Kaczmarek Wojciech
Bio.morph, Sp. z o.o., Warsaw, Poland

Kamiński Grzegorz
Krzysztof Mianowski
Rafał Rosołek
Tomasz Gołaszewski
Institute of Aeronautics and Applied Mechanics, Warsaw, Poland

Woch Marta
Głyda Krzysztof
Air Force Institute of Technology, Warsaw, Poland

Risk assessment system in the production process of medical devices on the basis of dynamics spine corrector

Keywords

risk assessment, dynamics spine corrector, Risk Priority Number, scoliosis, rehabilitation of the spine

Abstract

The article presents the methodology involved in creating a risk analysis of medical devices. General regulations contained in the PN-EN ISO 14971 provide manufacturers of medical basis for the concretization of standards in the form of risk assessment system for a particular process and product. However, there is no top-down regulations defining the level of acceptable risk and the decision to determine its value rests with the manufacturer. Effectiveness of taken measures was tested on the example of a analysis of dynamics spine corrector – medical device that is allowing independent rehabilitation under the supervision of a physiotherapist and current control of the kinematics and dynamics of the human spine.

1. Introduction

Medicine is constantly looking for new diagnostic and therapeutic solutions, which would allow to take effective treatment while minimizing the risks to the health of the patient. These risks arise from the use of specific technologies, medicinal materials and medicines. Scoliosis are known for a long time and they are a serious social problem. This distortion is a severe faulty posture, accompanied also by secondary changes in the cardiopulmonary system, which significantly limits the efficiency of the patient. There are simple traction and exercise devices used to strengthen muscles mainly postural, which reinforced correct shape and silhouette spine. Unfortunately, they do not have computerized measuring system, which allows for continuous registration parameters characterizing the behavior of the person exercising [5--7].

The main assumption during designing of medical device for dynamic spine corrector (DKK) is to allow the restoration of motor function (joint play of spine segments with simultaneous neuromobilization nerve endings in muscle fibers) in order to restore the natural curvature of the spine, elimination of local muscle contractures. [7] Simultaneous extortion of lightweight traction with dynamic torsional movements should ensure the restoration of the correct mutual positioning of vertebral and change spacing of intervertebral discs.

DKK consists of a fixed frame and a movable manner, which can pivote on a horizontal axis using linear actuators. It changes the horizontal (*Figure 2*) position DKK to the working position (*Figure 1*). During the exercise the patient in the sitting position is zipping his/her foot in the stirrup supports and is clutching hands on the top lavers.

Patient is buckled in his/her waist belt using a special clamp hip. In this position, the movable frame is switched to the horizontal position in which the patient begins the exercise. Exercises consist of alternating bench in front of the left hand - right leg and right hand - the left leg by running alternating torsional movements of the spine.

Launch of new medical devices requires a risk analysis to determine the dangers arising from their use. This analysis provides a qualitative assessment of the level of risk indicates the significant threats and ways to avoid them [2-3].

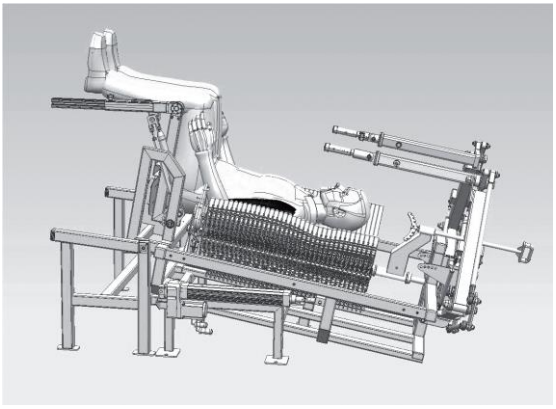

Figure 1. DKK stand – ready to use position

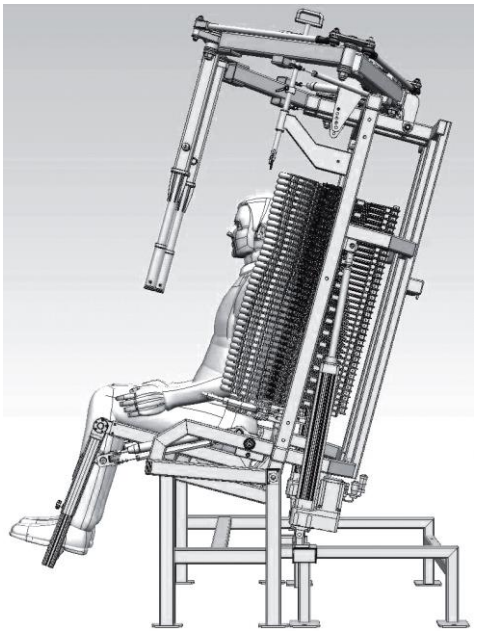

Figure 2. DKK stand for the dynamic spine correction – general side view

2. Risk assessment method

During the risk analysis, each risk or failure is analysed and rated with respect to its severity (S), probability of occurrence (O), and detection rate (D), according to the standard [8]. The rating for each of the three aspects ranges from 1 (low security risk/failure, low probability of occurrence, high detection probability) to 10 (severe injuries or death, high probability of occurrence, no/low probability for detection) (*Table 1÷3*).

Figure 3. DKK stand – real view

Table 1. Severity rating [8].

Rating S	Criteria: Severity of effect	Consequence	Treatment
10	Death	-	-
9	Quadriplegia	Life-long medical care necessary / coma / permanent damage	Hospital stay
8	Amputations, paraplegia, blindness, deafness, traumatic brain injury (severe), fourth-degree burns	Life-long medical care necessary / coma / permanent damage	Hospital stay
7	Complex fractures, open fracture, inner injuries, traumatic brain injury (severe), third-degree burns	Permanent damage possible	Hospital stay

6	Gash, fractures, torn muscles, articular cartilage injury, traumatic brain injury (moderate), second-degree burns	Permanent damage possible	Hospital stay
5	Gash, fractures, torn muscles, articular cartilage injury, traumatic brain injury (mild), second-degree burns	Reversible injury	Hospital stay or ambulant treatment
4	Severe cuts, severe scratches, severe contusions, strains, first-degree burns	Reversible injury	Ambulant treatment or self-treatment
3	Minor cuts, minor scratches, minor contusions, stiff muscles, tension, blisters, excoriations, sickness, first-degree burns	Discomfort during application up to three days after application	Self-treatment
2	Slight sickness, pressure marks	Discomfort	-
1	No harm	-	-

Table 2. Occurrence rating [8].

Rating O	**Criteria: Probability of occurrence**
10	Occurs or may occur very likely during every use of the session
9	Occurs or may occur likely during every use of the session
8	Occurs in 1 of 5 sessions (less than once a day)
7	Occurs in 1 of 10 sessions (less than once a day)
6	Occurs in 1 of 50 sessions (less than once half a month)
5	Occurs in 1 of 100 sessions (less than once a month)
4	Occurs in 1 of 500 sessions (less than once half a year)
3	Occurs in 1 of 1000 sessions (less than once per year)
2	Occurrence very unlikely
1	Occurrence nearly impossible

Table 3. Detection rating [8].

Rating D	**Criteria: Likelihood of detection by design control**
10	No chance of detection
9	Very remote chance of detection
8	Remote chance of detection
7	Very low chance of detection by indirect methods (hardware or software)
6	Low chance of detection by indirect methods (hardware or software)
5	Moderate chance of detection by indirect methods (hardware or software)
4	High chance of detection by indirect methods (hardware or software)
3	High chance of detection by direct or indirect methods (hardware/software)
2	Direct and indirect detection: Hardware or software
1	Direct detection: Hardware or safe software (category 4, performance level e)

The product out of these three ratings is called Risk Priority Number (RPN), which can be described as:

$$RPN = S \cdot O \cdot D \tag{1}$$

In case, the RPN is greater than a critical threshold, preventing measures are required in order to reach a final RPN below or equal to the critical threshold by means of reasonable and justifiable security measures. Risk assessment procedure requires knowledge of the process technology and consists of the following steps:

- identification of the process properties or medical device, which affect the safety of the product,
- identification of known, or foreseeable hazards, together with their consequences,
- estimation the risk seriousness, the probability of its occurrence and the detection measure.

The first stage consists of the activities designed to obtain and clarify the information about the process and the product. The information relates to the intended application of the product, its structure and the manufacturing process.

The second stage concerns the hazard identification based on the prior information about the process with the simultaneous categorization of threats. Submitted questions, discussed in the standard [8], shall be subsequently analysed and then one should complete the table regarding to the categorization of threats.

The third stage contains the determination of the seve rity (S), probability of occurrence (O) and detection r ate (D), for each hazard. Ordinal scales from 1 to 10 i s being used. As a synthetic measure Risk Priority Nu mber (RPN) is assumed (*Table 4*). Risk Priority Num ber can be categorizes down to four levels:

- minor risk level,
- average risk level,
- critical risk level,
- unacceptable risk level.

Table 4. Summary of the risk categories [8].

RPN	Risk levels
0-30	minor risk level
30-55	average risk level
55-75	critical risk level
>75	unacceptable risk level

Critical risk level means the necessity to take appropr iate corrective actions, including of the process or sus pension of the finished product sale. Average risk lev el is an acceptable risk area. Preventive actions are re quired, which should lead to a constant reduction of r isk up to lower level (changes in technology should b e proposed, warning measures should be consider). M inor risk level of risk does not require taking any acti on.

The aim of the work is to build a computer model of r isk assessment in the production process of a medical device, taking into account the requirements of more specific standards, based on the example of dental co mposites.

3. Risk assessment results

Risk analysis showed that there are: one unacceptable risk state, five critical levels, nine average and two minor (*Table 5*). It also showed that there is a need to create some mechanism that prevent the cause of the failure mode from occurring or that detect the failure and stop the application before an incident can happen. It could also reduce the severity by e.g. designing softer and rounder edges. Preventing measures includes specific inspection, testing or quality assurance procedures; selection of other components or materials; derating; limiting environmental stresses or operating ranges; redesign of the item to avoid the failure mode; monitoring mechanisms; performing preventative maintenance; or inclusion of back-up systems or redundancy (Table 6).

The preventive actions taken have allowed to reduce the level of risk to the acceptable level (average and low level of risk).

A graphical representation of the results is shown in Figure 4.

Table 5. Detailed risk analysis and effects.

No.	Risk and effect	S1	O1	D1	RPN before
1	the presence of electric fields, magnetic (cables)	1	9	2	**18**
2	the heating up of the medical device	2	5	4	**40**
3	uncontrolled drop of the movable frame from horizontal (base) position to working position	6	3	3	**54**
4	oscillation of components with sharp edges	4	4	5	**80**
5	moving components causing injury	4	4	6	**96**
6	uncontrollable forces on the device	6	2	6	**72**
7	unpleasant sounds of moving components	2	7	2	**28**
8	biological risks resulted from contact with the body parts to the medical device	3	8	8	**192**
9	the use of chemical cleaning and disinfection (allergies)	2	3	7	**42**
10	incorrect initial measurement (qualification to exercise)	3	5	3	**45**
11	consumption components of the medical device	5	4	4	**80**
12	errors of use (distraction exerciser, the incorrect-petent warm-up)	3	5	4	**60**
13	risks associated with the use of errors (incorrect calibration of the device)	3	4	3	**36**
14	incomplete documentation device (manual)	3	2	6	**36**
15	risks associated with errors of use (indication contraindications to exercise)	5	2	5	**50**
16	risks associated with taking the wrong decisions based on the readings during exercise	2	4	5	**40**
17	risks associated with incorrect calibration of the components	4	2	4	**32**

Table 6. Preventive actions in detailed risk analysis.

No.	Preventive actions	S2	O2	D2	RPN after
1	the presence of electric fields, magnetic (cables)	1	9	2	**18**
2	the heating up of the medical device	2	5	4	**40**
3	uncontrolled drop of the movable frame from horizontal (base) position to working position	6	3	3	**54**
4	oscillation of components with sharp edges	4	3	3	**36**
5	moving components causing injury	4	3	4	**48**
6	uncontrollable forces on the device	5	2	4	**40**
7	unpleasant sounds of moving components	2	7	2	**28**
8	biological risks resuled from contact with the body parts to the medical device	3	5	4	**60**
9	the use of chemical cleaning and disinfection (allergies)	2	3	7	**42**
10	incorrect initial measurement (qualification to exercise)	3	5	3	**45**
11	consumption components of the medical device	5	3	3	**45**
12	errors of use (distraction exerciser, the incorrect-petent warm-up)	3	4	3	**36**
13	risks associated with the use of errors (incorrect calibration of the device)	3	4	3	**36**

14	incomplete documentation device (manual)	3	2	6	**36**
15	risks associated with errors of use (indication contraindications to exercise)	5	2	5	**50**
16	risks associated with taking the wrong decisions based on the readings during exercise	2	4	5	**40**
17	risks associated with incorrect calibration of the components	4	2	4	**32**

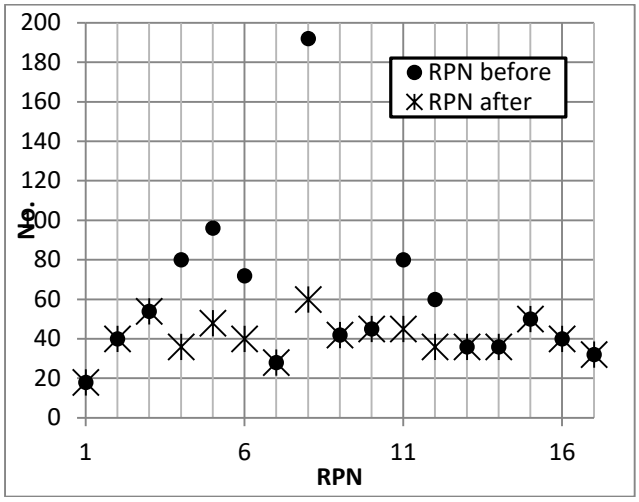

Figure 4. Detailed risk analysis results

4. Conclusion

Risks can be placed throughout the whole lifecycle of the product and the risks which become apparent in a one moment of the lifecycle can be managed by action taken in a completely different time of lifecycles. For this reason it is necessary that the analysis concerned the total life cycle. This means that the manuals for manufacturers of medical devices regarding the rules for the application of risk management from initial concept to final withdrawal from the production and disposal.

The scope of this analysis does not include decisions about the use of a medical device. This decision in the context of a particular clinical procedure requires the residual balance of risks to the anticipated benefits of the procedure or the risks and anticipated benefits of alternative procedures. It is recommended for such evaluations to take the intended use, functional characteristics and risks associated with the medical device, as well as the risks and benefits associated with Stored Procedures or clinical circumstances be used [8].

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