

VERIFICATION REPORT

ISO 14971:2007

Medical devices- Application of risk management to medical devices

Report Reference No	200807
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Date of issue	
Verification laboratory	System Safety, Inc.
Address	5150 Corte Playa Catalina San Diego, CA 92124-1558
Verification location	
Applicant	
Address	
Standard	ISO 14971:2007
Test Report Form No	03092000
Test procedure	Audit / Review
Procedure deviation	None
Non-standard test method	None
Type of end product	
End product Trademark	
End product Model and/or type reference	
End product Manufacturer	
End product Address	See above
End product Rating(s)	

PEMS/PESS Configuration Information:	No special hardware configuration necessary.
Software Designer (if different than end Product manufacturer).	NA
Address	NA
	NA
Method of Identification of Software:	Revision
Particular Risks Addressed by Software:	As contained in hazard analyses

GENERAL INFORMATION

Particulars: verification item vs. verification requirements

As EN 60601-1-4 is a collateral standard to EN 60601-1, this report is to be used in conjunction with Test Report Reference No.: N.N.

Possible verification case verdicts

Verification case does not apply to the verification item ----- : **N(ot)/A(pplicable)**
 Verification item is available ----- : **N(oted)**
 Verification item does meet the requirement ----- : **P(ass)**
 Verification item does meet the requirement under the limited scope of this assessment ----- : **P(ass) L(imited Scope)**
 Verification item does not meet the requirement ----- : **F(ail)**
 Verification item does not meet the requirement under the limited scope of this assessment -- : **F(ail) L(imited Scope)**

Minor non-compliances are noted in regular case and font
 Major non-compliances are note in **ALL CAPS** and / or **BOLD**

General remarks

"(See enclosure #)" refers to an enclosure appended to this report.
 "(See appended table)" refers to a table appended to the report.
 Throughout this report a period is used as the decimal separator.
 The verification results presented in this report relate only to the item being verified.
 This verification report shall not be reproduced except in full without the written approval of the verification laboratory.

SUMMARY OF CONTENTS:

The equipment has been evaluated according to standard ISO 14971:2007 2nd Edition.
 All applicable verifications according to the above-specified standard(s) have been carried out, however the scope was limited to sub-system evaluation.
 These verifications fulfil the requirements of standard EN 45001.

Note: As per ISO 14971, determination of compliance is by inspection and audit, the attachments should be documents or parts of documents.

Acronyms and Abbreviations:

COTS	Commercial of the shelf software
DFU	Directions for Use
H&RA	Hazard and Risk Analysis
MDD	European Medical Device Directive
PEMS	Programmable Electronic Medical Devices
RMP	Risk Management Plan
SOP	Standard Operating Procedure
V&V	Verification and Validation



Results and Conclusions:

Clause	Requirement	Result- Remark	Verdict
3.	General requirements for risk management		
3.1	Risk management process		
	<p>The manufacturer shall establish, document and maintain throughout the life-cycle an ongoing process for identifying hazards associated with a medical device, estimating and evaluating the associated risks, controlling these risks, and monitoring the effectiveness of the controls. This process shall include the following elements:</p> <ul style="list-style-type: none"> - risk analysis; - risk evaluation; - risk control; - production and post-production information. <p>Where a documented product realization process exists, such as that described in Clause 7 of ISO 13485:2003, it shall incorporate the appropriate parts of the risk management process.</p> <p><i>NOTE 1 A documented quality management system process can be used to deal with safety in a systematic manner, in particular to enable the early identification of hazards and hazardous situations in complex medical devices and systems.</i></p> <p><i>NOTE 2 A schematic representation of the risk management process is shown in Figure 1. Depending on the specific life-cycle phase, individual elements of risk management can have varying emphasis. Also, risk management activities can be performed iteratively or in multiple steps as appropriate to the medical device. Annex B contains a more detailed overview of the steps in the risk management process.</i></p>		
3.3	Management responsibilities		
	<p>Top management shall provide evidence of its commitment to the risk management process by:</p> <ul style="list-style-type: none"> - – ensuring the provision of adequate resources and - – ensuring the assignment of qualified personnel (see 3.3) for risk management. <p>Top management shall:</p> <ul style="list-style-type: none"> - – define and document the policy for determining criteria for risk acceptability; this policy shall ensure that criteria are based upon applicable national or regional regulations and relevant International Standards, and take into account available information such as the generally accepted state of the - art and known stakeholder concerns; - – review the suitability of the risk management process at planned intervals to ensure continuing effectiveness of the risk management process and document any decisions and actions taken; if the manufacturer has a quality management system in place, this review may be part of the quality - management system review. <p><i>NOTE The documents can be incorporated within the documents produced by the manufacturer's quality management system and these documents can be referenced in the risk management file.</i></p>		

Clause	Requirement	Result- Remark	Verdict
3.4	Qualification of personnel		
	<p>Persons performing risk management tasks shall have the knowledge and experience appropriate to the tasks assigned to them. These shall include, where appropriate, knowledge and experience of the particular medical device (or similar medical devices) and its use, the technologies involved or risk management techniques. Appropriate qualification records shall be maintained.</p> <p><i>NOTE Risk management tasks can be performed by representatives of several functions, each contributing their specialist knowledge.</i></p>		
3.5	Risk management plan		
	<p>Risk management activities shall be planned. Therefore, for the particular medical device being considered, the manufacturer shall establish and document a risk management plan in accordance with the risk management process. The risk management plan shall be part of the risk management file.</p> <p>This plan shall include at least the following:</p> <ul style="list-style-type: none"> a) the scope of the planned risk management activities, identifying and describing the medical device and the life-cycle phases for which each element of the plan is applicable; b) assignment of responsibilities and authorities; c) requirements for review of risk management activities; d) criteria for risk acceptability, based on the manufacturer's policy for determining acceptable risk including criteria for accepting risks when the probability of occurrence of harm cannot be estimated; e) verification activities; f) activities related to collection and review of relevant production and post-production information. <p><i>NOTE 1 Refer to Annex F for guidance on developing a risk management plan.</i></p> <p><i>NOTE 2 Not all parts of the plan need to be created at the same time. The plan or parts of it can be developed over time.</i></p> <p><i>NOTE 3 The criteria for risk acceptability are essential for the ultimate effectiveness of the risk management process. For each risk management plan the manufacturer should choose appropriate risk acceptability criteria.</i></p>		
	<p>Options could include, among others:</p> <ul style="list-style-type: none"> - indicating in a matrix, such as Figures D.4 and D.5, which combinations of probability of harm and severity of harm are acceptable or unacceptable; - further subdividing the matrix (e.g., negligible, acceptable with risk minimization) and requiring that risks first be made as low as reasonably practicable before determining that they are acceptable (see D.8). 		

Clause	Requirement	Result- Remark	Verdict
	Whichever option is chosen, it should be determined according to the manufacturer's policy for determining criteria for risk acceptability and thus be based upon applicable national or regional regulations and relevant International Standards, and take into account available information such as the generally accepted state of the art and known stakeholder concerns (see 3.2). Refer to D.4 for guidance on establishing such criteria.		
	If the plan changes during the life-cycle of the medical device, a record of the changes shall be maintained in the risk management file.		
3.6	Risk management file		
	<p>management file. In addition to the requirements of other clauses of this International Standard, the risk management file shall provide traceability for each identified hazard to:</p> <ul style="list-style-type: none"> - the risk analysis; - the risk evaluation; - the implementation and verification of the risk control measures; - the assessment of the acceptability of any residual risk(s). <p><i>NOTE 1 The records and other documents that make up the risk management file can form part of other documents and files required, for example, by a manufacturer's quality management system. The risk management file need not physically contain all the records and other documents; however, it should contain at least references or pointers to all required documentation. The manufacturer should be able to assemble the information referenced in the risk management file in a timely fashion.</i></p> <p><i>NOTE 2 The risk management file can be in any form or type of medium.</i></p>		

Clause	Requirement	Result- Remark	Verdict
4.	Risk analysis		
4.1	Risk analysis process		
	<p>Risk analysis shall be performed for the particular medical device as described in 4.2 to 4.4. The implementation of the planned risk analysis activities and the results of the risk analysis shall be recorded in the risk management file.</p> <p><i>NOTE 1 If a risk analysis, or other relevant information, is available for a similar medical device, that analysis or information can be used as a starting point for the new analysis. The degree of relevance depends on the differences between the devices and whether these introduce new hazards or significant differences in outputs, characteristics, performance, or results. The extent of use of an existing analysis is also based on a systematic evaluation of the effects the changes have on the development of hazardous situations.</i></p> <p><i>NOTE 2 Some risk analysis techniques are described in Annex G.</i></p> <p><i>NOTE 3 Additional guidance on risk analysis techniques for in vitro diagnostic medical devices is given in Annex H.</i></p> <p><i>NOTE 4 Additional guidance on risk analysis techniques for toxicological hazards is given in Annex I. In addition to the records required in 4.2 to 4.4, the documentation of the conduct and results of the risk analysis shall include at least the following:</i></p> <ul style="list-style-type: none"> <i>a) a description and identification of the medical device that was analyzed;</i> <i>b) identification of the person(s) and organization who carried out the risk analysis;</i> <i>c) scope and date of the risk analysis.</i> <i>d)</i> <p><i>NOTE 5 The scope of the risk analysis can be very broad (as for the development of a new device with which a manufacturer has little or no experience) or the scope can be limited (as for analyzing the impact of a change to an existing device for which much information already exists in the manufacturer's files).</i></p>		
4.2	Intended use/intended purpose and identification of characteristics related to the safety of the medical device		
	<p>For the particular medical device being considered, the manufacturer shall document the intended use and reasonably foreseeable misuse. The manufacturer shall identify and document those qualitative and quantitative characteristics that could affect the safety of the medical device and, where appropriate, their defined limits. This documentation shall be maintained in the risk management file.</p> <p><i>NOTE 1 In this context, misuse is intended to mean incorrect or improper use of the medical device.</i></p> <p><i>NOTE 2 Annex C contains questions such as those relating to use that can serve as a useful guide in identifying medical device characteristics that could have an impact on safety.</i></p>		

Clause	Requirement	Result- Remark	Verdict
4.3	Identification of hazards		
	The manufacturer shall compile documentation on known and foreseeable hazards associated with the medical device in both normal and fault conditions.		
	This documentation shall be maintained in the risk management file. <i>NOTE The examples of possible hazards in E.2 and H.2.4 can be used as guidance by the manufacturer to initiate hazard identification.</i>		

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4.4	Estimation of the risk(s) for each hazard		
	<p>Reasonably foreseeable sequences or combinations of events that can result in a hazardous situation shall be considered and the resulting hazardous situation(s) shall be recorded.</p> <p><i>NOTE 1 To identify hazardous situations not previously recognized, systematic methods covering the specific situation can be used (see Annex G).</i></p> <p><i>NOTE 2 Examples of hazardous situations are provided in H.2.4.5 and E.4.</i></p> <p><i>NOTE 3 Hazardous situations can arise from slips, lapses, and mistakes.</i></p>		
	<p>For each identified hazardous situation, the associated risk(s) shall be estimated using available information or data. For hazardous situations for which the probability of the occurrence of harm cannot be estimated, the possible consequences shall be listed for use in risk evaluation and risk control. The results of these activities shall be recorded in the risk management file.</p>		
	<p>Any system used for qualitative or quantitative categorization of probability of occurrence of harm or severity of harm shall be recorded in the risk management file.</p> <p><i>NOTE 4 Risk estimation incorporates an analysis of the probability of occurrence and the consequences. Depending on the application, only certain elements of the risk estimation process might need to be considered. For example, in some instances it will not be necessary to go beyond an initial hazard and consequence analysis. See also D.3.</i></p> <p><i>NOTE 5 Risk estimation can be quantitative or qualitative. Methods of risk estimation, including those resulting from systematic faults, are described in Annex D. Annex H gives information useful for estimating risks for in vitro diagnostic medical devices.</i></p> <p><i>NOTE 6 Information or data for estimating risks can be obtained, for example, from:</i></p> <ul style="list-style-type: none"> <i>a) published standards;</i> <i>b) scientific technical data;</i> <i>c) field data from similar medical devices already in use, including published reported incidents;</i> <i>d) usability tests employing typical users;</i> <i>e) clinical evidence;</i> <i>f) results of appropriate investigations;</i> <i>g) expert opinion;</i> <i>h) external quality assessment schemes.</i> 		
5.	Risk evaluation		
	<p>For each identified hazardous situation, the manufacturer shall decide, using the criteria defined in the risk management plan, if risk reduction is required. If risk reduction is not required, the requirements given in 6.2 to 6.6 do not apply for this hazardous situation (i.e., proceed to 6.7). The results of this risk evaluation shall be recorded in the risk management file.</p> <p><i>NOTE 1 Guidance for deciding on risk acceptability is given in D.4.</i></p> <p><i>NOTE 2 Application of relevant standards, as part of the medical device design criteria, might constitute risk control activities, thus meeting the requirements given in 6.3 to 6.6.</i></p>		

Clause	Requirement	Result- Remark	Verdict
6.	Risk control		
6.1	Risk reduction		
	When risk reduction is required, risk control activities, as described in 6.2 to 6.7, shall be performed		
6.2	Risk control option analysis		
	The manufacturer shall identify risk control measure(s) that are appropriate for reducing the risk(s) to an acceptable level.		
	<p>The manufacturer shall use one or more of the following risk control options in the priority order listed:</p> <ul style="list-style-type: none"> a) inherent safety by design; b) protective measures in the medical device itself or in the manufacturing process; c) information for safety. <p><i>NOTE 1 If implementing option b) or c), manufacturers can follow a process where reasonably practicable risk control measures are considered and the option providing the appropriate reduction in risk is chosen before determining whether the risk is acceptable.</i></p> <p><i>NOTE 2 Risk control measures can reduce the severity of the harm or reduce the probability of occurrence of the harm, or both.</i></p> <p><i>NOTE 3 Many standards address inherent safety, protective measures, and information for safety for medical devices. In addition, many other medical device standards have integrated elements of the risk management process (e.g., electromagnetic compatibility, usability, biocompatibility). Relevant standards should be applied as part of the risk control option analysis.</i></p> <p><i>NOTE 4 For risks for which the probability of occurrence of harm cannot be estimated, see D.3.2.3.</i></p> <p><i>NOTE 5 Guidance on information for safety is provided in Annex J.</i></p>		
	The risk control measures selected shall be recorded in the risk management file		
	If, during risk control option analysis, the manufacturer determines that required risk reduction is not practicable, the manufacturer shall conduct a risk/benefit analysis of the residual risk (proceed to 6.5).		
6.3	Implementation of risk control measure(s)		
	The manufacturer shall implement the risk control measure(s) selected in 6.2.		
	Implementation of each risk control measure shall be verified. This verification shall be recorded in the risk management file.		
	<p>The effectiveness of the risk control measure(s) shall be verified and the results shall be recorded in the risk management file.</p> <p><i>NOTE The verification of effectiveness can include validation activities.</i></p>		

Clause	Requirement	Result- Remark	Verdict
6.4	Residual risk evaluation		
	After the risk control measures are applied, any residual risk shall be evaluated using the criteria defined in the risk management plan. The results of this evaluation shall be recorded in the risk management file.		
	If the residual risk is not judged acceptable using these criteria, further risk control measures shall be applied (see 6.2).		
	For residual risks that are judged acceptable, the manufacturer shall decide which residual risks to disclose and what information is necessary to include in the accompanying documents in order to disclose those residual risks. <i>NOTE Guidance on how residual risk(s) can be disclosed is provided in Annex J.</i>		
6.5	Risk/benefit analysis		
	If the residual risk is not judged acceptable using the criteria established in the risk management plan and further risk control is not practicable, the manufacturer may gather and review data and literature to determine if the medical benefits of the intended use outweigh the residual risk. If this evidence does not support the conclusion that the medical benefits outweigh the residual risk, then the risk remains unacceptable. If the medical benefits outweigh the residual risk, then proceed to 6.6.		
	For risks that are demonstrated to be outweighed by the benefits, the manufacturer shall decide which information for safety is necessary to disclose the residual risk		
	The results of this evaluation shall be recorded in the risk management file. <i>NOTE See also D.6.</i>		
6.6	Risks arising from risk control measures		
	The effects of the risk control measures shall be reviewed with regard to: a) the introduction of new hazards or hazardous situations; b) whether the estimated risks for previously identified hazardous situations are affected by the introduction of the risk control measures.		
	Any new or increased risks shall be managed in accordance with 4.4 to 6.5.		
	The results of this review shall be recorded in the risk management file.		
6.7	Completeness of risk evaluation		
	The manufacturer shall ensure that the risk(s) from all identified hazardous situations have been considered. The results of this activity shall be recorded in the risk management file		

Clause	Requirement	Result- Remark	Verdict
7.	Evaluation of overall residual risk evaluation		
	<p>overall residual risk posed by the medical device is acceptable using the criteria defined in the risk management plan.</p> <p><i>NOTE 1 For guidance on overall residual risk evaluation, see D.7.</i></p>		
	<p>If the overall residual risk is not judged acceptable using the criteria established in the risk management plan, the manufacturer may gather and review data and literature to determine if the medical benefits of the intended use outweigh the overall residual risk. If this evidence supports the conclusion that the medical benefits outweigh the overall residual risk, then the overall residual risk can be judged acceptable. Otherwise, the overall residual risk remains unacceptable.</p>		
	<p>For an overall residual risk that is judged acceptable, the manufacturer shall decide which information is necessary to include in the accompanying documents in order to disclose the overall residual risk.</p> <p><i>NOTE 2 Guidance on how residual risk(s) can be disclosed is provided in Annex J.</i></p>		
	<p>The results of the overall residual risk evaluation shall be recorded in the risk management file</p>		
8.	Risk management report		
	<p>Prior to release for commercial distribution of the medical device, the manufacturer shall carry out a review of the risk management process. This review shall at least ensure that:</p> <ul style="list-style-type: none"> - the risk management plan has been appropriately implemented; - the overall residual risk is acceptable; - appropriate methods are in place to obtain relevant production and past-production information. 		
	<p>The results of this review shall be recorded as the risk management report and included in the risk management file</p>		
	<p>The responsibility for review should be assigned in the risk management plan to persons having the appropriate authority [see 3.4 b)].</p>		
9.	Production and post-production information		
	<p>The manufacturer shall establish, document and maintain a system to collect and review information about the medical device or similar devices in the production and the post-production phases.</p>		
	<p>When establishing a system to collect and review information about the medical device, the manufacturer should consider among other things:</p> <ul style="list-style-type: none"> a) the mechanisms by which information generated by the operator, the user, or those accountable for the installation, use and maintenance of the medical device is collected and processed; <p>or</p> <ul style="list-style-type: none"> b) b) new or revised standards.. 		

Clause	Requirement	Result- Remark	Verdict
	The system should also collect and review publicly available information about similar medical devices on the market		
	This information shall be evaluated for possible relevance to safety, especially the following: <ul style="list-style-type: none"> - – if previously unrecognized hazards or hazardous situations are present or - – if the estimated risk(s) arising from a hazardous situation is/are no longer acceptable. 		
	If any of the above conditions occur: <ol style="list-style-type: none"> 1) the impact on previously implemented risk management activities shall be evaluated and shall be fed back as an input to the risk management process and 2) a review of the risk management file for the medical device shall be conducted; if there is a potential that the residual risk(s) or its acceptability has changed, the impact on previously implemented risk control measures shall be evaluated. 		
	The results of this evaluation shall be recorded in the risk management file. <i>NOTE 1 Some aspects of post-production monitoring are the subject of some national regulations. In such cases, additional measures might be required (e.g., prospective post-production evaluations).</i> <i>NOTE 2 See also 8.2 of ISO 13485:2003.</i>		

Mapping of Required Evidence and Client Documents

Standard Clause	Deliverables	Title	Revision	Date
	Instructions for Use			
	Statements of Residual Risk			
	Quality Record Procedures			
	Document Control/Configuration Management Procedures			
	Risk Management Summary			
	Risk Management Plan			
	Statement of Quality Policy			
	Definition of Responsibility and Authority for all Development Personnel			
	Identification of Verification Resources and Personnel			
	Identification of Management Representative			
	Records of Management Review			
	Life-cycle Definition			
	Hazard Analysis Procedures			
	Hazard Identification Methods			
	Record of Results of Hazard Identification Methods			
	Hazard List and Initiating Causes			
	Risk Estimation Procedures			
	Severity Categorization Methods			
	Likelihood Estimation Methods			
	Record of Estimated Risk for each Hazard			
	Risk Control Procedures			
	Risk Control Method for each Hazard			
	Record of Estimation for the Effectiveness of each Risk Control Method			
	Training Procedures			
	Training Records			
	PEMS Requirements Specification			
	Subsystems Requirements Specification			
	PEMS Architecture Specification			
	Subsystems Architecture Specification			
	Design Specification			
	Test Specification			
	Requirements Specification for CASE Tools, Human-PEMS Interface, Programming Languages and Third Party Software			
	Verification Plan			
	Verification Methods and Results for each Hazard			
	Validation Plan			
	Validation Methods and Results for each Hazard			
	Modification/Change Procedures			
	Risk Management Report			