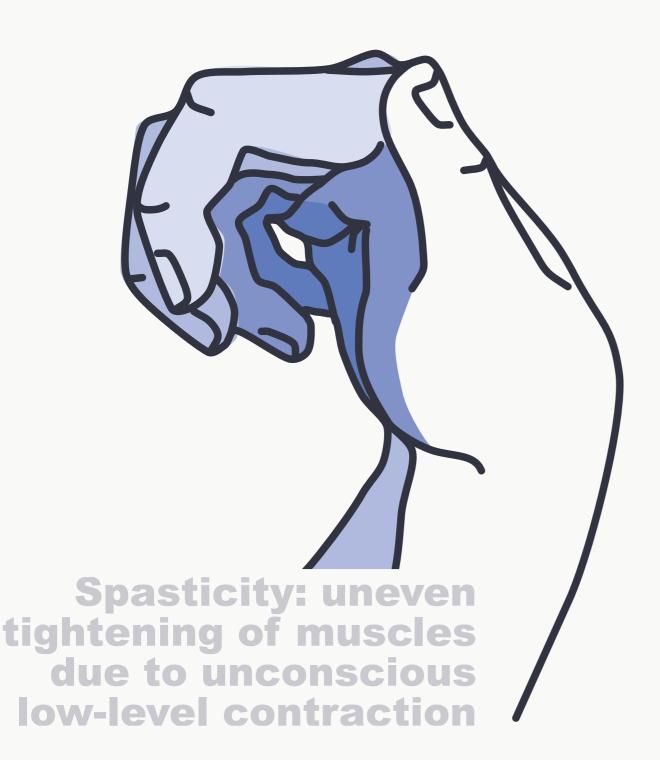
Product opportunity



1 in 3 stroke sufferers experience spasticity caused by **damage** to the parts of the **brain** responsible for voluntary movement.

Without **regular rehabilitation**, it's likely sufferers will **lose function** in the affected limb.

It can develop **months after a stroke**, and significantly impacts survivors' **quality of life**.

Rehabilitation is normally facilitated by either a physiotherapist or occupational therapist. These are expensive privately and the NHS is unable to provide sufficient support.

More than half of those receiving inpatient care do not have access to the recommended daily minimum of physiotherapy [1], and half of survivors feel abandoned after being discharged.

Physiotherapy has been shown to **reduce the risk** of a second stroke by **35**%, saving the NHS an average of £13,500 per patient [2].



Our aims:



To design a tool **for stroke sufferers** themselves to tackle upper limb spasticity.



To track rehabilitation and provide means for users to set and control their own goals.



To **build consistency** and promote and **affirm form** in at-home exercise.



To help **tackle isolation** and **promote independence** in stroke survivors.



To be **accessible** regardless of NHS services available, and suitable for those who suffer with **aphasia**.



To motivate users to complete the recommended 45 minutes / day of physiotherapy exercises.

Throughout the project, three key elements are considered:



Design for manufacture & assembly



Compliance and user safety considerations



Accessibility to aphasic users

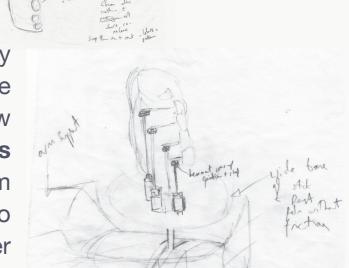


Mechanism development

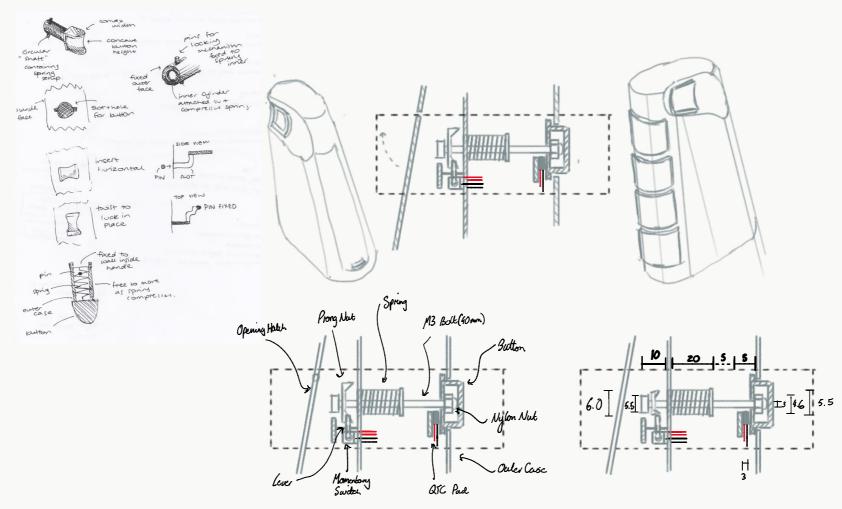
In order for the product to be appropriate for users with various levels of spasticity, and throughout an individual's recovery, an adaptable resistance mechanism is necessary to reduce the assistance the user gets with grip release and promote functional independence.

As each button can be **controlled individually**, the mechanism must be **compact** enough to be repeated five times within the confines of the joystick itself.

Motor-controlled mechanisms to modify spring tension, mounted in the base of the joystick, were considered. This would allow the largest number of discrete resistances to be achieved, however the mechanism is complex and bulky, and more liable to malfunction and expensive than simpler solutions.



One concept included using modular, self-contained buttons with springs of different stiffness. This allows for the individual buttons to be modified independently, and facilitates replacement if the mechanism fails. However, only very few discrete resistances can be achieved.



The solution we chose incorporates a discretised screw mechanism to increase or decrease tension in a spring, along with a QTC sensor to measure the release pressure for each finger. While still a discrete solution, the sensor allows progress within levels to be measured consistently and provides the user with data about their progression every time they use the product.



Button detail Difficulty Settings

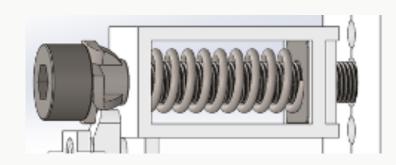
Assistive Forces

The force required to pull open each finger was used to establish benchmark assistance values for each button [3].

Force (N)	Left	Right
Thumb	18.1	17.9
Index	11.8	12.4
Middle	13.7	13.9
Ring	12.0	11.8
Little	10.6	10.7

A spring with 10mm compressible length, constrained by the casing, must have spring constant of ~1.8 N/mm.

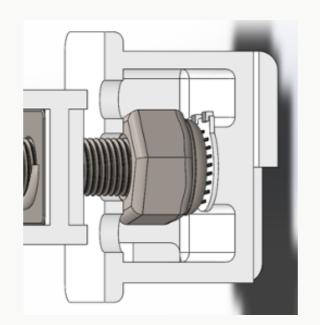
A 20mm spring with k = 2 N/mm was chosen, to provide working range 0 - 17.4 N



Sensing

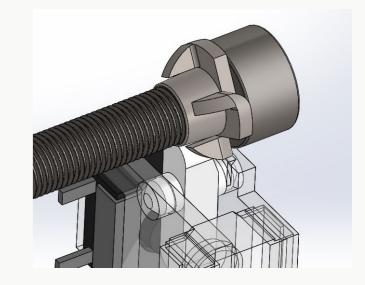
A Peratech SP200-5 QTC sensor placed between the button's internal face and the locknut acts as a force-varied resistor, measuring only the force applied from the button against the sprung bolt. This means the force readings are independent of spring tension.

Changes in force will be used to **detect when** the user releases their finger, and measure progress as the degree of achievable release improves.



To maintain the challenge, and ensure the device is useful throughout all stages of **stroke recovery**, varying difficulty is essential.

The spring chosen provides 104 unique difficulty settings, each varying by 0.64N and corresponding to a quarter-turn of the M3 thread bolt, which can be easily translated into a percentage value.



A quarter-turn of the prong nut will provide audible and mechanical feedback and be registered digitally using a pair of **microswitches** - one to count increases. and the other decreases - so that the adjustment can be displayed on screen and difficulty logged alongside performance.



Button detail II





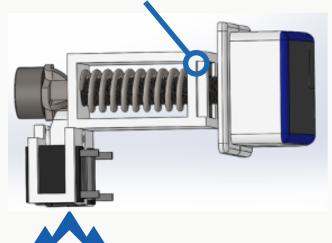
DFMA Considerations

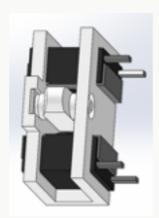
Off-the-shelf components were used wherever possible to **minimise the production of proprietary components**.

The support structure for the mechanism was designed so all features could be created with minimal material, to prevent shrinkage and along two axes for mold separation.

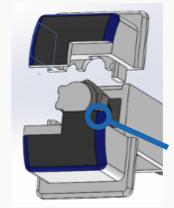
Similarly, the buttons are created from two identical halves to reduce necessary tooling, and are modular in design to minimise perunit costs.

Indexing points are included throughout, both to support and locate components and ensure that the modules are placed inside the casing with the correct orientation, reducing assembly time and complexity.





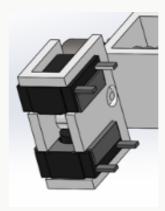
Within the support structure, the ABS lever is inserted via chamfer groove where the **compliance** of the structure allows it to flex and then be **self-retained**.



The locknut and sensor are sandwiched between two halves of the button, which include indexing features to easily locate the internal components correctly.

The split line is staggered to minimise the stress on any one part of the user's finger.

Similarly, the tactile switches can be inserted from the opposite direction and retained via interference fit. The outer casing provides full motion constraint.



The pronged nut is then threaded onto the bolt, which is inserted through the support structure and compression spring, through the square nut and out of the other side of the support structure, into the locknut.

Module Components

Component	Quantity	Unit cost (£)
Actuator Supports Button outers Bolt Tactile switch Spring Locknut Square nut QTC pad Prong nut	1 1 2 1 2 1 1 1 1	0.48* 0.68* 0.61* 0.04 0.13 0.62 0.03 0.04 5.63 0.18
Assembly estimates	2 minutes	5.55
Collinates	Total cost:	9 24

Total cost: 9.24

Casing development

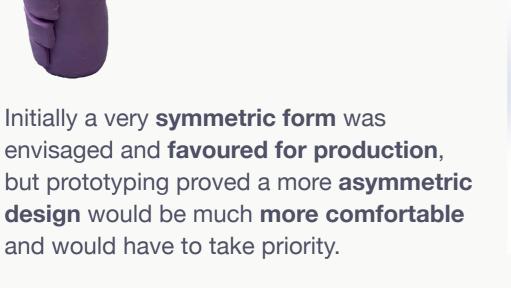
Clay was used to **prototype ergonomic form**, whilst within the confines of grip dimensions as indicated for stroke sufferers from Jo McMeechan, a physiotherapist and the journal Frontiers in Neurology [neu].

Without later stage physical prototyping, trial and error adjustments to CAD derived 3D prints would not be possible. Ensuring an accurate CAD model from the initial clay prototype was paramount.

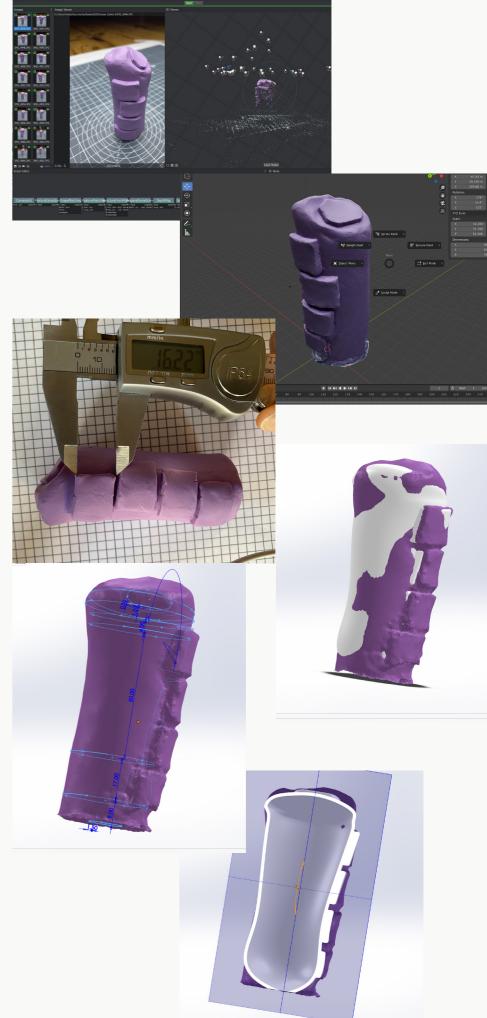


So we developed a process that allowed us to "scan" the clay prototype and that form was correctly scaled and imported into SOLIDWORKS and a CAD model built around the scan, ensuring the correct form and ergonomics of the CAD model.









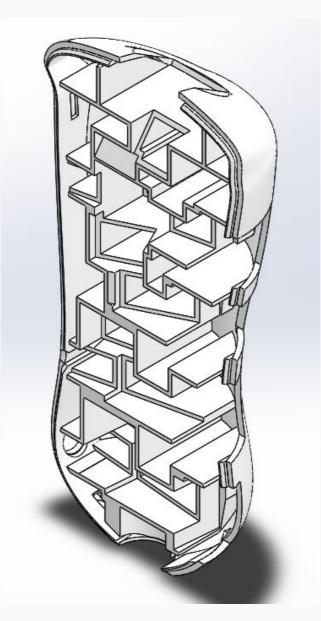
Casing detail





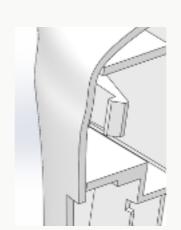
The casing features access holes to adjust the tension in each spring mechanism, and therefore the level of difficulty. This must be adjusted fairly frequently to maintain challenge, however the process is simple, as illustrated below.

The holes are covered by a silicone rubber flap, which is fixed by a rubber pin at the top, and has shaped extrusions which interfere with the holes for location and stability in use. This flap also covers the split line, reducing the risk of irritation to the user's hand.



The injection-moulded internal ribbing is key for maintaining rigidity and fixing the modular mechanism in place.

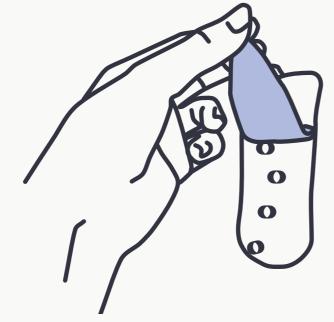
All ribs are **drafted at one degree**, and principles of wall thickness on two axes have been followed to promote **mould separation** and **uniform cooling**.



Indexing features such as tongue-and-grooves are included for ease and speed of assembly. Snap fits are also used in the outer casing to allow the casing to be quickly assembled without the need for external fasteners, reducing complexity in the small housing.

Wiring routes are cut into the ribs to allow the electrical components to interface with the microcontroller in the base.









Support development





Aims:

Comfortable and easy to interact with using one hand.

Provide a consistent and repeatable environment for testing to collect accurate and meaningful data.

Shield users from the mechanism so that they can't injure themselves.

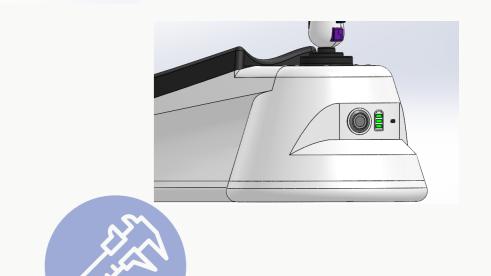
Support the arm to prevent shoulder subluxation and ensure good form while minimising discomfort.

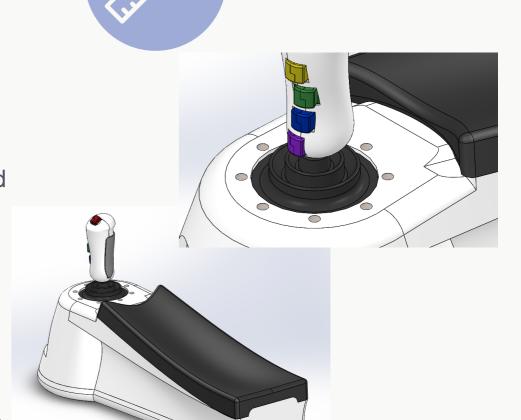
The base came to only **1.73kg** which is comfortable for most people to hold and manipulate with one hand. All the buttons and charging port are positioned such the users non affected hand can easily operate them.

By supporting the elbow it becomes difficult users to 'cheat' the measurement by instigating movements with their torso. As the mechanism is strongly constrained the measurement sensors can be calibrated easily to ensure accurate data collection over time.

A silicone rubber sheath is riveted to the inside of the base and transition fit H7/k6 to the joystick shaft. This provides a flexible barrier between the user and the mechanism and helps the joystick to return to a centred position.

The armrest supports the elbow which alleviates strain on the shoulder. The grooved high density foam makes it simple for the user to find the exact arm position expected from them while having a large surface area to reduce pressure points. This is comfortable up to the 95th percentile of users [4].







Mechanism detail l



Measurement

In order to measure the position of each axis, a A clutch mechanism was developed using potentiometer is used. The analogue position 2 rubber discs that are pressed together is read using a 16 bit ADC allowing for highly and the frictional moment allows for the accurate measurements. This can be used to transmission of power. By controlling the drive the axes in a closed loop control system. normal forces between these plates the

Drive

Each axis is driven by a 6V N20 motor with a 1:398 gear ratio reduction. By testing able bodied individuals a torque of **0.5 Nm** provides a moderate level of difficulty, meaning that users who can overcome this are likely fully recovered. The stall torque of the chosen motor is 1 Nm so short loads of 0.5 Nm should cause no damage to the motor.

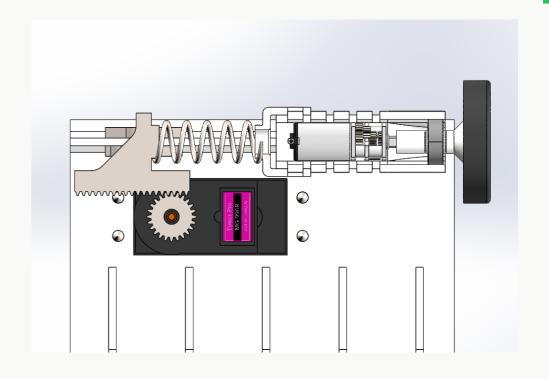
The rotation is transmitted through a frictional clutch mechanism and a 1:1 gear ratio to ensure safety and efficient pack.

Clutch

torque experienced by the user can be varied precisely.

The normal forces are produced by compressing a spring using a high torque **servo** motor. This **decouples** the servo from the action of the friction plates. A trade-off between the working length of the spring, motor torque, pinion diameter, spring constant and the required force and moments were considered.

To separate the rotational motion from the linear motion used to press the plates together; the N20 motor, which is connected to a friction plate and mounted in a housing using a thrust bearing, is supported on rails. The whole assembly can be moved by the servo to engage or disengage the clutch mechanism.



Module Components

Component Friction disk Overmold Sprung rack Spring 24T pinion DC housing Housing cap DC motor Servo Thrust bearing Left rail Right rail	Quantity 2 2 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	Unit cost (£) 0.79* 0.77* 1.20* 0.57 0.30 1.31* 1.18* 1.56 1.84 0.18 1.78* 1.78*
Assembly estimates	2 minutes	5.55





Mechanism detail II



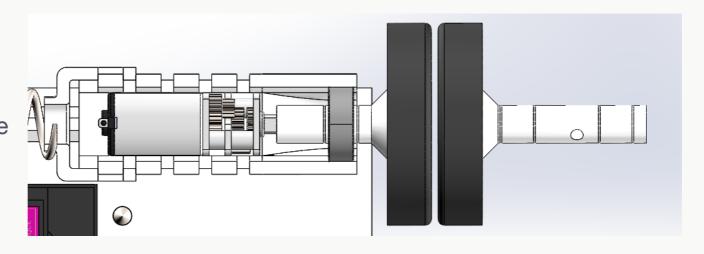
Safety by design

The clutch mechanism is used to protect the user. By carefully limiting the normal force applied it's **impossible** for the N20 motor to exert more torque than the moment of friction provided by the plate otherwise slipping will occur. Equally, the user can't damage the motor by over torquing it for the same reason.

As spasticity is **velocity dependant** its important to be able to limit the speed of any movement caused by the drive chain. To do this we can use a velocity-based PID controller. This will dynamically vary the power to the motor to ensure that the movement is steady and even.

To ensure the user safety all systems would be further designed with consultations from medical professionals.

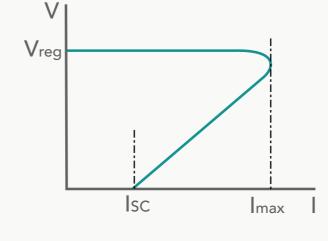




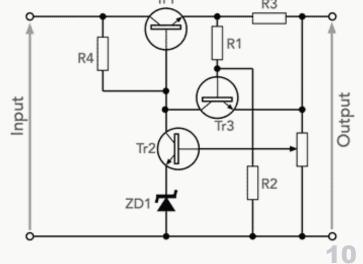
Additional measures

While the mechanisms and systems should ensure the safety of our users there is always potential for errors. To mitigate this a current limiting circuit, implementing foldback limiting [5], will be included on the PCB to protect the user against jerking caused by current surges or faulty components.

Jerking motions can seriously damage the user's muscles and significantly set back their rehabilitation.









Electronics & Interaction







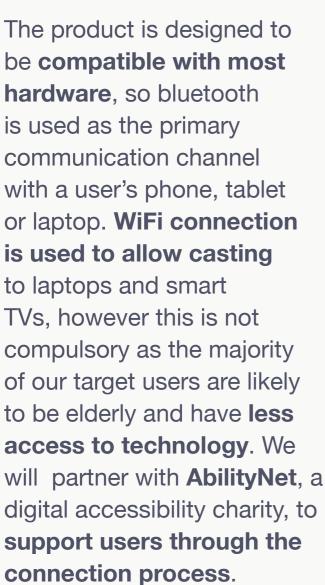
Use your phone or tablet to scan the QR code on the left side of this box.

> It will take you to the SaeboStick app, where videos and other resources are available.



Download and open the an account.

> If you have been referred by your physiotherapist, enter their pairing code when prompted. You can update this at any time from the settings menu.







app, and sign in or create



Make sure your phone's bluetooth is switched on, then press and hold the power button on the SaeboStick base for three (3) seconds.

The power light will begin to pulse, and your SaeboStick will appear on the list of bluetooth devices on

If you need help with this step, watch the video on the app where the process is explained in detail.

All of the user-facing functions are located on the same face of the product and designed to be easily operated one-handed. The power button has an LED with two modes: lit to signal switched on, and pulsing to signal bluetooth pairing mode is active.

Similarly, the three battery indicators are used to give a physical visual representation of how much charge is remaining. When the device is charging, the lights pulse up to the current capacity, and show solid when fully charged.



The power light will stop pulsing when your device is connected. Reopen the Saebo app, which will walk you through how to get started with using the SaeboStick.

See the User Guide included for more information about

Current Draw

The current draw per motor averages around **300mA**, and as all four motors are unlikely to be engaged simultaneously, idle motor draw is likely to be ~100mA. As the other electrical components draw comparatively insignificant current, they can be neglected.

45 minutes of exercises per day is recommended for stroke sufferers, as such a weeks' exercise solely using SaeboStick corresponds to 6300 mAh. Therefore, it's necessary to use four 3.6 V 3350 mAh batteries, two in series and two in parallel, to produce 6.2 V and allow more than a week's exercises on one charge.

Electronics Costing

Component	Quantity	Unit cost (£)
28-pin 16-bit PDIP Custom PCB USB-C female port Strip LEDs LED power button 3.6V 3350mAh battery WiFi / bluetooth module Potentiometer	1 1 5 cm 1 4 1	0.62 2.13 0.06 1.12 / m 0.78 3.03 1.34 0.05

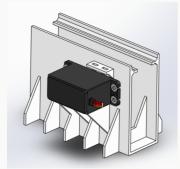
Assembly estimates 1.5 minutes

Total cost: 17.34

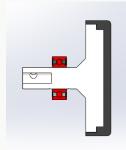
5.55

Support assembly

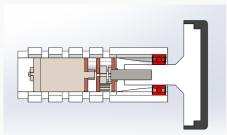




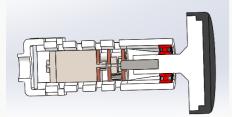
Insert the servo into the railed component, screw into place, and press fit the pinion onto its shaft.



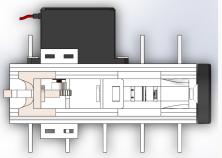
Press the bearing onto an overmoulded friction plate and circlip into place.



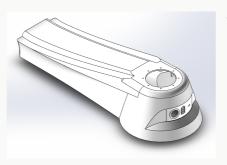
Fit the motor into the casing and fit the shaft into the keyed friction plate drive shaft.



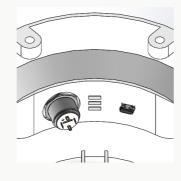
Fix the motor in place and attach the end cap to the casing.



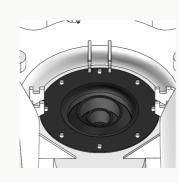
Slide the motor housing onto the rails, and the rack onto the other side. Fit the spring between them to complete the motor subassembly.



Take the injection moulded top casing.



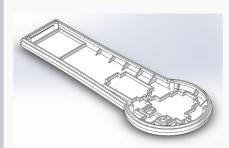
From the inside, fit the power button, LEDs, and USB-C charging connector. Wire & solder to the PCB.



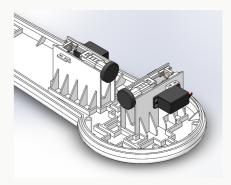
Fit and rivet into place the flexible silicone cover to the inside top face.



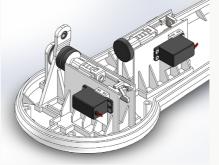
Glue on the foam armrest to complete the top subasssembly.



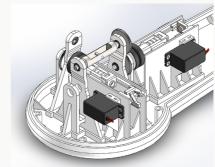
Take the casing base, check quality is sufficient.



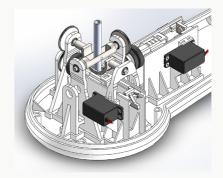
Fit two motor subassemblies in the finned base.



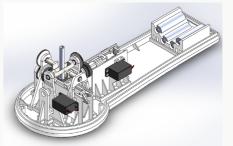
To the front of the base, place the axis support with friction plate, gear and bearings.



Add the two supports for the long axis with the first support bar, bearings, friction plate and drive gears.



Rotate the support bar to insert the joystick shaft, second support bar, and final axis support with gears.

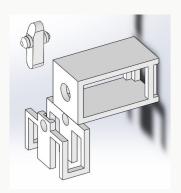


Press the batteries into the support component, and locate in the base.

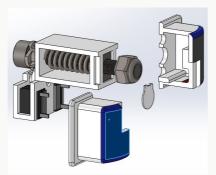


Assembly analysis II





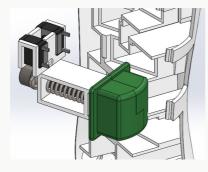
Push the actuator pin into the support structure until it snaps into place.



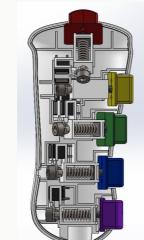
Fit the QTC sensor and snap on the button casing halves.



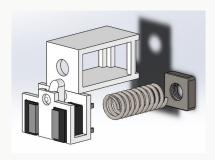
Insert the tactile switches into the housing.



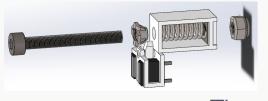
Insert the button assembly into the outer casing, locating using ribs and fins.



Repeat for all five button subassemblies, then snap on second casing half.



Fit the spring and nut into the support casing.



Thread the bolt, prong nut and locknut into the assembly.



Connect the wires to the pin connector in the shaft and fit the joystick over it. Pin in place and secure.



Casing & Assembly Costing

Component Button module Axis control module Electronics	Quantity 5 2 1	Unit cost (£) 9.24 15.01 13.34
70T spur gear Ball bearing Battery support Y gear support X gear support X roof support Hollow joystick shaft Slotted axis Pinned axis	4 4 1 2 1 2 1 1 1	0.30 0.16 1.93* 2.06* 2.06* 1.40* 0.47 4.54 2.89
Silicone pad Stick left casing Stick right casing Base top Base lower Base foam Dust cover M6 self-tapping screw M3 rivets	1 1 1 1 1 1 1 6 8	0.70* 1.83* 1.80* 2.37* 2.23* 0.01 1.92* 0.16 0.03

Assembly estimates 10 [+15.5] 5.55 minutes

Total cost: **122.19**



Assembly analysis III

Assuming a relatively conservative 100% markup to cover R&D costs, overheads and profit, the device would still retail around £250. While this is not unreasonable - products in a similar market space retail between \$300 and \$500 - in order to make the product more accessible cost reduction was considered.

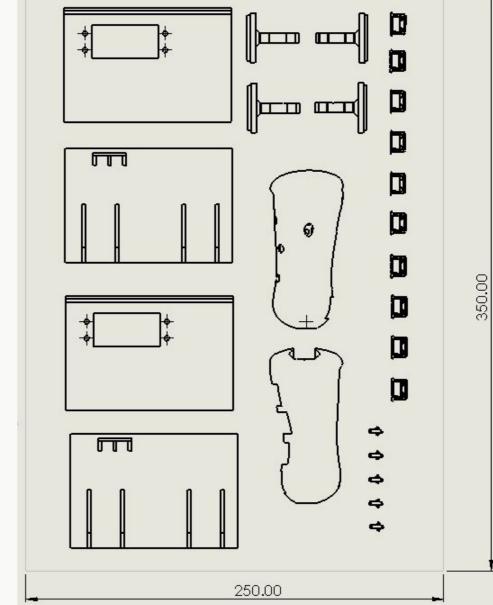
Saebo's existing relationships with manufacturers and suppliers will contribute to minimising costs. Additionally, as a run of 10,000 devices will require 50,000 QTC pressure pads, the most expensive part in the assembly, negotiation with the manufacturer for bulk prices would occur - a reduction of 50% on consumer retail price would reduce the cost of the device by 11%.

The large casing parts could be manufactured using vacuum forming as opposed to injection molding to reduce tooling costs, however this would require significant redesign to eliminate complex ribbing not suitable for the process.

So far, the parts marked *
have been modelled as being
injection molded individually
with a run of 10,000 [6],
resulting in high tooling
costs that has increased the
total cost.

molding was investigated to reduce the amount of tooling necessary. There is only one free axis for mold separation, but several low-complexity parts are suitable to mold this way.

A 250 x 350 mm sprue was designed, **reducing manufacture costs** for the 25 included parts **by 68**%.





Sprue costing

Component	Quantity	Old cost (£)
Button outer Actuator Stick left casing Stick right casing Motor support left Motor support right Friction disk	10 5 1 1 2 2 4	6.10 2.40 1.83 1.80 3.56 3.56 3.16

New cost: 7.16 Amount saved: 15.25

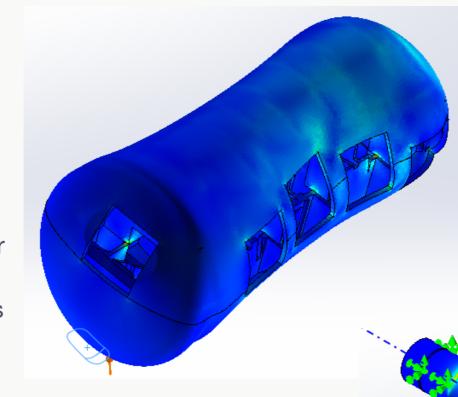
OVERALL TOTAL: 110.40



Digital prototyping I

Casing shell must survive knocks and falls

As the part which is most frequently interacted with by the user, the casing rigidity and strength is important. It was tested against a 'squeeze' force of up to 40 kg and passed with a safety factor of 1.8. A major contributing factor is the lattice of internal locating ribs that help distribute load and limit local deformation.

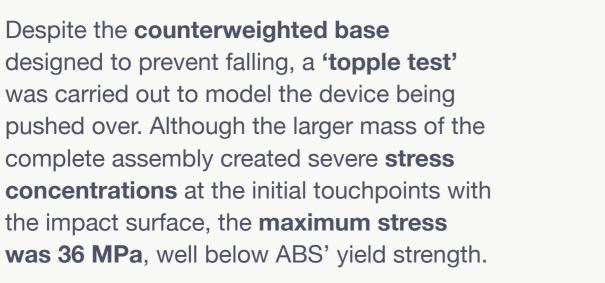




Mechanism must survive knocks and adverse loading

The mechanism shaft and axes were tested under a range of loading conditions to model users slamming the joystick back and forth, applying horizontal load, and loading directly downwards. In the first two cases, the mechanism performs well, withstanding the equivalent of 40 kg of load without damage. However, the vertical performance is weaker due to the thin axis geometry around the supporting pin, and will only support up to 27 kg before failure.

This model is considered an acceptable failure as it's unlikely to be loaded so severely in use, though **future iterations** would still seek to **strengthen the part** for safety.

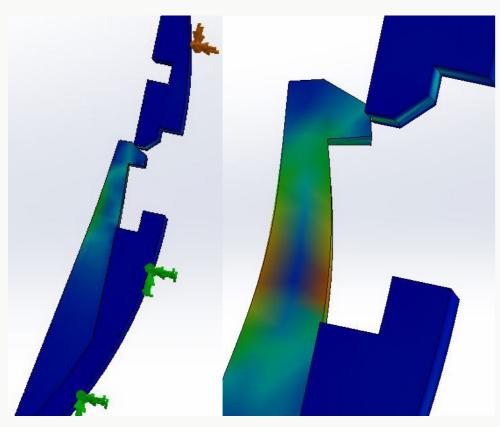


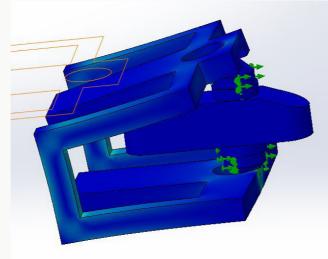


Digital prototyping II

Deforming components must be robust to assembly

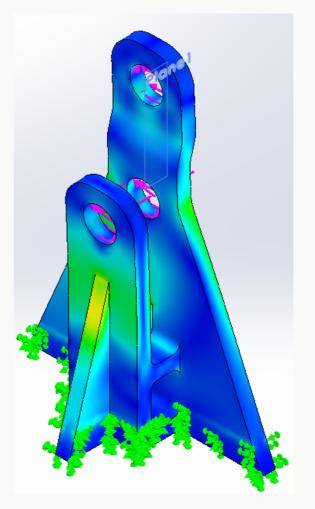
Snap fit and deforming features in the assembly were tested to ensure they are robust. Both bi- and uni-directional deformations were tested, with a minimum assembly safety factor of 1.27 for the curved feature below. All features passed the in-use testing with safety factors greater than 2.





While this is not ideal, the assembly line environment is closely controlled and so parts are unlikely to experience forces or deformations larger than predicted. If parts are faulty and snap during assembly, the modular design reduces the disruption to the production line due to breakage.

Supports must withstand forseeable use



Supports throughout the assembly were tested to ensure they could support the requisite loads.

The axis support, left, is designed to withstand simultaneous 100 N loads both in the direction of the holes and horizontally, which models the user applying a large lateral force while resisting a significant rotational assistance.

While this is an extreme use case, and unlikely to occur often at all in the device's lifetime, the part was tested for fatigue behaviour. The minimum lifetime was 70,000 cycles, which is acceptable due to the rarity of the case in a standard lifetime.



XBOX LIVE

XBOX's Live functionality is a free online platform for users to play games together, which emulates our desire in our second phase to give users access to virtual physio advice based on data collected while using the product.

We would also introduce a paid tier which represents the more in-depth advice we could offer to those who can afford it.

Furthermore, XBOX will have access to and contacts with manufacturers and suppliers of standard controller parts in our product, which may result in lower production costs.

Existing brands



evaluation set, goniometers. £900

JAMAR

Jamar is a manufacturer of diagnostic and measurement tools for Jamar physiotherapists, including 8-piece hand- dynamometers and

> Some are available to buy on Amazon, however the prices are often prohibitively high and the tools themselves can be complex to use.

They will have existing relationships with manufacturers of measuring equipment, and a pre-existing network of physio therapists who have bought their products.



Saebo is an international medical device company specialising in rehabilitation of neurological disorders. Their consumer base is **mostly stroke sufferers**, however they have a global network of more than 10,000 therapists that endorse their products.

Saebo Core Values

- Evidence-Based Practice
- Education
- Affordability
- Accessibility
- Unique Innovation
- Restorative



Their core values align closely with our aims and need-case, and so our product would fit well within their product portfolio.

Their **network of physiotherapists** and existing customers will also help promote widespread uptake of our product among stroke survivors, while their relationships with manufacturers and distributors will help keep costs low.



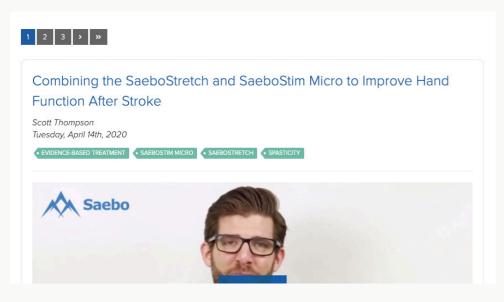
XBOX Live cross-platform functionality



Saebo Affiliation

Founded in 2001 to tackle the expensive and often inaccessible nature of existing physiotherapeutic tools. Saebo's disruptive pledge of "No Plateau in Sight" for stroke survivors has seen them grow to an international company with \$5.6M annual revenue.

Their aims perfectly align with ours in that they include making innovation in healthcare accessible to everyone, at any stage post-stroke, to promote restoration of lost functionality and ultimately, rehabilitation.



Their marketing follows an optimised content strategy, producing content such as videos and blogs curated to engage and retain prospective users, who will then go on to purchase Saebo's products.

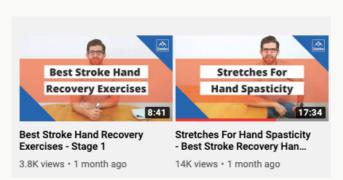
and using their products, FAQs and exercises and receive up to 10,000 views.

Their new VR therapeutic tool (£12k, right) provides a virtual activities of daily living rehab system. Although developed for physios, it shows their willingness to enter digital products and a backend requirement for customer service and YouTube videos include fitting support of such technologies.

As a healthcare technology company, Saebo already has valuable **experience** trialling and certifying medical products, as well as the capital to invest in the multi-year-long certification process.

Their network of more than 10,000 physiotherapists worldwide will also be a valuable resource in operating the **virtual** feedback aspect of our roll out model.

As such, they are an ideal brand partner as they align closely with our product's aims and ideals.



Their product suite includes SaeboFlex and SaeboStretch to tackle symptoms of spasticity, however neither utilise motivational tools to **encourage** exercise repetitions or make them more enjoyable for users.

Our product fits in the gap between the divisions of their current offerings, yet also brings a new dimension social gaming and at home care assistance. Providing new avenues for advertising products and potentially a **subscription revenue** they do not yet have.







Porter's Five Composition of Composi

Supplier Power: Medium- High

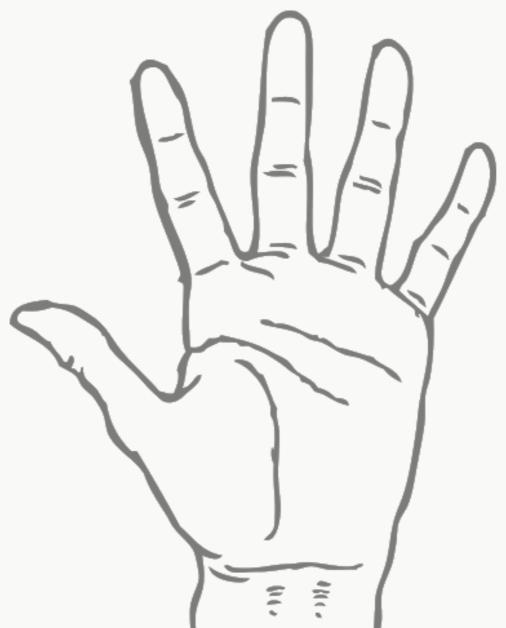
- Most parts either standard or switchable.
- One specialist part (SP200-05) is a 5mm QTC pressure sensor only produced by Peratech.
- Mitigated by partnership with Saebo and politics of such a product being for the vulnerable with no alternative.
- Key future focus to find alternative to critical part to products USP

Threat of Substitution: Low

- Only product to digitally measure release profile.
- Only digital product many spasticity sufferers can use owing to small girth.
- Only product to use social gaming to aid with stroke rehabilitation.
- Will be only product to incorporate a
 access to virtual physios a lifeline for
 those in remote areas and without access
 to the NHS.

Competitive Rivalry: Low

- Saebo is a global leader in therapy solutions for individuals suffering from impaired mobility and function.
- They have over 100,000 customers, and are one of the few companies that market directly to stroke survivors.
- No other manufacturer comes close in range of products or distribution and that creates a brand loyalty we would inherit by partnering with them.



Threat of New Entry: Low

- Product has complex parts which require expensive tooling of injection moulding dies.
- Economies of scale required to be competitive with pricing, partnering with Saebo allows us to combine expertise with established manufacturer.
- Saebo already has a brand loyalty and a network of 10,000 Physios as well as specialist stockists across the globe [7]
- Saebo also already has a variety of distribution networks we will leverage and increase by introducing a social gaming network.

Buyer Power: Medium

- · No release measurement alternative.
- No individual digit alternative.
- No forearm support and control provided in other products.
- No readily available product providing gamification of exercises.

Future partnership with National Health Services would increase buyer power as these organisations can negotiate based on order sizes and integration.



Key Partners

NHS

OEMs

Medical studies and research (expensive, time consuming and arduous)

CSP partnership (Chartered Society of Physiotherapy)

Stroke association - subsidies and lead generation

AbilityNet partnership to help promote and develop social gaming features

Key Activities

Research, analysis and product development

Second Phase: Gain medical approval (Transition from exercise tool to medical device)

Key Resources

Trust of OTs and Physios

Licensing (Authenticity and trust signalling)

Game designers

Network of OTs, Physios and stroke groups

Value Proposition

Improve function of arm, recovery

Gain control and independence of rehabilitation

Trust, accessibility and normality in product and brand

Remote measuring and predictive ability

Priced to be affordable to stroke survivors & their families

Physiotherapy hours for qualification

Reduce in person hours required per patient - longer term contact/lower cost

Customer Relations

Physio or OT referrals

NHS usage/scheme

Providing long term training plan, goals and metrics

Provide therapy hours to student physios

Channels

www.saebo.co.uk

NHS schemes

Insurance (US)

Affiliates/Stroke groups and charities - word of mouth

AbilityNet courses & recommendations

Customer Segments

Stroke sufferers /
Carers buying product

Physios and OTs, practices buying product for patient loan

NHS - subsidising our product to reduce hours on physio

Stroke / Physio / Therapy groups buying product to loan

Physio practices / NHS subscribing to data analysis package

Stroke sufferers without access to physios who subscribe to additional virtual services

Cost Structure

Research and development

Manufacturing

Logistics

Licensing and trials

Data storage, analysis and protection

Revenue Streams

Sale of physical product

Selling additional games

Virtual Physio - Subscription service priced at £9.99 / mo

Access to machine learning predictive analysis -Subscription service priced dependent on data quality and model success



The **planned secondary phase** of our product roll out would include integration and **partnership with NHS** (and eventually other national health services) physios and aftercare treatment programs.

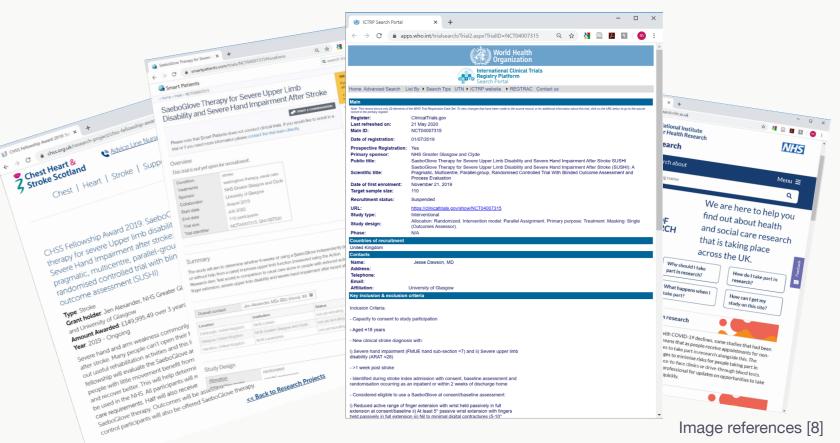
Hence a clinical trial would be required.

Validation of concept has been found in a similar clinical trial program which Saebo is currently undertaking with NHS Greater Glasgow and Clyde.

Saebo is a brand that not only makes sense from product positioning but, being an American company that is involved in this UK based clinical trial from a reverse enquiry, we look to leverage on this experience and pro actively seek to partner with the NHS and replicate the format of this trial with our product, which adds another, more interactive and tailored string to Saebo's product suite bow.

To reduce the financial risk of a clinical trial we would seek a grant from a related charity such as the stroke association, or as has been provided previously by Chest Heart & Stroke Scotland in this example (£150k over 3 years)





Participation in this trial has been advertised on Smart Patients - An online community where patients and their families learn from each other. We would also use sign up via national sponsored trial programs such as bepartofresearch.nihr.ac.uk in the UK.

Clinical Trial Case Study

Start date 21 Nov 2019

Completion date 1 Jul 2022

Participants 110

Location Edinburgh, Glasgow, Lancashire

Intervention model A pragmatic, multicentre, parallel-group, randomised

controlled trial

Allocation Randomised

Treatment 6 weeks use of SaeboGlove with an individualised self-

management training programme involving repetetive grasp

and release

Control Standard NHS rehabilitation care for 6 weeks + 2 study visits

+ 1 study phone call

Outcome Change in upper limb function measured by the Action

Research Arm Test (0-6 weeks)

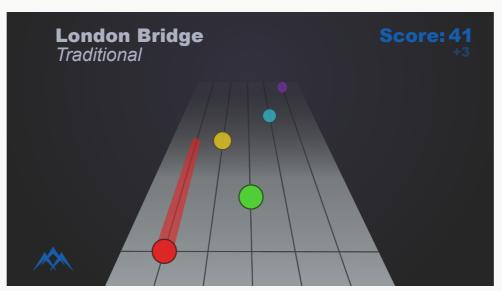


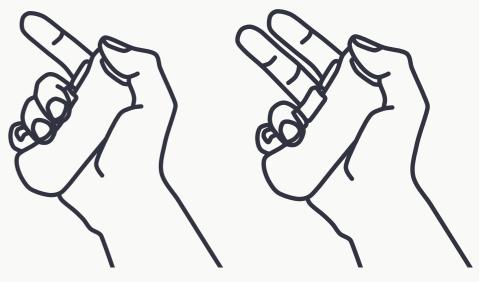
Interface



As measurement and consistency are two cornerstones of our design, the games available for the first prototypes will each focus on one of the three key movements - release, wrist supination, and ulnar deviation, which will produce results which are clear and easy to comprehend for both patient and physio.

The tone of the games was crucial to strike correctly. While it's obvious that they should be light-hearted and engaging to play for those with all levels of cognition, they mustn't be patronising. One way to combat this is through opportunities for user control and by varying difficulty [9], although this cannot compensate for poor game design.





Independent release

The first of these movements is the independent release of one or two fingers simultaneously. Repetition of this exercise will help to **ease finger and thumb spasticity**, allowing more **functional use** of the affected hand.

It is promoted using the four release-activated buttons in conjunction with a musical game, where users must **lift each finger in time** with the dots on the screen that represent notes in the tune.

Users can choose from a library of songs at different difficulties, and revisit those previously played to **beat their high score**.



Existing products in the virtual / gamified therapy market are **limited**, **expensive**, and **designed for physiotherapists** rather than patients. As such they're exclusive before the interface is even considered.

The interfaces demonstrated above, while functional, are dated-looking and busy, and contain large amounts of text, which is exclusionary towards aphasic users at all levels of comprehension.



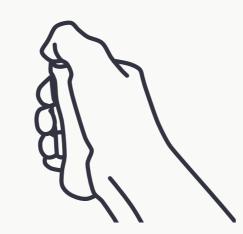
Interface II

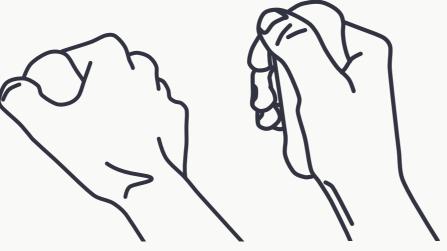


Supination

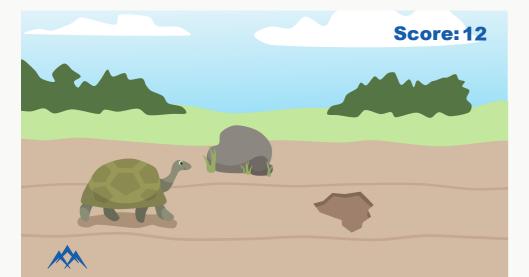
For supination, a slightly more whimsical approach was taken, building a racing game where points are awarded for the **avoidance of obstacles** while progressing along a track.

Users tilt the joystick left and right to move the character up and down and avoid the obstacles in his path, with speed and frequency of obstacles increasing with points to add challenge.











Ulnar deviation

To practice ulnar deviation a fishing game is used due to the **intuitive link** with the motion to build familiarity and confidence in users.

Fish of various sizes and speeds swim along the screen, and users have to judge when the fish is below the float and move the joystick at the right time to catch the fish.

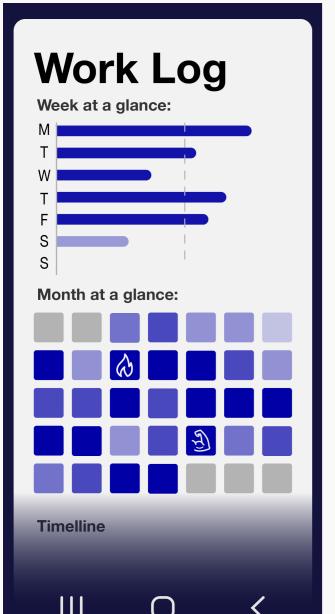


Throughout the game interfaces, the **score** is visible to the user to provide knowledge of result, which has been shown to **encourage** desirable change in users' behaviour [9] and improve motivation.



Interface III





Users

To maintain motivation in users, it's key to visualise their progress. As the tool is designed to be used frequently, trends can easily be visualised and identified, and goalsetting can be used to encourage users to challenge themselves each week while returning some element of control to their rehabilitation.

Milestones are used to provide **common**, **achievable and measurable goals** between users.

Additionally, **community is fostered** in the interface by allowing users to **see the progress of their friends** that day, and **challenge them**

to reach a target or to play a game.

In order to keep the interfaces simplistic and appropriate for all target users, including those with poor vision or aphasia, colour and icons are predominant in displaying progress visually [10].



Physiotherapists

The physio interface is markedly different. Visual representation is in the form of **charts** and **graphs** so the specifics of patients' progress are clear, both between appointments and since their most recent stroke.

Feedback can be left in real time based on the progress that is evidenced and the users' functionality score, a metric that represents general progress towards rehabilitation.

For those without physio access, the service could be **offered remotely**, and in the future **neural networks** could be used to **alleviate workload by automating some of these tasks** and suggesting modifications to users' rehabilitation plans, reducing necessary physio time per patient and NHS costs.



EU Standards To be sold in the EU, and be affixed with a CE mark for conformity, our product must

To be certified, the product must adhere to the 2014/95/EU General Product Safety

The GPSD states that **consumers** must be provided with relevant information to enable them to "assess the risks inherent in a product throughout the normal or reasonably foreseeable period of its use". As such, a comprehensive user guide was drawn up, containing warnings and guidance relating to standard use-cases of the product.

Precautions

Directive (GPSD).

Always follow on-screen guidance. Overuse can result in clinical injury.

Always take regular breaks when using SaeboStick.

If the device starts to get warm from extended use, take a break to let it cool.

Ensure that the SaeboStick base is secure on a table or your lap before use.



Do not place hands or fingers in the SaeboStick joint.



The SaeboStick is not a toy. Do not leave unattended with children.





product's **Bluetooth** communication, it must be certified against both the 2014/30/EU **Electromagnetic Compatibility** and the 2014/53/EU Radio Equipment Directives.

Due to **electronic components** and the

The directives states that the product must:

- Be protected against harmful interference
- Not produce harmful interference
- Adhere to standards regarding to local frequency banding (RED only)



For bluetooth products, the frequency band is standardised across the EU to 2.4 GHz ISM. As our product's bluetooth chip adheres to this, and utilises device pairing to limit accepted communication and target emitted signals, it can be considered compliant with this standard.



Product descriptions, technical schema, design calculations and tests must be submitted and maintained to the certifying body, and must demonstrate that users are reasonably protected against physical injury in both standard use, foreseeable misuse and electrical overload.

CE mark for conformity, our product must

adhere to several of the EU's harmonised

standards. Adherence demonstrates that the

product complies fully with EU regulation[11].

Additionally, the product must be marked with the producer and a product reference, including batch number, for sample testing and recalls if necessary.

Regular sample testing must be carried out by a **UKAS** certified testing body to ensure product compliance is maintained throughout all products. 25





Additional Certification



Secondary Roll Out

The product is not initially marketed as a medical device, and so the packaging and user guide contain warnings about only using the device with medical guidance. After several rounds of product development it's our aim to certify it under the 93/42/EEC Medical Device Directive as a Class I Medical Device.

As the requirements are much more complex to adhere to this standard, we would partner with a compliance consultancy to achieve certification.







As Saebo is an international company, further development is likely to include expansion across the Atlantic to Canada and the US, Saebo's main markets.

Both the Canadian Interference-Causing Equipment Standard #3 (ICES-003) and the limits for a Class B device under section 15 of FCC regulation are sufficiently similar to the EU EMC and RED directives that the device would not require any modification for FCC compliance.

Intertek Testing & Certification Ltd was chosen as a certified body for the EU Standards due to their breadth of expertise: they are certified to test on all of the necessary directives, as well as the Medical Device Directive, so that our professional relationship can be maintained throughout product development and the second-phase roll out.

Furthermore, the device must be certified as a Class I Medical Device in Canada, and Class II in the US. Similarly to the EU standards, an international standards consultancy would be used to ensure certification.





Labelling







Compliance certification, medical disclaimer, manufacturer and product identifier. The EU Waste Electrical & Electronic Equipment Directive symbol dictates that the product should not be disposed of with household waste.

IMPORTANT: your SaeboStick controller is not a medical certified product. Please consult your GP or physiotherapist before use. Read the health and safety guidance included before setup and use.

Designed in the UK by Dyson School of Design Engineering in partnership with Saebo UK

The manufacturer declares this CE-marked device is in compliance with the applicable essential requirements of the Council Directives 2014/35/EU and 2014/53/EU.

Saebo (UK) Ltd. Weltech Centre, Ridgeway, Welwyn Garden City AL7 2AA







QR code for easy and inclusive access to app download and digital instructions including step-by-step videos and more detailed visual guides.

Illustrated contents label for aphasia inclusivity and **clarity of expression.**





User Guides





Cutouts and slots for the user's hand promotes intuitive opening of the box once the sealed tab has been released.

Also infers on the presence of the user guide underneath the flaps.

Comprehensive user guide, including compliance information, safety instructions and product warnings. Audio and visual versions available through the app.



Compostable PaperFoam insert to secure all components in one place for easy comparison to the contents. The device is shipped fully assembled to reduce complexity of set up and promote independent use.

Clear, highly visual stretching guide to encourage users to stretch at home to see the best progress using the device.

Bold and visual quick start guide printed on internal flaps so user can see the product as they read the guide to improve clarity. Provides information on how to read the QR code, download the app and pair a Bluetooth device with the product.





SaeboStick

Engaging game-based recovery programme

Only release-focussed rehab tool

Only tool with arm & shoulder support

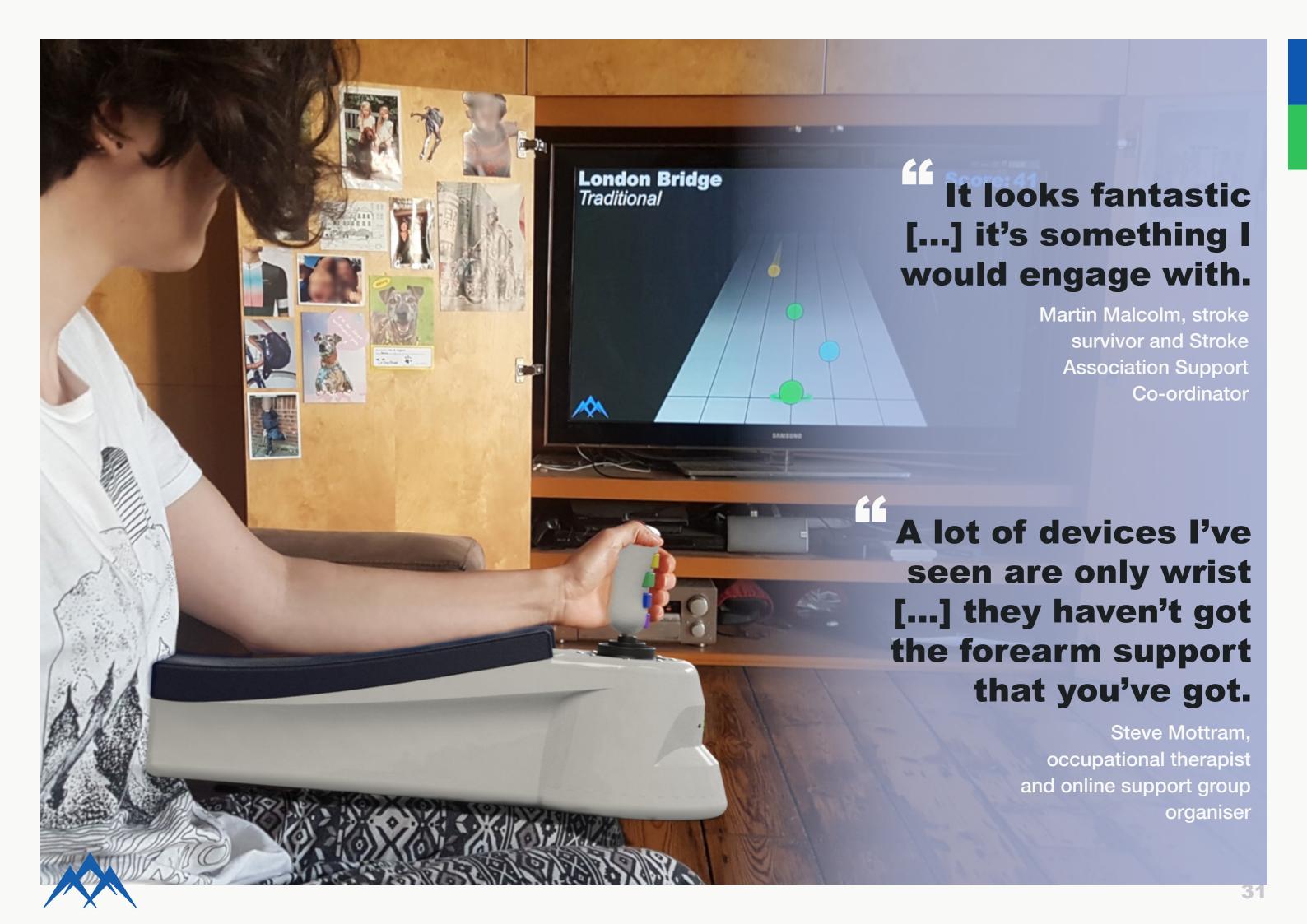
Suitable for at-home use

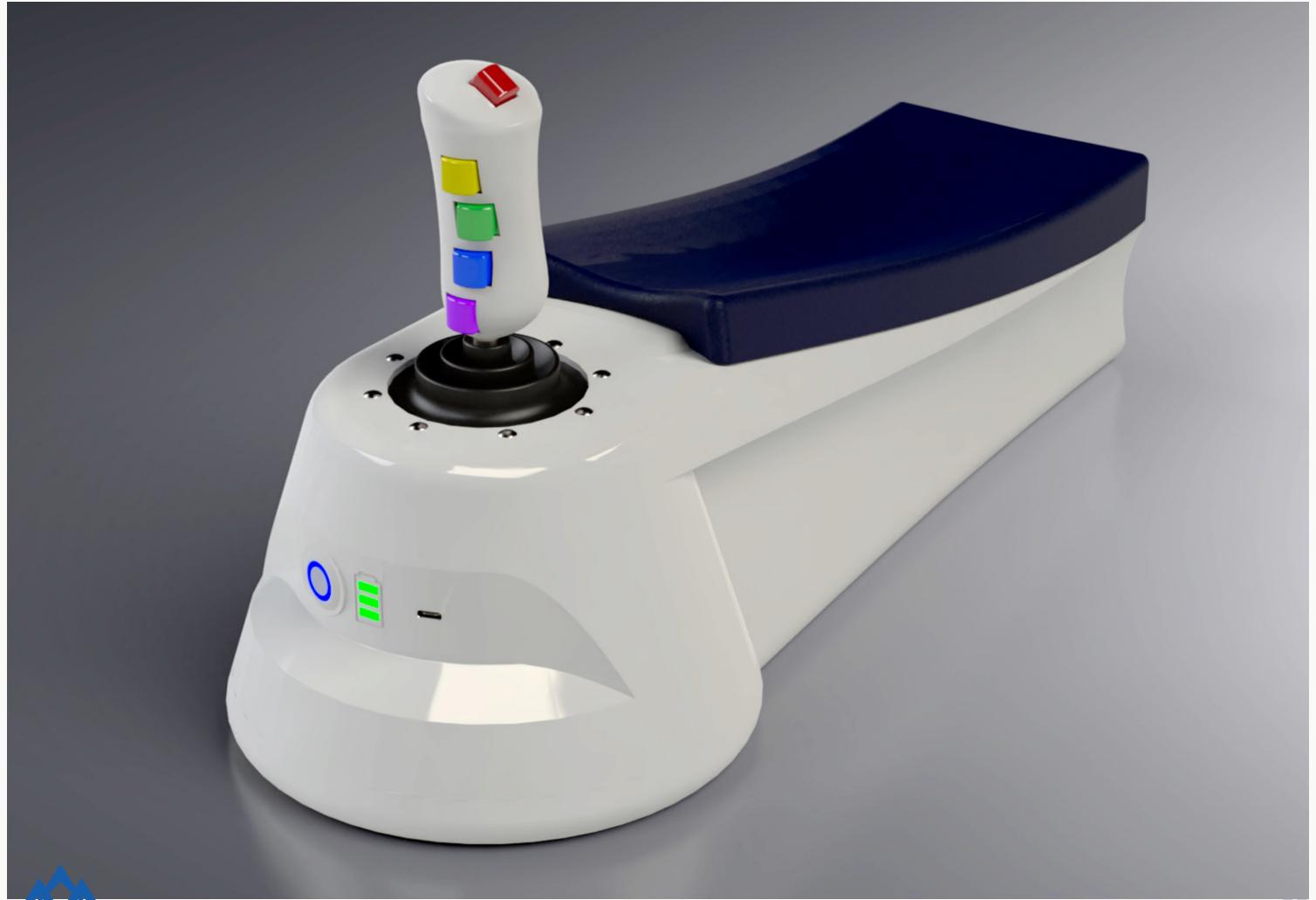
Social gaming compatible

Accessible to aphasic users









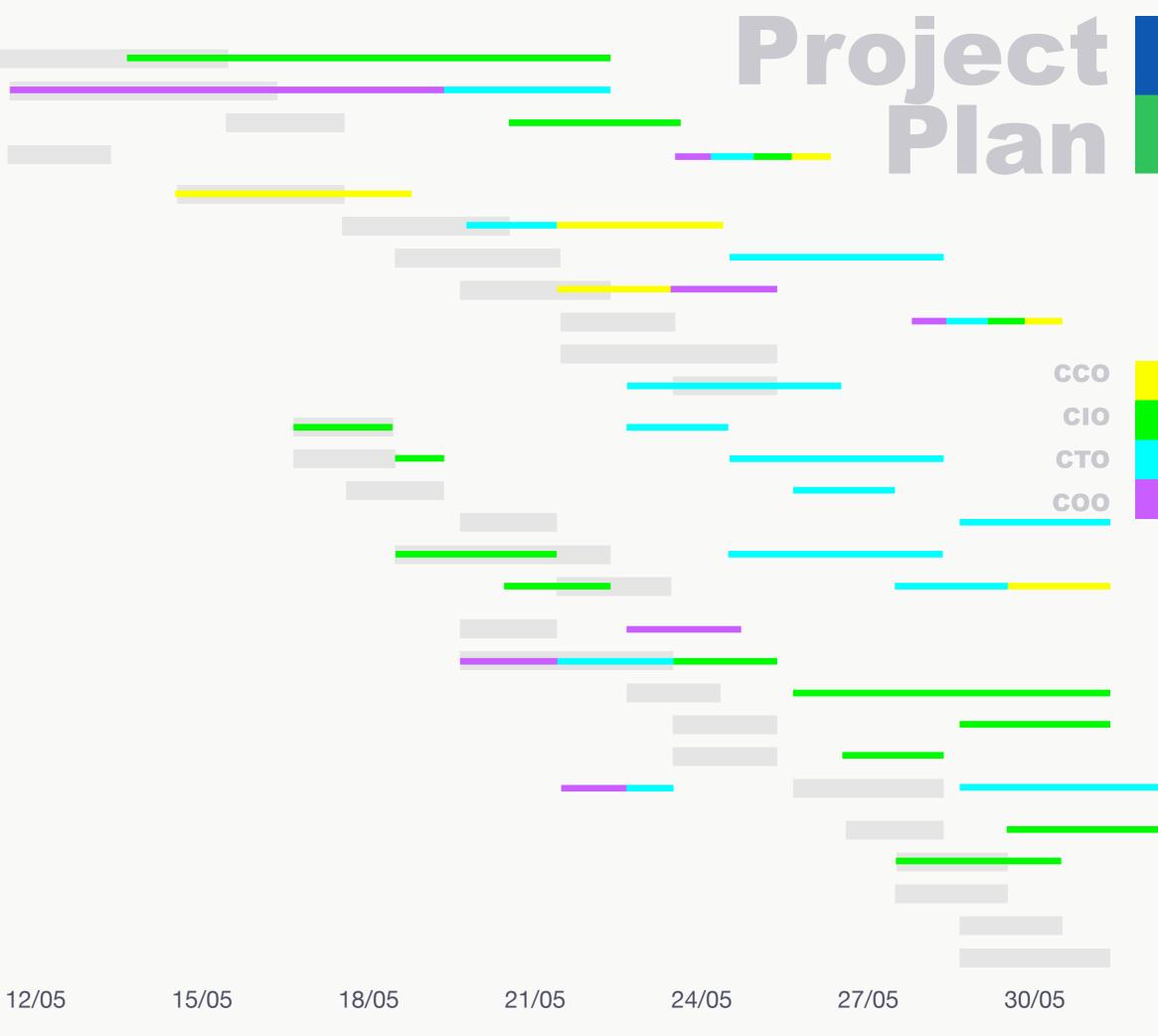
Mechanism development
Form development
Integration of form & mechanism
Evaluation with physio

Incorporation of motivation
Game development
Measurement interface
Game interface
Audio & tactile response
User testing of game / interface
Graphical analysis of progress

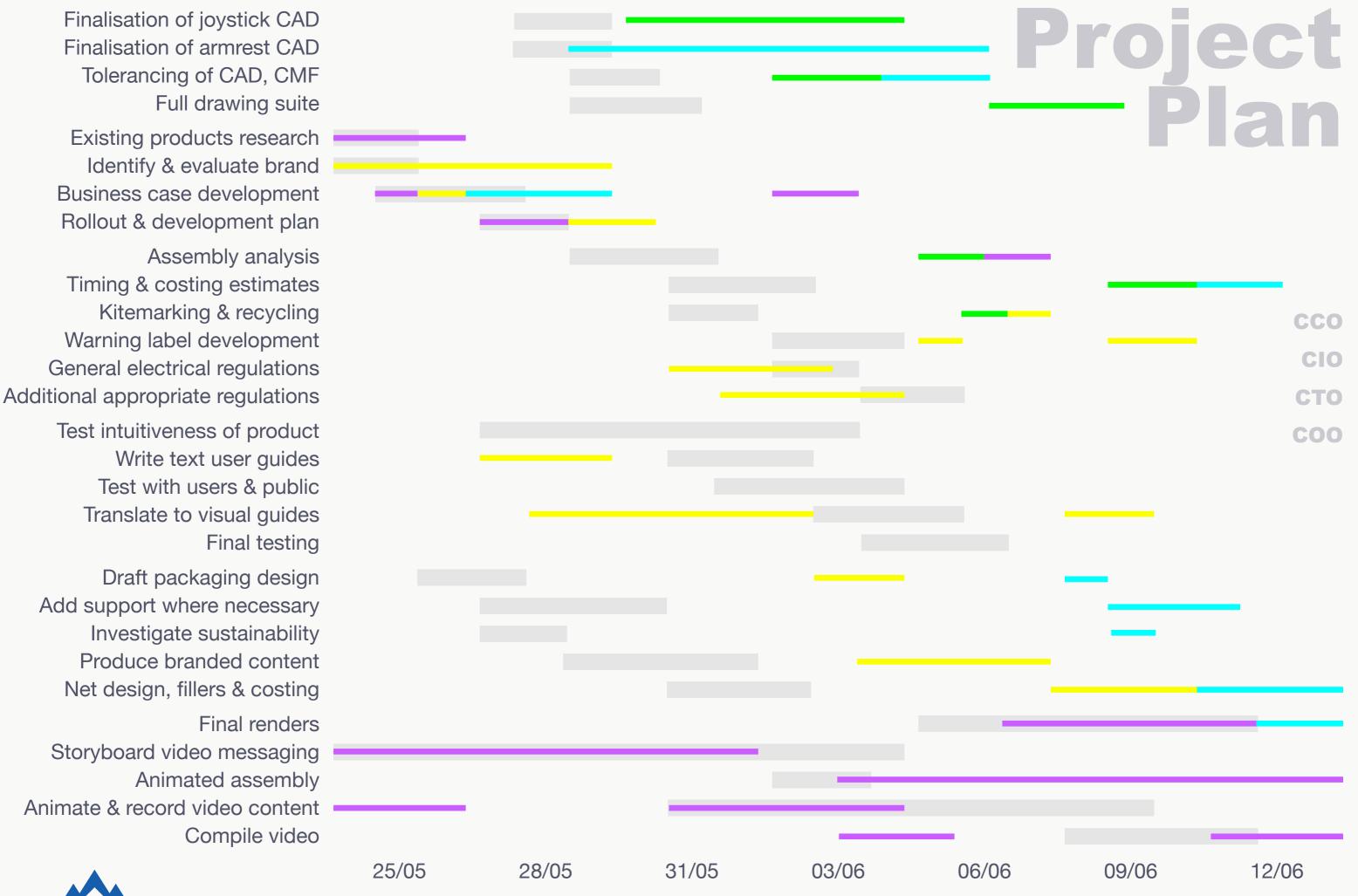
Calculate maximum load
Spring selection
Mechanical friction calculations
Circuit diagrams & analysis
Component specification
Component sourcing

Packaging dimensions
Digital prototyping
Ribbing & finning of models
Snap fit development
Part replacement considerations
FEA evaluation

Finalisation of joystick CAD
Finalisation of mechanism CAD
Finalisation of armrest CAD
Tolerancing of CAD, CMF
Full drawing suite









Endnotes & References

- 1 https://www.stroke.org.uk/resources/physiotherapy-after-stroke [Accessed 1/6/20]
- 2 https://www.csp.org.uk/publications/physiotherapy-works-stroke [Accessed 20/5/20]
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- 10 https://www.toptal.com/designers/ui/ui-design-for-older-adults [Accessed 26/5/20]
- 11 https://ec.europa.eu/info/business-economy-euro/product-safety-and-requirements/product-safety/product-safety-rules_en [Accessed 8/6/20] https://www.ukas.com/wp-content/uploads/schedule_uploads/00011/00295/0010Product%20Certification.pdf certification body [Accessed 10/6/20]
- BOM https://imperialcollegelondon.box.com/s/hcdwh17kxtez5pab1tj31dc3ofafl1xh

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