Imperial College London

Institute for Molecular Science and Engineering

Briefing Paper No 6
June 2021

The future of wearable technologies

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https://doi.org/10.25561/88893

Headlines

The wearable device industry is rapidly expanding, predominantly due to the growth of health and fitness monitoring devices. However, there is now an increasing interest in how these devices can revolutionise medical care.

Issues

- Medical and wellness devices are subject to differing levels of regulation, with the latter subject to less stringent guidelines.
- With advances in technology, there is now a blurring of the divide between what constitutes a medical or wellness device.
- In the wellness device industry, there are growing concerns about the improper storage and transfer of a user's personal data. No current legislation exists to stop companies from collecting data from each user, which can be used in targeted advertisements and product development.

Solutions

- The introduction of clear legislation that requires commercial companies inform the user exactly how their personal data will be used, and seek the user's permission to the commercial use of their data.
- Clear, concise and up-to-date regulation needs to be issued for wearable devices. Such regulation needs to be published in a form that can be understood by non-specialist audiences such as app developers. This should involve a multidisciplinary approach that includes regulators, wearable tech companies, academia and medical professionals working together to provide the safest and most effective solutions.
- Imperial College London has the broad range of interdisciplinary expertise needed to develop the technology and is uniquely placed to inform future policy and regulation for wearable technology. With medical professionals highlighting requirements, researchers investigating human-technology interactions, and scientists and engineers implementing ideas into devices, Imperial is already at the forefront of designing the next generation of wearable devices.

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Introduction

The wearable technology industry is expanding rapidly. The most obvious example is the growth of the Apple Watch. First launched in 2015, it sold 31 million units in 2019 alone, 10 million more than the entire Swiss watch industry.[1] Globally, the wearable technology market was valued at $32.63bn in 2019, and is forecast to expand at an annual growth rate of 15.9% to 2027.[2]

Wearable devices can typically provide continuous measurements of a user's pulse, motion, movement and interaction with others. This data can be useful for disease detection, allowing for earlier diagnosis and potentially a reduction in the severity or even occurrence of illness. This could be a step towards achieving personalised healthcare as a result of increased data passively collected from wearable devices outside of clinical settings.

What is wearable technology?

Wearable technology is a broad term encompassing all products that a user can wear on their body, integrating technology with their everyday actions and duties. These devices use sensors to detect and transmit information regarding an aspect of the user's life such as health or activity. The expansion of the wearable technology market can be attributed to several factors, but what has made wearable devices the phenomenon they are today is their emergence as fitness and wellbeing monitors, such as the Apple Watch and FitBit's range of smartwatches and activity trackers. However, there is now significant interest in how the technology could revolutionise medical care.

Wellness and medical devices

Wearable devices come in a variety of forms; common examples are smartwatches (e.g. Apple Watch), bracelets (e.g. Fitbit) and rings (e.g. Oura Ring). However, with new research developments, we can soon expect a broad range of wearable devices such as smart sport patches capable of monitoring hydration levels, or even smart contact lenses that can identify early signs of glaucoma or cancer. Technological advances have facilitated an explosion in the range of new devices which can gather data linked to the health of the wearer. Although wearable technology can observe conditions which are related to health, there are significant and important separations between devices.

Regulators have struggled to keep up with this rapidly expanding industry. Many early producers of wearable technology often claimed practical applications that their devices were unable to adequately accomplish. To counteract these claims regulatory bodies have set specific definitions of a wellness device versus a medical device. The US Food and Drug Administration (FDA) uses the following definitions.

Medical devices: "An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

1. recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,

2. intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes."[3]

Wellness devices: [a low-risk product] "for maintaining or encouraging a healthy lifestyle and is unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition."[4]

We are still discovering the full potential of wearable devices, but based on consumer interest since the release of the first Apple Watch 5 years ago, it is certain that they will become a more integral part of modern life over the next decade. By considering current research taking place in this area at Imperial College London from medical, scientific, engineering and business perspectives, this paper aims to assess how wearable technology is likely to change, and the ethical and legal challenges that the industry may face in future.

Current state of wearable tech

Design and manufacture

Physical Sensors

With the emergence of fitness monitors, such as Fitbit and smartphone apps, driven by low-cost microelectromechanical systems (MEMS) and optical sensors, wearable wellness monitors have become mainstream. These wearable devices are often worn over the wrist and typically provide activity monitoring (e.g., step count) using an accelerometer and heart rate monitor (HRM). In modern fitness devices, HRMs use an optical sensor to measure the amount of light scattered from the skin due to the cyclic changes in blood pressure.

A wellness device vs a medical device

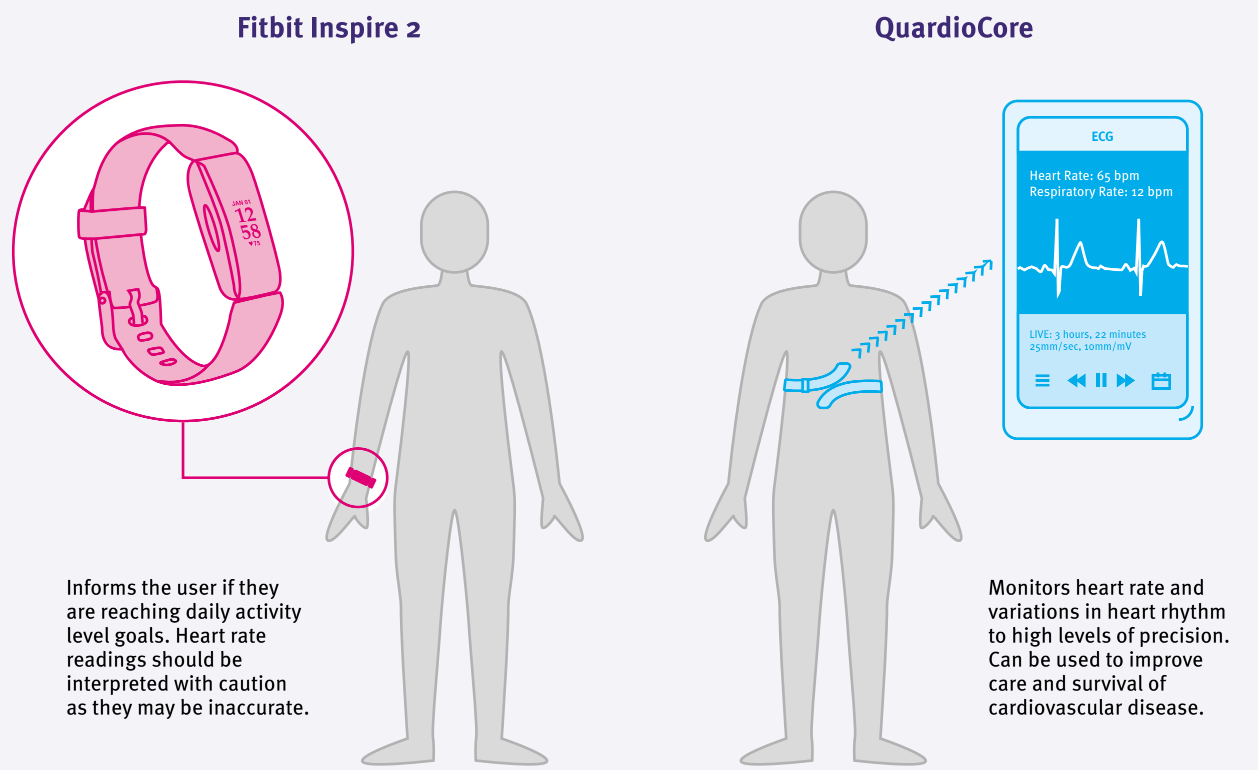


Figure 1: A comparison between a wellness device (Fitbit Inspire 2) and a medical device (QardioCore). Both devices measure the user's heart rate, but to different levels of precision.

In summary, a wellness device can assist the user in generally living a healthy life, whereas a medical device is intended to deliver a medical diagnosis, monitoring or therapeutic effect. Take, for example, a Fitbit Inspire 2[5] wellness device and a QardioCore[6] wearable medical device. Features of the Fitbit include monitoring movement of the arm via a three-axis accelerometer to estimate the "number of steps taken" and heart rate. This data can help to inform a person if they are reaching daily activity level goals. At the other end of the spectrum, the QardioCore wearable medical device delivers real-time measurements of the user's heartbeat to monitor variations in rhythm to improve care and survival of cardiovascular disease. Although both devices quantify parameters of a person's daily life, including heart rate, the impact of their function is significantly different. Medical devices, due to their greater importance to the health of the user, require a higher level of precision in their measurements and are subject to a significantly greater number of regulations than wellness devices.

The first wearable device: the Holter monitor

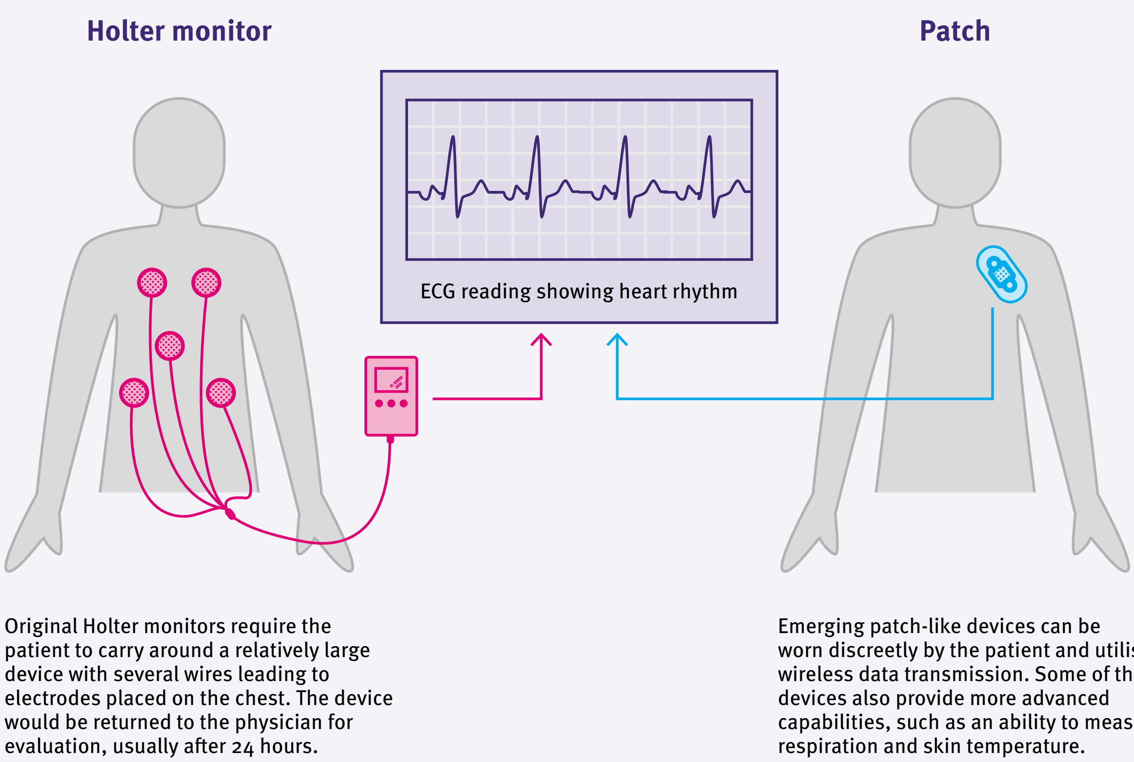


Figure 2: A Holter monitor vs a modern patch device.

Up until now, wearable devices have predominantly been used to measure heart activity or patterns of respiration. One example of a widely used wearable device in healthcare is the Holter monitor. Dating back to the 1960s, it measures the electrical activity of the heart, termed an electrocardiogram (ECG), over a longer period of time than the traditional resting ECG that typically collects just a few beats for analysis. Original Holter monitors required the patient to carry around a relatively large device with several wires leading to electrodes placed on the chest. The device would be returned to the physician for evaluation, usually after 24 hours. Such approaches will likely be replaced by emerging patch-like devices such as Zio by iRhythm,[7] Sensium by the Surgical Company,[8] BardyDx CAM[9] or BioStamp by MC10 Inc.[10] These patches can be worn discreetly by the patient and utilise wireless data transmission technology. Some of these devices also provide more advanced capabilities to measure respiration and skin temperature.

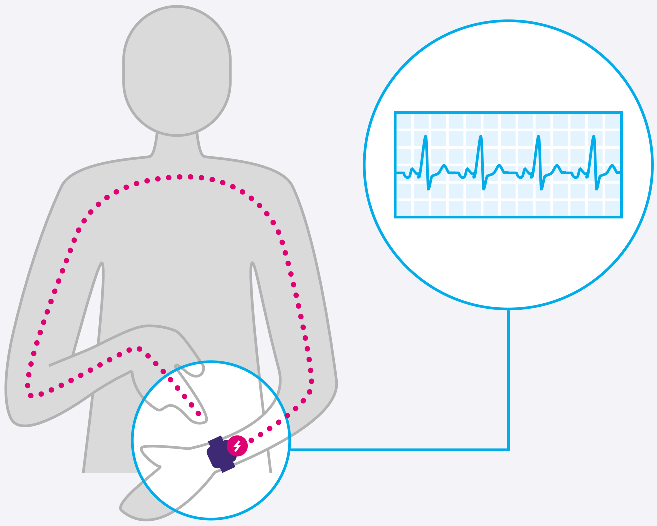
Wearable sensors for animals

Apart from human applications, wearable devices have huge potential in both livestock farming and domestic pets. In animal farming, the lack of an ability to distinguish sick animals from healthy ones has led to mass antibiotic usage or culling, resulting in antimicrobial resistance and economic issues, respectively. High-intensity farming has also contributed to the spread of many pathogens of animal origin to humans, for example, the highly pathogenic avian influenza (bird flu), and may also be associated with the COVID-19 pandemic.[11] Low-cost animal sensors could significantly reduce disease spread and antibiotic use, by continuously monitoring an animal's health.[12] Examples include physical sensors (such as the MooMonitor+ from Dairymaster, which tracks a cow's general health[13]), and implantable biosensors[14] which work with other external sensors integrated into a sensor network for precision farming.[15]

Wearable technology for domestic pets has also started to take off, particularly for cats and dogs. This growth is due to the variety of applications that wearables have for pets, including monitoring of health, such as tracking daily activities and calories burnt, and safety and security. Companies such as PitPat and PetPace use an accelerometer to track animals' activity in place of using GPS through

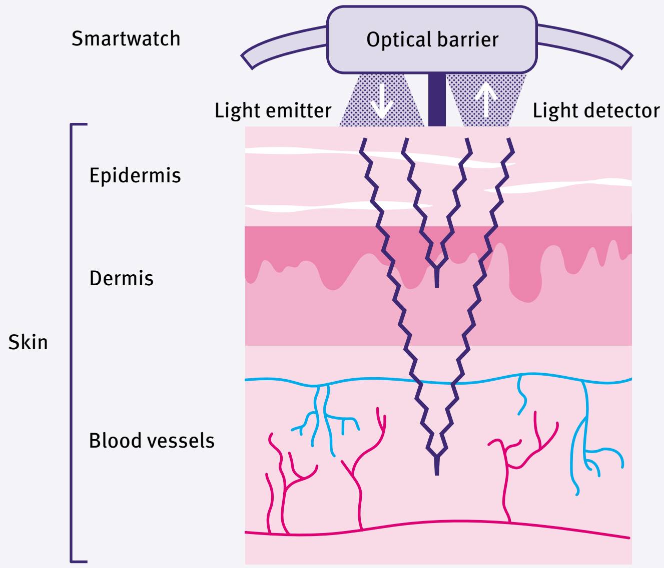
Modern smartwatches – blurring the lines between wellness and medical devices

ECG reading



An ECG is taken by completing an electrical circuit across your body. This is typically done by placing a contralateral finger on the crown (negative electrode on the side of the watch), with the back of the watch serving as the positive electrode.

Heart rate and blood oxygen measurement



Heart rate
By shining light onto the skin and measuring the returning light back, the user's heart rate can be estimated. This is possible as when the heart beats, blood vessels in the skin expand. Expanded blood vessels absorb certain wavelengths of light more than when the vessels are contracted between beats.

Blood oxygen level
When light of multiple wavelengths is shone onto the skin, the rate at which it is reflected or absorbed depends on how red the blood is. By examining the light that comes back, the colour of the blood can be estimated. The redder the blood, the higher the blood oxygen level.

Figure 3: Examples of common sensors found in smartwatches. With the inclusion of being able to perform an ECG, for which certain smartwatch manufacturers have received medical regulatory approval, modern smartwatches are blurring the divide between wellness and medical devices.

In addition to optical HRMs, Apple and others have also released devices that can perform an ECG. Apple was first to obtain clearance from the FDA, and has received similar clearance from regulators in the UK and EU, to use their ECG as a medical device for diagnosing atrial fibrillation, a heart condition that causes an irregular and often abnormally fast heart rate. This exemplifies how the line between medical and wellness devices is becoming blurred. This blurring is facilitated by low-cost, yet powerful, solid-state electronics and mass manufacturing.

location monitoring. These wearable devices are worn on the collar to allow for easy attachment. Pedometer algorithms are designed to count the number of steps taken to track the animal's movement, while classification algorithms can interpret the acceleration data and predict the type of activity an animal is performing (e.g., walking, running, playing). Using this information, the number of calories can also be estimated and is relayed to the owner.

It can be difficult for pet owners to realise when something is physiologically wrong with their pet. In response to this, wearable physiological monitors have been developed that record and send the pet's vital signs continuously to the owner or veterinarian. PetPace's "smart collar", in addition to offering activity monitoring, also measures the animal's temperature, pulse, and respiration rate.[16] Their proprietary data analysis algorithms allow them to identify and signal heart-rate variations to the owner. PetStemo also provide a wearable vital sign monitoring device that is placed against the animal's chest using a wearable band.[17] The device measures heart rate, heart rhythm, and respiration rate. Using irregularities in heart rhythm and identification of heart murmurs, PetStemo claim to provide diagnoses of common diseases such as hypertrophic cardiomyopathy in cats and chronic degenerative valve disease in dogs. Their technology, however, only includes the development of an audio recording device, which is a kind of digital stethoscope for pets. In addition, the diaphragm of the stethoscope is solid, such that it does not conform to the body well; hence it is prone to motion artefacts.

Relevance to healthcare

Although wearable technology is still relatively novel, it has already made a significant impact on healthcare worldwide with the growing ability to monitor serious illnesses such as hypertension, diabetes, and cardiac health.[18–20] The focus of the first wearable devices was primarily related to monitoring fitness and mobility, but improved technology has increased the range of monitorable conditions and capability. Wearable technology is becoming more integrated into day-to-day healthcare activities and becoming more widely accepted by healthcare providers.

Healthcare providers are starting to embrace wearable devices as tools that can remotely deliver care. In 2019 the NHS undertook a pilot scheme to reduce the occurrence of diabetes in high-risk groups. The programme supplied participants with fitness trackers paired with an app where professional advice on healthy choices would be available, with the goal of preventing further illness in the future.

A wearable canine navigation system

Researchers at Imperial College London are developing a wearable canine navigation system that uses an inertial measurement unit to provide low-power offline animal location tracking and activity monitoring.

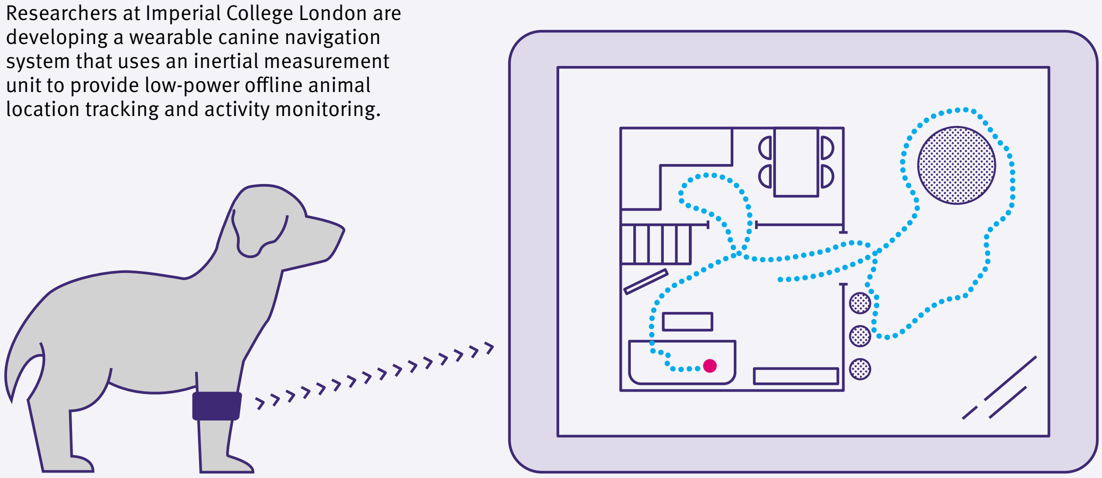


Figure 4: A wearable canine navigation system developed by Imperial College London.

Although accelerometer-based wearable devices provide more in-depth information about the animal's behaviour, tracking information is lost. This means that navigation is limited to the estimated distance travelled (using the number of steps taken), with no information on the location of the animal. Researchers at Imperial College London are developing a wearable canine navigation system that uses an inertial measurement unit (IMU) to provide low-power offline animal location tracking and activity monitoring.

Another example is the NHS providing a continuous glucose monitoring device to certain patients with type 1 diabetes.[21] These examples highlight how wearable devices can aid the global shift for healthcare providers from treating illness when it occurs, to preventing a patient becoming ill in the first instance, saving money and improving quality of life.[22] This shift is expected to continue as the analysis capabilities of wearable technology are improved, and in turn, the potential for improving the health of populations alongside reducing the financial burden of medical care.

Despite the range of wearable devices developed by the main medical device manufacturers, many of which have been FDA approved, their adoption in healthcare remains at an early stage. This is primarily because:

- Wearable devices have mainly focused on measuring the most accessible aspects of physiology – related to cardiac electrical monitoring, blood pressure and pulse.
- Several wearables have undergone proof-of-concept in humans, but still lack the larger clinical studies required to validate their usefulness in a real-life patient population.
- Other contributing factors include slow adoption of novel interventions in medicine generally, lengthy clinical validation process, cost and public acceptability.

Wearables in the hospital setting

Although the need is not as pressing, the mobility of monitoring devices can be advantageous in hospital settings. Examples include patients transferring between departments or undergoing procedures. Monitoring in hospital takes place through fixed continuous cardiac monitors (blood pressure, pulse, oxygen saturation, respiratory rate) in critical care settings, or intermittently through the nursing team in the form of vital signs observations. These instruments are usually non-portable and expensive, but provide high fidelity measurements. Continuous monitoring of patients using

Diabetes

The issue

A good example of how wearable devices are currently improving medical care is with the treatment of diabetes. Diabetes is an illness that is increasing in prevalence to such an extent that it is predicted that 10% of the global population will have the illness by 2045.[23] Constant monitoring of blood glucose is required to keep levels within a safe range.

Conventional methods

Conventional methods require a “finger stick test” to obtain a blood sample for analysis, known as self-monitoring of blood glucose (SMBG). Although effective, adherence to monitoring regimes can be as low as 24% in patients with type 2 diabetes in Australia, Europe and North America.[24] Low patient adherence can be linked to either forgetting to keep up the monitoring regime or actively deciding not to. The latter can be linked to factors such as complexity of measurement, financial constraints, recurring pain incurred from blood sample collection, and scarring from years of repeated sample collection.[25,26]

How wearable technology is currently helping

Wearable technology offers a route to improving adherence through continuous glucose monitoring (CGM). Utilising a minimally invasive device, blood is sampled at intervals of 1–5 minutes and data is presented to the user via a smartphone app.[27] The introduction of CGM allows for more comprehensive reporting whilst removing the obligation of the subject to manage their sampling regime. CGM devices combat a common issue with SMBG whereby fatigue occurs with perpetual testing. It does this by applying CGM technology to automatically signal dangerous glucose levels without patient involvement. Furthermore, CGM can inform the patient of the rate of change of blood glucose, something which SMBG does not do as it only provides a single glucose value per reading. Although CGM devices give the opportunity to improve the analysis of the user’s condition, they still require the initial action of applying the device.

How wearable technology could help in the future

All CGM systems currently on the market require an invasive analysis device and action when prompted, both of which hinder adherence. Current research is focused on glucose monitoring through non-invasive techniques. Simple wearable devices that allow for CGM using minimally-invasive techniques, such as FreeStyle Libre by Abbott, is widely anticipated to improve monitoring adherence. CGM is one example of how wearable technologies has begun improving lives, either by guiding therapy for patients with type 1 diabetes, or guiding diet and lifestyle choices for people with type 2 diabetes.

COVID-19 and infectious diseases

Another important potential use for wearable technology is when a patient has an infectious disease and direct contact with healthcare workers is not desirable. In this scenario, rudimentary surrogate measures of health provided by wearables could be useful for the clinician. This has become much more relevant during the COVID-19 pandemic. One example of how wearables have been utilised by healthcare providers during the pandemic is the use of wireless pulse oximeters to detect early deterioration of COVID-19 patients.[28] Patients are able to remain at home, monitored by the oximeter, which notifies healthcare providers should the patient require hospitalisation. This allows severely ill patients to receive timely medical treatment while reducing contact between infectious patients and healthcare workers.

Lower cost versus lower quality measurements

The downside of using wearable technology, as opposed to more expensive conventional medical devices, is their lower quality of measurements – contributing to false positives and alarm fatigue. However, this could at least in part be solved by the use of big data analytics to infer patient health from a large set of continuous basic physiological measurements. One previous example of this is a study that looked at predicting influenza from resting pulse rate alone.[29]

wearables could benefit in-hospital healthcare by allowing more frequent, mobile monitoring at a lower cost.

For healthcare settings in low- and middle-income countries, the promise of using low-cost wearables to derive actionable information and address staffing issues may also be attractive.

Outside hospital settings

At present, existing wearable devices in routine use in the UK healthcare system typically monitor patients discharged from hospitals in community healthcare settings. Such wearables include:

- 24-hour ECG monitoring (Holter monitors) for arrhythmia detection
- Ambulatory blood pressure cuffs for home monitoring
- Home-based polysomnography devices for sleep apnoea

However, several issues have been identified with these devices:

- Connectivity is an issue – devices have to be brought back and forth to the clinic for data acquisition, or undergo interrogation through specialist devices. Future devices will require a common protocol for data transfer.
- Patient engagement is limited by the technology – there are no readouts on the device; specialist monitoring is required. A notable exception to this is continuous blood glucose monitoring devices, which is largely patient-driven. Chronic diseases (where both patient medical knowledge and engagement are higher) are more suited for wearables use and self-monitoring.

Looking to the future

Wearable technologies have progressed significantly since their conception and their potential is growing constantly with new scientific discoveries and technological developments. The future opportunities presented by wearable technology are multifaceted, from improving personalised care, to assisting medical professionals remotely monitor their patients' disease, and informing users of how their actions affect their health.

How the capabilities of wearable tech are expected to change

Medical devices

One of the biggest advantages of wearable sensors is the production of continuous time series data, providing insights into the behaviour and physiological state of the individual over time. However, as most wearable devices use non-invasive sensors, they are not able to accurately measure most biomarkers.*

The next generation of medical devices is likely to be more invasive and able to give quantitative real-time measurements of biomarkers in point of care settings. Continuous monitoring of a patient's biomarkers could alert care professionals to take immediate and timely action. This would be particularly valuable within intensive care settings where patient health can deteriorate rapidly.

Wellness devices

The next generation of wearable technology will further blur the division between wellness and medical devices due to improved analytical ability. As the capability of non-invasive biosensors improves, it becomes more

[*] A biomarker is defined as "a characteristic that is objectively measured and evaluated as an indicator of normal biological processes, pathogenic processes, or pharmacologic responses to a therapeutic intervention."[30]

The next generation of wearables

At Imperial College London, numerous new avenues to bring chemical and biochemical wearables to their full potential are currently being researched. One example includes employing biochemical engineering and optical outputs to design simple medical devices capable of diagnosing and monitoring medical conditions.[31] These sensors focus on building the next generation of wearable technology.

Injectable sensors

Because most wearable physical sensors are completely non-invasive, it is also not possible to measure important metrics such as the core-body temperature. To solve these problems, researchers at Imperial College London are developing minimally invasive, injectable sensors that can be implanted under the skin to perform measurements inside the body.

viable for wellness devices such as smartwatches to incorporate these sensors into their design. This, coupled with the constant improved medical understanding of the relationship between biomarkers and serious illnesses, will allow the sensors developed to be more precise in their monitoring of disease.

We are slowly moving towards a point where users will have a small chemical lab on their wrist. The ability for them to access the data generated will open opportunities for improving the health of the world's population. These technological advances allow for medical analysis to be incorporated into consumer wearable technology, which

Wireless auscultation of dogs

Researchers at Imperial College London have developed a stretchable wearable device made of a polymer composite which can be used for wireless auscultation* of dogs.[32] The wearable sensor takes the shape of the body and removes air bubbles among the fur to improve the conduction of signals on the contact surface, allowing the recording of heart sounds. Recently, the group have also developed and integrated an additional sensor for monitoring breathing patterns, including sniffing and panting.

[*] Auscultation is the term for listening to the internal sounds of the body, such as the heart or lungs, typically using a stethoscope.

could perform standard medical testing more frequently

Future benefits of wearables devices for low- and middle-income settings

In low- and middle-income countries, challenges exist for healthcare diagnostics and monitoring. Such challenges include cost, access to medical professionals and limited healthcare infrastructure. Wearable devices could:

- Reduce the number of diagnostic tests medical professionals need to carry out manually on patients and make faster and more accurate diagnoses. This would reduce overcrowding in hospitals and lower healthcare costs.
- Advance digital health technologies and digital literacy. A good example of this is the rise in both 4G subscriptions and the consumer readiness index for telecoms and affordability in Vietnam.[33]

However, challenges exist in terms of physical access to wearables. In Vietnam, for example, where the average monthly salary is approximately $265, wearables can range from $30 to more than $300.[33]

and remotely, increasing opportunities for early signalling of health issues.

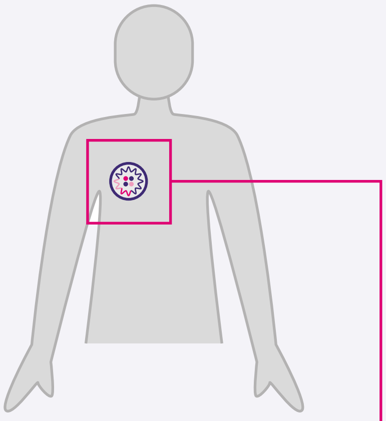
The development of wearable technologies for pets is also expected to expand. This will not only facilitate health tracking for pet owners but may transform other fields in which pets' physiology is exploited, such as the use of sniffer dogs for the detection of explosives. Dogs are the best mobile odour detectors, able to discriminate tens of scents from each other almost instantly. Reducing their training costs (typically around £60k over two years) would allow for the deployment of more dogs in the field. When sniffer dogs detect a target object, such as an explosive device, their heart and breathing rates increase because they are excited to be rewarded for correctly identifying their target. Thus, providing handlers with behavioural and physical analysis of the dogs throughout search and detection tasks has the potential to improve both training time and efficiency.

Chemical and biochemical sensors

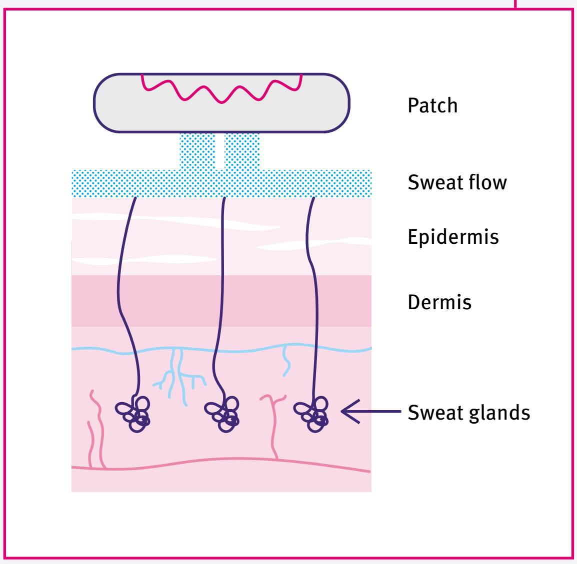
In comparison to wearable devices that contain sensors capable of measuring physical signals as outlined above, wearable devices that use chemical or biochemical sensors have been mainly limited to laboratory prototypes, with the exception of glucose monitoring (e.g., FreeStyle Libre by Abbott).

Wearable chemical and biochemical devices

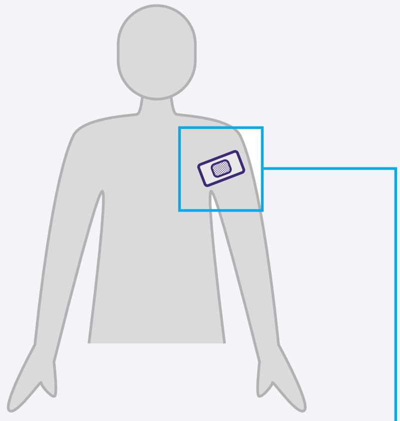
Microfluidic patch



By utilising microfluidic channels these patches non-invasively sample minute volumes of sweat released from the skin. Passing analytes over sensing components probes allows for real time readout of biomarkers such as electrolytes. Sensing mechanisms can be either electrochemical, colourimetric, or fluorescent, able to be analysed via smartphone analysis.



Microneedle patch



Microneedles penetrate the outer layer of skin to gain access to the interstitial fluid. This minimally invasive technique allows for more in-depth analysis of the body homeostasis. Microneedles act as electrodes for simple electrochemical analysis of biomarker concentrations. These patches are worn in a similar way to a plaster and leave little imprint upon removal making them ideal for point-of-care analysis.

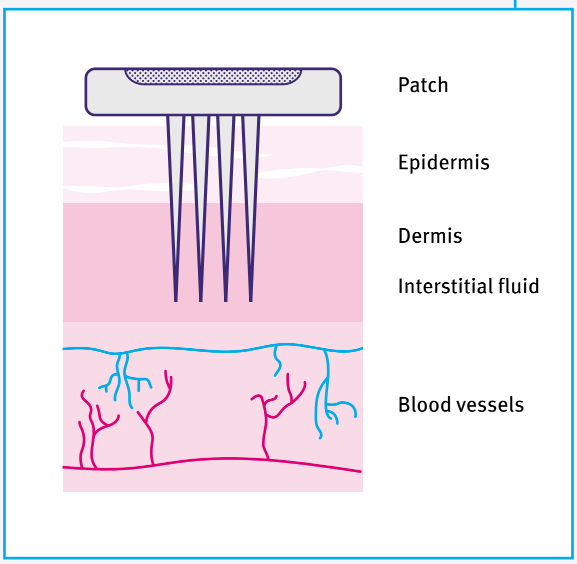
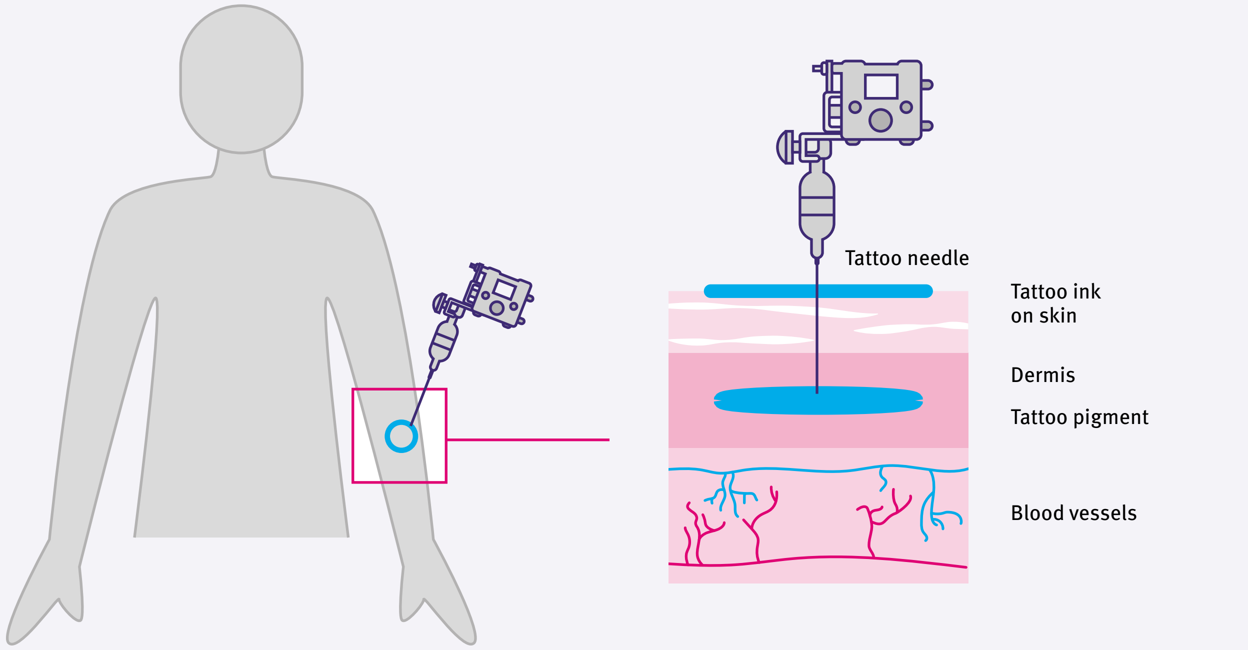


Figure 5: Two common examples of chemical wearable devices and how they work.

There are currently two main approaches to wearable biochemical sensing: 1. non-invasive sweat sensing and 2. minimally invasive microneedle sensors. Sweat sensing can include different modalities such as colourimetric and electrochemical techniques. Microneedle-type sensors, which penetrate only 100s of micrometres under the skin to obtain biological samples, typically utilise electrochemical approaches for performing analytical measurements.

Smart tattoos

The tattooing process



How it works

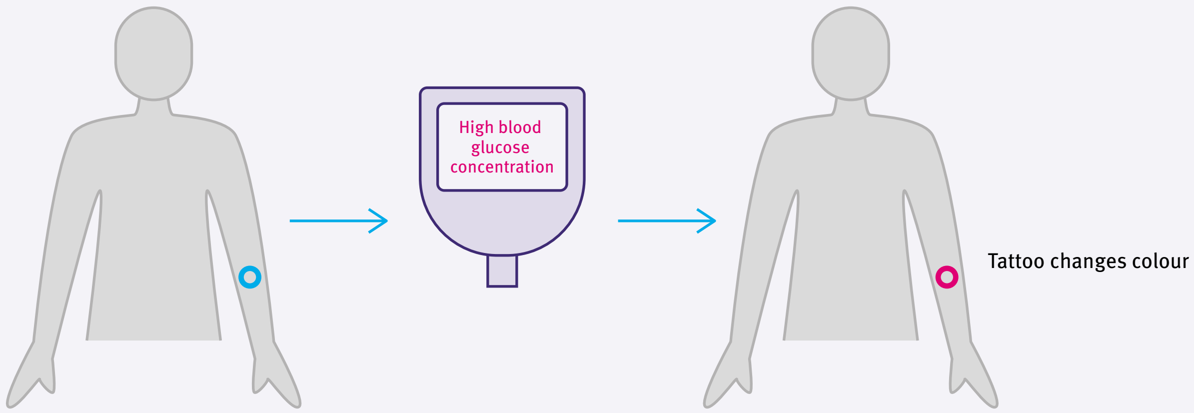


Figure 6: An illustration of how smart tattoo technology works. In this example, the tattoo is able to change colour depending on the concentration of glucose within the blood.

An interesting technique to monitor analytes is smart tattoos. In normal tattoos, the ink is in contact with analyte solution under the skin. By including pigments that are sensitive to changes in biomarkers (such as pH, glucose, ions and enzymes), the tattoo responds to changes in biomarkers by changing colour. This allows simple analysis with the naked eye, removing the requirement for large analytical equipment, improving device portability, reducing costs, and increasing accessibility.

By expanding our chemical and biochemical analysis capabilities of biomarkers such as electrolytes or glucose levels, we can start to build the platform for the next generation of wearable devices, initially analysing more readily available biomarkers.

(Bio)chemical wearable sensing is an emerging area still in its infancy. However, further development is warranted due to the importance of this class of sensors in healthcare, sport and wellbeing.

What are the main barriers to progress?

Privacy concerns

As the internet of things becomes more widespread, the public are becoming more conscious of how much of their life is quantified in data, and may feel uncomfortable with sharing large quantities of personal data collected by wearable devices. This issue is also compounded by the suspicion users have about where their data is going. For wearable sensors to reach their full potential, protecting user information is paramount.

Accurate, non-invasive, measurements

Non-invasive analysis requires the sampling of readily available analytes, such as sweat, tears or saliva. Although these analytes contain valuable information about the user's homeostasis, reliable sampling required for accurate analysis can be difficult to achieve.

To counter this, novel methods of accessing the analytes with simple optical readouts are currently being developed. An active area of research is the utilisation of microfluidic device contact lenses that regularly sample tear fluids, to ensure that samples collected are representative.

Implications for policymakers and regulators

Privacy concerns and public perception

Although wearable technologies hold great promise for medical and wellness applications, issues concerning data privacy are on the rise. In the wellness device industry particularly, there are growing concerns about the improper storage and transfer of user's personal data and how this data is used and protected. Wearable tech largely falls into the "smart device" category, with the vast majority connected to servers that continuously send the data generated from the device back to its parent company. Though this might not appear problematic at first, there are thorny issues concerning invasions of privacy linked to digital traces left behind by each wearer.

Terms & Conditions

Most wellness devices require users to adopt a long list of Terms & Conditions (T&C's), which are seldom, if ever, read due to their length and complexity. T&C's often include clauses about data made available to third parties, such as external commercial companies. Using complex algorithms and a wide range of data from each individual wearer, both parent and third-party companies are increasingly able to deduce not only individuals' physical whereabouts and movements, but also their emotional states – making them the perfect targets for commercial nudges via adverts and marketing. For instance, a study involving researchers from Imperial College London has shown that EEG data can be used to detect stress and anxiety,[34] and when paired with information on web clicks (using a paired smartphone) it can give companies unprecedented ability to nudge individual purchase behaviours. Further research from Imperial College London has also shown that smart devices collect paralinguistic information (such as emotional content[35]) to advertise more efficiently, but academic research is yet to confirm this for wearable devices. A sensor for monitoring breathing patterns – including sniffing and panting – has recently been developed.

Relevance to policymakers

Although there are large differences between companies regarding the value they place on privacy (e.g., Apple vs Fitbit), no current legislation exists to stop commercial companies from collecting data from each user that can be misused. The General Data Protection Regulation (GDPR) framework helps to ensure individuals can trust companies to use their data fairly and responsibly, though the framework has led to a number of poor design decisions in terms of how companies deal with cookies, for instance, thereby impacting usability. Nevertheless, a public perception backlash concerning data misuse via digital technologies is on the rise, with wearable tech falling into that category.

Age-Appropriate Design Code

In the UK, the Information Commissioner's Office (ICO) is beginning to legislate in the digital area. One recent example is the "Age-Appropriate Design Code", which the ICO has been testing since 2020 in collaboration with Dr Nejra Van Zalk in her Design Psychology Lab at the Dyson School of Design Engineering, Imperial College London. From September 2021, companies will no longer be able to collect data freely from children, which will likely drive the need for age-verification in the digital space even further. Companies will also no longer be allowed to collect excessive data, and they will be forced to make the use of cookies or nudging techniques transparent to children and young people. Though this legislation is primarily focused on digital spaces such as social media or websites, it extends to wearable technologies as many have increasingly social elements as part of their design concept. More research is required on how data collection from (primarily) commercial devices is used to provide personalised targeted advertisements. Stronger and clearer policies concerning commercialising data from wearable technologies are also required.

Our recommendations to UK policymakers

Most people are unaware how their data is used due to lack of education or engagement, though when asked, most express a real concern. We recommend:

- Introducing legislation that makes it a requirement for commercial companies to inform the user clearly how their data will be used. Only if the user provides consent can the data then be collected and used for commercial purposes.

Relevance to regulators in the UK

In the UK, the Medicines and Healthcare products Regulatory Agency (MHRA) is responsible for regulating medical devices. If a wearable is not a medical device but is focused on health and fitness, such as in most wellness devices, then it is classed as a consumer electronics device. Whilst consumer electronic devices still carry certain regulatory requirements, such as the "CE" mark in the European Economic Area (EEA), to demonstrate that it conforms with applicable health, safety and environmental standards, they are not as stringent as the regulation for medical devices. However, with the anticipated blurring of what is considered a medical *versus* a wellness device, regulating this already complex field, and licensing devices and software, will become more difficult. In the UK, this complexity has been compounded with the uncertainty surrounding the regulation of consumer devices in the aftermath of the UK's exit from the EU.

Can an app be a medical device?

One good example of the complexity in determining what is a medical or wellness device is the software (including apps) that the device uses. In the US, the FDA has recently announced a programme aimed at ensuring smartphone or tablet apps are of sufficient quality before being made publicly available.[36] In the UK, it is only an official requirement to register apps with the MHRA if it is medical device software. To determine this, the MHRA provides a list of indicative words and phrases which it uses as a guide when considering if medical device software (including apps) should be classed as a medical device.[37] This list includes the terms such as "marker" and "prognosis" as well as generic terms such as "indicates" and "alarms". However, with the anticipated blurring of what is considered a medical *versus* a wellness device, this relatively simple set of definitions will become increasingly obsolete.

Our recommendations to UK regulators

At present, wearable devices are subject to relatively cumbersome regulations, directives and guidance documents. We recommend:

- Due to the fast-changing capabilities of wearable devices, regulation needs to be constantly reviewed and adapted. This should involve a multidisciplinary approach, involving regulators, wearable tech companies and medical professionals working together to provide the safest and most effective solutions.
- Regulation needs to be clear, simple and easy to implement for non-medically trained individuals, such as app developers, to follow.
- Once clear, concise and up-to-date regulation is issued, the MHRA should explore the potential for criminal sanctions for non-compliance of regulation.

How Imperial College London, industry and entrepreneurs can work together

At Imperial College London, we have the interdisciplinary skills, expertise and capabilities to take ideas from concept to reality. With medical professionals highlighting requirements, researchers able to model the interactions, chemists to synthesise compounds and engineers to develop ideas into devices, Imperial is already at the forefront of designing the next generation of wearable devices.

Imperial Enterprise – connecting Imperial with industry

At Imperial College London, we have enterprise in our DNA. We were founded in 1907 with a mission to offer the most advanced education and research, collaborate with other organisations, and apply our work to industry. Today, we offer opportunities to access the expertise of our academics, the talent of our students, our high-tech resources and spaces on our campuses. Together, we can achieve great things in a rapidly changing world. To talk about how you can access Imperial's entrepreneurial ecosystem, contact **enterprise@imperial.ac.uk**, or visit **www.imperial.ac.uk/enterprise**.

With Imperial Enterprise, the Institute for Molecular Science and Engineering is looking to bring researchers from across Imperial together with industry to design the next generation of wearable technology. Imperial's capabilities and activities in this field are outlined below. **You can find out more about the Institute's activities, and how to contact us, on page 19.**

The Hamlyn Centre – designing the next generation of wearable sensors

The Hamlyn Centre, part of Imperial's Institute of Global Health Innovation, is at the forefront of research in imaging, sensing and robotics for addressing global health challenges. The Centre designs new wearable sensors and sensing platforms, along with addressing associated informatics challenges in collaboration with leading companies, such as Intel. Key research activities related to wearable devices include: miniaturised biosensor design suitable for both wearable and implantable devices, biocompatibility and materials to ensure long-term deployment; low-power wireless communication; integrated circuits and systems; techniques to scavenge power from the body; autonomic sensing; and standards and integration.

Academic expertise in wearable sensors

Dr Benny Lo is one of the pioneers in Body Sensor Networks (BSN) research. He has helped build the foundation of the BSN research through the development of platform technologies and the introduction of novel sensors.

Professor George Hanna researches volatile organic compound analysis for biomarker discovery to develop non-invasive breath tests to diagnose oesophageal and gastric cancer.

National Institute for Health Research – a streamlined approach to clinical studies

There is often a barrier in obtaining test data in a clinical trial context. Imperial College London is well placed for development due to its strong links with the National Institute for Health Research's (NIHR's) clinical research facility at Hammersmith Hospital. This opens up a streamlined approach to clinical studies.

Microneedle testing

Professors Alison Holmes and Danny O'Hare in the Centre for Antimicrobial Optimisation at Imperial College London are undertaking a study on microneedle testing for lactate in the first half of 2021.

Examples of startups and companies

Spyras – an Imperial College London led startup

Spyras (www.spyras.com), a startup company spun out of the Güder Research Group at Imperial College London, has developed a technology that analyses breathing patterns using sensors integrated into disposable facemasks. Respiration rate is one of the four vital signs of health, however, it is generally not measured using high-precision instruments. Spyras measures patterns of breathing, and breath biochemistry, which can play an important role in the early detection and monitoring of diseases and inform treatments.[38,39] Real-time respiratory monitoring is also expected to play a growing role in the wellness segment in sport, meditation, and sleep.

Flow Bio – Imperial expertise in industry

The flowPATCH is a wearable, non-invasive patch that captures an athlete's sweat and interprets key bio-markers in real-time, starting with electrolytes and total body fluid loss. This system provides users with personalised recommendations that allows them to improve their performance. Ali Yetisen, from the Department of Chemical Engineering, is the Science Advisor to Flow Bio, the company that developed the flowPATCH.

Educational courses

MRes Medical Device Design and Entrepreneurship

This course combines the development of medical devices and biomedical engineering knowledge alongside entrepreneurship skills. The focus is on the intricate and unique field of medical device development and the key entrepreneurship and management skills required to get the device to market, from concept to business planning and market emergence.

You can find out more about the course at www.imperial.ac.uk/study/pg/bioengineering/medical-device-design-mres.

MRes in Molecular Engineering

Rapid innovation in industry and universities relies more than ever on a combination of engineering excellence and molecular-level science. Students on the course develop the skills needed to work at the interface of science and engineering. This Master's in Research (MRes) programme trains students through a combination of taught modules and a research project with industry. This programme prepares graduates to work in multi-disciplinary teams, in both academia and industry.

You can find out more about the course at www.imperial.ac.uk/study/pg/chemical-engineering/molecular-science-engineering-mres.

Conclusions and summary of key findings

The wearable device industry is rapidly expanding, blurring the divide between medical and wellness devices

- The industry's rapid expansion is predominantly due to health and fitness monitoring, and there is an increasing interest in how this could revolutionise medical care.
- Medical devices and wellness devices are subject to different regulation, with the latter not currently subject to such stringent rules.
- With advances in technology, there is now a blurring of the divide between what constitutes a medical and wellness device.
- We are still discovering the full potential of wearable devices; based on rapid consumer uptake, it is certain that they will become a more integral part of human life in years to come.

We need clear legislation and regulations, following a multidisciplinary approach

- There are growing concerns regarding what happens to personal data once it leaves the wearable device.
- Clear legislation is required to ensure commercial companies inform the user exactly how their personal data will be used, and seek the user's permission to the commercial use of their data.
- Clear, concise and up-to-date regulation is urgently needed for wearable devices. These regulations must be published in a form that can be understood by non-specialist audiences such as app developers. Development of regulations should follow a multidisciplinary approach, involving regulators, wearable tech companies, academia and medical professionals working together to generate the safest and most effective solutions.

Imperial College London is at the forefront of designing the next generation of wearable devices

- With medical professionals identifying applications and requirements, researchers investigating human-technology interactions, and scientists and engineers developing fundamental research into devices, Imperial College London is at the forefront of designing the next generation of wearable devices.
- Imperial is uniquely placed to inform future policy and regulation for wearable technology.

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About the Institute for Molecular Science and Engineering

Founded in 2015, the Institute for Molecular Science and Engineering is one of Imperial College London's Global Challenge Institutes. The Institute brings engineers, scientists, clinicians and business researchers together from Imperial's four faculties to find molecular-based solutions to grand challenges facing our world. By blurring the boundaries between molecular science and engineering, and changing the way scientists and engineers work together, the aim of the Institute is to accelerate the pace of development to address these challenges. The Institute coordinates a range of integrated activities to enable researchers at Imperial and elsewhere to engineer novel products and solutions that are firmly based on advances in molecular science and engineering.

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For more information about this subject, to discuss how the issues covered affect you and your work, or to contact the authors, please email us at:
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About Imperial College London

Consistently rated amongst the world's best universities, Imperial College London is a science-based institution with a reputation for excellence in teaching and research that attracts 13,000 students and 6,000 staff of the highest international quality.

Innovative research at Imperial explores the interface between science, medicine, engineering and business, delivering practical solutions that improve quality of life and the environment – underpinned by a dynamic enterprise culture. Since its foundation in 1907, Imperial's contributions to society have included the discovery of penicillin, the development of holography and the foundations of fibre optics.

This commitment to the application of research for the benefit of all continues today, with current focuses including interdisciplinary collaborations to improve health in the UK and globally, tackle climate change and develop clean and sustainable sources of energy.

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