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62366-1: Medical devices – Application of usability engineering to medical devices

SoftwareCPR® Tiered Checklist and Assessment Forms

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1.0 Purpose

This document is intended as a job aide to assessments for conformance to **ANSI/AAMI/IEC 62366-1:2015/A1:2020 Amendment 1 - Medical devices - Part 1: Application of usability engineering to medical devices**. It serves as a checklist and provides space to map the internal process to the standard's requirements. The information collected can be used as a mapping of the internal process to 62366-1 to aide 3rd party conformance assessments.

2.0 Usage

- **This job aide should only be applied by those who are knowledgeable about 62366-1 and its proper interpretation** and have an understanding of software engineering and validation principles. Also note that the text is not the full or exact text in the standard.
- **A tiered approach to conformance assessment is incorporated into these forms. One can assess at several levels:**
  - Are all required processes established
  - Are all required tasks and activities performed
  - Are all documentation requirements met
  - Do tasks and deliverables incorporate all required and relevant items (usually by sampling not all in every deliverable)

A group could conform at one or more levels but not be in full conformance. Or a group could completely conform for maintenance or initial development but not both. These forms are intended to highlight the degree of conformance rather then just provide a straight list of items.

The forms provided can be just used as a checklist with notes taken separately for document and procedure references and comments.

DISCLAIMER: These forms should not be used in place of the standard itself and may have unintended omissions or inaccuracies as well as paraphrased verbiage.

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3.0 Identification and Conclusion

Company/Division/Department/Group:_____

Project/Product:_____

Scope/portion of 62366-1 Assessed: (Indicate portions of 62366-1 included or excluded whichever is the shorter list):

_____

_____

Depth of Assessment (Describe which tiers included and the degree of document review and interviewing)

_____

_____

Performed by: _____

Analysis and Conclusion: Optional: Normally this would go in a separate report.

State degree of conformance determined using the Tiered method. List:

- Processes Missing
- Tasks and activities omitted /out-of-sequence (or summarize)
- Documentation requirements omitted (or summarize)
- Required low level tasks and deliverables omitted (or summarize)

4. High-level Conformance Evaluation

The Procedure/Plan column is to note where the approach or method for the activity is defined. The deliverable/documents column is to note the output of the activity in terms of documents and other deliverables that provide objective evidence that the process and activity was performed. One procedure, plan or document could be referenced multiple times. If all elements of this table are satisfied, one demonstrates conformance with the processes and activities requirements of 62366-1. Note that 62366-1 also requires specific tasks and these more detailed requirements are not addressed in this table. The amount of risk and the safety classification of the device may be applied while determining the adequacy for each element.

The “initially”column indicates whether the initial development was conformant and the “now”column indicates whether the current process is conformant.

Enter NE if the requirement was NOT EVALUATED. Enter NA if it is not applicable. These forms can be just used as a checklist with notes taken separately for document and procedure references and comments.

62366-1	Initially (Y, N, NE)	Now (Y, N, NE)	Procedure, Plan Titles	Deliverables/documents	Comments
2. Medical Device Risk Management standard ISO 14971					
5.1 Use Specification					
5.2 Identification of User Interface characteristics related to Safety and potential Use Errors					
5.3 Identification of known or foreseeable Hazards and Hazardous Situations related to Use of the MD					
5.4 Identification and Description of Hazard-related Use Scenarios					
5.5 Selection of the Hazard-related use scenarios for Summative Evaluation					
5.6 User Interface Specification established and maintained					
5.7 User Interface Evaluation Plan					
5.7.1 General planning					
5.7.2 Formative Evaluation planning					
5.7.3 Summative Evaluation planning					
5.8 Perform User Interface desing, implementation and Formative Evaluation					
5.9 Summative Evaluation of the Usability of the User Interface					

5.10 User Interface of Unknown Provenance (if the case exists)					

62366-1 Processes Detailed Section by Section Checklist

For items that are outside the scope of the assessment use **NE** – ***not evaluated*** – and be clear about the scope of the assessment in any summary report or conclusions.

For items that are not relevant use **NA** – *not applicable* – **and document your rationale.**

NOTE: This checklist can be used to evaluate if plans and procedures address all relevant items but for a full assessment results of actual development and maintenance should be evaluated to determine if in practice all conformance was achieved with all items.

5 Usability Engineering Process

62366-1 Conformity Requirements	**Y/ N /NE/ NA**	**Procedure, Plan, or Document references** (If level of detail in section 4 is not considered a sufficient mapping)	**Comments**
5.1 Use specification exists. It includes:			
• Intended medical indication (conditions or diseases to be monitored, screened, treated, diagnosed, or prevented)			
• Intended patient population (age, weight, health, condition)			
• Intended part of the body or type of tissue applied to or interacted with			
• Intended user profile			
• Intended use environment; and			
• Operating principle			

62366-1 Conformity Requirements	**Y/ N /NE/ NA**	**Procedure, Plan, or Document references** (If level of detail in section 4 is not considered a sufficient mapping)	**Comments**
5.2 Identify user interface characteristics related to safety and potential use errors. NOTE: This identification may also be performed using the tools and techniques from the usability engineering process. • This identification includes consideration of the primary operating functions if they are provided in applicable product-specific medical device safety standards.			
• Identify the use errors that could occur and are related to the user interface. A task analysis may be used to perform this identification.			
• The results of this identification of characteristics related to safety and potential Use Errors are stored in the usability engineering file.			
5.3 Identify known or foreseeable hazards and hazardous situations. This identification is conducted as part of a risk analysis performed according to ISO 14971:2019, 5.4. The following is considered:			
• Use specification, including user profile(s) (see 5.1).			
• Information on hazards and hazardous situations known for existing user interfaces of medical devices of a similar type.			
• Identified use errors (see 5.2).			

62366-1 Conformity Requirements	**Y/ N /NE/ NA**	**Procedure, Plan, or Document references** (If level of detail in section 4 is not considered a sufficient mapping)	**Comments**
The results of this identification of hazards and hazardous situations are stored in the usability engineering file.			
5.4 Identify and describe hazard-related use scenarios.			
• The description of each identified hazard-related use scenario includes all tasks and their sequences as well as the severity of the associated harm.			
5.5 Select the hazard-related use scenarios for summative evaluation. The scenarios should cover:			
• All hazard-related use scenarios			
• a subset of the hazard-related use scenarios based on the severity of the potential harm that could be caused by use error (e.g. for which medical intervention would be needed); or.			
• a subset of hazard-related use scenarios based on severity of the potential harm and based on other circumstances specific to the medical device and the manufacturer.			
• A summary of any selection scheme, the rationale for its use, and the results of applying it, is stored in the usability engineering file.			
5.6 Establish and maintain a user interface specification.			

62366-1 Conformity Requirements	**Y/ N /NE/ NA**	**Procedure, Plan, or Document references** (If level of detail in section 4 is not considered a sufficient mapping)	**Comments**
The user interface specification considers: • the use specification (see 5.1);			
• the known or foreseeable use errors associated with the medical device (see 5.2); and			
• the hazard-related use scenarios (see 5.4).			
The user interface specification includes: • testable technical requirements relevant to the user interface, including the requirements for those parts of the user interface associated with the selected risk control measures;			
• an indication as to whether accompanying documentation is required; and			
• an indication as to whether medical device-specific training is required.			
The user interface specification is stored in the usability engineering file. The user interface specification may be integrated into other specifications.			
5.7 Establish user interface evaluation plan.			
5.7.1 General: The user interface evaluation plan does: • 5.7.1.a document the objective and identify the method of any planned formative evaluations and summative evaluations;			

62366-1 Conformity Requirements	**Y/ N /NE/ NA**	**Procedure, Plan, or Document references** (If level of detail in section 4 is not considered a sufficient mapping)	**Comments**
• 5.7.1.b if usability tests are employed: o document which user groups are intended to be included in the test; multiple user profiles may be combined into a user group for the purposes of a usability test;			
o document the test environment and other conditions of use, based on the use specification;			
o specify whether accompanying documentation is provided during the test;			
o specify whether medical device-specific training is provided prior to the test and the minimum elapsed time between the training and the beginning of the test.			
5.7.2 Formative evaluation planning is conducted: The user interface evaluation plan for formative evaluation addresses:			
a) the evaluation methods being used;			
b) which part of the user interface is being evaluated; and			
c) when in the usability engineering process to perform each of the user interface evaluations.			
5.7.3 Summative evaluation planning is conducted: For each selected hazard-related use scenario (see 5.5), the user interface evaluation plan for summative evaluation specifies:			

62366-1 Conformity Requirements	**Y/ N /NE/ NA**	**Procedure, Plan, or Document references** (If level of detail in section 4 is not considered a sufficient mapping)	**Comments**
a) the evaluation method being used and a rationale that the method produces objective evidence;			
b) which part of the user interface is being evaluated;			
c) where applicable, the criteria for determining whether the information for safety is perceivable, understandable and supports correct use of the medical device (4.1.3);			
d) the availability of the accompanying documentation and provision of training during the summative evaluation			
e) for a usability test: • how the characteristics of the test participants are representative of the intended user profiles;			
• justifying how the test participants are grouped into distinct user groups for the purpose of determining the number of test participants;			
• the test environment and conditions of use and a rationale for how they are adequately representative of the intended use environment;			
• the definition of correct use for each hazard-related use scenario; and			
• the method of collecting data during the usability test for the subsequent analysis of observed use errors and use difficulties.			
5.8 The manufacturer performs user interface design, implementation and formative evaluation and documents this in the UI specification.			

62366-1 Conformity Requirements	**Y/ N /NE/ NA**	**Procedure, Plan, or Document references** (If level of detail in section 4 is not considered a sufficient mapping)	**Comments**
The manufacturer utilizes usability engineering methods and techniques, including formative evaluation to accomplish this design and implementation. The results are stored in the usability engineering file. Where new use errors, hazards, hazardous situations or hazard-related use scenarios are discovered during this step, repeat the steps of clause 5 as appropriate.			
If training on the specific medical device is required for the safe use of the medical device by the intended user, design and implement a training capability for the expected service life of the medical device by doing at least one of the following:			
• Provide the materials necessary for training;			
• Ensure that the materials necessary for training are available;			
• Make the training available; or			
• Make training available to the responsible organization that enables it to train its users.			

62366-1 Conformity Requirements	**Y/ N /NE/ NA**	**Procedure, Plan, or Document references** (If level of detail in section 4 is not considered a sufficient mapping)	**Comments**
5.9 Perform summative evaluation of the usability of the user interface. • The manufacturer may use data obtained from the summative evaluations of products with an equivalent user interface together with a technical rationale for how this data is applicable. • Results are recorded in the Usability Engineering File.			
• An analysis of the data of the summative evaluation shall identify all use errors and use difficulties that occurred. • If a use error or use difficulty can lead to a hazardous situation, the root cause of any such use error or use difficulty shall be determined. The root causes should be determined based on methods including observations of user performance as well as subjective comments from the user.			
If new use errors, hazards, hazardous situations or hazard-related use scenarios are discovered during this data analysis: • if yes, then the manufacturer shall repeat the activities of Clause 5 as appropriate;			
• if not, the manufacturer shall determine whether further improvement of the user interface design as it relates to safety is necessary and practicable. 1. if yes, then the MANUFACTURER shall re-enter the USABILITY ENGINEERING PROCESS at 5.6;			

62366-1 Conformity Requirements	**Y/ N /NE/ NA**	**Procedure, Plan, or Document references** (If level of detail in section 4 is not considered a sufficient mapping)	**Comments**
2. if not, then the MANUFACTURER shall: i. document why improvement is not necessary or not practicable; ii. identify the data from the usability engineering process needed to determine the residual risk related to use; and iii. evaluate the residual risk according to ISO 14971:2019, 7.3.			
5.10 If UOUP (User interface of unknown provenance) is used, it may be evaluated according to Annex C rather than according to the requirements of 5.1 – 5.9.			

END OF CHECKLIST

REMEMBER TO REFER TO THE STANDARD ITSELF AS THIS CHECKLIST IS NOT INTENDED TO BE USED IN ISOLATION FROM THE STANDARD OR KNOWLEDGE AND TRAINING IN PROPER INTERPRETATION OF THE STANDARD.