RAYALERT

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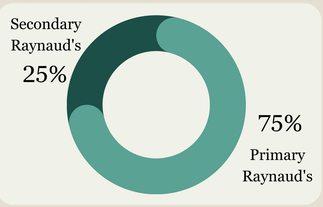
SCLERODERMA & RAYNAUD'S UK — Imperial College London

Raynaud's

- Vasoconstriction of peripheral arteries that causes coldness, numbness, pain and lowered motility in areas e.g. hands and feet
- Primary Raynaud's is when the disease happens on its own
- Secondary Raynaud's is caused by a primary condition e.g. scleroderma, lupus

Triggers include:
- Cold temperatures
- High stress
- Nicotine



A Raynaud's Episode

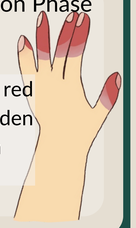
Ischemic Phase

Skin turns white due to vasoconstriction

Hypoxia Phase

Skin turns blue due to deoxygenation of blood (cyanosis)

Reperfusion Phase



Skin turns red due to sudden vasodilation (erythema)

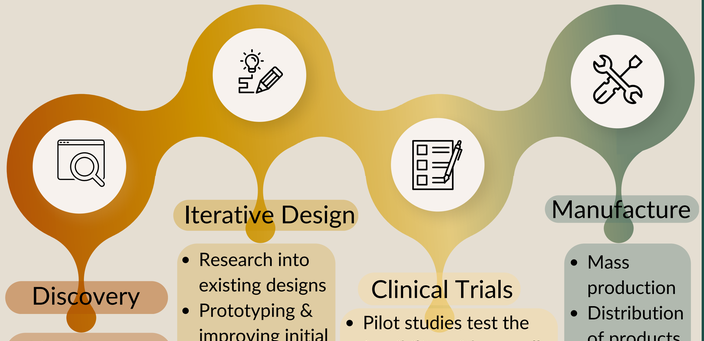
Unmet Needs

No **objective & quantitative measurement**
- Heavy reliance on self-report
- Pulse oximetry (gold standard) is not suitable for Raynaud's monitoring due to lowered accuracy from the cold and stress

No **remote & continuous monitoring**
- Unpredicted Raynaud's episodes
- After asking our teacher who suffers from Raynaud's, we found that patients take a long time to identify their main triggers

No **bespoke treatment** plan
- General advice is not tailored to the patient's individual needs
- Whilst cold temperatures are the main trigger for Raynaud's, our teacher had an episode despite being in Spain with 40°C weather, which shows that people have different triggers

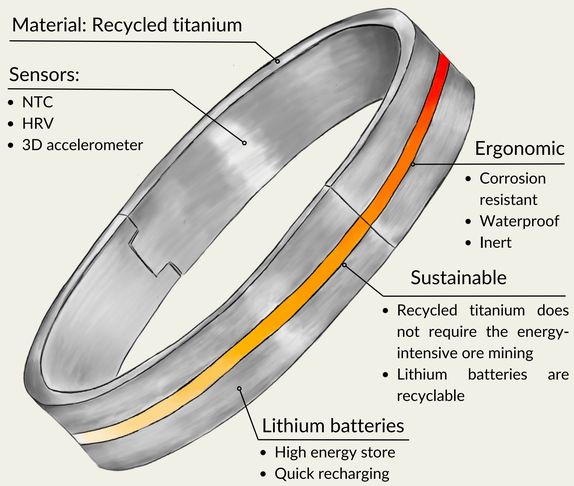
Production Timeline



Our Product

We aim to design a wearable wristband that continuously monitors and objectively measures the effects of changes in body temperature, stress, and exercise levels on the frequency and intensity of Raynaud's episodes. By processing the collected data, insights can be gained into the primary triggers and optimal conditions for each individual patient. Our wristband serves as a non-invasive, preventive tool by predicting the onset of a Raynaud's episode and warning patients to return to an optimal environment. Additionally, it controls symptoms by incorporating personal data with an SRUK-affiliated app. Overall, delivering a customised treatment device tailored to each individual's condition.

Wristband



Past Optimum — Warning — Danger

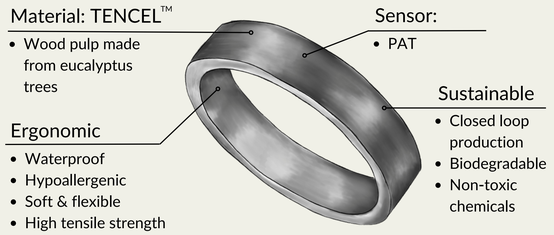
- The trackers for temperature, stress and exercise are commonly used in products e.g. Fitbit, Apple watch
- However, PAT is a novel technology that is rarely used for Raynaud's, but is most commonly used for diagnosing sleep apnea and is popularised by WatchPAT.
- The function of PAT to measure vasoconstriction aligned with the symptoms of Raynaud's, which is why we decided to use it after researching and comparing other options

	Suitability for Raynauds	Research on Raynaud's	Market Availability	Compact & Lightweight	Cost-effective
Pulse Oximeter			✓	✓	✓
Photoacoustic Oximeter	✓				
Hyperspectral imaging	✓	✓			
PAT	✓	✓		✓	✓

Ethics

- In clinical trials, participants must be briefed on RayAlert and that their data will be used for research
- Participants must give fully informed consent, they have the right to withdraw from the study whenever they wish
- After introducing RayAlert to the market, patients must be given a simple and a comprehensive description of the product to give fully informed consent
- The anonymised data is collected and processed, it will not be seen by anyone unless they consent to share their data with the NHS for research purposes

Ring



Technology	What it measures	Description
Peripheral arterial tonometry (PAT)	Frequency & intensity of Raynaud's	Measures vasoconstriction by changes in blood volume (detected by photoplethysmographic sensors) and blood flow (detected by pressure sensors).
Negative temperature coefficient thermistor (NTC)	Body temperature	Measures the relationship between resistance and temperature. The higher the temperature, the lower the resistance.
Heart rate variability (HRV)	Long-term stress	Measures the fluctuations in time intervals between consecutive heart beats longitudinally.
3D Accelerator	Physical activity	Measures the changes in stationary and dynamic movement and velocity along 3 axes.

Inclusivity

Ethnicity

- Many imaging techniques e.g. pulse oximeters, and hyperspectral imaging are racially biased because they rely on absorbance and reflectance of light waves to measure oxygen saturation of blood
- Patients with darker skin tones have higher melatonin e.g. Asians and Black people and often get an overestimated reading, giving inaccurate results
- PAT is not just dependent on light waves but also pressure sensors, so it is not as affected by skin colour

Disability

- Secondary Raynaud's is comorbid with other diseases eg. scleroderma and lupus, which causes hardening and inflammation of the skin
- Our ergonomic design and careful material selection ensure comfort on the hands by preventing constriction

App : RayAlert — Click here

Bibliography

The data on the frequency and intensity of Raynaud's episodes measured by PAT is sent from the finger-cuff to the app via Bluetooth connection.

The data measured by NTC thermistor, EDA and HRV sensors in the wristband on body temperature and stress levels are sent to the app via bluetooth connection.

Data is processed to quantify the effects of temperature and stress on the frequency and intensity of Raynaud's.

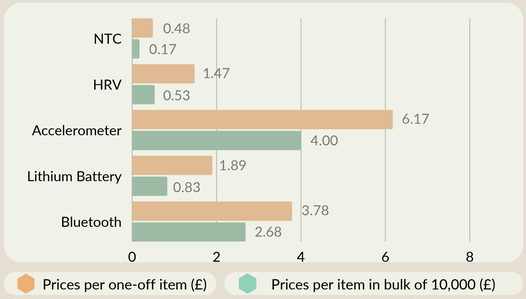
An algorithm analyses the data and produces a personalised profile of which triggers the patient is most susceptible to.

The wristband becomes yellow/orange/red to alert the individual when their statistics of body temperature and stress levels are about to approach the danger zone.

The wristband also tracks exercise through an accelerometer, which feeds back to the app which type and intensity of exercise that is optimal for the wearer.

The app algorithm will generate a customised workout plan with specific targets to maximise health and control symptoms.

Feasibility & Affordability



These prices are estimates as we have not accounted for shipping and labour. PAT is a novel technology so we were not able to obtain reliable information on the general prices. However, based on the cost of PAT wearables, we concluded that RayAlert costs £300-500.