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Dealing with medical systems – a device based approach

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Abstract: Medical device systems are often created out of combinations of equipment and accessories where no contracts or agreements exist between different parties, creating a degree of confusion and inconsistency about how regulatory standards and system specifications should be met. There is a natural and well intentioned bias towards system tests as the most reliable solution, but on careful review these do not meet regulatory requirements and can mask the need to develop appropriate specifications for the individual medical device. This article outlines the correct, legally sound approach for compliance, explores the mystery of system testing, as well as practical implementation and related issues.

Basic interpretation

Compliance with product standards such as IEC 60601-1 is based on a "type test", which is defined as a test on a sample representative of regular production[1]. During development, many tests are performed on samples, prototypes and as part of larger systems, however in a regulatory context these reports are meaningless unless the results are representative of the actual marketed device.

For a result to be representative, the manufacturer also needs to apply controls in design and production, such as the appropriate selection of discrete parts, consideration of tolerances, expected variations, production adjustments and tests. Thus for a result to be representative, and hence a *type test*, involves significantly more than sending a sample to a test laboratory and receiving a positive result.

A judgement on being *representative* is rarely documented and in practice is implicit by the action of including or referencing a report in a regulatory file. Even so, the need for results to be *representative* of the marketed medical device is at the heart of regulatory compliance, and it is a mandatory requirement in IEC 60601-1.

This *representative* aspect takes on a special focus in the case of medical systems. Medical electrical systems are frequently formed using one or more items of equipment[2] together with accessories such as sensors, electrodes, cables, catheters, infusion sets, syringes and so on. In many cases different parts of the system are made by different manufacturers and there is no contract, agreements or even contact between the parties.

By definition[3], it is *not* possible to provide a *type test* report on the *system*, because the manufacturer of one component in the system cannot know or be responsible for ensuring that the results are *representative* for other components in the system.

Equally, it is not possible to provide a *type test* report on a individual medical device if the test report is based on *system tests* where compliance is influenced by other parts of the system, again because

[1] IEC 60601-1:2005/A1:2012, Clauses 3.135 and 5.1
[2] In this document "equipment" refers to a powered device (mains or battery)
[3] It is possible to prepare a test report on a system, but this report cannot be referred to as a "type test" and therefore has no role in the IEC 60601 series nor suitable for regulatory applications.

the manufacturer of the subject medical device cannot know or be responsible for the tests being *representative*.

Instead, the only legitimate solution is for a *type test* to be performed on a subject medical device against specifications developed *for that device*. If the device is intended to be used as part of a system, then in preparing the device specifications, designers should take into account each discrete system specification in one of three possible ways:

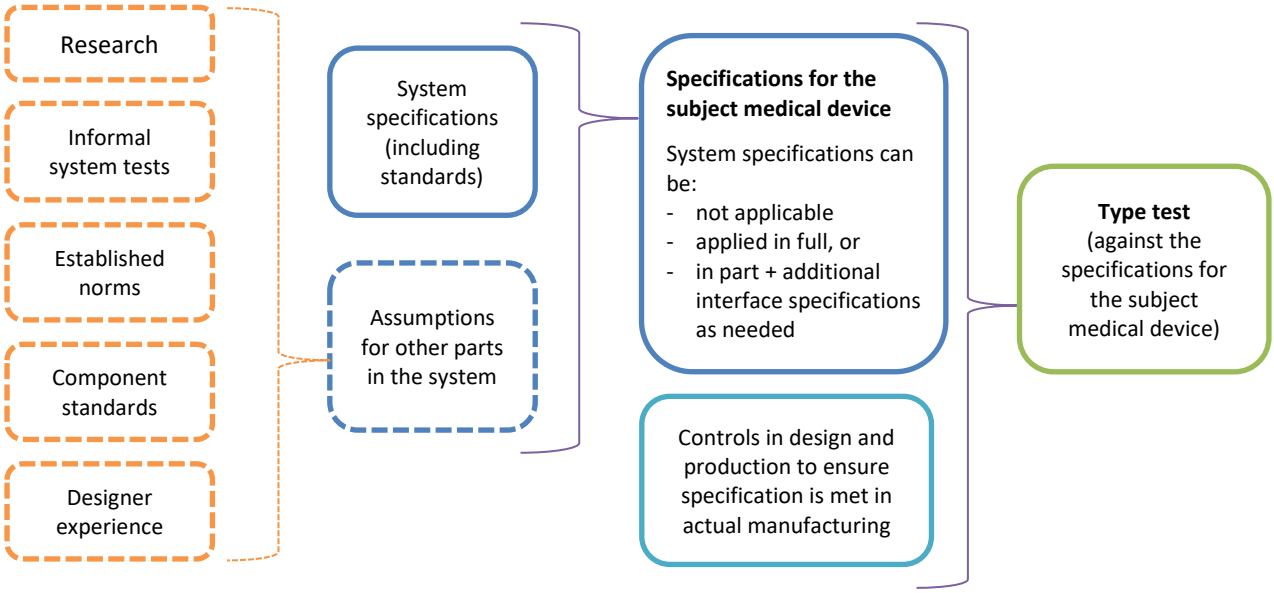
- the system specification is not applicable as compliance is assumed *not* to be influenced by the subject medical device;

- the system specification is applicable *in full* to the subject medical device, because compliance is assumed to be influenced by *only* that device

- the system specification is applicable and compliance is assumed to be influenced by the subject medical device *and* other devices in the system, in which case device specifications (including possible new *interface specifications*) are derived from system specifications based on assumed characteristics of other devices in the system.

The word *assumed* is used here deliberately to mean not necessarily supported by proof or objective evidence. This is required at the general level as there are likely to be a large number of assumptions, most of which are obvious or well established in industry and hence would be onerous to prepare a written justification. In practice, the assumptions will be based on experience, research, informal system testing, established practice, published standards (for components) and common sense. Consideration as to whether written evidence is needed should be done on a case by case basis.

The above analysis can be summarised in the following diagram for a medical device which is intended to be used with other medical devices in a larger system:



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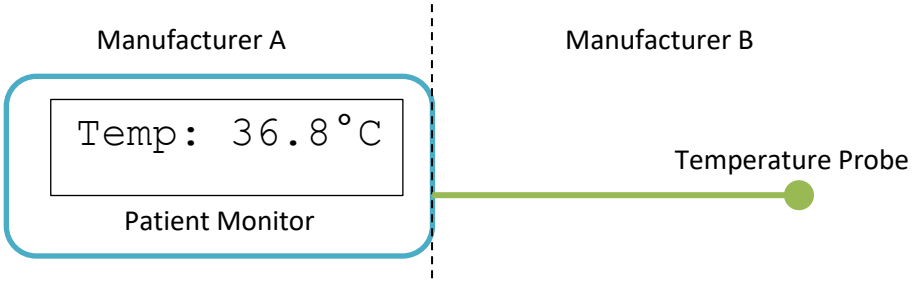
Worked example

The following diagram is an example of a common real world system, and can be used to explore the three ways in which system specifications are handled. The example consists of a patient monitor placed on the market by manufacturer (A), connected to a probe from manufacturer (B):



The following table has various samples of system requirements from ISO 80601-2-56:2017/A1:2018, broken down into device requirements for each part of the system:

Clause	Requirement (simplified, for illustration only)	Patient Monitor	Probe	Notes
201.7.4.3.101	A CLINICAL THERMOMETER shall express the temperature in either °C, °F, or both	Applicable in full	N/A	Obvious
201.11.6.6	Surfaces … that can become contaminated with body fluids … shall be designed to allow for cleaning/disinfection/sterilization	N/A	Applicable in full	Obvious
201.12.1.101	When the THERMOMETER is not capable of accurately indicating a temperature, it shall provide a TECHNICAL ALARM CONDITION or it shall not provide an OUTPUT TEMPERATURE	Applicable in full	N/A	Assumes the patient monitor range is smaller typical probes
201.12.2.101	For thermometers intended for home use, the temperature display shall be at least 4 mm high	N/A	N/A	N/A for the patient monitor as not for home use; obviously N/A for probe
201.101.2	The LABORATORY ACCURACY within the RATED OUTPUT RANGE … shall be within ±0,3 °C	Partly applicable	Partly applicable	The specification of ±0.3°C would need to be split (e.g. ±0.15°C for each). The sensitivity (°C/Ω) of the sensor would also need to be defined (e.g. use YSI400), as well as current limit for self heating (typically 0.1mA).

Clauses 201.7.4.3.101 and Clause 201.11.6.6 are good examples of requirements that apply exclusively to one device (patient monitor and probe respectively). These are also good examples which are so obvious that written justification would be superfluous.

Clause 201.101.2 (laboratory accuracy) is a good example of requirements that need to be split or distributed between the monitor and the probe. It also indicates how additional (new) *interface specifications* may be necessary to meet the system specification, in this example the sensitivity of the probe (°C/Ω) and maximum sensing current.

Clause 201.12.1.101 contains a questionable assumption[4]. It is included here to show that not all cases are clear cut, and may be subject to bias leading to unsafe decisions. This is true of any engineering task, and not a problem specific to systems. Note that in this particular case, it is likely to be a technicality and not expose the patient to any risk.

[4] Outside of the core accuracy range (25-45°C) the accuracy of probes vary, so it is hard for the patient monitor to be sure that the range of the patient monitor is smaller than the probe.

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Benefits of medical systems

The above approach of having each manufacturer make assumptions about other devices in the system sounds perilous – particularly in a competitive environment, and taking into account the normal bias that exists in decision making. It's easy to assume that a requirement, specification or risk will be handled by other devices in the system. Thus it is reasonable to ask the question: *why allow medical systems?*

The simple answer is flexibility, the benefits of which far outweigh the risks involved in medical systems. Every patient is different, and hospital practices, professional preferences and budgets vary. Thus allowing a system to be adapted to the individual situation means that a lot more patients can be treated at a significantly lower cost than could be done with fixed systems.

It could be argued that a system should still be developed by a single manufacturer, to ensure that all combinations are safe and effective; or at least, *responsibility* for the system can be clearly assigned. Again, this would be impractical given the nature of modern medical systems which can involve vastly different technologies. It would also increase risks associated with monopolies (increased prices, reduced quality, lack of innovation), and also increase risks as single manufacturers attempt to take responsibility for areas outside of their core competence.

Although competition does have serious negative implications on quality and safety, most of these are due to lack of appropriate specifications for the device. This problem is exacerbated by the focus on system specifications, which mask the necessary interface specifications in order to make a system safe and reliable.

Consider for example the system of a syringe pump with a syringe: while the syringe pump can provide a very accurate drive to the syringe plunger, the flow to the patient is often stop/start due to stiction around the plunger head. It's also known that the amount of stiction varies hugely with different manufacturers of the syringe. However, the standard IEC 60601-2-24 only tests the system. Naturally the pump manufacturer wants to show case *their* performance, so they select the best quality brand for the purpose of the tests and marketing. This in turn masks the true problem of stiction which is occurring in real world applications.

The correct approach is to separate the pump and the syringe and derive appropriate specifications for each individual device. This would then make it clear that syringe stiction plays a big part in the accuracy of drug delivery to the patient. Standards could then be drawn up to test for stiction, declare performance, encouraging syringe manufacturers to develop better quality syringes.

Risk management for systems

In principle, ISO 14971 risk analysis should allow manufacturers to decide whether a system risk should be addressed by the manufacturer. However, contemporary risk analysis tends to measure risk in isolation without the impact of resources, excessive use of which can increase risk. A broader assessment including resources would conclude that the manufacturer that is in the most efficient position reduce the risk should take responsibility. For example, both the patient monitor and accessories could use a ferrite to minimize EMC issues. However, it is more efficient if only the patient monitor has this, since this would drastically reduce the number of ferrites needed.

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Challenging system testing bias

There is an understandable bias towards system testing: the idea that components, individually specified and tested, can work reliably when combined in a system *without* system tests seems wrong. The risk of unexpected outcomes, interference, in-compatibility and incorrect assumptions is so high as to be clearly unacceptable especially when dealing with patient safety.

This bias towards system testing can be found in the IEC 60601 series and also in FDA guidance documents such as for Electrosurgical Devices. IEC 60601-1 states that "ME equipment" *includes* accessories[5]; IEC 60601-2-34 for invasive blood pressure monitoring states that with respect to accuracy tests, "For the protection of the PATIENT, the *system* needs to be tested for compliance"[6].

It is worth to note that not all agencies promote this view: some ISO, EN-original, ANSI/AAMI and JIS standards apply to parts of a system (e.g. sensor) or are structured to allow each part of a system to be tested separately. For example, ANSI/AAMI BP22 is written just for IBP sensors, allowing them to be comprehensively tested independent of the patient monitor (directly contradicting the above statement in IEC 60601-2-34); EN 12470 (original EN standard for thermometers) provided separate specifications for the monitor and probe, allowing them to be assessed independently.

European regulators are also likely to be supportive of device specifications as opposed to system specifications, as they have a well established legal framework based on the need for traceable responsibility[7].

Even so, the IEC/FDA view has a strong influence, particularly in the case where third parties are involved. There are numerous reports[8], for example, that the FDA is insisting on EMC tests for passive accessories due to their potential to influence EMC results. And to be fair, these are not aspects which are obvious at first glance, most engineers would assume system testing is reasonable.

The following case study[9] helps to explore some of the issues and determine which view is right:

A manufacturer of a patient monitor is subjected to a third party test for the accuracy of the temperature measurement function in accordance with ISO 80601-2-56. The test is performed with a sample temperature probe from another manufacturer. The initial test result was a failure, with the displayed temperature +0.5°C error against a criteria of ±0.3°C. The manufacturer applied a software offset of -0.5°C which brought the result into compliance. The test was repeated with a positive third party report used in a regulatory application and the monitor cleared to market.

Later investigation found that the cause of the fail result was excessive sensing current, causing self heating in the sensor. Self heating is a well established issue and the true root cause is likely to be a lack of competence in the designer of the circuit. A simple software offset solution does not work as the self heating is highly variable due to many factors. The final solution, applied as a post market fix, was to reduce the sensing current so that self heating is negligible, and remove the software offset.

[5] See Note 1 in IEC 60601-1 definition for ME equipment (3.63)
[6] IEC 60601-2-34:2011, Annex AA, Subclause 201.12.1.101.1
[7] Official Journal 2016/C 272/01 (Blue Guide), Section 4.4
[8] Based on several direct contacts to the author and also discussion on Elmar Cove. Most reports appear to be interpretations of the guide by FDA third party program and consultants, and as such the FDA itself may reasonably claim that this was never the intention in the guide.
[9] This example is based on a true case, however the device type is changed to protect confidentiality

This example illustrates both the benefits and flaws in system testing. Without the system test, the self heating issue may remain undetected. At the same time, the quick fix only worked for the individual system tested, using the particular test set up and accessory, and was not effective in the real world, despite the positive result in the system test.

From an academic view, the contradiction can be explained by understanding that as the number of components or parts in a system increases, it becomes *exponentially* more difficult to ensure a test is representative. This not only applies to the selection of test samples, but also many aspects of the test set up, including the selected environment, input conditions, output loading, modes, physical layout, expected variations in the samples themselves, thermal state (cold, warming up, warmed up), other states (sequence before, during, after alarms, etc.), yielding a near-infinite[10] number of combinations.

Stated another way: even for a mildly complex system an impossibly large number of tests would be required to achieve the goal of being *representative*, and hence become a *type test*.

Another, more unexpected, corollary is that while a failed test result on a particular system provides valuable information, *a positive result is meaningless*. This is similar to the situation of sampling, say, a single apple from a truckload of apples, and trying to infer something meaningful. If the apple is bad, it suggests that something is wrong. But if the apple is good, it doesn't really mean anything about all the other apples in the truck.

System tests are nevertheless a well established part of good design, so there still appears to be a contradiction in claiming that a positive result is somehow meaningless. This paradox is explained by the existence of numerous unstated assumptions behind a system test.

By far the most important is that for system specifications to have any chance of being met, there *must* be good controls at the component level whether documented or not. Without such controls, system tests would just be a random jumble of results: some pass, some fail, from which little meaning could be established. It is even likely that various parts of the system will interact in such a way as to mask problem areas, with errors in one part of the system neatly cancelling out errors in another part of the system, giving the appearance of conformity - a deceptive trap that designers are sure to have fallen into many times in their careers.

With the assumption of good controls at the component level, system tests then take on more meaning, for example to:

- investigate residual weak points in the system (particular components)
- detect integration errors
- provide a spot check for non-critical aspects
- provide a single report to simplify the regulatory records

[10] Theoretically infinite, but in practice we can usually establish discrete zones where the effect of changing one variable is negligible, vastly reducing the number of combinations. Even so, as the number of components in a system increases, the number of combinations necessary to establish conformity quickly becomes impractical.

In this discussion it is worth to take a sideways step and look at the role of the manufacturer's *declaration of conformity,* normally drawn up based on ISO 17050-1. According to Clause 4, a primary purpose of the declaration is "… to make clear who is responsible for that conformity and declaration".

The standard is more relaxed when it comes to *evidence* of conformity: "… supporting information *may* be provided to relate the declaration to the conformity on which it is based", with various examples provided. ISO 17050-2 provides more details on "supporting documentation", but this only gives more examples with no strict requirements. In other words, a *type test* report is not actually required. This vagueness is necessary taking into account complex real world scenarios in which it would be impractical or onerous to insist on a *type test* report in every case.

The relevance here is to highlight that although system tests are an extremely weak form of evidence, it does not matter in the regulatory context. A manufacturer of a complex system, placing it on the market as a single device, may offer a system level test report as evidence even though it is far from being a *type test*. The background assumptions such as good controls at the component level need not be documented, as long as the manufacturer takes responsibility. In fact, from a legal perspective, having a hard link to a *type test* report specific to the object of the declaration could enable loopholes in establishing responsibility. Instead of saying "I take responsibility for compliance as evidenced by report XYZ", it is better to say "I take responsibility for compliance" … full stop.

It may appear that for medical systems made up of medical devices placed on the market separately that the same applies: the manufacturer of the subject device could declare compliance with various standards, and then point to system test reports as evidence, even though these reports would not fit the definition of a *type test*.

To some extent this is true. There may be similar backstories which justify the use of system tests in particular cases. However, as a general rule it is unlikely that using system tests will make sense, and as such it is best to use a default position which questions if the system tests are appropriate.

Any evidence provided is essentially a *proxy* for a *type test*. In other words, while it may not be a type test, the evidence should be seen as *equivalent to a type test*. If compliance with a system standard is heavily dependent on other parts in the system that are not under the control of the manufacturer (such as EMC testing of passive accessories with another manufacturer's equipment), there is no way the manufacturer of the accessory could plausibly be held responsible for compliance. Thus the primary objective for a declaration of conformity, to establish traceable responsibility, breaks down.

Risks from using system tests

It could be argued that focusing on system tests creates no harm, and could potentially detect important problems. Unfortunately, this is not true: the focus can in fact increase risks by allowing the manufacturer to skip over the preparation of appropriate specifications for the individual medical device.

It is true that system tests are valuable to gain experience with the system and the interaction of individual components. However, ultimately this experience should lead to formal, device specific

specifications, and the system tests should be viewed purely as part of the trial and error phase prior to developing those specifications.

In the above patient monitor example, the system test revealed an error of +0.5°C, which (assuming normal design methods) would have been a surprise result. Rather than simply applying a software fix for the individual system, the designers should have researched why this error was occurring, discovered the self heating problem, and then prepared new interface specifications (limiting the sensing current) to ensure the issue is solved generally.

If regulators, test agencies, auditors, standard writers, accreditation schemes and consultants insist on using system tests and standards applicable to systems, they are failing to ensure that such device specific specifications are being properly identified, implemented and verified.

Compliance with standards

As mentioned, most standards in the IEC 60601 series are developed on the system test basis. As the above analysis shows, manufacturers of discrete devices should then take each individual requirement and develop device specific specifications using one of the three options: not applicable; applicable in full; in part with new specifications.

The question then arises: it is OK then to declare compliance with a regulatory standard, when the device itself only complies with part of the standard? This is an important question - in places such as Europe, USA, Canada and Japan, compliance with product standards is not mandatory but their use triggers a fast track approach. The question then arises as to whether manufacturers that use only part of the specifications from these standards are allowed to use the fast track. In Europe and Japan, this is a legal question; in the US and Canada it is not part of the law but nevertheless affects the handling of an application in a similar way.

In principle, it is possible to claim compliance with a regulatory standard, provided that a type test report shows both the *device specification* as well as the *assumed specifications for other parts in the system*, in such a way that it is clear the system standard is met. Continuing the example for patient monitor temperature function (ISO 80601-2-56), a test report could state for the patient monitor:

Clause	Requirement	Remarks	Verdict
201.101.2	The LABORATORY ACCURACY within the RATED OUTPUT RANGE in NORMAL USE shall be within ±0.3°C	The patient monitor is tested using dummy resistors according to the published YSI400 relation with a specification of ±0.1°C. In addition the excitation current is tested to be ≤ 0.1mA. See detailed report TR123456. The above specification is based on an assumption that probe (accessory) has an accuracy of ±0.1°C per the published relation for a YSI400 probe and is designed to have no self heating using an excitation current of ≤0.1mA.	Pass

The accessory manufacturer would view the same clause from the opposite side:

201.101.2	The LABORATORY ACCURACY within the RATED OUTPUT RANGE in NORMAL USE shall be within ±0.3°C	The probe is tested in a water bath to match with YSI400 relation with a specification of ±0.1°C. A dry probe is tested to have <0.05°C change in air with an excitation current of 0.1mA. See detailed report TR654321. The above specification is based on an assumption that the equipment has an accuracy of ±0.1°C (for the YSI400 relation) and assumed to use an excitation current of ≤0.1mA.	Pass

By declaring assumption such as these, it is possible for both the patient monitor and probe manufacturers to independently declare compliance with the whole standard, which then allows access to the fast track methods for regulatory standards.

In stating these assumptions, it is not required that a manufacturer guarantee that the assumptions are true. The responsibility for ensuring the assumptions are reasonable falls into the normal responsibility for developing specifications which are often based on assumptions, stated or not. The key point responsibility for the assumptions is clear, and able to be held liable in the case of gross negligence, such as making assumptions that are favourable for the subject device but are obviously not true in practice, or failing to have appropriately qualified engineers that should know what specifications are appropriate for the subject medical device.

Accessory manufacturers

It is noted that for accessory manufacturers, large sections and even whole standards in the IEC 60601 series may be deemed not applicable as compliance is not influenced by the subject medical device. This may in turn lead to a relaxed approach to standards compliance, for example declaring compliance without a formal test report, or preparing reports with selected requirements.

In practice, the best solution is to prepare full reports using the normal four column format used by the CB scheme, with the not applicable sections collapsed to clause or sub-clause titles in order to reduce the size of the reports. This ensures that not only are applicable (or partly applicable) requirements are identified, but acts as a formal record indicating which requirements were deemed not applicable, and ensuring a systematic approach to finding applicable requirements. The “remarks” column in the CB scheme format allows the manufacturer to document the reasons why a clause is not applicable (which can be brief) and as well the assumptions made for other parts of the system. For a particular accessory type, this method may be somewhat onerous for the first device, but once a pattern is established the reporting can be done smoothly.

Influence of the IEC and IECEE CB scheme

The IECEE CB scheme was originally intended to allow the transfer of test results between agencies, for the purpose of product certification such as NRTL marks. However, its influence has grown to impact the general operation of third party test laboratories, irrespective of whether product certification is involved. Thus it has an important role in how discrete medical devices are treated when they are intended for use in a larger system.

At present, the IEC and IECEE both promote the use of system tests rather than extracting device specific requirements. As such, a change to device specific specifications would require significant

effort to overcome this pre-existing bias, and introduce rules and structures that ensures that a test report only applies to a discrete medical device. The system should also promote testing accessories on their own, as discussed above.

Although the bias will take effort to overcome, it should be noted that the rules for product certification (ISO/IEC 17065) already prohibit the inclusion of other medical devices (such as accessories) from another manufacturer, if compliance depends on those devices[11]. The rules require that the manufacturer has production controls and reports changes to the certification body, actions which cannot be taken if the other medical devices are placed on the market independently.

Further, IEC 60601-1:2005/A1:2012, Clause 5.1 requires that the tests are a *type test*, i.e. representative of regular production, and allocates many other responsibilities to the manufacturer. Again, this cannot be done if the medical device in the system are placed on the market separately.

Thus, the continued bias in the IEC and IECEE CB scheme towards system testing places not only patients, operators and manufacturers at risk, but also test agencies, certification bodies and the IECEE itself at risk of legal liability.

FDA Guide

A key example of the bias towards system testing is this following extract from the FDA guide for electrosurgical devices, with respect to EMC testing:

> *"… particular attention should be paid to the effects of connected accessories and instruments, such as cord length (for resonant frequency) and instruments that contain electronics. For instruments with different cord lengths, connection types, or electronic components, it may not be appropriate to use a single "representative" instrument model for testing purposes"*

While this statement is correct, the implication is that, in effect, the manufacturer of passive accessories needs to test all the different types and lengths and with all the possible generators that the accessory might be used with. However, even this would not be effective since the accessory manufacturer does not know about the design and production controls for each generator, nor have the necessary agreements in place to report any changes in the design of the generator, which might trigger re-assessment. Thus the above statement, written with good intent, is not feasible in practice. The FDA should take care to review its guidance and ensure that device specific specifications are developed, which can take into account system specifications as appropriate.

Application to EMC testing of accessories

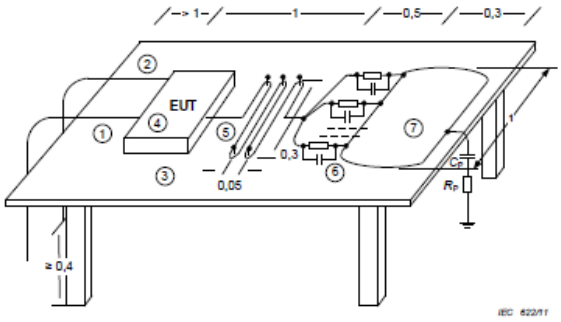
In EMC, there is a concern (as per the FDA guidance above) that the use of accessories may significantly impact both emission and immunity profiles in unpredictable ways. Thus the preference towards system testing will inevitably be raised. As this document states, system tests should not be used and instead device specific specifications should instead be developed. However, extracting

[11] In principle, a manufacturer should be able to use other manufacturer reports in order to establish compliance for their device, in the same way that manufacturers can rely on certified components such as opto-couplers and Y1 capacitors. However this would require a suitable structure to be developed to ensure lines of responsibility are clear, which does not exist at this time.

device specific specifications is less clear cut when dealing with EMC, and hence it deserves a special focus.

EMC is a special case in that there are anyhow a large number of assumptions which a have highly questionable relationship with the real world. Instead, priority is deliberately given to having a controlled test in order to improve the repeatability of results.

For example, the standard IEC 60601-2-27 has the following diagram for EMC testing:



This layout serves to create a higher degree of certainty by defining the ECG cable layout and impedance between electrodes and the earth. However, there is no attempt to pretend that this layout is *representative* of the real world, which it obviously is not.

Even with this controlled layout, there is still a high degree of uncertainty in EMC testing, with laboratories typically stating uncertainties in the order ±3dB to ±6dB (k=2). Translated into to plain English a claim of ±6dB means that the laboratory is 95% sure the actual value is somewhere within ±50% of the stated value – hardly the realm of precision we normally expect for laboratories.

The standards themselves assume user actions such keeping portable RF communications equipment no closer than 30 cm from any part of the equipment, a requirement that is likely to be ignored in practice, as users are mostly unaware and it is anyhow impractical since it applies not only to the main unit but also to cables and accessories.

Finally, the industry has a complete blind spot to the possibility of a fault that affects the EMC compliance. For example, a simple broken wire can impact the shielding effectiveness far more than variations caused by accessories.

Thus, an engineer that frets over the potential that an accessory might change the EMC profile of a medical system causing a critical incident lacks perspective. There is no doubt that the accessories can change the profile. But that's just one in a myriad of issues with EMC testing. It would be inconsistent to highlight accessories without also addressing the many other issues in EMC testing.

The hidden justification for all this ambiguity is that EMC testing, while important, is nevertheless highly conservative in the criteria. Real world situations may have 100% or 200% higher emission or susceptibility, but this is extremely unlikely to cause any interference issues in practice, by virtue of the very strict limits applied in testing a particular configuration.

Also, due to the high uncertainties, no reasonable engineer would rely on EMC testing alone as a critical risk control measure. Designers of high risk devices such as infusion pumps, dialysis systems, ventilators, surgical lasers and wheelchairs typically use redundant systems, internal monitoring, check sums and other system integrity tests to detect abnormal operation.

Wireless communication protocols also apply CRC checks, redundancy and alternate paths to ensure the quality of data transmission.

As such failures in EMC, which do definitely occur, are mostly an annoyance factor and are rarely safety critical. If they do cause a critical incident, this suggests a breakdown in good defensive design, rather than EMC.

Since compliance with EMC standards is largely based on actions by the equipment manufacturer (shielding, filters, layout, limiting digital rise times), it makes sense that these manufacturers are subject to testing and need to comply with the criteria. When the equipment manufacturer considers accessories, it makes sense to focus on creating a repeatable condition rather than attempting to be representative. Thus a “test accessory” might take the form of a known length of cable, shielded or not (depending on research), with a defined layout.

For manufacturers of passive accessories, it makes sense to limit compliance to aspects that are specific to their device. An example may be the use of shielded cable, if such shielding is commonly used or reasonably expected for that type of accessory.

Summary

When a medical device is placed on the market, the manufacturer is responsible that this device meets specifications that are developed specifically for that device.

If the device is intended to be used in a system that includes devices placed on the market separately, the manufacturer must take into account system specifications, system standards, system risks, knowledge and experience from use in real systems. This information is then analysed, processed and filtered so as to produce specifications for the individual medical device.

Although the manufacturer should take system aspects into account, the manufacturer of each device in a system is not required to be responsible for, nor to provide evidence of, compliance with standards applicable to the system, unless the system is placed on the market as a system by a single manufacturer.

The length of this document should not be used to indicate that any of the above summary is in contention. There is no doubt that professionals familiar with medical device regulations and the need to establish clear lines of responsibility would acknowledge this approach as being correct. The length of this document reflects the need to counteract the natural bias towards system testing and also indicate how system issues may be dealt with in practice.

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