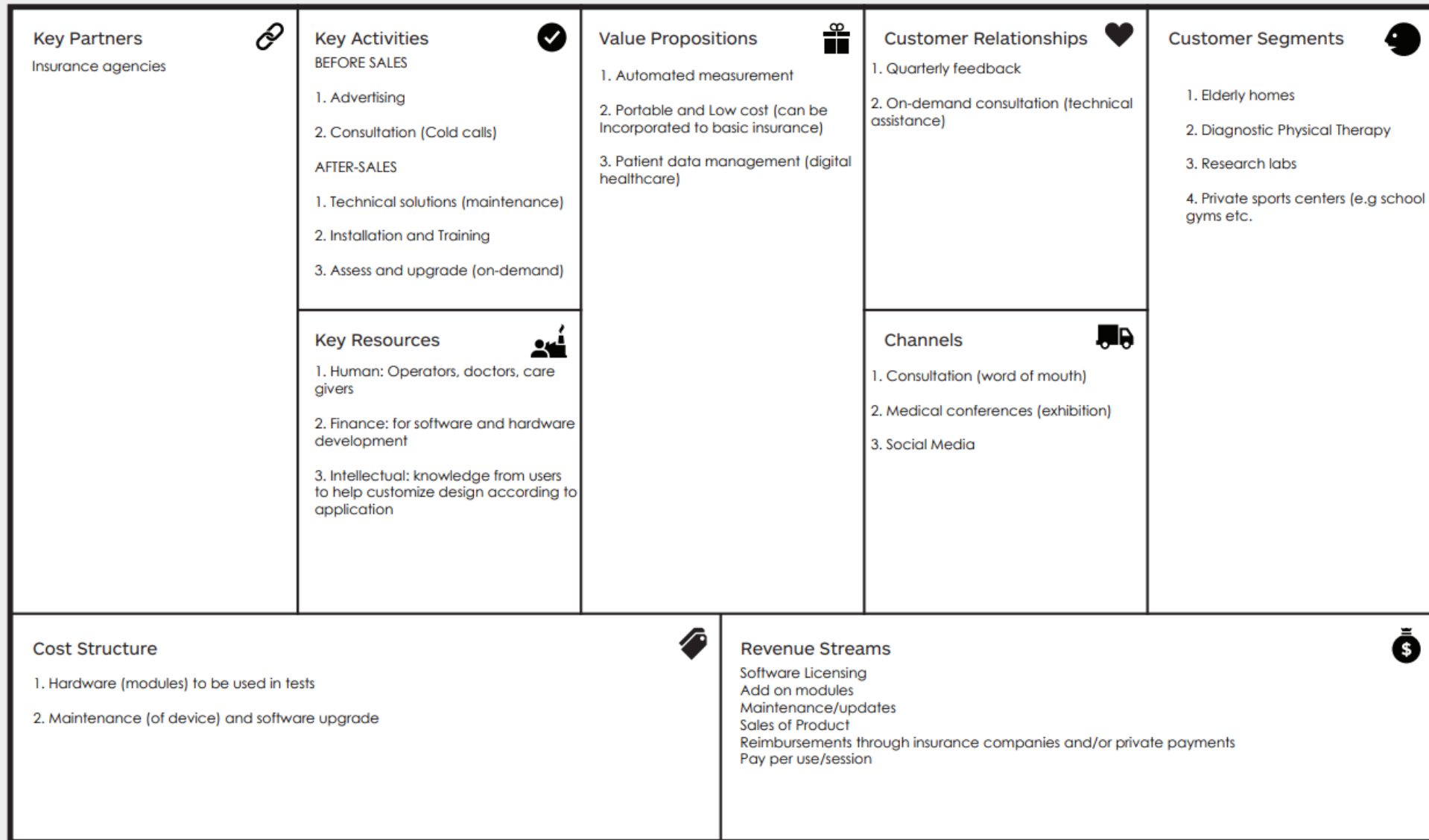
The Business Model Canvas

Designed for: MASTER'S PROJECT

Designed by: MICHAEL CHUKUDI

Date: 27-01-2020

Version:



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PROJECT PLAN

Start

Product launch in market



Work Package 1
Validate Proof of concept

Work Package 2
Value Proposition Creation

Work Package 3
Validate prototype

Work Package 4
First sample trials

Work Package 5
Increased Fund raising

Work Package 6
Expand sample trials

Work Package 7
Notarization and CE mark

TASK 1
• Review with third-party experts

TASK 2 – market analysis
2.1 Brief investigation on value to user
2.2 Business model creation

TASK 3 – prototyping
3.1 Hardware development
3.2 Build software
3.3 Run initial simulations
3.4 Set up test and use cases

TASK 4 – sign up healthy volunteers
4.1 Partner with research labs in university
4.2 Get ethical approval
4.3 One-on-one discussion with healthy volunteers

TASK 5 – seek out investments
5.1 Pitch idea in conferences
5.2 Scheduling meetings with VCs

TASK 6 – sign up risk groups identified
6.1 Partnership with hospitals and physicians
6.2 Hire technicians or specialist groups

TASK 7 – submission of relevant documents
7.1 Hire legal services
7.2 Internal audit of documents
7.3 Review with third-party experts

Pitch idea and seek out investments

Work Package 8
Evaluate market readiness level

Work Package 9
Scale up production

TASK 8
8.1 Engage potential customers
8.2 Set up exhibition stands in conferences
8.3 Review business model

TASK 9
9.1 Invoice first customers
9.2 Order first inventory