Approval of medical devices with radio

The requirement for EMC risk considerations for medical devices is evident in the harmonised standards. But how do these risk considerations work in conjunction with the performance requirements for radio equipment, and how are tests best optimised to ensure compliance with the Medical Device Directive and the Radio Equipment Directive when dealing with medical devices with Bluetooth, Wi-Fi or other built-in radios?

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Manufacturers of medical devices with built-in radios must ensure and declare that their equipment meets the requirements of both the Radio Equipment Directive (RED) and the Medical Device Directive (MDD) DIR93/42/EEC. In May 2020, the latter will be replaced by the Medical Device Regulation MDR2017/745. But the combination of requirements from two worlds that handle compliance fundamentally differently provides high complexity in test planning.

Essential requirements must be respected

For companies that are accustomed to manufacturing medical devices, the essential requirements of RED will be very limited in number. Luckily, there is a good synergy between the directives at the directive level.

RED essentially has three essential requirements:

- Article 3.1(a): (...) Safety persons and of domestic animals and the protection of property (including the objectives set out in the Low Voltage Directive, but with no voltage limit applying).
- Article 3.1(b): an adequate level of electromagnetic compatibility as set out in the EMC directive.
- Article 3.2: Effectively uses and supports the efficient use of radio spectrum in order to avoid harmful interference.

The essential requirements are typically met by the application of well-chosen harmonised standards, which the equipment through testing and assessment is determined to comply with. At this overall level, it is

convenient that compliance with Article 3.1(a) and 3.1(b) of RED can be observed by applying the tests of electrical medical devices known from EN 60601-1 (safety) and EN 60601-1-2 (EMC). Thus, only Article 3.2 is added concerning the authorisation of non-radio electrical medical devices. Or so it appears when you only look at the surface.

Digging deeper, you realise that the addition of a radio in a medical device has implications for both for the risk management and for what to look for during testing – the appliance's performance criteria. Careful planning of the testing of a medical product with radio is required, so that all relevant functions are monitored simultaneously and adequately, not to have first to test the compliance with MDD and afterwards test again to ensure compliance with RED.

Testing for EMC is not straightforward

When testing for electromagnetic compatibility, it is not possible to test for the combined requirements from MDD and RED. If the equipment has a built-in radio, it is necessary to reduce the pass criteria for the medical part. And this is always the case, as the adding of radio gives rise to the definition of several performance criteria and considerations of these in the risk management file of the equipment (typically prepared according to ISO 14971 for medical devices).

To monitor the issue, it is pivotal to know how to ensure compliance with the standards methodology for the establishment of performance criteria. In the EN 60601-1-2 standard, that deals with electromagnetic compatibility for medical devices, the concepts of Essential Performance and Basic Safety are used. In EN 60601-1 ed. 3.1 (which is the mother standard of EN 60601-1-2), these concepts are described as follows:

- 3.10 * BASIC SAFETY

Freedom from unacceptable RISK directly caused by physical HAZARDS when ME EQUIPMENT is used under NORMAL CONDITION and SINGLE FAULT CONDITION.

- 3.27 * ESSENTIAL PERFORMANCE

Performance of a clinical function, other than that related to BASIC SAFETY, where loss or degradation beyond the limits specified by the MANUFACTURER results in an unacceptable RISK.
NOTE: ESSENTIAL PERFORMANCE is most easily understood by considering whether its absence or degradation would result in an unacceptable RISK.

The Basic Safety criterion means that no physical danger may arise as a result of a single fault during normal operation of the equipment. A physical danger could be, for example, that the equipment moves unintentionally or catches fire because an electronic component ignites. Many consider the Basic Safety to be the least complicated of the two performance criteria.

The Essential Performance criterion is about maintaining that part of the equipment's clinical functionality, where it is associated with an unacceptable level of risk, should this functionality fail. That is, keeping track of all the functionality other than the clinical is not required, and keeping track of clinical functionality, which entails acceptable risk when failing is not even required.

Understand the concept of clinical functionality

The intended use of the equipment determines clinical functionality. It may well be complex to do as the standard prescribes – namely to define in the risk analysis what is acceptable and what is unacceptable if it fails.

An example of a common understanding of the acceptable failure of clinical function is, for instance, if a hearing aid does not amplify the sound. A case of unacceptable absence is, for example, if a heart-lung machine fails to function. It is also stipulated that the manufacturer must assess the risk of failure or degradation of functionality beyond the values specified by the manufacturer.

The environment determines the EMC test levels

The levels at which EMC are to be tested are specified in the current version of EN 60601-1-2 (ed. 4) based on the environment in which the equipment will operate. This can be a home environment, clinical or special environments such as ambulances or in aircraft.

Many people mistakenly believe that it is permitted to define your non-special environment, such as a clinical environment with lower levels of ESD (electrostatic discharges) than in a normal clinical environment. It is not!

Failure to comply with the standards definitions of test levels in a predefined home or clinical environment means that by definition, you are in a special environment. In special environments, risk analysis is required for both test levels, the tests to be conducted, and the extent of these tests. Thus, a significant increase in the number of issues to be addressed in the electromagnetic compatibility section of the risk analysis.

The performance criteria under RED

When assessing radio appliances (which, after all, must comply with RED), the performance criteria are viewed quite differently. As regards the EMC requirement, RED is concerned with ensuring durable radio communication, taking into account the operation of other appliances. Not as MDD, which is concerned with hazards.

For radio appliances for use within the EU, most standards – Including for EMC testing – have been prepared by the organisation ETSI. Here the concepts of Continuous Phenomena, "CP" and Transient Phenomena, "TP" apply. Thus, we are dealing with the performance of the appliances when we address EMC performance criteria – not the appliances' safety to people.

In the ETSI standards, the manufacturer is asked to define the parts of the radio appliance's function that must function without being affected by CP and to define the parts of the function of the equipment that must function without being affected by TP in regard to transmitting and receiving operations as well as the other performance of the equipment. This is illustrated in Figure 1.

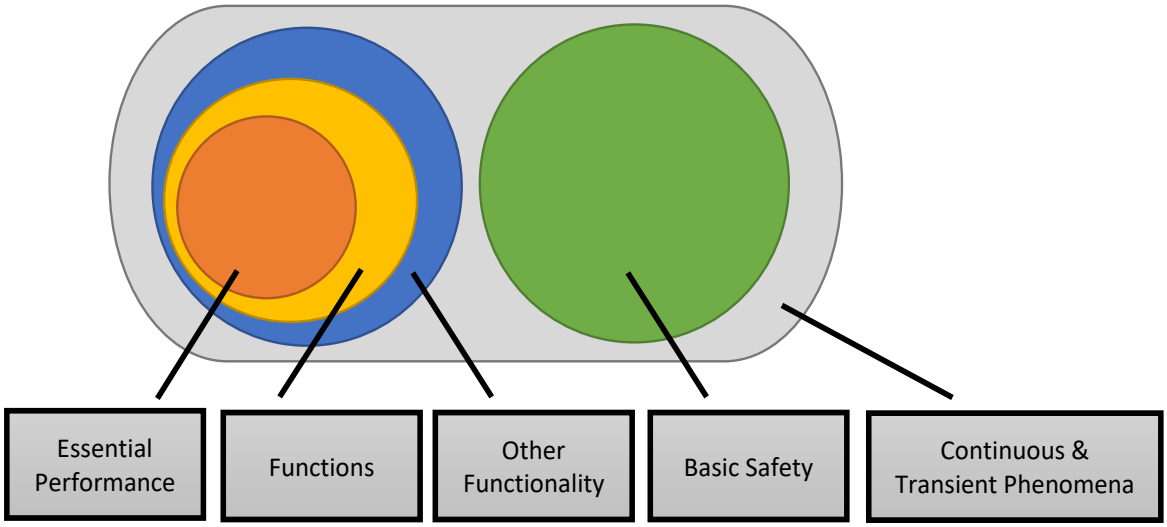

Figure 1: Performance criteria to be defined by manufacturers of medical devices with radio.

Explanations for Figure 1:
Essential Performance: The subset of performance where it is subject to unacceptable clinical risk if the performance is failing or degraded.

Functions: The functions required to perform the intended use (Intended use), but not other functions.

Other functionality: The functions of the medical device, which are neither Essential Performance nor Functions, but which are to be monitored during testing.

Basic Safety: The incidents that may not occur as they are considered unacceptable risk (catches fire, starts by itself…). Also, basic elements such as electrical insulation must be proper.

Continuous & Transient Phenomena: Concepts of affecting phenomena. The impact of both phenomena on all functions must be defined, as what may and may not happen during testing must be described. This must be done within the definitions of CP and TP, as set out in the ETSI standards.

When to do EMC test?

One can rationalize that a medical device does not always have Essential Performance. This applies if all clinical function is acceptable to fail if the equipment fails – for example, during EMC testing.

For equipment that is so simple that even Basic Safety - according to the manufacturer's risk analysis - cannot be compromised during EMC testing, there is really no reason for EMC testing for immunity, and the manufacturer can, in principle, try to convince its Notified Body of the adequacy of this strategy. However, when introducing a radio into the equipment, according to RED, it is required to test and monitor 'everything' defined to a sufficient level of operation.

Complexity arises in particular when the radio function of a medical device is considered to be associated with an unacceptable risk to the clinical functionality if the radio function fails or degrades. But no matter what, individual product EMC-related risk analysis will always be required to determine the performance criteria to comply with both MDD and RED.

Facts:

- EMC: ElectroMagnetic Compatibility is a term that describes the ability to co-exist without interference between electronic devices.
- RED: Radio Equipment Directive DIR2014/53/EU. According to the directive, all equipment intentionally emits and/or receives radio waves for the purpose of radio communication (...), defined as radio equipment and thus subject to the directive.
- The types of equipment not covered are listed In Annexe 1 of the RED. Medical devices are not listed in Annexe 1. Therefore, manufacturers of medical devices must ensure and declare conformity with both the RED and the Medical Device Directive DIR93/42/EEC.
- MDD: Medical Device Directive DIR93/42/EEC. In May 2020, MDD is replaced by the Medical Device Regulation MDR2017/745.

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