



VERIFICATION REPORT ISO 14971:2000 (partial)

Medical devices- Application of risk management to medical devices

Report Reference No	20000710
Compiled by (+ signature)	Markus Weber
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Date of issue	
Verification laboratory	System Safety, Inc.
Address	10849 Penara Street San Diego, CA 92126-5936
Verification location	
Applicant	
Address	
Standard	ISO 14971:2000
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 14971:2000 First 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



Clause	Requirement	Result- Remark	Verdict
3.	General requirements for risk management		
3.2	Risk management process		
	<p>The manufacturer shall establish and maintain a process for identifying hazards associated with a medical device, estimating and evaluating the associated risks, controlling these risks, and assessing the effectiveness of the control. This process shall be documented and shall include the following elements</p> <ul style="list-style-type: none"> a) risk analysis; b) risk evaluation; c) risk control; and d) post-production information <p>Where a documented product design/development process exists, it shall incorporate the appropriate parts of the risk management process.</p> <p>NOTE 1-A documented product design/development process can be used to deal with a systematic manner, in particular to enable the early identification of hazards in complex systems and environments. NOTE 2-A schematic representation of the risk management process is shown in Figure 1 NOTE 3-See the bibliography.</p>		
3.3	Management responsibilities		
	<p>The manufacturer shall:</p> <ul style="list-style-type: none"> a) define the policy for determining acceptable risk, taking into account relevant International Standards and national or regional regulations, b) ensure the provision of adequate resources, c) ensure the assignment of trained personnel (see 3.4) for management, performance of work and assessment activities, and d) review the results of risk management activities at defined intervals to ensure continuing suitability of the risk management process <p>The above shall be documented in the risk management file</p>		
3.4	Qualification of personnel		
	<p>The manufacturer shall ensure that those performing risk management tasks include persons with knowledge and appropriate to the tasks assigned to them. This shall include, where appropriate, knowledge and experience of the medical device and its use and risk management techniques. Records of the appropriate qualifications shall be maintained</p>		



Clause	Requirement	Result- Remark	Verdict
3.5	Risk management plan		
	<p>For the particular medical device or accessory being considered, the manufacturer shall prepare 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>The plan shall include the following:</p> <ul style="list-style-type: none"> a) The scope of the plan, identifying and describing the medical device and the life cycle phases for which this plan is applicable; b) A verification plan c) Allocation of responsibilities d) Requirements for review of risk management activities; and e) Criteria for risk acceptability <p>NOTE The criteria for risk acceptability will do much to determine the ultimate effectiveness of the risk management process. Refer to annex E for guidance on establishing such criteria.</p> <p>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.</p>		



Clause	Requirement	Result- Remark	Verdict
4.	Risk analysis		
4.1	Risk analysis procedure		
	<p>Risk analysis, as described in 4.2 to 4.4, shall be performed, and the conduct and results of the risk analysis shall be recorded in the risk management file.</p> <p>NOTE-If a risk analysis is available for a similar medical device, it may be used as a reference provided it can be demonstrated that the processes are similar or that the changes that have been made will not introduce significant differences in results. This should be based on a systematic evaluation of the changes and the ways they can influence the various hazards present.</p> <p>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:</p> <ul style="list-style-type: none"> a) a description and identification of the medical device or accessory that was analyzed; b) identification of the person(s) and organization which carried out the risk analysis; c) date of the analysis. 		
4.3	Identification of known or foreseeable hazards		
	<p>The manufacturer shall compile a list of known or foreseeable hazards associated with the medical device in both normal and fault conditions. Previously recognized hazards shall be identified. This list shall be maintained in the risk management file.</p> <p>Foreseeable sequences of events that may result in a hazardous situation shall be considered and recorded.</p> <p>NOTE 1-The examples of possible hazards listed in annex D and in clause B.2 for in vitro diagnostic medical devices can be used as a memory aid. NOTE 2-To identify hazards not previously recognized, systematic methods covering the specific situation can be used (see annex F).</p>		
5.	Risk evaluation		
	<p>For each identified hazard, the manufacturer shall decide, using the criteria defined in the risk management plan, whether the estimated risk(s) is so low that risk reduction need not be pursued. In this case, the requirements given in 6.2 to 6.6 do not apply for this hazard (i.e., proceed to 6.7). The results of this risk evaluation shall be recorded in the risk management file.</p> <p>NOTE 1-Guidance for deciding on risk acceptability is given in clause E.3.</p> <p>NOTE 2-Application of relevant standards as part of the medical device design criteria might constitute risk control activities, thus necessitating application of the requirements given in 6.3 to 6.6</p>		



Clause	Requirement	Result- Remark	Verdict
6.	Risk control		
6.1	Risk reduction		
	When risk reduction is required, the manufacturer shall follow the process specified in 6.2 to 6.7 to control the risk(s) so that the residual risk(s) associated with each hazard is judged acceptable.		
6.2	Option analysis		
	<p>The manufacturer shall identify risk control measure(s) that are appropriate for reducing the risk(s) to an acceptable level. Risk control shall consist of an integrated approach in which the manufacturer shall use one or more of the following 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>NOTE 1-Measures of risk control can reduce the severity of the potential harm or reduce the probability of occurrence of the harm, or both. NOTE 2-Technical standards address inherent, protective, and descriptive safety for many medical devices. These should be consulted as part of the risk management process. See also annex G.</p> <p>The risk control measures selected shall be recorded in the risk management file.</p> <p>If, during option analysis, the manufacturer determines that further risk reduction is impractical, the manufacturer shall conduct a risk/benefit analysis of the residual risk (see 6.5); otherwise, the manufacturer shall proceed to implement the selected risk control measures.</p>		



Clause	Requirement	Result- Remark	Verdict
6.4	Residual risk evaluation		
	<p>Any residual risk that remains after the risk control measure(s) are applied 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.</p> <p>If the residual risk does not meet these criteria, further risk control measures shall be applied (see 6.2).</p> <p>If the residual risk is judged acceptable, then all relevant information necessary to explain the residual risk(s) shall be placed in the appropriate accompanying documents supplied by the manufacturer.</p> <p>Compliance is checked by inspection of the risk management file and the accompanying documents.</p>		



Clause	Requirement	Result- Remark	Verdict
7.	Overall residual risk evaluation		
	<p>After all risk control measures have been implemented and verified, the manufacturer shall decide if the overall residual risk posed by the medical device is acceptable using the criteria defined in the risk management plan. If the overall residual risk is judged unacceptable using the criteria established in the risk management plan, the manufacturer shall gather and review data and literature on the medical benefits of the intended use/intended purpose to determine if they outweigh the overall residual risk. If this evidence does not support the conclusion that the medical benefits outweigh the overall residual risk, then the risk remains unacceptable. The results of the overall residual risk evaluation shall be recorded in the risk management file.</p>		
8.	Risk management report		
	<p>The results of the risk management process shall be recorded in a risk management report. The risk management report shall provide traceability for each hazard to the risk analysis, the risk evaluation, the implementation and verification of the risk control measures, and the assessment that the residual risk(s) is acceptable. The risk management report shall form part of the risk management.</p> <p>NOTE-This report may be held on paper or on electronic media.</p>		



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			
	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			
	Verification Plan			
	Verification Methods and Results for each Hazard			
	Validation Plan			
	Validation Methods and Results for each Hazard			
	Modification/Change Procedures			
	Assessment Report			