Technical Report

10 most common mistakes made during risk analysis for medical devices according to ISO 14971 2007/(R)2010

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Before marketing of electric or electronic medical devices each manufacturer should conduct a risk analysis. If conducted correctly, the analysis will become useful and will support the manufacturer in the control of product-related risks. Otherwise, it will be an unpleasant duty - a task which will swallow up company resources in vain and slow down the process of launching the product on the market.

Below, there are 10 most common mistakes made during preparation of risk analysis.

1. Conducting risk analysis at the end of the product development process

This mistake is made most often by the manufacturers who design a medical product for the first time. Usually, such a mistake is made because a manufacturer learns of the requirements of product compliance with IEC 60601-1 standard (that requires conducting a risk analysis acc. to ISO 14971) only at the time of applying for permission to ntroduce a product on the market.

Conducting a risk analysis when a product is ready to be launched becomes very frustrating for all parties involved. It is then necessary to return to the phase of development of product specification and document all operations conducted beforehand, which confirms the safety of the product.

Let's take a look at the following situation: a manufacturer considers exposure of a user to the electric shock in the phase of product specification development. In order to eliminate the hazard, they decide to use battery power. The risk analysis will be conducted as follows:

- the manufacturer determines the harm resulting from the electric shock the user was exposed to,
- decides that such risk is unacceptable,
- minimizes the risk by application of battery power,
- adds a requirement to the product specification,
- decides that the risk of the electric shock the operator is exposed to is acceptable.

This consideration can be documented in the following manner.

Harm	Before introduction of risk control measures			Risk control measures	After introduction of risk control measures		
	Severity	Probability	Acceptable?		Severity	Probability	Acceptable?
Death of the user as the result of the electric shock	Very high	High	No	Application of battery power instead of mains supply	Low	Low	Yes

Thanks to preparation and documentation of such an analysis at the initial phase of product development, the manufacturer is aware that application of battery power reduces to the acceptable level the risk of the electric shock the user is exposed to. Moreover, the manufacturer is aware of the need to conduct another risk analysis related with the electric shock if the idea to use mains supply occurs at any other development phase.

Conducting similar analysis at the end phase of product development leads to frustration among all parties involved. They often fail to see the sense in revision of the already implemented methods of risk reduction. Therefore, it is recommended to introduce a standardized risk management process. For medical devices ISO 14971 is the relevant standard.

2. Assumption that the product is safe

Let's consider the following example. We are preparing a heart rate monitor strap for marketing. This device has been designed for permanent wear for elderly people, and one of its tasks is to inform the doctor and the family about detection of a health-threatening situation. Our product is lightweight (200 g), made of silicone and powered by a battery charged via USB.

Having read this introduction, most readers would wonder why to prepare a risk analysis for this type of device. Such product is certainly safe, after all. Let's have a look at some examples of risks and harms related with this product:

- battery explosion,
- electric shock to the user when charging the device,
- failure to identify a life-threatening situation,
- failure to inform the doctor/family about a life-threatening situation due to lack of access to the network,
- failure to inform the doctor/family about a life-threatening situation due to battery discharge,
- burning the patient due to excessive temperature of the housing,
- allergic reaction to the material from which the housing is made of,
- child choking on small parts of the device,
- injury from a sharp edge of the display.

In conclusion, even if a product seems to be safe, its use may still carry potential for harm. Therefore, the risk analysis is necessary in the case of each medical device. Having read the presented list of risks and harms, some readers are still wondering why anyone should consider risks such as injury from a sharp edge of the display. The display of such a device cannot have sharp edges, after all. This question leads us to another, most often occurring reason for conviction that a device is safe. This reason is conducting risk analysis on the very late phase of the product development.

The manufacturers often evaluate the level of risk posed by a medical device as acceptable when the device is ready for marketing. However, the risk analysis should begin at the early phase of the product development.

The example of threat which is most often disregarded in the situation when the manufacturer conducts risk analysis too late, is the possibility of injury from a sharp edge of the device. The display on our strap has no sharp edges because, at one of the product development phases, we evaluated the risk of injury from the edge as unacceptable. We decided to round the edges and evaluated that after such a modification the risk for the user will be acceptable. The risk analysis should be documented as follows:

Harm	Before introduction of risk control measures			Risk control measures	After introduction of risk control measures		
	Severity	Probability	Acceptable?		Severity	Probability	Acceptable?
Injury as a result of the contact with sharp edges of the display	Slight bodily injury	>50%	No	The requirement of the product specification (doc. no. SP-01) that the display edges should be rounded with 1 mm radius.	None	<0.01%	Yes

3. Conducting risk analysis without following the standards applying to the device

We already know that in the case of our heart rate monitor strap, the risk analysis should be conducted from the very beginning. Let's consider which types of risks should be taken into account.

The IEC 60601-1 standard requires consideration of specific device-related risks. Besides, the following standards apply to our device:

- IEC 60601-1-2 Standard concerning electromagnetic disturbances
- IEC 60601-1-6 Standard concerning usability of medical devices
- IEC 60601-1-8 Standard concerning alarm systems in medical devices
- IEC 60601-1-11 Standard concerning medical devices for households
- IEC 60601-2-49 Standard concerning multi-functional medical devices for monitoring the patient's health condition
- IEC 60601-2-51 Standard concerning ECG devices

Each of the above-mentioned standards requires consideration of additional risks.

In order to prepare a risk analysis properly and be sure that all necessary considerations have been taken into account, first it is necessary to determine which standards will apply to the straps. Then, it is necessary to get familiar with the requirements of those standards and, thus, prepare a list of risks to be analyzed. A document OD-2044 published by IECEE may support the performance of this task.

Conducting the risk analysis without following the applicable safety standards will entail the need to make amendments at the phase of product quality certification.

4. Incorrect determination of risk acceptability criteria

Prior to the analysis of product-related risks, it is necessary to determine the acceptable level of risk. In other words, it is necessary to determine the risk acceptability criteria. The ISO 14971 standard requires that the risk evaluation include probability and severity of each risk. Based on that, it is necessary to decide whether the risk needs to be mitigated. To this end, manufacturers usually prepare a table which is similar to the one presented below.

		Probability				
		>50%	50%-10%	10%-1%	1%-0.01%	<0.01%
Severity	Death					
	Severe, permanent injury					
	Severe, non-permanent injury					
	Slight injury					
	Temporary discomfort					
	None					

Unacceptable level Acceptable level

Depending on the currently analyzed device, the table may consist of the different number of probability and severity levels. The manufacturer has also the right to decide if a particular level of risk is acceptable for their products. In the case of a diagnostic device the levels of acceptance/non-acceptance, presented in the table below, seem to be adequate, but taking into account life-saving devices (e.g. a defibrillator) the manufacturer may decide that slight bodily injury which occurred during the use of the device is acceptable.

The most common mistake during determination of risk acceptability criteria is the lack of accuracy in specification of probability and severity. For instance, instead of numerical determination of probability, the following definitions are used: “often”, “rarely”, “very rarely”. In this case it is difficult to explicitly indicate the difference between “rarely” and “very rarely”, thus, it is impossible to properly attribute probability to the analyzed risk.

Another mistake is the determination of risk acceptability criteria without following the local/international regulations, standards which apply to a particular device, current state of knowledge, level of technology development and common business practice.

Sometimes, the manufacturer attributes probability and severity to all product-related risks at first, and then determines the risk acceptability criteria so the risk for each identified and potentially hazardous situation becomes acceptable. This causes non-compliance with the ISO 14971 standard which requires the determination of acceptance levels, acc. to the guidelines described in the manufacturer’s policy prior to the preparation of risk analysis for different, potentially hazardous situations.

5. Incorrect determination of essential performance

The IEC 60601-1 standard requires that the manufacturer determine essential performance for a medical device. The IEC 60601-1 standard defines essential performance as a clinical device function, lack of which causes unacceptable risk level.

For instance, in relation to a medical ventilator, essential performance will be respiratory action support because, in the case of a respiratory arrest, the patient put on a ventilator may die. It is similar as in the case of the incubator for newborns. Essential performance of this device is to maintain inside it a particular level of temperature, as its decrease may lead to a disease or death of the baby.

Let's consider if the heart rate monitor strap for an elderly person is of essential performance to ensure safety. To do this we have to identify the functions of the strap:

1. Monitoring the heart rate of the elderly person.
2. Generating an alarm signal in the case of detection of improper heart rate.
3. Transferring information about the improper heart rate to the family.
4. Transferring information about the improper heart rate to the doctor.

Now, it is necessary to consider whether the absence of any of the above-mentioned functions constitutes an unacceptable risk.

Since the strap is designed to substitute traditional diagnostics and in the case of receiving incorrect information the doctor is likely to make a bad decision, incorrect monitoring of the heart rate by the strap may lead to the patient's death. Thus, proper monitoring of the heart rate is the essential performance of the device.

We can assume, however, that the strap will only supplement traditional diagnostics and the doctor, who is guided by other tests, will be able to detect the strap malfunction. Consequently, the doctor will not choose an improper therapy, basing only on the incorrect information from the strap. In this case proper monitoring of the heart rate would not be the essential performance of the device.

Similar considerations should be taken into account for all functions of the strap.

It is necessary to remember that if a device has essential performance, it must maintain the functionality also in emergency situations, even if one of the components is damaged. Therefore, to avoid further difficulties during safety tests, it is recommended to determine essential performance as precisely as possible. The recommended algorithm for identification of essential performance has been presented in point 4.3 of the IEC 60601-1:2005+A1:2012(E) standard.

As part of the summary of this issue, it is necessary to consider the fact that some of IEC 60601 family standards for particular types of medical devices (IEC 60601-2-xx) enforce specific essential performance.

They can be for example:

- generation of alarm signals in emergency situations,
- provision of particular therapy,
- level of accuracy of particular therapy,
- level of accuracy of diagnostics.

Therefore, at the beginning of the medical device development, it is always recommended to determine which standard will apply to it. Essential performance forced by a detailed standard (IEC 60601-2-xx) may be extended depending on the result of risk analysis for the particular device.

6. Absence of objective evidence to prove particular probability and possible severity for each hazardous situation

According to the ISO 14971 standard, estimation of probability and possible severity of each hazardous situation, needs to be based on facts. They can be for example:

- historical reports for similar devices,
- experts' opinions in a given field,
- statistical surveys,
- tests.

Conducting risk analysis on the basis of above-mentioned information is expensive and time-consuming. Therefore, sometimes the manufacturer - particularly while preparing documentation for the risk analysis at the late phase of the product development - tends to "speed up" the process. Sometimes in such a situation, instead of searching for information, the manufacturer determines the probability and severity of a hazardous situation at their own discretion. It is non-compliant with the ISO 14971 standard, leads to incorrect risk evaluation and, if a certification authority demands information on the course of determination of particular probability and severity levels for particular threats, may be a source of problems.

7. Minimizing all risks thanks to instruction manual/user information

The manufacturer tends to add warnings for the user, instead of mitigating risks, especially when they identify the threat at the late phase of the product development. Housing of the device becomes hot - let's add a label "Caution - hot". The user's hand can get stuck in the device - let's add information in the manual that says: Do not put your hands in here, etc. Such situations take place most often because adding a warning is the easiest and cheapest solution. Unfortunately, it is the least effective one at the same time. While it can be assumed that medical personnel will get familiar with all warnings related with the device, patients cannot be expected to do the same. In addition, in a stress situation, people tend to lose their reason, therefore, even medical personnel may fail to follow the warnings.

This is included in the ISO 14971 standard which requires that the manufacturer try to mitigate the risk at first (e.g. try to protect the product housing from overheating). If it turns out to be impossible, they should try to provide some protection (e.g. additional covers). Only when the two solutions turned out to be insufficient or inefficient, the manufacturer should include a warning either in the manual or on the product in order to efficiently reduce the risk to the acceptable level. This standard does not allow to apply warnings if there is other, more efficient method to reduce the risk.

8. Premature resignation from further risk mitigation

Sometimes the risk analysis of the manufacturer shows that the risk is at the unacceptable level but further reduction will be too expensive, thus, the manufacturer ceases to continue the process. In accordance with the EN ISO 14971:2012 (E) standard, such an approach is unacceptable.

In accordance with the standard, leaving the risk at the unacceptable level is possible only in the case the medical benefit for the patient, resulting from the use of the device, exceeds the level of risk. Automated external defibrillator (AED) is an example of such a device. Application of AED can cause skin burn (which can be determined as unacceptable risk) but it can also save the patient's life. Adding skin burn to the harms and the possibility of saving life to the benefits, it is obvious that the benefit largely exceed the risk.

In some cases, the manufacturer argues that the risk is at the unacceptable level but also points out that it occurs in all similar products available on the market. In this case, the manufacturer has probably badly determined the risk acceptability criteria for their devices. The ISO 14971 standard indicates that risk acceptance levels should be determined, inter alia, on the basis of the current state of technical data. Therefore, if the level of risk is the same for all similar devices, it is probably at the acceptable level.

9. Improper documentation of risk control measures implemented to minimize the risk

In accordance with the ISO 14971 standard, the manufacturer should indicate the manner of minimizing the risk, apply measures to reduce the risk, and verify the effectiveness of the implemented measures.

Harm	Before introduction of risk control measures			Risk control measures	After introduction of risk control measures		
	Severity	Probability	Acceptable?		Severity	Probability	Acceptable?
Injury as a result of the contact with sharp edges of the display	Slight bodily injury	>50%	No	Rounding the edges	None	<0.01%	Yes
Discomfort of the user resulting from the contact with hot components of the device	Passing discomfort	>50%	No	Instruction manual	Passing discomfort	10% - 1%	Yes
The device fell over the user/ patients causing bone fracture	Severe, non-permanent bodily injury	10%-1%	No	Compliance with the IEC 60601-1 standard	Severe, non-permanent bodily injury	<0.01%	Yes
Infection in the patient as a result of selection of bad cleaning method	Death	10%-1%	No	Instruction manual	Death	<0.01%	No
* information contained in the table is for illustrative purposes only							

As in the example presented above, the manufacturer often fails to precisely determine the method of minimizing the risk. General determination of risk reduction methods gives no opportunity to effectively verify whether the measures have been implemented. How should the measure described as "instruction manual" be understood and what should the person responsible for the verification examine? Does the instruction manual really exist? Does it contain special information?

Therefore, risk control measure should be determined in detail. It would be best to refer to the document and the related entries. For instance, in the manner presented below:

Harm	Before introduction of risk control measures			Risk control measures	After introduction of risk control measures		
	Severity	Probability	Acceptable?		Severity	Probability	Acceptable?
Injury as a result of the contact with sharp edges of the display	Slight bodily injury	>50%	No	The requirement of the product specification (doc. no. SP-01) that the display edges should be rounded with 1 mm radius.	None	<0.01%	Yes
Discomfort of the user resulting from the contact with hot components of the device.	Temporary discomfort	>50%	No	"Device instruction manual....." chapter "Warning" entry "Caution: The heating surface of the device can be hot when in use"	Temporary discomfort	10% - 1%	Yes
The device fell over the user/ patient causing bone fracture	Severe, non-permanent bodily injury	10%-1%	No	Product test procedure (PTP-01) test of stability during 10 degree inclination	Severe, non-permanent bodily injury	<0.01%	Yes
Infection in the patient as a result of selection of bad cleaning method	Death	10%-1%	No	"Device instruction manual....." chapter "Cleaning" entry "After each test, the device should be carefully cleaned with the use of 90% spirit"	Death	<0.01%	No
* information contained in the table is for illustrative purposes only							

If the manufacturer has expressly determined the risk control measures, it would be easy to verify their effectiveness of implementation. In addition, if the manufacturer is eager to modify the device, documentation or instruction manual, it is easy to verify whether the change requires an update of the risk analysis.

10. Risk analysis is not FMEA

Many manufacturers while designing products, prepare a FMEA document (Failure mode and effects analysis). Since in the process of FMEA preparation the manufacturer determines, inter alia, the effects, frequency and severity of failure, they think they develop the risk analysis documentation according to the ISO 14971 standard at the same time. However, it is not like that. While the manner of conducting risk analysis and FMEA is similar, the reasons behind them are different. While FMEA focuses on failures and their influence on the device functionality (e.g. loss of some functions, damage to the device etc.), the risk analysis concentrates on the health of patients, users or third parties or life-threatening events. Therefore, risk analysis cannot be substituted by FMEA documentation.

In conclusion, if conducted correctly, the risk analysis is an important and useful tool. However, it should be prepared as soon as possible. The condition for obtaining satisfactory results of the risk analysis is proper preparation. It should include both training of the staff and reservation of resources necessary to conduct the analysis. If we are conducting such an analysis for the first time, it is recommended to use some support from people who are familiar with the ISO 14971 standard in order to avoid serious mistakes. Prior to preparation of the risk analysis for a product, it is possible to apply for a certificate of risk management process introduced to the company. During the certification process, an external organization will help in the identification of discrepancies between the implemented process and the requirements of the standard.

For more information on risk management process for medical devices, please visit UL.com/Healthcare or contact us by e-mail: Medical.Inquiry@ul.com.

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