IEC 60601-1-2 Amendment 1:2020 - Catching Up with Reality

With Mario Klessascheck, Prof. Dr. Christian Johner

Transcript

00:00:05 Speaker 1

Medical Device Insights, a podcast by the Jona Institute for medical device manufacturers, authorities and notified bodies.

00:00:16 Speaker 2

At the end of 2020, a new version of the IEC 6061-1-2 standard was published.

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This means that all manufacturers who have to comply with this standard should know what this standard consists of.

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Changes exist and what they should do now.

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And that's exactly what I would like to discuss with Mario Gläserschek.

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Many of you know that I have a long-standing friendship and partnership with Mario.

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We wrote the book on IEC 60601 together, so I know what infinite knowledge he has in this area.

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Mario, how did you learn all this?

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How did you come to this incredible wealth of experience?

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Hello Christian, have a nice day.

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Yes, the topic has been on my mind for over 20 years, namely since my studies in electrical engineering,

which I completed in 1999.

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During my studies, I already started working in the office of an E.K.G.

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to repair equipment to finance my studies and in this context I was also allowed to be on the road in hospitals, in doctors' surgeries and in principle got to know and love and appreciate the world of medical technology and have

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therefore also deepened in the direction of biomedical engineering during his studies.

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Through my studies, I finally ended up in Switzerland.

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I was allowed to write a diploma thesis here on the subject of cardiac catheterization laboratories and that kept me in Switzerland and since then I have worked as a developer for devices for patient monitoring in the intensive care unit and also devices for the rescue service, defibrillators.

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I've had that for 13 years

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In this context, I had to deal intensively with this whole standard landscape, that we are now building safe devices, and then I decided via this track to ultimately leave the path of development and then also to help other companies to build safety concepts for medical devices through consulting, those that take place in the metropolitan area of the 60-6 or 1.

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Now you have already mentioned the norm.

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Maybe that we have a frame for a very short time.

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We have now talked about IEC 60601.

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In the introduction, however, I spoke of an IEC 60601 dashed 1 dash 2.

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So quite a lot of digits.

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Can you give us a very brief overview of what it is about, what standards there are and what they are all about?

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Yes, of course, it all plays together, so in that.

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In the field of medical-electrical devices, which is the umbrella term, we find a whole world of standards and that is the 60601-1 series.

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The family of standards includes almost 100 standards and in addition to these standards we deal with certain technological aspects of these devices and one of these aspects is the whole electromagnetic compatibility, that devices

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other devices in the environment are not right or are not allowed to influence each other, so that the function may be disturbed and the patient will be harmed.

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So this series of standards deals with the 2 main topics, one is safety, i.e. that devices may be used safely on the patient, but must also not harm the operator.

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But with medical devices, there is also the issue that they have to function safely, and this safe function also represents

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would also like to ensure the EMC standard, the 60601 dash 1 dash 2.

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This is 1 of the main topics that the standard deals with.

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So, we then have this basic standard, the IC 60601, yes, which gives us the principles, also electrical safety and other basic safety and essential performance characteristics.

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And one aspect, if I understood you correctly, namely electromagnetic compatibility, is dealt with in the further standard, IC 60601 deleted 1 dashed 2.

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Yes, exactly.

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The aim of this standard is explicitly to test the interference sensitivity of devices.

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So, the standard is essentially a test standard that gives the manufacturer guidance over the test methods.

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which aspects should be paid attention to when developing the device.

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This goes in the direction of conducted interference coupling or field-bound interference coupling, so that the essential performance characteristics that devices usually have are not affected in such a way that it leads to unacceptable risks.

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The standard deals exclusively with the topic.

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Of course, we also have other issues in connection with radiation, such as biological hazards.

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by electromagnetic radiation, the standard does not deal with this topic.

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So this is simply about the coexistence of medical devices and the safe functioning of medical devices.

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The fact that, for example, when a doctor is not walking around with a mobile phone and the mobile phone then interferes with the medical device with its radiation, that is what this standard focuses on.

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Exactly, and you‘re changing right now, which also fits the topic today, you‘re changing your focus a little bit right now.

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So yes, if you remember, we had this ban on turning on the cell phone on the plane for a long time or switching on the cell phone when we went to an intensive care unit, that‘s no longer state of the art, it can‘t be set up today.

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So the trend today is actually more that the devices can actually cope with this, with this changed electromagnetic environment

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and that is why the standard has also introduced new tests in this context.

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Yes, we're in the middle of the topic, maybe let's go through it.

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So, what has changed at the end of the year?

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So, what does this version 2020 bring with it or maybe it also cuts things out again compared to the previous standard?

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What would you characterize as the most important changes?

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Yes, first of all, it was important that the

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This is the norm that in turn refers to other norms, now these dated references.

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So that means that if a standard refers to another standard, then it can be undated, then the last version of the standard always applies or with a dated reference, then exactly this state of the standard applies.

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These dates have been adjusted.

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This applies, for example, to ISO 14971, where reference is made to the 2019 version now.

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which then also has an influence.

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The other thing that has changed or what has been added, a new test has been added, which we will talk about in more detail later, that is the immunity test in the near field for H.

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F.

00:06:27 Speaker 1

Transmitters or for devices that contain electromagnetically sensitive components.

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There are additions or explanations on how to use large equipment

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large systems are, for example, magnetic resonance tomographs or devices that are used for tumor treatment, which fill entire rooms.

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And there is also an addition, which is an aid for the manufacturers to apply risk management in connection with E.M.V.

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Yes, that means we have a few formal things, like these changed references, then some help.

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in the appendix to risk management, some of the terms then concern only the very large devices manufacture.

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But as I understand you now, the most exciting change that the 60 6 and 1 dash 1 dash 2 brings with it is in this context with these transmitters.

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Help me very briefly, what's a transmitter or who transmits there?

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and what has changed regarding these transmitters?

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So transmitters are essentially all devices that transmit, i.e. radio transmitters, i.e. those that transmit data and distribute information with the help of electromagnetic radiation.

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The best-known technologies for us are WLAN, Bluetooth, DECT phones, but also increasingly the emerging technologies such as RFID or now also new bands such as our 5G, for example in near-field communication.

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These are typical transmitters.

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And something has changed now regarding this.

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So the requirements have become stricter?

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Perhaps you can also say in this context that this is about the fact that we have to deal better with external transmitters, i.e. that we are more resistant to interference with new forms of external transmitters.

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Yes, that's exactly how you can say it.

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There are more and more reports that medical devices fail or do not work correctly, and this is especially true now for products that are being used more and more in the home environment, such as pain pumps that I wear on my body, insulin pumps, other assist systems that I now have with me.

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With such devices, you can't really take it anymore

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keep your distance from any source of interference, for example, as would now be possible for devices that are operated in the clinical environment.

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And that's why the standard didn't increase the requirements in that sense, but introduced a new test.

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So there has always been a test that dealt with the interference, i.e. with the near-field, i.e. with the interference sensitivity in the near-field range, but it was not adequate,

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exactly for this type of interference sources and that is why a new test standard has been specified, which has been wanted to be done for a long time, namely the one that deleted IEC 61 0004 39 whose title is ‚Testing and Measurement Technics for Radiated Fields in Closed Proximity Immunity Tests'.

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And it deals precisely with the immunity test with regard to magnetic, electromagnetic high-frequency fields from such sources that are used in the immediate vicinity of other electrical devices.

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And this is especially true in the home environment, where we now have networked, networked services via smart homes.

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We have electric stoves, induction stoves at home, these are all examples of sources.

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with which medical devices have to cope today, I am also thinking of wireless energy transfer, i.e. this Q.

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Charging station, for example.

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This will go as far as perhaps in the future that our electric car can also be charged inductively, and medical devices will have to cope with that.

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You can, it would no longer be state of the art to demand that you keep your distance.

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And it's also unlikely to explain to grandma that her cell phone charging station is now there, that she is somehow no longer allowed to put her pain pump next to it.

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You can demand that, but it probably won't be taken into account so much.

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You've already hinted at a bit, but maybe we'll take a closer look at that.

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Which devices are now affected?

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Because probably many manufacturers are now asking themselves, do I only have to deal with the new standard if I now have devices in the home or

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Which devices or which manufacturers are now affected by this in a certain way?

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So the devices that are affected by this have not been controlled by the range, so to speak, but simply say, if devices contain electromagnetically sensitive components or circuits or functions, then these, then these devices are now the focus of this new test standard.

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So this does not only apply to devices that are used in the home environment, but also to devices that are used in the clinical environment.

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Namely, the electromagnetic environment has also changed significantly there.

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I'll give you a few examples.

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R.F.I.D.

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is increasingly used in the O.P.

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used as a transponder or as a reader for position detection of surgical instruments or.

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to identify correct accessories.

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Even swabs have become R.F.I.D.

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transmitter to determine that according to the O.P.

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really all swabs have been removed from the patient again, so that nothing what, which happens quite often, nor that swabs remain in the patient.

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So in this context, too, products that are in this clinical environment have to cope with these new environmental conditions.

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So in summary, this concerns devices that

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contain electromagnetically sensitive components and their interference leads to the failure of the basic safety or, in particular, to the, in particular, to the essential performance characteristics.

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How does a manufacturer know or is it clear which components are among the interference-sensitive components?

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That's a good question.

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Of course, the manufacturer should determine this during the design or draft.

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In other words, when it comes to the selection of components.

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so many of these devices, especially now in the field of therapeutic systems, which often work with sensors to build control loops, have such components in them, which are wired connected sensors, are very sensitive to such electromagnetic fields, but also the technology of the sensors under certain circumstances.

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And so that means that the manufacturers, they should therefore

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those who have such devices in the design should already know about it when they design or construct the device.

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But this also perhaps, say, less experienced manufacturers such as startups that buy ready-made units and think, they may be certified for themselves, these components, a WLAN component or a ready-made temperature sensor that you can buy,

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they should then also deal with the topic and then perhaps also ask whether a certain sensitivity to interference is to be expected with these components.

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You can put it this way, there is no canonical list of components, so that we want to say what I want.

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So this canonical list does not exist, but has to decide it on a case-by-case basis, so to speak.

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Is what I suspect correct?

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Yes, very exactly, it's about, of course it's about exactly that.

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Components whose function or which provide functions in the area of basic safety or in the area of essential performance characteristics.

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For example, if we have a sensor that is highly sensitive, for example EEG currents.

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Measurement should, yes, we will increasingly have devices in the home in the future that we can control via brain waves.

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These are highly sensitive components and if these functions result in aspects of basic safety or essential performance characteristics, then such components now fall within the scope of this test standard.

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O.

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K., that is, it actually depends more on the function of the components and not primarily on the type of components.

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Exactly, it is not the technology that is decisive, but the function.

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Yes, now we have a lot with these transmitters that you have to deal with and where you have to check that exactly this basic safety and essential performance characteristics must also be given in the new transmitters.

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I guess that's the heart of the changes.

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What else do you think is worth mentioning for changes to this standard that manufacturers should take care of?

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I would also like to mention the risk

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risk management, which began with the fourth edition of the E.M.V.

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standard of 2016 and which is still a problem for manufacturers.

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And the standard has improved again and in Appendix F.

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a table with specific guidance for those subsections of the E.M.V.

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standard that include risk management aspects.

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So it contains the table of a manual for each application

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in relation to risk management and E.M.V.

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measures.

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Could you give an example of what exactly this table tells us?

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Well, there seems to be some extra help, after people obviously didn't quite get it after the fourth edition.

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Could you give us an example of what's in the table?

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Yes, exactly, gladly.

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For example, the standard for M.E.

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Devices and M.E.

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systems that they must be tested in a representative configuration, namely A.

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is consistent with the intended use and on the

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and B.

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are most likely to lead to an unacceptable risk.

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This means that if a manufacturer sells a device in different configurations or offers it with different accessories, such as the ultrasound system, which is offered with a large number of probes, then the manufacturer should choose the individual or configuration for the test that represents the most critical combination in the risk assessment.

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Yes,

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and the risk management file, which is now also required by the standard, should provide a justification for the selection of the configuration.

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This means that it is not enough that the manufacturer is in the E.M.V.

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You want to find a risk management file and a derivation of why exactly this configuration is representative of the entirety of the system.

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Or even particularly critical, as you just said.

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I'm just saying, if I understand you correctly, a worst-case consideration that should also be made.

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Exactly, and that doesn't even have anything to do with an estimation of probabilities, because manufacturers often always include risk analysis with F.M.E.A.

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and probability estimates, but also a simple yes-no consideration, for example, that such a dangerous situation is probable enough, is sufficient there to say,

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that you carry out a test or then build the configuration in the test on a certain one.

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Yes, so the definition of the E.M.V.

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environment, an activity of risk analysis and that's a simple yes-no decision.

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I'm in the home environment, I'm in the clinical environment, that doesn't always have anything to do with estimating probabilities.

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O.K., 1 of the very central aspects that we have in the whole family of standards is this topic of functional safety and you now have about that

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already indirectly at least reported.

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Do we also have a direct reference to our E.M.V.

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The standard we are talking about today, with this, indeed the topic of functional safety, how does that interact and what has changed?

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Unfortunately, there is no direct reference yet that the standard now refers to the topic of functional safety, for example, or even mentions the term.

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On the one hand, this is due to the fact that

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that the topic is also quite new for medical devices, but efforts to make it applicable to medical devices as well, but not yet so far, so the standard does not make any concrete reference.

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But you can clearly feel that the view of the authors of the norm goes in this direction, namely by also including an E.M.V.

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equitable development process.

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So that also means an E.M.V.

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fair design must be produced.

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And that means that manufacturers should integrate exactly these design methods into the design process and just like we did from the I.E.C.

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62 304, which wants to design exactly the quality into the product with its process and does not want to test it purely.

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It would be the same with the E.M.V.

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the aspect that you make sure through the development process in the draft that the just, that the passing of the exam is not a coincidence, but really

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wanted design, wanted result.

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So here, too, the idea is actually that we not only have analytical quality assurance, we are not only looking for errors, yes, which one would expect with the test standard, but quite explicitly, as with the basic standard or 62 304, as you just said, the constructive safety, i.e. the processes, methods, procedures and tools, in order to achieve predictable quality.

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So I find it interesting that a test standard is developing in this direction.

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We have to make sure that she doesn't leave her original scope completely.

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But very exciting thought.

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What would you recommend the manufacturers to do now?

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Yes, we have a new version there now.

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Maybe we have to ask the question first,

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when should they do what, so when is it valid, so that we may have talked about the urgency and then we think about it in the second step and yes, and what else needs to be done.

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So, what are the timelines in which manufacturers should react?

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So, I would like to start a small passage again, namely the important question you asked, i.e. who, who is affected by it or when is it affected.

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And that would also be an introduction to risk management, namely to ask yourself the 3 questions at the beginning.

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First of all, do I have exactly such interference-sensitive components or circuits in my system and if so, can they lead to the loss of the basic safety or the essential performance characteristics and is it not possible to build a solution there through internal constructive measures, for example distances of more than 15 centimeters to such sources of interference?

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So, if the 3 questions are answered with yes, so to speak, then I'm in the scope of this test for the time being.

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Yes, and even if I can answer it with no, I have to justify and document exactly in the test plan why I am skipping this test.

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If you now

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2 situations are considered, namely that there are manufacturers who develop a new device or there are manufacturers who have had devices on the market for a long time, which they now continue to deliver in an unchanged way, where no major changes were planned over the last few years.

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This results in 2 questions.

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One is, so I don't have to deal with the M.

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D.

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R.

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also monitor my products on the market in general and meet the general requirement that my systems correspond to the state of the art.

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And

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And since the state of the art is of course not a new topic with this changed electromagnetic environment, but the authors, they are also aware that this has to be raised gradually, because otherwise many devices would probably also fail the test.

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We also have to provide security of supply, but this gradual adaptation to the state of the art also affects precisely manufacturers who have had devices on the market for a long time, for which we now recommend, even this one.

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Testing, in order to perhaps only carry out this test of this standard, i.e. according to this new test standard, to determine how much reserve they have in their design or whether they are just so close to it and then to make a decision in the post-market area, to document it.

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Yes, we are still compatible with the state of the art

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Or we would change something in the design to adapt it step by step.

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I understood you that way now.

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So, the first question they should ask themselves, the manufacturers, would be: Do we fall into it at all?

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Yes, so we have components at all that are now sensitive, that are exposed to these transmitters, that have a negative impression on basic safety and essential performance characteristics and that just now do not have such distances with this 15 centimeter rule, whether that could then just be compensated for.

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If you realize, oh, I'm affected by this, then yours was

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Recommendation that you measure it, that you just know where we stand.

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So we are de facto still state of the art or do we have here, time has caught up with us here via the new electromagnetic environment and we can no longer guarantee that.

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That would be the first two considerations, so to speak.

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So we are affected by it, if so, what comes with our device or how does the device behave in these environments to then react accordingly.

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So how quickly can a notified body, for example, demand this examination and yes, this monitoring?

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Do we have certain deadlines that have to be met?

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Amendment 1 to IEC 60601 deleted 1 indent 2 is not yet on the list of harmonized standards in Europe.

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This list will be made now.

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by 2024 and the focus is first of all on the fourth edition of the standard, that it becomes harmonizable.

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That is to say, of these Appendices Z.

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Z., which then closed ranks with M.

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D.

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R.

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must be worked out.

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Yes, and there now, so to speak, under the M.

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D.

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R.

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harmonised standard does not yet exist, according to the definition of the state of the art, the most recent standard should always be applied and that the

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he will also be the F.D.A.

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because the F.D.A.

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the standard is already listed as a Recognized Standards and the F.D.A.

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published a guidance document on this last year, namely the Guidance for Electromagnetic Compatibility of Medical Devices and there also her view on these amended E.M.V.

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environments.

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And so, from 2023, the F.D.A.

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also corresponding testing for medical devices.

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This means that we once again have the F.D.O.

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ahead of us, also in clarity, because there is an exact date, I think you once said, even the 17th.

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December 23, on which this is activated, like a Europe, we wobble around there again.

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I can really imagine how this will work with all the tag file checks.

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The manufacturer will say, yes, we don't have any, it's not harmonized at all, what do you have?

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And the examiner will say, yes, state of the art, I want to see it again right now.

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That means we have a certain uncertainty, if I understand you correctly, when exactly this amendment can be demanded.

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Can you say that?

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From a legal point of view, there are no concrete dates, that's true.

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And now both sides refer to the state of the art and the state of the art from the manufacturer's point of view means that the standard is not yet there and the state of the art from the point of view of the notified body or the examiner simply means that the standard is there.

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And there you have to

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and the distinction would be to say at this point, if I have new devices now, I would always test it, regardless of whether I have such components in it or not.

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The test is not very complex, if I have to test the device anyway, then I go into the test right away and in the area, I mentioned that earlier, in the area of the postmarket for existing devices, I would recommend the test, i.e. only this test, because the manufacturer then also meets the requirement

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in accordance with the state of the art to place the equipment on the market by being able to prove that his equipment is still compatible with this amended Ö.

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M.

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V.

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environment.

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And so the manufacturer can also sound out design reserves in his design, so to speak, and also has a sure feeling about whether the devices are still compliant.

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Mhm, with the new devices, I think it's obvious what needs to be done.

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This must be taken into account immediately.

00:25:52 Speaker 2

But with the old devices, yes, I think to a certain extent the result of the risk analysis is also the result of the risk analysis, and that's what you said earlier, namely the analysis of whether these essential performance characteristics and the basic security are possibly at risk.

00:26:06 Speaker 2

Before there is, or perhaps now, so to speak, open the really big cutlery or maybe do nothing at all on the one hand, how could you support so that the church is left in the village on the one hand and yes, the right thing is done to

00:26:21 Speaker 2

Patient safety, but also not to do unnecessary work.

00:26:25 Speaker 2

How could you help with these considerations?

00:26:29 Speaker 1

So first of all, we would start with the documentation, because that's exactly what the inspectors or the inspectors look at first and what they look at is of course also, how does the manufacturer manage his product on the market and it's the most central document, always the risk analysis

00:26:46 Speaker 1

And we would then supplement the risk analysis accordingly in a section, for example measures on the E.M.V.

00:26:53 Speaker 1

aspects.

00:26:53 Speaker 1

And that's where we would write down exactly or build up the lines of argumentation that, for example, a device that has no essential performance characteristics does not have any unacceptable risk if that fails, this test may not be necessary for this device, this test may not be necessary.

00:27:10 Speaker 1

Or we would also be able to make a concrete statement in this context

00:27:14 Speaker 1

whether the device has essential performance characteristics, because we also find quite often that this is often a blanket statement that is not reliable and could then also follow up in this context.

00:27:26 Speaker 1

The second point, i.e. in addition to the risk analysis, would of course be the test plan.

00:27:32 Speaker 1

That has to be reflected, i.e. whether there are also certain verifications, considerations, just to determine that this design is suitable for construction and could also be included in the test plan

00:27:43 Speaker 1

just build up exactly the required arguments that an examination is necessary or not necessary.

00:27:48 Speaker 1

The audit plan as a whole also includes the E.M.V.

00:27:51 Speaker 1

Testing, i.e. the standard requires the E.M.V.

00:27:54 Speaker 1

Protocol and in this E.M.V.

00:27:56 Speaker 1

This consideration will then be documented.

00:27:58 Speaker 2

Yes, what you have already said, is also in the preliminary discussion, with some manufacturers it is quite good if you check whether version 4 is adhered to at all, because there you always come across gaps, which sooner or later also appear in the tag file reviews

00:28:12 Speaker 2

would then also be revealed anyway.

00:28:15 Speaker 2

So just get in touch with Mario or with us.

00:28:18 Speaker 2

I have entered the contact details at the bottom of the show notes and then we make sure that your products will continue to function safely in the new electromagnetic environment in the future and that you do not do any unnecessary tests on the other hand.

00:28:34 Speaker 2

Mario, thank you so much for these insights you gave us, this insight into the world of the 60601 family.

00:28:42 Speaker 2

is a very complex one for some outsiders, because it's no wonder, as you said, because we have to operate with hundreds of norms.

00:28:49 Speaker 2

Thank you, Mario.

00:28:51 Speaker 2

Thank you very much, Christian.