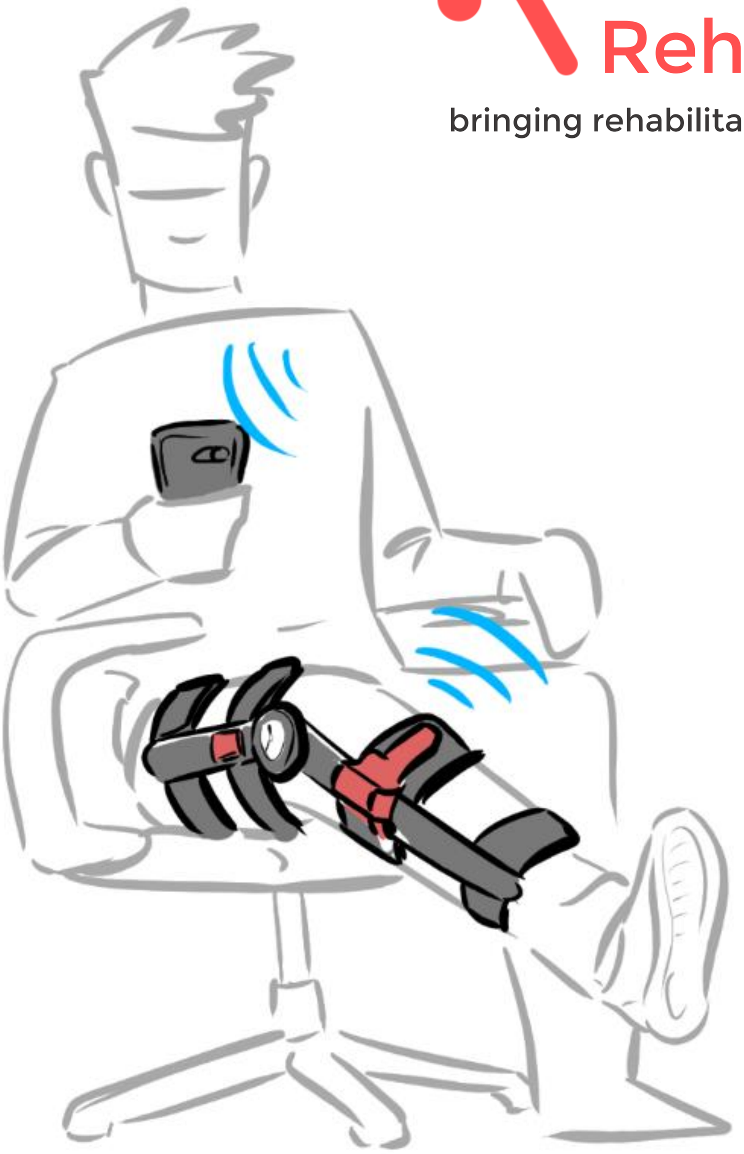

RehApp

bringing rehabilitation home

Project Report

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This report details the development of a novel joint rehabilitation aid to improve patient outcomes post ACL reconstruction surgery.

From reviewed literature and considering the project specification given in the introductory lecture - ”designing rehabilitation systems and assistive devices, integrating mechatronics, human factors and computer games [...] by developing a complete system for rehabilitation or assistance” – needs identification was carried out. Resulting from this, a device to assist joint rehabilitation after injury was produced. The device produced consists of hardware (a microprocessor, two IMUs and two haptic motors), a user interface (written in PyQT5) and a back-end data handling system using Python. The main aims of this device are threefold: 1) to aid patients to perform rehabilitation exercises correctly, 2) to increase the engagement of patients with rehabilitation outside of the clinical setting and 3) to create the ground work for a more fluid information system for both the patient and the clinician. The device performed well in the demonstration, owing to the robustness of the algorithm and its clinical relevance.

For reference, the code and CAD files can all be found in the GitHUB repository - https://github.com/emclaughlin215/HCARD.

A video showing the device in action can be found on YouTube https://youtu.be/aXwiwWS7wVg

Background

As the workload on national health systems increases due to rising and ageing populations, bringing the point of care out of the clinical setting will be a driving factor in reducing this growing strain. The NHS has itself identified improved efficiency through actioning a 10-point-plan and use of innovative technology as two parts of their 5 year plan to help the NHS (NHS England, 2017a,b,c). Furthermore, the World Health Organisation (WHO) has identified rehabilitation as one of the key areas in which healthcare must improve in the 21st century, stating that ”Coordinated and concerted action is needed to scale up rehabilitation services and address the profound unmet needs that exist” (World Health Organisation,2017b), and that effective health information systems should pay a big part in augmenting the process of rehabilitation (World Health Organisation, 2017a).

The demand for personal and portable medical devices is ever increasing as the population of the world continues to grow exponentially and age. The UK population grew by half a million in 2014 and is due to rise to more than 70 million by 2026. The UK population is ageing due to the ’baby boom’ after world war two, coupled with low fertility in the 1970s-1990s. Furthermore, the life expectancy of males and females in the UK has increased by 5.7 and 4 years respectively for those born in 2015 compared with those born in 1991 (Office for National Statistics, 2017). This is not just a problem localised to the UK; the problem on a worldwide scale is demonstrated in Figure 8. It can be seen that developed countries already have the largest populations while developing countries are currently experiencing large increases in population numbers. This shift in the world demographic puts greater strain on the public and private health systems of the world since an older and larger population will require more hours of care. In recent years this has been prevalent in the NHS where problems have been rife concerning both funding and the increase in volume of patients (NHS England, 2017b).

The number of arthroscopic (keyhole joint surgeries) and in particular ACL reconstruction surgeries reported in literature varies considerably depending on the Current Procedural Terminology (CPT) codes which are considered. The number of arthroscopic surgeries has been reported in the region of 980,000 in 2006 in the US - an increase of 49% since 1996 (Kim et al., 2011). The number of ACL reconstructions in US was reported to be around 130,000 in 2006 (Kim et al., 2011; Griffin et al., 2006; Malletal.,2014), a considerable increase from 87,000 in 1994 (Mall et al., 2014) or 72,000 in 1996 (Kim et al., 2011) depending on the considerations of the research undertaken. Even taking into account the increase in population over this period, there is still a substantial increase in respective surgeries per capita. Furthermore, in Griffin et al. (2006) it was reported that ACL reconstruction ranked sixth and third most common surgeries by sports medicine fellows and general surgeons respectively.

The total cost of care for an ACL reconstruction surgery is estimated to have a mean of $13,000 (£11,000) per patient. The postoperative care contributes considerably to this cost. Furthermore, if post-operative rehabilitation is not performed appropriately and consistently, subsequent operations or procedures are necessary and in many cases more costly in terms of the total care package (expense for the 3 month pre-operative and 6 month post-operative periods) (Herzog et al., 2017). These complications can arise from conditions such as meniscus debridement and arthrofribrosis.

The cost of rehabilitation is not just monetary. Patients are required to see a physiotherapist every 2-3 weeks to assess their recovery. Assuming that the assessment takes half an hour, the round trip travel time is 45 minutes and there is a 15 minute wait in the hospital, these appointments cost patients a minimum of an hour and a half per visit, where these visits could last up to 6 months. Knowing that the are an estimated 100,000 ACL reconstruction surgeries in the US, this has a total cost of 1.5 million man hours to the US economy in ACL reconstruction surgery without considering rehabilitation post total or half knee surgery, or any other joint rehabilitation.

Finally, Dr P. Rinne, CEO and co-founder of Gripable, expressed concern during his talk that patients undertaking rehabilitation perform around half of the recommended time of rehabilitation and that only 30% of patients continue rehabilitation unsupervised. It became abundantly clear to our group that there is a social and economic need for a device or clinical protocol which ensures successful joint rehabilitation. One way to achieve this is to provide a device which allows clinical level rehabilitation to be accessible to patients throughout their daily life. In section 2, our research into clinical need is shown and consequently a gap in the status quo of care is identified.

The Clinical Need

The need was first identified by a relative of one of the authors. Their grandfather, who recently underwent a total knee replacement, regularly expressed uncertainty as to whether he was healing fast enough. Vague knee extension exercises were prescribed for him to perform at home without doctor supervision. The pain and lack of quantified progress left him feeling distressed and unsure about whether he was doing it correctly. The result was an unnecessary return to the hospital where the physiotherapist confirmed that indeed he was progressing as normal. Lack of information exchange between patient and doctor resulted in worry, and time wasted for both the patient and the clinician.

This testimonial was followed up with orthopaedic registrar Dr Amy Garner who spoke in detail about the problem. She confirmed that in orthopaedic medicine, joint rehabilitation is not an exact science and can at times be ambiguous. Rehabilitation exercise routines after joint damage (from injury or surgery) are crucial to recovery. However, once the patient leaves the hospital the only means for the patient, or indeed the clinician, to know if the rehabilitation is progressing well is monthly or bimonthly check-ups. This can lead to problems such as patients not committing appropriate time to rehabilitation, unnecessary check-ups when good progress is made or a lack of check-up when the progress is not as expected. In the best case scenario the patient returns to the hospital unnecessarily to check costing the NHS £120 per visit and more in lost man hours. Conversely, in the worst case the patient rehabilitates poorly and is left with lingering injury for life or the need for further surgery.

Dr. Garner noted that, although true for knee surgery rehabilitation, this problem was particularly acute for patients recovering from Anterior Cruciate Ligament (ACL) injuries. The rehabilitation exercises for this injury is simple and standardised. A patient is provided a hinged knee brace which restricts bending of the joint to between specific angles. The rehabilitation routines themselves make use of this, asking the patient to extend their leg to the maximum angle allowed by the brace and holding it, to build range of movement but also rebuild thigh strength. As time progresses the knee brace angle limits are increased until back to full range of motion. However, rehabilitation programmes can last over 6 months and if done incorrectly can lead to severe impairment of mobility.

Although there have been attempts to solve this issue, namely apps such as myrecovery (https://www.myrecovery.ai/), or other medical wearable devices, current devices remain bulky, and applications do not have a standardised programme to measure progress against and still require clinicians to log on and monitor in real time which in practise doctors simply do not have time to do. Furthermore no devices make use of the current wearable support braces and no devices incorporate directly with the prescribed rehabilitation routines prescribed to patients.

Thus, a clinical need was identified for a device that allows the patient to monitor their own rehabilitation progress accurately and confidently and which allows clinicians to track their patients progress on demand after the patient has left the hospital.

Figure 1 – medical standard hinged knee brace (source healthandcare.co.uk)

Thus from the literature reviewed and clinical needs identified the following specification for the device was laid out:

- to aid patients to perform rehabilitation exercises correctly;
- to increase the engagement of patients with rehabilitation outside of the clinical setting;
- to create the ground work for a more fluid information system for both the patient and the clinician.

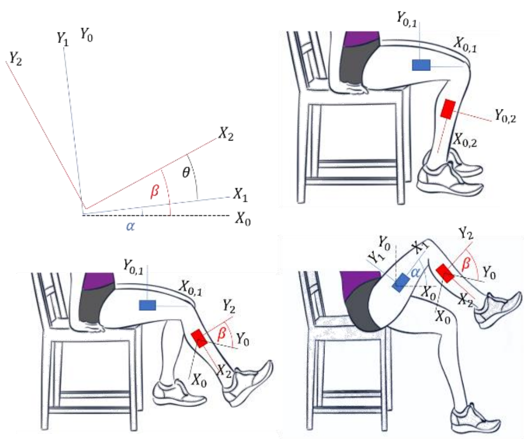

Figure 2. Example of the standard knee rehab exercise. Our device must measure the true joint angle; given by the net angle made by the angle of the lower leg relative to its neutral position, β, and the angle made by the upper leg relative to its neutral position, α.

Our Solution

From our needs identification, a design specification was constructed, namely that the device needed to guide the patient to extend and hold their knee joint at the correct angle, in an intuitive, informative, engaging, practical and generalised way. As 70% of patients do not continue rehabilitation outside of a clinical setting, the combination of these properties must make independent rehabilitation at least as appealing and accessible as with a clinician. Each of these will now be explained in turn, along with the means by which they were achieved.

By 'instructive' it is meant that the device must effectively coach the patient through the given rehabilitation exercise, to the same level as may be done in a clinical setting. To achieve this, real-time visual and haptic feedback are given. Visual direction and progress can be seen visually on the app (Figure 5). Haptic directions are given on the front and rear of the leg. One of the haptic motors vibrating indicates which direction to rotate the leg while simultaneous vibration indicates to hold the current position. This combination of feedback allows the patient to extend their knee joint to the correct angle with haptic feedback alone or complimented by a graphical interface.

By 'intuitive' it is meant that the device must be ergonomic and easy to use independently from a clinical setting. To achieve this, the graphical interface consists of a simple set of menus, which guide the patient through the exercise program in an unambiguous manner. Furthermore, the directional movements implied by the haptic feedback are simple and consist of only three commands: rotate up, rotate down and hold.

By 'informative' it is meant that the device must provide useful information both to the patient and to the clinician. To achieve this for the patient, both verbal feedback (to indicate how to improve) as well as Range of Motion (RoM) graphs and program progress trackers are provided. These metrics are available to the clinician at any time and are emailed directly to the clinician after each session and in weekly summary reports. Moreover, to ensure direct communication channels are still open between the patient and the clinician, feedback comments may be left by the patient after each session and the clinician can then flag up any serious issues (and perhaps determine that a face-to-face session is necessary) or make general comments.

Figure 3 – (left) the device in red attached to a medically standard knee brace (middle) the RehApp device (right) the visual user interface

By 'practical' it is meant that the device must be small, easy to attach and detach and difficult to misuse. To achieve this, the two casings fix to two ports on the brace, a microprocessor with built in bluetooth was chosen to avoid the use of wires and two IMUs were implemented to ensure the true joint angle is measured. The manner in which the true joint angle is measured is shown in Figure 1. Additionally, the game was created for use on a computer, however the final product was intended to be used on smart phones and other portable devices.

By 'engaging' it is meant that the device must hold the attention of the patient and make rehabilitation a more enticing activity, akin to smartphone games. To achieve this, the games which were developed gave visual goals (such as filling a target, or growing a flower) as well as star ratings representing achievement level. Development of a diverse genre of games is intended to maximise the demographic appeal of the application. The inclusion of haptic feedback is intended to increase engagement rates and the immersive feel of a game. This is based on the evidence from the ubiquitous use of haptic feedback in portable and home gaming consoles alike.

From the beginning of the project, it was asserted that while the needs identification was orientated around knee rehabilitation, Dr Garner was adamant that it is an issue ubiquitous to joint rehabilitation in general. As such, developing a device for knee rehabilitation is a means of proof of concept for the wider domain of post-operation joint rehabilitation. Since the primary metric is the current joint angle, the technology has no specification directly towards one joint or exercise. Thus it's applicable to other exercises and adaptable to other joints (e.g. the elbow or hip) through slight adjustments to the software of current games or introduction of new games (for example a game more intuitive for the elbow might be striking a ping pong ball).

Design Development

Hardware

The hardware required for this project can be broken down into three major component groups. The microprocessor, the two IMU's and the vibration motors used to generate haptic feedback.

Microprocessor and IMUs

The Adafruit Feather MO Bluefruit LE was used as the device controller. This board was chosen as it consists of a powerful Atmel microprocessor, as well as an onboard Bluetooth device. Additionally, it is relatively small in size (51mm x 23mm x 8mm) and it is very well supported, with a significant amount of existing open-source code for a number of different applications, making it a wise choice for rapid prototyping projects.

In terms of the IMU's, two MPU-6050s, embedded on the GY-521 break out boards were used. These boards are very well priced (approximately £1.50 each) and are able to achieve very good accuracies once correctly calibrated. Additionally, like the Adafruit board, they are incredibly well supported and easily adaptable open-source code (thanks to Jeff Rowberg https://github.com/jrowberg/i2cdevlib/tree/master/Arduino/MPU6050) producing the roll, pitch and yaw angles was used. Again, this is very well suited for rapid prototyping projects. Adapting this code to read the angles from two IMU's was slightly more challenging and required a good understanding of I2C communication.

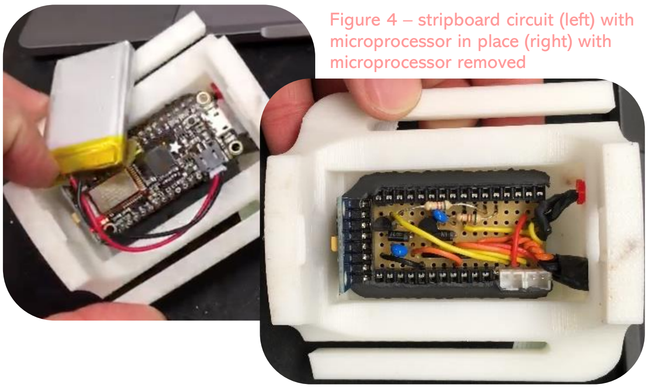

Figure 4 – stripboard circuit (left) with microprocessor in place (right) with microprocessor removed

Casing

The focus of the casing design was to prioritise ease of use and to be naturally implemented into current medical practice.

Medical braces are the current wearable apparatus provided to patients with ACL and similar joint surgeries to help recovery.
This presented an opportunity to develop the system to work hand-in-hand with a current medical practice. Fixing the device to the brace needed to be made in an accurate and repeatable manner by the patient to ensure consistent data is gathered. As such, several methods of fixing the device to the brace were explored before settling on a twist lock for the main casing, and a slide lock for the satellite IMU. The males of the twist lock and slide locks are glued to the rigid frame of the brace, with the female geometries moulded into the casing. This allows the device to be easily removed, for example, when the patient needs a shower (as the brace should be left on).

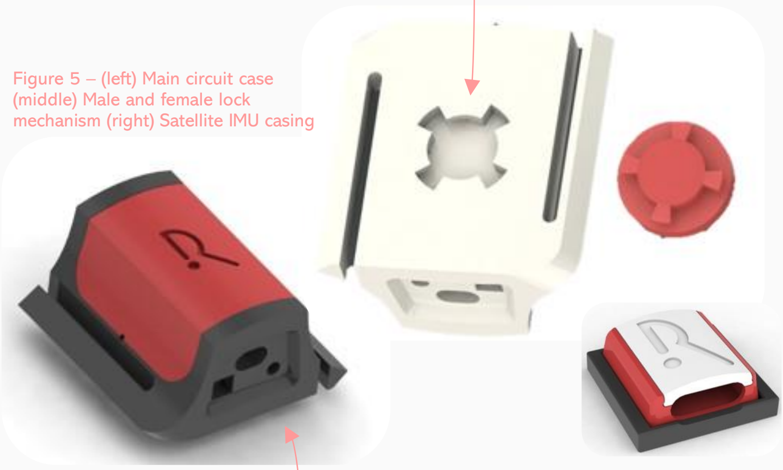

Figure 5 – (left) Main circuit case (middle) Male and female lock mechanism (right) Satellite IMU casing

The casings themselves were designed to be compact and sleek, fitting seamlessly with the aesthetic of the brace to make doctors and patients comfortable with the device. Several iterations were prototyped before settling on the low-profile design shown, slightly curved in design to match the curvature of the limb.

To allow for easy attachment of the haptic motors to the brace each motor is sewn securely into a fabric strap backed with Velcro. This allows each strap to be attached to the existing straps provided by the brace for consistent and secure attachment allowing the user to feel the vibration feedback clearly.

Haptic Feedback

In order to generate the haptic feedback, two vibration motors where used. These motors were driven using a simple NPN transistor circuit and a command signal from a GPIO pin of the microprocessor. The transistor circuit, which can be seen in the appendices, made use of a capacitor and a diode in parallel with the vibration motor. The diode was used to discharge the back EMF, protecting the microprocessor and the capacitor ensured constant voltage across the motor while active.

Stripboard circuit

These three elements were then carefully integrated and connected using Stripboard circuit. The strip board layout was designed such that the vibration motor circuitry sat beneath the microprocessor, minimizing the space required, see Figures 2 & 3. The stripboard also included connectors for the haptic motors allowing them to be connected or removed as necessary. Two additional circuits were added for control purposes, these circuits included a simple tactile push button and an LED. The tactile button allowed the user to initiate the activity and the LED indicated that the device was working correctly and ready for the exercise. The full circuit diagram, including the microprocessor and IMU pin-outs can be seen in Figure 9.

Software

The overall aim of the software was to interface with the hardware components and to create a user-friendly GUI that assisted with rehabilitation exercises.

Firmware

The firmware consisted of standard, sequential set-up code initialising the IMU's, serial communications and other peripherals followed by a main loop. The main loop continuously calculated the relative angle between the two IMU's and sent it via serial communications to the GUI controller. During each loop, a switch case was used to control the haptic feedback commands, without delays, in order to ensure the relative angle was continuously sent. After ten exercises were completed, the program was terminated. Figure 4 below is a flow diagram of the firmware, showing the structure and details of the switch case used to control the haptic feedback

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GUI

A graphical user interface (GUI) was developed to improve the rehabilitation process by:

1. Technique improvement: visual indicators of desired angle of leg movement, duration of hold, and upper leg position are used to encourage correct technique (Figure 7 images 3 and 5). Feedback after each exercise provide unique recommendations on how to improve (Figure 7 image 6).

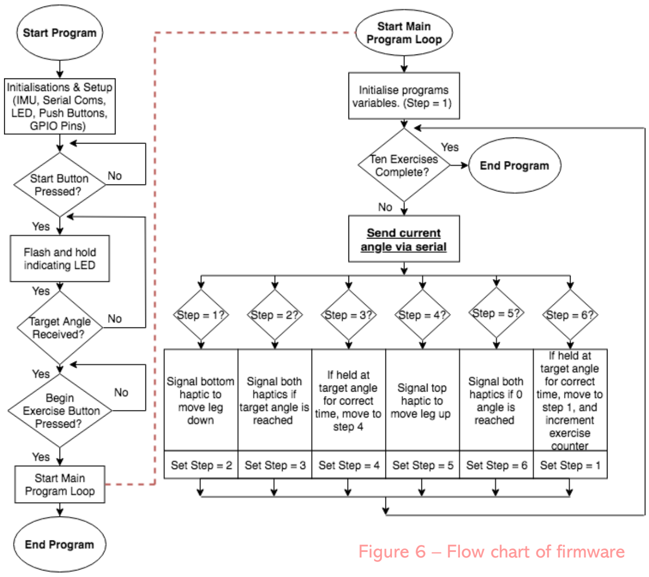


Figure 6 – Flow chart of firmware

2. Long term progression: Gamification made the exercises more rewarding and fun. This enhanced the sense of achievement and should enable long term engagement with physiotherapy. Two games were developed; flowers and targets. Both games involve the user holding their leg in the correct position for the correct amount of time for an animation to play. For instance, allowing a flower to grow or a target to fill with colour (Figure 7 images 3 and 5). In addition to this, levels with increased target RoM are unlocked depending on the performance of the last session. Progression tracking is used to give users long term motivation, awareness of how well they are performing compared to standard rehabilitation progression and how far they are in the total recovery procedure (Figure 7 image 7).

3. Clinical communication: after each exercise session, an email detailing the performance of the patient including personal comments on how the exercise felt, are sent automatically to the relevant practitioner. This allows physiotherapists and doctors to keep track of their patients performance and identify problems as they happen, keeping appointments efficient as well as reducing required clinician/patient contact hours and ultimately saving the health service money.

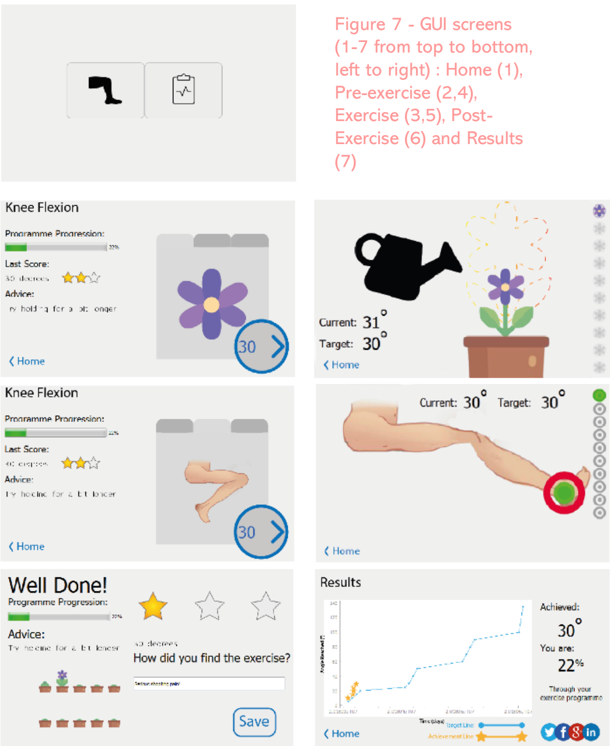


Figure 7 - GUI screens (1-7 from top to bottom, left to right) : Home (1), Pre-exercise (2,4), Exercise (3,5), Post-Exercise (6) and Results (7)

Technical details

The GUI runs using PyQt 5, a UI and application toolkit. The graphics were designed using Adobe Illustrator and Adobe Animate, then compiled into a UI form using Qt Designer and converted into a python file. These python files containing all the graphical information are accessed by a main python file that launches the GUI window and contains all the detailed coding. An overall system diagram is shown in Figure 10. All graphics and data files are contained in local folders (indicated in purple) and retrieved when required.

The recorded information of previous exercises is stored in a text file data backend. Using an object orientated class system, each previous exercise can be accessed easily, and new exercise information can be saved. Accessing past information is used when setting the current target angle for each new exercise as well as displaying data in the results page.

The exercise pages display dynamic animations that are controlled by the angle of the user's leg. Values of leg angle were obtained using a serial connection between the python file and the microprocessor (indicated by dashed line in Figure 10) . The movement of the watering can and leg were created easily using Adobe Animate and each degree of movement was exported as an individual frame. This way any integer reading of the angle from the microcontroller could be used to assign the image for the correct angle. Similar animations were created for the growing flower and target. These incremented in frame value when the leg angle was inside a threshold of the target angle. Hence, if the target angle is held, a visual prompt will increase until the duration of the hold is complete. When each move is returned to starting position, a counter increments on the right hand of the screen (Figure 7 images 3 and 5) showing how many movements are left. The results page offers a summary of all exercises performed in the session (Figure 7 image7). This is achieved with smaller images of the achievement indicator from the exercise page, verbal feedback and a score rating. The score is established based on the average time held on all the movements. A summary of the session as well as an update on the overall progression of the patient is sent automatically by email to the clinician.

Future works

- Bluetooth was not incorporated into the final design due to a compatibility issue between the computer used to run the GUI and the Bluetooth low energy module on the featherboard. A wired serial connection was used instead for the purpose of demonstration.
- Secondly, the GUI was run on a computer screen. Integrating the GUI and all its functionality into a smart phone app is important, making physiotherapist accessible any time, anywhere.
- Thirdly, the system is focused on knee flexion and extension and incorporates two games to assist in this. However, the principle demonstrated can be extended to any joint where RoM is relevant. For this, a new range of relevant games should be developed.
- Finally, the circuitry should be miniaturised and potentially integrated into a custom made knee brace.

Conclusion

The device produced allows patients to correctly perform rehabilitation exercises freely in their daily life, while still maintaining contact with the clinician. Furthermore, the clinician can keep track of the patient's progress through the use of the system which sends pre-handled data, saving the clinician time. These feats are achieved by making the system intuitive and rewarding for the patient (both the hardware and the software), ensuring the system is robust in its ability to measure the true joint angle and effectively collecting session data and providing it to the clinician in a clear and concise manner.

References

Griffin, L. Y., Albohm, M. J., Arendt, E. A., Bahr, R., Beynnon, B.D., DeMaio, M., Dick, R.W., Engebretsen, L., Garrett, W.E., Hannafin, J. A., Hewett, T. E., Huston, L. J., Ireland, M. L., Johnson, R. J., Lephart, S., Mandelbaum, B. R., Mann, B. J., Marks, P. H., Marshall, S. W., Myklebust, G., Noyes, F. R., Powers, C., Shields, C., Shultz, S. J., Silvers, H., Slauterbeck, J., Taylor, D. C., Teitz, C. C., Wojtys, E. M. and Yu, B. (2006), 'Understanding and preventing noncontact anterior cruciate ligament injuries: A review of the Hunt Valley II Meeting, January 2005', American Journal of Sports Medicine34(9), 1512–1532.

Herzog, M. M., Marshall, S. W., Lund, J. L., Pate, V. and Spang, J. T. (2017), 'Cost of Outpatient Arthroscopic Anterior Cruciate Ligament Reconstruction Among Commercially Insured Patients in the United States, 2005-2013', Orthopaedic Journal of Sports Medicine 5(1), 1–8.

Kim, S., Bosque, J., Meehan, J. P., Jamali, A. and Marder, R. (2011), 'Increase in Outpatient Knee Arthroscopy in the United States: A Comparison of National Surveys of Ambulatory Surgery, 1996 and 2006', The Journal of Bone and Joint Surgery-American Volume 93(11), 994–1000.

Mall, N. A., Chalmers, P. N., Moric, M., Tanaka, M. J., Cole, B. J., Bach, B. R. and Paletta, G. A. (2014), 'Incidence and trends of anterior cruciate ligament reconstruction in the United States', American Journal of Sports Medicine 42(10), 2363–2370.

NHS England (2017a), 'NHS England - Funding and efficiency'. URL: https://www.england.nhs.uk/five-year-forwardview/next-steps-on-the-nhs-five-year-forward-view/fundingand-efficiency

NHS England (2017b), 'NHS England - Harnessing technology and innovation'. URL: https://www.england.nhs.uk/five-year-forwardview/next-steps-on-the-nhs-five-year-forward-view/harnessingtechnology-and-innovation

NHS England (2017c), 'NHS England: 5 Year Plan - Executive summary'. URL: https://www.england.nhs.uk/five-year-forwardview/next-steps-on-the-nhs-five-year-forward-view/executivesummary

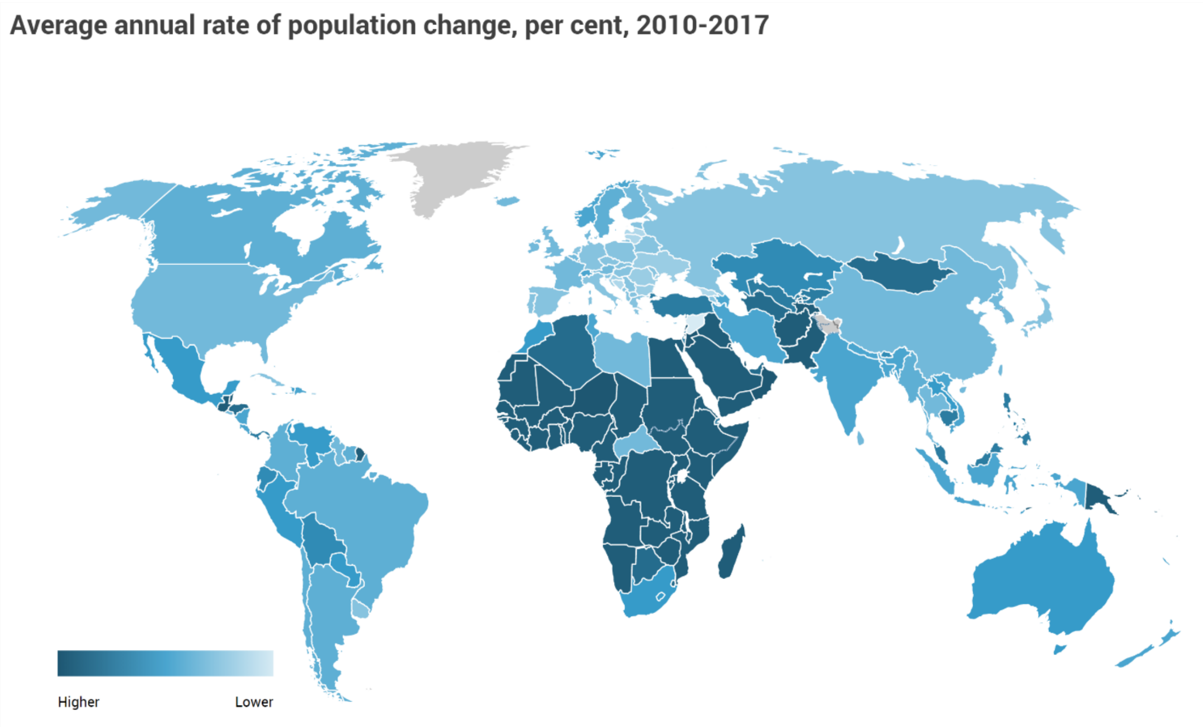
Office for National Statistics (2017), 'Overview of the UK population'. URL: https://tinyurl.com/h64vhme

UNFPA - United Nations Population Fund (2017), 'World Population Dashboard'. URL: https://www.unfpa.org/data/world-populationdashboard

World Health Organisation (2017a), Health Information Systems and Rehabilitation, in 'Rehabilitation 2030 A Call to Action', Genveva, WHO.

World Health Organisation (2017b), Rehabilitation: key for health in the 21st century, in 'Rehabilitation 2030 A Call to Action', Geneva, WHO.

Appendices



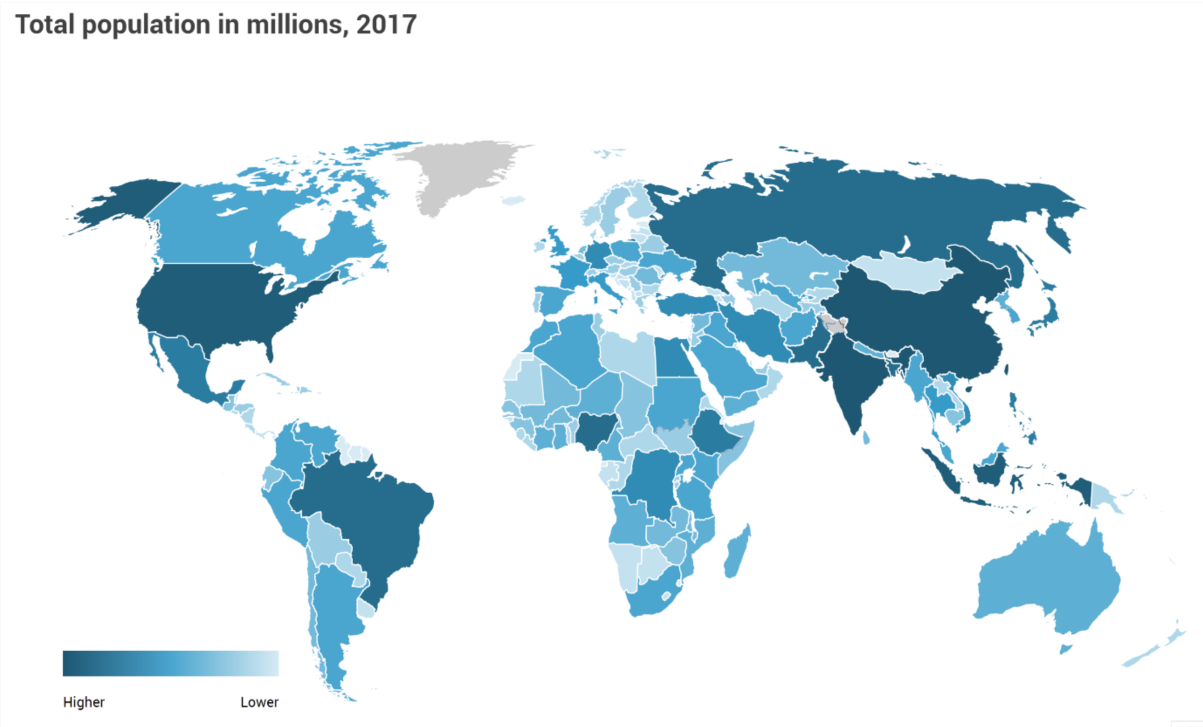


Figure 8 - Interactive maps which demonstrate the growing world population. (UNFPA - United Nations Population Fund, 2017)

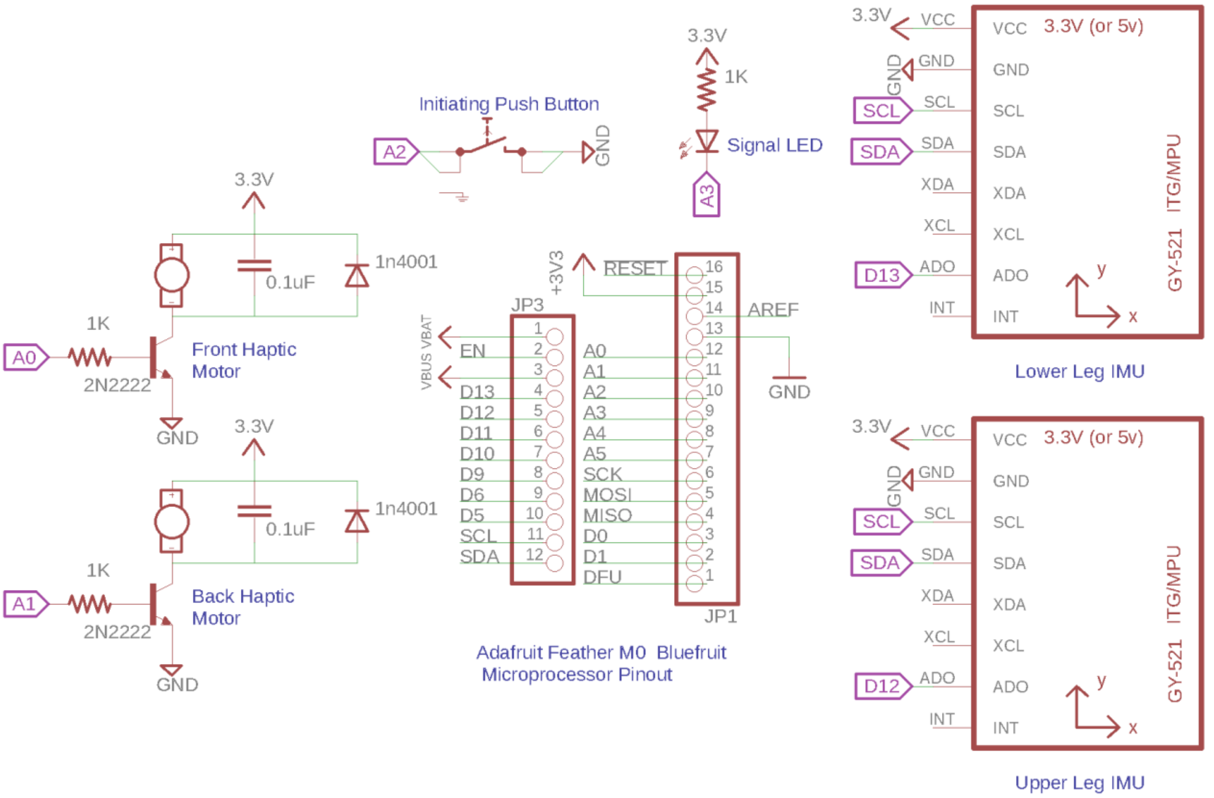


Figure 9 - Electronic circuit diagram

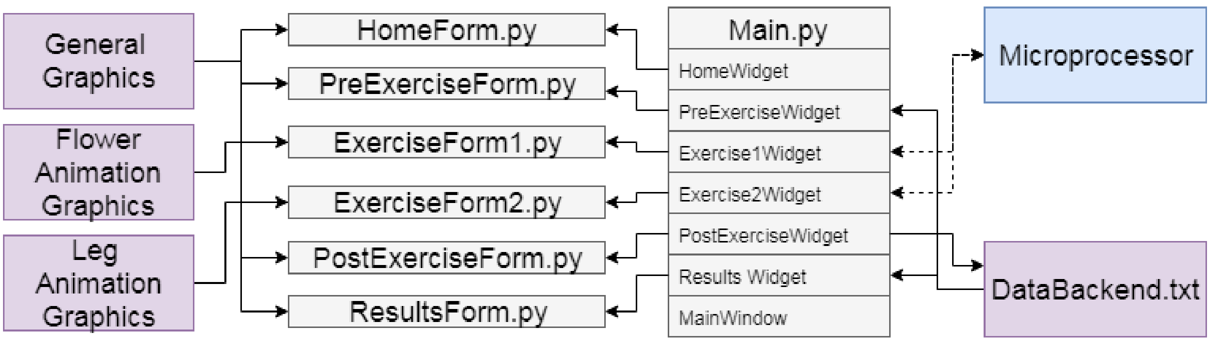


Figure 10 - Software system diagram