Recommendations and Information about regulatory aspects related to the use of hand-held ultrasound devices

Introduction

Nowadays hand-held ultrasound devices are offered by a range of manufacturers and in various designs: there are models with a small monitor and fixed connection to the transducer/s or transducers with external tablet/notebook connected via USB or WiFi. All are battery-powered and require special software for imaging, measuring and image storage. The price of these devices varies depending on the quality of transducer and technical configuration.

Regulatory aspects

Modern hand-held devices are active diagnostic medical devices. The device includes any connected instruments and software necessary for the device's proper application for the diagnosis, prevention, monitoring treatment or alleviation of disease or injury.

Such devices are subject to a medical device regulation - the Council directive 93/42/EEC (1993) in Europe [1] and the national implementation is undertaken under the Medical Product laws of the individual countries [2,3]. The Medical Product laws define a medical product as being "*a separate or connected device, instrument, accessory and software including the manufacturer´s used software for its diagnostic or therapeutic purpose and the device´s proper function*" (§2 in [2,3]).

A special institution, so-called notified body, within Europe certifies if the device is in compliance with these directives before the product is sold by the manufacturer or importer. After a positive evaluation the CE-Mark is given with a 4-digit number to identify this notified body [4].

In the USA medical devices are regulated by the FDA [5]. These regulations classify the application risk of a device and can define upper output limits or output values that have to be displayed by the manufacturer to the users. Additionally information about the compliance with international/national standards concerning general requirements for basic safety and essential performance are required to be stated [6-8].

Legal consequences for hand-held devices

A modern hand-held ultrasound device consists of a transducer, display unit and software for acquisition of data, displaying the images and measurement of other parameters as well as for storing and transferring of image.

That means that all these components have to be in compliance with the laws [1-3]. Therefore the display unit and software are also regarded as medical products, involving some stricter performance requirements for their use in medicine.

In the United States the FDA has started to regulate mobile medical applications in general, i.e. software programs that run on smartphones and other mobile communication devices (e.g. tablets). Additionally these applications can be accessories that attach to a smartphone or tablet, or a combination of accessories and software [9]. The FDA apply the same risk-based approach the agency uses to assure safety and effectiveness for other medical devices. The first hand-held ultrasound devices have received FDA clearance under this regulation already.

Essential declarations

For medical use it is essential that an ultrasound device must
- be shipped with a complete manual,
- be classified by a notified body
  - according to Council Directive 93/42/EEC (for Europe) or
  - FDA-regulated (for USA),
- have a CE-mark with a 4-digit number (e.g. visual as a label on the housing)
- give some output information and
- display *TI*/*MI* values during scanning (thermal (TI), mechanical (MI) index).

Caution:

A hand-held ultrasound device and accessory not having, or shipped without, the information above, may not be used legally for diagnosis nor within medical workshops.

Technical properties

There are no strict international regulations yet for the size of the hand-held device display unit or the necessary properties of the device´s software.
The following technical specifications are relevant for mobile ultrasound devices in order to achieve an FDA clearance statement:

Monitor specifications (FDA):
- display size ≥ 4” (1136 x 640 pixel)
- pixel density ≥ 326 pixels per inch (ppi)
- contrast ratio ≥ 800:1
- max. brightness ≥ 500 cd/m²
- full sRGB colour

Software specifications (selected, FDA):
- text labelling
- display *TI*/*MI* values during scanning
- measurement of distance & area
- gain setting
- TGC setting (at least: near, mid, far)
- depth setting
- data storage

Other aspects to consider for users

Settings:

The number of user-selectable parameters tends to be limited.

Display:

The display tends to be very small (smartphone size) or if using tablet solutions the individual screen resolution (ppi) is not often comparable with monitors routinely used in hospital clinical settings.

Image format:

Many handheld devices store still images or video clips in a PC-based format (jpg, avi, mp4) but not necessarily in DICOM format.

Operation time:

Depending on the battery installed, the operation of the device without recharging can be short (< 1 h) and thus limit the working time.

System requirements:

The processor power and operating system of the smartphone or tablet may be limited and unsuitable to run the transducer and display the ultrasound information. Consequently it is essential, to check the manufacturers´ requirements (e.g. dual WLAN 2.4 GHz & 5 GHz, Bluetooth Vers. 4.1 and later, IOS 9.0 or later; Android 4.4.2 and later).

Warranty:

Most devices have a warranty of one to two years. In case of failures the service quality of the manufacturer is important.

Recommendations

Before purchasing or starting to use a hand-held device make clear that at least

- the device is classified according to the European regulations (CE-Mark with 4-digit number from an European testing center).
- the maximum output data for adjustable imaging modes are given by the manufacturer
- during scanning the actual mechanical (MI) and thermal (TI) values are displayed.

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References

[1] European Commission, Council directive 93/42/EEC (1993) concerning medical devices. http://www.mdss.com/pdf/MDD93_42EEC.pdf

[2] Bundesgesetz betreffend Medizinprodukte (Medizinproduktegesetz – MPG, Fassung v. 12.9.2018, BGBl. No. 657/1996), Austria https://www.ris.bka.gv.at/GeltendeFassung/Bundesnormen/10011003/mpg, Fassung vom 12.09.2018.pdf

[3] Gesetz über Medizinprodukte (Medizinproduktegesetz – MPG, BGBl. I p. 1133) 7.8.2002, adopted 18.7.2017; Germany https://www.gesetze-im-internet.de/mpg/MPG.pdf

[4] European Commission, Single Market and Standards, Notified Bodies, Brussels https://ec.europa.eu/growth/singlemarket/goods/building-blocks/notified-bodies_en

[5] FDA. FDA Basics https://www.fda.gov/aboutFDA/transparency/basics/ucm194468.htm

[6] International Electrotechnical Commission (IEC). IEC 60601-1-2. Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electro-magnetic disturbances - Requirements and tests. International Standard, Geneva.

[7] International Electrotechnical Commission (IEC). IEC 60601-2-37. Medical electrical equipment – Part 2-37: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment. International Standard, Geneva.

[8] International Electrotechnical Commission (IEC). IEC/TR 80002-1:2009 Medical device software – Part 1: Guidance on the application of ISO 14971 to medical device software, Geneva.

[9] U.S. Food & Drug Administration (FDA). Medical Devices – Mobile Medical Application. Website 9.4.2018. https://www.fda.gov/medicaldevices/digitalhealth/mobilemedicalapplications/default.htm#b

Appendix :

For European markets:
The Council directive 93/42/EEC (1993) includes a classification scheme (Article 9) and medical products must be in compliance with it to get the CE-mark. Class 1 and Class 2a are in general used for ultrasound devices. The higher the class the higher the potential risk; Class 2 b and Class 3 are high-risk devices.

For USA market:
The FDA regulates the medical device products and there are different classification schemes [1]:

FDA-listed:
A medical device is FDA-listed if the firm that manufactures or distributes the medical device has successfully completed an online listing for the device through the FDA registration system

FDA-(510k) exempt:
Medical devices that do not require FDA review before the devices are marketed are considered "510(k) exempt." These medical devices are mostly low-risk, Class I devices and some Class II devices

FDA-Cleared:
These medical devices are ones that FDA has determined to be substantially equivalent to another legally marketed device. A premarket notification, referred to as a 510(k), must be submitted to FDA for clearance.

FDA-approved:
Approved medical devices are those devices for which FDA has approved a premarket approval (PMA) application prior to marketing. This approval process is generally reserved for high-risk medical devices and involves a more rigorous premarket review than the 510(k) pathway.
The derated global maximum acoustic output should not exceed: spatial peak temporal averaged intensity $I_{spta} \leq 720 mW/cm^2$, mechanical index $MI \leq 1.9$ or derated spatial peak pulse averaged intensity $I_{sppa,\alpha} \leq 190 mW/cm^2$.