Telemedicina 2018

Diagnostické monitory, klasifikace a třída zdravotnického prostředku

Classification of Medical Device, relevant class for diagnostic displays

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Which criteria determine the class of a medical product?

The most important criterium is **intended use** of the medical product;

What is intended use?

Intended use = what you say on the label that the device is to be used for;

Example: monitors can be used for different purposes:

(A) Secondary viewing of medical images by any medical practitioner;

(B) Primary or direct diagnosis done by radiologist;

Active devices for diagnosis and monitoring are class II

EU Directive 2017/745, Rule 10, third paragraph:

„Active devices intended for diagnosis and monitoring are classified as class **IIa**:

- if they are intended to allow **direct diagnosis or** monitoring of vital physiological processes, **unless** they are specifically intended for monitoring of vital physiological parameters and the nature of variations of those parameters is such that it could result in immediate danger to the patient, for instance variations in cardiac performance, respiration, activity of the central nervous system, or they are intended for diagnosis in clinical situations where the patient is in immediate danger, **in which cases they are classified as class IIb**."

- Nowadays more than 50% of applications is already functional (physiological);

- Some examples of vital physiological processes in radiology:

  Nuclear Medicine: PET/SPECT;

  Contrast Enhanced: CT/ MRI (breast, brain, prostate), PET, SPECT, US;

  US: doppler (cardiac, blood flow);

  Elastography (US): breast;

Why is it important to refer to the certain type of PACS?

Generally speaking there are various types of PACS:

(a) PACS used for viewing, archiving and transmitting images.

(b) Where the post-processing of the image for diagnostic purposes is such as:

- **image processing functions which alter the image data** (e.g. filtering, multiplanar reconstruction, 3D reconstruction);

- **complex quantitative functions** (e.g. arterial stenosis evaluation, ventricular volume calculation, calcium scoring, automatic indication (detection) of potential lesions;

(c) with image enhancing by controlling image acquisition.

Note: ***quantitiative functions*** *are also Standard Uptake Values (SUVs) or blood absorption levels.*

Why is it important to refer to the certain type of PACS?

In cases where the PACS falls under the definition of a medical device, *i.e.* is specifically intended by the manufacturer to be used for one or more of the medical purposes set out in the medical device definition, the following situations can be foreseen:

(i) In relation to **PACS (a)** intended by its manufacturer to be used for viewing, archiving and transmitting images, it is considered that applying rule 12 could be appropriate and accordingly this type of PACS **are generally classified as Class I medical devices**.

(ii) Those types of **PACS (b)** which drive a device or influence the use of a source device fall automatically in the same class in accordance with implementing rule 2.3, **which classifies them as Class IIa or IIb**. If this type of PACS does not drive or influence the use of the source device, this type of PACS can be classified under rule 10 if such PACS are intended to allow direct diagnosis, **classifying them as Class IIa**.

Why is it important to refer to the certain type of PACS?

(iii) PACS with image enhancing by controlling image acquisition **(c)** should fall into the same class as the source device. This is based upon, firstly, implementing rule 2.3*"Software, which drives a device or influences the use of a device, falls automatically in the same class*." and the last paragraph of MEDDEV 2.4/1 - rev. 8, Section 3.2 stating that: "*Standalone software, e.g. software which is used for image enhancement is regarded as driving or influencing the use of a device and so falls automatically into the same class. Other standalone software, which is not regarded as driving or influencing the use of a device, is classified in its own right*". Applying this classification rule and the interpretation of the MEDDEV allows this type of PACS **to be classified as Class IIa or IIb** medical devices according to the classification of the device itself.

Source:

MANUAL ON BORDERLINE AND CLASSIFICATION IN THE COMMUNITY REGULATORY FRAMEWORK FOR MEDICAL DEVICES
Version 1.18 (12-2017)

Medical monitors are integral part of diagnostic workstation

- Monitors are not stand alone devices, they are provided as part of workstations that are intended to display diagnostic images, as such the display is an integral part in the decision chain to come to a diagnostic conclusion.

- If you look at the whole chain from x-rays that are delivered to a patient, resulting in an image, that gets processed by a viewing software and gets transferred to a display where it gets converted into visible light, which strikes the eye of the radiologist, who's brain makes a diagnostic decision, each of the parts in the chain contribute or might alter the diagnostic conclusion and is therefore subject to the MDD device regulation, a wrong conclusion can result in a safety hazard for the patient.

- According to DICOM and other standard directives, the conversion from the processed image into visible light should be done in a very specific way (specific curve, specific brightness, contrast, ambient conditions, etc.).

- Monitors being a part of a diagnostic imaging chain are supposed to have the same class as the other devices and software in the imaging chain – if you allow the diagnostic monitors to be class I while the other parts of the chain are class II, the entire chain breaks;

Free sales certificate imposes compliance with EU directive

The FAGG (Ministry of Health) document is in Dutch.

From: Bauwin Philippe [mailto:Philippe.Bauwin@health.fgov.be]
To: Carrein, Geert
Cc: Users_DG3_MedicalDevices
Subject: RE: tav Mr Philippe Bauwin

"Voor wat betrfet uw schermen , als ik uw brochure lees het is helemaal duidelijk dat uw schermen en de software die daarmee geleverd wordt medische hulpmiddelen zijn maar zeker niet classe I : het zijn actieve medische hulpmiddelen voor diagnostiek en volgens de Meddev guidelines en het gebruik beschreven in uw brochure en de meddev guideline regel 10 zouden zij in classe IIb vallen "

Translated it means:

"For what concerns your displays, when I read through the brochure it is perfectly clear that your displays and the software that is delivered with it , **are medical devices but definitely NOT class I**
These are active medical devices used for diagnostic and according to the MEDDEV guidelines and the intended use as described in your brochure, **MEDDEV guideline 10 puts them in Class IIb**"

Barco provides medical monitors with class I and class IIb

FAMILY	**EU_CLASS**	Rationale	FDA_CLASS
Clinical Review/Eonis	**I**	Rules 1 and 12	I
Nio	**IIb**	Rule 10 Active devices intended to emit ionizing radiation and intended for diagnostic and therapeutic interventional radiology including devices which control or monitor such devices, or which directly influence their performance, are in Class IIb.	II
Nexxis OR	**I**	The Nexxis products do not perform a medical function as defined in the definition of a medical device, according to MDD and FDA. However, the Nexxis OR is specifically designed and intended by Barco to work with medical devices to enable them to be used in accordance with their intended use. As such, Nexxis OR is n the scope of the medical device regulations. according rule 1 & 12; class I.	II
Mammo	**IIb**	Rule 10 Active devices intended to emit ionizing radiation and intended for diagnostic and therapeutic interventional radiology including devices which control or monitor such devices, or which directly influence their performance, are in Class IIb.	II
Coronis	**IIb**	Rule 10 Active devices intended to emit ionizing radiation and intended for diagnostic and therapeutic interventional radiology including devices which control or monitor such devices, or which directly influence their performance, are in Class IIb.	II
Surgical Displays	**I**	Rules 1 and 12	I
Dentistry	**IIb**	Rule 10 Active devices intended to emit ionizing radiation and intended for diagnostic and therapeutic interventional radiology including devices which control or monitor such devices, or which directly influence their performance, are in Class IIb.	II

Barco provides medical monitors with class I and class IIb

Clinical review (including Surgical)

Class I

Diagnostic Imaging (including Mammo)

Class IIb

Final indications for use of medical monitors class I & IIb

- If they are class IIb it means that in any clinical application the monitors will always fulfill the existing regulatory standards and boarderline requirements, also when they are combined with other components of the imaging chain certified as class IIb;

- In case of products with class I it is important to keep in mind the following:
  - They **cannot be used for**:
    - **direct diagnosis** and/or **monitoring of physiological processes** (as indicated in EU Directive 2017/745, Rule 10;)
  - They **can only be used for review of morphological data** (after initial diagnosis on class II device), **excluding**:
    - diagnosis in clinical situations where the patient is in immediate danger,
    - monitoring of vital physiological parameters when the nature of variations of those parameters is such that it could result in immediate danger to the patient,
    - any image processing functions and/or quantitative imaging techniques,
    - when PACS drives a device or influences the use of a source device,
    - when PACS is controlling image aquistition.

What is the impact of class IIb certification?

- Higher and more stringent requirements in documentation and quality system (processes and procedures) controlled by an independent Notified Body:
  - Yearly audit
  - Re-certification audit every 4 years
- Ability to execute processes that allow recall of the product from the market in case of product related issues and/or any type of patient hazard;

- **Conclusion:**

- **The rules are very clear and as such they directly impact patient safety – those who do not comply are responsible for any risk to the patient;**

- **BARCO didn't create those rules and we did not create our own interpretation, authoritites told us what to do and we simply need to comply with it (we are also watched by those authorities);**

- **For applications in diagnostic or therapeutical radiology, Class IIb certification is a must !**

ENABLING BRIGHT OUTCOMES