Guideline

Mobile Devices and 'Apps' in Medical Technology and Hospital IT

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Medical Engineering Division

Mobile Devices in Medical Technology

Mobile devices are generally understood to be portable devices that may be used anywhere, and may have a variety of different functions. Examples are notebook computers, netbooks, smartphones, and tablets. Specially developed software programs, so-called "apps," can be installed on these devices.

Such mobile devices are finding their way increasingly into modern medical practice, where their fields of application among medical professionals are broad:

- Pure data transfer (as a modem)
- Mobile rounds
- Review of ECGs and x-ray images
- Alphanumeric displays
- Diagnostic and therapeutic decision making

Even more rapid is the advance of mobile apps among private consumers, where the number of apps has been growing continuously, and the access thereto has become ever more simple and convenient. The variety in the consumer sector is large, and ranges from cosmetics and fitness-related apps (BMI calculators, UV filter recommendations) to physiological monitoring (temperature, blood sugar, ECG data) to medical apps with diagnostic and/or therapeutic relevance (liver spot diagnosis, medication dosage calculations)

The computational power of tablets and smartphones enables the use of programs that are capable of complex, quasi-intelligent data processing, the results of which can be made available rapidly to a broad audience. The user may get the impression that he/she is receiving the expert knowledge normally reserved for a physician or pharmacist.

Not only the technical implications, but also the legal implications of mobile devices and apps must be considered. Today, application software for mobile devices (apps) can be brought to market quickly and easily. Apps that had no medical functionality in a previous version may, through a small change in functionality, be transformed into a medical device (in the legal sense). This major change in product status often goes unrecognized by app creators/manufacturers and users. App programmers may under certain circumstances become the legal manufacturer of a medical device, and may not understand the legal consequences for themselves or for the users of their app.

This poses particular challenges for both the creators and the users of such apps. A further challenge is that technical advances are shortening hardware and software development cycles, enabling an even larger variety of combinations of hardware, system-software and application software. This may require frequent updating of the user's IT infrastructure, as well as continuing education of its users.

In particular, it may not even be obvious to users, whether the app they are using constitutes a medical device that has been classified and validated (tested and approved) according to the applicable national regulatory requirements.

What must be considered for apps used in a medical context?

The Intended Use of an app (device) determines whether or not it constitutes a medical device, and this Intended Use, in turn, is determined by the manufacturer of the device/app. Article 3 (Definitions) of the Medical Devices Act (MPG) clarifies the legal framework in Germany.

Medical device' means any …. software, ….. intended by the manufacturer to be used for human beings for the purpose of:
a) diagnosis, prevention, monitoring, treatment or alleviation of disease,
b) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap…..

The Intended Use can be set by the manufacturer, for example, by declaring it explicitly in the device's instructions for use. Alternatively, the Intended Use can also be determined from other information provided by the manufacturer, for example, statements made on the distribution platform for the app, or even through the design/appearance of the device/app itself. If inconsistent information about the Intended Use is available from the manufacturer (for example, via different media), both the manufacturer and the user must assume the more critical

application as the Intended Use. For example, an app supposedly intended solely for patient use can become a medical device if the manufacturer's marketing material describes its use by physicians for diagnostic purposes.

So, a device – in general, but also, specifically, software on a mobile device – is a medical device when it falls under the definitions in the MPG. In this case, compliance with all of the requirements of the MPG and its accompanying regulations must be ensured, in order not to act illegally. Users, in particular, medical users must ascertain themselves whether the app they wish to use is also intended for the purpose for which they wish to use it (see MPG, §3 Abs.10, §4).

Although the regulatory requirements for medical devices are largely harmonized within the EU, other countries, for example, the USA, may have different requirements to demonstrate explicitly that a mobile app (on a smartphone or tablet) is suited for a medical purpose.

When is an app a medical device?

In the European Union, medical-device manufacturers must meet numerous requirements. Prior to being placed on the market, each medical device must be subjected to (and pass) a conformity assessment procedure, the purpose of which is to ensure that only safe devices, those without unacceptable risk to patients, users or third parties, are allowed to be distributed. Successful passage of the conformity assessment procedure is indicated to the user/customer by the documented Intended Use and the CE-marking.

It is possible for an app to convert a nonmedical device (e.g. a mobile device) into a medical device. This, at least, is the point of view of the responsible authority for medical devices in the USA, the Food and Drug Administration (FDA).

Depending on the level of patient risk during a malfunction, the mobile device itself can then be part of the Intended Use of the app (not vice-versa) and will be classified accordingly. In this case, the app manufacturer (clearly defined by the FDA) becomes responsible for compliance with all relevant medical-device regulations. This holds for manufacturers from any country if their app is (or can be, for example, by download or internet service) placed on the market in the USA. However, an approval to market in one region, for example, a 510(k) notification in the USA, does not automatically imply an approval for the European Union.

So, how can a user recognize that a given device/app is an approved medical device for his/her region?

- As a starting point, it is recommended to verify that the manufacturer's Intended Use allows/enables the user's intended application.
- Furthermore, the available manufacturer information (on the distribution platform, but also on the manufacturer's website) should be reviewed in order to determine which statements regarding device approvals are available

If in doubt, it is recommended to contact the manufacturer directly to obtain a confirmation of approval for the country in which the app will be deployed. For the EU, a copy of the Declaration of Conformity could be requested before the medical device is first used for diagnosis or therapy.

Compared to the traditional computer, mobile devices, such as smartphones and tablets, have special features that must be considered during the development and use of an app. Depending on the application, the following characteristics may play an important role.

Characteristics	Details / Description	Examples	Risks / Hazards
Mobile device screen/GUI	Matrix size/"Resolution:" determines the amount of information that can be displayed and evaluated simultaneously	Different requirements for different types of information, e.g., diagnostic interpretation of projection radiographic images, 1600 x 1200 or 1:1 pixel representation (from DIN 6868-157:2014-11	Loss of detail visibility in smaller objects, with the danger of overlooking a finding
	Pixel size: determines, together with matrix size, the size of the displayed area	Minimum requirement according to DIN 6868-157 is ≥ 140 µm in both directions. On a smartphone, this value can be around 80 µm or even smaller.	The human eye can visualize the image as a whole, without appreciating the details. Important details may be overlooked.
	Brightness/Luminance and contrast determine, together with ambient light conditions, the visibility of image contents	For projection radiography DIN 6868-157 specifies that display-luminance be ≥ 250 cd/m^2, and contrast (luminance ratio) be ≥ 250:1. Requires special test images and measuring tools.	Inappropriate luminance and/or contrast result in loss of detail visibility
Ambient conditions	Ambient light (e.g., nearby light sources, sunlight) affect the visibility of image contents	Ambient light alters contrast perception and can lead to reflections, mirroring, and artifacts	Loss of contrast perception and potentially incorrect image interpretation
	Visual adaptation: human visual system changes its "operating point" based on ambient light conditions	A change of ambient light conditions causes an adjustment/adaptation in the sensitivity of the human visual system to light	Reduced contrast sensitivity and detail visibility. Potential to overlook image information.
Perception of acoustic signals	Speaker volume control, >On-Off<,	Medical alarm systems' requirement from EN 60601-2-49: 2001: Sound pressure level of the alarm function must be at least 45 dB(a)	A missing alarm can lead to incorrect or delayed treatment
	Perceptibility	Acoustic "reminder" to take medication	An unperceived acoustic reminder can lead to incorrect or delayed treatment.
Wireless connections (WLAN/Wi-Fi, Short-Range Radio, etc.)	Availability	Access to removed files (archives, patient information systems, PDMS)	Missing information can lead to delayed or incorrect diagnosis or treatment
	Stability	Dropouts in the existing network communications	
	Access rights	Access to the required data is denied	
	Bandwidth	Data transmission in emergency situations (Which patient? Which vital signs? When? Where? How?, etc.)	
	Unauthorized access	Access restrictions to data are bypassed	Unauthorized third-party access to confidential data
Use concept	Touch-screens, gesture- or voice-control instead of conventional keyboard and mouse	Operation with (OR-) gloves: the desired information is not displayed or the device does not behave as expected	Missing information can lead to delayed or incorrect diagnosis or treatment

Characteristics	Details / Description	Examples	Risks / Hazards
Design / form factor	Display/touch-screen resistance to disinfectants, dirt, etc.	Surface contamination or damage due to chemical/organic substances	Loss of the desired device function
	Small, portable form factor	Theft, "leaving behind," forgetting	Increased risk of loss
		Damages due to drops and shocks	Loss of the desired device function
Mobile electrical power supply	Device operating time limited by energy available in battery	Simultaneously running applications (e.g., image viewing with a download in the background)	Shortened or no availability in case of an urgent medical need
Data security	Special caution required when handling sensitive personal health information	Theft or loss of device Use in unsecured networks Visualization of sensitive information in public environments	Unauthorized third-party access to confidential data (e.g., deletion, modification, copying)

That an app can lead to a health risk is shown by an event reported to the (German) Federal Institute for Drugs and Medical Devices (BfArM). The app, for iPhones and Android smartphones, placed on the market by a company, calculated incorrectly certain quantities used to make therapeutic decisions (see www.BfArM.de -> Medical Devices-> Field Corrective Actions)

Consequences for Manufacturers (Programmers, Software originators, also software vendors, distributors or manufacturers)

The first step is to define the Intended Use and the functionality of the app in the context of the legal framework(s) in which it will be used. Should the desired functionality lead to the app's classification as a medical device according to the MPG, then all MPG requirements must be fulfilled.

The biggest challenge awaits manufacturers or programmers who, for the first time, desire to move their app into the domain covered by the Medical Devices Act. To start with, they must inform themselves about the current regulatory requirements, quality-, documentation- and conformity assessment procedures, and must integrate these procedures into their own product-development processes. This should happen as early as possible, since the choice of risk-management and risk-reduction processes can have a substantial impact on the choice of development and testing procedures, on the characteristics of the app or on the target systems (smartphones, tablets, operating systems). Under certain circumstances, it may be necessary to start the development process from scratch after the initial risk analysis has been performed.

The MEDDEV guideline 2.1/6, issued by the European Commission, provides useful advice on the determination of whether a given software/app should be considered a medical device or not.

The following checklist for first-time manufacturers of software-only medical devices might be helpful:

- Determination of the Intended Use, from which the corresponding regulatory requirements can be derived
- Determination and procurement of the applicable standards
- Generation of conformity assessment and risk management documentation, device labeling, and the accompanying documentation
- Establishment of a post-market surveillance and adverse-event reporting systems
- Consideration of product liability issues, e.g., §823 German Civil Code, §1 Product Liability Act
- Consideration of the conditions on movable goods, §2 Product Liability Law

Rapid innovation cycles pose a challenge even to established manufacturers. While a software-only medical device may require and work for years with a specific version of an operating system, the app developer is confronted with a multiplicity of operating systems, versions, and form factors. The malware and spyware embedded in some apps, which may not be possible to neutralize on the destination system, pose additional risks that must be considered.

Consequences for users (professionals and lay persons)

Sufficiently validated, safe apps will not always run immediately on the latest mobile devices. Further, medical-device apps may be affected by various other installed apps or exposed to certain risks, for example, those related to data security/integrity.

Medical professionals, such as physicians and caregivers, may not always be aware that in using an app they may be operators of a medical device and, as such, must comply with the Medical Device Operator Ordinance.

Against this backdrop, plug incompatibilities are presumably still the easiest to recognize and resolve.

Consequences for operators (e.g. management, IT-department, biomedical engineering, or purchasing in a hospital)

Professional/clinical operators face numerous challenges. For example, can the use of mobile devices brought by users (BYOD, Bring Your Own Device) be permitted and controlled, such that sensitive or clinically relevant data do not leave the facility or become corrupted?
In this case, known techniques, perhaps already established, such as inventories, user training records, and data security policies can help.

The use of apps may expose users/operators to legal liability claims under tort law (e.g., §823 BGB) or as the consequence of a treatment relationship between a patient and a physician or hospital operator. In a treatment relationship between a physician and patient, the physician has a comprehensive duty to inform, which includes any risks associated with the adjuvant use of a medical app.

A professional user/operator should take precautions, within the context of his/her organizational responsibility, to ensure that no apps are deployed that are not safe and reliable for their intended use. This is especially important in cases where the manufacturer or his EU-Authorized Representative according to the Medical Devices Act cannot be recognized as such.

Written instructions and appropriate controls, as well as the establishment of corresponding internal structures can lead to effective liability prevention

Especially dangerous are apps that have been installed by employees themselves, and that are not known within the organization. If, for example, a program has been downloaded from a foreign country, the question is more than just who is is responsible for the placing on the market of the medical device.

The operator is well advised to examine critically whether his established processes for purchasing, deployment, applications, and maintenance are sufficient to ensure the legally safe operation of mobile devices and apps.

Summary

Clearly, mobile applications will play an ever increasing role in the medical field, for both personal use and professional use in healthcare institutions. There are many reasons for this, for example:

- Faster provision of care
- Large-area coverage
- Often intuitive operation and usable by lay persons

In order to meet safety needs, certain prerequisites must be met, including the classification and evaluation of any app intended for use as a medical device. Users and operators must be aware of these prerequisites, and ask themselves if the desired app is truly suited to their planned application.

Fundamentally, the following holds:

- The legal framework for medical apps is well defined
- All stakeholders must implement these requirements responsibly and diligently

Reference:
"Mobile Medical Applications, Guidance for Industry and Food and Drug Administration Staff" published October 22nd, 2013
http://www.fda.gov/downloads/MedicalDevices/.../UCM263366.pdf

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