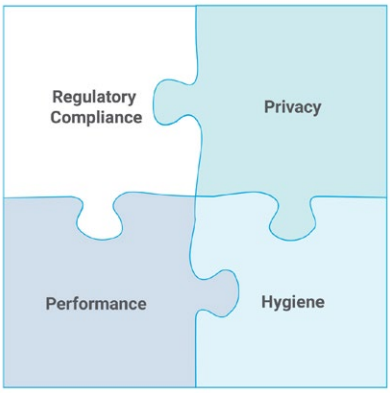
Essential considerations for a medical device for telehealth and remote monitoring applications

Advancements in technology regularly present new opportunities in telehealth for home monitoring of respiratory conditions, helping to ease the burden of long-term care on both patients and medical professionals. Technology or devices used to monitor patients and store or share their health information must be capable of safely and securely completing the tasks required. When an app performs medical device functions, the software platform on which it is hosted must function as intended, or clinically significant results and warnings may be missed.



Why are some mobile apps classified as medical devices and why does it matter?

Regulatory Compliance

The scope of a medical device as defined in the current European Medical Devices Directive includes both devices and standalone software used for a variety of medical applications including the "*diagnosis, prevention, monitoring, treatment or alleviation of disease*" (European Commission, 1993).

The new EU MDR (Medical Devices Regulation), which will replace the MDD in 2024, is similar but not identical. The MDR defines the term "medical device" to include an *"instrument, apparatus, appliance, software, implant, reagent, material, or other article"* including the following uses:

- "Diagnosis, prevention, monitoring, treatment or alleviation of disease, disability, or injury, but not for disability or injury prevention
- Investigation, replacement, or modification of an anatomical, physiological, or pathological process" (European Commission, 2017)

The definition covers a broad range of existing devices, but that's not all. The MDR newly specifies certain types of products that need to obtain a CE marking, including products used to clean, disinfect, or sterilize medical devices, and devices used to control and support conception, whether through pharmacological, immunological, or metabolic means.

While the old MDD essentially served as a manual for how medical device companies could get their CE marking and get to market, the new regulations encourage policies and procedures that elevate the responsibilities of medical device companies for their products throughout the product lifecycle.

According to the MHRA (2014) guidance on standalone software, software that fulfils the definition of a medical device is considered a medical device including relevant smart phone apps. Specifically, where data is collected and processed in some way in order to make some recommendation or diagnosis, a product satisfies the definition. Devices which support a decision (e.g. by calculating heart rate, monitoring the status of a disease or determining what/when medicine is required), are medical devices. In addition, a product is considered a medical device if it is intended as one by the manufacturer. Intention is construed in light of the data supplied by the manufacturer on the labelling, in the instructions and/or promotional materials.

CE marking of a medical device attests compliance with the relevant regulatory requirements ("relevant essential requirements"), which will differ depending on the type of device. Medical devices cannot be marketed in the European

economic area without a CE mark (or CA mark), regardless of the category they fall under. As such, it is crucial to determine whether a certain product amounts to a medical device.

A medical device manufacturer must put vigilance procedures in place in order to ensure that any adverse reactions can be reported.

Approaches to Remote Monitoring Device Applications

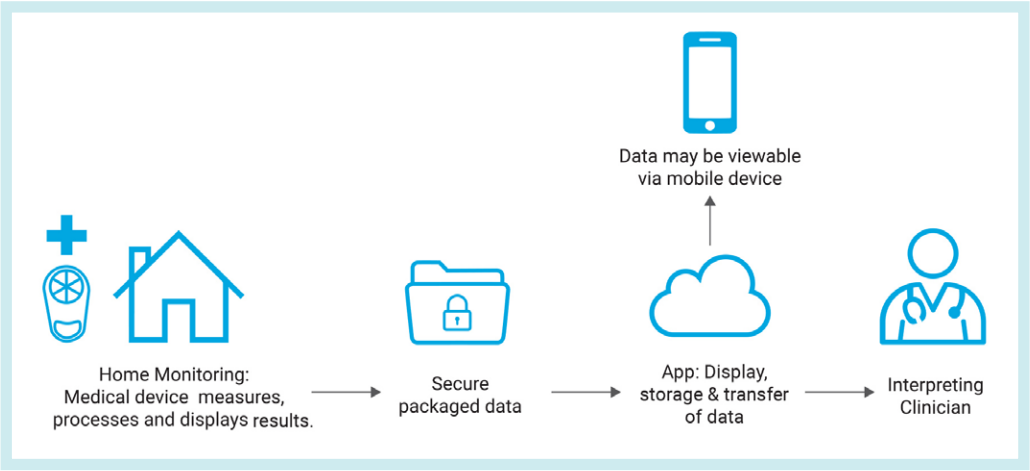
In general, there are two approaches to using telehealth apps in remote monitoring systems.

1. In the first approach, the app is not classified as a medical device because the medical device functionality is completed by the medical (monitoring) device.
2. In the second approach, an app completes some of the medical device functions (e.g. controls the device and/or processes the raw data) meaning that the app becomes a medical device and together with the associated mobile platform requires validation as such. Therefore, where the mobile platform performs medical device functions, the user's own mobile platform should not be used without validation.

Table 1: Functions of Apps for use with remote monitoring devices

Approach 1 : App is not a medical device	Approach 2 : App is a medical device
• App helps your patient to document, show, or communicate potential medical conditions. • App transfers, stores, converts formats, and displays medical device data or results, without controlling or altering the functions or parameters of any connected medical device. **Vitalograph remote monitoring devices use this approach**	• App connects to a device for the purpose of controlling the device. • App connects to the device for the purpose of analysing medical device data. • App uses attachments, display screens, sensors or other similar components to transform a mobile platform into a medical device. • App performs patient-specific analysis. • App provides patient-specific diagnosis. • App provides treatment recommendations. **Each of these functions makes the App a medical device**

Telehealth Approach 1. The app is not a medical device



Telehealth approach 1. The Telehealth platform does not need to be a medical device to transfer, store, view or communicate data to healthcare providers.

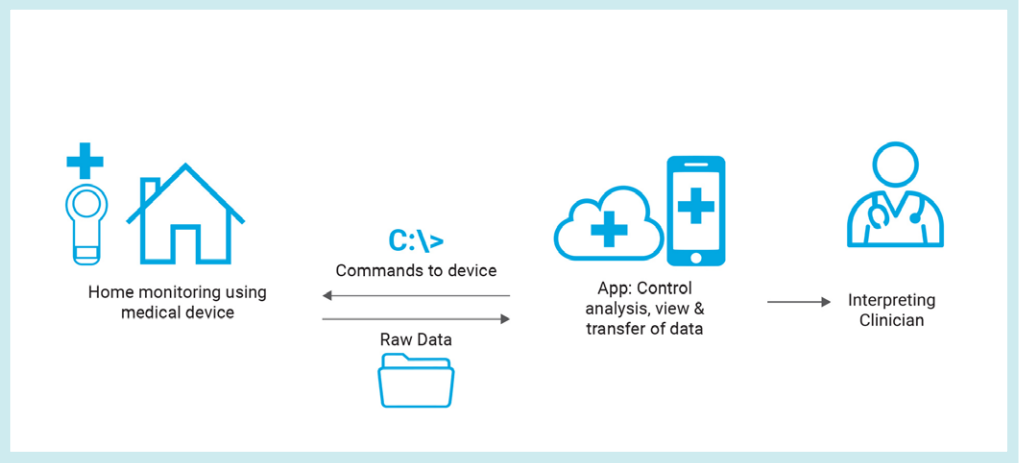
In this approach the mobile phone or tablet app transmits the data but is not required to control the device, make measurements, process or view the results as the medical device completes all these functions. Test results or graphs may be viewed via an app but the primary results (including user personalization where set) are generated on the device itself. A mobile telehealth app is only required to transmit the results to a clinician or cloud-based service although the app may also allow the patient to view and store data.

Having all the medical functionality built into the testing device allows it to be used in a flexible way with the app hosted on any compatible platform.

Vitalograph remote respiratory monitoring and testing devices are CE 2797 marked, class IIa medical devices that may be used with non-medical mobile telehealth applications (apps) developed by Vitalograph or by third parties.

The beneficial result of this approach is that telehealth apps incorporating Vitalograph respiratory monitoring and testing devices can be hosted on any platform without additional medical device validation required.

Telehealth Approach 2. The app is a medical device



Telehealth approach 2. The mobile device, app and any platform that hosts it are medical devices.

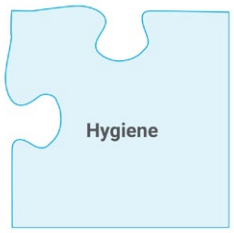
In this approach the device only functions in conjunction with the app, therefore the device and the app running on the host mobile platform are considered to be medical devices.

The advantage of this approach is that the device can be far more basic without the need to incorporate controls, process or view results. The up-front cost of the device may be lower as it harnesses the functionality of the platform hosting the mobile telehealth app.

The disadvantage is that functions carrying patient safety risk become subject to the inherent instability of a mobile platform (for example operating system updates or other apps added to the mobile device). With any addition or update the system will require a risk assessment to assess the potential risks that the mobile platform may pose to the Medical Device App.

Devices that use an app to harness mobile device capabilities as part of the medical device function are in a race to keep up with the inexorable advance of the hardware and software platforms.

Where the app is a medical device, clinically significant results and warnings may be missed by a patient if the platform or telehealth app fails to function as intended.



Hygiene

The degree to which infection control risk can be managed is a very important consideration in mobile medical device technology.

For patient groups with chronic conditions which carry a risk of re-infection, the ability to keep a monitoring device clean is a key concern. For devices used for short-term monitoring or in mobile clinics, it should be possible to provide protection from cross infection without affecting the function of the device.

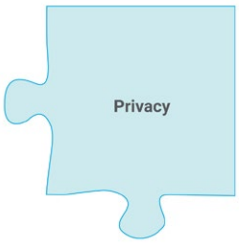
Vitalograph respiratory testing and monitoring devices are designed for use with Bacterial-Viral Filters (BVF). The low cost disposable Eco BVF™ is an example. Using a BVF protects the device from contamination, the patient from cross-infection and other people in the room from aerosolised droplets exhaled during testing.

Respiratory monitoring devices used without an effective hygiene solution allow aerosols and particulate matter to be expelled into the device and surrounding air.

The Vitalograph BVF has been independently validated by testing at low and high flow rates which demonstrated cross contamination efficiency to 99.999% protection from cross infection from all pathogens including Coronavirus.

This means that where a new BVF is used for every test session, wiping the external surfaces of the device with a suitable disinfectant wipe is the only cleaning that would normally be required.

Read the report at https://vitalograph.com/downloads/view/284



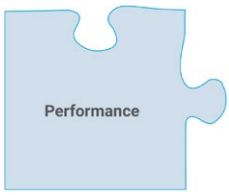
Privacy

Medical devices may collect sensitive health data which is subject to data protection obligations laid down by the Data Protection Directive (Directive 2002/58/EC) and derivative national laws. A mobile telehealth app may act as a transfer medium for test data but, under privacy regulations, the user must have control and give specific and informed consent for whether and where to transfer their results.

Mobile apps used as part of any telehealth solution should employ the highest level of security to ensure that data privacy is always maintained. The user should have complete control over their own data and can choose to share that data securely with whomever they deem appropriate (e.g. their own clinician).

- Access to a mobile telehealth app should be controlled by username and password adding an extra level of security on top of the mobile platform security.
- Data should be stored securely on the mobile platform with access to the data only allowed through the mobile telehealth app with valid credentials.
- Data should not be transmitted outside of the mobile platform unless the user decides to do so.
- If the user decides to share their data with their clinician, they should be able to choose to sign up to a secure cloud based service or secure web portal.
- Communication from the mobile telehealth app should be controlled via secure web services to ensure that privacy of personal data is maintained end to end.
- Any cloud service or web portal should be secured through its own layer of security and with additional user credentials where the user can access their own data in the cloud or decide to allow access to their own registered clinician.

Vitalograph devices transmit data securely, in real time, to the associated mobile telehealth application reducing the need for any personal identifying data to be stored on the Vitalograph device.



Performance

The data results from any telehealth mobile app are only as good as the device or technology used for the actual monitoring and/or testing of the patient.

It is therefore essential that the device is reliable, repeatable, consistent and performs to the required standards.

ISO standards are adopted by national standards agencies, e.g. BSI thus bringing them into national laws. They provide technical specifications to ensure that products and services are safe and effective, i.e. the device performs as expected. (www.iso.org)

The ISO international standards system is intended to ensure that not only consumers, but also regulators and governments can have confidence that products are safe and reliable. The standards are agreed by international panels of experts drawn from users, manufacturers, designers, and technical experts to ensure product safety and performance.

Vitalograph produces respiratory monitoring and testing devices that meet ATS/ERS guidelines and ISO standards (including the mandatory ISO23747, ISO26782) and are audited frequently by regulatory authorities requiring us to provide evidence that all products are designed, manufactured and distributed to the required standard and perform as intended.

Many independent clinical studies have demonstrated the excellent reliability and performance of Vitalograph devices.

Dickens et al (2020) compared the test performance of a Vitalograph respiratory monitor against confirmatory post-bronchodilator spirometry. The results confirmed that the accurate, easy-to-use Vitalograph device offered the opportunity to screen out non-symptomatic patients quickly and easily, saving time and resources in primary care. The respiratory monitor was described as being accurate and particularly useful as a screening device due to its simplicity of use, the minimal number of blows required and the good test performance.

Fujita et al 2020 confirmed that the Vitalograph monitoring device (copd-6) used in their study was “significantly advantageous” and yielded the best detection rates for COPD. Using a reliable and trusted medical device is an essential part of a successful telehealth remote monitoring system and ensures accurate and valid data is recorded.

References:

Council directive 93/42/EEC European Medical Devices Directive, as amended (1993) *Official Journal* L169, pp.1-60.

Council directive (EU) 2017/745 on medical devices (2017) *Official Journal* L117/1.

Dickens, A. P., et al. (2020). “Accuracy of Vitalograph lung monitor as a screening test for COPD in primary care.” NPJ Prim Care Respir Med **30**(1). 10.1038/s41533-019-0158-2.

Fujita, M., et al. (2020). “Handheld flow meter improves COPD detectability regardless of using a conventional questionnaire: A split-sample validation study.” Respirology **25**(2). 10.1111/resp.13602.

ISO, 2019. Standards [Online]. Available at: https://www.iso.org/standards.html (Accessed 30 July 2020).

MHRA (2014). Medical device stand-alone software including apps [Online]. From https://www.gov.uk/government/publications/medical-devices-software-applications-apps (Accessed 18 September 2020)

Vitalograph, 2019.Vitalograph Cross Contamination Report for Bacterial Viral Filters [Online]. Available at: https://vitalograph.co.uk/downloads/view/284 (Accessed 30 July 2020).

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