**IFTEST**

Innovative healthcare solutions with connected healthcare and wearable devices

Could Apple and Google soon also be pioneers in doctors' surgeries and hospitals? The digitalisation of healthcare is in full swing, and many technology companies have understood its potential for a while. The latest playing field in this area is called connected healthcare. The development of medical wearable devices for improved preventative care has been made possible thanks to significant technological progress. Marketing research company Yole Développement, based in Lyon, estimates that the number of wearables sold on the healthcare market will surge from 27 million in 2016 to 94 million by 2022. These include wearables designed for preventative care, as well as approved medical devices.

Asthma	Diabetes	Kardio
300 Mio.	400 Mio.	1.5 Mrd.
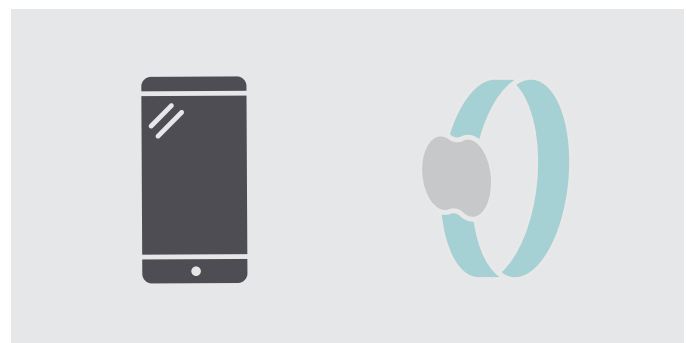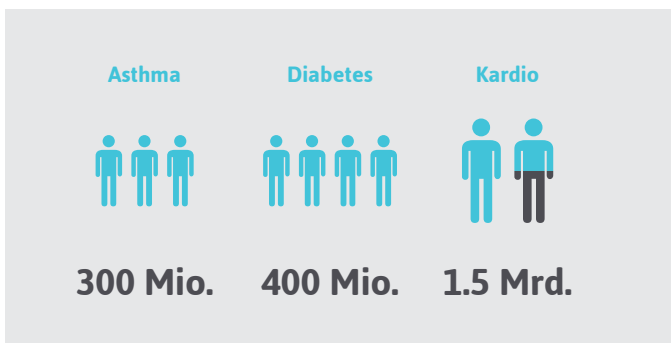
Growing cost pressure in the field of healthcare
Healthcare costs have exploded in all the largest markets, particularly as a result of chronic illnesses.


Digitalisation of healthcare
Thanks to this new form of data exchange, patients and consumers have access to a much greater amount of medical information and have more control over their well being.

Patient empowerment through networking
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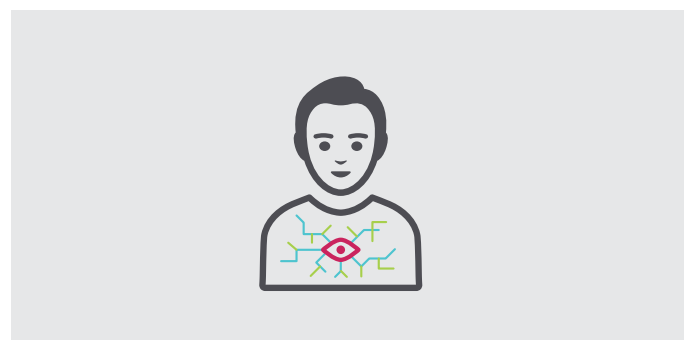
Innovative approaches with wearables
Thanks to new sensor technologies that can be integrated into wearables and networking, completely new innovative approaches to improved healthcare are emerging.
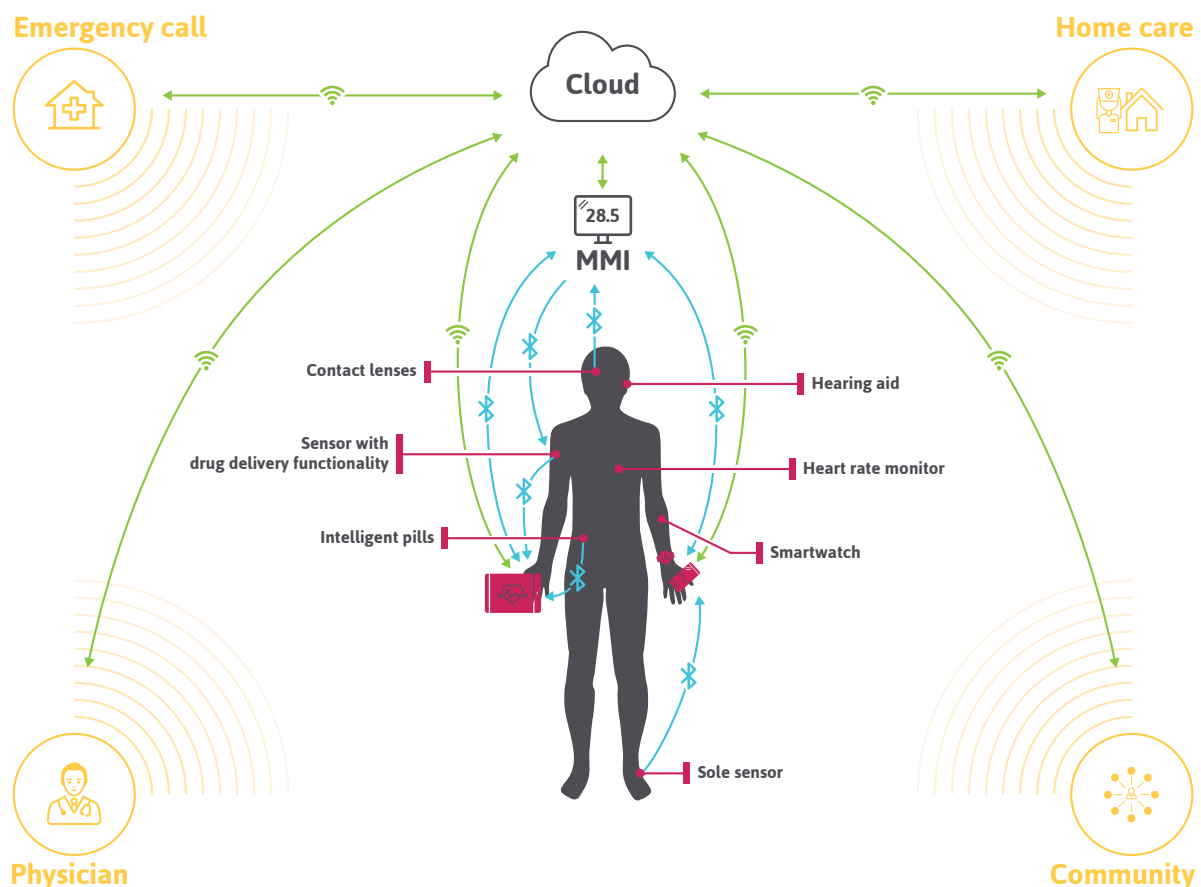
Connected Healthcare

The systematic recording of physiological data and its secure transfer between patients, doctors and hospitals creates entirely new opportunities for overall patient care and healthcare administration.

Wearables currently available on the market cater primarily to the consumer and lifestyle sectors, but the real opportunities lie in medical approval, which differentiate medical wearables from consumer products. Given that the regulatory authorities have stringent requirements for medical electronics, this is a challenge that can be overcome only with the right kind of expertise.

The possibilities for wearables in this segment are endless. The trend is away from purely laboratory diagnostics towards medical products that digitally connect patients with

their doctors, thus opening the door to the area of telemedicine. Further applications that could be made a reality with the help of connected healthcare include wearables with an integrated SOS function that link patients with a homecare professional. This would be a real asset, particularly for older people suffering from dementia.

Another aspect is the growing phenomenon of community building. Patients can be connected with other patients and institutions in order to support one another and gain information.

Wearable Devices

Wearable devices represent the foundation of connected healthcare. These devices are worn on the body and record physiological data in order to transmit it wirelessly to a digital network.

Wearables can generally be divided into four categories:

Head-worn devices, which are worn on the head (e.g. head-up display)

Wrist-worn devices, which are worn on the wrist (e.g. smartwatch, fitness tracker)

Body-worn devices, which are worn on the body (e.g. smart plasters, bandages)

Smart Clothing, which contains a device (e.g. sportswear for recording vital data)

Wearable devices are currently booming on the market, but registered medical products represent the smallest market segment with the greatest market potential.

One of the biggest challenges of bringing medical wearables on to the market is compliance with the stringent regulatory requirements. Approval of medical products requires systematic measurement and extensive documentation of clinical data. This is uncharted territory for technological companies, as requirements for medical products differ vastly from regulations for consumer products. A further obstacle on the path towards successful marketing is gaining approval for reimbursement for the product by health insurance companies.

What is clear is that the performance of wearable devices is constantly improving, allowing for greater functionality within smaller spaces. This lays the foundation for a digital revolution in healthcare, alongside the development of new apps.
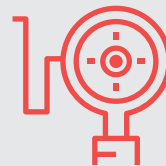
Iftest process for wearable devices

As part of its activities in the design and contract manufacturing of smartwatch electronics, Iftest has developed a manufacturing process that can be used for both wearable devices and connected healthcare. Thanks to this highly precise and fully developed process, Iftest is able to produce thousands of highly miniaturised wearable PCBs daily, which can then be assembled into a wearable device. This manufacturing process is ISO13485-certified, guaranteeing a seamless transition into medical technology.
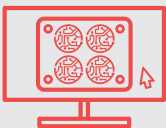
1 Development
Conceptualisation and design of the wearable device (hardware, embedded software) in close collaboration with the customer, based on use case requirements and applications.
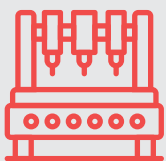
2 Product design
The PCB layout is optimised in terms of design for manufacture, quality and costs with the help of computer-aided design (CAD).

3 PCB production
Manufactured by PCB producers using state-of-the-art methods and scaling effects.

4 PCB assembly
Fully automated assembly of the electronic components on PCBs.

5 Quality inspection of device
Fully automated control and error analysis using automated optical inspection (AOI).

6 Milling of wearable electronic individual pieces
Detachment of individual boards using precise milling separation technology.

7 Wearable device assembly
Assembly of PCB with mechanical components to form wearable device

IFTEST

Iftest Toolbox for development, industrialisation and contract manufacturing of medical electronics

Iftest offers a toolbox that supports clients throughout the entire product lifecycle, from development and production to after-sales service.
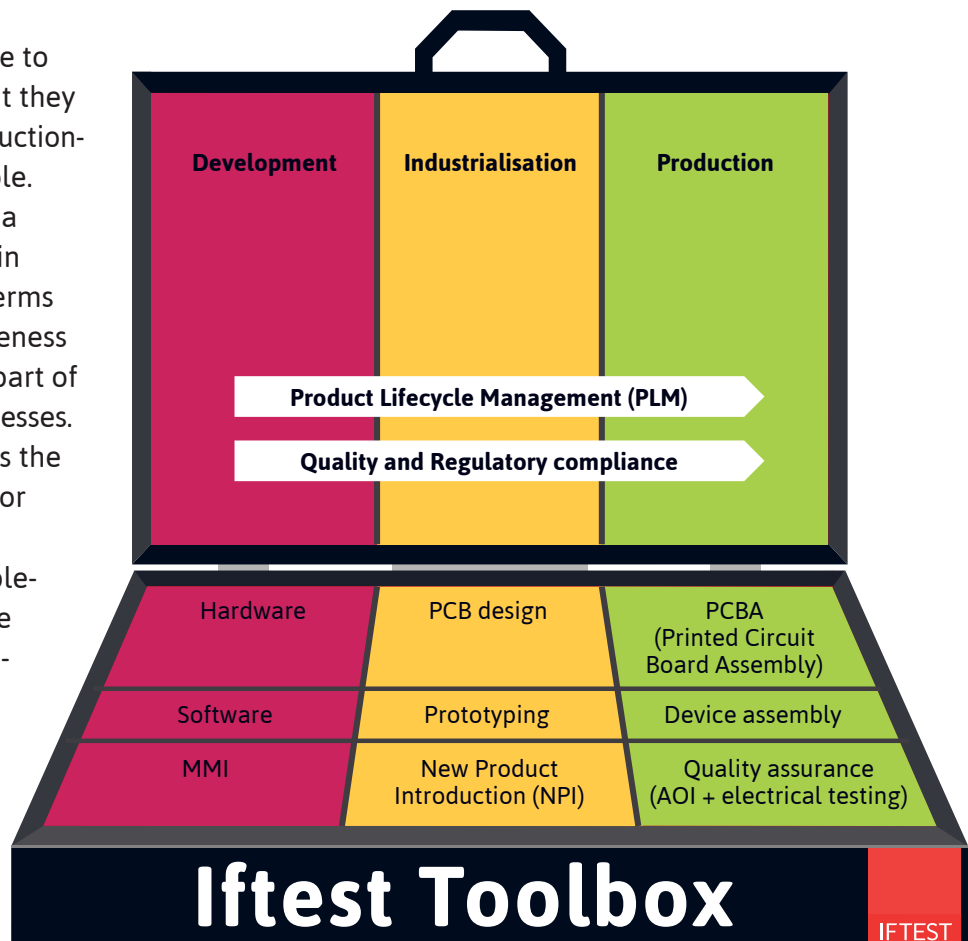
Product development
Starting with development services for hardware and embedded software, Iftest supports its customers at every step of product development, taking into account all applicable regulatory requirements for use on the healthcare market. If necessary, Iftest can also enlist help from its development partner, Centre d'Electronique et Microtechnique (CSEM) in Neuchatel, an expert in the area of sensor technology and algorithms for evaluation and interpretation of physiological data and the generation of clinical trials, with extensive experience in obtaining approvals.

Serial production
Iftest has a great deal of experience when it comes to the manufacture of products in high volumes. During the duration of the project, customers enjoy seamless support from the Iftest customer team, which works hard to ensure quality, smooth logistics and good coordination. The customer is always the focus. All processes are certified according to ISO13485 – production of medical products is standard for Iftest.

Industrialisation
In some use cases, customers come to Iftest with an operating model that they wish to transform into a series production-ready product as quickly as possible. In the context of industrialisation, a redesign is frequently carried out in order to optimise the product in terms of feasibility, quality, cost-effectiveness and logistics. These activities are part of the New Product Introduction Processes. An important factor in this phase is the rapid manufacture of prototypes for verification and validation testing at the customer. Planning and implementation of test concepts and the construction and assembly of electronic test systems also form part of this development stage. Qualification and validation batches are manufactured through to release for serial production.

Development	Industrialisation	Production
Product Lifecycle Management (PLM)		
Quality and Regulatory compliance		
Hardware	PCB design	PCBA (Printed Circuit Board Assembly)
Software	Prototyping	Device assembly
MMI	New Product Introduction (NPI)	Quality assurance (AOI + electrical testing)

Iftest Toolbox

IFTEST

Iftest AG

+ System partner for industrial and
  medical electronics

+ Services
  – Consulting
  – Hardware development
  – Embedded software development
  – PCB design
  – Fast prototyping
  – PCB Assembly: SMT and THT
  – Module and device assembly

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